

## **PART 30--RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL**

### **General Provisions**

[30.1 Scope.](#)

[30.2 Resolution of conflict.](#)

[30.3 Activities requiring license.](#)

[30.4 Definitions.](#)

[30.5 Interpretations.](#)

[30.6 Communications.](#)

[30.7 Employee protection.](#)

[30.8 Information collection requirements: OMB approval.](#)

[30.9 Completeness and accuracy of information.](#)

[30.10 Deliberate misconduct.](#)

### **Exemptions**

[30.11 Specific exemptions.](#)

[30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.](#)

[30.13 Carriers.](#)

[30.14 Exempt concentrations.](#)

[30.15 Certain items containing byproduct material.](#)

[30.16 \[Removed\].](#)

[30.18 Exempt quantities.](#)

[30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.](#)

[30.20 Gas and aerosol detectors containing byproduct material.](#)

[30.21 Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.](#)

[30.22 Certain industrial devices.](#)

### **Licenses**

[30.31 Types of licenses.](#)

[30.32 Application for specific licenses.](#)

[30.33 General requirements for issuance of specific licenses.](#)

[30.34 Terms and conditions of licenses.](#)

[30.35 Financial assurance and recordkeeping for decommissioning.](#)

[30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.](#)

[30.37 Application for renewal of licenses.](#)

[30.38 Application for amendment of licenses.](#)

[30.39 Commission action on applications to renew or amend.](#)

[30.41 Transfer of byproduct material.](#)

#### **Records, Inspections, Tests, and Reports**

[30.50 Reporting requirements.](#)

[30.51 Records.](#)

[30.52 Inspections.](#)

[30.53 Tests.](#)

[30.55 Tritium reports.](#)

#### **Enforcement**

[30.61 Modification and revocation of licenses.](#)

[30.62 Right to cause the withholding or recall of byproduct material.](#)

[30.63 Violations.](#)

[30.64 Criminal penalties.](#)

#### **Schedules**

[30.70 Schedule A--Exempt concentrations.](#)

[30.71 Schedule B.](#)

[30.72 Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.](#)

[Appendix A to Part 30--Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning](#)

[Appendix B to Part 30--Quantities of Licensed Material Requiring Labeling](#)

[Appendix C to Part 30--Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning](#)

[Appendix D to Part 30--Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds](#)

[Appendix E to Part 30--Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals](#)

**Authority:** Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. No. 109–58, 119 Stat. 549 (2005). Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

[72 FR 55924, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 73 FR 63570, Oct. 24, 2008]

## **General Provisions**

### **§ 30.1 Scope.**

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. This part also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 30.10.

[63 FR 1895, Jan. 13, 1998]

### **§ 30.2 Resolution of conflict.**

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

[30 FR 8185, June 26, 1965]

### **§ 30.3 Activities requiring license.**

(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on November 30, 2007, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.

(2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before December 1, 2008.

(c)(1) The requirements, including provisions that are specific to licensees in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to all persons, other than those included in paragraph (b)(1) of this section, on August 8, 2009, or earlier as noticed by the NRC, when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of this section.

(2) Except as provided in paragraph (b)(2) of this section, all other licensees, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits an amendment application within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(3) Except as provided in paragraph (b)(3) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(d) If a person or licensee is required to file an application for a license or amendment in accordance with paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section, but does not file for the license or amendment within the required time, the authority provided by paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section to receive or use the accelerator-produced radioactive material or discrete sources of radium-226 shall expire with respect to the person's or licensee's authority to receive and use such byproduct material. This authority shall not expire with respect to the responsibility of the person or licensee regarding the

possession of such byproduct material, the decommissioning (including financial assurance) of facilities, or the disposal of such byproduct material.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 72 FR 55924, Oct. 1, 2007]

#### **§ 30.4 Definitions.**

*Accelerator-produced radioactive material* means any material made radioactive by a particle accelerator.

*Act* means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

*Agreement State* means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-agreement State* means any other State;

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

*Byproduct material* means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

*Commencement of construction* means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

*Commission* means the Nuclear Regulatory Commission and its duly authorized representatives;

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

Formatted: Font: (Default) Times New Roman, 12 pt, Italic

Formatted: Font: (Default) Times New Roman, 12 pt

*Curie* means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

*Cyclotron* means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

*Decommission* means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

- (1) Release of the property for unrestricted use and termination of the license; or
- (2) Release of the property under restricted conditions and termination of the license.

*Dentist* means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

*Department and Department of Energy* means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, 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 sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

*Discrete source* means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

*Effective dose equivalent* means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

*Government agency* means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

*License*, except where otherwise specified means a license for by-product material issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter;

*Medical use* means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

*Microcurie* means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

*Millicurie* means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second;

*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 at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.

*Person* means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

*Physician* means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

*Podiatrist* means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

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

*Production facility* means production facility as defined in the regulations contained in part 50 of this chapter;

*Quantities of Concern* means the quantities of the radionuclides meeting or exceeding the threshold limits set forth in Table I-1 of Appendix I of part 73 of this chapter.

*Research and development* means: (1) Theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

*Sealed source* means any by product material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

*Site area emergency* means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

*Source material* means source material as defined in the regulations contained in part 40 of this chapter;

*Special nuclear material* means special nuclear material as defined in the regulations contained in part 70 of this chapter;

*United States*, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States;

*Utilization facility* means a utilization facility as defined in the regulations contained in part 50 of this chapter;

[30 FR 8185, June 26, 1965, as amended at 36 FR 1466, Jan. 30, 1971; 37 FR 5746, Mar. 21, 1972; 38 FR 29314, Oct. 24, 1973; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 45 FR 14200, Mar. 5, 1980; 45 FR 18905, Mar. 24, 1980; 48 FR 39037, Aug. 29, 1983; 51 FR 36967, Oct. 16, 1986; 52 FR 8241, Mar. 17, 1987; 53 FR 24044, June 27, 1988; 54 FR 14059, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 36034, July 15, 1994; 59 FR 61780, Dec. 2, 1994; 62 FR 28963, May 28, 1997; 62 FR 39089, July 21, 1997; 65 FR 54950, Sept. 12, 2000; 72 FR 55924, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; [76 FR 56962, Sept. 15, 2011](#); [79 FR 58671, Sept. 30, 2014](#)]

#### **§ 30.5 Interpretations.**

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and parts 31 through 36 and 39 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

#### **§ 30.6 Communications.**

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in parts 30 through 36 and 39 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed: ATTN: Document Control Desk, Director, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by calling (301) 415-0439, by e-mail to [EIE@nrc.gov](mailto:EIE@nrc.gov), or



by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(b) The Commission has delegated to the four Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted to the appropriate Regional Administrator. The Administrators' jurisdictions and mailing addresses are listed in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproducts, source, or special nuclear material.

(2) *Submissions--(i) Region I.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, King of Prussia, Pennsylvania 19406-1415; where e-mail is appropriate it should be addressed to [RidsRgn1MailCenter@nrc.gov](mailto:RidsRgn1MailCenter@nrc.gov).

(ii) *Region II.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement States and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region II, Material Licensing/Inspection Branch, Sam Nunn Atlanta Federal Center, Suite 23T85, 61 Forsyth Street, SW, Atlanta, GA 30303-8931; where e-mail is appropriate it should be addressed to [RidsRgn2MailCenter@nrc.gov](mailto:RidsRgn2MailCenter@nrc.gov).

(iii) *Region III.* The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region III non-Agreement States: Indiana, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination, request of an existing license specified in paragraph (b)(1) of

this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532- 4352; where e-mail is appropriate it should be addressed to [RidsRgn3MailCenter@nrc.gov](mailto:RidsRgn3MailCenter@nrc.gov).

(iv) *Region IV*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and a territory: Alaska, Hawaii, Montana, Oklahoma, South Dakota, Wyoming, and Guam. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011-4005; where e-mail is appropriate it should be addressed to [RidsRgn4MailCenter@nrc.gov](mailto:RidsRgn4MailCenter@nrc.gov).

[48 FR 16031, Apr. 14, 1983, as amended at 49 FR 19630, May 9, 1984; 49 FR 47824, Dec. 7, 1984; 50 FR 14693, Apr. 11, 1985; 51 FR 36000, Oct. 8, 1986; 52 FR 8241, Mar. 17, 1987; 52 FR 38392, Oct. 16, 1987; 52 FR 48093, Dec. 18, 1987; 53 FR 3862, Feb. 10, 1988; 53 FR 43420, Oct. 27, 1988; 58 FR 7736, Feb. 9, 1993; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 68 FR 58803, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 71 FR 15007, Mar. 27, 2006; 72 FR 33386, Jun. 18, 2007; 73 FR 5717, Jan. 31, 2008; [74 FR 62681, Dec. 1, 2009](#); [75 FR 21980, Apr. 27, 2010](#); [75 FR 73942, Nov. 30, 2010](#); [76 FR 72085, Nov. 22, 2011](#); [77 FR 39905, Jul. 6, 2012](#); [77 FR 43689, Jul. 25, 2012](#); [78 FR 17006, Mar. 19, 2013](#); [78 FR 32338, May 29, 2013](#); [79 FR 75739, Dec. 19, 2014](#)]

### **§ 30.7 Employee protection.**

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for--

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, by calling (301) 415-5877, via e-mail to [forms@nrc.gov](mailto:forms@nrc.gov), or by visiting the NRC's Web site at <http://www.nrc.gov> and selecting forms from the index found on the home page.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[58 FR 52408, Oct. 8, 1993, as amended at 60 FR 24551, May 9, 1995; 61 FR 6764, Feb. 22, 1996; 68 FR 58803, Oct. 10, 2003; 72 FR 63969, Nov. 14, 2007; [79 FR 66603, Nov. 10, 2014](#)]

#### **§ 30.8 Information collection requirements: OMB approval.**

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0017.

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and appendices A, C, D, and E to this part.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, NRC Form 313 is approved under control number 3150-0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150-0028.

(3) In § 30.34, DOC/NRC Forms AP-1, AP-A, and associated forms are approved under control number 0694-0135.

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997; 62 FR 63639, Dec. 2, 1997; 63 FR 29541, June 1, 1998; 67 FR 67099, Nov. 4, 2002; 73 FR 78604, Dec. 23, 2008; [77 FR 43689, Jul. 25, 2012](#)]

#### **§ 30.9 Completeness and accuracy of information.**

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

[52 FR 49371, Dec. 31, 1987]

#### **§ 30.10 Deliberate misconduct.**

(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]

## **Exemptions**

### **§ 30.11 Specific exemptions.**

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any licensee's activities are exempt from the requirements of this part to the extent that its activities are licensed under the requirements of part 72 of this chapter.

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

(d) Except as specifically provided in part 61 of this chapter, any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 61 of this chapter.

[37 FR 5746, Mar. 21, 1972, as amended at 39 FR 26279, July 18, 1974; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 21, 1978; 45 FR 65530, Oct. 3, 1980; 46 FR 13979, Feb. 25, 1981; 47 FR 57480, Dec. 27, 1982;

52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 66 FR 51838, Oct. 11, 2001; 66 FR 55790, Nov. 2, 2001]

**§ 30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.**

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for:

- (a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of byproduct material to or from such site and the performance of contract services during temporary interruptions of such transportation;
- (b) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or
- (c) The use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel.

In addition to the foregoing exemptions and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and 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.

[40 FR 8784, Mar. 3, 1975, as amended at 43 FR 6921, Feb. 17, 1978]

**§ 30.13 Carriers.**

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and parts 31 through 37 and 39 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

[37 FR 3985, Feb. 25, 1972, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; [78 FR 17006, Mar. 19, 2013](#)]

**§ 30.14 Exempt concentrations.**

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

#### **§ 30.15 Certain items containing byproduct material.**

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece,

(ii) 5 millicuries of tritium per hand,

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(iv) 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece,

(v) 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand,

(vi) 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(vii) The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(A) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(B) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(C) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before October 23, 2012 for use under the general license then provided in § 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission. ~~[Reserved]~~

**Formatted:** Space Before: Auto, After: Auto, Line spacing: single

**Formatted:** Font: (Default) Times New Roman, 12 pt

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

(4) [Reserved]

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

(6) [Reserved]

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

(8) Electron tubes: *Provided*, That each tube does not contain more than one of the following specified quantities of byproduct material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(ii) 1 microcurie of cobalt-60;

(iii) 5 microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) 5 microcuries of cesium-137;

(vi) 30 microcuries of promethium-147;

*And provided further*, That the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.<sup>1</sup>



(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material: *Provided, That*;

(i) Each source contains no more than one exempt quantity set forth in § 30.71, Schedule B, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

(10) [Reserved]

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

[31 FR 5316, Apr. 2, 1966, as amended at 31 FR 14349, Nov. 8, 1966; 32 FR 785, Jan. 24, 1967; 32 FR 6434, Apr. 26, 1967; 32 FR 13921, Oct. 6, 1967; 34 FR 6651, Apr. 18, 1969; 34 FR 19546, Dec. 11, 1969; 35 FR 6427, Apr. 22, 1970; 35 FR 8820, June 6, 1970; 43 FR 2387, Jan. 17, 1978; 43 FR 6921, Feb. 17, 1978; 46 FR 26471, May 13, 1981; 46 FR 46876, Sept. 23, 1981; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; [77 FR 43689, Jul. 25, 2012](#)]

<sup>1</sup> For purposes of this paragraph "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

#### **§ 30.16 [Removed].**

[32 FR 4241, Mar. 18, 1967, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

#### **§ 30.18 Exempt quantities.**

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007]

#### **§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.**

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

~~(b) Any person who desires to manufacture, process, or produce self luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.22 of this chapter, which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.~~

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[34 FR 9026, June 6, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; [77 FR 43689, Jul. 25, 2012](#)]

#### **§ 30.20 Gas and aerosol detectors containing byproduct material.**

~~(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements. (a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.~~

~~(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter. (b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.26 of this chapter, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.~~

[34 FR 6653, Apr. 18, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 77 FR 43689, Jul. 25, 2012]

**§ 30.21 Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.**

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1  $\mu$  Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

[62 FR 63640, Dec. 2, 1997]

Formatted: Font: Not Bold

#### **§ 30.22 Certain industrial devices.**

Formatted: Font: Bold

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

Formatted: Font: Not Bold

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

[77 FR 43689, Jul. 25, 2012]

### **Licenses**

#### **§ 30.31 Types of licenses.**

Licenses for byproduct material are of two types: General and specific.

(a) The Commission issues a specific license to a named person who has filed an application for the license under the provisions of this part and parts 32 through 36, and 39.

(b) A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. However, registration with the Commission may be required by the particular general license.

[65 FR 79187, Dec. 18, 2000]

#### **§ 30.32 Application for specific licenses.**

(a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

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

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and parts 32 through 35 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a byproduct material license, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to subpart A of part 51 of this chapter.

(g)(1) Except as provided in paragraphs (g)(2), (g)(3), and (g)(4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either--

(i) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or

(ii) Contain the information identified in § 32.210(c) of this chapter.

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the application must include:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

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

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

~~(g) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either--~~

~~(1) Identify the source or device by manufacturer and model number as registered with the Commission under~~

~~§ 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or~~

~~(2) Contain the information identified in § 32.210(e) of this chapter; or~~

~~(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(e) of this chapter, the applicant must provide:~~

~~(i) All available information identified in § 32.210(e) of this chapter concerning the source, and, if applicable, the device; and~~

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

(h) As provided by § 30.35, certain applications for specific licenses filed under this part and parts 32 through 35 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

(i)(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 § 30.72, "Schedule C--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 paragraph (i)(1)(i) of this section:

(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 § 30.72 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 § 30.72;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in § 30.72; or

(vii) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (i)(1)(ii) of this section 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 radio-active 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 NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination.* A commitment to and a brief description of the means to promptly notify 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. 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 NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.<sup>1</sup>

(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 NRC.

(x) *Training.* A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including 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 byproduct 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 NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

(j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter.

(4) Information identified in § 32.72(a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.

<sup>1</sup> These reporting requirements do not supercede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

~~(k) Each applicant for a license for byproduct material shall protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21, 73.22 and/or 73.23 of this chapter, as applicable.~~



[30 FR 8185, June 26, 1965, as amended at 36 FR 145, Jan. 6, 1971; 37 FR 5747, Mar. 21, 1972; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 49 FR 27924, July 9, 1984; 52 FR 27786, July 24, 1987; 53 FR 24044, June 27, 1988; 54 FR 14060, Apr. 7, 1989; 68 FR 58804, Oct. 10, 2003; 72 FR 55925, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; [77 FR 43689, Jul. 25, 2012](#); [79 FR 58671, Sept. 30, 2014](#)]

~~<sup>4</sup> These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.~~

### **§ 30.33 General requirements for issuance of specific licenses.**

(a) An application for a specific license will be approved if:

- (1) The application is for a purpose authorized by the Act;
- (2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;
- (3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;
- (4) The applicant satisfies any special requirements contained in parts 32 through 36 and 39; and

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment, the Director, Office of Federal and State Materials and Environmental Management Program or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC 374, "Byproduct Material License").

[30 FR 8185, June 26, 1965, as amended at 36 FR 12731, July 7, 1971; 37 FR 5747, Mar. 21, 1972; 39 FR 26279, July 18, 1974; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 73 FR 5717, Jan. 31, 2008; [76 FR 56962, Sep. 15, 2011](#); [78 FR 17006, Mar. 19, 2013](#); [79 FR 75739, Dec. 19, 2014](#)]

### **§ 30.34 Terms and conditions of licenses.**

(a) Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b)(1) No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(2) An application for transfer of license must include:

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

(ii) Financial assurance for decommissioning information required by § 30.35.

(c) Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b.- d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 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 Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(145)) controlling the licensee or listing the licensee as property of the estate; or

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

(2) This notification must indicate:

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

(ii) The date of the filing of the petition.

(i) Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

(k) As required by the Additional Protocol, each specific licensee authorized to possess and use byproduct material shall file with the Commission location information described in § 75.11 of this chapter on DOC/NRC Forms AP-1 and associated forms. The licensee shall also permit verification of this information by the International Atomic Energy Agency (IAEA) and shall take other action as may be necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

(l) Each licensee shall ensure that Safeguards Information is protected against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.23 of this chapter, as applicable.

[30 FR 8185, June 26, 1965, as amended at 38 FR 33969, Dec. 10, 1973; 43 FR 6922, Feb. 17, 1978; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 53 FR 23383, June 22, 1988; 54 FR 14061, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 61780, Dec. 2, 1994; 65 FR 79187, Dec. 18, 2000; 70 FR 2009, Jan. 12, 2005; 72 FR 55926, Oct. 1, 2007; 73 FR 78604, Dec. 23, 2008; 74 FR 7785, Feb. 20, 2009; [76 FR 35564, Jun. 17, 2011](#); [77 FR 39905, Jul. 6, 2012](#); [79 FR 58671, Sept. 30, 2014](#)]

#### **§ 30.35 Financial assurance and recordkeeping for decommissioning.**

(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding  $10^5$  times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if  $R$  divided by  $10^5$  is greater than 1 (unity rule), where  $R$  is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding  $10^{12}$  times the applicable quantities set forth in appendix B to part 30 (or when a combination of isotopes is involved if  $R$ , as defined in § 30.35(a)(1), divided by  $10^{12}$  is greater than 1), shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must be submitted to NRC by December 2, 2005.

(b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section shall either--

(1) Submit a decommissioning funding plan as described in paragraph (e) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (d) of this section using one of the methods described in paragraph (f) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section must be submitted to NRC before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

(c)(1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to \$1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan as described, in paragraph (e) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 30.37 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

(5) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 10 CFR part 20. The decommissioning funding plan must be submitted by December 2, 2005.

(d) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the \$1,125,000 amount must do so by December 2, 2004. Licensees required to submit the \$113,000 or \$225,000 amount must do so by June 2, 2005. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

Greater than $10^4$ but less than or equal to $10^5$ times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by $10^4$ is greater than 1 but R divided by $10^5$ is less than or equal to 1.)	\$1,125,000
Greater than $10^3$ but less than or equal to $10^4$ times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by $10^3$ is greater than 1 but R divided by $10^4$ is less than or equal to 1.)	225,000
Greater than $10^{10}$ but less than or equal to $10^{12}$ times the applicable quantities of appendix B to part 30 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by $10^{10}$ is greater than, 1, but R divided by $10^{12}$ is less than or equal to 1)	113,000

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain –

(i) A\* detailed cost estimate for decommissioning, in the amount reflecting:

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

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

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

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

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

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

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

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

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

(iv) Facility modifications;

(v) Changes in authorized possession limits;

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

(vii) Onsite disposal; and

(viii) Use of a settling pond and a description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

(f) 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. 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 A to this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. 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 Commission, 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 Commission 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 Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission 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 (f)(2) of this section.

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

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

(g) Each person licensed under this part or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of--

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

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

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(ii) All areas outside of restricted areas that require documentation under § 30.35(g)(1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

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

[53 FR 24044, June 27, 1988, as amended at 56 FR 23471, May 21, 1991; 58 FR 39633, July 26, 1993; 58 FR 67659, Dec. 22, 1993; 58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 60 FR 38238, July 26, 1995; 61 FR 24673, May 16, 1996; 62 FR 39090, July 21, 1997; 63 FR 29541, June 1, 1998; 68 FR 57335, Oct. 3, 2003; [76 FR 35564, Jun. 17, 2011](#); [79 FR 75739, Dec. 19, 2014](#)]

#### **§ 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.**



(a) Each specific license expires at the end of the day on the expiration date stated in the license, unless the licensee has filed an application for renewal under § 30.37 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

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

(1) Limit actions involving byproduct material to those related to decommissioning; and

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

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 30.6, each licensee shall provide notification to the NRC 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 NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (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 NRC 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 NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 30.35 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 paragraph (g)(4)(v) of this section.

(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 November 24, 1995.

(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 Commission.

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

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

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

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

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

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

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission 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.

(3) Procedures such as those listed in paragraph (g)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

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

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

(ii) A description of planned decommissioning activities;

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

(iv) A description of the planned final radiation survey; and

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

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

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

(h)(1) Except as provided in paragraph (i) 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 paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

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

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

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

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

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

(1) Byproduct material has been properly disposed;

(2) 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 the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 30.51 (d) and (f) have been received.

[59 FR 36034, July 15, 1994, as amended at 60 FR 38238, July 26, 1995; 61 FR 1114, Jan. 16, 1996; 61 FR 24673, May 16, 1996; 61 FR 29637, June 12, 1996; 62 FR 39090, July 21, 1997; 73 FR 42673, July 23, 2008]

#### **§ 30.37 Application for renewal of licenses.**

(a) Application for renewal of a specific license must be filed on NRC Form 313 and in accordance with § 30.32.

(b) If any licensee granted the extension described in 10 CFR 30.36(a)(2) has a currently pending renewal application for the extended license, that application will be considered withdrawn by the licensee and any renewal fees paid by the licensee for that application will be refunded.

[59 FR 36035, July 15, 1994, as amended at 61 FR 1114, Jan. 16, 1996; 66 FR 64738, Dec. 14, 2001; [75 FR 73942, Nov. 30, 2010](#)]

#### **§ 30.38 Application for amendment of licenses.**

Applications for amendment of a license shall be filed on Form NRC-313 in accordance with § 30.32 and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment.

[49 FR 19625, May 9, 1984; [77 FR 43690, Jul. 25, 2012](#)]

#### **§ 30.39 Commission action on applications to renew or amend.**

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 30.33 and parts 32 through 36 and 39 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; [77 FR 43690, Jul. 25, 2012](#)]

#### **§ 30.41 Transfer of byproduct material.**

(a) No licensee shall transfer byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer byproduct material:

- (1) To the Department;
- (2) To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under section 274 of the Act;
- (3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;
- (4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;
- (5) To any person authorized to receive such byproduct material under terms of a specific license or a general license or their equivalents issued by the Atomic Energy Commission, the Commission, or an Agreement State;
- (6) To a person abroad pursuant to an export license issued under part 110 of this chapter; or
- (7) As otherwise authorized by the Commission in writing.

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

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

- (1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;
- (2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;
- (3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: Provided, That the oral certification is confirmed in writing within 10 days;
- (4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or
- (5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the byproduct material.

[38 FR 33969, Dec. 10, 1973, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6922, Feb. 17, 1978]

## Records, Inspections, Tests, and Reports

### § 30.50 Reporting requirements.

(a) *Immediate report.* Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report.* Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) 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;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) 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.

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

(i) 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;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) 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.

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

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

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

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.<sup>1</sup> To the extent that the information is available at the time of notification, the information provided in these reports must include:

- (i) The caller's name and call back telephone number;
- (ii) A description of the event, including date and time;
- (iii) The exact location of the event;
- (iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and
- (v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the NRC using an appropriate method listed in § 30.6(a); and a copy must be sent to the appropriate NRC Regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

- (i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- (ii) The exact location of the event;
- (iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;
- (iv) Date and time of the event;
- (v) Corrective actions taken or planned and the results of any evaluations or assessments; and
- (vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72.

[56 FR 40767, Aug. 16, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 68 FR 58804, Oct. 10, 2003]

<sup>1</sup> The commercial telephone number for the NRC Operations Center is (301) 816-5100.

#### **§ 30.51 Records.**

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and parts 31 through 36 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

- (1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.
- (2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by the regulations in this part and parts 31 through 36 of this chapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part and parts 31 through 36 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. 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, 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.

(2) If there is a conflict between the Commission's regulations in this part and parts 31 through 36 and 39 of this chapter, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and parts 31 through 36 and 39 of this chapter for such records shall apply unless the Commission, pursuant to § 30.11, has granted a specific exemption from the record retention requirements specified in the regulations in this part or parts 31 through 36 and 39 of this chapter.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981<sup>41</sup>), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with § 30.34(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by § 30.35(g) to the appropriate NRC Regional Office.

[41 FR 18301, May 5, 1976, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 58 FR 7736, Feb. 9, 1993; 61 FR 24673, May, 16, 1996]



<sup>1</sup> A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

#### **§ 30.52 Inspections.**

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

[30 FR 8185, June 26, 1965]

#### **§ 30.53 Tests.**

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and parts 31 through 36 and 39 of this chapter, including tests of:

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

[30 FR 8185, June 26, 1965, as amended by 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

#### **§ 30.55 Tritium reports.**

(a)-(b) [Reserved]

(c) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess tritium shall report promptly to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter by telephone and telegraph, mailgram, or facsimile any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year. The initial report shall be followed within a period of fifteen (15) days by a written report submitted to the appropriate NRC Regional Office which sets forth the details of the incident and its consequences. Copies of such written report shall be sent to the Director, Office of ~~Nuclear Material Safety and Safeguards~~~~Federal and State Materials and Environmental Management Programs~~, using an appropriate method listed in § 30.6(a). Subsequent to the submission of the written report required by this paragraph, the licensee shall promptly inform the Office of ~~Federal and State Materials and Environmental Management Programs~~~~Nuclear Material Safety and Safeguards~~ by means of a written report of any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of tritium.

(d) The reports described in this section are not required for tritium possessed pursuant to a general license provided in part 31 of this chapter or for tritium contained in spent fuel.

[37 FR 9208, May 6, 1972, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 2330, Jan. 24, 1973; 41 FR 16446, Apr. 19, 1976; 43 FR 6922, Feb. 17, 1978; 46 FR 55085, Nov. 6, 1981; 49 FR 24707, June 15, 1984; 52 FR 31611, Aug. 21, 1987; 68 FR 58804, Oct. 10, 2003; 73 FR 5718, Jan. 31, 2008; [79 FR 75739, Dec. 19, 2014](#)]

## **Enforcement**

### **§ 30.61 Modification and revocation of licenses.**

(a) The terms and conditions of each license issued pursuant to the regulations in this part and parts 31 through 35 of this chapter shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

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

[30 FR 8185, June 26, 1965, as amended at 35 FR 11460, July 17, 1970; 43 FR 6922, Feb. 17, 1978; [77 FR 43690, Jul. 25, 2012](#)]

### **§ 30.62 Right to cause the withholding or recall of byproduct material.**

The Commission may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefore or approved by the Commission.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975]

### **§ 30.63 Violations.**

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55072, Nov. 24, 1992]

#### **§ 30.64 Criminal penalties.**

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 30 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 30 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 30.1, 30.2, 30.4, 30.5, 30.6, 30.8, 30.11, 30.12, 30.13, 30.15, 30.31, 30.32, 30.33, 30.37, 30.38, 30.39, 30.61, 30.62, 30.63, 30.64, 30.70, 30.71, and 30.72.

[57 FR 55072, Nov. 24, 1992; 73 FR 42673, July 23, 2008]

#### **Schedules**

#### **§ 30.70 Schedule A--Exempt concentrations.**

[See [footnotes](#) at the end of this table]

Element (atomic number)	Isotope	Col. I	Col. II
		Gas Concentration μCi/ml <sup>1</sup>	Liquid and Solid Concentration μCi/ml <sup>2</sup>
Antimony (51)	Sb 122		3 x 10 <sup>-4</sup>
	Sb 124		2 x 10 <sup>-4</sup>
	Sb 125		1 x 10 <sup>-3</sup>
Argon (18)	A 37	1 x 10 <sup>-3</sup>	

	A 41	$4 \times 10^{-7}$	
Arsenic (33)	As 73		$5 \times 10^{-3}$
	As 74		$5 \times 10^{-4}$
	As 76		$2 \times 10^{-4}$
	As 77		$8 \times 10^{-4}$
Barium (56)	Ba 131		$2 \times 10^{-3}$
	Ba 140		$3 \times 10^{-4}$
Beryllium (4)	Be 7		$2 \times 10^{-2}$
Bismuth (83)	Bi 206		$4 \times 10^{-4}$
Bromine (35)	Br 82	$4 \times 10^{-7}$	$3 \times 10^{-3}$
Cadmium (48)	Cd 109		$2 \times 10^{-3}$
	Cd 115M		$3 \times 10^{-4}$
	Cd 115		$3 \times 10^{-4}$
Calcium (20)	Ca 45		$9 \times 10^{-5}$
	Ca 47		$5 \times 10^{-4}$
Carbon (6)	C 14	$1 \times 10^{-6}$	$8 \times 10^{-3}$
Cerium (58)	Ce 141		$9 \times 10^{-4}$
	Ce 143		$4 \times 10^{-4}$
	Ce 144		$1 \times 10^{-4}$
Cesium (55)	Cs 131		$2 \times 10^{-2}$
	Cs 134m		$6 \times 10^{-2}$
	Cs 134		$9 \times 10^{-5}$
Chlorine (17)	Cl 38	$9 \times 10^{-7}$	$4 \times 10^{-3}$
Chromium (24)	Cr 51		$2 \times 10^{-2}$
Cobalt (27)	Co 57		$5 \times 10^{-3}$
	Co 58		$1 \times 10^{-3}$
	Co 60		$5 \times 10^{-4}$
Copper (29)	Cu 64		$3 \times 10^{-3}$
Dysprosium (66)	Dy 165		$4 \times 10^{-3}$
	Dy 166		$4 \times 10^{-4}$
Erbium (68)	Er 169		$9 \times 10^{-4}$
	Er 171		$1 \times 10^{-3}$
Europium (63)	Eu 152 (T/2=9.2 hrs)		$6 \times 10^{-4}$
	Eu 155		$2 \times 10^{-3}$
Fluorine (9)	F 18	$2 \times 10^{-6}$	$8 \times 10^{-3}$

Gadolinium (64)	Gd 153		$2 \times 10^{-3}$
	Gd 159		$8 \times 10^{-4}$
Gallium (31)	Ga 72		$4 \times 10^{-4}$
Germanium (32)	Ge 71		$2 \times 10^{-2}$
Gold (79)	Au 196		$2 \times 10^{-3}$
	Au 198		$5 \times 10^{-4}$
	Au 199		$2 \times 10^{-3}$
Hafnium (72)	Hf 181		$7 \times 10^{-4}$
Hydrogen (1)	H 3	$5 \times 10^{-6}$	$3 \times 10^{-2}$
Indium (49)	In 113M		$1 \times 10^{-2}$
	In 114M		$2 \times 10^{-4}$
Iodine (53)	I 126	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I 131	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I 132	$8 \times 10^{-8}$	$6 \times 10^{-4}$
	I 133	$1 \times 10^{-8}$	$7 \times 10^{-5}$
	I 134	$2 \times 10^{-7}$	$1 \times 10^{-3}$
Iridium (77)	Ir 190		$2 \times 10^{-3}$
	Ir 192		$4 \times 10^{-4}$
	Ir 194		$3 \times 10^{-4}$
Iron (26)	Fe 55		$8 \times 10^{-3}$
	Fe 59		$6 \times 10^{-4}$
Krypton (36)	Kr 85M	$1 \times 10^{-6}$	
	Kr 85	$3 \times 10^{-6}$	
Lanthanum (57)	La 140		$2 \times 10^{-4}$
Lead (82)	Pb 203		$4 \times 10^{-3}$
Lutetium (71)	Lu 177		$1 \times 10^{-3}$
Manganese (25)	Mn 52		$3 \times 10^{-4}$
	Mn 54		$1 \times 10^{-3}$
	Mn 56		$1 \times 10^{-3}$
Mercury (80)	Hg 197M		$2 \times 10^{-3}$
	Hg 197		$3 \times 10^{-3}$
	Hg 203		$2 \times 10^{-4}$
Molybdenum (42)	Mo 99		$2 \times 10^{-3}$
Neodymium (60)	Nd 147		$6 \times 10^{-4}$
	Nd 149		$3 \times 10^{-3}$
Nickel (28)	Ni 65		$1 \times 10^{-3}$

Niobium (Columbium) (41)	Nb 95		1 x 10 <sup>-3</sup>
	Nb 97		9 x 10 <sup>-3</sup>
Osmium (76)	Os 185		7 x 10 <sup>-4</sup>
	Os 191M		3 x 10 <sup>-2</sup>
	Os 191		2 x 10 <sup>-3</sup>
	Os 193		6 x 10 <sup>-4</sup>
Palladium (46)	Pd 103		3 x 10 <sup>-3</sup>
	Pd 109		9 x 10 <sup>-4</sup>
Phosphorus (15)	P 32		2 x 10 <sup>-4</sup>
Platinum (78)	Pt 191		1 x 10 <sup>-3</sup>
	Pt 193M		1 x 10 <sup>-2</sup>
	Pt 197M		1 x 10 <sup>-2</sup>
	Pt 197		1 x 10 <sup>-3</sup>
Potassium (19)	K 42		3 x 10 <sup>-3</sup>
Praseodymium (59)	Pr 142		3 x 10 <sup>-4</sup>
	Pr 143		5 x 10 <sup>-4</sup>
Promethium (61)	Pm 147		2 x 10 <sup>-3</sup>
	Pm 149		4 x 10 <sup>-4</sup>
Rhenium (75)	Re 183		6 x 10 <sup>-3</sup>
	Re 186		9 x 10 <sup>-4</sup>
	Re 188		6 x 10 <sup>-4</sup>
Rhodium (45)	Rh 103M		1 x 10 <sup>-1</sup>
	Rh 105		1 x 10 <sup>-3</sup>
Rubidium (37)	Rb 86		7 x 10 <sup>-4</sup>
Ruthenium (44)	Ru 97		4 x 10 <sup>-4</sup>
	Ru 103		8 x 10 <sup>-4</sup>
	Ru 105		1 x 10 <sup>-3</sup>
	Ru 106		1 x 10 <sup>-4</sup>
Samarium (62)	Sm 153		8 x 10 <sup>-4</sup>
Scandium (21)	Sc 46		4 x 10 <sup>-4</sup>
	Sc 47		9 x 10 <sup>-4</sup>
	Sc 48		3 x 10 <sup>-4</sup>
Selenium (34)	Se 75		3 x 10 <sup>-3</sup>
Silicon (14)	Si 31		9 x 10 <sup>-3</sup>
Silver (47)	Ag 105		1 x 10 <sup>-3</sup>
	Ag 110M		3 x 10 <sup>-4</sup>

	Ag 111		4 x 10 <sup>-4</sup>
Sodium (11)	Na 24		2 x 10 <sup>-3</sup>
Strontium (38)	Sr 85		1 x 10 <sup>-4</sup>
	Sr 89		1 x 10 <sup>-4</sup>
	Sr 91		7 x 10 <sup>-4</sup>
	Sr 92		7 x 10 <sup>-4</sup>
Sulfur (16)	S 35	9 x 10 <sup>-8</sup>	6 x 10 <sup>-4</sup>
Tantalum (73)	Ta 182		4 x 10 <sup>-4</sup>
Technetium (43)	Tc 96M		1 x 10 <sup>-1</sup>
	Tc 96		1 x 10 <sup>-3</sup>
Tellurium (52)	Te 125M		2 x 10 <sup>-3</sup>
	Te 127 <del>5</del> M		6 x 10 <sup>-4</sup>
	Te 127		3 x 10 <sup>-3</sup>
	Te 129M		3 x 10 <sup>-4</sup>
	Te 131M		6 x 10 <sup>-4</sup>
	Te 132		3 x 10 <sup>-4</sup>
Terbium (65)	Tb 160		4 x 10 <sup>-4</sup>
Thallium (81)	Tl 200		4 x 10 <sup>-3</sup>
	Tl 201		3 x 10 <sup>-3</sup>
	Tl 202		1 x 10 <sup>-3</sup>
	Tl 204		1 x 10 <sup>-3</sup>
Thulium (69)	Tm 170		5 x 10 <sup>-4</sup>
	Tm 171		5 x 10 <sup>-3</sup>
Tin (50)	Sn 113		9 x 10 <sup>-4</sup>
	Sn 125		2 x 10 <sup>-4</sup>
Tungsten (Wolfram) (74)	W 181		4 x 10 <sup>-3</sup>
	W 187		7 x 10 <sup>-4</sup>
Vanadium (23)	V 48		3 x 10 <sup>-4</sup>
Xenon (54)	Xe 131M	4 x 10 <sup>-6</sup>	
	Xe 133	3 x 10 <sup>-6</sup>	
	Xe 135	1 x 10 <sup>-6</sup>	
Ytterbium (70)	Yb 175		1 x 10 <sup>-3</sup>
Yttrium (39)	Y 90		2 x 10 <sup>-4</sup>
	Y 91M		3 x 10 <sup>-2</sup>
	Y 91		3 x 10 <sup>-4</sup>
	Y 92		6 x 10 <sup>-4</sup>
	Y 93		3 x 10 <sup>-4</sup>
Zinc (30)	Zn 65		1 x 10 <sup>-3</sup>

	Zn 69M		7 x 10 <sup>-4</sup>
	Zn 69		2 x 10 <sup>-2</sup>
Zirconium (40)	Zr 95		6 x 10 <sup>-4</sup>
	Zr 97		2 x 10 <sup>-4</sup>
Beta and/or gamma emitting byproduct not listed above with half-life less than three years		1 x 10 <sup>-10</sup>	1 x 10 <sup>-6</sup>

#### Footnotes to Schedule A

1. Values are given only for those materials normally used as gases.
2.  $\mu\text{Ci/gm}$  for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

*Example:*

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

[30 FR 8185, June 26, 1965, as amended at 35 FR 3982, Mar. 3, 1970; 38 FR 29314, Oct. 24, 1973; 59 FR 5520, Feb. 7, 1994]

#### § 30.71 Schedule B.

Byproduct material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10



Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10

Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0,1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10

Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100

Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100

Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10
Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct materials	0.1

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 59 FR 5519, Feb. 7, 1994; 72 FR 55926, Oct. 1, 2007]

**§ 30.72 Schedule C--Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.**

Radioactive material <sup>1</sup>	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium 241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	<del>g-2</del> (20 mg)
Carbon-14 (non-carbon dioxide)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000

Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technitium-99	.01	10,000

Technitium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma <sup>4</sup>	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha <sup>4</sup>	.0001	20
Combinations of radioactive materials listed above <sup>1</sup>		

<sup>1</sup> For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

<sup>2</sup> Waste packaged in Type B containers does not require an emergency plan.

[54 FR 14061, Apr. 7, 1989, as amended at 61 FR 9902, Mar. 12, 1996; 72 FR 55926, Oct. 1, 2007]

## Appendix A to Part 30--Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

### I. Introduction



An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

## **II. Financial Test**

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

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

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or AAA, AA, A, or BAA as issued by Moody's; and

(ii) Tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)); and

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

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial

statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Commission of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

### III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Commission, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

[53 FR 24046, June 27, 1988 as amended at 63 FR 50479, Sept. 22, 1998; [76 FR 35565, Jun. 17, 2011](#)]

### Appendix B to Part 30--Quantities<sup>1</sup> of Licensed Material Requiring Labeling

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10

Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1

Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100

Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10

Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.10
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100

Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural) <sup>1</sup>	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural) <sup>2</sup>	100
Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

<sup>1</sup>Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

<sup>2</sup>Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

[35 FR 6425, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 38 FR 29314, Oct. 24, 1973; 39 FR 23991, June 28, 1974; 45 FR 71763, Oct. 30, 1980. Redesignated at 56 FR 23391, May 21, 1991, and further redesignated at 58 FR 67659, Dec. 22, 1993]

## **Appendix C to Part 30--Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning**

### **I. Introduction**

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

### **II. Financial Test**

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof (Tangible net worth shall be calculated to exclude the net book value of the nuclear unit(s)).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used), or, for a power reactor licensee, at least 10 times the amount of decommissioning funds being assured by a self guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all reactor units or parts thereof.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that



cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

### **III. Company Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

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

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 63 FR 50479, Sept. 22, 1998; [76 FR 35566, Jun. 17, 2011](#)]

## **Appendix D to Part 30--Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds**

### **I. Introduction**

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning

costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

## **II. Financial Test**

A. To pass the financial test a company must meet the following criteria:

- (1) Tangible net worth greater than \$10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
- (3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

- (1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited yearend financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
- (2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.
- (3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the NRC of intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

## **III. Company Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

- A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the NRC. Cancellation may not occur until an alternative financial assurance mechanism is in place.
- B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the NRC of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[63 FR 29542, June 1, 1998; [76 FR 35567, Jun. 17, 2011](#)]

## **Appendix E to Part 30--Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals**

### **I. Introduction**

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

### **II. Financial Test**

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the NRC of its intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

### **III. Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Commission. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service.

[63 FR 29542, June 1, 1998; [76 FR 35568, Jun. 17, 2011](#)]

## PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

[31.1 Purpose and scope.](#)

[31.2 Terms and conditions.](#)

[31.3 ~~Certain devices and equipment.~~ \[Reserved\]](#)

[31.4 Information collection requirements: OMB approval.](#)

[31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.](#)

[31.6 General license to install devices generally licensed in § 31.5.](#)

[31.7 Luminous safety devices for use in aircraft.](#)

[31.8 Americium-241 and radium-226 in the form of calibration or reference sources.](#)

[31.9 General license to own byproduct material.](#)

[31.10 General license for strontium 90 in ice detection devices.](#)

[31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.](#)

[31.12 General license for certain items and self-luminous products containing radium-226.](#)

[31.13 \[Reserved\]](#)

[31.14 \[Reserved\]](#)

[31.15 \[Reserved\]](#)

[31.16 \[Reserved\]](#)

[31.17 \[Reserved\]](#)

[31.18 \[Reserved\]](#)

[31.19 \[Reserved\]](#)

[31.20 \[Reserved\]](#)

[31.21 Maintenance of records.](#)

[31.22 Violations.](#)

[31.23 Criminal penalties.](#)

**Formatted:** Default Paragraph Font, Font: (Default) +Body (Calibri), 11 pt

**Formatted:** Default Paragraph Font, Font: (Default) +Body (Calibri), 11 pt

**Formatted:** Underline, Font color: Blue

**Authority:** Atomic Energy Act of 1954, secs. 81, 161, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); 44 U.S.C. 3504 note.

Formatted: Space Before: 0 pt

Formatted: Font: (Default) Times New Roman, 12 pt, No underline, Font color: Auto

[72 FR 55926, Oct. 1, 2007; 73 FR 42673, Jul. 23, 2008; 77 FR 39905, Jul. 6, 2012; 77 FR 43690, Jul. 25, 2012; 80 FR 54233, Sep. 9, 2015]

Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), P. Law 109-58, 119 Stat. 806-810 (42 U.S.C. 2014, 2021, 2021b, 2111).

[72 FR 55926, Oct. 1, 2007; 73 FR 42673, Jul. 23, 2008]

### **§ 31.1 Purpose and scope.**

This part establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Specific provisions of 10 CFR Part 30 are applicable to general licenses established by this part. These provisions are specified in § 31.2 or in the particular general license.

[65 FR 79187, Dec. 18, 2000]

### **§ 31.2 Terms and conditions.**

The general licenses provided in this part are subject to the general provisions of Part 30 of this chapter (Secs. 30.1 through 30.10), the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, of this chapter<sup>1</sup> unless indicated otherwise in the specific provision of the general license.

[65 FR 79187, Dec. 18, 2000]

<sup>1</sup> Attention is directed particularly to the provisions of Part 20 of this chapter concerning labeling of containers.

### **§ 31.3 ~~Certain devices and equipment.~~**

~~A general license is hereby issued to transfer, receive, acquire, own, possess and use byproduct material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the Commission:~~

~~(a) *Static elimination device.* Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device.~~

~~(b) (c) [Reserved]~~

~~(d) *Ion generating tube.* Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium 210 per device or of a total of not more than 50 millicuries of hydrogen 3 (tritium) per device. **[Reserved]**~~

Formatted: Level 2

[30 FR 8189, June 26, 1965, as amended at 34 FR 6652, Apr. 18, 1969; 35 FR 3982, Mar. 3, 1970; [77 FR 43690, Jul. 25, 2012](#)]

**§ 31.4 Information collection requirements: OMB approval.**

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0016.

(b) The approved information collection requirements contained in this part appear in §§31.5, 31.8, 31.11, and 31.12.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 31.11, NRC Form 483 is approved under control number 3150-0038.

(2) [Reserved]

[62 FR 52186, Oct. 6, 1997, as amended at 67 FR 67099, Nov. 4, 2002; 72 FR 55926, Oct. 1, 2007]

**§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.<sup>5</sup>**

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b)(1) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in--

(i) A specific license issued under § 32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State; or

(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.

Formatted: No underline, Font color: Auto

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1) of this section or through a transfer made under paragraph (c)(9) of this section.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:



(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels; or

(ii) By a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage of radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 of this chapter or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director, ~~Office, Office of Federal and State Materials and Environmental Management Programs of Nuclear Material Safety and Safeguards,~~

ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days. Under these circumstances, the criteria set out in § 20.1402 of this chapter, "Radiological criteria for unrestricted use," may be applicable, as determined by the Commission on a case-by-case basis;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with part 110 of this chapter;

(8)(i) Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, ~~Office of Nuclear Material Safety and Safeguards, Office of Federal and State Materials and Environmental Management Programs~~, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter. The report must contain~~---~~

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by ~~paragraph (c)(1) of this section~~) so that the device is labeled in compliance with § 20.1904 of this chapter; ~~however the manufacturer, model number, and serial number must be retained; paragraph (c)(1) of this section~~ so that the device is labeled in compliance with § 20.1904 of this chapter; ~~however the manufacturer, model number, and serial number must be retained;~~

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

(9) Shall transfer the device to another general licensee only if--

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, a copy of § 31.2, 30.51, 20.2201, and 20.2202 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to

the Director, ~~Office of Nuclear Material Safety and Safeguards, ATTN: Office of Federal and State Materials and Environmental Management Programs, ATTN:~~ Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter--

(A) The manufacturer's (or initial transferor's) name;

(B) The model number and the serial number of the device transferred;

(C) The transferee's name and mailing address for the location of use; and

(D) The name, title, and phone number of the responsible individual identified by the transferee in accordance with paragraph (c)(12) of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director, ~~Office of Nuclear Material Safety and Safeguards, Office of Federal and State Materials and Environmental Management Programs,~~ by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of paragraph (c)(13)(i) of this section, shall register these devices annually with the Commission and shall pay the fee required by Sec. 170.31 of this chapter. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Commission. The registration information must be submitted to the NRC within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (c)(13)(i) of this section is subject to the bankruptcy notification requirement in § 30.34(h) of this chapter.

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Commission--

(A) Name and mailing address of the general licensee.

(B) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (c)(12) of this section.

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph (c)(13)(i) of this section are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, ~~Office of Nuclear Material Safety and Safeguards, Office of Federal and State Materials and Environmental Management Programs~~, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

<sup>5</sup> Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

[39 FR 43532, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 40 FR 14085, Mar. 28, 1975; 42 FR 25721, May 19, 1977; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 53 FR 19246, May 27, 1988; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 64 FR 42275, Aug. 4, 1999; 65 FR 79188, Dec. 18, 2000; 68 FR 58804, Oct. 10, 2003; 72 FR 55926, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 73 FR 5718, Jan. 31, 2008; 73 FR 42673, July 23, 2008; 79 FR 75739, Dec. 19, 2014]

~~§ Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.~~

#### **§ 31.6 General license to install devices generally licensed in § 31.5.**

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in § 31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter: *Provided*, That:

(a) [Reserved]

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

(c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

[30 FR 8189, June 26, 1965, as amended at 30 FR 10947, Aug. 24, 1965; 39 FR 43533, Dec. 16, 1974; 46 FR 44151, Sept. 3, 1981]

#### **§ 31.7 Luminous safety devices for use in aircraft.**

(a) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147 and that each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions of § 32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an Agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of parts 19, 20, and 21, of this chapter, except that they shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter.

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

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

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

[30 FR 8189, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 38 FR 22220, Aug. 17, 1973; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

**§ 31.8 Americium-241 and radium-226 in the form of calibration or reference sources.**

(a) A general license is issued to those persons listed in this section to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 or radium-226 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued under this chapter which authorizes receipt, possession, use, and transfer of byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4 of this chapter, which holds a specific license issued under this chapter which authorizes it to receive, possess, use, and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued under § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State, or in accordance with a specific license issued by a State with comparable provisions to § 32.57.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 0.185 megabecquerel (5 microcuries) of americium-241 or 0.185 megabecquerel (5 microcuries) of radium-226 in such sources;

(2) Shall not receive, possess, use, or transfer a source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:<sup>1</sup>

The receipt, possession, use, and transfer of this source, Model XX, Serial No. XX, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission 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 AMERICIUM-241 [or RADIUM-226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued under this chapter or by an Agreement State to receive the source.

(4) Shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 which might otherwise escape during storage.

(5) Shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium-226.

[30 FR 8189, June 26, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991; 72 FR 55927, Oct. 1, 2007]

<sup>1</sup> Sources generally licensed under this section before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226 generally licensed under this section and manufactured before November 30, 2007 shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

#### **§ 31.9 General license to own byproduct material.**

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

[30 FR 8189, June 26, 1965]

#### **§ 31.10 General license for strontium 90 in ice detection devices.**

(a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to § 32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:

(1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to part 30 or 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of § 20.2001.

(2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

(3) Are exempt from the requirements of parts 19, 20, and 21, of this chapter except that such persons shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202 of this chapter.

(c) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

[30 FR 9905, Aug. 10, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

**§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.**

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.



(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director, Office of ~~Federal and State Materials and Environmental Management Programs~~ Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, and has received from the Commission a validated copy of NRC Form 483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.

(c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

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

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:<sup>1</sup>

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of Manufacturer)

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of ~~Federal and State Materials and Environmental Management Programs~~ **Nuclear Material Safety and Safeguards**, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License." Form NRC-483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

<sup>1</sup> Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 34110, Dec. 11, 1973; 39 FR 26147, July 17, 1974; 40 FR 8785, Mar. 3, 1975; 41 FR 16446, Apr. 19, 1976; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 42 FR 28896, June 6, 1977; 44 FR 50325, Aug. 28, 1979; 51 FR 36967, Oct. 16, 1986; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 68 FR 58804, Oct. 10, 2003; 72 FR 55927 Oct. 1, 2007; 73 FR 5718, Jan. 31, 2008; **79 FR 75739, Dec. 19, 2014**]

~~<sup>+</sup> Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.~~

#### **§ 31.12 General license for certain items and self-luminous products containing radium-226.**

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to November 30, 2007.

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(3) Luminous items installed in air, marine, or land vehicles.

(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days.

(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter.

(4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.

(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

[53 FR 19246, May 27, 1988; 72 FR 55927 Oct. 1, 2007; 79 FR 75739, Dec. 19, 2014]

§ 31.13 [Reserved].

[57 FR 55072, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

**§ 31.14 [Reserved].**

[57 FR 55073, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

**§ 31.15 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.16 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.17 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.18 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.19 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.20 [Reserved].**

[72 FR 55927 Oct. 1, 2007]

**§ 31.21 Maintenance of records.**

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. 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 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, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[72 FR 55927 Oct. 1, 2007]

**§ 31.22 Violations.**

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[72 FR 55927 Oct. 1, 2007]

#### **§ 31.23 Criminal penalties.**

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 31 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, ~~31.3~~, 31.4, 31.9, 31.~~2213~~, and 31.~~2314~~.

[72 FR 55927 Oct. 1, 2007; 77 FR 43690, Jul. 25, 2012]

**PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL**

[32.1 Purpose and scope.](#)

[32.2 Definitions.](#)

[32.3 Maintenance of records.](#)

[32.8 Information collection requirements: OMB approval.](#)

**Subpart A--Exempt Concentrations and Items**

[32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.](#)

[32.12 Same: Records and material transfer reports.](#)

[32.13 Same: Prohibition of introduction.](#)

[32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.](#)

[32.15 Same: Quality assurance, prohibition of transfer, and labeling.](#)

[32.16 Certain items containing byproduct material: Records and reports of transfer.](#)

[32.17 \[Removed\].](#)

[32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.](#)

[32.19 Same: Conditions of licenses.](#)

[32.20 Same: Records and material transfer reports.](#)

[32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing: Requirements for a license.](#)

[32.21a Same: Conditions of license.](#)

[32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.](#)

[32.23 Same: Safety criteria.](#)

[32.24 Same: Table of organ doses.](#)

[32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.](#)

32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

32.27 Same: Safety criteria.

32.28 Same: Table of organ doses.

32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

32.40 [Removed].

#### **Subpart B—Generally Licensed Items**

32.51 Byproduct material contained in devices for use under § 31.5: requirements for license to manufacture or initially transfer.

32.51a Same: Conditions of licenses.

32.52 Same: Material transfer reports and records.

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

32.54 Same: Labeling of devices.

32.55 Same: Quality assurance; prohibition of transfer.

32.56 Same: Material transfer reports.

32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

32.58 Same: Labeling of devices.

32.59 Same: Leak testing of each source.

32.60 [Reserved]

32.61 Ice detection devices containing strontium-90: requirements for license to manufacture or initially transfer.

32.62 Same: Quality assurance; prohibition of transfer.

32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

#### **Subpart C—Specifically Licensed Items**

32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

Formatted: Font: +Body (Calibri), 11 pt

[32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.](#)

~~[32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.](#)~~

~~[32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226.](#)~~

~~[32.103 Schedule D—prototype tests for ice detection devices containing strontium-90.](#)~~

#### ~~Subpart C—Quality Control Sampling Procedures~~

~~[32.110 Acceptance sampling procedures under certain specific licenses.](#)~~

#### ~~Subpart D—Specifically Licensed Items~~

[32.201 Serialization of nationally tracked sources.](#)

#### Subpart D—Sealed Source and Device Registration

[32.210 Registration of product information.](#)

Formatted: Font: +Body (Calibri), 11 pt

#### Subpart E—Violations

[32.301 Violations.](#)

[32.303 Criminal penalties.](#)

Formatted: Font: +Body (Calibri), 11 pt, No underline, Font color: Auto

Field Code Changed

**Authority:** Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

**Source:** 30 FR 8192, June 26, 1965, unless otherwise noted.

[72 FR 55928, Oct. 1, 2007; 72 FR 58488, Oct. 16, 2007]

#### § 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

- (1) Persons exempted from the licensing requirements of part 30 of this chapter, or
- (2) Persons generally licensed under part 31 or 35 of this chapter.

This part also prescribes certain regulations governing holders of these licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be



used by persons specifically licensed under part 30 of this chapter or equivalent regulations of an Agreement State.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part.

(c)(1) The requirements in this part, including provisions that are specific to licensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on November 30, 2007 except that the agency or tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998; 72 FR 55928 Oct. 1, 2007]

### **§ 32.2 Definitions.**

As used in this part:

*Dose commitment* means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

*Lot Tolerance Percent Defective* means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

*Nationally tracked source* is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E to part 20 of this Chapter. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than

the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974; 71 FR 65686, Nov. 8, 2006]

### **§ 32.3 Maintenance of records.**

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy of 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, 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.

[53 FR 19246, May 27, 1988]

### **§ 32.8 Information collection requirements: OMB approval.**

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6 1997; 62 FR 63640, Dec. 2, 1997; 72 FR 58486, Oct. 16, 2007]

## **Subpart A--Exempt Concentrations and Items**

### **§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.**

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

(a) Satisfies the general requirements specified in § 30.33 of this chapter; *provided, however*, that the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement State;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct 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

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984; 72 FR 58487, Oct. 16, 2007]

#### **§ 32.12 Same: Records and material transfer reports.**

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of ~~Federal and State Materials and Environmental Management Programs-Nuclear Material Safety and Safeguards~~ by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

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

(2) The report must indicate that the byproduct material is transferred for use under § 30.14 of this chapter or equivalent regulations of an Agreement State.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.11 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 14863, Apr. 6, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

#### **§ 32.13 Same: Prohibition of introduction.**

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

[30 FR 8192, June 26, 1965; 72 FR 58487, Oct. 16, 2007]

#### **§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.**

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) 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;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007]

**§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.**

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that 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.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

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

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

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

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007; 73 FR 42673, July 23, 2008]

#### **§ 32.16 Certain items containing byproduct material: Records and reports of transfer.**

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~ Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

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

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

#### **§ 32.17 [Removed].**

[32 FR 4241, Mar. 18, 1967, as amended by 38 FR 29314, Oct. 24, 1973; 43 FR 6922, Feb. 17, 1978; 72 FR 58488, Oct. 16, 2007]

#### **§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.**

An application for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct 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;

(c) The byproduct 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

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

### **§ 32.19 Same: Conditions of licenses.**

Each license issued under § 32.18 is subject to the following conditions:

- (a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter 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 in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.
- (b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter 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 § 30.18 of this chapter. 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.
- (c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."
- (d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

[35 FR 6428, Apr. 22, 1970]

### **§ 32.20 Same: Records and material transfer reports.**

- (a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.
- (b) The licensee shall file a summary report with the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~ Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.
  - (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
  - (2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.
  - (c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.



(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

[48 FR 12333, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

**§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.**

(a) An application for a specific license to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, 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

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

**§ 32.21a Same: Conditions of license.**

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words "Radioactive Material."

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."

[62 FR 63640, Dec. 2, 1997]

**§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.**

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) 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 self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) 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.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) 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.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

(xv) 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.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978]

#### **§ 32.23 Same: Safety criteria.**

An applicant for a license under § 32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, 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 § 32.24 of this part.

(b) 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 II of the table in § 32.24.

(c) 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.

(d)<sup>1</sup> In use and disposal of a single exempt unit, or 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 III of the table in § 32.24, 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 IV of the table in § 32.24.

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

[34 FR 9027, June 6, 1969]

<sup>1</sup> It is the intent of this paragraph 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.

**§ 32.24 Same: Table of organ doses.**

Part of body	Column I (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

[34 FR 9329, June 13, 1969]

**§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.**

Each person licensed under § 32.22 shall:

(a) 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 Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Maintain records of all transfers and file a report with the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~ **Nuclear Material Safety and Safeguards** by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

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

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 9027, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 48 FR 12334, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008]

**§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.**

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer

byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) 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 § 32.27. The information should include:

- (1) A description of the product and its intended use or uses;
- (2) The type and quantity of byproduct material in each unit;
- (3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;
- (4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;
- (5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;
- (6) 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;
- (7) Degree of access of human beings to the product during normal handling and use;
- (8) Total quantity of byproduct material expected to be distributed in the product annually;
- (9) The expected useful life of the product;
- (10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of § 32.29(b);
- (11) 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;
- (12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;
- (13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;
- (14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;
- (15) 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

(16) Any additional information, including experimental studies and tests, required by the Commission.

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980]

**§ 32.27 Same: Safety criteria.**

An applicant for a license under § 32.26 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 § 32.28.

(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.

(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 § 32.28, 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 in § 32.28.<sup>1</sup>

[34 FR 6654, Apr. 18, 1969]

<sup>1</sup> It is the intent of this paragraph 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 one million exempt units distributed.

**§ 32.28 Same: Table of organ doses**

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

[34 FR 6654, Apr. 18, 1969]

**§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.**

Each person licensed under § 32.26 shall:

(a) 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 Commission;

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

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

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

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

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of ~~Federal and State Materials and Environmental Management Programs~~ Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

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

(2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State.



(3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

#### **§ 32.40 [Removed].**

[30 FR 8192, June 26, 1965, as amended at 31 FR 5317, Apr. 2, 1966; 43 FR 6923, Feb. 17, 1978; 72 FR 58489, Oct. 16, 2007]

### **Subpart B--Generally Licensed Items**

#### **§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.**

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

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

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

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct 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 1 year a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

(iii) 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 dose to the appropriate organ as specified in Column IV of the table in § 32.24.

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

(i) 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);

(ii) The requirements, 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

(iii) The information called for in the following statement in the same or substantially similar form:<sup>1</sup>

The receipt, possession, use, and transfer of this device Model \_\_\_\_\_,<sup>2</sup> Serial No. \_\_\_\_\_,<sup>2</sup> are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

#### CAUTION--RADIOACTIVE MATERIAL

\_\_\_\_\_  
(Name of manufacturer, or initial transferor)<sup>2</sup>

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in § 20.1901 of this chapter, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of § 31.5(c)(13)(i) of this chapter, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in § 20.1901 of this chapter.

#### (6) The device has been registered in the Sealed Source and Device Registry.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission will consider information which includes, but is not limited to:

- (1) Primary containment (source capsule);
- (2) Protection of primary containment;
- (3) Method of sealing containment;
- (4) Containment construction materials;
- (5) Form of contained radioactive material;
- (6) Maximum temperature withstood during prototype tests;
- (7) Maximum pressure withstood during prototype tests;
- (8) Maximum quantity of contained radioactive material;
- (9) Radiotoxicity of contained radioactive material; and
- (10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter.

[39 FR 43533, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 42 FR 25721, May 19, 1977; 43 FR 6923, Feb. 17, 1978; 58 FR 67660, Dec. 22, 1993; 59 FR 5520, Feb. 7, 1994; 65 FR 79189, Dec. 18, 2000]

<sup>1</sup> Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

<sup>2</sup> The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

#### **§ 32.51a Same: Conditions of licenses.**

(a) If a device containing byproduct material is to be transferred for use under the general license contained in § 31.5 of this chapter, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the general license contained in § 31.5 of this chapter; if paragraphs (c)(2) through (4) or (c)(13) of § 31.5 do not apply to the particular device, those paragraphs may be omitted.

(2) A copy of §§ 31.2, 30.51, 20.2201, and 20.2202 of this chapter;

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

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

(5) An indication that NRC's policy is to issue high civil penalties for improper disposal.

(b) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the Agreement State's regulations equivalent to §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter or a copy of §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

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

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

(4) The name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the Commission.

(d) Each device that is transferred after February 19, 2002 must meet the labeling requirements in § 32.51(a)(3) through (5).

(e) If a notification of bankruptcy has been made under § 30.34(h) or the license is to be terminated, each person licensed under § 32.51 shall provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under § 32.52(c).

[65 FR 79189, Dec. 18, 2000; 65 FR 80991, Dec. 22, 2000]

#### **§ 32.52 Same: Material transfer reports and records.**

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report to the Director, Office of ~~Federal and State Materials and Environmental Management Programs~~ Nuclear Material Safety and Safeguards, ATTN: GLTS, by an appropriate method listed in § 30.6(a) of this chapter, all transfers of such devices to persons for use under the general license

in § 31.5 of this chapter and all receipts of devices from persons licensed under § 31.5 of this chapter. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

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

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

(iii) The date of transfer;

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

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

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

(3) For devices received from a § 31.5 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a § 31.5 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

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

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

(7) If no transfers have been made to or from persons generally licensed under § 31.5 of this chapter during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5 of this chapter and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State agency. The report must be submitted on Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes--

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

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

(iii) The date of transfer;

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

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

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

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

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

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

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

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

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

[65 FR 79189, Dec. 18, 2000; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008]

**§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer.**

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 § 31.7 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

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

- (1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;
- (2) Details of construction and design;
- (3) Details of the method of binding or containing the tritium or promethium-147;
- (4) 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;
- (5) ~~Any quality control~~ Quality assurance procedures ~~proposed as alternatives to those prescribed by § 32.55;~~ followed that are sufficient to ensure compliance with § 32.55;
- (6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) 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.

(d) The Commission determines that:

- (1) 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;
- (2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;
- (3) The device is so designed that it cannot easily be disassembled; and

(4) ~~The Prototypes of the~~ device have been subjected to and ~~have~~ satisfactorily passed the ~~prototype~~ tests ~~prescribed~~ required by ~~§ 32.101, Schedule B, paragraph (e) of this part.~~ section.

(e) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(f) The device has been registered in the Sealed Source and Device Registry.

[30 FR 8192, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 43 FR 6923, Feb. 17, 1978; 77 FR 43693 Jul. 25, 2102]

**§ 32.54 Same: Labeling of devices.**

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.1901 of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:<sup>1</sup>

The receipt, possession, use, and transfer of this device, Model\* \_\_\_\_\_, Serial No.\* \_\_\_\_, containing \_\_\_\_\_ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

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

\*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.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

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

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,



(iii) The model number,

(iv) 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 U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

[33 FR 16331, Nov. 7, 1968, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 63 FR 39483, July 23, 1998]

<sup>1</sup> Devices licensed under § 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

**§ 32.55 Same: Quality assurance; prohibition of transfer.**

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any ~~which~~that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall ~~take a random sample~~:

(1) Maintain quality assurance systems in the manufacture of the size required luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by the table in § 32.110 for procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and will not be exceeded.

(c) The licensee shall subject each unit in the sample to inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following tests criteria for defective:

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

(2) The immersion test water from the preceding test in paragraph (b)(1) of this section 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.

~~(3) The levels~~(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

~~(ii) Levels of radiation from each device containing promethium 147 shall be measured. Any device which has a radiation level in-in excess of 5 microgray (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-if the device contains promethium-147; and~~

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

~~(1) 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~~

~~(2) 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.~~

~~(d) No person licensed under § (iii) Any other criteria specified in the license issued under § 32.53.~~

~~(d) No person licensed under § 32.53 shall transfer to persons generally licensed under §-31.7 of this chapter; or under an equivalent general license of an Agreement State;~~

~~(1) Any~~(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

~~(2) Any luminous safety device which contained within any lot that 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 paragraph (b) of this section; or~~

~~(2) Any inspection lot which has been sampled and rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (e) (b)(2) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section;~~

~~(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and~~

~~(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.~~

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974; 77 FR 43693, Jul. 25, 2012]

**§ 32.56 Same: Material transfer reports.**

(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of ~~Federal and State Materials and Environmental Management Programs~~Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must 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 must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, 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. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.

[60 FR 3737, Jan. 19, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 77 FR 43694, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

**§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.**

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

- (a) The applicant satisfies the general requirements of § 30.33 of this chapter;
- (b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:
  - (1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;
  - (2) Details of construction and design;
  - (3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;
  - (4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;
  - (5) Details of quality control procedures to be followed in manufacture of the source;
  - (6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed ~~the prototype appropriate~~ tests ~~prescribed required~~ by ~~§ 32.102, Schedule C, paragraph (e)~~ of this ~~part~~ section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 72 FR 55928, Oct. 1, 2007; 73 FR 42674, July 23, 2008; 77 FR 43694, Jul. 25, 2012]

#### **§ 32.58 Same: Labeling of devices.**

Each person licensed under § 32.57 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:<sup>1</sup>

The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission 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 AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or initial transferor

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 72 FR 55929 Oct. 1, 2007]

<sup>1</sup> Sources licensed under § 32.57 before January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

#### **§ 32.59 Same: Leak testing of each source.**

Each person licensed under § ~~32.57~~ shall perform a dry wipe test upon each source containing more than 3.7-kilobecquerels (0.1-microcurie) of americium-~~241~~ or radium-~~226~~ before transferring the source to a general licensee under § ~~31.8~~ of this chapter ~~or under equivalent regulations of an Agreement State~~. This test ~~shall~~must 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 filter paper ~~shall~~must be measured ~~by~~ using ~~radiation detection instrumentation methods~~ capable of detecting 0.185-kilobecquerel (0.005 microcurie) of americium-~~241~~ or radium-~~226~~. ~~If this test discloses a source has been shown to be leaking or losing more than 0.185-kilobecquerel (0.005-microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226-226 by the methods described in this section, the source must be rejected and shall~~must not be transferred to a general licensee under § ~~31.8~~ of this chapter ~~or equivalent regulations of an Agreement State~~.

[30 FR 8192, June 26, 1965; 72 FR 55929 Oct. 1, 2007; 77 FR 43694, Jul. 25, 2012]

#### **§ 32.60 [Reserved]**

#### **§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.**

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

- (a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;
- (b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:
  - (1) Chemical and physical form and maximum quantity of strontium-90 in the device;
  - (2) Details of construction and design of the source of radiation and its shielding;
  - (3) Radiation profile of a prototype device;
  - (4) 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;
  - (5) Details of quality control procedures to be followed in manufacture of the device;
  - (6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device;

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

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.1901(a) of this chapter, 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;

(e) The Commission determines that:

(1) 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;

(2) 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 circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) ~~The Prototypes of the device have~~ been subjected to and ~~have~~ satisfactorily passed the ~~prototype~~ tests ~~prescribed~~required by ~~§ 32.103; and paragraph (f) of this section.~~

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

(f) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device;  
or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(g) The device has been registered in the Sealed Source and Device Registry.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 77 FR 43694, Jul. 25, 2012]

**§ 32.62 Same: Quality assurance; prohibition of transfer.**

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 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.

(c) Each person licensed under § ~~32.61~~ shall ~~take a random sample~~:

(1) Maintain quality assurance systems in the manufacture of the size required ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by the table in § 32.110 for procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and will not be exceeded.

(d) Each person licensed under § 32.61 shall subject each unit in the sample to the following tests inspection lot to:

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

(2) The immersion test water from the preceding test in paragraph (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 (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 in from the device and any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a other criteria specified in the license may include a description of procedures proposed as alternatives to those prescribed by paragraph (c) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

Formatted: Font: Arial, 11 pt

~~(1) 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~~

~~(2) 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 issued under § 32.61.~~

(e) No person licensed under §-32.61 shall transfer to persons generally licensed under §-31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device ~~which has been containing strontium-90~~ tested and found defective under the criteria ~~and procedures specified in this §-a license issued under § 32.6261,~~ unless the defective ~~units~~ ice detection device has been repaired or reworked ~~and then met, retested, and determined by an independent inspector to meet the tests set out in paragraph (c) of this section~~ applicable acceptance criteria; or

(2) Any ~~inspection~~ ice detection device containing strontium-90 contained within any lot which that has been sampled and rejected as a result of the procedures in § 32.110 ~~or alternative procedures in paragraph (d) (c)(2) of this section, unless the defective units have been sorted;~~

(i) A procedure for defining sub-lot size, independence, and ~~removed or have been repaired or reworked~~ additional testing procedures is contained in the license issued under § 32.61; and have then met the tests set out in paragraph

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of this section the license issued under § 32.61.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978; 77 FR 43694, Jul. 25, 2012]

#### **§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.**

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.



(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

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

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:<sup>1</sup>

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

---

(Name of Manufacturer)

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.2001

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 72 FR 55929 Oct. 1, 2007]

<sup>1</sup> Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

### **Subpart C—Specially Licensed Items**

**§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.**

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

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

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

(ii) Registered or licensed with a state agency as a drug manufacturer;

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

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

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

(3) 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

(4) The applicant satisfies the following labeling requirements:

(i) 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.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

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

(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

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

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

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

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

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

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

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

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

[59 FR 61780, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994, as amended at 60 FR 324, Jan. 4, 1995; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 67 FR 77652, Dec. 19, 2002; 71 FR 15007, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 72 FR 55929 Oct. 1, 2007; [77 FR 43695, Jul. 25, 2012](#)]

**§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.**

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if:

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

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

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

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

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

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

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

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

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b)(1) 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 shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission 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;
- (x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

[39 FR 26149, July 17, 1974, as amended at 51 FR 36967, Oct. 16, 1986; 62 FR 59276, Nov. 3, 1997; 67 FR 20370, Apr. 24, 2002; 71 FR 15008, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 77 FR 43695, Jul. 25, 2012]

**~~§ 32.101 Schedule B—prototype tests for luminous safety devices for use in aircraft.~~**

~~An applicant for a license pursuant to § 32.53 shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:~~

~~(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in the following steps:~~

~~Step 1. The internal temperature of the test chamber shall be reduced to -62° C. (-80° F.) and the device shall be maintained for at least 1 hour at this temperature at atmospheric pressure.~~

~~Step 2. The internal temperature of the test chamber shall be raised to -54° C. (-65° F.) and maintained until the temperature of the device has stabilized at -54° C. at atmospheric pressure.~~

~~Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54° C.~~

~~Step 4. The internal temperature of the chamber shall be raised to -10° C. (+14° F.) and maintained until the temperature of the device has stabilized at -10° C., and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.~~

~~Step 5. The internal temperature of the chamber shall be raised to +85° C. (185° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +85° C. and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.~~

~~Step 6. The chamber temperature shall be reduced to +71° C. (160° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +71° C. for a period of 30 minutes.~~

~~Step 7. The chamber temperature shall be reduced to +55° C. (130° F.) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.~~

~~Step 8. The internal temperature of the chamber shall be reduced to +30° C. (86° F.) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.~~

~~Step 9. The temperature of the test chamber shall be raised to +35° C. (95° F.) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.~~

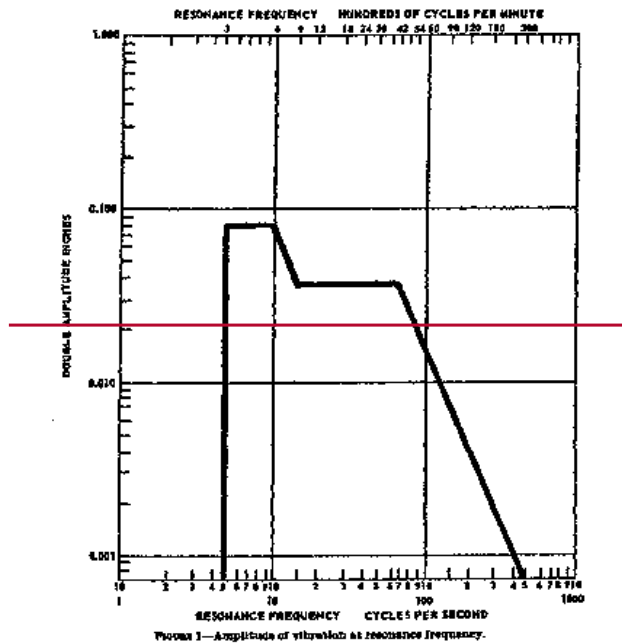
~~Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20° C. (68° F.) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.~~

~~(b) *Vibration tests.* This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted directly on gas turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under both resonant and cycling conditions.~~

~~Vibration Test Schedule Table I  
[Times shown refer to one axis of vibration]~~

Type	Vibration at room temperature (minutes)	Vibration at 160° F. (71C.) (minutes)	Vibration at -65° F. (-54C.)(minutes)
Resonance	60	15	15
Cycling	60	15	15

(1) *Determination of resonance frequency.* Individual resonance frequency surveys shall be conducted by applying vibration to each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.



(2) *Resonance tests.* The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

(3) *Cycling.* Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1 minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15 minute cycles for the periods and temperature conditions shown in Table I.

(c) *Accelerated weathering tests.* The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Correx D glass shall surround the area to cut off the ultraviolet radiation below a wave length of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50°C plus or minus 3°C. Temperature measurements shall be made with a black panel thermometer.

(d) *Shock test.* The device shall be dropped upon a concrete or iron surface in a 3 foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

(f) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium-147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium-147 from each tested device shall be measured 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 amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test prescribed by test paragraph (e) of this section shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium-147 in any device shall be cause for rejection of the tested device.

[30 FR 8192, June 26, 1965]

**~~§ 32.102 Schedule C—prototype tests for calibration or reference sources containing americium-241 or radium-226.~~**

An applicant for a license under § 32.57 shall, for any type of source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:

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

(b) *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.

(c) *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.

(d) *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.

(e) *Dry wipe test.* On completion of the preceding test in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

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

[30 FR 8192, June 26, 1965, as amended at 31 FR 15145, Dec. 2, 1966; 72 FR 55929 Oct. 1, 2007]

#### **~~§ 32.103 Schedule D—prototype tests for ice detection devices containing strontium 90.~~**

An applicant for a license pursuant to § 32.61 shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of § 32.101(a).

(b) *Vibration tests.* The device shall be subjected to vibration tests as set forth in § 32.101(b).

(c) *Shock test.* The device shall be subjected to shock test as set forth in § 32.101(d).

(d) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium 90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium 90 shall be considered leakage.

(e) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium 90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium 90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium 90 from each tested device shall be measured 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 amount of strontium 90 in the water used in the hermetic seal and waterproof test prescribed in paragraph (d) of this section shall also be measured. The detection on the filter paper of more than 2,200 disintegrations per minute of strontium 90 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of strontium 90 in any device, shall be cause for rejection of the tested device.

[30 FR 9906, Aug. 10, 1965]

**Subpart C—Quality Control Sampling ProceduresD—Sealed Source and Device Registration**

**§ 32.110 Acceptance sampling procedures under certain specific licenses.**

(a) A random sample shall be taken from each inspection lot of devices licensed under §§ 32.14, 32.53, or 32.61 of this part for which testing is required pursuant to §§ 32.15, 32.55, or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

(b) Single sampling tables for Lot Tolerance Percent Defective

(1) Lot Tolerance Percent Defective 0.5 percent:

Lot size	Sample Size	Acceptance No.
1 to 180	All	0
181 to 210	180	0
211 to 250	210	0
251 to 300	240	0
301 to 400	275	0
401 to 500	300	0
501 to 600	320	0
601 to 800	350	0
801 to 1,000	365	0
1,001 to 2,000	410	0
2,001 to 3,000	430	0
3,001 to 4,000	440	0
4,001 to 5,000	445	0
5,001 to 7,000	450	0
7,001 to 10,000	455	0
10,001 to 20,000	460	0
20,001 to 50,000	775	1
50,001 to 100,000	780	1

(2) Lot Tolerance Percent Defective 1.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 120	All	0

121 to 150	120	0
151 to 200	140	0
201 to 300	165	0
300 to 400	175	0
401 to 500	180	0
501 to 600	190	0
601 to 800	200	0
801 to 1,000	205	0
1,000 to 3,000	220	0
3,001 to 5,000	225	0
5,001 to 10,000	230	0
10,001 to 100,000	390	1

(3) Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 75	All	0
76 to 100	70	0
101 to 200	85	0
201 to 300	95	0
301 to 400	100	0
401 to 600	105	0
601 to 800	110	0
801 to 4,000	115	0
4,001 to 10,000	195	1
10,001 to 100,000	200	1

(4) Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

(5) Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0
101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

(6) Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

(7) Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

(8) Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample Size	Acceptance No.
1 to 20	All	0
21 to 50	17	0

51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,00	39	0

[39 FR 22130, June 20, 1974]

#### **~~Subpart D--Specifically Licensed Items~~**

##### **§ 32.201 Serialization of nationally tracked sources.**

Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[71 FR 65686, Nov. 8, 2006; 77 FR 43695, Jul. 25, 2012]

#### **Subpart D--Specifically Licensed Items**

##### **§ 32.210 Registration of product information.**

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

(b) The request for review must be sent to the NRC's Office of ~~Federal and State Materials and Environmental Management Programs~~Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter.

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

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with--

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

(2) The provisions of the registration certificate.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008]

## **Subpart E--Violations**

### **§ 32.301 Violations.**

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55073, Nov. 24, 1992]

### **§ 32.303 Criminal penalties.**

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 32 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.18, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.51, 32.53, 32.57, 32.61, 32.71, 32.74, 32.301, and 32.303.

[57 FR 55073, Nov. 24, 1992, as amended at 59 FR 61781, Dec. 2, 1994; 73 FR 42674, July 23, 2008]