

## § 30.4

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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.

[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 com-

mmercial, 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 taking any action defined as “construction” or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

- (1) Radiological health and safety; or
- (2) Common defense and security.

*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.

*Construction* means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a

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facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes;

(2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

(5) Excavation;

(6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(7) Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9) Taking any other action that has no reasonable nexus to:

- (i) Radiological health and safety, or
- (ii) Common defense and security.

*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 com-

monly 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

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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 byproduct 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;

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*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]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §30.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

### § 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 proc-

ess 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 e-mail to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@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.