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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).

SOURCE: 58 FR 7728, Feb. 9, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of

parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

(c) The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

§ 36.2 Definitions.

Annually means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

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.

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

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in §36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed

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sources or the space subject to irradiation without entering the pool.

[58 FR 7728, Feb. 9, 1993, as amended at 76 FR 56963, Sept. 15, 2011]

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part 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.

§ 36.8 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 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21, 36.53, 36.69, 36.81, and 36.83.

(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 § 36.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[58 FR 7728, Feb. 9, 1993, as amended at 62 FR 52187, Oct. 6, 1997]

Subpart B—Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of

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sealed sources in an irradiator on Form NRC 313, “Application for Material License.” Each application for a license, other than a license exempted from part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in §§ 30.33(a)(1)–(4) and 30.33(b) of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including—

(1) Classroom training;

(2) On-the-job or simulator training;

(3) Safety reviews;

(4) Means employed by the applicant to test each operator’s understanding of the Commission’s regulations and licensing requirements and the irradiator operating and emergency procedures; and

(5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.