package, repackage, 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]

§30.22 Certain industrial devices.

(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.

(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, July 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), (3), and (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.

(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.[1]

(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

[1] These reporting requirements do not superceed 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.

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.

[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 58004, Oct. 10, 2003; 72 FR 55925, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; 77 FR 43689, July 25, 2012; 79 FR 58671, Sept. 30, 2014]

§ 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 37 and 39 of this chapter; 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 NRC determines will significantly affect the quality of the environment, the Director, Office of Nuclear Material Safety and Safeguards or his/her 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