

## § 30.20

### § 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 20 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 life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.26 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 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]

### § 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

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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, 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]

## LICENSES

### § 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part and parts 32 through 36 and 39 of this chapter. General licenses are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

[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]

EFFECTIVE DATE NOTE: At 65 FR 79187, Dec. 18, 2000, § 30.31 was revised, effective Feb. 16, 2001. For the convenience of the user, the revised text is set forth as follows:

### § 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.

### § 30.32 Application for specific licenses.

(a) A person may file an application in duplicate 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) 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 or with an Agreement State; or

(2) Contain the information identified in §32.210(c).

(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 off-site 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,

<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.

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 off-site 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.

[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]

### § 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 of Nuclear Material Safety and Safeguards 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]

### § 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) 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