

PROPOSED AMENDMENTS TO RADIOISOTOPES REGULATION

726731

1. Amend Section 30.2 by adding the following definitions:

✓ "Specific authorization" is defined in Section 30.30(b).

✓ "General authorization" is defined in Section 30.³⁰(b).

✓ "Medical use" means the internal or external administration of radioisotopes, or the radiation therefrom, to human ~~beings.~~ ^{beings.}

The addition of the foregoing references in Section 30.2 will require changes in the lettering of the various paragraphs presently in Section 30.2.

2. Amend Section 30.2 by adding the following at the end thereof:

30.2 (1) "Research and Development" means theoretical analysis, exploration, and experimentation, and 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 herein does not include the internal or external administration of radioisotopes, or the radiation therefrom, to human beings. *

3. Amend Section 30.21 to read as follows:

30.21 REQUIREMENTS FOR THE GRANTING OF APPLICATIONS

(a) Requirements of General Applicability

A domestic application for radioisotopes procurement will not be approved unless:

- (1) the radioisotope is requested for one or more of the

• As drafted in Oak Ridge, the last sentence was in parentheses and did not include the quotation marks.

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and ?

following purposes: research or development, medical therapy, industrial uses, processing or making of compounds, or such other useful applications as may be developed; and

- (2) the applicant has suitable equipment and facilities for the protection of health and safety (such as, for example, handling devices, work areas, shields, measuring and monitoring instruments, etc.); and
- (3) the applicant has suitably trained and experienced personnel and is otherwise qualified to use radioisotopes for the requested purpose.

(b) Special Requirements Applicable to Medical Uses by Institutions

An application by an institution for authorization to procure radioisotopes for medical use will not be approved unless:

- (1) the applicant satisfies the general requirements set forth in paragraph (a) of this section; and
- (2) the institution has appointed a local isotopes committee of at least three members to evaluate all proposals for research, diagnosis, and therapeutic use of radioisotopes within that institution. Membership of the committee should include persons expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations; and

- (3) the institution possesses adequate facilities for the clinical care of patients; and
- (4) the physician designated on the application as the individual user (Item 3, Form AEC-313) is licensed by a state or territory of the United States to dispense drugs in the practice of medicine, and has had substantial experience in the proposed medical use of radioisotopes, the handling and administration of radioisotopes, and, where applicable, the clinical management of radioactive patients; and
- (5) the applicant, if the application is for a general authorization, has also (i) previously received a reasonable number of authorizations for radioisotopes procurement for a variety of radioisotopes for a variety of medical uses; (ii) appointed a radiological safety officer who will be responsible for the safe handling of radioisotopes; and (iii) appointed a local isotope committee (see Sec. 30.21(b)(2)) which will review and approve, in advance of purchase of radioisotopes, proposals for their medical use.

(c) Special Requirements Applicable to Medical Use by Individuals

An application by an individual for authorization to procure radioisotopes for medical use will not be approved unless:

- (1) the applicant satisfies the general requirements specified in Section 30.21(a); and
- (2) the applicant is a physician licensed by a state or territory of the United States to dispense drugs in the practice of medicine; and
- (3) the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
- (4) the applicant has had substantial experience in the proposed medical use of radioisotopes, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients. (The physician must furnish suitable evidence of such experience with his application. A statement from the local isotope committee in the institution where he acquired his experience, indicating its amount and nature, may be submitted as evidence of such experience.)

(d) Special Requirements Applicable to General Authorizations for Use in Research and Development

An application for a general authorization to procure radioisotopes for use in research and development will not be approved unless:

- (1) the applicant satisfies the general requirements specified in Section 30.21(a); and

- (2) the applicant has received a reasonable number of authorizations for radioisotopes procurement for a variety of radioisotopes for a variety of research and development uses; and
 - (3) the applicant has established a local isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which must review and approve, in advance of purchase of radioisotopes, proposals for such use of radioisotopes; and
 - (4) the applicant has appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.
- (e) Special Requirements Applicable to General Authorizations for Processing

An application for general authorization to procure radioisotopes for use in processing will not be approved unless:

- (1) the applicant satisfies the general requirements specified in Section 30.21(a); and
- (2) the applicant has received a reasonable number of authorizations for radioisotopes procurement for processing, resale, and distribution of a variety of radioisotopes; and

(3) the applicant has appointed a radiological safety officer who will advise on or be available for advice and assistance on radiological safety problems.

(f) Special Requirements Applicable to Use of Sealed Sources of Radiation Devices *for medical use*

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language*

An application for authorization to procure radioisotopes in sealed sources for medical use will not be approved unless:

- (1) the applicant or, if the application is made by an institution, the physician designated as the individual user has had specialized training in the therapeutic use of the radioactive device considered (teletherapy unit, beta applicator, etc.) or has had experience equivalent to such training; and
- (2) the applicant satisfies all applicable requirements set forth in paragraphs (a), (b) and (c) of this Section.

4. Amend Section 30.30 to read as follows:

30.30 ISSUANCE OF AUTHORIZATIONS

(a) Upon approval of an application, the Commission will issue an Authorization for Radioisotope Procurement, Form AEC-374. The authorization shall be the only valid approval for procurement, and its issuance shall be based upon the representations made in the application and shall be subject to and in accordance with the regulations in this part and the terms and conditions stated in the application.

(b) An Authorization for Radioisotope Procurement issued by the Commission is a "specific" authorization unless the authorization expressly states that it is a "general" authorization. A specific authorization authorizes procurement only of the radioisotopes specified in the authorization, in the quantity or quantities and for the specific use or uses designated therein. General authorizations are issued only to governmental agencies, institutions, commercial firms, or similar entities. A general authorization authorizes the procurement of any quantity of any radioisotope of atomic No. 3 to 83.

5. Amend Section 30.32 to read as follows:

30.32 EXPIRATION

An Authorization for Procurement of Radioisotopes shall expire at the end of the period stated therein without the necessity of notice or warning from the Commission. The holder thereof shall neither order nor receive radioisotopes after the expiration of such authorization and no person shall transfer radioisotopes to another person after the expiration date of the transferee's authorization. Expiration of a holder's authorization does not affect his authority to retain possession of previously acquired radioisotopes for the use or uses specified in the authorization and subject to all the conditions ^{and limitations} incorporated therein, or otherwise imposed by this regulation.

6. Amend Sections 30.13 and 30.54 in the manner proposed in the last draft received from Oak Ridge.