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2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

SOURCE: 51 FR 36951, Oct. 16, 1986, unless otherwise noted.

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

ALARA (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

Authorized nuclear pharmacist means a pharmacist who is:

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(1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;

(2) Identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or

(3) Identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

Authorized user means a physician, dentist, or podiatrist who is:

(1) Board certified by at least one of the boards listed in Paragraph (a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;

(2) Identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.

Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

Dental use means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

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.

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic

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clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

Management means the chief executive officer or that person's delegate or delegates.

Medical Institution means an organization in which several medical disciplines are practiced.

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.

Ministerial change means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

(i) Involving the wrong individual, or wrong radiopharmaceutical; or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong individual, or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) A brachytherapy radiation dose:

(i) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

(i) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Mobile nuclear medicine service means the transportation and medical use of byproduct material.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Pharmacist 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 pharmacy.

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.

Podiatric use means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

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.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

- (1) In a written directive; or
- (2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
- (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license.

Recordable event means the administration of:

- (1) A radiopharmaceutical or radiation without a written directive where a written directive is required;
- (2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

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

Teletherapy physicist means the individual identified as the teletherapy physicist on a Commission license.

Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

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(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 34120, July 25, 1991; 59 FR 61781, Dec. 2, 1994; 60 FR 48626, Sept. 20, 1995]

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19247, May 27, 1988]

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities

by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

[59 FR 61781, Dec. 2, 1994]

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

[59 FR 61782, Dec. 2, 1994]

§ 35.8 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 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.20, 35.21, 35.22, 35.23, 35.29, 35.31, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.75, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, 35.980, and 35.981.

(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 as follows:

(1) In § 35.12, NRC Form NRC 313 is approved under control number 3150-0120.

(2) [Reserved]

(d) OMB has assigned control number 3150-0171 for the information collection