[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 32 and 35

RIN 3150- AI14

Medical Use of Byproduct Material - Minor Corrections and Clarifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to correct or clarify the rule language in several sections in the regulations that govern specific domestic licenses to manufacture or transfer certain items containing byproduct material and medical use of byproduct material. The regulations that govern medical use of byproduct materials were amended in their entirety on April 24, 2002 (67 FR 20249). Subsequently, these regulations were amended again to revise the training and experience requirements for the medical use of byproduct material on March 30, 2005 (70 FR 16336). Through implementation of these revised regulations, the NRC has identified additional changes that need to be made to these regulations. This action is necessary to clarify certain provisions and to make certain conforming changes to the regulations.

DATES: Comments on the proposed rule must be received on or before (**insert date 30 days after publication in the Federal Register**).

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150- AI14) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at

http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415- 0253, e-mail eml1@nrc.gov.

SUPPLEMENTARY INFORMATION:

For additional information see the Direct Final Rule published in the Final Rules section of this Federal Register.

Because NRC considers this action noncontroversial and routine, we are publishing this proposed rule concurrently as a direct final rule. The direct final rule will become effective on (**insert date 75 days after publication in the Federal Register**). However, if the NRC receives significant adverse comments on the proposed rule by (**insert date 30 days after publication in the Federal Register**), then the NRC will publish a document to withdraw the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period for this action if the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the staff to make a change (other than editorial) to the rule.

List of Subjects

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Parts 32 and 35.

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

1. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note), Energy Policy Act of 2005, Pub. L. No. 109-58, 119 Stat. 594 (2005).

2. In § 32.72, paragraph (b)(5) is revised to read as follows:

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.

* * * * *

(b) * * *

(5) Shall provide to the Commission a copy of each individual's:

(i)(A) Certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or

(B) The Commission or Agreement State license; or

(C) The permit issued by a licensee of broad scope; and

(ii) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

* * * * *

3. In § 32.74, the introductory text of paragraph (a) is revised to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if:

* * * * *

PART 35--MEDICAL USE OF BYPRODUCT MATERIAL

4. The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

5. In § 35.2, the definition of *Medium dose-rate remote afterloader* is revised to read as follows:

§ **35.2 Definitions.**

* * * * *

Medium dose-rate remote afterloader, as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

* * * * *

6. In § 35.41, paragraph (b)(4) is revised to read as follows:

§ **35.41 Procedures for administrations requiring a written directive.**

* * * * *

(b) * * *

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000.

* * * * *

7. In § 35.75, the text of paragraph (a) is republished and footnote 1 is revised to read as follows:

§ **35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.**

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

* * * * *

[1]The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Medical Licenses" describes methods for Calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

8. In § 35.92, the introductory text of paragraph (a) is revised to read as follows:

§ **35.92 Decay-in-storage.**

(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it--

* * * * *

9. In § 35.190, paragraph (a)(1) is revised to read as follows:

§ **35.190 Training for uptake, dilution, and excretion studies.**

***** ***** ***** ***** *****

(a) * * *

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for

uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and

* * * * *

10. In § 35.290, paragraph (a)(1) is revised to read as follows:

§ **35.290 Training for imaging and localization studies.**

***** ***** ***** ***** *****

(a) * * *

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

* * * * *

Dated at Rockville, Maryland, this 31st day of July, 2007.

For the Nuclear Regulatory Commission.

/RA/
Martin J. Virgilio
Acting Executive Director for Operations

uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and

* * * * *

10. In § 35.290, paragraph (a)(1) is revised to read as follows:

§ **35.290 Training for imaging and localization studies.**

* * * * *

(a) * * *

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and

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Dated at Rockville, Maryland, this 31st day of July, 2007.

For the Nuclear Regulatory Commission.

/RA/
Martin J. Virgilio
Acting Executive Director for Operations

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