[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: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending 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.

EFFECTIVE DATE: The final rule is effective on (**insert date 75 days after publication in the Federal Register**), unless significant adverse comments are received by **(insert date 30 days after publication in the Federal Register**). 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. If the rule is withdrawn due to significant adverse comments, timely notice will be provided in the Federal Register.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 to the public in their entirety on the NRC rulemaking web site. Personal information, such as name, address, phone, e-mail address, etc., will not be removed from 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:

Background

The purpose of these amendments is to amend 10 CFR Parts 32 and 35 to clarify and make certain conforming changes related to the NRC's requirements for the medical use of byproduct material.

Discussion

This direct final rule revises several sections in 10 CFR Parts 32 and 35 to correct or clarify rule language. It also includes conformatory changes that should have been incorporated in the regulations but were inadvertently left out. The changes and clarifications

are minor in nature and noncontroversial. The following changes are being made to the regulations:

Section by Section Analysis

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

During the rulemaking completed in 2005, conforming changes to § 32.72, to reflect the changes made in § 35.55, were inadvertently omitted. The 2005 revision of the training and experience requirements for an authorized nuclear pharmacist (ANP) in § 35.55 removed the requirement for a preceptor statement as a condition for recognition of a specialty board's certification process. Instead, an individual seeking ANP status on an NRC license must provide a preceptor statement, in addition to documentation of the board certification. This amendment makes the necessary conforming changes to § 32.72.

Additionally, certification by the Board of Pharmaceutical Specialties is removed from § 32.72 because specialty boards recognized by the Commission or Agreement States are posted on the NRC's web page and are no longer listed in NRC regulations.

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

Section 32.74(a) states that an application will be approved 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 or reference source or for the uses listed in §§ 35.400, 35.500, and 35.600 if certain conditions are met. When Part 35 was amended on April 24, 2002 (67 FR 20249), a new section, § 35.1000, "Other medical uses of

byproduct material or radiation from byproduct material," was added to address radiation safety issues associated with new modalities. A conforming change should have been made in § 32.74(a) to reference § 35.1000, but was inadvertently left out. This change amends this section by adding § 35.1000 after §§ 35.400, 35.500, 35.600.

3. Section 35.2 Definitions.

The definitions in this section include both *medium-dose rate remote afterloader* and *high-dose rate remote afterloader*. The medium-dose rate remote afterloader is defined as a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed. The high-dose rate remote afterloader is defined as delivering a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed. The dose rate of equal to 12 gray (1200 rads) per hour was inadvertently excluded. This section is being amended to revise the definition of *Medium dose-rate remote afterloader* to include "equal to" 12 gray. In addition, for clarification, the phrase "per hour" will be added after the phrase "delivers a dose rate of greater than 2 gray (200 rads)" to read as "delivers a dose rate of greater than 2 gray (200 rads) per hour."

4. Section 35.41 Procedures for administrations requiring a written directive.

Section 35.41(b)(4) requires a licensee to have procedures verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600. When Part 35 was amended on April 24, 2002 (67 FR 20249), a new section, § 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," was added to address radiation safety issues associated with new modalities. A

conforming change should have been made in § 35.41(b)(4) to reference § 35.1000, but was inadvertently left out. This changes this section by adding § 35.1000 after § 35.600.

5. Section 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

In § 35.75(a), the footnote states that 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). NUREG-1556, Vol. 9, is not the current version of this NUREG. The current version, “Revision 1,” is expected to be revised. Thus, the footnote is revised to add the phrase “The current version of” before the phrase “NUREG-1556, Vol. 9.”

6. Section 35.92 Decay-in-storage.

This section permits decay-in-storage by medical use licensees for radionuclides with half-lives of less than 120 days. This section inadvertently excluded radionuclides with half-lives equal to 120 days. This change revises this section to include “equal to” 120 days.

7. Section 35.190 Training for uptake, dilution, and excretion studies.

Section 35.190(a)(1) provides that in order for a specialty board’s certification process to be recognized, the board must require all candidates for certification to complete 60 hours of training and experience “that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section.” The intent of the regulation is that candidates must obtain their work experience involving the topics listed in (c)(1)(ii) under the supervision of a specified authorized user. The change of the phrase to “as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section,”

clarifies that all of the requirements in § 35.190(c)(1)(ii), including that candidates must obtain their work experience under the supervision of a specified authorized user, are also applicable to the board certification pathway.

8. Section 35.290 Training for imaging and localization studies.

Section 35.290(a)(1) provides that in order for a specialty board's certification process to be recognized, the board must require all candidates for certification to complete 700 hours of training and experience "that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section." The intent of the regulation is that candidates must obtain their work experience involving the topics listed in (c)(1)(ii) under the supervision of a specified authorized user. The change of the phrase to "as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section," clarifies that all of the requirements in § 35.290(c)(1)(ii), including that candidates must obtain their work experience under the supervision of a specified authorized user, are also applicable to the board certification pathway.

Procedural Background

This rulemaking will become effective on **(insert 75 days after publication in the Federal Register**). However, if the NRC receives significant adverse comments by (**insert 30 days after publication in the Federal Register**)**,** then the NRC will publish a document that withdraws the direct final rule and will address the comments received in a final rule as a response to the companion proposed rule published elsewhere in this issue of the *Federal Register*. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

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.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC corrects and clarifies the rule language in several sections in 10 CFR Parts 32 and 35. This action does not constitute the establishment of a standard that contains generally applicable requirements.

Issues of Compatibility for Agreement States

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997 (62 FR 46517), specific requirements within this rule should be adopted by Agreement States for purposes of compatibility or because of health and safety significance. Implementing procedures for the Policy Statement establish specific categories which have been applied to categorize the requirements in Parts 32 and 35. A Compatibility Category “A” designation means the requirement is a basic radiation protection standard or deals with related definitions, signs, labels, or terms necessary for a common understanding of radiation protection principles. Compatibility Category “A” designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category “B” designation means the requirement has significant transboundary implications. Compatibility Category ‘‘B’’ designated Agreement State requirements should be essentially identical to those of the NRC. A Compatibility Category “C” designation means the essential objectives of the requirement should be adopted by the State to avoid conflicts, duplications, or gaps. The manner in which the essential objectives are addressed in the Agreement State requirement need not be the same as NRC provided the essential objectives are met. A Compatibility Category “D” designation means the requirement does not have to be adopted by an Agreement State for purposes of compatibility. The Compatibility Category Health and Safety (H&S) identifies requirements that are not required for compatibility, but which have particular health and safety significance. Agreement States should adopt the essential objectives of such requirements in order to maintain an adequate program.

Summary of NRC Rules With Compatibility or Health and Safety Designations Under the Direct Final Rule Covering 10 CFR Parts 32 & 35.

Section and paragraph	Section title
	CATEGORY B
§ 32.72(b)(5).....	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.
§ 32.74(a).....	Manufacture and distribution of sources or devices containing byproduct material for medical use.
§ 35.190.....	Training for uptake, dilution, and excretion studies.
§ 35.290.....	Training for imaging and localization studies.
	CATEGORY C
§ 35.75(a).....	Release of individuals containing unsealed byproduct material or implants containing byproduct material.
	CATEGORY D
§ 35.2.....	Definitions - *Medium dose-rate remote afterloader*.
§ 35.41(b)(4).....	Procedures for administrations requiring a written directive.
	CATEGORY H&S
§ 35.92.....	Decay-in-storage is an “H&S” for States authorizing this activity and “D” for States that do not authorize this activity.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, “Plain Language in Government Writing” directed that the Government’s writing be in plain language. The NRC requests comments on this direct final rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading “ADDRESSES” above.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in the categorical exclusion at 10 CFR 51.22(c)(2). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This direct final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0001 and 3150-0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

A regulatory analysis has not been prepared for this direct final rule because this rule is considered a minor nonsubstantive amendment and it has no economic impact on NRC licensees or the public.

Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small

entities. This rule merely corrects or clarifies the rule language in several sections in 10 CFR Parts 32 and 35.

Backfit Analysis

The NRC has determined that the backfit rule (§§ 50.109, 70.76, 72.62, or 76.76) does not apply to this final rule and therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

Congressional Review Act

Under the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

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. 552 and 553; the NRC is adopting 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

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

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