

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AH08

Medical Use of Byproduct Material: Clarifying and Minor Amendments

AGENCY: Nuclear Regulatory Commission

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. This action would clarify the definitions of authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers; clarify the notification requirements if the patient is in a medical emergency or dies; clarify the recordkeeping requirements for calibration of brachytherapy sources; correct the title for the National Institute of Standards and Technology; clarify that prior to October 24, 2004, individuals who meet the training and experience requirements in Subpart J may undertake responsibilities specified in certain sections in Subparts B and D-H; and eliminate a restriction that training for ophthalmic use of strontium-90 can only be conducted in medical institutions. These amendments are necessary to clarify certain inconsistencies within the regulations and to allow training in ophthalmic treatment to be conducted in eye clinics or private practices, in addition to medical institutions.

DATES: Comments on the proposed rule must be received on or before **[insert 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-AHO8) 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 will not be removed from your comments.

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.

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 examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including

comments, can 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/NRC/ADAMS/index.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: Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, telephone (301) 415-6233, email: ant@nrc.gov.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the Rules and Regulations section of this Federal Register.

Because the 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 75 days after publication in the Federal Register]**. However, if the NRC receives significant adverse comments on the direct final rule, by **[insert 30 days after publication in the Federal Register]**, the NRC will publish a document that withdraws 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 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 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 in 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 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 Part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

1. 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).

2. In § 35.2, the definitions for authorized medical physicist, authorized nuclear pharmacist, authorized user, and radiation safety officer, are amended by revising paragraph (1) of each definition to read as follows:

§ 35.2 Definitions

* * * * *

Authorized medical physicist means an individual who --

(1) Meets the requirements in §§ 35.51(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.961(a), or (b), and 35.59; or

* * * * *

Authorized nuclear pharmacist means a pharmacist who --

(1) Meets the requirements in §§ 35.55(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.980(a) and 35.59; or

* * * * *

Authorized user means a physician, dentist, or podiatrist who --

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or, before October 24, 2004, meets the requirements in §§ 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59; or

* * * * *

Radiation Safety Officer means an individual who --

(1) Meets the requirements in §§ 35.50(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.900(a) and 35.59; or

* * * * *

3. In § 35.51, the second sentence of paragraph (b)(2) is revised to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(b) * * *

(2) * * *The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2004, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

4. In § 35.100, paragraph (b) is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

* * * * *

(b) Prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) an individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in (1) or the physician who is an authorized user in (2); or

* * * * *

5. In § 35.190, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

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

* * * * *

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

* * * * *

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, involving –

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

6. In § 35.200, paragraph (b) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(b) Prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) an individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in (1) or the physician who is an authorized user in (2);

* * * * *

7. In § 35.290, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(b) Is an authorized user under § 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements; or

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, involving --

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

8. In § 35.300, paragraph (b) is revised to read as follows:

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

* * * * *

(b) Prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) an individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in (1) or the physician who is an authorized user in (2); or

* * * * *

9. In § 35.310, paragraph (a)(5) is revised to read as follows:

§ 35.310 Safety instruction.

(a) * * *

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

* * * * *

10. In § 35.315, paragraph (b) is revised to read as follows:

§ 35.315 Safety precautions.

* * * * *

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

11. In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required

(b) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in

§ 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve --

* * * * *

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35. 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

12. In § 35.392, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

* * * * *

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve--

* * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

13. In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(2), or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve--

* * * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

14. In § 35.432, paragraph (b) is revised to read as follows:

§ 35.432 Calibration measurements of brachytherapy sources.

(b) Instead of a licensee making its own measurements as required in (a), the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

* * * * *

15. In § 35.490, the introductory text of paragraph (b)(1)(ii), paragraphs (b)(2), and (b)(3) are revised to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(b) * * *

(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements at a medical institution, involving –

* * * * *

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

* * * * *

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

16. In § 35.491, paragraph (a), the introductory text of paragraph (b)(2), and paragraph (b)(3) are revised to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(a) Is an authorized user under § 35.490, or, before October 24, 2004, §§ 35.940 or 35.941, or equivalent Agreement State requirements; or

(b) * * *

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve --

* * * * *

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or, before October 24, 2004, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

17. In § 35.630, paragraph (a)(1) is revised to read as follows:

§ 35.630 Dosimetry equipment.

(a) * * *

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American

Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

* * * * *

18. In § 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2) and (b)(3) are revised to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(b) * * *

(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements at a medical institution, involving --

* * * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of

therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

19. In § 35.2432, paragraph (b)(5) is revised to read as follows:

§ 35.2432 Records of calibration measurements of brachytherapy sources.

* * * * *

(b) * * *

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Dated at Rockville, Maryland, this 31st day of March, 2003.

For the Nuclear Regulatory Commission.

/RA/

William D. Travers,
Executive Director for Operations.

therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

19. In § 35.2432, paragraph (b)(5) is revised to read as follows:
 § 35.2432 Records of calibration measurements of brachytherapy sources.

* * * * *

(b) * * *

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Dated at Rockville, Maryland, this 31st day of March, 2003.

For the Nuclear Regulatory Commission.

/RA/

 William D. Travers,
 Executive Director for Operations.

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