

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AH08

Medical Use of Byproduct Material: Clarifying and Minor Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. The direct final rule will 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: The final rule is effective on **[insert 75 days after publication in the Federal Register]** unless significant adverse comments are received by **[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, DC 20555-0001, telephone (301) 415-6233, email: ant@nrc.gov.

SUPPLEMENTARY INFORMATION:

Procedural Information

Because NRC considers this action to be noncontroversial, the NRC is using the direct final rule process for this rule. The amendments in this rule will become effective on **[insert 75 days after publication in the Federal Register]**. However, if the NRC receives significant adverse comments on this direct final rule by **[insert 30 days after publication in the Federal Register]**, then the NRC will publish a document that withdraws this action and will

subsequently address the comments received in a final rule as a response to the companion proposed rule published elsewhere in this *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 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.

Background

The NRC published in the Federal Register a final rule amending 10 CFR Part 35 regarding medical use of byproduct material on April 24, 2002 (67 FR 20249) (final rule). Subsequently, the NRC staff (staff) identified typographical and editorial errors as well as inconsistencies in the Part 35 final rule. The staff published a document correcting the typographical and editorial errors on October 9, 2002 (67 FR 62872). Both the final rule and the correction became effective on October 24, 2002. This amendment addresses certain inconsistencies that have been identified in the Part 35 final rule and implements a minor change to eliminate a restriction that training for ophthalmic use of strontium-90 can only be conducted in a medical institution.

Section-by-Section Analysis

(1) Section 35.2, Definitions. In this section, “Authorized medical physicist” (AMP), “Authorized nuclear pharmacist” (ANP), “Authorized user” (AU), and “Radiation Safety Officer” (RSO) are defined as individuals who meet the criteria in certain referenced sections of this final rule. However, the staff has specifically reinserted Subpart J (as contained in the proposed rule (63 FR 43516; August 13, 1998)) for a two-year transition period. Therefore, until October 24, 2004, individuals certified by medical boards listed in that subpart are also qualified as authorized users. It is inconsistent to recognize as authorized users individuals who meet Subpart J requirements, but not include them in the relevant definitions in §35.2.

The definition of AU is therefore amended to include individuals qualified under §§35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a) and 35.960(a), until October 24, 2004.

Similarly, the definitions of AMP, ANP, and RSO are amended to include individuals authorized pursuant to §§35.961(a) and (b), 35.980(a), and 35.900(a), respectively.

(2) Section 35.51, Training for an authorized medical physicist. The second sentence in paragraph (b)(2) states: “The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements....” However, during the two-year transition period, an individual who meets the requirements of § 35.961 in Subpart J is also qualified to be a preceptor authorized medical physicist. Therefore, this sentence is amended by replacing the phrase “in § 35.51 or equivalent Agreement State requirement” with the phrase “in § 35.51, or, before October 24, 2004, § 35.961, or equivalent Agreement State requirements....”

The following additional sections reflect similar inconsistencies: §§ 35.190(b), (c)(1)(ii), (c)(2); 35.290(b), (c)(1)(ii), (c)(2); 35.390(b)(1)(ii), (b)(2); 35.392(b), (c)(2), (c)(3); 35.394(b), (c)(2), (c)(3); 35.490(b)(1)(ii), (b)(2), (b)(3); 35.491(a), (b)(3); and 35.690(b)(1)(ii), (b)(2), (b)(3). Therefore, these sections are also amended to include the corresponding sections from Subpart J.

(3) Section 35.100, Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required. Paragraph (b) states: “Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27.” However, during the two-year transition period, an authorized user who meets the requirements of § 35.920 in Subpart J is also qualified to prepare unsealed

byproduct material for medical use. Therefore, this sentence is amended by replacing the phrase “in §§ 35.290 or 35.390” with the phrase “in §§ 35.290 or 35.390, or, before October 24, 2004, § 35.920.” In addition, the format of this paragraph has been modified to clearly identify the three categories of persons who can prepare unsealed byproduct material for medical use for uptake, dilution, or excretion.

The following additional sections reflect similar inconsistencies: §§ 35.200(b) and 35.300(b). Therefore, these sections are also amended to include § 35.920.

(4) Section 35.310, Safety instruction. Paragraph (a)(5) provides that a licensee must notify “the” AU if the patient has a medical emergency or dies. However, corresponding sections for brachytherapy and external beam therapy (i.e., §§ 35.410(a)(5), 35.415(c), and 35.615(f)(4)) require that “an” AU, instead of “the” AU, be notified. Section III of the Supplementary Information in the April 24, 2002, final rule states: “Therefore, because of the type of dosages that are administered under § 35.300, we believe it is important that an AU be available to be contacted in case of a medical emergency or death.” Notifying “an” AU should meet this requirement because “the” AU who treats the patient may be unavailable when the patient has a medical emergency or dies. This section is revised to replace the words “the” AU with the words “an” AU.

(5) Section 35.315, Safety precautions. Paragraph (b) provides that a licensee must notify the RSO, or his or her designee, and “the” AU if the patient has a medical emergency or dies. This section is modified to replace the words “the” AU with the words “an” AU for the reasons explained in (4), above.

(6) Section 35.432, Calibration measurements of brachytherapy sources. Paragraph (a) provides in part that a licensee shall determine the source output and source positioning accuracy. Paragraph (b) states that a licensee may use measurements provided by the source manufacturer or by a calibration laboratory. However, it is not clear that the licensee may perform its own measurement or, as an alternative, use measurements from manufacturer or calibration laboratory. For clarification, this section is therefore revised to add a phrase to the beginning of paragraph (b) to read as follows: "Instead of a licensee making its own measurements as required in (a), the licensee may use measurements provided by..."

(7) Section 35.491, Training for ophthalmic use of strontium-90. Paragraph (b)(2) currently provides in part that an authorized user of strontium-90 for ophthalmic radiotherapy must have completed supervised clinical training under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This current requirement unnecessarily excludes authorized users at eye clinics and private practices from being allowed to provide training. This restriction should be eliminated because many authorized users for ophthalmic treatment work in clinics or private practices. This section is therefore revised to add "clinic or private practice" to "medical institution" as acceptable locations where the requisite supervised clinical training may be provided.

(8) Section 35.630. Paragraph (a)(1) states: "The system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and...." The title of NIST is "National Institute of Standards and Technology." Thus, the word "Science" is replaced by the word "Standards."

(9) Section 35.2432, Records of calibration measurements of brachytherapy sources. This section provides that a licensee must maintain a record of the calibration of brachytherapy sources required by §35.432. Paragraph 35.2432(b)(5) requires that the record must include the signature of the authorized medical physicist (AMP). Section 35.432, Calibration measurements of brachytherapy sources, requires that a licensee shall have a brachytherapy source calibrated or the licensee may use measurements provided by the source manufacturer or by a calibration laboratory. However, §35.432 does not specify that an AMP must perform the calibration. Thus, it is inconsistent to require a record of the signature of the AMP in §35.2432 without a requirement for the AMP to perform the calibration in §35.432.

In the proposed rule (63 FR 43516; August 13, 1998), §35.2432 would have provided that the record of calibration must contain "the name of the individual or the source manufacturer who performed the calibration." This language was consistent with the language of proposed §35.432.

In the final rule, (67 FR 20249; April 24, 2002), § 35.432 was changed from that in the proposed rule to allow the licensee to rely on measurements provided by a calibration laboratory, in addition to those provided by a manufacturer. The language in §35.2432 was also changed but was not consistent with §35.432.

The Supplementary Information to the final rule includes a discussion of the changes made to §35.2432 between the proposed rule and the final rule. That discussion does not include any rationale for changing the proposed rule language requiring "the name of the individual or the source manufacturer who performed the calibration" to the final rule language requiring "the

signature of the authorized medical physicist." Section 35.2432(b)(5) is therefore modified to replace the phrase "the signature of the authorized medical physicist" with the phrase "the name of the individual, the source manufacturer, or the calibration laboratory who performed the calibration." This modification resolves inconsistency between § 35.2432 and § 35.432.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this direct final rule is a matter of compatibility between NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. A Compatibility Category "B" designation means the requirement has significant direct transboundary implications. Compatibility Category "B" designated Agreement State requirements should be essentially identical to those of NRC. A Compatibility Category "D" designation means the requirement does not need 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.

The Compatibility Categories for the sections amended in this direct final rule are the same as the sections in the current regulations. The revisions to §§35.2, 35.51, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, and 35.690 are classified as Category B. The

revisions to §§ 35.100, 35.200, 35.300, 35.310(a), 35.315, and 35.630 are classified as Category H&S. The revision to §35.2432 is classified as Category D.

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 direct final rule, NRC is amending 10 CFR Part 35 to clarify certain inconsistencies with the regulations and to allow training in ophthalmic treatment to be conducted in eye clinics or private practices, in addition to medical institutions. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Environmental Impact: Categorical Exclusion

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

Paperwork Reduction Act Statement

This direct final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). However, the rule

makes a technical change to correct an error in a record requirement that appeared in the Part 35 final rule. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0010.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

A regulatory analysis has not been prepared for this direct final rule. The clarifying amendments are for ease of understanding of certain aspects of Part 35. The minor amendment on ophthalmic treatment is to provide flexibility that clinical training can be conducted under supervision of an authorized user in clinics or private practices, in addition to medical institutions. This flexibility could potentially result in a small reduction in burden for an individual who is undertaking the clinic training.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This direct final rule simply amends present regulations to clarify

certain inconsistencies with the regulations and to allow training in ophthalmic treatment to be conducted in eye clinics or private practices, in addition to medical institutions. The companies that own these facilities do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards adopted by NRC (10 CFR 2.810).

Backfit Analysis

NRC has determined that the backfit rule does not apply to this direct final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

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. 552 and 553; NRC is adopting 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.

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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