[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AI59

[NRC-2009-0098]

Medical Use of Byproduct Material – Authorized User Clarification

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to clarify that individuals who do not need to comply with the training and experience requirements as described in the applicable regulations for the medical use of byproduct material (i.e., are "grandfathered") may serve as preceptors and work experience supervisors for individuals seeking recognition on NRC licenses for the same medical uses of byproduct material. The regulations that govern the medical use of byproduct material were amended in their entirety in 2002 and again in 2005. Currently, individuals who were identified on an NRC or Agreement State license or permit before the regulations were amended do not need to requalify by meeting the training and experience (T&E) requirements of the applicable regulations. When the regulations were revised, the NRC intended that those authorized individuals would also be able to serve as preceptors and work experience supervisors. However, the regulations as they are currently written do not specifically state that grandfathered individuals can be work experience supervisors and preceptors.

This direct final rule amends the regulations to clarify that all individuals grandfathered under the applicable regulations may serve as preceptors and work experience supervisors for individuals seeking recognition on an NRC license for the same uses. Additionally, several minor administrative changes are included in this rulemaking.

DATES: The final rule is effective (**insert date that is 75 days after publication in the Federal Register**), unless a significant adverse comment is received by **(insert date that is 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 If the rule is withdrawn, timely notice will be published in the *Federal Register*.

ADDRESSES: Please include the number RIN 3150-AI59 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's web site in the Agencywide Documents Access and Management System (ADAMS) and at http://www.regulations.gov. Personal information, such as your name, address, telephone number, e-mail address, etc., will not be removed from your submission. You may submit comments by any one of the following methods:

Federal e-Rulemaking portal: Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2009-0098 and follow instructions for submitting comments. Address questions about NRC dockets to Carol Gallagher at 301-492-3668, e-mail Carol.Gallagher@nrc.gov.

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

E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1677.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1677).

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), Room O-1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including any comments, may be viewed and downloaded via the e-Rulemaking Portal at http://www.regulations.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 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 PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr.resource@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 - Edward.Lohr@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

On April 24, 2002 (67 FR 20250), and again on March 30, 2005 (70 FR 16336), the NRC revised the T&E requirements contained in 10 CFR Part 35 for individuals seeking recognition on NRC medical licenses. Individuals who were authorized on a license or permit at the time that the 2002 and 2005 regulations went into effect were "grandfathered" under § 35.57 (i.e., did not need to comply with the new training and experience requirements). However, § 35.57 does not specifically state that those individuals may also provide work experience supervision or preceptor attestations for individuals seeking recognition for the same uses on NRC licenses or permits.

Discussion

The current language of the T&E requirements contained in 10 CFR Part 35 is inconsistent as to whether individuals grandfathered under § 35.57 may serve as preceptors and/or work experience supervisors. Under § 35.50, Training for Radiation Safety Officer, any individual who is identified as the Radiation Safety Officer on an NRC or Agreement State license or permit may serve as a preceptor or work experience supervisor; however, only those physicians who meet the current requirements for authorized users (AUs) may serve as work experience supervisors. Under § 35.51, "Training for an authorized medical physicist," work experience may be obtained under the supervision of an individual who meets the requirements for an authorized medical physicist (AMP) for the type of use for which the individual is seeking authorization; however, individuals seeking recognition on an NRC license or permit must obtain a written attestation that may be signed only by a preceptor AMP who meets the current

requirements. Section 35.55 does not limit work experience supervisors or preceptors to individuals meeting the current requirements, as it provides that supervised practical experience may be in "a nuclear pharmacy," and the written attestation may be signed by "a preceptor authorized nuclear pharmacist." With regard to AUs, under §§ 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, and 35.690, only those AUs who meet the current requirements may serve as either preceptors or work experience supervisors. However, under § 35.491, while the preceptor must be an AU who meets the current requirements, the regulation provides that supervised clinical training may be under the supervision of "an authorized user."

The Supplementary Information section of the preamble to the final rule amending 10 CFR Part 35 in 2005 indicated that it was the NRC's intent to permit individuals grandfathered under § 35.57 to serve as work experience supervisors and preceptors for individuals seeking recognition on NRC licenses or permits for the same uses. Specifically, in the Summary of Public Comments and Responses to Comments, a comment from the public on the proposed rule stated that clarification was needed for grandfathering AMPs so "there could be an initial pool of AMPs to serve as preceptors." In response to this comment, the NRC stated: "These individuals, who have been identified on a license, would also be able to serve as preceptors for individuals to become AMPs." However, § 35.51, "Training for an authorized medical physicist," was not revised to implement that intent. Specifically, § 35.51(b)(2) states that individuals seeking recognition on an NRC license or permit must have obtained a written attestation that "must be signed by a preceptor authorized medical physicist who meets the requirements in section 35.51, or equivalent Agreement State requirements for an authorized medical physicist…."

Although the response to the comment addresses only AMPs, it was the NRC's intent to allow other individuals authorized on NRC and Agreement State licenses and permits to serve as both preceptors and work experience supervisors for individuals seeking recognition on NRC licenses or permits for the same uses. If individuals grandfathered under § 35.57 are unable to provide attestations and work experience supervision for applicants, there will not be a sufficient pool of professionals to provide attestations or work experience supervision for new applicants to become authorized individuals on NRC medical use licenses. This may create a serious shortage of authorized individuals in the medical community, which may result in a negative impact on health care. Therefore, the NRC is revising the T&E regulations to implement its intent that all individuals grandfathered under § 35.57 may serve as preceptors and work experience supervisors for individuals seeking recognition on NRC licenses or permits for the same uses.

Discussion of Amendments by Section

1. Section 35.50 Training for Radiation Safety Officer.

This section is amended to clarify that radiation safety officers may have practical training and/or supervised experience in medical physics under the direction of physicians who meet the requirements for authorized users in § 35.57.

2. Section 35.51 Training for an authorized medical physicist.

This section is amended to clarify that authorized medical physicists may have practical training and/or supervised experience in medical physics under the direction of physicians who meet the requirements for authorized users in § 35.57 and that preceptors for medical

physicists may be medical physicists who meet the requirements in § 35.57. Additionally, a minor administrative change is made for clarification.

3. Section 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

This section is amended to clarify that individuals who need not comply with training requirements as described in § 35.57 may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

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

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57.

5. Section 35.290 Training for imaging and localization studies.

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57. Additionally, a minor administrative change is made to the language to make it consistent throughout the section.

6. Section 35.390 Training for use of unsealed byproduct material for which a written directive is required.

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57.

7. Section 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).

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57. Additionally, a minor administrative change is made for clarification.

8. Section 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).

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57.

9. Section 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57 and may

obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57.

10. Section 35.490 Training for use of manual brachytherapy sources.

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57, may have supervised clinical experience in radiation oncology under authorized users who meet the requirements in § 35.57, and may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57. Additionally, a minor administrative change is made for clarification.

11. Section 35.491 Training for ophthalmic use of strontium-90.

This section is amended to clarify that authorized users may obtain written attestations signed by preceptor authorized users who meet the requirements in § 35.57. Additionally, a minor error in the text of § 35.491(b)(3) is corrected to clarify that the preceptor authorized user does not need to attest that the individual has completed the requirements in paragraph (a) and (b), but only that the individual has completed the requirements in paragraph (b).

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

This section is amended to clarify that authorized users may have work experience under the supervision of authorized users who meet the requirements in § 35.57, may have supervised clinical experience in radiation therapy under authorized users who meet the requirements in § 35.57, and may obtain written attestations signed by preceptor authorized

users who meet the requirements in § 35.57. Additionally, a minor administrative change is made for clarification.

Procedural Background

The amendments contained in this rule will become effective on **(insert date that is 75 days after publication in the Federal Register**). However, if the NRC receives a significant adverse comment by (**insert date that is 30 days after publication in the Federal Register**), then the NRC will publish a document that withdraws this action 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.

Agreement State Compatibility

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 10 CFR 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 & Safety (H&S) identifies program elements that are not required for purposes of compatibility, but have particular health and safety significance. States should adopt the essential objectives of such program elements in order to maintain an adequate program.

Summary of NRC Rules With Compatibility or Health and Safety Designations Under the Proposed Rule Covering 10 CFR Part 35.

Section	Section title
	CATEGORY B
§ 35.50.....	Training for Radiation Safety Officer.
§ 35.51.....	Training for an authorized medical physicist.
§ 35.57.....	Training, for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.
§ 35.190.....	Training for uptake, dilution, and excretion studies.
§ 35.290.....	Training for imaging and localization studies.
§ 35.390.....	Training for use of unsealed byproduct material for which a written directive is required.
§ 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).
§ 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).
§ 35.396.....	Training for the parenteral administration of unsealed byproduct material requiring a written directive.
§ 35.490.....	Training for use of manual brachytherapy sources.

§ 35.491.....	Training for ophthalmic use of strontium-90.
§ 35.690.....	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Plain Language

The Presidential Memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883), directed that the Government's documents be in clear and accessible 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 "ADDRESSES" heading.

Voluntary Consensus Standards

The National Technology Transfer and Advancement 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, the NRC is amending its regulations to clarify that individuals who do not need to comply with the training and experience requirements as described in § 35.57 may serve as preceptors and work experience supervisors for individuals seeking recognition on NRC licenses or permits for the same medical uses of byproduct material. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC 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.). Existing information collection requirements were approved by the Office of Management and Budget, approval number 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 request 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 non-substantive amendment and it has no economic impact on NRC licensees or the public. This rule does not impose any new requirements. It only clarifies the rule language in several sections in 10 CFR Part 35.

Regulatory Flexibility Certification

In accordance with 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. The majority of 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 established by the NRC (10 CFR 2.810). This rule does not impose any new requirements. It only clarifies the rule language in several sections in 10 CFR Part 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 because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter I. Therefore, a backfit analysis is not required.

Congressional Review Act

In accordance with 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 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 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 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); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

2. In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:

§ 35.50 Training for Radiation Safety Officer.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390;

* * * * *

3. In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) * * *

(2) * * *

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in §§ 35.57, 35.490, or 35.690; and

* * * * *

(b) * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, 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; and

* * * * *

4. In § 35.57, a new paragraph (c) is added to read as follows:

§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.

* * * * *

(c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

5. In § 35.190, 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.

* * * * *

(c)(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving—

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (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 § 35.290, 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.

* * * * *

(c)(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving--

* * * * *

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (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.

7. 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 §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising

authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve--

* * * * *

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (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 attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.

8. In § 35.392, 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).

* * * * *

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, 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 35.390(b)(1)(ii)(G)(*2*). The work experience must involve--

* * * * *

(3) Has obtained written attestation 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 attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, 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 35.390(b)(1)(ii)(G)(*2*).

9. In § 35.394, 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).

* * * * *

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, 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 attestation 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 attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, 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*).

10. In § 35.396, the introductory text of paragraph (d)(2) and paragraph (d)(3) are revised to read as follows:

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

* * * * *

(d) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*). The work experience must involve--

* * * * *

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of

unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*).

11. In § 35.490, the introductory text of paragraph (b)(1)(ii) and 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 §§ 35.57, 35.490, 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 §§ 35.57, 35.490, 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 Royal College of Physicians and Surgeons of Canada 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 attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or 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.

12. In § 35.491, paragraph (b)(3) is revised to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(b) * * *

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (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.

13. 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 §§ 35.57, 35.690, or equivalent Agreement State requirements at a medical institution, involving--

* * * * *

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, 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 Royal College of Physicians and Surgeons of Canada 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 attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), 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 attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, 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; and

* * * * *

Dated at Rockville, Maryland, this 26th day of June, 2009.

For the Nuclear Regulatory Commission.

/RA/

R. W. Borchardt,
Executive Director for Operations.

for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

* * * * *

Dated at Rockville, Maryland, this 26th day of June, 2009.

For the Nuclear Regulatory Commission.

/RA/

R. W. Borchardt,
Executive Director for Operations.

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