

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AH47

Medical Use of Byproduct Material
Minor Amendments: Extending Expiration Date for Subpart J

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations governing the medical use of byproduct material to extend the expiration date for training and experience requirements that will be superseded (Subpart J) for 1 year, from October 24, 2004, to October 24, 2005. The rulemaking is necessary to allow sufficient time for implementation of the forthcoming final rule that amends the training and experience requirements, including new requirements for recognition of specialty board certifications.

EFFECTIVE DATE: October 22, 2004.

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SUPPLEMENTARY INFORMATION:

Background

The 2002 Final Rule.

On April 24, 2002 (67 FR 20249), the NRC published a final rule amending its regulations regarding the medical use of byproduct material. The final rule addressed, among other things, new training and experience (T&E) requirements for radiation safety officers, authorized medical physicists, authorized nuclear pharmacists, and authorized users. This rule also addressed the requirements for recognition of medical and other specialty boards whose certifications may be used to demonstrate the adequacy of the T&E of individuals mentioned above. This final rule was effective on October 24, 2002. In addition, NRC retained the existing T&E requirements, designated as Subpart J in 10 CFR Part 35, for a 2-year period. Therefore, Subpart J remains effective until October 24, 2004.

Statements in the Preamble of the 2002 Final Rule.

In the preamble, NRC stated that during an NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) briefing of the Commission on February 19, 2002, the issue of recognition of medical and other specialty boards was discussed. In that meeting, two committee members expressed concern that some boards did not qualify for recognition and might not be ready to apply for recognition within 6 months after publication of the final rule. Therefore, implementation of the new Part 35, without Subpart J, could disrupt the current license authorization process for new medical personnel because many license authorizations are granted based on recognition of board certification.

The preamble further stated that NRC had considered this matter and decided to retain the training requirements in Subpart J for a 2-year period after the effective date of the final rule. During this transition period, the NRC would continue working with the ACMUI and the medical community to resolve any concerns about the training and experience requirements. The NRC would consider changes to the T&E requirements, as appropriate.

The T&E Proposed Rule.

After the publication of the 2002 final rule, the NRC worked with the ACMUI and other stakeholders to consider what changes were necessary to the T&E requirements. Several public meetings were held to discuss the changes. On December 9, 2003 (68 FR 68549), a proposed rule on T&E requirements was published for a 75-day public comment period. The NRC is currently considering public comments and developing the T&E final rule.

One commenter stated that the current transition period for Subpart J, which ends on October 24, 2004, must be extended to allow time for boards to prepare applications and for NRC to process applications, including ACMUI review. The NRC agrees that additional time for implementation of the changes to T&E should be allowed beyond October 24, 2004.

Actions Taken in This Final Rule.

NRC is amending Part 35 to extend the expiration date of Subpart J for 1 year, from October 24, 2004, to October 24, 2005. The NRC believes that it is prudent to extend the expiration date of Subpart J at this time to allow affected stakeholders (i.e., medical and other specialty boards, and medical use licensees) to effectively plan their implementation.

The following sections are revised by changing the date from October 24, 2004, to October 24, 2005: § 35.2, paragraph (1) of the definitions of "Authorized medical physicist,"

“Authorized nuclear pharmacist,” “Authorized user,” and “Radiation Safety Officer”; §§ 35.10(b) and (c); 35.51(b)(2); 35.100(b)(2); 35.190(b), (c)(1)(ii) and (c)(2); 35.200(b)(2); 35.290(b), (c)(1)(ii), and (c)(2); 35.300(b)(2); 35.390(b)(1)(ii) and (b)(2); 35.392(b), (c)(2), and (c)(3); 35.394(b), (c)(2), and (c)(3); 35.490(b)(1)(ii), (b)(2), and (b)(3); 35.491(a) and (b)(3); and 35.690(b)(1)(ii), (b)(2), and (b)(3).

Because these amendments constitute minor administrative changes to the regulations, the notice and comment provisions of the Administrative Procedure Act do not apply, pursuant to 5 U.S.C. 553(b)(B).

Environmental Impact: Categorical Exclusion

NRC has determined that this 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 final rule.

Paperwork Reduction Act Statement

This final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0010 and 3150-0120.

Public Protection Notification

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

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this 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, 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 for 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).

2. In § 35.2, the definitions of “authorized medical physicist,” “authorized nuclear pharmacist,” “authorized user,” and “Radiation Safety Officer” are amended by republishing the introductory text and 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, 2005, 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, 2005, 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, 2005, 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, 2005, meets the requirements in §§ 35.900(a) and 35.59; or

* * * * *

3. In § 35.10, paragraph (b) and the introductory text of paragraph (c) are revised to read as follows:

§ 35.10 Implementation.

* * * * *

(b) A licensee shall implement the training requirements in §§ 35.50(a), 35.51(a), 35.55(a), 35.59, 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a) on or before October 25, 2005.

(c) Prior to October 25, 2005, a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either:

* * * * *

4. In § 35.51, paragraph (b)(2) is revised to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(b) * * *

(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 medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who

meets the requirements in § 35.51, or, before October 24, 2005, § 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.

5. In § 35.100, paragraph (b)(2) 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) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2005, § 35.920; or

* * * * *

6. 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, 2005, §§ 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, 2005, §§ 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, 2005, §§ 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.

7. In § 35.200, paragraph (b)(2) 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) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2005, § 35.920; or

* * * * *

8. 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, 2005, § 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, 2005, § 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, 2005, § 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.

9. In § 35.300, paragraph (b)(2) is revised to read as follows:

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

* * * * *

(b) * * *

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2005, § 35.920; or

* * * * *

10. 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, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 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, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 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.

11. 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, 2005, §§ 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, 2005, §§ 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, 2005, §§ 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).

12. 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, 2005, §§ 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, 2005, §§ 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, 2005, §§ 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).

13. 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 § 35.490, or, before October 24, 2005, § 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, 2005, § 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, 2005, § 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.

14. In § 35.491, paragraphs (a) and (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, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements; or

(b) * * *

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or, before October 24, 2005, §§ 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.

15. 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, 2005, § 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, 2005, § 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, 2005, § 35.960, or equivalent Agreement State

