

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