

April 9, 2008

ALL AGREEMENT STATES, MICHIGAN, NEW JERSEY, PENNSYLVANIA, VIRGINIA

**NOTICE OF COMPATIBILITY RESOLUTION ON CLARIFICATION OF TRAINING FOR
OPHTHALMIC USE OF STRONTIUM-90 (FSME-08-035)**

Purpose: This is to inform you that the U.S. Nuclear Regulatory Commission (NRC) staff has prepared the enclosed Compatibility Resolution CR-08-01 dealing with 10 CFR 35.491(b)(3), Training For Ophthalmic Use Of Strontium-90.

Background: There is an error in the requirements of training for ophthalmic use of strontium-90 in 10 CFR 35.491(b)(3). 10 CFR 35.491 states the authorized user of strontium-90 for ophthalmic radiotherapy is a physician who meets the requirements in either §35.491(a) or (b). However, the attestation statement in § 35.491(b)(3) requires the preceptor authorized user to attest that the individual meets the requirements in §35.491(a) **and** (b). The effect of this regulation as written, requires an attestation statement for individuals that are already authorized users under the requirements of §35.490. There is uncertainty as to what was the intent of the regulations since this provision is designated as Compatibility Category B. Many Agreement States have adopted and are in the process of adopting the medical regulations required to maintain compatibility with the Nuclear Regulatory Commission.

The NRC staff has concluded that Agreement States may adopt the enclosed proposed administrative change to §35.491(b)(3) prior to its promulgation to address the error.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosure:
Compatibility Resolution CR-08-01

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10 CFR 35.491(b)(3) COMPATIBILITY RESOLUTION CLARIFICATION OF TRAINING FOR OPTHALMIC USE OF STRONTIUM-90

ISSUE:

There is an error in the requirements of training for ophthalmic use of strontium-90 in 10 CFR 35.491(b)(3). 10 CFR 35.491 states the authorized user of strontium-90 for ophthalmic radiotherapy is a physician who meets the requirements in either §35.491(a) or (b). However, the attestation statement in § 35.491(b)(3) requires the preceptor authorized user to attest that the individual meets the requirements in §35.491(a) and (b). The effect of this regulation as written, requires an attestation statement for individuals that are already authorized users under the requirements of §35.490. There is uncertainty as to what was the intent of the regulations since this provision is designated as Compatibility Category B. Many Agreement States have adopted and are in the process of adopting the medical regulations required to maintain compatibility with the Nuclear Regulatory Commission.

DISCUSSION:

The State of Ohio identified to NRC staff the potential issue in §35.491 while revising Ohio's medical regulations to maintain compatibility with the NRC regulations. The Statements of Consideration for Part 35 (67 FR 20310) state that physicians who meet the requirements in §35.490 automatically meet the requirements to become an authorized user under §35.491(a). The intent of this provision is that an attestation is not required under the §35.491(a) pathway. To support this interpretation, other sections in Part 35 that are structured similar to §35.491(a) (e.g., §35.190(b), §35.290(b), §35.392(b) and §35.394(b)) that require a physician to be a specific authorized user do not refer to the section requiring an attestation and the corresponding attestation paragraphs do not reference the authorized user paragraphs.

Consequently, staff has proposed an administrative change for §35.491(b)(3) as follows:

(3)Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph **(b)(1) and (b)(2)** of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Staff expects to amend the regulations later in 2008 to reflect this change.

CONCLUSION:

The NRC staff concludes that Agreement States may adopt the proposed administrative change to §35.491(b)(3) prior to its promulgation and effective date and will meet the Compatibility Category B designation assigned to §35.491(b)(3).