

**POLICY ISSUE
(Notation Vote)**

November 20, 2008

SECY-08-0179

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RECOMMENDATIONS ON AMENDING PRECEPTOR ATTESTATION
REQUIREMENTS IN 10 CFR PART 35, MEDICAL USE OF
BYPRODUCT MATERIAL

PURPOSE:

To provide the staff's recommendations for amending the preceptor attestation requirements in 10 CFR Part 35, "Medical Uses of Byproduct Material." The Commission requested these recommendations in staff requirements memorandum (SRM) M080429, entitled "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 P.M., Tuesday, April 29, 2008," dated May 15, 2008. This paper does not address any new commitments.

BACKGROUND:

The training and experience (T&E) requirements for authorized individuals in 10 CFR Part 35 generally require that the individual seeking authorization obtain written attestation signed by a preceptor with that authorization that the individual has satisfactorily completed the necessary T&E requirements and has achieved a level of competency sufficient to function independently in the position for which authorization is sought. During a meeting held on April 29, 2008, with the Commission, the ACMUI recommended that the attestation requirements that are part of the medical use training and experience (T&E) requirements in 10 CFR Part 35 be modified.¹

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¹ See the presentation for the ACMUI by Douglas F. Eggli, M.D., nuclear medicine physician member, ACMUI, at <http://www.nrc.gov/reading-rm/doc-collections/commission/slides/2008/20080429/080429-slides-eggli.pdf>

The stated main reason for this recommendation was the ACMUI's belief that these requirements have had unintended consequences that if not corrected will impact the availability of authorized individuals; i.e., there is likely to be a shortage of authorized individuals to provide medical care as a result of the reluctance of already-authorized individuals, for various reasons, to sign the preceptor attestations required by individuals seeking authorized status.

The May 15, 2008, SRM² directed staff to work with the ACMUI and the Agreement States to provide recommendations to the Commission on amending U.S. Nuclear Regulatory Commission's (NRC's) requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway. The staff was also directed to consider additional methods, such as the attestation being provided by consensus of an authoritative group. The ACMUI and the Commission have previously considered these same modifications to the attestation requirements.³

DISCUSSION:

The ACMUI recommended that the attestation requirements be eliminated for individuals seeking authorized status via the board certification pathways. The ACMUI also recommended that the attestation requirements associated with the more prescriptive alternate pathways to authorized status be modified to delete the requirement for an attestation of an individuals' radiation-safety-related competency being sufficient to function independently as authorized persons for the medical uses associated with the authorizations sought. Finally, the ACMUI recommended that the attestation submitted under the alternate pathway for an individual completing a residency program be considered acceptable if provided by a residency program director representing a consensus of an authoritative group; e.g., the residency program faculty, regardless of whether the program director personally met the requirements for authorized status.

Agreement State Comments

In All-Agreement-States Letter FSME-08-072, the Agreement States were provided an opportunity to comment on the specific modifications to the attestation requirements that were recommended by the ACMUI. Specifically, answers to the following questions were requested.

- 1) Do you support the recommended elimination of the attestation requirement for individuals seeking authorized status via the board certification pathways?
- 2) Do you support the recommended modification of the attestation requirement for individuals seeking authorized status via the alternate pathways, to delete text associated with preceptors attesting to individuals' competency being sufficient to function independently as authorized persons for the medical uses associated with the authorizations sought?

² On the NRC public web site at: <http://www.nrc.gov/reading-rm/doc-collections/commission/srm/meet/2008/m20080429.html>

³ For explanation, see, on the NRC public web site, at <http://www.nrc.gov/reading-rm/doc-collections/#comm>, the following Commission papers plus their associated SRMs and Commissioner voting records: SECY-02-0194; SECY-03-0145; and SECY-05-0020.

- 3) Do you support additional methods for attestations, such as the attestation being provided by consensus of an authoritative group, e.g., a residency program faculty, represented by a residency program director?

Responses were received from nine Agreement States⁴ plus from the Conference of Radiation Control Program Directors' Committee on Suggested State Regulations, SSR-G (healing arts). These comments are summarized as follows.

- 1) Respondents strongly supported (80 percent "for") elimination of the attestation requirement for individuals seeking authorized status via the board certification pathways.
- 2) Respondents marginally opposed (60 percent "against") modification of the attestation requirement for individuals seeking authorized status via the alternate pathways, to delete text associated with preceptors attesting to individuals' competency.
- 3) Respondents very strongly supported (90 percent "for") additional methods for attestations.

Regional Staff Comments

Responses to the questions posted in FSME-08-072 were also received from Regional staff. Similar to Agreement State regulatory bodies, Regional staff regularly receive credentials from applicants seeking authorized status, and through inspections, Regional staff also review the performance of individuals who were approved for authorized status.

Comments from Regional staff are summarized as follows.

- 1) The Regional staff unanimously supported elimination of the attestation requirement for individuals seeking authorized status via the board certification pathways.
- 2) The Regional staff unanimously supported modification of the attestation requirement for individuals seeking authorized status via the alternate pathways, to delete text associated with preceptors attesting to individuals' competency. Staff noted that if the attestation text on competency was deleted, the attestation itself should probably be renamed, to "recommendation for authorized status," or something similar.
- 3) The Regional staff strongly supported, but not unanimously, allowing additional methods for attestations. The staff noted that since residency program directors are typically not authorized users, to accept attestations from them, multiple T&E sections of Part 35 would require modification.

The recommended modifications to the attestation requirements that were provided by the ACMUI during its April 29, 2008, meeting with the Commission are, as noted above, consistent with its long-held positions on this issue. This is apparent from review of the transcripts from multiple previous meetings of the ACMUI at which this issue was discussed and from its previous recommendations. Accordingly, since the ACMUI position on the issue was clear, no additional interactions with the ACMUI were deemed necessary in order to provide recommendations to the Commission on amending NRC's requirements for preceptor attestation.

⁴ California, Florida, Illinois, Iowa, Kansas, Louisiana, Minnesota, North Carolina, and Wisconsin

The staff recommends the Commission eliminate the requirement for preceptor attestations for individuals certified by specialty boards with certification processes that are recognized by NRC or Agreement States.⁵ This recommendation is based on the combined positions of the ACMUI, the Agreement States, and the NRC staff, as summarized above, and reflects regulatory operational experience with both NRC-regulated and Agreement State-regulated medical use licensees and authorized individuals over many years.

With regard to the alternate pathway, the staff observes that among stakeholders, most of the concern about the current Part 35 T&E attestation requirements appears to revolve around the requirement that a preceptor attest that an individual "has achieved a level of competency," which appears in all but one of the current requirements.⁶ Even though the Commission has noted that, as used in these requirements, "competency" does not refer to general clinical competency,⁷ it is commonly interpreted as meaning exactly that. As a result, many would-be signors of attestation statements appear reluctant to do so, for liability reasons. The staff's position on this issue is that attestation statements would more readily be provided if the "competency" statement were revised. Such a revision is proposed for the attestation required for the alternate pathway, which the staff recommends should be retained, as it provides important assessments of the qualifications of non-certified individuals seeking authorized status from authorized individuals having direct knowledge of the duties and responsibilities of authorized status.

As noted above, the staff is recommending retention, albeit modified, of the attestation requirement for individuals seeking authorized status via the alternate pathway. These individuals would include physicians who have completed approved residency programs⁸ but have not yet completed the requirements for certification. For these physicians, the persons most meaningfully able to attest to their having completed the training and experience requirements listed in the regulations are the residency program directors. Attestations from these individuals would be expected to reflect the combined input of the entire residency program faculty. However, many program directors are not themselves authorized individuals. Accordingly, the staff recommends that attestations from residency program directors be accepted, provided that the attestation represent the consensus of the residency program faculty and that the faculty include at least one member who is an authorized individual in the same category as that designated by the applicant seeking authorized status.

The staff believes that any modifications of the Part 35 T&E attestation requirements authorized by the Commission could be included as additional proposed changes in the proposed rule for various Part 35 modifications that is already scheduled for development beginning in mid-2009. Under this approach, a rulemaking plan for modifications of Part 35 T&E attestation requirements would not be required.

RECOMMENDATIONS:

The staff recommends that the Commission approve development of the following modifications to the Part 35 T&E attestation requirements, for the Part 35 modifications that are scheduled to begin in 2009.

⁵ As listed on the NRC public web site, at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

⁶ The exception being in §35.50(d), for Radiation Safety Officer (RSO) authorization, which reads "...has achieved a level of radiation safety knowledge...."

⁷ Most recently, in the Federal Register notice for the 2005 Part 35 T&E revisions, on the NRC public website, at <http://www.nrc.gov/reading-rm/doc-collections/cfr/fr/2005/20050330.pdf>

⁸ See 10 CFR 35.390(a)(1), 35.490(a)(1) and 35.690(a)(1)

- 1) Eliminate the attestation requirement for individuals seeking authorized status via the board certification pathways.
- 2) Retain the attestation requirement for individuals seeking authorized status via the alternate pathways; replace the text stating that the attestation demonstrate that the individual “has achieved a level of competency to function independently” with alternative text such as “has demonstrated the ability to function independently” to fulfill the radiation-safety-related duties required by the license.
- 3) Accept attestations from residency program directors, representing consensus of residency program faculties, as long as at least one member of the residency program faculty is an authorized individual in the same category as that designated by the applicant seeking authorized status.

RESOURCES:

No additional resources would be required to include modifications of Part 35 T&E attestation requirements among the various Part 35 modifications already scheduled for rulemaking in 2009.

COORDINATION:

The Office of the General Counsel has reviewed this paper, and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA Martin Virgilio for/

R. W. Borchardt
Executive Director
for Operations

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OFC	DMSSA/MSEA	DMSEA	DMSSA	DILR	DMSSA
NAME	RZelac: sxg6	CEinberg	JLuehman	MShaffer	RLewis
DATE	10/14/08	10/15/08	10/27/08	10/30/08	11/6/08
OFC	OGC	TechEd	FSME	EDO	
NAME	BJones	CPoland	CMiller	RBorchardt (MVirgilio for)	
DATE	10/27/08	11/13/08	11/17/08	11/20/08	

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