UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

October 3, 2003

NRC REGULATORY ISSUE SUMMARY 2003-17: COMPLYING WITH 10 CFR 35.59, "RECENTNESS OF TRAINING," FOR BOARD-CERTIFIED INDIVIDUALS WHOSE TRAINING AND EXPERIENCE WERE COMPLETED MORE THAN 7 YEARS AGO

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials license medical-use permittees.

INTENT

NRC is issuing this Regulatory Issue Summary (RIS) to provide guidance for licensees and permittees seeking to have individuals identified as authorized users (AUs), authorized medical physicists (AMPs), and authorized nuclear pharmacists (ANPs), under the following conditions:

1. The individual is certified by a specialty board recognized by NRC, but the board certification was received beyond the 7-year time frame allowed in 10 CFR 35.59; and

2. The individual is not currently identified on a medical-use license nor permit as an AU, AMP, or ANP, as appropriate in 10 CFR 35.13(b)(4).

This RIS: (1) clarifies that for limited-specific, Type B broad-scope, and Type C broad-scope medical-use licensees, only NRC with input from the Advisory Committee on the Medical use of Isotopes (ACMUI), as necessary, may determine what constitutes adequate "related continuing training and experience," for purposes of complying with 10 CFR 35.59, "Recentness of Training"; (2) describes the criteria NRC uses to evaluate "related continuing training and experience," under 10 CFR 35.59; (3) describes the information NRC reviews to make the determination; and (4) describes NRC's expectations for Type A broad-scope medical-use licensees. No specific action nor written response is required.

BACKGROUND

Periodically, individuals who at one time met the board certification requirements to be identified as AUs, AMPs, or ANPs, but have not been involved in licensed medical-use activities for extended periods of time (7 years or more) seek to become involved in these activities again as

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AUs, AMPs, or ANPs. If these board-certified individuals had remained actively involved in licensed medical-use activities, then the limited-specific, Type B broad-scope, or Type C broad-scope medical-use licensee could have notified NRC, under the provisions of 10 CFR 35.14(a), that it had permitted such individuals to work as AUs, AMPs, or ANPs, without first obtaining license amendments. The Type A broad-scope medical-use licensee's Radiation Safety Committee could also approve the individual who remained actively involved in licensed medical-use activities as an AU, AMP or ANP, as appropriate.

However, to use the provisions of 10 CFR 35.14(a), the individual must meet the conditions specified in 10 CFR 35.13(b)(1) through 10 CFR 35.13(b)(4). Note that for this RIS, 10 CFR 35.13(b)(4) does not apply because, as stated in the "Intent" section, the RIS pertains only to the case where an individual is not listed on a license or permit described in 10 CFR 35.13(b)(4). Section 35.13(b)(1) requires that an individual meet both the board certification training and experience requirements specified in the applicable section of 10 CFR Part 35 [e.g., 10 CFR 35.290(a), 10 CFR 35.920(a), etc.] and the "recentness of training" provisions of 10 CFR 35.59. The "recentness of training" provisions of 10 CFR 35.59 require that an individual must have: (1) completed his/her training and experience within 7 years preceding the date of application; or (2) had related continuing education and experience since the required training and experience were completed. A board-certified individual who did not receive his/her board certification within the last 7 years cannot meet the first criterion.

SUMMARY OF ISSUE

The process for evaluating the "related continuing training and experience" required by 10 CFR 35.59 is not specifically addressed within the regulations. However, the "Supplementary Information" for 10 CFR 35.59 (67 FR 20294 and 20346) clarifies that the continuing training and experience requirements are reviewed by NRC on a case-by-case basis, with input from the ACMUI, as necessary. The provisions of 10 CFR 35.59 apply to all medical uses of licensed material. Therefore, unless exempted by the regulations, a licensee must apply for and receive an amendment before permitting a board-certified individual whose training and experience has not been obtained within the preceding 7 years to work as an AU, AMP, or ANP, when the individual is not currently listed on a license or permit, as described in 10 CFR 35.13(b)(4).

In evaluating the adequacy of "related continuing training and experience" to determine compliance with 10 CFR 35.59, the NRC staff considers the training and experience criteria specified in the applicable regulations, and whether the continuing training and experience would further competency in those areas. The number of hours required of continuing education and clinical experience depends on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use.

When reviewing the description of the continuing training and experience of an individual, NRC considers the individual's recent training and experience with respect to the following:

1. Each topic found in 10 CFR 35.51(b) or 10 CFR 35.961(b) for an individual seeking to be recognized as an AMP; or

2. Each topic for the appropriate medical use in 10 CFR 35.190(c)(1); 35.910(b); 35.290(c)(1); 35.920(b); 35.390(b)(1); 35.930(b); 35.392(c)(1) and (2); 35.932; 35.394(c)(1) and (2); 35.934; 35.490(b)(1) and (2); 35.940(b); 35.491(b)(1) and (2); 35.941; 35.590(b); 35.950(b); 35.690(b)(1) and (2); or 35.960(b) for an individual seeking to be recognized as an AU; or

3. Each topic found in 10 CFR 35.55(b)(1) or 10 CFR 35.980(b)(1), for an individual seeking to be recognized as an ANP.

The limited-specific, Type B broad-scope, or Type C broad-scope medical-use licensee should therefore submit an amendment request, to NRC, containing information that would support a determination that the individual's continuing training and education demonstrate competency in the topics specified in the applicable regulation. To facilitate NRC's review, the licensee may also elect to provide a preceptor statement attesting to current competency in the identified radiation safety areas.

The Type A broad-scope medical-use licensee is exempted in 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope," from having to apply for and receive an amendment or notifying NRC when it permits an individual to work as an AU, AMP, or ANP. This type of licensee must have the Radiation Safety Committee approve the individuals using the byproduct material under the license. The Type A broad-scope medical-use licensee is not exempted from meeting the training and experience requirements of 10 CFR Part 35, Subparts B, D, E, F, G, and H, or the recentness of training requirements in 10 CFR 35.59.

The Type A broad-scope medical-use licensee's Radiation Safety Committee is expected to review the individual's continuing education and experience similarly to NRC. Therefore, the committee should compare the individual's continuing training and experience with the training and experience criteria specified in the applicable regulations and determine whether the continuing training and experience would further competency in those areas. Whether the number of hours and types of continuing education and clinical experience are adequate will depend on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use. The Type A broad-scope medical-use licensee should have sufficient AUs, AMPs, or ANPs to permit the individual to work under the supervision of an appropriate staff AU, AMP, or ANP, before approval by the Radiation Safety Committee.

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the person listed below or the appropriate regional office.

/RA/

Charles L. Miller, Director
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Office of Nuclear Material Safety
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Technical contact: Donna-Beth Howe, Ph.D., NMSS
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Attachment: List of Recently Issued NRC Regulatory Issue Summaries

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NAME	D. Howe*	RTorres*	EKrauss*fax	TEssig*	STreby*-nlo	CMiller/PHolahan/for
DATE	08/26/2003	08/26/2003	08 /22/03	09/10/03	09/24/03	10/3/03

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LIST OF RECENTLY ISSUED
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2003-15	Consolidation of the Region I and Region Ii Materials Program	09/05/2003	All materials licensees.
2003-14	Preparation And Scheduling of Operator Licensing Examinations	08/27/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-13	NRC Review of Responses to Bulletin 2002-01, “Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity”	07/29/2003	All holders of construction permits or operating licenses for nuclear power reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-12	Clarification of NRC Guidance for Modifying Protective Actions	06/24/2003	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2003-11	Reporting Requirements for Distributors of Devices Subject to the General License Requirements of 10 CFR 3.5	07/16/2003	All licensees authorized to distribute devices containing byproduct material under 10 CFR 32.51, or equivalent Agreement State regulation.

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