UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

December 07, 2006

NRC REGULATORY ISSUE SUMMARY 2006-26
TRAINING AND EXPERIENCE AND GRANDFATHER PROVISIONS FOR AUTHORIZED MEDICAL PHYSICISTS UNDER 10 CFR PART 35.

ADDRESSEES

All NRC medical-use licensees and Radiation Control Program Directors.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the provisions for recognizing and "grandfathering" authorized medical physicists (AMPs) under 10 CFR 35.2, 35.14, 35.51 and 35.57. The regulatory use of the term authorized medical physicist includes only medical physicists for the following medical uses: Strontium-90 (Sr-90) eye applicators, remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery (Gamma Knife®) units. Therefore, this RIS applies only to licensees with these devices. No specific action nor written response is required.

BACKGROUND

On March 30, 2005, the Commission published a final rule, in the *Federal Register*, amending specific sections in 10 CFR Part 35 (70 FR 19336). The rule revised regulations for the recognition of specialty boards, whose certification processes can demonstrate the training and experience of individuals for serving as radiation safety officers, authorized nuclear pharmacists, AMPs, or authorized users. The rule also included additional revisions to other training and attestation requirements for these individuals. Subpart J, of prior 10 CFR Part 35 (Training and Experience Requirements), remained in effect for a transition period, and expired on October 25, 2005. Agreement States have until April 29, 2008, three years from the effective date of the final rule, to establish regulations compatible with the revised rule.

All specialty boards listed in former 10 CFR Part 35, Subpart J, were contacted about application for NRC recognition of one or more of their certification processes, under the boards' recognition requirements, in the revised training and experience sections of Part 35, Subparts B, and D through H. Each specialty board was requested to supply NRC with an effective date for when its certification process met, or would meet, the revised training and experience requirements in 10 CFR Part 35. The procedures for NRC recognition of board certifications and the recognized certification processes, with the associated effective dates, are listed on NRC's medical-use tool kit web site under "Other Guidance" at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

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The revised Part 35 offers four methods for individuals seeking to be recognized as AMPs at NRC licensed medical-use facilities. The regulations in 10 CFR 35.51 specify two of these methods: (1) Approval of an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State as meeting the NRC's requirements for training and experience, referred to as the "certification pathway"; or (2) Approval by NRC, an NRC master materials licensee (MML), an NRC broad-scope medical-use licensee, or an MML broad-scope medical-use permittee, based on an evaluation of an individual's training and experience, against the requirements described in 10 CFR 35.51(b), referred to as the "alternate pathway."

The third method is described in the provisions of 10 CFR 35.57. Under this section, teletherapy or medical physicists identified on existing Commission or Agreement State licenses or permits before October 24, 2002, or AMPs identified on Commission or Agreement State licenses or permits between October 24, 2002, and April 29, 2005, are exempt from the requirements in 10 CFR 35.51. The intent of 10 CFR 35.57 is to "grandfather" those individuals named on existing Commission or Agreement State licenses or permits, so that they may continue functioning as AMPs for those uses for which they have been previously approved.

The fourth method is implemented through the definition of an AMP in 10 CFR 35.2 and 10 CFR 35.14, medical physicists who are listed as AMPs or teletherapy physicists on Commission or Agreement State medical-use licenses or permits may work as AMPs without the licensee needing to apply for a license amendment. The limited-specific medical-use licensee or permittee only has to notify the NRC or the NRC MML that the individual is working as an AMP, and provide documentation required in 10 CFR 35.14. Some Agreement States have not adopted the notification provisions in 10 CFR 35.14. Accordingly, this method may not be available to medical physicists moving to a new licensee in a particular Agreement State.

There are approximately 109 Gamma Knife® units, 765 remote afterloader units, 12 teletherapy units, and 100 Sr-90 eye applicators licensed in the U.S. NRC licenses about 260 of these devices, and approximately 725 devices are licensed by Agreement States.

SUMMARY OF ISSUE

For many years, NRC has listed medical physicists on licenses for remote afterloader units, teletherapy units, Sr-90 eye applicators, and Gamma Knife® units. In the 2002 revision of 10 CFR Part 35, NRC began identifying these medical physicists as AMPs. However, not all the Agreement States list medical physicists on medical-use licenses. Based on a recent NRC survey, 28 of the 34 Agreement States indicated that they have been or are now listing AMPs on their limited-specific medical-use licenses. The remaining six States indicated they did not previously list AMPs on their licenses, but they will list them by the April 29, 2008, deadline for establishing regulations compatible with the revised rule.

A medical physicist moving from an Agreement State to an NRC licensed medical facility, who was named on a Commission or Agreement State medical-use license or permit that was valid on April 29, 2005, is eligible to use the grandfather provision, in 10 CFR 35.57, to be named as an AMP on the new facility's NRC license. If the medical physicist is listed as a teletherapy physicist, medical physicist, or AMP on an Agreement State license issued subsequent to

April 29, 2005, the new NRC licensed medical facility can permit the individual to work as an AMP under the provisions of 10 CFR 35.2 and 35.14.

Medical physicists for whom the grandfather provisions do not apply, but who are professionally active in Agreement States that do not list medical physicists on their limited-specific medical-use licenses, must apply by either the board certification pathway or the alternate pathway, described in 10 CFR Part 35.51, when seeking AMP recognition on an NRC license or a license in another Agreement State. A board certified medical physicist may not be able to use the board certification pathway to obtain recognition as an AMP if his or her certification board and certification year are not listed on NRC's web site. Furthermore, medical physicists applying for recognition as AMPs by either the board certification pathway or the alternate pathway are subject to the recentness-of-training provisions in 10 CFR 35.59.

Therefore, a medical physicist to whom the grandfather provisions and the notification provisions do not apply and who is practicing in an Agreement State licensed limited-specific medical-use facility is strongly encouraged to request being identified as an AMP listed on the Agreement State license for his or her present facility if the medical physicist may in the future seek to be listed as an AMP on an NRC license or on a license in another Agreement State. Once listed on an Agreement State license, the medical physicist can seek recognized status via the notification provisions described in 10 CFR 35.2 and 10 CFR 35.14, or equivalent regulations in the particular Agreement State.

Even if an Agreement State does not identify teletherapy physicists, medical physicists, or AMPs on limited-specific medical-use licenses, a medical physicist located at a broad-scope medical-use facility licensed in such an Agreement State is encouraged to have the licensee name the physicist on a permit. This will enable the medical physicist to use the notification provisions described in 10 CFR 35.2 and 10 CFR 35.14, if he or she seeks to be listed as an AMP on an NRC license, or a license in another Agreement State.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

CONTACT

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

/RA/

Janet R. Schlueter, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Technical Contact: Ronald Zelac, FSME
(301) 415-7635
E-mail: rez@nrc.gov

Duane White, FSME
(301) 415-6272
E-mail: dew2@nrc.gov

Enclosure: "List of Recently Issued NMSS Generic Communications"

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Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
09/14/06	RIS-06-20	Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems	All community water systems (CWSs), in U.S. Nuclear Regulatory Commission (NRC) non-Agreement States, that during the treatment of drinking water, may accumulate and concentrate naturally-occurring uranium in media, effluents, and other residuals, above 0.05 percent by weight.
08/15/06	RIS-06-16	Transfer of the Management Oversight Of Certain NRC Region I Licensees in Mississippi To the NRC Region IV Office	All NRC materials licensees.
09/14/06	RIS-06-19	Availability of Guidance on Radioactive Seed Localization	All NRC medical licensees.
08/31/06	RIS-06-18	Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients	All NRC medical licensees.
09/22/06	RIS-06-14	Enforcement Discretion for Facility Changes Under 10 CFR 70.72(c)(2)	All fuel cycle licensees regulated under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, Subpart H.
07/20/06	RIS-06-11	Requesting Quality Assurance Program Approval Renewals Online by Electronic Information Exchange	All 10 CFR Part 71 quality assurance program and certificate holders.
04/23/06	RIS-06-10	Use of Concentration Control for Criticality Safety	All licensees authorized to possess a critical mass of special nuclear material.
01/26/06	RIS-02-15, Rev. 1	NRC Approval of Commercial Data Encryption Products For the Electronic Transmission Of Safeguards Information	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
01/24/06	RIS-06-01	Expiration Date for NRC-Approved Spent Fuel Transportation Routes	The U.S. Nuclear Regulatory Commission (NRC) licensees who transport, or deliver to a carrier for transport, irradiated reactor fuel (spent nuclear fuel (SNF)).
01/13/06	RIS-05-27, Rev. 1	NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review	All 10 CFR Parts 71 and 72 licensees and certificate holders.

Date	GC No.	Subject	Addressees
07/10/06	IN-06-13	Ground-Water Contamination Due to Undetected Leakage of Radioactive Water	All holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor and those authorized by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 72 licenses to store spent fuel in water-filled structures.
07/06/06	IN-06-12	Exercising Due Diligence When Transferring Radioactive Materials	All materials licensees.
06/12/06	IN-06-11	Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures	All medical licensees.
03/31/06	IN-06-07	Inappropriate Use of a Single-parameter Limit as a Nuclear Criticality Safety Limit	All licensees authorized to possess a critical mass of special nuclear material.
03/21/06	IN-02-23, Supl. 1	Unauthorized Administration of Byproduct Material for Medical Use	All medical licensees.
01/19/06	IN-06-02	Use of Galvanized Supports and Cable Trays with Meggitt Si 2400 Stainless- Steel-jacketed Electrical Cables	All holders of operating licenses for nuclear reactors except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel; and fuel cycle licensees and certificate holders.

Note: NRC generic communications may be found on the NRC public website at http://www.nrc.gov, under Electronic Reading Room/Document Collections.