

MEMORANDUM TO: Chairman Meserve  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan

July 23, 2002

FROM: William D. Travers /RA/  
Executive Director for Operations

SUBJECT: UPDATE ON THE 10 CFR PART 35 GUIDANCE RELATED TO  
DIAGNOSTIC APPLICATIONS

The purpose of this memorandum is to inform the Commission of the status of staff's efforts to revise the 10 CFR Part 35 guidance related to diagnostic applications.

In Staff Requirements Memorandum (SRM) M020219, dated February 28, 2002, the Commission directed that the staff issue revised draft guidance documents for implementing the revised 10 CFR Part 35, for public comment, including a stand-alone guide for diagnostic applications. The staff was further directed to develop the document such that the schedule would allow for resolution of public comment on the guidance document and issuance of the final guidance before the implementation date of the revised 10 CFR Part 35. Since the SRM was issued, the staff has interacted with stakeholders in the medical community seeking input on the development of these documents and, as a result, the staff has pursued an approach as described in this memorandum that meets the intent of the requirements in the SRM.

On April 4, 2002, the staff made draft NUREG-1556, Volume 9, "Consolidated Guidance About Material Licenses, Program Specific Guidance about Medical Use Licenses," publicly available for comment. The comment period ended June 4, 2002. On April 25 and 30, 2002, the U.S. Nuclear Regulatory Commission (NRC) conducted public meetings on the licensing guidance. The purpose of the meetings was to gather stakeholder input on the licensing guidance. The April 30th meeting was focused on guidance for diagnostic applications. Stakeholder views, expressed at that meeting, were to retain NUREG-1556, Volume 9, as a single document rather than creating a separate document for diagnostic applications, but to improve its usability by providing applicants with a way to locate the sections applicable to a given type of license (e.g., diagnostic or therapeutic).

On May 14, 2002, NMSS staff and management held a telephone conference call with Alan H. Maurer, MD, President, Society of Nuclear Medicine (SNM), Jeffrey A. Siegel, Ph.D., American College of Nuclear Physicians (ACNP/SNM), and William Uffleman, Esq., Counsel to SNM.

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The purpose of the call was to clarify whether, in light of the views raised during the April 30, 2002 public meeting, the ACNP/SNM continued to believe that a separate guidance document was needed for licensing of diagnostic applications of byproduct materials under revised 10 CFR Part 35. During the teleconference, options for a more navigable single document, such as a web-based format or a "roadmap," were discussed. However, SNM shared its view that a diagnostic-only guidance document is still needed because NUREG-1556, Volume 9, contains too much information. The SNM committed to produce an outline of a stand-alone guide, specific to diagnostic applications by the end of the comment public period for NUREG-1556, Volume 9. NRC agreed to review SNM's submittal and emphasized that the guide must not implicitly or explicitly add to, subtract from, or change the requirements of the rule.

Currently, the staff expects to receive SNM's draft of the diagnostic-only guidance document during the week of July 22, 2002. The staff will review this submittal with the overall objective of endorsing the document developed by SNM and to issue it as a joint SNM and NRC interim final document. This document would assist applicants in understanding the regulatory aspects of licensing for the use of byproduct material in diagnostic medicine. The staff expects to issue the interim final document before the effective date of the rule, October 24, 2002. Public comments would be incorporated in an updated version, as experience is gained in 10 CFR Part 35.

Staff will continue its dialogue with the SNM to ensure that the SNM document meets the needs of the diagnostic nuclear medicine community and to work out the mechanics of issuing a joint document. This includes interactions with the SNM to address staff comments on the content and form of the guide and the logistics of publication as an NRC document. In the unlikely event that the objective of a collaborative effort with SNM cannot be achieved (for example, the initial product reviewed is completely unsuitable), the staff has a contingency plan to develop and issue an NRC generated diagnostic guidance document. If the staff finds it necessary to use this contingency plan, the staff will notify the Commission. However, the staff strongly believes that publication of a joint SNM and NRC interim final guidance document would be the best outcome because it will demonstrate our willingness to work constructively with the medical community.

The staff believes that this joint effort with the SNM will ensure a level of ownership and support on the part of the diagnostic medical community. Concurrently with the joint SNM and NRC effort to develop a diagnostic only guidance document, the staff will continue development of its comprehensive diagnostic and therapeutic guidance in NUREG 1556, Volume 9, as part of the established guidance development process. The staff believes that this approach meets the intent of SRM-M020219, and absent further direction from the Commission, will continue to proceed as indicated.

cc: SECY  
OGC  
OCA  
OPA  
CFO

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Document Name: E:\Filenet\ML021550106.wpd

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