

July 2, 2002

William R. Uffelman
General Counsel and Director of Public Affairs
American College of Nuclear Physicians /
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Mr. Uffelman:

This is in reply to your letter of June 4, 2002, conveying a draft outline for a guidance document for licensing diagnostic nuclear medicine facilities under revised 10 CFR Part 35, "Medical Use of Byproduct Material." We extend our thanks both to you for your efforts as well as to Drs. Maurer and Siegel for their direction and effort in producing the draft.

Your letter also contained comments on draft NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses." These comments are being handled as part of the set of public comments received on the draft NUREG during the public comment period.

I suggest that, after receiving the next draft, that we discuss the steps in producing a guidance document specific to diagnostic nuclear medicine, in cooperation with the American College of Nuclear Physicians / Society of Nuclear Medicine (ACNP / SNM).

NRC staff reviewed the draft and found that the outline represents a good start towards a guide for the diagnostic nuclear medicine community. We found that most of the elements of a guide were present but offer that it would be useful to new applicants to include mention of the regulatory requirements for training and experience of Radiation Safety Officers, authorized users, etc. The guide should also include a brief mention of the requirements for financial assurance, sufficient to indicate when applicants should address this in an application and the Department of Transportation regulations for shipments. These additions are in accordance with the principle discussed in our telephone conversation on May 14, namely, that the guidance must be solely based on the requirements in the revised rule.

William R. Uffelman

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Thank you for your efforts and I look forward to discussing the steps necessary for making the guidance document for the diagnostic community available this fall.

Sincerely,

/RA/

Susan M. Frant, Deputy Director
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc:

Alan H. Maurer, MD, President
Society of Nuclear Medicine

Jeffry A. Siegel, Ph.D., Chair
ACNP / SNM Government Relations Committee

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Susan M. Frant, Deputy Director
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ADAMS Accession No. ML021780527

Distribution: RGordon/RF SFrant DCool MVirgilio

Document Name: C:\ORPCheckout\FileNET\ML021780527.wpd

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