April 16, 2002

Alan H. Maurer, M.D., President
Society of Nuclear Medicine
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Dr. Maurer:

I am responding to your letter to Chairman Meserve, dated February 20, 2002, in which you welcomed the opportunity to work with the U. S. Nuclear Regulatory Commission (NRC) in developing guidance for implementation of revised 10 CFR Part 35. In addition, you indicated concerns with the NRC's intention to submit the revised Part 35 for publication in the Federal Register while guidance is being further developed. As I noted in my letter to you dated February 11, 2002, the NRC is committed to providing guidance before the effective date of the revised Part 35.

We continue to believe that it is important to issue and begin the process of implementing revised 10 CFR Part 35 in a timely manner. Although Congress permitted the NRC to implement some aspects of the revised rule before reporting to Congress, the Commission chose to await implementation of any portion of the revised rule until the report to Congress had been filed. Having now transmitted a report to Congress, the NRC intends, as it stated to Congress, to submit the revised rule for publication in the Federal Register. As a part of its approach for this final rule on 10 CFR 35, the existing requirements of Subpart J will be retained for a 2-year period after the revised Part 35 becomes effective. During that period, licensees will have the option of meeting the requirements of Subpart J or the requirements in Subparts B and D-H. Such an approach will lead to achieving both the reduction of unnecessary regulatory burden and the maintenance of safety for all medical uses of byproduct material.

NRC staff is proceeding with plans and activities to develop guidance for implementation of Part 35 in a timely manner while seeking stakeholder input. The schedule for these activities, including training for license reviewers and inspectors, is enclosed.

As indicated on the enclosed schedule, activities are already underway to meet these goals. NRC staff has contacted several representatives of stakeholder groups, in both the diagnostic and therapeutic community, to participate in a public planning meeting for the development of guidance specific to diagnostic nuclear medicine and ensure that regulatory guidance is risk-informed and performance-based. The NRC is committed to effecting a smooth transition and implementation of the revised Part 35.

The NRC appreciates your continued interest in 10 CFR Part 35 and the efforts of individuals in your community to work with us in moving forward with a risk-informed, performance-based approach. If you have any further questions, please feel free to contact me.

Sincerely,

/RA/

Martin J. Virgilio, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: Schedule for Part 35 Activities

The NRC appreciates your continued interest in 10 CFR Part 35 and the efforts of individuals in your community to work with us in moving forward with a risk-informed, performance-based approach. If you have any further questions, please feel free to contact me.

Sincerely,

/RA/

Martin J. Virgilio, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: Schedule for Part 35 Activities

This correspondence formulates policy or expands, revises, or interprets policy, involves matters pending Commission decision, contains items relating to the performance of Commission duties and responsibilities, or involves items of high Commission interest.

Identical letters sent to:
Gary L. Dillehay, M.D., President
American College of Nuclear Physicians

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

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Gary L. Dillehay, M.D., President
Society of Nuclear Medicine
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Dr. Dillehay:

I am responding to your letter to Chairman Meserve, dated February 20, 2002, in which you welcomed the opportunity to work with the U. S. Nuclear Regulatory Commission (NRC) in developing guidance for implementation of revised 10 CFR Part 35. In addition, you indicated concerns with the NRC's intention to submit the revised Part 35 for publication in the Federal Register while guidance is being further developed. As I noted in my letter to you dated February 11, 2002, the NRC is committed to providing guidance before the effective date of the revised Part 35.

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NRC staff is proceeding with plans and activities to develop guidance for implementation of Part 35 in a timely manner while seeking stakeholder input. The schedule for these activities, including training for license reviewers and inspectors, is enclosed.

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The NRC appreciates your continued interest in 10 CFR Part 35 and the efforts of individuals in your community to work with us in moving forward with a risk-informed, performance-based approach. If you have any further questions, please feel free to contact me.

Sincerely,

Martin J. Virgilio, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: Schedule for Part 35 Activities

Jeffry A. Siegel, Ph.D., Chair
Society of Nuclear Medicine
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

Dear Dr. Siegel:

I am responding to your letter to Chairman Meserve, dated February 20, 2002, in which you welcomed the opportunity to work with the U. S. Nuclear Regulatory Commission (NRC) in developing guidance for implementation of revised 10 CFR Part 35. In addition, you indicated concerns with the NRC's intention to submit the revised Part 35 for publication in the Federal Register while guidance is being further developed. As I noted in my letter to you dated February 11, 2002, the NRC is committed to providing guidance before the effective date of the revised Part 35.

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The NRC appreciates your continued interest in 10 CFR Part 35 and the efforts of individuals in your community to work with us in moving forward with a risk-informed, performance-based approach. If you have any further questions, please feel free to contact me.

Sincerely,

Martin J. Virgilio, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure: Schedule for Part 35 Activities

Schedule for Part 35 Activities	
Planning meeting on development of guidance documents and Public Workshops	March 13 (Completed)
Publish draft NUREG Vol 9.	Late-March — 60 day comment period
Publish Revised Part 35.	April
Conduct public workshop on draft NUREG 1556 Vol 9, with emphasis on therapeutic applications of byproduct material.	April 25
Conduct public workshop on draft NUREG 1556 Vol 9, with emphasis on diagnostic applications of byproduct material.	April 30
Develop performance-based / risk-informed inspection guidance.	March — May
†Post inspection guidance to web.	Mid-May
†Public workshop on inspection guidance	June 6
Finalize guidance, including for inspections.	July
Publish final guidance (NUREG and guidance for diagnostic nuclear medicine).	August
Regional training of staff and State representatives.	June — July
Effective Date of Revised Part 35	6 months after date of publication

†Meeting dates are tentative; they will be announced in the Federal Register and posted on the NRC web site at www.nrc.gov — click on “Public Meeting Schedule”

Enclosure