EDO Principal Correspondence Control

FROM: DUE: / / EDO CONTROL: G20020094
DOC DT: 02/20/02
FINAL REPLY:

Dr. Alan H. Maurer
Dr. Gay L. Dilehay
Dr. Jeffry A. Siegel
American College of Nuclear Physicians/
Society of Nuclear Medicine (ACNP/SNM)

TO:

Chairman Meserve

FOR SIGNATURE OF : ** GRN ** CRC NO: 02-0123

DESC:

NRC Regulation of Diagnostic Nuclear Material - 10 CFR Part 35

ROUTING:

Travers
Paperiello
Kane
Norry
Craig
Burns/Cyr
Collins, NRR

DATE: 02/24/02

ASSIGNED TO: CONTACT:

NMSS Virgilio

SPECIAL INSTRUCTIONS OR REMARKS:

Appropriate Action
Ref. G20020019

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AUTHOR:	Dr. Alan Maurer		
AFFILIATION:	SNM		
ADDRESSEE:	CHRM Richard Meserve		
SUBJECT:	Concerns NRC Regulation of Diagnostic Nuclear Medicine		
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LETTER DATE:	02/20/2002		
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ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

February 20, 2002

The Honorable Richard A. Meserve
Chairman
U.S. Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

Re: NRC Regulation of Diagnostic Nuclear Medicine

Dear Chairman Meserve:

Thank you for calling last Friday to report on the status of your review of the proposals made by the Society of Nuclear Medicine and the American College of Nuclear Physicians to revise certain portions of 10 C.F.R. Part 35, as adopted by the Commission as well as the draft regulatory guides (e.g., NUREG-1556, Volume 9) which materially impact the way in which diagnostic nuclear medicine licensees are expected to comply with Part 35. We provided these proposals to you after our December 19, 2001 meeting. We also acknowledge receipt of your letter of February 11, 2002, as well as its attachments (copies of letters to Congress and Report to Congress).

We are grateful to you for recognizing that there are problems with the regulatory guides for licensing and inspection and for your willingness to discuss changes to the substantive regulations. We agree that much needs to be done to properly train license reviewers and inspectors before the revised rule is implemented. We also appreciate your recognition of the need to have separate guidance for diagnostic nuclear medicine and therapeutic uses of byproduct materials. We have always believed that cooperative discussions between the nuclear medicine community and the Nuclear Regulatory Commission are the best approach to devising an appropriate solution to the issues we have raised.

We would welcome, as you suggested, the opportunity to work with the Commission to make changes to the new Part 35 and the associated regulatory guidance. We are joining with ACR, ASNC, and other nuclear medicine organizations to create a task force to work with NRC staff to further refine Part 35 and help draft the new guidance document separating diagnostic nuclear medicine from therapeutic uses of byproduct material.

We are distressed, however, with your decision to publish the revised Part 35 in the Federal Register as a final rule prior to revising the licensing and inspection guidance or the rule. Since the rule will have a six month delayed effective date, you stated that you would like to use this six month period to discuss revisions and to make appropriate changes. The reason that major rules like the new Part 35 have a delayed effective date is because it is time-consuming and expensive to make the changes that would be necessary to comply with the new rule. Thus, the costs associated with the new Part 35 would be incurred regardless of whether or not, at the end

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of the six months, the Commission chose to make revisions to it or the regulatory guides. We respectfully suggest that that makes little sense.

In addition, we believe that publishing Part 35 as a final rule and then revisiting it does not conform to the Congressional mandate. Congress prohibited the Commission from expending any funds to implement or enforce most of the new Part 35 until the Commission provided a report to Congress that explains why the burden imposed could not be further reduced. Since your letter concedes that revisions to the licensing and inspection guidance are necessary, and the regulatory guidance is an integral part of compliance with the rule, we believe that the Commission should not implement the new Part 35 until the necessary changes are made. We also disagree with your conclusion that further reduction in the regulatory burden on diagnostic nuclear medicine would endanger the public health and safety; there is simply no factual basis for that conclusion. We also believe that, in view of the Commission's increased workload post-9/11, we are concerned that once the final rule is published it may be extremely difficult to ensure that any meaningful change would take place.

We do wish to thank you for working with us on this important matter and we look forward to continuing this dialogue.

Sincerely,

Alan H. Maurer, M.D.
President
Society of Nuclear Medicine

Gary L. Dillehay, M.D.
President
American College of Nuclear Physicians

Jeffry A. Siegel, PhD.
Chairman
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Cc: Commissioner Greta Joy Dicus
Commissioner Nils J. Diaz
Commissioner Edward McGaffagan, Jr.
Commissioner Jeffrey S. Merrifield