February 11, 2002

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

Dear Dr. Maurer:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to your letter of January 9, 2002, in which you identified a number of issues with the revised Part 35 and its implementation. I appreciate the opportunity to meet with you and hope that we can work together cooperatively in the future.

The NRC agrees with several of the concerns expressed in your letter. In particular, we agree that the licensing and inspection guidance needs to be improved and that the license reviewers and inspectors will need to be trained to implement the revised rule effectively and efficiently. As a result, we have already launched an effort to revise the guidance, which we believe will address many of the issues that you raise. At the same time, however, the Commission believes it is important to issue and begin implementing the revised Part 35 in a timely manner in order to achieve both the reduction of unnecessary regulatory burden and the maintenance of safety for all medical uses of radioactive material. The outcome which I believe we all seek is to ensure that the implementation of the rule through licensing and inspection meets our common objectives of both protecting public health and safety and providing effective regulation that minimizes the burden in a risk-informed manner. As experience is gained by both the NRC and our licensees, we remain open to future rule changes. We hope that this approach provides a mutually agreeable path forward.

As explained in the enclosed letter to Congress, although the Energy and Water Development Appropriations Act of 2002, (PL 107-66) permitted NRC to proceed with certain aspects of the revised rule before reporting to Congress, the NRC has not implemented any portion of the revised Part 35 for medical licensees. We concluded that fragmentation of the rule would be resource intensive and would introduce a confusing, dual regulatory system. Accordingly, and in recognition of the need for timely implementation of a rule that both reduces unnecessary regulatory burden and maintains safety for all medical uses of radioactive material, the enclosed letter to Congress indicates our intention to submit the revised Part 35 to the Office of the Federal Register, for publication, in approximately 30 days.

During the six-month period preceding the effective date of revised Part 35, we intend to finalize the implementing guidance with input from stakeholders. To that end, we plan to publish the draft final NUREG-1556, Volume 9, “Consolidated Guidance about Materials Licensees: Program-Specific Guidance About Medical Use Licensees,” publish a separate stand-alone guide for diagnostic applications, and solicit comment and conduct public

workshops on the licensing and inspection guidance. This process should help all of us to reach agreement on the expectations for licensing and inspection.

We understand your request to separate diagnostic nuclear medicine from the therapeutic uses of byproduct material. In fact, early in the development of Part 35, consideration was given to separating the rule for diagnostic and therapeutic uses. It was determined, however, that such a format would result in numerous duplicative regulations and therefore would not be an effective and efficient approach. Nonetheless, we believe that development of specific licensing guidance to assist diagnostic nuclear medicine licensees would simplify and clarify the rule. We would welcome your early input in this effort. The staff will contact you to discuss your interest in assisting in the development of such a guide.

You also raised issues in your letter about license conditions, guidance and inspection procedures, and identified certain sections of revised Part 35 that you believe should not be applied to diagnostic nuclear medicine. The NRC staff has developed specific responses to these issues. These are reflected in Enclosure 2 to this letter.

If you have any further questions, please feel free to contact me. The Commission hopes that it can find a way to alleviate your concerns, while simultaneously satisfying our regulatory objectives.

Sincerely,

/RA/

Richard A. Meserve

Enclosures:
(1) Letter to Congress transmitting NRC's report on Part 35 burden
(2) Specific responses to Issues in January 9, 2002 letter

Identical letter sent to:

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

Gary L. Dillehay, M.D., President
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Enclosure 1

February 11, 2002

The Honorable Sonny Callahan, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to the direction in the Conference Report on H.R. 2311, "Energy and Water Development Appropriations Act, 2002," I am pleased to provide the enclosed report, which was prepared by the U. S. Nuclear Regulatory Commission staff, to the House and Senate Committees on Appropriations. As you are aware, NRC was directed not to implement certain parts of the recently revised 10 CFR Part 35 relating to diagnostic nuclear medicine until the NRC had provided a report to Congress explaining why the regulatory burden could not be reduced further without adversely affecting public health and safety.

The revised Part 35 has generally achieved a significant reduction in the regulatory burden associated with diagnostic nuclear medicine, although certain requirements are maintained. The NRC believes that the regulatory burden of the revised rule for diagnostic nuclear medicine is commensurate with the low risk of adverse impact on health and safety from these procedures. As shown in the enclosed report, we believe that further reduction of regulatory burden beyond that currently proposed in the revised rule has the potential to increase the risk to public health and safety.

Nonetheless, we acknowledge that our stakeholders have identified substantial concerns related to the perceived burden of the guidance and inspection programs that will implement the new rule. We believe that many of these concerns are more reflective of licensing and inspection practices under the current rule -- practices we seek to modify in connection with the revised rule. Based on this feedback, the NRC agrees that the licensing and inspection guidance should be improved and that the license reviewers and inspectors will need to be trained to implement the revised rule effectively and efficiently. We have committed to undertake this reform.

The revised Part 35 includes only minimal requirements that are unique for diagnostic nuclear medicine, and most of the requirements listed in the staff's report apply to any licensee that has a specific license from NRC for medical uses of byproduct material. Consequently, the Commission believes that health and safety and reduction of unnecessary regulatory burden will best be served by implementing the revised Part 35. In the meantime, we are revising the implementing guidance to accommodate many of the concerns that have been raised, and we are committed to work with stakeholders to ensure the licensing and inspection procedures implementing the new rule continue to enhance the burden reduction offered by revised Part 35. In addition, consideration of future rule changes will remain possible through the NRC's

established rulemaking processes as experience with the rule is gained by NRC staff and licensees.

Although the Act permitted NRC to implement some aspects of the revised rule before reporting to Congress, the NRC has not implemented any portion of the revised Part 35 for medical licensees at this time. We concluded that fragmentation of the rule would be resource intensive and would introduce a confusing, dual regulatory system. The Commission therefore plans to submit the revised Part 35 to the Office of the Federal Register, for publication, in approximately 30 days. The rule would not become effective until 6 months thereafter, which should allow time for the guidance to be revised.

Please feel free to contact me if you have any questions.

Sincerely,

/RA/

Richard A. Meserve

Enclosure:
"Report to Congress Regarding the
Revised 10 CFR Part 35"

cc: Representative Peter J. Visclosky

Identical letter to:

The Honorable Sonny Callahan, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States House of Representatives
Washington, D.C. 20515

cc: Representative Peter J. Visclosky

The Honorable Harry Reid, Chairman
Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate
Washington, D.C. 20510

cc: Senator Pete V. Domenici

REPORT TO CONGRESS
REGARDING THE REVISED 10 CFR PART 35

[Note: This Report may be found at ADAMS Accession No.: ML013550321.]

Enclosure 2

Reply to Issues
(from SNM/ACNP, January 9, 2002)

General Issues in the Letter

You raised concerns about license conditions that add requirements, or remove the rights given in the regulations. We believe there is misunderstanding in this area regarding our approach, and we see license conditions as very limited in scope under revised Part 35, as described in the following responses to the three examples given in your letter.

1. The conditions of use specified in a license for diagnostic nuclear medicine refer to Sections 35.100 and 35.200, not specified radioisotopes, and authorize possession and use of byproduct material in quantities needed for diagnostic procedures. In this manner, flexibility is provided and specific radionuclides, chemical/physical forms, and maximum possession limits are not listed on the license, as was the practice many years ago. Inspectors will check for unauthorized uses, e.g., uses of byproduct material indicated in Sections 35.100 and 35.200 that are not used for procedures indicated in Section 35.100 (i.e., uptake, dilution, and excretion studies) and Section 35.200 (imaging and localization studies).

2. Guidance will be clarified to ensure that the physician can prescribe any appropriately authorized and available diagnostic radiopharmaceutical. As described in the previous response, this is already the intent of the revised Part 35.

3. We agree with your statement that emphasis be placed on the licensee's own responsibility for developing safe radiation practices as a way to produce better results than detailed regulation and license conditions. By not making the licensee's procedures a condition of the license, the need for license amendments to procedure changes will be eliminated under revised Part 35. The applicant may adopt a model procedure, use a procedure endorsed by a professional society or consensus organization, or develop their own procedure to meet a requirement. Draft NUREG-1556, Volume 9 (July, 2001), clearly indicates that model procedures contained in the appendices are an acceptable approach. NRC inspectors are instructed to evaluate licensee performance through observations, interviews of licensee personnel, and physical measurements. Only if an inspector finds that licensee personnel or equipment repeatedly fail to perform a radiation safety function, then a licensee's written procedure may be reviewed in order to understand the licensee's corrective action. As noted in the letter, NRC will review the draft final guidance with input from stakeholders. In addition, NRC will provide training for our reviewers and inspectors to ensure effective, efficient, and consistent implementation of the risk-informed, performance-based regulation.

The issue of separating diagnostic nuclear medicine requirements from therapeutic nuclear medicine requirements will be addressed by the NRC through guidance specific for diagnostic nuclear medicine. In the near future, NRC will work with SNM/ACNP and other stakeholders in a facilitated public workshop to outline the key points to be made for diagnostic nuclear medicine licensees.

Specific Issues in Attachment to the Letter

The issues raised in the attachment to the letter were grouped into three categories, (1) proposed revisions to 10 C.F.R. Part 35 (as adopted by the Commission on October, 23, 2000), (2) requirements that do not appear to apply to diagnostic nuclear medicine that would most likely apply to therapeutic uses of byproduct material, and (3) requirements that have been eliminated but appeared in an earlier draft of in NUREG-1556, Volume 9 that was based on the proposed rule. These categories are discussed below.

1. Proposed revisions to Part 35

   Section 35.6, "Provisions for the protection of human research subjects," is applicable to diagnostic nuclear medicine. Paragraph (a) authorizes research to be conducted under a specific license that authorizes byproduct material identified in Sections 35.100 and 35.200 that is used for diagnostic procedures indicated in those sections. Paragraph (c) ensures protection of patients and human research subjects by the Federal Policy, regardless of the source of funding for the research. As explained above, the authorized user may use any byproduct material indicated in Sections 35.100 and 35.200 for diagnostic procedures indicated in those sections. Except for the type of human research specified in 35.6(c)1 and 35.6(c)2 a license condition is not placed on a medical use license to address use of byproduct material for research because this requirement is already in the current and revised Part 35 and Section 35.6 applies to all medical use licensees.

   Section 35.10, "Implementation," addresses how a licensee can determine if it must comply with the requirements of the revised Part 35 when it becomes effective or if it must continue to comply with the requirements of its license conditions. Paragraphs (b) and (c) are applicable to both therapeutic and diagnostic medical use. With regard to diagnostic medical use, paragraph (b) continues an exemption from current Part 35 to revised Part 35, and paragraph (c) clarifies that a current license condition that is different from a requirement in revised Part 35 is superceded by revised Part 35. Paragraph (d) applies to therapeutic uses under Subpart H.

   Section 35.13, "License amendments," paragraphs (a) and (d) apply to both therapeutic and diagnostic medical use. It is applicable to diagnostic medical use because a radiation safety evaluation of significant changes to a proposed use of byproduct material must be completed before authorizing such a use. However, we expect such amendments to be rare due to the breadth of Sections 35.100 and 35.200 which indicate byproduct material may be used for diagnostic procedures identified in those sections without further amendment of the license and with no license conditions to tie down licensee procedures.

   Section 35.63, "Determination of dosages of unsealed byproduct material for medical use," is applicable to diagnostic nuclear medicine because it is essential for radiation safety of a patient that the dosage is verified and recorded prior to administration. This section provides options to a licensee to comply with this verification requirement. In addition, based on instructions from an authorized user, the dosage or range of dosage may be adjusted for a patient or group of patients, as appropriate for the conditions of

use and equipment involved. In every case, the administered dosage must be recorded. The Commission believes this provision reflects and does not exceed standard medical practice.

Section 35.204, "Permissible molybdenum-99 concentration," does not require a licensee to maintain a dose calibrator to assay molybdenum-99 concentration as the determination can also be based on mathematical calculations. The record keeping requirement applies to a licensee who is required to measure molybdenum-99 concentration, e.g., a licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical. NRC recognizes that not all diagnostic nuclear medicine licensees use such generator systems and would therefore not be required to keep a record of molybdenum-99 concentration. It should be noted that even if a licensee is subject to this requirement, the regulatory burden on the licensee will be substantially reduced because of the revised requirement to measure only the first eluate after receipt of a generator, rather than measure each eluate.

2. Sections more likely to be applicable to therapeutic uses of byproduct material.

Although the sections may more frequently impact therapeutic uses, NRC intends that the following sections in revised Part 35 do apply to diagnostic nuclear medicine: Section 35.27, "Supervision"; Section 35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct material"; Section 35.2063, "Records of dosages of unsealed byproduct material for medical use"; Section 35.3045 "Report and notification of a medical event"; Section 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child."

We believe that in 10 CFR 35.27, "Supervision," the regulatory burden was significantly reduced by eliminating the current requirements for periodic review of the supervised individual's use and preparation of (as appropriate) byproduct material, and the records kept to reflect that work. The burden reduction applies to all medical licensees, including small clinics as well as large hospitals and medical centers that may also operate a nuclear pharmacy. We believe what remains is essentially required for all NRC licensees, in principal by 10 CFR 19.12, "Instructions to Workers," and in fact reflects the normal medical standard of care. If this is not true we would be willing to bring the requirements in line with accepted medical practice.

We believe the requirements in 10 CFR 35.2060, 35.2063, 35.3045, and 35.3047 reflect the standard of care in medicine that protects patients and human research subjects from unnecessary radiation exposure and the necessity to report abnormal occurrences to Congress. We recognize that such reports from diagnostic nuclear medicine licensees are extremely rare, but the reporting thresholds were exceeded in the past and may be exceeded in the future. However, we will continue to work to be consistent with existing professional standards on this issue and other issues. We believe revised 10 CFR Part 35 is commensurate with the standard of care in medicine.

Section 35.2045, "Records of medical events," and Section 35.2047, "Record of a dose to an embryo/fetus or a nursing child," no longer appear as individual sections in revised

Part 35 and certain elements of these sections were respectively inserted into the appropriate provisions of Sections 35.3045 and 35.3047.

We agree that diagnostic nuclear medicine is unlikely to result in an event that would require a record or notification pursuant to paragraphs 35.2045 - 35.3046. However, in the rare event that a dose far above current, normal diagnostic ranges is delivered, we believe that the event should be evaluated and notifications made to ensure the problem resulting in the event is promptly corrected. Since this type of an event is rare, we believe the overall burden to the average licensee to be very small.

3. Sections in the current Part 35 that were eliminated in the revised Part 35, but that reappear in draft NUREG-1556, Volume 9 (July, 2001).

Section 35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material," is applicable for certain diagnostic nuclear medicine licensees that assay byproduct material for diagnostic procedures indicated in Sections 35.100 and 35.200. We will ensure that the diagnostic licensing guide is clear as to when a dose calibrator is needed.

Section 35.70, "Surveys of ambient radiation exposure rate," does not apply to uses of byproduct material under Sections 35.100 and 35.200. However the draft NUREG-1556, Volume 9 proposes radiation survey requirements for diagnostic nuclear medicine in Appendix R (Model Procedure for Area Surveys) that was intended to address all the possible types of radiation surveys for medical use of byproduct material, including diagnostic nuclear medicine. We will seek to develop a limited survey procedure that would be most appropriate for a diagnostic nuclear medical licensee.