

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