August 15, 2001

The Honorable Joseph I. Lieberman
United States Senate
Washington, D.C. 20510

Dear Senator Lieberman:

I am responding to your letter of June 28, 2001, which forwarded a letter from your constituent, Dr. John P. Seibyl, Chief of Nuclear Medicine at Yale University. Dr. Seibyl expresses concerns about the Nuclear Regulatory Commission's (NRC's) proposed revisions of regulations which cover, in part, diagnostic nuclear medicine (10 CFR Part 35). These regulations are currently under review by the Office of Management and Budget (OMB). As discussed below, we do not agree with Dr. Seibyl's view that the revised regulations will impose undue burdens on the practice of nuclear medicine. In fact, we believe that the regulations will significantly reduce regulatory burden, while maintaining protection of the public health and safety.

First, Dr. Seibyl expresses a concern that the regulations will impose an excessive level of regulation on medical procedures, will be more burdensome than the existing regulations, and are inconsistent with the NRC stated goal of reducing regulation of low-risk activities. I want to assure you that the NRC has made every effort to ensure that the revised regulations contain safety requirements which are commensurate with the associated radiation risk, and as a result, we believe the revisions will significantly reduce the regulatory burden to licensees. For example, we have substantially reduced the prescriptive requirements for radiation safety committees, instrument calibration, and safety procedures, because of the associated low risk that some medical procedures impose.

Second, Dr. Seibyl states that the revised Part 35 will significantly increase the cost of nuclear medicine procedures. As part of the package submitted to OMB for review on March 15, 2001, NRC included a detailed analysis which projects a significant decrease in the cost to licensees from implementing the final rule as compared to the current rule. Furthermore, we disagree with the estimate cited by Dr. Seibyl that first-year costs from the new rule will be over $494 million, which would be about $85,000 per institution. We believe that the transition costs will be substantially less, and are justified by the significant out-year reduction in regulatory burden.

Third, Dr. Seibyl expresses concern that the regulations will impose additional training and education requirements for radiation safety officers. This will be true in some cases. We concluded that some existing training and education requirements did not provide adequate assurance that radiation safety officers would have adequate training on the safe medical use of radioactive material. As a result, some modifications in training requirements were made.

However, we do not believe that the modified requirements will impose an undue burden on the medical community.

Finally, Dr. Seibyl states that the NRC has disregarded recommendations by the National Academy of Sciences (NAS) and others. I can assure you that, in developing the revised regulations, NRC provided opportunities for a significant level of stakeholder and public participation. The recommendations and comments of the NAS, as well as comments received from the nuclear medicine community, were carefully considered as part of that process.

NRC will continue to interact with the medical community and other stakeholders as the revised regulations are implemented. We are confident that, as this process moves forward, the safe medical use of radioactive material will be maintained, while the regulatory burden will be reduced.

I trust that this information responds to Dr. Seibyl's concerns.

Very truly yours,

/RA/

Richard A. Meserve