

The Honorable Sonny Callahan
Member, United States
House of Representatives
1141 Montlimar Drive
Suite 3010
Mobile, AL 36609

September 19, 2001

Dear Congressman Callahan:

I am responding to your letter of August 13, 2001, to Dennis Rathbun, which forwarded a letter from your constituent, Dr. John T. Renz, Chairman of Nuclear Medicine at Mobile Infirmary Medical Center. Dr. Renz expresses concerns about the U.S. Nuclear Regulatory Commission's (NRC's) proposed revisions of regulations that 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. Renz'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 and cost, while maintaining protection of the public health and safety.

First, Dr. Renz expresses a concern that the regulations 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 that projected a significant decrease in the cost to licensees from implementing the final rule, as compared to the current rule. The analysis showed that, although some new or modified requirements for notification and training will increase costs in some cases, the modification or elimination of other reporting, recording, and calibration requirements will result in a significant net decrease in cost.

Secondly, Dr. Renz stated that these regulations will unnecessarily increase the burden on practitioners and inhibit the practice of nuclear medicine, while providing no increase in safety to the patient or public. I want to assure you NRC has made every effort to ensure that the revised regulations contain safety requirements commensurate with the associated 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 calibrations, and safety procedures, because of the associated lower risk that some medical procedures impose.

In developing the revised regulations, NRC provided opportunities for a significant level of stakeholder and public participation. 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, and the regulatory burden will be reduced.

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

Sincerely,

/RA/

William D. Travers
Executive Director
for Operations

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