United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

October 8, 1996

The Honorable Shirley Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Jackson:

As chairman of the Clean Air, Wetlands, Private Property, and Nuclear Safety Subcommittee of the Senate Environment and Public Works Committee, I have reviewed the report of the National Academy of Sciences-Institute of Medicine (NAS-IOM) entitled, "Radiation in Medicine, A Need for Regulatory Reform." It would appear that adopting many or all of the report's recommendation could lead to an increase in effectiveness and safety in nuclear medicine departments in hospitals and clinics around the country.

The NAS-IOM report, with which the NRC Advisory Committee for the Medical Uses of Isotopes has agreed, states that the NRC should not be the agency involved in the regulation of ionizing radiation in medicine. This rather frank assessment especially deserves our attention because it is made by independent experts, giving it much more weight than so many other tendentious recommendations we receive. I can see no reason why an extended period is need to respond to such direct advice from the NAS and your own Advisory Committee.

As you know, the states currently regulate all other forms of ionizing radiation used in medicine, including accelerator-produced radioactive material. I am not aware of any significant safety problems occurring in these state-regulated areas that are above and beyond the normal risks associated with the practice of medicine. With the states potentially assuming more control of byproduct material and the NRC moving towards a more performance-based regulatory scheme, I am interested in the Commission's views on the safety risks of byproduct versus accelerator produced material.

I am aware that the NRC has published a notice of receipt of the NAS-IOM report that solicited comments from the public by April 22, 1996. However, there has been no substantive progress on your acceptance and implementation or your rejection of this report. It is my hope that the Commission will respond to the straightforward recommendations of this report without delay, or suggest alternate recommendations and their reasons.

Enclosed are several questions that would assist us in our consideration of this important issue. Please provide responses to our office by the end of this month.

Sincerely,

Lauch Faircloth
Chairman, Subcommittee on Clean Air,
Wetlands, Private Property, and Nuclear Safety

Attachment

QUESTIONS CONCERNING REGULATION OF NUCLEAR MEDICINE

1. Regarding the use of radiopharmaceuticals for diagnostic and therapeutic treatments, for the period that such records are available. How many associated unusual incidents have been noted? How many of these were only administrative in nature and how many involved actual misapplications? Of the latter, how many actually resulted in patients, occupational workers, or members of the general public receiving harmful levels of diagnostic or therapeutic radiopharmaceuticals? And of those receiving harmful levels, how many actually have displayed symptoms of radiation sickness?

   After providing specific numerical responses for the above categories, please provide any other quantifiable information that is available and may help put the data into proper perspective.

2. What studies or any other work has the NRC performed or had performed to compare either the cost of compliance of its regulatory program with the benefits of the medical use of byproduct material, or to compare other statistical evidence associated with the use of radiopharmaceuticals with similar types of statistical evidence associated with the success or failure of medical procedures not involving radioactive materials?

3. What is the range of costs that medical facilities must incur for compliance, inspection, and licensing? Has NRC done a cost versus risk assessment to form an opinion as to whether the costs are reasonable? If so, what is that opinion?

4. What views has the Commission formed on any of the recommendations on page 22 of the report? If the Commission has not yet reached a consensus on any particular recommendation, what positions have any of the individual Commissioners formed? What information is the Commission awaiting that is imperative for determining a complete response to this report's recommendations?

5. With regard to the additional public opinions on NRC oversight in the nuclear medicine field that may be received from the Strategic Assessment Rebaselining process, do you expect those additional public opinions to reflect new, important views outside the range of comments that have already been received?