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American College of Nuclear Physicians
The Society of Nuclear Medicine

August 9, 1990

Mr. John Telford
US Nuclear Regulatory Commission
Washington, DC 20555

Dear John,

We would like to thank you for all the effort that went into organizing the workshop held on July 23, 1990 to discuss the proposed NRC QA rule. We appreciate the opportunity to meet with NRC and discuss these important issues which affect our patients and medical practice. I would like to take a moment to summarize our views on the subjects after the discussion.

1. We believe that NRC would be making an unwarranted intrusion into the practice of medicine should the draft rule, or one similar to it, be adopted.

2. When one separates misadministrations of sealed and unsealed sources one finds that the incidence of unsealed source therapeutic misadministrations (I-131) have been below 5 cases per year in recent years. NRC staff did not disagree with this number.

   We strongly believe that the distinction between unsealed and sealed sources is critical, as they are similarly used by two different groups of practitioners, the nuclear medicine physicians and the radiation oncologists, respectively. While these two groups may be regulated under the same institutional license, in most cases, their institutional operations are totally independent.

   Since we speak only for the nuclear medicine community, we believe that no further corrective action of any type is required to deal with the handful of patients per year who experience I-131 therapeutic misadministration.

3. There is ample evidence of satisfactory hospital QA based on the Joint Commission on Accreditation of Health Care Organizations (JCAHO). As was demonstrated during our review with you, JCAHO equivalent QA programs currently perform all the items intendend by your proposed rule.

4. The estimates by your staff that the NRC proposed QA rule might cost only 1% of our operating costs translates to highly significant dollar amounts. For example, at a 500 bed hospital that amounts to $40,000 per year. This cost, multiplied by approximately 150 departments of similar size in the U.S. indicates a national cost potential, based on your current estimates, of about 6 million dollars. True costs would undoubtedly be higher because there are almost 6000 licensees who are smaller. The loss of technical staff or physicist time to satisfy record keeping requirements would result in a greater likelihood of misadministration than would be offset by introduction of this program.

5. At the time we were meeting, testimony was being presented in Congress indicating that 37 million people cannot get adequate healthcare because of a lack of funds to pay their bills. These people are all at higher risk of death and serious injury than any of our therapeutic misadministration patients. The funds being spent by NRC on this program, and by medicine to respond to this program, would be better spent in an area where there are more than three patients per year, nationwide, who can potentially benefit. In an era of budget deficits, as citizens and physicians, we cannot agree that the good of the general public is served by these expenditures. Furthermore, we do not believe that the 3-5 misadministrations per year will be impacted by duplitive QA regulations.

You indicated you felt that you were responding to a directive from the Commissioners to pursue this project. We are quite willing to reopen discussions with the Commissioners, and for that matter with Congress, as to whether this is indeed a significant national problem that requires the priority assigned to it and the fund expenditures associated with it.

We made reference to the reporting requirements for misadministration, indicating that there was a need to even consider diagnostic errors because they are of no consequence and their incidence (>1%) is so small as to approach the expected unavoidable human error factor.

Sincerely,

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