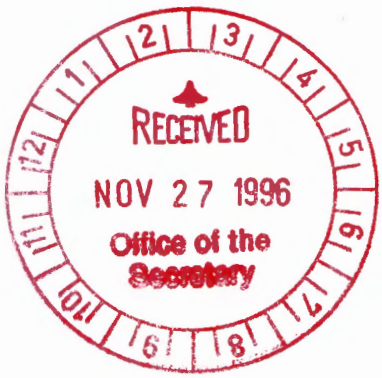
DSI-7
(27)

November 27, 1996



Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
ATTN: Chief of Docketing and Services Branch
Washington, D.C. 20555-0001

Dear Mr. Hoyle:

On behalf of over 30,000 physician and physicist members of the American College of Radiology (ACR), we appreciate the opportunity to comment on the NRC's strategic assessment and rebaselining initiative. ACR's comments focus specifically on Direction Setting Issue (DSI) No. 7 Materials/Medical Oversight.

DSI No. 7 poses the following question—what should be the future role and scope of NRC's Nuclear Materials Program, and in particular, NRC's Regulation of the Medical Use of Nuclear Materials? The ACR fully supports the current effort by the Commission to reevaluate the level of control and regulation needed to oversee the NRC's regulation of the medical use of nuclear materials. We believe that the role of the NRC in the future regulation of ionizing radiation should be more limited and more flexible in its mandates, should attempt not to interfere with the practice of medicine and should better utilize the expertise and resources of professional societies for both patient care and fiscal reasons.

Despite its best intentions, the NRC has too often deviated from the standards established by Congress in the Atomic Energy Act of 1954 (42 USC 2134) and by its own Commissioners in the 1979 medical policy statement. NRC regulations have generally not minimized intrusion into medical care but instead have frequently added administrative procedures and protocols which actually detract from good patient care. The approach used by the NRC with its quality management and inspection program is overly prescriptive and does not lend itself well to the concept of quality improvement.

While there is a role for the government to play in protecting the public from possible radiation harm, the adherence to strict regulations alone does not result in today's generally safe environment. Generally, the current system of requiring the physician authorized user to meet well-defined training and experience requirements has served the patient, the health care industry and the public well. However, factors such as adherence to standards of care, mandatory and voluntary quality assurance programs, and an ethical and professional commitment to patients also enhance the safe delivery of care to the patient and general protection of the public. These factors have for too long been overlooked by the NRC.

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Acknowledged by card 12/23/96

We support the goal of NRC's effort already underway to identify regulations that are unnecessarily burdensome and too prescriptive, however, we believe that the problems inherent in the current regulation of ionizing radiation in medicine would be better addressed through a comprehensive effort to rebuild and thoroughly reassess the objectives of the medical use program. The NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) made a similar recommendation to the Commission earlier this year. The ACR is in the process of developing specific recommendations along these lines.

Within this context and in response to the options posed by DSI No. 7, the ACR supports a decrease in the oversight of "low risk" activities with improvements in the oversight of "high risk" activities. The College supports the goal of decreasing regulatory responsibility for all materials that pose a low risk to the workers and the public. We further support the goal of revising regulations and guidance in both "low risk" and "high risk" areas to make them more "risk-informed and performance-based."

However, we believe it is imperative that there be a mechanism for input into the development of these risk criteria by professional organizations and an assurance from the NRC that the regulated community will be actively involved in this effort. As opposed to the public comment process, we would recommend the establishment of an advisory panel of users who could, through a participatory process, exchange views and assist in the development of risk criteria *with* the NRC.

In closing, we share the goal of adequately protecting the patient, medical personnel and the public from unnecessary radiation risk and support the NRC's current effort to reassess its activities in the medical use arena. The ACR would like the opportunity to play an active, ongoing role and stands ready to assist in this process.

Sincerely,

Melanie T. Young

Melanie T. Young
Assistant Director
Government Relations

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