

No. S-22-94  
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Remarks by Ivan Selin, Chairman  
U.S. Nuclear Regulatory Commission  
before the  
National Academy of Sciences,  
Institute of Medicine  
Committee for Review and Evaluation of the Medical Use  
Program of the Nuclear Regulatory Commission  
Washington, DC  
October 13, 1994

Dr. Putman, distinguished members of the Committee, I am pleased to be here this morning to speak to you regarding regulatory options in the medical use of byproduct material in therapy treatments. The overall goal of NRC's regulation of medical use of byproduct material is to assure patient, worker, and public safety with minimal intrusion into the practice of medicine. Determining the most appropriate method of reaching this goal has been a concern of the Commission for a number of years and is the focus of your deliberations.

It is not my intention this morning to re-describe the scope of work provided to this Committee. On the contrary, I want to take this opportunity to challenge this committee to respond directly to what I consider to be the fundamental questions at issue -- SHOULD THE NRC BE IN THE BUSINESS OF REGULATING MEDICAL USE OF IONIZING RADIATION? IF SO, WHAT DEPTH IS SUFFICIENT?

By way of introduction, I would like to provide the Committee with a perspective on the activity that has occurred on this issue over the past year and a half. During that period of time, the scope and implementation of the medical use regulatory program has received a great deal of Commission attention in general and my attention in particular. This issue has been the focus of numerous Commission and staff actions. Much of this activity was initiated following the Commission briefing of Senator John Glenn and the Committee he chairs, the Committee on Governmental Affairs on May 6, 1993.

Since May 6, 1993, the Commission has been briefed three times on issues related to the medical use regulatory program. These Commission briefings covered a series of initiatives being

taken to examine all aspects of the medical use regulatory program. Specifically, the Commission directed the staff to perform an internal senior management review of the implementation of NRC's current regulatory medical use program. This review was completed in June, 1993. In addition, responding to a request from Senator Glenn to examine the broader issue of the proper scope for Federal regulation of the medical use of ionizing radiation, the NRC Office of Policy Planning initiated a task force to study the issue. The Task Force, which included membership from the Food and Drug Administration, completed a report in September 1993, (Task Force Report on Medical Radiation Protection, OPP-93-04). You have a copy of the Task Force Report in your reference material. Finally, a Memorandum of Understanding between the NRC and the Food and Drug Administration providing for sharing of information between the two agencies has been signed. The MOU was one of the recommendations of the Task Force and addresses coordination in the areas of notification of product complaints, misadministrations or emergency situations, coordination of investigational activities, information exchange, and the NRC licensee and Agreement State notification.

The final component of this comprehensive evaluation of the NRC's medical use program is your review. Your independent and more comprehensive review of the medical use program will provide a critical contribution to the Commission on this issue.

Now I want to return to the reason all of this activity has occurred, that is, I would like to go back to what I consider to be the key issues and/or "concerns" related to NRC's regulatory program for medical use of byproduct material. As the situation now exists, the regulation of medical radiation is a patchwork with differing requirements based on the source of the radiation being administered and on where in the United States the administration takes place. You are undoubtedly aware, that the NRC regulates the medical use of byproduct material in 21 states. In the other 29 states, that is, in the Agreement States, the NRC has discontinued its direct regulatory authority over byproduct material under agreement with each state. However, byproduct materials used for sealed source therapy, subject to the control by the NRC or the 29 Agreement States, represents only 25 percent of radiation therapy treatments. The remaining 75 percent of patient treatments, involving electronically generated radiation (radiation produced by linear accelerators), is not subject to regulation or control by the NRC.

The Food and Drug Administration regulates the manufacture and distribution of all radiation devices used in therapy treatments. This regulation extends only to the level at which the device reaches the marketplace, with some regulation applied through post market surveillance of the devices. Electronically

generated radiation procedures are regulated under a range of state regulatory programs. Thus, Federal regulatory authority for electronically generated radiation currently only extends to equipment before it reaches the marketplace, while Federal regulatory authority over byproduct material extends down to the patient level.

This unevenness in regulatory authority does not appear to be justified by anecdotal information on the rates of misadministration per therapy treatment. This information led the NRC Task Force to conclude that the rate of misadministration would not be less for machine-produced sources than for byproduct sources of radiation because the procedures and processes are much the same.

This unevenness or disparity in the level of regulatory authority in the medical use of radiation can result in ineffective application of regulation for assuring public health and safety. For example, in December of 1992, the NRC suspended the license of Oncology Services Corporation (OCS) of Harrisburg, PA, as a result of a serious misadministration that occurred the previous month. During the period of license suspension, OCS was not able to use sources licensed under the Atomic Energy Act by the NRC. However, during that same period, OCS continued to administer electronic and particle accelerator generated radiation not under NRC jurisdiction. Thus, even though OCS had its NRC license suspended and was subsequently fined for violations in its radiation safety program, its radiation program involving electronically generated radiation was unaffected.

Therefore, as noted in my introductory remarks, a fundamental question that this committee should address is whether the depth of regulation applied to the 25 percent of therapy treatments that NRC regulates provides a significant benefit to public health and safety? Is this the best way to use limited resources to achieve the goal of protection of the public?

In my testimony before the Committee on Governmental Affairs last May, I proposed three options for the regulation of medical use of byproduct material:

- 1) limiting NRC's regulatory involvement to approval for use of sealed sources and devices containing byproduct material with the states then regulating their medical use, a program comparable to that conducted by the Food and Drug Administration for electronically generated radiation,
- 2) continuing to write standards and guidelines with the states assuming all responsibility of inspection and enforcement,

3) extension of NRC regulation to all radiation sources used for therapy, not just byproduct material, an extension of regulatory authority that would require legislation.

Any of these options would, if adopted and implemented, address the disparity in the level of regulation currently applied to medical radiation. However, only option #1 provides, by decreasing the level of regulation, a distinct break with past approaches and, thus, represents a different paradigm regarding NRC's medical use of byproduct material. Thus my focus will be on the first of the above options -- That is, should the NRC be regulating medical practice, particularly to the depth (i.e., to the patient level) currently applied, or could the NRC achieve the same level of health and safety protection by limiting our involvement? In other words, is there any public policy justification for the continuation of regulation at the present depth.

Fundamental to the question of the appropriate role the NRC should play in regulating medical practice is the fact that our regulation of medical use of byproduct material is apparently unique in that there does not appear to be a comparable degree of Federal regulation in any other area of medicine; for example NRC's requires patient notification in the event of a misadministration. Therefore, if NRC did not regulate medical use of byproduct material, but limited itself to the review and approval of the design and manufacture of sealed sources and devices, radiation medicine would not go unsupervised, it would instead receive the same oversight as other areas of medicine.

I would challenge this panel to address the issue directly -  
- Is this difference in the depth of regulation appropriate to protect public health and safety?

Thank you, this completes my presentation. I will be pleased to answer any questions that you and the Committee may have.

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