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February 8, 1997

Secretary,  
Nuclear Regulatory Commission  
Washington, DC 20555-0001

Attention: Docketing and Service Branch

DOCKET NUMBER  
PROPOSED RULE **PR 33**  
**(61FR58346)**

RE: 10 CFR Part 33 Advanced Notice of Proposed Rulemaking

Thank you for the opportunity to comment on the Advanced Notice of Proposed Rulemaking (ANPR) regarding the amending of 10 CFR Part 33. We wish to respond to three questions in your "Request for Comments on General Considerations." The order of the questions has been changed to support our argument that highly trained RSOs would be expected to operate a more rigorous program than RSOs who have no special training in radiation safety and that performance based programs will achieve the mission of the licensee while assuring public health and safety.

*Should the NRC Incorporate Requirements for the Duties and Responsibilities of the RSO and the RSC?*

The qualifications for the RSO should be commensurate with the proposed types, quantities, and uses of the radioactive material. A broadscope license by design allows considerable latitude on the uses of radioactive materials. Therefore, the qualifications for the RSO should be somewhat rigorous to assure the protection of public health and safety. We recommend that the NRC set high standards for training and experience with the expectation that highly trained individuals are more likely to run a rigorous program that protects public health and safety. We would support RSO training requirements of a nature similar to those of 10 CFR 35.900, which include certification by the American Board of Health Physics as one means for individuals to demonstrate their competency in radiation protection. While training requirements in the proposed sec. 33.21(b) may be sufficient for a specific license of limited scope, we question whether they are sufficiently rigorous to assure that highly qualified individuals would be appointed by licensee management to the important position of RSO for a broadscope license. An individual, who is certified by the American Board of Health Physics or a similar professional organization, or someone who has completed training similar to that specified in 10 CFR 35.900(b) is more likely to have the knowledge and insight expected to adequately protect public health and safety from activities associated with a broadscope license.

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We also strongly recommend that the regulation allow the delegation of certain elements of the radiation safety program to other individuals within the licensee organization who meet the qualification requirements for RSO. In large programs, e.g. research/teaching universities or medical centers, several individuals may be needed in radiation safety to conduct a rigorous program. If these individuals meet the qualification requirements for RSO, the licensee should be allowed to appoint deputy RSOs who would become fully responsible for implementing and maintaining the radiation safety program for part of the organization. For example, within our organization where we have more than 1000 physicians on staff and a large research program, we appoint one health physicist to oversee the radiation safety program for the laboratory clinical and research programs, another to oversee the radiation safety program for diagnostic nuclear medicine, and a third to oversee the radiation safety program for radiation oncology and machine generated radiation. All three of these health physicists meet the training requirements specified in 10 CFR 35 Subpart J.

*Should the Responsibilities of Licensee Management for the Radiation Safety Program be Specified in Part 33?*

We do not support the specification of licensee management responsibilities in Part 33. Management typically does not understand nor have the time to understand the complexities of a radiation safety program for a broadscope license. In fact, modern management philosophy suggests that employees should be empowered to carry out their responsibilities, which requires the appointment of highly trained individuals who are held accountable for achieving the goals of the program. A radiation safety program for a broadscope license with performance based goals should be managed by a highly qualified RSO who is accountable to licensee management for achieving the goals of a performance based program. We would be much more supportive of a performance based regulation that requires the appointment of a highly qualified RSO who would be expected to carry out a program that protects public health and safety.

*What Balance Should Be Maintained Between a Performance-Based and a Prescriptive Approach to Regulating Broad Scope Licensees.*

We recognize that certain elements of a regulation must be somewhat prescriptive to assure that radioactive materials will be utilized only by appropriately trained individuals in appropriately designed facilities. On the other hand, regulations that are overly prescriptive increase the cost of radiation safety programs without a concomitant increase in safety. Many members of the Society have experience in the implementation of 10 CFR Part 35 which incorporates a very prescriptive approach to essentially all elements of the medical use program. The overwhelming consensus of opinion based on this experience is

Secretary, NRC  
February 8, 1997  
Page 3

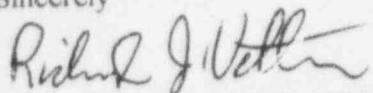
that the prescriptive nature of 10 CFR Part 35 has significantly increased the effort required to maintain compliance without a concomitant increase in safety. A performance based approach would allow more flexibility in the design of radiation safety programs but still require that certain radiation protection benchmarks be met. Therefore, while we support a prescriptive approach to the training and experience requirements for RSOs and authorized users, we strongly encourage the Commission to adopt a performance-based approach to the program as a whole.

Broadscope licensees (assuming the RSO meets rigorous training and experience requirements) should be allowed considerable flexibility to design and change their radiation safety program to assure that the licensee is meeting radiation safety performance goals while facilitating progress by users of radioactive materials. For example, if the licensee discovers a method to improve its program or to maintain the same standards at a lower cost, they should be allowed to make the change without a license amendment as long as performance based goals are achieved.

In response to the four key elements of a performance-based approach as suggested in the ANPR, we agree that such elements are essential for accomplishing the purposes of the Atomic Energy Act of 1974 as amended. For example, if the radiation dose limit to members of the public is 1 mSv, licensees should be allowed to demonstrate by measurement or calculation (including reasonable assumptions and occupancy factors) that no member of the public receives an effective dose in excess of this value. Criteria established to assess performance should be objective, e.g. can the licensee demonstrate that doses to members of the public are below the limits. The regulatory consequences for failure to meet performance criteria should be commensurate with the significance of the outcome. For example, an effective dose slightly in excess of the limit should be treated quite differently from an effective dose that results in deterministic effects.

Thank you again for the opportunity to comment on this ANPR. If you have any questions about our comments, please feel free to contact me.

Sincerely



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cc: Radiation Safety Committee