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ADDRESSEE: CHRM Richard Meserve

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August 14, 2001

Richard Meserve
Chairman
Nuclear Regulatory Commission

Dear Chairman Meserve:

I am a practicing cardiologist and nuclear medicine physician and was very disappointed to learn that the United States Senate prohibited funds for implementing the revision of 10 CFR Part 35 in its version of the Energy and Water Appropriations bill. As a member and current Chairman of the Advisory Committee on the Medical Uses of Isotopes I have worked on these revisions over the last 4 years. I recognize that these revisions are an initial step towards a fully risk based system of regulation, but I strongly support the revised rule as it will immediately relieve some of the more burdensome aspects in the current regulations that limit public access to diagnostic services and increase the overall costs of providing health care services. The Senate action is a major setback for those of us who have worked long and hard on the new regulatory framework. I urge the Nuclear Regulatory Commission to work with stakeholders who support 10 CFR Part 35 revision to reverse the Senate's action.

The regulated community, consisting of professionals involved in both the diagnostic and therapeutic use of radioisotopes in the practice of medicine, had every opportunity to make our views known in the course of the regulatory process. This consisted of open public meetings throughout the United States, opportunities to submit material in response to Federal Registrar publications, and numerous open public comment periods during meetings of the ACMUI. Those of us involved in the process recognized that based on the available scientific evidence of the involved risk, some aspects of the regulations continued to be burdensome especially with regards to diagnostic as opposed to therapeutic applications. This was the view that was presented on many occasions by the Nuclear medicine community that participated fully in the hearings and submitted comments to the commission along with other interested parties. The nuclear medicine community's views took the extreme position that no regulation of low-level radioactivity was necessary for diagnostic nuclear medicine procedures. The commission ruled that public health and safety would not be protected if it adopted the nuclear medicine position. The nuclear medicine community received fair treatment during the regulatory process. Its views were rejected because they were extreme and would not fully protect public health and safety.

Having failed in the regulatory process, the nuclear medicine community took its case to Congress. It is disappointing to me that the Senate Appropriation Committee accepted uncritically the extremist views of the nuclear medicine community. The Senate Appropriations

Committee explanation of their reason for denying funds for the revised 10 CFR Part 35 states: "The Committee has taken this action because it believes that the Commission has failed to adequately consider, as it has repeatedly promised, adopting regulations which properly reflect the very low risk posed by the use of diagnostic nuclear medicine procedures." Those of us directly involved in the revision process recognize that this statement is untrue. It is my personal feeling that the Commission has recognized and acknowledged that protecting public health and safety is a complicated process that extends beyond the mere recognition of the scientific data and into the realm of public perception and existing past precedents for the regulation of nuclear materials. The Commission and the ACMUI were acting in a responsible manner to protect patients, medical professionals and the public.

As someone who has been closely involved in the process of revising Part 35, I stand ready to take whatever action that you believe is necessary and proper to get the Senate action reversed in the final Energy Appropriations measure that is sent to President Bush. Please let me know what actions you feel would be most effective in reaching this goal.

I also wish to take this opportunity to let you know that many stakeholders in 10 CFR Part 35 are very unhappy with this development in the Senate. They do not intend to let this extremist view go unchallenged. I hope that these stakeholders will work with the NRC's Office of Congressional Affairs in their campaign to restore funding for the draft final rule on 10 CFR Part 35 on the legislative front. Finally, I hope that the Commission will vigorously assert its regulatory authority in the matter of 10 CFR Part 35.

Sincerely,

Manuel D. Cerqueira, MD