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November 27, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine Technologist at Mercy-Memorial Medical Center in Benton Harbor, Mi. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact my ability to practice high quality Nuclear Medicine and are preventing me from providing optimized care to individual patients.

For example, the current expiration time for Technetrium products is 6 hours. Although the Molybdenum break-through may still be well within acceptable limits (35.204a). Technetium is Technetium until it decays to Molybdenum. At which time, the content of Molybdenum exceeds permissable allowance, should the Technetium be considered expired. This could enable the user of Technetium for as long as twelve hours. Therefore reducing waste, and expenses.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physian-sponsored IND's that describe new indications for approved drugs. In many cases, manufacturers will never go back to the FDA to revise a package insert to include a new indication because it is not required by the FDA and there is simply no economical incentive to do so.

I would like to point out that highly restrictive NRC regulations will only jeopardise public health and safety by: restricing access to appropriate Nuclear Medicine procedures; exposing patient so higher radiation absorbed doses from alternative legal, but non-optimal studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted, repetitive procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should rely on the expertise of the FDA State Boards of Pharmacy, State Boards of Medical Quality Assurance, the JCAHO, Radiation Safety Committess, institutional Q/A review procedures, and most importantly, the professional judgement of physicians and pharmacists who have been well trained to administer and prepare these materials.

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I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of midadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such a study will demonstrate that the NRC's efforts to impose more and more stringent regulations are unnecessary and not cost effective in relation to the extremely low health risks of these studies.

In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for rulemaking as expeditiously as possible.

Sincerely,

Cheryl Dimas, CNMT

Cheryl Dimas, C.N.M.T.
Chief Technologist
Mercy-Memorial Medical Center

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