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DOCKET NUMBER PETITION RULE PRM-35-9 (54FR 38239)

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November 8, 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 physician at Emory University Hospital in Atlanta, Georgia. I am deeply concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material. These regulations adversely impact my ability to practice high-quality Nuclear Medicine/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

Several years ago, I was at a VA hospital which was cited by the NRC for administering Tc-99m pertechnetate to detect a Meckel's diverticulum. At that time, a possible Meckel's diverticulum was not an "approved" indication for Tc-99m pertechnetate yet I have seen this agent detect the cause of gastrointestinal hemorrhage that was not detected by any other test. There was clearly an appropriate clinical indication. Unfortunately, the hospital was cited for providing optimal medical care.

Package inserts describe the minimal clinical indications. I have been actively involved in the development of a new radiopharmaceutical, Tc-99m MAG_3. It will soon be approved by the FDA as a Tc-99m substitute for I-131 hippuran. If a child is referred to me for a first pass cardiac ejection fraction, I currently administer Tc-99m DTPA. Once Tc-99m MAG_3 becomes available, I will administer MAG_3 because the diagnostic quality of the study will be identical and the total body radiation dose to the child will be less. Under the current NRC proposals, the NRC would require me to give more total body radiation to the child than is medically necessary because Tc-99m MAG_3 will not be approved for first pass cardiac studies in the package insert.

The NRC regulations thwart optimal patient care and will ultimately lead to a further increase in the cost of medical care. Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving

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diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, 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 misadministrations from Nuclear Medicine diagnostic and therapeutic studies. I firmly believe that the results of such will demonstrate that the NRC's efforts to impose more and more stringer regulations are neither necessary nor cost-effective in relation to the extremely low health risks of diagnostic studies.

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

Sincerely,

Andrew Taylor, M.D.
Co-Director, Division of Nuclear Medicine
Emory University Hospital

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