

**UNITED  
HOSPITALS  
MEDICAL  
CENTER**

DOCKET NUMBER  
PETITION RULE PRM

35-9  
(54 FR 38239)



345

- Presbyterian Hospital
- Children's Hospital of New Jersey
- Newark Eye and Ear Infirmary
- Eye Institute of New Jersey
- United Hospitals Orthopedic Center

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DOCKETING SERVICE  
December 5, 1989

Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Docketing and Service Branch, Docket #PRM-35-39  
Washington, D.C. 20555

Dear Mr. Secretary:

I am writing to express my strong support for the Petition for Rule making filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I am a practicing Nuclear Medicine physician at the Hospital Center of Orange in Orange, New Jersey. I am deeply concerned over the revised 10-CFR-35 regulations (effective April, 1987) governing the medical use of by-product material as they significantly impact my ability to practice high-quality Nuclear Medicine and are preventing me from providing optimized care to individual patients. These regulations have an adverse impact on diagnostic services when forced to strictly follow the manufacturer's instructions for kit preparation and expiration times and for therapeutic services when forced to follow manufacturer's instructions for kit preparation and expiration times and also for FDA--approved indications, route of administration, and activity levels.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physicians--sponsored IND's that describe new indications for approved drugs. The package insert was never intended to prohibit physicians from deviating from it for other indications; On the contrary such deviation is necessary for growth in developing new diagnostic and therapeutic procedures. 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 economic incentive to do so.

Currently, the regulatory provisions in part 35 (35.100, 35.200, 35.300 and 33.17 (a) (4) do not allow practices which are legitimate and legal under FDA regulations and State medicine and pharmacy laws. These regulations, therefore, inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

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A MAJOR TEACHING AFFILIATE OF  
THE COLLEGE OF MEDICINE AND DENTISTRY OF N.J. NEW JERSEY MEDICAL SCHOOL

Secretary of the Commission

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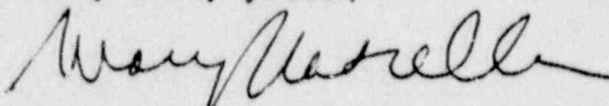
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Finally, I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate Nuclear Medicine procedures; exposing patients to higher radiation absorbed doses from alternative legal but none optimal studies; and exposing hospital personnel to higher radiation absorbed doses because of unwanted 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 Joint Commission on Accreditation of Health Care Organizations, Radiation Safety Committees, Institutional Q/A Review Procedures and most importantly the professional judgment of physicians and pharmacists who have been well trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations particularly those involving 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 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 Rule making as expeditiously as possible.

Very truly yours,



Mary Natrella, M.D.  
Director  
Nuclear Medicine Hospital Center  
of Orange

MN:cm