DOCKET NUMBER
PETITION RULE PRM 35-9
(54FR38239)

SHANDS HOSPITAL
at the University of Florida
Gainesville, Florida 32610

Pharmacy Services
Box J-316, JHMHC
(904) 395-0404

194

'89 NOV 13 P12:29

November 09, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket #PRM-35-9
Washington, DC 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 have been a practicing nuclear pharmacist since 1975. I currently practice at Shands Hospital in Gainesville, Florida.

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 Nuclear Pharmacy. These regulations prevent optimum care to individual patients, increase the costs of medical care and increase the radiation exposure to the patient.

For example for diagnostic services the regulations state that the package insert must be strictly adhered to. This causes considerable problems for several technetium based radiopharmaceuticals. Particularly Ceretec by Amersham, it is an excellent brain scanning agent that can be of great help in diagnosing a variety of diseases including alzheimer disease. The package insert states that,"Radiochemical purity determination must be performed before administration to the patient." The quality control procedures described take a minimum of 20 minutes to perform. The package insert also states,"Do not use the preparation more than 30 minutes after time of formulation." This allows, at the most, 10 minutes for use in patients. Due to the rapid changes that occur in this compound it has been shown that these images are of poor quality compared to those injected in the first 10 minutes. It is therefor common practice to inject the patients immediately after formulation and perform quality control after the patients are injected. This practice actually reduces the number of patients that must be repeated due to poor quality radiopharmaceutical, reducing radiation exposure, and reducing expenses!

The NRC should recognize that a principle involved in the formation of regulations is to make rules that people can respect and follow. This is not the case with the current regulations. They often cause a conflict between professional quality patient care and what the NRC says is legal.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs, and actively discourages the submission of physician-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(44 FR 8242 Published 2/9/79 Effective 2/9/79):

D510

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards or compliance with these standards are inadequate.
3. The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

What risks have been identified that would cause the enforcement of regulations which deprive patients of the best most economical medical care available??? I firmly believe that strict adherence to these regulations is much more of a risk to patients.

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 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 regulation 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 Healthcare Organization, radiation safety committees, 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.

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 Rulemaking as expeditiously as possible.

Sincerely,

John H. Kuperus, MS,BCNP,R.Ph.
Radiologic Pharmacy Coordinator
Shands Hospital at the University
of Florida
Clinical Assistant Professor
Univeristy of Florida
College of Pharmacy