



The
University of Oklahoma
Health Sciences Center

NUCLEAR PHARMACY
College of Pharmacy

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OFFICE OF THE SECRETARY
DOCKETING AND SERVICE BRANCH

December 7, 1989

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

Subject: ACNP/SNM Petition for Rulemaking

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 concerned citizen of the O.U.H.S.C. College of Pharmacy, Nuclear Pharmacy in Oklahoma City, Oklahoma. 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/Nuclear Pharmacy and are preventing me from providing optimized care to individual patients.

For examples 1) diagnostic services, I am forced to strictly follow the manufacturer' instructions for kit preparation and expiration times are preventing appropriate preparation of pediatric doses, preventing appropriate preparation of doses order by physicians for indicated procedures, and in general causing patients to receive poor and unnecessary procedures because the better procedures can't be offered and 2) for therapeutic services I am forced to follow the instructions not only for kit preparation and expiration times, but also for FDA-approved indications, route of administration, activity levels, etc.) are: cause patients to be unable to receive appropriate care unless a untrained NRC employee is contacted to make a medical judgement 200 to 1000 mile from the patient.

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

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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/pharmacy laws. These regulations therefore inappropriately interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

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 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 Healthcare Organizations, 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.

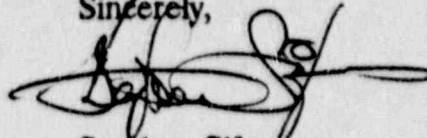
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In closing, I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as possible.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephen Sifers', with a large, sweeping flourish extending to the right.

Stephen Sifers
Courier
Nuclear Pharmacy Services

SLM:caf