Thomas Jefferson University Hospital

Department of Radiation Therapy and Nuclear Medicine
Division of Nuclear Medicine

Philadelphia, PA 19107
(215) 928-6707

146

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

October 31, 1989

'89 NOV -3 A11:12

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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 currently a Nuclear Medicine physician at Thomas Jefferson University Hospital in Philadelphia, PA. I am writing this letter in support of the Petition for Rulemaking filed by both the Society of Nuclear Medicine and the American College of Nuclear Physicians. I firmly believe that the revised 10 CFR 35 regulations, which regulates the medical use of byproduct material, easily conflict with our number one priority which is providing optimum patient care.

For example, one regulation dictates that manufacturers' instructions for kit preparation as well as expiration times, most be strictly followed. This means that after six hours, most kits involving Tc-99m cannot be utilized, even if the radiopharmaceutical is in the same condition as it was soon after preparation. Not only does this result in wasting many kits, but it would unnecessarily delay performing a nuclear medicine examination because a brand new kit must be prepared.

Another problem arises with the enforcement of FDA approved indications for certain radiopharmaceuticals. It should be kept in mind that the FDA more often than not discourages the submission of physicians sponsored IND's that contain new indications for approved drugs. The package insert was never intended to prevent physicians from deviating from it for other indications. Remember that such deviation is essential for growth and development of new diagnostic and therapeutic procedures. The 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 therefore there is no financial incentive to do so. It should be kept in mind that these restrictive NRC regulations interfere with public health and safety by restricting access to certain nuclear medicine procedures, thereby exposing the patients to higher radiation burdens from alternative radiological procedures, and exposing hospital personnel to higher radiation

DS10

burdens because of repetitive procedures. The NRC should rely on the expertise of the FDA, the state board of pharmacy, the quality assurance regulators and the joint commission on accredidation of hospitals, as well as radiation safety committees, to control and govern such policies. Please remember, it is the physicians, technologists and radiopharmacists who interact directly with patients, and are ultimately responsible for patient care. Morever, the NRC should work with, and not against, health care personnel.

In summary, I strongly plead with the NRC to adopt the ACNP-SNM Petition for Rulemaking as soon as feasible.

Sincerely,

Charles M. Intenzo, M.D.

Charles M. Intenzo, M. D.
Assistant Professor
Division of Nuclear Medicine
Dept. of Radiation Oncology