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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 Technologist 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. A more serious example is with the new perfusion brain agent Tc-99m HMPAO). According to the package insert, this agent must be used within one half hour after its preparation. This means that the kit cannot be prepared until the patient (often an ill in-patient) is actually in the department, often accompanied by ancillary personnel, such as the floor nurses. The patient must then wait until the radiopharmaceutical is prepared, and because the examination itself takes a fairly long time since SPECT is performed, the total time required for the examination is unnecessarily long. An additional problem arises if two patients on the same day are required to have the same kind of brain scan. This means that two separate kits must be prepared which ultimately increases medical costs. (The Tc-HMPAO expires one half-hour after preparation). When this happens, third party insurance carriers complain that costs are two high and make every attempt to not reimburse the hospital for the procedure.

Another problem arises with the enforcement of FDA approved indications for certain radiopharmaceuticals. It should be kept in mind that the FDA more often that 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

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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 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,

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