Veterans Administration

(337)

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'89 DEC -7 P3:08

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

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Dec. 1, 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 you to express my deep support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I have been practicing Nuclear Medicine at the VA Medical Center in Muskogee for over .0 years. I am extremely concerned over the revised 10 CFR 35 (4/87) regulations governing the medical use of byproduct material as they profoundly affect my ability to practice high-quality Nuclear Medicine by preventing me from providing individualized optimal care to our patients.

For example, new regulations force us to strictly follow package insert in the preparation and use of the radiopharmaceuticals for patient diagnosis and treatment, impeding our ability to use medical judgement in the best interests of our patients. FDA, on the other hand has recognised this limitation of the package inserts and wisely allows and encourages "non-label" clinical uses for approved drugs, and discourages expensive and time-consuming IND's. Such deviation is rather essential in developing new/improved diagnostic and therapy procedures.

Currently, the NRC regulations 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 unnecessarily interfere with the practice of medicine, which directly contradicts the NRC's Medical Policy statement against such interference.

Finally, I would stress that extremely restrictive NRC regulations will only jeopardize public health and safety by restricting access to appropriate nuclear medicine procedures, increasing personnel radiation exposures and raising costs. These excessive restrictions are detrimental to the advancement of nuclear medicine which is already so heavily overregulated.

The NRC should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, JCAHO, radiation safety committees, and most importantly professional judgement of physicians and pharmacists who have the ultimate responsibility for patient care.

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It is my opinion that excessive and confusing regulations often add to unavoidable human errors, exactly opposite of the outcome desired by the NRC. I firmly believe that NRC's efforts to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks associated with isotope misadministrations.

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

Sincerely,

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