SNM/ACNP Petition NRC To Change 10 CFR 35

The Society of Nuclear Medicine and the American College of Nuclear Physicians (ACNP) have jointly petitioned the Nuclear Regulatory Commission (NRC) to amend 10 CFR Part 35, "Medical Uses of Byproduct Material." In the petition, SNM/ACNP requests that the NRC change the regulation to allow the use of radiopharmaceuticals that are not being studied under Investigational New Drug Applications (IND) or New Drug Applications (NDA).

The request, submitted on June 6 by Barbara Y. Croft, PhD, immediate past president of the Society, and E. William Allen, MD, president of the College, was developed by Carol S. Marcus, PhD, MD, director of the nuclear medicine outpatient clinic at Harbor-UCLA Medical Center, in response to rising discontent among nuclear physicians and nuclear pharmacists with the provisions of 10 CFR 35. Norman L. McElroy, section leader of the NRC's medical and academic section, was the NRC contact person for the petition.

Under the current regulations, NRC licensees may use only radiopharmaceuticals that are IND-accepted or NDA-approved, and they must strictly adhere to the manufacturer's instructions when reconstituting them.

"This directly impinges on a physician's ability to provide optimum clinical care and to prescribe needed pharmaceuticals and prevents state-licensed radiopharmacists from practicing their profession," Dr. Marcus told *Newsline*. At a June meeting of the SNM Government Relations Committee in St. Louis, Capt. William H. Briner (ret.), chairman of the committee and director of the radiopharmacy at Duke University Medical Center, noted, "Until about 1975, the FDA [Food and Drug Administration] exempted radiopharmaceuticals from its regulation, and the AEC [Atomic Energy Commission, the predecessor of the NRC] was responsible for making safety and efficacy determination. But NRC's current interpretation of FDA-approved labeling as being restrictive rather than informative contradicts both FDA regulation and the Food, Drug, and Cosmetic Act (FDCA)." Dr. Marcus said in an interview, "All therapy indications that require variations in kit reconstitution, which are not on the package inserts, are illegal under NRC regulations."

Under the regulations proposed in the petition, physician authorized users would be permitted to use any radiopharmaceutical accepted or approved by the FDA or exempt from FDA regulation under Section 510(g) of the FDCA. State licensed radiopharmacies would be permitted to compound radiopharmaceuticals prescribed by an authorized user physician.

If the provisions of the petition are accepted by the NRC, said Dr. Marcus, "The practice of pharmacy, the very existence of which is not recognized by the NRC under the current regulations, would be restored to its proper professional level, with its appropriate rights and privileges. The conduct of research in nuclear medicine and nuclear pharmacy would be set squarely in the hands of the medical institution's Radiation Safety Committee and its federally-regulated Institutional Review Board."

The NRC was expected to publish a notice of the petition's receipt in the *Federal Register* at the end of July, 1989. All SNM members are encouraged to comment within the comment period, which will be either 60 or 90 days. During the meeting, the Government Relations Committee members underscored the importance of commenting on the petition and discussed various methods of conveying this to the SNM membership. Sample letters have been prepared for the membership; contact Melissa Brown at the joint SNM/ACNP Government Relations Office at (202) 429-5120 for a copy. ■

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