NRC Proposed Amendments: Too Little, Too Late?

A PETITION SUBMITTED TO the Nuclear Regulatory Commission (NRC) by the Society of Nuclear Medicine and the American College of Nuclear Physicians over four years ago is finally getting some response. The reaction from the petition's original author, however, has been less than favorable.

Carol S. Marcus, PhD, MD, Director of Nuclear Medicine and Outpatient Clinic at Harbor-UCLA Medical Center and the principal author of the petition is not overwhelmed by the NRC's response. "This is not the great panacea we were hoping for after four years of tug-of-war," she says.

According to Dr. Marcus, the NRC has already poorly addressed one proposal in the SNM-ACNP petition regarding package inserts. In August 1990, an interim rule was established for a three-year period that allowed modification of FDA-approved package inserts by authorized user physicians only if medical results were not otherwise attainable or if the departure would reduce medical risks to particular patients because of their medical conditions.

One change currently under consideration is to allow departures from package inserts approved by the FDA regarding the diagnostic preparation and use of therapeutic radioactive drugs by deleting the remaining restrictions of the interim rule making NRC regulations and license conditions consistent with state medical and pharmacy laws and the Food, Drug and Cosmetics Act. "Physicians practicing nuclear medicine must be able to use their best judgment about drug preparation and use regardless of package inserts," Dr. Marcus says.

Another proposed change is to include the concept of "authorized nuclear pharmacist" and specify training and experience requirements. "The only thing the NRC has to worry about is whether or not a person is qualified to use radioactive materials safely," Dr. Marcus says. "A nuclear pharmacist's rights and privileges are decided by each individual state. Medical and pharmacy decisions are outside the jurisdiction of the NRC."

The NRC also is considering an amendment allowing physician authorized users and authorized nuclear pharmacists to use any necessary nonradioactive or byproduct material to prepare radioactive drugs and to perform research involving human subjects. "Nuclear medicine physicians and nuclear pharmacists find it appropriate, advisable or necessary to compound radiopharmaceuticals on occasion," says Dr. Marcus. "Some necessary drugs are not commercially available at present and may never become commercially available."

Concerning the research aspect of the new proposal, Dr. Marcus says that this is an effort to repair an earlier mistake the NRC made in 1987 when it was revising its regulations and research criteria were unintentionally omitted. "When the FDA lifted its exemption for radiopharmaceuticals in 1975, both clinical use and research went to the NRC from the FDA. When the NRC revised its 10CFR Part 35, it forgot to permit the activity, even though the FDA regulates it, not the NRC," Dr. Marcus says.

The use of radiolabeled biologics containing byproduct material is another proposal under consideration. "We've been using radiolabeled biologics since the late 1940s!" says Dr. Marcus. "The problem is really another NRC mistake. Radiolabeled biologics used to be reviewed by the Center for Drug Evaluation and Research at the FDA; they were able to be sold commercially when they had approved New Drug Applications (NDAs). Some radiolabeled biologics are now being reviewed in the Center for Biologics Evaluation and Research; approved products have Product License Applications (PLAs). NRC required licensees to use products with NDAs, which automatically disqualified approved biologics with PLAs (or approved devices). We never did actually decide on products with ANDAs (Abbreviated NDAs) but went on and used them anyway. What the NRC meant to say was 'accepted or approved by the FDA' and it should forget the FDA's 'alphabet soup.'

"The proposed regulations also contain some inappropriate labeling requirements," says Dr. Marcus. "Drug labels are the business of the FDA and Boards of Pharmacy. The NRC has no statutory authority here except for information needed for radiation protection purposes. Hopefully, this section will be omitted in the final rule so that we won't have any more mistakes to fix."

Dr. Marcus says the unfortunate problem with NRC's proposed rule is that a major issue of the petition, "license abuse," is not addressed. "The statements of consideration are so misleading that it is astonishing the NRC signed off on them. Seeds are sewn for a new round of license and inspection abuse.

According to a spokeswoman for the NRC any statements regarding the proposed regulations should be submitted in writing to the commission. "We want these regulations to assure that the practice of nuclear medicine is not hampered," says Charleen Raddatz, nuclear physicist with the NRC. "And we want to ensure the health and safety of patients undergoing treatment with radiopharmaceuticals as well as physicians, technologists and the general public."

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