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NRC PROPOSES CHANGES TO INCREASE FLEXIBILITY IN MEDICAL USES OF NUCLEAR MATERIAL

The Nuclear Regulatory Commission is considering changing its regulations for the medical use of nuclear material to provide greater flexibility for authorized user physicians and qualified pharmacists.

The proposed changes are responsive to a petition for rulemaking submitted to the NRC by the American College of Nuclear Physicians and the Society of Nuclear Medicine. Notice of receipt of the petition and opportunity for public comment was published in the Federal Register on September 15, l989.

The Commission has already addressed some issues raised in the ACNP-SNM petition by publishing, on August 23, l990, an interim rule that allows, for a period of three years, specific departures from the package inserts under the direction of a physician authorized user.

Previously, NRC regulations restricted medical use licensees to using or preparing certain radioactive drugs in accordance with the Food and Drug Administration (FDA) approved package inserts, although FDA generally does not require physicians or pharmacists to follow these inserts.

In addition, current NRC regulations do not specifically allow medical use licensees to use byproduct material in research involving human subjects, in radiolabeled biologics (blood and other body materials to which radioactive material has been added) and in preparing radioactive drugs.

In response to the petition, the Commission is proposing to amend its regulations to

(1) Allow departures from FDA-approved package inserts regarding the preparation and use of radioactive drugs by deleting the remaining restrictions of the interim rule published on August 23, l990;

(2) Include the concept of an "authorized nuclear pharmacist" and specify training and experience requirements;

(3) Allow physician authorized users and authorized nuclear pharmacists to use byproduct material to prepare radioactive drugs;

(4) Allow the use of byproduct material in research involving human subjects; and

(5) Allow the use of radiolabeled biologics containing byproduct material.

The proposed changes also include miscellaneous changes to clarify, update and simplify the current regulations, such as accepting certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

The Commission does not believe that these proposed changes will result in any significant increase in radiation exposure to the public or the environment beyond the exposures currently resulting from medical uses of nuclear material.

Interested persons are invited to submit written comments on the proposed regulations by October 15. The comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

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