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NRC REVISES REGULATIONS ON RELEASE OF PATIENTS ADMINISTERED BYPRODUCT MATERIAL

The Nuclear Regulatory Commission is amending its regulations governing the release of patients from a hospital or other licensed medical facility after they have received radioactive material for treatment or diagnostic purposes. The revisions respond to three petitions received on this subject.

Radioactive pharmaceuticals or radioactive implants are administered to approximately 8 to 9 million patients in the United States each year for diagnosis or treatment of disease. These patients can expose other persons around them to radiation until the radioactive material has been excreted from their bodies or has become less intense due to radioactive decay.

Under the final rule, licensees may not authorize the release of patients if the estimated dose, to anyone in contact with the patient, would be greater than 500 millirems. (Typical natural background radiation in the United States is 300 millirems per year.) The new criteria are consistent with recommendations of the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements.

Under current NRC medical use regulations, licensees are not permitted to authorize the release of patients to whom nuclear material has been administered until either (1) the measured dose rate from the patient is less than 5 millirems per hour at a distance of 1 meter or (2) the radiopharmaceutical content of the patient is less than 30 millicuries.

The final rule amends the NRC's general radiation protection regulations to exclude doses to individuals exposed to released patients. Release of patients containing radioactivity is instead governed by the more explicit requirements of revised medical use regulations, which include, in addition to the 500-millirem limit, a requirement that, if the dose to an individual exposed to the patient is likely to exceed

100 millirems, the licensee must provide the patient with written instructions on how to minimize exposures to others. If the released individual may be breast-feeding an infant or child, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance.

The revisions partially grant three petitions for rulemaking on criteria for release of patients who have been administered radioactive material. On June 12, 1991, March 9, 1992, May 18, 1992, and July 26, 1994, the NRC published Federal Register notices concerning receipt of the petitions from Dr. Carol S. Marcus, the American College of Nuclear Medicine and the American Medical Association.

A proposed rule on this subject was published in the Federal Register on June 15, 1994. The final rule reflects public comments received.

The rule will be effective May 29 (120 days after publication of a Federal Register notice on January 29).

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