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NRC PROPOSES REVISIONS TO REGULATIONS ON RELEASE OF PATIENTS ADMINISTERED BYPRODUCT MATERIAL

The Nuclear Regulatory Commission is proposing to amend its regulations to clarify which portions govern 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 would also update the regulations and respond to two petitions received on this subject.

From a health and safety viewpoint, the proposed standard for patient release is essentially the same as the present standard.

Radioactive pharmaceuticals or 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 proposed rule, patients could not be released if the estimated dose to an individual from exposure to the patient would be greater than 500 millirems in any one year. (Typical natural background radiation in the United States is 300 millirems per year.) The new criteria would be consistent with the recommendations of the International Commission on Radiological Protection.

Current NRC requirements on release of patients containing radioactive material are contained in a portion of the Commission's regulations that deals specifically with medical uses of radioactive material. Medical 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. For the most commonly used radioactive material, this is equivalent to approximately 500 millirems per year.

When the Commission's new regulations on general radiation protection standards, which became mandatory on January 1, were published, the question arose (as evidenced by petitions for rulemaking) as to whether it was the Commission's intention to supersede the specific requirements for release of patients. In fact, the Commission did not.

The proposed rule would therefore amend the general radiation protection regulations to exclude doses to individuals exposed to released patients. Release of patients containing radioactivity would be governed by the more explicit requirements of the specific medical-use regulation.

The medical-use regulation would simultaneously be revised from the current 5 millirems per hour at 1 meter or 30 millicuries radiopharmaceutical content to a flat estimated 500 millirems maximum per year to an individual exposed to the patient. This change would provide flexibility to allow case-by-case calculation of doses in special circumstances, such as when a released patient lives alone. In addition, the change would allow licensees to take into account the specific characteristics of the radioactive material to be used, while maintaining a consistent overall level of protection.

Before releasing a patient, licensees would be required to determine the expected radiation dose to individuals exposed to the patient, taking into account the fact that radiation decays and that the dose rate immediately upon release would be higher than the dose rate a few days or weeks later. The NRC is issuing a draft Regulatory Guide DG-8015, "Release of Patients Administered Radioactive Material," that includes a table and method for estimating the annual dose. Single copies are available by written request to: Printing and Mail Services Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or Fax: (301) 504-2260.

In addition to the 500-millirems-per-year limit, the proposed rule would require that, if the annual dose to an individual exposed to the patient is likely to exceed 100 millirems, the licensee would have to:

(1) Provide the patient with written instructions on how to maintain doses to other individuals as low as reasonably achievable and

(2) Maintain for three years a record of the released patient and the calculated total dose to the individual likely to receive the highest dose from the patient.

The draft Regulatory Guide provides guidance on acceptable instructions and recordkeeping.

The proposed revisions would partially grant two petitions for rulemaking on criteria for release of patients who have been administered radioactive material. On June 12, 1991, March 9, 1992, and May 18, 1992, the NRC published Federal Register notices concerning receipt of the petitions from Dr. Carol S. Marcus and the American College of Nuclear Medicine. The proposed rule reflects public comments received.

Interested persons are invited to submit written comments on the proposed changes, which are to Parts 20 and 35 of the Commission's regulations, by August 29 (75 days after publication of a notice in the Federal Register on June 15).

The comments should be addressed to Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

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