New NRC Guidance on Release of Patients After ¹³¹I Treatment

n May 16 the Nuclear Regulatory Commission (NRC) announced the issuance of new guidance to medical licensees addressing the post-radioidine therapy release of patients who might come into contact with infants and/or young children. The NRC announce-

ment was met with immediate comment and consternation in the nuclear medicine community (see Newsline Commentary, facing page). For this reason, Newsline is reproducing the press release in its entirety and without editorial amendment. \Rightarrow

NRC ISSUES NEW GUIDANCE ON RELEASE OF THYROID PATIENTS ADMINISTERED RADIOACTIVE IODINE

The Nuclear Regulatory Commission has issued new guidance to medical licensees to strengthen existing precautions against the possibility that infants and young children who come in contact with thyroid cancer patients may receive unnecessary doses of radiation. The guidance was prepared in response to concerns raised by the International Commission on Radiation Protection, most

recently in its 2007 recommendations on radiation protection, and in a Petition for Rulemaking submitted by Peter G. Crane.

The guidance recommends that patients given therapeutic doses of radioactive iodine-131 should avoid direct or indirect contact (for example, through shared living space) with infants and young children for a specific period of time following the therapy. The guidance also recommends that physicians should consider hospitalizing patients whose living conditions may result in the contamination of infants and young children.

The new guidance is explained in a Regulatory Issue Summary (RIS) for NRC medical licensees and for medical licensees in the 35 Agreement States that regulate the use of radioactive materials.

"These simple precautions—including, if appropriate, hospitalization of the patient—can avoid unnecessary exposure for children, who can be more sensitive to radiation than adults," said Charles Miller, director of the NRC's Office of Federal and State Materials and Environmental Management Programs, which is responsible for licensing the medical uses of radioactive materials.

NRC regulations, implemented in 1997, allow licensees to release patients treated with radioactive material if the total radiation dose to any other person exposed to the patient is not likely to exceed 500 millirem. To put this in context, the average person in the United States receives about 300 millirem each year from natural background radiation.

These regulations were based on the assumption that internal doses to family members or others from a patient released following iodine therapy would be small compared to external doses received from being near the patient. However, concern has increased in recent years that contamination of infants and young children with saliva from a patient in the first few days following treatment may result in significant radiation doses to the child's thyroid. There have been no known incidents of infants or young children being contaminated in this way.

The new guidance for licensees to provide patients or their guardians includes:

- A recommendation that patients avoid direct or indirect contact with infants and young children for a specific period of time—for example, by having the children stay outside the home with other family members;
- A recommendation that patients have adequate living space at home (such as a bedroom and bathroom) that can be used exclusively by the patient for a specific period of time; and
- Information on the potential consequences, if any, of failure to follow these recommendations.

The guidance also suggests that licensees consider hospitalization for patients whose living conditions may result in contamination of infants and young children. The specific period of time for which patients should follow these recommendations would be determined by the physician, depending on the amount of iodine-131 administered; typically, this period would be for two to seven days following treatment.

In his Petition for Rulemaking, Peter G. Crane requested that the NRC revise its patient release regulation to require hospitalization of thyroid patients administered a certain amount of iodine-131. The NRC has determined that additional rulemaking is not necessary because current NRC regulations provide adequate protection to family members and others. In addition, the agency believes issuing new guidance to medical licensees will effect a change in practice more quickly and efficiently than developing and implementing new regulations.

Regulatory Issue Summary 2008-11, "Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131," and the new guidance will be available on the NRC Web site here: /reading-rm/ doc-collections/gen-comm/reg-issues/2008/index.html. Previous guidance for licensees to provide patients is available in Appendix U of NUREG-1556, volume 9, revision 2, "Program-Specific Guidance About Medical Use Licensees," available at /reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/.