UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, D.C. 20555

January 25, 2011

NRC REGULATORY ISSUE SUMMARY 2011-01
NRC POLICY ON RELEASE OF IODINE-131 THERAPY PATIENTS UNDER 10 CFR 35.75 TO LOCATIONS OTHER THAN PRIVATE RESIDENCES

ADDRESSEES

All medical and Master Materials Licensees. All Radiation Control Program Directors and State Liaison Officers.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of NRC's policy on the release of iodine-131 therapy patients (i.e., patients and human research subjects) under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.75 to locations other than private residences. No specific action or written response is required. NRC is providing this RIS to the Agreement States for their information and for distribution to their licensees as appropriate.

BACKGROUND

When the staff developed the patient release rule in 10 CFR 35.75, the staff's intent was to create a rule that would allow licensees to release patients where the dose to third parties was not likely to exceed 5 mSv. As the rulemaking record and regulatory guidance make clear, the NRC anticipated that the 5 mSv standard, in contrast to the standard of 1 mSv generally applicable to the public under 10 CFR 20.1301(a)(1), would apply principally to the patient's family or other caregivers, typically in a home setting (See for example, NUREG-1492 (pp. 11-12); NUREG-1556 (Appendix U, p. U-18)).

The regulations require that instructions on how to keep doses as low as reasonably achievable (ALARA) be given to patients if there is a possibility that doses to third parties would exceed 1 mSv. To develop instructions adequate to meet this requirement, licensees need to analyze each patient's specific circumstances to determine the appropriate recommendations to give to the patient prior to the patient being released. The NRC is aware of continuing concerns regarding instances when patients are released to hotels or motels and this RIS provides information in response to those concerns.

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, Department of Public Service
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SUMMARY OF ISSUE

The NRC regulations in 10 CFR 35.75 permit a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)." Although release to family or other caregivers in a home setting is the longstanding practice by most licensees, current NRC regulations neither authorize nor restrict release of patients to particular destinations. But in all cases the patient must meet the release criteria in 10 CFR 35.75. If the total effective dose equivalent to any third party is likely to exceed 1 mSv, licensees must provide sufficient instructions to patients which, if followed, will assure that doses to other individuals will be ALARA. Licensees therefore must necessarily consider the destination (such as a private home, apartment, hotel, dormitory, etc.) to which a patient will be released, and consider the potential for exposures to others, to assure instructions compliant with 10 CFR 35.75 are provided to the patient.

Although 10 CFR 35.75 does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the NRC strongly discourages this practice because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses which are not ALARA. Licensees are reminded that the ability of the licensee to provide adequate instructions under 10 CFR 35.75(b) of necessity may depend upon the licensee's consideration of the destination to which the patient will be released. When the licensee is aware of the likely patient destination, the licensee can best estimate the likely cumulative exposures to other members of the public (*e.g.*, hotel workers and guests) and direct appropriate protective measures. In accordance with the requirements of 10 CFR 35.75(b) licensees must provide specific instructions highlighting the steps to follow by the patient if there is a possibility that doses to surrounding individuals may exceed 1 mSv.

When an iodine-131 therapy patient is released to a private residence, the patient is likely able to fully describe details of the living situation that allow the licensee to make reasonable estimates of exposures to other individuals. The NRC recognizes, however, that there may be infrequent cases in which patients who would potentially be eligible for release to a private residence under 10 CFR 35.75(a) will be adamant on not being hospitalized or going to a private residence and will select an alternative location (e.g., hotel, motel, etc.) as their post-therapy destination. In any case, if the potential dose to third parties would exceed 1 mSv, licensees must provide adequate instructions to assure that, if followed, the dose to members of the public from the released patient meets the ALARA requirement.

While not specifically required by 10 CFR 35.75, as part of a licensee's approach for determining safe patient release, a licensee may choose to encourage patients who share living space with individuals whose exposure to radiation may pose a higher risk (e.g., young children and pregnant females) to temporarily relocate such individuals to alternative locations. This recommendation is in keeping with the additional instructions provided in RIS 2008-11, "Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration with Iodine-131," and is consistent with the recommendations of the International Commission on Radiological Protection, Publications 94 and 103. Furthermore, as also recommended in RIS 2008-11, licensees should consider not releasing patients whose living conditions may result in the contamination and exposure of infants and young children.

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List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

Date	GC No.	Subject	Addressees
05/25/10	RIS-2010-04	Monitoring the Status of Regulated Activities During a Pandemic	All holders of operating licenses for nuclear power reactors and research and test reactors under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have ceased operations and have certified that fuel has been permanently removed from the reactor vessel and have no spent fuel stored on-site. All U.S. Nuclear Regulatory Commission (NRC) fuel cycle facilities licensed under 10 CFR Part 40, "Domestic Licensing of Source Material" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" and gaseous diffusion plants certified under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." All holders of site-specific licenses for independent spent fuel storage installations (ISFSIs) under the provisions of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater than Class C Waste," and all holders of 10 CFR Part 50 licenses with ISFSIs under the general license provisions of 10 CFR Part 72. All NRC materials licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, under the provisions of 10 CFR Parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, and 70.
09/10/10	RIS-2010-09	Radiation Safety Officers For Medical-Use Licenses Under 10 CFR Part 35	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, NRC master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

Note: This list contains the six most recently issued generic communications, issued by the Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html

10 CFR §35.75(b) also lists specific requirements for instructions related to nursing infants and children.

Licensees are reminded that, in accordance with 10 CFR 35.2075(a), they are required to maintain a record of the basis for authorizing the release of a patient.

BACKFIT DISCUSSION

This RIS requires no action or written response. Any action on the part of addressees in accordance with the guidance contained in this RIS is strictly voluntary and, therefore, is not a backfit under any requirement. Consequently, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is a rule as designated in the Congressional Review Act (5 U.S.C. §§ 801–808). The NRC has determined this RIS is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

RELATED GENERIC COMMUNICATIONS

RIS 2008-11, "Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration with Iodine-131."

PAPERWORK REDUCTION ACT STATEMENT

This RIS contains and references information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing information collection requirements were approved by the Office of Management and Budget, approval number 3150-0010.

PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the technical staff member listed below or the appropriate regional office.

/RA/

Robert J. Lewis, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Contact: Said Daibes, PhD, FSME/MSSA
(301) 415-6863
E-mail: Said.Daibes@nrc.gov

Enclosure:
List of Recently Issued FSME
Generic Communications

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications

Date	GC No.	Subject	Addressees
11/13/09	IN-2009-27	Revised International Nuclear and Radiological Event Scale User's Manual	All holders of an operating license or construction permit for a power reactor, test reactor or research reactor issued under 10 CFR Part 50; holders of or applicants for an early site permit, standard design certification, standard design approval, manufacturing license, or combined license issued under 10 CFR Part 52; holders of a materials license, certificate, approval, or registration issued under 10 CFR Parts 30, 31 through 36, 39, 40, 61, 70, 71, 72, and 76; Agreement State Radiation Control Program Directors and State Liaison Officers.
11/19/2010	IN-2010-24	Notice of Possible Source Leakage During Non-Routine Maintenance on a Gammacell 40 irradiator	All academic Type A broad scope licensees; all medical institutions; all self shielded irradiators less than or equal to 10,000 cues licensees; all Radiation Control Program Directors and State Liaison Officers.
12/03/09	RIS-2009-15	National Source Tracking System Annual Inventory Reconciliation	All licensees possessing Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.
01/21/10	RIS-2010-02	The Global Threat Reduction Initiative (GTRI) Federally Funded Voluntary Security Enhancements for High-Risk Radiological Material	All holders of operating licenses for nuclear power reactors and research and test reactors under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have ceased operations and have certified that fuel has been permanently removed from the reactor vessel and have no spent fuel stored on-site. All U.S. Nuclear Regulatory Commission (NRC) fuel cycle facilities licensed under 10 CFR Part 40, "Domestic Licensing of Source Material" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" and gaseous diffusion plants certified under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants." All holders of site-specific licenses for independent spent fuel storage installations (ISFSIs) under the provisions of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater than Class C Waste," and all holders of 10 CFR Part 50 licenses with ISFSIs under the general license provisions of 10 CFR Part 72. All NRC materials licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, under the provisions of 10 CFR Parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, and 70.