

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

May 12, 2008

**NRC REGULATORY ISSUE SUMMARY 2008-11
PRECAUTIONS TO PROTECT CHILDREN WHO MAY COME IN
CONTACT WITH PATIENTS RELEASED AFTER THERAPEUTIC
ADMINISTRATION OF IODINE-131**

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

INTENT

NRC is issuing this regulatory issue summary (RIS) to inform licensees of supplemental guidance to NUREG 1556, Volume 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses" on the precautions that should be taken to protect infants and young children who may come in contact with patients released after administration of therapeutic amounts of iodine-131 (I-131), such as oral sodium iodide I-131. No specific action or written response is required. NRC is providing this RIS to Agreement States for their information and for distribution to their medical licensees, as appropriate.

BACKGROUND

On January 29, 1997, NRC published a final rule in the *Federal Register* on the "Criteria for the Release of Individuals Administered Radioactive Material" (62 FR 4120). This rule amended the patient release criteria in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," replacing the activity-based or dose-rate-based release limit with a limit based on projected radiation doses to other individuals exposed to a patient released after therapeutic administration of radionuclide, such as oral sodium iodide I-131. These dose-based release limits used assumptions that the internal doses for individuals who may come in contact with released patients were very small compared with doses from external exposures. Also, these criteria were consistent with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) at the time.

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However, in ICRP Publication 94 “Release of Patients after Therapy with Unsealed Radionuclides,” published in 2004, ICRP cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that “contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child’s thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer.” ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, “The 2007 Recommendations of the International Commission on Radiological Protection,” which states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

SUMMARY OF ISSUE

The 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).” However, as described in the Background section of this RIS, for some I-131 therapies, such as oral administration of sodium iodide I-131, the ICRP cautions that the internal dose to infants and young children who may come in contact with a released patient could be significant.

NRC has developed guidance on recommended instructions that licensees should give I-131 therapy patients who are about to be released from licensee control and who will or may have contact with infants and young children. The guidance recommends that licensees consider not releasing patients, administered I-131, whose living conditions may result in unnecessary exposure of infants and young children.

The guidance mentioned above may be found in Enclosure 1 of this RIS and at the NRC’s Web page entitled “Medical Uses Licensee Toolkit” at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 “Program-Specific Guidance About Medical Use Licenses.”

FEDERAL REGISTER NOTIFICATION

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

CONGRESSIONAL REVIEW ACT

In accordance with the Congressional Review Act, the NRC has determined that this RIS is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

CONTACT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the individual 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

Technical Contact: Duane White, FSME
(301)415-6272
E-mail: dew2@nrc.gov

Enclosures:

1. Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131
2. List of Recently Issued FSME Generic Communications

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OFFICE	FSME/DMSSA	Tech.Editor	DILR/RBB	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA
NAME	DWhite	QTE via email	NBhalla	AMcIntosh	CFlannery	SWastler
DATE	01/ 25 /08	01/ 25 /08	2/ 04 /07	02/ 01 /08	02/ 05 /08	02/ 04 /08
OFFICE	OIS	OGC - NLO	OGC - CRA	DMSSA		
NAME	TDonnell	BJones	TRothschild	RLewis		
DATE	02/ 22 /08	02/ 21 /08	02/ 21 /08	03/ 04 /08		

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Guidance to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131

The Nuclear Regulatory Commission (NRC) regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," permits 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)." For this guidance document, the individual or human research subject to whom the radioactive material has been administered is called the "patient." Please note that this guidance is a supplement to the guidance found in Appendix U of NUREG-1556, Vol. 9, Rev. 2 "Program-Specific Guidance About Medical Use Licenses."

NRC's current patient release criteria were based, in part, on the assumption that internal doses to an individual from a patient released after therapeutic administration of a radionuclide, such as oral sodium iodide I-131, was small compared with doses from external exposures. However, in 2004, the International Commission on Radiation Protection (ICRP), in ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides," cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose from external exposure. ICRP Publication 94 states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." ICRP also repeats this statement in its new comprehensive radiation safety recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection," which states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

Section 35.75(b) of 10 CFR Part 35 requires the licensee to provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA) if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). In consideration of the more recent ICRP recommendations described above, the licensee, in implementing the requirements on written instructions in 10 CFR 35.75(b), should take into account whether the released patient may come in contact with infants or young children. In such a situation, in order to protect infants and young children from possible I-131 contamination, the licensee should provide the patient with additional instructions. These additional instructions should include:

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

Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children.

List of Recently Issued FSME Generic Communications			
Date	GC No.	Subject	Addressees
10/04/07	RIS-07-22	Status Update For Implementation Of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission materials licensees, radiation control program directors, State liaison officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes.
10/04/07	RIS-07-23	Date For Operation Of National Source Tracking System	All licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Radiation Control Program Directors and State Liaison Officers.
12/05/07	RIS-07-27	Improving Public Understanding of the Risks Associated with Medical Events	All U.S. Nuclear Regulatory Commission medical use licensees. All Radiation Control Program Directors, and State Liaison Officers
12/07/07	RIS-07-28	Security Requirements for Portable Gauges	U.S. Nuclear Regulatory Commission portable gauge licensees and Agreement State Radiation Control Program Directors and Liaison Officers
12/14/07	RIS-07-38	Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users	All U.S. Nuclear Regulatory Commission medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers
02/01/08	RIS-08-02	Actions to Increase the Security of High Activity Radioactive Sources	All U.S. Nuclear Regulatory Commission Materials and Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
<p>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</p>			