

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIAL AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
WASHINGTON, DC 20555-0001

July 29, 2009

NRC INFORMATION NOTICE 2003-22,
SUPPLEMENT 1:

HEIGHTENED AWARENESS FOR
PATIENTS CONTAINING DETECTABLE
AMOUNTS OF RADIATION FROM
MEDICAL ADMINISTRATIONS

ADDRESSEES

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

PURPOSE

The NRC is issuing this supplement to Information Notice (IN) 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations" (December 9, 2003), to provide additional information regarding medical-use licensees' provision of instruction and information to individuals released in accordance with Title 10, Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," of the *Code of Federal Regulations* (10 CFR 35.75) and to remind addressees of the importance of various NRC requirements, guidance, and communications on this topic.

Recipients should review the information for applicability to their facilities and consider appropriate actions to ensure the adequacy of the information they provide to individuals released in accordance with 10 CFR 35.75. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required.

The NRC is providing this IN to the Agreement States for their information and for distribution to their medical-use licensees, as appropriate.

BACKGROUND

Requirements

The requirements of 10 CFR 35.75 provide in part the following:

- (a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent [TEDE] to any other individual from exposure to the released individual is not likely to exceed 5 mSv [millisievert] (0.5 rem).

ML090500018

- (b) A licensee shall 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).

Guidance

The NRC has provided guidance on licensee compliance with 10 CFR 35.75 in the form of a model procedure. The latest version of this guidance appears in NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 9, "Program-Specific Guidance About Medical Use Licenses," Revision 2, issued January 2008. Appendix U, "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials," to this NUREG provides specific guidance and sample instructions that licensees can issue to patients and human research subjects upon their release, in compliance with 10 CFR 35.75(b).

On May 12, 2008, the NRC issued Regulatory Issue Summary (RIS) 2008-11, "Precautions to Protect Children Who May Come in Contact with Patients Released after Therapeutic Administration of Iodine-131," which provides licensees with a supplement to the guidance found in NUREG-1556, Volume 9, Revision 2. Specifically, RIS 2008-11 provides licensees with additional suggested patient release instructions that licensees should give to iodine-131 therapy patients who are about to be released from licensee control and who will or may have contact with infants and young children. These recommended additional instructions, as listed in Enclosure 1 to RIS 2008-11, include the following:

- 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.

Additionally, in Enclosure 1 to RIS 2008-11, the NRC recommends that licensees consider not releasing patients who have been administered I-131 and whose living conditions may result in the contamination of infants and young children.

Generic Communications

The original IN 2003-22 indicates that licensees should consider the following voluntary actions for all patients who, after receiving diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants, emit detectable amounts of radiation at the time of release:

1. Released patients who are administered diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants should be aware that their treatment may have additional implications, because of

heightened security measures. Accordingly, provide all patients that still emit detectable amounts of radiation with an appropriate explanation about the potential of alarming radiation monitoring equipment.

2. To assist the patient and avoid unnecessary concern by law enforcement authorities and other public officials, consider providing the patient with the licensee's business card and written information for law enforcement use, stating that the radiation received by the patient poses no danger to the public and that it is allowed by NRC medical use regulations.

DESCRIPTION OF CIRCUMSTANCES

In 2006 and 2007, the NRC collaborated with the Centers for Disease Control and Prevention (CDC) in collecting information during routine unannounced inspections of NRC medical-use licensees. This information collection was designed to assess how health care facilities informed patients released in accordance with 10 CFR 35.75 about radiation and security checkpoints. The goal of the study was to examine the range of patient release procedures and practices among NRC-licensed health care facilities—*not* to evaluate the adequacy of the existing regulation or the degree of compliance. The results of the study appeared in *The Journal of Nuclear Medicine* in December 2007.¹

The sampling included facilities located in 12 states and ranging in size from 0 to 1,700 beds and performing inpatient and outpatient procedures involving both diagnosis and therapy. Thus, the information collection represented a range of practices in a variety of clinical settings. Important findings from the CDC study include the following:

1. At 5 of the 66 surveyed facilities (8 percent), contrary to the regulatory requirement in 10 CFR 35.75(b), no instruction was provided to patients when the TEDE to other individuals was likely to exceed 1 mSv (0.1 rem).² On the other hand, 74 percent of the surveyed facilities (49 of 66) exceeded the regulatory requirement and provided verbal or written instructions (or both) to patients when the TEDE to other individuals was not likely to exceed 1 mSv (0.1 rem).
2. At 34 of the 66 surveyed facilities (51 percent), communication procedures for patients being released in accordance with 10 CFR 35.75 had not changed in the past 5 years, despite the 2003 NRC Information Notice.
3. Twelve of 78 respondents (15 percent) were not familiar with IN 2003-22. Eleven of these 12 respondents were based in outpatient facilities, and most of these 12 respondents (10 of 12) were at facilities that offered only diagnostic procedures.

¹ Katz, Luba, and Ansari, Armin, "Survey of Patient Release Information on Radiation and Security Checkpoints," *Journal of Nuclear Medicine* Vol. 48, Issue 12: 14N–23N, 2007.

² These five licensees with released patient instruction deficiencies were identified by NRC inspectors during on-site inspections - follow up actions for these licensees would have been consistent with NRC inspection procedures.

4. Of the 54 respondents that were involved in the release in accordance with 10 CFR 35.75 of patients that had undergone diagnostic procedures, eleven (20 percent) indicated that it was possible for a patient to leave the facility without the knowledge that their treatments had caused them to emit detectable levels of radiation.
5. At 39 of the 66 surveyed facilities (59 percent), special instruction was provided to persons who cared for young children.

DISCUSSION

A report from the National Council on Radiation Protection and Measurements³ summarizes the work of numerous investigators who had published on the subject of patient release as follows: “The release of patients treated with therapeutic amounts of radiopharmaceuticals is not likely to expose any member of the public, inclusive of both external and internal dose contributions, >5 mSv *provided that adequate instructions are provided at discharge to the patient and the family members.*” [Emphasis added.] The caveat in this statement directly supports the NRC requirement in 10 CFR 35.75(b) for the provision by the licensee of instructions, including written instructions, on actions recommended to keep doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). This supplement to IN 2003-22 reemphasizes the importance of compliance with all of the requirements in 10 CFR 35.75.

The CDC findings suggest that many individuals involved in the administration of radiopharmaceuticals to patients are unaware of the voluntary actions that the NRC recommends in IN 2003-22 for all patients who, after receiving diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants, emit detectable amounts of radiation at the time of release. The vast majority of these individuals appear to be involved exclusively in the administration of diagnostic quantities at outpatient facilities. The CDC study also indicates that there are facilities providing therapeutic administrations that have not adopted the recommendations of IN 2003-22. The CDC study notes that informed and aware patients will tend to keep radiation doses to others ALARA. This supplement to IN 2003-22 reemphasizes the importance, for all individuals at all facilities involved in the administration of radiopharmaceuticals to patients, of being aware of and following the recommendations in the original IN 2003-22.

At the time of the CDC information collection in 2006–2007, which preceded RIS 2008-11 discussed above in the background section, 59 percent of surveyed facilities recognized the importance of providing special instruction to patients being released who cared for young children. For the other 41 percent, this supplement to IN 2003-22 reemphasizes the importance of licensees providing additional instructions in order to protect infants and young children from unnecessary exposure.

This supplement to IN 2003-22 also notes the importance of licensees assessing the nature of a patient’s anticipated living accommodations after release and tailoring the instructions to prevent

³ National Council on Radiation Protection and Measurements, Report No. 155, “Management of Radionuclide Therapy Patients,” 2006.

contamination transfer to infants and young children based on the nature of those accommodations, whether in the house or elsewhere. Under current regulations, a licensee may release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, licensees should consider the destination to which a patient may be released, consider the potential for exposure to others, and provide release instructions specific to the patient's circumstances.

CONTACT

This IN requires no specific action or written response. Please direct any questions to the technical contact listed below or the appropriate regional office.

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

Technical Contact: Ronald Zelac, FSME
(301) 415-7635
E-mail: Ronald.Zelac@nrc.gov

Enclosure: "List of Recently Issued Office of Federal and State Materials and
Environmental Management Programs (FSME) Generic
Communications"

contamination transfer to infants and young children based on the nature of those accommodations, whether in the house or elsewhere. Under current regulations, a licensee may release a patient to any destination as long as the patient meets the release criteria in 10 CFR 35.75. However, licensees should consider the destination to which a patient may be released, consider the potential for exposure to others, and provide release instructions specific to the patient's circumstances.

CONTACT

This IN requires no specific action or written response. If you have any questions about the information in this notice, please notify the technical contact listed below or the appropriate regional office.

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

Technical Contact: Ronald Zelac, FSME
(301) 415-7635
E-mail: Ronald.Zelac@nrc.gov

Enclosure: "List of Recently Issued Office of Federal and State Materials and Environmental Management Programs (FSME) Generic Communications"

ML090500018

OFFICE	MSSA/MSEA	MSSA/MSEA	Tech. Editor	MSSA/MSEA
NAME	RZelac: sxx6	CFlannery	QTE via e-mail	AMcIntosh
DATE	8/ 18 /08	11/ 14 /08	12/ 9 /08	01/ 02 /09
OFFICE	MSSA/MSEA	OGC-NLO	DMSSA	
NAME	CEinberg	BJones	RLewis	
DATE	01/ 13 /09	01/ 29 /09	07/29/09	

OFFICIAL RECORD COPY

List of Recently Issued Office of Federal and State Material and Environmental Management Programs Generic Communications			
Date	GC No.	Subject	Addressees
05/13/08	RIS-2008-10	Notice Regarding Forthcoming Federal Firearms Background Checks	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and applicants for a license or certificate of compliance who use armed security personnel as part of their physical protection system and security organization. All Radiation Control Program Directors and State Liaison Officers.
06/16/08	RIS-2008-13	Status And Plans 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
07/18/08	RIS-2008-17	Voluntary Security Enhancements for Self-Contained Irradiators Containing Cesium Chloride Sources	All U.S. Nuclear Regulatory Commission Materials Licensees Authorized to Possess Self-Contained Irradiators Containing Cesium Chloride (CsCl) ; all Agreement State Radiation Control Program Directors and State Liaison Officers; all members of the Advisory Committee on the Medical Uses of Isotopes.
10/03/08	RIS-2008-23	The Global Threat Reduction Initiative (GTRI) Domestic Threat Reduction Program & Federally Funded Voluntary Security Enhancements For High-Risk Radiological Material	All U.S. Nuclear Regulatory Commission Materials Licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials. All Agreement State Radiation Control Program Directors and State Liaison Officers. Members of the Advisory Committee on the Medical Uses of Isotopes
10/03/08	RIS-2008-24	Security Responsibilities Of Service Providers and Client Licensees	All U.S. Nuclear Regulatory Commission licensees that hire service providers to install, service, repair, maintain, relocate, exchange, or transport radioactive materials in quantities of concern, service provider licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers
12/22/08	RIS-2008-10, Suppl. 1	Notice Regarding Forthcoming Federal Firearms Background Checks	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and applicants for a license or certificate of compliance who use armed security personnel as part of their physical protection system and security organization. All 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>			