

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

February 3, 1994

NRC INFORMATION NOTICE NO. 94-09: RELEASE OF PATIENTS WITH RESIDUAL RADIOACTIVITY FROM MEDICAL TREATMENT AND CONTROL OF AREAS DUE TO PRESENCE OF PATIENTS CONTAINING RADIOACTIVITY FOLLOWING IMPLEMENTATION OF REVISED 10 CFR PART 20

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

NRC is issuing this information notice to notify addressees of the Commission's intent for release of patients pursuant to 10 CFR 35.75. It is expected that licensees will review this information for applicability to their operations and distribute it to appropriate staff. The information contained in this notice does not include new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

NRC's current patient release criteria, adopted in 1986, are contained in 10 CFR 35.75, "Release of patients containing radiopharmaceuticals or permanent implants." Specifically, this section states:

- (a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:
  - (1) The measured dose rate from the patient is less than 5 millirems (mrem) per hour at a distance of one meter; or
  - (2) The activity in the patient is less than 30 millicuries (mCi).
- (b) A licensee may not authorize the release from confinement for medical care of any patient administered a permanent implant until the measured dose rate is less than 5 millirems per hour at a distance of one meter.

In the discussion of the proposed 10 CFR 35.75 in 1985, the Commission stated that the proposed limits (30 millicuries (mCi) of activity or 6 milliroentgens per hour dose rate at 1 meter, based on the exposure rate from 30 mCi iodine-131), provided an "... adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable

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considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement." Subsequently, the 1986 Statements of Consideration for the revision to 10 CFR Part 35 discuss that the release criteria, specified in 10 CFR 35.75 (30 mCi of residual activity or 5 millirems per hour (mrem/hr) dose rate at 1 meter) are based, in part, on the considerations addressed in NCRP Report No. 37, "Precautions in the Management of Patients who Have Received Therapeutic Amounts of Radionuclides." Again, the Commission reiterated that the release limit provided an adequate measure of public health and safety.

On May 21, 1991, NRC published a final rule (56 FR 23360) that amended 10 CFR Part 20, "Standards for Protection Against Radiation." Licensees are required to implement the revised Part 20 by January 1, 1994. 10 CFR 20.1301(a) requires, in part, that a licensee conduct operations so that: 1) the total effective dose equivalent to any individual member of the public from licensed activities does not exceed 1 millisievert (mSv) (0.1 rem) in a year; and 2) the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. There has been some concern, in the medical community, that a licensee, assuming compliance with 10 CFR 35.75 and other applicable Part 35 requirements, in releasing, from confinement, a patient containing byproduct material, could be in violation of the revised Part 20, if the dose limits specified in 10 CFR 20.1301(a) are exceeded as a result of radiation emitted from a patient undergoing a medical procedure.

#### Discussion

The adoption of 10 CFR 35.75 in 1986 was based on an independent NRC public health and safety judgment specific to patient release, and was neither tied to, nor designed to implement, the more general Part 20 dose limits that were later revised in 1990. When Part 20 was revised, there was no discussion in the "Statements of Consideration" on whether or how the provisions of 10 CFR 20.1301 would apply to the release of patients. Since a general and a specific regulation of the Commission both address the same subject, the staff, in consultation with the Commission, has taken an interim position that the more specific regulation prevails in this case, pending action to formally resolve the issue in response to pending rulemaking petitions.

Therefore, licensees should continue past practices regarding radiation exposure to individual members of the public from radioactive materials administered to patients, whether inpatients or outpatients. The provisions of 10 CFR 20.1301(a) should not be applied to radiation received by a member of the general public from patients released from confinement in accordance with 10 CFR 35.75 and other applicable requirements in Part 35. Furthermore, if a patient is not required to be confined, pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms or hospital rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.



Carl J. Paperiello, Director  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material  
Safety and Safeguards

Technical contacts: Patricia K. Holahan, NMSS  
(301) 504-2694

Catherine T. Haney, NMSS  
(301) 504-2628

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

**LIST OF RECENTLY ISSUED  
NMSS INFORMATION NOTICES**

<b>Information Notice No.</b>	<b>Subject</b>	<b>Date of Issuance</b>	<b>Issued to</b>
94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20	01/28/94	All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.
93-80	Implementation of the Revised 10 CFR Part 20	10/08/93	All byproduct, source, and special nuclear material licensees.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.
93-69	Radiography Events at Operating Power Reactors	09/02/93	All holders of OLs or CPs for nuclear power reactors and all radiography licensees.
93-60	Reporting Fuel Cycle and Materials Events to the NRC Operations Center	08/04/93	All fuel cycle and materials licensees.
93-50	Extended Storage of Sealed Sources	07/08/93	All licensees authorized to possess sealed sources.
93-36	Notifications, Reports, and Records of Misadministrations	05/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-31	Training of Nurses Responsible for the Care of Patients with Brachytherapy Implants	04/13/93	All U.S. Nuclear Regulatory Commission medical licensees.

LIST OF RECENTLY ISSUED  
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-08	Potential for Surveillance Testing to Fail to Detect an Inoperable Main Steam Isolation Valve	02/01/94	All holders of OLs or CPs for nuclear power reactors.
93-26, Supp. 1	Grease Solidification Causes Molded-Case Circuit Breaker Failure to Close	01/31/94	All holders of OLs or CPs for nuclear power reactors.
94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20	01/28/94	All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.
94-06	Potential Failure of Long-Term Emergency Nitrogen Supply for the Automatic Depressurization System Valves	01/28/94	All holders of OLs or CPs for boiling water reactors.
93-85, Rev. 1	Problems with X-Relays in DB- and DHP-Type Circuit Breakers Manufactured by Westinghouse	01/20/94	All holders of OLs or CPs for nuclear power reactors.
94-05	Potential Failure of Steam Generator Tubes with Kinetically Welded Sleeves	01/19/94	All holders of OLs or CPs for pressurized water reactors (PWRs).
94-04	Digital Integrated Circuit Sockets with Intermittent Contact	01/14/94	All NRC licensees except licensed operators.
94-03	Deficiencies Identified during Service Water System Operational Performance Inspections	01/11/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License  
 CP = Construction Permit

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EKraus, TechEd  
 11/17/93

\*See attached concurrence

OFC	IMAB*		IMAB*		IMAB*		IMOB*	
NAME	PKHolahan		LWCamper		JEGlenn		FCCombs	
DATE	12/15/93		12/15/93		12/15/93		12/15/93	
OFC	OE*		OGC*		DD/IMNS*		D/IMNS*	
NAME	PSantiago		STreby		EWBrach		CJPaperiello	
DATE	12/20/93		12/17/93		12/20/93		12/20/93	

DOCUMENT NAME: 94-09.IN

The Commissioners

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**RECOMMENDATION:**

That the Commission: Note that the staff will issue the enclosed Information Notice within 10 working days of the date of this paper, unless directed otherwise by the Commission.

James M. Taylor  
Executive Director  
for Operations

**Enclosures:**

- 1. Draft Information Notice
- 2. OGC memo dtd 10/22/93

cc: OGC  
SECY

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OFC	IMAB	E	IMAB	E	IMAB	E	IMOB	E	OE
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OFC	RES	F	NO COPY ON 2/17/93 OGC			DD/IMNS		D/IMNS	
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DATE	12/18/93		12/17/93		12/20/93		12/22/93		
OFC	DD/NMSS		D/NMSS		DEDO		EDO		
NAME	Garlotto		RMBernero		HLThompson		JMTaylor		
DATE	12/ /93		12/ /93		12/ /93		12/ /93		

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