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

April 13, 1993

NRC INFORMATION NOTICE NO. 93-31: TRAINING OF NURSES RESPONSIBLE FOR THE CARE OF PATIENTS WITH BRACHYTHERAPY IMPLANTS

Addressees

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to recent events resulting in unnecessary radiation exposure, and to emphasize the need for adequate training of nurses responsible for the care of patients, particularly those treated with brachytherapy implants. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, information contained in this notice does not constitute a new requirement, and no specific action or written response is required.

Description of Circumstances

The following cases are recent events, reported to NRC, that have resulted in therapeutic misadministrations to patients, and unnecessary exposure of licensee personnel.

Case 1:

During a brachytherapy implant, radioactive seeds (a total of 25, each containing 3.5 millicuries of iridium-192) were spaced at 0.5-cm intervals and located in a ribbon that was inserted through the patient's nose into an endobronchial catheter positioned in the patient's bronchi. The Ir-192 ribbon became dislodged from the catheter during the night (11 p.m. to 7 a.m.) shift. A nurse observed the ribbon outside the patient's nose at 2 a.m. The nurse did not realize that the seeds were within the ribbon. She handled the ribbon with her bare hands and taped it to the patient's face, which contributed to the consequence of the misadministration and resulted in unnecessary radiation exposure of approximately 17.8 rem to the nurse's hands. Before the nurse taped the ribbon, it dangled in front of the patient's face and, for an unidentified interval, the patient repositioned the ribbon in her hair. The patient received an estimated dose of 1032 rad to the left side of the face. A root cause of this misadministration was a failure of the licensee to instruct the nurse concerning radiation safety precautions associated with the care of the patient who had received the brachytherapy implant. The nurse had attended training sessions on such implants, but had

not been provided specific instructions nor assigned primary responsibility for care of an endobronchial implant patient.

Case 2:

During a brachytherapy implant procedure, two ribbons, each containing six Ir-192 seeds, with a total activity of 48.25 mCi, were implanted into two catheters inserted into the patient's common bile duct, through an abdominal incision. During the night (11 p.m. to 7 a.m.) shift, the patient's dressings on the wound were wet and loose. A licensed practical nurse (LPN), who responded to the patient, found the Ir-192 ribbons dislodged and lying loose on the patient's abdomen. The LPN, not realizing that the Ir-192 seeds were in the ribbon, changed the patient's dressing and bed, and coiled each Ir-192 ribbon around her hand and taped them to the patient's abdomen. The oncologist had left verbal orders with the day shift charge nurse "not to change the dressing" but these orders were not passed on to the LPN. The patient's abdominal skin received an unnecessary exposure over various areas ranging from 172 rad to 1032 rad. The skin exposure to the hand of the LPN was 7.6 rad. One root cause of the misadministration was failure of the licensee to provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. The LPN had not received sufficient instruction to be able to recognize the brachytherapy seeds and handle them appropriately if, and when, they became dislodged.

Discussion

Both of these misadministrations, and the related unnecessary exposure, were directly attributable to insufficient training of nursing staff responsible for the care of patients with brachytherapy implants. There are general and specific requirements, described in 10 CFR that address training of licensee employees, including nurses involved with treating patients undergoing brachytherapy procedures.

10 CFR 19.12 requires, in part, that individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed. This training would include aspects of radiation biology, radiation physics, risk estimates, and ways of maintaining doses As Low As is Reasonably Achievable (ALARA). Regulatory Guide 8.29 describes the instruction that should be provided to the worker, concerning biological risks from occupational radiation exposure. This instruction includes both high dose effects (e.g., deterministic or non-stochastic effects) and low dose effects (e.g., carcinogenesis, teratogenesis, and genetic effects) of radiation. The intent of providing this information, including a comparison of radiation risk to other types of health risks, is that workers will develop an understanding of the risks involved and appropriate responses rather than excessive fear or lack of concern.

10 CFR 35.410(a) requires, in part, that the licensee provide radiation safety instruction to all personnel caring for patients undergoing implant therapy. This instruction must include the size and appearance of the brachytherapy

sources; procedures for patient and visitor control; and safe handling and shielding instructions in case of a dislodged source. The description of the brachytherapy source would include the appearance of the source during the implant (e.g., the difference between an isolated radioactive seed and a seed inserted into a ribbon for treatment). The instruction should include the various types of implants used by the licensee. In the event of a dislodged source, the source must be shielded so that neither the patient nor any other persons receive unnecessary exposure. Appropriate training should include practice drills to demonstrate handling of dummy (nonradioactive) sources and appropriate use of safety equipment (e.g., tongs and shielded containers). 10 CFR 35.410(a)(5) requires that the radiation safety instruction must include procedures for notification of the Radiation Safety Officer (RSO) if the patient dies or has a medical emergency. It is not the intent of this regulation that this notification be made before, or in lieu of, notification of the patient's physician, to allow the medical emergency to be handled. Exhibit 20 of Regulatory Guide 10.8, Revision 2, provides a sample form for nursing instructions for patients treated with temporary implant sources, which includes individuals to contact in the event of an emergency.

10 CFR 35.25(a)(1) requires that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program (QMP). Furthermore, 10 CFR 35.25(a)(2) requires that a licensee shall require the supervised individual, in part, to follow the instructions of the supervising authorized user, and follow the written radiation safety and quality management procedures. It is essential that nursing personnel are provided adequate radiation safety training, as frequently they are attending the patient in the absence of the authorized user or the RSO. One of the specific objectives of the QMP is to ensure that each administration is in accordance with the written directive. Therefore, any nurse attending brachytherapy patients must be instructed in the licensee's QMP and be familiar with the written directive. If an authorized user has any specific instructions regarding care of the patient that pertain to radiation safety, the licensee has the responsibility to ensure that the supervised individual receives and follows these instructions. The instruction should also include the necessary procedures to follow in the event of either a medical emergency or radiological emergency.

Licensees are reminded that 10 CFR 35.21(a) requires that an RSO be appointed to be responsible for implementing the radiation safety program. Furthermore, the licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. This includes, as specified in 10 CFR 35.21(b)(2)(x), that the RSO shall, in part, implement written policy and procedures for training personnel who work in or frequent areas where byproduct material is used or stored.

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

Richard E. Cunningham

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Patricia K. Holahan, Ph.D., NMSS
(301) 504-2694

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

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-30	NRC Requirements for Evaluation of Wipe Test Results; Calibration of Count Rate Survey Instruments	04/12/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-19	Slab Hopper Bulging	03/17/93	All nuclear fuel cycle licensees.
93-18	Portable Moisture-Density Gauge User Responsibilities during Field Operations	03/10/93	All U.S. Nuclear Regulatory Commission licensees that possess moisture-density gauges.
93-14	Clarification of 10 CFR 40.22, Small Quantities of Source Material	02/18/93	All Licensees who possess source material.
93-10	Dose Calibrator Quality Control	02/02/93	All Nuclear Regulatory Commission medical licensees.
93-07	Classification of Transportation Emergencies	02/01/93	All Licensees required to have an emergency plan.
93-05	Locking of Radiography Exposure Devices	01/14/93	All Nuclear Regulatory Commission industrial radiography licensees.
93-04	Investigation and Reporting of Misadministrations by the Radiation Safety Officer	01/07/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-03	Recent Revision to 10 CFR Part 20 and Change of Implementation Date to January 1, 1994	01/05/93	All byproduct, source, and special nuclear material licensees.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
93-30	NRC Requirements for Evaluation of Wipe Test Results; Calibration of Count Rate Survey Instruments	04/12/93	All U.S. Nuclear Regulatory Commission medical licensees.
93-29	Problems with the Use of Unshielded Test Leads in Reactor Protection System Circuitry	04/12/93	All holders of OLs or CPs for nuclear power reactors.
93-28	Failure to Consider Loss of DC Bus in the Emergency Core Cooling System Evaluation May Lead to Nonconservative Analysis	04/09/93	All holders of OLs or CPs for nuclear power reactors.
93-27	Level Instrumentation Inaccuracies Observed during Normal Plant Depressurization	04/08/93	All holders of OLs or CPs for nuclear power reactors.
93-26	Grease Solidification Causes Molded Case Circuit Breaker Failure to Close	04/07/93	All holders of OLs or CPs for nuclear power reactors.
93-25	Electrical Penetration Assembly Degradation	04/01/93	All holders of OLs or CPs for nuclear power reactors.
93-24	Distribution of Revision 7 of NUREG-1021, "Operator Licensing Examiner Standards"	03/31/93	All holders of operator and senior operator licenses at nuclear power reactors.
93-23	Weschler Instruments Model 252 Switchboard Meters	03/31/93	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

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

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: Patricia K. Holahan, Ph.D., NMSS
(301) 504-2694

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

*See previous concurrence.

OFC	IMAB*		IMAB*		IMAB*		IMOB*	
NAME	PKHolahan		LWCamper		JEGlenn		FCombs	
DATE	03/08/93		03/08/93		03/09/93		03/11/93	

OFC	OGC*		D/IMNS*		TechEd*			
NAME	STreby		RECunningham		EKraus			
DATE	03/* /93		03/05/93		03/01/93			

OFFICIAL RECORD COPY/93-31.IN