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

October 13, 1994

NRC INFORMATION NOTICE 94-74: FACILITY MANAGEMENT RESPONSIBILITIES FOR PURCHASED OR CONTRACTED SERVICES FOR RADIATION THERAPY PROGRAMS

Addressees

All U.S. Nuclear Regulatory Commission Medical Licensees.

Purpose

This information notice is provided to remind licensees of their responsibilities regarding management of radiation therapy programs (involving byproduct material) for which all or part of the services is purchased or contracted. It is expected that licensee management will review this information for applicability to their programs, and consider this information, in the future, when planning to purchase or contract services. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific actions nor written response is required.

Description of Circumstances

The following incidents are examples of licensees who contracted for radiation therapy services, and failed to maintain management oversight of the contracted program.

Incident 1. An NRC licensee (community hospital) contracted with a large teaching institution to provide brachytherapy services at the licensee's facility. The contractual services provided all oversight of the program including the radiation safety and medical physics support, the dosimetrist, and the physician authorized user, who also performed brachytherapy at the teaching institution. The managers of the licensee's facility delegated management of the brachytherapy program to the contractor. Additionally, the licensee's Radiation Safety Officer had little knowledge or contact with the brachytherapy program.

On June 21, 1994, a patient was scheduled to receive a transperineal prostate iodine-125 seed implant. The written directive, sent to the facility by the contractor via facsimile, prescribed 112 iodine-125 seeds, with an activity of 16 - 17 MBq (0.43 - 0.46 mCi) per seed. The order for the seeds was placed by the licensee's chief nuclear medicine technologist. However, there was an apparent miscommunication between the licensee and the supplier regarding the seed activity. The packing slip shipped with the order listed the actual activity of the seeds as 166 MBq (4.49 mCi) per seed. When the order was

received at the licensee's facility, the seeds were logged in by a nuclear medicine technologist using the actual activity as recorded on the packing slip. The order was not checked against the written directive prepared by the authorized user. Subsequently, the (contracted) dosimetrist removed the seeds from storage for the implant, but did not verify that the activity of the seeds was as specified in the written directive.

After the seeds were implanted, the (contracted) dosimetrist discovered that the activity of the implanted seeds was actually 166 MBq (4.49 mCi) per seed, or approximately 10 times the intended activity. The initial planned peripheral tumor dose (PTD) was 16,000 cGy (16,000 rad). The factor of 10 error in seed strength implied that the PTD, if the seeds were left in place, would have been 160,000 cGy (160,000 rad) to decay.

Within 5 hours of the implant, the patient underwent a radical prostatectomy which resulted in the removal of 69 of the 112 seeds. During this surgery, one of the seeds was inadvertently cut, resulting in a dose to the patient's thyroid. The patient was later transferred to the contractor's facility. A second surgery, 6 days following the initial implant, recovered 15 additional seeds. A total of 28 seeds were left in place (scattered throughout the perineum, perirectal area and left sacrum) with a total activity of 4651 MBq (125.7 mCi).

The licensee did not have a quality management program (QMP) that addressed brachytherapy. The contractor's facility had implemented a QMP that required, among other things, that the activity of the seeds be assayed prior to implantation. The licensee did not adopt the contractor's program nor ensure that the contractor followed the same QMP procedure described in the QMP implemented at the contractor's facility.

Incident 2. Two NRC Licensees jointly finance a non-NRC licensed cancer treatment center. Both licensees utilize a computerized treatment planning system, located at the cancer center. Sometime between July and September 1992, the linear source data files, in the computer planning system, apparently were deleted and an incorrect data file was created. Both licensees failed to adequately validate data used in the computer planning system. Consequently, the radiation dose administered to 11 patients was calculated to be in excess of the dose prescribed by the authorized users, by 5 to 30 percent.

Both licensees had written QMPs at their facilities. Because the treatment planning was done at the cancer center, neither licensee had directly addressed treatment planning as part of their QMP. The cancer center was not an NRC licensee, and was not required to establish a QMP. The licensee's managers assumed that the authorized users had responsibility for oversight of all aspects of the patients' treatments and that the licensees need only be aware of those aspects of the treatment actually conducted at the licensee's facility.

Discussion

Licensees may contract for patient services for which they do not have in-house expertise. In those instances where the contracted service is regulated by the NRC, the licensee should be aware that the licensee remains responsible for regulatory compliance and implementation of the radiation safety program and QMP. The licensee should not assume that by hiring a contractor to perform certain tasks that it has fully satisfied all regulatory requirements or that it has somehow transferred responsibility for the licensed program to a contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the licensee's QMP is effectively implemented by the appropriate individuals, to provide high confidence that byproduct material is administered as directed by the authorized user.

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

Carl J. Paperiello

Carl J. Paperiello, Director
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Medical Nuclear Safety
Office of Nuclear Material Safety
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Technical contacts: Sally L. Merchant, NMSS
(301) 415-7874

Patricia K. Holahan
(301) 415-7847

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

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ATTACHMENTS filed in JACKET.

OFC	IMAB		IMAB		IMAB		TECH ED	
NAME	SLMerchant		LWCamper		JEGlenn		EKraus	
DATE	09/01/94		09/01/94		09/02/94		09/01/94	

OFC	IMOB		OGC		DD/IMNS		D/IMNS	
NAME	FCombs		STreby		WBrach		CPaperiello	
DATE	09/06/94		09/20/94		09/ /94 10/7/94		09/27/94	

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LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-73	Clarification of Criticality Reporting Criteria	10/12/94	All fuel fabrication facilities.
94-70	Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals	09/29/94	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-65	Potential Errors in Manual Brachytherapy Dose Calculations Generated Using a Computerized Treatment Planning System	09/12/94	Al U.S. Nuclear Regulatory Commission medical licensees.
94-64	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	08/31/94	All holders of OLs or CPs for nuclear power reactors and all fuel fabrication licensees.
94-47	Accuracy of Information Provided to NRC during the Licensing Process	06/21/94	All U.S. Nuclear Regulatory Commission Material Licensees.
94-39	Identified Problems in Gamma Stereotactic Radiosurgery	05/31/94	All U.S. Nuclear Regulatory Commission Teletherapy Medical Licensees.
94-38	Results of a Special NRC Inspection at Dresden Nuclear Power Station Unit 1 Following a Rupture of Service Water Inside Containment	05/27/94	All holders of OLs or CPs for NPRs and all fuel cycle and materials licensees authorized to possess spent fuel.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-73	Clarification of Criticality Reporting Criteria	10/12/94	All fuel fabrication facilities.
94-72	Increased Control Rod Drop Time from Crud Buildup	10/05/94	All holders of OLs or CPs for pressurized water reactors.
94-71	Degradation of Scram Solenoid Pilot Valve Pressure and Exhaust Diaphragms	10/04/94	All holders of OLs or CPs for boiling water reactors (BWRs).
94-70	Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals	09/29/94	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-69	Potential Inadequacies in the Prediction of Torque Requirements for and Torque Output of Motor-Operated Butterfly Valves	09/28/94	All holders of OLs or CPs for nuclear power reactors.
94-68	Safety-Related Equipment Failures Caused by Faulted Indicating Lamps	09/27/94	All holders of OLs or CPs for nuclear power reactors.
94-67	Problem with Henry Pratt Motor-Operated Butterfly Valves	09/26/94	All holders of OLs or CPs for nuclear power reactors.
94-66	Overspeed of Turbine-Driven Pumps Caused by Governor Valve Stem Binding	09/19/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit