UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

September 19, 1995

NRC INFORMATION NOTICE 95-39: BRACHYTHERAPY INCIDENTS INVOLVING TREATMENT PLANNING ERRORS

Addressees

All U.S. Nuclear Regulatory Commission Medical Licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to brachytherapy incidents involving treatment planning errors. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

NRC has become aware of the following brachytherapy incidents related to treatment planning errors:

1) On November 21, 1994, an NRC licensee discovered that an error had occurred during the programming of a high-dose-rate (HDR) Gamma Med II-i brachytherapy device on November 18, 1994. While programming treatment data into the HDR unit, the technologist failed to press the AUTOMATIC TIME FACTOR button. After entering the dwell positions and the total treatment time, the technologist attempted to start the treatment by pressing the START and SOURCE IN IRRAD. POS. buttons. The HDR unit displayed an error message on the screen indicating the need for MANUAL TIME FACTOR. The technologist interpreted this to mean that the computer had not received the total treatment time data and reentered the data. The total treatment time data were inadvertently used as the MANUAL TIME FACTOR, resulting in the administration of approximately twice the intended radiation dose. The failure of the technologist to press the AUTOMATIC TIME FACTOR button, during initial entry of the treatment data, was exacerbated by an apparent defect, in the GAMUHR card, that permitted the technologist to manually enter and accept the inappropriate decay factor during the programming process. The device contained a nominal 370-giga becquerel (GBq) (10-curie (Ci)) iridium-192 sealed source. As a result, the patient received a dose of 12 Gray (Gy) (1200 rad) to the vaginal cavity instead of the prescribed dose of 6 Gy (600 rad).

2) On September 23, 1994, a licensee informed Region III that a patient undergoing a uterine brachytherapy implant received a 31 percent

underdose. On September 13, 1994, the patient was implanted with two cesium-137 (Cs-137) brachytherapy sources, in an ovoid applicator, to deliver 65 Gy (6500 rad) to the uterine lining, in approximately 48 hours. During review of the completed treatment, the licensee's medical physicist determined that the wrong tissue volume was used during the treatment planning process, resulting in a smaller volume being treated than the administering physician intended. Although the physician reviewed and approved the treatment plan before administration, it was not apparent that a smaller tissue volume was represented in the plan. The licensee believes that the dosimetrist who prepared the treatment plan used incorrect spatial coordinates to define the treatment volume and failed to verify the dose calculations. The licensee determined that the treatment of the smaller volume resulted in the delivery of 45 Gy (4500 rad) to the intended treatment volume, which was a 31 percent underdose. To compensate for the 20 Gy (2000 rad) underdose, the administering physician modified a previously intended boost dose, using external beam therapy (via a linear accelerator).

3) An Agreement State licensee reported an event in which an incorrect dose conversion factor was used for planning a treatment. One patient was treated with three Cs-137 seeds during a gynecological implant procedure during the period of May 4-8, 1994. The patient received approximately 91.3 Gy (9130 rad) to the treatment area, which was about 283 percent greater than prescribed. Further investigation revealed that the error involved six additional patients, with the patients receiving doses from 37 percent to 144 percent in excess of their intended doses. The calculation error was caused when the physicist entered the wrong gamma constant when editing the treatment planning program. The physicist was attempting to convert from "milligram radium equivalent" to "millicurie" and entered 3.256 "radium" instead of "millicurie," resulting in an error ratio that was 2.5 times greater than expected.

4) On April 8, 1994, an NRC licensee reported an incident involving a data entry error in the treatment planning process. The written directive specified two fractions of 6 Gy (600 rad) per fraction for a total dose of 12 Gy (1200 rad). Before the first treatment, a radiation therapist correctly entered the treatment parameters into the GammaMed II-i HDR. A second radiation therapist and the radiation physicist verified that this entry of data was correct. The GammaMed II-i HDR device used the European date format (day-month-year) for this parameter. At the time of the treatment, the radiation therapist recalled the correct treatment parameters from the computer memory, but inadvertently entered the treatment date in the incorrect format (i.e., 4.06.94 instead of 6.04.94). Because the HDR computer automatically adjusts for source decay, the exposure time was modified by a factor of 3.17 (for June 4) instead of the required modifying factor of 1.83 (for April 6). This resulted in an administered fractional dose of 10.39 Gy (1039 rad) instead of the intended prescribed 6 Gy (600 rad). However, the total prescribed dose of 12 Gy (1200 rad) was not exceeded because the error was detected before the second treatment was administered.

5) On October 11, 1993, an NRC licensee reported a therapeutic misadministration, discovered during a routine review of records, that occurred on April 23, 1993, during a brachytherapy procedure involving a high-dose-rate (HDR) remote afterloader. According to the medical physicist, a patient was scheduled to receive vaginal brachytherapy treatment using a Nucletron HDR unit with a 157.14 GBq (4.247 Ci) iridium-192 source. The prescribed dose for the fraction was 5 Gy (500 rad). During the planning of the second of the three treatments, an error was made in the input of the offset distance. Instead of 992 millimeter (mm), a distance of 920 mm was entered. The source was programmed to travel 45 mm outward from the offset distance in nine increments of 5 mm each. The medical physicist indicated that the treatment progressed as was planned. However, because of the erroneous input for the offset distance, a portion of the dose was administered to the wrong site.

6) On August 18, 1993, a therapeutic misadministration occurred at a licensee's facility when a patient who was scheduled to receive a 6 Gy (600 rad) dose of radiation to his esophagus actually received a 10 Gy (1000 rad) dose. The licensee identified the error during a routine physics check conducted that same day. The licensee indicated that a treatment plan was developed to deliver the 6 Gy (600 rad) dose and that this plan was reviewed by the physicist and physician and found to be correct. However, before administering the dose, the physicist reaccessed the HDR treatment planning system to modify a noncritical factor. The physicist reported having a problem maneuvering between the various menus in the treatment planning system, which involved pressing the "Esc" key several times. This caused the treatment planning program to change the value of the treatment dose to 10 Gy (1000 rad). According to the licensee, the modified plan was put into the HDR control computer without an additional in-depth review and the treatment was delivered.

Discussion

The incidents listed above demonstrate the importance of following plans and procedures to meet the objective stated in 10 CFR 35.32(a)(3) that final treatment plans and related calculations are in accordance with the written directive. Attention to details in treatment planning and independent verification of treatment plans may be involved in meeting this objective. If independent verification of treatment plans is so relied upon, it should include verification of the data used to calculate the initial treatment plan, as well as the calculations. It is important to note that recalculation of the treatment plan from the same data set used to prepare the initial treatment may not catch errors introduced by initially inputting incorrect treatment parameters.

This information notice requires no specific action nor 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.

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contact: James A. Smith, NMSS
(301) 415-7904

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
95-29	Oversight of Design and and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors
95-25	Valve Failure during Patient Treatment with Gamma Stereotactic Radiosurgery Unit	05/11/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
94-64, Supp. 1	Reactivity Insertion Transient and Accident Limits for High Burnup Fuel	04/06/95	All holders of OLs or CPs for Nuclear Power Reactors and all fuel fabrication licensees.
95-07	Radiopharmaceutical Vial Breakage during Preparation	01/27/95	All U.S. Nuclear Regulatory Commission medical licensees authorized to use byproduct material for diagnostic procedures.
95-01	DOT Safety Advisory: High Pressure Aluminum Seamless and Aluminum Composite Hoop-Wrapped Cylinders	01/04/95	All U.S. Nuclear Regulatory Commission licensees.
94-89	Equipment Failures at Irradiator Facilities	12/28/94	All U.S. Nuclear Regulatory Commission irradiator licensees.
89-25, Rev. 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/07/94	All fuel cycle and material licensees.

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-38	Degradation of Boraflex Neutron Absorber in Spent Fuel Storage Racks	09/08/95	All holders of OLs or CPs for nuclear power reactors.
95-37	Inadequate Offsite Power System Voltages during Design-Basis Events	09/07/95	All holders of OLs or CPs for nuclear power reactors.
95-36	Potential Problems with Post-Fire Emergency Lighting	08/29/95	All holders of OLs or CPs for nuclear power reactors.
95-35	Degraded Ability of Steam Generators to Remove Decay Heat by Natural Circulation	08/28/95	All holders of OLs or CPs for pressurized water reactors (PWRs).
95-34	Air Actuator and Supply Air Regulator Problems in Copes-Vulcan Pressurizer Power-Operated Relief Valves	08/25/95	All holders of OLs or CPs for nuclear power reactors.
93-83, Supp. 1	Potential Loss of Spent Fuel Pool Cooling After a Loss-of-Coolant Accident or a Loss of Offsite Power	08/24/95	All holders of OLs or CPs for nuclear power reactors.
95-33	Switchgear Fire and Partial Loss of Offsite Power at Waterford Generating Station, Unit 3	08/23/95	All holders of OLs or CPs for nuclear power reactors.
95-10, Supp. 2	Potential for Loss of Automatic Engineered Safety Features Actuation	08/11/95	All holders of OLs or CPs for nuclear power reactors.
95-32	Thermo-Lag 330-1 Flame Spread Test Results	08/10/95	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

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DOC NAME: 95-39.IN

*See previous concurrence.
Closes IMAB-1800 IMAB 1161,and IMAB 747

OFC	IMAB	E	IMAB	E	IMAB	E	Tech Ed	
NAME	JASmith*		JMPiccone*		LWCamper*		EKraus*	
DATE	09/06 /95		08/18/95		08/21/95		07/26/95	

OFC	IMOB		OGC		DD/IMNS		D/IMNS	
NAME	FCCombs*		STreby*		FCCombs*		DACool*	
DATE	08/22/95		09/06/95		09/11 /95		09 /11 /95	

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DATE	9/6/95		08/18/95		08/21/95		07/26/95	

OFC	IMOB		OGC		DD/IMNS		D/IMNS	
NAME	FCCombs		STreby		FCCombs		DACool	
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OFC	IMAB	E	IMAB	E	IMAB	E	Tech Ed	
NAME	JASmith		JMPiccone		AJCamper		EKraus	
DATE	7/26/95		8/8/95		8/21/95		07/26/95	

OFC	IMOB		OGC		DD/IMNS		D/IMNS	
NAME	FCCombs		STreby		EWBrach		DACool	
DATE	8/ /95		9/6/95		/ /		/ /	

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