

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

May 31, 1994

NRC INFORMATION NOTICE 94-39: IDENTIFIED PROBLEMS IN GAMMA STEREOTACTIC
RADIOSURGERY

Addressees

All U.S. Nuclear Regulatory Commission Teletherapy Medical Licensees.

Purpose

NRC is issuing this information notice to alert addressees to problems identified in gamma stereotactic radiosurgery. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific actions nor written response are required.

Description of Circumstances

NRC has become aware of the following incidents and areas of concern in gamma stereotactic radiosurgery:

- 1) An incident involving the failure of the treatment timer to activate after collimator alignment;
- 2) Symmetrical primary beams of radiation exiting the stereotactic unit when the shielding door was opened in the treatment mode;
- 3) An incident involving inadvertently inverting film of the treatment site for input into the treatment planning system and the subsequent overriding of the detection of the error by the treatment planning system; and
- 4) A published study revealing the frequency of generating and detecting human error in setting stereotactic coordinates for radiosurgery.*

Incident 1. A licensee started patient treatment and noticed that the timer activation light and the timer did not come on when the patient was positioned

* Flickinger, J.C., Lunsford, L.D., and Kondziolka, D., "Potential Human Error in Setting Stereotactic Coordinates for Radiosurgery: Implications for Quality Assurance," Int. J. Radiat. Oncol. Biol. Phys. 27(2); 397-41;1993. Reprint requests to: John C. Flickinger, M.D., Joint Radiation Oncology Center, 230 Lothrop St., Pittsburgh, PA 15213.

9405240145

6/6/94
updated

PDR I&E Notice

94-039

DF01 940531
11

in the treatment radiation field. The licensee reported that it used backup timing by stopwatch to complete the exposure, when the patient couch did not eject as expected. After completion of the treatment, the patient was removed without incident. The equipment was inspected and a switch that should have triggered the two timers and an indication of "Treatment Underway" was found to be loose. After the switch was secured and adjusted, the unit operated properly. The licensee concluded that this type of malfunction might occur at any time when there is a gross misalignment of microswitches, broken wire, or other disconnect between the switch and the timer mechanism.

Incident 2. In March 1992, an Agreement State notified NRC that a hospital physicist detected two symmetrical beams of radiation exiting the stereotactic radiosurgery unit when the shielding door was open in the treatment mode. The same problem was identified at two other facilities. The Agreement State required the manufacturer of the unit to evaluate the problem and take corrective action. The manufacturer subsequently informed the Agreement State that two channels had allowed radiation to exit the unit unshielded. As a corrective action, the manufacturer designed and completed a retrofit of all existing units with a wall extension, to shield the two channels, by October 1992.

Incident 3. An arteriovenous malformation on the left side of the brain was being treated. An x-ray film was inverted before input into the treatment planning system. The treatment planning system initially rejected the image, recognizing it only as an older orientation system. Eventually, the neurosurgeon and physicist overrode the program and instructed the program to accept the reversed image. They then proceeded to generate treatment plans for two separate targets. After completing the first of two 8-minute shots for the first treatment plan and initiating the second, the physicist noticed that the X coordinates of the target points for the second treatment plan indicated a right-sided target, not left-sided as had been desired. He immediately terminated the second shot, with approximately 5½ minutes remaining. After dose reconstruction, it was determined that the Y and Z coordinates were correct; however, the X offset resulted in a target miss of 16 mm.

Journal Article. The journal article describes the determination of the error rate in setting 396 isocenter treatments for 101 patients. Of the first 200, the spontaneous errors in setting the stereotactic coordinates ≥ 0.25 mm were determined to be 12 percent. The errors were attributed to visual limitation, transposition of coordinates, and wrong isocenter set-up. The second part of the study determined the detection efficiency of observers in detecting 25 intentionally introduced errors in isocenter coordinate settings. The error detection efficiency of observers was 60.0 percent for 0.25 mm, 95.0 percent for 0.50 mm, 94.4 percent for 1 to 20 mm, and 83.5 percent for all errors.

Discussion

The treatment-timer failure (Incident 1, above) highlights the importance of proper maintenance and housekeeping of the stereotactic treatment unit, and having a backup timing system to verify treatment time. If a check of the system had been performed before the treatment, the loose switch might have been detected and the incident avoided. If the treatment facility had not had

an auxiliary treatment timing system, the stopwatch, there might have been difficulty in determining that the prescribed dose had been delivered. However, according to the manufacturer, in the described condition, the stereotactic treatment unit is equipped with a safety circuit that terminates the treatment within approximately 2 minutes after the "Treatment Start" button is pushed, and had the physicians not decided to interrupt the treatment, the couch would have been ejected and the treatment interrupted automatically, within a few seconds, thus limiting the total dose.

The radiation leakage (Incident 2, above) is of concern because if a staff member had needed to attend to a patient during treatment, he/she might have been exposed to this unshielded primary beam of radiation. The potential existed for exceeding occupational dose limits. Acceptance testing of teletherapy units and gamma stereotactic radiosurgery units should always include health physics surveys, to ensure the safety of staff members during routine and non-routine uses. In this instance, the shielding retrofit by the manufacturer should eliminate this particular area of concern.

The use of the inverted image (Incident 3, above) demonstrates to the importance of understanding the software package used in treatment planning, and not bypassing warning signals without understanding or addressing the warning or its cause. Uninformed use of treatment planning software, without independent verification (e.g., hand calculation, double check by a second individual, etc.), may lead to serious consequences. Fortunately, in this case, the licensee reported that the dose was delivered to areas of the brain "... with extremely high tolerance for deficit, and that the dose delivered was well below the dose-volume threshold for inducing any neurological damage"; however, this may not be the case for future incidents of this nature.

The journal article (Item 4, above) points out the importance of verification of coordinate setting by a person other than the one setting the coordinates. According to the study, an individual will set the coordinates incorrectly 12 percent of the time. If the coordinates are checked by an observer, the errors will be detected on average 83.5 percent of the time, reducing the number of undetected errors to approximately 2 percent.

Licensees are reminded that 10 C.F.R. §35.32 requires, in part, the establishment of a written Quality Management Program (QMP), to meet five specific objectives for gamma stereotactic radiosurgery:

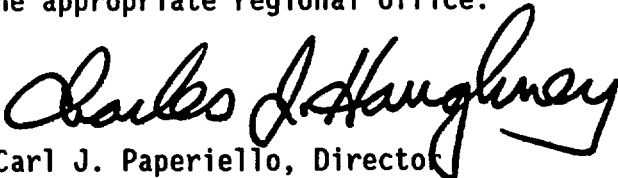
- 1) Prior to administration, a written directive** is prepared;
- 2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

** For gamma stereotactic radiosurgery, a written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the target coordinates, collimator size, plug pattern, and total dose. 10 C.F.R. §35.2(3).

- 3) That final plans of treatment and related calculations are in accordance with the respective written directives;
- 4) That each administration is in accordance with the written directive; and
- 5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Licensees should review their QMP to ensure that policies and procedures are adequate to provide, as required by 10 C.F.R. §35.32(a), high confidence that the radiation from the byproduct material will be 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.

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

Technical contact: James 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
94-37	Misadministration Caused by a Bent Interstitial Needle during Brachytherapy Procedure	05/27/94	All U.S. Nuclear Regulatory Commission Medical Licensees authorized to use brachytherapy sources in high-, medium-, and pulsed-dose-rate remote afterloaders.
94-35	NIOSH Respirator User Notices, "Inadvertent Separation of the Mask-Mounted Regulator (MMR) from the Facepiece on the Mine Safety Appliances (MSA) Company MMR Self-Contained Breathing Apparatus (SCBA) and Status Update"	05/16/94	All holders of OLs or CPs for nuclear power reactors, and all licensed fuel facilities.
94-23	Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of A Waste Minimization Program	03/25/94	All NRC licensees.
94-21	Regulatory Requirements when No Operations are being Performed	03/18/94	All fuel cycle and materials licensees.
94-17	Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use	03/11/94	All U.S. Nuclear Regulatory Commission Medical Use Licensees.
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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.
94-37	Misadministration Caused by a Bent Interstitial Needle during Brachytherapy Procedure	05/27/94	All U.S. Nuclear Regulatory Commission Medical Licensees authorized to use brachytherapy sources in high-, medium-, and pulsed-dose-rate remote afterloaders.
94-36	Undetected Accumulation of Gas in Reactor Coolant System	05/24/94	All holders of OLs or CPs for nuclear power reactors.
91-81, Supp. 1	Switchyard Problems that Contribute to Loss of Offsite Power	05/19/94	All holders of OLs or CPs for nuclear power reactors.
94-35	NIOSH Respirator User Notices, "Inadvertent Separation of the Mask-Mounted Regulator (MMR) from the Facepiece on the Mine Safety Appliances (MSA) Company MMR Self-Contained Breathing Apparatus (SCBA) and Status Update"	05/16/94	All holders of OLs or CPs for nuclear power reactors, and all licensed fuel facilities.
94-34	Thermo-Lag 330-660 Flexi-Blanket Ampacity Derating Concerns	05/13/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
 CP = Construction Permit

- 3) That final plans of treatment and related calculations are in accordance with the respective written directives;
- 4) That each administration is in accordance with the written directive; and
- 5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Licensees should review their QMP to ensure that policies and procedures are adequate to provide, as required by 10 C.F.R. §35.32(a), high confidence that the radiation from the byproduct material will be 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, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

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

Attachments:

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

Closes IMAB-1650 ★ See previous concurrence

OFC	IMAB		IMAB	C	IMAB	E	Tech Ed		IMOB	
NAME	JASmith★		LWCamper★		JEGlenn★		Ekraus★		FCCombs★	
DATE	03/18/94		03/18/94		03/31/94		04/06/94		04/06/94	
OFC	OGC		DD/IMNS		D/IMNS					
NAME	STreby★		WBrach★		CPaperiello★					
DATE	05/12/94		05/19/94		05/20/94					

DOC NAME: 94-39.IN

Official Record Copy

NMSS HEADQUARTERS DAILY REPORT FORM

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

May 31, 1994

INFORMATION NOTICE NO. 94-39, "Identified Problems In Gamma Stereotactic Radiosurgery"

was issued on May 31, 1994.
(date)

The technical contact is James A. Smith, Jr., NMSS, ext. 415-7904

Summary: The NRC has identified the following areas of concern in gamma stereotactic radiosurgery: a published study of the frequency of generating and detecting human error in setting stereotactic coordinates for radiosurgery; symmetrical primary beams of radiation exiting the stereotactic unit when the shielding door was opened in the treatment mode; an incident inadvertent inverting of film of the treatment site for input into the treatment planning system and the subsequent overriding of the detection of the error by the treatment planning system; and an incident involving the failure of the treatment timer to activate after collimator alignment.

- 3) That final plans of treatment and related calculations are in accordance with the respective written directives;
- 4) That each administration is in accordance with the written directive; and
- 5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Licensees should review their QMP to ensure that policies and procedures are adequate to provide, as required by 10 C.F.R. §35.32(a), high confidence that the radiation from the byproduct material will be 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, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

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

Attachments:

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

Closes IMAB-1650 * See previous concurrence

OFC	IMAB	C	IMAB	C	IMAB	E	Tech Ed		IMOB	
NAME	JASmith		LWCamper*		JEGlenn*		Ekraust*		FCCombs*	
DATE	3/18/94		03/18/94		03/31/94		04/06/94		04/06/94	
OFC	OGC		DD/IMNS		D/IMNS					
NAME	STreby		WBrach		CPaperiello					
DATE	5/17/94		5/19/94		1/1					

C = COVER

E = COVER & ENCLOSURE

N = NO COPY

Official Record Copy G:\IMAB1650