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

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.

[Signature]

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

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

Attachments:
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2. List of Recently Issued NRC Information Notices
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OL = Operating License
CP = Construction Permit
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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

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Closes IMAB-1650 * See previous concurrence
Information Notice No. 94-39, "Identified Problems in Gamma Stereotactic Radiosurgery"

was issued on May 31, 1994.

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.
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