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

December 18, 2000

NRC INFORMATION NOTICE 2000- 22: MEDICAL MISADMINISTRATIONS CAUSED BY HUMAN ERRORS INVOLVING GAMMA STEREOTACTIC RADIOSURGERY (GAMMA KNIFE)

Addressees:

All medical licensees authorized to conduct gamma stereotactic radiosurgery treatments.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to remind addressees of the importance of following written directives and treatment planning procedures, and the need to pay attention to detail during preparation and administration of gamma stereotactic radiosurgery. 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 IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

NRC has become aware of 16 medical misadministrations, involving gamma stereotactic radiosurgery, that have occurred during the past few years. Fifteen of these 16 misadministrations were attributed to human error, especially while entering data into a computer treatment program and during the verification of patient coordinate settings. The descriptions of the 15 misadministrations are summarized in Attachment 1.

Discussion:

The most common reported human error is the transposition of coordinate settings, mainly the Y and Z coordinates. Other human errors are the selection of incorrect parameters such as treatment sites, doses, and exposure times, and failure to follow established procedures.

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Licensees have adopted the following corrective actions to prevent recurrence of misadministrations:

1. A licensee requires two independent checks of the X, Y and Z coordinate settings before each exposure, instead of one independent check, to reduce the transposition of coordinates. In a "single check," the coordinates are called out and person A sets the coordinates, then Person B checks them against the written treatment plan. In a "double check," person A sets the coordinates, then Persons B and C independently check them against the written treatment plan.

2. Another licensee requires a minimum of three staff members to set the X, Y, and Z coordinates on the stereotactic frame to reduce the probability of transposition errors. Treatment is administered only after the three staff members concur on the coordinate settings.

3. A licensee limits the conversations in the treatment room to only those required for the treatment of the patient, and restricts telephone calls in the treatment control area. These actions reduce distractions to members of the treatment team.

4. A licensee requires the neurosurgeon, the radiation oncologist, and the medical physicist to verify the treatment plan before each procedure. The neurosurgeon and either the radiation physicist or the radiation oncologist has to be physically present during the treatment. This oversight improves procedure adherence and attention to detail.

5. A licensee requires marking each page of the patient treatment plan with a unique name and time stamp that the radiation oncologist or medical physicist has to initial before delivery of the radiosurgery treatment. This prevents the transposition of a patient treatment sheet from one medical file to another among patients receiving the same type of treatment on the same day.

The medical physicist participation in the entire treatment-planning process is important, especially during the pretreatment review of the treatment plan. Neurosurgeon and radiation oncologist collaboration at critical points in the process, such as dose selection, approval of the written plan, and initiation of the treatment, is also essential. Licensees are reminded that 10 CFR 35.32(a)(1) requires that written directives be prepared before administration of gamma sterotactic radiosurgery. Subsections 35.32(a)(3) and (4) require that final treatment plans and related calculations, and each administration, are in accord with the respective written directives. It is important that written directives and procedures are kept up to date and provide adequate information. It is also important that management place a high value on staff following all procedures and directives; that all staff are adequately trained; and that training programs are effective in relaying necessary information. In all the cases listed in Attachment 1, written directives and procedures were in place. However, a lack of attention to detail, failure to adhere to the procedures and directives, or a failure to perform adequate, independent verification of treatment plans, patient identities, and treatment doses, contributed to misadministrations.

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.

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

Technical Contact: Roberto J. Torres, NMSS
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Attachments:
1. Description of event circumstances
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

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DESCRIPTION OF EVENT CIRCUMSTANCES

1. A patient being treated for brain lesions was undergoing the fourth of five planned treatments, when a treatment site received an unintended repeat dose because of inattention to detail. The treatment site was supposed to receive 1200 centiGray (cGy) (rad), but instead received 2400 cGy (rad).

2. A patient being treated for pituitary adenoma received a dose of 1260 cGy (rad) to an unintended site of his frontal lobe. The unintended site was approximately 4.2 centimeters (cm) (1.65 inches) away from the intended site. The treatment planning for the patient was uneventful. A nurse and the medical physicist checked the adjustments on the device stereotactic frame for accuracy. Nonetheless, when staff members started to set up the patient for a second administration, they realized the Y and Z coordinates on the stereotactic frame were transposed on the previous treatment.

3. A gamma knife unit was set up incorrectly and delivered a dose to the wrong site on a patient's brain. A radiosurgery treatment was to be delivered to Patient A's left trigeminal nerve. On that same date, Patient B was also scheduled to receive the same treatment as Patient A. During the signature phase of treatment plan approval, Patient B's dose delivery treatment sheet was inadvertently transposed with that of Patient A. Therefore, Patient A was treated with the radiosurgery parameters that were intended for Patient B. This resulted in a dose of 8000 cGy (rad) delivered to the wrong treatment site. The actual dose received by the intended treatment site was 20 cGy (rad).

4. A patient being treated for an arteriovenous malformation, in the left part of his brain, received treatment to the right side of his brain. During the treatment planning process, the computer software refused several times to accept the "correct" orientation (as viewed by the planning team) of the patient's image. Eventually, the neurosurgeon and the medical physicist instructed the computer system to accept the image they believed to be correct. After initiating the treatment, the physicist noticed that the X coordinates indicated a definite right-side target and stopped the treatment. The physicist and the neurosurgeon were unaware that a different angiography room had been used to acquire the patient's X-ray images during the quality assurance (QA) runs. QA tests had been performed in what the physicist believed to be the only angiographic suite. This room was equipped in such a way that the lateral X-ray tube could only be on the patient's right side, with the patient in a supine position. The actual angiographs were performed in another room where the tube focus was on the patient's left side.

5. A patient received a dose of 3000 cGy (rad) to the intended site of his brain, instead of the prescribed dose of 2300 cGy (rad). This event was caused because the licensee did not follow the treatment plan and used an incorrect collimator helmet.

6. A patient received a dose 54.5 percent below the intended dose. The prescribed dose was 2200 cGy (rad) and the patient received a dose of 1000 cGy (rad). The treatment physician failed to enter the prescribed dose into the treatment planning system. This resulted in the system's default value (1000 cGy) (rad) being used for the treatment. The error was missed by all three team members involved in the treatment planning.

7. A patient received a total treatment dose that differed from the prescribed dose by more than 10 percent. As the third treatment site was being prepared for treatment administration, the licensee discovered that the patient's position would have to be changed from supine to prone, to physically achieve the appropriate coordinates. When replanning the third area of treatment, the neurosurgeon and the medical physicist realized the Y and Z coordinates were transposed during the previous treatment.

8. A patient was prescribed a treatment of 9000 cGy (rad) to the left trigeminal nerve of his brain. However, the treatment was actually administered to the right trigeminal nerve. The medical physicist had inadvertedly prepared a treatment plan for the wrong side of the patient's head and the radiation oncologist (authorized user) signed the treatment plan without properly verifying the neurosurgeon's request identifying the correct site.

9. A patient received treatment to an unintended area of his brain. The treatment plan called for three doses of radiation. The first treatment was set up and delivered to the patient. When the coordinates for the second treatment were set, it was discovered that the Y and Z coordinates had been transposed on the first treatment. The prescribed dose for the first treatment was 1100 cGy (rad), but 50 cGy (rad) were administered. The licensee indicated that possible contributing factors to this event were: a) the reduction to two staff members, instead of the usual three, for setting up the patient; and b) the Z coordinate was set before attaching the Z bar to the stereotactic frame.

10. A patient received a dose of 2600 cGy (rad) to the first of three lesions, instead of the prescribed dose of 1600 cGy (rad). During preparation of the treatment plan for the second lesion, the settings for the first treatment site were unintentionally used. This resulted in two treatments to the first lesion. The error was not identified, even though the neurosurgeon and the radiation oncologist reviewed and signed the treatment plan.

11. A patient being treated for brain cancer received a therapeutic underdose of 12.3 percent. The licensee selected the wrong-year date in the treatment planning system, which resulted in the administration of 1052 cGy (rad) instead of the prescribed dose of 1200 cGy (rad). The licensee failed to recognize a computer warning that the entered treatment date differed from the system date.

12. A patient received treatment to an unintended area of his brain, resulting in a dose of 500 cGy (rad) being delivered 1 to 5 cm (0.4 to 2 inches) from the intended location. An error in treatment geometry occurred because licensee staff members transposed the Y and Z coordinates.

13. A patient received treatment to an unintended area of his brain in excess of 1000 cGy (rad). The treatment plan that was developed indicated a single exposure of 1600 cGy (rad) to a brain lesion. One of the seven parameter settings of the gamma knife, the "left Y" coordinate, was erroneously set, resulting in a 5-millimeter (0.2 inch) translocation of the treatment volume. This event was caused by one member of the treatment team setting an initial erroneous coordinate setting, and by another member of the treatment team failing to independently verify the coordinate setting.

14. A patient received a therapeutic overdose to the intended part of his brain. The dose was 11 percent greater than the prescribed dose. The authorized user failed to enter the correct exposure time in the treatment-planning software system, and the exposure time from the previous treatment fraction was used.

15. A patient received treatment to an unintended area of his brain, resulting in a dose of 460 cGy (rad) being delivered 11-millimeter (0.43 inches) from the intended location. The radiosurgery treatment prescribed three administrations of 1200 cGy (rad) each to a tumor volume. When the licensee started setting up the coordinates for the second administration, it was discovered that the Y and Z coordinates had been transposed on the first administration. The event was caused because the licensee had not checked the coordinates of the patient’s head frame against those required by the written treatment plan prior to the first treatment administration.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2000-19	Implementation of Human Use Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials	12/05/2000	All medical use licensees
2000-18	Substandard Material Supplied by Chicago Bullet Proof Systems	11/29/2000	All 10 CFR Part 50 licensees and applicants All category 1 fuel facilities All 10 CFR Part 72 licensees and applicants
2000-16	Potential Hazards Due to Volatilization of Radionuclides	10/5/2000	All licensees that process unsealed byproduct material
2000-15	Recent Events Resulting in Whole Body Exposures Exceeding Regulatory Limits	9/29/2000	All radiography licensees
2000-12	Potential Degradation of Firefighter Primary Protective Garments	9/21/2000	All holders of licenses for nuclear power, research, and test reactors and fuel cycle facilities
2000-11	Licensee Responsibility for Quality Assurance Oversight of Contractor Activities Regarding Fabrication and Use of Spent Fuel Storage Cask Systems	8/7/2000	All U.S. NRC 10 CFR Part 50 and Part 72 licensees, and Part 72 Certificate of Compliance holders
2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits	7/18/2000	All material licensees who prepare or use unsealed radioactive materials, radio-pharmaceuticals, or sealed sources for medical use or for research and development
2000-07	National Institute for Occupational Safety and Health Respirator User Notice: Special Precautions for Using Certain Self-Contained Breathing Apparatus Air Cylinders	4/10/2000	All holders of operating licenses for nuclear power reactors, non-power reactors, and all fuel cycle and material licensees required to have an NRC approved emergency plan

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NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2000-21	Detached Check Valve Disc Not Detected by Use of Acoustic and Magnetic Nonintrusive Test Techniques	12/15/2000	All holders of OL for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor
2000-20	Potential Loss of Redundant Safety Related Equipment Due to Lack of a High-Energy Line Break Barrier	12/11/2000	All holders of operating licenses or construction permits for nuclear power reactors
2000-19	Implementation of Human Use Research Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials	12/05/2000	All medical use licensees
2000-18	Substandard Material Supplied by Chicago Bullet Proof Systems	11/29/2000	All 10 CFR Part 50 licensees and applicants. All category 1 fuel facilities. All 10 CFR Part 72 licensees and applicants
2000-17 S1	Crack In Weld Area of Reactor Coolant System Hot Leg Piping At V.C. Summer	11/16/2000	All holders of OL for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-17	Crack In Weld Area of Reactor Coolant System Hot Leg Piping At V.C. Summer	10/18/2000	All holders of OL for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel
2000-16	Potential Hazards Due to Volatilization of Radionuclides	10/5/2000	All NRC licensees that process unsealed byproduct material

OL = Operating License
CP = Construction Permit