

OHIO INFORMATION NOTICE 2006-03

APPLICABILITY OF PATIENT INTERVENTION IN DETERMINING MEDICAL EVENTS FOR GAMMA STEREOTACTIC RADIOSURGERY AND OTHER THERAPY PROCEDURES

TO: All affected Ohio Radioactive Material Licensees.

NRC INFORMATION NOTICE 2006-11: APPLICABILITY OF PATIENT INTERVENTION IN DETERMINING MEDICAL EVENTS FOR GAMMA STEREOTACTIC RADIOSURGERY AND OTHER THERAPY PROCEDURES

ADDRESSEES

All medical Gamma Knife licensees.

PURPOSE

The Ohio Department of Health, Bureau of Radiation Protection (BRP) is issuing this information notice (IN) to inform addressees of a BRP concern that has arisen, regarding licensees assessing the contribution of patient activities to errors, in medical administrations, when determining whether the events constitute reportable medical events under OAC rule 3701:1-58-101 (NRC 35.3045), "Report and notification of a medical event." It is expected that recipients will review this information for general applicability to all their licensed medical use operations and consider actions, as appropriate, to avoid similar problems. The information contained in this IN does not constitute new BRP requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

Event 1

During a routine inspection of an NRC medical use licensee, NRC inspectors discovered records of a medical administration involving the licensee's gamma stereotactic radiosurgery (Gamma Knife®) unit that should have been reported as a medical event under §35.3045. Specifically, following a Gamma Knife treatment, the licensee noted that the z-axis (up and down) coordinate of the head frame had been displaced 7 centimeters (cm) (2.8 inches) during the course of treatment. The x- and y-coordinates, however, had remained unchanged. The licensee believed the misalignment occurred when the patient moved "vigorously" more than half way through the procedure.

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The misalignment of the z-axis coordinate of the head frame resulted in an estimated absorbed dose of 35 Gray (Gy) (3500 rads) [or 35 Sievert (Sv) (3500 rem) dose equivalent] to an unintended site--a dose that was greater than 50 percent of the dose expected to that unintended site from the administration defined in the written directive.

The patient had complained of discomfort and back pain and had asked attending staff if he could move his legs to a more comfortable position. Permission was granted to move "a little," but the licensee noted that the patient moved "vigorously." This occurred approximately 30 minutes into a 51-minute treatment. Although the patient moved "vigorously," treatment continued until completion of the procedure. The licensee stated that there had been no observable reorientation of the patient in the Gamma Knife after the movement and that no permanent functional damage to the patient had occurred from the dose delivered to the wrong site, after the movement of the z-axis coordinate. The latter conclusion was based on the licensee's analysis of subsequent magnetic resonance images.

The licensee inspected the head frame and stated that there was no observable damage to the z-bar, which controls the positioning of the z-axis coordinate. As a corrective action, the licensee replaced the z-bars for that particular head frame. Although the z-bars were removed from service, the licensee did not return them to the manufacturer for component failure evaluation. Other corrective actions taken or planned included: (1) upgrading to the Model C head frame with Automatic Positioning System; (2) instructing patients not to move; and (3) increasing monitoring of patients during treatments that last 30 minutes or longer.

The licensee believed that the 7-cm (2.8-inch) change in the z-axis coordinate was caused by the patient's "vigorous" movement. Accordingly, the licensee believed that the patient's movement qualified as "patient intervention." Since the licensee also determined that the dose delivered to the wrong site had not resulted in permanent functional damage, the licensee concluded that the criteria for reporting an event, in §35.3045(b), had not been met, so the event was not reported to NRC. NRC, however, concluded that this occurrence should have been reported under §35.3045.

Event 2

During a routine inspection of another NRC medical use licensee, NRC inspectors discovered records of a medical administration, involving the licensee's Gamma Knife unit, that also should have been reported as a medical event, under §35.3045. Specifically, after an 11-exposure Gamma Knife treatment, the licensee noted that the left anterior pin attaching the head frame to the patient's head had been displaced laterally, resulting in a shifting of the isocenter an estimated 6 millimeters (mm) (0.24 inches) during the course of the treatment. The licensee initially believed that the movement of the head frame occurred when the patient coughed at the start of the 11th exposure. The movement of the head frame resulted in a licensee initially estimated additional absorbed dose of approximately 5 Gy (500 rads), or an additional dose equivalent of approximately 5 Sv (500 rem), to an unintended site.

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This movement resulted in a licensee initially estimated total absorbed dose of approximately 7.6 Gy (760 rads), or a dose equivalent of approximately 7.6 Sv (760 rem), to an unintended site, which was greater than 50 percent above the approximately 2.6 Gray (260 rads) absorbed dose [or 2.6 Sv (260 rem) dose

equivalent] expected to that unintended site from the administration defined in the written directive.

In a standard Gamma Knife procedure, the head frame is secured to the patient's head using four sharp pins screwed in place and tightened sufficiently to embed the point of the pin into the table of the patient's skull. During patient preparation, the neurosurgical team performed physical tests and measurements to determine if there would be collisions between either the patient's head or frame and the collimator helmet. In this specific case, there would have been a collision with the right anterior pin, and the licensee made a decision to remove this pin and proceed with the Gamma Knife procedure, using only three pins (three-pin technique). The licensee indicated that after the other three pins were tightened, the right anterior pin was removed.

The procedure then continued without event until the final 11th exposure, when the patient coughed, initially reported as occurring at the beginning of the exposure. It was not until after the treatment was completed and the patient was removed from the unit that the staff noted the patient was bleeding because the left anterior pin had moved from its original position.

The licensee determined the shift of the head frame from the movement of the pin from its original position on the skull. From this observation, the licensee estimated the isocenter shifted laterally by 6 mm (0.24 inches) and reviewed earlier magnetic resonance images to approximate the location of the new isocenter and the wrong treatment site. Based on this analysis, the licensee believed the location of the isocenter for the misdirected final exposure was inside the auditory canal.

As corrective action, the licensee initially prohibited use of the three-pin technique for Gamma Knife treatments. No other corrective actions were initially taken or planned. In later discussion with NRC staff, the licensee indicated it was reevaluating its prohibition of the three-pin technique.

The licensee believed that the movement of the left anterior pin was caused by the patient's cough, and that the patient's coughing movement constituted "patient intervention." The licensee's staff concluded that there was "...no harm" to the patient, since the patient received almost the complete dose to the treatment site, and the wrong treatment site for the one exposure was in the auditory canal, which did not result in permanent functional damage. The licensee therefore believed that the criteria for reporting an event, in §35.3045(b), had not been met, so the event was not reported to NRC. NRC, however, concluded that this occurrence should have been reported, under §35.3045.

DISCUSSION

In each of the two events discussed, the licensee asserted that the patient's movement constituted "patient intervention."

Each licensee also decided that each event was not reportable, because §35.3045(b) only requires reporting of an event resulting from intervention of a patient "...in

which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or physiological system, as determined by a physician," and this condition did not occur. However, NRC concluded that neither licensee provided sufficient evidence to exclude equipment setup as the cause of its medical event, rather than patient movement. Therefore, NRC concluded that these occurrences should have been reported to NRC as medical events, under §35.3045(a)(3). This, in part, requires that the licensee report any event (except for an event that results from patient intervention) in which the administration of byproduct material, or radiation from byproduct material, results in a dose to the skin, or to an organ or tissue other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more, and 50 percent or more, of the dose to the skin, or organ or tissue other than the treatment site, that was expected from the administration defined in the written directive. See Enclosure 1 for discussion of these two Gamma Knife events.

For each of these events, the licensee's corrective actions are silent about stopping treatments when a patient moves, in order to ensure that the movement did not result in patient position changes that could result in a medical event. In fact, the licensee for Event 1, through one of its corrective measures, implies that it is unnecessary for it to increase patient monitoring during treatments that last less than 30 minutes.

As a measure for prevention of patient movement during Gamma Knife treatment, a licensee could respond to a patient's expression of discomfort by: (1) halting the treatment; (2) assisting the patient in moving to become comfortable; (3) checking the head frame for correct positioning; and (4) then resuming the treatment. We also believe that, as a potentially corrective measure, regardless of the treatment time, a licensee authorized for Gamma Knife treatments, or other high dose-rate treatments, should monitor the patient and stop the treatment when a patient moves, in order to ensure that the movement did not result in a patient position change that could result in a medical event.

The licensees believed that both of these Gamma Knife events resulted from patient intervention. However, NRC views these as resulting primarily from patient equipment setup. Similarly, incorrect decisions as to causes of events when patient actions are involved have also been made by medical use licensees employing other treatment modalities, such as temporary implant brachytherapy. Medical use licensees employing any treatment modality in which patient actions may potentially interfere with licensees properly implementing physicians' intentions, as expressed in prescribed doses or dosages, should be aware that patient movement or other involvement in an occurrence or event alone is not sufficient to rule out the need to report the occurrence as a medical event. NRC's position is that a medical event has occurred, even when the occurrence had patient movement or other involvement, if the licensee has not followed appropriate preventative and corrective procedures for usage, and if the criteria specified in §35.3045(a) or (b) are met.

Medical use licensees should review this IN and consider whether their procedures for use are in accordance with the following recommended actions:

- Monitor patient and/or source placement at reasonable frequencies;
- Correctly identify patient and/or source displacement during monitoring;
- Take prompt and appropriate actions should patient and/or source displacement occur;
- Have trained personnel present or available to prevent or mitigate patient actions during usage procedures that may impact treatment;
- Promptly report all medical events to NRC; and
- Promptly report all equipment malfunctions or problems to the vendors and, if required, To BRP (under OAC rule 3701:1-38-23 or OAC rule 3701:1-40-20(B)(2)) and the device licensing authorities (NRC or Agreement States).

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CONTACT

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact Mark Light, Medical Licensing and Inspection Supervisor at 614-644-2727.

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Enclosure 1

Discussion of Gamma Stereotactic Surgery Events 1 and 2

In Event 1, the licensee believed that the change in z-bar position was caused by two factors: (1) the large stature of the patient (mass); and (2) the "vigorous" movement of the patient's legs and torso (force-of-movement). However, historical evidence from the device manufacturer has shown that z-bar movement has only been observed when the associated screws were not properly tightened, or there was a lubricant on the z-bar. Although the patient movement in this case may have contributed to the medical event, the purpose of the head frame design and function is to keep the head from moving in spite of patient movement. The head frame essentially immobilizes the patient's head, limiting the patient's degree of upper body movement. For movement of a properly secured z-bar to occur, the patient would have to exert an extreme force on the head frame. Since the pins that secure the head frame to the patient's head are screwed directly into the patient's skull, the extreme amount of force that must be exerted to move the z-bar would be expected to also cause one or more of the pins to move. There was no indication that these pins moved during the "vigorous" movement.

Also, 7 cm (2.8 inches) of z-bar slippage at one time would be expected to result in an observable reorientation of the patient, which should have prompted the licensee to stop the treatment and recheck the coordinates before continuing treatment. As stated earlier, the treatment was not interrupted, and the licensee claimed that there was no observable reorientation of the patient after the "vigorous" movement. The licensee's not noting observable patient reorientation, after the "vigorous" movement, is inconsistent with the licensee's belief that the patient's "vigorous" movement caused the 7-cm (2.8-inch) change in the z-axis coordinate.

This administration of radiation resulted in an unintended dose of 35 Sv (3500 rem), in an area of the brain that was 7 cm (2.8 inches) away from the intended treatment site, and the patient was expected to receive negligible dose in this area, which is distant from the treatment site. Therefore, NRC staff has concluded that the licensee should have reported this event, under §35.3045(a)(3).

At NRC's request, the licensee subsequently returned the z-bars to the manufacturer for testing. The manufacturer determined that the z-bars failed (slipped) at 50 percent of their designed locking force specification. After dismantling and thoroughly cleaning the z-bars, lubricating the locking screw and nut, and then reassembling the component, the z-bars functioned at 100 percent of their design specification. The manufacturer concluded that the slippage was caused by the reduced locking force of the z-bars, which was corrected by the manufacturer's dismantling, cleaning, and lubricating process. The licensee indicated that it "cleaned" the z-bars before sending them to the manufacturer. But the licensee's routine cleaning, which involves soaking the intact components, is not as rigorous as the "cleaning" performed by the manufacturer. The manufacturer revised its cleaning and lubricating instructions, but those instructions do not include the dismantling and rigorous cleaning performed by the manufacturer.

In Event 2, the licensee believed that the patient's cough caused the movement of the left anterior pin. NRC, confirms that the three-pin technique the licensee used does not provide the same level of immobility as the four-pin procedure. An article from the 2002 Journal of Neurosurgery that the licensee provided to the manufacturer of the Gamma Knife offers a number of different size screws and posts to permit repositioning of the patient's head within the head frame, if it appears a collision will occur. The manufacturer has also designed a front piece, specifically for a three-pin technique, that more evenly spaces the attachment pins and distributes the forces on the pins around the skull. Furthermore, historical evidence from the manufacturer has shown that the attachment pins will move when the screws are not properly tightened into the table of the skull. Movement of improperly tightened screws is also more likely to happen in certain screw positions (e.g., when the screws are not positioned almost perpendicularly to the tangential skull plane). Additionally, a loose screw may not be apparent until the patient has gone through a number of preparation steps, such as pre-treatment imaging or other movements that put dynamic stresses on the pin-skull interface. The movement is usually detected by the presence of blood, caused as the sharp pin moves from its initial location. The licensee's failure to retighten the three remaining screws may have contributed to the pin slippage; the angle of the screws and positioning of the head frame medially, to accommodate the patient's head size, may have also contributed to the slippage.

The licensee in this medical use occurrence did not provide sufficient evidence to justify the claim of "patient intervention." Specifically, the licensee did not provide sufficient evidence to exclude improper tightening of the left anterior pin once the right anterior pin was removed or to demonstrate that the three-pin technique used would provide the same immobilization provided by either use of the fourth pin or equipment designed by the manufacturer specifically for a three-pin head frame attachment. As noted previously, §35.3045 (a)(3) requires a licensee to report any event (except for an event that results from patient intervention) where the administration of byproduct material, or radiation from byproduct material, results in a dose to the skin, or an organ or tissue other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more, and 50 percent or more, the dose to the skin, or organ or tissue other than the treatment site, that was expected from the administration defined in the written directive. Based on the licensee's initial assessment, this administration resulted in an unintended dose of 7.6 Sv (760 rem) in an area of the brain that was 6 mm (0.24 inches) away from the intended treatment site and was expected to receive approximately 2.6 Sv (260 rem). Therefore, at the time of the licensee's initial assessment, the licensee should have reported this event under §35.3045(a)(3).

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Subsequent to NRC's determination that the administration was a reportable medical event, the licensee provided additional information that corrected errors in earlier

information, concerning the location of the unintended site and the dose to that site. The new information more accurately set the time of the head frame slippage to halfway through the 11th exposure. This reduced the estimated dose to the unintended site to 2.5 Sv (250 rem). The licensee also corrected the location of the unintended site to the 30 percent isodose line, and not the 10 percent isodose line, as previously reported. The result of these corrections is that the event is no longer considered a reportable medical event, under §35.3045(a)(3), because the additional dose to the unintended site was 32 percent of the dose to that site (7.8 Sv, or 780 rem) expected from the administration defined in the written directive, which is less than the 50 percent threshold for reporting a medical event under this criterion. However, the event is included in the IN because the additional information the licensee subsequently provided did not change NRC's conclusion that the event was not the result of patient intervention.