UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

February 23, 2010

EA-09-289
NMED 45184

Mr. Sean Nicholson, Chief Financial Officer
Gamma Knife Center of the Pacific
2226 Liliha St, B1 Level
Honolulu, Hawaii 96817

SUBJECT: NRC SPECIAL INSPECTION REPORT 030-34629/09-002 AND NOTICE OF VIOLATION

Dear Mr. Nicholson:

This refers to the special inspection initiated on July 30, 2009, in response to a stereotactic radiosurgery medical event that occurred at the Gamma Knife Center of the Pacific (Gamma Knife Center) on July 2, 2009, and that was reported to the NRC on July 3, 2009. The inspection was chartered in response to an unintended radiation overexposure of cobalt-60 to a patient under going brain cancer treatment at the Gamma Knife Center because of the use of an incorrect collimator. The overexposure resulted in tissue outside the prescribed treatment site receiving a dose approximately six times the dose expected from the administration defined in the written directive. However, we understand from discussions with your medical staff that no adverse health effects have been observed in the patient since the event occurred. Preliminary inspection findings were discussed with members of your staff at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and your radiation safety officer on January 12, 2010. The enclosed inspection report (Enclosure 2) documents the NRC's review of this event.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observation of activities and interviews with personnel. The inspection included a review of an NRC-contracted medical consultant's evaluation of the event. The medical consultant is experienced in radiation oncology. The medical consultant's review of this event is documented in Section 7 of the enclosed report.

The focus of the inspection was to address the elements of the inspection charter dated July 21, 2009 (ADAMS Accession No. ML092020608). Enclosure 3 provides a copy of the inspection charter. The inspection was a focused review of the circumstances surrounding the medical event that occurred at your facility on July 2, 2009, and a review of aspects of the Gamma Knife Center's radiation therapy department and its procedures, with in-office review through January 12, 2010.

In a telephone conversation on January 12, 2010, Messrs. Anthony Gaines, Senior Health Physicist, and Larry Donovan, Health Physicist, of my staff informed you that the NRC was considering escalated enforcement for an apparent violation of NRC requirements. The apparent violation involved the failure to have written procedural requirements to demonstrate a high confidence to verify that an administration requiring a written directive was in accordance with the treatment plan and the written directive. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you at the final inspection exit briefing. Additionally, you have initiated corrective actions, which are documented in your letter dated July 15, 2009, your facsimile received on December 09, 2009, and the enclosed inspection report, to address the violation. On the basis of our review, this medical event appears to be an isolated occurrence. Further, we provided you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a pre-decisional enforcement conference. Mr. Gaines informed you that the NRC had sufficient information regarding the apparent violation and your corrective actions to make an enforcement decision without the need for a pre-decisional enforcement conference or a written response from you. You agreed that a pre-decisional enforcement conference or written response was not needed.

Based on the information developed during the inspection, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding it are described in detail in the subject inspection report. As noted above, the violation involved the failure to have written procedural requirements to demonstrate a high confidence to verify that an administration was in accordance with the treatment plan and the written directive.

The NRC considers this violation significant because the failure to have adequate procedures to verify that the medical use of a stereotactic radiosurgery unit is in accordance with the treatment plan and written directive could result in clinically significant adverse health effects to a patient. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The NRC Enforcement Policy may be found on the NRC's web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the NRC Enforcement Policy, a base civil penalty of $3,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for corrective action in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Based on your prompt and comprehensive corrective actions, the NRC has determined that corrective action credit is warranted. Your corrective

actions included sending a letter to all radiation oncologists and neurosurgeons that perform gamma knife treatments. The letter informed them of the incident and stressed their responsibility for verifying the set coordinates and collimator size before each treatment is delivered. Procedures as specified in your Quality Management Program were changed to prevent recurrence. Specifically, the Quality Management Program was modified to require a double verification of all settings as stated in the treatment plan. Two treatment team members, who would be independent of the initial set-up team, will perform the verification and document it on the treatment record. The radiation oncologist will initial next to the collimator size on the treatment plan before each treatment to verify that the correct collimator is being used.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case.

However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in your letter dated July 15, 2009 (ADAMS Accession ML091980412), facsimile received on December 09, 2009 (ADAMS Accession ML100210537), and supplemented in NRC Inspection Report 030-34639/03-002. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's Rules of Practice, a copy of this letter, enclosures, and your response, if you decide to submit one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal

privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Should you have any questions concerning this letter, please contact Ms. Vivian Campbell at (817) 860-8287.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket: 030-34629
License: 53-11966-02

Enclosures:
1. Notice of Violation
2. NRC Special Inspection
   Report 030-34629/09-002
   With Attachment
3. Special Inspection Charter

cc w/enclosure:
Russell Takata, Branch Manager
Department of Health,
Indoor Air and Radiological Health Branch
591 Ala Moana Blvd., Rm 133
Honolulu, HI 96813

bcc w/enclosures (via E-Mail Distribution):
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Hard copy:
RIV Materials Docket File (5th Floor)

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final: R:_DNMS

ADAMS	☐ No	X Yes	X SUNSI Review Complete	Reviewer Initials: LD
X Publicly Available	☐Non-publicly Available		☐Sensitive	X Non-sensitive
Category – **KEYWORD**:				

RIV:DNMS:NMSB-A	C:NMSB-A	C:NMSB-B	ACES	RC
LDonovan	VHCampbell	JEWhitten	MCMaier	KFuller
/RA/	***/ADG for VHC/***	***/RTC for JEW/***	***/MCM/***	***/RA/***
11/17/09	01/15/10	12/07/09	01/21/10	01/19/10

DD:DNMS	DRA	FSME	OE	RA
ATHowell	CACasto	MBurgess	NHilton	EECollins
/RA/	***/RA/***	***By e-mail to OE***	***SWoods for N Hilton***	***/RA/***
02/03/10	02/05/2010	02/18/2010	02/19/2010	2/23/2010

OFFICIAL RECORD COPY T=Telephone E=E-mail F=Fax

NOTICE OF VIOLATION

Gamma Knife Center of the Pacific
Honolulu, Hawaii

Docket: 030-34629
License: 53-11966-02
EA: 09-289

During an NRC reactive inspection conducted during the period of July 30, 2009, through January 12, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, licensees shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).
>
> 10 CFR 35.41(b)(2) states, in part, that at a minimum, the procedures required by paragraph (a) must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.
>
> Contrary to the above, as of July 2, 2009, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that, the procedures did not require explicit verification that the administration was in accordance with the treatment plan and the written directive. Accordingly, the treatment plan and written directive were not followed to ensure that the proper collimator was used in the treatment of a patient.

This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in your letter dated July 15, 2009, facsimile received on December 9, 2009, and supplemented in NRC inspection report 030-34639/09-002. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201, if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-09-289," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's Web site at www.nrc.gov/reading-rm/pdr.html or www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice of Violation within two working days.

Dated this 23rd day of February 2010.

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-34629
License:	53-11966-02
Report.:	030-34629/09-002
Licensee:	Gamma Knife Center of the Pacific
Location:	Honolulu, Hawaii
Dates:	July 30, 2009 – January 12, 2010
Inspector:	Lawrence Donovan, Health Physicist, M.S. LMP Nuclear Materials Safety Branch-A
Approved By:	Vivian H. Campbell, Chief Nuclear Materials Safety Branch-A
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Gamma Knife Center of the Pacific, Honolulu Hawaii
NRC Inspection Report 030-34629/09-002

This was a reactive, announced inspection of licensed activities involving a medical event that occurred on July 2, 2009. The licensee reported the event to NRC in accordance with the requirements in 10 CFR 35.3045 (a)(3). The medical event involved the use of cobalt-60 sources used in a gamma stereotactic radiosurgery system (gamma knife) that resulted in a radiation dose to an unintended site. The treatment plan called for a dose of 24 Gray (2400 rads) at the 90 percent isodose line using cobalt-60 sealed sources contained in a gamma knife. Because of the use of the wrong sized collimator, an 18 millimeter (mm) versus 8 mm, in two of the seven discrete treatment sites, the patient received a higher dose of 24.7 Gray (2407 rads), representing a dose 3 percent higher than the prescribed dose of 24 Gray to the treatment site. The increase in collimator size resulted in an additional 2.35 cubic centimeters (cc) of tissue volume receiving the prescribed dose outside the intended treatment site. If the 8 mm collimator had been used, then this tissue would have received approximately 4.3 Gray. The inspection involved a review of the medical event focusing on the direct, contributing, and root cause(s) of the medical event, and the licensee's stereotactic radiosurgery program. It also included a review to determine whether similar past events have occurred that had not been reported to NRC.

The charter for this special inspection included a review of the chronology of events; an assessment of the licensee's investigation, reporting, and corrective actions; an evaluation of the report provided by NRC's medical consultant; and an assessment of the level of compliance with the license and other NRC requirements with respect to the protocols followed for gamma knife treatments. The inspector reviewed licensee records, evaluation reports, and the medical consultant's report, as well as conducted interviews with licensee personnel at the licensee's facility.

Direct Cause

The use of a collimator helmet not prescribed in the written directive and treatment plan directly led to the radiation overexposure to unintended tissue in the patient. (Section 4.2)

Contributing Causes

Human error contributed to the failure to use the prescribed collimator helmet. Inattention to detail resulted in not installing the correct collimator helmet and not verifying that the correct helmet was installed. (Section 4.2)

Root Cause

The licensee's failure to ensure all gamma knife treatment parameters were set, as specified in the treatment plan and written directive, led to the failure to verify properly that the correct collimator was installed prior to patient administration. Explicit instructions to ensure each individual parameter was checked prior to treatment were not specified in the licensee's quality management program or written procedures. This failure was identified as the root cause of the medical event. (Section 4.2)

Notifications and Reports

The licensee fulfilled the regulatory requirements pertaining to patient, referring physician, and NRC notifications. (Section 5.2)

Corrective Actions

The licensee instituted corrective actions that appear adequate to prevent similar types of medical events from occurring. Specifically, the quality management program was revised explicitly to require that the proper treatment parameters be followed, including verifying that the collimator is in place as required by the written directive and treatment plan, and documenting the verification by a second independent member of the medical team. (Section 6.2)

Medical Consultant's Review

The NRC's medical consultant reviewed the case and determined that the attributing cause of the medical event was inattention to detail by the attending staff. The consultant took exception with the licensee's long-range deterministic effects and suggested a slight increase in risk of adverse consequences; although, the licensee's follow up of the patient shows that no adverse health effects have been observed since the event occurred. The consultant agreed that the licensee's proposed corrective actions were reasonable and appropriate to preclude recurrence. (Section 7)

Regulatory Issues

The inspector identified one violation of NRC requirements involving the failure to develop, implement, and maintain written procedural controls to demonstrate and verify at a high confidence that the administration requiring a written directive was delivered in accordance with the written directive as required by 10 CFR 35.41(a)(2) and (b)(2). (Section 8.2)

Report Details

1 Program Overview (87103 and 87133)

1.1 Inspection Scope

An NRC special inspection was initiated in response to a medical event that was reported by the Gamma Knife Center of the Pacific (Gamma Knife Center) to the NRC on July 3, 2009 (Event Notification No. 45184). The licensee reported the event as required by 10 CFR 35.3045 (a)(3). The event involved the unintended radiation overexposure of cobalt-60 to a patient undergoing brain cancer treatment. The inspection was chartered to review the circumstances surrounding the medical event. The inspector interviewed licensee personnel, reviewed the license application, supporting documentation, gamma knife operating procedures, treatment plan, and other records maintained by the licensee.

1.2 Observations and Findings

The Gamma Knife Center, under NRC License 53-11966-02, is authorized to use byproduct material in sealed form for use in medical therapeutic treatments as defined in 10 CFR 35.600. The therapeutic treatments performed under the NRC license at the Gamma Knife Center use cobalt-60 contained in sealed sources housed inside the gamma knife system. The sealed sources are used for stereotactic radiosurgery. At the time of the inspection, the oncology treatment team was comprised of a radiation oncologist, a medical physicist, a neurosurgeon, and a registered nurse. All gamma stereotactic radiosurgery procedures performed at the Gamma Knife Center were under the supervision and direction of the radiation oncologist with the medical physicist attending. Since the license was issued there have been approximately 1200 patients treated at the Gamma Knife Center without a reportable incident. A representative sample of treatment plans administered over the past 5 years was reviewed. The NRC inspector determined that there were no deviations from the prescribed written directives and treatment plans.

1.3 Conclusion

The licensee is authorized to perform therapeutic medical gamma stereotactic radiosurgery procedures using cobalt-60 sealed sources as specified in 10 CFR 35.600 with an authorized user and a medical physicist present.

2 Background (87103)

On July 2, 2009, a patient was scheduled to receive a gamma stereotactic radiosurgical treatment using cobalt-60 for metastatic cancer of the brain, and had already undergone three previous treatments at the Gamma Knife Center. The treatment team consisted of a neurosurgeon, radiation oncologist, medical physicist, registered nurse, and other ancillary staff, as needed. The neurosurgeon and radiation oncologist were medical doctors, the medical physicist held a Master of Science degree in medical physics, and all three were board certified in their respective specialties. The registered nurse held a Master of Science degree in nursing. The referring physician prescribed the stereotactic

radiosurgery treatment, requiring seven discrete sites of cobalt-60 irradiation of the brain using an 8 millimeter (mm) collimator. The treatment plan specified a total dose of 24 Gray (2400 rads) to the 90 percent isodose line. Previous treatments of this patient at the Gamma Knife Center had been uneventful. At the completion of the second discrete site, the treatment team entered the room to adjust the parameters for the treatment of the third site. The neurosurgeon noted the 18 mm collimator helmet was being used on the patient instead of the 8 mm collimator helmet that had been prescribed. The neurosurgeon immediately notified the treatment team of the error. The 18 mm collimator helmet was replaced with the prescribed 8 mm collimator helmet and the remaining sites were treated according to the treatment plan. The licensee informed the patient of the error and advised that no adverse health effects were expected to occur as a result of the medical event. The RSO was notified on July 3, 2009, and he immediately contacted the NRC Operations Center to report the medical event.

3 Event Chronology (87103)

3.1 Inspection scope

The inspector interviewed licensee personnel, reviewed procedures and corresponding documentation, and inspected equipment associated with the medical event to reconstruct the sequence of events.

3.2 Observations and Findings

The following is a chronological sequence of events that led to the medical event and subsequent licensee identification:

On July 2, 2009, the Gamma Knife Center had three patients scheduled for treatment that day. The first patient's appointment was at 0700, the second patient's appointment was at 0730, and the third patient at 1010. The third patient of the day is the subject of this report.

An 8 mm collimator helmet was used for the first patient. The patient was admitted at 0700. Frame placement began at 0800 followed by a magnetic resonance imaging (MRI) scan at 0830. The gamma knife treatment commenced at 0940 and ended at 1015. The patient was discharged at 1040.

The 8 mm collimator helmet was then replaced with an 18 mm collimator helmet for use with the second patient. The second patient was admitted at 0730, frame placement occurred at 0815, an MRI commenced at 0830 and was completed at 0940. The gamma knife treatment began at 1130 and ended at 1230. The patient was discharged at 1245.

The third patient reported to the Gamma Knife Center for routine treatment, arriving at 1010 in order to obtain vital preparatory blood work. Frame placement began at 1100. The usual procedures for set up involved the registered nurse

greeting and escorting the patient into a room to prepare for the radiosurgery, and then to prepare the treatment room.

At 1130, the patient proceeded to radiology to obtain an MRI scan.

At 1215 after the MRI scan was completed, the patient waited as the oncology treatment team prepared the treatment plan.

From 1230 to 1330, the treatment team attended the usual mid day conference to discuss cases of the day.

At 1400, the patient was placed in the gamma knife treatment room and treatment commenced.

The registered nurse assisted the radiation oncologist and medical physicist with setting the machine parameters. The machine parameters included setting the X, Y, Z, and G (patient tilt angle) coordinates. Initial coordinates set for the first discrete site were X = 76.5 mm, Y = 94.0 mm, Z = 114.0 mm, G = 110 degrees, collimator = 8mm. The X, Y, Z, and G coordinates were adjusted as stated in the treatment plan. However, the proper collimator was not checked, nor verified by any of the treatment team. The 18 mm collimator helmet that was used for the treatment of the second patient was not replaced with the 8 mm collimator helmet as required in the treatment plan and written directive for the third patient.

The treatment of the first discrete site lasted for 14 minutes. At the completion of the treatment of the first discrete site, the oncology team entered the treatment room to adjust X, Y, Z, and G coordinates to 89.0 mm, 63.0 mm, 132.0 mm and 120 degrees, respectively. No one on the treatment team checked the collimator to ensure that it was 8 mm. The collimator remained at 18 mm.

The treatment of the second discrete site lasted for 13.1 minutes. At the completion of the treatment of the second discrete site, the treatment team re-entered the treatment room to adjust the parameters for the third discrete site of X, Y, Z, and G coordinates respectively, at 115.0 mm, 87.0 mm, 61.0 mm, and 110 degrees. However, at this time, the neurosurgeon noticed that the collimator helmet was 18 mm and announced to the team that the wrong collimator had been used for the first two discrete sites. The team checked the treatment plan and confirmed that all seven discrete sites for this patient required an 8 mm collimator helmet. The helmet was then replaced with the 8 mm collimator helmet.

The remaining discrete sites were treated without incident. As previously discussed, at the completion of each discrete site, the team had to go into the treatment room to reset the X, Y, Z, and G parameters, as each coordinate parameter had a separate discrete value for each subsequent treatment site. Treatment times varied for each of the remaining discrete treatment sites at 12.6, 12.1, 11.9, 11.6 and 10.4 minutes, respectively. Total treatment time for all

seven discrete sites was 85.7 minutes. Allowing for 5 minutes between discrete sites for parameter adjustment, the total time of the treatment was 2 hours.

The third patient treatment was completed at 1600 hours. The patient was discharged at 1630 hours.

The radiation oncologist notified the patient and reported that no adverse health effects were expected because of using the wrong collimator in the treatment of two of the seven discrete sites.

On July 3, 2009, the RSO notified NRC Operations Center to report the medical event as required by 10 CFR 35.3045(a)(3).

4 Causes of the Medical Event (87103)

4.1 Inspection Scope

The inspector conducted interviews with licensee personnel, evaluated the equipment used for the gamma stereotactic radiosurgery administration, reviewed the procedures and records to determine the direct, contributing, and root causes of the medical event.

4.2 Direct, Contributing and Root Causes

4.2.1 Direct Causes

The use of a collimator helmet that was not prescribed in the written directive directly led to the radiation overexposure to unintended tissue in the patient. As discussed in Section 2 of this report, the referring physician prescribed the treatment, requiring seven discrete sites of cobalt-60 irradiation of the brain using an 8 mm collimator helmet. The treatment plan specified a total dose of 24 Gray (2400 rads) to the 90 percent isodose line for each site. An 18 mm collimator helmet was used to administer the treatment to two of the seven discrete sites. Consequently, 2.35 cc of unintended tissue surrounding the intended treatment site received 24 Gray, instead of the 4.3 Gray this tissue would have received if the 8 mm collimator helmet had been used.

4.2.2 Contributing Causes

Human errors contributed to the failure to use the prescribed collimator helmet. One member of the treatment team was responsible for ensuring the proper operation of the gamma knife daily, and for initially setting up the gamma knife for specific therapy treatments, including the selection of the prescribed collimator size. The team's normal protocol involved other members of the treatment team verifying the treatment parameters. In addition, at the conclusion of a patient treatment, the team manually reset the correct frame parameters for the next patient. Since the 18 mm collimator helmet was used for the preceding patient, it was still configured on the treatment table of the gamma knife. On the basis of interviews, the team focused on setting the frame parameters, and in particular, the X, Y, Z, and G coordinates. Each member thought

that the other team member had performed the collimator check. Consequently, the correct collimator helmet was not installed and the collimator size was not verified by other members of the team.

4.2.3 Root Causes

The failure to have detailed written procedures that required staff to check treatment plan parameters prior to treatment was identified as the root cause of the medical event. At the time of the event, the licensee's written procedures and quality management program did not explicitly describe each individual parameter to be checked prior to administering the treatment. While staff concentrated on all other treatment parameters, verifying the collimator helmet size with the treatment plan was not completed.

4.3 Conclusions

The root cause appeared to be the failure to have detailed written procedures identifying the specific treatment parameters that must be checked prior to treatment. Human error by the treatment team appears to have contributed to the failure to use the collimator helmet size as prescribed in the written directive and treatment plan.

5 Notifications and Reports (87103)

5.1 Inspection Scope

The inspector interviewed the Gamma Knife Center personnel and reviewed licensee records and documentation relative to the patient, referring physician, and NRC notification requirements.

5.2 Observations and Findings

10 CFR 35.3045 specifies the notification and reporting requirements of a medical event. 10 CFR 35.3045(a)(3) requires, in part, the licensee to report any event in which radiation from byproduct material results in a dose to tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to tissue, and 50 percent or more of the dose expected from the administration defined in the written directive. The inspector determined that the medical event was reported by the authorized user to the patient and RSO on July 2, 2009. The medical event was reported to NRC by the licensee's RSO on July 3, 2009. On July 16, 2009, NRC Region IV received the written report dated July 15, 2009 (ADAMS Accession No. 091980412), from the licensee by facsimile.

5.3 Conclusions

The licensee properly identified and reported the gamma knife medical event to the patient, referring physician, and NRC as required by 10 CFR 35.3045.

6 Licensee Evaluation and Corrective Actions (87103)

6.1 Inspection Scope

The inspector interviewed licensee personnel, reviewed the licensee's proposed corrective actions and written report, and independently verified the licensee's assessment of the dose to the patient.

6.2 Observations and Findings

As discussed during the onsite portion of the inspection on July 30, 2009, and noted in the written report received July 16, 2009, the licensee provided a description of the medical event, the cause of the event, an assessment of the effect on the individual receiving the unintentional radiation dose, a description of the corrective actions taken to prevent recurrence, and certification that the patient had been informed of the medical event.

The patient was prescribed to receive a gamma stereotactic radiosurgery treatment to seven discrete brain metastases. The prescribed dose to the seven discrete sites was 24 Gray to 90 percent isodose. Details of the event chronology are discussed in Section 3 of this report.

The licensee's investigation found that the preceding patient had received a treatment using the 18 mm collimator, and the 8 mm collimator helmet was not installed in preparation for treatment of the following patient. The error was identified by the neurosurgeon after the second site was treated and during the setup for the treatment of the third site. The licensee determined that the treatment team had neglected to change the collimator and to verify the collimator size prior to treatment of the next patient.

The licensee determined that the use of the larger collimator (18 mm) increased the treatment site dose by 3 percent. The corresponding radiation dose was 24.7 Gray (2407 rads) to the brain metastasis at the two discrete sites located in the right cerebellum. The volume of the treatment area for each of the two sites treated was increased by 2.35 cubic centimeters, resulting in tissue receiving an unintended dose. This additional tissue received a radiation dose of 24 Gray. The licensee determined that if the correct collimator (8 mm) had been used, then this tissue would have received 4.3 Gray.

The licensee also described the actions they had taken after the medical event to prevent recurrence. The licensee sent a letter dated July 6, 2009, to all radiation oncologists and neurosurgeons that perform gamma knife treatments. The letter informed them of the incident, and stressed their responsibility for verifying the set coordinates and collimator size before each discrete site is irradiated. Additionally, the Quality Management Program was changed to require a double check for all settings as stated in the treatment plan. The Program now requires that before a site is treated on a patient, all settings will be verified independently by two staff who did not make the adjustments for the treatment parameters. The treatment record and treatment plan will

be initialed by the responsible treatment team members confirming that the treatment parameters and correct collimator size have been verified.

6.3 Conclusions

The NRC inspector independently verified the licensee's assessment of the dose to the patient. The dose delivered to the tissue outside the treatment site met the criteria in 10 CFR 35.3045(a)(3), and met the criteria for a medical event. The overexposure through the use of the 18 mm collimator helmet resulted in tissue, outside the prescribed treatment site, receiving a dose approximately six times the dose expected from the administration defined in the written directive. Specifically, the written directive prescribed the use of an 8 mm collimator helmet, which would have resulted in a lower dose to this tissue.

The 3 percent increase of dose to the treatment site met the dose variance allowed in 10 CFR 35.3045. The licensee has instituted corrective actions that appear adequate to address the causes of the medical event and prevent recurrence.

7 NRC Medical Consultant's Review

As part of the special inspection charter, the NRC staff contracted with a medical consultant to review the event, perform a root cause analysis, and determine possible health effects associated with the overexposure to the patient's brain. The medical consultant's report agreed with the licensee and the NRC assessments that the attributed cause for the event was simply human error. Further, the consultant found the licensee's corrective actions to be reasonable, easily implemented, and should reduce the risks of future occurrences.

The consultant's assessment of the possible health effects associated with the radiation dose to unintended tissue indicated that there was a slight risk of adverse consequences. The consultant stated that on the basis of a recently published study, the onset of new seizures was the most common complication. However, the consultant further indicated that this was unlikely given the location in the brain of the two overdosed treatment sites.

The consultant independently assessed the volume of tissue that was overexposed. The consultant estimated the volume of the treatment area using the 8 mm collimator helmet to be 268.08 cubic millimeters (0.268 cc), and using the 18 mm collimator helmet, 3053.6 cubic millimeters (3.054 cc). The consultant's calculations estimated an increased volume of 2.786 cc of treatment area (rather than 2.35 cc as calculated by the licensee). The consultant's report indicated that although the volume was modest in absolute terms, the relative increase in brain tissue volume that received 24 Gray was a factor of 11.4 higher (3.054 cc divided by 0.268 cc) with the 18 mm collimator helmet.

The consultant stated that in stereotactic radiosurgery, the volume of a brain target is directly related to the risk of radiation related adverse effects. The consultant further stated that given the very small volumes involved, and despite the relatively high

prescription dose of 24 Gray and the 11.4-fold increased volume, the risk of serious complications was not expected to be very high. The consultant also noted that the prescription was written to the 90 percent isodose line instead of the commonly used 50 percent isodose line in gamma knife prescriptions. The consultant indicated that the written directive and treatment plan used in this case may have reduced the probability of complications by reducing the overall volume of tissue receiving the dose of 24 Gray and reducing the maximal dose within the target.

Notwithstanding, the consultant's review of the case and the aforementioned assessment, the actual patient's prognosis remains positive. Since the event over the ensuing 6 months, the licensee has been closely evaluating the patient's health and has not observed any adverse health effects since the medical event.

8 Regulatory Issues (87103)

8.1 Inspection Scope

The inspector also reviewed the regulatory requirements, the license commitments, and the licensee's gamma knife written directive procedures and the records and reports related to the medical event.

8.2 Observations and Findings

Although there were several issues identified that contributed to the medical event, the licensee failed to perform a verification of the written directive. 10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration will be conducted in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). 10 CFR 35.41(b) requires, in part, that at a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material – (1) verifying the identity of the patient or human research subject; and (2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

The licensee had not developed or implemented written procedures to provide a high confidence that each administration would be in accordance with the written directive. Specifically, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b)(2), in that the procedures did not require verification that the administration was conducted in accordance with the treatment plan and the written directive. Specifically, the licensee's procedures did not explicitly list and require the verification of all parameters: (X, Y, Z, G and collimator size) in order to provide the high confidence level required to demonstrate that the administration would be carried out as specified in the treatment plan and written directive. This was identified as a violation of 10 CFR 35.41(a)(2) and (b)(2). (030-34629/09002-01)

The inspector performed a thorough review of random patient charts and written directives for treatments administered over the past five years to assess whether the treatments were administered as prescribed. The inspector found no additional deviations from the prescribed treatment plans in the gamma knife treatments reviewed, and determined that this event was most likely an isolated occurrence.

8.3 Conclusions

One violation was identified during the inspection. The inspector determined that prior to July 02, 2009, the licensee's written procedures for administrations requiring a written directive were not explicit to demonstrate or did not provide high confidence that each administration would be in accordance with the written directive. Specifically, the licensee's written procedures for the implementation of treatment plans with its gamma knife did not require a check of each of the treatment plan parameters, and specifically to ensure that the correct collimator prescribed for each patient was placed onto the unit frame. As a result, the licensee failed to administer treatments using the correct collimator; and administered a dose to tissue, other than the treatment site and a dose greater than 50 rem to brain tissue. This failure was identified as a violation of 10 CFR 35.41(a)(2) and (b)(2).

9 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on site inspection with the gamma knife staff. A final telephonic exit briefing was conducted with the radiation safety officer and the chief financial officer on January 12, 2010, to review the inspection findings as presented in this report. They acknowledged the inspector's findings. No proprietary information was identified.

LIST OF PERSONS CONTACTED

Licensee

*#Sean Nicholson, Chief Financial Officer (in person)
#Paul DeMare, MD, Radiation Oncologist and authorized user (in person)
Todd Thompson, MD, Neurosurgeon (by phone)
#Maureen O'Neill, MS, Registered Nurse (in person)
*#Ronald Frick, MS, Radiation Safety Officer (in person)
Hong Gyo, MS, Medical Physicist (by phone)
Maurice W. Nicholson, MD, Medical Director

Present at entrance
* Present at exit

INSPECTION PROCEDURES USED

87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing
87133	Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs

ITEMS OPENED, CLOSED AND DISCUSSED

Opened

030-34629/09002-01	VIO	Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written plan, if applicable, and the written directive.

Closed
None

Discussed
None

List of Acronyms Used

ABR	American Board of Radiology
AU	Authorized User
LMP	Licensed Medical Physicist
MP	Medical Physicist
MRI	Magnetic Resonance Image
NRC	Nuclear Regulatory Commission
NS	Neurosurgeon
RO	Radiation Oncologist
RSO	Radiation Safety Officer
RN	Registered Nurse

Attachment

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

July 21, 2009

MEMORANDUM TO: Lawrence Donovan, Health Physicist
Division of Nuclear Materials Safety

FROM: Arthur T. Howell, Director */RA/*
Division of Nuclear Materials Safety

SUBJECT: SPECIAL INSPECTION CHARTER TO EVALUATE THE MEDICAL EVENT AT THE GAMMA KNIFE CENTER OF THE PACIFIC, HONOLULU, HAWAII

A Special Inspection is being chartered in response to a medical event that occurred at the Gamma Knife Center of the Pacific, Honolulu, Hawaii. You will be the lead for this Special Inspection.

BACKGROUND AND BASIS

The licensee contacted the Headquarters Operations Center on July 3, 2009 (EN 45184), in accordance with 10 CFR 35.3045(a)(3) about a medical event. The event involved the use of an incorrect collimator during the gamma knife treatment of multiple brain metastatic sites of a patient, which resulted in exceeding the abnormal occurrence reporting criteria of greater than 1000 rads delivered to the wrong treatment site.

A gamma knife treatment was prescribed for a patient being treated for multiple brain metastatic sites using an 8 mm collimator. The prescribed dose was 24 Gray (Gy). The treatment was prescribed for seven discrete sites in the brain. After the second discrete site had been treated, it was found that an 18 mm collimator had been used to administer the treatment instead of the prescribed 8 mm collimator. After discovery, the 18 mm collimator was replaced with an 8 mm collimator. Treatment to the remaining five discrete sites was administered with the 8 mm collimator.

As reported by the licensee, the use of the 18 mm collimator instead of the 8 mm collimator increased the treatment site dose by 3%. The larger collimator caused the volume of each of the two treatment areas to increase by 2.35 cubic centimeters. This additional tissue received a dose of 24 Gy. If the correct collimator had been used, this tissue would have received a dose of approximately 4.3 Gy.

Both the patient and the patient's physician were notified of the use of the wrong collimator. The licensee states that there should be no clinical effects to the patient as a result of this medical event.

In an effort to prevent recurrence, the licensee will send a notice to all authorized users, neurosurgeons, and medical physicists that they should each independently check collimator size before each treatment is started.
A review of the Nuclear Material Events Database indicated that this licensee had not had any other medical events.

The NRC is chartering this Special Inspection pursuant to NRC Manual Chapter 1301, "Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Response Plan." The basis for this response is described in Section 1301-06.03 of the Manual Chapter which refers to an occurrence that meets the threshold for an abnormal occurrence pursuant to MD 8.1, "Abnormal Occurrence Reporting Procedure." As part of the Special Inspection, you may decide to conduct additional onsite reviews.

SCOPE

The inspection should seek to address the following items as a minimum:

1. Develop a sequence of events associated with the incident (i.e., a chronology leading up to and including the incident, the initial response by the licensee, and the follow-up response by the licensee).

2. Assess the level of compliance with the license and other NRC requirements (as applicable) with respect to the protocols followed for gamma knife treatments.

3. Assess the information contained in the licensee's 15-day report required by 10 CFR 35.3047.

4. Assess the licensee's overall investigation, including root and contributing causes, as well as, the extent of cause/condition. Determine, through discussions with the licensee, whether there may have been previous instances in which the wrong collimator was used and the use did not rise to the level of a medical event (as determined by the licensee). If there were such incidents, then review these incidents in the same context as this current event, with particular emphasis on trends/patterns analysis and the adequacy of corrective actions.

5. Review the licensee's corrective actions for consistency with the regulations, license requirements, and approved procedures regarding the nature of the gamma knife incident and its reporting to the NRC. Assess the adequacy of the licensee's immediate and long-term corrective actions to prevent similar events.

6. Based on the NRC's independent medical consultant's report, provide an assessment of the exposures and the potential radiological consequences to the patient.

7. Notify and discuss with Region IV and the program office, as necessary, any new developments or significant changes.

8. Assess whether there are any generic implications associated with this incident.

GUIDANCE

NRC Manual Chapter 1301, “Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Incident Response Plan,” provides guidance on the level of response. This Manual Chapter identifies Inspection Procedure 87103, “Inspection of Material Licensee Involved in an Incident or Bankruptcy Filing,” for specific use by the team in reviewing the event.

The inspection should emphasize fact-finding in its review of the circumstances surrounding the incident. It is not the responsibility of the inspection to examine the regulatory process. Safety concerns identified that are not directly related to the event should be reported to NRC management for appropriate action.

This charter may be modified should significant new information be identified that warrants review. Should you have any questions concerning this charter, contact me at (817) 860-8106.