UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 8, 2007

Docket No. 03015163 License No. 37-06864-06
EA No. 06-308
NMED No. 060596

Daniel R. Wilson
Clinical Director, Ambulatory and Ancillary Svcs.
Pennsylvania Hospital
800 Spruce Street
Philadelphia, PA 19107-6192

SUBJECT: NRC INSPECTION REPORT NO. 03015163/2006002, PENNSYLVANIA HOSPITAL, PHILADELPHIA, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Mr. Wilson:

On September 18, 2006, Sandy Gabriel of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your correspondence dated September 19, 2006, and October 23, 2006, was also examined as part of the inspection. The findings of the inspection were discussed at an exit meeting with you and Leonard Shabason, Ph.D., your Radiation Safety Officer, by telephone at the conclusion of the inspection on December 11, 2006. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.**

The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The first violation involves the delay in making the required report to the NRC of a medical event that occurred on May 19, 2006, and did not result solely from patient intervention. The second violation involves a gamma stereotactic radiosurgery treatment for which your procedures did not include verification that the patient's head remained in a fixed position within the stereotactic head frame.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed on the docket in this letter, in your letters dated September 19, 2006, and October 23, 2006, and/or in Inspection Report No. 03015163/2006002. Therefore, you are not required to respond to this letter unless the description herein 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, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Docket Room or from the NRC's document system (ADAMS), accessible from the NRC website 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 it can be made available to the Public without redaction.

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
1. Inspection Report No. 03015163/2006002
2. Notice of Violation

cc:
Leonard Shabason, Ph.D., Radiation Safety Officer
Commonwealth of Pennsylvania

Distribution:
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Enclosure 2

NOTICE OF VIOLATION

Pennsylvania Hospital
Philadelphia, PA

Docket No. 03015163
License No. 37-06864-06
EA No. 06-308

Based on an NRC inspection conducted on September 18, 2006, at your facility in Philadelphia, Pennsylvania and review of additional information that you provided through October 23, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.3045(a)(1) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the administration of radiation from byproduct material results in a dose that differs from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more.

10 CFR 35.3045©) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after the discovery of the medical event.

Contrary to the above, as of September 18, 2006, the licensee had not reported, either by telephone or in writing, an event that occurred on May 19, 2006, in which the reporting criteria specified in 10 CFR 35.3045(a)(1) were met and the event did not result solely from patient intervention. Specifically, on May 19, 2006, a patient became agitated during a gamma stereotactic radiosurgery treatment, causing a shift in head position. The licensee terminated the treatment after delivery of dose to the treatment site that differed from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent or more. The licensee discovered the medical event on the day it occurred and believed the cause to be patient intervention, therefore the licensee did not notify the NRC Operations Center by the next calendar day or submit a written report within 15 days. However, after reviewing Information Notice 2006-11 in late August 2006, and realizing that the event might not have been entirely due to patient intervention and needed to be reported, the licensee still failed to report the event until September 20, 2006, which was several weeks later than the requirement to notify the NRC no later than the next calendar day.

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

B. 10 CFR 35.41(b)(2) requires that the licensee's procedures for administration of licensed material requiring a written directive include verification that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, a written directive was prepared for a stereotactic radiosurgery treatment and the treatment plan required the patient's head to remain in a fixed position within the stereotactic head frame to ensure that the prescribed dose was delivered to the proper treatment site, however the licensee did not ensure that the patient's head remained in a fixed position within the stereotactic head frame. Specifically, on May 19, 2006, the licensee observed the patient become agitated and move her body during the first treatment shot and the licensee's procedures did not require the licensee to pause the treatment to ensure that the patient's head remained in a fixed position within the stereotactic head frame. At the conclusion of the first treatment shot, the licensee halted treatment to check on the patient and it was discovered that the patient's head position had changed due to pin slippage.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved are already adequately addressed on the docket in the letter transmitting this Notice, in your letters dated September 19, 2006, and October 23, 2006, and/or in Inspection Report 03015163/2006002. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description herein 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 No. 06-308," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administration, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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 Web site at http://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 within two working days.

Dated This _8th_ day of _January_ 2007

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

EA No.	06-308
Inspection No.	03015163/2006002
Docket No.	03015163
License No.	37-06864-06
NMED No.	060596
Licensee:	Pennsylvania Hospital
Location:	Eighth and Spruce Streets Philadelphia, Pennsylvania 19107
Inspection Dates:	September 18, 2006 with continued in-office review through December 5, 2006; by telephone December 11, 2006
Dates of Followup Information:	September 19 and October 23, 2006

Inspector: ***/RA/*** _____ ***1/3/07*** _____
Sandra Gabriel — date
Senior Health Physicist

Approved By: ***Original signed by Pamela J. Henderson*** _____ ***January 8, 2007*** _____
Pamela J. Henderson, Chief — date
Medical Branch
Division of Nuclear Materials Safety

Document Name: C:\FileNet\ML070090528.wpd

EXECUTIVE SUMMARY

Pennsylvania Hospital
NRC Inspection Report No. 03015163/2006002

A routine, unannounced onsite inspection was performed on September 18, 2006, to review the licensee's limited scope medical program including the gamma stereotactic radiosurgery (GSR) program. The inspection revealed that for a 3-pin GSR treatment conducted on May 19, 2006, the patient became agitated during the first of 9 treatment shots. At the end of this treatment shot, it was determined that the patient's head position had changed due to pin slippage. The treatment was terminated and rescheduled to be performed on a different day. Upon review, the licensee concluded that the event was caused by patient intervention, therefore it was not reportable to the NRC.

Within the scope of this inspection, two apparent violations of NRC regulations were identified:

(1) failure to report to the NRC a medical event, as required by 10 CFR 35.3045; and

(2) failure to verify that the administration is in accordance with the treatment plan and written directive, as required by 10 CFR 35.41(b)(2).

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspector toured the licensee's Radiation Oncology department, GSR facility, and Nuclear Medicine department; interviewed licensee personnel; and reviewed applicable records to establish the current scope of the licensee's program.

b. Observations and Findings

The licensee operates a university-affiliated community hospital, which includes Nuclear Medicine, Radiation Oncology, and a GSR facility.

Nuclear Medicine images 10-15 patients a day with 4 cameras and is staffed by 4 technologists. Students from Thomas Jefferson University's nuclear medicine technology training program also perform clinical rotations at the licensee's facility. Nuclear Medicine receives a combination of unit doses and bulk shipments of Tc-99m pertechnetate, MAA, MDP, and Choletec. Lung ventilation scans are performed using Xe-133. All dosages are assayed in a dose calibrator prior to administration. In calendar year 2006, Nuclear Medicine has performed 25 iodine-131 administrations requiring a written directive, including 6 administrations greater than 33 millicuries. Most iodine-131 administrations are performed on an outpatient basis, with justification for patient release evaluated and documented.

In calendar year 2006, Radiation Oncology has performed 9 cesium-137 temporary gynecological implants and 5 permanent prostate implants using iodine-125 seeds. The most recent intravascular brachytherapy (IVB) treatment was done in November 2005, with a total of 8 treatments that year. The licensee continues to possess IVB sources, with up-to-date leak tests and inventory results maintained on file. Radiation Oncology plans to begin high dose rate remote afterloader (HDR) treatments in the near future.

GSR treatments are conducted typically on Wednesdays and Fridays, with 162 treatments performed since initiation of the program in October 2005. The majority of the lesions treated are arteriovenous malformations, meningiomas, trigeminal neuralgia, and acoustic neuromas.

The Radiation Safety Officer (RSO) is a radiation oncology physicist who is on site daily. He shares duties with an assistant physicist and an additional physicist has been hired.

c. Conclusions

No safety concerns were identified.

II. Management Oversight of the Program

a. Inspection Scope

The inspector reviewed minutes of the Radiation Safety Committee (RSC) meetings, reviewed an audit of the radiation safety program and interviewed licensee personnel.

b. Observations and Findings

The inspector noted that the licensee has an active RSC that was overseeing implementation of the program, as evidenced by the discussions held during the meetings and the results of interviews with personnel. A detailed review of the radiation safety program was conducted a year ago by the University of Pennsylvania RSO.

c. Conclusions

No safety concerns were identified.

III. Facilities and Equipment

a. Inspection Scope

The inspector toured the licensee's facilities, including the proposed HDR facility, and evaluated the adequacy of the facilities and equipment to assure that radioactive material could be used safely and that radiation exposures to workers and members of the public could be maintained ALARA.

b. Observations and Findings

The facilities and equipment, including emergency response equipment, were as described in the license and adequate to ensure safety. Posting and labeling were also found to be adequate.

c. Conclusions

No safety concerns were identified.

IV. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspector interviewed licensee personnel and reviewed a sampling of records of material inventories and periodic checks of dose calibrators, survey instruments, and the GSR device.

b. Observations and Findings

The licensee's procedures for maintaining accountability and security of licensed material, instrument calibration, and material use were reviewed and confirmed to be in accordance with the regulatory requirements. An AMP conducts all full calibrations and spotchecks of the GSR device. The inspector confirmed that these were performed in accordance with the licensee's procedures and the regulatory requirements.

c. Conclusions

No safety concerns were identified.

V. Medical Administration on May 19, 2006

a. Inspection Scope

The inspector reviewed records and interviewed licensee personnel concerning a GSR treatment on May 19, 2006, during which the patient's head position changed due to pin slippage.

b. Observations and Findings

Description of the Event

An elderly patient was framed and imaged for GSR treatment of a single metastatic lesion. Measurements indicated that there would be a collision between the anterior left post and the gamma knife helmet. The neurosurgeon decided it would be in the best interest of the patient to remove the anterior left pin and post rather than having to re-frame and re-image the patient. The remaining 3 pins were checked to confirm that they remained firmly attached to the patient. Partway through the first of 9 treatment shots (3.86 minutes in duration), the patient became very agitated and her body was observed to shift, however head movements are not observable when the patient is in the treatment position. The licensee completed the first shot, then paused the treatment in order to further sedate the patient. When licensee personnel approached the patient, they found that she "had worked loose of the remaining pins." It was not possible to determine the exact time at which the patient's head moved and the exact position to which the patient's head moved. The neurosurgeon immediately spoke with the patient's daughter to inform her of what had occurred and decided to reschedule the treatment for the following week. Licensee personnel concluded that it was unnecessary to report this event to the NRC because they believed it was caused by patient intervention. On May 26, 2006, the patient was successfully treated using a 4-pin technique.

Dosimetry Evaluation

The prescribed dose was 15 Gy (1,500 rads) to a volume of approximately 5.5 cc. The licensee concluded that if the patient was in the proper, stationary position for the entire

first treatment shot (delivered using the 8 mm helmet), a dose of approximately 6 Gy (600 rads) would have been delivered to a volume of approximately 0.6 cc. It was not possible to determine exactly what dose was delivered to what location in the brain (both inside and outside the target volume), except that no more than 6 Gy (600 rads) could have been delivered to a volume of 0.6 cc either inside or outside the target volume.

Notification of the Event

10 CFR 35.3045(a)(1)(I) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the delivered dose differs from the prescribed dose by more than 50 rem to an organ or tissue and the total delivered dose differs from the prescribed dose by 20 percent or more. 10 CFR 35.3045(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after the discovery of a medical event.

In reviewing 10 CFR 30.3045, licensee personnel determined that this was not a medical event requiring a report to the NRC because they believed it was caused by patient intervention. Later, during the summer of 2006, the licensee received a copy of NRC Information Notice 2006-11: "Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures." Licensee personnel realized that the guidance in this Information Notice might apply to the medical administration on May 19, 2006 and the cause of the event might not have been due only to patient intervention, and thus would be considered a reportable medical event. During the unannounced NRC inspection on September 18, 2006, the RSO informed the inspector of the medical administration on May 19, 2006 and provided a copy of a draft written report being prepared for submission to the NRC.

Licensee's Corrective and Preventive Actions

The licensee implemented the following corrective and preventive actions:

- more careful monitoring during GSR treatments to identify undue patient movement;
- prompt pausing and direct inspection of the patient if undue movement is noted;
- better pre-procedure mental status screening so that patients at higher risk of non-compliance during treatment can be appropriately medicated;
- technique modifications to minimize the likelihood that a 3-pin technique would be required; and
- prompt reporting to the NRC of any similar medical events that may occur in the future.

c. Conclusions

The cause of the medical event appears to be use of the 3-pin technique combined with inadequate tightening of at least one of the three remaining pins. Contributing causes were patient motion and the failure of licensee personnel to immediately pause the treatment when they first saw the patient move. Because the administered dose differed from the prescribed dose by more than 50 rem to an organ or tissue, the total dose delivered from the prescribed dose was more than 20 percent and the event was not due only to patient intervention, the NRC concluded that a medical event occurred and required reporting under 10 CFR 35.3045. Failure to report the medical event is an apparent violation of NRC requirements.

The licensee's corrective and preventive actions appear to be adequate.

10 CFR 35.41(b)(2) requires, in part, that procedures for administrations requiring a written directive include verifying that the administration is in accordance with the written directive. The NRC concluded that the licensee's procedures to ensure compliance with 10 CFR 35.41(b)(2) were inadequate in that they did not provide for the immediate pausing of the treatment and re-evaluation of the patient when the patient's body was observed to shift. This is an apparent violation of NRC requirements.

VI. Medical Consultant's Report

a. Inspection Scope

The NRC contracted a medical consultant to review the event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events.

b. Observations and Findings

The medical consultant's report dated October 10, 2006 noted that the licensee could not estimate at what point during treatment the head position changed nor did they attempt to document the final head position after pin slippage. Therefore, it is not possible to accurately determine what volumes (both inside and outside the intended target) received what dose, except to say that this dose would be less than 6 Gy (600 rads) and the volume would be small. The consultant was unable to provide an estimate of deterministic events, however he concluded that "the risk of an important late event is small." In the consultant's assessment of the root cause of this event, he stated: "My sense is that both patient intervention and inadequate tightening of a pin played a role in this event, though I cannot quantify the relative contributions." The consultant reviewed the licensees' corrective actions and stated that they are "very appropriate and will markedly reduce the likelihood of such an event recurring."

c. Conclusions

The consultant concluded that this event is unlikely to be of significant consequence to the patient. He also concluded that the licensee's corrective actions are appropriate.

VII. Exit Meeting

On September 18, 2006, a preliminary exit meeting was conducted with the licensee's staff identified at the end of this report to discuss the initial findings. On September 20, 2006, the inspector informed the licensee that the medical administration on May 19, 2006, was a reportable medical event. The licensee reported the event to the NRC Operations Center on September 20, 2006. On November 1, 2006, the inspector informed the RSO of the results of the medical consultant report. In a telephonic exit meeting on December 11, 2006, the inspector informed licensee management and the RSO of the apparent violations of 10 CFR 35.3045 and 10 CFR 35.41(b)(2).

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*+ Leonard Shabason, Ph.D., Radiation Safety Officer/Authorized Medical Physicist
Natcole Porter, Nuclear Medicine Technologist
Tanya Cain, Nuclear Medicine Supervisor
* Jack Hering, Administrative Director of Radiology
Thomas E. Price, Assistant Radiation Physicist
Jeffrey Rosenstock, M.D., Radiation Oncologist Authorized User
* Ronald J. Kumar, Chief Operating Officer
*+ Daniel R. Wilson, Clinical Director of Ambulatory and Ancillary Services
* Stephen A. Wanta, Vice President Support Services and Allied Health

* Present at preliminary exit meeting conducted on September 18, 2006
+ Present at telephonic exit meeting conducted on December 11, 2006