



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

February 27, 2007

Docket No. 030-29418  
EA Nos. 06-266 and 06-278

License No. 37-00245-09

Randy P. Juhl, Ph.D.  
Vice Chancellor for Research, Conduct  
and Compliance  
University of Pittsburgh  
Radiation Safety Office  
G-7 Parran Hall/GSPH  
130 Desoto Street  
Pittsburgh, PA 15261

SUBJECT: INSPECTION 03029418/2005001, UNIVERSITY OF PITTSBURGH MEDICAL  
CENTER, AND OFFICE OF INVESTIGATIONS (OI) REPORT NOS. 1-2005-008  
AND 1-2006-023

Dear Mr. Juhl:

In a telephone conversation on January 31, 2005, NRC informed the University of Pittsburgh Medical Center (UPMC) that its request for an exemption from NRC regulations, to allow a neurosurgeon to fulfill the Authorized User (AU) physical presence requirement for gamma stereotactic radiosurgery (GSR) treatments, would not be granted. UPMC then requested that NRC staff visit their GSR facilities to discuss the exemption request and to familiarize NRC staff with its program. NRC staff, including Pamela Henderson and Randolph Ragland from NRC Region I, as well as Cynthia Flannery, Dr. Donna-Beth Howe, and Ivelisse Cabrera from NRC Headquarters, visited the UPMC GSR facilities on March 4, 2005.

During the March 4, 2005, visit, the NRC staff observed an apparent violation of 10 CFR 35.615(f)(3), which requires that an AU and an Authorized Medical Physicist (AMP) be physically present throughout all GSR patient treatments. Specifically, during a GSR treatment, NRC staff observed your AMP leave the treatment monitoring console, walk approximately 100 feet to the opposite end of the suite, and enter a separate GSR treatment planning room. As a result, the NRC staff opened an inspection to review UPMC's compliance with the NRC physical presence requirements during the conduct of GSR treatments.

The NRC inspection was conducted on March 16 and 17, 2005, and the results are included in the enclosed Inspection Report No. 03029418/2005001. The inspection identified that UPMC did not meet the physical presence requirements for GSR treatments. As a result, the NRC issued Confirmatory Action Letter (CAL) No. 1-05-002 on April 22, 2005, which documented UPMC's commitment that there will be at least one AU and one AMP physically present (i.e., at or near the GSR unit console) throughout all GSR treatments. By letter dated April 28, 2005, UPMC sent NRC a letter describing corrective actions to meet the intent of CAL 1-05-002, including a commitment that an AU and AMP would be within 20 feet of the treatment console during all GSR treatments. On May 12, 2005, NRC confirmed compliance with CAL 1-05-002.

Based on the initial NRC staff inspection findings, the NRC Office of Investigations (OI), Region I Field Office, initiated an investigation, OI Case No. 1-2005-008, to determine whether UPMC deliberately violated the physical presence requirements on March 4, 2005. During the investigation, additional concerns were identified that Neurosurgeons A and B had willfully conducted simultaneous treatments in the three GSR suites when only one AMP was on duty, and whether Neurosurgeon A had willfully initiated a GSR treatment without a written directive signed by an AU and without the presence of an AU. The Investigation Report was issued on June 15, 2006. Subsequently, a second investigation, OI Case No. 1-2006-023, was initiated to determine whether Neurosurgeon A had willfully entered the AU's initials on written directives without the AU's knowledge or consent. The Investigation Report was issued on October 10, 2006. A Factual Summary of evidence obtained during the OI investigations is enclosed.

As a result of the inspection and two subsequent OI investigations, the NRC identified three apparent violations, one with three examples. The apparent violations are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at [www.nrc.gov](http://www.nrc.gov).

The first apparent violation involves UPMC's failure to meet the physical presence requirements of 10 CFR 35.615(f)(3), with three separate examples, and UPMC's initiation of a GSR treatment without the signed written directive required by 10 CFR 35.40. Specifically, (1) on March 4, 2005, a GSR treatment was conducted without the continuous physical presence of an AMP; (2) on multiple occasions between May 13, 2004, and March 10, 2005, Neurosurgeons A and B initiated and/or conducted simultaneous GSR treatments in separate GSR suites when there was only one AMP available, in careless disregard of the physical presence requirement. Although an AU warned Neurosurgeons A and B that such simultaneous treatments might violate the physical presence requirement, Neurosurgeons A and B continued to perform such treatments; and (3) on February 22, 2005, Neurosurgeon A willfully initiated a GSR treatment without a written directive signed by an AU and without the physical presence of an AU. Neurosurgeon A was aware of the requirements, but initiated the treatment when he either knew that the AU was not present and had not signed the written directive, or did not know whether the AU was present and had signed the written directive.

The second apparent violation involves an example of the licensee's failure to ensure that radiation safety activities were performed in accordance with regulatory requirements, as required by 10 CFR 35.24(b). Specifically, in April 2004, apparent violations of 10 CFR 35.615(f)(3) had occurred and the licensee, through the RSO, did not assure compliance with the requirement that an AMP be physically present during GSR treatments.

The third apparent violation involves multiple occasions between 1998 and 2000 when Neurosurgeon A wrote the AU's initials on GSR written directives, in violation of 10 CFR 35.32, "Quality Management Program," which required that written directives be signed by an AU prior to administration of GSR treatments.

Before an enforcement decision is made regarding the three apparent violations, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC) at the Region I office. This conference will be closed and transcribed. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a

violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty of the apparent violations. The NRC requests that you and others as discussed during a telephone conversation with Pamela Henderson and Randolph Ragland on February 27, 2007 attend the PEC. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

Instead of a PEC, UPMC may request Alternative Dispute Resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and UPMC) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Additional information concerning the NRC's ADR can be obtained at [www.nrc.gov](http://www.nrc.gov). The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting the parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at 607-255-1124 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Please contact Ms. Pamela Henderson at (610) 337-6952 within 10 days of the date of this letter to notify the NRC of your decision to either participate in a PEC or ADR.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures 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>.

Your cooperation is appreciated.

Sincerely,

/RA/

Brian E. Holian, Director  
Division of Nuclear Materials Safety

R. Juhl

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Enclosures:

- 1) NRC Inspection Report No. 03029418/2005001
- 2) Factual Summary of OI Investigation Report Nos. 1-2005-008 and 1-2006-023
- 3) Excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION"
- 4) NUREG/BR-0317, "Post-Investigation ADR Program"

cc:

Michael Sheetz, Radiation Safety Officer  
Dennis Swanson, Chair, Radiation Safety Committee  
Commonwealth of Pennsylvania

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\*Per e-mail S Merchant to J Wray on 2/26/07

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## ENCLOSURE 2

### FACTUAL SUMMARY OF OI INVESTIGATIONS 1-2005-008 AND 1-2006-023

#### **OI Report 1-2005-008**

On March 10, 2005, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, initiated an investigation to determine whether the Authorized Medical Physicist (AMP), an Authorized User (AU), two Neurosurgeons, the Radiation Safety Officer (RSO), and a Senior Health Physicist (HP) at the University of Pittsburgh Medical Center (UPMC) deliberately violated and/or participated in causing a deliberate violation of 10 CFR 35.615(f)(3) governing Gamma Stereotactic Radiosurgery (GSR) treatments performed at UPMC during an NRC licensing visit on March 4, 2005. 10 CFR 35.615(f)(3), commonly referred to as the physical presence requirement, requires that an AU and an AMP be physically present throughout all patient treatments involving gamma stereotactic radiosurgery. In the Federal Register published on April 24, 2002 (67 FR 20355), the NRC defined the term "physically present" as within hearing distance of a normal voice.

During a visit to UPMC on March 4, 2005, the NRC staff observed the AMP to be approximately 100 feet from the GSR treatment console during a GSR treatment, and the AU standing at a nurse's station within the GSR suite. The NRC staff promptly notified the Radiation Safety Officer (RSO) and the Chairman of the Radiation Safety Committee (RSC) that an apparent violation of 10 CFR 35.615(f)(3) was taking place. In response, the RSO stated that based on his interpretation, UPMC met the physical presence requirements of 10 CFR 35.615(f)(3), as long as the AU and AMP were within the physical boundary of the GSR suite. There was no attempt to conceal from the NRC the AU's and AMP's absence from the console. The AU and AMP believed that being within the suite in which a treatment was conducted met the physical presence requirement.

Neurosurgeons A and B, on nine separate occasions between May 13, 2004, and March 10, 2005, initiated simultaneous treatments in separate GSR suites when only one AMP was on duty. Several UPMC staff members observed simultaneous GSR treatments being conducted in the treatment suites without the presence of the AMP, and that Neurosurgeons A and B had initiated those treatments. Although the AU had warned Neurosurgeons A and B that conducting simultaneous GSR treatments with only one AMP on duty might be a violation of the physical presence requirements, Neurosurgeons A and B conducted the simultaneous treatments.

On February 22, 2005, Neurosurgeon A initiated a GSR treatment without an AU being physically present, and without an AU having first signed the written directive. The AU arrived in the treatment suite approximately 10 minutes after Neurosurgeon A began a GSR treatment. The written directive was not signed by the AU prior to the start of the treatment.

### **OI Report 1-2006-023**

On March 24, 2006, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, initiated an investigation to determine if Neurosurgeon A had deliberately written the signature/initials of the AU on written directives without the AU's knowledge or approval, and contrary to the requirements of the UPMC's broad scope NRC license and 10 CFR 30.9, which requires complete and accurate information. An audit of activities for that period revealed that Neurosurgeon A had written the AU's initials on written directives 46 times during 1998, 21 times during a four month period in 1999, and on three occasions in April 2000. Prior to the administrations, the AU had verbally agreed with the treatment protocol described in the written directive, and the AU was aware that Neurosurgeon A had entered the AU's initials on written directives.



U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No. 03029418/2005001

Docket No. 030-29418

License No. 37-00245-09

Licensee: University of Pittsburgh

Address: G-7 Parran Hall/GSPH  
130 DeSoto Street  
Pittsburgh, Pennsylvania 15261

Locations Inspected: Presbyterian University Hospital  
230 Lothrop Street  
Pittsburgh, Pennsylvania 15261

Inspection Dates: March 4, 2005 - February 27, 2007

Date Followup  
Information Received: April 28, 2005, CAL 1-05-002 Response

Inspectors: \_\_\_\_\_/RA/\_\_\_\_\_ 2/27/07

Penny Lanzisera  
Senior Health Physicist

\_\_\_\_\_  
Date

\_\_\_\_\_/RA/\_\_\_\_\_ 2/27/07

Randolph C. Ragland, Jr.  
Senior Health Physicist

\_\_\_\_\_  
Date

Approved By: \_\_\_\_\_/RA/\_\_\_\_\_ 2/27/07

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

\_\_\_\_\_  
Date

## **EXECUTIVE SUMMARY**

University of Pittsburgh Medical Center  
NRC Inspection Report No. 03029418/2005001

In a telephone conversation on January 31, 2005, NRC informed the University of Pittsburgh Medical Center (UPMC) that their request for an exemption to NRC regulations to allow a neurosurgeon to fulfill the Authorized User (AU) physical presence requirement for gamma stereotactic radiosurgery (GSR) treatments would not be granted. NRC staff explained that the reason for voiding the November 3, 2004, exemption request was because it was similar to the October 3, 2002, exemption request that had been carefully considered by NRC but was not granted. Upon notification, the UPMC Radiation Safety Officer (RSO) invited NRC staff responsible for evaluating GSR exemption requests to visit the UPMC GSR facility, in order for NRC staff to better understand UPMC's GSR program and to show NRC staff how UPMC can meet the intent of NRC regulations if granted an exemption to 10 CFR 35.615(f)(3). NRC staff accepted the invitation and visited the UPMC GSR facilities on March 4, 2005.

During the visit, NRC staff observed an apparent violation of the physical presence requirements for GSRs (10 CFR 35.615(f)(3)) which require that an AU and an Authorized Medical Physicist (AMP) be physically present throughout all GSR patient treatments. Specifically, on March 4, 2005, during a GSR treatment, the UPMC AMP left the treatment monitoring console, walked approximately 100 feet to the opposite end of the suite, and entered a separate GSR treatment planning room. Based on this observation, NRC issued Confirmatory Action Letter (CAL) No. 1-05-002 and opened a special inspection to review UPMC's GSR program.

Within the scope of this inspection, an apparent violation of 10 CFR 35.615(f)(3) was identified.

In addition, based on initial NRC staff inspection findings, the NRC Office of Investigations (OI), Region I Field Office, opened OI Investigation No. 1-2005-008. Subsequently, a separate investigation was initiated under Case No. 1-2006-023. Within the scope of the OI investigations, two examples of apparent violations of 10 CFR 35.615(f)(3) were identified, as well as apparent violations of 10 CFR 35.24(b) and 10 CFR 35.32. The results of these investigations are summarized in "Factual Summaries With Staff Conclusions, OI Investigations Report Nos. 1-2005-008 and 1-2006-023."

## **REPORT DETAILS**

### **I. Organization and Scope of the Program**

#### **a. Inspection Scope**

The inspectors reviewed the organization and scope of the University of Pittsburgh Medical Center (UPMC) gamma stereotactic radiosurgery (GSR) program. Information was gathered by a review of records, discussions with cognizant personnel, and tours through the facility.

#### **b. Observations and Findings**

UPMC operates a GSR program under a limited scope license that includes three GSR units. The GSR license includes approximately six authorized users (AUs) and typically three authorized medical physicists (AMPs). However, at the time of the March 4, 2005, inspection, only one AMP was actively working in the GSR program.

At the time of the March 4, 2005, tour, Mr. Jerry Rosen was the Radiation Safety Officer (RSO), Dr. Neil Wald was the Chair of the Radiation Safety Committee (RSC), Michael Sheetz provided oversight of GSR activities for the radiation safety office, and Ms. Anne Maitz provided routine radiation safety and emergency response training for the GSR staff. As of December 2006, Michael Sheetz assumed the RSO role and as of November 2005, Mr. Dennis Swanson assumed the RSC Chair role.

#### **c. Conclusions**

Licensed activities were limited to the scope of activities authorized by NRC License Number 37-00245-09. No safety significant issues were identified.

### **II. Facilities and Equipment**

#### **a. Inspection Scope**

The inspectors performed a review of the GSR program facilities and equipment. Information was gathered by a review of licensee records, discussions with cognizant personnel, and tours of the facilities.

#### **b. Observations and Findings**

UPMC operates three GSR units located in two separate suites in the UPMC Presbyterian Hospital. The first unit (GSR 1) is located in a separate suite. Unit 1 is a Leksell Gamma System Type U unit that was originally licensed in February 1987. The U unit has a "clam shell" type design that requires the upper portion of the shell to be lifted for source reloading. This unit was last reloaded in 1996; the Cobalt-60 sources have decayed through approximately two half-lives, and recently due to low activity the U unit is seldom used. Because source reloading in the U unit requires construction of a hot-cell, UPMC has not yet made a formal decision regarding future plans to either decommission or reload the unit.

The second (GSR 2) and third unit (GSR 3) are located approximately 100 feet from one another, in separate rooms that both open to the F-Wing GSR suite. GSR 2 is a Leksell

Gamma System Model 23004 C/B unit that was first licensed in June 1996. GSR 3 is a Model 24001 Type C unit, and was licensed in December 2003. GSR 2 and GSR 3 are equipped to use an automatic positioning system (APS), to allow for remote automatic target position changes.

A treatment planning room also opens to the F-Wing GSR suite and is located adjacent to GSR 2. An audio-visual system has also been installed to allow for remote monitoring of patient treatments from the treatment planning area. See Item III.b. of this report regarding NRC's response to UPMC's request to use this remote monitoring system to meet NRC GSR physical presence requirements.

c. Conclusions

UPMC facilities and equipment appeared as described in NRC licensing documents. No safety significant issues were identified.

**III. UPMC Requests for Exemption From the  
Physical Presence Requirements in 10 CFR 35.615(f)(3)**

a. Inspection Scope

UPMC has previously submitted three requests for exemptions from the physical presence requirements in 10 CFR 35.615(f)(3). NRC voided the first and third requests, and partially granted the second request as described below. During a January 31, 2005, telephone call between UPMC and NRC staff, UPMC requested NRC staff responsible for evaluating and approving GSR physical presence exemption requests, to visit the UPMC GSR facility. The purpose of the visit was to: 1) provide NRC staff with a better understanding of UPMC procedures for performance of GSR treatments, 2) facilitate a discussion on the physical presence requirements for GSR operation, and 3) provide an educational opportunity for NRC staff to observe GSR units and their operation.

On March 4, 2005, NRC staff visited the UPMC GSR facility. Information was gathered by a review of UPMC's previous 10 CFR 35.615(f)(3) exemption requests, reviews of NRC and licensee records, interviews with cognizant personnel, tours of the UPMC GSR facilities, and direct observations of patient GSR treatments.

b. Observations and Findings

UPMC 10 CFR 35.615(f)(3) Exemption Requests:

Exemption Request No. 1: By letter dated October 3, 2002, UPMC requested an exemption to allow a trained neurosurgeon to substitute for the physical presence of an AU. In addition, UPMC established an audio-visual link from GSR 1 and GSR 2, to a centralized treatment planning room located adjacent to GSR 2, and requested an exemption to allow either the AU or AMP to meet the physical presence requirements in 10 CFR 35.615(f)(3), through audio and visual monitoring of patient treatments. NRC responded that based on the information provided by UPMC, approval of the exemption was not appropriate. NRC referenced the following to support the decision:

Supplementary Information to the Final Rule that stated: “We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency...” and “NRC requires the physical presence of an AU and AMP throughout all patient GSR treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient.”

Exemption Request No. 2: By letter dated April 9, 2004, UPMC submitted an exemption request to authorize substitution of a “Qualified Neurosurgeon” for an AU during concurrent patient treatments. On October 5, 2004, NRC Region I issued a license amendment (ML042870609) that included an exemption to 10 CFR 35.615(f)(3) allowing an AU to supervise two concurrent GSR treatments provided that each unit has a qualified neurosurgeon and an AMP present throughout the treatments, and one of the units has the AU physically present.

Exemption Request No. 3: By letter dated November 3, 2004, UPMC requested a modification to their 10 CFR 35.615(f)(3) exemption to allow the substitution of a “Qualified Neurosurgeon” for the physical presence of an AU during a GSR treatment. In a telephone conversation on January 31, 2005, NRC informed UPMC that their exemption request would not be granted because it was similar to their October 3, 2002, exemption request that was carefully considered by NRC but not granted. Upon notification, the UPMC RSO invited NRC staff responsible for evaluating GSR exemption requests to visit the UPMC GSR facility, in order for NRC staff to better understand UPMC’s GSR program and to show NRC staff how UPMC can meet the intent of NRC regulations if granted an exemption to 10 CFR 35.615(f)(3). NRC staff accepted the invitation and visited the UPMC GSR facilities on March 4, 2005.

#### Tour and Observation of GSR Treatments

On March 4, 2005, NRC staff toured and observed the UPMC GSR facilities. NRC staff included Pamela Henderson and Randolph Ragland from NRC Region I, as well as Cynthia Flannery, Dr. Donna-Beth Howe, and Ivelisse Cabrera from NRC Headquarters. UPMC GSR staff provided a detailed briefing regarding how UPMC conducts GSR procedures from beginning to end. NRC staff observed the installation of a stereotactic frame on a patient’s head, two high resolution imaging procedures, computerized treatment planning, GSR unit setup including daily quality control spot checks, and the actual administration of a GSR treatment.

The GSR medical staff explained that GSR treatments at UPMC are performed using a team approach that includes Neurosurgeons, an AMP, an AU, and at least one nurse. The GSR medical staff added that all members of the GSR team are trained to respond to a patient emergency involving either an equipment issue or a patient’s medical condition.

The GSR medical staff explained that the majority of actions taken to ensure the correct delivery of dose are performed before the treatment and not during the actual treatment. This includes secure installation of the stereotactic frame by experienced neurosurgeons, high resolution imaging procedures, collaborative development of a precise computerized treatment plan, use of high quality equipment, multiple quality control checks, and routine use of an APS which automatically moves a patient’s head to precise coordinates.

The GSR medical staff explained that all GSR team members are physically present in the F wing GSR suite (GSR Units 2 and 3) during initiation and continuation of treatment. GSR medical staff stated that patients being treated are under constant observations by several GSR team members. Further, although UPMC takes no credit for use of audio and visual monitoring in the central treatment planning room, it significantly enhances UPMC's ability to monitor patient treatments.

UPMC GSR staff reported that UPMC trains approximately 80% of the AUs and AMPs in the country on the use of GSRs, and the GSR facility has operated for more than 18 years and treated more than 7,000 patients without a medical event or significant NRC non-compliance. The GSR medical staff stated that it was their belief that UPMC's team approach to GSR treatments provides a higher level of patient safety than is required by NRC regulations and ensures correct delivery of dose and timely emergency response. The RSO stated that trained and qualified neurosurgeons were fully capable of substituting for the physical presence requirements for an AU during patient treatments and that UPMC was interested in pursuing an exemption to 10 CFR 35.615(f)(3), in order to allow the AMP and AU to attend to other patient needs.

c. Conclusions

UPMC's proposed alternatives for meeting the GSR physical presence requirements were discussed. NRC staff obtained a better understanding of UPMC's GSR program. No safety significant issues were identified.

#### **IV. Observations of GSR Patient Treatments**

a. Inspection Scope

The inspectors conducted independent observations of UPMC GSR treatments. Information was gathered by interviews with UPMC GSR staff, review of records including written directives, and direct observations of GSR medical staff actions during GSR treatments.

b. Observations and Findings

The inspectors noted that the AU and AMP who signed the GSR written directive, were listed on the license and were present during the initiation of GSR patient treatments. A review of training records showed that all GSR staff who were monitoring GSR patient treatments had received annual emergency response training. The inspectors also observed that several neurosurgeons were present at the GSR treatment console and continuously monitored the patient during the course of the treatments.

However, while observing a GSR patient treatment being performed at the GSR 3 unit, NRC staff observed the AMP leave the GSR 3 treatment monitoring console, walk approximately 100 feet to the opposite end of the suite, and enter a separate GSR treatment planning room. Based on that observation, NRC Region I staff determined that the AMP was not meeting the physical presence requirements of 10 CFR 35.615(f)(3).

NRC staff promptly notified the UPMC Radiation Safety Officer (RSO) of the observed deficiency. In response, the RSO stated that based on his interpretation, UPMC met the physical presence requirements of 10 CFR 35.615(f)(3), as long as the AMP and AU were within the physical boundary of the GSR suite. The RSO pointed out that other GSR team members (the AU, Neurosurgeon, and nurse) were continuously monitoring the patient during the treatment and that the AMP could easily be summoned from anywhere within the suite within 15 - 30 seconds or less to respond to an equipment or patient medical emergency, simply by raising ones voice and calling out to the AMP. NRC staff informed the RSO and the Chairman of the UPMC RSC that an apparent violation of 10 CFR 35.615(f)(3) had occurred and that NRC was opening a special inspection to review UPMC compliance with NRC GSR physical presence requirements.

Based on NRC staff inspection findings, NRC Office of Investigations (OI), Region I Field Office, opened OI Investigation Nos. 1-2005-008 and 1-2006-023. The results of these investigations are summarized in "Factual Summaries With Staff Conclusions, OI Investigations Report Nos. 1-2005-008 and 1-2006-023."

On March 16 - 17, 2005, NRC staff conducted additional onsite inspections of the UPMC GSR program. The inspection included an initial review of the use of the Leksell Gamma System Model 24001 Type C unit that had been installed since the last routine inspection of the GSR program and included a specific focus on how the UPMC GSR program meets the NRC physical presence requirements in 10 CFR 35.615(f)(3), during the conduct of GSR treatments. At the conclusion of that review, the inspectors met UPMC representatives and affirmed NRC's conclusion that NRC's physical presence requirements for GSR procedures require the AU and AMP to remain at or near the treatment console, and the AMP's lack of physical presence during a GSR treatment on March 4, 2005, represented an apparent violation of NRC requirements.

On April 22, 2005, NRC issued Confirmatory Action Letter (CAL) No. 1-05-002 that documented NRC's understanding that when UPMC conducts GSR treatments there will be at least one AU and one AMP physically present (i.e., at or near the GSR unit console) throughout all patient treatments. By letter dated April 28, 2005, UPMC described corrective actions implemented to meet the intent of CAL 1-05-002, including a requirement for the AU and AMP to be within 20 feet of the respective treatment console during all GSR treatments. In addition, if multiple treatments are performed concurrently, an AU and AMP would be physically present at each console.

On May 12, 2005, NRC Region I conducted an onsite inspection to evaluate compliance with CAL 1-05-002. The inspector noted that a procedure describing the physical presence requirements required by CAL 1-05-002 was posted near all three GSR treatment consoles, and that GSR medical staff had been briefed on the requirements of the procedure. NRC also observed several GSR patient treatments and noted that the AU and AMP were physically present at or near the treatment console (i.e., within 20 feet) during the initiation and duration of the patient treatments.

On October 7, 2005, NRC issued Regulatory Information Summary RIS-2005-23 "Clarification of Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments." This document explained that if an AU or AMP is away from the GSR treatment console and cannot communicate with the other standing at the

console without raising their voices, the requirement for physical presence would not be met.

c. Conclusions

A violation of 10 CFR 35.615(f)(3) was identified when an AMP left the treatment console during a GSR treatment. Specifically, on March 4, 2005, during a GSR treatment, a UPMC AMP left the treatment monitoring console, walked approximately 100 feet to the opposite end of the suite, and entered a separate GSR treatment planning room.

**V. Exit Meeting**

An exit meeting was conducted on February 27, 2007, with the individuals identified at the end of this report, to discuss NRC staff inspection findings and NRC OI investigation findings, and to notify UPMC that NRC is requesting a Pre-Decisional Enforcement Conference, with the option for Alternate Dispute Resolution.



## **PARTIAL LIST OF PERSONS CONTACTED**

### **Licensee**

√ Randy P. Juhl, PhD, Vice Chancellor for Research Conduct and Compliance  
\*#☒ Jerry Rosen, former Radiation Safety Officer  
#John Flickinger, M.D., Radiation Oncologist  
\*#☒√ Michael Sheetz, Radiation Safety Officer  
\*#Ann Maitz, Authorized Medical Physicist  
\*#L. Dade Lunsford, M.D., Neurosurgeon  
\*#√ Dennis Swanson, Chair, Radiation Safety Committee  
\*Neil Wald, former Chairman of the Radiation Safety Committee  
\*#Douglas Kondziolka, M.D., Neurosurgeon  
Cheryl Rodgers, RN  
Frank Taormina, Surgical Technical Specialist  
Jonet Vacsulka, Lead GSR RN  
√ Patrick Noonan, General Council  
√ Bill Yates, Co-Director for Research Conduct and Compliance

### **NRC Staff**

\*√ Pamela Henderson, Chief Medical Branch, RI  
\*#☒√ Randolph Ragland, Senior Health Physicist, RI  
#Penny Lanzisera, Senior Health Physicist, RI  
\*Cindy Flannery, Team Leader, Medical Radiation Safety Team  
\*Dr. Donna-Beth Howe, Health Physicist, Medical Radiation Safety Team  
\*Ivelisse Cabrera, Health Physicist, Medical Radiation Safety Team

\*Indicates presence at exit meeting conducted March 04, 2005  
#Indicates presence at exit meeting conducted March 17, 2005  
☒Indicates presence at exit meeting conducted May 12, 2005  
√Indicates presence at final exit meeting conducted February 27, 2007