

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

[7590-01-P]

In the Matter of
University of Pittsburgh

EA-06-266, 06-278

CONFIRMATORY ORDER
(EFFECTIVE IMMEDIATELY)

I

University of Pittsburgh (UPitt or licensee) is the holder of Byproduct Material License 37-00245-09 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. License No. 37-00245-09 was originally issued on February 5, 1987, and is due to expire on May 31, 2015.

II

On March 10, 2005, and March 23, 2006, the NRC Office of Investigations (OI) initiated investigations (OI Case Nos. 1-2005-008 and 1-2006-023) to determine whether UPitt willfully violated the physical presence requirements on March 4, 2005, and whether a neurosurgeon had willfully entered the authorized user's (AU) initials on written directives without the AU's knowledge or consent. The investigations were completed on June 15, 2006 and October 10, 2006. Based on a March 5, 2005, visit to the UPitt Medical Center Gamma Knife facility and the investigations, the NRC informed UPitt, in a letter dated February 27, 2007, that three apparent violations were being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. To address the three apparent violations, the February 27, 2007, letter offered UPitt a choice to (1) attend a Predecisional Enforcement Conference (PEC), or (2) request Alternative

Dispute Resolution (ADR) with the NRC in an attempt to resolve any disagreement on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions.

III

Subsequent to the NRC's identification of the apparent violations, UPitt took several actions to assure that these events would not recur. These actions included: (1) ensuring that an Authorized Medical Physicist (AMP) and an AU are present during each GSR treatment; (2) issuance of a procedure for physical presence requirements and posting it at each GSR unit; and, (3) hiring another AMP.

Also, in response to the NRC's February 27, 2007 letter, UPitt requested the use of ADR to resolve the apparent violations and pending enforcement action. ADR is a process in which a neutral mediator, with no decision-making authority, assists the NRC and UPitt to resolve any disagreements on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. At UPitt's request, an ADR session was held in the Region I Office in King of Prussia, PA on May 17, 2007, between UPitt and the NRC. This ADR session was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. Based on the discussion during the ADR session, a settlement agreement was reached regarding this matter. The elements of the settlement agreement are as follows:

1. As noted in an NRC letter dated February 27, 2007, based on an NRC inspection and NRC investigations, the NRC identified three apparent violations of NRC requirements at the

University of Pittsburgh Medical Center Gamma Knife facility. The first apparent violation, which involved a failure to meet physical presence requirements described in 10 CFR 35.615(f)(3), included three examples, two of which involved willfulness. The examples included: (1) a March 4, 2005, failure to meet physical presence requirements in that a GSR treatment was conducted without the continuous physical presence of an AMP; (2) multiple incidents between May 13, 2004 and March 10, 2005, when two neurosurgeons, in careless disregard of NRC regulations, initiated GSR treatments in separate suites with only one AMP available to meet physical presence requirements; and, (3) a February 22, 2005, incident when one neurosurgeon willfully initiated a treatment without a written directive signed by an AU and without the physical presence of an AU. The second apparent violation involved licensee management's failure to ensure that GSR activities met NRC requirements, as required by 10 CFR 35.24(b). The third apparent violation involved multiple occasions when a neurosurgeon recorded the Radiation Therapist's initials on the GSR written directive, causing the licensee to violate 10 CFR 35.32. In the NRC February 27, 2007 letter, the NRC noted that it had not determined that violations had occurred or that enforcement should be taken, and the NRC offered the licensee an opportunity to attend a PEC prior to making an enforcement decision. In the alternative, the NRC offered the licensee the opportunity to attend an ADR mediation session to resolve these matters.

2. As a result of an ADR mediation session conducted on May 17, 2007, the licensee and the NRC agreed to final disposition of this matter by way of a single violation of the regulatory requirements in 10 CFR 35.24(b). Specifically, the licensee through the Radiation Safety Officer: (a) failed to ensure from May 13, 2004 through March 10, 2005, the physical presence requirements of 10 CFR 35.615(f)(3) were consistently met; and (b) failed to

ensure between 1998 and 2000 that written directives were consistently signed by all three members of the Gamma Knife team prior to administration of GSR treatments in accordance with 10 CFR 35.32. The NRC concluded that certain aspects of the 10 CFR 35.24(b) violation were willful. The licensee disputed this conclusion. The NRC and the licensee have agreed to disagree regarding any willful aspects of this violation.

3. Prior to the ADR mediation session, the licensee described the actions that it had taken to address the apparent violations identified by the NRC. Those actions included: (1) ensuring that an AMP and an AU are present during each GSR treatment; (2) issuance of a procedure for physical presence requirements and posting it at each GSR unit; and, (3) hiring another AMP. Some of these actions were verified by the NRC during the following: (1) an on-site inspection on March 15-17, 2005; (2) the NRC's review of the UPitt response to a Confirmatory Action Letter (CAL), dated April 28, 2005; (3) an on-site inspection on May 12, 2005 to follow-up on the CAL; and, (4) a routine inspection performed September 25- 29, 2006.
4. During the ADR mediation session, the licensee also described additional corrective actions that it had taken or planned, which includes: (1) having the RSO initiate a requirement for a physical presence log to be maintained at each gamma knife treatment console, to include patient name, AU physically present, AMP physically present, date, and start/stop time of treatment; (2) having the RSO staff provide annual radiation safety training to the gamma knife staff, including a review of all applicable requirements in 10 CFR Parts 19, 20, and 35, with emphasis on the physical presence and written directive requirements; (3) having an outside independent consultant (medical RSO) conduct an audit of the Radiation Safety Program with special emphasis on the gamma knife program and management

oversight; (4) increasing surveillance of GSR treatments by RSO staff; and, (5) developing a program to heighten awareness of the need to report concerns, and including this program in initial and refresher training for all radiation workers, to foster an environment for raising safety concerns.

5. To provide further opportunity for other licensees in the industry to learn from this incident, UPitt also agreed to: (1) enhance its 40 hour GSR training course provided to users at other facilities throughout the United States, including expanding the lecture on NRC regulatory requirements to include the physical presence requirements, including a description of this experience as part of the training; and, (2) submit a lessons-learned article for the Operational Radiation Safety publication and the Elekta Newsletter, *eWavelength*, describing these occurrences. The licensee will provide a copy of the training syllabus before conducting the training, and a copy of the article to the NRC at least 30 days prior to the submittal of the article to the organization.
6. In light of the actions that the licensee has taken, or committed to take, as described in Items 3-5 above, as well as the fact that the violation did not result in any known safety consequences to patients, workers, or the public, the NRC agrees to issue a Notice of Violation without a civil penalty for the violation as characterized in Item 2 and to classify the violation at Severity Level III. This action will be publically available in ADAMS and on the NRC "Significant Enforcement Actions" website.
7. The licensee also agreed to issuance of a Confirmatory Order confirming this agreement.

IV

In light of the actions UPitt has taken and agreed to take to correct the violations and prevent recurrence, as set forth in Section III above, the NRC has concluded that its concerns can be resolved through implementation of UPitt's commitments as outlined in this Confirmatory Order. The NRC has also determined that these commitments shall be confirmed by this Confirmatory Order. Based on the above and UPitt's consent, this Confirmatory Order is immediately effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR Part 2.202 and 10 CFR Part 30 and 35, IT IS HEREBY ORDERED, THAT WITHIN ONE YEAR OF THE DATE OF THIS ORDER:

1. UPitt will enhance its 40 hour GSR training course provided to users at other facilities throughout the United States, including expanding the lecture on NRC regulatory requirements to include the physical presence requirements, including a description of this experience as part of the training;
2. UPitt will provide the NRC a copy of the training syllabus before conducting the training;
3. UPitt will submit a lessons-learned article for the Operational Radiation Safety publication and the Elekta Newsletter, *eWavelength*, describing these occurrences;

4. UPitt will provide a copy of the article to the NRC at least 30 days prior to the submission of the article to the organization; and
5. UPitt will send a letter to the NRC informing the NRC that the actions in Sections V.1-4 are complete, and UPitt will send the letter within 30 days of completion of all of these actions.

The NRC Region I Regional Administrator may relax or rescind, in writing, any of the above conditions upon a showing by UPitt of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than UPitt, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, DC 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, to the Director of the Division of Regulatory Improvement Programs at the same address, to the NRC Region I office at 475 Allendale Rd., King of Prussia, PA 19406, and to UPitt. Because of potential disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to hearingdocket@nrc.gov and also

to the Office of the General Counsel by means of facsimile transmission to 301-415-3725 or e-mail to OGCMailCenter@nrc.gov. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order, and shall address the criteria set forth in 10 CFR Part 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained. AN ANSWER OR A REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Marc L. Dapas
Deputy Regional Administrator

Dated this 23th day of July 2007.