

July 13, 2007

Docket No. 030-29418
EA-06-266, EA-06-278

License No. 37-00245-09

Randy P. Juhl, Ph.D.
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh
4200 5th Avenue
132 Cathedral of Learning
Pittsburgh, PA 15260

SUBJECT: NOTICE OF VIOLATION AND CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY) (NRC Office of Investigations Report No. 1-2005-008, 1-2006-023), AND CLOSURE OF CONFIRMATORY ACTION LETTER NO. 1-05-002

Dear Dr. Juhl:

In a letter dated February 27, 2007, the NRC provided you with the results of investigations completed by the NRC Office of Investigations (OI), Region I Field Office, on June 15, 2006, and October 10, 2006. The purposes of the investigations were to determine whether the University of Pittsburgh (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. Our letter noted that, based on the evidence developed during the investigation, the staff determined that (1) on March 4, 2005, a gamma stereotactic radiosurgery (GSR) treatment was conducted without the continuous physical presence of an authorized medical physicist (AMP); (2) on multiple occasions between May 13, 2004 and March 10, 2005, simultaneous GSR treatments were conducted in separate GSR suites when there was only one AMP available, in careless disregard of the physical presence requirement; and, (3) on February 22, 2005, a neurosurgeon willfully initiated a GSR treatment without an AU present, or without having had the AU sign a written directive. A Factual Summary of the OI investigations was enclosed with our February 27, 2007 letter.

The February 27, 2007, letter informed you that three apparent violations at the UPitt Medical Center Gamma Knife Facility were being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The first apparent violation involved failure to meet the physical presence requirements of 10 CFR 35.615(f)(3), with three separate examples, and UPitt's initiation of a GSR treatment without the signed written directive required by 10 CFR 35.40. The NRC staff identified one of the examples of the apparent violation of 10 CFR 35.615(f)(3) during a March 4, 2005, visit to your GSR facility. At that time, NRC staff notified the Chair of your Radiation Safety Committee, that the NRC was opening a special inspection of your GSR program to review compliance with NRC GSR physical presence requirements. On April 22, 2005, NRC staff issued Confirmatory Action Letter (CAL) No. 1-05-002, that documented your agreement to take actions to assure that during the conduct of each

GSR treatment, there will be at least one AU and one AMP physically present at each unit throughout all patient treatments involving the unit. In a letter dated April 28, 2005, you responded to the CAL by informing the NRC that although you disagreed with the NRC interpretation of the requirements of 10 CFR 35.615(f)(3), you agreed to comply with the actions documented in the NRC April 22, 2005, letter, and you provided specific procedural steps that you would take in order to comply with the NRC's GSR physical presence requirements. On May 12, 2005, NRC Region I conducted an onsite inspection of your GSR program and confirmed: (1) your compliance with the requirements of 10 CFR 35.615(f)(3); and, (2) adherence to the commitments in the CAL and your April 28, 2005 response to the CAL. In addition, on October 7, 2005, the NRC issued Regulatory Information Summary (RIS) 2005-23, "Clarification of Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments." We trust that you understand the NRC's GSR physical presence requirements described in RIS-2005-23, and will conduct your GSR program to assure continued compliance with 10 CFR 35.615(f)(3).

Our February 27, 2007, letter also described two other apparent violations, which involved: (1) failure to ensure that radiation safety activities were performed in accordance with regulatory requirements described in 10 CFR 35.24(b); and, (2) failure to have written directives signed by an AU prior to administration of GSR treatments on various occasions between 1998 and 2000. To address the three apparent violations, the NRC February 27, 2007, letter offered you 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.

At your request, on May 17, 2007, an ADR session was held in the Region I Office in King of Prussia, PA, between UPitt and the NRC. Based on the discussions during the ADR sessions, 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 an NRC investigation, the NRC described 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 physical presence of an AMP; (2) 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 a neurosurgeon's actions to record the Radiation Therapists' initials on the GSR written directive, causing the licensee to be in violation of 10 CFR 35.32. In the NRC February 27, 2007, letter, the NRC noted that it had not determined that a violation 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 (RSO): (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 a 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 the 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 GSR 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 include 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 experience, 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) submitting a lessons-learned article for 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. The licensee agreed to complete the additional actions in Items 4 and 5 within one year of the date of issuance of a confirmatory order confirming these commitments. The licensee also agreed to send a letter to the NRC, within 30 days of completion of all actions, stating that all commitments have been met.
7. In light of the actions that the licensee has taken, or committed to take, as described in Items 3-6 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 agreed 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.
8. The licensee also agreed to issuance of a Confirmatory Order confirming this agreement.

UPitt's agreement, in principle, at the May 17, 2007, ADR session was confirmed on July 12, 2007, when the Consent and Hearing Waiver form, a copy of which is enclosed, was signed. Also enclosed with this letter is the Notice of Violation (Notice) and the Confirmatory Order (Order).

You are not required to respond to this letter or Notice. However, in accordance with the settlement agreement, you are required to respond to the Order. Your written response to the Order, and your response to the Notice, if you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Open by Addressee Only", within 30 days of the date of this letter. Further, in light of the actions completed to date, the NRC considers CAL No. 1-2005-002 closed. No further response is required regarding the CAL.

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). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter, and its attached Notice of Violation and Confirmatory Order, on its website. Your response, if you choose to provide one, will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

Randy P. Juhl, Ph.D.

5

If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301.

Sincerely,

/RA/ Original Signed by Marc L. Dapas for

Samuel J. Collins,
Regional Administrator

Enclosures: As Stated

cc:
Commonwealth of Pennsylvania

Randy P. Juhl, Ph.D.

5

If you have any questions or comments concerning this letter, please contact Mr. Karl Farrar of my staff at 610-337-5301.

Sincerely,

/RA/ Original Signed by Marc L. Dapas for

Samuel J. Collins,
Regional Administrator

Enclosures: As Stated

cc:

Commonwealth of Pennsylvania

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Enclosure 1

JUL-11-2007 16:42

NRC

610 337 5241

P.02

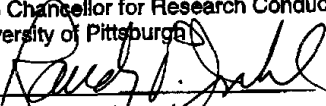
Enclosure 1

Consent and Hearing Waiver Form

The University of Pittsburgh (UPitt) hereby agrees with the attached draft Notice of Violation (NOV) and Confirmatory Order that will be immediately effective upon issuance. I recognize that by signing below, UPitt consents to the issuance of the NOV and Confirmatory Order, effective immediately, containing commitments agreed to as incorporated into the draft Confirmatory Order. The agreement was reached during the ADR mediation session held in the NRC Region I Office in King of Prussia, PA, on May 17, 2007. By agreeing to the attached NOV and Confirmatory Order, pursuant to 10 CFR 2.202(a)(3) and (d), UPitt waives the right to request a hearing on all or any part of the Confirmatory Order.

Randy P. Juhl, Ph.D.
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh

Date


7/12/07

NOTICE OF VIOLATION

University of Pittsburgh
Pittsburgh, PA

Docket No. 030-29418
License No. 37-00245-09
EA-06-266, EA-06-278

During an NRC inspection conducted on March 16 and 17, 2005, and May 12, 2005, and during investigations completed by the NRC Office of Investigations on June 15, 2006 and October 10, 2006, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.24(b) requires that a licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

Contrary to the above, the licensee did not, through the Radiation Safety Officer, ensure that radiation safety activities were being consistently performed in accordance with licensee-approved procedures and regulatory requirements. Specifically, the licensee through the Radiation Safety Officer: (1) 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, (2) 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 and licensee-approved procedures.

This is a Severity Level III violation.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved has been already adequately addressed in the letter forwarding this Notice, and at the ADR mediation session held on May 17, 2007. Therefore, you are not required to respond to this Notice. However, if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-05-125" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, and marked, "Open by Addressee Only" within 30 days of the date of the letter transmitting this Notice.

Because 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>, to the extent possible, it 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, then 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 material, 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 13th day of July 2007.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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/ Original Signed by Marc L. Dapas for

Samuel J. Collins,
Regional Administrator

Dated this 13th day of July 2007.