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Facsimile Transmittal Sheet

To: George Pangburn, Director	From: Paul A. Supowitz, Associate Vice Chancellor For Commonwealth and City/County Relations
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Fax Number: 610-337-5269	Total Pages Including Cover: 4
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Date:
April 29, 2005

Message:

Re: Confirmatory Action Letter No. 1-05-002

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University of Pittsburgh

Pittsburgh, Pennsylvania 15260

April 28, 2005

BY FAX AND U.S. MAIL

George Pangburn, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission-Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Confirmatory Action Letter No. 1-05-002

Dear Director Pangburn:

This letter is written in response to your Confirmatory Action Letter No. 1-05-002, dated April 22, 2005, to notify you as requested in item 3 on page 2 of that letter, that the University of Pittsburgh has completed the actions addressed in the Confirmatory Action Letter. The University has done so by virtue of the University Radiation Safety Executive Committee's approval of the enclosed procedure entitled "Physical Presence Requirements for Gamma Stereotactic Radiosurgery Procedures at UPMC Presbyterian Hospital." This procedure was approved by the Radiation Safety Executive Committee on April 26, 2005, and is effective on May 2, 2005, as required by the Confirmatory Action Letter and as we discussed during the April 22, 2005, conference call with members of your staff.

Regarding this procedure, the Radiation Safety Executive Committee felt it necessary to establish a prescriptive definition of the term "near", as per the Confirmatory Action Letter issued by the NRC-Region I, which states, "at least one AU and one AMP physically present at each unit (i.e., at or near the GSR treatment console)..." It is noted that representatives of NRC-Region I have indicated their belief that our previous procedures may not meet their interpretation of the current vague and ambiguous NRC regulations at 10 C.F.R. 35.615 (f) (3). However, during our teleconference on April 22nd, these representatives were unwilling to provide us with a specific interpretation of the similarly ambiguous term "near". In consideration of the events to date regarding this matter, the Radiation Safety Executive Committee felt that a prescriptive definition of "near" was required in order to prevent possible future NRC concerns based on the agency's currently unspecified interpretation of this term.

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George Pangburn, Director
April 28, 2005

As we stated during the April 22nd conference call, the University's acquiescence to the Confirmatory Action Letter and the Radiation Safety Executive Committee's approval and implementation of the enclosed procedure are not to be construed as agreement with the position NRC-Region I has expressed in that letter, and absolutely is not to be construed as an admission that our prior procedures were not in compliance. To the contrary, the University believes its prior procedure met the letter and intent of 10 C.F.R. § 35.615 (f) (3), taking into account the vagueness of that provision and its performance-based application.

Sincerely,



Dr. Niel Wald
Chairman, University of Pittsburgh
Radiation Safety Committee

Enclosure

Cc: Alexander Ciocca, Esq.
Jerome Cochran, Esq.
Dr. Randy Juhl
Jerry Rosen
Paul A. Supowitz, Esq.
Dennis Swanson

Physical Presence Requirements for Gamma Stereotactic Radiosurgery Procedures at UPMC Presbyterian Hospital

**(Approved: University of Pittsburgh Radiation Safety Executive Committee
on April 26, 2005 -- Effective May 2, 2005)**

NRC regulations at 10 C.F.R. § 35.615 (f) (3) require that an Authorized User (Radiation Oncologist) and an Authorized Medical Physicist be physically present throughout all patient treatments involving a Gamma Stereotactic Radiosurgery unit. Pursuant to NRC Confirmatory Action Letter No. 1-05-002, physical presence is defined as follows:

For All Gamma Knife Radiosurgery Treatments

Both an Authorized Radiation Oncologist and an Authorized Medical Physicist must be physically present throughout all Gamma Stereotactic Radiosurgery treatments and must remain within approximately 20 feet of the respective treatment console. To meet the physical presence requirement, the Authorized individual may not enter a separate room.

A treatment is defined as the period from initiation of radiation exposure through to the termination of that radiation exposure (shielding door closed).

For Concurrent Gamma Knife Radiosurgery Treatments

For two concurrent treatments, both an Authorized Radiation Oncologist and an Authorized Medical Physicist must be physically present, as defined above, at each console; i.e., if two treatments are carried out simultaneously, two Authorized Radiation Oncologists and two Authorized Medical Physicists must be present.

For three concurrent treatments, both an Authorized Radiation Oncologist and an Authorized Medical Physicist must be physically present, as defined above, at each console; i.e., if three treatments are carried out simultaneously, three Authorized Radiation Oncologists and three Authorized Medical Physicists must be present.

For any questions, contact the Radiation Safety Office at 412-624-2728.