



# University of Pittsburgh

## *Research Conduct and Compliance*

132 Cathedral of Learning  
Pittsburgh, PA 15260  
412-624-9111  
Fax: 412-624-6903  
E-mail: rjuhl@pitt.edu

Randy P. Juhl, PhD  
Vice Chancellor

March 12, 2007

Mr. Brian E. Holian  
Director, Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

RECEIVED  
REGION I  
2007 MAR 13 AM 10:11

**Re: Request for Alternative Dispute Resolution  
Inspection Nos. 0329418/2005001  
OI Report Nos. 1-2005-008/1-2006-023**

Dear Mr. Holian:

Please be advised that the University of Pittsburgh (License No. 37-00245-09) is in receipt of your letter dated February 27, 2007, in which you apprise the Licensee of the results of the above-referenced inspections and investigations, and contemporaneously describe three alleged violations under consideration for escalated enforcement in accordance with NRC Enforcement Policy. While the University continues to take issue with some aspects of the NRC findings, we welcome the opportunity to participate in the Alternative Dispute Resolution process so as to clarify these issues and explore possible resolution through mediation with the NRC.

The University of Pittsburgh radiation safety program is an outstanding program with a successful history of regulatory compliance. The assertions in your letter focus on one component of the University license, namely the gamma stereotactic radiosurgery (GSR) suites and program located within UPMC Presbyterian Hospital and operated by the University of Pittsburgh Medical Center (UPMC). The UPMC Presbyterian Hospital GSR program has been in operation for over 20 years; has been inspected by the NRC on multiple occasions during this period; and has, to date, treated more than 7,000 patients without a patient safety incident or radiation dose misadministration.

Regarding the alleged violation of 10 CFR 35.615(f)(3) that was observed on March 4, 2005, we acknowledge that there was indeed a difference of professional opinion on interpretation of the NRC's physical presence requirements; however, we believe such differences cannot be viewed reasonably as deliberate violations, or conduct

Mr. Brian E. Holian  
March 12, 2007  
Page Two

in careless disregard, of such requirements in view of the excellent license history here. For example, our invitation to the NRC to visit our GSR treatment center for the purpose of "... facilitat(ing) a discussion of the physical presence requirements ..." provides strong evidence of our desire to both understand and comply with the NRC physical presence requirements. Furthermore, the subsequent issuance by the NRC of Regulatory Issue Summary 2005-23, clarifying its physical presence requirements, suggests that the NRC also determined that reasonable professionals could in good faith have variant interpretations of the requirements as originally written. We also make note of the timely corrective action taken by the University after the NRC provided us with their more explicit interpretation of these requirements in the Confirmatory Action Letter of April 22, 2005.

In regard to your assertion that, on multiple occasions between May 2004 and March 2005, the Authorized Medical Physicist was not physically present during GSR treatments, the Licensee implemented procedures in accordance with the April 2005 Confirmatory Action Letter and subsequent NRC inspections have identified no physical presence regulatory concerns.

We also wish to clarify that the incident of February 22, 2005 involving neurosurgeon A was immediately addressed as a regulatory matter by the University's Radiation Safety Officer. That immediate action was followed by timely appropriate corrective action approved by the University Radiation Safety Committee, with proper documentation made available for subsequent on-site NRC inspection review. There were no safety issues associated with that incident.

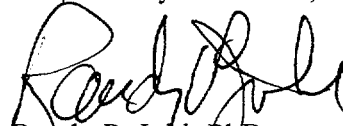
Clarification also seems appropriate for the allegation concerning neurosurgeon A reportedly writing the radiation oncologist-AU's initials on GSR written directives on occasion between 1998 and 2000. As the OI findings indicate, the radiation oncologist-AU had verbally approved the treatment protocol/written directive and was aware that neurosurgeon A included the radiation oncologist-AU's initials on the written directive. The radiation oncologist-AU did not bring such events to the attention of the University Radiation Safety Office until 2006, whereupon the issue was internally investigated and appropriate action was taken.

In summary, the University licensee and the University of Pittsburgh Medical Center GSR programs and professionals have historically, and continuously, placed the highest priority on patient safety and meeting the common expectations of the NRC for regulatory compliance. This fact is perhaps best reflected in the licensee having maintained an excellent regulatory history with the NRC; to include proactively involving the NRC in addressing areas of concern.

Mr. Brian E. Holian  
March 12, 2007  
Page Three

The University takes very seriously the NRC's alleged findings. Excellence in all aspects of radiation safety and regulatory compliance remains our goal. We look forward to presenting, at the ADR proceeding, our positions including without limitation evidence of long-term comprehensive corrective action and programmatic adjustments intended to address the NRC's stated regulatory concerns.

Respectfully submitted,



Randy P. Juhl, PhD