



NRC NEWS

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NRC CITES UNIVERSITY OF PITTSBURGH FOR VIOLATION

The Nuclear Regulatory Commission has cited the University of Pittsburgh for a violation of agency requirements involving radiation therapy in its gamma stereostatic radiosurgery (GSR) program. The violation stems from a failure to ensure that radiation safety activities adhered to regulatory requirements as well as the university's own procedures. Under the enforcement action – the details of which were determined during the NRC's Alternate Dispute Resolution (ADR) process – the university is required to take several actions to prevent recurrence.

GSR uses radiation therapy to treat tumors and other abnormalities.

In a letter sent to the university on Feb. 27, 2007, the NRC provided the results of an investigation conducted by the agency's Office of Investigations in 2006. The investigation was undertaken to determine whether the university and a neurosurgeon had willfully violated requirements with regard to the use of GSR.

The university was offered the option of a predecisional enforcement conference or ADR. University officials requested ADR, which, in this context, refers to a process in which a neutral mediator with no decision-making authority assists the NRC and license-holders in reaching an agreement resolving any differences regarding an enforcement action. Toward that end, an ADR mediation session involving NRC and University of Pittsburgh officials took place on May 17, 2007 at the agency's Region I Office in King of Prussia, Pa.

As a result of that session, a settlement agreement was reached. The terms have now been confirmed by the NRC via a Confirmatory Order issued to the university. Under the agreement, the NRC and the university agree that a non-compliance with regulatory requirements occurred. The violation has been classified as Severity Level III. The NRC classifies violations from Severity Level I to IV, with I being the most significant.

“This demonstrates that the Alternate Dispute Resolution Process can work and achieve a result that protects the public health and safety. The extensive commitments made by the university provide the NRC with confidence that radiation safety activities will be performed according to NRC requirements,” said NRC Region I Deputy Regional Administrator Marc L. Dapas.

Specifically, the university did not meet physical presence requirements consistently from May 13, 2004 through March 10, 2005. (Those requirements state that for GSR units, an authorized user and an authorized medical physicist must be physically present throughout all patient treatments.) Further, the university failed to ensure that between 1998 and 2000 written directives (detailed instructions regarding radiation treatments) were consistently signed by the authorized user prior to the administration of GSR treatments. The NRC and the university have agreed to disagree whether any aspects of the violation were willful.

Both before and during the ADR mediation session, the university described corrective actions it has taken to prevent a recurrence. They include: ensuring that an authorized medical physicist and authorized user are present during each GSR treatment; having the radiation safety officer initiate a requirement for a physical presence log; having the radiation safety office staff provide annual radiation safety training to the GSR staff; having an outside independent consultant conduct an audit of the radiation safety program, with special emphasis on the GSR program and management oversight; and, increasing surveillance of GSR treatments by radiation safety office staff.

As a result of the ADR session, the university has agreed to: (1) enhance its 40-hour GSR training course provided to GSR users at other facilities throughout the U.S., including an expansion of the lecture on NRC regulations to encompass physical presence requirements and a description of this experience as part of the training; and (2) submit a lessons-learned article for several trade publications that describes these occurrences.

In light of the actions that the university has taken and committed to take, 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 an accompanying civil penalty.

The agreement requires that the university complete the additional steps within 1 year of the issuance of the Confirmatory Order. The university must provide the NRC with a letter within 30 days of completion of all actions stating that all commitments have been met.

A copy of the enforcement action will be posted on the NRC web site at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

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