NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs, Region I
475 Allendale Road, King of Prussia, Pa.
www.nrc.gov

No. I-06-004 January 30, 2006

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NRC CITES NUCLEAR MEDICINE FIRM FOR VIOLATION OF REQUIREMENTS

The Nuclear Regulatory Commission has cited a nuclear medicine company for a violation of agency requirements involving the submission of inaccurate information. The enforcement action against Digirad Imaging Solutions, Inc., does not entail a fine but does require several corrective actions by the firm.

"This enforcement action strikes the proper balance between making it clear that the submission of inaccurate information to the NRC is unacceptable and ensuring that concrete steps are being taken to prevent a recurrence," said Mike Johnson, Director of the NRC's Office of Enforcement. "Nuclear medicine licensees routinely provide the NRC with complete and accurate information. However, the occurrence of these violations is an opportunity for members of that community to review their processes and procedures to ensure the NRC continues to receive the correct information and that any inaccuracies are promptly identified and corrected."

Digirad, which has offices in New York State and California, holds a mobile medical license from the NRC authorizing the possession of nuclear materials for medical diagnostic purposes. Under the license, the firm is allowed to use the nuclear materials at specific facilities in Indiana, Michigan, Missouri, New Jersey, Pennsylvania, Virginia and West Virginia. In addition, it is permitted to use the radioisotopes at temporary job sites anywhere in the United States where the NRC has jurisdiction for the use of certain licensed radioactive materials.

In a license amendment request sent to the NRC on Oct. 16, 2003, Digirad provided information regarding the training and experience of a physician. Specifically, Digirad submitted a statement attesting that the doctor had the required training and experience to be named as an Authorized User on the license issued to the company by the NRC. However, an investigation conducted by the NRC's Office of Investigations (OI), completed in June 2005, determined that inaccurate training and experience information was submitted to Digirad by the physician for the purpose of adding the physician as an Authorized User on the company's NRC license.

In response to the OI finding, Digirad requested the use of the Alternative Dispute Resolution (ADR). ADR is a process in which a neutral mediator with no decision-making authority assists the NRC and licensees in reaching an agreement resolving any differences regarding an enforcement action. An ADR mediation session between NRC staff and Digirad representatives was held on Nov.

14, 2005, in King of Prussia, Pa. As a result of that session, as well as subsequent discussions held on Dec. 14 and 15, 2005, a settlement agreement was reached.

The elements of the agreement include:

- The NRC and Digirad agreed to disagree on whether the violation represented careless disregard of agency requirements. While the NRC agreed that Digirad did not knowingly submit the inaccurate information, the agency also pointed out that the company is responsible for the acts and omissions of its agents.

- It was acknowledged that Digirad implemented several corrective actions prior to attending the ADR session on Nov. 14. Also, the company agreed to take further actions to ensure similar violations will not occur, including submitting commentary to nuclear medicine publications so that others in the industry will learn from the incident.

- The company agreed to audit the training and experience credentials of a certain number of Authorized User applicants each year.

- The NRC agreed to issue a Severity Level III Notice of Violation to Digirad but to not issue a civil penalty.

The terms of the enforcement action have been confirmed via a Confirmatory Order issued by the NRC to the company.

The physician involved also took part in a separate ADR, and was issued a Severity Level III Notice of Violation and agreed to take certain corrective actions to ensure a similar violation did not occur in the future.

Both the company and the physician may respond to the enforcement actions in writing within 30 days.

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