



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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NRC PROPOSES \$6,500 CIVIL PENALTY FOR NUCLEAR MEDICINE COMPANY FOR VIOLATIONS AT SITES IN NEW JERSEY AND PENNSYLVANIA

The Nuclear Regulatory Commission (NRC) staff has proposed a \$6,500 fine for a California-based company for two violations of agency requirements at nuclear medicine facilities in New Jersey and Pennsylvania. The violations by Digirad Imaging Solutions (DIS), Inc., of Poway, Calif., involve documentation pertaining to a proposed radioactive material user's qualifications and the control and security of radioactive materials.

Based on an inspection conducted from July 20 to 25, 2007 at DIS base and client sites in New Jersey and Pennsylvania, as well as a subsequent investigation performed by the NRC Office of Investigations, the NRC identified three apparent violations. (Base sites are locations where the company has regular access and can store materials. Client sites are locations where the company has access for brief periods of time and no materials are stored there.) The base locations were in Allentown, Pa., and Ridley Park, Pa. The client sites were in Egg Harbor Township, N.J., and Philadelphia.

The NRC staff has proposed the fine for two of three violations identified; enforcement discretion is being exercised on a third violation involving the submittal of incomplete and inaccurate amendment applications to the NRC requesting additional base site locations.

The violations being cited are:

- In April 2006, Digirad asked the NRC for permission to add a doctor to its license as an authorized user. Specifically, the firm stated the doctor it wanted to add had trained under an approved physician-supervisor for at least 700 hours in 2,000 cases. In fact, the training never occurred. Further, the doctor was not qualified to become an authorized user under Digirad's license because the physician who was supposed to have provided the training was himself not an authorized user, as required by NRC regulations.

"The NRC concluded that this inaccurate information could have resulted in an individual being added to an NRC license who did not fully meet NRC requirements as an authorized user," NRC Region I Administrator Samuel J. Collins wrote in a letter to the company regarding the enforcement action.

Mr. Collins said the violation was of “particular concern to the NRC” since the firm was cited for the same infraction several years ago and settled that violation through the agency’s Alternate Dispute Resolution process in 2005.

- Digirad failed, over a period of years, to secure NRC-licensed radioactive materials from unauthorized removal or access. The materials were stored at Digirad client sites as opposed to sites under the direct control of the company. Contrary to NRC requirements, the company did not control and maintain constant surveillance over such materials when they were in storage in unsecured areas. Specifically, client physicians and other staff had unauthorized access to doses of technetium-99m over several years since they had keys to the areas where the materials were stored.

“This created the potential for licensed material to be accessed and used by unauthorized individuals,” Mr. Collins wrote.

Digirad took part in a predecisional enforcement conference with NRC staff on Jan. 17, 2008. The purpose of the conference was to allow the company to discuss the apparent violations, their significance, their root causes and any corrective actions. Digirad described the corrective actions taken by the company, which included verifying the credentials of all authorized user applicants; contacting all company physician-supervisors to validate the information they submit; and ensuring that all present and future lease agreements carry appropriate “exclusive control” language requiring proper access control for licensed radioactive materials.

The company is required to provide the NRC with a written reply within 30 days.

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