



# NRC NEWS

## U.S. NUCLEAR REGULATORY COMMISSION

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### **NRC TO DISCUSS APPARENT VIOLATIONS BY NUCLEAR MEDICINE COMPANY**

Three apparent violations of Nuclear Regulatory Commission (NRC) requirements by a California-based company which occurred at nuclear medicine facilities in New Jersey and Pennsylvania will be discussed during a meeting on Thursday, Jan. 17, between NRC staff and representatives of the firm. The apparent violations by Digirad Imaging Solutions (DIS), Inc., of Poway, Calif., involve the submission of inaccurate information to the NRC in documentation pertaining to a radioactive material user's qualifications, deliveries of materials to sites not licensed to have them, and the control and security of materials.

The meeting, which is called a predecisional enforcement conference, is scheduled to begin at 10 a.m. in the Public Meeting Room at the NRC Region I Office, 475 Allendale Road, King of Prussia, Pa. It will be open to the public. Those in attendance will have an opportunity to ask questions of NRC staff before the meeting is adjourned.

NRC inspectors identified the apparent violations during an inspection conducted from July 20 to 25, 2006, and during follow-up reviews at DIS base and client sites in New Jersey and Pennsylvania. (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 apparent violations are:

- In a letter dated April 19, 2006, Digirad submitted an amendment request to the NRC seeking to add an Authorized User of NRC-licensed radioactive materials that was not complete and accurate in all material respects. Specifically, a physician who indicated in writing that the prospective user gained experience under his direction was not qualified to have provided that statement, in addition to admitting he had not supervised the prospective user.
- In multiple amendment requests from November 2001 to April 2006 seeking to add facilities to its license as base sites, Digirad submitted information that was not complete and accurate in all material respects. Specifically, the facilities were sites owned by clients

of Digirad and some were not controlled by Digirad. These amendments resulted in several locations being added to Digirad's NRC license as base sites even though Digirad did not provide the controls to be used at a licensed base site. Further, these amendments led to several doses of technetium-99m, a radioisotope, being delivered from a manufacturer or distributor to a Digirad client even though the clients did not hold an NRC license to possess such material.

- Digirad failed from Dec. 14, 2001, to April 7, 2006, 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 has unauthorized access to doses of technetium-99m over several years since they had keys to the areas where the materials were stored.

The purpose of the Jan. 17 conference is to discuss the apparent violations and provide the company an opportunity to respond and to provide details of its corrective actions and other additional information to enable the NRC to determine what, if any, enforcement action is warranted.

No enforcement decision will be made by the NRC staff at the conference. Agency management will render a decision following a final evaluation of the apparent violations.

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