



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 15, 2005

Docket No. 03035802
EA No. 05-136

License No. 31-30666-01

Paul J. Early, DABSNM, DABR
Vice President, Corporate Radiation Safety Officer
Digirad Imaging Solutions, Inc.
P.O. Box 340
4814 Whiteside Parkway
Bemus Point, NY 14712

SUBJECT: OFFICE OF INVESTIGATIONS REPORT NO. 1-2004-034

Dear Dr. Early:

This refers to an investigation completed by the NRC Office of Investigations (OI), Region I (RI) on June 15, 2005. The purpose of the investigation was to determine whether (1) a physician submitted inaccurate information to Digirad Imaging Solutions, Inc. (Digirad) to become an authorized user (AU) on Digirad's existing NRC license, and (2) if Digirad deliberately provided the inaccurate information to the NRC in a letter requesting a license amendment dated October 16, 2003. Pursuant to their NRC license, Digirad conducts diagnostic medical procedures in NRC states

As a result of the investigation, OI concluded that (1) a physician listed as an AU on Digirad's NRC license deliberately provided inaccurate information to Digirad to become an AU on their license, and (2) Digirad did not knowingly submit the false information to the NRC. Enclosure 1 is a Factual Summary of the OI Report.

Since licensees are responsible for the acts and omissions of their staff, including an AU, an apparent deliberate violation occurred. The apparent deliberate violation involved the submission of inaccurate information to the NRC regarding the previous experience and qualifications of a cardiologist in an amendment request for Digirad's license dated October 16, 2003. This is an apparent violation of 10 CFR 30.9(a) and 30.10(a)(1). 10 CFR 30.9(a) states, in pertinent part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects. 10 CFR 30.10(a)(1) states, in pertinent part, that a licensee may not engage in deliberate misconduct that causes that licensee to be in violation of any regulation. Enclosure 2 is a copy of 10 CFR 30.10, the NRC's Rule on Deliberate Misconduct. One apparent violation is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) attend a Predecisional Enforcement Conference (PEC); or (2) request Alternative Dispute Resolution (ADR). If you choose to attend a PEC, you will have the opportunity to discuss the apparent violation before an enforcement decision is made by the NRC. This conference will be held at the Region I Office in King of Prussia, PA. The NRC will issue a press release to announce the conference. Since the PEC will be based, in part, on the findings of an OI Investigation, the PEC will be closed to the public and will be transcribed. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The conference will be held to achieve a common understanding of the facts in the case, obtain appropriate information so that we can determine whether a violation occurred, to determine the significance of any violation which did occur, to understand how the violation was identified, and to understand any corrective actions taken or planned. The conference will provide an opportunity for you to provide your perspective on these matters, including any errors in the OI factual summary, and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Our final decision on enforcement action will not be available at the conclusion of the PEC. You will be advised by separate correspondence of the results of our deliberations on all the information pertaining to the violation including that received at the PEC.

Instead of a PEC, you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program, which is now in effect, is mediation. Additional information concerning the NRC's pilot program is described in the enclosed brochure (NUREG/BR-0317) and can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program via a neutral party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

No response regarding the apparent violation is required at this time. However, you must contact Mr. Willie Lee at (610) 337-5090 within 10 days of the date of this letter to notify the NRC of your decision to either participate in a PEC or pursue ADR. A PEC or an ADR session will generally be held within 30 days of the date of this letter. If you do not participate in either process, we will make an enforcement decision based on the available information.

P. Early
Digirad Imaging Solutions, Inc.

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/Original signed by FCostello/

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosures:

1. Factual Summary For OI Investigation Report No. 1-2004-034
2. 10 CFR 30.10, Rule Prohibiting Deliberate Misconduct
3. Brochure NUREG/BR-0317
4. Excerpt from NRC Information Notice 96-28

cc:

State of New York
Commonwealth of Pennsylvania
State of New Jersey

P. Early
Digirad Imaging Solutions, Inc.

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OFFICE	ORA/RI	N	OI/RI		OE			
NAME	KFarrar		EWilson MAM		MJohnson J Luehman for MJ per email from AHayes to JRW3 on 9/7/05 (incl. OGC & NMSS concurr)			
DATE	8/2/05		8/12/05		9/9/05			

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Enclosure 1

FACTUAL SUMMARY FOR OI REPORT 1-2004-034

This investigation was initiated by the Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region I, on August 6, 2004, to determine if a cardiologist who was approved as an Authorized User (AU) on Digirad Imaging Solutions, Inc. (Digirad) NRC Materials License knowingly provided false, inaccurate and/or misleading information to Digirad in order to be named as an AU on Digirad's license.

Based on the evidence developed during this investigation, OI substantiated that a cardiologist deliberately provided false, inaccurate and misleading information to Digirad to become an AU on Digirad's existing NRC Materials License. Specifically, in September 2003, the cardiologist created preceptor letters for another cardiologist and himself, subsequently signed by the Chairperson of the Radiology Department of the Greater Southeast Community Hospital (GSCH) in Washington, DC., containing inaccurate and misleading information outlining their qualifications. Digirad accepted these letters and submitted them to the NRC, adding the two cardiologists to Digirad's existing license. OI did not substantiate that Digirad knowingly submitted the false information to the NRC.

In concluding that a cardiologist deliberately provided inaccurate information to Digirad, OI noted that (1) Digirad provided the cardiologist with a sample preceptor letter, but no one at Digirad told him what information or numerical values to place in the letter, (2) the cardiologist admitted sending the preceptor letter to Digirad with inaccurate and misleading information without reading the details of the letter, (3) the Chairperson of the Radiology Department of the GSCH signed the preceptor letter prepared for her by the cardiologist without reading the details of the letter and later acknowledged that the information regarding the cardiologist's experience was inaccurate, (4) the cardiologist did not consult with the other cardiologist about his qualifications, and (5) the cardiologist had several opportunities to check the authenticity of the letters, but nonetheless, submitted the preceptor letters to Digirad.

In concluding that Digirad did not knowingly submit the false information to the NRC, OI noted that Digirad did not question the authenticity or accuracy of the preceptor letters and believed that it was the cardiologist's responsibility to provide them with complete and accurate information, which in turn they would provide to the NRC for action. When Digirad discovered that the information providing the basis for the cardiologists being AUs on their NRC license was not accurate, they removed them as authorized users.

Licensee Name: Digirad Imaging Solutions, Inc.

License Number: 31-30666-01

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