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

October 23, 2007

Docket No. 03035802 License No. 31-30666-01
EA-07-223
EA-07-224
EA-07-225

Michael J. Keenan
President
Digirad Imaging Solutions, Inc.
13950 Stowe Drive
Poway, CA 92064-8803

SUBJECT: NRC INSPECTION NO. 03035802/2006002, DIGIRAD IMAGING SOLUTIONS, INC., VARIOUS SITES

Dear Mr. Keenan:

During licensing activities, NRC staff identified that Digirad Imaging Solutions, Inc., (DIS) was delivering and storing licensed material at client sites and issued Confirmatory Action Letter (CAL) No. 1-06-003 on April 7, 2006. The CAL documented NRC's understanding that DIS immediately ceased delivery of licensed material to all client sites; immediately removed all licensed material stored at client sites; and that DIS would either submit a copy of a lease agreement or proof of ownership for each base location currently listed on NRC License No. 31-30666-01 or confirm that the location listed on their license is a client facility.

On July 20-25, 2006, Penny Lanzisera and Tara Weidner of this office conducted a safety inspection at four DIS locations; including two base locations (Allentown, PA and Ridley Park, PA), and two client sites (Egg Harbor Township, NJ and Philadelphia, PA). The inspection was limited to an assessment of the status of the commitments from: (1) a November 14, 2005, Alternative Dispute Resolution (ADR), mediation session and finalized in a Confirmatory Order (EA-05-136) dated January 27, 2006; and, (2) CAL No. 1-06-003 dated April 7, 2006. The findings of the inspection were discussed with yourself; Paul Early, Vice President and Corporate Radiation Safety Officer; Vera Pardee, Vice President and General Counsel; and Daniel Leddy, Eastern Regional Radiation Safety Officer of your organization on August 21, 2006. The results of NRC inspection activities are included in the enclosed Inspection Report No. 03035802/2006002. Based on preliminary inspection findings, the NRC Office of Investigations (OI), Region I Field Office, initiated an OI investigation to determine: (1) if DIS submitted inaccurate information in an NRC license amendment request, dated April 19, 2006, to add an Authorized User (AU); and, (2) whether DIS continued to store NRC licensed material, in the form of radioactive waste and sealed sources, at client sites in violation of NRC requirements and a CAL dated April 7, 2006.

After considering the results of the inspection and the OI investigation, three apparent violations were identified, all of which are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. First, in an apparent violation of 10 CFR 30.9 "Completeness and Accuracy of Information," DIS provided materially inaccurate information to the NRC in a

preceptor statement which was part of a license amendment request dated April 19, 2006, to add an authorized user. The amendment application stated that the preceptor supervised all required clinical work of the proposed authorized user, when in fact the preceptor had never supervised any clinical work of the proposed authorized user. Second, in violation of 10 CFR 30.9, numerous amendment applications submitted to NRC between November 2001 and April 2006, requesting certain additional base site locations, were materially incomplete. DIS did not reveal that the locations were in fact client sites, over which DIS had no control and in which DIS had no ownership interest, facts which would have resulted in denials of the amendment requests. The third apparent violation involves the failure to secure from unauthorized removal or access licensed materials stored in an uncontrolled area at various client sites, as required by 10 CFR 20.1801 "Security of Stored Material."

Before an enforcement decision is made, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC) at the Region I office. This conference will be open and 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. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty of the apparent violations. The NRC requests that Paul Early, your Corporate RSO, be one of the attendees to the PEC, along with other members of your staff as you deem necessary. 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.

Please contact Ms. Pamela Henderson at (610) 337-6952 within 10 days of the date of this letter to notify the NRC to schedule a date for the PEC.

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.

Your cooperation is appreciated.

Sincerely,

/RA/

Brian Holian, Director
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report No. 03035802/2006002
2. Excerpt from NRC Information Notice 96-28, “SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION”

cc:
Paul J. Early, Vice President, Corporate Radiation Safety Officer
Daryl Shapiro, Esquire
State of California
State of New York
State of New Jersey
Commonwealth of Pennsylvania

Your cooperation is appreciated.

Sincerely,

/RA/

Brian Holian, Director
Division of Nuclear Materials Safety

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cc:
Paul J. Early, Vice President, Corporate Radiation Safety Officer
Daryl Shapiro, Esquire
State of California
State of New York
State of New Jersey
Commonwealth of Pennsylvania

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03035802/2006002
Docket No.	03035802
License No.	31-30666-01
Licensee:	Digirad Imaging Solutions, Inc.
Address:	P.O. Box 340 Bemus Point, NY 14712
Locations Inspected:	Egg Harbor Township, New Jersey; Philadelphia, Pennsylvania; Ridley Park, Pennsylvania; and Allentown, Pennsylvania
Inspection Dates:	July 20-25, 2006
Date Followup Information Received:	September 20, 2006 and January 26, 2007

Inspectors:

/RA/ _____ ***09/27/07*** _____
Tara L. Weidner — date
Health Physicist

/RA P. J. Henderson for/ _____ ***10/01/07*** _____
Penny Lanzisera — date
Senior Health Physicist

Approved By:

/RA/ _____ ***09/28/07*** _____
Pamela J. Henderson, Chief — date
Medical Branch
Division of Nuclear Materials Safety

Document Name: G:\Docs\Current\Insp Report\R31-30666-01.2006002.wpd

EXECUTIVE SUMMARY

Digirad Imaging Solutions, Inc.
NRC Inspection Report No. 03035802/2006002

An announced, onsite inspection was performed July 20-25, 2006, at four Digirad Imaging Solutions, Inc. (DIS) locations, including two base locations (Allentown, PA and Ridley Park, PA) and two client sites (Egg Harbor Township, NJ and Philadelphia, PA). The inspection was limited to an assessment of the status of the commitments made during a November 15, 2005, Alternative Dispute Resolution (ADR) mediation session, finalized in a Confirmatory Order (EA-05-136) dated January 27, 2006; and the April 7, 2006, Confirmatory Action Letter (CAL). Preliminary results of the inspection, including three apparent violations, were discussed with the licensee on August 21, 2006, and on September 28, 2006.

Based on the results of the inspection, three apparent violations were identified:

1. DIS provided to the Commission information, in an amendment request dated April 19, 2006, to add a physician as an authorized user, that was not complete and accurate in all material respects, as required by 10 CFR 30.9 (see Section II).

2. DIS provided to the Commission information, in multiple amendment requests between 2001 and 2006, that was not complete and accurate in all material respects, as required by 10 CFR 30.9. Specifically, DIS submitted incomplete and inaccurate information to the NRC in amendment requests which resulted in the NRC adding facilities to the license as base sites, when in fact the sites were client sites (see Section III).

3. DIS failed to secure from unauthorized removal or access, licensed materials that were stored in various unrestricted areas (client sites), an activity prohibited by 10 CFR 20.1801 (see Section III).

REPORT DETAILS

I. Organization and Scope of the Program

According to DIS's website "Digirad is the world's largest provider of mobile nuclear cardiology imaging services performing thousands and thousands of procedures each year." DIS's license authorizes the possession of radionuclides for medical diagnosis, including uptake, dilution, and excretion studies permitted by 35.100; and imaging and localization studies permitted by 35.200. Presently they service approximately 1000 clients in twenty five states, seven of which are regulated by the Region I license. Mobile vans transport cameras, dosages, and nuclear medicine technologists (NMTs) from thirteen base sites to client sites. DIS offers client physicians three types of imaging services at the client's office. For all options, DIS provides radioactive dosages and the NRC/Agreement State license and offers the client the choice of (1) DIS providing the camera; (2) the client physician providing the camera purchased from DIS; or (3) DIS renting the camera to facilities undergoing renovations, through a short term lease.

II. ADR and CONFIRMATORY ORDER

a. Inspection Scope

The inspection scope was limited to a review of the status of the commitments made during the ADR session on November 14, 2005 and finalized in a Confirmatory Order (EA-05-136) dated January 27, 2006. The settlement agreement stated that DIS would: (1) audit the training and experience credentials of the first 10 authorized user (AU) applicants and 25% of the remaining AU applicants over two years; (2) submit commentaries to various professional journals highlighting 30.9 and 30.10 requirements; and (3) include accuracy statements on physician applicant and preceptor attestation forms. In accordance with the settlement agreement, the training and experience audit was to include contacting preceptors as well as Continuing Medical Education providers to verify the information provided by the applicant AU, and the accuracy statement was to cover the provisions of 10 CFR 30.9 that require the information provided by physician applicants and preceptors to be accurate in all material respects.

b. Observations and Findings

With regard to DIS's commitments to audit credentials, NRC staff reviewed two requests to add three AUs total. On April 19, 2006, DIS's Vice President/Radiation Safety Officer (RSO) submitted an amendment request to add a cardiologist as an AU. In support of the request, DIS included: (1) a letter signed by a preceptor radiation oncologist stating that the proposed AU (a cardiologist) "obtained supervised nuclear cardiology clinical and work experience under my direction and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses in this medical specialty field;" (2) a copy of a training certificate indicating that the proposed AU received 200 hours of classroom training in basic radioisotope handling; (3) accuracy statements signed by the proposed AU and the preceptor; and (4) documentation of the audit (required by the Confirmatory Order) of the proposed AU's training/experience performed

by DIS's Eastern Regional RSO. On May 30, 2006, a second letter, dated March 16, 2006, was faxed to the NRC requesting that two additional cardiologists be added to the license as AUs. Supporting documents for the March 16, 2006, letter included board certificates (CBNC) dated October 2005 and signed accuracy statements from both proposed AUs.

After reviewing the amendment requests, the license reviewer noted that the preceptor letter submitted with the April 19, 2006 request was inadequate because the preceptor did not meet the requirements in §§ 35.290, §§ 35.390, (or before October 24, 2005, §§ 35.920), or an equivalent Agreement State requirement. In order for the preceptor to meet the training and experience requirements in 10 CFR 35.290, the preceptor should have: (I) been board certified; or have (ii) completed 700 hours of training and experience applicable to the medical use of unsealed byproduct material for either uptake, dilution, and excretion studies or clinical use requiring a written directive along with generator experience. When NRC staff contacted the preceptor on July 27, 2006, the preceptor confirmed that he had not used unsealed material and that he was not board certified. In addition, DIS's VP/RSO stated during the inspection that training institutions providing continuing medical education had not been contacted as required by the Confirmatory Order. Also, for the March 16, 2006, request, a preceptor attestation required by 10 CFR 35.290(c)(2) was not submitted for either of the proposed AUs.

When DIS's VP/RSO was contacted to discuss the findings of the amendment review, he indicated that the proposed AU from the April 19, 2006, license amendment request should not be added to the license and that a statement from a qualified preceptor would be obtained at a later date and submitted in a future amendment request. The license reviewer also informed DIS's VP/RSO that in order to add the proposed AUs from the March 16, 2006, letter, a preceptor attestation statement for each would need to be provided. On July 17, 2006, the amendment request to add the three proposed AUs was voided by the NRC due to the licensee's failure to provide the requested preceptor attestation statements.

As a result of the preliminary inspection findings and the review of information contained in the license amendment dated April 19, 2006, the NRC Office of Investigations (OI), Region I Field Office, initiated an OI investigation on August 8, 2006.

With regard to the commentaries to professional journals, in a letter dated January 26, 2007, DIS's VP/RSO submitted the status of journal publications. The NRC responded in a letter dated May 22, 2007, acknowledging publication of an article entitled, "Validation of Authorized Users" by the Journal of Applied Clinical Medical Physics.

With regard to accuracy statements, the inspectors determined that these statements were present on physician applicant and preceptor attestation forms that were provided to the NRC.

c. Conclusions

Based on the inspection findings,

1. DIS performed an audit of the training and experience of three proposed AUs (April 19, 2006, and March 16, 2006), as required by the Confirmatory Order. However, they failed to identify that the March 16, 2006, request did not include preceptor attestation statements and the April 19, 2006, request contained an attestation statement signed by a physician not authorized to act as a preceptor. 10 CFR 35.290(c)(2) states that the written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.290 or §§ 35.390 and §§ 35.290(c)(1)(ii)(G), (or before October 24, 2005, §§ 35.920), or equivalent Agreement State requirements.

2. DIS provided materially inaccurate information to the Commission in an amendment request dated April 19, 2006, to add a physician as an authorized user, an apparent violation of 10 CFR 30.9. The amendment request contained a preceptor statement which stated that the preceptor supervised all required clinical work of the proposed authorized user. In fact, the preceptor had never supervised any clinical work of the proposed authorized user.

3. DIS submitted commentaries to various professional journals highlighting 30.9 and 30.10 requirements. The Journal of Applied Clinical Medical Physics (Volume 7, Issue 3) published the article in their Summer 2005 edition. DIS also submitted the article to the Journal of Nuclear Medicine and the Journal of Nuclear Medicine Technologists on October 1, 2006. To date, neither of these publications has printed the article.

4. Accuracy statements were included on physician applicant and preceptor attestation forms that were provided to the NRC.

III. CAL AND LICENSE RENEWAL

a. Inspection Scope

The inspection scope was limited to a review of the commitments made as part of a CAL issued on April 7, 2006. The CAL stated that DIS would: (1) immediately cease delivery of licensed material to client sites for which they did not have control of the facility by either a formal written lease agreement with the facility owner, or ownership of the facility; (2) immediately remove all license material currently stored at client sites for which they did not have control of the facility by either a formal written lease agreement with the facility owner, or ownership of the facility; and (3) submit a copy of lease agreements or proof of ownership for each base location currently listed on the license, or confirm that the location listed on the license is a client facility.

b. Observations and Findings

Since November 2001, DIS submitted numerous amendment requests to add locations to their license as base sites. Once approved, the locations would be listed on their license allowing them to receive, store, and use the licensed material at that base location. During the renewal process, the license reviewer noted that some of the base locations listed on the license did not appear to be under DIS's control. After several months of correspondence on the issue, DIS indicated that they did not have complete control over several facilities listed on the license, in that the clients' employees had access to the areas where licensed material was stored. Therefore, because DIS provided incomplete information in their amendment requests to add base locations, the NRC inaccurately listed several client sites as DIS controlled base locations on the DIS license. This resulted in: (1) licensed material in the form of unit dosages of technetium-99m being delivered to client sites, a violation of 10 CFR 35.80(b), and (2) client employees having access to the licensed material, a violation of 10 CFR 20.1801. 10 CFR 35.80(b) states that, a mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. None of the sites inaccurately listed on the DIS license as base sites possessed an NRC or Agreement State license.

On April 7, 2006, a CAL was issued wherein DIS agreed to stop delivery of and remove licensed material from sites where they did not control access to the licensed material. On April 12, 2006, the license renewal was issued removing five previously listed base sites because DIS did not own these facilities or have a lease agreement in place with the facility owner.

On April 5, 2006, DIS contacted the sites which did not have leases and informed them that they could no longer have licensed materials delivered to the site. DIS instructed their NMTs to pick up licensed material at the radiopharmacy or at a DIS base location for transport to the client site. In addition, the NMTs at the client sites were informed that licensed material could no longer be stored at the client sites and that all licensed material, including radioactive waste would have to be returned to the radiopharmacy or a DIS base location. After the calls were made to the client sites informing the clients and NMTs of the change in policy, DIS's management did not confirm that the policy was being implemented. As a result, during the subsequent NRC inspection, inspectors identified that licensed material in the form of radioactive waste and check sources continued to be stored at three of the client sites after the issuance of the April 7, 2006 CAL.

c. Conclusions

1. DIS provided to the Commission, in multiple amendment requests between 2001 and 2006, information that was not complete and accurate in all material respects, as required by 10 CFR 30.9. Specifically, DIS submitted inaccurate information to the NRC in amendment requests which resulted in the NRC adding facilities to the license as base sites, when in fact the sites were client sites, an apparent violation of 10 CFR 30.9.

2. DIS had licensed material delivered from the manufacturer or distributor to several client sites that did not have a license allowing the possession of licensed material. Since these sites were not under DIS control, DIS did not restrict client access to licensed material delivered to client sites, an apparent violation of 10 CFR 20.1801.

3. As of April 7, 2006, DIS ceased delivery of licensed material to all sites where they did not have control of the facility by either a formal written lease agreement with the facility owner, or ownership of the facility. DIS also provided lease agreements and proof of control for their remaining base sites.

4. As of July 21, 2006, DIS did not remove licensed material from client sites where they did not have control of the facility by either a formal written lease agreement with the facility owner, or ownership of the facility. Specifically:

   (1) between April 7, 2006, and July 21, 2006, the Egg Harbor Township client site was storing radioactive waste and a cesium-137 dose calibrator check source.

   (2) between April 7, 2006, and July 13, 2006, the Ridley Park site was considered a client site because DIS had not provided a copy of a lease agreement. During this time, radioactive waste and a cesium-137 well counter source was stored at this site.

   (3) between April 7, 2006, and July 21, 2006, the Philadelphia client site stored radioactive waste.

   As a result, DIS failed to secure licensed materials from unauthorized removal or access that were stored in an unrestricted area (client site), an apparent violation of 10 CFR 20.1801.

IV. Exit Meeting

A preliminary exit meeting was conducted on August 9, 2006, with Paul Early, Vice President/RSO and Daniel Leddy, Eastern Regional RSO. The inspectors informed the licensee of the apparent violations identified during the inspection. An exit meeting was also held by telephone on August 21 2006 with Michael Keenan, President; Vera Pardee, Vice President & General Counsel; Paul Early, Vice President/RSO; and Daniel Leddy, Eastern Regional RSO, wherein the inspectors informed the licensee of the apparent violations identified during the inspection. A final exit meeting was conducted on September 28, 2007 with Paul Early, Vice President/RSO.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Paul J. Early, Vice President and Corporate Radiation Safety Officer
Daniel Leddy, Eastern Regional Radiation Safety Officer
Vera Pardee, Vice President & General Counsel
Michael Keenan, President
Jennifer Armstrong, Office Manager, Ridley Park (base location)
James Grist, Nuclear Medicine Technologist, Ridley Park (base location)
Teresa McKay, Nuclear Medicine Technologist, Egg Harbor Township (client site)
Jamie Payne, Nuclear Medicine Technologist, Egg Harbor Township (client site)
Ilyas Rajput, M.D., Egg Harbor Township (client site)
Rosemarie Belan, Nuclear Medicine Technologist, Philadelphia (client site)
Joanne Avalino, Office Manager, Philadelphia (client site)
Steven Nierenberg, M.D., Philadelphia (client site)