April 3, 2008

EA-07-223
EA-07-224
EA-07-225
EA-05-136

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY – $6,500 (NRC Inspection Report No. 03035802/2006002); CLOSURE OF CONFIRMATORY ACTION LETTER 1-06-003 AND ORDER EA-05-110; AND, EXERCISE OF ENFORCEMENT DISCRETION

Dear Mr. Keenan:

This refers to an NRC inspection conducted at two Digirad Imaging Solutions, Inc. (DIS) base locations (Allentown, PA and Ridley Park, PA) and two client sites (Egg Harbor Township, NJ and Philadelphia, PA) on July 20-25, 2006. The inspection was performed, in part, to confirm adherence to commitments DIS made during an Alternative Dispute Resolution (ADR) Session conducted on December 1, 2005, to disposition a previous violation involving submission of inaccurate information to the NRC in the form of a preceptor statement (EA-05-136).

After considering the results of the inspection, as well as a subsequent investigation conducted by the NRC Office of Investigations (OI) (OI Report No. 1-2006-50), the NRC identified three apparent violations, which were initially discussed at the inspection out-briefing on August 21, 2006, and were subsequently described in an October 23, 2007, letter that transmitted Inspection Report No. 03035802/2006002 to you. The three apparent violations described in our October 23, 2007 letter included: (1) submitting to the NRC materially inaccurate information involving a written attestation that was to be signed by a preceptor authorized user, in a license amendment request dated April 19, 2006, which the NRC noted as a repeat violation; (2) failing to secure from unauthorized removal or access licensed materials stored in an uncontrolled area at various client sites; and, (3) submitting materially incomplete amendment applications to the NRC requesting additional base site locations. Our October 23, 2007, letter offered you the opportunity to attend a predecisional enforcement conference (PEC) to address the violations.

On January 17, 2008, a PEC was conducted in the Region I office with you and members of your staff, to discuss the apparent violations, their significance, their root causes, and your corrective actions. Based on the results of the inspection, and additional information provided at the PEC, and in the letter from Traci Hollingshead, Vice President & Corporate Radiation Safety Officer, received on January 25, 2008, the NRC has determined that three violations of NRC requirements occurred. However, only two of the violations are cited in the enclosed Notice of

Violation (Notice), and are described below. The NRC is exercising enforcement discretion to not cite the third violation, for the reasons provided herein.

With respect to the first violation, involving the failure to provide complete and accurate information to the NRC in a written attestation submitted with an April 19, 2006 license amendment request, 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. This violation is of particular concern to the NRC since a similar violation was the subject of prior escalated enforcement action, and a resultant ADR agreement in 2005 (EA-05-136). This more recent violation occurred notwithstanding commitments by DIS to prevent such violations, as required by the Confirmatory Order (EA-05-136) issued to DIS on January 27, 2006, following the ADR agreement. As part of the ADR agreement, DIS committed to take certain actions, including auditing, on a yearly basis for a two year period, the training and experience credentials of the first 10 authorized user (AU) applicants and 25% of any additional AU applicants. The audits were to include locating and calling preceptors and Continuing Medical Education providers to verify information provided by the AU applicants. The Order also required DIS to notify the NRC as soon as practical after identification of any discrepancies identified. Since this violation had significant potential for impacting the NRC's ability to perform its regulatory function, the NRC has classified this violation at Severity Level (SL) III, in accordance with the Enforcement Policy.

With respect to the second violation, involving the failure to secure licensed materials that are stored in uncontrolled or unrestricted areas from unauthorized removal or access, the NRC concluded that DIS, over a period of years, did not secure from unauthorized removal, or limit access to, licensed material in the form of several 20-30 millicurie dosages of technetium-99m located at several clients' facilities, which were unrestricted areas. In addition, DIS did not control and maintain constant surveillance of this licensed material, as client physicians were allowed unauthorized access to this licensed material, since they had keys to the storage areas. This created the potential for licensed material to be accessed and used by unauthorized individuals. Therefore, in accordance with the Enforcement Policy, the NRC has classified this violation at SL III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for each SL III violation. Since your facility has been the subject of escalated enforcement action within the last two years or two inspections, involving a similar SL III violation and Confirmatory Order (EA-05-110) that was issued on January 27, 2006, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy, for each violation. Credit is not warranted for *Identification* for either violation, because the NRC identified the violations during the inspection. Credit for *Corrective Actions* is warranted for both violations, because your actions, described at the PEC, and in the letter from Traci Hollingshead, Vice President & Corporate Radiation Safety Officer, received on January 25, 2008, were considered to be prompt and comprehensive.

The NRC notes your corrective actions include many that exceed the requirements in the Confirmatory Order for the prior SL III violation, and include: (1) verifying the credentials of all AU applicants; (2) requiring the AU applicants to sign a Memorandum of Understanding that commits the applicant to comply with the DIS Radiation Safety Procedure Manual and provides guidance and supervision for the receipt, use, and transfer of all licensed radioactive materials;

(3) providing better administrative controls to ensure that the preceptors provide accurate information to DIS and understand the regulatory consequences of providing inaccurate information; (4) contacting all preceptors to validate the information they provide; (5) providing guidance to your supervisors to train the nuclear medicine technologists (NMTs) on changes in the NRC regulations; (6) disciplining NMTs who failed to implement the directions of the RSO regarding receipt and storage of licensed radioactive materials; and, (7) ensuring that all present and future lease agreements carry appropriate "exclusive control" language to ensure proper access control for licensed radioactive materials.

Therefore, in order to emphasize the importance of submitting complete and accurate information to the NRC, maintaining security of licensed material, and promptly and comprehensively identifying and correcting violations when they occur, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $6,500 for these two SL III violations. But for your corrective actions, the civil penalty would have been higher.

With respect to the third apparent violation, involving the failure to provide the NRC complete and accurate information regarding license applications to add base or client site locations to the DIS license, the NRC considered the information that you provided at the PEC and concluded that enforcement discretion to not cite the violation was appropriate in this case. The NRC notes that during the course of NRC's review of the applicable license application, confusion existed as to how to properly implement the requirement, that may have resulted in miscommunication between DIS and the NRC. Therefore, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion in accordance with Section VII.B.6 of the Enforcement Policy and not cite this violation.

The NRC has concluded that the information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in this letter, in Inspection Report No. 03035802/2006002, in the additional information you provided at the January 17, 2008 PEC, and/or in the DIS letter, received by the NRC on January 25, 2008. Therefore, although you are required to provide a response to the enclosed Notice of Violation and Proposed Imposition of Civil Penalty, you are not required to address the provisions of 10 CFR 2.201 unless the description herein, as well as in the inspection report, does not accurately reflect your corrective actions or your position. In that case, you should follow the instructions specified in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. If you choose to provide additional information, to the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Additionally, the NRC issued Confirmatory Action Letter (CAL) No. 1-06-003 on April 7, 2006, which documented your agreement to take actions to assure that: (1) delivery of licensed material to client sites which were not controlled by a formal written lease agreement with the facility owner, or by ownership of the facility, ceased; (2) all licensed material stored at uncontrolled client sites was removed; and, (3) a copy of a lease agreement or proof of ownership for each base location currently listed on NRC License No. 31-30666-01, or confirmation that the location listed on the license was a client facility, was submitted to the NRC. During the inspection conducted July 20-25, 2006, the inspectors confirmed that Items 1 and 3 were completed. With regard to Item 2, you confirmed removal of all licensed material, including waste, during the PEC. The NRC has determined that all of the commitments listed in the CAL were satisfied, and therefore, this CAL is closed.

The January 27, 2006 Confirmatory Order EA-05-136, Section III, required that DIS submit the following to the NRC: (1) documentation of the results of the AU applicant audits, at the end of the two year audit period; and, (2) notification that commentaries had been submitted to the Journal of Nuclear Medicine, the Journal of Nuclear Medicine Technology and the Journal of Medical Physics, by one year subsequent to the date of the Order. By correspondence dated May 22, 2007, the NRC informed you that we confirmed DIS completed the commentary submittals to each of the three journals referenced above. The letter also stated that DIS was still required to submit documentation of the results of the AU applicant audits at the end of the two year audit period. In documentation of the inspection and investigation completed in 2006 and 2007, respectively, as well as your presentation materials from the January 17, 2008 PEC, the NRC has docketed sufficient information regarding the AU applicant audits by DIS and the results of the audits, including the circumstances involved in Violation A in the enclosed Notice. Therefore, after consultation with the Director, Office of Enforcement, I have decided that DIS is not required to document the results of the audits, as stated in Section III of the Order. As such, the Order is closed.

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. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov.

Sincerely,

/RA/ *Original Signed By Marc L. Dapas for*

Samuel J. Collins
Regional Administrator

Docket No. 03035802
License No. 31-30666-01

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc:
State of California
Commonwealth of Pennsylvania
State of New Jersey
State of New York
Traci Hollingshead, Vice President & Corporate Radiation Safety Officer
Daryl M. Shapiro, Counsel for Digirad

Additionally, the NRC issued Confirmatory Action Letter (CAL) No. 1-06-003 on April 7, 2006, which documented your agreement to take actions to assure that: (1) delivery of licensed material to client sites which were not controlled by a formal written lease agreement with the facility owner, or by ownership of the facility, ceased; (2) all licensed material stored at uncontrolled client sites was removed; and, (3) a copy of a lease agreement or proof of ownership for each base location currently listed on NRC License No. 31-30666-01, or confirmation that the location listed on the license was a client facility, was submitted to the NRC. During the inspection conducted July 20-25, 2006, the inspectors confirmed that Items 1 and 3 were completed. With regard to Item 2, you confirmed removal of all licensed material, including waste, during the PEC. The NRC has determined that all of the commitments listed in the CAL were satisfied, and therefore, this CAL is closed.

The January 27, 2006 Confirmatory Order EA-05-136, Section III, required that DIS submit the following to the NRC: (1) documentation of the results of the AU applicant audits, at the end of the two year audit period; and, (2) notification that commentaries had been submitted to the Journal of Nuclear Medicine, the Journal of Nuclear Medicine Technology and the Journal of Medical Physics, by one year subsequent to the date of the Order. By correspondence dated May 22, 2007, the NRC informed you that we confirmed DIS completed the commentary submittals to each of the three journals referenced above. The letter also stated that DIS was still required to submit documentation of the results of the AU applicant audits at the end of the two year audit period. In documentation of the inspection and investigation completed in 2006 and 2007, respectively, as well as your presentation materials from the January 17, 2008 PEC, the NRC has docketed sufficient information regarding the AU applicant audits by DIS and the results of the audits, including the circumstances involved in Violation A in the enclosed Notice. Therefore, after consultation with the Director, Office of Enforcement, I have decided that DIS is not required to document the results of the audits, as stated in Section III of the Order. As such, the Order is closed.

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. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov.

Sincerely,

/RA/ *Original Signed By Marc L. Dapas for*
Samuel J. Collins
Regional Administrator

Docket No. 03035802
License No. 31-30666-01

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

SUNSI Review Complete: scg (Reviewer's Initials)
DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\DIGIRAD\Digirad NOV,CP & CAL Closure & Enf Discretion.doc
After declaring this document "An Official Agency Record" it will be released to the Public. ADAMS Accession No.: ML080950308
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/RC	RI/ORA
NAME	*ADeFrancisco	*PHenderson	*JKinneman	*KFarrar	*DHolody
DATE	1 / 25 /08	1 / 29 /08	1 / 30 /08	2 / 6 /08	2 / 6 /08
OFFICE	OI/RI	HQ/FSME	HQ/OGC	HQ/OE	RI/RA
NAME	*E Wilson	*GMorell	*C. Marco	*NHilton for CCarpenter	SCollins/MLD for
DATE	2 / 6 /08	2/26/08	3/07/08	3/25/08	04/03/08

OFFICIAL RECORD COPY

*see previous concurrence page

DISTRIBUTION:
ADAMS (PARS)
SECY
CA
OEMAIL
OEWEB
L Reyes, EDO
WKane, DEDR
MVirgilio, DEDMRT
JLamb, OEDO
CCarpenter, OE
SMerchant, OE
SWoods, OE
CMarco, OGC
GLongo, OGC
CMiller, FSME
GPangburn, FSME
RLewis, FSME
DRathbun, FSME
Enforcement Coordinators RII, RIII, RIV
LLopez, OE
NHilton, OE
MVazquez, RIV
CCarpenter, OE
SMagruder, OE
EHayden, OPA
HBell, OIG
GCaputo, OI
DScrenci, PAO-RI
NSheehan, PAO-RI
BHolian, RI
MMiller, RI
KFarrar, RI
DHolody, RI
ADeFrancisco, RI
RSummers, RI
RUrban, RI
CO'Daniell, RI
SVillar, RI
RIDNMS_Mail
Region I OE Files (with concurrences)

NOTICE OF VIOLATION
AND PROPOSED IMPOSITION OF CIVIL PENALTY

Digirad Imaging Solutions, Inc.
Poway, CA

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

During an NRC inspection conducted on July 20-25, 2006, as well as a subsequent investigation by the NRC's Office of Investigations (OI) which was completed on June 12, 2007, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (AEA) 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

A. 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

10 CFR 35.290 requires, in part, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under 10 CFR 35.200 to be a physician who has completed 700 hours of training and experience which must include work experience under the supervision of an authorized user who meets the requirements in 10 CFR 35.290, or 35.390 and 35.290(c)(ii)(G), or equivalent Agreement State requirements.
10 CFR 35.290(c)(2) requires that the licensee shall obtain written attestation, signed by a preceptor authorized user, who meets the requirements in 10 CFR 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Contrary to the above, on April 19, 2006, the licensee provided to the Commission information that was not complete and accurate in all material respects. Specifically, with its letter dated April 19, 2006, the licensee provided to the NRC a preceptor attestation in support of a request to add a physician as an authorized user to the license. The preceptor attestation stated that between 1988 and 2006, the physician had received clinical and work experience of not less than 700 hours in 2000 cases under the supervision of the preceptor. In fact, the physician had never worked with or under the supervision of the putative preceptor. Moreover, even if the physician had worked under the supervision of the preceptor, the physician was not qualified to become an authorized user because the preceptor was not an authorized user. The inaccurate information was material because it contributed to concealing that the physician had not met the requirements to become an authorized user and could have resulted in an individual being added to an NRC license who did not fully meet NRC requirements as an authorized user.

This is a Severity Level III violation (Supplement VII)
Civil Penalty - $3,250

B. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, from December 14, 2001 until April 7, 2006, the licensee did not secure from unauthorized removal or limit access to licensed material in the form of several 20-30 millicurie dosages of technetium-99m located at several clients' facilities, which were unrestricted areas, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, client physicians who were not authorized users on the license were allowed unauthorized access to this licensed material, since they had keys to the storage areas.

This is a Severity Level III violation (Supplement IV)
Civil Penalty - $3,250

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in the letter transmitting this Notice, in Inspection Report No. 03035802/2006002, in the additional information you provided at the January 17, 2008 conference, and/or in the DIS letter received by the NRC on January 25, 2008. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation under 10 CFR 2.201. Therefore, although you are required to provide a response to the Notice and Proposed Imposition of Civil Penalty, you are not required to respond to the provisions of 10 CFR 2.201 unless the description herein, as well as in the inspection report, does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond with additional information, clearly mark your response as a "Reply to a Notice of Violation; EA 07-223," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice.

The licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 (copy enclosed) and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a letter clearly marked "Statement as to Payment of Civil Penalty" indicating when and by what method payment was made.

The licensee may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the licensee fail to answer within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty, an order imposing the civil penalty will be issued. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Atomic Energy Act, 42 U.S.C. 2282c.

The responses noted above (Reply to a Notice of Violation; EA 07-223, Statement as to Payment of Civil Penalty, or Answer to a Notice of Violation) should be addressed to: Cynthia Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy addressed to: Samuel Collins, Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, PA 19406-1415.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 3rd day of April 2008.