



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

January 27, 2006

EA-05-136

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: NOTICE OF VIOLATION AND CONFIRMATORY ORDER (EFFECTIVE IMMEDIATELY) (NRC Office of Investigations Report No. 1-2004-034)

Dear Mr. Early:

In a letter dated September 15, 2005, the NRC provided you with the results of an investigation completed by the NRC Office of Investigations (OI), Region I Field Office, 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) DIGIRAD deliberately provided the inaccurate information to the NRC in a letter requesting a license amendment dated October 16, 2003. Our letter noted that, based on the evidence developed during 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 its license, and (2) DIGIRAD did not knowingly submit the false information to the NRC. A Factual Summary of the OI investigation was enclosed with our September 15, 2005, letter.

Our September 15, 2005, letter also informed you that, as a result of this OI investigation, and since licensees are responsible for the acts and omissions of its staff (including an AU), an apparent deliberate violation was identified and was being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. This apparent deliberate violation involved the submission of inaccurate information to the NRC regarding the previous experience and qualifications of a cardiologist. The inaccurate information was contained in an amendment request, dated October 16, 2003, for DIGIRAD's license. Specifically, in September 2003, a physician provided DIGIRAD: (1) a preceptor letter, signed by the Chairperson of the Radiology Department of the Greater Southeast Community Hospital (GSCH) attesting that the physician had the required minimum level of supervised clinical and work experience required by the NRC to be an AU; and (2) a statement that he was an AU on the GSCH NRC license. As a result of the OI investigation, the NRC determined that the physician did not have the required level of supervised clinical and work experience required to be an AU, nor was he listed as an AU on the GSCH NRC license.

In addition, our September 15, 2005, letter offered you a choice to (1) attend a Predecisional Enforcement Conference, or (2) request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve any disagreement on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party, and the NRC currently has a pilot program for using ADR. The technique that the NRC decided to employ during the pilot program, which is now in effect, is mediation.

At your request, an ADR mediation session was held between DIGIRAD and the NRC in King of Prussia, PA, on November 14, 2005. Based on the discussions during the ADR session, as well as subsequent discussions held on December 14 and 15, 2005, between Vera Pardee, Vice President and General Counsel for DIGIRAD, and Karl Farrar, Region I Counsel, a settlement agreement was reached regarding this matter. The elements of the settlement agreement are as follows:

1. Digirad Imaging Solutions, Inc. (DIGIRAD) agreed that a physician, listed as an Authorized User (AU) on DIGIRAD's NRC license, provided inaccurate information to DIGIRAD to become an AU on its license in careless disregard of NRC requirements. On October 16, 2003, DIGIRAD provided that information to the NRC in a request to amend its NRC license. The NRC agreed that DIGIRAD did not knowingly submit the inaccurate information to the NRC, but nonetheless, the NRC maintained that a violation in careless disregard of NRC requirements occurred because the licensee is responsible for the acts and omissions of its agents. DIGIRAD agreed that it must submit complete and accurate information to the NRC in accordance with 10 CFR 30.9(a). DIGIRAD maintained that the submission of inaccurate information was not in careless disregard of NRC requirements since it had no knowledge of the inaccuracies in the information provided to it by the AU. The NRC and DIGIRAD agreed to disagree on the violation being in careless disregard of NRC requirements.
2. DIGIRAD took the following corrective actions prior to attending the ADR Mediation Session on November 14, 2005.
 - (A) DIGIRAD immediately removed two AUs from its license as soon it became aware that the NRC was conducting an investigation;
 - (B) When DIGIRAD received the September 15, 2005, letter from the NRC that discussed the findings of the OI investigation and an apparent violation, DIGIRAD cancelled a contract it had with one of the AUs;
 - (C) DIGIRAD now attaches to physician and preceptor statements a notice equivalent to the following:

“Notice to Physician and Preceptor: 10 CFR Sections 30.9(a) and 30.10(a) require that all information provided to the Nuclear Regulatory Commission by a licensee or its agents shall be complete and accurate in all material respects. The submission of false information constitutes a serious violation of applicable regulations and may cause you or us to be fined, to lose licensing privileges, or to suffer other significant penalties.”

- (D) DIGIRAD now requires any physician that is added to its license to sign and date a document containing a statement equivalent to the following:

“In connection with my application to be named as an Authorized User on Digirad Imaging Solution’s (“DIS”) radioactive materials license, I am aware that the submission of information that is not complete and accurate in all material respects is a violation of 10 CFR Sections 30.9(a) and 30.10(a). I hereby represent and warrant that, to the best of my knowledge, the information I have submitted to DIS in connection with my application to be named as an Authorized User is complete and accurate in all material respects.”

3. As a means to provide added assurance to meet the requirements of 10 CFR 30.9(a) and 30.10(a), DIGIRAD agreed that for all future NRC AU applicants, on a yearly basis, it will audit the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10. DIGIRAD will audit by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by the AU applicants. This does not eliminate the requirement that DIGIRAD provide complete and accurate information to the NRC on all AU applicants. The results of this audit will be documented and submitted to the NRC at the end of a two-year period. However, DIGIRAD will notify the NRC as soon as practicable after identification of any discrepancies identified as a result of the audit. If no falsifications are uncovered during the two-year period, DIGIRAD will discontinue the practice.
4. DIGIRAD agreed to take other actions to ensure that similar violations will not recur. These actions will include the Vice President and Corporate Radiation Safety Officer preparing and submitting a commentary to the (a) Journal of Nuclear Medicine, (b) Journal of Nuclear Medicine Technology, and (c) Journal of Medical Physics to provide an opportunity for other licensees in the industry to learn from this incident. DIGIRAD will advise NRC upon completion of these items and not later than one year from the date of this agreement.
5. In light of the corrective actions that DIGIRAD has taken or has committed to take as described in Items 2, 3, and 4, the NRC agreed to issue a Severity Level III Notice of Violation to DIGIRAD (10 CFR 30.9(a)), but to not issue a Civil Penalty. This action will be publicly available in ADAMS and on the NRC “Significant Enforcement Actions” website, and the NRC will issue a press release announcing this action, as well as the actions DIGIRAD has taken and committed to take to address the violation.
6. DIGIRAD agreed to issuance of a Confirmatory Order confirming this agreement.

Enclosed with this letter is the Notice of Violation (Notice) and the Confirmatory Order (Order). You are not required to respond to this letter or Notice. However, in accordance with the settlement agreement, you are required to respond to the Order. Your written response to the

Order, and your response to the Notice, if you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Open by Addressee Only," within 30 days of the date of this letter.

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). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter, and its attached Notice of Violation and Confirmatory Order, on its website for a period of one year at www.nrc.gov; select **What We Do, Enforcement, Significant Enforcement Actions**. Your response, if you choose to provide one, will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions or comments concerning this letter, please contact Ms. Sally Merchant of my staff at 301-415-2747.

Sincerely,

/RA/

Michael Johnson, Director
Office of Enforcement

Enclosures: As Stated

Digirad Imaging Solutions, Inc.

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DATE	12/9/05		12/12/05		12/15/05		12/16/05		12/20/05			
OFFICE	RI/ORA	<input type="checkbox"/>	NMSS	<input type="checkbox"/>	HQ/OGC	<input type="checkbox"/>	HQ/OE	<input type="checkbox"/>	HQ/OE	<input type="checkbox"/>	RI/RA	<input type="checkbox"/>
NAME	DHolody		GMorell		BJones		C Nolan		MJohnson		SCollins	
DATE	12/20/05		12/21/05		01/04/06		1/27/06		1/26/06		12/20/05	

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NOTICE OF VIOLATION

Digirad Imaging Solutions, Inc.
Bemus Point, New York

Docket No. 03035802
License No. 31-30666-01
EA-05-136

During an investigation completed by the NRC Office of Investigations on June 15, 2005, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.9(a) requires, in part, that information provided to the Commission by an applicant for a license shall be complete and accurate in all material respects.

Contrary to the above, in a license amendment request dated October 16, 2003, DIGIRAD provided information to the NRC regarding training and experience of a physician which was not accurate in all material respects. Specifically, the licensee submitted a preceptor statement, signed by the Chairperson, Department of Radiology, Greater Southeast Community Hospital (GSCH), attesting that the physician had the required training and experience to be named as an Authorized User (AU) on the Digirad NRC license. In addition, the licensee submitted a statement from the physician asserting that he was listed as an AU on the GSCH NRC license. These statements were inaccurate because (1) the physician did not have the required training and experience as described in the preceptor statement, and (2) the physician was not listed as an AU on the GSCH NRC license.

This is a Severity Level III violation (Supplement VII).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved has been already adequately addressed in the letter forwarding this Notice, and at the ADR mediation session held on November 14, 2005. Therefore, you are not required to respond to this violation. However, if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-05-136," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I within 30 days of the date of the letter transmitting this Notice

Because your response 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>, to the extent possible, it 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, 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 withholding of such material, 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.

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

Dated this 27th day of January 2006

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of
Digirad Imaging Solutions, Inc.

EA-05-136

CONFIRMATORY ORDER
(EFFECTIVE IMMEDIATELY)

I

Digirad Imaging Solutions, Incorporated (DIGIRAD or Licensee) is the holder of Byproduct Material License 31-30666-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. This mobile medical license authorizes possession of radionuclides for medical diagnosis, including uptake, dilution and excretion studies permitted by 10 CFR 35.100; and imaging and localization studies permitted by 10 CFR 35.200. The license further authorizes possession and use of byproduct material at specified facilities located in Indiana, Michigan, Missouri, New Jersey, Pennsylvania, Virginia, and West Virginia. The license also authorizes use of byproduct material at temporary jobsites of the licensee anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. The license was originally issued on August 21, 2001, was due to expire on July 31, 2005, and is currently under timely renewal pursuant to 10 CFR 30.36(a)(1).

II

On August 6, 2004, the NRC Office of Investigations (OI) initiated an investigation (OI Case No. 1-2004-034) to determine if a physician listed on the DIGIRAD NRC license submitted false information to DIGIRAD in October 2003 to become an Authorized User (AU) on its existing NRC

license. Based on the evidence developed during its investigations, OI substantiated that false and/or inaccurate information was submitted to DIGIRAD by the physician for the purpose of adding that physician as an AU on the existing DIGIRAD NRC license. The results of the investigation completed on June 15, 2005, were sent to DIGIRAD in a letter dated September 15, 2005. This letter stated that a physician listed as an AU on DIGIRAD's NRC license deliberately provided inaccurate information to DIGIRAD to become an AU on DIGIRAD's license, but that DIGIRAD did not knowingly submit the false information to the NRC in an amendment request dated October 16, 2003, that it submitted to the NRC to add the physician to the list of AUs on the license.

III

Subsequent to becoming aware of the NRC investigation and of the apparent violation, DIGIRAD took several actions to assure that these events would not recur. These actions included:

(a) immediately removing two AUs from its license; (b) cancelling a contract it had with one of the physicians; (c) attaching to physicians and preceptors statement form a notice equivalent to the following: **“Notice to Physician and Preceptor: 10 CFR Sections 30.9(a) and 30.10(a) require that all information provided to the Nuclear Regulatory Commission by a licensee or its agents shall be complete and accurate in all material respects. The submission of false information constitutes a serious violation of applicable regulations and may cause you or us to be fined, to lose licensing privileges, or to suffer other significant penalties.”**; and (d) requiring any physician that is added to its license to sign and date a document containing a statement equivalent to the following: **“In connection with my application to be named as an Authorized User on Digirad Imaging Solution's (“DIS”) radioactive materials license, I am aware that the submission of information that is not complete and accurate in all material**

respects is a violation of 10 CFR Sections 30.9(a) and 30.10(a). I hereby represent and warrant that, to the best of my knowledge, the information I have submitted to DIS in connection with my application to be named as an Authorized User is complete and accurate in all material respects.”

Also, in response to the NRC’s September 15, 2005, letter, DIGIRAD requested the use of Alternative Dispute Resolution (ADR) to resolve this apparent violation and pending enforcement action. ADR is a process in which a neutral mediator, with no decision-making authority, assists the NRC and DIGIRAD to resolve any disagreements on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. An ADR session was held between DIGIRAD and the NRC in King of Prussia, PA, on November 14, 2005, and was mediated by a professional mediator, arranged through Cornell University’s Institute of Conflict Management. Based on discussions at the ADR mediation session, as well as subsequent discussions held on December 14 and 15, 2005, between Vera Pardee, Vice President and General Counsel for DIGIRAD, and Karl Farrar, Region I Counsel, a settlement agreement was reached. The elements of the settlement agreement consisted of the following:

7. The NRC and DIGIRAD agreed to disagree on the violation being in careless disregard of NRC requirements.
8. DIGIRAD took the corrective actions described in Section II above prior to attending the ADR Mediation Session on November 14, 2005.
9. As a means to provide added assurance to meet the requirements of 10 CFR 30.9(a) and 30.10(a), DIGIRAD agreed that for all future NRC AU applicants, on a yearly basis, it will

audit the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10. DIGIRAD will audit by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by the AU applicants. This does not eliminate the requirement that DIGIRAD provide complete and accurate information to the NRC on all AU applicants. The results of this audit will be documented and submitted to the NRC at the end of a two-year period. However, DIGIRAD will notify the NRC as soon as practicable after identification of any discrepancies identified as a result of the audit. If no falsifications are uncovered during the two-year period, DIGIRAD will discontinue the practice.

10. In addition, DIGIRAD will take other actions to ensure that similar violations will not recur. These actions will include the Vice President and Corporate Radiation Safety Officer preparing and submitting a commentary to (a) the Journal of Nuclear Medicine, (b) the Journal of Nuclear Medicine Technology, and (c) the Journal of Medical Physics to provide an opportunity for other licensees in the industry to learn from this incident. DIGIRAD will advise NRC upon completion of these items and not later than one year from the date of this agreement.
11. In light of the corrective actions that DIGIRAD has taken or has committed to take as described in Items 2, 3 and 4, the NRC agreed to issue a Severity Level III Notice of Violation to DIGIRAD (10 CFR 30.9(a)), but to not issue a Civil Penalty. This action will be publicly available in ADAMS and on the NRC "Significant Enforcement Actions" website, and the NRC will issue a press release announcing this action, as well as the actions DIGIRAD has taken and committed to take to address the violation.
12. DIGIRAD agreed to issuance of a Confirmatory Order confirming this agreement.

IV

In light of the actions DIGIRAD has taken and agreed to take to correct the violation and prevent recurrence, as set forth in Section III above, the NRC has concluded that its concerns regarding the violation can be resolved through the NRC's confirmation of the commitments as outlined in this Confirmatory Order.

I find that DIGIRAD's commitments as set forth in Section III above are acceptable. However, in view of the foregoing, I have determined that these commitments shall be confirmed by this Confirmatory Order. Based on the above and DIGIRAD's consent, this Confirmatory Order is immediately effective upon issuance.

V

Accordingly, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR § 2.202 and 10 CFR Part 30 and 35, IT IS HEREBY ORDERED, THAT BY AUGUST 23, 2006:

1. DIGIRAD will audit, for all future NRC AU applicants, on a yearly basis, the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10. DIGIRAD will audit by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by the AU applicants. This does not eliminate the requirement that DIGIRAD provide complete and accurate information to the NRC on all AU applicants. The results of this audit will be documented and submitted to the NRC at the end of a two-year period. However, DIGIRAD

will notify the NRC as soon as practicable after identification of any discrepancies identified as a result of the audit. If no falsifications are uncovered during the two-year period, DIGIRAD will discontinue the practice.

2. The DIGIRAD Vice President and Corporate Radiation Safety Officer will prepare and submit a commentary regarding this violation to the Journals of Nuclear Medicine, Nuclear Medicine Technology, and Medical Physics to provide an opportunity for other licensees in the industry to learn from this incident.
3. DIGIRAD will advise NRC upon completion of these items and not later than one year from the date of this agreement.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above conditions upon a showing by DIGIRAD of good cause.

VI

Any person adversely affected by this Confirmatory Order, other than DIGIRAD, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, D.C. 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission,

Washington, D.C. 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, to the Director of the Division of Regulatory Improvement Programs at the same address, and to MSHMC. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to hearingdocket@nrc.gov and also to the Office of the General Counsel by means of facsimile transmission to 301-415-3725 or e-mail to OGCMailCenter@nrc.gov. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained. AN ANSWER OR A REQUEST FOR A HEARING SHALL NOT STAY THE EFFECTIVENESS DATE OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Michael Johnson, Director
Office of Enforcement

Dated this 27th day of January 2006