

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

April 7, 2006

Docket No. 03035802 CAL No. 1-06-003 License No. 31-3

31-30666-01

Paul J. Early Vice President and Radiation Safety Officer Digirad Imaging Solutions, Inc. P.O. Box 340 Bemus Point, NY 14712

SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-06-003

Dear Mr. Early:

License Number 31-30666-01 for Digirad Imaging Solutions, Inc. (Digirad), a mobile service provider, located in Bemus Point, New York, authorizes mobile nuclear medicine activities at base and client sites. 10 CFR 35.80(b) states that a mobile service provider 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.

Following numerous discussions in support of your license renewal, on March 31, 2006, you acknowledged that you do not own or lease the property that you have been using as base facilities at six locations where you perform services for clients. The locations are in New Jersey, Pennsylvania, and Indiana. You further indicated that licensed material was delivered to these client sites and received by the clients.

Pursuant to a telephone conversation with Penny Lanzisera and Tara Weidner of this office, on April 5, 2006, you committed to discontinue delivery of licensed material to these six client sites. In a letter dated April 6, 2006, you confirmed that both the clients and the radiopharmacies supplying these clients were notified on April 5, 2006 of this agreement. However, in Item 3 of your letter you stated that Digirad could continue servicing clients out of the base locations if you had an agreement with the clinical site that included an understanding of exclusive access to areas of receipt and/or storage of radioactive materials by Digirad personnel or authorized agents of Digirad (e.g. radiopharmacy personnel). Such an agreement with your clients does not meet the requirements of 10 CFR 35.80(b). We will review your proposed client agreement as a request for an exemption to 10 CFR 35.80(b) and will notify you of the results of that review in a separate correspondence.

Pursuant to a telephone conversation between you, Tara Weidner and Pamela Henderson of this office on April 7, 2006, it is our understanding that you have taken or will take the following actions:

- 1. Immediately cease delivery of licensed material to all client sites for which you do not have control of the facilities by either a formal written lease agreement with the facility owner, or ownership of the facility;
- 2. Immediately remove all licensed material currently stored at client sites for which you do not have control of the facilities by either formal written lease agreement with the facility owner, or ownership of the facility; and
- 3. By April 30, 2006, 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 your license is a client facility.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

- 1) Notify me immediately if your understanding differs from that set forth above;
- Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and
- 3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee, nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

Current NRC regulations are included on the NRC's website at <u>www.nrc.gov</u>; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then **toolkit index page.** The current NRC Enforcement Policy is included on the NRC's website at <u>www.nrc.gov</u>; select **What We Do, Enforcement,** then **Enforcement Policy.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR 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

P. Early

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.

Sincerely,

Original signed by Pamela Henderson

George Pangburn, Director Division of Nuclear Materials Safety

cc: Commonwealth of Pennsylvania State of Indiana State of New Jersey State of New York P. Early

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