



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

July 13, 2006

Docket No. 03035802
Control No. 138704

License No. 31-30666-01

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

SUBJECT: DIGIRAD IMAGING SOLUTIONS, INC., LICENSE AMENDMENT, CONTROL
NO. 138704

Dear Mr. Early:

This refers to the license amendment requests in your letters dated April 14, 2006 and May 2, 2006. Enclosed with this letter is the amended license adding the base locations at 1 Bartol Avenue, Suite 10, Ridley Park, Pennsylvania and 100 Washington Street, Michigan City, Indiana.

In your letter dated March 31, 2006 you requested an exemption to 10 CFR 35.80(b) to permit byproduct material to be delivered directly to a secured hot lab located within a client's property, without Digirad Imaging Solutions, Inc. (DIS) personnel being present to receive it. As an alternative, in your letter dated April 14, 2006, you requested an exemption to 10 CFR 35.80(b) to permit receipt of byproduct material in the DIS mobile gamma-camera transport van, parked on a client's property and occupied by trained DIS personnel. The Region I office requested a review of your application and exemption requests by the NRC, Division of Industrial and Medical Nuclear Safety (NMSS).

Based on the NMSS review, the exemption request to receive and store byproduct material at client locations when DIS personnel are not present to receive it has been denied. Receipt of byproduct material at a client site may be approved if information is submitted which clearly demonstrates that DIS personnel will be present at the client facility to accept delivery and ensure security and control of the licensed material.

As an alternative, a client site, that is neither owned nor leased by DIS may be listed on the license as a base location if a written agreement between DIS and the client for each site is provided which includes:

- a. a diagram of the receipt and storage location,
- b. confirmation that the DIS has sole access to the receipt/storage location, and
- c. confirmation that in the event of disharmony between DIS and the client, DIS will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary.

P. Early
Digirad Imaging Solutions, Inc.

2

Client sites that are listed on the DIS license as base locations may have licensed material delivered to and stored at these locations without DIS personnel being present to receive it.

The request for an exemption to 10 CFR 35.80(b) to permit receipt of byproduct material in the DIS mobile gamma-camera transport van, parked on a client's property and occupied by trained DIS personnel may be approved if information is submitted which clearly demonstrates that DIS personnel will be present to accept delivery and ensure the security and control of the licensed material.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. 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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 46

DOCUMENT NAME: E:\Filenet\ML061950016.wpd

SUNSI Review Complete: TWeidner

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|--------|--------------|---|----------------|---|---------|--|--|--|
| OFFICE | DNMS/RI | N | DNMS/RI | N | DNMS/RI | | | |
| NAME | TWeidner/TLW | | PHenderson/PJH | | | | | |
| DATE | 7/13/2006 | | 7/13/2006 | | | | | |

OFFICIAL RECORD COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

| | | |
|--|---|---|
| <p>Licensee</p> <p>1. Digirad Imaging Solutions, Inc</p> <p>2. P.O. Box 340 Bemus Point, New York 14712</p> | <p>In accordance with the letters dated April 14, 2006 and May 2, 2006,</p> <p>3. License number 31-30666-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2016</p> <hr/> <p>5. Docket No. 030-35802 Reference No.</p> | |
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> |
| <p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p> | | |

CONDITIONS

10. A. Licensed material may be used or stored at the licensee's facilities located at 1811 Executive Drive, Suite 1, Building #18, Indianapolis, Indiana; 1203 North High Street, Unit B, Millville, New Jersey; 24301 Catherine Industrial Drive, Suite 112A, Novi, Michigan; 212 West Spring Street, Frackville, Pennsylvania; Westpark Business Center, 7584 Morris Court, Suite 228, Allentown, Pennsylvania; 50 Williams Parkway, East Hanover, New Jersey; 10727 Trenton, St. Louis, Missouri; 1433 East Michigan Avenue, Lansing, Michigan; 840 Hospital Drive, Blacksburg, Virginia; 5215 Monticello Avenue, Suite A, Williamsburg, Virginia; 223 S. Church, Suite A, Ripley, West Virginia; 77 Pension Road, Unit #15, Manalapan, New Jersey; 100 Washington Street, Michigan City, Indiana; 1 Bartol Avenue, Suite 10, Ridley Park, Pennsylvania; and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
31-30666-01

Docket or Reference Number
030-35802

Amendment No. 46

If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

- B. Licensed material may be delivered to the licensee's mobile van located at temporary job sites when trained licensee personnel are present to receive the licensed material. Licensed material may not be stored in the mobile van when trained licensee personnel are not present.
11. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

| <u>Authorized Users</u> | <u>Material and Use</u> |
|-----------------------------|-------------------------|
| Bindukumarc Kansupada, M.D. | 35.100; 35.200 |
| Geetha M. Reddy, M.D. | 35.100; 35.200 |
| David Kovacich, M.D. | 35.100; 35.200 |
| Joel S. Raichlen, M.D. | 35.100; 35.200 |
| Christopher J. Hollon, M.D. | 35.200 |
| Frank J. Conte, M.D. | 35.100; 35.200 |
| J. William Whitaker, M.D. | 35.200 |
| Nathan E. Millikan, M.D. | 35.100; 35.200 |
| Leonard Feitell, M.D. | 35.200 |
| Robert Litchfield, D.O. | 35.100; 35.200 |
| Anirudh Khanna, M.D. | 35.200 |
| Charles H. Curtiss, D.O. | 35.100; 35.200 |
| Elmer P. Manalo, M.D. | 35.200 |
| Jeffrey Rogers, M.D. | 35.200 |
| Benny Sin-Ping Ko, M.D. | 35.200 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
31-30666-01

Docket or Reference Number
030-35802

Amendment No. 46

| <u>Authorized Users</u> | <u>Material and Use</u> |
|---------------------------------|-------------------------|
| Susan Farkas, M.D. | 35.200 |
| John P. Smith, D.O. | 35.200 |
| Barry E. Shapiro, D.O. | 35.200 |
| Edward H. Aprahamian, D.O. | 35.100; 35.200 |
| Christopher J. Ostromecki, M.D. | 35.200 |
| Rodolfo Farhy, M.D. | 35.200 |
| Amando C. Madrozo, M.D. | 35.200 |
| Ahmad Bahjat Shahbandar, M.D. | 35.200 |
| Michael Shen, M.D. | 35.200 |
| Parag A. Madhani, M.D. | 35.200 |
| Anthony J. Cossell, M.D. | 35.200 |
| Nate E. Lebowitz, M.D., FACC | 35.200 |
| Won Chae, M.D. | 35.100; 35.200 |
| Santosh M. Pandit, M.D. | 35.200 |
| Zubair Khan, M.D. | 35.200 |
| Ponnambalam Sundram, M.D. | 35.200 |
| Kusai S. Aziz, M.D. | 35.200 |
| Edward D. Williams, M.D. | 35.100; 35.200 |
| David T. Rayne, M.D. | 35.100; 35.200 |
| Brian J. McVey, M.D. | 35.100; 35.200 |
| John H. Chotkowski, M.D. | 35.100; 35.200 |
| John R. Mootz, M.D. | 35.100; 35.200 |
| Jude A. Leblanc, M.D. | 35.100; 35.200 |
| Edwin P. Hutsal, M.D. | 35.100; 35.200 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
31-30666-01

Docket or Reference Number
030-35802

Amendment No. 46

| <u>Authorized Users</u> | <u>Material and Use</u> |
|-----------------------------|-------------------------|
| Debbie Wright, M.D. | 35.200 |
| Adel Yaaskoub, M.D. | 35.200 |
| Daniel E. Stobbe, M.D. | 35.200 |
| Rajendra Vallabhaneni, M.D. | 35.200 |
| Steven Craig Vranian, M.D. | 35.200 |
| Michael J. Fleissner, M.D. | 35.200 |
| S. Craig Vranian, M.D. | 35.200 |
| Vasudev G. Ananthram, M.D. | 35.200 |
| Lane J. Benoff, M.D. | 35.200 |
| Jack Newman, M.D. | 35.200 |
| Raed Bargout, M.D. | 35.200 |
| Salvador Borges-Neto, M.D. | 35.200 |
| John Scott, D.O. | 35.100; 35.200 |
| Gregory J. Elberfeld, M.D. | 35.100; 35.200 |
| Krishnakant Raiker, M.D. | 35.100; 35.200 |
| Mark Karabajakian, D.O. | 35.100; 35.200 |
| Andrew Keenan, M.D. | 35.100; 35.200 |
| David I. Freilich, M.D. | 35.200 |
| Mark Younis, M.D. | 35.100; 35.200 |
| Larry Handlin, D.O. | 35.100; 35.200 |

12. The Radiation Safety Officer for this license is Paul J. Early.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
31-30666-01Docket or Reference Number
030-35802

Amendment No. 46

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated June 29, 2005 [ML051870153]
 - B. Letter dated December 4, 2005 [ML053530235]
 - C. Letter dated May 24, 2006 [ML061460398]
 - D. Letter dated April 14, 2006 [ML061090217]
 - E. Letter dated May 2, 2006 [ML061220665]

For the U.S. Nuclear Regulatory Commission

Date July 13, 2006

By

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Region I
King of Prussia, Pennsylvania 19406