



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

November 29, 2004

Docket No. 03036657
Control No. 135601

License No. 29-30951-01

Borys R. Krynycky, M.D.
Radiation Safety Officer/Owner
Personal Care Molecular Imaging
1514 Highway 138
Wall, NJ 07719

**SUBJECT: PERSONAL CARE MOLECULAR IMAGING, ISSUANCE OF NEW LICENSE,
CONTROL NO. 135601**

Dear Dr. Krynycky:

This refers to your request for an NRC license. Enclosed with this letter is the license. Please note that your license was written in a format compatible with the revised 10 CFR Part 35, dated April 24, 2002 (enclosed). Please review the enclosed document carefully and be sure that you understand all conditions. 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.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. Please note that the last condition on your license indicates that "This license condition applies only to those procedures that are required to be submitted in accordance with the regulations." Therefore, any procedures submitted that were not required by regulation to be submitted, e.g., calibration of dose calibrators, will not be considered a part of your license and were not reviewed during the licensing process. These procedures will be reviewed during inspections, as necessary.

Please note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify the NRC in writing when:

- a) an authorized user, authorized nuclear pharmacist, authorized medical physicist or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
 - b) the mailing address changes;
 - c) the name on the license changes; or
 - d) permitting an individual to function as a temporary Radiation Safety Officer in accordance with 10 CFR 35.24(c).
3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
- a) when you decide to terminate all activities involving materials authorized under the license; or
 - b) if you decide not to acquire or possess and use authorized material.
4. Request and obtain a license Amendment before you:
- a) permanently change Radiation Safety Officers;
 - b) receive byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or
 - c) add or change the areas of use, except as allowed by 10 CFR 35.13(e) and with the appropriate notification described in 10 CFR 35.14(b)(4);
 - d) change the name or ownership of your organization;
 - e) change the address(es) of use identified on the license;
 - f) receive, prepare, or use byproduct material for a type of use that is not authorized on the license;
 - g) permit anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist, except as allowed by 10 CFR 35.13(b) and with the appropriate notification described in 10 CFR 35.14(a); or
 - h) revise procedures required by 10 CFR 35.610, 35.642, 35.643, or 35.645, as applicable, where such revision reduces radiation safety.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in NUREG 1600, "General Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy).

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

In accordance with 10 CFR 2.390, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>.

Thank you for your cooperation.

Sincerely,

Original signed by Tara L. Weidner

Tara L. Weidner
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosures:

1. License No. 29-30951-01
2. 10 CFR Parts 19, 20, 21, 30, 35, 71, 170, and 171
3. NRC Forms 3, 313, and 531
4. Section 206 of the Energy Reorganization Act of 1974
5. NUREG 1600, General Policy and Procedure for NRC Enforcement Actions (Enforcement Policy)

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| OFFICE | DNMS/RI | N | DNMS/RI | N | DNMS/RI | | | |
| NAME | RRagland/TLW for | | TWeidner/TLW | | | | | |
| DATE | 11/29/04 | | 11/29/04 | | | | | |

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.

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|---|--|
| Licensee | |
| 1. Personal Care Molecular Imaging | 3. License number 29-30951-01 |
| 2. 1514 Highway 138 Wall, New Jersey 07719 | 4. Expiration date November 30, 2014 |
| | 5. Docket No. 030-36657 Reference No. |

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|---|----------------------------------|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Any byproduct material permitted by 10 CFR 35.200 | A. Any | A. As needed |

9. Authorized use:
A. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1514 Highway 138, Wall, New Jersey.
- 11. The Radiation Safety Officer for this license is Borys R. Krynyckyi, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user 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> |
| Borys R. Krynyckyi, M.D. | 35.200 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-30951-01

Docket or Reference Number
030-36657

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.
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 August 30, 2004
B. Letter dated November 26, 2004 (Change of Address)

For the U.S. Nuclear Regulatory Commission

Date November 29, 2004

By ***Original signed by Tara L. Weidner***

Tara L. Weidner
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406