

July 9, 2008

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

Re: Amendment to 13-09788-01

Dear Madam or Sir:

We wish to amend our Material's License 13-09788-01 as follows:

ADD AUTHORIZED USER

Shamin Dada, M.D. for 10 CFR 35.100, 35.200, 35.300

In support of this request we have attached a copy of Materials License 13-32273-01 which notes Dr. Dada as an authorized user.

If you have any questions, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S., DABR of Medical Physics Consultants, Inc. 800.321.2207 or tkumpuris@mpcphysics.com.

Sincerely,



Terrance Wilson, CEO Saint Elizabeth Regional Health

RECEIVED JUL 17 2008



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

MAR 21 2008

Paul E. Gandy, M.D.
Radiation Safety Officer
St. Elizabeth Regional Health
d/b/a Greater Lafayette Health Services, Inc.
2400 South Street
Lafayette, IN 47904-3027

Dear Dr. Gandy:

Enclosed is Amendment No. 58 to your NRC Material License No. 13-09788-01 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

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 III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

A handwritten signature in cursive script that reads "Toye L. Simmons".

Toye L. Simmons
Materials Licensing Branch

License No. 13-09788-01
Docket No. 030-01642

Enclosure: Amendment No. 58

U.S. NUCLEAR REGULATORY COMMISSION

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 style="text-align: center;">Licensee</p> <p>1. St. Elizabeth Regional Health d/b/a Greater Lafayette Health Services, Inc. Nuclear Medicine Department</p> <p>2. 2400 South Street Lafayette, IN 47904-3027</p> | <p>In accordance with letter dated January 1, 2008,</p> <p>3. License number 13-09788-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date November 30, 2013</p> <hr/> <p>5. Docket No. 030-01642 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>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 35.500</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources (Mills Biopharmaceuticals Model I-125 SL & SH; Best Industries Model 2300 series; Theragenics Model 200; Nuclear Enterprises Model 2503/3; IAI-125A (Advantage™ I-125))</p> <p>E. Sealed sources (North American Scientific, Inc. Model MED 3601, Du Pont Merck Pharmaceutical Company Model NES-8412 or Isotopes Products Laboratories, Inc. Model A3410)</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>C. As needed (not to exceed 1 curie of iodine-131)</p> <p>D. One curie</p> <p>E. 0.3 curies per source and 2 curies total</p> |
|--|--|--|

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 58

9. Authorized Use:
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
 - B. Any imaging and localization study permitted by 10 CFR 35.200.
 - C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
 - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
 - E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

CONDITIONS

10. Licensed material listed in Subitems 6.A. through 6.E. shall be used at the licensee's facilities located at Lafayette Home Hospital, 2400 South Street, Lafayette, Indiana and St. Elizabeth Medical Center, 1501 Hartford Street, Lafayette, Indiana.
11. The Radiation Safety Officer is Paul E. Gandy, 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 in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users

Material and Use

| | |
|--------------------------|--|
| David R. Schmidt, M.D. | 10 CFR 35.200 and 35.500. |
| Adel Yaacoub, M.D. | 10 CFR 35.200 and 35.500. |
| Irene C. Gordon, M.D. | 10 CFR 35.300, 35.400 and 35.500. |
| Debbie Wright, M.D. | 10 CFR 35.200 and 35.500. |
| Robert Mehl, M.D. | 10 CFR 35.100, 35.200, 35.300 (limited to sodium iodide I-131) and 35.500. |
| John F. Fiederlein, M.D. | 10 CFR 35.100, 35.200, 35.300, and 35.500. |
| Steven B. Jones, M.D. | 10 CFR 35.100, 35.200, and 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries), and 35.500. |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 58

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| Sam Hansen, M.D. | 10 CFR 35.100, 35.200, and 35.500. |
| Timothy J. Lach, M.D. | 10 CFR 35.100, 35.200, 35.300, and 35.500. |
| Alexander Boutselis, M.D. | 10 CFR 35.100, 35.200, 35.300, and 35.500. |
| Paul E. Gandy, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| William J. Miller, M.D. | 10 CFR 35.100, 35.200, and 35.300. |
| Paul DesRosiers, M.D. | 10 CFR 35.400. |
| Loubna T. Scally, M.D. | 10 CFR 35.400 |
| Michael F. Busch, M.D. | 10 CFR 35.100 and 35.200. |

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. 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.
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 August 29, 2003; and
- B. Letters dated November 25, 2003 and February 26, 2004.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

MAR 21 2008

Date _____

By _____

Toye L. Simmons
Toye L. Simmons
Materials Licensing Branch
Region III

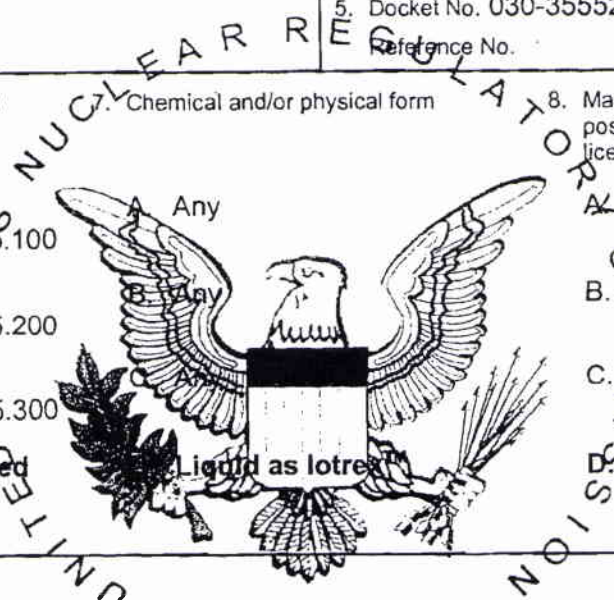
MATERIALS LICENSE

Corrected copy

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. InnerVision Advanced Medical Imaging Center LLC, 2. 3801 Amelia Avenue Suite A Lafayette, IN 47905</p> | <p>In accordance with letter dated August 15, 2006 and September 13, 2006,</p> <p>3. License number 13-32273-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date November 30, 2010</p> <p>5. Docket No. 030-35552</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>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Iodine-125, as permitted by 10 CFR 35.1000</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Liquid as lotrex</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>C. As needed (not to exceed one curie of iodine-131)</p> <p>D. 8.0 curies</p> |
|---|--|--|



9. Authorized Use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. **For medical use permitted by 10 CFR 35.1000, in the Cytoc Surgical Products GliaSite® Radiotherapy System.**

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 3801 Amelia Avenue, Lafayette, Indiana.
- 11. The Radiation Safety Officer for this license is John Fiederlein, M.D.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-32273-01

Docket or Reference Number
030-35552

Amendment No. 07
Corrected copy

12. 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> |
|------------------------------|--|
| Alexander G. Boutselis, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| Steven B. Jones, M.D. | 10 CFR 35.100, 35.200 and 35.300 (excluding thyroid carcinoma therapy). |
| John F. Fiederlein, M.D. | 10 CFR 35.100, 35.200 and 35.300. |
| Irene C. Gordon, M.D. | 10 CFR 35.300. |
| Stephen J. Matthews, M.D. | 10 CFR 35.100, 35.200 and 35.300 (excluding thyroid carcinoma therapy). |
| Debbie Wright, M.D. | 10 CFR 35.200. |
| Adel Yaacoub, M.D. | 10 CFR 35.200. |
| Paul DesRosiers, M.D. | Administering ¹²⁵ I in the Cytoc Surgical Products GliaSite® Radioactive Source |
| Shamin Dada, M.D. | 10 CFR 35.100, 35.200 and 35.300 |



- 13. In addition to the possession limits in ~~13~~ 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limits 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."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

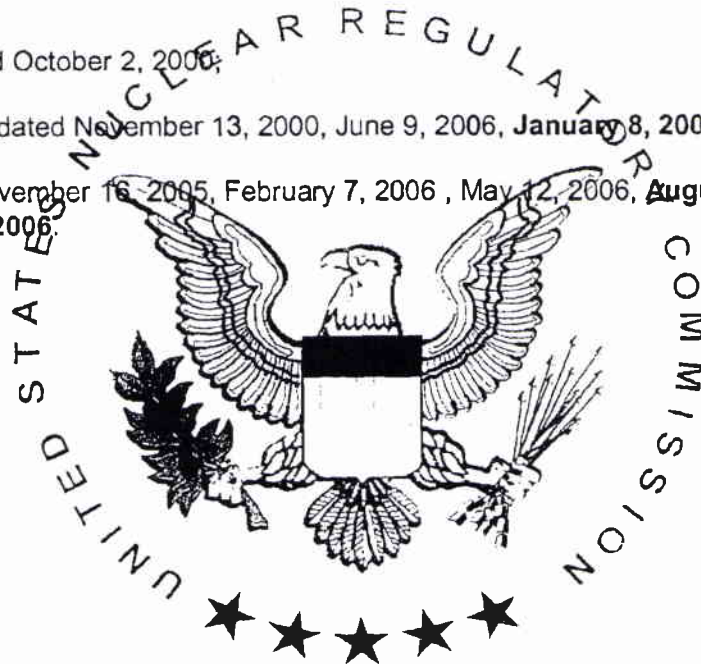
License Number
13-32273-01

Docket or Reference Number
030-35552

Amendment No. 07

Corrected copy

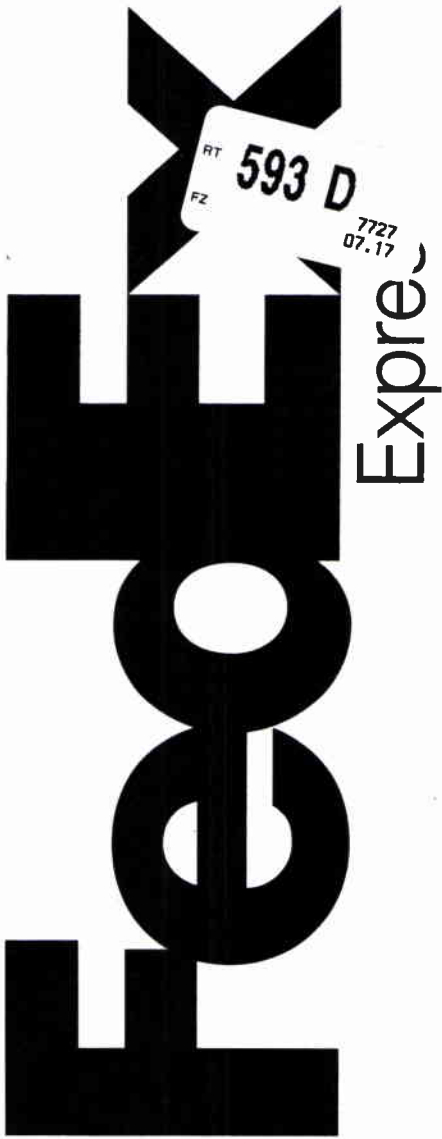
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are 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 October 2, 2000;
- B. Fax transmittals dated November 13, 2000, June 9, 2006, ~~January 8, 2007~~; and
- C. Letters dated November 16, 2005, February 7, 2006, May 12, 2006, ~~August 15, 2006~~ and ~~September 13, 2006~~.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JAN 18 2007

By *Toye L. Simmons*
Toye L. Simmons
Materials Licensing Branch
Region III



From: Origin: ID LAF4 (765)423-6073
REC: DEPARTMENT
ST ELIZABETH
1501 HARTFORD ST

LAFAYETTE, IN 47904



Ship Date: 16JUL08
ActWgt: 1 LB
System#: 4048122/INET8061
Account#: S*****

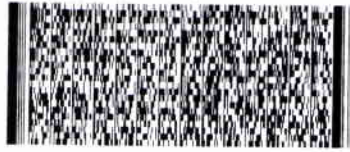
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Ref #
Invoice #
PO #
Dept #

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REGION III--MATERIALS LICENSING BR
US NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE RD STE 210

LISLE, IL 605324352

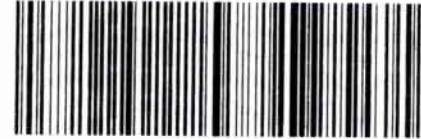


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