

November 17, 2017

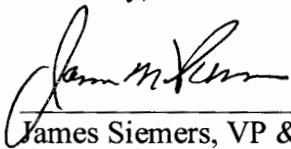
U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

Franciscan Health - Lafayette East (Byproduct Materials license number 13-09788-01) would like to add Gary Malnar, D.O. as an authorized user of 35.100, 35.200, and 35.300 (limited to oral administrations of sodium iodide I-131 in quantities less than or equal to 33 mCis) materials. Dr. Malnar is currently listed on the license of Franciscan St. Anthony Health - Crown Point (Byproduct Materials license number 13-15933-01) for the same materials use. A copy of the license is enclosed.

If there are any questions concerning this amendment request, please contact our nuclear medicine physicist, Bryce A. Caudle, at 317-443-9035 or by email at bcaudle@mpcphysics.com.

Sincerely,



James Siemers, VP & COO
Executive Management

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 4 PAGES
Amendment No. 32

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, 37, 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. Franciscan St. Anthony Health-Crown Point</p> <p>2. 1201 South Main Street Crown Point, Indiana 46307</p>	<p>In accordance with letter dated April 18, 2015,</p> <p>3. License number 13-15933-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2022</p> <hr/> <p>5. Docket No. 030-10047 Reference No.</p>
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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 35.100	A. Any	A. As needed.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. One Curie.
D. Cesium-137 as permitted by 10 CFR 35.400	D. Sealed Sources (Radiation Therapy Resources, Inc. Model Nos. 1862, 1864, and 1866)	D. 1200 millicuries.
E. Iodine-125 as permitted by 10 CFR 35.400	E. Sealed Sources (Bard Brachytherapy Model No. STM1251)	E. 300 millicuries.
F. Iridium-192 as permitted by 10 CFR 35.400	F. Sealed Sources (Best Medical International, Inc. Model No. 81-01)	F. 500 millicuries.
G. Strontium-90 as permitted by 10 CFR 35.400	G. Sealed Sources (Amersham International Model No. SIA.20)	G. 100 millicuries.
H. Gadolinium-153	H. Sealed rod source	H. 1 source not to exceed 1 millicurie.

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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-15933-01

Docket or Reference Number
030-10047

Amendment No. 32

- I. Any byproduct material permitted by 10 CFR 31.11 I. Prepackaged Kits I. 2 millicuries.

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. through G. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
 H. For storage only incident to disposal.
 I. In vitro studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at St. Anthony Medical Center, Inc., 1201 South Main Street, Crown Point, Indiana.
11. The Radiation Safety Officer for this license is Frank Godlewski, M.S.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

H. S. Kim, M.D.

10 CFR 35.100, 35.200, and 31.11.

Abdul W. Khan, M.D.

10 CFR 35.400.

Mir J. Shah, M.D.

10 CFR 35.400.

Geetha Narasimhan, M.D.

10 CFR 35.300 and 35.400.

Mohammed A. Abbas, M.D.

10 CFR 35.100, 35.200, and 31.11.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

13-15933-01

Docket or Reference Number

030-10047

Amendment No. 32

Authorized UsersMaterial and Use~~A. Melinda Liller, M.D.~~

10 CFR 35.100, 35.200, 35.300, and 31.11.

Trent G. Orfanos, M.D.

10 CFR 35.100 and 35.200.

Boris Sagalovsky, M.D.

10 CFR 35.100 and 35.200.

~~David P. Megramis, D.O.~~

10 CFR 35.100, 35.200 and 35.300.

Perry M. Gilbert, M.D.

10 CFR 35.100, 35.200 and 35.300.

Gregory Henkle, M.D.

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries.

Joseph E. Judge, M.D.

10 CFR 35.100 and 35.200.

Michael A. Wilczynski, D.O.

10 CFR 35.100 and 35.200.

✓ Jong-Il Marcus Lee

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries.

- Peter John Georgis, M.D.

10 CFR 35.100, 35.200, and 35.300.

Saud S. Ahmed, M.D.

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131. *only one for Xofigo*

Matthew J. Rose, M.D.

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131.

Richard Dobben, M.D.

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131. *NO Xofigo*

Steven R. Klepac, M.D.

10 CFR 35.100, and 35.200.

Garry Malnar, D.O.

10 CFR 35.100, 35.200, and 35.300 limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries..

Virag Dandekar, M.D.

10 CFR 35.400.

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. Notwithstanding the requirements of 10 CFR 30.32(g), 35.49, and 35.400, the licensee may use Radiation Therapy Resources, Inc., Model Nos. 1862, 1864, and 1866 manual brachytherapy sources for medical uses authorized under the provisions of 10 CFR 35.400.

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U.S. NUCLEAR REGULATORY COMMISSION

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-15933-01

Docket or Reference Number
030-10047

Amendment No. 32

16. 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.

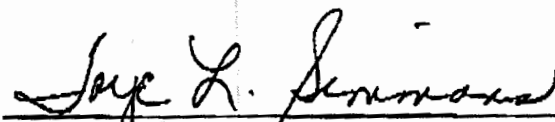
- A. Applications dated October 26, 2010 and March 9, 2011, and
- B. Letters dated January 26, 2012, March 13, 2012 and April 2, 2012.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

ate

JUN 29 2015

By



Toy L. Simmons
Materials Licensing Branch
Region III

MATERIALS LICENSE

uant 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, 37, 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. Franciscan St. Elizabeth Health Lafayette Nuclear Medicine Department</p> <p>2. 1701 S. Creasy Lane Lafayette, IN 47905</p>	<p>In accordance with letter dated January 8, 2016,</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, 2023</p> <hr/> <p>5. Docket No. 030-01642 Reference No.</p>
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<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 35.500</p> <p>E. Strontium-90</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 (North American Scientific, Inc. Model MED 3601, Du Pont Merck Pharmaceutical Company Model NES-8412 or Isotopes Products Laboratories, Inc. Model A3410)</p> <p>E. Sealed source (Atlantic Research Corporation, Model B-1)</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. One Curie.</p> <p>D. 0.3 curie per source and 2 curies total</p> <p>E. 120 millicuries</p>
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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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 67

- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- E. For storage only incident to disposal.

CONDITIONS

10. **A. Licensed materials may be possessed, used and stored at 1701 S. Creasy Lane, Lafayette, Indiana.**
- B. Licensed materials listed in Subitem Nos. 6.A. and 6.B. may be used and stored at the licensee's facilities located at 1104 East Grace Street, Rensselaer, Indiana.**
11. The Radiation Safety Officer is Michael F. Busch, 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, authorized nuclear pharmacist, and/or authorized medical physicist 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>
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 and 35.500.
Robert Mehl, M.D.	10 CFR 35.100, 35.200, 35.300 (limited to the oral administration of sodium iodide I-131), and 35.500.
Sam Hansen, M.D.	10 CFR 35.100, 35.200, and 35.500.
William J. Miller, M.D.	10 CFR 35.100, 35.200, and 35.300.
Michael F. Busch, M.D.	10 CFR 35.100, 35.200, and 35.300.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
13-09788-01

Docket or Reference Number
030-01642

Amendment No. 67

Authorized Users

Farouk E. Mercho, M.D.

Priit Jaagosild, M.D.

Material and Use

10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries).

10 CFR 35.100 and 35.200

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. 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 25, 2013. (ML13296A111)
 - B. Letter dated September 30, 2013. (ML13273A500)
 - C. Letter dated February 26, 2015. (ML15063A576)
 - D. Letter dated March 23, 2015. (ML15082A406)
 - E. **Letter dated April 11, 2016. (ML16104A231)**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 15 2016

By Jennifer L. Bishop
Jennifer L. Bishop
Materials Licensing Branch
Region III

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-26527-01Docket or Reference Number
030-33299

Amendment No. 09

Franciscan Health - Rensselaer

1104 East Grace Street
Rensselaer, IN 47978

In accordance with NRC Form 314 'Certificate of Disposition' dated January 11, 2016, License Number 13-26527-01 is hereby terminated.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 15 2016By Jennifer L. Bishop
Jennifer L. Bishop
Materials Licensing Branch
Region III



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

APR 15 2016

Michael F. Busch, M.D.
Radiation Safety Officer
Franciscan St. Elizabeth Health Lafayette
Nuclear Medicine Department
1701 S. Creasy Lane
Lafayette, IN 47905

Dear Dr. Busch:

Enclosed is Amendment No. 67 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**.

In addition, the NRC staff has reviewed your final status surveys provided in NRC Form 314 'Certificate of Disposition' dated January 11, 2016, request to terminate NRC License Number 13-26527-01. Based on its review, the staff has concluded that residual radioactive material attributable to licensed activities does not exceed current NRC criteria. Based on these conclusions no further remediation or actions with respect to NRC regulated material is required. This facility has been added to NRC license number 13-09788-01 and NRC license number 13-26527-01 is hereby terminated.

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.

You will be periodically inspected by 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 the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

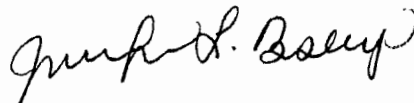
The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

M. F. Busch, M.D.

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In accordance with 10 Code of Federal Regulations 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Jennifer L. Bishop
Health Physicist
Materials Licensing Branch

License No. 13-09788-01 and 13-26527-01
Docket No. 030-01642 and 030-33299

Enclosure: 1. Amendment No. 67 for License No. 13-09788-01
2. Amendment No. 09 for License No. 13-26527-01

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1 From
Date 11/17/17
Sender's Name Yannie /Gargan Phone 765 502-4680
Company FRANCISCAN ST ELIZABETH HEALTH
Address 1701 S CREASY LN
City LAFAYETTE State IN ZIP 47905

2 Your Internal Billing Reference
3 To
Recipient's Name n Materials / Licensing Section 317 442-9032
Company U.S. Nuclear Regulatory Commission
Address 2443 Wacrenville Rd Ste 210
City Lisle State IL ZIP 60532-4352

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5 Packaging
 FedEx Envelope* FedEx Pak* FedEx Box FedEx Tube Other

6 Special Handling and Delivery Signature Options
 Saturday Delivery
 No Signature Required
 Direct Signature
 Indirect Signature
Does this shipment contain dangerous goods?
 No Yes Yes (Dangerous Declaration not required) Dry Ice Cargo Aircraft Only

7 Payment Bill to:
 Sender Recipient Third Party Credit Card Cash/Check
Total Packages 388 Total Weight 388



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Insert shipping document here.

Use this line for the MSD location address or for combination of your shipping address.
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