



# Franciscan ST. FRANCIS HEALTH

April 28, 2011

United States Nuclear Regulatory Commission Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

A

Re: USNRC Material License No. ~~13-26260-01~~

Dear Sir or Madam:

In order for **Franciscan St. Francis Health** and **Integrated Medical Imaging** to more effectively serve the needs of our patients and community and in order to achieve this common goal, it has become apparent of the necessity for both organizations to reach common ground and effectively implement the Transfer of Control of USNRC licensed activities. Both **Franciscan St. Francis Health** and **Integrated Medical Imaging** are in agreement and support the decision to proceed with the concurrent termination of Integrated Medical Imaging (USNRC Materials License No. 13-32709-01) with the addition of this location of use and to amend the USNRC Materials License **Franciscan St. Francis Health** No. 13-02128-03 (see enclosure).

The type of transaction that is occurring is an asset purchase. The business name of **Integrated Medical Imaging** will no longer exist once the concurrent transfer has occurred. The only change in personnel will be that of the Radiation Safety Officer (RSO). RSO duties will be transferred to Berry Stewart, M.S. of **Franciscan St. Francis Health** at the time of transfer. Ms. Nancy Wooldridge will no longer serve as RSO.

The **Integrated Medical Imaging** organizational structure shall not change in this asset purchase. The location of **Integrated Medical Imaging**, at 1040 Greenwood Springs Boulevard, Greenwood, IN 46143, will now be identified as a new location of use under **Franciscan St. Francis Health** materials license No. 13-02128-03.

At this time there are no known issues of noncompliance at either organization and/or facility. Both facilities are in full compliance with USNRC regulations and license conditions as they now stand. Neither organization foresees any issue contrary to be identified now or at the time of transfer.

We confirm all records as prescribed in "NUREG 1556, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses, Appendix G "Information Needed for the Transfer of Control, Final Report, Vol. 9, Rev. 2, January 2008", from **Integrated Medical Imaging** shall be transferred to **Franciscan St. Francis Health** and maintained by same at the time of transfer and shall be made available to the USNRC upon request.



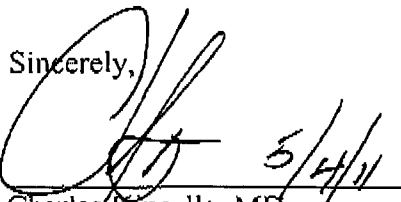
United States Nuclear Regulatory Commission Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352  
April 18, 2011 (continued)

Page 2

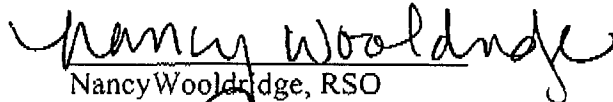
*Franciscan St. Francis Health* will abide by all constraints, conditions, requirements, and commitments stated by *Integrated Medical Imaging*. Moreover, the constraints, conditions, and commitments stated by *Integrated Medical Imaging* are consistent with those constraints, conditions, requirements, and commitments stated by *Franciscan St. Francis Health*, USNRC Materials License No. 13-02128-03.

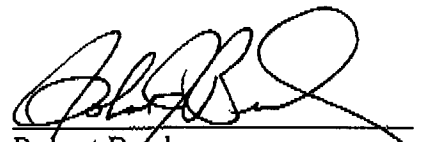
If you have any questions regarding this request concerning the concurrent termination of USNRC materials license 13-32709-01 with the addition onto USNRC materials license 13-02128-03, please contact Mr. Berry Stewart, Radiation Safety Officer at 317/865-5173.

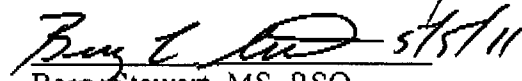
Sincerely,

  
Charles Kinsella, MD  
CEO

Integrated Medical Imaging

  
Nancy Wooldridge, RSO  
Integrated Medical Imaging

  
Robert Brody  
President, CEO  
Franciscan St. Francis Health

  
Berry Stewart, MS, RSO  
Franciscan St. Francis Health

Cc: USNRC Materials License File  
Berry Stewart, MS, RSO  
Nancy Wooldridge, RSO

Enclosures



NRC FORM 374

PAGE 1 OF 2 PAGES

## 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.

|  |                                  |  |
|--|----------------------------------|--|
| Licensee   |                                  |  |
| 1. Integrated Medical Imaging                          |                                  | 3. License number 13-32709-01  |
| 2. 1040 Greenwood Springs Blvd.<br>Greenwood, IN 46143 |                                  | 4. Expiration date October 31, 2018  |
|  |                                  | 5. Docket No. 030-37808<br>Reference No.                                       |
| 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. Flourine-18 as permitted by 10 CFR 35.200           | A. Any                           | A. 1 curie   |

## 9. Authorized use:

A. Any flourine-18 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 1040 Greenwood Springs Blvd., Greenwood, Indiana.
11. The Radiation Safety Officer for this license is Nancy Wooldridge.
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

Charles Kinsella, M.D.

Robert Shellman, M.D.

Material and Use

Flourine-18

Flourine-18



NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 5 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
13-32709-01Docket or Reference Number  
030-37808

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 July 15, 2008; and
- B. Letter dated October 14, 2008 (with attachment)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 17 2008By Kevin G. Null  
Kevin G. Null  
Materials Licensing Branch  
Region III

TOTAL P.02



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NRC FORM 374

**U.S. NUCLEAR REGULATORY COMMISSION**

PAGE 1 OF 8 PAGES

Amendment No. 47

**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 align="center"><b>Licensee</b></p> <p>1. St. Francis Hospital &amp; Health Centers</p> <p>2. 1600 Albany Street<br/>Beech Grove, IN 46107</p> |  | <p>In accordance with letter dated<br/><b>September 4, 2010,</b></p> <p>3. License number 13-02128-03 is amended in its entirety to read as follows:</p> |  |
|  |  | <p>4. Expiration date <b>June 30, 2012</b></p>   |  |
|  |  | <p>5. Docket No. <b>030-09398</b></p> <p align="center">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>F. Iridium-192 permitted by 10 CFR 35.600</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Iodine-125 sealed sources (Bard Model No. STM1251) and Palladium-103 (Theragenics Model No. 200)</p> <p>E. Ba-133 sealed sources (IPL PHI-133 GFS Series)</p> <p>F. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt BV or AEA Technology, Inc.)</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. 3 curies</p> <p>E. 30 millicuries</p> <p>F. 2 sources, 1 source not to exceed 12 curies and 1 source not to exceed 10 curies</p> |
|---|---|--|

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# **Official Use Only – Security-Related Information**

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 8 PAGES

## **MATERIALS LICENSE SUPPLEMENTARY SHEET**

License Number  
13-02128-03  
Docket or Reference Number  
030-09398  
Amendment No. 47

- |   |  |  |
|---|--|--|
| G. Cesium-137                                   | G. Sealed source (Tech<br>Ops Model 77302)   | G. 160 millicuries   |
| H. Cesium-137                                   | H. Sealed source<br>(Nordion Model<br>C3001)   | H. Two sources not to exceed<br>3050 curies total                  |
| I. Yttrium-90 as permitted by<br>10 CFR 35.1000 | I. Sealed sources as<br>SIR- Spheres<br>(ANSTO<br>radiopharmaceuticals<br>and industrials Model<br>Microspheres) | I. Not to exceed 108<br>millicuries/vial, 540<br>millicuries total |

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. Any sealed source for diagnostic medical use permitted by 10 CFR 35.500.
  - F. One source for therapeutic medical use permitted by 10 CFR 35.600, in a Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device. The source activity may not exceed 10 curies at the time of installation. One source in its shipping container for source replacement.
  - G. To be used in a Technical Operations Model 773 survey instrument calibrator for the calibration of survey instruments.
  - H. For irradiation of materials in self-shielded irradiator devices in accordance with the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.
  - I. For medical use, as permitted by 10 CFR 35.1000, in a Sirtex Medical Limited brachytherapy afterloader delivery system.

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NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 3 of 8 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02128-03  
Docket or Reference Number  
030-09398  
Amendment No. 47

**CONDITIONS**

10. A. Licensed material listed in Items 6.A. through 6.D. may be used at the licensee's facility located at 1201 Hadley Road, Mooresville, Indiana.
- B. Licensed material listed in Items 6.A. through 6.E and 6.G and 6.H. may be used at St. Francis Hospital & Health Centers, 1600 Albany Street, Beech Grove, Indiana.
- C. Licensed material listed in Items 6.A., 6.B., 6.C., 6.D. (limited to permanent implants as described in your letter dated November 14, 2002), 6.E and 6.F. may be used at St. Francis Hospital & Health Centers, South Campus, 8111 South Emerson Avenue, Indianapolis, Indiana.
- D. Licensed material listed in Item 6.I. may be used at St. Francis Hospital & Health Centers, South Campus, 8111 South Emerson Avenue, Indianapolis, Indiana and 1600 Albany Street, Beech Grove, Indiana.
- E. Licensed material listed in Items 6.A. and 6.B. may be used at 5255 E. Stop Eleven Rd., Suite 240, Indianapolis, Indiana and 1201 Hadley Road, Mooresville, Indiana.
11. Radiation Safety Officer: Berry L. Stewart, 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**

|                            |   |
|----------------------------|---|
| Orin W. Perkins, M.D.      | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Franklin W. Sequeira, M.D. | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Richard L. Scales, M.D.    | 10 CFR 35.100, 35.200 and 35.500.         |
| Gregory A. Merchun, M.D.   | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Ramchandra Reddy, M.D.     | 10 CFR 35.100, 35.200 and 35.500.         |
| Thomas Guy Belt, M.D.      | 10 CFR 35.100, 35.200, 35.300 and 35.500. |
| Paul W. Sheets, M.D.       | 10 CFR 35.100, 35.200 and 35.500.         |
| John T. Mail, M.D.         | 10 CFR 35.100, 35.200 and 35.500.         |
| Mary Below, M.D.           | 10 CFR 35.100, 35.200 and 35.500.         |

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# Official Use Only – Security-Related Information

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 4 of 8 PAGES

## **MATERIALS LICENSE SUPPLEMENTARY SHEET**

License Number

13-02128-03

Docket or Reference Number

030-09398

Amendment No. 47

### Authorized Users

Colleen M. Madden, M.D.

Peter G. Garrett, M.D.

Thomas C. Dugan, M.D.

Newell O. Pugh, M.D.

David B. Ross, M.D.

Scott Ackley, M.D.

James C. Currier, M.D.

Mark Joseph Paluszny, M.D.

Thomas N. Murphy, M.D.

James Blahunka, M.D.

Jarlan C. Graybill, M.D.

Daniel C. Han, M.D.

Stephen H. Kliman, M.D.

David Kovacich, M.D.

Richard Shea, M.D.

Alexander Yeah, M.D.

### Material and Use

10 CFR 35.100, 35.200 and 35.500.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.100 and 35.200.

10 CFR 35.100 and 35.200.

10 CFR 35.100, 35.200 and 35.300.

10 CFR 35.300, 35.400 and 35.600 iridium-192 in HDR remote afterloading device.

10 CFR 35.300, 35.400 and 35.600 iridium-192 in HDR remote afterloading device.

10 CFR 35.200.

10 CFR 35.200.

10 CFR 35.200.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

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**Official Use Only – Security-Related Information**

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 5 of 8 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02128-03  
Docket or Reference Number  
030-09398  
Amendment No. 47

Authorized Users

Daniel Weed, M.D.

Valeri Goutsouliak, M.D.

Michael Barron, M.D.

Umesh Khot, M.D.

Saeed R. Shaikh, M.D.

Babu Krishna Doddapaneni, M.D.

Michael Eaton, M.D.

Material and Use

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.300, 35.400, 35.600 iridium-192 in HDR remote afterloading device and 35.1000 yttrium-90 as SIR-Spheres.

10 CFR 35.100 and 35.200.

10 CFR 35.100 and 35.200.

10 CFR 35.200.

10 CFR 35.200.

10 CFR 35.600 limited to iridium-192 in HDR remote afterloading device.

C. The following individuals are authorized users for non-medical uses as indicated:

Authorized Users

Berry L. Stewart, M.S.

Edward E. Wroblewski, M.A.

William K. Breeden III, M.S.

Material and Use

Cesium-137 for use in irradiator in Subitem No. 6.G.

Cesium-137 for use in irradiator in Subitem No. 6.G.

Cesium-137 for use in irradiator in Subitem No. 6.G.

D. The following individuals are Authorized Medical Physicists:

Authorized Users

Berry L. Stewart, M.S.

Paul Mason, M.S.

Material and Use

Iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device and for calibration, spot checks and training.

Iridium-192 in High Dose Rate Remote Afterloading Brachytherapy device and for calibration, spot checks and training.

E. Licensed material in Subitem 6.H. shall be used by, or under the supervision of, individuals who have received the training described in the application dated December 29, 1999, and the letter dated December 29, 1999. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.

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NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 6 of 8 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02128-03  
Docket or Reference Number  
030-09398  
Amendment No. 47

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. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
  - B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified by the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
  - C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
  - D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
  - E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
  - F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

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NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 7 of 8 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
13-02128-03  
Docket or Reference Number  
030-09398

Amendment No. 47

17. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
18. Except for maintaining labeling as required by 10 CFR 20 or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
20. For the self-shielded irradiator devices: the licensee shall not repair, remove, replace or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
21. For the self-shielded irradiator devices: except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
22. A. The licensee shall comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML053130364) as Attachment B to the "Order Imposing Increased Controls" (ADAMS Accession No. ML053130218) published in the Federal Register on December 1, 2005 (70 FR 72128); and with the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials" (Fingerprinting-Order) (ADAMS Accession No. ML073230831) published in the Federal Register on December 13, 2007 (72 FR 70901).
- B. The licensee shall complete implementation of the said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Fingerprinting Order (ADAMS Accession No. ML080160582).
- C. Notwithstanding any provisions of the Commission's regulations to the contrary, all measures implemented or actions taken in response to these Orders shall be maintained until the Commission orders otherwise or until the Commission explicitly modifies its regulations to reflect the increased controls and fingerprinting requirements, and states in modifying its regulations that the revisions are to supercede these Orders.

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Official Use Only – Security-Related Information

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 8 of 8 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

13-02128-03

Docket or Reference Number

030-09398

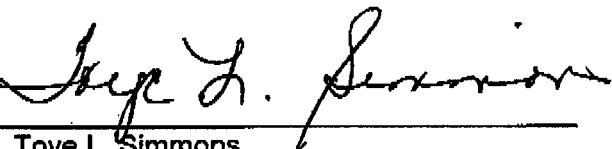
Amendment No. 47

- D. The licensee shall notify the Director, Office of Federal and State Materials and Environmental Management Programs, USNRC, Washington, DC, 20555, in writing, within 25 days after it has completed the requirements of this condition. In addition, licensee responses applicable to this license condition shall be marked as "Security-Related Information - Withhold Under 10 CFR 2.390."
23. 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 March 14, 1995, December 29, 1999, and December 27, 2001;
- B. Letters with attachments dated February 27, 1990, September 18, 1995, October 9, 1996 (with attachments), January 27, 1999, December 29, 1999, January 19, 2001, February 28, 2001, March 9, 2001, September 19, 2001, May 19, 2002, December 22, 2001, (excluding item 10.2), July 24, 2002, November 14, 2002, May 12, 2003, July 18, 2003, October 8, 2004, February 28, 2005, April 24, 2006; August 26, 2007 (excluding item 2), March 11, 2009, and July 21, 2009; and
- C. Facsimiles dated July 2, 2001, August 6, 2003, June 15, 2006, (received July 20, 2006), March 6, 2007, and March 9, 2007.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date OCT 29 2010

By



Toy L. Simmons  
Materials Licensing Branch  
Region III

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# ST FRANCIS CANCER CARE SERVICES

## FAX TRANSMITTAL SHEET

TO: MATERIALS LICENSING,  
REGION III

FAX: 630-515-1078

FROM: Berry L. Stewart, MS, RSO

DATE: 5/13/11

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