

**MATERIALS LICENSE**

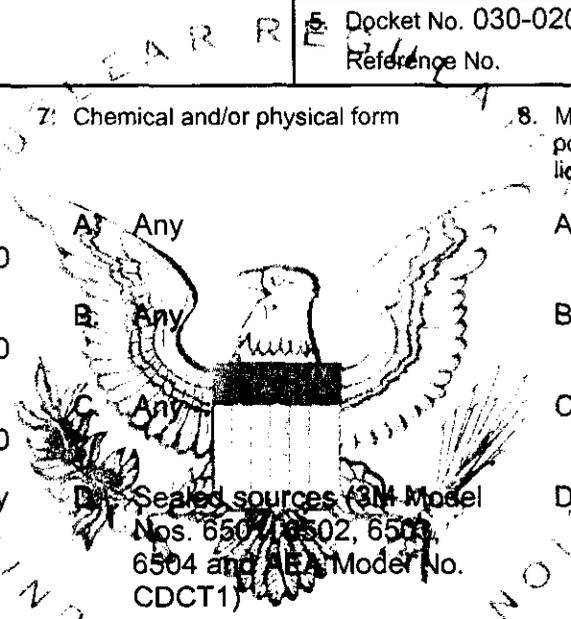
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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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<p>Licensee</p> <p>1. Lakeland Medical Center, St. Joseph</p> <p>2. 1234 Napier Avenue St. Joseph, MI 49085</p>	<p>In accordance with letters dated <b>April 3, 2006 and April 11, 2006,</b></p> <p>3. License number 21-04177-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date February 28, 2015</p> <p>5. Docket No. 030-02049 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. Cesium-137 as permitted by 10 CFR 35.400</p> <p>E. Iodine-125 as permitted by 10 CFR 35.400</p> <p>F. Gadolinium-153</p> <p>G. Strontium-90 permitted by 10 CFR 35.1000</p> <p>H. Iridium-192 as permitted by 10 CFR 35.400</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 (GM Model Nos. 6501, 6502, 6503, 6504 and AEA Model No. CDCT1)</p> <p>E. Sealed sources (North American Scientific, Inc., Model No. MED 3631)</p> <p>F. Sealed sources (North American Scientific, Inc. Model 3601)</p> <p>G. Sealed sources (BEBIG Model Sr0.S03 or AEAT Model SICW Series (SICW.1 and SICW.2)</p> <p>H. Sealed Sources in ribbon (Best Medical International, Inc. Model 81-01 Series)</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 I-131</p> <p>D. Total not to exceed 165 millicuries</p> <p>E. Total not to exceed 1 curie</p> <p>F. 4 sources not to exceed 250 millicuries each</p> <p>G. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries.</p> <p>H. Total possession not to exceed 100 millicuries.</p>
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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
21-04177-01

Docket or Reference Number  
030-02049

Amendment No. 73

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. and E. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- F. Two sources to be used in Adac Laboratories Transmission Line Source Housing VANTAGE device for medical radiography in humans. Two sources in shipping containers for replacement of the sources.
- G. The source assemblies may be used in Novoste Model A1000 series devices for medical use permitted by 10 CFR 35.1000; source assemblies may also be used for physics calibrations and quality assurance testing; one source assembly in a shipping container for replacement and disposal.
- H. Any manual brachytherapy procedure permitted by 10 CFR 35.400.

**CONDITIONS**

- 10. A. Licensed material shall be used only at the licensee's facilities located at Lakeland Medical Center - St. Joseph, 1234 Napier Avenue, St. Joseph, Michigan.
  - B. Licensed material listed in subitems 6.A., 6.B., 6.C., 6.E. and 6.F. may be used at Lakeland Medical Center - Niles, 31 North Saint Joseph Avenue, Niles, Michigan.
  - C. Licensed material listed in subitems 6.A. and 6.B. 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.
11. A. **Radiation Safety Officer for this license is David E. Sieffert, M.S.**
- B. The Authorized Medical Physicist for this license is Christopher Baird, M.S.

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SUPPLEMENTARY SHEET**

License Number  
21-04177-01

Docket or Reference Number  
030-02049

Amendment No. 73

12. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for medical uses:

<u>Authorized Users</u>	<u>Material and Use</u>
William F. Leahey, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma therapy) and gadolinium-153 in VANTAGE device for medical radiography.
Roman Hyszczak, M.D.	10 CFR 35.100, 35.200 and gadolinium-153 in VANTAGE device for medical radiography.
Daniel F. Kreider, M.D.	10 CFR 35.100, 35.200, 35.300 and gadolinium-153 in VANTAGE device for medical radiography.
Kent T. Lancaster, M.D.	10 CFR 35.100, 35.200, 35.300 and gadolinium-153 in VANTAGE device for medical radiography.
Brad Bastow, M.D.	10 CFR 35.100, 35.200 and gadolinium-153 in VANTAGE device for medical radiography.
Dilip Arora, M.D.	10 CFR 35.100, 35.200 (excluding Tc-99m aerosols and generators), limited to cardiovascular clinical studies and gadolinium-153 in VANTAGE device for medical radiography.
Brian T. Eller, M.D.	10 CFR 35.100 and 35.200, limited to cardiovascular clinical studies.
Srinivasan Dhathrecharan, M.D.	10 CFR 35.100 and 35.200, limited to cardiovascular clinical studies.
Peter Lai, M.D.	10 CFR 35.300, 35.400, strontium-90 in Novoste Model A1000 series intravascular brachytherapy devices and phosphorus-32 in the Guidant Galileo for intravascular brachytherapy procedures.
Jose Cassini Pacheco, M.D.	10 CFR 35.100 and 35.200.
Denis L. Gibbs, D.O.	10 CFR 35.100 and 35.200.
Mark Ottmar, M.D.	10 CFR 35.100 and 35.200.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

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Amendment No. 73

Thomas K. Pow, M.D.

10 CFR 35.100 and 35.200, limited to cardiovascular clinical studies.

13. Licensed material listed in Subitem Nos. F. and G. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No. 12., and in the physical presence of an authorized user named in Condition No. 12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition No. 12. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.
14. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. In addition to the possession limits in Condition 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.
16. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:
- Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each Guidant Galileo and Novoste treatment.
  - Promptly make a survey of the area of use to confirm that no sources have been misplaced.
  - Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr ( $\mu$ Sieverts/hr), time, date and name of the individual making the survey.
  - Retain the record of the survey in lieu of the record required in 10 CFR 35.406(c).
17. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. All intravascular brachytherapy afterloader devices shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.
19. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration referred to in 10 CFR 32.210 or under equivalent regulations of an Agreement State.
  - Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
21-04177-01Docket or Reference Number  
030-02049

Amendment No. 73

- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 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, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be leak tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the radionuclide is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma- emitting material or not more than 10 microcuries of alpha-emitting material.
- E. 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.
- F. 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(e)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
20. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
21-04177-01

Docket or Reference Number  
030-02049

Amendment No. 73

21. 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 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 December 28, 2004.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 05 2006

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