

MATERIALS LICENSE

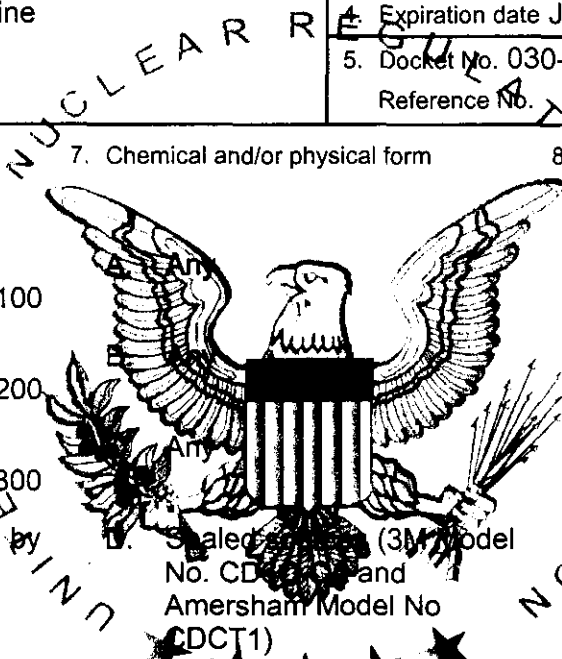
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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.

PL 02120

315342

|   |  |
|---|--|
| <p>Licensee</p> <p>1. Saint Joseph Regional Medical Center<br/>South Bend Campus</p> <p>2. Department of Nuclear Medicine<br/>801 East LaSalle Street<br/>South Bend, IN 46617-1935</p> | <p>In accordance with letter dated<br/><b>March 17, 2006, and facsimile dated<br/>April 21, 2006,</b></p> <p>3. License number 13-02650-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date June 30, 2014</p> <hr/> <p>5. Docket No. 030-13685<br/>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. Cesium-137 as permitted by 10 CFR 35.400</p> <p>E. Depleted uranium</p> <p>F. Gadolinium-153</p> <p>G. Strontium-90</p> <p>H. Technetium-99m</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 (3M Model No. CDCT1 and Amersham Model No. CDCT1)</p> <p>E. Cadmium plated metal</p> <p>F. Sealed Sources (North American Scientific, Inc. Model 3601)</p> <p>G. Sealed source (Tracer Lab, Inc. Model No. 64)</p> <p>H. Any</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. 1 curie</p> <p>E. 300 kilograms</p> <p>F. 4 sources not to exceed 10 millicuries total</p> <p>G. 50 millicuries</p> <p>H. 100 millicuries</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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02650-02

Docket or Reference Number  
030-13685

Amendment No. 37

- 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. Shielding in a linear accelerator.
- F. For storage only incident to disposal.
- G. For storage only incident to disposal.
- H. For research and development as defined in 10 CFR 30.4, limited to animal studies.

CONDITIONS

- 10. A. Location of Use: 801 East LaSalle Street, South Bend, Indiana.
- B. Location of use for material listed in Subitem 6-E: St. Joseph's Radiation Oncology Center, Suite 100, 707 East Cedar Street, South Bend, Indiana.
- 11. Radiation Safety Officer: ~~Toora Torabian~~
- 12. Licensed material is only authorized for use by or under the supervision of:
  - A. Individuals permitted to work with authorized licensed nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4), and 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

|                         |   |
|-------------------------|---|
| Douglas S. Kuehn, M.D.  | 10 CFR 35.100, and 35.200.  |
| Robert Rust, M.D.       | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for the treatment of thyroid carcinoma).    |
| Victor Jones, II, M.D.  | 10 CFR 35.100, and 35.200.  |
| Michael McCrea, M.D.    | 10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for the treatment of thyroid carcinoma). |
| Brett A. Stephens, M.D. | 10 CFR 35.100, 35.200, 35.300.  |
| Toby Mathews, M.D.      | 10 CFR 35.100, 35.200 and 35.300.   |
| David Cory, M.D.        | 10 CFR 35.100 and 35.200.   |

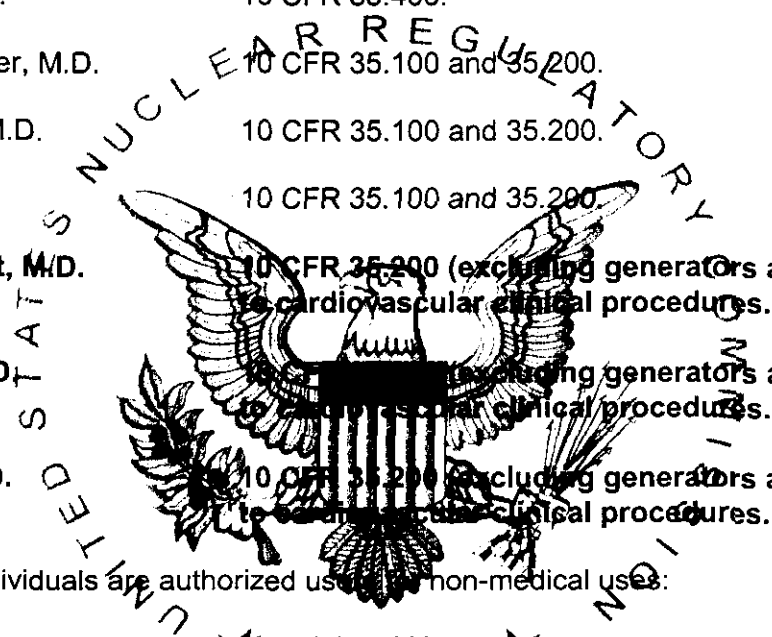
**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02650-02

Docket or Reference Number  
030-13685

Amendment No. 37

- Edward Yang, M.D. 10 CFR 35.100 and 35.200.
- Guy Kedziora, M.D. 10 CFR 35.400.
- Timothy Scott Smith, M.D. 10 CFR 35.100, 35.200 and 35.300.
- Linda L. Tuthill, M.D. 10 CFR 35.100, 35.200 and 35.300.
- Jon Frazier, M.D. 10 CFR 35.400.
- Steven T. Gerstler, M.D. 10 CFR 35.100 and 35.200.
- Vu H. Nguyen, M.D. 10 CFR 35.100 and 35.200.
- Paul Shu, M.D. 10 CFR 35.100 and 35.200.
- William S. Arnat, M.D.** 10 CFR 35.200 (excluding generators and xenon-133), limited to cardiovascular clinical procedures.
- Sahin Patel, M.D.** 10 CFR 35.200 (excluding generators and xenon-133), limited to cardiovascular clinical procedures.
- Sanjay Lall, M.D.** 10 CFR 35.200 (excluding generators and xenon-133), limited to cardiovascular clinical procedures.



C. The following individuals are authorized use for non-medical uses:

**Material and Use**

- John D. Scheu, Ph.D. Cesium-137 for survey instrument calibration and technetium-99m for animal research studies.
- Brett A. Stephens, M.D. Technetium-99m for animal research studies.

D. Authorized Nuclear Pharmacist: John D. Scheu, Ph.D.

- 13. Experimental animals administered licensed materials or their products shall not be used for human consumption.
- 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

13-02650-02

Docket or Reference Number

030-13685

Amendment No. 37

- B. 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.
- 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 the licensee or by one of its employees licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.
15. The licensee shall conduct a physical inventory every six months or at other intervals approved by the U.S. Nuclear Regulatory Commission for all sealed sources and/or devices received and possessed under the license.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02650-02

Docket or Reference Number  
030-13685

Amendment No. 37

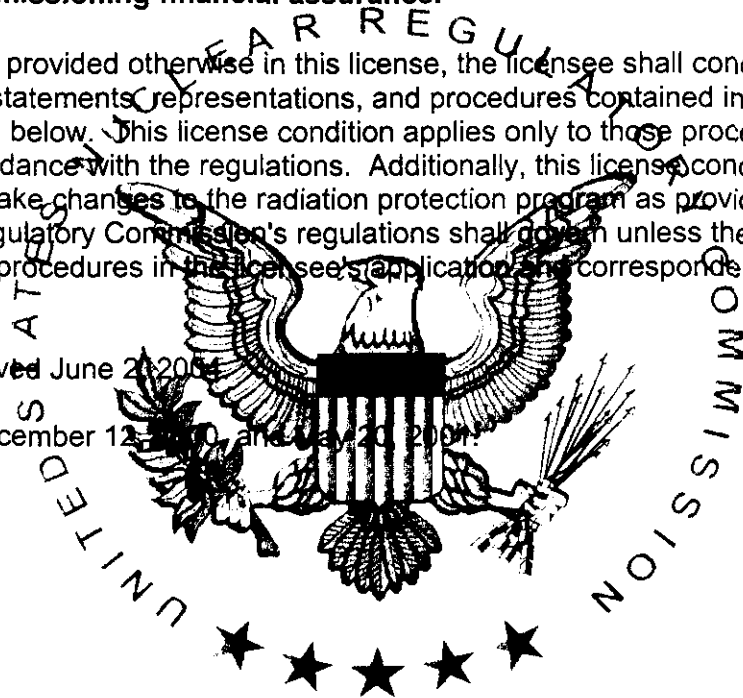
C. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. 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.

20. 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 received June 21, 2004

B. Letters dated December 12, 2000, and July 20, 2001



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUL 05 2006

By Colleen Carol Casey  
Colleen Carol Casey  
Materials Licensing Branch  
Region III