

WOODLAWN HOSPITAL



ROCHESTER — INDIANA  
1400 E. Ninth Street  
Rochester, Indiana 46975-8937

September 18, 2006

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

Re: Amendment to Material's License 13-20338-01

Dear Madam or Sir:

We wish to amend our Material's License 13-20338-01 as follows:

**CHANGE AUTHORIZED USER (AU) AND RADIATION SAFETY OFFICER (RSO)**

Add Suk Lee, M.D. as our Authorized User and RSO.

**DELETE AUTHORIZED USER AND RSO**

Richard Fox, M.D. (Dr. Fox is no longer affiliated with our institution.)

If you require any additional information, please contact our Medical Nuclear Physicist,  
Thomas M. Kumpuris, M.S. DABR of Medical Physics Consultants, Inc. 800.321.2207.

Sincerely,

John Alley  
CEO

RECEIVED SEP 21 2006



WOODLAWN HOSPITAL  
ROCHESTER — INDIANA  
1400 E. Ninth Street  
Rochester, Indiana 46975-6937  
September 12, 2006

Dr. Suk Lee, M.D.  
Radiation Safety Officer  
Woodlawn Hospital  
1400 East 9<sup>th</sup> Street  
Rochester, Indiana 46975

Re: Radiation Safety Officer / Executive Management Letter of Understanding

Dear Dr. Suk Lee,

You have been appointed the Radiation Safety Officer (RSO) for this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program.
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.

Furthermore, in compliance with 10 CFR 35.24(e), (g), the executive management of this facility agrees to provide you as RSO:

- Specific written notification of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
  1. Identify radiation safety problems;
  2. Initiate, recommend, or provide corrective actions;
  3. Stop unsafe operations; and,
  4. Verify implementation of corrective actions.

Our signatures below attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

  
Executive Management

  
Radiation Safety Officer

# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America  
and the Section on Radiology of the American Medical Association  
Hereby certifies that*

**Suk Soon Lee, M.D.**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of  
The American Board of Radiology*

**On this ninth day of June, 1973**

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Radiology**

*Ralph W. Seely*  
President

*C. Allen Good*  
Secretary



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On this ninth day of June, 1973

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Radiology**

*R. Lee, S. D.      P. M. Hand*



# The American Board of Nuclear Medicine

Incorporated 1971

A conjoint Board organized with the sponsorship of the American Board of Internal Medicine,  
American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine  
hereby certifies that

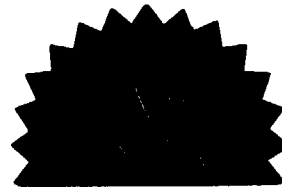
**Suk Doon Lee, M.D.**

has met the requirements of this Board and is  
certified as qualified to practice as a specialist in  
all aspects of clinical and laboratory

**Nuclear Medicine**

including but not limited to Radiobioassay, Nuclear Imaging,  
in Vivo Measurements & Therapy with unsealed Radionuclides.

*Joseph F. Ron M.D.*



*S. J. Abelstein*  
SECRETARY

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

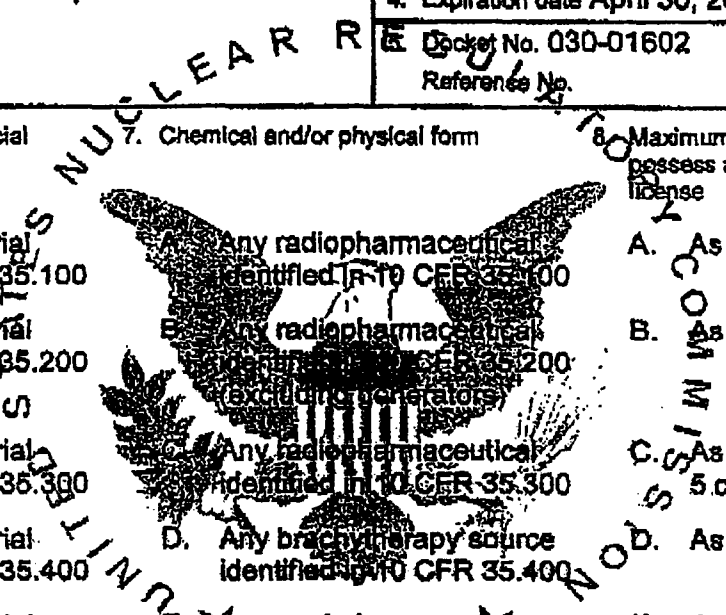
PAGE 1 OF 6 PAGES  
Amendment No. 53

**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>Licensee</p> <p>1. Saint Margaret Mercy Healthcare Centers</p> <p>2. 5454 Hohman Avenue Hammond, IN 46320</p>	<p>In accordance with the letter dated April 28, 1999,</p> <p>3. License number 13-02047-02 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2005</p> <p>Docket No. 030-01602 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material identified in 10 CFR 35.100</p> <p>B. Any byproduct material identified in 10 CFR 35.200</p> <p>C. Any byproduct material identified in 10 CFR 35.300</p> <p>D. Any byproduct material identified in 10 CFR 35.400</p> <p>E. Any byproduct material identified in 10 CFR 35.500</p> <p>F. Any byproduct material identified in 10 CFR 31.11</p> <p>G. Americium-241</p> <p>H. Iridium-192</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical identified in 10 CFR 35.100</p> <p>B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators)</p> <p>C. Any radiopharmaceutical identified in 10 CFR 35.300</p> <p>D. Any brachytherapy source identified in 10 CFR 35.400</p> <p>E. Any sealed source identified in 10 CFR 35.500</p> <p>F. Prepackaged kit</p> <p>G. Sealed source (Amersham/Searle Model AMC-24)</p> <p>H. Sealed source (Byk Mallinckrodt Model CI LBV)</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 5 curies of iodine-131)</p> <p>D. As needed</p> <p>E. As needed</p> <p>F. As needed</p> <p>G. Three sources not to exceed 14 millicuries each</p> <p>H. Two sources not to exceed 10 curies each</p>
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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02047-02

Docket or Reference Number  
030-01602

Amendment No. 53

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200 (excluding generators).
- C. Medical use described in 10 CFR 35.300.
- D. Medical use described in 10 CFR 35.400.
- E. Medical use described in 10 CFR 35.600 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.
- F. In vitro studies.
- G. For use in Searle Analytic Anatomical Marker Model SS-1024.
- H. One source to be used in a Nuclotron Corporation Micro Selectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary/intracanalicular radiotherapy. One source in its shipping container to be in possession of licensee as necessary for replacement of the source in the irradiation device.

10. Locations of use:

- A. Licensed material may be used at the licensee's facilities located at St. Margaret Mercy Healthcare Centers, North Campus, 5454 Hohman Avenue, Hammond, Indiana.
- B. Licensed material listed in Item 6.H. may be used only in the Varian Accelerator Room, St. Margaret Mercy Healthcare Centers, North Campus, 5454 Hohman Avenue, Hammond, Indiana.
- C. Licensed material listed in Items 6.A. through 6.G may be used at the licensee's facilities located at St. Margaret Mercy Healthcare Centers, South Campus, 24 Joliet Street, Dyer, Indiana.

11. Radiation Safety Officer: Renate Muller-Runkel, Ph.D.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

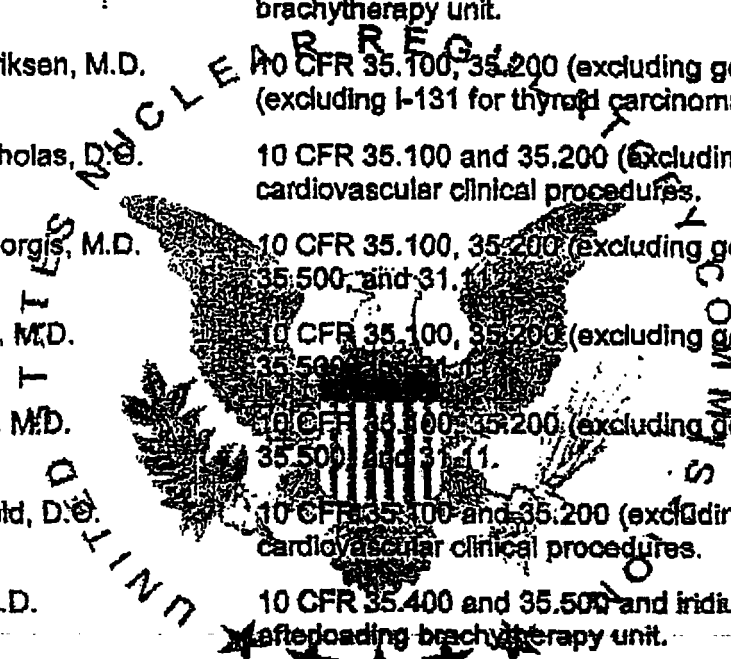
License Number  
13-02047-02

Docket or Reference Number  
030-01602

Amendment No. 53

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
A. Lisbeth A. Gallagher, M.D.	10 CFR 35.100, 35.200 (excluding generators), and 31.11.
B. Urmi P. Kalokhe, M.D.	10 CFR 35.300, 35.400 and Iridium-192 in remote afterloading brachytherapy unit.
C. Brenda Lee Eriksen, M.D.	10 CFR 35.100, 35.200 (excluding generators), 35.300 (excluding I-131 for thyroid carcinoma therapy), and 31.11.
D. Michael A. Nicholas, D.O.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
E. Peter John Georgis, M.D.	10 CFR 35.100, 35.200 (excluding generators), 35.300, 35.500, and 31.11.
F. Suk Soon Lee, M.D.	10 CFR 35.100, 35.200 (excluding generators), 35.300, 35.500, and 31.11.
G. Byung Il Hyun, M.D.	10 CFR 35.100, 35.200 (excluding generators), 35.300, 35.500, and 31.11.
H. Robert Litchfield, D.O.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
I. Mir J. Shah, M.D.	10 CFR 35.400 and 35.500 and Iridium-192 in remote afterloading brachytherapy unit.
J. Abdul Khan, M.D.	10 CFR 35.400 and 35.500 and Iridium-192 in remote afterloading brachytherapy unit.
K. Kenneth J. Ramsey, D.O.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
L. Sangho Han, M.D.	10 CFR 35.100, 35.200 (excluding generators), 35.300 (excluding I-131 for thyroid carcinoma therapy), and 31.11.
M. Amit D. Vyas, M.D.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
N. Kannan Kandallu, M.D.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
O. Parag M. Doshi, M.D.	10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02047-02

Docket or Reference Number  
030-01602

Amendment No. 53

- P. Vijay P. Shah, M.D. 10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
- Q. Mark T. Nootens, M.D. 10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
- R. Donald J. Tanis, M.D. 10 CFR 35.100 and 35.200 (excluding generators), limited to cardiovascular clinical procedures.
- S. Anita T. Chen Lee, M.D. 10 35.300, 35.400 and Iridium-192 in remote afterloading brachytherapy units.
13. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).
14. 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 remote afterloading brachytherapy procedure.
  - 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(d).
15. Prior to initiation of a treatment program, and subsequent to each source exchange using the MicroSelectron-HDR remote afterloading brachytherapy device, a radiation survey shall be made of:
- The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.
  - All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:
    - That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.
    - That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 5 of 6 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
13-02047-02

Docket or Reference Number  
030-01602

Amendment No. 53

16. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:
- Installation and replacement of the sealed sources contained in the MicroSelectron-HDR afterloading brachytherapy device.
  - Any maintenance or repair operations on the remote afterloading brachytherapy unit involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
17. A. Access to the rooms housing the MicroSelectron-HDR afterloading brachytherapy device shall be controlled by a door at each entrance.
- B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on the entrance door to the irradiation room shall be tested for proper operation at least once each day of use.
- D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
18. 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.
19. Notwithstanding the provisions of Section 35.415(a)(4), "Survey precautions" of Title 10, Code of Federal Regulations, the licensee is authorized to perform radiation surveys in accordance with procedures outlined in letters dated November 28, 1991, January 14, 1992, April 23, 1992, November 16, 1992 and December 23, 1992.

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 6 of 6 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

13-02047-02

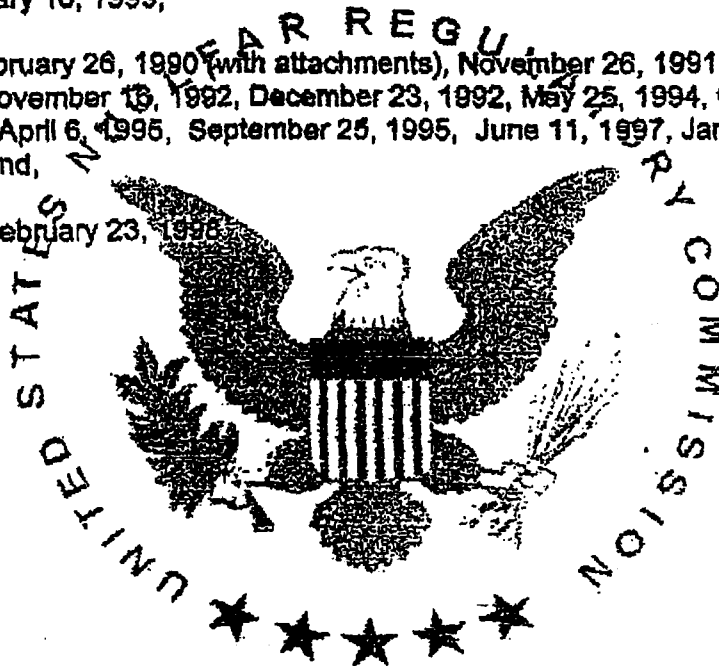
Docket or Reference Number

030-01602

Amendment No. 53

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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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. Applications dated May 24, 1994; July 20, 1995 (with attached letter dated July 20, 1995), June 11, 1997, and February 18, 1999;
- B. Letters dated February 26, 1990 (with attachments), November 26, 1991, January 14, 1992, April 23, 1992, November 13, 1992, December 23, 1992, May 25, 1994, October 31, 1994, March 23, 1995, April 6, 1995, September 25, 1995, June 11, 1997, January 15, 1998, and April 28, 1999; and,
- C. Letter received February 23, 1998



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date APR 29 1999

By Michael F. Weber

Michael F. Weber  
Materials Licensing Branch  
Region III

## Extremely Urgent

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WOODLAWN HOSPITAL



ROCHESTER INDIANA

NUCLEAR REGULATORY COMMISSION  
REGION III

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