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

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

September 12, 2006

Dr. Suk Lee, M.D.
Radiation Safety Officer
Woodlawn Hospital
1400 East 9th 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

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA

Ralph M. Scott
President

C. Allen Good
Secretary

AMERICAN BOARD OF MEDICAL SPECIALTIES

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
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On this ninth day of June, 1973
Thereby demonstrating to the satisfaction of the Board
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Radiology

AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF

AMERICAN BOARD OF MEDICAL SPECIALTIES

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 Soon 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 Ross MD
CHAIRMAN

[redacted]

SECRETARY

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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 ...Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations ...retofore 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	In accordance with the letter dated April 28, 1999,
1. Saint Margaret Mercy Healthcare Centers	3. License number 13-02047-02 is amended in its entirety to read as follows:
2. 5454 Hohman Avenue Hammond, IN 46320	4. Expiration date April 30, 2005 5. Docket No. 030-01602 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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators)	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 5 curies of iodine-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Any byproduct material identified in 10 CFR 35.500	E. Any sealed source identified in 10 CFR 35.500	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged kit	F. As needed
G. Americium-241	G. Sealed source (Amersham/Searle Model AMC-24)	G. Three sources not to exceed 14 millicuries each
H. Iridium-192	H. Sealed source (Byk Mallinckrodt Model CI LBV)	H. Two sources not to exceed 10 curies each

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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 35.500 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-10244.

H. One source to be used in a Nucletron Corporation Micro Selectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary/intraluminal radiotherapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

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.

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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:

	Authorized Users	Material and Use
A.	Lisbeth A. Gallagher, M.D.	10 CFR 35.100, 35.200 (excluding generators), and 31.11.
B.	Urmi P. Kalokhe, M.D.	10 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, [redacted]
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.

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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 unit.

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:

    A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

    B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

    C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

    D. 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:

    A. 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.

    B. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

        (1) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.

        (2) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

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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:

    A. Installation and replacement of the sealed sources contained in the MicroSelectron-HDR afterloading brachytherapy device.

    B. 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 irradiator 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 26, 1991, January 14, 1992, April 23, 1992, November 16, 1992 and December 23, 1992.

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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 16, 1999;

B. Letters dated February 26, 1990 (with attachments), November 26, 1991, January 14, 1992, April 23, 1992, November 19, 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 2 9 1999

By _____
Michael F. Weber
Materials Licensing Branch
Region III

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WOODLAWN HOSPITAL
ROCHESTER — INDIANA

NUCLEAR REGULATORY COMMISSION
REGION III

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