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PUBLIC/PDR

030-17578

HEALTH SERVICES ST. JOSEPH HEALTH CENTER

August 4, 1997

U.S.N.R.C.
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: License Number 34-13394-02

To Whom It May Concern:

Please allow this correspondence to serve as notification that Shereif Khalil, M.D. has been authorized by the radiation safety committee to perform duties as an authorized user on our byproduct material license. Dr. Khalil will be using materials identified in 10 CFR 35.100, 35.200, and 35.300.

Dr. Khalil is certified by the American Board of Radiology in Diagnostic Radiation and is named as an authorized user for the noted materials on NRC license number 34-01856-01. A copy of his certification and license number 34-01856-01 is attached.

Thank you for your attention in this matter.

Sincerely,

Kenneth Lavin
Director
Clinical & Diagnostic Services

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PDR ADOCK 03007578
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enc

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REGION III

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Pm: 8-11-97

667 Eastland Avenue, S.E. / Warren, OH 44484 / (330) 841-4000
MEMBER OF THE HUMILITY OF MARY HEALTH CARE SYSTEM

AUG 15 1997

NRC FORM 374 (P 94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 43

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. Columbia St. Vincent Charity Hospital	In ~~accordance with letters~~ dated November 22, 1995, January 2, 1996, May 15, 1996 and June 11, 1996
2. 2351 East 22nd Street Cleveland, Ohio 44115	3. License Number 34-01856-01 is amended in its entirety to read as follows:
	4. Expiration Date October 31, 2000
	5. Docket or Reference No. 030-02689

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	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
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 31.11	E. Prepackaged Kits	E. As needed
F. Uranium depleted in Uranium-235	F. Cadmium plated metal	F. As needed
G. Iridium-192	G. Sealed sources (ByK Mallinckrodt Model CI L BV)	G. 2 sources, 1 source not to exceed 444 gigabecquerels (Gbq) (12 curies (Ci)), and 1 source not to exceed 370 Gbq (10 Ci).

COPY

9610070104-7pp

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-01856-01

Docket or Reference number: 030-02689

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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.

C. Medical use described in 10 CFR 35.300.

D. Medical use described in 10 CFR 35.400.

E. In vitro studies.

F. Shielding in a linear accelerator.

G. One source to be used in a Nucletron-Oldelft Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 370 Gbq (10 Ci) at the time of installation. One source in its shipping container for source replacement.

CONDITIONS

10. Location of Use: St. Vincent Charity Hospital, 2351 East 22nd Street, Cleveland, Ohio.

11. A. Radiation Safety Officer: Robert J. Porter, M.D.

B. Assistant Radiation Safety Officer, limited to HDR brachytherapy: Robert Carlson, B.A., R.T.(T).

C. Brachytherapy Physicists: Ronald Scala, M.S., Raymond Kaczur, M.S., and Neal Smarra, M.S.

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. Robert J. Porter, M.D.	10 CFR 35.100, 35.200, 35.300, 34.400, 31.11 and iridium-192 in remote afterloading brachytherapy unit.

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Authorized Users	Material and Use
B. John L. Porter, M.D.	10 CFR 35.100, 35.200, 35.300 (except iodine-131 for treatment of thyroid carcinoma), 35.400 and iridium-192 in remote afterloading brachytherapy unit and 31.11.
C. Dong Kim, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.
D. Christine M. Zirafi, M.D.	10 CFR 35.100 and 35.200, limited to clinical cardiovascular studies.
E. Robert M. Konstan, M.D.	10 CFR 35.100, 35.200 and 35.300.
F. Shereif Khalil, M.D.	10 CFR 35.100, 35.200 and 35.300.
G. Dawn Donich, M.D.	10 CFR 35.100, 35.200 and 35.300.
H. Christina M. Wirtz, M.D.	10 CFR 35.100, 35.200 and I-131 for treatment of hyperthyroidism and cardiac dysfunction.

13. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material in the molybdenum-99/technetium-99m generators authorized by this license.

14. The licensee shall establish and implement Items 6.g through 6.k of Appendix C to Regulatory Guide 10.8 for measuring geometry independence of their dose calibrator(s).

15. The licensee's survey instruments shall be calibrated by a commercial service licensed by the NRC or an Agreement State to perform such services.

16. 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.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 2351 East 22nd Street, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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18. A. The source(s) specified in Item(s) 7.G. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date of the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

19. A. Access to the room housing the MicroSelectron-HDR irradiation 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 a month. Records of test results shall be maintained for inspection by the Commission.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" condition 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.

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NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

License number
34 01856 01

or Reference number
030-02609

Amendment No. 43

MATERIALS LICENSE
SUPPLEMENTARY SHEET

20. Prior to the initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron-HDR, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 Centimeters from the surface of the source head shall not exceed 3 milliroentgens per hour.

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

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.1201, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standard for Protection Against Radiation."

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301.

B. Records of the survey results shall be maintained for inspection by the Commission.

21. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of sources contained in the MicroSelectron-HDR irradiation device.

B. Any maintenance or repair operations on the irradiator involving work on the source head, the source driving 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.

22. 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 conform 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).

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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,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Shereif N. Khalil, 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 November, 1992

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

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

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Executive Director

DATE: 8-15-97

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: ~~BJ HOLT~~ WATSON

LICENSEE: ST. Joseph

LICENSE NUMBER: 34-13394-02

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No._____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not started.

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.

Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☑ Licensee is adding authorized users.

A check is included _____. No check is included ✓.

Amendment is necessary _____. Amendment is not necessary X.
(This is a Notification)

☐ Process in as a new licensing action:

A. Amendment _____
B. Renewal _____
C. New License Application _____

☐ Other: _____

Thank You For Your Help!!! 10/16/96