



**HENRY FORD
MACOMB HOSPITALS**

Department of Nuclear Medicine

15855 Nineteen Mile Rd.
Clinton Township, Michigan 48038
Phone: (586) 263- 2465
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DATE: _____ TIME: _____

TO: NAME: _____ Materials Licensing Section _____
 COMPANY: _____ Nuclear Regulatory Commission _____
 FAX #: _____ 630-829-9782 _____

COMMENTS: Attached is a request for a license amendment to add Indrin Chetty, Ph.D as an Authorized Medical Physicist.

Supporting documentation is attached.

FROM: NAME: _____ Michael E. Ward _____
 DEPT: _____ Nuclear Medicine _____
 FAX #: _____ 586-263-2927 _____

TOTAL # OF PAGES INCLUDING COVER LETTER: _____ 9 _____

IF YOU DID NOT RECEIVE ALL THE PAGES, PLEASE CALL:

NAME: _____ Michael E. Ward _____
PHONE: _____ 586-263-2465 _____

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HENRY FORD MACOMB HOSPITALS

15855 Nineteen Mile Road
Clinton Township, Michigan 48038
(586) 263-2300

January 21, 2009

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: License No. 21-11850-01

Please amend our license to add Indrin Chetty, Ph.D as an Authorized Medical Physicist . Dr. Chetty is listed as an Authorized Medical Physicist on Radioactive Material License No. 01-88—01 from the State of Nebraska, Department of Health and Human Services Regulation and Licensure. Documentation is enclosed for your review..

Thank you for you cooperation with this matter. If you have any questions or require additional information please contact our physicist, Qing Chen, MS, at (586) 263-2498

Sincerely,

A handwritten signature in cursive script that reads "Barbara W. Rossmann".

Barbara W. Rossmann
President & Chief Executive Officer

NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM



DEPARTMENT OF SERVICES • DEPARTMENT OF REGULATION AND LICENSURE
DEPARTMENT OF FINANCE AND SUPPORT

STATE OF NEBRASKA

DAVE HEINEMAN, GOVERNOR

January 3, 2007

The Nebraska Medical Center
987400 Nebraska Medical Center
Omaha, NE 68198-7400

ATTN: Frank Rutar, CHP
Radiation Safety Officer

Dear Mr. Rutar:

Enclosed is Amendment No. 31 to Radioactive Material License No. 01-88-01. This amendment adds the Varian HDR unit and medical physicist Indrin Chetty, Ph.D., to the license.

If you have any questions or concerns regarding this amendment, please contact me at (402) 471-8444.

Sincerely,

Bryan G. Miller, Health Physicist
Radioactive Materials Program
HHS Regulation & Licensure

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PO Box 95007, LINCOLN, NE 68509-5007 PHONE (402) 471-2133

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Form 10/04
Revised August 2001STATE OF NEBRASKA
DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION
RADIOACTIVE MATERIALS PROGRAM

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RADIOACTIVE MATERIAL LICENSE

Pursuant to the Radiation Control Act, 1963, and 180 NAC 3 of the Nebraska regulations, 'Control of Radiation,' and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below, and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of the Nebraska Department of Health and Human Services Regulation and Licensure and to any conditions specified below.

1. Licensee	The Nebraska Medical Center	3. License Number	01-00-01
		License Type	Nuclear Medicine/Radiation Therapy
2. Address	667400 Nebraska Medical Center Omaha, NE 68198-7400	4. Amendment Number	31
		License Amended In Its Entirety To Read As Follows:	
		5. Expiration Date	August 31, 2009
6. Radioactive Material	7. Chemical And/Or Physical Form	8. Maximum Quantity License May Possess At Any One Time Under This License	9. Authorized Use
A. Any radioactive material identified in 180 NAC 3-008.00	Any radiopharmaceutical as indicated in 180 NAC 3-008.00	As needed	In Vitro clinical or laboratory tests described in 180 NAC 3-008.00
B. Any radioactive material identified in 180 NAC 7-034	Any unsealed radioactive material prepared for medical use in accordance with 180 NAC 7-034	As needed	Uptake, dilution, and excretion studies authorized by 180 NAC 7-034
C. Any radioactive material identified in 180 NAC 7-035	Any unsealed radioactive material prepared for medical use in accordance with 180 NAC 7-035, except generators	As needed	Imaging and localization studies authorized by 180 NAC 7-035
D. Any radioactive material identified in 180 NAC 7-040	Any unsealed radioactive material prepared for medical use as indicated in 180 NAC 7-040	5 curies	Any therapeutic use described in 180 NAC 7-040
E. Any radioactive material identified in 180 NAC 7-040, except Cobalt 60	Any sealed source as indicated in 180 NAC 7-040	5 curies	Any therapeutic use described in 180 NAC 7-040
F. Technetium-99m	Sodium pertechnetate	500 millicuries	Open calibration linearity testing
G. Iridium-192	Sealed source (Coulton International Model SL-77V; or Varian Medical Model SL-77V or V82800)	11 curies in afterloader, 13 curies replacement source stored for decay at facility - not to exceed 21 curies total	Used in a Varian Medical Systems Model VariSource-HDR afterloader for therapeutic procedures
H. Iodine-125	Sealed source in seeds	300 millicuries	To be used for the superficial treatment of intraocular tumors

Form 1004-6
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I. Iodine-125	Unsealed Iodex aqueous solution	0 curies	To be used in a Proxima 6160/16 Radiation Therapy System catheter in the treatment of malignant brain tumors
J. Yttrium-90	Sealed source (Australian Isotopes Model SIR-Spheres)	108 millicuries per vial not to exceed 288 millicuries total	To be used in a SIRTaX Medical SIR-Spheres brachytherapy system for the treatment of malignant hepatic tumors
K. Strontium-90	Sealed Source (BEGGS Model SVO-303 or AEAT SICW Series)	For all models, no single source to exceed 5.0 mCi, 4 trains total Model A1722: 85 mCi Model A1723: 85 mCi Model A1724: 120 mCi Model A1727: 120 mCi	To be used in Neurovascular Beta-Cath System for intravascular brachytherapy (NIB)
L. Yttrium-90	Sealed source (NDS Nordion Model TheraSphere)	840 millicuries per vial not to exceed 750 millicuries total	To be used in a NDS Nordion TheraSpheres brachytherapy system for the treatment of malignant hepatic tumors
M. Cobalt-60	Sealed source (Dupont Model NBS 392, 8469, 8498; Amersham Model CTR 201, 401, 501, 601, 701, 801; AEA Tech/OGA 1000C and 1000R Series; North American Scientific Model MSD 2700, 2740; CHS Inc. Model 4414, 4416, 4418; or IPL Model PL Series)	25 millicuries per source	Quality control and instrument calibration

CONDITIONS

10. Licensed material listed in item 8. is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized User

Jordan H. Hankins, MD
Charles H. Morris, MD
Karen J. Phillips Holdeman, MD
Charles A. Enko, MD
Chi Lin, MD
Robert D. Thompson, MD
Weining Zhen, MD
Jonathan A. Jaksha, MD
Anthony B. Adelson, MD
Debra M. Lyddon, MD
Marcie H. Peterson, MD

Material and Uses:

3-008.09, 7-034, 7-036, 7-040, Co-60, Tc-99m, Y-90
3-008.09, 7-034, 7-036, 7-040, Co-60, Tc-99m
3-008.09, 7-034, 7-036, 7-040, Co-60, Tc-99m, Y-90 in item 6.L.
3-008.09, 7-040, 7-046, I-125 in item 6.H. and 6.I., Sr-90, Y-90, Ir-192
3-008.09, 7-040, 7-046, Y-90 in item 6.L., Ir-192
3-008.09, 7-040, 7-046, I-125 in item 6.H. and 6.I., Sr-90, Y-90, Ir-192
3-008.09, 7-040, 7-046, I-125 in item 6.H. and 6.I., Sr-90, Y-90, Ir-192
3-008.09, 7-034, 7-036, 7-040 items 1 and 2, Co-60, Tc-99m
3-008.09, 7-034, 7-036, Co-60, Tc-99m
3-008.09, 7-034, 7-036, Co-60, Tc-99m
3-008.09, 7-034, 7-036, Co-60, Tc-99m

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11. A. The Radiation Safety Officer for this license is Frank Rutar, CHP.
- B. The medical physicists for this license are Paul Medin, PhD; Siuong Li, PhD; Susha Pillai, MS; Indrin Chetty, PhD; and Tim Solberg, PhD
12. Licensed material shall be used only at the licensee's facility located at University Tower at 4400 Emile St, Clarkson Tower at 4350 Dewey St, Lied Transplant Center at 4310 Emile Ave, Writson Hall at 528 S. 42nd St, Poynter Hall at 510 S. 42nd St, College of Pharmacy at 525 S. 42nd St and Schackelford Hall at 4367 Emile St.
13. The licensee is authorized to transport licensed material only in accordance with the provisions of 180 NAC 13.
14. The licensee is authorized to hold licensed material with a half-life of less than 300 days for decay-in-storage before disposal in ordinary trash provided the requirements of 180 NAC 7-033 are met.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. Needles or standard medical applicator cells containing licensed material as wire shall not be opened by the licensee.
17. Prior to the initiation of a treatment program, and subsequent to each source exchange, using the remote afterloading brachytherapy device, 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 main source shall not exceed 1 milliroentgen 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 180 NAC 4-005.
 - (b.) That radiation levels in unrestricted areas do not exceed the limits specified in 180 NAC 4-013.
18. The following shall be provided only by manufacturer's representatives or persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services:
- A. Installation and replacement of the sealed source contained in the remote afterloading brachytherapy device listed in Item 6.G.

Form HRA-4
Revised August 2001STATE OF NEBRASKA
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- B. Any maintenance or repair operations on the remote afterloading brachytherapy device listed in Item 6.G. 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 device and result in increased radiation levels.
19. A. Access to the rooms housing the remote afterloading brachytherapy device listed in Item 6.G. 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 necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
20. In lieu of 180 NAC 7-050.01, 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 180 NAC 7-050.02.
21. In lieu of the source inventory required in 180 NAC 7-049, 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 millirem/hr (microsieverts/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 180 NAC 7-049.04.
22. In addition to the possession limits in Item 6., the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 180 NAC 3-018.04 for establishing financial assurance for decommissioning.
23. In lieu of 180 NAC 7-050.01, patients that have been treated with I-125 eye plaques for the treatment of intraocular tumors may be released in accordance with requirements outlined in 180 NAC 7-030. The patient must return to the licensee's facility for removal of the eye plaque. Upon removal of the eye plaque, the regulations outlined in

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180 NAC 7-050 shall be followed.

24. Notwithstanding the requirements of 180 NAC 7-048.03, the licensee may post the required information on the patient's or human research subject's door during treatment. Once the implant therapy is completed, the information outlined in 180 NAC 7-048.03, items 1-4, shall be included in the patient's or human research subject's chart.
25. Notwithstanding the requirements of 180 NAC 7-048, The Nebraska Health Center is authorized to perform intravascular brachytherapy using the Food and Drug Administration's approved Novoste Beta-Cath Systems.
26. Notwithstanding the requirements in 180 NAC 7-048, The Nebraska Medical Center is authorized to perform low dose rate brachytherapy with I-125 Iotrex solution using an approved Proxima Therapeutics G1aSite Radiation Therapy System with catheter Models 1020, 1030, and 1040. (FDA 510(k) Number K003206)
27. Notwithstanding the requirements in 180 NAC 7-048, The Nebraska Medical Center is authorized to perform microsphere brachytherapy with Y-90 using an approved SIRTex SIR-Sphere brachytherapy system. (FDA 510 (k) Number P980005)
28. Notwithstanding the requirements in 180 NAC 7-048, The Nebraska Medical Center is authorized to perform microsphere brachytherapy with Y-90 using an approved MDS Nordion TheraSphere brachytherapy system. (FDA 510 (k) Number H980005)
29. Except as specifically provided otherwise by 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. Title 180 shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application with attachments dated July 28, 2004, signed by Terry Paulsen, VP.
 - B. Reply to deficiency letter dated October 18, 2004, signed by Frank Rutar, RSO.
 - C. Delegation of authority letter dated January 3, 2005, signed by Terry Paulsen, Vice President.
 - D. New RSO office outlined in letter with attachments dated October 18, 2005, signed by Frank Rutar, CHP.
 - E. TheraSphere procedures outlined in letter with attachments dated March 18, 2006, signed by Frank Rutar, CHP.
 - F. Relocation of the Nuclear Medicine Department received July 10, 2006 signed by Frank Rutar, CHP.

Form HDR-10
Revised August 2001

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- G. HDR procedures outlined in letter with attachments dated October 10, 2006, signed by Frank Rutar, CHP.
- H. Reply to deficiency letter dated December 11, 2006, signed by Frank Rutar, CHP.

Date: January 5, 2007

FOR THE NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES
REGULATION AND LICENSURE

Manya Sue Semerara
Julia A. Schmitt
Radioactive Materials Program