

Centra Health

1000 Peachtree Street, N.E.
Atlanta, Georgia 30309
404.521.1111

DL-030398-04

Nuclear Regulatory Commission
Attn: Diane Heim
Atlanta Federal Center
61 Forsyth St. S.W.
Suite 23T85
Atlanta, GA 30323-8931

March 3, 1998

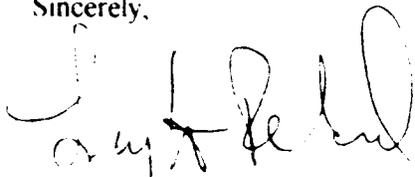
Subject: Notice of Change to NRC License # 45-10542-02 and
License # 45-02207-01

Ms Heim,

Please reference our Material License # 45-10542-02, with the expiration date October 31, 2000, Item 12, Teletherapy Physicist. We wish to make a change to this license to remove D Jay Freedman, MS as the Teletherapy Physicist and add Brian R. Hames, MS as the new Teletherapy Physicist. In addition, Mr. Hames will also function as the Radiation Safety Officer for both licenses with myself as the alternate. The Radiation Safety Committee has reviewed the credentials of Mr. Hames in accordance with 10 CFR Part 35.961. A check in the amount of \$860.00 (\$460 for teletherapy physicist and \$400 for RSO) is enclosed.

If you have any questions, please call the Radiation Oncology Administrative Director, Gienn Dalton at 804-947-4006 or FAX 804-947-7400 or Brian Hames at 804-947-7406. Thank you.

Sincerely,



Larry H. Redmond, MD
Alternate Radiation Safety Officer

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MATERIALS LICENSE

Amendment No. 35

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 in 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 letter dated July 3, 1997

1 Mid-Michigan Regional Medical Center

3 License Number 21-01549-02 is amended in its entirety to read as follows:

2 4005 Orchard Drive
Midland, MI 48670

4 Expiration Date September 30, 2004

5 Docket or Reference No 030-02013

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 Xenon-133)

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 35.500

E. Sealed sources identified in 10 CFR 35.500

E. As needed

F. Any byproduct material identified in 10 CFR 31.11

F. Prepackaged Kits

F. As needed

G. Uranium depleted in Uranium-235

G. Cadmium plated metal

G. 400 kilograms

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- | | | |
|---|---|---|
| 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 |
| H. Iridium-192 | H. Sealed sources (Omnitron International Model SL-77V) | H. 4 sources, 2 sources not to exceed 13 curies and 2 sources not to exceed 10 curies |

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200 (excluding Xenon-133).
- 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. Shielding in a linear accelerator.
- H. Two sources to be used in Varian-TEM Ltd. Model Var:Source HDR remote afterloading brachytherapy devices for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 10 Ci at the time of installation. Two sources in shipping containers for source replacement.

CONDITIONS

- 10. A. Licensed material shall be used at the licensee's facilities located at 4005 Orchard Drive, Midland, Michigan.
- B. Licensed material listed in Item 6.F. may also be used at The Center for Women's Health, 2200 N. Saginaw Road, Midland, Michigan.

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C. Licensed material listed in Item 6.H. may also be used at the licensee's facilities located at Bay Regional Oncology Center, 3180 East Midland Road, Bay City, Michigan.

11. Radiation Safety Officer: Larry N. Langrill, M.S.

Assistant Radiation Safety Officer: Brian R. Hames, 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:

<u>Authorized Users</u>	<u>Material and Use</u>
A. Richard T. Monpetit, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300, 35.500, and 31.11.
B. Rajnikant Mehta, M.D.	10 CFR 35.400, 35.500, and iridium-192 in remote afterloading brachytherapy unit.
C. Norman E. Young, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300, 35.500, and 31.11.
D. Rajesh P. Kotecha, M.D.	10 CFR 35.400, 35.500, and iridium-192 in remote afterloading brachytherapy unit.
E. Paul G. Kocheril, M.D.	10 CFR 35.400 and iridium 192 in remote afterloading brachytherapy unit.
F. Steve Pavlock, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300, 35.500 and 31.11.
G. Michael J. Miller, M.D.	10 CFR 35.500.
H. Thomas E. Rush, M.D.	10 CFR 35.500.
I. John Lozak, D.O.	10 CFR 35.100, 35.200 (excluding xenon-133), and 31.11.
J. Jeffery Herman, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300, and 35.500.
K. Mary J. Hestness, M.D.	10 CFR 35.100, 35.200 (excluding xenon-133), 35.300, 35.500, and 31.11.

13. The brachytherapy physicist for this license is Larry N. Langrill, M.S. or Brian R. Hames, M.S.

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14. In addition to the possession limits in Condition 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.
15. 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).
16. 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 (μ Sieverts/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).
17. Prior to initiation of a treatment program, and subsequent to each source exchange using the VariSource HDR remote afterloading brachytherapy devices, 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 100 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.
 - (2) All areas adjacent to the treatment 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 10 CFR 20.101 (10 CFR 20.1201).
 - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

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18. 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 6.H. afterloading brachytherapy device(s).
 - B. Any maintenance or repair operations on the remote afterloading brachytherapy unit(s) listed in Item 9.. Subitem(s) 6.H. 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
19. A. Access to the rooms housing the Varisource 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 irradiator 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.
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 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 dated June 30, 1994; and
 - B. Letters dated July 11, 1994, July 3, 1997, September 4, 1997 and September 24, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SEP 30 1997

Date

By Deborah A. Picura

The American Board of Medical Physics

Hereby certifies that

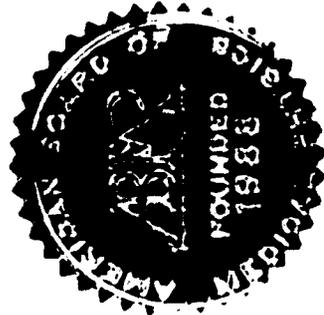
Brian Robert James

Has satisfactorily met the professional standards
and clinical experience requirements
in medical physics to qualify for

Certification in Medical Physics

with special competence in

Radiation Oncology Physics



May 14, 1997
DATE

Fajiz M. Khan
CHAIRPERSON

Law S. Wright
SECRETARY