Amendment No. 36

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.

Licensee	
1. Elizabeth General Medical Center-West	In accordance with the letter dated April 29, 1997,
2. 925 East Jersey Street Elizabeth, New Jersey 07201	3. License Number 29-01600-02 is amended in its entirety to read as follows:
	4. Expiration Date January 31, 2002
	5. Docket or Reference No. 030-02437

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. 1 curie
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 2 curies
E. Iridium 192	E. Sealed source (Mallinckrodt, Model CI L-BV)	E. 10 curies per source and 20 curies total

9. Authorized use

A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
B. Any imaging and localization procedure approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
D. Any brachytherapy procedure approved in 10 CFR 35.400.
E. For use in a Nucletron Corp. microSelectron HDR 080.000 remote after loading brachytherapy unit for the treatment of humans. One source in its shipping container as necessary for the replacement of the source in the irradiation device only.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 925 East Jersey Street, Elizabeth, New Jersey

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11. A. The Radiation Safety Officer for this license is Uvadee Chaibongsai, M.D.

B. The Medical Physicists for this license are Linda Veldkamp and Daniel Alessandro.

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
Robert Silbey, M.D.	35.100; 35.200
Khee Tiang Oen, M.D.	35.100; 35.200
Uvadee Chaibongsai, M.D.	35.100; 35.200
Israel Rebarber, M.D.	35.100; 35.200
Surekha Khedekar, M.D.	35.100; 35.200
Eli Finkelstein, M.D., Ph.D.	35.300; 35.400 Iridium 192 in remote afterloading brachytherapy unit

13. 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), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

14. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.

B. Each entrance to the treatment 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 each entrance door to the treatment room shall be tested for proper operation at least once a month. Records of test results shall be maintained for three years.

D. In the event of malfunction of the door interlock, the unit 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.

15. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit:

    A. A radiation survey shall be made of:

        (1) The 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.

        (2) All areas adjacent to the treatment room with the source in the exposed 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.

            (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b).

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

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

    A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.

    B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, 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.

17. A high dose rate afterloading brachytherapy unit shall be used in accordance with the following conditions:

    A. The unit may only be used in a permanently shielded treatment room.

    B. Following removal of a source from a patient, the licensee shall make a radiation survey of the patient with an appropriate radiation detection survey instrument, as specified in 10 CFR 35.420, to confirm that the source has been removed.

    C. During all patient treatments, both the authorized user and either the medical physicist or radiation safety officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

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D. The licensee shall have and post in the vicinity of the treatment console, written emergency procedures describing the actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition.

E. The licensee shall ensure that personnel are trained in both the routine use of the unit and emergency procedures necessary to return the source to a safe position.

F. The licensee shall immediately, after implanting the source, visually check the permanently installed room radiation monitor to verify that it indicates an exposed radiation source.

G. The licensee shall visually monitor the patient during treatment through a continuous observation system.

H. The licensee shall permit no visitors in the treatment room.

18. In lieu of the source inventory described 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 high dose remote 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 time, date and name of the individual making the survey.

D. Retain the record of the survey for a period of three years.

19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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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 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 28, 1990
B. Letter dated october 8, 1991
C. Letter dated November 11, 1991
D. Letter dated July 9, 1993
E. Letter dated November 1, 1993
F. Letter dated November 15, 1993
G. Letter dated January 6, 1994
H. Letter dated January 24, 1994
I. Letter dated April 29, 1997

For the U.S. Nuclear Regulatory Commission

Date JUN - 9 1997

By Original Signed By:
Michelle Beardsley

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JUN - 9 1997

David A. Fletcher
President
Elizabeth General Medical Center- West
925 East Jersey Street
Elizabeth, NJ 07201

Dear Mr. Fletcher:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 29-01600-02
Docket No. 030-02437
Control No. 124566

Enclosure:
Amendment No. 36

DOCUMENT NAME: R:\WPS\MLTR\L2901600.02
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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	Beardsley MRB							
DATE	05/27/97		05/ /97		05/ /97		05/ /97	

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