MATERIALS LICENSE

Amendment No. 79
CORRECTED COPY

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. Oakwood Hospital and Medical Center - Dearborn 2. 18101 Oakwood Boulevard Dearborn, MI 48123-2500	In accordance with application dated May 24, 1995 3. License Number 21-04515-01 is renewed in its entirety to read as follows: 4. Expiration Date August 31, 2001 5. Docket or Reference No. 030-02051

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 (not to exceed 1 curie 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 31.11	E. Prepackaged Kits	E. As needed
F. Iridium-192	F. Sealed sources (BYK Mallinckrodt Model CI LBV)	F. Two sources not to exceed 12 curies each
G. Cesium-137	G. Sealed sources (ORIS/CBI Model CSL-15)	G. Three sources not to exceed 1700 curies each

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-04515-01

Docket or Reference Number
030-02051

Amendment No. 79

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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. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, and bronchial 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.

G. Three sources to be used in an International CIS self shielded blood irradiator, Model IBL-437C for the irradiation of biologic matter excluding materials that are flammable and/or explosive.

CONDITIONS

10. Location of Use: 18101 Oakwood Boulevard, Dearborn, Michigan.

11. A. Radiation Safety Officer: David S. Yates, M.D.

B. The high dose rate afterloading brachytherapy physicist is Taljit S. Sandhu, Ph.D., Barbara G. Orton, M.S., and Lisa A. Langenstein, M.S.

12. A. 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. Alan R. Hennessey, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.400.
B. Arthur J. Bady, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.400.
C. John B. Junker, M.D.	10 CFR 35.100, 35.200, and 31.11.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-04515-01

Docket or Reference Number
030-02051

Amendment No. 79

CORRECTED COPY

Authorized Users	Material and Use
D. Choon K. Lee, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.
E. James I. Breckenfeld, M.D.	10 CFR 35.100, 35.200, 35.300, (excluding iodine-131 for thyroid carcinoma), and 31.11.
F. Jung H. Chang, M.D.	10 CFR 35.400, and iridium-192 in remote afterloading brachytherapy unit.
G. Reza Abghari, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
H. David S. Yates, M.D.	10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for treatment of hyperthyroidism and cardiac dysfunction), and 31.11.
I. Kyriakos C. Demetropoulos, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
J. Jerry W. Drake, M.D.	10 CFR 35.100, 35.200, and 35.300.
K. Sharon Helmer, M.D.	10 CFR 35.100, 35.200 (excluding generators), and 35.300.
L. Kenneth D. Bartold, M.D.	10 CFR 35.100, 35.200, and 35.300.
M. Arnold Herskovic, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
N. Dong Hyuck Kim, M.D.	10 CFR 35.100, 35.200, and 31.11.
O John H. Finger, M.D.	10 CFR 35.100, 35.200, and 35.300.
P. Eric J. Groskind, M.D.	10 CFR 35.100, 35.200 and 35.300.
Q. Daniel B. Schumaker, M.D.	10 CFR 35.100, 35.200, 35.300, and 31.11.
R. Sophia Roumanis, M.D.	10 CFR 35.100, 35.200, and 35.300.

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License Number 21-04515-01

Docket or Reference Number 030-02051

Amendment No. 79

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Authorized Users	Material and Use
S. T. G. McDonald, M.D.	10 CFR 35.100, 35.200 and 35.300.
T. Paul B. Lattin M.D.,	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.
U. Donald J. Conn, M.D.,	10 CFR 35.100, 35.200 and 35.300.

B. Licensed material listed in subitem 6.G. shall be used by or under the supervision of Cheryl Starbuck upon completion of training by the vendor at installation in accordance with letters dated April 15, 1996, and May 15, 1996.

13. Notwithstanding the provisions of 10 CFR 35.400(d), the licensee may use iridium-192 seeds encased in nylon ribbon as described in letter dated February 7, 1992, for intracavitary/intraluminal treatment of cancer.

14. 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.

15. A. (1) The source(s) specified in Item 7.G. shall be tested for leakage and/or contamination at intervals not to exceed six months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within six months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

16. 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.

17. Prior to 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 100 centimeters from the surface of the source head shall not exceed 0.25 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" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301(b) 10 CFR 20.

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

18. 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.

19. The licensee may possess 24 curies of iridium-192 (not to exceed 12 curies per source) for use in the Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by an authorized individual.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 21-04515-01

Docket or Reference Number 030-02051

Amendment No. 79

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20. 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).

21. 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 35.406(d).

22. 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. Application dated May 24, 1995 (excluding the Quality Management Program); and

    B. Letters dated July 18, 1995, March 27, 1996 (excluding the Quality Management Program), April 15, 1996, May 15, 1996, June 19, 1996 and August 5, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/17/96

By James Dwyer
Nuclear Materials Licensing Branch, Region III

COPY

MATERIALS LICENSE

Amendment No. 79
CORRECTED COPY

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.

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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 (not to exceed 1 curie 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 31.11	E. Prepackaged Kits	E. As needed
F. Iridium-192	F. Sealed sources (BYK Mallinckrodt Model CI LBV)	F. Two sources not to exceed 12 curies each
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CONDITIONS

10. Location of Use: 18101 Oakwood Boulevard, Dearborn, Michigan.

11. A. Radiation Safety Officer: David S. Yates, M.D.

B. The high dose rate afterloading brachytherapy physicist is Taljit S. Sandhu, Ph.D., Barbara G. Orton, M.S., and Lisa A. Langenstein, M.S.

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P. Eric J. Groskind, M.D.	10 CFR 35.100, 35.200 and 35.300.
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14. 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.

15. A. (1) The source(s) specified in Item 7.G. shall be tested for leakage and/or contamination at intervals not to exceed six months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within six months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

16. 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.

17. Prior to 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 100 centimeters from the surface of the source head shall not exceed 0.2 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" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.1301(b) 10 CFR 20.

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

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

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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.

19. The licensee may possess 24 curies of iridium-192 (not to exceed 12 curies per source) for use in the Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by an authorized individual.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 21-04515-01

Docket or Reference Number 030-02051

Amendment No. 79

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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).

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    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 35.406(d).

22. 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. Application dated May 24, 1995 (excluding the Quality Management Program); and

    B. Letters dated July 18, 1995, March 27, 1996 (excluding the Quality Management Program), April 15, 1996, May 15, 1996, June 19, 1996 and August 5, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/17/96

By James Dwyer
Nuclear Materials Licensing Branch, Region III

COPY

OCT 18 1996

Loretta L. Lee
Senior Vice President,
Acute Care
Oakwood Hospital and Medical
Center - Dearborn
18101 Oakwood Boulevard
Dearborn, MI 48123-2500

Dear Ms. Lee:

It has come to our attention through your consultant, Tracy King, that Amendment Number 79 to License Number 21-04515-01 issued on August 22, 1996 contain errors.

Enclosed is a corrected copy reflecting the areas noted to be in error. Specifically, the following 4 changes were made to your NRC license: (1) the amendment No. was changed from 78 to 79; (2) Subitems 6.G., 7.G., 8.G. and 9.G. were added to your NRC license authorizing the use of your international CIS self shielded blood irradiator; (3) License Condition No. 12.B. was added to your NRC license authorizing the use of the blood irradiator by or under the supervision of Cheryl Starbuck and (4) letters dated April 15, 1996, and May 15, 1996 were added to License Condition 22.B. These letters were provided to the NRC in support of your request for the blood irradiator. We apologize for any inconvenience this may have caused you.

Sincerely,

Original Signed By
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No.: 21-04515-01
Docket No.: 030-02051

Enclosure: Corrected Copy of
Amendment No. 79

DOCUMENT NAME: M:\03002051.CC6

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NAME	JMULLAUER:jaw									
DATE	10/7/96									

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