MATERIALS LICENSE

Amendment No. 56
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. St. Elizabeth Hospital	In accordance with letter dated February 24, 1994 3. License Number 48-10219-01 is renewed in its entirety as follows:
2. 1506 South Oneida Street Appleton, WI 54915	4. Expiration Date February 28, 2002
	5. Docket or Reference No. 030-03466

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 10 curies of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed sources (Byk Mallinckrodt Model CI L BV)	E. 2 sources, 1 source not to exceed 444 gigabecquerels (Gbq) (12 curies (Ci)), and 1 source not to exceed 370 Gbq (10 Ci).

260048

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10215-01

Docket or Reference Number
030-03466

Amendment No. 56

CORRECTED COPY

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 and for instrument calibrations.

E. One source to be used in a Nucletron-Oldelft Corporation MicroSelecton HDR remote afterloading brachytherapy device for interstitial and intracavitary radiotherapy in humans and for instrument calibration. 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. Licensed material shall be used only at the licensee's facilities located at 1506 South Oneida Street, Appleton, Wisconsin and at 1611 Madison Street, Appleton, Wisconsin.

11. Radiation Safety Officer: Stanley Reed, M.S.

12. Brachytherapy Physicist: Stanley Reed, M.S.

13. 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. John I. Halloran, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
B. Gregory J. Knudson, M.D.	10 CFR 35.100, 35.200 and 35.300.
C. Patrick O'Brien, M.D.	10 CFR 35.100 and 35.200, limited to cardiovascular clinical procedures.
D. Henry Chessin, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.
E. Stanley A. Reed, M.S.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit for survey meter calibration.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01

Docket or Reference Number
030-03466

Amendment No. 56

CORRECTED COPY

F.	Robert G. Brucker, M.D.	10 CFR 35.100 and 35.200.
G.	T. O. Reinke, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.
H.	Robert R. Kinde, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.400 and iridium-192 in remote afterloading brachytherapy unit.
I.	James E. Murphy, M.D.	10 CFR 35.100 and 35.200.
J.	Timothy H. Seline, M.D.	10 CFR 35.100 and 35.200.
K.	Michael W. Milde	10 CFR 35.100 and 35.200.
L.	Stephanus J. Macrander, M.D.	10 CFR 35.100 and 35.200.
M.	Fred D. Panzer, M.D.	10 CFR 35.100 and 35.200.
N.	Peter Podlusky, M.D.	10 CFR 35.100.
O.	Kent W. Powley, M.D.	10 CFR 35.100 and 35.200.
P.	Sue A. Hausserman-Dugan, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
Q.	Uri Vaisman, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
R.	Rosita Sio Go, M.D.	10 CFR 35.300, 34.400, 35.500 and iridium-192 in remote afterloading brachytherapy unit.
S.	William O. Fletcher, M.D.	35.100 and 35.200 limited to cardiovascular clinical procedures.
T.	M. David Yoseloff, M.D.	35.100, 35.200, 35.300 and 35.500.
U.	John R. Iglar, M.D.	10 CFR 35.100 and 35.200.
V.	Robert A. Belgam, M.D.	10 CFR 35.300, 35.400 and iridium-192 in remote afterloading brachytherapy unit.
W.	Kevin Dul, M.D.	10 CFR 35.100 and 35.200.
X.	Marion H. Scholz, M.D.	10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01

Docket or Reference Number
030-03466

Amendment No. 56

CORRECTED COPY

Y. Brian Hebl, M.D. 10 CFR 35.100, 35.200, 35.300 and 35.500.

Z. Stephen M. Brink, M.D. 10 CFR 35.500.

14. 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).

15. 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 CFR 35.406(d).

16. A. Access to the rooms housing the Nucletron-Oldelft, Micro-Selectron 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 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 may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01

Docket or Reference Number
030-03466

Amendment No. 56

CORRECTED COPY

17. Prior to initiation of a treatment program, and subsequent to each source exchange using the Nucletron-Oldelft, Micro-Selectron 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 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 "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).

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 afterloading brachytherapy device(s).

    B. Any maintenance or repair operations on the Nucletron-Oldelft, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. 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. The licensee shall perform the following safety checks as a minimal on a monthly basis on the Nucletron-Oldelft, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. The safety checks shall be performed in accordance with the manufacturer's instructions:

    A. Source position accuracy within the catheter guide tube to within ± 1 millimeter of the programmed position;

    B. Timer accuracy and linearity;

    C. Measurement of source guide tubes to confirm length to 1 mm accuracy; and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-10219-01

Docket or Reference Number
030-03466

Amendment No. 56

CORRECTED COPY

D. Backup battery test to verify emergency source retraction capability upon power failure.

20. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care patients with temporary eye plaque implants in place, provided that the survey requirements for permanent implant patients specified in 10 CFR 35.75(b) are met. Upon removal of the eye plaque, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The license shall retain a record of the patient survey in accordance with 10 CFR 35.404(b).

21. Notwithstanding the requirements of 10 CFR 35.406(a), after removal of each eye plaque, the patient may be released from the medical treatment facility after an inventory of the sources in each eye plaque is performed to confirm recovery of all sources. This must include disassembling the plaque to conduct a physical inventory of the seeds.

22. Notwithstanding the temporary nature of each eye plaque implant, the licensee must meet the requirements of 10 CFR 35.415(a)(5).

23. 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.

24. 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. Letters dated February 24, 1994 (with attachments), February 7, 1995, March 31, 1995, July 27, 1995 (with attachments), September 24, 1996, November 19, 1996, and December 30, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date February 20, 1997

By Richard Walker
Nuclear Materials Licensing Branch, Region III

FEB 2 0 1997

Stanley Reed, M.S.
Radiation Safety Officer
St. Elizabeth Hospital
1506 South Oneida Street
Appleton, WI 54915

Dear Mr. Reed:

It has come to our attention that Amendment Number 56 to License Number 48-10219-01 issued on January 30, 1997 contained an error.

Enclosed is a corrected copy reflecting Condition 13. noted to be in error. We apologize for any inconvenience this may have caused you.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 48-10219-01
Docket No.: 030-03466

Enclosure: Corrected Copy of
Amendment No. 56

DOCUMENT NAME: M:\03003466.CC7

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	DNMS/RIII								
NAME	GWATSON:jaw								
DATE	02/20/97								

OFFICIAL RECORD COPY

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

February 6, 1997

Gidget Watson
Nuclear Materials Licensing Branch
US-NRC Region III
801 Warrenville Road
Lisle, IL 60532-4351

License No. 48-10219-01

Dear Ms. Watson:

It has come to my attention that there was an omission for use of radiopharmaceuticals listed under part 35.300 for M. David Yoseloff, MD. This physician was approved for this byproduct material group through amendment 53, however, this area apparently has been omitted for all subsequent amendments. Please correct this item to have M. David Yoseloff, MD as an authorized user for material in 35.100, 35.200, 35.300 and 35.500.

Contact Stanley A. Reed (414-738-2190) if there are any questions concerning this request. This correspondence will be faxed to you per your telephone request on February 5, 1997, and also will be sent by mail.

Respectfully submitted,

Stanley A Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm

pm; 2-7-97

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949