NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 76

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. Froedtert Memorial Lutheran Hospital 2. 9200 W. Wisconsin Avenue Milwaukee, WI 53226	In accordance with letter dated December 14, 1995 3. License Number 48-04193-01 is amended in its entirety to read as follows: 4. Expiration Date April 30, 2003 5. Docket or Reference No. 030-03444

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
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources 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. Any byproduct material with Atomic Nos. 3-83; inclusive, with half-lives less than or equal to 120 days	G. Any	G. Not to exceed 100 millicuries per radionuclide. Total possession not to exceed 30 curies except as listed below:

270081

2 mc 30 SD

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 48-04193-01

Docket or Reference Number: 030-03444

Amendment No. 76

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. Phosphorus-32	H. Any	H. 1000 millicuries
I. Phosphorus-33	I. Any	I. 500 millicuries
J. Sulfur-35	J. Any	J. 1000 millicuries
K. Chromium-51	K. Any	K. 500 millicuries
L. Iodine-125	L. Any	L. 750 millicuries
M. Iodine-131	M. Any	M. 500 millicuries
N. Any byproduct material with Atomic Nos. 1-83; inclusive, with half-lives greater than 120 days	N. Any	N. Possession limit not to exceed 10^4 x 10 CFR Part 30 Appendix B limits for each radionuclide. Total possession not to exceed $R/10^4$ is less than or equal to 1; R is the sum of the ratios of the quantity of each radionuclide to the applicable value in 10 CFR Part 30 Appendix B.
O. Any byproduct material with Atomic Nos. 3-83; inclusive	O. Sealed sources (registered pursuant to Section 32.2110 of 10 CFR Part 32 or an Agreement State)	O. 2 curies
P. Iridium-192	P. Sealed sources (BYK Mallinckrodt Model CIL BV)	P. Two sources not to exceed 12 curies each

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 48-04193-01

Docket or Reference Number: 030-03444

Amendment No. 76

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
Q. Iridium-192	Q. Brachytherapy source wire (CIS-US, Inc. Model IRF, IREC or IREL Series)	Q. Not to exceed 150 millicuries per source. Total activity not to exceed 2500 millicuries.
R. Americium-241	R. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)	R. 100 millicuries

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 interstitial; intracavitary; intraluminal; or plesiotherapy treatment including the use of iodine-125 as sealed sources in seeds in an eye plaque.

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. through O. To be used for research and development as described in letter (with attachments) dated January 20, 1993, excluding human research outside the confines of an FDA approved IND, NDA or RDRC.

P. One source to be used in a Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial and intracavitary radiotherapy in humans, in accordance with Condition 34. of this license. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

Q. To be used for interstitial, intercavitary, intraluminal and plesiotherapy treatment of cancer.

MATERIALS LICENSE
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License Number
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R. To be used for research and development as described in letter (with attachments) dated January 20, 1993 excluding human research outside the confines of an FDA approved IND, NDA or RDRC.

CONDITIONS

10. A. Licensed material shall be used only at the licensee's facilities located at 8700 W. Wisconsin Avenue and 8701 Watertown Plank Road, Milwaukee, Wisconsin. Licensed material for medical diagnosis and therapy may also be used at Foedtert Memorial Hospital, 9200 West Wisconsin Avenue, Milwaukee, Wisconsin.

B. Licensed material listed in Item 6.P. shall be used only at the licensee's facilities located in rooms 37-1 or 37-5, Radiation Oncology Department, Basement, N-S Wing, 8700 West Wisconsin Avenue, Milwaukee, Wisconsin.

11. The Radiation Safety Officer for this license is Ralph Grunewald, Ph.D.

12. A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J(a) and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

14. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to Perform such services.

15. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.

16. The licensee shall conduct a physical inventory every 3-months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400 and 10 CFR 35.500 and every 6 months for all other sources and/or devices. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the information required in 10 CFR 35.59(g).

17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

18. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

19. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, and 10 CFR 35.500, the licensee may use for any medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.

20. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except Sections 35.49(a) and (b), 35.100, 35.200, and 35.300.

21. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

22. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

D. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

23. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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

25. The licensee shall maintain records of information related to decommissioning at 9200 W. Wisconsin Avenue, as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

26. A. Access to the rooms housing the MicroSelectron-HDR afterloading brachytherapy unit 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" 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.

27. Prior to initiation of a treatment program, and subsequent to each source exchange for the MicroSelectron-HDR afterloading brachytherapy units, 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 20.1201.

(b) That quantities of radiation in unr[illegible]cted areas do not exceed the limits specified in 10 CFR 20.1301.

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

28. 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 the sealed sources contained in the MicroSelectron-HDR after[illegible]oading brachytherapy unit(s).

B. Any maintenance or repair operations on the MicroSelectron-HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) R. 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.

29. In addition to the possession limits in Condition 8, the licensee shall further restrict the possession of unsealed [illegible]icensed material or readily dispersible source material to quantities less than 10^4 times the applicable limits in Appendix B of Part 30 as specified in 10 CFR 30.35(d).

30. 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 19, 1991, for intracavitary treatment of cancer.

31. Notwithstanding the provisions of 10 CFR 35.400(f), the licensee may use iodine-125 as sealed sources in seeds in an eye plaque as described in letters dated February 19, 1991 and June 6, 1991, for topical treatment of choroidal melanoma.

32. Notwithstanding the provisions of 10 CFR 35.59(a), the licensee may deviate from the radiation safety and handling instructions supplied by the manufacturer only for the iodine-125 eye plaque procedure as described in letters dated February 19, 1991 and June 6, 1991.

33. The licensee shall implement the procedures in 10 CFR 35.59 for iridium-192 wire identified in Subitem Q of Items 6., 7. and 8.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-04193-01

Docket or Reference Number
030-03444

Amendment No. 76

34. 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.

35. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care a patient (described in letter dated July 22, 1996) with a temporary eye plaque implant 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. This survey must include disassembling the plaque to conduct a physical inventory of the seeds. The licensee shall retain a record of the patient survey in accordance with 10 CFR 35.404(b).

36. 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 February 18, 1992 (only); and

    B. Letters with attachments dated February 19, 1991, June 6, 1991, May 14, 1992, January 20, 1993; March 17, 1993, April 6, 1993 (excluding all references to move HDR unit between 2 treatment rooms), May 12, 1994, September 30, 1994, and August 11, 1995 (except Amendment Items 4. and 6.), December 14, 1995, March 26, 1996 and July 22, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 19, 1996

By Patricia A. LeDoux
Nuclear Materials Licensing Branch, Region III

COPY

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B 2B
EXP. DATE: 19980430
FEE COMMENTS: CODE 13
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: FROEDTERT MEMORIAL LUTHERAN
RECEIVED DATE: 951219
DOCKET NO: 3003444
CONTROL NO.: 399668
LICENSE NO.: 48-04193-01
ACTION TYPE: AMENDMENT

R6

2. FEE ATTACHED
AMOUNT: $0
CHECK NO.: 0

3. COMMENTS

SIGNED Lisa O. Hersey
DATE 12-26-95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 07.15 ENTERED)

1. FEE CATEGORY AND AMOUNT: 7B FEE NOT REQUIRED

2. CORRECT FEE PAID / APPLICAT[illegible] MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED SC
DATE 12/27/95

R6

RECEIVED
JAN 0 2 1996
REGION III

add Info 399668

RECEIVED BY LFDCB
Date Dec. 27, 1995
Log Dec R3 III
By SC
Date Completed 12/27/95

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee WI 53226-3596
Telephone: 414 259 3000

Staffed by physicians of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

December 14, 1995

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01
Control number 399068

Dear Sir/Madam:

Enclosed is additional information concerning item 3 of our license amendment request dated August 11, 1995.

If you have any questions concerning this amendment request, please contact Ralph Grunewald, Ph.D. or Robert Yoss at (414)257-6540. Thank you for your prompt attention to this matter.

Cordially

Charles Runge
Vice President, Clinical\Support Services

ADD'L info - 399068
FEE NOT REQUIRED

RECEIVED
DEC 19 1995
REGION III

399668

Additional information in support of item 3 of amendment request dated August 11, 1995.

Transport of HDR unit between rooms.

We confirm that the following conditions shall be adhered to when transporting the HDR unit between rooms 37-1 and 37-5.

1. The source drive mechanism shall be secured using the Nucletron provided key lock during transport from room to room.
2. The HDR unit shall be moved in the presence of a medical physicist trained in the operation of the HDR unit and with the knowledge of the Radiation Safety Office.
3. During the transport of the HDR unit a survey meter shall accompany the transfer to constantly monitor radiation levels.

Facility checks

We confirm that the following facility checks shall be completed prior to clinical use after movement from one treatment room to the other treatment room.

1. The door interlock system shall be checked to ensure the source retracts when the door is opened and that the unit does not automatically start when the door is closed.
2. Check to assure the source can not be driven out of the safe when the door is open.
3. Check the radiation warning lights in the room and over the door for proper function.
4. Assure the "Caution High Radiation Area" and "Caution Radioactive Materials" signs are posted.
5. Check the closed circuit television and intercommunication system for proper function.
6. Ensure the independent radiation monitor performs properly.
7. Assure that any other radiation producing equipment cannot be activated simultaneously with the HDR.
8. Test the performance of backup systems of source retraction for proper function.

NOV 19 1996

Ralph Grunewald, Ph.D.
Radiation Safety Officer
Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, WI 53226

Dear Dr. Grunewald:

Enclosed is Amendment No. 76 to your NRC License No. 48-04193-01 which authorizes your request to use the HDR afterloading device in both treatment rooms 37-1 or 37-5.

Please review the enclosed document and assure that you understand all the terms and conditions. If you have any questions, please contact me at (630) 829-9868.

In addition, as a result of the inspection conducted at your facility on September 23-26, 1996, it was brought to our attention that you have been routinely compacting iodine-131 waste generated from in-patient therapies that involve doses greater than 30 millicuries. After further review of your license file, we determined that we did not receive your procedures for compacting waste. Although we do not believe that there is any health and safety concern with the procedures you described to the inspector(s), we are requesting that you submit the following information:

1. A description of the type and model of the compactor used;

2. A description of the type(s), quantities, and concentrations of waste to be compacted;

3. An evaluation of the potential for airborne release of radioactive material during compaction activities;

4. Specify the location (temporary and permanent) of the compactor;

5. Specify the types and frequencies of surveys that will be performed for contamination control;

6. Submit a copy of the instructions that will be provided to compactor operators; and

7. Based on information obtained during the inspection, it appears that you transport the compactor between patient rooms. If this is the case, describe the permanent storage location for the compactor and describe the surveys that are performed prior to transport to assure no residual contamination is present.

Please submit this information within 30 days of receipt of this letter and reference previous **Control Number 99668.**

Sincerely,

Patricia J. Pelke
Nuclear Materials Licensing Branch

Enclosure: As stated

DOCUMENT NAME: M:\

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

OFFICE	DNMS/RIII	C							
NAME	PELKE:sjd								
DATE	11/19/96								

OFFICIAL RECORD COPY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

96-40

October 7, 1996

MEMORANDUM TO: John R. Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED MAY 9, 1996, FROEDTERT MEMORIAL LUTHERAN HOSPITAL, MILWAUKEE, WISCONSIN, LICENSE NO. 48-04193-01

I am responding to your technical assistance request dated May 9, 1996, (attached) wherein FROEDTERT Memorial Lutheran Hospital in Milwaukee, Wisconsin, requested authorization to transport between, and use, their HDR unit in two treatment rooms within their facility. The requested locations of use consist of the presently licensed location and second treatment room that was previously licensed and equipped for the use of the HDR device in an earlier license amendment.

The licensee initially applied for this authorization by letter to Region III, dated August 11, 1995, followed by additional information on the movement authorization request by letter, dated December 14, 1995. Further by letter dated March 26, 1996, in response to your request for a safety analysis of the proposed relocation of the device between the two specifically authorized rooms on a repetitive basis, the licensee committed to meet the minimum conditions for such transport as established in my memorandum on safety considerations and criteria for the safe movement of high dose rate afterloading devices, dated June 23, 1995. Since the licensee has committed to adhering to all of the previously established NRC criteria for the safe movement of their HDR device, their request for authorization for the movement of the device between the two requested locations should be granted and the license amendment granting this authorization should incorporate these licensee commitments as tie-down conditions.

Attachment: TAR dtd 5/9/96

CONTACT: Robert L. Ayres, NMSS
(301) 415-5746

DISTRIBUTION: Closes IMNS5366
IMNS Central Files NRC File Ctr NMSS r/f PCVacca
BR&SL REGSL REGCHFS IMOB(GAP)

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OFC	IMAB		IMAB		IMAB			
NAME	RAyres		JSchlueter		LCamper			
DATE	/ /96		/ /96		/ /96			

C = COVER E = COVER & ENCLOSURE N = NO COPY

MAY 0 9 1996

96-40

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: MAY 9, 1996

Mail or E-Mail to: *Don Cool (DAC), Director*
Division of Industrial and Medical Nuclear Safety, NMSS

From: for Kwin D. Null
John Madera (JRM4) Region III
Chief, Nuclear Materials Safety and Safeguards Branch

Licensee: FROEDTERT MEMORIAL LUTHERAN HOSPITAL License No. 48-04193-01

X Control No. 99668 (if applicable)

☐ Letter dated: _____(if applicable)

☐ Suggested change in licensing procedure (enclosed):

X Problem/Issue: LICENSEE IS REQUESTING TO USE THEIR HDR UNIT BETWEEN TWO ROOMS AT THEIR INSTITUTION. ENCLOSED ARE COPIES OF THEIR ORIGINAL REQUEST DATED 8/11/95, ADDITIONAL INFORMATION DATED 12/14/95, OUR DEFICIENCY LETTER DATED 3/1/96, AND THE LICENSEE'S RESPONSE DATED 3/26/96.

X Action Required: PLEASE REVIEW AND PROVIDE YOUR COMMENTS.

X Recommended Action (with revisions): X Approve or ☐ Reject

Remarks: MEMORANDUM DATED 6/25/95 (COPY ENCLOSED) FROM LARRY CAMPER TO JOHN MADERA REGARDING "SAFETY CONSIDERATIONS AND CRITERIA FOR THE SAFE MOVEMENT OF HIGH DOSE RATE REMOTE AFTERLOADING DEVICES" WAS REFERENCED IN ORDER TO PREPARE THIS SUBMITTAL.

Headquarters Reviewer: _____
Regional Reviewer: PATTY PELKE
Reviewer Code: R6
Reviewer Phone No.: (708) 829-9868 Fax No.: (708) 515-1259
Request Needed by: 6/30/96 (date) *Form TAR-10*

Attachments: 1. Ltrs. dtd. 8/11/95, 12/14/95, 3/1/96, and 3/26/96
2. Memorandum dated 6/23/95

8/93

cc w/atts: C. Pederson

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 23, 1995

MEMORANDUM TO: John R. Madera, Chief
Nuclear Materials Licensing Section
Division of Radiation Safety and Safeguards, RIII

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: SAFETY CONSIDERATIONS AND CRITERIA FOR THE SAFE MOVEMENT OF HIGH DOSE RATE REMOTE AFTERLOADING DEVICES

This refers to the four letters (Attachments 1 - 4), sent on May 24, 1994, to those licensees presently authorized to move their High Dose Rate Remote Afterloading Devices (HDRs) between treatment rooms and the corresponding safety analyses submitted by the four licensees (Attachments 5 - 8), for the relocation of these devices. The responses of the four licensees have been reviewed and generic guidance is provided, as follows:

Those licensees presently authorized to transport these first generation HDR devices between specifically authorized treatment rooms, within a single facility, shall be permitted to continue this practice provided they meet the following minimum conditions for such transport.

A. Written procedures shall be developed and followed for each movement of the device.

B. Movement of the device shall be restricted to that between those locations authorized by license condition. It is recognized that such movement may result in the device being transported through unrestricted and public use areas.

C. The source shall be mechanically locked within the device's storage safe, if possible, during each movement between locations.

D. Prior to, and after relocation, of the device a radiation survey shall be performed around the source safe at a distance of 10 cm. If the radiation levels exceed those normally expected by more than 5 mR/hr, use of the device shall be discontinued and the device examined by competent service personnel.

E. Movement of the device will require a minimum of two individuals. One will carry a radiation survey device for use in an emergency, such as, tip over of the device. An emergency shielded source container shall also be transported along with the device.

CONTACT: Robert L. Ayres, NMSS
(301) 415-7874

JUN 23 1995

F. After completion of a relocation of the device, and prior to patient treatment, the safety checks set forth in VIII.B.(1) and (2), except VIII.B(2)(c), of Policy and Guidance Directive FC 86-4; Revision 1, shall be performed.

In reviewing the safety analysis of the four licensees, all four do not commit to having an emergency shielded container for the source available during their movement of the device. Except for this, the analysis and procedures submitted by the three of the four licensees appear to conform with the previously stated conditions necessary for safe movement of the device. However, Bethesda Oaks Hospital's submission also lacks written procedures for the movement of the device. The region should relay these concerns to the affected licensees and incorporate the recommended conditions (Items A-F) for the safe movement of these devices upon renewal of the individual licenses.

Attachments: 1 - 4 Four RIII ltrs
5 - 8 Four Licensee safety analyses

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee WI 53226-3596
Telephone: 414 259 3000

Staffed by physicians of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

March 26, 1996

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
ATTN: Patricia J. Pelke
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01
Control Number 99668

Dear Ms. Palke:

This correspondence is to respond to and provide additional information for your review as directed by your letter, dated March 1, 1996 regarding the amendment request to use the HDR therapy unit in either of two rooms.

With regard to your concern that the HDR unit is being relocated to a new location, we must emphasize that, in fact, the HDR device is not being "reinstalled" to a "new" location. The proposed locations for the use of the HDR are the currently approved location, room 37-5, and the location originally approved by the NRC, room 37-1. When the HDR unit was originally installed in room 37-1, in accordance with NRC license amendment 69, the installation was performed by Nucletron Engineering BV. When the unit was moved from room 37-1 to room 37-5, in accordance with NRC license amendment 72, all of the existing connections, terminals, interlocks, monitors, etc. for room 37-1 were left intact. New connections, terminals, interlocks, monitors, etc. were installed in room 37-5 by the manufacturer, Nucletron Engineering BV. The HDR unit will be literally "unplugged" from one location and moved to the other location and "plugged in". Therefore, this is not a "reinstallation" or even an " installation" to a "new location", rather it is the use of the device in two previously approved locations that were installed by authorized personnel in such a manner that to move from one site of use to the other requires minimum intervention.

The following are statements of our confirmations, descriptions and commitments to ensure the HDR unit will be moved safely and will be checked thoroughly to ensure safe operation upon being reconnected.

1. *Transport of the HDR unit between rooms 37-1 and 37-5.* The unit shall only be transported by or in the presence of an authorized medical physicist from the Radiation Oncology Department. Prior to transferring the HDR unit the physicist will ensure that all personnel in the area are aware of the transfer, that the pathway between the rooms is clear of obstacles and unnecessary traffic and that the head of the HDR unit is in the down position with the source mechanically locked in the device storage safe. As can be seen on the enclosed floor plan, the total distance the HDR unit will be moved is approximately 70 feet. There are no inclines in the floor between the rooms. The floor is concrete with unexcavated dirt beneath the floor.

2. *A description of the procedures for performing quality control checks.* Prior to treating a patient, quality control checks shall be performed by an authorized medical physicist. Attached is the current "**HDR Morning Checklist**" that is our written record of the quality control checks performed and maintained. Although the form may be changed as part of a ministerial change, the content of the form shall not change. In addition to the attached QC check, a radiation survey will be performed, in the same way as after a source change, to include the date and time of the survey, the initials of the authorized physicist performing the survey and the results of a radiation survey.

3. *A commitment that records of the quality control checks be maintained.* We confirm that records of the quality control checks will be maintained and, further, that they will be reviewed periodically by the Radiation Oncology Department Quality Assurance program.

4. *Confirmation that movement of the device shall be restricted.* We confirm that the movement of the device shall be restricted to that between rooms 37-1 and 37-5 and that the movement shall be the most direct route safely possible. The movement does not involve transport through unrestricted or" public" use areas nor does it involve the use of elevators.

5. *Confirmation that the source shall be mechanically locked.* We confirm that the source shall be mechanically locked within the device's storage safe and that the head shall be in the down position while in transit.

6. *Confirmation that a radiation survey will be completed.* We confirm that prior to and after relocation of the device, a radiation survey will be performed around the source safe at a distance of 10 cm. If the radiation levels exceed those normally expected by more than 5 mR/hr, use of the device will be discontinued and the device examined by competent service personnel.

7. *Confirmation of number of individuals for movement.* We confirm that movement of the device will require a minimum of two individuals. One will carry a radiation survey instrument for use in an emergency and an emergency shielded source container will also be transported with the device.

8. *Confirmation of safety checks*. We confirm that after completion of the device relocation and prior to patient treatment, we shall perform the safety checks outlined in VIII.B.(1) and (2) , except VIII.B.(2)(c), of Policy and Guidance Directive FC-86-4; Revision 1. We will modify our procedures to include all of the required safety checks outlined above and confirm that we will maintain records of the results of the safety checks.

With the option to use the HDR in two locations we will be able to more efficiently utilize our facilities to perform clinical services and thus more effectively serve our patients. The ability to move the HDR unit between therapy rooms provides three treatment modalities while employing only two specially designed and shielded rooms. Again, only one unit will be allowed to be operated at a time within each room. Additionally, approval of the requested amendment will help to reduce the potential for misadministrations and recordable events by permitting flexibility in a multi-faceted medical setting.

Sincerely,

Charles W. Runge
Vice President, Clinical/Support Services
Attachment

Attachment

HDR Morning Checklist

Day	M	T	W	R	F	S	N	M	T	W	R	F	S	N
Date	*Date QC check performed*													
Time	*Time QC check performed*													
Initials	*Initials of person performing QC check*													
Door Interlock	*check to ensure source can not be exposed when door to room is opened*													
Cable Attachment	*check to see proper cable attachment*													
Console Warning Light	*check to ensure function of console warning lights*													
Door Light	*check to ensure light above door to room is on when source is exposed*													
Door Interrupt	*check to ensure source retracts when door to room is opened*													
TV Monitor Works	*check to ensure video is functioning to maintain contact with patient*													
Primalert (AC)	*check of room monitor*													
Primalert (DC)	*check of room monitor with AC power off*													
Emergency Off	*check to ensure source retracts when Emergency Off button engaged*													
Treatment Interrupt	*test to ensure treatment interrupt functions properly*													
Timer Ends Tx	*test to ensure timer ends treatment*													
Wrong Channel CK	*test to ensure proper channel function*													
Position CK-Film	*test to ensure source position (radiograph & autoradiography)*													
Ion Chamber CK	*check source output*													
Source Retraction CK	*test source retraction function properly*													
Portable GM CK	*check GM survey meter with a dedicated check source to ensure function*													
Forceps & Cutters/Pig	*check to ensure equipment is present in the event of an emergency*													
Paper	*check to ensure enough treatment printout paper for treatments*													
KD / Ortho Check	*check to ensure other treatment unit can not be activated when HDR is on*													

Comments

MAR 0 1 1996

Ralph Grunewald, Ph.D.
Radiation Safety Officer
Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, WI 53226

Dear Dr. Grunewald:

This letter is a follow-up to your December 14, 1995 letter which included additional information in order to continue our review of your request for multi-room use of the HDR device. In order for us to further consider your request, it will be necessary for you to submit the following information:

Be advised that relocating remote afterloading devices to a new location requires the remote afterloading device to be "reinstalled". We further determined that the remote afterloading device is currently authorized for installation by the manufacturer only, Nucletron Engineering BV. In addition, our review identified the need to have, as part of your radiation safety program, specific quality control procedures to ensure that the device is functioning properly after relocation.

In order to ensure that the device is being relocated safely, it will be necessary for you to perform a safety analysis for our review. The safety analysis should include, as a minimum:

1. A description of your procedures for transporting the device, e.g., personnel involved along with a description of their training and experience relative to the use and transport of the HDR device, device lock-out (source in shielded safe position), route of transport (i.e., elevators), etc. The procedures submitted in your December 14, 1995 letter were not complete and lacked sufficient detail to ensure that you had developed adequate procedures to transport the device safely.

2. A description of the procedures for performing **quality control checks** (i.e., source exposure mechanisms, external radiation levels [source shield], interlock systems, etc.) **on the device** to ensure that, prior to treatment, all safety features are operating properly. Please specify whether these quality control checks will be performed by your radiation safety staff or the manufacturer.

3. A commitment that records of the quality control checks described above will be maintained.

4. Confirm that movement of the device shall be restricted to that between rooms 37-1 and 37-5. It is recognized that such movement may result in the device being transported through unrestricted and public use areas.

399668

5. Confirm that the source shall be mechanically locked within the device's storage safe, if possible, during each movement between locations.

6. Confirm that prior to, and after relocation of the device, a radiation survey will be performed around the source safe at a distance of 10 cm. If the radiation levels exceed those normally expected by more than 5 mR/hr, use of the device will be discontinued and the device examined by competent service personnel.

7. Confirm that movement of the device will require a minimum of two individuals. One will carry a radiation survey instrument for use in an emergency, such as, tip over of the device; and an emergency shielded source container will also be transported along with the device.

8. After completion of a device relocation, and prior to patient treatment, the safety checks outlined in VIII.B.(1) and (2), except VIII.B(2)(c), of Policy and Guidance Directive FC 86-4; Revision 1 (copy enclosed), shall be performed. Please modify your procedures to include all of the required safety checks outlined above and confirm that you will maintain record of the results of the safety checks.

We will continue our review upon receipt of this information. Please respond within 30 days and refer to Control Number 99668. Be advised that once we have received your response to the information outlined in this letter, we will forward your request to our Washington, D.C. office for further evaluation. If you have any further questions or require additional clarification, please contact me at (708) 829-9868.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

Sincerely,

Original Signed By
Patricia J. Pelke
Licensing Reviewer

License No. 48-04193-01
Docket No. 030-03444

Enclosure: Policy and Guidance Directive
FC 86-4; Revision 1

DOCUMENT NAME: M:\03003444.DF6
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OFFICE	DNMS/RIII									
NAME	PJPELKE:jaw									
DATE	02/29/96									

OFFICIAL RECORD COPY

FROEDTERT
Memorial Lutheran Hospital

A
030-03444

December 14, 1995

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee WI 53226-3596
Telephone: 414 259 3000

Staffed by physicians of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Rb

Re: License number 48-04193-01
Control number 399068

Dear Sir/Madam:

Enclosed is additional information concerning item 3 of our license amendment request dated August 11, 1995.

If you have any questions concerning this amendment request, please contact Ralph Grunewald, Ph.D. or Robert Yoss at (414)257-6540. Thank you for your prompt attention to this matter.

Cordially

Charles Runge
Vice President, Clinical\Support Services

Additional information in support of item 3 of amendment request dated August 11, 1995.

Transport of HDR unit between rooms.

We confirm that the following conditions shall be adhered to when transporting the HDR unit between rooms 37-1 and 37-5.

1. The source drive mechanism shall be secured using the Nucletron provided key lock during transport from room to room.
2. The HDR unit shall be moved in the presence of a medical physicist trained in the operation of the HDR unit and with the knowledge of the Radiation Safety Office.
3. During the transport of the HDR unit a survey meter shall accompany the transfer to constantly monitor radiation levels.

Facility checks

We confirm that the following facility checks shall be completed prior to clinical use after movement from one treatment room to the other treatment room.

1. The door interlock system shall be checked to ensure the source retracts when the door is opened and that the unit does not automatically start when the door is closed.
2. Check to assure the source can not be driven out of the safe when the door is open.
3. Check the radiation warning lights in the room and over the door for proper function.
4. Assure the "Caution High Radiation Area" and "Caution Radioactive Materials" signs are posted.
5. Check the closed circuit television and intercommunication system for proper function.
6. Ensure the independent radiation monitor performs properly.
7. Assure that any other radiation producing equipment cannot be activated simultaneously with the HDR.
8. Test the performance of backup systems of source retraction for proper function.

JOHN L. DOYNE HOSPITAL

August 11, 1995

A
030-03444

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01

Dear Sir/Madam:

This correspondence is to request that the above license be amended to include the following items:

1. a change of ownership of the NRC license from John L. Doyne Hospital (JLDH) to Froedtert Memorial Lutheran Hospital (FMLH);
2. a change of possession limit which reduces the financial assurance commitment for decommissioning from $750,000 to $150,000;
3. the use of the HDR in either of two rooms within radiation oncology;
4. a modification of license condition 26.B. to allow compliance;
5. an increase of the possession limit for Ir-192 sources to 12 Curies; and
6. the restoration of a license condition previously approved as amendment 62.

Support information for the amendment request is submitted in the attachments and enclosures to this correspondence.

We request separate consideration for the change of ownership item if it is not possible to approve all the items within the 90 days prescribed in IN-89-25, revision 2. Since the JLDH will cease operation no later than December 31, 1995, we prefer the license transfer to take place after October 1, 1995 but before December 31, 1995.

Enclosed is a check for $500.00 as required by 10 CFR 170 Schedule of Fees for an amendment of license type 7B. If you have any questions concerning this amendment request, please contact Ralph Grunewald, Ph.D., Radiation Safety Officer at (414)257-6540. Thank you for your prompt attention to this matter.

Sincerely,

Charles R. Runge
Associate Hospital Administrator

cc: J Apple, Sr. VP FMLH

RECEIVED
REGION III

8700 West Wisconsin Avenue Milwaukee, WI 53226 TTY: 414/257-5774 414/257-7996
On the campus of the Milwaukee Regional Medical Center

JOHN L. DOYNE
HOSPITAL

August 23, 1995

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01
License number 48-04193-03
License number 48-04193-04

Dear Sir/Madam:

Enclosed are amendment requests for each of the above licenses. Each request involves the change of ownership of the three licenses from John L. Doyne Hospital to Froedtert Memorial Lutheran Hospital. Additional amendment request items are included in the "01" license.

If you have any questions concerning this amendment request, please contact me or Robert Yoss at (414)257-6540. Thank you for your prompt attention to this matter.

Cordially,

Ralph Grunewald

Ralph Grunewald, Ph.D.
Radiation Safety Officer

8700 West Wisconsin Avenue · Milwaukee, WI 53226 · TTY: 414/257-5774 · 414/257-7996
On the campus of the Milwaukee Regional Medical Center

List of Enclosures

Attachment I
Support data for amendment request, 5 pages

Attachment II
FMLH financial commitment letter, 2 pages

FMLH Administrative Organizational Chart

MRMC Campus Map and Directory

Letter from Nucletron Corporation

Floor Plan of Radiation Oncology

Check
Check payable to the NRC in accordance with 10 CFR 170

Attachment I

Amendment item 1.

RESPONSES TO IN-89-25, REV. 1 FOR LICENSE TRANSFER

1. The new name of the licensed organization is Froedtert Memorial Lutheran Hospital (FMLH), 9200 West Wisconsin Avenue, Milwaukee, Wisconsin 53226.

2. The licensee contact person to facilitate communication will continue to be Ralph Grunewald, Ph.D., Radiation Safety Officer, (414) 259-2601. Jerry Apple, Senior Vice-President of Administrative and Clinical Services, (414) 259-2601, will be the FMLH person responsible for the license.

3. Responsibility for maintaining the license will be with the administration of FMLH instead of John L. Doyne Hospital (JLDH). There are no other changes in personnel at other levels, including the RSO or authorized users. An organizational chart of FMLH administration is enclosed.

4. John L. Doyne Hospital will not remain in non-licensed business. The hospital will discontinue operations no later than December 31, 1995.

5. JLDH is a publicly owned hospital and a department of Milwaukee County Government. FMLH is a privately owned hospital. JLDH and FMLH are located on the campus of the Milwaukee Regional Medical Center. JLDH and FMLH are adjacent to one another and physically connected at several levels. There has been substantial integration of services between the two hospitals. On April 13, 1995, Milwaukee County Board of Supervisors approved a plan to discontinue the operation of JLDH no later than December 31, 1995. FMLH and Milwaukee County have agreed that FMLH will provide those clinical services regulated by the NRC which are to be discontinued at JLDH.

   The radiation oncology and nuclear medicine departments will remain in their present locations, with no changes with respect to authorized users, facilities, equipment or procedures for human or research use. The administration of the departments will change from JLDH to FMLH.

   The research use of byproduct material will not be affected by the change in ownership and will continue to be administered by MCW.

6. The ONLY change is the organization possessing the license. The license will transfer from the administration of JLDH to FMLH. There are no changes in the location, facilities, equipment, or procedures.

7. There are NO changes in the use, location or storage of licensed byproduct material. This amendment request includes a reduction in the possession limit quantities of radionuclides that we can possess with half-lives greater than 120 days (refer to amendment item 2) and the corresponding reduction in the decommissioning funding level from $750,000 to $150,000. A statement of financial commitment is included with this correspondence.

8. The only change is the administration of the license from JLDH to FMLH. There are NO changes in the location, facilities, equipment, procedures, staff or personnel that would require an amendment. Licensed byproduct material will be used at currently approved facilities at 8700 W. Wisconsin Avenue, Milwaukee, Wisconsin 53226; 9200 W. Wisconsin Avenue, Milwaukee, Wisconsin 53226; and 8701 Watertown Plank Road, Milwaukee, Wisconsin 53226.

9. Surveillance items and records are current and will remain current at the time of the transfer. The records have been and will continue to be maintained in the radiation safety program offices. There are no staff changes that will affect surveillance. Records will be maintained as required under the 10 CFR.

10. The records concerning the safe and effective decommissioning of the facilities will become the responsibility of FMLH, and all licensed activities will continue at the same locations as they are now taking place. The records concerning public dose, sewer disposal, incineration, radioactive material spills, etc., will remain at the radiation safety program offices under the responsibility of FMLH.

11. At the present time there are not any contaminated areas at FMLH, JLDH or MCW.

12. There is no need for a decontamination plan. The clinical use of byproduct material involves either sealed sources or short half-life radionuclides. Therefore, for clinical use there is a very low likelihood of contamination. MCW will continue to be responsible for the research use of byproduct material and contamination that may result. There will not be a division of the transferor's assets. Financial assurance is provided in the amount of $150,000 as described in number 7 above.

13. FMLH agrees to abide by all commitments and representations in the current license as FMLH already abides by these as one of the sites of human and research use under the current license.

    With regard to contamination of facilities and equipment, FMLH provides financial assurance in the amount of $150,000 as described in number 7 above.

    With regard to open inspection items, JLDH, the transferor, will collaborate with FMLH, the transferee, to close any open inspection items.

14. JLDH, the transferor, and FMLH, the transferee, agree to the change in ownership and control of the byproduct material and activity within the scope of the license,

effective following NRC approval, but no later than December 31, 1995. JLDH confirms all open inspection items will be revealed to FMLH and it's responsibility for possible resulting enforcement actions.

15. FMLH, the transferee, agrees to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license.

Approved

Thomas A. Brophy
Interim Administrator
John L. Doyne Hospital

Date: 8/11/95

Approved

William D. Petasnick
President
Froedtert Memorial Hospital

Date: 8/22/95

Amendment item 2.

A change for item 6, 7, and 8 to correspond to the $150,000 decommissioning fund level. Attachment II of this correspondence includes the financial assurance commitment from FMLH.

6.N. does not change
7.N. does not change
8.N. change to: Total possession less than 10E+4 times the applicable limits in Appendix C of 10 CFR Part 20.
6.O. delete
7.O. delete
8.O. delete
6.P. delete
7.P. delete
8.P. delete

Amendment item 3.

We request to use the Nucletron Microselectron HDR in rooms 37-5 and 37-1 of the Radiation Oncology Department. The HDR is currently authorized for use in room 37-5 and was originally authorized for use in 37-1. Shielding specifications for both rooms were previously submitted as parts of amendments 69 and 73. A floor plan of the treatment section of the department showing the proximity of the rooms is included at the end of this attachment.

Amendment item 4.

We request to modify a statement in licensee condition 26.B., namely to delete the last 11 words, which state, "and the source "on-off" control is reset at the control panel." This request is based on the March 1994 inspection where an inspector informed us that the HDR unit would have to be withdrawn from use until that control was added to the HDR unit. That issue was not followed after the inspection. We have since learned that the HDR device approval does not include a reset on the control panel. Therefore, we cannot comply with that license condition without violating the device registration conditions.

Amendment item 5.

We request that item 8R of our license, possession limit of iridium-192 for use in a Nucletron Microselectron HDR, be amended to two sources not to exceed 12 curies each. We stipulate that no source greater than 10 curies will be installed by a Nucletron engineer in the remote afterloader. Attached to this amendment is a letter from Nucletron in support of the request.

Amendment item 6.

We request the reinstatement of condition 30 as stated in amendment 62, dated April 9, 1991, involving alternate radiation dose limits during the medical use of radionuclides for therapy when FMLH Rm 4179 is used. The request, which was included in the renewal application, dated January 1993, attachment 10.10, was not included as a condition in the renewed license. We were informed by an inspector during the March 1994 NRC inspection that this request must be specified as a license condition in order to be in effect.

ATTACHMENT II

FROEDTERT
MEMORIAL LUTHERAN HOSPITAL

June 30, 1995

U.S. Nuclear Regulatory Commission
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01

Dear Sir/Madam:

In accordance with NRC regulations in 10 CFR 30.35, financial assurance for decommissioning is provided in the amount of $150,000, by the instrument attached to this letter, to apply to the above referenced license. It is understood that decommissioning will be necessary in the event that no further activities authorized by this license are conducted. It is also understood that decommissioning is required to take place promptly. This statement of financial assurance covers the use of licensed byproduct materials at:

Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, Wisconsin 53226 and

Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, Wisconsin 53226 and

Facilities located at
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226

If you have any questions concerning the financial assurance commitment, please contact Ralph Grunewald, Ph.D., Radiation Safety Officer at (414) 257-6540.

Sincerely,

Jerry Apple
Senior Vice President

CONFIRMATION AND ADVICE
Non-Assignable/Non-Negotiable

,I MARSHALL & ILSLEY BANK
IVESTMENT DEPT (414)765-8056
'0 N WATER STREET
:LWAUKEE WI 53202

EXECUTION TIME FURNISHED
UPON YOUR WRITTEN REQUEST

DATE CONFIRMED	TRADE DATE	REFERENCE NO
06/26/1995	06/26/95	129080

; PRINCIPAL WE SELL TO YOU

AR VALUE	RATE	MATURITY DATE	PRICE	YIELD	BASIS	SETTLEMENT DATE
150,000.00	6.25	05/31/2000	101.9375	5.791	P101-30	06/27/95

; TREASURY NOTE
1/4 NOTE L 00

PRINCIPAL 152,906.25

\TED 05/31/95 1ST COUPON 11/30/95
JSIP 912827U26
)OK ENTRY ONLY

INTEREST FROM 05/31/1995
INTEREST AMOUNT 691.60

N NO	SECURITY NO	SLS	CUST NO	ACCOUNT NO
)-0806261 028	C10005614	LB	110211	000000002270579

NET AMOUNT 153,597.85

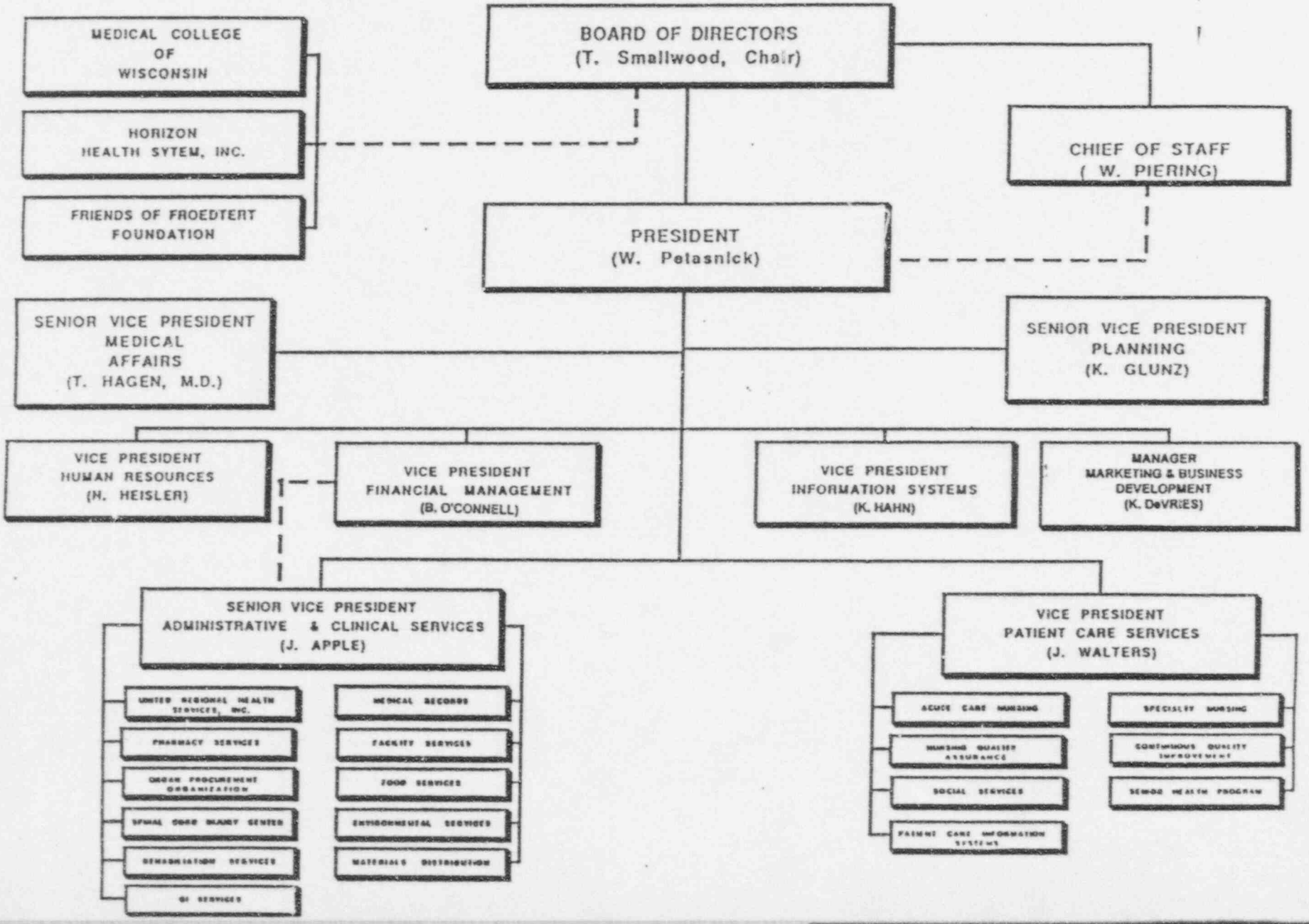
MEDICAL COLLEGE OF WISCONSIN 0000
NRC DECOMMISSIONING FUND
P O BOX 26509
8701 WATERTOWN PLANK RD
MILWAUKEE WI 53226

PAYMENT AND DELIVERY INSTRUCTIONS
WE WILL CHARGE YOUR CHECKING
HELD IN SAFEKEEPING - 03
SUBJECT TO TERMS ON REVERSE

114033 03 0 0 B Y W T 000
PLEASE RETAIN FOR INCOME TAX PURPOSES

Froedtert Memorial Lutheran Hospital

FUNCTIONAL TABLE OF ORGANIZATION



nucletron®

NUCLETRON CORPORATION
7080 Columbia Gateway Drive
Columbia, Maryland 21046-2133
Telephone: 410-312-4100
FAX: 410-312-4199

January 20, 1995

Attn: All Radiation Safety Officers

RE: LICENSE AMENDMENT - MICROSELECTRON-HDR SOURCE POSSESSION LIMITS

Dear Radiation Safety Officer:

Nucletron has recently received Special Form Certification for the microSelectron-HDR source manufactured by Mallinckrodt Diagnostica in Holland. As a result of this certification, it is possible to ship microSelectron-HDR sources to customers with greater than 10Ci activity on the date of shipment.

Most licensees are limited to possession limits of 10Ci per source for the two sources listed on the license. To enhance the ability of each licensee to have a 10Ci source installed in their remote afterloader on schedule, Nucletron wishes to ship the sources at approximately 11.5Ci to each customer prior to the source exchange.

Each licensee must amend their Radioactive Materials License to authorize a possession limit of 12Ci per source with the stipulation that no source greater than 10Ci will be installed by a Nucletron engineer in a remote afterloader. The documents accompanying the source will indicate the Special Form Certification.

After the amendment has been received by the licensee, please fax a copy to Nucletron Corporation at 410-312-4197.

Should you have any questions concerning this letter, please contact the undersigned directly.

Sincerely,
NUCLETRON CORPORATION

Stephen P Teague

Stephen P. Teague
Technical Manager/Radiation Safety Officer

Treatment Section
of the
Radiation Oncology Department
John L. Doyne Hospital