NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 63

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.

302012

Licensee	
1. William Beaumont Hospital	In accordance with letter dated October 31, 1996 3. License Number 21-01333-01 is amended in its entirety to read as follows:
2. 3601 W. 13 Mile Road Royal Oak, MI 48073-6769	4. Expiration Date April 30, 2003
	5. Docket or Reference No. 030-02006

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. Uranium depleted in Uranium-235	G. Cadmium plated metal	G. 300 kilograms

120017

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01333-01

Docket or Reference Number
030-02006

Amendment No. 63

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. Iridium-192	H. Source sets of wire or seeds encased in nylon ribbon that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	H. 8 curies
I. Any byproduct material with Atomic Nos. Between 1-83, inclusive, except as specified below	I. Any	I. 300 millicuries per Radionuclide. Total possession limit not to exceed 5 curies
J. Any byproduct material with Atomic Nos. between 3-83, inclusive, except as specified below	J. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)	J. 1 curie per source. Total possession limit not to exceed 2 curies
K. Cesium-137	K. Sealed source (ORNL Model RAMCO-50)	K. One source not to exceed 380 curies
L. Cesium-137	L. Sealed sources (CEA-ORIS-LAPI13 Model 437C)	L. Two sources not to exceed 2,040 curies each

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-01333-01

Docket or Reference Number: 030-02006

Amendment No. 63

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
M. Iridium-192	M. Sealed sources (Byk Mallinckrodt Model CILBV)	M. 3 sources not to exceed 10 curies each
N. Iridium-192	N. Sealed sources (Byk Mallinckrodt Model CILBV)	N. 4 sources not to exceed 1 curie each
O. Any byproduct material listed in Subitems A. through N.	O. Solid and/or liquid waste	O. See subitem 9.0. below:

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. Medical use described in 10 CFR 35.500.

F. In vitro studies.

G. Shielding in a linear accelerator.

H. Source sets to be used in Nucleotron Model SEL 4000 remote afterloading devices for intercavitary treatment of cancer and medical research on humans. Additional source sets up to the possession limit may be held in their shipping containers incident to source exchange.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01333-01

Docket or Reference Number
030-02006

Amendment No. 63

I. Medical diagnosis and therapy, research and development as defined in Section 30.4 of 10 CFR Part 30 including animal studies.

J. Medical diagnosis and therapy, research and development as defined in Section 30.4 of 10 CFR Part 30 including animals studies, and instrument calibration.

K. To be used in a Isomedix, Inc. Gammator Model 50-B irradiator for irradiation of biological materials (excluding flammable and explosive materials).

L. To be used in a CIS-US Model IBL-437C irradiator for irradiation of blood, blood products and biological materials.

M. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial, intracavitary, and bronchial radiotherapy and medical research on humans. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

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

One source to be used in a Nucletron Corporation MicroSelection - HDR remote afterloading brachytherapy unit for in vitro research studies for the irradiation of cells or for in vivo research studies for the irradiation of rodents as described in letter with enclosures dated March 15, 1993. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

O. Possession incident to interim storage of waste until December 31 1995, in accordance with statements, representations and procedures contained in application dated July 1, 1992. Disposal of waste will commence within one year after access to a disposal site becomes available.

CONDITIONS

10. A. Licensed material listed in Subitems A. through O. shall be used only at the licensee's facilities located at William Beaumont Hospital-Royal Oak, 3601 West 13 Mile Road, Royal Oak, Michigan.

B. Licensed material listed in Subitems A. through C., Subitems E., F., and I. may also be used at William Beaumont Hospital - Troy, 44201 Dequindre, Troy, Michigan.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01333-01

Docket or Reference Number
030-02006

Amendment No. 63

C. Exempt quantities of hydrogen-3 and carbon-14 may also be used and stored (as needed) at the licensee's facilities located at the First America Bank Building, 3127 North Woodward Avenue, Royal Oak, Michigan.

D. Licensed material listed in Subitems A., B., and C. (limited to hyperthyroidism and cardiac dysfunction studies) may also be used at the William Beaumont-West Bloomfield Medical Office Building, 6900 Orchard Lake Road, West Bloomfield, Michigan 48033.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by Darlene Fink-Bennett, M.D., Chairperson, Radiation Safety Committee.

B. The Radiation Protection Officer for the activities authorized by this license is Cheryl M. Culver-Schultz, M.S.

C. Physicians designated to use licensed material in or on humans shall meet the training criteria established in Subpart J. of 10 CFR Part 35.

12. 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.

13. In addition to the possession limits in Condition 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01333-01

Docket or Reference Number
030-02006

Amendment No. 63

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

20. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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.

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

22. 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.

23. 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.

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. 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.

26. 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 20.101.

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

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

27. 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 afterloading brachytherapy unit(s).

    B. Any maintenance or repair operations on the MicroSelectron-HDR afterloading brachytherapy unit(s) listed in Item 9., Subitems M. and N. 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.

28. Notwithstanding the requirements of 10 CFR 35.315(a)(4), the licensee may measure the dose rates in contiguous restricted and unrestricted areas in accordance with procedures described in letters dated November 9, 1994, and July 11, 1995 and December 19, 1995.

29. Notwithstanding the requirements of 10 CFR 35.315(a)(8), the licensee may perform bioassays in accordance with procedures detailed in letters dated November 9, 1994 and July 11, 1995, and December 19, 1995.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
21-01333-01

Docket or Reference Number
030-02006

Amendment No. 63

30. 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 July 1, 1992; and

B. Letters dated October 13, 1992 (with attachment), March 15, 1993 (with attachments), July 28, 1993, April 21, 1994, November 9, 1994, July 11, 1995, December 19, 1995, and April 28, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 20 1997

By Patricia J. Pelke
Nuclear Materials Licensing Branch, Region III

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 3E 2B
Exp. Date: 20030430
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

R6

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: WILLIAM BEAUMONT HOSPITAL
   Received Date: 961101
   Docket No: 3002006
   Control No.: 302012
   License No.: 21-01333-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 580
   Check No.: 093259

3. COMMENTS

Signed D. Hersey
Date 11-5-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: (7B) 3E 2B $580

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal ____
   License ____

3. OTHER ____

Signed SC
Date 11/14/96

NOV 18 1996

Log Nov 5 II
Remitter
Check No. 93259
Amount 580
Fee Category (7B) 3E 2B
Type of Fee AMND
Date Check Rec'd 11/12/96
Date Completed 11/14/96
By: SC

96 NOV 21 AM 9:59

Beaumont
William Beaumont Hospital
Royal Oak

October 31, 1996

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

Re: Amendment Request to NRC License No. 21-01333-01

Dear Patricia J. Pelke:

Please expedite the review of the first part of this amendment request as discussed during our recent telephone conversation on October 16, 1996.

This amendment is a request for approval of the following items: (I) temporary approval to possess and use the new Ir-192 source in Nucleotron's latest model high dose rate afterloading device, the Microselectron HDR Version 2, to perform pre-release clinical testing during the last two weeks of November 1996, and (II) approval of our attached Application to use the device for patient treatments, once the device is approved for human use.

I. Nucletron Corporation has asked the Radiation Oncology Department at William Beaumont Hospital to perform testing (i.e., pre-clinical release and acceptance testing) on the new Microselectron HDR Version 2 device and the new Ir-192 source.

We request temporary approval to possess and use one Ir-192 source (designed for the new version) inside the Microselectron HDR Version 2 device to perform pre-release clinical testing for a period of two weeks under the following conditions.

A. Purpose and Testing Procedures

On October 18, 1996, the Microselectron HDR Version 2 device and HDR Control Unit were shipped to William Beaumont Hospital for initial testing without a radioactive source (Phase I). Phase I of the gamma testing will check the non-radiation functions such as, programming, and simulated treatments with dummy sources. Phase II of the testing requires the installation of the new Ir-192 source. The following functions will be tested during this phase: accuracy of positioning of the source measured with an autoradiography device, source calibration function, and the function of the built in radiation detector. No testing will be performed that would compromise the integrity of the source. See **Attachment 1** for the Nucletron Gamma Test Protocols.

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769 (313) 551-5000
VHA, Member of Voluntary Hospitals of America, Inc.

B. Description of Source

Radionuclide: Ir-192
Manufacturer name and model number: Mallinckrodt Medical B.V.
Model No. *To be assigned.*
Maximum activity (in Curies): 10 Curie ± 20%
Number of Sources: One for testing in the new device which will be returned to the manufacturer upon completion of the gamma testing.
The new Ir-192 source specifications and a sample of the Sealed Source Certificate are attached, however, this is proprietary information of Nucletron Corporation (See **Attachment 2**).

C. Device Description

Manufacturer: Nucletron
Model name/number: Microselectron HDR Version 2
The FDA approval dated July 30, 1996 (K953946) reviewed section 510(k) notification from Nucletron and ruled that the upgraded device was substantially equivalent to the original HDR unit.

D. Facilities

The source and device would be tested in the room that currently houses our 6 MV linear accelerator. During testing, the HDR Control Unit will be rolled out of the treatment room and set up near the doorway to the treatment room. Cables will be routed through the cable cut out in the door. The operator will be present at all times while the HDR control unit is outside the treatment room. When the HDR control unit is not in use, the HDR Control unit will be stored inside the treatment room, which is always locked. See **Attachment 3** for the Diagram of the Testing Set Up. Also, see **Appendix B** of the Application for Approval of Remote Afterloading Device for a more detailed drawing of the HDR Room and the adjacent areas.

E. Shielding Evaluations and Calculations

It is anticipated that the testing will take approximately five days, with a total source exposure time of five hours. The dose calculations included in **Appendix B** and on page 5 of the attached Application for Approval of Remote Afterloading Device are applicable.

F. Authorized Operators

1. William Beaumont Hospital Authorized Operator Who Will Perform the Testing

Greg Edmundson is the Clinical Research Associate for the Department of Radiation Oncology. He is currently an authorized medical physicist for our remote afterloading device therapy program (as referenced in Amendment No. 60, letter submitted to NRC dated April 21, 1994,

and Condition No. 31.B. of our NRC License).

2. Nucletron Service Engineer Authorized to Perform the Source Installation and Removal

Mr. Brent Loudy, a service engineer for Nucletron, has been trained in the Microselectron HDR Version 2. He will be the person who unpacks the source from the shipping container, installs the source inside the device, removes the source from the device, and repackages the source inside the original shipping container. See **Appendix A** of the enclosed Application for the qualifications of Nucletron engineers (dated June 1996).

G. Radiation Safety Precautions

1. Inside the HDR treatment room a wall mounted area monitor (Primalert) displays a red flashing warning light when an exposed or partially exposed source is detected. The unit is mounted where it can be viewed from outside, through the window in the door. See the drawing in **Appendix B**. The function of the area monitor is checked before the testing begins each day with the Ir-192 source incorporated in the Microselectron HDR Version 2 device. In the event of a failure of the Primalert, testing will be canceled until it is repaired.

2. A GM survey meter will also be used upon entry into the HDR Room during the Phase II testing.

3. A continuous viewing system consisting of a closed circuit television with back up via a mirror located opposite the door of the HDR Room is available during the testing. The video monitor is located inside the Control Room adjacent to the HDR Room.

4. The operator will wear his assigned film badge and TLD ring badge during the testing procedures.

5. The source will be leak tested prior to and at the time of the source exchange in accordance with NRC regulations.

6. The HDR Room entryway will be posted with signs that read, "Caution -- High Radiation Area" and "Caution -- Radioactive Materials" at all times while the source is on-site.

7. The Emergency Procedures during the Gamma Testing are included in **Attachment 4**.

H. Security

1. During testing, the HDR Control Unit will be located immediately adjacent to the HDR Room, assuring that the operator will be available to restrict entry to the area. The HDR Control Unit will always be attended when in use, and will be locked inside the HDR room when not in use.

2. The HDR Control Unit and device keyswitches will always be locked when not attended. The operator will maintain personal possession of the keys to the HDR device. When not in use, the keys will be locked inside the operator's office in the Rose Cancer Center. It is not possible to operate the device without a proper log in to the computer system of the HDR Control Unit. This safeguard will also be tested during Phase II.

3. The door to the HDR Treatment Room will remain locked at all times while the source is present in either the device or the shipping container. The only time that this door will be unlocked is when the operator is physically present at the HDR Control Unit and access to the HDR Room is required for testing purposes.

4. The Ir-192 source will be delivered to and stored inside the HDR room at all times until it is returned to the manufacturer at the conclusion of the testing period. The trained Nucletron service engineer, Brent Loudy, will remove the source from the device, package it inside the original shipping container, and arrange for its return to the manufacturer.

5. No person is permitted inside the HDR room when the source is exposed. This is true for loading and unloading of the source, and for all testing procedures.

6. The linear accelerator installed in the treatment room has been decommissioned, and will not be used during the time of the testing. The keys controlling the operation of the accelerator have been removed from the clinic, and are under the custody of the Director of Clinical Physics, Mr. Purushottam Sharma. They are stored in the office area assigned to clinical physics, which is physically remote from the site of testing in the Rose Cancer Center.

I. Interlocks

During the testing, the standard door interlock on the HDR device will NOT be connected to the built in door switches. A separate junction box is provided adjacent to the HDR Control Unit, with switches installed to simulate the operation of the door switch. The operation of the interlock function is included in the testing procedures.

J. No patients would be treated with the device or source during this testing period.

K. Other Pertinent Information

1. The radiation monitor (Primalert) is installed inside the HDR room which is visible through the observation port installed in the door. No outside annunciator will be installed for the testing period. The HDR Room will be prominently posted with "Caution -- High Radiation" and "Caution -- Radioactive Materials" signs at all times while the source is present.

2. A secondary radiation monitor will be installed inside the device (if it is available at the time of testing). This new item is intended to provide additional assurance that the HDR Control Unit

can discriminate between normal exposure and dangerous unintended exposure. If this monitor is available, the operator will also test its functionality.

3. We currently possess two Ir-192 sealed sources (Byk Mallinckrodt Model CI LBV) that are more than 1 Curie and less than 10 Curie each: one in our currently approved Microselectron HDR device, and one in storage for later use in our Research Microselectron. The next source exchange for our currently approved Microselectron HDR device is scheduled for the first week in December, at which time we will have three Ir-192 sealed sources (Byk Mallinckrodt CILBV) in our possession.

We, respectfully, request that the review of this part of the amendment be expedited as soon as possible.

II. Once approved for human use, we request approval for an additional high dose rate (HDR) remote afterloading device. The enclosed Application for Approval of Remote Afterloading Device responds to the NRC required information for approval of the Microselectron HDR Version 2 for human use.

Enclosed is the fee for $580.00 for review of this amendment request.

Please contact Cheryl Culver Schultz, M.S. at 810-551-0548 for any additional information.

Sincerely,

Cheryl Culver Schultz, M.S.
Radiation Safety Officer

Darlene Fink-Bennett, M.D.
Chair, Radiation Safety Committee

James Safran
Assistant Hospital Director

Enclosures:
Attachment 1: Nucletron Gamma Testing Protocols Phase I and II
Attachment 2: New Ir-192 Source Specifications and Sample Leak Test Certificate
Attachment 3: The Diagram of Testing Set Up
Attachment 4: Emergency Procedure for Microselectron-HDR Version 2 Gamma Testing
Application for Approval for Remote Afterloading Device
Appendix A: Qualifications of Engineers and Training Personnel - Nucletron
Appendix B: Shielding Calculations, Exposure Rate Table and Facility Diagrams
Appendix C: Emergency Procedures

nrcamen.o96

5. Scope of Test

The behaviour of the system will be tested under the following conditions:

- Normal operating conditions
- Operator errors

6. Tests

The test items for the gamma test are described below in sections 6.1 through 6.4. Any abnormality (i.e deviation from expected behaviour) must be recorded on a Test Report Form (TRF). Use one form per abnormality and note down the following on each form:

- Product: mHDR-V2
- Version: TCS1.00;TCP1.00;TU1.00F (Note: the version may change during the gamma test. Make sure that the current version is filled in on a TRF)
- Serial No.: The serial number of the treatment unit
- Report No.: Fill in the TRF identification no, using the format: xxxx-p-n, whereby

  xxxx: your hospital acronym

  p: "3", identifying the gamma test of the Test Configuration described above

  n: TRF number 1 to n
- Reported by: name of tester
- Date
- Test Plan Used: Fill in the Test Plan Version (see above) and Test item number, e.g. for 6.1.1.D "Defining Staff Members" (see below) it will be: ARD-043/4024/961009 - 6.1.1.D

  Note: Use item number 6.1.15 (Miscellaneous) for your own free tests.
- Reported Problem/Description: Give a full description of the abnormality and the circumstances leading to it as well as the configuration item concerned.

  Note: If applicable, attach additional information to the TRF, e.g. printouts, radiographs, etc., i.e. anything that could help identify the problem. Please identify each attachment with the Report Number.

  Note: All test below are to be done with a dummy source in the system, unless stated otherwise.

ATTACHMENT 1 NUCLETRON GAMMA TESTING

PROTOCOLS PHASE I AND II

6.1 Normal Operating Conditions

6.1.1 Setting System Parameters

A. Login procedure (Super user/password)

B. Setting Date and Time

C. Defining Staff Members

D. Defining User groups and permissions

E. Source Exchange

F. Check Cable Exchange

G. Source Calibration

6.1.2 Staff Member Permissions

For each staff member define the user group(s) to which he/she belongs.

6.1.3 Programming Patient Data

Enter new fictious patients.

6.1.4 Programming Applicator Data

Define applicators.

6.1.5 Programming Standards

Make standard treatment programs.

6.1.6 Programming Treatment parameters

6.1.6.1 Manually Programming Treatment parameters

Enter treatment data for a patient

Perform a few treatment sessions with different versions of treatment plans

6.1.6.2 Treatment Parameters from PLATO (if available)

Enter treatment data which has been programmed on a PLATO system via a 3.5 inch disk.

Note: For this PLATO-BPS v13.2 will have to be installed on PLATO. Do this via a tape called "Gamma release, PLATO BPS v13.2" (labeled 96-06-25) and "installation procedures PLATO-BPS v13.2" Ref:FKB/95.037/fks, dated 27 June 1996.

Perform a few treatment sessions with different versions of treatment plans (manually edited).

6.1.7 Special Functions

6.1.7.1 Self Test

6.1.7.2 Source Exchange

Note: Perform this mode with the dummy source only

6.1.7.3 Check Cable Exchange

6.1.7.4 Source Calibration

6.1.7.5 Check Ruler

Perform a source position test with the check ruler (dummy source only!)

6.1.7.6 Autoradiograph (if live source available)

Make an autoradiograph of the source in programmed dwell positions with the live source loaded (test phase 2 only).

6.1.7.7 Extra Check Cable Run

6.1.7.8 Back up

6.1.7.9 Restore

6.1.7.10 Hand-held Terminal operations

6.1.7.11 Emergency Stop

Give an emergency stop in different situations during treatment

6.1.8 Applicators

6.1.8.1 Lumencath (bronchial) catheters

Simulate a typical bronchial application (geometry!) and perform a treatment using the dummy source

6.1.8.2 Interstitial Needles

Simulate a typical needle implant (geometry!) and perform a treatment using the dummy source

6.1.8.3 Flexible Implant Tubes

Simulate a typical catheter implant (geometry!) and perform a treatment using the dummy source

6.1.8.4 Gynaecological applicators

Simulate a typical gynaecological application (geometry!) and perform a treatment using the dummy source

6.1.9 Radiation Detector

Check the integrated radiation detector (test phase 2 only)

6.1.10 Emergency Container

6.1.11 Reporting

If possible, make printouts of all tests you perform.

6.1.12 Sounds

Verify if sounds are settable and appropriate.

6.1.13 Displaying

Verify if the screen layout is clear, colurs used are appropriate, etc.

6.1.14 Terminology

Verify if the correct terms are used and are spelled correctly.

6.1.15 Miscellaneous

6.2 Operator Errors

Try possible operator errors, e.g. indexer locking ring "unlocked" and verify if system behaves appropriately.

6.3 Missing Functions

Test if the functions you think are necessary are available.

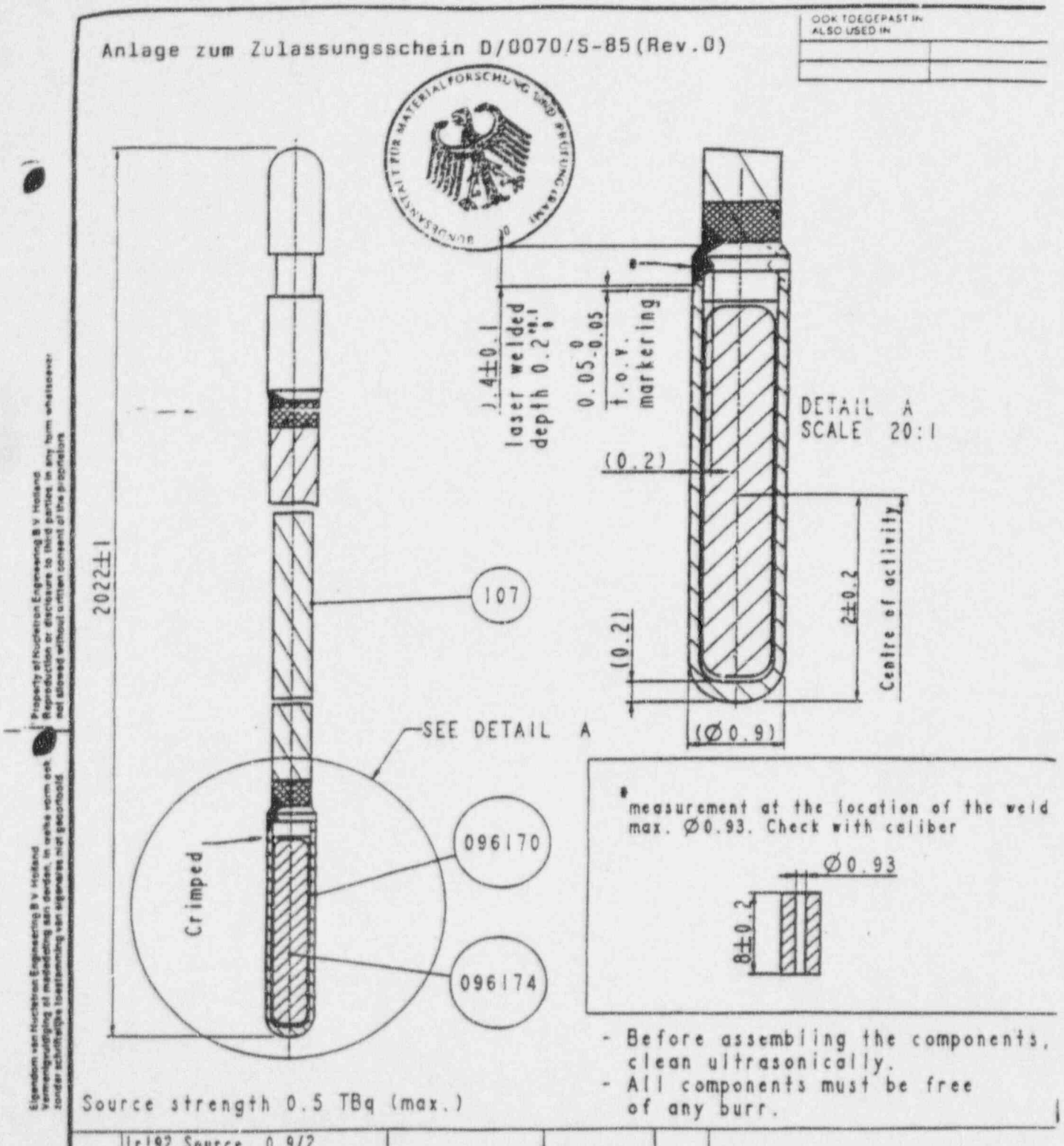
6.4 Superfluous Functions

Verify if there are any unnecessary functions.

6.5 Gamma Test Report

Make your final report, using this test plan as a guideline. Refer to Test Report Forms where appropriate. Give your overall impression, also stating the functions that you find useful and your conclusions/remarks.

ATTACHMENT 2: SOURCE SPECIFICATION



	Ir192 Source 0.9/2			
POS NR	BENAMING DESCRIPTION	MATERIAAL MATERIAL	SAMENSTELLING ASSEMBLY	BEHANDELING TREATMENT
RUWHEID ROUGHNESS NEN 3634 ✓	VORM- EN PLAATSTOLERANTIES TOLERANCES OF FORM AND POSITION NEN 3311	AMER PROJ	EENHEID UNIT mm SCHROEFDRAAD THREAD ISO 6g / 6H	
micro SELECTRON HDR V2			SCHAAL SCALE 10:1	
nucletron	GET DRWN EB	NORM GEC. STD. CHECK	A4	105002
	GEC.	DATUM 15-03-96	SER	AANTAL BLADEN NUMBER OF SH 1 BLAD SHEET 1

ATTACHMENT 2. SAMPLE LEAK TEST CERTIFICATE

CERTIFICATE FOR SEALED SOURCES

Issue Date: 1996/05/13
Production no: LGETST /1
Source no: D36-001
CC. No:

Product code: DRN 07736
Serial no. Transport Container: 1

SOURCE SPECIFICATIONS

Air Kerma Rate: 19.05 mGy m^2h^{-1} +/- 5% (1)
Measured at: 1996/05/13 16:35 CET
Apparent Activity: 173GBq(4.7Ci) at date of measurement(2,3)

Source type: Microselectron HDR (Ir192) V2
Capsule dimensions: 0.9 mm diameter, 4.5 mm length
Source pellet dimensions: 0.65 mm diameter, 3.6 mm length
Source pellet form: solid, Iridium-192 metal
Encapsulation: single
Capsule material: stainless steel, AISI 316L
Classification: ISO/C53211

QUALITY CONTROL

Laser Weld Visual Check: passed
Source Capsule Integrity(15 N pull test): passed
Leakage Test(hot liquid bubble test): leakfree
Surface Contamination(wipe test): < 185 Bq (5 nCi)

The undersigned, authorized officer of Mallinckrodt Medical B.V., certifies that the source complies with requirements of ISO2919 and that all of the information given in this certificate is true and correct.

QUALITY CONTROL SUPERVISOR ...

(1)At Confidence level of 99.7%.

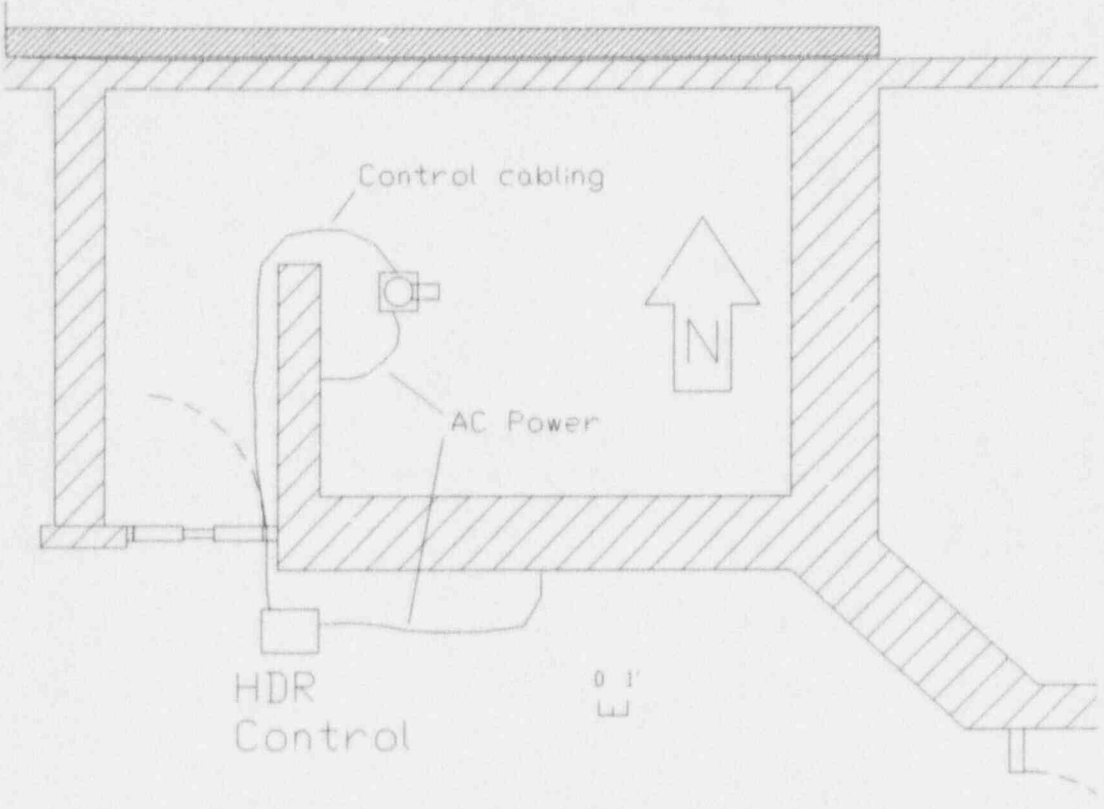
(2)The Apparent Activity is determined by applying a conversion factor(0.110 mGy m^2h^{-1}/GBq) to the measured gamma radiation output of the sealed source determined with a calibrated instrument. The instrument is calibrated against the standard of the Physikalisch- Bundesanstalt (PTB), Braunschweig, Germany.

(3)The Apparent Activity is the Iridium-192 activity; other radionuclides are detectable.

Attachment 3: Diagram of Testing Set Up

Please refer to Appendix B of the Application for Remote Afterloading Device dated October 30, 1996 for the location of the Primalert radiaiton monitor and back up viewing mirror.

Room 02B0040



The testing facility, above, is located in the basement of the main hospital building. The Control Room is located to the left of this diagram and is the control room for a decommissioned 6 MV linear accelerator. The diagrams of the adjacent areas, shielding calculations, and instantaneous exposure rate table are shown in Appendix B of the Application for Approval for Remote Afterloading Device dated October 30, 1996. The dose calculations for the unrestricted areas are shown on page 5 of the Application for Approval for Remote Afterloading Device dated October 30, 1996.

ATTACHMENT 4

Emergency Procedure for MicroSelectron-HDR version 2 Gamma Testing

Note: this procedure is for use ONLY for preliminary clinical testing of this device, which will NOT involve any patient. The purpose of the procedure is therefore to reduce exposure to the operating staff.

If the source should fail to return to the safe after a simulated treatment.

1. **Do not enter the room to retract the source manually.**

2. **Notify the Radiation Safety Officer, Ms. Cheryl Schultz, ext 551-0548.**

3. **If the Radiation Safety Officer is not immediately available, notify the RSO designate for Radiation Oncology, Mr. Purushottom Sharma, ext 551-7072, pager #9970.**

4. **Secure the treatment room, posting the door with a prominent sign reading:**

RADIOACTIVE MATERIALS: DO NOT ENTER

Date: ___/___/___

For information call: _____(Radiation Safety Officer)
ext _____

Fill in the name and phone number of a person known to be available.

5.Call Nucletron Corp. 1-800-336-2249, and notify them that we have a radiation emergency involving the HDR remote afterloader.

APPLICATION FOR APPROVAL OF REMOTE AFTERLOADING DEVICE

DESCRIPTION OF THE SOURCE AND DEVICE

Source Description:

1. Radionuclide: Ir-192
2. Manufacturer name and model number
   Mallinckrodt Medical B.V. Model No. *To be assigned.*
3. Maximum activity (in Curies):
   10 Curie ± 20%
4. Number of Sources:
   One in the machine, one in the shipping container for exchange
   (Total Activity: 20 Curie ± 20%)

Device Description:

1. Manufacturer:
   Nucletron
2. Model name/number
   Microselectron HDR Version 2
   FDA approval dated July 30, 1996 (K953946) reviewed section 510(k) notification from Nucletron and ruled that the upgraded device was substantially equivalent to the original HDR unit.

INTENDED USE

The Microselectron HDR will be used for intraluminal, intracavitary and interstitial treatment of cancer, and other approved clinical treatments.

PROPOSED USERS

All physician users will be approved by the Radiation Safety Committee, AND possess certification from one of the following:

1. ABR in Therapeutic Radiology or Radiology
2. AOBR in Radiation Oncology
3. Canadian Royal College of Physicians and Surgeons (RCPS) in Therapeutic Radiology

TRAINING FOR INDIVIDUALS

Provide an outline of training given to device operators.

1. A manufacturer installation engineer provides on-site training to Beaumont Physics staff in programming and operating the device, to include:
- Programming the console
- A normal patient setup
- Connection of machine to patient
- Description of safety features, location and use of emergency-stop buttons
- Initiation, interruption, and termination of treatment
- Routine diagnosis of fault conditions
- Emergency procedures, including "dry runs" of emergency removal (using "dummy" source)
- Location of the emergency phone list
- Securing the unit when not in use.

2. Beaumont Hospital physics staff will train and supervise dosimetrists/therapists in the operation of the machine. Items covered are identical to above.

Describe additional training provided to individuals who will conduct the source exchanges

Only trained and approved Nucletron engineers will load and unload sources from the transport container, and conduct the source exchanges.

Provide the name and affiliation of the instructor conducting the training described above

Installation, all source exchanges, emergency instruction, and training described in item 1. above of William Beaumont Hospital individuals will be provided by one of the trained and approved individuals, employed by Nucletron, listed in Appendix A.

The Beaumont Hospital employees responsible for training and supervision will be the same as referenced in the letter dated April 21, 1994 and included in Amendment No. 60 with one exception. Marianne Plunkett is no longer employed at William Beaumont Hospital and has been deleted from the list.

Confirm that the individuals who are trained in the use of the device and have practiced the emergency procedures will be on-site while the device is in use.

During all HDR patient treatments, both the physician authorized user and an individual approved by the Radiation Safety Committee to serve as medical physicist or Radiation Safety Officer Designate are required to be physically present or within audible distance.

All physician authorized users and individuals approved by the Radiation Safety Committee to serve as medical physicists, or Radiation Safety Officer designate are required to have training in both the routine use of the Microselectron HDR device and emergency procedures necessary to return the source to a safe condition. This training is provided annually. One of the Nucletron staff listed in Appendix A provides the Emergency Training.

FACILITIES

Submit an annotated drawing indicating the following: See Appendix B

1. Scale
   Marked on drawing (Appendix B)
2. Direction of North
   Marked on drawing (Appendix B)
3. Identification of room (i.e., room number)
   2B0040
4. Type, density and thickness of all shielding materials, walls, floor, ceiling.
   High density concrete. Thicknesses are indicated in the Table of Appendix B. Please note that this room was designed for our 6 MV linear accelerator which is no longer in use.
5. Location of entrance, windows, conduits, etc.
   Marked on drawing (Appendix B)
6. Nature of and distance to adjacent areas
   The minimum distances are marked on the drawings. The contiguous areas are indicated on Appendix B. The level above is the first floor of the hospital which includes a corridor and public area. There is nothing below the room.
7. Use of the adjacent areas (i.e., restricted or unrestricted)
   For the purpose of this application, all adjacent areas are to be considered uncontrolled or unrestricted areas.

Describe continuous viewing system:

1. Primary
   The primary viewing system is via a closed circuit television.
2. Backup if the primary system fails or a commitment to halt treatments.
   A mirror system set up in the HDR room that can be seen through the viewing port in the door is used as a backup system.

Describe area security:

1. Interlocks on entry, etc.

The door switch is interlocked to the Microselectron HDR Control Unit. The source is retracted into the "safe" position if the door is opened when the source is exposed. One emergency stop button is mounted on the HDR Microselectron device in the room and another at the HDR Control Unit outside the room.

2. Restricted area controls (i.e., signs, locks, alarms, lights, etc.)

   a. The treatment room entryway is posted with signs that read "Caution -- High Radiation Area" and "Caution --Radioactive Materials."

   b. The treatment room door is locked after normal treatment hours. When in use, the door is interlocked to the Microselectron HDR Control Unit, initiating the "STOP" sequence if the door is opened during treatment. The HDR Control Unit is locked with a keyswitch when not in use.

   c. An independent radiation monitor is installed in the room, with a flashing red indicator inside of the treatment room which is visible outside the room when radiation is present.

   d. The HDR Control Unit indicates the source position.

3. If other radiation producing devices are in the room, a means of assuring only one device in operation at a time.

The 6 MV accelerator is no longer used for patient treatments and will be decommissioned and removed prior to use of the Microselectron HDR device for patient treatments. No other radiation producing device will be housed in this room except for a C-arm portable fluoroscopic unit. Since only the patient is present in the room during HDR treatments, it is not possible for these two devices to be operated simultaneously.

4. Means of verifying source "safe" condition (i.e., permanently installed monitor)

Inside the HDR treatment room a wall mounted area monitor (Primalert) displays a red flashing warning light when an exposed or partially exposed source is detected. The unit is mounted where it can be viewed from outside, through the window in the door. See the drawing in Appendix B. The function of the area monitor is checked in the morning of each patient treatment day with the Ir-192 source incorporated in the Microselectron HDR as part of the daily HDR dosimetry and quality control tests. If the area monitor fails the check source test, a backup survey meter will be used.

5. Confirm that once tripped, the entry interlock must be reset before activation of the device.

Yes the entry interlock must be reset before activation of the device.

Shielding evaluations/Calculations

Only the patient will be in the treatment room during the use of the Microselectron HDR. Any attempted entry into the room during the treatment time will cause the source to be withdrawn from the patient, to the Microselectron HDR safe.

1. Estimate the maximum "on-time" per hour, and per week.

20 minutes per hour, 300 minutes per week.

2. Calculation of the exposure rate in each adjacent area with the most adverse source orientation.

See Appendix B. The calculations ignore attenuation in the patient's body.

3. Unrestricted areas must meet the following conditions: (1) with "on" time considered and occupancy = 1.0, the exposure rate must be less than or equal to 0.002 rem/hr in one hour, and (2) less than 0.1 rem per year.

Refer to Appendix B. The maximum instantaneous exposures calculated and shown in the Table of Appendix B are all less than 0.002 rem per hour.

Point A: (2.1×10^{-3} mR/hr) x 5 hours/week x 52 weeks/year = 0.6 mR per year (<0.1 rem)
Point B: (1.9×10^{-4} mR/hr) x 5 hours/week x 52 weeks/year = 0.05 mR per year (<0.1 rem)
Point C: (2.9×10^{-1} mR/hr) x 5 hours/week x 52 weeks/year = 76 mR per year (<0.1 rem)
Point D: (2.1×10^{-3} mR/hr) x 5 hours/week x 52 weeks/year = 0.6 mR per year (<0.1 rem)
Point E: (1.2×10^{-4} mR/hr) x 5 hours/week x 52 weeks/year = 0.03 mR per year (<0.1 rem)
Point F: (5.4×10^{-3} mR/hr) x 5 hours/week x 52 weeks/year = 1.4 mR per year (<0.1 rem)
Point F: (4.7×10^{-2} mR/hr) x 5 hours/week x 52 weeks/year = 12 mR per year (<0.1 rem)

As expected, the exposure rates are far below requirements, since the HDR room was designed for the 6 MV linear accelerator.

4. For the restricted areas, the following should be described:

The HDR treatment room is the restricted area.

a. Physical and administrative control of access

The remote control console is located immediately adjacent to the HDR room in the Control Room. The console is always attended during treatments. The keyswitch to activate the device is always removed from the console at the end of each treatment. The source and device are locked inside the HDR room at all times when not in use.

b. Signs: location, number and wording

The HDR treatment room entryway is posted with the following two signs: "Caution--High Radiation Area" and "Caution--Radioactive Materials."

c. Personnel monitoring:

All personnel working in the restricted area are monitored with permanently assigned film badges. Ring TLD dosimeters are assigned to each operator of the HDR Microselectron and worn in the event of emergency handling of the source. Both sets of badges are exchanged monthly.

d. Training (ref. 10 CFR 19.12)

All personnel working in the area are given yearly in service training in accordance with 10 CFR 19.12.

e. Surveys

Leak testing of the Ir-192 source will be performed in conformance with 10 CFR Part 35.59. The Nucletron staff authorized to perform the source exchange is responsible for the leak test requirements prior to and after the source is exchanged.

Area surveys are conducted quarterly in the HDR treatment room and adjacent areas.

OPERATING PROCEDURES

<u>You need not provide a copy of procedures but should confirm the following minimum commitments:</u>

All of the following provisions are incorporated into written procedures available in the Radiation Oncology Department.

1. Implementation of written operating procedures.
2. Copies of procedures given to the appropriate staff
3. Procedures:
   - Require securing the unit, console, and HDR room when not attended.
   - Require that only the patient is permitted inside the HDR room when the device is activated.
   - Require that the patient is surveyed to confirm that all sources have been removed immediately after the completion of the therapy procedure and prior to removal of the patient from the HDR treatment room.
4. Daily (or each day of use) checks will be performed including
   - Interlocks
   - Reproducibility of source positioning within the catheter within ± 1 mm.
   - Verification of source position indicators (e.g., lights, alarms, room monitor)
   - Inspection of the guide tubes for kinks and other imperfections
5. The treatment time calculations will be independently verified.
6. The Quality Management Program will also be implemented.

Calibrations of Source in Device:

1. Describe procedures, frequencies and equipment to determine:

a. Dose accuracy within 5%

The dose accuracy will be determined by measuring the integrated exposure and exposure rate in air at a standardized distance from the source, utilizing a specially constructed calibration jig which holds a standard Farmer-type ionization chamber a fixed distance from the source, under conditions of low and reproducible scatter. The dosimetry system has calibration traceable to NIST. Recalibration is performed biannually. These measurements will be conducted monthly, and whenever a source exchange is made.

b. Travel time error

The system has dual timers. The primary timer is activated only when the source is in treatment position, and is stopped during source motion. The backup timer is activated when the source leaves the safe, and is stopped when it arrives back in the safe. This arrangement explicitly measures both the travel time and dwell time for every treatment. The travel time error will be measured quarterly. The acceptance criterion is less than one second.

c. Accuracy of timing devices

The timing device will be checked with a stopwatch on a quarterly basis.

2. Describe the qualifications of the individuals performing these calibrations if they do not meet the criteria in 10 CFR 35.961.

Individuals meet the criteria in 10 CFR 35.961.

If the device with the installed source will be moved from one treatment room to another, describe the checks that will be conducted after each move and before use to ensure proper operation of both the device and associated safety systems (e.g., interlocks, lights)

Not Applicable

EMERGENCY PROCEDURES

See Appendix C for the Emergency Procedures. These procedures will be prominently posted near the HDR Control Unit.

WASTE DISPOSAL

Sources will be returned to the manufacturer for disposal.

APPENDIX A NUCLETRON STAFF QUALIFICATIONS

Qualifications of Engineers and Training Personnel

RADIATION SOURCE LOADING FOR MICROSELECTRON-HDR

The personnel listed below have been trained in the installation of the microSelectron Remote Afterloading equipment and the loading of the radiation sources into the storage safe of the microSelectron-HDR from the transport container. (listed below).

Person	Years Experience	Experience and Training
A. ten Brinke	10	International Service Manager of Nucletron Engineering B.V., responsible for worldwide warranty and service of the 200+ Selectron systems. He has installed over 50 systems. Training "Ionizing Radiation" Level B (handling of Encapsulated Radioactive Sources-IVBS Rotterdam).
C. Mellink	10	Trained by Nucletron, Engineering B.V. (L. van Zwol and R Hermanus). Has carried out installations in USA, Canada, China, Europe.
O. Dionne	1	Nucletron Corporation Radiation Safety Officer
C. Jones	8	Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
H. Archibald	8	West Coast Service Manager. Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources
B. Loudy	7	" "
C. Scott	7	" "

APPENDIX A NUCLETRON STAFF QUALIFICATIONS

Person	Years Experience	Experience and Training (June. 1996)
J. Cowan	5	East Coast Service Manager. Trained by Nucletron Corporation on operation, service and safety of the machine and sources.
P. Koonce	5	Trained by Nucletron Corporation on operation, service and safety of the machine and sources.
D. Glessner	5	" "
L. Vincent	4	" "
C. Tow	4	" "
Mark Irvin	3	" "
C. Hicks	3	" "
K. Ertugrul	2	" "
C. Valentine	1	" "
M. Cerniack	1	" "

NUCLETRON CORPORATION

By: Ovila J. Dionne, Jr.

Ovila J. Dionne, Jr. Radiation Safety Officer

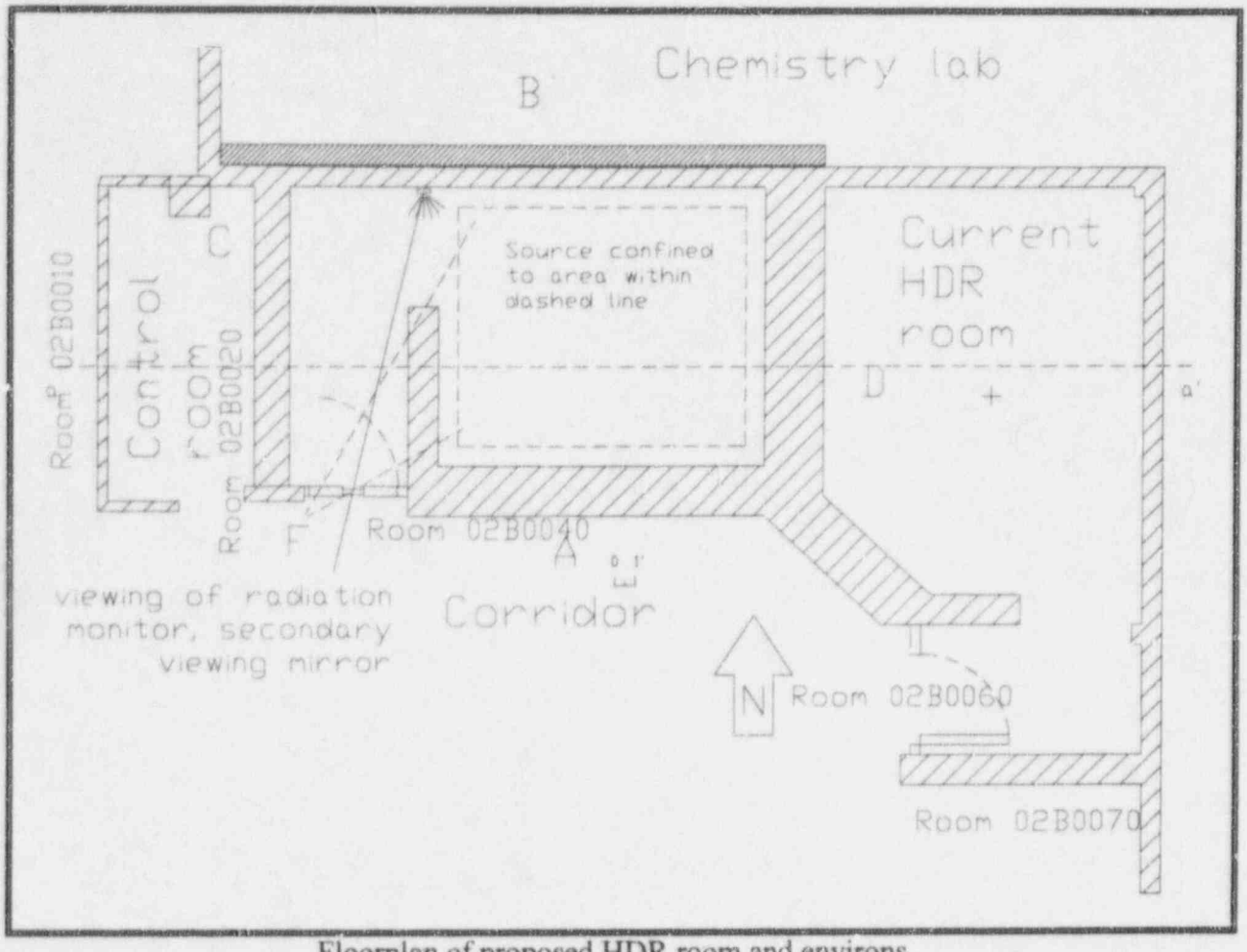
APPENDIX B: SHIELDING CALCULATIONS AND EXPOSURE RATE TABLE FACILITY DIAGRAMS

Shielding calculations:
6 points are considered

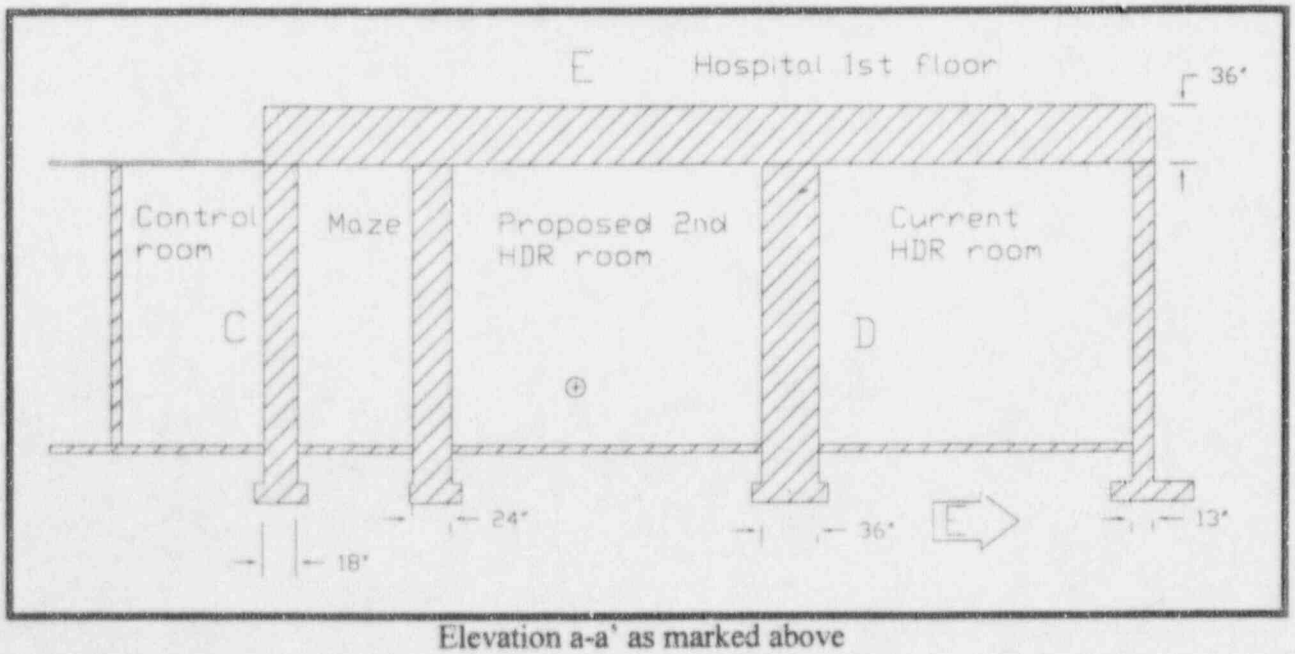
A in adjacent corridor
B in adjacent chemistry lab
C in control room
D in current HDR brachy room
E on floor above
F at doorway

Assumptions:
Γ for ^{192}Ir = 0.466 R m^2 Ci^{-1} hr^{-1}
Source Activity = 10.0 Ci.
Tenth Value Layer (TVL) for ^{192}Ir for:
concrete = 14.7 cm (NCRP 49 Table 28, p. 89)
lead = 2.0 cm
Source position variable, but more than 12" from any wall, 36" above floor.
Points are assumed to be 12" from adjacent wall.

Point	Distance	Shielding material, thickness	TVL	Exposure Rate, mR/hr
A	**1.5 m**	**36" (0.909 m) concrete**	**6**	**2.1×10^{-3}**
B	**1.24 m**	**13" (0.328 m) concrete +** **12" Ledite** **4" (0.101 m) lead-equivalent**	**2.2** **5**	**1.9×10^{-4}**
C	**3.6 m**	**18" (0.455 m) concrete**	**3.1**	**2.9×10^{-1}**
D	**1.5 m**	**36" (0.909 m) concrete**	**6**	**2.1×10^{-3}**
E	**6.3**	**36" (0.909 m) concrete**	**6**	**1.2×10^{-4}**
F	**5.2 m** or **2.8 m**	**25" (.62 m) concrete +** **0.25" (0.64 cm) lead** **22" (.56 m) concrete +** **0.25" (0.64 cm) lead**	**4.2** **0.32** **3.8** **0.32**	**5.4×10^{-3}** **4.7×10^{-2}**



Floorplan of proposed HDR room and environs



Elevation a-a' as marked above

APPENDIX C

EMERGENCY PROCEDURES

FOR
microSelectron-HDR ^{192}Ir
IF THE SOURCE FAILS TO RETURN TO THE SAFE

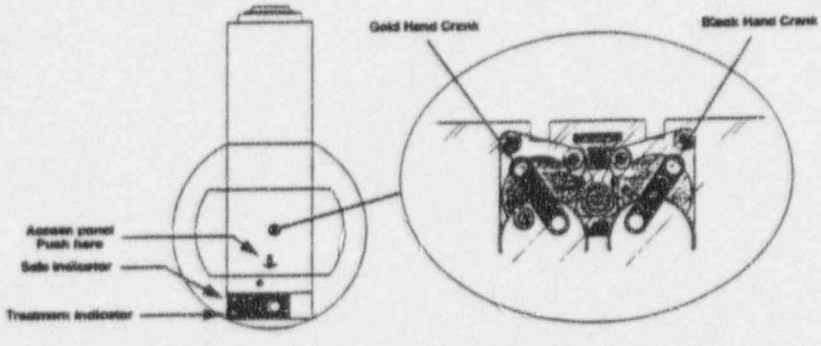
---

1. Depress **RED EMERGENCY STOP BUTTON** on emergency stop switch in control room. If the source retracts, go to step 5, otherwise, step 2.

2. Enter the treatment room with a hand held survey meter.

   - **PUSH** down on the access panel on top of the treatment unit to access the **GOLD** hand crank. Turn it in the direction of the arrows until it stops.

   - If the source retracts, go to 5, otherwise step 3.



Access Panel Location **Gold Hand Crank Location**

3. Remove the applicator from the patient. **DO NOT** disconnect any transfer tubes from the machine or applicators. Place the applicator, still attached to the machine, into the shielded emergency container. (See Specific Instructions)

4. If a survey still shows radiation in the room, move the patient to the anteroom, and survey the patient. If there is no radiation in the patient, remove the patient from the room. Otherwise, activate Surgical Emergency Procedures.

5. Retain the treatment data printout, and record the time the source was removed from the patient, and estimated exposure time of employees. Contact the following:

Physicist:	Elizabeth Mele	Phone#:55-17077 B#:3296
Physician:	Gary Gustafson	Phone#:55-17090 B#:8757
RSO:	Cheryl Culver Schultz	Phone#:55-10548 B#:2372
Nucletron Representative:		
	Charles Jones	B#1(800)759-7243 #8835441

The unintended radiation dose to which those present have been subjected should be estimated and recorded by the RSO and/or a suitable qualified person.

APPENDIX C

EMERGENCY PROCEDURES — SPECIFIC INSTRUCTIONS

1. Using the print out from the HDR control unit, ascertain the channel number currently being treated when the Error Code is generated.

2. Enter the room with the hand held Keithley survey meter at its highest setting (at 20R/hr) and confirm that there is radiation in or near the patient's body.

3. **ENDOBRONCHIAL - ESOPHAGEAL TREATMENT**

- Rapidly and smoothly remove the applicator from the patient's body maintaining its connection to the afterloading device.

INTRACAVITARY APPLICATORS

- Rapidly disassemble the applicator and remove any packing material. The applicator components should be removed in the reverse order of insertion.

- Rapidly and smoothly remove the applicator from the patient's body maintaining its connection to the afterloading device.

INTERSTITIAL IMPLANTS - FLEXIBLE

- Using a suture removal kit, sever any sutures that are retaining the implant tubes to the patient. If the distal end of the implant tube is protruding from the patient's skin and secured with a button, remove the button from the tube without severing the tube.

- Rapidly and smoothly remove the tube in the identified channel or the tubes/applicator containing the flexible tubes from the patient's body maintaining patient's connection to the afterloading device.

INTERSTITIAL IMPLANTS - RIGID

- Using the appropriate tool, loosen the needle clamp on the effected needle and withdraw it from the template or fixing mechanism. If required, using a suture removal kit sever any sutures that are retaining either the needle or applicator to the patient.

- If a specific needle cannot be identified containing the source, then rapidly and smoothly remove all the needles and applicator from the patient's body maintaining it's connection to the afterloading device.

INTERSTITIAL IMPLANTS - HDR MUPIT (TEMPLATES)

- Unlock the clamp on the transrectal ultrasound probe and remove the probe.

- Disconnect the stepper unit from the operating table by loosening the knob on the quick-release coupling just below the stepper.

- Remove the stepper, template and needles from the patient as a unit, maintaining its connection to the afterloading device.

4. A shielded emergency container is available for insertion of the removed applicator unit.

5. Cover the wound left by the applicator with sterile drapings.

6. After the applicator has been removed, survey the patient with the hand held survey meter to confirm that the source has indeed been removed from the patient.

7. Record the time of source removal from the patient's body.

8. Evacuate and lock the room, post the door with a large, handwritten "DO NOT ENTER" sign.

9. Notify the hospital R.S.O., Nucletron Corporation R.S.O., and the appropriate NRC Regional Office if the R.S.O. cannot be reached.

APPENDIX C

SURGICAL EMERGENCY PROCEDURES

SURGICAL REMOVAL OF AN UNSHIELDED SOURCE FROM THE PATIENT'S BODY.

1. Local anesthesia and a surgical kit for minor surgery are available in the Treatment Room.

2. In case that General Anesthesia and a major Surgical Procedure are required, call the Operating Room to obtain immediately the use of an operating room (OR) for the removal of the radioactive source from the patient.

3. Notify the hospital R.S.O. who will distribute radiation badges for surgery personnel, and obtain the rolling radiation shields from the North Tower rooms.

4. Utilize institution approved procedures for transportation of patients with radioactive material.

5. Take the patient, the portable shielded container and the emergency radioactive source handling packet to the operating room.

6. After the source has been removed, place the source in a portable shielded container placed in the operating room.

7. Survey the patient with the hand held survey meter to confirm that the radioactive material has been removed from the patient. Survey the patient before he/she is sent to the recovery room.

8. Record the time when source was removed from patient.

9. Record the time from beginning to end of each employee involved in the source removal procedure.

10. Return the source in its shielded container to the Radiation Oncology Department HDR room.

11. Lock the HDR room and post the door with a large, handwritten "DO NOT ENTER" sign.

12. Notify Nucletron Corporation R.S.O. and the appropriate NRC Regional Office, if the RSO has not done so.

MAY 20 1997

Ms. Cheryl Culver-Schultz, M.S.
Radiation Safety Officer
William Beaumont Hospital
3601 W. 13 Mile Road
Royal Oak, MI 48073-6769

Dear Ms. Culver-Schultz:

Enclosed is Amendment No. 63 to your NRC Material License No. 21-01333-01 in accordance with your request.

10 CFR Part 30, Section 30.36 was amended (Federal Register Notice dated January 16, 1996) to include provisions for a one-time, five year license renewal extension for licensee that satisfied specific criteria. Your institution satisfied the criteria and Item 4 (Expiration Date) of your license has been amended to include the five year extension. In addition, we deleted Condition 25. (recordkeeping requirement for decommissioning) from your license; however, you are still required to maintain these records by regulation (10 CFR Part 30, Section 30.35(g)).

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Sincerely,

Original Signed By
Patricia J. Pelke
Nuclear Materials Licensing Branch

License No.: 21-01333-01
Docket No.: 030-02006

Enclosure: Amendment No. 63

DOCUMENT NAME: M:\03002006.CL7
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								
NAME	PJPELKE:jaw								
DATE	05/20/97								

OFFICIAL RECORD COPY

302012

Beaumont
William Beaumont Hospital
Royal Oak

April 28, 1997

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

RE: License No. 21-01333-01 Supplemental Information for Amendment Request (Control No. 02012)

Dear Ms. Patricia Pelke,

A. In reference to our telephone conversation on April 22, 1997, please withdraw Sections I and II of our amendment request dated October 31, 1996. There have been unforeseen delays by the manufacturer of the Nucletron HDR Version II. Once the new version and Ir-192 source device have been approved for human use, then we will resubmit Section II of this amendment request for NRC approval.

B. In reference to research proposals involving human subjects, we affirm that:

(1) The Human Investigation Committee at William Beaumont Hospital reviews and approves all research projects (including those utilizing byproduct material) prior to their initiation. Under certain conditions, the Radiation Safety Committee is asked by the Human Investigation Committee to review and approve research using byproduct material.
(2) Prior to the conduct of the research, informed consent of each human subject is obtained.
(3) The Human Investigation Committee functions as the "Institutional Review Board" in accordance with terms described in the Federal Policy for the Protection of Human Subjects.
(4) Research involving human subjects is conducted in accordance with the Investigational Device Exemption regulations of the FDA.

C. Please amend condition 9. Section H of our NRC license to include "research" as an authorized use (i.e., "6.H. Source sets to be used in the Nucletron Model SEL 4000 remote afterloading devices for intracavitary and interstitial treatment of cancer, and research on human subjects."). Under condition 9. Section M, please include both "peripheral vascular and research use" as an authorized use (i.e., "6.M. One source to be used in the Nucletron Corporation Microselectron-HDR remote afterloading brachtherapy unit for interstitial, intracavitary, bronchial , peripheral vascular and research radiotherapy on humans.")

Please contact Cheryl Culver Schultz, M.S. at 810-551-0548 for any additional information.

Sincerely,

Cheryl Culver Schultz, M.S.
Radiation Safety Officer

Darlene Fink-Bennett, M.D.
Chair, Radiation Safety Committee

James Safran
Assistant Hospital Director

nrcamen.497

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769 (313) 551-5000

Pm: 4-29-97

CONVERSATION RECORD

TIME 10:20 am DATE 4/22/97

○ VISIT ○ CONFERENCE X TELEPHONE

○ INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: CHERYL CULVER SCHULTZ
ORGANIZATION (OFFICE, DEPT.ETC.): WILLIAM BEAUMONT HOSPITAL
TELEPHONE NO.: 810-551-0548

SUBJECT
AMENDMENT TO LN 21-01333-01 TO PERFORM QA TESTING OF A NEW NUCLETRON HDR AFTERLOADING SOURCE AND DEVICE COMBINATION CN 02012

SUMMARY
I CONTACTED CHERYL CULVER SCHULTZ (THE RSO) TO DISCUSS THE INFORMATION SUBMITTED IN THEIR AMENDMENT REQUEST TO PERFORM QA TESTING ON A NEW NUCLETRON HDR SOURCE/DEVICE COMBINATION (THE SOURCE/DEVICE IS NOT YET REGISTERED) AND SUBSEQUENT APPROVAL TO USE THE DEVICE TO TREAT PATIENTS.

MS. CULVER SCHUTLZ INDICATED THAT AT THIS TIME, THE INSTITUTION DOES NOT WISH TO PURSUE THIS REQUEST. THERE HAVE BEEN SOME UNFORESEEN DELAYS BY THE MANUFACTURER WHICH HAVE DELAYED THE QA TESTING OF THE SOURCE/DEVICE COMBINATION. THEY WILL INDICATE THEIR REQUEST TO WITHDRAW THIS ITEM IN RESPONSE TO OUR TELECON.

IN ADDITION, WE ALSO DISCUSSED THE REQUIREMENTS NECESSARY TO USE AN HDR FOR "ENDOVASCULAR USE" (PREVENTION OF CARDIAC RESTENOSIS). THE INSTITUTION IS CURRENTLY AUTHORIZED TO USE THEIR HDR DEVICE (SUBITEM M OF THE LICENSE) FOR INTERSTITIAL, INTRACAVITARY, AND BRONCHIAL RADIOTHERAPY ONLY; RESEARCH ON HUMANS IS NOT INCLUDED (WHICH IS THE USE CATEGORY THAT WOULD ALLOW ENDOVASCULAR USE UNDER AN FDA "IDE"). MS. CULVER SCHULTZ INDICATED THAT BEAUMONT HAS RECEIVED AN "IDE" FROM THE FDA IN ORDER TO PERFORM THIS PROCEDURE. IN ADDITION, SHE CONFIRMED THAT THEY WILL COMPLY WITH THE REQUIREMENTS OF 35.6 AND 35.7 SPECIFIC TO THIS USE. I INDICATED THAT IN ORDER TO AMEND THE LICENSE TO INCLUDE "RESEARCH ON HUMANS" WITH THE HDR DEVICE, WE WOULD NEED THE FOLLOWING INFORMATION:

1. CONFIRMATION THAT THE RESEARCH WILL BE CONDUCTED UNDER AN "IDE" FROM THE FDA;

2. CONFIRMATION THAT THE INSTITUTION WILL RECEIVE "INFORMED CONSENT " FROM THE SUBJECTS; AND

3. AN INSTITUTIONAL REVIEW BOARD (APPROVED BY THE FDA) WILL REVIEW AND APPROVE THE RESEARCH.

PLEASE SUBMIT THIS INFORMATION **IN DUPLICATE, WITHIN 15 DAYS, AND REFER TO CONTROL NUMBER 02012.**

ACTION REQUIRED
FAX COPY OF TELECON TO LICENSEE AT 810-551-7481

NAME OF PERSON DOCUMENTING CONVERSATION: PATRICIA PELKE
SIGNATURE
DATE: 4/23/97

ACTION TAKESIGNATURE
TITLE
DATE

P. J. Pelke

4/23/97

Beaumont
William Beaumont Hospital
Royal Oak

April 17, 1997

Roy J. Caniano, Acting Director
Division of Materials Safety
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

SUBJECT: Area of Concern from the NRC Inspection Report for License No. 21-01333-01

Dear Mr. Caniano:

In the NRC Inspection Report dated March 19, 1997, we were asked to respond to the following concern within 30 days.

> "An area of concern was identified for lack of contingency planning and use of appropriate facilities and equipment to control accidental releases of iodine-131 in the Radiopharmacy. During the inspection, it was learned that vials of iodine-131 solutions were routinely stored in the elution room. In the event of a leaking vial, the volatile iodine-131 vapors would not be immediately controlled by the fume hood."

I. Description of Facilities and Equipment:

A. Fumes Hoods and Exhaust from Storage Locker

1. Fume Hoods in Nuclear Medicine (two)

One fume hood is located inside the Radiopharmacy. Routine handling and preparation of iodine-131 doses are performed inside this fume hood. A second fume hood is located in the In Vitro Laboratory, which is adjacent to the newly renovated Bone Imaging Suite in the Nuclear Medicine Department. This fume hood serves as a back up in the event of a spill of I-131 solution in which liquid iodine-131 is not contained within a sealed unopened container. The operation of each fume hood is certified semiannually.

2. Hot Locker Radionuclide Storage Room ("Storage Locker")

The lead shielded Storage Locker (i.e., referred to as the "elution room" above) is located inside the Radiopharmacy. The lead lined door to the Storage Locker is routinely closed when not in use. The ventilation in the Storage Locker was designed for negative pressure at all times whether the door is open or closed. The Exhaust Register is located just above the counter top as shown on the attached diagram. The most recent airflow measurements were as follows: the Supply Diffuser measured 72 CFM. The Exhaust Register measured 115 CFM. The Room is under negative pressure with a negative velocity under the closed door of 174 feet per minute. Airflow measurements which verify negative pressure in the Storage Locker are conducted semiannually.

B. Operation and Release Point for the Fume Hoods (Radiopharmacy and In Vitro Laboratory), and the Exhaust Register in the Storage Locker inside the Radiopharmacy:

All of these exhaust systems are operated continuously. The exhaust from these fume hoods and the Exhaust Register are combined into a single exhaust duct and released above the roof of the North Tower of the Main Hospital. The

3601 West Thirteen Mile Road Royal Oak, Michigan 48073-6769 (313) 551-5000

release point is from the penthouse located on the northeast corner of the building at a height of 106 feet above the ground. There is one master shut off switch for these exhaust units located inside the penthouse. The access to the penthouse is limited to Nuclear Medicine, the authorized contractor who tests and certifies the fume hoods and HEPA filter, and authorized maintenance staff.

C. Description of the Effluent Controls that are used at the release point and an estimate of the efficiency for each device:

Our supplier of oral sodium iodinde-131 solution is Mallinckrodt, which has the least volatile commercially available oral solution on the market (0.491 nanocurie/millicurie $\pm$ 0.205 S.D.). The exhaust from the fume hoods and Exhaust Register (in the Radiopharmacy Storage Room) is passed through an HEPA filter system located inside the penthouse prior to the release at the roof of the building. The efficiency of this filter is above 99% for volatile sodium iodide (I-125, and I-131). The efficiency of the filter is tested annually and the filter is either replaced or repaired to maintain its efficiency.

II. Contingency Procedures

A. All liquid iodine-131 that must be uncapped and opened are handled in one of the two fume hoods in the Department of Nuclear Medicine (Radiopharmacy or In Vitro Lab).

B. When not in use, sodium iodine-131 solutions are sealed inside unopened containers which are stored inside the manufacturer's lead shielded containers with the lead shielded lids securely attached. These containers are stored on the counter top immediately next to the exhaust register in the Storage Locker which is located inside the Radiopharmacy. See the attached Diagram.

C. In the event of breakage or a leaking vial, the items that could be volatile will be stored inside one of the fume hoods to control the release of I-131 vapors.

D. The Spill Procedures, Area Survey Procedures, Decontamination Procedures and Bioassay Procedures included as conditions of our NRC license, and other applicable NRC regulations will be followed in the event of an accidental release of I-131.

Sincerely,

Cheryl Culver Schultz, M.S.
Radiation Safety Officer

Darlene Fink-Bennett, M.D.
Assistant Director, Department of Nuclear Medicine
Chairman, Radiation Safety Committee

James M. Safran, P.E.
Assistant Hospital Director

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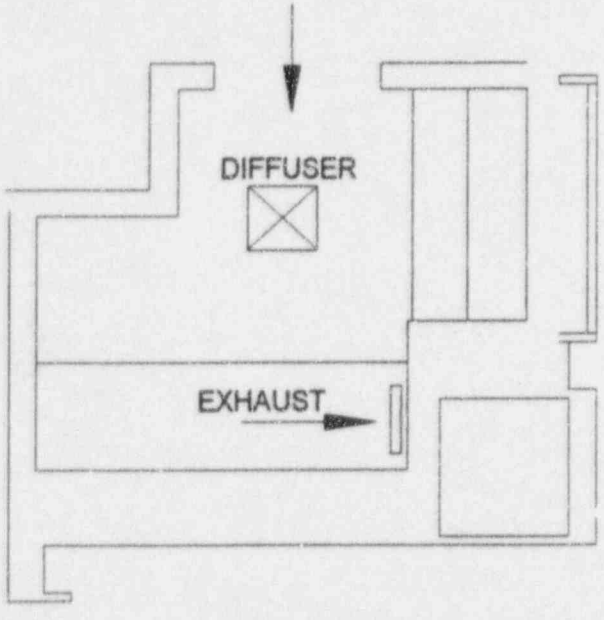
William Beaumont Hospital
Department of Nuclear Medicine

DIAGRAM OF THE STORAGE LOCKER IN THE RADIOPHARMACY



Next to the Exhaust Register on the Counter top, the I-131 solution is stored in capped and unopened lead shielded containers.

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

November 5, 1996

Cheryl Culver Schultz
Radiation Safety Officer
William Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI 48073-6769

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/31/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

___ New License _X_ Amendment ___ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is nonroutine and has been assigned to Patty Pelke for an expedited review. If you should have any questions please contact Ms. Pelke at (630) 829-9887.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302012
License No. 21-01333-01