MATERIALS LICENSE

Amendment No. 47

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.

302211

Licensee	
1. St. Mary's Health Center	In accordance with letter dated January 7, 1997 3. License Number 24-08960-02 is amended in its entirety to read as follows:
2. 6420 Clayton Road St. Louis, MO 63117	4. Expiration Date May 31, 2001
	5. Docket or Reference No. 030-02351

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (Not to exceed 1 curie of iodine-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed sources (Byk Mallinckrodt Model CI L BV)	E. Two sources, 1 source not to exceed 444 gigabecquerels (GBq) (12 curies (Ci)), and 1 source not to exceed 370 GBq (10 Ci).

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9702260080 970204
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C PDR

License Number
24-08960-02

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference Number
030-02351

Amendment No. 47

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. One source to be used in a Nucletron Corporation MicroSelectron HDR remote afterloading brachytherapy device for interstitial, intraluminal, and intracavitary radiotherapy in humans. The source activity may not exceed 370 GBq (10 Ci) at the time of installation. One source in its shipping container for source replacement.

CONDITIONS

10. Location of Use: 6420 Clayton Road, St. Louis, Missouri.

11. Radiation Safety Officer: Munir Ahmad, M.D.

12. Authorized Users:

    A. Munir Ahmad, M.D., for material in 10 CFR 35.100, 35.200, and 35.300.

    B. Barbara Sterkel, M.D., for material in 10 CFR 35.100, 35.200, and 35.300.

    C. Garrett A. Hagen, M.D., for material in 10 CFR 35.300.

    D. James Z. Chen, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

    E. Venkata Rao Devineni, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

13. The medical physicist for this license is Alex M. Hashemi, M.S.

14. A. Sealed sources 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. 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.

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MATERIALS LICENSE
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Amendment No. 47

C. 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.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. 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 in accordance with 10 CFR 30.50(b)(2), 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, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

E. 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. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

COPY

16. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

    A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

    B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

    C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

    D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

17. Prior to initiation of a treatment program, and subsequent to each source exchange using the MicroSelectron-HDR remote afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:

    A radiation survey shall be made of:

    A. 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.

    B. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:

        (1) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.

        (2) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.

18. Notwithstanding the requirements of 10 CFR 35.400(d), the licensee may use iridium-192 as seeds encased in nylon ribbon as a sealed source in seeds for intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

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

License Number
24-08960-02

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference Number
030-02351

Amendment No. 47

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The 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 March 22, 1995; and

    B. Letters dated April 26, 1996, May 20, 1996, January 7, 1997 (with attachments) and January 29, 1997.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date February 4, 1997

By [signature]
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: 02230
Status Code: 0
Fee Category: 7C
Exp. Date: 20010531
Fee Comments:
Decom Fin Assur Reqd: N

SS
MS-15

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. MARY'S HEALTH CENTER
   Received Date: 970113
   Docket No: 3002351
   Control No.: 302211
   License No.: 24-08960-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 440
   Check No.: 103133

3. COMMENTS

Signed D. Hensey
Date 1-15-97

1997 JAN 22 PM 1:49

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

1. Fee Category and Amount: 7C $440

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

3. OTHER

Signed SC
Date 1/22/97

Log	Jan 8 III
Remitter	
Check No.	103133
Amount	$440
Fee Category	7C
Type of Fee	AmD
Date Check Rec'd	1/22
Date Completed	1/22/97
By:	SC

JAN 2 8 1997

St. Mary's SM Health Center

6420 Clayton Road
St. Louis, Missouri 63117
(314) 768-8000
TDD: 768-8367

January 7, 1997

Ms. B.J. Holt
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL. 60532

License No. 24-08960-02

Dear Ms. Holt:

As stated in our license the Nucletron High Dose Rate (HDR) remote afterloader unit is located in the simulator room in the department of Radiation Oncology. We are going to replace our current simulator with a new one and the room has to go through construction work. We intend to move the HDR unit to the accelerator vault and continue treating patients with HDR during the construction period. We will relocate the HDR unit back to the simulator room after the construction is completed and the new simulator is installed. The movement of the HDR remote afterloader unit and the wiring of the accelerator vault will be done by the manufacturer (Nucletron). We intend to begin the construction on February 13, 1997. Please refer to the appendix for the information regarding the accelerator room.

I would like to file an amendment to our license to include the accelerator vault as an alternate location for the Nucletron HDR remote afterloader unit whenever the simulator room cannot be used for HDR treatments for reasons such as construction or safety.

We wish no delays or early termination to our patients' treatment and we believe this is a medical emergency. I would like to request expedition in processing this amendment. Your cooperation in this matter is greatly appreciated.

Please find enclosed the information necessary for this amendment. A check for the amount of $440 dollars is included for this amendment. Should you have any questions please feel free to contact our Medical Physicist, Alex Hashemi, at (314)768-8267 or (314)344-6090.

Sincerely,

Michael E. Zilm

Michael E. Zilm, President
St. Mary's Health Center

Pm: 1-9-97

RECEIVED
JAN 1 3 1997
REGION III

INFORMATION REQUIRED FOR LICENSING HIGH DOSE RATE REMOTE AFTERLOADING BRACHYTHERAPY DEVICE

I. DESCRIPTION OF THE SOURCE(S) AND DEVICES(S)

A. Source Description

1. Radionuclide: Iridium-192
2. Manufacturer's name and model number: BYK Mallinckrodt, Model CILBV or MS-HDR.
3. Maximum Activity (in curies): 12 Ci for possession limit per source. However, no source greater than 10 Ci will be installed in the remote afterloader.
4. Maximum number of sources: 2 sources-20 curies.
5. Our remote afterloader device and source container do not contain depleted uranium.

B. Device Description

1. Manufacturer's name: Nucletron Corporation
   Address: 7080 Columbia Gateway Drive
   Columbia, Maryland 21046-2133
   Phone: (410) 312-4100
2. Model/Number: MicroSelectron-HDR (080.000)
   Serial Number: 9289

II. INTENDED USE

To be used for interstitial and/or intracavitary treatment of cancer in humans.

III. PROPOSED USERS

A. Physician Authorized Users

1. Venkata Rao Devineni, M.D.
   Dr. Devineni is also an authorized user on the NRC license number 24-02490-03.

2. James Chen, M.D.

B. Authorized Physicist

The authorized physicist is Alex M. Hashemi. He is currently on our license. Mr. Hashemi has also been approved as an authorized brachytherapy physicist for the NRC license number 24-02490-03.

IV. TRAINING FOR INDIVIDUALS

A. An outline of initial training given to device operators and authorized physician users for the MicroSelectron-HDR unit is provided in the appendix. This training included a minimum of 16 hours "hands on" device operation.

B. The names, affiliation and qualification of the instructor(s) conducting the training is provided in the appendix.

C. The outline of the topics to be covered during periodic retraining of device operators is provided in the appendix. Retraining is conducted at intervals not exceeding 12 months.

D. Only the radiation oncology nurse and/or radiation oncology therapists provide patient care during treatment. These staff are given orientation training and refresher training at intervals not exceeding 12 months. An outline of the ancillary personnel training is provided in the appendix.

E. The records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years.

V. FACILITIES

A. The room dedicated for HDR treatment is equipped with continuous viewing system to allow for patient observation during treatment. The system includes:

1. CCTV with monitor and also intercom system at operator's console.
2. In the event of CCTV failure, the treatment will be halted until the CCTV system is functional.

B. <u>Area Security</u>

1. For the HDR remote afterloader device which is used in a dedicated treatment room, the following is confirmed:

   a. The source is locked in safe when not in use. The door to the treatment room is locked when not in use.
   b. There is electrical interlock system installed at the entry door. The source automatically retracts when the interlock system is interrupted.
   c. Following interruption of the interlock prior to resuming treatment, the interlock must be reset before the afterloading device can be activated.
   d. In the event of a malfunction of the interlock system for the HDR treatment room, the afterloading device will be

locked in the "off" position and not used, except as necessary for repair or maintenance of the interlock system, or until the interlock system is shown to be functioning properly.

e. The entry door to the treatment room is posted with a "CAUTION HIGH RADIATION AREA-RADIOACTIVE MATERIALS" sign (9x6 inches in size). An independent radiation indicator will produce a visible flashing light during treatment.

f. It is the policy of this facility to disable other ionizing radiation producing devices by using Key-Control to insure that only one device can be activated at a time. The remote afterloading device will be disabled when not in use by the above method.

g. Whenever the afterloader device is not in use or is unattended, the console key will be removed from the console and placed in a locked area inaccessible to unauthorized persons.

C. A permanent radiation monitor capable of continuously monitoring the source status is installed in the HDR treatment room.

1. The radiation monitor provides visible notice of the afterloader device malfunction that results in an exposed or partially exposed source and is observable by an individual entering the room.
2. The radiation monitor is equipped with a back up power supply battery separate from power supply to the afterloader device.
3. The radiation monitor will be checked for proper operation each day before the afterloader device is used. This check may be performed either by observing the monitor when HDR source is out of safe for testing or with a dedicated check source. A record of radiation monitor check will be maintained for a period of three years.
4. If a radiation monitor is found inoperable, this facility will require any individual entering the treatment room to use a survey instrument to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey instrument will be checked with a dedicated check source for proper operation at the beginning of each day of use.
5. The radiation monitor will be repaired or replaced promptly if found to be either inoperable or evidence of intermittent problems.

D. A radiation survey is performed following source replacement to assure compliance with 10 CFR 20.1301. The survey program must confirm the following:

1. Max. radiation levels at 10 cm from the nearest accessible surface surrounding the main source safe of the afterloader should not exceed 1 mr/hr with the source in the shielded position.
2. Radiation levels in restricted areas accessible to radiation workers should not cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.
3. Radiation level in unrestricted areas will not result in a dose to any member of public in access of the limits specified in 10 CFR 20.1301.
4. Records of the survey results will be maintained for inspection by the commission for the duration of the license.

E. This facility confirms that labels stating "Caution Radioactive Material" or the equivalent, are affixed to the outer surface of the afterloader device.

VI. PERSONNEL MONITORING

It is the policy of this facility that personnel involved with treating patients using the remote afterloading device must be monitored (whole body badges may be worn) when entering the treatment room.

VII. SURVEY INSTRUMENTS

This facility confirms the possession and availability of a portable radiation measurement and detection survey instrument in accordance with 10 CFR 35.420. The instrument will be available to device operator and ancillary personnel at all times when the afterloading device is in use. The following 10 CFR 35.51 requirements will be met:

A. The survey instrument shall be calibrated before first use, annually and following repair. This facility shall:

1. Calibrate all scales with readings up to 1000 millirem per hour with a radiation source.
2. Calibrate two separated readings on each scale that must be calibrated.
3. Note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration and the date of calibration.

B. This facility considers a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall attach a correction chart to the instrument.

C. The survey instrument is checked for proper operation with the dedicated check source each day of use.

D. It is the policy of this facility to retain a record of each survey instrument calibration for at least three years. The record will include:

1. A description of the calibration procedure.
2. The date of calibration, a description of the source used and the exposure rates from the source, and rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

VIII. OPERATING AND CALIBRATION PROCEDURES

A. Copies of operating procedures are provided to appropriate staff and one copy is maintained at the afterloading device console. Please see the appendix for a copy of this procedure.

B. Safety Checks

1. At the beginning of each day of use. Certain safety checks are performed, a copy of which is included in the appendix.
2. Monthly safety checks are performed prior to use of a new source and monthly thereafter. Please see the appendix for a copy of these checks.

C. Calibration of the HDR source must be performed only by the authorized physicist. A description of the method used for calibration is included in the appendix.

D. A physical inventory of the HDR source will be conducted quarterly and the records of the inventories will be maintained for five years. The presence of the HDR source may be verified with the radiation monitor in the room or an autoradiograph.

E. The records of HDR source calibration and monthly safety checks for the HDR afterloader device will be maintained for a period of three years.

IX. EMERGENCY PROCEDURES

Copies of the emergency procedures are provided to device operators and authorized users. In addition a copy of the procedure is posted at the afterloading device console and in the treatment room by the afterloader device. Please refer to the appendix for a copy of the emergency procedures.

X. MAINTENANCE

A. Only Nucletron personnel will perform maintenance and repairs on the HDR afterloading device, including installation, relocation, or removal of the sealed

source. A record of any maintenance and repair performed on the afterloading device will be maintained for the duration that the device is in use.

B. This institution confirms the following:

1. The afterloading device will be inspected and serviced at intervals not to exceed one year.
2. Inspection and service will only be performed by the Nucletron.
3. Records of inspection and service will be maintained for the duration of the license and will include the date of the inspection/service, the name of the individual who performed the inspection/service, the agreement state or NRC license number authorizing the individual to perform inspection/service, a description of the nature of the inspection/service including a list of the components inspected and a list of components serviced or replaced, and signature of the inspector.

X WASTE DISPOSAL

The depleted sources will be returned to the manufacturer (Mallinckrodt BYK). Shipping documents are provided by the manufacturer of the sources.

APPENDIX

Facility Design:

A. The Nucletron HDR remote afterloader unit will be located in our radiation therapy simulation room. This room was originally designed to contain a 6 MV linear accelerator. The walls range in thickness from slightly over 2 feet to more than 4 feet of concrete. The entry door contains 3/16 inch lead and is protected from direct radiation by a maze.

Location	Adjacent area Occupancy	Thickness of concrete
South Wall	Outside Wall	27 inches
East Wall	Cafeteria	62 inches min.
North Wall	Control Area	38 inches
West Wall	18 MV Linac Room	62 inches
Roof		30 inches

The room is located at ground level. The floor is on grade. There is a roof above with controlled access.

The unit will be located in the northwest corner of the room adjacent to a room housing an 18 MV linear accelerator. The unit will be about 6 feet from the control area wall.

It does not appear that the unit will be in a position where the extended source could be in direct line of sight of the entry door.

B. The alternate location for the Nucletron HDR remote afterloader unit is our radiation therapy accelerator room. This room contains an 18 MV linear accelerator. The walls range in thickness from 3 feet to more than 6 feet of concrete. In addition, more than 2 inches of lead is added to the primary walls. The entry door contains more than 2.5 cm of lead and is protected from direct radiation by a maze.

Location	Adjacent area Occupancy	Thickness of concrete
South Wall	Outside Wall	36 inches
East Wall	Simulator Room	66 inches
North Wall	Control Area	36 inches
West Wall	Corridor	72 inches
Roof		36 inches

The room is located at ground level. The floor is on grade. There is a roof above with controlled access.

The Nucletron unit will be located in the southwest corner of the room and for the HDR treatment it will be moved near the treatment couch in the center of the room.

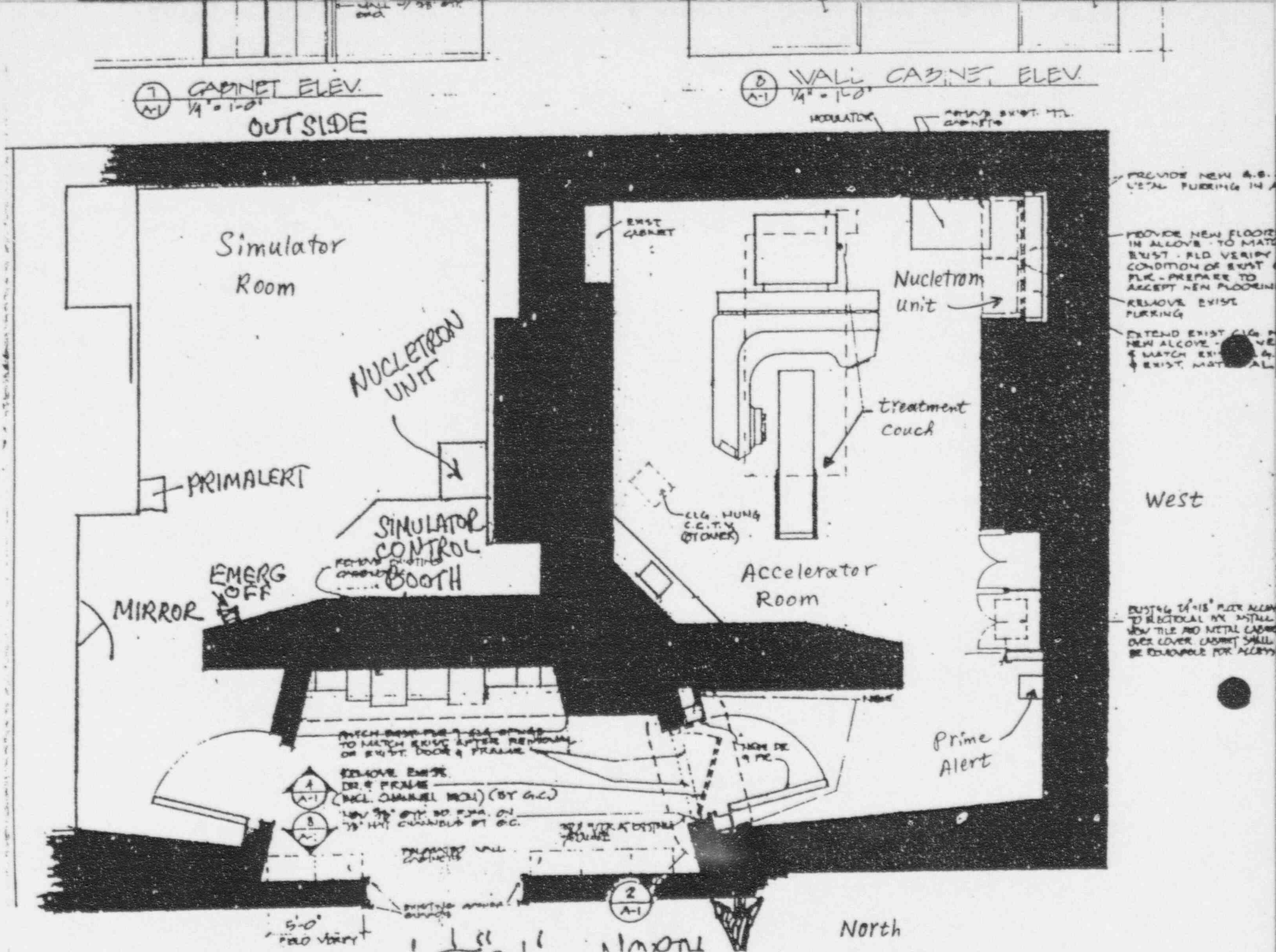
It does not appear that the unit will be in a position where the extended source could be in direct line of sight of the entry door.

The primary location for the Nucletron HDR unit is the simulator room. The HDR unit may be moved to the accelerator room only when HDR treatment in the simulator room is not possible, for reasons such as construction or safety. The accelerator room must be equipped with all safety features indicated in section V (facilities). Daily QA must be performed any time the HDR unit is moved from or to the simulator or the accelerator rooms.

C. In order to demonstrate the adequacy of the existing shielding walls, we calculate the exposure rate assuming that the source is placed immediately adjacent to a 3 foot concrete shielding wall.

The maximum "on time" will be taken to be 1 hour/day. From other institutions, the average treatment time is about 6 minutes per catheter, so the estimated time is extremely conservative.

Air kerma rate at 1 meter from 10 Ci source:		4620 mR/hr
Transmission factor:		
Broad Beam HVL in concrete:	4.3 cm	
$T = \exp-((.693/4.3cm) \times 100cm)$		
$T = \exp(-16.1) = 10^{-7}$		1.0×10^{-7}
Exposure rate at wall:		0.0005 mR/hr
Weekly exposure rate:		0.0030 mR/wk
Annual exposure rate:		0.1560 mR/yr



CABINET ELEV.
1/4" = 1'-0"
WALL CABINET ELEV.
OUTSIDE
Simulator Room
NUCLETRON UNIT
PRIMALERT
SIMULATOR CONTROL BOOTH
EMERG OFF
MIRROR
EXIST CABINET
Nucletron Unit
treatment couch
Accelerator Room
West
Prime Alert
North
REMOVE EXIST FURRING

ST. MARY'S HEALTH CENTER
RADIATION ONCOLOGY CENTER
HDR OPERATING AND EMERGENCY PROCEDURES

This procedure complies with NRC Bulletin 93-01 released April 20, 1993 and asks all HDR users to adopt a physicist-physician attendance policy as well as post treatment survey procedures.

I. Patient Radiation Survey Following an HDR Treatment

1. A radiation survey is required for all temporary implants after removal of all brachytherapy sources from the patient to confirm that all sources have been removed.

2. A calibrated, portable survey instrument capable of measuring from 1 mR/hr to at least 1000 mR/hr must be used regardless of whether or not an area radiation monitor indicates the presence of radiation.

3. The survey shall be performed immediately after completion of the treatment and before the patient exits the treatment room.

4. The area radiation monitor provides an immediate indication of a possible problem (exposed or partially exposed source) and must be observable immediately on entry into the treatment vault.

5. The area radiation monitor must be equipped with an independent source of backup power and checked for proper operation each day of use of the HDR unit.

II. Emergency Procedures When Source Does Not Return to the Safe at the Conclusion of Treatment

1. Prior to initiating an HDR treatment, emergency procedures will be reviewed by attending physician, physicist and technologist.

2. Emergency equipment readily available shall include:

   a. hand held radiation survey meter

   b. long pickups

   c. portable lead shields

   d. scissors and wire cutters

   e. suture removal kit

   f. diagram of surgical staple locations

   g. suction apparatus

h. shielded container

i. other equipment as required for special procedures, e.g., flexible implant tube heat sealer, retractors, etc.

3. A failure of source retraction should assumed under the following conditions:

   (i) Treatment does not terminate at the end of the programmed treatment time

   (ii) The area monitor indicates radiation or yellow "source out" light remains activated following an operator-initiated interruption, following machine-initiated error conditions, or interruption of treatment by an error code compatible with source retraction failure.

   (iii) The post-implant survey indicates that radiation is present.

   The following emergency actions shall be carried out immediately by the Physicist and the Radiation Oncologist attending the treatment. At completion of each step, the portable survey meter shall be used to determine whether that action has successfully secured the source.

   a. Depress the Red Emergency Stop button above the treatment console and note if source retraction is indicated. Carrying the hand held survey meter, observe the remote area monitor display and open the treatment room door.

   b. Activate the Red Emergency Stop Button on the maze wall of the treatment vault if the area monitor or survey instrument still indicates radiation.

   c. If possible, take advantage of the portable shield as you depress the access panel on top of the treatment unit to open it and turn the Gold hand crank in the direction of the arrows until it cannot turn any more.

   d. If the survey meter or area monitor indicates that the source has not retracted, disconnect the transfer from the indexer and move the machine well away from the patient, noting whether the source cable is still extended beyond the indexer. If the cable is still extended then interpose the rolling shield between the source and any people present. Grasp the source cable with the long pickups, sever the cable with the wire cutters, and deposit the source into the emergency shielded container.

      Alternatively, if the patient applicator is easily removable, the physician may remove the applicator at this time without disconnecting the transfer tubes from the indexer. The patient must be removed from the room immediately and surveyed to verify complete source removal.

   e. If the cable is retracted, survey the patient. If the radiation is detected in the patient, remove all applicators immediately and carefully place them into the shielded container so as not to spill any of the contents.

   f. Remove the patient from the treatment vault and survey again to verify complete removal of iridium.

   g. Leave the room, lock the door and post a DO NOT ENTER sign.

   h. Retain the treatment data and contact the local Nucletron representative, Steve Teague at 1-800-336-2249.

i. The unintended radiation dose to the patient and others present shall be estimated by the Radiation Oncology Physicist and reported to the Radiation Safety Officer, Radiation Oncologist and recorded according to our Quality Management Program guidelines.

j. Report the incident to the FDA and/or NRC as appropriate.

III. During all HDR Treatments, both a Radiation Oncology physician authorized to perform brachytherapy procedures and either the medical physicist or Radiation Safety Officer must be physically present (within earshot for normal human speech).

IV. Training

1. Training shall be provided immediately to new personnel and periodic retraining, at intervals not exceeding 12 months, shall be provided for all personnel. Records of this training shall be retained for a period of 3 years.

2. HDR device operator training shall be provided at intervals not to exceed 12 months.

3. The emergency procedures II.3.a-d and II.3.g-i are the responsibility of the physicist. The annual operator training will include review of these procedures.

4. Emergency removal of the applicator (II.3.e) is the responsibility of the attending physician. Removal is a standard component of the Radiation Oncology residency curriculum and CME requirements.

V. Operation

1. The afterloading device, console and source storage room will be secured when unattended. The keys will be placed in a locked area inaccessible to unauthorized persons.

2. Only the patient will be in the treatment room during activation of high dose rate afterloading device.

3. The HDR treatment planning computer system stores each patient's treatment data on a removable program card. Each card must be labelled with the corresponding patient's name and identification number. Such cards may be reused and must be relabelled.

4. Do not conduct any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container, as determined by the authorized user with consultation by the medical physicist or Radiation Safety Officer.

5. If the survey of patient at the end of treatment indicates that the source is not fully retracted to a shielded position in the device, personnel will immediately implement the applicable emergency procedure.

6. The patient will be surveyed prior to removal from the treatment room. The records of patient surveys will be maintained for three years. A copy of patient survey form is included in the appendix.

7. If the daily check of interlocks for the remote after loading device indicates that the interlock is not operating properly, the treatment will be suspended until the interlock is repaired.

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 (Jan. 1995)
A. ten Brinke	8	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	9	Trained by Nucletron, Engineering B.V. (L. van Zwol and R Hermanus). Has carried out installations in USA, Canada, China, Europe.
S. Teague	8	Technical Manager - Nucletron Corporation Radiation Safety Officer
J. Harrison	7	Service Manager, Nucletron Corporation, responsible for North and South American installations, warranty and service. Trained by Nucletron Engineering B.V.
T. Speck	7	Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
C. Jones	7	See Above
H. Archibald	7	" "
B. Loudy	6	" "

Person	Years Experience	Experience and Training (Jan. 1990)
D. Cook	6	Trained by Nucletron Corporation. Attended 4 weeks' certified training in Holland on operation, service and safety of the machines and sources.
C. Scott	6	" "
J. Oliver	4	" "
J. Cowan	4	" "
P. Koonce	4	" "
D. Glessner	4	" "
L. Vincent	3	" "
C. Tow	3	" "
M. Irvin	3	" "
C. Hicks	2	" "

NUCLETRON CORPORATION

By:____________________

S. P. Teague Radiation Safety Officer

CUSTOMER TRAINING - MICROSELECTRON-HDR

I. **Teaching Aids Required:**

1. microSelectron-HDR Installed System
2. microSelectron-HDR User Manual
3. Note Pads and Pens
4. Applicators & Accessories
5. Source container and Dummy Source
6. Survey Meter provided by customer

II. **Introduction to microSelectron-HDR**

1. What is Remote Afterloading Brachytherapy **(30 minutes)**

   a) radiation protection
   b) treatment control
   c) short treatment times

2. Applications of microSelectron-HDR **(30 minutes)**

   a) Bronchus
   b) Interstitial
   c) Intracavitary
   d) Intraoperative

3. Demonstration of Applicators and Accessories **(30 minutes)**

   a) Bronchus
   b) GYN
   c) Esophagus
   d) Interstitial

III. **General Information microSelectron-HDR**

1. Specifications **(30 minutes)**

   a) Source
   b) Radiation protection
   c) Power requirements
   d) Number of channels
   e) Moving and handling

2. Equipment Operation (1 hour)

a) Explanation of Console
b) Explanation of Treatment Unit
c) Programming Mode

d) Treatment mode
   i) Start
   ii) Interrupt
   iii) Emergency Stop
   iv) alarm and error codes

e) Demonstration (30 minutes)
f) Student practice (estimated 1½ hours - varies with number of students)

IV. Isotope (^{192}Ir) Shipping and Receiving (30 minutes)

1. Delivery

a) Unpacking
b) Acceptance into Inventory
c) Calibration Data
d) Installation by engineers (Discussion Only)

2. Shipping

a) Release from Inventory
b) Packing
c) Shipping Documents
d) Measurement of Transport Index (TI)

V. **Questions and Answers**

Note 1: this training course is given by Nucletron Corporation engineers and is included in the purchase price of the unit. Annual re-training is available to all customers as part of the Nucletron Service Agreement.

Note 2: facility radiation protection requirements and record keeping will be discussed by the licensee's R.S.O. or designated deputy.

IV. Isotope (^{192}Ir) Shipping and Receiving

1. Delivery

    a. Unpacking
    b) Acceptance into Inventory
    c) Calibration Data
    d) Installation by engineers
    (Discussion Only)

2. Shipping

    a) Release from Inventory
    b) Packing
    c) Shipping Documents
    d) Measurement of Transport Index (TI)

VI. Ancillary Staff Training microSelectron-HDR

1. What HDR unit looks like and what it is used for.

2. Location of HDR Device and Console

   a) Device posses Radioactive Source
   b) Safety Instructions about entrance into Room (what to look for, who to ask, prior to entrance

3. Basic Radiation Safety Techniques

   a) Time, Distance and Shielding
   b) Use of whole body radiation badges (if issued film badge)
   c) Survey Meter use (if applicable)

4. Awareness of Safety Devices and Locations

   a) Locations and understanding of caution signs and devices
   b) Awareness and understanding of Applicators/Connectors/Tubing, etc.
   c) What to look for in the event of emergency

5. Who to Contact in Event of Emergency

   a) Radiation Safety Officer (RSO)
   b) Authorized Users (M.D.'s and Physicists)

6. Care of Patient Receiving Treatment

VII. Retraining of the Micro-Selectron-HDR Operators

1. Source
    a. Radioisotope and activity
    b. What the source looks like

2. Equipment Operation
    a. Start
    b. Interrupt
    c. Emergency Stop
    d. Alarm and error codes

3. Radiation Safety
    a. Time, distance and shielding
    b. Use of whole body radiation badges
    c. Use of survey meter
    d. Safety instructions about entrance into room

4. Review of HDR Emergency Procedures

Calibration of Device

Calibrations will be performed after each source change and monthly thereafter. The calibration procedures include the items listed below.

a. A well-type ionization chamber (HDR-1000) with an electrometer will be used to calibrate the IR-192 source. This chamber eliminates the additional correction factor for scatter and distance in the calibration. A narrow opening is provided into the sensitive volume of the chamber to insert a Nucletron Microselectron catheter. This catheter runs the source to the bottom of the of the chamber well and after 20 seconds it moves the source upward 2.5 mm. This is repeated at 2.5 mm intervals until the source is about to leave the chamber. The source spends 20 seconds at each interval. The maximum electrometer reading will be used in calculation. The following equation is used to calculate the source activity:

activity(ci) = (max nA rdg) (ctp) (nA/rdg) (decay) (ACF)

Where:

max nA rdg = max, electrometer reading
CTP = correction for temp. and pressure
nA/rdg = electrometer correction factor
decay = source decay factor to 00:00 o'clock

ACF = activity calibration factor for the well chamber

b. A record of calibration measurements and associated calculations will be maintained for a period of three years. The records will include the following:

(1) The date of calibration
(2) Manufacturer's name, model number and serial number of HDR unit and source.
(3) Manufacturer's name, model number and serial number of the instrument used to measure the output of the device.
(4) Name of the individual(s) who performed the calibration.

The record will also include the output of the device expressed in roentgens per hour and a comparison of manufacturer's (expected) output value (corrected for decay). The expected and measured output values should be within $\pm$ 5%. If the measured value differs by greater than 5% of the expected value, the medical physicist or RSO should be consulted prior to performing further treatments.

c. Method-2:

After the initial calibration of a new source is completed using the method decribed, an alternative method (method-2) may be used to perform the monthly calibration. This method should also be within $\pm 5\%$ of the manufacturer's output value. The following is a description of the method-2:

Phantom: 2.5 cm thick acrylic
Ionization chamber: cylindrical farmer with buildup cap
Distance between the source and ion chamber: 1.5 cm
Collect maximum reading for 60 seconds on 10^{-8} coulomb scale

S=(rdg) (ctp) (CF)

Where:
S=source strength in cGy.m^2/hr
rdg=electrometer reading for 60 sec.
ctp=correction for temp. and pressure
CF=system calibration factor

d. Calibration Equipment:

The dosimetry system which is used to perform the initial calibration measurements, consists of a well-type ionization chamber and two identical electrometers:

Well-Type Chamber		Electrometers	
Manufacturer:	Standard Imaging Inc.	Manufacturer:	Keithley
Model No.:	HDR-1000	Model No.:	602 (modified)
Serial No.:	A950882	Serial No.:	124150
			54815A

Following is the dosimetry system used to perform method-2 calibration measurements:

Ionization Chambers		Electrometers	
Manufacturer:	PTW	Manufacturer:	Keithley
Model No.:	N30001	Model No.:	602 (modified)
Serial No.:	0767	Serial No.:	124150
			54815A
Model No.:	N30004		
Serial No.:	0023		

The dosimetry system must be calibrated by a laboratory accredited by NIST or AAPM in an interval not exceeding two years. The record of dosimetry system calibration will be maintained for inspection.

ST. MARY'S HEALTH CENTER
RADIATION ONCOLOGY CENTER
Ir-192 HDR DAILY QA AND SAFETY TESTS

Performed by ______________________________ Date ____________________

Afterloading Device Serial Number _______________ Source Serial Number _________

	Test	Sat.	Unsat.
1.	Verify emergency instructions displayed.	☐	☐
2.	Verify proper operation of the HDR CCTV system.	☐	☐
3.	Verify proper operation of the HDR intercom system.	☐	☐
4.	Verify proper operation of the prime alert in the treatment room.	☐	☐
5.	Verify proper operation of the treatment indicator light at the door.	☐	☐
6.	With "beam on" verify proper operation of the interrupt button on the console.	☐	☐
7.	With "beam on" open the door and confirm that the source retracts.	☐	☐
8.	Disconnect the catheter and try to "beam on." Confirm proper operation of the interlock.	☐	☐
9.	With "beam on" simulate a power failure. Verify source retraction and ability to restart when power is restored.	☐	☐
10.	With "beam on" activate the emergency off and verify proper operation.	☐	☐
11.	Verify proper operation of the source status indicators on the console.	☐	☐
12.	Verify proper operation of all functions on the console.	☐	☐
13.	Verify mechanical integrity of applicators, source guide tubes, and connectors to be used.	☐	☐
14.	Verify proper operation of the survey meter.	☐	☐
15.	Verify the activity on the printout is within $\pm$ 1.0% of expected activity.	☐	☐
16.	Verify the presents of adequate printer paper supply.	☐	☐
17.	Verify the presents of the emergency kit (long forceps, shielded safe and wire cutter).	☐	☐
18.	Verify the presents of the operator's manual.	☐	☐

Comments ____

____

ST. MARY'S HEALTH CENTER
RADIATION ONCOLOGY CENTER
HDR PATIENT RADIATION SURVEY FORM

Survey form for monitoring HDR patients after the completion of their treatment to insure that the Ir-192 source has returned to the Micro-Selectron afterloader's shielded safe.

Patient Name ______________________________ Roc No.:________________

Treatment Date ____________________________

Survey Instrument:

Manufacturer ____________ Model No. ____________ Serial No. ___________

Afterloading Unit:

Manufacturer ____________ Model No. ____________ Serial No. ___________

Instructions: A radiation survey is to be obtained by a properly trained individual using a calibrated survey meter at approximately 12 inches from the most appropriate anatomical surface closest to the treatment area. If the exposure rate is less than 1.0 mR/hr, it can be assumed that the Ir-192 source has returned to the shielded safe of the afterloader unit.

Radiation Level Measured ______________ mR/hr

Survey Performed by __________________________ Date _________________

ST. MARY'S HEALTH CENTER
RADIATION ONCOLOGY CENTER

HDR BRACHYTHERAPY CHECKLIST

Patient Name:____________________________ Frac. No.:________ Roc No.:________

		Yes	No
1.	HDR daily QA completed.	☐	☐
2.	Prescription completed and signed by authorized physician.	☐	☐
Treatment Plan			
3.	Computer treatment plan reviewed and signed by physician.	☐	☐
4.	Isodose curves checked against prescription.	☐	☐
5.	Treatment site checked against prescription.	☐	☐
6.	HDR printout checked against treatment plan and prescription.	☐	☐
7.	Physicist review completed before treatment initiation.	☐	☐
8.	HDR printout signed by physician and okay to treat the patient.	☐	☐
9.	Check matching of HDR channel and applicator numbers.	☐	☐
Treatment			
10.	Patient identified by two methods.	☐	☐
11.	Physician and physicist are present.	☐	☐
12.	Physician authorized patient treatment.	☐	☐
13.	Patient surveyed.	☐	☐

Comment____

____

Form reviewed by__________________________ D ____________________

St. Mary's Health Center
Radiation Oncology Center

HDR Brachytherapy Prescription

Name: ______ ______________________________ Birthdate: ____/____/____ SS#: _____-_____-_____

Rad. Onc. No.: __________________ Ref. Physician: ______________________ Implant No.: ___________

Primary Site: __________________ Applicators: ____

Treatment Site: ______________ ______________

Radioisotope: ______________________________

No. of Fractions: ____________________________

No. of Fractions/week(s):_______________________

Total Dose: ________________________________

Dose Defined At: ___________________________

Physician: ________________________ Date: __________

Modifications: ______________________________

____

Date						Total
Fraction No.	1	2	3	4	5	
No. of Catheters						
Dose (cGy)						
Source Activity (Curi)						
No. of Dwell Positions						
Physicians Initials						
Total Dwell Times (sec)						
Treatment Authorized By						
Isodose Curves Planned By						
Physicist Review By						
Treatment Delivered By						

ST. MARY'S HEALTH CENTER
RADIATION ONCOLOGY CENTER
Ir-192 HDR MONTHLY QA

Afterloading Unit:		Source:	
Manufacturer	____________	Manufacturer	____________
Model No.	____________	Model No.	____________
Serial No.	____________	Serial No.	____________

Ionization chamber: Model No. ____________ Serial No. ____________
Electrometer: Model No. ____________ Serial No. ____________

Timer Accuracy and Linearity

Timer setting (sec)	Ionization Reading	Measured Time	Time % Diff.	Linearity % Diff	Satisfactory	Unsatisfactory
______	______	______	______	______	☐	☐
______	______	______	______	______	☐	☐
______	______	______	______	______	☐	☐
______	______	______	______	______	☐	☐
______	______	______	______	______	☐	☐

Source Activity (A)

Bias= ________ volts T= ______ °c P= ______ mm Hg TPC= ______

Electrometer Reading= ____________ Reading Time= ____________

System Calibration Factor= ____________

A= (RDG) (TPC) (CF) Curi
A= (   ) (   ) (   )= ______ Curi

Expected source activity= ____________ Curi % Diff.= ________

Satisfactory ☐ Unsatisfactory ☐

Safety	Satisfactory	Unsatisfactory
1. With "beam on," simulate a power failure by switching off the A.C. Power. Verify that back up battery retracts the source.	☐	☐
2. With "beam on," activate the emergency off and verify proper operation (You need to turn the reset key to restart the system).	☐	☐
3. Verify proper operation of the prime alert in the treatment room.	☐	☐

Source Position Accuracy

Verify source position accuracy within ± 1 mm by autoradiography.	☐	☐

Comments ____

____

____

Performed by ______________________ Date ______________

FEB 05 1997

Michael E. Zilm, President
St. Mary's Health Center
6420 Clayton Road
St. Louis, MO 63117

Dear Mr. Zilm:

Enclosed is Amendment No. 47 to your NRC Material License No. 24-08960-02 in accordance with your request.

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.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

302211

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;

   b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;

   c. Change Radiation Safety Officers;

   d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   f. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements,

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No. 24-08960-02
Docket No. 030-02351

Enclosure: Amendment No. 47

DOCUMENT NAME: M:\03002351.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	GWatson:brt								
DATE	~~01~~/04 /97 GW 02								

OFFICIAL RECORD COPY

St. Mary's Health Center

6420 Clayton Road
St. Louis, Missouri 63117
(314) 768-8000
TDD: 768-8367

January 29, 1997

Ms. G.M. Watson
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL. 60532

License No. 24-08960-02
Control No. 302211

Dear Ms. Watson:

The following is the necessary information that you requested in order to complete the HDR amendment to our license:

1. Prior to the movement of the device, the manufacturer (Nucletron) will install all necessary electrical hook ups and safety devices, such as, emergency buttons and prime alert in the room. The simulator and the treatment rooms are adjacent, therefore the HDR device should not have to be moved more than 50 ft. There is no elevator or steps in the way. The HDR afterloader will be moved by Nucletron personnel and the HDR Physicist must be present during the movement. The radioactive source must be locked in the afterloader's shielded safe prior to the movement.

2. After the completion of the movement of remote afterloader device and prior to treatment, quality control checks must be performed to ensure that all safety features are operating properly. The procedures to perform these checks are included in the " HDR daily QA and Safety Tests " forms. These quality control checks may be performed by the radiation safety staff or the manufacturer and must be reviewed by HDR Physicist.

Pm: 1-31-97

RECEIVED
FEB 03 1997
REGION III

FEB 03 1997

3. The records of the quality control checks will be maintained for a period of three years.

4. The movement of the device will be restricted to that between those location (within the radiation oncology department) authorized by our license condition.

5. The source will be mechanically locked within the afterloader's shielded safe during each movement between locations.

6. 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 the manufacturer.

7. During movement of the device, two individuals will be present. One will carry a radiation survey device for use in emergency, such as, tip over of the device

8. An emergency shielded source container will also be transported along with the device.

9. After completion of a relocation of the device, and prior to patient treatment, the safety checks set forth in sections VIII. B. (1) and (2) of Policy and Guidance Directive FC 86-4; revision 1 will be performed.

Should you have any questions, please feel free to contact our Medical Physicist, Alex Hashemi at (314)768-8267 or (314)344-6090.

Sincerely,

Michael E. Zilm, President
St. Mary's Health Center

CONVERSATION RECORD

TIME	DATE
	1/21/97

O VISIT   O CONFERENCE   X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Alex Hashemi, HDR Physicist	St. Mary's Health Center	314/344-6090

SUBJECT
License No. 24-08960-02

SUMMARY
I requested the following information in regards to HDR amendment request dated January 7, 1997:

1. A description of the procedures for transporting the device, e.g., personnel involved, device lock-out (radioactive source in safe shielded position), route of transport (i.e., elevators), etc.

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

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

6. A commitment that 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.

7. A commitment that during movement of the device, two individuals will be present. One will carry a radiation survey device for use in a emergency, such as, tip over of the device.

8. A commitment that an emergency shielded source container (i.e., lead pig) shall also be transported along with the device.

9. A commitment that 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.

Mr. Hashemi stated that he would respond to the aforementioned accordingly. The response will be signed by management personnel and sent to the Region III via overnight mail by 2/3/97.
Office

A copy of this phone record will be sent via fax to Mr. Hashemi.

ACTION REQUIRED

Gidget Watson — 1/21/97

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

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

January 16, 1997

Munir Ahmad, M.D.
Radiation Safety Officer
St. Mary's Health Center
640 Clayton Road
St. Louis, MO 63117

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 01/07/97)

L .. 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 routine (see 1-3 below, as applicable).

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 processeu 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 decontamin?:ion/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. 302211
License No. 24-08960-02