Feb 24, 2005

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REGION 1

'05 MAR -1 P2:13

US NRC Region One Office
Medical Licensing Section
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License renewal for License 37-07722-04 03003094

To Whom It May Concern:

We are writing to request a renewal of our NRC license at Bryn Mawr Hospital. Along with this letter we have included an application in duplicate of the information needed to process this amendment request.

In the immediate future we plan to request a license amendment to relocate our HDR unit to another treatment area. We are sending the HDR relocation amendment separately since we would like it to take priority over the renewal. This amendment will supersede documents referenced in this renewal regarding our current HDR treatment location.

If there are any questions in the processing of this amendment, please contact:

Bryn Mawr Hospital
130 S. Bryn Mawr Ave.
Bryn Mawr, PA 19010
Attn: Tara Bachman, Nuclear Medicine Department

Email: tarabach@comcast.net
Phone: 908-788-9440 x49

Sincerely,

Brenda DeFeo

Brenda DeFeo, Senior Vice President

136521
NMSS/RGNI MATERIALS-002

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION

(10-2002)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

03003094

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 37-07722-04

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

The Bryn Mawr Hospital
130 South Bryn Mawr Avenue
Bryn Mawr, PA 19010

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

SAME AS #2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Tara M. Bachman, M.S.

TELEPHONE NUMBER

908-788-9440 x 49

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form, and c. maximum amount

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7C
AMOUNT ENCLOSED $

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Brenda DeFeo, Senior Vice President	Brenda DeFeo	8/05/05

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

136521

NRC FORM 313 (10-2002)

PRINTED ON RECYCLED PAPER

NMSS/RGN1 MATERIALS-002

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION
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Tara M. Bachman, M.S.

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8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

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CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Brenda DeFeo, Senior Vice President	Brenda DeFeo	8/26/05

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TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

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While this represents the implementation of the program that we plan to follow, we are requesting the authorization to make future changes to our radiation safety program, provided the following conditions are met:

- The revision is in compliance with the regulations, specifically in accordance to 10 CFR 35.26 and 35.2026
- The revision has been reviewed and approved by the licensee's Radiation Safety Committee
- The affected individuals are instructed on the revised program before the change is implemented
- A record of each change will be retained for 5 years. This record will include the old procedure, the new procedure, the date of change and the date the change was approved.
- In addition, we will follow the requirements of 10 CFR 35.13(g) to apply for and receive an amendment before we revise procedures required by 35.610 (HDR safety procedures) or 35.643 (HDR periodic spot-check procedures), if the revision may reduce radiation safety.

Since we are applying for a renewal of our current license, we ask that the statements, requests and procedures provided in this application supersede all statements, requests and procedures from the previous license.

NRC FORM 313
Sub items 5 through 11

ITEM 5. RADIOACTIVE MATERIAL
ITEM 6. PURPOSE

Radionuclide	**Form or Manufacturer/Model**	**Maximum Quantity**	**Purpose of Use**
Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200
Any byproduct material permitted by 10 CFR 35.300	Any	500 millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300
Byproduct Material permitted by 10 CFR 35.400 (Radionuclide I-125)	Sealed source or device (Manufacturer: Source Tech Medical, Model No.: STM1251)	1000 millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400
Byproduct Material	Sealed source or device	1000 millicuries	Any brachytherapy

permitted by 10 CFR 35.400 (Radionuclide Ir-192)	(Manufacturer: Best Industries Model 81-01)		procedure permitted by 10 CFR 35.400
Byproduct Material permitted by 10 CFR 35.500 (Gd-153)	Sealed source or device (Manufacturer: North American Scientific, Model No.: MED3601)	300 millicuries per source and 2 curies total	Diagnostic Medical Use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
Iridium-192 permitted by 10 CFR 35.600	Sealed source or device (Manufacturer: Nucletron, Model No.: 105.002)(manufactured by Mallinckrodt Medical or AEA Technology Inc.)	12 curies per source and 22 curies total	One source for medical use permitted by 10 CFR 35.600, in a Nucletron Model No. 105.999 remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
Strontium 90/Yttrium 90	Sealed source or device (Bebig, Model No. SrO.S03 or AEAT SICW Series SICW.1 and SICW.2)	5 millicuries per source and 800 millicuries total	For medical use in Novoste A1000 series intravascular brachytherapy remote afterloader units.
Any byproduct material under 10 CFR 31.11	Prepackaged kits	1 millicurie	In vitro studies.
Depleted Uranium	Metal	60 kilograms	Shielding in an ADAC Laboratories Model MED/AC system attenuation correction device.

- Purpose of Sr-90 source: The sealed sources will be used as they are provided, as part of the Novoste Beta-Cath IVB system (ref:SS&D certificate GA-1115-D-101-S, Model A1732) for Intravascular Brachytherapy as covered under 10 CFR 35.1000.
- Device Description: Device is the Nucletron microSelectron HDR Remote afterloader model 105.999. Please reference the Sealed Source and Device Registry for this device (MD-0497-D-108-S). We are requesting that the maximum installed activity of the source be listed at 10 Ci.
- Source Description: Source is Nucletron Iridium 192 Sealed Source Model 105.002. Please reference the Sealed Source and Device Registry for this device (MD-0497-S-107-S). This registry authorizes AEA Technology and Mallinckrodt B.V as contract manufacturers for Nucletron Corporation for this source.

Item 7 – Authorized Users (all are listed on license #37-07722-04)

Authorized Users	Material and Use
Marchello J. Barbarisi, M.D	35.100; 35.200; 35.300; 35.500; In vitro studies; Depleted Uranium
Richard J. Carella M.D	35.400; 35.500; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90/Yttrium 90 in a Novoste Beta-Cath System
Erik D. Assarsson, M.D.	35.300; 35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90/Yttrium 90 in a Novoste Beta-Cath System
Vikram Dravid, M.D	35.100; 35.200; 35.300; 35.500; Depleted Uranium
Nancy V. Roman, M.D.	35.100; 35.200; 35.500; Depleted Uranium
Nancy Sherwin, M.D.	35.100; 35.200; 35.300; In vitro studies
Harris Miller, M.D.	35.100; 35.200; 35.300; In vitro studies
Valerie Hunt, M.D.	35.100; 35.200; In vitro studies
Julia Barbarisi, M.D. (listed on license as Julia Salwen, M.D. – she has been married since)	35.100; 35.200
Richard M. Yelovich, M.D.	Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit

Item 7 – Authorized Medical Physicists (all are listed on license #37-07722-04)

Authorized Medical Physicist	Material and Use
Kathleen K. Spillane, Ph.D.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training
Paula Salanitro, M.S.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training
Nathan Anderson, M.S.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training
Margaret Henzler, M.S.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training
Michael Bieda, M.S.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training

Della Hutchinson, M.S.	Iridium 192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training

ITEM 7

Radiation Safety Officer

Marchello J. Barbarisi, M.D.

For Dr. Barbarisi's training and experience please refer to USNRC license No. 37-07722-04.

ITEM 9 – FACILITIES AND EQUIPMENT

9.A Facility Design

Diagrams for the Nuclear Medicine and Radiation Oncology Departments are enclosed that describe the facilities and identifies the activities conducted in all contiguous areas surrounding the area of use.

- The area of use for HDR treatments will be the linear accelerator room. The shielding calculations demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded. See Appendix A for diagrams.
- Novoste Beta-Cath devices (Sr-90 source) will be stored in the Radiation Oncology department hot lab. Use will be permitted in any room that is able to medically permit the procedure as there no concerns about exposure outside the treatment room, as Sr-90 is a pure beta emitter. The procedure room will be temporarily posted with appropriate signage during the procedure and will be removed after verification that the source has been safely returned to the transport device and locked in place. See Appendix A for diagrams of the hot lab.
- The Ir-192 and I-125 sealed sources will be stored in the hot lab in lead-lined shipping containers prior to use. This lab is a secure storage area for radioactive materials. Use for I-125 seed implantation will be permitted in any room that is able to medically permit the procedure. Most of our patients who receive I-125 seed implantation can be released in accordance with 10 CFR 35.75. For patients undergoing temporary brachytherapy implantation with Ir-192 we will use room 679. All adjacent areas will be surveyed to ensure that dose levels do not exceed 2 mR/hr when the patient is in this room. Portable lead shield are available to use in this room if needed. The spent Ir-192 and unused I-125 sources will be returned to the hot lab after use. See Appendix A for diagrams of room 679 and the hot lab.
- The Nuclear Medicine department has a radioactive waste storage room in the H-wing of the basement for waste from longer-lived isotopes and bigger storage items. See Appendix A for diagrams.
- We use patient room 679 for those patients who are receiving inpatient radiopharmaceutical therapy. All adjacent areas will be surveyed to ensure that dose levels do not exceed 2 mR/hr when the patient is in this room. Portable lead shield are available to use in this room if needed. See Appendix A for diagrams of room 679.

9. B. Radiation Monitoring Instruments

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements of 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61

The Radiation Oncology department possesses two portable exposure rate meters (Innovision 451P and Keithley model 36100 ion chambers) capable of readings in the .1-1000 mREM per hour range. A Ludlum Model 3 survey meter with NaI scintillation probe capable of readings in the 100-300000 cpm range will be used to survey the patient's room or operating room at the time of discharge for I-125 and Ir-192 brachytherapy procedures.

The Nuclear Medicine department possesses the following:

2 Ludlum GM survey meters
1 Victoreen 450B ion chamber
1 Capintec Captus 2000 Well and Probe Uptake system (NaI)

We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

9.C. Dose Calibrator and Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

9.D. Afterloader Calibration and Use

Attached to this document as Appendix B are the procedures and worksheets for full calibration and periodic spot-checks as required in 10 CFR 35.633 and 10 CFR 35.643, respectively.

9.E. Other Equipment and Facilities

For HDR treatments in the linear accelerator room the following additional equipment and safeguards are in place:

- The device will be secured so that it may not be removed from the treatment room except by authorized personnel.

- The keys needed to unlock and operate the device will be secured separately from the device console area to prevent unauthorized use of the afterloader unit. The keys will be stored in the physics office in Radiation Oncology department.

- The treatment room will be equipped with primary intercom and closed circuit TV systems so that the patient may be observed continuously during treatment. If the systems are not functional then further treatments will be suspended until they are returned to working order.

- Only the patient will be present inside the room during treatment except in the activation of emergency procedures

- There will be an indicator outside of the room indicating if the source is outside of the safe

- An electrical interlock shall be installed at the entrance to the room. A door switch will be connected to the treatment console in such a way that it can initiate "STOP" sequences. If the door is opened during a procedure, the exposed source will automatically retract into the shielded source safe

- When the door interlock is tripped, the door must be closed and a reset operation must be performed at the treatment control unit (console) before the treatment can be resumed

- In the event of a malfunctioning door interlock, the mHDR device shall be locked to prevent exposure of the radioactive source. All patient procedures shall be suspended until the interlock system is functioning properly.

- An independent radiation monitor will be placed just inside the room that will illuminate if radiation levels are elevated. This will act independently of the console indicators and will be visible upon entering the room.

- The operability of the radiation monitor will be checked daily for functionality.

- If for any reason, the room monitors are not functional, including power failure to the monitors, individuals will use a portable survey instrument to monitor for an exposed source during each entry of the room following use of the afterloader. The operability of the survey meter will be verified independently before use in this manner. A survey meter will be available for each treatment.

- The treatment room also contains a Varian Clinac 21EX linear accelerator. Therefore, a manual keyed switch will be placed near the door that will prohibit both the linear accelerator and the HDR unit from both being activated at the same time by means of the door interlock.

- Either the AMP or AU will transport the device from the hot lab to cardiology suite where the procedure is to be performed.

- In the event that the source cannot be withdrawn from the patient, the delivery catheter containing the source train will be withdrawn and placed in the bailout box (a beta shield container). All tools needed to perform this in a manner consistent with ALARA will be available in the room for each procedure.

Manual Brachytherapy

- The manufacturer's lead shielded shipping containers will be used for transporting Ir-192 and I-125 brachytherapy sources from the hot lab to place of use.

- Emergency response equipment includes:
  - Long handled forceps and hemostats for handling brachytherapy sources
  - The lead-lined shipping container or the ADC model MC-315 lead shielded cart will be available in the patient's room while the sources are in use.

Nuclear Medicine

The following radiation safety equipment is present:

1. Syringe shields
2. Lead syringe shields
3. Disposable rubber gloves
4. Absorbent pads
5. Vials are stored in their lead pigs
6. Lead L-block shield is present
7. Remote handling devices are present
8. Lab coats are worn by technologists
9. Leaded radioactive waste storage bin present
10. Lead fort constructed from lead bricks is present

ITEM 10 – RADIATON PROTECTION PROGRAM

10. A. Emergency Procedures

Procedures are attached to this application as Appendix C for both medical emergencies and emergency response to a stuck, dislodged or separated source as required by 10 CFR 35.610. Additionally, the policy on emergency response equipment and its location is included in Appendix C. These procedures will be available at the Afterloader control console and all users will be trained in the emergency response annually. These procedures will be in addition to all emergency procedures provided by Nucletron.

10. B. Device Specific Training for Individuals

Bryn Mawr Hospital Currently provides in-service training to all appropriate employees on an annual basis in radiation protection and instrumentation, including the proper use of dosimeters, survey instruments and radiation monitors. These records are kept on site as required.

HDR facility specific training in department emergency procedures will be conducted annually in conjunction with the Nucletron training

Nucletron's installation engineer will provide initial on-site training in programming and operating the treatment control unit and selected components of the remote after loader. Nucletron will also provide on-site training in Nucletron approved emergency procedures for Authorized Users, physicists and other operators. This will include practice in implementing the emergency procedures using a dummy source. Retraining will occur at annually as scheduled with the Nucletron engineers. Appendix D is included as a general outline of what is included in the training.

10. C. Occupational Dose

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556 Volume 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Use Licensees", dated October 2002.

10. D. Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

10. E. Safe Use of Unsealed Licensed Material

We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

10. F. Spill Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

10. E. Waste Management

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meets the requirements of applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92

Appendix A

Item 9A

Facilities Diagram 1

Room Name – Linear Accelerator Vault

Use – Room will house the HDR Afterloader in a secured place. Also houses 6/10 MV Linear accelerator

Legend to Diagram

1. Afterloader Control Console Location
2. Interlocked Vault door entrance
3. Maze
4. Treatment table for Linac – HDR
5. Proposed storage area for Afterloader – Afterloader will be secured in place inside the vault
6. Public Area Outside
7. Film viewing area
8. Dark Room
9. Block cutting room
10. Psych Ward above the room

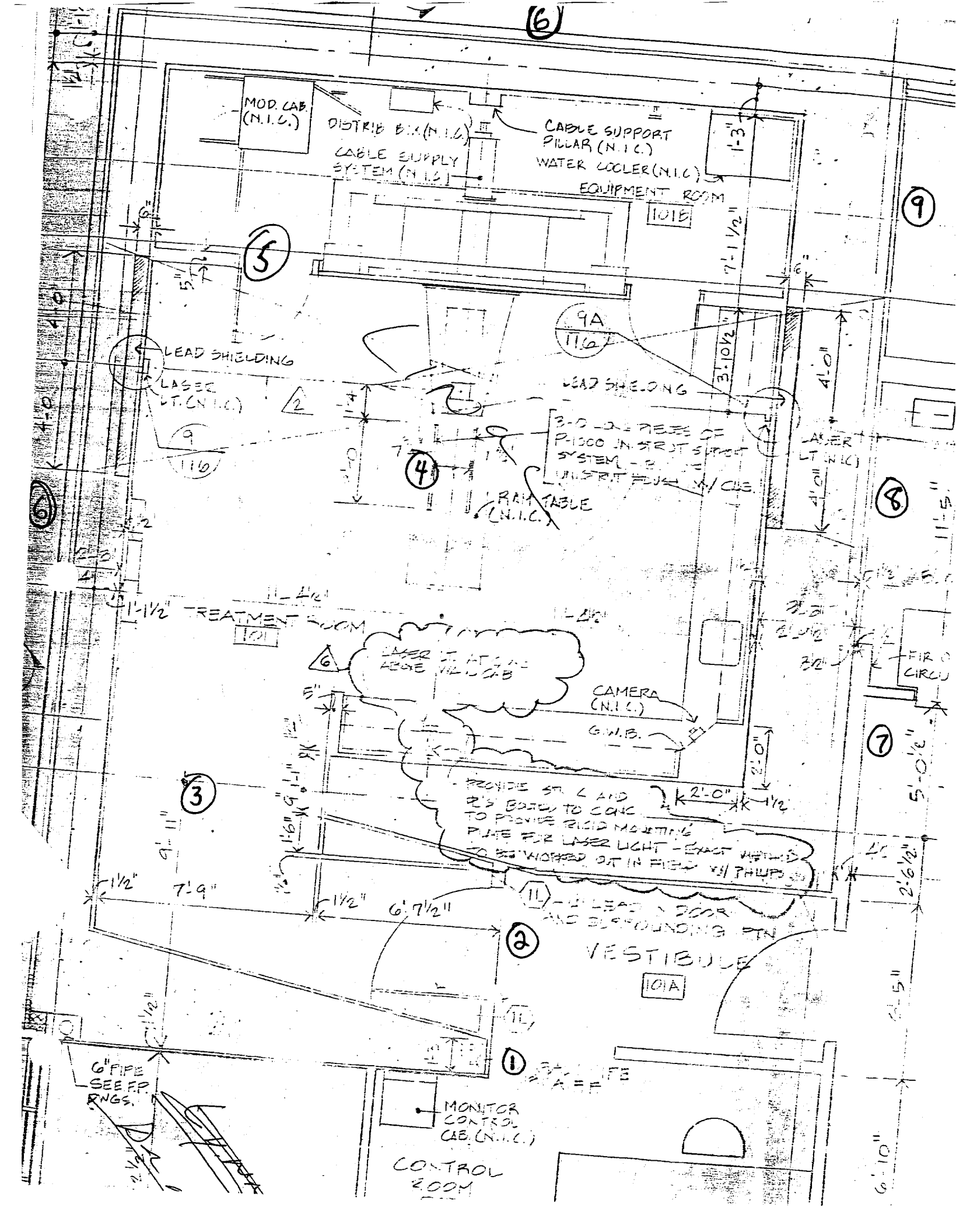
Facilities Diagram 2

Room Name – Radiation Oncology Hot Lab

Use – Room is currently used for long term and short term storage of sealed sources. HDR sources will be stored in their shipping containers in this room after they are logged in and checked. Sr-90 IVB sources will also be stored here. This room is accessable only by keypad by authorized individuals.

Legend to Diagram

1. Physics Office area
2. Nurse's Office
3. Secure Hot lab area
4. Public Hallway
5. Facilities Department Conference Room
6. Dressing Room
7. Psych Ward above the room


MOD. CAB. (N.I.C.)
DISTRIB B.X (N.I.C.)
CABLE SUPPLY SYSTEM (N.I.C.)
CABLE SUPPORT PILLAR (N.I.C.)
WATER COOLER (N.I.C.)
EQUIPMENT ROOM
101B
LEAD SHIELDING
LASER LT. (N.I.C.)
LEAD SHIELDING
3-0 LONG PIECES OF P-1000 IN. STRUT SUPPORT SYSTEM
RAM TABLE (N.I.C.)
LASER LT. (N.I.C.)
TREATMENT ROOM
101
LASER LT. ASSY ABOVE MOD. CAB
CAMERA (N.I.C.)
G.W.B.
PROVIDE 5" L AND B'S BOTTOM TO CONC TO PROVIDE RIGID MOUNTING PLATE FOR LASER LIGHT - EXACT METHOD TO BE WORKED OUT IN FIELD W/ PHILIPS
LEAD DOOR AND SURROUNDING FIN
VESTIBULE
101A
6" PIPE SEE F.P. RNGS.
MONITOR CONTROL CAB. (N.I.C.)
CONTROL ROOM
9A
11/6
4'-0"
5'-0 1/2"
7'-1 1/2"
1'-3"
1'-1 1/2"
6'-7 1/2"
7'-9"
2'-6 1/2"
2'-0"

Bryn Mawr Hospital

HDR Ammendemnt

Shielding Calculation

Dose Limitations

Dose limitations are assumed to be those for the general public as defined in 10 CFR Part 20, 2 mR in any hour and 100 mR per year whole body exposure

Population

Assumption that all areas are unrectricted and occupied by members of the general public

Occupancy

All areas are considered to have 100% occupancy factor

Distance to Point of Occupation

The minimum distance in any given direction from the linac isocenter is assumed to be the distance to all points outside the control area. For this room the distance from the room isocenter to the point of occupancy is at a minimum when measured towards the ceiling. This distance is 4 meters.

Use Factor

For an HDR unit, the dose from the source will be assumed to emit and dose field that has no anisotropy and is not attenuated by the patient or any other movable objects in the room

Workload

The workload for this machine is derived below for the maximum hourly workload and the annual workload.

Maximum Hourly Workload – It can be assume that there will be no more than four treatments delivered to a patient for any one hour. The maximum estimated dose per patient is 8 Gy at 1 cm from the source. For a 10 Ci source, this would result in a treatment time of approximately 8 minutes. A 10 Ci source has an exposure rate of 4.8 R/hr at 1 meter so the workload will be .64 R at 1 meter

Expected Annual Workload – The total fractions expected to be delivered per week would be 25 fractions per week at 8 Gy per fraction. This would result in a source delivery total of 200 Gy per week and 10000 Gy per year. The total time that a 10 Ci source would be exposed would be 10000 minutes or 170 hours. A 10 Ci source has an exposure rate of 4.8 R/hr at 1 meter so the workload will be 816 R~~/hr~~ at 1 meter

CTHICKNESS AS IND' TED ON PL
1/4" EXTRUDED ALUM. FRAME
LEAD GLASS 18" W X 24" H CLEAD EQUIVALE AS INDICATED ON P
REMOVABLE AL GLASS STOP
2X4 CONT. AROUND F
CONT. HTL. RUN
5/8" GWB
3 5/8" HTL. STUD
3"=1'-0"

Radiation Oncology
Hot Lab

1. Physico Office
2. Nurses Office
3. Secure Hot Lab
4. Public Hallway
5. Facilities Conference Room
6. Dressing Room
7. Above Hot Lab - Psych Wa

Attenuation

Tenth Value Layers of IR-192 from NCRP Report 49
Concrete = 14.7 cm
Steel = 4.3 cm
Lead = 2.0 cm

The minimum equivalent thickness of concrete for any barrier in the room is 53.34 cm on concrete and 6.35 cm of lead. This is equal to an attenuation of 3.175 lead TVL's and 3.63 concrete TVL's for a total of 6.8 TVL. This results in an attenuation of 1.58x10-7

Expected Dose Calculations

Dose = (Workload * Use * Occupancy * Transmission) / (Distance^2)

Max Instantaneous Dose = (4.8 R/hr) * (1) * (1) * (1.58x10-7)) / (4m * 4m) = .047 mR/hr

Maximum Hourly Dose = (.64 R)*(1)*(1)*(1.58x10-7)/(4*4) = 6x10-6 mR/hr

Annual Exposure = (816 R)*(1)*(1)*(1.58x10-7)/(4*4) = 8 x 10-3 mR

Conclusions

All calculations show that the doses expected in the worst case scenario for each parameter will still limit doses below 2 mR/hour for a fully exposed 10 Ci source and far below the 100 mRem limit for annual exposure to the public.

Item 9A

MAIN LINE HEALTH HOSPITALS
& AMBULATORY CENTERS

Division of Nuclear Medicine + Group 35.400

Procedures for Use of Radiopharmaceuticals in Group 35.300 for Treatment of Patients (Phosophorus-32 or Iodine-131) (Ir-192 ribbons)

Patient's Name: _____

Room No.: 679 Physician's Name: _____

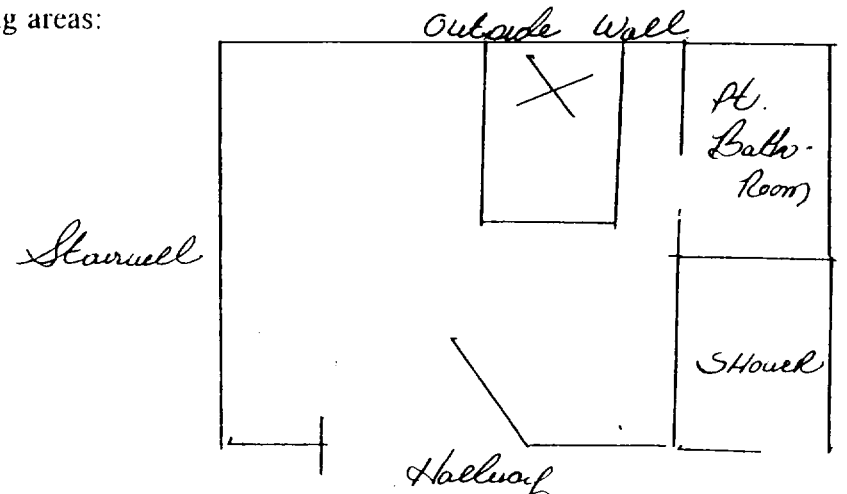
Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr.

Illustration of room and surrounding areas:

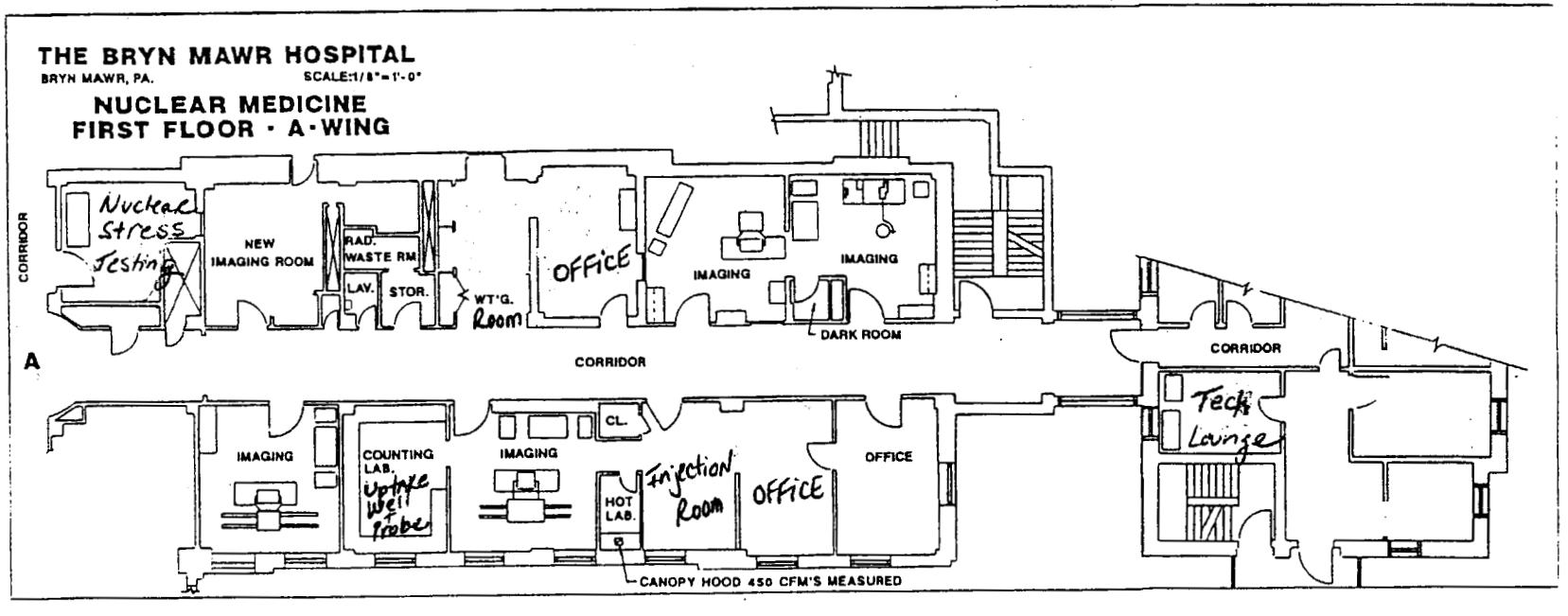


Location	Time	Exposure (mR/hr.)	Maximum Attendance
1. Adjacent to bed			
2. 3 feet from bed			
3. Visitor safe line			
4. Doorway			
5. Hallway Stairwell			
6. ~~Adjacent patient room~~			
7. Room below			
8.			

*For Gold-198 the times should be doubled after 3 days from date of administration, and doubled again at the end of the first week. For Iodine-131 the times should be double again after two weeks.

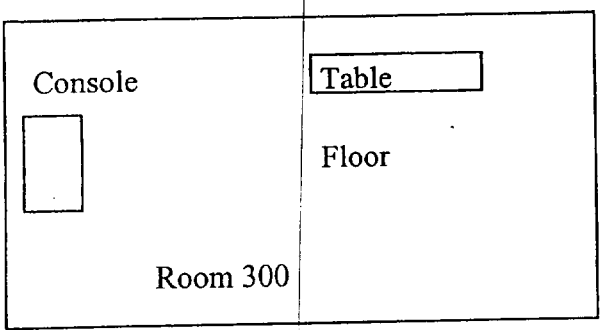
(to be completed by Physicist)

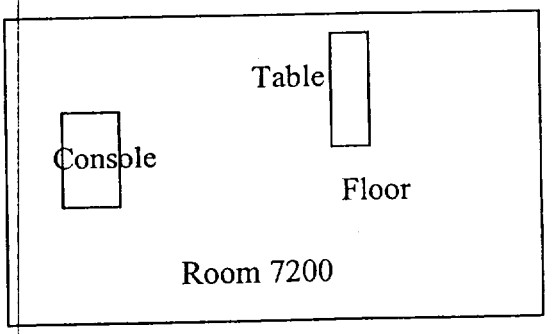
May 1999; 4/00

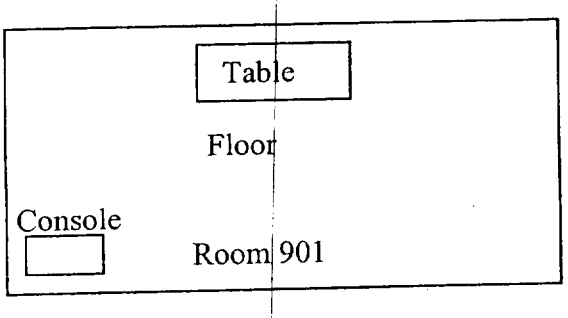

THE BRYN MAWR HOSPITAL
BRYN MAWR, PA.
SCALE: 1/8" = 1'-0"
NUCLEAR MEDICINE
FIRST FLOOR · A-WING
CORRIDOR
Nuclear Stress Testing
NEW IMAGING ROOM
RAD. WASTE RM.
LAV.
STOR.
WT'G. Room
OFFICE
IMAGING
IMAGING
DARK ROOM
A
CORRIDOR
CORRIDOR
Tech Lounge
IMAGING
COUNTING LAB.
Uptake Well + Probe
IMAGING
CL.
HOT LAB.
Injection Room
OFFICE
OFFICE
CANOPY HOOD 450 CFM'S MEASURED

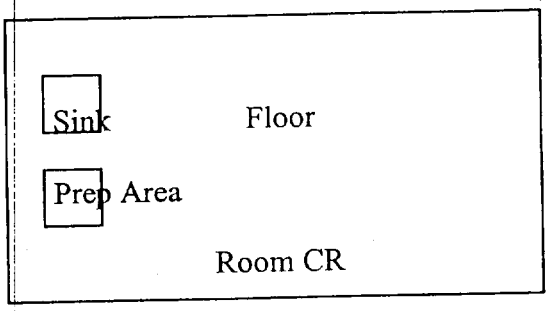
Item 9A

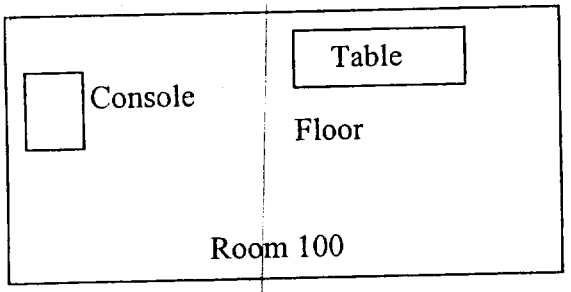
Nuclear Medicine Department
Weekly Area Monitoring Diagram

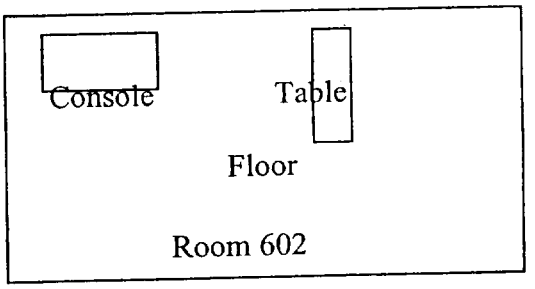


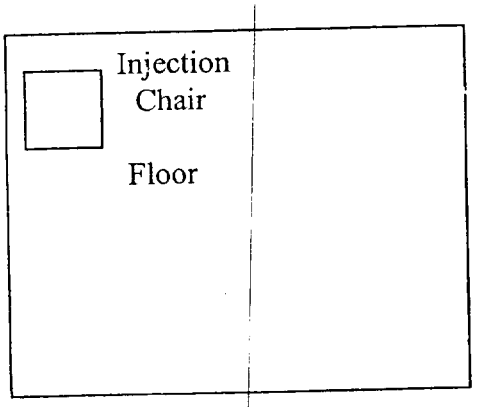




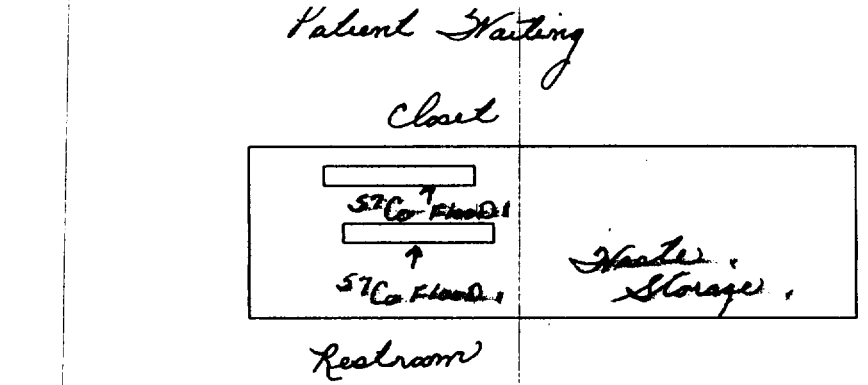




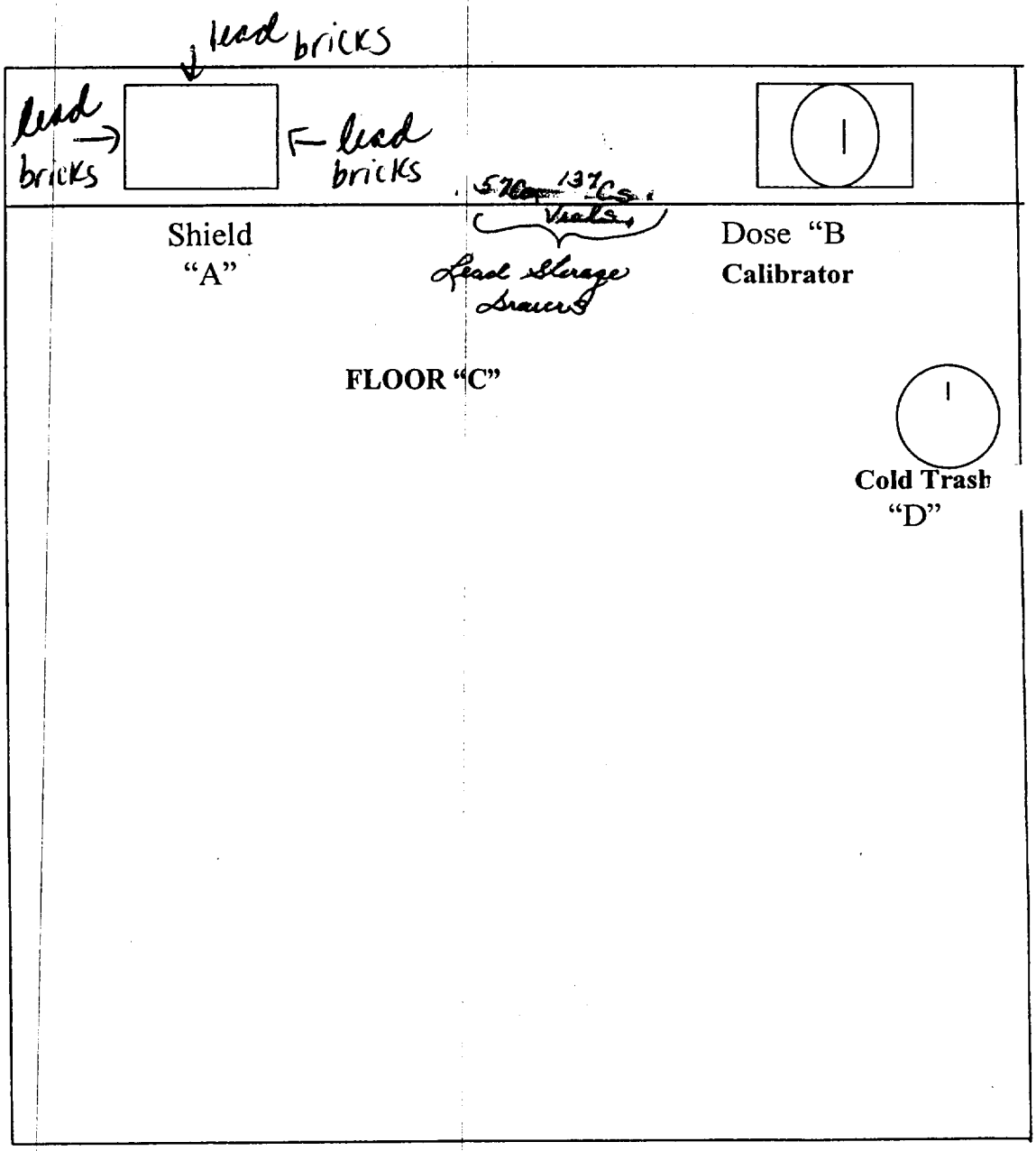




Item 9A

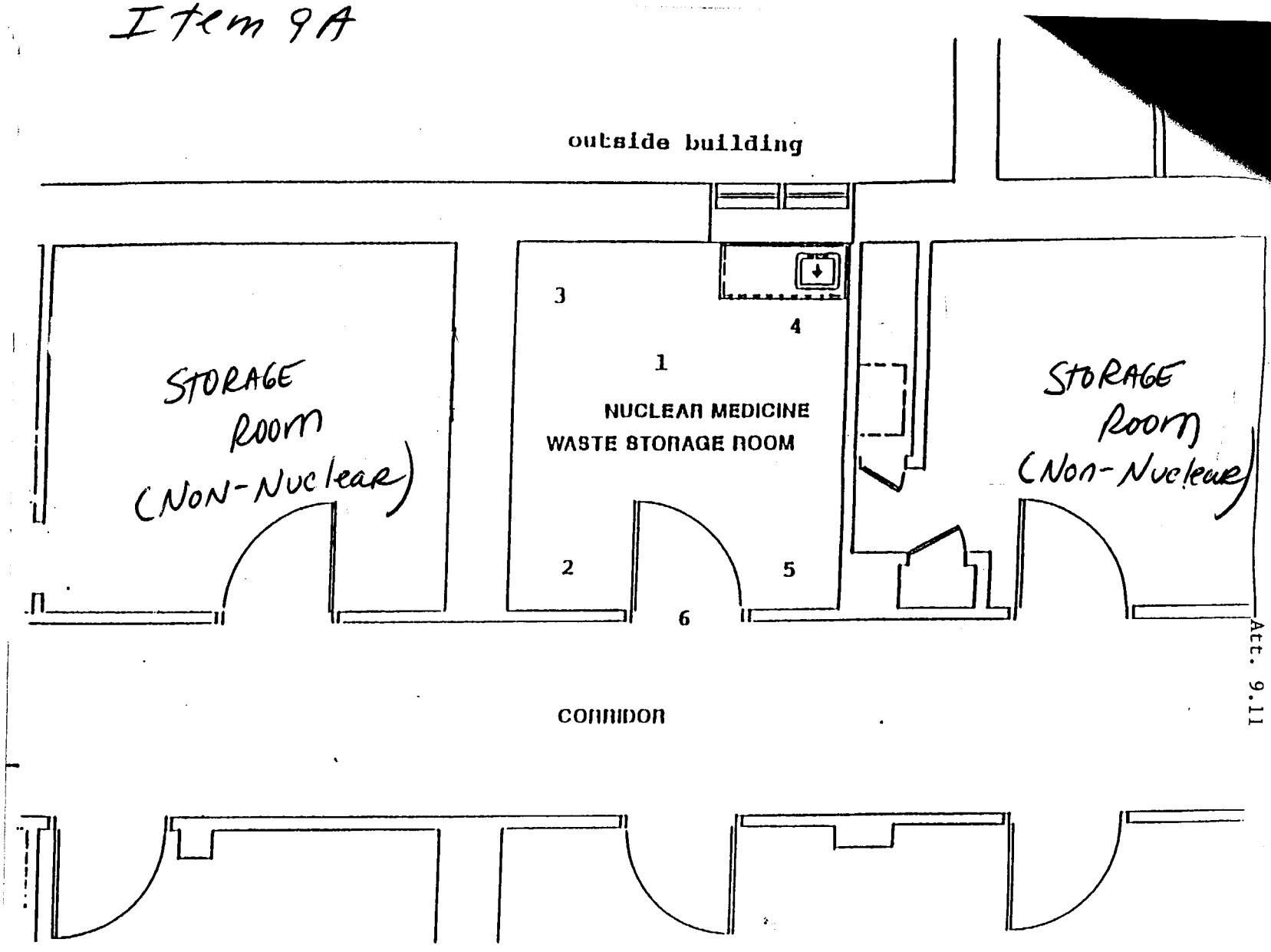


Hot Lab Diagram



Item 9A

Item 9A



Att. 9.11

BASEMENT H-WING
Area Monitoring
Remote Radioactive Waste Storage Room
Department of Nuclear Medicine

Ext 4299
Bob Schenker

Appendix B

Bryn Mawr Hospital

Department of Radiation Oncology

Procedure:	Nucletron HDR Daily Quality Assurance Testing
Frequency:	Each patient treatment day prior to patient treatment
Purpose:	To ensure device is functioning within normal operating limits as defined by the manufacturer and applicable regulations
References:	Nucletron microSelectron HDR Afterloader Manuals NRC 10CFR35.643 AAPM Task Group Reports #56 and #40
Author:	Nathan Anderson, MS
Version:	1
Date:	April 19, 2004

Initial preparations

1. Locate the following and have on hand at the HDR console:
    a. Keys to HDR unit and storage lock
    b. Radiation Exposure Survey Meter
    c. Bryn Mawr Hospital HDR Daily QA Form
    d. Timer/Stop Watch
    e. Radiation Check Source
    f. Film
    g. Personal Dosimeter
2. Turn on the film processor

Console preparations

1. Turn on HDR computer using the power on button on the PC
2. Insert the three keys into the HDR in their appropriate slot at the control console for reset, operation, and override
3. Activate the unit operation by turning the Operation key from standby to operation

Initial Tests

1. The HDR unit will begin a set of automatic initialization tests. These are reviewed below.
    a. Test: Communication between Treatment Control Panel and Treatment Control Workstation
       Passing Result: Communication Established
    b. Test: Random Access memory
       Passing Result: Ram Treatment Control Panel...OK Ram Treatment Unit...OK
    c. Test: EPROM/Flash Memory
       Passing Result: EPROM Treatment Unit...OK Flash Treatment Control Pane...OK
    d. Test: Battery Check Treatment Unit
       Passing Result: Battery Treatment Unit...OK
    e. Test: Indexer Treatment Unit
       Passing Result: Indexer Treatment Unit...OK
    f. Test: Indicators Treatment Control Panel
       Check: "Are all indicators being lit except Power present, Out of Safe, Radiation and Reset? Can the beeper of Treatment Control Panel be heard?" These lights are only illuminated for a very short time.
       Passing Result: Indicators Treatment Control Panel...OK
    g. Test: Real Time Clock Treatment Unit
       Passing Result: Real Time Clock...OK
    h. Test: Sound
       Check: Can the alarm sound from the audio system be heard?
       Passing Result: Sound...OK
2. After all of the self-tests are done, they should all have green check marks to indicate that they passed.
3. Press the print button to print the results
4. Press the close button to close the Self Test results window

General Preparation

1. Unlock HDR unit from floor and remove the plastic cover
2. Push HDR unit to table, lock the wheel position.
3. Raise the head to table level, and open top cover to expose the emergency hand cranks
4. Check the source lock position. The key slot should point towards the "| " to indicate the source is not locked
5. Place HDR Emergency Source Container in position next to the unit and open the top. The forceps should be with the container

Radiation Safety

1. Using the check source, verify that the in room prime alert is functional. If the primalert does not function, do not proceed with this QA procedure any further. Contact a physicist immediately
2. Turn on the hand held survey meter
3. Set the meter to the 200 mR/hr scale
4. Record the survey meter information on the Daily QA sheet
5. Place the check source on the meter at the spot indicated. The value should be approximately 2.7 for Kiethley Model 36100 S/N 17468 used with the 10 uCi check source.
6. Record the check source reading on Daily QA sheet
7. Use the survey meter to determine maximum reading near the head of the HDR unit. Record results on the QA form

Position Verification Device

1. Place black position verification device on treatment table with connector end for the GYN cables toward the HDR unit
2. Place one sheet of Kodak "XV Ready Pack" film (10 x 12) in device by sliding it into the slot with the latch in the open position. Make sure that the film is fully inserted.
3. Slide the latch on top from open to close
4. Obtain the Numbers 1, 2 and 3 GYN transfer tubes from the storage cabinet and connect HDR unit to positioning device
5. Make sure the numbered catheter is attached to same numbered channel on both the HDR unit and the positioning device. If not, you will not be able to continue.
6. Turn locking ring on HDR face to the right to lock the transfer tubes in place

Preparation for treatment

1. Verify that the HDR Emergency Procedures are posted at the console. Record whether they are there on the daily QA form.
2. Verify proper function of audio and video patient monitors. Record whether they are functioning on the daily QA form.'
3. Turn the door toggle switch to the HDR position
4. Click on the Login button to bring up the login window.
5. Enter the username that you have been assigned and the password, then press OK to log in.
6. Select the Prepare button at the right of the screen.
7. Click on the drop down list of patients using the Name field in the upper left hand part of the screen.
8. Select the daily qa patient available in the menu by clicking on the name. The name of the patient will be similar to 2004dailyqa1, NGA.
9. After selecting the patient, click on the "Treatment..." button at right.

10. A window will appear showing the treatment to be delivered using the QA patient. Do not print the "Pre-Treatment Record". Press the "Close" button to proceed
11. Enter your treatment confirmation password at the prompt.
12. A final box of interlock statuses will be displayed. Close box when all interlocks are clear as indicated by 3 green check marks.

Treatment and interlock verification

1. Press "Start" on console to start treatment
2. As treatment progresses, verify function of the following and record on the QA form when the following interlocks are successfully activated. After each interlock interruption, the printout should be skipped and the daily QA continued. The interlocks to test are:
    a. Interrupt – Button on console should return the source back to the safe.
    b. Door Interlock Toggle Switch - Turn interlock switch from HDR back to Linac. This should trigger a door interlock and return the source to the safe.
    c. Door Open Interlock – Open the door with the source exposed only enough to trigger a door interlock. The source should return to the safe.
    d. Emergency stop on Console – Pressing Emergency Stop should return the source to the safe. The reset key is needed to reset the Emergency Stop interlock before proceeding.
    e. Emergency stop – maze wall – After resetting the console Emergency Off switch, you can enter the maze with meter in hand and activate the maze switch. This should reactivate the emergency stop. Reset this again
    f. Emergency stop – HDR unit – After resetting the maze wall emergency stop, the HDR unit emergency stop button should be checked. This should re-enable the alarm. Use the Reset key to continue.
3. Before you reset for the last time, note the time remaining on channel 1 position 1 out of the original time.
4. After starting the unit again, watch the dot at Catheter 1, position 1. As soon as it turns red, you should start the timer. As soon as it is no longer red, you should stop the timer.
5. Compare the time on the stopwatch with the time noted before restarting for Catheter 1 position 1. They should be within 1 second of each other. Record if this true on the QA form.
6. While treating the rest of the QA patient, verify that the in-room primalert, the remote primalert, Radiation light on console and the door light are all illuminated. Record the results on the QA form

Completing Treatment

1. Following the end of the treatment, print the record and close out of the treatment.
2. Close the Status Window and the Prepare Treatment window.
3. Logout at the Main Screen.
4. On the treatment record, check the date and time as it is listed in the row "Current Source Strength". They should be accurate. Record the result on the QA form
5. On the treatment record, note, the activity in Ci as displayed in the "Current Source Strength" row. Verify that the activity listed is within 1 percent of the daily activity posted at the console. Record the results on the QA form
6. Record that the printer is functional and record on the QA form

Entering room after treatment

Before you re-enter the treatment room at any time during or after a treatment, the following steps should be followed

1. Make certain the prime alert is not flashing
2. As you enter, carry survey meter with you and look to assure it is reading background
3. Approach the treatment unit and verify that all readings near the head have returned to the levels of pre-treatment.

Completion and Paperwork

1. Remove the film from the position verification device by sliding it open.
2. Take the film and process it
3. Disconnect the three transfer tubes from the unit and the position device and hang them in cabinet
4. Lower the HDR head, close the lid on the emergency hand cranks, unlock the wheels, return it to its storage place, replace the cover and lock the unit to the floor
5. Close the Emergency Source container and return to storage.
6. Remove all three keys from the console and the key from the floor lock. Return these to the hot lab for secure storage.
7. When the film is processed, verify that the cross lines are within $\pm$ 1mm of the source dwell marking and record this on the QA form.
8. Sign the film and place it in the film jacket for HDR QA
9. Sign and date the QA form, self test and treatment record.
10. The printouts for the week can be placed in the QA binder with the QA form by the week.

Action For Failed QA Tests

If any of the tests indicated here are failed, the unit is to be secured and not used until physics is contacted. An authorized medical physicist will make the determination of the appropriate actions for the specific circumstances.

Bryn Mawr Hospital
MicroSelectron HDR

HDR Daily QA

Date					
Emergency Pig, forceps available					
Prime Alerts Functional w/ check source					
Survey Meter Used Model Serial Number					
Meter Check Source Reading within Spec					
Maximum Survey Meter Reading at Head of HDR (mR/hr)					
Emergency Procedures Posted					
Video Monitoring Functional					
Audio Monitoring Functional					
Emergency Off Interlocks Functional Console Maze Wall HDR Unit					
Safety Interlocks Functional Interrupt Door Interlock Linac/HDR switch					
Console Indicator of Radiation when Source Exposed Is Functional					
Door Radiation Warning Light Functional					
Prime Alert Functional with Source Exposed					
Stop watch reading for remaining dwell time within ± 1 second					
Console Date and Time Correct					
Console Activity (Ci) / Posted Activity within 1 %					
Printer Functional					
Source Position within 1mm by autoradiograph					
Performed by:					
Verified by:					

Bryn Mawr Hospital

Department of Radiation Oncology

Procedure:	Nucletron HDR Quarterly Quality Assurance Testing
Frequency:	This procedure will be performed when a new source is installed or quarterly if a new source install is not scheduled. It will also be preformed following any repair of the unit that includes removal of the source or major repair of the components associated with the source assembly
Purpose:	To ensure device is functioning within normal operating limits as defined by the manufacturer and applicable regulations
References:	Nucletron microSelectron HDR Afterloader Manuals NRC 10 CFR 35.633 NRC 10 CFR 35.643 NRC 10 CFR 35.652 AAPM Task Group Reports #56 and #40
Author:	Nathan Anderson, MS, Mike Bieda, MS
Version:	2
Revisions:	Mike Bieda, 2/14/04

Radiation Safety

1. The newly installed source will be documented on the quarterly QA form for its serial number, calibrated activity, and calibration date and calibration time.
2. The exposure rate of the area surrounding the treatment unit will be measured with the source in the safe
3. The maximum values in each of the cardinal directions from the safe at 10 cm and 1 meter from the safe will be recorded on the quarterly QA form.
4. The source will then be connected to an applicator catheter and exposed on the treatment couch.
5. These numbers will be recorded and calculated on the quarterly QA form.

Calibration of Source Strength

1. Before use of a new source or quarterly, the source activity will be verified by performing a independent calibration.
2. An electrometer and a re-entrant well ion chamber with a current ADCL or NIST calibration for an Ir-192 HDR source will be used for the calibration. This system will have a calibration from within the previous two years or since the last event that may cause changes to its calibration, whichever is more recent
3. A 5 French endobronchial catheter and connector will be attached to the unit. The tip end of the catheter will be placed in the HDR source holder in the well chamber.
4. Multiple dwell positions will be used to identify the maximum reading of current for the source in the chamber
5. Calculation of the activity from the maximum chamber current will be made based on AAPM accepted protocol for calibration of brachytherapy source strength.
6. The readings and the measured/calculated activity are then recorded on the quarterly QA form
7. The measured activity should fall within 5% of the decay corrected activity on the manufacturer calibration sheet. If it does not, the activities will be investigated by an authorized medical physicist and any discrepancy will be resolved before treatment is continued with the source.
8. The source calibrations will then be updated in both the treatment unit and the treatment planning computer

Timer Accuracy and Linearity

1. Calibration set up from above will be used to verify accuracy and linearity
2. The afterloader will be programmed for a variety of dwell times at the center of the chamber.
3. For each of these dwell times, a stopwatch will be used to record the time dwell. These will be recorded on the quarterly QA form.
4. These values will be compared to the values expected and if not within 1% of these values, problem will corrected before treatment with the source
5. In addition, the charge collected for each dwell will be recorded on the quarterly QA form
6. The linearity of the time will be verified by deriving the slope of the graph of the dwell collections.
7. If these values are non-linear by more than 1%, the problem will be corrected before treatment is resumed

Timer End Effect

1. Using the setup from the calibration, two reading will be taken for dwells of two times differing by a factor of two

2. The time and their readings will be used to calculate the end effect from the source travel

Battery Back-up Source Retraction

1. In the presence of the Nucletron service engineer, power will remotely be cut to the unit.
2. When this is done, the battery should retract the source automatically using its battery backup
3. If this fails to occur, the unit will not be used until the problem has been resolved and the test can be passed

Source Positioning Check

1. Source dwell positions will be programmed into the afterloader for multiple dwell distance
2. The distance of the actual dwell will be determined either visually through a camera, with the Nucletron approved measuring device or radiographically.
3. The difference between the programmed dwell position and the actual dwell position must be no more than 1 mm. If the difference is more than 1 mm, the test has failed and nucletron will adjust the source positioning.
4. The test will be repeated after each iteration of adjustment.

Primalert Battery Backup Check

1. The power will be removed from the battery pack of the Primalert.
2. A check source will be held to the primalert in this state to check that the unit will function even if power is lost.
3. If this test fails, the battery backup unit will be prepared as quickly as possible. In the interim, a functioning survey meter will be used whenever personnel enter the room following a source exposure.

Activity Decay Correction Charts

1. Following source calibration, the calibration activity as entered in the treatment planning computer and the afterloader, will be used to calculate a daily activity decay sheet.
2. This sheet will be printed and made available to verify the decay on a daily basis

Applicator Lengths

1. All applicator lengths will be checked before use clinically. Due to the infrequent use of many applicators, these checks will not be done every

quarter but rather when the applicator will enter use again or quarterly if frequently used.

Functionality of Transfer tubes and applicators

1. All transfer tubes will be checked for functionality before use clinically by visual inspection of connectors and lengths.

Additional Test

1. In addition to the testing above, the authorized medical physicist may verify the tests included on the monthly QA form attached. These tests are the daily pre-treatment tests as well.

Calibration Physicist:	Mike Bieda	**Calibration Date :**	8-Feb-05	
Check Physicist:	Nathan Anderson	**Calibration Time :**	18:00	EST

A. Mallinckrodt Source Specifications

Model #:	D36A		**Isotope:**	Ir-192	
Serial # :	6471		**Manufacturer Calibration Date :**	2-Feb-05	
Calibration Certificate Activity :	10.469	Ci	**Manufacturer Calibration Time :**	18:00	CET
			Local Time Zone Calibration Time	12:00	EST

B: Exposure Rate Survey of Treatment Unit

Survey Meter Model:	451P
Survey Meter Serial Number:	945
Calibration Date :	6/30/04

Location	Right	Left	Above	Below	Front	Specs
Reading @ 5 cm (mR/hr)	0.06	0.06	0.09	0.07	0.04	< .27 mR/hr for 12 Ci source
Reading @ 1 meter (mR/hr)	0	0	0	0	0	< .02 mR/hr for 12 Ci source

bkgd = .01

All Values Less than those stated on Sealed Source Certificate:

x YES, Passed

_____ No, Failed, Do Not Use

Physicist:_____

C. Calibration

Date of Physics Calibration:	2/8/2005	
Calibration Time:	18:00	
Source Serial #:	6471	
Electrometer Model:	Max 4000	
Electrometer Serial Number:	E012531	(tlh)
Calibration Date:	02.11.03	
Voltage Setting:	-300	
Chamber Model:	IDR 1000 Plus	
Chamber Serial Number:	A981257	
Chamber Calibration Date:	05.18.04	

Electrometer Factors

P_{elec} :	1.0010	

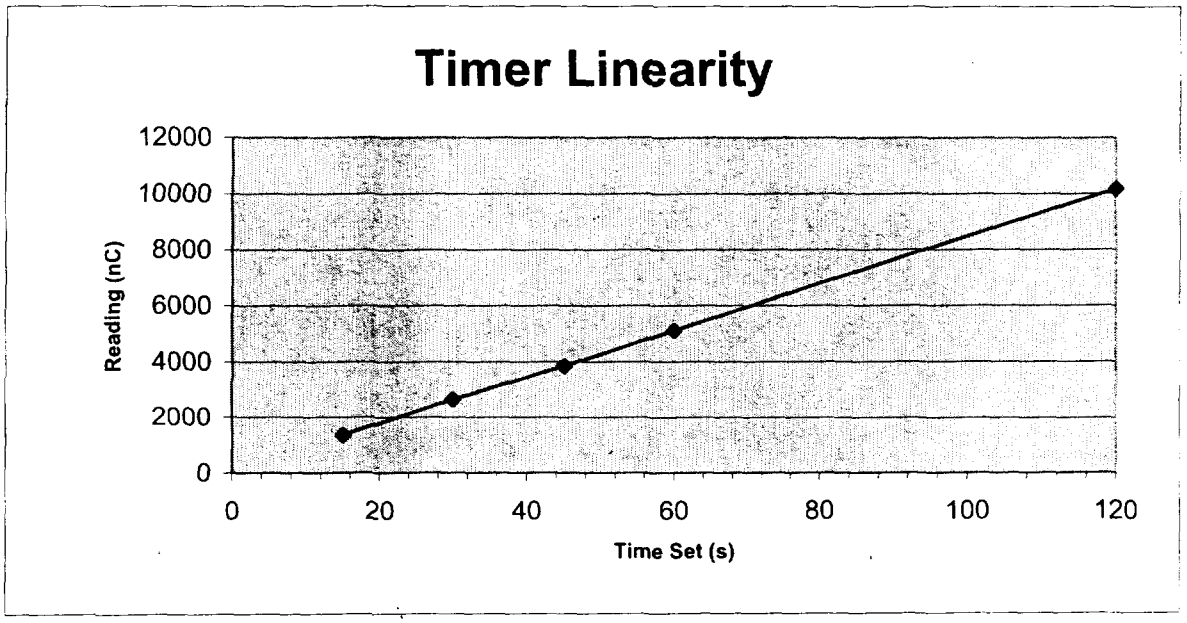
Chamber Factors

Air Kerma Cal:	4.656E+05	Gy m^2 / hr A
Location For Measurement of Cal:	1450.0	mm
Aion :	1.000	
Air Temperature:	23.9	
Air Pressure:	756.4	mm Hg
$C_{t,p}$:	1.011	
Indexer Length:	1455	mm
Chamber Reading at Indexer Length:	8.4690E-08	A
Gy to cGy Conversion Factor:	100	
App Act Cal:	0.4082	(cGy m2 /hr) / Ci
Measured Air Kerama Rate	3.991E+00	**cGy m^2 / hr**
Manufacturer Decay Corrected Air Kerma Rate	4.0300	**cGy m^2 / hr**
Percent Difference From Manufacturer Cal	0.97%	
Air Kerma Rate Stated On Unit	3.991	
Percetn Difference From Console	0.01%	
Measured Activity	9.778	**Ci**
Manufacturer Decay Corrected Activity	9.873	**Ci**
Percent Difference From Manufacturer Cal	0.97%	
Activity Stated On Unit	9.778	
Percent Difference From Console	0.00%	

D. Timer Linearity and Accuracy

Programmed Dwell Time (sec)	Collection Time Set for Electrometer (sec)	**Reading (nC)**	Calclated Dwell Times From Readings	Absolute Difference (sec)	Stopwatch Readings (sec)	Stopwatch Differences
15	45	**1341.3**	15.43	-0.43	**15.10**	0.10
30	60	**2651.6**	31.05	-1.05	**29.90**	-0.10
45	75	**3841.6**	45.24	-0.24	**45.10**	0.10
60	90	**5106.6**	60.32	-0.32	**60.20**	0.20
120	150	**10166**	120.64	-0.64	**120.20**	0.20

Least Square Fit Y = A + B X
x-intercept = **-1.09** s Slope = **83.88** nC / s
Correlation = **1.000**



Timer Linearity

Correlation is 1.000 +/- .01 ___X___ PASS
Correlation is outside above Range _____ FAIL

Timer Accuracy

Stopwatch Difference <1 second ___X___ PASS
Stopwatch Difference >1 second _____ FAIL

E. Timer End Effect

Programmed Dwell Time (sec)	Collection Time Set for Electrometer (sec)	Reading (nc)
60	75	**5106.6**
120	135	**10166**

(Rdg2 * T1 - Rdg1 * T2) / (Rdg2 - Rdg1) = -0.56 seconds

F. Backup Battery Source Retraction

Results Of Back Up Battery Performance: x

G. Source Position Check using film (20 MU+1cm bolus,dummy seed

strand #1 or #3, patient name"Source Position Check PRS)

Length Programmed	**Length Measured* (mm)**	Difference (mm)	Acceptable
1500.0	**1499.5**	-0.5	YES
1490.0	**1489.5**	-0.5	YES
1480.0	**1479.5**	-0.5	YES

*length measured = ruler reading - 2.15 mm = source center position

Results: PASS

H. PrimeAlert Battery Backup Functional

x YES
NO

Performed by : mrb Date: 2/10/2005

Signature: _____

K. Applicator Length Test

L. Applicator and Connector Function Test

All Connectors and applicator used during the quarter were tested at least once

Applicators Used

Functionality Test Results

Pass: x

Fail: _____

Lengths of Connector cables verified for all clinically used connector tubes

Pass: x

Fail: _____

Performed by : _____ Date: _____

Signature: _____

Physicist: Date:

Tape measure: Starrett 8m

Place tape-measure on flat surface and pulling gently on transfer tube at each end in a straight line, measure the total length. Note the measured total length excluding the plunger at end of the transfer tube and compare with nominal total length. Inspect the transfer tubes for kinks, debris or damage; the tubes pass inspection upon finding none of these.

Exceeding spec. and/ or failing inspection: Contact Nucletron

	Transfer tube part #	for indexer channel number	Nominal total length (mm)	within tolerance of 1 mm	Inspection results acceptable
Nucletron microSelectron-HDR Transfer Tube Set for 6F, Flexibles	111.032	1	1055.6	yes	yes
	111.033	2	1055.6	yes	yes
	111.034	3	1055.6	yes	yes
	111.035	4	1055.6	yes	yes
	111.036	5	1055.6	yes	yes
	111.037	6	1055.6	yes	yes
	111.038	7	1055.6	yes	yes
	111.039	8	1055.6	yes	yes
	111.040	9	1055.6	yes	yes
	111.042	10	1055.6	yes	yes
	111.043	11	1055.6	yes	yes
	111.044	12	1055.6	yes	yes
	111.045	13	1055.6	yes	yes
	111.046	14	1055.6	yes	yes
	111.047	15	1055.6	yes	yes
	111.048	16	1055.6	yes	yes
	111.049	17	1055.6	yes	yes
	111.050	18	1055.6	yes	yes

Physicist: Date:

Tape measure: Starrett 8m

Place tape-measure on flat surface and pulling gently on transfer tube at each end in a straight line, measure the total length.
Note the measured total length of the transfer tube and compare with nominal total length.
Inspect the transfer tubes for kinks, debris or damage; the tubes pass inspection upon finding none of these.

Exceeding spec. and/ or failing inspection: Contact Nucletron

	Transfer tube part #	for indexer channel number	Nominal total length (mm)	within tolerance of 1 mm	Inspection results acceptable
Nucletron microSelectron-HDR Transfer Tube Set for (stainless steel) needles	111.012	1	1250.6	yes	yes
	111.013	2	1250.6	yes	yes
	111.014	3	1250.6	yes	yes
	111.015	4	1250.6	yes	yes
	111.016	5	1250.6	yes	yes
	111.017	6	1250.6	yes	yes
	111.018	7	1250.6	yes	yes
	111.019	8	1250.6	yes	yes
	111.020	9	1250.6	yes	yes
	111.022	10	1250.6	yes	yes
	111.023	11	1250.6	yes	yes
	111.024	12	1250.6	yes	yes
	111.025	13	1250.6	yes	yes
	111.026	14	1250.6	yes	yes
	111.027	15	1250.6	yes	yes
	111.028	16	1250.6	yes	yes
	111.029	17	1250.6	yes	yes
	111.030	18	1250.6	yes	yes

Physicist: Date:

Tape measure: Starrett 8m

Place tape-measure on flat surface and pulling gently on transfer tube at each end in a straight line, measu
Note the measured total length of the transfer tube and compare with nominal total length.
Inspect the transfer tubes for kinks, debris or damage; the tubes pass inspection upon finding none of thes

Exceeding spec. and/ or failing inspection: Contact Nucletron

	Transfer tube part #	for indexer channel number	Nominal total length (mm)	within tolerance of 1 mm	Inspection results acceptable
Nucletron microSelectron-HDR Gynaecological Transfer Tubes	111.002	1	1254.6	yes	yes
	111.003	2	1254.6	yes	yes
	111.004	3	1254.6	yes	yes
Nucletron microSelectron-HDR Gynaecological CT/MR Tubes	111.007	1	1259.2	yes	yes
	111.008	2	1259.2	yes	yes
	111.009	3	1259.2	yes	yes

Appendix C

BRYN MAWR HOSPITAL

Department Of Radiation Oncology

EMERGENCY PROCEDURES FOR NUCLETRON REMOTE AFTERLOADER HDR

Scope: If at any time during a procedure that involves an active source that fails to return to the safe fully or source cable separation, this procedure should be implemented.

1. DEPRESS THE RED EMERGENCY STOP BUTTON on the afterloader control console.
   a. If the source retracts fully, go to step 7 below,
   b. If the source does not retract fully, continue to step two.
2. ASSESS IMMEDIATELY IF THERE IS ANY IMMINENT RISK TO EITHER PERSONNEL OR PATIENTS who may be under treatment.
   a. If this occurs without a room occupant, precede cautiously though the following procedure being sure to utilize the advantages of time distance and shielding. Keeping the room locked until the vendor is contacted should be considered
   b. If a patient is in the room, proceed immediately to step three
3. ENTER THE ROOM WITH A SURVEY METER AND CHECK THE RADIATION EXPOSURE LEVELS as you approach the patient.
   a. If radiation exposure levels are still indicating an exposed source or partial source, stand opposite the catheter connections at the afterloader and turn the GOLD HAND CRANK CLOCKWISE until it locks.
4. Re-survey the area for radiation exposure.
   a. If the radiation source has now fully retracted, continue to step 7
   b. If the source still has not fully retracted into a shielded position, THE APPLICATOR SHOULD BE REMOVED FROM THE PATIENT INTACT to ensure that the radioactive material is confined to the applicator. Insert the applicator containing the source into the well of the emergency container using the forceps. Close the lid of the container and leave the radiation symbol hanging from the container to indicate that it contains radioactive material.
5. Once the applicator is removed from the patient, assist the patient from the room. Once the patient is in a low background area, survey the patient to ensure that the entire source has been removed from the patient.
6. Lock the source in its current place by inserting the key into the lock between the gold and black hand cranks on top of the treatment unit
7. The room should be posted with a "NO ENTRY sign, the door closed and the room either locked or under authorized supervision until it can be secured.
8. Once the room is secure, contact the following people to notify them of the incident

   Authorized User: Richard Carella, MD Tel/Beeper: 52-3370 / Beeper 1378
   Physicist: Mike Bieda, MS Tel/Beeper: 52-3372
   Radiation Safety Officer: Marchello J. Barbarisi Tel/Beeper: (610) 526-3530
   Nucletron Rep: Bill Meyer Tel/Beeper: 800 826 2258
9. The authorized medical physicist should make notes on estimated distances and time of personnel being exposed to the source in the room and the additional time that the patient was exposed to the source. The unintended dose to which those present have been subjected can then be estimated and recorded by a suitably trained person using this data.

THE UNIT SHOULD NOT BE USED AGAIN UNTIL SERVICE AND A FULL CALIBRATION IS COMPLETED

BRYN MAWR HOSPITAL

Department of Radiation Oncology

Policy: Medical Emergency Procedure For HDR Treatments

Scope: This procedure should be used in the event of a medical emergency during an HDR afterloader treatment.

Procedure:

If there is a medical emergency the treatment delivery should be interrupted immediately.

1. Interrupt the treatment by pressing the interrupt button on the control console.
2. Verify by viewing the controller screen and the primalert that the source has been returned to its safe fully
3. Enter the room and survey the patient with an exposure meter to verify that the source has been fully and safely returned to the safe
4. Disconnect the connector tubes and remove applicators as is necessary for care.
5. If after care is complete, the treatment is to resume, reconnect the connector tubes and resume the treatment from the console. If the treatment cannot be continued, the treatment should be ended from the console controls.
6. Incomplete treatments should be reviewed by the authorized medical physicist and the authorized user to asses whether there was a medical event involved in the delivery of the treatment

BRYN MAWR HOSPITAL

Department of Radiation Oncology

Policy: Nucletron microSelectron Emergency Equipment for Treatment

Purpose: This policy delineates the necessary safety and monitoring equipment necessary for each HDR treatment.

Author: Nathan Anderson

Version: 1

Date: 1/14/03

Equipment:

The equipment below should be available for each treatment for personnel administering the HDR afterloader treatments

In Room

- Emergency Container
- Radiation Tag for Emergency container
- Long Forceps
- Emergency Applicator Removal Kit as necessary for each application type

Outside Room

- Radiation Survey Meter
- Personnel badges for radiation exposure
- Key for locking source in place on unit

Appendix D

1 Customer Training

Purpose

This document describes the training provided by Nucletron to microSelectron-HDR customers following installation.

Note

This outline can be provided to the NRC or Agreement States for license applications or license renewals (USA only).

Nucletron provides initial Customer Training to purchasers of the microSelectron-HDR to inform the user in the theory and operation of the unit as described in this document. This training consists of theory and operation of the unit, and covers the Emergency Procedures including Cautions and Warnings. This training is applicable to the physician, device operator, technologist, nurse, physicist, dosimetrist and the Radiation Safety Officer (RSO).

Note

This training may be used in support of NRC Guidance FC 86-4, Rev.1-IV, IV-A,2, 3, and 4 (USA only).

Periodic re-training (recommended yearly) in emergency procedures can be provided on site by Nucletron Engineers during one of the scheduled Preventive Maintenance Procedures.

Note

This is offered in support of NRC Guidance FC 86-4, Rev.1-IV.C (USA only).

Clinical training in use of the microSelectron-HDR can be provided in addition to any required PLATO Brachytherapy Treatment Planning Training. This training may include, but not be limited to clinical patient mock-treatment using the microSelectron-HDR. This training is described in the document "Brachytherapy Customer Training Syllabus, PLATO", part no. 090.982.

Note

This is offered in support of NRC Guidance FC 86-4, Rev.1.4 (USA only).

Hands-on and didactic clinical training of the physician is not the responsibility of Nucletron. If this is required, contact your local Nucletron office for a list of possible clinical sites.

Note

Additionally the American Brachytherapy Society sponsors a yearly hands-on course to provide the opportunity for physicians to acquire the requisite training required in support of NRC Guidance FC 86-4, Rev.1-A (USA only).

Note

In support of NRC Guidance FC 86-4, Rev.1-IV.A.1 (USA only).

The name, affiliation and qualifications of Nucletron instructors conducting the training will be provided upon request.

Reference:Policy and Guidelines Directive, FC 86-4; Revision 1, Information Required for Licensing Remote Afterloading Devices, Section IV, Training for Individuals.

Note

The training as described is subject to change depending on local regulations and on the current software and hardware versions installed.

Note

It is understood that certain training components are the responsibility of the customer, for example, radiation protection and instrumentation, including proper use of personnel dosimeters and survey instruments.

Definition of Terms

TCS	Treatment Control Station
TCP	Treatment Control Panel
TU	Treatment Unit

Validity

This training syllabus is applicable for the following remote afterloader configurations:

microSelectron-HDR: part number 105.998, 105.999

- User Manual (part number 092.515)
- Emergency Procedures Card (part number 092.515)
- System Log Book (part number 092.517)

microSelectron-HDR Classic with TCS: part number 080.000, 096.998, 096.999 and 076.070, 076.071

- User Manual (part number 092.510)
- Emergency Procedures Card (part number 092.510)

2 Customer Training Agenda

This agenda and following report must be completed by Nucletron personnel during the training. Check the box upon completion of each item.

Functions of the Treatment Control Station

	Check Box
1 Verification of User Information	
Serial Number	☐
Source Calibration Data	☐
2 Self Test Dialog Window	
Review of Internal Checks TCS Performs	☐
Self Test Failure	☐
Operating the Self Test from the Maintenance Option	☐
3 System	
New Password	☐
Settings	☐
System Overview	☐
4 Maintenance	
Self Test	☐
Source Exchange	☐
Source Calibration	☐
Check Cable Exchange	☐
5 Database Menu	
Applicators/Standards	☐
Staff Members	☐
Groups	☐
Messages	☐
Authorisation	☐
Edit Message	☐
Backup and Restore	☐
6 Reports	
Standards	☐
Message Logbook	☐
Reporting Text	☐

7 Help

Contents ❑

About microSelectron ❑

Treatment Session

1 Explanation of the Patient Data Panel ❑

2 Explanation of the Session Plan Panel ❑

3 Programming the Treatment Data

Via Keyboard ❑

Using Standard Modes ❑

Importing from PLATO ❑

4 Sample Treatment Administered Using Dummy Source

Doorswitch ❑

Dosimeter Interrupt ❑

Power Failure ❑

Treatment Control Panel

1 Treatment Control Panel Interface to Treatment Unit

Treatment Unit ❑

Status Messages/Event Log ❑

Emergency Stops ❑

2 Explanation of Key Operated Switches

Standby/Operation ❑

Override Switch ❑

Reset Switch ❑

3 Explanation of System Status Indicators

Interrupt ❑

Alarm ❑

Engaged ❑

Action ❑

Out of Safe ❑

Print ❑

Radiation ❑

4 Source Location

Out of Safe ❑

In Safe ☐

5 Power Status

Power Present ☐
Power Fail ☐

Treatment Unit

1 Handling of mHDR

Telescope Up/Down Switch ☐
Wheel Locks ☐
Access to Top Panel ☐

2 Power Requirements and Function

Dedicated Power Outlet ☐
Power Conditioner (if applicable) ☐
Power Switch Location ☐

3 Treatment Unit Radiation Detector (mHDR only) ☐

4 Ir-192 Source

Source Design ☐
Radiation Safe ☐
Cable Drive Theory ☐
Check Cable Theory ☐
18 Channel Indexer ☐

5 Source Head Lock Mechanism ☐

6 Applicators and Accessories (appropriate items)

Connections of Applicators/Accessories to Transfer Tubes, Adapters and Treatment Unit ☐
Autoradiographic Check Device ☐
Source Position Check Ruler ☐
Hand Held Terminal ☐

7 Reference Optopair ☐

Documentation

1 User Manual (status codes) ☐

2 Log Book ☐

3 Bulletins ☐

Question and Answer Session

1 Frequently Asked Questions.....❑

2 Do's and Don'ts.....❑

Customer Training Report

This form must be completed in conjunction with the training agenda.

Facility Name:	
Facility Address:	
Date:	
Instructor:	
Afterloader Config.:	microSelectron-HDR / microSelectron-HDR Classic with TCS

Site Physicist/RSO:	

Customer Training Attendees

Name	Position	Remarks	Signature

The original copy must be kept in the Nucletron files. A copy is filed at the training site.

This is to acknowledge the receipt of your letter/application dated

2/28/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Renew 37-07722-04

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

---

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136521.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	----------
	:	
License Fee Management Branch, ARM	:	Program Code: 02230
and	:	Status Code: 2
Regional Licensing Sections	:	Fee Category: 7C 2B
	:	Exp. Date: 20050331
	:	Fee Comments: CODE 23
	:	Decom Fin Assur Reqd: N
	::	

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
   Applicant/Licensee: BRYN MAWR HOSPITAL (THE)
   Received Date: 20050301
   Docket No: 3003094
   Control No.: 136521
   License No.: 37-07722-04
   Action Type: Renewal

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Rebecca Jarrett
Date 3/1/2005

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

1. Fee Category and Amount: _____

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

3. OTHER _____
   _____

Signed _____
Date _____