Amendment No. 44

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. McLaren Regional Medical Center Department of Radiology	In accordance with letter dated March 28, 1994 3. License Number 21-04171-04 is renewed in its entirety to read as follows:
2. 401 South Ballenger Highway Flint, MI 48532	4. Expiration Date May 31, 2000
	5. Docket or Reference No. 030-02048

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. 1 Curie
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed Sources (ByK Mallinckrodt Model CI LBV)	E. Two sources not to exceed 12 curies each
F. Uranium depleted in uranium-235	F. Cadmium plated metal	F. As needed

9. Authorized Use: 230101

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
21-04171-04
Docket or Reference number
030-02048

Amendment No. 44

D. Medical use described in 10 CFR 35.400.

E. One source to be in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary and bronchial radiotherapy. One source in its shipping container to be in possession of the license as necessary for replacement of source in the irradiation device.

F. Shielding in a generator.

CONDITIONS

10. A. Locations of Use: 401 South Ballenger Highway, Flint, Michigan and G3239 Beecher Road, Suite F, Flint, Michigan.

B. Licensed material listed in subitem 6.E. shall be used only at McLaren Regional Cancer Center, Room 200, 4100 Beecher Road, Flint, Michigan.

11. Radiation Safety Officer: F. Carlyle Stebner, M.D.

12. Authorized Users — Material and Use

A. Sylvia M. Kosciolek, M.D., 10 CFR 35.100, 35.200 and 35.300.

B. Blake M. Berman, M.D., 10 CFR 35.100, 35.200 and 35.300.

C. F. Carlyle Stebner, M.D., 10 CFR 35.100, 35.200 and 35.300.

D. Hesham M. El Gayar, M.D., 10 CFR 35.100, 35.200, 35.300, 35.400, and iridium-192 in remote afterloading brachytherapy unit.

E. Jack O. Nettleton, M.D., 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit.

13. The licensee may dispose of spent molybdenum-99/technetium-99m generators to Associated Metals, Inc., NRC License No. 21-19623-01, as described in Item 3 of letter dated October 19, 1989, excluding Option Number 2 involving dismantling of the generators by Associated Metals at your facilities.

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

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

A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 0.25 milliroentgen per hour.

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

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101 (10 CFR 20.1201).

(b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

16. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of the sealed sources contained in the afterloading brachytherapy device(s).

B. Any maintenance or repair operations on the remote afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) E. involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

17. A. Access to the rooms housing the MicroSelectron afterloading brachytherapy device shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once each day of use.

MATERIALS LICENSE
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D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

17. The licensee may possess 24 Ci iridium-192 (not to exceed 12 Ci per source) for use in the Nucletron Corporation Micro Selection-HDR, provided the individual source activity does not exceed 10 Ci at the time of installation, and the source is installed by an authorized individual.

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Letters dated October 19, 1989, September 22, 1993, December 23, 1994, March 28, 1994, February 6, 1995, March 13, 1995 and April 18, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date May 11, 1995

By Cynthia D. Pederson
Materials/Licensing Section, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 2
FEE CATEGORY: 7C (2B)?
EXP. DATE: 19940430
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MCLAREN REGIONAL MEDICAL CENTER
RECEIVED DATE: 940401
DOCKET NO: 3002048
CONTROL NO.: 396744
LICENSE NO.: 21-04171-04
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: $1,400.00
CHECK NO.: 5794397

3. COMMENTS

SIGNED P. Ortloff
DATE 4-14-94

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /)

1. FEE CATEGORY AND AMOUNT: 7C (2B)? $1400.00

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL ✓
LICENSE

3. OTHER

SIGNED SC
DATE 4/19/94

RECEIVED
APR 19 1994
REGION III

McLAREN
REGIONAL
MEDICAL CENTER

Executive Offices

March 28, 1994

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

To Whom It May Concern:

Re: Renewal of License No. 21-04171-04

Enclosed is our renewal license application. The $1,400 amendment fee is enclosed. If you have any questions regarding this matter, please contact Tracy King, our consultant, at (313) 662-3197.

Thank you for your cooperation in this matter.

Sincerely,

Gregory L Beckman

Gregory L. Beckman
Executive Vice President

GLB/cd
Enclosure

License Fee Information on Application

401 South Ballenger Highway • Flint, Michigan 48532-3685 • (313) 762-2443 FAX (313) 762-2428

An Affiliated Teaching Hospital of the Michigan State University College of Human Medicine

NRC FORM 313
(6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 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. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, 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

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 21-04171-04

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

McLaren Regional Medical Center
401 Ballenger Highway
Flint, MI 48532

3 ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

401 Ballenger Highway
Flint, MI 48532

4 NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Maureen Snyder

TELEPHONE NUMBER
810-762-2209

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 which will be possessed at any one time.	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	LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 7C / AMOUNT ENCLOSED $1400

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

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 ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

RECEIVED

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
Renewal	APR 6 III	7C	$1400.00	534297	Lead Shield for Generators
APPROVED BY			DATE 4/11/94		

APR 07 1994
REGION III

CONTROL NO. 393744

NRC FORM 313 (6-93)

PRINTED ON RECYCLED PAPER

McLaren Regional Medical Center
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APPLICABILITY TABLE

Item	Topic	
8.1	Training Program	Enclosed
8.2	Other Training Program	N/A
9.1	Facility Diagram & Equipment List	Enclosed
9.2	Survey Instrument Calibration	Per 10CFR35.51
9.3	Dose Calibrator Calibration	Enclosed
9.4	Personnel Monitoring Program	Enclosed
9.5	Mobile Imaging Equipment QA	N/A
9.6	Other Equipment and Facilities	N/A
10.1	Radiation Safety Committee	Enclosed
10.2	ALARA Program	Enclosed
10.3	Leak Test	Per App.H, Reg. Guide 10.8
10.4	Safe Use of Radiopharmaceuticals	Enclosed
10.5	Spill Procedures	Enclosed
10.6	Ordering and Receiving	Enclosed
10.7	Opening Packages	Enclosed
10.8	Unit Dose Records	Enclosed
10.9	Multidose Vial Records	Enclosed
10.10	Mo-99 Concentration Records	Enclosed
10.11	Implant Source Use Records	Enclosed
10.12	Area Survey Procedures	Enclosed
10.13	Air Concentration Control	Enclosed
10.14	Radiopharmaceutical Therapy	Enclosed
10.15	Implant Therapy	Enclosed
10.16	Other Safety Procedures	N/A
11.1	Waste Disposal	Enclosed
11.2	Other Waste Disposal	N/A
12.1	Quality Management Program	Enclosed

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RADIOACTIVE MATERIAL AND USE

Item 5 *Byproduct Material*	*Item 6* *Amount*	*Purpose*
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200 excluding radioactive gases	As Needed	Imaging and localization studies
Material in 35.300	As Needed	Radiopharmaceutical therapies
Material in 35.400	As Needed	Brachytherapy
Iridium - 192	Two sources not to exceed 10 curies	High dose rate;Remote Afterloading.

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1 *Authorized Users*	*Materials*
P. B. Lauber, M.D.	35.100, 35.200, 35.300
S. Stocking, M.D.	35.100, 35.200, 35.300
Gary Rudder, M.D.	35.100, 35.200, 35.300
Jeanne K. Hicks, M.D.	35.100, 35.200, 35.300
Hesham M. El Gayar, M.D.	35.100, 35.200, 35.300, 35.400
Julie K. Bush, M.D.	35.100, 35.200, 35.300
Jamal Akbar, M.D.	35.100, 35.200, 35.300
Heramb Singh, M.D.	35.100, 35.200
Mark Weiss, M.D.	35.100, 35.200

Item 7.3
Radiation Safety Officer

Gary Rudder, M.D.

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PERSONNEL TRAINING PROGRAM

Item 8.1

Personnel

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction. Ancillary personnel may include housekeeping, security, nursing, maintenance, and ECG technologists.

Training Frequency

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Instruction Topics

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has been posted or made available, notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

Documentation will be kept on hand for review of the list of topics covered, the date of the instruction, and the names of those attending.

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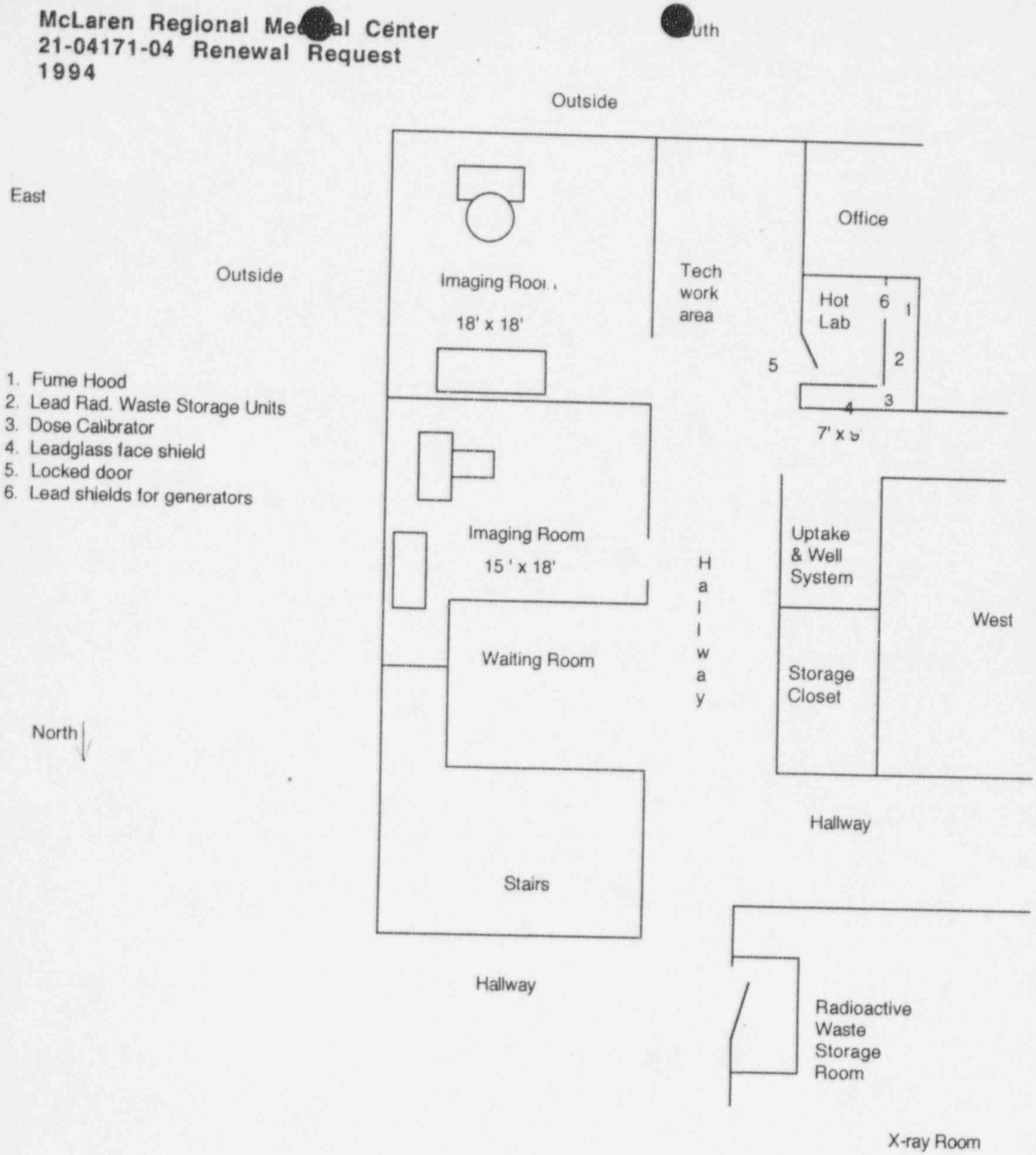
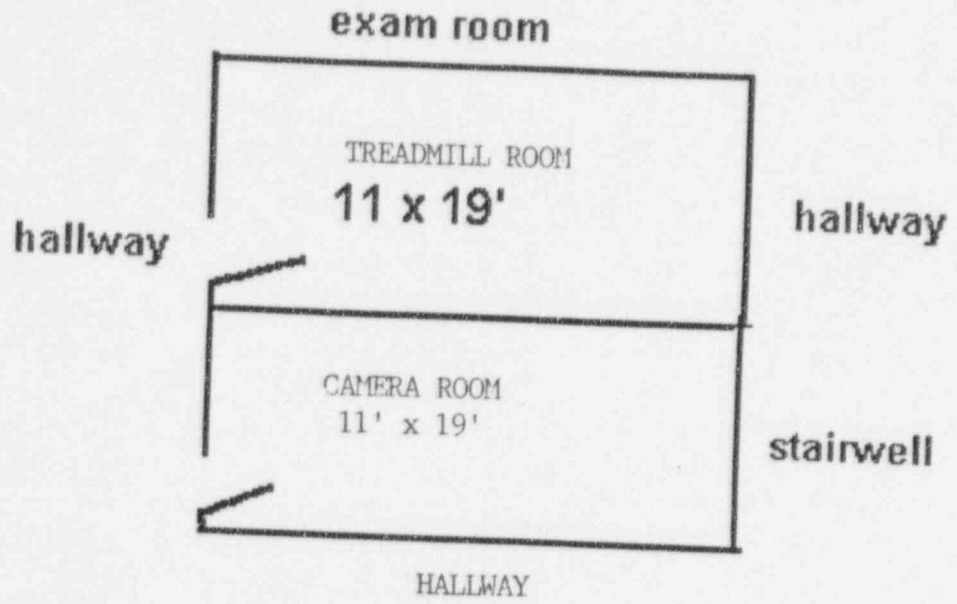
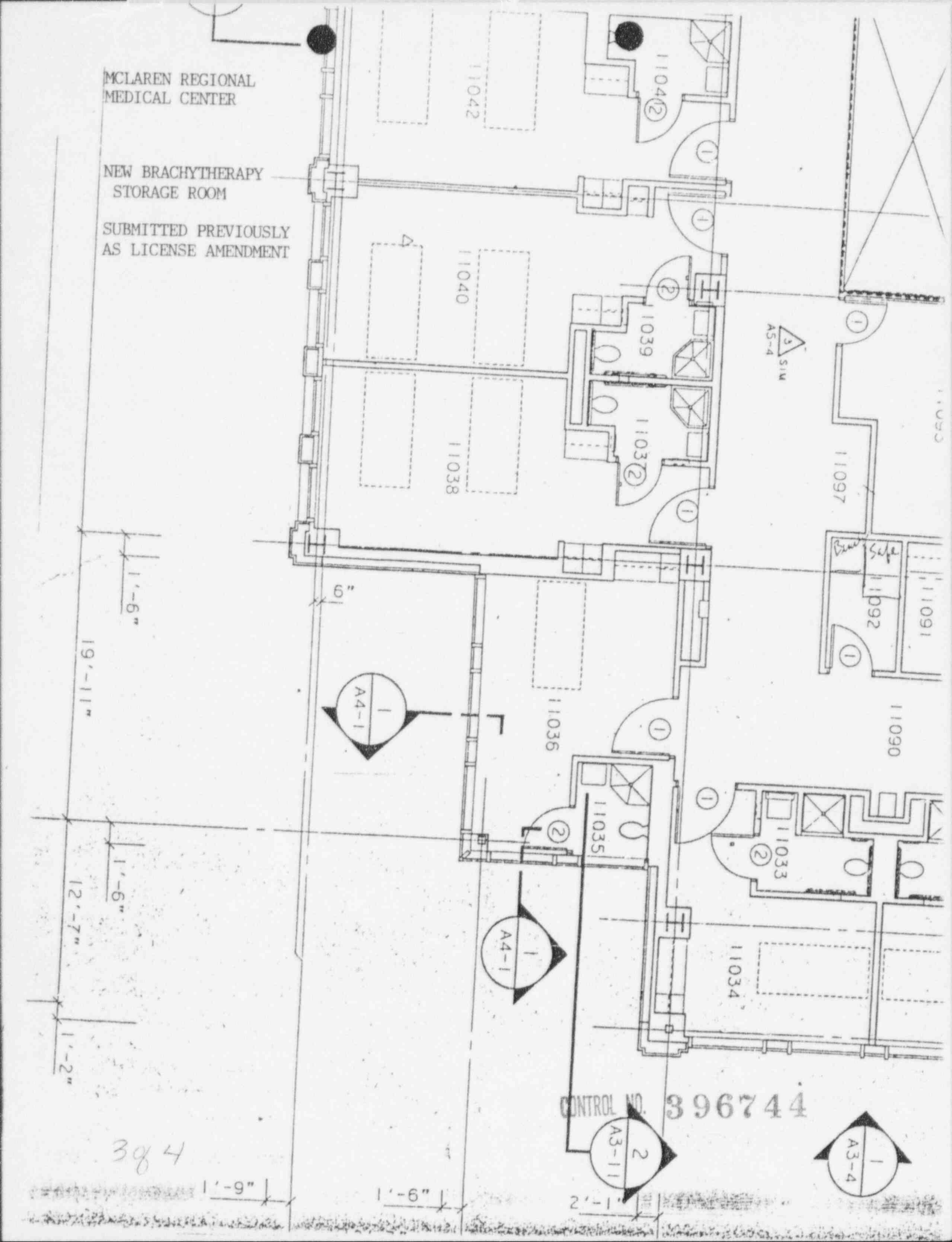


McLaren Regional Medical Center
License No. 21-04171-04

North



Cardiology Department



CONTROL NO. 396744

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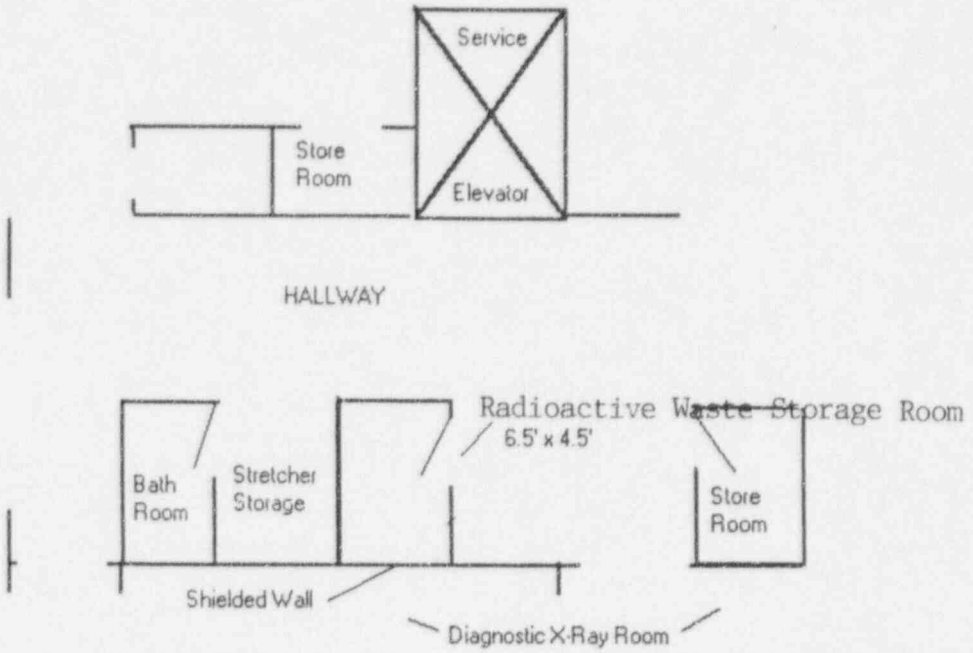

This room was previously the brachytherapy storage room. It is now being used for radiopharmaceutical waste storage.

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EQUIPMENT LIST

Item 9.1 *(cont.)*

Imaging Equipment
Scintillation Cameras

Dose Calibrator
Capintec

Counting Equipment
Uptake probe and well counter system

Other
Lead Glass Face Shield
Leaded Syringe Shields
Remote Handling Tools
Lead Bricks
RadiacWash
Gloves
Lead Storage Containers

Survey Meters

Victoreen G.M. Survey Meter
High Range (0-1000 mR/hr)
Low Range (0-1 mR/hr)

Bicron Ion Chamber
High Range (0-5000 mR/hr)
Low Range (0-5 mR/hr)

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CALIBRATION OF SURVEY INSTRUMENTS

Item 9.2

All survey Instruments will be calibrated and checked in accordance with 10 CFR 35.51. Survey instruments will be calibrated by :

1. The manufacturer:

2. Medical Physics Consultants: (NRC License # 21-20153-01)

3. Any authorized user licensed to perform survey meter calibrations as a service.

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CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Test	Frequency	Tolerance
Constancy	Daily prior to patient dose assays	+/- 10%
Linearity	Installation, following repair, and quarterly	+/- 10%
Accuracy	Installation, following repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium-99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity.

Decay method: Assay the source at approximately 0, 6, 24, 30, 48, etc hours over the entire range of use(between the highest activity administered to patients and 10 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients,calculate the expected readings and compare to the measured readings. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of activity

Sleeve method: The sleeves will be calibrated at the time of a decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

ACCURACY testing will be performed using Cesium-137 and Cobalt-57 or Barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of technetium-99m having an activity concentration of 1-10 mCi/ml. The dose calibrator will be tested for syringe geometry dependence. Vial geometry dependence will also be tested in vials of radiopharmaceuticals are assayed.

Syringe geometry dependence: assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for patient doses and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Vial geometry dependence: assay 1.0 cc of the solution in a vial of the type most commonly used. The solution in the vial will then be diluted with water and assayed at incremental volumes of 1-3 ml up to the maximum volume assayed in the vial. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

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PERSONNEL MONITORING PROGRAM

Item 9.4

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unexpectedly high or low.

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor.

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.

4. The exposure results of ancillary personnel who are badged may be reviewed at six month intervals. If the results show that they do not receive greater than 10% of the quarterly permissible limits, their badges may be discontinued. If their duties change and increased exposure to radiation is possible, they will be issued badges at that time.

6. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

7. Film and TLD badges for nuclear medicine technologists will be changed on a monthly basis. Badges supplied for personnel who do not normally receive 10% of the maximum permissible yearly dose may be changed on a quarterly basis. In all cases the manufacturer/supplier's recommendations will be followed with regard to length of use and frequency of processing.

8. All film and TLD badges will be processed by a NVLAP contract service.

RADIATION SAFETY COMMITTEE CHARTER
AND
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY

Item 10.1

RESPONSIBILITIES

The Radiation Safety Committee (RSC) shall:

1. Ensure that ionizing radiation will be used safely, to include the review as necessary of training programs, equipment, facility design, supplies and procedures.

2. Ensure that ionizing radiation is used in compliance with al state and federal regulations and all licenses and registrations granted for usage.

3. Ensure that the usage of ionizing radiation is consistent with the As Low As Reasonably Achievable (ALARA) philosophy and program.

4. Establish investigation levels for individual occupational radiation exposures, consistent with the ALARA philosophy and program.

5. Entrust to the Radiation Safety Officer (RSO), the day to day responsibility of management of the radiation safety program, reportable to the committee as noted below.

MEMBERSHIP REQUIREMENTS

The RSC membership must consist of:

1. The Radiation Safety Officer

2. An authorized user of each type of use of ionizing radiation.

3. A representative of Nursing Service.

4. A representative of management, who does not serve in one of the capacities noted above.

5. Other members as deemed appropriate.

DUTIES

The RSC shall:

1. Be familiar with all pertinent regulations, all license applications, all licenses their conditions and amendments.

2. Review the training and experience of the proposed authorized users, the RSO and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and all licenses issued to the facility.

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the facility.

4. Review recommendations on ways to maintain individual and collective doses ALARA.

5. Prescribe special conditions that will be required during a proposed method of use of ionizing radiation such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review on the basis of safety, and approve with the advice and consent of the RSO and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted within the regulations.

7. Review quarterly with the assistance of the RSO a summary of the occupational radiation dose records, consistent with the ALARA program.

8. Review quarterly with the assistance of the RSO, all incidents or unusual occurrences, such as misadministrations of ionizing radiation, spills, etc. which involved ionizing radiation.

9. Identify radiation safety problems, as well as initiate, recommend, provide and verify corrective actions.

10. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used are appropriately instructed as required in 10CFR19.12.

11. Review at least annually the radiation safety program to insure compliance with all regulations, conditions of licensure and the ALARA program to include records, reports from the RSO, inspection results and adequacy of the management control system.

12. Maintain written minutes of all RSC meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions and results of all ballots.

13. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

MEETING POLICIES

1. The RSC shall meet as often as necessary to conduct its' business, but not less than quarterly.

2. To conduct business, at least one-half of the membership must be present including the RSO and management's' representative.

RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, Misadministrations, and other deviations from the radiation safety practices approved by facility management and/or the Radiation Safety Committee, if applicable.

2. Establish, implement, and collect in a centralized location policies and procedures as follows:

    a. Authorization for the purchase of radioactive material.
    b. Receipt and opening of packages containing radioactive material.
    c. Storage of radioactive material.
    d. Inventory control of radioactive material.
    e. Safe use of radioactive material.
    f. Emergency procedures in the event of loss, theft, etc.
    g. Periodic radiation surveys
    h. Checks of radiation survey and other radiation safety instruments.
    i. Disposal of radioactive material.
    j. Personnel training of those who work in or frequent areas of radiation

3. Maintain a record systems to include at least the following:

   a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.

   b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

4. Review and sign the following radiation safety program records, if applicable:

   a. Sealed Source Inventories
   b. Sealed Source Leak Tests
   c. Dose Calibrator Linearity Tests
   d. Dose Calibrator Accuracy Tests
   e. Dose Calibrator Geometrical Variation Tests
   f. Misadministration documentation
   g. Changes in the radiation safety program
   h. Radiation surveys of sealed source storage.

5. Inform facility management at least annually of the status of the licensed material program.

6. Establish in concert with the Radiation Safety Committee (RSC), if applicable, personnel exposure investigational levels as a part of the ALARA program and philosophy.

7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management and the RSC, if applicable.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

Item 10.2

1. Management Commitment

   a. We, the management of this medical facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our facility. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the effons of the applicant to maintain exposures ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(1) The RSC will delegate authority to the RSO for the enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its actions in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigation levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigation levels are exceeded.

Table I: Investigation Levels

Body Part Exposed (mrems per calendar quarter)	Level I	Level II
1. Whole body; head and trunk; active blood forming organs; or gonads	125	375
2. Hands and forearms; feet and ankles	1250	3750
3. Skin of the whole body	1250	3750
4. Eye (lens)	375	1125

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Review of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for the ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to followed.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA in not being promoted on the job.

6. Establishment of Investigation levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigation levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSC and/or RSO. The investigation levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigation levels as stated in Table 1:

a. Personnel dose less than Investigation Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigation Level I.

b. Personnel dose equal to or greater than Investigation Level I but less than Investigation Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigation Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigation Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigation Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigation Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's NRC Form-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Re-establishment of investigation Levels to levels above those listed in Table 1.

In cases where a worker or group of workers' doses need to exceed an investigation level, a new, higher investigation level maybe established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented. he RSC will review the justification for and must approve or disapprove all revisions of investigation levels

7. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.

Gary L. Rudder M.D.

Signature

GARY L. RUDDER, M.D.

Name (Print or Type)

RADIATION SAFETY OFFICER

Title

CONTROL NO. 396744

McLaren Regional Medical Center
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PROCEDURE FOR LEAK-TESTING SEALED SOURCES

Item 10.3

Leak tests will be analyzed by Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or anyone licensed by the NRC to perform leak testing as a service.

McLAREN
REGIONAL
CANCER CENTER

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
Attn: Deborah A. Piskura
Health Physicist
799 Roosevelt Road
Glen Ellyn, Illinois 60137

October 18, 1993

Re: Amendments to NRC License No. 21-04171-04
Control Number: 95601

Dear Ms Piskura:

This letter is to be submitted for your review on the modifications of model procedures NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131, PHOSPHORUS-32, OR GOLD-198 and NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH TEMPORARY IMPLANT SOURCES. This letter is also to notify you that Room 11034 designation has been changed to Room 1110.

1. Exempt from taking radiation exposures in Rooms 1109 and 1103, since Room 1110 is lead-shielded.

2. Exempt from taking bedside radiation exposures for patients treated with Iodine-131.

   a) We do not use bedside radiation exposures to decide how long a nurse can stay with an iodine-131 patient. We believe thirty minutes each day per nurse in the room will give quality care to the patient as well as maintaining ALARA philosophy to the nurses. Past film badge radiation dosimetry reports of nurses have shown that the maximum radiation exposure to a nurse in one month in the previous year was ten millirems.

   b) When a person is trying to take a radiation exposure from an iodine-131 patient, quite often the patient is sitting on a chair and watching a television. It is an unnecessary disturbance to have the patient go to the bed and lie down in order to get the reading. It also gives unnecessary radiation exposure to the radiation surveyor.

   c) We continue to take radiation exposures at 3 feet away from the patient, at the safe line, by the door, and in the hallway.

4100 Beecher Road • Flint, MI 48532 • (313) 234-2273

Bedside radiation exposures are still to be taken for patients with temporary radioactive source implants.

If you have any questions or require any clarification of the above information, please contact me at (313)234-2273.

Sincerely,

Michael Kan

Michael Kan, M.S., DABR
Medical Physicist

Enclosure: Evaluation of the lead shielding on Room 1110

Conclusions:

Radiation exposures at all measuring points were less than 2 mR/hr. No voids or hot spots were detected through the floor, ceiling or the wall adjacent to room 1109.

Surveyed By:

Michael Kan, M.S., DABR M. K...
Medical Physicist

Date: October 18, 1993.

EVALUTATION OF THE LEAD SHIELDING ON ROOM 1110
McLAREN REGIONAL MEDICAL CENTER

Instruments: 1) Keithley Ion Chamber Survey Meter, Model 36105, S/N 43548; Calibrated on July 6, 1993. Resolution 0.1 mR/hr.

2) Ludlum GM Counter, Model 14C, S/N 92355; Ludlum Detector, Model 44-6, S/N PR 089510; Calibrated on May 27, 1993.

Method: A 32.0 mg Ra equivalent Cs-137 source was placed in the middle of the bed in room 1110, and radiation exposures at different points were then measured. Mobile lead shieldings were used in this survey. The radiation exposures were taken from the Keithley meter, and compared with those obtained from the GM meter. The GM meter was also used for surveying for voids and hot spots. The radiation exposures were then calculated for Cs-137 of activity 100 mg Ra equivalent, the maximum activity a brachytherapy patient may have.

Results:

Room 1110

Areas	Measuring Points	Points on Diagram	Exposures (mR/hr)
Rm 1109	1 ft. from wall	A	less than 0.3
Hall	1 ft. from wall	B	1.3
Door	1 ft. from door	C	less than 0.3
Rm 1103	1 ft. from wall	D	less than 0.3

Room 1010 (Below Room 1110)

Measuring Points	Exposures (mR/hr)
3 ft from floor	less than 0.3
7 ft from floor	0.32

Room 1210 (Above Room 1110)

Measuring Points	Exposures (mR/hr)
1 ft from floor	0.32
3 ft from floor	less than 0.3

3. Results and Calculations:

Location	Occupancy Factor	mR/week (100 min.)
North	1/4	0.3
East	1	0.3
Door	1	1.5
South	1/4	0.7
West	1/4	0.3
*Roof	---	---

* There is no plan of occupancy on the roof.

The results of the above calculations indicate that the anticipated weekly dose in any occupiable areas outside the room does not exceed 2 millirems.

If you have any questions or require clarification of any of the above stated information, please feel free to contact Michael Kan, M.S., DABR, Medical Physicist, at (810) 234-2273.

Enclosed, please find a check of $500 for the license amendment fee.

Sincerely,

Philip A. Incarnati
President and Chief Executive Officer
McLaren Regional Medical Center

Item 10.4

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored.

6. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for contamination.

11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

12. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

13. Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than ten percent, except prescriptions of less than 10 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

14. Always keep radioactive materials in shielded locations or containers.

15. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.

16. Do not pipette by mouth.

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Item 10.5

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons nearby that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

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PACKAGE ORDER AND RECEIPT PROCEDURES
Nuclear Medicine Department

Item 10.6

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

   (1) Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.

   (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials such as therapeutic dosages

   (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

   (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

Nuclear Medicine Department

For deliveries during normal working hours, packages are received at the Nuclear Medicine Department.

If off duty deliveries are necessary, the carrier has been asked to delivery the package to the Hot Lab immediately. They will then place the package within the Nuclear Medicine Hot Lab and re-lock the door.

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Item 10.7

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3. If there is reason to suspect contamination or leakage, measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.

4. Wipe the external surface of the package. Assay the wipe with a instrument sufficiently sensitive to detect 2000 dpm to determine if there is any removable activity. If removable contamination exceeds 2200 dpm/100 cm^2, notify the RSO. Packages containing only special form or gas radioactive material will not be tested for removable contamination.

5. Follow the steps listed below when opening the package.

   a) Remove the packing slip.
   b) Open the outer package following the supplier's instructions, if available.
   c) Open the inner package and verify that the contents agree with the packing slip.
   d) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
   e) If anything unusual is noticed, stop and notify the RSO.

6. Verify that the material received is the material ordered.

7. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

8. Record the receipt and all readings taken.

9. For packages received under a general license in 31.11, follow the steps listed below for each package.

   a) Visually inspect the package for damage. If damage is noted, stop and notify the RSO.
   b) Verify that material received is the material ordered.

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BYPRODUCT MATERIAL USE

Item 10.8 **Unit Dose Records shall contain:**

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of receipt
   d. Activity as recorded on the packing slip
   e. Supplier
   f. Lot or control number

2. Administrative Data
   a. Time and date of administration
   b. Measured activity
   c. Patient name and ID number
   d. Method and date of disposal
   e. Initials of person recording the information

Item 10.9 **Multidose Vial Records shall contain:**

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of preparation
   d. Date, time, and activity of initial assay
   e. Supplier of kit manufacturer

2. Administrative Data
   a. Date and time dosage was drawn
   b. Precribed dosage
   c. Calculated inverse concentration (cc/mCi) at drawing time
   d. Calculated volume needed for prescribed dose
   e. Measured activity, time and date of administration
   f. Patient name and ID number
   g. Method of disposal and date
   h. Initials of person recording information

Item 10.10 **Molybdenum Concentration Records shall contain:**

a. Date the generator was received
b. Date and time of elution
c. Measured Mo-99 activity in microcuries
d. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
e. Measured Tc-99m activity in millicuries
f. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and documentation that the ratio is less than or equal to 0.15 uCi Mo-99 per mCi of Tc-99m
g. Initials of the person who made the record

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KEEPING AN INVENTORY OF IMPLANT SOURCES

Item 10.11

We will adopt Appendix M.4 Keeping an Inventory of Implant Sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

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AREA SURVEY PROCEDURES

Item 10.12

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed at the end of each day of use for ambient radiation exposure rates and weekly for removable contamination. Special care will be taken to remove all paraphernalia from rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.

2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removablecontamination.

3. Laboratory areas where each process involves less than 200 uCi of byproduct materials will be surveyed monthly for ambient radiation exposure rates and removable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h. The results will be recorded in millirem per hour.

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive tc detect 2000 dpm. The results will be recorded as net dpm per 100 square centimeters.

6. The trigger level for exposure rate surveys will be established based upon typical readings for specific areas and will be in accordance with 10CFR20.

7. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8. For example, the action level for Tc-99m contamination will be 2000 dpm or lower.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to the trigger levels or lower on repeat surveys.

9. A record shall be kept of all survey results. The record will include:

   a. Location, date, and type of equipment used.
   b. Initials of the person conducting the survey.
   c. Drawing of the area surveyed.
   d. Trigger levels keyed to the location on the drawing.
   e. Results keyed to the location on the drawing.
   f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

10. The RSO or their designee will review the survey results on a quarterly basis for conformance to established trigger levels.

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

    A= Calculated source activity of sample isotope in dpm

    B= Measured source counts of sample isotope in cpm

    C= Measured background counts in cpm

    D= B-C (Net Counts in cpm)

    $$\text{Efficiency Factor} = \frac{\text{Calculated activity in dpm (A)}}{\text{Net counts in cpm (D)}}$$

    Wipe sample in dpm = Net counts of wipe sample x Efficiency factor

12. The RSO will be notified of all positive wipe test and ambient survey results.

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AIR CONCENTRATION CONTROL

Item 10.13.1

We will not use radioactive gases at this facility.

WORKER DOSE FROM AEROSOLS

Item 10.13.2

We will collect spent aerosol in a single-use shielded trap device.

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Item 10.13.3

"We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary."

McLaren Regional Medical Center
21-04171-04 Renewal Request
1994

RADIATION SAFETY PROCEDURES FOR IODINE THERAPIES OVER 30 MILLICURIES

Item 10.14

We will adopt Appendix P Model Procedure for Radiation Safety During Iodine Therapy over 30 milliCuries that was published in Appendix Q to Regulatory Guide 10.8, Revision 2 with the exception that due to personnel scheduling, the bioassays of individuals preparing or administering the therapy I-131 dosage will preferably be performed at 24 hours but may be performed at any time between 6 hours and 72 hours post exposure.

McLaren Regional Medical Center
21-04171-04 Renewal Request
1994

RADIATION SAFETY PROCEDURES FOR TEMPORARY IMPLANT THERAPIES

Item 10.15

We will adopt Appendix Q Model Procedure for Radiation Safety During ImplantTherapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2.

Item 11.1

WASTE DISPOSAL

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20.303. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits numerated in Table II of Appendix B of 10 CFR 20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay in Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Each container will be tagged to include:
   a. the date sealed or set into storage
   b. the longest-lived isotope in the container
   c. the initials of the person setting the waste for decay.

3. Material will be decayed for at least 10 half-lives.

4. Prior to disposal as in-house waste, each container will be monitored as follows:

   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from background radiation levels will be disposed of after all radioactive labels have been defaced.
   f. The date on which the container was placed in storage will be recorded.
   g. The date of disposal will be recorded.
   h. The type of material will be recorded.

5. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/hr) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal. Manufacturer's instructions will be followed.

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.

McLAREN
REGIONAL
CANCER CENTER

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
799 Roosevelt Road
Glen Ellyn, Illinois 60137

FOR AMENDMENT #40

August 9, 1993

Re: Amendments to NRC License No. 21-04171-04

Dear Sirs:

We hereby request the following amendments to our NRC license:

I. Relocations of Brachytherapy Source Room to Room 11092 on the 11th floor of the New Tower and the patients to be treated with therapeutic quantities of radionuclides or sealed sources of radionuclides to Room 11034 on the 11th floor of the New Tower (Diagram 1).

II. Authorization for the use of Ir-192 Remote Brachytherapy Afterloader.

The following is the supportive information for amendment I.

1. A "CAUTION, RADIOACTIVE MATERIAL" sign, size 10" x 8", is to be posted on the door of Room 11092. The room is locked when not in use.

2. Shielded Storage Safe - A four-drawer safe is made of steel, with 4 inches of lead; the safe is fire-proof and has a door key lock. The safe is locked when not in use.

3. L-Block Lead Shield - A solid lead shield of 2 inches thick, with a tilted lead-glass window of 2 inches thick and a density of 6.2 gm. per cubic cm. to view the work area.

4. Additional 2 inches thick lead blocks are placed on the other two sides of the work area.

5. A source carrier shielded with 1 inch of lead will be used for transportation of radioactive sources to Room 11034 across the hallway.

6. Room 11034 is lead-shielded.

7. A radiation protection survey of the previous Brachytherapy Source Room will be performed before other use.

CONTROL NO. 396744

The following is the supportive information for amendment II:

I. Description of the Source and Device

A. Source description:

1. Radionuclide: Ir-192
2. Manufacturer name and model number:
   BYK Mallinckrodt: Model CI L BV
3. Maximum activity: 10 Curies per source
4. Number of sources: 2 sources, one in the device and one in the shipping container prior to or after source replacement.

B. Device description:

1. Manufacturer: Nucletron
2. Model: MicroSelectron-HDR (080.000)

II. Intended Use

The device is to be used for interstitial, intracavitary and intraluminal treatment of cancer.

III. Proposed User

The device will be used by, or under the supervision of Hesham M. El Gayar, M.D.

IV. Training For Individuals

A. An outline of training given to device operators is attached.

B. Source exchanges are conducted by Nucletron Corporation engineers.

C. The initial instruction for A is provided by Nucletron Corporation engineers. Subsequent training will be performed by the authorized users or by those previously trained.

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

E. Retraining will be performed annually and will follow the outline specified in IV-A above. This training includes "dry-runs" of emergency procedures.

V. Facilities

A. The HDR Unit will be located at McLaren Regional Cancer Center, Room 144, 4100 Beecher Road, Flint, MI. 48532. The room is currently housing a 6 MV Linear Accelerator. HDR treatments will be given to patients on the Linear Accelerator Couch. Facilities diagrams of the treatment room are attached (Diagrams 2 & 3). The room is on the first floor, with nothing below and with only the roof above.

Location	Thickness (inches of concrete)	Distance Source (feet)
North (A)	72	16
North-West (B)	44	18
West (C)	44	14
South-West (D)	44	18
South (E)	84	17
South-East (F) Equipment Room	36	14
Door (G)	22 (Maze) 1/8 (Pb)	19
East HDR Control Console (H)	36	20
North-East Mechanical Room (I)	44	18
Roof (J)	36	11

All walls and roof are poured concrete of density 147 lbs/cu. ft. The door is sandwiched with lead of density 709 lbs/cu. ft. North and West outside walls are adjacent to parking areas. South wall is adjacent to an 18 MV Linear Accelerator. For simplicity, an occupancy factor of 1 is taken for all areas in the dose calculations.

B. Continuous Viewing System:

A CCTV with monitor at operator's console is used. In the event of CCTV failure, treatments will be halted until the CCTV system is functional.

C. Area Security

1. A door interlock is provided at the entrance to the treatment room.

2. The treatment area will be posted with a "CAUTION - RADIATION AREA" sign on the door. A warning light at the door will produce a visible flashing light during treatment.

3. Operating keys to both units will be placed on the same key ring, preventing simultaneous operation. Administrative controls over key access will be strictly enforced.

4. A permanently installed, independent radiation monitor will be in use at all times. The monitor will produced a flashing light during treatment and will be visible upon entrance to the room.

5. When the door interlock is tripped, a reset operation must be initiated before the treatment can be started or continued.

6. Only the patient will be in the treatment room during the use of the microSelectron-HDR. Attempted entry into the room during treatment time will cause the source to be withdrawn from the patient, to the microSelectron-HDR safe.

7. The microSelectron-HDR will be stored in the treatment room and locked when not in use.

D. Shielding Calculations

1. Assumptions:

a) Specific Gamma-Ray Constant = 0.5 R/hr. per Ci at 1 meter
b) Activity = 10 Ci
c) Maximum on times:
   5 min. per patient
   3 patients per hour or 15 min/hr.
   20 patients per week or 100 min/week
d) No exposure reduction by patient
e) HVL = 4.3 cm. concrete or 0.6 cm. lead
   TVL = 14.7 cm. concrete or 2.0 cm. lead
f) Leakage = 0.25 mR/hr.

2. Dose rate from a 10 Ci Ir-192 source = 5 R/hr. at 1 meter while source is out.

Location	Distance Meters	Unshielded Exposure Rate (R/hr.)	Wall Thickness (cm.)	# of TVL's	Shielded Exposure Rate(mR/hr)
A	4.8	0.217	182	12.4	8.6×10^{-11}
B	5.4	0.171	111	7.6	4.3×10^{-6}
C	4.2	0.283	111	7.6	7.1×10^{-6}
D	5.4	0.171	111	7.6	4.3×10^{-6}
E	5.1	0.192	213	14.5	6.1×10^{-13}
F	4.2	0.283	91	6.2	1.8×10^{-4}
G (door)	5.7	0.154	61	4.1	8.5×10^{-3} *
H	6.0	0.139	91	6.2	8.8×10^{-5}
I	5.4	0.171	111	7.6	4.3×10^{-6}
J (roof)	3.3	0.459	91	6.2	2.9×10^{-4}

* Attenuation by 1/8 inch lead on the door is included

3. Maximum Net Doses while Source is out

Location	Weekly Dose (100 min) in mR
A	1.4×10^{-10}
B	7.2×10^{-6}
C	1.2×10^{-5}
D	7.2×10^{-6}
E	1.0×10^{-12}
F	3.0×10^{-4}
G (door)	1.4×10^{-2}
H	1.5×10^{-4}
I	7.2×10^{-6}
J (roof)	4.8×10^{-4}

VI. Operating Procedures

A. The following are included in our operating procedures

1. Have implemented written operating procedures
2. copies given to appropriate staff
3. Procedures: secure unit and console when unattended
4. Procedures: only patient in room with device activated
5. Daily checks to include:
   - ✓. interlocks
   - ✓. reproducibility of source positioning to within +/-1 mm.
   - ✓. verification of source position indicators
   - ✓. inspection of guide tubes for kinks and other imperfections
6. Confirm that treatment time calculations will be independently verified.

B. Calibration of Device:

1. The device will be calibrated at a time of each source replacement, or semi-annually, whichever is shorter.

   a) Dose accuracy will be determined to within +/-5%. a HDR 1000 well ionization chamber, or equivalent, and a Keithley Model 602 electrometer, or equivalent, will be used.

   b) Travel time error will be evaluated by comparing the total dose received from several short exposures as compared to the dose received from one long exposure.

   c) Timer accuracy will be evaluated with a stop watch.

2. Individuals performing the above calibration will meet the qualification criteria as specified in 10 CFR 35. 961.

C. The device will not be used in any room other than the enclosed specified treatment room.

D. The source will be leak-tested on a semi-annual basis. As it is anticipated that the source will be replaced quarterly, leak testing in-house is not likely to be required.

VII. Emergency Procedures

Enclosed is a copy of the emergency procedures for the unit. These procedures will be posted near the unit. Names and phone numbers will be noted on the posted copy.

VIII. Waste Disposal

Depleted sources will be returned to the manufacturer.

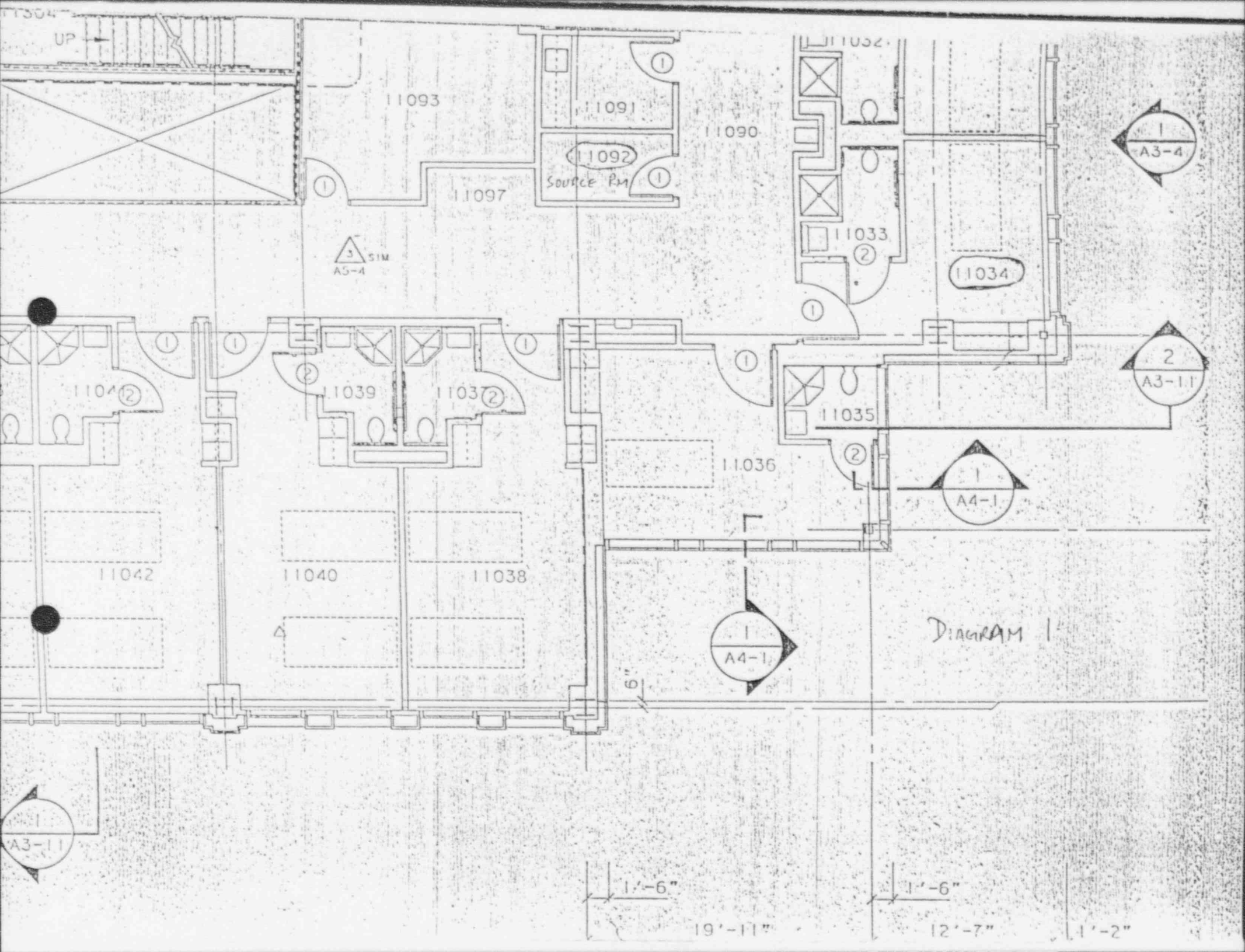
If you have any questions or require clarification of any of the above stated information, please feel free to contact Michael Kan, M.S., DABR, Medical Physicist, at (313) 234-2273.

Enclosed, please find the check for the amount of $460.00 for the license amendment fee.

Sincerely,

Philip A. Incarnati
President and Chief Executive Officer
McLaren Regional Medical Center

MK/nal


UP
11093
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3 SIM A5-4
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2 A3-1.1
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1 A4-1
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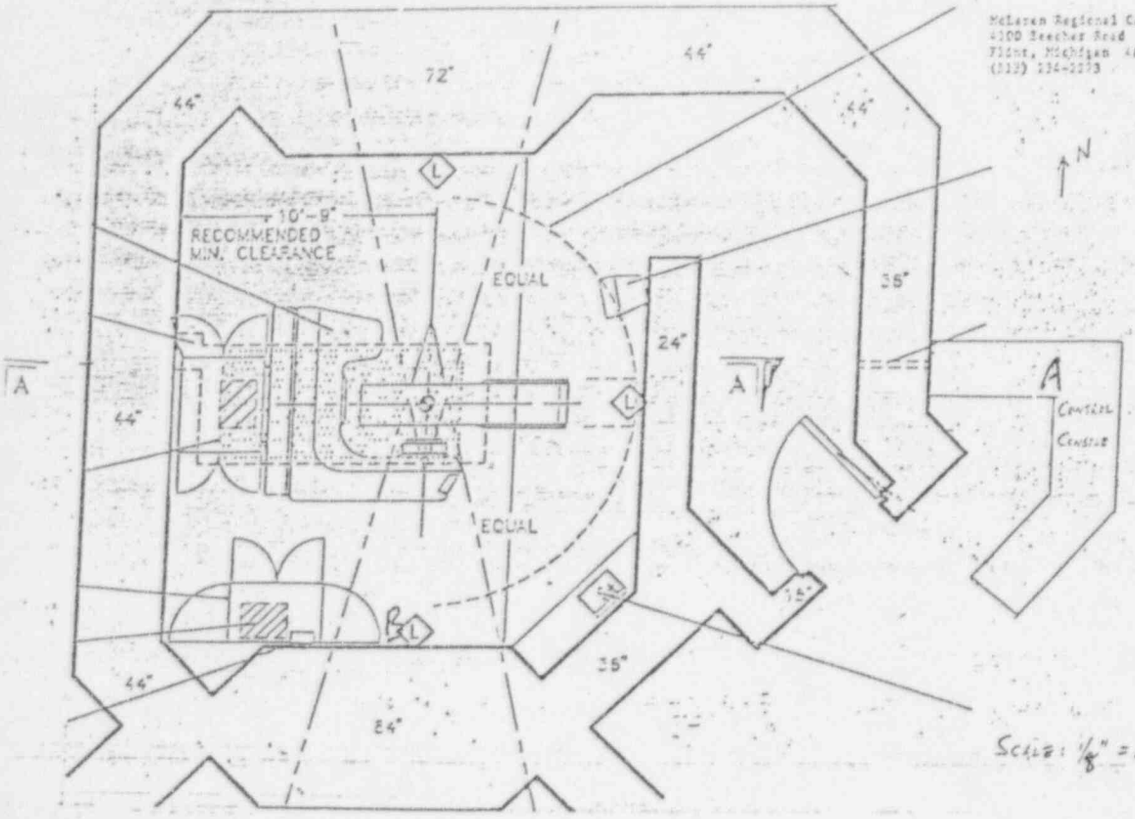
1'-6"
19'-11"
12'-7"
1'-2"
DIAGRAM 1



McLaren Regional Cancer Center
4100 Beecher Road
Flint, Michigan 48532
(313) 234-2273

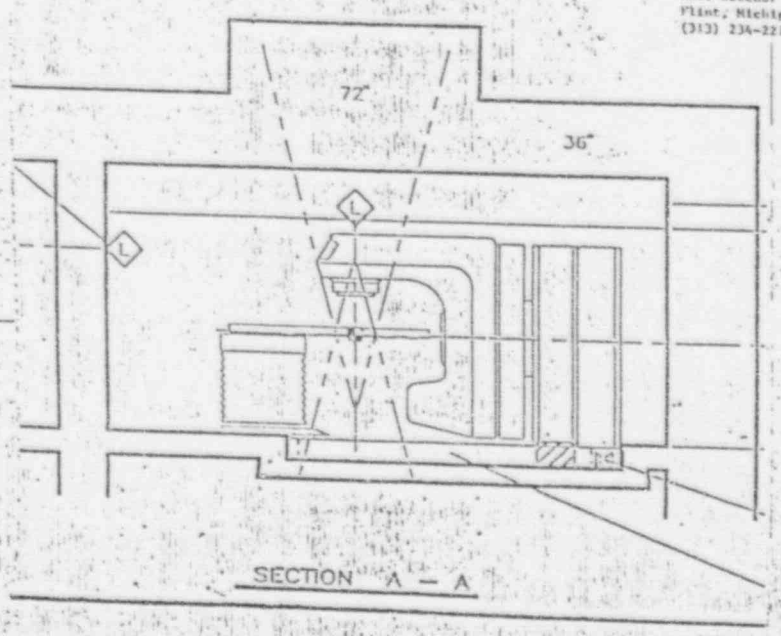
SCALE: 1/8" = 1'-0"

A = HDR CONTROL

B = HDR STORAGE

DIAGRM 2

McLaren Regional Cancer Center
4100 Beecher Road
Flint, Michigan 48532
(313) 234-2273



SECTION A — A

DIAGRAM 3

Scale: 1/8" = 1'-0"

EMERGENCY PROCEDURES

FOR microSELECTRON - HDR, Ir 192

IF THE SOURCE FAILS TO RETURN TO THE SAFE

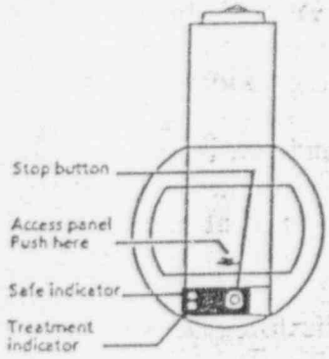
---

1. Depress RED EMERGENCY STOP BUTTON on master emergency stop switch. If the source retracts, go to step 7, otherwise step 2.

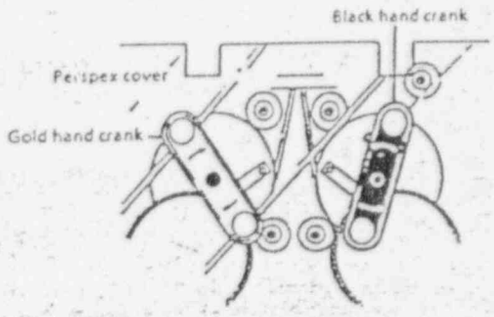
2. Enter the treatment room.

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

   - If the source retracts, go to step 7, otherwise step 3.



Access panel location



Gold hand crank location

3. Disconnect the applicator from the machine. Move the machine well away from the patient.

4. Check the patient for radiation. If detected, remove the applicator from the patient, ensuring that radiation is confined to the applicator.

5. IMMEDIATELY assist the patient from the room. A suitably qualified person must now ensure that the applicator is shielded.

6. Leave the room. Close the door. Mark it NO ENTRY.

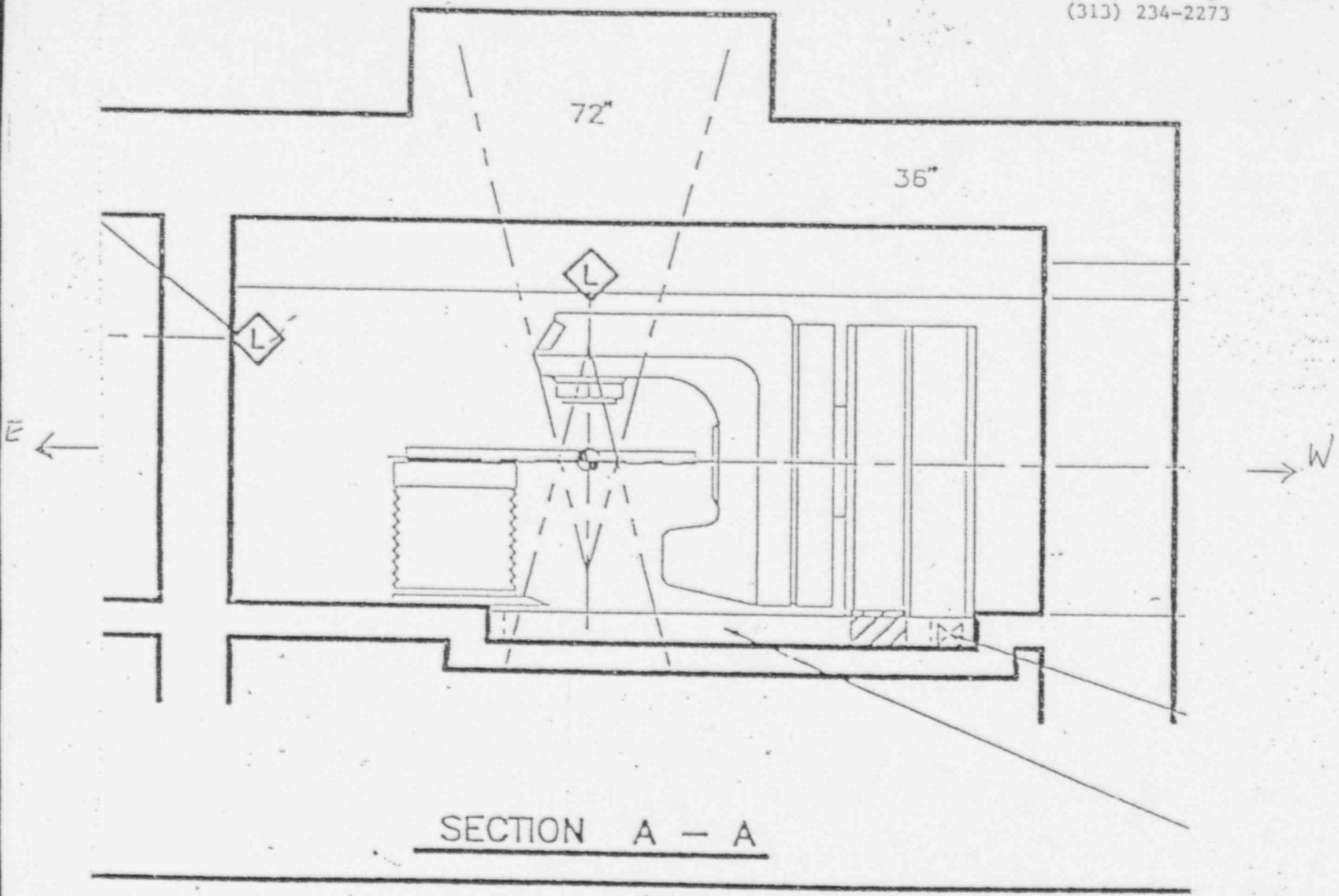
7. Retain the treatment data printout and contact the following:

   Physicist: ..... Tel. .....
   Doctor: ..... Tel. .....
   Nucletron representative: ..... Tel. .....

   The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

CONTROL NO. 396744

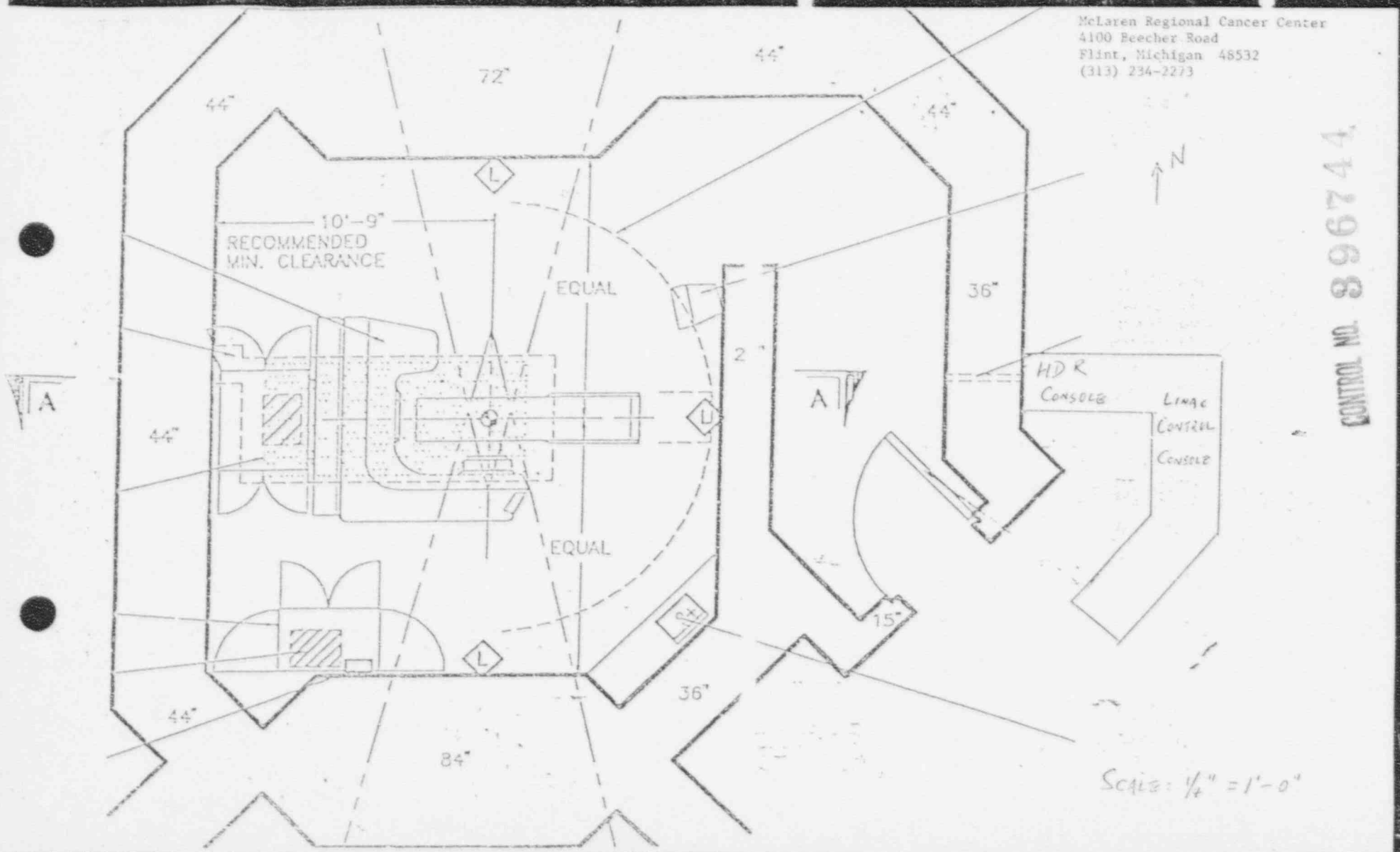
McLaren Regional Cancer Center
4100 Beecher Road
Flint, Michigan 48532
(313) 234-2273



SECTION A – A

SCALE: 1/4" = 1'-0"

McLaren Regional Cancer Center
4100 Beecher Road
Flint, Michigan 48532
(313) 234-2273



U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
799 Roosevelt Road
Glen Ellyn, Illinois 60137

January 7, 1994

Re: Amendments to NRC License No. 21-04171-04

Dear Ms Piskura:

We hereby request to relocate the use of Ir-192 HDR Remote Brachytherapy Afterloader to Room 200, HDR Treatment Suite, from Room 144, 6 MV Linear Accelerator. The address remains at 4100 Beecher Road, Flint, Michigan 48532.

The following are the supportive information for this amendment:

A. Facilities

The HDR suite is on the first floor, with nothing below and with only the roof above. Diagrams one and two of the HDR Treatment Suite are attached. Room shieldings and distances from the Ir-192 source are summarized as follows:

Location	Thickness (inches of concrete)	Distance from Source (feet)
North	18	8
East	20	10.5
Door	12 (Maze) 1/4 Lead (Door)	16.5
South	12	17
West	18	8
Roof	10	12

All walls and roof are poured concrete of density 147 lbs/cu.ft.. The door is sandwiched with lead of density 709 lbs/cu. ft.. North, West and South outside walls are adjacent to parking areas. East wall is a HDR control room which is also used as an examination room when the HDR unit is not in use. An occupancy factor of 1/4 is taken for all the Outside Walls; and 1 for East Wall and the door.

B. Continuous Viewing System

A CCTV with monitor at operator's console is used. In the event of CCTV failure, treatments will be halted until the CCTV system is functional.

C. Area Security

1. A door interlock is provided at the entrance to the treatment room. In the event of a malfunction of the interlock system, the afterloading device will be locked in the "off" position and not used, except as necessary for repair or maintenance of the interlock system, until the interlock system is shown to be functioning properly.

2. The treatment area will be posted with a "CAUTION - RADIATION AREA" sign on the door. A warning light at the door will produce a visible flashing light during treatment.

3. A permanently installed, independent radiation monitor will be in use at all times. The monitor will produce a flashing light during treatment and will be visible upon entrance to the room.

   The radiation monitor will be equipped with a backup battery pack power supply separate from the power supply to the afterloading unit.

   The radiation monitor will be checked with a dedicated check source for proper operation each day before the HDR device is used. A record of the radiation monitor check described above will be maintained for a period of three years.

   If the radiation monitor is found inoperable, any individual entering the treatment room will use a survey meter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey meter will be checked with a dedicated check source for proper operation at the beginning of each day of use and records maintained of these checks.

   A radiation monitor that is found to be either inoperable or evidence of intermittent problems will be repaired or replaced promptly.

4. When the door interlock is tripped, a reset operation must be initiated before the treatment can be started or continued.

5. Only the patient will be in the treatment room during the use of the microSelectron-HDR. Attempted entry into the room during treatment time will cause the source to be withdrawn from the patient, to the microSelectron-HDR safe.

4. The Microselectron-HDR will be stored in the treatment room and locked when not in use.

D. Shielding Calculations

1. Assumptions:

a) Specific Gamma-Ray Constant of Ir-192 = 0.5 R/hr. per Ci at 1 meter.
b) Activity = 10 Ci.
c) Maximum on times:
   5 min. per patient
   3 patients per hour or 15 min/hr
   20 patients per week or 100 min/week.
d) No exposure reduction by patient.
e) HVL = 0.6 cm lead, and TVL = 2.0 cm lead, or 14.7 cm concrete.
f) Leakage = 0.25 mR/hr at 1 meter from the HDR unit.

2. Dose rate from a 10 Ci Ir-192 source = 5 R/hr. at 1 meter while source is out.

Location	Distance Meters	Unshielded Exposure Rate (mR/hr.)	Wall Thickness (in.)	# of TVL's	Shielded Exposure Rate(mR/hr)
North	2.43	847	45.7	3.10	0.7
East	3.20	488	50.8	3.45	0.2
Door	5.02	199	30.4(maze) 1/4 inch Pb (door)	2.38*	0.9
South	5.18	187	30.4	2.06	1.7
West	2.43	847	45.7	3.10	0.7
Roof	3.65	375	25.4	1.72	7.2

* TVL includes lead-lined door

3. Results and Calculations:

Location	Occupancy Factor	mR/week (100 min.)
North	1/4	0.3
East	1	0.3
Door	1	0.9
South	1/4	0.7
West	1/4	0.3
*Roof	---	---

* There is no plan of occupancy on the roof.

The results of the above calculations indicate that the anticipated weekly dose in any occupiable areas outside the room does not exceed 2 millirems.

If you have any questions or require clarification of any of the above stated information, please feel free to contact Michael Kan, M.S., DABR, Medical Physicist, at (810) 234-2273.

Enclosed, please find a check of $500 for the license amendment fee.

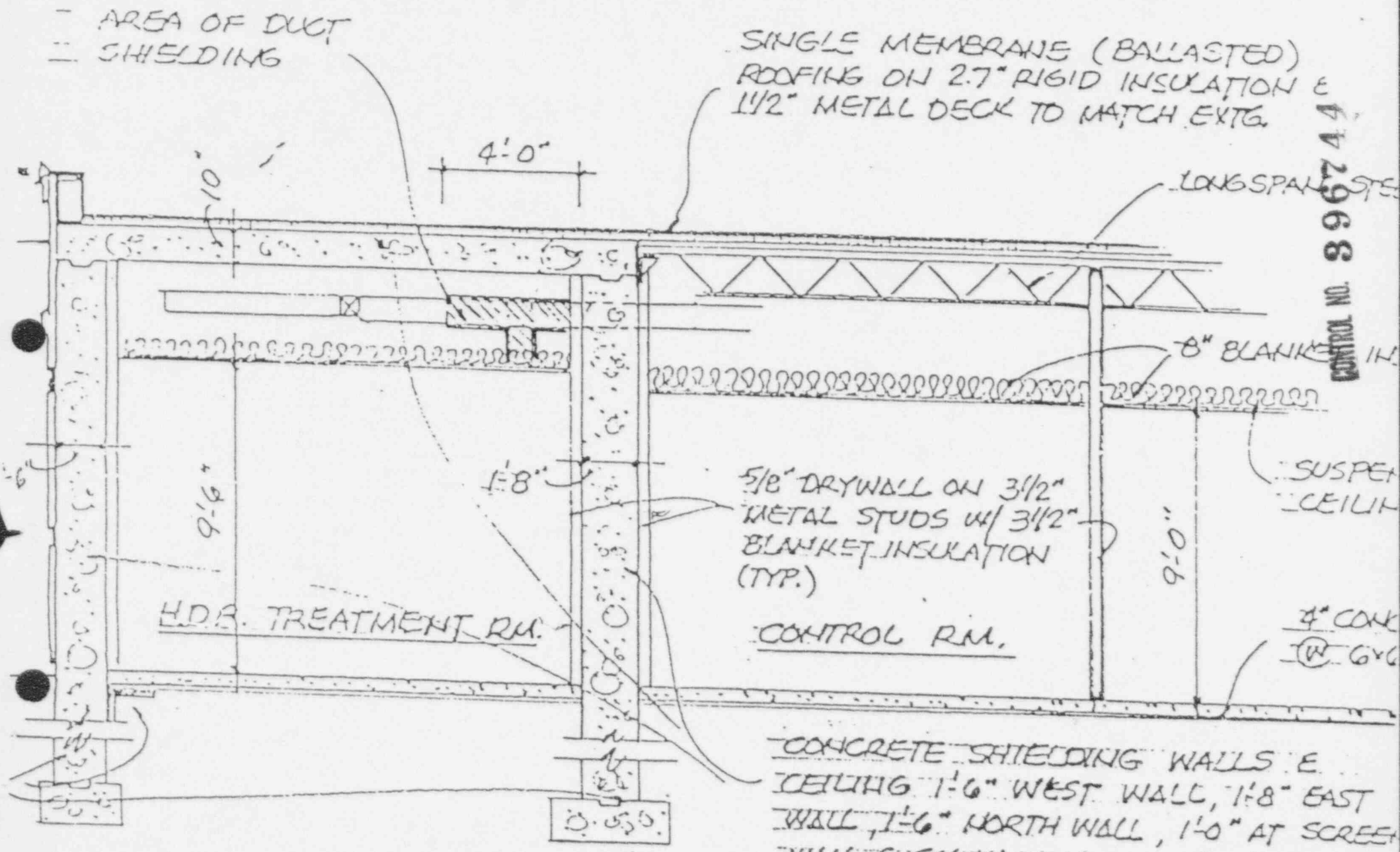
Sincerely,

Philip A. Incarnati
President and Chief Executive Officer
MeLaren Regional Medical Center

REVISED PARTIAL
HDR POOM PLAN

SCALE 1/4" = 1'-0"

DIAGRAM 1



CONTROL NO. 39674

SECTION "A" – "A"

SCALE : 1/4" = 1'-0"

DIAGRAM 2

MAY 1 1 1995

McLaren Regional
Medical Center
Department of Radiology
ATTN: Philip A. Incarnati
President/CEO
401 South Ballenger Highway
Flint, MI 48532

Dear Mr. Incarnati:

Enclosed is Amendment No. 44 renewing your NRC Material License No. 21-04171-04 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 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).

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; or

397377

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 a visiting authorized user described in 10 CFR 35.27, 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, 10 CFR Part 2, Appendix C. 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 Section

License No. 21-04171-04
Docket No. 030-02048

Enclosure: Amendment No. 44

DOCUMENT NAME: M:\03002048.CL5
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	DRSS/RIII							
NAME	GWatson:brt							
DATE	04/09/95							

05

OFFICIAL RECORD COPY

McLAREN
REGIONAL
MEDICAL CENTER

April 18, 1995

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Medical Licensing
801 Warrenville Road
Lisle, Illinois, 60532

To Whom It May Concern:

Re: License No. 21-04171-04
Control No. 96744

The purpose of this letter is to provide you with notification to adjust regulation of 10 CFR Group 35.300 from as needed to a limit of 1 Curie.

This was requested by Inspector Gidget Watson for the renewal of our License. Therefore, no amendment fee is required.

Thank you for your cooperation.

Sincerely,

Maureen Snyder, NMT

Maureen Snyder, NMT
Supervisor, Nuclear Medicine

401 South Ballenger Highway • Flint, Michigan 48532-3685 • (810) 762-2000

McLAREN
REGIONAL
CANCER CENTER

DATE: 4/18/95 TIME: 10:45

TO: Gidget Watson

FAX: 1-708-515-1259

FROM: Dr J Nettleton

FAX: (313) 235-4902

TOTAL NUMBER OF PAGES: 3 (INCLUDES COVER SHEET)

SUBJECT:

1100 Beecher Road • Flint, MI 48532 • (313) 234-2273

McLAREN
REGIONAL
CANCER CENTER

Hesham E. Gayar, M.D.
Director of Radiation Oncology

Jack L. Nettleton, M.D.
Radiation Oncology

Jack L. Nettleton, M.D.

University of Minnesota NRC license number is: 22-00218-29.

JOHN ENGLER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMERCE

H 224570

BOARD OF MEDICINE

PHYSICIAN
LICENSE

JACK LEE NETTLETON MD
U OF MINNESOTA HOSP & CLI
DEPT OF THERAP RADIOLOGY
HARVARD ST AT EAST RIVER
MINNEAPOLIS MN 55455

PERMANENT I.D. NO.	EXPIRATION DATE	
4301047760	01/31/97	2623533

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN.

McLAREN
REGIONAL
MEDICAL CENTER

PHILIP A. INCARNATI
PRESIDENT and
CHIEF EXECUTIVE OFFICER

U.S. Nuclear Regulatory Commission
Region III
Material Licensing Branch
ATTN: Ms Gidget Watson
801 Warrenville Road
Lisle, Illinois 60532-4351

March 13, 1995

License Number: 21-04171-04
Control Number: 96744

Dear Ms Watson:

This is to respond to your letter dated February 16, 1995, requesting additional information for the NRC Material License No. 21-04171-04 renewal.

1. Authorized User

The training and experience of Dr. Jack L. Nettleton are attached as Exhibits A, B, C and D. Please authorize Dr. Nettleton for material in (10 CFR 35.400) and Ir-192 for remote afterloading. I-131 (10CFR 35.300) is to be excluded from the authorized user.

ok
2. Training Program to authorized physician users and device operators

a. A minimum of 8 hours of didactic training and "hands on" training are to be given. This training includes:

(1) radiation protection and instrumentation, including the proper use of personnel dosimeters, survey instruments, and radiation monitors;

(2) operating and emergency procedures;

(3) the design, use and function of the device, including the safety systems; and

(4) "hands on" training, under the direct supervision of experienced device users, which includes "dry runs" using dummy sources for routine patient [illegible] treatment, as well as the implementation of emergency procedures.

b. Authorized user and ancillary staff training will be given initially and at intervals not to exceed 12 months. The authorized user retraining will include "hands on" training, which includes emergency procedures "dry runs" using dummy sources. An outline of the retraining program is attached as Exhibits E, F, G, H, I, and J.

c. Each trainee's competency to use the device will be determined by observation and questioning from an experienced device user.

d. Records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. These records include the instructor(s) name, the attenders names, the training date(s), and an outline of the topics discussed.

3. Facilities

a. Area security procedures are attached as Exhibit E.

The console keys will be stored in the treatment room closet and locked when not in use.

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

(1) the radiation monitor will be promptly repaired or replaced if found to be either inoperable or evidencing intermittent problems; and

(2) if the radiation monitor is found inoperable, any individual entering the treatment room will use a survey meter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey meter will be checked with a dedicated check source for proper operation at the beginning of each day of use and records maintained of these checks.

4. Compliance With Restricted/Unrestricted Area Radiation Level Limits

a. A radiation protection survey will be performed, following source replacement. The survey will demonstrate:

(1) the maximum radiation level at 10 centimeters from the nearest accessible surface of the source safe with the source in the shielded position is less than 1.5 millirem per hour;

(2) the radiation levels in restricted areas accessible to radiation workers are less than 2 millirem per hour; with a workload of 100 minutes per week, the personnel exposure is not likely to be in excess of the limits specified in 10 CFR 20.1201; and

(3) the radiation levels in unrestricted areas are less than 2 millirem per hour; with a worload of 100 minutes per week and an occupancy factor of 1/4 for outside walls, the radiation exposure to any member of the public is not likely to be in excess of the limits specified in 10 CFR 20.1301.

The records of these surveys will be maintained for the duration of the license.

b. A conspicuous, durable label stating "Caution, Radioactive Materials," will be affixed to at least one outer surface of the remote afterloading device as specified in 10 CFR 20.1904.

5. Survey Instruments

a. It is confirmed that we possess and have available a portable radiation detection survey instrument and a portable radiation measurement survey instrument in accordance with 10 CFR 35.420 that is operational in accordance with 10 CFR 35.51.

b. It is confirmed that the survey instrument possessed in accordance with 10 CFR 35.420 requirements will be checked with a dedicated check source for proper operation at the beginning of each day of use and records maintained.

c. It is confirmed that any individual entering tne treatment room will be required to use a portable hand held survey instrument if the permanent radiation monitor is found to be, or suspected to be, inoperable.

6. Operation Procedures

a. A copy of operating procedures is attached as Exhibit F.

(1) For a HDR remote afterloading unit, a patient is treated as an out-patient. Nursing personnel instrutions for patient care during treatment is not required.

b. It is confirmed that records of device and patient surveys will be maintained for three years and will include: the survey date; device identification (model and serial number); patient identification; survey

instrument identification (make, model, and serial number); background dose rate; the survey results; and initials of the individual performing the survey.

c. It is confirmed that written, as well as verbal instructions will be provided to individuals assigned to complete the daily and monthly safety checks.

d. It is confirmed that the following daily checks of our remote afterloader device will be performed, with the descriptions of method used to perform these checks if not self-explanatory:

(1) the permanent radiation monitor check with a dedicated check source for proper operation;

(2) TV monitor and intercom system check to verify proper operation;

(3) console operational function check, indicator lamp test, other status and operational displays;

(4) applicator and connector mechanical integrity check;

(5) source status indicators to verify proper operation;

(6) electrical door interlocks check for proper operation; and

(7) applicators and connectors visually inspected for mechanical integrity.

e. It is confirmed that if the daily check of interlocks for our remote afterloading device indicates that the interlock is not operating properly, treatment will be suspended until it has been repaired.

f. It is confirmed that records of the daily safety checks of our remote afterloader device will be maintained for three years and will include the following information:

(1) the date of the check;

(2) the results; and

(3) the initials of the individual who performed the check.

g. It is confirmed that the following monthly safety checks of our remote afterloader device will be performed:

(1) timer accuracy and linearity;

(2) measurement of source guide tubes to confirm length to 1 mm accuracy;

(3) backup battery test to verify emergency source retraction capability upon power failure; and

(4) procedures:

g(1) timer accuracy and linearity -- timer accuracy will be verified with stop watch against typical treatment dwell time settings while timer linearity will be verified by calculating net current from different dwell time settings and corresponding charges collected, "end effect" will be corrected by subtracting the charge reading and the time of a smaller dwell time setting from the charge reading and the time of a bigger dwell time setting to obtain the net charge and time;

g(2) measurement of source guide tubes to confirm length to 1 mm accuracy will be verified by both radiograph/autoradiograph and check ruler; and

g(3) backup battery test to verify emergency souce retraction capability upon power failure will be done as following:

1) activate the HDR unit;

2) cutoff the power supply to the HDR unit by tripping a circuit breaker;

3) verify that the source has returned to the storage safe by the room radiation monitor; and

4) survey the HDR device with a survey meter to ensure that the source has returned to the fully shielded position in the storage safe.

h. It is confirmed that records of our monthly safety checks will be maintained for three years and will include the following information:

(1) the date of the checks;

(2) the results of the checks;

(3) for the source position accuracy check, the programmed position and actual position of the source following activation of the device; and

(4) the initials of the individual who performed the check.

i. The activity of the Iridium source is to be calibrated in curie with a HDR-1000 chamber and an electrometer in current mode. A 6F catheter connected to to HDR unit is inserted into the HDR-1000 chamber and secured. Several dwell positions in 0.25 cm stepsize are programmed to ensure a "sweet spot" is found in the HDR-1000 chamber. The activity of the Iridium source is then calculated by using the calibration factors of the HDR-1000 chamber and the electrometer, together with the temperature and pressure correction factors.

j. It is confirmed that calibration measurements and associated calculations will be maintained for three years and will include:

(1) the calibration date;

(2) the manufacturer's name, model number and serial number for both the HDR and the source;

(3) the manufacturer's name, model number and serial number of the instrument used to measure the HDR device output;

(4) the name of the individual who performed the measurement; and

(5) the HDR radioactivity expressed in curie; and the manufacturer's "expected" radioactivity after decay correction; these values should be within +/- 5 percent.

k. It is confirmed that the medical physicist will be consulted prior to performing further patient treatments if the measured radioactivity differs by greater than +/-5 percent from the manufacturer's "expected" decay corrected radioactivity.

l. The dosimetry system to perform calibration measurements consists of a HDR-1000 well ionization chamber, or equivalent; and a CNMC electrometer, or equivalent. It is confirmed that the dosimetry system will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have affected the dosimetry system. It is also confirmed that the dosimetry system calibration records will be maintained for inspection.

m. The HDR physical source inventories will be performed quarterly. The inventory records contain the source number (source ID), the nominal activity, and the location of each source and the signature of the Radiation Safety Officer. The inventory record will be retained for five years.

7. Emergency Procedures

a. The step-by-stepin structions/actions are attached as Exhibits G, H, I, and J.

b. It is confirmed that the authorized user, the medical physicist, and the RSO will be nofitied immediately of any problem requiring implementation of emergency procedures. It is also confirmed that the appropriate telephone numbers will be posted.

c. The emergency cart will be stored in the HDR treatment room. The emergency equipment includes shielded storage containers, remote handling tools, scissors, cable cutters, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient.

d. It is confirmed that our emergency procedures were established by an authorized user and a medical physicist.

e. Please see Exhibits G, H, I, and J.

f. It is confirmed that emergency procedures are provided to device operators, authorized users, physics staff and nursing staff. It is also confirmed that a current copy is posted at the device console.

g. In the emergency source recovery, the HDR treatment room door entrance will be guarded or sealed to prevent unauthorized entry.

8. Maintenance

a. It is confirmed that all maintenance and repair of the device will be performed by the manufacturer.

b. It is confirmed that the HDR inspection and service records will be maintained for the duration of device use. These records will include: the inspection/service date; the name of the individual who performed the inspection/service; a description of the inspection/service performed, including a list of the components inspected

and a list of components serviced or replaced; and the signature of the inspector.

c. It is confirmed that the following inspection and service criteria for the HDR device:

(1) the HDR device will be fully inspected and serviced at intervals not to exceed 12 months, to ensure proper functioning of the source exposure mechanism;

(2) all scheduled service recommedned by the manufacturer will be performed in accordance with the manufacturer's instructions; and

(3) inspection and service will only be performed by the manufacturer.

If you have any questions or require any clarification on any information, you may contact Michael Kan, MS, DABR, at (810)234-2273.

Sincerely,

Philip A. Incarnati

Philip A. Incarnati
President and CEO

EXHIBIT A

SUPPLEMENT A

SUPPLEMENT — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR FINISHLAND, STATE OR TERRITORY WHERE LICENSED
Jack L. Nettleton, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Board Eligible in Radiation	Oncology 10/94.	

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	7/1/91-6/30/94	200	400
b. RADIATION PROTECTION	7/1/91-6/30/94	30	50
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	7/1/91-6/30/94	20	50
d. RADIATION BIOLOGY	7/1/91-6/30/94	36	30
e. RADIOPHARMACEUTICAL CHEMISTRY	7/1/91-6/30/94	5	1

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
^{137}Cs	300	Uterus, vagina	300 hrs.	Brachytherapy cancer treatment
^{192}Ir	250	Pelvis, brain, billiary, bronchial, head and neck	50 hrs.	Brachytherapy cancer streatment
^{125}I	7	Brain	10 hrs.	
^{90}Sr	40	Eye	1.5 hrs.	Pterygium

EXHIBIT B

SUPPLEMENT B

SUPPLEMENT

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to accumulate experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME

Dr. Jack L. Nettleton, M.D.

STREET ADDRESS

4100 Beecher Road

CITY | STATE | ZIP CODE

Flint, MI. 48532

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and the recommendation for a therapeutic dosage.

2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	-0-	
	Thyroid uptake	-0-	
	Lung perfusion scan	-0-	
	Xenon ventilation study	-0-	
	Aerosol ventilation scan	-0-	
	Renal flow scan	-0-	
	Brain scan	-0-	
	Liver/spleen scan	-0-	
	Bone scan	-0-	
	Oesophageal study	-0-	
	LeVeen shunt study	-0-	
	Cystogram	-0-	
	Cystogram	-0-	
	Cardiac perfusion scan.	-0-	
	Cardiac stress ventriculogram	-0-	
	Cardiac rest ventriculogram	-0-	
	Gallium scan	-0-	

EXH-6

EXHIBIT C

EXPOSED TRAINING USER

Dr. Jack L. Nettleton, M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (ADDITIONAL HOURS OF EXPERIENCE MAY BE ESTIMATED IN LIEU OF NUMBER OF CASES) D
P-32 (Colloid)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	-0-	
P-32 (Ceramic)	INTRACAVITARY TREATMENT	-0-	
I-131	TREATMENT OF THYROID CARCINOMA	-0-	
	TREATMENT OF HYPERTHYROIDISM	-0-	
Au-198	INTRACAVITARY TREATMENT	-0-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-0-	
	INTRACAVITARY TREATMENT	60	
I-125 or Ir-192	INTERSTITIAL TREATMENT	8	
Co-60 or Cs-137	TELETHERAPY TREATMENT	-0-	
Sr-90	TREATMENT OF EYE DISEASE	1	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	-0-	
Sn-113/ In-113m	GENERATOR	-0-	
Tc-99m	REAGENT KITS	-0-	
Other			

1. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
University of Minnesota Hospital	7/1/91-6/30/94 (3 years)	531

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Seymour H. Levitt, M.D.

b. NAME OF INSTITUTION
Univ. of MN. Hospital, Box 494

c. MAILING ADDRESS
Harvard St. at E. River Road

d. CITY
Minneapolis, Minnesota 55455

e. MATERIALS LICENSE NUMBER(S)

5. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME (Print or type)
Seymour H. Levitt, M.D.

8. DATE
2/13/95

EXHIBIT D (Continued)

PROPOSED PHYSICIAN USER

Dr. Jack L. Nettleton, M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheet.) D
P-32 (Sealed)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	-0-	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	-0-	
I-131	TREATMENT OF THYROID CARCINOMA	-4-	
	TREATMENT OF HYPERTHYROIDISM	-0-	
Au-198	INTRACAVITARY TREATMENT	-0-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-0-	
	INTRACAVITARY TREATMENT	-2-	
I-125 or Ir-192	INTERSTITIAL TREATMENT	-0-	
Co-60 or Cs-137	TELETHERAPY TREATMENT	-0-	
Sr-90	TREATMENT OF EYE DISEASE	-0-	
	RADIOPHARMACEUTICAL PREPARATION	-0-	
Mo-99/ Tc-99m	GENERATOR	-0-	
Sn-113/ In-113m	GENERATOR	-0-	
Tc-99m	REAGENT KITS	-0-	
Other	Iridium - 192 Remote Afterloading Brachytherapy Unit	-20-	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
*McLaren Regional Medical Center	7/05/94 to Present	50

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Hesham E. Gayar, M.D.

b. NAME OF INSTITUTION: McLaren Regional Cancer Center

c. MAILING ADDRESS: 4100 Beecher Road

d. CITY: Flint, Michigan 48532

e. MATERIALS LICENSE NUMBER(S):

5. PRECEPTOR'S SIGNATURE: Hesham E. Gayar

7. PRECEPTOR'S NAME (Please type or print): Hesham E. Gayar, M.D.

8. DATE: 3/13/95

EXHIBIT E

Facilities, Equipment and Area Security Procedures

1. Door Interlocks

   In the event of a malfunction of the door 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. Treatment will be suspended until the interlock system is shown to be functioning properly.

   When the door interlock is tripped, a reset operation must be initiated before the treatment can be started or continued.

2. The HDR treatment room door will be posted with a "CAUTION - RADIATION AREA" sign on the door. A warning red light above the door will be on during treatment.

3. A permanently installed, independent radiation monitor will be in use at all times. The monitor will produce a flashing red light during treatment and will be visible upon entrance to the room.

   The radiation monitor will be equipped with a backup battery pack power supply separate from the power supply to the afterloading unit.

   The radiation monitor will be checked with a dedicated check source for proper operation each day before the HDR device is used. A record of the radiation monitor check described above will be maintained for a period of three years.

   If the radiation monitor is found inoperable, any individual entering the treatment room will use a survey meter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The survey meter will be checked with a dedicated check source for proper operation at the beginning of each day of use and records maintained of these checks.

   A radiation monitor that is found to be either inoperable or evidence of intermittent problems will be repaired or replaced promptly.

4. A CCTV system with monitors at the operator's console is used. In the event of CCTV failure, treatments will be halted until the CCTV system is functional.

5. The HDR console keys and the HDR device itself will be stored in the treatment room closet and locked when not in use.

6. Only the patient will be in the treatment room during the use of the HDR.

EXHIBIT F

HDR Operating Procedures

1. Daily checks will be performed by a trained HDR operator each day of use of the HDR unit. Records will be maintained for three years.

2. Treatment time calculations will be independently verified before treatment. Treatment planning computer removable media will be labelled with the corresponding patient's name and identification number.

3. Both the authorized user and the medical physicist must be physically present (within the range of normal human speech) during all patient treatments.

4. Surveys of the patient before treatment and prior to removing the patient from the treatment room will be performed. Records of device and patient surveys will be maintained for three years.

5. A survey of the device will be performed immediately after each use of the device; including the connectors and applicator apparatus, the full catheter guide tube length, and the device external surface to ensure that the source is fully retracted to the safe store position.

6. If the above survey indicates that the source is not fully retracted to the shielded position in the device, emergency procedures will be immediately implemented.

7. No treatment procedure will be conducted for which a decoupled or jammed source cannot be removed expeditiously from the patient.

8. Monthly checks will be performed by a qualified physicist. Records will be maintained for three years.

9. A radiation protection survey will be performed by a qualified physicist, following each source replacement. The records will be maintained for the duration of the license.

10. The HDR physical source inventories will be performed quarterly. The records will be maintained for five years.

EXHIBIT G

EMERGENCY PROCEDURE FOR microSELECTRON HDR UNIT

When the HDR control panel or the radiation monitor on the wall indicates that:

a. the source fails to retract automatically upon the completion of the treatment or after attempted treatment interruption using the "interruption key" on the control panel, or

b. the source fails to leave the safe (the radiation monitor is not activated) despite the control panel indicating that the normal treatment has started,

the Radiation Therapist operating the HDR unit is responsible for carrying out the following actions:

1. Strike the Nucletron Master "Emergency Stop" button located on the wall above the control panel.

2. Use the overhead paging to announce "Code HDR" alarm. Nursing staff and additional physics staff will go to the HDR treatment room to help.

3. Enter the treatment room with the radiation survey meter and strike the "Emergency Stop" button located on the wall to the right in the maze.

4. Stand behind the HDR unit, strike the "Emergency Stop" button on the HDR unit and verify the source location with the survey meter. If the source is in the safe, the authorized user with the assistance of nursing staff will proceed with the removal of the catheter(s), or applicator(s).

5. Survey the patient with the survey meter and the HDR device, including the connectors and applicator apparatus, the full catheter guide tube length, and the device external surface.

6. If the source has not returned to the safe, open the access panel and retract the source cable by rotating the gold hand crank in the indicated direction until it stops.

7. Go to 5 to make sure the source is in the safe.

If the source cable cannot be retrieved back to the safe by using the gold hand crank, the authorized user will assess the situation and make decision to either a) or b):

a) maitain a closed source environment;

   1) the authorized user and the nursing staff will remove the applicator or catheter from the patient while still

EXHIBIT H

connected to the indexer ring;

2) the physicist will insert the removed applicator or catheter into a shielding open-top container;

3) the authorized user and the nursing staff will immediately assist the patient out of the treatment room;

4) the physicist or the radiation therapist will survey the patient;

5) the physicist will close the room door, seal the room and call Nucletron for assistance; and

6) the physicist will notify the hospital R.S.O. and NRC Regional Office.

b) proceed with an open system source environment;

1) the authorized user and the nursing staff will turn the indexer locking ring to unlock position, and disconnect all treatment tubes or catheters from the indexer ring;

2) the physicist will wheel the Nucletron source container with funnel on top below the unit's head;

3) the physicist will use the forceps to hold the source cable and then pull the source cable out from the tube or catheter, and drop into the container's funnel;

4) the physicist will ensure the source is pushed into the container, and push the vertical locking rod to horizontal position;

5) at the same time, the authorized user and the nursing staff will assist the patient out of the treatment room;

6) the physicist or the radiation therapist will survey the patient;

7) the physicist will close the room door, seal the room and call Nucletron for assistance; and

8) the physicist will notify the hospital R.S.O. and NRC Regional Office.

If the source cannot be retrieved from the patient, the authorized user will direct further actions.

* SEE THE SPECIFIC EXAMPLES FOR A DETAILED EXPLAINATION ON EACH HDR PROCEDURE *

EXHIBIT I

HDR EMERGENCY PROCEDURE EXAMPLES

1. ENDOBRONCHIAL - ESOPHAGEAL TREATMENT

a) Ascertain the channel number currently being treated when the **Error Code** is generated using the print out.

b) Enter the room with a hand held survey meter at its highest setting (>1000 millirem per hour) and confirm that there is radiation in or near the patient's body.

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

d) A shielded emergency container should be available for insertion of the removed applicator.

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

2. INTRACAVITARY APPLICATORS

a) Ascertain the channel number currently being treated when the **Error Code** is generated using the print out.

b) Enter the room with a hand held survey meter at its highest setting (>1000 millirem per hour) and confirm that there is radiation in or near the patient's body.

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

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

e) A shielded emergency container should be available for insertion of the removed applicator.

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

EXHIBIT J

3. INTERSTITIAL IMPLANTS - FLEXIBLE

a) Ascertain the channel number currently being treated when the **Error Code** is generated using the print out.

b) Enter the room with a hand held survey meter at its highest setting (>1000 millirem per hour) and confirm that there is radiation in or near the patient's body.

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

d) Have available sterile drapings to cover the wound left by the applicator removal.

e) A shielded emergency container should be available for insertion of the removed applicator.

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

4. INTERSTITIAL IMPLANTS - RIGID

a) Ascertain the channel number currently being treated when the **Error Code** is generated using the print out.

b) Enter the room with a hand held survey meter at it highest setting (>1000 millirem per hour) and confirm that there is radiation in or near the patient's body.

c) Using the appropriate tool, loosen the needle clamp on the effected needle and withdraw it from the template or fixing mechanism.

d) A shielded emergency container should be available for insertion of the removed applicator.

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

FEB 16 1995

McLaren Regional Medical Center
ATTN: Gregory L. Beckman
Executive Vice President
401 Ballenger Highway
Flint, Michigan 48532

Dear Mr. Beckman:

We have reviewed your application dated March 28, 1994, requesting a renewal of NRC Material License No. 21-04171-04 and find that we will need additional information as follows:

1. Authorized Users

In order to authorize Dr. Nettleton for material in 10 CFR 35.400 and Ir-192 in remote aterloading unit, please submit documentation in accordance with 35.940(2) and 35.940(3). Please be advised that if the training and experience was obtained under different preceptors, a signed preceptor form must be submitted for each preceptor. You may submit the aforementioned information on NRC Supplement A and B forms.

2. Training Program

a. Provide an outline of the training given to authorized physician users and device operators, including a description of the didactic portion of the training and the practical or "hands on" device operation training. Specify the number of hours of didactic training and the number of hours of "hands-on" training. This training must include:

(1) radiation protection and instrumentation, including the proper use of personnel dosimeters, survey instruments, and radiation monitors;

(2) your operating and emergency procedures;

(3) the design, use and function of the device, including the safety systems; and

(4) "hands-on" training, under the direct supervision of experienced device users, which includes "dry runs" using dummy sources for routine patient set-up and treatment, as well as the implementation of your emergency procedures.

Note: Any operation of the device must be under the direct supervision of an experienced device user (i.e. physically present).

b. Confirm that authorized user and ancillary staff training will be given initially and at intervals not to exceed 12 months. In addition, confirm that your authorized user retraining will include "hands-on" training (using dummy sources) for your emergency procedures (i.e. "dry runs"). Please submit an outline of your authorizer user and ancillary staff **retraining** program.

c. Specify the method you will use to determine each trainee's competency to use the device for each type of proposed use.

d. Confirm that records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. These records must include the instructor(s) name, the attenders names, the training date(s), and an outline of the topics discussed.

3. Facilities

a. Provide a current and accurate description of the security provided for the room where HDR treatments are administered and/or the device is stored including:

the method to ensure that the console keys are inaccessible to unauthorized persons.

b. Confirm that a permanent radiation monitor capable of continuously monitoring the source status is installed in the HDR treatment room. In addition, please confirm the following:

(1) that the radiation monitor will be promptly repaired or replaced if found to be either inoperable or evidencing intermittent problems; and

(2) emergency entry provisions.

4. Compliance With Restricted/Unrestricted Area Radiation Level Limits

a. Describe the survey program that will be implemented to demonstrate compliance with 10 CFR 20.1501; including a requirement to conduct surveys following source replacement. These surveys must demonstrate:

(1) the maximum radiation levels at 10 centimeters from the nearest accessible surface of the source safe with the source in the shielded position;

(2) that radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201; and

(3) that radiation levels in unrestricted area will not result in a dose to any member of the public in excess of the limits specified in 10 CFR 20.1301.

Please confirm that records of these surveys will be maintained for the duration of the license.

b. Confirm that a conspicuous, durable label stating "Caution Radioactive Materials," will be affixed to at least one outer surface of the remote afterloading device as specified in 10 CFR 20.1904.

5. Survey Instruments

a. Confirm that you possess and have available a portable radiation detection survey instrument and a portable radiation measurement survey instrument in accordance with 10 CFR 35.420 that is operational in accordance with 10 CFR 35.51.

b. Confirm that the survey instrument possessed in accordance with 10 CFR 35.420 requirements will be checked with a dedicated check source for proper operation at the beginning of each day of use and records maintained.

c. Confirm that any individual entering the treatment room will be required to use a portable hand held survey instrument if the permanent radiation monitor is found to be, or suspected to be, inoperable.

6. Operating Procedures

a. Provide a copy of your operating procedures. These procedures must require the following:

(1) nursing personnel will be provided specific (written) instructions for patient care;

(2) treatment planning computer removable media will be labelled with the corresponding patient's name and identification number;

(3) a survey of the device will be performed immediately after each use of the device; including the connectors and applicator apparatus, the full catheter guide tube length, and the device external surface;

(4) a survey of the patient prior to removing the patient from the treatment room;

(5) immediate implementation of the applicable emergency procedures if the survey indicates that the source is not fully retracted to a shielded position;

(6) no treatment procedure will be conducted for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in shielded container; and

(7) both the authorized user and either the medical physicist or radiation safety officer must be physically present (within the range of normal human speech) during all patient treatments.

b. Confirm that records of device and patient surveys will be maintained for three years and will include: the survey date; device identification (model and serial number); patient identification; survey instrument identification (make, model, and serial number); a representative background dose rate; the survey results; and initials of the individual performing the survey.

c. Confirm that written, as well as verbal instructions will be provided to individuals assigned to complete the daily and monthly safety checks.

* d. Confirm that the following **daily** safety checks of your remote afterloader device will be performed and describe the method used to perform these checks:

(1) the permanent radiation monitor check with a dedicated check source for proper operation;

(2) TV monitor and intercom system check to verify proper operation;

(3) console operational function check, indicator lamp test, other status and operational displays;

(4) applicator and connector mechanical integrity check;

(5) source status indicator(s) to verify proper operation;

(6) electrical interlocks check at each entrance check for proper operation; and

(7) applicators and connectors visually inspected for mechanical integrity.

e. Confirm that if your daily check of interlocks for your remote afterloading device indicates that the interlock is not operating properly that you will suspend treatment until it has been repaired.

f. Confirm that records of your daily safety checks of your remote afterloader device will be maintained for three years and will include the following information:

(1) the date of the check;

(2) the results; and

(3) the initials of the individual who performed the check.

g. Confirm that the following **monthly** safety checks of your remote afterloader device will be performed in accordance with the manufacturer's instructions at intervals not to exceed 30 days:

(1) timer accuracy and linearity;

(2) measurement of source guide tubes to confirm length to 1 mm accuracy;

(3) backup battery test to verify emergency source retraction capability upon power failure (i.e., a function test with the AC power disconnected); and

(4) procedure submitted.

h. Confirm that records of your monthly safety checks will be maintained for three years and will include the following information:

(1) the date of the checks;

(2) the results of the checks;

(3) for the source position accuracy check, the programmed position and actual position of the source following activation of the device; and

(4) the initials of the individual who performed the check.

i. Provide a description of the method used to determine the exposure rate under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in-air" measurement or

done using a phantom, configuration of the chamber with respect to the source guide tube and device, scatter factors used to compute the exposure rate, etc.).

j. Specify your calibration recordkeeping requirements, including a commitment to maintain a record of calibration measurements and associated calculations for a period of three years. The records must include:

(1) the calibration date;

(2) the manufacturer's name, model number and serial number for both the HDR and the source;

(3) the manufacturer's name, model number and serial number of the instrument used to measure the HDR device output;

(4) the name of the individual who performed the measurement; and

(5) the HDR output expressed in R/hr; and the manufacturer's "expected" output value (decay corrected); These values should be within ±5 percent.

k. Confirm that the radiation safety officer or medical physicist will be consulted prior to performing further patient treatments if the measured output differs by greater than ±5 percent from the manufacturer's "expected" decay corrected output.

l. Provide a description of the dosimetry system which will be used to perform calibration measurements. Confirm that the dosimetry system will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have affected the dosimetry system. Confirm that dosimetry system calibration records will be maintained for inspection.

m. Describe your method for conducting source inventories. Specify that physical source inventories will be performed quarterly (10 CFR 35.59) and records maintained in accordance with 10 CFR 35.59(g).

7. Emergency Procedures

a. Specify step-by-step instructions/actions for single and/or multiple equipment failures and the individual(s) responsible for implementing the actions. Clearly specify which steps are to be taken under different scenarios (i.e., source decoupling versus a

jammed source). The actions specified for emergency source removal should give primary consideration to minimizing exposure to the patient and healthcare personnel while maximizing patient safety.

b. Confirm that the authorized user and medical physicist or RSO will be notified immediately of any problem requiring implementation of emergency procedures. Please confirm that the appropriate telephone numbers will be posted.

c. Identify where you will store emergency source recovery equipment and specify what equipment may be necessary for the various equipment failures described in the procedures. At a minimum, emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

d. Please confirm that your emergency procedures were established by an authorized user(s) and radiation safety officer or medical physicist.

e. Specify exactly when emergency procedures are to be implemented. State the circumstances (i.e., when the source cannot be retracted to a fully shielded position, source decoupling, jammed source, console indicates that source is not retracted).

f. Confirm that emergency procedures are provided to device operators, authorized user(s), and other personnel as necessary. Confirm that a current copy is posted at the device console or in a conspicuous location within the treatment area.

g. Specify requirements for restricting and posting the treatment area to minimize the risk of inadvertent exposure to personnel not directly involved in the emergency source recovery.

8. Maintenance

a. Confirm that all maintenance and repair of the device will be performed by the manufacturer or by individuals specifically authorized by the NRC or an Agreement State. If maintenance and repair will be performed by someone other than the manufacturer, specify the individual and provide a copy of the NRC or Agreement State license authorizing this individual for maintenance and repair activities.

Note: Maintenance and repair means installation, replacement, relocation or removal of the sealed source or an afterloading device that contains a sealed source; or any adjustment involving any mechanism on the afterloading device, treatment console, or interlocks that could expose the source, reduce the shielding around the source or affect the source drive controls.

b. Confirm that HDR inspection and service records will be maintained for the duration of device use. These records must include: the inspection/service date; the name of the individual who performed the inspection/service; the NRC or Agreement State license number authorizing the individual to perform the inspection/service; a description of the inspection/service performed, including a list of the components inspected and a list of components serviced or replaced; and the signature of the inspector.

c. Confirm the following inspection and service criteria for the HDR device:

(1) the HDR device will be fully inspected and serviced at intervals not to exceed 12 months, to ensure proper functioning of the source exposure mechanism;

(2) all scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer's instructions; and

(3) inspection and service will only be performed by the manufacturer or other persons specifically licensed to do so by the NRC or an Agreement State.

d. An employee trained by the manufacturer may be authorized to perform maintenance and repair functions. This authorization will list the employee by name and specify only those maintenance and repair functions described in a certificate or letter from the manufacturer of the device which documents and outlines the training. A copy of the training certification and a training outline must be submitted with the request.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 96744.

If you have any questions or require clarification on any of the information stated herein, you may contact us at (708) 829-9887.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Section

License No.: 21-04171-04
Docket No.: 030-02048

Enclosures: 1. 10 CFR Part 35
2. NRC Bulletin 93-01
3. P&GD 86-4

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WATSON

MCLAREN REGIONAL MEDICAL CENTER

401 South Ballenger Highway
Flint, Michigan 48532-3685

February 6, 1995

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
801 Warrenville Road
Lisle, IL 60532

Re: Close-out of cardiac imaging room and stress room License No. 21-04171-04.

Enclosed is the close-out survey of the cardiac imaging room and stress room. Re-location of this area was authorized in an amendment issued under Control No.397991.

Please contact our consultant, Tracy King, at (313) 662-3197, if you have any questions.

Sincerely,

Maureen Snyder, NMT

Maureen Snyder, Supervisor
Nuclear Medicine Department
(810) 762-4978

Enc

Close-out Survey
McLaren Regional Medical Center
Cardiac Imaging Suite Only
License No. 21-04171-04

Date Performed: 2-3-95

Performed By: Maureen Snyder, NMT

Hot Lab wipe tests analyzed with Captus 500 2" x 2" well counter with a 5-800 keV window. Efficiency for Technetium-99m is 93%. MDA is 46 dpm. Only Tc-99m was used in this area.

Survey performed with Victoreen GM 498 survey meter with side window probe S/N 113 calibrated on 05-25-94. Range used was 0-0.5 mR/hr.

Visual Check

The area was checked to ensure that all radioactive waste had been removed. No radioactive material was located.

Radiation Level Survey

No area within the area demonstrated radiation levels in excess of the background reading of 0.05 mR/hr.

Removable Contamination

Camera Room/Stress Room

1 minute counts, 100 square centimeter area
The Captus 500 automatically subtracts background and coverts cpm to dpm

Area	Result	Area	Result
1	46.1 dpm/100 cm^2	16	12.8 dpm/100 cm^2
2	24.1	17	8.5
3	20.0	18	24.0
4	8.0	19	18.6
5	12.0	20	21.6
6	4.0	21	16.2
7	60.8	22	11.5
8	92.0	23	8.2
9	18.1	24	16.8
10	21.8	25	40.1
11	40.1	26	30.6
12	30.8	27	24.9
13	24.9	28	39.1
14	9.1	29	17.9
15	15.8	30	10.5

Maximum removable contamination: 92 dpm/100 cm^2

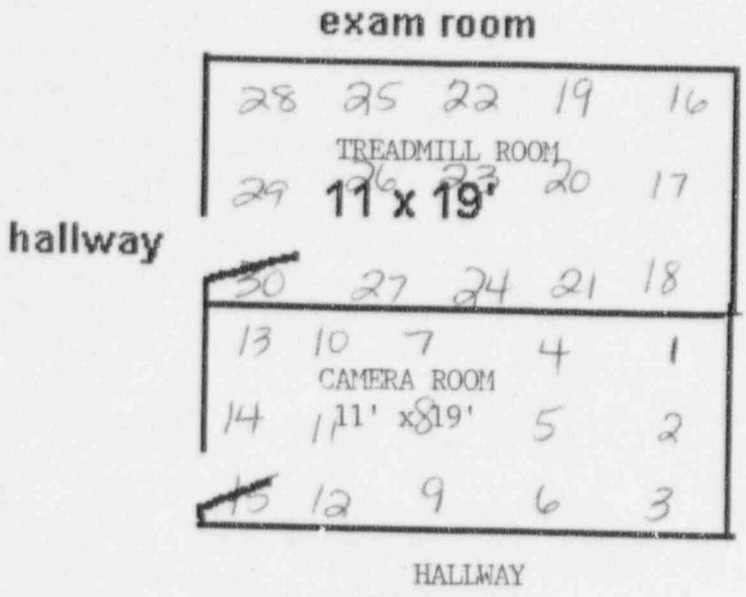
Conclusion

As of February 3, 1995 all radioactive materials were removed from the site and no removable contamination was present.

Closeout survey done: February 3, 1995
by: Maureen Snyder, NMT

McLaren Regional Medical Center
License No. 21-04171-04

North →



Cardiology Department

* surveys done with the Victoreen 450 GM counter
Background reading = .05 mr/hr.

* Wipe tests done with the Capintec Captus 500 well counter.

1-30 - wipe areas = results in dpm / 100 cm²

1-30 - survey areas = results in mR/hr.

Area	Survey	Wipe
1.	.05 mr/hr	46.1 dpm.
2.	.05 mr/hr	24.1 dpm
3.	.05 mr/hr	20.0 dpm.
4.	.05 mr/hr	8.0 dpm.
5.	.05 mr/hr	12.0 dpm.
6.	.05 mr/hr	4.0 dpm.
7.	.06 mr/hr	60.8 dpm.
8.	.07 mr/hr	92.0 dpm
9.	.05 mr/hr	18.1 dpm.
10.	.05 mr/hr	21.8 dpm.
11	.06 mr/hr	40.1 dpm.
12.	.05 mr/hr	30.8 dpm.
13.	.05 mr/hr	24.9 dpm.
14.	.05 mr/hr	9.1 dpm.
15.	.05 mr/hr.	15.8 dpm.

Area	Survey	Wipe
16.	.05 mr/hr.	12.8 dpm.
17.	.05 mr/hr	8.5 dpm.
18.	.05 mr/hr.	24.0 dpm.
19.	.05 mr/hr.	18.6 dpm
20.	.04 mr/hr	21.6 dpm.
21.	.04 mr/hr	16.2 dpm.
22.	.02 mr/hr.	11.5 dpm.
23.	.03 mr/hr	8.2 dpm.
24.	.05 mr/hr.	16.3 dpm.
25.	.05 mr/hr.	40.1 dpm
26.	.05 mr/hr.	30.6 dpm
27.	.05 mr/hr.	24.9 dpm.
28	.05 mr/hr	39.1 dpm.
29.	.05 mr/hr.	17.9 dpm.
30.	.05 mr/hr.	10.5 dpm.

Close-out Survey
McLaren Regional Medical Center
Cardiac Imaging Suite Only
License No. 21-04171-04

Date Performed: 2-3-95

Performed By: Maureen Snyder, NMT

Hot Lab wipe tests analyzed with Captus 500 2" x 2" well counter with a 5-800 keV window. Efficiency for Technetium-99m is 93%. MDA is 46 dpm. Only Tc-99m was used in this area.

Survey performed with Victoreen GM 498 survey meter with side window probe S/N 113 calibrated on 05-25-94. Range used was 0-0.5 mR/hr.

Visual Check

The area was checked to ensure that all radioactive waste had been removed. No radioactive material was located.

Radiation Level Survey

No area within the area demonstrated radiation levels in excess of the background reading of 0.05 mR/hr.

Removable Contamination

Camera Room/Stress Room

1 minute counts, 100 square centimeter area
The Captus 500 automatically subtracts background and coverts cpm to dpm

Area	Result	Area	Result
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5	12.0	20	21.6
6	4.0	21	16.2
7	60.8	22	11.5
8	92.0	23	8.2
9	18.1	24	16.8
10	21.8	25	40.1
11	40.1	26	30.6
12	30.8	27	24.9
13	24.9	28	39.1
14	9.1	29	17.9
15	15.8	30	10.5

Maximum removable contamination: 92 dpm/100 cm^2

Conclusion

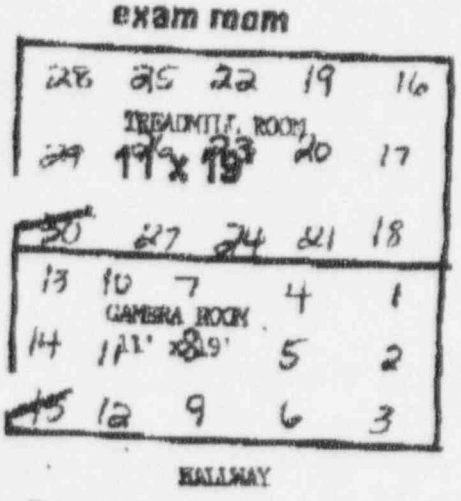
As of February 3, 1995 all radioactive materials were removed from the site and no removable contamination was present.

Clearance survey done: February 3, 1995

by: Maureen Snyder, NMT

McLaren Regional Medical Center
License No. 21-04171-04

North →



* surveys done with the Victoreen 498 Ion counter Background reading .05 mr/hr.

* wipe tests done with the Capintec 500 well counter.

Cardiology Department

1-30 - wipe areas = results in dpm / 100 cm²

1-30 - survey areas - results in mR/hr.

Area	Survey	Wipe	Area	Survey	Wipe
1.	.15 mr/hr	46.1 dpm.	16.	.05 mr/hr.	12.3 dpm.
2.	.05 mr/hr	24.1 dpm	17.	.05 mr/hr	8.5 dpm.
3.	.05 mr/hr	20.0 dpm.	18.	.05 mr/hr.	24.0 dpm.
4.	.05 mr/hr	9.0 dpm.	19.	.05 mr/hr.	18.6 dpm.
5.	.05 mr/hr	12.0 dpm.	20.	.04 mr/hr	21.6 dpm.
6.	.05 mr/hr	4.0 dpm.	21.	.04 mr/hr	16.2 dpm.
7.	.06 mr/hr	60.8 dpm.	22.	.02 mr/hr.	11.5 dpm.
8.	.07 mr/hr	92.0 dpm	23.	.08 mr/hr	8.6 dpm.
9.	.05 mr/hr	18.1 dpm.	24.	.05 mr/hr.	16.8 dpm.
10.	.05 mr/hr	31.8 dpm.	25.	.05 mr/hr.	40.1 dpm
11.	.06 mr/hr	40.1 dpm.	26.	.05 mr/hr.	30.6 dpm
12.	.05 mr/hr	30.8 dpm.	27.	.05 mr/hr.	24.9 dpm.
13.	.05 mr/hr	24.9 dpm	28	.05 mr/hr	39.1 dpm.
14.	.05 mr/hr	9.1 dpm	29.	.05 mr/hr.	17.9 dpm.
15.	.05 mr/hr	15.8 dpm.	30.	.05 mr/hr.	10.5 dpm.

2 of 4

APR 07 1994

McLaren Regional Medical Center
ATTN: Gary Rudder, M.D.
Radiation Safety Officer
401 South Ballenger Highway
Flint, MI 48532-3685

License No. 21-04171-04
Control No. 396744

Dear Dr. Rudder:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Section

RIII
Meenan/bt
04/3/94

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QUALITY MAMAGEMENT PROGRAM
McLAREN REGIONAL MEDICAL CENTER

Implemented: 1/27/92

1. **Objective**

"...to provide high confidence that byproduct material will be administered as directed by the authorized user."

2. **Responsibility, Authority, and Audit**

The responsibility and authority to establish and implement the Quality Management (QM) Program shall be given to Maureen Snyder, Chief NMT for Nuclear Medicine and Michael Kan, Cancer Center Physicist for Brachytherapy.

Elements for Medical Use - Radiopharmaceutical Therapies and Nal 1-125 or 1-131 >30 uCi

A. Prior to administration, a written directive will be prepared for:

1. any therapeutic administration of a radiopharmaceutical and
11. any administration of Nal 1-125 or 1-131 greater than 30 uCi.

With regard to diagnostic and therapeutic radiopharmaceuticals "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

patient name
patient identification number, if available
radiopharmaceutical
dosage
route of administration
the type of procedure desired

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B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

2. The patient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directives. A procedure which requires a written directive shall not be initiated until a written protocol approved by an authorized user is available.

The technologists shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them.

The protocols shall contain the following elements:

-pharmaceutical
-radionuclide
-routine dosage
-route of administration
-indications
-contraindications

Each change in protocol shall be approved by an authorized user before the change is implemented and before the change is incorporated into the procedure manual. Each technologist shall be instructed in the change before it is implemented or incorporated into the procedure manual.

D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Upon identification of an unitended deviation, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of Part 35.

4. **Elements of Brachythoraphy**

A. Prior to administration, a written directive will be prepared for:

Any brachytheraphy radiation dose.

With regard to brachytheraphy: A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical or radiation, containing the following information.

1. Prior to implantation: the radioisotope, number of sources, and source strengths; and

2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time(or, equivalently, the total dose).

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive.

C. Each administration is in accordance with the written directive.

D. Any unintended deviation from the written direcive is identified and evaluated, and appropriate action is taken.

E. Final plans of treatment and related calculations for brachytheraphy are in accordance with the written directive.

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Annual Review

The annual review shall be conducted by a member of management(E. Edward Adamson, R.T., Director of Radiology Services for Nuclear Medicine and Hesham M. El Gayer, M.D. for Brachytheraphy) and the consulting medical physicist. The review shall be conducted at intervals not to exceed 12 months. The review shall determine the effectiveness of teh QM program. Areas identified as inadequate shall be modified to meet the objectives of 35.32(a).

Records of each review, including the evaluations and findings in an auditable form for three years.

Audit:

Frequency: An audit of quality management program shall be conducted at twelve(12) month intervals.

Responsibility: The audit shall be conducted by the Radiology Administrator/Office Manager and/or consulting medical physicist. If the audit is performed by consulting physicist alone, management shall be briefed in writing of the findings.

Scope: The audit shall evaluate the following items,

1. The compliance rate of having written directives prior to administration of the radiopharmaceutical or radiation in those cases where written directives are required.

2. The content of the written directive is as required.

3. The instruction of the supervised individual(s) in the licensee's written quality management program and requirement of following the authorized user's instructions.

4. The methods of verifying the patient's identity by more than one method is performed as stated in the QM program.

5. The compliance rate of verifying the patient's identity by more than one method.

6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.

7. The compliance of the staff in identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directive.

8. The compliance with the requirement to respond to each recordable event.

9. The compliance with the requirements to notify and report a misadministration.

10. The compliance with the requirements to keep the appropriate records, including:
- the annual reviews
- the written directives
- the radiopharmaceutical dosages
- the recordable events
- the misadministrations

Brachytherapy Only

11. The final treatment plans and related calculations are in accordance with the written directive.

Method: Items 1, 2, 3, 4, 5, and 6. Spot checks of the administration records for the previous twelve months shall be made at numerous intervals. A minimum of twenty (or if the volume is less than this, all) administrations records where written directives were required shall be reviewed for compliance.

Item 7, 8, and 9. Any unintended deviations discovered in the above review shall be tracked to determine if they were identified by staff. Records made by the staff shall be reviewed for thoroughness.

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MEDICAL CENTER

McLaren Regional Medical Center Page 6

Item 10. Records made by the staff shall be reviewed for appropriateness. Current practices shall be reviewed with the staff to determine if the actions taken to address the unintended deviations are being followed.

Item 11 (Brachytherapy Only) The final treatment plans shall be reviewed by Hesham M. El Gayar, M.D. on what was administered and what was prescribed with respect to number of sources, source configurations, source strengths and treatment time.

McLAREN REGINAL CANCER CENTER

Quality Management Program for the use of High Dose Rate Remote Afterloading Device. This program is intended to provide quidelines for HDR applications.

A. Written Directive

The Physician will issue a written directive. This directive must be written prior to the administration of any brachytherapy treatment and is to be signed and dated by the physician.

B. Patient Identification

Before administering a brachtherapy treatment the identity of the patient must be determined to be that of the patient in the written directive by more than one method. The procedure will be to ask the patient's name and to confirm it by checking the patient's record: birth date, address, social security number, signature, or the name on the patient's hosptital ID bracelet.

C. Dose Calculation and Verification

The dose calculation will be performed by a dosimetrist, or a radiation physicist. A second person, who whenever possible did not make the original calculations, should verify the dose calculation. Computer-generated dose calculations should be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations. The computer-generated dose calculations for input into the brachytherapy afterloading device should be checked to verify correct transfer of data from the computer. Current source activity will be verified prior to administration. The physicist will insure the final plan of treatment is in accordance with physician's written directive prior to administration.

D. Applicator/Source Postion Verification

Radiographs of implant applicators with dummy sources will be taken as the basis for verifying the position of the sources and calculating the dose.

Actual source position vs. programmed position shall be verified by autoradiograph at calibration and periodically thereafter. A trial run with the dummy source is performed through each catheter/dwell position prior to the initiation of HDR brachy-therapy to insure no impediments in the planned source path.

E. Charting

After administering the brachytherapy treatment, the physician is to sign or initial and date a written record of the calculated administered dose in the patient's chart.

F. Questions

All workers are encouraged to seek guidance and clarification if there is any doubt how to carry out the written directive.

G. Assess of Treatment Planning or Dose Calculating Computer Program

Acceptance testing of treatment planning or dose calculating program should be performed by a qualified radiation physicist before the first use.

H. Periodic QM Program Review

On an annual basis the entire QM program will be reviewed for completeness and viability. Changes may be made to enhance patient's care. The program will be reviewed by a minimum of two persons: a physician and a physicist.

Prepared by: Michael Kan, Date: 2-8-94

Approved by: [signature], Date: 2-9-94

NRC FORM 577 (10-94)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

McLaren Regional Medical Center
Attn: Gregory L. Beckman
Executive Vice President
401 South Ballenger Highway
Flint, Michigan 48532

TYPE OF ACTION

- [ ] NEW LICENSE
- [x] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: March 28, 1994

LICENSE NUMBER: 21-04171-01

CONTROL NUMBER: 396744

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Feder. Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$ 1400	$
2B	$	$ 160	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE $1560
PAYMENT RECEIVED $1400
AMOUNT DUE $160

- [ ] Your request was received without the prescribed application fee.
- [ ] We received your Check No. _____ in the amount of $_____. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
  - [ ] We received your Check No. _____ in payment of the fee.
  - [ ] The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
  - [ ] Your request was combined, prior to review, with your _____ request, Control No. _____

III. CHECK RETURNED

- [ ] Enclosed is Check No. _____ which was returned to us by the bank for:
  - [ ] INSUFFICIENT FUNDS
  - [ ] ACCOUNT CLOSED
  - [ ] OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- [x] License No. 21-04171-01, Amendment No. 44, issued on May 11, 1995 was issued without the required fee being collected. The fee required is noted in Section I of this form.
- [ ] The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE - LICENSE FEE ANALYST	LFDCB	LFDCB
Shirley Crutchfield	5C	
	5 25 95	/ /

DISTRIBUTION
NCDAF RF
LFDCB R/F (2)
Pending Fee File
Region 3

DATE: May 25, 1995

NRC FORM 577 (10-94)

Per Cassandra, U-235 is necessary on this license 6/20/95

McLAREN
REGIONAL
MEDICAL CENTER

June 9, 1995

Shirley Cruthfield
U.S. Nuclear Regulatory Commission
License Fee and Dept Collection Branch, OC/DAF
Division of Accounting and Finance
Office of the Controller

Re: Absence of source material for shielding at McLaren Regional Medical Center, License No. 21-04171-01

In response to your letter dated May 25, 1995 I am informing you that this institution does not possess source material for shielding and I do not foresee obtaining it for future use. Therefore, we do not wish to be authorized for it's use and will not be including any additional fees.

Thank you for your cooperation in this matter.

Sincerely,

Gregory L. Beckman
Executive Vice President

'95 JUN 15 P4:12
DAI /CPS

401 South Ballenger Highway • Flint, Michigan 48532-3685 • (810) 762-2000
An Affiliated Teaching Hospital of the Michigan State University College of Human Medicine
An Affiliate of McLAREN HEALTH CARE CORPORATION

NRC FORM 577 (10-94)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

McLaren Regional Medical Center
Attn: Gregory L. Beckman
Executive Vice President
401 South Ballenger Highway
Flint, Michigan 48532

TYPE OF ACTION

- [ ] NEW LICENSE
- [x] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: March 28, 1994

LICENSE NUMBER: 21-04171-04

CONTROL NUMBER: 396744

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$	$ 1400	$
2B	$	$ 160	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE $1560
PAYMENT RECEIVED $1400
AMOUNT DUE $160

- [ ] Your request was received without the prescribed application fee.
- [ ] We received your Check No. _____ in the amount of $_____. Payment of the additional fee noted above is required.
- [ ] Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- [ ] Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

- [ ] Enclosed is Check No. _____ which accompanied your request. The fee is not required because:
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- [ ] Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE -- LICENSE FEE ANALYST: Shirley Crutchfield (301) 415-6097

DATE: May 25, 1995

NRC FORM 577 (10-94)