



**Children's Hospital
of Michigan**

Detroit Medical Center / Wayne State University

September 23, 2004

3901 Beaubien
Detroit, MI 48201

UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Office of Materials Licensing
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: License Renewal Application
License # 21-03298-05

Dear Sir/Madam:

Please find the enclosed license renewal application for a NRC Byproduct materials license for:

Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

ITEM 1

Please remove 10 CFR 35.500 use from our license, as we no longer possess this type of material. The equipment that once contained the 35.500 sealed source was properly decommissioned.

ITEM 2

We have added authorized physicists to our license. We have enclosed documentation that verifies that these individuals are approved authorized medical physicists under Harper University Hospital Material License 21-04127-02.

ITEM 3

We have enclosed details of the brachytherapy procedure performed at our facility.

If you have any questions or require additional information, please contact our Medical Physics Consultant, Cari Dzanbazoff, (800) 321-2207.

Sincerely,

Larry E. Fleischmann, M.D.
President, Children's Hospital of Michigan

Enclosures

We treat your children like our own.



www.chmkids.org

SEP 29 2004

NRC FORM 313
(4-2004)
10 CFR 30, 32, 33,
34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

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 _____
- C. RENEWAL OF LICENSE NUMBER 21-03298-05

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

Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Cari Dzanbazzoff, B.S., Medical Physics Consultants, Inc.

TELEPHONE NUMBER

(734) 662-3197

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. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7C AMOUNT ENCLOSED \$ 0.00

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

Larry E. Fleischmann, MD - President

SIGNATURE



DATE

1/23/05

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		

APPROVED BY

DATE

Applicability Table

8.1	License Action Type	Enclosed
8.2	Applicant's Name and Mailing Address	Enclosed
8.3	Address where Material Used or Possessed	Enclosed
8.4	Person to Be Contacted	Enclosed
8.5	Radioactive Material	Enclosed
8.6	Sealed Sources and Devices	Enclosed
8.7	Recordkeeping for Decommissioning	N/A
8.8	Purpose for which Licensed Material is Used	Enclosed
8.9	Responsibility for Radiation Safety Program	Enclosed
8.10	Radiation Safety Officer	Enclosed
8.11	Authorized Users	Enclosed
8.12	Authorized Nuclear Pharmacist	N/A
8.13	Authorized Medical Physicist	Enclosed
8.14	Facilities and Equipment	Enclosed
8.15	Facility Diagram	Enclosed
8.16	Radiation Monitoring Instruments	Enclosed
8.17	Equipment to Measure Dosages	Enclosed
8.18	Dosimetry Equipment Calibration and Use	N/A
8.19	Other Equipment and Facilities	Enclosed
8.20	Radiation Protection Program	Enclosed
8.21	Safety Procedures and Instructions	N/A
8.22	Occupational Dose	Enclosed
8.23	Area Survey Procedures	Enclosed
8.24	Safe Use of Unsealed Licensed Material	Enclosed
8.25	Spill Procedures	Enclosed
8.26	Therapy Devices With Sealed Sources	N/A
8.27	Minimization of Contamination	Enclosed
8.28	Waste Management	Enclosed
8.29	Fees	Enclosed
8.30	Certification	Enclosed

Children's Hospital of Michigan
NRC License Renewal # 21-03298-05
September 2004

LICENSE ACTION TYPE

8.1 Item 1

Renewal of a NRC License:

APPLICANT'S NAME AND MAILING ADDRESS

8.2 Item 2

Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

8.3 Item 3

Same as Above

PERSON TO BE CONTACTED ABOUT THIS APPLICATION

8.4 Item 4

Cari Dzanbazoff, Medical Physics Consultants
Phone: 734-662-3197
Fax: 734-662-9224
cdz@mpcphysics.com

RADIOACTIVE MATERIAL

8.5 Item 5

Byproduct Material.	Chemical and/or Physical Form	Amount
A. Material in 35.100	Any radiopharmaceutical in 35.100	As Needed
B. Material in 35.200	Any radiopharmaceutical in 35.200	As Needed
C. Material in 35.300	Any radiopharmaceutical in 35.300	As Needed
D. Material in 35.400	Any brachytherapy source in 35.400	As Needed
E. Hydrogen-3	Any	200 millicuries
F. Carbon-14	Any	200 millicuries
G. Chromium-51	Any	400 millicuries
H. Zinc-65	Any	20 millicuries
I. Iodine-125	Any	100 millicuries
J. Sulfur-35	Any	100 millicuries
K. Phosphorus-33	Any	100 millicuries
L. Phosphorus-32	Any	100 millicuries
M. Any byproduct Material Listed in Subitems E.,F.,J.	Solid and/or liquid waste	Sub Item
N. Technetium-99m	Any	5 millicuries

SEALED SOURCES AND DEVICES

8.6 Item 5

Byproduct Material	Chemical/Physical Form	Maximum Amount
I-125 (specific radiation brachytherapy temporary eye plaque implants; OncoSeed)	Sealed Sources OncoSeed (I-125 Seeds) Manufacturer – Oncura Model – 6711	500 mCi

PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

8.8 Item 6

A. 10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies – Written Directive not Required
B. 10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies – Written Directive not Required
C. 10 CFR 35.300	Medical Use of Unsealed Byproduct Material – Written Directive Required
D. 10 CFR 35.400	Medical Use for Manual Brachytherapy
E-L. Any byproduct material listed in Subitems E.- L.	In Vitro Clinical Diagnosis and In Vitro Laboratory Research
M. Any byproduct material listed in Subitems E., F., and J.	Solid and/or Liquid Waste – Possession incident to interim storage of waste in accordance with statements, representations, and procedures
N. Technetium-99m	Research and Development; In Vitro Studies

RADIATION SAFETY PROGRAM RESPONSIBILITY

8.10 Item 7

Radiation Safety Officer

Chad M. Grant

8.11 Item 7

Authorized Users

Materials

Christie Becker, MD	35.100, 25.200 and 35.500
Daniel E. Eggleston, MD	35.100, 25.200 and 35.500
Joseph Kaplan, MD	Subitems 6.E. through 6.L.
Patrick Long, MD	Subitems 6.E. through 6.L.
J. Michael Zerlin, MD	35.100 and 35.200
William Lyman, MD	Subitems 6.E. through 6.L.
Jeffrey Forman, MD	35.400
David A. Bloom, MD	35.100 and 35.200
Richard N. Joyrich, MD	35.100, 35.200 and 35.300
Jacqueline Parker, BSc	Subitems 6.E. through 6.L.
Kay Beharry	Subitems 6.E. through 6.L.
Fangyu Peng, MD	35.100, 35.200 and Subitem N.

Children's Hospital of Michigan
NRC License Renewal # 21-03298-05
September 2004

AUTHORIZED MEDICAL PHYSICISTS

8.13 Item 7

Margaret M. Syrian, M.S.

Azucena Garzon, M.S.

Mark Yudelev, PhD, ABMP

Patrick N. McDermott, PhD, ABMP

Jay Burmeister, PhD, ABR

Renu Sharma, MS

Frank Van den Heuvel, PhD, ABMP

Archana R. Somnay, MS, ABR

Paul H. Mobit, PhD, ABMP

Above are also approved authorized medical physicists under Harper University Hospital Material License 21-04127-02. See enclosed letter for verification.

Children's Hospital of Michigan
NRC License Renewal # 21-03298-05
September 2004

FACILITIES AND EQUIPMENT LIST

8.14 Item 9

Imaging Equipment

Scintillation Cameras

Counting Equipment

Uptake Probe System

Well Counter

Liquid Scintillation Counters

Dose Calibrator

Capintec

Survey Meters Nuclear Medicine

Eberline GM Survey Meter

High Range (0-2000 mR/hr)

Low Range (0-0.02 mR/hr)

Biodex GM Survey Meter

High Range (0-2000 mR/hr)

Low Range (0-0.02 mR/hr)

Biodex TBM-3

Range (0-15 mR/hr)

Survey Meters PET Facility

Ludlum 14C GM Survey Meter

High Range (0-2000 mR/hr)

Low Range (0-0.02 mR/hr)

(2) Victoreen 290 GM Survey Meter (PET)

Range (0-1000 mR/h)

Survey Meters Research Labs

Eberline E-120 GM Survey Meter

Range (0-50 mR/h)

Victoreen V-700 GM Survey Meter

Range (0-50 mR/h)

Ludlum 14C GM Survey Meter

High Range (0-2000 mR/hr)

Low Range (0-0.02 mR/hr)

Children's Hospital of Michigan
NRC License Renewal # 21-03298-05
September 2004

FACILITIES AND EQUIPMENT LIST

8.14 Item 9
Continued

(2) Ludlum Model 2 GM Survey Meter
Range (0-50 mR/h)

Bicron Surveyor 50 GM Survey Meter
Range (0-50 mR/h)

Other

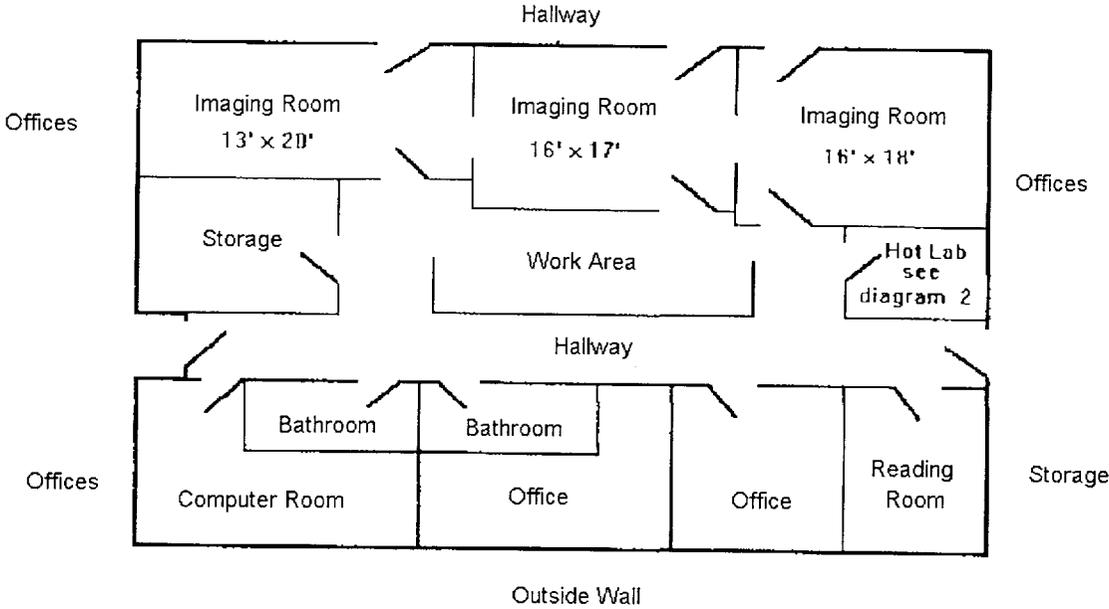
Lead Glass Face Shields
Leaded Syringe Shields
Lead Shielding
Lucite Shielding
Remote Handling Tools
Lead Bricks
RadicWash
Absorbent Pads

FACILITY DIAGRAM

NUCLEAR MEDICINE DEPARTMENT

8.15 Item 9
Diagram 1 of 2

North ↑



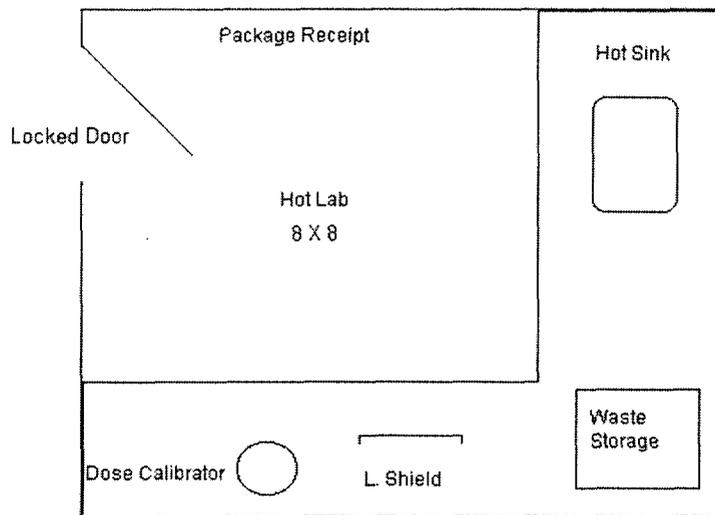
Located above the Nuclear Medicine Department – 3 Floor Research Labs
Located below the Nuclear Medicine Department – Administrative Offices

FACILITY DIAGRAM

NULCEAR MEDICINE HOT LAB

8.15 Item 9
Diagram 2 of 2

North ↑



Located above the Hot Lab – 3rd Flood Research Labs
Located below the Hot Lab – Administrative Offices

Currently we are not using a Mo-99/Tc-99m generator. If we use a generator, additional shielding will be purchased.

Access is restricted to authorized personnel only and is secured by push combination lock. All sources are properly shielded.

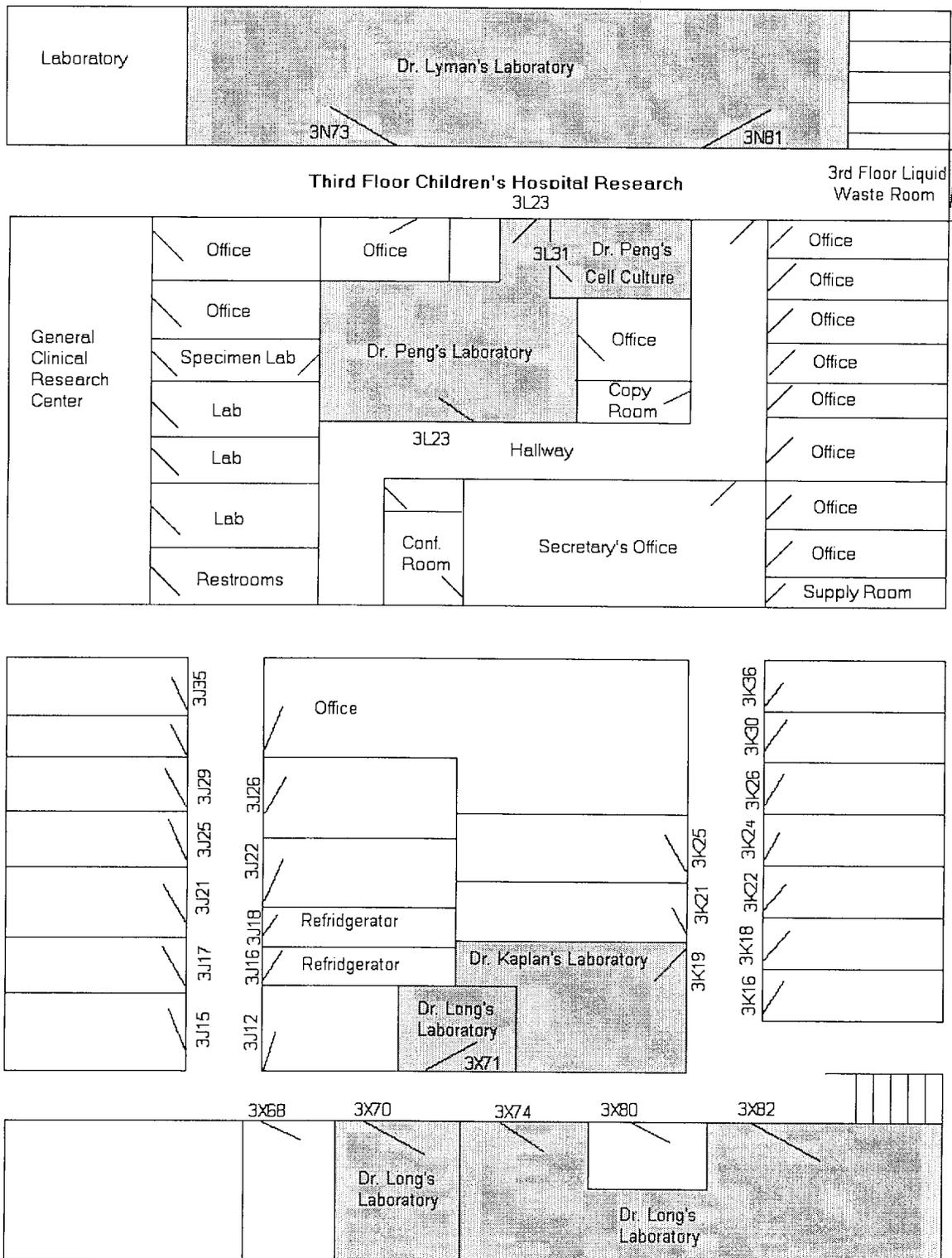
FACILITY DIAGRAM

3RD FLOOR RESEARCH LAB LAYOUT

8.15 Item 9

Shaded Areas are Radioactive Use Areas

North ↓

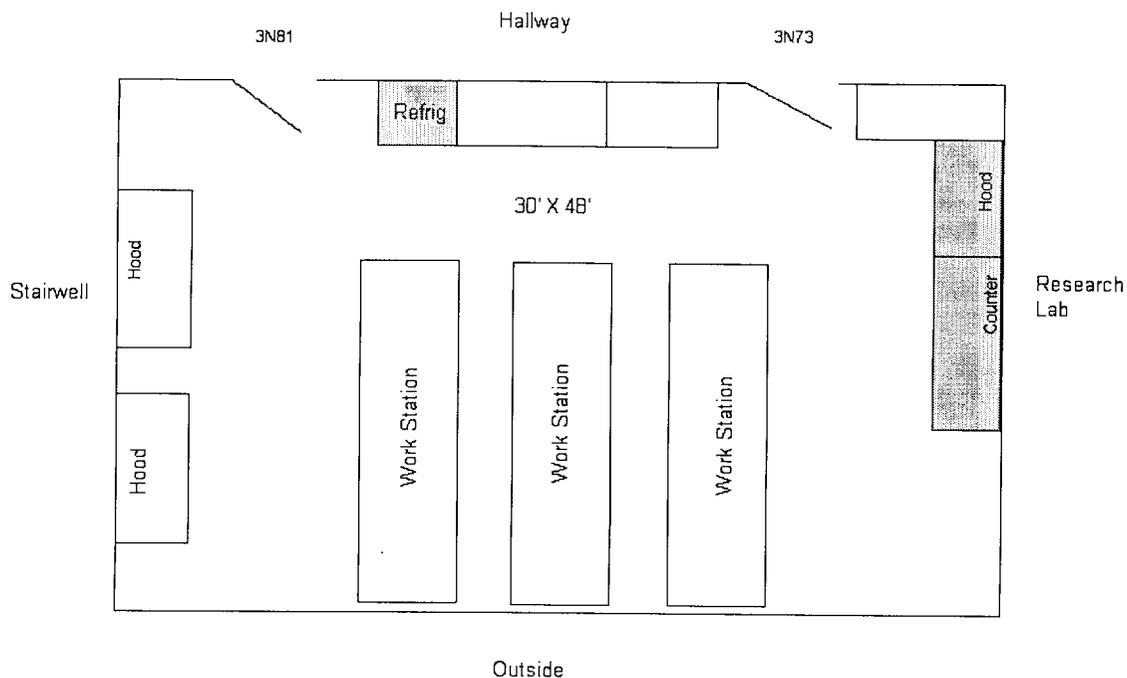


FACILITY DIAGRAM

DR. LYMAN'S RESEARCH LAB

8.15 Item 9

Shaded Areas are Radioactive Use Areas



Cement Separating Floors Above and Below – approx 12”
Floor to Floor Distance – approx 12’

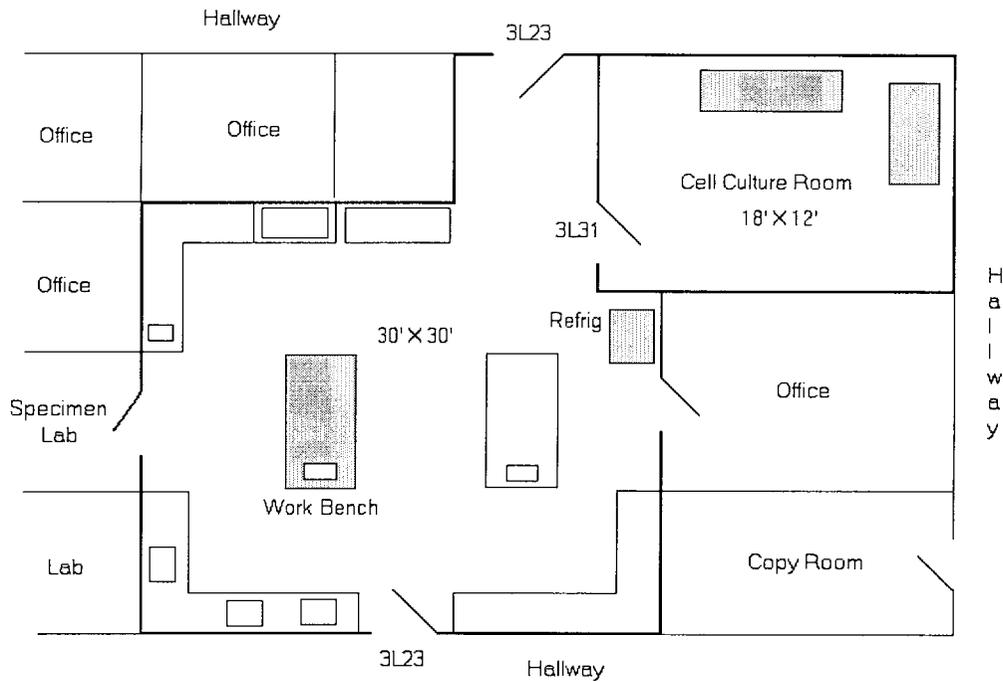
**Access is restricted to authorized personnel only and is secured by lock and key.
All sources are properly shielded.**

FACILITY DIAGRAM

DR. PENG'S RESEARCH LAB

8.15 Item 9

Shaded Areas are Radioactive Use Areas



Cement Separating Floors Above and Below – approx 12"
Floor to Floor Distance – approx 12'

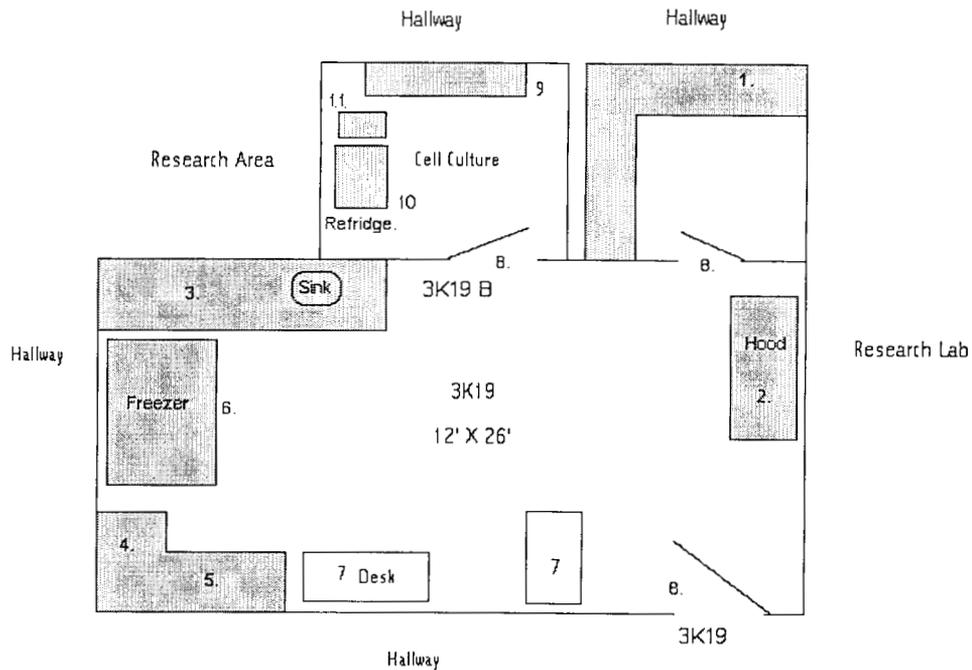
**Access is restricted to authorized personnel only and is secured by lock and key.
All sources are properly shielded.**

FACILITY DIAGRAM

DR. KAPLAN'S RESEARCH LAB

8.15 Item 9

Shaded Areas are Radioactive Use Areas



- 1) Lab Cabinets
- 2) Fume Hood
- 3) Lab Cabinets
- 4) Lab Cabinets
- 5) Lab Cabinets
- 6) Freezer
- 7) Desk
- 8) Locked Door
- 9) Hood
- 10) Refrigerator
- 11) Waste

Cement Separating Floors - approx 12"
 Floor to Floor Distance - approx 12'

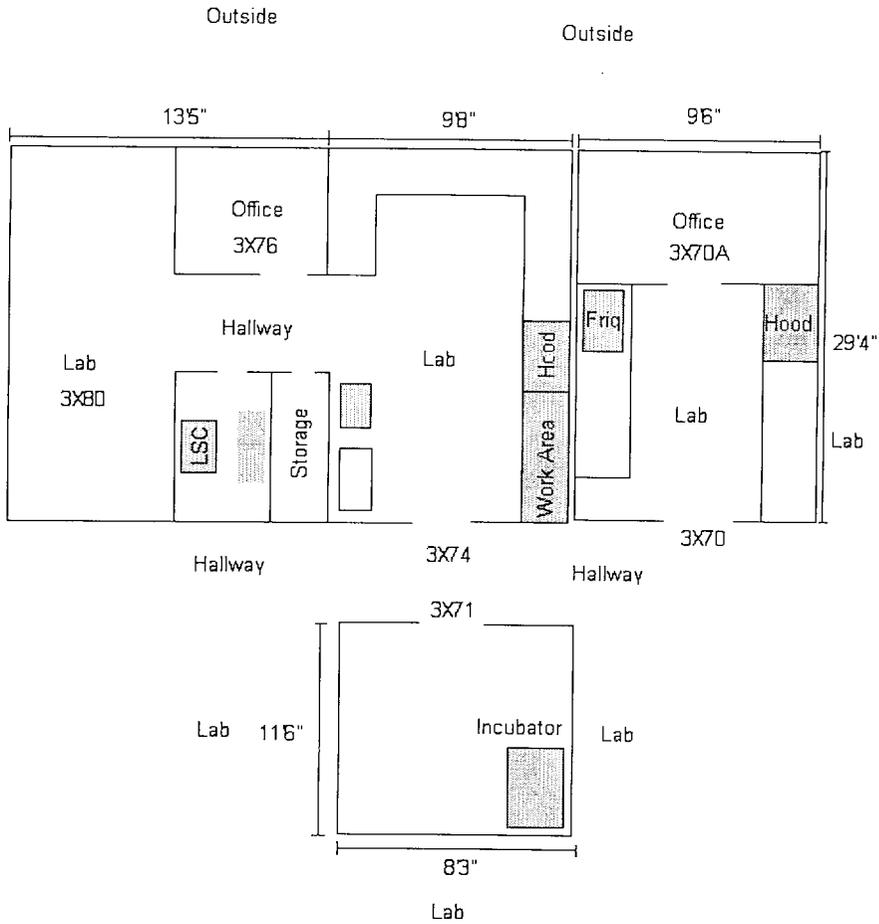
**Access is restricted to authorized personnel only and is secured by lock and key.
 All sources are properly shielded.**

FACILITY DIAGRAM

DR. LONG'S RESEARCH LAB

8.15 Item 9

Shaded Areas are Radioactive Use Areas



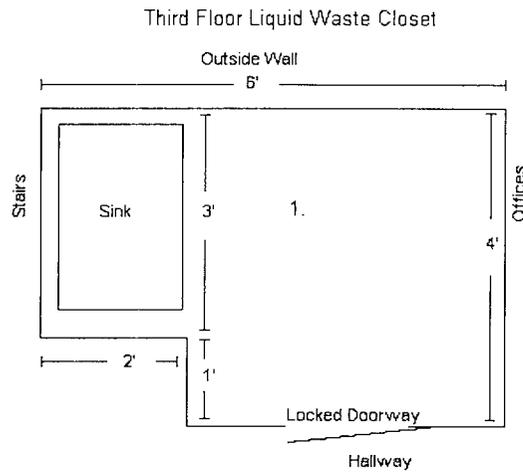
Cement Separating Floors Above and Below – approx 12"
 Floor to Floor Distance – approx 12'

**Access is restricted to authorized personnel only and is secured by lock and key.
 All sources are properly shielded.**

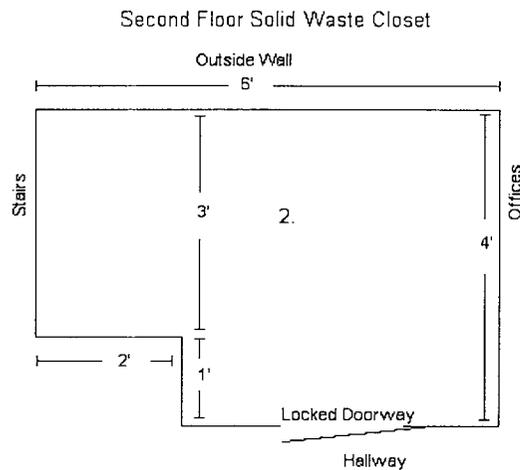
FACILITY DIAGRAM

RADIOACTIVE WASTE STORAGE AREAS

8.15 Item 9



Above Third Floor Storage Area – Hallway/Storage
Below Third Floor Storage Area – 2nd Floor Solid Waste Storage



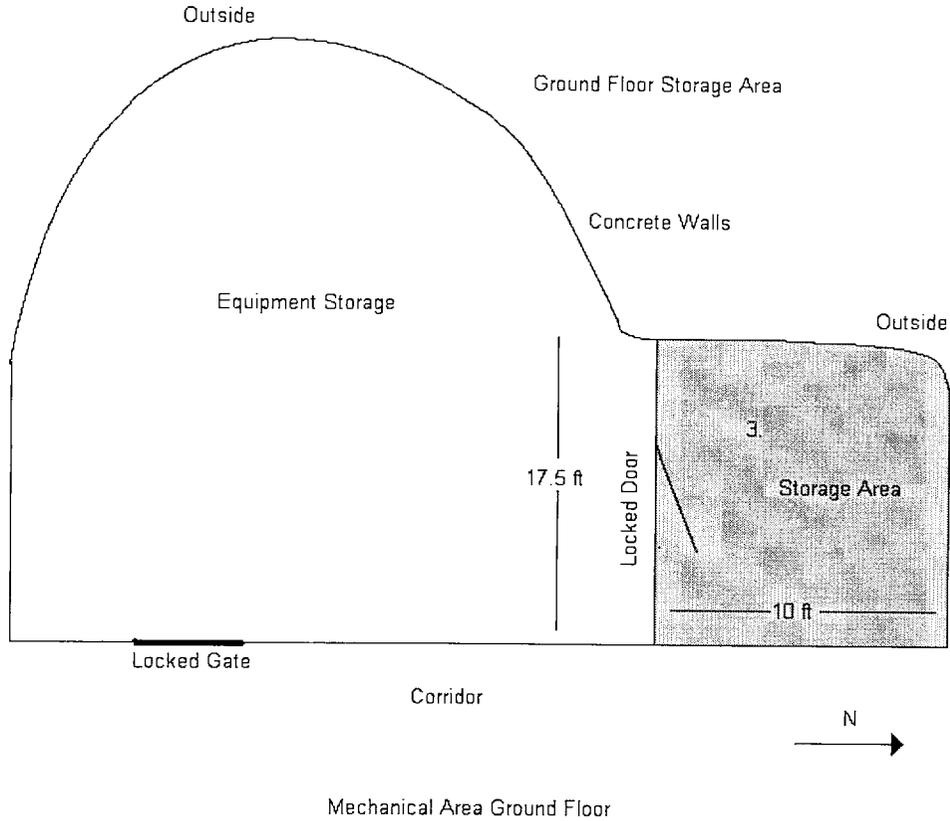
Above Second Floor Storage Area – 3rd Floor Liquid Waste Storage Area
Below Second Floor Storage Area – Medical Records

Access is restricted to authorized personnel only and is secured by lock and key.
All waste is properly labeled and shielded.

FACILITY DIAGRAM

RADIOACTIVE WASTE STORAGE AREAS CONTINUED

8.15 Item 9



Above Ground Floor Storage Area – Outside

**Access is restricted to authorized personnel only and is secured by lock and key.
All waste is properly labeled and shielded.**

RADIATION MONITORING INSTRUMENTS

8.16 Item 9

The licensee shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

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

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.

DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

8.17 Item 9

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions.

OTHER EQUIPMENT AND FACILITIES

8.19 Item 9

Equipment and facilities available for transportation and the safe use of byproduct material listed in Item 5 (Temporary Implants I-125 Eye Plaques) includes:

- Tweezers or forceps to handle sealed sources
- Lead lined storage and transportation containers
- Appropriate radiation detection equipment
- Personnel monitoring devices
- Shielding for eye plaque implants
- Signage for posting requirements
- Instruction sheets

Accidental Damage to the Seed:

Although the seeds have high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing to rupture a seed causing it to release "free" I-125. If this happens, the area of the accident should be closed off, the seeds should be sealed in a lead container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to the established procedures. Personnel working in or near the accident should undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

For additional information, please see the enclosed procedure Temporary Implants (Iodine-125 Eye Plaques).

RADIATION PROTECTION PROGRAM

8.20 Item 10

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 unusual.
2. All individuals who are occupationally exposed to 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. All individuals who are occupationally exposed to significant radiation levels on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.
5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.
6. All film and TLD badges will be changed on a monthly basis.
7. We will use a NVLAP accredited dosimetry processor.

OCCUPATIONAL DOSE

8.22 Item 10

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

AREA SURVEYS

8.23 Item 10

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

SAFE USE OF UNSEALED LICENSED MATERIAL

8.24 Item 10

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

SPILL PROCEDURES

8.25 Item 10

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

Children's Hospital of Michigan
NRC License Renewal # 21-03298-05
September 2004

MINIMIZATION OF CONTAMINATION

8.27 Item 10

WASTE MANAGEMENT

8.28 Item 11

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

FEES

8.29 Item 12

Refer to NRC Form 313

CERTIFICATION

8.30 Item 13

Refer to NRC Form 313



Harper University Hospital
Detroit Medical Center / Wayne State University

3990 John R.

Detroit, MI 48201

September 14, 2004

To Whom It May Concern:

This letter shall certify that the following named individuals are authorized physicists under the United State Nuclear Regulatory Commission (NRC) Materials License 21-04127-02.

Individuals: Mark Yudelev, Phd, ABMP
 Patrick N. McDermott, Phd, ABMP
 Jay Burmeister, Phd, ABR
 Renu Sharma, MS
 Margaret M. Syrian, MS
 Azucena Garzon, MS, ABR
 Archana R. Somnay, MS, ABR
 Paul H. Mobit, Phd, ABMP

Authorized Use: Human Use under 10 CFR 35.400 and
 Non Human Use Cs-137 and Cf-252 Instrument Calibration

If you have any questions regarding this matter, please contact me a 313.745.8418.

Sincerely,

Richard N. Joyrich, M.D., ABNM
Authorized User
Radiation Safety Officer



Harper University Hospital
Detroit Medical Center/Wayne State University

Your name here

3990 John R Rd.
Detroit, MI 48201

**HYBRID MATERIAL LICENSE 21-04127-02
PRINCIPAL INVESTIGATORS OR AUTHORIZED USERS
OF
RADIOACTIVE MATERIAL**

HUMAN USE - 10 CFR 35.100, 35.200, 35.300, 35.500

August 24, 2004

Richard N. Joyrich, MD, ABNM	ALL	
Subash Chander, MD, ABNM	ALL	
Cheryl Gregorian, MD, ABR	ALL	Excluding 10 CFR 35.500 and ¹³¹ I for Thyroid Ca Tx
Arthur T. Porter, MD, RCPSC	ALL	Excluding 10 CFR 35.100, 35.500 and ¹³¹ I for therapy

HUMAN USE - 10 CFR 35.100, 35.200, 35.300 – Thyroid Diagnosis & Therapy Only

Nandalal Bagchi, MD, ABIM
Gina Sleilati, M.D., ABIM

HUMAN USE - 10 CFR 35.200, Nuclear Cardiology Only

Florence Prigent, M.D., ABNM
Frank Mohammed Fayz, M.D., ABR
Edouard Daher, MD, CBNC
Deepak Thatai, MD

HUMAN USE - 10 CFR 35.400, 35.600, Ir-192 HDR, I-125 Gliasite, Ir-192 IVB

Arthur T. Porter, MD, RCPSC
Jeffery D. Forman, MD, ABR
Kenneth J. Levin, MD, ABR, ABIM
Harold E. Kim, MD, ABR
Kimberly B. Hart, MD, ABR
Augustine Fregene, MD, ABR
Tara Washington, MD, ABR
Laura Michelle Freedman, MD, ABR
Andrew T. Turrisi, III, M.D., ABR
Donald D. Howell, M.D., ABR
meer Keole, M.D.

**HYBRID MATERIAL LICENSE 21-04127-02
PRINCIPAL INVESTIGATORS OR AUTHORIZED USERS
OF
RADIOACTIVE MATERIAL**

HUMAN USE - 10 CFR 35.100, 35.200, 35.300, 35.500

August 24, 2004

Richard N. Joyrich, MD, ABNM	ALL	
Subash Chander, MD, ABNM	ALL	
Cheryl Gregorian, MD, ABR	ALL	Excluding 10 CFR 35.500 and ¹³¹ I for Thyroid Ca Tx
Arthur T. Porter, MD, RCPSC	ALL	Excluding 10 CFR 35.100, 35.500 and ¹³¹ I for therapy

HUMAN USE - 10 CFR 35.100, 35.200, 35.300 – Thyroid Diagnosis & Therapy Only

Nandalal Bagchi, MD, ABIM
Gina Sleilati, M.D., ABIM

HUMAN USE - 10 CFR 35.200, Nuclear Cardiology Only

Florence Prigent, M.D., ABNM
Frank Mohammed Fayz, M.D., ABR
Edouard Daher, MD, CBNC
Deepak Thatai, MD

HUMAN USE - 10 CFR 35.400, 35.600, Ir-192 HDR, I-125 Gliosite, Ir-192 IVB

Arthur T. Porter, MD, RCPSC
Jeffery D. Forman, MD, ABR
Kenneth J. Levin, MD, ABR, ABIM
Harold E. Kim, MD, ABR
Kimberly B. Hart, MD, ABR
Augustine Fregene, MD, ABR
Tara Washington, MD, ABR
Laura Michelle Freedman, MD, ABR
Andrew T. Turrisi, III, M.D., ABR
Donald D. Howell, M.D., ABR
Sameer Keole, M.D.

BLOOD BANK IRRADIATOR – GAMMACELL 3000 ELAN

Maria E. Dan, M.D.



Harper University Hospital
 Detroit Medical Center / Wayne State University

Your name here

3990 John R Rd.
 Detroit, MI 48201

BLOOD BANK IRRADIATOR – GAMMACELL 3000 ELAN

Maria E. Dan, M.D.

HUMAN USE - RESEARCH

<u>Principal Investigator</u>	<u>Radiopharmaceutical</u>	<u>Use</u>	<u>FDA/ Phase</u>	<u>Approval Date</u>
Michael Kraut, MD	^{99m} Tc-DTPA	Aerosol Lung Deposition, Predict ChemoTx	NDA	08/14/01
Anthony Shields, MD, Ph.D.	¹⁸ F-FLT	IV Brain Tumors	IND	09/2001

NON-HUMAN USE - IN VITRO - MPL (Prin. Investigator, Contact)

<u>Principal Investigator</u>	<u>Radiopharmaceutical</u>	<u>Use</u>	<u>FDA/ Phase</u>	<u>Approval Date</u>	
Gerald L.. Feldman, MD, Ph.D. Holly Pinder or Andriana	³² P Any 10 mCi	Molecular Genetics	N/A	08/14/01	Pathology WG1254
Michael Joyner, Ph.D. ROC	⁶⁰ Co Irradiator 1000 Ci	Cell Irradiation at Low Dose Rates	N/A	6/25/02	

NON-HUMAN USE - ANIMAL RESEARCH

NO ACTIVE PRINCIPAL INVESTIGATORS

NON-HUMAN USE - Cs-137 & Cf-252 INSTRUMENT CALIBRATION

Human Use - Brachytherapy Medical Physicists

- Mark Yudelev, Ph.D., ABMP
- Patrick N. McDermott, Ph.D., ABMP
- Jay Burmeister, Ph.D., ABR
- Renu Sharma, MS
- Margaret M. Syrian, MS
- Frank Van den Heuvel, Ph.D., ABMP
- Lucena Garzon, MS, ABR
- Archana R. Somnay, MS, ABR
- Paul H. Mobit, Ph.D., ABMP



**Children's Hospital
of Michigan**

Detroit Medical Center/Wayne State University

3901 Beaubien Blvd
Detroit, MI 48201

Temporary Implants (Iodine-125 Eye Plaques)

Each Iodine-125 seed is a titanium encapsulated source of 4.5 mm in length and 0.8 mm in diameter. From four to twenty four sources are placed into a silicone rubber seed carrier insert with a gold backing. The plaque is sewn directly to the sclera and is left in place from 3 to 5 days. At the end of this time a second surgery is performed to remove it.

Since I-125 emits very low energy x-rays, there is virtually no external radiation hazard associated with these implants. The plaque is completely shielded on the side away from the eyeball. Further shielding is provided by a lead lined eye patch.

Sources are prepared in Harper Hospital's source storage room and are transported to Children's Hospital in a shielded container through the underground tunnel by a physicist from the Radiation Oncology Center (ROC).

A physician from children's Hospital will perform the implant in the operating room. A physician and a physicist from the ROC will be present during the procedure.

After completion of the implant, a radiation survey is performed. This survey includes the unshielded and shielded eye and all other instruments utilized during the procedure and confirms that no loose seeds remain. Retrieved seeds are kept in a lead storage container and returned together with any unused seeds to the source storage from Harper Hospital.

A "CAUTION – RADIOACTIVE MATERIAL" sign is placed on the patient's chart at this time.

The patient returns to a private room after recovery. Shortly thereafter, a ROC physicist performs a radiation survey in the patient's room. This survey is documented on the form entitled "I-125 Protection Survey and Implant Record". This form is placed in the patient's chart. The door is posted with a "CAUTION – RADIOACTIVE MATERIAL" sign and with a sheet of information for hospital personnel and visitors. An instruction sheet entitled "Nursing Instructions for Patients Receiving I-125 Eye Plaques" is placed in the chart.

At the end of the prescribed treatment time a physician from Children's Hospital will remove the eye plaque in the operating room. A physicist from the ROC will be present and will count the seeds and verify that the implanted seeds have been removed. A



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radiation survey of the eye that was implanted will be performed. The eye plaque will be placed in a shielded container and returned to the source room at Harper Hospital.

On discharge of the patient, the "CAUTION – RADIOACTIVE MATERIAL" signs are removed from the door and chart together with the nursing instructions. The survey form is filed in the ROC.

Although these seeds have a high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing, to rupture a seed causing it to release "free" I-125. If this happens, the area of the accident will be closed off, the seeds will be sealed in a lead container; personnel movement will be controlled to avoid spread of any radioactive contamination and the area and personnel will be decontaminated according to our established procedures (see section 14, "Radioactive Spills"). Personnel working in or near the accident will also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

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