

### 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.**

<p><b>FEDERAL AGENCIES FILE APPLICATIONS WITH:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS WASHINGTON, DC 20546</p> <p><b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:</b></p> <p><b>CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR MATERIAL SECTION 9 931 PARK AVENUE RING OF PRUSSIA, PA 19043</p> <p><b>ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION II MATERIAL RADIATION PROTECTION SECTION 101 MARIETTA STREET, SUITE 2620 ATLANTA, GA 30333</p>	<p><b>IF YOU ARE LOCATED IN:</b></p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION III MATERIALS LICENSING SECTION 790 ROOSEVELT ROAD GLEN OLLYR, IL 60137</p> <p><b>ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, DELAWARE, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION IV MATERIAL RADIATION PROTECTION SECTION 611 RYAN PLAZA DRIVE, SUITE 1000 ARLINGTON, TX 76011</p> <p><b>ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION V MATERIAL RADIATION PROTECTION SECTION 1450 MARIA LANE, SUITE 210 WALNUT CREEK, CA 94590</p>
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PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL OR STATED SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

<p><input checked="" type="checkbox"/> THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. REMOVAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)</p> <p>MENNONITE GENERAL HOSPITAL Nuclear Medicine Laboratory G.P.O. Box 1379 Aibonito, P.R. 00609</p>
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Calle José C. Vazquez No.120  
Barrio Caonillas - AIBONITO, P.R.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION	TELEPHONE NUMBER
Sandra C. Gracia-López, M.D.	(809) 735-8001 / 758-7575 Ex.3254

SUBMIT ITEMS 6 THROUGH 11 ON 8 1/2" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

<p>6. RADIOACTIVE MATERIAL a. Isotopes and their number, b. chemical and/or physical form, and c. maximum amount which will be processed at any one time. See ATT. 5 and 6</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED. See ATT. 5 and 6</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE. See ATT. 7</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS See ATT. 8</p>
<p>9. FACILITIES AND EQUIPMENT. See ATT. 9</p>	<p>10. RADIATION SAFETY PROGRAM See ATT. 10 and 11</p>
<p>11. WASTE MANAGEMENT. See ATT. 10 and 11</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$ 580.00</p>

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, 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.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE

14. VOLUNTARY ECONOMIC DATA										
<p>a. ANNUAL RECEIPTS</p> <table border="1" style="width:100%;"> <tr><td><input type="checkbox"/> &lt;\$250K</td><td><input type="checkbox"/> \$1M - 3.5M</td></tr> <tr><td><input type="checkbox"/> \$250K - 500K</td><td><input type="checkbox"/> \$3.5M - 7M</td></tr> <tr><td><input type="checkbox"/> \$500K - 750K</td><td><input type="checkbox"/> \$7M - 10M</td></tr> <tr><td><input type="checkbox"/> \$750K - 1M</td><td><input type="checkbox"/> &gt;\$10M</td></tr> </table>	<input type="checkbox"/> <\$250K	<input type="checkbox"/> \$1M - 3.5M	<input type="checkbox"/> \$250K - 500K	<input type="checkbox"/> \$3.5M - 7M	<input type="checkbox"/> \$500K - 750K	<input type="checkbox"/> \$7M - 10M	<input type="checkbox"/> \$750K - 1M	<input type="checkbox"/> >\$10M	<p>b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)</p> <p>c. NUMBER OF BEDS</p>	<p>d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollars and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial - proprietary - information furnished to the agency in confidence)</p> <p style="text-align: center;"><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<input type="checkbox"/> <\$250K	<input type="checkbox"/> \$1M - 3.5M									
<input type="checkbox"/> \$250K - 500K	<input type="checkbox"/> \$3.5M - 7M									
<input type="checkbox"/> \$500K - 750K	<input type="checkbox"/> \$7M - 10M									
<input type="checkbox"/> \$750K - 1M	<input type="checkbox"/> >\$10M									

FOR NRC USE ONLY			
TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
APP	Jul-1-II	7C	Code 23
AMOUNT RECEIVED	CHECK NUMBER	APPROVED BY	
\$580	003381	M. Messier	
		DATE	
		7/5/89	
		9001250454 890907 REG2 LIC30 50-25058-01 PDR	

## PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission  
Director, Division of Fuel Cycle and Material Safety  
Office of Nuclear Material Safety and Safeguards  
Washington, D.C. 20555

MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY  
June 10, 1989

Attachments 5 and 6

Item 5 : Radioactive materials

Item 6 : Purpose

Table 1 indicates the use and the maximum amounts of radioactive materials to be used at the Mennonite General Hospital Nuclear Medicine Laboratory.

Table 1

<u>Byproduct material</u>	<u>Amount</u>	<u>Purpose</u>
5.a material in & 35.100	as needed	6.a medical use
5.b material in & 35.200	as needed	6.b medical use
5.c material in & 35.300	as needed	6.c medical use
5.f material in & 35.500	as needed	6.f medical use

MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY  
June 10, 1989

Attachments 7.1 and 7.3

Authorized users, Radiation Safety Officer ( RSO ), Radiation Physics Consultant ( RPC ) and Radiation Safety Technologist (RSTech ).

- 7.1.1 Sandra C. Gracia-López, MD, Authorized user and RSO. Certified by the American Board of Nuclear Medicine (please see enclosed copy ) and Institutional Authorized User for the U.P.R. Medical Sciences Campus - NRC Broad Scope Lic. No. 52-01946-07.

Proposed use : medical use

Byproduct materials : Groups 5a - 5b - 5c - 5f

- 7.1.2 Jose R. Vázquez-Selles, MD, Authorized user. Certified by the American Board of Nuclear Medicine ( please see enclosed copy ) and Institutional Authorized User for the U.P.R. Medical Sciences Campus - NRC Broad Scope Lic. No. 52-01946-07.

Proposed use : medical use

Byproduct materials : Groups 5a - 5b - 5c - 5f

- 7.3.1 Santiago Gómez-Figueroa, MS, Radiation Physics Consultant. Reference is made to NRC Licenses No. 52-17273-01 and 52-23044-01 Nuclear Medicine laboratories where Mr. Gómez Figueroa is the Radiation Physics Consultant and also to NRC Lic. No. 52-17420-01 for Leak Testing.
- 7.3.2 Maritza Consuegra-Cárdenas, BS, Radiation Safety Technologist. Reference is made to NRC Licenses No. 52-17273-01 and 52-24916-01. She works as RSO and RPC assistant.

*Handwritten notes:*  
not RSO  
see pg 12 #3  
Do Maritza Consuegra as RSO

# The American Board of Nuclear Medicine

Incorporated 1971

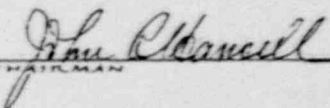
Organized with the cooperation of the American Board of Internal Medicine,  
American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine  
hereby certifies that

**Sandra E. Gracia López, M.D.**

has met the requirements of this Board and is  
certified as qualified to practice as a specialist in  
all aspects of clinical and laboratory

## Nuclear Medicine

including but not limited to Radiobioassay, Nuclear Imaging,  
in Vivo Measurements & Therapy with unsealed Radionuclides.

  
CHAIRMAN



  
SECRETARY

05366  
NUMBER

9/10/88  
DATE

# The American Board of Nuclear Medicine

Incorporated 1971

Organized with the cooperation of the American Board of Internal Medicine,  
American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine  
hereby certifies that

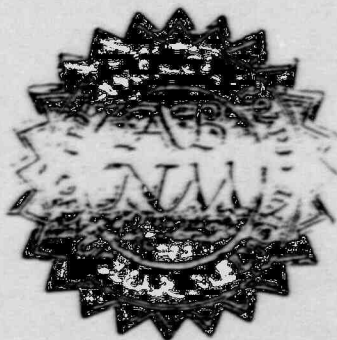
## José R. Vázquez Selles

has met the requirements of this Board and is  
certified as qualified to practice as a specialist in  
all aspects of clinical and laboratory

## Nuclear Medicine

including but not limited to Radiobioassay, Nuclear Imaging,  
in Vivo Measurements & Therapy with unsealed Radionuclides.

*J. Ross Mc'Dougall*  
CHAIRMAN



*[Signature]*  
SECRETARY

05265  
NUMBER

9/12/87  
DATE

MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY  
June 10, 1989

Attachment 8

Training for individuals working in or frequently entering restricted areas.

8.1 Training Program

1 - We will establish and implement the model training program that was published in appendix A to Regulatory Guide 10.8 Revision 2 ( August 1987 ).

2 - The following Table identifies the group of workers, method of training and frequency : *(Appendix A requires annual refresher training)*

a - Nuclear Medicine Physician :

Any human use of byproduct material must be carried out by or under the supervision of a physician as defined in 10 CRF 35.2. Subpart J of the Nuclear Regulatory Commission revised 10 CRF Part 35 outlines the training and experience that the Commission has found acceptable for physicians who will use byproduct materials for human use, listed in sections 35.100, 35.200, 35.300 and 35.500.

b - Radiation Protection Officer :

Shall fulfill the training and experience requirements as provided in Part 35 Subpart J, 35.900 and/or 35.901.

c - Radiation Physics Consultant :

Shall have the following minimum training and experience:

1 . A Master or Doctors Degree in Physics, Biophysics, Radiological Health or Health Physics.

2 . One year of full-time training in Nuclear Medicine Laboratories.

3 . One year of full- time experience in an institution with Nuclear Medicine facilities including the use of safety devices and equipment calibration.

d - Nuclear Medicine Technologist :

1 . Shall have a formal or on the job training in Nuclear Medicine Technology and Radiation Protection. Technologist with formal training in a recognized institution in Puerto Rico or Continental USA are preferred.

2 . Shall have a working knowledge of the rules and regulations promulgated by the Nuclear Regulatory Commission and/or shall be instructed as specified in 10 CRF 19.12.

3 . Shall comply with all the regulations of the Mennonite General Hospital Nuclear Medicine Laboratory.

e - All other personnel :

Including housekeeping, nurses, security personnel, etc. will be required an initial training prior to starting working in the Mennonite General Hospital Nuclear Medicine Laboratory. This training will include laboratory demonstrations and lectures on :

Basic concepts of radiation

Different types of radiation and effects

Laws and regulations

Basic principles of radiation protection

Patient care during radioisotopes treatment

Procedures to minimize radiation exposure and applicable provisions and regulations in accordance with Section 10 CRF-19.12.

This initial training will be followed by annual refreshing lectures.



MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY

June 10, 1989

Attachment 9

Facilities and equipment

9.1 Annotated drawings

1 . The appended Att. 9.1.1 Layout Diagram describes the rooms and adjacent areas where radioactive materials will be used at the Mennonite General Hospital Nuclear Medicine Laboratory.

2 . The appended Att. 9.1.2 is the expanded view of the "hot room" showing the additional safety equipment of the laboratory.

9.2 Survey Instrument Calibration

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

9.3 Dose Calibrator Calibration

We will establish and implement the model procedure for calibrating our Dose Calibrator that was published in Appendix B to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

9.4 Personnel Monitor Program

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

9.5 Imaging Equipment

N/A

9.6 Other equipment and facilities

See appended Att. 9.6.

MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY  
June 10, 1989

Att. 9.6

Other Equipment and Facilities

1. Survey meter

a. Manufacturers name : Ludlum Corp.

Manufacturers model number : 14 C Probe model 44-6

Number of instruments available : 1

Minimum range : 0.0 mR/hr to 0.2 mR/hr

Maximum range : 0.0 mR/hr to 2000 mR/hr

2. Dose calibrator

a. Manufacturers name : Capintec Inc.

Manufacturers model number : CRC - 30 BC Dose Calibrator

Number of instruments available : 1

3. Instruments used for diagnostic procedures

<u>Type of instrument</u>	<u>Manufacturers name</u>	<u>Model No.</u>
a. Sophy Gamma Camera Integrated All Purpose Camera/Computer System	Sopha Medical Systems	DS-7
b. Thyroid Uptake System	Atomic Products	cat.# 187-295
4. Other		
a. Radioiodine Fume Hood	Atomic Products	cat.# 190-210
b. Protective Lead Barrier	Atomic Products	cat.# 56-608
c. Lineator (linearity check)	Atomic Products	cat.# 34-210

MENNONITE GENERAL HOSPITAL  
NUCLEAR MEDICINE LABORATORY  
June 10, 1989

Attachments 10 and 11

Radiation Safety Program-Waste Management

10.1 Radiation Safety Committee/Radiation Safety Officer/Radiation  
Physics Consultant

1. Radiation Safety Committee

The Radiation Safety Committee shall be advisory on all matters of radiation safety and medical uses of isotopes that may arise from the activities of the medical institution. The Radiation Safety Committee of the Mennonite General Hospital shall insure that all nuclear radiation workers have sufficient training and experience to perform their duties in a safe manner and in accordance with NRC regulations and the conditions of the license.

The Radiation Safety Committee Charter, i.e. duties, responsibilities and administrative information as specified in Appendix F, Regulatory Guide 10.8, Revision 2 ( August 1987 ).

2. Radiation Safety Officer

The Radiation Safety Officer shall have full authority to stop without consultation any procedure using radionuclides which he or she deems unsafe. Has no disciplinary authority which shall reside instead with the hospital Administrator. The following outline delineates his or her responsibilities for ensuring radiological safety in the Mennonite General Hospital.

- a. General surveillance over all radioisotope activities at Mennonite General Hospital including the procurement, use and disposition of radioactive materials.
- b. Supervision and coordination of the radiation safety inspections to the laboratory facilities and keeping records.
- c. Maintaining and operating a personnel monitoring service suited to the needs of the radiation sources being used.
- d. Contacting a calibration facility for survey instruments and monitoring devices used.
- e. Supervision and coordination of the waste disposal program, including the keeping of temporary radwaste storage records, the collections and processing of solid waste for ultimate disposal.

- f. Receiving, delivering and shipping all radionuclides coming to or leaving the Mennonite General Hospital facilities.
- g. Maintaining a periodic inventory of all radioisotopes and storage of those radioactive materials not in continual use at the Institution.
- h. Notifying individuals and the proper authorities whenever a radiation exposure or situation reaches maximum permissible levels and recommending appropriate remedial action.
- i. Supervising decontamination procedures in cases of contaminating accidents.
- j. Furnishing consulting services to personnel at all levels of responsibility on any aspect of radiation protection.
- k. Organizing lectures or seminars for new personnel and refresher courses once a year on topics concerning radiation hazards and protection.
- l. Attending as active member the meetings of the Radiation Safety Committee.
- m. Delegation of authority as specified in Appendix F, Regulatory Guide 10.8, Revision 2 ( August 1987 ).

### 3. Radiation Physics Consultant

- a. The RSO, Dr. Sandra Gracia-López, is the person in charge of the Radiation Safety Program on a day by day basis .
- b. The Radiation Physics Consultant, Mr. Santiago Gómez Figueroa will realize both functions as advisor on radiation matters for the Hospital and assistant to the RSO.
- c. Duties :

1-To collaborate with the RSO in the implementation of the radiation safety program and control the emergencies in the hospital.

2-Visit the hospital and the Nuclear Medicine Laboratory at least quarterly, perform an overall safety inspection of the facilities, review the records and make a report.

3-Supervise the radiation safety and the nuclear medicine technologist in the implementation of the quality control program

in the laboratory.

4-Attend meetings of the radiation safety committee as an invited guest.

5-Advise and collaborate to answer any communication with the NRC, Department of Health of Puerto Rico and any other federal or local agencies concerning radiation safety and compliance with regulations.

d. The Radiation Safety Technologist, Ms. Maritza Consuegra Cárdenas will be an assistant to the RSO to collaborate in performing radiation surveys, wipe tests, handling radioactive waste and other clerical health physics work which will be evaluated and recorded under the supervision of the RSO and/or the Radiation Physics Consultant.

#### 10.4 Safe use of radiopharmaceuticals

We will establish and implement the model safety rules published in Appendix (1) to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

#### 10.5 Spill procedures

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

#### 10.6 Ordering and receiving

We will establish and implement the model guidance for ordering and receiving radioactive materials that was published in Appendix (J) to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

#### 10.7 Opening packages

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2 ( August 1987 ), Alternate record form as appended in Att. 10.7.

#### 10.8 Unit dosage records

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

#### 10.9 Multidose vial records

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

10.10 Molybdenum Concentration records

We will establish and implement the model procedure for measuring and recording Molybdenum concentrations that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

10.11 Implant source use records

Not applicable

10.12 Area survey procedures

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2 ( August 1987 ). Sample record forms are appended as Att. 10.12.

10.13 Air concentration controls

We will establish and implement the model procedure for monitoring, controlling and calculating worker dose from aerosols that was published in Appendix O to Regulatory Guide 10.8, Revision 2 ( August 1987 ).

10.14 Radiopharmaceutical therapy

We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2 ( August 1987 ). Sample record form is appended as Att. 10.14.

10.15 Implant therapy

Not applicable

Item 11 : Waste management

11.1 Waste disposal

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2 ( August 1987 ). Sample record form is appended as Att. 11.1.

A T T A C H M E N T 10.2

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES  
A L A R A

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Licensee's Name: MENNONITE GEN. HOSPITAL - Nuclear Medicine Laboratory  
NRC Lic. No. \_\_\_\_\_  
Date: June 10, 1989

I. Management Commitment

- a) We, the management of this Medical Institution, are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our Institution. The organization will include a Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO).
- b) We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c) Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, 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 where reasonable. Where 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.

## II. Radiation Safety Committee (RSC)

### a) Review of Proposed Users and Uses:

1. The RSC will thoroughly review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that the user 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 efforts of the authorized users 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

The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.

1. The RSC will delegate sufficient authority to the RSO for enforcement of the ALARA concept.
2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action 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 where Investigational Levels in Table I below are exceeded.

The principal purpose of this review is to assess trend in occupational exposure as an index of the ALARA Program quality and to decide if action is warranted when Investigational Levels are exceeded. (See paragraph VI).

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

### III. Radiation Safety Officer (RSO)

#### a) Annual and Quarterly Review

##### 1. Annual Review of the Radiation Protection Program

The RSO will perform an annual review of the Radiation Protection Program for adherence to ALARA concepts. Reviews of specific procedures 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 paragraph VI 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 doses 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 an ALARA Program

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

2. The RSO will assure 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 formulation of the procedures that they will be required to follow.

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 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 determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

IV. Authorized Users

a) New methods of use Involving Potential Radiation Doses

1. The authorized user will consult with, and receive the approval of the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
2. The authorized user will review all procedures before using radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

- b) Responsibility of the Authorized User to supervised individuals
1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all supervised individuals.
  2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Doses

- a) Workers will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- b) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

VI. Establishment of Investigational Level in Order to Monitor Individual Occupational External Radiation Doses

This Institution hereby establishes Investigational Levels for occupational external radiation doses which when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

T A B L E I

	Investigaitonal Levels - (mrems per calendar quarter)	
	<u>LEVEL I</u>	<u>LEVEL II</u>
1) Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2) Hands and forearms; feet and ankles	1875	5625
3) Skin of whole body	750	2250

The Radiation Safety Officer will review and record the results of Personnel Radiation Exposure Reports, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table I:

- a) Personnel dose less than Investigational 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 I values for the Investigational Level I.

- b) Personnel dose equal to or greater than Investigational Level I, but less than Investigational Level II

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational 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 Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such dose 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 Investigational Level II

The RSO will investigate in a timely manner the cause(s) of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken and a copy of the individual's Radiation Exposure Record will be presented to the RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes.

- d) Re-establishment of Investigational Levels to Levels above these listed in Table I.

In cases where a worker's or a group of worker's doses need to exceed an Investigational Level, a new, higher Investigational Level may be established on the basis

that it is consistent with good ALARA practices for that individual or group. Justification for new Investigational Levels will be documented.

The Radiation Safety Committee will review the justification for and must approve or disapprove all revisions of Investigational Levels.

VII. Signature of Certifying Official

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

INSTITUTION'S NAME AND ADDRESS:

MENNONITE GENERAL HOSPITAL  
Nuclear Medicine Laboratory  
Calle José C. Vazquez No. 120  
Barrio Caonillas  
AIBONITO, Puerto Rico



Signature

Ramón Alvarado Torres

(Name - Print or type)

Administrator

Title

June 16, 1989

Date

HPO-FORM	RADIOACTIVE SHIPMENT RECEIPT REPORT	MONTH _____ YEAR _____
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1. P.O.# \_\_\_\_\_ SURVEY DATE \_\_\_\_\_ TIME \_\_\_\_\_  
SURVEYOR \_\_\_\_\_

2. CONDITION OF PACKAGE:

\_\_\_\_\_ O.K. \_\_\_\_\_ PUNCTURED \_\_\_\_\_ STAINS \_\_\_\_\_ WET  
\_\_\_\_\_ CRUSHED \_\_\_\_\_ OTHER \_\_\_\_\_

3. RADIATION UNITS OF LABEL: \_\_\_\_\_ UNITS (mR/hr)

4. MEASURED RADIATION LEVELS: a. Package surface \_\_\_\_\_ mR/hr  
b. 1 meter from surface \_\_\_\_\_ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. Radionuclide \_\_\_\_\_ yes \_\_\_\_\_ no difference \_\_\_\_\_  
b. Amount \_\_\_\_\_ yes \_\_\_\_\_ no difference \_\_\_\_\_  
c. Chem From \_\_\_\_\_ yes \_\_\_\_\_ no difference \_\_\_\_\_

6. WIPE RESULTS FROM: a. Outer \_\_\_\_\_ CPM = \_\_\_\_\_ DPM  
eff = ( )  
b. Final source container \_\_\_\_\_ CPM = \_\_\_\_\_ DPM  
eff = ( )

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS \_\_\_\_\_ mR/hr.CPM  
above Bkg.

8. IF PACKAGE WAS SHIPPED WITH DRY ICE, WAS DRY ICE PRESENT IN PACKAGE AT  
TIME OF RECEIPT? \_\_\_\_\_ YES \_\_\_\_\_ NO \_\_\_\_\_ N/A

9. DISPOSITION OF PACKAGE AFTER INSPECTION: \_\_\_\_\_

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME. DATE, PERSONS NOTIFIED.

HPO FORM

RADIATION LEVELS AND REMOVABLE CONTAMINATION

YEAR ATT.10.12

# SURVEYS

MONTH           

MENNONITE GEN.HOSPITAL - Nuclear Medicine Lab.

Instrument \_\_\_\_\_ MODEL \_\_\_\_\_ Efficiency \_\_\_\_\_  
S/N \_\_\_\_\_

- 23 -

NUCLEAR MEDICINE LABORATORY  
DIAGRAM

HOT ROOM  
(Expanded view)

						mR/hr at location						Bgd _____		SIGNED
1	2	3	4	5	6	7	8	9	10	11	12			
TRIGGER														
DATE														

						dpm 100cm <sup>2</sup> at location						Control _____		
TRIGGER														
DATE														

Remarks:  Daily Survey

ALTERNATE FORM	I-131 THERAPEUTIC TREATMENT RECORD MENNONITE GEN. HOSPITAL	No. _____
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Patient's name : \_\_\_\_\_ Age: \_\_\_\_\_  
 Place: \_\_\_\_\_ Room No. \_\_\_\_\_  
 Dose: \_\_\_\_\_ Administered by: \_\_\_\_\_  
 Date: \_\_\_\_\_ Hour: \_\_\_\_\_  
 Physician in charge: \_\_\_\_\_

EXPOSURE RATES FROM BED (mR/hr)

Date:                      1.0 m:                      3.0 m:                      Outside:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

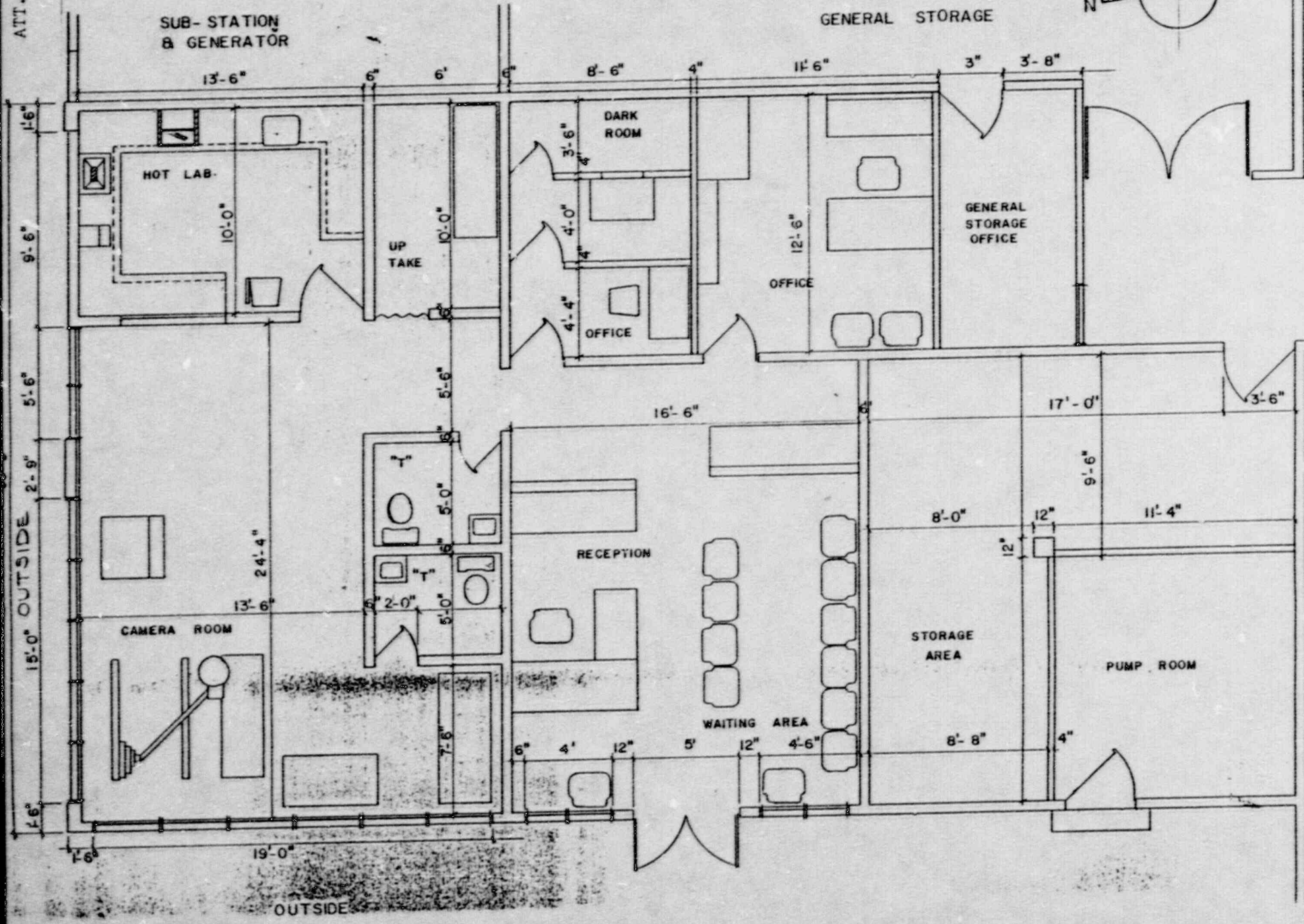
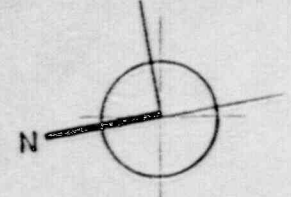
Patient released on: \_\_\_\_\_ Hour: \_\_\_\_\_  
 Max. Radiation level at one meter from patient: \_\_\_\_\_  
 Surveyor: \_\_\_\_\_ Instrument used: \_\_\_\_\_  
 Room decontamination required: Yes \_\_\_\_\_ No \_\_\_\_\_  
 Radioactive waste collected and stored: Yes \_\_\_\_\_ No \_\_\_\_\_  
 Maximum Radiation Levels: \_\_\_\_\_  
 Room released to Admitting Office on: \_\_\_\_\_

Remarks:

Signed by: \_\_\_\_\_ Date: \_\_\_\_\_







NUCLEAR MEDICINE LABORATORY GENERAL DIAGRAM

# SUB-STATION & GENERATOR

4" CONCRETE BLOCK FLOOR CABINET WITH DOORS COVERED WITH A LEAD SHEET TO BE USED FOR STORAGE AND WATERS

"L"-SHIELD  
13'-6"

HOT SINK

FUME HOOD

HOT LAB.

DOSE CALIBRATOR

INJECTION CHAIR

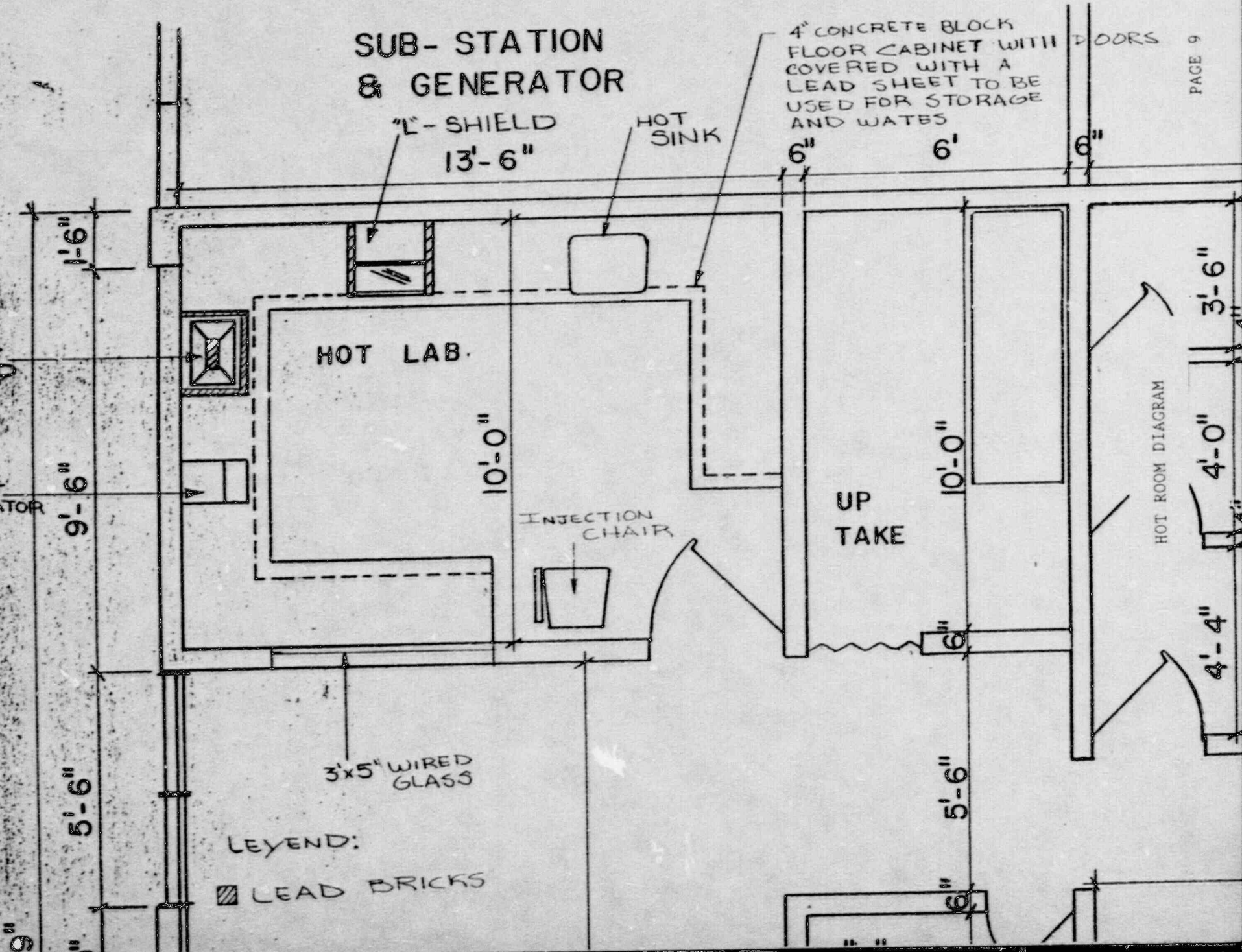
UP TAKE

HOT ROOM DIAGRAM

3x5" WIRED GLASS

LEYEND:

LEAD BRICKS



9"

9"

5'-6"

9'-6"

1'-6"

10'-0"

5'-6"

10'-0"

4'-4"

4'-0"

3'-6"

6"

6'

6"

6"

" "