NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Saint Elizabeths Hospital
Blackburn Laboratory
Washington, D.C. 20032

TELEPHONE NO.: AREA CODE (202) 574 7343

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Willie T. Maar, M.D.

TELEPHONE NO.: AREA CODE (202) 574 7105

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 08-15484-02

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Suryabala Kanhouwa, M.D.
Willie T. Maar, M.D.
Both presently listed on #08-15484-02

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Suryabala Kanhouwa, M .D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 mCi
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 Ci
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Cesium-137	Any	200 uCi	Instrument calibration
Cobalt-57	Any	5 mCi	Instrument Calibration

39-15113

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
X	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Siemens Gamm asonics, Inc.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens Gammasonics, Inc.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: Exempt (DHHS)

(2) LICENSE FEE ENCLOSED: $ ---

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

S. Kanhouwa, M.D.

(1) NAME *(Type or Print)*

Surya Kanhouwa, M.D.

(2) TITLE

Radiation Safety Officer

c. DATE

3/22/84

NRC FORM 313M (9-81)

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 313M. 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 30-36 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 used: (a) to provide records to State health departments for their information and use; and (b) to provide information 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 a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

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.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

RADIATION SAFETY COMMITTEE

Meeting Frequency

The radiation safety committee shall meet as often as necesary to conduct its business but not less than once in each calendar quarter.

Responsibilities

The committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.
3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by 19.2 of 10 CFR part 19.
4. Review and approve all requests for use of radioactive material within the institution.
5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license, to include the ALARA Program. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC instpections, written safety procedures, and management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

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RADIAITON SAFETY COMMITTEE

Duties (continued)

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.
9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Members

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;

2. the hospital administrator, or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;

3. a physician specialist from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

ITEM 7

Item #3 - Training and Experience

A. Authorized Users

1. Willie T. Maar, M.D., previously authorized to use radioactive materials requested in the application under NRC License No. 08-15484-02, Amendment No. 04, May 6, 1983.

2. Suryabala Kanhouwa, M.D., certified by American Board of Nuclear Medicine, 1976, previously authorized to use radioactive materials requested in the NRC License No. 08-15484-02.

B. Health Physics Consultants

1. Hugh B. O'Neil, Jr. (Refer to NRC License No. 08-15484-02)

INSTRUMENTATION

Survey Meters

1. Nucleus Model S-101, 0-50,000 cpm
2. Nucleus Model L, 0-50 cpm
3. Eberline E-130G, 0-50 mR/hr
4. Victoreen CDV-17, 0.5 R/hr
5. Victoreen CDV-700, 0-25 mR/hr

Dose Calibrators

1. Searle, Model CRC-22NB
2. Squibb, Model CRC-6A

Imaging and Scanning Systems

1. Picker Magnascanner V
2. Picker Dynacamera 4
3. Raytheon Gamma Camera

Well Counters

1. Ames-Volemetron, Model 5022
2. Searle Gamma Counter, Model 1185
3. Beckman 5500 Gamma Counter

#5

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted on a quarterly basis by Health Physics Services, Inc., Potomac, Maryland, using sealed Cesium-137 sources of approximately 500 mCi, authorized by the State of Maryland under License Number MD-31-035-01. The calibration procedures are on file with the NRC, under License No. 19-19791-01.

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of ±5%. Should the error of the constancy measurement be greater than ±5%, appropriate adjustment or instrument repair will be conducted.

2. On a quarterly basis, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator calibrations under Maryland License Number MD-31-035-01.
   A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than ±5%, appropriate adjustment or instrument repair will be conducted. This quarterly procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of 100±5%.

3. The linearity of the dose calibrator will be determined quarterly, by Health Physics Services, Inc., in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than ±5%, appropriate corrective action will be conducted.

4. Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

CALIBRATION OF DIAGNOSTIC INSTRUMENTATION

Calibrations of diagnostic instrumentation, to include gamma cameras and associated instrumentation will be conducted in accordance with the manufacturers' instructions.

Daily floods will be conducted to insure integrity of the camera.

LEAK TESTING OF SEALED SOURCES

On a semi-annual basis, all sealed sources of radioactive material will be leak tested by Health Physics Services, Inc., in accordance with their Maryland license, No. MD-31-035-01.

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FACILITIES AND EQUIPMENT

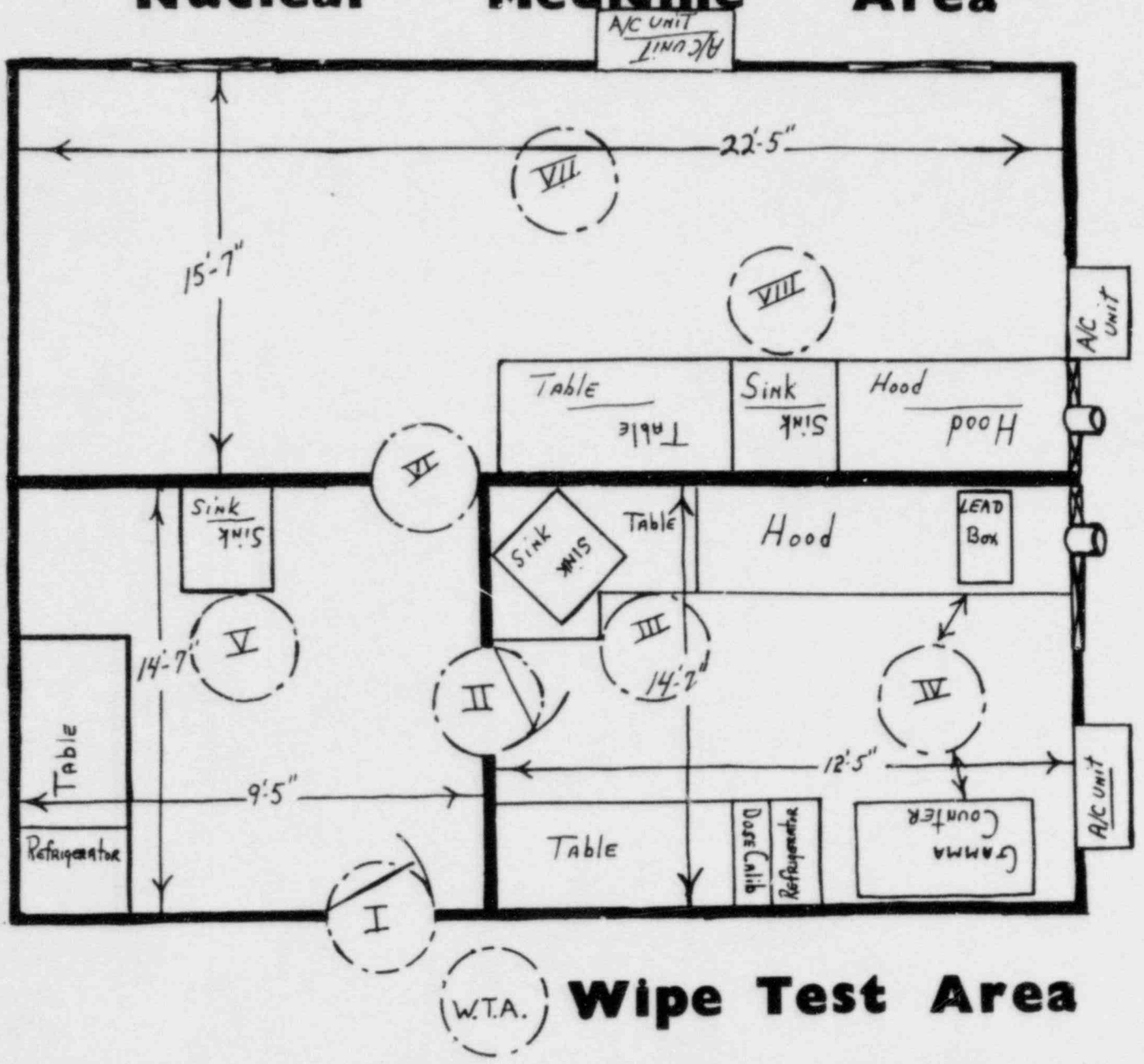
Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine laboratory will have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine Department.

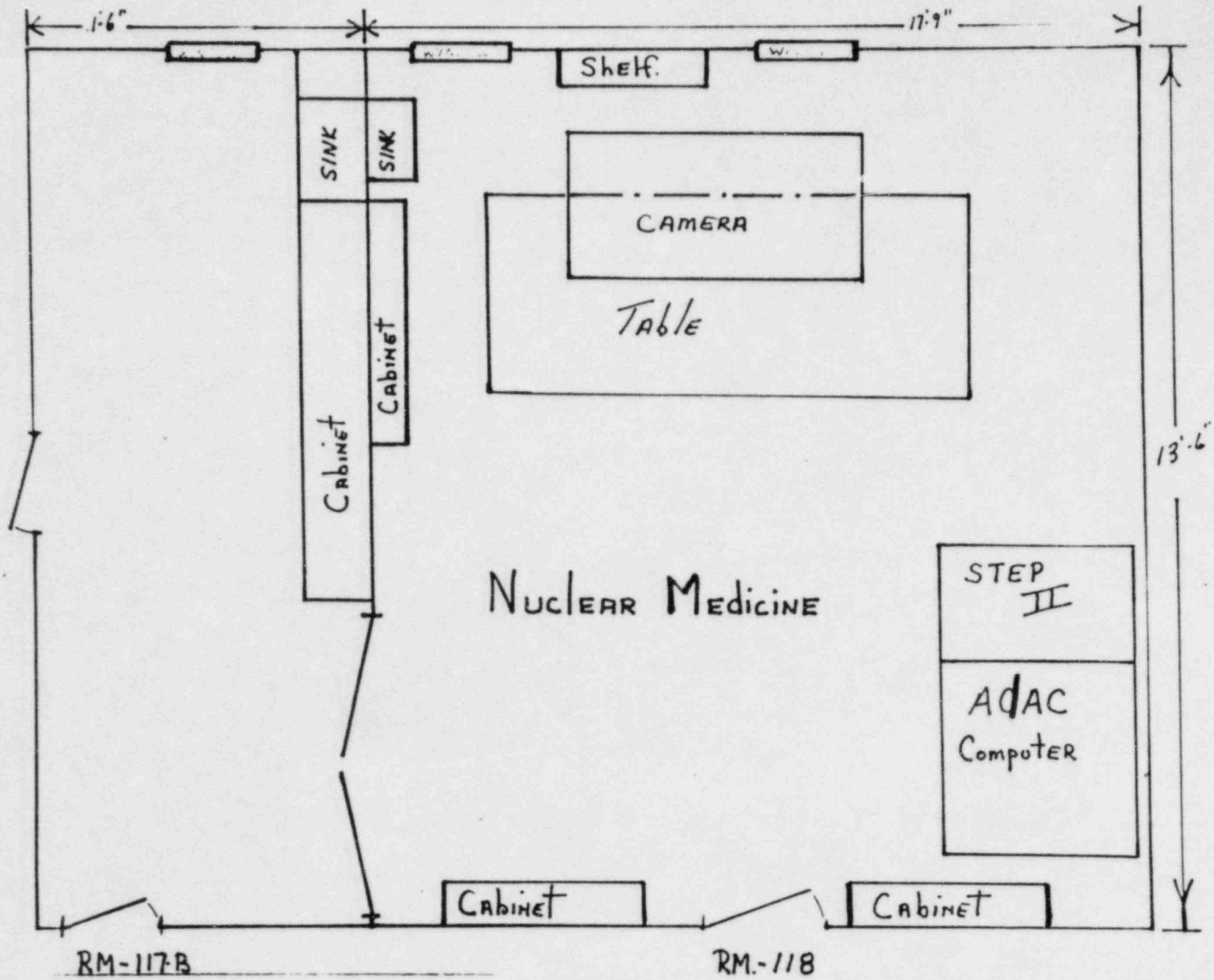
- Lead bricks
- Lead vial and container shields
- Laboratory coats or equivalent
- Absorbent pads
- Disposable gloves
- Decontaminating agents
- Signs and labels indicating the presence of radioactive material
- Syringe shields

A diagram of the facilities is also enclosed herewith.

Nuclear Medicine Area



ITEM 11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17'-9"
Shelf.
SINK
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CAMERA
TABLE
CABINET
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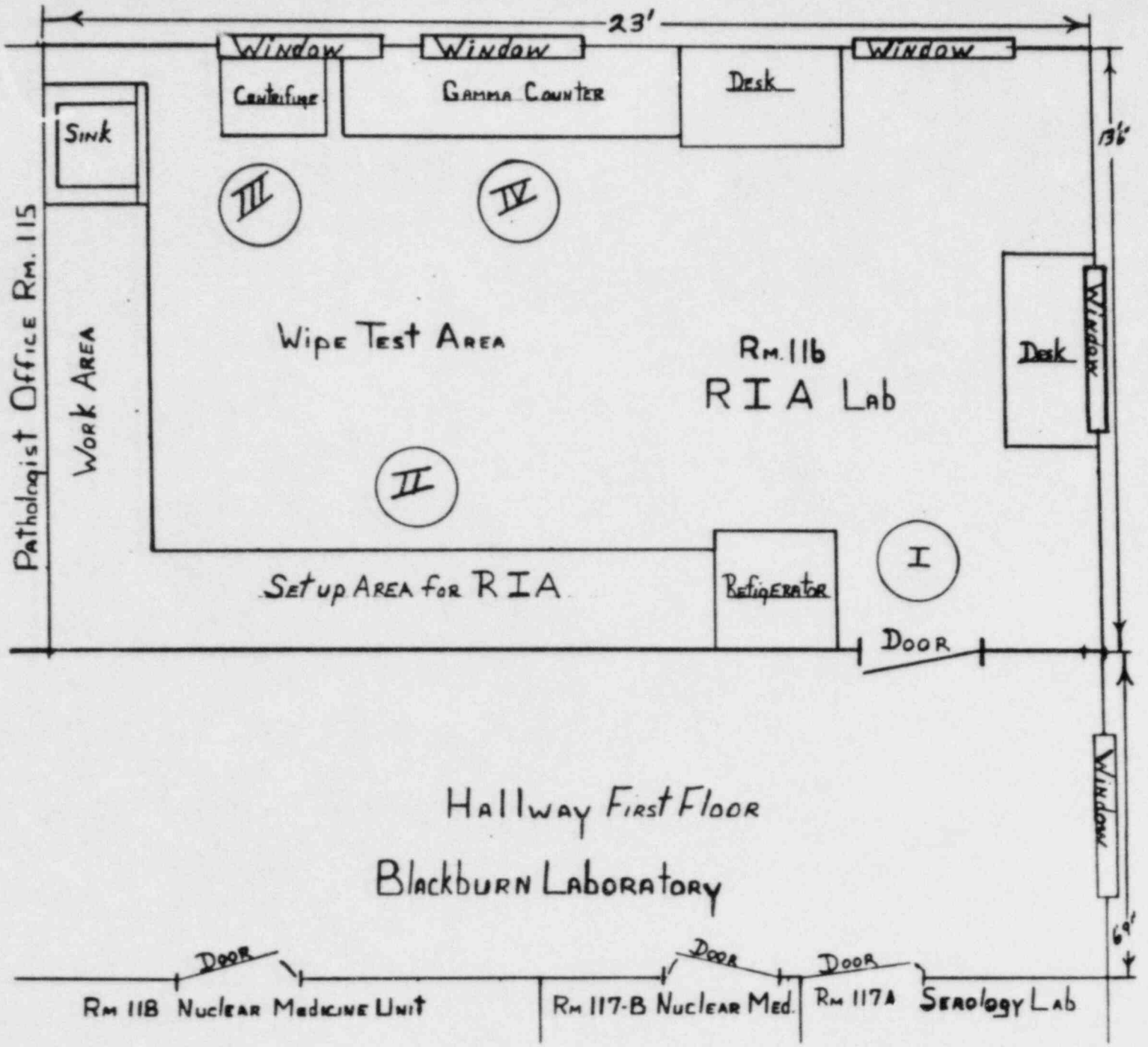
13'-6"
NUCLEAR MEDICINE
STEP II
ADAC
COMPUTER
CABINET
CABINET
RM-117B
RM.-118


23'
Window
Window
Window
Centrifuge
Gamma Counter
Desk
Sink
13½'
III
IV
Pathologist Office Rm. 115
Work Area
Wipe Test Area
Rm. 11b
RIA Lab
Desk
Window
II
I
Set up Area for RIA
Refrigerator
Door
Window
Hallway First Floor
Blackburn Laboratory
6'9"
Door
Door
Door
Rm 118 Nuclear Medicine Unit
Rm 117-B Nuclear Med.
Rm 117A
Serology Lab

PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

A. Areas where radioactive materials are used or stored.
B. Potential hazards associated with radioactive material
C. Radiological safety procedures appropriate to their respective duties.
D. Pertinent NRC regulations.
E. Rules and regulations of the licensee.
F. Pertinent terms of the license.
G. Their obligation to report unsafe conditions.
H. Appropriate response to emergencies or unsafe conditions.
I. Their right to be informed of their radiation exposure and bioassay results.
J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

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 the terms of the license.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist or his designee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours carriers will be instructed to deliver radioactive package directly to the Nuclear Medicine Department.

3. During off-duty hour, the Medical Technologist on duty will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed procedure.

4. A system for ordering and receiving radioactive material will be established and maintained. The system will consist minimally of the following:

   a. Ordering of routinely used materials
      (1) Written records that identify the isotope, compound, activity level, and supplier, etc., will be used.
      (2) The written records will be referenced when opening or storing radioactive shipments.

   b. Ordering of specially used materials

      (1) A written request* will be obtained from the physician who will perform the procedure.
      (2) Persons ordering the materials will be reference the physician's written request when placing the order. The physician' request will indicate isotope, compound, and activity level, etc,
      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written record* be maintained for all ordering and receipt procedures.

* In the case of special orders, the physician's written request and appropriate shipping/recept records will be referenced and the dose assayed prior to its administration.

PROCEDURE FOR
EMERGENCY RECEIPT OF RADIOPHARMACEUTICALS
DAMAGED PACKAGES

A. Shipments of radionuclides arriving between 5 p.m. and 8:30 a.m. are received by the Medical Technologist on duty in Blackburn Laboratory. Those arriving during the regular working hours are received by the Chief, Technologist in Nuclear Medicine. All radionuclides are stored in the lead brick well in room 101.

B. Should any cartons be crushed or wet, instructions are posted to notify immediately, Dr. Kanhouwa or Mr. Horton.

C. The following materials will be needed in surveying and/or decontamination. Decontamination kits are kept in room 101.

1. G-M Survey Meter
2. Warning Tapes, signs, and tags
3. Disposable gloves
4. Masking tape
5. Forceps, tongs and scissors
6. Large and small plastic bags.
7. Sponges, 4x4
8. Paper towels
9. Radiac wash or detergent
10. Scouring powder
11. Whatman #1 filter paper
12. Chux or absorbent towels

D. THINGS TO DO

1. Monitor carton and area. If radiation level exceeds background, evacuate personnel from area.

2. If container is wet, spray with Rad-Con, wrap in absorbent towel and place in plastic bag. Label bag with radiation sign. Blot any other spills, and monitor area. Record all readings. Continue to decontaminate area until reading does not exceed 0.1 mr/hr.

3. Remove all contaiminated materials to Lab "Hot Storage Area".

#9

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive material, the technologist will:

1. Put on gloves to prevent hand contamination.
2. Visually inspect packages for any sign of damage (wetness, crushed, etc.). If damage is noted, the procedure will be stopped and the radiation safety officer notified.
3. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR per hour, the procedure will be stopped and the radiation safety officer notified.
4. Measure surface exposure rate and record. If greater than 200 mR per hour, the procedure will be stopped and the radiation safety officer notified.
5. Wipe external surface of shipping container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a thin end window GM survey meter. The procedure will be stopped if removable contamination is greater than 22,000 dpm/100 sq. cm. above background. The radiation safety officer and health physics consultant shall be notified to determine the "exempt" status of the package with respect to wipe testing. If the package is not exempt, then appropriate notification of regulatory offices will be made.
6. Open the package with the following precautionary steps:
   A. Open the outer package following manufacturer's instructions, if supplied, and remove packing slip.
   B. Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle.
   C. Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
   D. Check also that shipment does not exceed possession limits.
7. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100 sq. cm., etc.). Check wipes with a well counter/scintillation detector or thin end window GM survey meter, and take precautions against the spread of contamination as necessary. The acceptable level of removable contamination will be 200 dpm/ 100 sq. cm. above background. The procedure will be stopped and the radiation safety officer notified if this level is exceeded.
8. Monitor the packing material and packages for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, radiation labels will be obliterated before discarding in regular trash.

Records will be maintained of the results of checking each package (see following sample).

#9

RADIOACTIVE SHIPMENT RECEIPT REPORT (SAMPLE)

1. P. O. #_____ Survey Date _____ Time _____
(if applicable)
Surveyor _____

2. CONDITION OF PACKAGE:
_____O. K. _____Punctured _____Status _____Wet
_____Crushed _____Other

RADIOACTIVE MATERIAL PACKAGES LABEL CRITERIA
(173.399)
DOSE RATE LIMITS

LABEL	AT ANY POINT ON ACCESSIBLE SURFACE OF PACKAGE	AT THREE FEET FROM EXTERNAL SURFACE OF PACKAGE (TRANSPORT INDEX)
"RADIOACTIVE-WHITE I"	Ø.5mR/hr	Ø
"RADIOACTIVE-YELLOW II"	5Ø mR/hr	1.Ø mR/hr
"RADIOACTIVE-YELLOW III"	2ØØ mR/hr	1Ø mR/hr

3. Radiation Label number _____

4. MEASURED RADIATION LEVELS:

a) Bkg = _____mRem/hr.

b) Package surface _____mRem/hr.

c) 3 feet or 1 meter from surface _____mRem/hr.

5. Notification to the NRC or Agreement state is voluntary if mR/hr levels exceed those indicated for applicable Labels I & II. Notification of the RSO, health physics consultant, carrier, and NRC/ Agreement state is mandatory if levels of exposure exceed either 1ØmR/hr at three feet or 2ØØmR at the surface of the package.

6. DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. Radionuclide _____yes _____no, difference _____

b. Amount _____yes _____no, difference _____

c. Chem form _____yes _____no, difference _____

7. WIPE RESULTS

a. Bkg _____CPM (Eff.= ____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____bkg. DPM

b. Outer _____CPM (Eff.=____%) -> CPM x $\frac{100}{\text{eff.}}$ = _____ DPM

c. Final source container _____CPM (Eff.= ____%)

-> CPM X $\frac{100}{\text{eff.}}$ = _____DPM

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____mRem/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION_____

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

_____

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.

2. Disposable gloves will be worn at all times while handling radioactive materials.

3. Hands and clothing will be monitored for contamination at the end of each working day.

4. Syringe shields for preparation of patient doses and administration to patients will be used except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

5. There will be on eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.

6. Each patient dose will be assayed in the dose calibrator just prior to administration. Any doses that differ from the prescribed dose by more than 10% will not be used.

7. Personnel monitoring devices (film badge or TLD) will be worn at all times while in areas where radioactive materials are used or stored.*

8. TLD finger badges will be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Radioactive waste will be disposed of only in specially designated receptacles.

10. There will be no pipetting by mouth.

11. Generator, kit preparation, and injection areas will be surveyed for contamination after each procedure or at the end of the day and will be decontaminated if necessary.

12. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Radioactive material will always be transported and maintained in shielded containers.

14. The laboratory will be locked when personnel are not present.

15. Emergency notification home telephone numbers will be posted on the door.

16. There will be no storage of food, drink, or personal effects with radioactive material.

* Personnel monitoring devices will be stored in a designated low background area when not being worn.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (cont'd)

17. For therapeutic doses, the following will be verified with the order written by the physician who will perform the procedure:
    A. Patient's name
    B. Radionuclide
    C. Chemical form
    D. Activity

USE OF MOLY/TECH GENERATORS, PREPARATION OF REAGENT KITS AND DOSE ADMINISTRATION

1. In all cases, all instructions supplied by the manufacturers of the generators and radiopharmaceutical kits will be followed precisely, including procedures for elution, assay, kit preparation, radiation precautions and the use of special equipment such as syringe shields, and other accessories.

2. Areas used for elution of Mo-99/Tc-99m generators, for preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses will be surveyed for contamination after each procedure or at the end of each work day.

3. Every elution of generators will be assayed by use of the dose calibrator for technetium-99m activity and molybdenum-99 breakthrough contamination. The eluates will not be used if there is more than one (1) microcurie of Moly-99 per millicurie of technetium-99m or more than five (5) microcuries of Moly-99 per administered dose of technetium-99m.
   NOTE: Molybdenum breakthrough tests will be performed in accordance with the instructions provided in the Operating/Instruction Manual for the dose calibrator.

4. Individuals who elute Mo-99/Tc-99m generators, prepare radiopharmaceuticals from reagent kits, and all personnel who prepare patient doses or work in areas used for elution of generators, preparation of radiopharmaceuticals or preparation of individual patient doses will monitor their hands and clothing for contamination before leaving those areas.

5. The activity of all radionuclides or radiopharmaceutical doses to be administered to patients will first be determined by mathematical calculations. Once drawn, the total activity contained in the syringe will be double checked by use of the dose calibrator. Except for this determination, the syringe will be kept in the syringe shield and/or pig. All radiopharmaceuticals will be assayed just prior to administration to the patient.

6. Patient dose information of administered technetium-99 and all other administered radioactive materials will be recorded in the patient dose log.

EMERGENCY PROCEDURES

Minor Spills

1. All persons in the area will be notified when a spill has occurred.

2. The spill will be covered with absorbent paper to prevent its spread.

3. Disposable gloves and remote handling tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.

4. The survey will be conducted using a low-range, thin-window G-M survey meter. The area around the spill, hands, and clothing will be checked for contamination.

5. The incident will be reported to the radiation safety officer.

Major Spills

1. All persons not involved in the spill will be notified to vacate the room.

2. The spill will be covered with absorbent pads, but no attempt to clean it up will be made. The movement of all personnel potentially contaminated will be confined to prevent the spread.

3. If possible, the spill will be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. The room will be vacated, and the door(s) locked to prevent entry.

5. The radiation safety officer will be notified immediately.

6. Contaminated clothing will be removed and stored for further evaluation by the radiation safety officer. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Suryabala Kanhouwa, M.D.

OFFICE PHONE: 574-7343

HOME PHONE: 365-5464

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: Charles Horton, 584-6136

Willie Maar, M.D. 460-5251 or (703) 636-3120

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AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Chief Technologist of the department or his designee, in each area where radioactive material is used or stored:

1. Preparation and injection areas will be surveyed on a daily basis with an appropriately low range G-M survey meter and decontaminated if necessary.

2. All other laboratory areas will be surveyed weekly.

3. The weekly survey will consist of:
   A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem per hour.

   B. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 sq. cm. for the contamination involved.

4. A permanent record will be kept of all survey results, including negative results. The record will include:

   A. Location, date, and type of equipment used.

   B. Name of person conducting the survey.

   C. A drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   D. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   E. Detected contamination levels, keyed to locations on drawing.

   F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

5. The area will be cleaned if the contamination level exceeds 200 dpm per 100 sq. cm.

NOTE: For daily surveys where no abnormal exposures are found, only the date, identification of the person performing the survey and the survey results will be recorded.

#13

WASTE DISPOSAL PROCEDURES

Solid radioactive waste will be divided into two groups: long lived and short lived.

Adequate lead or other suitable shielding will be provided as necessary to reduce the radiation exposure levels to the lowest reasonable level while radioactive waste is in temporary storage.

Solid radioactive waste (short and long-lived) will be held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Once this has been achieved, all radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash. Appropriate documentation will be maintained.

Needles, syringes, and unused patient doses may also be returned to the nuclear pharmacy for disposal under their license.

Liquid radioactive waste will be disposed of in the sanitary sewerage system in accordance with Section 20.303 of 10 CFR 20.

Generators will be disposed of by either of the following methods:

1. Returned to the manufacturer in accordance with applicable DOT, NRC and/or State regulations governing the transport of radioactive materials.

2. Generators will be disassembled after a minimum of 10 half-lives from the original assay date. The Molybdenum core will be placed in the long-lived waste container for subsequent storage and monitoring as described above. The lead will be surveyed as above and disposed of accordingly.

NOTE: The radioactive waste area is located within the Nuclear Medicine Hot Lab, which is locked when staff personnel are not present. Radiation surveys are conducted at least weekly.

Long-lived waste may be disposed of through a licensed commercial vendor such as Radiac Research Corporation if long term storage is not available.

ITEM 18

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTE OF MENTAL HEALTH
WASHINGTON, D.C. 20032

SAINT ELIZABETHS HOSPITAL

FOREWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the uses of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straight-forward purpose: to protect the patients, employees, and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposures to "As Low As Reasonably Achievable" (ALARA) to employees, visitors, students, and patients who are not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer, health physics consultant, and the Radiation Safety Committee.

We, the management of this hospital, are committed to the program procedures and develop new procedures as appropriate to implement the ALARA concept.

William G. Prescott

William G. Prescott, M.D.
Superintendent

2/22/84
Date

PROGRAM FOR MAINTAINING ALARA OCCUPATIONAL #14
RADIATION EXPOSURES AT THE INSTITUTION

HEALTH AND HUMAN SERVICES DEPARTMENT
NATIONAL INSTITUTE OF MENTAL HEALTH
MARTIN LUTHER KING AVENUE
WASHINGTON D.C. 20032
NRC LIC # 08-15484-02
(Licensee's Name)

March 22, 1984
(Date)

I. Management Commitment

a. We, the management of Saint Elizabeths Hospital 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 describe an administrative organization for radiation safety and will 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)[1] and a 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.

E. The services of Health Physics Services, Inc., have been contracted to assist in the program management to insure that all permanent hospital staff and employees receive appropriate briefings and training in radiation safety including ALARA concepts.

III. RADIATION SAFETY COMMITTEE

In addition to other responsibilities delineated in pertinent radiation control standards, the Radiation Safety Committee (RSC) shall:

A. Determine whether current procedures are, in fact, maintaining radiation exposures to ALARA. The efforts of the radiation safety officer (RSO), health physics consultant, users and supervisors of radiation sources will be reviewed during the committee meeting.

B. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

C. Perform an annual audit of all aspects of the radiation safety program to insure that the overall philosophy and policies of the ALARA program are being accomplished.

D. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and the uses for which he has applied, to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

E. Delegation of Authority

1. The RSC will delegate authority to the RSO and his consultant staff 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 Committee's quarterly meeting.

F. Review of the 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 1 below are exceeded. The principle 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 Investigational Levels are exceeded.

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.

IV. RADIATION SAFETY OFFICER, AND HIS CONSULTANT STAFF ARE RESPONSIBLE FOR THE FOLLOWING:

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. 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 exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VII of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted andf restricted areas to determine that they were at ALARA levels during the previous quarter.

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 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 the 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 RSC will establish procedures for receiving and evaluating the suggestion 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 require changes in the program to maintain exposures ALARA.

V. AUTHORIZED USERS

A. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radiation sources for a new procedure.

2. The authorized user will evaluate all procedures before using radiation sources to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

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.

VI. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

A. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

B. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VII. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or consultant staff. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

	Investigational Levels - (mrems per calendar quarter)	
	LEVEL I	LEVEL II
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

* Not normally applicable to medical facilities except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review the results of personnel monitoring, film badge report, 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 1:

A. Quarterly exposure of individuals to 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 exposure is less than Table 1 values for the Investigational Level I.

B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure 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 exposure 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. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's film badge record will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

D. Re-establishment of an individual occupational worker's Invewstigational Level II above that listed in Table 1.

In cases where a worker's or a group of workers' exposure needs to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Levewl II will be documented.

The Radiation Safety Committee will review the justification fro, and will approve, all revisions of Investigational Levels II. In such cvases, when the exposure equals or exceeds the newly established Investigational Level II, thuse actions listed in paragraph C above will be followed.

VIII. SIGNATURE OF CERTIFYING OFFICIAL

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

William G. Prescott

Signature of Administrator

William G. Prescott, M.D.
Name (type or print)

Superintendent
Title

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