FORM NRC-313M (8-78) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved: GAO R0557

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

Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, D.C. 20016

TELEPHONE NO.: AREA CODE (202) 537-4000

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

William G. Battaile, M.D., Pathologist

TELEPHONE NO.: AREA CODE ( )

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

- a. ☐ NEW LICENSE
- b. ☐ AMENDMENT TO LICENSE NO.
- c. ☒ RENEWAL OF LICENSE NO. 08-07398-03

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

William G. Battaile, M.D.
Robert A. Dietrich, M.D.
Thomas A. Fleury, M.D.
Domenic F. Sabatini, M.D.

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.)*

William G. Battaile, 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	2
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	3000
10 CFR 35.100, SCHEDULE A, GROUP IV	x	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	x	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.	x	200

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
SEE ATTACHED			

RECEIVED BY LFMS
Date 10/19/83
Log Oct 8 I
By Brown
Orig. To

Applicant
Check No. 128039 -7B
Amount/Fee Category $150
Type of Fee Renewal
Date Check Rec'd. 10/19/83
Received By Brown

01811

OCT 14 1983

ML10

"OFFICIAL RECORD COPY"

8501220353 850104
NMS LIC30
08-07398-03 PDR

ATTACHEMENT (6.b)

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OR EACH FORM	DESCRIBE PURPOSE OF USE
Americium 241	Sealed source Amersham/Siemans Model # AMC 24	30 MCi	Authorized use to be used in Siemans (Searle) Analytic Model SS-10244 Anatomical Marker
Strontium 90	Sealed source Tracer Lab Model (RA-1A or RA-2A)	100 MCi	Authorized use tratment of superficial eye disease
Cobalt-57	Sealed source Vial E NEN 2060283 A-22	8 MCi	Authorized use calibration check of dose calibrator
Co-57	Sealed source Flood Disc NEN 391-0183 G-01	8 MCi	Authorized use Pho-Gamma Camera Quality Control

Item 6b
9-30-83

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	
X	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	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)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	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
X	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	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Siemens Gammasonics, Inc. Des Plaines, Illinois	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER	X	FILM	Siemens Gammasonics, Inc. Des Plains, Illinois	Monthly
		TLD		
		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:

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Mr. John M. Shiver

(2) TITLE
Associated Administrator

c. DATE
9-30-83

FORM NRC-313M (8-78)

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 Form NRC-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.

MEDICAL ISOTOPES COMMITTEE

The Medical Isotopes Committee is established by the authority of the Administrator as the Committee responsible for the safe use of radioactive material throughout Sibley Memorial Hospital, Washington, D.C. 20016.

Committee Responsibilities

1. Review and grant permission, or disapprove, the use of byproduct material within the institution. This will be done from the standpoint of radiological health and safety and patients or radiation workers, or other factors that the committee may wish to establish for medical uses of byproduct materials, prior to submission of an application to the regulatory agency for licensing action.

2. Prescribe special conditions that will be required during a proposed use of radioactive material, such as requirements for bioassays and physical examinations of users, minimum level of training and experience of users..

3. Review records and reports from the radiation safety officer.

4. Recommend remedial action to correct safety infractions.

5. Formulate and review the institutional training programs for the safe use of radioactive material.

6. Maintaing written records of actions taken by the committee.

7. No ammendment needed to change members, but document members in inst. files

Committee Administrative Duties and Frequency

1. The committee will meet at least quarterly to review safety aspects of present programs to consider cases or problems.

2. Minutes of committee meetings will be maintained by the Chairman of the committee.

3. The senior technologist in each department utilizing radioactive material will serve as the assistant radiation safety officer and will be responsible for maintaining health physics records and the daily management of the radiation safety in his department.

4. The radiation safety officer will be responsible for preparation and distribution of radiation safety training materials. In addition, he will insure that necessary classes on radiation safety for staff personnel be conducted.

MEMBERS
A user of each type of use permitted by license representative of the nursing staff and management and a person trained in radiation safety.

Item No.7a & b
9/30/83

MEDICAL ISTOPES COMMITEE MEMBERS

Domenic Sabatini, M.D., Chairman

Charles Duvall, M.D.

Thomas Fleury, M.D.

John MacDonald, M.D.

Stanley Schwartz, M.D.

J.Shivar

Phil Vincent

Lois Clatterbuck, R.N.

William G. Battaile, M.D.
(Radiation Safety Officer)

Item 7
9-30-83

FORM NRC-313M-SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
William G. Battaile, M.D.	District of Columbia

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B]	MONTH AND YEAR CERTIFIED C
A. Please refer to NRC License Number 08-07398-03 for Dr. Battaile's training and expierience codumentation.		

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
A. Robert A. Dietrich, M.D. B. Domenic E.Sabatini, M.D.	District of Columbia

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
A. Please refer to NRC License Number 08-07398-03 for Dr. Dietrich's training and experience. B. Please refer to NRC License Number 08-07398-03 for Dr. Sabatini's training and experience.		

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Thomas A. Fleury, M.D.	District of Columbia

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Training and experience documentation for Dr. Fleury is attached herewith.		
Clinical and Anatomic Pathology		1980

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
Brown University Georgetown University	Providence, RI, 1967-1971 Washington, DC 1972-1976		
a. RADIATION PHYSICS AND INSTRUMENTATION	Brown Univ.-Prov.RI 1967-71 Georgetown-Wash.DC 1972-1976	100	40
b. RADIATION PROTECTION	Brown Univ.-Prov.RI 1967-71 Georgetown-Wash.DC 1972-1976	30	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Brown Univ.-Prov.RI 1967-71 Georgetown-Wash.DC 1972-1976 Peter Bent Brigham-Boston,Mass.1976-80	60	
d. RADIATION BIOLOGY	Mt.Siani Review Course-Bost.-4-1-80 to 6-20-80 Georgetown-Wash.DC 1972-1976 Mt.Siani-Boston Mass. ~~Beth Israel-review course 8-29-83 to 9-1-83~~	30	
e. RADIOPHARMACEUTICAL CHEMISTRY	Beth Israel,review course 4-1-80 to 6-20-80 Mt.Siani Reveiw course 8-28-83 to 9-1-83	35	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Thomas A.Fleury, M.D.

STREET ADDRESS

5255 Loughboro Road, N.W.

CITY | STATE | ZIP CODE

Washington, D.C. 20016

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	140	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	13	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	Cr-51 Red Cell Volume	4	
	99 mTc DTPA GFR Rate	4	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	13	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING	26	
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER	In^{111}DTPA Cisternography	5	
Tc-99m	BRAIN IMAGING	344	
	CARDIAC IMAGING	22	
	THYROID IMAGING	184	
	SALIVARY GLAND IMAGING	3	
	BLOOD POOL IMAGING	7	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	598	
	LUNG IMAGING	326	
	BONE IMAGING	890	
OTHER	99mTc Desofenin -Gallbladder	72	

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	19	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	10	
Other Rb-81/Kr 81m	Generator-Ventilation lung	216	
Xe-133	Lung ventilation	56	

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

July 1980 to present time-in excess of 100

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

a. NAME OF SUPERVISOR
William G. Battaile, M.D.

b. NAME OF INSTITUTION
Dept. of Pathology & Nuclear Medicine

c. MAILING ADDRESS
5255 Loughboro Rd. N.W.
Sibley Memorial Hospital

d. CITY
Washington, D.C.20016

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

W Battaile M.D.

7. PRECEPTOR'S NAME *(Please type or print)*

William G. Battaile, M.D.

8. DATE

9-30-83

FORM NRC 313M-SUPPLEMENT B
(8-78)

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

THOMAS A. FLEURY MD

STREET ADDRESS

5255 LOUGHBORO RD N.W.

CITY | STATE | ZIP CODE

WASHINGTON D.C. 20016

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING	50	
	CARDIAC IMAGING	75	
	THYROID IMAGING	25	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	200	
	LUNG IMAGING	25	
	BONE IMAGING	200	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	10	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	10	
Other			

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

Apr 1, 1980 thru June 20, 1980
Approximately 400 hours

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

a. NAME OF SUPERVISOR
William Kaplan MD

b. NAME OF INSTITUTION
Division of Nuclear Med (SFCI)

c. MAILING ADDRESS
444 Binney St

d. CITY
Boston, Mass 02115

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

William Kaplan MD.

7. PRECEPTOR'S NAME *(Please type or print)*

William D. Kaplan, M.D.

8. DATE

May 3, 1982

FORM NRC-313M-SUPPLEMENT B
(8-78)

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

   Manufacturer's model number: 7092

   Number of instruments available: 1

   Minimum range: 0.02 mR/hr to 0.5 mR/hr

   Maximum range: 10 mR/hr to 50 mR/hr

   b. Manufacturer's name: Eberline

   Manufacturer's model number: 6707

   Number of instruments available: 1

   Minimum range: .5 mR/hr to 10 mR/hr

   Maximum range: 50 mR/hr to 1000 mR/hr

2. Dose calibrator

   Manufacturer's name: Searle

   Manufacturer's model number: CRC-22 NB CR 8560

   Number of instruments available:

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name		Model No.
Pho-Gamma Camera	Seimen	ZLC with Scinti-view	3705
Pho-Gamma Camera	Seimen	LFOV with Scinti-View	6413
ADC Spectrometer with probe and well	ADC		300,201, 330

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Dosimeter Victoreen 2000 A

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CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 1. Survey instruments will be calibrated at least annually and following repair.

_____ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. Readings within ±20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ±10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used
or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name General Health Physics

(2) Location 7217 Lockport Place, Lorton, Virginia 22079

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. 45-21037-01

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

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CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/Tc-99m generator

or

X Other* (specify) 100 MCi ^{99m}Tc from Syncor

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	5	NES-206
Ba-133	0.1-0.5		
Cs-137	0.1-0.2	0.2	
Ra-226	1-2	0.18	

C. X The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

_____ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

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FACILITIES AND EQUIPMENT

The Nuclear Medicine Clinic is divided into three separate functional areas:

1. Office
2. Imaging and Scanning Areas
3. Radioisotope Laboratory

The radioisotope laboratory contains an area shielded with lead bricks for storage of radioisotopes and generators. Also located in this area is a refrigerator for storage of perishable materials, a sink, the dose calibrator and adequate bench space for preparation of radiopharmaceuticals.

The laboratory area has available additional lead bricks, lead pigs, syringe shields, automatic pipettes, forceps, etc., for the preparation and administration of patient doses. The decay storage bin and radioactive waste receptacle are also located in this laboratory.

The radioisotope laboratory is locked when the Nuclear Medicine physician or technician is not in attendance. The keys to this facility are maintained by the Nuclear Medicine personnel and hospital security service.

RADIATION HANDLING EQUIPMENT

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicien Laboraotyr must have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine and Radiation Therapy Departments.

SHIELDING EQUIPMENT

Lead bricks-(e.g., 2" x 4" x 6")

Lead syringe holders for transporting syringes containing radioactivity

Lead syringe shields for reducing exposure during injection of radio-pharmaceuticals

Lead vial and container shields (pigs), for reducing exposure during transport and storage of vials, etc., that contain radioactivity.

REMOTE HANDLING

Remote pipetters

Tongs and other remote handling tools

CONTAMINATION CONTROL

Disposable gloves

(Disposable shoe covers and boots for emergency spills)

Absorbent pads (absorbent layer backed by non-absorbent plastic material) for covering work surfaces.

Decontaminating agents. Special agents are commercially available for decontaminating hands, utensils, work areas, etc.

Signs and labels indicating the presence of radioactive materials in areas or rooms where they are being used or stored. Labels on containers indicating radionuclide, activity and date.

Monitoring

Eberline 7092

Eberline 6707

Ionization chamber "Dose Calibrator " (stationary, wall plug).

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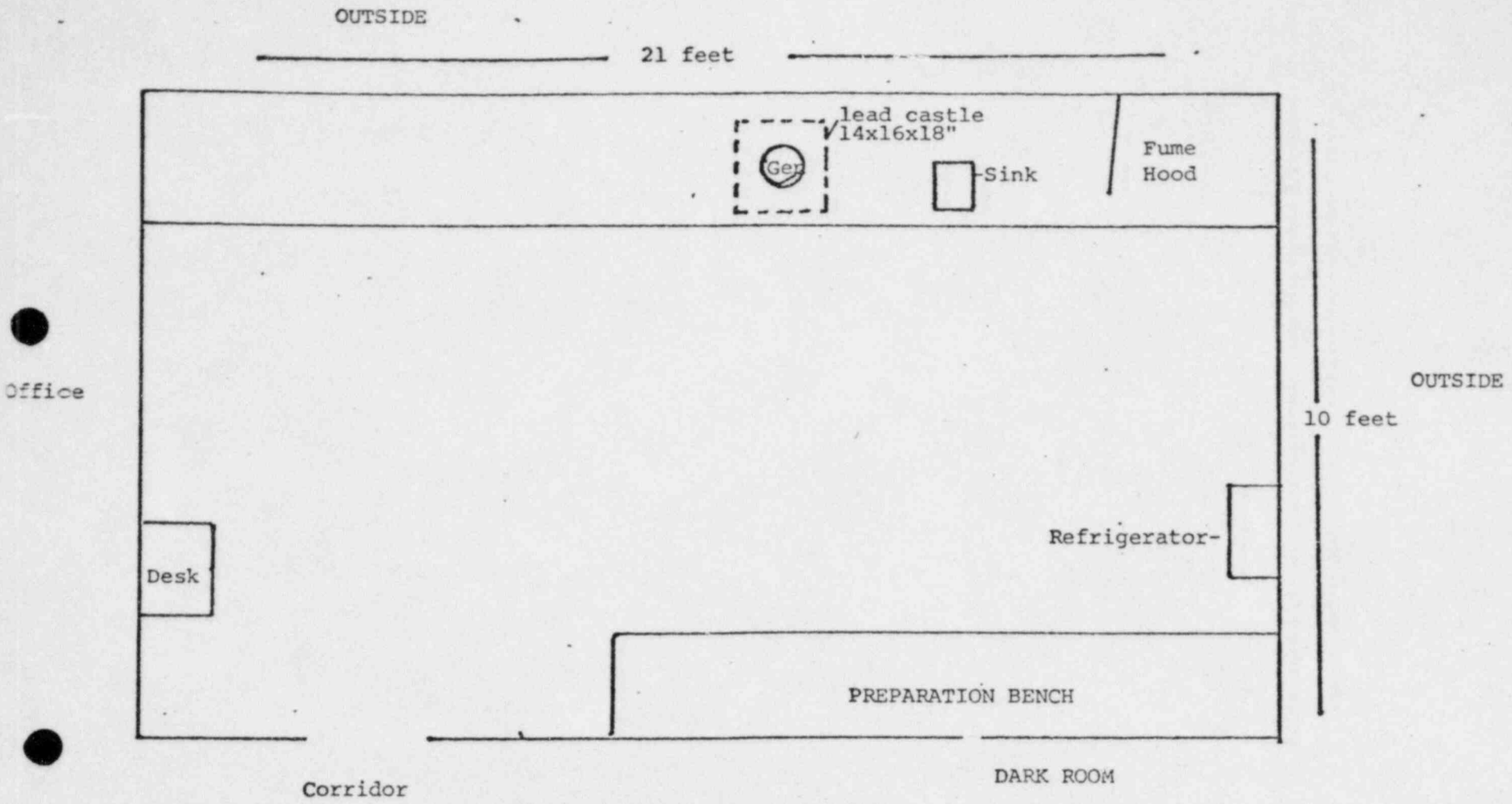

The Tc-99 generator is shielded with two inch thick lead brick. Additional lead bricks are available for proper shielding of Group III radiopharmaceuticals and thus will reduce unnecessary radiation exposure to the unrestricted and restricted areas.

SIBLEY MEMORIAL HOSPITAL
LABORATORY
WASHINGTON, D. C.

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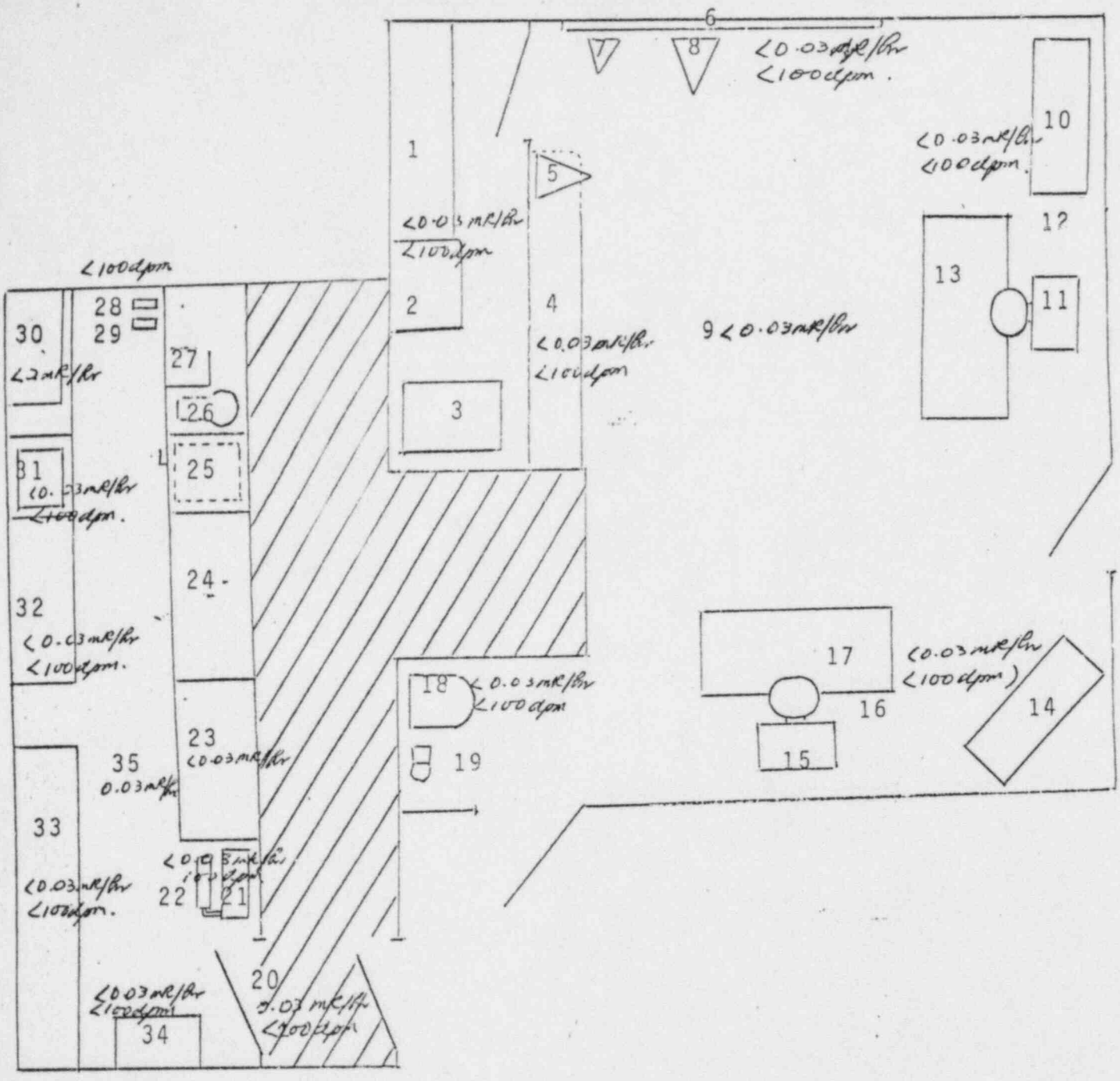
9-30-83

WEEKLY MONITORING FORM

Reported By: _____ Date: _____

DATA: Battery check 7092 _____ 6707 _____
Survey meter background _____
Scaler background _____ cpm
Constancy I-129 _____ cpm
Constancy Cs-137 _____ cpm

Area & Equipment	cpm	ncpm	dpm	resurvey dpm	survey meter mR/hr
0. Background					
1. Darkroom counter					
2. Darkroom sink					
3. Darkroom film processor					
4. Counter top (view box)					
5. LFOV collimator cart					
6. Window ledge					
7. Hamper					
8. LFOV pinhole coll. cart					
9. General area in scanning room					
10. LFOV scintiview					
11. LFOV scanner					
12. Floor around LFOV scanner					
13. Table A					
14. ZLC scintiview					
15. ZLC scanner					
16. Floor around ZLC scanner					
17. Table B (adjustable)					
18. ZLC collimator cart					
19. Krpton 81 generator & O_2 tank					
20. Floor of doorway in lab. rm					
21. Well counter					
22. Probe					
23. Index file counter					
24. Work area counter					
25. Refrigerator					
26. Dose calibrator					
27. Dosing area					
28. HOT wastepaper basket					
29. Wastepaper basket					
30 HOT storage area					
31. Sink					
32. Sink counter					
33. Window counter					
34. Desk					
35. General area in lab. rm					
36. Syringe holders					
37. Gloves, wipes, chucks					
38. Needles, syringes, vials					
39. Background					



NUCLEAR MEDICINE DEPARTMENT

SIBLEY MEMORIAL HOSPITAL

Item 11
9-30-83

SUBJECT: Radiation Safety Training Program

CLASS PRESENTED TO: Radiation Workers and Ancillary Personnel*

FREQUENCY: Instruction presented initially, and annually thereafter

CLASS OUTLINE

1. Introduction

   A. Purpose: To familiarize radiation workers with the e established standards for protection against unwarranted exposure to ionizing radiation and their rights related to working with radiation.
   B. References:
      1) Title 10, Code of Federal Regulations Parts 19 & 20

      2) NBS Handbook 92

      3) NCRP Reports No. 39 and 48

2. Principles of Radiation Protection

   A. Philosophy of radiation exposure control

   B. Physicial safeguards

   C. Regulations and recommendations

3. Radioisotope Laboratory Safety Procedures

   A. Isotope Receipt and Inspection

   B. Radiation Caution Signs and Labels

   C. Anti-contamination proced.res

   D. Radioactive Waste Disposal

   E. Personnel Monitoring

   F. Radiation Emergency Procedures

4. Helath Physics Surveys

   A. Criteria and Periodicity

   B. Measurement of Radiation levels

   C. Assessment of Laboratories Procedures

   D. Facility Evaluation

   E. Records Review

5. Question and Answer Period

* Instructions will generally be limited to requirements outlined in Section 19.12 of 10CFR-19

PROCEDURES FOR ORDERING RADIOACTIVE MATERIALS

Radioactive materials will be ordered by the Chief Technologist or Chief of Service for the Nuclear Medicine Department. Prior to placing an order, the inventory will be reviewed to insure that possession limits will not be exceeded.

The Radiation Safety Office will review these inventories and related procedures on a monthly basis.

During normal work hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

During off duty hours, shipments of radioactive material will be received by the Pathology Dpartment on-durty tech, who will examine the package for damage such as stains, wetness, etc. If the shipment appears to be intact, the package wo;; be taken immediately to the Nulcear Medicine Department and placed on the floor in the middle of the room. The soor will then be locked.

If the shipment appears damage, the Radiation Safety Officer or his designee will be notified. The carrier will remain in the Hospital until it can be degermined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER:	William G. Battaile, M.D. Office: 202-537-4000 Home: 301-229-1625
CHIEF TECHNOLOGIST- NUCLEAR MEDICINE	Janie Reid Office: 202-537-4000 Home: 301-933-0922

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PROCEDURES FOR EXAMINING INCOMING RADIOISOTOPE PACKAGES

1. Federal regulations and pertinent parts of Agreement State Regulations for Radiation Control require that procedures be established and maintained for "Safely Opening Packages" in which radioactive material is received, and shall assure that such procedures are followed and due consideration is given to special instructions for the type of package being opened.

2. The following outline is provided for fullfillment of this requirement:

   A) General set-up

      1. All packages containing radioactive materials will be inspected for damage, lleakage or contamination by monitoring with a beta-gamma survey meter and wipe testing the outside of the shipping container and the external surface of the final source container.

      2. A crecord shall be maintained to show the results of such monitoring.

      3. Packages shall be delivered to one specific location in the laboratory or clinic for receipt and inspection. Treat as contaiminated until proven otherwise, especially if damaged.

      4. Open and inspect packages as soon after receipt as possible,but not later than three (3) hours during normal working hours, or eighteen (18) hours if received after normal work hours.

   B) Procedure for Package Inspection

      1. Place package on surface with absorbent material. Plastic or other protective gloves and lab coats shall be worn for opening packages for protection of surveyor.

      2. Observe package for leakage stains. Record condition.

      3. Monitor the unopened package with a survey meter. Record result. If the radiation level exceeds 200 mR per hour at the surface, or 10 mR per hour at three (3) feet, proceed with caution.

PROCEDURES FOR EXAMINING INCOMING RADIOISOTOPE PACKAGES

(continued)

4. Wipe 100 cm^2 area of outer package with dry wipe, and measure amount of removable activity with count rate meter. Record the results. If greater than the maximum allowable limit of 22,000 dpm, proceed with caution.

   NOTE: If radiation measurements exceed the levels in either steps 3 or 4 above, DO NOT OPEN PACKAGE. Immediately notify the Radiation Safety Officer or Health Physics consultation and the Chief of the Department for further instructions. The Radiation Safety Office or Consultant, will; notify the appropriate officials of the Nuclar Regulatory Commission, the final delivery carrier and the vendor.

5. If radiation levels of the outer container are within prescribed limits, open the outer package and remove packing slip.

6. Open inner package to verify contents (compare packing slip, prucahse order, label or inner container) and integrity of final source container. (Inpsect for breakage of seals or vials, loss of content, discoloration, of packing material).

7. Wipe external surface of final source container with moistened wipe stick, assay and record the results. If internal contamination (500 dpm) is found, the shipment should be decontaminated by the Radiation Safety Officer or senior technician prior to use. However, contaminated shipments will not be used in patient studies, but will be disposed of as radioactive waste.

8. Monitor the packing material and empty packages for contamination before discarding:

   a. If contaminated, (any reading above bakcground level), treat as radioactive waste.

   b. If not contaminated, obliterated radiation labels/wording before discarding to regular trash.

C) Radioisotope Receipt Record

The results of wipe testing monitoring shall be recorded in the Radioisotope Use Record (see attached sample).

D) Receipt of Radioisotope Packages After Normal Duty Hours

Shipments of radioactive material arriving after normal working hours will be delivered directly to the Pathology Department which is open 24 hours a day. The technologist on duty is responsible for the receipt procedure outlined below.

If a package appears wer or damaged, immediately notify the Radiation Safety Officer or head of the Department. The delivery agent shall be detained until his person and vehicle have been surveyed for contamination by either of the above personnel.

Inspect of the damaged shipment, by either of the above individuals will be conducted in accordance with the above "Procedures for Package Inspection".

The radioactive material will be immediately taken to the Nuclear Medicine Department by the technologist and placed in the middle of the room on the floor. The Nuclear Medicine Lab will then be locked and the key returned to the main desk.

The Nuclear Medicine technologist, upon arrival during normal working hours,will process the radioactive material in accordance with previous instructions.

DEPARTMENT OF NUCLEAR MEDICINE AND PATHOLOGY
SIBLEY MEMORIAL HOSPITAL

RECEIPT INSPECTION

D	TIME:	MR/HR			STAINS	WIPE TEST				TECH
						REC		RETURN		
		SURFACE	3 FEET	EMPTY CARTON	YES/NO	BKG	WIPE	BKG	WIPE	INITIALS

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GENERAL RULE FOR THE SAFE USE OF RADIOACTIVE MATERIAL

To be done in accordance with Regulatory Guide 10.8

Rev 1 Oct 1980

Item 15
9-30-83

Emergency Procedures to be done in accordance with

Regulatory Guide 10.8

Rev 1 Oct 1980

Item 16
9-30-83

Area survey procedures to be done in accordance with

Regulatory Guide 10.8

Rev 1 Oct 1980

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9-30-83

RADIOACTIVE WASTE PROGRAM

Radiactive waste will be divided into two groups, i.e., 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 practical limit while radioactive waste is in temporary storage.

Short lived isotopes will be returned to supplier or stored until the radiation level from the surface of their unshielded container, plastic bag/cardboard box, etc., is measured with a low-level GM survey meter and is equal to or less than natural radiation background levels. Onc this levle has been determined, all radiation labels and symbols will be removed prior to disposal as non-radioactive waste. Appropriate documentation will be maintained on file in the department utilizing radioactive material.

Long lived radioactive wate will be stored in a suitable container properly shielded until disposed of when below Natural BKG radiation or returned to supplier.

Records of such disposal will also be properly maintained and reviewed as necessary by the Radiation Safety Officer.

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IODINE-131 HANDLING PROCEDURES

1. In order to minimize the potential volatilization and contamination during patient dose preparation, the use of radioiodine with mainly be in the physical form of capsules.

2. When uncontained high specific activity is used, such as in treatment of thyroid carcinoma, the following additional procedures will be followed:

   A. The vial containing the radioiodine will remain unopened and stored in the lead shipping container in the isotope storage area until just prior to patient administration.

   B. When ready for patient administration, while using rubbery gloves and forceps, the vial will be opened in the fume hood to allow any volatized buildup of iodine to escape. The vial will then be closed, and the surface of the unshielded container will be wiped with alcohol sponge pad to remove any possible contamination. It will then be assayed in teh dose calibrator and replaced in its shield. Smears will be taken to assure that no contamination has occured in the work area.

C. The unopened vial will be taken to the patient administration area in its shield. While using rubbery gloves, the vial will be opened and a straw inserted. The shielded container will be given to the patient to drink.

D. When does has been administered, the shielded vial will be placed in a plastic bag, sealed and returened to the isotope storage area for decay and disposal.

E. Several smears of the patient administration area will be taken to check for contamination.

F. Individuals involved with dose administration will wash their hands thoroughly with soap and water and will have their thyroid checked for possible uptake as described in the Bioassay Procedures.

G. The procedures described in the Health Physics Aspects of Nursing Care of Therapy patients with <u>Unsealed</u> Sources will be followed when the patient is hospitalized.

Item No. 19
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HEALTH PHYSICS ASPECTS OF NURSING CARE

OF RADIATION THERAPY PATIENTS WITH NON-SEALED SOURCES OF RADIATION

1. PURPOSE:
The purpose of this notice is to famaliarized the nursing staff with their responsibility to the patient and themselves in the prevention of unnecessary exposure to radiation.

2. GENERAL:
This type of radioactive source is usually in liquid form, and therefore is classified as a non-sealed source. The source material will remain in the patient until it decays by half-life and/or is exreted; therefore, contamination of the linen, etc., is possible.

A. Place the patient in a private room with the bed near the outside wall of the room. Room survey will be done daily and the door posted with Radioactive sign.

B. Cover the mattress and pillow on the bed with plastic or rubber material.

C. Place a plastic-lined waste basked and linen hamper in the patients room.

D. Wear <u>your</u> film bade or dosimeter when entering the room.

E. Consistent with adequate care for the patient, carry out only minimum nursing procedures close to the patient. If the patients clinical status requires constant observation, rotate the personnel required to perform adequate care in order to minimize exposure to personnel.

F. Personnel are not to remain in the room unless engaged in specific activity.

G. A television, set, telephone, books, etc., may be provided the patient.

H. Wear gloves when changing bed lined, dressings, etc.

I. Place waste, soiled linen, etc., in the designated containers for monitoring the disposal.

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J. Personal items for patient care (thermometer,bedpan, etc.), will be kept in the patients room. Bath water may be disposed of in the commode.

K. Ambulatory patients will use the commode in their room. The commode should be flushed three times after use when Iodine is the radioactive material.

L. Diagnostic samples of blood, urine and feces should only be obtained when authorized by the Radiotherapist.

M. Disposable food trays will be monitored after use, then discarded.

N. The patient may have visitors. Except for geeting, the visitor should stay on the "safe" side of the line indicated on the floor.

O. Urine is radioactive; spills, bedwetting, or any accident with urine, are radiation hazards. Wear gloves. Cover with absorbent material and place the absorber in the designated waste container.

PATIENT RADIATION SURVEY LOG

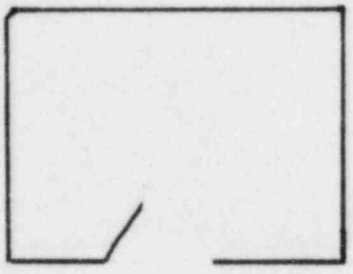
Patient	Room	Therapy start date
_____	_____	_____

Isotope _____ Activity _____ (mCi,or mg Ra eq)

Therapist's name _____

SKETCH OF PATIENTS ROOM/BED

Adjacent room yes/no



Adjacent room yes/no

(indicate specific location of bed in room)

Survey meter measurements: Doorway _____ mR/hr
Occupied adjacent room(s)_____mR/hr
1 meter from source _____mR/hr

THERAPY TERMINATION DATA

Date residual activity less than 30 mCi: _____*

Radiation survey of patients room conducted by _____

NOTE: IF RADITATION LEVELS ARE DETECTED ABOVE NATURAL BACKGROUND LEVELS, IMMEDIATELY NOTIFY THE RADIATION SAFETY OFFICER.

GENERAL

Have nurses been given dosimeters and log? yes/no
Has the 2mR/hr tape been placed on the floor? yes/no
Has patient been positioned in such a way that exposure to others is minimal? yes/no
Have the nurses a copy of appropriate protocol for nursing care of radiation therapy patients? yes/no (supply as required)

NOTE: If Iodine-131 is source material and the patient remains hospitalized, continue controls until residual activity is less than 30 mCi.

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SIBLEY MEMORIAL HOSPTAL

XENON-131 HANDLING PROCEDURES

QUANTITY TO BE USED

1. Approximately 750 patients per year will be studies with an average activity of 10 millicures per patient.

2. Desired possession limits: 200 millicuries.

USE AND STORAGE AREAS

The Xe-133 will be used and stored in the Nuclear Medicine Clinic. Storage of the individual Xe-133 doses will be in a lead container in the isotope storage area surrounded by lead bricks in the "hot lab". Patient doses will be administred in the camera room of the Nuclear Medicine Department

DESCRIPTION OF VENTILATION SYSTEM

1. The total area of the camera room is approximately 3113 cubic feet. The room will be under negative pressure with the normal air return system exhausted directly to the outside atmosphere at the rate of 2000 cfm through ceiling exhaust vent with no re-circulated air.

2. The "hot lab", where radioactive material is stored and prepared for dosing is 13 feet x 22.5 feet with an 8.5 foot veiling for a total volume of 2486 cubic feet. Room air is exhausted to the outside atmosphere at an average rate of 500 cfm through the fume hood.

PROCEDURES FOR ROUTINE USE

1. Xe-133 will be procured in precalibrated doses and delivered directly to the Nuclear Medicine Lab. It will be stored in its shipping container in the Istope storage area until ready for patient administration. Upon receipt, the package will be inspected in accordance with the "Procedures for Examing Incoming Radioisotope Packages", per Item 14, of our original license application (enclosed).

2. Immediately prior to administration, the dose will be measured in the dose calibrator. A Radax Xenon System or equivalent, will be used-Xenon injected into the dispensing system. The patient will be positioned with self-contained breathing system and mask. All valve positions will be checked for proper settings. The patient will be instructed, the valve re-positioned and the scan started. After the scan is completed, the exhaled Xe-133 gas will be collected in the intergrated gas trap system and allowed to decay to baCKGROUND. No Xe-133 gas will be exhausted into the atmosphere.

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RECORD OF ISOTOPE THERAPY MONITORING

Radioisotope administered: _____

Dose of administration: _____

Dose administered: _____

Patients name: _____ Room number: _____

Type survey instrument: _____ Site: _____

LOCATION / TIME	SKIN	3 FT.	6 FT.	DOOR	EASY CHAIR	LINENS	WASTE	MISC.
DAY OF ADMINISTRATION								
24 hrs.								
48 hrs.								
72 hrs.								
96 hrs.								
120 hrs.								

WIPE TEST: _____

OTHER COMMENTS: _____

_____

_____

Emergency Procedures

1. If, during the patient study, an accidental release of Xe-133 occurs, the room will be evacuated immediately and the doors closed.

2. The room will remain vacated for a minimum of fifteen minutes, which will allow for at least 9 room air exchanges.

3. At the end of fifteen minutes, the floor will be monitored with a low-range GM survey meter to check for any residual Xe-133 gas. If the resulting measurements are greater than background, the room will be vacated for another fifteen minutes and then monitored again to assure that no Xe-133 is present.

Air Concentrations of Xe-133 in Restricted Areas

1. Camera Room

   A. Ventilation rate (V) is 2000 cfm.

   B. MPC for restricted area for 40 hour week is 1×10^{-5} uCi/ml.

   C. Maximum activity used per week (A):

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{15 \text{ patients}}{\text{week}} \times \frac{1 \times 10^{3} \text{uCi}}{\text{mCi}} = 1.5 \times 10^{5} \text{uCi/week}$$

   D. Assume five complete patient doses lost per week (ultra conservative), or 25% of activity used. Therefore f=0.25.

   E. Volume of air available per week for dilution of Xe-133:

$V = 2 \times 10^{3} ft^{3}/min \times 2.8 \times 10^{4} ml/ft^{3} \times 2.4 \times 10^{3} min/40\text{-hour week} =$
$1.34 \times 10^{11} ml/week$

   F. Volume of air required to meet MPC is

$$V = \frac{A \times f}{1 \times 10^{-5} \text{uCi/ml}} = \frac{1.5 \times 10^{5} \text{uCi/wk} \times 0.25}{1 \times 10^{-5} \text{uCi/ml}} = 3.75 \times 10^{9} \text{ml/week}$$

   Therefore, the available ventilation rate is more than one order of magnitude above that required to insure compliance with Section 20.103 of 10CFR-20.

2. Hot Lab

   A. Ventilation rate (V) 500 cfm

   B. MPC is 1×10^{-5} uCi/ml

   C. Maximum activity on hand per week: 200 mCi or 2×10^{5} uCi

   D. Assume a leakage rate of 20%

   E. Volume of air available per week for dilution of Xe-133:

$V = 5 \times 10^{2} ft^{3}/min \times 2.8 \times 10^{4} ml/ft^{3} \times 2.4 \times 10^{3} min/40\text{-hour week} = 3.36 \times 10^{10} ml/wk$

Air Concentrations of Xe-133 in Restricted Areas (continued)

2. Hot Lab

F. Volume of air required to meet MPC is

$$V = \frac{A \times f}{1\times10^{-5}\text{uCi/ml}} = \frac{2\times10^{5}\text{uCi/week} \times 0.20}{1\times10^{-5}\text{uCi/ml}} = 4.0\times10^{9}\text{ml/week}$$

Therefore, the available ventilation rate is above that required to insure compliance with Section 20.103 of 10CFR-20.

Method of Disposal

1. The Xe-133 expired air will be vented through the exit port into the integrated gas trap system. This system will be monitored weekly with a GM survey meter to insure that it is performing adequately.

2. If there should be leakage in the gas trap system or storage container, the Xe-133 gas will be exhausted to the outside, or unrestricted area, through the fume hood vent at the rate of 500 cfm.

3. If there should be an accidental release of Xe-133 in the camera room, the gas will be exhausted to the outside or unrestricted area through the ceiling vent at the rate of 2000 cfm.

4. Initially, to insure that collection and ventilation systems are performing satisfactorily, exposure rate measurements will be made at one foot from the breathing bag, prior to venting to the integrated gas trap system. After the bag has been vented, exposure rate measurements will be made at the surface of the bag to assure that no residual radioactivity remains prior to routine disposal (meter reading <0.05mR per hour above background). Results of these measurements and disposals will be recorded and used to periodically check the performance of the system.

5. The air from the outlet port of the trap system will be recollected into the breathing bag, which will be monitored with a GM survey meter to check on system performance and to determine when the filters approach saturation point. Saturated filters will be removed from the system and stored in air-tight shielded containers until the Xe-133 activity decays to background (meter reading <0.05mR per hour above background), or are disposed of through a commercial vendor. Records will be maintained of such monitoring and disposal.

Method of Disposal

6. An Alnor Velometer, Series 6000, or similar type flow meter will be used to assure that the ventilation rate is adequate. This will be done prior to the initial use of Xe-133 studies, after any repairs which may alter the flow rate, and quarterly thereafter.

7. Periodic surveys shall be made of the storage area to insure that radiation levels are within allowable limits and as low as reasonably achievable.

Concentrations in Effluents to Unrestricted Areas

MPC for unrestricted area is 3×10^{-7} uCi/ml.

1. Camera Room Exhaust

   A. Maximum amount to be released per year (A):

   $$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{15 \text{ patients}}{\text{week}} \times 1 \times 10^{3} \text{uCi/mCi} \times 52 \text{ weeks/year} =$$

   7.8×10^{6} uCi/year

   Assume 25% actual loss during use = 1.95×10^{6} uCi/year

   B. Ceiling exhaust rate measured at 2000 cfm

   $$2 \times 10^{3} \text{ft}^3\text{min} \times 1.49 \times \frac{10^{10} \text{ml/year}}{\text{ft}^3\text{/min}} = 2.98 \times 10^{13} \text{ml/year}$$

   C. Concentration (C)

   $$C = \frac{1.95 \times 10^{6} \text{uCi/year}}{2.98 \times 10^{13} \text{ml/year}} = 6.5 \times 10^{-8} \text{uCi/ml.}$$ This is less than MPC.

2. Hot Lab Exhaust

   A. Maximum amount to be released per year (A)

   A = 200 mCi/week x 52 weeks/year x [illegible] Ci = 1.04×10^{7} uCi/year

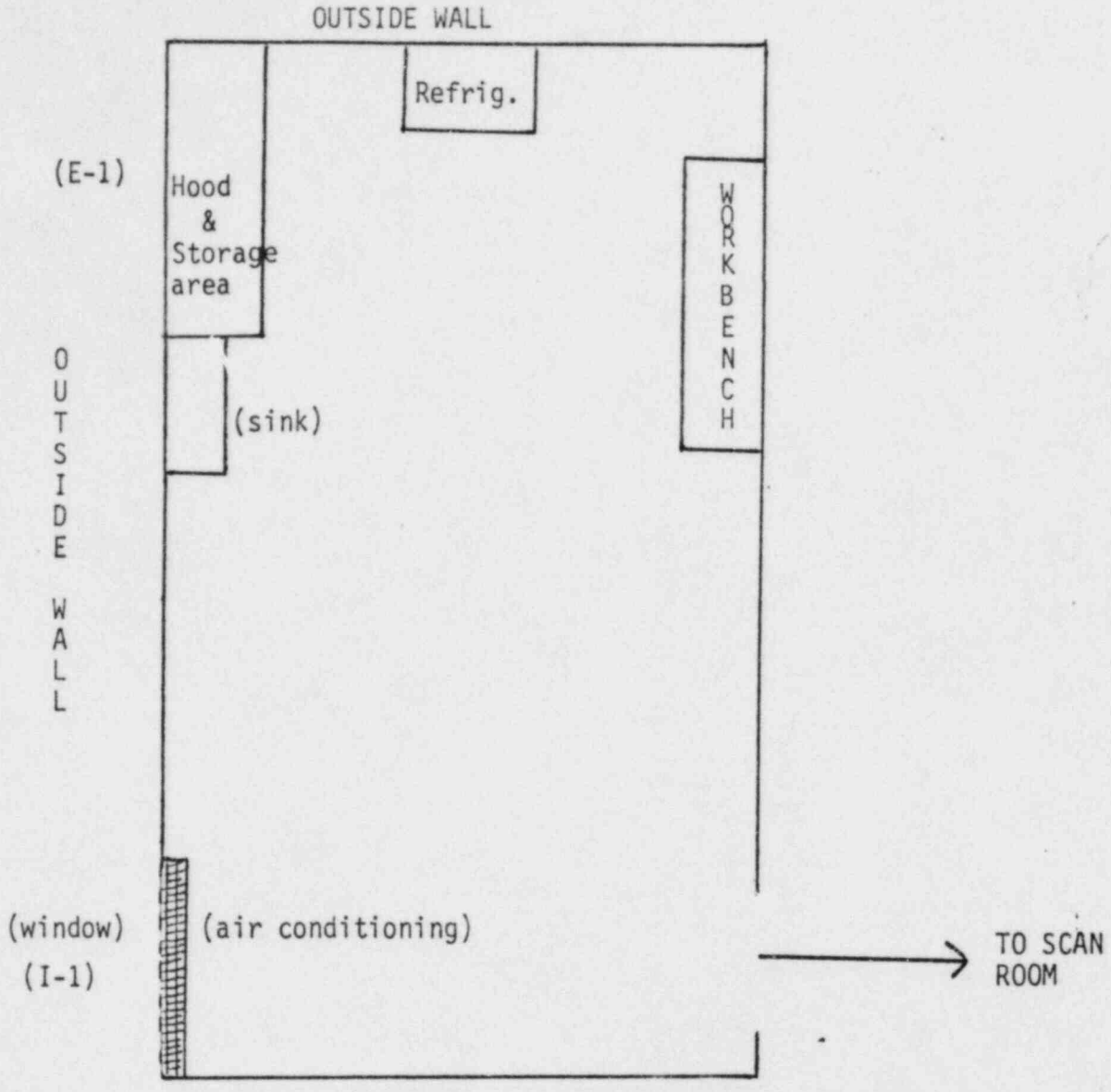
   Assume 20% Actual lost during sto[illegible] $\times 10^{6}$ uCi/year

   B. Fume hood exhaust rate is $5 \times 10^{2} \text{ft}^3\text{/min} \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3\text{/min}} = 7.45 \times 10^{12}$

   C. Concentration (C)

   $$C = \frac{2.0 \times 10^{6} \text{uCi/year}}{7.45 \times 10^{12} \text{ml/year}} = 2.6 \times 10^{-7} \text{uCi/cc.}$$ This is less than MPC.

Average amount of Xenon-133 that can be released per week without exceeding an average concentration of 3×10^{-7} uCi/ml at an exhaust rate of 2000 and 500 cfm is 171 and 42.9mCi, respectively. Whereas the maximum anticipated accidental release per week is 50 and 40mCi, respectively.



VENTILATION RATES

HOT LAB

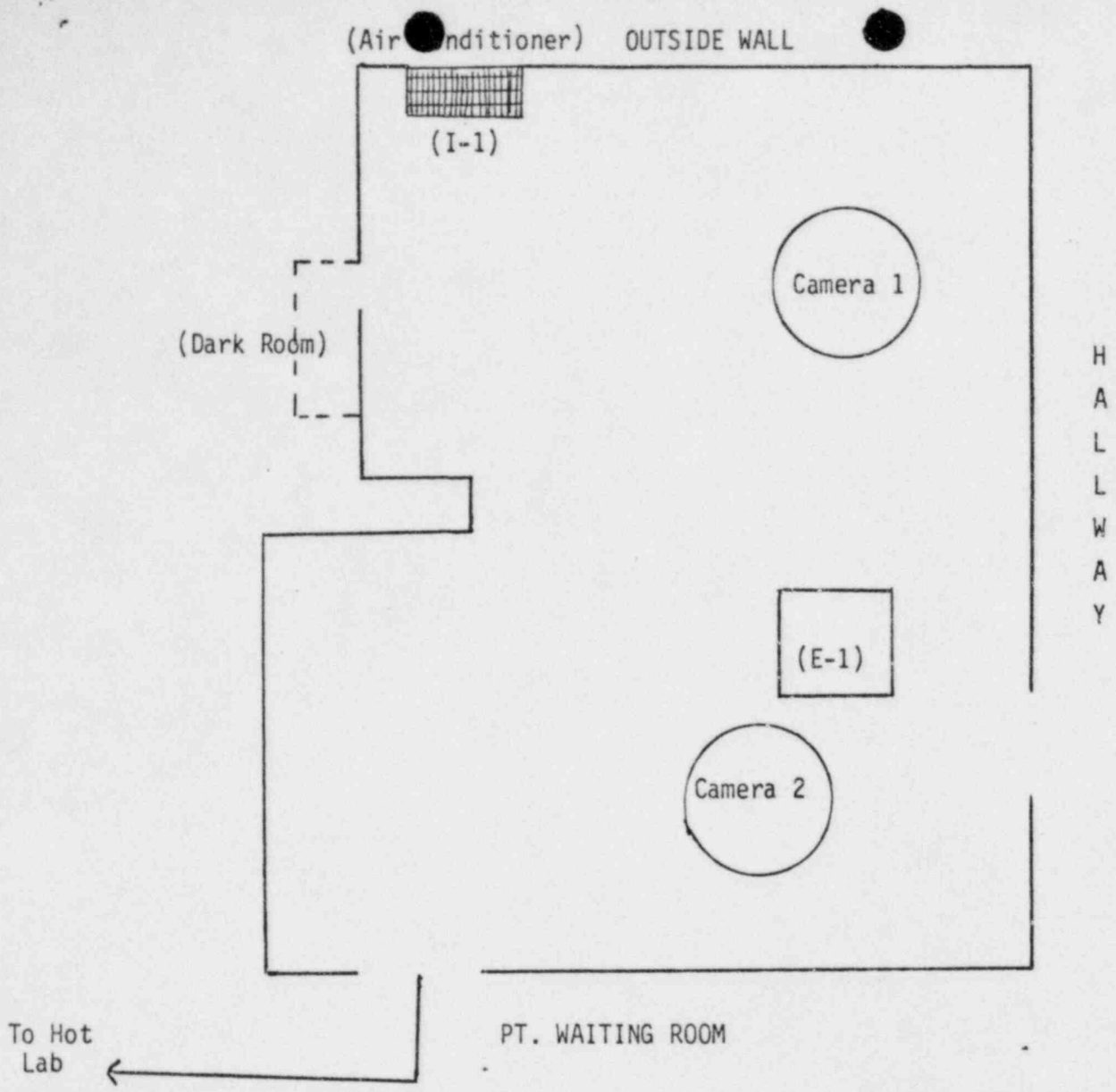
E-1 (exhaust) ave. 500 CFM
I-1 (input) ave. 300 CFM

Room size 13'x 22.5'x 8.5' = 2486 ft^3
One total exhaust every 5 minutes

The room is under negative pressure

Item 21
9-30-83

SIBLEY MEMORIAL HOSPITAL CAMERA ROOM SPECIFICATIONS



VENTILATION RATES

CAMERA ROOM

E-1 (exhaust) ave. 2000 CFM
I-1 (input) ave. 500 CFM

Room size = 3113 ft^3
One total exhaust every 1.55 minutes

The room is under negative pressure.

Item 21
9-30-83

Bio-assay to be done in accordance with

Regulatory Guide 8.2

Revised

Item 23
9-30-=83

DEPARTMENT OF PATHOLOGY
CLINICAL AND ANATOMIC PATHOLOGY
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FOREWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and bio-medical 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:

1. To 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 of reactive materials for diagnostic or therapeutic purposes.

2. To control operational procedures by the user of radiation sources.

3. To 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 described herein for keeping radiation exposures (individual and collective) to as low as reasonably achievable (ALARA). We are also committed to following the guidance provided by U. S. Nuclear Regulalatory Guides 8.0 and 8.18.

All primary users of radiation sources are encouraged to review current procedures and develop new procedures as appropriate for ways to implement the ALARA concept.

9/30/83

RADIATION SAFETY PROGRAM (ALARA)

1. INTRODUCTION

A. Purpose

This program sets forth the philosophy and general management policies that are established by this hospital to achieve the objective of maintaining radiation exposures to "as low as reasonably achievable" (ALARA), for employees, visitors students and patients not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

B. Polocy

In addition to complying with the limits set forth in pertinent regulations, guides, and standards, users and supervisors of radiation sources shall make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas to as low as reasonably achievable.

II. MANAGEMENT COMMITMENT

A. The management and the entire staff of this hospital are committed to the program described herein for keeping radiation exposures to as low as reasonably achievable.

B. The Radiation Safety Committee, of which the hospital Administrator is a member, shall in coordination with the radiation safety officer and health physics consultant, perform a formal audit on an annual basis to determine how effective is the ALARA program. A report containing the results of this audit will be maintained by the chairman of Radiation Safety Committee to facilitate inspections by regulatory accrediting agencies.

C. Based on the recommendations of the radiation safety staff, modification to operating procedures, equipment, and facilities shall be made where they will significantly reduce radiation exposures to reasonable costs.

D. The services of general Health Physics, has been contracted to assist in the program management to insure that all pertinent hospital staff and employees receive appropriate briefings and training in radiation safety including ALARA concepts.

VIII. STANDARDS FOR RADIATION PROTECTION (ontinued)

C. Perform radiation safety surveys of diagnostic x-ray facilities for conformance with pertinent standards.

D. Provide traininig to radiation workers on subjects relating to radiation protection.

E. Conduct calibrations of radiation measuring instruments and leak tests and inventory of sealed radioactive sources.

9/30/83

III. RADIATION SAFETY COMMITTEE

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

A. Determine whether current procedures are, in fact, maintaining radiation exposures to ALARA. The efforts of radiation safety officer, health physics consultant, users and supervisors of radiation sources, as well as those of management will be reviewed during the committee meetings.

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

IV. RADIATION SAFETY OFFICER

In addition to the responsibilities set forth in pertinent radiation control standards and guides, the radiation safety officer and his health physics consultants will:

A. Conduct periodic surveillance programs and investigations to insure that occupational radiation exposures are maintained to ALARA.

B. Communicate directly with the appropriate staff personnel, take necessary corrective action to enforce rules and procedures pertaining to the radiation safety program.

C. Schedule periodic briefings and educational programs to insure that users and supervisors of radiation sources understand the ALARA philosophy, and also, that the managers of the radiation safety program are committed to the ALARA concept.

D. Investigate and report all significant instances of deviation from ALARA concepts to the Radiation Safety Committee for review.

V. SUPERVISORS AND RADIATION SOURCES

A. The supervisor of radiation sources will insure that all radiation sources used under his jurisdiction are used only by personnel competent to use them.

B. he will insure that all personnel he assigns to work with radiation sources are trained in good health physics practices and in maintaining their radiation exposures to ALARA.

C. He will maintain coordination with the radiation safety officer and health physics consultant to insure that his procedures are in accordance with the ALARA concept.

VI. RADIATION WORKER

A. Take the necessary precautionary measures to protect hemself and others from unwarranted radiation exposure.

B. Report any radiation accident and/or unusual incident to the radiation safety officer as soon as possible after occurance.

C. Understand and implement the ALARA procedures developed by the radiation safety officer.

VII. RADIATION EXPOSURE ACTION LEVELS

Class of Operation	Action level (mRem/Quarter)	
	Whole Body	Extremity
1. Diagnostic Nuclear Medicine		
2. Diagnostic x-ray	125	1800
3. Clinical Laboratory	125	1800
4. Radiopharmaceutical Therapy	75	200
5. Miscellaneous (Nursing, ICU, Operating Room, etc.)	125	1800
6. Teletherapy	125	1800
7. Bracytherapy	125	1800

These action levels were initially established based upon 10% of MPD (10 CFR, Part 20.201) and/or review of previous radiation exposure histories for the class of operation. These levels will be reviewed and adjusted appropriately upon completion of each audit.

Any personnel exposure which exceeds the established action level will be investigated and appropriate records maintained.

VIII. STANDARDS FOR RADIATION PROTECTION

General Health physics is a private consulting firm which has been contracted to provide for the management of the overall radiation safety program in coordination with the radiation safety officer and the RAdiation Safety Committee. The following services are included:

A. Advise the hospital staff on all matters pertaining to radiation safety standards and criteria.

B. Perform periodic radiation safety surveys where radioactive materials are used, stored, and disposed of to assure compliance with pertinent regulations, guides, and standards.