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

Veterans Administration Medical Center
150 Muir Road
Martinez, California 94553

TELEPHONE NO.: AREA CODE(415) 228 6800

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Edwin M. Leidholdt, Jr., Ph.D. (11R)

TELEPHONE NO.: AREA CODE(415) 228 6800

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 04-02956-02

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

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.)*

Edwin M. Leidholdt, Jr., Ph.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 each byproduct mat.
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	2000 mCi each byproduct mat.
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 mCi

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

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. 1 Date: October 1980

7. MEDICAL ISOTOPES COMMITTEE	
X	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
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)*	
X	Appendix F Procedures Followed; or
	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)*	
	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)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	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)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
X	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	R. S. Landauer, Jr. & Co. Glenwood Science Park, Glenwood, IL 60452	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Same as above	monthly
		OTHER (Specify)		
c. WRIST	X	FILM	Same as above	monthly
		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: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

C. H. Nixon

(1) NAME *(Type or Print)*
C. H. NIXON

(2) TITLE
Director

c. DATE
OCT 25 1984

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(h)).

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.

INDIVIDUAL USERS

Albert Weinshelbaum, M.D.	Groups I, II, III, IV, and V In vitro studies, animal studies Americium 241 Anatomical Marker Xenon 133
Charles A. Barnett, M.D.	Groups I, II, III, IV, and V In vitro studies, animal studies Americium 241 Anatomical Marker Xenon 133
Paul A. Farrer, M.D.	Groups I, II, III, IV, and V In vitro studies, animal studies Americium 241 Anatomical Marker Xenon 133
Marguerite T. Hays, M.D.	Groups I, II, III, IV, V In vitro studies, animal studies Americium 241 Anatomical Marker
Ildiko Sandford, M.D.	In vitro studies
Emmanuel Samouhos, M.D.	Depleted uranium for shielding, Strontium-90 for treatment of superficial eye disease
Antolin Raventos, M.D.	Depleted uranium for shielding, Strontium-90 for treatment of superficial eye disease
Edward C. Larkin, M.D.	In vitro studies, animal studies
Corey Largman, Ph.D.	In vitro studies, animal studies
Robert Noth, M.D.	In vitro studies, animal studies
Alan Brautigam, Ph.D., M.D.	In vitro studies, animal studies
George Kaysen, Ph.D., M.D.	In vitro studies, animal studies
Albert Wheatley	Depleted uranium for shielding, Strontium-90 and Cs-137 for instrument calibration
Edwin M. Leidholdt, Ph.D.	In vitro studies, Cs-137 for instrument calibration

Item 4
Date _____

RADIATION SAFETY OFFICER

Edwin M. Leidholdt, Jr., Ph.D., is our Radiation Safety Officer. Dr. Leidholdt will be assisted by a consultant, Jerrold T. Bushberg, Ph.D., until Dr. Leidholdt has had two years experience at our medical center. Dr. Bushberg is the Medical Center Radiation Safety Officer, Technical Director of Nuclear Medicine, and Program Director for the School of Nuclear Medicine Technology at the University of California, Davis Medical Center in Sacramento, California.

Dr. Leidholdt, as our Radiation Safety Officer, has complete responsibility for all aspects of our radiation safety program. Dr. Bushberg serves as a technical expert who is consulted when Dr. Leidholdt believes that additional expertise is required to deal with a particular radiation safety problem or that a review of a portion of our radiation safety program would be desirable. In the past, Dr. Leidholdt has been consulting Dr. Bushberg about twice a month.

Item 5
Date _____

RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a.

Element & Mass No.	Chemical and/or Physical Form	Maximum Number of millicuries of each form	Describe Purpose of Use
Americium-241	Sealed Source (Amersham/Searle Model AMC.24)	14 millicuries	To be used in Searle Analytic Model SS-10244 Anatomical Marker
Uranium (depleted in Uranium 235)	Cadmium Plated Metal	140 kilograms	As shielding in a linear accelerator
Strontium-90	Sealed Source (Tracerlab Inc. Model RA-1A)	50 millicuries	For treatment of superficial eye disease
Strontium-90	Sealed Source (Nuclear Enterprises Model 25-031)	10 millicuries	Standard for instrument calibration
Cesium-137	Sealed Source contained in J.L. Shepard and Associates Model 28-5 Single Source Beam Calibrator	100 millicuries	Standard for instrument calibration
Hydrogen-3	Prelabelled organic chemicals	60 millicuries	In Vitro and animal studies
Carbon-14	Any	30 millicuries	"
Phosphorus-32	Any	20 millicuries	"
Sulfur-35	Any	10 millicuries	"
Chromium-51	Any	10 millicuries	"
Rubidium-86	Any	10 millicuries	"
Technetium-99m	Any	50 millicuries	"
Iodine-125	Any	20 millicuries	"
Iodine-131	Any	5 millicuries	"

Item 6.b.
Date _____

RADIATION SAFETY COMMITTEE

The membership of the Radiation Safety Committee will include the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the medical center's management, and the Radiation Safety Officer. The Chairman shall be an authorized user with at least one year of experience on the committee. A list of the names and specialties of the members of the committee will be maintained at the medical center. A list of the current committee membership is attached.

The responsibilities and duties of the committee are those specified in Appendix B of the Nuclear Regulatory Commission Regulatory Guide 10.8, dated October 1980, and also those specified in Station Memorandum 11-30 (ALARA Program) dated July 20, 1984 (attached). The Chairman of the Radiation Safety Committee and the Radiation Safety Officer may, if they deem it appropriate, jointly grant provisional approval for new uses of radioactive material (duties 4 and 5, Appendix B, Regulatory Guide 10.8) and also of the qualifications of users (duty 2, Appendix B, Regulatory Guide 10.8). Such provisional approvals shall remain in effect until the next committee meeting.

The Radiation Safety Committee shall meet at least quarterly.

Attachments

Item 7
Date _____

RADIATION SAFETY COMMITTEE

(CURRENT MEMBERSHIP)

A. Raventos, M.D., Associate Chief, Radiotherapy, Chair

A. Weinshelbaum, M.D., Associate Chief, Diagnostic Radiology

Charles Barnett, m.D., Nuclear Medicine Service

Alan Schwartz, M.D., Cardiology Section

Steven Levine, Ph.D., Laboratory Service

Corey Largman, Ph.D., Research Service

Alan Brautigam, M.D., Ph.D., Research Service

Albert Wheatley, Jr., Associate Radiation Safety Officer

Edwin Leidholdt, Jr., Ph.D., Radiation Safety Officer

Anita Straley, R.N., CCRN, Nursing Service

Claire Baie, Nuclear Medicine Service

Gary Whitfield, Office of the Chief of Staff

David Lawson, Chief, Engineering Service

Wayne C. Tippets, Associate Director

VA Medical Center
Martinez, California

Station Memorandum No. 11-30
(Revised)
July 20, 1984

ALARA PROGRAM FOR MINIMIZING EXPOSURE TO RADIATION

1. PURPOSE

To outline a uniform program for maintaining occupational radiation exposure at this medical center as low as reasonably achievable (ALARA).

2. POLICY

a. The management of this medical center is committed to the program described in this memorandum for keeping exposures (individual and collective) as low as reasonably achievable (ALARA).

b. A formal annual review of the radiation safety program, including ALARA considerations, will be performed. This shall include review of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost is considered to be unjustified. Improvements will be sought, and modifications will be considered and implemented where reasonable. Where modifications have been recommended but not implemented, the reasons for not implementing them will be described.

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.

3. AUTHORITY AND RESPONSIBILITY

a. Radiation Safety Committee (RSC)

(1) Review of proposed users and uses:

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

(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 this proposed use.

(c) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

(2) Delegation of Authority: (The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

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

(b) 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.

(3) Review of ALARA Program:

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

(b) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in the table below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph 6).[1]

(c) 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.

b. Radiation Safety Officer (RSO)

(1) Annual and quarterly review:

(a) 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.

(b) 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 Section 4 of this program.

---

[1]The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

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

(2) Education responsibilities for an ALARA Program:

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

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

(3) Cooperative efforts for development of ALARA procedures: Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

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

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

(4) 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.

c. Authorized Users

(1) New procedures involving potential radiation exposures:

(a) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(b) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

(2) Responsibility of the authorized user to those he supervises:

4.

(a) The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all those he supervises.

(b) The authorized user will ensure that those under his supervison who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

d. Persons Who Receive Occupational Radiation Exposure

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

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

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

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

	Investigational Levels (mrems per calendar quarter)	
	LEVEL I	LEVEL II
Whole body; head and trunk; active blood-forming organs; lens or eyes, or gonads	125	375
Hands and forearms; feet and ankles	1875	5625
Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

b. The Radiation Safety Officer will review and record on Form NRC-5 "Current Occupational External Radiation Exposures," or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20.401. The following actions will be taken at the Investigational Levels as stated in the table:

(1) 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 values for the Investigational Level I.

(2) 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 this review 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 in an index of ALARA program quality and will record the review in the Committee minutes.

(3) 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 Form NRC-5 or its equivalent 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.

(4) Reestablishment of an individual occupational worker's Investigational Level II above that listed in the table: In cases where a worker's or a group of workers' exposures need 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 Level II will be documented. The Radiation Safety Committee will review the justification for and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph (3) above will be followed.

5. AUTOMATIC REVIEW, RESCISSION OR REISSUE DATE: July 1986 (11R)

6. REFERENCES

Nuclear Regulatory Commission Regulatory Guide 10.8 dated October 1980.

7. RESCISSION: Station Memorandum No. 11-30 dated February 10, 1982.

C. H. NIXON
Director

Distribution C

TRAINING AND EXPERIENCE

a. Authorized Users - All Authorized Users were listed as Authorized Users on this license at the time of application for renewal, with the exception of Edwin M. Leidholdt, Jr., Ph.D. Dr. Leidholdt's qualifications are described in a letter from our medical center to the Nuclear Regulatory Commission, dated April 20, 1984.

b. Radiation Safety Officer - The information for this item is submitted under Item 5.

Item 8
Date _____

INSTRUMENTATION

1. Survey Meters

   a. Eberline E-520 GM Survey Meter with HP-270 Probe

   b. Eberline E-520 GM Survey Meter with HP-260 and HP-270 Probes

   c. 2 Eberline E-520 GM Survey Meters with HP-260 Probes

   d. Eberline PRM-6 Survey Meter with HP-260 Probe

   e. 2 Technical Associates TBM-3 GM Survey Meters

   f. Nuclear Chicago Model 2650 GM Survey Meter

   g. Texas Nuclear Exposure Ratemeter Model 2592 Ionization Chamber Survey Meter

   h. Technical Associates CP6M Ionization Chamber Survey Meter

   i. Eberline PRM-6 Survey Meter with LEG-1 Scintillation Probe

   The survey meters listed in b., c., d., and e. are G-M type instruments with window thicknesses equal to or less than $2mg/cm^2$ and are capable of detecting exposure-rates less than 0.1 mR/hr. The ionization chamber instrument listed in g. is capable of measuring exposure-rates up to 1 R/hr and the ionization chamber instrument listed in h. is capable of measuring up to 100 R/hr.

2. Dose Calibrators

   a. Squibb CRC-17 Radioisotope Calibrator

   b. Nuclear Chicago "Mediac" Dose Calibrator

3. Instrumentation Used for Diagnostic Purposes

   a. Siemens Pho-Gamma LEM 6580 Gamma Scintillation Camera

   b. Searle LFOV 6413 Gamma Scintillation Camera

   c. Searle Pho/Gamma V 6476 Gamma Scintillation Camera

   d. Searle Pho/Gamma IV 6472 Gamma Scintillation Camera

   e. Picker Spectroscaler 4R with Picker Scintillation Well Counter and Picker Omniprobe Thyroid Probe

f. Searle 1185 Automatic Gamma Well Counter

4. Other

a. 2 Searle Mark III Liquid Scintillation Counters (used for counting wipe samples)

b. Searle 1185 Automatic Gamma Well Counter (used for counting wipe samples)

c. Micromedic 4/2000 Automatic Gamma Counter (used for counting wipe samples)

d. Xetex 501A Area Radiation Monitor (used to monitor the Nuclear Medicine hot lab)

e. Sierra Instruments Model 615 thermoanemometer (used to measure fume-hood face velocities)

CALIBRATION OF SURVEY INSTRUMENTS

Our survey instruments will be calibrated by an outside firm, Radiation Detection Company of Sunnyvale, California. The required information for this item is attached.

Attachment

Item 10a
Date _____

RADIATION DETECTION COMPANY
162 Wolfe Road • P.O. Box 1414 • Sunnyvale, California 94088 • (408) 735-8700

METHODS OF CALIBRATION OF SURVEY METERS

A. Our California Radioactive Materials License Number is 0053-59. California is an agreement state with NRC.

B. We have three point sources that we use for meter calibration:
   1. 10 milligrams Radium-226
   2. 2 curies Cobalt-60
   3. 100 curies Cesium-137

C. The calibration of our sources is checked at least every six months, using Victoreen R-Meters, calibrated with Victoreen NBS secondary standards. Our accuracy is better than ± 5%.

D. We calibrate survey meters at three points on each range (two points for meters with overlapping ranges).

E. We calibrate to within ± 20% of fullscale indication. We try to calibrate to better than ± 10% and only use ± 20% because of nonlinear meter response. We will not calibrate a survey meter if it is not accurate to within ± 20%.

F. Calibrated meters are returned with a calibration label affixed indicating serial number, calibration date and due date.

G. Certificates of calibration are mailed separately, showing calibration data.

FACILITIES AND EQUIPMENT

NUCLEAR MEDICINE

Attached are a diagram of the fourth floor of the medical center showing the location of the Nuclear Medicine Service, a diagram of the Nuclear Medicine Service area, and a diagram of the Nuclear Medicine Hot Lab (C412). The Nuclear Medicine Service is located on the fourth floor of the medical center at the end of a wing. It is bounded on three sides by the building exterior. On the fourth side, it is bounded by elevator shafts and corridors, which are infrequently occupied. Immediately above the Nuclear Medicine Service is the roof, which is seldom occupied. Immediately below on the third floor are offices which are usually occupied. The distance from the third to the fourth floor and also from the fourth floor to the roof is 11.75 feet. Both the fourth floor and the roof are constructed of 9.5 inches of reinforced concrete. The distance from the third to the fourth floor and the thickness of the concrete floor ensure that exposure-rates in the third floor offices are well below the maximum permissible dose-equivalent for an unrestricted area.

Radioactive materials are used and stored only in the four imaging rooms (C409, C410, C413 and C414) and the Hot Lab (C412). Within the Nuclear Medicine Service only the Dark Room (C411), the bathroom (C406), the Computer Room (C408) the Chief Technologist's Office (C409), the Residents' and Viewing Room (C405), and two corridors are immediately adjacent to imaging rooms or the Hot Lab (C412). Access to all of these areas is controlled and they are therefore designated as restricted areas. With the exceptions of the Chief Technologist's Office and the Residents' and Viewing Room, all are infrequently occupied. The end of the Hot Lab adjacent to the Residents' and Viewing Room is seldom used for manipulations of large activities. The two storage wells adjacent to the Residents' and Viewing Room are surrounded by shielding which is described later in this item. The Chief Technologist's chair within her office is approximately 11 feet from the usual location of a patient being imaged in Room C409. The Chief Technologist and the resident physicians wear film badges when in the Nuclear Medicine Service area. To date, their film badge reports have indicated that their exposures are well below maximum permissible dose-equivalents and consistent with the ALARA philosophy.

The following items are specifically addressed:

a. Use and Storage of Mo-99, Tc-99m Generators

These generators are not currently used at the medical center. If such generators are used in the future, they will be located and shielded to maintain exposures to personnel within the Nuclear Medicine Service and adjacent unrestricted areas at less than maximum permissible dose-equivalents and consistent with the ALARA philosophy.

b. Storage of Radiopharmaceuticals.

Refrigerated radiopharmaceuticals are stored in a refrigerator in the Hot Lab (Room C412). The refrigerator is shielded with 1/8 inch of lead on all sides. Radiopharmaceuticals within the refrigerator are further shielded by lead vial-shields and lead annular shields 1/2 inch thick when the exposure rate in the vicinity of a particular vial renders additional shielding necessary to conform with the ALARA philosophy.

During working hours, radiopharmaceuticals not requiring refrigeration are stored in the preparation and dispensing area described in d. below.

c. Storage of Radioactive Waste

Radioactive waste is currently stored for short periods of time (up to several days) in the Hot Lab in a shielded trash-can lined with 1/8 inch of lead, behind a shadow-shield of 2 inch thick lead bricks within the fume-hood, or in a storage and decay cave. There are two storage and decay caves in the Hot Lab immediately adjacent to the Residents' and Viewing Room. The cave closest to the sink is shielded on all sides with 2 inch thick lead bricks and on the bottom with Ø.25 inch of lead. The cave closest to the Residents' and Viewing Room is shielded on three sides with 2 inch thick lead bricks and, on the bottom and on the side adjacent to the Residents' and Viewing Room, with Ø.25 inch of lead. Two storage cabinets that are shielded on all sides with 1/8 inch of lead will be installed to replace the short-term waste storage in the fume-hood.

Radioactive waste is stored for longer periods of time prior to disposal in accordance with Item 18 in the Radioactive Waste Storage Facility, which is administered by the Radiation Safety Officer and is described separately in this item.

d. Preparation and Dispensing of Group III Kit Radiopharmaceuticals.

The preparation and dispensing area for Group III radiopharmaceuticals is shown in the diagram of the Hot Lab. It consists of a lead glass shield of 1.5 mm lead equivalent that is shielded on the sides with 2 inch thick lead bricks and is shielded toward the corridor with Ø.25 inch of lead.

Estimations of the maximum exposures in one hour and the maximum exposures in seven consecutive days were calculated for the unrestricted areas nearest each imaging room. These exposures are shown in the attached table. For each imaging room, the nearest unrestricted area is the Medical Service office area immediately below on the third floor. (In the case of Room C409, the elevator shaft is approximately 11.5 ft. from the gamma camera, but the elevator is only infrequently in the vicinity of the fourth floor and is not occupied for a significant length of time.) For the sake of conservatism, the calculations ignore all shielding. Radionuclides which are infrequently administered to patients for imaging were ignored, since they have little effect on the calculated exposures. The exposure was then calculated for a 20 mCi point source at 11.75 ft. for one hour. The maximum exposure in one hour was calculated for each room. First, it was determined that the product of activity administered per patient and specific gamma ray constant was larger for Tc-99m (20 mCi per patient) than for any other commonly used imaging agent. The maximum exposure for seven consecutive days was also calculated for each room. These calculations were based on the activities used per day in each imaging room that are listed in the attached table. For the sake of conservatism, these activities are not average daily activities; instead, they are the activities that might be used on an extremely busy day. Since no imaging procedures last longer than two hours, the exposure for seven consecutive days was also based on the assumption that these activities are present as point sources beneath the camera for 2 hours a day over 5 consecutive days. The following example shows the calculations for Room C409:

Maximum Exposure in One Hour:

$$E = (20\ \text{mCi})(0.78\ \text{R-cm}^2/\text{mCi-hr})(1\ \text{hr})/(11.75\ \text{ft})^2$$

$$= 0.122\ \text{mR/hr}$$

Maximum Exposure in Seven Days:

$$E = [(60\ \text{mCi})(0.78\ \text{R-cm}^2/\text{mCi-hr}) + (4\ \text{mCi})(4.7\ \text{R-cm}^2/\text{mCi-hr})]$$

$$(2\ \text{hr/day})(5\ \text{day/wk})/(11.75\ \text{ft})^2$$

$$= 5.1\ \text{mR/week}$$

The maximum exposure in one hour in each unrestricted areas is clearly much less than 2 mR and the maximum exposure in seven consecutive days is much less than 100 mR. If the maximum exposure for seven consecutive days for each unrestricted area is multiplied by 52 to obtain an estimate of the maximum exposure per year, the calculated exposure is much less than 0.5 R. This is still true even if a location on the third floor under both the LFOV and PG IV cameras is selected, which necessitates the summation of the

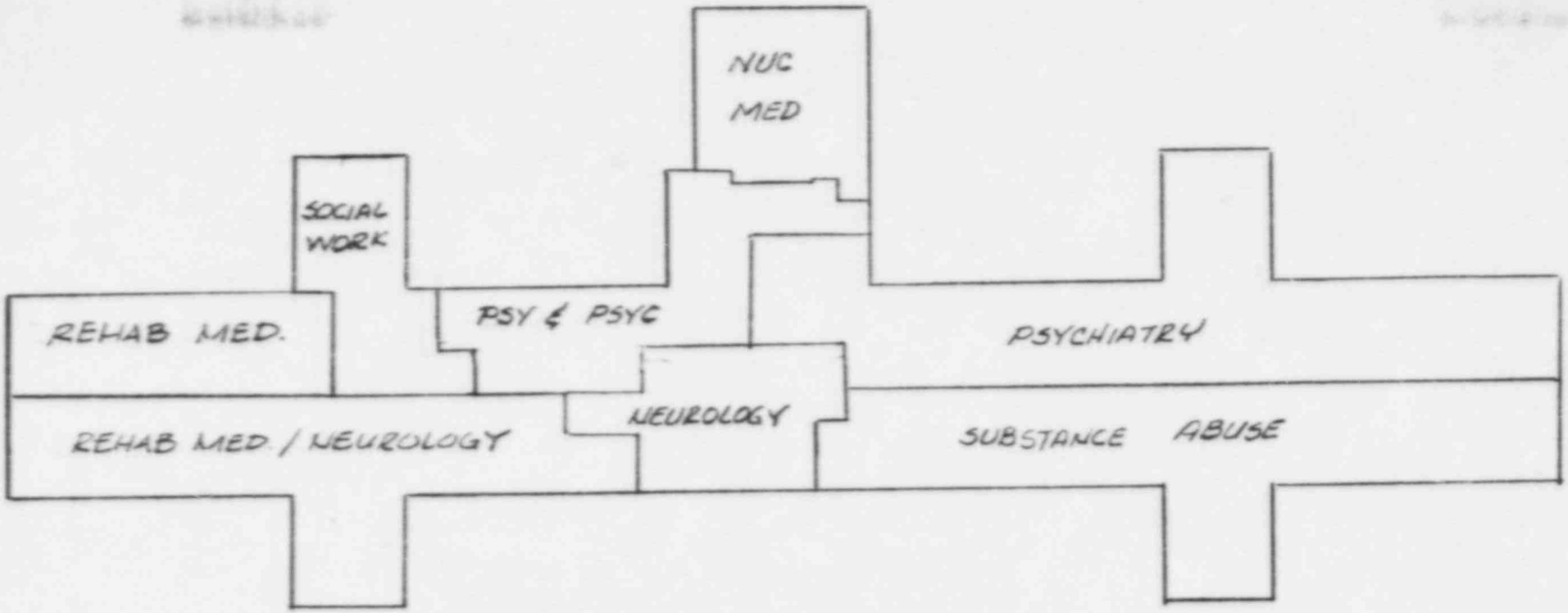
exposures from both cameras. It is therefore concluded that the exposures to personnel in unrestricted areas are within the allowable limits and consistent with the ALARA philosophy.

The sizes of the imaging rooms, as listed on the accompanying table, demonstrate that adequate distances are allowed between patients being imaged and technologists. Information on the use of Xenon-133 is contained in Item 21.

Room Number	Gamma Camera	Room Size (sq.ft.)	Nuclides Used	Activity Used (mCi/day)	Distance Patient to Unrestr.Area (ft.)	Maximum Exposure in One Hour (mR)	Maximum Exposure in 7 Days (mR)
C409	LEM	360	Tc-99m Tl-201	60 4	11.75	0.122	5.1
C410	PGIV	235	Tc-99m I-123	25 0.20	11.75	0.122	1.5
C413	PGV	235	Tc-99m	50	11.75	0.122	3.0
C414	LFOV	360	Tc-99m Ga-67 Xe-133	80 8 20	11.75	0.122	5.6

Table - Calculated Exposures in Unrestricted Areas Nearest to Patients Being Imaged.

For all rooms, the nearest unrestricted area is the Medical Service office area immediately below on the third floor. Shielding (primarily the 9.5 inch concrete floor) is ignored. The maximum exposure in one hour is based on the assumption of a 20 mCi point source of Tc-99m under the camera. The maximum exposure in seven days is based on the assumption that point sources of the activity used per day are placed under the cameras for 2 hours per day on 5 days of the week.

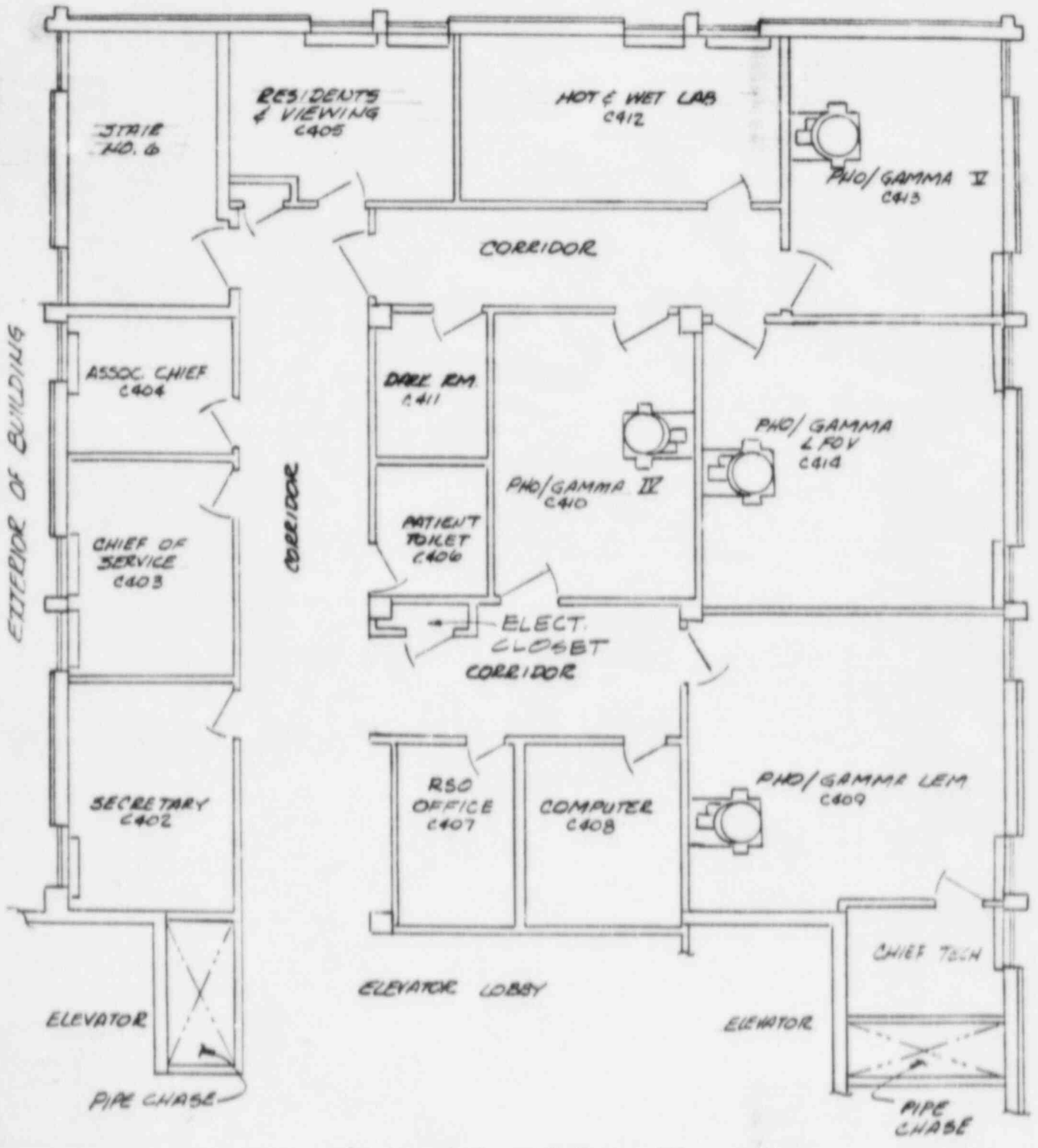


N

FOURTH FLOOR PLAN

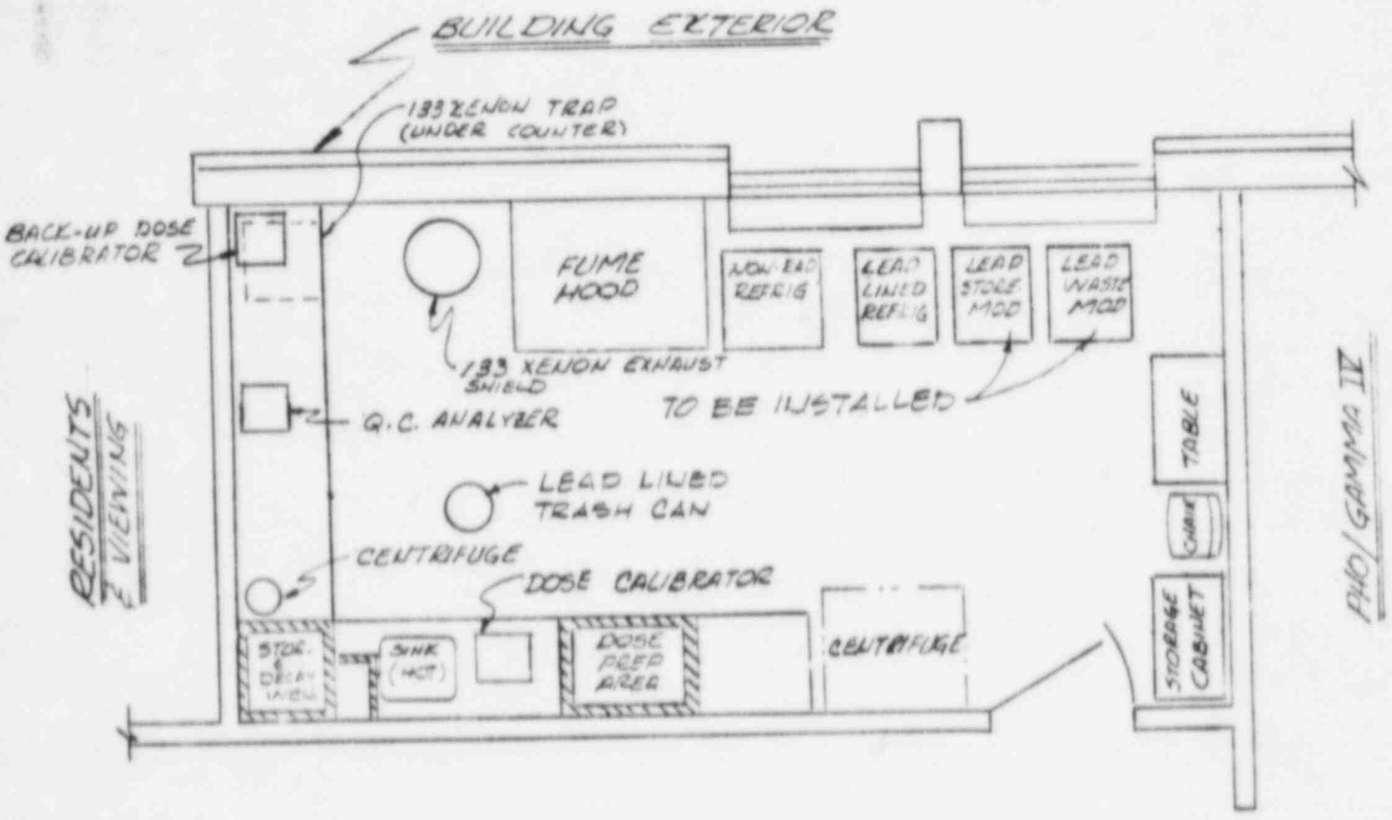
VAMC MARTINEZ, CAL

SCALE 1/4" = 15'-0"



NUCLEAR MEDICINE SUITE

SCALE 1/10" = 1'-0"



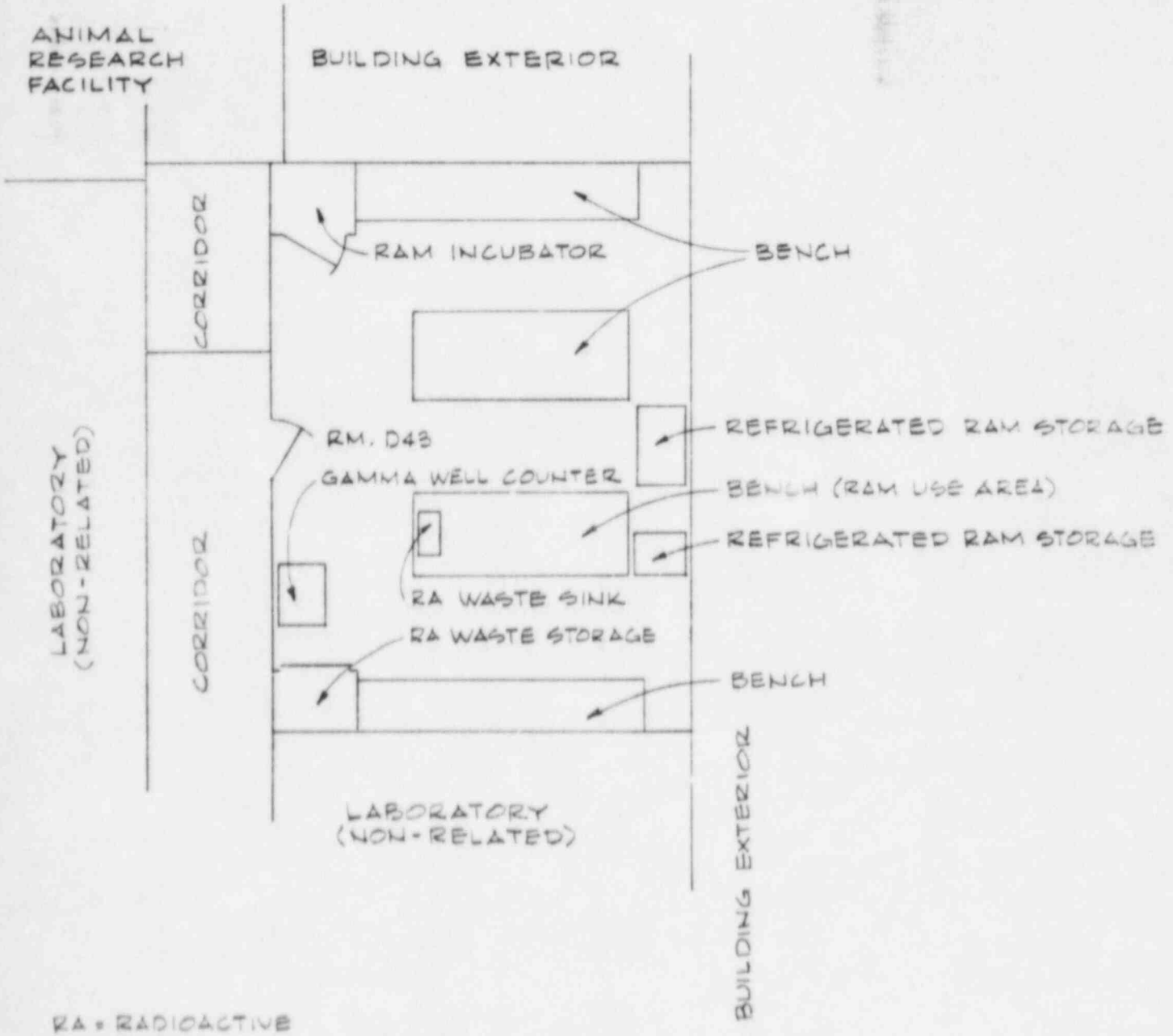
NUCLEAR MEDICINE HOT LAB.

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

CLINICAL RIA LABORATORY

The Clinical Radioimmunoassay (RIA) Laboratory is located in Room D43 in the basement level of the medical center. The only radionuclides used in the laboratory, with the exception of several small sealed sources used for gamma well counter calibration, are Cobalt-57 and Iodine-125. These radionuclides are used for *in vitro* clinical procedures only and the maximum amounts of these nuclides in the laboratory at any time are less than 1 millicurie of Iodine-125 and 100 microcuries of Cobalt-57. Due to the small activities in the laboratory at any time and also due to the low energy of the photons emitted by these radionuclides, there is no measurable radiation exposure in unrestricted areas adjacent to the laboratory. A diagram of this laboratory is attached and shows the radionuclide use areas, storage area, solid waste storage area, automated gamma well counter, and radioactive waste disposal sink. The small activities used in any procedure render fume hoods and remote manipulating equipment unnecessary. Film badges worn by laboratory personnel have never indicated a dose equivalent above 20 millirem in one month.

This medical center, with the approval of its Radiation Safety Committee, may rearrange the location of equipment, storage and use areas within the laboratory, and may also approve changes of the radionuclides and activities used. The laboratory may also be moved to a new room within the medical center with approval of the Radiation Safety Committee.



RA = RADIOACTIVE
RAM = RADIOACTIVE MATERIALS

CLINICAL RIA LABORATORY
BUILDING NO. 1
SCALE: 1/8" = 1'-0"

PROTEIN IODINATION FACILITIES

1. Facility Description

All protein iodinations at the medical center are performed in a fume hood in a small room that is contained within Laboratory Room B70A (diagram attached). This room contains a fume hood that has an average face velocity in excess of 100 feet per minute and exhausts 800 cubic feet per minute (cfm) from the room. The room contains no supply or exhaust vents and is therefore at a negative pressure with respect to room B70A. Most iodinations at our medical center are expected to be performed with iodine-125, but iodine-131 may also occasionally be used. The total activity of radioiodine used for iodinations in one month is expected to be much less than 50 millicuries. The sheet metal walls of the fume hood adequately attenuate the low-energy photons from I-125 except for ones emitted toward the face of the hood. The individual performing the iodination is protected from these by a shadow shield of two inch thick lead bricks in the fume hood. If iodinations are to be performed using I-131, shielding requirements will be evaluated and additional shielding will be used if needed to meet ALARA requirements.

2. Air Concentrations on the Fourth Floor Roof

The exhaust system of the fume hood releases the air at the roof above the fourth floor. Access to the roof above the fourth floor is controlled and it is therefore designated a restricted area. If it is assumed that 50 millicuries of radioiodine are used per month and ten percent released in gaseous form in the fume hood, the average concentration at the roof is:

$$Af/V = (50\ mCi/month)(10\%)/(800\ cfm)$$
$$= 2.1 \times 10^{-8}\ \mu Ci/ml$$

This exceeds the maximum permissible concentration for I-125 in restricted areas. For this reason, a sign will be placed on the door leading to the roof above the fourth floor while iodinations are in progress warning personnel who have access to the roof of the airborne radioactivity hazard and instructing them to stay off the roof.

3. Air Concentrations in Unrestricted Areas

The following calculations are used to demonstrate that air concentrations of radioiodine in unrestricted areas, including the ground around the medical center building and also the roofs of wings of the medical center which are less than four stories in height, do not exceed the maximum permissible concentration. The exit of the exhaust system serving the fume hood is in close proximity to the roof above the fourth floor and the effluent is therefore released into rather than above the building boundary layer. Since the effluent is entrained in the boundary layer,

methods based on the assumption of a gaussian plume are not sufficiently conservative. Instead, a method developed by Halitsky (1) was utilized. The concentration of radioactive material from a flush-mounted roof vent is

$$K = \frac{CAU}{Q}$$

where K is a dimensionless number that is less than 2.0 over the sides of a sharp-edged building and in the downwind wake cavity,
C is the concentration in activity per volume,
U is the wind speed,
Q is the source strength in activity per unit time, and
A is a characteristic area of the building being studied.

We assume the source strength is:

$$Q = (50 \text{ mCi/month})(10\%) = 5 \text{ mCi/month}$$

We assume the wind direction is constant over a month with a speed of 0.5 meters per second (2). We assume K = 2.0, and A = 400 meters^2 (the area of one end of the building). The values of all these parameters were selected to maximize C and the calculation is therefore very conservative.

$$\begin{aligned} C &= KQ/AU \\ &= (2.0)(5 \text{ mCi/month})/(400 \text{ meters}^2)(0.5 \text{ meters/sec}) \\ &= 1.9 \times 10^{-11} \ \mu\text{Ci/ml} \end{aligned}$$

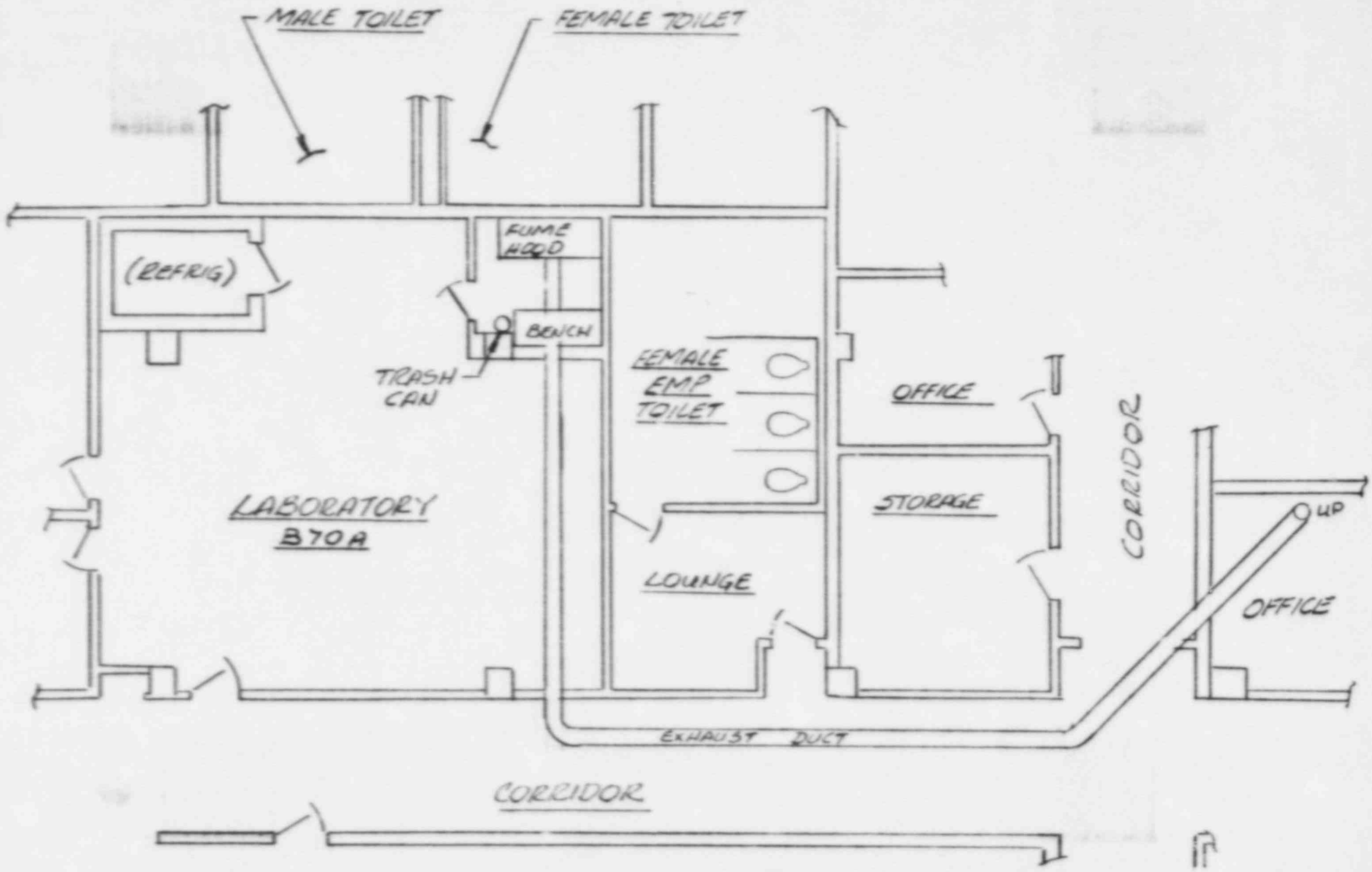
This is less than the maximum permissible concentration for an unrestricted area by a factor of about four.

REFERENCES

(1) Hanna SR, Briggs GA, Hosker RP: Handbook on Atmospheric Diffusion, Springfield, VA, NTIS, 1982, pp 22-24.

(2) Ibid, pp 25.

PARTIAL BASEMENT FL PLAN
VAMC MARTINEZ, CAL
SCALE 1/8" = 1'-0"



RESEARCH LABORATORIES

Unsealed radioactive materials may be utilized for *in vitro* and animal studies in various research laboratories in the medical center. Such use must have the approval of the Radiation Safety Committee (RSC) in writing. The radionuclides used in a particular laboratory will be restricted to those specifically approved by the RSC, the activities of these nuclides will be kept within limits approved by the RSC, and all conditions for the use of the radioactive materials specified by Federal Regulations, the Materials License, medical center regulations, and the RSC will be followed. In determining whether unsealed radioactive materials may be used in a particular laboratory, the Radiation Safety Committee will consider the following factors with respect to the proposed use:

1. Radiation exposure to personnel in areas adjacent to the laboratory.

2. Release of radioactive materials into unrestricted areas from laboratory exhaust systems, including fume hood exhaust systems.

3. Possible release of radioactive gases or aerosols to adjacent areas via laboratory doors.

4. Radiation exposure hazards to personnel within the laboratory.

5. Radioactive material ingestion hazards, including adequacy of laboratory ventilation and need for fume hoods or other protective measures.

6. Security of radioactive materials.

7. Ability to clean surfaces in case of spills or other contamination.

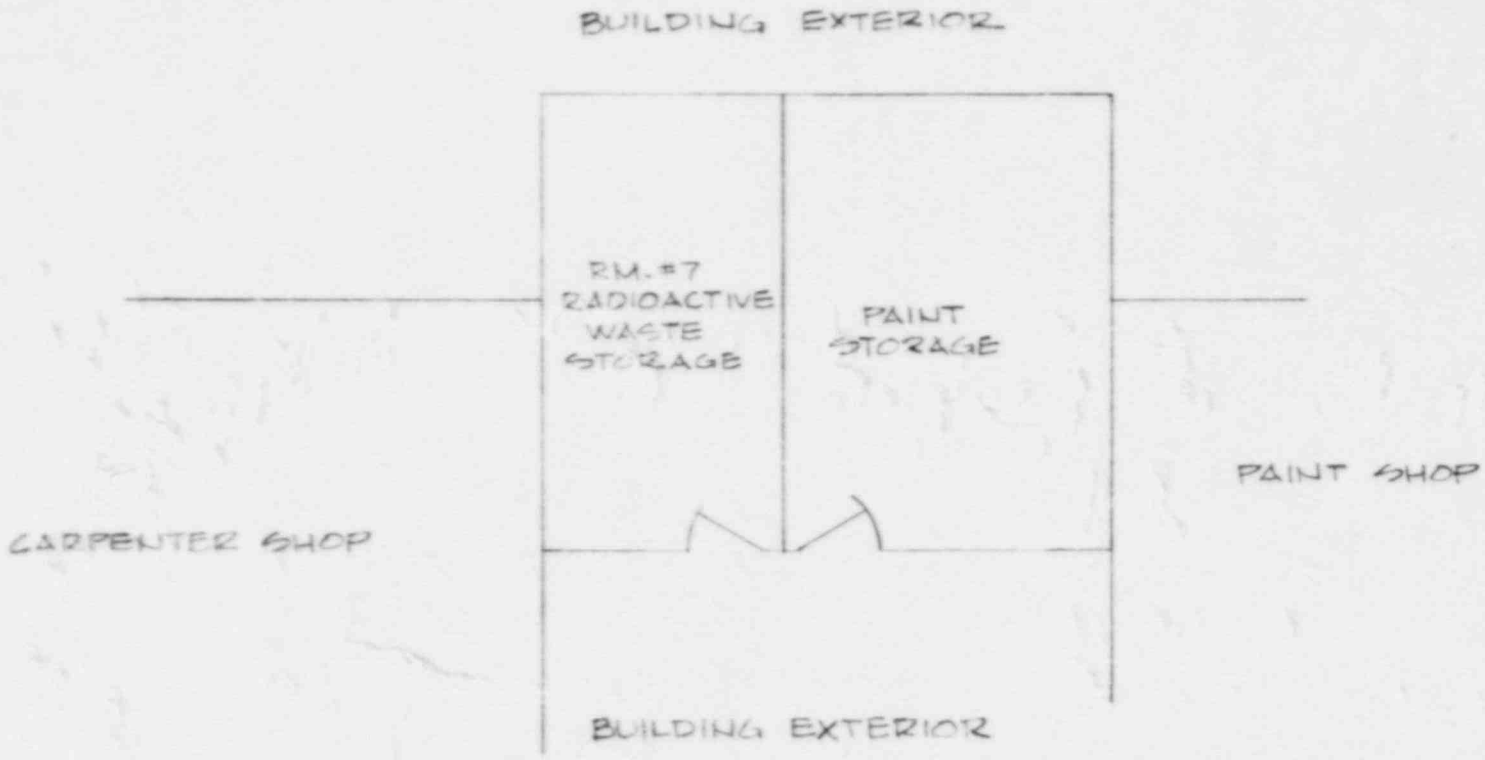
The Radiation Safety Officer and Chairman of the Radiation Safety Committee may jointly grant provisional approval for the use of radioactive materials in a particular laboratory. Such approval will remain in effect until the next meeting of the Radiation Safety Committee.

RADIOACTIVE WASTE STORAGE FACILITY

The Radioactive Waste Storage Facility (RWSF) is a room in a building separate from the main medical center building. A diagram of the facility is attached. The facility is used for the storage of radioactive waste prior to disposal as described in Item 18 and for decay in storage prior to disposal as non-radioactive waste. The building has only one story, so there are no occupied spaces above or below the facility. The walls of the facility are constructed of cinder block; the spaces in the cinder blocks are filled with concrete. Adjacent to the facility are the Carpentry Shop and the Paint Storage Room, which are often occupied. There is a single wall of concrete-filled cinderblocks between the RWSF and the Paint Storage Room and a double wall of concrete-filled cinderblocks between the RWSF and the Carpentry Shop. The remaining sides of the facility are exterior walls. All surrounding areas are non-restricted areas. The facility is locked when unoccupied.

Most waste stored in the facility is of quite low specific activity. Waste containing Tc-99m from the Nuclear Medicine Service is generally allowed to decay for two or three days prior to being transported to the facility for further decay. Any waste which might cause exposures in unrestricted areas to exceed maximum permissible dose-equivalents will be specially shielded. The film badges of personnel who routinely work in the facility indicate that the exposures received by these personnel are well below the maximum permissible dose-equivalents and are consistent with the ALARA philosophy. The RWSF will be surveyed at least weekly in accordance with Item 17.

Item 11
Date _____



RADIOACTIVE WASTE STORAGE ROOM
BUILDING "C"
SCALE: 1/8" = 1'-0"

PERSONNEL TRAINING PROGRAM

1. Initial Training

Personnel Service will ensure that new employees of the medical center or employees who change jobs within the medical center and who will work with or in the vicinity of radioactive materials report to the Radiation Safety Office for training as part of their check-in or transfer procedures. This policy will include employees in the following services and sections:

1. Nuclear Medicine Service
2. Radiotherapy Service
3. Cardiology Section of Medicine Service
4. Nursing Service (including escort personnel)
5. Building Management Service
6. Telephone Operators
7. Warehouse and Delivery Personnel of Supply Service
8. Police
9. Laboratory Service
10. Research Service (including Animal Research Facility Personnel)

All Authorized Users of radioactive material are also obligated to have any new personnel who will be working under their auspices with radioactive material report to the Radiation Safety Office. Voluntary Service will also ensure that any volunteers who will work with or in the vicinity of radioactive materials report to the Radiation Safety Office. The initial training for ancillary personnel (nursing; police; building management; telephone operators; animal research facility; and warehouse and delivery) may consist of a lecture or a videotape. When a videotape is used, it will be followed by a discussion session with a member of the Radiation Safety Office staff to ensure that the material is understood.

2.
Personnel Training Program

2. Refresher Training

The personnel of the following organizations will receive annual training from the RSO, his staff, or a person designated by the RSO:

1. Nursing Service (including escort personnel)
2. Building Maintenance Service
3. Telephone Operators
4. Warehouse & Delivery Personnel of Supply Service
5. Police
6. All research laboratories using radioactive materials
7. Animal Research Facility
8. Voluntary Service
9. Nuclear Medicine Service
10. Radiotherapy Service
11. Laboratory Service
12. Cardiology Section of Medicine Service

This refresher training may consist of lectures or videotapes and will be conducted by the RSO, a member of his staff, or a person designated by the RSO.

3. Training Content

The initial and annual training will include the following topics:

a. Terms of the license pertaining to radiation safety.

b. Areas where radioactive material are used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures pertaining to an individual's duties.

e. Pertinent NRC regulations.

f. Medical Center regulations pertaining to the use of radioactive materials.

g. Obligation to report unsafe conditions to the Radiation Safety Officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of personnel dosimetry and bioassay measurements

j. Locations where an individual may read NRC regulations, the license, and medical center regulations pertaining to radiation safety.

k. Instruction concerning prenatal radiation exposure (female employees and supervisors only)

4. Training Course for Laboratory Personnel

In addition, a course will be conducted at least semi-annually for personnel who use radioactive material for research purposes. This course will provide at least six hours of didactic instruction in the types of radioactive decay, the kinetics of decay, interactions of radiation with matter, simple radiobiology, detectors commonly used in the medical research laboratory environment, and radiation safety procedures commonly used in the medical research laboratory environment, as well as the topics listed above. This course, in conjunction with the use of radioactive materials under the direct supervision of an Authorized User, is intended to prepare an individual to safely utilize radioactive materials in a research laboratory environment without direct supervision. All research laboratory personnel working under the auspices of an Authorized User who have not had equivalent training, as determined by the Radiation Safety Committee, will be required to attend the next course offered.

PROCEDURES FOR ORDERING AND RECEIVING

RADIOACTIVE MATERIAL

The attached station memorandum contains the medical center's procedures for ordering and receiving radioactive materials.

Attachment

Item 13
Date _____

VA Medical Center
Martinez, California

Station Memorandum No. 11-70
(Revised)
September 21, 1984

PROCUREMENT, RECEIPT, DELIVERY AND TRANSFER OF RADIOACTIVE MATERIAL

1. PURPOSE

The Radiation Safety Officer (11R), reporting to the Chief of Staff, is responsible for maintaining an up-to-date inventory of all radioactive materials and assuring their safe and legal handling. The following procedures will be observed.

2. POLICY

a. All orders for radioactive material will be placed by the requesting service on a VA Form 07-2237, "Request, Turn-in, and Receipt for Property or Services." One additional copy should be completed by the requesting service and must be attached to the set of forms normally submitted to Supply Service.

b. All orders for radioactive material submitted by a service must include the following information, under the heading, "Order for Radioactive Material":

(1) Name of Authorized User.

(2) Chemical form of material (examples: glycine, human serum albumin); abbreviations which have not been approved by the Clinical Executive Board will not be acceptable as names of compounds.

(3) Quantity (activity) of material in microcuries or millicuries; if radionuclides in kit form are ordered in multiples of this unit quantity, the activity per unit (kit or package) must be stated so that it is possible to determine the total activity to be delivered by the vendor.

(4) Name and mass number of radionuclide (e.g., Iodine-131, Technetium-99m, etc.).

(5) Delivery location within the medical center. The delivery location for radioactive materials ordered by the Nuclear Medicine Service for routine clinical use is "Nuclear Medicine Service." The delivery location for radioactive materials ordered by the Laboratory Service for routine clinical testing is "Laboratory Service." The delivery location for all other radioactive materials is "Radiation Safety."

(6) NRC License Number 04-02956-02.

c. When radioactive materials are ordered for therapeutic purposes in humans, a written request will be obtained from the physician who will perform the procedure, stating the radionuclide, the chemical form,

the activity, and the time and date the particular activity is required. These requests will be retained in a file in Nuclear Medicine Service.

d. Requests for radioactive material will be forwarded directly to the Radiation Safety Officer (11R) for approval. The Radiation Safety Officer may, at his discretion, delegate the authority to approve the ordering of radioactive materials for in vivo and in vitro diagnostic testing and therapy of humans in the Nuclear Medicine Service to the Chief Nuclear Medicine Technologist. The Radiation Safety Officer may also, at his discretion, delegate the authority to approve the ordering of radioactive materials for in vitro clinical testing by the Laboratory Service to appropriate individuals in the Laboratory Service for use in emergency cases in which the Radiation Safety Officer cannot be contacted.

e. After approval by the appropriate individual, the request for radioactive materials will be forwarded to Supply Service. Supply Service will ensure that the shipping address contains the delivery location within the medical center (e.g., Deliver to: Chief, Supply Service (Radiation Safety); Deliver to: Chief, Supply Service (Nuclear Medicine Service); or Deliver to: Chief, Supply Service (Laboratory Service). Supply Service will also forward a copy of all orders for radioactive materials to the Radiation Safety Officer.

f. During normal working hours, packages of radioactive materials are delivered to the Supply Service warehouse. The warehouse personnel will deliver the packages to the appropriate delivery location within the medical center. The only permitted delivery locations are: Laboratory Service - Room D-43, Nuclear Medicine Service - Room C-412, and Radiation Safety - Room D-64. If the warehouse personnel are unable to determine the appropriate delivery location within the medical center, the package will be delivered to Radiation Safety - Room D-64. To minimize the radiation exposure of warehouse personnel, radioactive packages will be delivered as soon as is practicable. Radioactive packages will be transported on a cart at some distance from the person delivering the packages. If a radioactive package appears to be damaged or leaking, the package will not be handled, the Radiation Safety Officer will immediately be notified, and the carrier will be requested to remain until the arrival of the Radiation Safety Officer.

g. Outside of normal working hours, packages of radioactive materials are delivered to the telephone operator at the information desk in the front lobby (Room B-147). The telephone operator will immediately notify a medical center police officer. The police officer will deliver the package to the appropriate delivery location indicated on the package label. The only permitted delivery locations are: Laboratory Service - Room D-43, Nuclear Medicine Service - Room C-412, and Radiation Safety - Room D-64. If the police officer is unable to determine the appropriate delivery location within the medical center, the package should be delivered to the Nuclear Medicine Service - Room C-412. Packages whose labels state that refrigeration is required

will be placed in a refrigerator. To minimize the radiation exposure to the telephone operator and police officer, the following precautions will be observed:

(1) The telephone operator will immediately notify a police officer of the arrival of radioactive packages. The packages will be placed in the telephone operator's office as far as possible from the operators until the arrival of the police officer.

(2) The packages will not be carried by hand by the police officer, but will be delivered on a cart.

(3) The telephone operator or police officer will not handle packages that appear damaged or leaking. They will immediately notify the Radiation Safety Officer and request that the carrier remain at the medical center until his arrival.

h. No radioactive material may be transferred to the medical center without the prior approval of the Radiation Safety Officer. This includes gifts or samples and materials ordered through other institutions, but to be delivered to the medical center. This also includes material to be transferred to the medical center by an Authorized User who possesses the radioactive material at another institution. Requests for approval for any transfer of radioactive materials may be made by submitting VA Form 07-2237, completed as above, to the Radiation Safety Officer (11R).

i. Transfers of radioactive material from the medical center for any reason must be approved by the Radiation Safety Officer before the material leaves the hospital. Prior approval is required to ensure proper labeling of the package and to confirm that the consignee is authorized to receive the material.

j. All Authorized Users of radioactive material will maintain records of the receipt, transfer, and disposal of radioactive material in their laboratories.

3. AUTOMATIC REVIEW, RESCISSION OR REISSUE DATE: October 1986 (11R)

4. REFERENCES

Code of Federal Regulations, Title 10, Parts 10 and 30
Nuclear Regulatory Commission Materials License 04-02956-02

5. RESCISSION: Station Memorandum 11-70, January 16, 1984

C. H. NIXON
Director

Distribution C

EMERGENCY PROCEDURES FOR RADIOACTIVE MATERIALS

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

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

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

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

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

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

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

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water. If radioactive material is splashed into the eyes, flush thoroughly with water for several minutes.

Attachment:
Memo dtd 3/23/84, Call-List for Radiological Emergencies

Item 16
Date _____

Veterans Administration

Memorandum

Date: March 23, 1984

To: Users of Radioactive Materials or Equipment Producing Ionizing Radiation

Subj: Call-List for Radiological Emergencies

This is a list of persons to be notified in the event of a radiological emergency. Radiological emergencies include, but are not limited to: spills or accidental releases of radioactive materials, contamination of a person with radioactive materials (including accidental ingestions and injections), leaking packages of radioactive materials, the arrival of a patient contaminated with radioactive materials, or the suspected overexposure of a person to radiation. In case of a radiological emergency during working hours, attempt to notify a person on the call-list, starting at the top and continuing down the list until a person on the list has been contacted. After working hours, call the telephone operator (inside the VAMC, dial "0") and ask the operator to connect you with one of the people on the list.

		VAMC Ext.
Dr. E. Leidholdt	Radiation Safety Officer	658
Mr. A. Wheatley	Assoc. Radiation Safety Officer	637
Dr. C. Barnett	Acting Chief, Nuclear Medicine	381
Dr. A. Raventos	Assoc. Chief, Radiotherapy	636
Ms. C. Baie	Chief Technologist, Nuclear Medicine	381

Edwin M. Leidholdt, Jr.

EDWIN M. LEIDHOLDT, Jr., Ph.D
Radiation Safety Officer (115A)

EML/ps

VA FORM 2105
MAR 1980

AREA SURVEY PROCEDURES

Attached are the area survey procedures to be followed by all individual users of unsealed radioactive materials. All areas in which unsealed radioactive materials are stored or utilized will be surveyed in accordance with these procedures. In addition, the Radiation Safety Officer, a member of his staff, or a person designated by the Radiation Safety Officer will survey these areas at least quarterly. These surveys by the Radiation Safety Officer, his staff, or designee will include instrument surveys, wipe tests, examination of laboratory records, inspection to ensure proper posting of instructions and warning signs, measurement of fume hood face velocities, and a review of laboratory procedures.

Attachment

Item 17
Date _____

AREA SURVEY PROCEDURES

1. When unsealed radioactive materials are used, all work areas in which they are used will be surveyed at least daily with an appropriate low-range survey meter and decontaminated if necessary. In Nuclear Medicine, these areas include elution, preparation, and injection areas. In most other laboratories, they include fume hoods, bench tops, and immediately adjacent floor areas. If a laboratory uses less than 200 microcuries per day, the daily surveys are not required.

2. The entire laboratory will be surveyed weekly when unsealed radioactive materials are being used. If less than 100 microcuries of H-3 or 10 microcuries of C-14 or S-35 only are used daily, these surveys need only be performed monthly. The weekly and monthly surveys will consist of a survey with an appropriate low-range survey meter and a series of wipe tests to measure contamination levels.

3. If radioactive materials are stored but not used, the surveys listed in Paragraph 2 need only be performed monthly and only the vicinity of the storage area must be surveyed.

4. The survey meter should be capable of detecting the types of radioactive materials used in the laboratory and should be sufficiently sensitive to detect 0.1 mR/hr. In the case of laboratories using nuclides emitting only low-energy beta rays, such as C-14 and S-35, the survey meter should have a sufficiently thin window to detect these nuclides.

5. Each wipe should be obtained by rubbing a piece of filter paper over an area of approximately 100 cm^2 with moderate pressure. When the wipe tests are performed, each wipe shall be counted by a method sufficiently sensitive to detect 200 dpm per wipe for the contaminant involved. In laboratories using nuclides which emit only low-energy beta rays, such as H-3, C-14, and S-35, wipes should be counted in a liquid scintillation counter. For most other radionuclides, either a liquid scintillation counter or a gamma scintillation well counter will suffice.

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

   a. Equipment used (survey meter and instrument for counting wipes) including instrument serial numbers.

   b. Drawing of area surveyed, identifying relevant features such as hoods, radionuclide use areas, radionuclide storage areas, radioactive waste storage, and radioactive waste sinks.

   c. Date of survey and name of person conducting the survey.

d. Measured exposure rates which exceed background, keyed to location on drawing.

e. Counts from wipe tests, keyed to locations on drawing.

f. Corrective action taken in the case of excessive contamination or exposure rates and results of survey after corrective action.

g. For daily surveys in which no abnormal results are found, only the date, name of person performing the survey, and the fact that no abnormal exposure or significant contamination were found.

7. Areas in which the contamination level exceeds 200 dpm per 100 cm^2 will be cleaned.

8. The Radiation Safety Officer may, at his discretion, allow higher levels of removable surface contamination in situations in which cleaning is not practicable provided that the levels do not exceed those of Table 2 of the Nuclear Regulatory Commission Regulatory Guide 8.23.

WASTE DISPOSAL

1. Liquid radioactive waste will be disposed of by one of the following methods:

   a. In the sanitary sewer system in accordance with 10CFR20.303.

   b. By decay in storage followed by disposal in the sanitary sewer system in accordance with 10CFR20.303.

   c. By absorption in a solid material and decay in storage followed by disposal as solid waste as in Item 3.a. below.

   d. By a commercial waste disposal service.

2. Mo-99/Tc-99m generators are currently not used at the medical center. However, should generators be used in the future, they will be disposed of by one of the following methods:

   a. Returned to the manufacturer for disposal.

   b. Disposed of as in Item 3.a. below. Generator columns will be segregated so that they may be monitored separately.

   c. By a commercial waste disposal service.

3. Other solid waste will be disposed of by one of the following methods:

   a. Radionuclides with half-lives less than 65 days only: Held for decay until radiation levels, as measured in low-background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of as normal trash.

   b. Disposed of by a commercial waste disposal service.

   c. Returned to the manufacturer or supplier (as in the case of certain unused, partially used, or empty syringes or vials or radiopharmaceuticals).

4. Licensed material listed in 10CFR20.306 may be disposed of in accordance with 10CFR20.306.

5. The commercial waste disposal service used will be:

   Southwest Nuclear Company
   7066A Commerce Circle
   Pleasanton, CA 94566

   California Radioactive Material
   License No. 2873-60

Item 18
Date _____

PROCEDURES AND PRECAUTIONS FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS

(In addition to Appendix K of USNRC Regulatory Guide 10.8)

Therapeutic Use of P-32

Personnel administering P-32 for therapy shall:

a. Wear extremity dosimeters.

b. Use shielding composed of low atomic-number materials such as plexiglass, of sufficient thickness to attenuate the beta rays.

c. Monitor each worker's hands and clothing with an appropriate survey meter after each use.

d. Survey the injection and preparation areas with an appropriate survey meter after each use.

e. Cover areas of the patient which may become contaminated with plastic-backed absorbent paper.

f. Wear eye protection if the dose exceeds 10 millicuries.

g. Perform a dry-run with a non-radioactive sample if any member of the physician-technologist team has not performed the procedure within six months.

Therapeutic Use of Radioiodine

a. Personnel administering therapeutic doses of radioiodine in non-capsule form will be bioassayed in accordance with Regulatory Guide 8.20.

b. Personnel who handle unsealed radioiodine, such as the urine of therapy patients, in excess of the action levels in Regulatory Guide 8.20 will be bioassayed in accordance with the Regulatory Guide.

c. Personnel administering therapeutic doses of radioiodine will wear extremity dosimeters, as well as body dosimeters.

d. Containers of radioiodine in both capsule and liquid form will be opened in a fume-hood. The fume-hood will be surveyed quarterly in accordance with Regulatory Guide 8.23 to ensure that the average face velocity exceeds 100 feet-per-minute with the sash at the operating height.

Item 19b
Date _____

THERAPEUTIC USE OF SEALED SOURCES

The only sealed source at the medical center which is used for therapy is a 50 millicurie sealed Strontium-90, Yttrium-90 ophthalmic irradiator, which is used for the treatment of superficial eye disease.

The source is stored in a shielded container in a locked storage cabinet in a restricted area when not in use. The source is a pure-beta emitter. When the source is stored in its container, the measured exposure rate from bremsstrahlung is less than 1 mR/hr at 30 cm in all directions. There is no measurable radiation exposure from the source in any unrestricted area.

The source will be wipe-tested for leakage every six months. The hand of the person applying the source is protected by shielding which is a part of the source capsule and that blocks all beta rays emitted toward the handle, by a 5 cm rod connecting the source capsule to the handle, and by a 0.95 cm thick acrylic plastic shield which protects the hand from scattered beta rays. The exposure rate to the hand, primarily from bremsstrahlung, is less than 10 mR/hr. Due to the low exposure rate and the small amount of time that the source is used (currently less than one hour per year), our medical center does not require the user of the source to wear an extremity dosimeter.

Item 20
Date _____

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES AND AEROSOLS

The only radioactive gas or aerosol used at the medical center is xenon-133. The following information related to the use of xenon is submitted:

1. Quantities to be Used

a. We expect to perform approximately 10 studies a week. The average activity used per patient is 10 millicuries.

b. We request a possession limit of 200 millicuries of xenon-133.

2. Use and Storage Areas

a. Xenon-133 will be stored behind shielding in a fume hood in Room C412, the Nuclear Medicine Service Hot Lab. The xenon-133 will only be used in Room C414, the LFOV Camera Imaging Room. Diagrams of the entire Nuclear Medicine Service and of the Hot Lab (Room C412) are attached to Item 11.

b. The ventilation systems serving Rooms C412 and C414 are depicted on the attached diagram, which shows measured volumetric flow rates. In both rooms, all exhaust air is vented to the atmosphere; no air is recirculated. The exhaust flow rates are constant during the working day. The constancy of the net room exhaust rate has been confirmed by measuring the exhaust flow rate from each room with different thermostat settings and also with the door to each room open and closed. The supply flow rates vary with room temperature. The supply flow rates shown on the ventilation diagram are maximum values.

The fume hood in Room C412 has a volumetric flow rate in excess of 350 cubic feet per minute (cfm) and has an average face velocity in excess of 100 feet per minute with the sash in the operating position. On days in which xenon is used, the fume hood exhaust fan will be turned on prior to inserting the xenon container in the dispenser and will be left on for the remainder of working hours.

c. The only room in which xenon-133 will be used, Room C414, is always at a negative pressure with respect to the adjacent corridor during hours in which xenon will be used. The net room volumetric exhaust flow rate was measured to be 816 cfm, while the maximum volumetric supply flow rate (measured with the thermostat set to cause maximum flow) was 440 cfm. These flow rates were virtually the same with the door to the room open and closed.

The Hot Lab (Room C412) is at negative pressure with respect to the adjacent corridor when the fume hood exhaust fan is operating. The

net room exhaust flow rate is in excess of 650 cfm with the fume hood fan on, while the maximum volumetric supply flow rate was 200 cfm.

The negative pressure in both rooms was further verified by visual observation of the direction of smoke flow in the doorway. Measurements of the volumetric air supply and exhaust rates will be made of all vents in Rooms C412 and C414 at least semiannually. The fume hood will be surveyed at least quarterly to ensure the average face velocity exceeds 100 ft/min. with the sash in the operating position.

3. Procedures for Routine Use

a. Prior to an imaging procedure, the xenon gas shipping container will be loaded into the dispenser within the fume hood in the Hot Lab and the collection bag will be placed in a shielded holder. After the procedure, the collection bag will be exhausted into the xenon trapping device in the Hot Lab, and the exhaust from the trapping device will be directed into the fume hood. On days in which xenon is used, the fume hood exhaust fan will be turned on prior to inserting the xenon container in the dispenser and will be left on for the remainder of the working hours.

b. Xenon-133 will be administered to patients using a Medi-Physics E-XE Xenon Dispenser (manual attached). The patient will breathe the xenon and the patient's expirations will be collected in any one of several commercially available disposable xenon administration systems similar to the Amici system (manual attached). The bag of the administration system will be inside a Medi-Physics shield, lined with 1/16 inch of lead, during the study. The collection bag will be exhausted through an Atomic Products 127-313 Xenon Gas Trap after each study (manual attached). When the xenon is administered using a mouthpiece instead of a face-mask, nose clips will be placed on the patient.

4. Emergency Procedures

The most frequent cause of accidental xenon release is an onset of acute respiratory distress or interference from an uncooperative patient; therefore, most of the xenon loss is expected to occur in Room C414. If xenon-133 is accidentally released within the LFOV Camera Imaging Room (C414) during a patient study, in the interest of patient care and safety, the room normally will not be evacuated and the patient study will be completed. The average concentration if all the xenon used (100 millicuries per week) were released would be about one-fifth the maximum permissible concentration for a restricted area.

$$Af/V = (100\ mCi/wk)(100\%)/(815\ cfm)$$
$$= 1.8 \times 10^{-6}\ Ci/ml$$

Procedures and Precautions for Use of Radioactive Gases and Aerosols

If xenon-133 is accidentally released within the Hot Lab (Room C412), the room will not normally be evacuated. The average concentration if all the xenon used (100 millicuries per week) were released would be less than one-fourth the maximum permissible concentration for a restricted area.

$$Af/V = (100 \text{ mCi/wk})(100\%)/(650 \text{ cfm})$$

$$= 2.3 \times 10^{-6} \text{ } \mu\text{Ci/ml}$$

However, if equipment (such as the xenon dispenser) is suspected to be leaking xenon, it will be placed in the fume hood to keep the release of xenon to occupied areas ALARA.

5. Air Concentrations of Xenon-133 in Restricted Areas

Although our expected use of xenon-133 is less than 10 studies (100 millicuries) a week, we assume 250 millicuries are used a week for the sake of conservatism. We also assume 25 percent of the xenon used is released into Room C414. The measured exhaust flow rate from Room C414 is 815 cfm. The average air concentration in the room is:

$$Af/V = (250 \text{ mCi/wk})(.25)/(815 \text{ cfm})$$

$$= 1.13 \times 10^{-6} \text{ } \mu\text{Ci/ml}$$

This is less than the maximum permissible concentration by almost a factor of ten.

It is expected that little xenon will be released in the Hot Lab (C412) since the xenon shipping container is inserted into the dispenser within the fume hood and the charcoal trap is vented into the fume hood. However, we assume that ten percent of the xenon is released into Room C412. The measured exhaust flow rate from the room is the sum of the room exhaust flow rate and the fume hood flow rate:

$$V = 300 \text{ cfm} + 350 \text{ cfm} = 650 \text{ cfm}$$

$$Af/V = (250 \text{ mCi/wk})(.10)/(650 \text{ cfm})$$

$$= 5.7 \times 10^{-7} \text{ } \mu\text{Ci/ml}$$

This is less than the maximum permissible concentration by a factor of about 18.

6. Air Concentrations of Xenon-133 in Unrestricted Areas

During xenon studies, air exhaled by the patient is collected in a shielded bag. After the study has been completed, the bag is taken

to the Nuclear Medicine Hot Lab (Room C412) where it is pumped through a charcoal trap. Exhaust from the charcoal trap is vented into the fume hood. Most xenon loss is expected to occur in the imaging room (C414) during the administration of xenon to patients -- little is expected to occur in the Hot Lab (C412).

There are three pathways for xenon to reach unrestricted areas. One is the exhaust system serving most of Nuclear Medicine, including Rooms C412 and C414. The second is an additional exhaust system serving only Rooms C410 and C414. The third is the exhaust system serving the fume hood in room C412. Since the three systems discharge at separate locations in the roof and side of the building, the xenon concentrations in unrestricted areas must be calculated separately for all three systems. We assume 250 millicuries of xenon-133 are used weekly, 25 percent is lost in Room C414 and 10 percent is lost in Room C412.

The first exhaust system evacuates 440 cfm from Room C414, which is 54 percent of the total exhaust flow from C414. It also evacuates 300 cfm from Room C412, which is 46 percent of the total exhaust flow from C412. This system serves most other rooms in Nuclear Medicine and delivers a total of 1540 cfm to the exterior of the building.

For the first system:

$$Af = (250\ mCi/wk)(52\ wk/year)[(25\%)(54\%) + (10\%)(46\%)]$$

$$= 2.35 \times 10^{6}\ \mu Ci/year$$

$$Af/V = (2.35 \times 10^{6}\ \mu Ci/year)/(1540\ cfm)$$

$$= 1.03 \times 10^{-7}\ \mu Ci/ml$$

The second system evacuates 375 cfm from Room C414, which is 46 percent of the total exhaust from the room. It also serves one other room, in which xenon is not used, and delivers a total of 750 cfm to the exterior of the building.

For the second system:

$$Af = (250\ mCi/wk)(52\ wk/year)(25\%)(46\%)$$

$$= 1.5 \times 10^{6}\ \mu Ci/year$$

$$Af/V = (1.5 \times 10^{6}\ \mu Ci/year)/(750\ cfm)$$

$$= 1.3 \times 10^{-7}\ \mu Ci/ml$$

The third system is the exhaust system serving the fume hood in Room C412. It draws 350 cfm from Room C412, which is 54 percent of the total exhaust flow from the room. As above, we assume that 250 millicuries of xenon-133 are used a week and 10 percent is released into Room C412. We also assume that 5 percent of the 250 millicuries passes through the charcoal trap and is released into the fume hood.

For the third system:

$$Af = (250\ mCi/wk)(52\ wk/year)[(10\%)(54\%) + 5\%]$$

$$= 1.35 \times 10^{6}\ \mu Ci/year$$

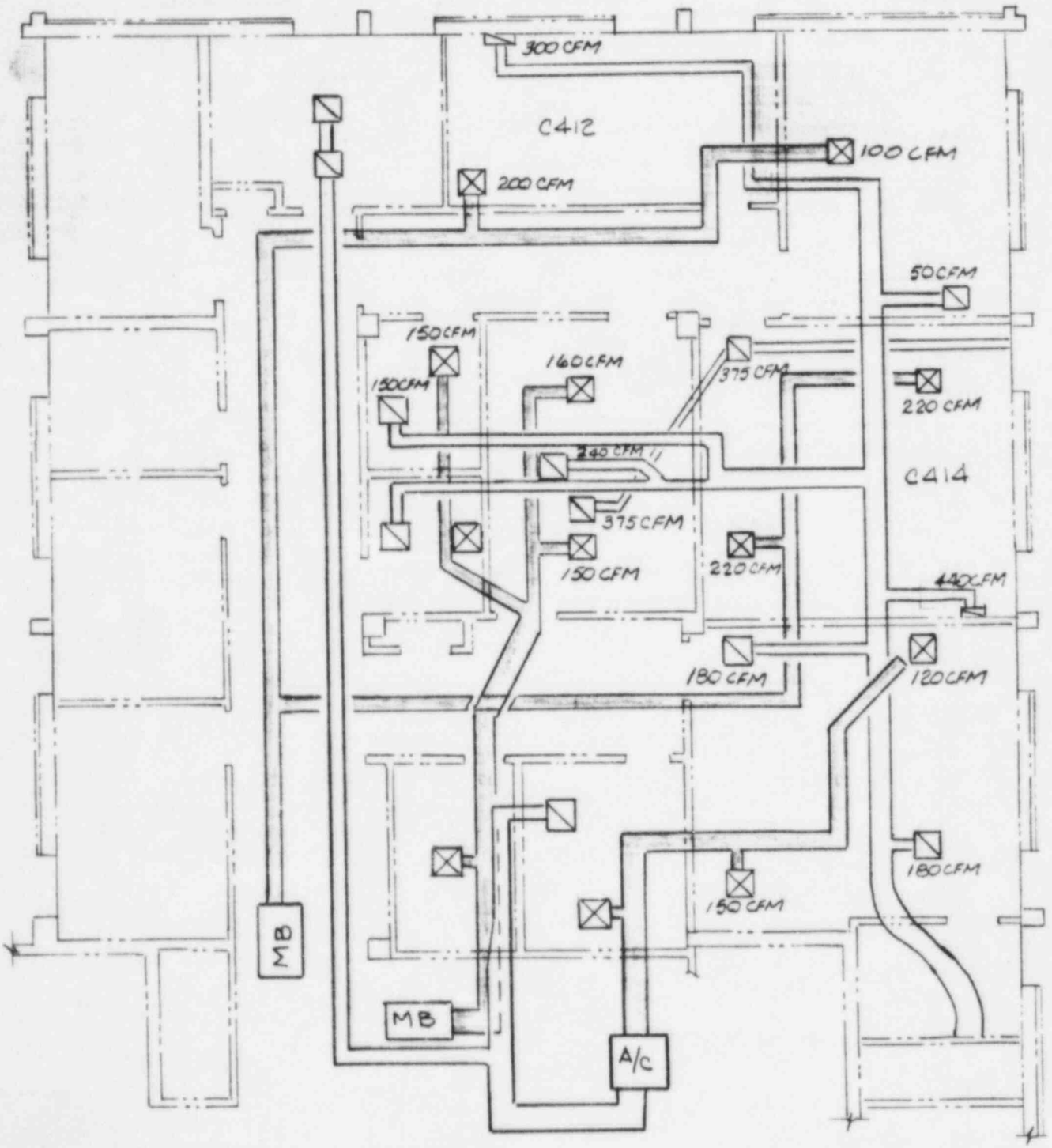
$$Af/V = (1.35 \times 10^{6}\ \mu Ci/year)/(350\ cfm)$$

$$= 2.6 \times 10^{-7}\ \mu Ci/ml$$

The average concentrations released to unrestricted areas by all three exhaust systems serving Rooms C412 and C414 are less than 3×10^{-7} μCi/ml.

Effluent from the xenon trapping device will be sampled and counted weekly in accordance with manufacturer's instructions, except during weeks in which no xenon is used during normal working hours. The charcoal cartridge will be replaced when the leakage from the trap exceeds 0.5 percent of the activity administered to a patient.

The charcoal cartridges used in the trap are constructed with 1/8 inch lead shielding on all sides. Saturated filters will be stored for decay in the Radioactive Waste Storage Facility described in Item 11 or Room C412. Dose rates in the vicinity of the filter will be measured at the time of removal and additional shielding will be used if necessary. The connections to the filter will be sealed while it is stored to prevent the escape of xenon-133.



NUCLEAR MEDICINE HVAC SYSTEM

⊠ DENOTES SUPPLY GRILL

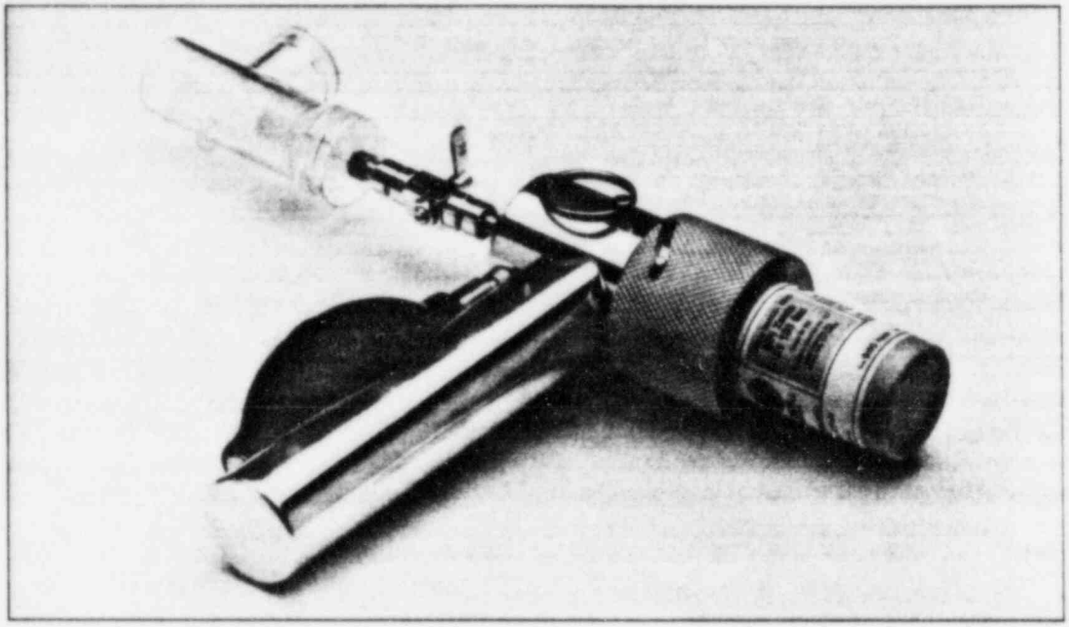
⊠ DENOTES EXHAUST GRILL

SCALE: 1/10" = 1'-0"

NEW

E-XE™ Dispenser

(Xenon Administration Unit/MPI)



- Designed and built for maximum safety
- Assures correct dosage with MPI Xenon Xe 133 Gas (Xenon Xe 133) 10 or 20 mCi vials.
- MPI Xenon vial remains in shipping container at all times, including administration.
- Easy to load
- Convenient operation
- Lightweight, durable metal construction

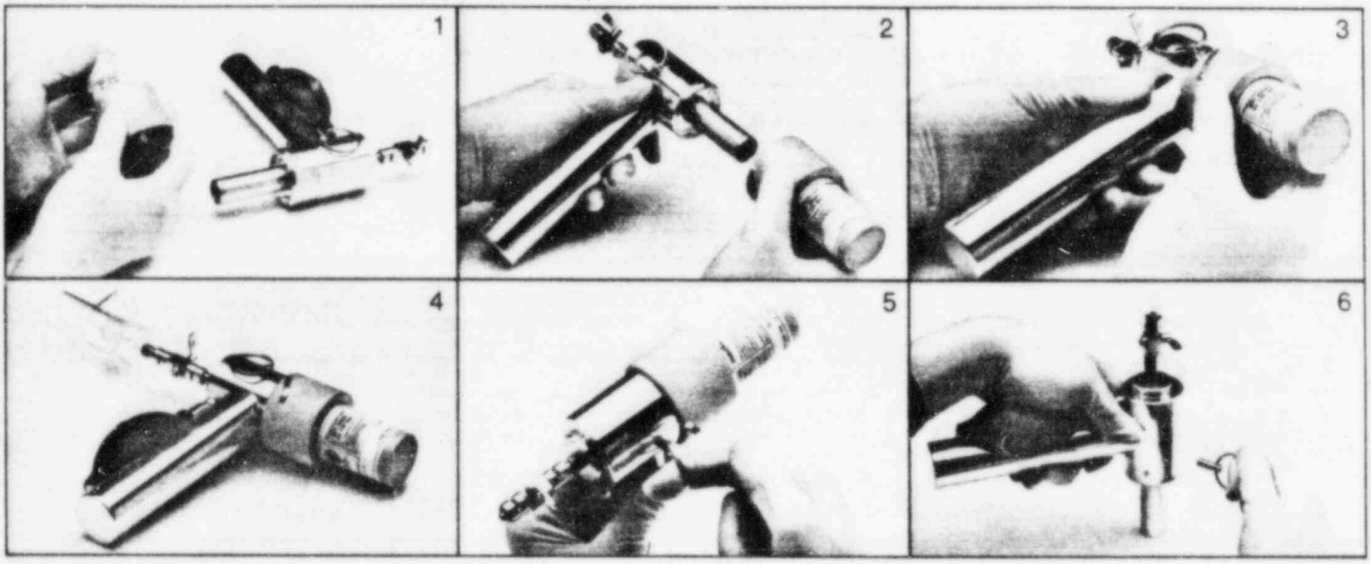
Please see complete operating instructions on other side of page.

medi+physics™

5801 Christie Avenue, Emeryville, CA 94608. For More Information, Please Call (415) 652-7650.
Inside California Toll Free (800) 772-2477. Outside California Toll Free (800) 227-0492.

MPI
E-XE Dispenser

(XENON ADMINISTRATION UNIT MPI)
(FOR VENTILATION
STUDY ONLY—NOT TO BE
INJECTED INTO HUMANS)



For radiation safety and your convenience, Steps 3 through 6 should not be initiated until after the patient has been positioned and the study is about to begin.

Directions for use:

1) Attach and close stopcock to luer fitting on front of E-XE Dispenser.™ (Stopcock is closed when the handle is turned 90° perpendicular.)
2) Remove textured sleeve from body of unit.
3) Using appropriate Radiation Safety technique, remove plastic and lead caps from MPI XENON Xe 133 GAS (Xenon Xe 133) 10 or 20 mCi shipping container by pulling off plastic tab.
4) Insert the Xenon Xe 133 shipping container through the textured sleeve as shown in Figure 1.
5) Attach the Xenon Xe 133 in the textured sleeve as seen in Figures 2 and 3, using a twisting motion.

   Figure 4 shows the E-XE Dispenser™ completely assembled, including the optional T-valve.
6) Attach the E-XE Dispenser™ to the desired administration apparatus.
7) As the patient takes a deep breath, open the stopcock by turning the handle 90° (in line with the unit) and immediately pump the bulb three to five times. Begin the ventilation study.
8) After completion of the study, close the stopcock and detach the E-XE Dispenser™ from the patient administration apparatus.
9) Using the "O" ring, pull the pin from the side of the E-XE Dispenser™ (see Figure 5). The lead container can now be removed using the reverse motion of Step 5. The spent vial should be discarded as radioactive waste.
10) Position the movable barrel of the E-XE Dispenser™ against a firm surface (e.g., counter top, etc.) and apply modest pressure in a downward direction to compress the barrel portion into the body of the unit about one (1) inch until no further compression is possible. Insert the retaining pin into the aperture as shown in Figure 6. The E-XE Dispenser™ is now ready for its next use.

    It is suggested that the plastic covered lead container be reattached (as in Step 5 above) for storage to prevent damage to the E-XE Dispenser™ (Radioactivity labeling should be removed prior to storing).

Note: If the internal needle assembly should become clogged with rubber from the vial septum, simply detach the rubber bulb from the E-XE Dispenser™ handle area and attach it to the luer fitting on the front of the E-XE Dispenser™ and pump once or twice to clear.

Manufactured for:
MEDI-PHYSICS, INC.
Emeryville, CA 94608

The Medi-Physics, Inc. E-XE Dispenser™ is designed for use only with the MPI Xenon Xe 133, 10 mCi or 20 mCi vials in the MPI lead and plastic shipping containers. Use of any other product could result in improper operation for which MPI will not be held responsible.

medi+physics

5801 Christie Avenue, Emeryville, CA 94608. For More Information, Please Call (415) 652-7650.
Inside California Toll Free (800) 772-2477. Outside California Toll Free (800) 227-0492.

369A May 1982 Printed in U.S.A.

exhaling into the **Collection Bag** Ⓔ . Three or four breaths are usually sufficient to clear the lungs of Xenon. However, this may continue until **Collection Bag** becomes full enough to offer resistance. Clamp tubing closed at position ② and quickly remove **Mouthpiece** and Nose Clamp from patient. Place entire unit with Kelly Clamps in place in a hood or other area for decay storage. Gas may be released in accordance with NRC directions and your license. The gas may be discharged by releasing the clamps and collapsing the **Collection Bag.** If the gas is to be stored for an appreciable length of time, leave Kelly Clamps in place.

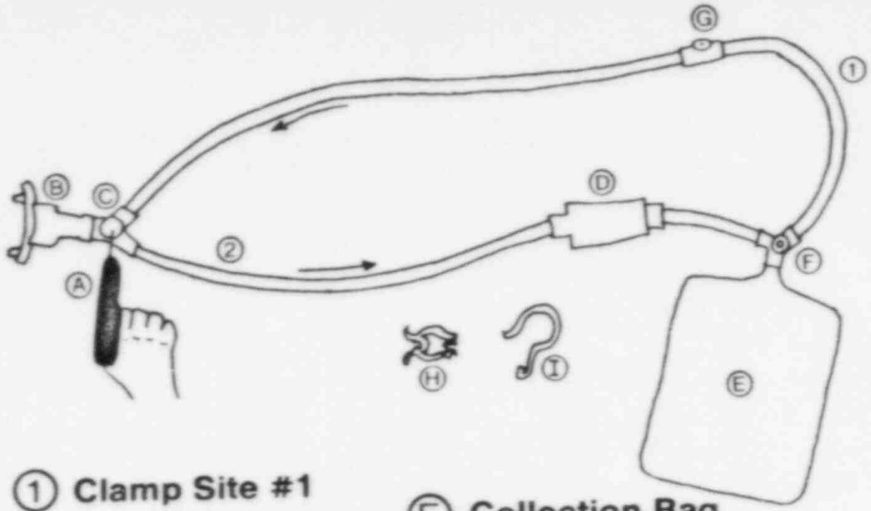
AMICI

AMICI, Inc.
373 Main Street • Collegeville, PA 19426

DISPOSABLE XENON — 133 ADMINSTRATION SYSTEM

• **Procedure Manual** •

PLEASE READ CAREFULLY BEFORE OPERATION



① **Clamp Site #1**

② **Clamp Site #2**

Ⓐ **Gas Device**

Ⓑ **Mouthpiece**

Ⓒ **Injection Site**

Ⓓ **CO_2 Absorber (prefilled with soda lime and dust filtered)**

Ⓔ **Collection Bag (35 Liter)**

Ⓕ **O_2 Inlet**

Ⓖ **Room Vent**

Ⓗ **Nose Clamp**

Ⓘ **Hanger Hook**

Instructions

This inexpensive, disposable system device is used to both administer Xenon-133 and to collect the expired gas. Made entirely of plastic, the system is used for one patient only and then discarded after the Xenon has been allowed to decay or has been exhaustd from the collection bag.

The system sonsists of Mouthpiece, which does not require sterilization, Injection site for administration of Xenon-133, CO_2 absorber, and Gas inlet for admission of oxygen to a 35 liter collection bag.

Xenon-133 is injected into the system and inhaled by the patient when the camera is turned on. The patient then holds his breath until sufficient counts are collected or until he must breathe. While the patient is breathing through the system, "equilibrium phase" data is collected. When sufficient data has been compiled, the appropriate valves are opened, and the patient inhales outside air and exhales into the collection bag until the bag is full enough to offer resistance. The entire rebreathing apparatus is then removed and placed in a hood or other area for decay storage and/or release of gas.

PROCEDURE

SPECIAL NOTE: NO SODA LIME REQUIRED!!

Step 1. For your convenience, a prefilled, dust free soda lime cartridge Ⓓ, a nose clamp Ⓗ, and a hanger hook Ⓘ, are provided at no extra charge.

Step 2. Position patient and rebreathing unit with **Collection Bag** Ⓕ, out of view of the camera.

Step 3. Clamp tubing closed at position ① with a Kelly Clamp.

Step 4. Remove plug from **O_2 Inlet** Ⓕ, attach O_2 tubing and add O_2 to **Collection Bag** Ⓔ. Experience will indicate the amount necessary, but about half-full is usually sufficient. **Note:** Care must be taken not to overfill **Collection Bag** Ⓔ, since the last phase (washout) of the procedure requires that a few exhalations of the patient must go into the **Collection Bag** Ⓔ. After O_2 has been added to the system, remove O_2 source and replug **O_2 Inlet** Ⓕ.

Step 5. Explain the procedure to the patient, and when ready to begin, place a **Nose Clamp** Ⓗ, on the patient. Release the Kelly Clamp from tubing and assist the patient in inserting **Mouthpiece** Ⓑ. Have the patient breathe normally through the system to establish confidence. Add more O_2 if required.

Step 6. Proceed with one of the following:

A. Insert the syringe needle of the **Gas Device** Ⓐ, (syringe, special gun, etc.) into the **Injection Site** Ⓒ. Have patient exhale completely, and upon inhalation, rapidly inject the Xenon and start camera. Have patient hold breath until sufficient counts are collected or until patient must breathe. In the meantime, remove the **Gas Device** Ⓐ.

OR

B. If perfusion study is intended, inject solution containing the dissolved gas I.V. while patient is "holding breath" and obtain the perfusion data.

Step 7. When the patient is breathing again through the system, begin collecting "equilibrium phase" data. Add more O_2 to system, if required. However, this is rarely necessary.

Step 8. When sufficient data is collected, simultaneously remove plug from **Room Vent** Ⓖ, and clamp tubing closed at position ① with Kelly Clamp. Patient is now inhaling outside air and

Atomic Products Corporation
Center Moriches, New York 11934, U.S.A.
(516) 878-1074

Atomlab

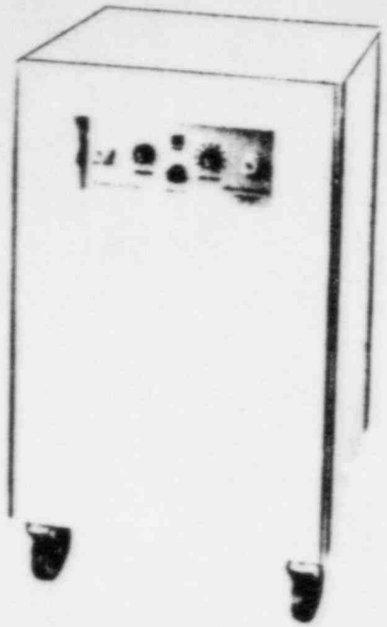
INSTRUCTION MANUAL

127-313

XENON GAS TRAP

Atomic Products Corporation
Center Moriches, New York 11934, U.S.A.
(516) 878-1074

127-313
XENON GAS TRAP



The Xenon Gas Trap comes assembled and ready for use. All that is necessary is to follow a few steps to properly connect the unit to your delivery system.

XENON TRAP INSTRUCTIONS:

1. Connect the 8" tube (supplied) to the plastic absorber cartridge provided with the system.
2. Fill the cartridge about half-way with No. 139-101 Drierite Moisture Absorber ($4.30/lb).
3. Connect the unattached end of the 8" tube to the trap port "GAS INLET".
4. Place a corrugated tube (several sizes are supplied) on the other end of the absorber cartridge.
5. Connect the corrugated tube to the xenon delivery system.
6. The system is now complete and ready for use. Set the timer to the time you will require for trapping.
7. Adjust the speed control to accommodate the patient or xenon system.
8. Monitor the trap. (See separate instruction sheet for monitoring trap).
9. The trap will automatically turn off when the timer stops.

Note: When the Drierite in the absorber cartridge turns from blue to pink, replace with fresh Drierite.

TEST PROCEDURE FOR MONITORING TRAP EXHAUST

Trap exhaust is monitored by using the gamma camera without a collimator. The following simple technique is used:

1. Remove the collimator from the camera.
2. With a 5 percent window, calibrate for Xe-133.
3. Fill a large plastic bag with a know volume of air (typically, 50 liters).
4. Inject a known quantity of Xe-133 (such as 100uCi) into the bag. The concentration will be 2×10^{-3} uCi cm^3).
5. Place the bag in front of the crystal and count for a known period of time. The c/m obtained is a measure of the efficiency.
6. Collect the exhaust of a typical study in another bag of the same volume (50 liters) and count as defined in Step #5.
7. Ratio the count rates to the standard taken to determine exhaust concentration.

   For example:

   If 2×10^{-3} uCi/cm^3 yielded 600,000 c/m above background, and collected effluent from the patient study was 150 c/m above background, then:

$$\text{Ratio} = \frac{1.5 \times 10^{2} \text{ c/m}}{6 \times 10^{5}} = 2.5 \times 10^{-4}$$

   Exhaust Concentration

   $= R\ (2 \times 10^{-3}$ uCi/$cm^3)$

   $= (2.5 \times 10^{-4})\ (2 \times 10^{-3})$

   $= 5 \times 10^{-7}$ uCi/cm^3*

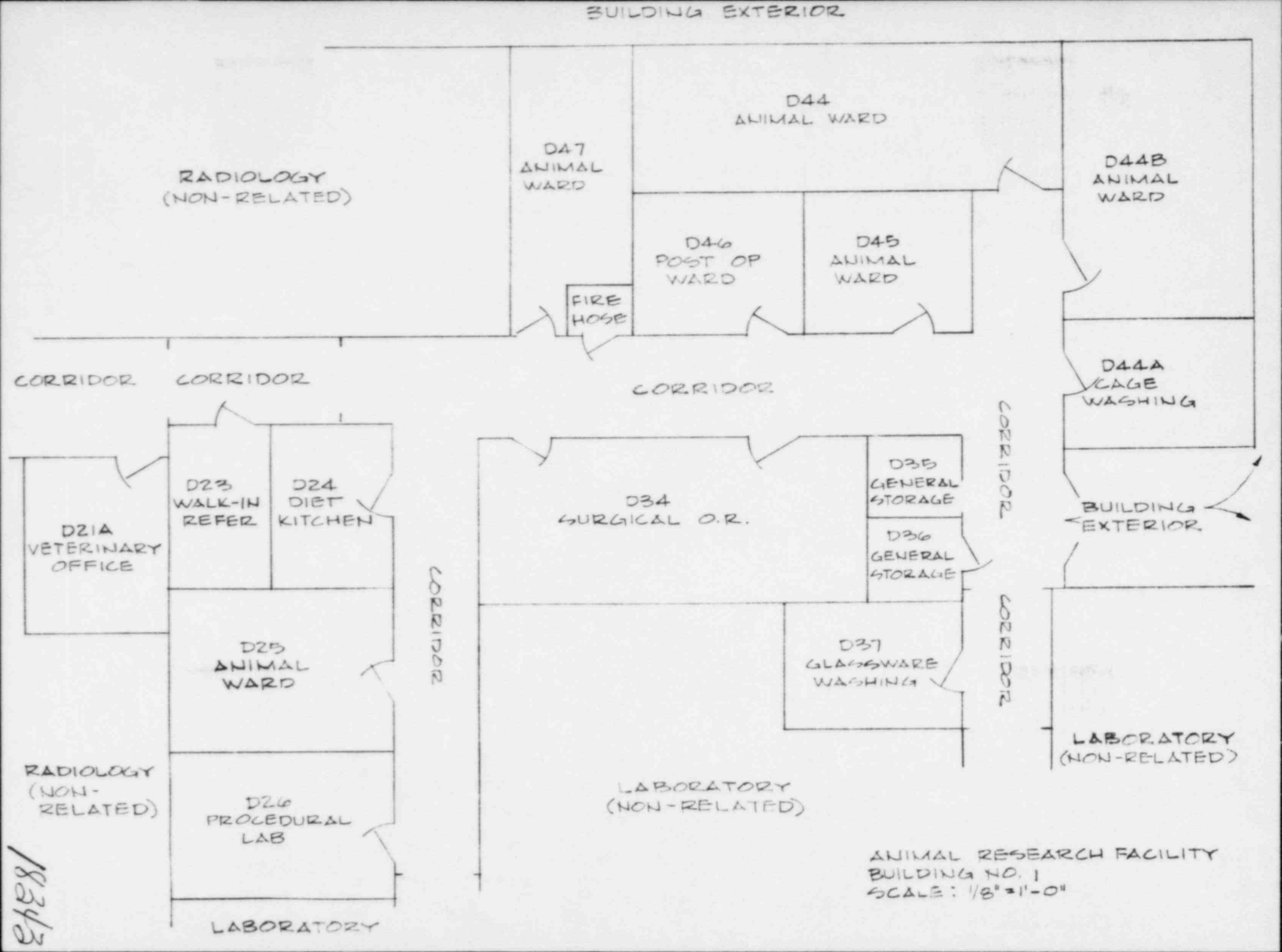
*MPC Xe-133 controlled area should not exceed 1×10^{-5} uCi/cm^3

Atomic Products Corporation
Center Moriches, New York 11934, U.S.A.
(516) 878-1074

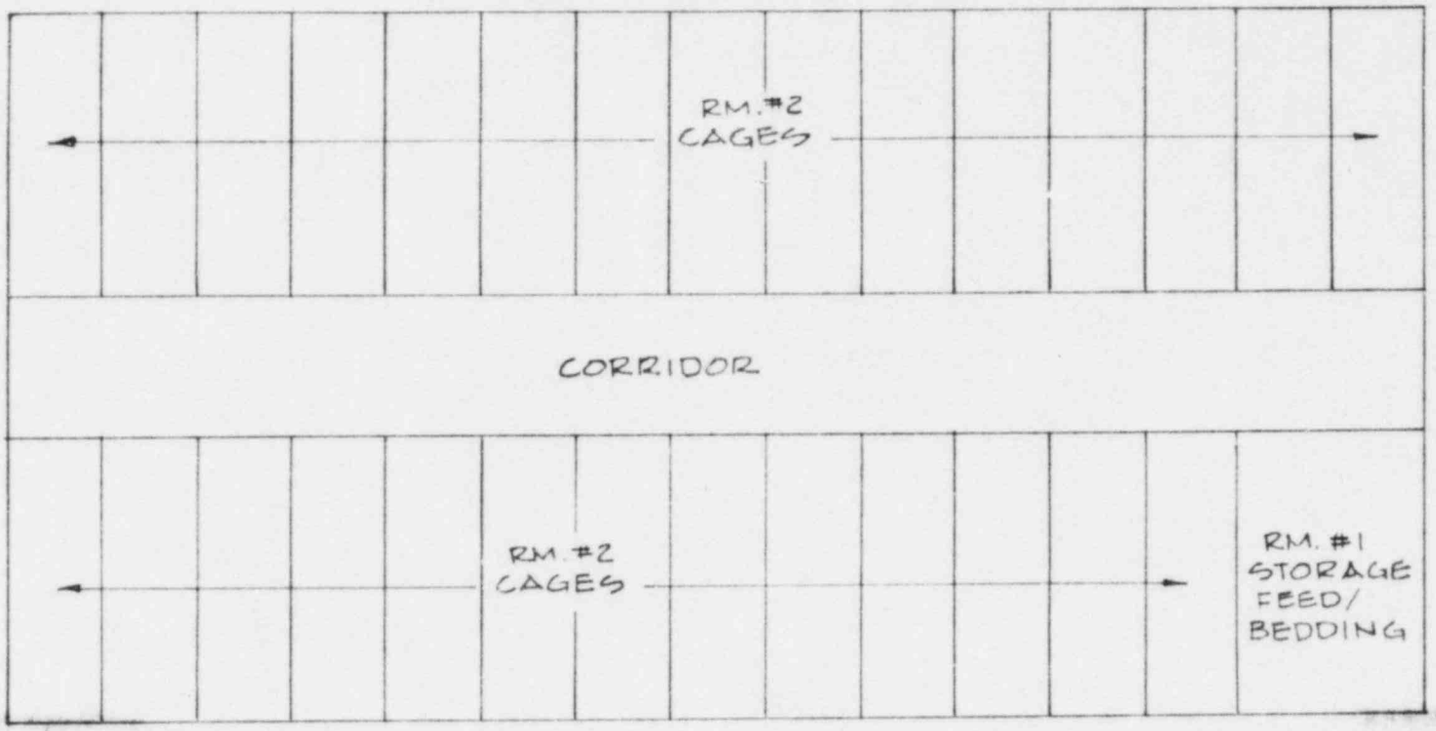
PROCEDURES FOR USE OF RADIOACTIVE MATERIALS IN ANIMALS

At the medical center, there is the Animal Research Facility (ARF) in the basement level, and the ARF Annex, which is used for housing large animals, in a small building separate from the main medical center building. Diagrams of these facilities are attached. The ARF is maintained by a full-time ARF Supervisor and staff. Radioactive materials may be utilized in animals in any portions of the ARF and ARF Annex, with the exception of the ARF office. Radioactive materials may also be utilized in animals in various research laboratories at the medical center. All uses of radioactive materials in animals, including the areas in which they may be used, must be approved by the Radiation Safety Committee, which will consider the radiation safety aspects of the proposed research just as they would any other experiment involving unsealed radioactive materials. All NRC and medical center regulations pertaining to the use of unsealed radioactive materials, including those pertaining to the posting of areas, surveys, safe use of radioactive materials, and waste disposal, will be followed. In addition, the attached "Procedures for the Use of Radioactive Materials in Animals" will also be followed.

Item 22
Date _____


BUILDING EXTERIOR
D44
ANIMAL WARD
D47
ANIMAL
WARD
RADIOLOGY
(NON-RELATED)
D44B
ANIMAL
WARD
D46
POST OP
WARD
D45
ANIMAL
WARD
FIRE
HOSE
CORRIDOR
CORRIDOR
CORRIDOR
D44A
CAGE
WASHING
CORRIDOR
D21A
VETERINARY
OFFICE
D23
WALK-IN
REFER
D24
DIET
KITCHEN
D34
SURGICAL O.R.
D35
GENERAL
STORAGE
D36
GENERAL
STORAGE
BUILDING
EXTERIOR
CORRIDOR
D25
ANIMAL
WARD
D37
GLASSWARE
WASHING
CORRIDOR
LABORATORY
(NON-RELATED)
RADIOLOGY
(NON-
RELATED)
D26
PROCEDURAL
LAB
LABORATORY
(NON-RELATED)
LABORATORY
ANIMAL RESEARCH FACILITY
BUILDING NO. 1
SCALE: 1/8"=1'-0"

BUILDING EXTERIOR



BUILDING EXTERIOR

ANIMAL RESEARCH FACILITY ANNEX
BUILDING NO. 6
SCALE: 1/8"=1'-0"

PROCEDURES FOR USE OF RADIOACTIVE MATERIALS IN ANIMALS

1. Authorization for Experiments

All experiments involving the administration of radioactive material to animals must be approved by the Radiation Safety Committee and must conform to Medical Center regulations for the use of unsealed radioactive materials.

2. Animal Housing

a. Animals which have been administered radioactive materials must be isolated from other animals that have not been administered radioactive materials. No live animals which have been administered radioactive material may be returned to the Animal Research Facility (ARF) for other use without the approval of the Radiation Safety Office.

b. Cages housing animals which have been administered radioactive materials must be marked with a "Radioactive Materials" sign. The cages must also be posted with the following information: radionuclide administered, activity administered to animal, date administered, and name of Authorized User.

c. Animals containing radionuclides must be housed in rooms which are marked in accordance with Medical Center regulations for the use of radioactive materials. These rooms must remain locked except when the Authorized User, ARF staff, or personnel authorized by the Authorized User or ARF staff are present.

d. The animals shall be assigned cages which allow urine and feces to be collected. Provisions must be made to prevent the spread of contamination from the cage by radioactive aerosols or splashings produced by the animals' movements, coughing, or other activities.

3. Waste Disposal

All animal excreta, bedding, body constituents from biopsies and autopsies, cadavers, and other waste materials will be treated as radioactive waste, unless specifically exempted by the provisions of the use authorization or Medical Center regulations for the use of radioactive materials. All radioactive waste will be disposed of in accordance with pertinent Medical Center regulations. Animal carcasses and tissues should be placed in a leak-proof plastic bag; clearly marked with "Radioactive Materials" tape and labeled with the name of the radionuclide, date, activity, and Authorized User. The Radiation Safety Office shall be contacted to remove carcasses and tissues. The carcasses and tissues shall be frozen until collected by the Radiation Safety Office, except when arrangements can be made for immediate collection by the Radiation Safety Office.

4. Control of Contamination and Surveys

a. A radioactive waste disposal container (30 gallons, with appropriate labelling) must be left in the animal housing area for use in case of spills or accidental contamination.

b. The animal must be mechanically restrained or chemically sedated to help ensure that accidental spillage will not occur during administration of the radionuclide. Any exceptions must be requested in writing from ARF Supervisor prior to administration.

c. The Authorized User is responsible for providing frequent inspections of the animal to minimize the surface contamination of the animal and cage area.

d. The Authorized User is responsible for ensuring that the Animal Research Facility Supervisor is adequately instructed in precautions to be followed by Animal Research personnel to ensure that they do not become contaminated or spread contamination and so that their exposure to radiation is minimized.

e. The Authorized User is responsible for performing surveys of portions of the Animal Research Facility in which radioactive materials are used and in which cages of animals which have been administered radioactive materials are kept. These surveys shall consist of a survey with an appropriate portable survey meter (except for experiments using H-3), and a series of wipe tests. After each procedure or series of procedures involving radioactive materials is completed, a survey shall be performed. Areas in which radioactive animals are housed shall be surveyed at the frequency required by Medical Center regulations for the use of unsealed radioactive materials and after the study is completed. The Authorized User shall maintain records (kept in the Animal Research Facility) of the surveys and shall notify the Radiation Safety Office when the study is completed. The Radiation Safety Office will evaluate the results of the Authorized User's survey and perform an independent survey to determine if the area can be released for general use. The Animal Research Facility Supervisor will be notified of the results by the Radiation Safety Office.

f. The Authorized User is responsible for the removal of any radioactive contamination in the Animal Research Facility.

g. The Authorized User is responsible for rendering cages in such a condition that they may be safely washed by the ARF staff at the conclusion of the study and for performing a survey of the cages for remaining radioactive contamination. The survey shall include a survey with a meter (except for cages in which only H-3 was used) and wipe tests. The limits for fixed and removable contamination of the cage are:

Removable contamination: 200 dpm per 100 cm

Fixed contamination: 0.1 millirem per hour at 2 inches from surface

(Fixed contamination is defined as the residual radioactivity remaining after repeated attempts at decontamination).

The Authorized User must keep a record of the survey including the following information: date, survey instrument and instrument used to count wipes, count-rates from wipe tests, and maximum exposure-rate from cage. The Authorized User will notify the Radiation Safety Office of the survey results. The Radiation Safety Office will evaluate the results and will perform an independent survey to determine if the cage can be released for general use. The Radiation Safety Office will notify the Animal Facility Supervisor of the results.

5. Personnel Protection

a. If the amount of radioactive material administered to an animal or group of animals is sufficient to create an exposure rate greater than 2 millirem-per-hour at the surface of the cage or group of cages, the Authorized User must notify the Radiation Safety Office.

b. In the case of radioactive spills or other emergencies involving radioactive materials, the Authorized User must immediately notify the Radiation Safety Officer and the Animal Facility Supervisor and must follow the Medical Center's procedures for emergencies involving radioactive materials.

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIALS SPECIFIED IN ITEM 6b

P-32 Precautions

Personnel using activities of P-32 exceeding 200 microcuries shall:

a. Wear extremity dosimeters.

b. Use shielding, composed of low atomic-number materials such as plexiglass, of sufficient thickness to attenuate the beta rays.

c. Monitor each worker's hands and clothing with an appropriate survey meter after each use.

d. Survey the laboratory work areas with an appropriate survey meter after each use.

Tritium Precautions

No tritiations are performed at the medical center. All tritium is obtained in the form of pre-labelled compounds. Any personnel using tritium in excess of the action levels in Draft Regulatory Guide "Applications of Bioassay for Tritium" shall be bioassayed in accordance with the Draft Regulatory Guide.

I-125 and I-131 Precautions

1. Protein iodinations

   a. All protein iodinations shall be performed in the fume hood in laboratory room B-70A, which exhausts directly to the exterior of the medical center.

   b. This fume-hood shall be surveyed quarterly in accordance with Regulatory Guide 8.23 to ensure that the average face velocity exceeds 100 feet-per-minute with the sash at the operating height.

   c. Personnel performing iodinations shall be bioassayed in accordance with Regulatory Guide 8.20.

   d. Personnel performing iodinations shall wear extremity dosimeters as well as body dosimeters.

Procedures and Precautions for Use of Radioactive Materials Specified in Item 6b

2. Other uses of radioiodine

All other personnel who use activities of radioiodine exceeding the action levels of Regulatory Guide 8.20 will be bioassayed in accordance with the regulatory guide.

Sealed Sources

1. a. Each sealed source containing licensed material, other than Hydrogen-3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. In the absence of a certificate from a transferor, indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

b. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

c. Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

2. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

3. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance of the test with the U.S. Nuclear Regulatory Commission,

Procedures and Precautions for Use of Radioactive Materials Specified in Item 6b

Region V, Office of Inspection and Enforcement, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596, describing the equipment involved, the test results, and the corrective action taken.

4. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services

Sealed sources containing licensed material shall not be opened.

EXTREMITY DOSIMETERS

In situations in which radiation doses to fingers are expected to substantially exceed wrist doses, finger dosimeters will be worn instead of wrist dosimeters, except in cases in which the Radiaion Safety Officer determines that circumstances preclude the use of finger dosimeters. In such cases, an attempt will be made to estimate finger doses from wrist dosimeter data.

At the present time, only one wrist dosimeter is in use. It is worn by a technologist who has a medical condition precluding the use of a finger dosimeter. Another technologist will wear a finger dosimeter and a wrist dosimeter for a month. The ratio of these doses will be used to estimate finger doses from wrist dosimeter measurements.

Item 24
Date _____