

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material 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, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet).

1. (a) NAME AND STREET ADDRESS OF APPLICANT. (Institution, firm, hospital person, etc. Include ZIP Code and telephone number.) Veterans Administration Hospital 4150 Clement Street San Francisco, Ca 94121 (415) 221-4810		(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. (If different from 1(a). Include ZIP Code.) Same as 1(a)	
2. DEPARTMENT TO USE BYPRODUCT MATERIAL As approved by the Isotope Committee		3. PREVIOUS LICENSE NUMBER(S). (If this is an application for renewal of a license, please indicate and give number.) Renewal of Lic. 04-00421-05 (expires 4/30/78)	
4. INDIVIDUAL USER(S). (Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.) As approved by the Isotope Committee Ralph R. Cavalieri, Chairman		5. RADIATION PROTECTION OFFICER. (Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.) Dennis R. Gonzales, M.S. (See attached)	
6. (a) BYPRODUCT MATERIAL. (Elements and mass number of each.) (see attached)		(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. (If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.) (see attached)	

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)

Diagnosis, therapy and medical research, including use in lower animals.

8408220103 840813
NMS LIC30
04-00421-05 PDR

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TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	(see attached)		Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		(see attached)		

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm ²)	USE (Monitoring, surveying, measuring)
(see attached)					

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE

(See attached)

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier.)

Film badges are changed monthly at the end of each month. Service is provided by:
 Radiation Detection Company Sunnyvale, Ca 94088
 P.O. Box 1414 (408) 735-8700

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached: (Circle answer) Yes No (see attached)

14. RADIATION PROTECTION PROGRAM Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source. (see attached)

15. WASTE DISPOSAL If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. (see attached)

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

License Fee Category \$ N/A

Fee Enclosed \$ _____

Date March 8, 1978

Veterans Administration Hospital

Applicant named in item 1

By:

Ralph R. Cavalieri
 Ralph R. Cavalieri, M.D.

Chief, Nuclear Medicine Service

Title of certifying official

Chairman, Isotope Committee

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

6.

(a) BYPRODUCT MATERIAL

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME.

	<u>Isotope</u>	<u>Form</u>	<u>Amount</u>
A.	Atomic #'s = 3-83	any	100mCi
B.	H-3	any	2000mCi
C.	C-14	any	300mCi
D.	P-32	any	300mCi
E.	Mo-99	any	1000mCi
F.	Tc-99m	any	1000mCi
G.	I-125	any	300mCi
H.	I-131	any	300mCi
I.	Xe-133	gas (free or in solution)	2000mCi
J.	Co-57	sealed source (1) Isotope Products Laboratory Model 231E	1.0mCi + 5%
K.	Co-57	sealed source (1) Isotope Products Laboratory Model 231E	0.3mCi + 5%
L.	Cs-137	sealed source (1) Isotope Products Laboratory Model 229E	0.2mCi + 5%
K.	Am-241	sealed source (1) Amersham/Searle Model AMC.W233	10000mCi

Total possession limit requested is 25 curies.

RENEWAL APPLICATION FOR BROAD MEDICAL ISOTOPE LICENSE
V.A. HOSPITAL, SAN FRANCISCO

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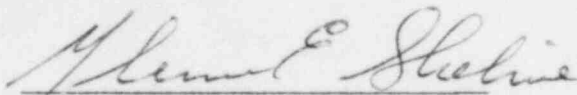
APPLICATION FOR BROAD ISOTOPE LICENSE

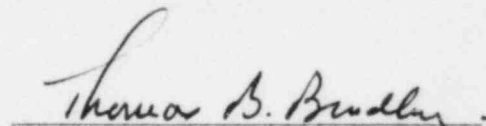
Statement of Approval by Isotope Committee

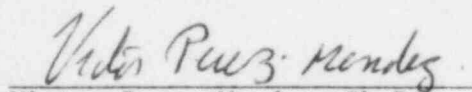
We, the undersigned, members of the Isotope Committee of the Veterans Administration Hospital, San Francisco, California, approve the enclosed application for a broad Medical Isotope License.



Ralph R. Cavalieri, M.D.
Chairman

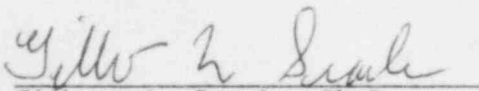

Dennis R. Gonzales, M.S.
Radiation Safety Officer

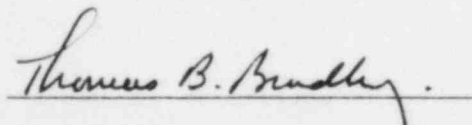

Glenn E. Sheline, M.D.


Thomas B. Bradley, M.D.


Victor Perez-Mendes, Ph.D.


William L. Schalker, M.S., R.Ph.D.


Gilbert L. Searle, Ph.D.


Associate Chief of Staff
for Research & Education

VETERANS ADMINISTRATION HOSPITAL
4150 Clement Street
San Francisco, California 94121

HOSPITAL MEMORANDUM
January 31, 1978

No.
Symbol: 11

SUBJ: Medical Isotope Committee

1. Definition: In accordance with Section 35.11(b), of Title 10, Code of Federal regulations, "Human Uses of Byproduct Material," a Medical Isotope Committee is hereby established. The Committee will include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assaying radioisotopes and in establishing radiation safety protection policies and practices against ionizing radiation.

2. Membership:

Chief, Nuclear Medicine Service (Chairman)
Chief Scientist, Nuclear Medicine Service
Chief, Hematology Section
Chief, Pharmacy Service
Consultant in Radiation Therapy
Consultant in Biophysics
Radiation Safety Officer
Associate Chief of Staff for Research (ex-officio)

3. Responsibilities and Duties: The Medical Isotope Committee is responsible for the safe use of all radioactive material within this institution. The Committee's specific responsibilities include:

- a. The Committee shall be familiar with all pertinent NRC regulations, the terms of the radioisotope license, and information submitted in support of the request for the license and its amendments. In addition, it will ensure that the license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel.
- b. It will review and grant permission for, or disapprove, all uses of radioactive byproduct material (both experimental and routine uses) within this institution in conformance with NRC regulations, specific conditions of the institutional license and its amendments, and with regard to established hospital radiation safety procedures and guidelines.
- c. The Committee will insure that all individuals who work with or have occasion to be in the vicinity of radioactive materials have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and conditions of the institutional license.
- d. The Committee will formulate and review the institutional radiation safety training program.
- e. The Committee will recommend remedial action to correct any deficiencies identified in the institutional radiation safety program.

f. The Committee will maintain written records of all committee meetings, actions, recommendations and decisions. It will receive and review records and reports from the Radiation Safety Officer and/or other individuals delegated with responsibility for health and safety practices in this institution.

4. Administrative Procedures:

a. The Medical Isotope Committee will hold regular meetings once every calendar quarter. Additional meetings may be called by the Chairman to conduct urgent business. A minimum of five members constitutes a committee quorum.

b. The minutes of each meeting will be recorded by the Chairman or his designee. Copies of minutes and other records of action or recommendations by the committee are distributed to each member for changes and final approval. Approved minutes will be filed with the Secretary of the Hospital Research and Education Committee, the Hospital Director and Chief of Staff.

c. Methods of Control over Procurement of Radioisotopes: The Radiation Safety Officer is responsible for recording the quantities of radioisotope byproduct material ordered, procured, and maintained at this hospital. The following procedure is designed to avoid exceeding the possession limit as set by the license.

(1) Purchase orders for radioisotopes are routed to the Radiation Safety Officer before the order is placed. If the RSO determines that the person ordering the material has been approved by the Isotope Committee and the quantity of material ordered is within the permissible license allowance for that particular isotope, he approves the order and forwards it to the Purchasing Office. If the quantity ordered does exceed the limit, he notifies the Chairman of the Isotope Committee and the individual who initiated the order so that the purchase order can be changed to comply with the license possession limit.

(2) All radioisotope shipments received at this station will be examined by personnel who are approved by the Radiation Safety Officer as qualified to receive and examine such shipments. The quantity, and date of receipt will be recorded as prescribed by the RSO. This mechanism will provide assurance that the possession limit for the particular radionuclide is not exceeded. The RSO will prescribe the methods by which containers are examined (e.g. by wipe testing) to insure that no leakage of radioactive material has occurred.

d. Maintaining Inventories: Records of the quantities of radioactive materials on hand at this institution will be maintained and kept current by individual users. The records will be reviewed at least monthly by the Radiation Safety Officer. Inventory records compiled from the user's records will be kept on file in the Radiation Safety Officer's office, Nuclear Medicine Service. These records are made available to the Medical Isotope Committee at each meeting.

5. Methods of Evaluating Proposals for the Use of Radioisotopes: All proposals for the use of radioisotopes in this hospital must be evaluated by the Medical Isotope Committee, particularly to ensure conformance with NRC regulations, provisions of the license, and with regard to radiation safety for human subjects and working personnel. The Medical Isotope Committee will recommend approval or disapproval of the proposal and report its decision to the Hospital Research and Education Committee, according to established VA procedure.

6. RECISSION: Hospital Memoranda No. 59-70.

7. EXPIRATION DATE: 1 May 1980.

HOSPITAL DIRECTOR

DISTRIBUTION

Type B

INFORMATION REQUIRED ON ALL APPLICATIONS INVOLVING
RESEARCH USES OF RADIOISOTOPES

A. Uses not involving human subjects. Research protocol applications must include the following:

1. Title and statement of purpose of the study.
2. List of personnel involved in the study.
3. List of radioisotopes to be used, chemical form and anticipated quantities to be kept on hand.
4. If animals are to be used,
 - a. Species
 - b. Number (per week or month; and total no. per study)
 - c. Total activity administered per animal and chemical form of dose.
 - d. Estimated duration of survival of animals containing radioactivity.
5. List of all locations where radioisotope work is to be performed, and information describing precautions to be taken for the protection of all personnel (including animal caretakers, housekeeping and non-radiation workers) against unwarranted radiation exposure.
6. A detailed description of the training and experience in handling of radioactive material of all personnel involved in the study.

B. Human use.

1. Title of the study.
2. Names and titles of principal investigator and others assisting in the study.
3. Statement of purpose.
4. Rationale and justification for the study, including background information and data from previous animal studies by the investigators, or from other laboratories.
5. The number of patients/subjects involved in the study, their ages, sex and clinical diagnosis before administration of the radio-pharmaceutical.
6. The number and type of human subjects to be studied. Include age, sex, method of selection, and medical conditions which would preclude their participation in the study. Justification for use of normal subjects.

7. Activity dose, route and rate of administration, specific activity, and chemical form of radioisotope administered must be given in addition to the rationale behind the selection of the proposed dose.
 8. The dosage schedule used and complementary drugs, if any, must be listed.
 9. The method of handling special problems, such as disposal of excreta, care of radioactive animals in the animal care facility, radioactive contamination, spillage monitoring and precautions to be taken in guarding hospital personnel and technicians against excessive radiation.
 10. List of instrumentation to be used for radiation detection and counting.
 11. Calculation of the expected radiation dose to the whole body and to primary and secondary organs. Include rationale behind these estimates and published data used in regard to the distribution and biological half-lives.
 12. Statement indicating that the subjects or responsible relatives will be informed of the nature and purpose of the study. Informed, written consent must be obtained prior to placing a subject in the study.
 13. A copy of the consent form(s).
 14. A complete and detailed description of the training and experience of the investigators and assistants in regard to the use of radioactive material.
- C. Criteria for evaluating the qualifications of a prospective user of radioisotopes. The Committee will consider the following factors in its evaluation of individuals proposing to use radioisotopes in humans:
1. Training.
 - a. Basic aspects: radiation physics, radiobiology, instrumentation, principles of tracer methodology.
 - b. Clinical: preferably in uses closely related to the proposed use. The number and type of clinical isotope procedures or treatments, the extent of participation, dates, institutions, and preceptors should be furnished.
 2. Experience.
 - a. A summary of clinical experience in regard to diagnostic and therapeutic applications of radioisotopes.
 - b. A selected bibliography and summary of research experience in the same use or related to that type proposed.

(For non-human uses, items 1a. and 2b. will be considered)

- D. Method of limiting the duration of an experimental or non-routine study involving the use of byproduct material in humans. At the time it approves a study of this kind, the Isotope Committee will set a limit to the duration of the study, e.g., one or two years, and will specify a limit to the number of subjects to be studied.

The Committee will also determine the frequency of Progress Reports (usually annually, but in certain cases more frequently). These reports must include the information outlined below. A final report including the same kind of information must be submitted within six weeks after the end of the study. Copies of progress and final reports are sent to: Chairman of the Isotope Committee, the Radiation Safety Officer, and the Secretary of the Hospital Research Committee.

Information which must be included both in Progress Reports and in Final Report of Studies Involving Experimental or Non-routine Use of Byproduct Material in Humans:

1. A statement of the purpose for conducting the study.
2. A summary of the results of the study.
 - a. The radioisotope administered, its chemical form, and route of administration.
 - b. The number of patients involved in the study, their ages, sex, and clinical diagnosis before administration of the radio-pharmaceutical.
 - c. Dosage schedule used.
 - d. Complementary drugs administered, if any.
 - e. The method of preparation of the radiopharmaceutical, if it was not obtained in a prepackaged, precalibrated, sterile and pyrogen-free form from a pharmaceutical supplier.
 - f. Special radiation detection instrumentation used.
 - g. A Statement of organ distribution and estimate of the respective biological half-life of the administered radioisotope as determined during the course of the study. State the rationale behind these estimates and/or the methods used to make the determinations.
 - h. A synopsis of the toxicity data obtained.
 - i. Brief clinical histories of all patients exhibiting any adverse reactions to any radiopharmaceutical administered. The investigator should describe the reaction and include his interpretation of the nature and cause of the reaction.

3. An evaluation by the investigator of the safety and efficacy of the diagnostic or therapeutic procedure. This evaluation should include a statement on side effects, toxicity, contraindications, and ineffectiveness. In the case of diagnostic procedures, the investigator should state whether or not the resultant diagnosis was confirmed by other methods.

The duration of each study is limited by the Isotope Committee to a maximum of two years at the time of approval, and will usually be granted for a period of one year. Application for continuation of the study beyond the approved period must include, (1) a report of findings already obtained (following the outline for final reports given above), (2) justification for the continuation of the study, and (3) a detailed protocol giving all the information necessary to an application for a new study, (and, in addition, specifying changes in the original protocol with an explanation of the reason for such changes).

Such an application for continuation is evaluated by the Isotope Committee in the same manner as an application for a new study. The Committee may request any additional supporting information it deems necessary to such an evaluation. The Committee, when it approves the continuation of a study, sets limits in duration and in number of subjects to be studied.

GUIDELINES IN EVALUATION OF APPLICATIONS FOR HUMAN STUDIES
EMPLOYING RADIOISOTOPES

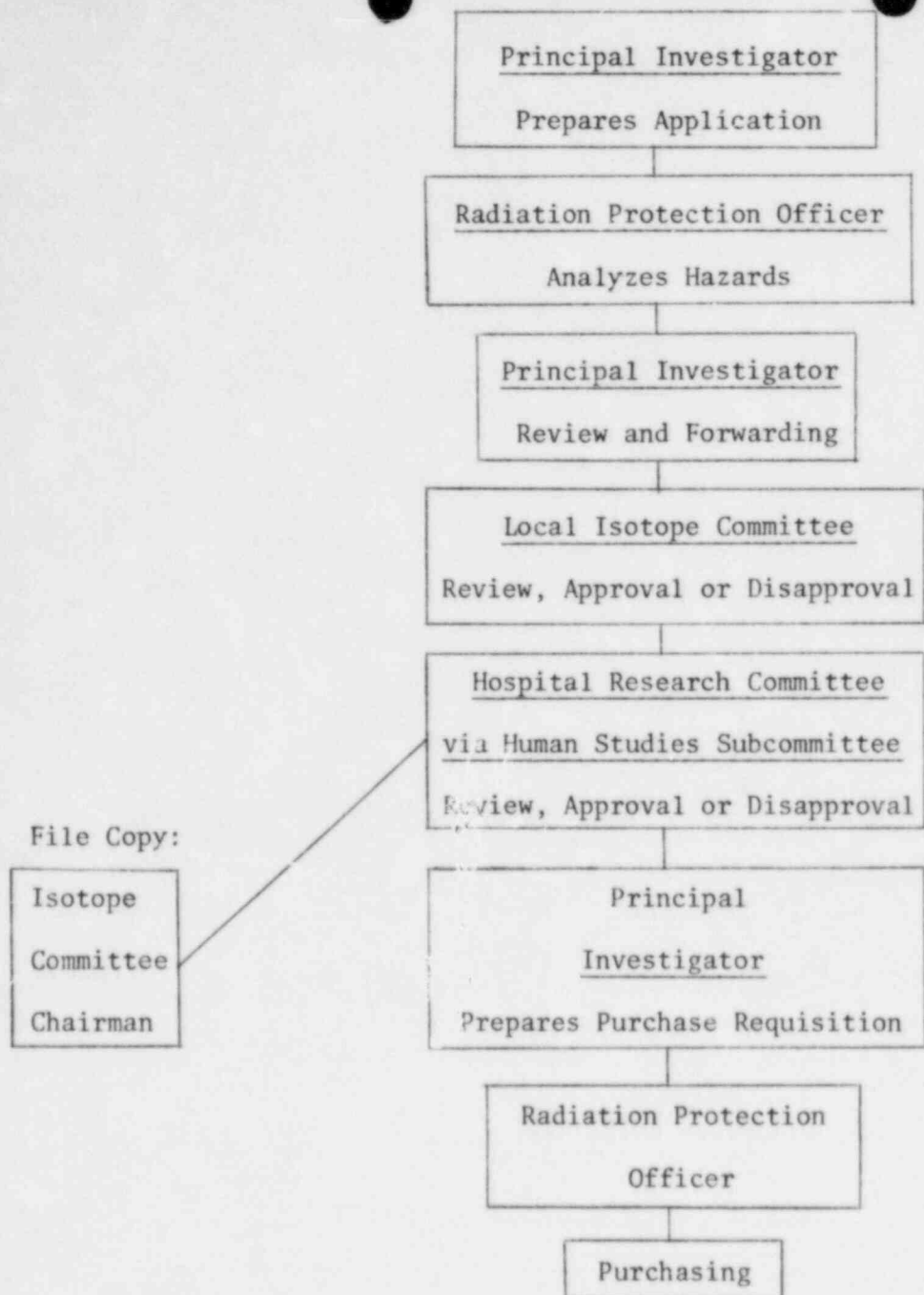
- I. Scientific merit and feasibility ought to be considered.
- II. Training and experience of investigators in the handling and use of radioactive materials must be considered.
 - A. General Training in Basic Aspects
 1. A working knowledge of:
 - a. Principles of radiological health safety.
 - b. Radioactivity measurements, standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
 2. Experience in the use of byproduct material of the type and quantity for which the application is being made.
 - B. Clinical Training in Medical Uses of Radioisotopes
 1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed.
 2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting of data.
 3. Adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.
 4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic and/or therapeutic procedures, limitations, contraindications, etc.
- III. Human subjects.
 - A. Patients: Consider life-expectancy and possible benefits to the individual arising from the study.
 - B. Control subjects - Are normal volunteers necessary? If so, consider age, sex, the number to be studied, and the following:

1. The use of radiation workers (e.g., laboratory personnel) as subjects is to be discouraged.
2. Labeled nucleic acids and derivatives ought not to be administered to normal subjects (because of possible somatic and general mutagenesis).
3. The Committee disapproves the use of normal volunteers under the age of 18 years and pregnant women of any age.

IV. Dosimetry.

- A. The Chairman of the Committee, or his designee, in consultation with experts on the Committee will review the assumptions used and calculations of radiation exposure made by the applicants.
 - B. On the principle that all radiation exposure to humans ought to be kept to a minimum, the applicant ought to provide adequate justification for the size of the dose of radioisotope to be administered. Such justification ought to be based upon considerations of factors such as, the most appropriate radionuclide available, the size of samples to be assayed, and the efficiency of the counting instruments.
- V. Consent Form: The aspects of risk from radiation exposure are of particular concern to the Committee. The Form must include a statement, in language easily understood by lay persons, regarding the somatic and genetic risks of radiation exposure. The magnitude of the radiation exposure could be compared to more familiar forms of exposure, such as diagnostic chest x-rays, living at elevations above sea level, etc.

TABLE I. Routing of Application for Non-Routine Use of Radioisotopes in Humans



R.R. Cavalieri, M.D.

Chairman, Isotope Committee
Chief, Nuclear Medicine Service

Specialties:

Internal Medicine
(Certified, American Board of Internal Med.,
1965
Nuclear Medicine
(certified, 1973)

Present Titles:

Chief, Nuclear Medicine Service, Veterans Administration Hospital, Associate Professor of Medicine & Radiology, UC San Francisco

Positions Held:

1959-1961	Staff Medical Officer Nuclear Medicine Branch U.S. Naval Hospital, Bethesda, Md. (Chief, E.R. King, Capt. USN).
1961-1962	Research Fellow (NATO), National Inst. for Medical Research, London, England. (Chief, Dr. R. Pitt-Rivers, F.R.S.).
1962-1963	Special NIH Fellow, Dept. of Nuclear Medicine, Johns Hopkins Medical Institution (Sponsor: Henry N. Wagner, M.D.).
1963-Present	Chief, Nuclear Medicine Service, VA Hospital, San Francisco

Training in Nuclear Medicine (See Supplement A. attached)

Jan.-April 1960	Course in Radioisotope Techniques and Nuclear Medicine, National Naval Medical Center.
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Clinical Experience:

1959-Present	All phases of Nuclear Medicine
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Clinical Experience since 1963:

<u>Isotope</u>	<u>Diagnostic Procedure</u>	<u>No. of Tests</u>
^{131}I	Thyroid uptake and/or scans	2,600
^{131}I and ^{125}I	In vitro T_3 and T_4 tests	15,100
^{131}I and ^{125}I	HSA Plasma volume	350

R.R. Cavalieri, M.D.

Clinical Experience since 1963 (continued)

<u>Isotope</u>	<u>Diagnostic Procedure</u>	<u>No. of Tests</u>
^{51}Cr	RBC Mass (blood volume)	460
^{57}Co	Vitamin B ₁₂ Absorption	700
^{197}Hg	Chlormerodrin brain scans	350
$^{99\text{m}}\text{Tc}$	Brain scans	5,200
^{198}Au	Liver scans	210
^{131}I	Rose Bengal liver scans	45
^{75}Se	Selenite tumor localization	70
^{85}Sr	Bone scans	100
^{18}F	Bone scans	67
$^{99\text{m}}\text{Tc}$	Colloid/liver and spleen scans	1,750
$^{99\text{m}}\text{Tc}$	Colloid/bone marrow scans	50
$^{99\text{m}}\text{Tc}$	Heart scans	210
$^{99\text{m}}\text{Tc}$	Renal blood flow	90
<u>Therapy</u>		<u>Cases</u>
^{131}I	Hyperthyroidism	65
^{131}I	Thyroid cancer	14
^{32}P	Polycythemia	35
<u>Research</u>	Sixty scientific papers in various fields of Nuclear Medicine.	

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
SUPPLEMENT A--HUMAN USE

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is not furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME

(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))

Ralph R. Cavalieri, M.D.

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR ALL CASES IN COLUMN D (circle applicable num- bers of items in accordance with key set forth below)
I-131	Diagnosis of thyroid function	1331	1 2 3 4
	Treatment of hyperthyroidism	23	1 2 3 4
	Treatment of thyroid cancer	7	1 2 3 4
	Treatment of cardiac conditions	2	1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations, T-3	712	1 2 3 4
	Others: Triolein, Pancreatic Function	71	1 2 3 4
	(Continued on reverse side)		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia	23	1 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases	43	1 2 3 4
	Others: Tracers (diagnostic)	19	1 2 3 4
			1 2 3 4
P-32 CrPO ₄	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites	21	1 2 3 4
	Others: Liver Scan	27	1 2 3 4
	(Continued on reverse side)		1 2 3 4
Cr-51	Blood determinations	391	1 2 3 4
	Others: Red Cell Survival	33	1 2 3 4
	(Continued on reverse side)		1 2 3 4
Other Isotopes	Co ⁶⁰ B ₁₂ Schilling Test	17	1 2 3 4
	Co ⁵⁷ B ₁₂ Schilling Test	13	1 2 3 4
	(Continued on reverse side)		1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion

**All four numbers in
Column D are applicable**

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be prescribed.
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period including reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING _____ hours (See reverse side)

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

E. R. KING, CAPT, MC USN

(Name of physician (preceptor))

**Chief of Radiology
U. S. Naval Hospital, NNMIC
Bethesda 14, Maryland**

(Institution)

[Signature]
(Signature)

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved:
Budget Bureau No. 38-R080.1

This page may be used for providing additional information.

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Staff Medical Officer, Nuclear Medicine Branch, Radiology Service, U. S. Naval Hospital, National Naval Medical Center, Bethesda, Md. - July 1959 to July 1961

Graduated from Medical Officers' Course in Radioisotope Techniques and Nuclear Medicine, Class No. 7 - 13 January 1960 to 3 April 1960

Thomas B. Bradley, M.D.

Specialty: Hematology

Present Titles: Chief, Hematology Section
Associate Chief of Staff, Research and Development
Veterans Administration Hospital, San Francisco
Professor of Medicine
University of California, San Francisco

Training in Nuclear Medicine

1959 - 1960 Course in Nuclear Medicine, Johns Hopkins Hospital,
Henry N. Wagner, M.D., and John McAfee, M.D., Directors.

Experience:

A. Supervision of diagnostic applications of
radioisotopes in hematology:

1960 - 1962 Muhlenberg Hospital, Plainfield, New Jersey

1962 - 1964 Jersey City Medical Center

1964 - 1969 Albert Einstein College of Medicine
(Bronx Municipal Hospitals)

B. Member, Institutional Isotope Committee

1965 - 1969 Albert Einstein College of Medicine

1973 - Present Veterans Administration Hospital, San Francisco

Gilbert L. Searle, Ph.D.

Physiologist

Position:

Chief Scientist, Nuclear Medicine Service
Veterans Administration Hospital
San Francisco, California

Lecturer in Physiology
University Of California
San Francisco Medical Center

Training and Experience in the Use of Radioisotopes:

1950-1955

Department of Physiology, University of California,
Berkeley, California. (Preceptor: I.L. Chaikoff,
M.D., Ph.D.)

Research involving C-14 glucose in animals.

1956-Present

Nuclear Medicine Service
Veterans Administration Hospital
San Francisco, California

Experimental research in animals

Research in humans (in collaboration with physicians
W.A. Reilly, M.D. and R.R. Cavalieri, M.D.) using
the following radionuclides:

C-14, I-131, P-32, Cr-51, Na-24, Fe-59, Co-60,
Ag-111, and Rb-86.

Publications:

Over 30 papers involving the use of radioisotopes
as tracers.

William L. Schalker, M.S., R.Ph.

Specialty: Pharmacy
(Licentiate Pharmacist State of North Dakota)

Present Titles: Chief Pharmacist
Veterans Administration Hospital

Training in Nuclear Medicine:

Sep - Dec 1957	A four credit Qt. Radiopharmaceutical course North Dakota State University
Jul - 1958	Radioisotope Training Course given by AEC at Oak Ridge, Tennessee (3 weeks)
1961	Radiopharmacist at Veterans Administration Hospital McKinney, Texas (10 months)
Jul - 1963	The "Basic Radiological Health" course given by the U.S. Department of Health (40 hours)
Dec - 1965	"Radiological Monitoring for Instructors" given by the Office of Civil Defense - Staff College (40 hours)
Jan - Jan 1969	Training seminar on Radioisotopes given by Squibb Division of Nuclear Medicine and is so certified (January 15-16)
April 15 1972	Training Seminar in Radiopharmacy at Letterman Medical Center supported by a grant from Roerig, Division of Pfizer Inc. (8 hours)
Oct - 1969- present	Supervise Radiopharmacy Laboratory at VAHSF

Glenn E. Sheline, Ph.D., M.D.

Specialty: Radiation Oncology

Present Titles: Professor and Vice-Chairman, Department of Radiology and Division of Radiation Oncology, University of California, San Francisco
Consultant to Radiology Department, Veterans Administration Hospital, San Francisco
Consultant to Division of Cancer Control and Rehabilitation of the National Institutes of Health, National Cancer Institute

Training in Nuclear Medicine:

Began using radioisotopes in 1939 and have participated in training programs as an Instructor. No formal training in isotope techniques.

Practical Experience:

1939-1965	Practical experience with radioisotopes including clinical and laboratory research.
1949-1965	Clinical research, diagnosis and therapy utilizing radioactive iodine and radiophosphorus.
1953-present	Radiation therapy using x-rays, Cobalt-60 irradiation, radium.
1955-1965	Head, Clinical Nuclear Medicine Section, University of California Medical School, San Francisco.

Publications:

Sheline, G.E., and Miller, E.R.: Radioiodine therapy of hypothyroidism. AMA Arch. Int. Med. 103:924, 1959

Sheline, G.E., Jones, M.D., and Bell, H.G.: Treatment of breast cancer by radical mastectomy, postoperative roentgen therapy, and intravenous radiophosphorus: hematologic effects. Amer. J. Roentgenol. 85:834, 1961

Sheline, G.E., Lindsay, S., McCormack, K.R., and Galante, M.: Thyroid nodules occurring late after treatment of thyrotoxicosis with radioiodine. J. Clin. Endocrinol. and Metab. 22:8, 1962

Sheline, G.E.: Thyroid proliferative potential as a function of age. Cell and Kinetics 2:123, 1969

Sheline, G.E., Field, S.F., Brennan, J.T., and Phillips, T.L.: Human tissue changes following neutron therapy. Amer. J. Roentgenol. III:31, 1971

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Becker, D.V., McConahey, W.M., Dobyns, B.M., Tompkins, E., Sheline, G.E. and Workman, J.B.: The results of radioiodine treatment of hyperthyroidism. A preliminary Report of the thyrotoxicosis therapy follow-up study. (In) Further Advances in Thyroid Research, ed. Fellingner and Hofer, Verlag der Wiener Medizinischen Akademie, Vienna, 1971

V. Perez-Mendez, Ph.D.

Specialty: Radiation Physics

Present Titles: Professor of Physics and Head of Physics Section
Radiology Department, University of California
San Francisco
Consultant to Nuclear Medicine Service, Veterans
Administration Hospital, San Francisco
Senior Scientists and Research Group leader,
Lawrence Berkeley Laboratory, University of
California, Berkeley

Training in Nuclear Medicine:

1948-1951 Course in Radioactivity, Nuclear Physics, Electronics,
and Instrumentation, Columbia University, New York

1951 Ph.D. Thesis on β decay of short-lived isotopes.

Practical Experience:

1962-1966 Use of β and γ emitting isotopes in research involv-
ing calibration of detectors, wire chamber develop-
ment, and general imaging procedures. Use of I-131,
I-125, I-123, Tc-99, Cd-109, Am-241, Co-57, Cs-131,
Xe-133 and positron emitters such as F-18, a-22.
Use of C-14 and other β emitters in course of Radio-
activity at University of California, Berkeley.

Publications:

Initial Results of MWPC Positron Camera. C.B. Lim, D. Chu, V. Perez-Mendez
and L. Kaufman, R. Hattner and D.C. Price. IEEE Trans. Nuc. Sci. NS-22
(1975) 388-394 - LBL 3617 (Dec 1974)

New Detectors for Radionuclide Imaging. M.R. Powell and V. Perez-Mendez.
Published in "Nuclear Medicine in Clinical Pediatrics" as Ch 17-p231-242.
Handmaker and Lowenstein Editors. (Society of Nuclear Medicine Inc. New York)
Feb. 1975.

Three Dimensional Imaging with a Positron Camera. C. Lim, D. Chu, V. Perez-Mendez,
L. Kaufman, R. Hattner and D. Price. A.N.S. Trans 21 (June 1974) 103.

A Xenon-filled Multiwire Area Detector for X-ray Diffraction. C. Cork,
R. Hamlin, W. Vernon and N.H. (Xuong (UCSD) and V. Perez-Mendez (LBL & UCSF)
Acta Cryst. (1975) A31, 702.

Multiwire Proportional Chambers in Nuclear Medicine: Present Status and
Perspectives. V. Perez-Mendez, L. Kaufman, C. Lim, D. Price, L. Blumin
and R. Cavalieri. J. Nuc. Med. and Biol. 3 (Jan 1976) 29.

High Efficiency Collimator-Converters for Neutral Particle Imaging with MWPC. D. Chu, C. Lim, V. Perez-Mendez, D. Lambert and S.N. Kaplan. LBL 3863 - IEEE Trans. Nuc. Sci. 23 (Feb 1976) 634-639.

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Comparisons of Coded Aperture Imaging Using Various Apertures and Decoding Methods. L.T. Chang, B. Macdonald, and V. Perez-Mendez. LBL-5342 (1976). Proceedings of Applications of Optics and Medicine and Biology, San Diego, California, August 1976, SPIE - Vol 89.

New Developments in Nuclear Medicine Imaging. V. Perez-Mendez. LBL 6114 Published in Proceedings - First Asia and Oceania Congress of Nuclear Medicine, Sydney, Australia, September 1976.

High Efficiency Gamma Converters and their Application in a MWPC Positron Camera. D. Chu, K. Tam, V. Perez-Mendez, S. Kaplan, C. Lim, R. Hattner, L. Kaufman, D. Price and S. Swann. LBL-5516 - Proc. IAEA Symposium on Medical Radionuclide Imaging (Los Angeles - Oct 1976) 171-193.

Channel Electron Multipliers: Properties, Developments and Applications. P. Lecomte and V. Perez-Mendez. LBL-6130 - (Feb 1977) To be published IEEE Trans. Nuc. Sci.

Elimination of Image Blurring due to Double Scatter Events in γ Imaging Detectors. D. Ortendahl, K.C. Tam, V. Perez-Mendez and C.B. Lim. LBL-6436 (Oct 1977). To be published IEEE Trans. Nuc. Sci. NS-25 (1978)

Three Dimensional Reconstruction in Planar Positron Cameras Using Filtered Fourier Deconvolution. K.C. Tam, G. Chu and V. Perez-Mendez - LBL 6781 (Oct 1977) To be published in Medical Informatics.

A Pressurized Multiwire Proportional Chamber for Neutron Imaging. B. Director, S.N. Kaplan and V. Perez-Mendez. LBL 6779 (Oct 1977) To be published IEEE Trans. Nuc. Sci. NS-25 (1978)

Dennis R. Gonzales, M.S.

Specialty: Nuclear Physics

Present Position: Health Physicist/Radiation Safety Officer

Education:

1970	B.S. -Physics, Math	California State Polytechnic University Pomona Campus, Pomona, California
1975	M.S. - Nuclear Physics	San Francisco State University San Francisco, California
1977	2 years Ph.D. work in Nuclear Engineering	University of California, Berkeley Berkeley, California

Training and Appointments:

1969-1970	Physics Laboratory Instructor, Undergraduate Physics California State Polytechnic University Pomona Campus
1970-1971	Assistant Leader, Sixth U.S. Army Radiological Monitoring Team Presidio of San Francisco
1971-1973	Leader, Sixth U.S. Army Radiological Monitoring Team Presidio of San Francisco
Sept., 1972	Nuclear Emergency Training Exercise, Training Course Kirkland AFB, New Mexico
1973-1975	Teaching Assistant and Laboratory Instructor, Undergraduate Physics San Francisco State University
1976	Radiation Safety Officer, V.A. Hospital San Francisco, California

Publications:

D.R. Gonzales, Radiation Safety, Chapter 15
Nuclear Medicine Physics, Instrumentation and Agents
C.V. Mosby, St. Louis, Mo. 1977

Isotopes Supervised:

H-3, C-14, P-32, S-35, Ca-45, Cl-36, Co-57, Co-60, Cr-51, Cs-137, Fe-59
Ga-67, I-123, I-125, I-131, Rb-86, Sr-89, Tc-99M, and Xe-133

RADIATION SAFETY MANUAL

Veterans Administration Hospital
4150 Clement Street
San Francisco, California 94121

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I. ISOTOPE COMMITTEE APPROVAL PROCEDURES

- A. Section 35.11 (b) of Title 10. Code of Federal Regulations (10CFR), requires that an Isotope Committee be established to supervise the use of all radioisotopes within an institution governed by a broad medical license issued by the U.S. Nuclear Regulatory Commission (NRC). This committee is invested with the authority to review and approve all radioisotope utilizing work performed at this institution. Prior approval must be obtained before an investigator can begin work involving a radioisotope. Non-V.A. investigators working at this institution are not exempt from this local requirement.
- B. In order to obtain approval for a proposed study, an investigator must,
 1. Establish written or verbal contact with the Chairman of the Isotope Committee.
 2. Establish contact with the Radiation Safety Officer to insure that his intended study does not violate any provisions of the institutional license.
 3. Submit in eight copies a written research protocol providing all the information as required by appendix A of this document.
- C. Approval will be granted for a maximum period of two years. Application for continuation of the study beyond the approved period must include,
 1. A report of findings already obtained.
 2. Justification for the continuation of the study.
 3. A detailed protocol giving all the information necessary to an application for a new study (and, in addition, specifying changes in the original protocol with an explanation of the reason for such changes).

Such an application for continuation is evaluated by the Isotope Committee in the same manner as an application for new study. The Committee may request any additional supporting information it deems necessary to such an evaluation. The Committee, when it approves the continuation of a study, sets limits as to the duration and in the number of subjects to be studied.

- D. Criteria for evaluating the qualifications of a prospective user of radioisotopes. The Committee will consider the following factors in its evaluation of individual proposing to use radioisotopes in humans:

1. Training

- a. Basic aspects: radiation physics, radiobiology, instrumentation, principles of tracer methodology.
- b. Clinical: preferable in uses closely related to the proposed use. The number and type of clinical isotope procedures or treatments, the extent of participation, dates, institutions, and preceptors should be furnished.

2. Experience

- a. A summary of clinical experience in regard to diagnostic and therapeutic applications of radioisotopes.
- b. A selected bibliography and summary of research experience in the same use or related to the type proposed. (For non-human uses, items 1a. and 2b. will be considered.)

II. LEGAL EXPOSURE LIMITATIONS AND POSTING REQUIREMENTS

A. Radiation Dose Units: There are three commonly used units in Radiation Safety:

1. The roentgen (R, formerly r) is a unit of radiation exposure for x- and gamma radiation. It measures the amount of ionization produced by photon radiation in a given sample of air at standard temperature and pressure. It is defined as being 1 esu of ions of either sign produced by the above radiation in 0.01293 gram of air at standard temperature and pressure. The roentgen measures total radiation exposure to penetrating radiation. Total exposure is the product of the exposure rate times the period of exposure.
2. The rad (radiation absorbed dose) is a measure of local energy deposition per unit mass of absorber by ionizing radiation. The rad is applicable to all types of ionizing radiation, i.e., alpha, beta, and gamma. Local energy deposition in an absorber depends upon the amount of ionization occurring in the absorber for the type of radiation in question. The rad depends upon the type of radiation, type of absorber, and intensity of the radiation field.
3. The rem (roentgen equivalent man) is related to the rad as follows:

$$\# \text{ rem} = \text{RBE} \times (\# \text{ rad})$$

RBE (relative biological effectiveness) is tabulated for different types and energies of radiation. For beta and gamma radiation, the NRC has legally established that RBE = 1. Alpha emitters are rarely

used in a medical environment. RBE measures the relative effect that a given dose of radiation produces when compared to a standard dose of x- or gamma radiation in a living system.

- B. Each of the above units will be used in your daily work environment. Survey meters are calibrated in milliroentgens/hour (mR/hr). Personnel dosimetry reports are recorded in millirem. The millirad is the most commonly used quantity when calculating whole body and critical organ radiation doses. Make sure you know the difference between milli (m) and micro (μ) prefixes when used with the above units.

- C. Permissible Doses of Radiation Safety Workers. Title 10 of the Code of Federal Regulations has established specific legal exposure requirements which must be followed. There are two general methods by which a radiation worker's dose may be limited.

METHOD A: Accumulated doses for different parts of the body will be limited to the following:

1. Whole body, head and trunk, active blood forming organs, lens of eye or gonad--1.25 rem/calendar quarter.
2. Hands and forearm, feet and ankles--18.75 rem/calendar quarter.
3. Skin of the whole body--7.5 rem/calendar quarter.

A separate NRC Form 5 or the equivalent must be kept for each of the above three categories of exposure for each separate radiation worker.

METHOD B: A radiation worker may be exposed to a maximum whole body dose of 3 rem per calendar quarter provided his accumulated whole body exposure does not exceed,

$$\text{MPD} = (5\text{rem}) \times ([\text{Age in years}] - 18)$$

at the end of the year for which his MPD is calculated. This method places a 5 rem per year dose accumulation limit on one's whole body dose. Exposure under this method requires that NRC Form 4 or its equivalent be maintained for each radiation worker. A word of caution is in order. Age calculated MPD values are legally established dose guidelines. It is good safety practice to limit one's exposure to any hazardous compound to the smallest degree possible. It is good radiologic procedure to limit exposure to values well below the legal maximum.

- D. In addition to the above two methods for determining radiation exposure, there exist several exceptions to the above exposure guidelines. They are as follows:

1. Persons under the age of 18 years will not be allowed to receive doses in excess of 10% of those listed in Method A above.
 2. An emergency dose of 25 rem will not be counted against a radiation worker's MPD account. This emergency dose can occur only once in a person's lifetime and must be for the purpose of performing a lifesaving function.
 3. Pregnant women are restricted to a total dose of 0.5 rem for the period of gestation.
 4. Nonradiation workers (the general public) are restricted to a dose of 0.5 rem per year.
 5. Medical doses are not counted as part of a radiation worker's accumulated occupational dose.
- E. Radiation Areas: An Unrestricted Area is an area which does not have controlled access for the express purpose of protecting an individual from radiation exposure, whereas a Restricted Area does.

Controlled access is usually in the form of locked doors to labs and radioisotope storage areas, but may be as extreme as electronic alarms and special access procedures.

1. Permissible levels in Unrestricted Areas are as follows:
 - a. The maximum whole body dose to an individual in an unrestricted area cannot exceed 0.5 rem per year.
 - b. Additionally, one who uses radioactive byproduct material should not create radiation levels in excess of,
 - i. 2 millirem per hour for 1 hour of continuous exposure
 - ii. 100 millirem per seven consecutive days of continuous exposure.
 - c. Airborne and liquid effluent contamination levels for the purpose of radiation area determination are strictly controlled by the V.A. Hospital Isotope Committee in conformance with NRC rules and regulations regarding unrestricted areas.
2. Permissible levels in Restricted Areas are as follows:
 - a. There are two types of restricted areas.
 - i. A Radiation Area is defined as one where an individual would receive 5 millirem for one hour of continuous exposure, or 100 millirem for five consecutive working days.

ii. A High Radiation Area is one where an individual would receive greater than 100 millirem in one hour of continuous exposure.

b. It is possible that an intentional airborne radioisotope concentration may exist in a restricted area by virtue of performing a specific radioisotope procedure. Before performing such a procedure, consult the Radiation Safety Officer so that he can evaluate the procedure to ensure that the requirements of Section 20.203 (d) of 10CFR are not violated.

F. Posting of Signs and Notices:

1. The conventional three-bladed magenta symbol on a yellow background is used to designate all restricted areas.

a. A Radiation Area must have signs conspicuously posted bearing:

i. The standard radiation symbol

ii. The warning, " CAUTION
RADIATION AREA"

b. A High Radiation Area must have signs conspicuously posted at all access points to the area bearing:

i. The standard radiation symbol

ii. The warning, " CAUTION
HIGH RADIATION AREA"

2. In addition, high radiation areas must have positive access control to the radioactive area in accordance with section 20.203 (c) of 10CFR.

3. Airborne radioactivity areas must be properly posted. Consult the Radiation Safety Officer prior to performing any procedure which would possibly produce an airborne radioactivity area.

4. NRC Form 3 must be conspicuously posted in every radiation area. A notice specifying the institution radioisotope license number and permanent location must be posted on NRC Form 3.

5. Permanent radioisotope storage areas must have a sign posted bearing:

i. The standard radiation symbol

ii. The warning, " CAUTION
RADIOACTIVE MATERIALS"

When in doubt about the specific posting requirements for your work area, consult the Radiation Safety Officer prior to the commencement of any radioisotope procedure. Note that waste disposal containers for dry and liquid wastes must be properly marked as well as any contaminated piece of apparatus or work area.

III. ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

- A. Ordering Procedures: Due to affiliation of this institution with the University of California there must exist two mechanisms for keeping the Radiation Safety Officer aware of the incoming radioisotope shipments to this institution. For orders that are placed with non-V.A. funds, either a copy of the order must be sent to the Radiation Safety Officer, or, written notification with the equivalent information must be sent to the Radiation Safety Officer at the time that the order is placed with the non-V.A. procurement source.
- B. The Radiation Safety Officer is responsible for maintaining a master inventory of all radioactive material ordered by and delivered to this institution. Purchase orders originated by a principal investigator or his designee are routed to the Radiation Safety Officer (or, in the event of his absence, the Isotope Committee Chairman) for final approval before the placement of the order. If the Radiation Safety Officer determines that the person ordering the material has been approved by the Isotope Committee and the quantity ordered is within the permissible license allowance for that particular isotope, he approves the order and forwards it to the Research Administration Purchasing Office.
- C. If the material ordered does violate the provisions of the institutional license, The Radiation Safety Officer notifies the Chairman of the Isotope Committee and the individual who originated the order so that the order can be rescinded, or changed to comply with the institutional license.
- D. Incoming Shipments: All radioisotope shipments received at this station will be examined by personnel who are approved by the Radiation Safety Officer as qualified to receive and examine such shipments. The quantity, date of receipt and results of the reception wipe test will be recorded as prescribed by the Radiation Safety Officer. When a new shipment is received, the person receiving the shipment will:
 - 1. Visually inspect the package for any sign of damage, or visible sign of leakage of the contents. If such damage is noted, the receiving individual will immediately notify the Radiation Safety Officer.
 - 2. Measure the exposure rate at 3 feet from the surface of the package and record it on the Radioactive Shipment Receipt Report which must be forwarded within the same workday to the Radiation Safety Officer. C-14 and H-3 shipments are exempt from this survey requirement. This report will be used to double check on the procurement process for all isotopes delivered to this institution.

3. Measure surface exposure rate and record. If the 3 foot exposure rate is greater than 10 mR/hr, or the surface rate is greater than 200 mR/hr stop the inprocessing procedure and immediately notify the Radiation Safety Officer.
 4. Put gloves on and have the necessary personnel dosimetry devices on your person prior to opening the package.
 5. Open the outer package (following the manufacturer's directions, if supplied) and remove the packing slip. Open inner package to verify contents (compare requisition, packing slips and label on the bottle); check integrity of final source container (inspect for breakage of seals or vials, loss of fluid, discoloration of packing material).
 6. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay and record.
 7. Monitor the packing material and packages for contamination before discarding. If they are contaminated, dispose of as radioactive waste. If they are not contaminated, then obliterate labels before discarding in regular trash.
- E. If the shipment is delivered after hours, it will be delivered to the Boiler Room in Bldg. 13. The boiler room personnel will have the carrier place the package in a locked refrigerator and will log-in the shipment on a Isotope Receipt Verification form. The boiler room person will call the appropriate laboratory early the next work day and arrange for pick-up of the material. The receiving laboratory personnel will sign for the package picked-up. The Radiation Safety Officer will constantly monitor this process and change the receipt log on a weekly basis.

IV. LABORATORY USE OF RADIOISOTOPES

- A. Work Areas: Contamination control, laboratory procedures and exposure reduction: Contamination may be a hazard to health and may ruin a laboratory experiment. Careful techniques and strict laboratory discipline are the primary methods by which one can prevent contamination. The main health hazard arising from contamination is the risk of ingestion of a radionuclide. Ingestion can occur by means of open wounds, drinking, eating, and breathing contaminated air. The following rules are recommended as safety guidelines to be used in your laboratory.
1. Radiation work areas, radioisotope storage containers and apparatus must be properly marked and restricted from access and use by unauthorized personnel.

2. Always work with proper ventilation. All iodination procedures and work with possible airborne contaminants must be done in a properly operating fume hood.
3. Use nonpermeable absorbent paper to cover radioisotope work areas, absorbent side up.
4. Wear laboratory coats, or other protective clothing at all times, in areas where radioactive material is being used.
5. Wear disposable gloves at all times while handling radioactive materials.
6. Monitor hands and clothing for contamination after each procedure or before leaving a radioactive area.
7. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used. Never store food in a radioisotope storage refrigerator or location.
8. Use remote handling devices and vial shields whenever possible when handling multi-millicurie amounts of activity.
9. Wear personnel monitoring devices (film badges or TLD badges) when working with gamma emitters and high energy beta emitters. These should be worn at chest or waist level on the exterior of your clothing.
10. Personnel working with high energy beta emitters should wear TLD finger rings.
11. Confine radioactive solutions to covered containers plainly identified as radioactive, and label with the name of the compound, radionuclide, date, activity, and radiation level if applicable. Bulk storage of radioactive solutions should be in nonbreakable containers. Dispose of radioactive liquids in one designated "hot" sink.
12. Never pipette by mouth.
13. Always transport millicurie amounts of radioactive material in shielded containers.
14. No person with open wounds on his hands should be allowed to do any radioactive work.
15. Dispose of radioactive materials and contaminated waste according to the waste disposal procedures outlined in Section IX of this document.

- B. One can effectively reduce one's exposure to radioactive material by properly utilizing three environmental factors within his control: distance, shielding and time. Maintain maximum distance from, as short a time as necessary near, and sufficient shielding around any radioactive material you are utilizing. Remember, high and low density shielding must be used to screen radiation from beta emitting radionuclides. The Radiation Safety Officer will provide necessary shielding information for your storage areas and any other special requirements which you may have.
- C. Care of Radioactive Animals: All radioactive preparations and procedures involving the use of experimental animals will be performed in the principal investigator's approved radioisotope preparation area. All previously described radiation safety precautions and procedures will be observed.
- D. Radioactive animals will be caged either in the principal investigator's laboratory or in the Animal Care facility in Bldg. 12. The animals will remain in their cages until their excretions contain only background amounts of radioactivity, or until they are sacrificed. It is recommended that disposable cages be used for small experimental animals. Radioactive animals caged in V.A. Animal Care facility must be cared for by the principal investigator's designated radiation safety person. It is the personal responsibility of the principal investigator to insure that the Animal Care facility personnel are properly instructed in radiation safety procedures which are to be observed at all times. The caged animals are to be properly marked according to NRC regulations regarding radiation areas. Isotope type and amount should be indicated on each cage, in addition to the principal investigator's name and extension.
- E. Animal excreta will be collected and placed in two separately sealed 4 mil plastic bags which contain sufficient absorbent material to absorb all free liquids. All radioactive animal wastes will be disposed via the V.A. Hospital Waste Disposal Program.
- F. Animal cages will be lined with a nonpermeable bottom cover. Upon removal of the experimental animal, the cage will be decontaminated with detergent and scrub brushes. Heavy duty rubber gloves will be worn by decontamination personnel. Contaminated water will be flushed down the laboratory "hot" sink, or down the appropriate Animal Care floor drain. Sufficient water will be used to substantially dilute the flushed contaminated water.
- G. All decontamination equipment will be surveyed with a survey meter to insure that excessive contamination does not exist. The animal room and/or laboratory will be surveyed for excessive contamination upon the completion of the decontamination procedures. Facilities and equipment must conform to the NRC standards for Unrestricted Areas.

- H. The Animal Care room will remain locked unless attended by authorized personnel. All animal care areas involved in a radioisotope utilizing research project will be surveyed by the Radiation Safety Officer during his semiannual radiation safety inspection. Additional information regarding care of radioactive animals can be obtained from the Radiation Safety Officer.

V. PERSONNEL DOSIMETRY

- A. Personnel dosimetry is accomplished by the use of film badges supplied and processed monthly by an authorized commercial firm. Radiology Service handles the film badge service for the entire hospital. Master reports are maintained by Radiology service and the Radiation Safety Officer. In order to initiate film badge service for new personnel, submit name, date of birth, and social security number for each individual to the Radiation Safety Officer. He will update his radioisotope personnel roster and forward your request to radiology.
- B. The Radiation Safety Officer will review the monthly film badge reports and promptly inform the person and his supervisor of any excessive exposure (typically between 200-400 mrem/month). The film badge is used to measure whole body exposure according to Method B of Section II of this document.
- C. If additional dosimetry devices are needed (such as TLD finger rings) call the Radiation Safety Officer for additional assistance. If separate arrangement is made for additional personnel dosimetry devices, then permanently maintain all dosimetry reports as part of your radiation safety records.
- D. A final termination report should be prepared for each employee summarizing the total exposure as reported for each device which he has worn. This information is essential to update a new employer's exposure record for that individual. If you hire a new employee who has had previous radiation work experience, then you must contact the previous employer and request an exposure history for that individual.

VI. CONTAMINATION SURVEYS

- A. If you are using gamma or strong beta emitters (e.g., P-32, S-35) purchase a survey meter to monitor your laboratory. Maintain the calibration of the meter in accordance with the guidelines of Section VIII of this document. All preparation, elution and injection areas will be surveyed daily with a G.M. survey meter and decontaminated if necessary. For daily surveys where no abnormal exposures are found, the entry into your survey record will include the date, identification of the person performing the survey, and result of the survey (either negative or specific positive results).

- B. Laboratory areas where only small amounts of radioactive material are used (less than 100 microcurie) will be surveyed monthly. Other radioactive areas will be surveyed weekly. The weekly and monthly survey will consist of:
1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr. Labs utilizing only H-3 and/or C-14 are exempt from this requirement.
 2. A series of wipe tests will be performed to measure contamination levels in the work areas of your laboratory. The method for performing such tests will be sufficiently sensitive to detect 100 disintegrations per minute.
 3. A permanent record will be kept of all survey results, including negative results.
- C. The wipe test procedure will consist of the following steps:
1. Draw a diagram of your work area and assign numbers to the work areas, sinks, etc., where radioisotope contamination is likely to exist. The numbers on the diagram are to be entered as the location entry on the laboratory contamination log.
 2. Protect your hands with disposable gloves.
 3. Take two wipe tests per selected area; the first with a water dampened 2" x 2" gauze sponge followed by a toluene dampened 2" x 2" gauze sponge. The area wiped must be 100 square centimeters.
 4. The two sponges should be prepared for counting as follows:
 - a. Water dampened sponge: Using disposable gloves, squeeze out sponge into a counting vial. Add Aquasol (or other water holding liquid scintillation counting fluid) to a total of 15 ml. Water: Aquasol proportion for optimum counting should not exceed 1.3.
 - b. Toluene dampened sponge: Put sponge in a small funnel and wash 2-3 aliquots of toluene-based liquid scintillation counting fluid through it into a counting vial, again to a maximum of 15 ml.
 5. Count for the appropriate radionuclide. Compare the results to control samples prepared in the same manner with only background levels. Divide the counts per minute by the efficiency of your counting machine and express the result as disintegrations per minute (dpm)/100 cm², and record.

D. The Survey meter procedure will consist of the following:

1. Utilizing the diagram of the above procedure, select a site to be surveyed and slowly scan the selected site. Allow sufficient time for the survey meter to respond (it does not respond instantaneously to the radiation being measured).
2. Repeat this process for all the numbered sites in your diagram. Express the results of your survey in mR/hr and record.

E. Forms are provided in appendix H of this document to record the results of your survey. Your contamination survey record must include as a minimum the following information:

1. Location, date and person performing the survey.
2. Type of survey meter and/or counter used.
3. Drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
4. Measured exposure rates, keyed to locations on the drawing (point out rates that require corrective action).
5. Detected contamination levels as per wipe test results, keyed to locations on the drawing.
6. Corrective action taken in case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

If any area has greater than 100 dpm/100 cm², it must be decontaminated.

VII. CLINICAL USES OF RADIOISOTOPES

- A. The isotope content specified by the supplier is not accepted without question. Patient doses will be assayed to an accuracy of 10% in a dose calibrator. All multi-millicurie doses are best left in the original shipping container. Each millicurie dose is assayed by the following procedure: In the case of therapeutic doses of I-131 and P-32, an aliquot is assayed in the Nuclear Medicine dose calibrator. After the dose is administered, disposal is carried out according to the waste disposal guidelines of this document. For intravenous administration of therapeutic doses, sterile lead shields are used in holding the syringe for dose preparation and administration. Plastic gloves should be worn to prevent contact contamination. All needles, syringes, and gloves are disposable and are disposed of in the radioactive waste receptacle.
- B. In the dilution, preparation and handling of therapy doses, the patient's dose bottle is first prepared. The required amount of

liquid is remotely pipetted. Solutions are made up to volume with a remote filling flask and capped remotely. No more than three doses are carried by one person. Handling and rinsing of the dose bottles at the bedside is done with tongs. The patient drinks the isotope through a straw; both the bottle and straw are returned to Nuclear Medicine for disposal in the radioactive waste container.

C. Procedures for the use of Group IV and V radiopharmaceuticals for the treatment of patients consist of the following:

1. All patients treated with I-131 will be placed in a private room with a toilet.
2. The patient's room will be properly posted in accordance with Section 20.203 of Title 10 of the Code of Federal Regulations.
3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treated dose. Exposure rates will be measured at the patient's bedside, three feet away and the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times in the patient's chart and on his door. The results of daily surveys will be used to recalculate maximum permitted exposure times which will be posted on the patient's chart and on his door.
4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, or Iodine-131 will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.
5. Radiation levels in unrestricted areas will be maintained at less than the limits specified in Section 20.105 (b), 10CFR Part 20.
6. All linens will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held for decay.
7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designee) checked for contamination, and disposed of as normal or radioactive waste as appropriate.
8. Nondisposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay or decontaminated, as appropriate.

9. Urine and vomitus, from iodine-131 therapy patients will be stored for decay in our radioactive waste storage area. When it has reached background levels as measured with a low-level survey meter, it will be released to the sanitary sewer system.
 10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination (and decontaminated if necessary) and all radioactive waste and waste containers will be removed.
- D. Specific nursing instructions as outlined in appendix C will be separately distributed to all nursing personnel.
- E. Housekeeping personnel will be instructed never to handle any potentially radioactive substance or object. Radioactive waste disposal receptacles are not to be removed or emptied by janitorial personnel. Supply personnel should inspect incoming isotope packages for obvious damage. If such damage exists, they should have the freight carrier wait and immediately notify the Radiation Safety Officer. Supply personnel should never open isotope shipments and should use disposable gloves when handling such shipments. Personnel who ask for work to be done on laboratory facilities which may possibly be contaminated should contact the Radiation Safety Officer prior to having work begin. He will survey the work site and allow work to proceed only if contamination levels are less than 0.1 mR/hr (or, wipe test results are negative). (See Appendix D)

VIII. INSTRUMENTATION CALIBRATION

- A. This institution requires that all laboratories which utilize survey meters to maintain the calibration in accordance with the NRC standards for instrument calibration. This procedure must be done every six months and records maintained therefore.
- B. Survey meter calibration will consist of the following requirements:
1. Calibration sources shall be approximate point sources with activities traceable within $\pm 5\%$ to the U.S. Bureau of Standards (N. 3).
 2. Calibration shall be done semi-annually.
 3. Each scale of the instrument shall be calibrated at approximately $1/3$ and $2/3$ of FULL scale.
 4. The measured exposure rate will differ from the true exposure rate by less than 10% of FULL scale. Readings within $\pm 20\%$ will be considered acceptable if a calibration chart is prepared and attached to the instrument.

5. CS-137 and RA-226 sources are available for calibration purposes. A long-lived source capable of calibrating your meter on all ranges up to 1R/hr should be used.
6. A long half-life check source, e.g. CS-137 shall be read immediately after calibration. Using the same geometry as the post-calibration reading, the check source should be tested:
 - a. Before each use.
 - b. After each maintenance and/or battery change.
 - c. And, at least quarterly.
7. A check source reading not within $\pm 20\%$ of the post-calibration value requires recalibration of the survey meter.
8. Energy dependent meters need to be specifically calibrated for low energy radiation detection (i.e., for Tc-99m, Xe-133, I-125, etc.).
9. Records must be kept of items 1-4, 6(b) and 7 above (see appendix E).

Contact the Radiation Safety Officer for specific calibration instructions and assistance.

C. Calibration of a dose calibrator is a very complex process. Specific instructions can be obtained from the Radiation Safety Officer. The instrument must be checked for the following:

1. Instrument linearity (quarterly).
2. Geometrical variation (Initial installation).
3. Instrument accuracy (Initial installation and annually).

In addition, to the above requirements, daily reference checks of a long-lived source yielding a reading accuracy of $\pm 5\%$ is required. Variation greater than $\pm 5\%$ dictates that recalibration is necessary. Records are required for all of the above dose calibrator checks and tests.

Other radiation detection equipment should be calibrated annually according to the manufacturer's instructions. Sound laboratory practice dictates that instrument accuracy be maintained.

IX. RADIOACTIVE WASTE DISPOSAL

- A. No radioactive waste will be disposed of by conventional trash disposal methods. All potentially contaminated materials are considered radioactive until and unless a survey by the Radiation

Safety Officer or his designee reveals that contamination levels are less than 0.1 mR/hr as measured with a G.M. survey meter (low energy beta contaminants will be wipe tested). The only radiation related wastes that will be allowed to be disposed of by conventional means are shipping containers which have been tested and found to be free of contamination. Destroy all radiation symbol markings on shipping containers which are disposed of in normal trash.

- B. Insure that all liquid and solid wastes are kept in separate disposal containers. Label all waste with the words, "CAUTION RADIOACTIVE MATERIAL." For dry waste in step-on cans, instruct the janitor not to remove or empty these cans. All waste disposal containers should be placed on nonpermeable, absorbent paper which should be regularly changed and disposed of with each periodic disposal at the main hospital radioactive waste disposal site (Room 10, Bldg. 6). Provide 4 mil plastic bag liners for the step-on cans or other appropriate waste containers. Remove the plastic bag before it is full, seal the neck, label appropriately and remove to the main disposal site according to the next scheduled reception date as scheduled by the Radiation Safety Officer. Never allow waste levels to build up to a point where dangerous exposure levels may exist in your laboratory. All activity that is removed from your laboratory must be logged in your waste disposal log.
- C. INCINERATION OF RADIOACTIVE WASTE IS PROPHIBITED. Never incinerate any radioactive animal carcass: Keep it frozen until the date it is picked up. Other biological wastes including the contents of cages (shavings, FOOD, ETC.) must be double bagged, labeled and kept frozen until the Radiation Safety Officer arranges for the disposal by the commercial contractor. Human excreta containing radioactivity may be disposed of via the hospital sewer system.
- D. If liquid wastes are stored temporarily in glass containers, the container should be placed in a deep tray such that if the container should break, the contamination is confined to a small area. Liquid waste containers should be tightly capped, and plainly marked as radioactive. The only acceptable method of disposal at the main hospital disposal site for liquids is to have all free liquids totally absorbed in non-breakable containers filled with diatomaceous earth. Pre-filled carboys are provided by the Radiation Safety Officer for this purpose. Scintillation vials may be placed in plastic bags to which enough absorbent is placed which will absorb all the free liquids contained in the vials.
- E. Liquid waste may also be disposed of by flushing down the hospital sewage system via your "hot" sink. Appendix G describes the maximum permissible concentrations that will be allowed by this method. The NRC has established that an annual maximum of one (1) curie of activity may be disposed of in this manner for the entire hospital. Calculate the number of microcuries of any isotopes which are put into your "hot" sink from experimental recovery data. Do this

for representative procedures which give an overall picture of your work. Express these results on a monthly basis and record in your disposal log. From this data the Radiation Safety Officer will establish individual laboratory disposal limits and keep each investigator informed of these limits, and will make disposal limit alterations as necessary.

- F. Xenon-133 is the only radioactive gas that is permitted to be used at this institution. Specific guidelines for the disposal thereof are covered in a separate document to the institutional license. The Radiation Safety Officer will provide any information regarding this procedure.

X. RECORDKEEPING REQUIREMENTS

- A. The principal investigator is responsible for the proper maintenance of the necessary radioisotope records as prescribed by the Radiation Safety Officer. He should either personally maintain these records or appoint a responsible radiation safety person to act as a records custodian. The records custodian receives and documents all isotope shipments, labels and records all radioactive waste disposals made at the main hospital radioactive waste disposal site, and maintains all the required personnel dosimetry and instrument calibration documentation.
- B. Recordkeeping is a mandatory requirement of the law. Do not put off learning what is required of you. Your research project could be terminated if your records are not kept or are incomplete. Provide a single three-ringed binder for your records. Keep it in a central place so that it is readily accessible to the Radiation Safety Officer and/or NRC inspector.
- C. You are expected to maintain the records as provided in appendix H of this document or their equivalent according to the following schedule:
 - 1. Work Area Diagram--upon initial set-up of the lab and after any changes in the physical configuration of the lab.
 - 2. Isotope Receipt Verification--upon receipt of each shipment.
 - 3. Receipt and Usage--used on a daily basis to aid in bookkeeping of activity amounts used for all isotopes drawn from bulk quantity vials.
 - 4. Waste Disposal Log--Upon the removal of any radioactive waste from your laboratory.
 - 5. Bioassay Record--Monthly or as prescribed by the Radiation Safety Officer during his semiannual inspections.

6. Contamination Log--as prescribed under the guidelines for radiation surveys in Section VI of this document.

7. Instrument Calibration Records--as prescribed in Section VIII of this document.

D. Any additional information regarding the use of these forms will be provided by the Radiation Safety Officer at ext 461.

XI. RADIATION SAFETY EDUCATIONAL RESPONSIBILITIES

A. Personal

1. It is the personal responsibility of every person working with radioactive material to know as a minimum the following information:

- a. Symbol and mass numbers of the radioisotopes utilized.
- b. Type of emission from both the parent and daughter nuclides.
- c. Proper activity amounts to be used in all phases of a given research study.
- d. Half-lives of the radioisotopes used.
- e. Expected exposure and dose rate for a given procedure.

B. Laboratory Chief

1. The principal investigator has the responsibility of insuring that the personnel are familiar with Parts 19 and 20 of Title 10 of the Code of Federal Regulations which govern the rights and responsibilities of radiation workers. Draw the attention of your personnel to NRC Form 3 and associated information posted on your bulletin board. Train your personnel in the principles and practice of radiologic health and safety, radioactive measurement and monitoring, and the biologic effect of radiation. You should provide reference sources which discuss basic nuclear and health physics (National Bureau of Standards publications are excellent for this purpose). New personnel should be immediately instructed on specific laboratory procedures to be observed at all times.

C. Radiation Safety Officer

1. The Radiation Safety Officer will conduct lectures and discussions with laboratory groups regarding all aspects of radiation safety and basic nuclear physics. Prepared slide/tape programs entitled "Concepts of Ionizing Radiation," and "Prenatal

Radiation Exposure" are available on a checkout basis from the Radiation Safety Officer for viewing your laboratory group's convenience. See appendix I for other specific duties and responsibilities of the Radiation Safety Officer regarding safety education.

XII. EMERGENCY PROCEDURES

- A. Personnel Decontamination. Special techniques have been developed for the removal of contamination from skin, hair, etc. These methods require experience and expertise not normally possessed by most laboratory personnel. Whenever personnel contamination occurs, the Radiation Safety Officer must be immediately notified at ext. 461.

Personnel who have been externally contaminated should observe the following precautions and guidelines:

1. Make a quick survey of exposed skin, hair and clothing with a G.M. survey meter to localize all hot spots.
2. Remove contaminated clothing and place in plastic bags for further decontamination and safekeeping.
3. Beginning with the "hottest" spots wash the contaminated areas paying particular attention to prevention of the spread of the external contamination. Keep radioactive materials out of eyes, nose and mouth.
4. Dry thoroughly and resurvey.
5. If contamination still exists, then attempt to remove it by a second washing.
6. Further removal of contamination should only be done under the supervision of the Radiation Safety Officer.
7. Bandages may be used to cover the contamination site to prevent further spread until the Radiation Safety Officer arrives.

A few precautionary measures should be observed when washing. Excessive scrubbing of the body should be avoided. Never, by any means, continue decontamination efforts if the skin begins to thin or redden. Warm water is recommended. Hot water increases the circulation to the contaminated area and enhances the absorption of the radioactivity into the bloodstream. Minor cuts should be encouraged to bleed, but major wounds should be treated medically before any decontamination efforts are begun.

If the above procedures are not effective in reducing the contamination levels, or internal contamination is suspected, the Radiation Safety Officer will contact Nuclear Medicine Service for further medical assistance.

The Radiation Safety Officer will personally maintain control of all contaminated personal effects and release or dispose of them whichever is appropriate.

A record of the decontamination procedures, results of decontamination, personnel involved, and facts surrounding the incident must be prepared by the principal investigator and submitted to the Radiation Safety Officer within 24 hours of any personnel contamination incident.

B. Equipment and Facilities Contamination

Minor Contamination Incidents:

1. NOTIFY: Notify personnel in the area that a given area has been contaminated.
2. PREVENT THE SPREAD: If the contamination is liquid or spreadable, cover the contamination 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. Dispose of all other contaminated materials such as disposable gloves and aprons.
4. SURVEY: With a G.M. survey meter, check the area around the contamination site, and your hands and clothing. If the area is still contaminated, decontaminate using the appropriate detergents, reagents and solvents necessary.
5. REPORT: Telephonically inform the Radiation Safety Officer at ext. 461 and follow up by submitting a written report specifying nature and amount of contamination, personnel involved, and procedures utilized during decontamination and survey.

C. Facilities and Equipment Contamination

Major Contamination Incidents:

1. CLEAR THE AREA: Immediately notify all personnel in the area to vacate in an orderly manner.
2. PREVENT THE SPREAD: Cover liquid, or spreadable contamination with absorbent paper, 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 contamination site should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. SECURE THE AREA: Insure that all personnel have vacated the contaminated area and lock all doors. Insure that all access points to the contaminated area are either locked or manned by personnel to prevent access to unauthorized personnel.
5. CALL FOR HELP: Notify the Radiation Safety Officer at ext. 461 immediately upon securing the area or before if possible.
6. PERSONNEL DECONTAMINATION: Begin removing contaminated clothing and personal effects taking precautions to prevent the additional spread of contamination. Place the contaminated articles in plastic bags, mark and seal them. Hold the contaminated articles for further evaluation by the Radiation Safety Officer. Survey the total exterior of the contaminated person to locate external contamination sites. Decontaminate personnel using the previously described decontamination procedures. Arrange with the Radiation Safety Officer to have bioassays performed on all personnel who may have had internal exposure such as those performing iodination procedures.
7. REPORT: Prepare a detailed report specifying nature and amount of contamination, all personnel involved (include both contaminated and noncontaminated personnel in the contamination area), specify the exposure times for all personnel involved and approximate distance from the contamination site, and provide an accurate narrative account of all events surrounding the incident. Submit this report within 24 hours of the incident.

Appendix Listings

- A. Protocol requirements for Isotope Committee
- B. Radioactive Shipment Receipt Report.
- C. Instructions to Nursing Personnel
- D. Instructions to nonradiation Hospital Personnel
- E. Survey Meter Calibration Forms.
- F. Sealed Source Leak Testing Procedures
- G. Liquid Waste Disposal Via The Hospital Sewage System
- H. Recordkeeping Forms:
 - 1. Work Area Diagram
 - 2. Isotope Receipt Verification
 - 3. Daily Receipt and Usage
 - 4. Waste Disposal Log
 - 5. Contamination Log
 - 6. Bioassay Log
- I. Responsibilities of the Radiation Safety Officer

PROTOCOL REQUIREMENTS

ANIMAL:

1. Title of the study and statement of the purpose of the study.
2. List of personnel involved in the study.
3. List of radioisotopes to be used, chemical form and anticipated quantities to be kept on hand.
4. If animals are to be used,
 - a. Species
 - b. Number (per week or month; and total no. per study)
 - c. Total activity administered per animal and chemical form of dose.
 - d. Estimated duration of survival of animals containing radioactivity.
5. List of all locations where radioisotope work is to be performed, and information describing precautions to be taken for the protection of all personnel (including animal caretakers and housekeeping and non-radiation workers) against unwarranted radiation exposure.
6. A detailed description of the training and experience in the handling of radioactive material of all personnel involved in the study.

HUMAN USE:

1. Title of the study.
2. Names and titles of principal investigator and others assisting in the study.
3. Statement of propose.
4. Rationale and justification for the study, including background information and data from previous animal studies by the investigators, or from other laboratories.
5. The number of patients/subjects involved in the study, their ages, sex and clinical diagnosis before administration of the radio-pharmaceutical.
6. Number and type of human subjects to be studied. Include age, sex, method of selection, and medical conditions which would preclude their participation in the study. Include justification for use of normal subjects.

7. Activity dose, route and rate of administration, specific activity, and chemical form of radioisotope administered must be given in addition to the rationale behind selection of the proposed dose.
8. The dosage schedule used and complementary drugs, if any, must be listed.
9. The method of handling special problems, such as disposal of excreta, care of radioactive animals in the animal care facility, radioactive contamination, spillage monitoring and precautions to be taken in guarding all hospital personnel and technicians against excessive radiation exposure.
10. List of instrumentation used for radiation detection and counting.
11. Calculation of the expected radiation dose to the whole body and to primary and secondary critical organs. Include rationale behind these estimates and published data used in regard to distribution and biological half-lives.
12. Statement indicating that the subjects or responsible relatives will be informed of the nature and purpose of the study. Informed, written consent must be obtained prior to placing the subject in the study.
13. A copy of the Consent Form(s).
14. A complete and detailed description of the training and experience of the investigators and assistants in regard to the use of the radioactive material.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. # _____ SURVEY DATE _____ TIME _____
SURVEYOR _____
2. CONDITION OF PACKAGE:
_____ O.K. _____ PUNCTURED _____ STATUS _____ WET
_____ CRUSHED _____ OTHER _____
3. RADIATION UNITS OF LABEL: _____ UNITS (mR/hr)
4. MEASURED RADIATION LEVELS: a. Package surface _____ mR/hr
b. 3' from surface _____ mR/hr
5. DO PACKING SLIP AND VIAL CONTENTS AGREE?
a. Radionuclide _____ yes _____ no; difference _____
b. Amount _____ yes _____ no; difference _____
c. Chem Form _____ yes _____ no; difference _____
6. WIPE RESULTS FROM: a. Outer _____ CPM = _____ PM
eff = ()
b. Final source container _____ CPM = _____ DPM
eff = ()
7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CPM
8. DISPOSITION OF PACKAGE AFTER INSPECTION _____
9. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE AND PERSONS NOTIFIED.

NURSING INSTRUCTIONS

- A. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precautions sheet in the patient's chart. Nurses should read these instructions before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients.
- B. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precautions sheet in the patient's chart.
- C. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.
- D. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
- E. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.
- F. Attending personnel must wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- G. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Nuclear Medicine Department for proper disposal of the contents of the designated waste container.
- H. All clothes and bed liners used by the patient should be placed in the laundry bag provided and left in the patient's room to be checked by a member of the Nuclear Medicine Department.
- I. All non-disposable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.
- J. Surgical dressings should be changed only as directed by physician. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Nuclear Medicine Department. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

K. For iodine-131 patients:

1. Urine from iodine-131 patients will be collected in special containers provided by the Nuclear Medicine Department. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.
 2. If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards she should wash her hands with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Nuclear Medicine Department.
 3. Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.
 4. Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Nuclear Medicine Department at Ext. 461. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.
 5. All vomitus must also be kept in the patient's room for disposal by the Nuclear Medicine Department. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).
- L. Utmost precautions must be taken to see that no urine or vomitus, is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Nuclear Medicine Department.
- M. If a nurse, attendant or anyone else knows or suspects that his skin, or clothing, including shoes, is contaminated, notify the Nuclear Medicine Department immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.
- N. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately.
- O. When the patient is discharged call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

Date: _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32 or IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration _____

Exposure Rates in mR/hr

Date _____ 3 feet from bed _____ 10 feet from bed _____

(Comply with all Check Items)

____ 1. Visiting time permitted: _____

____ 2. Visitors must remain _____ from patient.

____ 3. Patient may not leave room.

____ 4. Visitors under 18 not permitted.

____ 5. Pregnant visitors not permitted.

____ 6. Film badges must be worn.

____ 7. Use and complete the following tags:

____ door

____ bed

____ chart

____ wrist

- ____ 8. Gloves must be worn while attending patient.
- ____ 9. Patient must use disposable utensils.
- ____ 10. All items must remain in room until ok'd by Radiation Safety.
- ____ 11. Smoking is not permitted.
- ____ 12. Do not release room to admitting until ok'd by Radiation Safety.
- ____ 13. Other instructions.

In case of an emergency contact:

RSO _____
Name

On/Off duty telephone number

INSTRUCTIONS TO NONRADIATION PERSONNEL

Be constantly aware of those situations which may make it necessary to work near radioactive facilities and equipment. When in doubt about the "Cleanliness" of a work site or object, first seek advice from the appropriate laboratory radiation safety person. If your questions are not answered to your satisfaction, contact the Radiation Safety Officer for further clarification or assistance at ext 461.

SUPPLY PERSONNEL:

1. All incoming shipments should be visually examined for signs of damage and leakage. If such damage is noted, have the delivery carrier wait and call the Radiation Safety Officer for further evaluation of possible contamination.
2. All radioactive shipments should be placed in a properly marked radioactive materials holding area.
3. Never open a radioactive shipment package. Have the appropriate laboratory radiation safety person retrieve packing slips contained within the package.
4. It is recommended disposable plastic gloves be worn when handling radioactive shipments.
5. When working with radioactive shipments, wash your hands before eating during breaks, etc., and at the end of each workday.

HOUSEKEEPING PERSONNEL:

1. Never remove or empty trash containers that are marked with radiation warning labels.
2. Do not clean areas in a laboratory plainly marked as being radioactive.
3. Plumbing personnel should have the proposed work site surveyed for radiation by the appropriate laboratory radiation safety person, prior to beginning work.
4. Plumbing personnel should wear heavy duty rubber gloves when working on "hot" sink plumbing.

INSTRUMENT CALIBRATION (QUARTERLY/EACH MAINTENANCE) YEAR: _____

MANUFACTURER'S NAME: _____

METER MODEL NUMBER: _____

SERIAL NUMBER: _____

DATE	RANGE	READING	SOURCE ACTIVITY	TYPE OF CALIBRATION

TYPE OF CALIBRATION: Quarterly

After Maintenance

After Battery Change

Use same geometry for all check source readings.

YEAR: _____

METER MODEL NUMBER: _____

SERIAL NUMBER: _____

Minimum range: _____ to _____ mr/hr

Maximum range: to mr/hr

Calibration source activity: _____ Tolerance: _____

NBS Traceable	Yes/No
---------------	--------

D = Probe to source Distance

[illegible]

SEALED SOURCE LEAK TESTING PROCEDURE

Sealed sources will be leak tested upon arrival from the manufacturer and quarterly thereafter. The Radiation Safety Officer will be responsible for all leak testing of sealed sources governed by the license of the institution.

Leak test procedure: The source shall be wiped with a soft tissue or a cotton swab, which shall be placed in a counting vial and counted in the appropriate counter. The count will be taken for a minimum of five (5) minutes. This count will be compared to a reference standard and absolute activity of the source will be determined taking into account the efficiency of the counting device. Activity under 0.005 microcuries will be detectable by this method. (A count rate corresponding to five times the background count will be considered significant.) The Radiation Safety Officer will record and maintain all leak testing records.

Limited quantities of H-3, C-14, P-32, S-35, CR-51, Fe-59, I-125 and I-131 may be disposed of via the hospital sewage system. Only compounds which are water soluble, or are readily dispersible in water are allowed to be disposed of in this manner. All radioactive sewage disposal must be logged in your waste disposal log. The concentration of any isotope disposed of in this manner must be less than the maximum permissible concentration (MPC) allowed for that isotope as listed on the attached table. For a mixture of isotopes, the sum of the individual concentrations expressed as a percentage of the respective MPC, may not exceed 100%. Only a limited amount of any isotope may be disposed of via the hospital sewage on any one day as specified in column 4 of the attached table. Anyone disposing of approximately the maximum amount in one day must inform the Radiation Safety Officer in advance. The Radiation Safety Officer will monitor your sewage disposals on a monthly basis to insure that the limitations as established by the NRC are not exceeded.

MPC's and maximum daily amounts for sewage disposal are;

<u>Isotope</u>	<u>Chem. form</u>	<u>MPC (microcurie/liter)</u>	<u>Max.Amt./day</u>
H-3	soluble	100	5000uCi
	insoluble	100	
C-14	soluble	20	500uCi
	insoluble	---	
P-32	soluble	0.5	50uCi
	insoluble	0.5	
S-35	soluble	2	50uCi
	insoluble	8	
CR-51	soluble	50	5000uCi
	insoluble	50	
FE-59	soluble	2	5uCi
	insoluble	2	
I-125	soluble	0.04	5uCi
	insoluble	6	
I-131	soluble	0.06	5uCi
	insoluble	2	

RADIATION SAFETY PROGRAM

LABORATORY _____ BLDG _____

DIAGRAM OF WORK AREA

Illustrate with a floor plan the principal work areas, storage areas, and waste disposal areas for radioisotopes in your laboratory. Assign numbers to the principal areas, for reference on the Laboratory Contamination Log.

THIS FORM IS DESIGNED TO BE SELF SUFFICIENT FOR THE COMPUTATION OF ALL ENTRIES.

When beginning this form for a new vial:

1. The Precalibration Factor (PF) is computed for the period P_0 between date (hour) of receipt and calibration date (hour). Compute Δ_0 for precalibration periods as follows:

$$\Delta_0 = P_0/T \text{ where } P_0 \text{ is as defined above.}$$

T is half-life of Isotope.

he precalibration factor is

$PF = 1/DF$ for DF values corresponding to $\Delta = \Delta_0$ values listed in table on right.
(Enter this value in item 1.)

Items 2 through 4 are left blank.

5. (Volume Remaining) = (Total Volume)
6. (Activity Remaining) = (Total Activity) x (Precalibration Factor)

Thereafter,

1. Decay Factor (DF) values for computed Δ values are listed in table on right. Let $\Delta = P/T$ where P is the period between the last entry in days (hours), and T is the half of listed isotope. For istopes with half lives less than 10 days, use hours for time calculations. Periods calculated in days can be simplified by using 5 digit dates on your log as computed from date table on right.

BE AS ACCURATE AS POSSIBLE

NOTE: 1 hr - 0.04167 day; 1 month = 30 days
1 year = 365.25 days

2. Volume Remaining of previous study
3. (DF) x (Activity Remaining of previous enry)
4. Volume drawn for dose administration
5. (2. above) - (4. above)
6. (Activity Remaining) = (Activity on Hand) x $\frac{\text{(Volume Remaining)}}{\text{(Volume on Hand)}}$

WHEN THE CONTENTS OF LISTED VIAL HAVE BEEN USED UP OR HAVE EXPIRED, DISPOSE OF VIAL VIA RADIO-ACTIVE WASTE DISPOSAL PROCEDURES AND TERMINATE THIS LOG SHEET, WITH ONE DIAGONAL LINE CROSS OUT UNUSED ENTRY LINES AND ENTER TERMINATION DATE ON THE DIAGONAL AND INITIAL.

DATE TABLE

1/31 = 031	7/ = 212	CORRECT FOR LEAP
2/28 = 059	8/31 = 243	YEARS BY ADDING
3/31 = 090	9/30 = 273	(1) TO ALL DATES
4/30 = 120	10/31 = 304	AFTER 2/28.
5/31 = 151	11/30 = 334	
6/30 = 181	12/31 = 365	

To compute a 5 digit date, find 3 digit No. for the last day of the previous month and add to it present monthly date, e.g.,
11/26/77 = 77(304+26) = 77330.

Δ	DF	Δ	DF
0.05	0.9659	1.55	0.3415
0.10	0.9330	1.60	0.3299
0.15	0.9013	1.65	0.3186
0.20	0.8706	1.70	0.3078
0.25	0.8409	1.75	0.2973
0.30	0.8123	1.80	0.2872
0.35	0.7846	1.85	0.2774
0.40	0.7579	1.90	0.2679
0.45	0.7320	1.95	0.2588
0.50	0.7071	2.00	0.2500
0.55	0.6830	2.05	0.2415
0.60	0.6598	2.10	0.2333
0.65	0.6373	2.15	0.2253
0.70	0.6156	2.20	0.2176
0.75	0.5946	2.25	0.2102
0.80	0.5743	2.30	0.2031
0.85	0.5548	2.35	0.1961
0.90	0.5359	2.40	0.1895
0.95	0.5176	2.45	0.1830
1.00	0.5000	2.50	0.1768
1.05	0.4830	2.55	0.1708
1.10	0.4665	2.60	0.1649
1.15	0.4506	2.65	0.1593
1.20	0.4353	2.70	0.1539
1.25	0.4204	2.75	0.1487
1.30	0.4061	2.80	0.1436
1.35	0.3923	2.85	0.1387
1.40	0.3789	2.90	0.1340
1.45	0.3660	2.95	0.1294
1.50	0.3536	3.00	0.1250

LOT LABEL

RADIATION SAFETY PROGRAM

LABORATORY _____ BLDG _____

WASTE DISPOSAL LOG

Estimate activity in microcuries (uCi) or millicuries (mCi). If the waste is disposed of via hospital sewage, list concentration in Column 4.

User or Room No.	Isotope	Acti- vity	Concen- tration	Date Removed	User or Room No.	Isotope	Acti- vity	Concen- tration	Date Removed
---------------------	---------	---------------	--------------------	-----------------	---------------------	---------	---------------	--------------------	-----------------

[illegible]

LABORATORY _____ BLDG _____

BIOASSAY LOG

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RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The Radiation Safety Officer is responsible for the overall radiation protection program for all users of radioisotopes as provided by the institutional license. His authority and responsibilities are as follows:

1. General surveillance over all radioisotope activities at this institution and will conduct semiannual surveys of all areas where radioactive material is utilized.
2. Furnish consulting services to personnel at all levels of responsibility on all aspects of radiation protection.
3. Monitor all receiving, delivering and shipping of radioactive material coming to or leaving this institution.
4. Assist in the establishment of personnel film badge service in conjunction with Radiology Service, monitor monthly exposure reports, notify individuals and their supervisors of exposures approaching maximum permissible levels, and recommending appropriate action.
5. Conducts an instructional program to keep radiation workers informed of the proper procedures for the use of radioactive material.
6. Supervision and coordination of the waste disposal program, including the keeping of waste storage records.
7. Storage of all radioactive material not currently in use.
8. Perform leak tests on all sealed sources.
9. Maintain a running inventory of all radioisotopes at this institution, and confirm it during his semiannual inspection.
10. The Radiation Safety Officer has the authority to immediately terminate work on any project which would be a threat to health or property. He is directly responsible to the Chairman of the Isotope Committee for any such action undertaken.

RADIATION DETECTION INSTRUMENTS
NUCLEAR MEDICINE

TYPE	MAKE	MODEL	NUMBER	RADIATION	RANGE	PURPOSE
Survey Meters	Victoreen	740-F	One	Alpha/Beta/Gamma	0 - 25 Mr/hr min 0 - 25,000 mR/hr max	Survey
	Victoreen	496	One	Beta/Gamma	0 - 500 CPM, min 0 - 500,000 CPM, max	Lab Alarm Monitor
	Picker-Nuclear	655-180	Two	Beta/Gamma	0 - 0.5 mR/hr, min 0 - 50 mR/hr, max	Survey
	Nuclear Chicago	9120	One	Gamma	0.02 - 200 mR/hr	Survey
Dose Calibrator	Picker	632-500	One	Gamma	0.1 - 1,000 mCi	Assay
Autofluorescent Scanner	Picker	2806F	One	Gamma	---	Diagnostic
Xenon Ventilation Delivery Systems	Radx	2000A/120	Two	Gamma	---	Diagnostic
Gamma Camera	Searle	7400 Pho-Gamma 1V	Two	Gamma	---	Diagnostic
Gamma Camera	Nuclear Chicago	6403 Pho-Gamma 111	One	Gamma	---	Diagnostic
Whole Body Scanner	Picker	1000	One	Gamma	---	Diagnostic
Whole Body Scanner	Diagnostics Electronics Corporation	PS-1	One	Gamma	---	Diagnostic
Dual Probe	Picker	2801	One	Gamma	---	Diagnostic

TYPE	MAKE	MODEL	NUMBER	RADIATION	RANGE	PURPOSE
Counter	Searle	1185	Two	Gamma	---	Assay
		1285	One	Gamma	---	Assay
	Packard "Tricarb"	B2450	One	Beta	---	Assay
Multichannel Analyzer	Picker "Spectron 100"	---	One	Gamma	---	Assay
	Canberra "Omega-1"	---	One	Gamma	---	Assay

CALIBRATION PROCEDURES AND SOURCES

1. Survey instruments will be calibrated at least annually and following repair.
2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within $\pm 10\%$ of the calculated or known values for each point checked. Readings within $\pm 20\%$ are considered acceptable if a calibration chart is prepared and attached to the instrument.
3. Survey instruments will be calibrated:
 - A. Initially by the manufacturer.
 - B. Thereafter, at this facility by the Radiation Safety Officer. Calibration sources to be used for this purpose are as follows:

Isotope Products Laboratory
Co-57 Gamma Reference Source
Model No. 231E
1.0 mCi @ $\pm 5\%$ accuracy
Traceable to NBS Standard

Isotope Products Laboratory
Co-60 Gamma Reference Source
Model No. 236E
0.05 mCi @ $\pm 5\%$ accuracy
Traceable to NBS Standard

Isotope Products Laboratory
Co-57 Gamma Reference Source
Model No. 231E
0.3 mCi @ $\pm 5\%$ accuracy
Traceable to NBS Standard

Isotope Products Laboratory
Cs-137 Gamma Reference Source
Model No. 229E
0.2 mCi @ $\pm 5\%$ accuracy
Traceable to NBS Standard

- C. Calibration procedures will be in accordance with Appendix D of the Nuclear Regulatory Commission Licensing Guide for Broad Medical Licenses.
4. Calibration of Dose Calibrator:
 - A. Sources used for linearity test will be a 50 mCi Tc-99m shipment from:

Medipysics
5801 Christie Avenue
Emeryville, Ca 94608
 - B. Sources used for instrument accuracy and constancy tests are the same as those listed for survey meter calibration purposes.
 - C. The procedures described in Appendix D, Section 2 of the U.S. Nuclear Regulatory Commission Licensing Guide for Broad Medical Licenses will be used for dose calibrator calibration.

WASTE DISPOSAL PROCEDURES

1. Liquid waste will be disposed of:
 - A. By Commercial waste disposal service.
 - B. In the sanitary sewer system in accordance with Section 20.303 of Title 10 of the Code of Federal Regulations.
2. Mo-99/Tc-99m generators will be returned to the manufacturer for disposal, or disposed of by commercial waste disposal service.
3. Other solid waste will be:
 - A. Held for decay until radiation levels as measured with a low level survey meter (with all shielding removed) have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.
 - B. Or, disposed of by commercial waste disposal service.
4. The commercial waste disposal service will be provided by:

Nuclear Engineering Company Inc.
Western Operations Headquarters
P.O. Box 156
San Ramon, Ca 94583
(415) 837-1561

NRC/Agreement State License No.'s:

Beatty, Nevada	13-11-0043-02
Richland, WA	13-10042-1 & WN-1019-2

NUCLEAR MEDICINE RESTRICTED AREAS

Nuclear Medicine Service maintains three basic types of restricted areas; a "hot" room, four clinical imaging rooms and a temporary holding area for radioactive waste.

1. "Hot" room: GB-64 is used as an isotope delivery room, permanent storage location, and patient dose preparation site. It contains a cold box for storage of microcurie samples which must remain refrigerated. A lead shielded refrigerator is used to store millicurie containers which require refrigeration. A fume hood is used to store all volatile radioactive compounds in addition to being a storage location for Iodine radioisotopes and Xe-133. A shielded area to the immediate right of the fume hood is used to hold millicurie vials and daily radioactive waste. To the immediate right of this area is a patient dose preparation area. In this area, the technician who prepares patient doses works behind a lead shield, prepares the dose and assays it in the dose calibrator to his immediate right. The preparation of a patient dose follows a logical progression from left to right.
2. Clinical imaging rooms: Rooms GB-60, 61, 62 and 54 are used to image all patients. Room GB-60 contains the Picker Dual Probe thyroid scanner and the Picker Whole Body Rectilinear Scanner. GB-61 and 62 both contain a Pho-Gamma IV imaging camera and associated consoles. GB-54 contains the autofluorescent scanner. All of the imaging rooms are restricted areas.
3. Radioactive waste holding room: GB-51 is a locked room which is used to temporarily hold daily waste removed from the "hot" room. It contains a steel cabinet into which the radioactive waste is placed. It also contains large lead pigs which are used to store the sealed sources for calibration of equipment. This room is surveyed weekly to insure that excessive radiation fields do not exist in accordance with NRC requirements for restricted areas. The radioactive waste in this room is removed on a weekly basis to the main hospital disposal site.

The restricted areas of Nuclear Medicine Service act as a model for all other restricted areas of the hospital. They are maintained in accordance with NRC standards. They are properly marked with the appropriate signs and notices. They serve as a basis upon which to judge the other user restricted areas.

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NUCLEAR MEDICINE SERVICE
VETERANS ADMINISTRATION HOSPITAL, SAN FRANCISCO

STANDARD OR ROUTINE DIAGNOSTIC AND THERAPEUTIC USES OF RADIOISOTOPIC AGENTS

<u>PROCEDURE</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM</u>	<u>DOSAGE RANGE (μCi)</u>	<u>ROUTE</u>
1. Thyroid Uptake	^{131}I	Iodide	3 - 10	p.o.
	^{123}I	Iodide	100 - 200	p.o.
	$^{99\text{m}}\text{Tc}$	Pertechnetate	1,000 - 2,000	i.v.
2. Thyroid Scan	^{131}I	Iodide	25 - 100	p.o.
	^{125}I	Iodide	25 - 100	p.o.
	^{123}I	Iodide	100 - 200	p.o.
	$^{99\text{m}}\text{Tc}$	Pertechnetate	1,000 - 2,000	i.v.
3. Survey for Metastatic Thyroid Carcinoma	^{131}I	Iodide	1,000 - 2,000	p.o.
4. Brain Imaging	$^{99\text{m}}\text{Tc}$	Glucuheptonate	20,000 - 25,000	i.v.
	$^{99\text{m}}\text{Tc}$	DTPA	20,000 - 25,000	i.v.

<u>PROCEDURE</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM</u>	<u>DOSAGE RANGE (μCi)</u>	<u>ROUTE</u>
5. Cysternography and CSF shunt function	^{131}I	Albumin	100 - 150	intrathecal
	$^{99\text{m}}\text{Tc}$	Albumin	1,000	intrathecal
6. Liver & Spleen Imaging	$^{99\text{m}}\text{Tc}$	Sulfur-Colloid	2,000 - 4,000	i.v.
7. Bone Marrow Imaging	^{99}Tc	Sulfur-Colloid	4,000 - 6,000	i.v.
8. Skeletal Imaging	$^{99\text{m}}\text{Tc}$	Polyphosphate	10,000 - 15,000	i.v.
	$^{99\text{m}}\text{Tc}$	Pyrophosphate	10,000 - 15,000	i.v.
	$^{99\text{m}}\text{Tc}$	Methylene Diphosphonate	10,000 - 15,000	i.v.
	$^{99\text{m}}\text{Tc}$	Hydroxyethyethene Diphosphonate	10,000 - 15,000	i.v.
	^{18}F	Fluoride	2,000 - 4,000	i.v.
	^{85}Sr	Strontium Nitrate	50 - 100	i.v.
9. Pancreas Imaging	^{75}Se	Selenite	250 - 350	i.v.
	^{75}Se	Selenomethionine	100 - 250	i.v.

<u>PROCEDURE</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM</u>	<u>DOSAGE RANGE (μCi)</u>	<u>ROUTE</u>
10. Lung (Perfusion) Imaging	^{99m}Tc	Macro-Albumin	2,000 - 4,000	i.v.
	^{131}I	Macro-Albumin	100 - 300	i.v.
11. Lung (Ventilation) Imaging	^{133}Xe	Xenon Gas	5,000 - 20,000	inhalation
12. Cardiac Blood Pool and Great Vessel Imaging	^{99m}Tc	Pertechnetate	10,000 - 15,000	i.v.
	^{99m}Tc	Albumin	5,000 - 15,000	i.v.
13. Salivary Gland Imaging	^{99m}Tc	Pertechnetate	5,000 - 15,000	i.v.
14. Joint Visualization	^{99m}Tc	Pertechnetate	5,000 - 15,000	i.v.
	^{99m}Tc	Pyrophosphate or -Diphosphonate	10,000 - 15,000	i.v.
15. Renal Imaging and Function Tests	^{131}I	Hippuran	50 - 100	i.v.
	^{203}Hg	Chlormerodrin	100 - 200	i.v.
	^{197}Hg	Chlormerodrin	100 - 200	i.v.
	^{99m}Tc	Pertechnetate	3,000 - 15,000	i.v.

<u>PROCEDURE</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM</u>	<u>DOSAGE RANGE</u> (μ Ci)	<u>ROUTE</u>
15. Renal Imaging and Function Tests (Cont'd)	^{99m}Tc	DTPA	3,000 - 10,000	i.v.
	^{99m}Tc	Glucuheptonate	5,000 - 15,000	i.v.
16. Tumor or Abscess Localization	^{67}Ga	Gallium Citrate	1,000 - 3,000	i.v.
	^{75}Se	Selenite	150 - 350	i.v.
17. Myocardial Imaging	^{81}Rb	Rubidium Chloride	1,000 - 2,000	i.v.
	^{201}Tl	Thallium Chloride	1,000 - 2,000	i.v.
	^{99m}Tc	Pyrophosphate	10,000 - 15,000	i.v.
18. Red Blood Cell Mass, Survival & Sequestration	^{51}Cr	Chromate	50 - 100	i.v.
19. Gastrointestinal Protein Loss	^{51}Cr	Chromate	10 - 50	i.v.
20. Plasma Volume	^{125}I	Albumin	2 - 7	i.v.
21. Iron Turnover	^{59}Fe	Ferric Chloride	10 - 35	i.v.
21a. Glycocholate	^{14}C	Glycocholic Acid	5 - 5	p.o.

<u>PROCEDURE</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM</u>	<u>DOSAGE RANGE (μCi)</u>	<u>ROUTE</u>
22. Vitamin B ₁₂	⁵⁷ Co	Cyanocobalamine	1 - 3	p.o.
23. Therapeutic Procedures For:			<u>DOSE (millicuries)</u>	
Hyperthyroidism	¹³¹ I	Iodide	3 - 15 mCi	p.o.
Thyroid Ablation	¹³¹ I	Iodide	30 - 100 mCi	p.o.
Metastatic Thyroid Cancer	¹³¹ I	Iodide	up to 200 mCi	p.o.
For:				
Polycythemia Vera	³² P	Phosphate (soluble)	3 - 7 mCi	i.v.
Lukemia	³² P	"	1 - 2 mCi	i.v.
Osseous Metastases	³² P	"	1 - 2 mCi	i.v.
Peritoneal or Pleural Metastases	³² P	Chromic Phosphate	1 - 5 mCi	intracavitary

USE of Xenon-133

The intended use of Xe-133 is for several types of diagnostic applications which differ sufficiently in procedure to require a separate description for each procedure. All applications involve human use with a in vivo administration of the isotope. Local approval for non-routine uses of Xe-133 is governed by the VA Hospital Isotope and Human Experimentation Committees.

- A. 1. The types of studies to be performed and the estimated number of patients per year per study are as follows:

Lung ventilation with intravenous administration	50	1-3 mCi
Lung ventilation with respiratory administration	150	15 mCi
Cerebral blood flow with intra-arterial administration	50	1-3 mCi
Cerebral blood flow with respiratory administration	150	15 mCi
	—	—
	400	4.80 Ci (max)

Based upon the maximum activity per patient and totaled for all studies, the average activity per patient is 12.0 mCi. Total usage per week is as follows:

$$4.80 \text{ Ci/year} \div (52 \text{ weeks/year}) = 93 \text{ mCi/week} \div 1 \times 10^5 \mu\text{Ci/week}$$

Weekly patient load and administered activity per patient will on an average be less than the maximum amounts upon which the concentration calculations are based. Therefore, current usage complies with the provisions of Section 20.1 (c) of T10 CFR Part 20.

2. The desired possession limit is 2 curies. Purchases are intended for 1 curie shipments. Storage is available for 2 curies.

- B. 1. Facilities available:

The lung and cerebral studies shall be performed in the Nuclear Medicine Area in Rooms GB61 and GB62 (see attached floor plan). No bedside procedures will be performed. The rooms in the Nuclear Medicine Area have thick concrete walls facing the exterior of the building, but have no special shielding from radiation. The Nuclear Medicine Area is a restricted area and is accessible only to Nuclear Medicine personnel, authorized medical personnel and by patients for the duration of their study. All studies will be performed in these restricted areas.

2. Xenon preparation and storage will be accomplished under the fume hood in GB64. A wall of 2" thick lead bricks are used in the fume hood to shield isotopes stored there. Room GB64 is under 40% negative pressure which is exhausted directly to the exterior (no recirculation). Ventilation ducts are shown on Figure 2. Rooms GB60 and GB61 maintain a 15% negative pressure and have a typical non-recirculation design exhaust ventilation rate of 840 CFM. Room GB62 is under a 15% negative pressure and has a non-recirculated exhaust ventilation rate of 865 CFM.

C. 1. Procedures employed in each type of study are as follows:

- a. A dose of 1-3 mCi of Xe-133, dissolved in saline with a concentration of approximately 2-5 mCi/ml, will be injected in the patient's antecubital vein. The patient is positioned in front of a scintillation camera for imaging. From the end of the injection the patient holds his breath for approximately 30 seconds, for data collection to measure regional blood flow. He exhales into a breathing mask which provides for collection of radioactivity without release to the atmosphere. He continues breathing with the mask for several minutes.
- b. A dose of about 15 mCi of gaseous Xe-133 is diffused in air within a closed system, 15 liters in volume. Through a breathing mask the patient breathes this atmosphere once, then holds his breath while an image is collected with a scintillation camera, for measurement of region ventilation within the lungs. This is followed by continuous rebreathing for 4-5 minutes, after which the patient again holds his breath for collection of an image, for measurement of regional ventilation in the alveolar space within the lungs. Finally, the patient continues breathing with the mask, inhaling non-radioactive air, and exhaling into a Xenon collection system for several minutes, removing more than 95% of the radioactivity from the patient.
- c. A dose of about 1-3 mCi of Xe-133 is injected in the carotid artery as a bolus. Probes about the head collect data for measurement of regional blood flow. The patient exhales for 10 minutes into a Xenon collection system to remove radioactivity from his body.
- d. A dose of about 15 mCi of gaseous Xe-133 is diffused in air within a closed system. After 5 minutes of rebreathing, the patient begins to inhale room air, exhaling into the Xenon collection system for 10 minutes. After rebreathing is stopped, activity previously absorbed in the extravascular space within the cerebrum freely diffuses back into the bloodstream. This washout of the activity is monitored by an array of external probes.

2. Special Apparatus:

Injectons of Xe-133 dissolved in saline are drawn from commercially-supplied vials for all applicable studies (a,c). Respiratory adminis-

tration of gaseous Xe-133 is performed with equipment supplied by Radx Corporation. This equipment consists of:

- a. A "Xenon Kow", for storage of up to 3 curie of gaseous Xenon at atmospheric pressures.
- b. A gas delivery system, containing the volume of air used for rebreathing, a spirometer for monitoring system response to breathing, a pump for maintaining flow and uniform mixing, and filters for bacteria (inlet) and CO₂ (outlet).
- c. A Xenon trap, connected through a hose and "expandable interface" to collect the activity and prevent its release to the atmosphere. The trap consists of activated charcoal preceded by a desiccant, and is supplied by a separate pump to give a flow of 7-9 liters/minute. The "expandable interface" is an unshielded plastic bag, to act as a gas reservoir, in order to provide a constant supply of gas to the pump, while the cyclical and normal rate of respiration provides a gas flow at a slightly faster rate of about 15 liters/minute. Exhaust from the gas trap is vented to the room, and is monitored by a G-M probe. See the enclosed literature from the company. The model number of the equipment are:

Gas delivery system: Model 101, w/195, 106, 109, 110, 127.

Xenon trap: Model 120.

All respiratory equipment is portable. Storage of the "Kow" will normally be in the "Hot lab", located within the Nuclear Medicine Area.

3. During a study with respiratory administration of Xenon, no exhalation directly to the atmosphere is allowed if the face mask is properly mounted. The face masks provided include one for nose and mouth, and another for mouth only, with a nose clamp provided. Transfer of activity from a crushable vendor's ampul to "Kow" is accomplished with Xenon released into a small evacuated space, after which the gas is diluted to atmospheric pressure with air. One-way valves minimize leakage at fittings.

Transfer of activity from the "Kow" to the gas delivery system is performed with a glass syringe and special fittings, to minimize gas leakage when loading the syringe. The fitting on the gas delivery system also contains a one-way valve, permitting loading only, with minimal leakage.

- D. 1. In the event of an accidental release of Xenon-133 in GB61 or GB62 personnel will be evacuated, the doors will be closed and the Radiation Safety Officer will assess the seriousness of the emergency. GB61 and GB62 are under a 15% negative pressure with exhaust ventil-

ation drawn from the ceiling ducts as shown in Figure 2. Return to safe conditions would be achieved by normal ventilation. Exhaust air from GB61 and GB62 is vented directly outdoors through a rooftop exhaust stack. All studies would be monitored by a GM detector equipped with a standard cylindrical probe with slide window. All personnel except the patient involved in a study will wear a film badge. The Radiation Safety Officer will use a GM detector as described above to assess any radiation hazard.

2. Failure of the gas delivery system to contain the patient's air after continuous breathing of Xenon-loaded air would be considered an emergency for a single patient. Failure of the transfer vessel or the "Kow" to contain the concentrated Xenon would initially be considered an emergency, until measurements indicate otherwise.

E. Air concentrations of Xe-133 in the Nuclear Medicine Area are expected to always be within the following limits:

1. Estimate of maximum amount of activity to be used per week, A.

$$\frac{400 \text{ patients/year}}{52 \text{ weeks/year}} \doteq \frac{8 \text{ patients}}{\text{week}}$$

$$\frac{4800 \text{ mCi/year}}{400 \text{ patients/year}} \doteq \frac{12 \text{ mCi}}{\text{patient}}$$

$$\begin{aligned} A &= 8 \left(\frac{\text{patients}}{\text{week}} \right) \times 12 \left(\frac{\text{mCi}}{\text{patient}} \right) \times \left(\frac{10^3 \text{ } \mu\text{Ci}}{\text{mCi}} \right) \\ &= 9.6 \times 10^4 \frac{\mu\text{Ci}}{\text{week}} \doteq 1 \times 10^5 \mu\text{Ci/week} \end{aligned}$$

2. Assume leakage rate of 25%, f.

3. The volumetric ventilation rate of GB61 and GB62 are approximately 840 CFM, V. The expected concentration is there

$$\begin{aligned} A \times f &= (1.0 \times 10^5 \frac{\mu\text{Ci}}{\text{week}}) \times (.25) \div (840 \text{ CFM}) \\ &\quad \times \left(\frac{1 \text{ CFM}}{6.8 \times 10^7 \text{ ml/40 hr week}} \right) \\ &= 4.38 \times 10^{-7} \mu\text{Ci/ml} \end{aligned}$$

This is well within the limit of $1 \times 10^{-5} \mu\text{Ci/ml}$ for restricted areas.

- F. 1. Disposal of Xenon is achieved by absorption onto a charcoal trap with a 98% Xenon removal efficiency. The exhaust from the trap is monitored by a GM probe which triggers a resettable alarm when an exhaust concentration of $2 \times 10^{-2} \mu\text{Ci/ml}$ has been reached. This

exhaust concentration has been chosen by Radx to indicate that filter saturation has occurred. The alarm calibration is preset by Radx. The exhaust will be vented to the restricted study area used (either GB61 or GB62). The following calculation indicates the adequacy of this procedure.

Since the filter's Xenon removal efficiency is in reality a decreasing function of the filter lifetime, the Xenon concentration in the exhaust will gradually increase with time until the filter efficiency allows a 2×10^{-2} $\mu\text{Ci/ml}$ Xenon concentration to be in the exhaust (this is true precluding isotopic surges thru the system). Therefore, a conservative estimate would be to use the maximum exhaust concentration at a steady flow rate as follows:

$$\text{Concentration: } C = 2 \times 10^{-2} \mu\text{Ci/ml}$$

$$\text{Volume flow rate: } V_{\text{ex}} \doteq 8 \text{ L/min} = 4.8 \times 10^5 \text{ ml/hr}$$

$$\text{Activity release rate: } A_t = C \times V_{\text{ex}}$$

$$A_t = 9.6 \times 10^3 \mu\text{Ci/hr}$$

For 8 patients per week with each study lasting 1 hr;

$$A = A_t \times t \times (\# \text{ of patients})$$

$$\begin{aligned} A &= \left(\frac{10^4 \mu\text{Ci}}{\text{hr}} \right) \times \left(\frac{1 \text{ hr}}{\text{patient}} \right) \times \left(\frac{8 \text{ patients}}{\text{week}} \right) \\ &= 8 \times 10^4 \frac{\mu\text{Ci}}{\text{week}} \quad \doteq 1 \times 10^5 \frac{\mu\text{Ci}}{\text{week}} \end{aligned}$$

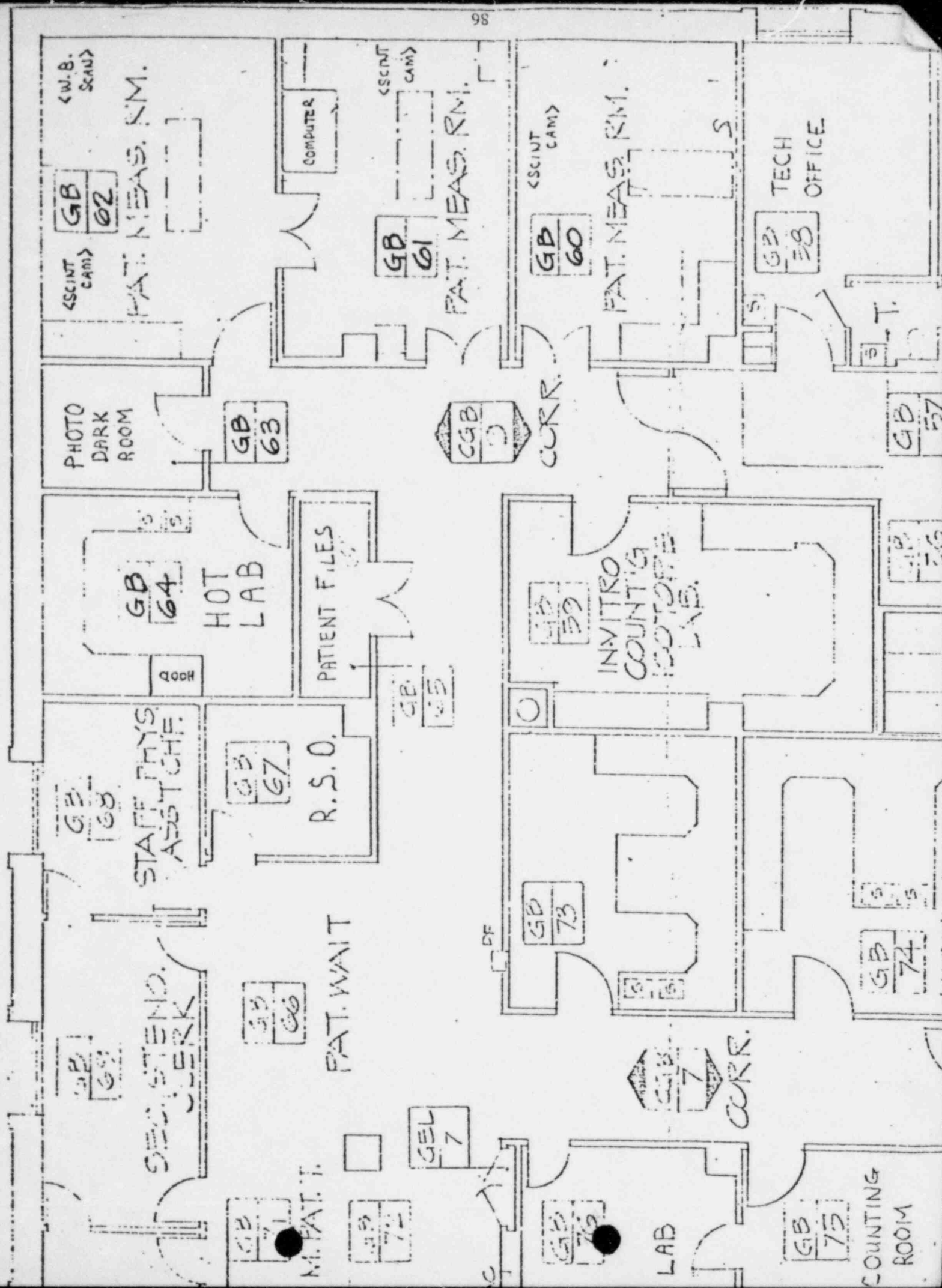
And, the expected air concentration in the exhaust of the room's ventilation system is;

$$\begin{aligned} \frac{A}{V} &= \frac{10^5 \mu\text{Ci}}{\text{week}} \times \left(\frac{1}{840 \text{ CFM}} \right) \times \left(\frac{1 \text{ CFM}}{6.8 \times 10^7 \text{ ml/40 hr wk}} \right) \\ &= 1.8 \times 10^{-6} \mu\text{Ci/ml} \end{aligned}$$

Room air is exhausted without recirculation via the roof of the building, a restricted area. Thus, even with conservative assumptions the above calculated concentration is well within the restricted area requirement of $1 \times 10^{-5} \mu\text{Ci/ml}$.

2. The filter is in a disposable container approximately 1 cubic foot in volume which when saturated (as indicated by triggering of the alarm) may be easily removed and replaced by a new unit. The saturated filter will have all openings sealed and will be monitored for its surface exposure rate immediately upon removal. The saturated trap will be stored for 80 days in a lead lined

receptacle in the fume hood in room GB64. At the end of 80 days the trap will then be monitored for its surface exposure rate and be disposed of via the hospital radioactive disposal system.

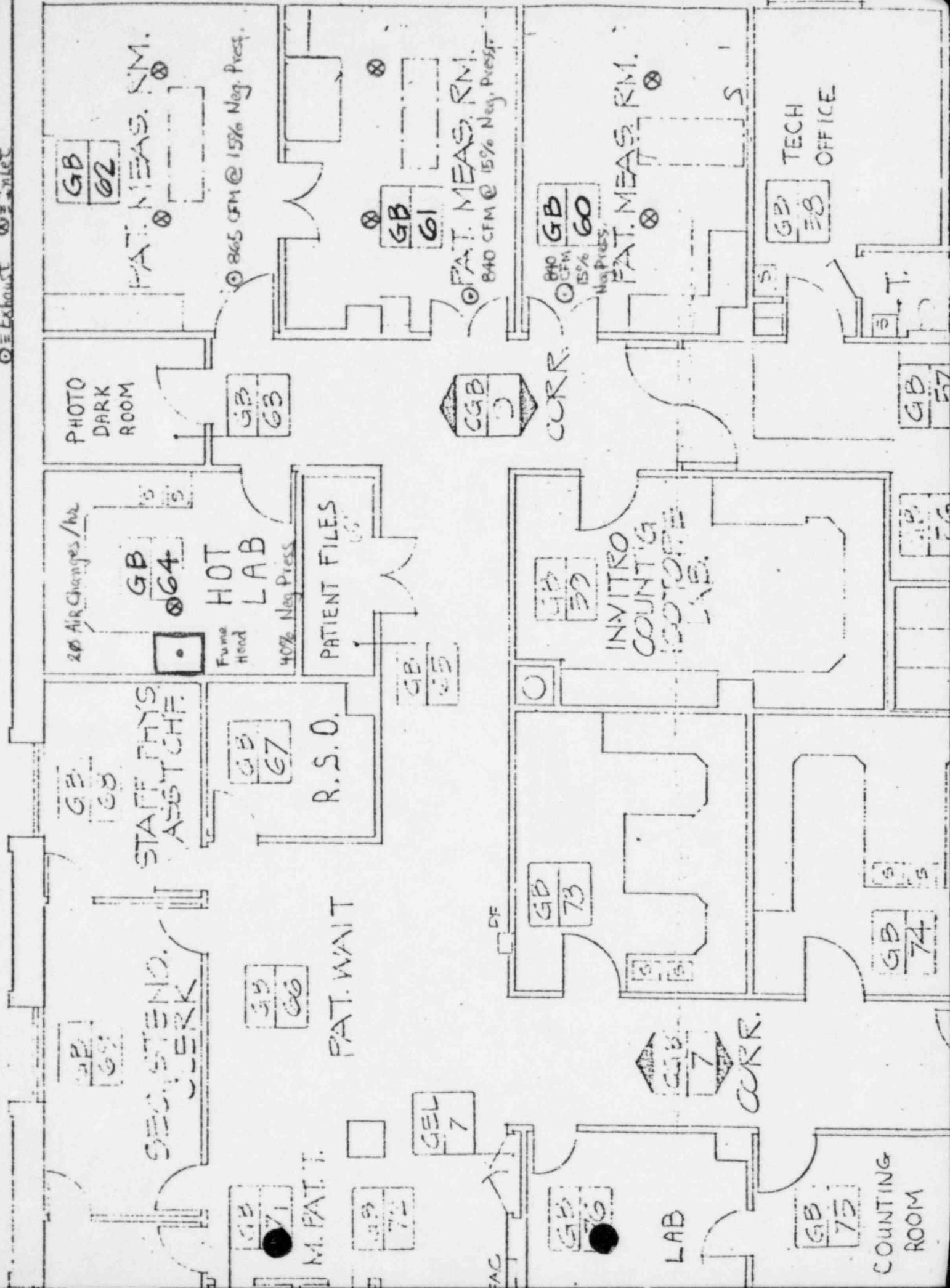


NUCLEAR MEDICINE INCLUDING RESEARCH

2

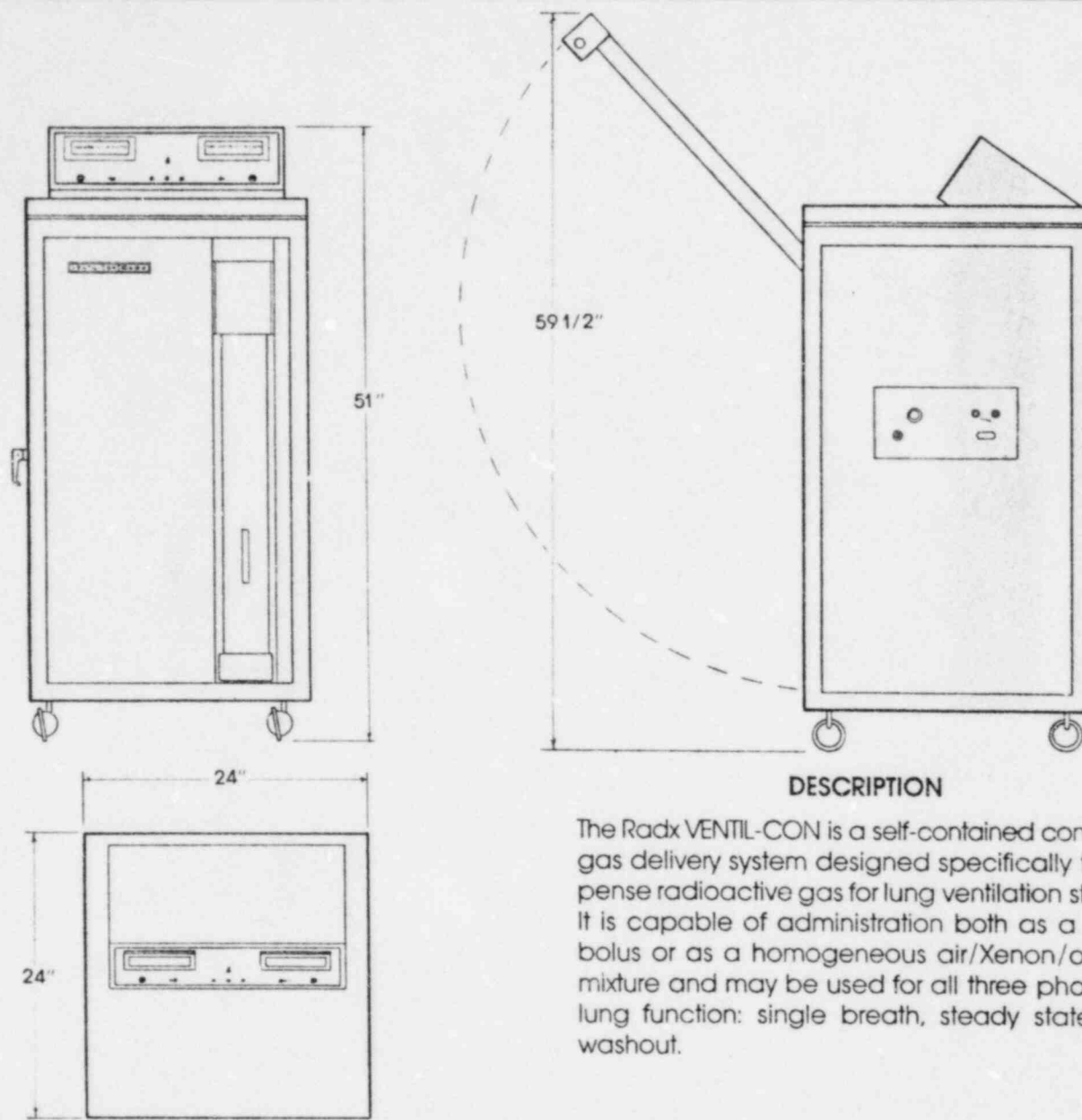
Exhaust Inlet

48



RADIX

Ventil-Con Controlled Gas Delivery System



DESCRIPTION

The Radix VENTIL-CON is a self-contained controlled gas delivery system designed specifically to dispense radioactive gas for lung ventilation studies. It is capable of administration both as a direct bolus or as a homogeneous air/Xenon/oxygen mixture and may be used for all three phases of lung function: single breath, steady state and washout.

Features/Specifications

Free Standing Mobile—The Ventil-Con is completely self-contained in a mobile, coaster-mounted console that is easily and conveniently positioned to perform the clinical study. The Ventil-Con occupies only 4 square feet of floor space, which easily facilitates temporary storage.

Large Volume Spirometer—The Ventil-Con has a 10 liter capacity horizontal rolling spirometer. All airway plumbing is fabricated of non corrugated, low resistance, smooth surface reinforced PVC tubing. The expansion/contraction factor of the ball bearing mounted spirometer diaphragm is negligible, offering a resistance of 0.05 inches of water to normal breathing. The spirometer mechanism is completely shielded with 1/8 inch lead (1/8 inch option available for ^{127}Xe) for personnel safety. The spirometer volume is displayed on the

control panel on a large scale analog meter and on one channel of a dual strip chart recorder on model 102.

Uniform Gas Mixture—The Ventil-Con incorporates a flame isolated motor and recirculating pump to insure a homogeneous gas mixture. Equilibrium is reached within minutes of being charged.

Concentration—Concentration is continuously monitored by an in-line GM tube and displayed as mCi/liter on a large scale analog meter on the control panel and on one channel of the dual strip chart recorder on model 102. The concentration may be varied by using one or all of the following controls: the evacuate mode, oxygen replenishment, and/or Xenon charge port.

Features/Specifications Cont.

Oxygen Replenishment Mode—The Ventil-Con is equipped with controls that allow the addition of oxygen in three different modes from an external supply. The three modes are:

1. Auto—replaces oxygen removed by patient during "Xenon rebreathing" phase at the spirometer.
2. Manual—allows oxygen to be added to the spirometer by manually operating the momentary oxygen solenoid switch.
3. Emergency Oxygen Assist—delivers oxygen directly to the patient and is activated by a momentary switch at the head valve.

Delivery Arm—The delivery arm of the Ventil-Con recesses into the cabinet during transportation or when not in use. The arm is 28 inches long, continuously adjustable up to 60 inches in height and is shielded with $\frac{1}{8}$ " lead. An additional $\frac{1}{8}$ " may be added on two sides as an option to provide adequate shielding for ^{127}Xe .

Valve Head—The Ventil-Con employs the Radx patented three-way valve which transfers the patient from "Stabilization" where they breathe room air, to "Xenon Rebreathing" where they are in closed loop with the radioactive gas mixture to "Washout" where the patient inhales room air and exhales out the exhaust port. Proper use of the head valve allows for a single breath study utilizing the homogeneous mixture of the Ventil-Con.

Masks—A variety of masks are available for use with the Ventil-Con. The unit is supplied with one "Adult Mouthpiece" and will be supplied with an Adult Mouthpiece for Bolus Injection upon request at no additional charge.

Swivel Adapter—The Ventil-Con comes equipped with a right angle swivel adapter which allows multiple views during the equilibrium phase of the study. The adapter is designed for use with the patient in the sitting position.

Carbon Dioxide Trap—The Ventil-Con incorporates a rechargeable CO_2 trap using soda lime granules. These granules are normally pink, turn blue when saturated with CO_2 and are a visual indicator that the CO_2 trap needs recharging.

Xenon Gas Storage—The Ventil-Con is designed in such a fashion that the only Xenon loss during a study is that which is in the patient's lungs at the start of washout. This combined with the bacteriological filter allows reuse of the Xenon gas mixture on subsequent patients. The concentration may be adjusted after each patient.

Control Functions—The Ventil-Con control panel includes remote controls for the scintillation camera which allows the technologist to operate the gamma camera from the patient's side.

Power Requirements—110 volt, 60 Hz single phase 5 amp., dual-fused, chassis ground

Dimensions—Height—51 inches

Width—24 inches

Depth—24 inches

Weight—Approximately 350 lbs.

Special Application—A Radx Ventil-Con has been modified for Xenon-133 gas administration to determine Regional Cerebral Blood Flow by the inhalation technique of Obrist, et. al.¹ Modification includes a constant flow pump which draws directly from the head valve during washout.

¹Obrist, W.D. et al. "Determination of Regional Cerebral Blood Flow by Inhalation of Xenon-133." *Circulation Research*, XX, 124-134, January, 1967.

PRICE LIST

Radx No.	Description	Price	Radx No.	Description	Price
101	Ventil-Con Controlled Gas Delivery System without Dual Channel Strip Chart Recorder	\$4,615.00	105	Autoclavable Bacteriological Filter	25.00
102	Ventil-Con Controlled Gas Delivery System with Dual Channel Strip Chart Recorder	5,615.00	106	Remote Control Cable—20 feet	60.00
	Both of the above units include the following:		107	Chart Recorder Paper—12 rolls (minimum)	180.00
	(1) 12" Flex tube with Adult Mouthpiece and headstrap. Please specify Adult Mouthpiece for Bolus Injection if desired.		108	Infant Mask (small, medium or large)	15.00
	(1) Nose depressor		109	Adult Mouthpiece	15.00
	(1) Quart of soda lime granules		110	Adult Face Mask	15.00
	(1) 20' remote control cable		111	Adult Mouthpiece for Bolus Administration	20.00
	(1) Installation and instruction manual		127	Tubing—interface Ventil-Con/Xenon trap	15.00
103	Dual Channel Strip Chart Recorder	1,200.00	128	Tubing—exhaust port—per foot	.75
104	Soda Lime Granules—1 Case (20 quarts/case)	40.00		Xenon-127 Additional lead shielding	200.00
				Cerebral Blood Flow Modification	400.00

Terms: Net 30 days; F.O.B. Houston, Texas

Prices effective April 1, 1975

Maintenance

Routine cleaning and replacement of the soda lime granules is all the service your Ventil-Con will require. Complete procedures for good care are outlined in the instruction manual.

RADX Warranty

RADX warrants the Ventil-Con to be free from all defective material and workmanship for a period of one year from date of shipment. RADX Corporation's liability shall be limited to the repair or replacement of the defective material or component at its option.

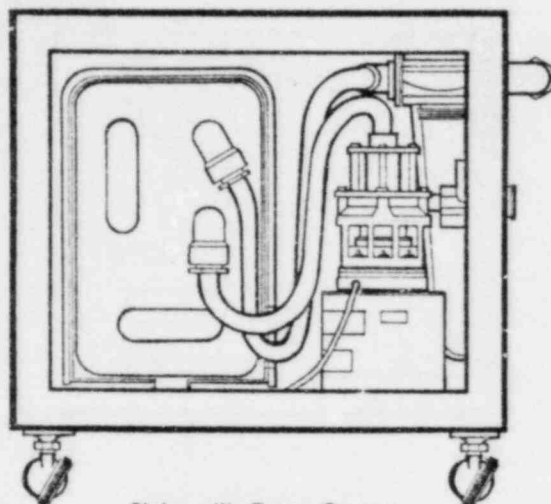
Prices are subject to change without notice.

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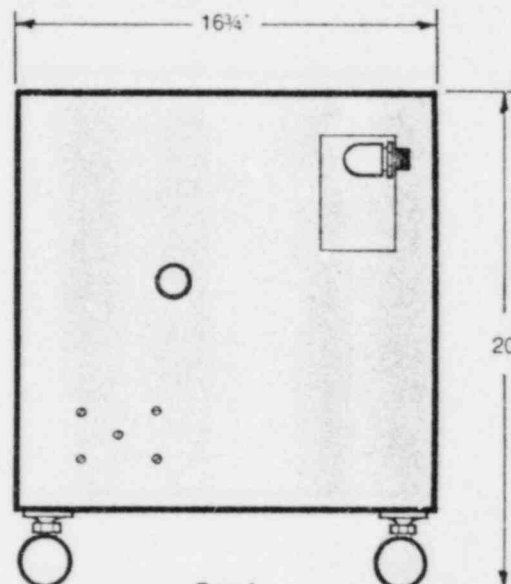
RADX

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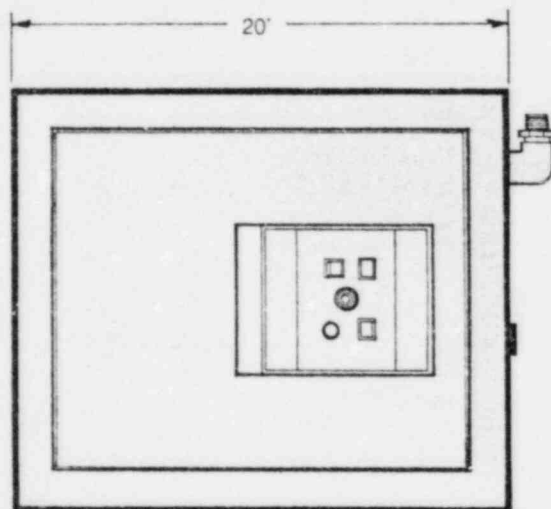
P. O. Box 19164 • Houston, Texas 77024 • 713-468-9628



Side with Door Open



Front



Top

DESCRIPTION

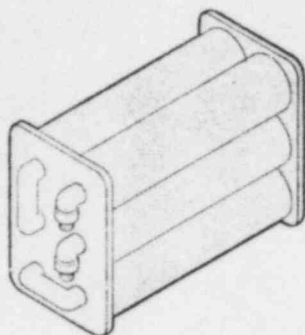
The RADX Xenon Trap was designed to economically and safely absorb radioactive xenon gas, primarily ^{133}Xe , as an effluent from patient washout in lung ventilation studies. The absorbent material is a special grade of activated charcoal, factory-filled into a sealed disposable cartridge pack. Total system absorption efficiency is better than 98% of the radioactive gas and under routine use conditions will last for many months.

The cartridge pack was designed for easy removal and replacement when it becomes saturated. After decay in storage the pack may be either reused or disposed of, depending on its residual absorption capacity. The entire cartridge pack storage area is lined with 3/16" lead which effectively shields large quantities of the very low energy gamma rays of ^{133}Xe .

Two models are available; one with and one without a GM detector. The detector constantly monitors the Xenon Trap exhaust port to warn when the cartridge pack has reached capacity. An audio "beeper" and visual red light warning system is built in to indicate immediately when the radiation level exceeds a pre-selected figure.

The electric motor of the circulation pump used to move the potentially oxygen enriched gaseous mixture through the charcoal trap is "flame isolated" from the flow. This feature eliminates the possibility of electric motor-induced combustion.

Product Specifications Price List



Cartridge pack — disposable pressure-tested sealed unit with entrance and exit ports

Number of charcoal cylinders/cartridge pack — 6

Cartridge size — 3 1/2" x 12"

Cartridge pack life — use dependent

Lead shielding — 3/16"

Xenon detector (optional) — GM tube. User threshold adjust for activation of warning system.

Warning system — Audio "beeper", visual red light. Warning system requires user action to deactivate.

Moisture trap — Heat reconstitutable silica gel desiccant

PRICE LIST

Radx No.	Description	Price
120	Xenon Trap with removable 6-cylinder cartridge pack, flame isolated circulation pump motor, 3/16" lead shielding and ¹³³ Xe detector warning system	\$1195.00
121	Xenon Trap with removable 6-cylinder cartridge pack, flame isolated circulation pump motor and 3/16" lead shielding (does not include ¹³³ Xe detector warning system)	950.00
125	Cartridge Pack - 6-cylinder for No. 120 or No. 121 Xenon Trap	175.00
126	Silica Gel Desiccant - 2 lbs.	15.00
127	Tubing - interface to Ventil-Con	15.00
128	Tubing - Exhaust Port per foot	.75

Terms: Net 30 days, F.O.B. Houston, Texas
Prices effective June 1, 1975
Minimum order \$20.00

RADX Warranty

RADX Corporation warrants its products to be free from all defects in material and workmanship for a period of one year from the date of shipment. RADX Corporation liability shall be limited to the repair or replacement of the defective material at its option.

Service Policy

Should any unit fail to perform satisfactorily within the tolerances as stated in the specifications, we will upon notification, ship immediately via air express an exchange unit to be used while the defective unit is being repaired and returned. This service will be provided on a no-cost basis during the warranty period.

RADX

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P. O. Box 19164 • Houston, Texas 77024 • 713-468-9628

RADX CORPORATION
XENON TRAP
(Preliminary Instruction Manual)

1.0 Introduction

Since the inception of inert radioactive gases, particularly ^{133}Xe for the evaluation of lung ventilation, proper disposal has presented an interesting problem. A number of methods have been employed including venting to the atmosphere, preferential liquification of Xenon from expired air by cooling and adsorption by activated charcoal.

The latter is the method employed by Radx in our Xenon Trap. Activated charcoal is contained in six 12-inch PVC tubes which, connected in series, comprise the cartridge pack. The air/Xenon mixture is moved through the unit by a flame isolated bellows pump after first passing through a desiccant jar to remove moisture.

On units so equipped, a G-M tube constantly monitors the cartridge pack exhaust and gives an audible warning when as little as 2 uCi of activity is seen. This serves as an indication that the cartridge pack is becoming saturated and should be replaced.

1.1 Control Console

The control console is located on top of the unit and contains the power and alarm reset switch plus the audio "beeper."

When the power switch is depressed, the pump and alarm system are activated and a light comes on in the power button. Pressing the button a second time turns the power off.

1.2 Alarm System

The alarm system consists of a G-M tube monitoring the cartridge pack exhaust, an audio "beeper," an alarm reset switch, plus the associated electronics. When the power is turned on the beeper activates and the alarm reset switch light comes on for several seconds to indicate that the alarm system is operational. Sensitivity is factory set to provide an audio indication of radioactivity at around 2-4 uCi.

A sensitivity screw adjust is provided through a small hole in the side of the power box. The audio portion may be deactivated by pressing the red alarm reset button. Visual indication of the presence of radioactivity is provided by the light in the alarm reset switch. It is operational regardless of the position of the reset button.

1.3 Cartridge Pack

The activated charcoal cartridge pack consists of six $3\frac{1}{2}$ x 12 inch tubes connected in series and surrounded by $3/16$ inch of lead. The total pack contains approximately 4500 grams which calculations indicate will adsorb 3.5 billion curies of ^{133}Xe . Unfortunately, the life of a cartridge pack is not determined by its Xenon adsorption but by the adsorption of a wide variety of airborne contaminants. At this time we anticipate a life time of at least six months and this may be extended considerably by observing the following precautions:

- 1.3.1 Run the trap only during Xenon washout or when Xenon is being adsorbed.
- 1.3.2 Renew the desiccant whenever the color begins to change from its dark blue. (The desiccant may be reused by heating it in a pan until the dark blue color returns.)

1.4 Pump System

The air movement system used in the Xenon Trap is a positive displacement "flame isolated" bellows type pump. Our studies indicate that maximum efficiency is obtained with the charcoal pack when the air movement is less than 10 liters per minute. The Xenon Trap is set to operate at between 7 and 9 liters per minute to assure adequate dwell time for proper Xenon adsorption.

2.0 Installation

- 2.1 Upon its arrival, carefully remove all shipping materials. Obtain and identify all items indicated on the packing slip to insure the shipment is complete.
- 2.2 Visually inspect the console for any indications of damage while in transit.
- 2.3 Open the door and inspect the water adsorber jar. It should be filled with desiccant and the desiccant should be dark blue in color.
- 2.4 The Xenon Trap is equipped with two ports, one marked intake on the front of the unit and the other exhaust at the rear. The ports are equipped to handle $3/4$ " ID tubing.

3.0 Interfacing

Proper interfacing of the Xenon Trap to your system is critical. The main problem involved is when the patient is connected directly to the Xenon Trap. Under normal conditions a patient will breathe at a rate of approximately 15 liters per minute while movement through the trap is set for approximately half that value. Proper hookup under this condition will require an expandable interface available as Radx Expandable Interface (Item #129).

3.1 Interfacing to Radx Ventil-Con

- 3.1.1 Attach a length of 3/4" ID tubing to the exhaust port of the Ventil-Con with the other end attached to the Expandable Interface.
- 3.1.2 Attach a second length of 3/4" ID tubing between the Expandable Interface and the input of the Xenon Trap.

NOTE: The above described method should be adaptable to other Ventil-Con type devices with appropriate plumbing connections.

3.2 Interfacing to the Medi Physics Chamber

- 3.2.1 Since the Medi Physics system is expandable itself, an expandable interface is not required.
- 3.2.2 At the end of the study, close the breathing valve and attach the Xenon Trap/Medi Physics adapter.
- 3.2.3 Attach a length of 3/4" ID tubing to the adapter and then to the Xenon Trap.

4.0 Operation

- 4.1 When the power switch is pressed the audio beeper and red alarm reset light are activated for a few seconds to indicate that both are operational. They will automatically stop if no radiation is detected.
- 4.2 Normal background radiation will occasionally give a "beep" and a flash. An occasional alarm does not indicate that the filter is saturated. When saturation is reached, the sound alarm will activate frequently giving a steady staccato sound.

- 4.3 The alarm system is factory set to give the steady state at a level of 2-4 uCi. The sensitivity may be changed by adjusting the potentiometer screw adjust located on the side of the power box marked "Sensitivity."
- 4.4 After proper interfacing as described in Section 3.1, only run the Xenon Trap when Xenon is being adsorbed. When the Expandable Interface or the Medi Physics system is used, the Trap should be operated for sufficient time to collapse the collection bag. This will normally require about five minutes for the Expandable Interface and about ten minutes for the MPI bag.
- 4.5 If during a patient study the audio alarm should go off indicating saturation of the filter, the sound may be turned off by pressing the alarm reset button. Immediately upon completion of the study the saturated cartridge pack should be removed by disconnecting the input and exhaust tube at the pack and reconnecting to a fresh cartridge pack.
- 4.6 The saturated pack should be capped and placed in storage for a period of not less than 15 half lives (approximately 75-80 days for ^{133}Xe). Although after decaying in storage the Cartridge Pack may be reused, it should be done with caution since the expected life would be significantly reduced from a new cartridge.

5.0 Maintenance

- 5.1 Inspect the silica gel desiccant jar frequently and replace or renew by heating when the color begins to change from a dark blue. Moisture entering the Cartridge Pack will render the charcoal ineffective for adsorbing Xenon.
- 5.2 Periodically inspect all hose connections to assure that they are in place.
- 5.3 Do not allow the pump to pull against a vacuum for any period of time.

Am-241 Source

- A. The source is designated as Amersham/Searle Model AMC.W233.
- B. The source shall be used for in vivo fluorescence studies, to determine iodine levels in the thyroid gland; it shall also be used to develop new techniques for clinical laboratory work. It shall be used by the Nuclear Medicine Service of the hospital. The location of the source will be GB54. It will remain locked in GB54 when not in use. Hospital ambient conditions are expected for use of the source.
- C. The source strength shall be 10 curies of Americium-241, as specified by the manufacturer. Its chemical form is an inert, leach-resistant ceramic, which, in an unencapsulated state, passes standard tests for leakage-immersion and wipe tests. It is doubly encapsulated in stainless steel by welding.
- D. Capsule specifications are given in the enclosed engineering drawing (Fig. 1) from Amersham/Searle. Its form is a disk, 12mm thick, 54mm in diameter, with a diameter of 44mm for the activity itself.

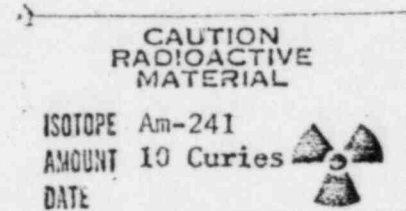
The source holder is a commercially available structure of lead and tungsten, manufactured by Kevex Corporation, Burlingame, CA, and designated as Kevex Scan II. The source is located behind a multihole focused collimator of lead, surrounded by a tungsten shield (Figs. 2,3). A solid state detector is located adjacent to the shield. The arrangement of source, collimator and detector is combined into an integrated assembly, denoted the "scan head," which is attached to the scan arm of a commercial rectilinear scanner by means of a yoke, which shall hold the existing detector, as well. A shutter is located on the front of the collimator and is part of the shield. It contains a tungsten insert; its position may be visually noted, and it may be latched shut.

When the source is not in use the shutter will remain shut, and the source shall remain in the scan head.

- E. Quarterly wipe tests shall be made of the source, in accordance with the provisions of the hospital license for byproduct material, to detect any leaks.

Leak test procedure: The source shall be wiped with a soft tissue or a cotton swab, which shall then be placed in a counting vial and counted in a well-type scintillation counter for at least five (5) minutes. Activity under 0.005 microcuries will be detectable by this method. (A count rate corresponding to five times the background count rate will be considered significant. The count rate of a 0.005 microcurie source would correspond to about 90 times the background count rate.)

G. Sample Label:



DANGER - RADIOACTIVE
MATERIAL
DO NOT HANDLE - NOTIFY
CIVIL AUTHORITIES IF FOUND

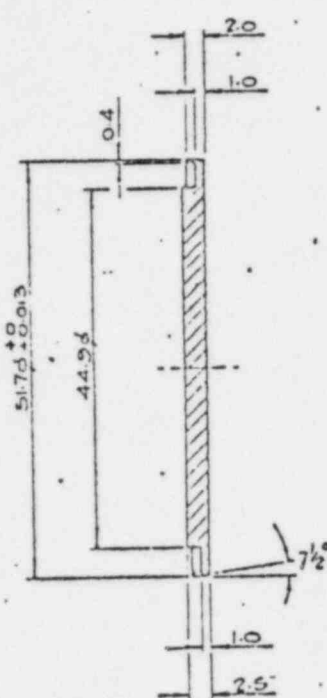
USED ON

NOT FOR PUBLICATION

DAG. BRC 10/97/S
No.

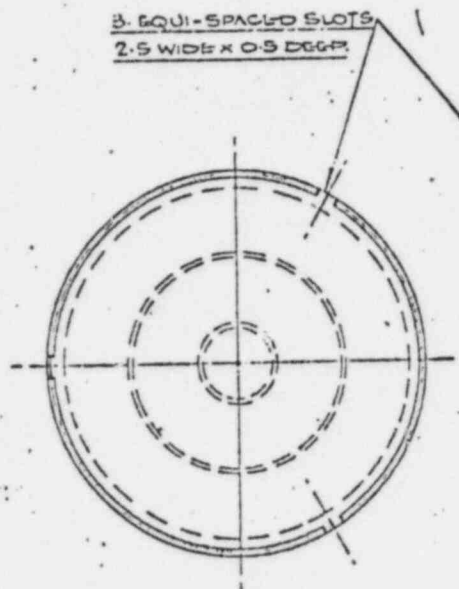
THIRD ANGLE PROJECTION

Länder

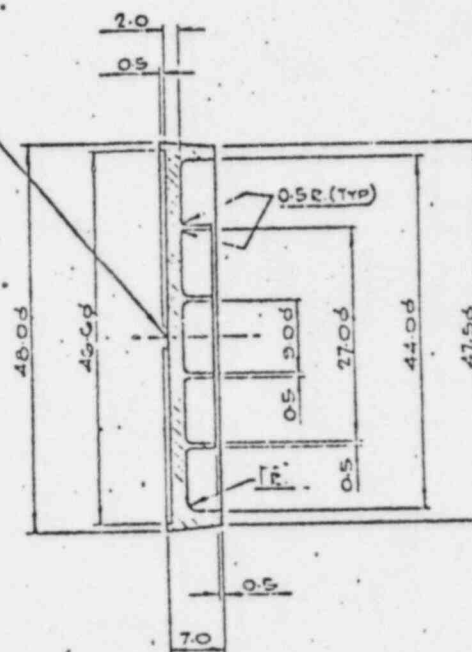


SECTION ON \mathcal{C}

LID.

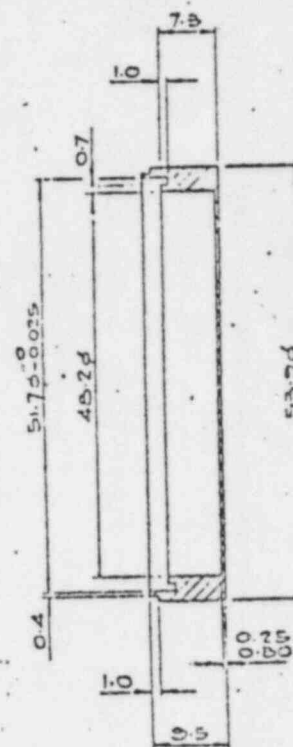


3. EQUI-SPACED SLOTS
2.5 WIDE x 0.5 DEEP.



SECTION ON ϕ

INSERT



SECTION ON E

BODY.

CHD.	MATERIAL & SPEC VACUUM MELTED ST. STL. 316L OR AISI 316L	FINISH CLEAN	TOLERANCES ± 0.03	THE RADIOCHEMICAL CENTRE AMERSHAM DUCKS	CONTRACTOR			
APPD.	REMOVE ALL BURRS	SURFACE TEXTURE ✓ UNLESS STATED	DIMS. IN MILLIMETRES SCALE 2:1	TITLE DOUBLE WELDED SG-10C Am 241 CAPSULE 14MM ACT. DIA.		DRAWING No. BRC 10197/5		

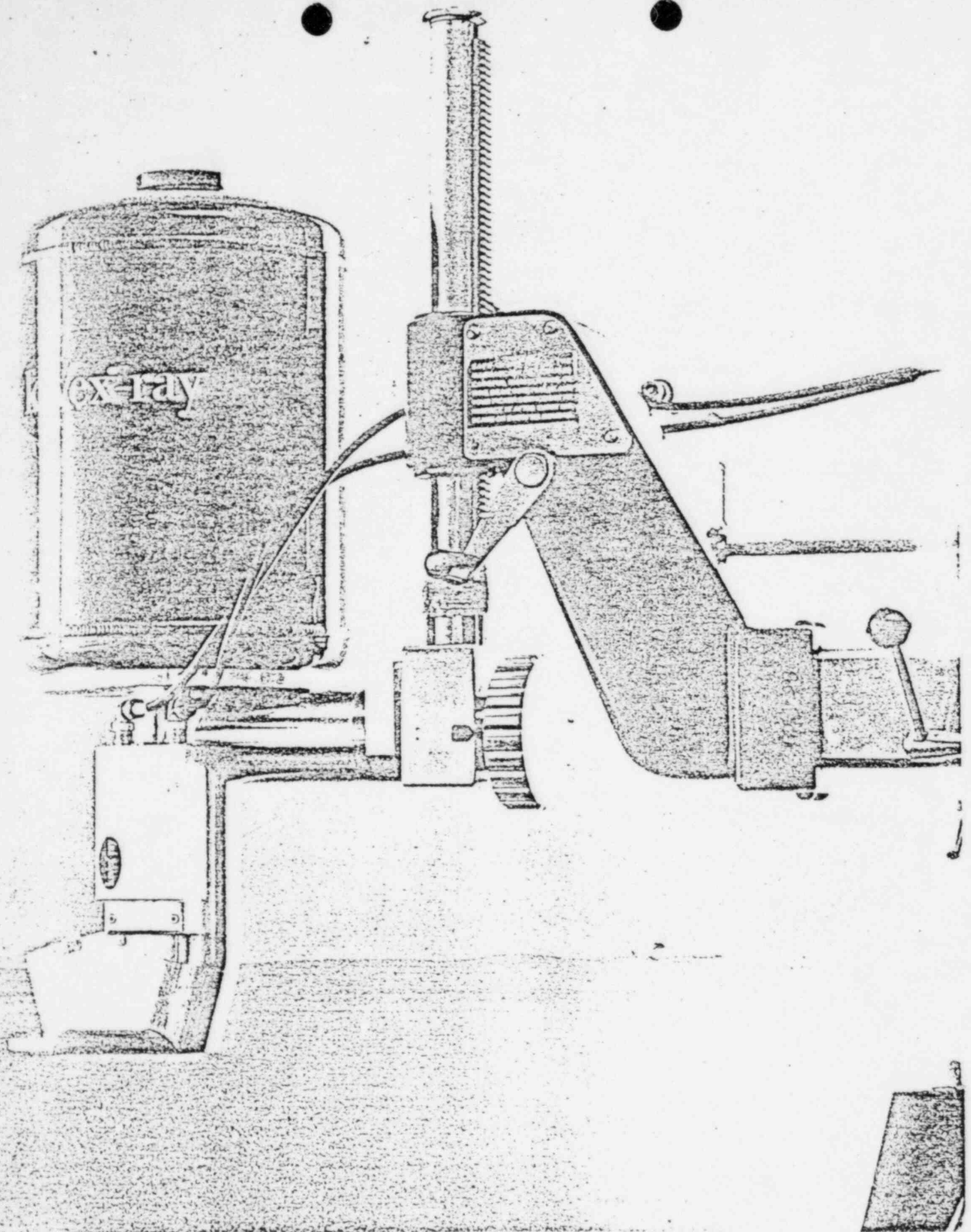
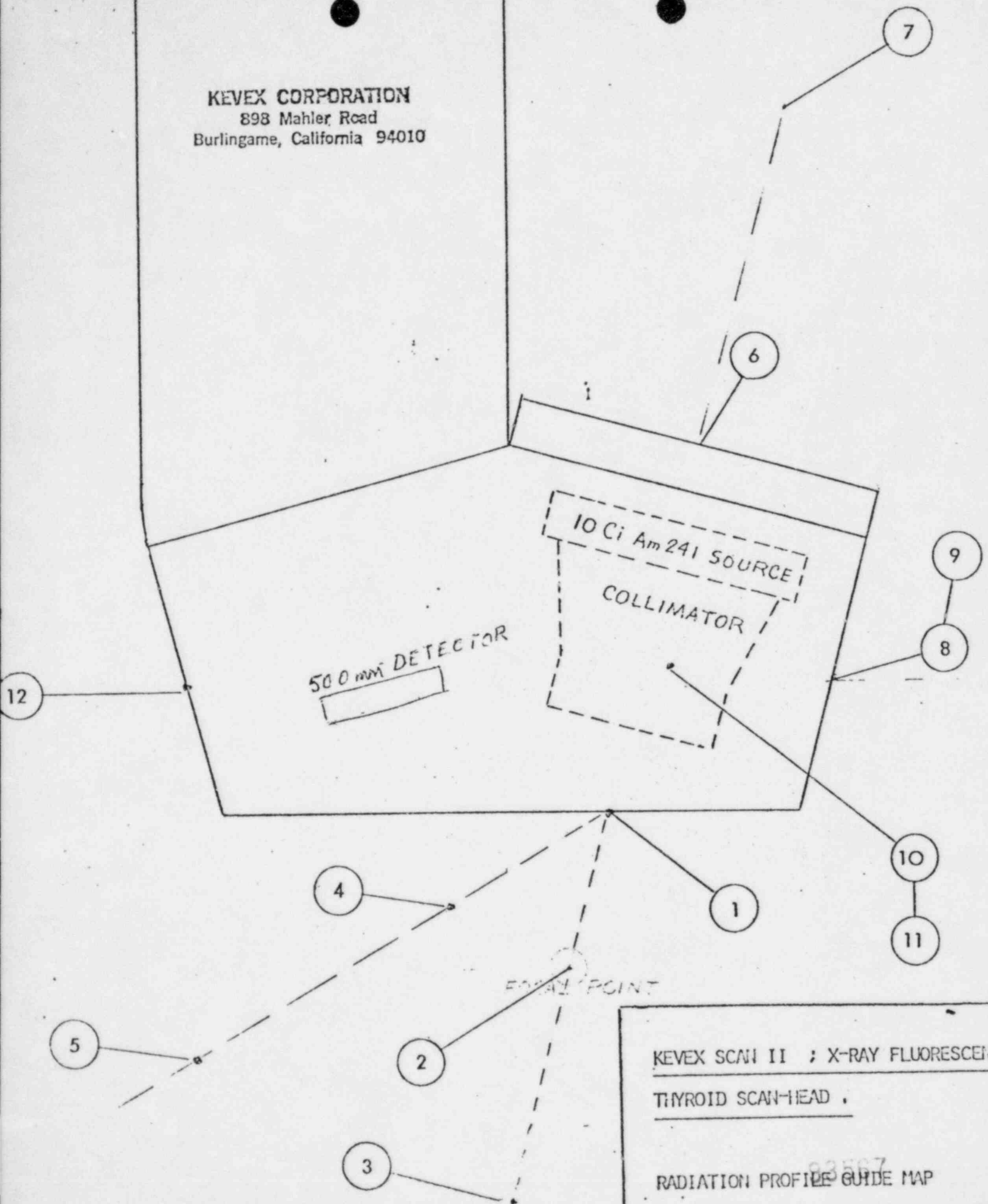


Figure 2 99

KEVEX CORPORATION
898 Mahler Road
Burlingame, California 94010



KEVEX SCAN II ; X-RAY FLUORESCENCE

THYROID SCAN-HEAD ,

RADIATION PROFILE GUIDE MAP

Figures 3

KEVEX SCAN II X-RAY FLUORESCENCE HEAD , RADIATION PROFILES WITH
LOADING OF 10 CURIE AM 241 LOADING ,

MEASUREMENTS MADE WITH EBERLINE MODEL E 510 , AMPEREX THIN END WINDOW
 PROBE (3.5 MG/SQ. CM). INSTRUMENT CALIBRATED 12/23/73 TO COBALT 60 .

WITH REFERENCE TO NUMBERED GUIDE MAP , RADIATION LEVELS ARE AS LISTED :

MEASUREMENT POINT	SHUTTER CLOSED	SHUTTER OPEN
1. SURFACE LEVEL OF SHUTTER	1.2 MR/HR	200 MR/HR
2. COLLIMATOR FOCAL POINT		180 MR/HR
3. ON COLLIMATOR AXIS DISTANCE 1 FT.	0.1 MR/HR	16 MR/HR
4. 45° OFF AXIS , 2 INCH DISTANCE (SYMMETRIC)		.8 MR/HR
5. 45° OFF AXIS , 1 FT. DISTANCE		.06 MR/HR
6. LID SURFACE , ON SOURCE AXIS	2 MR/HR	2 MR/HR
7. ON SOURCE AXIS , 1 FT. ABOVE LID	.08 MR/HR	.08 MR/HR
8. SURFACE ("FRONT")	2.5 MR/HR	2.5 MR/HR
9. "FRONT" , 1 FT. DISTANCE	.08 MR/HR	.08 MR/HR
10. "SIDE" SURFACE (SAME LEFT AND RIGHT)	1.5 MR/HR	1.5 MR/HR
11. "SIDES" , 1 FT DISTANCE		.08 MR/HR
12. "REAR" , SURFACE	.4 MR/HR	.4 MR/HR

SURFACE AND 1 FT. LEVEL MEASUREMENTS WITH SHUTTER OPEN WERE MADE WITH NO SCATTERER IN BEAM PATH EXCEPT AIR SCATTER , WHICH APPEARS NEGLIGIBLE

ROOM BACKGROUND LEVELS MEASUREMENTS WITH SYSTEM REMOVED ; .02 MR/HR

RADIOPHARMACEUTICAL LABORATORY

PURPOSE

To involve the specially trained hospital pharmacist with his facilities and expertise for procurement, preparing and processing of radioactive drugs. There is desirability and need of a separate, well-equipped area devoted exclusively to clinical radioisotopes to avoid cross-contamination from long-lived research isotopic materials. To control purity and sterility by proven methods of pharmaceutical practice. To provide for many ancillary services such as Research, Education and Training.

LOCATION

It is located in R 3-14 of the Pharmacy on the ground floor of the administrative Clinic Building.

DESIGN

The facility occupies 240 net square feet. It is designed to provide a very modern and safe preparation and teaching radiopharmaceutical laboratory. (See Fig. 2)

SAFETY

All operations in the laboratory conform to and are regulated by Parts 19, 20, 30 and 32 of the Code of Federal Regulations, USNRC, and all other regulations which the Commission may apply. The laboratory is properly shielded to afford necessary safety to those employees directly involved within its periphery and also to those employees in surrounding facilities and locations. (See Fig. 1)

All work areas are covered with absorbent paper with plastic backing to reduce any chance of contamination due to accidental spillage.

Copies of the NRC regulations are conspicuously posted.

Preventative Safety Procedures: (Also see Radiation Protection Procedures I & II)

No employees are permitted in the laboratory without permission of a radiopharmacist and a detection recording device will be required. All employees scheduled to work in the laboratory receiving comprehensive briefing on necessary safety procedures that are requisites to safety.

Large signs forbidding smoking and eating in the laboratory will be prominently displayed.

Large signs with step-by-step procedures to follow in case of accidental spillage will also be posted.

Caution-Radioactive signs are posted on the sterile hood containing the generator and other specific areas with which the radioactive substance comes in contact.

EQUIPMENT

Radiation Detection Equipment:

Picker Spectroscaler III A
Picker Well Counter
Picker Isotope Calibrator
Picker Labmonitor with Geiger Probe
Portable Survey Meter

Quality Control Equipment:

Microscope
Haemocytometer
High Intensity Lamp
Calculator, Electric

Compounding Equipment:

Becton-Dickinson Sterile Air Laminar Flow Hood
Dust Box
Unit Dose Storage Cart
Autoclave
Electric Hot Plate
Lafayette Transistor Power Supply
Rhodes Timer Switch
Zirconium Wire
Chromatography Apparatus
Lead Protective Devices
Laboratory Glassware
Radiopharmacy Accessories

RADIOPHARMACEUTICAL HOSPITAL PROGRAM

- A. The radiopharmaceutical laboratory involves itself in the ordering and maintenance of proper stock levels of all radiopharmaceuticals in accordance with the specified possession limits, and maintain complete area monitoring and waste disposal records.
- B. It will prepare radiopharmaceuticals (where applicable).
- C. It will calibrate dosage for each individual patient using the Picker Spectroscaler IIIA and the Picker Isotope Calibrator as a double check.
- D. The Molybdenum content of Technetium will not exceed the NRC requirements.
- E. It will deliver the individually calibrated patient dosage in lead shielded syringes for immediate physician use and maintain records of all such doses.
- F. It will keep detailed records of any untoward reactions.
- G. It will perform chromatography for the proper manufacture of all radionuclide colloids. (Principles of Nuclear Medicine p. 855)
- H. It will perform all necessary microscopic tests to insure that particle size of colloids prepared is in proper size range.
- I. It will insure an aseptic, pyrogen free product by doing sterility tests on all products required and frequent USP pyrogen tests on manufactured radionuclides, solutions and colloids. (See USP XVII)
- J. Radiopharmaceutical agents prepared or processed are for use in this hospital only.

ADMINISTRATIVE FILES

The following records are maintained in the Radiopharmaceutical Laboratory:

- a. Work records of all dosage calibrations.
- b. Copies of clinical records of patients.
- c. Scan results of patients.
- d. Procurement files.
- e. Quality Control records.
- f. Pyrogen Assay records.
- g. Chromatography file.
- h. Microscopic particle size file.
- i. Personnel radiation records.
- j. Minutes of Radioisotope Committee Meetings.

PERSONNEL

1. William L. Schalker, M.S., R.Ph. (Chief Pharmacist)

Licentiate Pharmacist State of North Dakota

Successfully completed the following:

A four credit Qt. Radiopharmaceutical course given at North Dakota State University. September - December 1957.

Radioisotope Training Course given by AEC at Oak Ridge, Tennessee. July, 1958 (3 weeks)

Radiopharmacist at VA Hospital, McKinney, Texas, 1961 (10 months)

The course, "Basic Radiological Health," given by the U.S. Department of Health. July, 1963. (40 hours)

"Radiological Monitoring for Instructors," given by the Office of Civil Defense - Staff College. December, 1965. (40 hours)

Training seminar on Radioisotopes given by Squibb Division of Nuclear Medicine and is so certified. January 15-16, 1969.

2. Lonnie Earl Adams

Licentiate Pharmacist State of California

Successfully completed the following:

Training seminar on Radioisotopes given by Squibb Division of Nuclear Medicine and is so certified. January 15-16, 1969.

The course, "Radioisotopes in Medicine and Biology," given by S. Landau, M.D., at Donner Laboratories, Berkeley, California. April 2, 1969 - May 28, 1969.

"Radioisotopes in Medicine," by K.G. Scott, Ph.D., University of California, San Francisco, California August 29 - September 30, 1969, and is so certified.

On the job experience from May 15, 1969 to present.

3. Bertram L. Lum

Licentiate Pharmacist State of California

HCL-238, Radiopharmaceuticals, 6 semester units, graduate course, University of the Pacific School of Pharmacy. September 1975 to December 1975.

HCL-185, Clinical Nuclear Pharmacy Clerkship, 15 semester units, University of the Pacific School of Pharmacy in conjunction with Letterman Army Medical Center, San Francisco. April 1976 to August 1976.

Staff Radiopharmacist, Letterman Army Medical Center, San Francisco. August through September 1976. Same experience as paragraph 2 above.

Veterans Administration Hospital, San Francisco. On the job experience from December 1976 to present.

4. Robert Gutterman

Licentiate Pharmacist State of California

Thirty-four In-service Course in Pharmacy.

On the job training from September 15, 1970 to present.

A RADIOPHARMACEUTICAL LABORATORY

B PERSONNEL

C PERSONNEL

Fig 1

