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

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

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

Yale-New Haven Hospital
20 York Street
New Haven, CT 06504

TELEPHONE NO.: AREA CODE (203) 785 - 2602

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Robert E. Peterson, Jr.

TELEPHONE NO.: AREA CODE (203) 785- 2950

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 06-00819-03

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

Used by or under the supervision of the Hospital Radioisotope Committee, Eugene A. Cornelius, M.D., Ph.D., Chairman

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

Robert E. Peterson, Jr.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	As needed
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	5,000
10 CFR 35.100,SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	5,000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	As needed
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	As needed
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	As needed
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	As needed
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	2,000

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Any byproduct material with Atomic nos. 3-83 inclusive	Any	200 millicuries of each byproduct material with Atomic nos. 3-83 inclusive	medical research and diagnosis
Americium-241	Sealed sources	40,000 mCi	medical research and therapy
Hydrogen-3	Any	200 millicuries	medical research and diagnosis
Gadolinuum-153	Sealed sources	2,000 mCi	bonemineral analyzer
Iridium-192	Sealed sources	50,000 mCi	remote afterloader-Gamma Med II
Selenium-75	Sealed sources	40,000 mCi	medical research and therapy
Uranium (depleted in Uranium-235)	Cadmium Plated Metal	137 kg.	radiation shielding material

License Fee Information on Next Page 12/13/84 Lower fee

DEC 18 1984

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: October 80

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

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	Detailed Information Attached; and
X	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached NOT USED AT YALE-NEW HAVEN HOSPITAL
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	L. S. LANDAUER, JR. & COMPANY	MONTHLY
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	L. S. LANDAUER, JR. & COMPANY	MONTHLY
		OTHER (Specify)		
c. WRIST	X	FILM	L. S. LANDAUER, JR. & COMPANY	MONTHLY
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY:
Category 7B of section 170.31, 10 CFR 170

(2) LICENSE FEE ENCLOSED: $ 700.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Eugene A. Cornelius M.D., Ph.D.

(1) NAME *(Type of Print)*
Eugene A. Cornelius , M.D.,Ph.D.

(2) TITLE
Chairman, Hospital Radioisotope Committee

c. DATE
December 13, 1984

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

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

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

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

Item 7 Hospital Radioisotope Committee Members

Eugene A. Cornelius, M.D. Ph.D.
Chairman, Hospital Radioisotope Committee

Robert J. Schulz, Ph.D.
Director, Radiological Physics

Ernest Kohorn, M.D.
Professor, Obstetrics and Gynecology

Richard Donabedian, M.D.
Associate Director, Clinical Chemistry

Robert C. Lange, Ph.D.
Associate Professor, Diagnostic Imaging

Richard E. Peschel, M.D., Ph.D.
Assistant Professor, Therapeutic Radiology

George Holeman, M.S.
Director, Yale University Health Physics Division

Daniel J. McIntyre, M.H.A.
Assistant Administrator, Administration

Leonard Quartararo, R.T.
Chief Technologist, Nuclear Medicine

Robert E. Peterson, Jr., B.S.
Health Physicist, Radiological Physics

Eleanor O'Connor
Head Nurse, Obstetrics and Gynecology

Responsibility

The Hospital Radioisotope Committee has the responsibility of establishing and enforcing the Hospital's Radiation Safety Program to ensure safety and welfare of hospital personnel and property as well as protecting the surrounding community from the potential hazards of all sources of ionizing radiation used at the hospital. The committee formulates and enforces such policies that are necessary to establish uniformly safe practice throughout the hospital for the use of all sources of ionizing radiation.

Membership

Membership on the Hospital Radioisotope Committee is through appointment by the Medical Board of Yale-New Haven Hospital.

Meetings

The Hospital Radioisotope Committee shall meet regularly once every calendar quarter.

Duties

Review and act upon application for the procurement and use of sources of ionizing radiation with the hospital. Applications shall be reviewed from the standpoint of radiation safety.

Prescribe specific conditions that may be necessary for the safe handling of any source of ionizing radiation in connection with granting approval of an application.

Review and take appropriate action with regard to violation of the hospital's Radiation Safety Program.

Establish a program for training personnel whose duties may require them to work in the vicinity of radiation sources (nursing, security, and housekeeping) are properly instructed.

Review the Radiation Safety Program on an annual basis to determine that activities involving radiation sources are being conducted safely. The review shall include an examination of records, reports from the radiation safety officer (health physicist), results of inspections, written safety procedures and the adequacy of the hospital's administration.

Review the training and experience of all individuals who use radiation sources (including physicians, technologists, and physicists) and determine that their qualifications are sufficient to enable them to perform their duties safely.

Be familiar with all pertinent regulations.

Recommend remedial action to correct any deficiencies identified in the hospital's Radiation Safety Program.

Maintain written records of all committee meetings, actions, recommendations and decisions.

To institute, implement, and review the ALARA Program at the hospital.

Item 8 Training and Experience

A. Under a broad license, the use of radioactive materials will be under the supervision of the Hospital Radioisotope Committee; Eugene A. Cornelius, M.D. Ph.D., Chairman. This is the the same as under our present license 06-00819-03.

B. Enclosed is Supplement A for Robert E. Peterson, Jr., Radiation Safety Officer for Yale-New Haven Hospital.

YALE-NEW HAVEN HOSPITAL

Personnel Department

TITLE: Health Physicist CODE: 143017

DEPARTMENT: Radiology-Physics CLASSIFICATION: Non-rated exempt

SUMMARY

Under the direction of the Director, Radiological Physics, responsible for the maintenance of radiation safety as required to assure that safety requirements are satisfied, order, store, and maintain records for radioisotopes used in radiation therapy, instruct students, nurses, and attending staff on matters relating to radiation safety.

POSITION DUTIES AND RESPONSIBILITIES

Responsible for overall surveillance of all health physics activities, including personnel and environmental monitoring.

Responsible for consultation service to all departments of the Hospital on matters relating to radiation protection and safety.

Supervise records of receipt, delivery, and shipping of all radioactive materials entering or leaving Yale-New Haven Hospital.

Monitor all devices capable of producing ionizing radiation from the standpoint of the safety of patiers and Hospital personnel. These duties include, but are not limited to: measurement of patient exposure from diagnostic x-ray equipment; measurement of radiation levels in the rooms surrounding x-ray equipment,

radioactivity storage, and patients containing radioactivity; surveying operating rooms following radioactive procedures.

Distribute and process personnel monitoring equipment: maintenance of records of personnel exposure, notification of individuals and their supervisors of exposures approaching the maximum permissible amounts and recommending appropriate remedial action.

Instruct personnel in proper procedures for the use of radioactive materials.

Supervise and coordinate the waste disposal program, incluing keeping of waste, storage, and disposal records.

Maintain a current inventory and perform leak tests on all sealed radioactive sources.

Supervise radioactive-decontamination procedures in case of accidents involving radioactivity, and coordinate with emergency room personnel in the event of a radiation accident.

Review all protocols for use of radioactive materials in humans and supervise the monitoring of all patients who have received a therapeutic amount of radionuclides.

Provide consultation services to the chairman of the Radio-isotope Committee and any other committees that are concerned with the safe and efficacious use of ionizing radiations.

Through membership in scientific organizations, attendance at scientific meetings, and readings of scientific journals, maintain up-to-date knowledge of developments in radiological physics, and introduce new developments into the Yale-New Haven Hospital.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Robert E. Peterson, Jr. Radiation Safety Officer	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
N/A	N/A	N/A

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	1972-76 Purdue University West Lafayette, Indiana	~~semester~~ 10	~~hours~~ 10
b. RADIATION PROTECTION	" " "	10	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	" " "	10	10
d. RADIATION BIOLOGY	" " "	3	--
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Atomic Nos. 3-83	millicurie amounts	University of Cincinnati Cincinnati, Ohio	1 year 1976-77	Radiation Safety Procedures
H-3 Sealed Sources	curie amounts	Medical College of Ohio Toledo, Ohio	2 years 1977-79	
		University of Illinois Urbana, Illinois	2 years 1979-81	
		Yale-New Haven Hospital New Haven, CT	3 years 1981- present	

CURRICULUM VITAE

Eugene Albert Cornelius

Birthdate: November 16, 1926

Marital and Family Status: Married, One Child

Social Security No: 476-42-5258

Education:

1948	B.A., University of Saskatchewan (Biology)
1952	M.D., University of Toronto
1956	M.S., University of Minnesota (Major - Radiology) (Minor - Pathology)
1961-62	Graduate School, Massachusetts Institute of Technology (Molecular Biology)
1966	Ph.D., University of Minnesota Major - Immunology and Physiology Minor - Physical Chemistry Advisor - Robert A. Good, M.D., Ph.D. Professor of Microbiology, Pediatrics, and Pathology

Career:

1952-53	Rotating Internship, Toronto General Hospital
1953-56	Radiology Fellowship, Mayo Clinic
1956-58	Practice of Radiology, Beloit, WI
1958-61	Practice of Radiology, Hermann Hospital, Texas Medical Center, Houston, TX
1961	Associate Director, Department of Radiology, Hermann Hospital (Now University of Texas Medical Center) Design of original and complete neuroradiologic facility.
1967-70	Assistant Professor of Radiology, Yale University School of Medicine.
1967-Pres	Associate Director, Section of Nuclear Medicine, Yale-New Haven Hospital
1970-75	Associate Professor of Diagnostic Radiology (Nuclear Medicine), Yale University School of Medicine
1975-Pres	Associate Professor of Diagnostic Radiology (Nuclear Medicine) with tenure

Awards:

Best academic record of high school graduating class.
Best academic record in B.A. graduating class.
Silver Medal in Medicine for best academic record in first two years of medical school.

Licenses and Certification:

Licensed by National Board of Medical Examiners
Licensed to practice medicine in State of Connecticut
Certified in Radiology, American Board of Radiology, 1956, in Diagnostic Radiology, Therapeutic Radiology, and Nuclear Medicine

Committee Memberships:

1967-Pres	Member, Yale-New Haven Hospital Radioisotope Committee
1971-Pres	Chairman, above Committee
1971-Pres	Member, Yale University Human Investigation Committee
1975-Pres	Member, Yale University Radiation Protection Committee

Society Memberships:

1) Society of Nuclear Medicine
2) American Association of Pathologists
3) Sigma Xi
4) Association of University Radiologists

1. Cornelius, E.A.; Betlack, E.A.: Silo-Filler's Disease. Radiology 74:232-238, 1960.

2. McMullen, F.; Glass, H.; Cornelius, E.: Percutaneous retrograde selective aortography. Texas State J. Med. 56:779-782, 1960.

3. Cornelius, E.A.; Grimm, J.H.; Wallace, G.C.: Cholecystography with Orabilex. Amer. J. Roentgenol. Rad. Ther. and Nuc. Med. 84:1125-1134, 1960.

4. McClendon, J.L.; Anderson, D.E.; Cornelius, E.A.: Cherubism-Hereditary Fibrous Dysplasia of the Jaws. II. Pathologic Considerations. Oral Surgery, Oral Medicine, and Oral Pathology 15:supp. 2, 17-42, 1962.

5. Cornelius, E.A.; Hilgard, H.; Martinez, C.: Further studies on the mechanism of parabiosis intoxication. Fed. Proc. 23:238, 1964 (abstract).

6. Cornelius, E.A.; Yunis, E.; Martinez, C.: Studies on parent-F_1 hybrid parabiosis intoxication. The Physiologist 7:107, 1964 (abstract).

7. Hilgard, H.; Cornelius, E.; Martinez, C.; Good, R.A.: Immune mechanisms in parabiosis intoxication. J. Exp. Med. 119:567-579, 1964.

8. Cornelius, E.A.; Yunis, E.; Martinez, C.: The cause of death in parabiosis intoxication. The Physiologist 8:140, 1965 (abstract).

9. Cornelius, E.A.; Martinez, C.: Transfusion experiments and survival studies in parabiosis intoxication. Proc. Soc. Exp. Biol. & Med. 120:426-432, 1965.

10. Cornelius, E.A.; Yunis, E.; Martinez, C.: Pathologic features of parent-F_1 hybrid parabiosis intoxication. Proc. Am. Assn. Canc. Res. 7:15, 1966. (Abstract)

11. Cornelius, E.A.; Yunis, E.; Martinez, C.: Hematologic features of parabiosis intoxication. Fed. Proc. 25:231, 1966 (abstract).

12. Cornelius, E.A.; Yunis, E.; Martinez, C.: Clinical, hematologic and serologic features of parabiosis intoxication. Transplantation. 5:112-134, 1967.

13. Cornelius, E.A.; Meyer, M.: Syngeneic parabiosis intoxication. Fed. Proc. 26: 640, 1967.

14. Cornelius, E.A.; Martinez, C.; Good, R.A.: Pathology of runting of tolerant mice injected with syngeneic spleen cells. Exp. Hematol. 12:23-24, 1967.

15. Yunis, E.J.; Hong, R.; Greive, M.A.; Martinez, C.; Cornelius, E.; Good, R.A.: Post-thymectomy wasting associated with autoimmune phenomena:
    1. Antiglobulin positive anemia in A and C57BL/6 Ks mice. J. Exp. Med. 125: 947-957, 1967.

16. Cornelius, E.A.; Martinez, C.; Yunis, E.J.; Good, R.A.: Hematologic and pathologic changes in tolerant mice following the injection of syngeneic lymphoid cells. Transplantation 6:33-44, 1968.

17. Cornelius, E.A.: Clinical, hematologic, and pathologic changes following parabiosis of syngeneic tolerant and nontolerant mice. Lab. Invest. 19:282-289, 1968.

18. Cornelius, E.A.; Martinez, C.; Yunis, E.; Good, R.A.: Pathologic features of parabiosis intoxication. Lab. Invest. 19:324-332, 1968.

19. Cornelius, E.A.; Spencer, R.P.: Studies of recovery from acute intestinal irradiation damage through parabiosis. XXIV Internatl. Congress of Physiological Sci. 7:92, 1968.

20. Cornelius, E.A.; McClendon, J.L.: Cherubism-Hereditary fibrous dysplasia of the jaws III. Roentgenographic features. Am. J. Roentgenol., Rad. Ther. and Nuc. Med. 106:136-143, 1969.

21. Spencer, R.P.; Cornelius, E.A.: Tumor and organ uptake of nutrient: relationship to blood flow. Fed. Proc. 28:829, 1969.

22. Cornelius, E.A.; Spencer, R.P.: Studies of the effects of supralethal irradiation through parabiosis. J. Nuc. Med. 10:328-329, 1969.

23. Cornelius, E.A.; Spencer, R.P.: Radioisotopic studies of the pathologic physiology of graft-versus-host reactions. J. Nuc. Med. 10:396-397, 1969.

24. Spencer, R.P.; Cornelius, E.A.: Comparison of radiolabeled nutrient uptake with blood flow: an approach to tumor and organ growth. J. Nuc. Med. 10:440, 1969.

25. Cornelius, E.A.; Yunis, E.; Martinez, C.: Cyclic phenomena in the graft-versus-host reaction. Proc. Soc. Exp. Biol. and Med. 131:680-684, 1969.

26. Cornelius, E.A.; Yunis, E.; Martinez, C.: Depression of erythrocytes maturation as a result of the graft-versus-host reaction. Proc. Soc. Exp. Biol. and Med. 132:564-567, 1969.

27. Pearson, H.A.; Spencer, R.P.; Cornelius, E.A.: Functional asplenia in sickle-cell anemia. New Eng. J. Med. 281:923-926, 1969.

28. Cornelius, E.A.: Protein-losing enteropathy in the graft-versus-host reaction. Transplantation 9:247, 1970.

29. Cornelius, E.A.: Protein-losing enteropathy and other functional changes in the graft-versus-host reaction: comparison with the graft-versus-graft reaction. Exp. Hematology 20:48, 1970.

30. Cornelius, E.A.: Ureteral changes in the graft-versus-host reaction. Exp. Hematology 20:62, 1970.

31. Spencer, R.P.; Cornelius, E.A.; Antar, M.A.; Treves, S.: Testicular entry of radionuclides: use in estimating radiation exposure and following systemic disease. Fed. Proc. 29:247, 1970.

32. Cornelius, E.A.: Papillonephritis, hydroenphrosis and ureteral hyperplasia in the graft-versus-host reaction. Fed. Proc. 29:625, 1970.

33. Cornelius, E.A.: Amyloidosis and renal papillary necrosis in male hybrid mice. Amer. J. Path. 59:317, 1970.

34. Cornelius, E.A.: Animal models of protein-losing enteropathy. J. Nuc. Med. 11:311, 1970.

35. Freedman, G.S.; Treves, S.; Lange, R.C.; Cornelius, E.A.; Brown, R.: Renal transplant evaluation using technetium-DTPA, a gamma camera and a small computer. J. Nuc. Med. 11:320-321, 1970.

36. Pearson, H.A.; Spencer, R.P.; Cornelius, E.A.; Treves, S.; Lange, R.C.: Functional asplenia in sickle cell anemia - a reversible defect. J. Nuc. Med. 11:349-350, 1970.

37. Antar, M.A.; Freedman, G.S.; Cornelius, E.A.; Spencer, R.P.: Intracardiac and intravascular deposition of lung scan macroaggregates. J. Nuc. Med. 11:381-382, 1970.

38. Spencer, R.P.; Pearson, H.A.; Cornelius, E.A.; Antar, M.A.: Major variants in the liver and spleen scans of children. J. Nuc. Med. 11:402-403, 1970.

39. Spencer, R.P.; Touloukian, R.J.; Cornelius, E.A.; Treves, S.: Gut mucosa blood flow: discrepancy between isotope fractionation and microsphere methods. J. Nuc. Med. 11:403, 1970.

40. Cornelius, E.A.; Spencer, R.P.: Nutrient uptake in transplanted tumors: a dual-labeled study relating uptake to blood flow. X Internatl. Canc. Congress Abstracts, pp. 549, 1970.

41. Pearson, H.A.; Cornelius, E.A.; Schwartz, A.D.; Zelson, J.H.; Wolfson, S.L.; Spencer, R.P.: Transfusion reversible functional asplenia in young children with sickle-cell anemia. New Eng. J. Med. 283:334, 1970.

42. Spencer, R.P.; Cornelius, E.A.; Kase, N.G.: Breast secretion of ^{99m}Tc in the amenorrhea-galactorrhea syndrome. J. Nuc. Med. 11:467, 1970.

43. Cornelius, E.A.: Chronic graft-versus-host reactions: induction of tumors and the characteristics of such tumors. Exp. Hematology 21:26, 1970.

44. Cornelius, E.A.: Long-term study of neonatally thymectomized mice: induction of tumors and autoimmune changes. Exp. Hematology 21:32-33, 1970.

45. Nuland, S.B.; Cornelius, E.A.; Spencer, R.P.: Scan evidence of organ involution and improvement of hypersplenism in Hodgkin's disease following splenic artery ligation. J. Nuc. Med. 11:693, 1970.

46. Cornelius, E.A.: Induction of tumors and autoimmune changes in neonatally thymectomized mice. Fed. Proc. 30:302, 1971.

47. Cornelius, E.A.: Induction of tumors and autoimmune changes in neonatally thymectomized mice. Invest. Radiol. 6:343, 1971.

48. Spencer, R.P.; Cornelius, E.A.: Radionuclide studies of blood flow in a transplantable mouse mammary carcinoma. J. Nuc. Med. 12:465, 1971.

49. Spencer, R.P.; Treves, S.; Cornelius, E.A.; Antar, M.A.: Radionuclide entry and accumulation by the testes: clinical and experimental studies. J. Nuc. Med. 11: 643, 1970.

50. Cornelius, E.A.: Induction of tumors in neonatally thymectomized mice. Transplantation 12:531, 1971.

51. Cornelius, E.A.: Further studies of autoimmune changes and tumors in neonatally thymectomized mice. Exp. Hematology 22:64, 1972.

52. Cornelius, E.A.: Chronic graft-versus-host reactions: induction of both donor and host type tumors and other sequelae. Exp. Hematology 22:87, 1972.

53. Cornelius, E.A.: Induction of tumors and autoimmune changes in thymectomized mice. Amer. J. Roentgenol., Rad. Ther. & Nuc. Med. 114:784, 1972.

54. Cornelius, E.A.: Comparison of changes in the graft-versus-host reaction and post-thymectomy state. Fed. Proc. 31:930, 1972.

55. Cornelius, E.A.: Increased incidence of lymphomas in thymectomized mice - evidence for an immunological theory of aging. Experientia 28:459, 1972.

56. Cornelius, E.A.: Induction of both host and donor type tumors as a result of the graft-versus-host reaction. Transplantation 13:569, 1972.

57. Cornelius, E.A.: Rapid immunological induction of murine lymphomas: evidence of a viral etiology. Science 177:524, 1972.

58. Cornelius, E.A.: Rapid viral induction of murine lymphomas in the graft-versus-host reaction. J. Exp. Med. 136:1535, 1972.

59. Cornelius, E.A.: Viral etiology of immunologically induced lymphomas. Transplantation Proc. 5:957, 1973.

60. Cornelius, E.A.: Development of tumors as a result of the graft-versus-host reaction. Exp. Hemat. 1:135, 1973 (Invited review article).

61. Cornelius, E.A., and Aponte, L.J.: Sex-Linked abrogation of the graft-versus-h host-reaction. Transpl. 17:128, 1974.

62. Cornelius, E.A.: Effect of sex-linked abrogation of the graft-versus-host reaction on pathologic changes including tumor induction. Fed. Proc. 33:60, 1974.

63. Cornelius, E.A.: Comment on graft-versus-host-reactions in immunotherapy by David Katz. Symposium on interaction of radiation and host immune defense mechanisms in malignancy. Greenbrier, West Virginia, March 23-27, 1974.

64. Cornelius, E.A.: Comparison of immunologically induced and radiation induced tumors in mice. Invest. Rad. 9:321, 1974.

65. Cornelius, E.A.: Sex-linked abrogation of the graft-versus-host-reaction effect on pathologic features, including tumor induction. J. Nat. Cancer Inst. 53:759,. 1974.

66. Cornelius, E.A.: Sex-linked attenuation of the graft-versus-host-reaction: Effect on tumor induction and type. Proc. XI International Cancer Congress, Florence, 1974.

67. Cornelius, E.A.: Immune mechanisms in experimental leukemia. Proc. XI International Cancer Congress, Florence, 1974 (by invitation).

68. Cornelius, E.A.: Immunology, virology and cancer. Seminars in Roentgenology 10:53, 1975 (by invitation).

69. Cornelius, E.A. and Gray, D.G.: Inhibition of graft-versus-host reaction tumor induction by streptovaricin, a reverse transcriptase inhibitor. Fed. Proc. 34:960, 1975.

70. Cornelius, E.A.: Two year studies in neonatally thymectomized mice. Fed. Proc. 35:625, 1976.

71. Cornelius, E.A.: Increased incidence of spontaneous lymphomas in neonatally thymectomized mice. In Prevention and Detection of Cancer, Vol. I, No. 1. Etiology. N. Nieburgs, Ed., Marcel Dekker, NY, NY 1977, pp. 345-351.

72. Cornelius, E.A.: Tagged thymocytes for tumor localization: Experimental Study. Invest. Rad. 11:402, 1976.

73. Cornelius, E.A.: Cellular immunotherapy of post-thymectomy spontaneous lymphomas. Fed. Proc. 36:1290, 1977.

74. Cornelius, E.A.: Tumor induction in host-versus-graft disease. 1. Clinical and pathological features. Am. J. Path. 90:675, 1978.

75. Cornelius, E.A.: Tumor induction in host-versus-graft disease. Fed. Proc. 37:412, 1978.

76. Cornelius, E.A.: Tumor induction in host-versus-graft disease. II. Immunologic and virologic features. Fed. Proc. 38:992, 1979.

77. Cornelius, E.A.: Increased incidence of lymphomas in survivors of the host-versus-graft disease syndrome. Experientia 35:1672, 1979.

78. Cornelius, E.A.: Treatment of spontaneous murine lymphomas with syngeneic lymphoid cells. Experientia 35:1668, 1979.

79. Cornelius, E.A.: Immunologic and virologic studies of host-versus-graft disease - a lymphomagenic syndrome. Invest. Rad. 14:394, 1979.

80. Cornelius, E.A.: Tumor induction in host-versus-graft disease: immunologic and virologic features. J. Reticuloendoth. Soc. 28:1, 1980.

81. Cornelius, E.A.: "Activities of the Society of Nuclear Medicine and Impact of Low Level Waste Legislation on Nuclear Medicine". Address to Symposium on Low Level Radioactive Waste Management, March 27, 1980, Yale University.

82. Cornelius, E.A.: Immunologic and virologic studies of F. antiparental ($F_1 \rightarrow P$) runt disease. Exp. Hematol. 8:Suppl. 7, 24, 2980.

83. Cornelius, E.A.: Combined nuclear medicine and ultrasound studies in the evaluation of suppressed thyroid tissue. Clin. Nuc. Med. 7:8, 1982.

84. Cornelius, E.A.: Nuclear medicine imaging in rhabdomyolysis. Clin. Nuc. Med. 7:462, 1982.

85. Cornelius, E.A. and Atterburg, C.: Problems in the imaging diagnosis of hepatoma. Clin. Nuc. Med. 9:30, 1984.

86. Cornelius, E.A.: Sensitivity of sonography and cholescintigraphy in acalculous cholecystitis. Letter to the Editor. AJR, 1984. (In Press)

87. Auerbach, R.D., Kohorn, E.J., Cornelius, E.A., and Chambers, J.T.: Splenosis: a complicating factor in total abdominal hysterectomy. (In Press)

Item 9

1. Survey Meters

a. Manufacturer's name: Eberline

Manufacturer's model number: E-530

Number of instruments available: 2

Range: 0 to 200 mR/hr

b. Manufacturer's name: Eberline

Manufacturer's model number: E-520

Number of instruments available: 1

Range: 0 to 2000 mR/hr

c. Manufacturer's name: Eberline

Manufacturer's model number: E-120G

Number of instruments available: 1

Range: 0 to 1000 mR/hr

d. Manufacturer's name: Eberline

Manufacturer's model number: Rad Owl RO-1

Number of instruments available: 1

Range: 0 to 500 R/hr

e. Manufacturer's name: Keithley

Manufacturer's model number: 36100

Number of instruments available: 1

Range: 0 to 20 R/hr

f. Manufacturer's name: Victoreen

Manufacturer's model number: Thyac III 490

Number of instruments available: 1

Range: 0 to 200 mR/hr

g. Manufacturer's name: Civil Defense CDV-700

Manufacturer's model number: 6A

Number of instruments available: 2

Range: 0 to 50 mR/hr

2. Dose Calibrators

a. Manufacturer's name: Capintec, Inc.

Manufacturer's model number: CRC-17

Number of instruments available: 2

b. Manufacturer's name: Capintec, Inc.

Manufacturer's model number: CRC-16

Number of instruments available: 1

3. Instruments used for diagnostic procedures

a. Type of instrument: Whole body procedures

Manufacturer's name: Siemens

Manufacturer's model number: Pho/Con 192 scanner

b. Type of instrument: Gamma camera

Manufacturer's name: Siemens/Searle

Manufacturer's model number: LFOV with microdot

c. Type of instrument: Thyroid uptake probe and well

Manufacturer's name: Kimble Instruments, Inc.

Manufacturer's model number: Thyro-count

d. Type of instrument: Mobile camera

Manufacturer's name: Technicave

Manufacturer's model number: 550 V.P.

e. Type of instrument: Gamma Camera

Manufacturer's name: Baird

Manufacturer's model number System 77:

f. Type of instrument: Gamma Camera

Manufacturer's name: Siemens

Manufacturer's model number: Mobile LEM

g. Type of instrument: Gamma Camera

Manufacturer's name: Siemens

Manufacturer's model number: 21C-37

Number of instruments: 2

h. Type of instrument: Gamma Camera/ECT

Manufacturer's name: General Electric

Manufacturer's model number: 400 AT-star

Number of instruments: 2

4. Other instrumentation

a. Type of instrument: Xenon Delivery System/Trap

Manufacturer's name: Pulmonex

Manufacturer's model number: 130-500

b. Type of instrument: Computer

Manufacturer's name: MDS A2

c. Type of instrument: Computer

Manufacturer's name: Digital

Manufacturer's model number: PDP-11

d. Type of instrument: single channel analyzer, gamma counter

Manufacturer's name: Nuclear Chicago

Manufacturer's model number: 27354

Item 11

Facilities and Equipment

Nuclear Medicine

The core of the Nuclear Medicine facilities is located on the second floor of the new facility. Enclosed are diagrams showing the location of the nuclear medicine core on the second floor, overall floor plan for the second floor Nuclear Medicine department, detail plan of the radiopharmacy, floor plan of Nuclear Cardiology, and the satellite nuclear cardiology room.

The floor above the Nuclear Medicine facility contains surgical recovery rooms and surgical care unit, the floor below contains the Emergency Room's, Medicine, Surgery, and Satellite Radiology Services.

The diagram for the Radiopharmacy Laboratory details the location of the fume hood and work areas. Furnishings for this room are manufactured by the Kewaune Company of Adrian, Michigan. Model number and shielding specifications are indicated on the diagram. The fume hood (1080 CFM EXHAUST) will be used to store therapy doses (greater than 30 millicuries) of Iodine-131 in the liquid form, Xenon-133, and Technetium-99m generators. Each of these aforementioned radiopharmaceuticals will be kept in their perspective lead pigs as provided by the vendor. The radiopharmaceuticals which are prepared daily from kits are in individual lead pigs, and stored behind additional lead shielding.

Radioactive waste is separated into short term and long term decay, and stored in lead lined cabinets in the radiopharmacy laboratory. At the end of each week the contents are boxed,

marked as to short or long half-life, dated, and transferred to lead lined storage cabinets to await decay to background levels. Before the boxes are discarded into the regular trash they are monitored to be sure they are at background levels, and this measurement is then recorded in a log book. Effluent discharges through the sink will be in strict compliance with 10 CFR 20.303. L-block, lead pigs, syringe shields, disposable gloves, and long handle forceps are available.

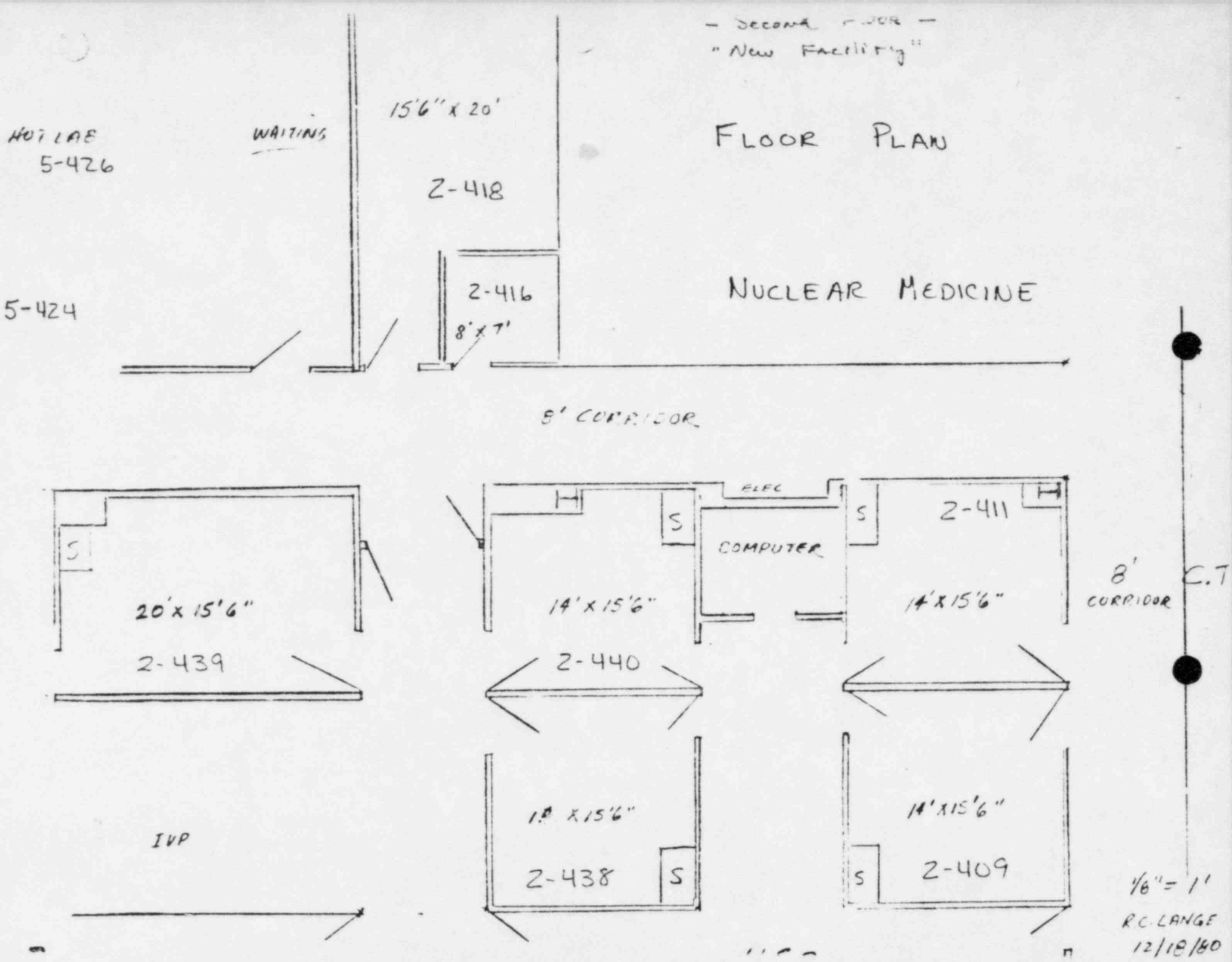
The core area of nuclear medicine (imaging rooms and radiopharmacy laboratory) is under negative pressure. Ventilation is a "once through" non-recirculating system.

The procedures and precautions for use of radioactive gases are described in item 21.

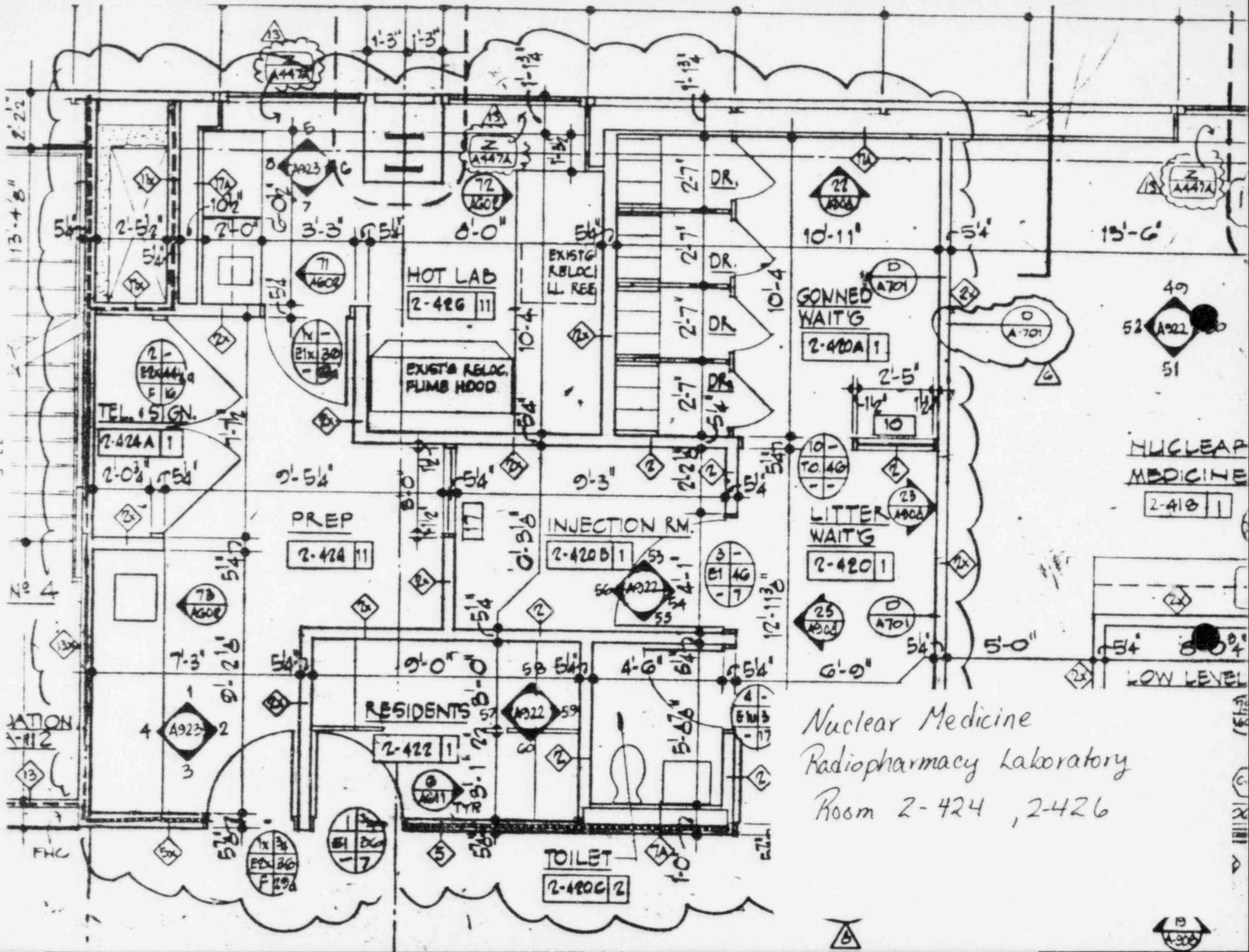
Nuclear Cardiology is operated on the second floor of the Fitkin Building. Radionuclides used in the imaging rooms are Technetium-99m and Thalium-201. There is also a satellite radiopharmacy laboratory where the radiopharmaceuticals are stored. L-block, lead pigs, syringe shields, disposable gloves, and long handle forceps are available. Nuclear Cardiology has a room on the fifth floor of the nuclear medicine, where Technetium 99m and Thalium-201 are used and stored. The fifth floor of the new facility houses both the intensive care and the cardiac intensive care units Protective devices as described previously, are available on the fifth floor (room 5-432). Survey meters and dose calibrators are located in each of the three areas of nuclear medicine (central radiopharmacy laboratory, Fitkin-2, and room 5-432). The survey meters, dose calibrators, and various imaging devices are described in item 9.

Clinical Laboratories

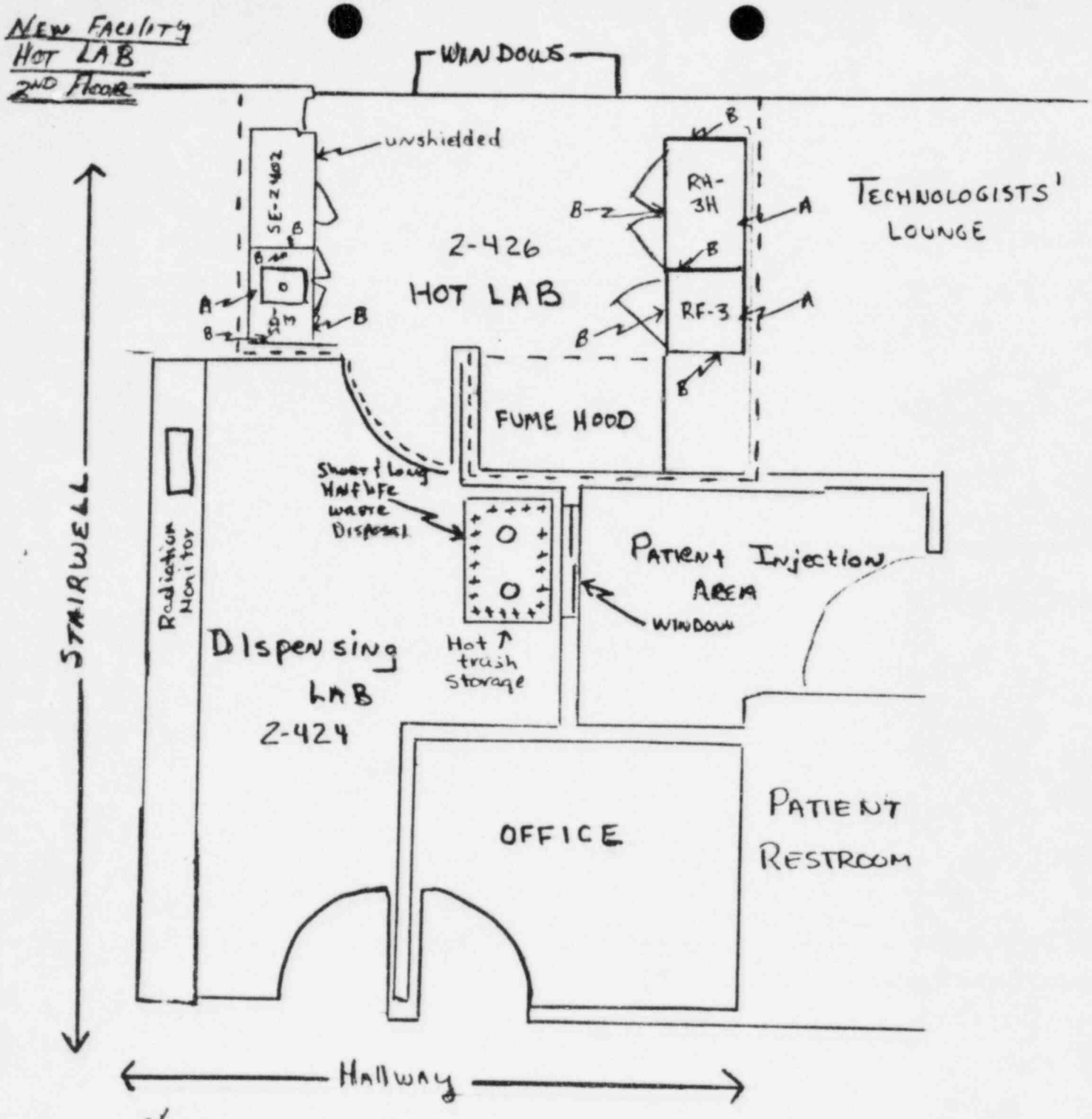
The clinical laboratories are located and will be located on the fourth, fifth, and sixth floors of the Clinic Buildings. Presently this area of the hospital is under constant renovation. These laboratories used the prepared radioimmunoassay kits, which contain minute amounts of iodine-125, hydrogen-3, carbon-14, and cobalt-57 in a bound form. No iodinations are being done; if iodinations are planned this will be approved by the Hospital Radioisotope Committee. Appropriate facilities and equipment will be installed prior to use. Counting equipment, survey meters, disposable gloves, and other items are available. Efficient discharges through the sinks will be in compliance with 10 CFR 20.303.


- SECOND FLOOR -
"New Facility"
FLOOR PLAN
NUCLEAR MEDICINE
HOT LAB
5-426
WAITING
15'6" X 20'
Z-418
Z-416
8' X 7'
5-424
8' CORRIDOR
S
20' x 15'6"
Z-439
ELEC
COMPUTER
14' X 15'6"
Z-440
Z-411
8'
CORRIDOR
C.T
IVP
14' X 15'6"
Z-438
Z-409
1/8" = 1'
R.C. LANGE
12/18/80

11-4

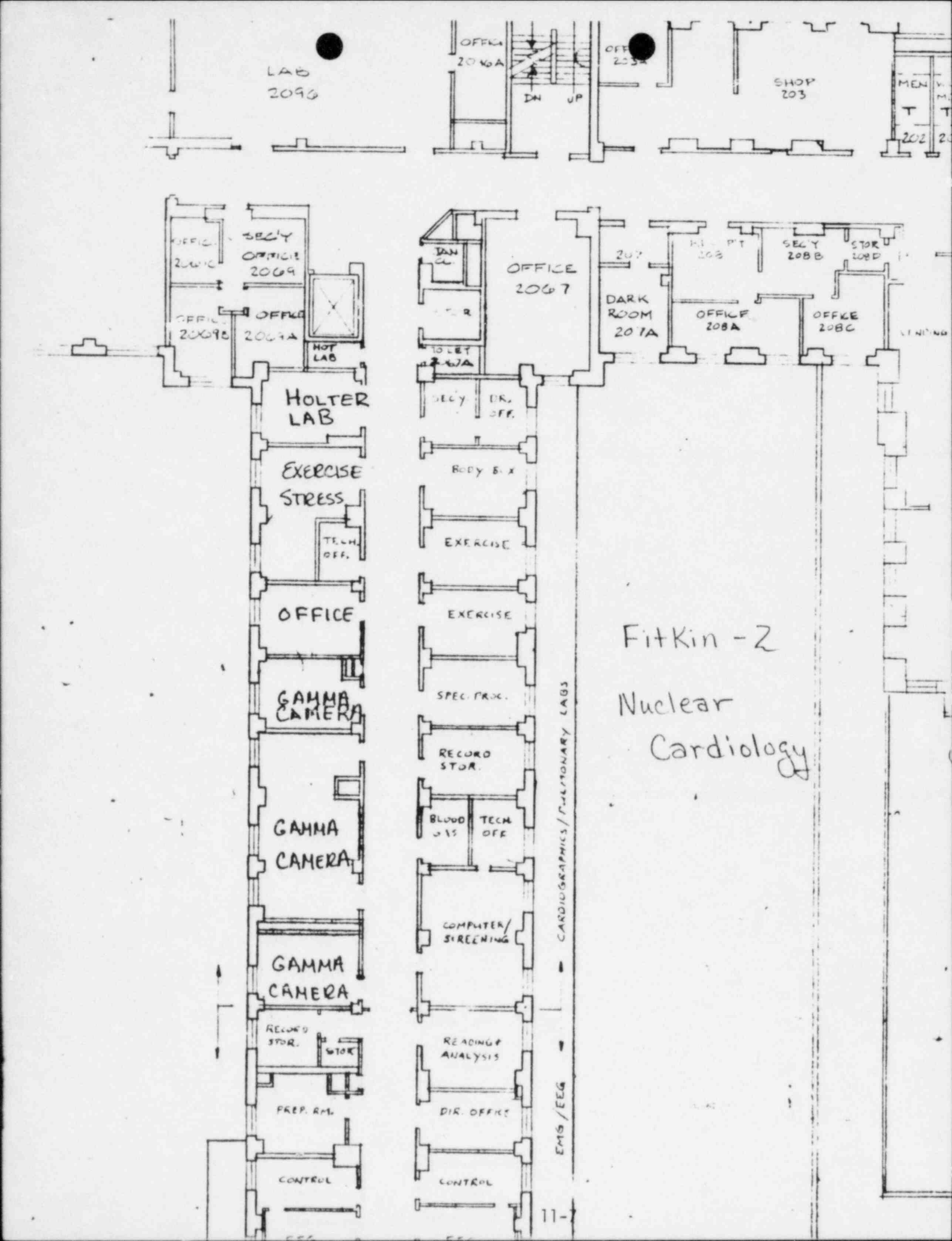


Nuclear Medicine
Radiopharmacy Laboratory
Room 2-424, 2-426



NOTES: --- = 1/16" Lead Shielding
A or +++ = 1/4" Lead Shielding
B = 1/2" Lead Shielding

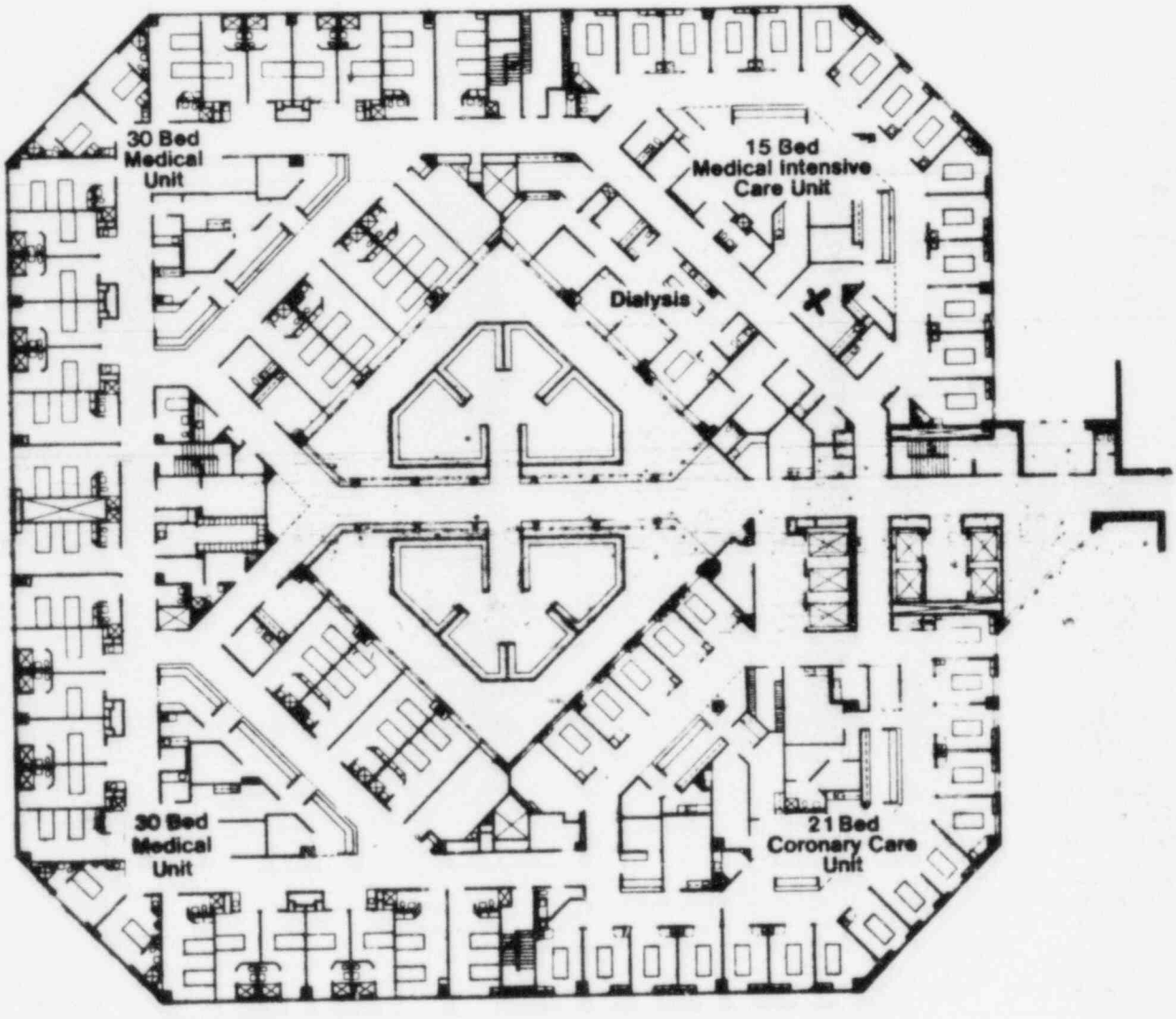
Modules RH-3H, RF-3 AND SD-3 have 1/2 lead shielding on the top AND 1/4" lead shielding on the bottom


LAB
2096
OFFICE
2096A
DN
UP
SHOP
203
MEN
202
OFFICE
2069C
SEC'Y
OFFICE
2069
OFFICE
2069B
OFFICE
2069A
HOT
LAB
HOLTER
LAB
EXERCISE
STRESS
TECH.
OFF.
OFFICE
GAMMA
CAMERA
GAMMA
CAMERA
GAMMA
CAMERA
RECORD
STOR.
STOR.
PREP. RM.
CONTROL
EEG
DAN
OFFICE
2067
TOILET
206A
SEC'Y
DR.
OFF.
BODY BOX
EXERCISE
EXERCISE
SPEC. PROC.
RECORD
STOR.
BLOOD
DRAW
TECH.
OFF.
COMPUTER/
SCREENING
READING/
ANALYSIS
DIR. OFFICE
CONTROL
CARDIOGRAPHICS/PULMONARY LABS
EMG/EEG
207
DARK
ROOM
207A
OFFICE
208A
OFFICE
208C
SEC'Y
208B
STOR
208D
FitKin - 2
Nuclear
Cardiology

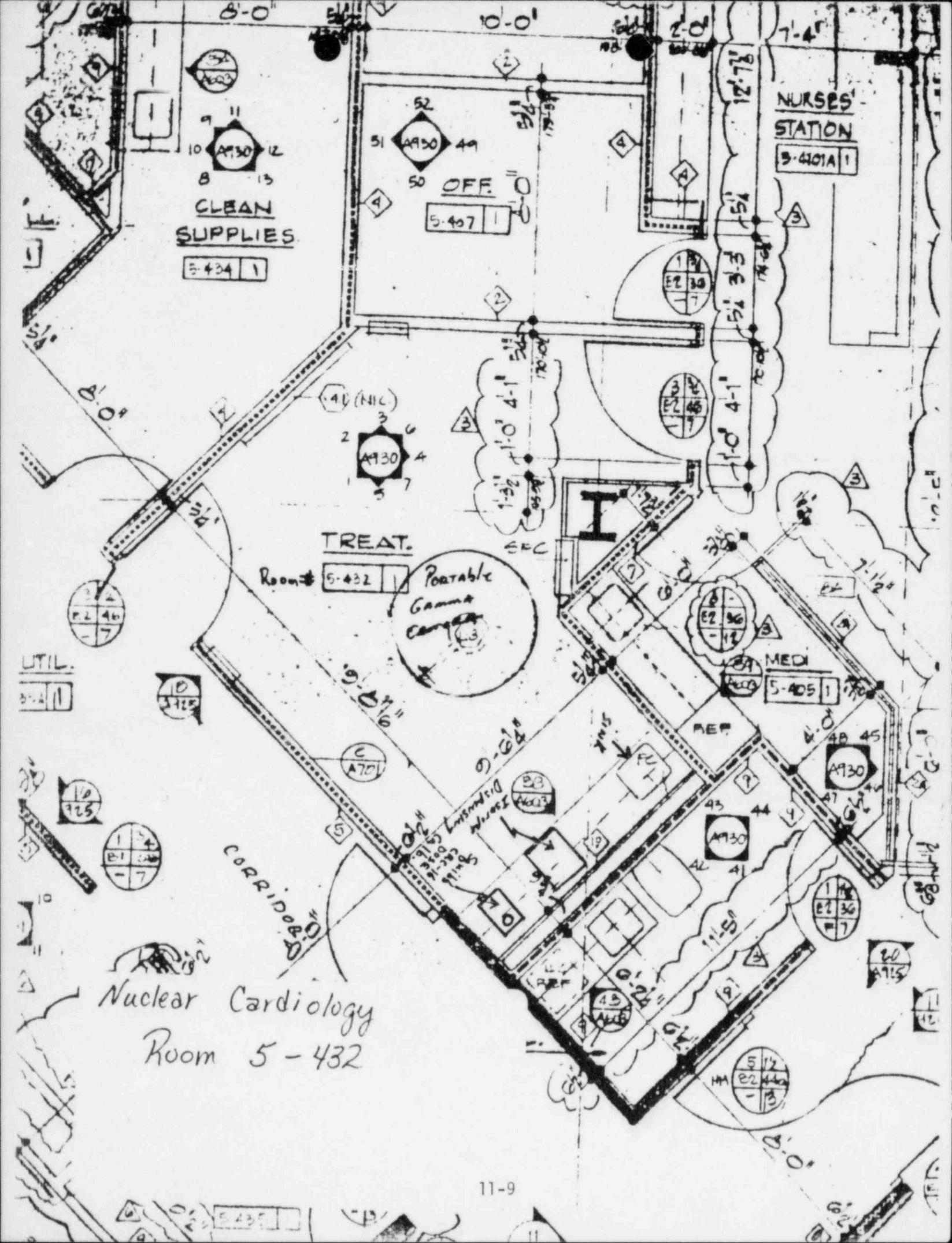
"NEW FACILITY"

Fifth Floor

Medicine



X = Room 5-432


NURSES' STATION
5-410 1A 1
OFF.
5-407 1
CLEAN SUPPLIES
5-434 1
TREAT.
Room # 5-432 1
Portable Gamma Camera
MED.
5-405 1
UTIL.
CORRIDOR
Nuclear Cardiology
Room 5-432

Item 12 Personnel Training Program

Radiation safety lectures will be given to hospital personnel who work with or in the near vicinity of radioactive materials. These lectures will be formal, and will be part of the continuing education of the hospital personnel. Depending upon job duties, the type of training will vary. Personnel training will follow closely the draft regulatory guide "Radiation Protection Training for Personnel Employed in Medical Facilities" Division 8, January 1984.

Comprehensive Radiation Safety Courses are given to nuclear medicine, radiation therapy, and diagnostic radiology technology programs. All nurses who work with the brachytherapy and radiopharmaceutical therapy are given a comprehensive safety lecture on radiation safety. The basic radiation safety lecture has the following format:

1. All terms of the license pertinent to radiation safety.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material.
4. Radiological safety procedures appropriate to their respective duties.
5. Pertinent NRC regulations.
6. Rules and regulations of the license.
7. Obligation to report unsafe conditions to the radiation safety officer.
8. Appropriate responses to emergencies or unsafe conditions.
9. Right to be informed to their radiation exposures.

10. Locations where the license has posted or made available notices, copies of pertinent regultions, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Item 13 Radioactive Material Procurement Instructions

The Purchasing Department will not honor a routine requisition for radioactive material unless it is approved by the Radiation Safety Officer.

The procedure for ordering a radioisotope on a routine requisition will be as follows:

1. Fill out standard purchase requisition. Mark it "Radioactive Material."
2. On purchase requisition, spell out clearly "Millicuries" or "Microcuries".
3. Forward the requisition to the Radiation Safety Officer for approval. The Radiation Safety Officer will forward the requisition to the Purchasing Department.
4. Radioisotopes purchased with Yale University grants must still be approved by the Hospital Radiation Safety Officer. After the requisition has been sent then forward to Yale University Health Physics Division.
5. Receiving Department will automatically forward all radioactive shipments to the respective departments.
6. During off hours, all radioactive shipments are stored in the Nuclear Medicine Radiopharmacy Laboratory until the next working day.

Yale-New Haven Hospital Memorandum

To: All Security Personnel

From: Robert E. Peterson, Jr., Radiation Safety Officer

Subject: Receipt of Packages Containing Radioactive Material

Any radioactive shipments that arrive after normal working hours and on weekends shall be signed for by the Security guard on duty and taken immediately to the Radiopharmacy Laboratory (Room 2-424). Unlock the door, place the package on the counter, and relock the door. If the package appears to be damaged immediately contact the Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

Radiation Safety Officer: Robert E. Peterson, Jr.

Office Phone: 2950

Home Phone: 481-5182

Item 14

Yale-New Haven Hospital

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O.# _____ SURVEY DATE _____ TIME _____

   SURVEYOR _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ PUNCTURED _____ STAINS _____ WET

   _____ CRUSHED _____ OTHER _____

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

4. MEASURED RADIATION LEVELS: a. Package surface _____ mR/hr

   b. 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 = _____ DPM
   eff = ( )

   b. Final source container _____ CPM = _____ DPM
   eff = ( )

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ MR/hr,CPM above Bkg.

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

9. DISPOSITION OF PACKAGE AFTER INSPECTION: _____

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

F. 2179 (New 1/78)

Item 15

A. Procedures for Obtaining Permission to Use Radioactive Materials

1. To obtain approval for the use of radioisotopes in humans under the Yale-New Haven Hospital's broad medical license, obtain application forms entitled, "Application for Clinical Use of Radioisotopes" from the Radiation Safety Officer, Radiological Physics. These must be filled out (with 11 copies) and returned to the Chairman of the Radioisotope Committee. The applicant should indicate both a maximum amount to be on hand at one time and a maximum amount to be purchased in a given time interval (2 years or less). Depending on the case, approval will be given for a purchase and/or a possession limit. Only one radioisotope should be applied for on each form.

These forms are circulated to the Radioisotope Committee, and when approved the requisition is sent to the Radiological Physics Office. A copy of the application and of the requisition is then sent to the applicant for his files. It should be noted that only one application for a given project is necessary.

2. Radioisotope Committee approval of any application will expire 24 months from the date of application. A renewal application must be submitted at this time.

3. Most radioisotopes for human use are covered by the Hospital's "Broad Specific License" and can be ordered without further NRC approval. This covers moderate amounts of any radioisotope from atomic number 3-83. Small quantities of tritium (H-3) may be ordered in the same manner. For Radioisotopes and uses not covered by the Hospital's License, the Radioisotope Committee and the NRC must both approve.

All radioactive radioisotopes will be delivered to Yale-New Haven Hospital Receiving Room. During normal working hours, Receiving will deliver the shipment to the respective department; shipments coming to the Receiving Room at other hours will be delivered to the Radiopharmacy Laboratory. The responsible clinician will be notified.

4. Disposition of Isotopes: Each clinician must maintain a written record, available for inspection, of the disposition of the isotopes he receives - stored, decayed, disposed of, etc. See 10 CFR 20 for approved disposal methods, or call the Radiation Safety Officer for advice on other problems. You will note that excreta discharged into the sewage by patient is exempt from the requirements 10 CFR 20. This excreta, however, contributes to the total radioactivity released to the sewage by the Medical Center. The Radioisotope Committee requires, therefore, that a record be kept, in conjunction with the regular disposal records, of the amount of such activity released to the sewer. If an estimate of this quantity cannot be made, the length of time the patient was in the hospital should be noted. In addition, a record of the quantity of radioisotope administered to each patient is required in order to facilitate control of inventories and possession limits. The Radiation Safety Officer will be happy to discuss the procedures of other radioisotope users in order to make this bookkeeping as painless as possible.

5. An approved clinician must not loan or give radioisotopes to another clinician unless the new application for the radioisotope

has been approved by the Committee. If the second clinician has not been approved by the Committee the person approved for that particular application must be the responsible clinician.

6. When a project has been completed, the data obtained in the experimental or non-routine use of radioisotopes should be submitted to the Committee.

B. Lab coats and disposal gloves must be worn at all times when handling radioactive materials. Lab coats are worn only in these areas, and not to other areas of the Hospital. Disposal gloves must be changed frequently to avoid contamination.

C. Classification of Facilities and Sources of Ionizing Radiation

1. Laboratory Areas

Type 3: Laboratories which are specifically designed for handling high levels of activity or highly toxic radioactive materials. They incorporate special apparatus equipment, materials of contruction and construction designed to limit the spread of contamination and to assist in maintaining high standards of laboratory hygiene.

Type 2: Laboratories which handle intermediate levels of activity or radioactive materials of intermediate toxicity. This type of laboratory incorporates many features being omitted.

Type 1: Laboratories intended for use with only low levels of toxicity or activity. This type of laboratory is usually one which has a few special features to accomodate work with radioactive materials.

Type 0: Laboratories in which the use of radioactive materials is limited to small tracer amounts. Here the activity shall not exceed the limits specified for Type 0 laboratories.

In a hospital setting, where it is very unlikely that radioactive materials will be used in quantities to classify a laboratory either as type 3 or 2. If and when there is a need for this type of operation, the Hospital Radioisotope Committee will be actively involved.

2. Generator Areas

Class A: High Energy Accelerators, X-Ray Generators; Radioisotopic Teletherapy Devices.

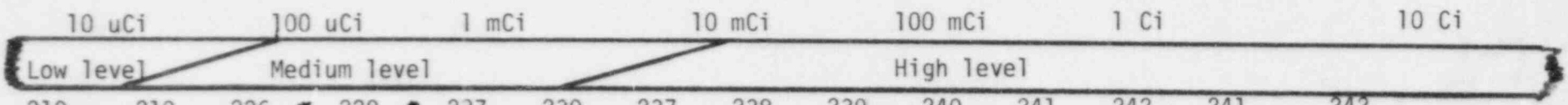
Class B: Those areas which contain generators rated below 250 kV that are housed in specially designed facilities.

Class C: Mobile x-ray machines; mobile isotopic devices; x-ray diffections; and other analytical equipment.

Class D: Areas where device not ordinarly considered as emitting ionizing radiation.

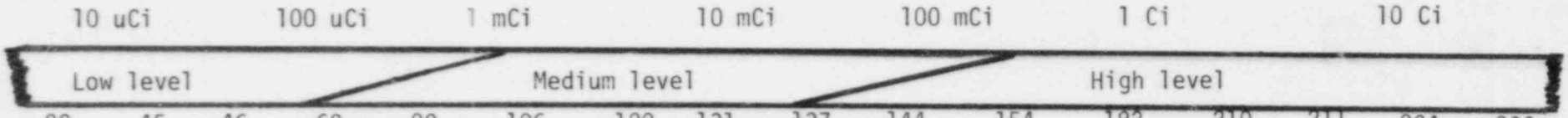
RELATIVE HAZARDS OF VARIOUS RADIOISOTOPES

Group 1. Very high hazard



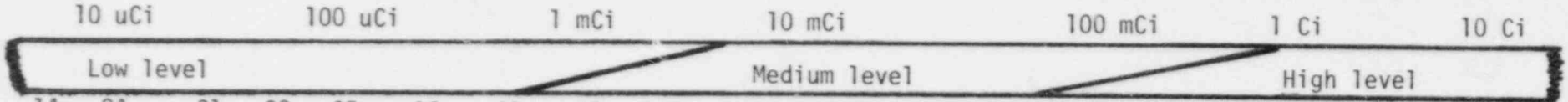
^{210}Pb*, ^{210}Po, ^{226}Ra*, ^{228}Ra*, ^{227}Ac, ^{230}Th, ^{237}Np, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu, ^{242}Pu, ^{241}Am*, ^{242}Cm

Group 2. High Hazard



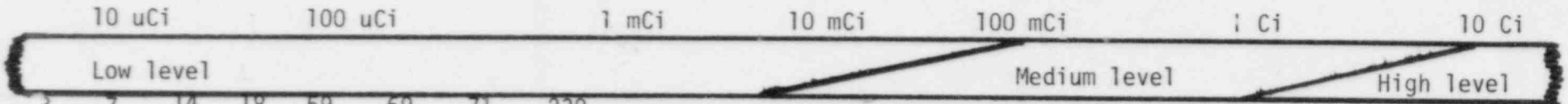
^{22}Na*, ^{45}Ca, ^{46}SC*, ^{60}Co*, ^{90}Sr, ^{106}Ru*, ^{129}I, ^{131}I*, ^{137}Cs, ^{144}Ce*, ^{154}Eu*, ^{182}Ta*, ^{210}Bi, ^{211}A+, ^{224}Ra, ^{233}U

Group 3. Medium Hazard



^{14}C, ^{24}Na*, ^{31}Si, ^{32}P, ^{35}S, ^{36}Cl, ^{42}K*, ^{47}Sc, ^{48}V*, ^{51}Cr*, ^{54}Mn*, ^{56}Mn*, ^{55}Fe, ^{59}Fe*, ^{64}Cu*, ^{65}Zn*, ^{72}Ga*, ^{76}As*, ^{86}Rb+, ^{89}Sr, ^{90}Y, ^{91}Y, ^{95}Zr*, ^{95}Nb*, ^{99}Mo*, ^{103}Ru*, ^{105}Rh*, ^{103}Pd, ^{105}Ag, ^{111}Ag, ^{109}Cb*, ^{113}Sn*, ^{127}Te*, ^{129}mTe*, ^{140}Ba*, ^{140}La*, ^{143}Pr, ^{147}Pm, ^{151}Sm, ^{166}Hu*, ^{170}Tm*, ^{177}Lu*, ^{183}Re*, ^{190}Ir*, ^{192}Ir*, ^{191}Pt*, ^{193}Pt*, ^{196}Au*, ^{198}Au*, ^{199}Au*, ^{200}Tl*, ^{202}Tl*, ^{204}Tl, ^{203}Pb*, ^{220}Rn, ^{235}U, ^{3}H+

Group 4. Low Hazard



^{3}H, *^{7}Be, ^{14}C, ^{18}F, ^{59}Ni, ^{69}Zn, ^{71}Ge, ^{238}U, Natural Thorium, Natural Uranium, Noble Gases

* Emits gamma radiation in significant amounts.
\+ Organic Materials

Classification of Laboratories for Handling Radionuclides

Group of Radionuclide	Type of Laboratories			
	Type 3	Type 2	Type 1	Type 0
1	>1mCi	10 uCi to 1mCi	0.1uCi to 10uCi	<0.1uCi*
2	>100mCi	100uCi to 100mCi	1uCi to 100uCi	<1uCi
3	>1Ci	10mCi to 1Ci	10uCi to 10mCi	<10uCi
4	>100Ci	1Ci to	100uCi	

*Excluding any alpha emitters.

Modifying factors for activities in above classification:

Procedure	Factor
Storage (Stock solution)	100
Very Simple Wet Operations	10
Normal Chemical Operations	1
Complex Wet Operation With Risk of Spill	0.1
Simple Dry Operation and Work With Volatile Radioactive Compounds	0.1
Dry and Dusty Operations	0.01

D. The preparation of radiopharmaceuticals are conducted behind a shielded L-block with lead blocks surrounding the shield. Remote handling tools are available at all times (such as forceps and tongs). If the material is volatile, the work is performed in a fume hood. Syringe shields are used throughout the process from the preparation to the administration. The various radiopharmaceuticals are stored in various lead pigs. The individual syringes are stored in lead shielded syringe holders. If syringes shields cannot be used, other methods will be used to minimize personnel exposure.

E. The preparation and assay of patient doses are done in the morning. The activity of the patient doses are standardized prescribed amounts. No dose will be used if the activity is greater than $\pm$ 10% of the standard. Pediatric doses are based upon the weight of the patient. If the dose differs by more than $\pm$ 10%, it is not administered to the patient. These checks are done with the dose calibrator. The therapy dose must be within $\pm$ 10% of the physician's request. The dose is checked with the dose calibrator prior to the administration.

F. Transport of radioactive materials must be done in unbreakable, spillproof, lead carriers. Depending on the type and activity of the radioactive material, it can either be transported by a hand carrier or on a cart with a lead pig. Radioactive materials in a liquid form that are transported must be placed on absorbent pads. Disposal gloves must be worn whenever handling radioactive materials. All transport containers must be labeled in accordance with State and Federal Regulations.

G. Radioactive materials are kept in containers, and are properly marked with the radionuclide, name of compound, date, activity and radiation level, if applicable. Areas in which radioactive materials are used or stored must be controlled to prevent any unnecesssary exposure to personnel. In order to assure good area controls, the methods listed below must be employed:

a. High Radiation Area

b. Radiation Area

c. Airborne Radioactivity Area

d. Caution Radioactive Materials

Areas will be posted and marked with respect to the appropriate regulations (10 CFR 20, Section 20.203, Paragraphs A through F).

H. Film badges and TLD rings are used as personnel monitoring devices. These devices are obtain through the Radiation Safety Officer through the Radiolgoical Physics Office. Film badges and TLD rings are distributed through the film badge deputies. Any department that have occupational radiation workers, a film badge deputy is appointed. Personnel monitoring devices are available on the first working day of the month. The individuals return their devices to their film badge deputy who then forwards to the Radiation Safety Officer. The exposure results are kept on file in the Radiation Safety Office, and a copy is sent to the respective deputy. The Radiation Safety Officer has badges and TLDs available at all times in case of a new employee or if a badge is lost or ruined. When the badge is not being worn, the individuals are instructed to keep the device in a control

area in their departments. The control dosimeters are kept in a low radiation area to monitor the background of the Hospital. Enclosed is the personnel policy regarding personnel monitoring devices.

PERSONNEL POLICY & PRACTICE

PERSONNEL MONITORS FOR EMPLOYEES OCCUPATIONALLY EXPOSED TO IONIZING RADIATION

September 1, 1976

I. Policy

It is the policy of Yale-New Haven Hospital to comply with State and Federal regulations regarding the provision and use of personnel montitoring devices by Hospital employees occupationally exposed to ionizing radiation.

II. Application

Any Hospital employee occupationally exposed to ionizing radiation who, in any calendar quarter, receives or is likely to receive a dose in excess of 25% of the applicable maximum permissible dose as recommended by the National Council on Radiation Protection and Measurements (NCRP), and incorporated in State and Federal regulations (see Exhibit "A").

III. Administrative Guidelines

A. Film badges will be issued by the Hospital Health Physicist to:

1. All technical and professional staff in the the departments of Diagnostic and Therapeutic Radiology;
2. Physicians and personnel who are routinely exposed to x-rays from procedures, such as cardiac catheterization and pacemaker implants;
3. Physicians and other personnel who routinely handle therapeutic quantities of radioactive materials, such as radium in Obstetrics-Gynecology; and,

4. Nursing personnel who care for patients containing therapeutic quantities of radioactivity. Badges will be routinely issued to nurses who care for radium patients, and on a temporary basis to nurses at other locations. (Note: Radium patients are to be admitted to M.U. 9 West whenever possible.)

B. Other Hospital employees who are occassionally exposed to ionizing radiation in the routine performance of their duties and suspect that their exposure is in excess of 25% of the applicable maximum permissible dose as outlined in Exhibit "A" should request an assessment of their situation by the Health Physicist. If, in the Health Physicist's judgement, there is likely to receive more than 25% of the applicable maximum permissible dose, film badges will be issued for a 3-month period. At the end of the trial period, the Hospital Health Physicist will discontinue film badge monitoring unless the trial period had indicated that the employees are being exposed to radiation in excess of 25% of the applicable maximum permissible dose.

C. The Hospital Health Physicist shall have the right to terminate existing film badge holders, if in the Health Physicist's judgement, the employee is not exposed to radiation in excess of 25% of the applicable maximum permissible dose.

IV. Responsibility

A. Health Physicist

Shall be responsible for the issuance of film badges, the termination of film badges, the collection of film badges and the recordkeeping requirements for the film badge program.

B. Film Badge Wearer

Shall be responsible for wearing his/her film badge during scheduled hours of work. The film badge must not be worn while the employee is off the Hospital premises or during a medical treatment r examintion requiring exposure to radiation. For assuring an accurate badge reading each period. Turning in the film badge within 5 calendar days of the end of each exposure period.

V. Disciplinary Action

A. Failure to turn in the film badge within 5 calendar days shall be considered a minor offense in accordance with Policy B:8.

B. Tampering with the badge reading in any way shall be considered a serious offense in accordance with Policy B:8.

VI. Distribution

All Manuals.

The present quarterly maximum permissible doses are:

1. Whole body; head and trunk; active blood-forming organs; lens of eye or gonads: 1-1/4 rem.
2. Hands and forearms; feet and ankles: 18-3/4 rem.
3. Skin of whole body: 7-1/2 rem.

I. Radioactive Waste Disposal Procedures

1. Liquid Waste - Some material in liquid form can be discharged into the sewage system. The factors which limit the amount of material disposable by these means are: half-life, chemical form, water flow, quantity introduced into the system by other laboratories, and the degree of contamination acceptable in the plumbing.

   a. Soluble low level liquid waste disposed down the drain must conform to the NRC regulations (10 CFR 20.303, a-e and 10 CFR 20.306, a).

   b. Insoluble or high level liquid waste must be neutralized, collected in inert polyethelene bottles and the Health Physics Division notified. Contents of polyethelene bottles should be liquid only, (no glass vials, ampoules or paper).

   c. When it is not feasible to pour the contents of liquid scinitllation vials down the drain and dispose of the vials in the solid waste containers, then metal drums will be provided, with sawdust, to collect the intact vials and contents.

   d. Safe storage of the liquid waste is the responsibility of the authorized investigator until removed by the Yale university Health Physics Division.

2. Solid Dry Waste - Special waste receptacle are provided by Yale University's Health Physics Division to the various departments utilizing radioactive materials for the disposal

of solid dry waste. These receptacles are identified with the magenta and yellow radiation symbol and the words, "Caution - Radioactive Materials".

a. Empty containers may be obtained by calling the Health Physics Division 436-2935 or 436-0570.

b. The corrigated cardboard containers are for <u>solid dry waste only</u>. The contents of these containers should not include liquid or animal tissue of any kind. Care should be taken to keep containers dry and within the weight capacity of 65 pounds.

c. All syringes used for injections with radioactive isotopes must be capped before discarding them into waste box.

d. Material must not be put into radioactive waste collection containers if there is any possibility of a chemical reaction during storage or shipment that might cause the release of radioactive gases, fire or explosion.

e. As the receptacle is being filled, records shall be kept of the radioisotopes and quantities being placed in the container.

f. All radioactive waste receptacles must be kept in the laboratory, NOT in the hall. The presence of the receptacle within the laboratory should not constitute a health hazard. If, however, large dose readings are received from the container, special arrangements will have to be made through the Health Physics Division for recommendations concerning proper shielding.

g. Full containers may be removed by calling the Health Physics Division (436-2935 or 436-0570) giving a two to three day notice. When the container is being removed from the laboratory the Health Physics Division representative should be informed of the radioisotope and quantity involved.

h. The solid dry waste is prepared for shipment and sent to an outside vendor to be buried. Due to the expense involved, everyone's cooperation is requested in keeping the waste volume to a minimum and also in using the containers for <u>radioactive waste only</u>.

i. The waste containers should not be filled to overflowing. The flaps on the top of the container have to be folded down and taped in accordance with regulations set forth by the NRC and the Department of Transportation.

3. <u>Gas Waste</u> - Radioactive waste in the gas form will be held in the fume hoods. Depending on the half-life of the radioisotope, it can be held for decay. Example of this Xenon-133, the unused vials are held for decay in the fume hood. Other gases can be released in accordance with 10 CFR 20 Appendix B, Table I, Column I. Approval of this disposal will be given only by the Radiation Safety Office.

At all times radioactive waste will be shielded if it is warranted. Radioactive waste is divided among long and short lived. When it is found to be at background levels, it is recorded than thrown out as regualr trash.

J. Contamination Control Procedures

To reduce the chance of contamination, the following procedures must be followed.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving the area.
4. Always use syringe shields, or use remote delivery systems when syringe shields cannot be used.
5. No eating, drinking, or apply cosmetics in any area where radioactive materials are used or stored.
6. Do not store food, drink, or personal effects with radioactive materials.
7. Never pipette by mouth.
8. Always survey areas where radioactive materials are used or stored. If contamination is foundm decontaminate immediately.

Item 16 Emergency Procedures

Procedures to be Followed in the Event of

Spillage of Radioactive Material

If any radioactive material is spilled, the following steps must be taken:

1. Close off the area to prevent the spread of contamination.
2. Shut off ventilation.
3. During normal working hours, immediately contact the Radiation Safety Officer (2950) or Nuclear Medicine (5055).
4. After hours, notify the Security Office (2500) and give details, security will then notify the appropriate personnel who will contact you.
5. If you are unfamiliar with decontamination procedures, or if you do not know or are not sure of the type of material and/or the quantity, wait for aid.
6. Begin decontamination by using suitable protection apparel, such as plastic or rubber gloves, boots, and coveralls. Do not begin decontamination if atmosphere contamination is a possibility.
7. Use absorbent pads to confine the area of the spill.
8. Dispose of all contaminated waste in a plastic box labeled "Radioactive Waste".

EMERGENCY CALL LIST

During normal working hours:

Radiation Safety Officer:	2950
Radiological Physics:	2951
Nuclear Medicine:	5055

After hours:

Security	2500

For Accidents Involving Radiation Exposure:

Emergency Room	2222
Hospital Security	2500
Radiological Physics	2951
Nuclear Medicine	5055

I. Emergency notification

A. Suspected radiation overexposure.

1. During normal working hours immediately call Radiation Safety Officer (2950) or Nuclear Medicine (5055).

2. During off hours imeediately call Hospital Security (2500) and give details of the accident and await instructions. Hospital Security will notifiy the appropriate personnel who will then contact the individual and give instructions.

B. Accident involving personnel injury and radiation.

1. Give first aid if necessary.

2. During normal working hours contact Hospital Security first and then either the Radiation Safety Officer (2950) or Nuclear medicine (5055) and give details of the accident.

3. During off hours, call Hospital Security (2500) give details of the accident and await instructions. Security will notify the appropriate personnel who will then contact the individual and give instructions.

4. If it is necessary to send individuals to the Emergency Room at Yale-New Haven Hospital, call the Emergency Room (2222) and talk to the charge nurse who will arrange for transportation. Inform her that an over exposed patient is coming.

5. Keep all uninjured personnel involved close to the accident area.

II. Hospital Security Procedures

A. Hospital Security upon receiving a call should collect the following information.

1. The location of the accident.
2. The number of injured persons.
3. The type of radiation exposure involved.
4. The name and telephone number of the individual giving the information.

B. Hospital Security after receiving a report of a radiation accident and dispatching an officer to the scene, should contact:

1. If injuries are involved: the Emergency Room (2222) either to warn of accident or indicate patients are coming. Inform them that the accident involved radioactive materials.
2. Radiological Physics Division (2951). Start at the top of the list and proceed down until one is reached. The individual should obtain the facts, contact the individual reporting the accident, give further instructions, and procedd to the accident area, if necessary.

Yale-New Haven Hospital	Office	Home
Mr. Robert Peterson	2950	481-5182
Dr. Robert C. Lange	5054	776-1885
Dr. E.A. Cornelius	5000	387-2838
Dr. A. Gottschalk	2384	281-6133
Dr. Robert J. Schulz	2975	453-4850

3. If the accident occurs at the University or involved University controlled radioisotopes at the Medical Center, also contact University Health Physics.

University Health Physics		
Mr. George R. Holeman	436-0570	777-1819
Mr. Kenneth Price	436-0570	248-2543
Mr. Joseph A. Greenhalgh	436-0570	248-8845

C. Hospital Security after reaching the scene of the accident should help determine if the individual needs emergency care. If the E.R. has not already been informed, call the Emergency Room (2222) and tell the charge nurse who will arrange for transportation.

Item 17 Area Survey Procedures

Areas surveys will be done by the individual in that laboratory. The frequency of surveying will depend on the radioisotope and the activity. The Radiation Safety Officer will survey laboratories quarterly.

1. All elution, preparation, and injection areas will be surveyed daily with a G.M. survey meter.
2. Laboratory areas where only small quantities of radioactive material are used (less than 200 Ci) will be surveyed monthly).
3. Waste storage areas, imaging rooms, and all other laboratory areas will be surveyed weekly.
4. The weekly and monthly surveys will consist of:
   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficient to detect 200 dpm per 100 cm^2 for the contaminant involved.

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

✓ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

✓ By [redacted] waste disposal service (see also Item 4 below).

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

____ Returned to the manufacturer for disposal.

✓ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

____ Disposed of by commercial waste disposal service (see also Item 4 below).

____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

✓ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

✓ Disposed of by [redacted] waste disposal service (see also Item 4 below).

____ Other (specify): _____

4. The [redacted] waste disposal service used will be

Yale University New Haven, CT

(Name) (City, State)

NRC/Agreement State License No. 06-00183-03

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

**These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

Item 19 Therapeutic Use of Radiopharmaceuticals

b(1). Presently, Iodine-131 is given in the capsule form. The Iodine-131 capsules are stored in their respective lead pigs in the fume hood. Disposable gloves and laboratory coats are worn whenever the capsules are handled. The specification of the fume hood are discussed in item 11 facilities and equipment.

(2). Since the Iodine-131 is in the capsule form, routine bioassays are not necessary. In order to reduce the potential release of airborne Iodine-131, the patient is asked to flush the toilet at least three times after urination. Iodine-131 is more volatile in an acidic solution, and urine is slightly acidic. If the patient is bedridden during the treatment then the nurse will undergo bioassay for handling the urine. Also bioassays will be done on personnel if their is significant spill involving Iodine-131. If a bioassay is warranted, than the person would be referred to Yale University's Health Physics Division. Regulatory Guide 8.20 "Application of Bioassay for I-125 and I-131" will be followed.

(3) The Iodine-131 therapy patient is treated as if he/she was in strict isolation. Before going into the room, hospital personnel have to wear shoe coverings, masks, gowns, hair covering, and disposal gloves. By treating the patient in this matter, the threat of contamination spreading would be greatly reduce. Hospital personnel will be trained to use a survey meter to ensure no contamination.

Air sampling will be required if there is an Iodine-131 spill to determine the amount of airborne radioactivity. Under

normal circumstances, (Using Iodine-131 capsules and no collection of urine) air sampling would not be required.

After a patient is released from the Hospital, the room cannot be cleaned by Hospital Housekeeping until it has been found clear of contamination by the Radiation Safety Officer. Any items that are twice background are considered to be contaminated and will be held in storage until background levels are reached. The radioactive waste will be stored by Nuclear Medicine.

Surveys will be conducted to ensure compliance with 10 CFR 20.103 and 10 CFR 20.106.

care for your baby. However, it is preferable not to have the baby too close, such as sitting in your lap, for more than a short time during the first 2 days after treatment.

- *If you have been breast feeding* your baby, you **must** stop because radioiodine is secreted in breast milk. Discuss with your doctor when you can resume breast feeding.

- *If you are pregnant*, or think you could be, tell your doctor because radioiodine treatment should not be given during pregnancy. Also, if your are planning to become pregnant, ask your doctor how long you should wait after treatment.

- *Wash your hands* with soap and plenty of water each time after you go to the toilet.

- *Keep the toilet especially clean*. Flush it 2 or 3 times after each use.

- *Rinse the bathroom sink and tub* thoroughly after you use them. Clean bathroom practices will reduce the chances of others becoming contaminated from the radioiodine in your saliva and sweat.

- *Drink plenty of liquids* such as water or juices. This will make you urinate more frequently and help the radioiodine to leave your body more rapidly, thus lowering the amount in your body.

- *Use separate (or disposable) eating utensils* for the first few days and wash them separately. This will reduce the chance of contaminating other family members with the radioiodine in your saliva.

- *Use separate towels and washcloths*. Launder your bath towels, bed linens, and underclothing separately.

you discuss your questions and concerns with your doctor.

You and your doctor should complete the checklist at the back of this pamphlet. It will explain what steps you can take in your situation to reduce radiation exposure to others from the radioiodine you receive.

How does radioiodine work?

The thyroid gland accumulates the iodine that enters the body in food and uses this iodine to perform its normal function, which is to make thyroid hormone. Radioiodine is similarly collected by the thyroid gland. The radiation given off by this form of iodine decreases the function of the thyroid cells and inhibits their ability to grow. This is the desired medical effect and the reason you will be given this medication. Radioiodine treatment is a common, well accepted form of treatment that has been used all over the world for more than 30 years.

Most of the radiation from the radioiodine will be received by your thyroid gland. However, the other tissues in your body will receive some incidental radiation. This small amount of radiation has **not** been shown to produce any adverse effect.

How long does the radioiodine stay in your body?

The radioiodine from your treatment will remain in your body only temporarily. Most of the radioiodine not collected by your thyroid gland will be eliminated during the first 2 days after your treatment. Radioiodine leaves your body primarily in your urine, but very small amounts may leave in your saliva, sweat, and feces. The amount of radioiodine remaining in your thyroid tissue is responsible for the desired medical effect. However, this amount also decreases rapidly. This means that the possibility of radiation exposure to you and others is reduced with time. At the end of treatment, **no** radioiodine remains in your body.

How can others be exposed to radiation from the radioiodine given to you?

Exposure to radiation from the radioiodine in your body may occur if other people remain very close to you for long periods of time. The radiation received is very similar to the radiation from medical and dental X-rays, which are the most common and familiar sources of external radiation exposure.

Contamination with radioiodine can occur if it is deposited in any place where other people may have contact with it. For instance, if some of the radioiodine in your saliva gets on the bathroom sink as you brush your teeth and then on to someone's hands, contamination has occurred. If this radioiodine is then taken into someone's body from the hands or from food that has been touched, it will cause a small amount of radiation exposure to that person.

Radioiodine disappears by itself as part of the physical processes that make it radioactive. For example, it will not remain on the sink indefinitely because its quantity is reduced by one-half every 8 days. This is what is meant when it is said that the "half-life" of radioiodine is 8 days.

How can you reduce radiation exposure to others?

The amount of radioiodine in your body during the treatment is small. Although there is no evidence that the radiation from this amount of radioiodine will cause any problem, it makes sense to take steps to minimize exposure, no matter how small. If you take some simple precautions during the first few days after your treatment (as explained below), you can reduce or eliminate the possibility of radiation exposure to others.

There are three **basic principles** to remember:

1. **Distance**—the greater the distance you are from others, the less radiation they will receive. Even an increase in distance of a few feet will greatly reduce the exposure. So try not to remain in close contact with others for longer than is necessary.

2. **Time**—radiation exposure to others depends on *how long* you remain close to them. You should try to minimize the time spent in close contact with others.

3. **Hygiene**—good hygiene minimizes the possibility that other people will be contaminated with the radioiodine that leaves your body. Since most of the radioiodine leaves your body in your urine, good toilet hygiene and careful and thorough washing of your hands will reduce the possibility of contamination.

Important guidelines to help you apply these basic principles:

Your doctor can best recommend which guidelines are important for you and how long you should follow them. Do not hesitate to ask your doctor for more information.

- *Sleep alone for the first few days* after your treatment. During this period avoid kissing or sexual intercourse. Also avoid prolonged physical contact, particularly with children and pregnant women; the thyroid glands of children and fetuses are more sensitive to the effects of radioiodine than those of adults.

- *If you have a baby*, or you are taking care of one, your doctor can best instruct you on how to follow the guidelines. You probably can do all the things necessary to

This pamphlet is for you—the patient—who will be treated with radioiodine, a radioactive form of iodine. It includes special instructions for you to follow when you go home after your treatment.

Why will you receive radioiodine treatment?

You will receive radioiodine because you and your doctor have agreed that it is the most appropriate treatment for your thyroid condition. Most of the radiation from the radioiodine will be absorbed by your thyroid gland and will interfere with the function of the thyroid cells. This is the desired and beneficial medical effect of the treatment. However, some of the radiation will leave your body, and individuals who are in close physical contact with you may be exposed to small amounts. There is no evidence that such exposure has ever caused any harm. Nevertheless, efforts should always be made to avoid unnecessary exposure to radiation.

Ask your doctor

The best source of additional information on your treatment is your doctor. This pamphlet lists some guidelines for you to follow for a short time immediately after your treatment (usually no more than 2 to 5 days, depending on your treatment and your doctor's instructions). You may decide, or your personal situation may require, that you will want to follow all or only some of the suggested guidelines. Remember, these are only suggestions to help you make more informed decisions as

This pamphlet was prepared by David V. Becker, M.D. and Barry A. Siegel, M.D. of the Publications Committee of The Society of Nuclear Medicine, Inc. in cooperation with Deborah A. Bozik, Health Physicist, and Carol A. Peabody, Technical Writer, of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission.

Important—Note that these guidelines are only carried out for the **first few days** after treatment. Your doctor will give you specific details as to how long you should follow these precautions.

A checklist for you and your doctor

Ask your doctor to help you decide which guidelines are most important for you and how long you should follow them.

	How long?
☐ Try to keep the time you spend in close contact with others to a minimum.	_____
☐ Try particularly to minimize time spent with pregnant women and young children.	_____
☐ Sleep alone, if possible.	_____
☐ Discuss how long you should wait before becoming pregnant after your treatment.	_____
☐ If you are breast feeding, ask when it may be resumed.	_____
☐ Use good hygiene habits. Wash your hands thoroughly after each toilet use.	_____
☐ Drink plenty of liquids.	_____
☐ Use separate bath linens (and launder these and underclothing separately).	_____
☐ Use separate (or disposable) eating utensils.	_____

NOTES

The Society of Nuclear Medicine
475 Park Avenue South
New York, NY 10016
(212)889-0717

Guidelines for Patients Receiving Radioiodine Treatment

Item 20 Therapeutic Use of Sealed Sources

A. There are two areas where sealed sources are stored; the CAVE (room 4A, basement of Hunter Radiation Therapy Building) and the radium room (room 2-703, Memorial Unit, One Day Surgery Center). Enclosed are diagrams for both the CAVE and the radium room.

There are no rooms either above or below the CAVE; as it is surrounded by earth. The sealed sources are stored in lead containers furnished by the company. A two-inch lead L-block, lead pigs and/or containers, remote handling tools (forceps and clamps), and other necessary lead shielding are available. Primarily Iodine-125 seeds, Iridium-192 seeds, Gold-198 seeds, Strontium-90 eye applicators, Radium-226 sources, and other sealed sources are stored in the CAVE.

The cafeteria is below and the post-partum care facility is above the One Day Surgery Center where the radium room (room 2-703) is located. Radiation areas are monitored on a quarterly basis, and are kept at or below 0.6 millirems per hour. The Radium-226 and the Cesium-137 tubes and needles are kept in the lead safe. Two inch lead blocks surround the lead safe. Work is done behind a two inch L-block. The Cesium-137 simon sources are stored in the lead containers furnished by the manufacturer. Remote handling tools such as forceps, clamps, etc are available. Both the CAVE and the radium room are kept locked at all times when not in use.

B. The personnel who are involved with handling the sealed sources are properly instructed. Remote handling tools are used at all times, and work behind lead shielding such as the L-block. They are also instructed in the fundamentals of radiation safety: time, distance, and shielding.

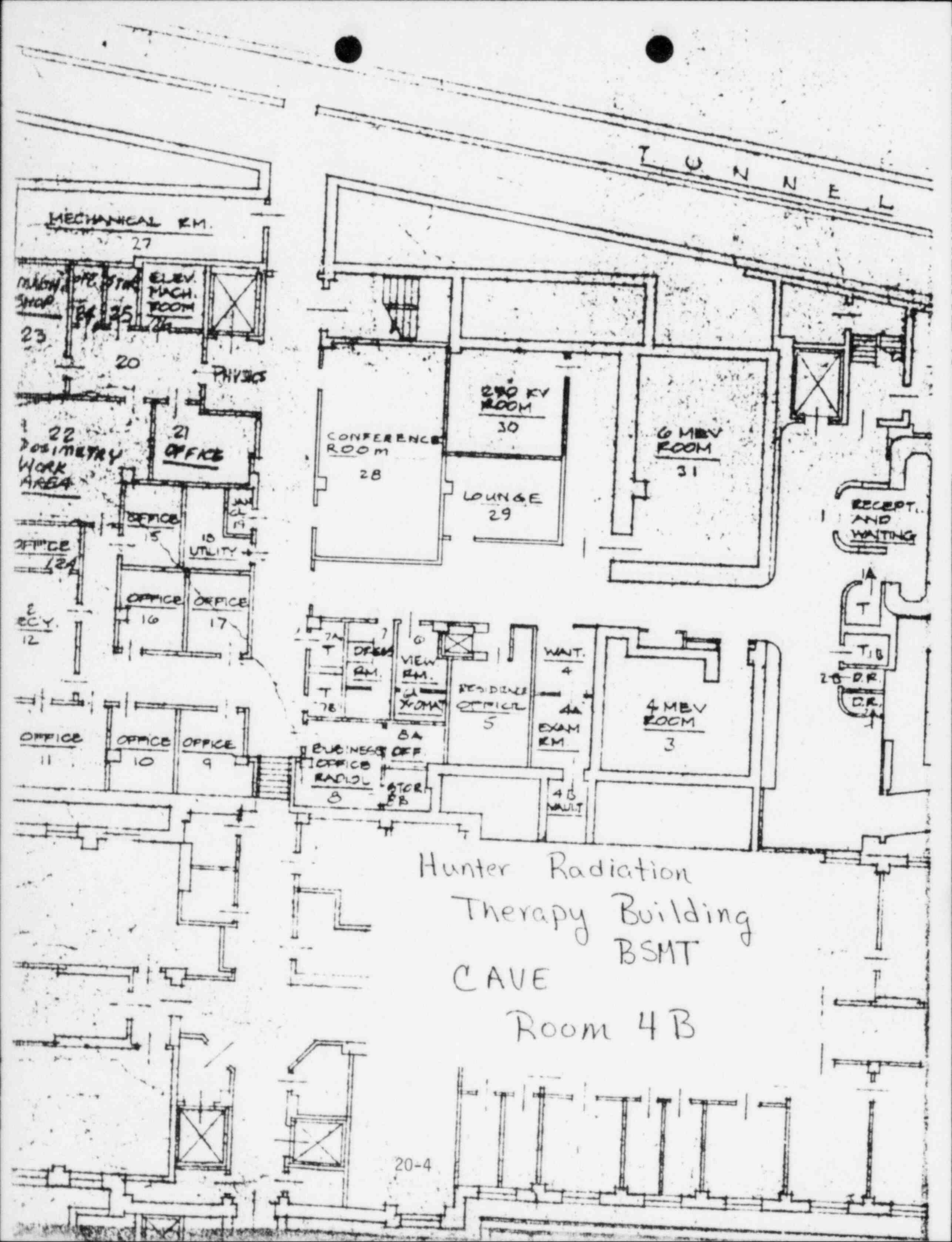
C. Personnel who handle sealed sources wear TLD rings, which monitor their extremity dose. These TLD rings are changed, as are the badges, on a monthly basis.

D. There are various ways to transport sealed sources depending on the radioisotope. Iodine-125 seeds are transported in the shipping container furnished by the company. Other sources are transported in lead pigs on carts. The amount of lead is sufficient to reduce the radiation exposures. Several lead pigs are available for transporting these sealed sources.

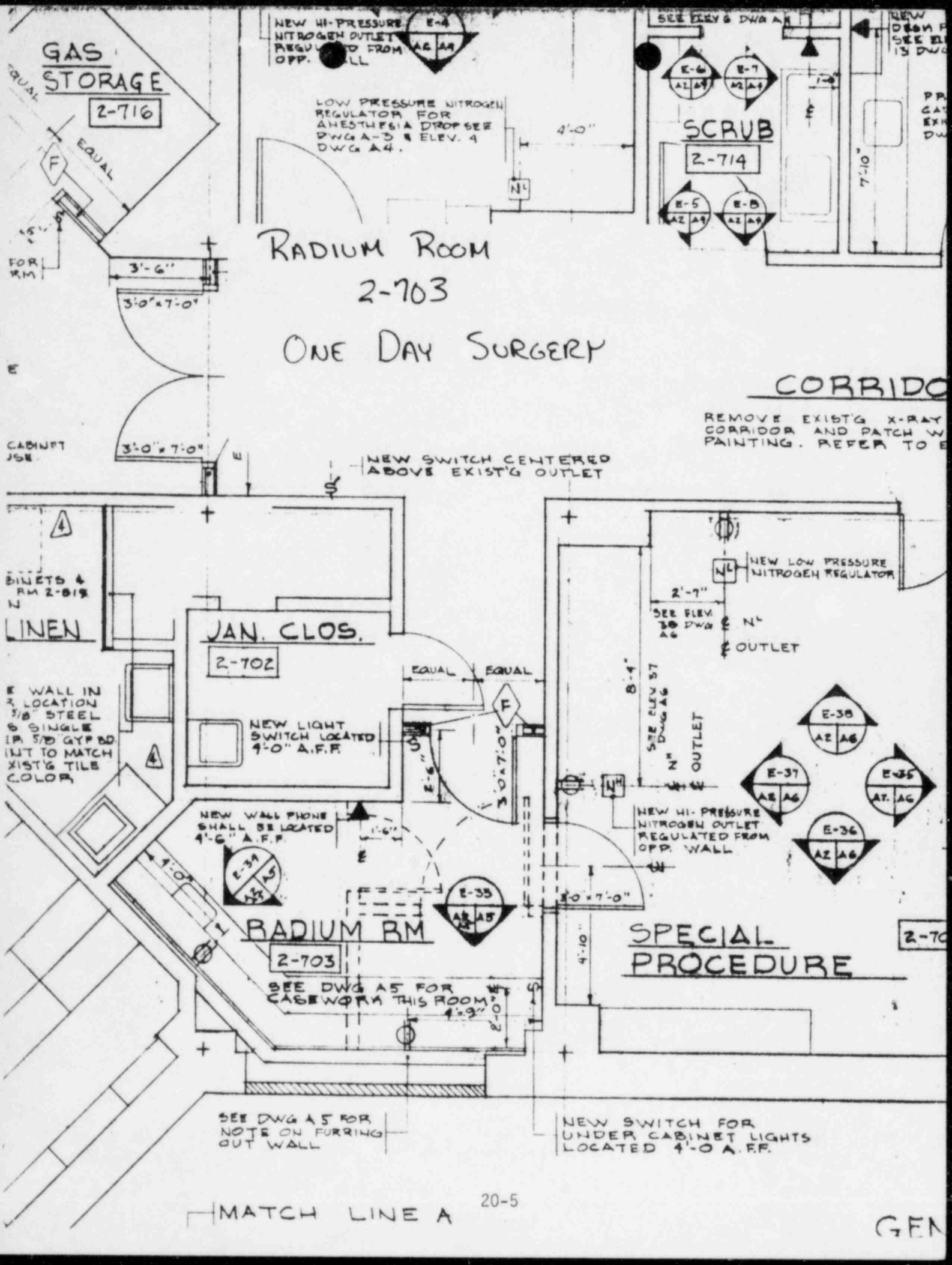
E. For interstitial treatment (the use of iodine-125 seeds, gold-198 seeds, and iridium-192 seeds) the sources are counted when they arrive at the facility and before they are put in the patient. Iodine-125 and gold-198 seeds are permanent implants. Any seeds left over are put in storage and held for decay. The iridium-192 ribbons are used as temporary implants. Any ribbons left over are put in storage, then when the iridium-192 ribbons are removed from the patient they are counted and put in the shipping container and sent back to the company for disposal. A record of when the sources were received, implanted, and final deposition of these sources is kept.

For the cesium-137 sealed sources, a record of the patient's name, number of sources used, date of implant, total activity of the implant are kept in the radiumn room and by the radiation safety officer. At all times all sealed sources are accountable. The dosimetrists keep accounting records whenever a therapy implant is done. The Radiation Safety Officer does a quarterly inventory. After the sources are removed from the patient, nurses conduct a final survey with a Geiger-Mueller survey meter to make sure the sources were removed. The resident on the floor removes the sources by lead pig to the radium room. The next working day, the dosimetrist accounts for each of the sources and then they are put back in storage.

F. Radiation safety surveys are conducted when the patient is back in the room. Readings are taken at 1 meter, entrance to the room, hallway, and the rooms next to the room. When the sources are removed from the patient and from the room, the nursing staff does a final survey to make sure all sources were removed. Records of all of this are kept at the nurses station on the patient floor.



Hunter Radiation Therapy Building
BSMT
CAVE
Room 4B


GAS STORAGE
2-716
EQUAL
F
EQUAL
FOR RM
3'-6"
3'-0"x7'-0"
CABINET USE
NEW HI-PRESSURE NITROGEN OUTLET REGULATED FROM OPP. WALL
E-4
A6 A4
LOW PRESSURE NITROGEN REGULATOR FOR ANESTHESIA DROP SEE DWG A-3 & ELEV. 4 DWG A4.
4'-0"
N
SEE ELEV 6 DWG A4
E-6
A2 A4
E-7
A2 A4
SCRUB
2-714
E-5
A2 A4
E-8
A2 A4
RADIUM ROOM
2-703
ONE DAY SURGERY
CORRIDO
REMOVE EXIST'G X-RAY
CORRIDOR AND PATCH W
PAINTING. REFER TO E
NEW SWITCH CENTERED ABOVE EXIST'G OUTLET
3'-0"x7'-0"
E
BINETS & RM 2-815
LINEN
JAN. CLOS.
2-702
EQUAL
EQUAL
E WALL IN LOCATION 3/8" STEEL & SINGLE LAYER 5/8" GYP BD INT TO MATCH EXIST'G TILE COLOR
NEW LIGHT SWITCH LOCATED 4'-0" A.F.F.
NEW WALL PHONE SHALL BE LOCATED 4'-6" A.F.F.
1'-6"
4'-0"
E-34
A5
E-35
A5
RADIUM RM
2-703
SEE DWG A5 FOR CASEWORK THIS ROOM
4'-9"
2'-0"
3'-0"x7'-0"
4'-10"
NEW LOW PRESSURE NITROGEN REGULATOR
2'-7"
SEE ELEV 3B DWG A6
N
OUTLET
8'-4"
SEE ELEV 37 DWG A6
N
OUTLET
NEW HI-PRESSURE NITROGEN OUTLET REGULATED FROM OPP. WALL
E-38
A2 A6
E-37
A2 A6
E-35
A2 A6
E-36
A2 A6
SPECIAL PROCEDURE
2-70
SEE DWG A5 FOR NOTE ON FURRING OUT WALL
NEW SWITCH FOR UNDER CABINET LIGHTS LOCATED 4'-0 A.F.F.
MATCH LINE A
20-5
GEN

Item 21 Procedures and Precautions for Useof Xenon-133

1. Quantities to be used.

   a. Patient information

      1. 10 patients per week

      2. 20 millicuries per patient

   b. 2.0 Curies possession limit

2. Use and Storage Areas

   a. Xenon-133 is stored in the Radiopharmacy Laboratory in a fume hood (Room 2-426). The Xenon-133 vials are packaged individually by the manufacturer. The vials are stored in long cylindrical lead pigs. Xenon-133 will be used in the core area of Nuclear Medicine. Enclosed are diagrams of the Radiopharmacy Laboratory and the imaging room where Xenon-133 will be used (See Item 11).

   b. The imaging rooms and the Radiopharmacy Laboratory where Xenon-133 will be used or stored, are under negative pressure. The air is exhausted directly to the outside (non-recirculating system). There are no changes in the flow rates between the heating and cooling seasons. The following are the rooms with the air flows and the changes:

      Room 409 (1) Total Air Supply: 220 cfm

      (2) Total Room Volume: 1701 ft^3

      (3) Total Exhaust Air: 227 cfm

      (4) Total Air Change: 6.1 minutes

Room 416 (1) Total Air Supply: 170 cfm

(2) Total Room Volume: 504 ft^3

(3) Total Exhaust Air: 213 cfm

(4) Total Air Change: 2.4 minutes

Room 424 (1) Total Air Supply: 170 cfm

(2) Total Room Volume: 1391 ft^3

(3) Total Exhaust Air: 242 cfm

(4) Total Air Change: 5.75 minutes

Room 426 (1) Total Air Supply: 180 cfm (Radiopharmacy Laboratory)

(2) Total Room Volume: 937 ft^3

(3) Total Exhaust Air: 270 cfm

(4) Total Air Change: 3.47 minutes

When the door is closed, the air induced three ceiling transfer the total exhaust air is 396 cfm; therefore the total air change is 2.4 minutes. The air flow rate for the fume hood in the Radiopahrmacy Laboratory is 1080 cfm.

Room 438 (1) Total Air Supply: 220 cfm

(2) Total Room Volume: 1701 ft^3

(3) Total Exhaust Air: 276 cfm

(4) Total Air Change: 6.2 minutes

Room 424 (1) Total Air Supply: 210 cfm

(2) Total Room Volume: 1226 ft^3

(3) Total Exhaust Air: 259 cfm

(4) Total Air Change: 4.7 minutes

c. The air flow rates (supply and exhaust) will be checked every six months by Hospital Engineering.

3. Procedures for Routine Use

a. The Xenon-133 is dispensed in individual glass vials; the activity is assayed with a CRC-17 Capintec Dose Calibrator. The Xenon-133 procedures are conducted in any of the rooms listed above, but primarily in room 2-440.

b. A Pulmonex Xenon System is used to administer the Xenon-133 (enclosed is a description of the system). The patient breathes through a mask. The Pulmonex system has a built in Xenon gas trap.

4. Emergency Procedures

Upon accidental release of Xenon-133, the room will be evacuated. Since the room is under negative pressure and the air exhausted directly to outside, the amount of time to reach 1×10^{-5} Ci/ml is approximately 19.2 minutes.

Room 4-440

20,000 Ci/1226 ft^3 x 2.832×10^4 ml = 5.76×10^{-4} Ci/ml

Exhaust Air Flow 259 ft^3/min = 7.33×10^6 ml/min

The air is exchanged once every 4.7 minutes

$$t = \ln \frac{1 \times 10^{-5} \text{ Ci/ml}}{5.76 \times 10^{-4} \text{ Ci/ml}} \quad \frac{-3.47 \times 10^7 \text{ ml}}{7.33 \times 10^6 \text{ ml/min}}$$

$$= (-4.05)(-4.74)$$

= 19.2 minutes for the room to reach 1×10^{-5} Ci/ml if 20 mG is accidentlally released

1. Notify all persons in the room to evacuate the area at once.

2. Notify the Radiation Safety Officer (2951).

3. Shut the door and seal with a masking or adhesive tape.

4. Give the Radiation Safety Officer the approximate activity that was released in the room.

5. Do not enter unless permitted by the Radiation Safety Officer.

5. Air Concentrations in Restricted Areas

A = 20 mCi/patients x 10 patients/wk

= 200 mCi/wk

= 2×10^5 Ci/wk

f = 0.20

$$V = \frac{A \times f}{MPC} = \frac{2 \times 10^5 \text{ Ci/wk}(.2)}{1 \times 10^{-5} \text{ Ci/ml}}$$

= 4×10^9 ml/wk

$$\frac{4 \times 10^9 \text{ ml/wk}}{40 \text{h/wk}} = 1.7 \times 10^6 \text{ ml/hr/ft}^3\text{/min} = 58.9 \text{ cfm}$$

Room 2-440 Exhaust 259 cfm = 1.76×10^{10} ml/wk

$$C = \frac{A}{V} \times f$$

$$= \frac{(2 \times 10^5 \text{ Ci/wk}(.2)}{1.76 \times 10^{10} \text{ ml/wk}} = 2.27 \times 10^{-6} \text{ Ci/ml}$$

Room 2-438 Exhaust 276 cfm = 1.86×10^{10} ml/wk

$$C = \frac{A}{V} \times f$$

$$= \frac{(2 \times 10^5 \text{ Ci/wk})(.2)}{1.86 \times 10^{10} \text{ ml/wk}} = 2.15 \times 10^{-6} \text{ Ci/ml}$$

Room 2-409 Exhaust 277 cfm = 1.88×10^{10} ml/wk

$$C = \frac{A}{V} \times f$$

$$= \frac{(2 \times 10^5 \text{ Ci/wk})(.2)}{1.88 \times 10^{10} \text{ ml/wk}} = 2.13 \times 10^{-6} \text{ Ci/ml}$$

Room 426 Radiopharmacy Laboratory

270 cfm = 1.83×10^{10} ml/wk

$(1.83 \times 10^{10}$ ml/wk$)(1 \times 10^{-5}$ Ci/ml$) = 1.83 \times 10^{5}$ Ci/wk

Which means the technologist would have dropped 9 vials of 20 mCi per vial to reach the 1.0×10^{-5} Ci/ml; which is very unlikely.

6. Air Concentrations in Unrestricted Areas

A. Room 2-440 MPC for unrestricted area = 3×10^{-7} Ci/ml

259 cfm = 3.84×10^{12} ml/yr

$(3.84 \times 10^{12}$ ml/yr$)(3 \times 10^{-7}$ Ci/ml$) = 1.15 \times 10^{6}$ Ci/yr

This would be equivalent to a total release from approximately 57 patients which is very unlikely.

Room 2-438

276 cfm = 4.09×10^{12} ml/yr

$(4.09 \times 10^{12}$ ml/yr$)(3 \times 10^{-7}$ Ci/ml$) = 1.22 \times 10^{6}$ Ci/yr

This would be equivalent to a total release from approximately 61 patients which is very unlikely.

Room 2-409

277 cfm = 4.11×10^{12} ml/yr

$(4.11 \times 10^{12}$ ml/yr$)(3 \times 10^{-7}$ Ci/ml$) = 1.23 \times 10^{6}$ Ci/yr

This would be equivalent to a total release from approximately 61 patients which is very unlikely.

Room 2-426 (Radiopharmacy Laboratory)

270 cfm = 4×10^{12} ml/yr

$(4 \times 10^{12}$ ml/yr$)(3 \times 10^{-7}$ Ci/ml$) = 1.2 \times 10^{6}$ Ci/yr

This would be equivalent to a total release from approximately 60 individual vials of Xenon-133 which is very unlikely.

Fume Hood (Room 2-426 - Radiopharmacy Laboratory)

1080 cfm = 1.6×10^{13} ml/yr

$(1.6 \times 10^{13}$ ml/yr$)(3 \times 10^{-7}$ Ci/ml$) = 4.8 \times 10^{6}$ Ci/yr

This would be equivalent to 240 vials (20 mCi/vial) being released in one year, which is unlikely.

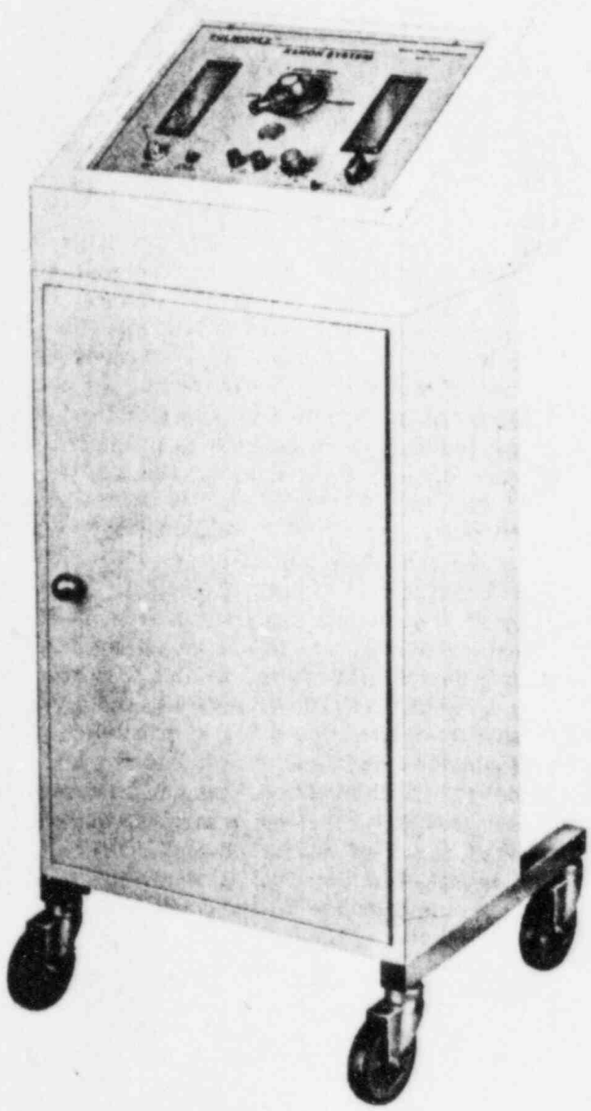
B. Absorption of Xenon-133 onto Charcoal Traps

The xenon trap is a part of the Pulmonex Xenon system. The reduce efficient concentrations are guaranteed to be less than 1×10^{-5} Ci/ml. The trap filter is replaced at the manufacturer's recommended interval. Used filter are shielded and stored in the hood in the Radiopharmacy Laboratory until background levels are reached. Release from filter traps is expected to be minimal, but in any case, the amount of Xenon-133 on the filters at removal should not exceed 200 millicuries. Even if complete release occurs in the hood, annual MPC for unrestricted area should not be exceeded.

The exhaust from the trap system is monitored monthly by collecting the effluent in a collective bag with a capacity of 4.8 liters. This bag is placed over the "out" pipe of the trap. Trap is turned on and effluent collected until bag is filled. The bag is sealed with an elastic band and counted on stretcher in front of LFOV camera fitted with the high sensitivity low-energy collimator. Obtain standard count by counting a calibrated (assayed) vial of Xenon-133 in about the same position. Count bag and vial for one minute, subtract background.

PULMONEX XENON SYSTEM

One technician can perform an entire study by simply moving a single handle.



Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

- Complete easy-to-use system.
- "Air-in"/"Air-out" breathing tubes and motor-driven circulator assures resistance-free breathing.
- Two lead glass windows permit observation of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- Accepts any commercial form of xenon.
- Rolls easily on large casters for positioning of supine or seated patients.
- Fully shielded.
- Carbon dioxide and moisture traps included.

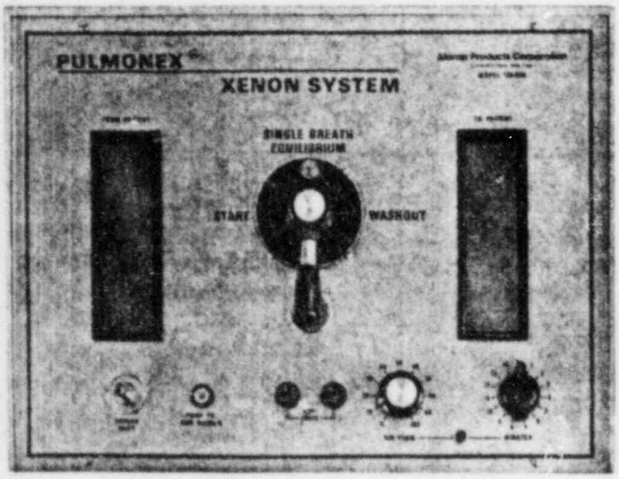
SIMPLE, SAFE OPERATION

The Pulmonex Xenon System is a simple to use, reliable and complete system for the performance of all regional ventilation studies. A built-in xenon gas trap with disposable charcoal cartridge removes xenon effluent after each study and eliminates the need for expensive venting systems. Motor-controlled air flow assures resistance-free breathing regardless of your patient's pulmonary condition. Practical cabinet design and total mobility permit easy patient positioning in the seated or supine positions.

PULMONEX. .the complete, self-contained xenon system

Pulmonex provides a completely integrated system (delivery unit, and built-in gas trap) for performing xenon studies. A sensitive, responsive master valve, controlled by a single handle on the front panel, and silent synchronized motors permit full-system control of xenon gas flow from initial application to ultimate disposition of the xenon effluent into the gas trap.

All controls are conveniently located on an "up-front" control panel. With the patient on-line, either seated or supine, the user can control the system and observe the patient and gamma camera from one position. The control panel is clearly marked and each mode in the study procedure is distinctivcly apparent. The two internal patient breathing bags (Air-in and Air-out) are easily observed through individual viewing windows on the front panel. An adjustable manual 15-minute timer initially activates all functions and automatically shuts down the system to complete the study after patient and system washout.



The PULMONEX SYSTEM

The Pulmonex Xenon System effectively integrates manual and electronic controls into a simple, sensitive system that provides maximum, reliable test results using minimum effort. System complexities have been eliminated. All internal circuitry, valves and tubing have been designed to afford ease of operation and patient comfort.

A master valve, controlled by one handle on the front panel, directs the flow of gases throughout the system. Oxygen may be added to the system any time during a study by fingertip button control. A push button operates a circulator blower motor to provide gentle positive system pressure. This, combined with a specially-designed master valve and wide diameter, short circuit airways, provides resistance-free patient breathing. There is no dead air space. An injected bolus of xenon reaches your patient exactly when desired. An in-line CO_2 absorber prevents hyperventilation. The system has automatic timer and pressure control dials to accommodate your patient's breathing pattern and to assure complete system washout into the gas trap.

All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter may be used at the mouthpiece to prevent system contamination.

INTEGRATED XENON GAS TRAP

The Pulmonex system has its own built-in gas trap. Exhaled xenon is gently pulled through activated charcoal contained within a "U" shaped cartridge made of 1/8" lead by an induction vacuum pump. The control panel timer and airflow pressure dial regulation of the trap pump assures complete patient and system purging. Only clean air leaves the trap exit port. Under normal usage the charcoal cartridge will last about a year. The gas trap cartridge is easily replaced when expended.

SPECIFICATIONS:
Motor UL approved. 115 VAC, 50/60 Hz.
Size: 18" x 19" x 46"
Weight: 150 lbs.

130-500	Pulmonex Xenon System, complete	**$2725.00**

Replacement Items

127-319	Replacement Charcoal Cartridge ...	**325.00**
130-550	Disposable Mouthpiece	**1.95 ea.**
130-700	Disposable Bacteria Filter	**3.25 ea.**
139-101	Moisture Absorber (Drierite)	**7.50 lb.**
130-019	Soda Lime, CO_2 Absorber	**5.25 lb.**
087-130	220V Converter	**150.00**

Item 22 Procedures and Precaution for Use of Radioactive Materials in Animals

This license renewal is only for the use of radioactive material for diagnosis and treatment in humans and human medical research.

Item 23 Introduction

As stated in our previous license applications, the use of radioactive materials in humans is performed by physicians. The Hospital Radioisotope Committee governs the use of radioactive materials. The Radiation Safety Officer has the day to day responsibility of the Radiation Safety Program. This license is only for humans, no animals work will be done.

For a physician to use radioactive materials, his research protocol must be approved by the Hospital Radioisotope Committee. This has already been documented throughout this license renewal application. It is very unlikely that a physician would use large quantities of radioactive materials in an unsealed form. Most of the research work deals with minute tracer amounts; such as 100 to 150 micrcuries of tritiated glucose. The Approved Physician has the responsibility to ensure that radiation safety practices will be done in his laboratory. Bioassays will be conducted if deemed necessary, enclosed is the criteria that is the criteria that our Bioassay Program will be based upon. The use of unsealed sources are very important in our program.

Gadolinium-153 source is use in our bone mineral analyzer. The device is stored in our satellite radiology department in the basement of the Dana Clinic. The source is leak tested every six months and inventoried every 3 months. Iridium-192 sources will be use in the Gamma Med II Remote Afterloader. The use of this device will reduce personnel exposure. Which coincides with our ALARA Program. Selenium-75 sources will be used as a replacement

for Iridium-192. Selenium-75 has a longer life than Iridium-192 and requires less shielding for the same degree of protection. The use of Americium-241 sealed sources in our brachytherapy will further reduce personnel exposures. These sources will be leak tested and inventoried.

Leak Testing of Sealed Sources

Each sealed sources obtain from a vendor and conducting byproduct material (other than tritium) with a half-life greater than thirty days, in any form other than gas, shall be tested for leakage prior to use. Each sealed source fabricated within the Hospital shall be tested for leakage immediately after fabrication. In addition to an initital test upon fabrication, the source will be stored for a period of seven days and retested prior to transfer. Each sealed source containing by product material other than tritium, with a half-life greater than th rty days, and in any form other than gas, shall have the following.

1. Test for leakage of intervals not to exceed six months.
2. Tests shall be capable of detected the presence of 0.005 microcuries of removable contamination.
3. Test wipings shall be taken from the sealed sources or from the surfaces of the device in which the sealed source is permanently or semi-permanently mounted or stored and on which one might expect contamination to accumulate.
4. Alpha sources shall be tested of intervals not to exceed three months.
5. Results of tests shall be recorded and maintained for inspection by Nuclear Regulatory Commission. If the test reveal the

presence of 0.005 microcuries or more of temovable contamination the Radiation Safety Officer shall notify the User and immediately withdraw the source from use, and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Hospital Radioisotope Committee's regulation.

Exception to Leak Test Requirements

No leak tests required for the following:

1. Seaied sources containing tritium.
2. Sealed sources containing byproducts material with a half-life less than thirty days.
3. Any sealed source, provided the quantity of byproduct material contained does not exceed ten times the quantity specified in Schedule B, Section 30.71 10 CFR Part 30.

BIOASSAY

Basically, the intent of bioassay is to monitor the radiation worker from the standpoint of possible INTERNAL expsouire (as the film badge monitors possible EXTERNAL exposure). Inherently, however, bioassay is fraught with assumptions and unknowns and is relatively expensive. Theeore, it is an unrealistic rool for widespread use among those radiation workers using relatively low biohazard radionuclides.

For work with low levels of radiation, the control of possible internal radiation exposure is best accomplised by the education and enforcement of the standard laboratory rules.

There are occasions, however, when the quantity of radionuclides are such that, should an ingestyion or inhalation occur, it is likely that the bioassay procedure would determine that occurrence (internal dose) with some degree of accuracy. This is not saying tha an internal overexposure had occurred to the worker. It is saying that some expsoure occurred as is commonly found with the film badge reports.

The following list of radionuclides is comprised of all radionulcides in use at the Hospital. This list will be updated to include other radionuclides if an when they are used.

The first column is a "threshold" quantity of radionuclide which, if exceeded, mandates the use f the bioassay schedule as presented.

Other forms of bioassay (whole body counts) cold become necessary should this exam be performed and some activity be found.

Quantity/Use Necessitating Bioassay	Type of Bioassay	Frequency of Exam
Single use of:		
1 Ci Tc-99m	Thyroid	Immediate
100 mCi Tl-201	Urine	Immediate
100 mCi S-35	Urine	Within 14 days
100 mCi P-32	Urine	Within 14 days
100 mCi Cr-51	Urine	Within 14 days
10 mCi I-125 (liquid)	Thyroid	Within 24-48 hours
1 mCi I-131 (liquid)	Thyroid	Within 18-30 hours
100 mCi Co-57	Urine	Within 14 days
100 mCi H-3	Urine	Within 14 days
100 mCi C-14	Urine	Within 14 days
Continuous use of:		
10 mCi H-3 organic	Urine	Weekly
10 mCi C-14 organic	Urine	Weekly
100 mCi H-3	Urine	Weekly
100 mCi C-14	Urine	Weekly

The following is a list of minimum standards which the Hospital Radioisotope Committee considers necessary for work with radioactive materials. Individual clinicians or depratment may wish to add to this list, particularly inasmuch as it is possible that contamination of laboratory space may present adminsitrative problems withour necessarily creating a serious safety hazard.

1. The responsible clinican shall be responsible for:
   a. All personnel who may be exposed to radiation, including visitors, personnel in neighboring laboratories, etc.
   b. Adequate training and supervision of all participating personnel.
   c. Securing film badges when necessary.
   d. Execution of safety measures, clean-up and decontamination procedures.
   e. Routine monitoring of his own operations.
   f. Keeping track of the disposition of all radioisotopes he acquires.
   g. Seeing that proper caution signs are posted and that there is adequate information available in case of emergencies arising when he is not present.
   h. Notifying the Committee of any substantial changes inworking conditions from the proposed on his application.
   i. Enforcing all other safety procedures as recommended herein or by the Committee.

2. A monitoring instrument capable of detecting the radiations emitted must be quickly available to any laboratory containing greater than LOW LEVEL amounts of radioisotopes, and should be used regularly to check for contamination.

3. All containers holding any amounts of radioactive materials must be labeled with type, amount and date of measurement.

4. A shielded storage space must be provided such that the maximum radiation intensity at any accessible place on the outside is not greater than 12 mR/day, (0.5 mR/hr for most areas). It is wise to keep the dose rate at any normal working area less than 1/10 this amount. This storage space must be clearly marked with radiation symbols, and should preferable be locked. If not locked, then the room must be locked when not in use.

5. If there is any possibility of radioactive materisl being airborne (gaseous products, finely powdered materials, boiling solutions, etc.) an adequate hood venting directly to the outside must be provided and used.

6. Surface contamination on benches, floors, etc., must be promptly removed. If contamination exceeds 0.5 mR/hr after removal attempt, the area should be covered and warnings posted.

Personnel must monitor skin and clothing regularly. Clothing with contamination exceeding 0.1 mR/hr should not be worn. Skin contamination should not exceed 0.1 mR/hr.

If contamination cannot be reduced to the above levels, call the Radiation Safety Officer.

The use of trays for performing all operations is recommended. It is also highly recommended that bench tops be covered with easily decontaminable or removable materials. Absorbent paper

with waterproof backing is sold for this purpose. Stripable paints are also useful. Easily replaceable asphalt tile or linoleum floor coverings are desirable. It must be recognized that the department involved is fully responsible for removing contamination to the satisfaction of the Isotope Committee.

7. Proper techniques must be used at all times, e.g., mechanical pipetting, use of tongs for handling hot samples, double containers for solutions, rubber gloves when there is danger of contaminating the hands, adequate shielding, etc. So far as external radiation hazards are concerned, the greatest safety factors are time and distance.

8. Contaminated glassware, tools, waste, etc., must be properly marked and stored in a shielded space (see #5 above).

9. Disposal of wastes must be in accordance with NRC rules given in 10 CFR 20. Consult the Radiation Safety Officer for advise on disposal methods not specified in 10 CFR 20.

11. Any spills or accidents involving more than LOW LEVEL quantities of isotopes must be reported immediately to the Radiation Safety Officer.

If there is any uncertainty regarding any of the above, the Radiation Safety Officer should be consulted.

HOSPITAL RADIOISOTOPE COMMITEE REVIEW

Protocol Number

Investigator

Date of Application

Radioisotope Desired

Approve

Disapprove

Comments

Signature of reviewer

Date

YALE UNIVERSITY/YALE-NEW HAVEN HOSPITAL

Application for experimental and nonroutine use of radioisotopes in humans.

Fill out completely, sign, and return, together with 8 copies to:

Dr. Eugene A. Cornelius, Chairman
Hospital Radioisotope Committee
Section of Nuclear Medicine
CB 3 (telephone 2428)

	University	Hospital
	_____	_____
	_____	_____
	_____	_____
		_____
		_____
		_____
		_____
		_____

Date _____ (Approval by the Yale-New Haven Hospital Radioisotope Committee expires 24 months from date of application.

Date of first order _____

1. Name of responsible investigator _____

   Faculty rank _____

   A. Room No. & Bldg. _____ Dept. _____

      Telephone Ext. _____

   B. All room numbers in which isotope is to be used _____

2. Radioisotope desired _____

   A. Total amount to be purchased in next two years _____ Millicuries

   B. Maximum amount to be purchased at any one time _____ Millicuries

   C. Maximum amount to have on hand at any one time _____ Millicuries

   D. Form (list compounds) _____

   E. Liquid, powder, or solid? _____

3. Will the isotope be received precalibrated and preassayed for pharmaceutical quality. If not give a desciption of the planned calibration and assay procedure.

4. Title of Study:

5. Purpose of Study: (a)

(b) Is this a "well established medical use" as defined by the NRC in the NRC Licensing Guide - Medical Programs? If not, indicate whether the study is clinical research or clinical evaluation and explain why. (Clinical research applies to a new use of radioisotopes in humans; such use is based on previous animal studies. Clinical evaluaton applies to the planned testing of a new diagnostic or therapeutic procedure in a series of control and diseased humans; this phase follows the clinical research phase).

6. Plan of investigation:

7. Will any complementary drugs or radioisotopes be administered?

8. Expected fate of the radioisotope. If a therapeutic procedure, what are the expected effects?

9. Background. Give pertinent references and a brief abstract of published and/or unpublished material including data on localization, effective

half-life, and radiation dosage. If application is for clinical research (as defined above) include data obtained in experimental animals; if no work has been conducted in animals, explain why.

10. Description of subject.

a. Control group - number, method of selection, age range.

b. Experimental group - number, nature of pathology, method of selection, age range.

c. If pregnant women are to be tested, explain why.

11. Please confirm that the consent of the subject of his/her representatives will be obtained.

12. Dose of radioisotop (microcuries or millicuries)

    a. Route

    b. Maximum amount to be given at one time

    c. Possible repeat dosages

    d. Total dosage

    e. Rationale for the dosage used

13. Calculation of radiation dose

    a. Total body

    b. Critical organ

    c. Expected half-life in various organs.

    d. Radiation dose from other radioisotopes given concurrently. (Please note that this rpotocol applies to one radioisotope only)

14. Institutional resources and radiation safety

    a. Physical facilities and equipment for study.

    b. List facilities for handling radioisotopes, i.e. monitoring and measuring equipment, shielding, hood, etc.

c. List procedures to be used to survey for radioactive contamination. (Note: For radioactive contamination resulting from work involving C-14 or H-3, dry smears of the area should be taken using #41 Watman fliter paper; counting should be done in a liquid scintillation counter.)

d. What plans have been made for decontamination in case of accident?

e. What plans have been made for easte disposal (gas, liquids, solids, animals)? NRC and STATE regulations require records of the disposition of all radioisotopes received by you. Please refer to the Yale University Radiation Committee Rules and Regulations concerning radioactive waste disposal procedures.

f. Name all persons who will use of be exposed to radiation (i.e., working in the same laboratory) from radioisotopes. See Yale University Radiation Safety Committee/Yale-New Haven Hospital Radioisotope Committe rules in regard to film badges. The following individuals have been instructed in the radiation protection problems associated with this isotope and in appropriate precautions to minimize expsoure.

Primary User:

Others:

List research training and experience of responsible investigator and pertinent training and experience in the use of radioisotopes.

Estimated duration of study.

Reports. The NRC requies a report on each nonroutine human use of radioisotopes. Please indicate schedule or reporting to this Committee - this may be in terms of time intervals or number of subject studied. If studies arelong range, interim reports (at least annually) should be submitted.

Each report should include:

a. Purpose of the study.

b. Summary of results of study.

1. The radioisotope administered, its chemical form, and route of administration.
2. The number of patients involved in the study, their ages, sex, and clinical diagnosis before adminstration of the radiopharmaceutical.
3. The dosage and frequency of administration.
4. Complementary drugs administration.
5. The method of preparation of the radiopharmaceutical, if it was not obtained in a prepackaged, precalibrated, sterile and pyrogrn-free form from a pharmaceutical supplier.
6. Special radiation detection instrumentation used.
7. A statement of organ distribution and an estimate of the respective biological half-life of the administered radioisotope as determined during the course of the study. State the rationale behind these estimated or methods used to make the determination.

8. A synopsis of the toxicity data obtained.

9. Brief clinical histories of allpatients 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.

c. An evaluation by the investigator of the safety and efficacy of the diagnostic or therapeutic procedure. This evaluation should include a statement of 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.

Signature below affirms that the responsible investigator/ clinician has read and will comply with the regulations set forth by the Yale University Radiation Safety Committee/Yale-New Haven Radioisotope Committee in the use of radioisotopes.

In case of prolonged absence or termination, please notify the Health Physics Division, 6-2935 or 6-2936 or Hospital Radiation Safety Officer, 2950.

Signature _____

PLEASE NOTE

This research protocol conforms with recommendations set forth in NRC licensing Guide - Medical Programs, April, 1972. The Hospital Radiation Safety Officer and the University Health Physics Division are available for consultation in calculation of radiation doses.