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	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
St. Marys Hospital Medical Center Department of Medical Imaging 707 S. Mills St. Madison, Wisconsin 53715-0450 TELEPHONE NO.: AREA CODE (608) 251 - 6100 ext 6933	Same as 1.a.
2. PERSON TO CONTACT REGARDING THIS APPLICATION Stephen Dudiak, M. D. TELEPHONE NO.: AREA CODE (608) 251 - 6100 ext 6933	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. _____ c. ☒ RENEWAL OF LICENSE NO. 48-00919-03
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)* Stephen Dudiak, M. D.; Ivan Kenzevic, M. D. George Roggensack, M. D.; Richard Lindgren, M. D. Tamnit Ansusinha, M. D.	5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)* Richard Lindgren, M. D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

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

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	400 mCi
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	50 mCi
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50 mCi
GOLD-198 AS COLLOID FOR INTRA-CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	400 mCi
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	500 mCi

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Americium-241	Sealed source Amersham-Searle, Inc. Model AMC-24	14 mCi	Anatomical Marker Model SS-10244

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

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

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer, Jr. & Co.	Monthly
	X	TLD		Monthly
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer, Jr. & Co.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

All personnel involved in generator elution, kit prepartion, radionuclide injections, and other general radionuclide handling wear both whole body film badges and TLD rings. All other personnel wear either whole body film badges or whole body TLD badges.

Applicant. Cp 2036
Check No. 59893
Amount Fee Category 7C Renew
Type of Fee
Date Check Rec'd 4/29/85
Received By

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: Renewal

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*: Mr. Larry Narum

(2) TITLE: Associate Director

c. DATE: 4-22-85

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.

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
Richard D. Lindgren, M. D.	Wisconsin

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology		June, 1961
Nuclear Medicine		May, 1972

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	Cook County, Illinois 1976 Detroit Receiving	10 hours 3 hours	10 hours
b. RADIATION PROTECTION	Cook County, Illinois 1976 Detroit Receiving, 1957-59	10 hours 20 hours	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Cook County, Illinois 1976	2 hours	
d. RADIATION BIOLOGY	Detroit Receiving, 1957 Indiana University, 1971	20 hours 3 hours	
e. RADIOPHARMACEUTICAL CHEMISTRY	Indiana University, 1971	2 hours	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I 131	10 mC	Detroit General	1958 - 6 months	Hyperthyroidism
I 131	100 mC/dose	St. Marys - Madison	5 years	Carcinoma
Tc 99m		St. Marys - Madison	1968 to 1979	Diagnosis
Indium 111		St. Marys	1972 to 1979	Diagnosis
Cr 51, Thallium				

ITEM #7 - RADIATION SAFETY COMMITTEE

The Radiation Safety Committee's responsibilities and functions are listed on the following page as outlined in St. Marys Hospital Medical Center's bylaws. This committee will meet when needed, but at least four times per year.

The committeee has the following members:

Dr. R. Lindgren - Radiology - Radiation Safety Officer
Dr. T. Ansusinha - Radiology
Dr. E. Walsh - Medical Staff
Dr. E. Henderson - Cardiology
Dr. W. Card - Pathology
Dr. P. Dibble - Medical Staff
Dr. R. Kuritz - Medical Staff
Dr. E. Prendergast - Oncology
Charles Zeisser - Administration
Lyndon Lawler - Cardiology
Robert Heinzel - Nuclear Medicine
Katie Jones - Nursing
Virginia Kruschel - Nursing

ITEM #8 TRAINING AND EXPERIENCE

Please refer to our application dated 1960 and 1980. Copies attached.

Radiation Safety Committee

Typically the Radiation Safety Officer serves as the executive arm of the Committee.

The Committee should be aware of and oversee all uses of radiation in the institution from the standpoint of radiation safety to both patients and staff.

In general, no one should be permitted to bring radioactive materials into an institution until:

1. The committee has reviewed the proposed use in detail and granted its approval in writing.

2. The committee is assured that there is or will be a license from the appropriate regulatory agency (NRC or Agreement State) to cover the proposed use.

3. The individual has stated in writing that he is familiar with and will observe pertinent regulatory requirements and relevant radiation safety regulations established by the committee.

4. The individual has agreed to notify the committee (or the radiation safety officer) each time he receives or brings radioactive materials into the institution (except for a routine diagnostic service). This notification can be accomplished most easily by routine use of a standard form, providing for information of the following type:

    a. The radionuclide and chemical form to be administered.

    b. The dosage schedule or number and individual strengths of sealed sources.

    c. The expected date and time of administration.

    d. The room where the patient is located while containing the radioactivity.

    e. The expected time of removal of sealed sources.

    f. The names of responsible persons and where they can be reached in an emergency.

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Richard D. Lindgren

STREET ADDRESS

6006 Green Tree Road

CITY	STATE	ZIP CODE
Madison	Wis	53711

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	3400	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	270	
	LIVER FUNCTION STUDIES	18	
	FAT ABSORPTION STUDIES	52	
	KIDNEY FUNCTION STUDIES	330	
	IN VITRO STUDIES	320	
OTHER			
I-125	DETECTION OF THROMBOSIS	-	
I-131	THYROID IMAGING	1450	
P-32	EYE TUMOR LOCALIZATION	5	
Se-75	PANCREAS IMAGING	80	
Yb-169	CISTERNOGRAPHY	90	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	-	
OTHER			
Tc-99m	BRAIN IMAGING	3200	
	CARDIAC IMAGING	250	
	THYROID IMAGING	450	
	SALIVARY GLAND IMAGING	10	
	BLOOD POOL IMAGING	150	
	PLACENTA LOCALIZATION	110	
	LIVER AND SPLEEN IMAGING	3300	
	LUNG IMAGING	1400	
	BONE IMAGING	2300	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	35	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	18	
I-131	TREATMENT OF THYROID CARCINOMA	15	
	TREATMENT OF HYPERTHYROIDISM	105	
Au-198	INTRACAVITARY TREATMENT	-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	15	
	INTRACAVITARY TREATMENT	-	
I-125 or Ir-192	INTERSTITIAL TREATMENT	-	
Co-60 or Cs-137	TELETHERAPY TREATMENT	85	
Sr-90	TREATMENT OF EYE DISEASE	8	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

1957-1961 Residency Wayne University Affiliated Hospitals Detroit, Michigan
1962-1979 Clinical Experience St Marys Hospital Medical Center Madison, Wisconsin
1972 American Board of Nuclear Medicine

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

a. NAME OF SUPERVISOR
Stephen Dudiak M.D.

b. NAME OF INSTITUTION
St Marys Hospital Medical Center

c. MAILING ADDRESS
707 S. Mills Street

d. CITY
Madison, Wisconsin 53715

5. MATERIALS LICENSE NUMBER(S)

48-00919-03

6. PRECEPTOR'S SIGNATURE

Richard D. Lindgren M.D.

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

Richard D. Lindgren

8. DATE

1-10-80

FORM NRC-313M-SUPPLEMENT B
(6-78)

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Tamnit Ansusinha M.D.

STREET ADDRESS

1102 Brookwood Road

CITY | STATE | ZIP CODE

Madison, Wis 53711

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	4200	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	300	
	LIVER FUNCTION STUDIES	-	
	FAT ABSORPTION STUDIES	180	
	KIDNEY FUNCTION STUDIES	360	
	IN VITRO STUDIES	420	
OTHER			
I-125	DETECTION OF THROMBOSIS	-	
I-131	THYROID IMAGING	1800	
P-32	EYE TUMOR LOCALIZATION	-	
Se-75	PANCREAS IMAGING	90	
Yb-169	CISTERNOGRAPHY	120	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	28	
OTHER			
Tc-99m	BRAIN IMAGING	3600	
	CARDIAC IMAGING	340	
	THYROID IMAGING	600	
	SALIVARY GLAND IMAGING	-	
	BLOOD POOL IMAGING	180	
	PLACENTA LOCALIZATION	120	
	LIVER AND SPLEEN IMAGING	3500	
	LUNG IMAGING	1800	
	BONE IMAGING	2400	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	12	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	-	
I-131	TREATMENT OF THYROID CARCINOMA	18	
	TREATMENT OF HYPERTHYROIDISM	540	
Au-198	INTRACAVITARY TREATMENT	-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-	
	INTRACAVITARY TREATMENT	-	
I-125 or Ir-192	INTERSTITIAL TREATMENT	-	
Co-60 or Cs-137	TELETHERAPY TREATMENT	-	
Sr-90	TREATMENT OF EYE DISEASE	-	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ [illegible]	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

1959-1962 Residency St Lukes Hospital Milwaukee, Wisconsin
1962-1963 Residency University of Washington, Seattle , Washington
1964-1979 Clinical Experience St Marys Hospital Medical Center Madison, Wisconsin
1963 American Board of Radiology and Nuclear Medicine
1975 American Board of Nuclear Medicine

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

a. NAME OF SUPERVISOR
Stephen Dudiak M.D.

b. NAME OF INSTITUTION
St Marys Hospital Medical Center

c. MAILING ADDRESS
707 S. Mills Street

d. CITY
Madison, Wisconsin 53715

5. MATERIALS LICENSE NUMBER(S)
48-00919-03

6. PRECEPTOR'S SIGNATURE
Tamnit Ansusinha

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

8. DATE
1-10-80

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

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Ivan Knezevic M.D.

STREET ADDRESS

35 Applewood Drive

CITY	STATE	ZIP CODE
Madison	Wis.	53711

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	2500	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	150-200	
	LIVER FUNCTION STUDIES	-	
	FAT ABSORPTION STUDIES	50	
	KIDNEY FUNCTION STUDIES	250	
	IN VITRO STUDIES	300	
OTHER			
I-125	DETECTION OF THROMBOSIS	15	
I-131	THYROID IMAGING	2000	
P-32	EYE TUMOR LOCALIZATION	-	
Se-75	PANCREAS IMAGING	50	
Yb-169	CISTERNOGRAPHY	100	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	-	
OTHER			
Tc-99m	BRAIN IMAGING	3000	
	CARDIAC IMAGING	500	
	THYROID IMAGING	1500	
	SALIVARY GLAND IMAGING	20	
	BLOOD POOL IMAGING	150	
	PLACENTA LOCALIZATION	100	
	LIVER AND SPLEEN IMAGING	1500	
	LUNG IMAGING	1000	
	BONE IMAGING	1000	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	50	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	10	
I-131	TREATMENT OF THYROID CARCINOMA	50	
	TREATMENT OF HYPERTHYROIDISM	100	
Au-198	INTRACAVITARY TREATMENT	5	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-	
	INTRACAVITARY TREATMENT	-	
I-125 or Ir-192	INTERSTITIAL TREATMENT	-	
Co-60 or Cs-137	TELETHERAPY TREATMENT	200	
Sr-90	TREATMENT OF EYE DISEASE	-	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

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

1963-1966 Residency Milwaukee County Hospital Milwaukee, Wisconsin
1966-1979 Clinical Experience St Marys Hospital Medical Center Madison, Wisconsin
1976 American Board of Nuclear Medicine

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

a. NAME OF SUPERVISOR
Stephen Dudiak M.D.

b. NAME OF INSTITUTION
St Marys Hospital Medical Center

c. MAILING ADDRESS
707 S. Mills Street

d. CITY
Madison, Wisconsin 53715

5. MATERIALS LICENSE NUMBER(S)

48-00919-03

6. PRECEPTOR'S SIGNATURE

Ivan Knezevic, MD

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

Ivan Knezevic

8. DATE

1-10-80

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

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
George F. Roggensack M.D.

STREET ADDRESS
1014 Hillside Drive

CITY	STATE	ZIP CODE
Madison	Wis	53705

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	1600	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	120	
	LIVER FUNCTION STUDIES	5	
	FAT ABSORPTION STUDIES	25	
	KIDNEY FUNCTION STUDIES	210	
	IN VITRO STUDIES	240	
OTHER			
I-125	DETECTION OF THROMBOSIS	-	
I-131	THYROID IMAGING	900	
P-32	EYE TUMOR LOCALIZATION	-	
Se-75	PANCREAS IMAGING	40	
Yb-169	CISTERNOGRAPHY	70	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	-	
OTHER			
Tc-99m	BRAIN IMAGING	2300	
	CARDIAC IMAGING	180	
	THYROID IMAGING	300	
	SALIVARY GLAND IMAGING	5	
	BLOOD POOL IMAGING	100	
	PLACENTA LOCALIZATION	90	
	LIVER AND SPLEEN IMAGING	2600	
	LUNG IMAGING	1200	
	BONE IMAGING	1900	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

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

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

1967-1970 Residency Edward Mallinckrodt Institute of Radiology, Washington University School of Medicine St. Louis Missouri
1970-1979 Clinical Experience St Marys Hospital Medical Center Madison, Wisconsin
1976 American Board of Nuclear Medicine

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

a. NAME OF SUPERVISOR
Stephen Dudiak M.D.

b. NAME OF INSTITUTION
St Marys Hospital Medical Center

c. MAILING ADDRESS
707 S Mills Street

d. CITY
Madison, Wisconsin 53715

5. MATERIALS LICENSE NUMBER(S)

48-00919-03

6. PRECEPTOR'S SIGNATURE

G F Roggensack MD

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

George F. Roggensack

8. DATE

1-10-80

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

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Nuclear Chicago

   Manufacturer's model number: 9121

   Number of instruments available: 1(one)

   Minimum range: 0.2 mR/hr to 2000 mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

   b. Manufacturer's name: Nuclear Chicago

   Manufacturer's model number: 2650

   Number of instruments available: 1 (one)

   Minimum range: 0 mR/hr to 0.10 mR/hr

   Maximum range: 0 mR/hr to 100 mR/hr

   C. Searle Model 2592 Min. Range 0-10 mr/hr. Max. range 0-1000 R/hr.

2. Dose calibrator

   Manufacturer's name: Capintec, Inc.

   Manufacturer's model number: CRC-10R

   Number of instruments available: 1 (one)

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	6406 Pho Gamma IV
Gamma Camera	Searle	6413 Pho Gamma LFOV
Phodot Scanner	Nuclear Chicago	1732

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

Well Scintillation Detector	ADC Medical	330
Scintillation Probe and Spectrometer	ADC Medical	201, 300
Squibb Q.C. Analyzer	Bionucleonics, Inc.	QC-10
Ventil-Con II	RADX	143
XenAlert	Nuclear Associates	36-751

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

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

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

3. Survey instruments will be calibrated

* X a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

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

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

or

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

X c. By a consultant or outside firm

(1) Name Standard Nuclear Consultants, Ltd.

(2) Location Manhattan, IL

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 12-20362-01

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

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

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

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

*Warrington
One Warrington Industrial Park
20702 Fm. 685
Pflugerville, Tx 78660

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments:

Nuclide	Activity or Exposure Rate at Specified Distance	Calibration Accuracy

Calibration Source:

Calibrated by _____ Date _____

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ±5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	300 uCi	± 3.25% done daily
Ba-133	0.1-0.5	250 uCi	± 3.25% done daily
Cs-137	0.1-0.2	200 uCi	± 3.25% done daily
Ra-226	1-2	_____	_____
_____		_____	_____

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

or

_____ Equivalent procedures are attached.

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

ITEM #10 CALIBRATION OF INSTRUMENTS

Appendix D procedures will be followed for survey instruments and dose calibrator calibrations.

Regulatory Guide 10.8, Rev. 1 Date: Oct. 1980

ITEM #II - FACILITY DIAGRAM

Please refer to the facility diagram to explain the following information.

All radioactive materials are received in the hot lab, Room 4214. All packages received by the hospital during off duty hours will be brought to this room per the procedure for receiving radioactive material on off duty hours, (see Item #13). All packages will be opened on the counter top covered by absorbant chux, according to the procedure for checking incoming packages, (see Item #14). Immediately after opening packages, radioactive materials are to be stored in either the lead lined refrigerator or the lead lined closet.

All 131-Iodine vials will be opened and dispensed in the hot lab with the fume hood running. All xenon unit dose vials will be stored in the hot lab closet. Please refer to amendment #19 to license #48-00919-03 for the description of our ventilation system.

The generators are stored in lead barns, supplied by the manufacturer, and supplemental shielding is provided by a lead body shield as shown in the enlarged view of the hot lab. The generators are eluted into lead shielded vials in the hot lab closet. Upon the completion of the elution procedure, the shielded vials are placed on a sturdy four wheel injection cart and transported to Room #4217-A for assay. Upon arrival, the shielded vials are placed behind the lead shield on the counter. The vials are then assayed using a long handled forceps. Immediately after assay, all vials are placed back into lead pigs.

All radiopharmaceutical preparation will take place in Room #4217 A, with the exception of Sulfur Colloid. Sulfur Colloid will be prepared in the hot lab in the shielded boiling area. All radiopharmaceuticals will be prepared according to the manufactures package inserts. All radioactive syringes will be in syringe shields at all times and disposable gloves will be worn during preparation. Following preparation, a survey will be taken of the area, body, and hands of the technologist and the results recorded.

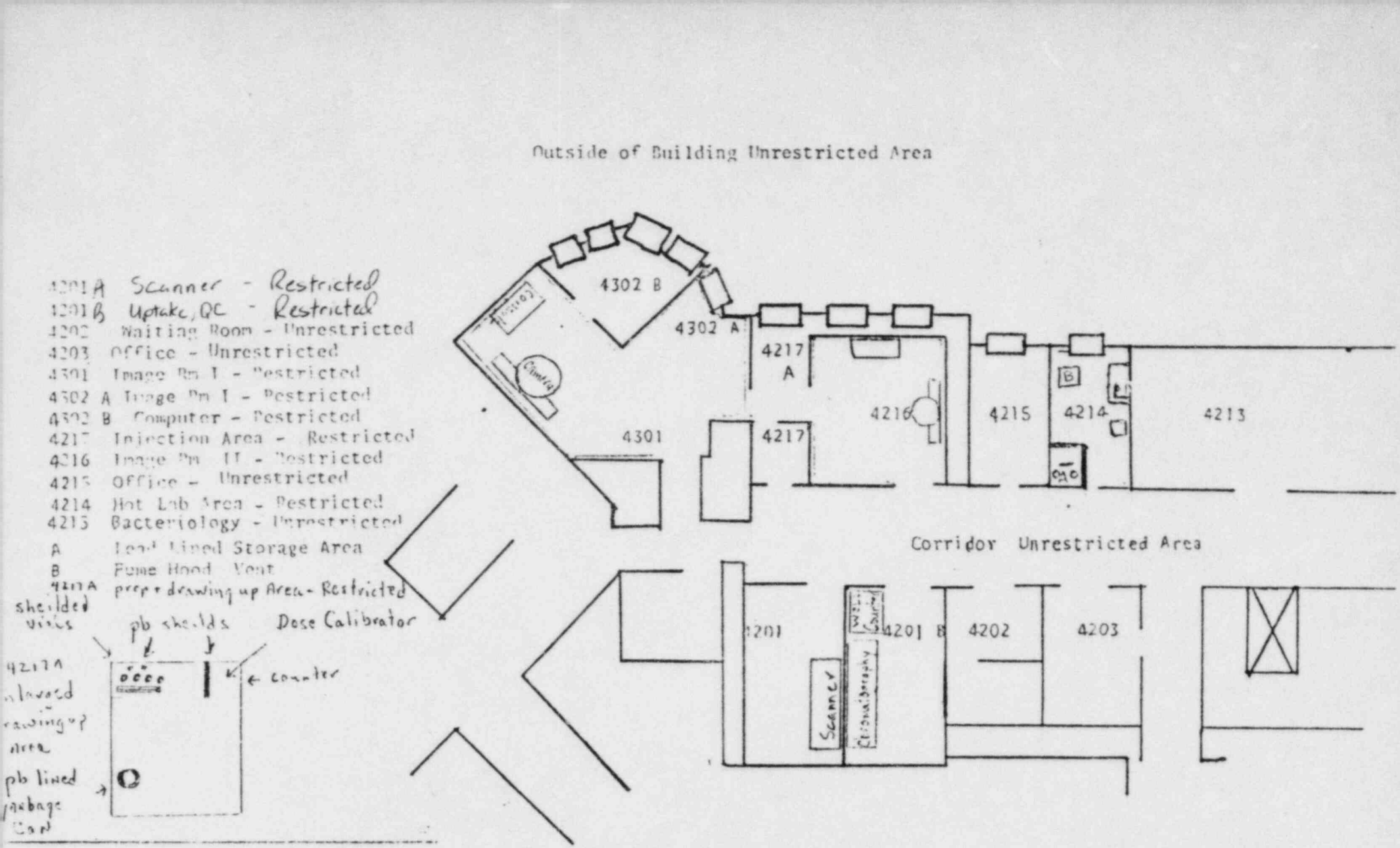
All patient doses will be drawn up in Room #4217-A, and transported to either Camera Room or the Injection Room (4217) using the injection cart. All doses will be placed in cylindrical syringe shield holders for further protection. Instant thin layer chromatography will be done on all radiopharmaceuticals in Room 4201-B. Radioactive samples will be transported in the above fashion to room 4201-B.

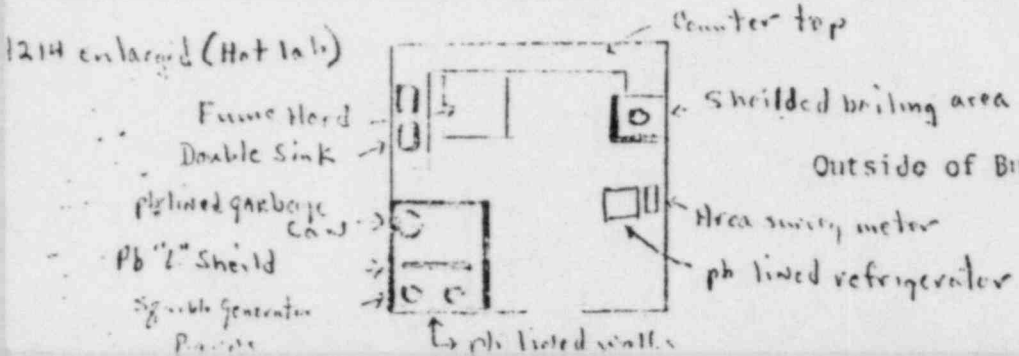
All used radioactive syringes will be placed into the lead lined garbage can. At the end of each day, the plastic bag in the garbage can will be removed, labeled, and taken to the lead lined closet for decay. All radiopharmaceutical vials will be removed from Room 4217-A in their lead shields at the end of each day and taken to the lead lined closet for decay.

All used radiopharmaceuticals and radioactive syringes will be labeled and transported to the decay room in shielded containers. Here, they will be held for a minimum of ten half-lives and allowed to decay to background. Before disposal, each item will be monitored for activity and the results recorded. If the item is no longer radioactive above background, then it will be disposed as non-radioactive trash. The appropriate disposal records will be kept on the disposal of all radioactive by-products.

Outside of Building Unrestricted Area

4201 A Scanner - Restricted
4201 B Uptake, QC - Restricted
4202 Waiting Room - Unrestricted
4203 Office - Unrestricted
4301 Image Rm I - Restricted
4302 A Image Rm I - Restricted
4302 B Computer - Restricted
4217 Injection Area - Restricted
4216 Image Rm II - Restricted
4215 Office - Unrestricted
4214 Hot Lab Area - Restricted
4213 Bacteriology - Unrestricted
A Lead Lined Storage Area
B Fume Hood Vent
4217A prep + drawing up Area - Restricted





Outside of Building Unrestricted Area

ITEM #12 PERSONNEL TRAINING PROGRAM

All personnel working in restricted areas are registered Nuclear Medicine technologists who have had in their formal training program, didactic as well as clinical instruction.

Ancillary personnel (e.g. clerical, nursing, housekeeping, security personnel), whose duties may require them to work in the vicinity of radioactive material will be informed about radiation hazards and appropriate precautions. Training will be via continued education sessions or during general safety education sessions. The training program will include annual refresher training.

Personnel who work with, or in the vicinity of, radioactive materials will be properly instructed:

a. Before assuming duties with, or in the vicinity of, radioactive materials.
b. During annual refresher training.
c. Whenever there is a significant change in duties, regulations, or terms of the license.

Instruction will be given at least once a year, under the supervision of the radiation safety officer, in the form of lectures and demonstrations. Instruction will include:

a. All terms of the license pertinent to radiation safety.
b. Areas where radioactive material is used or stored.
c. Potential hazards associated with radioactive material.
d. Radiological safety procedures appropriate to their respective duties.
e. Pertinent NRC regulations.
f. Rules and regulations of the licensee.
g. Obligation to report unsafe conditions to the radiation safety officer.
h. Appropriate response to emergencies or unsafe conditions.
i. Right to be informed of their radiation exposure and bioassay results.
j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions.

For personnel regularly working in a restricted area, evaluation of training will be determined through testing and on-the-job observation of work habits.

ITEM #13 PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

All radioactive materials will be ordered by registered Nuclear Medicine technologists. These individuals will have a thorough knowledge of our license's possession limits and will order materials accordingly. The following procedure will be followed:

1. All radioactive materials will be ordered by telephone from a reputable firm.
2. Each order will be logged in a permanent book, which will indicate the following: Date ordered, type and amount of radiopharmaceutical company, delivery date, and technologist.
3. All carriers will be instructed to deliver packages directly to Nuclear Medicine during working hours.
4. All packages brought to the hospital during off duty hours will be received per the following procedure:

Procedure for Receiving Radioactive Material on Off Duty hours:

1. All radioactive packages will be received through the Mills Street entrance and taken to the information desk.
2. Upon arrival of a package, the information desk person shall contact Central Supply.
3. A Central Supply employee will come to the Information desk and receive the package.
4. Receiving the package includes: a) inspecting the package for any leakage. b) completing a leakage slip which includes date, time, and results of leakage inspection. c) putting the package on a cart and taking it to the orthopedic equipment room in Central Supply.
5. The package is then picked up by a Nuclear Medicine technologist as soon as the Nuclear Medicine section has opened.
6. If the radioactive package is found to be leaking, the transport carrier must remain at the hospital and the Nuclear Medicine technologist on call must be notified immediately.
7. As soon as the technologist arrives he or she is to open the package according to the "Procedure for Safely Opening Packages Containing Radioactive Material".
8. If the outer package is contaminated indicating radioactive leakage, the transport carrier vehicle must be surveyed and decontaminated until a level of background is reached.
9. The areas in the hospital where a leaking radioactive package has been must also be surveyed and decontaminated to background.

ITEM #14 PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

Appendix F procedures will be followed.

Regulatory Guide 10.8, Rev. 1 Date: Oct. 1980

ITEM #15 GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

Appendix G rules will be followed.

Regulatory Guide 10.8, Rev. 1 Date: Oct. 1980

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

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

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

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

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

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

Major Spills

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

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

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

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

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

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

RADIATION SAFETY OFFICER: Dr. R. Lindgren*
OFFICE PHONE: 258-6933
HOME PHONE: 271-4494

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Eileen McKinley 271-3045
Robert Heinzel 238-3975

*The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

ITEM #17 AREA SURVEY PROCEDURES

Appendix I procedures will be followed.

Regulatory Guide 10.8, Rev. 1 Date: Oct. 1980

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)

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

_____ By commercial 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.

__X__ 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)

__X__ 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 commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

* 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

The following procedures will be used for administering therapeutic radiopharmaceuticals along with Appendix K for inpatients.

All patients receiving Iodine-131 may be done as outpatients if the intended dose is less than 30 milliCuries. The following procedure will be adhered to in these cases.

1. All Iodine-131 vials will be received and opened in the hot lab (Room 4214).

2. Gloves and lab coats will be worn when opening all vials and during administration of therapeutical doses.

3. The iodine vials will remain in their lead shipping containers and placed in a lead cylinder prior to useage. At this time, the sheilded vial will be placed on absorbant chux.

4. All vials will be opened near the running fume hood using long handled forceps.

5. All iodine will be administered in the hot lab with the fume hood running.

6. A radiologist will be present during the administration of therapeutic doses.

7. The patient will drink the Iodine-131 through a straw over absorbant chux. After the initial drink, the straw will remain in the vial and the vial will be rinsed with water several times.

8. After the therapy procedure, all used materials will be surveyed and any contaminated items will be put in a labeled plastic bag and sent to the decay room.

9. The patient may leave after a fifteen minute wait post therapy. We will instruct the patient on basic safety procedures and give them the Radiation Safety Officer's phone number and the Nuclear Medicine Department's number in case of any type of accident.

All therapeutic patients requiring hospitilization will receive their therapeutic doses in the hot lab following the above procedures. Therapeutic patients will be placed in Room 6526, a single room with a private toilet. This room is on the top floor and is at the end of the hall. There is only one adjacent room and one room below it.

Following therapy, the patient is taken to Room 6526 by a Nuclear Medicine Technologist. At this time the patient is put in bed and a baseline survey is done at bedside, 1 meter, and at the room's door. Daily surveys will be done following therapy until less than 30 milliCuries of Iodine-131 remain in the patient's body.

The guidiines set forth by Appendix K and its' nursing instructions will be followed for Phosphorus-32 and Iodine-31 inpatient therapy cases.

ITEM#21 PROCEDURES AND PRECAUTIONS
FOR USE OF RADIOACTIVE GASES

Please refer to our letter dated September 28, 1978 for amending our license to include the use of Xenon-133. This letter includes detailed information on our ventilation system and safety procedures for handling the radioactive gas.

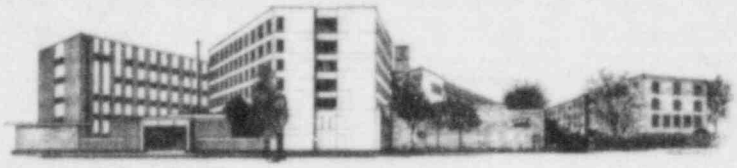
ITEM#23 PROCEDURES AND PRECAUTIONS FOR USE OF
RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6B

The Am-241 anatomical marker will be used only to mark anatomical landmarks. It will be housed in the sheilded slot in the Searle Large Field of View detector head at all other times.

8/31/79
7D

St. Marys Hospital Medical Center

707 South Mills Street
Madison, Wisconsin 53715
Telephone (608) 251-6100



A Hospital of the Sisters of Saint Mary

RECEIVED BY LFMB
Date OCT 3 1978
Log Rgl Oct II
By Brown
Orig. To
Action Compl. 10/5/78

August 30, 1978

Applicant St. Marys Hosp. Med. Ctr.
Check No. 13122
Amount/Fee $40-00
Type of Fee Amend
Date Check Rec'd OCT 3 1978
Received By Brown

U.S. Nuclear Regulatory Commission
Region III
Radioisotope Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137
Attention: Bernard Singer, Chief

Dear Sir:

Please amend our NRC License No. 48-00919-03 to include Xenon 133 gas which will be used to perform pulmonary ventilation studies.

We request a possession limit of 500 MCI Xenon 133. A maximum of 50 patients per month (600 per year). This examination will be performed using an average dose of 10 MCI per procedure. Higher doses will be used only when professional medical judgment indicates it to be necessary.

All doses for patient use will be checked immediately prior to administration with a Nuclear Chicaho Mediac, model o18903. The dose calibrator will be calibrated a minimum of two times a year and appropriate records maintained.

All personnel working in the department will use whole body film badges and TLD finger badges. The radiological safety equipment and procedures are the same as those described in our original license submission. They will be followed in addition to the special procedures described in this submission.

The radiopharmaceuticals will be supplied by:

a) New England Nuclear Corporation, Atomlight Place, Billerica, MA 01862

b) Med Physics, Inc., 9820 West Brynmawr, Rosemont, IL 60018

Attachments number 1 and 2 are the package inserts describing the Xenon 133 gas in unit dose vials. This product has NDA status with the Food and Drug Administration.

The special equipment to be used in conjunction with our Searle LOF gamma camera is listed below, the manufacturer's literature is attached.

1.	Xenon 133 lung function unit	36-001
2.	Kymograph chest paper	36-005
3.	Kymograph self-inking pen	36-006
4.	Disposable mouthpiece	36-007
5.	CO_2 absorber - 2 lb container	36-008
6.	"Nonex" Xenon gas trap	36-022
7.	Replacement cartridge pack	36-026

SEP 28 1978

Control No. 00811

Attachment number 4 is a scale drawing of our facility.

The Xenon 133 gas will be stored in its 1/8" thick lead shipping container within the storage cave (3" lead brick) located in the hot lab. A description of this room (No. 4214), the storage cave, work area, radiation monitoring equipment, dose calibrator and radiological safety procedures are the same as those described in our license submission. In addition, we have installed a fume hood over the work area.

Storage area calculation:

Room Number 4214
Dimension 14.5 x 8 x 9 $ft.^3$
Occupancy restricted area
Total air flow volume without hood installed = 344 $ft.^3/min.$
Air circulation: Non re-entrant type - Negative room pressure
Maximum activity of Xe 133 to be stored = 500 MCI

a) Time required to exchange the air volume once

$$= \frac{\text{total volume}}{\text{total air flow volume}}$$

$$= \frac{1116\ ft.^3}{344\ ft.^3} = 3.24\ min.$$

Maximum Xe 133 gas concentration in the storage area:

Maximum activity of Xenon/week = 500 MCI
Estimated escape fraction = 0.25
Air flow volume = 344 $ft.^3/min.$
Maximum concentration = $\frac{500 \times 10^3\ uci \times 0.25}{344\ ft.^3/min. \times 6.797 \times 10^7\ ml./40\ hr.\ week}$

$= 0.53 \times 10^{-5}$ uci/ml per 40 hr. week

The total air flow volume 344 $ft.^3/min.$ will be increased to 2000 $ft.^3/min.$ by installation of the fume hood over the storage area. And, under this condition, the maximum concentration of Xe 133 in the room will be = 0.09×10^{-5} uci/ml.

The time required to exchange the air volume 10 times will be 5.6 min.

Air can enter the room through - ceiling vents, the window and a door. All the air leaving the room is through the fume hood which also keeps the room ar negative pressure.

This concentration is less than the MPC of 1×10^{-5} uci/ml as stated in Section 20.103 10 CFR and Schedule B table.

In the event of an inadvertent release of the Xe 133 in this storage area, the following emergency procedure will be implemented.

-The selector switch of the hood will be pointed to the 2000 $ft.^3/min.$ setting, the window will be fully opened, all personnel will leave the room and the door will be closed.

- The room will remain unoccupied for 11.2 min. (20 times turn over) and will be surveyed with a low level survey meter (0 - 0.5 Mr/hr) immediately upon re-entry to insure that radiation levels have returned to normal for the area.

Patient Study Area Calculations

Rooms 4301 - 4302 - 4302B

Restricted Area

Air Circulation: non re-entrant type, negative room pressure

Total Volume -

$= 5264 \text{ ft.}^3$

Total Air Flow Volume $= 2219 \text{ ft.}^3/\text{min.}$

1. Time required to exchange the air volume once

$$= \frac{\text{Total Volume}}{\text{Total Air Flow Volume}}$$

$$= \frac{5264 \text{ ft.}^3}{2219 \text{ ft.}^3/\text{min}}$$

$= 2.37$ min.

2. Time required to exchange the air volume 10 times

$= 10 \times 2.37$

$= 23.7$ min.

3. Xenon 133 gas concentration exhausted into the unrestricted area due to an accidental spill.

Maximum activity spilled $= 10^2$ mCi.

$= 10 \times 10^3$ uci

Total air flow volume measured at the exhaust opening in the restricted area $= 9978 \text{ ft.}^3/\text{min.}$

The average concentration per year from an accidental spill

$$= \frac{10^2 \times 10^3 \text{ uci}}{9978 \times 1.484 \times 10^{10} \text{ ml/yr}}$$

$$= 6.77 \times 10^{-10} \text{ uci/ml/yr}$$

This concentration is less than the MPC of 3×10^{-7} uci/ml of Xe 133 in air in an unrestricted area averaged over a time period of one year.

4. Xe 133 gas concentration in the restricted area.

Estimated upper limit of the weekly patient load	= 50
Maximum amount of Xenon used per study	= 10 mCi
Maximum amount of Xenon used/wk (A)	= 50 x 10 mCi
	$= 5 \times 10^5$ uci
Estimated escape fraction (f)	= 0.25
Total air flow Volume (V)	= 2219 $ft.^3$/min.
	= 2219 $ft.^3$/min. x 6.797 x $10.^7$ml/40 hr. wk.
	= 1.51×10^{11} ml/40 hr. wk.
The concentration of Xenon	$= \frac{A}{V} \times f$
	$= \frac{5 \times 10^5 \text{ uci/40 hr. wk}}{1.51 \times 10^{11} \text{ ml/40 hr. wk.}} \times 0.25$
	= 0.83×10^{-6} uci/ml/40 hr. wk.

This concentration is below the MPC of 1×10^{-5} uci/ml of Xenon 133 in air in an restricted area for a time period of forty hours in any seven consecutive days.

5. Xenon concetration exhausted into the unrestricted area.

Estimated upper limit of the weekly patient load	= 50
Maximum amount of Xenon used per study	= 10 mCi
Maximum amount used/wk.	= 50 x 10 mCi
Maximum amount used per year	= 50 x 10 x 52 mCi
Escape fraction	= 0.25
Total amount of Xenon released per year	= 50 x 10 x 52 x 0.25
	= 6500 mCi
	= 6.5×10^6 uci

Total air flow
at the exhaust end = 9978 ft.^{3}/min.

= 9978 x 1.484 x 10^{10} ml/yr.

The average concentration for
one year period = $\frac{6.5 \times 10^6 \text{ uci}}{9978 \times 1.484 \times 10^{10} \text{ ml/yr.}}$

= 4.4 x 10^{-8} uci/ml/yr.

This concentration is less than the MPC of 3 x 10^{-7} uci/ml of Xenon in air in an unrestricted area as averaged over a period of one year.

Patient Study Area Calculations (Continued)

Room 4216

Restricted Area

Air circulation: non-re-entrant type, negative pressure

Total volume - 15 x 18 x 8 ft.^{3}

= 2160 ft.^{3}

Total air flow volume = 1008 ft.^{3}/min.

1. Time required to exchange the air volume once

= $\frac{\text{Total Volume}}{\text{Total Air Flow Volume}}$

= $\frac{2160 \text{ ft.}^3}{1008 \text{ ft.}^3\text{/min.}}$

= 2.14 min.

2. Time required to exchange the air volume 10 times

= 10 x 2.14 min.

= 21.4 min.

3. Xenon 133 gas concentration exhausted into the unrestricted area due to an accidental spill.

Maximum activity spilled = 10^2 mCi

= 10^2 x 10^3 uci

Total air flow volume
measured at the exhaust
opening in the
restricted area = 9978 ft.^{3}/min.

The average concentration per year from an accidental spill

$$= \frac{10^2 \times 10^3 \text{ uci}}{9978 \times 1.484 \times 10^{10} \text{ ml/yr.}}$$

$$= 6.77 \times 10^{10} \text{ uci/ml/yr.}$$

This concentration is less than the MPC of 3×10^{-7} uci/ml of Xenon 133 in air in an unrestricted are averaged over a time period of one year.

4. Xenon 133 gas concentration in the restricted area.

Estimated upper limit of the weekly patient load = 50

Maximum amount of Xenon used per study = 10 mCi

Maximum amount of Xenon used/wk. (A) = 50 x 10 mCi

$= 5 \times 10^5$ uci

Estimated escape fraction (f) = 0.25

Total air flow Volume (V) = 1008 $ft.^3$/min.

= 1008 $ft.^3$/min. x 6.797×10^7 ml/40 hr.wk.

$= 0.685 \times 10^{11}$ ml/40 hr. wk.

The concentration of Xenon $= \frac{A}{V} \times f$

$$= \frac{5 \times 10^5 \text{ uci/40 hr.wk.}}{0.683 \times 10^{11} \text{ ml/40 hr. wk.}} \times 0.25$$

$= 1.82 \times 10^{-6}$ uci/ml/40 hr. wk.

This concentration is below the MPC of 1×10^{-5} uci/ml of Xenon 133 in air in an restricted area for a time period of forty hours in any seven consecutive days.

5. Xenon concentration exhausted unto the unrestricted area.

Estimated upper limit of the weekly patient load = 50

Maximum amount of Xenon used per study = 10 mCi

Maximum amount used/wk = 50 x 10 mCi

Maximum amount used per year = 50 x ½0 x 52 Mci

Escape fraction = 0.25

Total amount of Xenon released per year = 50 x 10 x 52 x 0.25

= 6500 mCi

= 6.5×10^6 uci

Total air volume flow at the exhaust end = 9978 $ft.^3$/min.

= $9978 \times 1.484 \times 10^{10}$ ml/yr.

The average concentration for one year period = $\frac{6.5 \times 10^6 \text{ uci}}{9978 \times 1.484 \times 10^{10} \text{ ml/yr.}}$

= 4.4×10^{-8} uci/ml/yr.

This concentration is less than the MPC of 3×10^{-7} uci/ml of Xenon in air in an unrestricted area as averaged over a period of one year.

Patient Study Area Calculations

Room 3201 - 4302 - 4302B

Restricted Area

Air circulation: non-re-entrant type, negative pressure

Total volume = 5264 $ft.^3$

Total air flow volume = 2219 $ft.^3$/min.

1. Time required to exchange the air volume once

$= \frac{\text{Total volume}}{\text{Total air flow}}$

$= \frac{5264}{2219} = 2.37$ min.

2. Time required to exchange the air volume 10 times

= 2.37 x 10 = 23.7 min.

3. Xenon 133 gas concentration exhausted into the unrestricted area due to accidental spill

Maximum activity spilled = 10^2 mCi

= $10^2 \times 10^3$ uci

Total air flow volume measured at the exhaust opening in the restricted area = 9978 $ft.^3$/min.

The average concentration per year from an accidental spill

$$= \frac{10^2 \times 10^3 \text{ uci}}{9978 \times 1.484 \times 10^{10} \text{ ml/yr.}}$$

$$= 6.77 \times 10^{-10} \text{ uci/ml/yr.}$$

This concentration is less than the MPC of 3×10^{-7} uci/ml of Xenon 133 in air in an unrestricted area averaged over a time period of one year.

In the event that there is an inadvertent release of Xe 133 in imaging Room 4301, the following emergency procedure will be implemented.

-The patient will be removed from the room, the window will be opened.
-All personnel will leave the room and the door will be closed.
-The room will remain unoccupied for at least 23.7 min.

In the event that there is an inadvertent release of Xe 133 in imaging Room 4216, the following emergency procedure will be implemented.

-The room will remain unoccupied for at least 21.4 min. which will be equal to air volume 10 times.
-Upon re-entry, the rooms will be surveyed to insure the radiation levels have returned to normal.

All of the exhausted air from imaging Room 4301 and Room 4216 and the hot lab is released into an unrestricted area located on the roof of the hospital. The release point is isolated from all air intakes and adjacent building by the distance exceeding 50 feet.

The maximum concentration of Xe 133 over the period of one year for unrestricted area is calculated on pages 6 and 7.

The Xenon 133 gas will be used in the following manner after confirming the dose by measurement in our dose calibrator.

-The patient will be instructed on the details of the procedure and will be told why his cooperation is needed.
-Just prior to the study with the Xenon 133 gas, one or more practice runs will be accomplished.
-The unit dose vial will be loaded into the shield NEN Calidose Dispenser in the hot lab.
-The dispenser will be connected to the Xenon 133 lung function unit.
-The Xenon 133 gas will be administered to the patien via this unit.
-Nose clamps will be used to prevent the patient from exhaling the Xenon 133 into the room.
-The lung ventilation procedure will be composed of three standard phases breath hold, equilibrium and washout. These phases are automatically accomplished as the technologist operates the remote control switch of the unit.
-Upon completion of the study the used Xenon 133 gas will be drawn directly into "Nonex" Xenon gas trap.
-This will be checked for leakage by a Xenon trap monitor Model No. 136-250 from Atomic Products Corporation, P.O. Box 657, Center Moriches, NY 11934. The monitor will be placed at the exhaust point of the gas trap. This monitor automaticall trips a visual and aural alarm when concentrations of radioactive Xenon exceed 1×10^{-2} uci/ml.

-The system will be measured for Beta Gamma emissions. It is designed with an audio and flashing red light warning of excessive Xenon. If the alarm is activated during or after a study, the charcoal cartridge in the trap will be changed immediately after completion of the study. It is designed with a test button which permits activation of the alarm system to assure operation. A ^{137}Cs source is provided to calibrate the unit.

In order to insure that a minimum Xe 133 leakage occurs and that the equipment works correctly, the following procedure will be followed.

a) The Calidose dispenser delivery system will be checked prior to use to insure proper operation. The manufacturer's operating instructions will be followed.

b) The lung function unit will be checked at the beginning of each week by filling it with oxygen and checking for leakage. Its operation will be checked during the practice runs prior to administration of the Xe 133 gas. The manufacturer's operating instructions will be followed and the carbon dioxide absorber will be replenished as needed.

c) The Xenon trap will be checked prior to each ventilation procedure to insure that is is securely connected to the lung function unit. Xenon leakage from the exhaust port will be monitored as previously described. The manufacturer's operating instructions will be followed and the trap will be checked and replenished as needed. A replacement cartridge will be installed whenever there is a significant increase in the weekly CPM. The saturated cartridge will be placed in the radiation waste barrel in the hot lab with other radioactive waste and disposed of as previously described in the original license submission.

d) All the exhaust vents will be checked twice a year to confirm their continued efficiency. In addition, they will be checked whenever structural changes are made which would affect their efficiency. Records verifying these procedures will be maintained.

e) Attachment No. 5, - the survey report made by Dr. Bhudatt E. Paliwal, Ph.D.

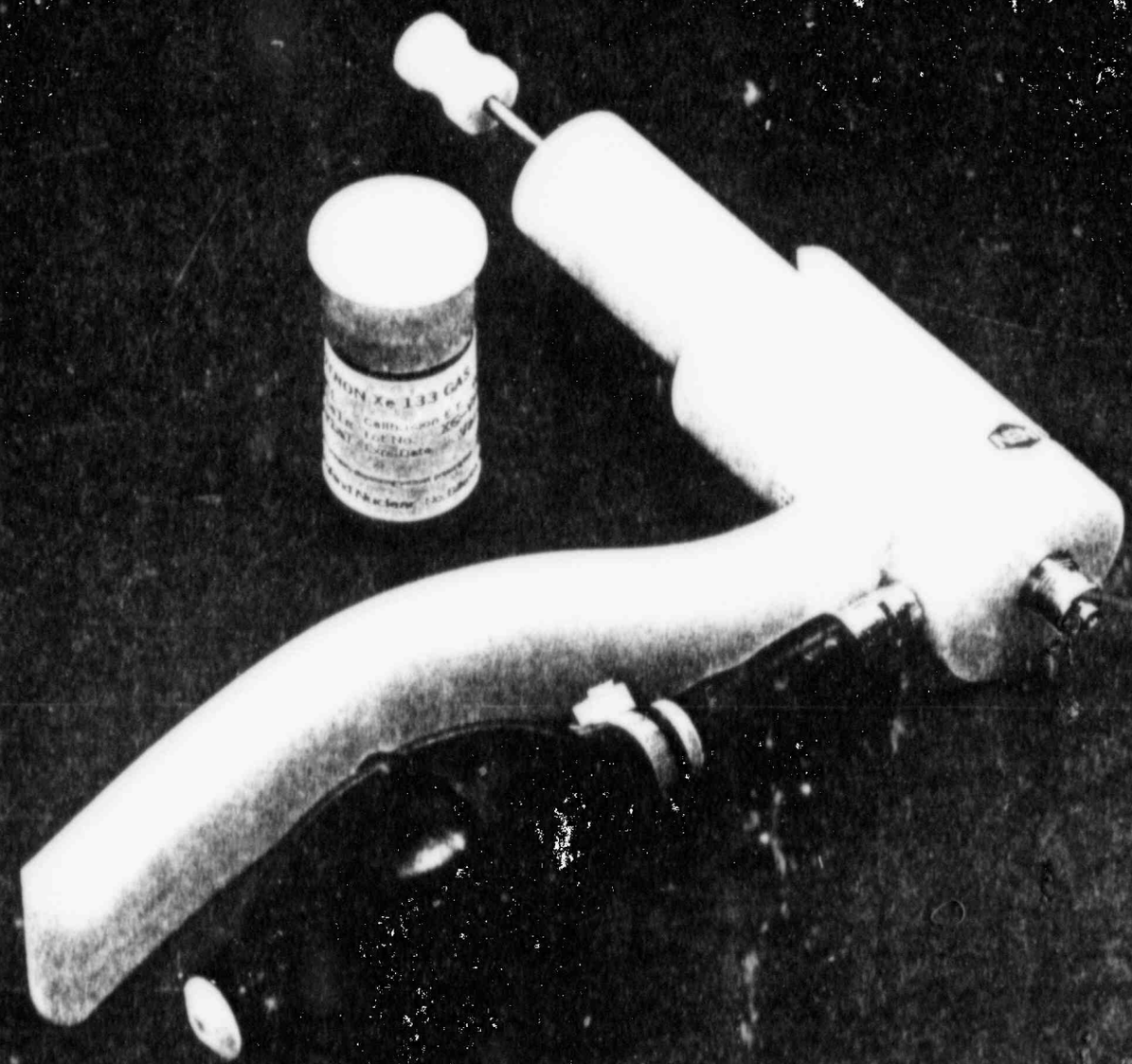
Sincerely,

T. Ansusinha, M.D.

TA:mvc
attachments

XENON Xe 133 GAS CALIDOSE™

Dispensing System



- Easy and accurate dispensing of unit doses
- Exceptional safety—unique shielding
- Sizes for single or multi-breath procedures
- Specificially designed for pulmonary ventilation studies

NEN's Xenon Xe 133 Gas CALIDOSE™ Dispensing System provides a convenient, accurate and safe method of administering xenon-133 gas. Specifically designed for pulmonary ventilation studies, NEN's Xenon-133 is available as 5% xenon gas in a carbon dioxide diluent of 95%.

Operation of NEN's Xenon Xe 133 Gas CALIDOSE Dispensing System is simple. After the dispenser is loaded, affix the dispenser to the breathing apparatus with a needle or other connector; push the plunger at the rear of the dispenser (puncturing the septum of the loaded vial by inner needles); and squeeze the rubber bulb.

Caution: Contents to be used *only* for inhalation.

ORDERING INFORMATION

NRP-186 Gas CALIDOSE Dispenser (Supplied at no charge during the term of an order)

NRP-127 Xenon Xe 133 Gas CALIDOSE refills are available in unit dose vials from 10mCi to 100mCi per vial.

BRIEF SUMMARY

For full information, refer to the complete package insert provided with each shipment

INDICATIONS

Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

CONTRAINDICATIONS

To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

WARNINGS

This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of the menses.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

PRECAUTIONS

As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations.

Xenon Xe 133 adhers to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ADVERSE REACTIONS

To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported.

DOSAGE AND ADMINISTRATION

Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spirometers.

The suggested activity range employed for inhalation by the average adult patient (70kg) is:

Pulmonary function including imaging: 2-30 mCi in 3 liters of air.

Cerebral blood flow: 10-30 mCi in 3 liters of air.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

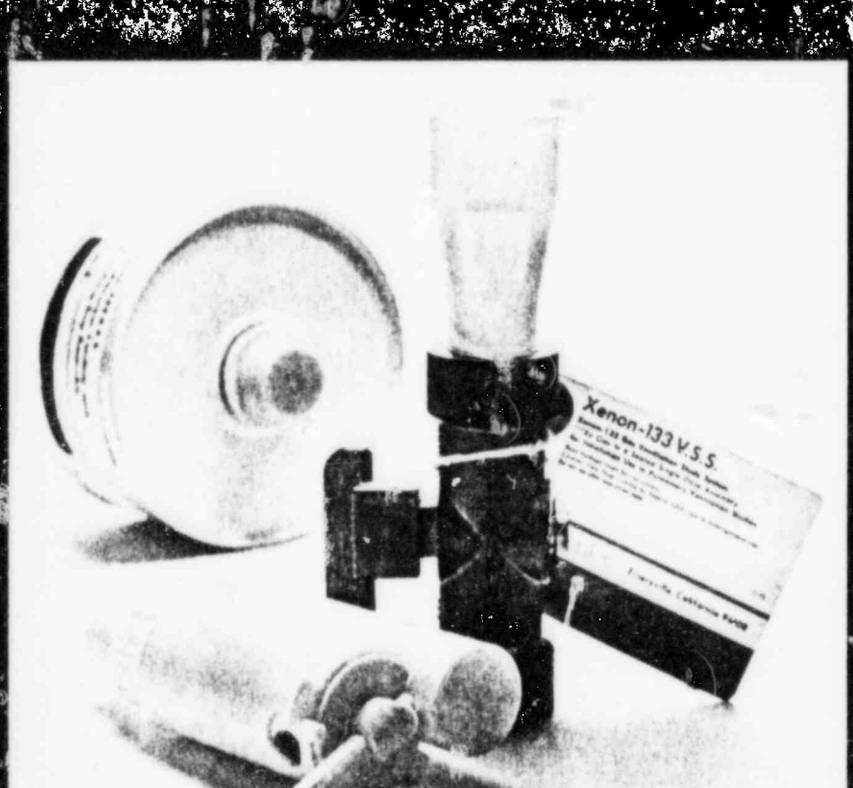
HOW SUPPLIED

The Xenon Xe 133 gas is supplied as part of the Calidose™ system, consisting of 2 ml unit dose vials and the Calidose dispenser* for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

*Patent Pending

Xenon-133 Ventilation Study System



medi+physics

XENON-133 VENTILATION STUDY SYSTEM

Xe-133 System for pulmonary ventilation studies.

A COMPLETE, DISPOSABLE SYSTEM

Everything needed for a Xe-133 ventilation study is provided including the Xe-133, a CO_2 absorber for rebreathing, a bag for rebreathing and collection of expired Xe-133, and a disposable mouthpiece.

A CHOICE OF DELIVERY OF Xe-133, BOLUS OR DISPERSED DOSE

With this system Xe-133 can be administered either as a concentrated bolus or as a more dispersed dose.

Xe-133 IS AN INTEGRAL PART OF THE SYSTEM

No need to transfer Xe-133 from its container to your system.

ACCESSORY COMPONENTS ARE AVAILABLE

A shield to reduce radiation exposure to the patient and attending personnel and a valve for rebreathing and washout studies are available.

USE OF Xe-133 V.S.S.

1. POSITION PATIENT

Position the patient with his back to the collimator of the scintillation camera and adjust the Xe-133 V.S.S. shield to a comfortable height. Switch the Xe-133 V.S.S. valve to position "One." Clamp the patient's nose and instruct him to breathe through the system.

2. SINGLE BREATH

To obtain a single-breath study using a sharp Xe-133 bolus, have the patient exhale and hold his breath. Turn the "Key" 180° to release the Xe-133 and have the patient inhale slowly and deeply. Perform scintigraphy during breath-holding.
To obtain a single-breath study using a dispersed dose of Xe-133, turn the "Key" 180° and instruct the patient to first exhale and then immediately inhale the Xe-133 which has been dispersed in the exhaled breath and the gas in the bag. Perform scintigraphy during the breath-holding.

3. REBREATHING

Following the single-breath study, a rebreathing study is performed by having the patient breathe back and forth through the system until equilibrium is achieved. Again, perform scintigraphy during breath-holding.

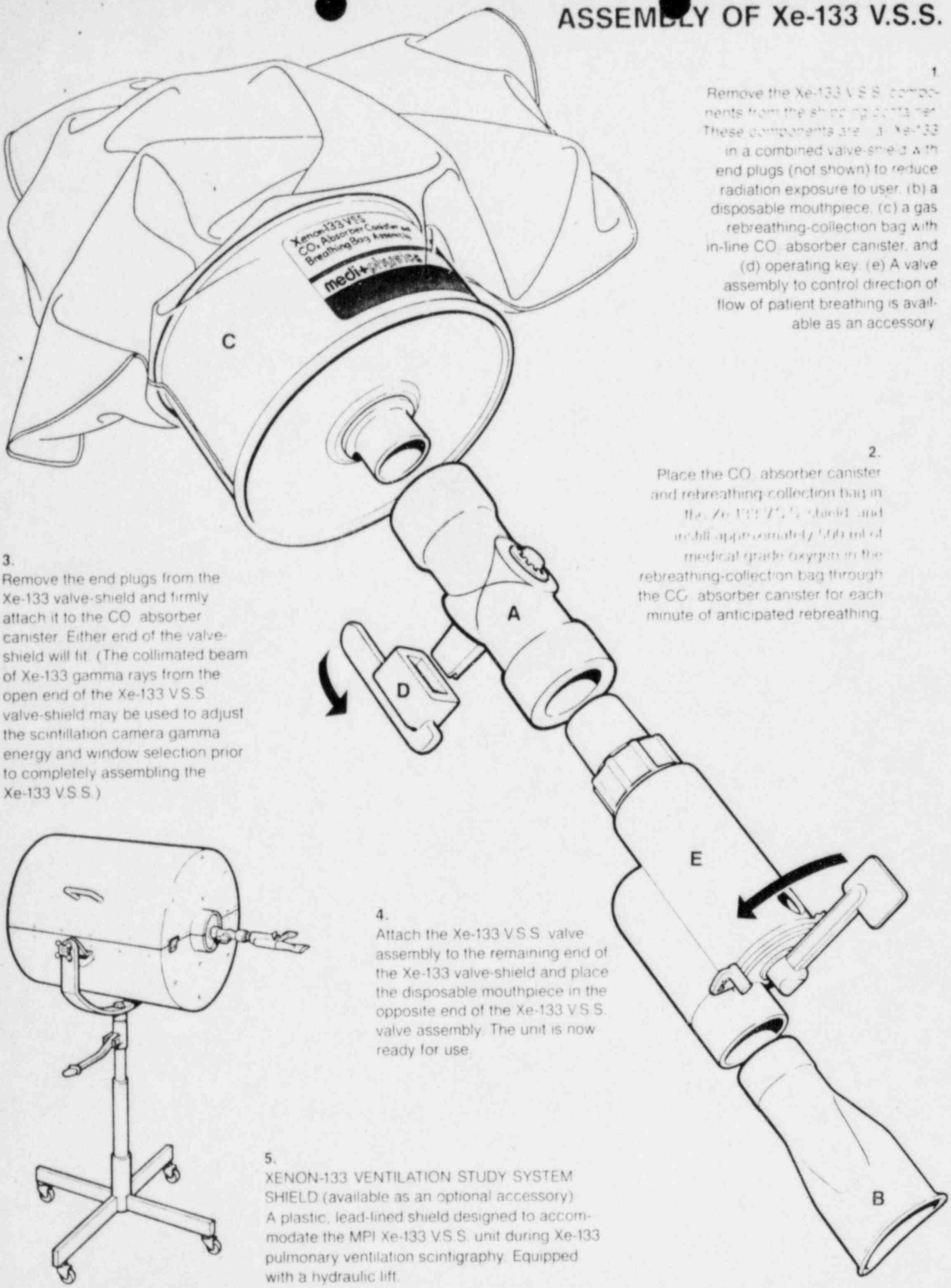
4. WASHOUT

Evaluation of Xe-133 washout is obtained by sequential scintigraphy after the Xe-133 V.S.S. valve is switched to position "Two" while the patient breathes normally. Collection of approximately 40 liters of expired air is possible using the collection bag provided.

Dispose of the trapped expired Xe-133 immediately upon completion of the study in a manner that is in compliance with appropriate governmental and institutional regulations, e.g., slow release into a chemical fume hood. Refer to the package insert for complete assembly and use instructions.

ASSEMBLY OF Xe-133 V.S.S.

1.
Remove the Xe-133 V.S.S. components from the shipping container. These components are: (a) Xe-133 in a combined valve-shield with end plugs (not shown) to reduce radiation exposure to user, (b) a disposable mouthpiece, (c) a gas rebreathing-collection bag with in-line CO_2 absorber canister, and (d) operating key. (e) A valve assembly to control direction of flow of patient breathing is available as an accessory.



2.
Place the CO_2 absorber canister and rebreathing collection bag in the Xe-133 V.S.S. shield and refill approximately 100 ml of medical grade oxygen in the rebreathing-collection bag through the CO_2 absorber canister for each minute of anticipated rebreathing.

3.
Remove the end plugs from the Xe-133 valve-shield and firmly attach it to the CO_2 absorber canister. Either end of the valve-shield will fit. (The collimated beam of Xe-133 gamma rays from the open end of the Xe-133 V.S.S. valve-shield may be used to adjust the scintillation camera gamma energy and window selection prior to completely assembling the Xe-133 V.S.S.)

4.
Attach the Xe-133 V.S.S. valve assembly to the remaining end of the Xe-133 valve-shield and place the disposable mouthpiece in the opposite end of the Xe-133 V.S.S. valve assembly. The unit is now ready for use.

5.
XENON-133 VENTILATION STUDY SYSTEM SHIELD (available as an optional accessory)
A plastic, lead-lined shield designed to accommodate the MPI Xe-133 V.S.S. unit during Xe-133 pulmonary ventilation scintigraphy. Equipped with a hydraulic lift.

ACTIONS

Xenon is a monatomic inert gas which appears to be freely diffusible across cell membranes. It has a limited water solubility and its partition coefficient strongly favors the gas phase. It has a greater solubility in lipids than in aqueous solutions and thus concentrates to a degree in body fat and lipid rich tissue. Prolonged inhalation of gas mixtures containing high partial pressure of xenon has demonstrated that xenon, similar to other lipid soluble inert gases, has some general anesthetic effects. However, the amount of xenon gas in ^{133}Xe V.S.S. is many orders of magnitude below that required for demonstration of such an effect. A small quantity of inhaled xenon gas enters the circulation by solution in blood as it passes through pulmonary capillaries. Most of the xenon contained in the blood is exhaled from the lungs after a single passage through the pulmonary vasculature. In normal subjects the rate constant for clearance of ^{133}Xenon from the lungs is approximately 2 min^{-1} and major initial clearance of ^{133}Xe dissolved in body water has a rate of approximately 0.14 min^{-1}. However, small quantities of ^{133}Xe are cleared from the body at slower rates due principally to slow xenon turnover in poorly perfused fat stores and lipid containing tissues. The clearance of ^{133}Xe from the body varies with ventilatory abnormalities and with size and perfusion of lipid tissue.

INDICATIONS

Study of Pulmonary Ventilation

CONTRAINDICATIONS

None

WARNINGS

^{133}Xe should not be administered to pregnant women, those liable to be pregnant, in lactation, or in patients under 18 years of age unless the benefits to be gained outweigh the risks. Radiopharmaceuticals produced in a nuclear reactor or charged particle accelerator should be used only by physicians who are qualified by specific training in the safe use of handling of radioisotopes and whose experience and training has been approved by the appropriate governmental agency authorized to license the use of radionuclides.

PRECAUTIONS

In the use of any radiopharmaceutical care should be taken to insure minimum radiation exposure to the patient and all personnel involved in the procedure by using the smallest dose of radioactivity consistent with safety and relative value of diagnostic information. Expired ^{133}Xenon should be controlled in a manner that is in compliance with appropriate governmental and institutional regulations, e.g., slow release into a chemical fume hood.

ADVERSE REACTIONS

To the best of our knowledge no adverse reactions from inhalation of diagnostic doses of ^{133}Xenon have been reported.

DOSAGE

Two to thirty mCi of ^{133}Xenon has been used in pulmonary ventilation studies.

RADIATION DOSIMETRY

Radiation dose to tissues is summarized in the accompanying table. The calculations were based on the following assumption: a) Effective rate of clearance from lungs of 2 min^{-1}. b) Five percent of inhaled dose dissolves in body fluids from whence it is cleared with an effective rate of clearance of 0.14 min^{-1}. c) Single breath study involves containment of 10 mCi of ^{133}Xe in lungs for 30 seconds followed by washout. d) Rebreathing involves rebreathing of 20 mCi ^{133}Xe into a bag containing 2 liters of gas for four minutes followed by washout.

DOSE IN MILLIRADS

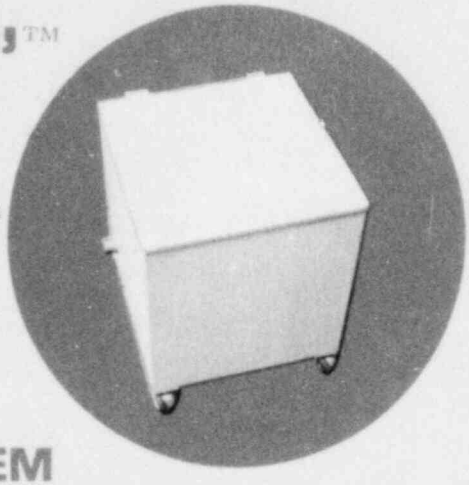
Organ	Single Breath of 10 mCi held for 30 sec. followed by Washout	Rebreathing 20 mCi in 2 liter bag for 4 min. followed by Washout
Lung	50	300
Total Body*	0.2	0.8
Ovaries	0.06	0.1
Testes	0.008	0.02

*Bone Marrow considered Total Body Dose.

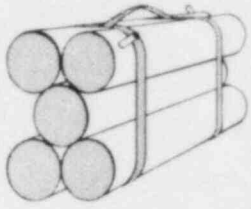
Medi+Physics, 5855 Christie Avenue, Emeryville, California 94608/Phone toll-free (800) 227-0483 or in California (800) 772-2446

9-73-10

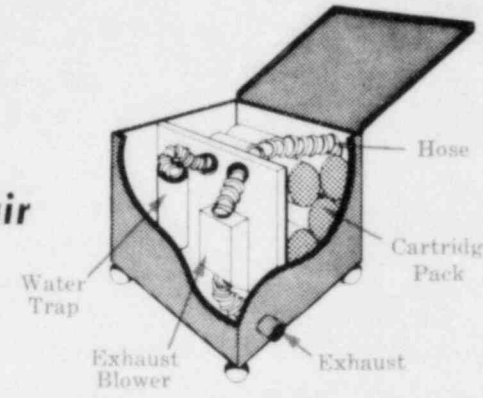
The "NONEX"™ XENON GAS TRAP*



Cartridge Pack



TURNS YOUR XENON CONTROL PROBLEM AROUND



Removes radioactive xenon from exhaled air

- **Ideal alternative to costly external vent systems.**
- **Compatible with any ^{133}Xe gas handling system.**
- **Fully shielded, self-contained, mobile.**

*TM Nuclear Associates Inc. *Patent Pending*

The efficient removal and containment of radioactive gases from exhaled air used in nuclear-medical studies is facilitated through the use of the "Nonex" Xenon Gas Trap.

The trap is designed specifically to adsorb inert radioactive gases such as ^{133}Xe. It removes ^{133}Xe from any exhaust flow, yielding an effluent concentration less than 1×10^{-5} $\mu Ci/cm^3$* throughout the useful life of its disposable filter cartridges. The 5-cartridge tandem pack provides a low-velocity flow path and sufficient dwell time to effectively strip the xenon gas from the effluent stream. A charcoal adsorbent, especially formulated for xenon removal, guarantees high efficiency.

Exhaled air is drawn by a vacuum pump through five fixed charcoal-filter cartridges. The ^{133}Xe remains in the cartridges and decays. Cartridge life is dependent upon usage; a nomogram relates usage to lifetime. Typically, 20 mCi of ^{133}Xe per day with a 50-liter washout, five days per week, anticipates a cartridge life of approximately six months.

Competitive systems use a single filter cartridge having a limited adsorbtive lifetime which, when exhausted, cannot be conveniently replaced. **The 5-cartridge tandem pack in the "Nonex" can be changed in seconds.**

This self-contained mobile trap can be integrated into any ^{133}Xe system or may be used independently as a patient exhalation unit with the use of a disposable face mask. It is fully shielded with a ⅛" lead barrier surrounding the cartridge pack, making external radiation levels negligible. An internal cartridge on the input line, when filled with a desiccant, serves as a water trap. The unit may be used as a convenient seat for the upright patient or may be easily rolled on its casters beneath an imaging table for supine studies.

Low cost, simple operation, and high efficiency make the "Nonex" Trap an ideal alternative to costly exhaust systems.

Mounted on four 2" casters for easy, silent mobility. Includes a disposable face mask, on-off switch, water trap, and 5-liter/minute vacuum pump. 115V, 60 Hz. 15" L x 15" W x 15¼" H. Net weight 105 lbs.

36-022	"Nonex" Xenon Gas Trap	$875.00
36-026	Replacement Cartridge Pack	275.00

*Maximum permissible concentration in a controlled area, per Title 10 CFR 20, Appendix B, Table I, Column 1.

NUCLEAR ASSOCIATES, INC.
Subsidiary of
RADIATION-MEDICAL PRODUCTS CORP.
35 URBAN AVE. • WESTBURY, N. Y. 11590 • (516) 333-9344

3/175/NA-125-F

Product Bulletin NA-125-F

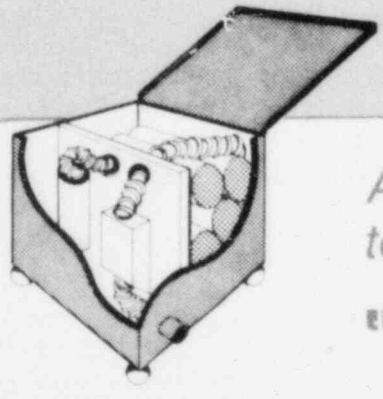
FOR PULMONARY FUNCTION STUDIES

Fully automatic, self-contained

Xenon-133 Lung Function Unit

The ONE and ONLY system that...

- **Allows delivery of a direct bolus of radioactive gas.**
- **Permits re-use of xenon for the same patient study.**
- **Performs single breath, steady state and washout studies with *any* commercially-available form of xenon.**



Also available...an economical alternative to costly external vent systems.

"NONEX" XENON GAS TRAP