MERCY
MEDICAL CENTER

4050 COON RAPIDS BOULEVARD • COON RAPIDS, MINNESOTA 55433 • (612) 427-2200

DIVISION
OF THE
HEALTH
CENTRAL
SYSTEM

6/13/85

Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Mail Control #78536

Attention: Dr. Bill Adam

Dear Dr. Adam,

Enclosed is the additional information that you requested on Drs. Joseph Collins and James Kollitz.

To add Xenon-133 to our license, included is the information requested in FORM NRC-313M Item 21, as described in detail in NUREG 10.8, Appendix M.

We would also like to do 99mTcDTPA aerosol lung scans, using 30mCi 99mTcDTPA with the Cadema nebulizer and lead shielding.

If you have any questions, please contact me at (612)427-2200, Extension 2683.

Sincerely,

Brynn Hofstedt

Brynn Hofstedt, Special Imaging Supervisor

Paul Halverson

Paul Halverson,
Certifying Official for License No. 22-17307-01

BBH/bbh

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
Joseph M. Collins, M.D.	MN, ND, IA

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Diagnostic Radiology		June 1, 1984 [illegible]

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	Mayo Clinic Rochester, Minnesota 1-3-83 to 4-8-83	85	15
b. RADIATION PROTECTION	Mayo Clinic Rochester, Minnesota 8-15-83 to 10-14-83	20	15
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Mayo Clinic Rochester, Minnesota 1-3-83 tc 4-8-83	24	0
d. RADIATION BIOLOGY	Mayo Clinic Rochester, Minnesota 1-3-83 to 4-8-83	15	5
e. RADIOPHARMACEUTICAL CHEMISTRY	Mayo Clinic Rochester, Minnesota 1-3-83 to 4-8-83	35	2

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}	125 mCi	Mayo Clinic	4 years during residency in diagnostic radiology (above dates)	diagnostic + therapy
Gallium^{67}	10 mCi	"		diagnostic
Yb^{169}	500 μCi	"		"
Xe^{133}	10 mCi	"		"
Thallium	2 mCi	"		"
Tc^{99m}	20 mCi	"		"
I^{123}	300 μCi	"		"

NRC FORM 313M S

NRC FORM 313M SUPPLEMENT B (9-81)

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: Joseph Michael Collins, M.D.

STREET ADDRESS: 376 36th Ave. NW

CITY: Rochester | STATE: MN | ZIP CODE: 55901

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES DTPA, DMSA, glu-hept	95	
	IN VITRO STUDIES		
OTHER	Gallium	36.	
I-125	DETECTION OF THROMBOSIS	5	
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	4	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	41	
OTHER	Thallium infarct scan	3	
Tc-99m	BRAIN IMAGING	8	
	CARDIAC IMAGING (MUGA)	30	
	THYROID IMAGING	40	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	4	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	228	
	LUNG IMAGING	41	
	BONE IMAGING	443	
OTHER	HIDA and DISIDA	15	

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	10	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	10	
Other	In-113m labelled WBC's	3	
	Tc-99m labelled RBC's	4	
	Tc-99m Meckel's scan	4	
	Tc-99m joint scan	9	

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

2/9/81, 2/16/81, 2/23/81, 3/2/81, 8/10/81, 8/17/81, 8/24/81, 8/31/81, 11/29/82, 12/6/82, 8/1/83, 8/8/83, 3/5/84, 3/12/84

630 hours

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

a. NAME OF SUPERVISOR
Manuel L. Brown, M.D.

b. NAME OF INSTITUTION
Mayo Clinic

c. MAILING ADDRESS
200 First Street SW

d. CITY
Rochester, MN 55905

e. MATERIALS LICENSE NUMBER(S)
22-00519-03

5. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*
Manuel L. Brown, M.D.

8. DATE
4/2/84

NRC FORM 313M SUPPLEMENT B
(-81)

GPO 890-813

FORM NRC 313M SUPPLEMENT A
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
James Kollitz	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology	Diagnostic Radiology	6/83

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	University of California SD. California 7-80 - 6-83	150	30
b. RADIATION PROTECTION	Same	30	5
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same	25	0
d. RADIATION BIOLOGY	Same	20	5
e. RADIOPHARMACEUTICAL CHEMISTRY	Same	30	4

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
99mTc	20mCi	U.C.S.D.	above dates	diag.
111In	200uci	"	" "	"
123I	300uCi	"	" "	"
131I	125mCi	"	" "	" & ther.
32P	30mCi	"	" "	" "
67Ga	10mCi	"	" "	"
201Tl	2mCi	"	" "	"
133Xe	10mCi	"	" "	"

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

NRC 313M SUPPLEMENT B

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Statement 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: James Kollitz

STREET ADDRESS: 18 Black Oak Rd.

CITY: North Oaks, | STATE: MN | ZIP CODE: 55110

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	95	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	40	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	20	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
~~Yb 169~~	CISTERNOGRAPHY In-III	45	
Xe 133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING	20	
	CARDIAC IMAGING	45	
	THYROID IMAGING	25	
	SALIVARY GLAND IMAGING	2	
	BLOOD POOL IMAGING	40	
	PLACENTA LOCALIZATION	-	
	LIVER AND SPLEEN IMAGING	150	
	LUNG IMAGING	90	
	BONE IMAGING	200	
OTHER			

PRECEPTOR STATEMENT (Continued)

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

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	6	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	6	
I-131	TREATMENT OF THYROID CARCINOMA	11	
	TREATMENT OF HYPERTHYROIDISM	10	
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	100	
Sn-113/ In-113m	GENERATOR	10	
Tc-99m	REAGENT KITS	40	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING 650

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

a. NAME OF SUPERVISOR
William Ashburn

b. NAME OF INSTITUTION
University of California

c. MAILING ADDRESS
225 Dickinson St.

d. CITY
S.D., California 92103

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
William L. Ashburn

7. PRECEPTOR'S NAME (Please type or print)
William L. Ashburn, M.D.

8. DATE
11/18/84

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

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4050 COON RAPIDS BOULEVARD • COON RAPIDS, MINNESOTA 55433 • (612) 427-2200
DIVISION OF THE HEALTH CENTRAL SYSTEM

Item 21, FORM NRC-313 Page 2 PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon-133)

1. Quantities to be used: 2 studies/week, 10-35mCi/study, 100mCi possession limit

2. Use and Storage Area: Xenon will be used in the camera room and stored in the hot lab. (see Item 11)
   The areas where Xe-133 will be used and stored are under negative pressure.
   Measurements of the airflow rates will be made semiannually.
   Ventilation features are indicated on the diagram attached.
   No air is recirculated by the system.

3. Procedures for Routine Use: Before using xenon, nuclear medicine department doors will be closed. The exhaust hood, which is vented separately from the hospital ventilation system, will remain running. Face masks will be provided for all patients except those with beards or whose facial contours might cause leakage; patients not using face masks will use mouthpieces and noseclips. After the xenon has washed out of the patient's lungs the washout of the dispensing system into the trap will be continued for at least five minutes. After the system has been shut down, the doors to the nuclear medicine department will be opened. The xenon will be returned to the hot lab and the exhaust hood will be turned off. See attached brochure of special apparatus for administration and collection of Xe-133.

4. Emergency Procedures: In case of an accidental release of Xe-133 the area will be immediately evacuated, the doors will be closed and the Radiation Safety Officer will be notified. The exhaust hood, which is vented separately from the hospital ventilation system will be kept running to evacuate the Xenon.

5. Air Concentrations of Xe-133 in Restricted Areas:

$$A = \frac{35\text{mCi}}{\text{patient}} \times \frac{2\text{ patients}}{\text{week}} \times 1 \times 10^{3} \frac{\text{uCi}}{\text{mCi}} = 7 \times 10^{4} \frac{\text{uCi}}{\text{week}}$$

$$V = \frac{A \times f}{1 \times 10^{-5}\text{uCi/ml}} = \frac{7 \times 10^{4}\text{uCi/week} \times 0.20}{1 \times 10^{-5}\text{uCi/ml}}$$

$$= 1.4 \times 10^{9}\text{ml/wk}$$

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DIVISION OF THE HEALTH CENTRAL SYSTEM

$$\frac{1.4 \times 10^9 \text{ml/week}}{40 \text{ hr/week}}$$

$$\div \frac{1.7 \times 10^6 \text{ml/hr}}{\text{ft}^3/\text{min}}$$

$$= 21 \text{ ft}^3/\text{min}$$

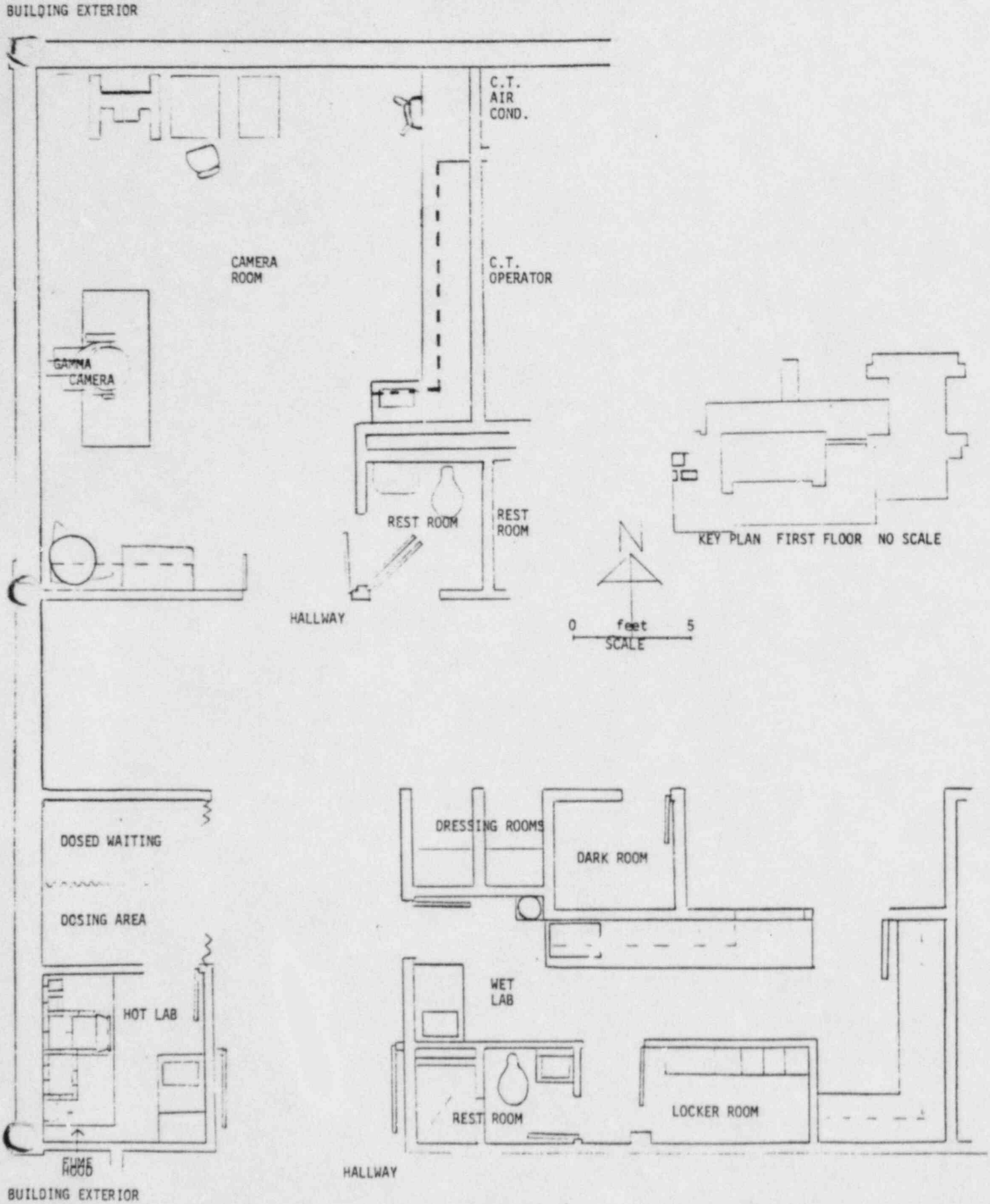
The above calculations assume a total 20% loss of Xe-133 from all sources during patient administration, storage and disposal.

The entire activity could be released every week without exceeding the permissible levels for Xe-133 in restricted areas. (100% loss)

6. Air Concentrations of Xe-133 in Unrestricted Areas: The Pulmonex system has a built-in xenon gas trap with disposable charcoal cartridge. It removes xenon effluent after each study and eliminates the need for venting systems. Exhaled xenon is gently pulled through activated sharcoal contained within a "U" shaped cartidge 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 system port. The gas trap will be tested initially and on a continuing basis for leakage. The manufacturer's recommendation on filter saturation and replacement will be followed. Saturated filters will be shielded within the fume hood in the hot lab (see Item 11) until taken by the centralized radiopharmacy's messenger.

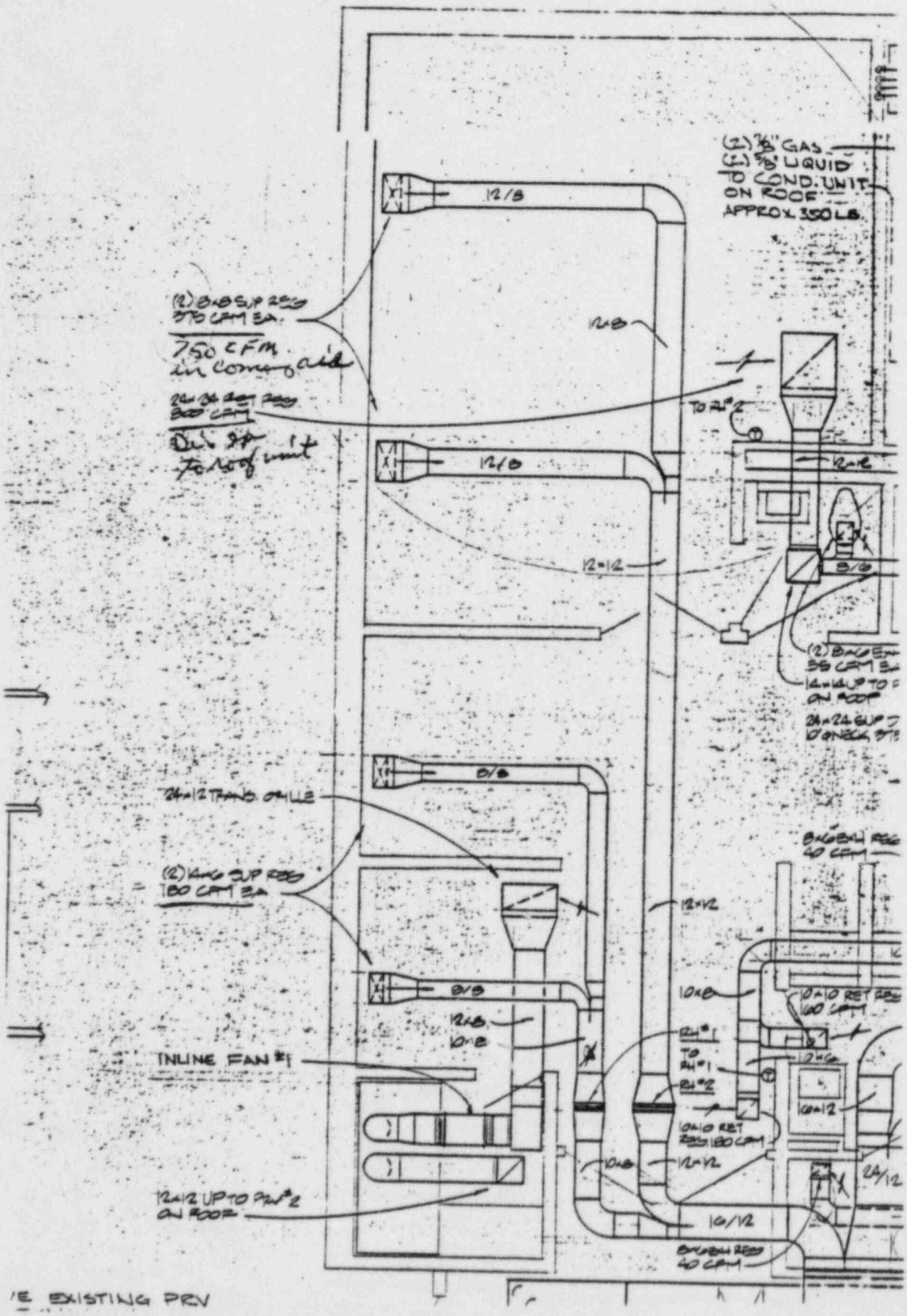
Attachment # 5

Item 11, FORM NRC 313 Page 2 FACILITIESAND EQUIPMENT



N

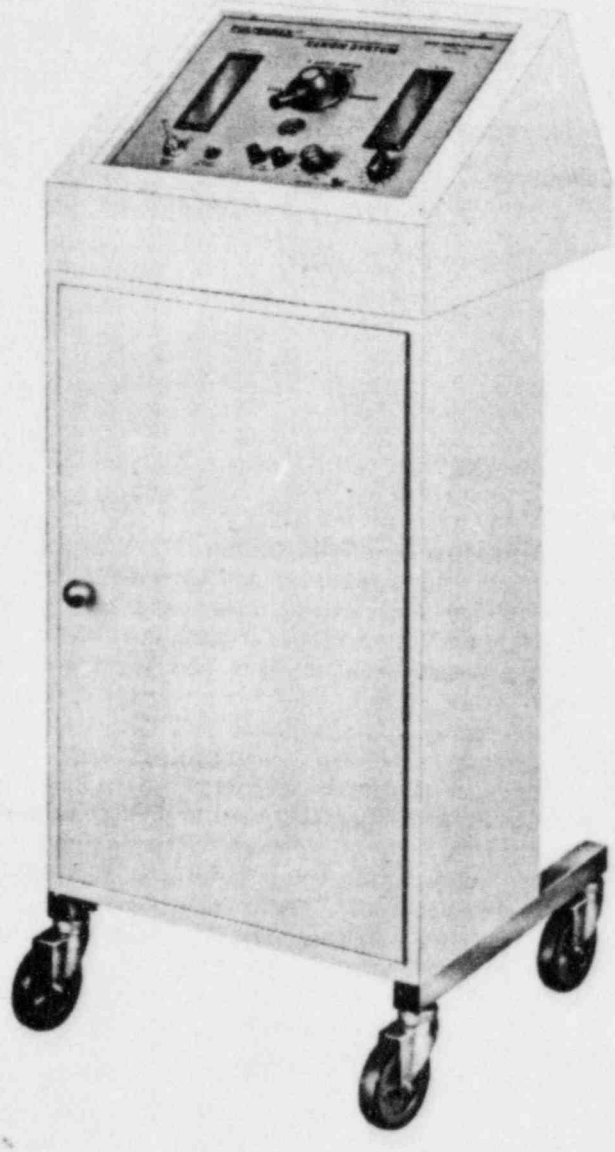
Item 11
Date: 2-24-82



1E EXISTING PRV

PULMONEX XENON SYSTEM

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



SIMPLE, SAFE OPERATION

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

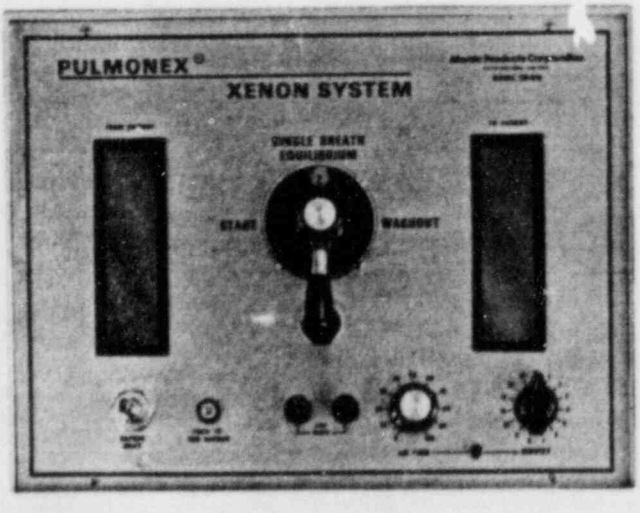
- Complete easy-to-use system.
- "Air-in"/"Air-out" breathing tubes and motor-driven circulator assures resistance-free breathing.
- Two lead glass windows permit observation of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- 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.

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 distinctively 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 ..anual 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.

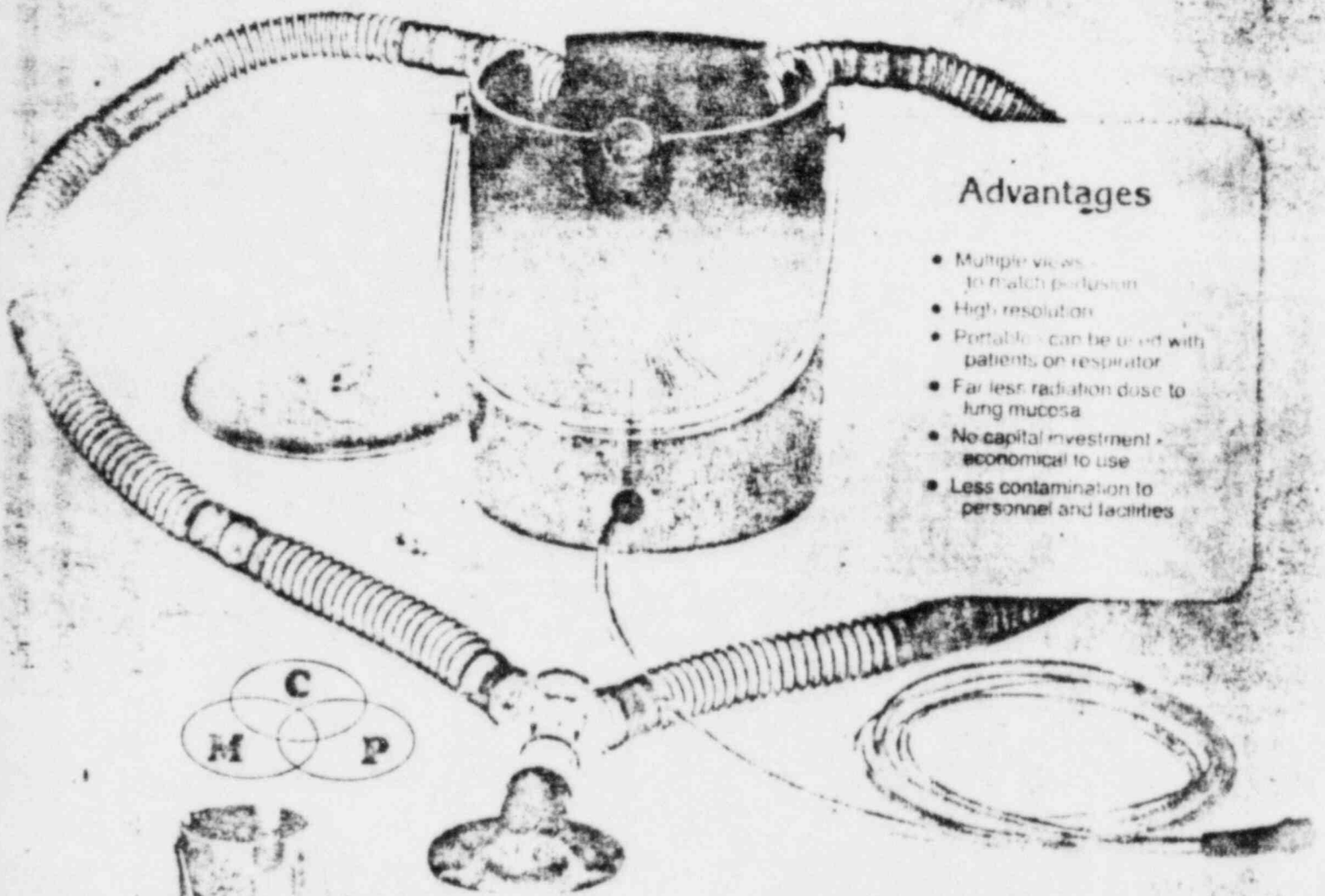
130-500	Pulmonex Xenon System, complete	**$2750.00**

Replacement Items

127-319	Replacement Charcoal Cartridge ...	**340.00**
130-550	Disposable Mouthpiece	**1.95 ea.**
130-700	Disposable Bacteria Filter	**3.50 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**

NUCLEAR REGULATORY COMMISSION APPROVES

Tc-DTPA Aerosol
For Lung Ventilation Studies



Advantages

- Multiple views to match perfusion
- High resolution
- Portable - can be used with patients on respirator
- Far less radiation dose to lung mucosa
- No capital investment - economical to use
- Less contamination to personnel and facilities

A - Nebulizer
B - Filter
C - Mouthpiece
D - Valves
E - O_2 Line – Gas Cylinder to Nebulizer
F - Lead Shield, 6" Diameter

Tc AEROSOL

A viable alternative to Kr-81m

Clinically superior to Xe-133

To Order, Call: Pharmatopes 1-312-666-8200

Cadema Medical Products, Inc.

P.O. Box 250, Middletown, New York 10940
Phone 914-343-7474

CONVERSATION RECORD

TIME 10:00A | DATE 4/9/85

TYPE: ☐ VISIT ☐ CONFERENCE ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Dr Collins	Mercy Medical Ctr	612 572-4583

ROUTING

NAME/SYMBOL	INT

SUBJECT C/N 78536

SUMMARY

Requested

1.) Item 5 of Supp. A be completed For Drs. Collins & J. Kolity

2.) Item 3 of Supp B. be completed for Dr. J. Kolity (specifically dates of tioning).

ACTION REQUIRED Will respond w/I 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	W. J. Adam	4/10/85

ACTION TAKEN

SIGNATURE	TITLE	DATE