A TRADITION OF CARING

ST. FRANCIS HOSPITAL

12935 South Gregory Street
Blue Island, Illinois 60406
312-597-2000

May 8, 1985

Applicant May 21 [illegible]
Check No. 117093 $1.80
Amount Fee Category 7C
Type of Fee carryd
Date Check Rec'd 5/21/85
Received By

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Ref: License No. 12-10094-01

Gentlemen:

We wish to amend Item 11 of our Radioactive Materials license application. We will be relocating our Nuclear Medicine Department to a temporary site and eventually to a renovated new site. Diagrams of the temporary and new sites are given in Attachments 1 and 2. Please note we are moving back and forth across the hallway during these two moves. The temporary site relocation date is tentatively set for May, 1985. The final site relocation date has not been set at this time.

The old department and temporary department areas affected by the construction changes (i.e. camera rooms and stress lab) will be surveyed and wipe tested for radioactive contamination immediately after the moves have been made. We wish to have the authority to release these areas for restricted use. Please refer to Attachment 4 outlining our radiation survey and radioactive contamination procedures and acceptance guidelines. Records of the surveys and wipe tests will be maintained for inspection.

The air exhaust system for both the temporary and final department sites will be the same as that given in our amendment application for Amendment 33 to our license. The air supply to the camera rooms will be at least 10% less than the air exhaust to these areas. Attachments 5 and 6 refer to the use of Xe-133 in our temporary and final sites, respectively.

Any questions about this amendment request may be directed to Mr. Emil Ernest, Technical Director at (312) 597-2000 or Mr. Gerald Wicks, Consulting Health Physicist at (312) 564-3330.

Sincerely,

RECEIVED
MAY 14 1985
REGION III

Bryant R. Hanson
Executive Director

8506100841 850522
REG3 LIC30
12-10094-01 PDR

BRH:ab
Enclosures

CONTROL NO. 78949

License number 12-12767-01

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference number

for Ingall's Memorial Hospital
Harvey, Illinois

Amendment No. 19

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at One Ingalls Drive, Harvey, Illinois.

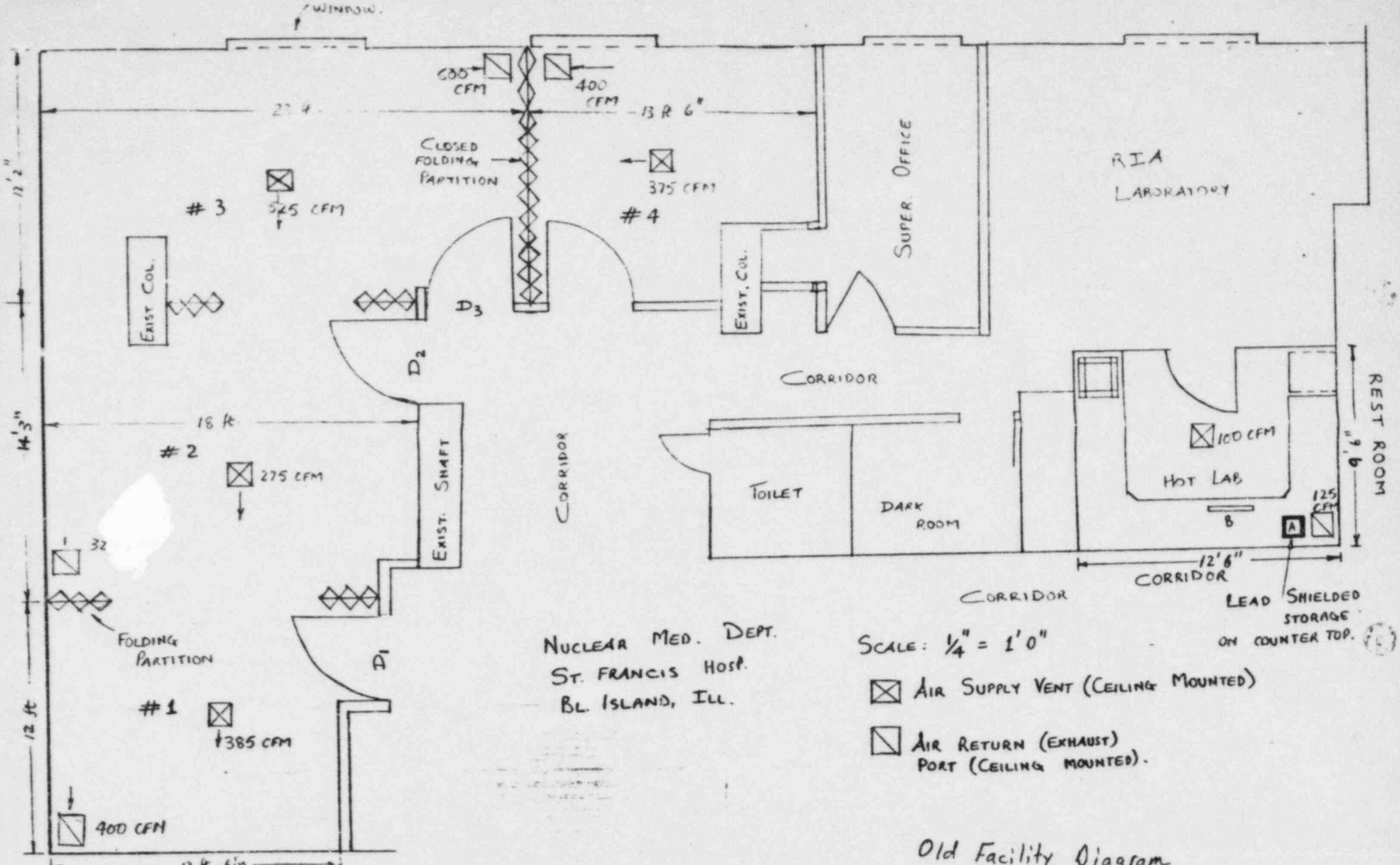
11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Harold Lipschutz, M.D.	All
Tijen Bo Jap, M.D.	All
Julius Heydemann, M.D.	All
Shankar Sanwalani, M.D.	All
Carol Meyers, M.D.	Groups I, II and III Xenon-133 In vitro studies
Ralph W. Riley, M.D.	Licensed material of the types, quantities and forms specified in Sections 35.31(a) of 10 CFR 35 and 31.11(a) of 10 CFR 31 in accordance with the provisions of paragraphs (a) and (c) of Section 35.31, 10 CFR 35 and paragraphs (a), (c), and (d) of Section 31.11, 10 CFR 31
Antimo Candel, M.D.	Licensed material of the types, quantities and forms specified in Sections 35.31(a) of 10 CFR 35 and 31.11(a) of 10 CFR 31 in accordance with the provisions of paragraphs (a) and (c) of Section 35.31, 10 CFR 35 and paragraphs (a), (c), and (d) of Section 31.11, 10 CFR 31
Jeffery Cullen, M.D.	Groups I, II and III Xenon-133 In vitro studies

Attachment 1
(5/85)

COPY



Old Facility Diagram

St. Francis Hospital Blue Island, Il.

ITEM # 11 (9|83)

(5725)

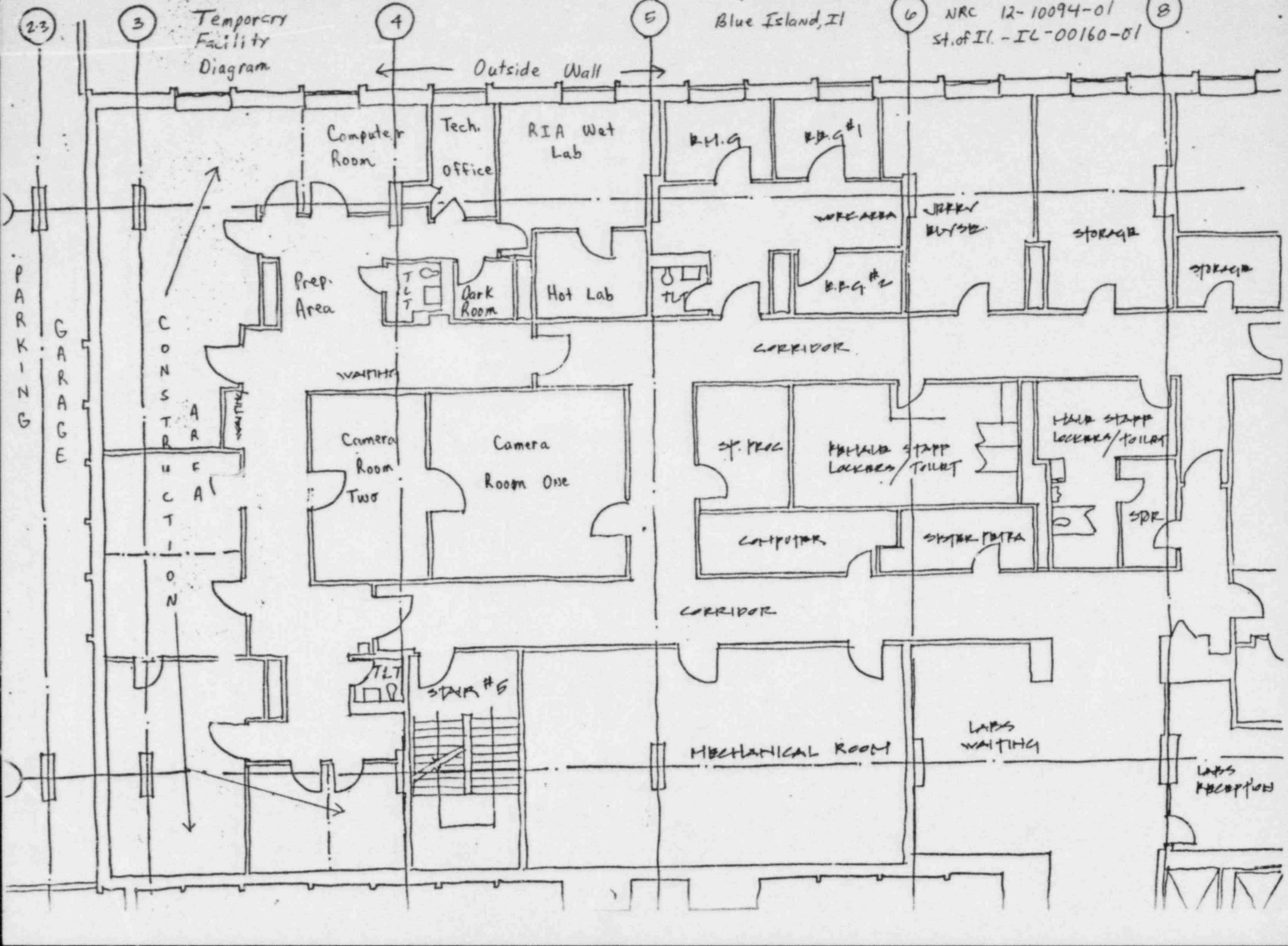
(5785)

Item 11 Attachment 2

St. Francis Hospital
Blue Island, Il

License No.
NRC 12-10094-01
St. of Il. - IL-00160-01

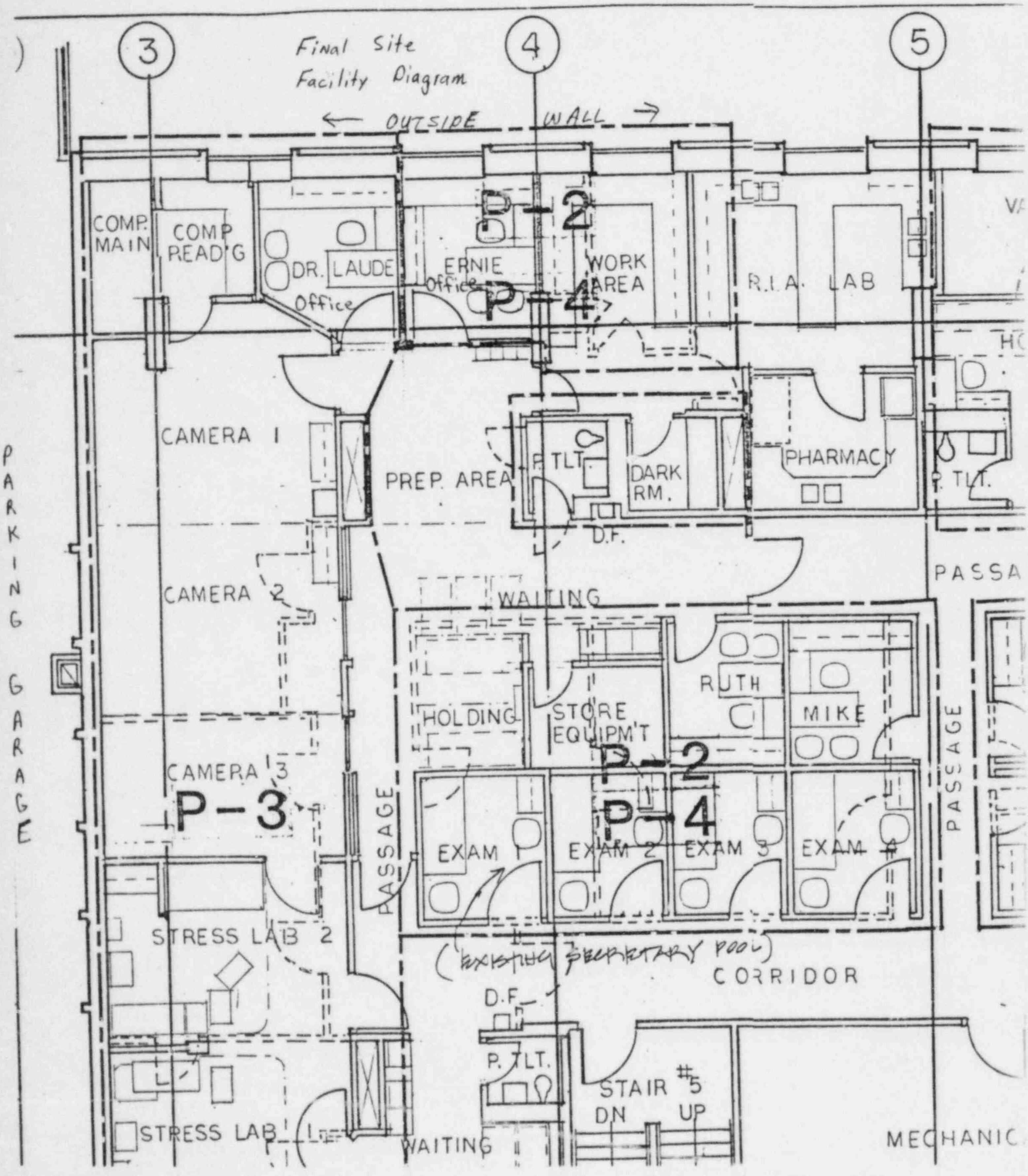
Temporary Facility Diagram



Attachment 3

St. Francis Hospital
Blue Island, Illinois

License No. NRC 12-10094-01
State of Il. IL-00160-01



CONTROL NO. 78949

Item 11
(5/85)

Attachment 4

GUIDELINES FOR SURVEYS AND WIPE TEST FOR RADIATION CONTAMINATION

Areas to be surveyed and wiped for radioactive contamination will include the injection sites, floors, lower walls and doors.

Equipment used for the radiation survey will be an open window low level GM survey meter capable of measuring 0.1 mR/hr. (Our survey meters are calibrated against a Cs-137 standard.) Equipment used to analyze the wipe test are a windowless gas flow proportional counter and a NaI(Tl) scintillation well counter available at Health Physics Associates, Ltd. in Northbook, Illinois - NRC license No. 12-01960-01, State of Illinois License No. IL-00244-01.

The wipes will be shipped in the mail and analyzed within two days after receipt by Health Physics Associates. (Descriptive material regarding wipe test analytical equipment is attached.) Acceptable levels of radioactive contamination for release as unrestricted areas are as follows for beta and gamma emitters:

Fixed on surfaces: 0.2 mR/hr ≈ 0.2 mrad/hr
Removable contamination: 100 pCi per 100 cm^2 or 222 dpm/100 cm^2

Note: No alpha emitters are used by our Nuclear Medicine Department.

All areas and wipes will be at or below the above listed levels for release as unrestricted areas. Any areas exceeding these levels will be decontaminated until these levels are obtained. Any materials used in the decontamination process and contaminated materials will be stored as radioactive waste and held for decay or proper disposal.

(5/65)

ATTACHMENT No. 4

1 a & b - Equipment list and uses

UNIT	EQUIPMENT	MANUFACTURER	MODEL No.	RADIATION TYPE DETECTED	RANGE OF RADIATION ENERGY DETECTED
1	Windowless Gas Flow Proportional Counter	G. D. Searle (Nuclear-Chgo)	480	Alpha Beta	All Alpha Particles Above 6 KeV
2	Window Gas Flow Proportional Counter	G. D. Searle (Nuclear-Chgo)		Alpha Beta	Above 4 MeV Above 50 KeV
3	Scintillation Well Counter	G. D. Searle	4216	Gamma	Above 25 KeV
4	Scintillation Well Counter	Picker	2804	Gamma	Above 25 KeV

1 c & d -

UNIT	RADIOACTIVE MATERIAL	RADIATION TYPE	*RADIATION ENERGY	**EFFICIENCY	**MINIMUM SENSITIVITY
1	Am-241	Alpha	5.4 MeV	46%	9.3×10^{-7} µCi
1	Ni-63	Beta	0.067	12%	1.8×10^{-5} µCi
	C-14	Beta	0.156	35%	6.1×10^{-6} µCi
	Pm-147	Beta	0.225	46%	4.6×10^{-6} µCi
	Tc-99	Beta	0.292	42%	5.1×10^{-6} µCi
	Cs-137	Beta	0.514	43%	5.0×10^{-6} µCi
	Co-60	Beta	0.314	31%	6.9×10^{-6} µCi
	Cl-36	Beta	0.714	47%	4.5×10^{-6} µCi
	Bi-210	Beta	1.16	42%	5.1×10^{-6} µCi
	Sr-90/Y-90	Beta	0.546 / 2.27	44%	4.8×10^{-6} µCi

Unit 2 is in the process of being recalibrated. Data will be submitted as soon as available.

* **NOTE:** Maximum beta energies are listed

** **NOTE:** Sample calculations follow

ATTACHMENT No. 4 - Page 2

UNIT	RADIOACTIVE MATERIAL	RADIATION ENERGY (MeV)	**EFFICIENCY	**MINIMUM SENSITIVITY
3	I-129	0.040	42%	1.1×10^{-5} µCi
	Cd-109	0.088	22%	2.1×10^{-5} µCi
	Co-57	0.122	70%	6.7×10^{-6} µCi
	Ra-226	0.186	85%	5.5×10^{-6} µCi
	Ba-133	0.356	80%	5.8×10^{-6} µCi
	Na-22	0.511/1.28	63%	7.4×10^{-6} µCi
	Cs-137	0.662	30%	1.6×10^{-5} µCi
	Mn-54	0.840	27%	1.7×10^{-5} µCi
	Co-60	1.17 /1.33	43%	1.1×10^{-5} µCi
4	Ra-226	0.186	9.9%	9.6×10^{-5} µCi

** NOTE: Sample calculations follow

CONTROL NO. 78949

c) Efficiency Calculations:

Efficiency = cpm / dpm

Sample Calculations

Am-241 efficiency = $\frac{30,000 \text{ cpm}}{65,400 \text{ dpm}}$ = 0.46

Cs-137 efficiency = $\frac{66,700 \text{ cpm}}{155,600 \text{ cpm}}$ = 0.43

Co-60 efficiency = $\frac{66,500 \text{ cpm}}{156,000 \text{ dpm}}$ = 0.43

d) Minimun Sensitivity Calculations:

Sensitivity of Instrument 1 at alpha voltage for Am-241

Alpha energy is calculated as follows:

Background count rate = 1 cpm
Background counted for 10 minutes
Background standard deviation (S.D.) = ±3.16 counts
3 S.D. confidence interval = ±9.49 counts
Minimun sensitivity for 10 minute counts of Am-241 alpha

$$\frac{9.49 \text{ counts}}{10 \text{ minutes}} \times \frac{1 \text{ disentegration}}{0.46 \text{ counts}} \times \frac{1 \ \mu\text{Ci}}{2.22 \times 10^6 \text{ dpm}}$$

$$= 9.3 \times 10^{-7} \ \mu\text{Ci}$$

Sensitivity of Instrument 2 at beta voltage

Background count rate = 25 cpm
Ten minute background count = 250 counts
One S.D. = ± 5.0 counts
3 S.D.Confidence Interval = ± 15.0 counts
Minimun sensitivity for 10 minute count of Cs-137 betas

$$\frac{15.0 \text{ counts}}{10 \text{ minutes}} \times \frac{1 \text{ d}}{0.43 \text{ counts}} \times \frac{1 \ \mu\text{Ci}}{2.22 \times 10^6 \text{ dpm}}$$

$$= 1.6 \times 10^{-6} \ \mu\text{Ci}$$

Sensitivity of Instrument 3 for Co-60 gammas

Background count rate = 120 cpm
Ten minute background count = 1200 counts
One S.D. = 34.6 counts
3 S.D. = 104 counts
Minimum sensitivity for 10 minute count of 1.2 - 1.3 gammas

$$\frac{104 \text{ counts}}{10 \text{ minutes}} \times \frac{1 \text{ d}}{0.43} \times \frac{1 \ \mu\text{Ci}}{2.22 \times 10^6 \text{ dpm}}$$

$$= 1.1 \times 10^{-5} \ \mu\text{Ci}$$

Similar calculations were performed for other intruments and radionuclides

C57/85

Attachment 5 Temporary Site

APPLICATION FOR THE USE OF XENON-133 GAS

NRC LICENSE AMENDMENT

A. QUANTITIES TO BE USED

1. It is estimated that approximately 1000 patients will be studied per year for Xenon-133 pulmonary ventilation. This averages out to be 20 per week. Approximately 10 mCi Xenon-133 will be used per patient; hence, the total quantity of Xenon-133 will be approximately 200 mCi per week.

2. A possession limit of 400 mCi is requested.

B. USE AND STORAGE AREAS (see attached diagram)

1. Xenon-133 sources used for pulmonary ventilation studies will be received in precalibrated single dose form from a radiopharmaceutical supplier. Until the source is used, it will be stored in its lead shipping container, which in turn is placed in the hot lab fume hood where the exhaust is provided.

2. Please refer to the diagram attached. As mentioned above, the Xenon-133 sources will be stored in the hot lab behind lead shielding in the fume hood.

   The hot lab is supplied with fresh air at a rate of 100 cfm, and is continuously exhausted into the atmosphere at a rate of 100 cfm, The fume hood exhaust is rated at 500 cfm.

   The exhaust duct from the hot lab is connected to the exhaust duct from the imaging rooms and the common duct leads to an exhaust system on the external wall of the parking garage. The fume hood exhaust is connected to the common duct also.

   The exhaust fan in the exhaust system

   (1) Pushes the air away from the parking garage
   (2) Is over thirty feet from any fresh air intakes, open doors or windows, and
   (3) is approximately 50 feet above ground level.

   The closest building is about 28 feet away (no open doors or windows facing the fan within 30 feet).

   The fan is rated at 7000 cfm providing continuous negative pressure in each section of the depatment where Xenon-133 may be stored or used. (The fan also provides exhaust to some other departments in the same building.)

continued

C5R

When Xenon-133 is used for pulmonary ventilation, the doors in Rooms 1 and 2 (D_1, D_2) will be kept closed to prevent the escape of Xenon-133 into the corridor. Doors between Rooms 1 and 2 will not be closed during Xenon-133 use. The only persons in the imaging section will be the patient (for ventilation study), the technologists performing the study and the physician, when necessary.

A paper strip taped near each exhaust port will act as a monitoring system to assure continuous exhaust from the rooms.

C. PROCEDURE FOR ROUTINE USE

1. Keep the door to the Hot Lab closed. Turn on the fume hood exhaust prior to obtaining Xe-133 dose.
2. All personnel not involved in the procedure should leave the imaging rooms (#1 and #2) .Keep the doors to the corridor closed.
3. Explain the procedure to the patient.
4. Disposable Xenon-133 re-breathing system will be used. Please refer to the copy of the literature from Nuclear Associates, Inc. attached to this application.

   A face mask with valves for flow direction will be affixed to the patient and attached to the re-breathing system. The gas will be injected in the incoming airway. A bag with CO_2 trap and/or O_2 supply will be used to collect the exhaled air during the equilibrium phase. For the washout phase, the gas will be collected in 30 liter bag, supplied commercially with the re-breathing system. Following the washout phase, the re-breathing system will be clamped closed and then connected to the exhaust port in Room #1.

   Four views are obtained - inhalation, exhalation, equilibrium, and washout. (Automatic unit providing inhalation, equilibrium and washout phases will be used in lieu of the above. The Xenon-133 will be exhausted through exhaust port in Room #1).
5. A visual inspection of all tubings, bags, connectors, valves and accessories will be made prior to each study to avoid leakage.
6. In order to avert a patient-associated release of the gaseous Xenon-133, a trial run with the face mask and the tubing will be performed with each patient.

continued

D. EMERGENCY PROCEDURES:

1. Accidental release of Xenon-133 gas in the imaging rooms -

The total air volume in the imaging rooms are :

Room #1: 24 x 21 X 8 = 4032 cu.ft.
#2: 14 x 21 X 8 = 2352 cu.ft.

TOTAL = 6404 cu.ft.

The total exhaust from the imaging rooms -

Old Section #1: 400 cfm
#2: 200 cfm
#3: 450 cfm

TOTAL = 1050 cfm

a) Initial concentration $= \frac{10,000 \text{ uCi}}{6404 \times 28,320}$

$= 5.51 \times 10^{-4}$ uCi/ml

b) Clearance Rate R $= \frac{1050 \text{ cfm}}{6404 \text{ cu.ft.}}$

$= 0.164$/min.

c) Desirable concentration level factor in the restricted area

$= \frac{1 \times 10^{-5} \text{ uCi/ml}}{5.51 \times 10^{-4} \text{ uCi/ml}}$

$= 1.81 \times 10^{-2}$

continued

d) Time required for the reduction of the concentration to an acceptable level is:

$$\text{Concentration level factor} = e^{-Rt}$$
$$0.0181 = e^{-0.164t}$$
$$-4.01 = -0.164t$$
$$t = 24.5 \text{ min}$$

In the event that 10 mCi of Xe-133 is released accidentally, the camera room will be evacuated for a minimum of 25 minutes. Doors to the corridor will be kept closed during this period.

2. Accidental release of Xe-133 in the hot lab -

The total air volume in the hot lab is 950 cu.ft. The total exhaust from the room is 600 cfm,(fume hood plus Hot Lab exhaust).

a) Initial concentration $= \frac{10,000 \text{ uCi}}{950 \times 27,000}$

$= 3.899 \times 10^{-4}$ uCi/ml

b) Clearance Rate $= \frac{600}{950} = 0.631$ /min.

c) Desirable concentration level factor in the restricted area

$$= \frac{1 \times 10^{-5} \text{ uCi/ml}}{3.899 \times 10^{-4} \text{uCi/ml}}$$
$$= 0.0256$$

d) Time required for the reduction of the concentration to an an acceptable level is:

$$\text{Concentration level factor} = e^{-Rt}$$
$$0.0256 = e^{-0.631}$$
$$-3.665 = -0.631t$$
$$t = 5.81 \text{ min}$$

If 10 mCi of Xenon-133 is accidentally released in the hot lab, the room will be evacuated for a minimum of 6 minutes and the door will be kept closed.

continued

E. AIR CONCENTRATIONS OF XENON-133 IN THE RESTRICTED AREA:

1. Imaging Rooms -

The following calculations indicate that the ventilation rate is more than adequate to maintain the Xenon-133 concentraton below 1 X 10^{-5} uCi/ml.

a) As mentioned previously, the maximum amount of Xenon-133 to be used is estimated at 60 mCi per week. Assuming that a total of 20% of the gas is lost during use, a total of 200 X 0.2 = 40 mCi will be lost.

b) The total volume of the air in the camera rooms is 6400 cu.ft. The ventilation rate of the rooms is 1050 cfm.

c) The total volume of air exhausted from the imaging rooms in a 40 hour week is:

$$1050 \times 6.797 \times 10^{7} = 7.1 \times 10^{10} \text{ ml/40 hour week}$$

d) The quantity of Xenon-133 that can be released without exceeding 1 X 10^{-5} uCi/ml:

$$7.1 \times 10^{10} \times 10^{-5}$$

$$= 7.1 \times 10^{5} \text{ uCi}$$

$$= 710 \text{ mCi}$$

This quantity is far above the 40 mCi of the Xenon-133 loss estimations. Hence, in accordance with 10 CFR 20.103, the concentration of Xenon-133 will not exceed 1 X 10^{-5} uCi/ml in the restricted area.

2. Hot Lab -

a) The maximum possession limit requested is for 400 mCi. Assuming that 5% of the gas leaks from the containers, a total of 20 mCi of Xenon-133 will be released into the room.

b) The exhaust from the room is 100 cfm.

c) The total volume of air exhausted from the room is:

$$100 \times 6.797 \times 10^{7} = 6.8 \times 10^{9} \text{ ml/40 hour week}$$

continued

d) The quantity of Xenon-133 that can be released without exceeding 1×10^{-5} uCi/ml:

$$6.8 \times 10^{9} \times 10^{-5} \text{ uCi}$$

$$= 6.8 \times 10^{4} \text{ uCi}$$

$$= 68 \text{ mCi}$$

This quantity is far above the 20mCi of Xenon-133 loss estimations. Hence, in accordance with 10 CFR 20.103, the concentrations of Xenon-133 will not exceed 1×10^{-5} uCi/ml in the restricted areas.

F. METHODS [illegible] XENON-133 DISPOSAL

When t[illegible] [illegible]on-133 pulmonary ventilation study is completed, the re-breath[illegible] system will be clamped closed and connected to the exhaust port in imaging room #1 for venting to the atmosphere.

The following calculations show the average concentration of Xenon-133 at the point of release from the fan. The fan moves air at a rate of 7000 cfm.

Total activity to be used per year:

$$A = 52 \times 200 = 10{,}400 \text{ mCi Xe-133}$$

$$= 10.4 \times 10^{6} \text{ uCi/year}$$

Total volume of air moved by the fan per year:

$$V = 7000 \times 1.49 \times 10^{10} \text{ ml/year}$$

$$= 1.04 \times 10^{14} \text{ ml/year}$$

Concentrations:

$$C = \frac{10.4 \times 10^{6}}{1.04 \times 10^{14}} = 1.0 \times 10^{-7} \text{ uCi/ml}$$

This activity is below the maximum permissible concentrations of 3×10^{-7} uCi/ml as specified by 10 CFR 20.106.

G. RADIATION SAFETY REGULATIONS FOR THE USE OF XENON-133 GAS

For the radiation safety of the nuclear medicine personnel and patients, the nine precautions listed on the following pages will be observed. A copy of radiation safety rules for the use of Xenon-133 gas will be posted in the department for ready reference by the employees.

C5785

RADIATION SAFETY FOR THE USE OF XENON-133

During the preparation, administration and performance of this study, all basic procedures of radiation safety, including the proper usage of time, distance and shielding, will be incorporated to reduce the radiation exposure to patient and hospital to an absolute minimum.

1. Store Xenon-133 sources in the hot lab so that radiation levels do not exceed 2 mR/hr at 2 feet from the storage area.

2. Visually inspect all tubings, bags, connectors, valves and accessories prior to each and every study to ensure that there are no apparent areas of possible leakage.

3. Absolutely no smoking, eating or drinking in the area.

4. The doors to the imaging section will be closed temporarily for the duration of the Xenon-133 ventilation study.

5. No personnel other than the patient, physician in charge and the technologist will be in the immediate area during this study.

6. A background count for Xenon will be performed with the scintillation camera system before and after all Xenon studies to ensure no unobservable release occurred. Should any release occur, any future images will not be initiated until post study background levels are less than twice that of the initial background.

7. In order to avert a patient-associated release, the face mask or mouthpiece and tubing will be effected with each patient, along with an explanation of the operation of the study.

8. Monitoring of the bag, tubing, face mask valves, etc. for residual or absorbed Xenon-133 will be accomplished by use of the low level GM survey meter. Contaminated articles will be aired near the vent for release from trapped or absorbed state in the hot lab.

9. In the event of accidental release of a 10 mCi dose of Xenon-133, the room in which the discharge occurs will be evacuated and doors locked for:

   6 minutes - in the hot lab
   25 minutes - in the imaging section

   Calculations are attached. Signs will be posted to this effect.

ITEM #21

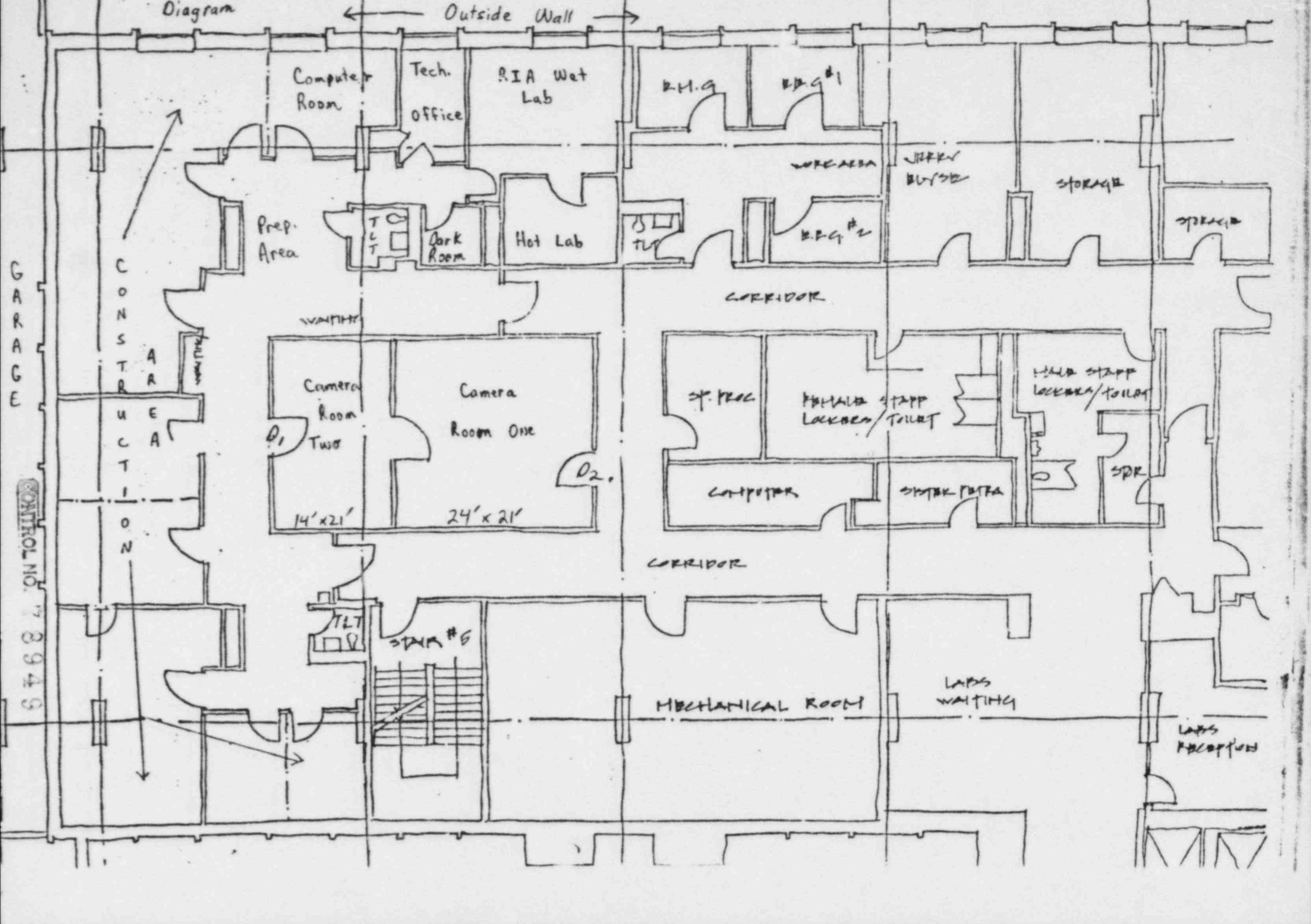
Item 11

Attachment 5

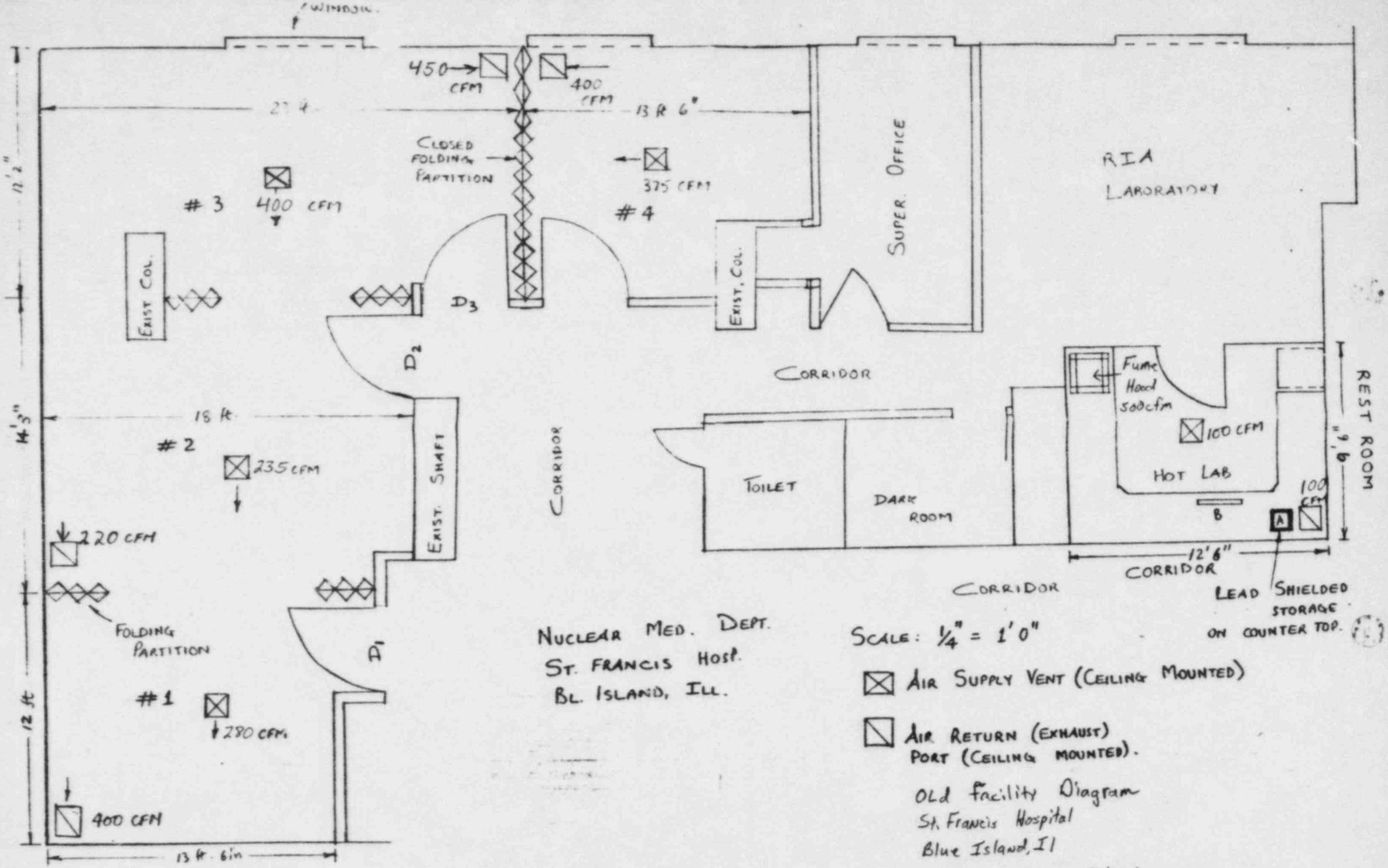
St. Francis Hospital
Blue Island, Il

License No
NRC 12-10094-01
St. of Il. - IL-00160-01

Temporary Facility Diagram



CONTROL NO. 78949



NUCLEAR MED. DEPT.
ST. FRANCIS HOSP.
BL. ISLAND, ILL.

SCALE: 1/4" = 1'0"

☒ AIR SUPPLY VENT (CEILING MOUNTED)

◸ AIR RETURN (EXHAUST) PORT (CEILING MOUNTED).

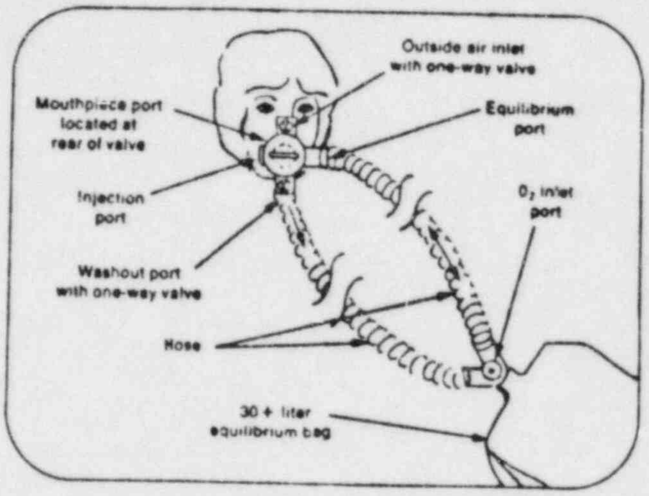
OLd Facility Diagram
St. Francis Hospital
Blue Island, Il
License No. 12-10094-01

ITEM # 11 (9/83)

An economical approach to ventilation and perfusion studies

"E-Xe-BREATHE"
Disposable Xenon Re-Breathing System

- Completely self-contained, lightweight.
- Large reservoir (30+ liters, neutral volume) for equilibrium and washout.
- Simple to operate . . . economical to use.
- Special, re-usable, two-way rotary valve control.



"E-Xe-Breathe" provides a safe, low-cost method of performing perfusion and ventilation studies using any radioactive gas. It is the ideal system for the budget-conscious nuclear medicine department when the use of more expensive equipment is unwarranted.

The system is lightweight, self-contained, and easy to operate. It comes complete with a disposable 30+ liter equilibrium bag, intake and exhaust tubing, an 0_2 port, a xenon injection port, and a mouthpiece. A specially-designed, two-way rotary valve assembly for controlling the gas mixture and patient breath flow completes the system.

he re-usable, two-way rotary valve allows the patient .o breathe either on a closed-loop equilibrium cycle or in a washout mode. In the latter, the patient breathes outside air only, exhaling into the equilibrium bag. The exhaust lines provide a convenient drain for the effluent xenon-air mixture. Oxygen may be added to the system through the 0_2 access port at the technologist's discretion. The xenon injection port accepts any xenon delivery system currently available.

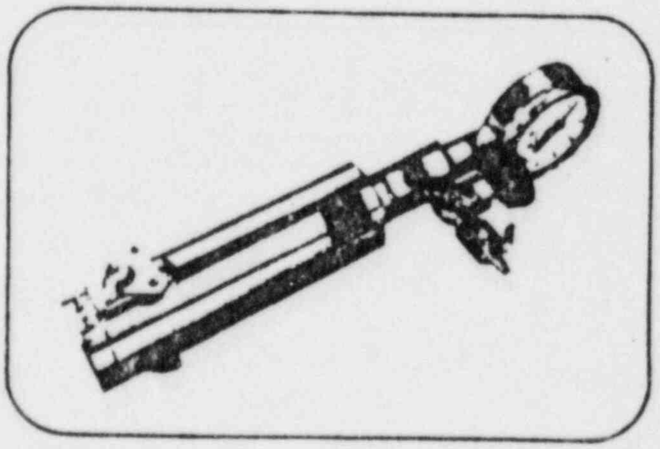
Available with or without rotary valve assembly. Bag and tubing are easily mated to rotary valve. Net weight 1 lb.

36-204	"E-Xe-Breathe" Disposable Xenon System, complete with re-usable Rotary Valve Assembly	$69.95
36-200	"E-Xe-Breathe" Disposable Bags, with tubing and connector	14.95
	12 or more each	13.95

Xenon-133 Gas Dispenser

Proven, economical way to dispense ^{133}Xe gas for pulmonary function studies

- Easy to load, easy to use.
- Double-valve system assures a safe, effective seal.
- Fully shielded.



The ^{133}Xe Gas Dispenser provides the large-volume xenon user with an economical, field-tested alternative to expensive unit dose packages of xenon-133 gas for lung function studies. It enables the technologist to control the flow of gas with relative ease while assuring accuracy and maximum personal safety.

This simple device accepts any commercially-available ampules of xenon gas. Its unique seal breaker ruptures he tip of the ampule with minimal effort. A built-in, 25 micron filter prevents any foreign matter from being drawn into the user's gas-tight syringe. A needle valve and a gate valve (with Luer adapter), coupled to a pressure/vacuum gauge, provide an effective, air-tight seal.

Operation is simple. The user merely attaches a gas-tight syringe to the Luer adapter, opens both valves and withdraws a dose. The system may be run at a positive or negative pressure. Seal integrity is maintained by means of Viton® O-rings and seals. When loaded with 1 curie of xenon-133, the dispenser has a radiation profile of less than 30 mR/hr at one foot.

Effective internal volume 50 ml. Length 13½". Net weight 7 lbs.

36-302	Xenon-133 Gas Dispenser	$275.00

(7/84)

Item 21

C5/8

Attachment 6 Final Site

APPLICATION FOR THE USE OF XENON-133 GAS

NRC LICENSE AMENDMENT

A. QUANTITIES TO BE USED

1. It is estimated that approximately 1000 patients will be studied per year for Xenon-133 pulmonary ventilation. This averages out to be 20 per week. Approximately 10 mCi Xenon-133 will be used per patient; hence, the total quantity of Xenon-133 will be approximately 200 mCi per week.

2. A possession limit of 400 mCi is requested.

B. USE AND STORAGE AREAS (see attached diagram)

1. Xenon-133 sources used for pulmonary ventilation studies will be received in precalibrated single dose form from a radiopharmaceutical supplier. Until the source is used, it will be stored in its lead shipping container, which in turn is placed in the hot lab fume hood where the exhaust is provided.

2. Please refer to the diagram attached. As mentioned above, the Xenon-133 sources will be stored in the hot lab behind lead shielding in the fume hood.

   The hot lab is supplied with fresh air at a rate of 100 cfm, and is continuously exhausted into the atmosphere at a rate of 100 cfm, The fume hood exhaust is rated at 500 cfm.

   The exhaust duct from the hot lab is connected to the exhaust duct from the imaging rooms and the common duct leads to an exhaust system on the external wall of the parking garage. The fume hood exhaust is connected to the common duct also.

   The exhaust fan in the exhaust system

   (1) Pushes the air away from the parking garage
   (2) Is over thirty feet from any fresh air intakes, open doors or windows, and
   (3) is approximately 50 feet above ground level.

   The closest building is about 28 feet away (no open doors or windows facing the fan within 30 feet).

   The fan is rated at 7000 cfm providing continuous negative pressure in each section of the depatment where Xenon-133 may be stored or used. (The fan also provides exhaust to some other departments in the same building.)

continued

ITEM #21

CONTROL NO. 73949

C578

The folding partitions between Rooms 1,2,and 3 are kept closed at all times. When Xenon-133 is used for pulmonary ventilation, the doors in Rooms 1 and 2 and 3 (D_1, D_2) will be kept closed to prevent the escape of Xenon-133 into the corridor and into Stress Lab 2. Partitions between Rooms 1, 2 and 3 will not be closed during Xenon-133 use. The only persons in the imaging section will be the patient (for ventilation study), the technologists performing the study and the physician, when necessary.

A paper strip taped near each exhaust port will act as a monitoring system to assure continuous exhaust from the rooms.

C. PROCEDURE FOR ROUTINE USE

1. Keep the door to the Hot Lab closed. Turn on the fume hood exhaust prior to obtaining Xe-133 dose.
2. All personnel not involved in the procedure should leave the imaging rooms (#1, #2 and #3). Keep the doors to the corridor closed.
3. Explain the procedure to the patient.
4. Disposable Xenon-133 re-breathing system will be used. Please refer to the copy of the literature from Nuclear Associates, Inc. attached to this application.

   A face mask with valves for flow direction will be affixed to the patient and attached to the re-breathing system. The gas will be injected in the incoming airway. A bag with Co_2 trap and/or O_2 supply will be used to collect the exhaled air during the equilibrium phase. For the washout phase, the gas will be collected in 30 liter bag, supplied commercially with the re-breathing system. Following the washout phase, the re-breathing system will be clamped closed and then connected to the exhaust port in room # 3 .

   Four views are obtained - inhalation, exhalation, equilibrium, and washout. (Automatic unit providing inhalation, equilibrium and washout phases will be used in lieu of the above. The Xenon-133 will be exhausted through exhaust port in room # 3).
5. A visual inspection of all tubings, bags, connectors, valves and accessories will be made prior to each study to avoid leakage.
6. In order to avert a patient-associated release of the gaseous Xenon-133, a trial run with the face mask and the tubing will be performed with each patient.

continued

D. EMERGENCY PROCEDURES:

1. Accidental release of Xenon-133 gas in the imaging section -

The total air volume in the imaging section is:

Rooms	#1:	15 × 18 X 8 =	2160 cu.ft.
	#2:	15 × 18 X 8 =	2160 cu.ft.
	#3:	12 × 18 X 8 =	1728 cu.ft.
		TOTAL =	6048 cu.ft.

The total exhaust from the imaging section -

Rooms	#1:	400 cfm
	#2:	200 cfm
	#3:	450 cfm
TOTAL	=	1050 cfm

a) Initial concentration $= \frac{10{,}000 \text{ uCi}}{6048 \times 28{,}320}$

$= 5.84 \times 10^{-4}$ uCi/ml

b) Clearance Rate R $= \frac{1050 \text{ cfm}}{6048 \text{ cu.ft.}}$

$= 0.174$ /min.

c) Desirable concentration level factor in the restricted area

$= \frac{1 \times 10^{-5} \text{ uCi/ml}}{5.84 \times 10^{-4} \text{ uCi/ml}}$

$= 0.0171$

continued

d) Time required for the reduction of the concentration to an acceptable level is:

$$\text{Concentration level factor} = e^{-Rt}$$
$$0.0171 = e^{-0.174t}$$
$$-4.07 = -0.174t$$
$$t = 23.4 \text{ min}$$

In the event that 10 mCi of Xe-133 is released accidentally, the camera room will be evacuated for a minimum of 25 minutes. Doors to the corridor will be kept closed during this period.

2. Accidental release of Xe-133 in the hot lab -

The total air volume in the hot lab is 950 cu.ft. The total exhaust from the room is 600 cfm,(fume hood plus Hot Lab exhaust).

a) Initial concentration $= \frac{10{,}000 \text{ uCi}}{950 \times 27{,}000}$

$= 3.899 \times 10^{-4}$ uCi/ml

b) Clearance Rate $= \frac{600}{950} = 0.631$ /min.

c) Desirable concentration level factor in the restricted area

$$= \frac{1 \times 10^{-5} \text{ uCi/ml}}{3.899 \times 10^{-4} \text{uCi/ml}}$$
$$= 0.0256$$

d) Time required for the reduction of the concentration to an an acceptable level is:

$$\text{Concentration level factor} = e^{-Rt}$$
$$0.0256 = e^{-0.631}$$
$$-3.665 = -0.631 t$$
$$= 5.81 \text{ min}$$

If 10 mCi of Xenon- [illegible] accidentally released in the hot lab, the room will be evacuated for a minimum of 6 minutes and the door will be kept closed.

continued

E. AIR CONCENTRATIONS OF XENON-133 IN THE RESTRICTED AREA:

1. Imaging Rooms -

The following calculations indicate that the ventilation rate is more than adequate to maintain the Xenon-133 concentraton below 1 X 10^{-5} uCi/ml.

a) As mentioned previously, the maximum amount of Xenon-133 to be used is estimated at 60 mCi per week. Assuming that a total of 20% of the gas is lost during use, a total of 200 X 0.2 = 40 mCi will be lost.

b) The total volume of the air in the camera room is 6048 cu.ft. The ventilation rate of the room is 1050 cfm.

c) The total volume of air exhausted from the imaging rooms in a 40 hour week is:

$$1050 \times 6.797 \times 10^{7} = 7.1 \times 10^{10} \text{ ml/40 hour week}$$

d) The quantity of Xenon-133 that can be released without exceeding 1 X 10^{-5} uCi/ml:

$$7.1 \times 10^{10} \times 10^{-5}$$

$$= 7.1 \times 10^{5} \text{ uCi}$$

$$= 710 \text{ mCi}$$

This quantity is far above the 40mCi of the Xenon-133 loss estimations. Hence, in accordance with 10 CFR 20.103, the concentration of Xenon-133 will not exceed 1 X 10^{-5} uCi/ml in the restricted area.

2. Hot Lab -

a) The maximum possession limit requested is for 400mCi. Assuming that 5% of the gas leaks from the containers, a total of 20 mCi of Xenon-133 will be released into the room.

b) The exhaust from the room is 100cfm.

c) The total volume of air exhausted from the room is:

$$100 \times 6.797 \times 10^{7} = 6.8 \times 10^{9} \text{ ml/40 hour week}$$

continued

d) The quantity of Xenon-133 that can be released without exceeding 1×10^{-5} uCi/ml:

$$6.8 \times 10^{9} \times 10^{-5} \text{ uCi}$$

$$= 6.8 \times 10^{4} \text{ uCi}$$

$$= 68 \text{ mCi}$$

This quantity is far above the 20mCi of Xenon-133 loss estimations. Hence, in accordance with 10 CFR 20.103, the concentrations of Xenon-133 will not exceed 1×10^{-5} uCi/ml in the restricted areas.

F. METHODS OF XENON-133 DISPOSAL

When the Xenon-133 pulmonary ventilation study is completed, the re-breathing system will be clamped closed and connected to the exhaust port in imaging room # 3 for venting to the atmosphere.

The following calculations show the average concentration of Xenon-133 at the point of release from the fan. The fan moves air at a rate of 7000 cfm.

Total activity to be used per year:

$$A = 52 \times 200 = 10{,}400 \text{ mCi Xe-133}$$

$$= 10.4 \times 10^{6} \text{ uCi/year}$$

Total volume of air moved by the fan per year:

$$V = 7000 \times 1.49 \times 10^{10} \text{ ml/year}$$

$$= 1.04 \times 10^{14} \text{ ml/year}$$

Concentrations:

$$C = \frac{10.4 \times 10^{6}}{1.04 \times 10^{14}} = 1.0 \times 10^{-7} \text{ uCi/ml}$$

This activity is below the maximum permissible concentrations of 3×10^{-7} uCi/ml as specified by 10 CFR 20.106.

G. RADIATION SAFETY REGULATIONS FOR THE USE OF XENON-133 GAS

For the radiation safety of the nuclear medicine personnel and patients, the nine precautions listed on the following pages will be observed. A copy of radiation safety rules for the use of Xenon-133 gas will be posted in the department for ready reference by the employees.

RADIATION SAFETY FOR THE USE OF XENON-133

During the preparation, administration and performance of this study, all basic procedures of radiation safety, including the proper usage of time, distance and shielding, will be incorporated to reduce the radiation exposure to patient and hospital to an absolute minimum.

1. Store Xenon-133 sources in the hot lab so that radiation levels do not exceed 2 mR/hr at 2 feet from the storage area.

2. Visually inspect all tubings, bags, connectors, valves and accessories prior to each and every study to ensure that there are no apparent areas of possible leakage.

3. Absolutely no smoking, eating or drinking in the area.

4. The doors to the imaging section will be closed temporarily for the duration of the Xenon-133 ventilation study.

5. No personnel other than the patient, physician in charge and the technologist will be in the immediate area during this study.

6. A background count for Xenon will be performed with the scintillation camera system before and after all Xenon studies to ensure no unobservable release occurred. Should any release occur, any future images will not be initiated until post study background levels are less than twice that of the initial background.

7. In order to avert a patient-associated release, the face mask or mouthpiece and tubing will be effected with each patient, along with an explanation of the operation of the study.

8. Monitoring of the bag, tubing, face mask valves, etc. for residual or absorbed Xenon-133 will be accomplished by use of the low level GM survey meter. Contaminated articles will be aired near the vent for release from trapped or absorbed state in the hot lab.

9. In the event of accidental release of a 10 mCi dose of Xenon-133, the room in which the discharge occurs will be evacuated and doors locked for:

   6 minutes - in the hot lab
   25 minutes - in the imaging section

   Calculations are attached. Signs will be posted to this effect.

ITEM #21

(5/85)

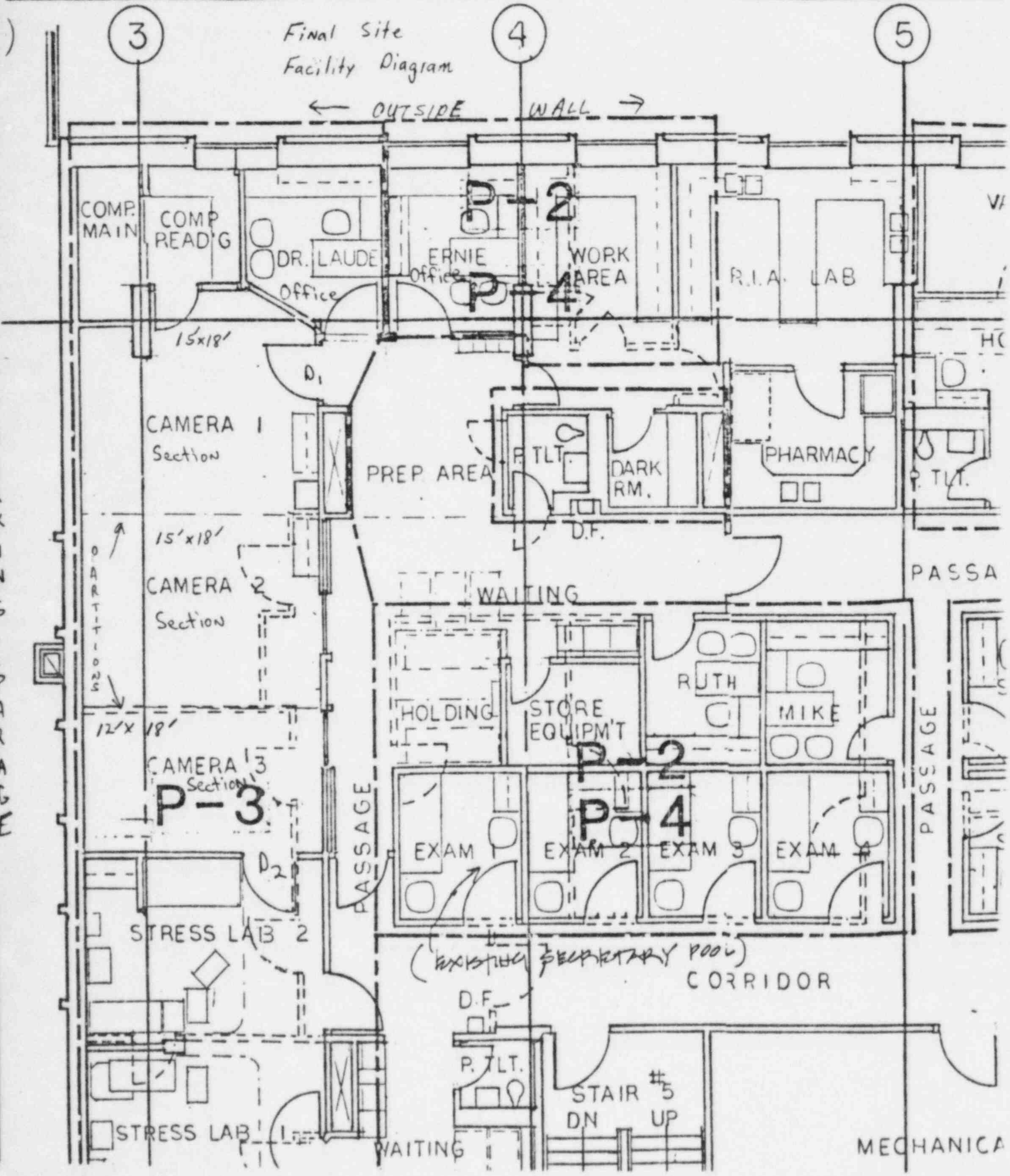
Attachment 6

St. Francis Hospital

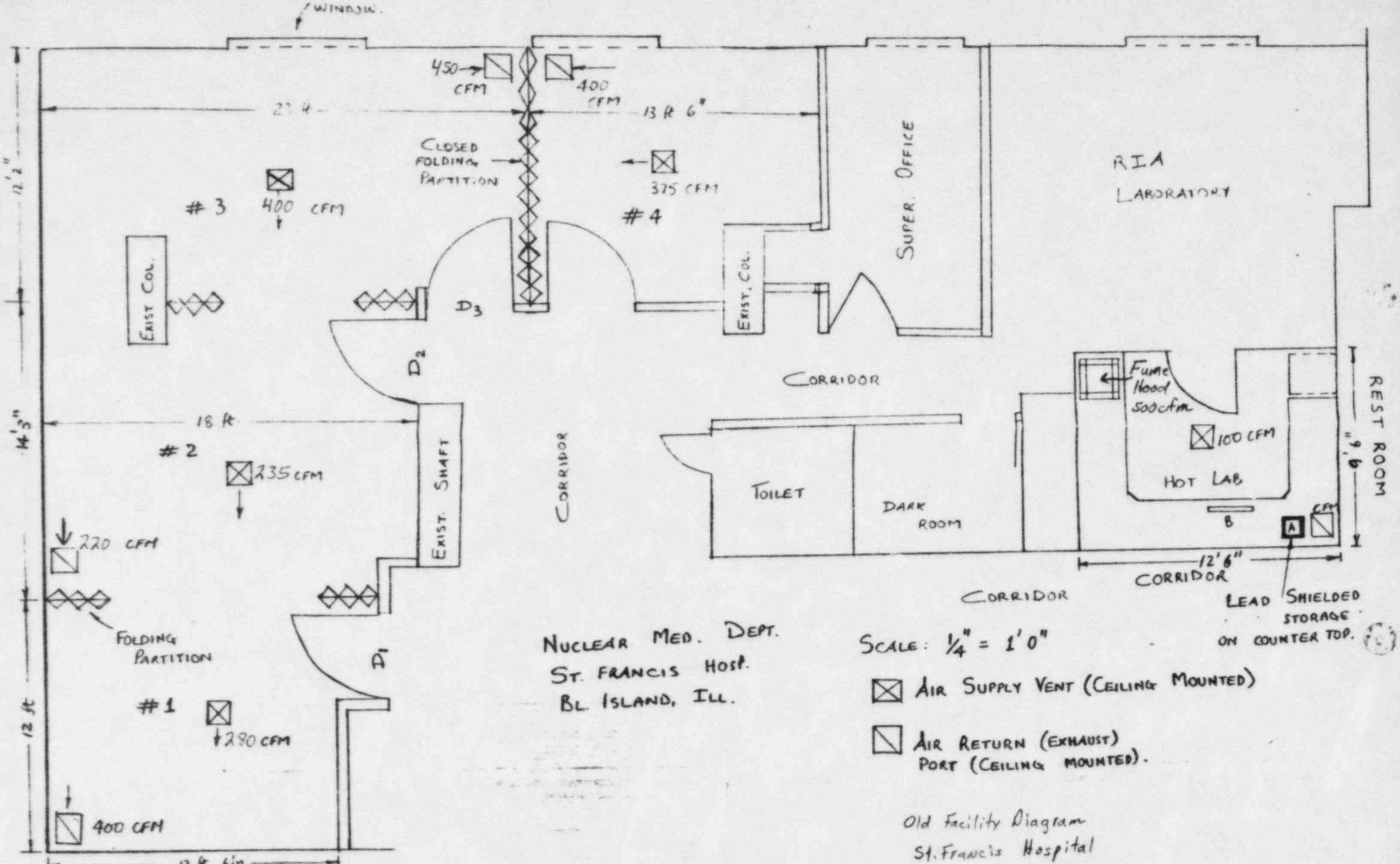
Blue Island, Illinois

License No. NRC 12-10094-01

State of Il. IL-00160-01



(5/85)



NUCLEAR MED. DEPT.
ST. FRANCIS HOSP.
BL. ISLAND, ILL.

SCALE: 1/4" = 1'0"

⊠ AIR SUPPLY VENT (CEILING MOUNTED)

◸ AIR RETURN (EXHAUST) PORT (CEILING MOUNTED).

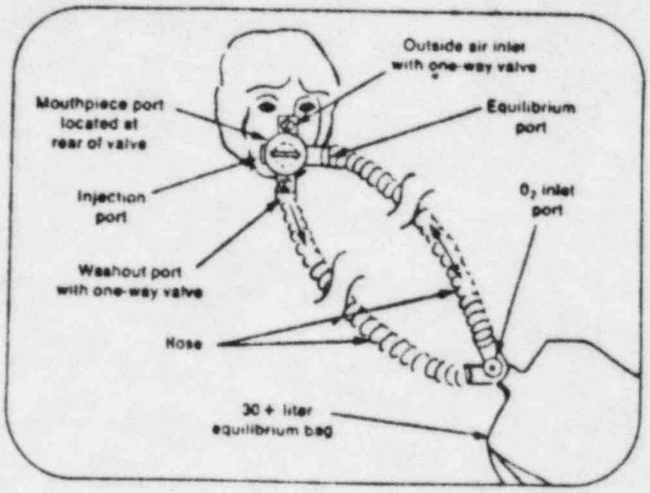
Old Facility Diagram
St. Francis Hospital
Blue Island, Il.
License No. 12-10094-01

ITEM # 11 (9/83)

An economical approach to ventilation and perfusion studies

"E-Xe-BREATHE"

Disposable Xenon Re-Breathing System



- Completely self-contained, lightweight.
- Large reservoir (30+ liters, neutral volume) for equilibrium and washout.
- Simple to operate . . . economical to use.
- Special, re-usable, two-way rotary valve control.

"E-Xe-Breathe" provides a safe, low-cost method of performing perfusion and ventilation studies using any radioactive gas. It is the ideal system for the budget-conscious nuclear medicine department when the use of more expensive equipment is unwarranted.

The system is lightweight, self-contained, and easy to operate. It comes complete with a disposable 30+ liter equilibrium bag, intake and exhaust tubing, an O_2 port, a xenon injection port, and a mouthpiece. A specially-designed, two-way rotary valve assembly for controlling the gas mixture and patient breath flow completes the system.

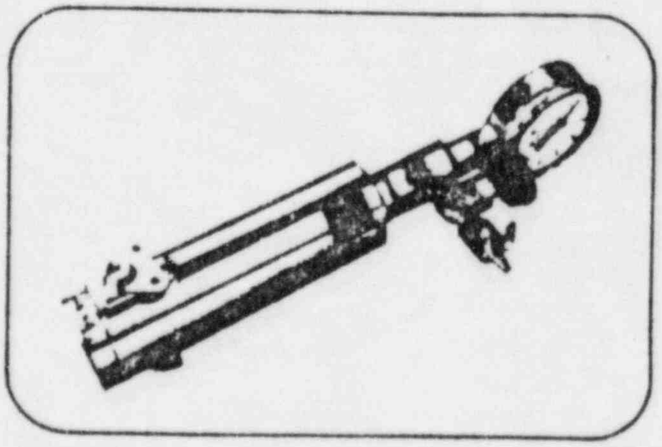
he re-usable, two-way rotary valve allows the patient .o breathe either on a closed-loop equilibrium cycle or in a washout mode. In the latter, the patient breathes outside air only, exhaling into the equilibrium bag. The exhaust lines provide a convenient drain for the effluent xenon-air mixture. Oxygen may be added to the system through the O_2 access port at the technologist's discretion. The xenon injection port accepts any xenon delivery system currently available.

Available with or without rotary valve assembly. Bag and tubing are easily mated to rotary valve. Net weight 1 lb.

36-204	"E-Xe-Breathe" Disposable Xenon System, complete with re-usable Rotary Valve Assembly	$69.95
36-200	"E-Xe-Breathe" Disposable Bags, with tubing and connector	14.95
	12 or more............each	13.95

Xenon-133 Gas Dispenser

Proven, economical way to dispense ^{133}Xe gas for pulmonary function studies



- Easy to load, easy to use.
- Double-valve system assures a safe, effective seal.
- Fully shielded.

The ^{133}Xe Gas Dispenser provides the large-volume xenon user with an economical, field-tested alternative to expensive unit dose packages of xenon-133 gas for lung function studies. It enables the technologist to control the flow of gas with relative ease while assuring accuracy and maximum personal safety.

This simple device accepts any commercially-available ampules of xenon gas. Its unique seal breaker ruptures the tip of the ampule with minimal effort. A built-in, 25 micron filter prevents any foreign matter from being drawn into the user's gas-tight syringe. A needle valve and a gate valve (with Luer adapter), coupled to a pressure/vacuum gauge, provide an effective, air-tight seal.

Operation is simple. The user merely attaches a gas-tight syringe to the Luer adapter, opens both valves and withdraws a dose. The system may be run at a positive or negative pressure. Seal integrity is maintained by means of Viton® O-rings and seals. When loaded with 1 curie of xenon-133, the dispenser has a radiation profile of less than 30 mR/hr at one foot.

Effective internal volume 50 ml. Length 13½". Net weight 7 lbs.

36-302 Xenon-133 Gas Dispenser $275.00

CONTROL NO. 3949
Item 21
(5/85)