FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved: GAO R0557

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 Material 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**

Louis A. Weiss Memorial Hospital
4646 N. Marine Drive
Chicago, Illinois 60640

TELEPHONE NO.: AREA CODE (312) 878-8700

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

As Above

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Arun G. Kaluskar, Ph.D.

TELEPHONE NO.: AREA CODE (312) 878-8700, X-2325

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 12-02418-01

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

Please refer to Supplement #1

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.)*

Arun G. Kaluskar, Ph.D., D.A.B.R.

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	10 mCi ea
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	2 Ci ea
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1500 mCi

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	1000 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
Please refer to our applications of February 26, 1979 and April 16, 1979			

License Fee Information on Next Page

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: 1980

7. MEDICAL ISOTOPES COMMITTEE Supplement #3

X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached

8. TRAINING AND EXPERIENCE Supplement # 2

X	Supplements A & B Attached for Each Individual User; and
X	Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)* Supplements 4(a) & 4(b)

X	Appendix C Form Attached; or
X	List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS Refer to our letters of 2/26/79 & 4/16/79

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 Refer to our application of 2/26/79 and Supplement 5

X	Description and Diagram Attached Supplement # 5

12. PERSONNEL TRAINING PROGRAM Please refer to our application 2/26/79

X	Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL Refer to our application of 2/26/79 and Supplemens 6 and 6(a)

X	Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

	Appendix F Procedures Followed; or
	Equivalent Procedures Attached Supplements 6(a) & 6(b)

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

X	Appendix G Rules Followed; or Refer to our application of 2/26/79
	Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

X	Appendix H Procedures Followed; or Refer to our application of Feb 26, 1978
	Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

	Appendix I Procedures Followed; or Please refer to our application of Feb 26, 1979
	Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)* Please refer to our letters of 2/26/79 & 7/9/80

	Appendix J Form Attached; or
X	Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)* Refer to our application of Feb 26, 1979

X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

X	Detailed Information Attached; and Supplements 7
	Appendix L Procedures Followed; or *(Check One)*
X	Equivalent Procedures Attached Supplements 7

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

X	Detailed Information Attached Supplement # 8

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

	Detailed Information Attached N. A.

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b

X	Detailed Information Attached Refer to our application of Feb 26, 1979

NRC FORM (9-81)

24. PERSONNEL MONITORING DEVICES

	TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer & Co, Illinois	1 to 2 per Month
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer & Co, Illinois	1 to 2 per Month
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

For our ALARA Program please refer to our letter of July 29, 1981

RECEIVED BY LFMB
Date 11/7/85
Log Jan 4
By
Orig. To
Action Compl

Applicant
Check No. 164148 $580
Amount
Type
Date Rec'd 11/1/85
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: 7 B

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
James Champer

(1) NAME *(Type or Print)*
James Champer

(2) TITLE
President

c. DATE
December 26, 1984

NRC FORM 313M (9-81)

CONTROL NO. 78017

SUPPLEMENT 1

Individual Users

1.	J. Singh, M.D.	Nuclear Medicine
2.	Y. Mehta, M.D.	Radiation Oncology
3.	P. Shirazi, M.D.	Consultant, Nuclear Medicine
4.	N. Khedkar, M.D.	Consultant, Nuclear Medicine
5.	P. Kurup, M.D.	Radiation Oncology Group VI and soluble P-32 for Therapy
6.	A. Sheikh, M.D.	Tc-99m for Cardiac Studies
7.	A. kaluskar, M.D.	In vitro studies/Calibration

L.A. Weiss Memorial Hospital
Chicago, Illinois 60640
NRC 12-02418-01

SUPPLEMENT #2

Training and Experience

1. J. Singh, M.d.
   Please refer to License number NRC 12-02418-01

2. P. Sirazi, M.D.
   Please refer to License number NRC 12-02418-01 (Weiss Hospital) and number NRC 12-09567-01 (Lutheran General Hospital).

3. N. Khedhar, M.D.
   Please refer to License number NRC 12-02418-01 (Weiss Hospital) and number NRC 12-09567-01 (Lutheran General Hospital, Illinois).

4. Yashbir Mehta, M.D.
   Please refer to our License number NRC 12-02418-01

5. Parvathy Devi Kurup, M.D.
   Please refer to our License number NRC 12-02418-01 and attached NRC form 313 M-Supplements A & B.

6. Amjad Sheikh, M.D.
   Please refer to our License number NRC 12-02418-01.

7. A. G. Kaluskar, Ph.D., R.S.O.
   Please refer to our License number NRC 12-02418-01.

L. A. Weiss Memorial Hospital
Chicago Illinois 60640
NRC 12-02418-01

FORM NRC-313M-SUPPLEMENT A (8-78) — 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
Parvathy Devi Kurup, M.D.	Illinois 36-058250-1

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiology	June 1981

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	Rush Presbyterian St. Luke's Medical Center, Chicago, IL July 1977-June 1981	120	120
b. RADIATION PROTECTION	As above	50	100
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Madras University Madras, India and RPSLMC	50	50
d. RADIATION BIOLOGY	RPSLMC July 1977-June 1981	60	100
e. RADIOPHARMACEUTICAL CHEMISTRY	RPSLMC July 1977-June 1981	50	100

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
CS 139	110 MgRaEq.	R.P.S.L.M.C.	July 1977-June 1981	Intracaitory
I125	100MCi	R.P.S.L.M.C.	July 1977-June 1981	Interstitial
Ir192	100MCi	R.P.S.L.M.C.	July 1977-June 1981	Interstitial
Co60	4000Ci	R.P.S.L.M.C.	July 1977-June 1981	Teletherapy
P-32	10 mCi	Weiss Memorial Hospital	Dec 1983-Dec 1984	Intravenous

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

Parvathy Devi Kurup, M.D.

STREET ADDRESS

4646 N. Marine Drive

CITY	STATE	ZIP CODE
Chicago	IL	60640

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		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
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		
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

December 1983 - December 1984, Over 20 Hours

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

a. NAME OF SUPERVISOR
Y. Mehta, M.D.

b. NAME OF INSTITUTION
L.A.Weiss Memorial Hospital

c. MAILING ADDRESS
4646 N. Marine Drive

d. CITY
Chicago, IL 60640

5. MATERIALS LICENSE NUMBER(S)
12-02418-01

6. PRECEPTOR'S SIGNATURE
Mehta

7. PRECEPTOR'S NAME *(Please type or print)*
Y. M. Mehta, M.D.

8. DATE
December 20, 1984

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

CONTROL NO. 78017

SUPPLEMENT #3

Radiation Safety Committee

NAME	SPECIALITY
Gabriel Angress, M.D.	Diagnotic Radiology
Arun Kaluskar, Ph.D.	Radiation Physicist, R.S.O.
Larry Keer, M.D.	Internal Medicine
Yashbir Mehta, M.D.	Radiation Oncology
Sanford Rabushka, M.D.	Diagnostic Radiology
Lewis Seagal, M.D.	Diagnostic Radiology
Amjad Sheikh, M.D.	Cardiology
Harold Shrifter, M.D.	Internal Medicine
Jaspal Singh, M.D.	Nuclear Medicine, Biochemistry
Martin Szanto, M.D.	Internal Medicine
Greg Banaszynski	Administration
Parvarthy Kurup, M.D.	Radiation Oncology
Jan Wadin	Nursing

A copy of the curriculum vitae is kept on file with the Radiation Safety Officer.

SUPPLEMENT 4 (a)

Louis A. Weiss Memorial Hospital
Chicago, Il 60640
12-02418-01

INSTRUMENTATION

1. Survey meters

. Manufacturer's name: Johnson Associate
Manufacturer's model number: GSM-5
Number of instruments available: 2

Minimum range: 0 mR/hr to 0.2 mR/hr
Maximum range: 0 mR/hr to 20 mR/hr

. Manufacturer's name: Victoreen
Manufacturer's model number: 498
Number of instruments available: 1

Minimum range: 0 mR/hr to 1 mR/hr
Maximum range: 0 mR/hr to 1000 mR/hr

. Manufacturer's name: Victoreen
Manufacturer's model number: Cutie Pie
Number of instruments available: 1

Minimum range: 0 mR/hr to 25 mR/hr
Maximum range: 0 mR/hr to 2500 mR/hr

. Manufacturer's name: _____
Manufacturer's model number: _____
Number of instruments available: _____

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

2. Dose calibrator

Manufacturer's name: Capintec
Manufacturer's model number: CRC-30
Number of instruments available: 1

Dose calibrator

Manufacturer's name: Squibb
Manufacturer's model number: CRC-6A
Number of instruments available: 1

SUPPLEMENT #4(b)

DIAGNOSTIC INSTRUMENTS

Type of Instrument	Manufacturer's Name	Model No.
1) Gamma Scanner	Siemens	Pho-gamma V
2) Gamma Scanner	Siemens	Scintiview II
3) Gamma Scanner	General Electric	LOFV
4) Gamma Scanner	General Electric	Portable Data Camera
5) Iodine Uptake	Picker	Spectroscaler 4R
6) Ventillator	RADX	Ventil-con

INSTRUMENTS

1) ADAC II Computer for Nuclear Medicine

2) Ludlum Measurements Model 177 - hands, feet, clothes Monitor

3) Nuclear Associates - Primalert II

4) Isodata, Model 20/10D well gamma counter - counting Radio-Immo Assays, wipe and Contamination Test.

5) BATEC, model 225 - bet CO_2 metabolism.

L. A. Weiss Memorial Hospital
Chicago, IL 60640
NRC 12-02418-01

SUPPLEMENT 6

Facilities and Equipment

A. Facilities and equipment in the Radiation Oncology Department .

The floor plan of the Radiation Oncology Department is showin in Figure 1 and the location of the Cesium storing facility.
Please refer to our letter of Feb 26, 1979 and Aug. 13, 1981

i) Cesium 137

a) Portable 8 hole Horwitz safe, 3M nuclear products Model 6624.

b) Radium chemical Model 799 Protective well.

c) Radium chemical Model 462 Modern Protection block with Model 461 high density glass shield.

d) Radium chemical Model 50100 Ernest carrier and Heyman carrier with cart.

e) Radium chemical Model 422 CR Heyman cap remover and Model 474 lead protective vise.

f) Assorted 10" and 12" handling forcepts.

g) Rolling Radiation Shield, 3M Nuclear Products, Model 6623.

ii) Phosphorous 32

No special equipment or facility is planned for use of collodial phosphorous, which will be obtained as a precalibrated solution, and administrated by the drip method.

iii) Iridium 192

Please refer to our letter of Feb 26, 1979 for the picture of the after loading system and description of the after loading method. Seeds will be ordered as and when needed from Rad/Irid Co, Washington, D.C. or Best Industries, Washington, D.C. or other qualified supplier.

iv) Iodine 125

Please refer to our letter of August 13, 1981 for the picture and description of Mick Applicator for I-125 seeds. Precalibrated seeds will be obtained from a proper supplier, with appropriate certificates - leak test, weld integrity, etc.

B. Facilities and Equipment in Nuclear Medicine Department.

i) The floor plan of the Nuclear Medicine Department is shown in Figure 2 and the description of the keyed location is given in the figure.

SUPPLEMENT 5

ii) The diagnostic Equipment is in areas I, II and III, IV

iii) Radiophamaceuticals are stored in the refrigerator in lead containers. The doses are prepared behind the protective barrier.

iv) Decay room (lead lined) - in the decay room all the needles, empty vials, etc., allowed to decay in lead containers. One radiation level outside the locked door is less than 0.05 MRhr.

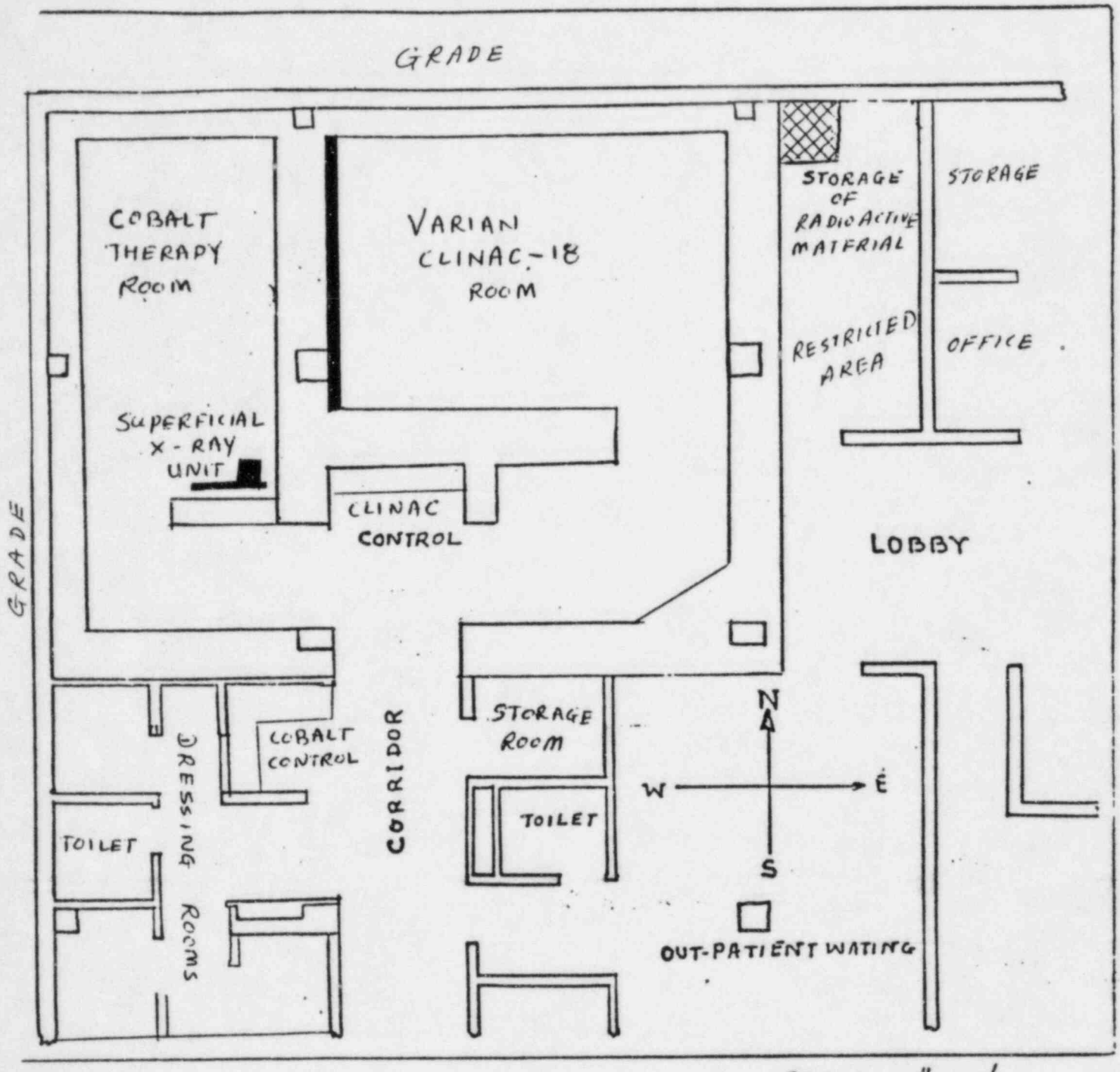
C. Clinical Microbiology and Clinical Biochemistry Laboratories. The floor plans are given in figures 3a and 3b.

i) In vitro detection A metabolic CO2 using C-14 labeled tryptic soy is done in the microbiology lab. (figure 3a). One labeled vials are stored in refrigerator.

ii) T-3, T-4, Schilling and other tests are done in the Radio-Immuno Assay laboratory. (figure 3b). Regrigerators are 1 and 2 and the storage places for all radioactive materials.

iii) The small radioactive waste generated is stored in a separate container and decayed temporarily.

iv) The radioimmuno assay lab moved from its old location to the new location in November 1984. The wipe tests results are given in Exhibit 5(a) and 5(b). (refer to Fig 3(b)). The wipe test shows that there was no radioactive contamination.



SCALE - 1" = 7'

Fig. 1 FLOOR PLAN
RADIATION ONCOLOGY

Cs-137/Ra-Safe.
Behind Lead Brick Wall.

L.A.Weiss Memorial Hospital, Chicago, Il.
NRC 12-02418-01

Supplement 5

Dept. of Nuclear Medicine
Louis A. Weiss Memorial Hospital

Radiation Survey Record

Name : _____

Date : _____

Locations	Readings	mR/hr
1)Refrigerator:	( )	
2)Pb Lined Storage Module	( )	
3)Dose Caliblator	( )	
4)Protective Barrier	( )	
5)I-131 Uptake Machine	( )	
6)BKG Scan Lab.	( )	
7)Well Counter	( )	
8)Out-Side Decay Room	( )	
9)In-Side Decay Room	( )	
10)Over The Containers	( )	
a.Tc-99m		
b.All except Se-75		
c.Se-75		
11)Xenon Room	( )	

* There are two wells for discarded needles, syringes and vials
a.For Tc-99m
b.For all other isotopes except Se-75
The Se-75 is kept in the container in one of the module drawers.

SIGNATURE: _____

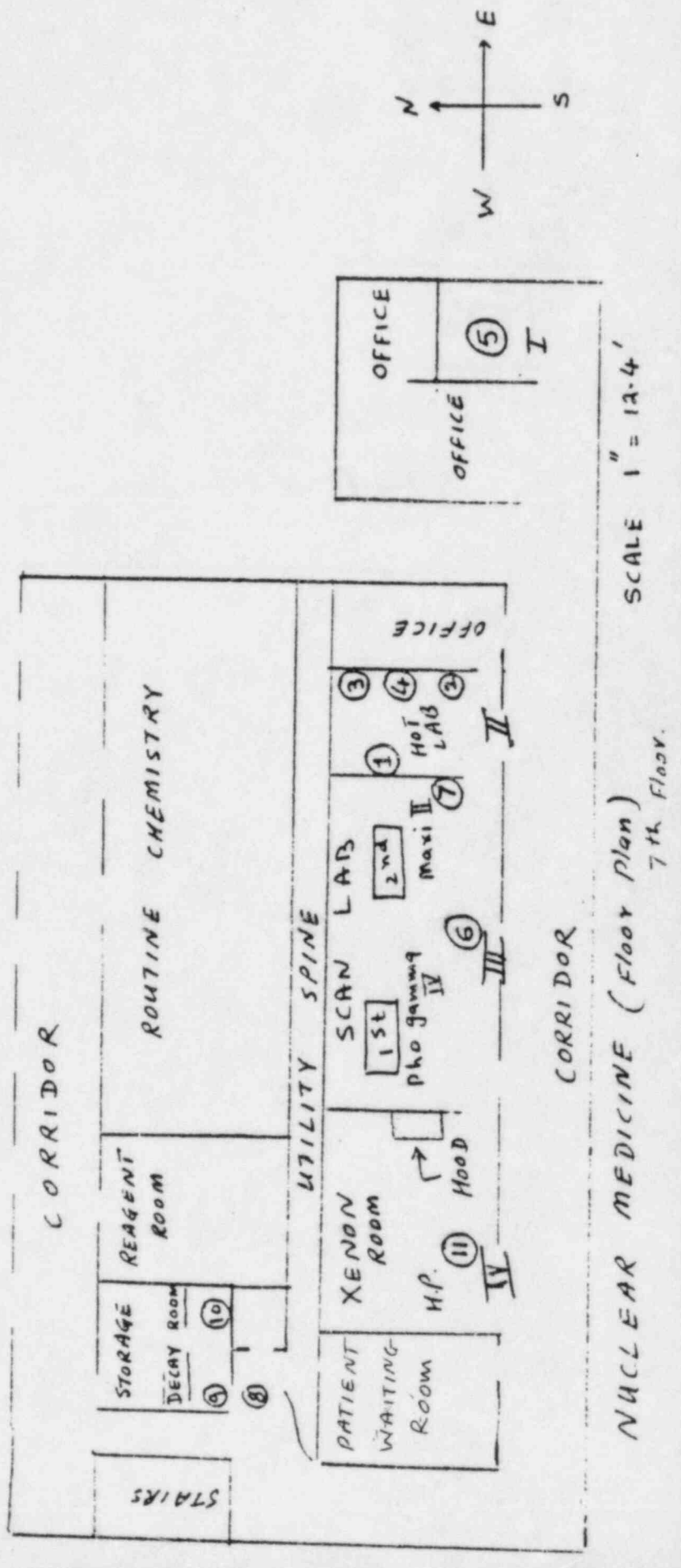
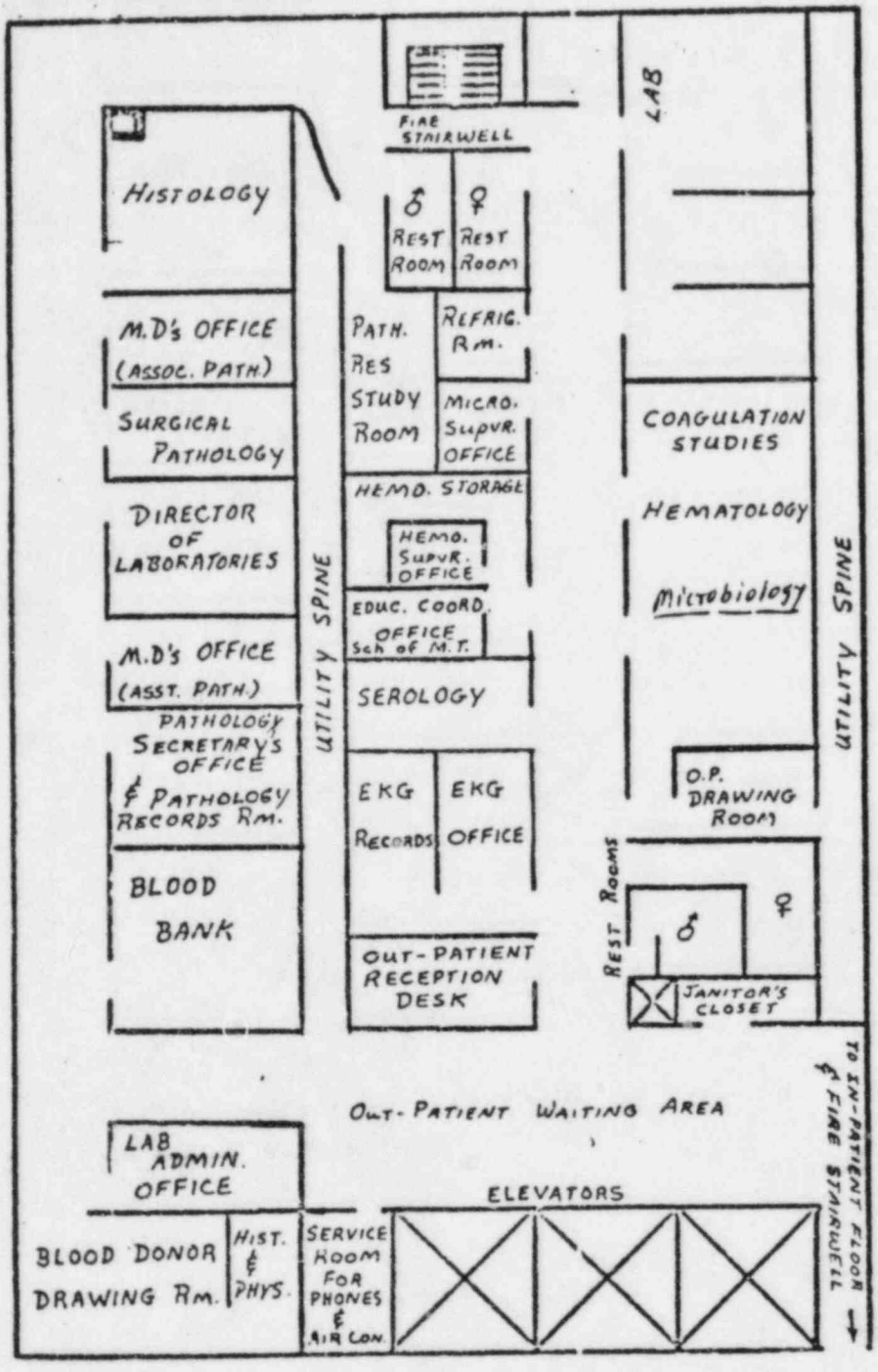


Figure 2

NRC - 12-02418-01

Supplement 5



LABORATORY FLOOR PLAN (8th Floor)

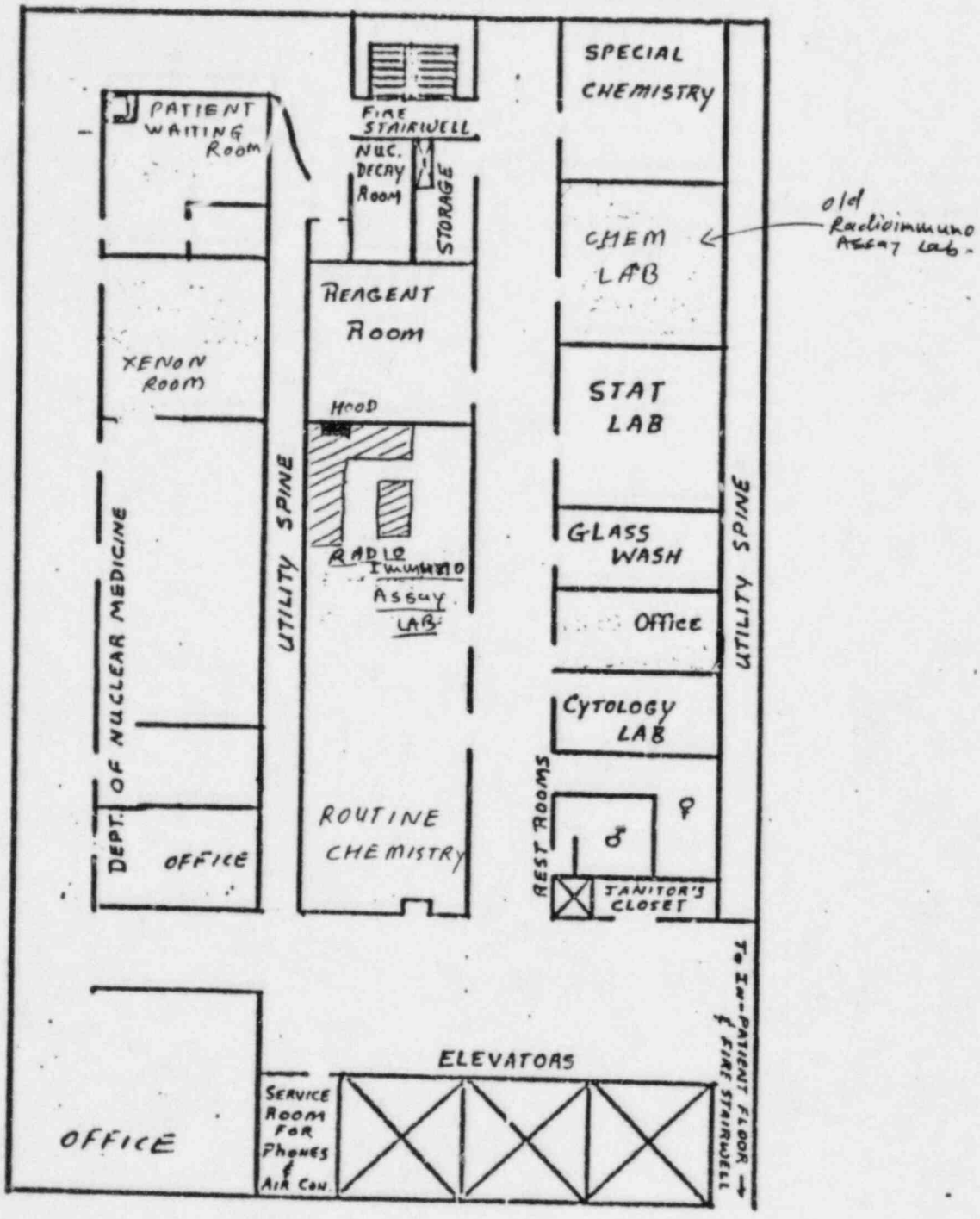
= 5 feet

FIGURE 3 (a)

L.A. Weiss Mem Hosp.

License # 12-02418-01

Supplement 5



LABORATORY FLOOR PLAN (7th Floor)

—— = 5 feet

FIGURE 3 (b)

L.A. Weiss Mem Hosp.

NRC-12-02418-01

CERTIFICATE OF WIPE TEST & SURVEY

(MONTHLY)

EXHIBIT 5(a)

Place : Biochemistry Labs, 7 th Floor, Weiss Memorial Hospital Chicago

NRC 12-02418-01

1. Description of Source(s): # 1 : RIA Room , Tech's Desk (Area 50×50 cm²)(0.025 mR/Hr)
   # 2 : RIA Room, Floor (Area: 100×100) Waste Can (0.03 mR/Hr)
   # 3 : RIA Room, Table # 1 (east)(Area : 100×50)(0.02 mR/Hr)
   # 4 : RIA Room, Table # 2 (north)(Area : 100×50)(0.025 mR/Hr)
   # 5 : RIA Room, RA Sink (0.02 mR/Hr)
   # 6 : RIA Room, Scintillation Counter (Area: 50×50 cm²)(0.025 mR/Hr)

2. Description of ~~Test~~:
   (a) Areas are wiped clean with alcohol swabs.
   (b) The swabs are counted in the Isodata Gamma Scintillation Counter (Channel B).
   (c) Average Backgorund : 0 substracted automatically
   (d) Survey Instrument Used : GSM-5 (NM)

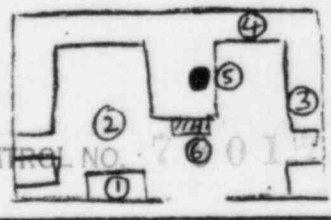
3. Results of Test:

Swab #	1	2	3	4	5	6	
Count Rate of Comparison Standard Above Background: C_s =			1190				cpm
Activity of Comparison Standard on Date of Test: Co-57 A_s =			8×10^{-4}				uCi
Count Rate of Test Sample Above Background: C_t =	9	1	0	3	15	3	cpm
Activity of Test Sample: $C_t A_s / C_s = A_t$ =	0	0	0	0	~0	0	uCi/

Activity of Test Sample Indicates Presence of Removible Contamination: $< 10^{-5}$ μCi/cm²

Within Acceptable Limits ~~In Excess of Acceptable Limits~~

4. Remarks and/or Comments: MONTHLY WIPE TEST
   Amount Radioactivity Used : < 200 μCi
   Radionuclides Used : Co-57, I-125,
   Radioimmuno assay lab changed to another location in Routine chemistry lab.



5. A. G. Kaluskar
   A. G. Kaluskar, Ph.D.
   Radiation Safety Officer

   NOV 1, 1984
   Date

(IIP/R.NGG-7/72)

CERTIFICATE OF WIPE TEST & SURVEY (MONTHLY)

EXHIBIT 5(b)

Place : Biochemistry Lab, 7 th Floor, Weiss Memorial Hospital, Chicago
NRC 12-02418-01

1. Description of Source(s): # 1 : RIA Lab, Refrigerator, Floor (Area 50 x 100 cm²)(0.02 mR/Hr)

2 : RIA Lab, Centriguge (0.02 mR/Hr)

3 : RIA Rm. Table #3 (West) (Area 50 x 100)(0.02 mR/Hr)
4 : RIA Rm Table #4 (East) (Area 50 x 100 cm²)(0.02 mR/Hr)
5 : Corridor (area/50 x 100) # 6 : Chemistry office

2. Description of Test:

(a) Areas are wiped clean with alcohol swabs.
(b) The swabs are counted in the Isodata Gamma Scintillation Counter (Channel 3).
(c) Average Backgorund : 0 subtracted automatically
(d) Survey Instrument Used : GSM-5 (NM)

3. Results of Test:

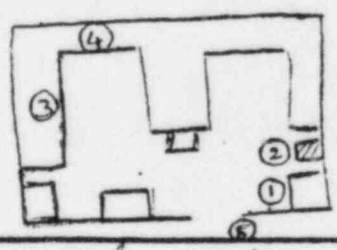
Swab #	1	2	3	4	5	6	
Count Rate of Comparison Standard Above Background: C_s =			1190				cpm
Activity of Comparison Standard on Date of Test: Co-57 A_s =			8×10^{-4}				uCi
Count Rate of Test Sample Above Background: C_t =	11	0	3	6	0	0	cpm
Activity of Test Sample: $C_t A_s / C_s = A_t$ =	0	0	0	0	0	0	uCi/dpm

Activity of Test Sample Indicates Presence of Removible Contamination: $< 10^{-5}$ uCi/cm²

Within Acceptable Limits ~~In Excess of Acceptable Limits~~

4. Remarks and/or Comments:

Amount of Radioactivity used : < 200 uCi
Radionuclides Used.: I 125, Co 57, I 125
Radioimmuno Assay lab moved to part of Routine chemistry Laboratory.



Ft

Nov. 1, 1984
Date

A. G. Kaluskar, Ph.D.
Radiation Safety Officer

(IEP/RNOG-7/72)

L.A.Weiss Memorial Hospital
Chicago, Illinois 60640

NRC 12-02418-01

Supplement 6

December 12, 1984

MEMORANDUM

TO: Ronald Cundiff
Director, Security and Safety

FROM: Arun Kaluskar, Ph.D.
Radiation Saftey Officer

SUBJECT: Receipt of Packages Containing Radioactive Material for Nuclear Medicine.
Please circulate amongst all security personnel.

Any packages containing radioactive material that arrive between 4:30 pm and 7:00 am, or on Saturday or Sunday shall be signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine Department, Radioactive Materials Storage Room. Unlock the door, place the package on floor to the right of the door and relock the door upon leaving.

If the package is wet or appears to be damaged, refuse delivery. In the event that delivery is refused, notify the Radiation Safety Officer or the party ordering the isotopes.

Radiation Safety Office:	Arun Kaluskar, Ph.D.	
	878-8700 ext 2325	work
	363-3087	home
Nuclear Medicine:	J. Singh, M.D.	
	878-8700 ext 1202	work
	852-7667	home

cc: Greg Banaszynski, Vice President

SUPPLEMENT 6 (a)

Item 13 and 14

PROCEDURE FOR RECEIVING AND RETURNING RADIOACTIVE MATERIAL

RECEIVING:

Radioactive material received from an outside supplier will be brought directly to the Radiation Oncology/Nuclear Medicine Departments by the Storeroom/Security/Supplier.

1) Packages received must be placed in the Storage Room behind the safe in Radiation Oncology or in the lead storage drawers in Nuclear Medicine.

2) Shipping label must accompany the package.

   a) Check the amount of activity and number of sources received.

   b) Check the exposure rate recorded on shipping label.

   c) In the event of Radium, a Leak Test certificate must accompany shipment.

   d) Remove shipping label and place in the folder for permanent record of shipment.

3) Using the survey meter take readings on surface of the package. (Read all sides and record the maximum).

4) Using the survey meter take readings at 1 meter. (Read all sides and record the maximum).

5) Enter all data required into the log of Radioactive Materials received and retured.

RETURNING:

Arrangements must be made through the Storeroom for the return of materials shipped by U.P.S. (or other shippers of this order).

1) Place the Radioactive Materials in the original shipping container. All packages must be properly sealed.

2) Using the survey meter take readings on the surface of the package. (Read all sides and record the maximum).

3) Using survey meter take readings at 1 meter. (Read all sides and record the maximum).

4) Record all data required in the log of Radioactive Materials received and returned.

5) Package must remain in the Physics/Storage Room behind the safe until shipper arrives for the pick up.

L. A. Weiss Memorial Hospital
Chicago, Illinois 60640

L. A. Weiss Memorial Hospital
Chicago, Il 60640
IL-00208-01
NRC-12-02418-01

SUPPLEMENT 6(b)

Item 14

PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

D. O. T.

Radioactive survey for the detection of contamination of radioactive materials in shipment.

Office of Hazardous Materials
U. S. Department of Transportation
GUIDE FULLFILLMENT

NUCLEAR MEDICINE DEPARTMENT

DATE	RADIOPHARMACEUTIAL CO. Medi	Mallinc.	Other	RADIONUCLIDE /QUANITY	G-M TUBE USED	MR/HR PRE-OPEN ON PACKAGE	MR/HR PRE-OPEN At 3'	MR/HR PACKING MATERIAL	MR/HR SWAB TEST ON PIGS	TECHNOLOGIST

Medi= Medi-Physics Mallinc.= Mallinckrodt
Disposable gloves should be worn while processing the packages and remote handling devices should be used when possible.
IF MR/HR PRE-OPEN READS 200 MR/HR - DO NOT OPEN PACKAGE.
ANY HIGH READINGS SHOULD BE REPORTED TO THE SUPERVISOR, NUCLEAR MEDICINE.
APPROPRIATE ACTION WILL BE TAKEN!

SUPPLEMENT 7

Therapeutic Use of Sealed Sources

a) The Cs-137 Sealed Sources are stored in the Horwitz safe, 3M Nuclear Products Model 6624. The safe is stored behind lead brick wall as shown in figure 1.

b) The sealed sources are handled using 12" handling forceps. The loading is done behind the Radium Chemical Model #799 protective wall. All the care is taken to see that the time taken to load is as short as possible.

c) For Nursing Instructions, please refer to Exhibits 7(a) and 7(b).

d) To determine the radiation exposure to the extremities of personnel handling sources we use finger (TLD) monitors.

e) For transporting the sealed sources from storage site to the place of use we use Radium Chemical Model #50100 Ernst carrier and Heyman carrier with cart.

f) The inventory of the sealed Cs-137 sources is taken at least quarterly and is logged in the log book. The attached sheets (Exhibits 7(c) and (7d) describe the method for maintaining source accountability, surveys to be performed during the course of treatment and the conclusion of treatment.

g) The radioactive seeds (e.g.,I-125,Ir-192,Rn-222 etc.) will be held for decay in the lead lined storage until radiation levels have reached background level. The procedures in our letters of 2/29/79 and 7/9/80 for Solid Radiactive Waste are strictly followed.

h) The sealed Cs-137 sources are never autoclaved and are leak-tested once every three (3) years.

L.A.Weiss Memorial Hospital
Chicago, Illinois 60640

LOUIS A. WEISS MEMORIAL HOSPITAL
RADIATION ONCOLOGY DEPARTMENT

EXHIBIT 7(a)

NURSING INSTRUCTIONS FOR PATIENTS RECEIVING TEMPORARY IMPLANTS OF RADIOACTIVE SOURCES

PATIENT: _____ RECEIVED: _____ MG. RA. Eq. of _____ CESIUM 137 / Ra 226
_____ IRIDIUM 192
_____ IODINE 125

ROOM NUMBER: _____ PHYSICIAN _____

DATE/TIME OF ADMISSION: _____ DATE/TIME OF SOURCE REMOVAL: _____

EXPOSURE RATES IN MR/HR

At bedside ( ), 3 feet from bed ( ), 10 feet from bed ( ), Entrance to room ( )

1) Patient Room: Patients are treated in private rooms with the bed at least 3 feet from the walls.

a) Patients with intravaginal implants are on strict bed rest. Those patients with implants in other parts of the body are sometimes permitted to sit and get out of bed but they must, however, be restricted to their room.
b) Radioactive material warning sign must be posted on the door. Do not remove or cover sign at any time.
c) The radiation therapy cart, the lead container for the sources, and a long handling forceps must be left in the patients room at all times.
d) The protective shield will be put in place at the patients bedside by the Radiation Therapy personnel. Always stand behind shield while giving patient care. Instructions for use are posted on the shield.

2) Badges: Each nurse who cares for the patient with the implant must wear a film badge. One badge is assigned per nurse. Wear the badge for the entire shift. Do not leave the film badge in the patients room. The same film badge must be worn as often as necessary by the person to whom it is assigned. Return the badge at the end of the shift to the clip board provided by Radiation Therapy. All badges must be returned to Radiation Therapy when the implant is completed.

3) Nursing Care: One nurse per shift should be assigned to the primary care of the patient. All nurses and attendants who care for the patient must be over 18 years of age and must not be pregnant. Consistent with good nursing care, only the shortest possible time should be spent close to the patient.

a) Unless otherwise notified, all excreta may be disposed of in the normal way.
b) Linens do not need to be changed while the implant is in place. If for some reason it becomes necessary to change the linens notify Radiation Therapy before proceeding.
c) The patient may eat and bathe unassisted.
d) Specific orders will be written for each patient but good planning for carrying out care will give the patient an unhurried feeling.

4) Visitors: Visitors must remain at least 3 feet from the patient. No visitor should remain in the room for more than _____ hours per day. No visitors are to be less than 18 years old or pregnant.

5) Precautions: No needles, applicators or capsules are to be touched or removed by anyone other than a responsible person from Radiation Therapy.

a) If the instruments become displaced or appear to have shifted call the Radiation Therapy Department for the Radiotherapist.
b) If a source capsule, needle, or applicator is accidentally removed or works itself out, do not touch it with hands. Immediately use the long forceps to put the capsule in the shielded container or in the far corner of the room. Call the Radiation Therapy Department for the Radiation Safety Officer or the Radiotherapist.

6) Hospital Discharge: No patient is to be released from the hospital until all radioactive material has been removed. A survey by the Radiation Safety Officer will be conducted after the radioactive material is removed from the patient and the room.

7) Emergency: In the event of emergency surgery, the onset of acute illness, or any emergency requiring persons to attend the patient for long periods, immediately notify the Radiation Safety Officer or the Radiotherapist. If death occurs, the body is not to be removed from the room until the radioactive material has been removed. Please contact the persons listed below in any emergency.

SPECIAL INSTRUCTIONS: No Bed baths; Don't change dressing, do not discard any dressings unless checked by R.S.O.; For patients with oral implants special orders be written.

If there are any questions related to these instructions please contact the Radiation Therapy Department between 8:00 A.M. and 4:30 P.M., Monday through Friday. Weekends and Holidays, contact the following people:

RADIOTHERAPIST
Yashbir Mehta, M.D.
Page # 1176
Extension 2325
Home: (312)530-0321

RADIATION SAFETY OFFICER
Arun Kaluskar, Ph.D
Page # 1517
Extension 2325
Home: (312)363-3087

NRC 12-02418-01

RT-11 (0600)

GUIDELINES EXHIBIT 7(b)

RADIATION SAFETY PRECAUTIONS FOR THERAPEUTIC USE OF I-125 SEEDS

GENERAL

1. Personnel who prepare, insert or retrieve I-125 seeds must wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.
2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.
3. In transporting seeds from storage - preparation areas to the place of use, adequate shielding must be employed to insure compliance with 10 CFR 20.105(b).

INSTRUCTIONS TO NURSES (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.
2. Handle dislodges seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.
3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer.
4. All bed linen must be checked with a radiation survey meter before being removed from the patient's room to insure that no dislodged sources are inadvertently removed.
5. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered.
6. Emergency Procedures

   a) If a seed becomes loose or dislodged from the patient, or

   b) If the patient dies, or

   c) If the patient requires emergency surgery, immediately call

	Y. Mehta, M.D.	A. Kaluskar, Ph.D.
Telephone No. (Days)	878-8700, X-2325	878-8700, X-2325
(Nights)	530-0321	363-3087

7. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

L.A.Weiss Memorial Hospital
Chicago, Illinois 60640
NRC 12-02418-01

July, '81

EXHIBIT 7(c)

Procedure for Room Survey

1. Using the survey meter on least sensitive scale x 100 (multiply readings x 100).

2. Record Readings at:
   a) Foot of patient
   b) 1 meter laterally from patient
   c) 2 meters laterally from patient
   d) In the hall behind the closed door.

3. Place Radioactive Materials Warning sign on patient's door

4. Place yellow caution sticker on front of patient's hospital chart. All survey readings must be recorded on sticker.

5. Record all readings in the log of use of Radioactive Isotopes.

Survey the room after the removal of the radioactive materials (or removal of the patient):

1. Using the survey meter on the most sensitive scale x 1.

2. Record reading in the log of use of Radioactive Isotopes.

L.A. Weiss Memorial Hospital
Chicago, Illinois 60640
NRC 12-02418-01

EXHIBIT 7(d)

LOUIS A. WEISS MEMORIAL HOSPITAL

DEPARTMENT OF RADIATION ONCOLOGY

RECORD OF USE OF RADIOACTIVE ISOTOPES

PAGE NO._____

DATE:_____ PATIENT:_____

TIME INSERTED:_____ ROOM:_____

ISOTOPE:_____ READINGS (MR/HR)

NUMBER:_____ WITHOUT SHIELD WITH SHIELD

AMOUNT:(MgRaEq/MCi)_____ AT FOOT:_____

NURSES
INSTRUCTIONS:_____ AT 1 METER:_____

AT 2 METER:_____

_____ AT HALLWAY:_____

_____ SIGNATURE:_____

DATE:_____ SURVEYS AFTER SOURCE REMOVAL

TIME REMOVED:_____ PATIENT ROOM:_____

ISOTOPE RETURNED:_____ STORAGE AREA:_____

NUMBER:_____

AMOUNT:(MgRaEq)_____

REMARKS:_____

SIGNATURE:_____

DIAGRAM OF SOURCE DISTRIBUTION

SUPPLEMENT 8

(1)

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES:

A. Quantities to be used

1. We estimate a patient load of 15 patients per week, or 780 per year with average use of 10 mCi of Xe-133 per patient.

2. Possession limit - presently 200 mCi Xe-133 increased to 1000 mCi Xe-133 with addition of model No 150 Radx-KOW II.

B. Use and Storage Areas

Please see Fig. 2.

1. Storage and use areas: The unopened ampules will be stored in hot lab, which is equipped with lead lined storage module. The 1000 mCi Xe-133 ampule will be stored in a Model No. 150 Radx Xenon-KOW II which is completely lined with 3/16 inch lead. The Radx Xenon KOW II will be stored in the Xenon (Imaging) Room. The dimensions of Xenon Room are 20.5 ft. x 14 ft x 8 ft.

2. Ventillation

The air flow rate in Xenon Room is 750 cfm through the ceiling vent, the air is not recirculated. The Xenon Room is also equipped with a hood the exhaust port of which is directly exposed to the atmosphere-12 ft.above the building roof. The air flow rate through the hood is 1200 cfm. The whole area is under negative pressure as measured by an anometer.

The exhaust port of the Xenon trap will be connected to the hood.

C. Procedures for routine use

Withdrawls of Xe-133 will be done with a lead shielded glass syringe. All personnel handling Xe-133 doses will wear finger badges in addition to their whole body badges in order to assess exposure to extremities.
Xe-133 will be administered to patients via a Radx Model 101 Ventilation in accordance with Radx instructions for use. Face masks or mouthpieces with nose clamps will be used to prevent loss of Xe-133 during patient study.

Exhaled Xe-133 will be collected in a Radx Model 120 Xenon trap. This model has a built-in saturation detector which gives an audio/visual signal when Xe-133 in the trap exhaust port reaches 2×10^{-2} μCi/ml.
Attached is a brochure of the whole Radx System (exibit 8)

D. Emergency Procedure

In case of accidental release of Xe-133, the following procedure will be followed:

The Xenon room will be evacuated. The Xenon trap and the exhaust system will be turned on, and the room closed. The room will not be reopened until a minimum of 10 complete air changes have taken place. The current exhaust system needs less than 5 minutes for one complete change of air.

The room willnot be opened for use until the radiation level in the room as determined by the survey meter shows less than 0.1 mR/hr.

E. Air Concentration of Xe-133 in Restricted Area

Assumptions:
a. 15 patients per week
b. 10 mCi of Xe-133 per patient
c. Loss rate of 20% (maximum) due to all sources, i.e. f=0.2
d. The air flow rate is 1200 cfm (This is due to the exhaust through the hood only. In reality there will also be a loss due to ventillation system which is not recirculated.)
e. Maximum activity used per week : A.

$$A = 10\ \frac{mCi}{patient} \cdot 15\ \frac{patients}{Week} \times 1\times10^{3}\ \frac{\mu Ci}{mCi}$$

$$\therefore A = 1.5\times10^{5}\ \frac{\mu Ci}{wk}$$

$$A \cdot f = 3\times10^{4}\ \mu Ci/wk$$

$$V = 1200\ cfm = 1200 \times 6.8\times10^{7}\ \frac{ml}{40\,Hr.\,wk}$$

$$V = 0.82\times10^{11}\ \frac{ml}{40\,Hr.\,wk}$$

$$\frac{A\cdot f}{V} = \frac{3\times10^{4}\ \mu Ci/ml}{0.82\times10^{11}\ ml/40\ Hr\ wk} = 3.68\times10^{-7}\ \frac{\mu Ci}{ml}$$

This concentration is well below the MPC of 1×10^{-5} μCi-ml for a restricted area as set forth in 20.103 of CFR part 20.

F. Concentration in Unrestricted area

The Xe-133 lost in the Xenon room and from the Xenon trap will be exhausted into the atmosphere 12 feet above the roof line of the hospital. There is not any unrestricted area within a radius of at least 200 feet from the exhaust port. However, calculations are made by treating this as an unrestricted area.

a. The Zenon trap activates a warning system when the concentration in the exhaust port exceeds 2×10^{-2} µCi/ml. It is assumed for this calculation that the level is at this for the washout period of each patient.

Trap pumps at 5 liter/min. average washout time = 10 minutes. Xenon loss per patient through trap $=5 \times 10^{3}$ ml/min x 10 min x 2×10^{-2} µCi/ml = 1×10^{3} µCi/pt.

It should be mentioned that this is a maximum figure and that the dynamics of Xe-133 adsorption on charcoal would dictate that once Xe-133 begins to pass through the system, concentration grows geometrically which would activate the alarm and the charcoal cartridge would be replaced. (The average life of the charcoal trap is approximately one year.) No. of patients per week = 15 Xe-133 lost per week = 15 x 10^{3} µCi/wk.

b. Xe-133 exhausted to the atmosphere 15×10^{3} µCi/wk (from trap) $+3 \times 10^{4}$ µCi/ml (loss in room, please refer E(e)).

$A = 4.5 \times 10^{4}$ µCi/wk

$A = 4.5 \times 10^{4} \frac{\mu Ci}{wk} \times \frac{52\ wk}{yr.}$

Volume, $V = 1200$ cfm $= 1200 \times 1.48 \times 10^{10}$ ml/yr $= 1.78 \times 10^{13} \frac{ml}{yr}$

$$\therefore \frac{A}{V} = 1.32 \times 10^{-7} \frac{\mu Ci}{ml}$$

This is wellbelow the MPC of 3×10^{-7} and since the calculations represent worse conditions, the safety margin appears adequate.

G. Adsorption onto Charcoal Traps

The Xenon trap from Radx has a GM detector system monitoring the exhaust port of the trap. It is designed in such a fashion that when the unit is first turned on the alarm activates for a few seconds to indicate the system is functional. The alarm is set to activate when the concentration in the exhaust port exceeds 2×10^{2} µCi/ml. The exhaust will empty into Xenon room and has been taken into account in the 20% fractional loss of Xe-133.

The proper working of the GM detector system will be checked using a standard Cs-137 source.

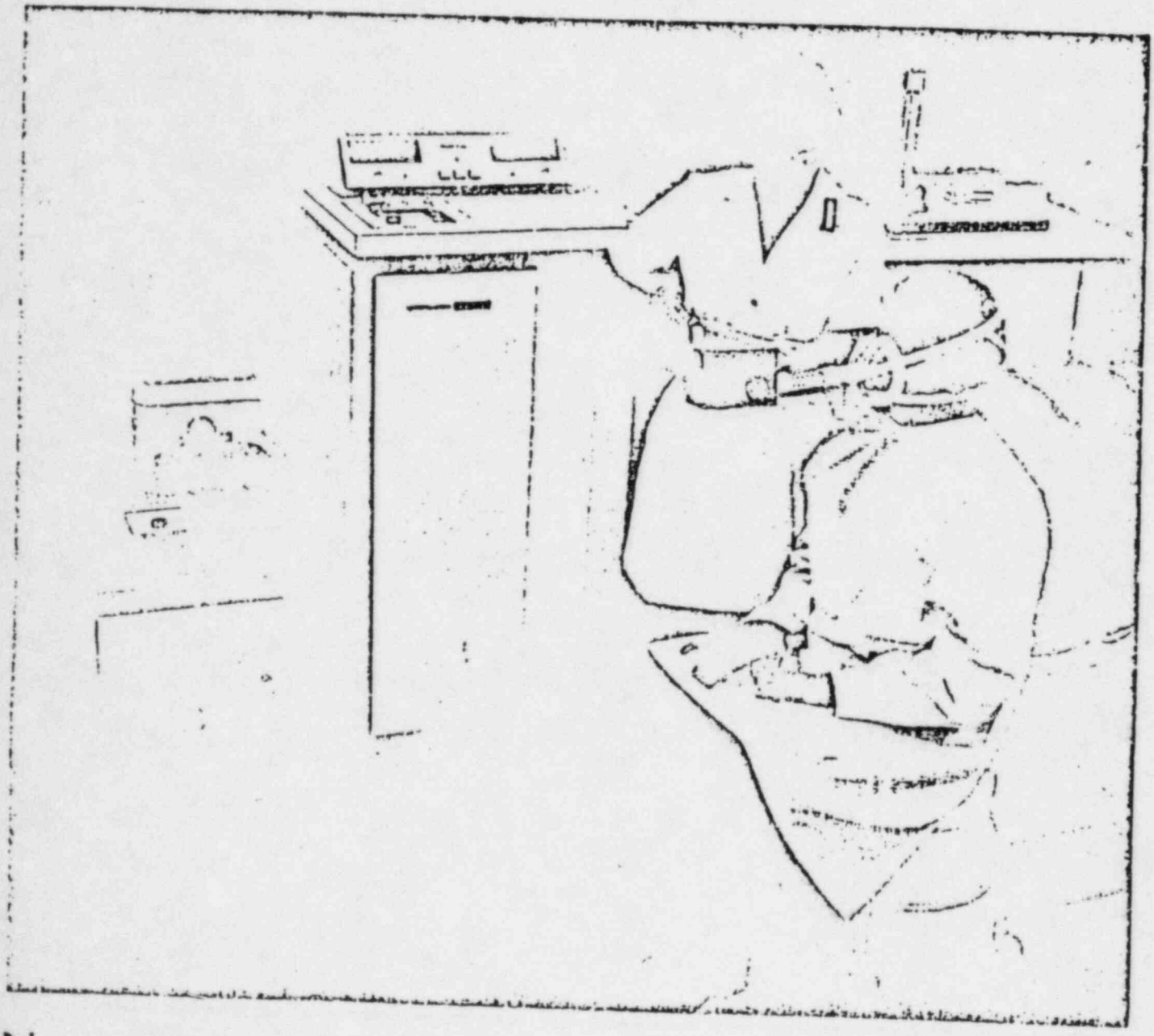
Saturated filters will be plugged and placed in storage in the decay room behind a minimum of ¼ inch lead shielding for a period of not less than 15 half lives. Since the filter is plugged and completely sealed, it is not anticipated that it will contribute to the Xe-133 air concentration.

L.A. Weiss Memorial Hospital
Chicago, Illinois
NRC 12-02418-01

EXHIBIT 8

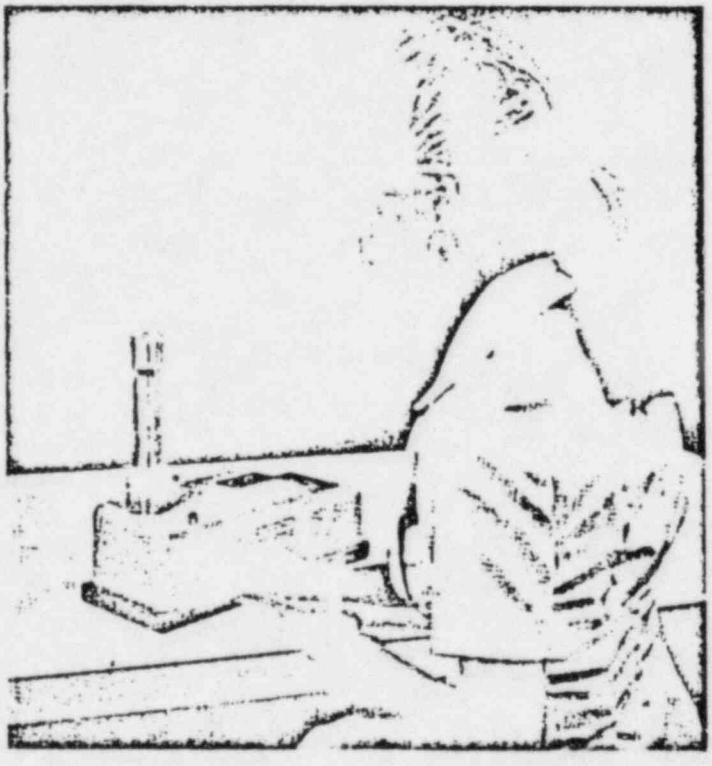
From Start to Finish...

a ^{133}Xe Gas Control System from RADX



Now you can dispense, administer and dispose of ^{133}Xe safely and economically under controlled conditions with a complete system from Radx.

Economy, Safety, Efficacy, Simplicity.. the criteria for the development of the Radx ^{133}Xe gas handling system.



Xenon Kow II safely crushes, dilutes and dispenses, using one curie "crusher" ampules.

Economy

How can a system which costs almost $7,000 be economical? Radx has the answers:

First: Design of the Ventil-Con lets you reuse the ^{133}Xe gas stored within the system. An inline autoclavable bacteriological filter facilitates reuse. The only ^{133}Xe lost is that in the patient's lung at the time washout is initiated. This normally represents only about 10% of the total gas in the system. Other systems, particularly those using "economical" disposable bags and "economical" homemade units, require complete dumping of ^{133}Xe between patients.

Second: If you do five or more studies per week and if you use the new Xenon-Kow II, you can save enough in a year to pay for a Ventil-Con, Xenon Trap and the Xenon-Kow II-and have enough left over to give yourself a raise! ^{133}Xe can now be purchased in one curie "crusher" ampules for less than $200. The Xenon-Kow II allows you to crush, dilute and dispense safely from these ampules. With the inherent ^{133}Xe conservation of the Ventil-Con, you should be able to get 20-25 days worth of ^{133}Xe from a one curie ampule.

Third: When you compare the cost of the Radx Xenon Trap to the cost of running a vent system above the roofline of the hospital, the choice is obvious.

IF YOU DO FIVE OR MORE STUDIES PER WEEK THE VENTIL-CON WILL SAVE YOU ENOUGH MONEY IN ONE YEAR OVER HOMEMADE AND DISPOSABLE BAG SYSTEMS TO PAY FOR ITSELF.

Safety

Xenon-Kow II—The Xenon-Kow II is completely shielded with 3/16" lead. All moving parts are precision machined. Both the crusher assembly piston and the storage vessel piston use double "O" rings for an effective seal and extra assurance against system failure if one "O" ring is damaged.

Ventil-Con—Some of the many built-in safety features include:

- 1/16" shielding on spirometer;
- Flame isolated circulation pump motor;
- ^{133}Xe concentration monitoring system;
- 3 modes of O_2 replenishment: automatic, manual and emergency assist;
- Large volume CO_2 trap;
- Inline, autoclavable, bacteriological filter;
- The Radx Ventil-Con uses a dry spirometer system (Some other units use a water spirometer which can serve as a bed for bacterial growth; and allows water-soluble Xenon to escape at the water/air interface).

Xenon Trap—The Xenon Trap activated charcoal cartridge pack is completely shielded by 3/16" lead. The unit uses a flame isolated positive displacement pump which eliminates sparks completely from the potentially O_2 enriched atmosphere. The unit employs one of the largest activated charcoal pathways available which increases absorption and prevents premature leaks. The Xenon Trap Model 120 also is equipped with a ^{133}Xe saturation detector warning system. When radioactivity is detected in the exhaust port an audio/visual alarm indicates the need for a cartridge change.

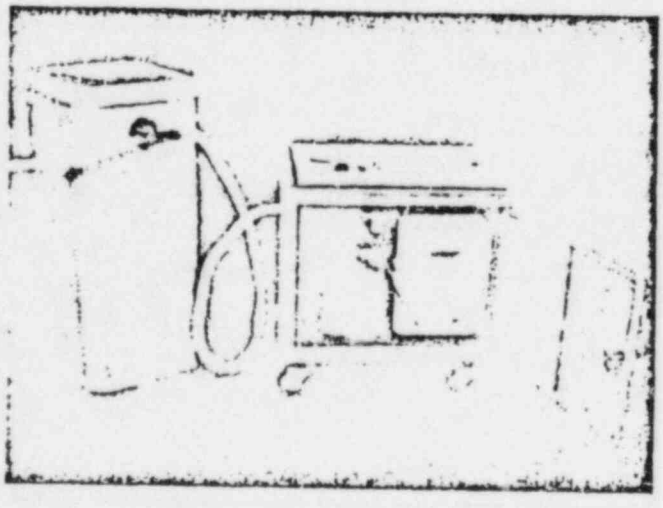
Efficacy

The Ventil-Con allows administration of the ^{133}Xe gas in two ways; as a homogeneous mixture or as a bolus, utilizing an optional mouthpiece. The three phases of lung-ventilation—washin, equilibrium and washout—can readily be performed. With the Radx automatic oxygen replenishment system the equilibrium portion may be run for as long as desired. Unlike units which require patients to sit up, the Ventil-Con allows studies to be done on patients who are bedridden.

It has become increasingly apparent that multiple view lung ventilation images are as necessary as multiple view perfusion studies. The Radx swivel adapter permits rotating the patient around a central vertical axis without disconnection from the Ventil-Con, which makes multiple view ventilation studies a reality.

The Ventil-Con also allows maximum ease of breathing. Measured resistance to normal breathing is less than 0.1 inch of water, barely noticeable even to the emphysema patient. Radx even designed the Expandable Interface because Xenon traps operate best at 5 liters per minute and people breathe best at 15 liters per minute. The interface compensates for the difference.

Optional expandable interface handles excess volume between trap operation of 5 liters per minute and normal breathing rate of 15 liters per minute.



Xenon Trap, with door open, shows lead-shielded charcoal pack (left) and flame isolated displacement pump (right).

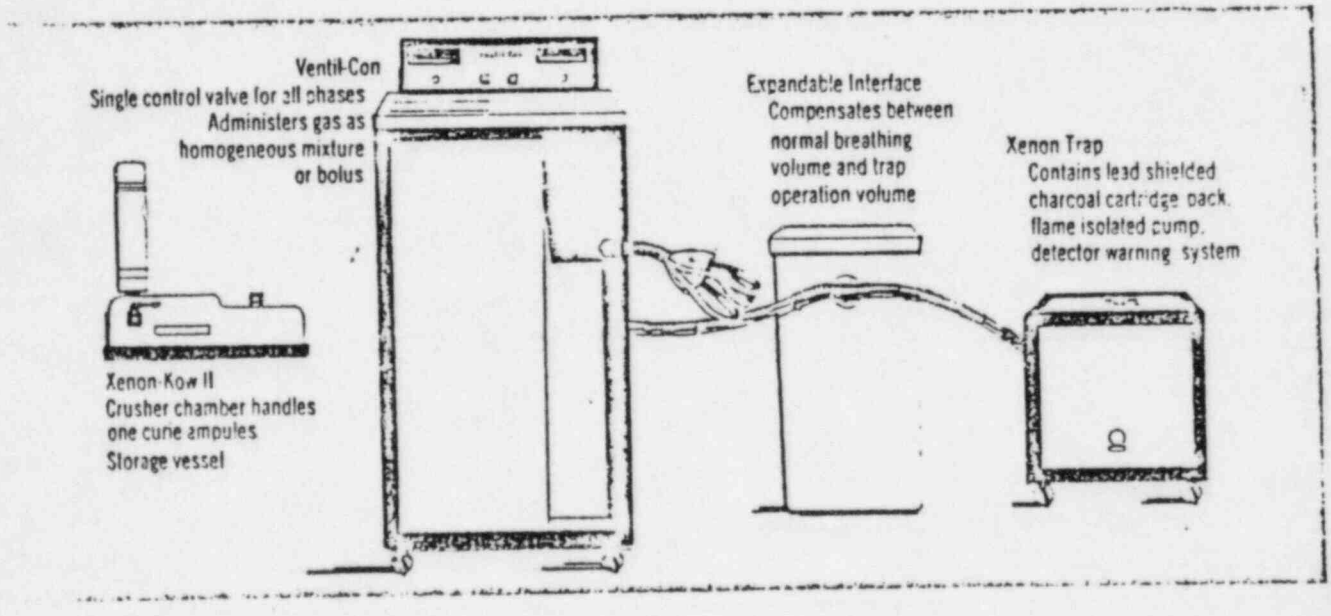
Simplicity

The entire system was designed for uncomplicated operation. The Ventil-Con has one control (a two-position valve) to operate the washin, equilibrium, and washout phases.

The Ventil-Con does not interfere with the patient's control of his own breathing, nor does it rely on complicated automatic sequential functioning. The Ventil-Con allows the technologist to stand next to the patient, control the administration of the ^{133}Xe and operate the gamma camera with the Radx console mounted remote gamma camera start, stop, reset push-buttons.

Economy. Safety. Efficacy. Simplicity. The entire system is well planned and well designed and all three components work independently or together Ask your Radx representative to supply the complete system or interface any one component to your existing system. Any way you elect to go it is guaranteed by Radx.

Schematic view of Ventil-Con System



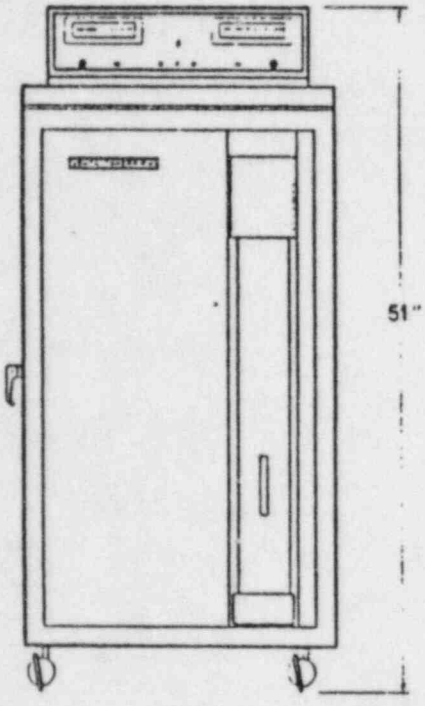
RADX

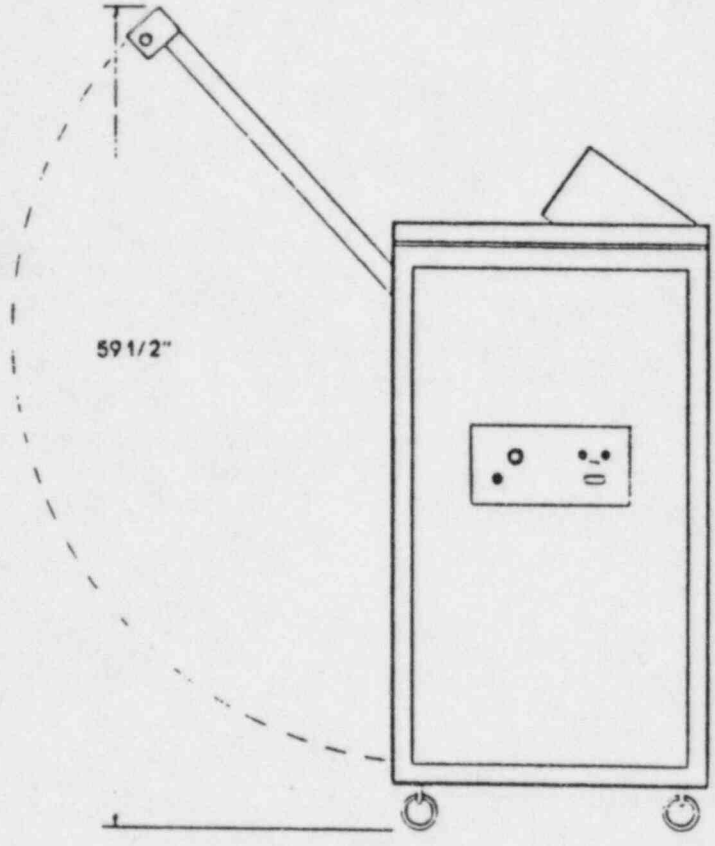
P.O. Box 19164, Houston, Texas 77024 • (713) 468-9628

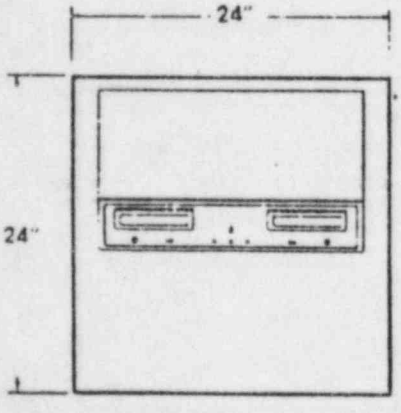
RADX

Ventil-Con
Controlled
Gas Delivery System

(5)







DESCRIPTION

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

Features/Specifications

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

Large Volume Spirometer—The Ventil-Con has a 10 liter capacity horizontal rolling spirometer. All airway plumbing is fabricated of non corrugated, low resistance, smooth surface reinforced PVC tubing. The expansion contraction factor of the ball bearing mounted spirometer diaphragm is negligible, offering a resistance of 0.05 inches of water to normal breathing. The spirometer mechanism is completely shielded with ½ inch lead (½ inch option available for ^{133}Xe) for personnel safety. The spirometer volume is displayed on the control panel on a large scale analog meter and on one channel of a dual strip chart recorder on model 102.

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

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

Features/Specifications Cont.

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

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

Delivery Arm—The delivery arm of the Ventil-Con recesses into the cabinet during transportation or when not in use. The arm is 28 inches long, continuously adjustable up to 60 inches in height and is shielded with $\frac{1}{16}$" lead. An additional $\frac{1}{8}$" may be added on two sides as an option to provide adequate shielding for ^{127}Xe.

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

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

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

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

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

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

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

Dimensions—Height—51 inches
Width—24 inches
Depth—24 inches
Weight—Approximately 350 lbs.

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

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

EXHIBIT 8(a)

DATE : 12/7/84

DEPARTMENT OF NUCLEAR MEDICINE
LOUIS A. WEISS MEMORIAL HOSPITAL
CHICAGO, ILLINOIS

XENON - 133 SURVEY

(1) VENTILLATION :
SPEED OF AIR AT THE VENTILLATOR : 220 FPM (Average)
(DETERMINED BY TYLOR VELOMETER, SL # M929)
AREA OF THEEXHAUST VENTILLATOR : 6 SQ.FT.

AIR FLOW RATE : 1320 CFM

(2) AVERAGE NUMBER OF STUDIES PER WEEK : 5
ACTIVITY ADMINISTERED PER STUDY : 10 MCI

ASSUMED LOSS RATE : 20 %

(3) CONCENTRATION OF XENON-133 IN AIR AVERAGED

OVER A WEEK : 5.6×10^{-7} μCI/ML

(4) THIS CONCENTRATION IS LESS/MORE THAT THE ALLOWED LIMIT
OF 1.0×10^{-5} μCI/ML

(5) THE PRESSURE GRADIENTS AT BOTH THE SOUTH AND EAST DOORS
ARE NEGATIVE (THE AIR FLOW IS INTO THE ROOM) : -ve

NOTES : THE SPECIFICATINS STATED IN LICENSE APPLICATION :
(A) NO. STUDIES PER WK : 15
(B) ACTIVITY ADMINISTERED PER STUDY : 10 MCI
(C) AIR FLOW RATE AT VENTILLATOR : 1200 CFM

Follow up of Nov 7, 1984 findings of Low CFM. (1120 CFM)
Fan belt change + Clean up done by P.O.E.M. on 12/5/84
see Exhibit 8(a')

ARUN G. KALUSKAR, PH.D.
RADIATION SAFETY OFFICER

12=02418-01

EXHIBIT 8(a')

DATE : Nov. 7, 1984

DEPARTMENT OF NUCLEAR MEDICINE
LOUIS A. WEISS MEMORIAL HOSPITAL
CHICAGO, ILLINOIS

XENON - 133 SURVEY

(1) VENTILLATION :
SPEED OF AIR AT THE VENTILLATOR : 170 FPM (Average)
(DETERMINED BY TYLOR VELOMETER, SL # M929)
AREA OF THEEXHAUST VENTILLATOR : ~~1020~~ 6 SQ.FT.

AIR FLOW RATE : 1020 CFM

(2) AVERAGE NUMBER OF STUDIES PER WEEK : 5
ACTIVITY ADMINISTERED PER STUDY : 10 MCI

ASSUMED LOSS RATE : 20 %

(3) CONCENTRATION OF XENON-133 IN AIR AVERAGED
OVER A WEEK : 7.2×10^{-7} µCI/ML

(4) THIS CONCENTRATION IS LESS/MORE THAT THE ALLOWED LIMIT
OF 1.0×10^{-5} µCI/ML

(5) THE PRESSURE GRADIENTS AT BOTH THE SOUTH AND EAST DOORS ~~are~~ ve
ARE NEGATIVE (THE AIR FLOW IS INTO THE ROOM) : ~~-----~~

NOTES : THE SPECIFICATINS STATED IN LICENSE APPLICATION :
(A) NO. STUDIES PER WK : 15
(B) ACTIVITY ADMINISTERED PER STUDY : 10 MCI
(C) AIR FLOW RATE AT VENTILLATOR : ~~2000~~ 1200 CFM

ARUN G. KALUSKAR, PH.D.
RADIATION SAFETY OFFICER

Note : Talked to Stan Jaskula P.O.E.M. will check the Vent and will take necessary ~~action~~ corrective action.

L.A.Weiss Memorial Hospital
Chicago, Illinois 60640
NRC 12-02418-01

EXHIBIT 8(b)

EMERGENCY PROCEDURE FOR XENON-133 RELEASE

In case of accidental release of xe-133 the following procedure be followed :

(1) Evacuate the Xenon room
(2) Turn on the Xenon trap and Exhaust system (if not already on) and close the room
(3) Call the Radiation Safety Officer (X-2325; Page # 1517)
(4) Do not open the room for 50 minutes (i.e. untill minimum of 10 complete air changes have taken place. The approximate time taken for 1 complete change of air in the room with present exhaust system is 5 minutes)
(5) After 50 minutes determine the radiation level in the room with a survey meter
(6) The room should not be opened for use untill the radiation level is less than 0.15 mR/Hr.

NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
Louis A. Weiss Memorial Hospital 4646 North Marine Drive Chicago, IL 60640	U.S. NUCLEAR REGULATORY COMMISSION REGION III 799 ROOSEVELT ROAD GLEN ELLYN, IL 60137

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030-01430 030-00156	12-02418-01 12-02418-02	December 5, 1984

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☒ 1. Within the scope of this inspection, no violations were observed.

☒ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☐ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. **THIS IS A NOTICE OF VIOLATION** which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42.

☐ B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

☐ D. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____.

☐ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

☐ H. _____

☐ I. _____

☐ J. _____

☐ K. _____

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

CONTROL NO. 78017

SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
		Roy Lanza	12/5/84

8412110259
1P

ORIGINAL TO LICENSEE