MOBILE MEDICAL SERVICES
Specializing in Diagnostic Ultrasound and Nuclear Medicine Procedures
METRO PLAZA OFFICES
2705 B INDUSTRIAL DRIVE
JEFFERSON CITY, MISSOURI 65101
314 - 893-2828

September 14, 1983

Ms. Pat Vacherlon
Material Licensing Section
Division of Fuel and Material Safety
U. S. NRC, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Ms. Vacherlon:

Please amend our license No. 24-18094-01, issued to Mobile Medical Services, to include the following items:

Item 1. We wish to perform Group I, II and III nuclear procedures and use 133 Xenon for ventillation lung scans in the Carroll County Memorial Hospital, 1502 North Jefferson Street, Carrollton, Missouri,64633. (See attached letter of approval from the hospital and schematic of the nuclear area.) We are currently licensed to use Xenon in this area with a mobile system. This hospital would be serviced by this same system described in letter amendment request dated March 2, 1982. The on-site nuclear physicians will be Robert McNaughton, M.D. and L. D. Furlong, M.D. These gentlemen are currently listed as users on our license for the Lexington Hospital, letter amendment request dated March 2, 1982. They are itinerate Radiologists for the Carroll County Hospital. The Carroll County Memorial Hospital currently has an institutional license with an outside physician's group listed as users. This license is No. 24-18314-01. We wish to close out this present license, and add the hospital to our license. (See attached explanation of the circumstances surrounding this transfer of license and close-out procedure.)

Item 2. We wish to perform Group I. II and III nuclear procedures in the Levering Hospital, 1734 Market Street, Hannibal, Missouri 63401.(See attached letter of approval and schematic of the nuclear areas.) The on-site nuclear physicians will be Lysle Bach, M.D. and J. Russell Comer,M.D. These gentlemen are currently listed as users on the Levering Hospital's current institutional license No. 24-15289-01. We wish to close out this present license and add this hospital to our license. The close out procedure will be performed on a date explained on the attached explanation of transfer procedure. Unlike the hospital request under Item 1.

this hospital is currently operating their own nuclear program with the Radiologists listed above.

Item 3. Please add to our license Fred L. King, D.O. as a licensed user for the Samaritan Memorial Hospital, Macon, Missouri. This hospital is already on our license as a satelite facility. Dr. King is now a staff Radiologist for this hospital. He is presently licensed as a nuclear medicine physician for the Laughlin Hospital in Kirksville, Missouri under license No. 24-05245-01.

All radiation safety procedures and policies stated on the original application dated 24 March 1978 will be followed in these added Hospitals.

Please find enclosed an amendment fee of $40.00.

Respectfully Submitted,

William H. Voss, D.O.
Radiation Safety Officer

Del Roberts, C.N.M.T.
President
Mobile Medical Services

DR:kr
enclosure

Carroll County Memorial Hospital

PHONE 542-1695 / 1502 NORTH JEFFERSON / CARROLLTON, MISSOURI 64633

JACK L. TINDLE
Administrator

August 29, 1983

Mr. Del Roberts
Mobile Medical Services
Route 3
Box 80
Karen Drive
Holts Summit, MO 65043

Dear Mr. Roberts,

The administration of Carroll County Memorial Hospital is granting approval for use of by-product material under the supervision of Robert A. MacNaughton, M.D. and Lawrence D. Furlong, M.D.

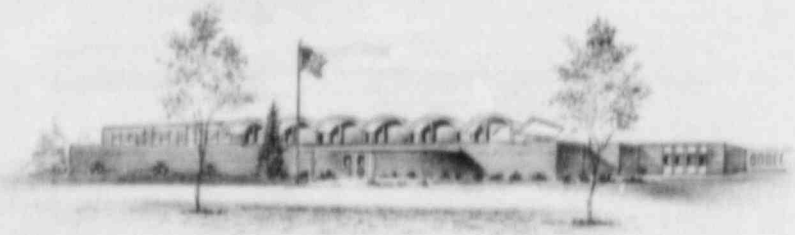
Please close out our current institutional license number 24-18314-01.

Sincerely yours,

CARROLL COUNTY MEMORIAL HOSPITAL

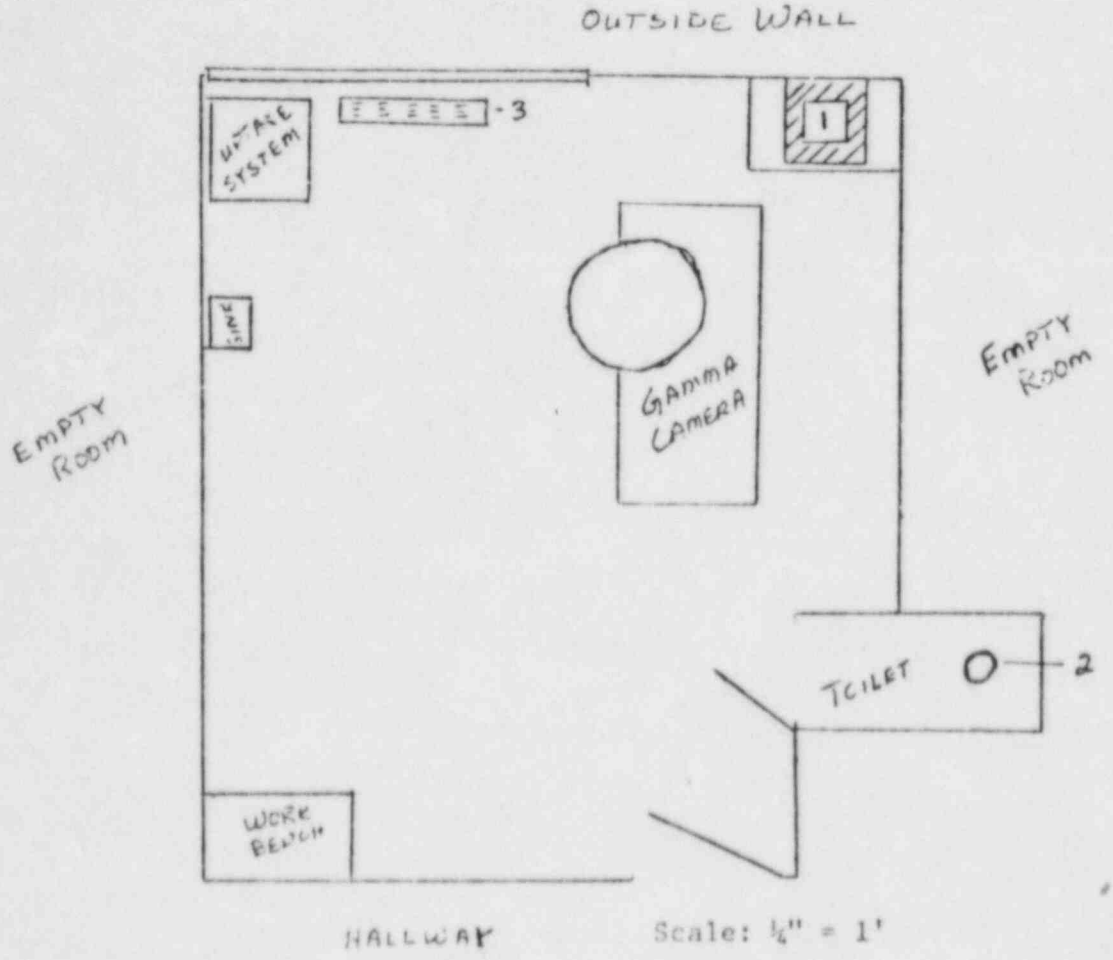
Jack L. Tindle
Administrator

JLT:er



Control No. 75814

Carroll County Hospital



1. 2" lead brick safe
2. Exhaust
3. Air Coil fan unit

LEVERING HOSPITAL

1734 Market Street Ph: (314) 221-6511
HANNIBAL, MISSOURI 63401

OFFICE OF ADMINISTRATOR

August 25, 1983

Mr. Del Roberts, President
Mobile Medical Services
Metro Plaza Offices
2705 B Industrial Drive
Jefferson City, Missouri 65101

Dear Mr. Roberts:

The administration of Levering Hospital is granting approval for the use of by-product material under the supervision of Lysle M. Bach, M.D. and J. Russell Comer, M.D.

Please close out our present institutional License number 24-15289-01.

Sincerely,

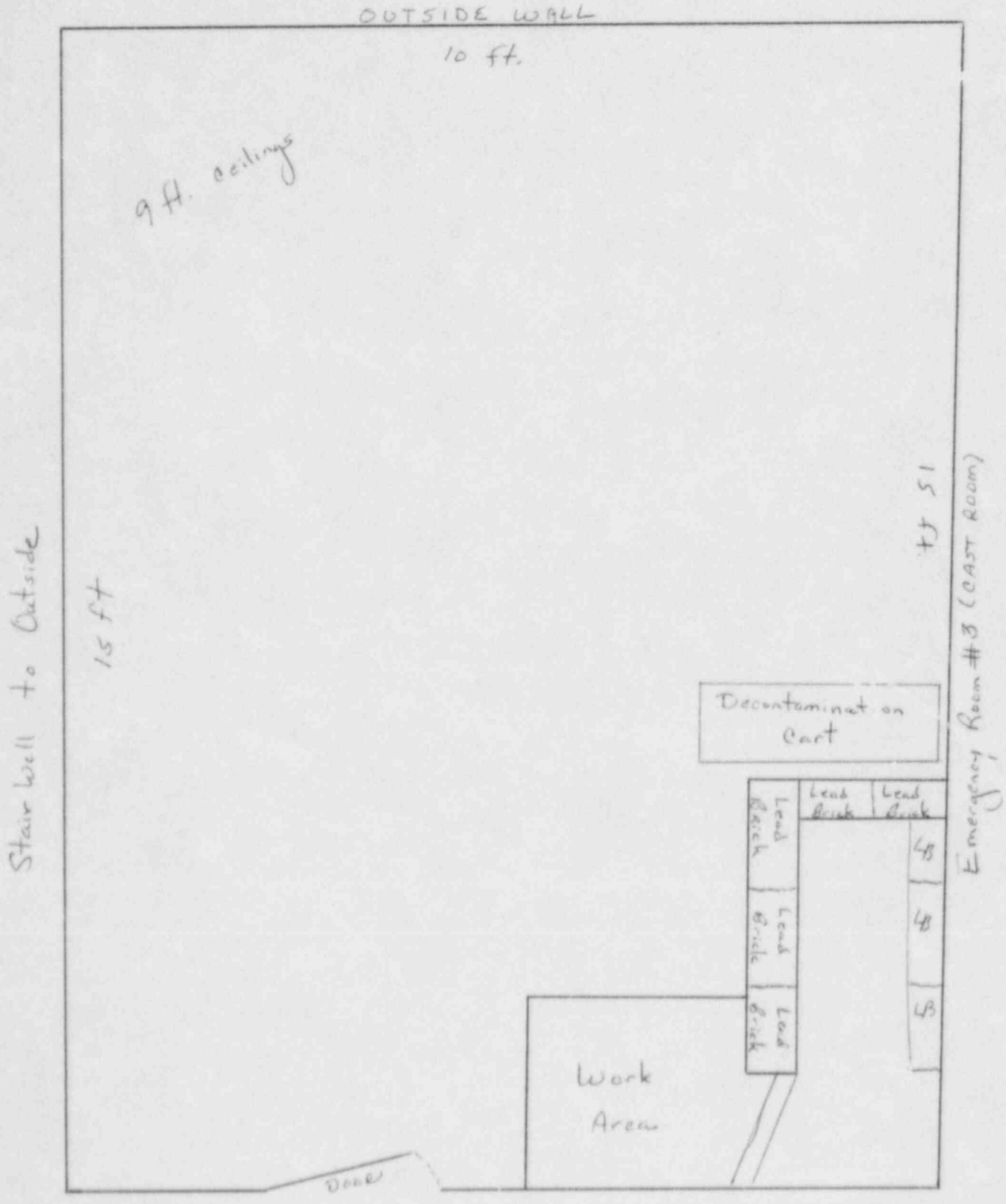
Woodrow Lee
Administrator

WL/gs

Control No. 75612

SCHEMATIC DRAWING OF ROOM TO BE USED FOR NUCLEAR MEDICINE

Levering Hosp.



Control No. 75012

MOBILE MEDICAL SERVICES
Specializing in Diagnostic Ultrasound and Nuclear Medicine Procedures
METRO PLAZA OFFICES
2705 B INDUSTRIAL DRIVE
JEFFERSON CITY, MISSOURI 65101
314 - 893-2828

Re: Transfer of Institutional License No. 24-18314-01 of the Carroll County Memorial Hospital and No.24-15289-01 of the Levering Hospital to the Mobile Medical Services license No. 24-18094-01.

The request to add the Carroll County Memorial Hospital and Levering Hospital to our mobile nuclear license is enclosed. A few comments concerning the circumstances in these changes are in order. I will explain each facility separately:

Carroll County Memorial Hospital--This facility under its present license is currently being provided nuclear procedures by an outside mobile source, the Research Hospital "Outreach Program", whose nuclear physicians are listed as the users. Although the present license is an institutional license, in reality, it is being used as a mobile operation. No Mo-99 generator has ever been delivered to this facility, only single doses. The change in license will list the Carroll County Hospital's own staff Radiologists as the users. The nuclear areas are not being abandoned but would continue. Because, the hospital must give the Research program a written notice of cancellation we must coordinate the transfer and close out survey to avoid interruption of service. Therefore, we request to be permitted to perform the license close out surveys on October 28, 1983 and start nuclear procedures under the mobile license the same day. No radioactive materials are kept at the Carroll County Memorial Hospital. All prepackaged doses are delivered to the facility, as single doses, by a central pharmacy. No radioactive material has been stored at this facility. Xenon ventillation studies are presently being done under their institutional license.
The close-out survey will be performed by a Mobile Medical Services nuclear technologist under the supervision of Frank Comer, Health Physicist. NRC forms 314 will be filled out in duplicate and copies will be sent to both Washington D.C. and Glen Ellyn, Illinois.

A sketch of the nuclear working areas will be made with numbers corresponding to the areas surveyed. An Eberline E-120 low level survey meter will be used for the area surveys. Wipe tests will be performed with Whatman filter paper. A 1x1 meter area will be wiped--they will be counted in a well counter in the Kansas City, Missouri Central Pharmacy, Syncorp, Inc.

Results of the surveys will be immediately forwarded to the appropriate places.

Levering Hospital--This facility under its present license is currently operating their own Nuclear Medicine Department. The same close out procedure will be followed as the above explanation.

I will be calling you to coordinate this transfer of license.

Respectfully Submitted,

Del Roberts, C.N.M.T.
President
Mobile Medical Services

030 - 14470

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

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

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

Mobile Medical Services
Metro Plaza
2705 B Industrial Drive
Jefferson City, MO 65101

TELEPHONE NO.: AREA CODE( ) _____ _____

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

See attached supplement

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Del Roberts

TELEPHONE NO.: AREA CODE(314) 893 2828

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 24-18094-01

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

See attached supplement

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.)*

William H. Voss, D.O. with consultation by Safety Science Group of Syncor.

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		
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	10,000 *
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
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.		

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

RECEIVED
JUN 29 1983
REGION III

RECEIVED BY REGION 3
Date 7/6/83
By Cap
Orig. to mc
Action Compl. Cap 7/6

Applicant
Check No. 003038
Amount/Fee Category 150 7B
Type Fee 7 KEH
Control No. 7517
Date Check Rec'd 7/6/83
Received By Cap

NRC FORM 313M (9-81)

*Note: This possession limit is based on use of 99m-Generators at four (4) satellite facilities.

JUN 29 1983

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

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

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

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7 B

(2) LICENSE FEE ENCLOSED: $ 150.00

Control # 95177

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* [signature]

(1) NAME *(Type or Print)* William H. Voss D.O.

(2) TITLE RSO

c. DATE June 24, 1983

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

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

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

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

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

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

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

NRC 313M

ITEM 1.b

Street addresses at which licensed material will be used:

Good Time Country Warehouse
Compartment #2, RR 4
Highway 163 and 63
Columbia, Missouri 65201

2402 Jefferson Street, Suite #4
Lexington, Missouri 64067

Space Center
3737 East 10th Street, Suite 12
Joplin, Missouri 64801

2500 South Halibruton, Bldg. #3
Room 1A
Kirksville, Missouri 63501

Group I and II material: Hospitals serviced by Mobile Medical previously approved by the NRC.

Community Memorial
319 Grand Avenue
Moberly, Missouri 65270

Grim-Smith Hospital and Clinic
112 East Patterson Avenue
Kirksville, Missouri 63501

John Fitzgibbon Memorial Hospital
868 South Brunswick
Marshall, Missouri

Wright Memorial Hospital
701 East First Street
Trenton, Missouri

Cooper County Memorial Hospital
Boonville, Missouri

Scotland County Memorial Hospital
Memphis, Missouri

Putnam County Memorial Hospital
Unionville, Missouri

Hedrich Medical Office Building, Suite 2A
103 East 11th Street
Chillicothe, Missouri 64601

Control No. 75177

NRC 313M ITEM 1.b. Cont'd.

Sullivan County Memorial Hospital
Milan, Missouri

General John J. Pershing Memorial Hospital
Brookfield, Missouri

Laughlin Osteopathic Hospital
900 East Laharpe Street
Kirksville, Missouri

St. Francis Hospital
225 West Hayde Street
Marceline, Missouri

Callaway Memorial Hospital
Fulton, Missouri

Samaritan Memorial Hospital
Macon, Missouri

Hutchinson Clinic
Northtown Shopping Plaza
North Highway 63
Kirksville, Missouri

Valuck Clinic
Northtown Shopping Plaza
North Highway 63
Kirksville, Missouri

Albert M. Keller Memorial Hospital
600 West Morrison Street
Fayette, Missouri

Kelling Clinic, Inc.
24 Highway West and Missouri Street
Waverly, Missouri

Grove General Hospital
1310 South Main
Grove, Oklahoma

Community Hospital
Bridge and Bay Streets
Sweet Springs, Missouri

McCune-Brooks Hospital
627 West Centennial
Carthage, Missouri

NRC 313M ITEM 1.b. Cont'd

Group I and II material and 133-Xenon:

Hospitals serviced by Mobile Medical previously approved by the NRC.

Lee's Summit Community Hospital
530 North Murray Road
Lee's Summit, Missouri 64063

Lexington Memorial Hospital
15th And State
Lexington, Missouri

Hedrick Medical Center
100 Central Street
Chillicothe, Missouri

ITEM 4 of NRC - 313M

Individual Users	Authorization	Prev. License Number
William H. Voss, D.O.	All	24-18094-01
John F. Rose, M.D.	All	24-18094-01
Kenneth L. Rall, M.D.	All	24-18094-01
Donald Q. Cochran, M.D.	All	24-18094-01
Kenneth M. Kays, M.D.	All	24-18094-01
James C. Clouse, D.O.	All	24-18094-01
Harve J. Helton, D.O.	All	24-18094-01
James R. Farkas, M.D.	All	24-18094-01
Michael K. Willman, D.O.	All	24-18094-01
Paul M. Williams, D.O.	All	24-18094-01
Charles W. Blackwell,M.D.	All	24-18094-01
Sam L. Gaston, M.D.	All	24-18094-01
Calvin C. Young, M.D.	All	24-18094-01
Ronald G. Shriner, M.D.	All	24-18094-01
Robert MacNaughton, M.D.	All	24-02704-01
L. D. Furlong, M.D.	All	24-02704-01
John E. Scott, M.D.	All	24-18655-01
Eugene G. Peterson, M.D.	All	24-18655-01
David E. Hazuka, M.D.	All	24-18655-01
Robert G. Schwegler, M.D.	All	24-18655-01
Stephen R. Kunz, M.D.	All	24-18655-01
Jon E. Gustafason, M.D.	All	24-18655-01
James Arnold, M.D.	All	24-17205-01
Raymond W. Hartwig, M.D.	All	24-00624-02
Rodney C. Hartman,M.D.	All	24-18094-01
Fred L. King, D.O.	All	24-05245-01

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victoreen

   Manufacturer's model number: Model 498

   Number of instruments available: 3

   Minimum range: 0.0 mR/hr to 10 mR/hr

   Maximum range: 0.0 mR/hr to 1000 mR/hr

   b. Manufacturer's name: Ludlum

   Manufacturer's model number: Model S

   Number of instruments available: 1

   Minimum range: 0.0 mR/hr to 0.2 mR/hr

   Maximum range: 0.0 mR/hr to 2000 mR/hr

2. Dose calibrator

   Manufacturer's name: (1) Picker (2) Radex (3) Capintec

   Manufacturer's model number: (1) Isotope Calib; (2) Isotope Calib, (3) CRC-5

   Number of instruments available: 4

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Mobile Scintillation Camera with Computer Board	Technicare	Series-42S-120

4 of these units are available.

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

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

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

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

3. Survey instruments will be calibrated

X a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source
Radionuclide _____
Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

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

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

X c. By a consultant or outside firm

(1) Name Syncor Corp

(2) Location Kansas City, Missouri 24-16617-01 MD

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 24-16617-01 M.D.

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

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

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

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

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

X Other* (specify) If generators are not in use, a source of Tc-99m with activity equivalent to the maximum activity assayed to clinical situations will be used.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within ± 5%
Ba-133	0.1-0.5	100 microcuries or more	within ± 5%
Cs-137	0.1-0.2	100 microcuries or more	within ± 5%
Ra-226	1-2	N/A	N/A
N/A		N/A	N/A

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

or

_____ Equivalent procedures are attached.

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

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)

2. Instrument accuracy (at installation and annually thereafter)

**3. Instrument linearity (at installation and quarterly thereafter)

4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).

2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

3. Calculate net activity of each source subtracting out background level.

* 4. For each source, plot net activity versus the day of the year on semilog graph paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based on decay calculations and the ±5 percent limits on the graph.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

8. Variations greater than ±5 percent from the predicted activity indicate the need for instrument repair or adjustment.

9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

**E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.

2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

---

*See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

**Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

Assay Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be, 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

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

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

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

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

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

5. Keep a log of these calibration checks.

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

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

* Actual % Variation will be calculated and recorded rather than plotting a graph.

** As an option, we request authorization to perform instrument linearity with the Calicheck ™, supplied by Calcorp, Inc. Cleveland, Ohio.

[redacted] 75177

FACILITY DIAGRAM
(Prepare and Attach to Application)

Submit a detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

a. Use and storage of Tc-99m generators.

b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)

d. Preparation and dispensing of Group III kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

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FACILITIES AND EQUIPMENT

a. All 99 Mo-99mTc generators are stored in an auxillary shield supplied by the manufacturer.

b. 2" lead bricks are utilized for waste storage. (syringes, cotton pledgets, used 99mTc vials, etc.)

Used generators are stored in their original shipping containers and returned to the manufacturer.

c. Preparation and dispensing of Group III kit radiopharmaceuticals is done behind ½" L-block and lead glass shields on the work benches shown.

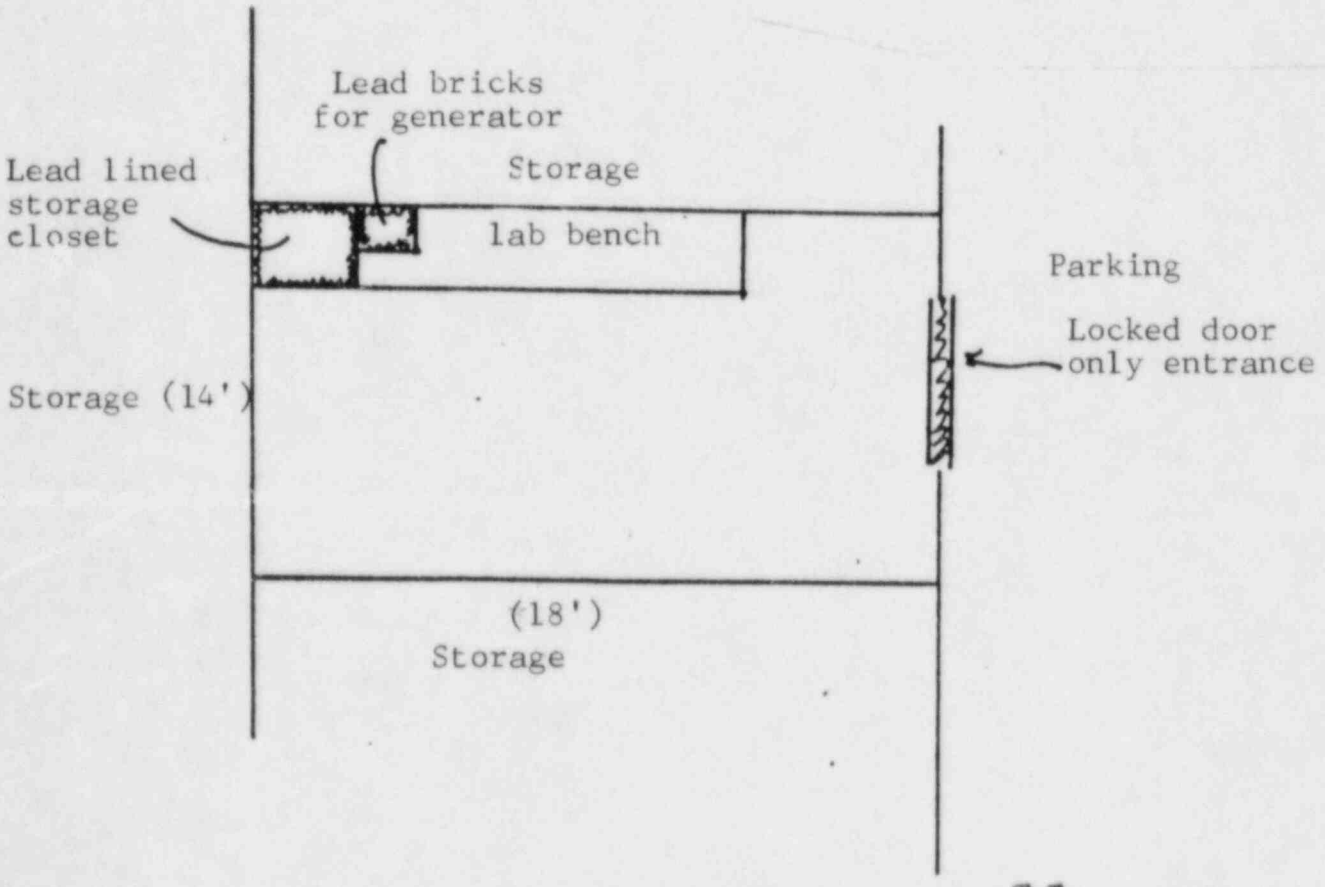
The satellite areas shown will be used for receipt, preparation, and measurement of all radiopharmaceuticals. Generators will be eluted only at these facilities. The following items are provided for handling radioactive materials and are used appropriately.

1. Disposable gloves
2. Lead syringe shields
3. Lead vial shields
4. Tongs and forceps
5. 2" x 4" x 8" lead bricks
6. Shielded devices for boiling, shaking, and processing kit materials.
7. Absorbent pads with plastic backing for counter tops and material handling trays.
8. Plastic bags.

Equipment to be used at 2402 Jefferson Street, Suite #4, Lexington, Missouri

(1) Technicare mobile gamma camera Model 120.
(2) Capintec dose calibrator Model 5 with molly breakthrough kit.
(3) Victoreen - 498 survey meter 0-1 R/hr
(4) Nuclear Associates low level survey meter Model 05-700 0-50 mR/hr.
(5) ADC Medical table top shield (lead glass) Model TTS-101 ¼" lead.

Lead lined closed 2½' high 1½" thick. (for storage)
Lead bricks for generator housing.
Lead storage container with lid.
Decontamination kit.
Syringe shields.

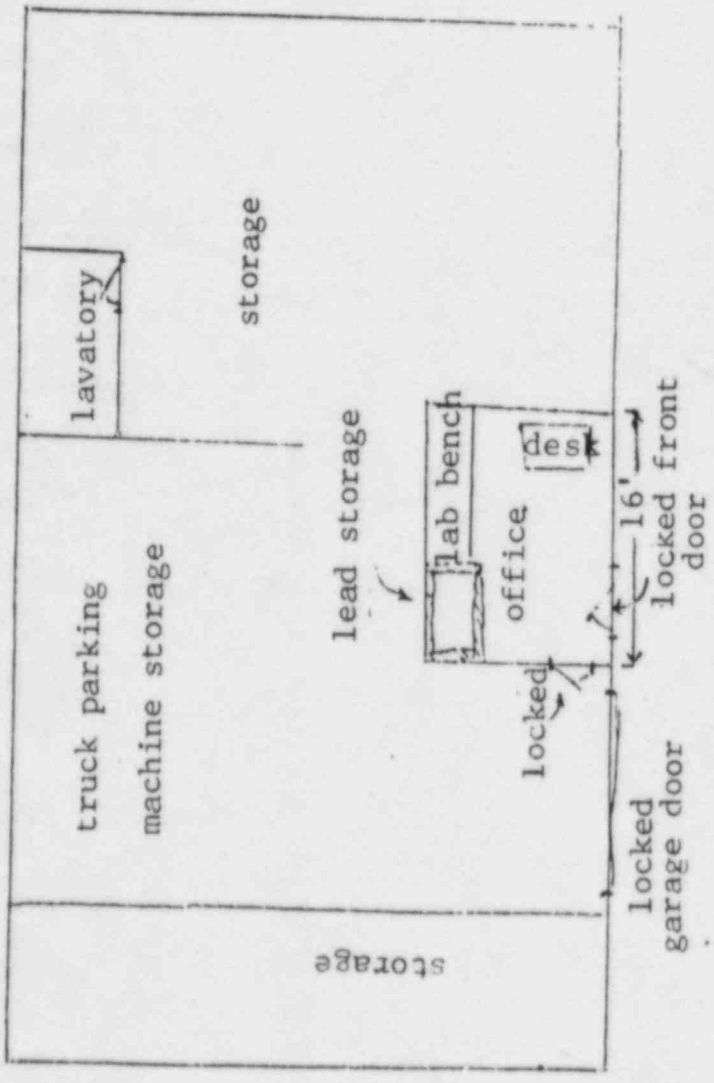


25122

ITEM 11

Satellite facility at, Good Time Country Warehouse, Compartment #2, RR 4, Highway 163 and 63, Columbia, Missouri

The building is all storage -- there are no other people in the building.
The building is surrounded by parking lot.



The lead storage area in the office will be at least 1½" thick lead sheets, 2½' high.

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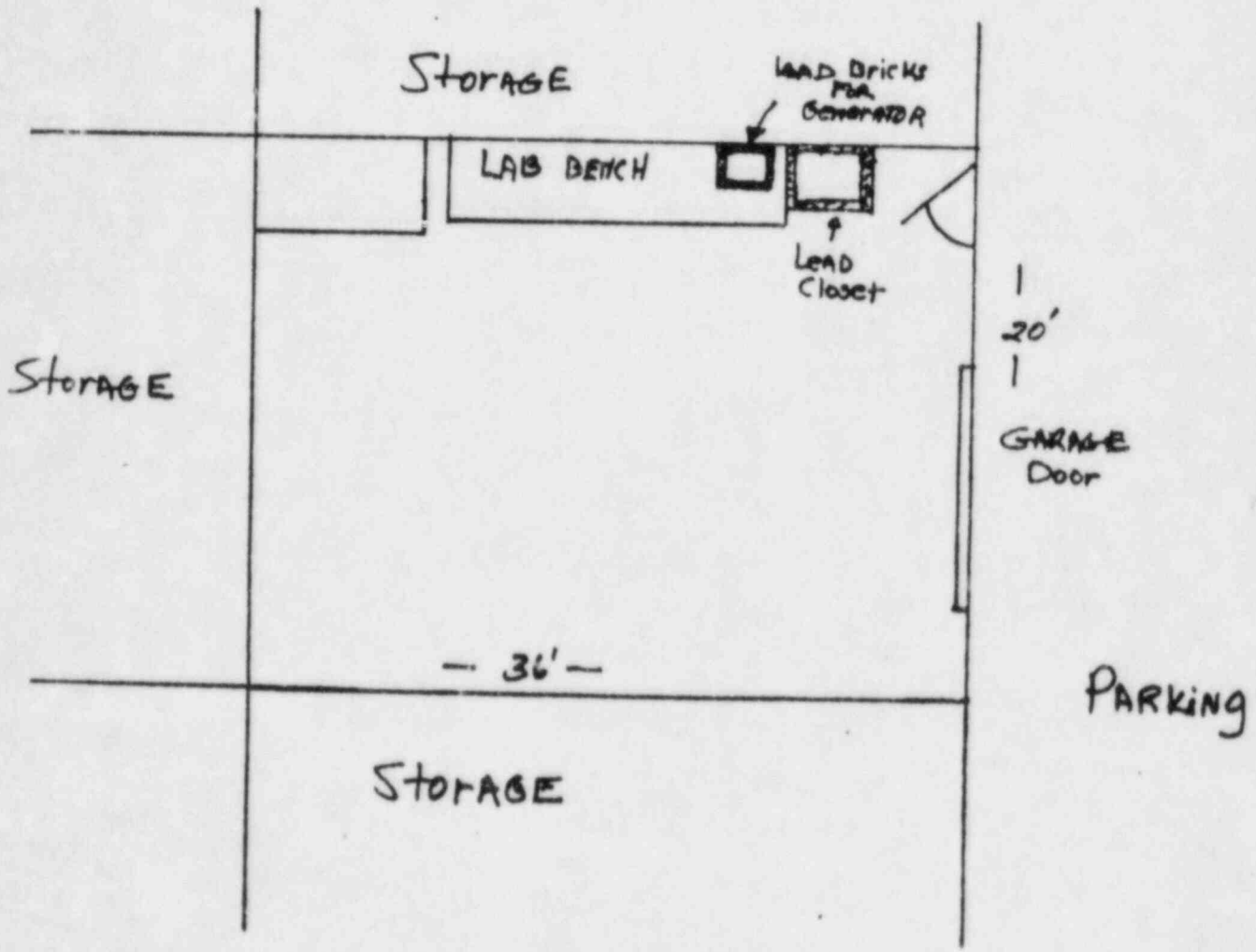
ITEM 11

Item 1

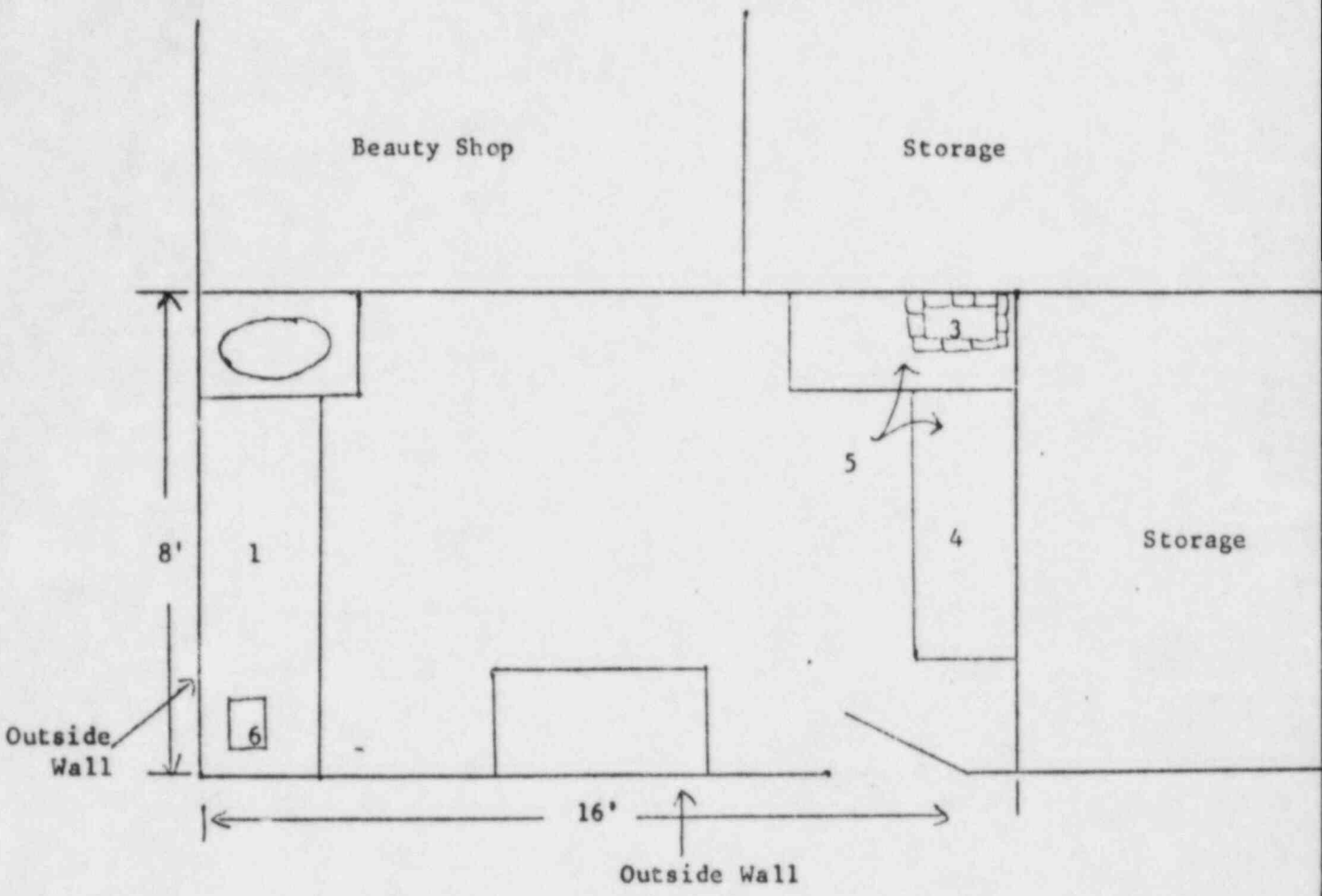
Joplin, Missouri Office and Nuclear Medicine Lab.

Address:

Space Center
3737 E 10th Street
Suite 12
Joplin, Missouri 64801



2500 S. Halliburton
Building 3, Room 1A
Kirksville, MO



1. Work Area
2. Sink
3. 2" lead brick safe
4. Package receipt area
5. ½" thick lead shielded waste/generator storage area
6. Dose Calibrator
7. Desk

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

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

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. Thi information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following.

   a. Ordering of routinely used materials.

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

3. During off-duty hours, common carriers will receive written instructions in accordance with the procedures outlined in the sample instructions below. These instructions will also be posted in each satellite facility.

ACCEPTING DELIVERY

All materials are delivered directly to the satellite facilities whose addresses appear on this license application. These materials are accepted by the Nuclear Medicine Technologist during normal working hours. For deliveries made during off-duty hours the common carrier will be given keys that will open the private entrance door to the satellite facility. They will be instructed in writing to leave the radioactive drugs on the bench in the satellite. They will be instructed to lock the door upon departure.

SAMPLE INSTRUCTIONS

INSTRUCTIONS FOR:_____(Common Carrier)

FROM:_____(Technologist)

SUBJECT: DELIVERY OF PACKAGES CONTAINING RADIOACTIVE MATERIALS

All packages containing radioactive material that arrive when no personnel are present are to be delivered. Unlock the door, place the package on top of the counter provided, and relock the door.

[illegible] 7517

If the package is wet or appears to be damaged, immediately contact the Nuclear Medicine Technologist. Ask the carrier to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

**NUCLEAR MEDICINE TECHNOLOGIST_____

**OFFICE PHONE_____

**HOME PHONE_____

**On the actual memo that is used, this information will be filled in and updated as necessary.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

   f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

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

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

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

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

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

Major Spills

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

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

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

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

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

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

*RADIATION SAFETY OFFICER: _____
*OFFICE PHONE: _____
*HOME PHONE: _____

*ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____
_____
_____

*On the actual copy that is posted in the nuclear medicine department, this information will be filled in and updated as necessary.

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.*

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

APPENDIX J

WASTE DISPOSAL

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

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

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

-or-

N/A By commercial waste disposal service (see also Item 4 below).

X Other (specify): See #3

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

X Returned to the manufacturer for disposal.

-or-

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

N/A Disposed of by commercial waste disposal service (see also Item 4 below).

N/A Other (specify): _____

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

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

N/A Disposed of by commercial waste disposal service (see also Item 4 below).

N/A Other (specify): _____

4. The commercial waste disposal service used will be

N/A

(Name) (City, State)

NRC/Agreement State License No. N/A

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

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

Control No. 75177

SUPPLEMENTAL INFORMATION

FOR USE OF 133-XENON

BY

MOBILE MEDICAL SERVICE

TRANSPORT OF 133-XENON:

Maximum activity to be transported:

2-20 mCi NEN unit dose 133-Xenon vials

Average 45 mCi in trap.

Total 85 mCi transported.

Leakage:

Vials: 40 mCi x .005 = 0.2 mCi

(see letter from NEN)

Trap: 0 (see manufacturers brochure)

Van volume in ml:

$12' \times 8' \times 6' = 576\ ft^3$

$576\ ft^3 \times 2.832 \times 10^4 ml/ft^3 = 1.63 \times 10^7 ml$

Concentration in van = $\frac{A}{V} = \frac{200\ uCi}{1.63 \times 10^7\ ml} = 1.22 \times 10^{-5} uCi/ml$

20.103 of CFR Part 20 requires for restricted areas, that:

$C = \frac{A}{V} \leq 1 \times 10^{-5} uCi/ml$

Note: The driver's cab of our vehicles are separate and isolated from the compartment transporting the 133-Xenon. When the truck doors are opened, air from the outside would contribute to dilution of any 133-Xenon which may have leaked from the vials being transported prior to the Technologist entering that portion of the truck.

We will subsequently know the amount of leakage from trap monitoring procedures and precautions will be taken to insure that the leakage does not occur in the van. A section of tubing will be permanently affixed to the rear air vent of the van. This tubing will be connected to the gas trap exhaust port at all times when the gas trap is being transported in the van. Trap monitoring procedures will be done by the driver/technologist, and the van will be surveyed at entry each day with the low level survey meter.

We confirm that 133-Xenon will be assayed in the dose calibrator prior to use.

Control No. 75127

The 133-Xenon trap will be monitored for leakage on a bi-weekly basis.

Supplemental information for 133-Xenon use at Lee's Summit Hospital, Lee's Summit, Missouri.

A. Quantities to be used:

1. Number of patients to be studied: 5 studies per week, dose per patient--20 millicuries.

B. Use area:

1. Please see enclosed sketch of Imaging Area with applicable air flow information.

2. Supply air--0
Return air -0
Exhaust air - 60 CFM

3. Air flow rates will be maintained by monthly checks by the hospital engineering department.

4. The exhaust from this area is tied to an exhaust system whose total exhaust at roof top is 3,860 CFM. There are no air intakes on the roof, with the nearest intake at least 50 feet from the exhaust fan located on the side of the building.

C. Procedures for routine use:

1. See enclosed Pulmonex instruction manual.

2. Atomic Products Corporation, Model 130-500

3. See enclosed instruction manual for special procedures.

D. Emergency procedures:

In case of accidental release of 133-Xenon into the counting room area, proceed as follows:

1. Procure survey meter and evacuate area. Insure that the access door to the nuclear medicine laboratory is closed. The low level survey meter shall be on hand and available as part of the equipment necessary while doing 133-Xenon procedures.

2. Wait 30 minutes, survey area. Room air must have returned to background levels before room may be entered for routine work. This 30 minute period is based on room volume and the amount of air being supplied and exhausted by the normal ventilation system as well as the emergency exhaust system.

E. Air concentration of 133-Xenon in restricted areas:

1. 100 mCi/week (maximum)

2. 20% (estimated loss and trap leakage)

3. Ventilation rate in the area is 60 CFM exhuast

4. For restricted areas, Section 20.103 of 10 CFR, Part 20 requires that:

$$\frac{A}{V} \times F = 1 \times 10^{-5} \text{uCi/ml}$$

5. Sample problem: What ventilation rate is required to ensure compliance with section 20.103 of 10 CFR, Part 20?

a. Maximum activity used per week

$$A = \frac{20 \text{ mCi}}{\text{patient}} \times \frac{5 \text{ patients}}{\text{week}} \times 1 \times 10^{3} \frac{\text{uCi}}{} = 1 \times 10^{5} \frac{\text{uCi}}{\text{week}}$$

b. Assume a loss rate of 20% (f)

$$V = \frac{A \times f}{1 \times 10^{-5} \text{uCi/ml}} = \frac{1 \times 10^{5} \text{uCi/wk} \times 0.20}{1 \times 10^{-5} \text{uCi/ml}} = 2 \times 10^{9} \text{ml/wk}$$

The required ventilation rate is:

$$\frac{2 \times 10^{9} \text{ml/wk}}{40 \text{ hrs/wk}} \times \frac{1}{1.76 \times 10^{5}} \frac{\text{CFM}}{\text{ml/hr}} = 28.4 \text{ CFM}$$

Ventilation rate as stated in 3, meets the requirements of Section 20.103 of 10 CFR, Part 20.

F. Methods of 133-Xenon disposal:

1. Adsorption onto charcoal trap

a. This unit will be vented into the imaging area and it is not anticipated that leakage of the entire system will exceed 20%. If breakdown of the trap occurs, it will be treated as an emergency procedure and emergency procedure "D" will be implemented.

2. The charcoal trap will be checked for leakage in accordance with the enclosed procedure at a bi-weekly frequency.

3. Saturated filters will be handled and replaced in the van using the manufacturer's suggested method for removing charcoal filters. This procedure will be carried out at least 30 feet from access to a restricted area. The individual removing the filter from its shield will use lead gloves and wear a lead apron containing 0.5 mm Pb. The filters will be placed in a plastic bag which will be sealed and returned to the centralized radiopharmacy for storage and decay to background. Film badges and ring badges will be worn at all times while performing this procedure.

4. Since one must consider that 20% of the 133-Xenon used is lost to the restricted area, through procedure faults, trap leakage, etc., one must consider that this 20% finally is exhausted into an unrestricted area. Using the information contained in Reg. Guide 10.8, page 10.8-54, the 3,860 CFM exhaust fan on the roof is more than adequate to reduce the 133-Xenon concentration to the unrestricted area to less than 3×10^{7} uCi/ml.

133-Xenon released to unrestricted area:

Calculations:

$$A = \frac{5 \text{ patients}}{\text{week}} \times \frac{20 \text{ mCi}}{\text{patient}} \times \frac{10^3 \text{uCi}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{year}} \times 0.2 =$$

$$A = 1.04 \times 10^6 \text{ uCi/yr}$$

$$V = 3{,}860 \text{ CFM} \times 1.49 \times 10^{10} \frac{\text{ml/yr}}{\text{ft}^3/\text{min}} =$$

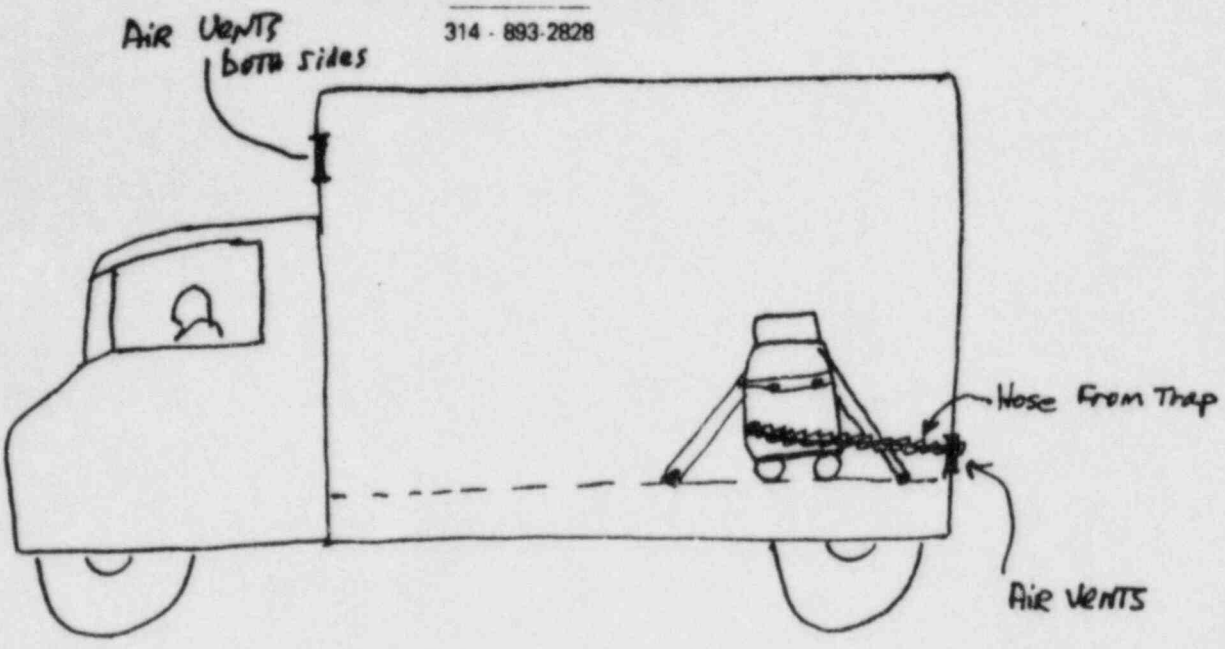
$$V = 5.75 \times 10^{13} \text{ml/yr}$$

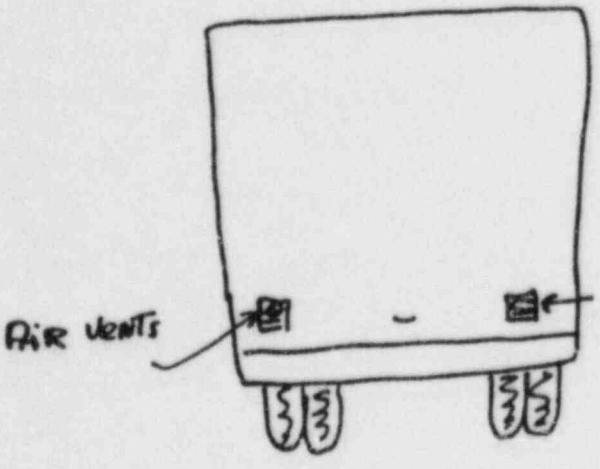
$$C = \frac{1.04 \times 10^6 \text{uCi/yr}}{5.75 \times 10^{13} \text{ml/yr}} = 1.81 \times 10^{-8} \text{uCi/ml}$$

We confirm that the supply to this room is 0 and air supply is from convection of air from the hall into this room as pulled through by the exhaust duct.

Prior to use of the 133-Xenon trapping system for patient procedures, a dry run will be performed to insure that the trap is working properly. Once it is ascertained that the unit and trap are working properly it will be utilized for patients as per procedures listed elsewhere in this application.

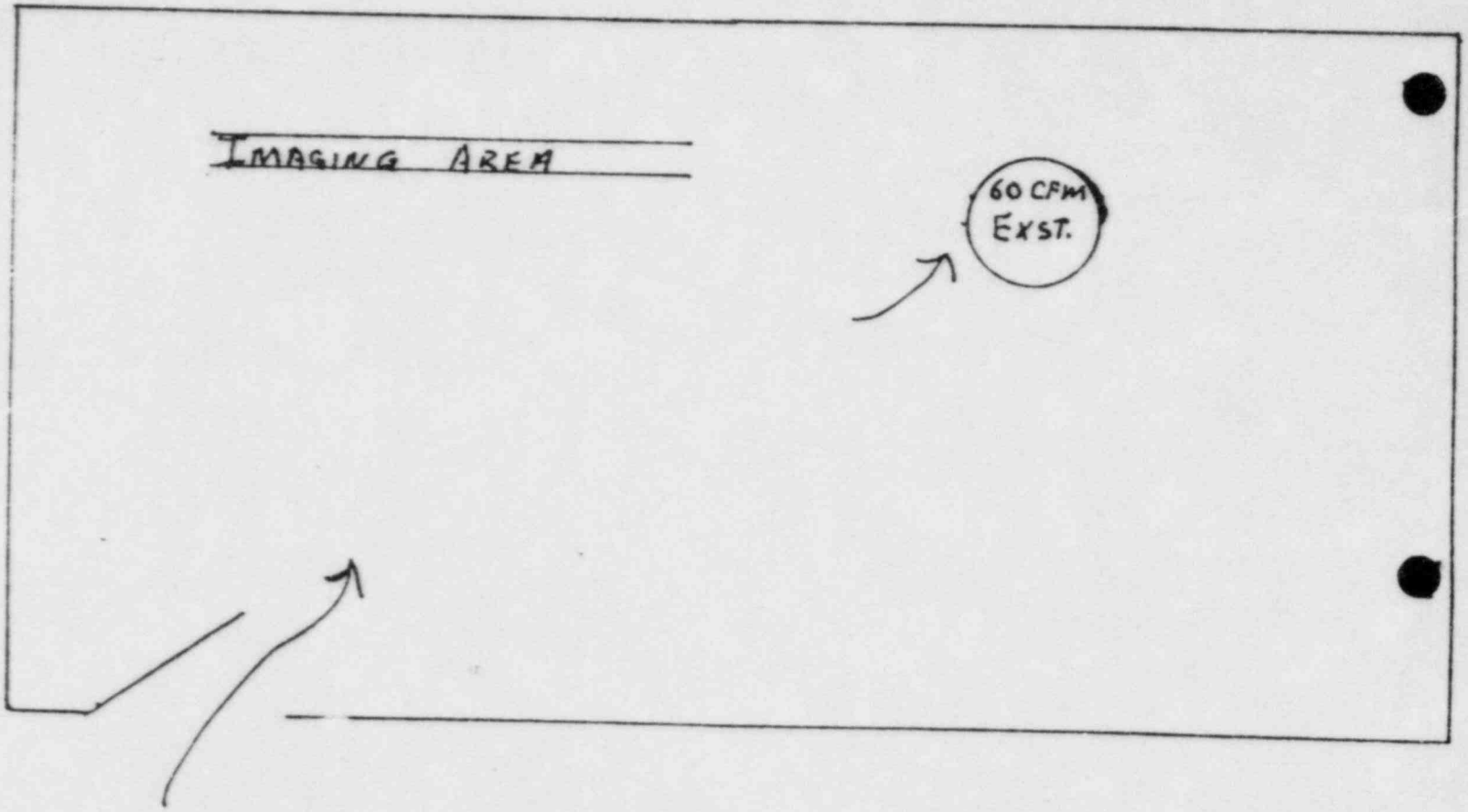
MOBILE MEDICAL SERVICES
Specializing in Diagnostic Ultrasound and Nuclear Medicine Procedures
METRO PLAZA OFFICES
2705 B INDUSTRIAL DRIVE
JEFFERSON CITY, MISSOURI 65101
314 - 893-2828





There is Also a Natural Vacuum behind a VAN That creates a suction While moving.

LEE'S SUMMIT HOSPITAL



SCALE 1/8" = 1'

Contract No. 75177 ITEM 21

This is a request to include the use of 133-Xenon, for lung ventilation studies, in the Lexington Memorial Hospital.

The Lexington Hospital has had 133-Xenon used in their hospital under their present institutional license, by the Research Medical Center's mobile nuclear service.

The following is the description of the area and related statistics.

A. Quantities to be used:

1. Number of patients to be studied: 2 studies per week. Dose per patient - 20 mCi

B. Use area:

1. Please see enclosed sketch of Imaging Area with applicable air flow information.

2. Ventilation to the area where 133-Xenon is used is indicated on the enclosed drawing. There is a Unit Trane air vent, Model B15A002, which circulates internal air plus about 10% external air over hot water pipes for heating. This unit has been reversed to act as an exhaust fan, and an exhaust fan capable of removing 150 CFM was installed in this room.

3. All areas where 133-Xenon is used will therefore be under negative pressure of approximately 150 CFM.

C. Procedures for routine use:

1. See enclosed Pulmonex instruction manual

2. Atomic Products Corporation, Model 130-500

3. See enclosed instruction manual for special procedures

D. Emergency procedures:

1. See attached procedure under Supplemental information for 133-Xenon use.

E. Air concentration of 133-Xenon in restricted areas:

1. 40 mCi/week (maximum)

2. 20% (estimated loss and trap leakage)

3. Ventilation rate is 150 CFM

4. For restricted areas, Section 20.103 of 10 CFR, Part 20 requires that:

$$\frac{A}{V} \times F = 1 \times 10^{-5} \text{ uCi/ml}$$

5. Sample problem: What ventilation rate is required to ensure compliance with Section 20.103 of 10 CFR, Part 20?

   a. Maximum activity used per week:

$$A = \frac{20\ mCi}{patient} \times \frac{2\ patients}{week} \times 1 \times 10^3\ \frac{uCi}{mCi} = 4 \times 10^4\ \frac{uCi}{week}$$

   b. Assume a loss rate of 20% (f):

   c. $$V = \frac{A \times f}{1 \times 10^{-5} uCi/ml}$$

$$= \frac{4 \times 10^4\ uCi/week \times 0.20}{1 \times 10^{-5} uCi/ml} = 8 \times 10^8 ml/week$$

   The required ventilation rate is:

$$\frac{8 \times 10^8\ ml/week}{40\ hr/week} \times \frac{1\ CFM}{1.7 \times 10^6 ml/hr} = 12\ CFM$$

Addendum to Lexington Information:

1. Exhaust rate 150 CFM. There is no air supply to this room except that which is brought in through the door by normal convection or when the exhaust fan is running.

2. We confirm that none of the exhausted air is recirculated back into the Imaging Room or any restricted area.

3. We confirm that semi-annual measurements of the air flow rates will be made in rooms where Xenon is used.

4. Calculations of 133-Xenon released, averaged over a year to the unrestricted area.

$$C = \frac{A}{V} \leq 3 \times 10^{-7} uCi/ml$$

$$A = \frac{2\ patients}{week} \times \frac{20\ mCi}{patient} \times \frac{10^3 uCi}{ml} \times \frac{52\ weeks}{yr} =$$

$$A - 2.08 \times 10^6\ uCi/year \times 0.2 - 4.16 \times 10^5 uCi/yr$$

Since a 133-Xenon trap will be used, only 20% of the above will be released to the unrestricted area.

$$V = 150\ ft^3 \times 1.49 \times 10^{10} \frac{ml/yr}{ft^3/min} =$$

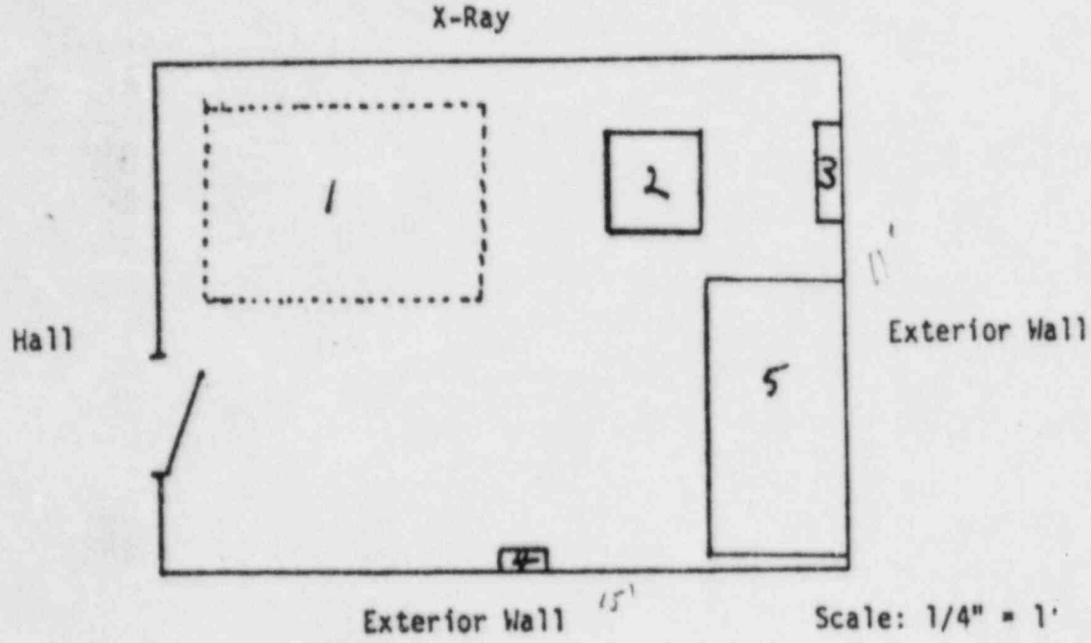
$$V = 2.24 \times 10^{12} ml/yr$$

$$C = \frac{4.16 \times 10^{5}\ uCi/yr}{2.24 \times 10^{12} ml/yr} - 1.85 \times 10^{-7} uCi/ml$$

5. We rely on the exhaust fan which has been installed in the Imaging Room at Lexington Hospital. The exhaust fan will be on at all times while the technologist is working in this room on days that 133-Xenon procedures are performed.

6. The distance to the nearest air intake is well over (30) feet.

Nuclear Medicine working area at the Lexington Memorial Hospital.



1. Gamma Camera
2. Thyroid uptake system
3. Unit Trane Air Vent
4. Exhaust fan (To be installed if Unit Trane cannot be reversed)
5. Work area with table.

All walls of this room consist of one foot concrete construction. In addition, the exterior walls have a 4" brick facing.

We request authorization to perform 133-Xenon studies at Hedrick Medical Center, Chillicothe, Missouri. Information concerning our 133-Xenon delivery system procedures for routine use and methods for transporting this system to our participating hospitals has previously been submitted for our license no. 24-18094-01. At the completion of these studies all radioactive materials and the 133-Xenon delivery and trapping device will be removed from the hospital. The following ventilation information is submitted for the area where 133-Xenon will be used.

1. Use and Storage Area

   a. No material will be stored at this institution. Proximity to the nearest unrestricted area is the hallway located 15 feet from the area of use.

   b. Ventilation: See enclosed sketch
      Supply: 650 CFM supplied from 2 vents.
      Return: 0
      Exhaust: 760 CFM

      The exhaust vent is located on the roof and is 32 feet from the nearest intake vent. There are no windows located on the indicated outside wall.

2. Air concentration of 133-Xenon in the restricted area.

   a. A pulmonex delivery and trapping device is used for all studies.

   b. It is estimated that an average 2 patients will be studied per week using a dose of 20 mCi of 133-Xenon.

Examples Calculations:

For restricted areas 20.103 of 10 CFR

Part 20 requires that

$$\frac{A}{V} \times f \leq 1 \times 10^{-5} \text{ uCi/ml}$$

Maximum activity used per week

$$A = \frac{20 \text{ mCi}}{\text{patient}} \times \frac{2 \text{ patients}}{\text{wk}} \times 1 \times 10^{3} \frac{\text{uCi}}{\text{ml.}} = 4 \times 10^{4} \frac{\text{uCi}}{\text{wk}}$$

Assume a loss rate of 20%

$$V = \frac{A \times f}{1 \times 10^{-5}\ uCi/ml} = \frac{4 \times 10^{4}\ uCi/wk \times 0.20}{1 \times 10^{-5}\ uCi/ml} = 8 \times 10^{8}\ ml/wk.$$

The required ventilation rate is:

$$\frac{8 \times 10^{8}\ ml/wk}{40\ hr/wk} \times \frac{1\ ft^{3}/min}{1.7 \times 10^{6}\ ml/hr} = 12\ ft^{3}/min$$

Ventilation rate in this area is 760 CFM

3. Air concentration of 133-Xenon in restricted area:

Section 20.106 of 10 CFR Part 20 requires that:

$$C = \frac{A}{V} \leq 3 \times 10^{-7}\ uCi/ml$$

Sample problem:

$$A = 8 \times 10^{3}\ uCi/wk \times \frac{52\ wk}{year} = 4.16 \times 10^{5}\ uCi/yr$$

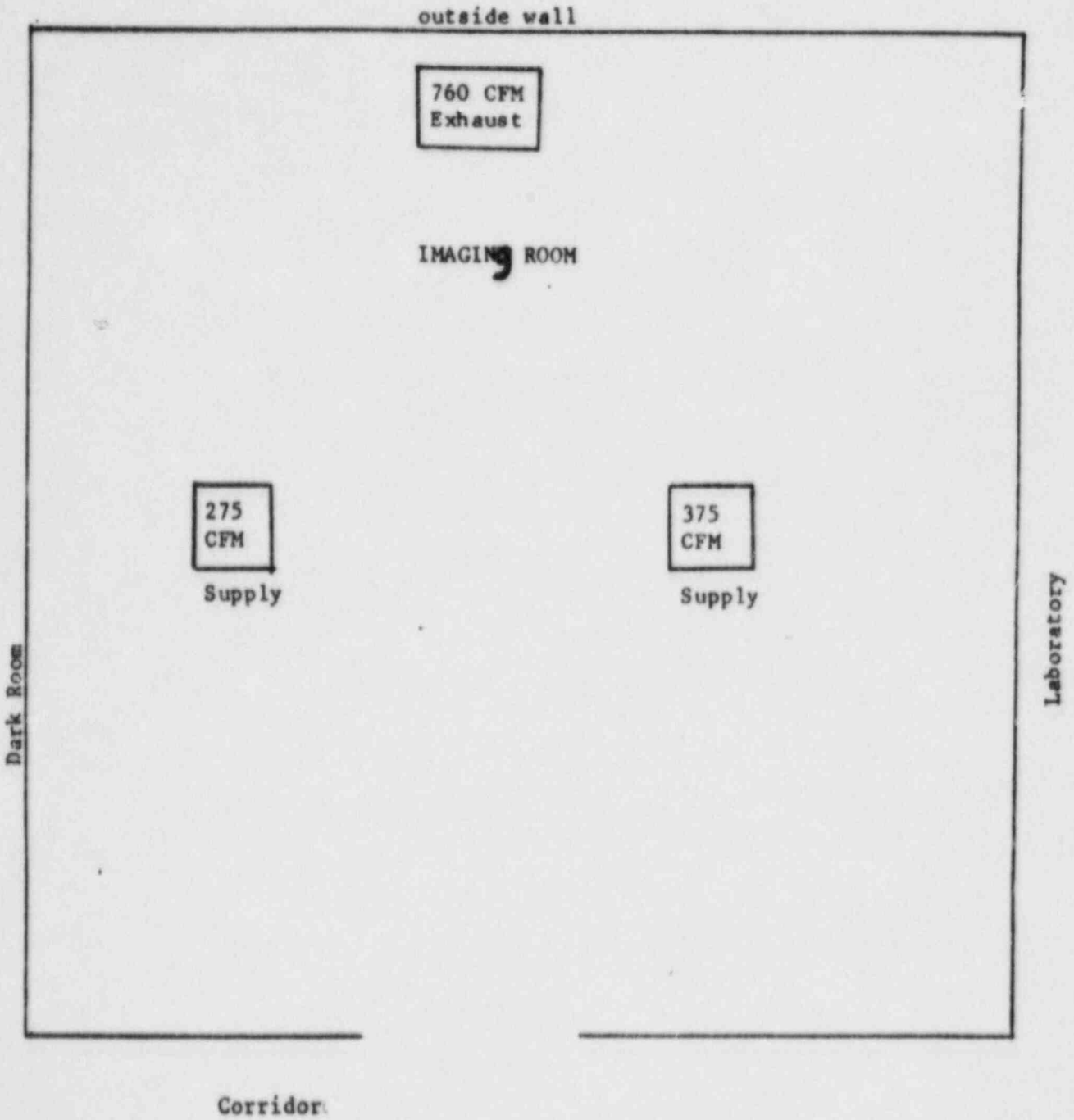
$$V = 760\ \frac{ft^{3}}{min} \times 1.49 \times 10^{10}\ \frac{ml/yr}{ft^{3}/min} = 1.13 \times 10^{13}\ ml/yr$$

$$C = \frac{4.16 \times 10^{5}\ uCi/yr}{1.13 \times 10^{13}\ ml/yr} = 3.68 \times 10^{-8}\ uCi/ml.$$

The area where 133-Xenon is used is under negative pressure. Air flow rates will be measured with an anemometer semiannually to determine that air flow rates are maintained as described.

HEDRICK MEDICAL CENTER

CHILLICOTHE MO



Scale ¼" = 1'

ITEM 21

SUPPLEMENT

METHOD FOR MONITORING AND EVALUATING 133-XENON COLLECTION AND TRAPPING DEVICES

I. Determine approximate gamma camera efficiency for low energy radionuclides. A 57-Co flood source, while having a somewhat higher energy than 133-Xe, may be used to approximate camera efficiency at this gamma energy range. The efficiency factor for 57-Co (.124MEV) will be lower than that for 133-Xenon (0.081MEV) when counted using similar detector geometries.

A. To determine counting efficiency Fe:

1. With camera detector facing up, place the 57-Co flood source close to the crystal and determine CPM.

2. With no activity in room, determine camera system background.

3. Using the calibration data from the flood source, calculate counting efficiency from:

(1) $$Fe = \frac{\text{Flood CPM-B}_g\ \text{CPM}}{2.22 \times 10^6 \text{DPM/uCi} \times \text{uCi (of flood source)}}$$

II. Using the counting efficiency Fe, we can approximate the number of microcuries present in an unknown sample (such as in a 133-Xe collection bag) that is reasonably close in energy level and counted using similar counting geometry from:

(2) $$\text{uCi} = \frac{\text{net CPM}}{2.22 \times 10^6 \text{ DPM/uCi} \times \text{Fe}}$$

III. To check the efficiency of the 133-Xenon trap, we connect a 10 liter gas collection bag at the exhaust port of the gas trap. When the collection bag fills, it is removed from the gas trap port and the time from the beginning of wash out, until the bag is filled, is noted. Total time of wash out is also noted. The uCi quantity of 133-Xenon in the bag is calculated from formulae (2).

IV. Since we know the assayed amount of 133-Xe administered to the patient, and we have approximated the uCi of 133-Xenon present in the bag, we can approximate the percent of administered dose present in the collection bag from:

$$(3)\quad \frac{\text{uCi in collection bag} \times 100}{\text{uCi administered to patient}} = \%\text{ of gas in bag}$$

To calculate the % of gas escaping from the trap for the entire procedure, one must assume that it is escaping at a uniform rate during trap wash out. If this assumption is made then:

$$(4)\quad \%\text{ of gas escaping} = \%\text{ of gas in bag} \times \frac{\text{Total wash out time}}{\text{Bag filling time}}$$

When the ratio of total wash out time to bag filling time equals 1 then:

% of gas escaping = % of gas in bag.

V. This procedure will be performed initially on the delivery and trapping unit, and as a minimum, on a bi-weekly basis. When our monitoring demonstrates that the trap is less than 90% efficient we will replace the Xenon trap filters.

VI. As an option a 99m-Tc99 flood source will be used which will demonstrate a lower efficiency factor than that of 57-Co. In equation (2) the term 2.22×10^6 DPM/uCi x F_e may be substituted for by expressing this term in CPM/uCi of activity in flood source.

[redacted] No. 7517

Atomlab

INSTRUCTION MANUAL

Model 130-500

PULMONEX XENON SYSTEM

ITEM 21

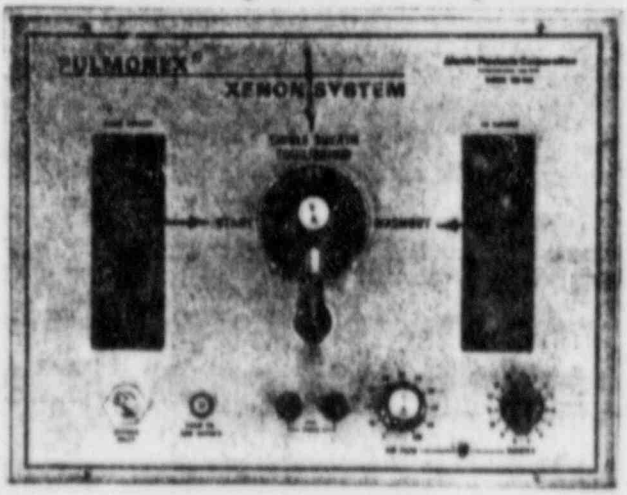
Atomic Products Corporation

Center Moriches, New York 11934, U.S.A.
(516) 878-1074

PULMONEX XENON SYSTEM

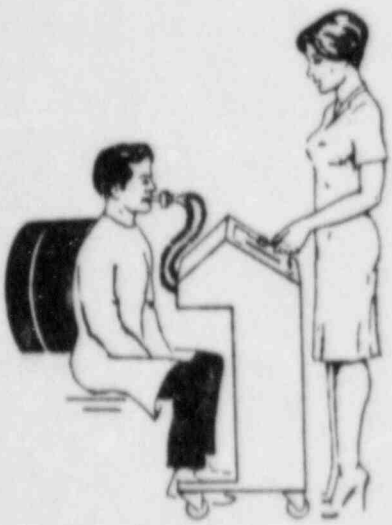
SIMPLE, SAFE OPERATION

There are only three valve positions.



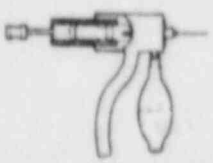
Position 1

Start: Patient breathes room air
System is charged with O_2



Position 2

Single breath and equilibrium imaging.



- This is when you add Xe, either a bolus or a homogeneous mixture.
- An in-line CO_2 filter prevents hyperventilation.
- When the patient equilibrates, switch the handle.

Position 3

Washout

- The patient is now breathing room air from a one-way valve through the delivery system and into the built in Gas Trap. During washout, the Gas Trap is activated. A pump draws the patient's expired breath through a purifying bed of activated charcoal. The Xenon is stripped away and only clean air leaves the Trap exit port.

Atomic Products Corporation

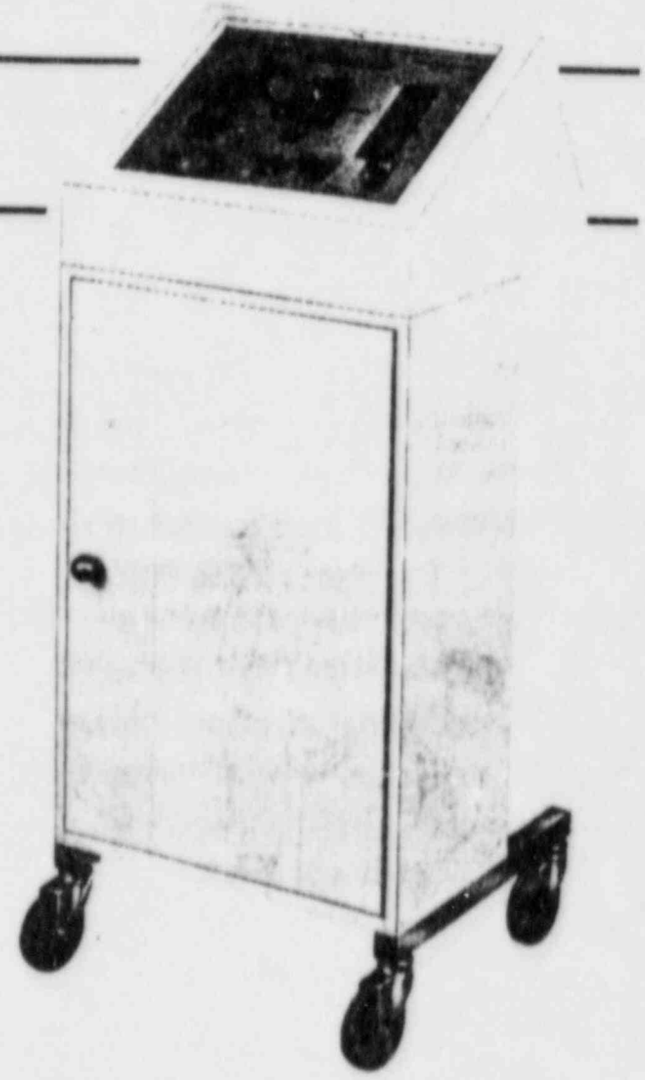
Center Moriches, New York 11934, U.S.A.
(516) 878-1074

breathing.

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

Single handle, 3-position control directs all functions for regional ventilation studies.

SYSTEM



to provide gentle positive system pressure. This, combined with a specially-designed master valve and wide diameter, short circuit airways, provides resistance-free patient breathing. There is no dead air space. An injected bolus of xenon reaches your patient exactly when desired. An in-line CO_2 absorber prevents hyperventilation. The system has automatic timer and pressure control dials to accommodate your patient's breathing pattern and to assure complete system washout into the gas trap.

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

INTEGRATED XENON GAS TRAP

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

Specifications:

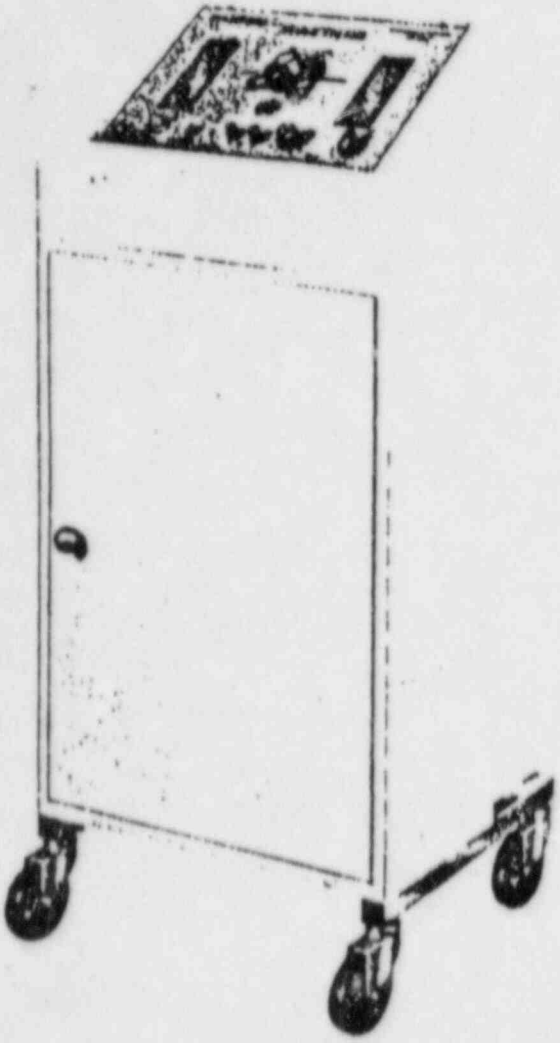
Motor UL approved. 115 VAC, 50/60 Hz.

Size: 18" x 19" x 46"

Weight: 150 lbs.

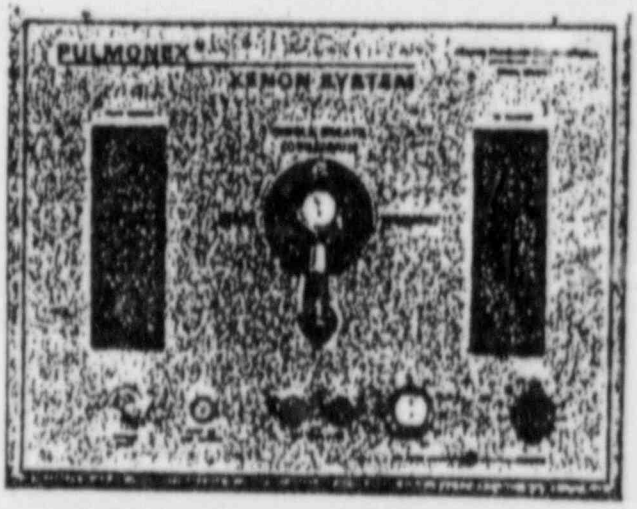
130-500 Pulmonex Xenon System, Complete	**$2725.00**
127-318 Disposable Charcoal Cartridge	**$325.00**
130-550 Disposable Mouthpiece	**$1.95 ea**
130-700 Disposable Bacteria Filter	**$3.00 ea**
139-101 Moisture Absorber (Drierite)	**$7.50 lb.**
130-019 Soda Lime, CO^2 Absorber	**$4.25 lb.**

PULMONEX XENON SYSTEM



COMPLETE XENON DELIVERY SYSTEM
WITH INTEGRATED
XENON GAS TRAP

ALL FUNCTIONS ARE CONTROLLED BY A SIMPLE HANDLE ON THE FRONT PANEL. ALL CONTROLS ARE CLEARLY MARKED FOR EASE OF OPERATION.



Control No. 75177

To thoroughly familiarize yourself with the equipment and methodology, it is suggested that you run through the procedure several times; first without any patient, then with a colleague as a "patient" without actually using xenon. When you are completely familiar with the routine, you can start doing xenon studies on patients with confidence.

FOLLOW THESE SIMPLE STEPS CAREFULLY:

1. Open the top rear door. Inspect the interior. All hoses should be connected to their respective ports. Bags should be lying flat.
2. Open the lower front door. All hoses should be connected to their respective ports.
3. Remove the empty plastic cartridge that hangs from the top of the lower compartment. Fill the cartridge about half way with the blue drierite(139-101) and return the cartridge to the hose fittings. This serves as a moisture trap for the air going into the charcoal cartridge. Close the lower compartment. Replace the drierite when it changes color (from blue to pink). Failure to change the drierite will significantly shorten the life of the charcoal cartridge.
4. Remove the empty plastic cartridge that is within the top compartment. Fill half way with white granule soda-lime (available in your hospital pharmacy or respiratory service department). Return it to the hose fittings. This serves as a carbon dioxide trap. Close the top rear door. Change the soda-lime between each patient. Failure to change the soda-lime will cause the patient to rebreathe too much carbon dioxide, causing hypo-ventilation.
5. Bring the unit to the area of operation. Make sure the timer is on "0" and plug into a nearby electrical outlet.
6. At the rear of the unit, there are two white hose connections, side by side. Attach the breathing tube/bacteria filter/mouthpiece assembly to the hose connections. The plastic plug and warning label *must* be facing up. You can use longer tubes (supplied) for a supine patient. It is advisable to use hose clamps to tighten the hoses to the hose connections. At the rear of the unit, just below the overhang, is the trap final vent. Connect a hose from the trap vent to your room vent as a safety precaution.
7. Attach an oxygen tank to the oxygen inlet port on on the front panel. Clamp a ¼ inch oxygen hose to the port. Turn the oxygen valve to 5 PSI and leave on. Be sure to use only 5 lbs. pressure. Overloading the system with oxygen will pull the interior connections apart. If possible, use a pediatric regulator on the oxygen tank.
8. Position the patient in front of the scintillation camera. Using a source, see that both the lungs are within the crystal area.
9. Set the camera for Xe-133. Record all data on tape.
10. Place the Pulmonex as close to the patient as possible and set the handle to the start position. The number "one" will appear under the handle.
11. Set the air flow control to seventy (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).
12. Set the timer at 9 minutes (an arbitrary figure that can be changed at any time depending on the study procedure you prefer).
13. Place the mouthpiece in the patient's mouth. Clip the patient's nose closed. Place a vertex cape on the patient.
14. Have the patient take a few breaths to become accustomed to breathing with a mouthpiece. Observe that the "from patient" bag will move slightly as the patient exhales.
15. Press the button on the front panel to add oxygen to the "to patient" bag. Only add a small amount of oxygen. Hold the button for a second or, at the most, two seconds. (The bag will only move slightly, do not fill it up). More oxygen can be added later if the patient requires. In many cases, it is possible not to add any oxygen and perform the entire study on ambient air. In all cases, the oxygen is only to enrich the air in the circuit.
16. Switch the handle to Single Breath, Equilibrium #2. With a NEN Gun or syringe filled with xenon, puncture the mouthpiece with the needle and add the xenon as you have the patient take a deep inspiration. Have the patient hold his breath for as long as possible and then continue to breathe normally. Advise the patient to breathe slowly and normally. Observe both breathing bags moving through the front panel windows. Add oxygen if the patient requires it. An alternative to puncturing the mouthpiece is to use the luer adapter plug provided.
17. When the patient reaches equilibrium (1 or 2 minutes, the counting rate on the camera stabilizes), switch to washout, #3. Take washout data on the camera (typical framing: first picture, 15 seconds; second, 30 seconds; third 60 seconds). Have the patient breathe normally slowly.
18. Carefully watch the "from patient" bag. If it blows up tight, the patient is breathing too fast. Advise him to normalize his breathing and increase the air flow speed. If the bag continues to expand against the glass, the patient will feel back pressure and resistance. To relieve this effect, open the lower cabinet. On the upper side there is a motor control. Turn it clockwise until the breathing bag becomes more flacid. Return the control to about ⅓ of its range. The use of the motor control will be a rare occurence. Do not adjust it unless it is absolutely necessary. If it is used, be sure to return it to its original position. To be effective, the increase in motor speed must be done immediately, so watch the "from patient" bag carefully during washout.
19. When the washout is complete, remove the patient and let the system run for a few more seconds or until both bags are empty.

October 12, 1982

Mr. Gary Redmore
Pharmatopes, Inc.
3402 Butler Street
Pittsburgh, Pa. 15201

Dear Mr. Redmore:

I received a note this morning from our Q.C. Manager, Jim Weston stating that he had spoken with you on the telephone. As I understand it, you require information on NEN's product Xenon to perform calculations for hood exhaust dilutions.

The maximum limit of SS/NDA of Xenon leakage rates is 0.5%/vial/day. This figure, however, is usually much lower.

Should you desire any additional information please feel free to give us a call.

Thank you.

Very truly yours,

NEW ENGLAND NUCLEAR CORP.

Pam Ducharme

Pam Ducharme
Technical Service

PD/

cc: G. Jones, Jr.
J. Weston
S. Flint

APPENDIX A

CORPORATE ALARA PROGRAM

November 28, 1980

I. Management Commitment

a. We, the management of Mobile Medical Services are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable. To achieve the concept set forth under the (ALARA) program, the policies setting standards and governing body are described herein.

b. We will perform a formal annaual review of the radiation safety program including ALARA recommendations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the Radiation Safety Staff which includes the Radiation Safety Medical Officer and Health Physicist Consultant -- who will be described later in detail.

c. Those modifications needed to improve the ability to implement the ALARA program will be made unless the cost, in our judgement, is prohibitive. We will be prepared to demonstrate improvements made, and show just cause for not implementing modifications thought unreasonable.

d. The purpose of our adhering to the ALARA concepts is to protect all persons, singly and collectively, by limiting their exposure to the lowest practicable level.

Radiation Safety Staff:

Because of the nature of our mobile nuclear medicine type service it is important to maintain two types of Radiation Safety Officers, which we designate as the "Radiation Safety Staff". This staff is composed of a Nuclear Medicine Physician and Consultant Health Physicist. These individuals will be referred to collectively as the RSS (Radiation Safety Staff). The medical officer will be referred to as the RSMO (Radiation Safety Medical Officer). The Health Physicist Officer will be referred to as the RSPO (Radiation Safety Physicist Officer).

II. Radiation Safety Staff (RSMO and RSPO)

a. Review of Proposed Users and Uses

1. The RSMO will review the qualifications of each applicant with respect to the types and quantities of materials and uses for which is applied to assure that appropriate measures are maintained to continue exposure ALARA.

2. When considering a new use of byproduct material, the RSMO will review the procedure to maintain exposure ALARA. The user will be guided by procedures to ensure ALARA, which incorporates the use of syringe shields, rubber gloves, etc. in the proposed use.

3. The RSMO will ensure that each user justifies their procedures and that the dose will be ALARA.

b. Delagation of Authority

1. The RSMO has full and final authority in the enforcement of the ALARA concept.

2. The RSPO will support and recommend procedures to carry out this concept in an advisory capacity. It is recognized that the RSPO (health physicist) is closer to many of the changing health safety procedures relative to equipment and new byproduct uses.

c. Review of the ALARA Program

1. The RSS will encourage all users to review current procedures and develope new procedures to implement the ALARA concept.

2. The RSPO will perform quarterly review of occupational radiation exposure with attention to instances where Investigational Levels in Table I are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to report to the RSMO for action, if warrented, when Investigational Levels are exceeded.

3. The RSS will evaluate our companies overall efforts for maintaining exposures ALARA on an annual basis. This review will include all authorized users, and workers as well as those of management.

III. Radiation Safety Staff Officers (RSS)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSMO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts.

2. Quarterly review of Occupational Exposure. The RSPO will review quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSPO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for the ALARA Program

1. The company management will inform users and workers of the ALARA program efforts.

c. Cooperative Efforts for Development of ALARA Procedures

1. The RSPO and management will be in close contact with all users and workers in order to develope ALARA procedures for working with radioactive materials.

2. The management will relly on ideas and recommendations from the RSPO (health physicist) because of their eduaction expertise and their ability to draw from ideas from other similar programs they're exposed to.

3. The RSPO will recommend changes in the ALARA program if a breakdown of good safety practices occurs. It will be the responsibility of management to correct the problem and report to the RSPO when the correction has been made.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with and receive approval of, the RSS during the planning stage before using radioactive materials for a new procedure.
This will be implemented through management -- because of the makeup of a mobile service, and its multiple users, all procedures are offered through management. There is continual contact between management and the users.

b. Responsibility of the Authorized User

1. The authorized user or (Mobile Service Management, the RSMO) will explain the ALARA concept and our commitment to maintain exposures ALARA to all those they supervise.

2. The authorized users will ensure that those under their supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he or she feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This company hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Staff or Radiation Safety Officer. The investigational levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

Table 1

		Investigational Levels- (mrems per calander quarter) LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body (applicable to beta emitting isotopes)	750	2250

The Radiation Safety Physicist will review the dosimeter processor's report of occupational external radiation exposure, not less than once in any calender quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSMO, no further action will be taken when an individual's exposure is less than Table 1 values for Level 1.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSPO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews to the RSMO (Radiation Safety Medical Officer) following the quarter the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSS (Radiation Safety Staff). The RSS will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review.

c. Exposure equal to or greater than Investigational Level II.

The RSPO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, action taken, if any, will be given to the RSMO following the investigation. The investigation and action taken will be made available to NRC inspectors for review at the time of the next inspection.

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VII. Signature of Certifying Official

I hereby certify that this Mobile Medical Service has implemented the ALARA Program set forth above.

Signature

William H. Voss, D.O.
Radiation Safety Officer

Signature

Delbert L. Roberts, C.N.M.T.
Mobile Medical Services, Management

APPENDIX B

Mobile Van, Nuclear Medicine Program

This application is for Nuclear Medicine Laboratories to support a mobile van system. These facilities will offer diagnostic nuclear medicine procedures to those hospitals which have granted approval for the use of these services at their institution. In support of this application, the following information is submitted:

1. The overall operation of the mobile nuclear van will be under the supervision of the nuclear medicine physician, named in Item I, NRC-313. On-site nuclear medicine physicians will approve the patients for radiopharmaceutical administration, prescribe the type of radionuclide and dosage to be administered, and interpret the results of diagnosis. A nuclear medicine physician will be on-site at the times the radiopharmaceuticals are administered.

2. All preparatory functions will be performed at the Nuclear Medicine Laboratory satellite facilities.

   99m-Tc generator elution, kit preparation, quality assurance testing and assay will occur at this site. Based on scheduled examinations, anticipated time of administration and radiopharmaceuticals necessary, each day doses will be prepared. These doses will be ready for use (dispensing or injection) at the hospital visited, thereby eliminating the necessity for further handling.

3. Packaging of radiopharmaceutical material for transport by van to the hospital will be as follows:

   a. The radiopharmaceutical will be placed in dose containers.

   b. These containers will be placed in packaging for which DOT Type A specification testing has been performed. A copy of this type of specification testing will be maintained on file at our Jefferson City office.

   c. All labeling requirements set forth by DOT and NRC will be met.

   d. All dose syringes and vials will be returned to their dose shield, sealed and placed in the above described packaging. This material will be returned to the satellite facility for storage until it can be disposed of.

The nuclear mobile van service will offer much needed diagnostic nuclear medicine studies to hospitals located in rural areas of of central Missouri. Only patients who have been referred to the nuclear medicine physician by their attending physician will receive these studies. Consultation forms will be supplied to the hospitals for use by the attending physicians. Patients will be scheduled for their examinations through the satellite facility. After preparation of the necessary radiopharmaceuticals the imaging equipment and dose material will be transported to the member hospital, or hospitals, for the performance of the test. Copies of all consultation forms as well as patient reports will be kept on file at the member hospitals.

A portable imaging system, survey instruments, dose calibrator, handling tray with obsorbent paper, syringe shields, rubber gloves, radiopharmaceuticals, etc. will be transported from the satellite facility to the member hospital. This will be a customized van specifically designed for the safe transport of the mobile imaging system. The mobile camera will be loaded on the van utilizing a ramp with guiding tracks which are contiguous with tracks mounted in the floor of the van. Although the camera will be self-powered, a safety winch will be mounted in the front of the van and attached to the mobile camera to ensure against accidental release of the imaging system which might cause damage to the camera or injury to the technologist. The camera while loaded in the van during transport will be securely locked in a fixed position. Prior to use for examinations at each site the following test will be performed on the camera to insure that the unit is functioning properly and that the best possible diagnostic information can be obtained from the system. If these procedures demonstrate that the equipment is not functioning properly, then all exams scheduled will be cancelled until the system is repaired.

Quality Assurance Test: Mobile Camera and Dose Calibrator

1. Energy dial calibration.

   a. This will be done with the isotope of use for each specific examination.

2. Field flood.

   a. This will be done with a Co-57 field flood source both with the collimator off and on the unit.

3. Bar phantom resolution check.

   a. This will be done with Co-57 flood source and appropriate bar phantom.

4. Perform daily constancy check prior to use, using Co-57 and 137-Cs standard in accordance with procedure listed in Item 10, Appendix D.

The following Radiation Safety Plan is supplied to each member hospital:

Radiation Safety Plan:

1. _____ Hospital will designate one room for use by the nuclear medicine service for the handling, administration, and performance of the diagnostic study.

2. Diagnostic quantities of radiopharmaceuticals will be administered in this room only by the Nuclear Medicine Technologist or the Nuclear Medicine Physician.

3. A handling tray with absorbent paper will be supplied by the nuclear medicine service for handling dose materials. All materials will be removed from their dose shields in this tray and placed in syringe shields, when necessary, for administration. Disposable gloves will be worn at all times while handling and administering radioactive doses.

4. After administration of patient dose, the empty syringe will be returned to the syringe shield which will be sealed and returned to the carrying case.

5. A survey with a low level survey meter will be performed by the Nuclear Medicine Technologist of: a. The tray and absorbent paper, b. the cot, chair, etc., where the dose was administered, c. the general room area.

6. Place all materials used for administration, into the small labeled plastic bag provided for return to the Jefferson City laboratory. This would include such items as cotton pledgets, extra needles, if one was used, etc.

7. At the conclusion of the days work, a general survey of the room area will be performed.

8. Document this information on the form provided.

A form will be provided by the nuclear medicine service which will be given to the member hospital certifying that the designated room has been cleaned and surveyed. This form will be signed by the Nuclear Medicine Technologist upon completion of the survey, and will indicate that this room may be used for general patient care, etc. All materials will be removed from the institution upon completion of the service.

[redacted] No. 75177

APPENDIX B