FORM NRC-313M
(8-78)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved:
GAO R0557

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a 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

Citizens General Hospital
651 Fourth Avenue
New Kensington, Pa. 15068

TELEPHONE NO.: AREA CODE (412) 337 - 3541

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

6972/ #150 tr/c
Renewal
1/28/85
Brown

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ronald J. Clearfield, M.D.

TELEPHONE NO.: AREA CODE (412) 337 - 3541

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 37 09016 01

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

Ronald J. Clearfield, M.D.
Frank D. Harrison, M.D.
Walter N. Zuck, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Ronald J. Clearfield, M.D.
Director, Department of Radiology

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	40 mCi
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	2000 mCi
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	—	—

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	10 mc.
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	25 mc.
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50 mc.
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	300 mc.
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	150 mc.
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	100 mc.

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

8511180765 850916
REG1 LIC30
37-09016-01 PDR

1985 JAN 13 PM 2:30

"OFFICIAL RECORD COPY"

21 JAN 1985
0333:19

Date 1/28/85
Jan 14
Brown
2/22/85

Applicant
Check No. 69832/rc
Amount, Fee Category #130, ML1D
Type of Fee Renewal
Date Check Received 2/22/85
Received By Brown

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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		**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*	
X	Names and Specialties Attached; and see page 5	X	Appendix G Rules Followed; or see page 18
X	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or see page 19
X	Statements of Qualifications Attached for Each Individual User; and see page 7		Equivalent Procedures Attached
	Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*	
9. INSTRUMENTATION *(Check One)*		X	Appendix I Procedures Followed; or see page 20
X	Appendix C Form Attached; or see page 8		Equivalent Procedures Attached
	List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or see page 21
X	Appendix D Procedures Followed for Survey Instruments; or see page 9 *(Check One)*		Equivalent Information Attached
	Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	X	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		**20. THERAPEUTIC USE OF SEALED SOURCES**	
X	Description and Diagram Attached see page 14	N/A	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached see page 15		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon -- 133)**	
X	Detailed Information Attached see page16	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**	
		N/A	Detailed Information Attached
X	Appendix F Procedures Followed; or see page 17	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**	
	Equivalent Procedures Attached	N/A	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer	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: 3-B

(2) LICENSE FEE ENCLOSED: $ $150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Robert E. Marino

(1) NAME *(Type or Print)*
Robert E. Marino

(2) TITLE
Executive Director

c. DATE
January 10, 1985

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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 Form NRC-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.

RADIATION SAFETY/Medical Isotopes Committee

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;

2. the hospital administrator, or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;

3. a physician* specialist from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

APPENDIX B

MEDICAL ISOTOPES COMMITTEE*

Responsibility

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

* A rule is expected in 1981 that would change the name, composition, and functions of this committee.

The following users:
Ronald J. Clearfield, MD
Frank D. Harrison, MD
Walter N. Zuck, MD
are listed on current NRC License NO.37-09016-01 for this institution. No new names have been added.

APPENDIX C

INSTRUMENTATION

1. Survey Meters

a. Manufacturer's Name: Victoreen

Manufacturer's Model Number: 00858

Number of Instruments Available: 1

Minimum Range: 0 mr/hr to 300 c/minute mr/hr

Maximum Range: 0 mr/hr to 0.5 mr/hr

b. Manufacturer's Name: Baird-Atomic Inc.

Manufacturer's Model Number: 414

Number of Instruments Available: 1

Ranges: _____

Minimum Range: 0 mr/hr to 1,000 mr/hr

Maximum Range: 0 mr/hr to 3,000 mr/hr

2. Dose Calibrator

Manufacturer's Name: Radex

Manufacturer's Model Number: 4196-72DT

Number of Instruments Available: 1

3. Diagnostic Instruments

Type of Instrument	Manufacturer's Name	Model No.
Well Counter	Searle	40-88, 33-13, 49-26, 54-7
Thyroid Uptake Machine	Searle	8725
Micro Dot	Searle	00-003132
Gamma Camera	Searle	000-080077-007
Gamma Console	Searle	000-070024-029

APPENDIX C

INSTRUMENTATION

1. Survey Meters

a. Manufacturer's Name: Heath Company

Manufacturer's Model Number: RC-1

Number of Instruments Available: 1

Minimum Range 0 mr/hr to .1 mr/hr

Maximum Range 0 mr/hr to 600 mr/hr

b. Manufacturer's Name: Victoreen Instruments

Manufacturer's Model Number: 120085

Number of Instruments Available: 1

Ranges: 0-5 r/hr

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

_____ 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

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

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

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

or

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

X c. By a consultant or outside firm

(1) Name Andrew G Bukovitz, CRP

(2) Location Pittsburgh, PA

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. _____

_____ 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.

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

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

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CALIBRATION OF SURVEY INSTRUMENTS

A. Sources

1. ICN Model CCSD-20E Irradiator containing 19.4 curies ^{137}Cs (as of 5/30/73), source W-748.
2. 62.8 millicurrie sealed ^{60}Co as of 11/16/77 (no model or number).
3. 9.9 ± 0.7% milligram sealed ^{226}Ra needle, NBS #47428 - 11/11/71

B. Traceability - Source Outputs

The radium needle is directly traceable to NBS

The exposure rate from the gamma source is measured at known distances using Victoreen Model 570 Condenser R-Meter and appropriate R-Chambers which are NBS traceable by calibration at Victoreen's Regional Calibration Facility in Cleveland, Ohio. Distance versus MR/hr curves are plotted periodically to account for slight decay and to insure repeatability. These curves are used on a day-to-day basis for routine calibrations.

C. Procedures Checks

1. Inspect or clean battery contact.
2. Check all battery for correct voltage.
3. Inspect cable and cable connecters.
4. Determine plateau region for detector..
5. Check high voltage for correct operating point.

D. Calibration Method

Instruments are normally calibrated to manufacturers instructions. Typically the instrument is placed in a known field of radiation which approximates mid-range of slightly above and the meter is adjusted to within ± 10%. Then as a final linearity check, 2 points at approximatel 1/3 and 2/3 full scale for each range are checked for exposure rate readings at known exposure rate distances. When meter reading versus true reading exceeds ± 20% the cause is investigated and instrument repair is possible.

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.

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:

Item 10 continued

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* 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 semi-log corrdinate paper, plot the measured net activity and the calculated activity versus time.

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 2.08, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

$$\text{4 ml Volume CF} = \frac{2.00}{2.04} = 0.95$$

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.

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The activity levels of 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.

item 10
-cont-
page 13

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).

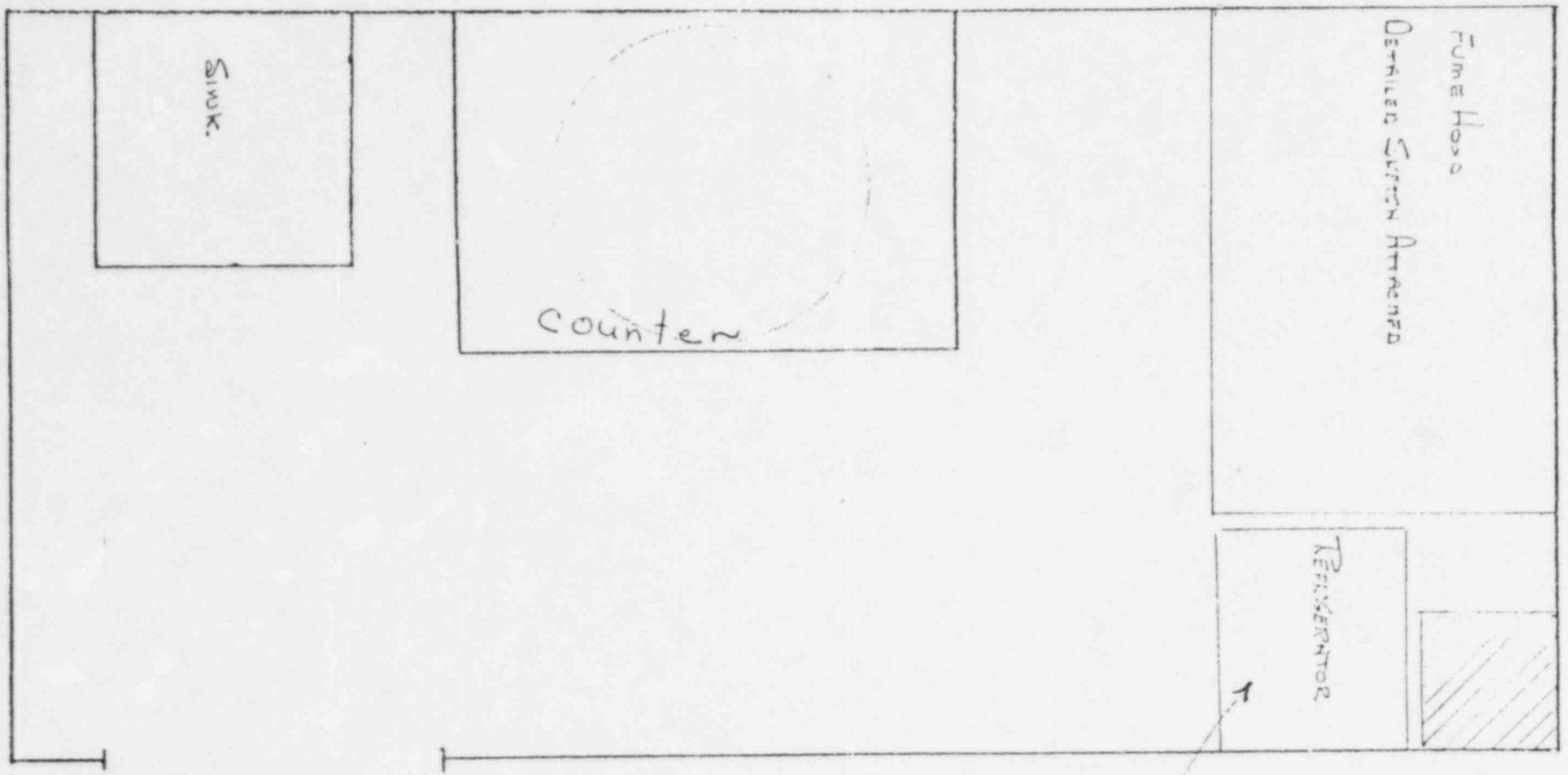
c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be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

To insure that radiation levels in unrestricted areas do not exceed the limits specified in paragraph 20.105 (b) of 10 CFR 20, these areas have been surveyed over a period of time with a GM survey meter during normal operations of the Nuclear Medicine Department.

Radiation levels have been background (~0.01 mR/hr) or no more than 2 times background.



All Refrigerated Radio-pharmaceuticals stored in Pb. Vial Shields & Covered with ¼" Pb. Doors.

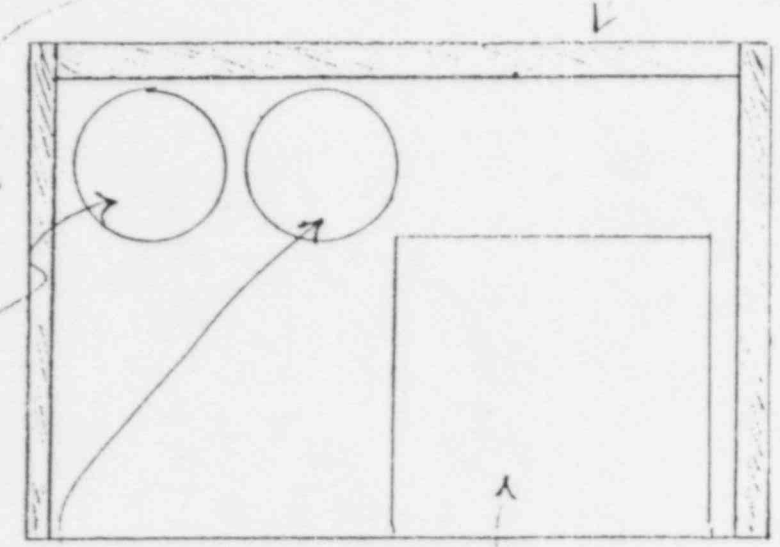
NIGHT

DEPARTMENT OF RADIOLOGY
"CITIZENS GENERAL HOSPITAL"
NEW KENSINGTON, PA.

Item 11
Dacc. 1440

FUME HOOD:

LEAD SHIELDING 2" THICK - 12" H:N



Tc^{99m} GEN. STORAGE
9" DIA. 1" THICK - PB.
(if generator will be used)

USED SYRINGE STORAGE
PB. 7" DIA ½" THICK

"L" BLOCK 16½ W - 19½ L - 13½ H 2" THICK
PB. GLASS WINDOWS 6" x 9" x 2"

EXHIBIT A

DEPARTMENT OF RADIOLOGY
"CITIZENS GENERAL HOSPITAL"
NEW KENSINGTON, PA.

Item 11
Page 14c

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. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

APPENDIX E

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.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request* will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

*In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE** MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: Hospital Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged immediately contact the Radiation Safety Officer. Ask the carrier to remain until it can be dtermined that neither he nor the delivery vehicle is contaminated.

**RADIATION SAFETY OFFICER _____

**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 (e)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Te-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 and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions 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.

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

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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 generater, 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 informat 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.

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* 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)

Y — 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.

APPENDIX K

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS*

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The materia will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions

    a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.

    b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

    d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

    e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

    f. Attending personnel should wear rubber or disposable plastic gloves when handling urine

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* Be sure to submit a complete response to Item 19b in addition to referencing procedures in Appendix K.

any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

[illegible] will be used by patients who are treated with I-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

l. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

Date _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name _____

Room No. _____ Physician's Name _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all checked items)

_____ 1. Visiting time permitted: _____

_____ 2. Visitors must remain _____ from patient.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 are not permitted.

_____ 5. Pregnant visitors are not permitted.

_____ 6. Film or TLD badges must be worn.

_____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.

_____ 8. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 9. Disposable gloves must be worn while attending patient.

_____ 10. Patient must use disposable utensils.

_____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.

_____ 12. Smoking is not permitted.

_____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

_____ 14. Other instructions.

In case of an emergency contact:

RSO _____

Name On-duty/Off-duty Telephone Numbers

NOTE:
THERE HAVE BEEN NO CHANGES IN THE LAYOUT OF THE NUCLEAR MEDICINE AREA OR IN THE USE OF XENON-133 SINCE THE USE OF XENON-133 WAS APPROVED BY THE NRC FOR THIS FACILITY.

THE FOLLOWING INFORMATION WAS THAT ORIGINALLY SUBMITTED AND IS INCLUDED FOR THE SAKE OF COMPLETENESS.

Item #21 Radioactive Gases (Xenon-133)

A. Quantities to be Used

1. Patient information

a. Four studies per week
b. Ten millicuries X-133 per exam

2. Desired Posession limits

a. One Hundred Millicuries

B. Use and Storage Areas

1. See drawing of area

2. Ventilation indicated on drawing

3. Room is under negative pressure

C. Procedures for Routine Use

1. All Xenon-133 ventilation studies are performed using the Xenon ventilation study system supplied by:

Medi Physics, Inc.
5801 Christie Ave.
P.O. Box 8684
Emeryville, California 94608

2. Breathing Bay is contained in lead lined shielding unit supplied by Medi Physics; Model #5029. (Picture enclosed)

3. Nose clamps and/or total face mask used to minimize leakage

D. Emergency Procedures

1. Evacuate area

2. Provide more adequate ventilation to increase negative pressure of room

E. Air Concentrations of Xenon-133

1. Maximum amount of activity used per week: approx. 50 mci

2. Estimate of Xenon lost during use and storage: approx. 20%

3. Air flow--minimum available 180 cfm

4. Air flow--minimum required 15 cfm

F. Methods of Disposal

1. Through Exhaust System

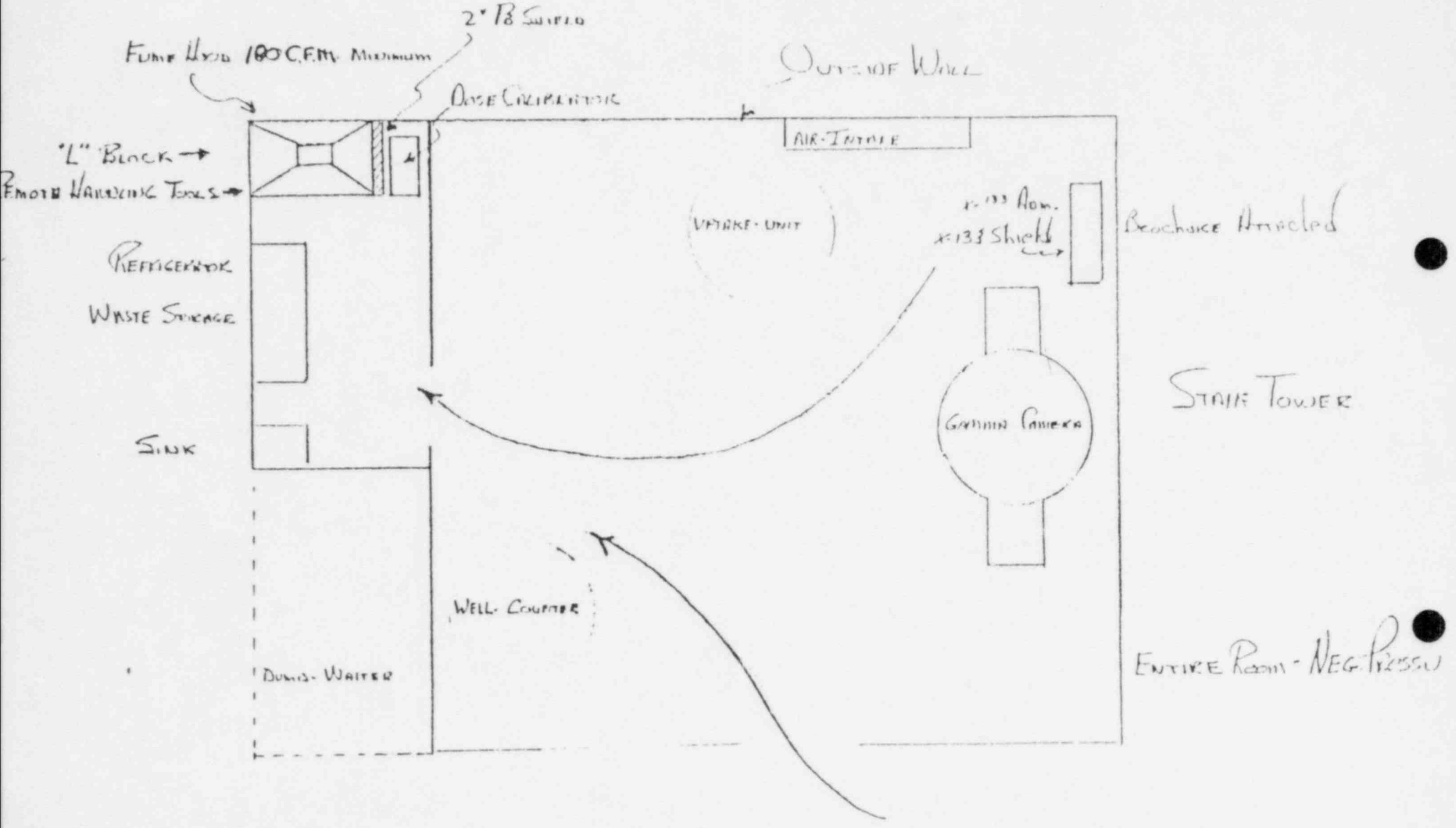
a. Maximum amount released per year is approx. 2.08×10^{6} uci/yr

b. Flow rate of hood approx. 180 cfm min.

c. Air flow per year 2.68×10^{12} ml/yr

d. Average Concentration

$$C = \frac{A}{V} = \frac{2.08 \times 10^{6}}{2.68 \times 10^{12}} = 0.07 \times 10^{6} \text{ uci/ml}$$



11-15-78

DEPARTMENT OF RADIOLOGY
"CITIZENS GENERAL HOSPITAL"
NEW KENSINGTON, PA.

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Scale: ½" = 1'

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DEPARTMENT OF RADIOLOGY
"CITIZENS GENERAL HOSPITAL"
NEW KENSINGTON, PA.

Item #1
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X-ray
Radiation Shield
Medi Physics

3. Following either 2(a) or 2(b), instruct the patient to take a single, smooth, deep breath through the mouthpiece and hold it.
4. Start scintigraphy while the patient is holding his breath.

Rebreathing

5. When single breath scintigraphy is complete, instruct the patient to breathe back-and-forth through the mouthpiece for at least one minute.
6. Have the patient inhale and hold his breath while a second scintigram is taken.

Washout

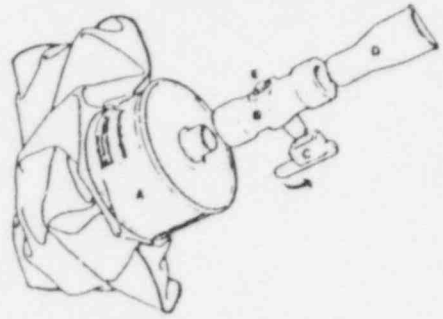
7. When scintigraphy is complete, instruct the patient to inhale room air deeply and exhale into the mouthpiece. Continue this washout procedure over a period of four to five minutes while taking sequential scintigrams.
8. Turn the Key 90° to close off the Xenon 133-V.S.S.
9. Dispose of the system in an appropriate manner.

These instructions may be modified to allow other types of studies.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of the radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Xenon Xe 133-V.S.S. (Ventilation Study System)
XENON Xe 133 Diagnostic

FIGURE I—ASSEMBLY OF XENON 133 VENTILATION STUDY SYSTEM (V.S.S.)



1. Remove the components from the shipping container. These components are:
   A—Breathing-collection bag with attached CO_2 absorber canister.
   B—Xenon 133 in a valve-shield with end plugs.
   C—Key.
   D—Disposable mouthpiece.
2. Remove the red cap from the CO_2 absorber canister.
3. Use the Key to remove the end plugs on the valve shield.
4. Attach either end of the valve-shield to the canister.
5. Wedge the mouthpiece into the other end of the valve-shield.
6. Place the Key on the fitting of the valve-shield. Do not turn the Key.
7. The Ventilation Study System is now ready for use.*

*In the event that the Key is difficult to turn when the system is in gently tap the retainer ring (E).

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RADIATION DOSIMETRY

The estimated absorbed radiation doses* to an average adult (70 kg) and ten-year old child (31.8 kg) for a single breath study using 10 mCi and an equilibrium breathing study using 20 mCi are shown in Table III.

Table III. Estimate of Radiation Absorbed Dose for Xenon 133 (in rads)

	SINGLE BREATH (10 mCi held for 30 seconds followed by washout)		EQUILIBRIUM BREATHING (20 mCi in 2 liter spirometer for 4 minutes followed by washout)	
Organ	Adult	Child	Adult	Child
Lung	0.050	0.1	0.300	0.36
Total Body	0.0002	0.001	0.0008	0.002
Ovaries	0.00008	0.0001	0.0001	0.0002
Testes	0.000008	0.00008	0.00002	0.0001

*Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, J. Nucl. Med. p. 7, 1968.

HOW SUPPLIED

Each Ventilation Study System (V.S.S.) contains Xenon 133 in a sealed plastic tube containing 10 mCi ± 20% at calibration time and date as stated on the label.

Xenon Xe 133-V.S.S. (Ventilation Study System)
XENON Xe 133 Diagnostic

The sealed plastic tube is enclosed in a metal valve shield which is sealed with a plastic shrink band to prevent accidental loss of Xenon 133 during shipping. A Key is provided to remove the end plugs of the valve shield and to turn the valve fitting which breaks the sealed plastic tube. The V.S.S. also includes a disposable mouthpiece and a breathing collection bag with an attached CO_2 absorber canister.

8/Jan /77

Xenon Xe 133-V.S.S. (Ventilation Study System)

XENON Xe 133
Diagnostic

MEDI-PHYSICS, INC.
5801 Christie Avenue
P.O. Box 8004
Emeryville, California 94608

1014

Printed in U.S.A.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS

Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

DOSAGE AND ADMINISTRATION

The recommended activity range for pulmonary ventilation studies in the average patient (70 kg) is 2 to 20 mCi (0.03 to 0.3 mCi/kg).

In order to assay the activity of the Xenon Xe 133 prior to patient administration, carefully remove the screen plug from one end of the valve-shield (B of figure I) and shake out the plastic capsule, using adequate radiation protection techniques. The capsule of Xenon Xe 133 can then be assayed in a precalibrated ionization chamber.

PREPARATION FOR USE

- Assemble the Xenon 133-V.S.S. as shown in Figure I.
- Place the breathing-collection bag in a suitable radiation shield.

Xenon Xe 133-V.S.S. (Ventilation Study System)
XENON Xe 133 Diagnostic

- Instill approximately 500 ml of medical grade oxygen in the bag through the CO_2 absorber canister for each minute of anticipated rebreathing time.
- Seat the patient with his back against the face of the collimator of a scintillation camera, positioned to allow imaging of the desired portion of the lungs. When a diverging collimator is used, position the patient so that both lungs are in field view.
- Clamp the patient's nose.

USE OF SYSTEM

When the Key is initially turned 180°, the plastic container of xenon is broken, and the gas is released into the system. In the event that the Key is difficult to turn, gently tap the retainer ring (Figure I, E). When the Key is turned 90°, the system is closed.

Instructions are given below for single breath study followed by a rebreathing study and a washout study.

Single Breath

1. Have the patient breathe normally through the mouthpiece.
2. (a) For a sharp dose, have the patient exhale completely and hold his breath. Turn the Key 180°.
   (b) For a diffuse dose, have the patient inhale through the mouthpiece and hold his breath. Turn the key 180°. Instruct the patient to exhale maximally through the mouthpiece.

Item 21
Page 34

DESCRIPTION

The Xenon Xe 133 Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 mCi ± 20% of Xenon 133 gas at calibration time and date with less than 1% carrier Xenon in air. Xenon Xe 133 is produced by fission of Uranium-235. It is chemically and physiologically related to elemental xenon, a non-radioactive mono-atomic gas which is physiologically inert except for anesthetic properties at high doses.

Physical Characteristics

Xenon Xe 133 decays by beta emission with a physical half-life of 5.31 days[1]. Photons that are useful for detection and imaging studies are listed in Table I.

Table I. Principal Radiation Emission Data

Radiation	Mean Percent per Disintegration	Mean Energy (keV)
Beta-3	98.30	100.8
Gamma-2	36.03	80.9
K int. con. electrons, gamma-2	52.61	45.0
L int. con. electrons, gamma-2	8.48	75.8
K α_2 rays, alpha	38.73	30.8
K α_1 rays, beta	8.62	35.4

[1]Lederer, C. M., Hollander, J. M., Perlman, I., Table of Isotopes, 6th Ed., John Wiley & Sons, Inc., New York, 1967.

[2]Johnson, L. T., Von der Lage, F. C., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, MIRD Pamphlet No. 10, Soc. Nucl. Med., (10): 5 p. 83.

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals before and after the date of calibration are shown in Table II.

Table II. Physical Decay Chart, Xenon Xe 133, half life 5.31 days

Days	Fraction Remaining	Days	Fraction Remaining
−4	1.686	9	0.309
−3	1.479	10	0.271
−2	1.298	11	0.238
−1	1.139	12	0.209
0*	1.000	13	0.183
1	0.878	14	0.161
2	0.770	15	0.141
3	0.676	16	0.124
4	0.593	17	0.109
5	0.521	18	0.095
6	0.457	19	0.084
7	0.401	20	0.073
8	0.352	21	0.065

*Calibration day

External Radiation

The specific gamma ray constant for Xenon Xe 133 is 0.58 R/mCi/hr at 1 cm. The first half value layer is 0.04 mm of Pb.

CLINICAL PHARMACOLOGY

Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes, freely exchanges between blood and tissue, and tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations recommended for diagnostic studies, it is physiologically inactive. Inhaled Xenon Xe 133 gas will enter the alveolar wall and enter the pulmonary venous circulation via the capillaries. Most of the Xenon Xe 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS AND USAGE

Study of pulmonary ventilation.

CONTRAINDICATIONS

None known.

WARNINGS

Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus.

There are no well-controlled studies in pregnant women which would allow any conclusions as to the safety of Xe 133 for the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

PRECAUTIONS

Xenon Xe 133 as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leak proof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ITEM #21

PROCEDURES FOR ROUTINE USE.

(XENON XE 133 DIAGNOSTIC)

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DESCRIPTION The Xenon Xe 133 Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 millicuries ± 20% of Xenon 133 gas at calibration time and date with less than 1% carrier Xenon in air. Xenon Xe 133 is produced by fission of Uranium 235. It is chemically and physiologically similar to elemental Xenon, a non-radioactive monoatomic gas which is physiologically inert except for anesthetic properties at high doses.

Physical Characteristics

Xenon Xe 133 decays by beta emission with a physical half-life of 5.31 days. Photons that are useful for detection and imaging studies are listed in Table I.

Table I. Principal Radiation Emission Data

Radiation	Mean Percent per Disintegration	Mean Energy (keV)
Beta 3	99.3[illegible]	100.6
Gamma 2	36.0[illegible]	80.9
K int. con. electron, gamma 2	52.61	45.0
L int. con. electron, gamma 2	8.48	75.6
K x-rays, alpha	38.7[illegible]	30.8
K x-rays, beta	8.62	35.4

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals before and after the date of calibration are shown in Table II.

Table II. Physical Decay Chart: Xenon Xe 133, half-life 5.31 days

Days	Fraction Remaining	Days	Fraction Remaining
-4	1.686	9	0.309
-3	1.479	10	0.271
-2	1.298	11	0.238
-1	1.139	12	0.209
0*	1.000	13	0.183
1	0.878	14	0.161
2	0.770	15	0.141
3	0.676	16	0.124
4	0.593	17	0.109
5	0.521	18	0.095
6	0.457	19	0.084
7	0.401	20	0.073
8	0.352	21	0.065

*Calibration day

External Radiation

The specific gamma ray constant for Xenon Xe 133 is 0.56 R/millicurie-hr at 1 cm. The first half value layer is 0.0[illegible] mm of Pb.

CLINICAL PHARMACOLOGY Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes, freely exchanges between blood and tissue, and tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations recommended for diagnostic studies it is physiologically inactive. Inhaled Xenon Xe 133 gas will enter the alveolar wall and enter the pulmonary venous circulation via the capillaries. Most of the Xenon Xe 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS AND USAGE Study of pulmonary ventilation.

CONTRAINDICATIONS None known.

WARNINGS Xenon Xe 133 should not be administered to children or to patients who are pregnant or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus.

There are no well-controlled studies in pregnant women which would allow any conclusions as to the safety of Xe 133 for the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

PRECAUTIONS Xenon Xe 133 as well as other radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leak-proof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

DOSAGE AND ADMINISTRATION The recommended activity range for pulmonary ventilation studies in the average patient (70 kg) is 2 to 20 millicuries (0.03 to 0.3 millicuries/kg).

In order to assay the activity of the Xenon Xe 133 prior to patient administration, carefully remove the screw plug from one end of the valve shield (B of Figure 1) and shake out the plastic capsule using adequate radiation protection techniques. The capsule of Xenon Xe 133 can then be assayed in a precalibrated ionization chamber.

PREPARATION FOR USE

- Assemble the Xenon 133-V.S.S. as shown in Figure 1.
- Place the breathing-collection bag in a suitable radiation shield.
- Insert approximately 500 ml of medical grade oxygen in the bag through the CO_2 absorber canister for each minute of anticipated rebreathing time.
- Seat the patient with his back against the face of the collimator of a scintillation camera, positioned to allow imaging of the desired portion of the lungs. When a diverging collimator is used, position the patient so that both lungs are in field view.
- Clamp the patient's nose.

USE OF SYSTEM When the key is initially turned 180°, the plastic container of xenon is broken and the gas is released into the system. In the event that the key is difficult to turn, gently tap the retainer ring (Figure 1, E). When the key is turned 90°, the system is closed.

Instructions are given below for a single breath study followed by a rebreathing study and a washout study.

Single Breath

1. Have the patient breathe normally through the mouthpiece.
2. (a) **For a sharp dose**, have the patient exhale completely and hold his breath. Turn the key 180°.
   (b) **For a diffuse dose**, have the patient inhale through the mouthpiece and hold his breath. Turn the key 180°. Instruct the patient to exhale maximally through the mouthpiece.
3. Following either 2(a) or 2(b), instruct the patient to take a single, smooth, deep breath through the mouthpiece and hold it.
4. Start scintigraphy while the patient is holding his breath.

Rebreathing

5. When single breath scintigraphy is complete, instruct the patient to breathe back and forth through the mouthpiece for at least one minute.
6. Have the patient inhale and hold his breath while a second scintigram is taken.

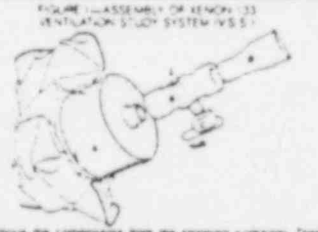
Washout

7. When scintigraphy is complete, instruct the patient to inhale room air deeply and exhale into the mouthpiece. Continue this washout procedure over a period of four to five minutes while taking sequential scintigrams.
8. Turn the key 90° to close off the Xenon 133-V.S.S.
9. Dispose of the system in an appropriate manner.

These instructions may be modified to allow other types of studies.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of the radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

FIGURE I—ASSEMBLY OF XENON 133 VENTILATION STUDY SYSTEM (V.S.S.)



1. Remove the components from the shipping container. These components are:
   A—Breathing-collection bag with attached CO_2 absorber canister
   B—Xenon 133 in a valve-shield with end plugs
   C—Key
   D—Disposable mouthpiece
2. Remove the red cap from the CO_2 absorber canister.
3. Use the key to remove the end plugs on the valve-shield.
4. Attach either end of the valve-shield to the canister.
5. Wedge the mouthpiece into the other end of the valve-shield.
6. Place the key on the fitting of the valve-shield. Do not turn the key.
7. The Ventilation Study System is now ready for use.*

*In the event that the key is difficult to turn when the system is in use, gently tap the retainer ring (E).

RADIATION DOSIMETRY The estimated absorbed radiation doses[1] to an average adult (70 kg) and ten-year old child (31.8 kg) for a single breath study using 10 millicuries and an equilibrium breathing study using 20 millicuries are shown in Table III.

Table III. Estimates of Radiation Absorbed Dose for Xenon 133 (in rads)

	SINGLE BREATH (10 millicuries held for 30 seconds followed by washout)		EQUILIBRIUM BREATHING (20 millicuries in 2 liter spirometer for 4 minutes followed by washout)	
Organ	Adult	Child	Adult	Child
Lung	0.050	0.1	0.300	0.36
Total Body	0.0002	0.001	0.0008	0.002
Ovaries	0.00008	0.0001	0.0001	0.0002
Testes	0.000008	0.00008	0.00002	0.0001

HOW SUPPLIED Each Ventilation Study System (V.S.S.) contains Xenon 133 in a sealed plastic tube containing 10 millicuries ± 20% at calibration time and date stated on the label.

The sealed plastic tube is enclosed in a metal valve shield which is sealed with a plastic shrink band to prevent accidental loss of Xenon 133 during shipping. A key is provided to remove the end plugs of the valve shield and to turn the valve fitting which breaks the sealed plastic tube. The V.S.S. also includes a disposable mouthpiece and a breathing-collection bag with an attached CO_2 absorber canister.

[1] Dillman, L.T., Van der Lage, F.C.: Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation. MIRD Pamphlet No. 10. Soc. Nucl. Med. (1975) p. 83.

Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides. Supplement No. 1, MIRD Pamphlet No. 1, J. Nucl. Med., p. 7, 1968.

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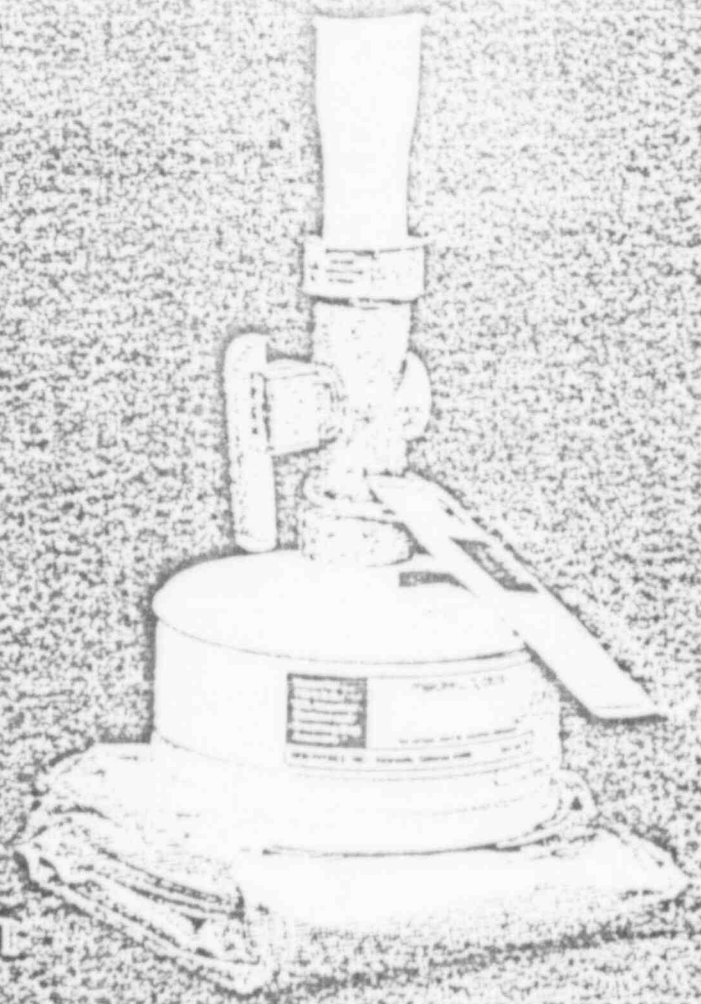
Xenon 133-V.S.S.
(Ventilation Study System)

(Xenon Xe 133
Diagnostic)



A complete
disposable
xenon gas
delivery system

SINGLE UNIT DOSE

SYSTEM VERSATILITY

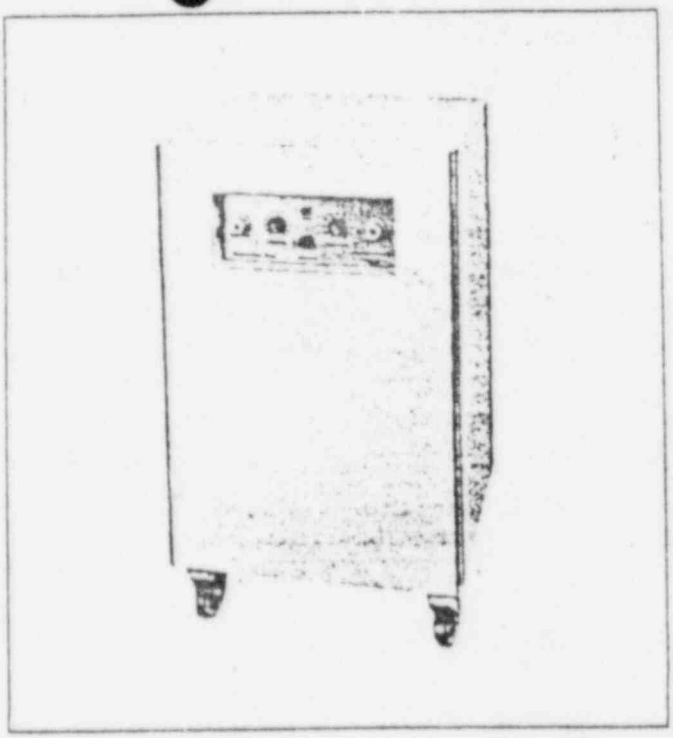
REDUCED RADIATION EXPOSURE

ECONOMICAL DELIVERIES

PLEASE SEE PACKAGE FOR COMPLETE PRESCRIBING INFORMATION

127-313

XENON GAS TRAP



Removes xenon from exhaled air

- Adjustable flow speed.
- Optimum Absorbtion efficiency.
- Selectable Washout time.
- Automatic shut-down.
- Trap effluent is virtually devoid of radioactivity.
- Easy cartridge replacement.

Now Xenon can be efficiently removed from exhaled air without the awkwardness and expense of venting to the outside. Such venting is regulated and may be completely prohibited by NRC or state law. The Atomlab 127-313 lead shielded Xenon Gas Trap draws air through a bed of specifically compounded activated charcoal aggregate. As expelled air migrates through the cartridge, radioactive xenon adheres to the charcoal aggregate and eventually decays. The cartridge is designed, packed and mounted to give optimal adsorbtion efficiency and prevent "channeling" and "walling" of the gas. The trap effluent is virtually devoid of radioactivity. The patient output is gently drawn in by an induction vacuum pump; flow speed can be adjusted and monitored to assure patient comfort. A timing device allows the operator to choose the desired washout time (1 to 15 minutes) and automatically shuts down when the study is completed. A pilot light indicates when the unit is in operation.

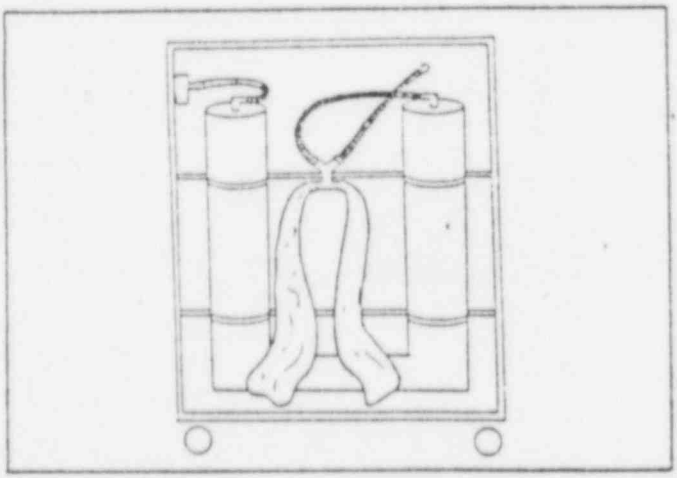
The 127-313 Xenon Gas Trap can be easily integrated into any 133Xe system or may be used independently as a patient exhalation unit. The 1/8" lead shielding makes external radiation levels negligible. A dessicant cartridge on the output line functions as a water trap.

SPECIFICATIONS:

Size: 18"x19"x34"
Mobility: Rolls on 4" casters
Weight: 125 Lbs.
Finish: White Formica
Power: 115V.
Controls: On-Off/Timer switch, Pilot Light, Air Flow Controls

127-313 Xenon Gas Trap ..... $ 895.00
127-318 Disposable Cartridge ..... $ 200.00

CARTRIDGES LAST LONGER ....



- The activated charcoal has been chemically treated for extra absorbing power.
- The charcoal has been packed in the traditional vertical position to prevent gas channeling.
- The overflow collection bags allow the pump to run slowly for maximum trapping.
- You can adjust the flow speed.
- The built-in timer automatically turns the pump off at the completion of the study.

Atomic Products Corporation

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

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EXHIBIT

SURVEY of VENTILATION SYSTEM
CITIZEN'S GENERAL HOSPITAL
NUCLEAR MEDICINE LAB
SEPT 21, 1979 1300 HOURS

SURVEY MADE WITH ALNOR VELOMETER SERIAL # 284

EXHAUST SOURCES:

① HOOD IN DRUG PREPARATION ROOM

② VENT IN EAST WALL OF DRUG PREPARATION ROOM.

BOTH ~~THESE~~ SYSTEMS EXHAUST TO HOSPITAL'S CENTRAL EXHAUST SYSTEM WHICH OPERATES CONTINUOUSLY

SUPPLY SOURCES

① VENT OVER SCANNING ROOM DOOR ~~THIS VENT~~ TO BE SEALED OFF TO PRODUCE MAXIMUM INFLUX OF SUPPLY AIR THRU SCANNING ROOM DOOR

② SCANNING ROOM DOOR

AIR RECIRULATION SYSTEM:

AIR CONDITIONING UNITS UNDER SOUTH WINDOWS RECIRULATE AIR WITHOUT UTILIZING ANY MAKE-UP AIR OR EXHAUSTING ROOM AIR TO ENVIRONS AND THEREFORE DO NOT EFFECT ROOM PRESSURE NOR ARE THEY A SOURCE FOR THE REVERSE OF RADIOACTIVE EFFLUENTS TO UN RESTRICTED AREAS.

Hamill
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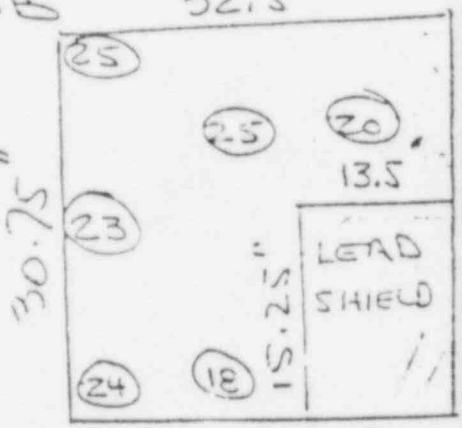
STA FOR EXHAUST SYSTEMS.

① HOOD IN DRUG PREPARATION LAB



25 fpm
23 "
24 "
25 "
18 "
20 "
135 ÷ 6 = 23 fpm.

EFFECTIVE AREA (A_{eff}) = [30.75" × 32.5"] − [13.5" × 15.25"]

$\div 144 \frac{in^2}{ft^2}$

$A_{eff} = 5.51\ ft^2$

EXHAUST RATE = $\bar{V} \times A_{eff}$

$= 5.51\ ft^2 \times 23\ fpm$

$= 127\ CFM$

ALL MEASUREMENTS MADE WITH HOOD DOORS OPEN.

I RECOMEND THAT HOOD DOORS BE REMOVED TO INSURE MAXIMUM EXHAUST DURING XENON-133 USAGE

② EXHAUST VENT - EAST WALL OF DRUG PREPARATION LAB.

200 fpm
210 "
220 "
235 "
250 "
260 "
1375 ÷ 6 = 229 fpm

EAST WALL VENT

EFFECTIVE AREA (A_{eff}) = 6.75" × 5" ÷ 144 in^2/ft^2

A_{eff} = 0.23 ft^2

EXHAUST RATE = $\bar{V}$ × AREA.

= 229 FPM × .23 ft^2

= 53 CFM.

TOTAL EXHAUST RATE FROM BOTH SOURCES

127 CFM + 53 CFM = 180 CFM.

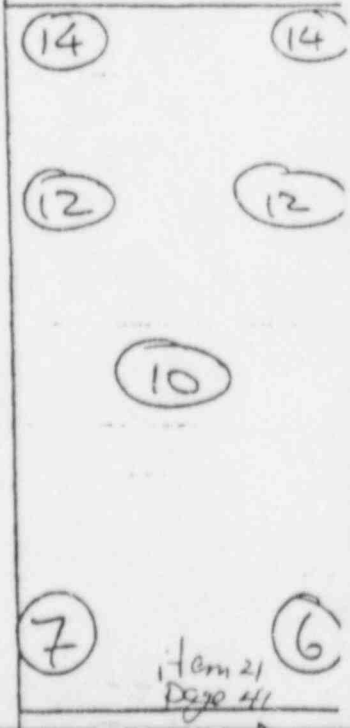
SINCE ALL THE EXHAUST VENTILATION IN THE SYSTEM UNDER QUESTION IS PROVIDED BY THE HOOD AND WALL VENT IN THE DRUG PREPARATION LAB, A MEASUREMENT OF THE VENTILATION RATE AT THE DOOR TO THIS ROOM SHOULD COMPARE CLOSELY WITH THE TOTAL RATE PROVIDED BY THE HOOD & VENT.

14
14
12
12
10
7
6

$\bar{V}$ = $\frac{6}{75} \div 7$ = 11 FPM

EFFECTIVE AREA = 27.5" × 82.5" ÷ 144 $\frac{in^2}{ft^2}$

= 15.8 ft^2



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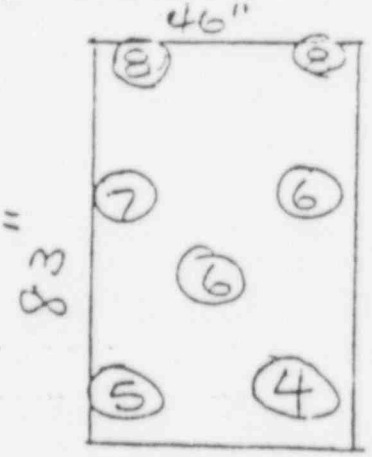
: HAUST RATE = $\bar{V} \times A_{eff}$
= 11 fpm × 15.8 ft²
= 174 CFM

COMPARISON 180 CFM Vs 174 CFM GOOD AGREEMENT

ATA FOR SUPPLY SOURCES

① VENT OVER SCANNING ROOM DOOR — TO BE SEALED. NO MEASUREMENTS MADE.
② ENTRANCE DOOR TO SCANNING ROOM

* NOTE: MEASUREMENTS MADE WITH VENT BLOCKED.
: VALUES ARE ON THE LOWER LIMITS OF THE VELOMETER'S CAPABILITIES.



8
8
7
6
6
4
5
44 ÷ 7 = 6 fpm

EFFECTIVE AREA (A_{eff}) = 46.0" × 83.0" ÷ 144 $\frac{in^2}{ft^2}$
= 26.5 ft²

SUPPLY RATE = $\bar{V} \times A_{eff}$
= 6 fpm × 26.5 ft²
= 159 CFM INFLUX

PARISON OF AVAILABLE VENTILATION VS REQUIRED.

1) FOR XENON CONCENTRATIONS IN RESTRICTED AREAS IE SCANNING ROOM

A = MAXIMUM ACTIVITY USED PER WEEK

$$= \frac{10\ mCi}{PATIENT} \times \frac{3\ PATIENTS}{WEEK} \times \frac{1\times10^{3}\ \mu Ci}{mCi}$$

$$A = 3\times10^{4}\ \frac{\mu Ci}{WK}$$

f = ASSUMED LOSS RATE of 20%

V = REQUIRED VENTILATION

$$= \frac{A \times f}{1\times10^{-5}\ \frac{\mu Ci}{ml}}$$

WHERE $1\times10^{-5}\ \frac{\mu Ci}{ml}$ IS THE MAXIMUM PERMISSABLE CONCENTRATION PER 10CFR20 PARAGRAPH 20.103

$$= \frac{3\times10^{4}\ \mu Ci/WK \times 0.2}{1\times10^{-5}\ \frac{\mu Ci}{ml}}$$

$$V = 6\times10^{8}\ \frac{ml}{WK}$$

OR

$$V = 6\times10^{8}\ \frac{ml}{WK} \times \frac{1}{40\ HRS/WK} \div \frac{1.7\times10^{6}\ ml/HR}{ft^{3}/MIN}$$

$$= \underline{9\ CFM}$$

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THE TOTAL EXHAUST RATE (180CFM) EXCEEDS THE REQUIRED VENTILATION RATE (9CFM) BY A FACTOR OF 20 PROVIDING ADEQUATE AIR FLOW FOR THE PATIENT LOAD ANTICIPATED.

FOR THE DISPOSAL OF XENON-133 BY VENTING THRU FUME HOOD. - SINCE WE CANNOT DETERMINE THAT XENON RELEASED IN THIS MANNER WILL NOT BE DISCHARGED INTO AN UNRESTRICTED AREA EITHER WITHIN THE HOSPITALS CENTRAL EXHAUST SYSTEM OR AT THE POINT WHERE IT IS DISCHARGED ON THE ROOF, ASSUME IT WILL BE DISCHARGED TO AN UNRESTRICTED AREA.

MAXIMUM PERMISSIBLE CONCENTRATION of XENON-133 RELEASED TO AN UNRESTRICTED AREA AVERAGED OVER A ONE YEAR PERIOD IS NOT TO EXCEED 3×10^{-7} μCi/ML.

C = AVERAGE CONCENTRATION PER YEAR AT POINT WHERE FUME HOOD ENTERS CENTRAL EXHAUST SYSTEM.

$$A = \frac{3 \text{ PATIENTS}}{\text{WK}} \times \frac{10 \text{ mCi}}{\text{PATIENT}} \times \frac{10^3 \mu\text{Ci}}{\text{mCi}} \times \frac{52 \text{ WKS}}{\text{YR}}$$

$$= 1.56 \times 10^6 \frac{\mu\text{Ci}}{\text{YR}}$$

V = 180CFM = TOTAL DISCHARGE RATE FROM HOOD AND VENT INTO CENTRAL EXHAUST SYSTEM.

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$C^{U} = \frac{A}{V}$

$= 1.56 \times 10^{6} \frac{uCi}{mL} \div \left[180CFM \times 1.49 \times 10^{0} \frac{ML/HR}{CFM}\right]$

$= 0.58 \times 10^{-6} = 5.8 \times 10^{-7} \frac{uC}{mL}$.

THIS IS APPROX. 2 TIMES GREATER THAN THE AVERAGE PERMISSABLE YEARLY RELEASE AND THEREFORE I RECOMMEND THAT SOME OTHER MEANS SUCH AS A CHARCOAL TRAP BE UTILIZED TO DISPOSE OF COLLECTED XENON-133.

ATTACHED IS A COPY OF YOUR ROOM PLAN INDICATING MEASURED VENTILATION RATES

PLEASE ADVISE IF YOU SHOULD REQUIRE ANY ADDITIONAL INFO REGARDING THIS MATTER

D. LEONE
9/23/79

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CITIZENS GENERAL HOSPITAL

NEW KENSINGTON, PENNSYLVANIA

ALARA

August, 1980

Reviewed 3-29-84

I. Management Commitment

a. We, the management of Citizens General Hospital are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below 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 decide if action is warranted when Investigational Levels are exceeded.

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least 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 RSO 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 an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

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

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all know instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. Tne authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his 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 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 institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the 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 I

		Investigational Levels- (mrems per calender 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*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, 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 I:

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

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

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

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when 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 Committee. The Committee 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 in the Committee minutes.

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

The RSO 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, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table I.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official

I hereby certify that Citizens General Hospital has implemented the ALARA Program set forth above.

Robert E. Marino
Signature

Robert E. Marino
Executive Director

Ronald J. Clearfield
Signature

Ronald J. Clearfield, M.D.
Director, Department of Radiology

Citizens General Hospital
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GUIDELINES FOR INVESTIGATION OF POSSIBLE EXPOSURE

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	Exposure Level (monthly)	Action
Level I	≤50 mR/month (whole body)	none
	≤600 mR/month (extremities)	none
Level II	up to 3 times Level I	1. briefly review exposure history of individual. 2. determine brief work history of individual during period of exposure 3. discuss exposure with individual. 4. report results to Radiation Safety Committee. 5. no further action needed, unless deemed necessary by Radiation Safety Committee.
Level III	greater than 3 times Level I	1. investigate in detail the work history of individual during period of exposure (what duties were, what duties were performed, frequency performed.) 2. review work habits relating to required duties during period of exposure (e.g., if in Dx, was back turned to unit, if in N.M., was proper shielding used.) 3. document in detail. 4. submit document to Radiation Safety Committee for its first meeting following completion of investigation. 5. send committee action and copy of investigation to hospital management and to the affected individual. 6. assess future duties of individual.

GUIDELINES FOR INVESTIGATION OF POSSIBLE EXPOSURE

Exposure Level(monthly)		Action
Level I	≤125mR/month (whole body)	none
	≤1800 mR/month (extremities)	none
Level II	up to 3 times Level I	1. briefly review exposure history of individual. 2. determine brief work history of individual during period of exposure 3. discuss exposure with individual. 4. report results to Radiation Safety Committee. 5. no further action needed, unless deemed necessary by Radiation Safety Committee.
Level III	greater than 3 times Level I	1. investigate in detail the work history of individual during period of exposure (what duties were, what duties were performed, frequency performed.) 2. review work habits relating to required duties during period of exposure (e.g., if in Dx, was back turned to unit, if in N. M., was proper shielding used.) 3. document in detail. 4. submit document to Radiation Safety Committee for its first meeting following completion of investigation. 5. send committee action and copy of investigation to hospital management and to the affected individual. 6. assess future duties of individual.