1983

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

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

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

Billings Deaconess Hospital
Department of Radiology
2813 Ninth Avenue North
Billings, Montana 59103

TELEPHONE NO.: AREA CODE ( ) 657 4141

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

2813 Ninth Avenue North
Billings, Montana 59103

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Lane Basso

TELEPHONE NO.: AREA CODE (406) 657- 4141

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 25-01051-01

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

Jerry D. Wolf, M.D. Gordon L. Cox, M.D.
V. P. Johnson, M.D. Walter C. Degnan, M.D.
Bruce C. Pinkerton, M.D. Dean A. Bruschwein, 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.)*

Jerry Wolf, M.D.
Radiation Safety Officer

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	5MCi
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	2000mCi
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	3500mCi For all

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	25
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	50
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	300
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	100
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	500

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
Cobalt - 57	Round, plastic Flood Source	10mCi as of 11/15/82	Serial #3921182A-01 New England Nuclear Flood Source for Camera Calibration

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

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Siemens Diagnostic Inc.	First of each month
		TLD		
		OTHER (Specify)		
b. FINGER		FILM	Siemens Diagnostic Inc.	First of each month
		TLD		
		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: 7B

(2) LICENSE FEE ENCLOSED: $ $150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Lane Basso

(1) NAME *(Type or Print)* LANE BASSO

(2) TITLE PRESIDENT

c. DATE 8/18/83

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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 NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

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

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

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

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

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

MEDICAL ISOTOPES COMMITTEE

A. The Medical Isotopes Committee has been set up to approve any new diagnostic radiopharmaceuticals for routine or non-routine use in the Nuclear Medicine Department. The committee has also set up a program for the necessity of radioactive therapeutic doses to be given to patients. The Isotope Committee oversees the radiation safety program and periodically reviews the program for evaluation of radiation protection. The responsibilities, duties, and meeting frequency will be as described in the Guide for Preparation of Applications for Medical Programs, Appendix B.

B. Routine Meetings are scheduled four times a year.

C. Isotope Committee Members:

Dr. Jerry D. Wolf	Radiologist
Dr. Walter Degnan	Cardiologist, Internal Medicine
Dr. Martin E. Kodish	Internal Medicine
Fred A. Deigert, M.D.	Therapeutic Radiologist
Dr. Gordon Cox	Pathologist
J. R. Rub, R.T.	Nuclear Medicine Technologist
Gene O'Hara	Vice President of Professional Services

Item No. 7
Date: 8/16/83

APPENDIX C

INSTRUMENTATION

1. Survey meters

A. Manufacturer's name: Ludlum

Manufacturer's model number: 14C

Number of instruments available: 1

Ranges: X0.1 - x1 - X10 - X100 - X1000

Minimum range: X0.1 mr/hr to .2 mr/hr

Maximum range: X1000 mr/hr to 2000 mr/hr

B. Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

Ranges: _____

Minimum range: _____ mr/hr to _____ mr/hr

Maximum range: _____ mr/hr to _____ mr/hr

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2. Dose Calibrator

Manufacturer's name: Squibb CRC-CA

Manufacturer's model number: CRC-CA

Number of instruments available: 1

3. Diagnostic instruments

TYPE OF INSTRUMENT	MANUFACTURER	MODEL NO.
Scintillation Camera	Nuclear-Chicago	6426B
Spectroscaler IIIA	Picker	628438
Scintillation Camera	General Electric	4-40032161
Data Camera	General Electric	0MH25044113

4. Other

Item No. 9
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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. 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% of the calculated or known values for each point checked. Readings within + - 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

__X__ 3. Survey instruments will be calibrated.

__X__ a. By the manufacturer -- Ludlum Measurements Incorporated

_____ b. At the licensee's facility

(i) Calibration source
Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

(ii) The calibration procedures in Appendix D, Section I will be used.

or

(iii) The step by step procedures, including radiation safety procedures are attached.

__X__ c. By a consultant or outside firm.

(i) Name Midwest Radiation Consultants
(ii) Location 543 Tomlyn Ave., St. Paul, MN 55112
(iii) Procedures and sources ** See below, Items 1 and 2

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

_____ are attached

** Item 1. Calibration is traceable to MBS.
Item 2. Two points source checks on each range.

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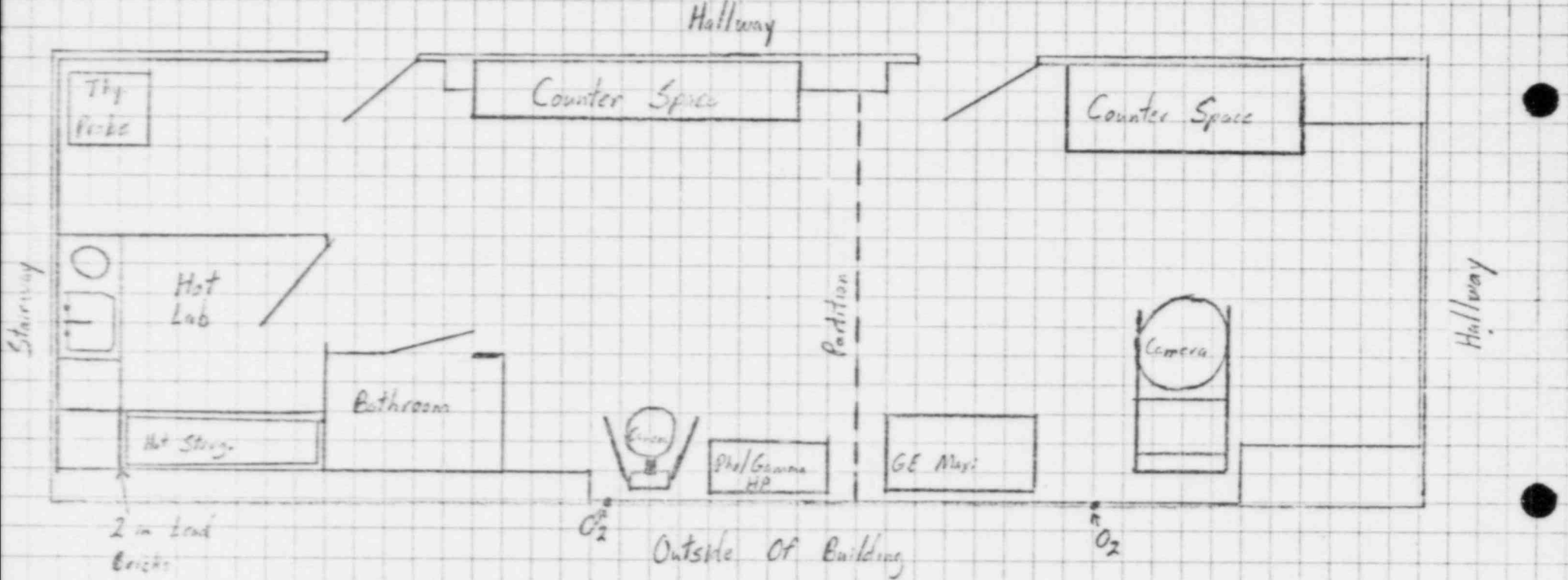
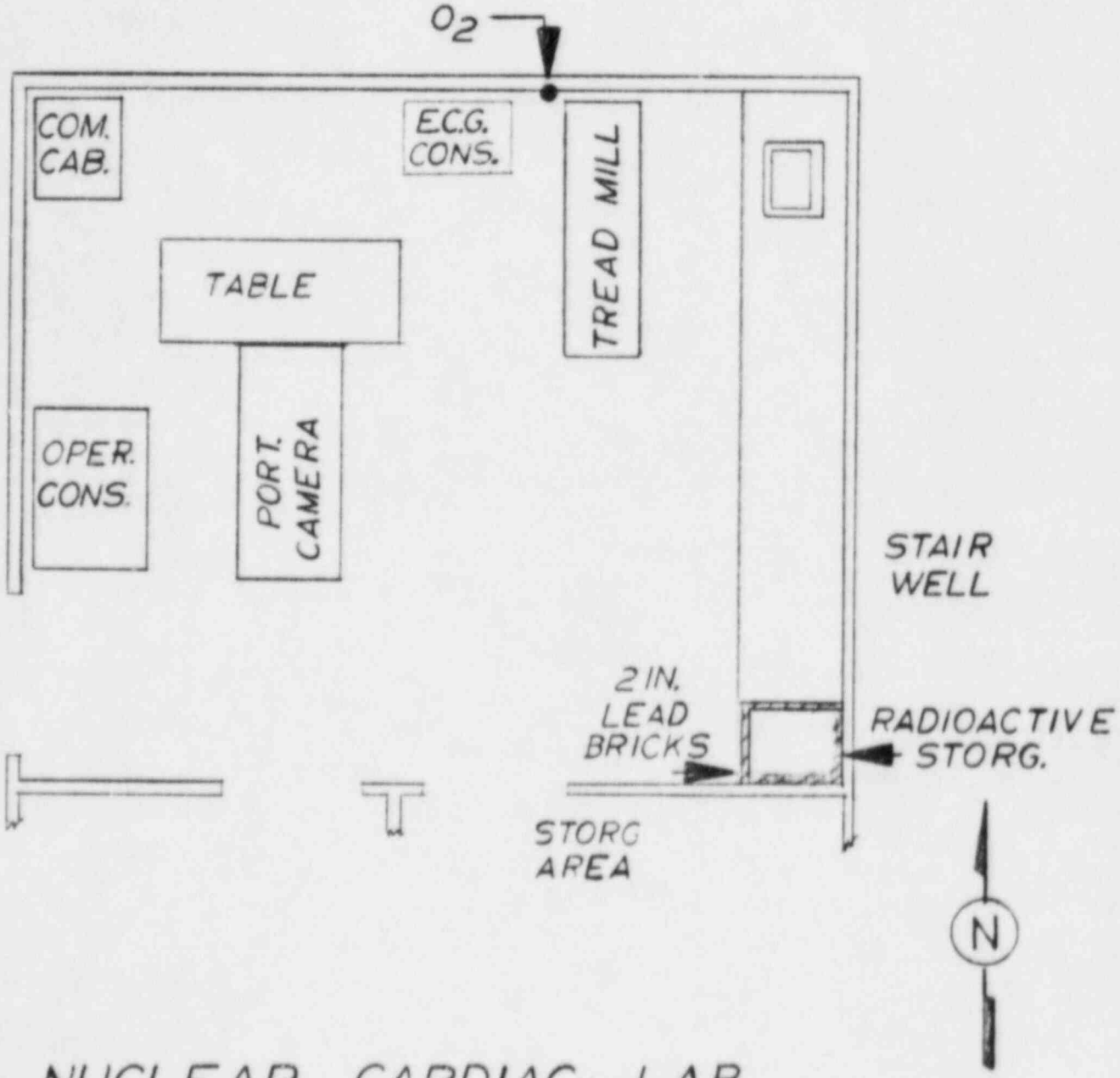
BDH NUCLEAR MEDICINE LAB



Scale 1 cm : 1 ft



NUCLEAR CARDIAC LAB.

SCALE 1/4 IN. = 1 FT.

PERSONNEL TRAINING PROGRAM

All personnel at Billings Deaconess Hospital who work directly with radioactive materials (handling and use of) will be trained in Nuclear Medicine Technology.

All personnel who work in the vicinity of radioactive materials are required to attend two one-hour lectures. The lectures include:

a. Areas where radioactive material is used or stored;
b. Potential hazards associated with radioactive material;
c. Radiological safety procedures appropriate to their respective duties;
d. Pertinent MRC regulations;
e. The rules and regulations of the licensee;
f. The pertinent terms of the license;
g. Their obligation to report unsafe conditions;
h. Appropriate response to emergencies or unsafe conditions; and
i. Their right to be informed of their radiation exposure and bioassay results.

Any new personnel working int he vicinity of radioactive material will be trained in the subject matter described above.

Item No. 12
Date: 8/16/83

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

A. Ordering Radioactive Materials.

Authority has been given by Dr. Jerry Wolf to the registered Nuclear Medicine Technologists for the inventory and ordering of all byproduct material used routinely under his supervision. Most of the byproduct material ordered is set up on a standing order basis and arranged so as not to exceed the maximum possession limits as stated by our license. Any byproduct material which is needed that is not routinely used must be approved by Dr. Jerry Wolf, V.P. Johnson or Bruce Pinkerton before the byproduct material can be ordered. If some of the byproduct material is inventory, it will be checked so the maximum possession limit will not be exceeded.

B. Receipt of Materials During Off-Duty Hours and Notification of Responsible Persons Upon Receipt of Radioactive Materials.

Instructions for receipt of radioactive materials are posted on the Nuclear Medicine door. The telephone operators have also been instructed concerning the receipt of radioactive materials to the hospital. After arrival of the material to the hospital, the carrier obtains a key from the telephone operator and unlocks the door to the Nuclear Medicine Department. He places all radioactive materials inside and then returns the key to the telephone operator. If there is any damage to the radioactive materials, the Nuclear Medicine technologist is notified at once to monitor the package for leaks. The personnel at Billings Deaconess Hospital who receive radioactive material during off-duty hours will be given written instructions for receiving, examining, and securing the packages if any damage has occurred. Any radioactive material received will be locked in the Nuclear Medicine Department.

Item No. 13
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PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

The opening of all radioactive packages at Billings Deaconess Hospital will be in accordance with the procedures described in Appendix F.

Item No. 14
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LABORATORY RULES FOR USE OF RADIOACTIVE MATERIAL

The laboratory rules for use of radioactive material will be in accordance with the rules described in Appendix G.

Item No. 15
Date: 8/16/83

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. Include all other contaminated materials such as disposable gloves.

4. SURVEY: With a G.M. Survey Meter, check the area around the spill, your 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: Dr. Jerry D. Wolf

OFFICE PHONE: (406) 657-4190

HOME PHONE: (406) 259-6301

Also: Denis Hully, Nuclear Medicine Technologist
Office Phone: (406) 657-4198 Home Phone: (406) 652-1275

J.R. Rub, R. T.
Office Phone: (406) 657-4196 Home Phone: (406) 252-6549

Item No. 16
Date: 8/16/83

EMERGENCY PROCEDURES

Emergency procedures of Billings Deaconess Hospital will be in accordance with the procedures described in Appendix H.

Radiation Safety Officer: Jerry D. Wolf, M.D.
Office Phone: 657-4190
Home Phone: 259-6301

Others to be notified in case of emergency:

Denis Hully
Office Phone: 657-4198
Home Phone: 652-1275

J. R. Rub, R.T.
Office Phone: 657-4196
Home Phone: 252-6549

Item No. 16
Date: 8/16/83

AREA SURVEY PROCEDURES

The radiation survey procedures will be performed in accordance with those referred to in Appendix I.

Item No. 17
Date: 8/16/83

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APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste Will be Disposed of

Check as appropriate

____ By commercial waste disposal service (See Also No. 4 below)

X___ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be:

Check as appropriate

____ Returned to the manufacturer for disposal

X___ Held for decay until radiation levels as measured 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 disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long lived radioactive contaminants)

____ Disposed of by commercial waste disposal service (see also No. 4 below)

____ Other (Specify): _____

3. Other Solid Waste will be:

Check as appropriate

X___ Held for decay until radiation levels as measured 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.

____ Disposed of by commercial water disposal service (See also No. 4 below)

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____ Other (Specify: _____

4. The commercial waste disposal service used will be: Billings Sanitary Department, Billings, Montana

NRC/Agreement State License No. 25-01051-01

Item No. 18
Date: 8/16/83

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

The precautions for patients treated with iodine-131, gold 198, and phosphorus-32 will be follwed in accordance with the procedures described in Appendix K.

The special precautions for patients treated with byproduct material listed in Groups IV and V will be in accordance with those described in Appendix K.

Item No. 19
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THERAPEUTIC USE OF SEALED SOURCES

A. See the enclosed blueprint of storage area and shielding equipment.

B. Sealed sources are never touched or held with the fingers but only with tongs available at the working area. Only the physicians manipulate the sealed sources and are adequately trained in the use of the tongs and forcepts. The forceps allow a distance of at least 20 cms. between the hands and the sources. When working with the sealed radioactive materials, we use 3 inches of lead shielding between ourselves and the radioactive material and utilize a 4.2 mm. leaded glass for eye and face protection. The entire working area is enclosed to prevent loss of sources.

C. Nursing personnel are advised regarding each patient with sealed radioactive source, i.e., the length of time that each nurse may care for the patient is determined by means of monitoring carried out by the Nuclear Medicine Technologist. Safe exposure times, both at the patient's bedside (1 meter distance) and also at the foot of the bed (6 meters distance), are determined and posted on the patient's door. The nurses then are required to enter the length of time that they spend each shift at the patient's bedside and with a 2 meter distance. The physician caring for the patient alerts the nursing supervisor if any one nurse has reached her daily maximum permissible does for wekkly radiation tolerance, in which case she is removed from further care of radiation patients. On the basis of our monitoring and record keeping, the nursing personnel is rotated in sequence for care of an individual patient. No nurses who may be pregnant are allowed to work with radiation patients. Periodically the nursing staff at both hospitals receive training courses regarding proper technique in dealing with patients who have interstitial or intercavitary radiation treatment. Nurses are instructed that if there is a change in the position of the source or packing, they are not to handle the sources but are to immediately call the physician and to appropriately isolate the patient or the patient's room.

D. The only personnel in this hospital handling sealed sources are the physicians who use the radiation film badges made by Searle which are analayzed monthly for determining whole body dosage.

Item No. 20
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E. We have a lead carrier which is hand held by a strap and is encased in stainless steel, containing a 4 cm. thick wall of lead. The maximum amount of radium that is carried in this device is 60 mgs. Exposure at 1 meter from that amount of radium inside the carrier is 50 mr. per hour.

F. Countability is maintained through log in-log out sheets for each shipment of radioactive sealed sources as they arrive at the hospital from the manufacturer and as they are used in each patient. We also carry out a quarterly inventory on these radioactive sources in the hospital, and all sources are counted on return to the storage area. They are kept in escrow or shipped back to the manufacturer.

G. Radiation surveys are conducted as outlined above and under Item No. 20.B, i.e., at 1 meter and 2 meters from the patient. The room is monitored after the radioactive sources are removed in each case. A background level of radioactivity upon complete monitoring of the room is sufficient evidence that all radioactive sources have been removed.

References for out techniques in handling sealed radioactive sources come from NUREG-0267 "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions as Low as Reasonably Achievable." This is published by the Office of Standards Development, U.S. Nuclear Regulatory Commission, published in December 1977. Reference No. 2: NCRP No. 37. Reference No. 3: Physicis of Radiology, 3rd edition by Harold Johns, Ph.D., page 670.

Item No. 20
Date 8/16/83

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THEORY OF OPERATION

There are three generally recognized phases of a lung ventilation study. Each phase has variations supported by some and denied by others. In some circles even the phases are debated. This manual describes the use of the Ventil-Con II to perform the three phases and gives information on some of the more popular variations.

The three phases with more common variations are:

1. Wash-In
   a. Homogeneous administration
   b. Bolus administration
2. Equilibrium
3. Washout

The Ventil-Con II is designed to allow the user to perform the three phases. The unit consists of two separate plumbing systems (Diagram 1). In stabilization/washout, the patient inhales room air through a one way valve in the bottom of the breathing valve. When the patient exhales, this valve closes and another one opens directing the exhaled breath through the Ventil-Con II console into the exhaust port. In Models 142 and 143 the exhaled breath then goes into the expandable interface where it is subsequently drawn through the activated charcoal cartridge pack by the xenon trap pump.

The Expandable Interface is required because the trap pump moves air at the rate of 5 liters per minute while people normally breathe at a higher rate. Sick patients can breathe at rates up to 20-25 liters per minute. The Expandable Interface is a reservoir which accepts the excess flow rate until the trap can catch up. It has a capacity of approximately 100 liters and normally gives around 10 minutes of breathing time in washout.

In Model 143 the exhaled breath upon leaving the charcoal pack and trap pump, enters a chamber of 150 ml/m volume viewed by an end window Geiger-Mueller tube (Figure 17). When excessive ^{133}Xe (greater than 1×10^{-2} mCi/ml) appears in the exhaust port, an audio visual alarm activates.

The second plumbing system consists of the breathing valve (Figure 18), autoclavable bacteriological filter (Figure 5), CO_2 absorber (Figure 5), blower (Figure 5), GM detector (Figure 19), and spirometer (Figures 5, 17, 19). This is a closed system which may be opened to the outside only through the breathing valve and Operate/Evacuate valve. The breathing valve is equipped with a standard female Leur fitting followed by a one way valve for the injection of ^{133}Xe gas (Figure 20).

With the Operate/Evacuate valve in the operate position and the breathing valve in rebreathe as the patient exhales a one way valve in the head valve closes and the patients breath is directed first into the CO_2 absorber, through the bacteriological filter and into the spirometer which expands to accomodate the increased volume. As the patient inhales, the one way valve opens and the patient breathes out of the spirometer thus contracting its volume. This sytem is actually a circuit with the patient on the opposite end of the spirometer with the spirometer providing opposite, but equal, reaction to the patients breathing.

The system is provided with an inline blower (Figure 5), which serves three functions:

1. Assist in providing one-way air flow
2. Overcomes inherent pathway resistance
3. Provides mixing to assure a homogenous mixture.

The rebreathing system is provided with two one-way input ports for the addition of O_2. Both are controlled by an electrical solenoid valve (Figure 21). One input port injects O_2 just before the spirometer allowing considerable mixing before reaching the patient. The second system (O_2 Assist) injects O_2 directly to any patient having breathing difficulties.

PROPER O_2 ADMINISTRATION DURING REBREATHING IS AN ABSOLUTE NECESSITY. Panic generally associated with O_2 deprivation is actually caused by a CO_2 build-up. Since the unit is equipped with an effective CO_2 absorber, CO_2 build-up cannot occur thus insufficient O_2 will result in unconsciousness without alarm.

Too much O_2 can result in pulmonary arrest which can be fatal.

With the breathing valve in the washout position and the Operate/Evacuate valve in the evacuate position, the blower forces the air from the internal rebreathing system through the Operate/Evacuate valve into the general exhaust of the unit and follows the same path as previously described.

XENON TRAP - The term "xenon trap" when used to describe activated charcoal devices is a serious misnomer. Activated charcoal does not trap xenon but only acts as a delaying mechanism. If the xenon is delayed long enough to allow it to decay, then the word trap, although not scientifically correct, is from an end result standpoint, correct.

The process is best described as a chromatagraphic process where charcoal is the suspending media, air the solvent, and xenon the solute.

The process is dependent on the amount of charcoal, pathway configuration, temperature, and most significantly, air flow per unit of time. The process is relatively independent of the amount of xenon. Desiccants are used in xenon traps to remove the excess humidity which could condense in the charcoal cartridge interfering with the ability to delay xenon. On a longer term basis, air pollutants, etc., will saturate the charcoal and negate its xenon delaying capacity.

The most important factors affecting the life of the cartridge is the velocity and volume of air passing through it.

The patients exhaled breath first enters the Expandable Interface (Figure 3) where it is pulled through the silica gel desiccant jar (Figure 5), and the activated charcoal filter (Figure 19 and 22) by the trap pump (Figure 5 and 17). From the pump it is blown past the exhaust port monitoring GM tube (Figure 17) and out the back of the Ventil-Con II through a brass bulk head fitting (Figure 4).

OPERATION

Unit Preparation

1. Calibration of Xenon Concentration System - On the initial use it is necessary to check the Xenon Concentration meter calibration. This is done as follows:

   a. Turn the main power "ON".

b With no ^{133}Xenon in the Ventil-Con II, adjust the concentration meter to zero by using the small screw in the center of the meter (Figure 23).

c. With the breathing valve in the rebreathe position, adjust the spirometer to 5.0 liters.

NOTE: If ^{133}Xe is in the unit, adjustment should be made by the Operate /Evacuate valve to lower the volume or the breathing valve to increase the volume. When the breathing valve is open, room air will be drawn into the unit.

CAUTION: During the addition of Xenon and at all times after Xenon has been added, the breathing valve should be in the Stabilization/ Washout position except when you want the patient to breathe Xenon.

d. Inject a known amount of ^{133}Xe into the breathing valve (Figure 24) and allow several minutes for it to mix. Note: Figure 24 is for illustration only. To assure adequate radiation protection, a lead syringe holder should be used. Calculate the concentration by the following formula:

$$\text{Concentration} = \frac{\text{Xenon added}}{\text{Spirometer Volume} + 5 \text{ liters}}$$

In the above formula the constant 5 represents the dilution volume outside the spirometer, i.e, in the tubing, bacteriological filter, etc.

Recommendation: Most physicians experienced in pulmonary function studies recommend an initial concentration of 5 mCi/liter.

Example: Spirometer Volume = 5 liters

^{133}Xe Injected = 50 mCi

Then:

$$\text{Concentration} = \frac{50 \text{ mCi}}{5 + 5} = \frac{50}{10} = 5 \text{ mCi/liter}$$

Using a small screwdriver, adjust the concentration gain potentiometer so that the meter corresponds to the calculated concentration (Figure 25).

CAUTION: When handling large quantities of ^{133}Xe, it should be properly shielded. The ^{133}XE to be injected into the Ventil-Con II should be calibrated in a dosecalibrator. However, the user should be aware that the type of container that the ^{133}Xe is assayed in can significantly affect the reading due to the low energy of the ^{133}Xe gamma ray.

The Ventil-Con II is designed in such a fashion that the only Xenon lost during a study is that Xenon in the patient at the start of washout. The remaining stays in the unit and may be used on subsequent patients. All parts having patient contact, such as face masks or mouthpieces and face mask tubing, should be sterilized after each use by an approved method.

Recommendation: In our experience, a concentration of 5 mCi/liter is the maximum required for a satisfactory study. As the stored Xenon is used, subsequent patient studies will require longer times to complete or counting statistics will suffer.

The minimum concentration is in the order of 2.5-3.0 mCi/liter.

Start with a concentration of 5.0 mCi/liter and when it drops below 2.5-3.0 mCi/liter, bring it back to 5.0 by adding Xenon. The amount of ^{133}Xe required may be calculated from the following formula:

$$A = (C_2 - C_1)(V + 5)$$

A = Activity to ad

C_2 = Desired concentration

C_1 = Current concentration

V = Spirometer Volume

Example: Current concentration = 2.0 mCi/l

Spirometer Volume = 4.0 l

Desired concentration = 5.0 mCi/l

then

$$A = (5.0\ mCi/l - 2.0\ mCi/l)(4.0\ l + 5.0\ l)$$

$$= (3.0\ mCi/l)(9\ l)$$

$$= 27.0\ mCi$$

2. Disconnect the O_2 line at the rear of the Ventil-Con II (Figure 4) and turn the O_2 supply on adjusting the flow rate to 2 liters per minute and not more than 5 psi pressure. Reconnect the O_2 line.

3. Set the Oxygen Replenishment selector to Auto and adjust the Oxygen Control to 0.5 liter below the starting spirometer volume (Figure 11).

   Example: Spirometer Volume = 5.5 liters

   Set control to 5.0 liters

   Explanation: Normal tidal volume is approximately 0.5 liter. In the above example, every time the spirometer volume drops below 5.0 liters, the O_2 replenishment solenoid will open allowing O_2 to enter the system. By using the control in this fashion, the O_2 concentration at the start of the study will be maintained throughout.

4. Check that the Expandable Interface bag is not inflated.

Patient Preparation

1. If the patient is to be studied in a sitting position, use the 5½" Face Mask Tubing. For the patient that cannot sit up, use the 8" tubing.

2. Face Masks are generally more comfortable that the Mouthpiece with Nose Clamp. When using a Face Mask, make sure you get a good seal particularly around the nose. A variety of patient hook-up accessories are available from Radx for use with the Ventil-Con II (Figure 26).

3. With the breathing valve in the Stabilization/Washout position, connect the face mask and tubing to the patient. The patient is now breathing room air through the Ventil-Con II. When they inhale a valve opens in the bottom of the breathing valve and admits room air. When they exhale, the intake valve closes and the exhaust valve opens and the patient's breath travels through the unit exhaust system.

   The patient should be allowed to breathe in this mode for several minutes to become acclimated to the system. If breathing difficulties are to be encountered, either psychological or otherwise, they will show up during the stabilization period where no Xenon is involved. It is during this time that the gamma camera should be set up and checked out. The trap pump should be operating during the entire time the patient is in the breathing circuit, whether as above or in the Rebreathe cycle.

Procedure

There are a multitude of procedures for performing Xenon Lung Ventilation studies. The procedures can vary significantly. The techniques and discussions which follow are based on our experience with our equipment and should not be construed as the only methodology. The user should feel free to change the recommended procedure to fit their particular requirements. The pros and cons of the "controversial" aspects of the study are presented below.

Bolus VS Homogeneous Administration

Bolus - Pro - Higher count rates provide a statistically superior image during the single breath phase of the procedure.

Con - Non-physiological. Humans do not breathe in large, forced single breaths - resultant camera images may not represent a true condition.

Homogeneous - Pro - Physiological.

Con - Relatively low count rates provide a statistically poor image; however, they are comparable to the washout images which are statistically poor.

Equilibrium/Washout VS Single Breath/Washout

Single Breath/Washout - Pro - Fast

Con - See "Pro" on Equilibrium/Washout below.

Equilibrium/Washout - Pro - One of the most diagnostic portions of the lung ventilation study is the washout phase where poorly ventilated areas appear as "hot" spots. In order for these areas to fill with sufficient ^{133}Xe to become "hot" on washout, an equilibrium must be established between normal ventilated areas and poorly ventilated areas. This requires a minimum of 3-5 minutes of rebreathing of the Xenon/air mixture in the unit.

Con - Adds approximately 3-5 minutes to the test.

Conclusion - The procedure which follows produces consistently reliable and efficacious results and consists of three phases:

1. Single breath - homogeneous mixture
2. Equilibrium 3-5 minutes
3. Washout

1. Single Breath Wash-In

   a. Homogeneous Administration - Set the gamma camera intensity for approximately 70,000 counts. NOTE: The proper intensity will vary from camera to camera, hospital to hospital and is dependent on camera efficiency and window width, lung volume, Xenon concentration, and the length of time the patient can comfortably hold his breath.

      With the patient in the Stabilization/Washout mode, instruct them to exhale completely; at end-volume switch the breathing valve to "Rebreathe" and instruct the patient to take a deep breath and hold it as long as possible. At the end of breath holding, stop the camera and tell the patient to breathe normally in the Rebreathe mode.

   b. Bolus Administration - Set the gamma camera intensity for approximately 150-200,000 counts (adjustments will be necessary for each department). Switch the breathing valve to Rebreathe and instruct the patient to exhale completely. At end volume, inject the ^{133}Xe dose into the head valve injection port at the same time the patient is taking a deep breath. Instruct the patient to hold their breath as long as possible. At the end of breath holding, stop the camera and tell the patient to breathe normally in the Rebreathe mode.

2. Equilibrium - After wash-in, either bolus or homogeneous, with the patient breathing normally in the Rebreathe mode you are now in the equilibrium phase. Rebreathing should be for 3-5 minutes. During this period, a high count rate image may be obtained similar to that used for your perfusion study.

3. Washout - After the equilibrium period, with the patient still in Rebreathe, set the intensity and present count of the gamma camera to 100,000 counts. Take an image for this count and record the time. Put this time into Preset Time and prepare the camera to take sequential images for the length of time indicated. Switch the patient from Rebreathe to Stabilization/Washout and start the sequence. Essentially total washout is usually obtained in 5 minutes. In some instances, longer times will be required. If your camera is equipped with a persistance scope, let it be the guide.

4. Shut Down - After removing the face mask from the patient, you allow the trap to run for approximately 5 minutes (10 maximum) to deflate the Expandable Interface. Operator observation of the bag through the plexiglass window is very important.

ROUTINE MAINTENANCE

CO_2 Absorber - The soda lime granules shipped with the Ventil-Con II have a color indicator to show when they are saturated with CO_2. The normal color is white and as they absorb CO_2, they turn violet to purple. The granules should be changed when about 2/3 of them have changed color, or 50 exams of 10 minute duration. Under low use conditions, the color may fade, thus we recommend changing them once a month or as the color changes, whichever comes first.

To change the absorber, do the following:

1. Evacuate the system by putting the Operate/Evacuate valve (Figure 9) in the Evacuate position. When the spirometer volume reaches 0, put the valve in the Operate position and fill the spirometer to 10 liters by opening the breathing valve (Rebreathe position). When the spirometer fills, close the breathing valve and evacuate the unit again.

2. Unscrew the "bell" jar and dispose of the soda lime granules.

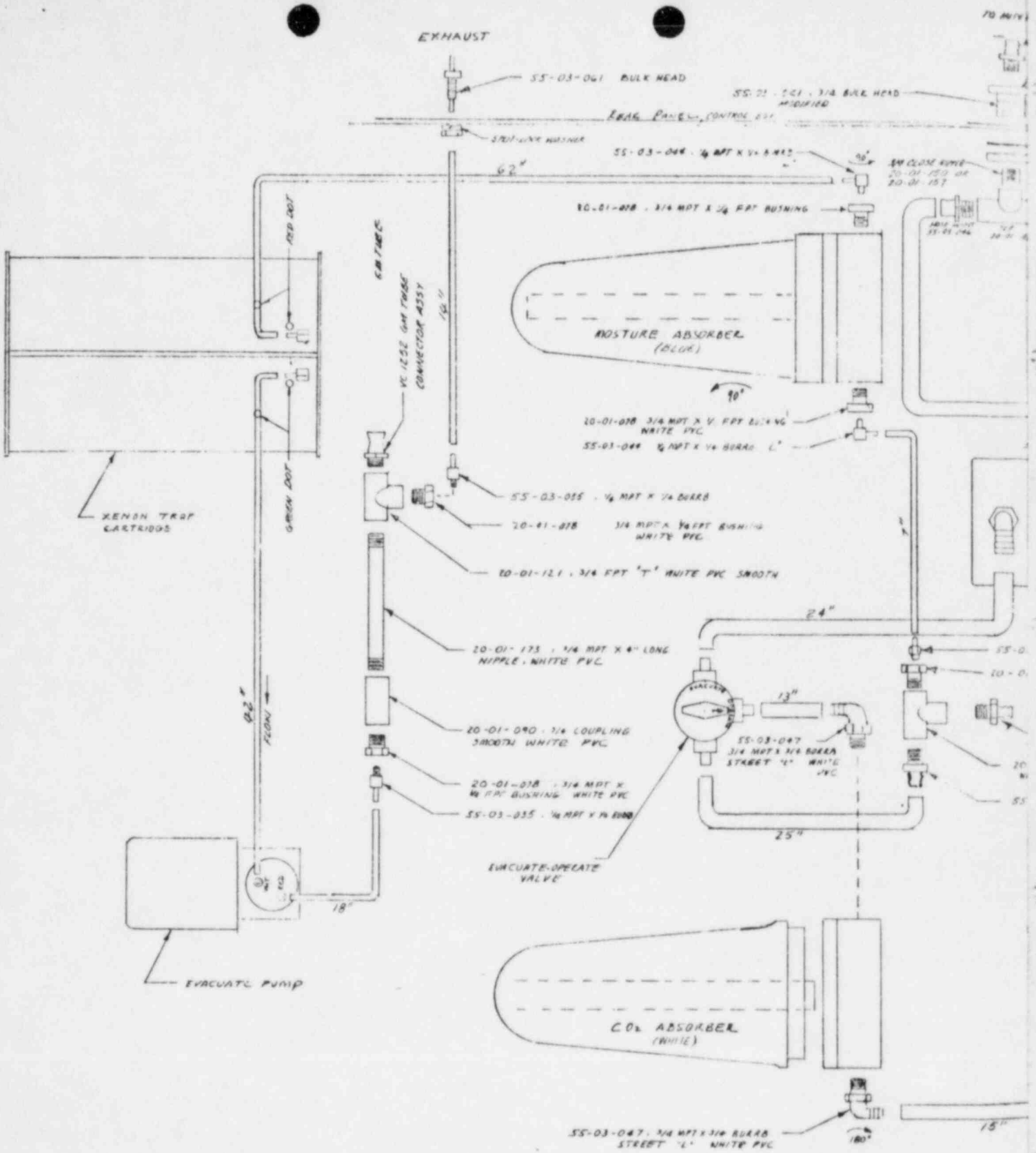
3. Refill the jar with fresh soda lime granules. When refilling, be sure the white tube is centered in the jar.

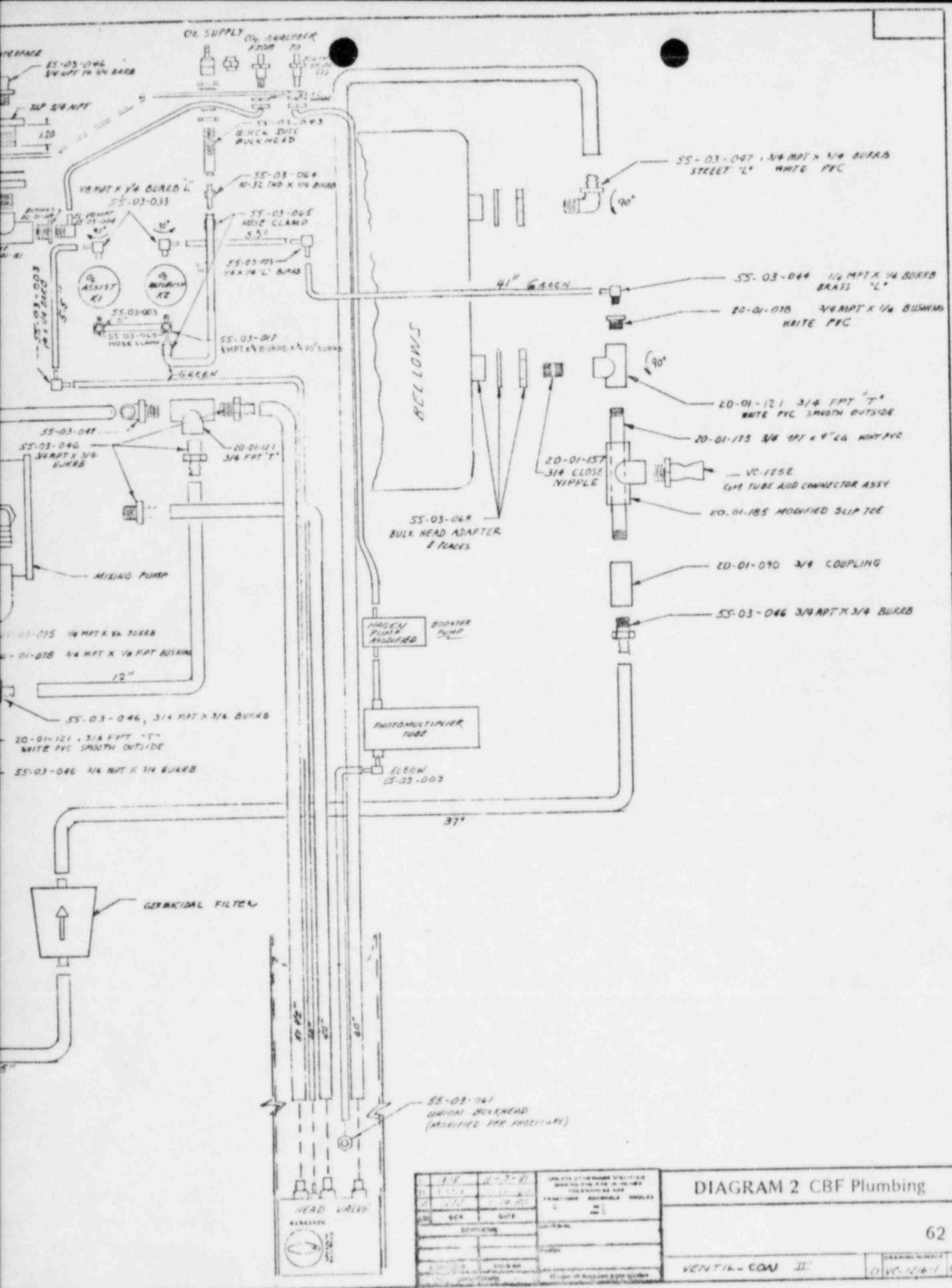
4. Clean the threads and O-ring. Apply fresh silicone grease, such as Dow Corning 970 V High Vacuum Grease to O-ring and threads.

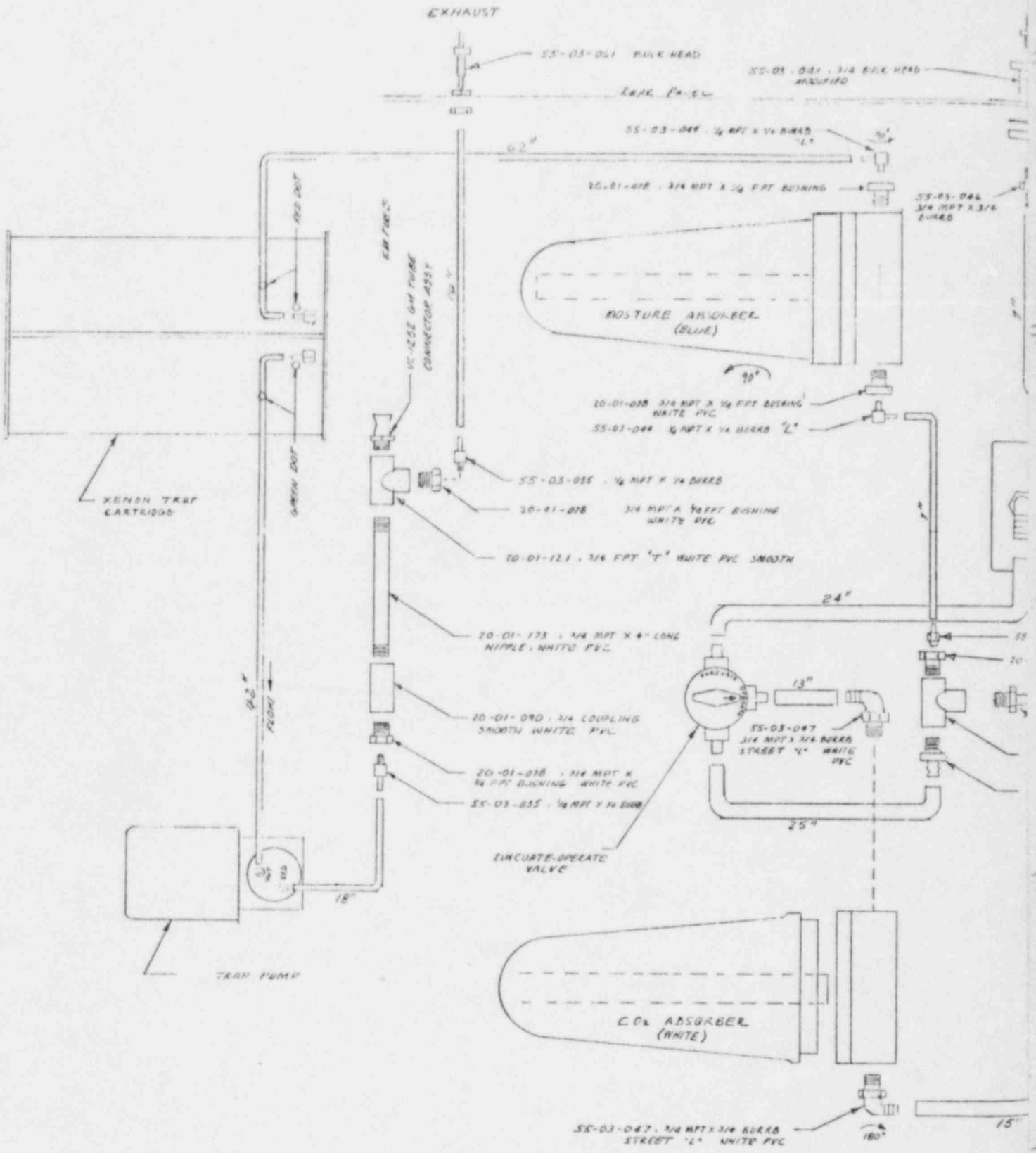
5. Screw the jar back onto the cap. If the jar tightens but still has a space between the blue cap and clear jar (check it with your finger nail), the tube was probably not adequately centered. The jar should be removed and the central tube recentered.
   IMPORTANT: Must be secured tightly to overcome loss of xenon and spirometer volume.

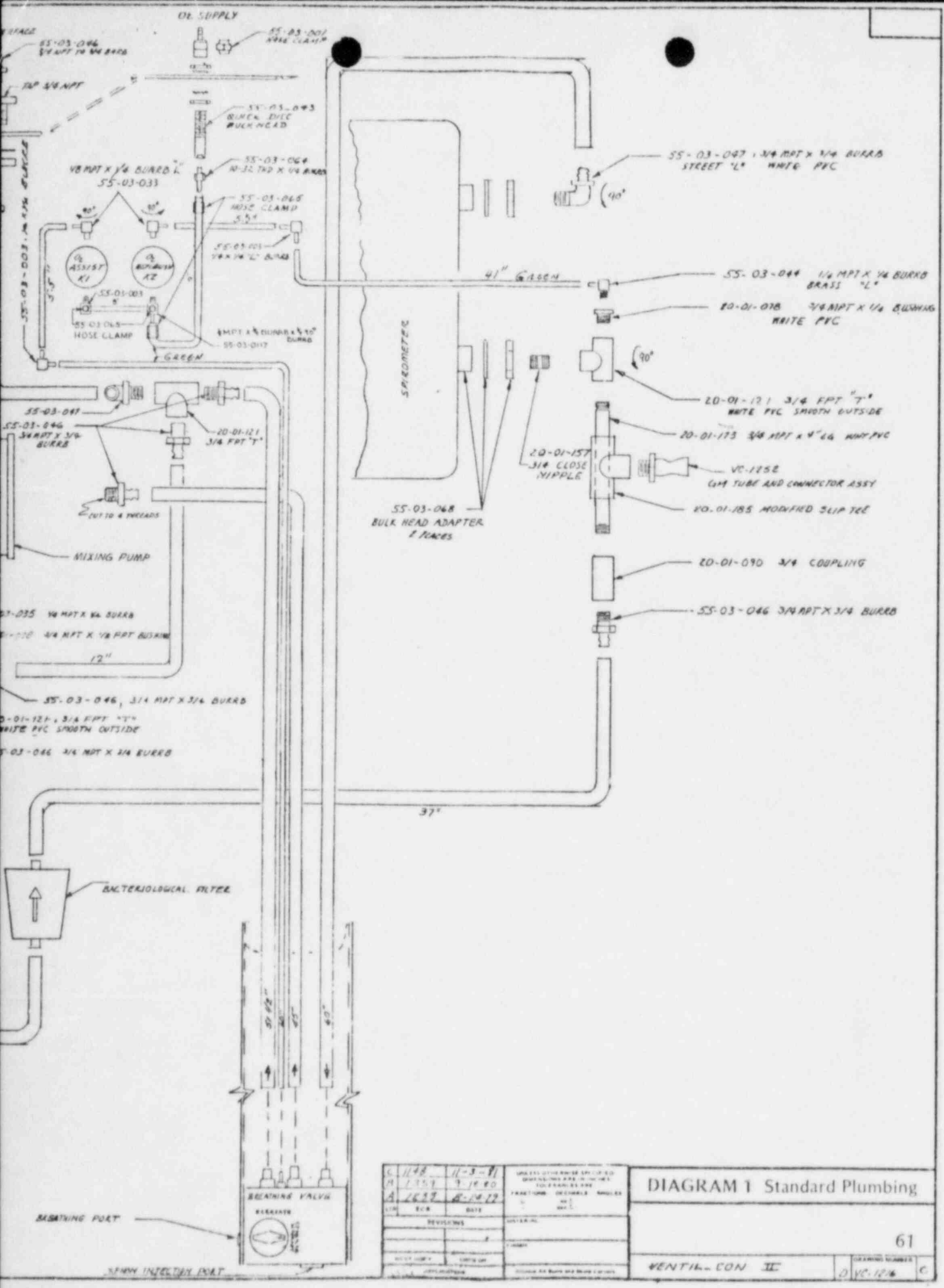
Bacteriological Filter - The Bacteriological Filter (Figure 5) should be removed and autoclaved each time you change the CO_2 absorber or no less often than once per month. It should be replaced entirely once per year. Before removing the Bacteriological Filter, evacuate the unit as described above for the CO_2 absorber.

Moisture Absorber - Units equipped with a Xenon Trap have a silica gel desiccant jar (Figure 5) to remove moisture from the air prior to entering the charcoal cartridge pack. Silica gel is normally a dark blue and turns clear to pinkish, as it becomes saturated with water. When the granules are approximately 2/3 saturated, remove the "bell" jar.


EXHAUST
55-03-061 BULK HEAD
55-03-044 . 1/4 MPT X 1/4 BARB
62"
RED DOT
GREEN DOT
XENON TRAP CARTRIDGE
MOISTURE ABSORBER (BLUE)
90°
20-01-078 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
55-03-044 1/4 MPT X 1/4 BARB
55-03-035 . 1/4 MPT X 1/4 BARB
20-01-078 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
20-01-121 . 3/4 FPT "T" WHITE PVC SMOOTH
20-01-173 . 3/4 MPT X 4" LONG NIPPLE . WHITE PVC
20-01-090 . 3/4 COUPLING SMOOTH WHITE PVC
20-01-078 . 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
55-03-035 . 1/4 MPT X 1/4 BARB
24"
13"
55-03-047 3/4 MPT X 3/4 BARB STREET "L" WHITE PVC
25"
EVACUATE-OPERATE VALVE
18"
EVACUATE PUMP
CO2 ABSORBER (WHITE)
55-03-047 . 3/4 MPT X 3/4 BARB STREET "L" WHITE PVC
180°
18"


O2 SUPPLY
55-03-046 1/4 NPT TO 1/4 BURB
3/4P 3/4 NPT
55-03-033 1/4 NPT X 1/4 BURB "L"
55-03-064 10-32 THD X 1/4 BURB
55-03-065 HOSE CLAMP
55-03-103 1/4 X 1/4 "L" BRASS
55-03-083
55-03-069 HOSE CLAMP
55-03-047 1/4MPT X 1/4 BURB X 1/4 90° BURB
GREEN
55-03-047
55-03-046 3/4 MPT X 3/4 BURB
20-01-121 3/4 FPT "T"
MIXING PUMP
20-01-078 3/4 MPT X 1/4 FPT BUSHING
12"
55-03-046, 3/4 MPT X 3/4 BURB
20-01-121, 3/4 FPT "T" WHITE PVC SMOOTH OUTSIDE
55-03-046 3/4 MPT X 3/4 BURB
GERMICIDAL FILTER
55-03-047 1/4 MPT X 1/4 BURB STREET "L" WHITE PVC
90°
41" GREEN
55-03-044 1/4 MPT X 1/4 BURB BRASS "L"
20-01-078 3/4 MPT X 1/4 BUSHING WHITE PVC
90°
20-01-121 3/4 FPT "T" WHITE PVC SMOOTH OUTSIDE
20-01-173 3/4 MPT x 4" LG WHITE PVC
20-01-157 3/4 CLOSE NIPPLE
VC-1758 GM TUBE AND CONNECTOR ASSY
20.01.185 MODIFIED SLIP TEE
55-03-068 BULK HEAD ADAPTER 8 PLACES
20-01-090 3/4 COUPLING
55-03-046 3/4 MPT X 3/4 BURB
MAGEN PUMP MODIFIED
BOOSTER PUMP
PHOTOMULTIPLIER TUBE
ELBOW 55-03-003
37"
55-03-061 UNIBAL BULKHEAD (MODIFIED PER PROCEDURE)
HEAD VALVE
DIAGRAM 2 CBF Plumbing
62
VENTIL-CON II
VC-1161


EXHAUST
55-03-051 BULK HEAD
55-03-051 3/4 BULK HEAD MODIFIED
55-03-044 1/4 MPT X 1/4 BARB "L"
62"
20-01-078 3/4 MPT X 1/4 FPT BUSHING
55-03-046 3/4 MPT X 3/4 BARB
RED DOT
GW FUSE
VC-125E GW FUSE CONNECTOR ASSY
54"
MOISTURE ABSORBER (BLUE)
90°
20-01-078 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
55-03-044 1/4 MPT X 1/4 BARB "L"
GREEN DOT
XENON TRAP CARTRIDGE
55-03-035 1/4 MPT X 1/4 BARB
20-01-078 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
20-01-121 3/4 FPT "T" WHITE PVC SMOOTH
24"
20-01-173 3/4 MPT X 4" LONG NIPPLE WHITE PVC
13"
20-01-090 3/4 COUPLING SMOOTH WHITE PVC
55-03-047 3/4 MPT X 3/4 BARB STREET "L" WHITE PVC
20-01-078 3/4 MPT X 1/4 FPT BUSHING WHITE PVC
55-03-035 1/4 MPT X 1/4 BARB
25"
62"
FROM
EVACUATE-OPERATE VALVE
18"
TRAP PUMP
CO2 ABSORBER (WHITE)
55-03-047 3/4 MPT X 3/4 BARB STREET "L" WHITE PVC
180°
15"



C	11-48	11-3-81
B	1359	9-14-80
A	2627	6-10-79
LTR	ECR	DATE

REVISIONS

DIAGRAM 1 Standard Plumbing

VENTIL-CON II

D VC-1016 C

PROCEDURES AND PRECAUTIONS FOR USE
OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6 B

The New England Nuclear Co-57 Flood Source is used to calibrate the gamma cameras. The flood source is stored in a sealed container in the Hot Lab. The flood source is placed on the gamma camera and after camera calibration the flood source is retruned to the source container and stored in the Hot Lab.

PRECAUTIONS

A leak test is performed every 6 months. The source is wiped with a cotton ball in alcohol and measured for activity. The source cottonball is compared to room background. Results are logged in the calibrations and source book.

Item No. 23
Date: 8/16/83

60060