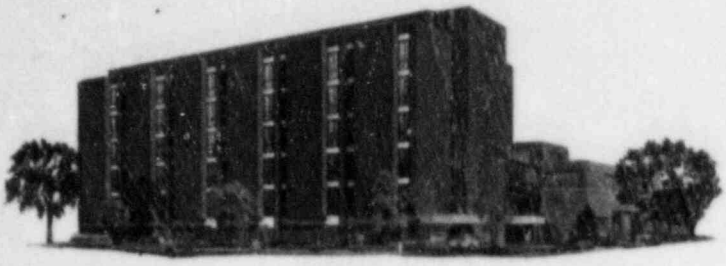
Ms-18
T1



William C. Nichols, Administrator

Memorial Hospital of Laramie County
Phone (307) 634-3341
300 East Twenty-third
CHEYENNE, WYOMING 82001

May 22, 1985

Mr. Jack E. Whitten
Materials Licensing Branch
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Re: License #49-01380-01
Control #460496

Dear Mr. Whitten:

Pursuant to your letter of March 12, 1985, requesting more information concerning our Xenon-133 procedures, we submit the following, utilizing the guidelines of Appendix M of Regulatory Guide 10.8:

1. Quantities to be Used

   Five studies per week are expected
   10mCi per patient will be used
   1Ci is the desired possession limit

2. Use and Storage Areas

   A. Xenon will be stored in the refrigerator in the hot lab. It will be transferred in a shielded container to the scanning room at the time of the study. These areas are shown in attachment I. All areas adjacent to the hot lab and scan room are restricted except the building exterior.

   B. Ventilation flow rates in botn the hot lab and scan room are shown in attachment I. Both rooms exhaust into the building central exhaust directly to the environment at the hospital roof. The exhaust and intake vents are on opposite sides of the hospital roof and are separated by a distance of sixty (60) feet. No changes in these flow rates occur between cooling and heating seasons.

   C. Hospital maintenance personnel will perform airflow rate measurements using a velometer twice a year to assure that stated flow rates are maintained.

460496

3. Procedures for Routine Use

A. Xenon ventilation studies routinely will utilize a New England Nuclear NRP - 186 Calidose Dispenser and a Pulmonex Model 130 - 500 Xenon System. The Xenon vial is housed in the dispenser following the loading procedure recommended by the manufacturer. This assures minimal radiation exposure to the technologist. The Xenon is then injected into the tubing directly in front of the patient's mouthpiece. Operating procedures described by the manufacturer are then followed to complete the study. The hot lab fume hood will remain on at least one (1) hour following each study.

B. The special apparatus used for administration and collection of Xenon-133 is described in the attached operator's brochures.

4. Emergency Procedures

In the event of an accidental release of Xenon-133 in either the scanning room or the hot lab, the following procedure will be followed:

1. All persons, including the patient, will be evacuated from the room where the release occurred.

2. Access will be limited to the room by closing the door to the hallway.

3. At least fifteen (15) minutes per 10mCi released will be allowed to elapse to allow the room's ventilation system to reduce the concentration of Xenon-133 to below the MPC of 1×10^{-5} µCi/ml.

The following calculations support the use of the above emergency procedure:

SCAN ROOM

Room volume (V) = 1800 ft^3 = 5.1×10^7 ml
Airflow exhaust rate (R) = 700 ft^3/min
Activity released (A) = 10 mCi

The average concentration (C) immediately after release =

$$C_o = \frac{A}{V} = \frac{10^4\ \mu Ci}{5.1 \times 10^7 ml} = 1.96 \times 10^{-4}\ \mu Ci/ml$$

The average concentration after fifteen (15) minutes =

$$C = C_o \exp\left(-\frac{R \times time}{V}\right) = (1.96 \times 10^{-4})\ [\exp - \frac{(700)\ (15)}{1800}] = 5.7 \times 10^{-7}\ \mu Ci/ml.$$

This is far below the MPC.

HOT LAB

Room volume (V) = 1200 ft^3 = 3.4 x 10^7 ml
Airflow exhaust rate (R) = 700 ft^3/min
Activity released (A) = 10 mCi

The average concentration immediately after release =

$$C_o = \frac{A}{V} = \frac{10^4\ \mu Ci}{3.4 \times 10^7\ ml} = 2.9 \times 10^{-4}\ uCi/ml$$

The average concentration after fifteen (15) minutes =

$$C = C_o \exp\left(-\frac{R \times time}{V}\right) = 2.9 \times 10^{-4}\ [\exp \frac{-(700)(15)}{1200}] = 4.6 \times 10^{-8}\ uCi/ml$$

This is also far below the MPC.

5. Air Concentration of Xenon-133 in Restricted Area

A. Maximum activity (A) used per week:

$$A = \frac{10\ mCi}{exam} \times \frac{5\ exams}{week} = \frac{50\ mCi}{week}$$

B. Fraction (f) of Xenon lost during use and storage = 0.2

C. Airflow exhaust rate (R) in scan room and hot lab = 700 ft^3/min
Volume (V) of air available for dilution of Xenon-133:

$$V = \frac{700\ ft^3}{min} \times \frac{60\ min}{hour} \times \frac{5\ hours}{week} \times \frac{2.832 \times 10^4 ml}{ft^3} = \frac{5.95 \times 10^9\ ml}{week}$$

D. $$C = \frac{A}{V} \times f = \frac{50 \times 0.2}{5.95 \times 10^9\ ml} = \frac{1.7 \times 10^{-9}\ mCi}{ml} = \frac{1.7 \times 10^{-6}\ \mu Ci}{ml}$$

This concentration is below the MPC of 1 x 10^{-5} mCi/ml for restricted areas stated in section 20.103 of 10 CFR Part 20.

6. Air Concentration of Xenon-133 in Unrestricted Areas

Xenon-133 disposal is by adsorption onto a charcoal trap that is integrated into the Pulmonex Xenon System. During the washout phase of each study, the Xenon-133 used in the study and exhaled by the patient is drawn through the charcoal trap. Any Xenon-133 emitted from the trap will be drawn into the hospital's central exhaust system and released into the environment at the roof of the hospital. The charcoal trap will be tested at least every six months using the attached protocol. The trap will be replaced if greater than 2% ofthe input Xenon-133 is detected at the exhaust port of the trap.

The following calculations show that the average concentration (C) of Xenon-133 at the exhaust port at the top of the hospital's roof will not exceed the MPC of 3×10^{-7} uCi/ml over one year:

Activity Released:

$$A = \frac{5 \text{ exams}}{\text{week}} \times \frac{10 \text{ mCi}}{\text{exam}} \times \frac{10^3 \ \mu\text{Ci}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{year}} \times 0.2 = \frac{5.2 \times 10^5 \ \mu\text{Ci}}{\text{year}}$$

Airflow Volume Per Year:

$$V = \frac{700 \text{ ft}^3}{\text{min}} \times \frac{60 \text{ min}}{\text{hour}} \times \frac{40 \text{ hours}}{\text{week}} \times \frac{52 \text{ weeks}}{\text{year}} \times \frac{2.832 \times 10^4 \text{ ml}}{\text{ft}^3} = \frac{2.5 \times 10^{12} \text{ ml}}{\text{year}}$$

$$C = \frac{A}{V} = \frac{5.2 \times 10^5 \ \mu\text{Ci}}{2.5 \times 10^{12} \text{ ml}} = 2.1 \times 10^{-7} \ \mu\text{Ci/ml}.$$

Saturated charcoal filters will be stored in the hot lab's decay closet after being sealed in a plastic bag to prevent leakage. Storage will be for at least ten (10) half lives or until only background radiation levels can be detected near the filter.

We hope this information will be sufficient to enable you to complete your review of our application, and grant our amendment request.

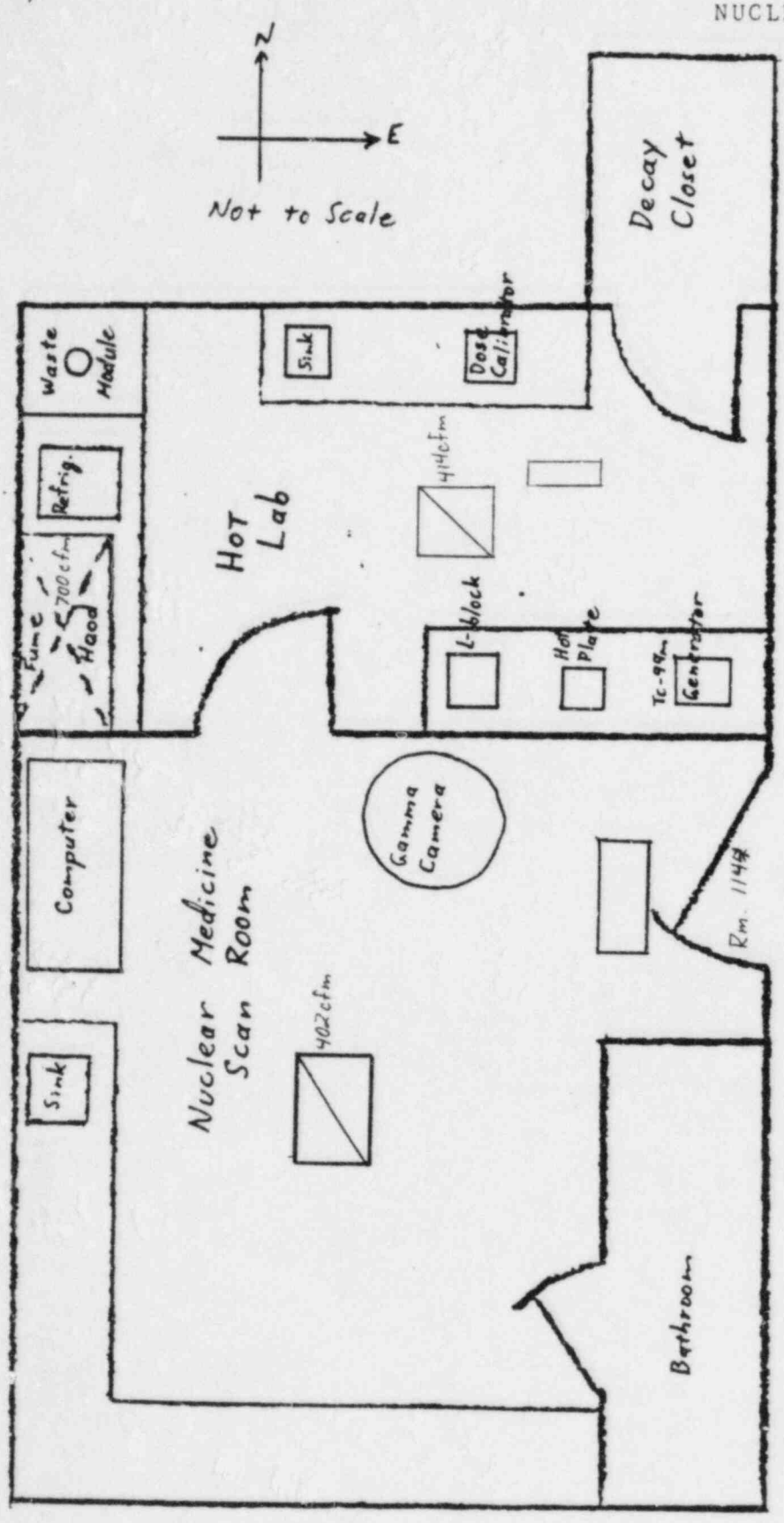
Sincerely

Jon M. Gates
Associate Administrator

Enc.

ATTACHMENT I

NUCLEAR MEDICINE SCAN ROOM AND HOT LAB



Atomlab

INSTRUCTION MANUAL

PULMONEX XENON SYSTEM

130-500

3-STEP SIMPLICITY OF OPERATION

1. Start: Set timer. Patient adjusts to breathing on system. Add oxygen. Set "Airflow" control. Switch handle to 2.

2. Single Breath-Equilibrium: Patient is brea[illegible]n closed loop. Inject Xenon at mouthpiece. Pa[illegible]hes until equilibrium (about 2 minutes). M[illegible]y be added during 2, if necessary. Switch to [illegible].

3. Washout: Patient breathes room air through unit, exhales into trap. Study is complete.

Atomic Products Corporation

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

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

FOLLOW THESE SIMPLE STEPS CAREFULLY:

A. Setting Up Your Pulmonex

1. Open the top rear door. Inspect the interior. All hoses should be connected to their respective ports. Bags should be lying flat. The elbows on the bags should be in their wall brackets. Hoses should not be kinked.
2. Open the lower front door. All hoses should be connected to their respective ports.
3. Remove the empty plastic cartridge that hangs in the lower compartment. Fill the cartridge about 1/4 to 1/3 full with the blue drierite (139-101) and return the cartridge. This serves as a moisture trap for the air going into the charcoal cartridge. Close the lower compartment. Replace the drierite when it changes color (from blue to pink). *Failure to change the drierite will significantly shorten the life of the charcoal cartridge.*
4. Remove the empty plastic cartridge that is within the top compartment. Fill 1/4 to 1/3 full with white granule soda-lime (Model #130-019). Reconnect to the hoses. This soda-lime serves as a carbon dioxide trap. Close the top rear door. Change the soda-lime between each patient. *Failure to change the soda-lime will cause the patient to rebreathe too much carbon dioxide thus causing hyperventilation.*
5. Bring the unit to the area of operation. Make sure the timer is on "0" and plug into a nearby electrical outlet.
6. At the rear of the unit, there are two white hose connections, side by side. Attach the breathing tubes/Y Fitting/bacteria filter/mouthpiece assembly to the hose connections. The plastic plug and warning label on the Y fitting must be facing up.

> **Note:** Keep the breathing tubes as short as possible. If a patient is supine bring the system to the bedside. Never add a length of tubing to the patient side of the Y fitting. If you need more tubing length replace both breathing tubes. The distance from the Y to the patient must be as short as possible.

It is advisable to use hose clamps to tightly fasten the breathing hoses to the hose connections. As a safety precaution you can connect a hose from your room vent to the exhaust port on the Pulmonex. This exhaust port is located on the patient side of the Pulmonex just below the overhang.

> **Caution:** Some patients are sensitive to oxygen. Consult a physician before using oxygen. If the physician prefers, substitute room air for oxygen.

7. To add oxygen connect and clamp a 1/4" oxygen hose from your oxygen supply to the oxygen inlet port on the Pulmonex front panel. Turn the oxygen valve to 5 psi or 6-8 liters/minute and leave it on. If possible, use a pediatric regulator on the oxygen tank.

> **Note:** Use a flow regulator, not a flow meter. Flow rates can be high (up to 50 liters/min.) but pressure must be low, 5 psi.

B. Performing a Study.

8. Using a source, position the patient in front of the scintillation camera. See that both the lungs are within the crystal area.
9. Set the camera for Xe-133. Record all data on tape.
10. Place the Pulmonex as close to the patient as possible and set the handle to the "Start" position. The number "1" will appear under the handle.
11. Set the "Air Flow" control to 30 (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).
12. Press the button on the front panel to add oxygen to the "To Patient" bag. Only add a small amount of oxygen, about 1/4 full. (The bag will only move slightly, do not fill it up.) More oxygen can be added later if the patient requires. In many cases, it is possible not to add any oxygen and perform the entire study on ambient air. In all cases, the oxygen is only to enrich the air in the circuit.

    To do a study with ambient air, before connecting the patient to the system, turn the Pulmonex on and go to position #2. When the "To Patient" bag is 1/4 full, switch the handle back to position #1. Now the system is ready to use.
13. Set the timer to 9 minutes (an arbitrary figure that can be changed at any time depending on the study procedure you prefer).
14. Place the mouthpiece in the patient's mouth. Clamp the patient's nose closed. A face mask may be used, if preferred. Place a vertex cape (#055-101) on the patient.
15. Have the patient breathe briefly on "Start" to become accustomed to breathing with a mouthpiece. The "from patient" bag will move slightly as the patient exhales.
16. Switch the handle to "Single Breath, Equilibium, #2". With a NEN Gun or syringe filled with xenon, puncture the mouthpiece's rubber with the needle and add the xenon as you have the patient take a deep inspiration. Have the patient hold his breath for as long as possible and then continue to breathe normally. Increase the "Air Flow" control to about 70, (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).

    Advise the patient to breathe slowly and normally. Observe both breathing bags moving through the front panel windows. Add oxygen if the patient requires it. An alternative to puncturing the mouthpiece is to use the luer adapter plug provided with the system.

A common problem is the xenon not getting into the patient for single breath. If this happens, try again with these changes:

A. Lower the "Air Flow" control to 20 or 10 five seconds before xenon administration.

B. Puncture the mouthpiece closer to the patient.

C. Have the patient take a deeper breath.

17. When the patient reaches equilibrium (1 or 2 minutes, the counting rate on the camera stabilizes), switch to "Washout, #3". Take washout data on the camera (typical framing: first picture, 15 seconds; second, 30 seconds; third, 60 seconds). Have the patient breathe normally slowly.

18. Carefully watch the "from patient" bag. If it starts blowing up, the patient is breathing too fast. Advise him to normalize his breathing and increase the "Air Flow" speed. If the bag continues to expand up towards the glass, the patient will feel back pressure and resistance. To relieve this effect, open the lower cabinet. In the center there is a motor control. Turn it clockwise until the breathing bag deflates. Return the control to about 1/2 of its range when the study is complete. The use of this motor control will be a rare occurence. Do not adjust it unless it is absolutely necessary. If it is used, be sure to return it to its original position. To be effective, the increase in motor speed must be done before the bag is full so watch the "From Patient" bag carefully during washout.

19. When the washout is complete, remove the patient and let the system run for a few more seconds or until both bags are empty.

To prolong the life expectancy of your charcoal cartridge, do the following:

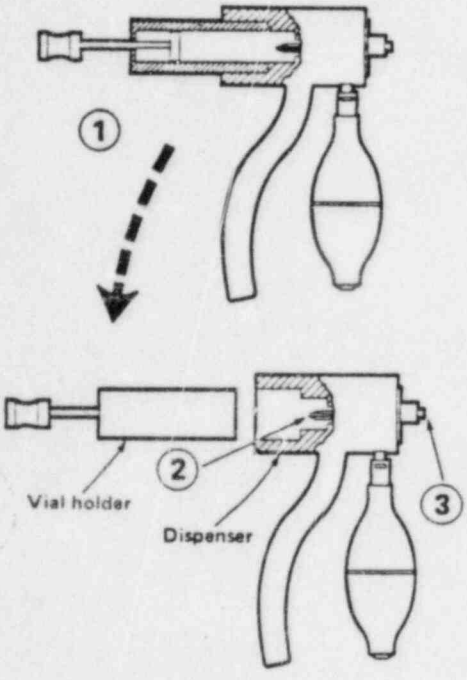
1. When the patient has completed the washout, do not leave the system running for more than 10 seconds.
2. Check the lower blower motor. It should be set on 50-60 and not increased unless a specific patient needs the extra evacuation power.
3. Make sure the drierite is replaced before it changes color.
4. Do not leave the Pulmonex in Position #3 when not in use.
5. Monitor the trap effluent at regular intervals and keep a formal record.
6. Spread studies out. If you perform all your studies in one day, xenon may break through.

Additional routine for maintenance program:

1. Remove the two breathing tubes on the back of the unit. Take one short tube about 8" and connect the two ports on the back of the unit together so that there is a C configuration made by the single tube. Place the handle in position #2 and press the oxygen button filling the unit with oxygen. Both bags should be blown up tight against the glass windows. They should remain tight for about two minutes. If they do not blow up tight or sag, you may have a leak somewhere in the system. Call us if this happens.

New England Nuclear

Operation Instructions for **NRP-186 CALIDOSE™ DISPENSER** for use with **NRP-127 XENON Xe 133 GAS**



Loading

1 Separate shielded vial holder from dispenser.

2 Check Huber point needles inside the dispenser body to insure that they are not blocked (if necessary, clean by pushing a fine wire through needles).

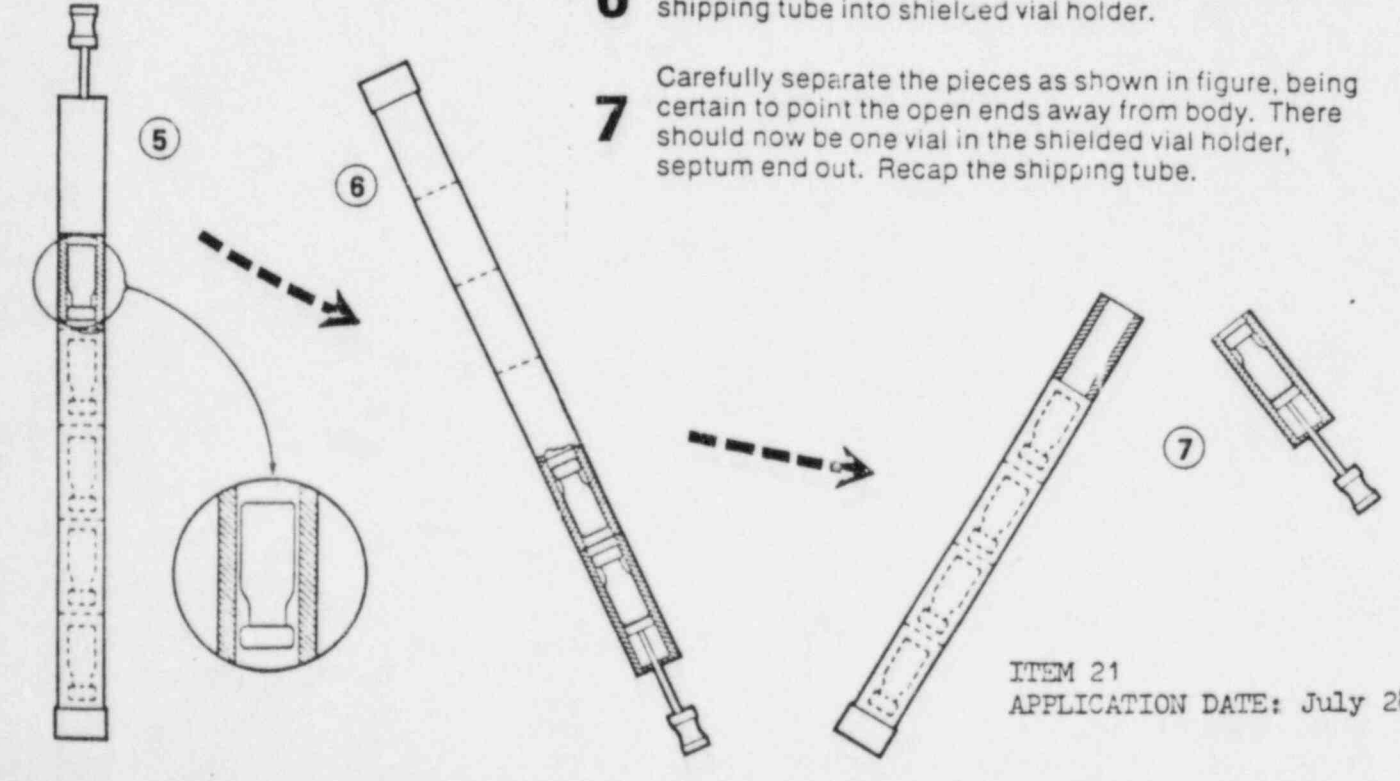
3 Attach a hypodermic needle (or other connector) securely to Luer Lock fitting on front end of dispenser.

4 Remove the yellow cap of the ^{133}Xe lead shipping tube, being careful to point opened tube away from body.

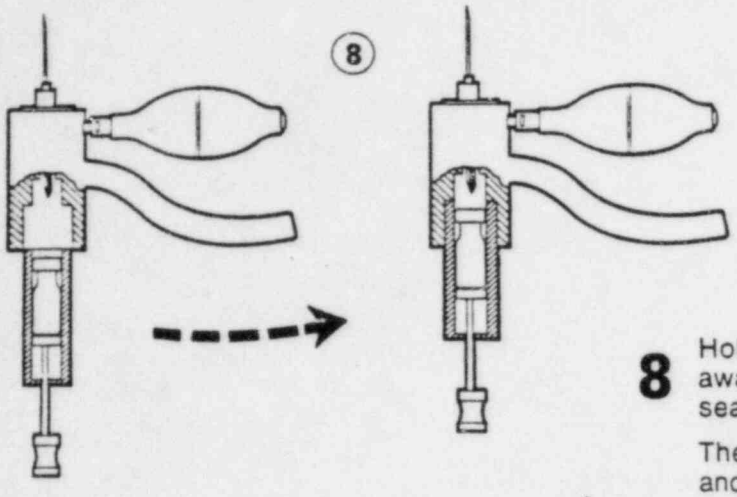
5 Place the open end of the shielded vial holder tightly against the open end of the shipping tube.

6 Simultaneously invert both to allow one vial to slip from shipping tube into shielded vial holder.

7 Carefully separate the pieces as shown in figure, being certain to point the open ends away from body. There should now be one vial in the shielded vial holder, septum end out. Recap the shipping tube.



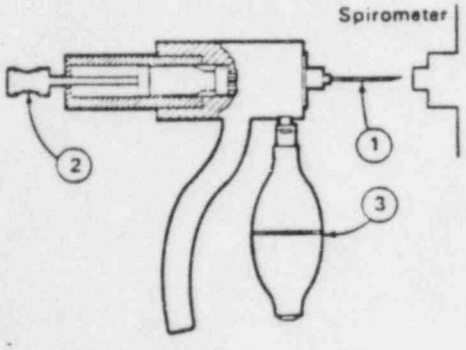
ITEM 21
APPLICATION DATE: July 28, 1983



8 Holding the shielded vial holder upright (and pointed away from body), insert it into the dispenser until seated. DO NOT PUSH PLUNGER IN AT THIS TIME.

The loaded CALIDOSE Dispenser is now ready for use and can be put aside until needed. Note that appropriate radiation protection precautions must be taken since radiation can escape from the front of the unit.

Using



1 Affix the CALIDOSE Dispenser to a spirometer or related breathing apparatus.

2 Puncture septum of loaded vial by pushing plunger into dispenser.

3 Immediately squeeze the rubber bulb, and then release.

4 Detach CALIDOSE assembly from breathing apparatus.

Storing

Remove vial holder from dispenser. The previously used vial will not contain enough residual ^{133}Xe to be harmful, and may be removed by hand for disposal in the radioactive waste. Replace vial holder in dispenser for easy storage.

Statement

This CALIDOSE™ Dispenser is a device protected by U.S. Patent 3,848,773 and other patents are pending. It is to be used solely for the purposes of dispensing New England Nuclear's Xenon 133 gas Catalog Number NRP-127 as defined in New England Nuclear's NDA No. 17-284 submission. This device remains the sole property of New England Nuclear, and must be returned to New England Nuclear, Atomlight Place, North Billerica, Mass. 01862, should it cease to be used as described.

New England Nuclear
Radiopharmaceutical Division
Atomlight Place, North Billerica, Mass. 01862
Telephone (617) 667-9531

S11174 DP-1118 Printed in U.S.A.

XENON TRAP TEST

1. Just before the Xe study, attach the red weather balloon to the trap exhaust outlet.

2. Do the study as usual, when the balloon is full, remove it, seal it with hemastats and put it in the hot lab.

3. After the lung exam is complete and the patient gone, use the gamma camera with the collimator off and raised to the level of the tape on the detector stand. Reset the machine to a Xe peak. Get a 1 min count of background, balloon, and empty Xe vial just used on the patient. Assay the vial in dose calibrator for remaining activity.

4. Use the formula on the special form for amount of Xe that escaped the trap. This should be less than 200 uCi.

CERTIFICATE OF XENON-133 TRAP TEST

LOCATION: _____ DATE: _____
_____ LICENSE NUMBER: _____
_____ FILE: _____

XENON TRAP

Manufacturer : _____
Model Number : _____
Serial Number: _____

ACTIVITY MEASUREMENTS

Patient Dose (A1): _____ mCi
Standard Dose (A2): _____ mCi
Standard Count (C1): _____ cpm
Balloon Count (C2): _____ cpm
Background Count (C3): _____ cpm

Activity emitted by trap per 10 mCi dose =

$$= \frac{(C2 - C3)}{(C1 - C3)} \times \frac{A2}{A1} \times 10{,}000$$

= _____ x ____ x 10,000 = _____uCi

COMMENTS

Activity emitted by trap per 10mCi dose less than 150uCi: YES NO
Xenon trapping efficiency acceptable : YES NO
Charcoal filters need replacing : YES NO
Date filters replaced : _____

PHYSICIST: _____ DATE: _____ NEXT TEST DUE: _____

ROCKY MOUNTAIN MEDICAL PHYSICS, INC.
Pavilion Tower 1, Suite 920
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(303 671-0408