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ITEM 21

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

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in accordance with the Freedom of Information
Act, exemptions 2
FOIA 2006-02-38

Portions Ex2

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ITEM 21 - INFORMATION FOR THE USE OF XENON-133

a. Quantities to be Used:

(1) Patient information:

(a) Number of studies expected per week: 8

(b) Average activity per patient: 20 millicuries

(2) The desired possession limit is 500 mCi (See also Item 6b of this application).

b. Use and Storage Areas:

(1) Xenon-133 studies are only performed in room [] Bldg 2, Walter Reed Army Medical Center (see attached drawing of the Xenon-133 dispensing room). Xenon-133 is stored in the Radiopharmacy, room [] which is kept locked after duty hours. The individual leaded storage drawers used to house unused Xenon-133 vials are also kept locked. Each drawer is individually lead lined on the top, bottom and all four sides. (See attached drawing of the Nuclear Medicine Radiopharmacy).

(2) The attached drawings show the ventilation air flow rates and location of the exhaust vents and the supply vents of the Xenon-133 dispensing room and Radiopharmacy.

(3) The air flow rates for the Radiopharmacy and Xenon-133 dispensing room are such that the rooms are by design under negative pressure at all times.

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c. Procedures for Routine Use:

(1) The Procedures to be followed for routine use of Xenon-133 are as follows: When Xenon-133 is to be used for a patient's study, the necessary vial is removed from the storage unit and assayed in a dose calibrator. Once the assay has been completed, the Xenon-133 vial is placed in a lead container with top and transported to the imaging room. The patient is positioned and the Xenon-133 vial is loaded into a Xenon-133 gas dispensing system which provides more than adequate shielding prior to administration of the Xenon-133 gas. The gas is injected directly into a non-reusable bacterial filter with a 40 inch tube which is fitted to a mouth piece that is completely inserted into the patient's mouth. Nose clamps are applied to reduce loss of the Xenon-133 gas through the nasal passages. The opposite end of the tubing is attached to a XDS (Xenon Delivery System). The XDS (which is lead lined) merely regulates air flow for the various phases of the ventilation procedure along with trapping the CO₂ gas released by the patient. Hooked in tandem with the XDS unit is the "NONEX" Xenon gas trap which draws the exhaled air by a vacuum pump through the five fixed charcoal filter cartridges. The cartridge pack is shielded with a 1/8" lead barrier which makes external radiation levels negligible.

(2) Special apparatus for administration and collection of Xenon-133 are:

(a) Xenon-133 gas dispensing system by New England Nuclear,
Model #: NRP 186 CALIDOSE.

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(b) XDS (Xenon Delivery System) by Nuclear Associates, Inc.,
Model 36-103.

(c) "NONEX" Xenon gas trap by Nuclear Associates, Inc., Model 36-022.

(3) Special procedures employed to reduce leakage: A patient nose
clamp and a fitted mouth piece are used to reduce leakage.

d. Emergency Procedures:

When a Xenon-133 study is compromised, personnel are instructed to leave
the room and to close the door. The negative pressure facilitates the re-
moval of the Xenon-133 gas.

e. Air Concentrations of Xenon-133 in Restricted Areas:

(1) The maximum activity used per week (A): 1.6×10^5 uCi (see para
(5)(a) below).

(2) Estimated fraction of Xenon-133 lost during use and storage (f): 20%

(3) Actual measured air flow: $908 \text{ ft}^3/\text{min}$

Calculated volume of air available per week for dilution of the
Xenon-133: $V = 908 \text{ ft}^3/\text{min} \times \frac{\text{year}}{52 \text{ week}} \times 1.49 \times 10^{10} \frac{\text{ml/year}}{\text{ft}^3/\text{min}} = 2.6 \times 10^{11} \text{ ml/wk}$

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

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

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(5) Calculation of required ventilation rate: A maximum of 20 mCi of Xenon-133 will be used per patient and a maximum of 8 studies per week will be performed. The ventilation rate required to ensure compliance with Section 20.103 of 10 CFR, Part 20:

(a) Maximum activity used per week:

$$A = \frac{20 \text{ mCi}}{\text{Patient}} \times \frac{8 \text{ Patients}}{\text{Week}} \times \frac{1 \times 10^3 \text{ uCi}}{\text{mCi}} = 1.6 \times 10^5 \text{ uCi/week}$$

(b) Assume a lost rate of 20% (f)

$$(c) \quad V = \frac{A \times f}{1 \times 10^{-5} \text{ uCi/ml}} = \frac{1.6 \times 10^5 \text{ uCi/week} \times 0.2}{1 \times 10^{-5} \text{ uCi/ml}} = 3.2 \times 10^9 \text{ ml/week}$$

The required ventilation rate is:

$$\frac{3.2 \times 10^9 \text{ ml/week}}{40 \text{ hrs/week}} \div \frac{1.7 \times 10^6 \text{ ml/hr}}{\text{CFM}} = 47 \text{ CFM}$$

Since the ventilation rate in the Xenon dispensing room is 908 CFM, the ventilation system is satisfactory for a restricted area. The maximum permissible level of release of Xenon-133 per 40-hour week for a restricted area (NRC Regulatory Guide 10.8, Appendix M, Page 6) would be approximately 600 mCi. The amount of air that is recirculated is unknown but is thought to be minute since the recirculated air is recirculated to vents with flow rates of more than 80,000 CFM giving a dilution factor of almost 10^2 .

f. Methods of Xenon-133 Disposal:

(1) Dilution through exhaust systems. Not used.

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(2) Absorption onto charcoal traps:

(a) An effluent concentration of less than 1×10^{-5} uCi/ml is released throughout the useful life of the filters as per the manufacturers literature.

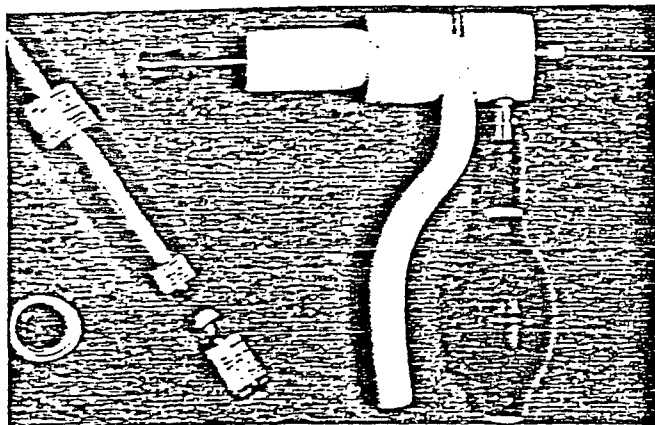
(b) A log is kept of the number of patients and the dose given to each patient. The filters are then changed using the Lifetime Graph (Fig 1, Instruction Manual "NONEX" Xenon Gastrap).

(c) The saturated filters are placed in a plastic bag and placed in a lead lined storage box in Nuclear Medicine Pharmacy. At the next waste collection date they are placed in a steel drum for radioactive waste disposal.

Xenon-133 Gas Dispenser

Xenon-133 gas

- Easy and accurate dispensing of unit doses
- Exceptional safety — unique shielding
- Sizes for single or multi-breath procedures
- Specifically designed for pulmonary function studies



Specifically designed for pulmonary function studies, NEN's Xenon-133 CALIDOSE™ Gas Dispensing System provides a convenient, accurate and safe method of administering xenon-133 gas.

The system consists of a dispenser which is loaded with a vial containing a calibrated dose of xenon-133 gas.

Vials containing 10-100mCi of xenon-133 gas are shipped in a lead tube and loaded into the dispenser as needed. The variety of sizes available permits either single or multi-breath procedures.

OPERATION

Operation of the unit is simple. After the dispenser is loaded, affix the dispenser to the breathing apparatus with a needle or other connector; push the plunger at the rear of the dispenser (puncturing the septum of the loaded vial by inner needles); and squeeze the rubber bulb.

Caution: Contents to be used *only* for inhalation.

ORDERING INFORMATION

NRP-186 CALIDOSE Gas Dispenser

Supplied at no charge during the term of an order.

NRP-127 Xenon-133 Gas CALIDOSE refills, in unit dose vials.

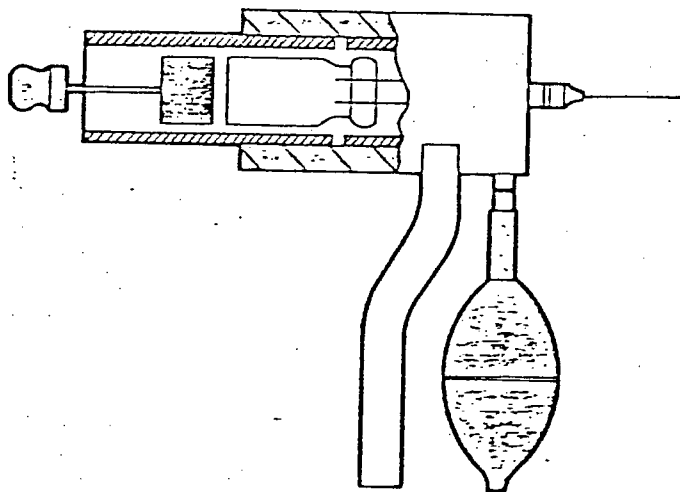
5 unit doses (10mCi each) — \$ 95

10 unit doses (10mCi each) — 135

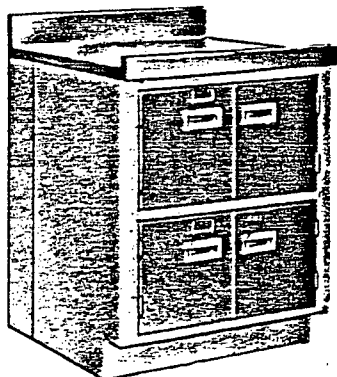
1 unit dose (100mCi each) — 85

5 unit doses (100mCi each) — 245

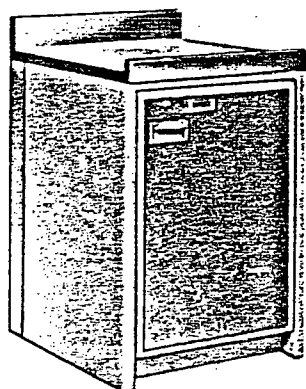
Intermediate quantities, quantities larger than listed, and standing order prices are available on request.



STANDARD SYSTEM MODULES



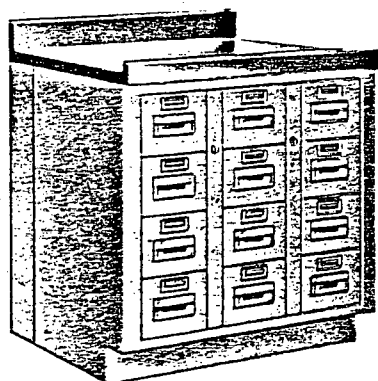
No. RH-3



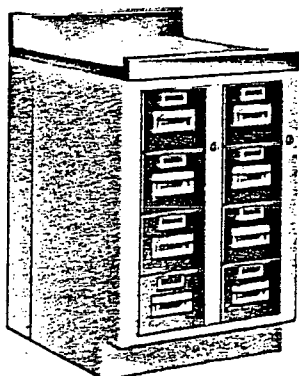
No. RF-3

No. RH-3 Receiving, Holding and Storage Module provides a lead shielded upper compartment for receiving and holding materials received into the Nuclear Medicine Department until time permits re-location and storage in the proper module. The lower lead shielded compartment may be used for short or long term decay.

No. RF-3 Refrigerator Module provides a 4 cu. ft. lead shielded refrigerator complete with a freezer compartment and two lead shielded drawers. The U.L. listed refrigerator operates on single phase, 60 cycle, 115 volt AC, and is equipped with wide range temperature control and push button defrost.



No. IS-3-12

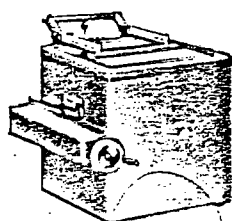


No. IS-3-8

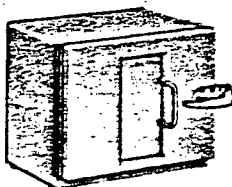
STORAGE FOR XENON-133

No. IS-3-12 Inventory and Storage Module provides for the inventory of generator prepared reagents and other radiopharmaceuticals. Utilization of this module will facilitate record keeping. The twelve drawers operate on heavy duty roller slides, and are individually lead shielded on the top, bottom and all four sides. All drawers are provided with coved interior plastic inserts for ease of cleaning and/or decontamination.

No. IS-3-8 Inventory and Storage Module is similar to No. IS-3-12, except provides only eight drawers.



No. GT-1



No. GT-1S

No. GT-1 Generator Safe (for top elution generators) is lead shielded on all four sides, top and bottom, and provides radiation protection from the generator during and between elutions. A front remote control is provided to raise the cover partially for elution, or full open for generator replacement. The underside of the cover is equipped with a mirror to allow an indirect view of the generator for positioning elution vials without exposing the technologist to the open safe. Wheels are provided on the bottom of the safe to enable the user to move it to the front of the work surface for elution, and to the rear when it is not being used.

No. GT-1S Generator Safe (for front elution generators) is lead shielded on all four sides, top and bottom, and provides radiation protection from the generator during and between elutions. It includes a full swinging front door for generator replacement and a sliding door for the elution process. Wheels are provided on the bottom of the safe to enable the user to move it to the front of the work surface for elution, and to the rear when it is not being used.