7/28-DCS

ST. JOSEPH'S HOSPITAL

March 28, 1980

Regional Licensing Section
Radioisotopes Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

The following additional information is provided in support of our renewal application for byproduct materials license no. 13-00418-02 (control no. 02846), as requested during Mr. Pettijohn's visit to our facility on February 28, 1980.

1. Enclosed are completed copies of the "Calibration of Survey Instruments" and "Calibration of Dose Calibrator" sheets from the Licensing Guide.

2. Airflow rates in the nuclear medicine rooms were measured with a velometer by our consulting medical nuclear physicist on March 21, 1980. Enclosed is a revised Item 21 incorporating these measurements in the format suggested in Appendix M of the Licensing Guide.

3. The first nursing instruction on the form "Radiation Safety Report for Patients Who Have Received Therapeutic (30 mCi) Amounts of Radioiodine" (see Appendix 2 of the renewal application) has been revised to read as follows:

   1. The patient must be confined to this room until the retained activity is less than 30 mCi.

4. Enclosed is a copy of our procedures for handling liquid Iodine-131.

5. The "appropriate shielding device" referred to in the "Precautions for Handling Sealed Radioactive Sources Containing Therapeutic Quantities of Radioactive Material", is a long-handled lead-lined cart designed specifically for the purpose of transporting sealed sources within the hospital. The lead shielding is sufficient to provide a reading of approximately 2 mR/hour at three feet from the cart when carrying 80 mg equivalents of Cs-137 (based on actual exposure rates measured on March 21, 1980).

700 BROADWAY • FORT WAYNE, INDIANA 46802 • (219) 423-2614

AN EQUAL OPPORTUNITY EMPLOYER

6. It does not appear necessary to add a no. 14 to the "Instructions for Care of Patients Containing Sealed Source Implants", since no. 7 already contains the statement, "When temporary implants are removed, the patient and all areas occupied by the patient will be surveyed to be sure that all sources have been removed."

U.S. Nuclear Regulatory Commission, Region III

7. All wipe samples are counted in a well counter with a wide PHA window (50 keV to 550 keV).

   Any sample counting less than background +3 standard deviations will indicate no removable contamination. Samples from unrestricted areas counting more than background +3 standard deviations will indicate the presence of removable contamination and the area will be cleaned. Samples from restricted areas with more than 200 net counts per minute per 100 cm^2 will be cleaned.

8. A revised "Instructions for Receipt of Packages Containing Radioactive Material" is enclosed.

9. A revised Item 12, "Personnel Training Program", is enclosed.

10. Enclosed is a copy of our protocol for determining Mo-99 breakthrough.

Also enclosed are Supplement's A and B of Form NRC-313M for John Daughdrille, M.D. We would like to request that Dr. Daughdrille be listed as an Individual User on the renewed license.

We hope this additional information satisfactorily answers the questions raised by Mr. Pettijohn.

Sincerely,

Sister Kathleen

Sister M. Kathleen
Administrator

SMK:cag

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

JOHN ERNEST DAUGHDRILL E

STREET ADDRESS

5601 BURNHAM WOODS LN.

CITY | STATE | ZIP CODE

FT. WAYNE IND 46804

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	100	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	4	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	27	
	IN VITRO STUDIES	200	
OTHER			
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	74	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	10	
Yb-169	CISTERNOGRAPHY	0	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	100	
OTHER	131 Cisternography	3	
Tc-99m	BRAIN IMAGING	421	
	CARDIAC IMAGING	0	
	THYROID IMAGING	10	
	SALIVARY GLAND IMAGING	0	
	BLOOD POOL IMAGING	30	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	195	
	LUNG IMAGING	170	
	BONE IMAGING	60	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	1	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	10	
I-131	TREATMENT OF THYROID CARCINOMA	3	
	TREATMENT OF HYPERTHYROIDISM	10	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	1866	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR *	1	*Used one manufacturer's generator for the entire year.
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	5	
Other Radium	Intracavitary	4	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

3/1/73 - 2/28/74 700 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Kenneth D. McGinnis, M.D.

b. NAME OF INSTITUTION
Mt. Carmel Mercy Hospital

c. MAILING ADDRESS
6971 West Outer Drive

d. CITY
Detroit, MI 48235

5. MATERIALS LICENSE NUMBER(S)
21-00998-01 & 21-00998-02

6. PRECEPTOR'S SIGNATURE
K D McGinnis M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
Kenneth D. McGinnis, M.D.

8. DATE
2-4-80

FORM NRC 313M-SUPPLEMENT B
(8-78)

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
JOHN ERNEST DAUGHDRILLE	INDIANA

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AMERICAN BOARD OF RADIOLOGY	NUCLEAR MEDICINE & DIAGNOSTIC	SEPTEMBER 1976

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	DETROIT, MICHIGAN MT CARMEL HOSPITAL 1971 - 1972	50	50
b. RADIATION PROTECTION	"	25	25
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	10	10
d. RADIATION BIOLOGY	"	10	10
e. RADIOPHARMACEUTICAL CHEMISTRY	"	5	5

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc^{99m}	20 mCi	MT CARMEL HOSP OAKWOOD HOSP HARPER HOSP ST MARY HOSP DETROIT, MICHIGAN DEARBORN, MICHIGAN BOSTON UNIVERSITY BOSTON MASS	4 YEARS	SUPERVISION OF DOSAGE
Xenon	5 mCi			
Gallium				
I^{131}	50 mCi			

A GUIDE FOR THE HANDLING OF SODIUM IODIDE I-131 SOLUTIONS

1. Store the I-131 solution bottle in the refrigerator in the lead shipping shield immediately upon receipt. The refrigerator should be maintained at 35° to 40° F. Keep the bottle in that shield at all times.

2. Always wear rubber or plastic gloves when handling I-131 solution.

3. Always remove the I-131 solution bottle cap at arm's length so that if any iodine escapes upon opening, inhalation of the iodine will be minimized.

4. If a fume hood is not available, do not open bottle in an area where there is a draft. Volatilized iodine is a heavy vapor and will not rise very far under static air conditions.

5. Always transfer the I-131 solution with a bulb(or similar device) aspirated pipet. Never mouth aspirate the pipet.

6. Always use a pipet with the smallest diameter at the tip consistant with the volume to be aspirated. The smaller the volume of the pipet itself, the smaller the volume of air displaced from the bottle.

7. If transferring I-131 solution to another closable container, cap both containers immediately after making the transfer.

8. If transferring I-131 solution to an open container such as a waxed cup or water glass, discharge the pipet at the surface of the water used for dose administration. The water should be chilled, but contain no ice.

9. If the entire contents of the I-131 solution bottle are used, make the transfer as in step 8. Do not pour the solution into the administration container.

DETERMINING Mo-99 BREAKTHROUGH

1. Peak the thyroid uptake system with Cesium-137.

2. Set the counting window of 300 with a centerline of 750.

3. Count background for one minute.

4. Count eluate in lead shield for one minute. Place lead shield as close as possible to the collimator.

5. Count simulated Mo-99 standard (vial labelled 104.8 uCi Mo-99) in the same shield in the same position as in step 4 for one minute.

6. Calculate the microcuries of Mo-99 in eluate.

$$\text{Mo-99 (uCi)} = \frac{85 \times \text{eluate net CPM}}{\text{simulated Mo-99 standard net CPM}}$$

7. Divide the calculated Mo-99 contamination from step 6 by the total millicuries of Tc-99m in the eluate.

8. Do not use the eluate if the Mo-99 contamination exceeds 1 microcurie of Mo-99 per millicurie of Tc-99m, or if the total Mo-99 contamination in a patient dose will exceed 5 microcuries.

The 85 in the calculation in step 6 is the actual equivalent Mo-99 activity (in microcuries) of the simulated Mo-99 source labeled 104.8 microcuries. The source is actually Cesium-137 and should decay corrected at the rate of 2.3% per year.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

X 2. Calibration will be performed at two points on each scale.

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.

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 _____
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 James Durlacher

(2) Location ~~At Licensee's Facility~~

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 13-07215-01

____ are attached

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	1-5	5%
Ba-133		
Cs-137	.200	5%

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

or

_____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

PROCEDURES AND PRECAUTIONS FOR USE OF XENON-133

The following information is provided in accordance with the format recommended in Appendix M of Regulatory Guide 10.8.

1. Based on prior experience, the anticipated number of Xenon-133 studies is approximately 4 per week. The usual administered activity per patient is 10 millicuries. Thus our desired possession limit of 500 millicuries should be sufficient to provide for shipments whose calibration dates are several days after receipt.

2. A diagram of the Nuclear Medicine facility is attached, including the location of supply and exhaust vents. Airflow rates for each vent were measured with a velometer by our consulting medical nuclear physicist on March 21, 1980. Similar measurements will be made at six month intervals in order to insure that all airflow rates are maintained as specified in this application.

   At the present time, the hood in the hot lab is not functioning. However, air leaving the hot lab through the doorway will be exhausted through the vent in the nuclear imaging room due to the large negative pressure at doorway A (see diagram). The 600 CFM exhaust vent in the imaging room exhausts directly to the outside with no recirculation and there are no intake vents in the imaging room. Thus, makeup air is provided only through doorway A, creating a substantial negative pressure in the vicinity of this doorway. This is accentuated by the fact that there are no exhaust vents in the ultrasound area, and that the air intake vent in the ultrasound room is located on the wall and directs the air across the ultrasound area toward doorway A.

   Since the Xenon-133 is obtained in unit dose vials, leakage of Xenon-133 is most likely to occur during the actual patient procedure which takes place in the imaging room. The unit dose vials are stored in the hood in the hot laboratory behind lead bricks. While this room is not under negative pressure at this time, the potential for release of Xenon in this room is small, and if present, any Xenon will be cleared through the imaging room exhaust vent after it leaves the hot lab. As soon as the hood exhaust is again functional, the hot lab itself will be under negative pressure.

3. The Xenon-133 is administered to the patient in the imaging room using an Atomic Products Corporation Model 130-330 Xenon Delivery Unit. The rebreathing system and the patient will be washed out through an Atomic Products Corporation Model 127-313 Xenon Gas Trap. The effluent from the trap will be continuously monitored with an Atomic Products Corporation Model 136-100 Gas Trap Efficiency Monitor. Nose clamps will be utilized to minimize the escape of Xenon-133 into the room during the procedure.

4. In the event that there is an accidental release of a full patient dose of Xenon-133 into the imaging room, the patient and staff will vacate the imaging room for approximately one hour. Based on the 600 CFM

minute exhaust rate, this allows for approximately six air changes. The room will be surveyed upon reentry in order to verify that no detectable Xenon-133 is remaining.

In the unlikely event that a full patient dose is released in the hot lab (for example, if a Xenon-133 vial is dropped and broken), the entire nuclear medicine facility (hot lab, ultrasound room, and imaging room) will be vacated for approximately one hour. Each area will be surveyed upon reentry in order to verify that no detectable Xenon-133 is remaining. At such time as the hood in the hot lab is again functional, the hot lab itself will be under negative pressure and it should then only be necessary to vacate the hot lab.

5. Air Concentrations in Restricted Areas

Assumptions: 4 studies per week or
40 millicuries/week = A

20% lost during use
and storage = f

$$\frac{A \times f}{1 \times 10^{-5} \text{uCi/ml}} = 8 \times 10^{8} \text{ ml/week}$$

$$\frac{8 \times 10^{8} \text{ ml/week}}{40 \text{ hr/week}} = 2 \times 10^{7} \text{ ml/hour}$$

$$\frac{2 \times 10^{7} \text{ ml/hour}}{1.7 \times 10^{6} \text{ ml/hr/CFM}} = 11.8 \text{ CFM}$$

Thus, in order to meet the requirements of 10 CFR Part 20.103, the imaging room must have a ventilation rate of at least 11.8 CFM with no recirculation of air.

The measured ventilation rate in our imaging room is 600 CFM with no recirculation, far in excess of the required minimum ventilation rate calculated above.

6. As described earlier, the Xenon-133 will be disposed of by adsorption onto a charcoal trap.

Assume 20% leakage:

A = 4 studies/week x 52 weeks/year x 10 mCi/study x.2 = 416 millicuries released/year

V = 600 CFM x 1.484×10^{10} ml/year/CFM

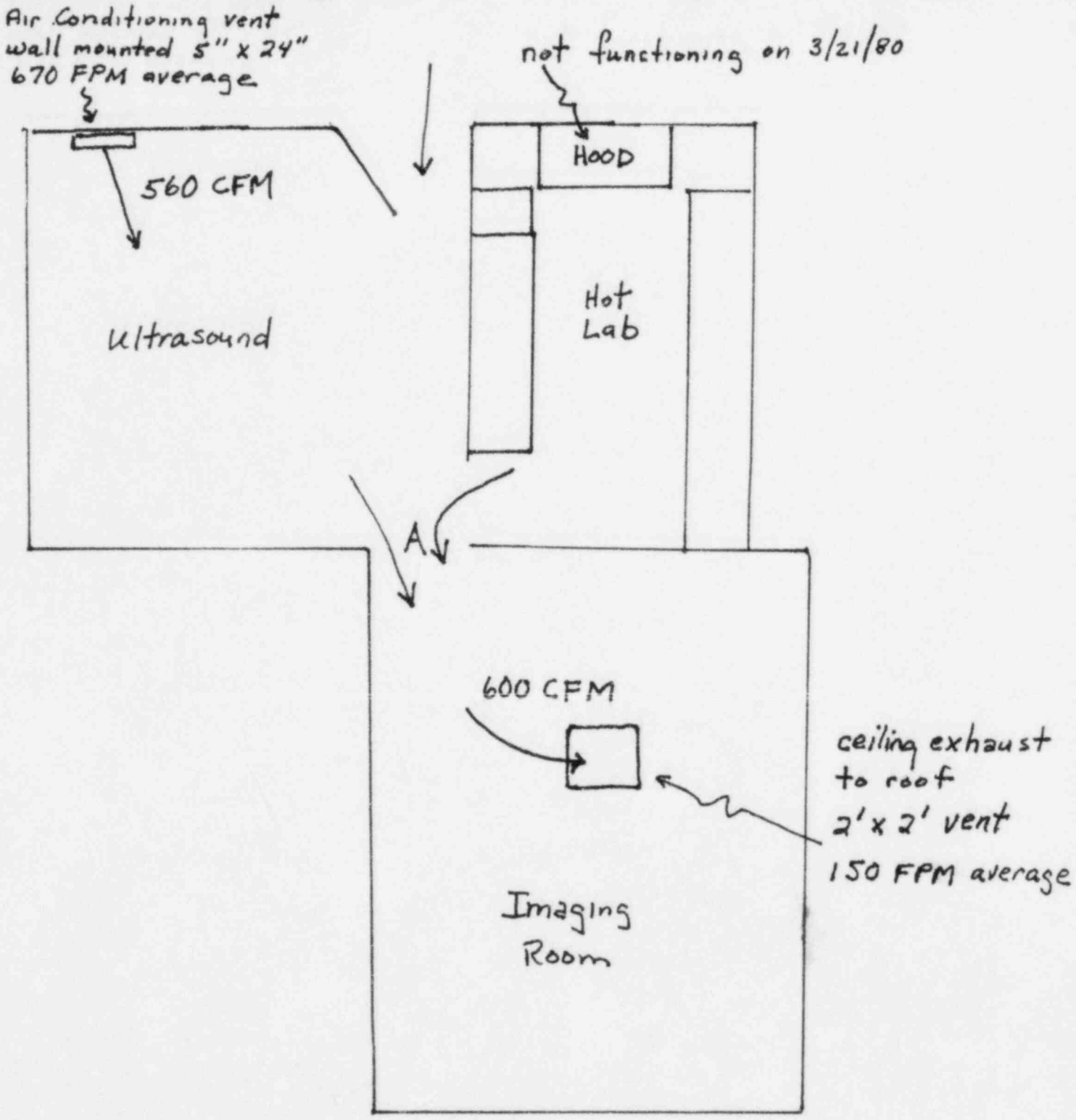
V = 8.9×10^{10} ml/year

$$C = \frac{4.16 \times 10^{5} \text{ uCi/year}}{8.9 \times 10^{12} \text{ ml/year}}$$

$$C = 4.7 \times 10^{-8} \text{ uCi/ml}$$

Thus, the maximum anticipated air concentration, averaged over one year, does not exceed 3×10^{-7} uCi/ml, as required.

As described earlier, the performance of the trap will be monitored continuously using the Atomic Products Gas Trap Efficiency Monitor. Saturated filters will be stored behind lead bricks in the hot lab until the filter reads background when surveyed with a GM survey meter. This assumes, of course, that the hood in the hot lab will be functional. If the filter saturates prior to that time, arrangements will be made to store the saturated filter in a corner of the imaging room, where the ventilation is known to be adequate.



Ventilation Pattern in Nuclear Medicine
Area as of March 21, 1980

INSTRUCTIONS FOR RECEIPT OF

PACKAGES CONTAINING RADIOACTIVE MATERIAL

During normal working hours, all incoming shipments of radioactive material are to be delivered directly to Nuclear Medicine.

After normal working hours and on weekends, the following instructions are to be observed for all incoming shipments of radioactive material:

1. Examine package for evidence of external damage.

2. If there is no evidence of external damage, take the package to the Nuclear Medicine hot laboratory.

3. If there is evidence of external damage, such as crushing, wetness or water stains, put on plastic gloves and place the package in a plastic bag. Seal the bag and take it to the Nuclear Medicine hot laboratory. Notify the Radiation Safety Officer immediately. Do not let carrier leave the facility until he and his vehicle have been checked for contamination by the Radiation Safety Officer.

Note: Radioactive material is to be ordered only by Nuclear Medicine personnel and packages containing radioactive material are to be opened only by Nuclear Medicine personnel.

Radiation Safety Officer: John N. Pasalich, M.D.
Office: 219/423-2614 ex 2281
Home: 219/432-6394

All hospital personnel who work with or in the vicinity of radioactive materials will receive proper instruction in accordance with Section 19.12 of 10CFR Part 19, including:

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 NRC 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.

i) Their right to be informed of their radiation exposure and bioassay results.

The above instruction will be provided in the form of an approximately one hour lecture to all technologists and other appropriate personnel, such as nursing, clerical, housekeeping and security personnel. Such instruction will be provided before these personnel assume their duties with or in the vicinity of radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations or in the terms of the license.