Lois Rutz, M.S.
Marshfield Clinic, 28
1000 N. Oak
Marshfield, Wi. 54449
May 16, 1985

William J. Adams, PhD.
Materials Licensing Branch
Nuclear Regulatory Commission
799 Roosevelt Rd.
Glen Ellyn, Illinois 60137

Dear Dr. Adams,

Please ammend our license renewal application by changing the Radiation Safety Officer from Lois Rutz, M.S. to Robert Peterson, B.S. Ms. Rutz will be listed as member of radiation safety committee. Mr. Peterson's C.V. is attached.

Thank you.

Sincerely,

Lois Rutz, M.S.

license number48-10966-03
control number 16248

CURRICULUM VITAE

Robert E. Peterson, Jr.

HOME ADDRESS: 124 South Montowese Street, #12
Branford, Connecticut 06405
(203) 481-5182

BUSINESS ADDRESS: Yale-New Haven Hospital
Radiological Physics
20 York Street
New Haven, Connecticut 06504
(203) 785-2950

PERSONAL DATA:

Date of Birth: December 19, 1954

Height: 5'10"

Weight: 185 lbs.

Physical Condition: Excellent

Marital Status: Married, one child

EDUCATION:

Purdue University
West Lafayette, Indiana 47907
B.S. Environmental Health (Bionucleonics, Health Physics)
1976

PROFESSIONAL EXPERIENCE:

12/81 - Present — Health Physicist
Yale-New Haven Hospital, Radiological Physics
20 York Street
New Haven, Connecticut 06504
Supervisor: R.J. Schulz, Ph.D.

11/79 - 11/81 — Health Physicist
University of Illinois
Division of Environmental Health and Safety
317 McKinley Hospital
1109 South Lincoln Avenue
Urbana, Illinois 61801
Supervisor: Hector Mandel

12/77 to 10/79 — Health Physicist
Medical College of Ohio
Radiation Safety Office
C.S. 10008
Toledo, Ohio 43699
Supervisor: Joe P. Windham, Ph.D.

PROFESSIONAL EXPERIENCE: (Cont'd)

11/76 - 11/77 Environmental Technician I
University of Cincinnati
Radioisotope Laboratory
Radiation Safety Office
Cincinnati, Ohio 45267
Supervisor: Kenneth M. Fritz, M.S.

Consultant: Stamford Hospital Radiology Department
Stamford, Connecticut

Griffin Hospital, Radiology Department
Derby, Connecticut

West Haven Veterans Administration Medical Center
Radiation Therapy Department
West Haven, Connecticut

New Milford Hospital, Radiology Department
New Milford, Connecticut.

Hospital Committees:

Hospital Radioisotope Committee

Hospital Radioisotope Subcommittee

Hospital Human Use Committee

Hospital Safety Committee

Associations:

Health Physics Society

American Association of Physicists in Medicine

Society of Nuclear Medicine

PRESENTATIONS: Schneider, A.J., Windham, J.P., Peterson, R.E., Jr., and Kereiakes, J.G., "Radiation Dose Rates Near Radium-226, Cesium-137, and Cobalt-60 Brachytherapy Sources", presented at the 20th annual meeting of the American Association of Physicists in Medicine, San Francisco, California, August 1978.

Schneider, A.J., and Peterson, R.E., Jr., "Performance Comparison Between Three Commercial Suppliers of X-Ray Equipment", presented at the 24th annual meeting of the Health Physics Society, Philadelphia, Pennsylvania, July 1979.

Sanders, L.J., and Peterson, R.E., Jr., "Injection of Liquid Scintillation Cocktail in Gas-Fired Boilers at the University of Illinois, Urbana/Champaign", presented at the 8th Campus Radiation Safety Officers Conference, Tuscon, Arizona, June 1981.

GROUP DISCUSSION LEADER:

"Dealing with Biohazard and Environmental Problems in Academic Health Centers", Educational Program of the Group on Institutional Planning at the National Meeting of the Association of American Medical Colleges, October 24, 1980, Washington, D.C.

MEMBERSHIP IN PROFESSIONAL SOCIETIES:

Health Physics Society

Society of Nuclear Medicine

American Association of Physicists in Medicine

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

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

Marshfield Clinic, 1000 N. Oak Ave.
St. Joseph Hospital, 611 St. Joseph Ave.
Marshfield Medical Foundation, 510 N. St. Joseph Ave.
Marshfield, WI 54449

TELEPHONE NO.: AREA CODE (715) 387 5511

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Lois Rutz

TELEPHONE NO.: AREA CODE (715) 387 9022

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 481096603

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

N/A - Broad Scope License

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.)*

Lois J Rutz, MS

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE See attached

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	as attached
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	6 Ci
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	4 Ci

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	0.5 Ci
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	0.2 Ci
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	0.2 Ci
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	0.35 Ci
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	1.0 Ci
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	3.0 Ci

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
Any byproduct material with atomic numbers between 3 and 83 inclusive	Any	See attached (over)	

ITEM 6 a and b

Radioactive Materials

Byproduct, source and/or special nuclear material	Chemical and/or physical form	Maximum amount that license may possess at any one time
1. Any byproduct material with atomic numbers between 3 and 83 inclusive.	Any	200 mCi of each byproduct material with atomic numbers between 3 and 83 inclusive except as stated below
2. Au-198	Any	350mCi
3. H-3	Any	30 mCi
4. H-3	Foil	150 mCi
5. U-235	Depleted uranium, cadmium plated, used as shielding for a medical accelerator	91Kg

ITEM 10B - Calibration of Instruments: Dose Calibrators

A. Annual tests

1. Accuracy of dose calibrators at three energy levels will be checked with calibrated reference sources obtained from commercial radiopharmaceutical companies. These sources will be in vials identical to those used in preparation of daily 99mTc doses. The three sources currently used are C_0-57 (3-5 mCi), Ba 133 (250 μCi) and C_S-137 (50% μCi).

   The activity measured as the average of three successive determinations should be within ±5% of the nominal activity after corrections for background and decay. If the dose calibrator cannot be adjusted to within ±5% an energy correction will be assigned and used for routine assays.

   The reference standards may change from time to time but will always encompass an equivalent range of energies and be an NBS traceable reference.

2. Activity of a Tc99m source is also determined at 6, 24 and 48 hr. after an initial assay. These readings are plotted on a decay graph constructed for 99mTc from the initial assay. Measured activity should be within ± 5% of predicted activity. If errors greater than ± 5% are noted, repair or adjustment of the instrument will be performed. If it is not possible to bring predicted activity within the error range, calibration factors for the correction of observed activity will be calculated, posted with the instrument and used for routine assays.

B. Initial evaluation

1. New dose calibrators and dose calibrators which have undergone repair will be checked as listed under 'Annual tests' (paragraph A above).

2. Additionally, a vial identical to that used for daily 99mTc preparation containing approximately 10 mC 99mTc in 5 cc will be assayed. Successively 5 cc containing approximately 10 mC 99mTc will be added to the vial to a total of 30 cc. Activity will be assayed after each addition.

   The activity measured at the volume of the commercially obtained source used for linearity testing will be designated the true activity. True activity for all other volumes will be calculated. Correction factors for observed activity at all other volumes will be calculated, graphed and used in routine assays.

3. Appropriate tests of the dose calibrator response to volume and geometry variations will be made. Necessary correction factors will be established and placed near or on the instruments.

C. Quarterly evaluation

1. At the time of the annual check and quarterly, a 137 Cs therapeutic source (3M needle) will be assayed on all radionuclide settings of each calibrator. Subsequent readings will be compared to those obtained at the annual accuracy determination and changes of greater than $\pm$ 5% will dictate need for adjustment or repair.

2. The calibrators will be inspected quarterly for mechanical condition, electrical cord fraying, instrument zero setting and to ascertain that the measurement chamber liner is in place.

3. All dose calibrators will be tested quarterly for linearity of response with varying activity.

D. Daily evaluation

1. Dose calibrators will be checked daily with a 137 Cs source (New England Nuclear NES-356) on 137 Cs and 99mTc channels. Results will be compared to results on the day of the annual check. Changes of greater than $\pm$ 5% will indicate need for repair or adjustment of the instrument prior to use.

ITEM 13 - Procedures for Receipt and Opening of Packages Containing Radioactive Materials

During normal working hours all orders for radioactive materials will be received by the central isotope receiving office. No individual users are authorized to receive direct shipments of radioactive materials. Each user will notify the central isotope receiving office of all material ordered.

After working hours, shipments will be accepted by the St. Joseph's Hospital outpatient admitting personnel. The outpatient admitting patient representative will be responsible for the receipt and correct handling of the packages. After the materials are received they will be locked up in the security office - adjacent to outpatient admitting - and kept there until no later than the next working day, at which time they will be transported by authorized personnel to the central isotope receiving office where the packages will be logged in and opened.

In the event that a package delivered after hours is found to be damaged the person(s) receiving the package will follow the attached outlined policy.

Instructions for Receiving Radioactive Materials Through Outpatient Admitting

During normal working hours radioactive materials are to be delivered directly to the Central Isotope Receiving office in Hospital Nuclear Medicine. Direct all delivery men to Nuclear Medicine during these hours.

Occasionally you will be asked to receive these materials after hours or on weekends. The procedure used will be as follows:

1. Before signing for a parcel inspect it for signs of damage of leakage.

   If the parcel is in good condition, receive it, call Security, and transfer the package to the Security office.

2. If there are signs of leakage take the following steps.

   a. Inform the carrier that you suspect contamination and ask him to wait until this can be confirmed.

   b. Call the Radiation Safety Officer, Lois Rutz, at 387-8054 (home phone).

      If she is not available call one of the following people (in this order).

      1. David Fetterolf - Director of Nuclear Medicine 387-8129
      2. Dr. Richard Miller - 387-3296
      3. Dr. R. Greenlaw - 387-3556
      4. Dr. David Loshek - 387-4848

3. If the package has leaked causing contamination in the area isolate the area by using tape or marking pens.

   Do not allow yourself or others to get the materials on their hands or clothes. Should you accidentally contaminate your skin - wash thoroughly with soap and water. The RSO or radiation safety committee member reached will assist you.

   If it is determined that there is contamination of the area, proper clean-up of procedures will be taken. This may include decontamination of personnel, clothing, area floors and delivery vehicle. Actions necessary will be determined by the RSO or other authorized member of the radiation safety committee.

ITEM 14 - Opening of Radioactive Material Shipments

Opening of radioactive material shipments will be as follows: For quantities and transport groups exempted by 10 CFR 20.205 special opening instructions from the manufacturer will be noted and followed. All packages will be visually inspected for damage, as will the contents of the package after opening. If damage is noted, the contents of the package will be surveyed and decontaminated if necessary. Any contaminated material will be treated as radioactive waste and the area cleaned before other packages are received.

For non-exempt quantities and transport groups the following procedure will be used:

1. Packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a) (1) and (c) (1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m) will be monitored for surface contamination and external radiation levels within 3 hr after receipt if received during working hours or within 18 hr if received after working hours, in accordance with the requirements of paragraphs 20.205 (a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.02 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 ft (or 1 m).

2. In addition, the procedures for opening ALL packages containing radioactive materials will be followed by receipt office personnel as stated in 14.2a through 14.3 of this license.

   a) Put on gloves to prevent hand contamination

   b) Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer

   c) Measure exposure rate at 3 ft (or 1 m) from package surface and record. If > 10 mR/hr, stop procedure and notify Radiation Safety Officer

   d) Measure surface exposure rate and record. If > 200 mR/hr, stop procedure and notify Radiation Safety Office

   e) Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip
      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle
      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material)

ITEM 15 - General Rules for Safe Use of Radioactive Material

A. All personnel within the complex who wish to use byproduct material will submit their proposed use to the Radiation Safety Committee for evaluation. No use is permitted until approval is obtained from the Committee. A copy of the following will periodically be distributed to all potential users in the complex and specifically to any personnel known to be preparing an application.

Instructions for Application for Use of Radioactive Material

All users of radioactive material within St. Joseph's Hospital, the Marshfield Clinic, the Marshfield Medical Foundation, and the Joint Venture Laboratory must be approved by the Radiation Safety Committee. The Committee will ask the Radiological Safety Officer to review your proposed use, and will then contact you indicating approval or disapproval of your request and noting any necessary additional safety procedures. You are not authorized to procure or use material until you are notified of such approval. Your application must include proposed procurement of radioisotopic material, amounts of material required, proposed handling methods (i.e., storage) after receipt from the Central Isotope Office and methods of handling radioactive wastes. Survey procedures of areas in which material will be stored and handled and personnel monitoring required must be included. A statement should be included that records of surveys, including negative results, will be kept by the user. If your proposal involves administration to humans, it must include an estimation of dose received with details of the calculation. Whole body and critical organ doses are to be included.

Evidence that the expected benefits justify the radiation exposure will be required. If exposure data are not well documented in the literature, you should include measurements to re-evaluate dose in your procedure and report such results to the Radiation Safety Committee. Appropriate literature references of dose received are required.

Evidence of satisfactory training in radiation safety procedures establishing your ability to handle the material and administer the program will be required. If you have any questions regarding survey requirements, personnel monitoring, waste disposal, storage or any other aspects, contact the Radiological Safety Officer and review the Byproduct Material License.

After review of a proposed use by the Radiological Safety Committee, the Radiological Safety Officer will inform the applicant of the decision of the Committee. If the application is approved, he will review the program with the applicant, including appropriate review and spot checking of surveys by the Radiological Safety Officer. Each approved user will receive the following:

Notification of Approval for Use of Radioactive Material

Your application for use of radioactive material has been approved. The statements in it become in effect an extension of our byproduct material license granted by the Nuclear Regulatory Commission and have the effect of Federal law.

You must:

Follow the safety program you outlined
Cooperate with the Radiological Safety Officer in monitoring your program
Have all orders of byproduct material delivered to the central isotope office
Transfer material to other users only with the approval of the Radiological Safety Officer
Handle wastes as outlined in your application, transferring wastes at periodic intervals to minimize personnel exposure and keep area restrictions at a minimum
Maintain a record of all receipts to include: isotope, chemical form, total activity, specific activity or activity per unit volume, manufacturer or distributor, lot number, use and ultimate disposal

You must not:

Order byproduct material without informing the central isotope office
Receive byproduct material directly
Dispose of material except as authorized in the application

In case of question or emergency contact:

The Radiological Safety Officer, the Chairman of the Radiation Safety Committee, or another Committee member

B. Appropriate laboratory equipment and apparel will be specified in the user proposals. All areas in which radioactive material is used will be clearly designated. Permanent surfaces will be covered with bench paper or trays will be used to prevent inadvertent contamination of the surface. Gloves and laboratory coats will be worn when contact with free nuclides or nuclides in solution is possible.

C. Uses involving labelling of materials with I-125, I-131, or I-123 will be conducted in a fume hood with a minimum flow of 100 cubic feet of air per minute. Labelling with activities in excess of 5 mCi will not be authorized without review of special procedures for handling possible volitalization of iodine.

D. Lead bricks, lead lined storage cabinets, lead line refrigerators, syringe holders, syringe shields, and other protective equipment will be used as required to maintain personnel exposure as low as practicable. Such devices will be obtained only from recognized suppliers or manufacturers. Where such devices are used, the user is responsible for maintenance in accordance with manufacturer's instructions. Periodic surveys will include survey of areas

specifically designed to check the continued integrity of such materials. Annual evaluations of approved users by the Radiological Safety Officer will include evaluation of all safety devices and recommendations regarding replacement.

Syringe holders will be used for holding all syringes of radioisotopic material while awaiting injection. Syringe shields will be used routinely for the preparation of doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well being.

E. All patient doses will be assayed in the dose calibrator prior to patient injection. Technologists are instructed to check all therapeutic doses against the physicians request. No therapeutic dose varying by greater than ± 10% of the requested dose will be administered.

Material received in the admitting office at other than normal working hours will be transported to the central office for inspection and opening in the original container unless the container shows evidence of physical damage and/or moisture.

F. All transfers of radioactive materials within and between institutions will be accomplished with double containment by placing the materials in their original shipping packages in a second container. Containers of liquids will have sufficient absorbent material to absorb all of the liquid. Transfers will be accomplished only by personnel properly trained in contamination control and authorized to perform transfers by the Radiation Safety Officer. Users wishing to transfer material will contact the central isotope office for help.

Should a package leak or spill during transport, the transporter will immediately notify the Radiation Safety Officer. He will remain with the spill until it has been determined that neither the transporter nor his cart and items for delivery are contaminated. At that time the transporter will be released and clean-up will proceed as per item 16 of this license. If contamination of personnel or materials is detected, decontamination will proceed as in item 16 of this license.

G. All materials will be stored such that the dose rate on contact with the exterior of the integral shielding (exterior walls in the case of material in an unoccupied room) will be such that a major part of the body of designated personnel in a controlled area may not receive in any one hour a dose in excess of 5 mRem or in any five consecutive days a dose in excess of 100 mRem or such that a major part of the body of anyone in a non-controlled area may not receive a dose in excess of 1/10 of the above. All materials will be secured against unauthorized access when unattended by locking the laboratory or the storage room where the materials are or by locking the cabinets where they are stored or a combination of these maeasures (e.g. lock cabinets and door to room). When radioactive materials are transported among institutions they will not be left unattended.

H. Personnel required to wear film badges, ring film badges, pocket dosimeters and other personnel monitoring devices will be determined by the Radiological Safety Officer and will include all personnel likely to receive an exposure in one year greater than 25% MPD.

The Radiological Safety Officer will arrange for exchange of film badges and other devices periodically and will maintain all records of personnel exposure. He will notify via their supervisor all personnel who receive more than 400 mRem exposure on their film badge measuring whole body dose in any one calendar month.

Should monitors be lost, contact the Radiological Safety Officer.

Monitoring devices will be stored in an area not exposed to radiation when not being worn and will be protected by heat, sunlight, and pressure at all times.

I. Waste will be segregated into long and short half-life and disposed of as described in ITEM 18 of this license. Each user will also maintain records of quantities, form and ultimate disposal of his own materials.

Interim storage areas and receptacles will be shielded such that the exposure rate at the surface will not exceed 2 mR/hr.

Interim storage areas will be designated as restricted areas.

J. Eating, drinking, smoking, application of cosmetics will be prohibited in all areas where radionuclides are prepared and administered. In large laboratories and work areas, the restricted sections will be designated clearly.

Refrigerators and storage areas for radioactive material may not be used to store personal effects or foods.

Personnel preparing radiopharmaceuticals will be instructed to monitor their hands periodically throughout the day. A continuous area monitor is provided in the Nuclear Medicine hot lab and may be used for this purpose.

K. The radiation safety officer will conduct periodic reviews of each user. The reviews will be a monthly inspection of each user's facility, a review of receipt, survey, and disposal records, and a general inspection of the isotope use area. Such reviews will take place monthly. In addition, a wipe test of two or more areas in the facility will be conducted quarterly. Any problems identified during the reviews will be brought to the attention of the user at the time of the review. If the problem can be corrected immediately it will be, otherwise corrective actions will be determined and carried out by the user as soon as is reasonably possible. In this case the attached form will be sent to the user and returned to the RSO.

ITEM 20 - Therapeutic Use of Sealed Source

Sealed sources of radiation will be used as therapeutic sources by the radiation oncologists, currently Dr. H. H. Russ and Dr. R. H. Greenlaw. Procedures for procurement, use and disposal of sources is outlined below.

Individuals handling sealed sources for radiation therapy will wear TLD ring badges, which will be changed monthly.

ITEM 21 Xe-133

Lung function ventilation studies will be done by inhalation and injection methods of Xe-133. An estimated 10 studies per week will be done with expected maximum dosage to be 15.0 mCi/study inhalation, 25 mCi/study I.V. Expected patient dose as per PDR 1978/79 is 3mr whole body, 150 mr lung. Maximum possession will be 3 Ci with predicted usage of 2 Ci/2 weeks. This will be stored in the fume hood in the hot lab. Dose will be drawn in hood with exhaust fan on.

Study will be performed in the camera lab using the RADX XENACON III cpntrolled gas delivery system. The specifications of the system are attached. Any replacement system will have equivalent or improved specifications.

The studies will be run with the backup ventilation system running creating a negative pressure in the camera lab. Ventilation rates are show in the accompaning floor plan. The exhaust hood in the hot lab exhausts at 1000 CFM . The ceiling exhaust vent has a rate of 200 CFM (vent A). In addition the hood is equiped with a HEPA filter and an activated charcoal filter with 95% efficiency. Nose clamps or full face mask inhalation system will be used to increase efficiency and reduce leakage.

In the event of unintentional release of radioactive gasses in either the imaging or drawing room, the room will be isolated and personnel evacuated (ventilation system will already be activated). A survey meter will be used to determine the release to the atmosphere through the vent system. Further survey will be done in the adjacent area to insure no residual contamination before returning the rooms to normal use. Wipe tests of relevant areas in the air flow path will be done. Decontamination procedures will be undertaken if activity is more than 100 cpm above background. Negative pressure will be maintained until room activity in main vent stream is less than 0.05 mR/hr.

Calculation of Xe-133 concentration in uCi due to gas leakage.

$V = A/1\times10^{-5}$ μCi/ml

A=15 mCi$\times$10 pts/week
$=150\times10^{3}$ μCi/week

$$V(\text{required}) = \frac{150\times10^{3}\ \mu\text{Ci}}{1\times10^{-5}\ \mu\text{Ci/ml-week}}$$

$=3.75\times10^{8}$ ml/hr

V(required)=220 cu ft/min

The actual ventillation rate in the area , with the fume hood on is 800 cu ft/min inlet, changed at a rate of 1200 cu ft/min exhaust. this exceeds the necessary ventillation rate by a factor of four.

The exhaust rate of 1000 CFM provides a dilution to

$$C = \frac{150 \times 10^{3}\ \mu Ci}{1000\ CFM \times 1.48 \times 10^{10}\ ml/yr}$$

$= 1 \times 10^{-8}$ uCi/ml averaged over one year.

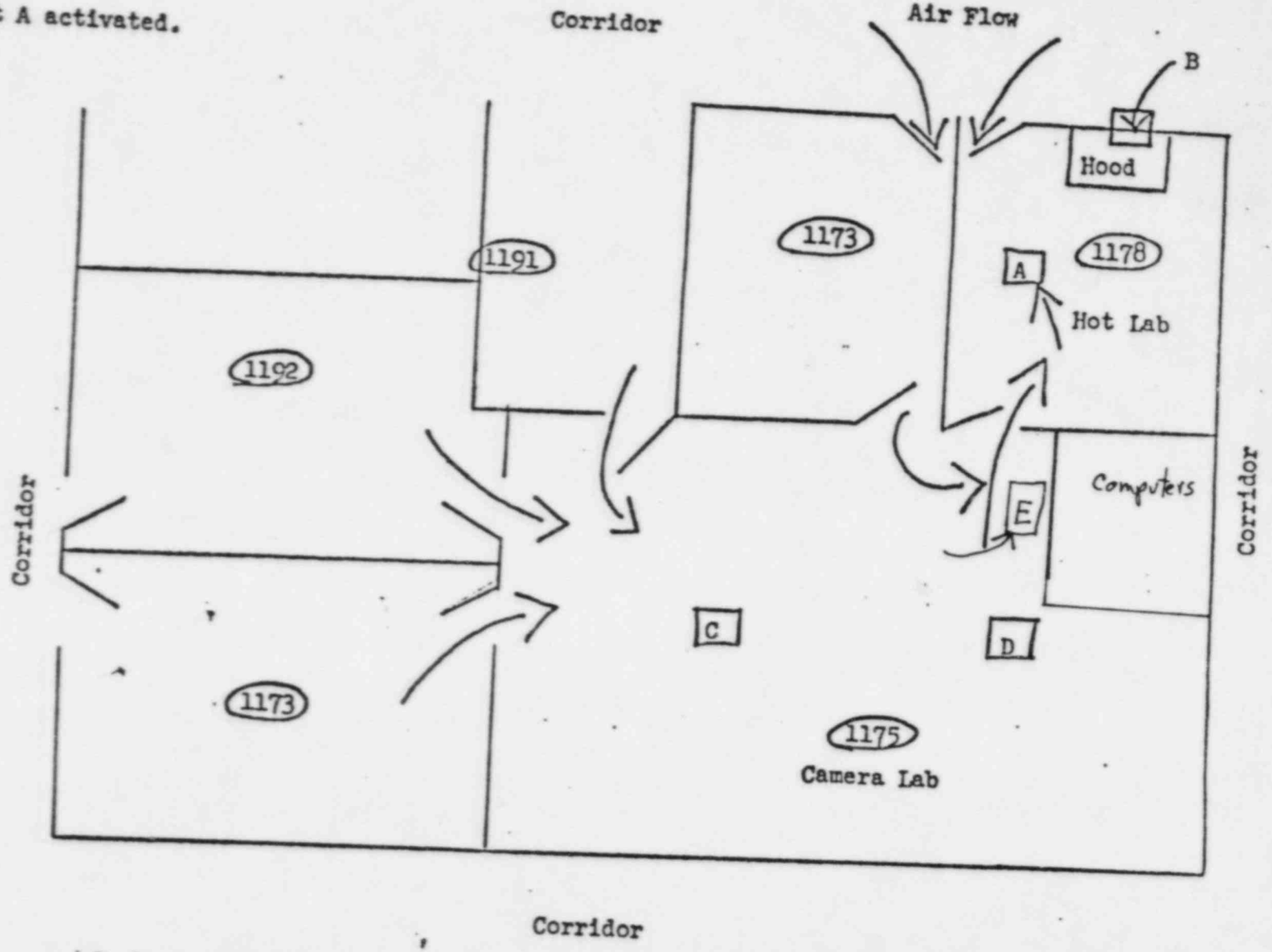
NOTE: Conservative estimates were made in both expected activity in gaseous form and percent leakage(100%). Further, the calculation is done without consideration of the filter system present, which reduces the activity released to the atmosphere by nearly a factor of 100 in an attempt to maintain a level of activity as low as possible.

Ventilation rates will be monitored at least semiannually by hospital maintenance personnel. The monitor used will be the ALNOR series 6000P velometer or equivalent device. In addition ventilation testing is done routinely on all ventilation systems throughout the hospital and is documented in test and balance reports kept on file by the hospital maintenance department.

Vents A - 200 CFM, B - 1000 CFM E - 800 CFM Exhausts

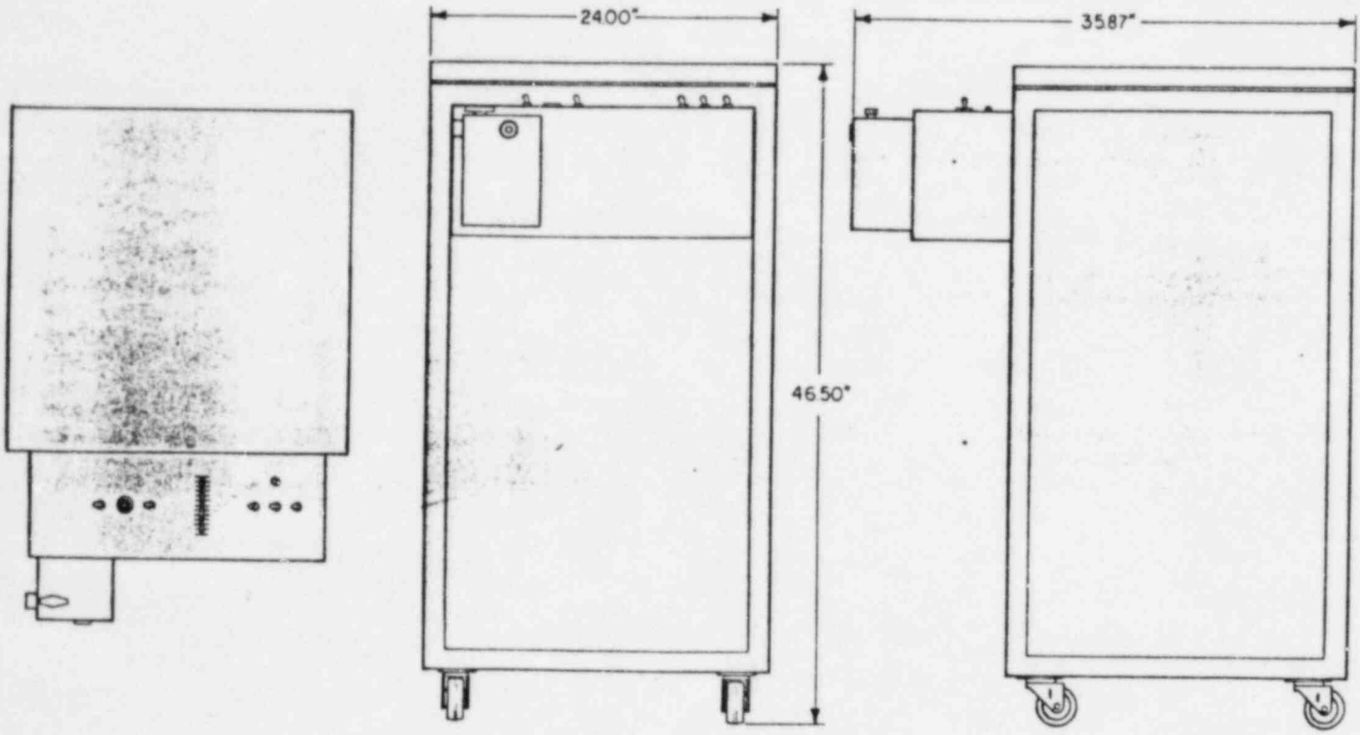
Vents C, D - 400 CFM Intakes

Air flow with Vent A activated.



RADX

XenaCon
Controlled Gas Delivery System



DESCRIPTION:

The Radx XenaCon is a patient administration device used to safely, efficiently, and economically dispense radioactive gas during a regional ventilation study. The XenaCon is available in three models, all properly lead shielded for the use of ^{133}Xenon. All three models utilize the exclusive Radx dry rolling diaphragm spirometer for resistance free breathing. The XenaCon I is the basic patient rebreathing unit consisting of a spirometer, volume indicator, bacteria filter, CO_2 absorber, recirculation blower, push-button oxygen replenishment valve, and the newly designed operator controlled washin, rebreathe, and washout head valve, all contained in a mobile steel housing.

The XenaCon II has all of the above features but with the addition of a built-in expandable interface and a shielded xenon gas trap.

The XenaCon III series contains all of the features of the XenaCon II but with the addition of a detector alarm system, which assures the proper and effective trapping of all of the radioactive gas.

XenaCon I, XenaCon II, XenaCon III

Mobile – All units of the XenaCon series are highly mobile. Both the XenaCon II and III with the built-in gas traps are particularly well suited for patient bedside studies. An oxygen supply is required – see accessories.

Large Volume Spirometer – All three XenaCon models employ the 10 liter dry rolling diaphragm spirometer used for years in the Radx Ventil-Con. All of the airway passages utilize a material which has been thoroughly tested and proven to be impervious to xenon gas.

The expansion/contraction factor of the ball bearing mounted spirometer diaphragm is negligible, offering a resistance of less than 0.1 inch of water to normal breathing.

The spirometer volume is displayed through mechanical linkage on a scale located on the control panel.

The entire upper section of the XenaCon series, which houses the spirometer and tubing, is completely shielded with 1/8 inch lead.

Uniform Gas Mixture – The XenaCon series incorporates a high volume recirculating blower unit to insure a homogeneous gas mixture.

Oxygen Replenishment – A push-button valve allows the operator to add oxygen at any time before or during the study.

Head Valve – The newly redesigned head valve has a dead space of approximately 25 cc. in both rebreathing and washout. The complete study from washin to rebreathing to washout is done with this simple two position valve.

A xenon injection port is built into this valve, which allows for either direct bolus or homogeneous patient administration of xenon gas.

Carbon Dioxide Trap – The XenaCon series utilizes a large capacity (2 lbs) CO_2 trap containing U.S.P. grade soda lime granules.

Bacteriological Filter – The XenaCon series uses an inline autoclavable bacteriological filter to aid in the prevention of disease transmission.

XenaCon II and III

Equipped with a built-in xenon trap.

Vertical Cartridge Pack – The newly redesigned cartridge pack (vertical instead of horizontal) has a minimum 6.5 ft. charcoal pathway. The pack consists of eight 3-1/2 x 11 inch cartridges connected in series. The new vertical configuration eliminates "channeling" as a possible cause of trap failure.

Lead Shielding – The self-contained xenon trap is completely surrounded with 1/4 inch of lead.

Expandable Interface – The XenaCon II and III have a built-in expandable interface to compensate for variations in the patient breathing rate and the trap pump rate of 5 liters per minute.

Trap Pump – The xenon trap air moving system is a positive displacement bellows-type pump, which prevents the potentially O_2 enriched gaseous mixture from coming into contact with the electrical arcing of the pump motor.

Moisture Trap – The XenaCon II and III have a large capacity water trap, which is clearly visible when the side door is open. Silica gel desiccant is used, which turns from a deep blue to clear as it becomes saturated with moisture.

XenaCon III

Identical to the XenaCon II except that it has a built-in xenon gas trap exhaust port monitor. When the concentration of xenon gas in the exhaust port exceeds 1×10^{-2} mCi/ml, an audio-visual alarm sounds. The audio portion may be deactivated during a patient study.

PRICE LIST

Radx No.	Description	Price
161	XenaCon I Gas Delivery System	$3425.00
162	XenaCon II Gas Delivery System with built-in Xenon Trap and Expandable Interface	$3950.00
163	XenaCon III Gas Delivery System with built-in Xenon Trap, Expandable Interface, and Xenon Trap Exhaust Port Monitor - Detector/Alarm	$4550.00

All of the above units include the following:
- (1) 8" Flex tube with Adult Mouthpiece and headstrap
- (1) Nose depressor
- (1) Quart of soda lime granules
- (1) Installation and Instruction manual

Terms: Net 30 days
Prices effective October 1, 1981
Shipping Weight: 400 lbs.
Export Packed: 555 lbs.

Maintenance

Routine replacement of the soda lime granules and periodic sterilization of the inline autoclavable bacteriological filter, plus reconstitution of the xenon trap silica gel desiccant in the XenaCon II and III is all of the routine service required. Complete care procedures are outlined in the instruction manual.

Prices and specifications subject to change without notice. Printed in U.S.A.

Accessories

104	Soda Lime Granules – 1 Case 12-3 pound (resealable) canisters	$85.00
105	Autoclavable Bacteriological Filter	50.00
108	Infant Mask	23.00
109	Adult Mouthpiece	23.00
110	Adult Face Mask	30.00
132	Adult Face Mask Tubing (5-1/2")	12.00
133	Adult Face Mask Tubing (8")	15.00
114	Infant Mask Harness	15.00
116	Adult Face Mask Harness	11.00
164	Cartridge Pack-8-cylinder, vertical	295.00
126	Silica Gel Desiccant - 2 lbs.	20.00
149	Breathing Port Adapter Ventil-Con II or Xena-Con	$15.00
160	NEN Gun Adapter	$15.00
115	Swivel Joint Adapter	$38.00
169	Oxygen Cylinder Holder, Size "E"	65.00
170	Mobility Handles for Ventil-Con II and XenaCon	50.00

RADX Warranty

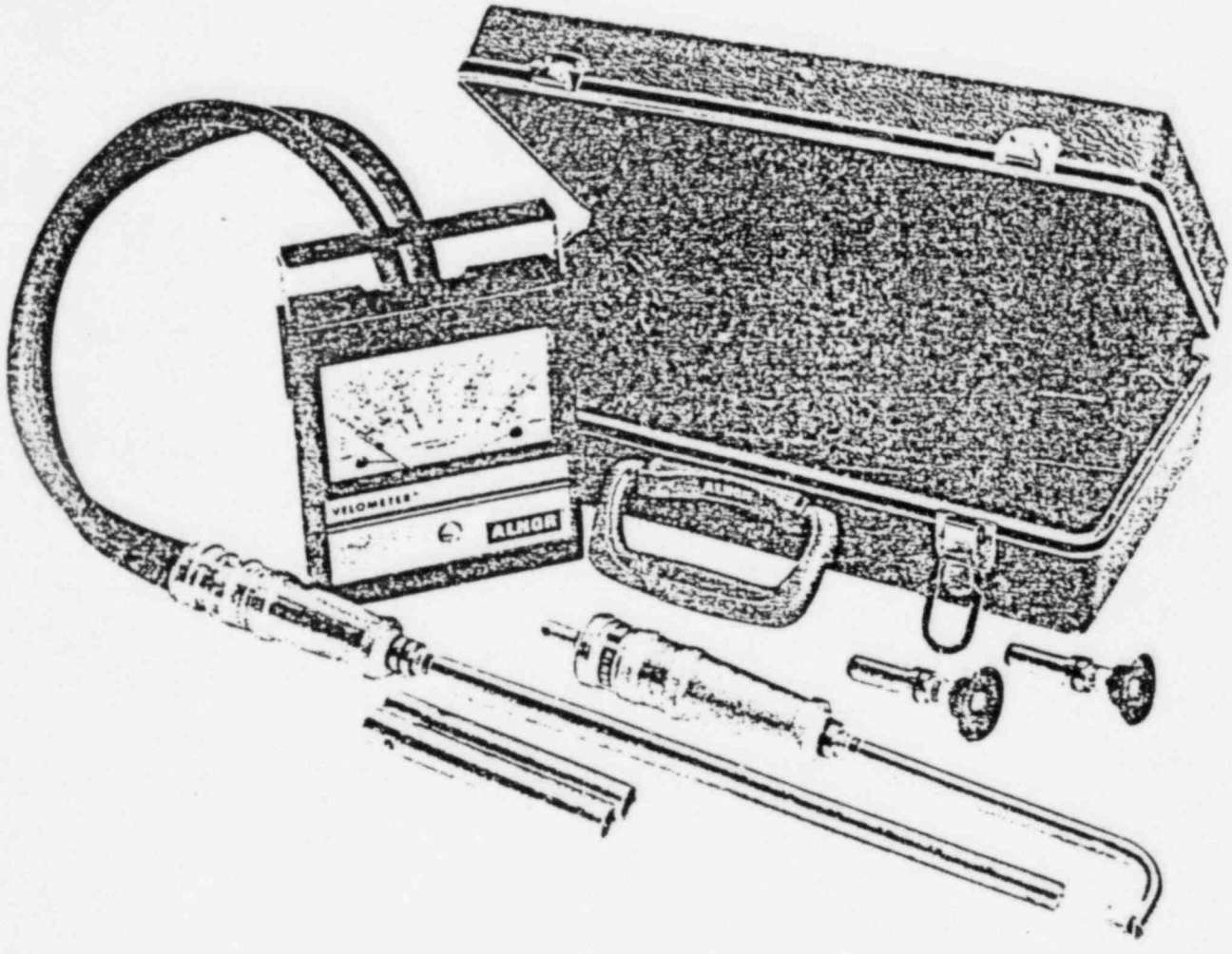
Radx warrants the XenaCon series to be free from all defects in material and workmanship for a period of one year from the date of purchase. Radx Corporation's liability shall be limited to the repair or replacement of the defective material or component at its option.

RADX CORP
P. O. BOX 19164 • HOUSTON, TEXAS 77024 • 713 468-9628
1390 West Belt Drive • Houston, Tx. 77043

ALNOR®

Series 6000-P Velometer®

OPERATING INSTRUCTIONS



INSTRUMENTS FOR INDUSTRIAL MEASUREMENTS

Temperature • Air Velocity • Dew Point

ALNOR INSTRUMENT COMPANY

7301 N. CALDWELL AVENUE • NILES, ILLINOIS 60648 • 312/647-7866

FORM 6270A

RECALIBRATION

Your Velometer should be returned to the factory for checking and/or recalibration at least once a year, depending on a) the frequency with which you use the instrument, i.e., daily, weekly, or only occasionally b) the atmosphere in which it's used, i.e., dusty or contaminated air, in and out of hot or cold weather, etc. c) the importance of verification in your work, such as involvement with OSHA regulations or legal proceedings, and d) the degree to which the instrument is subjected to rough handling.

The instrument should be well packed and shipped to

ALNOR INSTRUMENT COMPANY
7300 N. Natchez Avenue Niles, IL 60648
Attention: SERVICE DEPARTMENT

CERTIFICATES

There are three types of certificates available at extra cost:

Type 25A, certification that the instrument is in compliance with factory standards.

Type 25B, certification traceable to the National Bureau of Standards, but without data.

Type 25C, certification traceable to the Nationai Bureau of Standards and supplied with the test data.

These certificates can be provided on new instruments, or at the time they are sent in for recalibration.

OTHER ACCESSORIES AVAILABLE

All components of Velometer sets are available for individual purchase, and can be substituted without recalibration. Following is a list of available full Velometer sets, and components:

Series No. 6000-P Velometer Sets

Model No.	Component
6000AP	All Purpose Set
6000BP	Air Conditioning Set
6000AP-M/S	Metric All Purpose Set
6000BP-M/S	Metric Air Conditioning Set

Series 6000-P Components

6006AP	Velometer for Set A (1)
6006BP	Velometer for Set B (2)
6006AP-M/S	Velometer for Set A-M/S
6006BP-M/S	Velometer for Set B-M/S
6030BP	Range Selector (0-1250/2500 + 0-3") (2)
6030CP	Range Selector (0-1250/2500 + 0-1") (1)
6030DP	Range Selector (0-5000/10000 + 0-10") (1)
6030BP-M/S	Range Selector (0-6.25/12.5 MPS + 0-75 mmW)
6030CP-M/S	Range Selector (0-6.25/12.5 MPS + 0-25 mmW)
6030DP-M/S	Range Selector (0-25/50 MPS + 0-250 mmW)
6050P	Lo-Flow Probe (1) (2)
6060P-12	12" Pitot Probe (305 mm) (1) (2)
6060P-24	24" Pitot Probe (610 mm)
6060P-36	36" Pitot Probe (915 mm)*
6070P	Diffuser Probe, 7" Long — 90° (1) (2)
6070P36	Diffuser Probe, 36" Long — 90°
6070P-36S	Troffer Probe, 36" long, straight
6080AP	Static Probe (0-10.") (1)
6080BP	Static Probe (0-3.") (2)
6080CP	Static Probe (0-1.") (1)
6080AP-mmW	Static Probe (0-250 mmW)
6080BP-mmW	Static Probe (0-75 mmW)
6080CP-mmW	Static Probe (0-25 mmW)
2161	Single Hose (1) (2)
1010	Case — Set A or B (1) (2)

(1) Included in 6000 AP set, with two 2161 hoses
(2) Included in 6000BP set, with two 2161 hoses

* The 36" Pitot Probe, due to the friction of the air in the longer tube, will cause the Meter to read 100 feet per minute low across the entire scale.

CERTIFIED TEST & BALANCE COMPANY, INC.
1400 E. 97th PLACE • CHICAGO, ILLINOIS 60628
Phone 312-731-5500

VENTILATION TEST REPORT

Badger Mechanical, Inc.
1825 Nelson Street
MAdison, WI 53704

TESTED BY H. Crum
DATE 10/78

JOB NAME St. Joseph Hospital
ADDRESS MArshfield, Wisconsin

SYSTEM EF 27 EQUIPMENT LOCATION Roof Unit "E"
Hot Lab Ex.

FAN: MAKE Buffalo
SIZE 245F
TYPE BL

MOTOR: HP 1.1/2
RPM 1745

	RATED	ACTUAL
LINE VOLTS	230/460	480
MOTOR AMPS	5.0/2.5	2.2/2.3/2.3

	REQUIRED	ACTUAL
FAN RPM	2350	2296
OUTLET CFM	1000	1020
SYSTEM CFM	1000	1020

REMARKS: 3.3" sp System & Outlets @ 102%

CERTIFIED TEST & BALANCE COMPANY, INC.

BY: Kenneth Pegg

CERTIFIED TEST & BALANCE COMPANY, INC.
1400 E. 97th PLACE • CHICAGO, ILLINOIS 60628
Phone 312-731-5500

VENTILATION TEST REPORT - (CONT'D)

JOB NAME St. Joseph Hospital DATE 10/78

SYSTEM Marshfield, EF 27

AREA SERVED	OPENING		K FACTOR	REQUIRED		PERCENTAGE OF REQUIREMENT		ACTUAL	
	NO.	SIZE		VEL	CFM			VEL	CFM
1st floor "E"									
1175	1	18/18	HOOD		800		102		816
1178	2	10/10			200		102		204
opened to 12" high	3	48/12	4.0	250	1000*		102	255	1020

* CFM normal draw is from hood with hood on
CFM draw is from outlets with hood off

CERTIFIED TEST & BALANCE COMPANY, INC.
1400 E. 97th PLACE • CHICAGO, ILLINOIS 60628
Phone 312-731-5500

VENTILATION TEST REPORT

Badger Mechanical, Inc.
1825 Nelson Street
Madison, WI 53704

TESTED BY H. R. CRUM
DATE Sept. 1978

JOB NAME St. Joseph Hospital
ADDRESS Marshfield , Wisconsin

SYSTEM A C - 5 EQUIPMENT LOCATION Room 3117 (Serves Nuclear)

FAN:	
MAKE	Buffalo
SIZE	365
TYPE	BLD

MOTOR:	
HP	5
RPM	1750

	RATED	ACTUAL
LINE VOLTS	460	480
MOTOR AMPS	6.5	5.3-5.3-5.3

	REQUIRED	ACTUAL
FAN RPM	1622	1568
OUTLET CFM	5012	4680
SYSTEM CFM	5,015	5040

REMARKS: 3.5"
Outlets @ 93%
System @ 101%

CERTIFIED TEST & BALANCE COMPANY, INC.

BY: Kenneth Rogole

CERTIFIED TEST & BALANCE COMPANY, INC.
1400 E. 97th PLACE • CHICAGO, ILLINOIS 60628
Phone 312-731-5500

VENTILATION TEST REPORT - (CONT'D)

JOB NAME St. Joseph Hospital DATE Sept 1978

SYSTEM A C - 5

AREA SERVED	OPENING		K FACTOR	REQUIRED		PERCENTAGE OF REQUIREMENT	ACTUAL	
1st Floor "E"	NO.	SIZE		VEL	CFM		VEL	CFM
Room 1179	1	1206	Hood		130	92		120
1178	2	1206			170	91		155
1180	3	1206			130	96		125
1181	4	1206			130	96		125
1193	5	1206			157	92		145
1193	6	1206			157	96		150
1175	7	2410			400	90		360
1175	8	2410			400	93		370
1192	9	1206			157	92		145
1192	10	1206			157	92		145
1177	11	1206			170	91		155
1182	12	1206			130	96		125
1183	13	1206			120	92		110
1184	14	1206			120	96		115
1176	15	1206			100	95		95
"	16	1206			100	90		90
"	17				100	90		90
"	18				100	90		90
1194	19				100	95		95
1194	20				100	95		95
1185	21	1206			130	92		120
1185	22	1206			130	96		125
1195	23	1206			192	91		175

CERTIFIED TEST & BALANCE COMPANY, INC.
1400 E. 97th PLACE • CHICAGO, ILLINOIS 60628
Phone 312-731-5500

VENTILATION TEST REPORT - (CONT'D)

JOB NAME St. Joseph Hospital DATE Sept-1978

SYSTEM A C - 5 Cont.

AREA SERVED	OPENING		K FACTOR	REQUIRED		PERCENTAGE OF REQUIREMENT		ACTUAL	
st Floor "E"	NO.	SIZE		VEL	CFM			VEL	CFM
Room 1195	24	1206	Hood		192		94		180
1198C	25	1206			115		91		105
1198B	26	1206			115		100		115
1198	27	1206			100		100		100
1198	28	1206			100		95		95
1187	29	1206			155		94		145
1198A	30	1206			115		96		110
am. & Peep.	31	1206			155		97		150
1199	32	1206			192		96		185
1199	33	1206	V		192		91		175

CERTIFIED TEST & BALANCE COMPANY, INC.

AC - # 5

CFM Required: 5015

Condition Fan Tested @ 100% O.A. Date: Oct. 2 Tech: H.C. & M.M.

Duct Traverse Readings & Statics

Duct Size: = 18/32 =4.0 Sq. Ft. Taken at Disc. of Fan

(1)

No.	Vel. Press	Velocity
		1725

TOTAL = 1725

(2)

No.	Vel. Press	Velocity
		1675

TOTAL = 1675

(3)

No.	Vel. Press	Velocity
		1900

TOTAL = 1900

(4)

No.	Vel. Press	Velocity
		1800

TOTAL = 1800

(5)

No.	Vel. Press	Velocity
		1400

TOTAL = 1400

No.	Vel. Press	Velocity

TOTAL =

No.	Vel. Press	Velocity

TOTAL =

No.	Vel. Press	Velocity

TOTAL =

No.	Vel. Press	Velocity
	8500 ÷	1.35 = 6300

TOTAL =

Total FPM = 6300 / 5 = 1260 FPM Aver. X 4.0 Sq. Ft. = 5040 / 5015 CFM Act. / CFM Req.

STATICS:	DROP		DROP	
Upstream Filters = .11 Downstream Filters = .29	.18	Upstream Coil = .42 Downstream Coil = .98	.56	Inlet Fan = .98 Discharge Fan = 1.65
Face & Bypass Upstream Coil = .29 Downstream Coil = .42	DROP .13	Final Filter Upstream = 1.65 Downstream = 1.45	DROP .20	Fan Static Press = 2.63 Unit at: 101

Item 22 Procedures and Precautions for Use of Radioactive materials in animals

A. Animal housing facilities

All animals will be kept at the Marshfield Medical Foundation main facility (510 N. St. Joseph Avenue Marshfield, WI) or at the rural experimental facility (11713 West Lane, Marshfield, WI).

The stalls or pens will be clearly labelled and access will be restricted to the investigator and his/her designated animal handlers.

Trace amounts of C-14 and H-3 will be used with white tailed deer and sheep at the rural facility, located 8 miles from the Medical Complex. The facility is under the direct supervision of the study's principle investigator. The facility consists of a 35 x 100 foot barn, a 15 x 15 foot shed, and 3 1/3 acre pens. All animals used there for isotope experiments will be kept in a 8 x 10 foot stall in the shed. Experiments involving isotopes will be carried out within the stall and when the animals are maintained under anesthesia. After the experiements the animals will be kept in that stall for a minimum of five (5) days during which time all bedding and excrement will be collected and stored in garbage bags. This waste will be disposed of by incineration on site at a location 0.25 miles west of the nearest occupied building. During the five days the shed will be locked and only authorized persons will have access. All feeding, watering, and cleaning of the animal will be performed by the senior investigator or his designated assistance. At the end of the five days the area will be wipe tested and the wipes counted in a gas flow counter to determine that the level of contamination is below background. If the area is below background, the animal will be returned to his normal pen. If not, it will be confined for another five (5) days and the process repeated. At the time the animal dies it will be disposed of by burial at a distant site on the same property. Since this is private property, access to the barn, shed, and burial site is limited.

Small animals used for isotope research at the main Medical Complex will be handled identically, except that incineration will be in the main hospital incinerator and carcasses will be incinerated as well.

B. Instructions provided to care takers for handling of animals, animal wastes and carcasses related to animal isotope experiments.

1. When working around an animal that has been injected with radioactivity, all workers are instructed to wear designated coveralls and disposable rubber gloves.

2. All materials coming out of the pen should be placed in 4 mil plastic bags, labelled appropriately and stored in a designated area until disposed of.

3. All materials coming out of the pen will be disposed of by the senior investigator or radiation safety officer by incineration.

4. After the animal is removed from the pen, the pen will be washed down with hot soap and water and air dried. An aliquot of the wash water will be counted for radioactivity and if below background, the water will be disposed of

B. Con't.

5. All clothes will be kept in a separate area and used only when working in that area. All gloves and rubbers will be disposed of with the radioactive wastes.

APPENDIX C

Basic Research Involving Human Subjects

Basic Research involving human subjects will be conducted under a physician or institution sponsored IND or will be approved by the Marshfield Medical Foundation Institutional Review Board which also serves as the IRB for Marshfield Clinic and St. Joseph's Hospital. The Marshfield Medical Foundation IRB is FDA approved and undergoes periodic audit. A copy of the last audit report is enclosed as an example. Audit reports and subsequent actions taken are on file at the Marshfield Medical Foundation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 5, 1984

Sidney F. Johnson, M.D.
Chairman, Institutional Review Board
Marshfield Medical Foundation, Inc.
510 North St. Joseph Avenue
Marshfield, WI 54449

In reply refer to: HFN-350

Dear Dr. Johnson:

On May 3, 1984, Mr. Wayne Schaefer, an investigator with the Food and Drug Administration, met with you to review the procedures for the protection of human subjects of clinical investigations conducted at Marshfield Medical Foundation, Inc.

In order to systematically evaluate the procedures followed by the review committee, the records of the study IB-IND 1512 "Human Lymphoblastoid Interferon" were reviewed. Our review of the findings revealed that, except for one instance when the review board convened without a quorum, no deviations from federal regulations for institutional review boards were found.

The positive difference between this inspection and the one conducted in June 1982 is noted.

Should you wish to discuss this inspection or any aspects of institutional review procedures we invite you to contact this office. We appreciate the cooperation shown our inspector during the inspection.

Sincerely yours,

Sam T. Gibson, M.D.
Director, Division of Biological
Product Compliance
Office of Compliance
Center for Drugs and Biologics
(301) 443-7279

ADD

Drop: Schlosser & Pohlman

Thomas E. Bauer
~~403 S. Uvalda Circle~~
Aurora, ~~Colorado~~ 80012
303 ~~343-4418~~

0509 W 5th
Marshfield WI 54449
715/387-4557

Position Objective

To work as a computer programmer analyst with the goal of eventually qualifying for EDP management responsibilities.

Medical management

Personal Data

~~Age~~	32 DOB 12/10/39
Sex	Male
Marital Status	Married
Children	~~One~~ Two
Height	Six feet
Weight	~~165~~ 170
Selective Service	V A

Education — 1973-77 University of Wisconsin - Oshkosh, Oshkosh, Wisconsin, Masters in Business Administration

1969-70 University of Colorado, Denver, Colorado...Fifteen hours graduate work in computer science...Programmed CDC 6400 in assembly language, FORTRAN, ALGOL, and SNOBOL.

1967-68 Colorado State University, Fort Collins, Colorado...Received one year government training grant to study computer science and mathematics... Programming was for CDC 6400 using FORTRAN and ALGOL.

1958-62 Northwestern University, Evanston, Illinois...B.S. Journalism.

Experience

Feb 73

Feb 72-~~present~~ Auto-Trol Corporation, 7519 Grandview, Arvada, Colorado 80002...Programmer/Analyst...Design and develop real-time operating system for interactive graphic systems...Programming is for Varian 620 using assembly language.

Oct 71-Feb 72 Health Care Management Systems, 1849 Emerson, Denver, Colorado 80205...Temporary Contract Programmer...Designed and coded on-line appointment system for Denver Health and Hospitals...Programming was for PDP-15 using MUMPS.

1969-71 Department of Medical Automation, Presbyterian Medical Center, 1719 E. 19th Avenue, Denver, Colorado 80218...Programmer/Analyst...Had technical responsibility for design and development of a time-shared medical information management system...Assisted other hospital departments with data processing and systems design problems...Programming was for a time-shared CDC 6400 and a PDP-8 using FORTRAN.

1964-69 Computer Division, Army Research Laboratory, Fitzsimons General Hospital, Denver, Colorado 80240...Junior Programmer to Lead Programmer... Developed file storage, update, maintenance, and retrieval system for research investigators...Supervised junior programmers and operators... Programming was for RCA 301 in assembly language.

1973-79 Marshfield Clinic, Marshfield, WI 54449... Programmer/Analyst...

1979-present Marshfield Clinic _____ ... Assistant Director...

Publications

Minckler, T.M., Bauer, T.E., "Calculators and Computers," Chapter in Introduction to Pathobiology, Edited by Jeff Minckler, Harry Anstall, Tate Minckler, C.V. Mosby Company, 1971

Ringenberg, L.M., Bauer, T.E., Minckler, T.M., "Choosing A Computer Terminal," Hospital Management, 1972

Minckler, T.M., Bauer, T.E., Ringenberg, L.M., "Modeling As A Tool in Neuroscience," Chapter in Introduction to Neuroscience, Jeff Minckler, Editor, C.V. Mosby Company, 1972

Professional Societies & Certifications

~~Association for Computing Machinery~~ Medical Group Management Association
Certificate in Data Processing
Fellow American College of Medical Group Administrators

B. Radiological Safety Officer

The Radiological Safety Officer is appointed by the Radiation Safety Committee and is responsible to the Committee and to the Executive Committee of the Clinic and administration of St. Joseph Hospital for the radiation protection program.

1. He will be cognizant of all uses of byproduct material within the complex and will periodically evaluate each safety program to include review of routine and special surveys of all areas in which byproduct material is used.

2. He will evaluate and insure compliance with rules and regulations, license conditions of project approval specified by the Radiation Safety Committee for each specific use.

3. He will monitor all uses, storage and disposals of byproduct materials, including evaluation and inspection of special venting systems and filters prescribed for each use.

4. He will serve as consultant to administrative, scientific and support personnel on all aspects of radiation protection.

5. He is responsible for supervising the receipt, delivery and opening procedures for all material arriving at the complex and for receiving, packaging and shipping all radioactive material leaving the complex.

6. He is responsible for the personnel monitoring system. He will determine the need for and evaluate all bioassays. He will maintain records of personnel exposure and bioassay reports.

7. He is responsible for conducting the training program for proper use of byproduct material, for maintaining cognizance of changes in procedures of individual users and changes in regulations and for informing users and support personnel of those changes which will affect each of them.

8. He is responsible for supervising and coordinating the radioactive waste program. He will be aware of all transfers to the central disposal area, maintain records of contents of this area, make arrangements for transfer when storage amounts indicate, maintain records of such transfers and supervise the transfer procedure. He will evaluate disposal to sewage* under the guidelines established below and insure the limits established are not exceeded.

9. He is responsible for supervising and evaluating storage of all byproduct material not in current use, including wastes prior to transfer to the disposal agency.

10. He is responsible for performing leak tests on all sealed sources and maintaining records of such tests.

*add and incinerator

Instrumentation (Cont)

Location: Nuclear Medicine

1. Survey Meters

1 Victoreen Model 491
Minimum range: 0 mR/hr to 0.1 mR/hr
Maximum range: 0 mR/hr to 100 mR/hr

2. Dose Calibrators

1 Squibb CRC-6A
~~1 Nuclear-Chicago Mediac~~ Change to Capintec CRC 12R

3. Instruments used for Diagnostic Procedures

Type of Instrument	Manufacturer	Model Number
1 Scintillation Camera	General Electric	Maxicamera
2 Scintillation Cameras (portable)	Technicare	Sigma 420
1 Tomographic Imager	Siemans	Pho-Con 192
1 Computer	Digital Equipment Corp	PDP 11/34
1 Thyroid Uptake System	General Electric	INS-115
1 Deep Vein Thrombosis (DVT) System	Technicare Associates	FS-8M-SCAT
1 MCA/NaI probe	Nuclear Data	ND62T

4. Other

1 Picker Nuclear Model #642081 Area Monitor

APPENDIX A

The hospital incinerator is an Econotherm, double burn down incinerator with the following characteristics:

Double burndown in two chambers
Burn temperature: Chamber 1 - 1700°F
Chamber 2 - 3400°F
Total CFM at mouth of stack - 36100 CFM
Stack height - 150 ft
Total running time - 16 hr/day
5 days/week

The mouth of the stack is 76 ft above the roof of the building. There are no air inlets within this 76 ft.

Anticipated routine disposal would be weekly with an average activity disposed per week as follows:

C-14	1000 µCi/week
I-125	1 µCi/week
H-3	25 µCi/week

Based on a conservative 40 hour week of incinerator use (1/2 that anticipated), the maximum concentration at the mouth of the stack will be:

C-14	4×10^{-10} µCi/ml
I-125	4×10^{-13} µCi/ml
H-3	4×10^{-11} µCi/ml

Total effluent at the stack as a fraction of 10% the MPC for routine burns is:

$$\frac{4 \times 10^{-10}}{1 \times 10^{-8}} + \frac{4 \times 10^{-13}}{8 \times 10^{-12}} + \frac{1 \times 10^{-11}}{2 \times 10^{-8}} = .09$$

The maximum number of burns per year will be 65.

Non-routine burns would be of isotopes other than I-125, H-3 and C-14 or quantities of I-125 greater than those listed as routine disposals. This I-125 would be generated during iodination procedures which frequently utilize 2-5 mCi I-125 per iodination. Wastes resulting from each iodination will be assayed and contained. The specific activity will also be determine if appropriate. The material will then be stored until the total activity is less than or equal to 500 µCi. At most 500 µCi I-125 will be incinerated at any given time. At these times the maximum total stock emission will be 0.65 x MPC (0.63 x MPC for I-125, 0.02 x MPC other) based on a 40 hr/week air flow. In any case the effluent concentration resulting from non-routine burns should not result in greater than 70% of ~~MPD.~~ MPC

The operating procedure will be as follows:

stack

NRC FORM 313M
(9-81)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB
3150-0041

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

Marshfield Clinic, 1000 N. Oak Ave.
St. Joseph Hospital, 611 St. Joseph Ave.
Marshfield Medical Foundation, 510 N. St. Joseph Ave.
Marshfield, WI 54449

TELEPHONE NO.: AREA CODE (715) 387 5511

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Lois Rutz

TELEPHONE NO.: AREA CODE (715) 387 9022

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 481096603

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

N/A - Broad Scope License

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.)*

Lois J. Rutz, MS

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE See attached

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

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

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
Any byproduct material with atomic numbers between 3 and 83 inclusive	Any	See attached (over)	

ITEM 6 a and b

Radioactive Materials

Byproduct, source and/or special nuclear material	Chemical and/or physical form	Maximum amount that license may possess at any one time
1. Any byproduct material with atomic numbers between 3 and 83 inclusive	Any	200 mCi of each byproduct material with atomic numbers between 3 and 83 inclusive except as stated below
2. I-131	Any	1500 mCi
3. Au-198	Any	350 mCi
4. Xe-133	Any	3000 mCi
5. H-3	Any	30 mCi
6. H-3	Foil	150 mCi
7. Mo99/Tc99m	Generator	3000 mCi
8. Tc99m	Kit	3000 mCi
9. Cs-137	Needles, tubes	300 mCi
10. Ir-192	Seeds, Wires	3000 mCi
11. I-125	Seeds	500 mCi
12. Au-198	Seeds	200 mCi
13. U-235	Depleted uranium, cadmium plated, used as shielding for a medical accelerator	91 Kg

ITEM 10B - Calibration of Instruments: Dose Calibrators

A. Annual tests

1. The source will be used in all dose calibrators to check accuracy of the calibrator. The source will be contained in a vial identical to those used for daily 99mTc preparation. The activity measured as the average of three successive determinations should be within ± 5% of the activity of the reference 99mTc after decay correction. If not within such tolerance, the dose calibrator will be repaired or adjusted if possible. If impossible, a calibration factor will be calculated and used for routine assays.

2. Activity of the source is also determined at 6, 24 and 48 hr after the above measurement. These readings are plotted on a decay graph constructed for 99mTc from the initial assay. Measured activity should be within ± 5% of predicted activity. If errors greater than ± 5% are noted, repair or adjustment of the instrument will be performed. If it is not possible to bring predicted activity within the error range, calibration factors for the correction of observed activity will be calculated, posted with the instrument and used for routine assays.

B. Initial evaluation

1. New dose calibrators and dose calibrators which have undergone repair will be checked as listed under 'Annual tests' (paragraph A above).

2. Additionally, a vial identical to that used for daily 99mTc preparation containing approximately 10 mC 99mTc in 5 cc will be assayed. Successively 5 cc containing approximately 10 mC 99mTC will be added to the vial to a total of 30 cc. Activity will be assayed after each addition.

   The activity measured at the volume of the commercially obtained source used for linearity testing will be designated the true activity. True activity for all other volumes will be calculated. Correction factors for observed activity at all other volumes will be calculated, graphed and used in routine assays.

3. Appropriate tests of the dose calibrator response to volume and geometry variations will be made. Necessary correction factors will be established and placed near or on the instruments.

C. Quarterly evaluation

1. At the time of the annual check and quarterly, a 137 Cs therapeutic source (3M needle) will be assayed on all radionuclide settings of each calibrator. Subsequent readings will be compared to those obtained at the annual accuracy determination and changes of greater than ± 5% will dictate need for adjustment or repair.

2. The calibrators will be inspected quarterly for mechanical condition, electrical cord fraying, instrument zero setting and to ascertain that the measurement chamber liner is in place.

3. All dose calibrators will be tested quarterly for linearity of response with varying activity.

D. Daily evaluation

1. Dose calibrators will be checked daily with a 137 Cs source (New England Nuclear NES-356) on 137 Cs and 99mTc channels. Results will be compared to results on the day of the annual check. Changes of greater than ± 5% will indicate need for repair or adjustment of the instrument prior to use.

No Change

ITEM 13 - Procedures for Receipt and Opening of Packages Containing Radioactive Materials

During normal working hours all orders for radioactive materials will be received by the central isotope receiving office. No individual users are authorized to receive direct shipments of radioactive materials. Each user will notify the central isotope receiving office of all material ordered.

After working hours shipments will be accepted by the emergency room admitting office personnel and will be immediately locked up in safe isolation until no later than the next working day at which time they will be transported by authorized personnel to the central isotope receiving office where their receipt will be logged and the packages opened.

ITEM 14 - Opening of Radioactive Material Shipments

Opening of radioactive material shipments will be as follows: For quantities and transport groups exempted by 10 CFR 20.205 special opening instructions from the manufacturer will be noted and followed. All packages will be visually inspected for damage, as will the contents of the package after opening. If damage is noted, the contents of the package will be surveyed and decontaminated if necessary. Any contaminated material will be treated as radioactive waste and the area cleaned before other packages are received.

For non-exempt quantities and transport groups the following procedure will be used:

1. Packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a) (1) and (c) (1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m) will be monitored for surface contamination and external radiation levels within 3 hr after receipt if received during working hours or within 18 hr if received after working hours, in accordance with the requirements of paragraphs 20.205 (a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.02 $\mu Ci/100\ cm^2$ or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 ft (or 1 m).

2. **In addition, receipt office personnel will:**

   a) Put on gloves to prevent hand contamination

   b) Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer

   c) Measure exposure rate at 3 ft (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer

   d) Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Office

   e) Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip
      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle
      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material)

ITEM 15 - General Rules for Safe Use of Radioactive Material

A. All personnel within the complex who wish to use byproduct material will submit their proposed use to the Radiation Safety Committee for evaluation. No use is permitted until approval is obtained from the Committee. A copy of the following will periodically be distributed to all potential users in the complex and specifically to any personnel known to be preparing an application.

Instructions for Application for Use of Radioactive Material

All users of radioactive material within St. Joseph Hospital, the Marshfield Clinic, the Marshfield Medical Foundation, and the Joint Venture Laboratory must be approved by the Radiation Safety Committee. The Committee will ask the Radiological Safety Officer to review your proposed use, and will then contact you indicating approval or disapproval of your request and noting any necessary additional safety procedures. You are not authorized to procure or use material until you are notified of such approval. Your application must include proposed procurement of radioisotopic material, amounts of material required, proposed handling methods (i.e., storage) after receipt from the Central Isotope Office and methods of handling radioactive wastes. Survey procedures of areas in which material will be stored and handled and personnel monitoring required must be included. A statement should be included that records of surveys, including negative results, will be kept by the user. If your proposal involves administration to humans, it must include an estimation of dose received with details of the calculation. Whole body and critical organ doses are to be included.

Evidence that the expected benefits justify the radiation exposure will be required. If exposure data are not well documented in the literature, you should include measurements to re-evaluate dose in your procedure and report such results to the Radiation Safety Committee. Appropriate literature references of dose received are required.

Evidence of satisfactory training in radiation safety procedures establishing your ability to handle the material and administer the program will be required. If you have any questions regarding survey requirements, personnel monitoring, waste disposal, storage or any other aspects, contact the Radiological Safety Officer and review the Byproduct Material License.

After review of a proposed use by the Radiological Safety Committee, the Radiological Safety Officer will inform the applicant of the decision of the Committee. If the application is approved, he will review the program with the applicant, including appropriate review and spot checking of surveys by the Radiological Safety Officer. Each approved user will receive the following:

Notification of Approval for Use of Radioactive Material

Your application for use of radioactive material has been approved. The statements in it become in effect an extension of our byproduct material license granted by the Nuclear Regulatory Commission and have the effect of Federal law.

You must:

Follow the safety program you outlined
Cooperate with the Radiological Safety Officer in monitoring your program
Have all orders of byproduct material delivered to the central isotope office
Transfer material to other users only with the approval of the Radiological Safety Officer
Handle wastes as outlined in your application, transferring wastes at periodic intervals to minimize personnel exposure and keep area restrictions at a minimum
Maintain a record of all receipts to include: isotope, chemical form, total activity, specific activity or activity per unit volume, manufacturer or distributor, lot number, use and ultimate disposal

You must not:

Order byproduct material without informing the central isotope office
Receive byproduct material directly
Dispose of material except as authorized in the application

In case of question or emergency contact:

The Radiological Safety Officer, the Chairman of the Radiation Safety Committee, or another Committee member

B. Appropriate laboratory equipment and apparel will be specified in the user proposals. All areas in which radioactive material is used will be clearly designated. Permanent surfaces will be covered with bench paper or trays will be used to prevent inadvertent contamination of the surface. Gloves and laboratory coats will be worn when contact with free nuclides or nuclides in solution is possible.

C. Uses involving labelling of materials with I-125, I-131, or I-123 will be conducted in a fume hood with a minimum flow of 100 cubic feet of air per minute. Labelling with activities in excess of 5 mCi will not be authorized without review of special procedures for handling possible volitalization of iodine.

D. Lead bricks, lead lined storage cabinets, lead lined refrigerators, syringe holders, syringe shields, and other protective equipment will be used as required to maintain personnel exposure as low as practicable. Such devices will be obtained only from recognized suppliers or manufacturers. Where such devices are used, the user is responsible for maintenance in accordance with manufacturer's instructions. Periodic surveys will include survey of areas specifically designed to check the continued integrity of such materials. Annual evaluations of approved users by the Radiological Safety Officer

will include evaluation of all safety devices and recommendations regarding replacement.

Syringe holders will be used for holding all syringes of radioisotopic material while awaiting injection. Syringe shields will be used routinely for the preparation of doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well being.

E. All patient doses will be assayed in the dose calibrator prior to patient injection. Technologists are instructed to check all therapeutic doses against the physicians request. No therapeutic dose varying by greater than $\pm$ 10% of the requested dose will be administered.

Material received in the admitting office at other than normal working hours will be transported to the central office for inspection and opening in the original container unless the container shows evidence of physical damage and/or moisture.

All transfers will be accomplished with "double containment" of the material. The container of all liquids will include sufficient absorbent material to absorb the liquid. Transfers will be accomplished only by personnel properly trained in contamination control and authorized to perform transfers by the Radiation Safety Officer. Users wishing to transfer material will contact the central isotope office for help.

G. All materials will be stored such that the dose rate on contact with the exterior of the integral shielding (exterior walls in the case of material in an unoccupied room) will be such that a major part of the body of designated personnel in a controlled area may not receive in any one hour a dose in excess of 5 mRem or in any five consecutive days a dose in excess of 100 mRem or such that a major part of the body of anyone in a noncontrolled area may not receive a dose in excess of 1/10 of the above.

H. Personnel required to wear film badges, ring film badges, pocket dosimeters and other personnel monitoring devices will be determined by the Radiological Safety Officer and will include all personnel likely to receive an exposure in one year greater than 25% MPD.

The Radiological Safety Officer will arrange for exchange of film badges and other devices periodically and will maintain all records of personnel exposure. He will notify via their supervisor all personnel who receive more than 400 mRem exposure on their film badge measuring whole body dose in any one calendar month.

Should monitors be lost, contact the Radiological Safety Officer.

Monitoring devices will be stored in an area not exposed to radiation when not being worn and will be protected from heat, sunlight, and pressure at all times.

I. Waste will be segregated into long and short half-life and disposed of as described in ITEM 18 of this license. Each user will also maintain records of quantities, form and ultimate disposal of his own materials.

Interim storage areas and receptacles will be shielded such that the exposure rate at the surface will not exceed 2 mR/hr.

Interim storage areas will be designated as restricted areas.

J. Eating, drinking, smoking, application of cosmetics will be prohibited in all areas where radionuclides are prepared and administered. In large laboratories and work areas, the restricted sections will be designated clearly.

Refrigerators and storage areas for radioactive material may not be used to store personal effects or foods.

Personnel preparing radiopharmaceuticals will be instructed to monitor their hands periodically throughout the day. A continuous area monitor is provided in the Nuclear Medicine hot lab and may be used for this purpose.

ITEM 20 - Therapeutic Use of Sealed Source

Sealed sources of radiation will be used as therapeutic sources by the radiation oncologists, currently Dr. H. H. Russ and Dr. R. H. Greenlaw. Procedures for procurement, use and disposal of sources is outlined below.

ITEM 21 - Xe-133

Lung function ventilation studies will be done by inhalation and injection methods of Xe-133. An estimated 8 studies per week will be done with expected maximum dosage to be 15.0 mCi/study inhalation, 25 mCi/study I.V. Expected patient dose as per PDR 1978/79 is 3 mR whole body, 150 mR lung. Maximum possession will be 3 Ci with predicted usage of 2 Ci/2 weeks. This will be stored in the fume hood in the hot lab. Dose will be drawn in hood with exhaust fan on.

Study will be performed in the camera lab using a commercially available controlled gas delivery system. The system chosen will have the following: Activated charcoal filter trapping system with gas trap exhaust port monitor to alarm when exhaust exceeds 1×10^{-2} mCi/ml. Charcoal filters will be stored with radioactive wastes in the primary storage area and then removed to the waste disposal area.

The studies will be run with the backup ventilation system running, creating a negative pressure in the camera lab. Ventilation rate is 1100 CFM through vent A (see floor plan). Attached calculations show a maximum effluent concentration at the exhaust into the atmosphere to be 2.8×10^{-7} µCi/ml worst case. In addition, the vent system is equipped with a HEPA and activated charcoal filter with 95% efficiency. Nose clamps or full face mask inhalation system will be used to increase efficiency and reduce leakage.

In the event of unintentional release of radioactive gasses in either the imaging or drawing room, the room will be isolated and personnel evacuated (ventilation system will already be activated). A survey meter will be used to determine the release to the atmosphere through the vent system. Further survey will be done in the adjacent area to insure no residual contamination before returning the rooms to normal use. Wipe test of relevant areas in air flow path will be done. Decontamination procedures will be undertaken if activity is more than 100 cpm above background. Negative pressure will be maintained until room activity in main vent stream is less than 0.05 mR/hr.

Calculation of concentration of Xe-133 in µCi due to leakage of gas:

$$A = \frac{6 \text{ patients}}{\text{week}} \times \frac{15 \text{ mCi}}{\text{patient}} \times \frac{52 \text{ weeks}}{\text{year}} = 4.68 \times 10^{6} \text{ µCi/year}$$

(A = Annual activity assuming 100% leakage in µCi)

$$V = \frac{1100 \text{ ft}^3}{\text{minutes}} \times \frac{1.7 \times 10^{6} \text{ ml/hr}}{\text{ft}^3\text{/minute}} \times \frac{168 \text{ hr}}{\text{week}} \times \frac{52 \text{ weeks}}{\text{year}} = 1.64 \times 10^{13} \text{ ml/year}$$

(V = Volume of air for nonrecirculating negative pressure ventilation system in ml/year)

$$C = \frac{A}{V} = 2.8 \times 10^{-7} \text{ µCi/ml}$$

NOTES: Conservative estimates were made in both expected activity in gaseous form and percent leakage (100%). Further, the calculation is done without consideration of the filter system present, which reduces the activity released to the atmosphere by nearly a factor of 100 in an attempt to maintain a level of activity as low as possible.

Vents A, B - 1100 CFM

Vents C, D - 880 CFM

Air flow with Vent A activated.