DCS 03/16/81

FORM NRC-313M (8-78) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved GAO R0557

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

Elyria Memorial Hospital
630 East River Street
Elyria, Ohio 44035

TELEPHONE NO. AREA CODE (216) 323 3221

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

Refer to Item #1.b.

FILE COPY

2. PERSON TO CONTACT REGARDING THIS APPLICATION

David Close, Consultant
Nuclear Medicine Assoc., Inc.

TELEPHONE NO. AREA CODE (216) 663 7000

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 34-04307-02 (32-02227)

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

Refer to Item #4
(see attached)

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.)*

Paul P. Varley, M.D. with consultation from Nuclear Medicine Assoc., Inc., Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
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	2000
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	3000

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.	X	1200

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

FOR NRC USE ONLY

Date 3/4/81 Page I II
Log
By BROWN
Orig. To
Action Compl. 3/4/81

Applicant
Check No. 4190
Amount, Fee Category #150(7B)
Type of Fee Renewal
Date Check Rec'd 3/4/81
Received by BROWN

Control No. 04424

FORM NRC-313M (8-78)

8103300079-XA

FEB 17 1981

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

For item #8 refer to license #34-04307-02.

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Names and Specialties Attached; and		Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*	X	Equivalent Rules Attached
X	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE			Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and	X	Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
	Appendix C Form Attached; or	X	Equivalent Procedures Attached
X	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X	Equivalent Information Attached
X	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*		Appendix K Procedures Followed; or
X	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached	X	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached	X	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
			Detailed Information Attached
	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Equivalent Procedures Attached		Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	SIEMENS GAMMASONICS, INC.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens Gammasonics, Inc.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ $150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* James C. Brown

(1) NAME *(Type of Print)* JAMES C. BROWN

(2) TITLE ADMINISTRATOR

c. DATE 2-10-81

FORM NRC-313M (8-78)

Control No. 04424

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

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

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

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

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

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

Specific Instructions for Autopsy

(to be filled out by Radiation Safety Officer)

The following procedures should be followed if so indicated:

( ) Wear Safety Glasses.

( ) Wear Plastic (non absorbant) Gown.

( ) Cover Floor with Bench Liner.

( ) Wear Double Thickness Autopsy Gloves.

( ) Wear Whole Body Film Badge, or personnel exposure monitoring devices.

( ) Wear Ring Badge.

( ) Remove the _____area or tissue first before proceeding further. Identify it as radioactive.

( ) Leave the _____area or tissue untouched until last.

( ) Cover the _____area or tissue with shielding as provided.

( ) Use only long instruments --8" or greater.

( ) Fluids, Blood, Urine should be removed via closed system. Flush with copious amounts of water.

( ) Small Specimens need -- need not -- be handled with special precautions.

( ) Waste Container needs to be provided for contaminated sponges, gowns, and instruments.

( ) Organs are to be kept in storage for _____days before fixation.

Autopsy Performed by _____Patient Name_____

Whole Body or Ringer Badge No. _____ Exposure _____

Signed _____
Radiation Safety Officer

Date:_____

THIS REPORT MUST BE SAVED !

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHUS-32, GOLD-198, or IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotpe Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all Check Items)

_____1. Visiting time permitted: _____

_____2. Visitors must remain _____from patient.

_____3. Patient may not leave room.

_____4. Visitors under 18 not permitted.

_____5. Pregnant visitors not permitted.

_____6. Film badges must be worn.

_____7. Use and complete the following tags:

_____door

_____bed

_____chart

_____wrist

_____8. Gloves must be worn while attending patient.

_____9. Patient must use disposable utensils.

_____10. All items must remain in room until OK'd by Radiation Safety.

_____11. Smoking is not permitted.

_____12. Do not release room to admitting until OK'd by Radiation Safety.

_____13. Other instructions.

In case of Emergency Contact:

RSO_____ On/off duty telephone #_____/_____

Item #20

THERAPEUTIC USE OF SEALED SOURCES

Special procedures for patients treated with byproduct material listed in Group VI, Schedule A, Section 35.100 of 10 CFR Part 35, are as follows:

a. Areas where sealed sources will be stored will be found in map accompanying this item.

b. See "Safety Precautions in Clinical Applications". (Item #20, Form E).

c. The form, Nursing instructions for Patients Treated with Radioactive Sources, (Item #20, Form A), will be completed immediately after sources are implanted and placed in the patient's chart. Nurses will be instructed via Item #20, Form F).

d. Nurses caring for brachytherapy patients will be assigned film badges, or will wear a personnel monitoring device. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient and to personnel handling sealed sources.

e. Sources will be transported from the storage site to place of use via the original shipping containers or an equivalent lead container which is at least 1" thick.

Radium Chemical Co's. Model #500or #50100.

f. At the initiation of treatment, an inventory will be performed on all therapy sources to insure total accountability. At the conclusion of treatment, another inventory will be performed to insure that all sources have been returned. (Refer to Item #20, Form B). In addition, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges and all personnel monitoring devices assigned to nurses will be collected. Item #20, Form C will be used as a check-off procedure.

g. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart. Refer to Item #20, Form D. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR Part 20. (i.e., 2mrems in any one hour or 100mrems in any seven consecutive days).

ITEM 20, FORM A

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH RADIOACTIVE SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity: _____

Date and Time of Administration: _____

Date and Time Sources are to be removed: _____ Isotope: _____

Exposure Rates in mR/hr

Bedside	3 feet from bed	10 feet from bed

(Complete checked items)

_____1. Wear a personnel monitoring device.

_____2. Wear rubber gloves

_____3. Place laundry in linen bag and save.

_____4. Housekeeping may not enter the room.

_____5. Patient may not have visitors.

_____6. No pregnant visitors.

_____7. No visitors under 18 years of age.

_____8. A dismissal survey must be performed <u>before</u> patient is discharged.

_____9. Patient must have a private room.

_____10. Other Instructions.

RSO _____, _____/_____
(Name) on duty/off duty telephone number

FORM B

RECEIPT/SHIPMENT RECORD
RADIATION SOURCE THERAPY APPLICATIONS

Patient _____ ID# _____ RM _____

PRE-TREATMENT INVENTORY

			Subtotal
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____

Applicator(s) _____ Total _____ mg.

POST TREATMENT INVENTORY

_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____

Applicator(s) _____ Total _____ mg.

COMMENTS:

Certified by: _____ Date _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

Form C

RADIATION THERAPY SOURCE USAGE RECORD

Patient_____ I.D._____ Rm_____

Ordering Physician_____

Applicator(s) used_____ Sources_____
mR/hr at 1 meter from applicator (not after loading)_____mR/hr
Date and time of insertion_____a.m./p.m. _____

	Yes	See Comments
Lead aprons not worn during insertion?	( )	( )
X-ray techs informed prior to obtaining localizing films?	( )	( )
Recovery room nurses instructed to use time/distance?	( )	( )
Patient assigned private room?	( )	( )
Exposure monitors issued to nursing personnel?	( )	( )
Safety instruction given to nurses?	( )	( )
Safety procedures placed in patients chart?	( )	( )
Caution sign placed on patients chart?	( )	( )
Caution signs placed on patients room door?	( )	( )
Nursing care rotated?	( )	( )
Known pregnant nurses not attending patient ?	( )	( )
Pregnant visitors prohibited?	( )	( )
Visitors under 18 prohibited?	( )	( )
Safety survey performed and recorded?	( )	( )
Limits of nursing care time posted?	( )	( )
Removal notice posted in patients chart prior to removal of all posted signs?	( )	( )
All signs removed?	( )	( )
Room surveyed and background rad. levels present?	( )	( )

Date/Time of Removal_____ a.m./p.m. _____
Applicator_____ Sources_____

COMMENTS:

CERTIFIED BY_____ Date_____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

CALCULATIONS

Show line drawing of patients and neighboring rooms on other side of this form. Indicate location of patient and neighboring beds, patient orientation, visitors chair, hallways, doors, and outside walls. Room must be a private one, preferably with two outside walls and patients feet oriented to outside wall. Use G-M (low level) and ion (high level) chamber survey meter to determine radiation levels. Record obtained values on drawing at location of measured readings. Readings should be taken at (1) patients bedside, (2) visitors chair, and (3) mid-bed on all neighboring beds. Query for recently performed nuclear medicine procedures if elevated readings are obtained.

NURSES - limited to 2.0mRems/hr. (2.0 ÷ bedside reading) x 60 min. per hr = maximum minutes of bedside care each (but every) hour.

VISITORS - should be limited to 100mRems/total treatment time. If visitor's chair mr/hr x total treatment time is greater than 100mRems, limit visiting time as (100 ÷ (total treatment time x visitor's chair reading) x 60 min. per hr. = maximum minutes/hour for each hour.

NEIGHBORING PATIENTS - should be limited to 100mRems. Readings taken at mid-bed x total treatment time can usually be limited to less than 100mRems either through distance or shielding. Neighboring patients should be transferred if this is not possible when the total exposure approaches 100mRems.

Item #30, Form D
5 of 8 pages
Prepared 2/4/81
Lic. #34-04307-02

RADIATION SURVEY FORM

Room Diagram

Film Badges Issued to:

	Time Limit
Nurse @ Bedside	min/hr
Visitor @ Chair	min/hr.
Pt. Bed #	hrs
Pt. Bed #	hrs
Pt. Bed #	hrs
Pt. Bed #	hrs

Name	Date	mRem

CERTIFIED BY_____ DATE/TIME_____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

CALCULATIONS

Show line drawing of patients and neighboring rooms on other side of this form. Indicate location of patient and neighboring beds, patient orientation, visitors chair, hallways, doors, and outside walls. Room must be a private one, preferably with two outside walls and patients feet oriented to outside wall. Use G-M (low level) and ion (high level) chamber survey meter to determine radiation levels. Record obtained values on drawing at location of measured readings. Readings should be taken at (1) patients bedside, (2) visitors chair, and (3) mid-bed on all neighboring beds. Query for recently performed nuclear medicine procedures if elevated readings are obtained.

NURSES - limited to 2.0mRems/hr. (2.0 ÷ bedside reading) x 60 min. per hr = maximum minutes of bedside care each (but every) hour.

VISITORS - should be limited to 100mRems/total treatment time. If visitor's chair mr/hr x total treatment time is greater than 100mRems, limit visiting time as (100 ÷ (total treatment time x visitor's chair reading) x 60 min. per hr. = maximum minutes/hour for each hour.

NEIGHBORING PATIENTS - should be limited to 100mRems. Readings taken at mid-bed x total treatment time can usually be limited to less than 100mRems either through distance or shielding. Neighboring patients should be transferred if this is not possible when the total exposure approaches 100mRems.

ITEM #20, FORM E

SAFETY PRECAUTIONS IN CLINICAL APPLICATIONS

I. Transfer and Preparation of Sources

a. Forms will be used to record pre and post-use inventory.(Item #20,FormB)
b. Sources will be dispensed with suitable protective devices and techniques, to include long forceps & TLD finger badges.

II. Application of Sources to the Patient

a. Distance, time, and when possible shielding, will be used to reduce radiation exposure to personnel attending the patient.
b. Appropriate signs will be used to indicate levels of radiation exposure.
c. Consideration will be given to the proximity of patients in adjoining rooms.
d. A patient being treated with brachytherapy sources will wear suitable identification.
e. Patient will not be allowed to leave his room unless accompanied by a hospital attendant.
f. Persons who have short-lived sources which are not removable from their bodies will be allowed to leave the hospital provided precautions necessary to prevent other persons from receiving more than the permissible dose of radiation are observed.

III. Removal of Sources from Patient

a. Sources will be removed with same safety precautions as those used in their application.
b. No linens, dressings, clothing or equipment will be removed from room until all sources are accounted for.
c. Assurance of complete removal of all sources will be obtained using a G-M survey meter held in the treatment area of the patient.
d. Should the patient die before brachytherapy is complete, the sources will be removed at once.

IV. Return of Sources to Storage

a. Following cleaning, sources will be returned immediately to their storage place.
b. Post-use inventory forms will be completed to insure complete return of all sources to storage.
c. Inventory of all sealed sources will be performed on a quarterly basis and recorded.

ITEM #20, FORM F

INSTRUCTIONS TO NURSES

1. Special restricts may be noted on the precaution sheet in the patients chart. Nurses should read these instructions before administering to the patient. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

2. Nurses should spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear a personnel monitoring device.

3. When a nurse receives an assignment to a therapy patient, a film, and/or personnel monitoring device should be obtained immediately from the Nuclear Medicine Dept. A film badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

4. Pregnant nurses should not be assigned to the personal care of these patients.

5. Never touch needles, capsules or containers holding brachytherapy sources. If a source becomes dislodged,use long forceps and put it in the corner of the room or in the shielded container provided; contact the Nuclear Medicine Department at once.

6. Bed bath given by the nurse should be omitted while the sources are in place.

7. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.

8. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the radiologist or member of the Nuclear Medicine Department.

Special orders will be written for oral hygiene for patients with oral implants.

9. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, utensils or bedding unless specifically ordered.

10. These patients must stay in bed unless orders to the contrary are written.

11. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet in the patient's chart.

12. Visitors should sit at least three feet from the patient and should remain no longer than the times specified on the form posted on the patient's door and in his chart.

13. No nurse, visitor or attendent who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

14. Emergency Procedures:

a. If an implanted source becomes loose or separated from the patient, or

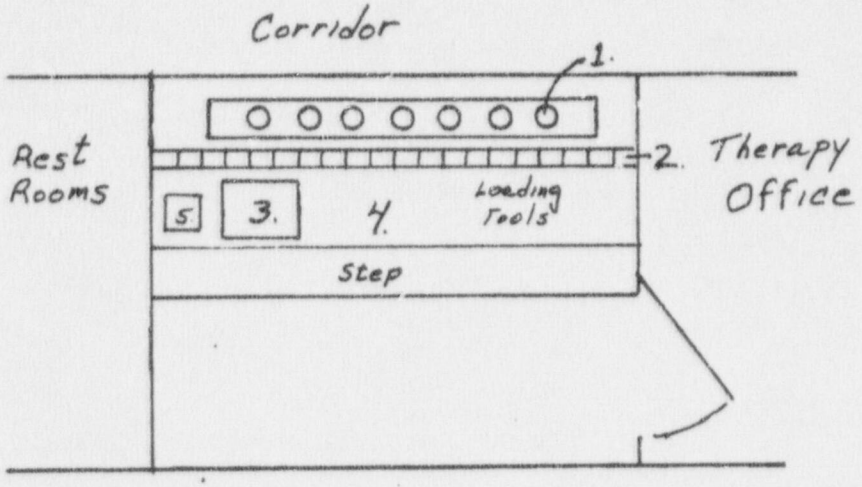
b. If the patient dies, or

c. If the patient requires emergency surgery, immediately call

_____. Phone NO. (days) _____ (nights) _____.

15. At the conclusion of treatment, call the Radiation Safety Officer and request that the patient and room be surveyed to be sure all radioactive sources have been removed.

Facilities and Equipment
Diagram



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KEY: L=Length, W=Width, H=Height, T=Thickness, N/A=Not Applicable

- ___ Air Supply
- ___ Air Exhaust
- ___ Sink
- ___ Lead Castle
- ___ Camera
- ___ Scanner
- ___ Uptake
- ___ Well
- ___ Scaler
- ___ Clerical/desk
- ___ File
- ___ Lockable Door
- ___ Isotope Receipt Area
- ___ Generator
- ___ Kit Preparation
- ___ Isotope Storage
- ___ Dose Preparation
- ___ Waste Storage
- ___ Dose Calibrator
- ___ Monitoring Equipment
- ___ Decontamination Kit
- ___ Refrigerator
- ___ Ceiling Height
- ___ Ceiling Height

		Shielding
1	Lead source containers	1 4" Dia. x 7" H x ½" T
2	Lead Bricks	2 8"L x 4"W x - H x 2" T
3	L-shield	3 12"L x 12"W x 15"H x 2" T
4	concrete "table"	___ L x W x H x T
5	Applicators	
___	___	

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g. Xenon-133)

I. Quantities to be Used:

A. Patient information

1. 10 studies per week.
2. 10 mCi per patient.

B. Possession limit: 1000 mCi

II. Use and Storage Area:

A. Xenon-133 will be stored in the closet in a leadlined fume hood (see diagram). The hood is connected to an independent exhaust system which exhausts the Xenon storage and use rooms. The closet will be used to prepare individual doses prior to use. The Xenon will be stored in its original shipping safe until used. Accessory lead shielding will be used (i.e. 1/8" - 1/4" lead vials or sheets) whenever survey measurements at the face of the hot lab hood are 2.0 mR/hr or more. The closest unrestricted area is a department office, approximately 10 feet away. The brick wall construction, storage cabinet, distance, and accessory lead shielding will reduce levels in this hall to well below 2 mR/hr.

The camera room is exhausted by this independent exhaust system leading to the exterior rooftop. The camera room exhaust system will be used to discharge all accidentally released Xenon to the outside. The camera room will be used for all patient administrations and for imaging procedures.

B. Ventilation Data:

1. Fan (Mounted on rooftop)
   2 speed capacity: 800 cfm and 400 cfm.

2. Distance from fan to nearest air intake: 56 feet

3. Air supply to camera room: 200 cfm
   Exhaust from camera room: 650 cfm (high speed fan activated)
   Air supply to storage closet: None. Exhaust - 150 cfm.

4. Refer to the attached diagram for the air flow schematic.

5. No air is recirculated.

C. With the high speed fan activated, the camera room will be a negative pressure during Xenon use. The low speed fan may be used when Xenon-133 is being stored in the fume hood. Negative pressure will be maintained in the closet. Air flow measurements will be taken annually to ensure the maintenance of negative pressure during Xenon use conditions.

III. Procedures for Routine Use:

A. The high speed fan will be activated. The door will be adjusted so a sensible draft is felt at opening. The patient will be fitted with the rebreathing apparatus and instructed as to the procedure. A trial run will be conducted when possible. The valving and tubing will be examined for continuity. The dose will be prepared and assayed on the dose calibrator, if possible. The Xenon will be administered to the patient (intravenously or into the tubing airway) and three to four views obtained. The gas will be collected in the washout bag until practically no Xenon remains in the patient as evidenced by the camera persistant scope. The gas will be absorbed in the charcoal trap. The gas will be shielded at all times up to patient administration, except during times of transfer from the shielded vial to a shielded syringe (if used). TLD finger badges and whole body film badges will be worn by all other occupational personnel present during Xenon usage. Visitors to the nuclear medicine department will be excluded from the camera room during the use of Xenon, unless their presence is required or desired.

B. A Xenon delivery system and charcoal trap, Pulmonex Model 130-500 or equivalent, will be used. A disposable face piece apparatus will be used in these closed systems. It should be pointed out that the "hardware" purchased was selected to achieve the maximum economics consistent with compliance with 10 CFR 20.106. The calculations that will follow will assume the minimum hardware and maximum utilization resulting in levels to unrestricted areas still below that specified in Appendix B of 10 CFR 20.

C. Face masks that cover both mouth and nose or nose clamps for use with the mouthpiece delivery systems will be employed to reduce leakage of the Xenon into the camera room.

IV. Accidental Release of Xenon-133:

In order to implement the ALARA philosophy in 10 CFR 2.1(c), the accidental release of Xenon into the camera room will result in evacuation of the room for a time period of 10 minutes, if the patient's condition permits. During this time, the concentration will be reduced as follows:

Data Assumptions:

A. Camera room size = 23.5' x 15.5' x 8.33' = 3034.2 cu.ft. = 8.59×10^7 ml.

B. Room clearance rate = 800 cfm

C. The dose is equally distributed in the room.

D. The clearance is essentially exponential in nature.

E. Standard dose = 10 mCi (10,000 uCi)

F. Entire 10 mCi dose is released in the restricted area by error.

G. The acceptable concentration of Xenon-133 in a restricted area = 1.0×10^{-5} uCi/ml.

Calculations:

1. Initial concentration = $\frac{10{,}000 \text{ uCi}}{8.59 \times 10^{7} \text{ ml}} = 1.16 \times 10^{-4}$ uCi/ml.

2. Clearance rate = $\frac{800 \text{ cfm}}{3034.2 \text{ cu.ft.}} \times 100 = 26.4\%/\text{min.}$

3. Desirable concentration factor = $\frac{1.0 \times 10^{-5} \text{uCi/ml}}{1.16 \times 10^{-4} \text{uCi/ml}} = 8.59 \times 10^{-2}$

4. Time required to reduce the concentration to an acceptable level is calculated as follows:

Concentration factor = e^{Rt} (R = clearance rate; t=time)

$$8.59 \times 10^{-2} = e^{-.264 \times t}$$

$$t = 9.30 \text{ minutes}$$

V. Air Concentration of Xenon-133 in Restricted Area:

A. Maximum amount of activity used per week:

A = 10 mCi x 10 patients/week = 100 mCi/week

B. Assume 25% Xenon loss, use, storage and disposal:

f = .25

C. Volume of air available per week for dilution of Xenon-133 = V

If $\frac{A}{V} \times f = 1 \times 10^{-5}$ uCi/ml

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

$$V = \frac{100 \text{ mCi} \times 1 \times 10^{3} \text{ uCi/mCi} \times .25}{1 \times 10^{-5} \text{ uCi/ml}}$$

$V = 2.5 \times 10^{9}$ ml/week

The required ventilation rate:

$$\frac{2.5 \times 10^{9} \text{ml/week}}{40 \text{ hours/week}} \times \frac{1 \text{ cfm}}{1.7 \times 10^{6} \text{ ml/hr.}} = 36.8 \text{ cfm}$$

The actual ventilation rate in this area is 650 cfm for 30 minutes per procedure from the imaging room and 150 cfm through the hood in the hot lab, which is greater than the required ventilation for a restricted area. During Non-Xenon conditions the total exhaust will be 400 cfm.

VI. Method of Xenon-133 Disposal:

All Xenon unused will be disposed of by decay in storage in the hood. Containers and apparatus will be surveyed unshielded with the low level survey meter held on contact with the source containing device. If levels are the same as background, the containers will be disposed after defacing the labels.

All used or escaped Xenon will be vented through the exhaust system.

A. It is anticipated that 1.3 Ci of Xenon will be vented to the atmosphere per year. This includes Xenon liberated as accidental losses, and leakage.

B. An air flow rate of 650 cfm will be used in the calculation. The exhaust blower will be oeprated at 800 cfm whenever Xenon studies are underway, or Xenon is being disposed of by purging collection bags at the conclusion of the studies, or if the camera room is being vented of an accidentally liberated dose, and at 400 cfm during Non-Xenon conditions.

C. Assuming that 10 studies per week will be performed, the calculations are as follows:

Air flow per year is (V).

$$V = 800 \text{ cfm} \times \frac{60 \text{ min.}}{\text{hour}} \times \frac{168 \text{ hrs.}}{\text{week}} \times \frac{52 \text{ weeks}}{\text{year}} \times 2.83 \times 10^{4} \text{ml/cu.ft.}$$

$$V = 800 \times 60 \times 168 \times 52 \times 2.83 \times 10^{4}$$

$$V = 1.19 \times 10^{13} \text{ml/yr.}$$

D. The average concentration of air to the environment is (C).

$$C = \frac{A}{V}$$

$$C = \frac{1.3 \times 10^{6} \text{ uCi}}{1.19 \times 10^{13} \text{ml.}}$$

$$C = 1.09 \times 10^{-7} \text{uCi/ml.}$$

This value is less than the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

VII. The maintenance of the charcoal trap will be as follows:

In order to detect a saturated charcoal trap, a survey will be conducted with the G-M probe held on contact with the trap inlet hose. The maximum levels will be recorded during the washout phase. Immediately afte maximum levels are reached, the probe will be placed on the discharge tube. If these levels reach 10% of the intake maximums, the trap will be considered less than 90% effective and will be replaced. This test will be conducted weekly.

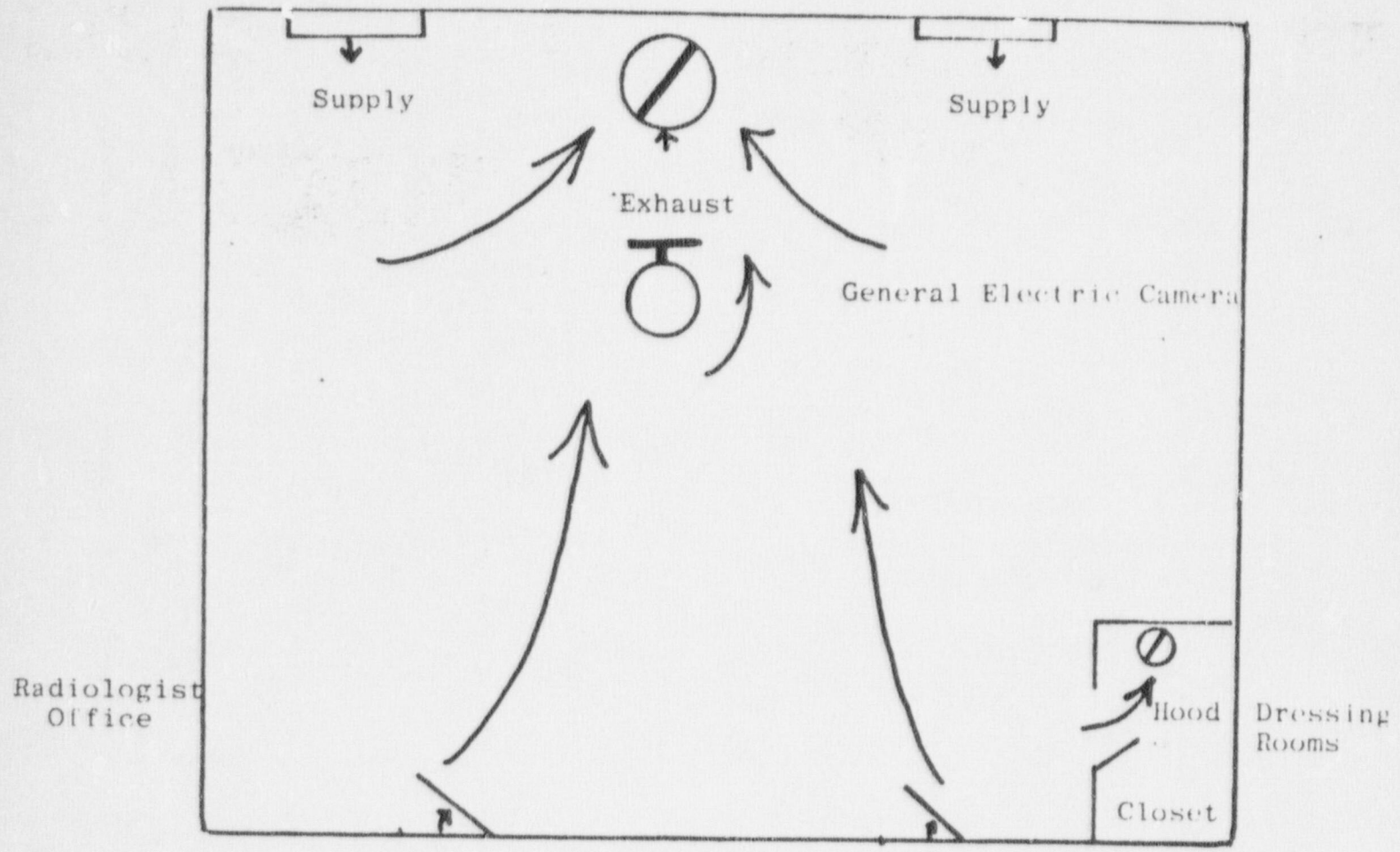
Saturated filters will be stored in the hood shielded such that levels do not exceed 2.0 mR/hr at the hood face. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded.

Elyria Memorial Hospital

Air Flow Schematic

Nuclear Medicine - camera room

Ventilation Data: (for Xenon-133 use conditions)
Total Supply: 200 cfm
Total Exhaust: 800 cfm
Resultant Pressure: Negative



Item #21
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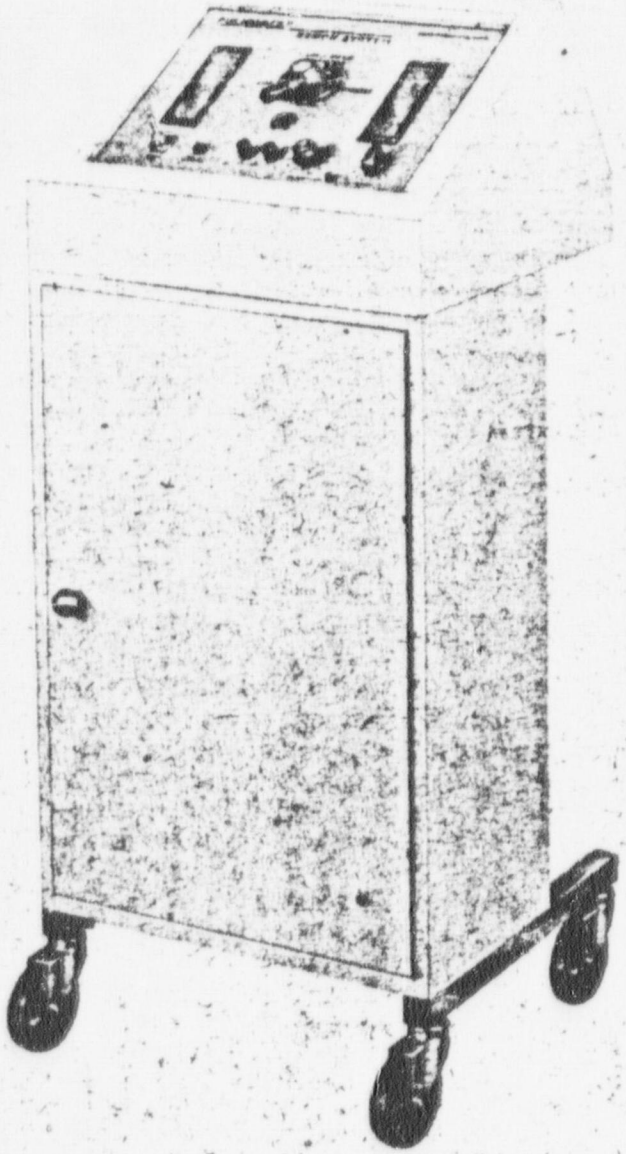
Prepared 2/4/81
Lic. #34-04307-02

PULMONEX XENON SYSTEM

One technician can perform an entire study by simply moving a single handle.



Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

- Complete easy-to-use system.
- "Air-in"/"Air-out" breathing tubes and motor-driven circulator assures resistance-free breathing.
- Two lead glass windows permit observati of patient breathing bags.
- All flow circuits automatically controlled by a master valve system.
- Automatically timed washout.
- Accepts any commercial form of xenon.
- Rolls easily on large casters for positioning of supine or seated patients.
- Fully shielded.
- Carbon dioxide and moisture traps included.

SIMPLE, SAFE OPERATION

Model Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

Elyria Memorial Hospital (Nuclear Med.) Elyria, Ohio
(Licensee's Name)

August 4, 1980
(Date)

I. Management Commitment

a. We, the management of this (medical facility, hospital, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1], and a Radiation Safety Officer (RSO). We are also committed to following the guidance provided by U.S. Nuclear Regulatory Guides 8.10 and 8.18.

b. We will perform a formal audit annually to determine how exposures might be lowered. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants. A brief summary of the audit will be prepared covering the scope of the review and the conclusions reached.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where practicable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

[1] Private practice physician licenses do not include a RSC.

II. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that the user will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the authorized user to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and should have considered the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that they will result in ALARA doses (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate sufficient authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action.

c. Review of ALARA Program

The RSC of our medical facility will perform an annual review of all radiation safety programs. This review will be performed independently of that performed by management.

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate for ways to implement the ALARA concept.

---

[2] The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section III.

2. The RSC will review all instances of deviations from the ALARA philosophy. Information in support of the review will normally be supplied by the RSO.

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

d. Public Statement of Commitment by the RSC to ALARA

All elements of our institution will be informed of the RSC's commitment to the ALARA concept.

1. The RSC will ensure that employees are aware of the RSC's commitment to the ALARA philosophy.

2. The RSC will demonstrate its commitment to the ALARA concept through the methods employed in its review of proposed users and uses.

III. Radiation Safety Officer (RSO)

a. Periodic Review and Audit of the Radiation Safety Program for Compliance with ALARA Concepts. (This is the key element in any ALARA program.) Frequent reviews of procedures will be conducted.

1. The RSO will review and audit, on a regular basis (at least annually), the effectiveness of his own radiation protection program in maintaining doses (individual and collective) ALARA.

2. The RSO will review exposures of authorized users and occupational workers to determine that their exposures are ALARA.

3. The RSO will review radiation levels in unrestricted and restricted areas and releases of effluents to unrestricted areas to determine that they are at ALARA level.

b. The RSO's Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, occupational workers and ancillary personnel understand the ALARA philosophy and know that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Individuals who must work with ALARA concepts will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will maintain close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for encouraging, receiving, and evaluating the suggestions of individual workers for improving health physics practices.

d. Reporting and Reviewing Instances of Deviation from Good ALARA Practices

1. The RSO will investigate all instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will propose changes in the program to maintain exposures ALARA.

2. The RSO will report all significant instances of deviation from ALARA concepts to the RSC for review.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult the RSO and RSC before using radioactive materials for a new procedure.

2. The authorized user will consider all procedures thoroughly before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

3. The authorized user will be responsible to the radiation safety concerns of the individuals that he supervises.

c. Continuing Review of ALARA Concepts by the Authorized User

1. The authorized user will continuously review his procedures to ensure that his ALARA program is optimal.

2. The authorized user will maintain contact with the RSO to ensure that he is aware of and employs the most current methods to maintain exposures ALARA.

V. Occupational Worker

a. What the Occupational Worker Must Consider about ALARA

1. The worker will implement ALARA procedures developed by the authorized user and the RSO.

2. The occupational worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

3. The occupational worker will understand that ALARA concept and will review his own working conditions and those of his fellow workers for the implementation of ALARA principles.

VI. Establishment of Action Levels in Order to Achieve Reductions in Individual Occupational Exposures

This institution (or private practice) hereby establishes exposure action levels for specific kinds or classes of operations which, when exceeded, will trigger investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The exposure action levels that we have established are listed in Section VII below. These levels apply to the exposure of individual workers. The exact levels have been determined based on our institution's radiation exposure history and a thorough analysis of our current program. We will maintain on file at our institution an account of the considerations used in establishing action levels.

Written justification is appended to this program for any exposure action levels that exceed 10% of MPD (10 CFR 20.201). This justification includes details of the past exposure history at this institution for the particular kind or class of operation, a summary of efforts taken to reduce this exposure, and an explanation of why further dose reductions are not feasible.

We will investigate the causes of personnel exposures that exceed our established exposure action levels. In the event of a personnel exposure that exceeds our established action levels or 10% of MPD, whichever is higher, we will maintain accounts of our investigation for inspection by the NRC. As a minimum, tnese accounts will include the cause of the exposure, the action taken to correct the situation and the follow-up action taken.

VII. Action Levels

(List the kinds or classes of operations at your institution that generate personnel exposure together with the associated exposure action levels that you have established. Be certain to include written justification for levels that exceed 10% of MPD. Include in your justification details of the past exposure history at your institution (or private practice) for the particular kind or class of operations, a summary of the efforts taken to reduce this exposure, and an explanation of why further dose reductions are not feasible. You may wish to identify such items as cost/benefit analysis and the possible increases in collective dose (man rem) as a result of proposed actions.)

The specific action levels established by this institution (or private practice), are as follows:

TABLE I

Kind or Class of Operation[3]	Investigational Levels - (mrems per calendar quarter)	
	LEVEL I Per quarter	LEVEL II Per Year
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

[3]Examples of kinds or classes of operations are: Diagnostic nuclear medicine, Radioimmunioassay procedures, teletherapy, etc.

VIII Signature of Certifying Official[4]

I hereby certify that this institution (or private practice), is committed to the ALARA Program set forth above.

James C. Brown
Signature

Mr. James C. Brown
Name (print or type)

Administrator
Title

Institution (or Private Practice) Name and Address:

4 The individual who is authorized to make commitments for the administration of the institution (e.g., hospital administrator, etc.) or, in the case of a private practice, the licensed physician.

ITEM #19, FORM D

Radiation Hazard Evaluation Form

(to be filled out by Radiation Safety Officer for his use)

Name _____ Date and _____

Time of Death _____

Radioisotope _____

Amount administered _____

Route of Administration _____

Amount present _____

Distribution within body _____

_____

_____

_____

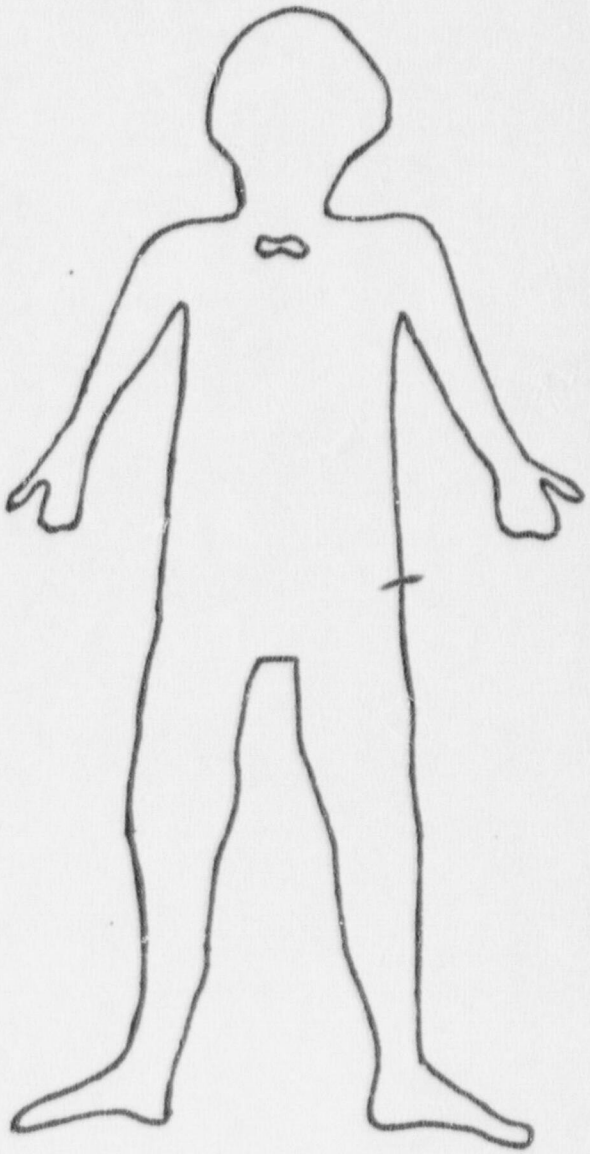
Indicate Distances _____

Suggest ring badges if exposure

0.25 R/hr @ 25 cm

See NCRP #37 p. 27.

Limit hand exposure to 1.5 Rems



Date of Survey _____

Instrument Used _____

Signed _____
Radiation Safety Officer

Date _____

ITEM #19 - FORM C

Specific Instructions to Reduce Radiation Exposure During Embalmment

(to be filled out by Radiation Safety Officer and forwarded to funeral director)

The following procedures should be implemented during the embalming of _____.

( ) This body does not contain significant amounts of radioactive material. No special precautions are necessary if standard embalming procedures are employed.

This body contains radioactive material. The following procedures should be observed:

( ) A closed system should be used to drain fluids. Use suction if necessary. Fluid can be disposed of via sewer, flush with copious amounts of water.

( ) Blood and urine should be removed via closed systems. Dispose via sewer with copious amounts of water.

( ) Other _____

_____

_____

Signed _____
Radiation Safety Officer

Date _____

Copy of this report is maintained in Radiation Safety Office files

ITEM #19 - FORM B

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHUS-32, or IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotpe Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all Check Items)

_____1. Visiting time permitted: _____

_____2. Visitors must remain _____from patient.

_____3. Patient may not leave room.

_____4. Visitors under 18 not permitted.

_____5. Pregnant visitors not permitted.

_____6. Film badges must be worn, or personnel exposure monitoring device

_____7. Use and complete the following tags:

_____door

_____bed

_____chart

_____wrist

_____8. Gloves must be worn while attending patient.

_____9. Patient must use disposable utensils.

_____10. All items must remain in room until OK'd by Radiation Safety.

_____11. Smoking is not permitted.

_____12. Do not release room to admitting until OK'd by Radiation Safety.

_____13. Other instructions.

In case of Emergency Contact:

RSO On/off duty telephone #

RADIATION SURVEY FORM

Room Diagram

Film Badges Issued to:

	Time Limit
Nurse @ Bedside	min/hr
Visitor @ Chair	min/hr.
Pt. Bed #	hrs
Pt. Bed #	hrs
Pt. Bed #	hrs
Pt. Bed #	hrs

Name	Date	mRem

CERTIFIED BY_____ _____ DATE/TIME_____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

CALCULATIONS

Show line drawing of patients and neighboring rooms on other side of this form. Indicate location of patient and neighboring beds, patient orientation, visitors chair, hallways, doors, and outside walls. Room must be a private one, preferably with two outside walls and patients feet oriented to outside wall. Use G-M (low level) and ion (high level) chamber survey meter to determine radiation levels. Record obtained values on drawing at location of measured readings. Readings should be taken at (1) patients bedside, (2) visitors chair, and (3) mid-bed on all neighboring beds. Query for recently performed nuclear medicine procedures if elevated readings are obtained.

NURSES - limited to 2.0mRems/hr. (2.0 ÷ bedside reading) x 60 min. per hr = maximum minutes of bedside care each (but every) hour.

VISITORS - should be limited to 100mRems/total treatment time. If visitor's chair mr/hr x total treatment time is greater than 100mRems, limit visiting time as (100 ÷ (total treatment time x visitor's chair reading) x 60 min. per hr. = maximum minutes/hour for each hour.

NEIGHBORING PATIENTS - should be limited to 100mRems. Readings taken at mid-bed x total treatment time can usually be limited to less than 100mRems either through distance or shielding. Neighboring patients should be transferred if this is not possible when the total exposure approaches 100mRems.

storage facilities are available, the organs may be stored for several days without significant alteration, or the viscera may be fixed. This would allow for the natural decay of the radioactive reducing possible exposure.

b. Emergency Surgery -

If surgery must be carried out within a highly radioactive cavity, speed is desirable. Accordingly, an experienced surgeon should perform the operation. The surgeon and his assistants should wear gloves and glasses or goggles for the protection of the eyes from possible splashing of foreign material, as well as from beta radiation.

Radioactive Iodine 131 Orally or Intravenously Administered.

a. Autopsy - Urine should be drained away and blood disposed of, if possible, in the same manner as if no autopsy were to be performed.

b. Surgery - Precautions are essentially the same as for autopsy. During the first day after administration, the blood may be expected to contain considerable radioactivity, and care should be taken not to let it accumulate on gloves or gowns. After the first day, the circulating radioiodine has greatly decreased, and regions of high activity can be identified and usually avoided.

Interstitial Implants and Colloidal Interstitial Infiltration.

At surgery or autopsy, these regions can be readily identified, and avoided as far as possible. At autopsy, if the entire block of tissue containing the radionuclide can be removed readily, this should be done first. If only a sample of the treated region is to be taken, this part of the body should be avoided until the rest of the autopsy has been carried out.

Accident or Injury During Surgery or Autopsy

If an injury occurs during surgery or autopsy, where the rubber gloves are cut or torn, radioactivity may be introduced into the wound. In addition to ordinary treatment of the wound, the Radiation Protection Officer shall be consulted with regard to any possible radiation hazard.

SUMMARY

In general, most procedures performed in nuclear medicine involve the use of Technetium 99m. Due to this radionuclides short half-life, six hours, a period of 24 hours should reduce even the highest dose encountered in nuclear medicine to a safe level. Most other procedures generally encountered in nuclear medicine involving nuclides other than Technetium-99m require dose of 5mCi or less. As indicated in the opening paragraph, activities at this level require little or no special procedures. Those situations involving special precautions and procedures are generally limited to quantities of radioactivity introduced into the patient during therapy treatment. The Radiation Protection Officer should be consulted to establish proper precautions and procedures for each individual case.

GUIDELINES FOR EMERGENCY SURGERY OR DEATH OF THE RADIOACTIVE PATIENT *

In most hospitals, deceased patients with large amounts of radionuclides will be encountered only rarely, since, in principle, radionuclide therapy is not given to moribund patients. If several days intervene between treatment and subsequent surgery or death, the radiation hazard is usually considerably reduced. In most hospitals, the number of patients receiving large internal doses of radionuclides in any one week is small. The need for emergency surgery would not be usual, nor would the death of one of these patients.

The identification of a particular patient as radioactive is the responsibility of the physician in charge of the case. The radioactive patient shall be properly identified at all times. If a radioactive patient dies in the hospital, the physician who pronounces him dead should be responsible for attaching a radioactivity precautions tag to the body. The physician in charge of the case and the Radiation Protection Officer shall be notified at once.

*In general bodies containing less than 5mCi. need no precautions for any type of handling. Those containing between 5 and 30mCi may be buried or cremated with no preparation or embalmed according to standard injection procedures without special precautions. If the body is to be subjected to autopsy, the Radiation Safety Officer will designate any special precautions. The body containing more than 30mCi. can be buried or cremated with no preparation, but if embalming is to be carried out, it should be with the guidance of a Radiation Safety Officer. Among patients that die outside the hospital, the funeral director will seldom encounter bodies with hazardous exposure rates.

Preparation for Burial or Cremation Without Autopsy:

Consider first the cases in which no autopsy is to be performed and the body need not be opened. Embalming will be by the injection method, and the likelihood of contamination of the embalmer is small. Nevertheless, even in these cases, rubber gloves shall be worn by all who are involved in the procedures in order to avoid the possibility of contamination by radioactive fluids from the body. The exposure rate at about 25cm. from the center of the radioactive material should be measured; if this is less than 0.25 R/h, no further precautions are necessary as far as the gamma radiations are concerned. Item #19, Form C and D will be completed.

Radioactive Iodine, I-131, Administered Orally or Intravenously; No Autopsy:

The dose of I-131 administered in the treatment of thyroid disease rarely exceeds 100mCi. Within an hour after a patient has received this dose, measurements with an ionization chamber type survey meter may be expected to indicate a surface exposure rate over the abdomen on the order of 0.3 R/h. During the first 24 hours after administration of I-131, the blood and urine may contain considerable radioactivity. These fluids should accordingly be removed into closed systems and later flushed directly into the sewer, followed by an adequate volume of water.

The day after administration, the general distribution of radiation is

*Summary of information found in NCRP Report #37.

greatly modified, both by urinary excretion of a large part of the radionuclide and by concentration of the remaining part in functioning thyroid tissue. At this time only radiation from these regions of iodine storage need be considered. Any region of high activity which is not to be removed, should be marked by the Radiation Protection Officer so that it can be avoided.

Any Radionuclide Injected Interstitially or in Seeds: No Autopsy:

Various colloidal radioactive preparations may be injected interstitially into tumors. Radon seeds, radioactive gold wires, radium wires, and other preparations may be implanted in limited regions. If the nuclide emits only beta rays, it is unlikely that there will be any appreciable external irradiation. If it is a gamma emitter, the active tissues may be extirpated or the region can be identified and avoided.

Body to be Opened for Surgery or Autopsy:

The usual precautions for preventing the spread of an infectious material should aid in keeping the radioactive material localized. At autopsy the general principle is to remove the main source of radiation hazard as early as possible, without causing general contamination. At surgery this cannot be usually be done, hence regions of high activity should be avoided or shielded. Item #19, Form D and E will be completed.

As long as the body remains unopened, the radiation received by anyone near it, is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Beta radiation is readily absorbed by material interposed between its source and the operator. Even rubber gloves are useful in this regard. The gamma rays are not absorbed appreciably by rubber gloves.

Any radionuclide in a Body Cavity which is to be Opened:

The Radiation Protection Officer will evaluate the radiation hazard and suggest suitable procedures regarding the safety of personnel during the entire operation.

a. Autopsy -

As much body fluid as possible should be removed before the body is opened. The remaining radioactive material may be expected to be widely distributed over the surfaces of the cavity and of the organs within it. The use of bare hands will not be permitted because of the contamination of skin and nails that would result and the difficulty of complete removal of such contamination.

Monitoring the body after removal of the viscera may indicate a radiation level low enough so that subsequent procedures can be carried out without special precautions. Regions of high activity, if present, can be indicated and avoided or approached with precautions. If the removed organs are to be disected immediately, each one should be monitored and treated in accordance with the findings. After desired small samples have been taken, the radioactive tissues that are to be retained should immediately be placed in appropriately shielded vessels for storage, or for disposal according to procedures approved by the Radiation Protection Officer. Where adequate cold

cups, and eating utensils will be used by patients who are treated with iodine-131. All clothes and bed linens used by the patient should be placed in the laundry bag provided and left in the patient's room to be checked by a member of the Nuclear Medicine Department. All non-disposable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.

f. See attached GUIDELINES FOR EMERGENCY SURGERY OR DEATH OF THE RADIOACTIVE PATIENT *

g.(1) Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination (and decontaminated if necessary) and all radioactive waste and waste containers will be removed.

g.(2) Instructions for Patient & Family - Patient will not be discharged until radioactivity reaches 30mCi. This will be determined by measuring the dose rate at time of administration from a distance of no less than 3 meters, allowing the patient to act as much like a point source as possible. Patient will be discharged when reading at identical location and circumstances reaches 30% of initial value, assuming 100mCi dose.

(i) In the event that all persons in the household of the radioactive patient, and hence all those persons with whom the patient will have appreciable contact, are over age of 45 years:

-The patient should be instructed to remain at distances greater than 3 feet from other people, except for brief periods for necessary procedures.

-Babies and young people (of ages less than 45 years) should not visit the patient, but if they do, the visits should be brief, and a distance of at least 9 feet from the patient should be maintained.

(ii) In the event that a person under the age of 45 years lives in the household of the patient:

-Stricter precautions shall be observed than when all contacts are with persons over 45 years of age.

-Children and persons under 45 years of age shall not be allowed in the same room, nor at a distance of less than 9 feet, for more than a few minutes a day. Observance of these conditions will insure that persons under 45 years of age will not be exposed to more than 0.5 R per year from the radioactive individual.

-Other restrictions may be specified by the physician.

With the exception of transferring the patient from a private room, all restrictions will be removed when the activity reduces to a point that will result in no greater than 0.5 R to persons in the family from that point until total decay. For I-131, that will be the time where radioactivity in the thyroid gland reaches 8 mCi or a reading of 1.8mR/hr @ 1 meter.

Item 19-1

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

Special precautions for patients treated with byproduct material listed in Groups IV or V, Schedule A, Section 35.100 of 10 CFR Part 35 are as follows:

a. Method for preparation and administration of therapeutic doses of Iodine-131. Therapeutic doses of I-131 will be ordered from reputable suppliers and received precalibrated, ready for dispensing to patients. These materials will be stored until time for use, in the isotope storage area behind sufficient shielding to reduce the radiation levels to 2.0mR/hr at a distance where occupational workers can conveniently stand. All liquid sources will be opened in a fume hood with the fan activated. Patients requiring therapeutic amounts of I-131 less than 30mCi will be dosed in the hot lab, held for 30 minutes for observation and sent home or to their room. Hospitalized patients receiving greater than 30mCi will be dosed in their rooms.

b.(1). All patients who have been administered I-131 for therapeutic reasons who require hospitalization will be placed in a private room with a toilet. Attempts will be made to use a corner room in a low traffic section of hallway.

b.(2). Patients will use disposable items whenever possible (e.g., dishes, utensils, etc.).

c.(1). Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after adminstration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet away and the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times which will be posted on the patient's chart and on his door. (Refer to Item #19, Form A). Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR Part 20. (i.e., 2mrems in any one hour or 100mrems in any seven consecutive days) Refer to Item #19, Form A.

c.(2). All linens will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held for decay. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designee), checked for contamination, and disposed of as normal or radioactive waste, as appropriate. Non-disposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Officer or his designate. Items may be returned for normal use, held for decay or decontaminated, as appropriate.

d. The form, Nursing Instructions for Patients Treated with Phosphorus-32 or Iodine-131, (Item #19, Form B) will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should

read these instructions before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precautions sheet in the patient's chart. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant. Attending personnel must wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

e.(1). Therapy patients will be allowed to use the toilet facilities since human excreta is exempt from waste disposal considerations. The patient will be instructed, however,to flush the toilet, urinal or bed pan several times after use. If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards she should wash her hands with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Nuclear Medicine Department. Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. If radioactive urine or feces is collected or spilled during collection, call the Nuclear Medicine Department, Ext. 2507. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination. All vomitus must also be kept in the patient's room for disposal by the Nuclear Medicine Department. Urine or feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times)after use. Precautions must be taken to see that no urine or vomitus, is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Nuclear Medicine Department. If a nurse, attendant or anyone else knows or suspects that his skin, or clothing, including shoes, is contaminated, notify the Nuclear Medicine Department immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately. When the patient is discharged call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

e.(2) Surgical dressings should be changed only as directed by the physician. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Nuclear Medicine Department. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

e.(3) Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Nuclear Medicine Department for proper disposal of the contents of the designated waste container. Disposable plates,

All radioactive material will be used at address in Item 1.a.

Group VI materials will also be used at:

1. St. Joseph Hospital, Lorain, Ohio
2. Lorain Community Hospital, Lorain, Ohio
3. Allen Memorial Hospital, Oberlin, Ohio
4. Amherst Hospital, Amherst, Ohio

Item #1.b.
Prepared 2/4/81
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Item No. 4

Individual Users	Authorized materials and uses
Robert D. Berkebile, M.D.	All
Warren N. Sheldon, M.D.	All
John E. Grauel, M.D.	Groups I, II, III, VI, and Xenon-133
Thomas R. Martin, M.D.	Groups I, II, III, and Xenon-133
H. E. Kleinhenz, M.D.	Group VI
Karoly Szentendrey, M.D.	Groups I and VI
John B. McCoy, M.D.	Groups, I, II, III, IV, VI, and Xenon-133
Lawrence G. Thorley, M.D.	All
Richard C. Zbornick, M.D.	All
Carlos E. Fernadez Pena, M.D.	All
A. R. Abla, M.D.	Groups I, II, III, IV, and Xenon-133
Mario A. Macchi, M.D.	Groups I, II, III, Xenon-133 and soluble Phosphorus-32 for therapy
Stephen M. Tkeich, M.D.	Groups I, II, III, IV, Xenon-133
R. G. Thomas, M.D.	Groups I, II, III, and In vitro studies
John Albert Vanek, M.D.	Groups I, II, III, Xenon-133, and Iodine-131 for therapy
Paul P. Varley, M.D. (re-add: incorrect amendment 14 was issued)	Groups I, II, III, and Xenon-133
Terisita S. Ocampo, M.D.	Groups I, II, III, and Xenon-133

Refer to license #34-17796-01, Lorain Community Hospital, for training and experience for Dr. Ocampo.

Item #4
Prepared 4/2/81
Lic. #34-04307-02

MEDICAL ISOTOPES COMMITTEE

Responsibility:

The Committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to ensure them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by Section 19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures and management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations and decisions.

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Lic. #34-04307-02

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Meeting Frequency:

The medical isotopes committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

MEDICAL ISOTOPES COMMITTEE

The following members compose the Medical Isotopes Committee of

Elyria Memorial Hospital

Name	Medical Specialty
Dr. P.F. Varley	Radiation Safety Officer
Mr. Ted W. O'Dell	Administration Member
Dr. R.S. Buchanan	Pathology
Dr. W.N. Sheldon	Radiology
Mr. Harish Parikh	Nuclear Tech CNMT

Nuclear Medicine Associates' visiting consulting physicists available periodically and/or as required.

RADIATION DETECTION INSTRUMENTS

TYPE OF INSTRUMENTS	MANUFACTURER	MODEL #	NUMBER AVAILABLE	MAXIMUM RANGE MINIMUM RANGE
Gamma Camera	G.E.	Maxi II	1	Imaging
Dose Calibrator	Rad-X	Mark V	1	0-1000mCi 0-1000mCi
G-M Survey meter	Victoreen	490-50	1	0-.2mR/hr 0-20mR/hr
Ionization Survey meter	Jordan	AGB-10KG-SR	1	.01-10mR/hr 10-10000R/hr
Uptake Probe	Picker		1	

Item #9
Prepared 2/4/81
Lic. #34-04307-02

CALIBRATION OF INSTRUMENTS

A. The survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. The highest recording obtainable will be included on all recorded surveys.

The units will be calibrated at annual intervals by the Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy and contancy. They will consist of:

Nuclide	Manufacturer	Model #	Activity (mCi) *
Cs-137	NEN	NES-356	0.200
Ba-133	NEN	NES-358	0.200
Co-57	NEN	NES-352(206)	1.0 (5.0)
Cs-137	Mallinckrodt	045-5AH	1.0

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standards sources.

3. The calibration procedure will be as follows:

a) The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in item 1 above.

The activity displayed by the dose calibrator must agree with the stated assay within ± 10%. This error may exceed ± 10% but correction factors will be determined. If the unit displays readings with an error greater than ± 10%, arrangements will be made for immediate repair or adjustment but the unit may be used in the interim using the predetermined correction factors.

b) The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ±10% of the predicted activity based on the value obtained at the time of the original accuracy test.

*At time of calibration

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± % of the activity shown at the time of the most recent accuracy check.

If variation greater than ± 10% are noted, arrangements will be made for immediate repair or adjustment but the unit may be used in the interim using the predetermined correction factors.

c) The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo/Tc generator. In the latter case, after assay of the entire contents of the generator elution vial, the concentration will be determined and an aliquot containing 20 mCi or up to 20% of the vial contents of the generator elution vial will be drawn. If 20% of the vial contents does not contain 20mCi, then the activity it does contain will be the maximum drawn and assayed for preparation of kits for the following quarter. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluant can be determined by dividing the displayed activity by the volume in the syringe. A 20 mCi aliquot contained in the proper volume can then be withdrawn from the elution vial and used for the linearity test. If greater than 20% of the vial contents would be used up for linearity check purposes, the amount drawn may be restricted to 20% for this test with the same limitation given in the paragraph above. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparations.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is less than the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a funtion of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 10%. If test result error exceeds ± 10%, arrangements will be made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

d). The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using a sufficient amount of activity in a geometrical configuration approximating a point source. The source will be inserted into the chamber along its central axis until the maximum activity response is displayed. The source will then be moved in the chamber to points above and below the maximum response point until displayed readings of 90% of maximum are found. This will include peripheral measurements within the chamber as well. The zone of 90% isoresponse will be identified. In routine assays, measurements will be made with all the activity within the 90% isoresponse zone of the chamber.

For nuclides with gamma energies less than 100 Kev such as Xenon and I-125 and those which may be received contained in unusual configurations (i.e.: syringes, capsules, cartridges or ampules), initial geometrical corrections will be determined using the manufacturer's assay and appropriate decay factors. The correction factors will be determined using the displayed activity vs. the manufacturer's assay at the time of receipt.

Acceptable correction factors may be on the order of $\pm$ 50% due to the unusual responses associated with these geometries. The manufacturer's assay will be assumed to be correct however, and the correction factor will be used only as a constancy value to be compared to future shipments of these nuclides. In the event the constancy value varies by greater than $\pm$ 10%, the dose calibrator will be adjusted or repaired.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium 99m and its Molybdenum 99 contaminant to with + 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

C. Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and uniform flood check which will be performed each day of use.

2. The Picker Uptake system will be calibrated each day of use with Cs-137 or another long-lived Radioisotope.

FACILITIES & EQUIPMENT
DECRIPTION

All radioactive source are stored in such a manner (lead, concrete, or refrigerator) so as to not exceed 2mR/hr at the surface of the barrier.

Mo-99/Tc-99m generators when used will be stored and eluted in the designated area. It will be shielded with lead bricks such that levels from all avenues of approach do not exceed 2.0mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patients well being may be compromised. Under these circumstances the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc) such that levels during the above period as measured by a low level survey meter do not exceed 2.0mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

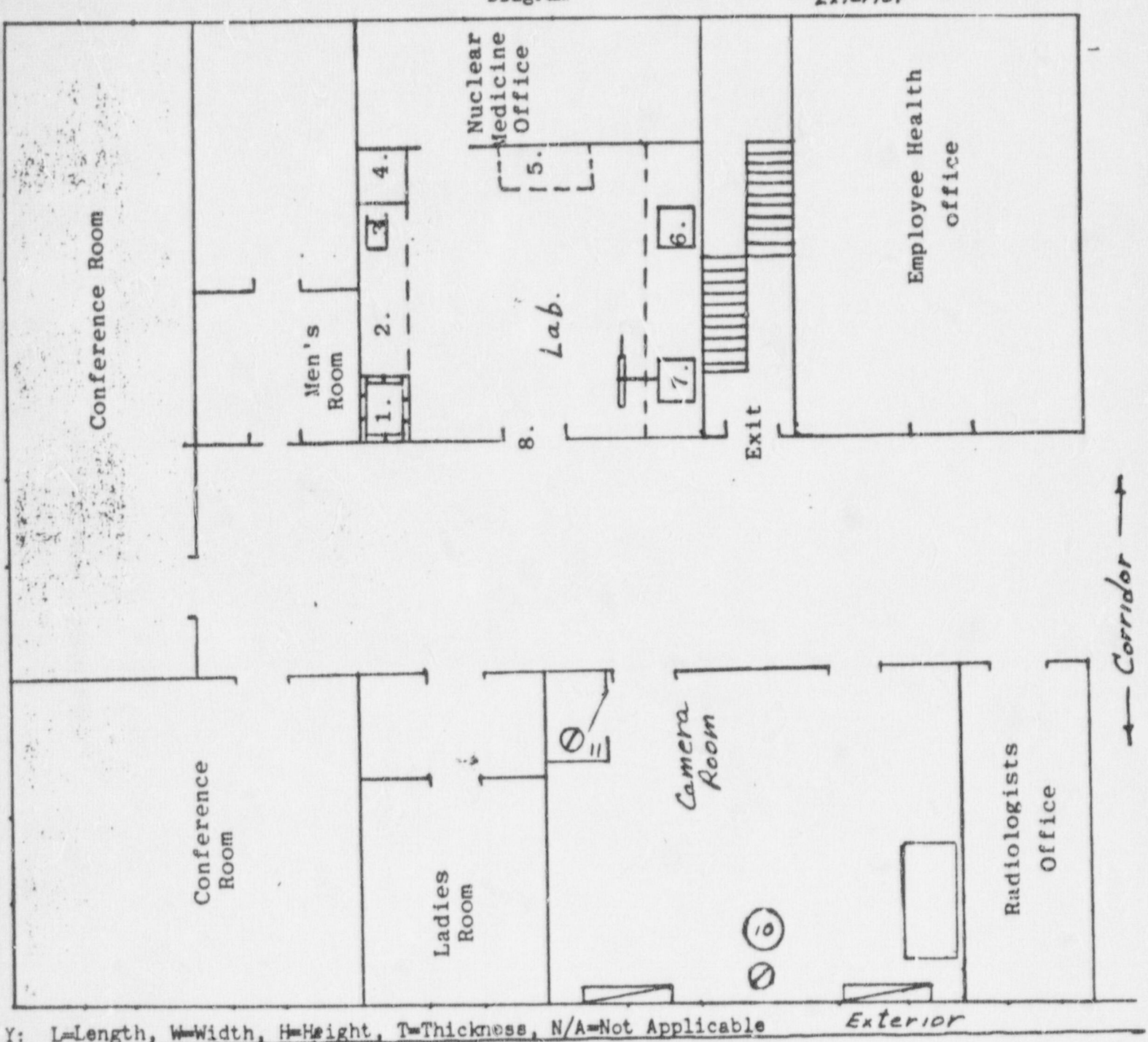
All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbant paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM	PURPOSE
1. Warning tape, chalk, & signs.	posting of area
2. Plastic bags, small	shoe covers, wet containers
3. Disposable gloves	hand protection
4. Masking tape	fasten shoe covers, etc.
5. Forceps, tongs	safe handling
6. Large plastic bags	for contaminated material
7. Sponges, 4 x 4	sopping up
8. Paper towels	blotting & drying
9. Radiac wash or detergent	detergent
10. Scouring powder	friction
11. Tags	identification
12. Scissors	cut absorbent paper, etc.
13. Whatman #1 filter paper	taking swipes following decontamination.
14. Chux	cover area following decontamination
15. G-M survey meter	monitoring

Facilities and Equipment
Diagram



KEY: L=Length, W=Width, H=Height, T=Thickness, N/A=Not Applicable

Air Supply	5	Isotope Receipt Area	
Air Exhaust	1	Generator	
Sink	2	Kit Preparation	
Lead Castle	1	Isotope Storage	
Camera	2	Dose Preparation	
Scanner	1	Waste Storage	
Uptake	6	Dose Calibrator	
Well	___	Monitoring Equipment	11 Hood
Scaler	___	Decontamination Kit	3 Hot Plate
Clerical/desk	4	Refrigerator	
File	___	Ceiling Height	
Lockable Door	___	Ceiling Height	

Item #11
3 of 3 pages

Shielding

1
42" L x 30" W x 18" H x 2" T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

1. The nuclear medicine department will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.

2. Every effort will be made to hire nuclear medicine technology registered or registry eligible personnel to work with radioactive material. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:

   a. Indicate areas where radioactive materials are used or stored.
   b. Potential hazards associated with radioactive materials.
   c. Radiological safety procedures appropriate to their respective duties.
   d. Pertinent NRC regulations.
   e. The rules and regulations of the license.
   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.

If evaluation of the radiation handling techniques of a new technologist is found to be inadequate, arrangements will be made to send the employee for a 40 hour formal course from our consulting physicists, Nuclear Medicine Associates, Inc., Cleveland, Ohio. This course combines didactic and clinical training which will include points "b" through "i" listed above as well as quality control and patient procedures.

3. Our consulting physicists, mentioned in this addendum, will visit our facility quarterly to review all procedures, equipment and records. Personnel will receive refresher training relative to duties, regulations, or terms of the license during these visits or by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.

4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, as in the case of certain patients who need special care. Personnel so involved will be present under the direction of the nuclear medicine technologist, who will ensure that the exposure of these persons is held to the minimum required for the performance of the nuclear medicine procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their hospital orientation process and annually thereafter in the form of verbal instructions and/or hospital interdepartment memos.

Item #12
Prepared 2/4/81
Lic. #34-04307-02

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist his/her designee will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area identified in the Item #11 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the nuclear medicine department. If this is not practical, responsible personnel (indicated in the memorandum below) will sign for packages containing radioactive materials and immediately take them to this location. Alternatively, trained nuclear medicine personnel will sign for and transport packages to the appropriate department.

3. During off-duty hours, supervisory personnel will arrange to have delivery of radioactive packages in accordance with the procedures outlined in the following directive:

TO: Managerial Personnel of: Nuclear Medicine
Radiology
Receiving
Security
Pathology

FROM: Administration

SUBJECT: Delivery of packages containing radioactive materials to the nuclear medicine department.

If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will make arrangements to have the package delivered to the designated receipt area by specially trained personnel who have been assigned this duty. The packages will be secured against unauthorized removal. If packages are wet or appear to be damaged, the RSO is to be immediately contacted.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials.

*Radiation Safety Officer: Paul P. Varley, M.D.

Item #13
Prepared: 2/4/81
Lic. #34-04307-02

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

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

2. Inspect the package for the presence of D.O.T. diamond-shaped radioactive White I, Yellow II, or Yellow III labels.

3. If no D.O.T. label or a White I label is present, go to step #7 below.

4. If a D.O.T. Yellow II or Yellow III radioactive label is affixed to the package, proceed to step #5 below.

5. Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR/hr, stop procedure and notify the Radiation Safety Officer.

6. Measure surface exposure rate and record. If greater than 200 mR/hr, stop procedure and notify the Radiation Safety Officer.

7. Put on gloves.

8. Open the outer package (following manufacturer's direction, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle), check integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.

9. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay and record. (To be performed on all shipments specified in Part 10, CFR 20.205(b), and any others suspected of being externally contaminated).

10. Monitor the packing material and packages for contamination before discarding and record results.

    a. If contaminated, treat as radioactive waste.

    b. If not, obliterate radiation labels before discarding in regular trash.

Item #14
Prepared: 2/4/81
Lic. #34-04307-02

LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling uncontained radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.

5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.

13. Always transport radioactive material in shielded containers.

Item #15
Prepared 2/4/81
Lic. #34-04307-02

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.

4. SURVEY: With a G-M survey meter, check the area around the spill, and your hands and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills: Activity $>$ 1mCi and $T_{\frac{1}{2}} > 20$ hrs or Activity $>$ 30mCi and $T_{\frac{1}{2}} < 20$ hrs.

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD. Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE. If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM. Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP. Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION. Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Paul P. Varley, M.D.

OFFICE PHONE: Through hospital operator

HOME PHONE: Through hospital operator

Item #16
Prepared 2/4/81
Lic. #34-04307-02

Control No. 04424

SURVEY PROCEDURES

A. All elution, preparation and injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200uCi) will be monitored monthly, via wipe test.

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1mR/hr.

2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm.

E. A permanent record will be kept of the weekly or monthly survey results, including negative results. The record will include:

1. Location, date, and type of equipment used.

2. Name of person conducting the survey.

3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

5. Detected contamination levels, keyed to locations on drawing.

6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

F. Area will be cleaned if the contamination level exceeds 200 dpm/100cm^2, except in the case of some Tc-99m spill where less radiation exposure would be received by personnel if the area is secured and contamination is allowed to decay.

Item #17
Prepared 2/4/81
Lic. #34-04307-02

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

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

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

__X__ Held for decay until radiation levels as measured with a low level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

____ Other (specify):_____

_____

_____

_____

_____

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

Check as appropriate

__X__ Returned to the manufacturer for disposal

__X__ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants).

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

____ Other (specify): _____

_____

_____

_____

_____

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Prepared 2/4/81
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3. Other Solid Waste will be:

Check as appropriate

__X__ Held for decay until radiation levels as measured with a low level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

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

____ Other (Specify): _____

_____

_____

_____

_____

4. The commercial waste disposal service used will be: _____

_____
(Name) (City, State)

NRC/Agreement State License No._____