NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83

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

Ohio Valley Medical Center
2000 Eoff Street
Wheeling, West Virginia 26003

TELEPHONE NO.: AREA CODE (304) 234 - 0123

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

Same as 1.a.

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2. PERSON TO CONTACT REGARDING THIS APPLICATION

Raymond Kaczur, Consultant, NMA Medical Physics Services, Cleveland, Ohio

TELEPHONE NO.: AREA CODE (216) 641 - 5799

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 47-17282-01

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

See Attached Item #8.

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.)*

Yong K. Park, Ph.D. with consultation from NMA Medical Physics Services, Cleveland, Ohio.

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	X	3.Ø
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	3000
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	2000

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	2000

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
U-235 (Depleted)	Cadmium plated metal	160 kg.	Shielding in linear accelerator.
Sr-90	Sealed Source	75	Treatment of superficial eye disease
Sr-90	Sealed Source	1.5mCi	Instrument Calibration Source

37514 Rec'd 4/14/87

License Fee Information on p. 3.

8801290287 870708
REG2 LIC30
47-17282-01 PDR

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: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
X	Appendix C Form Attached; or	X	Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*		Equivalent Information Attached
	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
	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		X	Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached		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
X	Appendix F Procedures Followed w/addendum	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached		Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. & Sons	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Sons	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Log ..... Agr - 2 - II
Remitter .....
Check No. 44364
Amount $560
Fee Category 7C
Type of Fee ..... Renewal
Date Check Rec'd 4/13/87
Date Cer. Mailed 4/14/87
By: ..... Maureen

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: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
x David Campbell

(1) NAME *(Type or Print)*
x David J. Campbell

(2) TITLE
x Chief Executive Officer

c. DATE
x 3-31-87

NRC FORM 313M (9-81)

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 NRC Form 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.

RADIATION SAFETY COMMITTEE

The requirements of Paragraph 35.22 of 10 CFR 35 will be followed as published on October 16, 1986.

Item #7
1 of 1 page
Prepared: 3/3/87
Lic. #47-17282-01

NAME OF AUTHORIZED USER	AUTHORIZATION
Leonidos Castro, M.D.	Groups I, II, III, IV, V, VI, In Vitro studies, Xenon-133, Depleted uranium shielding, Sr-90 eye applicator
Ronald K. Stupar, M.D.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma
Merrill F. Wymer, M.D.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thryoid carcinoma
Jeffrey M. Yost, M.D.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma
Ross O. Bell, M.D.	In Vitro studies
Curijala N. Reddy, M.D.	Group VI, Refer to preceptor for P32 Soluble
William Lee Noble, M.D.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma, Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.

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1 of 2 pages
Prepared: 3/3/87
Lic. #47-17282-01

NAME OF AUTHORIZED USER	AUTHORIZATION
Peter Caruso, M.D.	Groups I, II, III, Xenon-133
Vincent P. Almario, Jr., M.D.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma.
Bernard O. Garrett, D.O.	Groups I, II, III, Xenon-133, Iodine-131 as iodide for treatment of hyperthyroidism or cardiac dysfunction
Srini Govindan, M.D.	Groups I, II, III, Xenon-133

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Lic. #47-17282-01

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

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

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

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
GURIJALA N. REDDY, M.D.

STREET ADDRESS
2000 EOFF STREET

CITY: WHEELING, | STATE: WV | ZIP CODE: 26003

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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

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

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

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

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

PRECEPTOR STATEMENT *(Continued)*

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

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

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

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

a. NAME OF SUPERVISOR
LEONIDAS CASTRO, M.D.

b. NAME OF INSTITUTION
OHIO VALLEY MEDICAL CENTER

c. MAILING ADDRESS
2000 EOFF STREET

d. CITY
WHEELING, W.VA. 26003

5. MATERIALS LICENSE NUMBER(S)
47 - 17282 -01

6. PRECEPTOR'S SIGNATURE
Leonidas Castro

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

8. DATE
MARCH 31, 1987

FORM NRC-313M-SUPPLEMENT B
(8)

APPENDIX C
INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

      Manufacturer's model number: E-120

      Number of instruments available: one

      Minimum range: 0 mR/hr to 0.5 mR/hr

      Maximum range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 740D

      Number of instruments available: one

      Minimum range: 0 mR/hr to 25 mR/hr

      Maximum range: 0 mR/hr to 25,000 mR/hr

2. Dose Calibrator(s)

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-10

   Number of instruments available: one

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	Picker	5/15/61
Scintillation Camera	Picker	Dyna Mo
Scintillation Camera	Picker	4/15
Scintillation Camera	Picker	3C
Scintillation Camera	NOVO	SPECT Head Unit (Model Tomograph 810)

4. Other (e.g., liquid scintillation counter, area monitor, velometer)
   NOVO Cerebrograph 10a portable Xe-133 unit
   NOVO Cerebrograph 32-b unit with Victoreen "CRYO/SAFE" Xe-133 trapping system
   Gas delivery system - RadX Ventilcon 143 with 131.
   Gas delivery system - RadX Ventilcon II

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name:

      Manufacturer's model number:

      Number of instruments available:

      Minimum range: mR/hr to mR/hr

      Maximum range: mR/hr to mR/hr

   b. Manufacturer's name:

      Manufacturer's model number:

      Number of instruments available:

      Minimum range: mR/hr to mR/hr

      Maximum range: mR/hr to mR/hr

2. Dose Calibrator(s)

   Manufacturer's name: Picker

   Manufacturer's model number: ----

   Number of instruments available: one

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Well and Scaler	Picker	IIIA
Rectilinear Scaler	Picker	Magnascan 500
Uptake Probe	Picker	----

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

APPENDIX C
INSTRUMENTATION
(rCBF ROOM)

1. Survey meters

   a. Manufacturer's name: Eberline

      Manufacturer's model number: E-120

      Number of instruments available: one

      Minimum range: 0 mR/hr to 0.5 mR/hr

      Maximum range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 290

      Number of instruments available: one

      Minimum range: 0 mR/hr to 0.1 mR/hr

      Maximum range: 0 mR/hr to 1000 mR/hr

(ONCOLOGY)

2. Survey meters

   a. Manufacturer's name: Victoreen

      Manufacturer's model number: Panoramic 470-A

      Number of instruments available: one

      Minimum range: 0 mR/hr to 3 mR/hr

      Maximum range: 0 mR/hr to 1000 R/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 440-D

      Number of instruments available: one

      Minimum range: 0 mR/hr to 3 mR/hr

      Maximum range: 0 mR/hr to 300 mR/hr

CALIBRATION OF INSTRUMENTS

As regards the calibration of survey meters and dose calibrators, the dictates of paragraphs 35.50 and 35.51 of 10 CFR Part 35 as published on October 16, 1986 will be followed.

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1 of 1 page
Prepared: 3/3/87
Lic. #47-17282-01

FACILITIES AND EQUIPMENT DESCRIPTION

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

Mo-99/Tc-99m generator 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 patient's 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.

Facilities and Equipment

Diagram

7th Floor

Adjacent Areas

☒	Air Supply
⊘	Air Exhaust
___	Scanner
___	Uptake/Well
___	Camera
1	Lockable Door
___	Receipt Area
___	Generator
___	Kit Preparation
___	Isotope Storage
___	Dose Preparation
1	Waste Storage
___	Dose Calibrator
___	Refrigerator

☒	Sink
⬚	Lead Castle

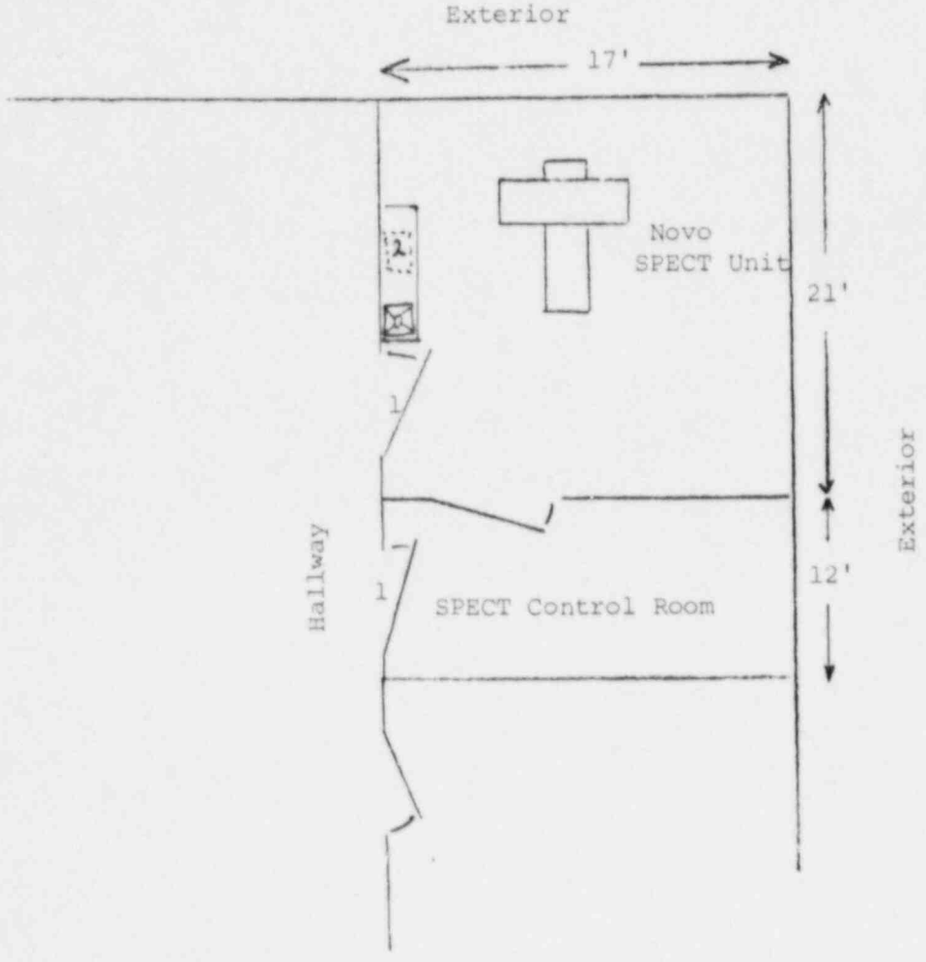
Lead Shielding

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T



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Prepared 3/3/87
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Facilities and Equipment

Diagram

☒ Air Supply
⊘ Air Exhaust
___ Scanner
___ Uptake/Well
___ Camera
1 Lockable Door
___ Receipt Area
___ Generator
___ Kit Preparation
___ Isotope Storage
___ Dose Preparation
___ Waste Storage
___ Dose Calibrator
___ Refrigerator

Adjacent Areas

___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____

⊠ Sink
⬚ Lead Castle

Lead Shielding

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

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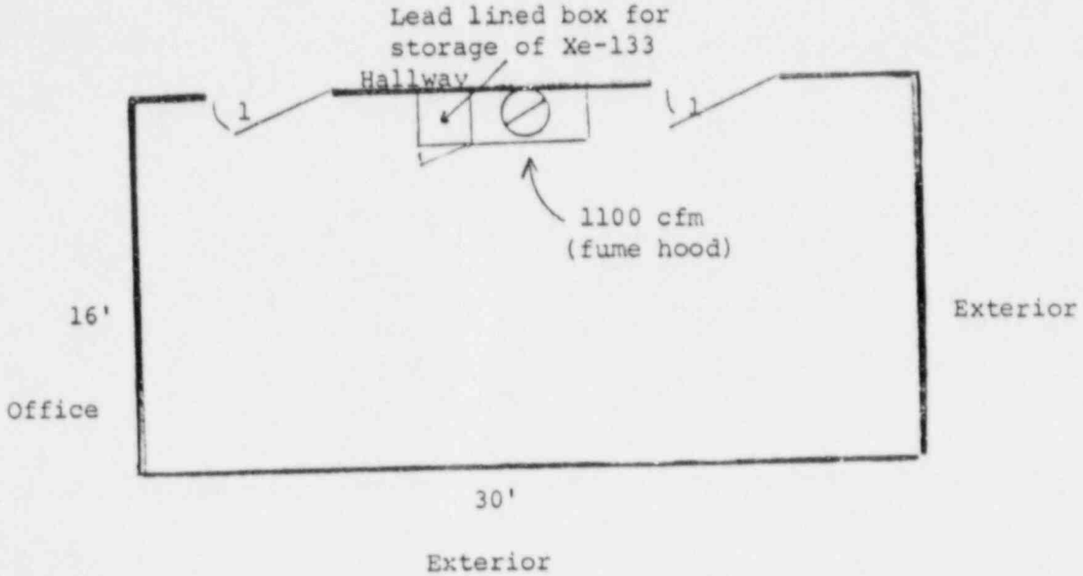
___L x ___W x ___H x ___T

6th Floor Cerebral Blood Flow Room



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Facilities and Equipment

Diagram

Air Supply

Air Exhaust

___ Scanner
___ Uptake/Well
___ Camera
___ Lockable Door
___ Receipt Area
___ Generator
___ Kit Preparation
___ Isotope Storage
___ Dose Preparation
___ Waste Storage
___ Dose Calibrator
___ Refrigerator

Adjacent Areas

___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____

Sink

Lead Castle

Lead Shielding

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

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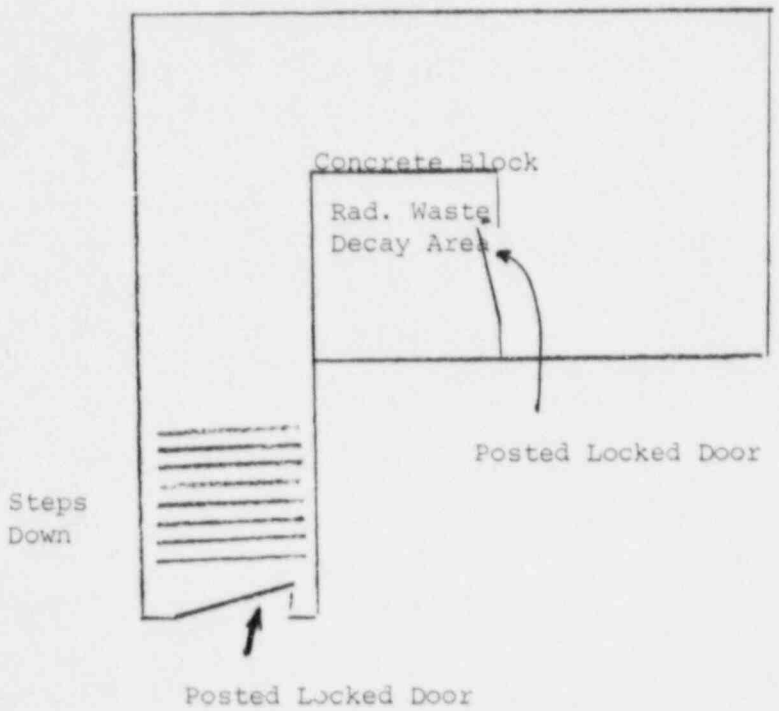
___L x ___W x ___H x ___T

Radioactive Waste Storage Area

(Located below 1st floor of old building)



Facilities and Equipment

Diagram

- Air Supply
- Air Exhaust
- 1 Scanner
- 2 Uptake/Well
- 3 Camera
- 4 Lockable Door
- ___ Receipt Area
- ___ Generator
- ___ Kit Preparation
- ___ Isotope Storage
- ___ Dose Preparation
- ___ Waste Storage
- ___ Dose Calibrator
- ___ Refrigerator

Sink

Lead Castle

Lead Shielding

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

Adjacent Areas

___ _____

___ _____

___ _____

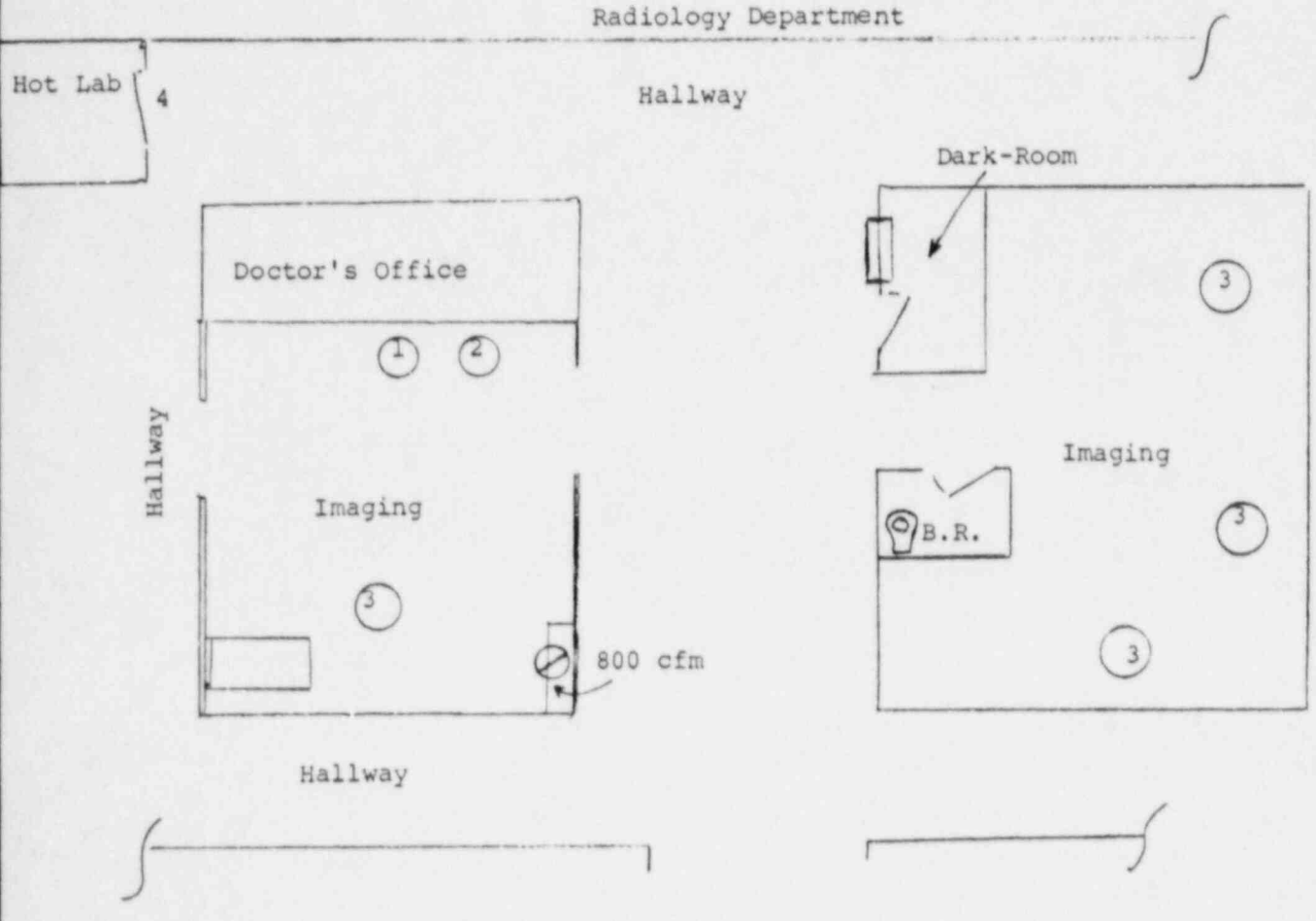
___ _____

___ _____

___ _____

___ _____

___ _____



Facilities and Equipment

Diagram

Air Supply

Air Exhaust

___ Scanner
___ Uptake/Well
___ Camera
1 Lockable Door
2 Receipt Area
___ Generator
___ Kit Preparation
3 Isotope Storage
4 Dose Preparation
3 Waste Storage
5 Dose Calibrator
6 Refrigerator

Sink

Lead Castle

Lead Shielding

3 Waste Storage Area
16" L x 8" W x 12" H x 2" T

___ L x ___ W x ___ H x ___ T

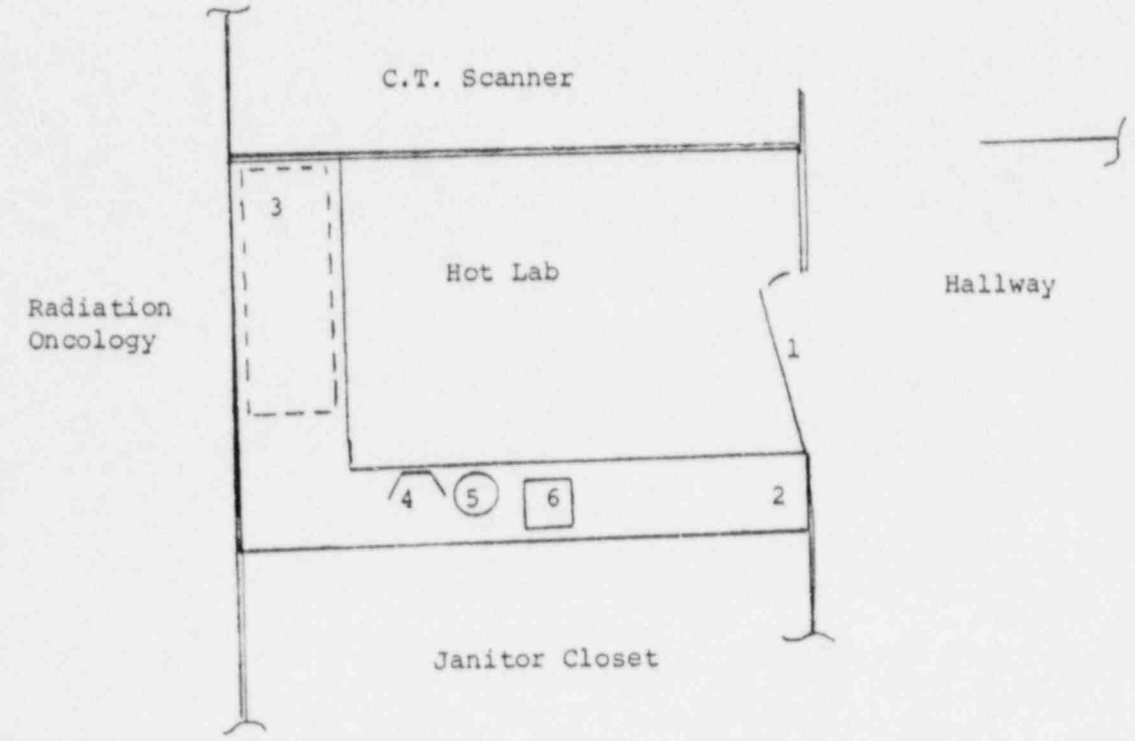
___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

Adjacent Areas

___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____

EXPANDED VIEW OF HOT LAB



*Presently utilizing unit doses from local radiopharmacy.

Facilities and Equipment Diagram

Air Supply

Air Exhaust

___ Scanner
___ Uptake/Well
1 Camera
2 Lockable Door
___ Receipt Area
___ Generator
___ Kit Preparation
___ Isotope Storage
___ Dose Preparation
___ Waste Storage
___ Dose Calibrator
___ Refrigerator

Sink

Lead Castle

Lead Shielding

___ ___L x ___W x ___H x ___T

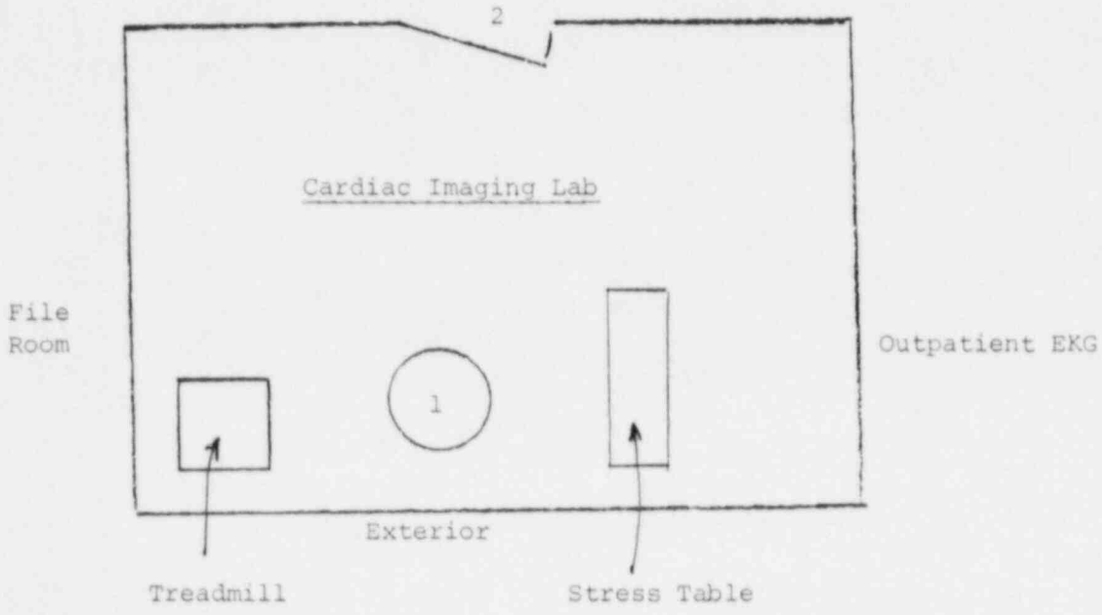
___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

___ ___L x ___W x ___H x ___T

Adjacent Areas

___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____



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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.
   j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions), as required by 10 CFR, Part 19.

   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, 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 orientation process and annually thereafter in the form of verbal instructions and/or interdepartment memos.

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PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist or 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 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 following procedures:

If couriers or common carriers attempt delivery of packages containing radioactive materials, the radiology supervisor on duty will be contacted or someone from the hospital security department. He/she will have the carrier escorted to nuclear medicine by personnel who have been assigned this duty. Alternatively, hospital personnel will deliver the package to the receipt area. Under these conditions, people transporting the packages will receive special training for this purpose. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials. The packages will be secured against unauthorized removal. When delivered packages are wet or appear to be damaged, the on call nuclear medicine technologist or nuclear medicine supervisor should be immediately notified. Depending on the severity of the damage to the radioactive package will the Radiation Safety Officer be notified.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

IMPORTANT: If at all possible, all shipments should be taken by the courier directly to the nuclear medicine hot lab.

*Radiation Safety Officer: Yong K. Park, Ph.D.

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APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours after receipt if received after working hours, in accordance with the requirements of paragraphs 20.205 (a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 1m.

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

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

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

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

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition*, packing slip, and label on bottle.

*In the case of special order (e.g., therapy doses) also compare with physician's written request.

(3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

(4) Check also that shipment does not exceed possession limits.

f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end window G-M survey meter, and take precaution against the spread of contamination as necessary.

g. Monitor the packing material and packages for contamination before discarding.

(1) If contaminated, treat as radioactive waste.

(2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package.

ADDENDUM ITEM #14

The procedure for safely opening packages containing radioactive materials as outlined in Appendix F, Licensing Guide 10.8 will be subscribed to with the following exceptions. The procedures shall not be applicable to prepackaged in vitro kits received without evidence of shipping damage except that radiation labels will be obliterated. Evaluation of final source container wipe smears will be performed with a survey meter listed in Item #9 of license application.

Pathology Department

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 the Pathologist on duty.

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 #5 below.

4. If a D.O.T. Yellow II or Yellow III radioactive label is affixed to the package, notify the nuclear medicine department. The package belongs to them.

5. 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 packaging material). Check also that shipment does not exceed possession limits.

6. Obliterate radiation labels before discarding packages or packing materials.

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APPENDIX G

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL IN THE NUCLEAR MEDICINE DEPARTMENT

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 radioactive materials.

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

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. 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 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

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 and properly shielded 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.

APPENDIX H
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. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

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

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

Major Spills

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

ALTERNATIVE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

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SURVEY PROCEDURES

A. All routine elution, preparation and designated injection areas will be surveyed at the end of each day of use with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) 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 0.1 mR/hr.

2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2000 dpm.

E. A permanent record will be kept of the daily, weekly or monthly survey results, including negative results. Survey records will be maintained for at least two years. The record will include:

1. Location, date, and equipment used.

2. Initials 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 2000 dpm/100cm2, 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.

ALTERNATE SURVEY PROCEDURE
IN THE EVENT OF WELL COUNTER MALFUNCTION

A. Routine elution, preparation and designated injection areas will be surveyed at the end of each day of use with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

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 0.1 mR/hr.

2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a low level G-M survey meter.

The procedure will be as follows:

a. Perform wipe tests.
b. Place smear(s) in a "baggy" or disposable glove.
c. Adjust response time to the longest time constant, if applicable.
d. Select most sensitive range.
e. Turn beta shield on probe to open position.
f. Wait until reading stabilizes.
g. Read and record background.
h. Place smear in contact with open position of probe.
i. Wait until the reading stabilizes.
j. Read and record wipe results.

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

E. A record will be kept of the daily, weekly or monthly survey results, including negative results. Survey records will be maintained for at least two years. The record will include:

1. Location, date and equipment used.

2. Initials 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.

PATHOLOGY DEPARTMENT

SURVEY PROCEDURES

A. The laboratory where small quantities of radioactive materials are used (less than 200 uCi) will be surveyed monthly via wipe test.

B. The monthly survey will consist of a:

Series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2000 dpm.

C. An area will be cleaned if the contamination level exceeds 2000 dpm/100cm2.

D. A record will be kept of the survey results, including negative results. The record will include:

1. Location, date, and equipment used.

2. Initials of the person conducting the survey.

3. Drawing of area surveyed, identifying relevant features such as countertops, refrigerator pulls, sink bowl, etc.

4. Detected contamination levels in dpm units keyed to locations on drawing.

5. Corrective action taken in the case of found contamination, reduced contamination levels after corrective action, and any appropriate comments.

SURVEY PROCEDURES FOR CBF ROOM (6TH FLOOR)

A. The CBF laboratory area will be surveyed weekly.

B. The weekly survey will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

C. A record will be kept of the weekly survey results, including negative results. The record will include.

1. Location, date, and equipment used.

2. Initials 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.

Records of the surveys will be maintained for at least two years.

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APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of:

X A. In the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.

X B. Held for decay until radiation levels, as measured in a low background area 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 generators will be disposed of as normal trash.

X C. Other (specify): Return to radiopharmacy.

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

X A. Returned to manufacturer for disposal.

X B. Held for decay until radiation levels, as measured in a low background area 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 generators will be disposed of as normal trash.

___ C. Disposed of by commercial waste disposal service.

___ D. Other (specify): Return to radiopharmacy.

3. Other solid waste will be:

X A. Held for decay until radiation levels, as measured in a low background area 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.

___ B. Disposed of by commercial waste disposal service.

X C. Other (specify): Return to radiopharmacy.

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APPENDIX K

RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with paragraphs 20.203 or 20.204 of 10 CFR Part.20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on 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.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. 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.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

10. 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.

11. Nursing Instructions:

    a. 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 on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Officer.

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

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

e. 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.

f. Attending personnel should 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 should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. 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 Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed 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 Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with I-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext._____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. 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). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

l. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No: _____ Physician's Name: _____

Radioisotope 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 checked items)

_____1. Visiting time permitted. _____
_____2. Visitors must remain _____ from patient.
_____3. Patient may not leave room.
_____4. Visitors under 18 are not permitted.
_____5. Pregnant visitors are not permitted.
_____6. Film or TLD badges must be worn.
_____7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
_____8. Tag the following objects and fill out the tag:

_____door _____bed _____chart _____wrist

_____9. Disposable gloves must be worn while attending patient.
_____10. Patient must use disposable utensils.
_____11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
_____12. Smoking is not permitted.
_____13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
_____14. Other instructions.

In case of an emergency contact:

RSO _____
Name On-duty/Off-duty Telephone numbers

ADDENDUM ITEM #19

The procedures and precautions for radiopharmaceutical therapy as described in Appendix K of Regulatory Guide 10.8 will be implemented for compliance with 35.75, with the following exceptions:

For I-131 Therapy

1. The urine will not normally be collected when patients are treated with I-131.

2. Appendix K procedures may be terminated when patient activity becomes less than 30 mCi or the exposure rate at one meter becomes less than 5 mrem/hr.

3. Liquid sources will be opened in a vented hood if available. Gloves, tongs, and lead shielding will be utilized by personnel handling I-131 sources.

ITEM #20

THERAPEUTIC USE OF SEALED SOURCES

Special procedures for patients treated with byproduct material listed in Subpart G, Section 35.400 of 10 CFR Part 35 are as follows:

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

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 personnel monitoring devices. 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 container or an equivalent lead container which is at least 1" thick.

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 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., 2 mrems in any one hour or 100 mrems in any seven consecutive days).

h. Patients treated with sealed sources will be assigned to a private room.

i. For I-125 seeds, the Radiation Safety Program to be implemented will be that as outlined in the attached Guidelines listed as page 10 of this item.

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 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 numbers

ITEM #20, 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

ITEM #20, FORM C

RADIATION THERAPY SOURCE USAGE RECORD

Patient _____ ID# _____ 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 nurse?	( )	( )
Safety procedures placed in patient's chart?	( )	( )
Caution sign placed on patient's chart?	( )	( )
Caution signs placed on patient's 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 patient's chart prior to removal of all posted signs?	( )	( )
All signs removed?	( )	( )
Room surveyed and background radiation levels present?	( )	( )

Date/Time of Removal _____ a.m./p.m. _____
Applicator _____ Sources _____

COMMENTS:

CERTIFIED BY: _____ Date _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

ITEM #20, 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 with body _____

_____

_____

_____

Indicate Distances _____

Suggest ring badges if exposure

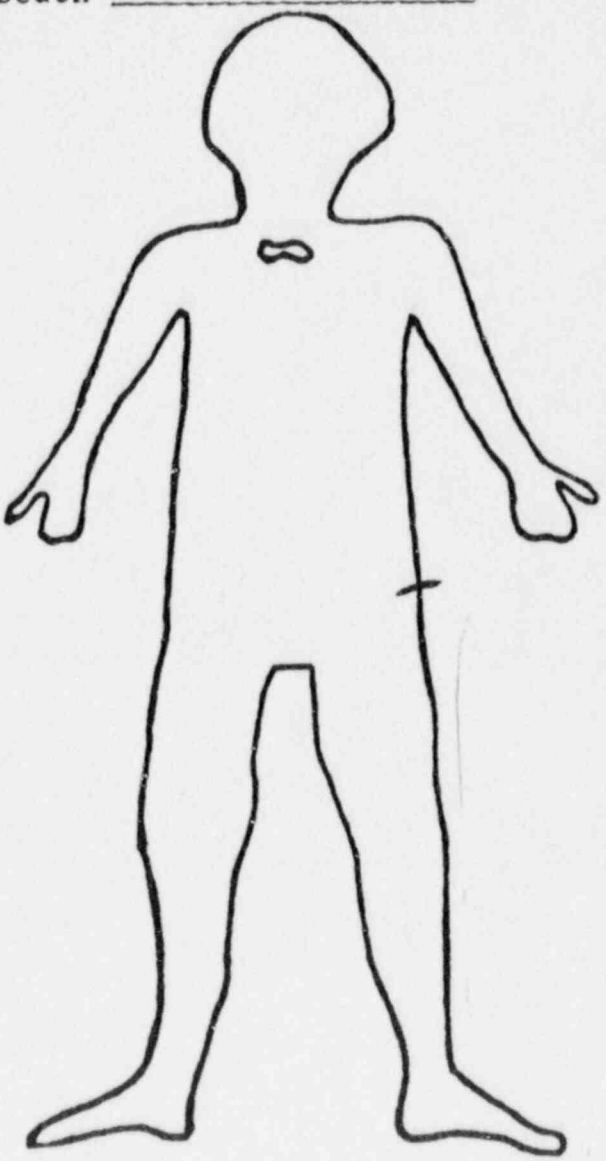
0.25 R/hr @ 25 cm

See NCRP #37 p. 27

Limit hand exposure to 1.5 Rems.

Date of Survey _____

Instrument Used _____



Signed: _____
Radiation Safety Officer

Date: _____

ITEM #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, Form B)
b. Sources will be dispensed with suitable protective devices and techniques, to include long forceps and 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

1. Special restrictions may be noted on the precaution sheet in the patient's 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 or TLD badge should be obtained immediately from the Nuclear Medicine Department. The 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 # _____ _____
    (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.

ITEM #20

GUIDELINES

RADIATION SAFETY PRECAUTIONS FOR THERAPEUTIC USE OF I-125 SEEDS

GENERAL

1. Personnel who prepare, insert or retrieve I-125 seeds must wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.

2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.

3. In transporting seeds from storage - preparation areas to the place of use, adequate shielding must be employed to insure compliance with 10 CFR 20.105(b).

INSTRUCTIONS TO NURSES (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.

2. Handle dislodged seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.

3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer.

4. All bed linen must be checked with a radiation survey meter before being removed from the patient's room to insure that no dislodged sources are inadvertently removed.

5. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instrumetns, or utensils unless specifically ordered.

6. Emergency Procedures

a) If a seed becomes loose or dislodged from the patient, or

b) If the patient dies, or

c) If the patient requires emergency surgery, immediately

call _____

Telephone # _____ _____
(Days) (Nights)

7. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

ITEM #20

THERAPEUTIC USE OF SEALED SOURCES

A. The Sr-90 opthalmic applicator and the Sr-90 calibration source are kept in a small locked room located in the Radiation Oncology Department. The cabinet is kept locked except when in attendance and the keys are held by the Radiation Physicists. The maximum exposure at the surface of the cabinet is 0.28 mR/hr. The twelve Cs-137 sealed sources are kept in a Nuclear Associates lead safe, Model No. 67-742 which has 3" of lead in its walls. The safe is locked with a combination lock except when the sources are attended. The 14 Cs-137 sealed tube sources are kept in a Radium Chemical lead safe (Model No. 470-3-H) which has 3" lead walls. The safe is located in the Radium/Cesium storeroom, about 4 1/2 x 6 1/2; which is kept locked at all times except when someone is present. The only keys to this room are held by the Chief Radiation Oncology Technologist and the Security Department. Also kept in this room is a locked radium safe containing 290 mg. of Ra-226. The lead safe provides at least 2 1/2" of lead shielding. In addition, a wall of interlocking lead bricks have been placed around the back and sides of the safe. Also present is a 2" thick lead L-shield (Radium Chemical Model 462). Any Group VI radionuclides such as Ir-192 seeds, would also be kept in this room in their shipping containers.

B. Radiation exposure to personnel will be reduced by use of equipment and techniques that make most efficient use of time, distance and shielding. After loading techniques will be used with all Ir-192 and Cs-137 procedures. All sources will be manipulated with long-handled forceps or tongs, utilizing the L-shield or other shielding when practicable. No one will touch the sources with their hands.

C. Any person who must work with the sealed sources will wear a ring-type radiation monitoring badge, in addition to his whole-body badge.

D. Sources from the radium or cesium safe will be transported in either a cylindrical source carrier having lead walls 1" thick (Radium Chemical Model 442C) or a boxlike carrier having walls 7/8" thick (Radium Chemical Model 479) placed on a 3-wheeled cart. Other sealed sources will be transported in their shipping container placed on a laboratory cart. If a patient must be taken from his room, a hospital attendant will accompany him. Except for the attendant, no one else will accompany the patient.

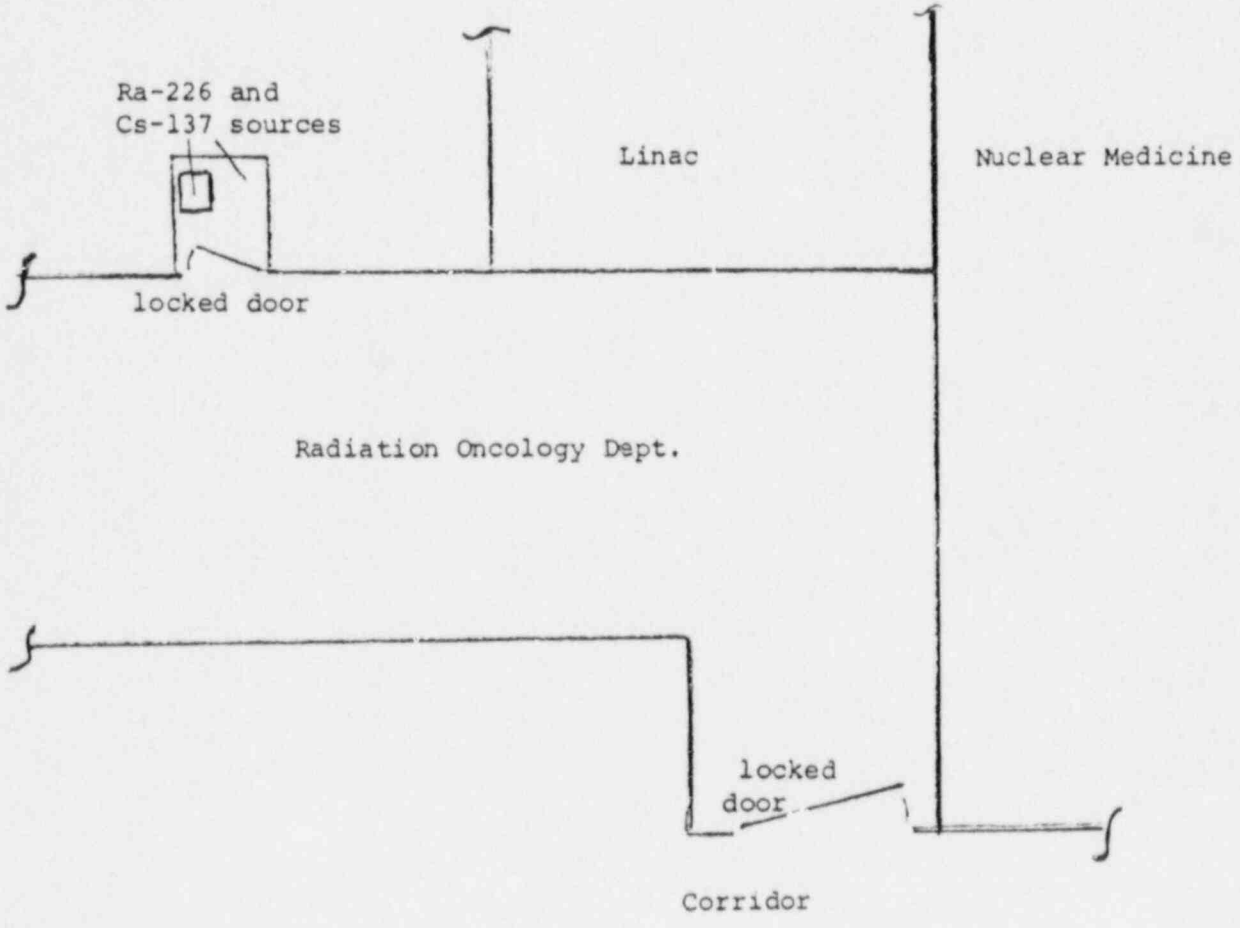
E. A log book will be kept to show source accountability. Whenever a person removes sources from the Radium/Cesium storeroom he will indicate in the log book the date, the number and strengths of the sources, the type of applicator if any, the name of the patient for whom they are intended, the physician to use them, and the person removing them. When a person returns sources to the Radium/Cesium storeroom, he will indicate on the log book his name, the date, and for temporary implants, the fact that all the sources were returned to the storeroom. In addition, an inventory will be taken at least quarterly.

F. When sealed sources have been inserted or implanted in a patient, a radiation survey will be performed at the time of insertion or as soon as practicable thereafter. The survey will encompass the patient's room and the areas adjacent to it. Steps will be taken at that time to ensure that radiation levels in unrestricted areas are in accordance with 10 CFR 20.105. A suitable survey meter will be used for the survey. The surveyor will check for proper posting and check that the nursing staff has the appropriate nursing instruction precautions. Results of the survey and visitation limitations will be posted on the patient's chart. When the sealed sources are removed from the patient, a source count will be made to verify that all temporary sources were removed. Also a survey will be taken using an appropriate survey meter to verify that none of the temporary implant sources remain in the patient or his room. The results of the survey will be recorded.

ITEM #20

Brachytherapy Source Location

Radiation Oncology



Item #20
Prepared: 3/3/87

License #47-17282-01

rCBF PROCEDURES & PRECAUTIONS FOR USE OF RADIOACTIVE GASES
OUTSIDE THE CEREBRAL VASCULAR LABORATORIES

I. Quantities to be Used:

A. Patient information

1. It is expected an average of 10 studies per week will be performed.
2. The average patient dose will be approximately 20 mCi.

II. Use and Storage Areas:

A. Xenon-133 in Saline solution only will be used in areas other than the Cerebral Vascular Laboratories or the rCBF room (6th floor). The other areas are as follows:

ROOM AIR FLOW AND ROOM DIMENSIONS FOR PORTABLE rCBF STUDIES

Area	Air Flow		Room Dimensions		
	In	Out	H	W	D
Emergency Room Trauma Room	650	459	9'5" x 16' x 13'		
Cardiac Care Unit Treatment Room	285	255	8' x 15'6" x 14'2"		
Patient Room	285	255	8' x 12'1" x 14'7"		
Intensive Care Unit Treatment Room	110	100	8' x 20'7" x 12'8"		
Patient Room	110	100	8' x 12' x 13'10"		
Operating Room Suite 1	1900	500	9'6" x 20' x 20'		
Suite 2	1900	500	9'6" x 22' x 23'		
Recovery Room Isolation Room	110	110	8' x 10' x 9'6"		

Areas of use outside the CBF Laboratory will be evaluated semi-annually to insure no considerable ventilation changes have occurred.

Item #21
Page 1 of 7
Prepared: 3/3/87
Lic. #47-17282-01

III. Procedures for Routine Use:

A. Xe-133 in Saline solution only will be used in conjunction with the NOVO Cerebrograph 10a portable unit or NOVO Cerebrograph 32b in those areas previously described. Xe-133 in saline solution will be used only as an active "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA or active "New Drug Application" (NDA) approved by FDA.

B. If possible, the door will be closed to minimize the purging of any accidental release of Xenon in the hallway. This will allow as much Xenon as possible to be removed via the exhaust system. The NOVO Cerebrograph 10a contains a small charcoal trap for retention of exhaled Xe-133. The patient will be fitted with the rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient condition permits.

The Xenon in saline solution will be administered (I.V.) and data collected. The Xenon will be collected in the gas trap until practically no Xenon remains in the patient as indicated by cerebrograph data. Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon.

C. Brochure information is attached regarding the NOVO Cerebrograph 10a unit.

D. Approximately every 20 patients, the discharge air from the charcoal gas trap will be monitored with a G-M survey meter held against the tubing to detect Xenon "pass through". When discharge air readings reach 1/10 of air intake maximum readings, it will be assumed the charcoal trap efficiency has fallen to less than 90%. At that time, the cartridge will be exchanged.

Saturated filters will be stored for decay such that levels do not exceed 2.0 mR/hr. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded or reused.

Saturated filters will also be stored in sealed plastic.

III. Procedures for Routine Use:

A. Xe-133 in Saline solution only will be used in conjunction with the NOVO Cerebrograph 10a portable unit in those areas previously described. Xe-133 in saline solution will be used only as an active "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA or active "New Drug Application" (NDA) approved by FDA.

B. If possible, the door will be closed to minimize the purging of any accidental release of Xenon in the hallway. This will allow as much Xenon as possible to be removed via the exhaust system. The NOVO Cerebrograph 10a contains a small charcoal trap for retention of exhaled Xe-133. The patient will be fitted with the rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient condition permits.

The Xenon in saline solution will be administered (I.V.) and data collected. The Xenon will be collected in the gas trap until practically no Xenon remains in the patient as indicated by cerebrograph data. Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon.

C. Brochure information is attached regarding the NOVO Cerebrograph 10a unit.

D. Approximately every 20 patients, the discharge air from the charcoal gas trap will be monitored with a G-M survey meter held against the tubing to detect Xenon "pass through". When discharge air readings reach 1/10 of air intake maximum readings, it will be assumed the charcoal trap efficiency has fallen to less than 90%. At that time, the cartridge will be exchanged.

Saturated filters will be stored for decay such that levels do not exceed 2.0 mR/hr. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded or reused.

Saturated filters will also be stored in sealed plastic.

IV. Air Concentration of Xe-133.

A. Due to the type of test being performed (i.e., CBF using injectable Xe-133 in Saline solution) and the type of collection apparatus, the chance of a total patient associated loss is highly remote. Therefore, any patient associated losses are considered to be included in the 15% Xenon loss used to calculate Average Concentration.

In the event of an accidental Xenon spill, all unnecessary personnel will evacuate the room. The room door will be guarded against inadvertent entry.

A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered.

B. It is estimated that up to 200 mCi of Xenon will be used per week in unrestricted areas. The following calculations assume a "worst case" average concentration of each of the eight rooms involved. Since the exhausts vary in the rooms identified on Page 1, the calculations include a limit for the number of procedures that may be performed in each area.

C. For the Emergency Room/Trauma Room, no more than 10 studies will be performed per week. This would equate to a maximum of 200 mCi being used (A). Of this amount, it is assumed that 15% will be lost due to trap leakage and any patient associated loss (f). Therefore, 15% or 30 mCi could be vented to room air per week.

A minimum room exhaust rate of 459 cfm will be used in this calculation:

$$V = 459 \text{ cfm} \times 1.699 \times 10^{6} \text{ ml/hr} \times 163 \text{ hr/wk}$$

$$V = 459 \times 2.85 \times 10^{8}$$

$$V = 1.31 \times 10^{11} \text{ ml/wk}$$

The average concentration (C) will be:

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

$$C = \frac{200\ mCi/wk \times 1 \times 10^{3}\ uCi/mCi \times .15}{1.31 \times 10^{11}\ ml/wk}$$

$$C = 2.29 \times 10^{-7}\ uCi/ml$$

This value is less than required for restricted and unrestricted areas (3.0×10^{-7} uCi/ml).

D. For the Cardiac Care Unit/Treatment Room and Patient Room, no more than 6 studies will be performed per week per room. This would equate to 120 mCi being used (A). Of this amount, it is assumend that 15% will be lost due to trap leakage and any patient associated loss (f). Therefore, 15% or 18 mCi will be vented to room air per week.

A minimum room exhaust rate of 255 cfm will be used in this calculation:

$$V = 255\ cfm \times 1.699 \times 10^{6}\ ml/hr \times 168\ hr/wk$$

$$V = 255 \times 2.85 \times 10^{8}$$

$$V = 7.28 \times 10^{10}\ ml/wk$$

The average concentration (C) will be:

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

$$C = \frac{120\ mCi/wk \times 1 \times 10^{3}\ uCi/mCi \times .15}{7.28 \times 10^{10}\ ml/wk}$$

$$C = 2.47 \times 10^{-7}\ uCi/ml$$

This value is less than required for restricted and unrestricted areas (3.0×10^{-7} uCi/ml).

E. For the Intensive Care Unit/Treatment Room and Patient Room, no more than 2 studies will be performed per week per room. This would equate to a maximum of 40 mCi being used per room (A). Of this amount, it is assumed that 15% will be lost due to trap leakage and any patient associated loss (f). Therefore, 15% or 6 mCi could be vented to room air per week.

A minimum room exhaust rate of 100 cfm will be used in this calculation:

$$V = 100 \text{ cfm} \times 1.699 \times 10^{6} \text{ ml/hr} \times 168 \text{ hr/wk}$$

$$V = 100 \times 2.85 \times 10^{8}$$

$$V = 2.85 \times 10^{10} \text{ ml/wk}$$

The average concentration (C) will be:

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

$$C = \frac{40 \text{ mCi/wk} \times 1 \times 10^{3} \text{ uCi/mCi} \times .15}{2.85 \times 10^{10} \text{ ml/wk}}$$

$$C = 2.10 \times 10^{-7} \text{ uCi/ml}$$

This value is less than required for restricted and unrestricted areas (3.0×10^{-7} uCi/ml).

F. For the Operating Room/Suites 1 & 2, no more than 10 studies will be performed per week per room. This would equate to a maximum of 200 mCi being used per room (A). Of this amount, it is assumed that 15% will be lost due to trap leakage and any patient associated loss (f). Therefore, 15% or 30 mCi could be vented to room air per week.

A minimum room exhaust rate of 500 cfm will be used in this calculation:

$$V = 500 \text{ cfm} \times 1.699 \times 10^{6} \text{ ml/hr} \times 168 \text{ hr/wk}$$

$$V = 500 \times 2.85 \times 10^{8}$$

$$V = 1.42 \times 10^{11} \text{ ml/wk}$$

The average concentration (C) will be:

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

$$C = \frac{200 \text{ mCi/wk} \times 1 \times 10^{3} \text{ uCi/mCi} \times .15}{1.42 \times 10^{11} \text{ ml/wk}}$$

$$C = 2.10 \times 10^{-7} \text{ uCi/ml}$$

This value is less than required for restricted and unrestricted areas (3.0×10^{-7} uCi/ml).

G. For the Recovery Room/Isolation Room, no more than 3 studies will be performed per week per room. This would equate to a maximum of 60 mCi being used per room (A). Of this amount, it is assumed that 15% will be lost due to trap leakage and any patient associated loss (f). Therefore, 15% or 9 mCi could be vented to room air per week.

A minimum room exhaust rate of 110 cfm will be used in this calculation:

$$V = 110 \text{ cfm} \times 1.699 \times 10^{6} \text{ ml/hr} \times 168 \text{ hr/wk}$$

$$V = 110 \times 2.85 \times 10^{8}$$

$$V = 3.13 \times 10^{10} \text{ ml/wk}$$

The average concentration (C) will be:

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

$$C = \frac{60 \text{ mCi/wk} \times 1 \times 10^{3} \text{ uCi/mCi} \times .15}{3.13 \times 10^{10} \text{ ml/wk}}$$

$$C = 2.87 \times 10^{-7} \text{ uCi/ml}$$

This value is less than required for restricted and unrestricted areas (3.0×10^{-7} uCi/ml).

rCBF PROCEDURES & PRECAUTIONS FOR USE OF RADIOACTIVE GASES
WITHIN THE CEREBRAL VASCULAR LABORATORY
(Refer to Item #11, page 3)
(6th Floor Laboratory)

I. Quantities to be Used:

A. Patient information

1. An average of 15 exams per week may be performed.
2. The average patient activity per exam is 20 mCi.

II. Use and Storage Areas:

A. Xenon-133 will be stored in the lead lined box or fumenood located in the rCBF lab. It will be stored in its original shipping container until used. Accessory lead shielding will be used (i.e., 1/8" - 1/4" lead vials or sheet) whenever survey measurements at the face of the hood are 2.0 mR/hr or more.

B. The exhaust system for the rCBF room is handled by a fumehood. The total exhaust capacity of the system is 1100 cfm. The exhaust system runs continuously ensuring negative pressure in these areas at all times. The system is dedicated with no air recirculation with hospital air.

III. Procedures for Routine Use:

A. While doing a Xenon study, the exhaust system will be on.

The patient will be fitted with the rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient condition permits.

The Xenon will be administered and the appropriate data will be acquired. During the washout phase, the Xenon will be collected in the gas trap until practically no Xenon remains in the patient as evidenced by instrument readings.

Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon. Visitors will be excluded from the camera room during Xenon use unless their presence is required for patient care or desired for educational or observational purposes.

B. Patient studies will be performed using a Novo Cerebrograph 32b. The Novo Cerebrograph 32b is a complete regional cerebral blood flow system. It is a Xenon-133 gas delivery and retention system, a 32 detector helmet assembly and PDP-11 minicomputer for collecting, processing and presentation of the data. The equipment houses a 6 liter reservoir of air containing 3-10 mCi/liter of radioactive Xenon. Concentration of this gas is monitored by a G-M detector. The patient will breathe the Xenon-air mixture for one minute, then the system automatically switches to normal air and the clearance of Xenon-133 is monitored by a set of external, collimated head detectors. The expired gas will be collected with a Nuclear Associates/Victoreen "Cyro/Safe" Xenon-133 trapping system. Manufacturer's instructions will be followed for monitoring the cyro/safe's charcoal filter efficiency.

When the charcoal trap becomes saturated, it will be replaced. The used trap will be stored for decay, sealed in plastic. If necessary, additional lead shielding will be used to reduce exposure levels to 2 mR/hr or less at the exterior surface of the storage barrier. Charcoal trapping efficiency will be evaluated every twenty procedures in which it was utilized.

C. On a semi-annual basis, the exhaust flow rates from the rCBF lab will be checked to assure that a change in exhaust rate has not occurred and a check of the air supply will be made to assure negative pressure in the rooms.

IV. Emergency Procedures:

In the event there is an accidental patient associated loss of Xenon into the room, the exhaust will clear the room to levels of 1×10^{-5} uCi/ml in 15 minutes.

A. Activity per loss (A) = 20 mCi = 2×10^{4} uCi

Room Volume (V) = 30' x 16' x 8'

= 3840 ft^3

= 1.11×10^{8} ml

Clearance rate (λ) = $\frac{1100 \text{ cfm}}{3840 \text{ ft}^3}$

= .28 $min.^{-1}$

Initial Concentration (C_o) = $\frac{2 \times 10^4 \text{ uCi}}{1.11 \times 10^8 \text{ ml}}$

= 1.80×10^{-4} uCi/ml

Evacuation time (t) = 15 minutes

Final Concentration C = $C_o e^{-\lambda t}$

= $1.8 \times 10^{-4} e^{-.28 \times 15}$

= 2.09×10^{-6} uCi/ml

This value is less than 1×10^{-5} uCi/ml

All unnecessary personnel will evacuate the room. The room door will be guarded against inadvertent entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When no significant reduction in exposure level is noted, the room may be re-entered.

V. Air Concentration of Xe-133 in Restricted Areas:

A. rCBF Room

1. It is estimated that 300 mCi will be used per week (A).

2. 10% of the Xenon will be lost into the CBF room due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon (f).

3. A minimum room exhaust rate of 1100 cfm will be used in this calculation.

V = 1100 cfm x 2.83×10^4 ml/m/cfm x 15 studies/wk x 30 min/study

V = 1100 x 2.83×10^4 ml/m/cfm x 10 x 30

V = 9.34×10^9

4. The average concentration (C) will be:

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

$$= \frac{300 \text{ mCi} \times 1 \times 10^3 \text{ uCi/mCi} \times .10}{9.34 \times 10^9 \text{ ml/wk}}$$

$$= 3.2 \times 10^{-6} \text{ uCi/ml}$$

This value is less than required for restricted areas (1×10^{-5} uCi/ml).

VI. Methods of Xenon-133 Disposal:

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

All escaped Xenon will be vented through the exhaust system.

B. It is estimated that up to 15,600 mCi of Xenon will be used per year in the rCBF laboratory.

C. Of this amount, it is assumed 10%, or 1560 mCi, will be lost due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon-133.

D. It is estimated that up to 62,400 mCi per year will be stored in the fumehood located in the rCBF laboratory.

E. Of this amount, it is assumed 5%, or 3120 mCi, will be lost due to leakage.

F. Therefore, a total of 4680 mCi will be vented to the atmosphere per year (A).

G. The total system exhaust of 1100 cfm will be used in this calculation:

Air flow per year is (V)

$V = 1100 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$

$V = 1.63 \times 10^{13} \text{ ml/yr}$

H. The average concentration of Xenon to the environment is (C)

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

$$= \frac{4.680 \text{ Ci} \times 1 \times 10^{6} \text{ uCi/Ci}}{1.63 \times 10^{13} \text{ ml/yr}}$$

$$= 2.87 \times 10^{-7} \text{ uCi/ml/yr}$$

This value does not exceed the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

ITEM #21
NUCLEAR MEDICINE DEPARTMENT
(Refer to Item #11, page 5)

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

I. Quantities:

a. An average of 15 exams per week may be done.
b. Average activity per exam is 20 mCi.
c. Possession limit of 2000 mCi is requested.

II. Use and Storage:

a. Xenon-133 will be stored in the fume hood located in the camera room. It 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 sheet) whenever survey measurements at the face of the hood are 2.0 mR/hr or more.

b. The fume hood where Xenon is stored is under negative pressure while the fan is in operation. The exhaust rate is at 800 cfm. Air is supplied to the camera room at a rate of 650 cfm. Therefore, the fume hood and entire camera room are under negative pressure. The hood will be on at all times that Xe-133 is in storage or use.

The exhaust fans, located on the roof, discharge air which is at least 30 feet from any other air intake louvers.

III. Procedure for Routine Use:

a. The camera room door will be opened to a six inch gap at the door jamb if patient's condition permits.

The patient will be fitted with rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient's condition permits.

During the washout phase, the Xenon will be collected in the gas trap until practically no Xenon remains in the patient as evidenced by the camera persistence scope.

Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon. Visitors will be excluded from the camera room during Xenon use unless their presence is required for patient care or desired for educational or observational purposes.

b. An activated charcoal gas trap will be used for patient studies. A RadX Ventil-Con delivery system with gas trap or equivalent is used. This sytem will be used in accordance with manufacturer's instructions.

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

c. On a semi-annual basis, the exhaust flow rates from the camera room will be checked to assure that a change in exhaust rate has not occurred and a check of the air supply will be made to assure negative pressure in the rooms.

IV. Emergency Procedures:

In the event there is an accidental patient associated loss of Xenon into the camera room, the exhaust system will clear the room to levels less than 1×10^{-5} uCi/ml in less than 20 minutes.

Activity per loss (A) = 20 mCi = 2×10^4 uCi

Room Volume (V) = 23' x 17' x 8'

= 3128 ft^3

= 8.7×10^7 ml

Clearance Rate (λ) = $\frac{800 \text{ cfm}}{3128 \text{ ft}^3}$

= 25 min^{-1}

Initial Concentration (C_o) = $\frac{2 \times 10^4 \text{ uCi}}{8.7 \times 10^7 \text{ ml}}$

= 3.2×10^{-4} uCi/ml

Evacuation Time (t) = 20 minutes

Final Concentration C = $C_o e^{-\lambda t}$

= $(2.3 \times 10^{-4})\ e^{-.25 \times 20}$

= 1.5×10^{-6} uCi/ml

This value is less than 1×10^{-5} uCi/ml.

All unnecessary personnel will evacuate the room. The camera room door will be guarded against inadvertent entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When no significant reduction in exposure level is noted, the room may be re-entered. Alternatively, the camera may be turned on periodically to collect counts for a present time. When no significant reduction in count rate is noted, the room may be re-entered.

V. Air Concentration of Xe-133 in Restricted Areas:

a. Camera Room

1. It is estimated that 300 mCi will be used per week (A).

2. 15% of the Xenon will be lost into the camera room due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon (f).

3. The room exhaust rate of 800 cfm will be used in this calculation.

$V = 800 \text{ cfm} \times 2.83 \times 10^4 \text{ml/m/cfm} \times 15 \text{ studies/wk} \times 20 \text{ min/study}$

$V = 800 \times 2.83 \times 10^4 \text{ml/m/cfm} \times 15 \times 20$

$V = 6.7 \times 10^9 \text{ ml/wk}$

4. The average concentration (C) will be:

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

$$= \frac{300 \text{ mCi} \times 1 \times 10^3 \text{uCi/mCi} \times .15}{6.7 \times 10^9 \text{ml/wk}}$$

$$= 6.7 \times 10^{-6} \text{ uCi/ml}$$

This value is less than required for restricted areas (1×10^{-5} uCi/ml).

VI. Methods of Xenon-133 Disposal:

a. 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 source containing device. If levels are the same as background, the containers will be disposed after defacing the labels.

All escaped Xenon will be vented through the exhaust system on the roof top to the atmosphere.

1. It is anticipated that 3.1 Curies of Xenon will be vented to the atmosphere per year. This includes activity liberated as accidental losses and leakage.

2. An air flow rate of 800 cfm will be used in the calculation.

3. Air flow per year* is: (V)

$V = 800 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$

$V = 1.18 \times 10^{13} \text{ ml/yr}$

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

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

$$= \frac{3.1 \text{ Ci} \times 10^{6} \text{ uCi/Ci}}{1.33 \times 10^{13} \text{ ml}}$$

$$= 2.33 \times 10^{-7} \text{ uCi/ml}$$

This value does not exceed the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

b. The discharge air from the gas trap will be monitored with the G-M survey meter held against the tubing to detect Xenon "passthrough". This will be done after approximately 20 patient exams. When discharge air readings reach 1/10 of air intake maximum readings during the equilibrium phase of the study, it will be assumed the charcoal trap efficiency has fallen to less than 90%. At that time, the cartridge will be exchanged.

Saturated filters will be stored for decay in the cabinet such that levels do not exceed 2.0 mR/hr at the exterior. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded or re-used.

*Calculations are extrapolated to show a yearly average as allowed per CFR 20.106(a).

Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

Ohio Valley Medical Center
(Licensee's Name)

3/3/87
(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 describe an administrative organization for radiation safety and will 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).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended 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.

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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 applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant 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 applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated 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 dose will be ALARA (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 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 in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

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

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

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).[3]

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

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. 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, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

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[3]The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection", serve as check points above which the results are considered sufficiently important to justify further investigation.

c. Cooperative Efforts for Development of ALARA Procedures

1. The RSO will be in 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 receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

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

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures 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 explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he surpervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

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

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practive) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

TABLE 1

		Investigational levels - (mrems per calendar quarter)	
		LEVEL I	LEVEL II
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.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.