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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB
3150-0041

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Mercy Hospital
2200 Jefferson Ave.
Toledo, Ohio 43624

TELEPHONE NO.: AREA CODE (419) 259 1500

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

SAME

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mary K. Raglow, RT(R&NM), CNMT
Section Leader, Nuclear Medicine

TELEPHONE NO.: AREA CODE (419) 259 1372

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 34-00305-03

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

M.B.Gordon, C.S.Shon, J.F.Brunner, D.T.Bolovan, G.B.Mehta, F.H.Mattes, B.J.Lemieux, B.M.Hammond J. Chakravarty

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.)*

Gunvantray B. Mehta, M.D.

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	0.5
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	100
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	30
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	30
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	X	450
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	600
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	500

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

8507290271 850710
REG3 LIC30
34-00305-03 PDR

Applicant. Mercy
Check No. 0879438
Amount. Fee Category
Type of Fee TC Renew
Date Check Rec'd 3/7/85
Received By

NRC FORM 313M
(9-81)

CONTROL NO. 7836

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. 1 Date: Oct. 1980

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
X	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
N/A	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
N/A	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
N/A	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
N/A	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7-C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* David C Renton

(1) NAME *(Type or Print)* David C. Renton

(2) TITLE Assistant Administrator

c. DATE Feb 22, 1985

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.

supersedes:

code no. 103 #7

MERCY HOSPITAL Toledo, Ohio	section:	RADIATION SAFETY MANUAL
POLICY & PROCEDURE MANUAL	subject:	RADIATION SAFETY AND ISOTOPE COMMITTEE

The Mercy Hospital Radiation Safety and Isotope Committee consists of the following members:

Michael B. Gordon, M.D. - Director of Radiology Department; Board Certified Radiologist and serves as Chairman of the Radiation Safety and Isotope Committee.

John F. Brunner, M.D. Board Certified in Internal Medicine and restricts his practice to subspecialty of Endocrinology and Nuclear Medicine. Director of Medical Education Department.

Michael B. Gordon, M.D., Chairman (Chairman, Dept. of Radiology)
John F. Brunner, M.D. (RIA Lab)
Edmund P. Ho, M.D. (Radiation Therapy)
Gunvantray B. Mehta, M.D. (Radiation Safety Officer)
John R. Sinkey, M.D. (Medical Staff rep.)
James R. Brown, R.T. (Manager, Radiological Services)
Ken Pikor (RIA Lab)
Kathy Raglow, R.T. (Nuclear Medicine)
Judy Steedman, R.T.
Andy Schneider
Janette Robertson, R.N. (Nursing Service rep.)
David Renton, Administrator

Committee Responsibilities:

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

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

COMMITTEE Duties:

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

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

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

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

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

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

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

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

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

Meeting Frequency

The Radiation Safety and Isotope Committee shall meet as often as necessary to conduct its business but not less than once each calender quarter.

Drs. M.B. Gordon, C.S. Shon, J.F. Brunner, D.T. Bolovan, F.H. Mattes, G.B. Mehta, and B.J. Lemieux are currently on our institutional license #34-00305-03. Please refer to prior applications for supplements A and B on them.

Drs. B.L. Hammond and J. Chakravarty are new applicants supplements A and B are enclosed.

Both Dr. Chakravarty and Dr. Hammond are practicing physicians at Mercy Hospital.

Dr. Chakravarty is practicing in partnership with Dr. Brunner who in addition to being the head of the RIA Lab. is the Director of Medical Education. Weekly conferences are held at which are discussed all Thyroid patients done during the past week as to diagnosis, treatment and all aspects of radiation treatment and safety. Dr. Chakravarty wants a specific license for the use of Iodine in the diagnosis and treatment of Thyroid and Thyroid related diseases.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
JYOTI CHAKRAVARTY, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Internal Medicine	Endocrinology & Metabolism	June 1976 October 1977

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	From July 1975-June 1977 Medical College of Wisconsin Milwaukee, Wisconsin	20	30
b. RADIATION PROTECTION	From July 1975-June 1977 Medical College of Wisconsin Milwaukee, Wisconsin	10	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	From July 1975-June 1977 Medical College of Wisconsin Milwaukee, Wisconsin	10	15
d. RADIATION BIOLOGY	Mercy Hospital Toledo, Ohio	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	Medical College of Wisconsin Milwaukee, Wisconsin	5	

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I 131	200 mCi	Nuclear Med. Lab. Mercy Hospital Toledo, Ohio 43624	7 yrs.	Therapeutic
I 125	100 uCi			Diagnostic
I 123	500 uCi			Diagnostic

CONTROL NO. 78367

NRC FORM 313M SUPPLEMENT B
(9-81)

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
Jyoti Chakravarty

STREET ADDRESS
2200 Jefferson Ave.

CITY	STATE	ZIP CODE
Toledo	Ohio	43624

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	800	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	I 123 Thyroid Function	200	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	800	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER	I 123 Thyroid Imaging	200	
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		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	25	
	TREATMENT OF HYPERTHYROIDISM	200	
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

130 hours

July 1975 through June 1977 Endocrine Fellowship Med. Col. of Wisconsin

July 1977 through June 1979 On the Job Mercy Hospital Toledo, Ohio

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

a. NAME OF SUPERVISOR
John F. Brunner, M.D.

b. NAME OF INSTITUTION
Mercy Hospital

c. MAILING ADDRESS
2200 Jefferson Ave.

d. CITY
Toledo, Ohio 43624

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

John F. Brunner, M.D.

7. PRECEPTOR'S NAME *(Please type or print)*

John F. Brunner, M.D.

8. DATE

Feb. 22. 1985

NRC FORM 313M SUPPLEMENT B
(9-81)

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GPO 890-913

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

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Bruce L. Hammond, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Diagnostic Radiology	June 4, 1982

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Michigan Hospitals 1405 E. Ann St. Dept. of Radiology Ann Arbor, MI 48109	35	175
b. RADIATION PROTECTION	Sept. 1980 to Sept. 1981	5	25
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		5	15
d. RADIATION BIOLOGY		12	
e. RADIOPHARMACEUTICAL CHEMISTRY		5	25

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I-131	150 mCi	Univ. of Mich. Hosp.	4 months	Therapeutic
Mo99/Tc99m	300 mCi	" " " "	"	Diagnostic
Xe-133	50 mCi	" " " "	"	Diagnostic
I-125	50 uCi	" " " "	"	Diagnostic
Ga-67	5 mCi	" " " "	"	Diagnostic

Curriculum Vitae

BRUCE L. HAMMOND, M.D.

1971 - 1975	Adrian College, Adrian Michigan, B.S. Degree
1975 - 1978	Ohio State University College of Medicine, M.D. Degree
1979	Diplomat, National Board Medical Examiners
1979	Licensure, State of Michigan
1978 - 1982	Radiology (Diagnostic) University of Michigan Hospitals
1982	Diplomat, American Board of Radiology
1982	Licensure, State of Ohio
1982 - Present	Group Practice with X-Ray Associates, Toledo, Ohio Medical Staff Member at both St. Luke's Hospital, Maumee, O and Mercy Hospital, Toledo, Ohio

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

Bruce L. Hammond, M.D.

STREET ADDRESS

Mercy Hospital
2200 Jefferson Avenue

CITY	STATE	ZIP CODE
Toledo,	Ohio	43624

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	50	
	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	1	
I-131	THYROID IMAGING	10	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	10	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	100	
OTHER			
Tc-99m	BRAIN IMAGING	50	
	CARDIAC IMAGING	100	
	THYROID IMAGING	200	
	SALIVARY GLAND IMAGING	5	
	BLOOD POOL IMAGING	100	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	200	
	LUNG IMAGING	200	
	BONE IMAGING	200	
OTHER			

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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		
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	5	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	15	
Other			

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

March 1979
October 1979
July 80 - Nov. 81 (6 weeks total) 4 Months (672 hours)

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

a. NAME OF SUPERVISOR
Wm. H. Beierwaltes, M.D.

b. NAME OF INSTITUTION
University of Michigan Medical Center

c. MAILING ADDRESS
1405 E. Ann St.

d. CITY
Ann Arbor, MI 48109

5. MATERIALS LICENSE NUMBER(S)
21-215-4

6. PRECEPTOR'S SIGNATURE
X Wm. H. Beierwaltes

7. PRECEPTOR'S NAME *(Please type or print)*
William H. Beierwaltes, M.D.

8. DATE
3/17/83

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

CONTROL NO. 78367

Instrumentation

I Camera Room -- LFOV

1. Counter with sink, storage above and below
2. Xenalert room air monitor. Model #36-751
3. Microprocessor Siemens #3196
4. Micro Dot Siemens #3207
5. Two collimator carts. One collimator #822883 or #822898
6. Large field of view Camera #6478
   Persistance scope (Hewlett-Packard 1915A)
7. C-Cylinder Oxygen Tank
8. Patient cart. Atomic Products #056-300

II Hot Lab

9. Storage Cabinet
10. Refridgerator Avanti 37 - 9 RG
11-12. Survey Meters CD Victoreen #6B with Side Window Probe #561-9
   Ludlum #3 with side window probe #44-6
13. Counter with storage below
14. Hood - inhouse manufacture
15. Interlocking lead bricks 14 x 18 x 22
16. Dose Calibrator Rad-Cal II
17. Std. Bench top shield #042-710
18. Eberline Room Monitor RM-14
19. Bed side table
20. Pulmonex Xenon delivery and trap system #130 - 500
21. School desk used as injection station

III Camera Room -- Portable

22. Counter and sink storage above and below
23. Patient cart Laberne treatment table
24. Format 9 camera ADAC 2081-3000A
25. Computer ADAC Cam II 2103-3000B

IV RIA Equipment

Onio Nuclear Rectilinear Scanner Series 800
Micro Medics Concept 4 Gamma Counter
Beckman Instruments Gamma Counter Gamma 300
Iso Data Multi well Gamma Counter Model 10/20
Ludlum Survey Meter Model 3 side window probe 44-6
Radx Dose Calibrator Assayer 1
Six (6) Victoreen Pocket dosimeters Model 385-1

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items

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

X 2. Calibration will be performed at two pionts on each scale used for radiation protection purposes.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 20% if a calibration chart, graph, or responce factor is prepared, attached to the instrument, and used to correct readings to within ± 10%. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated;

X a. By the manufacturer

X b. By an outside consultant: Schneider and Wuerst, Inc.
304 Mulberry St.
Perrysburg, Ohio 43551

1. Calibration source:

Manufacturer's name Radium Chemical Company

Model No. 10 mg.

Activity 10 needles at 10 mg. Ra each

Accuracy plus/minus 5%

Traceability to primary standard see Item 10 page 2

X 2. The calibration procedures in section 1 of Appendix D will be used.

X 3. The "Certificate of Instrument Calibration" is shown on page 3 of Item 10.

Radium Sealed Source Calibration

Date: October 13, 1983 By: Andrew J. Schneider

Instrument Used: RadX, Mark V, s/n 3314-71-PS

Calibrated on January 25, 1983

SOURCE	MEASURED ACTIVITY (mCi)	
Ra-226 needles	#5	10.4
Nominal Activity of 10 mg each	#6	10.5
Number Indicates	#7	10.0
Location in Radium Safe	#8	10.4
	#13	10.5
	#14	10.2
	#15	10.4
	#16	10.5
	#21	10.5
	#22	10.3
Average Activity (mCi)		10.37 + 0.16

CERTIFICATE OF INSTRUMENT CALIBRATION

HOSPITAL: _____ DEPT. _____

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments: _____

_____

_____

_____

	Nuclide	Activity	Calibration Accuracy
Calibration Source:	_____	_____	_____
	_____	_____	_____

Low energy (Co-57) response factor is _____

Calibrated by _____ Date _____

Reference readings: with 0.2 mCi Cs-137 source in styrofoam holder.

Date	Reading	Notes	By
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

CALIBRATION OF DOSE CALIBRATORS

A. The dose calibrators will be calibrated as follows:

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

Nuclide	Manufacturer	Model	Activity (mCi)
Cs-137	Nuclear Associates	S/N 3560279A-17	213 microCi 2-1-79
C-57	NEN	S/N 2060983A-42	4.9 milliCi 9-20-83
Cs-137	Nuclear Associates	S/N 90170582-24	218 microCi 5-28-82

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

3. The calibration procedure will be as follows:

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

      The activity displayed by the dose calibrators must agree with the stated assay within ± 5%. This error may increase to ± 10% but correction factors will be determined. If the unit displays readings with an error greater than ± 10%, it will be repaired or adjusted.

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

      The daily constancy check will be extended to include verifaction of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check.

c. The dose calibrators will be checked for activity linearity at quarterly intervals and following repairs. A sample of the linearity test results is shown on page 9 of Item 10.

The linearity test will be performed using a ^{99m}Technetium source with an activity equal to or exceding the maximum anticipated activity recieved for the performance of clinical studies. The linearity test will be continued by repeating the assay several times a day ove a two or three day period until a measurement is made in which the activity displayed is less than the activity displayed during the annual accuracy check using a standard with energy similar to that of Technetium. In this way, the accuracy of the dose calibrators will be assured in the measurement of individual doses throughout the entire clinical range of activity.

The above linearity test data will be plotted as a function of activity vs. time and compared to the predicted activities at those times. The acceptable range of error will be ± 5% but may increase to ±10% between which correction factors will be determined. If measurements indicate an error greater than ± 10% the unit will be adjusted or repaired.

d. The dose calibrators will be tested for geometrical variation at the time of installation and following chamber or linear repair or replacement. This test will be performed by placing an amount of activity of ^{99m}Tc in a vial made of the same material and in the same volume as the ^{57}Co standard. This vial will be assayed. Aliquots of activity will be removed using syringes representative of those being used for patient studies. In addition, aliquots will be drawn and transferred to kit vials similar to those used in synthesizing various Technetium compounds. The syringe and kit vial aliquots will then be assayed.

The stock vial volume will be returned to its original value after each withdrawal. The activity reduction in the stock vial as determined on re-assay will be assumed quantitively transferred to the syringe aliquot or the kit vial (residual activity in the transferring syringe will be considered). Correction factors for various geometries will be determined if the calculated and measured activies vary by more than ± 2% and will be considered in setting of dose schedules for Technetium 99m.

Initial geometrical correction factors will be established for other nuclides besides Tc99m which will be recieved bearing a manufacturer's assay. These sources, in such configuration as capsules, ampules, cartriges, etc. will be assayed and the initial correction factor will be established for these types of sources using the displayed assay vs. the manufacturer's assay at the time of reciept.

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

In the event either dose calibrator should fail or be away for repairs, the nuclear medicine and/or RIA program will be continued through the implementation of one or more of the following plans:

1. A substitute dose calibrator will be acquired.
2. The manufacture's assay of precalibrated activities will be relied upon.
3. Technetium eluents will be assayed and the Mo 99 containment will be determined using a dose calibrator located at the nearest cooperating institution having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels of exposure to 2.0 mR/hr or less on contact with shield, and wrapped in enough absorbant material to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of the authorized use.

B. Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analizer will be calibrated using a 99m Tc source and a uniform flood source will be imaged daily.
2. The uptake and well systems will be calibrated using a 137 Cs source each day of use.

Dose Calibrator Accuracy Test

RAO/CAL II
Nuclear Medicine
Mercy Hospital
Toledo, Ohio

Isotope	Actual Activity	Measured Activity	% Error
Cs-137	190.0 μCi	188 μCi	-1.1%
Co-57	1.41 mCi	1.346 mCi	-4.5
Co-60	15.2 μCi	15.8 μCi	3.9
Co-57	1.41 mCi	1.38 mCi (Tc-99 setting)	-2.1

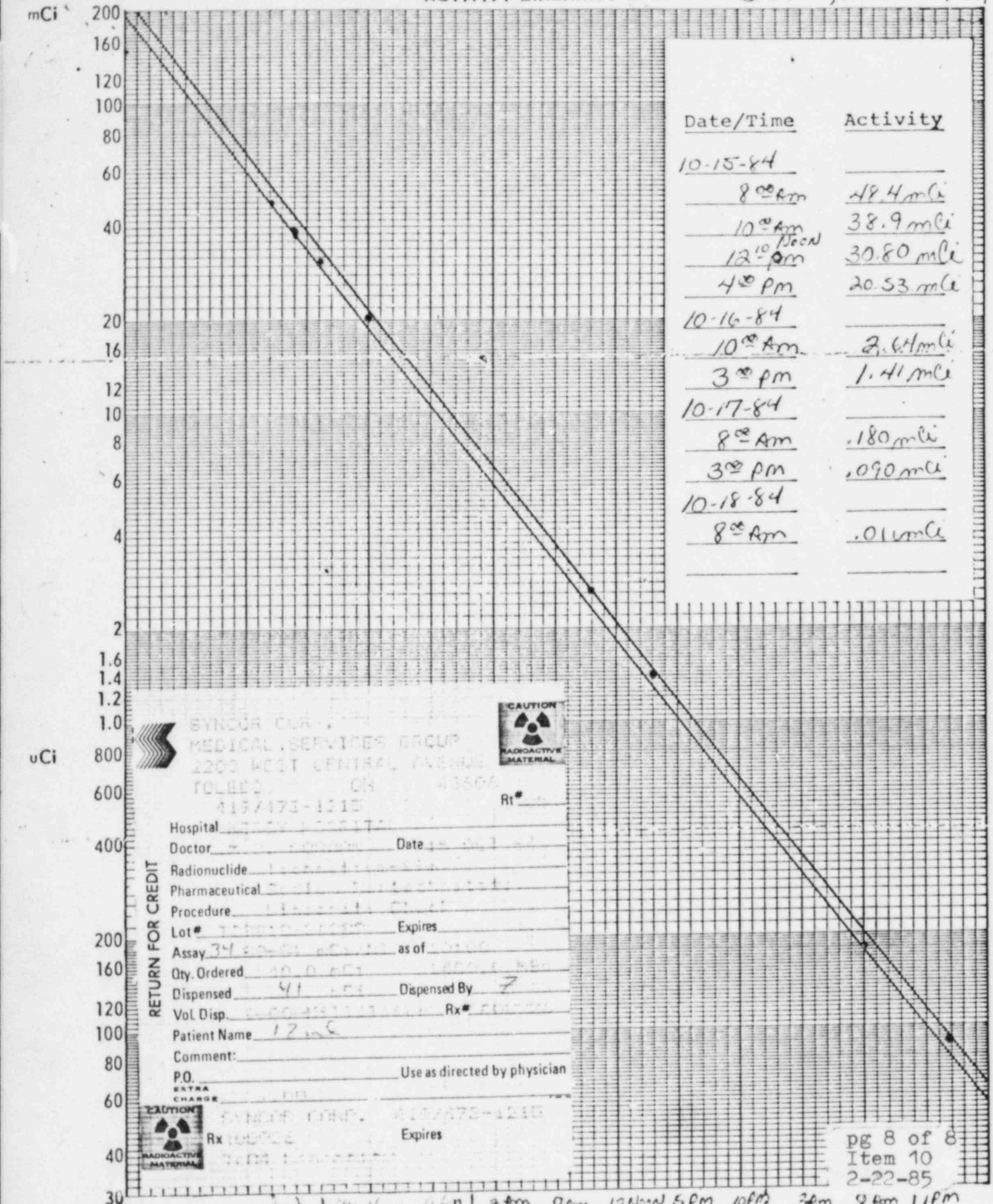
Jan 15, 1985
Date

Andrew J Schneider

Grad Col II

ACTIVITY LINEARITY CHECK

Oct 15, 1984 MKR



Date/Time	Activity
10-15-84	
8 Am	48.4 mCi
10 Am	38.9 mCi
12 Noon pm	30.80 mCi
4 pm	20.53 mCi
10-16-84	
10 Am	2.64 mCi
3 pm	1.41 mCi
10-17-84	
8 Am	.180 mCi
3 pm	.090 mCi
10-18-84	
8 Am	.01 mCi

SYNCOR CORP.
MEDICAL SERVICES GROUP
2200 WEST CENTRAL AVENUE
TOLEDO, OH 43606
419/473-1215

CAUTION RADIOACTIVE MATERIAL

Rt#

RETURN FOR CREDIT

Hospital
Doctor Date
Radionuclide
Pharmaceutical
Procedure
Lot# Expires
Assay 34 as of
Qty. Ordered
Dispensed 41 Dispensed By 7
Vol. Disp. Rx#
Patient Name 12 mC
Comment:
P.O. Use as directed by physician
EXTRA CHARGE

CAUTION RADIOACTIVE MATERIAL
Rx
Expires

SYNCOR CORP. 419/473-1215

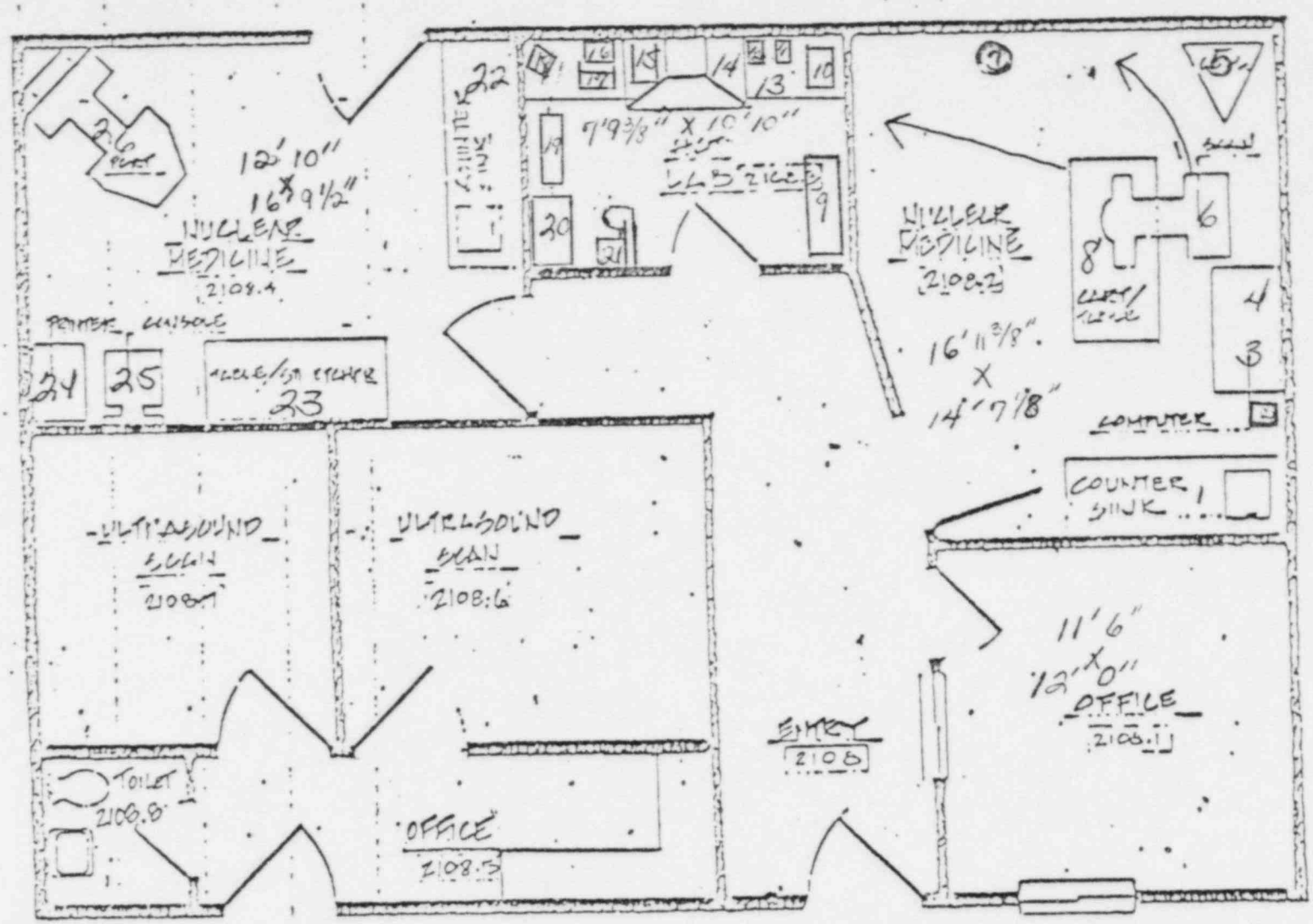
pg 8 of 8
Item 10
2-22-85

FACILITIES AND EQUIPMENT

The Nuclear Medicine Department of Mercy Hospital is located on the second floor of Our Mother of Mercy building within the Radiology department. (New building).

The Radioimmunossay department is located in the basement of St. Mary's East wing. (Old building).

Plans of both the Nuclear Medicine department and the Radioimmunossay department are enclosed designating the demensions of the rooms and list of equipment.



Item 11
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PG. 2 of 4

Item 11
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pg. 3 of 4

Instrumentation

I Camera Room -- LFOV

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6. Large field of view Camera #6478
   Persistance scope (Hewlett-Packard 1915A)
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9. Storage Cabinet
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   Ludlum #3 with side window probe #44-6
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Beckman Instruments Gamma Counter Gamma 300
Iso Data Multi well Gamma Counter Model 10/20
Ludlum Survey Meter Model 3 side window probe 44-6
Radx Dose Calibrator Assayer 1
Six (6) Victoreen Pocket dosimeters Model 385-1

PERSONNEL TRAINING

A. All radioactive materials will be handled by competent individuals, highly trained and skilled in radionuclide methodology. Qualifications of current employee's in Nuclear Medicine and RIA are enclosed.

All personnel (including technical, clerical, nursing, housekeeping, and security) working in or frequenting any portion of a restricted area will receive complete indoctrination as to specifications mentioned in Section 19.12 of 10 CFR. Part 19.

All employees of the Nuclear Medicine and RIA Departments will read and abide by the procedures, rules and regulations set forth by the departments and any ammendments.

B. New employees will receive orientation and any on-the-job training that is needed to familiarize them with their new position. This orientation will be conducted by the Supervisor or Section Leader in Nuclear Medicine. All aspects of their new position will be discussed.

C. Continuing Education will be an ongoing program with employees being permitted to attend both inservice and Society meetings (Local and National).

CURRICULUM VITAE

Name:	Mary K. Raglow, RT(R), RT(NM), CNMT	
Education:	Radiologic Science Institute Flint, Michigan Classes at Toledo Academy of Medicine	Sept. 1973 - Sept. 1974
Training:	Radiologic Technology Hospital Based Euclid General Hospital Euclid, Ohio	Jan. 1961 - Jan. 1963
	Nuclear Medicine Technology On-the-job Highland View Hospital Cleveland, Ohio	Mar. 1965 - Mar. 1966
Work Experience:	Suburban Community Hospital Warrensville Heights, Ohio X - Ray Technology	1963 - 1965
	Highland View Hospital Cleveland, Ohio Nuclear Medicine Technology	Mar. 1965 - Mar. 1966
	Mercy Hospital Toledo, Ohio Nuclear Medicine Technology	Apr. 1966 - Apr. 1980
	Section Leader, Nuc. Med.	Apr. 1980 - Present
Credentials:	American Registry Of Radiologic Technologists Radiology	Jan. 1, 1963 Certificate # 41985
	American Registry Of Radiologic Technologists Nuclear Medicine	May 1972 Certificate #NM 1935
	Nuclear Medicine Technology Certification Board Nuclear Medicine	Dec. 1978 Certificate #

Name:	E. Jean Guindon, RT(R), RT(NM), CNMT	
Education:	University of Toledo College of Arts and Sciences Radiology Technology	June 1966 - June 1968
	Radiologic Science Institute Flint, Michigan Nuclear Medicine Technology Classes at Toledo AMA Bldg. and Grace Northwest Hospital Detroit, Michigan	Sept 1973 - Sept 1974
	University of Toledo Radiology Management	Sept 1973 - Jan. 1979
Training:	St. Lukes Hospital Toledo, Ohio Technologist Assistant Student Radiologic Technologist	Jan. 1966 - June 1968
	Parkview Hospital Toledo, Ohio Nuclear Medicine On-the-Job	Jan. 1972 - Jan. 1975
Work Experience:	St. Lukes Hospital Toledo, Ohio Staff Technologist Radiology	June 1968 - Sept 1968
	Mercy Hospital Toledo, Ohio Staff Radiology Technologist	Sept 1968 - Sept 1971
	Parkview Hospital Toledo, Ohio Staff Radiology Technologist Staff Nuclear Medicine Technologist	Jan. 1972 - Jan. 1975
	Medical College of Ohio at Toledo Toledo, Ohio Staff Nuclear Medicine Technologist Animal Research -- Research Assistant Nuclear Cardiology	Jan. 1975 - Mar. 1976
	St Charles Hospital Oregon, Ohio Supervisor, Nuclear Medicine, Radiation Therapy and Ultrasound Acting Director, Radiology (4 mos.) Supervisor, Diagnostic Radiology and Educational Coordinator	Mar. 1976 - Sept 1981
	Mercy Hospital Toledo, Ohio Nuclear Medicine Technologist	Sept 1981 - present
Credentials:	American Registry of Radiologic Technologists Radiology	May 1968 Certificate #62090

E.Jean Guindon (cont'd.)

Credentials:	American Registry of Radiologic Technologists Nuclear Medicine	Nov. 1974 Certificate #62090
	Nuclear Medicine Technology Certification Board	Sept. 1980 Certificate # 004935

CURRICULUM VITAE

Name: Kenneth A. Pikor, B.S. NM (ASCP); CNMT

Education:

Oakland Community College
Auburn Heights, Michigan 1967-1969

Michigan State University
East Lansing Michigan, B.S. Chemistry 1972

Grace Hospital
Detroit, Michigan
Specialized Instruction Nuclear Medical Technology 1973-75
Radiological Science Corporation Certificate # 735704D

Training:

Department of Nuclear Medicine February, 1973 - Dec.,1975
Grace Hospital, Detroit,Michigan
Work Experience and Training in Nuclear Medicine Technology

Bio-Science Laboratories January, 1976 - Sept., 1977
Detroit, Michigan
Senior Medical Technologist
Assistant Supervisor RIA-Endocrinology Laboratory

Mercy Hospital October, 1977 - Dec., 1980
Toledo, Ohio
RIA Laboratory - Endocrinology Assistant Supervisor

Mercy Hospital
Toledo, Ohio
RIA Laboratory - Endocrinology Department Head
January, 1981 to Present

Professional Certifications and Organizations:

Certified Nuclear Medical Technologist by
American Society of Clinical Pathologists NM (ASCP) #000721

Society of Nuclear Medicine CNMT - Certificate # 001163

CURRICULUM VITAE

NAME: MYRNA L. BALONEK, B.S, NM (ARRT)

EDUCATION:

University of the East
MANILA,PHILIPPINES 1969-1972
B.S. Pre-Medicine

Nuclear Medecine Institute
Mayfield Heights,OH
Nuclear Medicine Technology 1978-1979

St. Vincent Hospital
Cherry St. Toledo,OH
SPECIAL TRAINING IN NUCLEAR MEDICINE

TRAINING: Nuclear Medicine Institute — January 1978-May 1,1978
Didactic training in Nuclear Medicine

St Vincent Hospital — May 2, 1978 - March 1979
Toledo,Ohio
Work Experience and Training in Nuclear Medicine Technology

St Charles Hospital — May 29,1979-Jan 2,1982
Oregon Ohio 43616
Nuclear Medicine Technologist

Mercy Hospital
Toledo,Ohio
RIA LABORATORY- Nuclear Medicine Technologist January 4,1982 to Present

PROFESSIONAL CERTIFICATION :

The American Registry of Radiologic Technologists
Certificat # 158044 Nuclear Medicine

CIRRICULUM VITAE

Name:	Margaret M. Welcheck, M Ed., B Ed., RT(R)	
Education:	Michael J. Owens Technical College Perrysburg, Ohio Associate of Science in Radiography	Jan. 1976 - Sep. 1979
	University of Toledo Bachelor of Education in Public Affairs and Community Services	Sep. 1979 - Aug. 1981
	University of Toledo Master of Science and Education in Public Health	Sep. 1981 - June 1983
Training:	Flower Hospital Toledo, Ohio Student Radiologic Technologist	Jan. 1976 - Sep. 1979
	Mercy Hospital Toledo, Ohio Nuclear Medicine Technologist On-the-Job	Oct. 1982 - Present
Work Experience:	Mercy Hospital Toledo, Ohio Staff Radiology Technologist	Oct. 1979 - Oct. 1982
	Michael J. Owens Technical College Lab Assistant and Instructor in Radiography	June 1980 - June 1892
	Mercy Hospital Toledo, Ohio Staff Technologist Nuclear Medicine	Oct. 1982 - Present
Credentials:	American Registry of Radiologic Technologists	Nov. 1980 Certificate #159789

supersedes: code no. 102 #13

MERCY HOSPITAL Toledo, Ohio POLICY & PROCEDURE MANUAL	section: RADIATION SAFETY MANUAL subject: ORDERING & RECEIVING RADIOACTIVE MATERIALS

All deliveries arriving during the regular daytime hours, Monday thru Friday, will be delivered to the Purchasing Department, unless the carriers are instructed to deliver directly to the department.
The Clinical Laboratory is open 24 hours, 7 days a week.
The Supervisor of the department, or his designee, must place all orders for radioactive materials and must ensure that the requested materials and quanities are authorized by the license and that possession limits are not exceeded.

Deliveries made when the department is closed:

1. The Security Department will be responsible for accepting deliveries to the hospital when the Purchasing Department and the R.I.A. Lab are closed.

2. Security will record: Company name, person delivering, time of delivery, description of item delivered, and the date.

3. Security personnel will take the delivery directly to the department, unlock the door to the dose room, and place the package behind the lead bricks and relock the door.

4. NOTE: If the package appears damaged in any way, the hospital Radiation Safety Officer who works in Radiology, extension 1356, is called, (home telephone: 865-2727). If the receiving department is open, contact the Department Head and they will call the proper officer.

   Ask the carrier to remain at the hospital until it can be determined that neither the delivery vehicle or driver is contaminated.

5. When security takes a delivery of in-vitro packages (which are marked accordingly), they should be refrigerated in the R.I.A. Lab as soon as possible. A key to the Nuclear Medicine Department is kept in Security Department to help with deliveries.

Ordering Procedure:

1. Radioactive materials will be ordered as needed from Syncor, Inc., Toledo, Ohio (NRC License #34-16654-01 MD). Their driver must be instructed to deliver packages according to hospital delivery policies.

2. Radioactive reagents shall be ordered from various suppliers for in-vitro nuclear testing.

PROCEDURE 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) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99 products). They will be monitored for surface contamination and external radiation levels within 3 hours of receipt if received during working hours or within 18 hours 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 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet or 1 meter.

2. Put on gloves to prevent hand contamination.

3. Visually inspect package if it appears damaged in any way stop and report to the Radiation Safety Officer or his designee.

4. Open outer package and check for possible breakage of inner containers (look for changes in color of absorbant material).

5. Compare contents with packing slip and with patient schedule to verify chemical compound, calibration time, and activity of doses ordered. Label with color coded stickers.

6. Store in assigned area.

7. Before return to Syncor check and record remaining activity on packing slip.

MERCY HOSPITAL
TOLEDO, OHIO
POLICY & PROCEDURE MANUAL

SECTION: RADIATION SAFETY MANUAL

SUBJECT: SAFE HANDLING & STORAGE OF RADIOACTIVE MATERIALS - GUIDELINES

These general instructions must be followed by physicians and technicians while working with radioactive materials.

1. Attire - Protective outer garments such as lab coat and plastic disposable gloves will be worn when handling radioactive byproduct material.

2. Area of Usage - All radioactive material will be confined to the area of usage. When necessary to transfer radioactive material to patient's bedside, the material will be placed in a highly protective shield with all precautions taken to minimize exposure and eliminate possible contamination hazards outside the department.

3. Handling Setup of Materials - All possible setups involving radioactive material will be made on easily cleanable trays. These trays and all other work surfaces will be covered with disposable absorbent papers.

4. NO MOUTH PIPETTING OF RADIOACTIVE MATERIALS IS ALLOWED - Syringes, bulbs or other devices are to be used. No food or beverages will be allowed in the areas where radionuclides are used.

5. NO SMOKING - will be permitted in this area. Good housekeeping will be maintained at all times. Waste or contaminated materials will not be allowed to accumulate.

6. Vial Disposal - After a therapy dose is given, using disposable gloves and a lead shielded vial, the used vial is placed in the lead pig and returned to the dose room where it will be returned to Syncor Inc., for disposal.

7. Contaminated material - This material from in-vitro testing is placed in marked container and checked daily for a safe radiation level. Since in-vitro tests contain less than 1.0 uci per test, the residues and/or washes may be discarded in the hot sink. In this manner, all activity that does not remain in the vial is disposed of via the sewer. Solid material and similar equipment is always disposed of in accordance with current existing regulations.

8. All department personnel working with radioactive byproduct material or in "radiation areas" will be required to wear whole body film badge monitors or pocket dosimeters and the use of TLD finger badges, when applicable. The exposure record of film and TLD badges along with: name, sex, and location will be kept on file in the department.

9. Monthly Records - The Department Head or Radiation Safety Officer will review these records monthly to determine which persons are receiving significant exposure.

10. Overexposure - The appropriate personnel will be notified whenever overexposure occurs, as well as the Regional NRC compliance office in accordance with Section 20.402 and Section 201403 of Title 10, Part 20.

11. Pregnant Employees - Refer to NRC Guidelines 8.13, pages one to three and risk selections form attached.

12. Dispose of radioactive waste only in specially designated receptacles; defacing all empty tracer vials before disposal.

13. Any contaminated article will be bagged in plastic and disposed of in the appropriate containers in accordance with current existing regulations.

14. Always - WASH HANDS before leaving work area or department. Wash hands before eating, smoking, and at the end of working with contaminated equipment.

15. NO EDIBLES - of any kind (food, gum, candy, beverages) shall be brought into the work area.

16. Personal items such as lipstick and other cosmetics must never be used in the work area.

17. Work area must be kept free from equipment and materials not needed for the immediate work. Orderliness is a prime requirement for eliminating the spread of contamination.

18. Radioactive material should be returned to storage area as soon as they are no longer needed.

19. Thyroid uptakes are performed on physicians who administer therapeutic amounts of I-131 24 hours post treatment.

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Page 2 of 2
2/22/85

CONTROL NO. [illegible]

MERCY HOSPITAL
TOLEDO, OHIO
POLICY & PROCEDURE MANUAL

SECTION: RADIATION SAFETY MANUAL

SUBJECT: EMERGENCY DECONTAMINATION PROCEDURE

DECONTAMINATION PROCEDURE

If a radioactive spill occurs in any area, the following procedure will be followed.

PROCEDURE

1. NOTIFY PERSONS IN THE AREA that a spill has occurred. Those not involved and not contaminated should leave the area. All potentially contaminated personnel will be confined to the spill area until contaminated clothing, including shoes, are removed.

2. PREVENT THE SPREAD - Cover the spill with absorbent pads/paper, but do not attempt to clean it up.

3. REPORT - Notify your department head, who will call the Radiation Safety Officer immediately.

   RADIATION SAFETY OFFICER: Gunvantray B. Mehta, M.D.
   Extension 1356
   Home: 865-2727

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

5. CLOSE THE ROOM - Follow the advise of the Radiation Safety Officer from this point. He may suggest that personnel leave the room and lock the door(s) to prevent entry.

6. CLEAN UP OF AREA GUIDELINES:

   a. Always put on rubber gloves and boots (if necessary) before entering the spill area. (Disposable shoe covers may be used.)

   b. Contaminated clothing and shoes are to be placed in a plastic bag for further evaluation.

   c. Using disposable gloves and remote handling tongs, carefully fold absorbent paper/pad, pick up and insert in radioactive waste container. Insert all contaminated materials, including disposable gloves.

   d. Area will be thoroughly cleaned following instructions of Radiation Safety Officer. Brushes will not be used to apply friction to surfaces since this may cause splattering and spread contamination. Radioactive particles are more easily removed from hard surfaces, such as stainless steel basins, etc., than from more porous materials.

   e. Personnel must wash and monitor thoroughly - this is essential. Particular attention must be paid to the hands and under the fingernails. Repeat washing if necessary. Excessive scrubbing of the body should be avoided; hot water should be avoided

e. continued -

because it increases circulation to the contaminated area of the body and enhances the absorption of radioactivity into the circulating blood. Use warm water only.

f. Minor cuts should be encouraged to bleed, thereby reducing absorption capabilities. The treatment of major cuts should be considered before decontamination.

7. SURVEY - With a low-range, thin-window GM survey meter. Check areas around the spill, hands and clothing of personnel, etc.

8. REPORTING TO REGULATORY AGENCY - Will be handled by the Radiation Safety Officer.

REMEMBER - The advise of the Radiation Safety Officer will be followed at all times.

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Page 2 of 6
2/22/85

POLICY

With the widespread utilization of radioactive materials, the possibility increases that the hospital emergency department may be faced with the need to provide assistance to an individual whose injuries are in some way related to or compounded by exposure to ionizing radiations.

The Emergency Services Department at Mercy Hospital will treat the radiation accident victim with the assistance of the hospital Radiation Safety Team. This team consists of the Radiation Safety Officer and the hospital RIA Laboratory personnel will will assist in peforming three major functions:

1. Supply necessary survey equipment
2. Monitoring of victims, personnel, and area
3. Decontamination

PURPOSE

1. To insure safe and proper treatment of radiation accident victims.

2. To insure proper radiation safety for emergency and all other related personnel dealing with radiation accident victims.

PROCEDURE

Immediate Action Prior to Arrival of Radiation Accident Victim

1. The Emergency Department must be notified by the ambulance or rescue squad that a radiation victim is being transported to Mercy Hospital.

2. Immediate notification of the Radiation Safety Team (see telephone listing on page 3).

3. While waiting for the arrival of the radiation contaminated victim and the Radiation Safety Team, the Emergency Department personnel should begin the following:

   a. Assign a specific room for the isolation of the patient.

   b. Cover the floor with absorbent paper (Chux).

   c. Line clothes hampers with large plastic bags (garbage or isolation bags).

   d. Isolation gowns, disposable rubber gloves and surgery boots should be worn by all Emergency Department personnel assigned to the victims care.

Upon Arrival of the Contaminated Victim

1. A shower located outside the Emergency Department should be used if the patient's condition allows.

2. All suspected persons should be surveyed for radioactive contamination, (e.g., victim, rescue squad personnel, police, fireman, etc.).

3. If the victim is seriously injured, emergency assistance should be given immediately.

4. If external contamination is involved, save all clothing and bedding from the ambulance, blood, urine, stool, vomitus, and all metal objects, (e.g., jewelry, belt buckles, dental plates, etc.). Save all contaminated materials in appropriately marked containers. Each container should be marked with a tag reading: "CAUTION - RADIOACTIVE".

5. Decontamination should start, if medical status permits, with cleaning and scrubbing the area of highest contamination first. When possible, the contaminated persons should be taken to a shower area for bathing.

   Cleansing should be done with warm water and commercially available detergents and soaps. Dial soap would suffice. Highly alkaline soaps (Lava and Comet), abrasives, organic solvents or cleaners that tend to increase permeability of the skin should not be used.

   Wash water waste, unless markedly radioactive, may be flushed into the community sewage system where dilution will obviate any hazardous effect.

   Several separate washings should be performed with special emphasis given to cleaning body orifices and body folds.

   Scrub brushes should be used, but care must be taken that the skin surfaces do not become abraded.

   After each washing or showering the body will be resurveyed and the amount of activity measured will be recorded.

   Small cuts and other breaks in the skin surface will be sought for carefully since absorption of radionuclides can occur by this route. Such lesions should be decontaminated after the above washes by repeated 5 minute scrubs, after the removal of scabs and crusts.

   If the wound is involved, prepare and cover the wound with self-adhering disposable drapes. Remove wound covering and irrigate wound with sterile water, catching and irrigating fluid in a basin or can, to be marked and handled as contaminated waste water. Again, each step in the decontamination process should be preceded and followed by

monitoring and recording of the location and extent of contamination.

If confronted with a grossly contaminated wound with dirt particles and crushed tissue, preliminary simple wet debridement may be necessary.

All nurses, doctors and attendants must follow the same monitoring and decontamination routine as the victim. All used equipment, bedding and other potentially contaminated items will be placed in plastic bags and kept in a restricted area until the radiation level is found safe.

6. Necessary reporting to the local and national authorities will be carried out by the Radiation Safety Officer.

RADIATION SAFETY TEAM

Radiation Protection Officer:	Gunvantray B. Mehta, M.D. Home: 865-2727
Assistant:	Jim Brown, Manager Home: 476-3396
	Kathy Raglow, RT(R),RT(NM),CNMT Home: 666-1543
Radiation Health Physicist: (available for consultation)	Andrew J. Schneider Home: 874-5947 Work: 381-4301

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SUPERSEDES: 10/18/77 CODE NO. 113

MERCY HOSPITAL
TOLEDO, OHIO
POLICY & PROCEDURE MANUAL

SECTION: RADIATION SAFETY MANUAL

SUBJECT: DECONTAMINATION KIT

The Decontamination Kit is located in the Emergency Department, Room #6. The following items contained in the kit will be used in each instance of cleaning a contaminated area. Supplies are ready for use at all times and will be replenished regularly. See Emergency Care for cleanup of patient.

ITEM:	PURPOSE:
Warning tape & signs	posted in the area
Plastic bags, small	shoe covers, wet containers
Disposable gloves	hand protection
Paper tape	fasten shoe covers, etc.
Forceps, tongs	safe handling
Large plastic bags	for contaminated material
Sponges, 4x4	sopping up
Paper towels	blotting and drying
1 box Dial soap	wash-up
Scouring powder	friction (cleaning surfaces and other people)
Tags	identification
Scissors	cut absorbent paper, etc.
Cotton tip applicators	taking swipes following decontamination
Chux	cover area during decontamination
G-M survey meter*	monitoring in Nuclear Medicine
4 scrub suits	surgical scrubs suits wear for cleanup
2 markers	writing
1 legal pad	recording
Red bags	contaminated goods
Water soluable bags	contaminated linens, etc.
Yellow bags	contaminated linens, etc.

CONTROL NO. 78367

* Survey meter is located in Nuclear Medicine Department

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DATE January, 1984 PAGE 1 OF 1

RIA

Area Survey Procedure:

1. Area room surveys will be performed monthly with our Victoreen CDV-700 #6A survey meter, in designated departments. Readings below 0.5 mr/hr have been designated acceptable and will not be recorded.

2. Wipe tests and supplemental room surveys will be conducted periodically by R.I.A. Lab personnel in their own department.

3. Permanent records will be maintained.

Unit Dose System:

As of September 1, 1975, the radioactive unit dose system as supplied by Pharmatopes* Inc., became effective. All radioactive waste accumulated prior to that date was disposed of as of 12/1/75.

All waste from September 1st, is being returned and disposed of by Pharmatopes, Inc.

Clinical Laboratory orders from Leeco & Abbott as of January, 1983.

*Pharmatopes, Inc., name changed 1983 to Syncor

Nuclear Medicine

Area Survey Procedures

1. Hot Lab. surveys will be performed daily with our Victoreen CDV-700 #6A survey meter or with our Ludlum Model 3 and recorded. Wipe tests of the following areas will be done weekly and counted either on the Beckman 300 or the Iso Data 20/10 DM well counter in the RIA Department. Any area that shows more than 2 times the background count rate will be decontaminated and re counted. Counts will also be recorded.

2. Areas to be wiped.

1. Dose calibrator
2. Inside bricks
3. Outside bricks (Hood)
4. Outside refridgerator
5. Inside refridgerator
6. Injection desk
7. Bedside table
8. Sink (camera rm.2)
9. Floor (camera rm.2)
10. Sink (camera rm.1)
11. Floor (camera rm.1)
12. Background

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Storage:

1. All radioactive materials when not in use will be stored in such a way as to preclude the possibility of inadvertent radiation exposure of individuals either from external radiations or from movement of the materials from its container into the air or in lab work areas.

2. Laboratory work areas are marked with the customary radiation signs. The Laboratory area handling radioactive materials is restricted to employees only.

3. The storage area is adequately protected by fire procedures, as is the entire hospital.

Waste Disposal:

1. Any waste (empty syringes, etc.) will be disposed of through Pharmatopes*, Inc., Toledo, Ohio (NRC License #34-16654-01 MD).

2. Contaminated material from the in-vitro testing is placed in a marked recepticle and checked daily for a safe radiation level, 0.5 mr/hr., or less. Before discarding empty tracer vials, labels will be defaced.

3. Other solid wastes will be held for decay until radiation levels as measured with our low-level survey meter have reached background levels. All radiation labels will be removed or defaced and the waste will be disposed of in the normal trash.

*Pharmatopes, Inc., name changed 1983 to Syncor.

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MERCY HOSPITAL
TOLEDO, OHIO
POLICY & PROCEDURE MANUAL

SECTION: RADIATION SAFETY MANUAL

SUBJECT: SPECIAL NURSING INSTRUCTIONS SCANNING/DIAGNOSTIC TESTS & THERAPY

DEFINITIONS OF SCANNING/DIAGNOSTIC TESTS AND THERAPY

1. Scanning or diagnostic tests are used to determine the patient's diagnosis.

   The radioactive substances that are used are of such low radioactive strength that risk to the patient, technologist, visitor, and nursing staff, is almost negligable. The only special precaution which should be undertaken concerns the handling of the patient's urine.

   If the patient is catheterized - urine should be disposed of in the toilet. Personnel handling the urine should wear rubber gloves and flush the toilet at least three (3) times, and then wash hands thoroughly. If urine is spilled; clean up with disposable, flushable material (toilet tissue, kleenex, etc.).

2. Therapy or radiotherapy is used for treating the disease, after the diagnosis has been made.

   Patients receiving more than 30 mc. (millicuries) must be admitted and the radiotherapy procedures must be followed (see page 2).

NURSING INSTRUCTIONS BEFORE TESTING

It is normal behavior for many patients to become apprehensive when they learn they are to receive a radioactive material. This is probably due largely to their lack of information about this material. Please try to alleviate their apprehension by briefly describing the appropriate procedure. Each exam will again be explained to the patient when he arrives in the department and any of this questions will be answered.

It is important that a patient lie perfectly still during a scan; more than the slightest movement will result in unnecessary dealys or an incomplete study. When a patient is unable to voluntarily lie still, as in the case of an infant, small child, comatose patient or an uncooperative neuropsychiatric patient, sedation is imperative. Please ask the patient's physician to order adequate sedation to assure completion of the examination; it is preferred that these patients be completely asleep.

PATIENT'S CHART MUST BE SENT - Please send patient's chart for every exam. If the proper patient preparation has not been given, be sure that we are notified of this fact.

PATIENTS WITH SPECIAL NEEDS - We should also be informed when a particular patient has special needs, i.e., epileptic, critical, or comatose patients, patients whose urine has to be saved or measured, or patients with emotional problems. With this notification in advance, we may be able to save misunderstandings at a later date.

NOTE: These instructions have been incorporated into the Nursing Care Manual, Code

ORDERS REGARDING PATIENTS TREATED WITH THERAPEUTIC AMOUNTS OF RADIOACTIVE MATERIALS

Therapeutic amounts of radioactive materials are always administered in the patient's room by an NRC licensed physician. RIA Lab personnel will add this sheet of instructions to the patient's chart, inform the nursing personnel, and post notices on the door to the patient's room.

_____ of radioactive _____ has been administered

to _____ at _____ AM/PM on _____
time date

These isolation procedures will be followed immediately:

1. Prior to administration of radioactive material the patient will be placed in a private room with bathroom facilities in the room, preferably away from other patients and routine work areas. Hospital pajamas will be issued and used throughout the patient's stay in isolation. All large surfaces likely to be contaminated (especially with urine) will be covered with Chux.

2. Each person entering the patient's room must wear a poket dosimeter (obtained at the nursing station) and record readings before entering the upon leaving the room. These forms are avaiable at the nursing station.

3. No pregnant personnel may enter the patient's room at any time.

4. No pregnant visitors or visitor under the age 18 are permitted. Visitors are restricted to the carpet area of the room and to amount of time spent in the room. Visiting instructions will be posted on the door. (The amount of time visitors are allowed in the room is computed by the physician on an individual basis and posted on the door.)

5. No pregnant patients are to be put into adjacent rooms.

6. Disposable materials will be used whenever possible: plastic utensils and paper products, etc. All vomitus, secretions from mouth and lungs, trays, syringes and needles, linens, dressings, gloves, etc., will be retained until checked by RIA personnel. Chux will be stored separetly. Feces and urine may be disposed of in the usual manner. If patient is bedridden or incontinent, an indwelling catheter must be used. Urine from catheter will be emptied frequently and bed pan rinsed thoroughly, at least 3 times. Use gloves when in direct contact with the patient. If urine is spilled, clean with disposable materials and tape a Chux (pad side down) over the area until decontaminated bu RIA personnel.

7. RIA personnel will survey room and all materials therein daily. Records of surveys will be kept in the Radiation Safety Officer's office, RIA and on patient's chart. All materials will either be stored until levels of contamination are below acceptable limits, or disposed of properly.

(over)

8. The patient will be discharged when the remaining quantity of radioactivity is below thirty (30) millicuries, or the survey meter readings are less than 1.8 milliroentgens per hour at 1 meter from the patient, as determined by the physician doing the treatment.

9. The room will not be assigned to another patient until cleared by the Radiation Safety Officer, or his designee.

10. Dosimeters, dosimeter reading records, and signs will be collected at the time of the final room survey.

11. In the very unlikely event that a patient who has received therapeutic smounts of radioactivity expires, notify the Radiation Safety Officer and the RIA Laboratory immediately at extension 1373.

12. If the patient must be moved, maintain isolation as much as possible during the move.

13. Call RIA Laboratory with any questions that may arise concerning these instructions, extension 1373.

John F. Brunner, M.D.

John E. Brunner, M.D.
Director, RIA Laboratory

Gunvantray B. Mehta, M.D.
Radiation Safety Officer

September 1983 update
and March/1984

NURSING INSTRUCTIONS ON THERAPY PATIENTS

Patient's Name: _____

Room #: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mRem/hr

Date	3 feet from the 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. Pocket dosimeters must be worn.

___7. Tag the following objects and fill out the tag:

___door ___chart

___bed ___wrist

___8. Gloves must be worn while attending patient.

___9. Patient must use disposable utensils.

___10. All items must remain in room until approved by the Radiation Safety Officer, or his designee.

___11. Smoking is not permitted.

___12. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

___13. Other instructions: _____

_____

In case of emergency contact:

RSO _____ / _____

Name On-duty/Off-duty telephone number

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES
(Xe-133)

1. Quantities to be used.

   A. Patient information
      1. 10 studies per week.
      2. 10 mCi per study

   B. Possession Limit: 500 mCi

2. Use and storage areas.

   A. Xenon will be used in the two camera rooms and stored in the fume hood as indicated in the attached diagram. The camera room doors will be closed during Xenom procedures.

   B. Air supply to each camera room is 300 cfm. Supply to the hot lab is 110 cfm. The ventilation exhausts 400 cfm from each of the camera rooms. This ventilation exhausts continuously, 24hrs/day, 365 dayd/year, at roof level with no recirculation of air. The exhaust for the hot lab is 220 cfm. This is also continuously exhausted at roof level with no recirculation of air.

   C. The camera rooms and hot lab are at negative pressure at all times. The ventilation will be checked semi-annually to assure that the exhaust rates have not decreased and to assure negative pressure in the hot lab and camera rooms. The ventilation measurements of 1-18-85 are shown on the attached figure.

3. Procedure for routine use.

   A. The Xe-133 gas will be used in the following manner: the dose will be assayed in the dose calibrator. The patient will be instructed on the details of the procedure with special emphasis on the areas where their cooperation is needed. Just prior to the study one or more practice runs will be performed before the Xenon gas is used. The unit dose will be loaded in the shielded dispenser and then taken to the camera room for the procedure. The technologists will be wearing film badges and thermoluminescent ring dosimeters during the entire procedure. This procedurd is a three phase process: inspiration and holding of breath, equillibrium, and washout. The expired Xenon and any remaining Xenon will be drawn directly into the Xenon trap. The Pulmonex delivery system (Model 130-500) will be used for the procedure. If the Pulmonex is temporarily out of service, The Medi-Physics V.S.S. system will be used. The collection bag will be vented in the hood of the hot lab. Manufacturers instructions will be followed

for the Pulmonex system. Nose clamps or a face mask will be used to prevent the patient from exhaling the Xe-133 into the room.

B. The great majority of the expired Xe-133 will be trapped in the Pulmonex trap, however, the exhaust from the trap will be checked weekly or after every 40 patients, which ever occurs first, for efficiency. The trap test will be performed by attaching the Pulmonex, at the exhaust port, to the Xenalert with a piece of flexible tubing. If it is calculated that more than 25% of the administered dose is not trapped the trap will be replaced.

4. Emergency Procedures
If an accidental release of Xe-133 occurs during a patient study, the following procedure will be performed:

A. Notify all persons in the area to evacuate the room at once.

B. The door to the hallway will be closed.

C. The room will remain unoccupied for 10 minutes. Upon re-entry, all areas in the Nuclear Medicine Department will be surveyed with a G-M Survey Meter to insure that the radiation levels are not above background levels.

5. Air concentration of Xe-133 in restricted areas.

A. Hot lab
100 mCi /week
0.25 escape fraction
220 CFM, exhausted continuously

$C = (A \times F)/V$

$= (1 \times 10^5$ uCi/week x 0.25) / (220 CFM x 6.8×10^7 ml/ 40 hr. wk.)

$= 3.98 \times 10^{-7}$ uCi/ml*

B. Camera rooms
50 mCi/week
0.25 escape fraction
400 CFM exhaused continuously each

$C = (A \times F)/V$

$= (1 \times 10^5$ uCi/week x 0.25)/400 6.8×10^7 ml/40 hr. wk.

$= 4.6 \times 10^{-7}$ uCi/ml*

6. Air concentrations in unrestricted areas.

5200 mCi / year
0.25 escape fraction
1560 CFM exhausted continuously

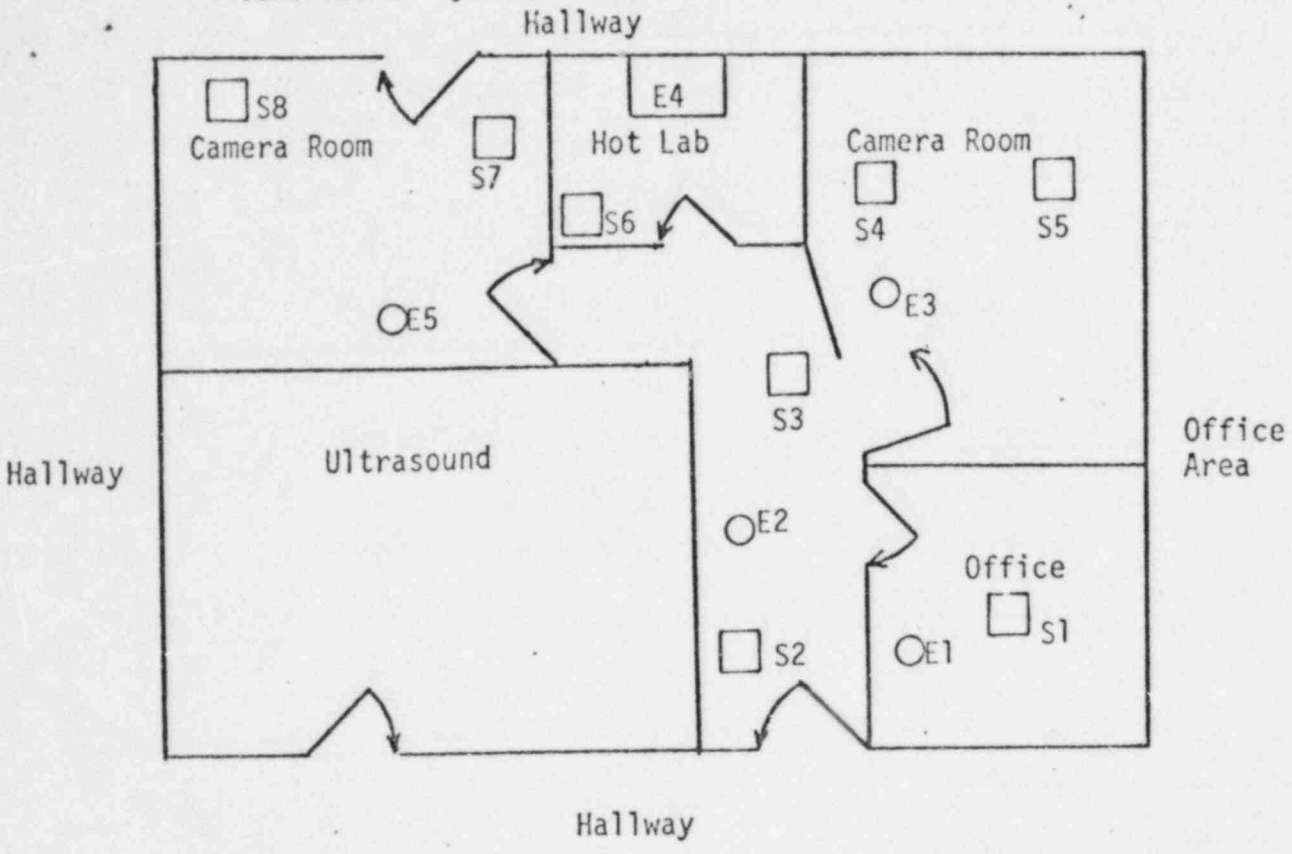
$C = (A \times F)/V$

$= (5.2 \times 10^{6}$ uCi/year x 0.25)/1560 CFM x 1.48×10^{10} ml/yr

$= 6.3 \times 10^{-8}$ uCi/ml**

* This is below the restricted area limit of 1×10^{-5} µCi/ml.
** This is below the unrestricted area limit of 3×10^{-7} uCi/ml.

MERCY HOSPITAL
Toledo, Ohio
Ventilation System Measurements for Nuclear Medicine Department



Location	Design CFM	Measured CFM
S1	185	193
S2	85	88
S3	90	88
S4	150	170
S5	150	176
S6	110	70
S7	150	170
S8	150	170
	Total Supply	1125
E1	185	282
E2	175	318
E3	400	424
E4(Hot Lab Hood)	220	518
E5	400	494
	Total Exhaust	2036
	Net Flow	-911

Measurements made with Alnor velometer, Model Velometer Jr.

Measurements performed on: 1-18-85

Measurements performed by: James Campbell

James Campbell

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#21

AIR BALANCE REPORT

AREA SERVED NUCLEAR MEDICINE BUILDING OMOM SECTOR A

SYSTEM AHU #3 - SUPPLY AIR DATE 1/18/85

TECHNICIAN'S NAME ARMSTRONG/CAMPBELL

ROOM		DESIGN		TEST	TEST	FINAL	
DESCRIPTION	NUMBER	% OF TOTAL	CFM	1	2	% OF TOTAL	CFM
W. SCAN	2108.4	14.0	150			15.1	170
W. SCAN	2108.4	14.0	150			15.63	176
E. SCAN	2108.2	14.0	150			15.1	170
E. SCAN	2108.2	14.0	150			15.1	170
HOT LAB	2108.3	10.3	110			6.25	70
CORRIDOR	2108.0	8.4	90			7.81	88
CORRIDOR	2108.0	8.0	85			7.81	88
OFFICE	2108.1	17.3	185			17.19	193
TOTALS		100.0	960			100.0	1125

COMMENTS: TOOLS USED: CAMBRIDGE HOOD WITH ALNOR VELOMETER.

AIR BALANCE REPORT

AREA SERVED NUCLEAR MEDICINE BUILDING DMOM SECTOR A

SYSTEM EXHAUST FAN # A0 DATE 1/18/85

TECHNICIAN'S NAME ARMSTRONG/CAMPBELL

ROOM		DESIGN		TEST	TEST	FINAL	
DESCRIPTION	NUMBER	% OF TOTAL	CFM	1	2	% OF TOTAL	CFM
OFFICE	2108.1	13.4	185			13.87	282
CORRIDOR	2108.0	12.6	175			15.61	318
E.SCAN	2108.2	29.0	400			20.81	424
HOT LAB	2108.3	16.0	220			25.43	518
W.SCAN	2108.4	29.0	400			24.28	424
TOTALS		100.0	1380			100.0	2036

COMMENTS: TOOLS USED: CAMBRIDGE HOOD WITH ALNOR VELOMETER. THE HOT LAB HOOD WAS MEASURED WITH A FLORITE VELOMETER. THE NUCLEAR MED. AREA IS NEGATIVE to THE ADJACENT CORRIDOR.

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APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Mercy Hospital

(Licensee's Name)

2-22-85

(Date)

1. 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 is 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 judgment, 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.

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

2. 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 ensure 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/her 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.

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

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.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal 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 Section 6).[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.

3. 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 Section 6 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 ALARA Program

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

(2) The RSO will ensure 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.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(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 will encourage 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, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. 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 Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

[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 investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

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

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

6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	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 required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

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 0-1 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 and will report the results of the 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, will 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 RSC 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. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

In cases where a worker's or a group of workers' 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 RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

David C Renton
Signature

David C. Renton
Name (print or type)

Assistant Administrator
Title

Institution (or Private Practice) Name and Address:
Mercy Hospital
2200 Jefferson Ave.
Toledo, Ohio 43624

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

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