NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved by OMB 3150-0047

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

Ponce District Hospital
Machuelo Road 14
Ponce, PR 00731

TELEPHONE NO.: AREA CODE (809) 844 2080

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

Evelyn Cintrón Ruiz, M.D.

TELEPHONE NO.: AREA CODE (809) 844-2080 ext: 246, 310

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. SNM 1363

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

Evelyn Cintrón Ruiz, M.D.

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.)*

Evelyn Cintrón Ruiz, 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	–	–
10 CFR 35.100, SCHEDULE A, GROUP I	–	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	–	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	–	–
10 CFR 35.100, SCHEDULE A, GROUP IV	–	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	–	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	–	–

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

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Plutonium 238	sealed source in cardiac pacemaker	150 mgs 1 source of 150 mgs Pu 238 (2.5 ci in 1972)	Implantation in humans (Cardiac pacemaker) -already implanted in a patient-

5/3/85 apr 811 Brown

5/9/85

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8507050264 850530
REG2 LIC70
SNM-1951 PDR

FEE EXEMPT 170.11(a)(4)

50578 Rec'd

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	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or _____ *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE Board of N.Med.	
	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	
X	Appendix D Procedures Followed for Survey Instruments; or _____ *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or _____ *(Check One)*
	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 Appendix E
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	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)* No	
	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES No	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or _____ *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133) No	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS No	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached Cardiac pacemaker with Pu 238

24. PERSONNEL MONITORING DEVICES

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

Please, send written request of fee, to request payment from Hosp. Administration Office.

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

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Evelyn Cintrón Ruiz MD

(1) NAME *(Type or Print)* Evelyn Cintrón Ruiz MD

(2) TITLE Nuclear Medicine Physician

c. DATE April 25, 1985

NRC FORM 313M (9-81)

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
Evelyn Cintrón Ruiz, M.D.	Puerto Rico

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Copy of Board certificate enclosed.		

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			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

RECEPTOR 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		
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

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

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

8. DATE

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-913

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

STREET ADDRESS

CITY | STATE | ZIP CODE

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			

6 (b) Plutonium 238 source in a nuclear pacemaker already implanted in nov. 4, 1975 to patient Gregorio Cruz Rodríguez case no. 3-40-91 with a clinical diagnosis of Sick Sinus Syndrome with bradycardia. The patient is followed at the cardiology outpatient clinic and at the Nuclear Medicine Section every 6 to 12 months. He is evaluated as to presence of symptons suggestive of pacemaker malfunction. A physical exam is performed to evaluate cardiovascular status and the site of insertion a long lead II or complete EKG is performed to assess pacemaker capture.

When pacemaker malfunction is suspected the patient is hospitalized for complete evaluation. (He was hospitalized in Feb 1980 because of dizzy spells. Pacamaker was functioning well).

If malfunction is established surgical exploration is performed to asess if failure of electrodes or failure of pacemaker generator. (These had been performed with 2 previously implanted nuclear pacemakers in other 2 patients. Patient is also examined at the Nuclear Medicine Department for activity (mr/hr) present at the site of pacemaker and at opposite site. Records are kept of all examinations.

Patient carries his identification card with him at all times.

RADIATION SAFETY COMMITTEE

Membership Requirements according to Nuclear Regulatory Commission Enforcement Policy 47, FR 9987 (May 9, 1982); 47, FR 401, 150 (Sept 13, 1982), and NRC Title 10, 35.11 (b).

1. Representative of the institution management:
   Hospital administrator (or medical director)
   name Nilda R. Camacho, FACHA
   specialty Hospital Administration
   Position Administrator
   Ponce Regional Hospital

2. Representative of the nursing staff:
   Hospital nurse supervisor
   name Juanita Marietti, R.N.
   specialty registered nurse
   Position Hospital nurse supervisor

3. Authorized user in licence (Nuclear medicine physician)
   name Evelyn Cintrón, M.D.
   Position Director-Nuclear Medicine

4. Radiation physicist
   name Mr. Daniel Torres
   specialty Radiation Physics
   Position Consultant

Radiation Safety Committee

NCR Chapter I 35.11 Specific licence for human use.

(b) appoint a radiation safety committee to

1-over see the use of licence material through out the institution.

2-review institution radiation safety program.

Membership of the committee(at least to include)

1-authorized user for each type of use permitted by the licence.

2-a representative of the nursing staff

3-a representative of the institutions management

4-a Radiation safety officer

Committee:

1. Name and specialty of members
2. Frecuency of meetings (quarterly)
3. Responsibility and Duties

(as described in appendix B or submit a description)

ISOTOPE COMMITTEE FUNCTIONS AND RESPONSIBILITIES GOVERNING THE USE OF RADIOPHARMACEUTICALS AT THE PONCE DISTRICT HOSPITAL

Responsibilities:

1. Approve or disapprove experimental or non-routine use of radioisotopes before licence is applied for such use, as well as proposals for diagnostic and therapeutic use of radionuclides.

2. Prescribe conditions required for a proposed use of radiopharmaceuticals such as physical examinations, training, experience of others, special equipment that is necessary.

3. Receive and review radiation safety records and reports. Review occupational radiation exposure quarterly and ensure that radiation occupational exposure is as low as reasonably acceptable.

4. Make recommendations to correct radiation safety infractions; formulate training program for safe use of radioisotopes.

5. Maintain record of actions taken by the committee.

6. Inform of any changes in the committee membership.

7. The Services of the Consultant(radiation physicist) will be used for inservice education, and refresher training to all personnel (trained and ancillary) annually; and for yearly instrument calibration.

8. Review the entire radiation safety program annually to determine that all activities are conducted safety in accordance with NRC licence.

9. The Committee should meet quarterly.

Administrative Procedures:

1. Make revision of radioisotope program as needed.

2. Review and keep up to date a nuclear medicine procedure manual of all diagnostic studies done.

3. Give instructions and laboratory rules to personnel using radioisotopes at the institution.

4. Give instructions regarding radiation safety to hospital personnel and patients during radioisotope therapy.

5. Maintain written records of receipts, transfers, and disposal of radioisotope; keep inventory of total quantity of material available at the institution; keep record of regular radiation surveys, calibrations and maintenance of equipment. Keep records of occupational radiation exposure.

6. Keep record of meetings, decisions, and recommendations.

7. Prepare a radiation safety program.

8. Dr. Evelyn Cintrón will be responsible for day to day radiation safety program.

APPENDIX B

MEDICAL ISOTOPES COMMITTEE*

Responsibility

The committee is responsible for :

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

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

Duties

The committee shall:

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

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

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

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

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

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and 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 medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

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*A rule is expected in 1981 that would change the name, composition, and functions of this committee.

The American Board of Nuclear Medicine

Incorporated 1971

A conjoint Board organized with the sponsorship of the American Board of Internal Medicine, American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine hereby certifies that

Evelyn Cintrón Ruiz, M.D.

has met the requirements of this Board and is certified as qualified to practice as a specialist in all aspects of clinical and laboratory

Nuclear Medicine

including but not limited to Radiobioassay, Nuclear Imaging, in Vivo Measurements & Therapy with unsealed Radionuclides.

Joseph F Ross MD
CHAIRMAN

S. A. Goldstein
SECRETARY

03918
NUMBER

10/27/76
DATE

J. SVAREN

RADIATION DETECTION INSTRUMENTS

NAME	MODEL
1. Nuclear Chicago Median Dose Calibrator	Model N. 6372
2. Deluxe isotope Calibrator II Victoreen	Model 34056 1 uci to 2 curies
3. Victoreen Cutie pie Survey meter	Model 740 D range 0-2,500 mr/hr.
4. Portable survey meter Contamination meter	Technical Associates Model TBM-3 Range 0-15 mr/hr 0-50,000 CPM
5. Nuclear Chicago 2" Scintillation Well counter	Model DS-202 v Scintillation detector with 8166 Decade scaler with dual timer
6. Nuclear Chicago uptake unit	Model 915 scintillation detector and Decade scaler timer Model 49-25
7. Picker dynaCamera 4/15/37 Whole Body System Dual Isotope with auto peak:	
8. MDS Computer system 10,000 Basic A2 Mobile system	
9. Automatic Processor- Kodak M6 aW	

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: PORTABLE METER TECHNICAL ASSOCIATES

Manufacturer's model number: TBM- 3

Number of instruments available: 1

Minimum range: 0 mr/hr to 0.17 mr/hr

Maximum range: 0 mr/hr to 17.0 mr/hr

b. Manufacturer's name: VICTOREEN CUTIE PIE

Manufacturer's model number: MODEL 740-D

Number of instruments available: 1

ranges: 0-2,500 MR/HR

Minimum range 0 mr/hr to 25 mr/hr

Maximum range 0 mr/hr to 2,500 mr/hr

2. Dose calibrator

Manufacturer's name: Victoreen

Manufacturer's model number: 34056 Deluxe Isotope Cal. II

Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.

4. Other

CALIBRATION OF EQUIPMENT

Method: According to Regulatory Guide 10.8 Preparation of Medical Programs, Appendix D, Sections 1 and 2, calibration of instruments.

A. Uptake and measurement equipment:

Equipment will be checked daily with Cesium 137 standard sources containing 0.1 uci and 1.21 uci. Counts per minute per microcurie of iodine tracer will be determined for thyroid uptake unit when used in uptake tests.

B. Frecuency of calibration of dose calibrator

1. Instrument constancy-daily.
2. Instrument accuracy-at installation and annually.
3. Instrument Linearrity, at installation and quarterly.

C. Standards used in calibration

1. constancy- Co 57 Standard of at least 1 mci
   Cs 137 200 uci source

2. accuracy- Cs 137 200 uci standard
   Co 57 5 mci Standard NES-206 Vial E (by New England Nuclear)

3. Linearity- first elution of new Tc generator

CALIBRATION OF SURVEY METERS ACCORDING TO APPENDIX D, SECTION 1: CALIBRATION OF INSTRUMENTS, REGULATORY GUIDE 10.8: GUIDE FOR PREPARATION OF MEDICAL PROGRAM

3. C. Survey instruments will be calibrated by a consultant: Mr.Daniel Torres, Radiation physicist and Safety Officer at the Medical Center in Mayaguez, Puerto Rico. Lic no. 52-18306. Also refer to Licence no.52-11832-01 Ponce Oncologic Hospital.

4. Calibration sources:

Co- 60	10 Ci (Calibrated by N.B.S.)
Ra- 226	10 MCi (Calibrated by N.B.S.)
Cs- 137	100 MCi(Calibrated by N.B.S.)
Cs- 137	200 uci supplied by New England Nuclear (calibrated by direct comparison with NBS standard) NES-206

5. The calibration procedures in Appendix D Section 1 will be used.

Sources of Cs-137, Ra-226 and CO-60 are appropriate for the performance of calibration. The activity of the standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1R/hour.

APPENDIX D

Section 1

METHODS FOR CALIBRATION OF SURVEY METERS, INCLUDING PROCEDURES, STANDARDS AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.
2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.
3. The frequency shall be at least annually.
4. Each scale of the instrument shall be calibrated at approximately 1/3 and 2/3 of full scale.
5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within $\pm$ 20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

NOTE: Sources of Cs-137, Ra-226, or Co-60 are appropriate for the performance of calibration. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hour.

B. A reference check source of long half-life, e.g. Cs-137 or Ra D and E, shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use.
2. After each maintenance and/or battery change.
3. At least quarterly.

If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration. The instrument should be recalibrated (see Step A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure in the I-125, Xe-133, or Tc-99m energy ranges.

This calibration may be done either:

1. As in A. above with calibrated standards of radionuclides at or near the desired energies, or
2. As a relative intercomparison with an energy independent instrument and uncalibrated radionuclides.

10

D. Records of the above, A, B-2, B-3, and C must be maintained.

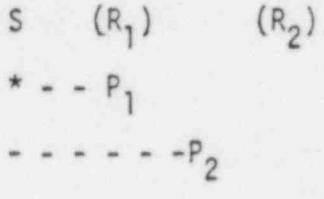
E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.

   a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distance.

   b. The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

2. INVERSE SQUARE LAW



Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2}{(P_2)^2} \times R_1$$

where (a) S is the point source

(b) R_1 and R_2 are in the same units (mR/h or R/h)

(c) P_1 and P_2 are in the same units (cm, meter, feet etc.)

3. RADIOACTIVE DECAY LAW:

Exposure rate t units of time after specified calibration date:

$$R_t = R_o \times e^{-\left[\frac{0.693}{T_{1/2}} \times t\right]}$$

where (a) R_o and R_t are in the units (mR/h or R/h):

(b) R_o is exposure rate on specified calibration date

(c) R_t is exposure rate t unit of time later

(d) $T_{1/2}$ and t are in the same units (years, months, days, etc.)

(e) $T_{1/2}$ is radionuclide half-life

(d) t is number of units of time elapsed between calibration and present time

4. Example: Source output is given by calibration certificate as 100 mR/h at 1 foot on 10 March 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on 10 March 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}} = 100 \times 0.77 = 77 \text{ mR/hr}$$

at 1 foot on 10 March 1977.

b. Output at 3 feet, 2.0 years after calibration date:

$$R_{3 \text{ feet}} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr} = \frac{1}{9} \times 77 = 8.6 \text{ mR/hr}$$

at 3 feet, 2.0 years after calibration.

12

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items

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

_____ 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

_____ 3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(i) Calibration source
Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

(ii) The calibration procedures in Appendix D, Section I will be used.

or

(iii) The step-by-step procedures, including radiation safety procedures are attached.

_____ c. By a consultant or outside firm

(i) Name _____

(ii) Location _____

(iii) Procedures and sources

_____ have been approved by NRC and are on file in License No. _____

_____ are attached

18

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

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

or

_____ other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests:

Radionuclide	Activity (mCi)	Accuracy
57 Co ✓	_____	_____
133 Ba	_____	_____
137 Cs ✓	_____	_____
other	_____	_____

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

or

____ Equivalent procedure are attached.

*Must be equivalent to the highest activity used.

Item No. 10
Date: _____

13

APPENDIX D

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument linearity (at installation and quarterly)
2. Geometrical variation (at installation)
3. Instrument accuracy (at installation and annually).

B. After repair or adjustment of the dose calibrator, repeat all of the appropriate tests listed above (dependent upon the nature of the repairs).

C. Daily or before each use of the the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment or recalibration.

2. Measure and record the apparent activity of a long-lived standard radionuclide such as Cs-137 or Radium-226 at all of the commonly used radionclide settings (when the unit was first calibrated against NBS-traceable standards). Choose a source with activity in the 100 μCi range

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufactuer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.

2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

3. Using the 30 hour activity measurement as a starting point calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time (hrs.)	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

Example: if the net activity measured at 30 hrs. was 15.625 millicuries, then the predicted activity for 6 and 48 hours would be 15.625 mCi x 16 = 250 mCi and 15.625 mCi x 0.125 - 1.95 mCi respectively.

4. Plot the measured net activity for each time interval versus the predicted activity on log-log graph paper.

5. The activities plotted should be within $\pm$ 5% of the predicted curve if the instrument is linear and functioning properly. Errors greater than $\pm$ 5% indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured, or to use the graph constructed in step 4 to relate measured activities to true activities.

G. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than $\pm$ 2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with volume of liquid, a 30 cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20 and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1.

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy) and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor.

   Example: if activities of 2.04, 2.02, and 2.00 mC are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected, then

$$\text{4 ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x CF

   Where the CF used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30 cc vial and a correction factor calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as I-125. Hence adequate correction factors must be established for this type of syringe.

   An alternate to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

H. Test For Instrument Accuracy

The accuracy of the dose calibrator should checked for several radionuclides such as Cs-137, Co-57, and Ba-133 using appropriate reference standards whose activity is traceable to NBS. The

activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within $\pm$ 5% after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks which do not agree within $\pm$ 5% indicate that the instrument should be repaired or adjusted. If this

is not possible a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated with the NBS traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument calibration at each settings (after correcting for decay of the long lived source), without requiring more NBS traceable standards. Keep a log of these initial and subsequent readings.

I. Test for Instrument Constancy

Two reference sources such as Cs-137 and Co-57 should be assayed using a reproducible geometry before each daily use of the instrument.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).

2. Measure background level at same instrument setting.

3. Calculate net activity of each source subtracting out background level.

4. For each source plot net activity versus the day of the year on semi-log graph paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based upon decay calculations and the ± 5% limits on the graph as illustrated.

7. Repeat the procedure for the Cs-137 source for all of the commonly used radionuclide settings.

8. Variations greater than ± 5% from the predicted activity indicate the need for instrument repair or adjustment.

9. Higher than normal background levels should be investigated to determine their origin and eliminated if possible by decontamination, relocation, etc.

Facilities and equipment

Facilities located on fifth and upper most floor of the hospital consist of three air conditioned rooms divided as follows.

a. A storage ("hot") room which has a lead wall on two sides, containing a table covered with formica where isotopes will be kept in original lead containers shielded by 2 X 4 X 8 inches bricks; a protective lead barrier with lead glass; a table monitor, a portable monitor with range up to 2.5 R/hr, remote handling equipment, a lead shield for generators, labeled waste liquid containers shielded by lead, a lead lined refrigerator, and a lead apron.

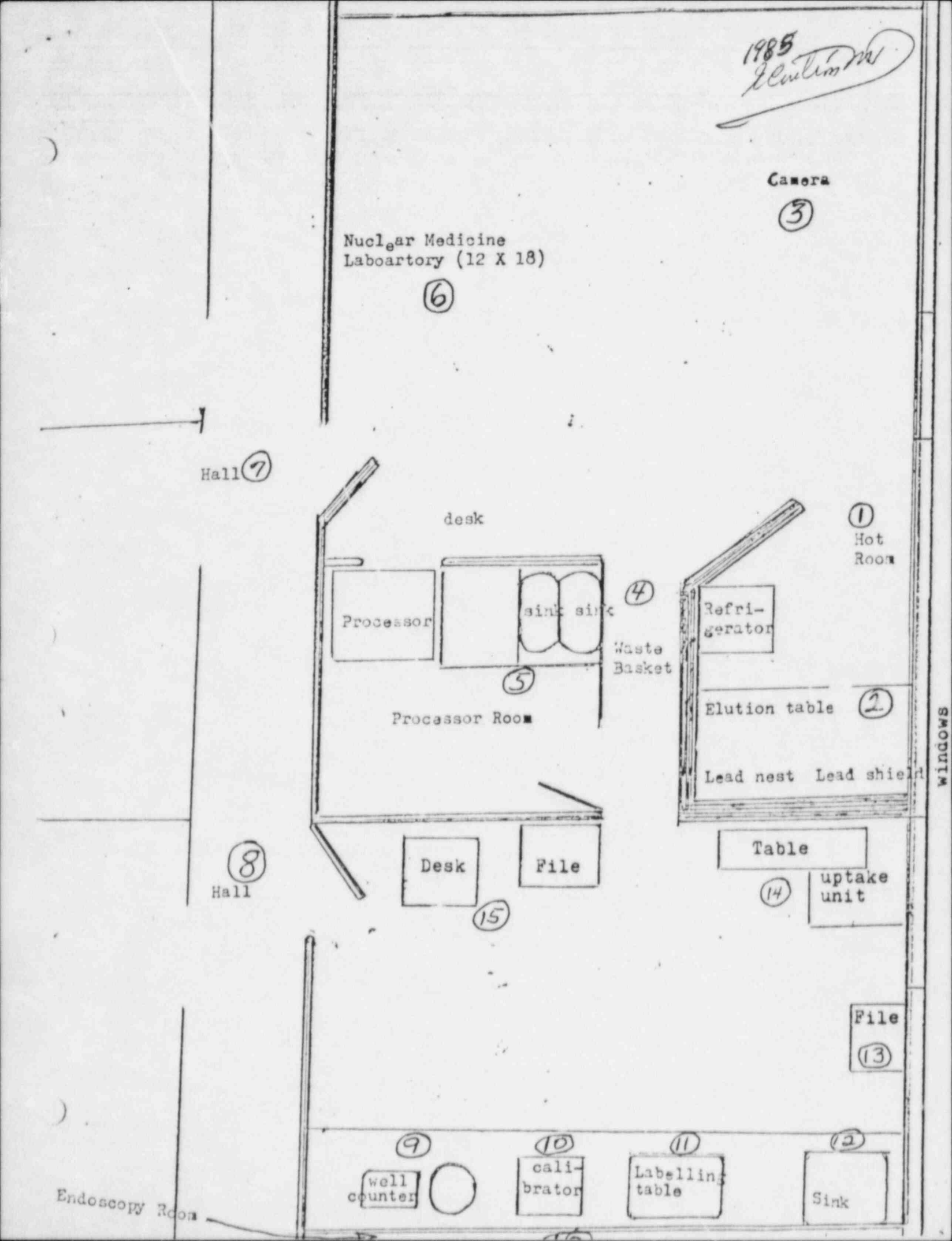
b. A diagnostic room containing Picker Dynacamera 4/15/37 Whole Body System with Mini Computer system, a portable survey meter with range up to 1 R/hr, a stainless steel waste container, physician desk, patient and isotope records.

c. A processor room with stainless steel table, two sinks with round corners, a fume extractor, and an automatic Kodak processor.

d. A counting room where doses will be calibrated, and uptakes measured, containing a dose calibrator, a well-counting scintillation detector and scaler, a thyroid uptake unit, patient record files, a portable survey meter with range up to 100 mr/hr, a desk and an examining table.

e. A small hall communicates rooms b, c and d.

f. across the hall and in front of room d, another room is available with desks use as waiting room or for interview of patients. A stretcher is available.


1985
Camera
3
Nuclear Medicine
Laboartory (12 X 18)
6
Hall
7
desk
1
Hot
Room
Processor
sink
sink
4
Refri-
gerator
Waste
Basket
5
Processor Room
Elution table
2
Lead nest
Lead shield
Table
8
Hall
Desk
File
14
uptake
unit
15
File
13
9
10
11
12
well
counter
cali-
brator
Labelling
table
Sink
Endoscopy Room
WINDOWS

IN SERVICE TRAINING FOR RADIATION WORKERS AND ANCILLARY HOSPITAL PERSONNEL ACCORDING TO 10 CFR 19:12 INSTRUCTIONS TO WORKERS IN A RESTRICTED AREA. IT WILL INCLUDE:

a. Information of storage, transfer, or use of radioactive materials or radiation in the restricted area.

b. Instructions in health protection problems, associated with exposure to radioactive materials and radiation.

c. Precautions or procedures to minimize exposure.

d. Function and purpose of protective devices.

e. Instructions in observation of provisions of Commission Regulations and licence.

f. Instructions of their responsibility to report promtly to the licencee any condition which may violate commission regulations and licence or unnecessary exposure to radiation or to radioactive material.

g. Instructions on how to respond appropriately to warning made in case of unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

h. Advise on radiation exposure records.

1. Training will also include on the job and in-service instructions in:

   a. Calibration and use of instrumentation

   b. quality control procedures for labeled radiopharmaceuticals

   c. Radiation assay measurements and Molybdenum determination

   d. diagnostic studies as to instructions and preparation of patients, purpose of procedure, new techniques or re-evaluation of performance of those already established.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL:

I Ordering

The nurse trained in Nuclear Medicine or the technologist will place orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the licence and that possession limits are not exceeded.

II A. Routinely used materials:

1. Have written record to identify isotope, compound, activity levels, supplier, catalog number, date when the radioactive material should be received in the Nuclear Medicine Facility.

2. Refer to these written records when opening and storing the radioactive shipment.

B. Materials for therapeutic use:

1. The nuclear medicine physician who will perform the procedure will give written instructions as to isotope, compound, amount of activity level, and date when it will be administered.

2. The person ordering the material will make reference to this written report when placing the order.

3. The physician written request will be referenced when receiving. opening, and storing the material.

4. Assay dose prior to administration.

C. Maintain records for all ordering and receipt procedures.

III DELIVERY OF RADIOACTIVE PACKAGES DURING NORMAL WORKING HOURS:

1. Carriers will be instructed to deliver radioactive packages directly to Nuclear Medicine Laboratory.

2. Arrival of shipments shall be notified inmediately to laboratory personnel or physician in change. Precautions should be taken to avoid unnecessary exposure to radiation. Package should be checked for spills or contamination. Records of surveys should be maintained.

3. Written instructions for opening packages with radioactive materials will be given.

IV Instructions to follow when receiving radioactive shipments during off duty hours:

Written instructions will be given. The security personnel and chief nurse supervisor will be informed of these policies and instructions. They will accept packages according to procedure outlined in memorandum sent to this personnel.

MEMORANDUM

From: Hospital Administrator
From: Nuclear Medicine Director

To: Security Personnel
Chief Nurse Supervisor

Subject: Receipt of packages containing radioactive material

Any packages containing radioactive material arriving between 3:00 PM and 7:00 AM or on Holidays, on Saturday and Sundays, shall be signed for by the Security Guard or chief hospital nurse supervisor on duty, and taken immediately to the nuclear medicine department. Unlock the door, place the package in the hot room area of the nuclear medicine laboratory, and relock the laboratory door.

Precaution: If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer (or Nuclear Medicine Physician). Ask the carrier to remain at the hospital until it is determined that neither he nor the delivery whicle is contaminated.

Radiation Safety Officer _____
Office Telephone _____
Home Telephone _____

Nuclear Medicine Physician _____
Office Telephone _____
Home telephone _____

PROCEDURES TO BE FOLLOWED WHEN OPENING PACKAGES WITH RADIOACTIVE MATERIALS

1. Inspect package visually for any sign of damage (wetness, crushed, etc.) If damage is noted, stop procedure and notify Radiation Safety Officer. Monitor External radiation levels within 3 hours after receipt during working hours or within 18 hours of receipt after working hours.

2. Put on gloves to prevent hand contamination.

3. Measure exposure rate at 3 feet from package surface and record. If activity greater than 10 MR/hr. stop procedure. Notify Radiation Safety Officer.

4. Measure surface exposure rate and record. If activity greater than 200 mr/hr. stop procedure and notify Radiation Safety Officer.

5. Monitor for surface contamination with wipe test. Notify Radiation Officer if contamination exceeds .01 uci/100

6. Open the outer package(follow manufacturers directions) Remove packing slip. Open inner package to verify contents (compare requisition, packing slips and label). Check integrity of final source container(inspect for breakage of seals or vials, loss of liquid, discoloration of package meterial). In case of therapy doses compare with physicians, written request.

7. Wipe external surface of final source container with moistened cotton-swab or wipe test smear, assay and record.

8. Monitor the packing material and packages for contamination before discarding.
   a. If contaminated, treat as radioactive waste.
   b. If not, obliterate radiation labels before discarding in regular trash.

9. Maintain records of results of cheking each package.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. Survey date:
   Time:
   Surveyor:

2. Condition of package:

   _____Ok _____wet
   _____Punctured____other
   _____Crushed

3. Radiation units of label_____mr/hr

4. Measured radiation levels
   a. Package surface _____mr/hr
   b. 3 feet from surface_____mr/hr

5. Agreement of packing slip and vial contents:
   a. Radionuclide _____yes_____no difference
   b. Amount _____yes _____no difference
   c. Chem form _____yes _____no difference

6. Wipe results: a. outer counts
   b. Final Source Container

7. Survey results of packing material and cartons __mr/hr CPM

8. Disposition of package after inspection _____

9. If NCR carrier notification required: Time _____
   Date _____
   Persons notified
   _____

PONCE DISTRICT HOSPITAL
NUCLEAR MEDICINE LABORATORY

SURVEY REPORT

RADIOISOTOPE SHIPMENT

AT ONE FOOT FROM SIDE ..... MR/h

SIDE 1 (ON CONTACT) ..... MR/h

SIDE 2 (" ") ..... MR/h

SIDE 3 (" ") ..... MR/h

SIDE 4 (" ") ..... MR/h

TOP (" ") ..... MR/h

TOTAL ACTIVITY: _____ curies

INSTRUMENT USED: _____

DATE _____

SURVEYED BY:

_____

RADIATION PROTECTION PROGRAM:

1. Isotopes will be used in a precalibrated form.
2. For short, half life isotopes obtained from generator, a dose calibrator is available for assay. Generators are kept for decay in a separate room kept locked and identified with radiation sign. Radiation sign is posted in the laboratory.
3. When radioactive shipments are received, packages should be delivered to the Nuclear Medicine Laboratory Hot Room. When processing package, use lead apron, gloves, and remote handling device. It should be checked for damage, breakage, or spills. Check outer containers for contamination, and keep records.
4. Radioisotope material will be kept in isotope lead nest, or in lead-lined refrigerator when indicated, or in isotope lead brick nest. Generator is kept behind lead shield. Prepare and dispense labeled radiopharmaceuticals behind crystal lead shield. Transport radioactive material in shielded container.
5. Solid radioactive waste should be kept in labeled waste container. Keep radioactive solutions in shielded containers, and identify by labeled compound, radioisotope, date, activity.
6. The laboratory will be surveyed regularly for contamination. Survey program will include the following:
   a) Daily routine wipe test in areas used for generator elution and isotope preparation.
   b) Laboratory survey of all areas for contamination with portable meter or wipe test weekly.
7. Personnel will be surveyed frecuently for contamination. Personnel will use film badges at all times, at chest or waist level.
8. Store personnel monitoring devices on low background area when not being worn to measure occupational exposure. Wear TLD ring badges during elution of generator, preparation, assay, and injection of radiopharmaceuticals.

9. Counting equipment, enviroment, hands, and clothes should be checked for contamination. Radiation background should be checked daily for each instrument and records kept.

10. Eating and use of cosmetics will not be allowed in the laboratory.

11. Smoking is prohibited in radioisotope laboratory areas.

12. No mouth pipetting is permitted. Automatic pipetter will be used.

13. Remote handling equipment shall be used.

14. Shielding containers will be used when handling radioactive material for calibration, or when carrying isotope from one place to another.

15. Syringe shields will be used during injection of radioactive material.

16. Rubber gloves, gowns, film badges will be used during manipulation and use of isotopes. After handling isotopes wash hands before and after removing gloves.

17. Gloves and decontamination solution should be used for washing materials.

18. In case of spills, turn off air circulation system, notify all persons in the room, and the radiation protection officer. In case of liquids, drop absorbent paper over area, mark areas with red pencil to indicate contamination. Also refer to Booklet Emergency Handling of Radiation Accidents, 1972-AEC.

19. Patients should be taken to the Radioisotope Laboratory for dose administration.

20. Each individual patient dose shall be assayed in the dose calibrator just prior to administration. For therapeutic doses, check patient's name, radionuclide, chemical form, activity, and refer to written order of physician to administer dose.

21. The registered nurse trained radioisotope technician or the Nuclear Medicine technician may calculate and administer radioisotope doses under supervision of nuclear medicine physician.

22. Female patients should be questioned for possibility of pregnancy. If condition is present, contact the attending physician. Radioactive materials will not be administered to pregnant patients.

23. Hospital personnel will receive instructions regarding protection against radiation when hospitalized patients receive radioisotopes.

24. Only authorized personnel will have access to hot room. The laboratory will be locked when no personnel is present.

25. Radiation precaution signs should be posted in areas of radiation.

26. License should be posted on Bulletin Board.

27. Manual of Nuclear Medicine procedures should be available.

RADIATION PROTECTION POLICY/PROCEDURE

Policy: To provide maximal protection against hazard to patients and personnel when using radioisotopes, by reducing radiation exposure as low as reasonably achievable.

Procedure:

1. Never expose a human being to radioactive material for demostration purposes only.

2. Never remain in hot room for more than necessary during work.

3. Always wear a film badge in Nuclear Medicine Laboratory.

4. Personnel radiation monitoring:

   1. Whole body Film badge and TLD ring services will be supplied regularly for persons working in the laboratory. Reports of radiation exposures will be evaluated by the Radiation Safety Committee. Records should be kept for each person.

   2. Your film badge radiation monitor is <u>your</u> responsability.

      a) film badge must be worn at all times on duty.
      b) when going off duty, place film badge in assigned area.
      c) note badge reading, including cumulative dosage monthly.

5. No personnel area is permitted in radiation areas unless properly badged and protected.

6. Isolate therapy patients, if hospitalized. Children are not permitted as visitors. Pregnant visitors or workers are not permitted. Other personnel and persons keep 3 feet distance from patient. Instructions are given to personnel and patients receiving therapy. Special radiation precautions will be followed.

7. Be sure proper verbal comunication with patient is available and written instructions before therapy is given regarding all these radiation precautions.

8. Know written policies or procedures for receipt for radioactive shipments, disposal, handling of radioisotopes.

9. Records:

   Keep records of all radioactive shipments; radioactive doses administered,
   disposal of radioactive wastes, calibration of equipment and date of repairs, radiation background recording and monitoring, quality control procedures.

RADIATION PROTECTION OF PERSONNEL DURING ELUTION OF GENERATORS AND HANDLING OF ELUATES:

Generator is placed behind lead brick wall. Lead apron and gloves will be used during elution. Lead lined 30 cc vial shield will be used for elution. Vials will be handled with remote device when handling radioactive material for calibration. Gamma vue syringe shileds 5, 10, 20 cc are available.

Whole body monitoring is done with film badges; and TLD ring monitors to measure extremity exposure are also available (monthly reports).

Personnel will be surveyed for contamination after elution and after preparing Tc labeled compounds.

During accidents or spills check radiation levels with survey meter. Shut off air circulation system to prevent spread of contamination. All persons in room will be notified, as well as the radiation protection officer. Use gown and gloves. Drop absorbent paper over liquid spills. Mark area with red pencil or close off the contaminated area. For dry spills, use wet absorbent paper over area with decontamination solution. If there is contamination of personnel or an individual, follow recommendations on yellow booklet "Emergency Handling of Radiation Accidents Gases- 1972" (USAEC), which is at hand. The manufacturer's procedures for elution and assay will be followed.

Written procedures for detection of Mo 99 contamination will be followed.

USE OF MOLYBDENUM 99M/ TECHNETIUM 99M GENERATORS

ELUTIONS;

Every elution will be assayed for Tc 99m activity and Mo 99 contamination using the Deluxe Isotope Dose Calibrator II Model 340056. The eluates will not be used if there is more than one microcurie of Mo 99 per millicurie of Tc 99m or more than 5 uc of Mo 99 per dose of Tc 99m administered.

ACCESORIES AND FACILITIES TO BE USED:

Mo 99 Generator in current use wil be located and eluted on a table in hot room. It will be protected with lead shield. A lead lined 30 cc vial shield will be used when eluting Tc 99m. Gamma vue TM syringes 5, 10, 20 cc are available to be used when handling doses. Lead apron and gloves will be used during milking generators. Remote handling of vial for assay of Tc 99m and Mo 99 will be used. A gamma vue vial shield (56-234) is also available.

Whole body film badges and TLD ring monitors will be used by personnel.

After their use, generators will be allowed to decay for 40 days in a separate storage room. Radiation signs will be placed at this area and on each generator. Each one will be marked with dates it may be removed from decaying area.

RADIATION MONITORING

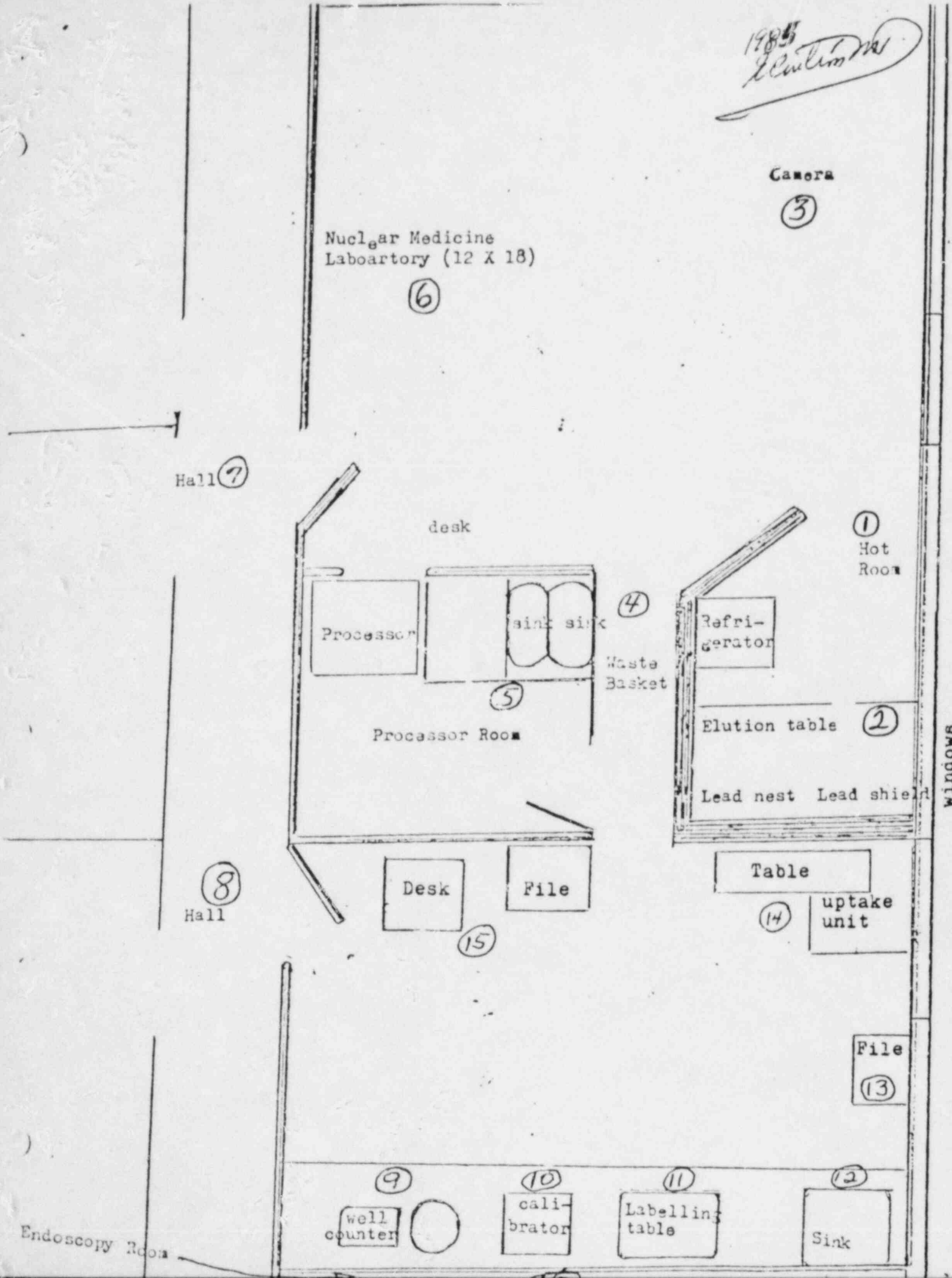
DOSIMETRY REPORTS

Film badges and TLD rings services by:

Siemens Gammasonics, Inc.
Health Physics Services
Box 1367
Des Plaines, Illinois 60018
Tel 800-323-6015

SMEAR TESTS

1. Entrance to Hot Room (Refrigerator top)
2. Hot Room (Elution table)
3. Camera imaging (Collimator face)
4. Inner hall (waste top)
5. Processor Room (sink)
6. Examining Room (area) (table or desk)
7. Hall
8. Hall- Entrance counting room
9. Well counter desk
10. Calibrator
11. Labelling table
12. Sink
13. File
14. Uptake unit
15. Desk
16. Endoscopy Room
17. Stress Test Room


1985
Camera
3
Nuclear Medicine
Laboartory (12 X 18)
6
Hall
7
desk
1
Hot
Room
Processor
sink
sink
4
Waste
Basket
5
Processor Room
Refri-
gerator
Elution table
2
Lead nest
Lead shield
WINDOWS
Table
14
uptake
unit
8
Hall
Desk
File
15
File
13
9
10
11
12
well
counter
cali-
brator
Labelling
table
Sink
Endoscopy Room

SEALED SOURCE LEAK TESTING OF RADIOACTIVE STANDARDS AT NUCLEAR MEDICINE LABORATORY

Procedure: Wipe (Smear) Test

Wipe all external surfaces of the source, including the source seal area, with a piece of H2O moistened filter paper or other suitable "swab". Measure the total activity on the paper or "swab" with an appropriately calibrated gamma scintillation counter. Care should be taken to assure proper counting time for reasonable statistical validity of values obtained. Record test results in proper source log for future reference.

In the total activity smeared from the source is less than the previous smear test, and less than 5 X 10-4 microcuries, then the source shall be considered leak free. If the total activity measured is significantly more than the previous test value, then the source should be removed from service until the source leakage can be confirmed or other source of contamination found. (even though the detected quantity may be less than that specified on the user's license for reportable source leakage). A "hot" smear should be checked every few days to determine if the activity is from a short-lived nuclide utilized nearby. If two smears at 7 day intervals reveal positive values, the source should be disposed of or returned to NEN for evaluation.

RADIATION PROTECTION SURVEY

1. Radiation protection written rules and regulations are established. They should be posted in laboratory. Check for compliance with NRC licence specifications,

2. Radiation protection surveys should be carried out every 6 months by the radiation safety Committee R.S.C.

3. Radiation protection program should be re-evaluated every three months by the radiation Safety Officer or the radiation physicist and determine if it is followed as indicated.

4. Records of receipt, stock amounts and disposal of radioactive material should be kept.

5. Records of patient identification, dose, procedure done, date, should be kept.

6. Bring to attention of personnel any non-compliance with laboratory regulations and of radiation protection program. Instruct other hospital personnel as needed. Give adequate training to laboratory personnel.

7. Determine needs of necessary radiation protection accessory equipment.

8. Check radiation monitors (portable survey meters) and calibrate annually.

9. Check personnel radiation exposure records every three months.

10. Check radiation levels of daily and weekly laboratory surveys. Establish if adequate decontamination procedure has been followed in cases contaminations or radiation spills.

11. The radiation safety committee shall work in cooperation with the hospital safety committee.

WASTE DISPOSAL

A. In older to reduce volume of radioactive waste, segregate radioactive from non-radioactive waste materials. Give instructions to laboratory personnel in this respect.

B. Solid material will be allowed to decay to background level in lead nest used for this purpose only or in lead waste container. A storage room will be used for decay of larger volume of radioactive wastes and Mo99m/Tc99m generators.

C. Generators Mo99/Tc99m will be kept for decay in the storage room and labeled with date they can be dispossed off according to half life of the isotope. The generator columm will be segregated and should be monitored separately for radiation level. If still radioactive, it will be kept for a longer time-in lead container. When it is in background levels it is dispossed in ordinary trash.

D. Liquid material will be kept in original lead protected vial and allowed to decay to background levels in lead nest. Liquids may be disposed also by release into monitory sewerage in conformance with section 20:303 part 20, Title 10 of code of Federal regulations.

E. All wastes will be surveyed prior to disposal(with all shielding removed) Records will be maintained. The Radiation Safety Committee will review and implement the adequate procedures.

DECAY-IN-STORAGE ROOM

1) Refer to diagram of area to indicate type, location, shielding available in area in order to reduce radiation levels according to 10 CFR 20.105. (Permissible levels of radiation in unrestricted areas).

2) Security measures for decay-in-storage area are specified and followed every time material is sent for storage or disposed off.

3) Radiation levels in this area will be surveyed regularly and recorded in diagram sheet.

4) Procedure for monitoring waste to assure that is has decayed to background levels prior to disposal:

   a. The waste will be monitored in a low background area.

   b. Monitor it with the G.M. survey portable meter with range 0-100 mr/hr, and using the most sensitive scale. (Survey meter appropriate for contamination levels).

   c. Remove all shielding prior to monitoring.

   d. Keep records of these surveys as required under 10 CFR 20.

   e. When waste is in background levels it can be disposed off in ordinary trash.

   f. Remove or erase all "radioactive" signs before disposal.

   g. All waste will be surveyed with all shielding removed prior to disposal.

   h. Radiation safety officer will review and implement adequate procedures.

DECAY-IN-STORAGE ROOM