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

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

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

KENNEDY MEMORIAL HOSPITAL AT SADDLEBROOK
P.O. BOX 561
SADDLEBROOK, NEW JERSEY 07662

TELEPHONE NO.: AREA CODE (201) 368-6000

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

SAME AS 1a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

WILLIAM L. PALAZZO, M.D.

TELEPHONE NO.: AREA CODE (201) 368-6000

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 29-18240-01

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

WILLIAM L. PALAZZO, M.D.
ED DAZO, M.D. (IN-VITRO)

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.)*

WILLIAM L. PALAZZO, 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	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		2000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	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	X	300
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	X	500
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

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
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and REFERENCE PREVIOUS LICENSE
	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)*
	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)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	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)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

WE THE REPRESENTATIVES OF THE HOSPITAL ARE COMMITTED TO THE ALARA PROGRAM AS PRESENTED IN APPENDIX O, OF NRC LICENSING GUIDE 10.8, REVISION I, OCTOBER 1980.

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)

PREVIOUSLY SUBMITTED

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

Paul Cardillo

(1) NAME *(Type or Print)*
PAUL CARDILLO

(2) TITLE
ASSIS. HOSPITAL ADMINISTRATOR

c. DATE
8/13/85

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

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

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

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

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

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

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

KENNEDY MEMORIAL HOSPITAL AT SADDLEBROOK

RADIATION SAFETY COMMITTEE

WILLIAM L. PALAZZO, M.D., FACR
RADIATION SAFETY OFFICER
DIRECTOR OF NUCLEAR MEDICINE

PAUL CARDILLO
ASSISTANT ADMINISTRATOR
REPRESENTING ADMINISTRATOR

MS. MARY MULVEHY, RN.
REPRESENTING NURSING

DAZO, M.D.
PATHOLOGIST

BIO-MED ASSOCIATES, INC.
RADIATION PHYSICS

ITEM 7 8/13/85

TRAINING AND EXPERIENCE

a.1. William L. Palazzo, M.D., F.A.C.R.
License # 29-01675-01
Certificate by: American Board of Radiology with special competence in Nuclear Radiology, June 1976.

Total clinical experience in Therapeutic Radiology and Isotope Therapy of 31 years, American Board of Radiology - Radiology, 1947.

a.2. Eduardo Dazo, M.D., Diplomat American Board of Pathology.

b. William L. Palazzo, M.D., F.A.C.R.

Instrumentation

Measuring Instruments

			Range
Nuclear Corp of America----------	CS 30	-1056	0- 400 mR/hr
Nuclear Corp of America----------	CS 40	1113	1mr/hr- 2 R/HR
Eberline GM meter Model E 120 ----------		2004	0.1 mr/hr---50mr/hr

Picker Isotope Calibrator Model 632507 Serial232176

Nuclear Chicago Pho Dot Rectilinear Scanner #143 (used for wipe testing)

Searle Scintiview Microdot Gamma Camera Model 035-400 000 Serial 80298 33583

CDV-700 Survey meter----------62621 --------0.1mr/hr----50 mr/hr

Calibration of Instruments

Methods for Calibration of a Dose Calibrator

All radiopharmaceuticals are assayed for activity to an accuracy of ±10%. The instrument is tested as follows:

I. Daily checks are performed using a long lived reference standard (e.g., 200uCi of Cs-137 or 1mCi of Co-57). The two standards will be alternated for the daily test. The standard reading is corrected for background and compared to the decay corrected calibrated activity. An observed deviation of greater than ±5% will warrant recalibration and/or repair. This check is performed by the nuclear medicine technician. The date, decay corrected activity, background, net standard assay, and percent deviation are logged. Deviations greater than ±5% are reported to the consultant radiation physicist for further evaluation.

II. Monthly checks are performed using each of the following long lived reference standards:

Radionuclide	Activity	Accuracy		
*Cobalt-57	5mCi	±4%	5.99mCi	Jan. 1, '82
Cesium-137	266uCi	±4%	266.1uCi	June 1, '81
Barium-133	250uCi	±4%	250uCi	May 15, '81

The standard readings are compared to their decay corrected calibrated activities as shown in the attached sample log sheet "Dose Calibrator Standard Sensitivity". A deviation of greater than ±5% on any standard will warrant recalibration or repair. This check is performed by the consultant radiation physicist. For dose calibrators employing activity concentration mode (Activity per ml.), this mode will be tested monthly employing one of the above reference standards according to the attached sample log sheet "Dose Calibrator Concentration Calculation Test". A deviation of greater than ±5% will warrant recalibration or repair. These monthly tests are performed by the consultant radiation physicist.

III. Quarterly tests are performed using a long lived reference standard (e.g., Cs-137) and recording the apparent activity indicated at all of the commonly used radionuclide settings. The source readout is compared to previous tests (correcting for decay) and a percent difference is computed. A deviation of greater than ±5% will warrant recalibration or repair. Tests of background energy linearity and condition of the chamber liner and source holder are also performed. A sample log sheet is attached specifying the "Quarterly Dose Calibrator Analysis".

IV. Tests of the instrument activity linearity are also performed quarterly employing a Tc-99m source. Only "instant" Technetium-99m is used, the largest acitivity per vial purchased will be used for the test, or largest anticipated administered dose or the largest amount used in preparation of radiopharmaceutical kits. The following specifies procedures for assaying a patient dose:

*Note: New source ordered
Co-57 (Nuclear Associates) 5mCi

1. All doses are prepared by Syncor, in single injectable syringes.

2. At the time the study is to be performed the concentration is decay corrected.

3. Prior to injection the individual dose is assayed (correcting for geometrical variation if necessary) to verify the proper activity.

The activity linearity test is performed by assaying the Tc-99m source at various times and comparing the readings to the expected decay corrected values. This is achieved by constructing a semi-log graph of the readings vs. time. (See attached sample log sheet "Activity-Range Sensitivity Check"). The graph permits data points to be plotted up to 56 hours of decay time. If more than 56 hours of decay time is required to encompass the entire range of activities administered, the data points will be compared to the calculated decay values and percentage errors computed. If the deviation between the instrument reading and decay corrected value is greater than ±5% at any point in the range of administered activities, the instrument will be repaired.

V. A one-time test is performed (usually at installation) to access the instrument accuracy with regard to geometrical variation of source containers. This test is performed with each radionuclide used. The following specifies procedures performed in the geometrical variation test:

(1) For each different vial and syringe used to contain a given radioactive material for assay, a 0.1ml aliquot (1-5mCi) of equal activity will be prepared.
(2) A 30cc vial will always be employed since each of the previously described reference standards are 20cc in a 30cc vial.
(3) Each 0.1ml aliquot will be transferred to each vial or syringe.
(4) Each vial and syringe will be diluted with water and reassayed as indicated in the attached sample log sheet "Geometrical Variation Test".
(5) All instrument readings for each volume of liquid in the vial or syringe will be divided by the reading obtained for 20cc of liquid in the 30cc vial to obtain the correction factor.
(6) The correction factor is a number to divide into the indicated instrument reading to obtain the true activity.

This test is performed by the consultant radiation physicist, who will make a determination as to whether a geometrical correction factor need be employed to assure overall ±10% accuracy. This determination will be made with regard to the magnitude of the inaccuracies encountered in the other tests, however, a geometrical correction factor greater than 4% will warrant use and less than 2% may be ignored.

DOSE CALIBRATOR STANDARD SENSITIVITY CHECK

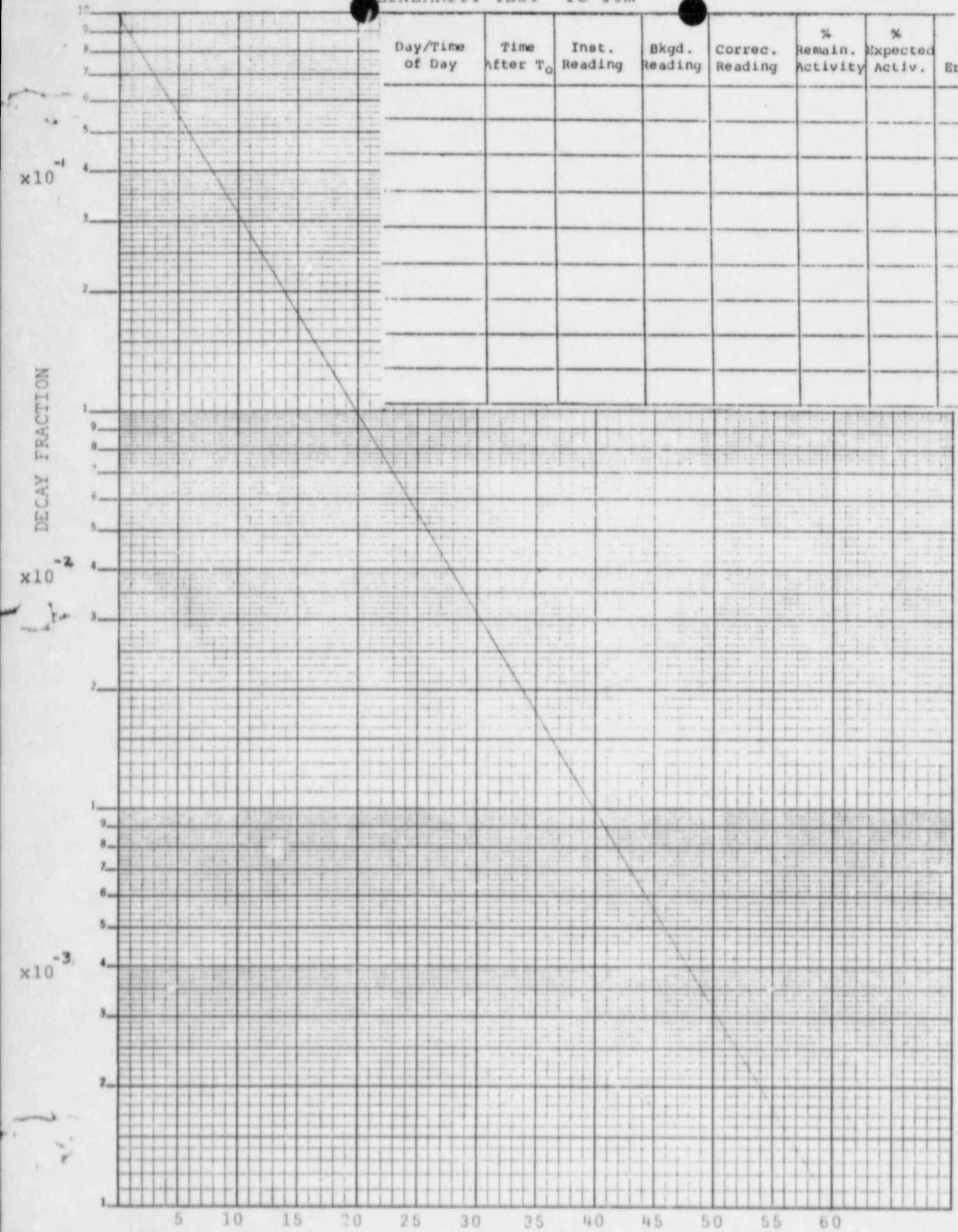
Date	Calibration Standard	Decay Factor	Decay Corrected Activity (uCi)	Background Activity (uCi)	Net Dose Calibrator Assay (uCi)	%Error From Standard	Comm

Radiological Physicist

Item 10

LINEARITY TEST Tc 99m

Day/Time of Day	Time After T_o	Inst. Reading	Bkgd. Reading	Correc. Reading	% Remain. Activity	% Expected Activ.	% Error



Item 10

Date _____

Geometrical Variation Test

Hospital: _____

Instrument: _____

Radionuclide: _____

30cc Vial

Time of Assay	Volume	Reading	Decay Corrected Reading	Correction Factor
	0.1 ml			
	2 ml			
	4 ml			
	6 ml			
	8 ml			
	10 ml			
	12 ml			
	14 ml			
	16 ml			
	18 ml			
	20 ml			1.000
	22 ml			
	24 ml			
	26 ml			
	28 ml			
	30 ml			

$$\text{Correction factor} = \frac{\text{Decay Corrected Reading @ Volume (x)}}{\text{Decay Corrected Reading @ Volume (20 ml for 30 ml)}}$$

Page 2 Geometrical Variation Test Continued

1cc Syringe

Time of Assay	Volume	Reading	Decay Corrected Reading	Correcti Factor
	0.1 ml			
	0.2 ml			
	0.3 ml			
	0.4 ml			
	0.5 ml			
	0.6 ml			
	0.7 ml			
	0.8 ml			
	0.9 ml			
	1.0 ml			

3cc Syringe

Time of Assay	Volume	Reading	Decay Corrected Reading	Correcti Factor
	0.1 ml			
	0.5 ml			
	1.0 ml			
	1.5 ml			
	2.0 ml			
	2.5 ml			
	3.0 ml			

QUARTERLY DOSE CALIBRATOR ANALYSIS

LOCATION:_____ DATE:

MODEL DOSE CALIBRATOR:_____

1. Check liner:
   a. Contaminated?____yes _____no
   b. In place? ____yes _____no
2. Check support:
   a. Intact? ____yes _____no
3. Instrument Zero:
   a. Zeroed (for Tc-99m)? _____yes ____no
   b. Adjustment necessary? _____Yes ____no
   c. Linearity acceptable? _____yes ____no
4. Lead shielded? _____yes ____no
5. Cs137 reference standard is _____uCi today. The following readings were obtained on the settings listed below:

ACTUAL READING	REF.	SETTING	CAP.	FON	PICK.	% DIFFERENT FROM REFERENCE
_____	_____	Mo-99	30x3.5	342	2133	_____
_____	_____	Tc-99	80	501	1117	_____
_____	_____	Ga-67	94	478	1139	_____
_____	_____	Co-57	112	453	1138	_____
_____	_____	I-131	151	327	1194	_____
_____	_____	Xe-133	188	497	1205	_____
_____	_____	Tl-201	205	458	____	_____
_____	_____	Cs137	220	260	1253	_____
_____	_____	Se-75	258	210	1236	_____
_____	_____	I-123	277	260	____	_____
_____	_____	I-125	319	421	0151	_____
_____	_____	Co-60	990	035	0218	_____
_____	_____	_____	____	____	____	_____

DATE OF INITIAL BASELINE MEASUREMENTS:_____, FACTOR= _____

6. Comparison of Pushbutton to Manual setting_____,_____, or N/A
7. Yes_____ No_____ Instrument was adjusted or repaired, to read ± 5%
   Yes_____ No_____ Instrument was within ±5% of previous values
   Yes_____ No_____ A correction factor was posted. It is _____
8. ACCURACY OF STANDARDS
   Decay corrected expected uCi/assay x 100 = % accuracy

Radionuclide	Test 1	Test 2	Test 3	Average
Cobalt 57	_____	_____	_____	_____
Cesium 137	_____	_____	_____	_____
Barium 133	_____	_____	_____	_____
Cobalt 60	_____	_____	_____	_____

9. COMMENTS:

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 points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

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 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

X 3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used

or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name Bio-Med Associates, Inc.

(2) Location 753 Boulevard, Kenilworth, N.J. 07033

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 29-14967-01

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

CALIBRATION OF INSTRUMENTS

Consistency Checks of Survey Meters

1. Prior to use, each survey meter is tested employing a long-lived check source in a reproducible geometry. The meter reading is noted for comparison in future tests to assure consistency of response.

2. The consultant physicist maintains a log of spot-checks on each survey meter. The variation of greater than ±20% from the initial check after calibration will warrant repair and/or re-calibration.

Equipment

Equipment located in the Nuclear Medicine department

one L-block with view glass (leaded min. of 2 mm of lead equiv.) 12" X 9" x18"

two (2) lead bricks----------2" x 4" x 8"

one Extension tongs

two (2) Syringe shields

one carrying case

two (2) lead pigs for storage of sealed sources and r/a materials 6" wide 9 " deep.

Description of Department

The Nuclear Medicine department at Kennedy Memorial Hospital at Saddlebrook (previously known as Saddle Brook Hospital) is located on the ground floor of the hospital. The department measures twenty six feet in length and sixteen feet in width. It is divided by partitions into a gamma camera room, a hot lab, and a Dr's office. Located inside a ceramic bathroom is a ceramic shower where the Nuclear waste not sent back to Syncor is stored in large leaded barrels. See waste disposal.

All Nuclear material is stored either inside leaded pigs with one inch walls or behind the L-block inside lead pigs. All other materials are stored in leaded pigs that contain the unit injectable materials.(provided by Syncor)

In referencing the enclosed facility diagram you will notice that the walls are concrete and all material is stored, handled,and assayed inside lead shields. The areas immediately surrounding the hot lab are the entrance corridor and a Doctor's office. Radiation levels to the controlled and non-controlled areas are kept to within safe ALARA levels.

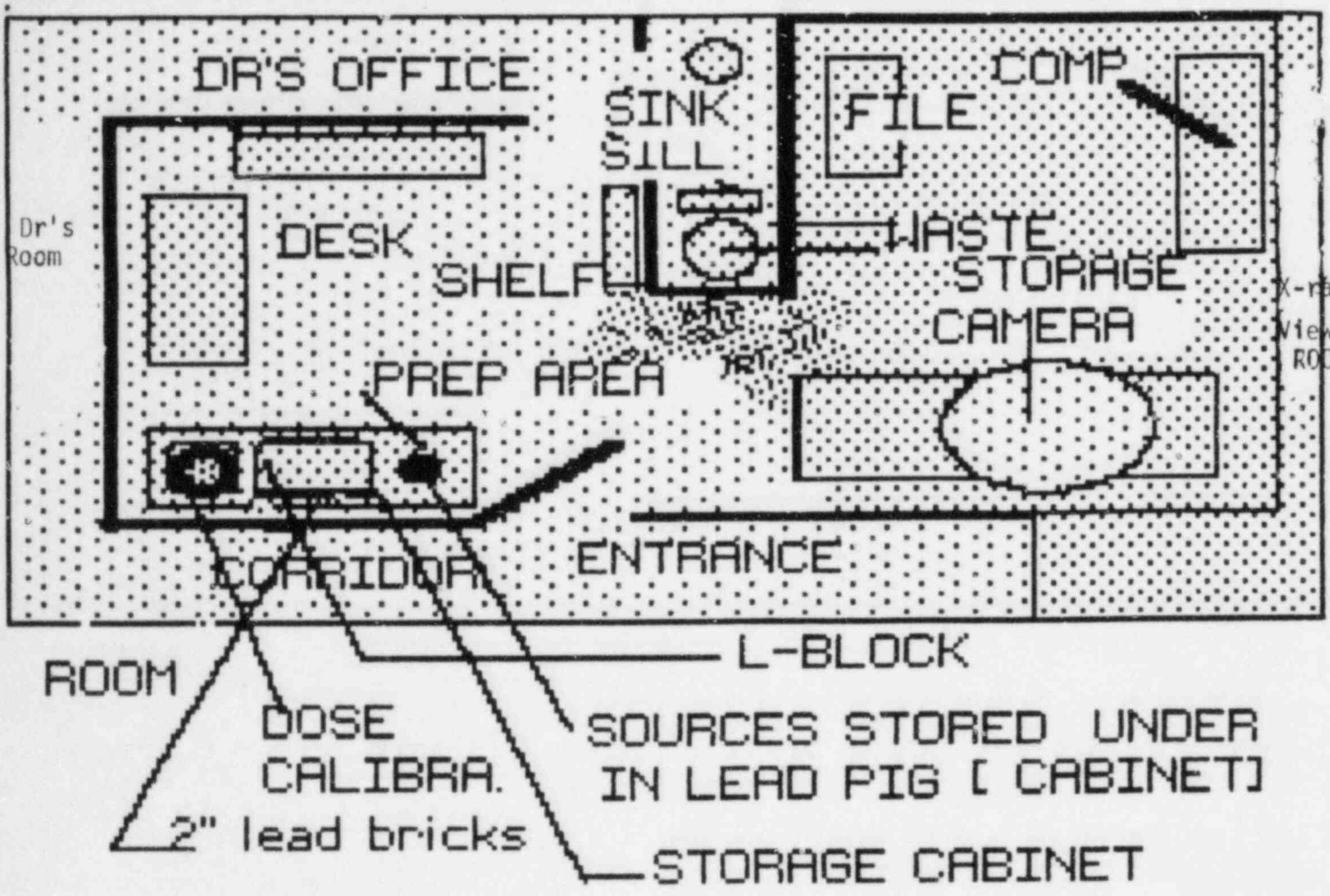
Measuring Instruments			Range
Nuclear Corp of America----------	CS 30	-1056	0- 400 mR/hr
Nuclear Corp of America----------	CS 40	1113	1mr/hr- 2 R/HR
Eberline GM meter Model E 120 ----------		2004	0.1 mr/hr---50mr/hr

Picker Isotope Calibrator Model 632507 Serial232176

Nuclear Chicago Pho Dot Rectilinear Scanner #143 (used for wipe testing)

Searle Scintiview Microdot Gamma Camera Model 035-400 000 Serial 80298 33583

Outside of Hospital



SADDLE BROOK DAILY SURVEY FORM INSTUMENT D.O.C._____

GM METER: CDV -700 SERIAL #_____ BCKG _____

DATE	L-BLOCK	PREP AREA	INJECTION AREA	COMMENT	IN.

Item 11

PERSONNEL TRAINING PROGRAM

In Service Subjects covered in training programs are as follows:

1. Areas of radionuclide storage
2. Potential hazards of radionuclides
3. Radiological safety procedures
4. N.R.C. regulations
5. License commitments
6. 10CFR 19 and right to report unsafe conditions and request an inspeciton
7. Responding to emergencies safely
8. Right to know radiation exposure and bioassay results - personnel dosimetry
9. Mathematics of decay, units, etc.
10. Radiopharmaceuticals - mechanisms and procedures
11. Instrumentation operation
12. Radiation Biology
13. Physical properties of radiation and radioactivity
14. Quality Control (Assurance)
15. Dose calculation and assay
16. Dosimetry
17. Exposures in perspective
18. Exposures during pregnancy
19. ALARA Philosophy

Personnel Categories

	Type	Subjects Covered	Total Duration
A. Physicians	D	4, 5, 6, 19	$\geq$ 3 hrs./yr.
B. Technologists	L,D,Q	1 - 19	$\geq$12 hrs./yr.
C. Orderlys	D	1,2,3,6,7,8,17,18	1 hr./yr.
D. Clerical	D	1,2,3,6,7,8,17,18	1 hr./yr.
E. Nursing	L	1,2,3,6,7,8,17,18	1 hr./yr.
F. Housekeeping	I,D	1,2,3,6,7,17	½ hr./yr.
G. Security	I,D	1,2,3,6,7,17	½ hr./yr.

Type: Formal Lecture = L Quiz = Q Personal Discussion = D Instruction Sheet = I

Physicians and technologists are provided with outside meetings for continuing education. All personnel will be properly instructed before assuming their duties in the vicinity of radionuclides. Annual refresher training as stated above will be provided, or as a significiant change in duties occurs, or if the terms of the license change.

Item 12 8/13/85

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIALS

A. Ordering

Personnel ordering radioactive materials will order only those and the amounts authorized by their license(s) from a manufacturer/distributor who holds a valid NRC license. The person ordering will have an adequate current knowledge of the department inventory as to prevent exceeding the possession limits. Only personnel authorized to place orders by the Radiation Safety Officer can make requests to manufacturers.

B. Receipt

1. During normal working hours carriers will be instructed to deliver radioactive packages directly to the department designated on the package. If no department is designated, it will be brought to Nuclear Medicine.

2. During off-duty hours security (or reasonable facsimile) personnel, who has been adequately briefed on the hazards (as described in Item 12) will accept delivery and bring the package immediately to the Nuclear Medicine Department. He will unlock the department's hot lab and place the package inside. In the event this is not possible, he will at least lock the package inside the Nuclear Medicine Department proper.

3. The technologist arriving on duty then assumes delivery as described in Item 14.

See instruction sheet for security or other personnel receiving packages attached.

Instruction to Security and other Non-occupationally Exposed Personnel Handling Radioisotope Packages in the Hospital

It has been determined that personnel following these instructions will retain their non-occupational status; however, if it is determined that the volume of service necessitates changing you to occupational status, film badges will be supplied, at least for a 3 month trial basis to justify existence of the necessity.

Instructions:

1. Courier will have security paged to pick-up packages and deliver them to Nuclear Medicine.

2. In general you will minimize your exposure to radioisotopes by maximizing your distance from them (use a remote carrying device as opposed to carrying by hand).

3. The least time you spend doing the job carefully, of course, the less exposure you will have.

4. The packages are adequately shielded so that they will not overexpose you if you carry 10 of them at a distance of 1 yard for 4 hours per month or carry 10 of them in your hands for 10 minutes per month.

5. Any additional lead-shielding surrounding the package will, of course, reduce this exposure.

6. If package looks physically damaged, damp, wet, and is suspected to be leaking, put on disposable rubber gloves, place package in a plastic bag, remove rubber gloves and place them in the bag, secure the bag's top, notify the Radiation Safety Officer listed below immediately, and do not transport package to the Nuclear Medicine Department.

7. If a carrier delivers a damaged or leaking package, instruct carrier to remain for monitoring and decontamination upon arrival of the Radiation Safety Officer.

8. If package integrity is normal, deliver to Nuclear Medicine Department of department of addressee.

9. Unlock hot lab door, place box on floor inside door, relock door, and return to your previous assignment.

Radiation Safety Officer: William Palazzo, M.D.

Office Phone: 201-368-6000

Home Phone: 201-837-3757

INSTRUCTIONS FOR PERSONNEL OPENING AND MONITORING PACKAGES CONTAINING RADIOACTIVE MATERIALS

1. The package once it is received by the Nuclear Medicine Department should be visually inspected for any signs of damage (e.g. wetness, crushed). If damage is noted, immediately notify the Radiation Safety Officer. If package is in acceptable condition, log appropriate identification in package monitoring log book (see attached sample "Package Monitoring Log Sheet").

2. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received during normal working hours, or eighteen hours if received after normal working hours.

3. The technician must wear rubber gloves prior to and during the opening of the package.

4. Before opening the package, the G.M. Survey Meter should be turned on and set on the 0-500 mrem/hour range. All six sides of the package should be monitored at the surface (if necessary reduce range on survey meter to enable a more accurate assessment of exposure rate). The maximum meter reading should be logged in the package monitoring log book. If any reading is in excess of 200 mrem per hour, at surface or 10 mR/hr at 3 feet, the package should immediately be placed in the lead storage area, behind the lead and the Radiation Safety Officer notified.

5. An area of not less than 100 cm^2 of external package surface shall be wiped with absorbent paper as specified in 10CFR 20.205 (b)(1). If the wipe is found to remove contamination, the Radiation Safety Officer should be notified. The results of the wipe test shall be logged in the package monitoring log book.

6. If the package is below 200mrem/hr at surface and exterior surface noncontaminated, the package should be opened carefully and the packing material visually inspected for stains, wetness or any unusual markings. Each source container shall be wipe tested for contamination before handling. If any of these conditions are not met, the package should be placed in the lead cave and the Radiation Safety Officer notified.

7. Once the exterior and packing material of the package has been found to be in order, the vial in the leaded container should be inspected to assure the vial has not broken in shipping. The shielding container should be carefully opened and visual inspection of the vial in the container should be made to assure the vial intactness. Once the vial has been found to be intact, the container and the vial should be stored in its proper place, i.e., the refrigerator or lead storage cave.

8. Verify that the package contents match the written request for the radioactive drug, and the packing slip supplied by the manufacturer. "Log" result of this check.

9. Before discarding, the empty package and packing material shall be monitored with the G.M. Survey Meter to assure they are not contaminated. The radiation labels shall be removed before discarding in the regular trash.

PACKAGE MONITORING LOG SHEET

NUCLIDE	MANUFACTURER	DATE	SURVEYOR	TIME	CONDITION O.K. ✓	RAD. UNITS OF LABEL mR/hr (DOT)	RADIATION LEVELS mR/hr SURFACE	RADIATION LEVELS mR/hr 3' FROM SURFACE*	CONTENTS & SLIP AGREE-YES ✓	WIPE RESULTS OUTSIDE	WIPE RESULTS SURFACE CONTAINERS	SURVEY RESULTS MATERIAL	SURVEY RESULTS CARTON	DISPOSITION OF PACKAGE O.K. ✓

May be omitted where surface readings are less than 10mR/hr. If package is contaminated and/or over 200mR/hr at surface 10mR/hr @ 3 feet), notify carrier and local Nuclear Regulatory Commission Office (215) 337-5000.

Item 14

LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIAL

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

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

3. Monitor hands, feet, and clothing for contamination after radiopharmaceutical kit preparation, and after each dose preparation/administration or before leaving area with the GM Survey Meter. Log the meter readings.

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

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

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

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

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

9. Dispose of radioactive waste only in specially designated receptacles. Survey receptacles daily to assure exposure levels are less than 2.0 mR/hr. in restricted areas and less than 0.2 mR/hr. in non-restricted areas.

10. Never pipette by mouth.

11. Survey kit preparation, and dose preparation areas after each procedure or at the end of the day with GM Survey Meter, and log readings. If necessary, reposition sources and/or shielding to maintain exposure levels less than 2.0 mR/hr. Also perform a wipe test for each area listed above and log results. Decontamination procedures are warrented if removable contamination found on any wipe yields a larger than background reading on the GM survey meter with the window open.

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

13. Always transport radioactive material in shielded containers.

14. Always use disposable coverings (with plastic backing) where radioactive materials in solution are prepared.

15. Always use remote handling tongs when handling or assaying unshielded sources, especially if in quantities greater or equal to patient doses.

EMERGENCY PROCEDURES

MINOR SPILLS:

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

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

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

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

5. SURVEY: With a G.M. Survey Meter, check the area around the spill, your hands and clothing for contamination. Perform a wipe test to assure the absence of removable contamination before resuming normal operations. Log survey and wipe test results and other related information on the incident for laboratory records.

MAJOR SPILLS:

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

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

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

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

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

6. PERSONNEL DECONTAMINATION:

   a. Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer.

   b. Rinse the affected area promptly with water.

   c. If contamination covers a large area and a shower is warranted, bring the G.M. Survey Meter and have someone survey the contaminated individual to assure that decontamination is effective.

d. Wash thoroughly with a non-abrasive detergent. Lanoclean is recommended. It contains corn meal that has a mild scrubbing action but doesn't scratch the skin.

e. Scrub the area thoroughly using detergent and a suitable brush but being careful not to abrade the skin.

f. Continue these procedures until there is no further reduction in the level of contamination, or until the possibility of damage to the skin makes further scrubbing inadvisable.

g. If the level of fixed contamination is more than 5 mR/hr. on a G.M. monitor or there are special circumstances contact the Radiation Safety Officer.

RADIATION SAFETY OFFICER: WILLIAM L. PALAZZO, M.D.

OFFICE PHONE: 201/368-6000

HOME PHONE: 201/837-3757

PHYSICIST: BIO-MED ASSOCIATES

PHONE: 201/241-5560

SURVEY PROCEDURES

A. Dose preparation areas will be surveyed daily with a G.M. survey meter and decontaminated if necessary as specified in Item 1 "Laboratory Rules for the Use of Radioactive Material", Section II.

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

C. All other laboratory areas will be surveyed weekly by the nuclear medicine staff and monthly by consultant radiation physicist.

D. The weekly and monthly survey will consist of:

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

2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect the contamination limits listed in Section F. (Page 2)

E. A permanent record will be kept of all survey results, including negative results. The record will include:

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

2. Name of person conducting the survey.

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

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

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

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

F. Ideally, any contamination more than a few dpm above background should be cleaned up; however, the following table specifies limits of acceptable levels of contamination for common medical radionuclides:

Type of Surface	I-131; Mo-99; Se-75; P-32 I-125; I-123	Tc-99m; Cr-51; Co-57; Ga-67; Tl-201;
	dpm/100 cm^2	dpm/100 cm^2
1. Unrestricted Areas	220	2200
2. Restricted Areas	2200	22000
3. Personal Clothing worn outside restricted areas	220	2200
4. Protective Clothing worn only in restricted areas	2200	22000
5. Skin	220	2200

Contamination levels exceeding those listed above warrant establishment of a contamination zone until contamination is removed. For fixed contamination; that which after repeated attempts fails to reduce levels significantly, 5 times the levels listed above in lines 1 and 2 are acceptable without isolation of the area.

Exact contamination on a wipe can be quantized if a NaI well crystal is possessed. Where no NaI well crystal exists the following instrumentation will be employed to assess contamination:

In performing the monthly department surveys the consultant radiation physicist estimates the dpm content of a wipe employing a Co-57 reference source of approximately 1000 dpm, and the NaI crystal detector contained in the Rectilinear Scanner, Thyroid Uptake Probe, or Gamma Camera.

In daily and weekly surveys the nuclear medicine staff assesses the removable contamination extent contained in a wipe by employing a thin end-window G.M. survey meter (with the beta shield removed). Wipes are counted in a low background area, bringing the detector window as close as possible to the wipe. Each wipe will be counted for a minimum of 15 seconds allowing 15 seconds between counts for the meter to equilibrate. A wipe that registers a reading that is larger than background levels will warrant decontamination procedures.

Weekly Survey Procedure

SURVEY FORM REFERENCES DIAGRAM MARKED ITEM 11
SADDLE BROOK NUCLEAR MEDICINE DEPARTMENT

SURVEYOR: _____ DATE: _____

SURVEY METER: D.O.C. _____

SERIAL# _____ BCKG_____MR/HR

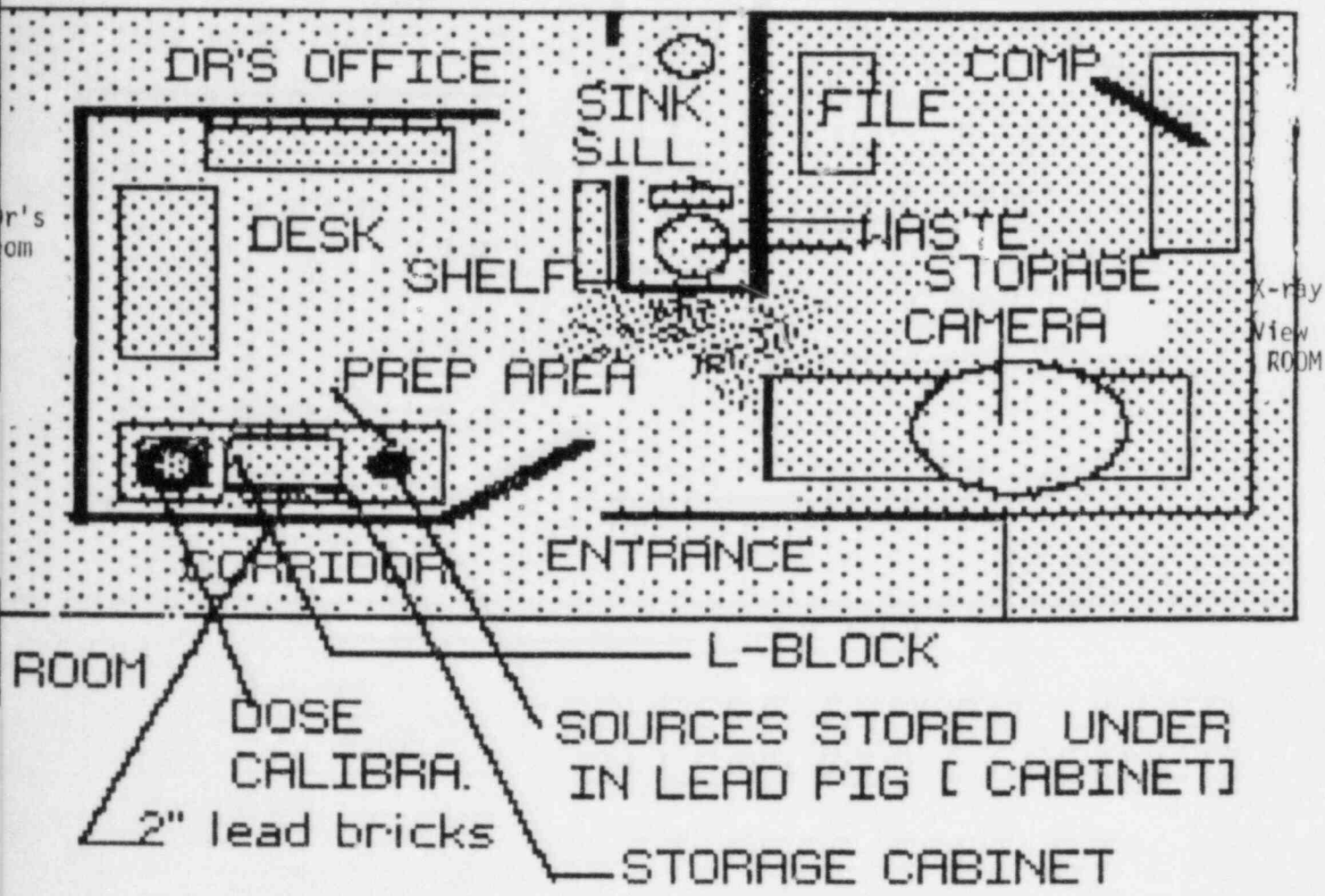
COUNTING INSTRUMENT: _____ BCKG _____CPM

INSTRUMENT SETTINGS:

AREAS	MR/HR	CPM	COMMENTS
ENRANCE CORRIDOR	_____	_____	_____
PREP AREA	_____	_____	_____
L-BOCK/FLOOR	_____	_____	_____
WASTE STORAGE WASTE FLOOR	_____	_____	_____
DOSE CAL.	_____	_____	_____
CAMERA	_____	_____	_____
CONSOLE	_____	_____	_____
DESK/FILE	_____	_____	_____
COMPUTER	_____	_____	_____
STAFF HANDS	_____	_____	_____

_____
SURVEYOR'S SIGNATURE

Outside of Hospital



SADDLE BROOK DAILY SURVEY FORM INSTUMENT D.O.C._____

GM METER: CDV -700 SERIAL #_____ BCKG _____

DATE	L-BLOCK	PREP AREA	INJECTION AREA	COMMENT	IN.

Item 17 8/13/85

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

   Check as appropriate

   ___ By commercial waste disposal service (See also No. 4 below)
   ___ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.
   * ___ Other (specify): all waste from previous day is sent back with Carrier(Syncor)

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

   Check as appropriate

   ___ Returned to the manufacturer for disposal
   ___ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants).
   ___ Disposed of by commercial waste disposal service (See also No. 4 below).
   ___ Other (specify): _____

3. Other Solid Waste will be:

   Check as appropriate

   * ___ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in the normal trash.
   ___ Disposed of by commercial waste disposal service (See also No. 4 below)
   ___ Other (specify): _____

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

   _____
   (Name) (City) (State)

   NRC/Agreement State License No. _____