030-20751
LAL = 20709

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 02200

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**

Radiology Imaging Associates
516 Hamberg Turnpike Sutie 6
Wayne, N.J. 07470

TELEPHONE NO.: AREA CODE (201) 942 2266

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

516 Hamberg Turnpike Suite 6
Wayne, N.J. 07470

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Arnold Olefson, M.D.
TELEPHONE NO.: AREA CODE (201) 942 2266

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

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

Arnold Olefson, M.D.
Jatin Gajarawala, M.D., A.B.R., A.B.N.M.

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.)*

Jatin Gajarawala, M.D. , A.B.R.,A.B.N.M.

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	2
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100, SCHEDULE A, GROUP IV	N/A	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	N/A	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	N/A	

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50 MCI
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	N/A	
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	N/A	
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	N/A	
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	N/A	
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	N/A	

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

RECEIVED BY LFMB
Date 5/17/84
Log No. May-10 I
By Brown
Orig. To

Applicant
Check No. 1035
Amount Fee Category 7190-7B
Type of Action Application
Date Check Rec'd 5/11/84
Received By D. Brown

02394
MAY 11 1984

NRC FORM 313M (9-81) Section Compl 5/17/84

8407170154 840618
NMS LIC30
29-20709-01 PDR

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. Oct., 1979 Date: Oct., 1979

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Siemens Gammasonics	MONTHLY
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Siemens Gammasonics	MONTHLY
		OTHER (Specify)		
c. WRIST		FILM	NOT USED	
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL
Refer to Item 25 on enclosed form.

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE
(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ 190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*

(2) TITLE

c. DATE

FORM NRC-313M (8-78)

It is requested that for this license application the licensee be relieved of the requirement for admission privileges at a local hospital for radioactive patients since only diagnotic imaging studies are to be done and that all patients refered to the licensee's facility for such studies will be under the primary care of another local physician who has admission privileges at the local hospitals.

Item 25
4/84

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Ludlum

   Manufacturer's model number: Model 2

   Number of instruments available: 1

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

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

   * b. Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

   Minimum range: _____ mR/hr to _____ mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

   Manufacturer's name: Squibb CRC-17

   Manufacturer's model number: CRC-17, 17533

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	Ohio Nuclear	100

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

   None

* If should a Technetium generator be used in the future, a survey meter with a minimum range of 0-1000 mR/hr will be obtained prior to the actual use of the generator.

Item 9
4/84

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. 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.

__X__ 3. Survey instruments will be calibrated.

_____ a. By 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.

__X__ c. By a consultant or outside firm

(i) Name Bio-Med Associates Inc.

(ii) Location 753 Boulevard, Kenilworth, NJ 07033

(iii) Procedures and sources

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

_____ are 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.

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 futher evaluation.

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

Radionuclide	Activity	Accuracy
Cesium 137	100uCi	±5%
Cobalt 57	5.0 mCi	5%

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. When only "instant" Technetium-99m is used, the largest activity per vial purchased will be used for the test. When generators are used, the first elution of a new generator will be used when practical. An activity of at least 100mCi will be used with generators since 100mCi is greater than or equal to the largest anticipated administered dose or the largest amount used in preparation of radiopharmaceutical kits. Although larger activities may be assayed (e.g., first elution of a Mo-99-Tc-99m generator), this is only used to provide an approximation of the volume needed to prepare an individual dose. The following specifies procedures for assaying a patient dose:

(1) Entire elution of a generator is assayed, the volume of the eluate is approximated, and the concentration is calculated. For example, the eluate may be 200mCi in 10ml or 20mCi/ml.
(2) At the time the study is to be performed the concentration is decay corrected.
(3) To prepare a given dose, the desired activity is divided by the decay corrected concentration yielding the volume to be administered.
(4) Prior to injection the individual dose is assayed (correcting for geometrical variation if necessary) to verify the proper activity.

A similar procedure is employed in administration of radiopharmaceutical kits. The activity to be used in the kit is assayed and volume approximated. After the kit is properly prepared, the concentration in mCi/ml is assayed using the total volume employed in the kit (correcting for the volume of saline or other diluting agent added). At the time of administration, the procedures listed above in steps (2) through (4) are followed.

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 $\pm 5\%$ 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. Generally, a geometrical correction factor of less than 2% may be ignored.

CALIBRATION OF DIAGNOSTIC EQUIPMENT

All the diagnostic equipment shall be calibrated in accordance to the manufacturer's recommendations. As needed any modifications requiring special attention, shall be noted and accomadations shall be made to implement any additional tests needed.

Instrument:

Source: ^{99m}Tc

Date:

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

% Remaining Activity

0 4 8 12 16 20 24 28 32 36 40 44 48 52

HOURS

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			

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

Page 2 Geometrical Variation Test Continued

1cc Syringe

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

Page 3 Geometrical Variation Test Continued

5cc Vial

Time of Assay	Volume	Reading	Decay Corrected Reading	Correctio Factor
	0.1 ml			
	0.5 ml			
	1.0 ml			
	1.5 ml			
	2.0 ml			
	2.5 ml			
	3.0 ml			
	3.5 ml			
	4.0 ml			
	4.5 ml			
	5.0 ml			

Other Container

Time of Assay	Volume	Reading	Decay Corrected Reading	Correctic Factor

QUARTERLY DOSE CALIBRATOR ANALYSIS

HOSPITAL: _____

MODEL DOSE CALIBRATOR: _____

DATE: _____

1. Check liner
   a. Contaminated?
   b. In place?

2. Check support
   a. In tact?

3. Instrument Zero
   a. Was zeroed?
   b. Adjustment necessary?

4. Lead shielded? Yes _____ No _____

5. _____ reference standard is _____ uCi today. When placed in the dose calibrator it read on the following settings:

		Cap.	Eon	Pick.	% different from original
_____	uCi @ Mo-99 setting	30x3.5	342	2133	_____
_____	uCi @ Tc-99 setting	80	501	1117	_____
_____	uCi @ Ga-67 setting	94	478	1139	_____
_____	uCi @ Cr-51 setting	100x10	459 x10	6596	_____
_____	uCi @ Co-57 setting	112	453	1138	_____
_____	uCi @ I-131 setting	151	327	1194	_____
_____	uCi @Xe-133 setting	188	497	1205	_____
_____	uCi @Tl-201 setting	205	458	--	_____
_____	uCi @Cs-137 setting	220	260	1253	_____
_____	uCi @ Se-75 setting	258	210	1236	_____
_____	uCi @ I-123 setting	277	260	--	_____
_____	uCi @ I-125 setting	319	421	0151	_____

Page 2. Quarterly Dose Calibrator Analysis

	Cap.	Eon	Pick.	% difference from original
_____ uCi @ P-32 setting	550x100	-	6347	_____
_____ uCi @ Ra-226 setting	778	058	0139	_____
_____ uCi @ Yb-169 setting	844	--	--	_____
_____ uCi @ Co-60 setting	990	035	0218	_____
_____ uCi @ Xe-127 setting	___	___	___	_____

6. Yes _____ No _____ Instrument was adjusted or repaired, to read ±

   Yes _____ No _____ Instrument was within ±5% of previous values

   Yes _____ No _____ A correction factor was posted. It is _____

7. Volume and Concentration Check

   a. _____ in 20 cc vial reads _____ uCi/cc _____ N/A

   b. _____ in 20 cc vial calculated is _____ uCi/cc

   c. % of difference is _____

8. Accuracy of Standards
   Decay corrected expected uCi/assay uCi x 100 = % accuracy

   Co-57

   Cs-137

   Ba-133

   Co-60

   Ra-226

9. Comparison of Pushbutton to Manual setting _____, _____ N/A

10. Any modules missing? _____, _____ N/A

11. Cs-137/Co-57 decay-corrected ratio =

    This is _____ % different from last quarter's; therefore,

12. Comments

Checked by: _____

DOSE CALIBRATOR CONCENTRATION CALCULATION CHECK

Date	Calibration Standard	Decay Corrected Activity (uCi)	Standard Volume (cc)	Standard Activity (uCi/cc)	Dose Calibrator Assay (uCi/cc)	%Error From Standard	Comment

Radiological Physicist

FACILITY AND EQUIPMENT LIST

The following radiation safety items are present and are to be used in the Nuclear Medicine Department:

1. Gm Survey meter
2. L shield
3. 1/16" thick lead lined dry radicactive waste container
4. Dose calibrator
5. Decontamination kit
6. Disposable chuxs for preparation area
7. Disposable rubber gloves
8. Lab coats
9. Forceps
10. Syringe shields
11. Lead brick for, 8" x 8" x 8" high, 2" thick
12. Vials are to be stored in their lead pigs
13. Precalibrated syringes from radiopharmacy vendor shall be stored in their lead containers

The hotlab is a posted and secured area such that only authorized personnel are allowed to enter. Please refer to the diagram of the Nuclear Medicine department for further information.

RADIOLOGY IMAGING ASSOCIATES
516 Hamburg Tp. Suite #6
Wayne, NJ 07470

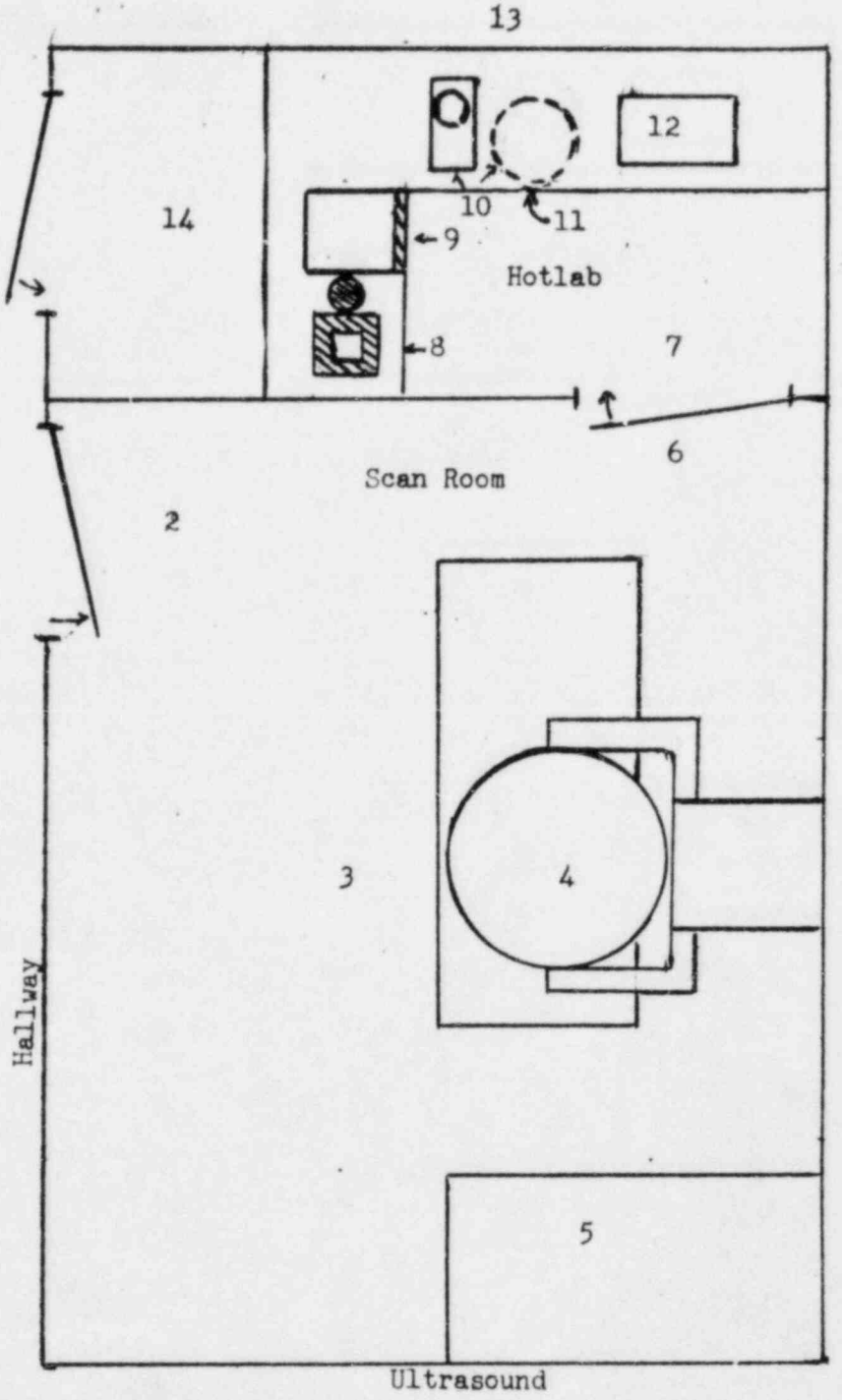
Date:_____

Surveyed by:_____

Instrumentation:_____

_____

_____



#	LOCATION	mR/hr	cpm/100 cm²
1	Door/Floor		
2	Floor		
3	Floor		
4	Camera/Table		
5	Console		
6	Floor/Door		
7	Floor		
8	Lead Fort		
9	L shield		
10	Dose Calib., Prep. Area		
11	R/A Waste		
12	Sink		
13	Darkroom		
14	Dressing Rm		
15	Background		

Notes: ▭ = lead shielding

_____

_____

_____

_____

_____

_____

_____

_____

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

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

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at [illegible] employee orientation sessions and annually thereafter at in-service meetings.

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 medic al facility

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 yo r previous assignment.

Radiation Safety Officer: Jatin Gajarawala, M.D.

Office Phone: 201-942-2266

Home Phone: 201-768-8928

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, 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 200 mrem/hour 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. ✓

ıy be omitted where surface readings are less than 10mR/hr. If package is contaminated and/or over 200mR/hr at surface

)mR/hr @ 3 feet), notify carrier and local Nuclear Regulatory Commission Office (215) 337-5000.

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 each generator elution and radiopharmaceutical kit preparation, and after each dose preparation/administration or before leaving the 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.

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 generator, 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 wipeyields 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. This is extremely important for the elution of a generator.

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 warrented, 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: Jatin Gajarawala, M.D.

OFFICE PHONE: 201-942-2266

HOME PHONE: 201-854-5112

SURVEY PROCEDURES

A. All elution, kit preparation, and dose preparation areas will be surveyed daily with a G.M. survey meter and decontaminated if necessary as specified in Item 15 "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	Tc-99m, I-125, Cr-51, Co-57, Ga-67, TL-201, I-123
	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 monthly department surveys the consultant radiation physicist estimates the dpm content of a wipe employing a ~1000 dpm Co-57 reference source 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 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.

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to relea certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

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

_____ By commercial waste disposal service (see also Item 4 below).

__X__ Other (specify): DECAY TO BACKGROUND

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

__X__ Returned to the manufacturer for disposal.

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

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

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

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

SYNCOR INC. _____
(Name) (City, State)

NRC/Agreement State License No. 29-19608-01

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

**These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

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ALARA PROGRAM

We, the management of this medical facility are committed to the ALARA program as specified in Appendix O, of Regulatory Guide 10.8, Rev. October 1980.

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