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

Nuclear Medicine Ltd.
3915 Watson Road
St. Louis, MO 63109

TELEPHONE NO.: AREA CODE (314) 644-7100

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

1) St. Louis Eye Hospital (Group IV only); 1027 Bellevue St., St. Louis, MO 63117
2) 6504 Lindenwood, St. Louis, MO

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ray Kaczur, Consultant, Nuclear Medicine Associates

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

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 24-09769-01

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

Retain: John A. Gantz, M.D., Berhard L. Hoover, M.D.
Delete: Neil I Gallagher
(Refer to License #24-09769-01.)

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.)*

David B. Hess with consultation from Nuclear Medicine Associates, Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3.0
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		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 INTRA-CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	100

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	RECEIVED BY LFMB DESCRIBE PURPOSE OF USE

Applicant .....
Check No. 1910 Southwest Med Cntr
Amount Fee Category $550
Type of Fee FC Camp
Date Check Rec'd 8/29/84
Received By .....

Date 8/29/84
Doc. ay 1-44
By .....
Orig. To 8/26 P 1-44
Action Compl. .....

8505090426 850429
REG3 LIC30
24-09769-01 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. 1 Date: October, 1980

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
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
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	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)	
X	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	X	FILM	R.S. Landauer, Jr. & Sons, Inc.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Sons, Inc.	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
St. Mary's Health Center

MAILING ADDRESS
6420 Clayton Road

CITY: St. Louis | STATE: MO | ZIP CODE: 63117

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
See page 4 NRC 313M

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

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

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

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

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
X John A. Gantz M.D.

(1) NAME *(Type or Print)*
John A. Gantz, M.D.

(2) TITLE
Director, Nuclear Medicine

c. DATE
X 13 Aug 84

Control No. 77312

PRIVACY ACT STATEMENT

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

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

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

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

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

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

25 b) John A. Gantz, M.D. is on staff at St. Mary's Health Center and has admitting privileges. Also refer to license #24-08960-02 for this hospital. Dr. Gantz is named on this license as an authorized user of byproduct material.

TRANSPORT OF RADIOACTIVE MATERIAL

Authorization is requested to transport Group IV byproduct material from Nuclear Medicine Limited, 6504 Lindenwood, St. Louis, Missouri 63109 to the following location:

St. Louis Eye Hospital
1027 Bellevue
St. Louis, Missouri 63117

Authorization is requested to transport Group IV byproduct material to the St. Louis Eye Hospital. If liquid I-131 is to be used, it will be used with Pharmatopes catalog 32 - 27 oral radioisotope administration set, which would eliminate the necessity of a fume hood. Authorization is also made to use this same device at the Nuclear Medicine Limited address of 6504 Lindenwood. All I-131 doses will be administered in less than 30 millicurie units. This would eliminate the necessity of admitting the patient to the hospital.

Prepared: 8-3-84
License#24-09769-01

TRANSPORT PROCEDURE

1. The byproduct material will be received, and/or prepared at Nuclear Medicine Limited, 6504 Lindenwood, St. Louis, Missouri 63109, in accordance with procedures, precautions and conditions stated in this application. The activity will be transported as necessary in a single dose.

2. The single dose will be shielded by sufficient plastic or lead containers composed of lead with thicknesses of 0.25 to 0.5 inches.

3. The item containing radioactivity will be assayed in the dose calibrator except P-32 and labeled with the following information:

   a. Radiopharmaceutical
   b. Date of assay
   c. Time of assay
   d. Total activity
   e. Total volume

4. Lot numbers will be maintained at the Nuclear Medicine Limited facility.

5. The radioactive sources in their shields will be wrapped with sufficient absorbant towelling to absorb ten times the liquid content of the syringe/, or vial and placed into a syringe carrier lined with one quarter inch of lead. Capsules will be transported in their original shipping safe or equivalent lead shielding. Residues such as the empty syringe, contaminated needles, alcohol swabs, linens and etc along with unused doses will be returned to the Lindenwood address for disposal. No radioactive materials will be disposed of through the St. Louis Eye Hospital address excepting dilute contaminated solutions generated from cleaning up a spill. Records of transport, use and disposal of byproduct material associated with procedures performed at the St. Louis Eye Hospital will be maintained at the Lindenwood address.

6. Each lead shield will carry a radioactive sign on the outer surface of the shield.

7. Two opposing sides of the carrying case will have a "Caution Radioactive Material" sign.

8. Prior to dispatch, the carrying case will be surveyed with the low level G-M survey meter to assure levels on contact do not exceed 2.0 mR/hr. If necessary, additional lead shielding will be provided to reduce the level to 2.0 mR/hr or less.

9. The radiopharmaceuticals will be transported using a personnel vehicle by either an employee, courier, or a technologist under the supervision of physicians named on the license. To monitor the radiation exposure, the "transporter" will wear a whole body film badge. The radiation exposure to the "transporter" will be maintained at "ALARA" levels, in accordance with our ALARA program.

10. For security, during transportation from one institution to another, the carrying case will be placed in the trunk of the vehicle and the trunk-lid locked.

11. If the vehicle becomes disabled during transport, the carrying case will either be maintained under lock and key, in the trunk, or the carrying case will be left in attendance of a civil employee (e.g. police officer, fireman), if the courier must leave the scene. In either situation, the Radiation Safety Officer will be notified as soon as practical.

12. The carrying case containing the radiopharmaceuticals will be taken directly to the designated department.

13. When the shielded radioactive sources are taken out of the carrying case, the "empty" carrying case will be surveyed on contact with a G-M probe, to rule out a "spill" during transportation.

14. Packaging, transport, and delivery of radioactive material will be performed in accordance with CFR Title 10, Chapter #1, Part 71.5 ("Packaging of Radioactive Material for Transport").

15. The vehicle will be surveyed after the completion of the daily deliveries.

16. All used or unused doses and paraphernalia will be returned to Nuclear Medicine Limited facility at the end of each day for decay in storage.

TRANSPORT PERSONNEL TRAINING

In accordance with section 19.12 of 10 CFR, Part #19, the following is a description of the training of personnel transporting radioactive materials:

1. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.

2. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:

   a. Indicate areas where radioactive materials will be delivered, used and stored at each facility.

   b. Potential hazards associated with radioactive materials.

   c. Radiological safety procedures appropriate to their respective duties.

   d. Pertinent NRC regulations.

   e. The rules and regulations of the license.

   f. The pertinent terms of the license.

   g. Their obligation to report unsafe conditions.

   h. Appropriate response to emergencies or unsafe conditions.

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

3. Personnel will receive refresher training relative to duties, regulations, or terms of the license by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.

Prepared: 8-3-84
License#24-09769-01

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name Victoreen

      Manufacturer's model number 498

      Number of instruments available one

      Minimum range: 0 mR/hr to 1 mR/hr

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

   b. Manufacturer's name Victoreen

      Manufacturer's model number ~~6RAY~~ ~~GRAY~~ Gray

      Number of instruments available one

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

      Maximum range: 0 mR/hr to 50.0 mR/hr

2. Dose calibrator(s)

   Manufacturer's name RadX

   Manufacturer's model number Mark I

   Number of instruments available one

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	Med-X Upgrade
Well Counter	Picker	Compac 120
Uptake Probe	Picker	III A

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

Item #9
1 of 1 page
Prepared: 8/3/84
Lic. #24-09769-01

CALIBRATION OF INSTRUMENTS

A. Survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within ± 20% of the reading displayed after calibration, the instrument will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

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

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3-5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1-0.5 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1-0.3 mCi	100 uCi or more	Within ± 5%

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

3. The calibration procedure will be as follows:

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

The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5% of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo/Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within ± 5%. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less than 200 mCi will be drawn and used. The reduced amount will then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the

proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be $\pm$ 5%. If test result error exceeds $\pm$ 5%, arrangements will be made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck kit from Calcorp, Inc. The manufacturer's instructions for use dated 3-2-82 will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed $\pm$ 2%.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within $\pm$ 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and a uniform flood check will be performed each day of use.

2. The well system will be calibrated using a long-lived radionuclide, such as Cs-137, Ba-133 or I-129 each day of use.

FACILITIES AND EQUIPMENT DESCRIPTION

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

Mo-99/Tc-99m generator when used will be stored and eluted in the designated area. It will be shielded with lead bricks such that levels from all avenues of approach do not exceed 2.0mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patients well being may be compromised. Under these circumstances, the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM	PURPOSE
1. Warning tape, chalk, & signs	posting of area
2. Plastic bags, small	shoe covers, wet containers
3. Disposable gloves	head protection
4. Masking tape	fasten shoe covers, etc.
5. Forceps, tongs	safe handling
6. Large plastic bags	for contaminated material
7. Sponges, 4 x 4	sopping up
8. Paper towels	blotting & drying
9. Radiac wash or detergent	detergent
10. Scouring powder	friction
11. Tags	identification
12. Scissors	cut absorbent peper, etc.
13. Alcohol prep pad	taking swipes following decontamination
14. Chux	cover area following decontamination
15. G-M survey meter	monitoring

Facilities and Equipment Diagram

Air Supply

Air Exhaust

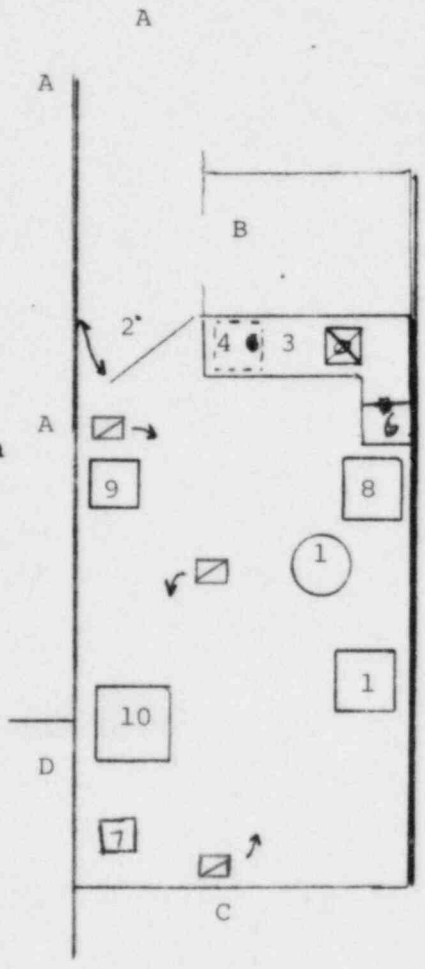
Sink

Lead Castle

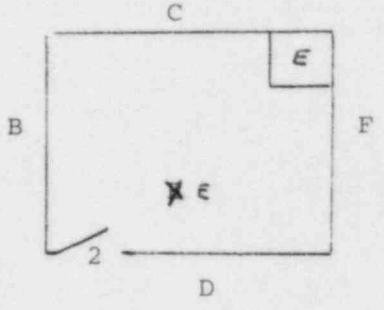
___	Scanner
9	Uptake
10	Well
___	Scaler
1	Camera
___	File
2	Lockable Door
3	Isotope Receipt Area
4	Generator
3	Kit preparation
6	Isotope Storage
3	Dose Preparation
6	Waste Storage
7	Dose Calibrator
8	Refrigerator

Adjacent Areas

A	Hall
B	Restroom
C	Exterior
D	Stairwell
E	Storage
F	Mechanical Room
___	_____
___	_____



First Floor



Basement

Lead Shielding

Old Generating Shield (Mallinckrodt)

4 Ultrashield #024
8" L x 10"W x 14"H x ½"T

6
8" L x 10" W x 8½" H x ½ T

___
___L x ___W x ___H x ___T

___
___L x ___W x ___H x ___T

Item #11
3 of 3 pages

Prepared 8/3/84
Lic. #24-09769-01

PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

1. The nuclear medicine department will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.

2. Every effort will be made to hire nuclear medicine technology registered or registry eligible personnel to work with radioactive material. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:

   a. Indicate areas where radioactive mterials are used or stored.
   b. Potential hazards associated with radioactive materials.
   c. Radiological safety procedures appropriate to their respective duties.
   d. Pertinent NRC regulations.
   e. The rules and regulations of the license.
   f. The pertinent terms of the license.
   g. Their obligation to report unsafe conditions.
   h. Appropriate response to emergencies or unsafe conditions.
   i. Their right to be informed of their radiation exposure and bioassay results.
   j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR, Part 19.

If evaluation of the radiation handling techniques of a new technologist is found to be inadequate, arrangements will be made to send the employee for a 40 hour formal course from our consulting physicists, Nuclear Medicine Associates, Inc., Cleveland, Ohio. This course combines didactic and clinical training which will include points "b" through "i" listed above, as well as quality control and patient procedures.

3. Personnel will receive refresher training relative to duties, regulations or terms of the license

by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.

4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, as in the case of certain patients who need special care, personnel so involved will be present under the direction of the nuclear medicine techologist, who will ensure that the exposure of these persons is held to the minimum required for the performance of the nuclear medicine procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their hospital orientation process and annually thereafter in the form of verbal instructions and/or hospital interdepartment memos.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist or his/her designee will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area identified in the Item #11 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to nuclear medicine.

3. During off-duty hours, if couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will make arrangements to have the package delivered to the designated receipt area by specially trained personnel who have been assigned this duty. The packages will be secured against unauthorized removal. If packages are wet or appear to be damaged, the RSO is to be immediately contacted.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials.

*Radiation Safety Officer: David B. Hess

Item #13
Prepared 8/3/84
Lic. #24-09769-01

Appendix F

Procedures For Safely Opening Packages Containing Radioactive Material

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a) (1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

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

   a. Put on gloves to prevent hand contamination.

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

   c. Measure exposure rate at 3 feet (or 1m) from package surface and record. If > 10 mr/hr, stop procedure and notify Radiation Safety Officer.

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

   e. Open the package with the following precautionary steps:

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

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

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

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

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

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

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

(1) If contaminated, treat as radioactive waste.

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

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

Appendix G

General Rules For the Safe Use of Radioactive Material in the Nuclear Medicine Department

1. Wear laboratory coats or other protective clothing at all times when radiactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials other then invitro kits.

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

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

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

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

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

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

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

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

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each prodecure or at the end of the day. Decontaminate if necessary.

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

13. Always transport radioactive materials in shielded containers.

APPENDIX H

Emergency Procedures

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands and clothing for contamination.
5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate 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: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: David Hess
OFFICE PHONE: 314-644-7100 ext 203
HOME PHONE: 314-353-0158

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Dr. John Gantz
314-768-8276
314-878-5082

Item #16
1 of 1 page
Prepared: 8/3/84
Lic. #24-09769-01

Control No. 7312

SURVEY PROCEDURES

A. All routine elution, preparation and designated injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be monitored monthly, via wipe test.

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

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

   2. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm.

E. A permanent record will be kept of the weekly or monthly survey results, including negative results. The record will include:

   1. Location, date, and type 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. Area will be cleaned if the contamination level exceeds 200 dpm/100cm^2, except in the case of some Tc-99m spill where less radiation exposure would be recieved by personnel if the area is secured and contamination is allowed to decay.

APPENDIX J

WASTE DISPOSAL

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.

__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 generators will be disposed of as normal trash.

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

__X__ Other (specify): Return to Central Radiopharmacy.

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

__X__ Returned to the manufacturer for disposal.

__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 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).

__X__ Other (specify): Returned to Central Radiopharmacy.

4. The commercial waste disposal service used will be:

_____
(Name) (City, State)

NRC/Agreement State License No. _____

Item #18
1 of 1 page
Prepared: 8/3/84
Lic. #24-09769-01

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

Special precautions for patients treated with byproduct material listed in Groups IV, Schedule A, Section 35.100 of 10 CFR, Part #35 are as follows:

Method for preparation and administration of therapeutic doses of Iodine-131: Therapeutic doses of I-131 will be ordered from reputable suppliers and received precalibrated, ready for dispensing to patients. These materials will be stored until time for use, in the isotope storage area behind sufficient shielding to reduce the radiation levels to 2.0 mR/hr at a distance where occupational workers can conveniently stand. I-131 doses will be administered in capsular form or liquid form utilizing the oral radioisotope administration set Model 32-27 from Paramedical, Inc., Watertown, Massachusetts or equivalent. Patients requiring therapeutic amounts of I-131 will be dosed in the hot lab area of the imaging section, held for 30 minutes for observation and sent home.

Patients treated with therapeutic amounts of byproduct material and then who require hospitalization, will be directed to St. Mary's Health Center. The radiation safety officer at St. Mary's will be immediately contacted. Upon admission to the hospital, the radiation program submitted in application for license #24-08960-02 will be implemented. This includes follow-up directives to family, referring physician, and if the patient should expire, to the mortician or autopsy team.

Patients receiving therapeutic amounts of byproduct material who are sent home will be given the attached directive (Item #19, page 2 of 2 pages).

Item #19

INSTRUCTIONS FOR FAMILY OF RELEASED PATIENT

Name of Patient _____

Name of Clinic _____ Address _____ Tel.No. _____

For further information contact _____ Tel.No. _____

Please show this form to every physician consulted concerning the patient until _____ (date)

_____ (Name of Patient) was treated on _____, 19___.

with _____ millicuries of _____ in the form of _____.

NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER _____ (date).

UNTIL THAT DATE:

Persons under 45 years of age should not remain closer than the following distances from the patient, for the time period indicated:

a) _____ (Date) to _____ (Date)

Permissible distance _____ feet or more, for _____ hours/week.
(At other times remain farther than 6 feet.)

Note: During the above times brief periods of closer contact (for example while shaking hands, or kissing the patient) are permissable.

SPECIAL PRECAUTIONS:

a) Spouse or other person caring for the patient.

_____

_____

_____

b) Children or pregnant women: _____

_____

_____

c) Sleeping Arrangements: _____

_____

IF THE PATIENT IS TO BE HOSPITALIZED, OR IF DEATH SHOULD OCCUR, NOTIFY THE FOLLOWING INDIVIDUAL(S) IMMEDIATELY:

_____

_____

A COPY OF THIS FORM SHOULD BE KEPT WITH THE PATIENT'S RECORD

Item #21

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

1. Quantities to be Used

   A. Patient Information

      1. One study per month
      2. 20 mCi per study

   B. Possession Limit: 100 mCi requested

2. Use and Storage Areas

   The imaging room is used for the storage and use of Xenon. See diagram #11.

3. Procedures for Routine Use:

   A. The dose will be prepared and assayed in the dose calibrator if possible. Shielding of the dose will be maintained at all times up to patient administration, except during identification and assay. Patients will be instructed as to the procedure and trial runs will be conducted if at all possible. Finger badges will be worn by all personnel handling Xenon. The camera room door will be left open.

   B. Face masks or mouthpieces along with a Xenon rebreathing system will be employed. The face mask covers both mouth and nose. A nose clamp will be employed with the use of a mouthpiece. Tubing and valves will be inspected prior to use to assure continuity.

4. Concentration in Unrestricted Areas

   A. The Xenon will be diluted in a total volume of air in the entire clinic building.

   B. The air handling system of the entire building exhausts at -200 cfm. Calculations are as follows:

      Activity (A) = 20,000 uCi/month

      Loss Factor (f) = 0.20 (patient associated losses)

Volume (V) = 200 cfm x 1.7×10^6 ml/hr/cfm x 168 hr/wk x 4 wks/month

(V) = 2.28×10^{11} ml/month

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

$$C = \frac{20{,}000 \text{ uCi/month} \times 0.20}{2.28 \times 10^{11} \text{ ml/month}} = 1.75 \times 10^{-8} \text{ uCi/ml}$$

This value is less than 3×10^{-7} uCi/ml for unrestricted areas.

5. Concentration in Restricted Areas

There are three supply vents in the camera room for a total of + 1180 cfm. Therefore, the camera room is under positive pressure.

Activity (A) = 20,000

Loss Factor (f) = 0.20

Volume (V) = 1180 cfm x 1.7×10^6 ml/hr/cfm x 168 hrs/wk x 4 wks/month

(V) = 1.35×10^{12} ml/month

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

$$\text{Concentration (C)} = \frac{20{,}000 \text{ uCi/month} \times 0.20}{1.35 \times 10^{12} \text{ ml/month}} = 2.96 \times 10^{-9} \text{ uCi/ml}$$

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

In order to implement the ALARA philosophy, the bag containing the collected Xenon will be carried to the external environment and the contents of the bag expelled.

Model Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

Nuclear Medicine Ltd.
(Licensee's Name)

8/3/84
(Date)

I. Management Commitment

a. We, the management of this medical facility, are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Office (RSO).

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

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Officer (RSO)

a. Review of Proposed Users and Uses

1. The RSO will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposures ALARA.

2. When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSO will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSO authority is essential to the enforcement of an ALARA program.)

1. The RSO will have authority for delegation of duties and for enforcement of the ALARA concept.

c. Review of ALARA Program

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

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

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

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

d. Annual and Quarterly Review

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

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

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

e. Education Responsibilities for an ALARA Program

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

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, and the RSO are committed to implementing the ALARA concept.

f. Cooperative Efforts for Development of ALARA Procedures

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

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

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

g. Reviewing Instances of Deviation from Good ALARA Practices

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

III. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

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

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises.

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

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

IV. Persons Who Receive Occupational Radiation Exposure

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

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

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

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

Table 1

		Investigational Levels - (mrems per calendar quarter) LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625

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

a. Quarterly exposure of individuals to less than Investigational Level 1.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level 1.

b. Personnel exposures equal to or greater than Investigational Level 1, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate. The RSO will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review.

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

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

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

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

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

VI. Signature of Certifying Official[3]

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

Melva A Long
Signature

Melva A. Long
Name (print or type)

Administrator
Title

Institution (or Private Practice) Name and Adress:

Southwest Medical Center - Nuclear Medicine Ltd.

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

Control No. 77312