FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

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

Woodland Medical Group
22341 W. Eight Mile Road
Detroit, Michigan, 48219
TELEPHONE NO.: AREA CODE (313) 538 4700

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Wiley Jordan
TELEPHONE NO.: AREA CODE (313) 538 4700

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*
a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 21-13255-01

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

Barry Samules, M.D.
Harold Daitch, M.D.
Richard Small, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Barry Samules, M.D.

5/31/79
RB

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
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	
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	x	30 capsule
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	x	10
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	x	200

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	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

RECEIVED BY LFMB
Date MAY 10 1979
Log May 06 III
By Borden
Orig. To
Action Compl. 5/14/79

Applicant
Check No. 15364 #150.00
Amount Fee Category Renewal
Type of Fee
Date Check rec'd MAY 10 1979
Received By Brown

30 1979

B/2

FORM NRC-313M (8-78)

Control No. 01676

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE N.A.	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
☐ Names and Specialties Attached; and	☒ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE Supplemental Sheet	☒ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	☐ Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	☒ Appendix I Procedures Followed; or
☒ Appendix C Form Attached; or	☐ 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)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
☒ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☒ Appendix K Procedures Followed; or
☐ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
☒ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☒ 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)
☒ Detailed Information Attached	☐ Detailed Information Attached See previous appli. License recently amended.
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
☐ Appendix F Procedures Followed; or	☐ Detailed Information Attached
☒ Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	R.S.Landauer, Jr. & Co.	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	R.S.Landauer, Jr. & Co.	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: see previous license application

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: $ 150.

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type of Print)*

(2) TITLE

c. DATE APR 25 1979

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

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

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

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

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

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

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

SUPPLEMENTAL SHEETS

Item 7. MEDICAL ISOTOPES COMMITTEE

N.A.

Item 8. TRAINING AND EXPERIENCE

Individual users previously licensed on License No. 21-13255-01

Item 9. INSTRUMENTATION

See attached APPENDIX C

Item 10. CALIBRATION OF INSTRUMENTS

See attached APPENDIX D

Item 11. FACILITIES AND EQUIPMENT

A. Facilities:

(see attached diagram)

B. Equipment:

For Health Physics and Clinical Instrumentation see Item 9.

For reducing internal exposures, disposable gloves, absorbent pads, etc. will be used.

For reducing external exposures, remote handling devices, shielding (lead bricks, lead glass "face" shield, syringe holders, lead "pigs") will be used. Syringe shields will be used when the use does not interfer with patient care (e.g. in the case of difficult injections).

Item 12. PERSONNEL TRAINING PROGRAM

All personnel will receive proper instruction in the items specified in 19.12 of 10CFR Part 19, including items a through j page 10.8-6 of REGULATORY GUIDE 10.8.

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Picker

Manufacturer's model number: G.M. Survey Meter

Number of instruments available: 1

Minimum range: 0 mr/hr to .5 mr/hr

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

b. Manufacturer's name: Eberline Instrument Corporation

Manufacturer's model number: E-520

Number of instruments available: 1

Minimum range 0 mr/hr to .2 mr/hr

Maximum range 0 mr/hr to 2000 mr/hr

(energy compensated with HP-270 Probe)

2. Dose calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-4

Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	LFOV
Uptake Probe	Picker	Spectroscaler 4R + 2"x2" NaI(Tl)
Autowell	Searle	1185

4. Other

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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.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

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

or

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

x c. By a consultant or outside firm

(1) Name Medical Physics Consultants

(2) Location Ann Arbor Michigan

(3) Procedures and sources

x have been approved by NRC and are on file in License No. 21-17126101 MD

____ are attached

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CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	1-5	± 3-5%
Ba-133		
Cs-137	.2	± 3-5%

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

or

____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

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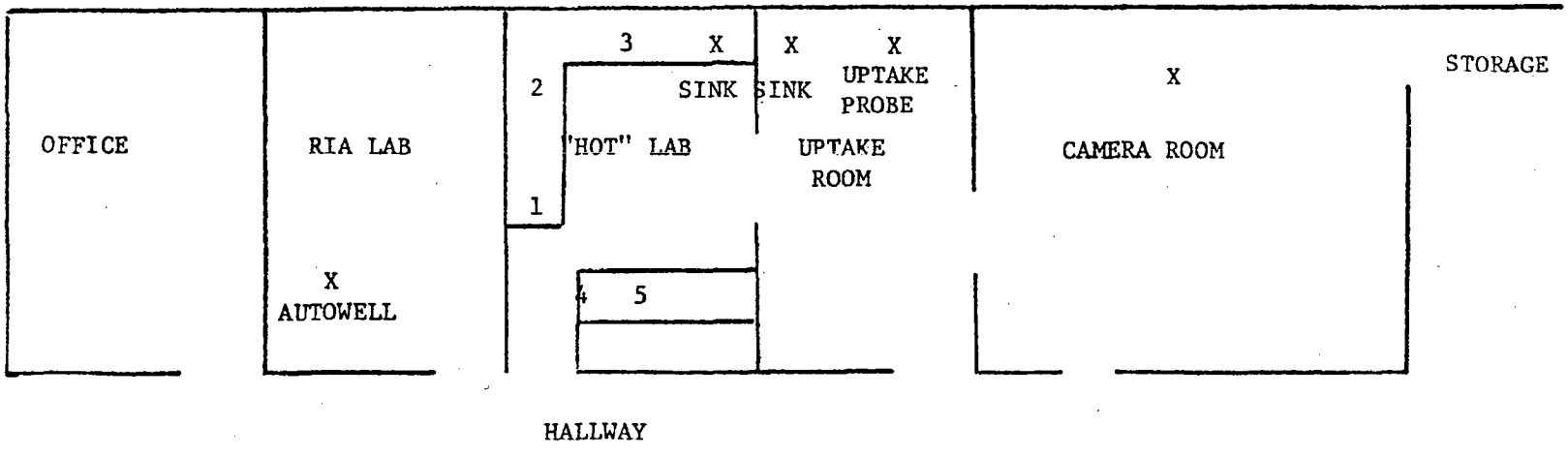
Woodland Medical Group
22341 W. Eight Mile Road
Detroit, Michigan 48219



1. Refrigerator
2. "Dose" Preparation and Compounding
   Lead-Glass "Face" Shield
3. Generator and Waste Storage Area (Lead Bricks)
4. Survey Meter(s) - Package Receipt
5. "Dose" Calibrator

Item 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

Byproduct material will be ordered by authorized personnel in accordance with licensed possession limits and conditions. Byproduct material received during off-duty hours will be delivered to a locked Nuclear Medicine room that has been identified for radiopharmaceutical receipt.

Delivery persons will be given the following instructions:

Take package(s) to designated Nuclear Medicine Room
Do not open or tamper with package(s) in any way
Place in designated area
Lock door upon leaving

ITEM 14

RECEIVING, OPENING AND LOGGING PACKAGES

CONTAINING RADIOACTIVE MATERIALS

Packages containing radioactive materials shall be received by authorized personnel and delivered to the nuclear medicine laboratory. They shall be placed in an area designated for processing and secured against unauthorized removal.

Packages shall be processed as soon as practicable after receipt.

Disposable gloves shall be worn while processing packages and remote handling devices shall be used when practicable. Absorbent pads shall be used to cover the processing area.

Procedure

1. Monitor the exposure rates at the package surface and at three feet from the package surface. If the exposure rate at the package surface exceeds 200 mR/hr or if the exposure rate at three feet exceeds 10 mR/hr, do not open. Place package behind the protective lead barrier and notify the Radiation Protection Officer.
2. Open the outer package and remove the packing slip. Open inner package and verify that the contents agree in activity, chemical form, and calibration date with the packing slip.
3. Check for possible breakage of seals or containers, loss of liquid, or change in color of liquid absorbing material.
4. If the package appears intact, remove the radioactive material from the outer package and place behind the protective lead barrier. If the shipment appears damaged or discrepant in any way, do not remove the radioactive material. Place the package behind the protective lead barrier and notify the Radiation Protection Officer.
5. With the radioactive material removed, monitor (G.M. survey meter) the package's outer surface and inner contents for contamination. If contamination is noted, place the package behind the protective lead barrier and notify the Radiation Protection Officer..
6. On form "log 1" record date, radionuclide, chemical form, activity, supplier, exposure rate at package surface and at three feet, and if contamination was noted.
7. Store the radioactive material at the assigned shielded location.
8. On form "log 2" record use and ultimate disposal of remaining radioactive material (see also the section on Radioactive Waste Disposal).

Note:

Title 10, Part 20, Section 20.205 requires that exposure rates be measured and if they exceed 200 mR per hour at the package surface or 10 mR per hour at three feet, the licensee shall notify the final delivering carrier and the Nuclear Regulatory Commission immediately. It also requires that removable package surface contamination be measured and if it exceeds 0.01 microcuries per 100 square centimeters of package surface, the licensee shall notify the final delivering carrier and the Nuclear Regulatory Commission immediately. In the procedure outlined above, if package surface contamination is noted using the G.M. survey meter, the package surface should then be "smeared" for removable contamination and the activity per 100 square centimeters quantified and required action taken.

Contaminated containers, liners, shields, etc. should be discarded in the assigned "hot" waste containers. Noncontaminated items may be discarded in the regular waste containers after removing or defacing any label indicating the presence of radioactive material.

Packages containing $Na^{131}I$ or ^{133}Xe should be processed in a fume hood.

LOG 2A MULTIPLE DOSE DISPOSITION RECORD - PREPARED RADIOPHARMACEUTICALS(SUPPLIER & KITS)

KIT _____

_____ mCi TOTAL

_____ DATE

@_____ AM PM

_____ ml TOTAL

_____ mCi/ml

SUPPLIER ASSAY(OR LABEL)	
mCi TOTAL	_____
DATE	_____
ml TOTAL	_____
mCi/ml	
LOT NUMBER	_____

DATE & TIME	PATIENT NAME & NUMBER	mCi to adminis.	÷mCi/ml x decay factor=	ml adminis.	INITIAL

DISPOSAL

DATE DISPOSED _____

mCi DISPOSED _____

METHOD INITIAL

LOC 1 RADIONUCLIDES RECEIVED - _____ (month)

DATE RECEIVED	RADIO-NUCLIDE	CHEMICAL FORM	ACTIVITY (mCi)	SUPPLIER	mR/hr SURFACE	mR/hr 3 feet	CONTAMINATION YES	CONTAMINATION NO	CHECKED BY

TOTAL ACTIVITY RECEIVED = _____ (mCi)

LOG 28 MULTIPLE DOSE DISPOSITION RECORD - Mo-99/Tc-99m GENERATOR & GENERATOR ELUATE

^{99m}ASSAY($Na\ ^{99m}TcO_4^-$)

_____ mCi TOTAL

_____ DATE

@_____ AM PM

_____ ml TOTAL

_____ mCi/ml

^{99}Mo CHECK

_____ uCi ^{99}Mo/mCi ^{99m}Tc

+++

Al

_____ ug/ml

SUPPLIER ASSAY(OR LABEL)	
mCi TOTAL(Mo-99)	_____
DATE	_____
LOT NUMBER	

DATE & TIME	PATIENT NAME & NUMBER	mCi to adminis.	÷mCi/ml x decay factor=	ml adminis.	INITIAL

^{99m}DISPOSAL($Na\ ^{99m}TcO_4^-$)
DATE DISPOSED _____
mCi DISPOSED _____
METHOD _____ INITIAL _____

DISPOSAL(GENERATOR)
DATE DISPOSED _____
mCi DISPOSED _____
METHOD _____ INITIAL _____

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: Dr. Samules
OFFICE PHONE: 538-4700
HOME PHONE: (b)(6) Ex 6

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____

_____

_____

APPENDIX J

WASTE DISPOSAL

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

____ By commercial waste disposal service (see also item 4 below).

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

____ Other (specify): _____

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

____ Returned to the manufacturer for disposal.

x
____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

____ Disposed of by commercial waste disposal service (see also item 4 below).

____ Other (specify): _____

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

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

_____
(Name) (City, State)

NRC/Agreement State License No. _____

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