

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
811 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Upsher Lab
20 E. 14th Street
Kansas City, MO 64142

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ms. Clare Rockenhaus

TELEPHONE NUMBER

816-842-4850

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITY

8506190275 850604
REG3 LIC30
24-24508-01 PDR

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7C AMOUNT ENCLOSED \$ 580.00

13. CERTIFICATION: (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

<input type="checkbox"/> < \$250K	<input type="checkbox"/> \$1M - 3.9M
<input type="checkbox"/> \$250K - 500K	<input type="checkbox"/> \$3.9M - 7M
<input type="checkbox"/> \$500K - 750K	<input type="checkbox"/> \$7M - 10M
<input type="checkbox"/> \$750K - 1M	<input type="checkbox"/> > \$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (For use and for staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE APP	FEE LOG May 26th	FEE CATEGORY 3P	COMMENTS \$350 refunded	APPROVED BY [Signature]
AMOUNT RECEIVED \$ 580	CHECK NUMBER 032042			DATE 5/29/85

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 313. 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, 32, 33, 34, 35 and 40 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 (a) provided to State health departments for their information and use; and (b) provided 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 an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
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. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

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CURRICULUM VITAE

R. EMORY LARIMORE

HOME: 4955 Westwood Terrace
Kansas City, Missouri 64112
(816) 931-2219

WORK: Radiation Consultants of Mid-America, Inc.
5460 Buena Vista, Suite 207
Shawnee Mission, Kansas 66205
(913) 236-5126

EDUCATION: University of Kansas, Lawrence, Kansas
Graduated 1977, M.S., Radiation Biophysics

Oklahoma State University, Stillwater, Oklahoma
Graduated 1972, B.S. Radiation & Nuclear Technology

Central Florida Jr. College, Ocala, Florida
Graduated 1969, A.A., Radiological Health

EXPERIENCE: Radiation Consultants of Mid-America, Inc., Shawnee Mission, Kansas, Radiological Physicist working as a consultant in nuclear medicine, x-ray and radiation therapy.
July 1980 - Present

Pharmaco Nuclear, Inc., Kansas City, Missouri
Health Physicist working as a consultant in nuclear medicine and x-ray.
September 1978 - June 1980

University of Kansas Medical Center, Kansas City, Kansas
Employed as the Health Physicist/Radiation Safety Officer.
1973 - 1978

Kansas Department of Health & Environment, Topeka, Kansas
Employed as a Health Physicist in x-ray and licensing.
1972 - 1973

Ingalls Shipbuilding Corp., Pascagoula, Mississippi
Employed as a radiation protection specialist during new construction and overhaul of naval nuclear submarines.

SOCIETIES: National Health Physics Society
Mid-America Chapter Health Physics Society
 A. President (1978)
 B. Vice President (1977)
Missouri Valley Chapter AAPM
International Radiation Protection Association
National American Association Of Physicist in Medicine
National Nuclear Medicine Society

Item #5: Radioactive Material

Items listed in 10 CFR 31.11 for invitro studies. We request a possession limit of 20 mCi total.

Item #6: Purpose(s) for Which Material Will Be Used

The requested material will be used for clinical in vitro studies.

Item #7: Individual Responsible for Radiation Safety

R. Emory Larimore from Radiation Consultants of Mid-America will be the Radiation Safety Officer for Upsher Labs. This individual will visit the facility at least quarterly and more often if necessary. Radiation Consultants of Mid-America was previously licensed under NRC license #24-18831-01. Radiation Consultants of Mid-America is now licensed under Kansas license #33-B429-01. A resume for Mr. Larimore is attached.

Ms. Clare Rockenhaus will be the on-site person responsible for radiation safety. Ms. Rockenhaus is a certified medical technologist with considerable experience in invitro use of radioactive materials.

Item #8: Training for Individuals Working in or Frequenting Restricted Areas

Individual	Specialty
Clare Rockenhaus, M.T.	Medical Technologist
Albert Upsher, M.D.	Pathologist
Robert Jensen, M.D.	Pathologist
G. Curtis Hoskins, M.D.	Pathologist

PERSONNEL TRAINING PROGRAM

Clinical, Housekeeping, and Security Personnel

These individuals will be required to attend lectures before assuming their duties with or in the vicinity of radioactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations or terms of the license. Lectures for presentation of this material will be two hours in duration. The training program will be of sufficient scope to insure that all personnel will receive proper instruction in the items specified in Section 1912 of 10 CFR, Part 19 and will include:

- A. Areas where radioactive material is 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 and unsafe conditions
- I. Their right to be informed of their radiation exposure and bio-assay results

Lectures will be given by the Nuclear Medicine Technologist, the Radiation safety Officer or a consulting physicist. Parts 19 and 20 of 10 CFR Regulatory Guide 10.8, Rev. , Dated , "A Guide for Preparation of Applications for Medical Programs" will be used as source material for these lectures.

Item #9: FACILITIES & EQUIPMENT

The following items are provided for handling radioactive material and will be used appropriately:

- a. disposable gloves
- d. tongs and forceps
- c. work bench area with absorbent paper
- d. survey meters

The lab area will be used for receipt, storage (including waste), preparation and measurement of radioactive material. Radioactive waste will be stored in labeled containers. The lab area will be locked when personnel are off duty and will be made available only to those people authorized by the lab supervisor. A diagram of the area is enclosed.

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

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

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 2.0 mR/Hr.

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

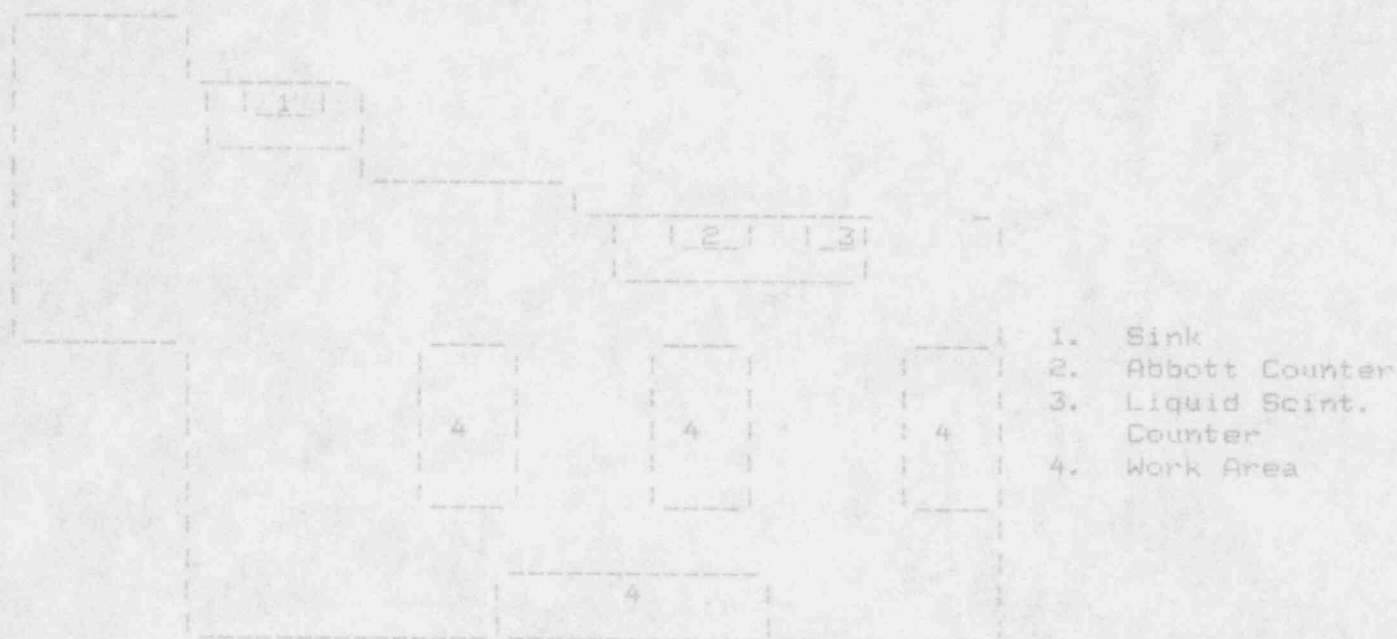
All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

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

DECONTAMINATION KIT

ITEM	PURPOSE
Warning tape, chalk, & signs	Posting of area
Plastic bags - small	Shoe covers, wet containers
Disposable gloves	Hand protection
Masking tape	Fasten shoe covers, etc.
Forceps, tongs	Safe handling
Large plastic bags	For contaminated material
Sponges, 4 x 4	Sopping up
Paper towels	Blotting & drying
Radiac wash or detergent	Detergent
Scouring powder	Friction
Tags	Identification
Scissors	Cut absorbent paper, etc.
Whatman #1 filter paper	Taking swipes following decontamination
Chux	Cover area following decontamination
G-M survey meter	Monitoring

LAB DIAGRAM



Item #10: Radiation Safety Program

A. Radiation Safety Officer

The Radiation Safety Officer will visit the facility routinely on a quarterly basis. During this quarterly visit a meeting will be held with the individuals who use and supervise the use of material at the lab. The RSO will also perform specific equipment checks on the gamma counters and survey meters to insure that they are working properly. He will also review the receipt, use, and disposal records generated during the past quarter to insure that the records are being maintained properly. On an annual basis the RSO will present an inservice to employees working in the areas where radioactive materials are used. The Radiation Safety Officer will be available for more frequent checks if the need should arise.

B. Equipment

1. Survey meter:

Victoreen Thyac III

0 - .2 mR/hr (minimum range)

0 - 20 mR/hr (maximum range)

2. Gamma Counter - Abbott Logic

Gamma Counter - Abbott ANSR

Beta Counter - Tracor Delta 300

3. Miscellaneous

Picker .8 - 1.0 uCi Cs-137 source \

Picker .5 - Ba-133 source

B-Quenching Set

} Equipment calibration

/

C. Survey Meter Calibration:

Performed by Radiation Consultants of Mid-America, Inc. Kansas License #33-B429-01. To be performed annually. A quarterly check (200 uCi Cs-137) will be performed on the instrument to insure that its response to radiation has not changed.

Clinical Equipment Calibrations:

The diagnostic equipment will be calibrated each day of use with the appropriate sources listed in B-3 above. The results will be recorded so that changes can be assessed over an extended period of time.

D. Monthly radiation/wipe test surveys will be performed in the laboratory area. The radiation survey will be performed with the Victoreen Thyac III low level survey meter. The wipe test will be counted on either the Abbott Logic well counter or the Abbott ANSR well counter. The surveys will be recorded on a form keyed to a diagram. The results, background levels, cleaning levels, and the equipment used will be maintained on the survey record.

E. Bioassays:

The quantity of material used on a routine basis falls below the levels outlined in Regulatory Guide 8.2. Bioassays will not be performed on personnel working in the clinical lab area.

F. Personnel Monitoring:

The types of material used in our facility result in radiation levels which are very low. The types of material routinely emit low energy gamma radiation and beta particles. The levels are such that we do not anticipate using personnel monitoring devices.

G. Procedures for Ordering & Receiving Radioactive Material:

1. The Chief Medical Technologist Pathologist will place all orders for radioactive materials and will insure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours, the receptionist on duty will accept delivery of radioactive packages in accordance with the procedures outlined in the following memorandum.

MEMORANDUM FOR

FROM: Dr. Albert Upsher
SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:00 p.m. and 7:30 a.m. or on Saturday or Sunday shall be signed for by the receptionist on duty and taken immediately to the clinical lab. Unlock the door and place the package on the work bench in the Hot Lab, and relock the doors.

If the package is wet or appears to be damaged, IMMEDIATELY contact the chief medical technologist. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

CHIEF MEDICAL TECHNOLOGIST Georgianna Darrell

OFFICE PHONE: _____

HOME PHONE: 913-384-0896

RADIATION SAFETY OFFICER: Emory Larimore

OFFICE PHONE: 913-236-5126

HOME PHONE: 816-931-2219

H. Laboratory Rules for 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.
 - a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
 - b. Do not store food, drink, or personal effects with radioactive material.
4. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
5. Never pipette by mouth.
6. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day.
7. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

I. 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: R. Emory Larimore

OFFICE PHONE: 913-236-5126

HOME PHONE: 816-931-2219

ALTERNATE NAMES AND TELEPHONE NUMBER DESIGNATED BY RADIATION SAFETY OFFICER:

Ms. Clare Rockenhaus

Item #11: Waste Disposal Procedures

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

☒ In the sanitary sewer system in accordance with sect. 20.303 of 10 CFR Part 20.

☐ By commercial waste disposal service (see also Item 4)

☐ Other (Specify) (see Item 3) _____

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

☐ Returned to the manufacturer for disposal.

☐ Held for decay* until radiation levels, as measured 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).

☐ Other (specify) _____

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

☒ 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.

☒ Test tubes will be rinsed several times, surveyed with the low level survey meter and disposed of as normal trash if background levels are found.

☐ Disposed of by commercial waste disposal service (see Item 4)

☐ Other (specify) _____

4. The commercial waste disposal service used will be:

NRC/Agreement State License No.: _____

*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.