NRC FORM 313
(7-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 6-30-90

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS 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 HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY 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
611 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
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

RECEIVED

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)

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Ultrasound Diagnostic Services, Inc.
Northland Medical Building
20905 Greenfield - Suite 106
Southfield, Michigan 48075

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

Same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Colleen Brady, Consultant NMA/Mallinckrodt, Inc.

TELEPHONE NUMBER: (313)268-5300

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170.31 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
x [signature]	x NORBERT C. ADAMIAN, MD	x RADIOLOGIST	x 6/20/88

8810260523 880628
REG3 LIC30
21-25932-01 PNU

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
appl	[illegible]	7C	RECEIVED JUN 23 1988 REGION III CONTROL NO 8563	CT
AMOUNT RECEIVED: $580	CHECK NUMBER: 5324			DATE: 9/6/28/88

JUN 2 3 1988

TABLE Of CONTENTS

ITEM

5 & 6 Radioactive materials - please refer to the attached Item #5 & 6

7 Individuals named on license - please refer to the attached Item #7

8.1 Training Program, Appendix A: We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, and have appended a table ATT 8.1 that identifies the groups of workers who will receive training and the method and frequency of training

8.2 Other Training Program: N/A

9.1 Facilities and Equipment: See ATT 9.1

9.2 Survey Instruments: We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.3.

9.3 Dose Calibrator: We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3.

9.4 Personnel Monitoring, Appendix D: We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

9.5 Mobile Nuclear Medicine Service: N/A

9.6 Other Equipment and Facilities: N/A

10.1 RSC/RSO, Appendix F: We will issue the model Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2. See ATT 10.1

10.2 ALARA, Appendix G: We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

10.3 Leak Test: We have developed a procedure for leak testing sealed sources for your review that is appended as ATT 10.3.

10.4 Safety Rules, Appendix I: We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

Lic.New
Prepared: 6/9/88

10.5 **Spills, Appendix J:** We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2.

10.6 **Ordering and Receiving, Appendix K** We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6.

10.7 **Opening Packages, Appendix L:** We will establish and implement the model procedure for opening packages that was published in Appendix L to the Regulatory Guide 10.8, Revision 2.

10.8 **Unit Dose, Appendix M.1:** We will establish and implement the model procedure for unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.

10.9 **Multi-doses, Appendix M.2:** We will establish and implement the model procedure for a multi dose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8,Revision 2

10.10 **Molybdenum Breakthrough,Appendix M.3:** We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2.

10.11 **Implant Sources,Appendix M.4:** N/A

10.12 **Area Surveys, Appendix N:** We have developed survey procedures for your review that are appended as ATT 10.12.

Lic: New
Prepared: 6/9/88

10.13.1 **Worker dose from Noble Gases, Appendix 0.1:** We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix 0.1 to Regulatory Guide 10.8, Revision 2. We will collect spent noble gas in a shielded container and will check the trap effluent according to the procedure that was published in Appendix 0.3 to Regulatory Guide 10.8, Revision 2 or to the procedure that is appended as ATT 10.13.1.

10.13.2 **Worker dose from aerosols:** We will collect spent aerosol in a shielded trap, and for reusable traps, monitor the traps effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

10.13.3 **Airborn Effluents:** We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.

10.13.4 **Clearance Time, Appendix 0.4:** We will calculate spilled gas clearance times according to the procedure only that was published in Appendix 0.4 to Regulatory Guide 10.8, Revision 2.

10.14 **Radiopharmaceutical Therapy:** N/A

10.15 **Implant Therapy:** N/A

10.16 **Other Safety Procedures:** N/A

11.1 **Waste Disposal, Appendix R:** We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2. In addition, authorization is requested to return waste materials to the radiopharmacy from which they were received.

11.2 **Other Waste Disposal:** N/A

ITEM #5		ITEM #6
BYPRODUCT MATERIAL	AMOUNT	PURPOSE
Material in 35.100	As needed	Medical use
Material in 35.200	As needed	Medical use

Item #5 & 6
1 of 1 page
Prepared:6/9/88
Lic:# New

INDIVIDUALS RESPONSIBLE FOR RADIATION
SAFETY PROGRAMS - THEIR TRAINING & EXPERIENCE

AUTHORIZED USERS FOR MEDICAL USE
ATT 7.1

AUTHORIZED USER	AUTHORIZATION
Norbert A. Sugayan, M.D.	All
John D'Alessandro, D.O.	All
Irwin Z. Phillips, D.O.	All

For the training and experience of the above, refer to License # 21-13807-01, Brent General Hospital.

AUTHORIZED USERS FOR NONMEDICAL USE

ATT 7.2

N/A

RADIATION SAFETY OFFICER

ATT 7.3

Norbert A. Sugayan, M.D.

Item #7
1 of 1 page
Prepared:6/9/88
Lic: New

TRAINING PROGRAM

INDIVIDUALS	FREQUENCY	METHOD
Chief Nuclear Medicine Technologist	Per the model program	Presentation by the RSO and/or as provided by our visiting consultants.
Staff Nuclear Medicine Technologist	Per the model program	Presentation by the RSO and/or the Chief Nuclear Medicine Technologist and/or as prcvided by our visiting consultants.
Other Clinic Staff	At orientation and annual thereafter	Presentation by RSO and/or Chief Nuclear Medicine Technologist and by annual memo to department heads.
Visitors	As needed	Immediate supervision by Radiation Safety Officer on Nuclear Medicine Staff

ATT 8.1
1 of 1 page
Prepared: 6/9/88
Lic.: New

EQUIPMENT

(Proposed list or equivalent)

1. Survey meters

   a. Manufacturer's name and model number: Picker 655-186

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 0.2 mR/hr

   Maximum range: 0 mR/hr to 2000 mR/hr

2. Dose calibrator

   Manufacturer's name and model number: Capintec CRC-4

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	Picker	4/11

Facilities and Equipment Diagram

- Air Supply
- Air Exhaust
- ___ Scanner
- ___ Uptake/Well
- 1 Camera
- 2 Lockable Door
- 3 Receipt Area
- ___ Generator
- 4 Kit Preparation
- 5 Isotope Storage
- 4 Dose Preparation
- 5 Waste Storage
- 6 Dose Calibrator
- ___ Refrigerator

Adjacent Areas

- Sink
- Lead Castle

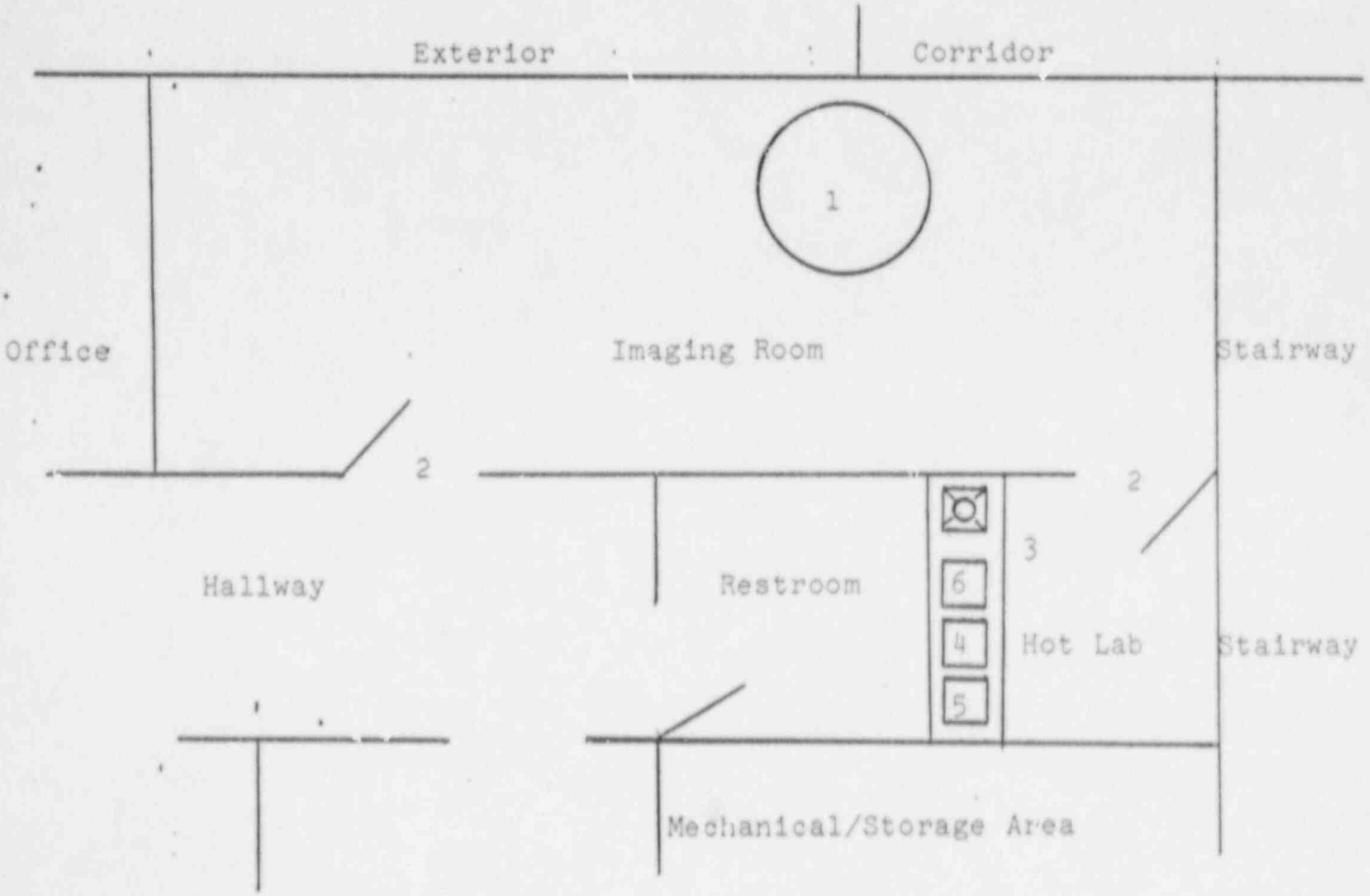
Lead Shielding

4 L-Shield
16"L x 18"W x 22"H x ¼" T

5 Lead Shielding
8"L x 8"W x 8"H x 2" T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T



ATT 9.1
2 of 2 pages
Prepared 6/9/88

Lic: New
Scale: 1"=4'

CALIBRATION OF SURVEY INSTRUMENTS

Survey meters will be checked for operability each day of 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 units will be calibrated after servicing and at least annually thereafter by the manufacturer; by other organizations licersed by the NRC; or by NMA/Mallinckrodt in accordance with the procedure outlined in the 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.

ATT 9.2
1 of 1 page
Prepared: 6/9/88
Lic: New

DOSE CALIBRATOR CALIBRATION

The dose calibrator will be calibrated as follows:

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

Nuclide	Activity
Co-57	.05 - 5 mCi
Ba-133	.05 - 0.5 mCi
Cs-137	.05 - 0.3 mCi

The accuracy of the assay of the above standards will be at least ±5% and traceable to National Bureau of Standard sources. The dose calibrator will be checked for accuracy at annual intervals and following repair. The activity displayed by the dose calibrator must agree with the stated assay, corrected for decay, to within ± 10%. If the unit displays readings with an error greater than ± 10%, arrangements will be made for repair or replacement.

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 ± 10% of the predicted activity based on the value obtained at the time of the last 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 ± 10% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 10% are noted, arrangements will be made for repair or replacement.

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 to be administered for patient studies. The linearity test will be continued by repeating the assay of the source 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, but not less than 10uCi, and also less than the activity displayed during the annual accuracy check utilizing the Co-57 accuracy standard.

The linearity test data will be plotted or calculated as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 10%. If test result error exceeds ± 10%, the unit will be evaluated for the necessity of repair. The unit may be used in the interim using correction factors if appropriate.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck Kit or the Lineator. The manufacturer's instructions for use will be followed. The source used shall be the activity of the largest dose used for patient studies. 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 repair or replacement. This test will be performed using approximately 1-10 mCi of Tc-99m in less than 0.5ml in a syringe. The volume in the syringe will be increased in steps by adding water. The syringe will be assayed at each step. Each reading will be compared against the reading obtained for a standard geometry. Correction factors will be used for those geometries that induce a variation in excess of ± 10%

This procedure will also be performed using a glass vial. The procedure will begin with an activity in excess of 1mCi in approximately 1 ml. Again, geometry induced variations in excess of ± 10% will result in the utilization of correction factors.

Radiation Safety Officer
Delegation of Authority

DELEGATION OF AUTHORITY

Memo To: All Employees
From: Chief Executive Officer
Subject: Delegation of Authority

Norbert A. Sugayan, M.D. has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

ATT 10.1
1 of 1 page
Prepared: 6/9/88
Lic: New

LEAK TESTING OF SEALED SOURCES

Sealed sources will be leak tested by our consultants, NMA/Mallinckrodt, Inc.in accordance with the procedures specified in NRC License #34-16272-01.

ATT 10.3
1 of 1 page
Prepared: 6/9/88
Lic: New

Model Guidance for Ordering and Receiving
Radioactive Material
(See 30.51 and 20.205)

Model Guidance

1. The Radiation Safety Officer (RSO) or a designee must authorize order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to nuclear medicine.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to comply with procedures outlined in the memorandum below.

Sample Memorandum

TO: All Clinic Personnel

FROM: Radiation Safety Officer

SUBJECT: Delivery of packages containing radioactive materials.

If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will have the carrier escorted to nuclear medicine by personnel who have been assigned this duty. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials. The packages will be secured against unauthorized removal. When delivered 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.

Radiation Safety Officer: Norbert A. Sugayan, M.D.

ATT 10.6
2 of 2 pages
Prepared: 6/9/88
Lic: New

AREA SURVEY PROCEDURES

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2 with the exception of paragraph #2 under records.

ATT 10.12
1 of 1 page
Prepared: 6/9/88
Lic.:New

Procedure for Checking Trap Effluent

The trapping efficiency of the charcoal trap will be evaluated once each month. A low level G-M probe will be placed against the inlet tube of the trap during the equilibrium phase of the study and a reading taken. The probe will then be placed against the outlet from the trap at the initiation of the washout phase. If the maximum exhaust reading exceeds 10% of the inlet reading, taking background into consideration, the trap will be considered saturated and the cartridge will be replaced.

ATT 10.13.1
1 of 1 page
Prepared: 6/9/88
Lic: New