

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 20545

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 9
801 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
301 MARIETTA STREET, SUITE 2000
ATLANTA, GA 30333

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
700 ROOSEVELT ROAD
GLEN ELLYN, IL 60127

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
1400 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94698

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.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item):</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>34-09621-01</u></p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code):</p> <p style="text-align: center;">Robinson Memorial Hospital P.O. Box 1204 Ravenna Ohio 44266</p>
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3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

6847 North Chestnut Street
Ravenna Ohio 44266

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION	TELEPHONE NUMBER
William H. Miller, Consultant NMA - Cleveland, Ohio	(216) 641-5799

SUBMIT ITEMS 6 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.

<p>6. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.</p>	<p>8. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p>
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>	<p>9. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p>
<p>8. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM</p>
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)</p> <p>FEE CATEGORY <u>7C</u> AMOUNT ENCLOSED <u>Exempt - 10CFR \$170.11(a)(9)</u></p>

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
<i>Ralph W. Kletzien</i>	Ralph W. Kletzien	President & C.E.O.	X

8904120075 880616
REG3 LIC30
34-09621-01 PNU

FOR NRC USE ONLY				RECEIVED	
TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY	
			MAY 09 1983		
AMOUNT RECEIVED	CHECK NUMBER	CONTROL NO. 8539		DATE	

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: 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 will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.
- 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: 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 Radiation Safety Committee/Radiation Safety Officer: We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2.
- 10.2 ALARA Program: 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 will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

- 10.4 **Safe Use of Radiopharmaceuticals:** We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.
- 10.5 **Spill Procedure:** 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** 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:** 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 Dosage Records:** 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-dose Vial Records:** 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 Concentration Records:** 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 Source Use Records:** We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.
- 10.12 **Area Survey Procedures:** We have developed survey procedures for your review that are appended as ATT 10.12.
- 10.13.1 **Worker Dose from Noble Gas:** We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix O.3 to Regulatory Guide 10.8, Revision 2.
- 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 **Public Dose from Airborne Effluent:** We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.
- 10.13.4 **Spilled Gas Clearance Time:** 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:** We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory guide 10.8, Revision 2.
- 10.15 **Implant Therapy:** We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 10.15.
- 10.16 **Other Safety Procedures:** N/A
- 11.1 **Waste Disposal:** We have developed a procedure for waste disposal for your review that is appended as ATT 11.1.
- 11.2 **Other Waste Disposal:** N/A

ITEM #5

ITEM #6

BYPRODUCT MATERIAL

AMOUNT

PURPOSE

Material in 31.11	3mCi	In-Vitro testing
Material in 35.100	As needed	Medical use
Material in 35.200	As needed	Medical use
Material in 35.300	As needed	Medical use
Material in 35.400	400 mCi	Medical use
Material in 35.500	As needed	Medical use

Item #5 & 6
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INDIVIDUALS RESPONSIBLE FOR RADIATION
SAFETY PROGRAMS - THEIR TRAINING & EXPERIENCE

AUTHORIZED USERS FOR MEDICAL USE
ATT 7.1

AUTHORIZED USER

AUTHORIZATION

Donald A. Hammel, M.D.	Material in 31.11, 35.100, 35.200 and 35.300 and 35.500
Albert James Cook, M.D.	Material in 31.11, 35.100, 25.200 and 35.300, 35.400 and 35.500
David D.Y. Lan, M.D.	Material in 31.11, 35.100, 35.200, 35.300 and 35.500
Michael D. McCloskey, M.D.	Material in 31.11, 35.100, 35.200 35.300 and 35.500
Manju Wigayvargiya, M.D.	Material in 35.100, 35.200, 35.300 and 35.500
A. Roger Tsai, M.D.	Material in 35.200 (Cardiac) and 35.500

Refer to License #34-09621-01 for evidence of user qualification for
all of the above physicians.

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AUTHORIZED USERS FOR NONMEDICAL USE

ATT 7.2

N/A

RADIATION SAFETY OFFICER

ATT 7.3

RSO

Donald A. Hammel, M.D.

Reference

License #34-09321-01

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TRAINING PROGRAM

ATT 8.1

<u>INDIVIDUALS</u>	<u>FREQUENCY</u>	<u>METHOD</u>
Chief Nuclear Medicine Technologist	Per the model program	One on one by the RSO supplemented by participation in quarterly audits provided by visiting consultants.
Assistant Nuclear Medicine Technologist	Per the model program	One on one by the RSO and/or the Chief Nuclear Medicine Technologist supple- mented by review of reports generated following quarterly audits.
Security	At orientation and semi-annual inservice	One on one by RSO and/or Chief Technologist
Housekeeping	At orientation and annual inservice	One on one by RSO and/or Chief Technologist
X-ray staff Nursing Service Maintainence Engineering	Annual	One on one by RSO and/or Chief Nuclear Medicine Technologist and/or by annual memo to department heads.
Visitors	As needed	Immediate supervision by Radiation Safety Officer or Nuclear Medicine Staff

ATT 8.1
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FACILITIES AND EQUIPMENT

Scale 1/8" = 1'

DIAGRAM

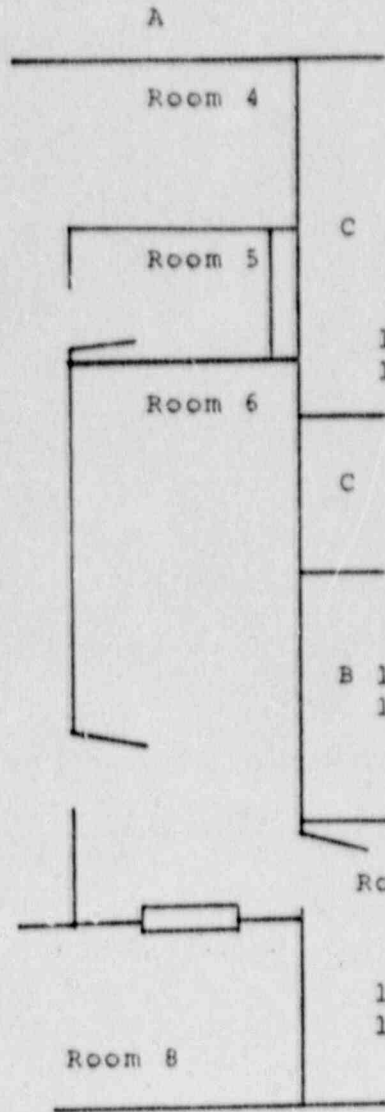
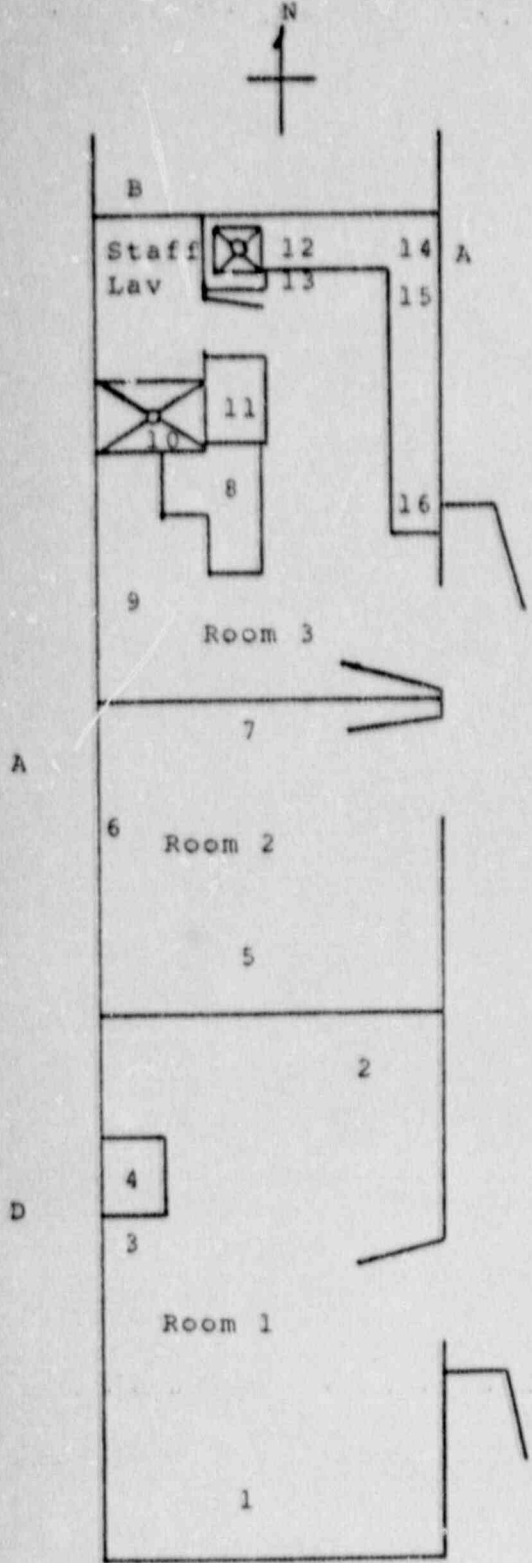
ATT 9.1

FACILITIES

- Room 1 Imaging
- Room 2 Imaging
- Room 3 Hot Lab
- Room 4 Disaster Cart Bed Storage
- Room 5 Patient Lav
- Room 6 Secretary, Files, Tech Office
- Room 7 Office
- Room 8 Patient Waiting

EQUIPMENT

- 1. Camera
- 2. Camera
- 3. Xenon Charcoal Trap
- 4. Xenon Canopy
- 5. Portable Camera
- 6. Well/Scanner
- 7. Uptake
- 8. RIA Countertop
- 9. Auto Sample Changer
- 10. Shower
- 11. A) Hood
- B) 2" Lead Castle
- C) Dose Calibrator
- D) Generator If Used
- E) L-Shield W/F Glass
- F) Current Use Nuclides
- G) Cs-137 Standard
- H) Current Waste
- I) Kit & Dose Prep
- B 12. Hot Sink
- 13. Sealed Source & Long Term Waste in Decay Shielded Cabinet - 1/2" Lead
- 14. Fibrinogen Detector
- 15. Isotope Receipt, Opening, Dispatch
- 16. G-M Survey Meters, 2 Inch Using one 0-2000 mr/hr.



DOSE CALIBRATOR CALIBRATION

ATT 9.3

We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2 except that if the sleeve method is used for linearity testing, Calicheck, or Lineator Systems will be used. The manufacturers directions for use and data handling will be followed because the procedure deviates from the model, but the results are the same.

ATT 9.3
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ORDERING AND RECEIVING

ATT 10.6

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2. except that the sample memorandum in the Appendix K model will be modified to the extent that it will be directed to the Manager of the emergency room services along with the Chief of Security. In addition, the instructions will carry the directive that couriers reporting to the above departments to effect delivery are to be escorted by the duty security guard who will ensure the package is placed in the hot lab and the area re-secured.

AREA SURVEY PROCEDURES

ATT 10.12

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2, except that quarterly surveys described in the model (Appendix N, Ambient Dose Rate Surveys 1.d.) will be performed using a radiation detection instrument calibrated with Cs-137 or Ra-226 and having the same or a conservative response in fields generated by radionuclides having a specific gamma ionization constants lower than the calibrating radionuclide.

The RSO's review and initialling of area survey records as outlined in the model (Appendix N, Records 2.) will be at least quarterly instead of monthly except where action levels are exceeded. In the latter case prompt documented review by the RSO will be initiated through notification by the surveyor.

ATT 10.6
ATT 10.12
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MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

FACILITY: Robinson Memorial Hospital LOCATION: Ravenna, Ohio

Estimated Number Of Studies Per Week N = 6

Activity Administered Per Study A = 15000 uCi

Estimated Activity Lost To Work Area Per Study L = 0.2
(enter 20% with trap or 100% without trap)

Total Airflow Exhausted

$$Q = \underline{300} \text{ cfm} \times 2.83 \times 10^4 \text{ ml/ft}^3 = \underline{8.49 \times 10^6} \text{ ml/min}$$

Unrestricted Area - Estimated Average Concentration

$$\frac{(A) \ 15000 \times (N) \ 6 \times (L) \ 0.2}{(Q) \ 8.49 \times 10^6 \times 10,080 \text{ min}} = \underline{2.10 \times 10^{-7}} \text{ uCi/ml}$$

* maximum permissible air concentration for:

Xe-133 - 3×10^{-7} uCi/ml

Tc-99m - 1×10^{-6} uCi/ml

MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

FACILITY: Robinson Memorial Hospital

LOCATION: Ravenna, Ohio

* Airflow exhaust must exceed supply to ensure negative pressure

Highest Activity Of Gas In A Single Container A = 27500 uCi

Maximum Permissible Air Concentration C = 1×10^{-5} uCi/ml
(value for Xe-133)

Volume of Room

$$V = \underline{2464} \text{ ft}^3 \times 2.83 \times 10^4 \text{ ml/ft}^3 = \underline{6.97 \times 10^7} \text{ ml}$$

Total Room Air Exhausted (Vented Not Recirculated)

$$Q = \underline{600} \text{ cfm} \times 2.83 \times 10^4 \text{ ul/ft}^3 = \underline{1.70 \times 10^7} \text{ ml/min}$$

CLEARANCE

$$\frac{(V) 6.97 \times 10^7}{(-Q) 1.70 \times 10^7} \times \ln \left(1 \times 10^{-5} \times \frac{(V) 6.97 \times 10^7}{(A) 27500} \right) = \underline{15} \text{ min}$$

MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS
OF GASES AND AEROSOLS IN WORK AREAS

FACILITY: Robinson Memorial Hospital LOCATION: Ravenna, Ohio

*Airflow exhausted must exceed supply to ensure negative pressure

Estimated Number of Studies Per Week N = 6
Activity Administered Per Study A = 15000 uCi

Estimated Activity Lost To Work Area Per Study L = 0.2
(enter 20% with trap or 100% without trap)

Total Airflow Exhausted In The Imaging Room
 $Q = \frac{150}{\text{cfm}} \times 2.83 \times 10^4 \text{ ml/ft}^3 = \frac{4.25 \times 10^6}{\text{ml/min}}$

Restricted Area - Estimated Average Concentration

$$\frac{(A) 15000}{(Q) 4.25 \times 10^6} \times \frac{(N) 6}{x} \times \frac{(L) 0.2}{2400 \text{ min}} = \frac{1.77 \times 10^{-6}}{\text{uCi/ml}}$$

*maximum permissible air concentration for:

Xe-133 - 1×10^{-5} uCi/ml

Tc-99m - 4×10^{-5} uCi/ml

IMPLANT THERAPY

ATT 10.15

We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2 except as applies to the use of I-125 seeds. For I-125 seed therapy, the Guidelines entitled "Radiation Safety Precautions for Therapeutic Use of I-125 Seeds" published by the USNRC in July 1981 will be implemented. See below.

GUIDELINES

RADIATION SAFETY PRECAUTIONS FOR THERAPEUTIC USE OF I-125 SEEDS

GENERAL

1. Personnel who prepare, insert or retrieve I-125 seeds must wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.
2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.
3. In transporting seeds from storage - preparation areas to the place of use, adequate shielding must be employed to ensure compliance with 10 CFR 20.105(b).

INSTRUCTIONS TO NURSES (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.
2. Handle dislodged seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.

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CONTROL NO. 8539 4

WASTE DISPOSAL

ATT 11.1

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, except that Radioactive materials received from a local radiopharmacy or other supplier having an NRC or agreement state approved return program will be transferred to that supplier as a method of disposal in accordance with their shipping and/or pick up instructions. The elements of the "Model Procedure for Returning Generators to the Manufacturer" as described in Appendix R to Regulatory Guide 10.8, Revision 2 will be applied to these radiopharmacy returns.

A copy of the recipient's license describing the return authorization and the procedure will be acquired and maintained on file for review.

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