NRC FORM 313
(7-83)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-86

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

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 _____
- [X] C. RENEWAL OF LICENSE NUMBER 21-17971-01

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

Muskegon General Hospital
Department of Nuclear Medicine
1700 Oak Avenue
Muskegon, MI 49442

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)826-8870

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 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 Roger Spoelman	X Roger Spoelman	X President and CEO	X 12/9/88

9001250427 890130
REG3 LIC30
21-17971-01 PDR

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Renew	Jan 10	7C	CONTROL NO. 86627	CP
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	53956			1/4/89

RECEIVED
DEC 29 1988
REGION III

DEC 29 1988

ITEM #5		ITEM #6
BYPRODUCT MATERIAL	AMOUNT	PURPOSE
Material in 35.100	As needed	Medical use
Material in 35.200	As needed	Medical use
Material in 35.300	As needed	Treatment of hyperthyroidism and caridiac dysfunction

Delete:

Material in 35.500

Item #5 & 6
1 of 1 page
Prepared:
Lic.#21-17971-01

INDIVIDUALS RESPONSIBLE FOR RADIATION
SAFETY PROGRAMS - THEIR TRAINING & EXPERIENCE

Item #7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER	AUTHORIZATION
Albie Hitrys, D.O.	35.100, 35.200
Darryl R. Stevens, D.O.	35.100, 35.200
Claude A. VanAndel, D.O.	All

For above physicians, refer to the application for license #21-17971-01 for evidence of training and experience.

Item #7
1 of 2 pages
Prepared:
Lic. #21-17971-01

Item #7.2

AUTHORIZED USERS FOR NONMEDICAL USE: N/A

Item #7.3

RADIATION SAFETY OFFICER

Albie Hitrys, D.O. with consultation from NMA/Mallinckrodt, Inc.

Item #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. The following identifies the groups of workers who will receive training and the method and frequency of training.

INDIVIDUALS	FREQUENCY	METHOD
Chief Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user and/or as provided by our visiting consultants.
Nuclear Medicine Technologist	Per the model program	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or as provided by our visiting consultants.
Other staff as appropriate	At orientation and annually thereafter	Review by RSO, authorized user, Chief Nuclear Medicine Technologist and/or participation in health physics audits or review of the audit reports as provided by our visiting consultants.

Item 8.2

Other Training Program: N/A

Item #8
1 of 1 page
Prepared:
Lic. #21-17971-01

Item #9.1

FACILITIES AND EQUIPMENT DIAGRAM

|_| Lead Castle

Lead Shielding

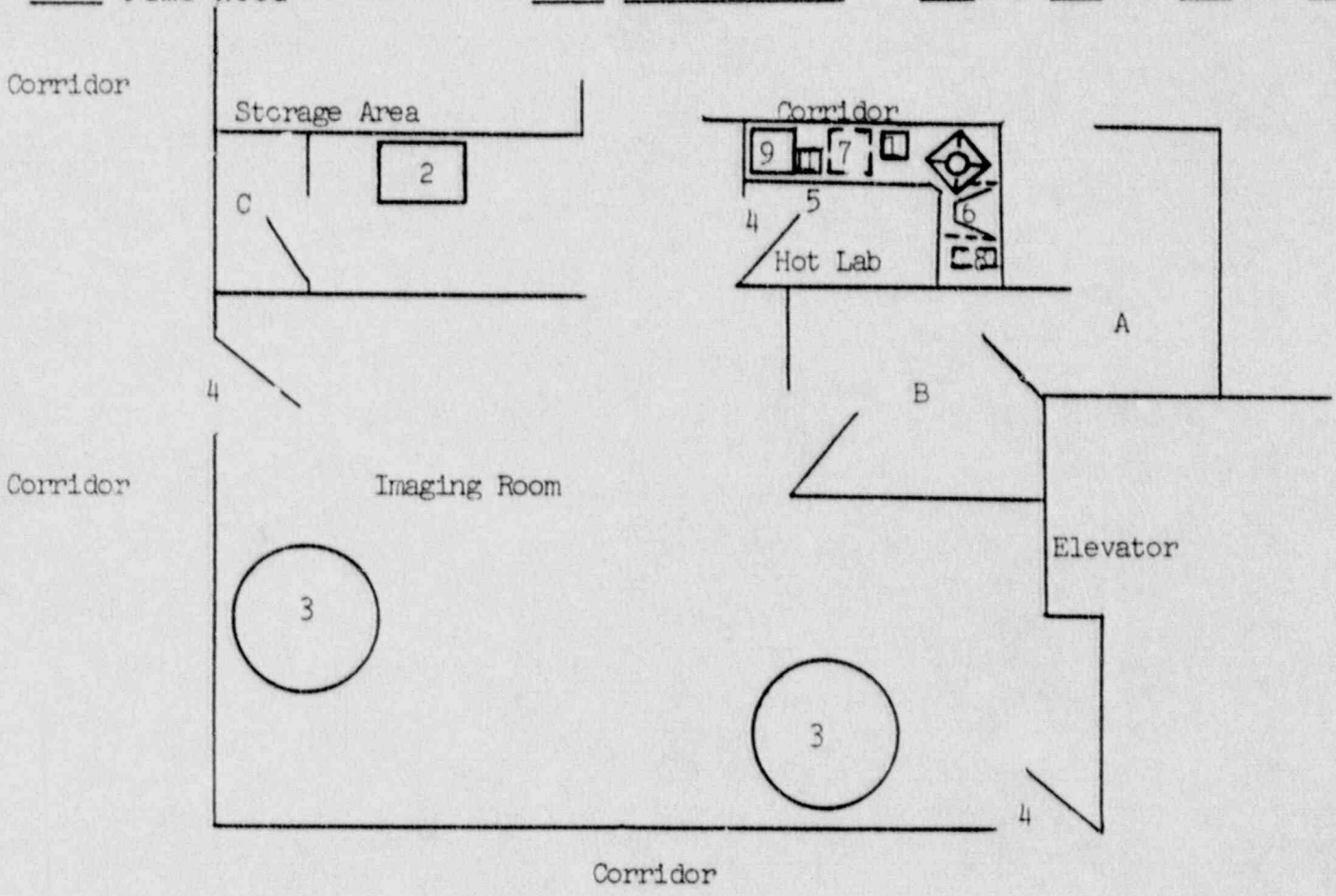
6 L-Shield
16"L x 18"W x 22" H x ½" T

7 Lead Bricks
19"L x 15"W x 10" H x 2" T

8 Waste Storage
8"L x 8"W x 11" H x 1" T

___L x ___W x ___H x ___T

1	Survey Equipment	
2	Uptake Probe	**Adjacent Areas**
3	Camera	
4	Lockable Door	A Mammography Room
5	Receipt Area	B Dressing/Waiting Room
___	Generator	
6	Kit/Dose Preparation	C Restroom
7	Isotope Storage	___ ___
8	Waste Storage	___ ___
9	Dose Calibrator	___ ___
___	Fume Hood	___ ___



Note: There is a locked storage decay area off the boiler room on the fifth (top) floor of the hospital. The boiler room area is restricted, and other than nuclear medicine, maintenance personnel are the only others having access.

Scale 1" = 8'

Item #9
1 of 5 pages
Prepared:
Lic. #21-17971-01

Item #9.2

CALIBRATION OF 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. Otherwise, the survey instruments will be calibrated after servicing and at least annually by the manufacturer or by a commercial service such as NMA/Mallinckrodt, Inc. The latter will be done in accordance with the procedure outlined in application for NMA's NRC license #34-16272-01 or by any other appropriately licensed facility. 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.

Item #9.3

CALIBRATION OF DOSE CALIBRATOR

The dose calibrator will be calibrated as follows:

A. Sealed sources will be used to establish accuracy. They will consist of Co-57, Ba-133 and Cs-137 with activities in excess of 50 uCi each.

The accuracy of the assay of these standards will be at least ±5% and traceable to National Bureau of Standards sources. The dose calibrator will be checked for accuracy at annual intervals and following repair using the sealed sources listed above. 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 immediate 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 accuracy standards. In this way, the accuracy of the dose calibrator will be assured throughout the entire ranges of doses drawn for patient studies.

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 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 a defined standard. Correction factors will be used in clinical assays when geometry induced errors exceed ±10%.

Item #9.4

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM: 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.

Item #9.5

MOBILE NUCLEAR MEDICINE SERVICE: N/A

Item #9.6

OTHER EQUIPMENT AND FACILITIES: N/A

Item #10.1

RADIATION SAFETY COMMITTEE CHARTER AND RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY: APPENDIX F

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.

Item #10.2

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT MEDICAL INSTITUTIONS 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.

Item #10.3

PROCEDURE FOR LEAK TESTING SEALED SOURCES: APPENDIX H

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.

Item #10.4

RULES FOR SAFE USE OF RADIOPHARMACEUTICALS: APPENDIX I

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

Item #10.5

SPILL PROCEDURES: APPENDIX J

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

Item #10.6

PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL: APPENDIX K

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. For receipt during off-duty hours, the following procedure will be followed.

If couriers or common carriers attempt delivery of packages containing radioactive materials, the switchboard operator on duty will be contacted. He/she will make arrangements to have the package delivered to the designated receipt area. Personnel not trained in the proper handling of radioactive materials are not to personnally 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/she nor the delivery vehicle is contaminated.

Item #10.7

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL: 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.

Item #10.8

RECORDS OF UNIT DOSAGE USE: 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.

Item #10.9

RECORDS OF MULTIDOSE VIAL USE: APPENDIX M.2

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.

Item #10.10

MEASURING AND RECORDING MOLYBDENUM CONCENTRATION: 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.

Item #10.11

INVENTORY OF IMPLANT SOURCES: N/A

Item #10.12

PROCEDURE FOR AREA SURVEYS: APPENDIX N

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 following exception. RSO review and initialing 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 document review by the RSO will be initiated through notification by the surveyor.

Item #10.13.1

WORKER DOSE FROM NOBLE GASES

We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

Item #10.13.2

WORKER DOSE FROM AEROSOLS

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

Item #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.

Item #10.13.4

SPILLED GAS CLEARANCE TIME

We will calculate spilled gas clearance times according to the procedure only that was published in Appendix O.4 to Regulatory Guide 10.8, Revision 2.

Item #10.14

RADIOPHARMACEUTICAL THERAPY: N/A

Item #10.15

IMPLANT THERAPY: N/A

Item #10.16

OTHER SAFETY PROCEDURES: N/A

Item #11.1

PROCEDURE FOR 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.

Item #11.2

OTHER WASTE DISPOSAL: N/A

Item #11
1 of 1 page
Prepared:
Lic. #21-17971-01