NRC FORM 313
(10-87)
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
475 ALLENDALE ROAD
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
NUCEAR 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)*

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

Please reference #34-16725-01

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

Good Samaritan Hospital
800 Forest Avenue
Zanesville, Ohio 43701

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

Same and see attached Item #3.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dan Patrick, Consultant, NMA Medical Physics Consultation, Folcroft, PA

TELEPHONE NUMBER: (215)532-0860

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
Anthony Rispoli	Anthony C. Rispoli	V.P. Finance	12/30/88

8903150344 890117
REG3 LIC30
34-16725-02 PNU

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
A04	Jan 13	7C	Code 21 JAN 03 1989	
AMOUNT RECEIVED	CHECK NUMBER		CONTROL NO. 80654	DATE
$580	59466			1/17/89

JAN 3 1989

Refer to Item #3, NRC 313

Please authorize our license to permit us to transport radionuclide materials to Bethesda Hospital in Zanesville, Ohio, and to receive radionuclide materials from them for use in our clinical Nuclear Medicine programs.

This will reduce the cost of radionuclide procedures as much as possible. There are many occasions when one of the hospitals might have a certain type of examination and must prepare a whole kit in order to perform just one procedure, whereas the other hospital might also have a use for the radiopharmaceutical. There are also occasions when one hospital needs material for a procedure which is not in stock at their hospital and it can be supplied by the alternate hospital. This saves delaying the procedure for a day or longer, reduces costs and provides better patient services.

The material may be transported either in the kit vials or in calibrated syringes. In either case, the doses will be assayed by the hospital administering the radionuclides to the patient, prior to injection.

Adequate D.O.T. records of transport and records of receipt and disposition shall be maintained.

The vials and/or syringes shall be placed in a lead-shielded carrier box. All additional space within the box shall be packed with absorbant material. The box shall then be taped closed. Transport will be by automobile and the box will be placed in a locked trunk.

The material will always be transported by one of our trained Nuclear Medicine technologists.

Item #3
1 of 1 page
Prepared: 12/23/88
New License

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	Medical use
Material in 35.400	1000 mCi	Medical use
Material in 35.500	As needed	Medical use

Item #5 & 6
1 of 1 page
Prepared: 12/23/88
New License

INDIVIDUALS RESPONSIBLE FOR RADIATION
SAFETY PROGRAMS - THEIR TRAINING & EXPERIENCE

Item #7.1

AUTHORIZED USERS FOR MEDICAL USE

AUTHORIZED USER	AUTHORIZATION
D.R. Boyse, M.D.	All
J.S. Safko, M.D.	All
J.W. Steinberger, M.D.	35.100, 35.200, 35.500, P-32 for treatment of polycythemia vera, leukemia and bone metastases
G. Girsh, M.D.	35.100
T. Forrestal, M.D.	35.100
J. Greenspan, M.D.	35.100, 35.200, 35.500, I-131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
R.L. Mellon, M.D.	35.100, 35.200
M.A. Graber, M.D.	35.100, 35.200, 35.500, I-131 for treatment of thyroid carcinoma
Zehra Salim Kaka, M.D.	35.300, 35.400, 35.500

For above physicians, refer to the application for license #34-16725-01 for evidence of training and experience.

For Dr. Kaka, refer to the attached documents for evidence of training and experience.

Item #7
1 of 2 pages
Prepared: 12/23/88
New License

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology,
and the Association of University Radiologists
Hereby certifies that

Zehra Salim Kaka, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology

On this eleventh day of June, 1987

Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Radiation Oncology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

M. Paul Capp, M.D.
President

Secretary

AMERICAN BOARD OF MEDICAL SPECIALTIES
EXCELLENCE
OPIBUSQUE

Item #7.2

AUTHORIZED USERS FOR NONMEDICAL USE: N/A

Item #7.3

RADIATION SAFETY OFFICER

J.S. Safko, M.D. 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: 12/23/88
New License

Item #9.1

FACILITIES AND EQUIPMENT DIAGRAM

Lead Castle

Lead Shielding

1 Survey Equipment
2 Uptake/Well
3 Camera
4 Lockable Door
5 Receipt Area
6 Generator
7 Kit/Dose Preparation
8 Isotope Storage
9 Waste Storage
10 Dose Calibrator

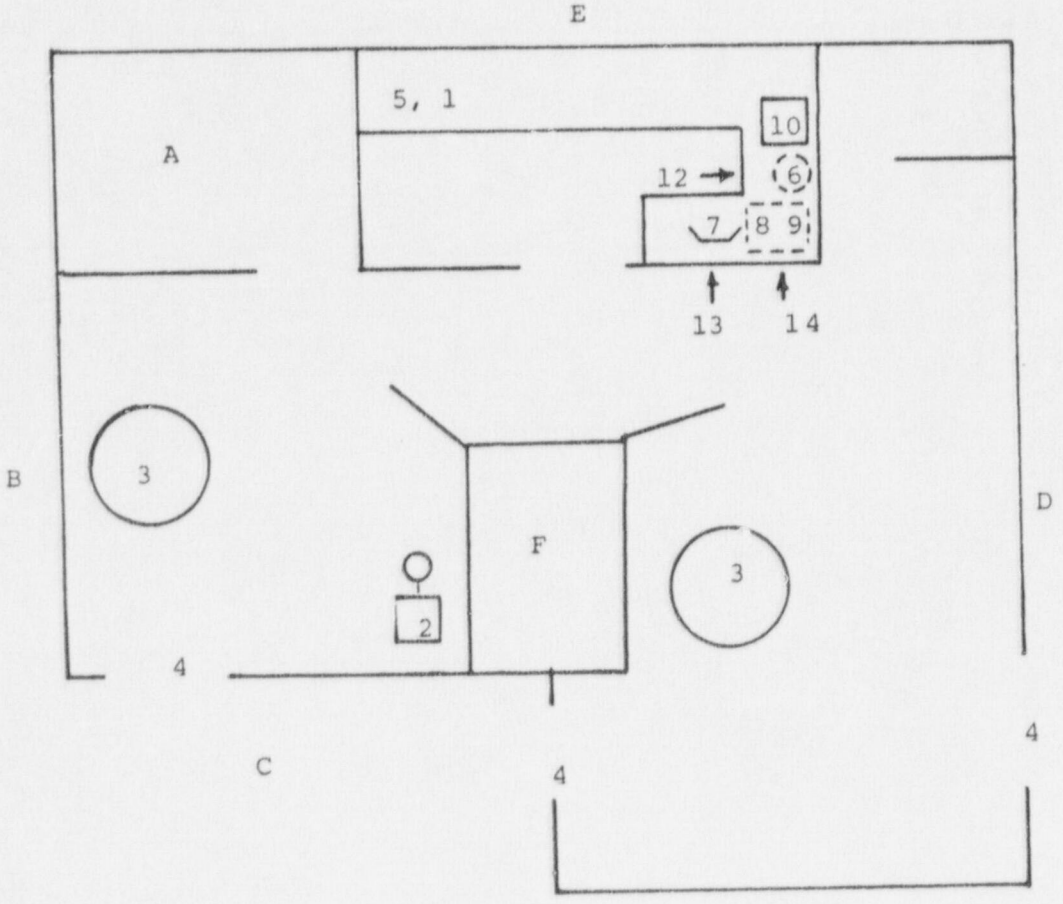
Adjacent Areas

A	Computer Room
B	Patient Waiting
C	Hall
D	Treadmill
E	Lobby
F	Elevator Shaft

12 Mfg. Generator Shield
___L x ___W x ___H x ½" T

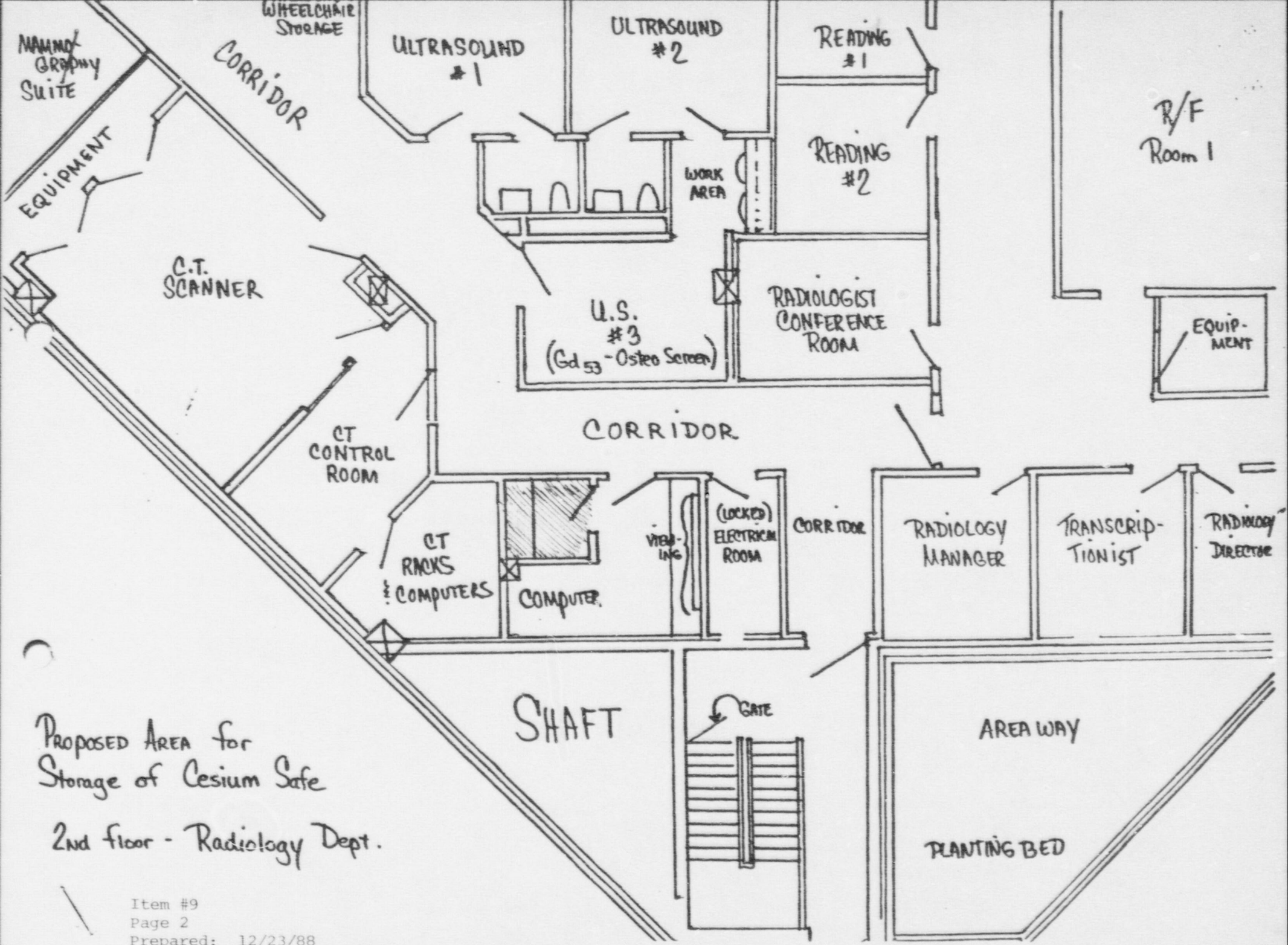
13 L-Shield
___L x 12" W x 16" H x ¼" T

14 Pb Castle
___L x ___W x ___H x 2" T



Scale 1/8"≈ 1'

Item #9
1 of 6 pages
Prepared: 12/23/8
Lic. #New



Proposed Area for Storage of Cesium Safe

2nd floor - Radiology Dept.

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

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 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.

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: APPENDIX M.4

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.

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 NOBILE GASES

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.

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

PROCEDURE FOR RADIATION SAFETY DURING IODINE THERAPY OVER 30 MILLICURIES: APPENDIX P

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.

Item #10.15

PROCEDURE FOR RADIATION SAFETY DURING IMPLANT THERAPY:
APPENDIX Q

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.

Item #10.16

OTHER SAFETY PROCEDURES: N/A

ITEM #10.13

Procedures for Radiation Safety During Implant Therapy
When Using 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 insure 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.

3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer.

4. All bed linen must be checked with a radiation survey meter before being removed from the patient's room to insure that no dislodged sources are inadvertently removed.

5. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered.

6. Emergency Procedures

a) If a seed becomes loose or dislodged from the patient, or

b) If the patient dies, or

c) If the patient requires emergency surgery, immediately call _____

Telephone #_____ _____
(Days) (Nights)

7. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

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: 12/23/88
New License