030-01908

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

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
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
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 _____
- [X] C. RENEWAL OF LICENSE NUMBER 20-09214-02

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

MALDEN HOSPITAL
HOSPITAL ROAD
MALDEN, MA 02148

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

MALDEN HOSPITAL
HOSPITAL ROAD
MALDEN, MA 02148

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Charles D. Chipman M.D. RSO

TELEPHONE NUMBER: (617) 322-7560

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. see attached

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. see attached

9. FACILITIES AND EQUIPMENT. see attached 9.1 thru 9.6

10. RADIATION SAFETY PROGRAM. see attached 10.1 thru 10.10

11. WASTE MANAGEMENT. see attached 11.1

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7.c
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
[signature]	Stanley Krygowski	President	4-22-88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$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 *(Dollar and/or 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	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
REN	May 15	7C	8910160311 880903 REG1 LIC30 20-09214-02 PDR	S. Kimberly
AMOUNT RECEIVED	**CHECK NUMBER**			**DATE**
$580	036875			5/18/88

"OFFICIAL RECORD COPY" ML18

103870
5/9/88

ATT. 5.6

	BYPRODUCT MATERIAL	AMOUNT	PURPOSE
	Material in 31.11	200 uCi	invitro clinical lab tests
5a.	Material in 35.100	AS NEEDED	6a. Medical Use
5b.	Material in 35.200	AS NEEDED	6b. Medical Use

ATT 7.1

LICENSE NUMBER 20-09214-02
Charles D. Chipman M.D. RSO
31.11, 5a,5b
Remedios Y. Strickland M.D.
31.11, 5a,5b

ATT. 7.3

Charles D. Chipman M.D. RSO Chief of Pathology

ATT. 8.1

Groups of workers who will recieve training:

1). Radiation Safety Committee (all members)
2). Nuclear Medicine Technologists
3). Nurses
4). Housekeeping Personnel
5). Security Personnel

The method of instruction will be videotape presentations, handouts and on the job training. Appendix A will be followed.
The frequency will be annually and upon initiation of employment.

ATT. 9.1

See attached annotated drawings.

ATT. 9.2

The Nuclear Medicine Department will have all the survey instruments calibrated at least annually and after servicing by the Nuclear Instrument Company, 65 Grove St., Rockland, MA. Their NRC license number is 20-16972-01. Calibration and servicing of the survey meters by Gamma Diagnostic Laboratories ,P.O. Box 1349, Attleboro Falls, MA. NRC license number 20-15215-01 will be used in a back-up capacity and in the case of emergencies. At the time of calibration, the apparent exposure rate from an owner supplied check source shall be determined and recorded with the availability of (3) survey meters, there will be at least (2) meters available for use at all times.

ATT. 9.3

We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to the Regulatory Guide 10.8 Revision 2 with the following modification.

Model Procedure C.5: Attached is the instruction manual for Cali-Check use which will be followed in its entirety, EXHIBIT 9.

Appendix C Reg. Guide 10.8 Rev 2. will be followed.

ATT. 9.4

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to the Regulatory Guide 10.8 revision 2. Whole body Badges and Ring TLD's are exchanged monthly and obtained from Siemens Gammasonics, 2000 Nuclear Drive Des Plaines, Ill. NRC license number 12-00369-01.

Any lost or damaged badge will precipitate an estimated dose based on the work-load during that month and will be made a part of the permanent badge record.

ATT. 9.6

See attachment 9.6.

ATT. 10.1

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.

See Attachmant 10.1

ATT. 10.2

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

ATT. 10.3

All sealed sources will be wipe tested by the Nuclear Medicine Technologist and counted by Siemens Gammasonics, 2000 Nuclear Drive, Des Plaines, ILL. NRC license number 12-00368-01. This procedure will be done every six months and Siemens will provide us with a written report. the sealed sources are used only for checking the dose calibrator, the survey meters, wipe test counter, and as a flood source for the gamma cameras.

ATT. 10.4

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

ATT. 10.5

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8 Revision 2.
See attached Exhibits 10 and 11.

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.
See attachment K-2.

ATT. 10.7

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8 Revision 2.
See attachments 12a, 12b, 12c.

ATT. 10.8

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8 Revision 2.
See attachments 13a, 13b, 13c.

ATT. 10.9

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.
See attachments, Exhibits 14a and 14b.

ATT.10.10

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.

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.
See Exhibit 16A-E.

ATT. 11.1

We will establish and implement the general guidance and model procedures for disposal of liquids and gases, decay-in-storage, release to in house waste, and returning generators and multidose vials to the manufacturer that was published in Appendix R to Regulatory Guide 10.8 Revision 2.

APPENDIX A

Model Training Program
(See §§ 19.12 and 35.24)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "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." You may use lectures, video-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of § 19.12. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.

ICL

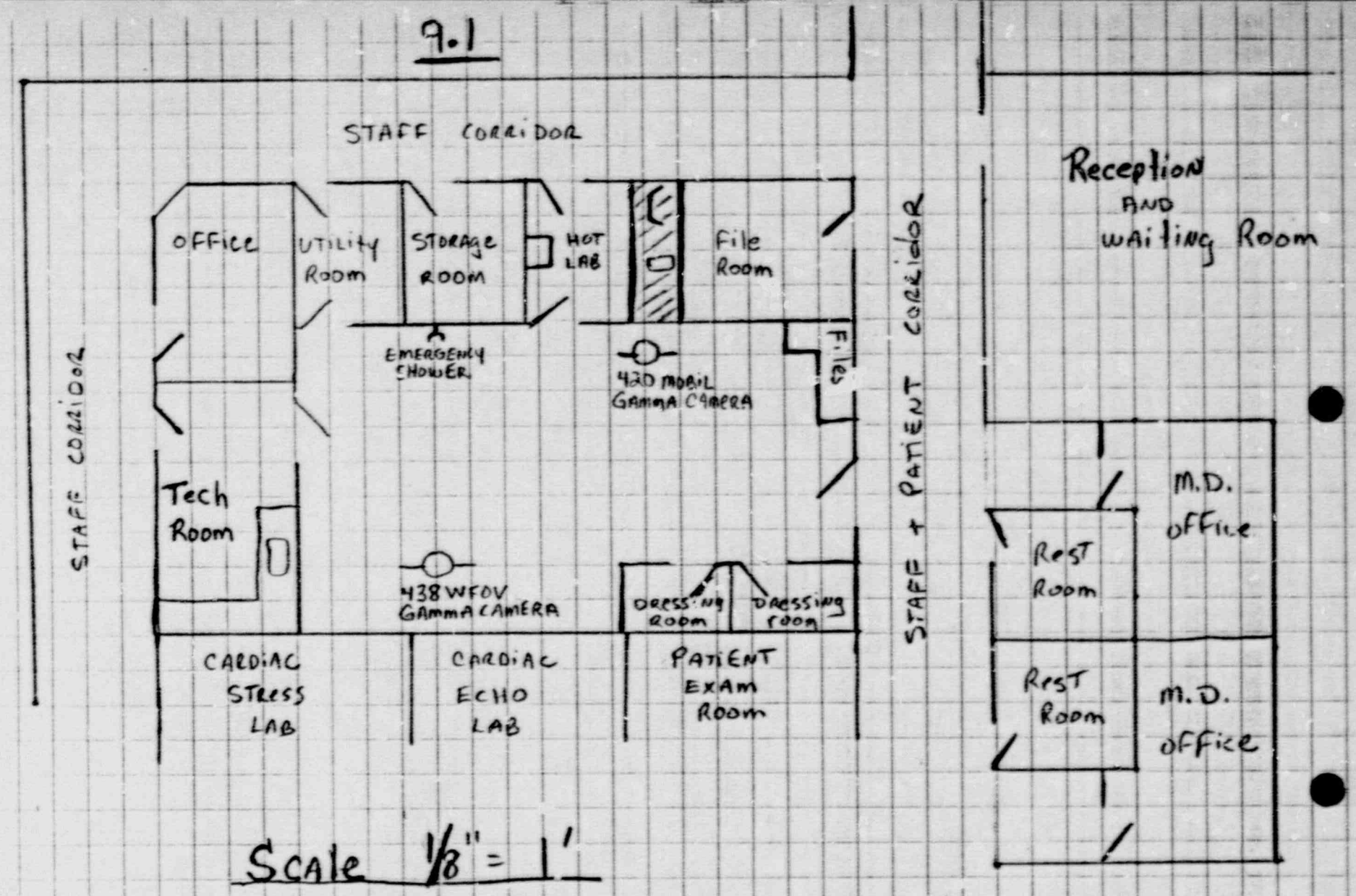
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

8. Worker's right to be informed of occupational radiation exposure and bioassay results.

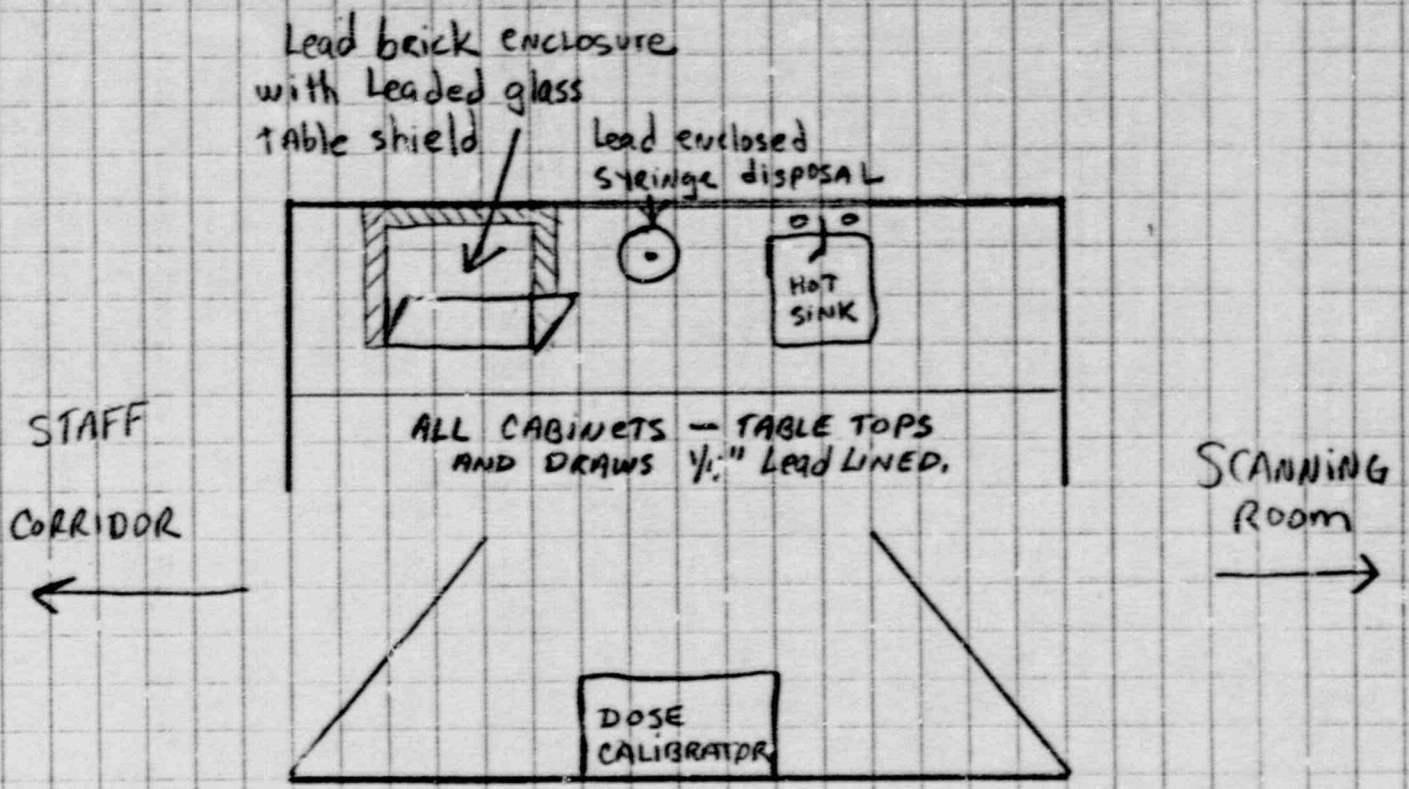
9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

10. Question and answer period.


9.1
STAFF CORRIDOR
OFFICE
UTILITY ROOM
STORAGE ROOM
HOT LAB
File Room
EMERGENCY SHOWER
420 MOBIL GAMMA CAMERA
Files
STAFF CORRIDOR
Tech Room
438 WFOV GAMMA CAMERA
DRESSING ROOM
DRESSING ROOM
CARDIAC STRESS LAB
CARDIAC ECHO LAB
PATIENT EXAM ROOM
STAFF + PATIENT CORRIDOR
Reception AND waiting Room
M.D. office
Rest Room
Rest Room
M.D. office
Scale 1/8" = 1'

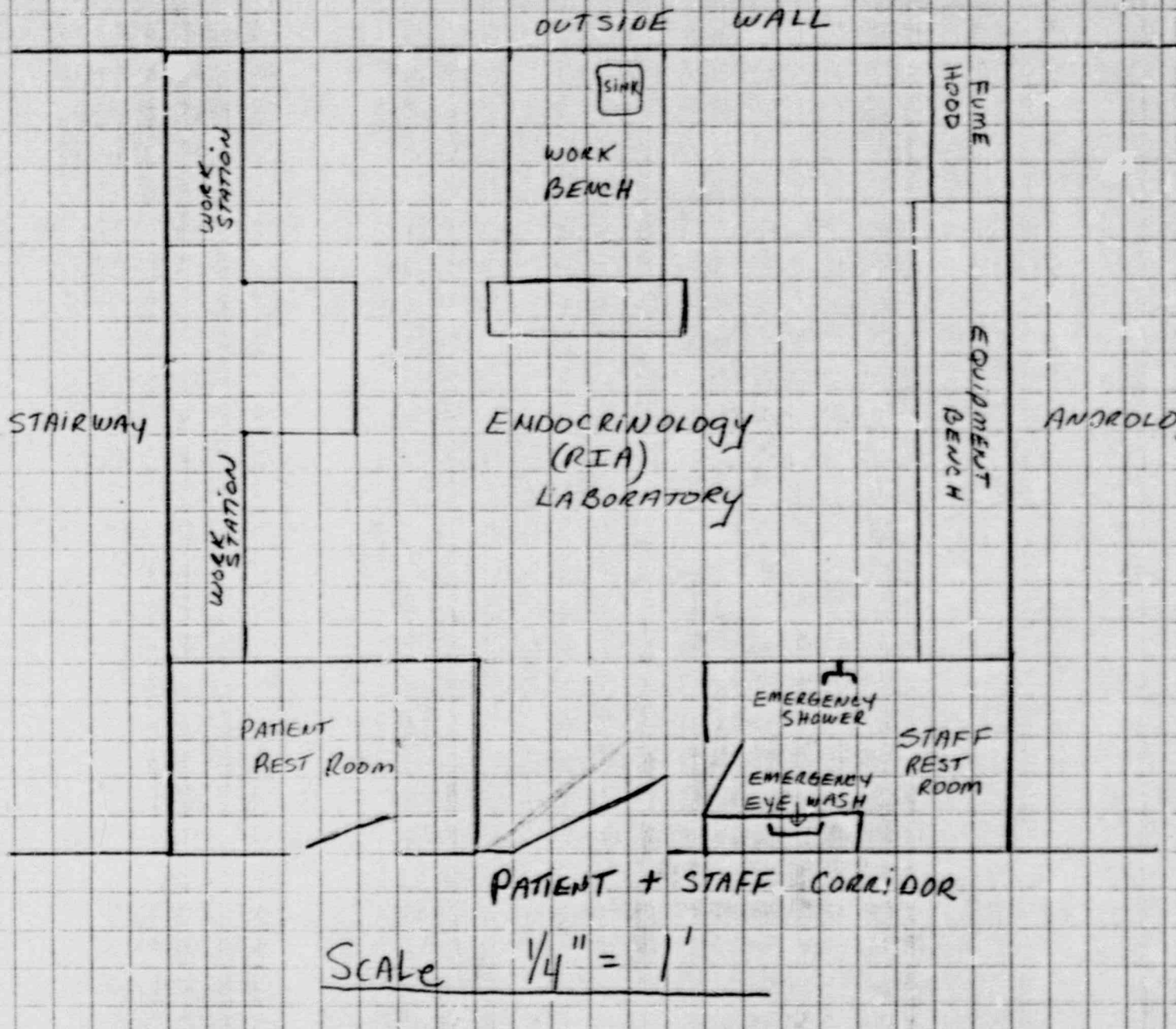
9.1

DETAILED DIAGRAM OF HOT LAB



SCALE ½" = 1'

9.1 (31.11)



SCALE 1/4" = 1'

APPENDIX B

Model Procedure for Calibrating Survey Instruments
(See § 35.51.)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "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."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.51. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

   a. The owner or user of the instrument;

   b. A description of the instrument that includes manufacturer, model number, serial number, and type of detector;

   c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

   d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;

   e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

   f. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument);

   g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h. The apparent exposure rate from the check source; and

i. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument;

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following as appropriate:

(1) The average correction factor,

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d. The angle between the radiation flux and the detector during the calibration; and

e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

See Exhibit 7 for a form you may want to use.

APPENDIX C

Model Procedure for Calibrating Dose Calibrator
(See § 35.50.)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "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."

If you develop your own dose calibrator calibration procedure for review, you should carefully review § 35.50 and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

   a. Constancy at least once each day prior to assay of patient dosages (±5 percent).

   b. Linearity at installation and at least quarterly thereafter (±5 percent).

   c. Geometry dependence at installation (±5 percent).

   d. Accuracy at installation and at least annually thereafter (±5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57,* or Ra-226* using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

   a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

   b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

*Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine its requirements for possessing this material.

c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacemer if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit 8). This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more than ± 0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary

to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

15

Revised: 3/2/82

INSTRUCTION MANUAL for CALICHECK

Caicorp, Inc.

P.O. Box 25589
Cleveland, Ohio 44125-0589
(216) 641-6841

DAVE CLOSE

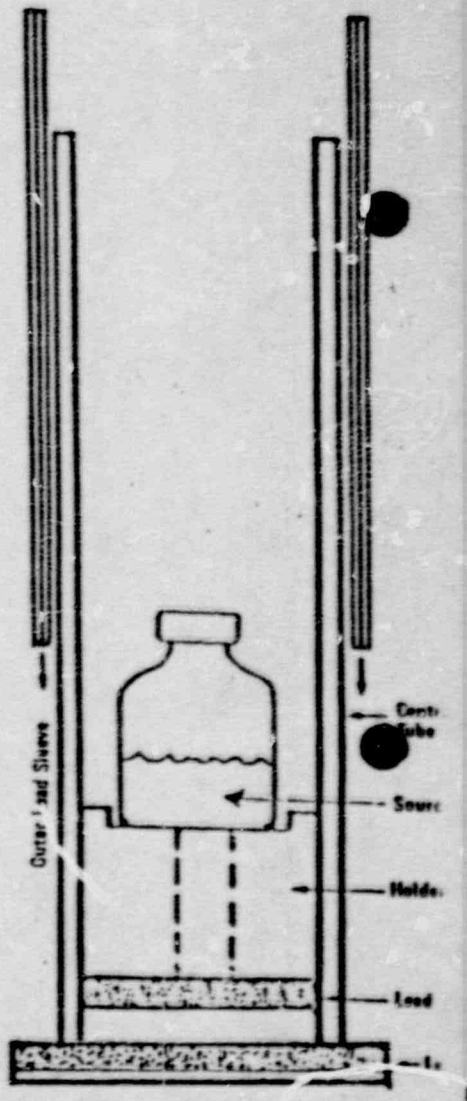
This apparatus and method for it's use is covered by United States Letters Patent No. 4,333,010 issued on June 1, 1982. Caldorp expressly withholds all license to use this apparatus to practice methods covered by this patent for calibrating equipment not owned by purchaser.

TABLE of CONTENTS

SECTION I

Product Description

Calicheck is a kit designed to perform the activity linearity test on a dose calibrator quickly and accurately. The kit consists of seven tubes, six of which are lead-lined to attenuate gamma radiation from radioactive sources, and a seventh, unlined tube. Each lead-lined tube varies in the thickness of lead so as to simulate various stages of radioactive decay. These tubes are sequentially placed over a source of radioactivity in the dose calibrator and, within minutes, seven successive measurements are acquired representing values that would have been obtained at approximately 0, 6, 12, 20, 30, 40 and 50 hours after the initial assay of Tc-99m. The need for determining linearity by fractionating eluants, or decaying the elution for several days while data is being collected, is eliminated – and at greatly reduced radiation exposures to personnel.



SECTION II

General Information

Several important points must be understood prior to using Calicheck. The points are as follows:

1. Calcorp performs thorough quality control on all kits. However, it is suggested that the kit be checked to ensure that the kit has not been damaged in shipment.
2. The components of the kit and/or the dose calibrator can be damaged if misused. It is especially important that damage does not occur to the ends of the tubes.
3. Should tubes become damaged or lost, replacement parts can be ordered with the form found on page 15 of this instruction manual.
4. Calicheck confirms activity linearity. It will not make your dose calibrator linear.
5. The dose calibrator must exhibit activity linearity prior to utilizing the Calicheck kit. This must be accomplished by performing an activity linearity test using standard techniques such as described in your license application. For NRC license holders, this test should be at a minimum equivalent to Appendix D of Regulatory Guide 10.8, October, 1980. If nonlinearity is demonstrated, the instrument should be repaired.
6. Calicheck must be specifically calibrated for each dose calibrator in the facility since variations between manufacturers (and sometimes, models) are known to exist. Similarly, kits should not be interchanged without first confirming calibration factors. Each tube in the Calicheck kit must be calibrated and each time a tube is replaced in the kit, the new tube must be calibrated. A procedure is enclosed that describes the calibration technique.
7. Readings obtained from Calicheck are not to be used for assay purposes.
8. The radionuclide used for testing must be Tc-99m, and it must be relatively free of Mo-99 contamination. The concentration of Mo-99 in the sample should be less than .15 uCi Mo-99/mCi Tc-99m. If a central radiopharmacy is used as the source of Tc-99m, ask the radiopharmacist for his assay results.
9. Do not use the tubes as shielding devices. The black center tube offers absolutely no radiation protection since it is plastic with lead in its side wall. The other tubes do contain varying amounts lead, but should never be regarded as a protective shield.
10. The entire kit should be stored in the mailing container in upright position when not in use. The black center tube should inserted upside down to avoid damage to the tubes.
11. Typically, regulatory agencies, such as the Nuclear Regulato Commission or state licensing agencies, require that methods activity linearity evaluations be filed with them in the form o license amendment application. Enclosed (see page 14 of t instruction manual) is a model letter requesting authorization use Calicheck, to be sent to the regulatory agency. Simply fill the blanks, transfer entire letter to hospital stationary, have application signed and forwarded to your licensing agency. Incl amendment fees, where applicable. Upon receipt of the ame ment, Calicheck can be put to use.
12. If you have questions regarding the kit, the directions for its use, the data generated, call (216) 663-1773 for assistance.

CAUTION: Calicheck should only be used by qualified personnel. Tubes should be carefully placed into the dose calibrator to avoid damage to the tube and/or chamber itself.

SECTION III

Calibration of Calicheck

OBJECTIVE:
To generate calibration factors for each tube in the Calicheck Kit, thereby expressing the amount of attenuation by each tube.

PREPARATION:
All radiation sources in the vicinity of the dose calibrator should be shielded to avoid erroneous readings. Further, the instrument may be sensitive to dosed patients in the vicinity. Move the patients to another location before you start. Both the "Kit Calibration" and the "Activity Linearity Procedure" must be performed in an environmentaliy stable background.

Syringe hangers and vial holder assemblies supplied with Capintec, Nuclear Associates, and some Picker dose calibrators must be removed. Molded chamber liners as supplied by RadX and some Picker dose calibrators must be lifted out. Calicheck will not fit the Mediac dose calibrators because the chamber diameter is too small.

The calibration source that is used should be the largest activity measured in the dose calibrator. This would normally be the Monday morning elution in the case of the generator, or the largest dose obtained from your radiopharmacy.

In order to use Calicheck, a source of Tc-99m must be placed into the central black tube. If the source is in a top loading lead elution shield, use extension tongs to transfer the source. If the source is in a bottom loading elution shield, remove the base cover, put the open end of the black tube to the bottom of the lead shield and allow the source to slide down into the black tube by tilting the tube at an angle. The center tube accommodates vial sizes up to 20 ml. and syringes up to 10 ml. Proper technique dictates that when using a syringe, a clean needle be used and it should be no longer than 1-1/2" in length. When the black tube is inserted into the dose calibrator, it should be done carefully with the open end in the upward position. The black tube must remain in the dose calibrator throughout all steps in the calibration cycle. Once the source is placed in the dose calibrator, the source must be kept in exactly the same position throughout the test to insure consistent geometry.

If the unit has a manual range adjust, adjust the range as necessary to acquire three significant figures for each reading.

When the activities displayed are at the uCi level (e.g., when the purple and possibly blue tubes are in place), dose calibrator displays may "float" or vary on successive measurements. Be sure to record an average figure on your data sheets. Record all values on the data sheets in mCi units.

Once the procedure is started, do not stop. All readings should be recorded within a matter of minutes. Otherwise, the short half life of Tc-99m will introduce unacceptable error.

Calibration Procedure: (To be performed only once.)*

1. Remove any syringe hanger or chamber liner, if necessary, from dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges, to add or subtract from final results when those ranges are used.
4. Place calibration source into black tube and insert black tube into dose calibrator CAREFULLY with the open end in the upward position. Read displayed activity.
5. Record reading in appropriate positions on Data Sheet #1 "Kit Calibration". (8 entries. See example on page 8.)

Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record reading as the appropriate denominator on Data Sheet #1, Kit Calibration Form.
7. Replace red tube with orange tube. Record.
8. Replace orange tube with yellow tube. Record.

* Or following repair of dose calibrator or Calicheck.

9. Replace yellow tube with green tube. Record.
10. Replace green tube with blue tube. Record.
11. Replace blue tube with purple tube. Record.
12. Remove the Calicheck assembly and place source in a shielded container. Place Calicheck in storage container provided.

DATA TREATMENT OF DATA SHEET #1:

1. Divide the numerator by the denominator in Column B to determine the Calibration Factor, and record in Column C. Retain these values for future reference. These factors will be used for all future activity linearity tests provided all conditions of the test are met (i.e., same dose calibrator, same kit, same radionuclide, same source configuration). Recalculation will be required following repair of dose calibrator or Calicheck.
2. Compare results to chart of "Typical Calibration Factors" on page 9. Differing values may be due to variations in geometry, in the response of the dose calibrator and/or in the kit manufacturing process itself.
3. Transfer determined Calibration Factors from Data Sheet #1 to appropriate place in Column C of Data Sheet #2. (See example on page 13.) To confirm the accuracy of the determined factors, complete Data Sheet #2. If no error has been made, all values in Column D (product of B x C) should be the same. If values differ, repeat the determination.

Kit Calibration

All readings must be taken at lowest range setting available and converted to mCi units.

TUBES		DISPLAYED ACTIVITY		CALIBRATION FACTORS
A				C
Black Only / Black Only	=	mCi / mCi	=	1.00
Black Only / Black & Red	=	mCi / mCi	=	
Black Only / Black & Orange	=	mCi / mCi	=	
Black Only / Black & Yellow	=	mCi / mCi	=	
Black Only / Black & Green	=	mCi / mCi	=	
Black Only / Black & Blue	=	mCi / mCi	=	
Black Only / Black & Purple	=	mCi / mCi	=	

SOURCE CONFIGURATION

Syringe

Vial

*Or following repair of dose calibrator or Calicheck Kit. In all instances these factors can only be determined following proof of activity linearity by standard techniques. **KEEP THIS FORM FOR FUTURE REFERENCE!**

Example

To determine the calibration factors for a Brand X dose calibrator, a source of Tc-99m was prepared. The source read 34.2 mCi in the black tube and generated the following data.

All readings were taken at the lowest range setting possible and converted to mCi units.

TUBES		READINGS		CALIBRATION FACTOR
A		B		C
Black Only / Black Only	=	34.2 mCi / 34.2 mCi	=	1.00
Black Only / Black & Red	=	34.2 mCi / 19.9 mCi	=	1.72
Black Only / Black & Orange	=	34.2 mCi / 10.6 mCi	=	3.23
Black Only / Black & Yellow	=	34.2 mCi / 3.59 mCi	=	9.53
Black Only / Black & Green	=	34.2 mCi / 1.16 mCi	=	29.5
Black Only / Black & Blue	=	34.2 mCi / .354 mCi*	=	96.6
Black Only / Black & Purple	=	34.2 mCi / .112 mCi	=	305

*Read as 354 uCi and converted to .354 mCi. Similarly 112 uCi has been converted to .112 mCi and 92 uCi would be converted to .092 mCi.

Typical Calibration Factors

	CAPINTEC		RADX		PICKER	
	VIAL	SYRINGE	VIAL	SYRINGE	VIAL	SYRINGE
Black	1.00	1.00	1.00	1.00	1.00	1.00
Red	1.83	1.74	2.27	2.16	1.73	1.[illegible]
Orange	3.59	3.32	4.58	4.24	3.31	3.49
Yellow	10.9	9.74	14.4	12.9	9.71	9.96
Green	34.9	30.4	48.6	42.3	31.1	30.7
Blue	121	103	164	140	105	104
Purple	399	334	565	473	342	326

These factors were determined using Tc-99m in a 10 ml vial and a [illegible] ml syringe. They represent an average of several determinations using the same kit in different dose calibrators of the same type as well as different kits in the same dose calibrator. These factors are not to be used as a substitute for determined calibration factors. They are listed here for comparison purposes only.

SECTION IV

Activity Linearity Procedure

OBJECTIVE:

To determine if a dose calibrator can respond linearly to a variety of levels of radioactivity via the Calicheck Technique.

PREPARATION:

Same as described under "Calibration of Calicheck". See page 4. Use the same source configuration as used in that calibration procedure.

PROCEDURE:

1. Remove any syringe hanger or chamber liner, if necessary, from dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges to add or subtract from final results when those ranges are used.
4. Place source to be used for the activity linearity procedure into the black tube and insert tube into the dose calibrator CAREFULLY with the open end in the upward position.
5. Record "displayed activity" on "Black Only" on Data Sheet #2 "Dose Calibrator Activity Linearity Check", (see page 13).

Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record "displayed activity" on "Black & Red" blank on Data Sheet #2.
7. Replace red tube with orange tube. Record on "Black & Orange" blank.
8. Replace orange tube with yellow tube. Record on "Black & Yellow" blank.
9. Replace yellow tube with green tube. Record on "Black & Green" blank.

10. Replace green tube with blue tube. Record on "Black & Blue" blank.
11. Replace blue tube with purple tube. Record on "Black & Purple" blank.
12. Remove Calicheck assembly and place source in shielded container.

DATA TREATMENT OF DATA SHEET #2: (To be completed each calendar quarter or at a frequency required by your license conditions.)

1. Enter appropriate Calibration Factors from Data Sheet #1 for your dose calibrator in Column C.
2. Multiply the value in Column B by the corresponding value in Column C to determine product of each entry for Column D. Record values. (Ideally, these values will all be the same.)
3. Add all products in Column D and divide by 7 to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of ±5% variation.

If all values in column D fall between these two limits, your dose calibrator has acceptable activity linearity. The test is complete, unless additional readings are required to check the microcurie range. If so, continue the determination by withdrawing an aliquot containing 2-3 mCi more activity than the displayed activity in the last measurement. The test is then repeated (Data Sheet #2 only), using the same source configuration as that used in determining the calibration factor on Data Sheet #1.

If any values in Column D fall outside the limits, repeat the study to rule out possible variations in the initial data. Consistent results that are outside the limits indicate that the instrument is exhibiting non-linearity. Corrective action is indicated.

DATA SHEET #2 *(to be completed each quarter)*

Dose Calibrator Activity Linearity Check

Dose Calibrator _____ Date _____

Model _____ Technologist _____

Source Configuration _____ *(must be same as on Data Sheet #1)*

All readings must be taken at lowest range setting available and converted to mCi units.

A	B		C		D
TUBE COLOR	DISPLAYED ACTIVITY		CALIBRATION FACTOR		PRODUCT OF B X C
Black Only:	_____ mCi	X	1.00	=	_____
Black & Red:	_____ mCi	X	_____	=	_____
Black & Orange:	_____ mCi	X	_____	=	_____
Black & Yellow:	_____ mCi	X	_____	=	_____
Black & Green:	_____ mCi	X	_____	=	_____
Black & Blue:	_____ mCi	X	_____	=	_____
Black & Purple:	_____ mCi	X	_____	=	_____
			SUM	=	_____

$$\text{MEAN} = \frac{\text{SUM}}{7} = \_\_\_\_\_$$

MEAN X 1.05 = _____ = UPPER LIMIT*

MEAN X 0.95 = _____ = LOWER LIMIT*

Compare Column D data to upper and lower limits to confirm linearity.

*Instead of a variation in the Column D data of ±5%, your radioactive material license may allow a difference of ± 10% in the test results. If so, multipliers of 1.10 and 0.90 can be used to determine the upper and lower limits.

Example

A Mo/Tc generator is eluted and yields 342 mCi. The entire elution is placed in the dose calibrator inside the black tube. Subsequent readings generated the following data.

Dose Calibrator Activity Linearity Check

All readings were taken at lowest range setting available and converted to mCi units.

A	B		C		D
TUBE COLOR	DISPLAYED ACTIVITY		CALIBRATION FACTOR		PRODUCT OF B X C
Black Only:	342 mCi	X	1.00	=	342
Black & Red:	201 mCi	X	1.72	=	346
Black & Orange:	106 mCi	X	3.23	=	342
Black & Yellow:	34.1 mCi	X	9.53	=	325
Black & Green:	10.2 mCi	X	29.5	=	301
Black & Blue:	3.54 mCi	X	96.6	=	342
Black & Purple:	1.19 mCi	X	305	=	363
			SUM	=	2361

$$\text{MEAN} = \frac{2361}{7} = 337$$

MEAN X 1.05 = 354 = UPPER LIMIT*

MEAN X 0.95 = 320 = LOWER LIMIT*

The readings for the green and purple tubes are outside the limits. The procedure should be repeated to confirm the data. Repair may be indicated. Failure to account for a re-zeroing problem between ranges *(see Procedure Step #3)* or an unstable background may also have produced this apparent non-linearity.

SECTION V

License Amendment Request

(To be placed on licensee's stationery)

NRC or State License Number _____

FACILITY _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

PERSON TO BE CONTACTED
REGARDING THIS APPLICATION:

_____ PHONE: _____

(RSO, Technologist, Consultant, Doctor, Admin.)

Gentlemen:

Please amend our license as follows:

As an alternative to our present procedure, the dose calibrator can be checked for activity linearity with the use of a device called Calicheck from Calcorp. Inc. The manufacturer's instructions for use as revised on March 2, 1982, will be followed. Test results will be recorded and retained for inspection. Corrective action as stated in our license application will be followed if unacceptable linearity is demonstrated.

Sincerely,

Administrator

done 9/3/83

SECTION VI

Calicheck Parts Order Form

ITEM	PRICE* (ea.)	QUANTITY	PRICE
Black Center Tube	$60.00	_____	_____
Lead Wrapped Tubes	$60.00		
Red		_____	
Orange		_____	
Yellow		_____	
Green		_____	
Blue		_____	
Purple		_____	
		TOTAL	_____
Storage Container	$ 6.00	_____	_____
		TOTAL ENCLOSED	_____

BILL TO:

Name: _____

Address: _____

_____

_____

P.O. # _____

SHIP TO:

Name: _____

Address _____

_____

_____

*Prices are subject to change without notice.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 8, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.

i. If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (see Exhibit 9).

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the

data and drew horizontal 5 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the

JC

Dose Calibrator Geometry and Accuracy Form (see Exhibit 9). Rep for a total of three determinations.

b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference sour mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accur data.

f. Put a sticker on the dose calibrator that says when the next accur test is due.

8. The RSO will review and sign the records of all geometry, linearity, an accuracy tests.

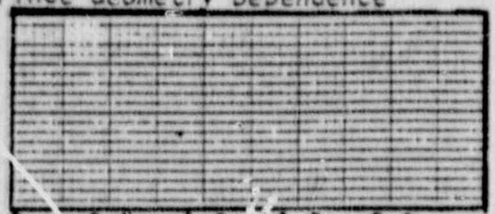
See Exhibits 8 and 9 for some forms you may want to use.

EXHIBIT 9

Dose Calibrator Geometry and Accuracy

Manufacturer:______________________ Model:________________ SN:___________

Syringe Geometry Dependence



__ __ __ __

Vial Geometry Dependence

__ __ __ __ __ __ __ __

__ __ __ __ __ __

Date:___________ By:_______________________ RSO:_______________________

Accuracy Sources	19___	19___
______mCi of ______ Model:____________ SN:______________ Calibration date: ________________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______
______mCi of ______ Model:____________ SN:______________ Calibration date: ________________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______
______mCi of ______ Model:____________ SN:______________ Calibration date: ________________	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______	first assay:______mCi second assay:______mCi third assay:______mCi average:______mCi ______mCi dev:______

Name: ____________________ ____________________

Date: ___________ ___________

APPENDIX D

Model Personnel External Exposure Monitoring Program
(See § 20.101.)

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of § 20.101. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4," and append your monitoring program.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis..

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX C
ATT 9.6
INSTRUMENTATION

1. Survey meters

a. Manufacturer's na: Eberline Instrument Corporation

Manufacturer's model number: E - 520

Number of instruments available: 1

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

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

b. Manufacturer's name: Eberline Instrument Corporation

Manufacturer's model number: E-120

Number of instruments available: 1

Minimum range: 0 mR/hr to .5 mR/hr

Maximum range: 0 mR/hr to 50 mR/hr

2. Dose calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC 10-R

Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Mobile Gamma Camera	Technicare	420/550 VIP computer
LFOV Gamma Camera	Technicare	438/560 VIP computer

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Mini Monitor 125		Decontamination Monitor
KinetiCount 48	Vitek	Gamma Counter
Picker Compac 120 Gamma Counter	Picker	Gamma Counter
Wipe Test Counter	Victoreen	Wipe Tester
RFM 5		Radiation Monitor

APPENDIX F

Model Radiation Safety Committee Charter
and Radiation Safety Officer Delegation of Authority
(See §§ 35.21, 35.22, and 35.23.)

You may use the following text as it appears here, saying on your application, "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."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of §§ 35.22. Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with NRC regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent NRC regulations, the license application, the license, and amendments;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required in § 19.12 of 10 CFR Part 19;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

ATT 10.1

THE MALDEN HOSPITAL
HOSPITAL ROAD, MALDEN, MA 02148-3591 • (617) 322-7560

APRIL 22,1988

MODEL DELEGATION OF AUTHORITY

MEMO TO: ALL EMPLOYEES

FROM: STANLEY KRYGOWSKI, PRESIDENT

SUBJECT: DELEGATION OF AUTHORITY

Charles D. Chipman 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.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

MODEL DELEGATION OF AUTHORITY

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

_____ _____ 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.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA (See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

MALDEN HOSPITAL

(Licensee's Name)

APRIL 22,1988

(Date)

1. Management Commitment

   a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

*The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

Table 1

Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by § 20 401 of 10 CFR Part 20. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature

STANLEY KRYGOWSKI
Name (print or type)

PRESIDENT
Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources
(See § 35.59.)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "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."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.59. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

   c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.

   d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals
(See § 35.21.)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part 35. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

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. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopnarmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J

Model Spill Procedures
(See § 35.21.)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 10.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report (see Exhibit 10) and the Radioactive Spill Contamination Survey (see Exhibit 11).

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparision of information from the following sources:

1. "Standards for Protection Against Radiation," Proposed Rule, Part 20, published January 9, 1986, Appendix B, Table 1, Column 3 (Derived Air Concentration Values) 51 FR 1092.

2. "Gamma Radiation Levels for One Curie of Some Radionuclides," Radiological Health Handbook, January 1970 edition, Department of Health, Education, and Welfare, Washington, DC, p. 1[illegible]

3. National Council on Radiation Protection and Measurements, "Safe Handling of Radioactive Materials," NCRP Report No. 30, paragraph 2.3 and Table 2, 1964.

4. "Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees," Advance Notice of Proposed Rulemaking on Parts 30, 40, and 70, 46 FR 29712, Table 1, June 3, 1981.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc-99m	100
Cr-51	100	In-111	10
Co-57	100	I-123	10
Co-58	10	I-125	1
Fe-59	10	I-131	1
Co-60	1	Yb-169	10
Ga-67	100	Hg-197	100
Se-75	10	Au-198	10
Sr-85	10	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
"Radioactive Material" labeling tape
1 china pencil or marking pen
3 prestrung "Radioactive Material" labeling tags
Supplies for 10 contamination wipe samples
Instructions for "Emergency Procedures"
Clipboard with one copy of Radioactive Spill Report Form
Pencil

Forms

You may want to use Exhibit 10, Radioactive Spill Report, and Exhibit 11, Radioactive Spill Contamination Survey Forms.

EXHIBIT 10

Radioactive Spill Report

The spill occurred at ___:___ am/pm on ___-___-___ room ___.

Instrument used to check for personnel contamination:
Meter model: _____ Meter S/N: _____ Probe model: ___ Probe S/N: ____

Personnel present	Personnel contamination results*

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a postcleaning contamination wipe-test.

Radioisotopes present or suspected in the spill:

____mCi of ____ as _____

____mCi of ____ as _____

____mCi of ____ as _____

Give a brief description of the accident: _____

Give a brief description of followup actions taken to prevent recurrence:

Name: _____
Date: _____

Radioactive Spill Contamination Survey

The spill occurred at ___:___ am on ___-___-___ in room _____. Decontamination completed at ___:___ am.

loc	pre-clean mR/hr	post-clean mR/hr	post-clean dpm/100cm^2

Name: _____

EXH-20

EXHIBIT 11

APPENDIX K

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

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "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."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of §§ 30.51 and 20.205. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each 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 a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

ATT-K2

THE MALDEN HOSPITAL
HOSPITAL ROAD, MALDEN, MA 02148-3591 • (617) 322-7560

APRIL 22,1988

MEMO TO: CHIEF OF SECURITY

FROM: RADIATION SAFETY OFFICER-- CHARLES D. CHIPMAN M.D.

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL (5pm to 7am)

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department Hot Lab. Upon arrival ,unlock the door to the Hot Lab and place the package behind the lead enclosure on top of the lead lined work bench. Always relock the Hot Lab door and be certain that the area is secure before leaving.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer Charles D. Chipman M.D. at extension 5205.

RADIATION SAFETY OFFICER: CHARLES D. CHIPMAN M.D. EXT. 5205
HOME (617) 729-6260

Chief Nuclear Medicine Technologist: KENNETH A. BROWN NM,NMT EXT. 5211
HOME (617) 851-6643

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room ____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension ___.

	Name	Home Telephone
Radiation Safety Officer:	_____	_____
Chief of Nuclear Medicine:	_____	_____
Chief Nuclear Medicine Technologist:	_____	_____
Nuclear Medicine Technologist on call (call page operator at extension ___)		
Nuclear Medicine Physician on call (call page operator at extension ___)		

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material
(See §§ 35.23, 30.51, 20.203(f)(4), and 20.205.)

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 10.7," and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))

   d. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

(2) Open the outer package following the supplier's instructions, if provided.

(3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in § 31.11, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

See Exhibit 12 for a sample record form you may want to use.

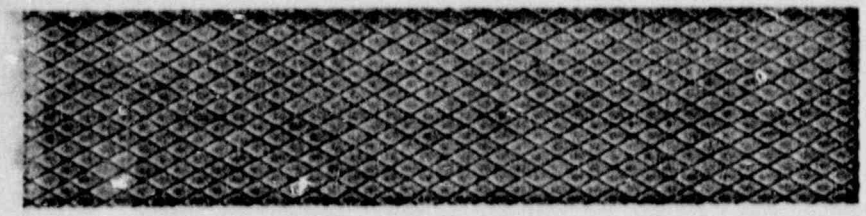
EXHIBIT 12 A

PACKAGE RECEIPT AND MONITOR LOG

date received	purchase order no.	packing slip no.	mCi	iso	chemical	supplier	catalogue number	pkg ok?	mR/hr surf	notes	init

EXHIBIT 26

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

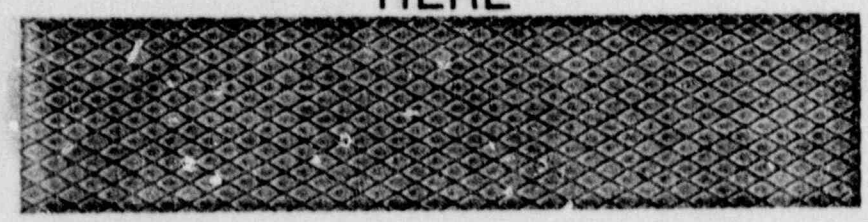
RETURNED TO NPI ( ) OR _____

VOLUME RETURNED _____

DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

RETURNED TO NPI ( ) OR _____

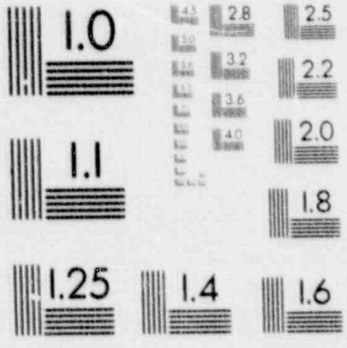
VOLUME RETURNED _____

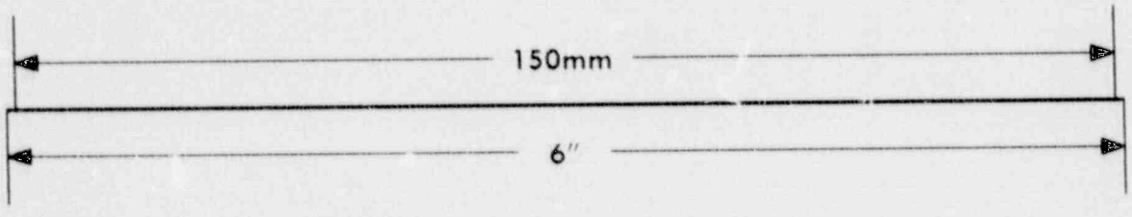
R1-84 DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

1

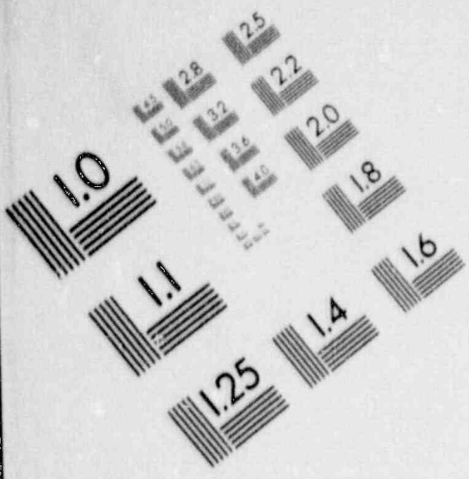
IMAGE EVALUATION TEST TARGET (MT-3)

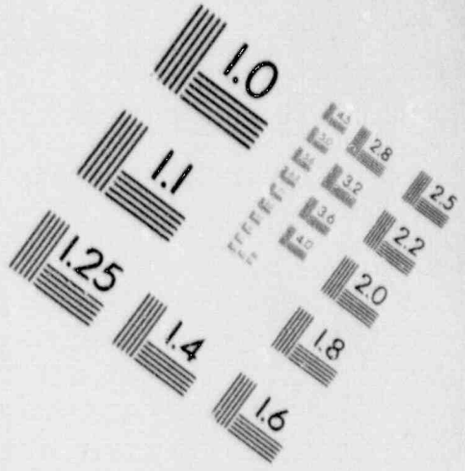


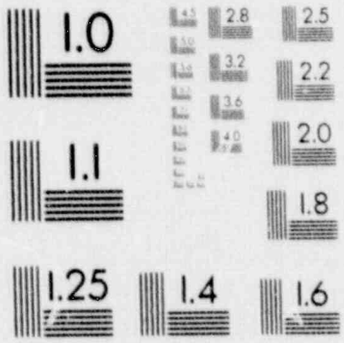


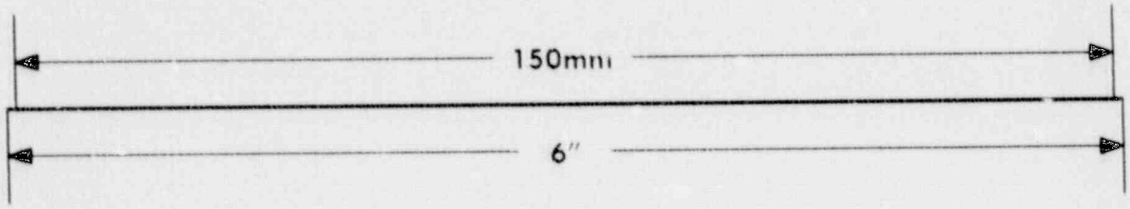
1

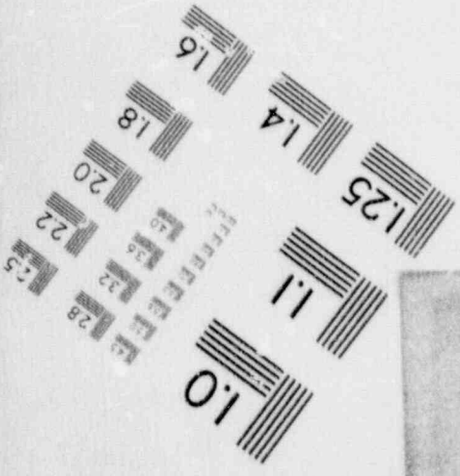
IMAGE EVALUATION TEST TARGET (MT-3)

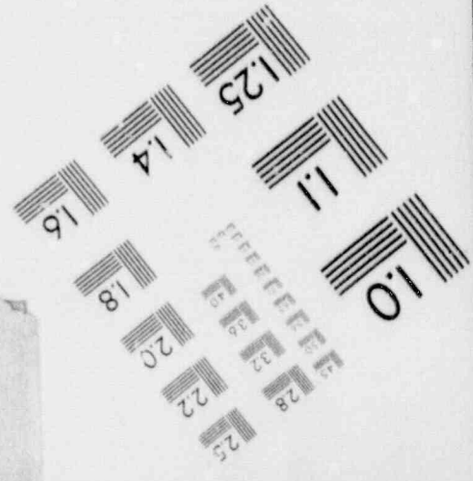


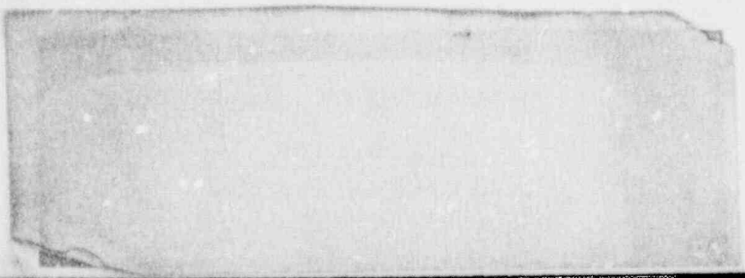


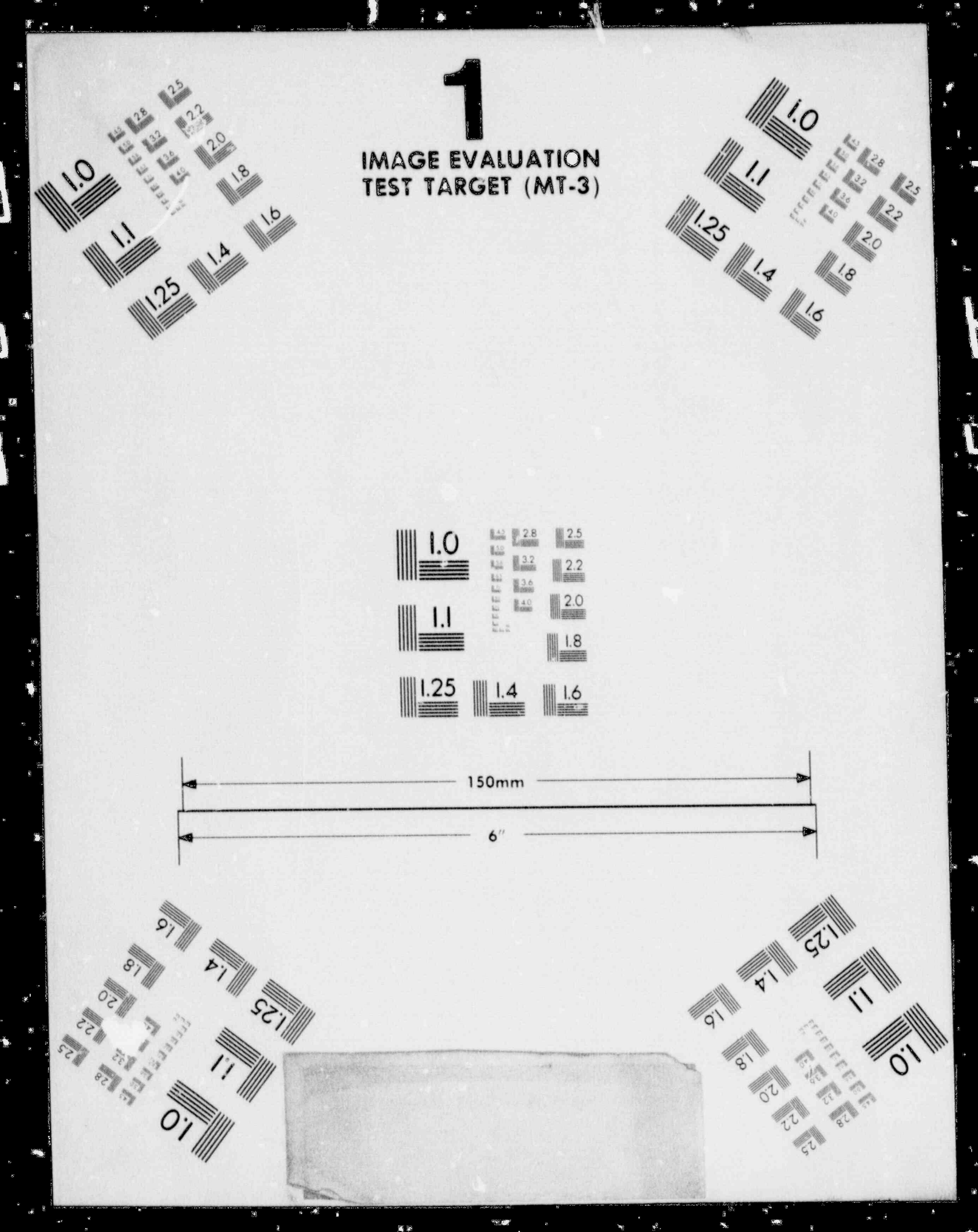











1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
150mm
6"

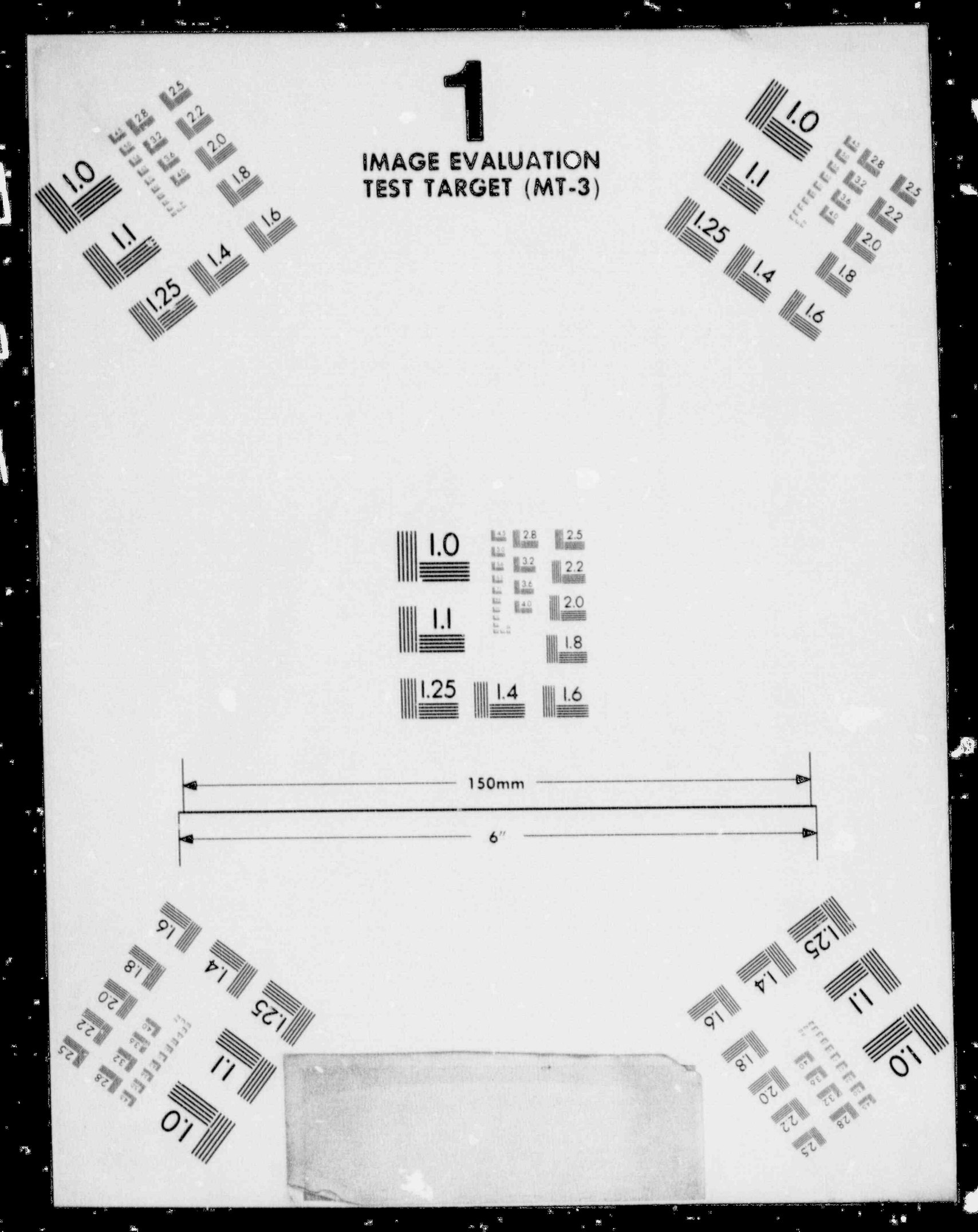

1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
150mm
6"

EXHIBIT 12c

syncor UNIT DOSE PRESCRIPTION RECORD

PRESCRIPTIONS	DISPOSAL RECORD
Place Top of Prescription #12 Here	DISPOSED BY_____ DATE_____ 12 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #11 Here	DISPOSED BY_____ DATE_____ 11 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #10 Here	DISPOSED BY_____ DATE_____ 10 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #9 Here	DISPOSED BY_____ DATE_____ 9 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #8 Here	DISPOSED BY_____ DATE_____ 8 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #7 Here	DISPOSED BY_____ DATE_____ 7 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #6 Here	DISPOSED BY_____ DATE_____ 6 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #5 Here	DISPOSED BY_____ DATE_____ 5 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #4 Here	DISPOSED BY_____ DATE_____ 4 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #3 Here	DISPOSED BY_____ DATE_____ 3 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #2 Here	DISPOSED BY_____ DATE_____ 2 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #1 Here	DISPOSED BY_____ DATE_____ 1 RETURNED TO SYNCOR ( ) OR_____

INSTRUCTIONS

To mount first report, pull off the two paper tabs indicated by the arrows. Position report edges to top and side guide lines, then press the report down over the exposed adhesive.

The adhesive is *pressure-sensitive:* be sure to press the report down over the exposed adhesive.

Press lightly to attach temporarily. Press firmly to attach securely and permanently.

DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	Surface (mr/hr.)	1/M
1			
2			
3			
4			
Bkg.			

APPENDIX M

Records of Byproduct Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8," and append your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),

b. Measured activity in millicuries or microcuries and date and time of measurement,
c. Patient name and identification number if one has been assigned;

9. If discarded, the date and method of disposal; and

10. Initials of the individual who made the record.

See Exhibit 13 for a Unit Dosage Receipt and Use Log Form you may want to use.

M.2 Records of Multidose Vial Use (§§ 30.51, 35.21, 35.53)

You may use the following model procedure to keep a record of multidose vial use. If you will follow the model procedure, you may say on your application, "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."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.53. Say on your application, "We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9," and append your multidose vial record procedure.

MODEL PROCEDURE

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Date and time dosage was drawn and measured,
   c. Calculated volume that is needed for the prescribed dosage,
   d. Measured activity in millicuries or microcuries,
   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

See Exhibit 14 for a Multidose Vial Preparation and Use Log Form you may want to use.

M.3 Measuring and Recording Molybdenum Concentration (§ 35.204)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported under paragraph 21.21(b) of 10 CFR Part 21.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may say on your application, "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."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.204. Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as ATT 10.10," and append your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with paragraph 21.21(b) of 10 CFR Part 21, the licensee must notify the NRC if

a leaking generator is detected.) [The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.]

7. Initials of the person who made the record.

M.4 Keeping an Inventory of Implant Sources (§§ 30.51, 35.21, 35.406)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may say on your application, "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."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of §§ 30.51, 35.21, and 35.406. Say on your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as ATT 10.11," and append your procedure for keeping an inventory and use record for implant sources.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

See Exhibit 15 for a sample form you may want to use.

EXHIBIT 13A

UNIT DOSAGE RECEIPT AND USE LOG FOR _____ AS _____

date received	supplier	lot	dosage mCi	label time	date dispensed	time	measured mCi	patient	ID number	init

EXH-24

EXHIBIT 13B

syncor UNIT DOSE PRESCRIPTION RECORD

PRESCRIPTIONS	DISPOSAL RECORD
Place Top of Prescription #12 Here	DISPOSED BY_____ DATE_____ 12 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #11 Here	DISPOSED BY_____ DATE_____ 11 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #10 Here	DISPOSED BY_____ DATE_____ 10 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #9 Here	DISPOSED BY_____ DATE_____ 9 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #8 Here	DISPOSED BY_____ DATE_____ 8 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #7 Here	DISPOSED BY_____ DATE_____ 7 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #6 Here	DISPOSED BY_____ DATE_____ 6 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #5 Here	DISPOSED BY_____ DATE_____ 5 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #4 Here	DISPOSED BY_____ DATE_____ 4 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #3 Here	DISPOSED BY_____ DATE_____ 3 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #2 Here	DISPOSED BY_____ DATE_____ 2 RETURNED TO SYNCOR ( ) OR_____
Place Top of Prescription #1 Here	DISPOSED BY_____ DATE_____ 1 RETURNED TO SYNCOR ( ) OR_____

INSTRUCTIONS

To mount first report, pull off the two paper tabs indicated by the arrows. Position report edges to top and side guide lines, then press the report down over the exposed adhesive.

The adhesive is *pressure-sensitive*: be sure to press the report down over the exposed adhesive.

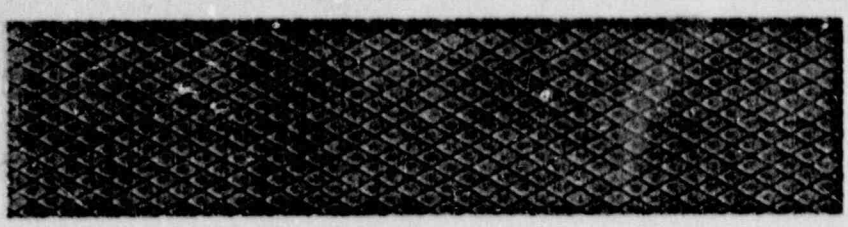
Press lightly to attach temporarily. Press firmly to attach securely and permanently.

DELIVERY BOX SURVEYS

Delivery	Wipe Survey	Surface (mr/hr.)	1/M
1			
2			
3			
4			
Bkg.			

EXHIBIT 13c

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

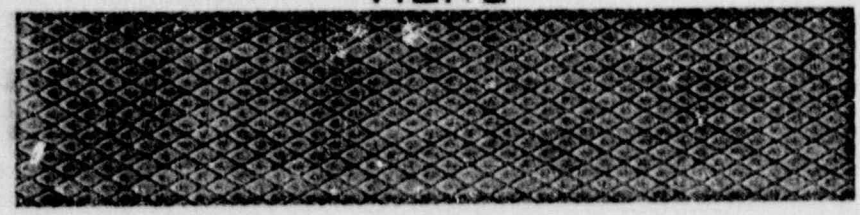
RETURNED TO NPI ( ) OR _____

VOLUME RETURNED _____

DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

RETURNED TO NPI ( ) OR _____

VOLUME RETURNED _____

R1-84 DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

EXHIBIT 14A

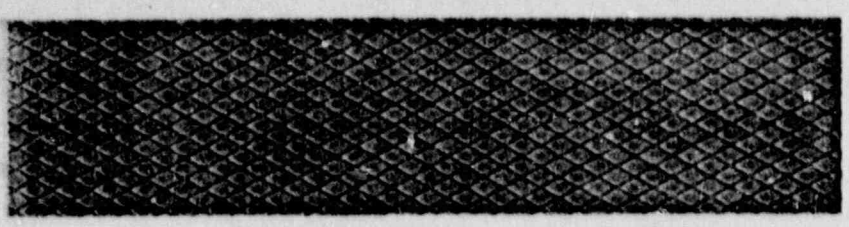
MULTIDOSE VIAL PREPARATION AND USE LOG FOR _____ AS _____

date prepared	time	generator received	kit source	kit lot	mCi/cc	cc	measured mCi	patient	ID number	init

EXH-26

EXHIBIT 46

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

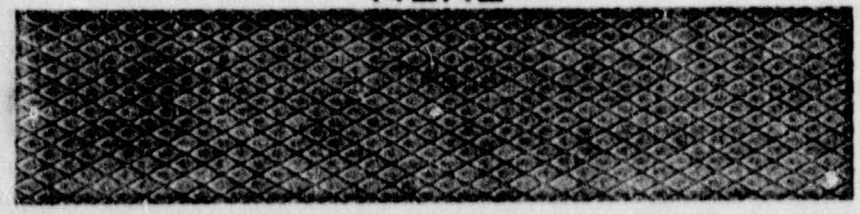
RETURNED TO NPI ( ) OR _____

VOLUME RETURNED _____

DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

AFFIX PRESCRIPTION HERE



DELIVERY BOX SURVEYS			
Delivery	Wipe Survey	(mr/hr.) Surface	3 Feet
1			
2			
3			
4			
Bkg.			

DISPOSAL RECORD

DISPOSED BY _____

RETURNED TO NPI ( ) OR _____

VOLUME RETURNED _____

R1-84 DATE _____

Date	Time	Use/Patient	Activity Read	Volume	Vol. Remaining	Initial

APPENDIX N

Model Procedure for Area Surveys
(See § 35.70.)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of § 35.70. Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 below for guidance in establishing your action levels.)

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

See Exhibit 16 for a sample record form.

Table N-1

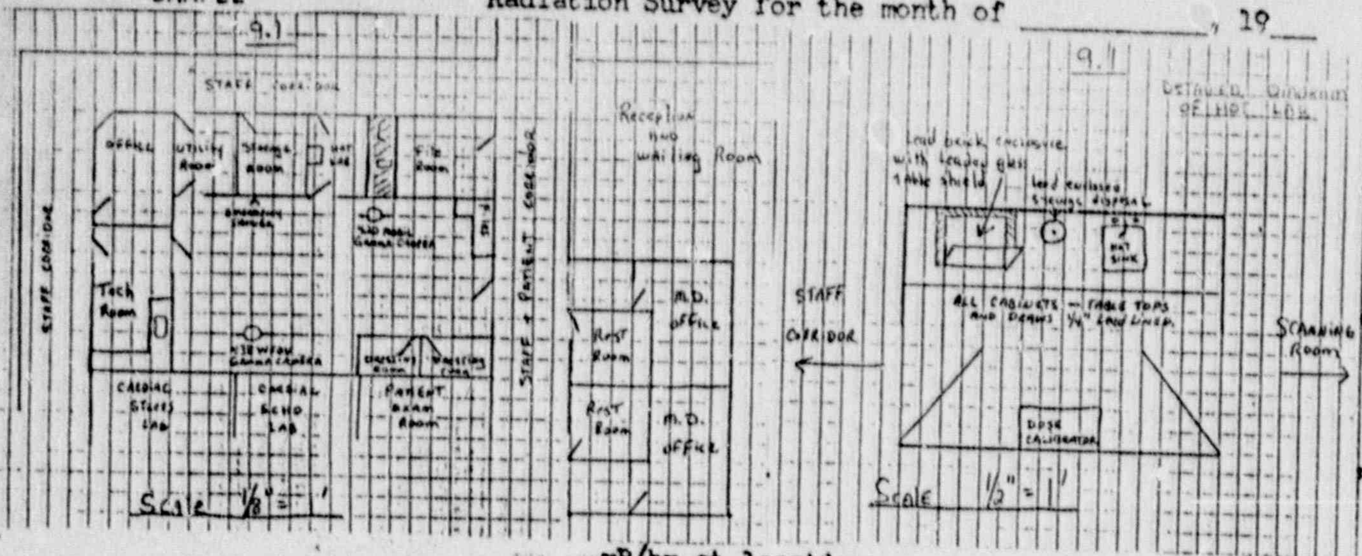
Recommended Action Levels in dpm/100 cm^2 for Surface Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

EXHIBIT 16 A

SAMPLE

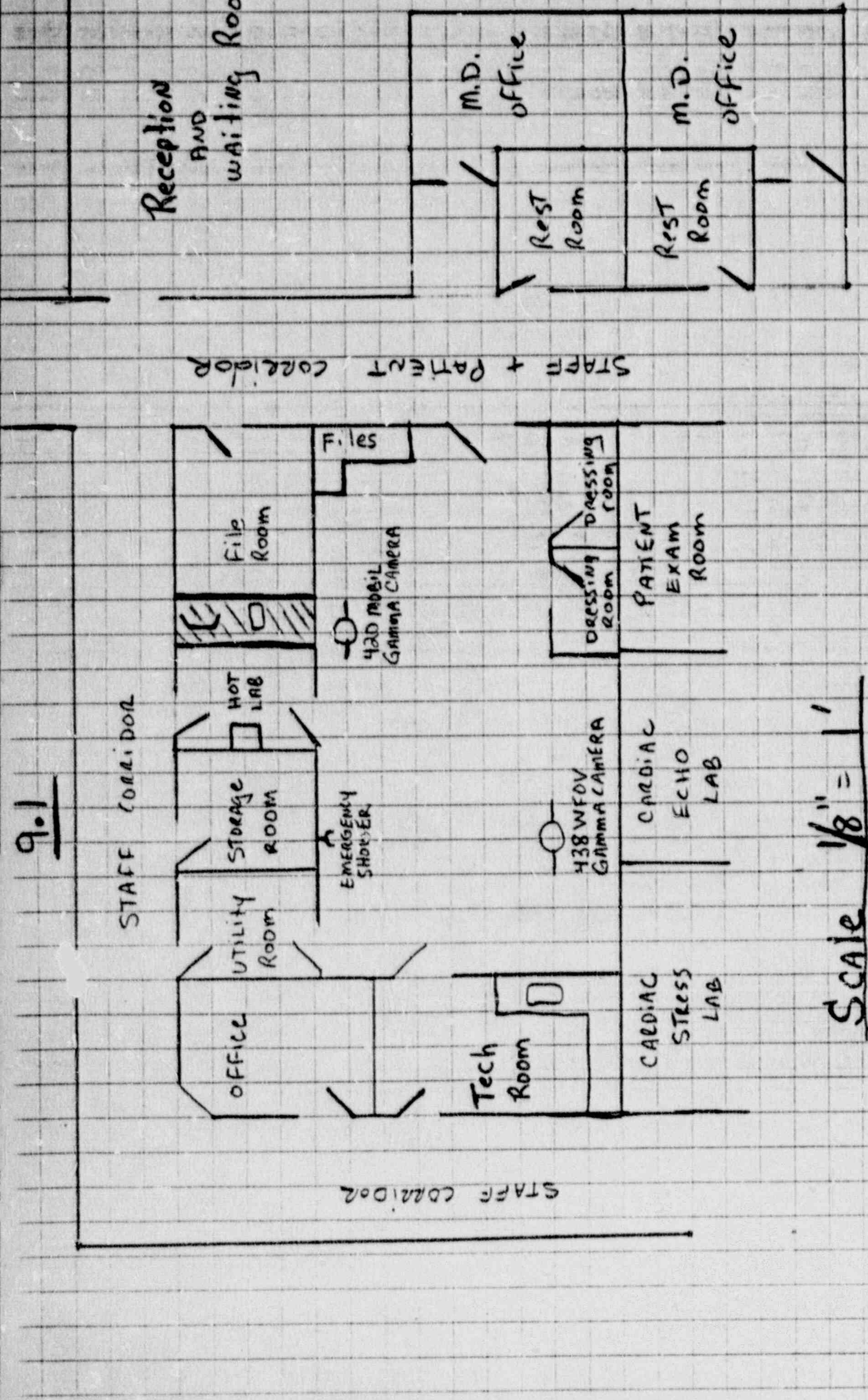
Radiation Survey for the month of ____________, 19___



mR/hr at location

date / trigger	1	2	3	4	5	6	7	8	9	10	11	12		init

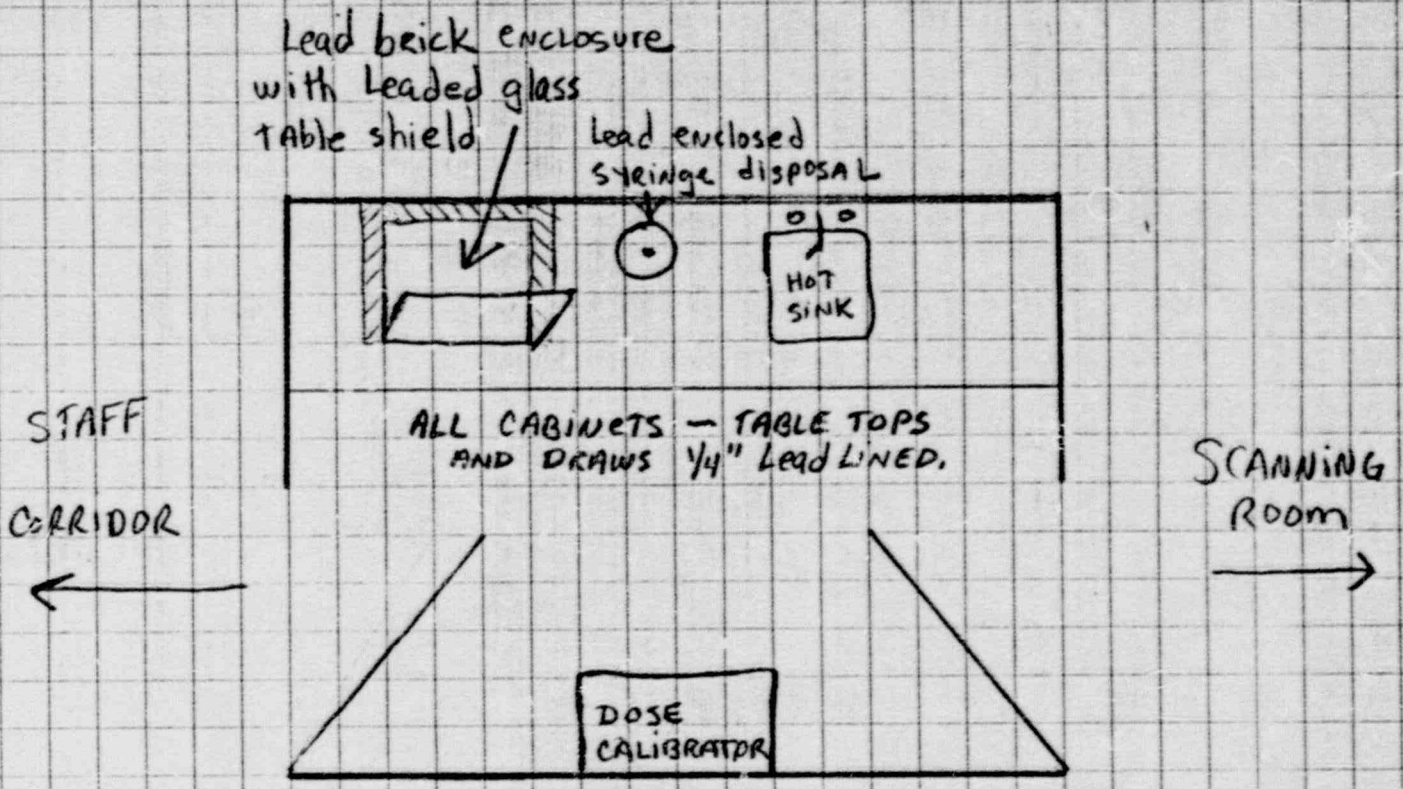
EXHIBIT 16 b



Reception and waiting Room
M.D. office
M.D. office
Rest Room
Rest Room
STAFF + PATIENT CORRIDOR
Files
File Room
420 MOBIL GAMMA CAMERA
DRESSING ROOM
DRESSING ROOM
PATIENT EXAM ROOM
HOT LAB
STAFF CORRIDOR
9.1
STORAGE ROOM
EMERGENCY SHOWER
UTILITY Room
438 WFOV GAMMA CAMERA
CARDIAC ECHO LAB
OFFICE
Tech Room
CARDIAC STRESS LAB
Scale 1/8" = 1'
STAFF CORRIDOR

9.1

DETAILED DIAGRAM OF HOT LAB

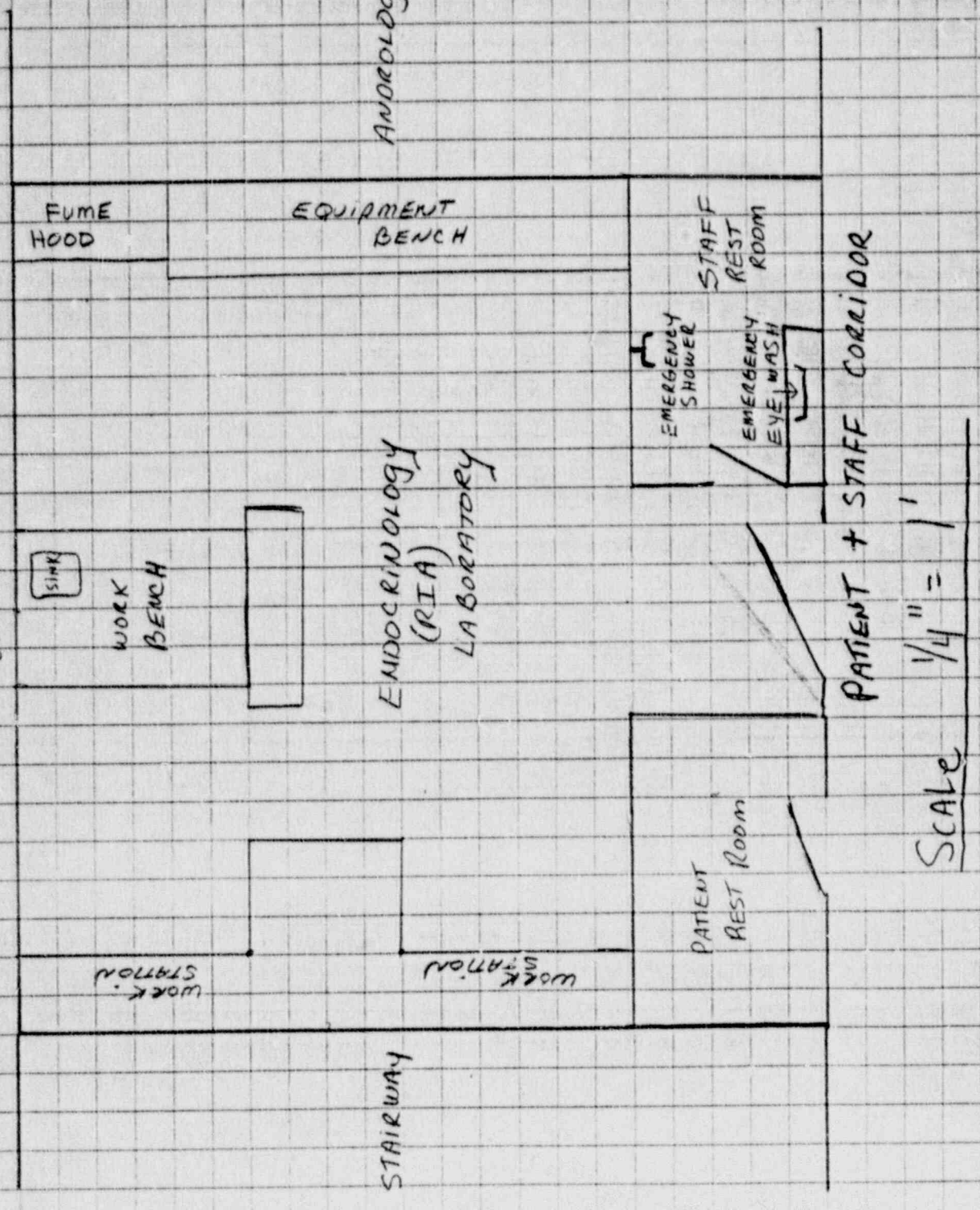


SCALE 1/2" = 1'

EXHIBIT 16c

EXHIBIT 16d

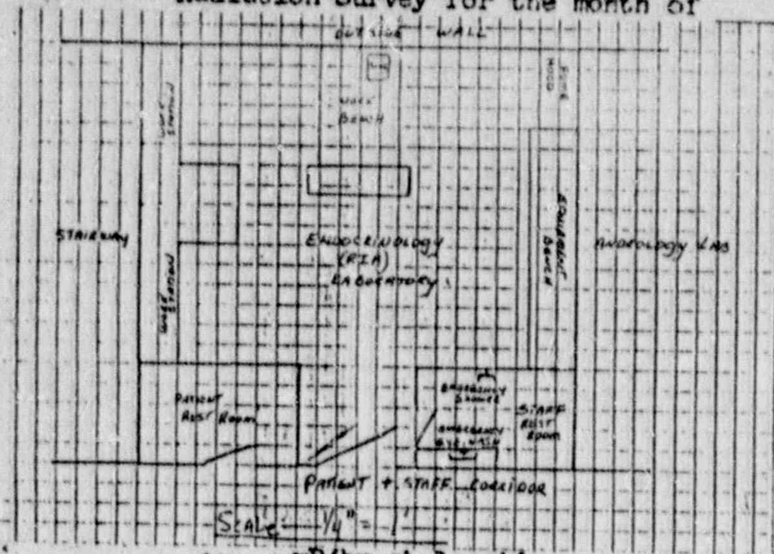
9.1 (31.11)



SAMPLE

EXHIBIT 16e

Radiation Survey for the month of ____________, 19___



(31.11)

mR/hr at location

date	1	2	3	4	5	6	7	8	9	10	11	BAT	CAL	init
trigger														

APPENDIX R

Model Procedure for Waste Disposal
(See §§ 20.301, 20.303, 20.306, and 35.92.)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "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."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of §§ 20.301, 20.303, 20.306, and 35.92. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (see paragraph 20.303(d)) and generally licensed in vitro kit exemptions (see paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See paragraphs 30.51(a) and 20.401(c)(3).)

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in § 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d).) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (§ 20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to § 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

24 MAY 1988

The Malden Hospital
ATTN: Charles D. Chipman, M.D., RSO
Hospital Road
Malden, Massachusetts 02148

Docket No. 030-01908

License No. 20-09214-02

Control No. 108870

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By:
Doris J. Foster

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

"OFFICIAL RECORD COPY" ML10

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 2
FEE CATEGORY: 7C
EXP. DATE: 19880630
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MALDEN HOSPITAL
RECEIVED DATE: 880509
DOCKET NO: 3001908
CONTROL NO.: 108870
LICENSE NO.: 20-09214-02
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: 380.00
CHECK NO.: 036875

3. COMMENTS

SIGNED BP
DATE 5/11/88

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) LFM

1. FEE CATEGORY AND AMOUNT: 7C $580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL ✓
LICENSE _____

3. OTHER _____

SIGNED S. Kimberley
DATE 5/19/88