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

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

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

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

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 34-01954-01

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

Timken Mercy Medical Center
1320 Timken Mercy Drive, N.W.
Canton, Ohio 44708

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

same

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Wayne R. Hedrick, Ph.D.

TELEPHONE NUMBER: 216-489-1067

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7C
AMOUNT ENCLOSED $580.00

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Mark A. Nadel	Mark A. Nadel, F.A.C.H.E.	President and Chief Executive Officer	9-22-88

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Rem	0056	7C	CONTROL NO. 86140	CP
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	19697			10/11/88

Radioactive Material

Any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug or Approved a New Drug Application".

Any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug or Approved a New Drug Application".

Molybdenum-99 / technetium - 99m generator with a possession limit of 3 Curies.

Possession limit of other radioactive material used in diagnostic studies is classified as needed.

Any byproduct material listed in section 31.11(a) with a possession limit of 3 mCi each.

Xenon-133 as gas or gas in saline for blood flow studies and pulmonary function studies with a possession limit of 200 millicuries.

Iodine-131 in the form of sodium iodide as needed for treatment of cardiac dysfunction, and hyperthyroidism, and thyroid carcinoma.

Soluble phophorus-32 as needed for treatment of polycythemia vera, leukemia and bone metastases.

Phosphorus-32 in the form of colloidal chromic phosphate as needed for intracavitary treatment of malignant effusions.

Uranium (depleted in Uranium 235) as cadmium plated metal used as shielding material for the linear accelerator. The total mass is 105 kilograms.

Gold-198 as a sealed source in seeds for interstitial treatment of cancer with a possession limit of 150 millicuries.

Item No. 5
September 1988

Purposes for which License Material will be used.

Preparation and use of diagnostic radiopharmaceuticals for diagnostic clinical procedures as deemed appropriate by the physicians who are authorized users of these materials.

In - vitro studies.

Iodine-131 as sodium iodide for treatment of cardiac dysfunction, hyperthyroidism and thyroid carcinoma.

Soluble phophorus-32 for treatment of polycythemia vera, leukemia and bone metastases.

Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

Depleted uranium as shielding in linear accelerator.

Gold-198 for interstitial treatment of cancer.

Item No. 6
September 1988

Radiation Safety Officer.
Authorized Users.

The radiation safety officer is designated as Richard V. Skibbens, M.D. who is currently listed as an authorized user and as RSO on this license.

All individuals listed below were authorized users on the current license of this hospital (license no. 34-01954-01).

Richard V. Skibbens, M.D.

Robert V. Wade, M.D.

George Drapeau

Myron R. Puterbaugh, M.D.

Carlos V. Rozenbom, M.D.

Dae Hyun Bang, M.D.

Robert E. Reaven, M.D.

Charles Edward Smith, M.D.

Pushpa Bathija, M.D.

Richard P. Levy, M.D. should not be listed as an authorized user, since this physician no longer maintains a research lab at this institution. Iodination of proteins is no longer performed at this institution.

Please add John N. Rauchenstein, M.D. as an authorized user. Dr. Rauchenstein was a resident in diagnostic radiology including nuclear medicine from July 1983 to June 1987 and was certified by the American Board of Radiology in Diagnostic Radiology in June 1987.

Item No. 7
September 1988

Radiological and Health Physics Services

For more than 17 years, consultation services have been provided to the Hospital as needed on a year round basis by members of Medical Physics Services, Inc. In the Nuclear Medicine area at Timken Mercy Medical Center support and consultation during this period have been provided exclusively by the following individuals from that group:

Dale E. Starchman, Ph.D.
Certified Radiological Physicist (all areas), American Board of Radiology
Certified Health Physicist (comprehensive), American Board of Health Physics

Wayne R. Hedrick, Ph.D.
Certified Diagnostic Radiological and Medical Nuclear Physicist, American Board of Radiology

David L. Hykes, M.S.
Certified Radiological Physicist (all areas), American Board of Radiology

Such consultation takes the form of frequent phone and written consultations and many visits throughout the year for work in radiation protection and consultation in the various areas of radiology. In addition, multiple comprehensive radiation physics and safety reviews of nuclear medicine are performed each year including complete documentation in formal reports as required by the Joint Commission on Accreditation of Hospitals. The above is simply an informational item providing a description of radiation safety resources available to and utilized by the Hospital at this time.

Item No. 7
September 1988

8. Training for individuals working in or frequenting restricted areas.

8.1 We have developed a training program for your review that is appended as ATT 8.1

8.2 NA

9. Facilities and Equipment

9.1 An annotated drawing of the nuclear medicine area and the waste storage area are enclosed as ATT 9.1.

9.2 We will have all survey instruments calibrated by commercial services which have established and implemented the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 (or the equivalent as demonstrated by their having had their procedures approved by the NRC). The survey meter calibration service currently being utilized is Health Physics Associates of Highland Park, Illinois.

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

9.4 We have developed an external exposure monitoring program for your review that is appended as ATT 9.4.

9.5 NA

9.6 NA

10. Radiation Safety Program

10.1 We will issue the model Radiation Safety Committee Charter that was published in Appendix F to Regulatory Guide 10.8, Revision 2. Alternates may be formally named by the Administrator to represent the RSO and management at meetings when the primary member is not present. We will issue the Radiation Safety Officer Delegation of Authority that is appended as ATT 10.1.

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

10.3 We will establish and implement the model procedure for leak testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

10.4 We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4.

10.5 We have developed spill procedures for your review that are appended as ATT 10.5.

10.6 We have developed a procedure for ordering and receiving radioactive materials for your review that is appended as ATT 10.6

10.7 We have developed a package opening procedure for your review that is appended as ATT 10.7.

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.

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

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.

10.11 The only therapy implant sources used will be Au-198 seeds. These will be stored in the manufacturer's shipping container in a locked area of nuclear medicine. We will establish and implement all applicable provisions of model procedure provisions 2-7 published in appendix M.4 to Regulatory Guide 10.8, Revision 2.

10.12 We have developed survey procedures for your review that are appended as ATT 10.12.

10.13.1 We have developed procedures to collect spent noble gas in a shielded container and to check the trap effluent. These are appended as part of ATT 10.13 for your review.

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

10.13.3 We calculated airborne effluent concentration. These calculations are appended for your review as part of ATT 10.13.

10.13.4 We have calculated spill gas clearance times. These are appended for your review as part of ATT 10.13.

10.14 We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 10.14.

10.15 We have developed a procedure for radiation safety for permanent implant therapy for your review that is appended as ATT 10.15.

10.16 NA

11.1 We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

11.2 NA

Personnel Training Program

All personnel will be properly instructed before assuming duties with, or in the vicinity of radioactive materials or whenever there is a significant change in duties, regulations, or the terms of the license.

At a minimum, an annual in-service will be provided for nuclear medicine technologists and any other persons whose duties require working in or frequenting any portion of a restricted area.

Instructions of personnel as required by 10CFR19 will include:

A. All terms of the license pertinent to radiation safety.

B. Areas where radioactive material is used or stored.

C. Potential hazards associated with radioactive material.

D. Radiological safety procedures appropriate to their respective duties.

E. Pertinent N.R.C. regulations.

F. Conditions of the licensee.

G. Obligation to report unsafe conditions to the Radiation Safety Officer.

H. Appropriate response to emergency or unusual occurrence.

I. Right to be informed of their radiation exposure and bioassay results.

J. 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 10CFR Part 19.

ATT 8.1
September 1988

TRAINING PROGRAM

Workers	Method	Frequency
1. Nuclear Medicine Supervisor	Lecture by Consulting Physicist	Annually*
2. Nuclear Medicine Technologist(s)	Instruction by Nuclear Medicine Supervisor	Annually*
3. Security Personnel	Instruction From Nuclear Medicine Technologists	Annually

*The number of nuclear medicine technologists is typically the Supervisor + 2 full time persons. The Nuclear Medicine Supervisor will be responsible for orienting any technologist employee with respect to radiation safety practices in a one-on-one session. Consulting physicist reviews overall radiation safety program in detail with Supervisor (or Acting Supervisor) twice a year and submits a written report. These reviews will be considered equivalent to an annual lecture. The Supervisor will be responsible for discussing any significant problem areas noted during the review with the technologist staff.

ATT 8.1
September 1988

Description of Nuclear Medicine Department

Pb Shield --- This is an L block made of 1/16" lead on 3 sides and leaded glass on top. All preparations are performed using this L block.

Two-inch thick lead bricks are available for shielding purposes.

Absorbent pads are used in areas where radioisotope storage and manipulation is performed with liquids.

All areas adjacent to the dep rtment are unrestricted areas inside the hospital. Survey results have shown that these levels do not exceed the limits specified in 20.105(b) of 10 CFR 20.

Five diagrams are enclosed:

1) Overall print of this area of hospital identifying location of nuclear medicine area.

2) Diagram identifying uses of individual rooms in nuclear medicine department and location of preparation area.

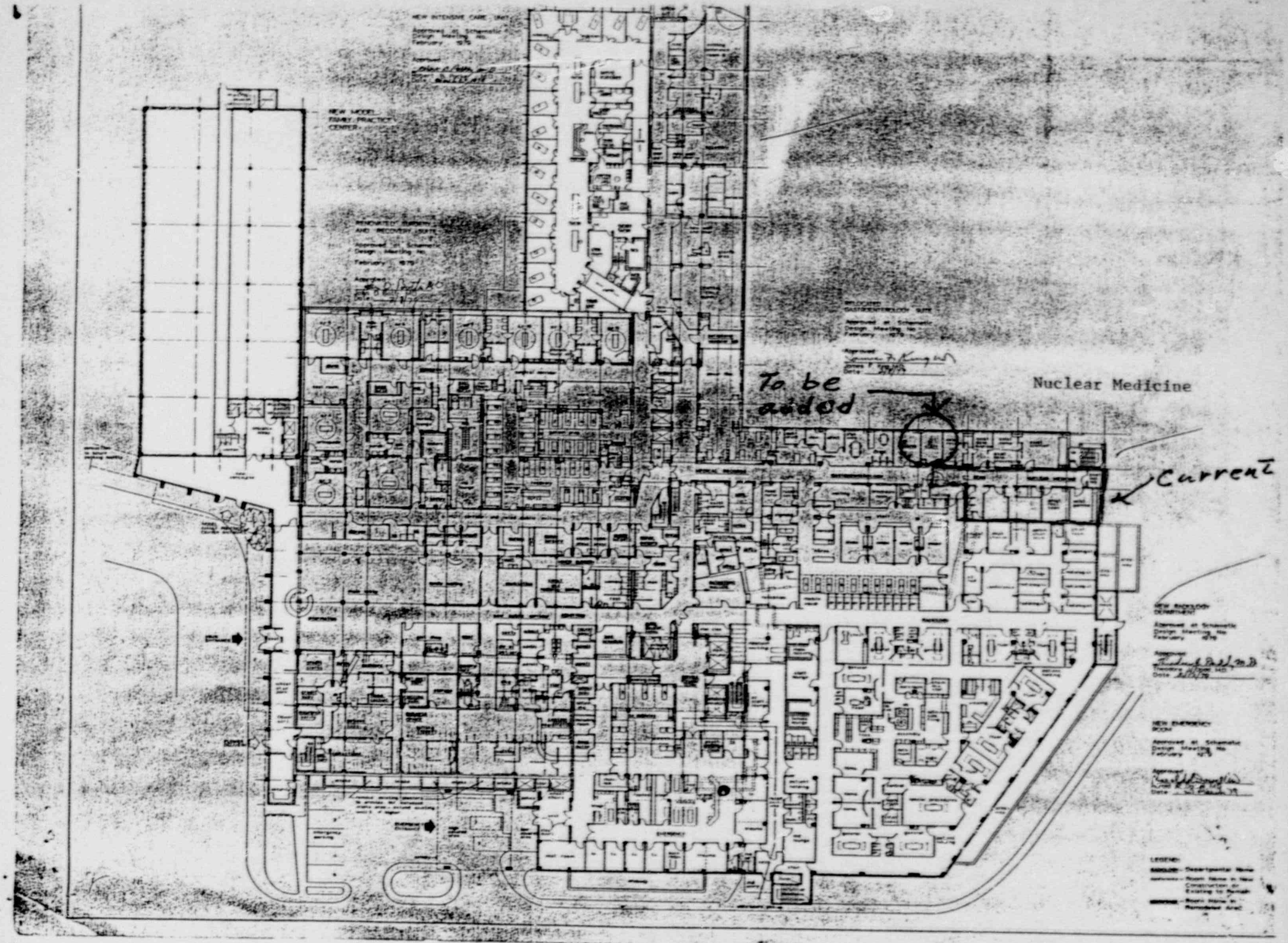
3) Diagram of hot lab.

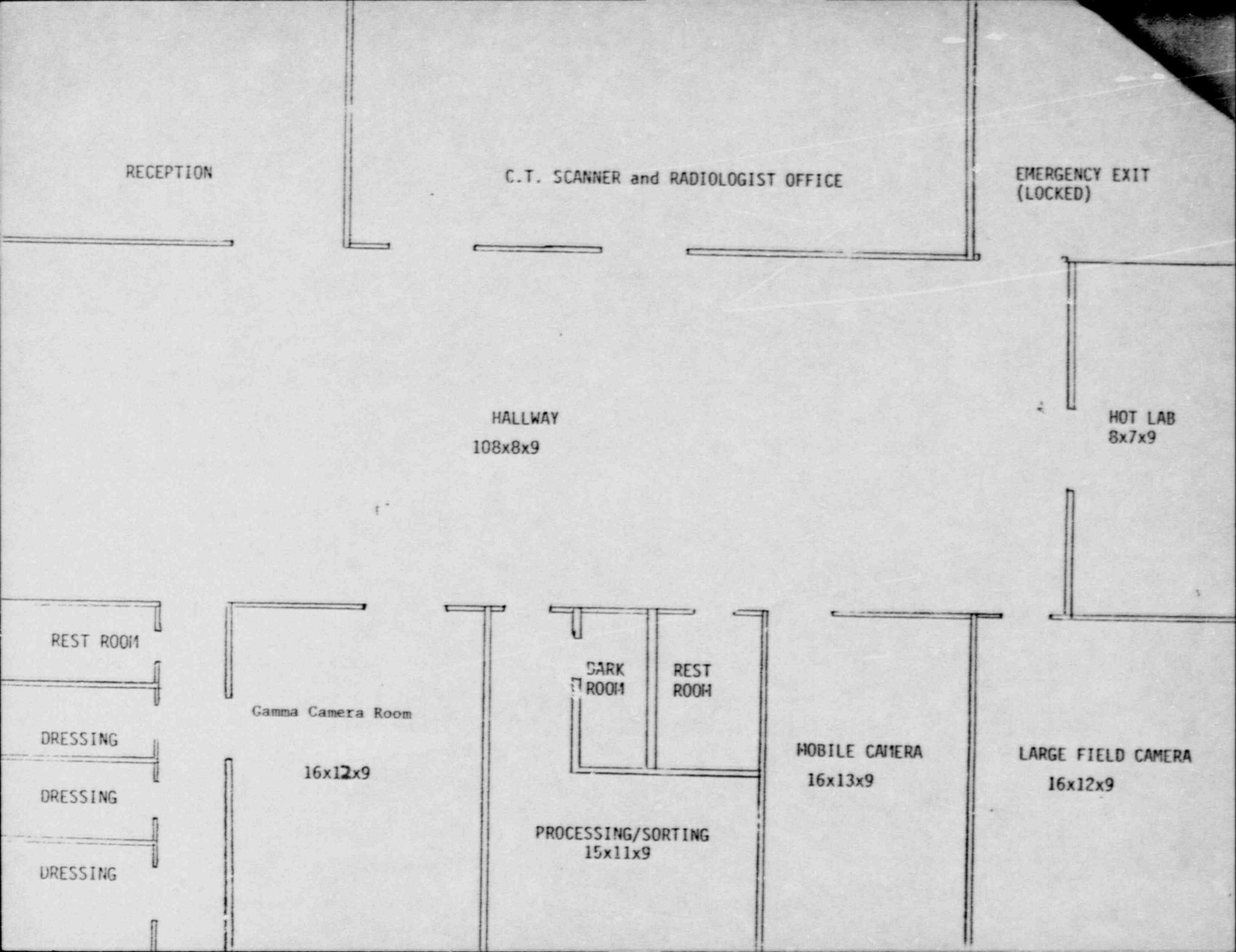
4) Diagram of waste storage area. This area is located in the basement across from the Pharmacy Office. The room designator is 56.

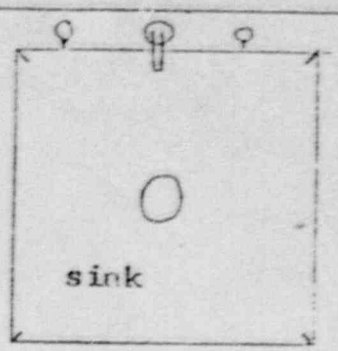
5) Diagram of RIA Lab (informational purposes).

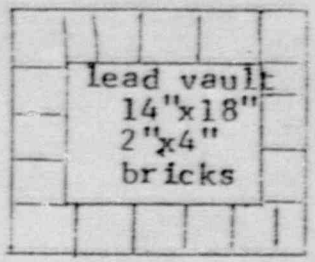
In addition, upon approval of this license application by the NRC, the GI Staff Room across the hall from the current nuclear medicine area, circled on the overall print of this area of the hospital, will be converted to a nuclear cardiac stress room. The floor will be of a non-porous material.

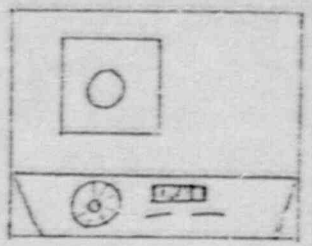
ATT 9.1
September 1988


To be added
Nuclear Medicine
Current

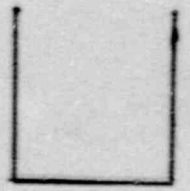

RECEPTION
C.T. SCANNER and RADIOLOGIST OFFICE
EMERGENCY EXIT
(LOCKED)
HALLWAY
108x8x9
HOT LAB
8x7x9
REST ROOM
DRESSING
DRESSING
DRESSING
Gamma Camera Room
16x12x9
DARK ROOM
REST ROOM
PROCESSING/SORTING
15x11x9
MOBILE CAMERA
16x13x9
LARGE FIELD CAMERA
16x12x9







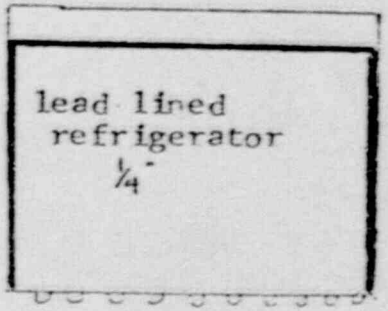
dose calibrator

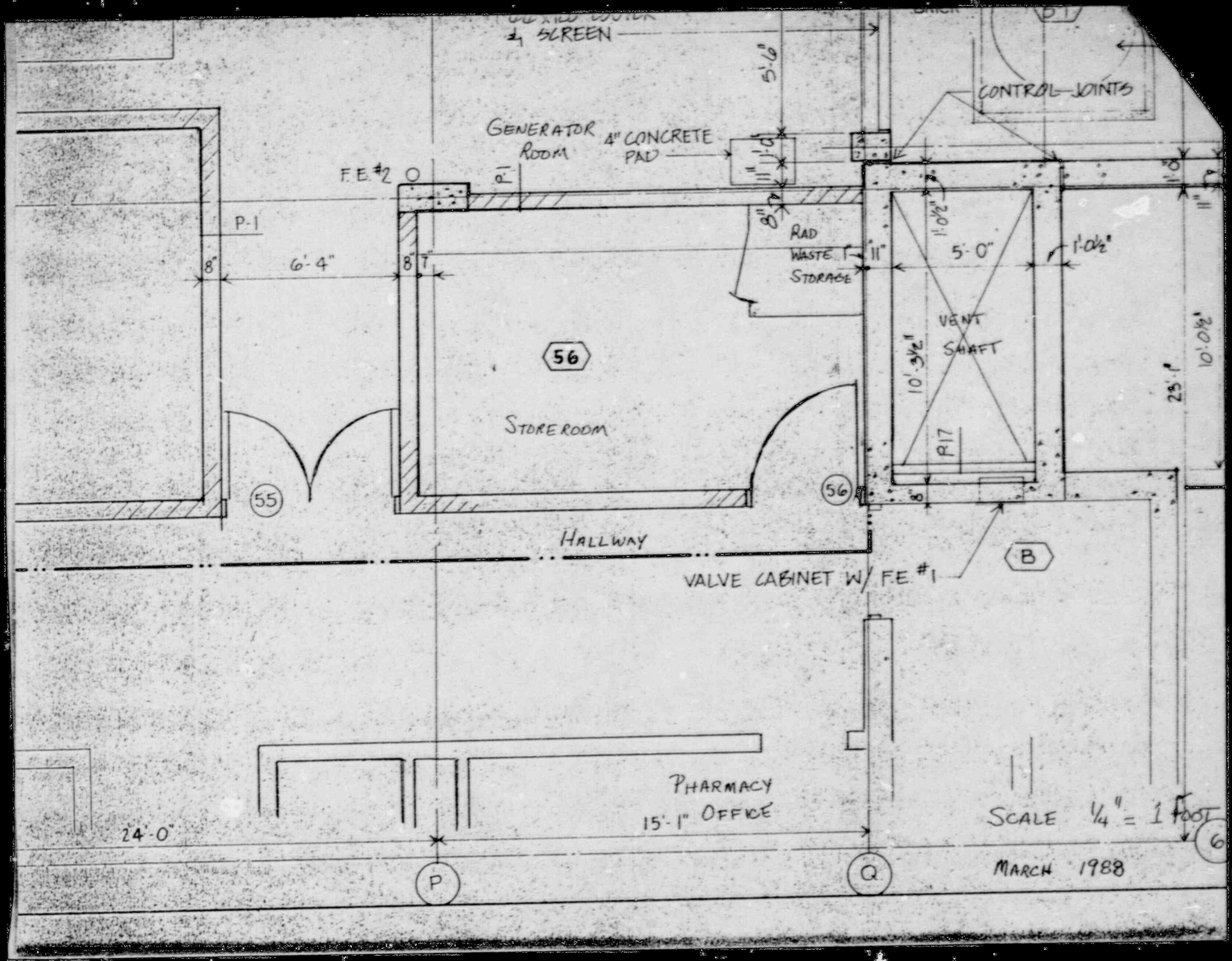


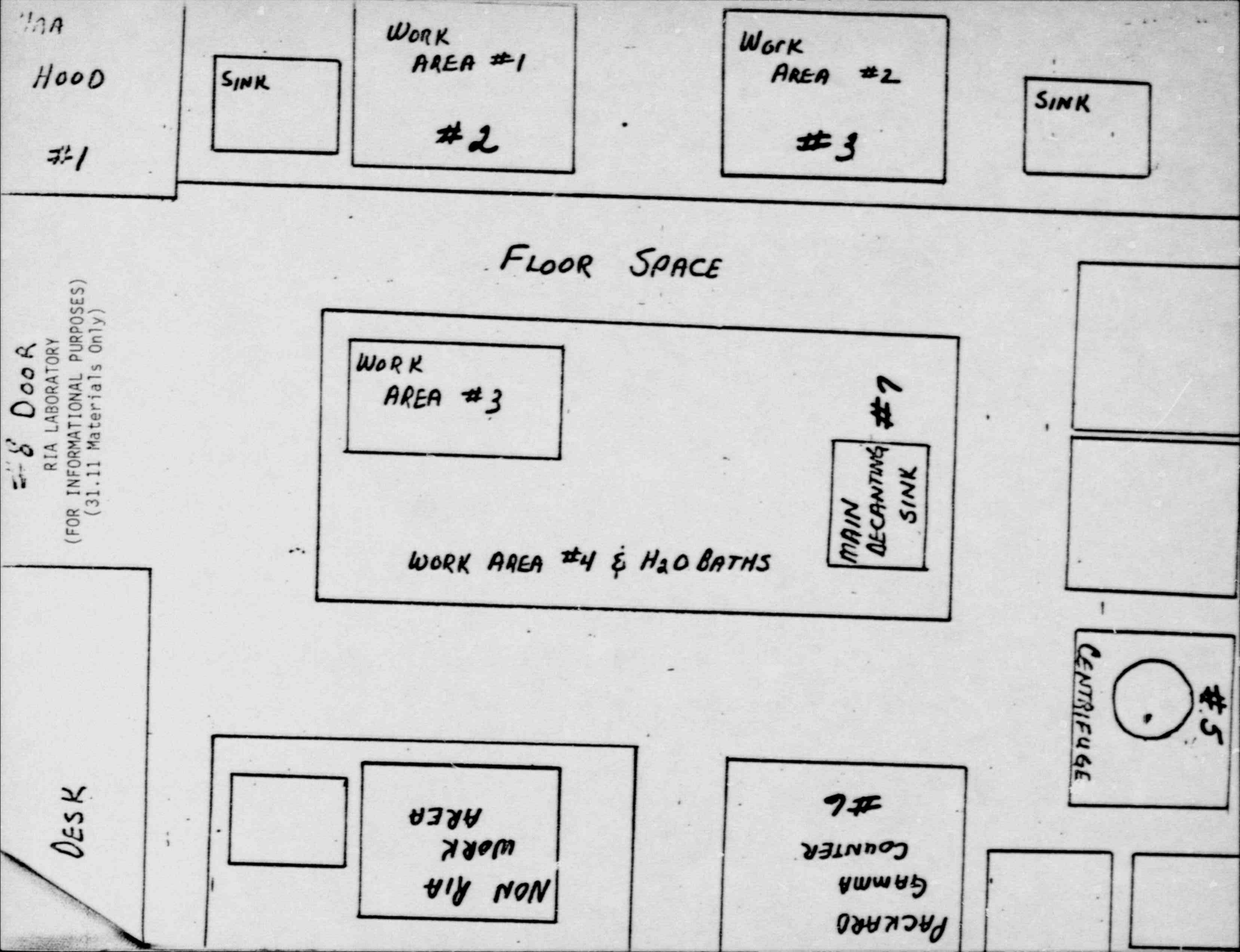
L-Block

Ho+ Lab Area

96" x 88" x 9'




SCREEN
5'-6"
CONTROL JOINTS
GENERATOR ROOM
4" CONCRETE PAD
F.E. #2
P-1
8"
6'-4"
8"
8"
RAD WASTE STORAGE
11"
5'-0"
1'-0½"
VENT SHAFT
10'-3½"
23'-1"
10'-3½"
56
STOREROOM
55
56
HALLWAY
VALVE CABINET W/ F.E. #1
B
PHARMACY
15'-1" OFFICE
24'-0"
P
Q
SCALE ¼" = 1 FOOT
MARCH 1988


HOOD #1
SINK
WORK AREA #1
#2
WORK AREA #2
#3
SINK
FLOOR SPACE
8' DOOR
RIA LABORATORY
(FOR INFORMATIONAL PURPOSES)
(31.11 Materials Only)
WORK AREA #3
#7
MAIN DECANTING SINK
WORK AREA #4 & H2O BATHS
CENTRIFUGE
#5
DESK
NON RIA WORK AREA
PACKARD GAMMA COUNTER
#6

Dose Calibrator Linearity Determination (Quarterly)

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity prepared for patient use.

1. Assay the Tc-99m vial in the dose calibrator to determine the net activity in milliCuries.

2. Repeat Step 1 at various time intervals over the next 48 hours after the initial assay.

3. Calculate the predicted activities at the respective time intervals.

4. Compare the predicted activities with the measured activities.

5. The measured activities should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate that the instrument may require repair or adjustment.

6. Notify the RSO if the linearity error exceeds 5 percent so that an evaluation of the status of the dose calibrator can be made.

Note: The standard lead cylinder attenuation technique may be substituted for steps 1-3 above if desired.

Dose Calibrator Geometry Independence

This is required only when a new dose calibrator is installed. In the event that we purchase a new dose calibrator (or this becomes appropriate because of a particular repair), we will establish and implement the model procedure for testing the geometric independence of the dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2. (Copy not attached to this application, but available in the Department).

ATT 9.3
September 1988

Dose Calibrator Accuracy Determination
(Annually)

Check the accuracy of the dose calibrator for two radionuclides e.g Cs-137 and Co-57. The activities of these reference standards have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

1. Assay each of the reference standards in the dose calibrator at the appropriate setting, and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement in the log.

2. The activity for each source should agree with the certified activity of the reference source within ±5 percent after decay corrections.

3. Keep a log of these accuracy checks.

4. Accuracy checks that do not agree within ±5 percent indicate that the instrument may require repair or adjustment. Notify the RSO if the accuracy error exceeds 5 percent.

ATT 9.3
September 1988

Daily Dose Calibrator Constancy Checks

1. At the beginning of each day of use, perform the dose calibrator constancy check.

2. Check ZERO by pressing button marked ZERO. If reading is not within ±0.0002 mCi, adjust potentiometer until the meter displays zero (± .0000).

3. Check the room background by pressing the button marked BKG. This will compensate for room background in about 30 seconds. The meter should display within 0.5 uCi. A fluctuation of a few tenths of a uCi is normal.

4. Place one relatively long lived source such as Cs-137, Co-60, Co-57, or Ra-226 in the dose calibrator. Assay this source using the setting appropriate to that source, then assay this reference source with the frequently used settings. Record the results. Compare each reading to previous values corrected for decay of the source.

5. If the measurements are not within ±5% of the predicted values, notify the RSO.

ATT 9.3
September 1988

Personnel External Exposure Monitoring 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 as deemed appropriate by the RSO. The monitoring devices 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 as deemed appropriate by the RSO. These monitors will be processed by a contract service on a monthly basis.

4. 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.

ATT 9.4
September 1988

Memo To: All Employees

From: Chief Executive Officer

Subject: Delegation of Authority

Richard V. Skibbens, MD 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 implemention 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.

ATT 10.1
September 1988

Rules for Safe Use of Radiopharmaceuticals

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, camera, or GM survey meter.

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 as prescribed by the Radiation Safety Officer.

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. Radiopharmaceuticals 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 radiopharmaceutical 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, identification number, the prescribed radionuclide, chemical form, and dosage before administering.

Model Spill Procedures

Minor Spills of Liquids and Solids:

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

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 the 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.

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 and the Radioactive Spill Contamination Survey.

ATT 10.5
September 1988

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

Procedures for Ordering and Accepting Delivery of Radioactive Material

1. All radioactive material for the Nuclear Medicine Service will be ordered by nuclear medicine technologists. These individuals will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. Ordering of routinely used materials in the Nuclear Medicine Service.

   a. Written records that identify the isotope, compound, activity levels, and supplier, etc. will be maintained.

   b. The written records will be referenced when opening or storing a radioactive shipment.

3. Ordering of radiopharmaceuticals or Gold-198 for therapeutic procedures.

   a. The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical or physical form, and activity.

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

4. Written records will be maintained for all ordering and receipt procedures.

5. During normal working hours, carriers will be instructed to deliver radioactive package directly to the Nuclear Medicine Service.

6. During off-duty hours, designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the memorandum attached.

ATT 10.6
September 1988

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. Unlock the doors, place the package in the hot lab 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, R. V. Skibbens, M.D.

Judy Stuckey, R.T.; Supervisor of Nuclear Medicine
Ext. 1069; Evenings - Ext. 1070

R. V. Skibbens, M.D.; Radiation Safety Officer
Ext. 1070

D. E. Starchman, Ph.D.; Medical Physicist
Ext. 1070; Evenings 494-7353

W. R. Hedrick, Ph.D.; Medical Physicist
Ext. 1070; Evenings 1-896-1377

ATT 10.6
September 1988

Opening Packages Containing Radioactive Material

Visually inspect the package for any sign of damage (e.g. wetness, crushed). If damage is noted, notify the Radiation Safety Officer.

All incoming packages will be surveyed at the surface and at three feet from the surface to assure that the exposure levels do not exceed 200 mR/hr and 10 mR/hr, respectively. If the above levels are exceeded, notify the Radiation Safety Officer.

If there is any reason to suspect contamination, wipe the external surface of the final source container and count the wipe sample in the NaI uptake probe. The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm) per 100 cm^2.

Monitor the packing material and package for contamination before releasing from area. If contaminated, treat as radioactive waste. If the material is to be discarded in regular trash, obliterate radiation labels.

Record the results of checking each package in the log book.

Verify that the contents agree with the packing slip. Check the user request to ensure that the material received is the material that was ordered.

ATT 10.7
September 1988

NTx that 35.70(c) requires that meters used for daily surveys also be sufficiently sensitive to detect 0.1 mR/hr

Area Survey Procedures
Nuclear Medicine

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.

2. Waste storage areas and scanning areas will be surveyed weekly.

3. The weekly surveys will consist of:

a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr. If the radiation level exceeds 0.6 mR/hr in the scanning area or 10 mR/hr in the hot lab, then the individual performing the survey shall notify the RSO immediately.

b. A series of wipe tests to measure contamination levels. A NaI uptake probe will be utilized to perform these measurements. Area will be cleaned and re-monitored if the reading exceeds 2000 dpm per 100 cm^2. If after cleaning the removable contamination still exceeds 2000 dpm per 100 cm^2 background, then the individual performing the survey shall notify the RSO immediately.

4. A record will be kept of all survey results, including negative results for at least two years. The record will include:

Model proc for area surveys in Appendix N [illegible] acceptable wipe procedure sufficiently sensitive to detect 200 dpm/100 cm2 removable contamination for isotopes of iodine.

a. Plan of the area surveyed.

b. Date of survey.

c. Trigger levels for each area.

d. Initials of persons conducting the survey.

e. Identification of equipment used to make the survey.

f. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

g. Detected contamination levels, keyed to locations on drawing.

h. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

Model proc [illegible] notification of RSO if find unexpectedly high levels. Proc. [illegible] require notification of RSO only [illegible] [illegible] RSO [illegible]

ATT 10.12
September 1988

133-Xe Ventilation and/or Perfusion Supplement

A. Use and Storage Areas

The 133-Xe will be stored before use in the stationary camera room. Storage will be near the exhaust fan having a flow rate of 300 CFM so as to exhaust any possible leakage. Shielding will consist of the manufacturer's lead-shielded container. The area will be surveyed with a survey meter to determine external exposure levels.

The 133-Xe will be used in the stationary camera room (see diagram attached). The total area exhaust rate is 300 CFM. There is no air supply for this room. The area is under negative pressure. All air is exhausted from the building directly without recirculation into the hospital. The exhaust fan is turned on at all times.

B. Procedures for Routine Use and Emergency Procedures

We will follow the instructions provided in the package insert with each shipment. Film badges are worn by all personnel. Xenon will be stored in the manufacturer's shielded containers.

Administration of 133-Xe will be accomplished by using the commercially available closed breathing system and gas trap. The breathing system will cover both nose and mouth to reduce leakage.

Gas trap cartridges will be held for decay for at least 10 half-lives. They will then be checked with a Geiger counter and, if the reading is less than or equal to background in a low background area, they will be approved for release to unrestricted areas after defacing or destroying any radioactive material labels.

As stated above, a closed system will be used for all procedures. However, emergency procedures would be based on the following analyses:

The total volume of the stationary camera room is approximately 1728 ft^3.

The room exhaust is 300 ft^3/min = 8.5×10^6 ml/min.

ATT 10.13
September 1988

If one postulates the worst credible accident, as the accidental release of the entire contents of the 20.0 mCi Xenon supply at any location in the room, the following procedure would be followed. The stationary camera room would be evacuated. The room has one door, which would be closed.

1. The highest activity of gas in a single container

   $A = 20{,}000$ microcuries

2. The total room air exhaust

   $Q = 8.5 \times 10^6$ ml/min

3. The maximum permissible air concentration in imaging room

   $C = 1.0 \times 10^{-5}$ uCi/ml

4. The volume of the room in milliliters (1728 ft^3) is

   $V = 4.9 \times 10^7$ ml

5. The evacuation time t is calculated as follows:

$$t = \frac{-V}{Q} \times \ln (C \times V/A)$$

$$t = \frac{-(4.9 \times 10^7 \text{ ml})}{8.5 \times 10^6 \text{ ml/min}} \times \ln(1 \times 10^{-5} \text{ uCi/ml} \times 4.9 \times 10^7 \text{ ml}/20000 \text{ uCi})$$

$t = 21$ minutes

The room itself would not be reoccupied for 21 minutes following the release.

ATT 10.13
September 1988

C. Air Concentration of 133-Xe in Restricted Areas and Non-Restricted Areas

See exhaust and physical facility data in B above.

1. The maximum average estimated amount of activity to be used per week is assumed to be 10 patients in any one week at 12.0 mCi each,

$$A = 1.2 \times 10^5 \text{ uCi/week}$$

2. The fraction lost into the room during use and storage will be very small with storage in the hood and with utilization of a closed system with mask over nose and mouth and with use of charcoal filters. We will, nevertheless, assume a much higher than likely leakage rate, 20% for all calculations, f = 0.20.

3. The ventilation rate is:

$$V = 8.5 \times 10^6 \text{ ml/min (40 hrs/week)(60 min/hour)} = 2.0 \times 10^{10} \text{ ml}$$

for a 40 hour week or 8.6×10^{10} for a 168 hour week

4. In the restricted areas:

$$\frac{A \times f}{V} = \frac{1.2 \times 10^5 \frac{\text{uCi}}{\text{week}} \quad (.20)}{2.0 \times 10^{10} \text{ ml/week}} = 1.2 \times 10^{-6} \text{ uCi/ml vs } 1 \times 10^{-5} \text{ uCi/ml MPC}$$

This is a factor of 8 below the MPC level.

5. In the nonrestricted area at the point of discharge, the levels of concentration would be determined by:

The fraction of the activity used each week that is released in the exhaust system is assumed to be 0.20.

$$\frac{12000 \text{ uCi/pt} \times 10 \text{ pt/week} \times 0.20}{8.6 \times 10^{10} \text{ ml/week}} = 2.8 \times 10^{-7} \text{ uCi/ml}$$

2.8×10^{-7} uCi/ml is less than the MPC of 3×10^{-7} uCi/ml.

D. 133-Xenon Disposal

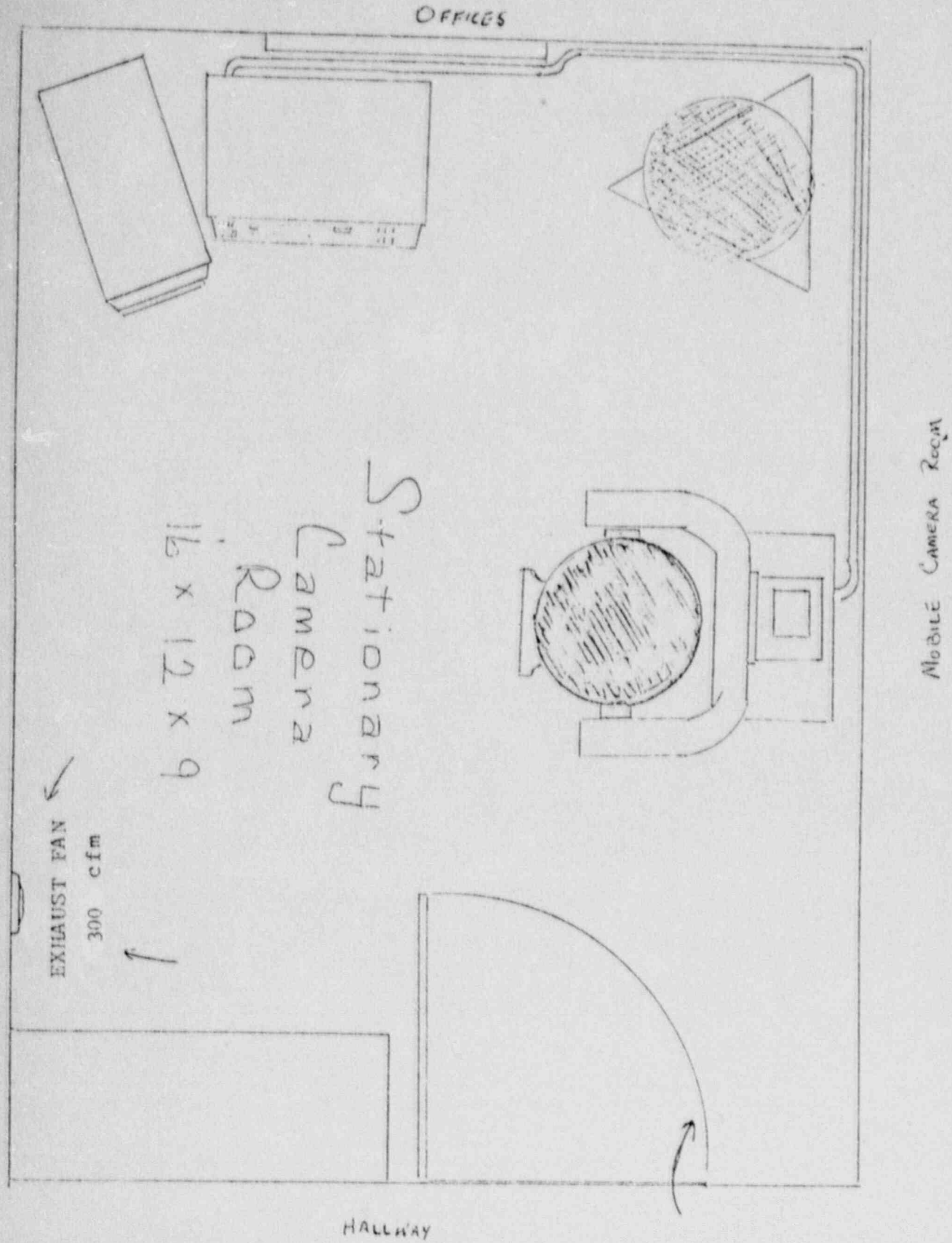
The Xenon from the study will be absorbed onto the charcoal trap as indicated above.

To insure that the trap is working efficiently, the following procedure will be performed on a monthly basis. During an Xe-133 ventilation study, a polyethylene bag will be placed over the exhaust part of the Xenon trap. The unit will be operated until the bag is full. The bag will be sealed and placed in front of the Gamma camera and counted for one minute on the Xenon window settings. The counts per minute (CPM) will be recorded in a record book and compared with previous readings. A replacement cartridge will be installed whenever the net count rate consistently exceeds the baseline count rate by a factor of three. The baseline count rate will be established by the average net count rate of several trap checks.

E. Ventilation

Air flow rates in the rooms where 133-Xe is used or stored will be measured semi-annually.

DIAGRAM FOR STATIONARY CAMERA ROOM
INCLUDING VENTILATION FLOW RATE



CONTROL NO. 86140

Iodine Therapy Over 30 Millicuries

Currently no hood is available for venting vials containing radio-iodine in liquid form. All therapeutic procedures using radioiodine will be performed with I-131 in capsule form.

ATT 10.14
September 1988

Radiation Safety During Iodine Therapy Over 30 Millicuries

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Use leak-proof absorbent paper to cover large surfaces (especially the floor around the toilet) that are likely to be contaminated. Small items (telephone, door-knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

   b. Prepare separate containers for linen, disposable waste, and nondisposable contaminated items.

   c. Urine will be discarded by release to the the sanitary sewer.

   d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table sevice for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs or pocket ionization chambers, if deemed appropriate by the Radiation Safety Officer.

5. Brief the nurses on radiation safety precautions. Use nursing instruction form for radioiodine therapy as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a "visitors' line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, and in the surrounding hallways and rooms [the last rates must conform to requirements in paragraph 10.105(b)]. Record this and any other necessary information on the nursing instructions form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Make a record of the worker's name, efficiency for counting I-131, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see 35.75). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

a. Remove all absorbent paper, and place it in the appropriate container.

b. Transfer all containers to a decay-in-storage or decontamination area.

c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

d. Notify the Housekeeping Office to remove the cleaning restriction and notify the Admitting Office to return the room to the vacant list.

ATT 10.14
September 1988

APPENDIX Q

Radiation Safety for Permanent Implant Therapy

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room.

2. Supply the nurses with film badges, TLD's or pocket ionization chambers as deemed appropriate by the RSO.

3. Brief the nurses on radiation safety precautions. Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105[b]). Record this exposure rate information on the chart or on the survey form. Post the room with a "Radioactive Materials" sign.

7. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

8. Provide the patient with radiation safety guidance before releasing the patient.

ATT 10.15
September 1988

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.

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

Timken Mercy Medical Center
(Licensee's Name)

September 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. [illegible] be instructed in recourses available if they feel that [illegible] 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

_____
Name (print or type)

_____
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.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

   e. Continue the same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)

   g. Sign and date the list of sources, data, and calculations.

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.

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.