6 6 7B 5/83

| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>APPLICATION FOR MATERIALS LICENSE – MEDICAL | Approved by OMB 3150-0041 Expires 9-30-83 |
|---|---|---|

**INSTRUCTIONS** - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Central Michigan Community Hospital
1221 South Drive
Mount Pleasant, Michigan 48858

TELEPHONE NO.: AREA CODE (517) 773 7941

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

same as 1.a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Tony R. Mason, M.S.

TELEPHONE NO.: AREA CODE (313) 662 3197

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

a. ☐ NEW LICENSE 030-02078
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 21-08966-01

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Peter Boss, M.D., Leonard Scherock, M.D., David Petrella, M.D., Ronald Moss, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Leonard Scherock, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

| RADIOACTIVE MATERIAL LISTED IN: | ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| 10 CFR 31.11 FOR IN VITRO STUDIES | | |
| 10 CFR 35.100, SCHEDULE A, GROUP I | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP II | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP III | X | 2000 |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP V | X | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | X | 500 |

| ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | | |
| PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | | |
| PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | | |
| XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES. | | |

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

| ELEMENT AND MASS NUMBER | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM NUMBER OF MILLICURIES OF EACH FORM | DESCRIBE PURPOSE OF USE |
|---|---|---|---|
| | | | |

Applicant
Check No. 40217
Amount/Fee Category $150 A 7B
Type of Fee Ren
Date Check Rec'd 5/11/83
Received By Cap

RECEIVED BY REGION 3
Date 5/11/83
Log May 3
By Cap
Orig. To
Action Compl. 5/16/83

APR 29 1983

NRC FORM 313M (9-81)

8905120197 880819
REG3 LIC30
21-08966-01 PDR

## 24. PERSONNEL MONITORING DEVICES

| TYPE (Check appropriate box) | | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | X | FILM | R. S. Landauer, Inc. | monthly |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | X | TLD | R. S. Landauer, Inc. | monthly |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

## 26. CERTIFICATE

*(This item must be completed by applicant)*

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
*(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7.b.

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: [signature]

(1) NAME *(Type or Print)*: Leonard Scherock, M.D.

(2) TITLE: Director of Radiology

c. DATE

NRC FORM 313M (9-81)



Control No. 07037

## RADIATION SAFETY COMMITTEE MEMBERS

Leonard J. Scherock, M.D., Radiologist

David Petrella, M.D., Radiologist

Hans J. Nowicki, M.D., Internist

Carol Temple, R.N.

Ronald A. Moss, M.D., Pathology

Arthur Homan, Administrative Assistant

Tamara Herbruck, Nuclear Medicine

## EQUIPMENT LIST

1) Picker Dyna Camera 4/15

   Head: Model #: 882696
   Serial #: 225901

   Control Panel: Model #: 615236
   Serial #: 225901

2) Picker Whole Body Table (Omniview)
   Model #: 617648
   Serial #: 228408

3) Picker Thyrodyne Uptake System
   Sealer: Model # 626970
   Serial # 252237

   Probe: Model # 621929
   Serial # 253217

4) Picker Isotope Calibrator
   Model #: 632-507
   Serial #: 221-003

5) Victoreen Survey Meter
   Model #: 6B Range: 0 - .5 mr/hr.
   Serial #: 129777 0 - 50 mr/hr

6) Pulmonex Xenon System (Atomic Products)
   Model #: 130-500

Control No. 07835

EQUIPMENT LIST Page - 2

7) Dosimeter high range survey meter

| | | | |
|---|---|---|---|
| Model #: | 3032 - 2 | Range: | 0 - 50 mR/hr |
| Serial No.: | 134 - 1082 | | 0 - 5000 mR/hr |

ITEM 8

## Radionuclide Users

Peter Boss - Radiologist
(see previous license # 21-08966-01)

Leonard J. Scherock - Radiologist (RSO)
(see previous license # 21-08966-01 and attached certification for Group VI approval)

David Petrella - Radiologist
(see attached forms A and B)

Ronald Moss - Pathologist (Director of Laboratory)
(see previous license # 21-08966-01)

ITEM 8

# The American Board of Radiology

Organized through the cooperation of the American College of Radiology, the American Roentgen Ray Society, the American Radium Society, the Radiological Society of North America and the Section on Radiology of the American Medical Association

hereby certifies that

## Leonard J. Scherock, M.D.

has passed an examination of graduate study and research work, has met all requirements and qualifications and has been duly certificated under the authority of the American Board of Radiology

On this twenty-third day of June, 1971

hereby is awarded by the Corporation of the Board this certificate in testimony of the specialty of

## Radiology

Robert M. Ledy — C. Allen Good

THE AMERICAN BOARD OF RADIOLOGY — 1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

ITEM 8

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

# PRECEPTOR STATEMENT

*Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.*

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
DAVID PETRELLA

STREET ADDRESS
117 S.Kinney

CITY | STATE | ZIP CODE
Mt.Pleasant MI 48858

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D |
|---|---|---|---|
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | 10 | I-123 |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | 9 | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | 3 | |
| | IN VITRO STUDIES | | |
| OTHER | TUMOR LOCALIZATION | 9 | GA-67 |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | 10 | I-123 |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | 1 | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | 10 | |
| OTHER | Red Cell Mass & Survival | 10 | CR-51 |
| Tc-99m | BRAIN IMAGING | 130 | Including blood flow (130) |
| | CARDIAC IMAGING | 45 | |
| | THYROID IMAGING | 5 | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | 5 | Plus wall motion |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | 105 | |
| | LUNG IMAGING | 30 | |
| | BONE IMAGING | 23 | |
| OTHER | Kidney | 3 | Tc-99m |



Control No. 07835

## PRECEPTOR STATEMENT *(Continued)*

### 2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | 5 | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | 5 | |
| Other | | | |

### 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

December 1, 1979 through February 29, 1980
520 hours

### 4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
F. Carlyle Stebner, M.D.

b. NAME OF INSTITUTION
Detroit General Hospital**

c. MAILING ADDRESS
4201 St. Antoine

d. CITY
Detroit, MI 48201

5. MATERIALS LICENSE NUMBER(S)
21-00741-08

6. PRECEPTOR'S SIGNATURE
F. Carlyle Stebner, M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
F. Carlyle Stebner, M.D.

8. DATE
3/1/82

**Detroit General Hospital is now closed. Records are available at Detroit Receiving Hospital and University Health Center at listed address.

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
# AUTHORIZED USER OR RADIATION SAFETY OFFICER

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| DAVID PETRELLA | Michigan |

3. CERTIFICATION

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| | | |

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES (Hours) C | SUPERVISED LABORATORY EXPERIENCE (Hours) D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | Detroit General Hospital and Detroit Receiving Hospital and University Health Center | 50 | 50 |
| b. RADIATION PROTECTION | " | 20 | 10 |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " | 10 | 10 |
| d. RADIATION BIOLOGY | " | 15 | - |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " | 5 | 25 |

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| Mo-99-Tc-99m | 1000 mCi | Detroit General Hospital | 3 mo | Human |
| I-131 | 100 mCi | " | 3 mo | Human |
| P-32 | 20 mCi | " | 3 mo | Human |
| Ga-67 | 50 mCi | " | 3 mo | Human |
| I-123 | 20 mCi | " | 3 mo | Human |
| Cr-51 | 5 mCi | " | 3 mo | Human |

ITEM 10

## CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

__XX__ 1. Survey instruments will be calibrated at least annually and following repair.

__X__ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used

or

_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

__X__ c. By a consultant or outside firm

(1) Name Medical Physics Consultants

(2) Location Suite B, 3200 W. Liberty, Ann Arbor, MI 48104

(3) Procedures and sources

__X__ have been approved by NRC and are on file in License No. 21-17126-01 ND

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

# Medical Physics Consultants

Suite B
3200 West Liberty
Ann Arbor, Michigan 48104
(313) 662-3197

## CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacture_____

Type_____

Model No._____

Serial No._____

| Nuclide | Exposure Rate at Specified Distance | Calibration Accuracy |
|---|---|---|
| | | |

Calibration Source:

Calibration Data:

| Scale | Exposure rate (mR/hr) | Instrument reading (mR/hr) | Exposure rate (mR/hr) | Instrument reading (mR/hr) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Comments:

Calibrated by _____ Date_____

APPENDIX D (Continued)

Section 2

## METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

*Instrument constancy* means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ±5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ±5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

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 to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

---

* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

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

| *Assay Time* (hr)* | *Correction Factor* |
|---|---|
| 0 | 31.633 |
| 6 | 15.853 |
| 24 | 1.995 |
| 30 | 1 |
| 48 | 0.126 |

*Example*: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

*Example*: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

ITEM 10

NRC License #21-08966-01

Gentlemen:

As an alternative to our present procedure (as outlined in Appendix D of Regulatory Guide 10.8) we will now be checking the linearity of our dose calibrator with a device called Calicheck. Calicheck is produced by the 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 will be taken if unacceptable linearity is demonstrated. Should there be any questions regarding this matter, please contact me.

Sincerely,

Tamara Herbruck

Tamara Herbruck, B.S.R.T.(N.)
(517) 773-7941 Ext. 162

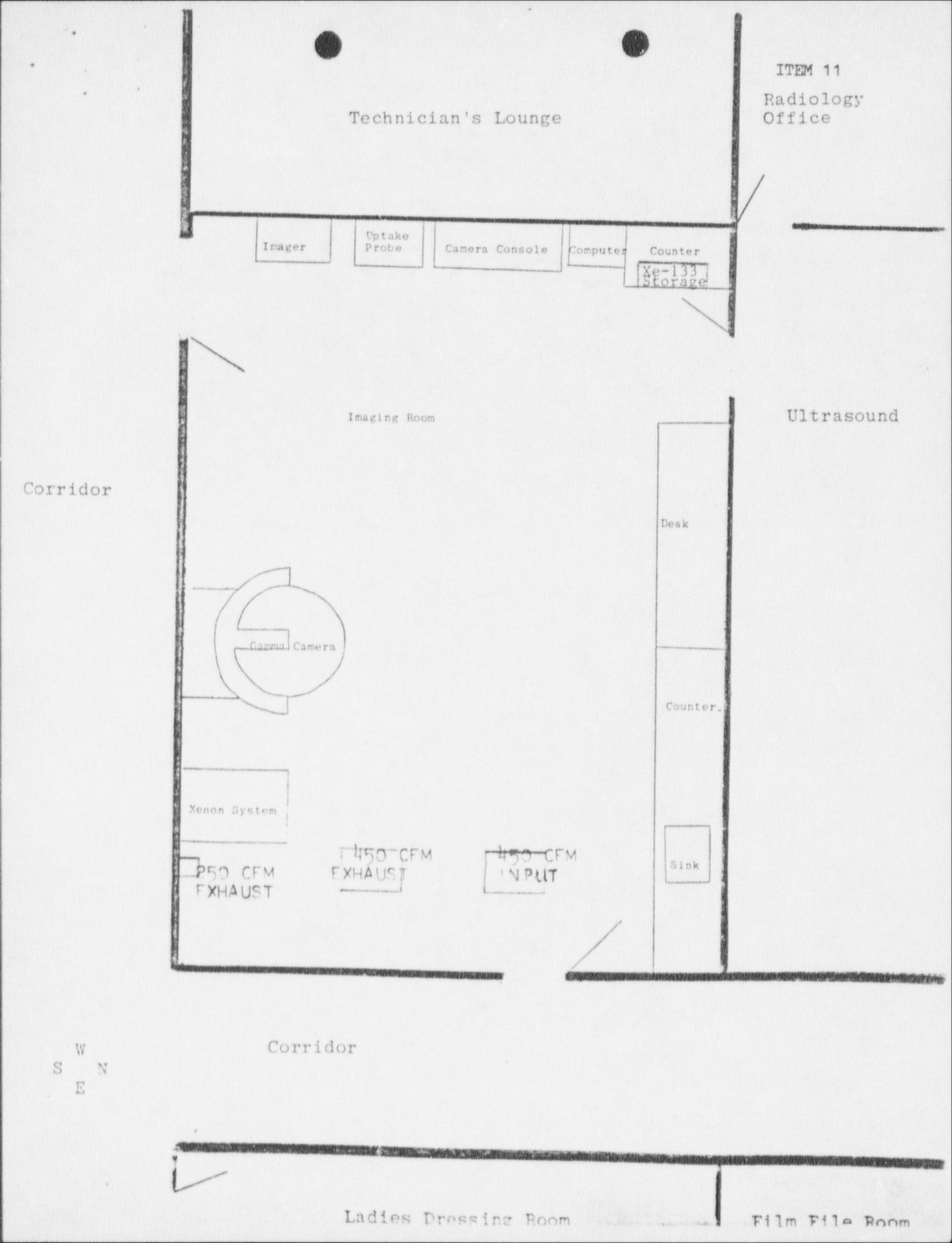
ITEM 11

IMAGING ROOM

1. The south side of the corridor to the south of the imaging room opens onto the x-ray rooms.

2. There is no second story above the imaging room. The wall between the Ultrasound Department and the imaging room was the exterior building wall before the hospital addition was built. It is now plaster over brick.

ITEM 11

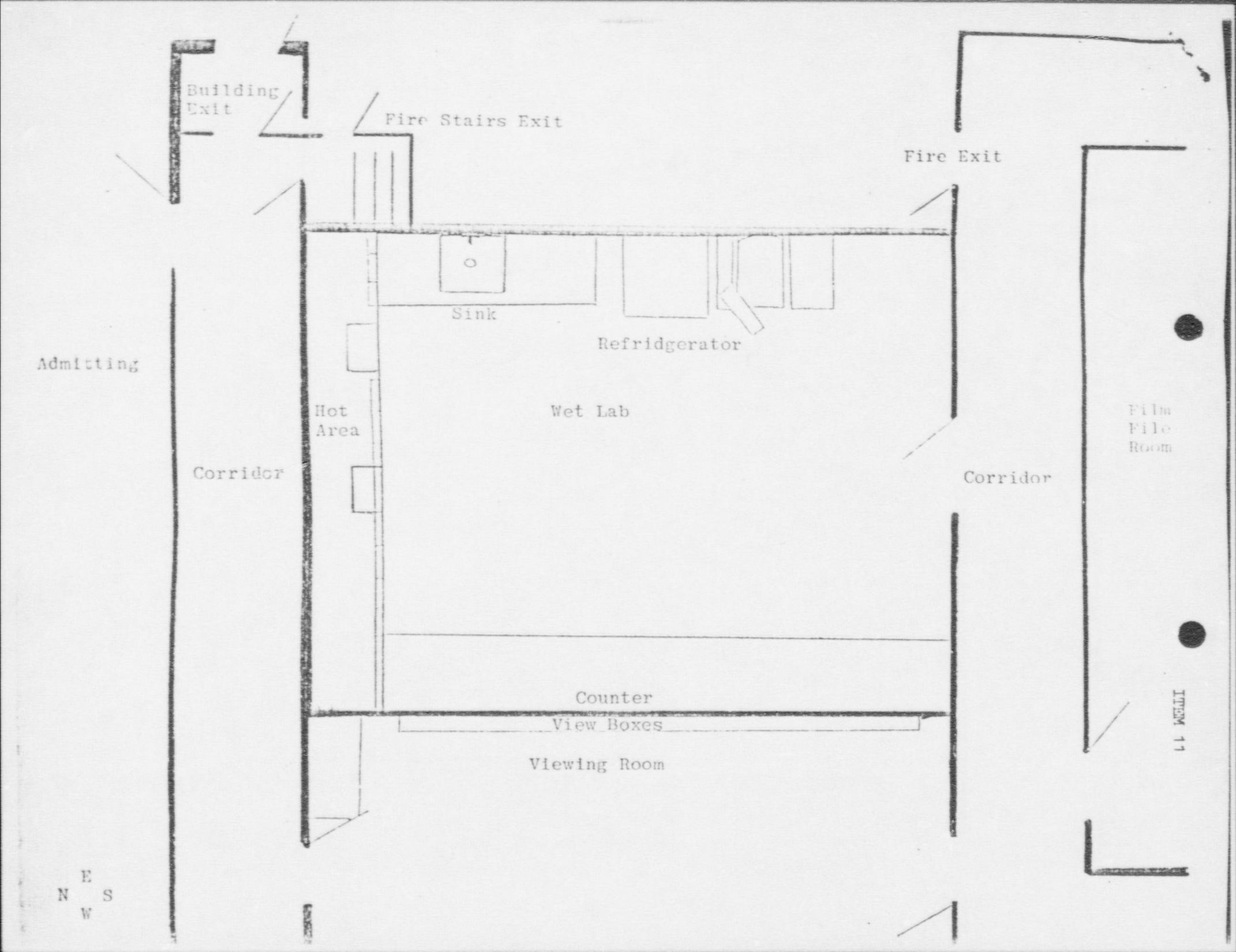

Technician's Lounge
Radiology Office
Imager
Uptake Probe
Camera Console
Computer
Counter
Xe-133 Storage
Imaging Room
Ultrasound
Corridor
Desk
Gamma Camera
Counter
Xenon System
Sink
450 CFM EXHAUST
450 CFM INPUT
450 CFM EXHAUST
Corridor
W
S N
E
Ladies Dressing Room
Film File Room

## WET LAB

1. At one time the Wet Lab and the Viewing Room were combined as a single X-ray room. The north and south walls of the Wet Lab and lead-lined.

2. There is a corridor centered above the Wet Lab running parallel with the East wall. Patient rooms open off each side of the corridor. Below the Wet Lab is foundation only.

3. The Hot Area counter is shielded with a lead brick wall twelve inches high. All radioactive materials are contained in this area or the refridgerator.


Building Exit
Fire Stairs Exit
Fire Exit
Sink
Refridgerator
Admitting
Hot Area
Wet Lab
Film File Room
Corridor
Corridor
Counter
View Boxes
Viewing Room
N
E
S
W
ITEM 11

# PERSONNEL TRAINING PROGRAM

The training program will be of sufficient scope to ensure that all personnel, including clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in Section 19.12 of 10 CFR Part 19, including:

a. Areas where radioactive material is used or stored.

b. Potential hazards associated with radioactive material.

c. Radiological safety procedures appropriate to their respective duties.

d. Pertinent NRC regulations.

e. The rules and regulations of the license.

f. The pertinent terms of the license.

g. Their obligation to report unsafe conditions.

h. Appropriate response to emergencies or unsafe conditions.

i. Their right to be informed of their radiation exposure and bioassay results.

Personnel will be properly instructed:

a. Before assuming their duties with or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

CENTRAL MICHIGAN COMMUNITY HOSPITAL
POLICY MANUAL

ITEM 13

SUBJECT: Ordering and Receiving Radioactive Material
DATE: Revised March, 1983
NUMBER: 704.67
DISTRIBUTION:
REFERENCE:

Original policy dated September, 1981

1. The Nuclear Medicine Technologist must place all orders for radioactive material and must ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours, carriers must deliver the radioactive packages directly to the Wet Lab. Carriers will go to the Radiology Office where the X-ray Technician on duty will sign for the package and unlock the Wet Lab for delivery.

4. If the package is wet or appears to be damaged, immediately contact the Nuclear Medicine Technician on call. He or she will then come in and make the determination as to whether or not the Radiation Safety Officer should be called in. Ask the courier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

ISSUED BY

REVIEWED BY

APPROVED BY

Form #p10-174 (6-79)

PROCEDURE FOR OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

1) Wear disposable gloves when handling package.

2) Survey package for leakage and contamination using G-M survey meter and record readings in log book.

Limits: surface - 200 mR/hr
three feet - 10 mR/hr

3) If package is contaminated store immediately in decay storage area to limit spread of contamination and notify Radiation Safety Officer.

4) If package is not contaminated open it and monitor the packing material. Notify Radiation Safety Officier if packing material is contaminated.

5) Wipe external surface of final source container and remove wipe to low background area. Check wipe with G-M survey meter set on the most sensitive scale. Notify Radiation Safety Officer if contamination is detected.

6) Store material in appropriate area for use and record in log book.

ITEM 15

## APPENDIX G

## GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

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. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

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

6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielding containers.

## APPENDIX H

## EMERGENCY PROCEDURES

Minor Spills

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

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: L. Scherock, M.I
OFFICE PHONE: (517)773-7941
HOME PHONE: (517)772-9554

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

Tony Mason
(313)662-3197
(616)451-4635

* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

APPENDIX I

ITEM 17

## AREA SURVEY PROCEDURES

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

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 $\mu$Ci) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 $cm^2$ for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

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

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

   f. 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.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 $cm^2$.

*For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

MODIFICATION: Items 4.b. and 6. should be modified to read that, "Any areas indicating removable contamination upon wipe testing, will be cleaned." (eliminating the 200 dpm per 100 $cm^2$ statement)

Wipe tests will be checked with the G-M Survey Meter on its most sensitive scale. A background reading will be recorded with each wipe test result.

## APPENDIX J

## WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

__x__ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

_____ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

__x__ Returned to the manufacturer for disposal.

OR

__x__ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

__x__ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____ _____
(Name) (City, State)

NRC/Agreement State License No. _____

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

## APPENDIX K

## RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS*

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with §§20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions

    a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.

    b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

    d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

    e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

    f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals,

* Be sure to submit a complete response to Item 19b in addition to referencing procedures in Appendix K.

bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with I-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

l. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

ITEM 19

Date _____

## NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

**Exposure Rates in mR/hr**

| Date | 3 feet from bed | 10 feet from bed |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

(Comply with all checked items)

_____ 1. Visiting time permitted: _____

_____ 2. Visitors must remain _____ from patient.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 are not permitted.

_____ 5. Pregnant visitors are not permitted.

_____ 6. Film or TLD badges must be worn.

_____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.

_____ 8. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 9. Disposable gloves must be worn while attending patient.

_____ 10. Patient must use disposable utensils.

_____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.

_____ 12. Smoking is not permitted.

_____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

_____ 14. Other instructions.

In case of an emergency contact:

RSO

Name On-duty/Off-duty Telephone Numbers

## APPENDIX L

## RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES*

1. All patients treated with brachytherapy sources will be placed in a private room that has a toilet.

2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at 3 feet (or 1 m) from the patient with sources implanted, at the patient's bedside, at 3 feet (or 1 m) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (or 1 m) from the patient on the patient's chart.

4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and attached to the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film or TLD badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient. Pocket dosimeters may be assigned in addition to a film or TLD badge.

7. At the conclusion of treatment, a survey will be performed in accordance with paragraph 35.14(b)(5)(vii) of 10 CFR Part 35 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient meets conditions for release from the hospital.

8. Instructions to Nurses

   a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. The Radiation Safety Officer should be contacted to answer any questions about the care of these patients in regard to radiation safety precautions.

   b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film or TLD badge or a pocket chamber as instructed by the Radiation Safety Officer.

   c. When a nurse is assigned to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged among nurses.

   d. Pregnant nurses should not be assigned to the personal care of these patients.

   e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.

   f. Bed bath given by the nurse should be omitted while the sources are in place.

   g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.

   h. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

      Special orders will be written for oral hygiene for patients with oral implants.

   i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.

* Be sure to submit complete responses to Items 20a through 20f in addition to referencing procedures in Appendix L.

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

k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

l. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

m. Visitors should sit at least 3 feet (or 1 m) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.

n. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

o. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call _____

_____

Telephone No. (days) _____

(nights) _____

p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room, (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient, and (3) record a summary of the final survey results on the patient's chart. If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.

## NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope and Activity: _____

Date and Time of Administration: _____

Date and Time Sources Are To Be Removed: _____ Isotope: _____

**Exposure Rates in mR/hr**

| Bedside | 3 feet from bed | 10 feet from bed |
|---|---|---|
| | | |
| | | |
| | | |

(Comply with all checked items.)

_____ 1. Wear film or TLD badge.

_____ 2. Wear pocket chambers for supplementary personnel monitoring of individual tasks.

_____ 3. Wear rubber gloves.

_____ 4. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 5. Place laundry in linen bag and save.

_____ 6. Housekeeping may not enter the room.

_____ 7. Visiting time permitted: _____

_____ 8. Visitors must remain _____ from patient.

_____ 9. Patient may not leave the room.

_____ 10. Patient may not have visitors.

_____ 11. Patient may not have pregnant visitors.

_____ 12. Patient may not have visitors under 18 years of age.

_____ 13. Patient must have a private room.

_____ 14. A dismissal survey must be performed before the patient is discharged.

_____ 15. All items must remain in the room until approved for disposal by the Radiation Safety Officer or his designee.

16. Contact the Radiation Safety Office when temporary sources (nonpermanent implants) are removed to perform a survey to be sure all sources are removed from the patient, to do a physical source count, and to be sure no sources remain in the room.

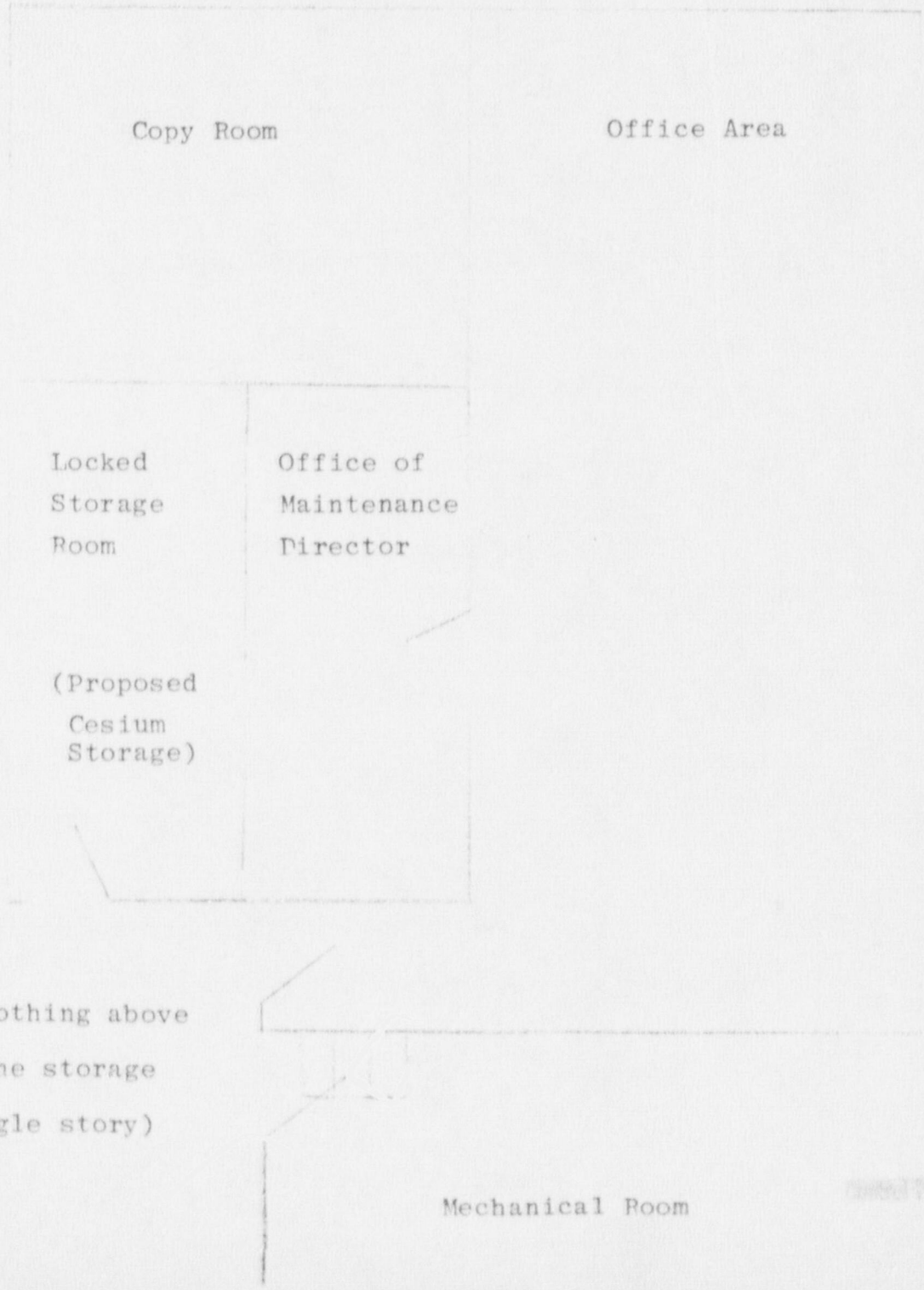
_____ 17. Contact the Radiation Safety Office when the patient is discharged to survey the room prior to its assignment to another patient.

_____ 18. Other instructions.

RSO

Name On-duty/Off-duty Telephone Numbers

The Cs-137 therapy implant sources will be stored in the room sketched below. The sources will be kept in a leaded pig in this locked and posted room. Exposure rates to areas adjacent to the room will meet requirements for unrestricted areas. Long forceps or handling tongs will be used during transfer. Personnel monitoring for individuals that handle sealed sources shall be the same as that listed in Item 24. Sources will be transported by a carrier and cart for personnel safety.



1) Quantities to be used

a. Patient information
   (1) 10 studies per week
   (2) 10 milliCurries average activity per study
b. 200 mCi possession limit

2) Use and Storage Areas

a. Xenon-133 will be stored in the storage area of the Imaging Lab and used (administered, imaged, trapped, and exhausted) in the Imaging Area (see Item 11).
b. Ventilation: The ventilation system in the Imaging Area is described in Item 11. A minimum 10% negative pressure differential will be maintained to insure airflow from hallways to the exhaust port located on the hospital roof. This system will carry away a major portion of any Xe-133 contamination to outside air. None of the ventilation air is recirculated. The exhaust port to outside air is at least 40 feet from any other intake vent. No changes in flow rates occur between heating and cooling seasons.
c. All areas where Xenon is used are under negative pressure. Semi-annual airflow measurements will be taken either with a velometer owned by the hospital or by outside consultants to assure that airflow (especially exhaust) has remained stable.

3) Procedures for Routine Use

a. The Xe-133 unit dose ampules will be stored in their 1/8 inch thick lead shipping tubes behind lead brick shielding in the Imaging Area. Individual "doses" will be assayed in the "dose" calibrator and administered using the NEN Calidose Gas Dispensing System. The ampule seal will only be broken in the Imaging Area.
b. Xe-133 will be administered to the patient and collected using the Pulmonex Xenon System, Model 130-500 (includes both a delivery system and built-in gas trap). For each patient study, the technologist will check the tubing of the xenon delivery system for defects and familiarize patients with the study. Nose clamps will be used to reduce leakage of the Xe-133 gas.

4) Emergency Procedures

a. Notify persons in the room that a release has occurred. All persons should vacate the room at once. Close the door to the room and prevent entry. Notify the radiation safety officer immediately. After 15 minutes* re-enter the room. Survey with G-M survey meter to assure that exposure rates have returned to "normal" levels.

*approximately 7 turnovers of room air

5) Air Concentrations of Xe-133 in Restricted Areas

a. 10 mCi/patient x 10 patients/week x $1x10^{3}$ uCi/mCi = $1x10^{5}$ uCi/week (A).
b. Assume a loss rate of 20% (f).
c. Airflow rate is area of interest = 700 CFM exhaust.

d. $V\ (\text{required}) = (A \times_5 f)/1\times10^{-5}\ \text{uCi/ml}$

$$= \frac{1\times10^{5}\ \text{uCi/week} \times 0.20}{1\times10^{-5}\ \text{uCi/ml}} = 2.0\times10^{9}\ \text{ml/week}$$

$$\frac{2.0\times10^{9}\ \text{ml/week}}{40\ \text{hr-week}} \div 1.7\times10^{6}\ \text{ml/hr} = 30\ \text{CFM}$$

Therefore, 700 CFM is adequate.

6) Methods of Xe-133 Disposal

Adsorption onto activated charcoal traps will be the beginning of the disposal process. The Xe-133 will be disposed of by adsorption onto the Pulmonex Xenon System - Gas Trap and then decayed to background.

Air concentration of Xe-133 in Unrestricted Are

$V\ (\text{required}) = (A \times_5 f)/3\times10^{-7}\ \text{uCi/ml}$

$$= \frac{1\times10^{5}\ \text{uCi/week} \times 0.20}{3\times10^{-7}\ \text{uCi/ml}}$$

$$= 6.67\times10^{10}\ \text{ml/week}$$

$6.67\times10^{10}\ \text{ml/week} \div 1.7\times10^{6}\ \text{m/hr} - \text{CFM} = 233.4\ \text{CFM}$

Therefore, 700 CFM is adequate.

(ii) Effluent from the trap exhaust will be tested monthly using a five liter sample collection bag that will be filled during washout phase of ventilation testing. Counts will be related to activity on the uncollimated Gamma Camera. Given a 10mCi dose and assuming a 95% trapping efficiency, with no residual Xe-133, a 500uCi action level for trap removal would seem reasonable. However, experience dictates that effluent is significantly less than 500uCi's in a properly operating system. Therefore, an action level of 100uCi's will be set, 100uCi's being a small fraction of the assumed 20% leakage from all sources.

(iii) Saturated filters will be sealed (per manufacturers instructions) to prevent leakage and stored in the "Decay-to-background" Radioactive Waste Storage Area.

## APPENDIX O

## MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Central Michigan Community Hospital

(Licensee's Name)

April 26, 1983

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) 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)[1] and a Radiation Safety Officer (RSO).

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

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where 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 where reasonable. Where 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 (RSC)[2]

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 uses for which he has applied 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. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

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 in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

[1] Private practice physician licenses do not include an RSC.

[2] The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

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 where Investigational Levels in Table 0-1 below 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).[3]

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures 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 (RSO)

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 procedures may be conducted on a more frequent basis.

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

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

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 formulation of 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 require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

[3] 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 further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

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

   b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures**

   This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure 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 O-1 below. These levels apply to the exposure of individual workers.

**Table O-1**

| | *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 nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer 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 O-1:

a. Quarterly exposure of individuals to 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 exposure is less than Table O-1 values for the Investigational Level I.

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

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure 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, consider each such exposure 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. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

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

   The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official**[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

L J Schwork

Signature

Leonard Scherock, M.D.

Name (print or type)

Director of Radiology

Title

Institution (or Private Practice) Name and Address:

CMCH
1221 South Drive
Mount Pleasant, MI 48858

[4]The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.