NRC FORM 313M
(9-81)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB
3150-0041

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

Lynn Hospital
An Atlanticare Medical Center
212 Boston Street
Lynn, Massachusetts 01904

TELEPHONE NO.: AREA CODE(617 598 5100

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

Lynn Hospital
An Atlanticare Medical Center
212 Boston Street
Lynn, Massachusetts 01904

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Herbert Leventhal, M.D.

TELEPHONE NO.: AREA CODE(617 598-5100

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 20-03339-02

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

See Item 8 page 7

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.)*

Herbert Leventhal, 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	X	3
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	3000
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	1000

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.	X	500mCi

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
Uranium (Depleted in Uranium-235)	Cadmium Plated Metal	250 Kilograms	As shielding in linear accelerator.

License Fee Information on Next Page
12/12/84 ltr,

"OFFICIAL RECORD COPY"
03264

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 *Rev. _____ Date: _____

*NOTE: All appendices referenced on this page are based on Regulatory Guide 10.8, Revision 1, and are attached to the application. Some appendices have been slightly modified to reduce the regulatory burden.

7. MEDICAL ISOTOPES COMMITTEE (Page 5)	
X	~~Names and Specialties Attached; and~~ (See Page 5)
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE (Page 7)	
X	~~Supplements A & B Attached for Each Individual User; and~~ (See Page 7)
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)* (Page 8)	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS (Page 9)	
X	~~Appendix D Procedures Followed for Survey Instruments; or~~ (See Page 9) *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT (Page 14)	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM (Page 15)	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL (Page 16)	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)* (Page 17)	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)* (Page 18)	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)* (Page 19)	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)* (Page 20)	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)* (Page 21)	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)* (Page 23)	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	Detailed Information Attached; and
X	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
N/A	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
N/A	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Co.	1/month
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Co.	1/month
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify) ALARA PROGRAM

This institution is committed to the ALARA program set forth in Appendix O, attached to this application beginning on page 31.

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: 7B

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X Edward F. Kittredge

(1) NAME *(Type or Print)*

X President

(2) TITLE

X

c. DATE

X

Lynn Hospital

An AtlantiCare Medical Center

ADD:

Authorized User	Uses
Khalid M. Butt, M.D.	Groups I, II, III

212 Boston Street
Lynn, Massachusetts 01904
617-598-5100

NRC FORM 313M SUPPLEMENT A
(9-81)

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
Khalid M. Butt, M.D.	Mass. and Maine

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Pathology (Anatomic & Clinical Pathology)		November 1974
Medical Microbiology		May 1980

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	New England Deaconess Hospital August 1972-May 1977 Lynn Hospital 1977 - 1983	100	100
b. RADIATION PROTECTION	New England Deaconess Hospital Lynn Hospital	30	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	New England Deaconess Hospital Lynn Hospital	20	20
d. RADIATION BIOLOGY	New England Deaconess Hospital 1972-1977 Lynn Hospital 1977-present	20	30
e. RADIOPHARMACEUTICAL CHEMISTRY	Lynn Hospital May 1977 to present	20	10

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
1-131 and 1-125		New England Deaconess Hospital and Lynn Hospital	11 years	in vitro Plasma volume, Kidney function tests

COLBY COLLEGE

This is to certify that

Khalid M. Butt, M.D.

has attended the

Seminar in Nuclear Medicine

given by COLBY COLLEGE, WATERVILLE, MAINE

20 Hrs., CATEGORY I, A. M. A.

William R. Cotter — President

July 23-27, 1984 — Date

Henry M. Wagner, Jr. — Director of Institute

WORKSHOP ON NUCLEAR CARDIOLOGY

December 7-8, 1979
Massachusetts General Hospital
Boston, Massachusetts

An an organization accredited for continuing education, the Society of Nuclear Medicine designates this continuing medical activity as meeting the criteria for 12 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

Use this card as a reference when reporting to the American Medical Association when you receive their Continuing Medical Education Report Form.

Kenneth A. McKusick

Kenneth A. McKusick, M.D., Course Director

Khalid N. Butt MD

The New England Roentgen Ray Society

Hereby certifies that

Khalid M. Butt, M.D.

Has pursued a course of study sponsored by this society covering the basic physics of radioisotopes with particular emphasis on their medical applications and has successfully completed the required studies, laboratory exercises, and examinations.

On this 30th *day of* June 1973.

President | *Secretary* | *Course Director*

NRC FORM 313M SUPPLEMENT B
(9-81)

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
Khalid M. Butt, M.D.

STREET ADDRESS
212 Boston Street

CITY | STATE | ZIP CODE
Lynn, MA 01904

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	3500	T3, uptake, T4, TSH, Free T3
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	80	
	LIVER FUNCTION STUDIES	850	
	FAT ABSORPTION STUDIES	-	
	KIDNEY FUNCTION STUDIES	32	All common in-vitro studies involving 1-131 and 1-125, continuously since 1972.
	IN VITRO STUDIES	15,000	
OTHER	Blood volume with Cr-51	150	
I-125	DETECTION OF THROMBOSIS	-	
I-131	THYROID IMAGING	600	
P-32	EYE TUMOR LOCALIZATION	-	
Se-75	PANCREAS IMAGING	2	
Yb-169	CISTERNOGRAPHY	12	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	6	
OTHER	in-vivo cross matches	36	
Tc-99m	BRAIN IMAGING	35	
	CARDIAC IMAGING	600	
	THYROID IMAGING	185	
	SALIVARY GLAND IMAGING	-	
	BLOOD POOL IMAGING	80	
	PLACENTA LOCALIZATION	-	
	LIVER AND SPLEEN IMAGING	3600	
	LUNG IMAGING	4600	
	BONE IMAGING	5400	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

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

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
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	4	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	–	
I-131	TREATMENT OF THYROID CARCINOMA	2	
	TREATMENT OF HYPERTHYROIDISM	20	
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	160	
Sn-113/ In-113m	GENERATOR	160	
Tc-99m	REAGENT KITS	20	
Other		–	

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

1977 - 1984
2500 hours.

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

a. NAME OF SUPERVISOR
E. Shen, M.D.

b. NAME OF INSTITUTION
Lynn Hospital

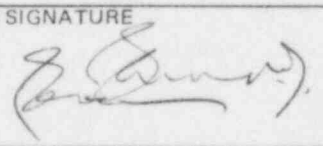
c. MAILING ADDRESS
212 Boston Street

d. CITY
Lynn, MA. 01904

5. MATERIALS LICENSE NUMBER(S)

20-03339-02

6. PRECEPTOR'S SIGNATURE



7. PRECEPTOR'S NAME *(Please type or print)*

KHALID M. BUTT, M.D.

8. DATE

12/12/84

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-913

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 20-03339-02

Docket or Reference number 030-01861

Amendment No. 46

Lynn Hospital
Isotope Laboratory
212 Boston Street
Lynn, Massachusetts 01904

In accordance with letter dated May 21, 1984, License Number 20-0339-02 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Ferris J. Bargoot, M.D.	Groups I. II, III, IV, V and VI In vitro studies Xenon 133 Depleted Uranium as shielding
Herbert Leventhal, M.D.	Groups I, II, III, IV, V and VI In vitro studies Xenon 133 Depleted Uranium as shielding
Harry G. Olken, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
Leonard Bouras, M.D.	Groups I, II, III and IV In vitro studies Xenon 133
Howard Rotner, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
E. Mei Shen, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
Polius Raslavicus, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133
Kenneth Bassion, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 20-03339-02

Docket or Reference number 030-01861

Amendment No. 46

(Continued)

Dean Wasserman, M.D.	Groups I, II, III and IV In vitro studies Xenon 133
Harold Weintraub, M.D.	Groups I, II and III In vitro studies Xenon 133
Magdi Christian Semine, M.D.	Groups I, II and III In vitro studies Xenon 133
Sheldon Cooperman, M.D.	Groups I, II and III In vitro studies Xenon 133 Iodine 131 for treatment or hyperthyroidism and cardiac dysfunction

For the U.S. Nuclear Regulatory Commission

Date JUL 1 1984

By Jeanne M. Johansen
Nuclear Materials and Safeguards Branch
Region I
King of Prussia, Pennsylvania 19406

RADIATION SAFETY/Medical Isotopes Committee

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;

2. the hospital administrator, or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;

3. a physician* specialist from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

*Some departments, such as the nuclear pharmacy, may not be under the supervision of a physician. In these cases, the supervisory paramedical professional will be a member of the committee.

APPENDIX B

MEDICAL ISOTOPES COMMITTEE*

Responsibility

The committee is responsible for :

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

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

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system.

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

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

Meeting Frequency

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

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* A rule is expected in 1981 that would change the name, composition, and functions of this committee.

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline Instrument Corporation

   Manufacturer's model number: Model E-120 Geiger Counter

   Number of instruments available: One

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

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

   b. Manufacturer's name: Victoreen Panoramic

   Manufacturer's model number: 470 A

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 3 > mR/hr

   Maximum range: 0 mR/hr to 10,000 mR/hr

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-10

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Technicare	Sigma 420
Gamma Camera	Technicare	Sigma 438
Gamma Counter	Searle	Model 1185

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

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Thyac III Victoreen

      Manufacturer's model number: 490

      Number of instruments available: 1

      Minimum range: 0 mR/hr to .2 mR/hr

      Maximum range: 0 mR/hr to 200 mR/hr

   b. Manufacturer's name: J & S Model 155A

      Manufacturer's model number: 7889

      Number of instruments available:

      Minimum range: 0 cpm mR/hr to 30 cpm mR/hr

      Maximum range: 0 cpm mR/hr to 3000 cpm mR/hr

2. Dose calibrator

   Manufacturer's name:

   Manufacturer's model number:

   Number of instruments available:

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.

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

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

X 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 Dr. Jacob Spira, Director, Dept. Of Radiation Physics

(2) Location Boston University Medical Center
80 East Concord St., Boston, MA

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. 20-03333-02

_____ 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.

APPENDIX D

CALIBRATION OF INSTRUMENTS

Section I

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.

2. The source activities or exposure rates at given distances shall be traceable by documented measurements to a standard source certified within 5 percent accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points located at approximately 1/3 and 2/3 of full scale.

5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10 percent at the two points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent for radiation protection purposes.

Note:

Sources of Cs-137, Ra-226, or Co-60* are appropriate for use in calibrations. Since these sources emit rather high-energy photons, they are not suitable for low-energy calibrations that may be required under special circumstances (see Item C below). The activity of the calibration standard should be sufficient to calibrate the survey meters on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Otherwise, a cautionary note that they have not been checked should be placed on the instrument.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, shall also be read at the time of the above calibration or as soon as the instrument is received from a calibration laboratory. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

If any reading with the same geometry is not within ±20 percent of the reading measured immediately after calibration, the instrument should be recalibrated (see Item A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and if the instrument is to be used for quantitative measurements in the Xe-133 or Tc-99m energy ranges.

The calibration may be done either:

1. As in Item A above with calibrated standards of radionuclides at or near the desired energies, or

2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

Alternatively, the manufacturer's energy-response curve(s) may be used to correct instrument readings appropriately when lower-energy radiation is monitored.

D. Records of the above Items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its exposure rate at a given distance.

*Minimum activities of typical sources are 85 mCi of Cs-137, 21 mCi of Co-60, and 34 mCi of Ra-226 (to give at least 700 mR/hr at 20 cm).

or its activity, measured on a specified date by the manufacturer or NBS.

a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

b. The Radioactive Decay Law may be used to calculate the exposure rates or source activities at times other than the calibration date.

2. Inverse Square Law

Consider a "point"* source of radiation at position S, as shown in Figure D-1. Then, the relationship between exposure rates R_1 and R_2 at detector positions P_1 and P_2, which are at distances D_1 and D_2 from S, respectively, is given by the following equation:

$$R_2 = \frac{D_1^2}{D_2^2} \times R_1$$

where R_1 and R_2 are exposure rates in the same units (e.g., mR/hr, R/hr), and D_1 and D_2 are the distances in Figure D-1 in the same units (e.g., m, cm, ft).

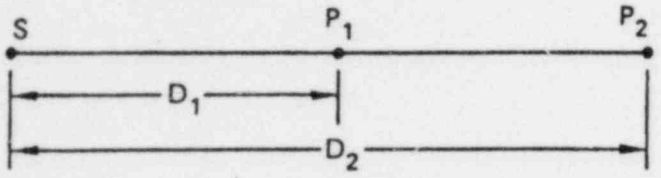


Figure D-1

3. Radioactive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-\left[\frac{0.693}{T_{1/2}} \times t\right]}$$

where

R_o and R_t are in the same units (e.g., mR/hr or R/hr).

R_o is exposure rate on the specified calibration date.

R_t is exposure rate t units of time later.

$T_{1/2}$ and t are in the same units (years, months, days, etc.).

$T_{1/2}$ is radionuclide half-life.

t is number of units of time elapsed between calibration and present time.

4. *Example*: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

$$= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 1977.}$$

b. Output at 3 feet, 2.0 years after calibration date:

$$R_3 \text{ feet} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr}$$

$$= \frac{1}{9} \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration.}$$

* A source may be considered a "point" source when the source and the radiation detector are small, in any dimension, compared to the distances at which radiation is to be measured. The center of the detector should be at distances D_1 or D_2 as shown in Figure D-1.

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 $\pm$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 $\pm$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.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ±5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

X First elution from new Mo-99/Tc-99m generator

or

X Other* (specify) If generators are not in use, a source of Tc-99m with activity equivalent to the maximum activity assayed to clinical situations will be used.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within ± 5%
Ba-133	0.1-0.5	100 microcuries or more	within ± 5%
Cs-137	0.1-0.2	100 microcuries or more	within ± 5%
Ra-226	1-2	N/A	N/A
N/A		N/A	N/A

C. X The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

_____ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

FACILITY DIAGRAM
(Prepare and Attach to Application)

Submit a detailed diagram of the facility, indicating the type, dimensions, position, and thickness of shielding that will be used for:

a. Use and storage of Tc-99m generators.

b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. (This area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste. If this area is located outside your department, describe how the material will be secured. Confirm that this area will be surveyed at least weekly.)

d. Preparation and dispensing of Group III kit radiopharmaceuticals (e.g., lead glass L-block).

Identify adjacent areas across the walls from use and storage locations, and show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

A: Use and Storage of 99mTc Generators:

A 400mCi 99mTc New England Nuclear generator is stored on the floor under the counter covered by the hood. The generator is shielded within a one inch thick, 26 inches round and 8½ inches high cylindrical lead container as provided by the manufacturer. In addition, the generator is enclosed by a lead brick shield measuring 8inches x 12 inches x 2 inches.

B: Storage of Radiopharmaceuticals:

Radionuclides are stored within a lead brick enclosure which measures 24in x 33in x 2in and sits against a wall. Xenon-133 gas is stores in a New England Nuclear generator shield which measures 26in round, 8½in high and 1in thick and sits on the counter under the fume hood.

C: Storage of Radioactive Waste:

All waste is stored for a period of one week in lead lined waste containers located within the hot room.

Vials - Stored in a 20qt, 1/8in lead waste container which sits on the floor next to the generator.

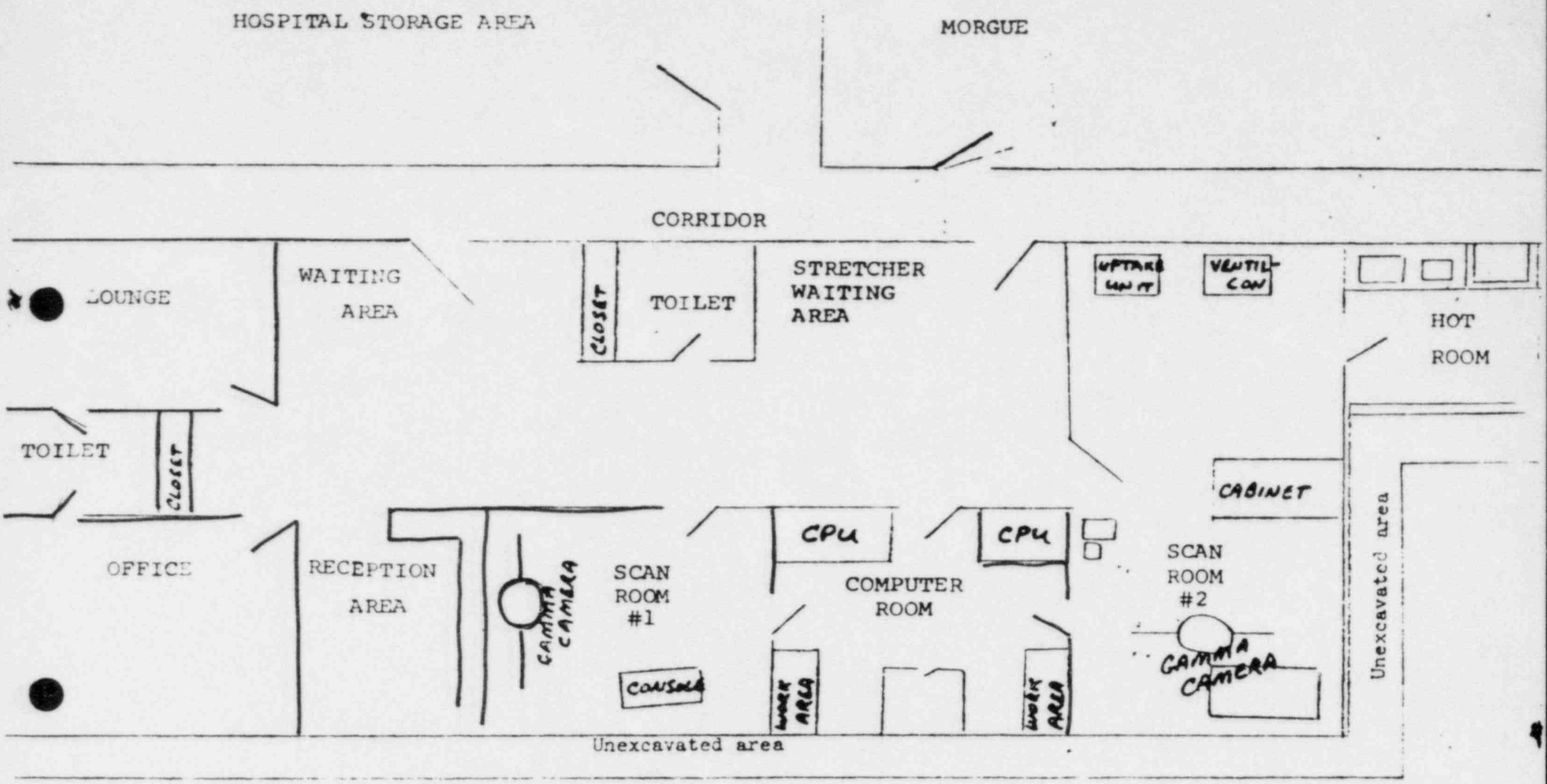
Syringes - Stored in a 20qt, 1/8in lead lined waste container. This container sits to the opposite side of the generator.

At weekly intervals all waste, including the generator is removed from the hot room and stored in the radioactive decay room which is located in the radiology file room basement. This room measures 9ft8in x 4ft2in and is constructed of 8in thick cinder block. This room is locked at all times and appropriate signs are posted regarding its contents. All material is held in this location for decay until it measures background radiation level in a low-level area with a low-level survey meter. At this point the material is incinerated. This area is surveyed weekly.

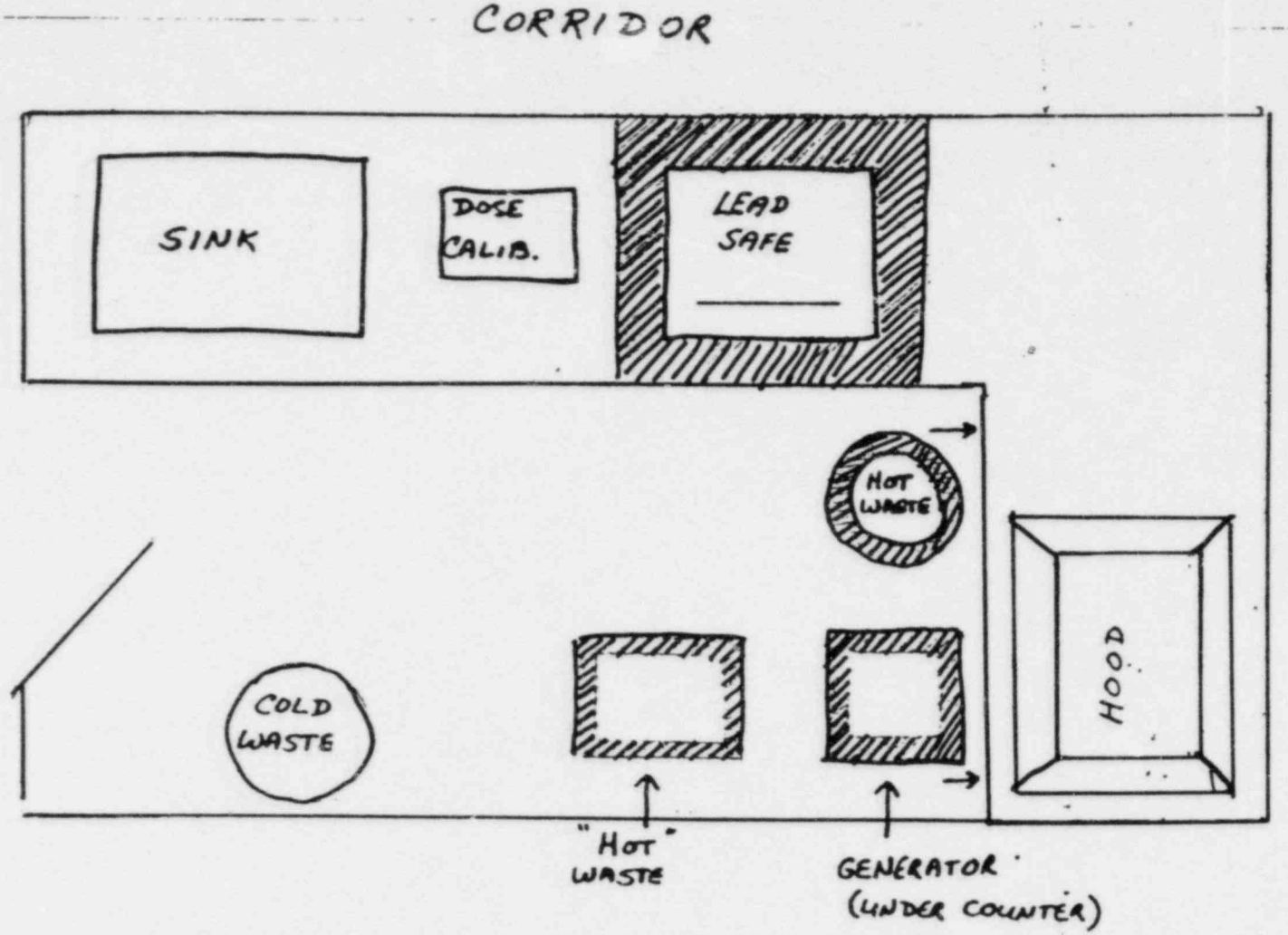
D: Preparation and Dispensing of Group III Radiopharmaceuticals:

All preparation and dispensing of radiopharmaceuticals is performed behind a table-top L shield which is constructed of lead and leaded glass with a slate base. This shield is located within the lead brick shield previously described in paragraph B. Disposable gloves, syringe shields and long-handled tongs are used. After preparation of "cold" kits, the vials are stored in lead containers.

E. Adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in paragragh 20.105(b) of 10 CFR Part 20.

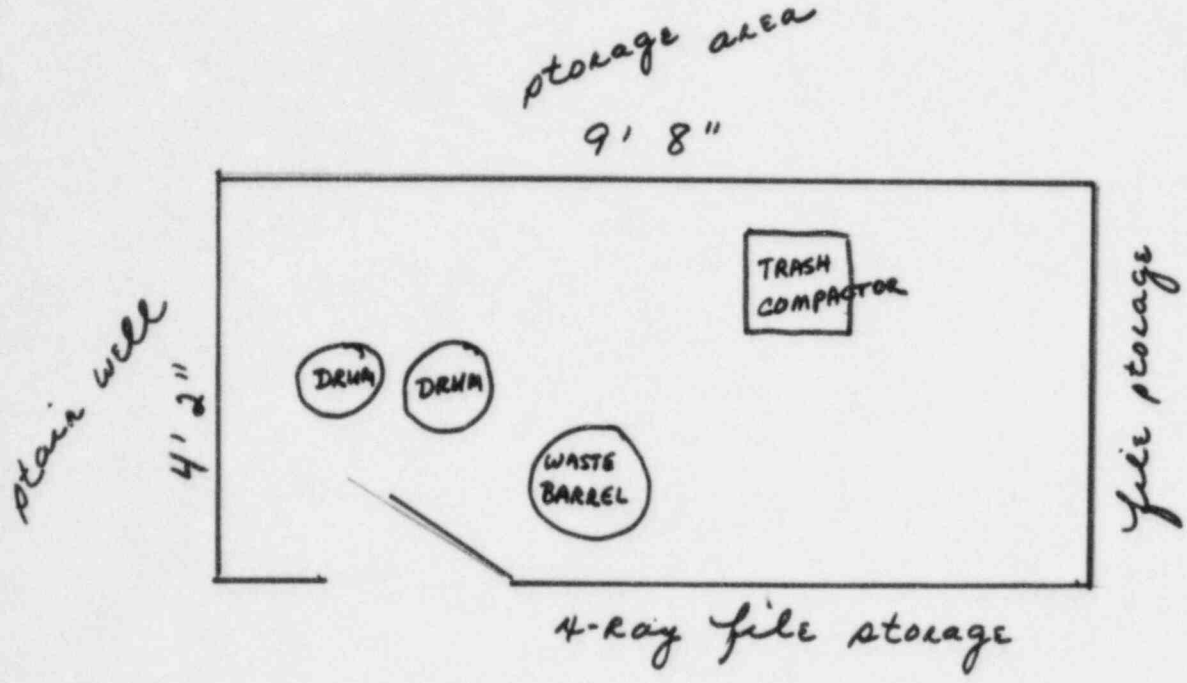


Lynn Hospital Nuclear Medicine Dept.



"Hot" Room (enlarged)

LYNN HOSPITAL



BASEMENT STORAGE AREA

WALLS = 8" CINDER BLOCKS

Lynn Hospital-Nuclear Medicine Department
Survey Imaging Labs.

Hot Lab: Background:_____mr/hr
Behind table top shield: _____mr/hr
In front of table top shield: _____mr/hr
Generator:_____mr/hr
Sink:_____mr/hr
Dose Calibrator:_____mr/hr
Floor:_____mr/hr
Hot Waste Containers:_____mr/hr
Scan Room 1:_____mr/hr

Scan Room 2:_____mr/hr

Computer Room:_____mr/hr

Reception Area:_____mr/hr

Waiting Area:_____mr/hr

Stretcher Waitng Area:_____mr/hr

Lounge:_____mr/hr

Dr.'s Office_____mr/hr

Patient Bathroom:_____mr/hr

Personnel Bathroom:_____mr/hr

"hot" waste containers

#1_____mr/hr

#2_____mr/hr

GM should read 10.0mr/hr

Checks_____

Storage Room:

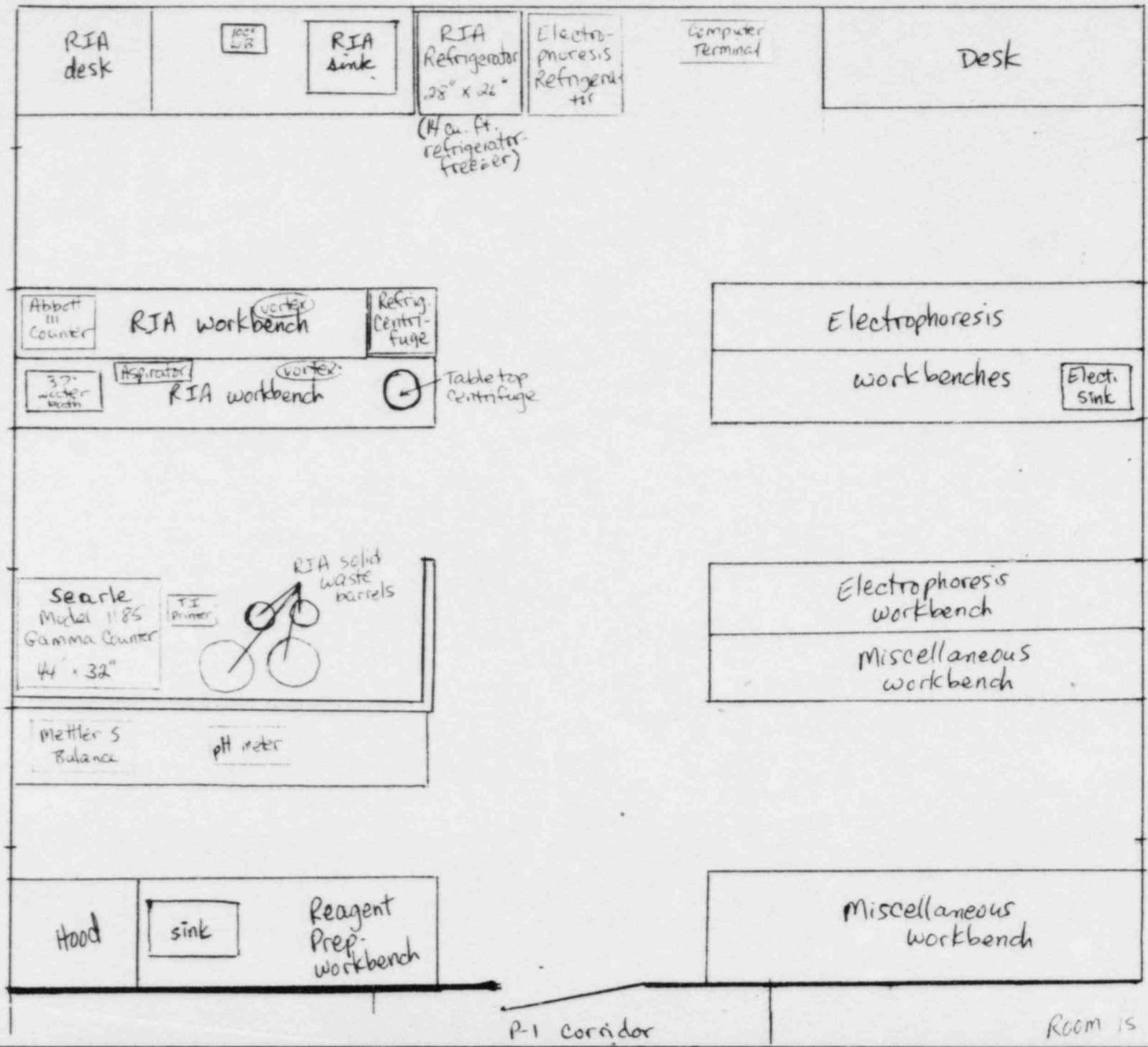
Background:_____mr/hr
Barrel #1:_____mr/hr
Barrel #2:_____mr/hr
Generators:_____mr/hr
Compactor Bags:_____mr/hr

All rooms no removable contamination unless otherwise indicated.

Signature:_____

Date: _____

SPECIAL CHEMISTRY LAB 12/12/84 gk



Room is 32' x 29'

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction 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 NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

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 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

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

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:

   a. Ordering of routinely used materials

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request* will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

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

4. During off-duty hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE** MEMORANDUM

MEMORANDUM FOR: Security Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, *immediately* contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

** Submit a copy of your own institution's memorandum.

Form 313M
Item 13

MEMORANDUM FOR: Security Personnel

FROM: Edward F. Kittredge, President

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive materials that arrive between 4:30 p.m. and 7 a.m. or on Saturdays, Sundays, or Holidays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package in the hot lab.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: Herbert Leventhal, M.D.

OFFICE PHONE: 598-5100 Ext.352

HOME PHONE: 599-4445

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

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

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

   f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

* In the case of special orders (e.g., therapy doses), also compare with physician's written request.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. No.: _____ Survey Date _____ Time _____

   Surveyor _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ Punctured _____ Status _____ Wet

   _____ Crushed _____ Other

3. RADIATION UNITS OF LABEL: _____ Units (mR/hr)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mR/hr

   b. 3 feet or 1 meter from surface _____ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide _____ yes _____ no, difference _____

   b. Amount _____ yes _____ no, difference _____

   c. Chem Form _____ yes _____ no, difference _____

6. WIPE RESULTS FROM:

   a. Outer _____ CPM = _____ DPM

      eff = ( )

   b. Final source container _____ CPM = _____ DPM

      eff = ( )

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____

Signature Date

APPENDIX G

GENERAL RULES FOR 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. Always use syringe shields for routine 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. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. 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 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

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. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

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 and properly shielded 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 shielded 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: Herbert Leventhal, M.D.*
OFFICE PHONE: (617) 598-5100 Ext. 2806
HOME PHONE: 599-4445

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____
_____
_____

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

APPENDIX I

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 μCi) 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.

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.

-or-

N/A — By commercial waste disposal service (see also Item 4 below).

X — Other (specify): See #3

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.**

N/A — Disposed of by commercial waste disposal service (see also Item 4 below).

N/A — 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.

N/A — Disposed of by commercial waste disposal service (see also Item 4 below).

N/A — Other (specify): _____

4. The commercial waste disposal service used will be

N/A

(Name) (City, State)

NRC/Agreement State License No. N/A

* 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. 2805. 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.

Date 12-12-84

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 Herbert Leventhal, M.D. (617) 598-5100 Ext. 2806

Name Herbert Leventhal, M.D. On-duty/Off-duty Telephone Numbers 599-4445

RADIATION SAFETY PROCEDURES FOR IODINE 131 THERAPY

Volatile iodine is released from therapeutic liquid iodine 131 solutions. Opening and preparing these solutions for patient administration can cause an airborn radioactivity hazard. The following procedures will be observed in order to prevent contamination and thyroid uptake in individuals who prepare and administer therapeutic quantities of iodine 131:

A. Therapeutic doses of iodine 131 will be received, possessed and used only in capsule form, or

B. If therapeutic doses of iodine 131 are ordered for use in liquid form, personnel will be instructed as follows:

(1) Conduct procedures that involve opening and preparing therapeutic liquid iodine 131 solutions in a fume hood with adequate airflow.

(2) Wear waterproof disposable gloves when opening and preparing iodine 131 solutions.

(3) Have your thyroid checked for the presence of iodine 131 approximately 24 hours after opening or preparing therapeutic liquid iodine 131 solutions. Use the thyroid uptake equipment for this check. Report any counts above background level to the radiation safety officer immediately.

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 _____
Herbert Leventhal, M.D.

Telephone No. (days) (617) 598-5100

(nights) 599-4445

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 Herbert Leventhal, M.D. (617) 598-5100 Ext. 2806/599-4445

Name — On-duty/Off-duty Telephone Numbers

Lynn Hospital

An AtlantiCare Medical Center

Group VI Procedures Lynn Hospital

1. Sealed sources will be stored in the radium room located in the sub basement of building C. Radium and Cesium sources will be kept in a radium chemical company lead safe (A) which has 7.6 cm of inherent lead shielding plus an additional 5cm of lead shielding from lead bricks surrounding the front, back, sides and top. All other sealed sources will be stored in a well (B) constructed of 5cm thick lead bricks to which additional bricks may be added if required.

2. The sealed sources will be handled with forceps while working behind a lead L-shaped block with a lead glass window.

3. All personnel handling sealed sources will be monitored with whole body film badges as well as finger badges on those individuals that will be loading or handling the sources.

4. A long handled lead walled carrier with forceps will be available to transport the sources and will be left in the patients room for the duration of the patients stay in the hospital.

5. The procedure for accountability of each sealed source will be as follows:
The sources will be logged in and signed for in the radionuclide receiving book. A data sheet is then filled out for each order. Whenever any of the sources are used the patient's name, number, location and # of sources will be recorded. The sources will be counted before leaving the storage area and upon return. All use will be recorded on the data sheet. All unused sources will be allowed to decay in the storage area or disposed of in radioactive waste barrels and receipts will be recorded. In the case of Irridium 192 the sources will be returned to the manufacture after use.

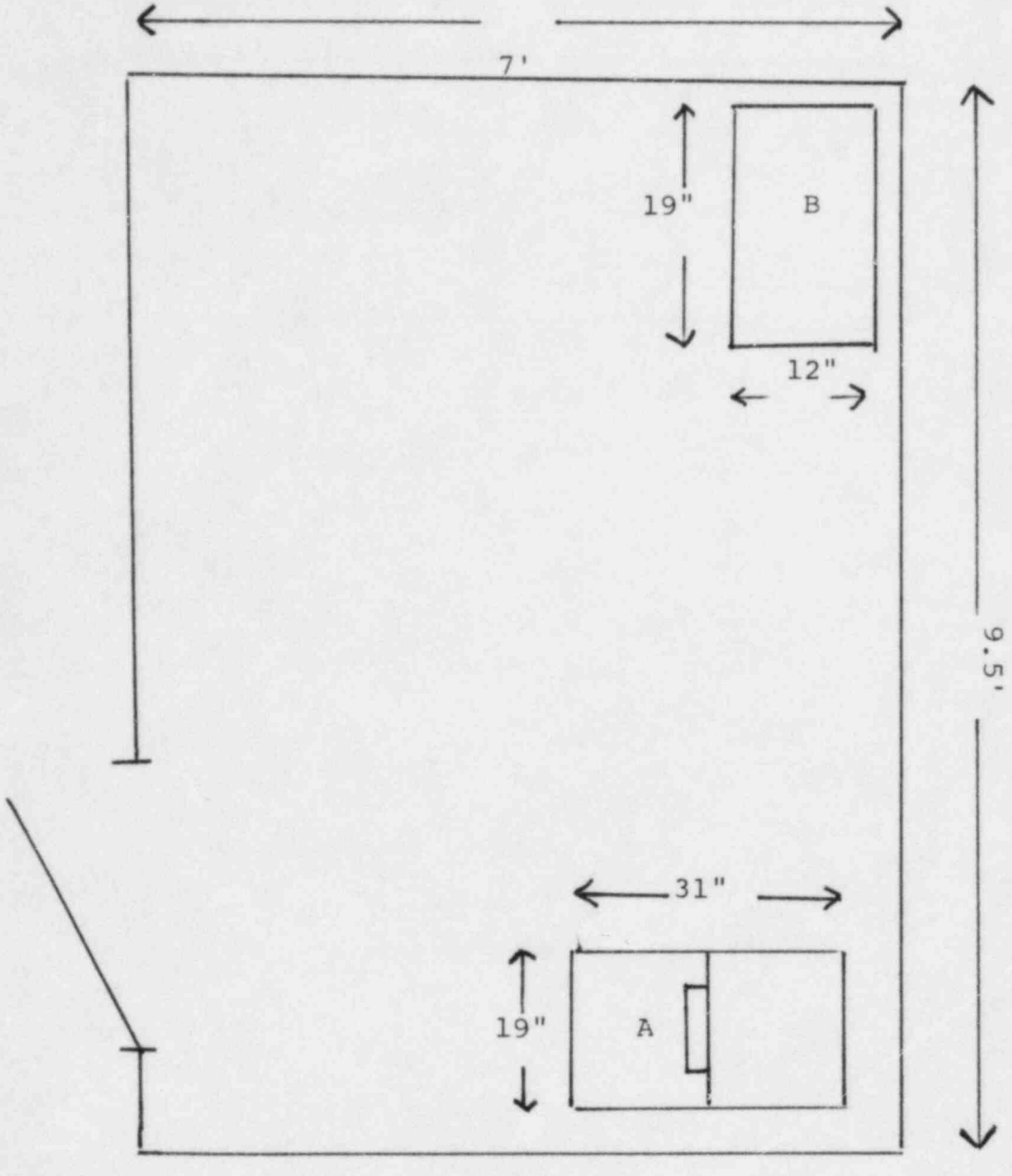
6. During the course of treatment, areas surrounding the patient will be monitored and the nursing personnel will wear personnel monitoring equipment. If sources are to be removed, they will be counted when returned to the storage area and if a permanent implant was performed, the area that the patient used will be monitored to be sure all radioactive material has been removed. Permanent implant patients will be instructed by the using physician before leaving the hospital and will be given a lead container in the event any sources should fall out and the patient finds them.

212 Boston Street
Lynn, Massachusetts 01904
617-598-5100

Lynn Hospital

An AtlantiCare Medical Center

Lynn Hospital Radium Room



212 Boston Street
Lynn, Massachusetts 01904
617-593-5100

RELEASE OF PATIENTS CONTAINING THERAPEUTIC QUANTITIES OF RADIOACTIVE MATERIAL

Patients will be discharged in accordance with the values and recommendations contained in NCRP 37.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Lynn Hospital/Atlanticare Medical Ctr.

(Licensee's Name)

12-12-84

(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.

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

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.

[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.

Edward F. Kittredge
Signature

Edward F. Kittredge
Name (print or type)

President
Title

Institution (or Private Practice) Name and Address

Lynn Hospital
An AtlantiCare Medical Center
212 Boston Street
Lynn, Massachusetts 01904

[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.