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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

Approved by OMB
3150-0041
Expires 9-30-83

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

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

Southwood Community Hospital
111 Dedham Street
Norfolk, Massachusetts 02056

Not associated w/State Non-government Not for profit

TELEPHONE NO.: AREA CODE 617) 668 - 0385

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

Same as 1.A.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Arthur Klein, M.D.

TELEPHONE NO.: AREA CODE 617) 769 4000

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

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

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

Arthur Klein, M.D.- NRC license No. 20-12560-01

Vinubhai C. Patel, M.D.
NRC License No. 20-04597-01

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.)*

Arthur Klein, M.D.
and
Vinubhai C. Patel, 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	
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	2 C
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 INTRA-CAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

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

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Uranium (Depleted in Uranium 235 For specifications see NRC License No. 20-04597-01	Cadmium Plated Metal	182 Kilograms	As shielding in a linear accelerator.

"OFFICIAL RECORD COPY" ML10

License Fee Information
see 4/13/82 ltr.
~~On Reverse Side~~

8602070100 851115
REG1 LIC30
20-20554-01 PDR

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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. 1 Date: 10/80

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and Klein NRC 20-12560-01 Patel NRC 20-04597-01
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	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)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached See NRC License No. 20-04597-01

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	Landauer Company	1 month
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Landauer Company	1 month
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL
SOUTHWOOD COMMUNITY HOSPITAL

MAILING ADDRESS
111 DEDHAM STREET

CITY: NORFOLK, | STATE: MA | ZIP CODE: 02056

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7.B.

(2) LICENSE FEE ENCLOSED: $ 190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
John Dalton

(1) NAME *(Type or Print)*
JOHN DALTON

(2) TITLE
ADMINISTRATOR

c. DATE
4-23-82

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PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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.

MEDICAL ISOTOPE COMMITTEE

CHAIRMAN	Arthur Klein, M.D.	Director of Nuclear Medicine
	Vinubhai C. Patel, M.D.	Director of Radiation Therapy
	Jeanne Morello, R.N.	Administrative member
	Gerald Reid, M.D.	Surgeon
	Bai Hoon Lee, M.D.	Pathologist
	Jacob Spira, Ph.D.	Senior Consultant Radiation Physicist
	Edna Sanroma	Consultant Radiation Physicist

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

   Manufacturer's model number: E-120

   Number of instruments available: 1

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

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

   b. Manufacturer's name: Victoreen

   Manufacturer's model number: 592-B Serial 4600 SK 525 - 4473 05929

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 10 mR/hr

   Maximum range: 0 mR/hr to 1000 mR/hr

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC - 6 A

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
GAMMA CAMERA	RAYTHEON	Step I 91 tube Serial # 028236

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

APPENDIX D

CALIBRATION OF INSTRUMENTS

Section 1

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).

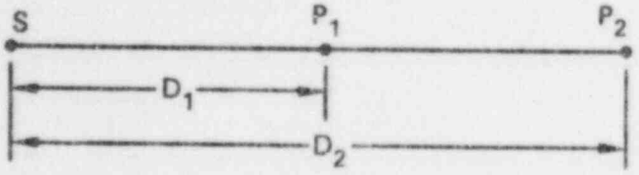

Figure D-1

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:

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

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

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

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

$= \frac{1}{9} \times 77 = 8.6$ 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.

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

X b. At the licensee's facility

(1) Calibration source

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

X (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 or member of his staff

(2) Location Southwood Community Hospital

(3) Procedures and sources

____ have been approved by NRC and are on file in License No. ____

____ 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.

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

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

Appendix D Survey Meter Calibration

For calibration of the radiation survey meters, 4 Radium sources, 25 mg. each totalling 100 mg. Radium will be used. All four Radium sources are from the Radium Chemical Company in New York. Two of these sources acquired in 1973 have certificates #33405 and #33406 stating the Radium content to be 24.63 and 24.60 respectively. The two other Radium sources of older origin do not have the certificate and they were calibrated against the above mentioned standards and found to be within $\pm$ 2% of the standard. The meters will be calibrated at 2 points on each scale annually and checked quarterly. The four Sources will be placed in a specially constructed plastic container at the distance of about 30 cm. from the survey meter's window to assure optimum geometry conditions. At this distance the expected reading of the instrument is .80 - .85 R/hr.

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

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

Comments:

Nuclide	Activity or Exposure Rate at Specified Distance	Calibration Accuracy

Calibration Source:

Calibrated by _____ Date _____

ML18

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

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

A. Test for the following:

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

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

C. Test for Instrument Constancy

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

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

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

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

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

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* 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) ^{99m}Tc Standard to be ordered from Gamma Diagnostics

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	1-5	± 4.5%
Ba-133	0.1-0.5	0.1-0.2	± 4.5%
Cs-137	0.1-0.2	0.1-0.2	± 4.5%
Ra-226	1-2		

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.

NRC Form 313M
Item 11

DESCRIPTION OF LABORATORY FACILITIES, REMOTE HANDLING EQUIPMENT, STORAGE CONTAINERS, SHIELDING, FUME HOODS, ETC.

A. The hot lab contains a square enclosure of 2" x 4" x 8" lead bricks sufficient to shield the radionuclides stored within it in a proper manner. A table shield is used when radionuclides are drawn up.

B. Remote handling tongs will be used to handle the vials of radioactive materials.

C. All vials of radioactive material are stored in the lead pigs in which they are delivered. These will be placed within the lead enclosure in the hot lab, which is a restricted area for which only authorized personnel have keys. This area will be labeled as a "Radiation Area" and all of the vials will be labeled "Caution, Radioactive Materials".

D. All instructions supplied by the kit manufacturers will be followed for assay, kit preparation, radiation safety precautions, use of special syringes, shields or other accessories.

E. Syringe shields will be used for the withdrawal and injection of all radiopharmaceuticals.

F. Through the implementation of items A through E, radiation dose to personnel will be kept to a minimum.

G. Whole body badges and ring badges will be worn at all times during working hours. These are changed and evaluated on a monthly basis.

H. The activity of radiopharmaceuticals will be assayed prior to injection using a Capintec CRC6A dose calibrator to insure that the recommended dose is not exceeded and that the accuracy of the injected dose is plus or minus 10% or 90% accurate.

I. All radioactive material is delivered to one area therefore, it is easy to insure by properly kept records that our maximum possession limit is not exceeded.

J. Radionuclides will not be kept in unrestricted areas. Therefore, radiation levels in these areas will not exceed the limits specified in section 20.105 of 10CFR20.

K. The hot lab is the area designated for the receipt, storage, preparation and measurements of radioactive materials. The attached sketch of laboratory facilities indicates the lay-out of this area.

L. Radioactive waste is stored within a lead brick enclosure. Doses are drawn up behind the lead brick enclosure. Vials in use are kept within an enclosure of 2" x 4" x 8" lead bricks. All storage and preparation is performed within the hot lab.

M. No liquid ^{131}I will be used in the Southwood Community Hospital for diagnosis or therapy, only ^{131}I capsules will be used so as to avoid possible ingestion of this radionuclide.

N. All byproduct material will be obtained in precalibrated form except the 99Mo/99mTc generator. After the generator is eluted, the 99mTc will be assayed in the Capintec CRC 6 A dose calibrator for 99mTc content. The eluate will be assayed in the dose calibrator for 99Mo breakthrough. The dose calibrator is routinely calibrated to ensure 90% accuracy of dose. The 99mTc will not be used if the 99Mo content exceeds 1 microcurie of 99Mo per 1 millicurie of 99mTc, but will not exceed 5 microcuries per patient dose. At the time being, instant 99m Tc is being used.

O No dose of radioactive material will exceed the manufacturer's recommendations.

NRC Form 313M
Item 12

TRAINING PROCEDURES FOR PERSONNEL

A. All individuals working in or frequenting any portion of a restricted area will be instructed as to the storage, transfer, or use of radioactive materials or of radiation in portions of the restricted area; will be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; will be instructed in, and instructed to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials occuring in such areas;will be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation or to radioactive material; will be instructed in the appropriate response to warnings made in the event of any unusual occurrence of malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

B. Housekeeping personnel are instructed on an individual basis as to the location of radionuclides and that they are not to be in contact with them. Anyone who empties the non-radioactive waste basket is instructed that he is to touch nothing else in the laboratory except that specific basket.

C. Nursing personnel will be instructed as to their responsibilities in attending patients with therapeutic quantities of radioactive materials and any other special topics which may apply to them.

D. Security personnel will be instructed to deliver incoming packages to the Nuclear Medicine laboratory which will be kept locked.

E. Personnel entering a restricted area who are not directly involved in the activities in the laboratory are instructed to state their business and leave immediately.

F. This training will be performed initially upon employment and annually thereafter.

SUBJECT: WRITTEN NOTIFICATION OF RADIOISOTOPE DELIVERY PROCEDURE
RE: NUCLEAR MEDICINE DEPARTMENT IN EFFECT

PROCEDURE:

DAILY 6 A.M. - 5 P.M.

The agent carrying the radioisotopes will be directed to the Department of Nuclear Medicine. The isotopes will be monitored for contamination and signed for (if accepted) by a registered Nuclear Medicine Technologist.

If the package is contaminated, broken, etc., the agent and material will be isolated and detained in separate areas. The Radiation Safety Officer and Consultant Physicists will be notified. Decontamination procedures will be put into effect. The radioisotope and delivery companies will be called and instructed on the exact procedure they are to follow. The Radiation Safety Officer and/or the Consultant Physicist upon arrival will then direct, extend or cancel operations in effect by departmental personnel.

NIGHTLY 5 P.M. - 6 A.M.

Area monitor device will be set up in the main lobby. Delivery agent will be directed to the night switchboard operator. A security guard will then take the package to the Department of Nuclear Medicine. The security guard will unlock the door and set the package inside the Department. The Department is continuously monitored for radiation leakage from any source. If the monitors are set off, the switchboard operator will notify the On-Call technologist, the Radiation Safety Officer and Chief Technologist of Nuclear Medicine. The monitors will be left on and the package left in the Department. The delivery agent will be detained in an isolated area. The On-Call technologist and/or Chief Technologist on arrival will put the daily procedure, described above into effect. Only a security guard may sign for receipt of the radioisotopes. Report any type of unusual occurence to the Chief Technologist at once.

SPECIAL PROCEDURE

Return of Waste 99mTc to Gamma Diagnostic Labs:

All waste vials will be capped with lead stopper, placed in Gamma Diagnostic package, sealed and a red label identifying the shipping date and the Hospital, and placed in the lead-lined receptacle used for delivery to the Department. Pick-up will be done at least weekly.

Richard Gowe

Richard Gowe
Nuclear Medicine Department

CC: Security
Switchboard

4/1/82

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: Arthur Klein, M.D.
OFFICE PHONE: 769-4000 Ext. 2266
HOME PHONE: 762-5885

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:
Vinubhai C. Patel, M.D. 668-0385 (work)
528-3643 (home)

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

"OFFICIAL RECORD COPY"

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.

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

__X__ Other (specify) Held for decay* etc.

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

_____ Returned to the manufacturer for disposal.

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

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

_____ Other (specify): _____

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

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

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

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

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

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

APPENDIX K

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS*

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

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

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

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

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

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

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

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

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

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

11. Nursing Instructions

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

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

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

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

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

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

---

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

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

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

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

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

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

k. For I-131 patients:

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

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

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

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

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

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

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

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

12. Waste Disposal

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

Date _____

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

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all checked items)

_____ 1. Visiting time permitted: _____

_____ 2. Visitors must remain_____from patient.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 are not permitted.

_____ 5. Pregnant visitors are not permitted.

_____ 6. Film or TLD badges must be worn.

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

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

_____ door _____ chart

_____ bed _____ wrist

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

_____ 10. Patient must use disposable utensils.

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

_____ 12. Smoking is not permitted.

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

_____ 14. Other instructions.

In case of an emergency contact:

RSO Vinubhai C. Patel, M.D. 668-0385 528-3643

Name On-duty/Off-duty Telephone Numbers

APPENDIX L

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES*

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

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

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

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

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

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

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

8. Instructions to Nurses

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

o. Emergency Procedures

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

(2) If the patient dies, or

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

Vinubhai C. Patel, M.D.

Telephone No. (days) 668-0385

(nights) 528-3643

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.

ML10

"OFFICIAL RECORD COPY"

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 disinissal 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 Vinubhai C. Patel, M.D. 668-0385 528-3643

Name On-duty/Off-duty Telephone Numbers

PROGRAM FOR MAINTAINING OCCUPATIONAL
RADIATION EXPOSURES AT ALARA

1. Management Commitment

a. We, the management of Southwood Community Hospital are committed to the program described in this paper for keeping exposures (individual and collective) As Low As Reasonably Achievable (ALARA). In accordance with this commitment, we empower the Medical Isotopes Committee of our Hospital to direct and coordinate administrative aspects of the radiation safety program and to develop the necessary written policy procedures and instructions to foster the ALARA concept within our institution. The Medical Isotopes Committee(MIC) will include a Radiation Safety Officer (RSO) designated in our application for license to use byproduct materials in our Hospital. We are also committed to follow the guidance provided by U. S. Nuclear Regulatory Commission, Regulatory Guides 8.10, 8.18 and 10.8 referring to maintenance of occupational radiation exposures ALARA.

b. We will perform a formal audit annually to determine how exposures might be lowered. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants. A brief summary of the audit will be prepared covering the scope of the review and the conclusions reached.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where practicable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Medical Isotopes Committee (MIC)

a. Review of Proposed Users and Uses

1) The MIC will thoroughly review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that the user will be able to take appropriate measures to maintain exposure to ALARA.

2) When considering a new use of byproduct material, the MIC will review the efforts of the authorized user to maintain exposure to ALARA. The user should have systematized procedures to ensure ALARA, and should have considered the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3) The MIC will ensure that the user justifies his procedures and that they will result in ALARA doses (individual and collective).

b. Delegation of Authority

1) The MIC will delegate sufficient authority to the RSO for enforcement of the ALARA concept.

2) The MIC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action.

c. Review of ALARA Program

The MIC of our medical facility will perform an annual review of all radiation safety programs. This review will be performed independently of that performed by management.

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

2) The MIC will review all instances of deviations from the ALARA philosophy. Information in support of the review will normally be supplied by the RSO.

3) The MIC will evaluate our institution's overall efforts for maintaining exposures ALARA. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

d. Public Statement of Commitment by the MIC to ALARA

All elements of our institution will be informed of MIC's commitment to the ALARA concept.

1) The MIC will ensure that employees are aware of the MIC's commitment to the ALARA philosophy.

2) The MIC will demonstrate its commitment to the ALARA concept through the methods employed in its review of proposed users and uses.

3. Radiation Safety Officer (RSO)

a. Periodic Review and Audit of the Radiation Safety Program for compliance with ALARA concepts. Frequent reviews of procedures will be conducted.

1) The RSO will review and audit, on a regular basis (at least annually), the effectiveness of his own radiation protection program in maintaining doses (individual and collective) ALARA.

2) The RSO will review exposures of authorized users and occupational workers to determine that their exposures are ALARA.

3) The RSO will review radiation levels in unrestricted and restricted areas and releases of effluents to unrestricted areas to determine that they are at ALARA level.

b. The RSO's Education Responsibilities for an ALARA Program

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

2) The RSO will assure that authorized users, occupational workers and ancillary personnel understand the ALARA philosophy and know that management, the MIC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Individuals who must work with ALARA concepts will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1) The RSO will maintain 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 encouraging, receiving, and evaluating the suggestions of individual workers for improving health physics practices.

d. Reporting and Reviewing Instances of Deviation from Good ALARA Practices

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

2) The RSO will report all significant instances of deviation from ALARA concepts to the MIC for review.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1) The authorized user will consult the RSO and MIC before using radioactive materials for a new procedure.

2) The authorized user will consider all procedures thoroughly 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 the Authorized User to Those He Supervises

1) The authorized user will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2) The authorized use will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

3) The authorized user will be responsible to the radiation safety concerns of the individuals that he supervises.

c. Continuing Review of ALARA concepts by the Authorized User

1) The authorized user will continuously review his procedures to ensure that his ALARA program is optimal.

2) The authorized user will maintain contact with the RSO to ensure that he is aware of and employs the most current methods to maintain exposures ALARA.

5. Occupational Worker

a. What the Occupational Worker Must Consider About ALARA

1) The worker will implement ALARA procedures developed by the authorized user and the RSO.

2) The occupational worker will know what resources are available if he feels that ALARA is not being promoted on-the-job.

3) The occupational worker will understand the ALARA concept and will review his own working conditions and those of his fellow workers for the implementation of ALARA principles.

6. Establishment of Action Levels in Order to Achieve Reductions in Individual Occupational Exposures.

This institution hereby establishes exposure action levels for specific kinds of classes of operations which, when exceeded, will trigger investigation by the MIC and/or the RSO. The exposure action levels that we have established are listed in Section 7 below. These levels apply to the exposure of individual occupational workers.

Analysis of our institution's radiation exposure history and review of results of monitoring of our occupational radiation workers permit us to accept the value of Level II. If the exposure does not equal or exceed investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by MIC. The MIC will however,

consider each such exposure is comparison with those of others performing similar tasks as index of ALARA program quality and will record the review in the Committee minutes.

7. Investigational Levels

The specific investigational level established by this institution is Level II.

8. Signature of Certifying Official

I hereby certify that this institution is committed to the ALARA Program set forth above.

John D. Dalton
Signature

John D. Dalton
Name (print or type)

Administrator
Title

ML18

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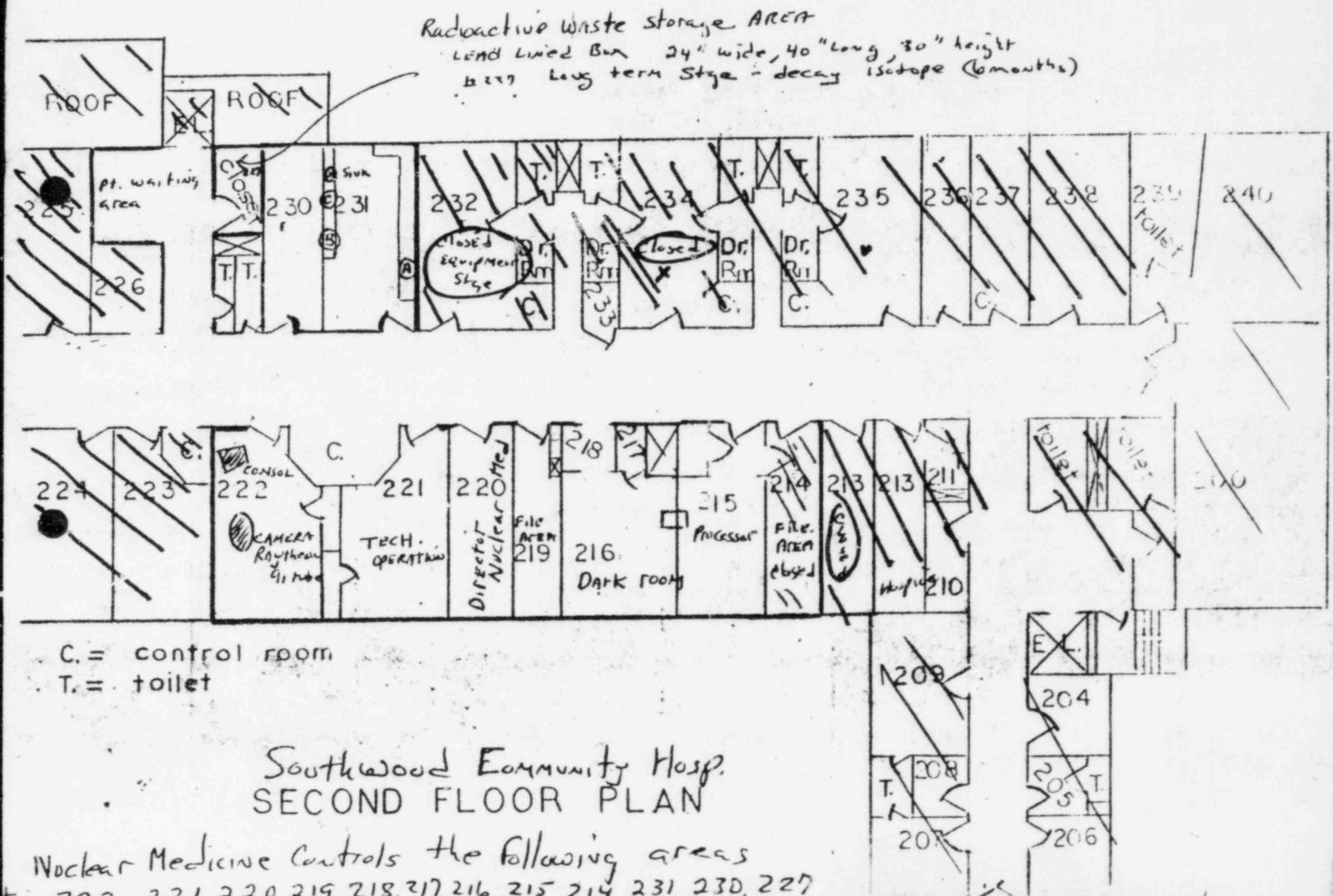
(A) Dose Calibrator
(B) Monitor (package)
(C) Daily Waste and isotope stge area, Lead Lined



C. = control room
T. = toilet

Southwood Community Hosp.
SECOND FLOOR PLAN

Nuclear Medicine Controls the following areas
Rs, 222, 221, 220, 219, 218, 217, 216, 215, 214, 231, 230, 227

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NUMBER OF PAGES: 1

ACCESSION NUMBER(S):

8602070100-01

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FTS 492-8989

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Southwood Community Hospital

Application Dated: 10/18/85

Control No.: 104539

License No.: 20-20554-01

2. FEE ATTACHED

Amount: $120.00

Check No.: 21643

3. COMMENTS

02120
6/87

Signed Brenda Platchek

Date 10/24/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C ($120)

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed G Jackson

Date 11/1/85

REGION I FORM 213
(MARCH 1983)

"SECTION COPY"

Southwood Community Hospital

111 Dedham Street
Norfolk, Ma 02056

10/18/85 No 21643

53-243
113

120 Dollars 00 Cents

Pay exactly

$****120.00

Pay to the order of

NUCLEAR REGULATORY COMM

Baybank Norfolk County Trust Company, Norwood, Massachusetts

:011302438: 111-59699