

FORM NRC-313M

(8-78)

10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE -- MEDICAL

Approved:
GAO R0557

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

Heartland Hospital West
8th & Farraon
St. Joseph, Missouri 64501

TELEPHONE NO.: AREA CODE(816) 271 7558

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mr. Mike McGeehan

TELEPHONE NO.: AREA CODE(816) 271 7558

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

a. ☐ NEW LICENSEb. ☐ AMENDMENT TO LICENSE NO. _____c. ☒ RENEWAL OF LICENSE NO. 74-13246-01

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

See attached

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.)

See attached

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 Ci	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	1 Ci
10 CFR 35.100, SCHEDULE A, GROUP VI					

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
I-125 8512050120 851025 REG3 LIC30 24-13246-01 PDR	Sealed Source		Permanent therapy implant
Applicant: <i>June 1980</i> Check No. <i>70998</i> Amount/Fee Category <i>75</i> Type of Fee <i>Renew</i> Date Check Rec'd <i>6/2/85</i> Received By <i>[Signature]</i>			

FORM NRC-313M
(8-78)

CONTROL NO. 79080

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: _____

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input checked="" type="checkbox"/>	Names and Specialties Attached; and	<input checked="" type="checkbox"/>	Appendix G Rules Followed; or
<input checked="" type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input checked="" type="checkbox"/>	Appendix H Procedures Followed; or
<input checked="" type="checkbox"/>	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
<input checked="" type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input checked="" type="checkbox"/>	Appendix I Procedures Followed; or
<input checked="" type="checkbox"/>	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input checked="" type="checkbox"/>	Appendix J Form Attached; or
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input checked="" type="checkbox"/>	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input checked="" type="checkbox"/>	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or _____ (Check One)
<input checked="" type="checkbox"/>	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input checked="" type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Appendix F Procedures Followed; or		Detailed Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
			Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE <small>(Check appropriate box)</small>		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	FILM	R.S. Landauer, Jr.	Monthly
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD	R.S. Landauer, Jr.	Monthly
	OTHER (Specify)		
c. WRIST	FILM		
	TLD		
	OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			
NAME OF HOSPITAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR. c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAU- TIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.	
MAILING ADDRESS			
CITY	STATE		

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 <small>(See Section 170.31, 10 CFR 170)</small>	b. APPLICANT OR CERTIFYING OFFICIAL (Signature) <div style="text-align: center; font-family: cursive;">Thomas J. Hesselmann</div>
(1) LICENSE FEE CATEGORY: 7C	(1) NAME (Type of Print) Thomas J. Hesselmann
(2) LICENSE FEE ENCLOSED: \$ 580.00	(2) TITLE Executive Vice-President
	c. DATE 5/16/85

Item #7: MEDICAL ISOTOPES COMMITTEE

Committee Members:

<u>Member</u>	<u>Speciality</u>
Edward Stevens, M.D.	Radiology, (RSO)
Mike McGeehan, BS, RT.	Radiology
Chris Crandell, CNMT	Nuclear Medicine
Emory Larimore, M.S.	Radiation Physicist
Donald Heins, M.D.	Radiologist
	Administration*
	Nursing*
Jacque Schackleford	Lab

* The committee representatives from these departments change periodically and as such we have indicated only the departments. The committee will have representatives appointed from these departments at all times.

The responsibilities, duties and meeting frequency will be as described in Appendix B, of "A Guide for Preparation of Application for Medical Programs," Regulatory Guide 10.8 Rev. _____, Dated. See next page.

Dated 4/25/85

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 sect. 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 office, 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.

Item #8: USERS' TRAINING AND EXPERIENCE

Name	Previous License Number	Authorized Uses
Edward M. Stevens, M.D.	24-13246-01	I, II, III, IV, Invitro Xe-133
Joseph L. Fisher, M.D.	24-13246-01	I, II, III, IV, Invitro Xe-133
Phillip Acuff, M.D.	24-13246-01	I, II, III, IV, Invitro Xe-133
Donald E. Heins, M.D.	24-13246-01	I, II, III, Invitro
Stephen C. Tines, M.D.		I, II, III, Invitro Xe-133, I-131 Iodine for Therapy
Eshwar K. Reddey, M.D.	24-16178-01	I-125 implants, Rad 192, Cs-137, P-32

Dated 4/25/85

Item #9: Instrumentation

APPENDIX C

1. Survey Meters

a. Manufacturer's name: Nuclear Chicago

Manufacturer's model number:

Number of instruments available: One

Minimum range: 0.0 mr/hr to 0.1 mr/hr

Maximum range: 0.0 mr/hr to 0 - 100 mr/hr

b. Manufacturer's name: Tracer Lab

Manufacturer's model number: SU14

Number of instruments available: One

Range:

Minimum range: 0.0 mr/hr to 15 mr/hr

Maximum range: 0.0 mr/hr to 1500 mr/hr

Date: 4/25/85

2. Dose Calibrator

Manufacturer's name: Squibb

Manufacturer's model number: CRC-6A

Number of instruments available: One

3. Diagnostic Instruments

TYPE OF INSTRUMENT	MANUFACTURER'S NAME	MODEL NO.
Gamma Camera	Siemens	ZLC-750
Micro Dot	Siemens	
Computer	ADAC	DPS-2800
Xe-133 Trap	Atomic Development	Xe-102
Uptake Probe	Picker	III A

4. Other

Well Counter	Nuclear Chicago	
Area Monitor	Victoreen	Frisker

Date: 4/25/85

CONTROL NO. 7 9 0 8 0

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items:

- ☒ 1. Survey instruments will be calibrated at least annually and following repair.
- ☒ 2. Calibration will be performed at two points on each scale. 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 $\pm 10\%$ of the calculated or known values for each point checked. Readings are within $\pm 20\%$ are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.
- ☐ 3. Survey instruments will be calibrated.
- ☐ a. By the manufacturer.
- ☐ b. At the licensee's facility.
- ☐ i. Calibration source
Manufacturer's name:
Model #:
Activity in millicuries:
Accuracy:
Traceability to primary standard:
- ☐ ii. The calibration procedures in Appendix D, Section I will be used, or
- ☐ iii. The step-by-step procedures including radiation safety procedures are attached.
- ☒ c. By a consultant or outside firm.
- ☐ i. Name: Radiation Consultants of Mid-America, Inc.
- ☐ ii. Location: 5500 Buena Vista, Shawnee Mission, KS 66205
- ☐ iii. Procedures and sources
- ☒ have been approved by ^{KANSAS} ~~NEC~~ and are on file in License #33-B429-01
- ☐ are attached

Date: 4/25/85

CALIBRATION OF INSTRUMENTS

APPENDIX D

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% 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% 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 $\pm 20\%$ 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% 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.

Item #10: CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

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

☐ Other* (specify) #D Below

B. Sources Used for Instrument Accuracy and Constancy Tests:

Radionuclide	Activity (mCi)	Accuracy
57 Co	5.0	$\pm 5\%$
133 Ba	.250	$\pm 5\%$
137 Cs	.2	$\pm 5\%$
Other		

C. ☒ The procedures described in Appendix D, Section 2, Regulatory Guide 10.8, Rev. , Dated , will be used for calibration of the dose calibrator. See next page.

☐ or
Equivalent procedures are attached.

D. ☒ An alternative to the linearity procedure described in Appendix D "A Guide for Applications for Medical Programs," dated 5/1/79 will be to use a calichack system. This system is available from Calcorp, Inc. The manufacturer's instructions for use will be followed.

*Must be equivalent to the highest activity used.

Date: 4/25/85

- 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 $\pm 20\%$ 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 curves(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, 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.

*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).

APPENDIX D
Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The 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. Tests 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 μ Ci 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 $\pm 5\%$ 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 $\pm 5\%$ 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

i. 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).

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

b. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

c. 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:

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 $15.625 \text{ mCi} \times 15.853 = 247.7 \text{ mCi}$ and $15.625 \text{ mCi} \times 0.126 = 1.97 \text{ mCi}$, respectively.

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

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

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

If available, a set of calibrated lead absorbers similar to the Cal-check or Lineator systems will be used for determining the dose calibrator linearity.

*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.

2. If available, a set of calibrated lead absorbers similar to the Cal-check or Lineator systems will be used for determining the dose calibration linearity.

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 $\pm 2\%$. (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:

$$\text{True Activity} = \text{Measured Activity} \times \text{Correction Factor}$$

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. 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 $\pm 5\%$ 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 $\pm 5\%$ 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.

Item #11: FACILITIES & EQUIPMENT

The following items are provided for handling radioactive material and will be used appropriately:

- a. disposable gloves
- b. syringe shields
- c. lead vial shields
- d. tongs and forceps
- e. 2" x 4" lead bricks
- f. work bench area with absorbent paper
- g. survey meters
- h. L-block shield

The area designated Hot Lab will be used for receipt, storage (including waste), preparation and measurement of radioactive material. Radioactive waste will be stored in the lead brick storage area in labeled containers. The Hot Lab will be locked when nuclear medicine personnel are off duty and will be made available only to those people authorized by Nuclear Medicine. A diagram of the nuclear medicine area is enclosed.

All radioactive sources are stored in such a manner (lead, concrete, or refrigerator) so as to not exceed 2 mR/Hr at the surface of the barrier.

Mo-99/Tc-99m generator will be stored and eluted in the designated area. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0 mR/Hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2 mR/Hr to less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patients' well-being may be compromised. Under these circumstances the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0 mR/Hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM	PURPOSE
Warning tape, chalk, & signs	Posting of area
Plastic bags - small	Shoe covers, wet containers
Disposable gloves	Hand protection
Masking tape	Fasten shoe covers, etc.
Forceps, tongs	Safe handling
Large plastic bags	For contaminated material
Sponges, 4 x 4	Sopping up
Paper towels	Blotting & drying
Radiac wash or detergent	Detergent
Scouring powder	Friction
Tags	Identification
Scissors	Cut absorbent paper, etc.
Whatman #1 filter paper	Taking swipes following decontamination
Chux	Cover area following decontamination
G-M survey meter	Monitoring

Item #12: PERSONNEL TRAINING PROGRAM

Nuclear Medicine Technologist

These individuals will be registered or registry eligible technologists by their respective registry group at this time, ARPT or ASCP.

Clinical, Nursing, Housekeeping, Nuclear Medicine Technologist, and Security Personnel

These individuals will be required to attend lectures before assuming their duties with or in the vicinity of radioactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations or terms of the license. Lectures for presentation of this material will be two hours in duration. The training program will be of sufficient scope to insure that all personnel will receive proper instruction in the items specified in Section 1912 of 10 CFR, Part 19 and will include:

- A. Areas where radioactive material is used or stored
- B. Potential hazards associated with radioactive materials
- C. Radiological safety procedures appropriate to their respective duties
- D. Pertinent NRC Regulations
- E. The rules and regulations of the license
- F. The pertinent terms of the license
- G. Their obligation to report unsafe conditions
- H. Appropriate response to emergencies and unsafe conditions
- I. Their right to be informed of their radiation exposure and bio-assay results

Lectures will be given by the Nuclear Medicine Technologist, the Radiation safety Officer or a consulting physicist. Parts 19 and 20 of 10 CFR Regulatory Guide 10.8, Rev. , Dated , "A Guide for Preparation of Applications for Medical Programs" will be used as source material for these lectures.

Date: 4/25/85

Item #13: PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

1. The Chief Nuclear Medicine Technologist, Nuclear Medicine Physician, or their designee will place all orders for radioactive materials and will insure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
3. During off-duty hours, Security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in the following memorandum.

MEMORANDUM FOR
Security Personnel

FROM: Mike McGeehan, Director, Radiology Services
SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrive between 4:00 p.m. and 7:30 a.m. or on Saturday or Sunday shall be signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine Department. Unlock both doors and place the package on the work bench in the Hot Lab, and relock both doors.

If the package is wet or appears to be damaged, IMMEDIATELY contact the 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: Dr. Edward Stevens

OFFICE PHONE: 816-271-7558

HOME PHONE: 816-273-4953

Date: 4/25/85

Item #14: PROCEDURES FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIALS

Procedures For safely opening packages will be in accordance with Regulatory Guide 10.8, "A Guide for Preparation of Applications for Medical Programs," Rev. , Dated

APPENDIX F

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 10 Ci for Mo99 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 19 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

2

contamination exceeds 0.01 uCi/100 cm² 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 1m) 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 or seals on 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 amount² of removable radioactivity (e.g. $\mu\text{Ci}/100\text{ cm}^2$, 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" or a form containing the same information.

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

Date: 4/25/85

Item #15: LABORATORY RULES FOR USE OF RADIOACTIVE MATERIAL

We will follow the laboratory rules described in Regulatory Guide
10.8, Rev , Dated

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.

Date: 4/25/85

Item #15: EMERGENCY PROCEDURES

Emergency Procedures will be posted in all laboratory areas where radioactive materials are used. The Emergency Procedures in Appendix H of Regulatory Guide 10.8, Rev. , Dated , will be used for this purpose.

APPENDIX H

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: Dr. Edward Stevens

OFFICE PHONE: 816-271-7558

HOME PHONE: 816-279-4953

ALTERNATE NAMES AND TELEPHONE NUMBER DESIGNATED BY RADIATION
SAFETY OFFICER:

Cris Crandall (816-271-7558 work) (816-279-7127 home)

Mike McGeehan (816-271-7558 work) (816-279-5502 home)

Date: 4/25/85

Item #17: AREA SURVEY PROCEDURES

Area surveys will be done in accordance with Appendix I of Regulatory Guide 10.8, Rev. , Dated .

APPENDIX I

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 uCi) 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 cm² 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.

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

*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.

Date: 4/25/85

Item #18: WASTE DISPOSAL PROCEDURES

APPENDIX J

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

☒ In the sanitary sewer system in accordance with sect. 20.303 of 10 CFR Part 20.

☐ By commercial waste disposal service (see also Item 4)

☒ Other (Specify) (see Item 3) _____

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

☒ Returned to the manufacturer for disposal.

☒ 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).

☐ Other (specify) _____

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

☒ 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 Item 4)

☐ Other (specify) _____

4. The commercial waste disposal service used will be:

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 radionuclides. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

Date: 4/25/95

ALARA PROGRAM

The administration of Heartland Hospital West is committed to maintaining radiation exposures to employees as low as reasonably achievable (ALARA). This commitment applies not only to maintaining individual exposures ALARA, but also to maintaining the sum of the doses received by all individuals ALARA. This philosophy and our commitment to it will be maintained by the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). The RSC and The RSO will be responsible for maintaining a radiation safe (ALARA) environment within the hospital. The RSC will delegate sufficient authority to the RSO so that enforcement of the ALARA philosophy is not impaired. The RSC will support the RSO in those instances where it is necessary to assert authority until a formal RSC review has been held. The RSC review of the RSO's action will be maintained in the quarterly RSC minutes.

Administrative input and participation will be through an administrative appointment to the RSC. The RSC and RSO will perform/participate in the following items:

1. Perform an annual review of the radiation safety program. This review will include reviews of operating procedures, exposure histories, inspections, and consultations between the radiation protection staff and outside consultants. An evaluation will also be made of the institution's overall effort to maintain radiation exposures ALARA.
2. Modification of procedures, equipment, and facilities when such changes will significantly reduce radiation exposures unless the cost of such changes is unjustified.
3. Review the qualifications and proposed uses of radioactive material of each applicant to insure that exposures will be ALARA. This review should include reviewing the types and quantities of material to be used, operating procedures, and equipment (shields, gloves, etc).
4. Perform a quarterly review of occupational radiation exposures to assess trends in radiation exposures to personnel. Particular attention will be given to those instances where the levels outlined in Table I are exceeded. When the exposures are less than those of level I of Table I, no action is required.

When the exposure falls between level I and level II, the RSC will decide if a formal review of the exposure is needed. If the RSC deems a formal review necessary, the RSO will be responsible for seeing that this review is performed and that appropriate action is taken.

When the exposure exceeds level II, the RSO will be responsible for seeing that a formal review is performed and that appropriate action is carried out which will possibly

prevent the exposure from occurring in the future. The review and action will be presented at the next RSC meeting.

In those cases where the exposure levels cannot be reduced to less than level II limits, the RSC may establish levels higher than level II if it can demonstrate that good ALARA practices are being followed.

Table I

Investigational Levels - mRem
Per Calendar Quarter

	Level I -----	Level II -----
a. Whole body; head & trunk; active blood forming organs, lens of eyes, gonads	125	375
b. Hands and forearms, feet and ankles	1875	5625
c. Skin of whole body	750	2250

5. Encourage all users to review current procedures and develop new ones as appropriate to implement the ALARA philosophy.

6. The Radiation Safety Officer will be responsible for seeing that the following items are performed:

a. quarterly review of radiation level surveys. These must be reviewed with the ALARA philosophy in mind.

b. briefings and educational sessions are held for individuals "using or coming into contact with radioactive material." Participants will be instructed on the ALARA philosophy and informed that the administration, the RSC, and the RSO are committed to the concept.

c. investigations of known instances of deviation from good ALARA practices will be instituted. When the cause is known, the RSO will initiate changes which will maintain exposures ALARA.

There will be a cooperative effort between the RSC, the RSO, and radiation workers to participate in the formulation and institution of the ALARA philosophy. A procedure for receiving and evaluating suggestions from radiation workers will be instituted.

Persons authorized by the RSC to use radioactive material will consult with the RSO prior to initiating a new procedure. The user will also review all operating procedures prior to starting a

new project to insure that radiation exposures will be ALARA. The authorized user will also insure that everyone under his/her supervision is aware of the ALARA concept and is aware of how to safely use radioactive material.

HOSPITALIZED

IV: A Patients Treated with Group IV activities and isotopes will be handled in accordance with the procedures below.

- A. Patients treated with between 12 mCi and 30 mCi of I-131 will be placed in a private room that has a toilet.
- B. The patient's room must be properly posted (See attached form).
- C. Surveys of the area around the patient room will be taken as soon after administration as possible. Measure the exposure rate at patient's bedside, 3 feet from the patient and at the entrance to the patient's room. Also check the surrounding rooms. Length of time a person may remain at these positions will be determined by the Radiation Safety Officer or his designee.
- D. The Nursing Instruction Form will be completed immediately after administration of the treatment dose. A copy will be posted on the chart.
- E. All wastes, i.e. disposable plates, cup, dressings, tissues will be placed in special containers. This material will be picked up daily by the Radiation Safety Officer or his designee. The material will be disposed of as normal trash.
- F. 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.
- G. Nurses should spend only that amount of time deemed necessary for ordinary patient care. Please note any special restrictions on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Nursing personnel who attend the patient will wear personal monitoring devices as advised by the Radiation Safety Officer. If any questions call the Nuclear Medicine Department or the Radiation Safety Officer.
- H. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet from the patient. Patients containing radioactive material are to be confined to their rooms except for special medical or nursing proposed approved by the Nuclear Medicine Department.
- I. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands after removing gloves. Leave gloves in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

- J. Disposable items should be used in the care of these patients whenever possible. These items should be placed in designated waste containers. All clothes and bed linen used by the patient should be placed in the laundry bag and should be left in the patient's room. All nondisposable items should be placed in a plastic bag and should be left in the patient's room.
- K. Surgical dressing should be changed only as directed by the physician. Discard only into plastic bags and turn over to the Radiation Safety Officer or his designee. Handle these dressings with tongs or tweezers. Wear disposable gloves.
- 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 adjacent area to the room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water several times.

Item #19: Form D

Radiation Hazard Evaluation Form
(to be filled out by Radiation Safety Officer for his use)

Name _____ Date _____

Time of Death _____

Radioisotope _____

Amount administered _____

Route of administration _____

Amount present _____

Distribution within body _____

Indicate Distances _____

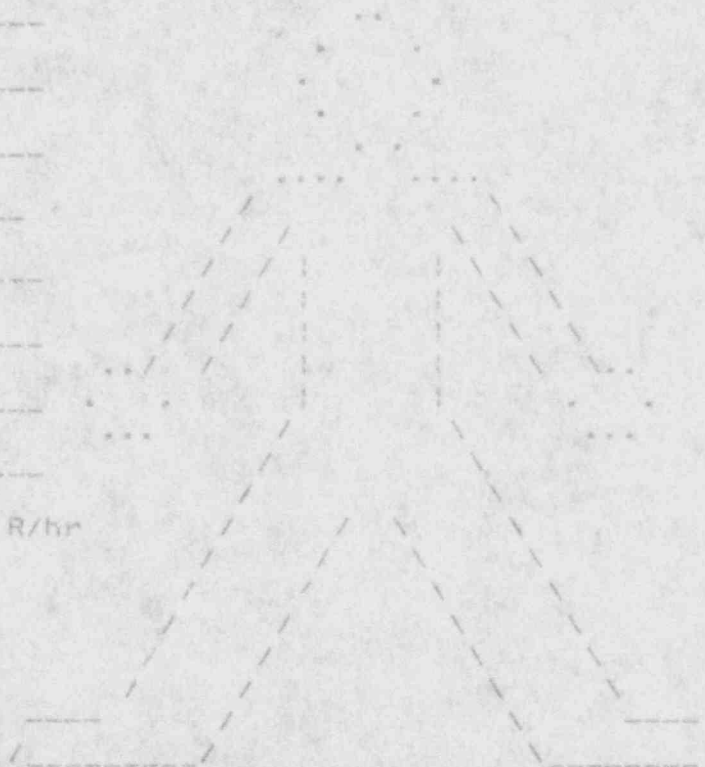
Suggest ring badges if exposure 0.25 R/hr

@ 25 cm. See NCRP #37 p. 27.

Limit hand exposure to 1.5 Rems.

Date of Survey _____

Instrument Used _____



Signed _____
Radiation Safety Officer

Date _____

G. Radiation safety precautions for therapeutic use of I-125 seeds

General

1. Personnel who prepare, insert or retrieve I-125 seeds shall wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.
2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.
3. In transporting seeds from storage/preparation areas to the place of use, adequate shielding must be employed to insure compliance with 10 CFR 20.105(b).

Instructions to Nurses (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.
2. Handle dislodged seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.
3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee.

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

5. No special precautions are needed for sputum, vomitus, stool, dishes, instruments, or utensils unless specifically ordered.

6. Urine should be collected and surveyed by the Radiation Safety Officer or his designee to insure no seeds have been excreted.

7. The Foley catheter should be surveyed by the Radiation Safety Officer or his designee after removal from the patient to insure no seeds have become lodged in it.

8. Emergency Procedures

- a) If a seed becomes loose or dislodged from the patient, on _____
- b) If the patient dies, on _____
- c) If the patient requires emergency surgery, immediately call _____
Telephone No. _____ (Days)
Telephone No. _____ (Nights)

9. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

Xe-133 Supplement

1. Quantities to be used:
 - a. 5 patients per week
 - b. 10 mCi/patient
 - c. possession limit: 1 Ci
2. Use and storage area:

Please see the attached diagram of the nuclear medicine area. The area has a hot lab which will house the Xe-133 trap when it is not being used.
3. Ventilation information:
 - a. Hot Lab: The hot lab has 230 CFM exhaust and 125 CFM supply
 - b. Imaging area: The imaging area has 525 CFM supply and 650 CFM exhaust.
 - c. Thyroid/Cold Lab: This area has 630 CFM exhaust and 610 CFM supply.
 - d. Ventilation Summary: Supply 1260 CFM; Exhaust 1510 CFM
 - e. The exhausted air from nuclear medicine is combined in a larger exhaust system which is vented on the top of the building. The exhaust rate of the system is not known exactly, so we will assume that it is equal to only the air exhausted from Nuclear Medicine. The system exhaust fan is located near the exhaust vent so that there is a negative pressure throughout the system. The nearest air intake vent is approximately 100 feet away.
 - f. Air flow rates will be insured by semi-annual preventive maintenance checks performed by the hospital engineering department or an outside consultant.
4. Procedures for routine use:

An Atomic Development Xe-133 delivery/trap system will be used. Procedures for its use will be as indicated in the instrument manual. In addition, patients will breathe through a face mask to prevent the accidental loss of Xe-133. For patients that cannot be fitted with a face mask a nose clamp will be used to prevent exhaling into the room.
5. Emergency Procedures:

In the event of an accidental release of Xe-133 into the room, proceed as follows:

 - a. Procure the low level survey meter, evacuate the area, and insure that all access doors to the area are closed (the low level survey meter shall be on hand and available as part of the equipment necessary while performing Xe-133 procedures).
 - b. Wait 30 minutes and resurvey the area. The room area must return to background levels before work may be resumed.

B. Air concentration of Xe-133

a. Restricted area:

1. Quantities to be used

- (a) 5 patients per week
- (b) 10 mCi per patient ⁴
- (c) 50 mCi/week = 5.0×10^{-5} uCi/week

$$2. \quad v = \frac{A \times f}{C}$$

$$= \frac{(5.0 \times 10^{-5} \text{ uCi/week})(.2)}{1 \times 10^{-5} \text{ uCi/ml}} = 1.00 \times 10^{-9} \text{ ml/week}$$

The required ventilation rate is

$$\frac{1.00 \times 10^{-9} \text{ ml/week} \times 1 \text{ CFM}}{40 \text{ hrs/week} \times 1.7 \times 10^{-6} \text{ ml/hr}} = 14.7 \text{ CFM}$$

The ventilation rate from the nuclear medicine scanning room greatly exceeds the required value.

b. Unrestricted area: From the table in Appendix M. 6 (a-5) it can be seen that the exhaust rate on the roof (1510 CFM minimum) greatly exceeds the volume needed to dilute any Xe-133 that is lost from the patients/trap in nuclear medicine.

7. The Charcoal trap will be monitored monthly to insure that it is trapping at least 80% efficiently. This determination will be made by (1) measuring the radiation level at the intake port of the charcoal trap, (2) taking a subsequent reading at the exhaust port of the trap and (3) comparing the two readings to insure that the exhaust port reading does not exceed 20% of the intake reading. If the exhaust reading exceeds 20%, the trap will be replaced.

Saturated filters will be handled and replaced in the hot lab area using the manufacturer's suggested methods. Ample lead shielding is available for storing the charcoal filters until they decay to background. The individual removing the filters will use lead gloves and wear a lead apron. The filters will be placed in a double plastic bag and sealed. After decay to background levels the filters will be monitored and disposed of as normal trash.

Miscellaneous Information

1. St. Joseph's Hospital and Methodist Hospital in St. Joseph, Missouri have combined. The new name for Methodist Hospital is Heartland Hospital West.

2. With the merger of the two facilities an effort is going to be made to utilize the hot lab facility at Heartland Hospital West. This facility will prepare kit material and ship it to the East facility in either unit doses or bulk dose. The utilization of a single hot lab facility will substantially reduce the cost between the two hospitals. A letter from the Administrator at the East and West facilities agreeing to this procedure is enclosed.

The initial plan is to have the Heartland Hospital West supply Heartland Hospital East Nuclear Medicine Department with unit doses in a syringe ready to inject. Any kit prepared material licensed under Group II might be transferred from the West facility to the East facility. In addition, long-lived materials such as ^{133}Xe , ^{90}Yb , ^{67}Ga , ^{111}In , etc. might be transferred. The activity per syringe to be transferred will depend on the normal prescribed dose at the East facility. There will be no Group VI transfers between these hospitals.

The procedure for initiating a transfer is for the Nuclear Medicine Technologist at the Heartland Hospital East to call the Heartland Hospital West Nuclear Medicine Department with the doses needed at that time. The technologist at the West facility will then draw up the doses, assay them in the dose calibrator, and place them in individual unit dose shields obtained from Syncor International in Kansas City. The unit doses/shields will be placed in a metal ammunition box which has been labeled that it is containing radioactive materials. There will also be a label placed on the box indicating the material shipped and the activities of each. A radiation survey will be performed at the surface of the container and at three feet. In addition, the outside of the ammunition carrier will be wipe tested and the wipe test counted on the thin end window GM probe. The ammunition carrier(s) will be placed in the trunk of the transporting vehicle. The placement in the trunk is to prevent any unauthorized removal from the vehicle. When the material is received at the Heartland Hospital East Nuclear Medicine Department, the material will be checked for correctness (compound/activity). In addition, a radiation survey will be performed at the surface and at three feet from the container. A wipe test will be performed on the final source containers. After the unit dose shields are removed from the ammunition carrier, a radiation survey will be performed on the carrier to insure that it is not contaminated. If the ordered material was received and the radiation/wipe tests do not reveal any contamination, the transporting vehicle will not be surveyed. If contamination is found on the material or if the received material does not coincide with what was ordered, the vehicle will be surveyed.

The Heartland Hospitals will employ a shared Nuclear Medicine Technologist. The individual will be a certified Nuclear Medicine Technologist. It will be his/her responsibility to transport the material from the West facility to the East facility. This individual will receive training in accordance with 10 CFR 19.12 and decontamination procedures to be followed in event of spills.

Safety procedures to be followed include having a decontamination kit in the transporting vehicle, having a notice on the dash board of the car informing personnel that radioactive material is contained in the trunk. This notice will indicate who to call in the event of an accident and give a description of the material being transported (unit dose, diagnostic quantity, etc.). The decontamination kit will include gloves, booties, radiation material tape, a cleaning solution, plastic bags, a low level thin end window GM survey meter, and paper tow.

In the event of an accident, the Nuclear Medicine Technologist will use the low level survey meter to determine whether or not the radioactive material has spilled or become lost. If it has been determined that a spill has occurred, the decontamination kit will be used to contain and clean up the material. The Nuclear Medicine Technologist will call the department supervisor at Heartland Hospital West to inform him of the accident.

RECEIVED

CONTROL NO. 79080