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

Liberty Memorial Hospital
2525 Glen Hendron Drive
Liberty, MO 64086

TELEPHONE NO.: AREA CODE (816) 781 7200

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. Steve Smith

TELEPHONE NO.: AREA CODE (816) 781 7200

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 24-16178-01

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.)*

Larry Nussbaum, 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	As needed
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	2.5 Ci
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	150

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

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
Cs-137 (NES-356, NEN)	Sealed Source	200 uCi	Dose calibrator accuracy

170.11(a)(9)
FEE EXEMPT #16

Applicant Apr 25 JH
~~Check No.~~ EX
Amount Fee Category 7C
Type of Fee Rem
~~Date Check~~ Rec'd 4/16/85
Received By

FORM NRC-313M
(8-78)

8506040414 850510
REG3 LIC30
24-16178-01 PDR

CONTROL NO. 78674

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)*
X Names and Specialties Attached; and	X Appendix G Rules Followed; or
X Duties as in Appendix B; or *(Check One)*	Equivalent Rules Attached
Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	X Appendix H Procedures Followed; or
X Supplements A & B Attached for Each Individual User; and	Equivalent Procedures Attached
X Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	X Appendix I Procedures Followed; or
X Appendix C Form Attached; or	Equivalent Procedures Attached
List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	X Appendix J Form Attached; or
X Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	Equivalent Information Attached
Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
X Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	X Appendix K Procedures Followed; or
Equivalent Procedures Attached	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
X Description and Diagram Attached	X Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	X Appendix L Procedures Followed; or *(Check One)*
X 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)
X Detailed Information Attached	X 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**
	Detailed Information Attached
X Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
Equivalent Procedures Attached	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY:
Not Applicable - City Hospital

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Joseph W. Crossett

(1) NAME *(Type or Print)*
Joseph W. Crossett

(2) TITLE
Assistant Administrator

c. DATE
April 4, 1985

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LICENSE REQUIREMENTS SUMMARY

I. Radiation Safety Committee: This committee should meet on a semi-annual or quarterly basis. If this is an NRC license, the requirement is quarterly, if it is a Kansas license, it should be on a semi-annual basis. The committee membership should be comprised of individuals from Radiology, Nuclear Medicine, Administration, Nursing, and Radiation Safety. Other members might include representatives from Clinical Lab, Interanl Medicine, Radiation Therapy, or Hematology. The primary responsibilities of the Committee would be to review the exposure reports, physicist reports, analyze any accidents or misadministrations, and perform the annual ALARA review required by the licensing agent.

II. Dose calibrator checks

A. A daily dose calibrator check must be performed with the Cs-137 source and Co-57 source. The results should be within ±5% of the true source activities. In addition to checking the calibration settings for Co-57 and Cs-137, the isotopes which are routinely used in this department must also be checked using the Cs-137 source. A sample dose calibrator sheet is attached.

B. On a quarterly basis the dose calibrator linearity and accuracy must be checked. The data for performing the dose calibrator linearity test is collected by the technologist. The results are analyzed and reviewed by the radiation physicist. The accuracy test is performed by the radiation physicist at his quarterly visit.

C. A dose calibrator geometrical variation check is performed by the radiation physicist at his initial visit and any time the dose calibrator has been sent in for repair.

III. Safety in Nuclear Medicine: The items listed below must be available and used routinely by personnel working in Nuclear Medicine and handling the radiation sources.

A. Disposable gloves
B. Syringe shields
C. Lead vial shields
D. Tongs and forceps
E. Lead shielding
F. Absorbent paper
G. Survey meters

The Nuclear Medicine/Hot Lab area will be used for the receipt, storage, and preparation of radioactive materials. The radioactive material will be stored in shielded areas to reduce the radiation exposure to personnel and patients.

Whenever the Nuclear Medicine Department is closed, the room should be locked and keys made available to those personnel authorized by the Radiation Safety Committee.

During elution the eluate must be collected, assayed, and stored in the lead vial shield. After eluting the generator, a Mo-99 breakthrough test must be performed on the material. The elution vial will be placed in the Moly breakthrough shield and assayed. The results must be recorded in uCi of Mo. After measuring the amount of Moly breakthrough, the concentration of Mo-99 to Tc-99 must be determined. The maximum allowable concentration is 1 uCi of Mo/mCi of Tc. In addition, no more than 5 uCi of Mo may be administered to a patient.

Syringe shields must be used whenever possible. The shields will be used in drawing up the doses and administration to the patient.

Protective outer garments, such as laboratory coats and rubber gloves, must be worn while handling radioactive materials in uncontained form.

Whenever possible work will be performed over absorbent paper which can be easily cleaned up. All trays and other work areas will be covered.

Film badges should be worn whenever handling radioactive materials. During the elution/kit preparation/patient injection ring badges should be worn. Care should be taken not to contaminate the exposure devices. The badges should be left in the department when leaving at the end of the day.

IV. Personnel Training Program: Individuals who work around radioactive materials or patients who have been administered radioactive materials must be presented an annual inservice covering the following:

A. Areas where radioactive material is used and stored

B. Potential hazards associated with radioactive materials

C. Radiation safety procedures appropriate to the respective duties

D. Pertinent NRC/Kansas regulations

E. The rules and regulations of the license

F. Pertinent terms of the license

G. Employee obligations to report unsafe conditions

H. Appropriate responses to emergencies and unsafe conditions

I. Employee right to be informed of their radiation exposure and bio-assay results

Lectures covering the various above will be given by a nuclear medicine technologist, a radiation safety officer, the Radiology Department Chairman, or the consulting physicist. A video tape covering the various Nuclear Medicine and Therapy procedures is available for review by the employees. On an annual basis the radiation physicist will present an inservice.

V. Procedures for Ordering and Receiving Radioactive Materials: The nuclear medicine technologist, nuclear medicine physician, or the RSO designate will place all orders for radioactive materials. Prior to ordering the material you should insure that the requested material and quantities are authorized by the license.

During normal working hours, the material will be delivered to the Nuclear Medicine Department. During off-duty hours, Security or Nursing will accept delivery of the radioactive materials and have them delivered to the Nuclear Medicine Department.

If the package appears to be wet or damaged, the Radiation Safety Officer should be contacted immediately.

All radioactive packages must be checked and surveyed upon arrival. The following procedure must be used:

A. Gloves should be worn to prevent contaminating the hands.

B. Inspect the package for any signs of damage (wetness, crushed, etc.) If damage is noted, stop the procedure and notify the Radiation Safety Officer.

C. Measure the radiation exposure rate at 3' from the package surface.

D. Measure the radiation exposure rate at the surface of the package. The 3' and surface rate must be recorded.

E. Open the package and verify that the isotope and activity is correct. Check to insure that the final source container has not been damaged.

F. Wipe the external surface of the final source container and assay it in the logic well counter. Readings which are twice background must be considered contaminated and further radiation studies performed on the package.

G. Perform a radiation survey on the packing material to make sure that the material is not contaminated. If the packing material is not contaminated, it must be discarded. A sample package recipt form is attached.

VI. Laboratory Rules for the safe use of radioactive materials and emergency procedures to be followed in the event of spills are posted in the Nuclear Medicine Department.

VII. Radiation Surveys

A. A daily radiation survey must be performed in the generator elution, kit preparation, and patient injection areas. The low level survey meter must be used for this.

B. Laboratory areas where only small quantities of radioactive materials are used must be surveyed monthly.

C. Waste storage area of the laboratory will be surveyed weekly.

D. A record must be kept of all survey results. The record will include:

1. The location, date, and identification of equipment used.
2. The name or initial of the person conducting the survey.
3. A drawing of the area surveyed identifying the relevant features of the area.
4. Measured exposure rates keyed to the location on the drawing.
5. The results of decontamination if the initial survey found levels above background.

VIII. Waste Disposal Procedure

Liquid radioactive waste can be disposed of into the sanitary sewer system in accordance with section 28-35-224 of the Kansas Radiation Protection Regulations. The concentration limits specified in this section must not be exceeded. In addition, no more than 1 curie per year can be disposed of into the sanitary sewer system.

The generators can be either returned to the manufacturer or held for decay until background levels are achieved.

Syringes, vials, and other waste generated during the operation of the Nuclear Medicine Department must be held for decay. The waste material must be held for a minimum of ten half lives. Prior to disposal of the waste materials, it must be surveyed with the low level survey meter. If radiation levels are found which exceed background levels, the material must be held for further decay. At the time of disposal, the container radiation level, the background radiation level, the type of waste being dispposed of, and the name of the individual disposing of the material must be recorded. A sample disposal form is attached.

IX. Xenon 133 Procedures

The ventilation in Nuclear Medicine is checked on a semi-annual basis. The ventilation system must provide a negative pressure in the Nuclear Medicine Department so that if Xe-133 is lost in the trap or the patient, it will be exhausted into the atmosphere.

If an accidental loss of xenon should occur, whether from a patient or the trap breaking down, the low level survey meter

should be secured. In addition, the area should be evacuated. Insure that all doors to the area are closed and controlled so that personnel cannot enter the area. You shuld wait 30 minutes to resurvey the Nuclear Medicine Department. If the radiation level has not returned to background, the room should not be used. Wait an additional 30, minutes and resurvey the area.

ALARA PROGRAM

The administration of Liberty Memorial Hospital 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 quantitites 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 eneded. 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 occurrring 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.

Date: 2/1/85

CONTROL NO. 78674

Item #7: **MEDICAL ISOTOPES COMMITTEE**

Committee Members:

Member	Specialty
Emmett K. Burke, M.D.	Internal Medicine
Larry Nussbaum, M.D., RSO	Radiology
Robert McNaughton, M.D.	Radiology
Richard Morrison, M.D.	Radiation Therapist
Steve Smith	Radiology
Emory Larimore	Radiation Physicist
Agnes Norman	Nursing
Joe Crossett	Administration

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

Date: 2/1/85

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 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, recomendations, 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
Larry Nussbaum, M.D.	24-16178-01	I, II, III, IV, V, Xe-133
Robert McNaughton, M.D.	24-16178-01	I, II, III, IV, V, Xe-133
Patrick Hunt, M.D.	24-16178-01	I, II, III, I-131 for hyperthyroidism, cardiac dysfunction, thyroid carcinoma P-32, & Xe-133
Richard Morrison, M.D.	24-16178-01	VI
Nasser Nakissa, M.D.	26-16178-01	VI
Emmett Burke, M.D.	24-16178-01	I, II, III, Xe-133
Primall Gukhool, M.D.	24-16178-01	I, II, III, Invitro, Xe-133
John Delegiorges, M.D.	24-16178-01	P-32 for Diagnosis
John Hagen M.D.	24-16178-01	P-32 for Diagnosis
Eashwar K. Riddy, M.D.	24-16178-01	I-125 seeds for therapy

Date: 2/1/85

Item #9: Instrumentation

APPENDIX C

1. Survey Meters

   a. Manufacturer's name: Picker

      Manufacturer's model number: 655-186

      Number of instruments available: One

      Minimum range: 0 - .2 mr/hr to 0.2 mr/hr

      Maximum range: 0.0 mr/hr to 0 - 2000 mr/hr

   b. Manufacturer's name:

      Manufacturer's model number:

      Number of instruments available:

      Minimum range _____ mr/hr to _____ mr/hr

      Maximum range _____ mr/hr to _____ mr/hr

Date: 2/1/85

2. Dose Calibrator

Manufacturer's name: Picker

Manufacturer's model number:

Number of instruments available: One

3. Diagnostic Instruments

TYPE OF INSTRUMENT	MANUFACTURER'S NAME	MODEL NO.
Gamma Camera	Ohio Nuclear	Sigma 400
Gamma Camera	Ohio Nuclear	420
Computer	MDS	2600
Spectroscaler	Ludlum	
Uptake/Well System	Atomic Products	
Xe-133 Delivery/Trap	RADIX	VENTL-CON

4. Other

Date: 2/1/85

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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 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% of the calculated or known values for each point checked. Readings are within ± 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.

_X_ 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

_X_ have been approved by KANSAS and are on file in License 33-B429-01.

___ are attached

Date: 2/1/85

Item #10: CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

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

_X_ Other* (specify) _#D Below_

B. Sources Used for Instrument Accuracy and Constancy Tests:

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

C. _X_ 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. _X_ 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 calicheck 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: 2/1/85

CALIBRATION OF INSTRUMENTS

APPENDIX D

Section 1

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INDLUDING 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 ± 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.

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% 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.

Alternaively, 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 manufacurer 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 then 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 uCi 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 caluclations and the ± 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 ± 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

1. 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 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

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

e. The activities plotted should be within ± 5% of the calculated activity if the instrument is linear and functioning properly. Errors greater than ± 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 fators 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 ± 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:

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 amy 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 applicatin the three sources that you will use. State nulcide, 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% 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% 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

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 patinet 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 of 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.

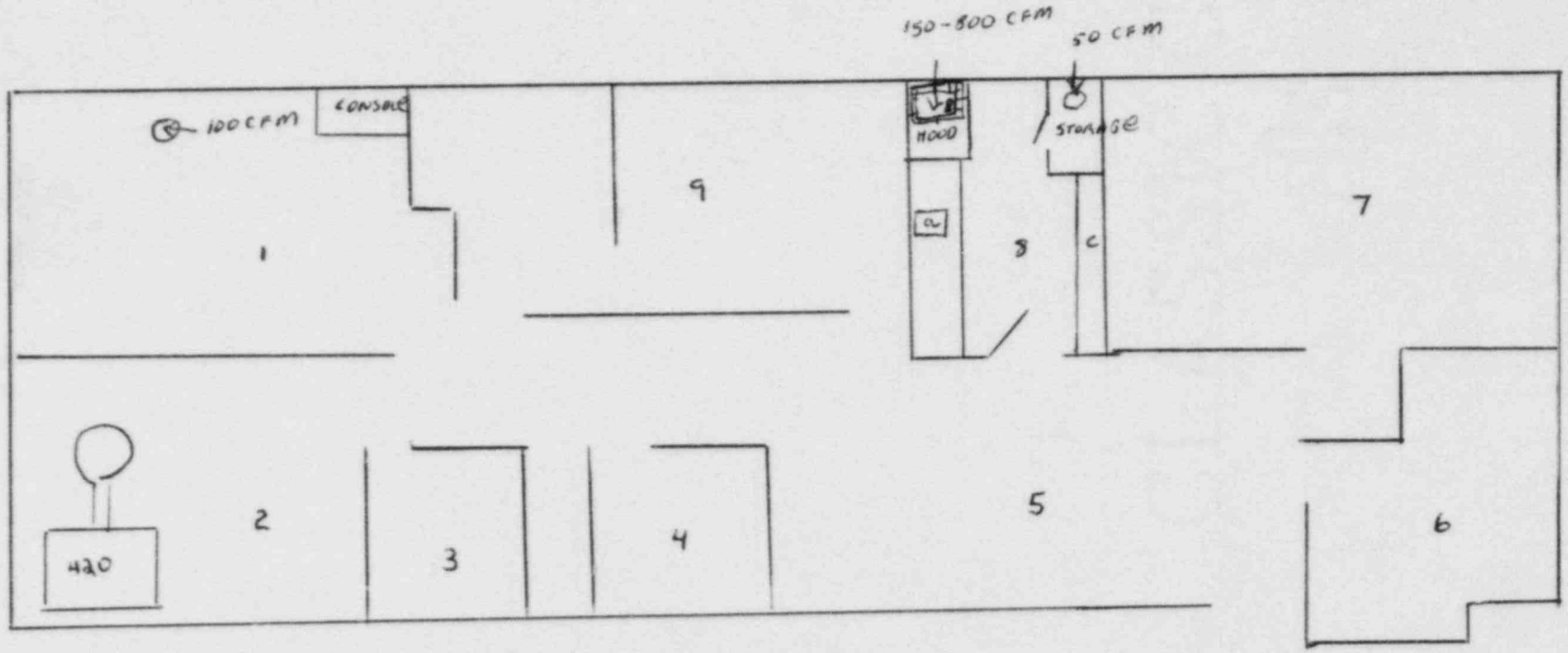
All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbant paper.

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

NUCLEAR MEDICINE DEPT.
LIBERTY MEMORIAL HOSPITAL
LIBERTY, MO 64068



CONTROL NO. 78674

1. SCAN Rm #1
2. SCAN Rm #2
3. Xe SYSTEM STORAGE
4. STORAGE / COMPUTER ROOM
5. RECEPTION AREA
6. UPTAKE ROOM
7. LASER ROOM
8. HOT LAB
9. EEG

a. DOSE CALIBRATOR
B. GENERATOR / BACK STORAGE
C. WORK AREA

3/27/85

Item #12: **PERSONNEL TRAINING PROGRAM**

Nuclear Medicine Technologist

These individuals will be registered or registry elegible 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: 2/1/85

Item #13: PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

1. The Chief Nuclear Medicine Technologist or Nuclear Medicine Physician 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, the Nursing Supervisor will accept delivery of radioactive packages in accordance with the procedures outlined in the following memorandum.

MEMORANDUM FOR NURSING

FROM: Larry Nussbaum, M.D.
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 Nursing Supervisor on duty and taken immediately to the Nuclear Medicine Department. Unlock the door and place the package on the work bench in the Hot Lab, and relock the door.

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: Larry Nussbaum, M.D.

OFFICE PHONE: 816-781-7200

HOME PHONE: 816-381-8718

Date: 2/1/85

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 quantitiy 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 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 regualtions if removable contamination exceeds 0.01 uCi/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 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 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. uCi/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" or a form containing the same information.

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

Date: 2/1/85

Item #15: ABORATORY 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: 2/1/85

Item #16: **EMERGENCY PROCEDURES**

Emergency Procedures will be posted in all laboatory 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: Larry Nussbaum, M.D.

OFFICE PHONE: 816-781-7200

HOME PHONE: 816-381-8718

ALTERNATE NAMES AND TELEPHONE NUMBER DESIGNATED BY RADIATION SAFETY OFFICER:

Mr. Steve Smith 816-781-7200 (work) 816-781-684 (Home)

Date: 2/1/85

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 quantitites 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 mesure 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.

Date: 2/1/85

Item #18: WASTE DISPOSAL PROCEDURES

APPENDIX J

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

_X__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)

_X__Other (Specify) (see Item 3)_____

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

_X__Returned to the manuracturer 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).

____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 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 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.

Date: 2/1/85

CONTROL NO. 78674

Item #19: **THERAPEUTIC USE OF RADIOPHARMACEUTICALS**

APPENDIX K

I. Patients treated with Group V activities will be handled in accordance with the procedures described in Appendix K of Regulatory Guide 10.8, Rev. , Dated 1980.

A. 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.

B. The patient's room will be properly posted or attended in accordance with sects. 20.203 or 20.204 of 10 CFR part 20.

C. 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.

D. 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, a copy of this form is enclosed.

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

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

G. 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.

H. 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.

I. Urine and vomits from I-131 therapy patients will not be collected. Patients will be insrtucted to use tha sanitary sewer system.

J. 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.

K. Nursing Instructions

1. 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.

2. 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.

3. 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.

4. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Depar+ment.

5. 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.

6. 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 them 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.

7. 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.

8. 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.

9. 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.

10. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture would may stain the dressings dark read 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.

11. For I-131 patients:

(a) 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.

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

(c) 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. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(d) Keep all contaminated wastes 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)

12. 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.

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

14. 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.

L. 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 restriced and unrestricted areas ALARA.

II. Miscellaneous information

A. Method for preparation and administration of therapeutic doses of Iodine-131. Therapeutic doses of I-131 will be ordered from reputable suppliers and received precalibrated, ready for dispensing to patients. These materials will be stored until time for use in the isotope storage area behind sufficient shielding to reduce the radiation levels to 2.0 mR/Hr at a distance where occupational workers can conveniently stand. All liquid sources will be opened in a fume hood with the fan activated. Patients requiring therapeutic amounts of I-131 less than 30 mCi will be dosed in the Nuclear Medicine Department, held for observation and sent home or to their room. Hospitalized patients receiving greater than 30 mCi will be dosed in their rooms.

B. Only patients treated with greater than 12 mCi I-131* or 23 mCi Au-198* who require hospitalization will be placed in a private room with a toilet. Attempts will be made to use a corner room in a low traffic section of hallway.

C. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will 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 Nuclear Medicine Department. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

D. Instructions for Patient & Family - Patient will not be discharged from the hospital until the residual radioactivity reaches 30 mCi. This will be determined by taking measurements at 3 feet from the patient from the time the activity is administered until the radiation level reaches a radiation level proportional to 30 mCi. For some patients the determination of 30 mCi will be made by direct measurement of urinary excretion (uCi/ml + decay.)

1) The patient will be instructed not to have intimate contact with his/her spouse for a period of 2 weeks.

2) The patient will be instructed to wash his hands and bathe frequently.

3) The patient will be instructed not to prepare food for other people for a period of 2 weeks.

4) Other restrictions may be specified by the physician.

All restrictions will be removed when the activity reduces to a point that will result in no greater than 0.5R to persons in the family from that point until total decay. For I-131, that will be the time where the radioactivity in the thyroid gland reaches 8 mCi. An effective half life of 6 days will be used for this computation. For Au-198, those values will be 23 mCi. An effective half life of 65 hours will be used for this computation.

III. GUIDELINES FOR EMERGENCY SURGERY OR DEATH OF THE RADIOACTIVE PATIENT

In most hospitals, deceased patients with large amounts of radionuclides will be encountered only rarely, since in principle, radionuclide therapy is not given to moribund patients. If several days intervene between treatment and subsequent surgery or

death, the radiation hazard is usually considerably reduced. In most hospitals, the number of patients receiving large internal doses of radionuclides in any one week is small. The need for emergency surgery would not be usual, nor would the death of one of these patients.

The identification of a particular patient as radioactive is the responsibility of the physician in charge of the case. The radioactive patient shall be properly identified at all times. If a radioactive patient dies in the hospital, the physician who pronounces him dead should be responsible for attaching a radioactivity precautions tags to the body. The physician in charge of the case and the Radiation Protection Officer shall be notified at once.

In general bodies containing less than 5 mCi need no precautions for any type of handling. Those containing between 5 and 30 mCi may be buried or cremated with no preparation or embalmed according to standard injection procedures without special precautions. If the body is to be subjected to autopsy, the Radiation Safety Officer will designate any special precautions. The body containing more than 30 mCi can be buried or cremated with no preparation, but if embalming is to be carried out, it should be with the guidance of a Radiation Safety Officer. Among patients that die outside the hospital, the funeral director will seldom encounter bodies with hazardous exposure rates.

A. **Preparation for Burial or Cremation Without Autopsy:**

Consider first the cases in which no autopsy is to be performed and the body need not be opened. Embalming will be by the injection method, and the likelihood of contamination of the embalmer is small. Nevertheless, even in these cases, rubber gloves shall be worn by all who are involved in the procedures in order to avoid the possibility of contamination by radioactive fluids from the body. The exposure rate at about 25 cm from the center of the radioactive material should be measured. If this is less than 0.25 R/h, no further precautions are necessary as far at the gamma radiations are concerned. Item #19, Form C and D will be completed.

B. **Radioactive Iodine, I-131, Administered Orally or Intravenously; No Autopsy**

If a 100 mCi dose of I-131 is administered in the treatment of thyroid disease, within an hour after a patient has received this dose, measurements with an ionization chamber type survey meter taken one hour after the administration may be expected to indicate a surface exposure rate over the abdomen on the order of 0.3 mR/h. During the first 24 hours after administration of I-131, the blood and urine may contain considerable radioactivity. These fluids should accordingly be removed into closed systems and later flushed directly into the sewer, followed by an adequate volume of water.

The day after administration, the general distribution of radiation is greatly modified, both by urinary excretion of a large part of the radionuclide and by concentration of the remaining part in functioning thyroid tissue. At this time only radiation from these regions of iodine storage need be considered. Any region of high activity which is not to be removed should be marked by the Radiation Protection Officer so that it can be avoided.

C. **Any Radionuclide Injected Interstitially or in Seeds: No Autopsy**

Various colloidal radioactive preparations may be injected interstitially into tumors. Radon seeds, radioactive gold wires, radium wires, and other preparations may be implanted in limited regions. If the nuclide emits only beta rays, it is unlikely that there will be any appreciable external irradiation. If it is a gamma emitter, the active tissues may be extirpated or the region can be identified and avoided.

D. **Body to be Opened for Surgery or Autopsy**

The usual precautions for preventing the spread of an infectious material should aid in keeping the radioactive material localized. At autopsy the general prinicple is to remove the main source of radiation hazard as early as possible, without causing general contamination. At surgery this cannot usually be done, hence regions of high activity should be avoided or shielded. Item #19, Form D and E will be completed.

As long as the body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when the operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Beta radiation is readily absorbed by material interposed between its source and the operator. Even rubber gloves are useful in this regard. The gamma rays are not absorbed appreciably by rubber gloves.

E. **Any radionuclide in a Body Cavity Which is to be Opened**

The Radiation Protection Officer will evaluate the radiation hazard and suggest suitable procedures regarding the safety of personnel during the entire operation.

1. Autopsy

As much body fluid as possible should be removed before the body is opened. The remaining radioactive material may be expected to be widely distributed over the surfaces of the cavity and of the organs within it. The use of bare hands will not be permitted because of the contamination of skin and nails that would results and the difficulty of complete removal of such contamination.

Monitoring the body after removal of the viscera may indicate a radiation level low enough so that subsequent procedures can be carried out without special precautions. Regions of high activity, if present, can be indicated and avoided or approached with precautions. If the removed organs are to be disected immediately, each one should be monitored and treated in accordance with the findings. After desired small samples

have been taken, the radioactive tissues that are to be retained should immediately beplaced in appropriately shielded vessels for storage, or for disposal according to procedures approved by the Radiation Protection Officer. Where adequate cold storage facilities are available, the organs may be stored for several days without significant alteration, or the viscera may be fixed. This would allow for the natural decay of the radioactivity reducing possible exposure.

2. Emergency Surgery
If surgery must be carried out within a highly radioactive cavity, speed is desirable. Accordingly, an experienced surgeon should perform the operation. The surgeon and his assistants should wear gloves and glasses or goggles for the protection ofthe eyes from possible splaxhing of foreigh material, as well as from beta radiation.

F. **Radioactive Iodine-131 Orally or Intravenously Administered**

1. Autopsy
Urine should be drained away and blood disposed of, if possible, in the same manner as if no autopsy were to be performed.

2. Surgery
Precautions are essentially the same as for autopsy. During the first day after administration, the blood may be expected to contain considerable radioactivity, and care should be taken not to let it accumulate on gloves or gowns. After the first day, the circulating radioiodine has greatly decreased and regions of high activity can be identified and usually avoided.

G. **Interstitial Implants and Colloidal Interstitial Infiltration**

At surgery or autopsy these regions can be readily identified and avoided as far as possible. At autopsy, if the entire block of tissue containing the radionuclide can be removed readily, this should be done first. If only a sample of the treated region is to be taken, this part of the body should be avoided until the rest of the autopsy has been carried out.

H. **Accident or Injury During Surgery or Autopsy**

If an injury occurs during surgery or autopsy, where the rubber gloves are cut or torn, radioactivity may be introduced into the wound. In addition to ordinary treatment of the wound, the Radiation Protection Officer shall be consulted with regard to any possible radiation hazard.

IV. 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 designtated 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.

V. Summary

In general, the most procedures performed in Nuclear Medicine involve the use of Technetium 99m. Due to this radionuclide's short half-life, six hours, a period of 24 hours should reduce even the highest dose encountered in Nuclear Medicine to a safe level. Most other procedures generally encountered in Nuclear Medicine involving nuclides other than Technetium 99m require doses of 5 mCi or less. As indicated in the opening paragraph, activities at this level require little or no special procedures. Those situations involving special precautions and procedures are generally limited to quantities of radioactivity introduced into the patient during therapy treatment. The Radiation Protection Officer should be consulted to establish proper precautions and procedures for each individual case.

Item #19: Form D

Radiation Hazard Evaluation From
(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 _____

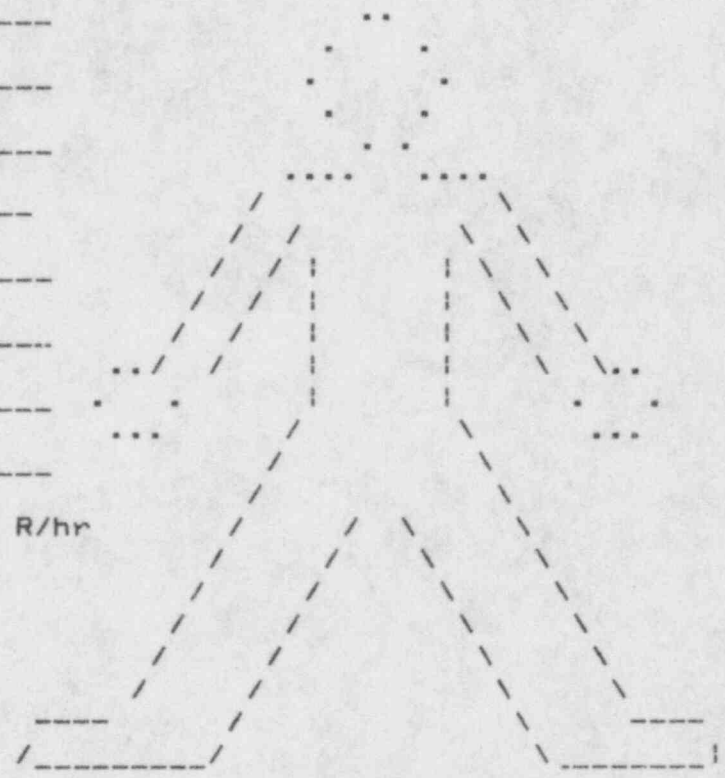
_____

_____

_____

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 _____

Item #19: Form E

Specific Instructions for Autopsy

(To be filled out by Radiation Safety Officer)

The following procedures should be followed if so indicated:

( ) Wear safety glasses.

( ) Wear plastic (non-absorbant) gown.

( ) Cover floor with bench liner.

( ) Wear double thickness autopsy gloves.

( ) Wear whole body film badge.

( ) Wear ring badge.

( ) Remove the _____area or tissue first before proceding further. Identify it as radioactive.

( ) Leave the _____area or tissue untouched until last.

( ) Cover the _____ area or tissue with shielding as provided.

( ) Use only long instruments - 8" or greater.

( ) Fluids, blood, urine should be removed via closed system. Flush with copious amounts of water.

( ) Small specimens need -- need not -- be handled with special precautions.

( ) Waste container needs to be provided for contaminated sponges, gowns, and instruments.

( ) Organs are to be kept in storage for _____days before fixation.

Autopsy performed by _____

Patient name _____

Whole body or ring badge number _____

Exposure _____

Signed _____
Radiation Safety Officer

Date _____

THIS REPORT MUST BE SAVED!

OMB NO. 0074

Item #19: Form F

INSTRUCTIONS FOR FAMILY OR RELEASED PATIENT

Name of Patient_____
Name of Hospital _____ Address _____Tel.No._____
For further information contact _____Tel.No._____

Please show this form to every physician consulted concerning the patient until _____(date)

_____was treated on _____, 19____.
(Name of patient)
with _____millicures of _____in the form of _____.

NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY AFTER _____.
(date)

UNTIL THAT DATE:

Persons under 45 years of age should not remain closer than the following distances from the patient, for the time period indicated:

a)_____ to _____
(date) (date)
Permissible distance _____ feet or more, for _____hours/week.
(At other times remain farther than 6 feet.)

Note: During the above times brief periods of closer contact (for example, while shaking hands, or kissing the patient) are permissible.

SPECIAL PRECAUTIONS:

a) Spouse or the person caring for patient:_____

_____

_____

b) Children or pregnant women:_____

_____

_____

c) Sleeping arrangements: _____

_____

_____

IF THE PATIENT IS TO BE HOSPITALIZED OR IF DEATH SHOULD OCCUR, NOTIFY THE FOLLOSING INDIVIDUAL(S) IMMEDIATELY:

_____

_____

A COPY OF THIS FORM SHOULD BE KEPT IN THE PATIENT'S RECORD.

Item #20: Therapeutic Use of Sealed Sources

I. Cs-137 & Ir-192

A. We request a waiver to 10 CFR 35.14 to receive Group VI sealed sources from the Radiarium for treatment only. No sealed sources will be permanently stored at our institution. The Radiarium is located at 17525 Medical Center Parkway, Independence, MO 64057. The Radiarium license has been amended to allow use of Group VI material at our facility.

B. Special precautions will be used while handling sealed sources. With the exception of permanent implants, all sealed sources will be handled using after-loading techniques. Appropriate forceps and handling techniques will be utilized to take advantage of inverse square law relationships. All preparations of sources for transport to bedside, surgery or the treatment room will be performed at The Radiarium.

C. TLD ring badges will be provided to all personnel handling sealed sources in order to monitor the radiation dose to their extremities. Normally, only personnel associated with The Radiarium will be handling the sources. Nursing personnel assigned to the care of the brachytherapy patient will be provided film badges, in order to monitor whole body dose.

D. Equipment and shielding are available for transporting sources from the storage site to the place of use. Sources will be transferred from The Radiarium by Dr. Richard A. Morrison or Dr. Nasser Nakissa. Cs sources will be transported in a Heyman source carrier with the thickness of 2.3cm lead on all sides. Ir-192 ribbons will be transported in the original shipping container.

E. Source accountability will be the responsibility primarily of personnel associated with The Radiarium. However, once Dr. Morrison has placed the sources in the hospitalized patient (except for permanent implants), this institution assumes temporary custody of the sources. The nurse in charge of caring for the patient at the time the sources are implanted will receipt for those sources at that time. During this period of temporary custody, this institution and its personnel have the responsibility to secure against unauthorized removal of the brachytherapy sources. At the conclusion of treatment this hospital will require Dr. Morrison or his designee to document that all temporary sources have been removed from the patient and returned to The Radiarium.

F. A survey of the patient's room and sourrounding areas will be conducted by Dr. Morrison or his designee as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, 3 feet (or 1 meter) from the patient, 3 feet (or 1 meter) from the bed and at the entrance to the room. Dr. Morrison 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 meter) from the

patient on the patient's chart. At the conclusion of treatment, a survey will be performed by Dr. Morrison or his designee to ensure that all sources have been removed from the patient, and that no sources remain in the patient's room or any other area occupied by the patient. A source count will be taken at this time, and all radiation signs will be removed and all film badges and TLD badges assigned to nurses will be collected.

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

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

I. 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.

J. 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, i.e., 2 m Rems in any one hour or 100 mRems in any 7 consecutive days.

K. Instructions to nurses

1. 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.

2. 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.

3. 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.

4. Pregnant nurses should not be assigned to the personal care of these pateints.

5. 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.

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

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

8. Surgical dressings and badges 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. Emergency Procedures

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

(b) If the patient dies, or

(c) If the patient requires emergency surgery, immediately call _____
Telephone # (days)_____
(nights)_____

16. 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 prmanent 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.

L. The radiation survey/wipe test procedures listed in our/ license application for Nuclear Medicine sources will not be followed for the Group VI sources. The physician transporting the sources from the Radiarium to Liberty Memorial Hospital will have with him a form which lists the number of seeds being delivered and the activity of the sources. Upon arrival at the hospital, a nursing supervisor will sign the receipt form indicating that the sources were received. At the conclusion of the treatment, the sources will be removed from the patient and placed in the lead carrier. A nursing supervisor will sign the receipt/disposition form to indicate that the sources had been removed. After removal of the sources from the patient, a radiation survey will be performed in the patient area to insure that all of the sources had been removed. A copy of this form will be sent to Nuclear Medicine.

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

A. 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 survery

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).

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, stools, 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, or
b) If the patient dies, or
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.

SUPPORTING DOCUMENTATION FOR 133-XENON USE

Liberty Memorial Hospital
Liberty, Missouri

A. Quantities to be Used

1. Number of patients to be studied: 5 studies per week
   Dose per patient: 10 millicuries

2. Possession limit: 100 millicuries

B. Use and Storage Area

1. Please see attached sketch of the Nuclear Medicine Department for the air flow information.

2. There is a 100 CFM exhaust vent in Scan Room #1. This room will be used for the performance of xenon ventilation studies. There is no supply air in this room.

   The Hot Lab has two exhaust vents. One of these is a 50 CFM exhaust. The other is the fume hood which constantly pulls 150 CFM. During Xe-133 exams the exhaust fan on the hood is increased to 800 CFM by activating an emergency switch. This switch would be activated if an accidental loss of xenon should occur in the Nuclear Medicine Department. There are no supply vents in the Hot Lab.

   The diagram of Nuclear Medicine indicates all of the supply and exhaust vents in the area. This is a dedicated exhaust system which vents above the roof level of the hospital. There are no air intake vents in the vicinity of the exhaust. There are no return air grills in the Nuclear Medicine Department.

   The xenon trap will be stored in room #3 when not being used. This room has a 60 CFM exhaust vent. There are no supply vents in this room.

   During normal operation, the exhaust above the roof level is 605 CFM. During ventilation studies this rate would increase to 1405 CFM.

3. Air flow rates will be maintained as specified by semi-annual checks performed by the hospital engineering department.

C. Procedures for Routine Use

1. Xe-133 will be purchased in unit dose vials. The Xe-133 will be introduced into the Radx-Ventil-Con system. The patient breathes air from the Ventil-Con. Expired air is stored in the Ventil-Con until the exam is completed at which time the unit is capped and moved to the Hot Lab. A flexible tube is connected to the Ventil-Con exhaust port and the open end placed in the fume hood. The unit is set to exhaust mode and the Xe-133 is exhausted from the unit.

2. The patient will have his nose clamped during the procedure. If the patient cannot have his nose clamped, a nose and mouth mask will be used. Prior to moving the Ventil-Con to the Hot Lab for exhausting, the unit will be capped to prevent leakage.

3. Prior to initiating a procedure, the fume hood high speed fan will be turned on. The fan will remain on until the Xe-133 has been exhausted from the Ventil-Con.

D. Emergency Procedures

In case of accidental release of Xenon-133 into the Nuclear Medicine area, proceed as follows:

1. Procure survey meter and evacuate the area. Insure that the access door to the Nuclear Medicine laboratory is closed. The low level survey meter shall be on hand and available as part of the equipment necessary while doing Xenon-133 procedures.

2. Wait 30 minutes, survey area. Room air must have returned to background levels before room amy be entered for routine work. This 30-minute period is based on room volume and the amount of air being supplied and exhausted by the normal ventilation system.

E. Air Concentration of Xenon-133 in Restricted Areas

1. 50 mCi per week

2. 20%

3.a Imaging Area

a. Xe-133 will be used in the imaging area. This area has an exhaust rate of 100 CFM and no supply. Exhaust from this area is tied into the exhaust from the Hot Lab.

b. For restricted areas, Section 20.103 of 10 CFR, Part 20, requires that:

$$\frac{A}{V} \times F \leq 1 \times 10^{-5} \text{ uCi/ml}$$

c. Sample problem for restricted area:

(1) $$A = \frac{10 \text{ mCi}}{\text{pt}} \times \frac{5 \text{ pt}}{\text{week}} \times \frac{10^3 \text{ uCi}}{\text{mCi}} = 5 \times 10^4 \text{ uCi/week}$$

(2) 20% loss (f)

$$V = \frac{A \times f}{1 \times 10^{-5} \frac{\text{uCi}}{\text{ml}}} = \frac{5 \times 10^4 \text{uCi/wk} \times .2}{1 \times 10^{-5} \text{ uCi/ml}} = 1 \times 10^9 \text{ ml/wk}$$

Required ventilation rate is:

$$\frac{1 \times 10^9 \text{ml/wk}}{40 \text{ hrs/wk}} \times \frac{1}{1.76 \times 10^6 \frac{\text{CFM}}{\text{ml/hr}}} = 14.2 \text{ CFM}$$

Ventilation rate as stated in 3.a a meets the requirements of Section 20.103 of 10 CFR, Part 20.

3.b Hot Lab

a. Xe-133 will be exhausted through the fume hood located in the Hot Lab. The total exhaust from the Hot Lab is 850 CFM.

b. For restricted areas, Section 20.103 of 10 CFR, Part 20, requires that:

$$\frac{A}{V} \times F \leq 1 \times 10^{-5} \text{ uCi/ml}$$

c. Sample problem:

(1) $A = \frac{10 \text{ mCi}}{\text{pt}} \times 5 \text{ pt/wk} \times 10^{3} \text{uCi/mCi} = 5 \times 10^{4} \text{ uCi/wk}$

(2) 20% loss

$$V = \frac{A \times f}{1 \times 10^{-5} \text{ uCi/ml}} = \frac{5 \times 10^{4} \text{ uCi/wk} \times .2}{1 \times 10^{-5} \text{ uCi/ml}} = 1 \times 10^{9} \text{ ml/wk}$$

The required ventilation rate is:

$$\frac{1 \times 10^{9} \text{ ml/wk}}{40 \text{ hrs/wk}} \times \frac{1}{1.76 \times 10^{6} \frac{\text{CFM}}{\text{ml/hr}}} = 14.2 \text{ CFM}$$

Ventilation rate stated in 3.b a. meets the requirements of Section 20.103 of 10 CFR, Part 20.

F. Xe-133 Disposal

Expired air containing Xe-133 will be stored in the Radx-Ventil-Con unit until the exam is completed. The unit is then capped and moved into the Hot Lab where the Xe-133 is exhausted through the fume hood. The Xe-133 is exhausted into an uncontrolled area (on top of the hospital) at the rate of 1405 CFM. It is assumed that the entire 50 mCi per week is lost to this uncontrolled area. From Regulation Guide 10.8, Appendix M, the 1405 CFM exahust is more than acceptable for keeping the Xe-133 concentration below 3×10^{-7} uCi/ml in an uncontrolled area.