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.*

Check No. 03645
Amount $380
Fee Category 1C
Type of Fee Ren
Date Check Rec'd. 10/16/87
Date Completed 10/16/87
By: [illegible]

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
St. Mary's Hospital of Blue Springs 201 West R.D. Mize Road Blue Springs, MO 64015 TELEPHONE NO.: AREA CODE (816) 228 - 5900	Same
2. PERSON TO CONTACT REGARDING THIS APPLICATION Joseph Goetz, M.D. RSO TELEPHONE NO.: AREA CODE (816) 228 - 5900	**3. THIS IS AN APPLICATION FOR:** *(Check appropriate item)* a. ☐ NEW LICENSE b. ☐ AMENDMENT TO LICENSE NO. c. ☒ RENEWAL OF LICENSE NO. 24-20274-01
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.)* Joseph Goetz, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	3.0 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		

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	250

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	SEaled Source	.2	Dose calibrator check
Ba-133	SEaled Source	.250	Dose calibrator check
Gd-153	Sealed Source	2 Ci	Bone mineral anal.

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REGION III

FORM NRC-313M (8-78)

CONTROL NO. 84312

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
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	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	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
Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
X Equivalent Procedures Attached	Detailed Information Attached

CONTROL NO 8431 2

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: St. Mary's Hospital of Blue Springs

MAILING ADDRESS: 201 W. R.D. Mize Road

CITY: Blue Springs | STATE: MO | ZIP CODE: 64015

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: 7C

(2) LICENSE FEE ENCLOSED: $ 550.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X

(1) NAME *(Type or Print)*

X Gary Wages

(2) TITLE

X Rec Director

c. DATE

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Minutes

The minutes of each Radiation Safety Committee Meeting must include:

a. the date of the meeting;

b. the members present;

c. the members absent;

d. summary of the deliberations and discussions;

e. recommended actions and numerical results of all ballots; and

f. ALARA program reviews described in Part 35.20 (c).

CONTROL NO. 84312

APPENDIX B

RADIATION SAFETY OFFICER

Responsibility

The Radiation Safety Officer shall be responsible for implementing the radiation safety program at the facility. The Radiation Safety Officer's responsibility will be to insure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements during the daily operation of the licensee's radioactive materials program.

Duties

The RSO shall:

1. Investigate overexposures, accidents, spills, loses, thefts, unauthorized receipts, uses, transfers, disposal, misadministrations, and other deviations from approved radiation safety practices and imolement corrective action when necessary.

2. Establish, collect, and implement written policy and procedures for

   a. authorizing the purchase of byproduct material;

   b. receiving and opening packages of byproduct material;

   c. storing byproduct material;

   d. keeping an inventory record of by product material;

   e. using byproduct material safety;

   f. taking emergency action if control of byproduct material is lost;

   g. performing periodic radiation surveys;

   h. performing checks of survey instruments and other safety equipment;

   i. disposing of byproduct material;

   j. training personnel who work in or frequent areas where byproduct material is used or stored;

   k. keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

3. Brief management once each year on the byproduct material program.

4. Establish personnel exposure investigational levels that when exceeded, will initiate an investigation.

5. Assist the Radiation Safety Committee in its performance of its duties.

Authority

A licensee (hospital) shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

a. identify radiation safety problems;

b. initiate, recommend, or provide corrective actions; and

c. verify implementation of the corrective actions.

Date: 8/22/87

Item #15: LABORATORY RULES FOR USE OF RADIOACTIVE MATERIAL

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

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure before leaving the area, or at least daily.

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: 8/22/87

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: Dr. Joseph Goetz

OFFICE PHONE: 816-226-5900

HOME PHONE: "will be supplied to hospital"

ALTERNATE NAMES AND TELEPHONE NUMBER DESIGNATED BY RADIATION SAFETY OFFICER:

Date: 8/22/87

Item #17: AREA SURVEY PROCEDURES

Area surveys will be done in accordance with Appendix I below.

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 measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 2000 dpm per 100 cm^2 for the contaminant involved (200 dpm for I-131). 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.

   g. Radiation and wipe test trigger levels.

6. Area will be cleaned if the contamination level exceeds 2000 dpm/100 cm^2.

7. Trigger levels will be established for the radiation surveys and wipe tests. The individual performing the surveys will notify the Radiation Safety Officer immediately if the dose rate or contamination levels exceed the trigger levels.

*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: 8/22/87

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) held for decay*

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

_X__Returned to the manufacturer for disposal.

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

____Disposed of by commercial waste disposal service (see also Item 4).

____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). Material must be held for at least ten (10) half-lives.

*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: 8/22/87

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 prccedure 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

ALARA PROGRAM

The administration of St. Mary's Hospital of Blue Springs 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

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.

Xe-133 Supplement

1. Quantities to be used:
   a. 7 patients per week
   b. 10 mCi/patient
   c. possession limit: 250 mCi

2. Use and storage area:
   Please see the attached diagram of the nuclear medicine area. The area has a hot lab which will house the Xe-133 trap when it is not being used.

3. Ventilation information:
   a. Hot Lab: The hot lab has 450 CFM exhaust and 400 CPM supply.

   b. Imaging area: The imaging area has 440 CFM supply and 490 CFM exhaust.

   c. The exhausted air from nuclear medicine is combined in a larger exhaust system which is vented on the top of the building. The exhaust rate of the system is 7700 CFM. The system exhaust fan is located near the exhaust vent so that there is a negative pressure throughout the system. The nearest air intake vent is approximately 100 feet away.

   d. Air flow rates will be insured by semi-annual preventive maintenance checks performed by the hospital engineering department.

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

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

   a. Procure the low level survey meter, evacuate the area, and insure that all access doors to the area are closed (the low level survey meter shall be on hand and available as part of the equipment necessary while performing Xe-133 procedures).

   b. Wait 45 minutes and resurvey the area. The room area must return to background levels before work may be resumed.

8. The Nuclear Medicine Lab is considered a restricted area. The maximum permissible concentration in a restricted area is 1×10^{-5} uCi/ml. Based on this concentration, the room clearance time in the event of an accidental release of a unit dose of Xenon is shown below. The estimated clearance time is 37.6 minutes. The area will be evacuated for at least 45 minutes. Upon re-entering the room the low level survey meter will be utilized to ensure that the radiation levels have returned to background. If levels exceeding background are encountered, the room will again be evacuated and allowed to clear for one clearance time (45 minutes). This procedure will be repeated until the radiation levels in the room have returned to background levels.

6. Air concentration of Xe-133

a. Restricted area:

1. Quantities to be used
   (a) 7 patients per week
   (b) 10 mCi per patient
   (c) 70 mCi/week = 7.0×10^{4} uCi/week

2. $V = \frac{Q \times f}{c}$

$$= \frac{(7.0 \times 10^{4}\ \text{uCi/week})(.2)}{1 \times 10^{-5}\ \text{uCi/ml}} = 1.4 \times 10^{9}\ \text{ml/week}$$

The required ventilation rate is

$$\frac{1.4 \times 10^{9}\ \text{ml/week}}{40\ \text{hrs/week}} \times \frac{1\ \text{CFM}}{1.7 \times 10^{6}\ \text{ml/hr}} = 20.6\ \text{CFM}$$

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

b. Unrestricted area: From the table in Appendix M, 6.(a-5) it can be seen that the exhaust rate on the roof (7700 CFM) greatly exceeds the volume needed to dilute any Xe-133 that is lost from the patients/trap in nuclear medicine.

7. The charcoal trap will be monitored on a monthly basis to ensure that the trap is working properly. The effluent from the trap during one patient study will be collected in a plastic bag. The bag will then be placed in front of the gamma camera which has been peaked for counting Xenon-133. The results of the check will be recorded. The record will include the date, background counts per minute, and bag counts per minute.

The results of the monthly check will be compared to the data collected from previous checks. If a significant increase is found in the bag counts per minute, further investigation will be performed. If it is determined by the Radiation Safety Officer that the trap is breaki g down, it will be replaced.

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

Item #7: MEDICAL ISOTOPES COMMITTEE

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

1. the Radiation Safety Officer,

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

3. an authorized user for each type of use permitted by the license, and

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

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC. The license will not be amended each time the committee membership changes.

Date: 8/22/87

APPENDIX A

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.

3. In order to conduct business a quorum of at least one half of the committee's membership must be present. This must include the Radiation Safety Officer and the representative from management.

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 prior to submitting the names to the NRC for approval and amendments.

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.

10. Review for approval or disapproval minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Part 35.31.

11. Review on a quarterly basis a summary of the occupational radiation dose records of all personnel working with byproduct material.

12. Review quarterly with the assistance of the RSO all incidents involving byproduct material with respect to the cause and subsequent actions taken.

13. Maintain minutes of each Radiation Safety Committee Meeting. The minutes must include the date of the meeting, members present, members absent, recommended actions and the numerical results of all ballots, and the ALARA program reviews.

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.

Authority

A licensee (hospital) shall provide the Radiation Safety Committee sufficient authority, organizational freedom, and management prerogative to:

a. identify radiation safety problems;

b. initiate, recommend, or provide corrective actions; and

c. verify implementation of the corrective actions.

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 below.

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.

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 below.

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 instructed to use the 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 Department.

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)

Item #13: 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!

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.

E. Radiation safety instructions shall be presented to all personnel caring for patients receiving radiopharmaceutical therapy. The instructions will include:

1) patient control;

2) visitor control;

3) contamination control;

4) waste control; and

5) notification of the RSO in case of the patient's death or medical emergency.

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.

i. 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 replaced 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 splashing of foreign 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 I-131 will be handled in accordance with the procedures below.

A. Inpatients 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.

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 desigree. 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 desigree immediately. This person should remain in an adjacent area to the room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water several times.

Item #19: Form 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 #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 _____

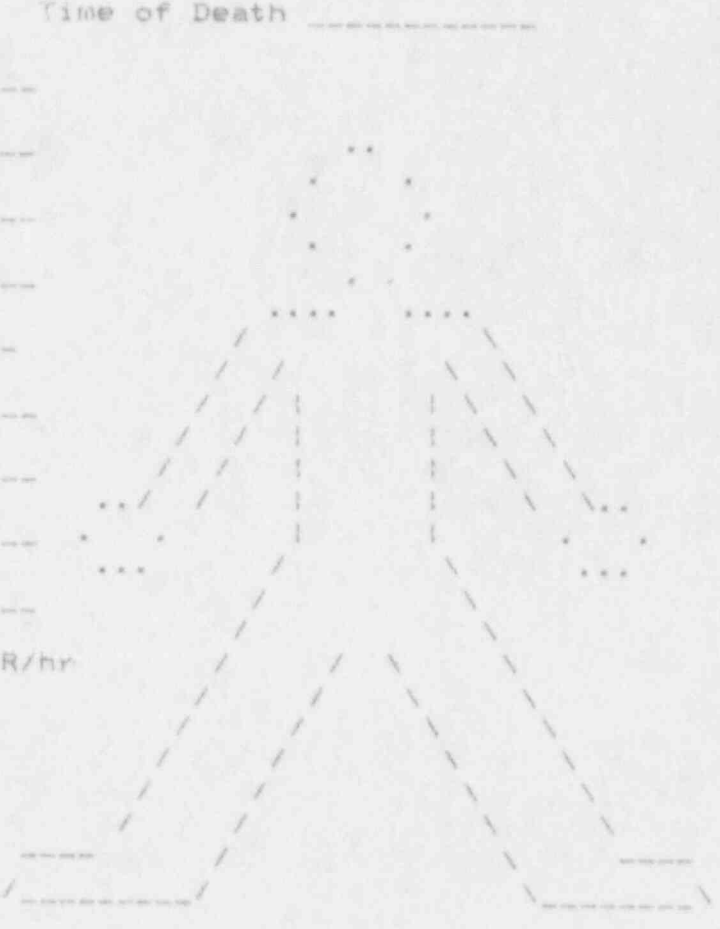
_____

_____

_____

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 _____

LICENSING INFORMATION FOR USE OF A GD-153 BONE MINERAL DENSITOMETER

1. Source: Gd-153 (See attachment for specific source details)

2. Manufacturer: Lunar Corporation / Norland Corporation (See general information below)

3. General Information

We wish to amend the license to authorize the use of Gd-153 to be used in a Lunar Radiation Corporation or Norland Corporation Bone orptionmeter System. We request approval for the specific sources listed on the attached information sheet or their equivalents as new sources are approved.

The material will be used in the Department of Nuclear Medicine. A diagram showing where the bone mineral densitometer system will be located is attached. The use of the material will be under the supervision of the physicians indicated in Item #4.

Except during source changes, the radioactive sources will be in the absorptionmenter system. The Gd-153 source is inside a lead lined source holder, Lunar Model A-SRC-0100-0 or Norland Corporation source holder (#N1081). Prior to installation, the source will be stored in its orignal shipping container in the Hot Lab area. There are no changes in the radiation detection instruments from those currently authorized, calibration services, personnel monitoring devices, or the radiation safety program which was outlined in the Radioactive Materials License application.

The procedures for source exchange will be explained and demonstrated during a two-day, on-site installation and training program. The program will be presented by a factory representative. This program will include instruction in installation of the sources, proter interpretation and use of the instrumentation, and any safety precautions which are necessary in its normal operation. The procedure for wipe testing the sources will also be explained and demonstrated by factory representatives. In addition, the physicisans responsible for the use and interpretati n of the system will recieve instruction at another institution which has been involved in the acquisition and interpretation of bone mineral data.

The area where the bone mineral analyzer will be placed will be posted with a sign bearing the standard radiation caution symbol and the words, "Caution Radioactive Materials."

In the event of an emergency, the Radiation Safety Officer will be notified immediately. The phone number of the Radiation Safety Officer and the alternative individual will be posted in the examining room.

The depleted sealed sources will be returned to the manufacturer for disposal. The depleted sources will be returned in the shipping container in which the new source was delivered. The manufacturer will be notified of the shipment and the anticipated delivery date.

LICENSING INFORMATION FOR USE OF A GD-153 BONE MINERAL DENSITOMETER

1. Source: Gd-153 (See attachment for specific source details)

2. Manufacturer: Lunar Corporation / Norland Corporation (See general information below)

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In the event of an emergency, the Radiation Safety Officer will be notified immediately. The phone number of the Radiation Safety Officer and the alternative individual will be posted in the examining room.

The depleted sealed sources will be returned to the manufacturer for disposal. The depleted sources will be returned in the shipping container in which the new source was delivered. The manufacturer will be notified of the shipment and the anticipated delivery date.

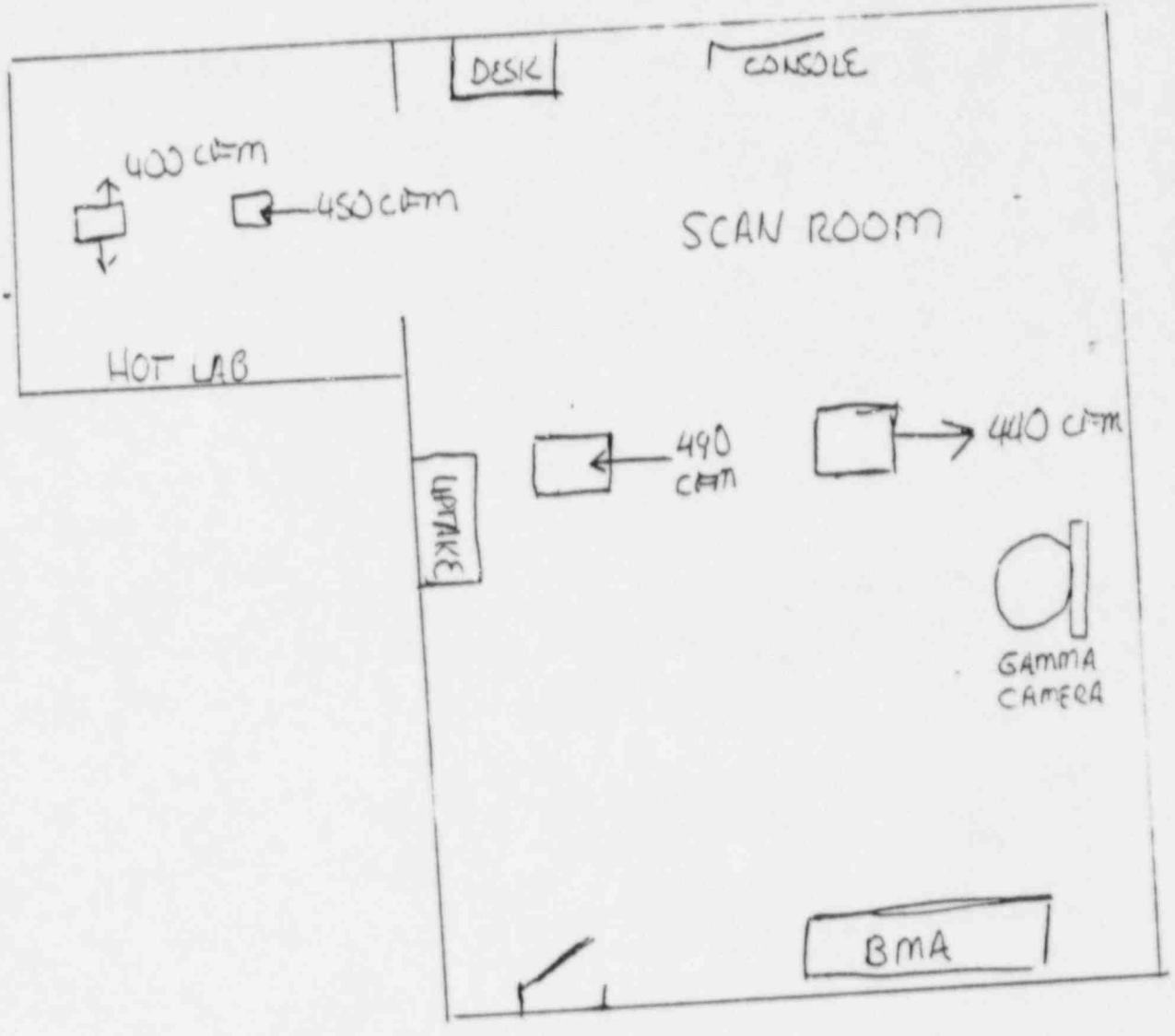
In the event that the manufacturer is no longer in business or for some other reason cannot accept the source, the depleted source will be stored in our Hot Lab. It will remain in the Hot Lab for a minimum of ten half lives. After this period the sources will be surveyed to insure that they have decayed to background levels with a low level survey meter. If the source has decayed to background levels the background level, source level, and date of disposal will be recorded.

4. Users: All physicians listed on the License who are licensed for Groups II & III.

Element and Mass Number	Chemical and/or Physical Form	Manufacturer and Model Number	Amount
Gd-153	GdO 2 Sealed Source	Gulf Nuclear, Webster, TX GD Series Sources New Eng. Nuclear #NER-430;or approved equivalent	1000 mCi each 1300 mCi total

SOURCE	DEVICE	NRC Device Registration
Gd-153	LUNAR DP3/4	NR-430-D-101-S (Gulf Nuclear GD1)
Gd-153	LUNAR DP3/4	NR-476-S-153-S (NER-430)
Gd-153	NORLAND 2600	NR-482-D-103-S

St. Mary's Hospital
of Blue Springs
A living resource.



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A MEMBER OF THE SISTERS OF ST. MARY HEALTH CARE SYSTEM

CONTROL NO. 84312

Item #8: USERS' TRAINING AND EXPERIENCE

Name	Previous License Number	Authorized Uses
T. J. Fritzlen, M.D.	24-03026-01	As currently listed
M. H. Brown, M.D.	"	"
R. J. Meegan, M.D.	"	"
W. B. Davis, M.D.	"	"
D. G. Wood, M.D.	"	"
T. D. Kennedy, M.D.	"	"
R. Stephenson, M.D.	"	"
J. J. Goetz, M.D.	"	"
J. Cowan, M.D.	"	"
H. Cloogman, M.D.	"	"

Date: 8/22/87

Item #9: **Instrumentation**

APPENDIX C

1. Survey Meters

   a. Manufacturer's name: Victoreen

      Manufacturer's model number: 6B

      Number of instruments available: One

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

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

   b. Manufacturer's name: Ludlum

      Manufacturer's model number: 14C/44-7

      Number of instruments available: One

      Ranges:

      Minimum range 0 mr/hr to .2 mr/hr

      Maximum range 0 mr/hr to 2000 mr/hr

Date: 8/22/87

2. Dose Calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-5

Number of instruments available: One

3. Diagnostic Instruments

TYPE OF INSTRUMENT	MANUFACTURER'S NAME	MODEL NO.
Gamma Camera	Raytheon	
Uptake Probe	Ludlum	2600
Xe Trap/Delivery System	Atomic Products	Pulmonex

4. Other

Date: 8/22/87

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

_X_ 4. At the time of calibration the exposure rate from a dedicated check source will be determined. This exposure rate will be conspicuously noted on the instrument.

_X_ 5. The licensee shall check each survey instrument for proper operation with the dedicated check source each day of use.

_X_ 6. The survey instrument calibration certificate shall include the date of calibration, a description of the source used and the certified exposure rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the exposure rate from a dedicated source.

Date: 8/28.87

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 that may be Used for Instrument Accuracy and Constancy Tests:

Radionuclide	Activity (mCi)	Accuracy
57 Co	).05	± 5%
133 Ba	).05	± 5%
137 Cs	).05	± 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 lineator system. This system is available from Atomic Products. The manufacturer's instructions for use will be followed.

*Must be equivalent to the highest activity used.

Date: 8/22/87

APPENDIX D
Section 1

CALIBRATION OF INSTRUMENTS

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 20% 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.

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. After each maintenance and/or battery change.

2. On the day of instrument use.

   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, Ba-133, or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 100-250 uCi of Ba-133 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. The source activity will be greater than 50 uCi.

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. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

5. Variations greater than ± 10% from the predicted activity

indicate the need for instrument repair or adjustment.

6. 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 (usually 100 mCi to 10 uCi). 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 three or four times a day. Record the date, sample activity, background activity, sample time until the source decays to less than 10 uCi.

c. Use the beginning activity as measured on the second day as a starting point calculate the predicted activities at each of the measurement points.

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 ±10% of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±10% 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.

*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 10-20 cc vial containing 1 - 2 mCi of Tc-99 or other appropriate radionuclide in a small volume 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, 15, and 20 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 (usually 2 ml), 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.

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

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 Tc-99 in a syringe may be compared with that of 10 ml in a 20-cc vial, and a correction factor may be calculated.

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

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

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, such as Cs-137, 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 will be greater than 50 uCi. 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 ±10% 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 ± 10% 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.

Date: 9/22/87

Item #11: FACILITIES & EQUIPMENT

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

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

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

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

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

During elution, the eluate will be collected, assayed, and stored in a 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.

Each syringe shield shall be conspicuously marked with a label that shows the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

All vial shields must be labeled to indicate the pharmaceutical name or its abbreviation.

Item #12: PERSONNEL TRAINING PROGRAM

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. Ar opriate response to emergencies and unsafe conditions
I. [illegible] right to be informed of their radiation exposure and b 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: 8/22/87

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 x-ray technologist on duty will accept delivery of radioactive packages in accordance with the procedures outlined in the following memorandum.

MEMORANDUM FOR
X-ray Technologists

FROM: Dr. Joseph Goetz
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 x-ray technologist on duty and taken immediately to the Nuclear Medicine Department. Unlock both doors and place the package on the work bench in the Hot Lab, and relock both doors.

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

RADIATION SAFETY OFFICER: Joseph Goetz, M.D.

OFFICE PHONE: 228-5990

HOME PHONE: "will be supplied to hospital

Date: 8/22/87

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 compare with physician's written request.

Date: 8/22/87