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

Maui Memorial Hospital
Radioisotope Service
221 Mahalani St.
Wailuku, Maui, HI 96793
TELEPHONE NO.: AREA CODE (808) 244 - 9056

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Don Tolbert, Ph.D., C.R.P.
TELEPHONE NO.: AREA CODE (808) 536 - 2774

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 53-13519-01

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.)*

James Bendon, 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	0.200
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	5,000 Each
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	3 of each

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	60
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	50
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	X	300
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	300

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
Strontium 90	Sealed	150	Eye applicator for superficial disease.

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
( ) Names and Specialties Attached; and	( ) Appendix G Rules Followed; or
( ) Duties as in Appendix B; or *(Check One)*	(X) Equivalent Rules Attached
(X) Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE (See Item 4)	( ) Appendix H Procedures Followed; or
( ) Supplements A & B Attached for Each Individual User; and	(X) Equivalent Procedures Attached
( ) Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	( ) Appendix I Procedures Followed; or
( ) Appendix C Form Attached; or	(X) Equivalent Procedures Attached
(X) List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	( ) Appendix J Form Attached; or
( ) Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	(X) Equivalent Information Attached
( ) Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
( ) Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	( ) Appendix K Procedures Followed; or
(X) Equivalent Procedures Attached	(X) Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES** NA
(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** NA
	( ) 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	(X) Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	A supplier with Certificate	Monthly
	X	TLD	of Accreditation with the NBS	
		OTHER (Specify)	National Voluntary Laboratory	
b. FINGER		FILM	Accreditation Program will be	Monthly
	X	TLD	used for personnel monitoring	
		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: 7C

(2) LICENSE FEE ENCLOSED: $ Exempt

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*: Jerry Walker

(2) TITLE: Administrator

c. DATE: April 29, 1985

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INDIVIDUAL USERS

The following individuals will be Authorized Users. These are as per License No. 53-13519-01.

Eugene Wasson, III, M.D.	Groups I, II, III, IV and V In vitro studies Xenon 133 Strontium 90 ophthalmic applicator
James Bendon, M.D.	Groups I, II, and III In vitro studies Xenon 133
Thomas Abram, M.D.	Groups I, II, III Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, or thyroid carcinoma Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases In vitro studies Xenon 133
David Joseph Heeney, M.D.	Groups I, II, and III Iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, or thyroid carcinoma In vitro studies Xenon 133

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RADIATION SAFETY COMMITTEE

1. The Radiation Safety Committee is established by authority of Maui Memorial Hospital administration as the administrative body responsible for the safe use of radioisotopes within Maui Memorial Hospital.

2. The membership of the Radiation Safety Committee and their specialties satisfy the requirements of 10 CFR 35.11.

3. Committee responsibilities:

   a. To ensure that 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.

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

4. Committee duties:

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

   b. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, and physicists) 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;

   c. Establish a program to ensure that all radiation workers and all other 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 Section 19.12 of 10 CFR Part 19;

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

e. 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;

f. 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 management control system;

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

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

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

5. Meeting frequency:

a. The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

mR?

INSTRUMENTATION

1. Survey Meters

   A. Manufacturer's name: Picker Nuclear
   Manufacturer's model number: 535-186
   Number of instruments available: 1
   Minimum range: 0 to 0.2 mR/hr
   Maximum range: 0 to 2000 mR/hr

   B. Manufacturer's name: Victoreen Instrument Division
   Manufacturer's model number: 6A
   Number of instruments available: 1
   Minimum range: 0 to 300 cpm and 0 - 0.5 mR/hr
   Maximum range: 0 to 30,000 cpm and 0 - 50 mR/hr ← should be 1 R/hr ?

2. Dose Calibrator

   Manufacturer's name: Rad-X
   Manufacturer's model number:
   Number of instruments available: 1

3. Diagnostic Instruments

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	Siemens	ZLC 750S & Scintiview
Scintillation Camera	Siemens	Pho/Gamma IV
Gamma Well Counter	Searle	8725
Thyroid Uptake Probe	Searle	----
Automatic Well Counter	Abbott	----
Automatic Gamma Counter	Abbott	ANZR

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standards used?

geometrical variation test?

CALIBRATION OF INSTRUMENTS

1. Dose Calibrator

The dose calibrator will be checked daily for instrument constancy with a source of Cs-137. The Cs-137 will be used to check the automatic windows for I-131, Tc-99m, and Xe-133. Variations in output greater than 5%, when corrected for decay of the cesium, will be investigated immediately.

Prior to initial use and quarterly thereafter, the instrument shall be checked for linearity. Checks for linearity shall be made by assaying a vial of Tc-99m of activity at the maximum activity normally used, then reassaying the same vial at 6, 24, 30, and 48 hours after the initial assay. Instances where the measured activity is more than 5% different from the calibrated activity shall be investigated. Prior to initial use and annually thereafter, checks for accuracy shall be performed by Mid-Pacific Medical Physics according to the procedures outlined in License No. 53-23207-01.

2. Portable Survey Instruments

The portable survey instruments shall be checked weekly for constancy with the built-in check source and calibrated annually by Mid-Pacific Medical Physics. The calibration procedure used is on file under License No. 53-23207-01.

3. Bioassay Uptake System

At least annually or after repair, the uptake system used for bioassay measurements will be tested to assure a sensitivity of at least 0.04 uCi.

4. Records of Calibrations

Log books will be maintained on instrument calibrations listed in 3 above.

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FACILITIES AND EQUIPMENT

1. The floor plans for the nuclear medicine facility are shown in Figure 1. All radiopharmaceuticals will be received in the nuclear medicine facility, where they will be checked for leakage before being opened and stored.

2. The laboratory counter surfaces of the nuclear facility will be of nonabsorbent material, such as stainless steel or plastic laminate, and will be covered with disposable absorbent paper.

3. Isotopes will be stored in appropriately shielded and labeled storage areas. Sufficient shielding shall be provided so that the dose rate outside the storage locations does not exceed 2 mR/hr.

4. Xenon-133 gas will be administered to patients through an Atomic Products Corporation Pulmonex Xenon System. All vials containing Xe-133 for dispensing will be contained in lead shielded glass vials, and will be stored in the shielded storage area prior to use. Expired gases containing Xe-133 will be exhausted through the gas trap in the Pulmonex Xenon System.

5. The trap for Xe-133 will be tested weekly by exhausting 5 liters of air through the trap into a plastic bag and positioning the bag in the front of the scintillation camera. When a significant increase in counts is recorded for a two minute count time, the cartridge will be replaced.

6. It is estimated that as much as 10% of the administered xenon might leak during administration and storage of the charcoal trap. A maximum workload of two patients per week is estimated, with an administration of 20 mCi per patient. The required ventilation flow rate to insure airborne activity concentrations are not exceeded is

$$V = \frac{(40\ mCi/wk)\ (.1)\ (1000\ uCi/mCi)}{(1 \times 10E\text{-}5\ uCi/ml)\ (40\ hrs/wk)} \times \frac{\text{\_\_\_\_\_ cfm \_\_\_\_\_}}{1.7 \times 10E6\ ml/hr}$$

$$V = 5.9\ cfm$$

The air from the imaging room is exhausted directly to the environment, and is not mixed with any air returning to the hospital. The exhaust flow rate from the imaging room is 1067 cfm, well in excess of the required ventilation flow rate.

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7. Using the assumptions given above, the estimated concentration of the air at the exhaust from the roof is

$$C = A/V$$

$$A = \frac{2 \text{ patients}}{\text{week}} \times \frac{2 \text{ mCi}}{\text{patient}} \times \frac{1000 \text{ uCi}}{\text{mCi}} \times \frac{52 \text{ weeks}}{\text{year}}$$

$$A = 2.1 \times 10E5 \text{ uCi/year}$$

$$V = \frac{1067 \text{ cu.ft.}}{\text{min.}} \times \frac{1.49\ 10E10 \text{ ml/year}}{\text{cu.ft./min.}}$$

$$V = 1.59 \times 10E13 \text{ ml/year}$$

$$C = \frac{2.1 \times 10E5 \text{ uCi/year}}{1.59 \times 10E13 \text{ ml/year}}$$

$$C = 1.3 \times 10E-7 \text{ uCi/ml}$$

An additional dilution factor of 10 minimum is estimated because of mixing and dilution. The estimated concentration of 1.3 x 10E-9 uCi/ml supplied to unrestricted areas is well below the allowable concentration of 3 x 10E-7 uCi/ml.

8. Should there be a patient who accidently comes off the apparatus losing the entire dose, the following air concentrations will be present in the imaging room:

Assumptions:

20 mCi released as patient comes off apparatus
4028 cu.ft. room volume (19x26.5x8)
1067 cu.ft. per minute total exhaust rate

Immediate dilution:

$$\frac{20 \text{ mCi}}{4028 \text{ cu.ft}} \times \frac{3.5 \text{ E-5 cu.ft.}}{\text{ml}} \times \frac{1000 \text{ uCi}}{\text{mCi}} = 1.7 \times 10E-4 \text{ uCi/ml}$$

$$\text{Removal constant} = \frac{1067 \text{ cu.ft.}}{\text{min}} \times \frac{1}{4028 \text{ cu.ft.}} = 0.26/\text{min.}$$

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After 11 minutes, the air concentration will be less than the allowable 40 hour average concentration for restricted areas, so the requirements of 10CFR 20.103 are met.

$C = CoE^{-kt}$

C = 1 x 10E-5 uCi/ml (10CFR20.103 requirements)

Co = 1.7 x 10E-4 uCi/ml (immediate dilution)

K = 0.26 (removal constant)

5 = time in minutes

t = 10.9

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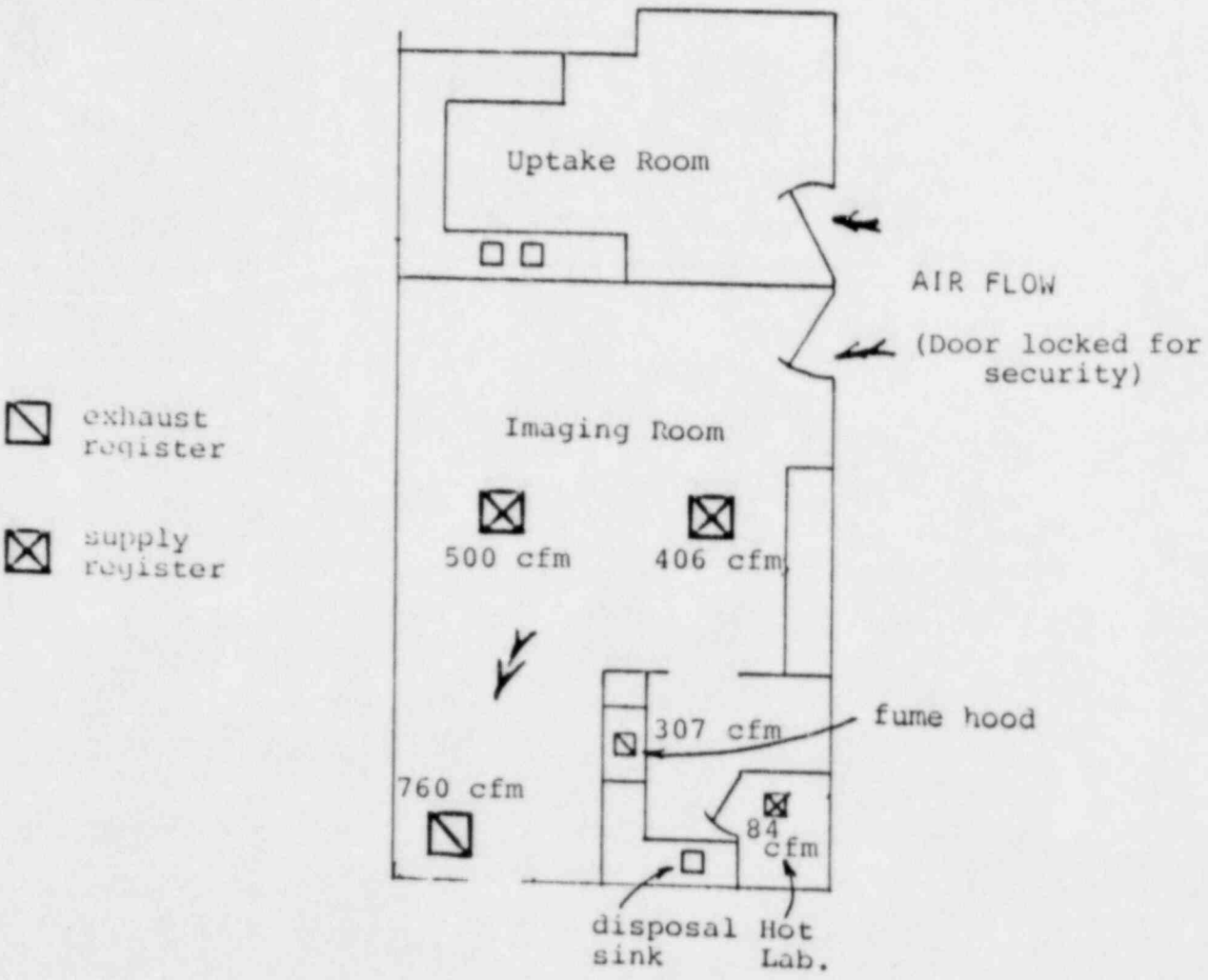
MAUI MEMORIAL HOSPITAL NUCLEAR MEDICINE

(Scale: 1/8" = 1')

FIGURE 1



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INSTRUCTION OF PERSONNEL

1. The training program for personnel who work with or in the vicinity of radioactive materials will be of sufficient scope to ensure that all personnel, including technical, clerical, housekeeping, and security personnel, receive proper instruction in the items specified in Section 19.12 of 10 CFR Part 19, including:

a. location of radioactive materials

b. possible health problems associated with exposure to such radiation;

c. precautions or procedures to minimize exposure for the duties involved;

d. purpose and function of protective devices employed;

e. applicable provisions and requirements of license and NRC regulations;

f. responsibility to report conditions which may violate the requirements of the license and NRC regulations;

g. familiarization with the emergency or unsafe condition responses;

h. location and explanation of radiation exposure reports and bioassay results; and,

i. locations where posting is required by 10 CFR Part 19.

2. New employees will be briefed on at least a. and c. above before assuming duties. All other areas will be covered within a month of the beginning of their employment.

3. An annual refresher covering a. thru i. above will be provided. The above areas will be covered also for employees whose duties change, or when regulations or terms of the license dictate.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

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

2. A system of ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of keeping written records of orders and receipts for radioactive material. These records must identify the isotope, compound, and activity levels.

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

4. During off-duty hours, security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in Mr. Walker's memorandum (see attached).

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phone nos.

M E M O R A N D U M

TO: Security Personnel

FROM: Jerry Walker, Administrator

SUBJECT: Receipt of Packages Containing Radioactive Material

Any packages containing radioactive material that arrives during non-normal working hours will be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on the top of the technologist's desk, and relock the door.

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

Radiation Safety Officer: James A. Bendon, M.D.

Office Phone: _____

Home Phone: _____

Beeper: _____

Radiation Supervisor: Eve Kiley

Office Phone: _____

Home Phone: _____

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PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

1. The regulations specified in 10 CFR 20.205 will be satisfied.

2. Other than the exceptions noted, the following procedures for opening packages will be carried out:

   Upon receipt* ---

   a. Visually inspect the package for any sign of damage (e.g. wetness or crushed package). If damage is noted, stop immediately and notify the Radiation Safety Officer or his designate;

   ---of radioactive materials exceeding the exempt quantities specified in 10 CFR 20.205(b) and (c)---

   b. Measure the exposure rate at three feet from and at the external surface of the package. If the exposure rate is greater than 10 mrems/hr at three feet or greater than 200 mrems/hr at the surface, notify the Radiation Safety Officer or his designate immediately and do not proceed further. The NRC must be notified as per 10 CFR 20.205 c(2);

   c. Wipe the external surface of the package with a dry wipe held with forceps. Count the activity on the wipe and record the results. If the removable contamination is greater than 0.01 microcuries (22,000 dpm) per 100 cm2, notify the Radiation Safety Officer or his designate immediately and do not proceed further. The NRC must be notified as per 10 CFR 20.205 c(2);

*Within three hours if received during working hours, or within eighteen hours if received after working hours.

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d. Open all packages with the following precautions:

(1) Put on protective gloves. Open the outer packages (following manufacturer's directions if supplied) and remove the packing slip. Open the inner package to verify the contents against the packing slip and the requisition. Also inspect the final container to ensure it is not broken or leaking, and that all seals are intact.

(2) Wipe the external surface of the final source container and remove the wipe to a low background area. Assay the wipe with a thin-window G-M survey meter and record the amount of removable activity.

(3) Monitor the packing material and the packages for contamination before discarding. If contaminated, discard as radioactive waste. If not, obliterate all radiation labels and discard in normal trash.

3. Maintain records of the above procedures on the Radioactive Shipment Receipt Record.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. Purchase/Requisition I.D. No.:_____ Date:_____

2. Package Condition: OK_____ Not OK_____

   Explain (if not):_____

---

3. Measured Radiation Levels:

   a. Surface_____mR/hr.

   b. 3 feet_____mR/hr.

4. Wipe Results:

   From the outside of the final container*:_____cpm

   Background:_____cpm

   Net:_____cpm

5. Does the activity, isotope & chemical form area agree with that ordered?

   Yes_____ No_____

   Explain (if no):_____

_____
SIGNATURE

* At least a 100 cm2 area.

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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. 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.

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.

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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.

14. When opening vials of I-131 containing activities greater than 0.1 mCi, wear gloves and open under a fume hood.

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EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold theabsorbent paper and pad.Insertintoa 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, checkthe 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 notattempt 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, butonlyif 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.

phone nos?

Radiation Safety Officer:_____

Office Phone:

Home Phone:

Beeper:

Radiology Supervisor: _____

Office Phone:

Home Phone:

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AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a GM survey meter and decontaminated if necessary. 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.

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 cpm per 100 cm2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Name of person conducting the survey.

   b. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   c. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   d. Detected contamination levels, keyed to locations on drawing.

   e. 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.

   f. The equipment used for the survey.

6. Area will be cleaned if the contamination level exceeds three times the background reading.

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WASTE DISPOSAL PROCEDURES

1. Solid radioactive waste generated in any laboratory will be segregated according to half-life and collected in specially designated waste containers lined with plastic bags. The waste containers will be lined with at least 1 mm lead. Radionuclides of less than 60 day half-life shall be collected and stored in a central waste storage area, and radionuclides of greater than 60 day half-life shall be stored in separate containers in the storage area. The short-lived waste will be stored until it measures less than background with a GM detector survey meter after all shielding has been removed. The long-lived waste will be packaged in accordance with D.O.T. requirements and shipped to a commercial waste disposal firm.

2. Liquid waste will be disposed of through the sink in the isotope storage room to the sanitary sewer system. The limits for maximum permissible concentration and quantities in water specified in 10 CFR 20.203 shall be adhered to. A log of all waste disposed of to the sewer will be maintained at the designated disposal sink.

3. Waste Xe-133 will be stored in the activated charcoal xenon trap until sufficient decay has occurred to enable the trap to be reused for further waste gas collection. Xe-133 gas that leaks during patient administration will be disposed of to the ventilation system. Calculations made in Item 11 show that release limits of 10 CFR 20 will not be exceeded.

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

Less than six patients per annum have received therapeutic doses of I-131 greater than 30 mCi for the last several years. The rate is not expected to increase.

The enclosed describes procedures for the general use of radiopharmaceuticals in therapeutic doses.

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PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS

The following are procedures which must be followed for handling patients containing therapeutic amounts of radioactive materials.

1. The patient's room must be posted with (1) a "Caution Radioactive Materials" sign containing the magenta or purple radiation propeller symbol on a yellow backing, and (2) a sign which states that "All visitors must check at the nursing station before entering."

2. A survey 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 after administration and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these "stay times" in the Chart Form in the patient's chart. The maximum exposure rate at 3 feet from the midline of the patient will be measured after administration of the dose. The stay time for this exposure rate will also be posted on the Chart Form. At least one additional measurement at 3 feet from the midline of the patient will be made in order to determine when the activity will reach 30 mCi.

3. The Chart Form will be completed immediately after administration of the treatment dose and placed in the front of the patient's chart.

4. Radiation levels in unrestricted areas (areas adjoining the patient's room where radioactive materials are not present) will be measured and maintained in compliance with 10 CFR 20.105(b).

5. All linens, disposables and non-disposables will be checked for contamination by the Radiation Safety Officer or his designate before processing as usual. Materials whose activity show exposure levels greater than 0.1 mrem/hr will be placed in the decay storage area until exposure levels are less than 0.1 mrem/hr.

6. Patients may be released from the hospital with greater than 8 mCi but less than 30 mCi of activity, if the instructions enclosed are given to the patient. These instructions shall be given by the Radiation Safety Officer or his designate. A copy of these instructions shall be maintained with the patient's file.

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7. The Radiation Safety Officer or his designate shall be consulted before surgery is performed on a patient with therapeutic levels of radionuclides. He shall also be consulted before an autopsy is performed on a deceased patient with therapeutic levels of radionuclides.

8. Hospital staff who will render care to patients containing therapeutic levels of radionuclides, will be furnished copies of Hospital Staff Instructions for Handling Patients with Therapeutic Doses of Radiopharmaceuticals.

9. The Chart Form will be removed from the patient's chart following the final survey and become the Radiation Safety Officer's record.

HOSPITAL STAFF INSTRUCTIONS FOR HANDLING PATIENTS WITH THERAPEUTIC LEVELS OF RADIOPHARMACEUTICALS

Introduction:

The following procedures refer to patients who have received therapeutic doses of radioactive materials. These doses are usually administered in liquid form, either by injection or orally. The radioactive material will remain in the patient until it either decays or is excreted (e.g. urine, perspiration, etc.).

Specific Procedures:

1. Place the I-131 and Au-198 patients in private rooms with a toilet. The bed should be placed near an outside wall, and to maximize the distance to other patients. P-32 patients may be placed in a double room.

2. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the patient's Chart Form. Nurses should read these instructions before administering to the patients. Call the physician in charge or the Radiation Safety Officer with questions concerning patient care.

3. "Stay times" at various distances from the patient will be posted in the Chart Form. These stay time restrictions should be observed. Custodial, utility, maintenance, and food service personnel should not enter the room until they have first checked at the nursing station.

4. Nurses caring for patients containing therapeutic levels of radioactive materials must have personnel monitors and exposure levels must be recorded.

5. Unless forbidden by the physician (see Chart Form), the patient may receive visitors who are over the age of 18. Patients must remain in bed while visitors are present and the visitors must stay at least 6 feet away from the patient. Under these conditions, the visitor may stay with the patient up to one hour per day.

6. Patients are to be confined to their room except for special medical or nursing procedures approved by the physician in charge.

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7. 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 if they are pregnant.

8. Attending personnel must 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. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

9. If the patient's clinical condition requires constant observation, rotate personnel required to perform adequate nursing care in order to minimize personnel exposure. The patient's bed should be approached only when required by nursing duties.

10. Disposable items should be used where possible. In particular, disposable plates, cups, and eating utensils must be used by patients treated with I-131. After use, these items should be placed in a designated waste container. The Radiation Safety Officer, or his designate, should be contacted for proper disposal.

11. All clothes and bed linens used by the patient should be placed in a laundry bag provided, and should be left in the patient's room to be checked by the Radiation Safety Officer or his designate before the items are allowed to leave the room.

12. Non-disposable items (e.g. books, magazines, etc.) may be provided for the patient, but these should be left in the room until the Radiation Safety Officer or his designate has determined them to be free of contamination.

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

14. Necessary contamination control measures are:

(a) The patient must wear hospital pajamas;

(b) Ambulatory patients will use the commode in their room, flushing at least three times after use;

(c) All patients will use the commode in a sitting position;

(d) Items used for patient care (e.g. thermometer, bedpan, etc.) will be kept in the patient's room.

(e) Diagnostic samples of blood, urine, and feces should be obtained only when authorized by the physician in charge;

(f) Urine and vomitus can be radioactive. In case of any accident involving spillage of urine or a patient who vomits, notify the Radiation Safety Officer or the Radiology Supervisor. Wear gloves to clean up the spill and place clean-up rags in the designated container.

15. If a nurse, attendant or anyone else knows or suspects that his skin, or clothing, including shoes is contaminated, notify Nuclear Medicine or the Radiation Safety Officer. This person should remain in the patient's room and not walk about the hospital.

16. If the patient dies, notify the physician who administered the radionuclide. The body must not be removed from the room until the physician advises on appropriate measures.

17. The room will not be returned to general use until a radiation safety survey of the room and it's contents have been done.

CAUTION RADIOACTIVE PATIENT

The following is a Chart Form for patients containing therapeutic levels of either Iodine-131, Phosphorous-32, or Gold 198. Instructions for hospital staff involved in the care of this patient are on file at the nursing station.

Patient's Name:_____

Room Number:_____ Physician's Name:_____

Iodine-131_____mCi; Gold-198_____mCi; Phosphorous-32_____mCi

Date & Time of Administration:_____

	Exposure Rate (mrem/hr.)/Stay Times* (min.)		
Date/Time	Bedside	3 Feet	Room Entrance
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Maximum Exposure Rate in Adjoining Unrestricted Area

_____mrem/hr.; _____Initial

Special Instructions:_____

_____

Final Survey Results: _____ Init.: _____

EMERGENCY INFORMATION

Radiation Safety Officer: James Bendon, M.D.
Office Phone:_____
Home Phone:_____
Beeper:_____

Patient's Physician:_____
Office Phone:_____
Home Phone:_____
Beeper:_____

* A "stay time" is the estimated time limit per 8 hour shift.

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INSTRUCTIONS FOR FAMILY OF RELEASED PATIENT

Name of Patient: _____

Name of Hospital: Maui Memorial Hospital

For further information contact:_____ Tel:_____

Please show this form to every physician consulted concerning the patient until:_____.

_____ was treated on _____, 19___, with

_____ millicuries of_____in the form of_____.

NO SPECIAL RADIATION SAFETY PRECAUTIONS ARE NECESSARY

AFTER:_____.

UNTIL THAT DATE:

Persons under 45 years of age must not be in the same room as the patient nor at a distance of less than 9 feet for more than a few minutes a day.

Persons over 45 years of age should not remain closer to the patient than 3 feet, except for brief periods for necessary procedures.

Babies and young people (of less than 45 years of age) should not visit the patient, but if they do, the visits should be brief, and a distance of at least 9 feet from the patient should be maintained.

SPECIAL PRECAUTIONS:

A. Spouse or other 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 FOLLOWING INDIVIDUAL(S) IMMEDIATELY.

_____ _____

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BIOASSAY PROCEDURE FOR I-131

1. Bioassay for I-131 will be required for all personnel who handle more than 1.0 mCi of I-131 in a fume hood or 0.1 mCi on an open bench.

2. Bioassays shall be performed at the following frequencies:

   a. Within two weeks prior to handling I-131 in the quantities previously defined.

   b. Between 24 and 72 hours after exposure to I-131 in the quantities previously defined.

   c. Within two weeks after the last possible exposure to I-131 when the employee is terminating activities involving I-131.

3. Bioassays shall consist of a determination of the individual's thyroid burden. The equipment used for this determination shall have a minimum detectable activity of 0.01 uCi I-131, as determined with a standard thyroid phantom.

4. If the measured thyroid burden exceeds 0.04 uCi I-131, the following action shall be taken:

   a. An investigation of the operations involved, including air and other in-plant surveys, shall be carried out to determine the causes of exposure and evaluate the potential for further exposures.

   b. If continued work in the area might cause the limits for air concentration in 10 CFR 20 to be exceeded, the worker will be restricted from such work.

   c. Actions shall be taken to reduce the potential for further exposures.

   d. Any reports of exposure required by 10 CFR 20 will be furnished to the employee.

5. If the measured thyroid burden exceeds 0.14 uCi I-131, the following actions shall be taken in addition to the steps outlined in 4 above:

   a. Refer the employee to appropriate medical/health physics consultation for administration of agents to accelerate removal of I-131.

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PROCEDURES FOR ADMINISTERING I-131 DOSES

1. Personnel administering therapeutic doses of I-131 should wear their personnel dosimeters, including ring dosimeters.

2. Never handle a therapeutic dose of I-131 directly with the hands. Use forceps or other remote handling devices. Whenever possible, keep the dose in a shielded container.

3. Always wear disposable gloves and a lab coat or other protective clothing when administering a therapeutic dose. After the administration is complete, dispose of the gloves as waste and monitor hands and clothing for contamination.

4. Liquid doses of I-131 will release vapors to the atmosphere when they are opened. Whenever opening a liquid dose, do so in a fume hood. Capsules do not release vapors and do not need to be handled in this manner unless they are crushed.

5. The number of personnel present in an area where administration of a therapeutic dose of I-131 is performed should be minimized.

6. Personnel who administer I-131 doses must complete a bio-assay between 6 and 72 hours following the administration.

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PROCEDURES FOR USING XENON-133

1. Each patient to use the Xe-133 system will first be evaluated by the physician or technologist to determine if the patient can complete the study and give quantative results. The patient will then be instructed on the purpose of the test and the hazards involved, as well as what the patient is expected to do to minimize leakage of xenon.

2. The patient will wear nose clamps and will be tested on the apparatus prior to injection of Xe-133.

3. If the patient accidentally comes off the apparatus prior to washout, the physician or technologist will immediately close the valve to the gas delivery system and assist the patient out of the room.

4. All other personnel will be instructed to vacate the room. The Radiation Safety Officer will be notified and personnel will not be allowed to re-enter the room for at least 11 minutes.

5. Ventilation flow measurements will be made every 6 months of all air flow vents in rooms designated as imaging area, laboratory, ultrasound and hot room.

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CALCULATIONS OF EXPECTED AIR CONCENTRATIONS FOR USE ON XENON-133

1. Xenon-133 gas will be administered to patients through an Atomic Products Pulmonex xenon system. All vials containing Xe-133 for dispensing will be contained in lead shielded glass syringes, and will be stored in the shielded storage area in the fume hood prior to use. Expired gases containin Xe-133 will be exhausted through the gas trap in the Pulmonex xenon system.

2. The trap is tested for excessive leakage by attaching a bag to the exhaust outlet, opening the outlet valve at the end of a patient study and collecting exhausted gas in the bag. The bag is assayed in the dose calibrator at the xenon setting. The charcoal trap is replaced if the assay shows detectable quantities of radioactive xenon.

3. It is estimated that as much as 20% of the administered xenon might leak during administration and storage of the charcoal trap. A maximum workload of 2 patients per week is estimated, with an administration of 20 mCi per patient. The required ventilation flow rate to insure airborne activity concentrations are not exceeded is:

$$V = \frac{(40\ mCi/wk)(.2)(1000\ uCi/mCi)}{(E\text{-}5\ uCi/ml)(40\ hrs/wk)} \times \frac{\text{cfm}}{1.7\ E6\ ml/hr}$$

$$V = 12\ cfm$$

The air from the imaging room is exhausted into a self-isolated system, and is not mixed with any air returning to the hospital. Figure 1 (see page 11-3) shows the measured flow rates at each exhaust and supply register. The total exhaust of 1067 cfm is well above the 12 cfm required. Measurements of air flow also showed that the nuclear medicine area is at negative pressure with respect to surrounding areas. Air flow directions are also given in Figure 1.

4. Using the assumptions given above, the airborne activity concentrations of air entering unrestricted areas can be estimated:

C = A / V

A = 2 patients/wk x 20 mCi/patient x 1000 uCi/mCi

x 52 weeks/yr x 0.2

A = 4 E5 uCi/yr

V = 1350 cfm x 1.49 E10 ml/yr/cfm

V = 2 E13 ml/yr

C = 4 E5 uCi/yr 2 E13 ml/yr

C = 2 E-8 uCi/ml

An additional dilution factor of 10 minimum is estimated because of mixing and dilution. The estimation concentration of 2 E-9 uCi/ml supplied to unrestricted areas is well below the allowable concentration of 3 E-7 uCi/ml (10CFR20.106).

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PROCEDURES FOR USING SR-90 BETA APPLICATOR

1. The Sr-90 source will be kept in a locked storage container when it is not being used. Sufficient shielding shall be provided in the container to reduce the dose rate at 12" from the container to less than 5 mR/hr.

2. The storage container will be stored in a locked storage room. Only authorized personnel will have access to the storage room.

3. Leak tests will be performed every six months by Mid-Pacific Medical Physics. The leak test procedures are on file under license No. 53-23207-01.

4. No service or repair of the source will be attempted by the licensee. The source will be returned to the manufacturer for any necessary repairs. Should repair of the source not be feasible, the source will be disposed of by transfer to an authorized waste disposal contractor. At present, Nuclear Engineering Company is used.

5. Before the source is disposed of, a check will be made to insure the disposal firm is licensed to receive the radioactive material being disposed of.

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MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

MAUI MEMORIAL HOSPITAL

(Licensee's Name)

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

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

2. Radiation Safety Committee (RSC)

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

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

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

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c. Review of ALARA Program

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

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).

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

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

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

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSC and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

   a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

   b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures**

   This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	*Level II*
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table O-1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

   In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

   The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

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the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official** *

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

_____

Signature

_____

Name (print or type)

_____

Title

Institution (or Private Practice) Name and Address

Maui Memorial Hospital
221 Mahalani St.
Wailuku, Maui, HI 96793

* The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.