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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

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

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

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

Philip J.W. Lee, M.D.
A.Y. Wong Bldg., Suite 101
1507 S. King St.
Honolulu, HI 96814

TELEPHONE NO.: AREA CODE 808 949-5938

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

Philip J.W. Lee, M.D.

TELEPHONE NO.: AREA CODE 808 949-5938

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 53-04935-01

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

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.)*

Philip J.W. Lee, 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		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		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	X	30
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		

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 source (Tracerlab Model RA-1A)	50 mCi	Treatment of superficial eye diseases

License Fee Information
on [illegible] Area ltr.

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

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer	monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer or Tracerlab (ICN)	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

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: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Philip J.W. Lee, M.D.

(1) NAME *(Type or Print)* Philip J.W. Lee

(2) TITLE M.D.

c. DATE Jan 21, 1985

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INSTRUMENTATION

1. SURVEY METER

Manufacturer's name: William B. Johnson & Associates, Inc.
Manufacturer's model number: GSM-10 s/n 157
No. of instruments available: 1
Minimum range: 0-0.2 mR/hr and 0-500 cpm
Maximum range: 0-20 mR/hr and 0-50,000 cpm

2. DOSE CALIBRATOR

Manufacturer's name: Victoreen
Manufacturer's model number: 34-061 s/n C-106
No. of instruments available: 1

3. DIAGNOSTIC INSTRUMENTS

TYPE OF INSTRUMENT	MANUFACTURER'S NAME	MODEL NO.
Pho Dot rectilinear scanner plus thyroid uptake collimator	Nuclear Chicago	1766

CALIBRATION OF RADIATION DETECTION INSTRUMENTS

1. SURVEY METERS

Survey meters will be calibrated annually by Gamma Corporation or other facility licensed to perform such calibrations. (Gamma Corporation's renewal application dated January 27, 1982 on file with the NRC under License No. 53-16847-01 contains their calibration procedures.) Survey meters will be checked for constancy against a built-in sealed source or other sealed source prior to each use. Readings differing greater than 20% will be cause for investigation and recalibration, if necessary.

2. LABORATORY INSTRUMENTS

1. The thyroid uptake counting system will be tested semi-annually with a known quantity of I-131 to insure that the minimum detectable thyroid activity is less than 0.04 uCi.

3. DOSE CALIBRATORS

1. The dose calibrator will be tested for response to geometrical variation of samples upon installation.

A 30 ml vial containing 2 mCi of Tc-99m in a volume of 1 ml will be used. The vial will be assayed at the appropriate setting, then the volume of liquid will be increased to 2, 4, 8, 10, 20, and 25 ml. After each addition, the vial will be gently agitated and reassayed. The 10 ml vial will be used as a standard, and the ratio of measured activities calculated for each volume to the reference volume. This is the volume concentration factor (F). The correction factors will be plotted against the volumes on linear graph paper. This graph will be used to select proper volume correction factors for routine assays if variations are greater than +-2%.

2. 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 instrument settings for Cs-137 and I-131. The dose calibrator will be adjusted or repaired whenever the results of the daily constancy checks vary from the true values by more than +-5%.

a. Place a clean, empty "blank" vial in the dose calibrator and observe the background reading. If the background is not higher than normal adjust the "zero adjust" to give a reading of zero.

b. Assay the Cs-137 source at each of the settings listed above. Record the readings.

c. Variations in the daily readings greater than +-5% require repair or adjustment of the dose calibrator.

d. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation or other means.

3. Prior to initial use and quarterly thereafter, the instrument shall be checked for linearity. Checks for linearity shall be made by counting 1 to 10 uCi of I-131. Recount after 8, 16 and 24 days. Compare dose calibrator readings with actual values calculated from decay of the I-131. Calculate the percent difference between the actual readings and the predicted readings and record them. Errors greater than +-5% require adjustment or repair of the dose calibrator.

4. Prior to initial use and annually thereafter, each dose calibrator shall be tested for accuracy using calibrated sealed sources certified traceable to NBS.

NUCLIDE	NOMINAL ACTIVITY	CALIBRATION ERROR
Cs-137	200 uCi	+-5%
Ba-133	250 uCi	+-10%
Co-57	5 mCi	+-10%

Measured activity differing from the decayed activity of the reference source by greater than +-10% shall require adjustment or repair of the dose calibrator.

a. Take a background reading with a "blank" vial and zero adjust.

b. Assay the reference standards in the dose calibrator at the appropriate settings.

c. Take three readings with each source and determine the average reading. Record the average reading of each source.

d. Correct the activity of each reference to determine the source activity at the day of the test. Record the corrected activity of each source.

e. Calculate the percent difference between the measured activity and the corrected activity. Record the percent difference.

f. Calibration checks that do not agree within +-5% indicate that the instrument should be repaired or adjusted. If this

is not possible, calculate a correction factor to be used during routine assay of radionuclides.

g. Keep a log of these calibration checks.

FACILITIES AND EQUIPMENT

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

2. The laboratory counter surfaces of the isotope laboratory will be 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. Waste radioactive materials will be stored in shielded waste receptacles. At least 1 mm of lead will be provided for the waste receptacles to reduce ambient radiation levels in the laboratory to an absolute minimum.

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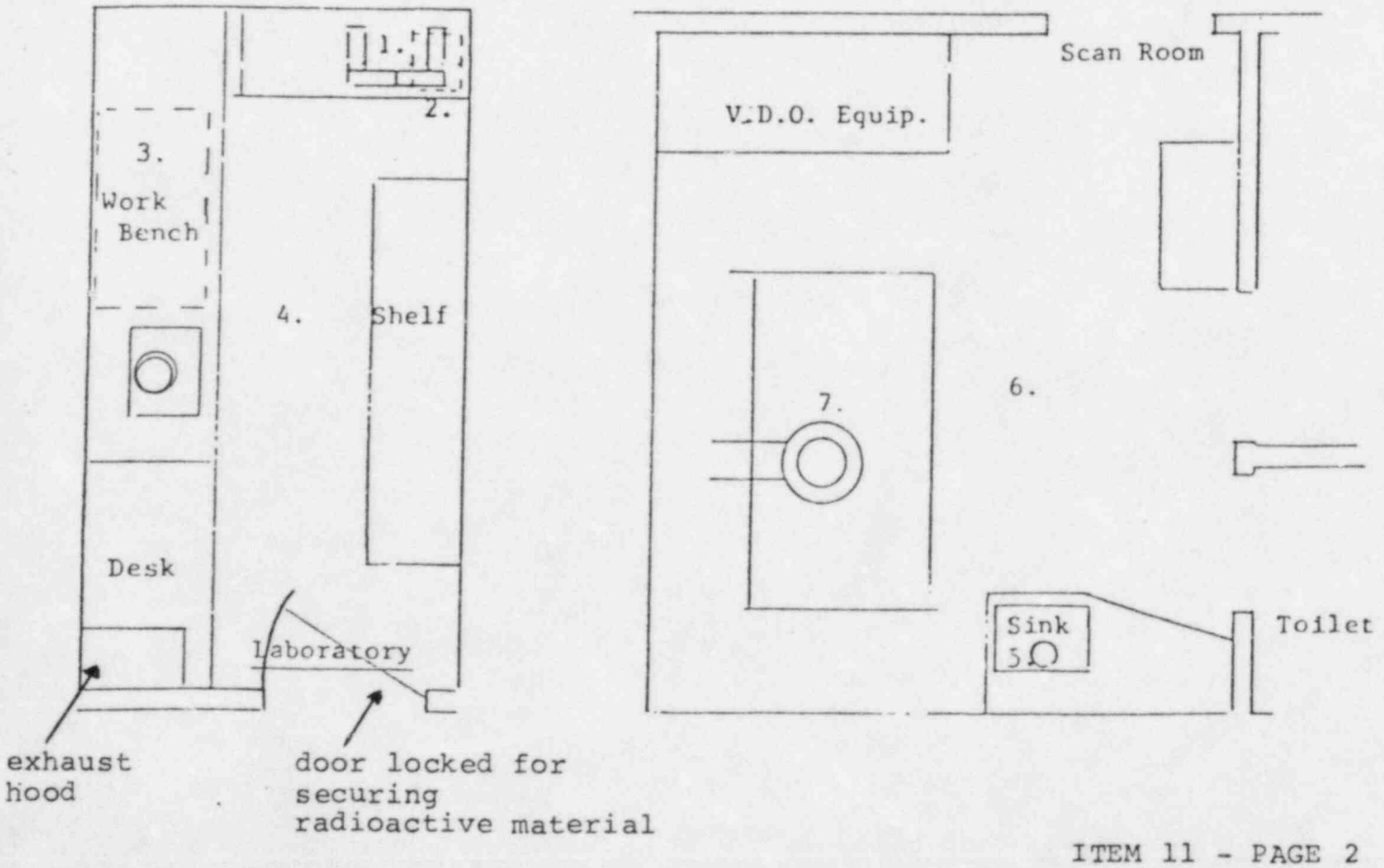
Figure 1

PHILIP J. W. LEE, M.D.
1507 S. King St., Suite 101
Honolulu, HI 96814

NUCLEAR MEDICINE LABORATORY

SURVEY LOCATION	DATES				
1. Lab, above I-131 storage (unshielded).					
2. Lab, beside Sr-90 storage box (shielded).					
3. Lab, work bench surface (contamination).					
4. Lab, floor at work bench (contamination).					
5. Scan, sink and sink bench (contamination)					
6. Scan, room floor, (contamination)					
7. Scan, scan table/ gurney (contamination)					
8. Other? (describe).					



PERSONNEL TRAINING PROGRAM

1. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to Dr. Lee.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR 19.

2. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure 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 packages containing radioactive materials directly to the office reception area.

3. Delivery personnel will be notified not to deliver packages of radioactive material during off-hours without first notifying Dr. Lee or Mr. Bill Hornig of the intended delivery. One of these people will arrive ahead of the delivery time and be on hand to receive the package.

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MEMORANDUM FOR: Delivery Personnel

FROM: Philip J.W. Lee, M.D.

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Before attempting to deliver packages of radioactive material outside of normal working hours, first notify one of the individuals below to arrange for receipt of the materials.

RADIATION SAFETY OFFICER: Philip J.W. Lee, M.D.
OFFICE PHONE: 949-5938
OTHER OFFICE: 455-1025

ALTERNATE: Mr. Bill Hornig
OFFICE PHONE: 949-5938
HOME PHONE: 672-9959

Do not attempt to deliver packages of radioactive material without first arranging with one of the above individuals for receipt.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

1. All packages that are labelled with YELLOW II and YELLOW III transportation labels will be monitored for external radiation levels. A survey shall be made around each package (1) at the surface and (2) at 3 feet from the package with a Geiger-Mueller detector. In addition, any package containing quantities of radioactive material in excess of Type A quantities shall be monitored as required by 10 CFR 20.05(c).

2. If the survey reveals radiation levels greater than 10 mrem per hour at 3 feet or greater than 200 mrem per hour at the package surface, stop the procedure and notify the Radiation Safety Officer or alternate. The RSO or alternate will make and record a more careful measurement of the radiation levels. These results shall be provided to the carrier and the NRC Region V as soon as available.

3. All shipments of liquid radioactive materials will be tested for leakage. Visually inspect the package for any sign of damage, i.e., wetness or crushed package. If damage is noted, stop immediately and notify the Radiation Safety Officer.

   a. Wipe the external surface of the package containing liquid radioactive material with a dry filter paper or section of a paper towel and count the wipe in a gamma counter or with a pancake detector and calibrated low level survey meter. If the removable contamination exceeds 0.01 uCi/100 sqcm, put on plastic gloves and seal the package in a plastic bag. Notify the Radiation Safety Officer immedately and do not proceed further. Record the results of this test.

   b. If the package is not contaminated, open the outer package following manufacturer's directions, as supplied. Put on protective gloves and remove the packing slip. Open the inner package to verify the contents against the packing slip. Also inspect the final container to insure it is not broken or leaking, and that all seals are intact.

   c. Wipe the external surface of the final container with a dry wipe held with forceps or a cotton swab on a stick. Count the wipe and record the results. In addition, records of monitoring required by 20.205(b) and (c) shall be maintained.

4. Monitor packaging materials with a pancake detector and survey meter before discarding. If the packaging material is contaminated, treat it as radioactive waste. If free of contamination, (no reading above background) obliterate or remove all radiation labels before discarding.

RADIATION SAFETY OFFICER: Philip J.W. Lee, M.D.
OFFICE PHONE: 949-5938 OTHER OFFICE: 455-1025
ALTERNATE: Mr. Bill Hornig
OFFICE PHONE: 949-5938 HOME: 672-9959

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 preparation and injection of patient doses except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used. Do not store food, drink, or personal effects with radioactive material.

6. 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%. For therapeutic doses, also check the patient's name, isotope, chemical form, and activity against the physician's order.

7. Wear personnel monitoring devices (film badges or TLD's) when required, at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level and always on the outside of a lead apron. When not used, store the devices in a designated low background area.

8. Wear TLD finger badges during preparation, assay, and injection of radiopharmaceuticals. Wear finger badges with the detector towards the palm of the hand.

9. Dispose of radioactive waste only in the specially designated waste containers.

10. Never pipette by mouth.

11. Survey dose preparation and administration 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 labelled with the name of the compound, radionuclide, date, activity, and radiation level if applicable.

13. Always transport radioactive material in shielded containers.

EMERGENCY PROCEDURES
(To be posted in all restricted areas)

MINOR SPILLS

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

2. PREVENT THE SPREAD by covering the spill with absorbent paper.

3. CLEAN UP the spill, using disposable gloves and remote handling tongs. Carefully fold the absorbent paper and wipe from the outer edge to the center of the spill area. Dispose of the absorbent paper into a plastic bag, along with the gloves and treat as radioactive waste.

4. SURVEY the area with a low-range, thin window G-M survey meter. Check the spill area, the area around the spill, and your hands and clothing.

5. REPORT the incident to Dr. Lee.

MAJOR SPILLS

1. CLEAR THE AREA and notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD by covering the spill with absorbent paper, but do not attempt to clean up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE if there is a direct radiation source problem, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM and lock the door behind you.

5. CALL FOR HELP by notifying Dr. Lee.

6. STAND BY FOR MONITORING and decontamination if necessary. Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer or alternate. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Philip J.W. Lee, M.D.
OFFICE PHONE: 949-5938 ANSWERING SERVICE: -

ALTERNATE: Mr. Bill Hornig
OFFICE PHONE: 949-5938 HOME: 672-9959

NOTE: For daily surveys where no abnormal exposures are found, only the date, identification of person performing the survey, and the survey results need be recorded.

Radiopharmaceuticals will not always be present continuously, but more likely only on days when they will be administered. Daily radiation surveys will be conducted whenever radiopharmaceuticals are stored in the isotope room.

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SURVEY PROCEDURES

1. TYPES OF SURVEYS

a. All preparation and administration areas will be surveyed daily with a GM survey meter and decontaminated if necessary.

b. Laboratory areas where less than 200 uCi are used will be surveyed monthly.

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

d. The weekly and monthly survey will consist of:

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

2) A series of wipe tests to measure contamination levels. The method for analyzing wipe test samples will be sufficiently sensitive to detect 200 dpm/100 sq.cm. Wipes taken in high background areas will be removed to a low background area for measurement.

e. To assure that radioactive materials are not spread to unrestricted areas of the A.Y. Wong Building, surveys will be conducted in the public restroom when frequented by patients who have been administered therapeutic doses of iodine-131.

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

a. A drawing of the area surveyed, identifying relevant features such as active storage area, etc.

b. The name of the person conducting the survey and the date of the survey.

c. The equipment used for the survey, including serial numbers and relevant sensitivities.

d. Measured exposure rates and contamination levels, keyed to locations on the drawing (including identification of contamination levels requiring reduction).

f. Corrective action taken to reduce radiation or contamination levels requiring reduction, and the radiation or contamination levels after the action was taken.

3. Areas will be cleaned if the contamination levels exceed 200 dpm/100 sqcm.

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.

2. Radionuclides of less than 8-day half-life shall be collected and stored in a central waste storage area, and radionuclides of greater than 8-day half-life shall be stored in separate containers in the storage area.

3. All waste of less than 65-day half-life will be held for at least 10 half lives before being monitored for disposal.

4. Each container of short-lived radionuclides (less than 8-day half-life) will be monitored in a low background area with a low level survey meter and a pancake GM detector to determine if the radiation levels are different from background. Prior to making this survey, all shielding will be removed from the final containers. All radiation warning signs and labels will be removed or obliterated.

5. All dose vials and unused radiopharmaceuticals will be returned to Pacific Radiopharmacy under the provisions of their license No. 53-16991-01MD if the radionuclide was originally purchased from them.

6. A record of the monitoring and results of all waste that is released will be maintained.

7. Liquid waste will be disposed of through the sink in the isotope room to the sanitary sewer system. A log of all waste disposed of to the sewer will be kept. Sewer releases will be in accordance with 20.303 of 10 CFR 20.

PROCEDURES FOR ADMINISTERING I-131 DOSES

1. Personnel administering therapeutic doses of I-131 should wear their personnel 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. The number of personnel present in an area where administration of a therapeutic dose of I-131 is performed should be minimized. All personnel present where administration of a greater than 0.1 mCi of liquid I-131 must have bioassays performed of their thyroid burden before and after the administration.

BIOASSAY FOR I-131

1. Bioassay for I-131 will be required for all personnel who handle unsealed sources of more than 1 mCi of I-131 in a fume hood, or more than 0.1 mCi of I-131 on an open bench. In addition, all personnel who are within 6 feet of operations involving more than the above mentioned quantities shall also participate in bioassays.

2. Bioassays shall be performed at the following frequencies:

   a. Prior to employment or beginning work with I-131 to establish a baseline level and annually thereafter to reconfirm the baseline levels.

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

   c. Within 2 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. The bioassay must be repeated within two weeks.

   c. 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.

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

   e. 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.

b. Determine thyroid burden at one-week intervals until the thyroid burden is less than 0.04 uCi I-131. If there is a possibility of other organs of the body containing I-131 that require evaluation, make measurements to determine the level of exposure to the other organs.

NOTE: I-131 in capsules are considered sealed sources unless the capsules are crushed or broken; consequently, no bioassays are required for personnel administering less than 100 mCi in a capsule.

RULES FOR SAFELY HANDLING A STRONTIUM-90 EYE APPLICATOR

1. Wear your personnel dosimeter(s) whenever you handle the strontium-90 eye applicator. Finger ring-type dosimeters should be worn with the detector on the palm side of the hand.

2. Remove the strontium-90 eye applicator from its secured storage location just before use. Do not leave it out any longer than necessary.

3. After removing the strontium-90 eye applicator from its secured storage location:

   a. Do not touch the treatment end of the applicator with your hands or other portion of your body.

   b. Always hold the applicator by its handle.

   c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.

4. If the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge or gauze dampened with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge or gauze. Do not sterilize by holding the swab or gauze in your hand.

5. During treatment, hold the patient's eye lids open with tape or other device, not with your fingers.

6. Immediately after treatment and/or resterilization, return the strontium-90 eye applicator to its storage container and to its secured location (e.g., locked cabinet).

7. Do not remove any metal or plastic inserts from the manufacturer-supplied storage container. These items are generally a part of the container's shielding. Removal of these items can lead to excessive and unnecessary radiation exposures.

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PROCEDURES FOR MAINTAINING OCCUPATIONAL
RADIATION EXPOSURES AS LOW AS REASONABLY ACHIEVABLE

1. MANAGEMENT COMMITMENT

a. Philip J.W. Lee, M.D. is committed to the philosophy of maintaining occupational radiation exposures as low as reasonably achievable (ALARA). The procedures described below outline the methods by which the philosophy will be implemented.

b. Dr. Lee will perform an annual review of the radiation safety program, including ALARA considerations. This review will include reviews of operating procedures and past exposure records and inspections, and consultation with the radiation protection staff or outside consultants.

c. Dr. Lee encourages changes to facilities or operating procedures where such changes will reduce occupational radiation exposure at reasonable costs.

d. Dr. Lee will review suggestions by employees of ways to reduce occupational radiation exposure. Where suggestions are not implemented, the reasons for not implementing them will be documented.

2. RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO) OR ALTERNATE RSO

a. When considering a new use of byproduct material, the RSO will review the measures taken to maintain exposures ALARA. The measures to be taken to maintain exposures ALARA, such as procedures or special equipment, should be outlined in the proposal to the RSO.

b. The RSO will audit the effectiveness of the radiation protection program on an annual basis. Included in this audit will be a review of the effectiveness of the ALARA program.

c. The RSO will review personnel occupational radiation exposures quarterly to determine that they are ALARA. He will perform an investigation of all exposures exceeding control levels and document in a report the cause of the high exposure and the steps taken to reduce exposures.

d. The RSO will review radiation levels in restricted and unrestricted areas and will review records of releases to unrestricted areas to determine that they are ALARA.

e. The RSO will instruct all occupational workers in the philosophy of ALARA, the commitment to ALARA, the control levels established by this medical facility, and the procedures to be taken when occupational exposure exceeds the

control level.

f. The RSO will establish a means for soliciting and evaluating employee suggestions for reducing occupational radiation exposure.

4. OCCUPATIONAL WORKER RESPONSIBILITIES

a. Occupational workers will follow radiation safety procedures and use any special equipment designated to keep his exposures ALARA.

b. Occupational workers will report instances to the RSO where they think their exposure may have exceeded the control levels, or where they think their personnel monitoring device may have been inadvertently exposed.

c. Occupational workers are encouraged to suggest any changes to operating procedures or special equipment that they think may reduce occupational radiation exposures. Such suggestions will be evaluated by the RSO.

5. ESTABLISHMENT OF CONTROL LEVELS FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES ALARA

a. In order to maintain exposures ALARA, this medical facility has established control levels for occupational radiation exposure. The control levels are as follows:

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

b. The RSO will review the results of personnel monitoring not less than once per calendar quarter and document the results of the review on the NRC-5 form or equivalent.

c. If personnel exposures are below Level I investigation level, no action is necessary.

d. If personnel exposures are greater than Level I but less than Level II, no further action is required unless deemed appropriate by the RSO, when the exposure is considered in context with overall department exposures and the exposure history of the individual.

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e. If personnel exposures are above Level II, the RSO will in a timely manner determine the cause of the exposures and, if necessary, take action. A report of the investigation, actions taken, and exposures recorded will be filed.