NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [XX] C. RENEWAL OF LICENSE NUMBER 53-05379-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Kaiser Foundation Hospital
3288 Moanalua Frontage Road
Honolulu, HI 96819

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Kaiser Foundation Hospital
3288 Moanalua Frontage Road
Honolulu, HI 96819

and

Kaiser Permanente - Honolulu Clinic
1010 Pensacola St.
Honolulu, HI 96814

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Elizabeth Rodenbeck or Don Tolbert

TELEPHONE NUMBER: (808) 536-2774

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: 7C
AMOUNT ENCLOSED: $580

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Ronald J. Mikolajczyk	Ronald J. Mikolajczyk	Administrator	JUN 16, 1988

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–$500K
- [ ] $500K–$750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollars and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Renew	Jul-1-88	7C		Kj, Messer
AMOUNT RECEIVED: $580	CHECK NUMBER: 73969			DATE: 7/14/88

PRIVACY ACT STATEMENT ON THE REVERSE

RADIOACTIVE MATERIAL AND PURPOSE

	By-Product Material	Amount		Purpose
5.A.	Material Identified in 10 CFR 35.100	As Needed	6.A.	Medical Use
B.	Material Identified in 10 CFR 35.200	As Needed	B.	Medical Use
C.	Material Identified in 10 CFR 35.300	As Needed	C.	Medical Use
D.	Material Identified in 10 CFR 31.11	As Needed	D.	In Vitro Studies
E.	Iodine-131 Metaiodobenzylguanidine	As Needed	E.	Medical Use Described in IND 26,061
F.	Strontium-90 Sealed Source Applicator	50 Millicuries	F.	Treatment of Superficial Eye Conditions
G.	Xenon-133	As Needed	G.	Medical Imaging
H.	Americium-241	15 Millicuries	H.	Imaging Anatomical Marker

Item 5 and 6
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INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS - THEIR EXPERIENCE AND TRAINING

7.1 Authorized Users

A. Decha Intaraprasong, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300, 31.11, I-131 for medical uses described in IND 26, 061, Xe-133 for medical imaging, and for Sr-90. Dr. Intaraprasong is currently an authorized user under NRC Materials License No. 53-05379-01.

B. Harry W. Russell, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300, 31.11, Xe-133 for medical imaging, and for Sr-90. Dr. Russell is currently an authorized user under NRC Materials License No. 53-05379-01.

C. Chung Ta Hsin, M.D., for materials identified in 10 CFR 35.100, 35.200, and 31.11, and Xe-133 for medical imaging. Dr. Hsin is currently an authorized user under NRC Materials License No. 53-05379-01.

D. Alfred G. Scottolini, M.D., for materials identified in 10 CFR 35.100, 35.200, and 31.11. Dr. Scottolini is currently an authorized user under NRC Materials License No. 53-05379-01.

E. Michihiko Hayashida, M.D., for Sr-90. Dr. Hayashida is currently an authorized user under NRC Materials License No. 53-05379-01.

F. John B. Thompson, M.D., for Sr-90. Dr. Thompson is currently an authorized user under NRC Materials License No. 53-05379-01.

G. Mary Frances O'Neal, M.D., for materials identified in 10 CFR 35.100, 35.200, 31.11, I-131 for medical use described in IND 26, 061, and Xe-133 for medical imaging. Dr. O'Neal is currently an authorized user under NRC Materials License No. 53-05379-01.

H. Stephen D. Miller, M.D., for Sr-90. Dr. Miller is currently an authorized user under NRC Materials License No. 53-05379-01.

I. Rickie A. Broadfoot, M.D., for materials identified in 10 CFR 25.100, 35.200, and 31.11, and Xe-133 for medical imaging. Dr. Broadfoot is currently an authorized user under NRC Materials License No. 53-05379-01.

J. Thomas C. Brown, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300, and 31.11, and Xe-133 for medical imaging. Dr. Brown is an authorized user under NRC Materials License No. 13-01787-01 for Good Samaritan Hospital, Vincennes, IN, (see attached NRC Form 374A).

7.2 Radiation Safety Officer

Decha Intaraprasong, M.D., is designated as the Radiation Safety Officer. Dr. Intaraprasong is currently designated as RSO under NRC Materials License No. 53-05379-01.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

All individuals working in or frequenting any portion of a restricted area shall receive training commensurate with paragraph 19.12 of 10 CFR. This will be accomplished with instruction at the beginning of their employment and during annual refresher training thereafter, or as required by a change of duties. Instructions shall include:

(1) Potential hazards associated with radioactive material;

(2) Areas where radioactive materials are used or stored;

(3) Radiation safety procedures and in-house work areas appropriate to their respective duties;

(4) Pertinent NRC regulations and license conditions;

(5) Obligations to report unsafe conditions to the radiation safety officer;

(6) Appropriate response to emergencies or unsafe conditions;

(7) Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions;

(8) Worker's right to be informed of occupational radiation exposure and bioassay results; and

(9) Question and answer period.

Item 8-1
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FACILITY DIAGRAMS

Figure 1 & 2	Diagram of Nuclear Medicine Section for uses of 35.100, 35.200, 35.300, I-131 MIBG imaging, Xe-133 imaging.
Figure 3 & 4	Diagram of RIA Lab Section for uses of 31.11 and waste storage.
Figure 5	Diagram of Eye Clinic storage area for use of Sr-90 sealed source.

Item 9-1
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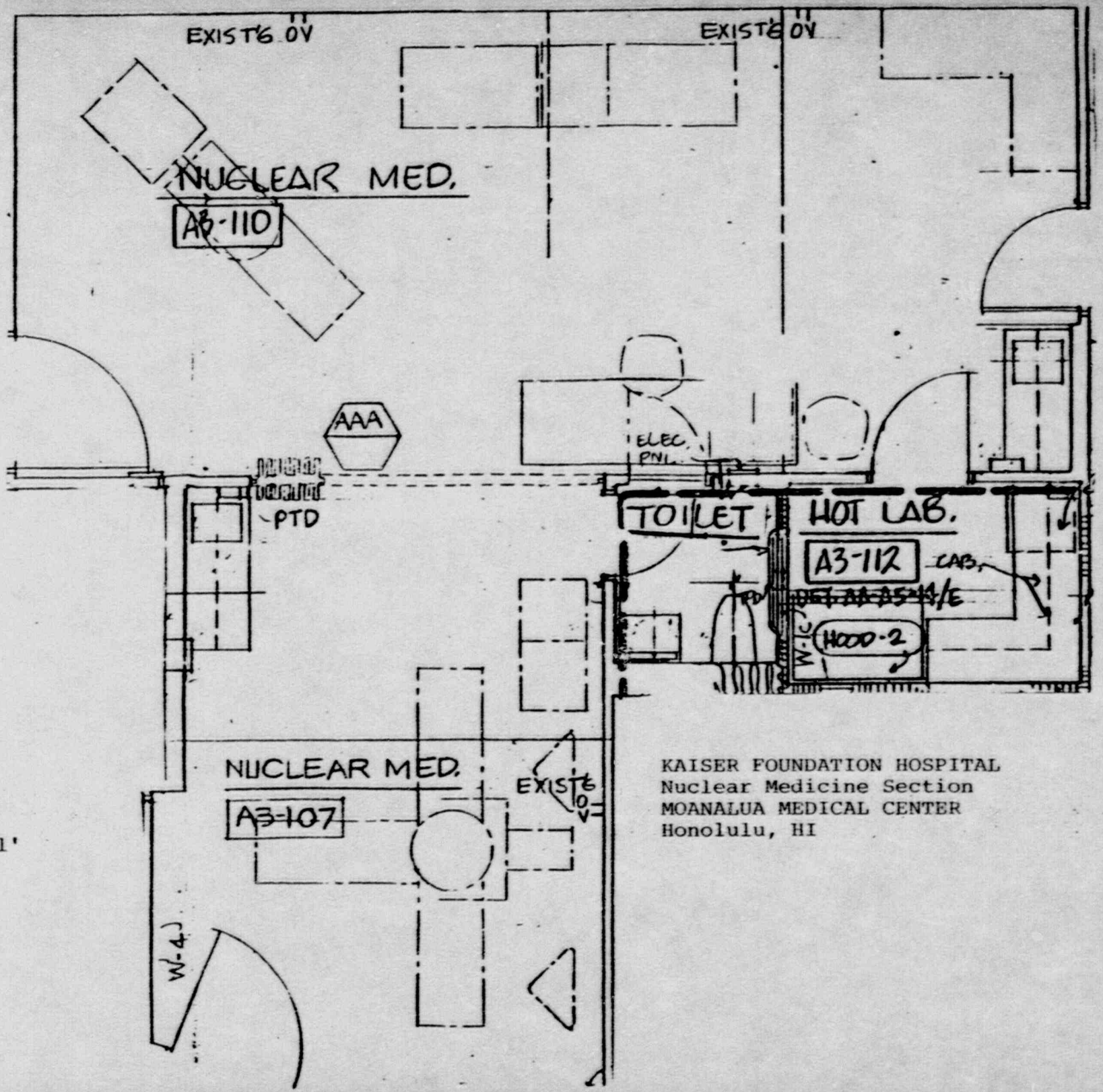


KAISER FOUNDATION HOSPITAL
Nuclear Medicine Section
MOANALUA MEDICAL CENTER
Honolulu, HI

Scale: ¼"=1'

Item 9-1 (Figure 1)
Date: 6-16-88

KAISER FOUNDATION HOSPITAL
NUCLEAR MEDICINE DEPARTMENT
ISOTOPE PREPARATION & STORAGE AREA

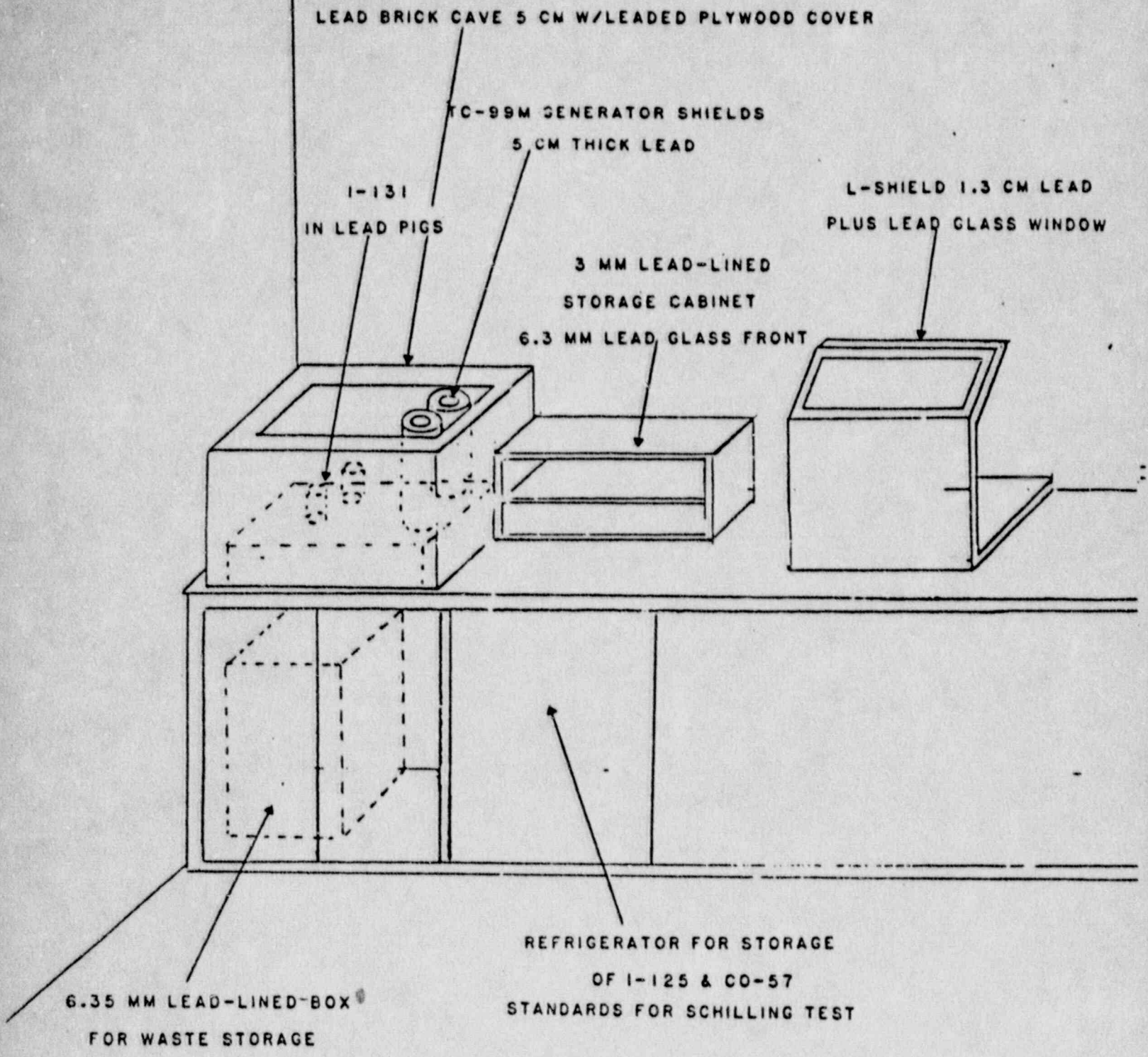


Figure 2

Item 9-1 (Figure 2)
Date: 6-16-88

SURVEY SHEET

FACILITY NAME: Kaiser Foundation Hospital - RIA laboratory

ADDRESS: 3288 Moanalua Road

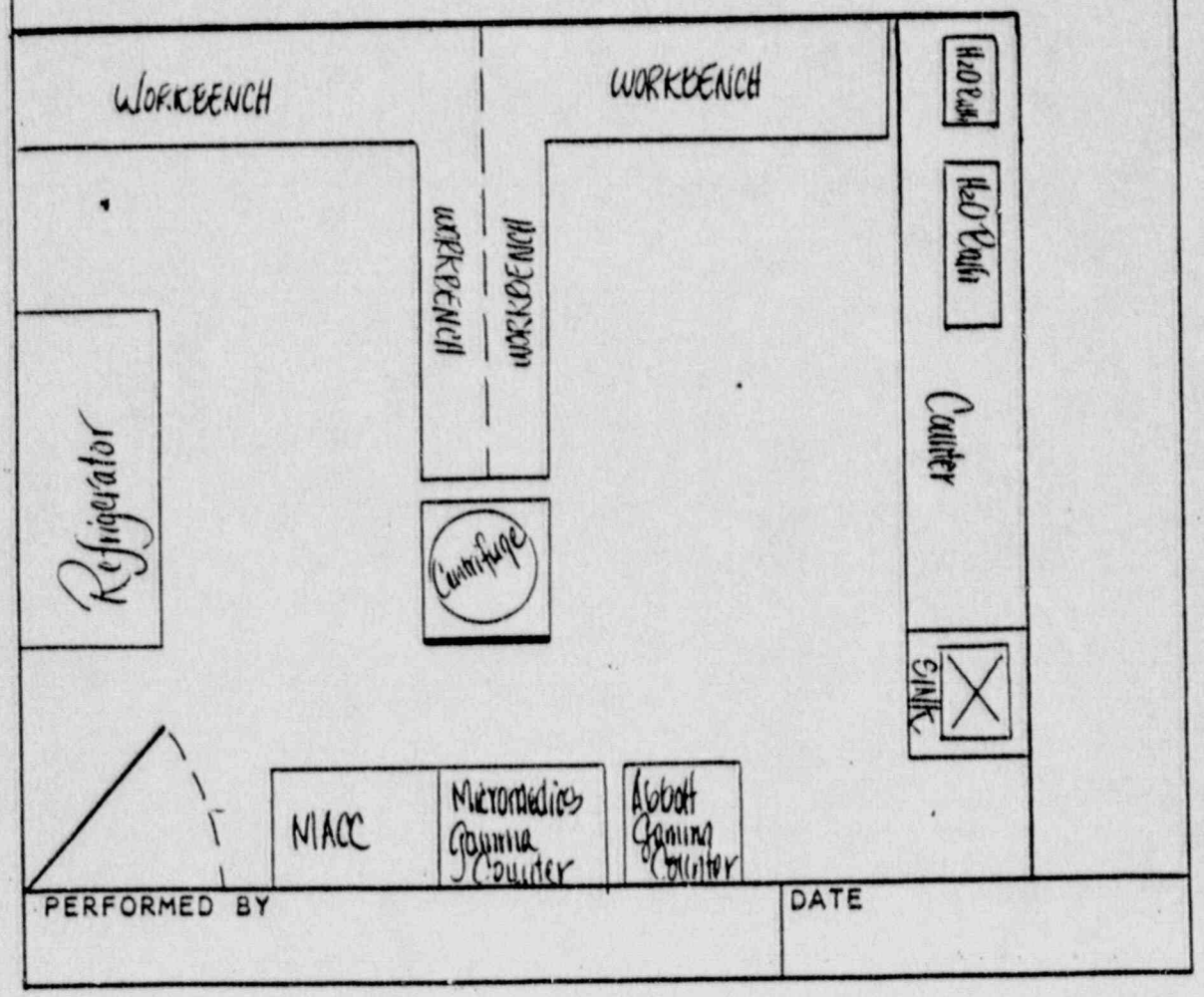
CITY: Honolulu | STATE: Hawaii | ZIP: 96819

TYPE OF SURVEY
☐ DAILY ☐ WEEKLY ☑ MONTHLY ☐ SPECIAL
☐ RADIATION ☑ CONTAMINATION ☐ AIRBORNE ☐ OTHER

INSTRUMENTS USED
1. Eberline E-120 Meter w/HP-260 GM Probe
2. Multimatic Gamma Counter (Abbott autologic) for wipes

MINIMUM DETECTABLE LEVEL: 20 dpm/100 cm²

DESCRIPTION OF SURVEY AND RESULTS



PERFORMED BY | DATE

Item 9-1 (Figure 3)
Date: 6-16-88

SURVEY SHEET

FACILITY NAME: Kaiser Foundation Hospital

ADDRESS: 3288 Moanalua Road

CITY	STATE	ZIP
Honolulu,	Hawaii	96819

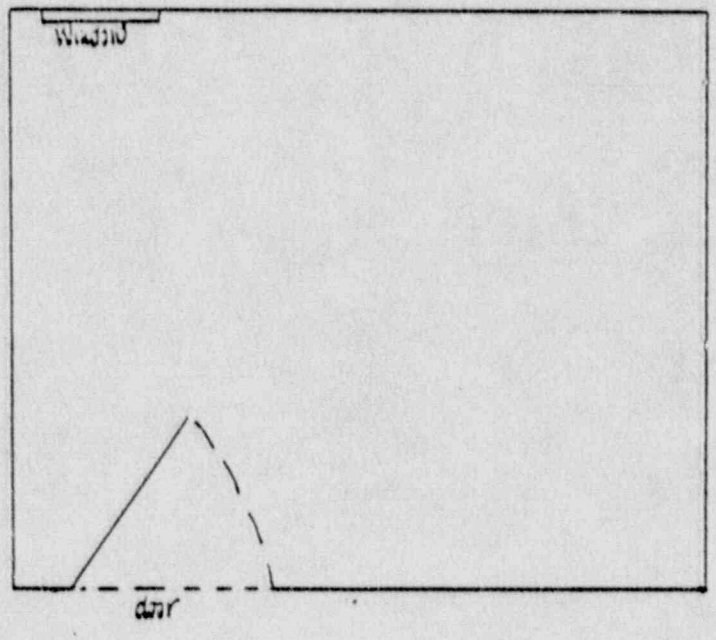
TYPE OF SURVEY

☐ DAILY ☑ WEEKLY ☐ MONTHLY ☐ SPECIAL

☐ RADIATION ☐ CONTAMINATION ☐ AIRBORNE ☐ OTHER

INSTRUMENTS USED	MINIMUM DETECTABLE LEVEL
1- Eberline E-120 Meter w/ HP-260 GM Probe 2- Abbott Autologic Automatic Gamma Counter for swipes	200 dpm/100 cm²

DESCRIPTION OF SURVEY AND RESULTS



PERFORMED BY	DATE

MID-PACIFIC MEDICAL PHYSICS
1301 Punchbowl Street, Suite 307
Honolulu, Hawaii 96813

Item 9-1 (Figure 4)
Date: 6-16-88

SURVEY SHEET

FACILITY NAME
Kaiser-Permanente Honolulu Clinic

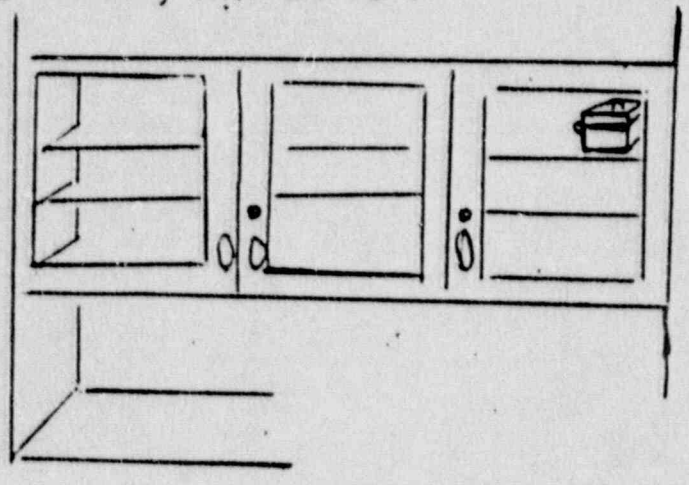
ADDRESS
1010 Pensacola St.

CITY	STATE	ZIP
Honolulu	HI	96814

TYPE OF SURVEY
☐ DAILY ☐ WEEKLY ☐ MONTHLY ☒ SPECIAL
☒ RADIATION ☐ CONTAMINATION ☐ AIRBORNE ☐ OTHER

INSTRUMENTS USED	MINIMUM DETECTABLE LEVEL

DESCRIPTION OF SURVEY AND RESULTS
Eye Clinic, Rm 6040



PERFORMED BY	DATE

MID-PACIFIC MEDICAL PHYSICS
1301 Punchbowl Street, Suite 307
Honolulu, Hawaii 96813

Item 9-1 (Figure 5)
Date: 6-16-88

CALIBRATION OF INSTRUMENTS

The dose calibrator and survey meters will be calibrated by Mid-Pacific Medical Physics according to the conditions given in NRC License No. 53-23207-01.

Survey meters will be calibrated prior to use, annually and following repair. Two separate readings on each scale up to 1000 mR/hr will be calibrated. The meter will be labeled with the reading of a check source at the time of calibration. If the meter reading differs by more than 10% from the calculated rate, a correction chart will be attached to the instrument. The survey meter calibration record will contain the date of calibration, calibration source used, the expected and instrument readings correction factors if needed, and signature of person performing the calibration. The record of survey meter calibration will be retained for two years.

These calibrations may also be performed by any other firm licensed by the NRC or an agreement state to perform calibrations for clients.

At such time as survey instruments may be calibrated by this institution, we will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.

The instrument used for diagnostic purposes will be calibrated, and quality control procedures performed and maintained, in accordance with accepted standards and manufacturers recommendations.

DOSE CALIBRATOR CALIBRATION

1. Dose Calibrator Constancy Check

The dose calibrator will be checked for constancy with a dedicated sealed source of Cs-137 of not less than 10μCi at the beginning of each day of use on the most frequently used settings. The record will include the model and serial number of the dose calibrator, the identity of the radionuclide in the check source, the date of the check, the activity measured, and the initials of the person performing the check. The record will be retained for two years. The dose calibrator will be repaired or replaced if the constancy error exceeds 10%.

2. Dose Calibrator Accuracy Check

The dose calibrator will be checked for accuracy upon installation, after repair or adjustment, and annually by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5% of its stated activity of greater than 50μCi of photon emitting radionuclide. At least one of the radionuclides will have a principal photon energy between 100 KeV and 500 KeV. The record will include the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, and the RSO's signature. The record will be retained for two years. The dose calibrator will be repaired or replaced if the accuracy error exceeds +/- 10%.

3. Dose Calibrator Linearity Check

The dose calibrator will be checked for linearity upon installation, after adjustment or repair and at least quarterly over the range of its use between the highest diagnostic dosage that will be administered to a patient and 10μCi. The method employed will be either a decay procedure or use of the Calicheck device following the procedures in the Calcorp, Inc. manual dated 3/2/82. Dosage readings will be mathematically corrected for any linearity error that exceeds 10% if the dosage is greater than 10μCi. The record shall include the model and serial number of the dose calibrator, the calculated activities and measured activities or Calicheck required data, the date of the test, and the RSO's signature. The record will be retained for two years.

4. Dose Calibrator Geometry Check

The dose calibrator will be checked for geometry dependence upon installation, following adjustment and after repair, over the range of volumes and volume configurations for which it will be used. Dosage readings will be mathematically corrected for any geometry error that exceeds 10% for a dosage exceeding 10 μCi. The record will contain the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the RSO's signature. The record will be retained for the duration of the use of the dose calibrator.

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. Nurses caring for radiopharmaceutical therapy patients will be issued whole body personnel monitors.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

INSTRUMENTATION

1. **Survey Meters**

   A. Picker GM, Model 655-186, Range 0.05 to 1000 mR/hr

   B. Victoreen GM, Model 493 with Pancake Detector, Range 100 - 30,000 cpm

   C. Eberline GM, Model E-120 with Pancake Detector, Range 0 - 50,000 cpm

   D. Victoreen Frisker, Model 425 with Scintillation Crystal Detector, Range 0 - 500,000 cpm

2. **Dose Calibrator**

   A. Capintec Model CRC-10R

3. **Diagnostic Equipment**

   A. Thyroid Uptake System, Nuclear Data, Inc., Model 88-0708

   B. Scintillation Well & Spectrometer, Picker, Model Spectroscaler III A

   C. Scintillation Camera, Searle, Model LFOV Standard

   D. Scintillation Camera, Siemens, Model ZLC 7500 SP

   E. Imaging Computer, ADAC, Model 3300

   F. Gamma Counter, Abbott, Auto-Logic

   G. Gamma Counter, Micromedics, 4/200 Automatic

   H. Xenon Lung Function Unit, Nuclear Associates, Model 36-002

   I. Xenon Gas Trap, Nuclear Associates, Model Nonex #36-023

RADIATION SAFETY COMMITTEE

1. This Committee has been established by authority of Mr. Mikolajczyk, Administrator of Kaiser Foundation Hospital, as the administrative body responsible for the safe use of radioisotopes at Kaiser Foundation Hospital.

2. The members of the Radiation Safety Committee (RSC) shall be composed of at least four members and will include:

   A. The Radiation Safety Officer;

   B. A Management Representative;

   C. A Representative of the Nursing Staff;

   D. A Physician Specialist from each department where radioactive material is used, and;

   E. The Consultant Health Physicist.

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. The Committee is responsible for:

   A. Ensuring that all individuals who work with or is 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 condition of the license.

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

5. In performing its duties, the Committee shall:

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

   B. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

Item 10-1
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C. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g. nursing, security, and housekeeping personnel) are properly instructed as required by 10 CFR 19.12.

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 quarterly summary of occupational exposure records of all personnel working with by-product material, and all incidents involving by-product material as to cause and action taken.

G. 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 inspections, written safety procedures, and the adequacy of the institution's management control system.

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

I. Maintain written records of all committee meetings which includes the date of the meeting, members present, members absent, summary of deliberations and discussions, recommended actions and the ballot results, required ALARA program reviews.

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

K. Make minor changes in radiation safety procedures that do not require a license amendment. Assure that any change made is in compliance with the requirements of the regulations and the license. Retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters considered, the signature of the RSO, the affected authorized users, the RSC chairman, and the management representative.

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

PROCEDURES FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS REASONABLY ACHIEVABLE

1. Management Philosophy and Responsibilities

A. The management of Kaiser Foundation Hospital 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 management philosophy will be implemented.

B. The management will perform an annual audit of the ALARA program of this medical facility. This review will include review of personnel exposure records and inspections, and consultation with the Radiation Safety Officer or alternate. The results of the audit will be documented.

C. The management encourages changes to facilities or operating procedures where such changes will reduce occupational radiation exposure at reasonable costs.

D. The management 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. The RSO will review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that appropriate measures will be taken to maintain exposures ALARA.

B. When considering a new use of by-product 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.

C. 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.

D. The RSO will present minor changes in radiation safety procedures to the RSC assuring that any change made is in compliance with the requirements of the regulations and the license.

E. 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.

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

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

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

3. **Authorized User Responsibilities**

A. Authorized users will consult with the RSO for proper procedures to maintain exposures ALARA for all new radioisotope procedures.

B. Authorized users will inform all people they supervise of the ALARA concept and their support of it.

4. **Occupational Worker Responsibilities**

A. Occupational workers will follow radiation safety procedures and use any special equipment designated to keep his exposure 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:

Organ	Investigational Levels (mrems per calendar quarter) 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.

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, the RSO will report the results to the next Radiation Safety Committee. No other action is required unless deemed appropriate by the Radiation Safety Committee, when the exposure is considered in context with overall department exposures and the exposure history of the individual.

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 presented to the next Radiation Safety Committee meeting, and the details of the report will be recorded in the RSC minutes.

LEAK TESTS

Leak tests of appropriate sealed sources will be performed by Mid-Pacific Medical Physics according to the conditions given in NRC License No. 53-23207-01. Leak tests may also be performed by any other firm licensed by the NRC or an agreement state to perform leak tests for clients. At such time as leak tests may be performed at this institution, we will develop and implement the model procedure for leak testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

Leak tests will be performed every six months of sealed sources containing by-product material with a half-life greater than 30 days which contain more than 100 μCi of beta or gamma-emitting material or more than 10 μCi of alpha-emitting material which are in active use and within six months of the date of transfer. The test will detect the presence of 0.005 μCi of radioactive material. The leak test record will include the serial number of each source, the identity of the radionuclide, the approximate activity of the source, the measured activity of removable contamination in μCi, the date of the test, and the signature of the RSO. If greater than 0.005 μCi of removable contamination is revealed by the leak test, the source will immediately be withdrawn from use and the appropriate report will be filed with the NRC. Leak test records will be retained for five years.

Item 10-7
Date: 6-16-88

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear protective clothing in areas where large quantities of radioactive materials are used.

2. Wear disposable gloves while handling millicurie amounts of 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 badge or TLD's) when required at all times while in areas where radioactive materials are used or stored. Whole body dosimeters 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 elution of generators and 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 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.

13. Always transport radioactive material in shielded containers.

EMERGENCY SPILL 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 wearing disposable gloves. 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 GM survey meter. Check the spill area, the area around the spill, and your hands and clothing.

5. REPORT the incident to the Radiation Safety Officer or the Radiation Safety Consultant.

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 the Radiation Safety Officer or the Radiation Safety Consultant.

Item 10-10
Date: 6-16-88

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 the Radiation Safety Consultant. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER:	Decha Intaraprasong, M.D.
OFFICE PHONE:	834-9747
HOME PHONE:	946-6027
RADIATION SAFETY CONSULTANT:	Don Tolbert, Ph.D.
OFFICE PHONE:	536-2774
HOME PHONE:	737-4282
BEEPER:	525-9086 (After the beep, enter number to be called then the "#" sign.)

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

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

2. When ordering therapy doses of Iodine-131 or Phosphorus-32, a written request will be obtained from the authorized physician who will perform the procedure. The Chief Nuclear Medicine Technologist will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity, and other medical information.

3. During normal working hours, carriers will be instructed to deliver packages containing radioactive materials directly to the nuclear medicine laboratory.

4. During off-duty hours, security officer will accept delivery of these packages in accordance with the procedures outlined in Mr. Mikolajczyk's memorandum (attached).

5. Occasionally, unopened RIA kits containing μCi quantities of radionuclides will be shared with other institutions. Before transfering by-product material, the RIA lab supervisor will verify that the receiver has a license authorizing him to receive the material.

Item 10-12
Date: 6-16-88

M E M O R A N D U M

FOR: Security Personnel

FROM: Ronald Mikolajczyk, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive outside normal working hours (7 a.m. to 4:30 p.m., Monday through Friday) shall be signed for by the security officer on duty and taken immediately to the Nuclear Medicine Department or the Laboratory, whichever is marked on the package. Unlock the door, place the package on top of the counter and relock the door.

If the package is wet or appears to be damaged, immediately contact the Radiation Safety Officer, the Nuclear Medicine Physician, or the Radiation Safety Consultant. Ask the carrier to remain at the building until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER:	Decha Intaraprason, M.D.
OFFICE PHONE:	834-9747
HOME PHONE:	946-6027
RADIATION SAFETY CONSULTANT:	Don Tolbert, Ph.D.
OFFICE PHONE:	536-2774
HOME PHONE:	737-4282
BEEPER:	525-9086 (After the beep, enter number to be called then the "#" sign.)

Item 10-13
Date: 6-16-88

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm^2.

2. For packages received under the specific license, the following procedure for opening each package will be followed:

   A. Put on gloves to prevent hand contamination.

   B. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   C. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see § 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See § 172.403 of 49 CFR Part 172.))

   D. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

      (2) Open the outer package following the supplier's instructions, if provided.

      (3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

E. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low background area. Assay the wipe sample to determine if there is any removable radioactivity. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Take precautions against the potential spread of contamination.

F. Check the user request to ensure that the material received is the material that was ordered.

G. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before dicarding in in-house trash.

H. Make a record of the receipt.

3. For packages received under the general license in §31.11, the following procedure for opening each package will be followed:

A. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

B. Check to ensure that the material received is the material that was ordered.

RECORD OF UNIT DOSAGE AND MULTIDOSE VIAL

RADIOPHARMACEUTICAL PRESCRIPTION

INSTITUTION: ______________________ DATED: ______________________

PATIENT NAME	TIME	ACTIVITY mCi/ml	DOSE mCi	VOLUME ml.	PRESCRIPTION NUMBER	PHYSICIAN SIGNATURE

Item 10 (Figure 1)
Date: 6-16-88

(SAMPLE)

RECORD OF UNIT DOSAGE AND MULTIDOSE VIAL

RADIOPHARMACEUTICAL PRESCRIPTION

INSTITUTION: KAISER DATED: 4-5-88

PATIENT NAME	TIME	ACTIVITY mCi/ml	DOSE mCi	VOLUME ml	PRESCRIPTION NUMBER	PHYSICIAN SIGNATURE
PACIFIC RADIOPHARMACY, Honolulu, Hawaii 96817 — 99mTc-MDP — ACT/ml: 25 — VOL/ml: 4 — DATE: — CONC mCi/ml: — LOT No: 109605	0820	25.63	102.2	4		
[redacted]	0915	23.0	20.0	0.9	Kai 109605	[redacted]
[redacted]	0900	23.8	21.3	0.9	Kai 109605	"
[redacted]	0950	24.5	20.3	0.93	Kai 109605	"
[redacted]	1030	17.4	26.3	1.0	Kai 4	Blank
PACIFIC RADIOPHARMACY, Honolulu, Hawaii 96817 — 99mTc-[redacted] — ACT/ml: 25 — VOL/ml: 5 — DATE: — CONC mCi/ml: — LOT No: 109601	0845	27.3	136.5	5		
[redacted]	0845	24.2	4.5	0.16	Kai 109601	[redacted]
[redacted]	0900	26.3	5.3	0.2	Kai 2	"
[redacted]	1100	2.1	1.4	0.67	Kai 3	Lung
[redacted]	1500	13.7	21.6	1.58	Kai 4	[redacted]
PACIFIC RADIOPHARMACY, Honolulu, Hawaii 96817 — Kai — 0.6 — 57 Co subsolide — ACT/ml: — VOL/ml: 1 unit — DATE: — CONC mCi/ml: — LOT No: 206402	0830		<0.01	cap		
[redacted]	0830		<0.01	cap	Kai 206402	[redacted]
PACIFIC RADIOPHARMACY, Honolulu, Hawaii 96817 — Kai — 99mTc-[redacted] — 50 — ACT/ml: — VOL/ml: 2.5 — DATE: — CONC mCi/ml: Co — LOT No: 109603	0845	18.6	46.4	2.5		
[redacted]	0840	18.1	6.4	0.35	Kai 1	Liver
[redacted]	1000	15.5	6.43	0.39	Kai 2 109603	[redacted]

SURFACE 42.0 mR/HR
SHEET 22.1 mR/HR
WIPES 4100 cpm/100cm²

VIALS & CONTAINERS

Item 10 (Figure 2)
Date: 6-16-88

MOLYBDENUM CONCENTRATION RECORDS

Radioactive medicines containing Tc-99m are obtained from the Pacific Radiopharmacy, Ltd. See NRC License No. 53-16991-01 MD for procedures for checking molybdenum concentration and records of concentrations. At such time as Mo-99 generators may be eluted by this institution, we will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2.

Item 10-16
Date: 6-16-88

SURVEY PROCEDURES

1. Types of Surveys

   A. All elution, preparation, and injection 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 imaging 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 2000 dpm/100 sqcm. Wipes taken in high background areas will be removed to a low background area for measurement.

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 areas, active waste areas, etc.

   B. The initials 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).

   E. 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 2000 dpm/100 sqcm or trigger levels for radiation exposure.

4. The RSO will review and initial the record monthly or promptly when action levels were exceeded.

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

NUCLEAR MEDICINE DEPARTMENT
KAISER MEDICAL CENTER

1. Calculation of Worker Dose from Concentrations of Gas in Work Areas

Assumptions:

2 Studies per Week
20,000 μCi per Study
20% Loss Maximum
1984 cfm Air Supply
2024 cfm Air Exhaust
Restricted Area Concentration 1×10^{-5} μCi/ml
Unrestricted Area Concentration 3×10^{-7} μCi/ml

Negative Pressure:

Σ Exhaust - Σ Supply
2024 cfm Exhaust - 1984 cfm Supply
Negative Pressure of Net 40 cfm Exhaust

Estimated Average Concentration in Restricted Area:

$$\frac{\text{Activity per Week} \times \% \text{ Lost}}{\text{Total Exhaust} \times \text{Work Week}} = <1 \times 10^{-5}\ \mu\text{Ci/ml}$$

$$\frac{2 \text{ Doses/Week} \times 20{,}000\ \mu\text{Ci/Dose} \times .2}{2024 \text{ cfm} \times 2.832 \times 10^{4} \text{ ml/cfm} \times 40 \text{ Hrs/Week} \times 60 \text{ Min/Hr.}}$$

$$= 5.8 \times 10^{-8}\ \mu\text{Ci/ml}$$

2. Calculation of Airborne Effluent Concentration

$$\frac{\text{Activity per Week} \times \% \text{ Lost}}{\text{Total Exhaust} \times \text{On Time in Week}} = <3 \times 10^{-7}\ \mu\text{Ci/ml}$$

$$\frac{2 \text{ Doses/Week} \times 20{,}000\ \mu\text{Ci/Dose} \times .2}{2024 \text{ cfm} \times 2.832 \times 10^{4} \text{ ml/cfm} \times 168 \text{ Hrs/Week} \times 60 \text{ Min/Hr.}}$$

$$= 8.2 \times 10^{-11}\ \mu\text{Ci/ml}$$

Item 10-19
Date: 6-16-88

3. Procedure for Checking Trap Effluent

Xenon-133 gas will be administered to patients through a Nuclear Associates Model 36-001 lung function unit connected to a Model 36-023 "Nonex" xenon gas trap. All vials containing Xenon-133 for dispensing will be stored in lead shields under the hood in the Hot Lab. The trap for Xenon-133 will be tested monthly during any month of trap use by exhausting approximately 70 liters of air through the trap into a plastic bag and positioning the bag in front of the scintillation camera. The count rate obtained will be converted to microcuries and the airborne concentration in the room calculated when the number of microcuries collected is equivalent to that which yields 0.01 MPC in the restricted area, the trap will be changed. Old traps will be sealed in a plastic bag and placed in the waste storage area for decay.

4. Calculation of Spilled Gas Clearance Time

A = 20,000 μCi Maximum Activity

Q = 2024 cfm Total Exhaust x 1.7×10^6 ml/Hr per cfm

C = Maximum Permissible Concentration in Restricted Area 1×10^{-5} μCi/ml; in Unrestricted Area 3×10^{-7} μCi/ml

V = 6400 Cu. Ft. Room Volume x 2.832×10^4 ml/Cu.Ft.

$$t = \frac{-V}{Q} \times \ln\left(C \times \frac{V}{A}\right)$$

$$t = \frac{-1.81 \times 10^8 \text{ ml}}{3.44 \times 10^9 \text{ ml/Hr}} \times \ln\left(1 \times 10^{-5} \mu\text{Ci/ml} \times \frac{1.81 \times 10^8 \text{ ml}}{20{,}000 \mu\text{Ci}}\right)$$

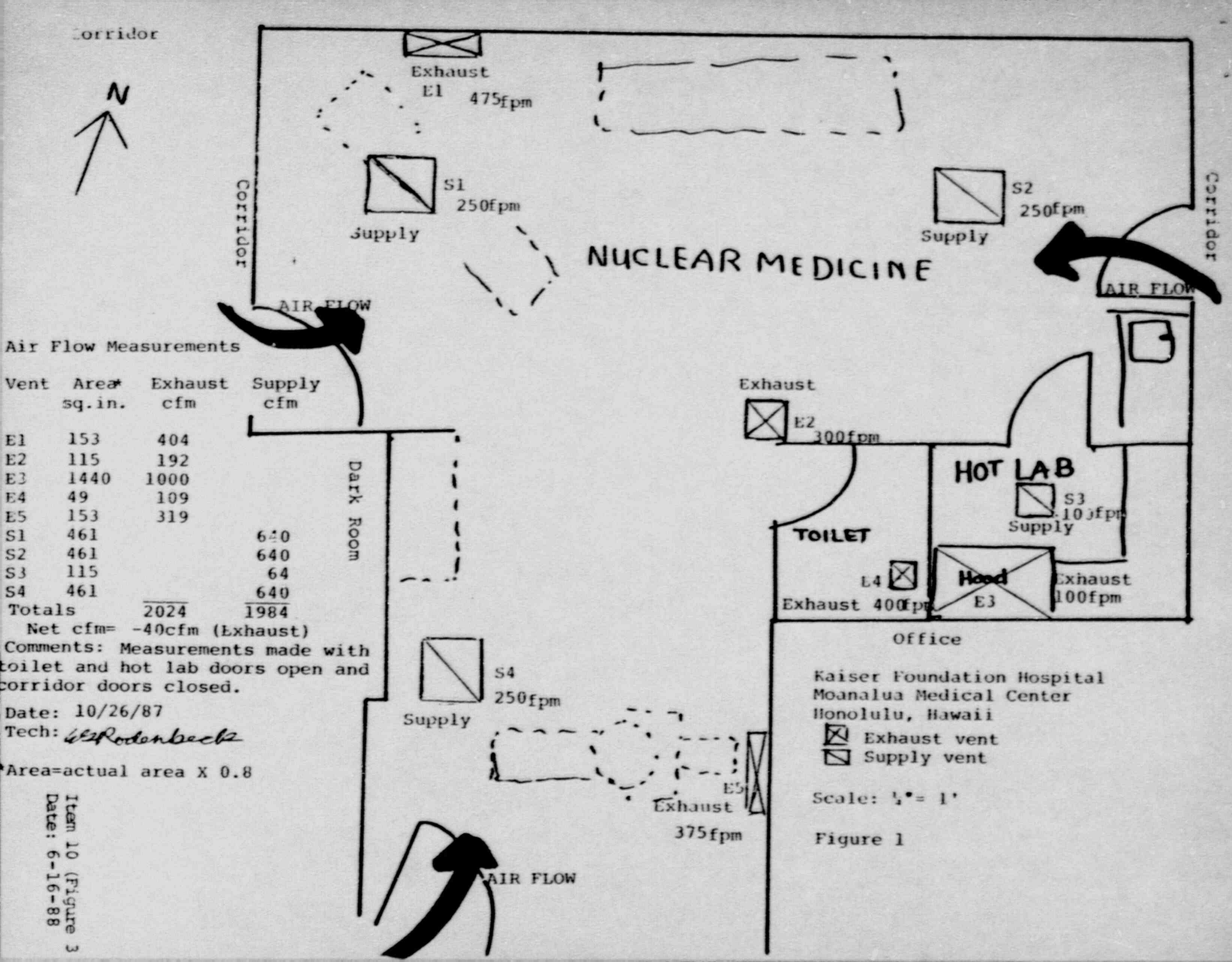
t = 0.13 Hrs. or 8 Minutes for Unrestricted Area

$$t = \frac{-1.81 \times 10^8 \text{ ml}}{3.44 \times 10^9 \text{ ml/Hr}} \times \ln\left(3 \times 10^{-7} \mu\text{Ci/ml} \times \frac{1.81 \times 10^8 \text{ ml}}{20{,}000 \mu\text{Ci}}\right)$$

t = 0.31 Hrs. or 19 Minutes for Unrestricted Area

Other Considerations:

Exhaust vents E1, E5, and E3 on Figure 1 are vented directly to the outside and do not recirculate within institution vent ventilation system. Vents E1 and E5 are located in the area designed for lung VP imaging and are situated near the floor.



Air Flow Measurements

Vent	Area* sq.in.	Exhaust cfm	Supply cfm
E1	153	404	
E2	115	192	
E3	1440	1000	
E4	49	109	
E5	153	319	
S1	461		640
S2	461		640
S3	115		64
S4	461		640
Totals		2024	1984

Net cfm= -40cfm (Exhaust)

Comments: Measurements made with toilet and hot lab doors open and corridor doors closed.

Date: 10/26/87

Tech: W.H. Rodenbeck

*Area=actual area X 0.8

Kaiser Foundation Hospital
Moanalua Medical Center
Honolulu, Hawaii

Exhaust vent
Supply vent

Scale: ¼"= 1'

Figure 1

Item 10 (Figure 3)
Date: 6-16-88

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 monitored personnel will not be allowed to re-enter the room for at least 8 minutes and others for 19 minutes.

Item 10-21
Date: 6-16-88

XENON TRAP EFFICIENCY TRAP

The total Xenon-133 activity in the 1620 cu.ft. nuclear medicine room that will result in a concentration equal to 0.01 MPC (1 x 10-7 uCi/ml or 0.0028 uCi/cu.ft.) is:

$$0.0028 \text{ uCi/Cu.Ft.} \times 1620 \text{ Cu.Ft.} = 4.5 \text{ uCi}$$

If the exhaust flow out of the xenon trap into the room is assumed to be continuous for 40 hours per week and the removal rate is only by ventilation from the room, then the activity input rate can be calculated:

$$A = \frac{P}{k}\left(1-e^{-kt}\right)$$

P = Activity Input Rate, uCi/min
K = Ventilation Removal Rate = 0.098 m-1
A = Activity to Give 0.01 MPC = 4.5 uCi
t = 40 Hours (2400 min)

$$P = \frac{4.5\ (0.098)}{1-e-(0.098 \times 2400)} = 0.44 \text{ uCi/min}$$

Therefore, if the activity input rate from the trap exceeds 0.44 uCi/min, then 0.01 MPC will be exceeded. This can be indirectly measured by knowing the time it takes to collect 70 liters of exhaust after a patient study, which is approximately 45 minutes. Therefore:

$$0.44 \frac{\text{uCi}}{\text{min}} \times 45 \text{ min} = 20 \text{ uCi}$$

If the activity collected in the sample collection bag approaches 20 uCi, make arrangements to have the filter package replaced.

Item 10-21a
Date: 6-16-88

I-131 DOSES 30 mCI OR GREATER PROCEDURE PROTOCOL, PREPARATION, AND INSTRUCTIONS

1. **Requests for this Procedure**

   A. Generally arranged by telephone by the patient's physician.

   B. Admitting is arranged by either the patient's physician or the Nuclear Medicine physician.

   C. The patient should be admitted on a Monday or Tuesday.

   D. Allow four days to order I-131 dose.

   E. Attempt to allow two weeks to elapse between individual procedures.

2. **Preparation Prior to Dose**

   A. The patient must be assigned to a private room, **ONLY.**

   B. Place absorbent material over the furniture, on the floor by the bed, and around the toilet. Secure with masking tape.

   C. Confirm that the mattress and pillow are covered with plastic.

   D. Cover the telephone with small plastic bags.

   E. Cover the door, toilet handles, and toilet seat with small plastic bags secured with tape.

   F. Provide specified waste recepticle for tissues used by the patient (small disposable tissues that may be slight contaminated may be flushed down the toilet). They should **NOT** go into the regular trash.

   G. Request disposable dishes and utensils for patient's use.

   H. Request a separate container for storage of uneaten food, this should **NOT** go into the regular trash.

Item 10-22
Date: 6-16-88

3. **Instructions to the Patient**

A. Flush the toilet at least three times after use.

B. Use care with saliva and urine to avoid contamination.

C. Remain in bed when receiving visitors.

D. Have the patient shower prior to administration of the dose, then refrain from taking a shower for 24 hours. This will help avoid shower stall contamination.

4. **Preparation of Radioactivity Tags and Labels**

A. To be posted inside and outside patient's chart, on the door to the room, on the patient's bed and on the patient's wrist band.

5. **Assay of Dose and Administration**

A. Just prior to assay, open the vial under a fume hood or exhaust, then assay in the dose calibrator.

B. Use a cart for transportation of the dose to the patient's room; cover the cart with absorbent paper as "chux"; include gloves, survey meter, labels, straw and 10 cc syringe.

C. Administer the dose via a straw. Use a syringe to add water to the vial, rinsing at least three times (do not remove straw from the vial until the administration is completed). Recap the vial and tape the cover on the lead pig, return all items to Nuclear Medicine for assay. Store and label as radioactive waste if indicated by the assay.

6. **Room Survey**

A. Following administration, measure and record exposure rates. At the bedside, with patient lying down, one meter from the bedside. This measurement is used to calculate stay time for hospital personnel which is 2 mR in any one hour. (2.0 divided by reading at one meter times 60 min/hr = _____ minute in any one hour). This reading is also entered on the patient's chart and door radioactive tags.

B. At the entrance to the room.

C. Adjacent hospital room (if applicable) not to exceed 2 mR/hour.

7. **Records of These Calculations and Measured Rates Shall be Maintained in a Designated Folder in the Nuclear Medicine Department**

8. **Subsequent Surveys and Stay Time Calculations**

A. Performed on a daily basis until the content of radioactivity is less than 5 mR/hr or 30 mCi.

NCRP #37	NO RESTRICTIONS AT DISCHARGE			mR/mCi/Hr	*If Dose = 100 mCi
Table 4 I-131	1 Meter mR/Hr 1.8	=	Activity 8 mCi	1 Meter 0.22	30 mCi = 30% of Initial Meter Read

B. If the patient is released with a body burden between 8 and 30 mCi, written instructions are given to him/her listing precautions to be followed until the body burden falls below 8 mCi.

9. **Close Out Survey** (After the patient has been discharged)

A. Survey **ALL** waste recepticles, linen hampers, and general areas used by the patient; door handles, toilet, shower, basin, etc.

B. These areas are noted and readings recorded in mR/hr as fixed contamination = >0.1 mR/hr.

C. Perform wipe tests to detect removable contamination as floor areas near bed, door handles, light switches, bed controls, etc.

D. These areas are identified and readings are recorded in dpm/100 cm^2 ; contaminated areas are to be decontaminated, resurveyed with final survey results recorded. (Wipe counts must be less than 200 dpm/sqcm.)

10. **All Contaminated Items will be Held for Decay in the Nuclear Medicine Lab until They may be Returned for Normal Use or Discarded**

A. * cpm meter reading x 4 = dpm. 200 dpm is background or maximum permissible amount.

B. Indicate in patient's chart that discharge instructions were given to the patient.

11. **Instructions to Nurses**

A. Pregnant nurses should not care for the patient.

B. Personnel monitoring shall be provided for nursing personnel who care for radiopharmaceutical therapy patients over 30 mCi I-131.

C. In therapeutic treatment with solutions, there exists a radiation field and also possibility of accidental contamination by contact with the patients or their excreta or vomitus. Wear gloves when necessary; discard in the waste storage in the patient's room.

12. **RSO or Designate**

A. If required to clean contamination due to vomitus or incontinence during the first 48 hours.

B. Contact Environmental Services Department for the necessary solutions and implements.

C. Use gloves and plastic bags to cover shoes.

D. Use yellow plastic bags from Environmental Services or Nuclear Medicine to hold contaminated materials used in clean up.

E. Perform survey and record results after decontamination is completed.

ENCOURAGE THE PATIENT TO DRINK FLUIDS DURING THE NEXT 24 HOURS AFTER TREATMENT AND ENCOURAGE VOIDING OFTEN, FLUSHING THE TOILET THREE TIMES AFTER USE. APPROXIMATELY 1/3 OF THE ADMINISTERED ACTIVITY IS EXCRETED IN 24 HOURS AND APPROXIMATELY 1/2 OF THE ACTIVITY IS EXCRETED BY 48 HOURS.

RADIONUCLIDE THERAPY - 131 INSTRUCTIONS FOR PATIENT AND FAMILY FOLLOWING DISCHARGE

_____ _____

(Name) (Date)

You have been discharged with a moderate amount of radioactivity still remaining in your body. For this reason you should follow some precautions to avoid unnecessary radiation to members of your family and co-workers. The majority of radioactivity will be excreted from your body when you go to the bathroom. However, a small amount will also be present in your saliva, sweat, and tears.

PRECAUTIONS TO BE TAKEN DURING THE FIRST FOUR DAYS:

Since most of the radioactivity will be coming out in the urine, the toilet should be flushed twice and any spilled or splashed urine should be wiped carefully with toilet paper and flushed in the toilet. You should sleep alone and should not engage in sex or kissing. Clothing, bedding, and towels with which you have come in contact should be washed separately from those used by other members of your family.

Contact with children and pregnant women should be avoided completely. Other people should not remain closer than three (3) feet for more than one-half (1/2) hour per day or closer than six (6) feet for more than two hours per day. For these reasons you should avoid prolonged sitting next to another person, such as in a theater or church.

FOR THE FIRST THREE MONTHS:

If you are a woman, you should not get pregnant. If you should have any questions, please feel free to call Dr. _____ at _____.

Item 10-26
Date: 6-16-88

RADIATION SAFETY PROCEDURES FOR USE OF SEALED SOURCES

The Sr-90 sealed source in the eye applicator will be used by the Eye Clinic at the Honolulu Clinic. The applicator is stored in the locked medicine cabinet in Room 6040. The source storage area is surveyed for ambient radiation levels quarterly, the source is inventoried quarterly, and the source is leak tested semiannually. The following procedures will be followed for use of Sr-90 eye applicator:

1. The Sr-90 source will be kept in a locked storage cabinet 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 source storage container will be stored in a locked medication room. Only authorized personnel will have access to the storage room.

3. 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.

4. Disposal of the source will be accomplished by transfer to an authorized waste disposal contractor. At present, U.S. Ecology is used, but other licensed waste disposal firms may also be 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.

The staff will follow the attached safety rules when handling the source.

Item 10-27
Date: 6-16-88

RULES FOR SAFELY HANDLING A STRONTIUM-90 EYE APPLICATOR

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

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

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

   A. Do not touch the treatment end of the applicator with your hands or other portions 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 Sr-90 eye applicator to its storage container and to its secured location (e.g., locked cabinet).

Item 10-28
Date: 6-16-88

WASTE DISPOSAL PROCEDURE

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

Procedure for Disposal of Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph 20.303(d). Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

Procedure for Disposal by Decay-in-Storage (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   A. Check your radiation detection survey meter for proper operation;

   B. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   C. Remove any shielding from around the container;

   D. Monitor all surfaces of each individual container;

   E. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

   F. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

Procedure for Release to In-House Waste

Waste from in vitro kits that are generally licensed pursuant to 31.11 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

Item 11-3
Date: 6-16-88

APR 11 1989

Kaiser Foundation Hospital
Department of Radiology
3288 Moanalua Frontage Road
Honolulu, Hawaii 96819

Attention: Ronald J. Mikolajczyk
Administrator

Gentlemen:

This is in reference to your request dated June 27, 1988 for renewal of your byproduct material license.

Our license renewal review process is designed to assure that you demonstrate your intent to comply with the revised 10 CFR Part 35 and other related regulations as appropriate. To guide licensees in preparing applications which conform to Part 35, we have developed NRC Regulatory Guide 10.8, entitled "Guide For the Preparation of Applications for Medical Use Programs". We note that in many portions of your renewal application you followed Regulatory Guide 10.8 closely.

The questions enclosed with this letter have resulted from portions of the Guide which were not addressed or information which may not comply with 10 CFR Part 35. You should address all topics in the Guide with acceptable alternative procedures or adopt the model procedure in the Guide.

We will continue the review of your license renewal request upon receipt of this information. In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate, and refer to Mail Control No. 70795.

Sincerely,

Beth A. Riedlinger
Health Physicist (Licensing)

Enclosure:
Regulatory Guide 8.23

REGION V
JMontgomery/jg
4/11/89

BARiedlinger
4/11/89

REQUEST COPY	REQUEST COPY
YES / NO	YES / NO

SEND TO PDR
YES / NO

QUESTIONS CONCERNING RENEWAL APPLICATION
FOR KAISER FOUNDATION HOSPITAL

1. Item 5.H. Specify the manufacturer and model number of the Americium-241 imaging anatomical marker.

2. Item 9-1 Figure 4 needs to be identified. If radioactive waste is to be stored in this room, show the location of waste containers and storage areas within the room. Also, identify the scale for all diagrams and show the room location relative to surrounding areas and the direction of north.

3. Item 9-3 Dose Calibrator Calibration (10 CFR 35.50)

   Paragraph (1) Constancy Check:

   Provide a step by step description of your constancy check procedure. Be sure to include the tolerance or action level at which the person performing the check would identify any suspected malfunction.

   Paragraph (2) Accuracy Check:

   a. Verify if your reference sources are National Bureau of Standards (NBS) sources or traceable to NBS sources.

   b. Identify the sources you intend on using

   c. Provide a step by step description of your accuracy test procedure.

   Paragraph (3) Linearity Check:

   a. Provide a step by step description of the "decay procedure" if you intend on using this method. If a Calicheck device is used, we will need to review a copy of the specific procedure you will be using.

   b. If you intend on administering radiopharmaceutical therapy doses, the Item 3 linearity check must include the highest therapy dosage that will be administered to a patient.

   Paragraph (4) Geometry Check

   a. Submit a step by step description of the geometry check procedure that will be used.

4. Item 9-5 Paragraph 4:

   Verify that all individuals who are occupationally exposed to radiation on an occasional basis (not just nurses) will be

issued a whole body monitor when caring for or working around radiation therapy patients (e.g. housekeeping personnel). (10 CFR 20.202)

5. Item 10-1 Radiation Safety Committee

You should confirm that the RSC's responsibilities include ensuring that the use of licensed material is consistent with the ALARA philosophy and program. (10 CFR 35.22)

6. Item 10-1 Radiation Safety Committee, paragraph 5.G:

You need to confirm that the RSC will evaluate the radiation safety program's consistency with the ALARA program and philosophy as part of their annual evalution of the RSO's summary report. (10 CFR 35.22)

7. Item 10-4 Procedures for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable, paragraph 1.B: (10 CFR 35.20, 35.21 and 35.22).

You need to confirm that during their annual audit of the ALARA program, management will include a review of radiation safety operating procedures.

You should confirm that management is committed to keeping the sum of radiation doses received by all exposed personnel as low as practicable.

Your application should describe the RSC's commitment to review and confirm each user's efforts to keep exposures ALARA and encourage efforts to review and refine procedures to achieve the optimum ALARA concept.

Paragraph 2.E:

The RSO must prepare a summary report for the RSC describing the results of the quarterly review. This needs to be addressed in paragraph 2.E.

This report must be prepared regardless of the investigational level.

Paragraph 2.F:

Again, the RSO must prepare a summary report for the RSC addressing the achievement at or below ALARA levels. This needs to be described in paragraph 2.F.

Paragraph 4:

Verify that workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

Paragraph 5.D:

You need to add the word "meeting" at the end of the first sentence.

8. Item 10-8 General Rules For Safe Use Of Radioactive Material

Paragraph 4:

You should confirm that if the use of syringe shields is impractical, alternate dose delivery methods will be considered to keep personnel radiation exposures as low as reasonably achievable.

Paragraph 11:

In addition to daily area radiation surveys, you need to describe your procedures for weekly wipe-testing of byproduct material storage, preparation, and administration areas for contamination. (10 CFR 35.70).

Paragraph 12:

Confirm that radioactive solutions will be kept in shielded containers which are clearly labeled. (10 CFR 35.61)

9. Item 10-17:

Paragraph 1.D.(2):

Describe the radioactive source you will use to convert sample measurements (e.g. counts per minute) to disintegrations per minute (DPM).

Paragraph 2.A.:

You need to specify the RSO established contamination and dose rate action levels for the areas surveyed. Regulatory Guide 8.23 (copy enclosed) may be of assistance to you. (10 CFR 35.70)

10. Item 10-19

Paragraph 2:

You should recalculate the airborne effluent concentration. Your answer of 8.2×10^{-11} uci/ml does not agree with our computation.

11. Item 10-20

Paragraph 3:

The second to last sentence needs to be rewritten. It appears that a period is missing.

Paragraph 4:

Provide the dimensions of the xenon room used in your calculation of the spilled gas clearance time.

12. Item 10-21a

You refer to the "Nuclear medicine room" volume as 1620 cubic feet. You need to explain the difference between this volume and the 6400 cubic feet used in your spilled gas clearance time calculation in item 10-20.

13. Item 10, Figure 3:

Explain the reason for multiplying the vent area by 0.8.

14. Item 10-25

Instructions to nurses:

You need to describe in more detail the instructions you will give nurses and how you will provide the necessary information. A copy of an instruction form to be used by the nursing staff should also be provided for review by this office. (10 CFR 35.310 and 35.410)

15. Item 10-22.

A description of your thyroid burden measurement procedures for attending personnel is required. You may wish to follow the model procedure in Appendix P of NRC Regulatory Guide 10.8 (Revision 2). (10 CFR 35.315)

NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 2 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-01787-01

Docket or Reference number: 030-01600

Amendment No. 31

Good Samaritan Hospital
520 South Seventh Street
Vincennes, IN 47591

In accordance with application dated March 21, 1985, License Number 13-01787-01 is amended as follows:

Condition 12. and 22. are amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Thomas C. Brown, M.D.	Groups I, II, III, IV, V and VI Xenon-133 In vitro studies
Malcolm S. Floyd, M.D.	Groups I, II, III, IV and V Xenon-133 In vitro studies Strontium-90 eye applicator
Howard W. Kays, M.D.	Group VI Phosphorus-32 in colloidal form for intracavitary treatment Gold-198 in colloidal form for intracavitary treatment
Timothy R. Whiteman, M.D.	Groups I, II and III Xenon-133 In vitro studies
Dennis E. King, D.O.	Groups I, II and III Phosphorus-32 (soluable) for treatment of polycythemia vera, leukemia and bone metastases Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction

22. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in applications dated January 26, 1983, April 22, 1983, April 3, 1984, and March 21, 1985; letters dated January 19, 1983 (except item 19(2)), July 20, 1983; and ALARA Program dated January 19, 1983. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

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COPY 5

NRC Form 374A (8-82) U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 1 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 13-01787-01

Docket or Reference number:

Amendment No. 28

Good Samaritan Hospital
520 S. Seventh St.
Vincennes, IN 47591

In accordance with letter dated June 15, 1984, License Number 13-01787-01 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Thomas C. Brown, M.D.	Groups I, II, III, IV, V and VI Xenon-133 In vitro studies
Malcolm S. Floyd, M.D.	Groups I, II, III, IV and V Xenon-133 In vitro studies Strontium-90 eye applicator
James A. Dennis, M.D.	Licensed material of the types, quantities and forms specified in Sections 35.31(a) of 10 CFR 35 and 31.11(a) of 10 CFR 31 in accordance with the provisions of paragraphs (a) and (c) of Section 35.31, 10 CFR 35 and paragraphs (a), (c), and (d) of Section 31.11, 10 CFR 31.
Howard W. Kays, M.D.	Group VI Phosphorus-32 in colloidal form for intracavitary treatment Gold-198 in colloidal form for intracavitary treatment

For the U.S. Nuclear Regulatory Commission

Date JUL 13 1984

By _____
Materials Licensing Section, Region III

Certified This date a true Copy Thomas C. Brown M.D.