L + L23297

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 8-31-87

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: READ 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)

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

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

Pali Momi Medical Center
98-1079 Moanalua Road
Aiea, HI 96701
Phone: (808) 486-6000

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

Same as #2 Above

NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Don Tolbert, Ph.D., or Elizabeth G. Rodenbeck, M.S., Consultants | (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
R Dale Reynolds	R. Dale Reynolds	Executive Director	6/8/89

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 (for you 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
Appl	Jun-2-V	7C	8912060272 890829 REG5 LIC30 53-23297-01 PDR	M. Mussi
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	108379			6/19/89

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, including sealed sources for calibration and reference	As Needed	B.	Medical Use
C.	Material Identified in 10 CFR 35.300	As Needed	C.	Medical Use
D.	Material Identified in 10 CFR 35.500	900 Millicuries per source	D.	Medical Use

Item 5 and 6
Date: 6/8/89

INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS - THEIR EXPERIENCE AND TRAINING

7.1 Authorized Users

A. Richard D. Wasnich, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300 and 35.500. Dr. Wasnich is currently an authorized user under NRC Materials License No. 53-17797-01.

B. Robert A. Nordyke, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300 and 35.500. Dr. Nordyke is currently an authorized user on NRC Materials License No. 53-18126-01.

C. Fred I. Gilbert, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300 and 35.500. Dr. Gilbert is currently an authorized user under NRC Materials License No. 53-18126-01.

D. Michael C. C. Ling, M.D., for materials identified in 10 CFR 35.100, 35.200, 35.300 and 35.500. Dr. Ling is currently an authorized user under NRC Materials License No. 53-17797-01.

RADIATION SAFETY OFFICER

Richard D. Wasnich, M.D., is designated as the institution's Radiation Safety Officer (RSO). Dr. Wasnich is currently designated as the RSO under NRC Materials License No. 53-17797-01.

Fred I. Gilbert, M.D., is designated as the institution's alternate Radiation Safety Officer (RSO) for purposes of attending any Radiation Safety Committee meeting on the rare occasions that Dr. Wasnich is not available.

Item 7-2
Date: 6/8/89

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.

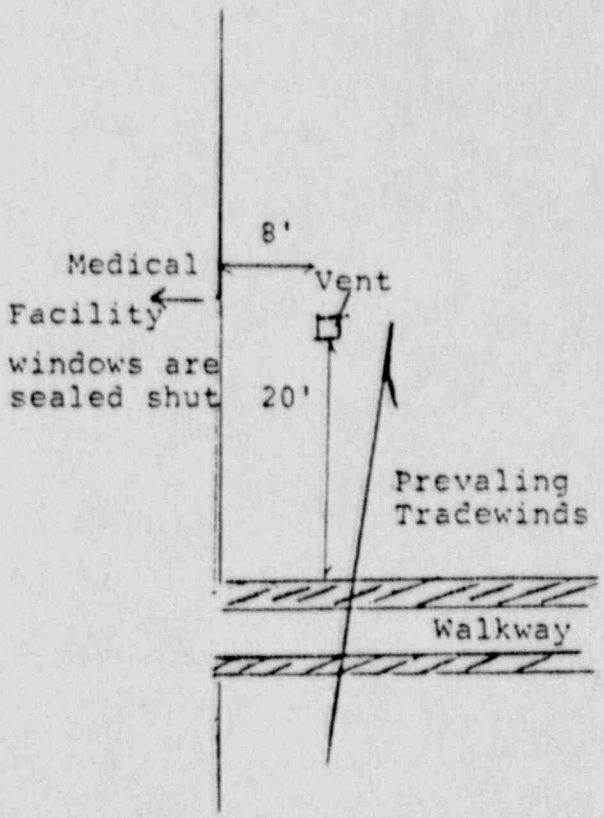
Item 8-1
Date: 6/8/89

FACILITIES AND EQUIPMENT

A. Facilities Description and Annotated Drawings

The Nuclear Medicine Section is located in the Radiology Department, on the second floor, of the Pali Momi Medical Center. The nuclear medicine facility consists of an imaging room, hot lab, and in-patient holding area (see Item 9, Figure 1).

The hot lab consists of a sink, dose calibrator, fume hood, and shielded dose preparation area. The Labconco fume hood is equipped with a fan which is rated at over 800 fpm. The face velocity of the hood will be checked following installation to assure a minimum rate of 100 fpm. Iodine-131 liquid therapy dosages will be stored under the hood. An L-shield and lead bricks have been ordered to provide a shielded work station. Radioactive waste will be stored in a shielded area under the hood. Shields for vials and syringes will be employed to minimize extremity exposure. The hot lab shall be locked when not physically attended and will be posted in accordance with 10 CFR Part 20. The dedicated exhaust stack of the fume hood vents on the fourth floor roof. The stack vent is located approximately 20 feet downwind of the closest unrestricted area, a railed walkway between the medical facility and physician's office facility on the fourth floor. The vent is directed toward a wall of windows which do not open approximately 8 feet away.



Item 9-1
Date: 6/8/89

B. **Equipment**

1. **Survey Meters**

   a. A GM survey meter with a detection range from 0.1 to 1,000 mR/hr.

   b. GM pancake detector with range of 0 - 1,000,000 cpm.

2. **Dose Calibrator**

   - A Capintec model is on order with a range of 1 μCi to 2 Ci.

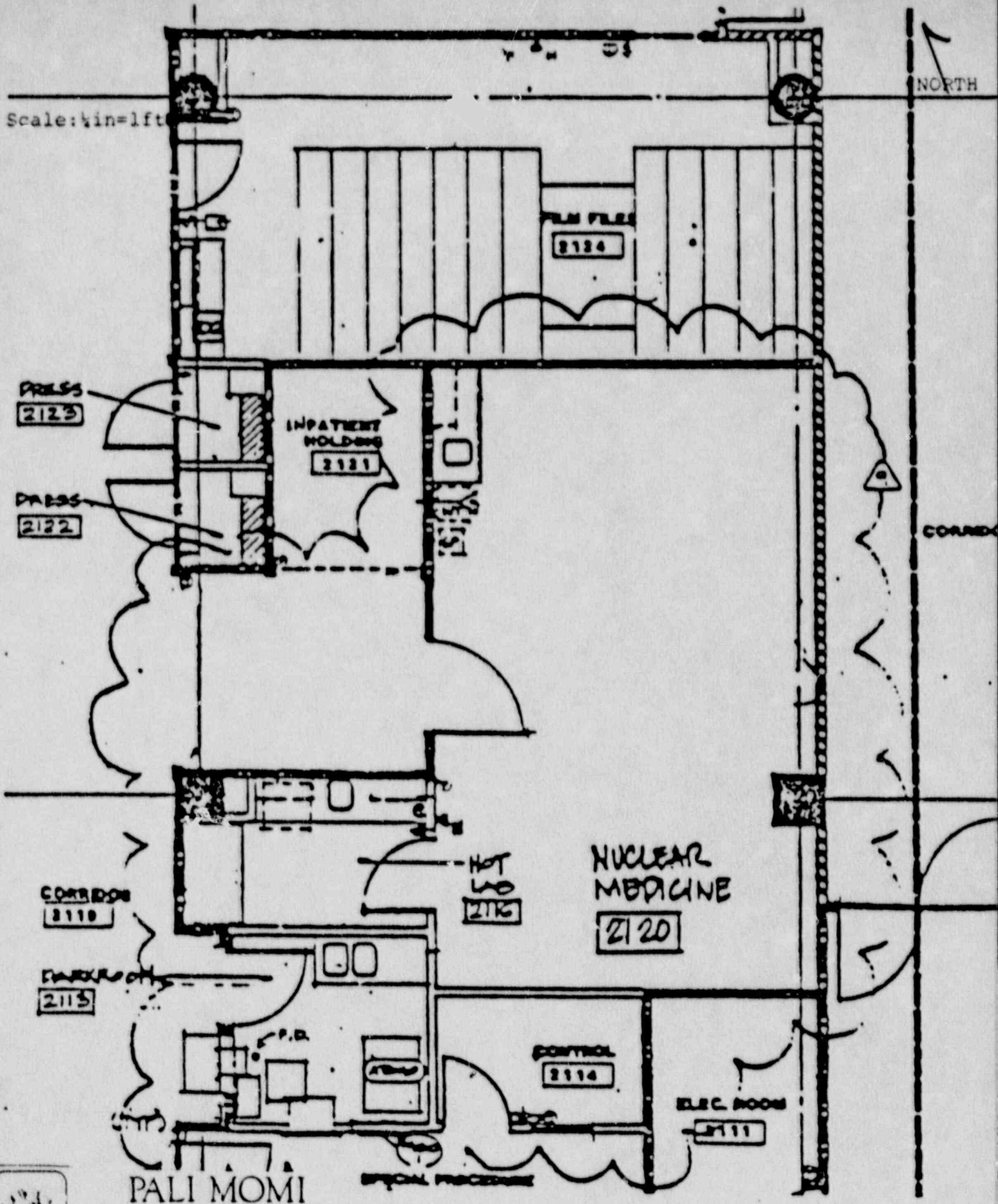
3. **Aerosol Delivery System**

   - Atomic Products Corporation, Model Venti-Scan II, disposable radioaerosol system is on order.

4. **Diagnostic Equipment**

   a. Picker SPECT imaging camera, Model 615 44-3-3, S/N 140.

   b. A thyroid uptake probe and scaler are on order to perform patient uptakes and worker bioassays. Minimum detectable activity will be less than 0.04 μCi of I-131.



PALI MOMI
MEDICAL CENTER

98-1079 Moanalua Road / Aiea, Hawaii 96701
Telephone (808) 486-6000 / FAX (808) 488-1457

Nuclear Medicine Section
Radiology Department
Second Floor

Item 9
Figure 1
Date: 6/8/89

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

Item 9-3
Date: 6/8/89

DOSE CALIBRATOR CALIBRATION

A. Dose Calibrator Constancy Check

Using a Cs-137 source of approximately 200 μCi, we shall check the constancy of the dose calibrator each day of use at the Cs-137, Tc-99m and I-131 settings. As per 10 CFR 35.50 (d), we shall repair or replace the dose calibrator if the constancy error exceeds 10%.

We shall retain the dose calibrator constancy check records for three years.

The dose calibrator constancy check record shall include: model and serial number of dose calibrator, radionuclide in the check source, the date of the check, the activity measured, and the initials of the person performing the check.

B. 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 7% of its stated activity of greater than 50 μCi 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 three years. The dose calibrator will be repaired or replaced if the accuracy error exceeds +/- 10%.

For the accuracy check, we shall use the services of Mid-Pacific Medical Physics or any other firm licensed by the NRC or an agreement state to perform calibrations for clients. See attached Mid-Pacific Medical Physics NRC License 53-23207-01 renewal for procedure.

Item 9-4
Date: 6/8/89

ITEM 10-6: MID-PACIFIC MEDICAL PHYSICS
NRC LICENSE 53-23207-01 RENEWAL

CALIBRATION OF THE ACCURACY OF DOSE CALIBRATORS

We shall follow the model procedure for calibrating the accuracy of dose calibrator described in 7.a. to 7.f. on pages C-5 and C-6 that was published in Appendix C to Regulatory Guide 10.8, Revision 2.

Item 9-4
Attachment
Date: 6/8/89

C. **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 10 μCi. The method employed will be either a decay procedure (see Attachment) or use of the Calicheck device following the procedures in the Calcorp, Inc., manual dated 3/2/82 (manual enclosed). Dosage readings will be mathematically corrected for any linearity error that exceeds 10% if the dosage is greater than 10 μCi. 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 three years.

D. **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 of 1, 2, 3, 4, 5, 10, 20, and 30 ml. 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.

DECAY PROCEDURE FOR DOSE CALIBRATOR LINEARITY CHECK

Checks for linearity shall be made by assaying a vial of Tc-99m of activity at the same maximum activity normally used, then reassaying the same vial at 6, 24, 30, 48, and 72 hours after the initial assay. Instances where the difference in the measured activity is greater than +/- 10% from the calculated activity shall be investigated.

A. Take a background with a "blank" vial and adjust to zero.

B. Assay the Tc-99m vial and record this value.

C. Repeat Step B at the time intervals stated above and record each time and reading.

D. Using the 30-hour activity measurements as a starting point, calculate the predicted activities at time listed above using the following table: (T/2 = 6.03 Hours)

Assay Time (Hours)	Correction Factor
0	31.4299
6	15.7716
24	1.9928
30	1.000
48	0.12636
72	0.0080

E. Calculate the percent difference between the actual readings and the predicted readings and record them. Errors greater than +/- 10% required repair or replacement.

Item 9-5
Attachment
Date: 6/8/89

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

A. 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).

B. 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 NVLAP approved contract service on a monthly basis.

C. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be be processed by a contract service on a monthly basis.

D. Nurses caring for radiopharmaceutical therapy patients will be issued whole body personnel monitors. Except for a medical emergency, only personnel wearing personnel monitors will enter the patient's room.

E. 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.

RADIATION SAFETY COMMITTEE

A. This Committee has been established by authority of Mr. R. Dale Reynolds, Executive Director of Pali Momi Medical Center, as the administrative body responsible for the safe use of radioisotopes at Pali Momi Medical Center

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

1. The Radiation Safety Officer;

2. A Management Representative;

3. A Representative of the Nursing Staff;

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

5. The Consultant Health Physicist.

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

D. The Committee is responsible for:

1. 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.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license, and consistent with ALARA philosophy and program.

E. In performing its duties, the Committee shall:

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

2. Review the training and experience of all authorized users and confirm the efforts of each authorized user to keep exposures ALARA by encouraging efforts to refine procedures to optimize the ALARA concept.

Item 10-1
Date: 6/8/89

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

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

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review quarterly summary of [illegible]onal exposure records of all personnel [illegible] by-product material, and all incide[illegible]g by-product material as to cause and act[illegible]

7. Review the entire radi[illegible]io[illegible]rogram at least annually to determine [illegible]t[illegible]ities are being conducted safely a[illegible]n [illegible] regu[illegible]ions and the condition[illegible]he l[illegible], nd[illegible]stent with the ALARA philosc[illegible]ny p[illegible]am[illegible]he[illegible]iew shall include an examinat[illegible]f all [illegible], re[illegible]s from the radiation safety o[illegible]er result[illegible]C inspections, written safety procedures, a[illegible] the a[illegible]acy of the institution's management control system.

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

9. 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.

10. 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.

11. 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.

F. 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

A. Management Philosophy and Responsibilities

1. The management of Pali Momi Medical Center is committed to the philosophy of maintaining occupational radiation exposures as low as reasonably achievable (ALARA) and to keeping the sum of radiation doses received by all exposed personnel as low as practical. The procedures described below outline the methods by which the management philosophy will be implemented.

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

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

4. 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.

B. Responsibilities of the Radiation Safety Officer (RSO) or Alternate RSO

1. 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.

2. 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.

3. 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.

4. 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.

5. The RSO will review personnel occupational radiation exposures and report to the Radiation Safety Committee quarterly. He will perform an investigation of all exposures exceeding control levels and document in the summary report the cause of the high exposure and the steps taken to reduce exposures.

6. The RSO will establish contamination and ambient radiation action levels for areas surveyed that conform to 10 CFR Part 20 and Regulatory Guide 8.23 Table 2 limits and review quarterly radiation levels in restricted areas and will review records of releases to unrestricted areas, and report to the RSC if they are not ALARA.

7. 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.

8. The RSO will instruct workers in recourses available if they feel ALARA is not being promoted on the job and establish a means for soliciting employee suggestions for reducing occupational radiation exposure.

C. **Authorized User Responsibilities**

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

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

D. **Occupational Worker Responsibilities**

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

2. 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.

3. 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.

E. Establishment of Control Levels for Maintaining Occupational Radiation Exposures ALARA

1. 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

2. The RSO will review the results of personnel monitoring not less than once per calendar quarter and document the results of the review.

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

4. If personnel exposures are greater than Level I but less than Level II, the RSO will report the results to the next meeting of the 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.

5. 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: 6/8/89

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. In such cases, the concepts of time, distance, and shielding will be used to reduce exposures as low as practical.

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.

Item 10-8
Date: 6/8/89

Table 1

SURVEY FREQUENCIES

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

2. Laboratory areas where only small quantities of radioactive material (less than 200 μCi at any one time) are used should be surveyed monthly.

3. All other laboratory areas should be surveyed weekly.

4. The weekly and monthly surveys should consist of the following:

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

   b. A series of smear tests to measure contamination levels. The method for performing smear tests should be sufficiently sensitive to detect the limits in Table 2 to one significant digit.

   c. Any air sample measurements necessary to determine compliance with §20.103 of 10 CFR Part 20 in cases where calculations alone are not sufficient.

Table 2

RECOMMENDED ACTION LEVELS FOR REMOVABLE SURFACE CONTAMINATION IN MEDICAL INSTITUTIONS*.

Type of Surface	Type of Radioactive Material**					
	Alpha Emitters		Beta or X-Ray Emitters		Low-Risk Beta or X-Ray Emitters	
	($\mu Ci/cm^2$)	($dpm/100 cm^2$)	($\mu Ci/cm^2$)	($dpm/100 cm^2$)	($\mu Ci/cm^2$)	($dpm/100 cm^2$)
1. Unrestricted areas	10^{-7}	22	10^{-6}	220	10^{-5}	2,200
2. Restricted areas	10^{-6}	220	10^{-5}	2,200	10^{-4}	22,000
3. Personal clothing worn outside restricted areas	10^{-7}	22	10^{-6}	220	10^{-5}	2,200
4. Protective clothing worn only in restricted areas	10^{-6}	220	10^{-5}	2,200	10^{-4}	22,000
5. Skin	10^{-6}	220	10^{-6}	220	10^{-5}	2,200

*As adapted from Table I of Reference 10. Averaging is acceptable over nonadjacent areas of up to 300 cm^2 or, for floors, walls, and ceilings, 1000 cm^2. Averaging is also acceptable over 100 cm^2 for skin or, for the hands, over the whole area of the hand, nominally 300 cm^2.

**Items in Array emitter values are applicable for all beta- or X-ray emitters other than those considered low risk. Low-risk nuclides include C-14, H-3, S-35, Tc-99m, and others whose beta energies are less than 0.2 MeV maximum, whose gamma or X-ray emissions yield less than 0.1 R/h at 1 meter per curie, and whose permissible concentration in air (see 10 CFR Part 20, Appendix B, Table I) is greater than 10^{-6} $\mu Ci/ml$.

Item 10-B
Attachment
Date: 6/8/89

12. Where millicurie quantities of radioactive material are handled, perform a weekly contamination survey by wipe testing active storage, preparation, and patient administration areas. Where only microcurie quantities of radioactive material are handled, perform a monthly wipe test survey for contamination. Obey action or trigger levels established by the RSO.

13. Confine radioactive solutions in shielded covered containers plainly identified, labeled, or coded.

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: 6/8/89

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:	Richard D. Wasnich, M.D.
OFFICE PHONE:	547-9459
BEEPER:	988-8224
RADIATION SAFETY CONSULTANT:	Don Tolbert, Ph.D.
OFFICE PHONE:	536-2774
BEEPER:	525-9086 (After the beep, enter number to be called then the "#" sign.)

Item 10-11
Date: 6/8/89

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, the security guard on duty will accept delivery of these packages in accordance with the procedures outlined in Mr. Dale Reynolds' memorandum (attached).

Item 10-12
Date: 6/8/89

9. Replace yellow tube with green tube. Record.
10. Replace green tube with blue tube. Record.
11. Replace blue tube with purple tube. Record.
12. Remove the Calicheck assembly and place source in a shielded container. Place Calicheck in storage container provided.

DATA TREATMENT OF DATA SHEET #1:

1. Divide the numerator by the denominator in Column B to determine the Calibration Factor, and record in Column C. Retain these values for future reference. These factors will be used for all future activity linearity tests provided all conditions of the test are met (i.e., same dose calibrator, same kit, same radionuclide, same source configuration). Recalculation will be required following repair of dose calibrator or Calicheck.
2. Compare results to chart of "Typical Calibration Factors" on page 9. Differing values may be due to variations in geometry in the response of the dose calibrator and/or in the kit manufacturing process itself.
3. Transfer determined Calibration Factors from Data Sheet #1 to appropriate place in Column C of Data Sheet #2. (See example on page 13.) To confirm the accuracy of the determined factors, complete Data Sheet #2. If no error has been made, all values in Column D (product of B x C) should be the same. If values differ, repeat the determination.

Kit Calibration

All readings must be taken at lowest range setting available and converted to mCi units.

TUBES		DISPLAYED ACTIVITY		CALIBRATION FACTORS
A		B		C
Black Only / Black Only	=	_____ mCi / mCi	=	1.00
Black Only / Black & Red	=	_____ mCi / mCi	=	_____
Black Only / Black & Orange	=	_____ mCi / mCi	=	_____
Black Only / Black & Yellow	=	_____ mCi / mCi	=	_____
Black Only / Black & Green	=	_____ mCi / mCi	=	_____
Black Only / Black & Blue	=	_____ mCi / mCi	=	_____
Black Only / Black & Purple	=	_____ mCi / mCi	=	_____

SOURCE CONFIGURATION

_____ Syringe

_____ Vial

*Or following repair of dose calibrator or Calicheck Kit. In all instances these factors can only be determined following proof of activity linearity by standard techniques. **KEEP THIS FORM FOR FUTURE REFERENCE!**

SECTION III

Calibration of Calicheck

OBJECTIVE:
To generate calibration factors for each tube in the Calicheck Kit, thereby expressing the amount of attenuation by each tube.

PREPARATION:
All radiation sources in the vicinity of the dose calibrator should be shielded to avoid erroneous readings. Further, the instrument may be sensitive to dosed patients in the vicinity. Move the patients to another location before you start. Both the "Kit Calibration" and the "Activity Linearity Procedure" must be performed in an environmentally stable background.

Syringe hangers and vial holder assemblies supplied with Capintec, Nuclear Associates, and some Picker dose calibrators must be removed. Molded chamber liners as supplied by RadX and some Picker dose calibrators must be lifted out. Calicheck will not fit the Mediac dose calibrators because the chamber diameter is too small.

The calibration source that is used should be the largest activity measured in the dose calibrator. This would normally be the Monday morning elution in the case of the generator, or the largest dose obtained from your radiopharmacy.

In order to use Calicheck, a source of Tc-99m must be placed into the central black tube. If the source is in a top loading lead elution shield, use extension tongs to transfer the source. If the source is in a bottom loading elution shield, remove the base cover, put the open end of the black tube to the bottom of the lead shield and allow the source to slide down into the black tube by tilting the tube at an angle. The center tube accommodates vial sizes up to 20 ml. and syringes up to 10 ml. Proper technique dictates that when using a syringe, a clean needle be used and it should be no longer than 1-1/2" in length. When the black tube is inserted into the dose calibrator, it should be done carefully with the open end in the upward position. The black tube must remain in the dose calibrator throughout all steps in the calibration cycle. Once the source is placed in the dose calibrator, the source must be kept in exactly the same position throughout the test to insure consistent geometry.

Typical Calibration Factors

	CAPINTEC		RADX		PICKER	
	VIAL	SYRINGE	VIAL	SYRINGE	VIAL	SYRINGE
Black	1.00	1.00	1.00	1.00	1.00	1.00
Red	1.83	1.74	2.27	2.16	1.73	1.90
Orange	3.59	3.32	4.58	4.24	3.31	3.49
Yellow	10.9	9.74	14.4	12.9	9.71	9.96
Green	34.9	30.4	48.6	42.3	31.1	30.7
Blue	121	103	164	140	105	104
Purple	399	334	565	473	342	326

These factors were determined using Tc-99m in a 10 ml vial and a 3 ml syringe. They represent an average of several determinations using the same kit in different dose calibrators of the same type as well as different kits in the same dose calibrator. These factors are not to be used as a substitute for determined calibration factors. They are listed here for comparison purposes only.

SECTION II

General Information

Several important points must be understood prior to using Calicheck. The points are as follows:

1. Calcorp performs thorough quality control on all kits. However, it is suggested that the kit be checked to ensure that the kit has not been damaged in shipment.
2. The components of the kit and/or the dose calibrator can be damaged if misused. It is especially important that damage does not occur to the ends of the tubes.
3. Should tubes become damaged or lost, replacement parts can be ordered with the form found on page 15 of this instruction manual.
4. Calicheck confirms activity linearity. It will not make your dose calibrator linear.
5. The dose calibrator must exhibit activity linearity prior to utilizing the Calicheck kit. This must be accomplished by performing an activity linearity test using standard techniques such as described in your license application. For NRC license holders, this test should be at a minimum equivalent to Appendix D of Regulatory Guide 10.8, October, 1980. If nonlinearity is demonstrated, the instrument should be repaired.
6. Calicheck must be specifically calibrated for each dose calibrator in the facility since variations between manufacturers (and sometimes, models) are known to exist. Similarly, kits should not be interchanged without first confirming calibration factors. Each tube in the Calicheck kit must be calibrated and each time a tube is replaced in the kit, the new tube must be calibrated. A procedure is enclosed that describes the calibration technique.
7. Readings obtained from Calicheck are not to be used for assay purposes.
8. The radionuclide used for testing must be Tc-99m, and it must be relatively free of Mo-99 contamination. The concentration of Mo-99 in the sample should be less than .15 uCi Mo-99/mCi Tc-99m. If a central radiopharmacy is used as the source of Tc-99m, ask the radiopharmacist for his assay results.

10. Replace green tube with blue tube. Record on "Black & Blue" blank.
11. Replace blue tube with purple tube. Record on "Black & Purple" blank.
12. Remove Calicheck assembly and place source in shielded container.

DATA TREATMENT OF DATA SHEET #2: (To be completed each calendar quarter or at a frequency required by your license conditions.)

1. Enter appropriate Calibration Factors from Data Sheet #1 for your dose calibrator in Column C.
2. Multiply the value in Column B by the corresponding value in Column C to determine product of each entry for Column D. Record values. (Ideally, these values will all be the same.)
3. Add all products in Column D and divide by 7 to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of ±5% variation.

If all values in column D fall between these two limits, your dose calibrator has acceptable activity linearity. The test is complete, unless additional readings are required to check the microcurie range. If so, continue the determination by withdrawing an aliquot containing 2-3 mCi more activity than the displayed activity in the last measurement. The test is then repeated (Data Sheet #2 only), using the same source configuration as that used in determining the calibration factor on Data Sheet #1.

If any values in Column D fall outside the limits, repeat the study to rule out possible variations in the initial data. Consistent results that are outside the limits indicate that the instrument is exhibiting non-linearity. Corrective action is indicated.

Example

A Mo/Tc generator is eluted and yields 342 mCi. The entire elution is placed in the dose calibrator inside the black tube. Subsequent readings generated the following data.

Dose Calibrator Activity Linearity Check

All readings were taken at lowest range setting available and converted to mCi units.

A	B		C		D
TUBE COLOR	DISPLAYED ACTIVITY		CALIBRATION FACTOR		PRODUCT OF B X C
Black Only:	342 mCi	X	1.00	=	342
Black & Red:	201 mCi	X	1.72	=	346
Black & Orange:	106 mCi	X	3.23	=	342
Black & Yellow:	34.1 mCi	X	9.53	=	325
Black & Green:	10.2 mCi	X	29.5	=	301
Black & Blue:	3.54 mCi	X	96.6	=	342
Black & Purple:	1.19 mCi	X	305	=	363
			SUM	=	2361

$$\text{MEAN} = \frac{2361}{7} = 337$$

MEAN X 1.05 = 354 = UPPER LIMIT*

MEAN X 0.95 = 320 = LOWER LIMIT*

The readings for the green and purple tubes are outside the limits. The procedure should be repeated to confirm the data. Repair may be indicated. Failure to account for a re-zeroing problem between ranges *(see Procedure Step #3)* or an unstable background may also have produced this apparent non-linearity.

This apparatus and method for it's use is covered by United States Letters Patent No. 4,333,010 issued on June 1, 1982. Calcorp expressly withholds all license to use this apparatus to practice methods covered by this patent for calibrating equipment not owned by purchaser.

SECTION VI

Calcorp, Inc.

PO BOX 25509
CLEVELAND OHIO 44125
(216) 663 1773

Calicheck Parts Order Form

ITEM	PRICE* (ea.)	QUANTITY	PRICE
Black Center Tube	$60.00		
Lead Wrapped Tubes	$60.00		
Red			
Orange			
Yellow			
Green			
Blue			
Purple			
		TOTAL	
Storage Container	$ 6.00		
		TOTAL ENCLOSED	

BILL TO:

Name: _____

Address: _____

_____

_____

P.O. # _____

SHIP TO:

Name: _____

Address _____

_____

_____

*Prices are subject to change without notice.

M E M O R A N D U M

FOR: Security Supervisor

FROM: Dale Reynolds, Executive Director ROR

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, and 7 a.m. to 12 noon on Saturday) shall be signed for by the nurse supervisor on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter, and relock the door.

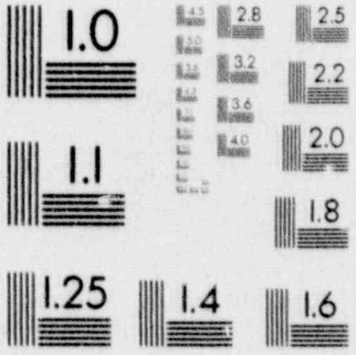
If the package is wet or appears to be damaged, immediately contact the Radiation Safety Officer or alternate. Ask the carrier to remain at the building until it can be determined that neither he nor the delivery vehicle is contaminated.

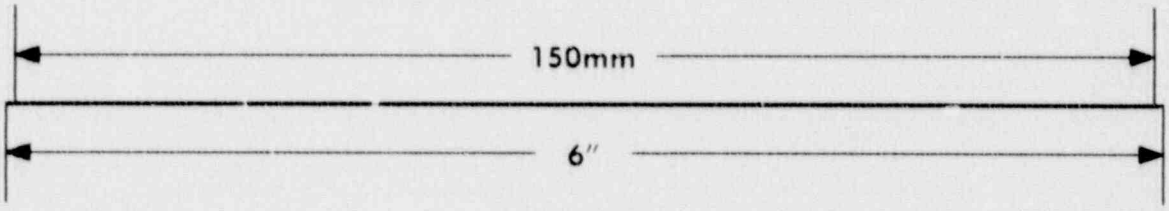
RADIATION SAFETY OFFICER:	Richard D. Wasnich, M.D.
OFFICE PHONE:	547-9549
BEEPER:	288-8224
RADIATION SAFETY CONSULTANT:	Don Tolbert, Ph.D.
OFFICE PHONE:	536-2774
BEEPER:	525-9086 (After the beep, enter number to be called then the "#" sign.)

Item 10-13
Date: 6/8/89

2

IMAGE EVALUATION TEST TARGET (MT-3)

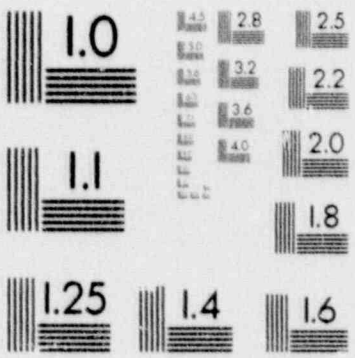


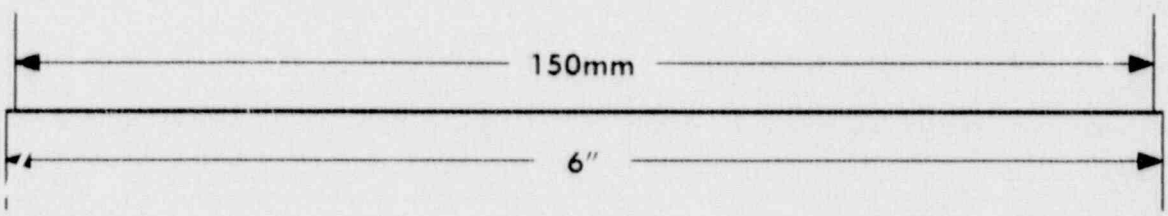


PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

2

IMAGE EVALUATION TEST TARGET (MT-3)

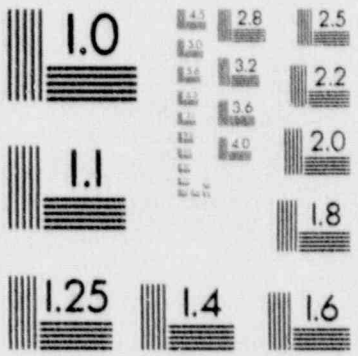


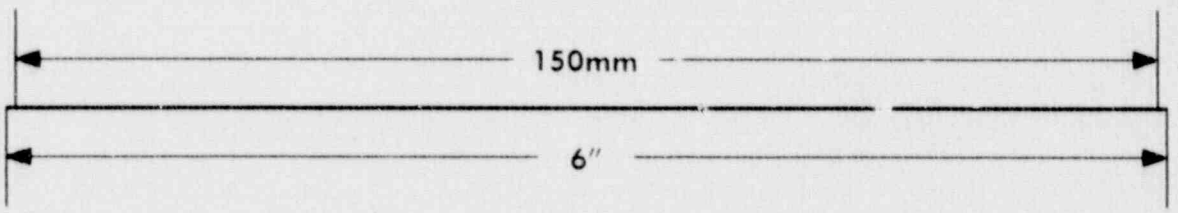


PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

2

IMAGE EVALUATION TEST TARGET (MT-3)

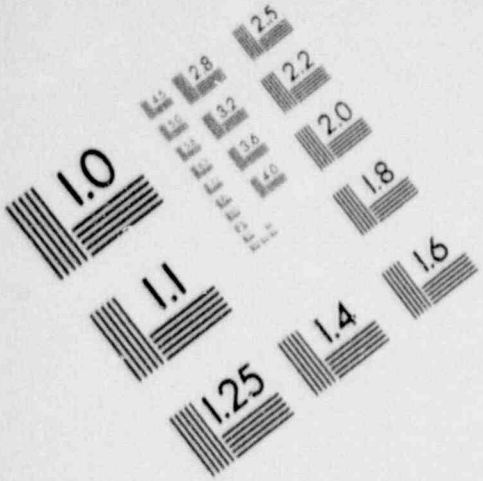


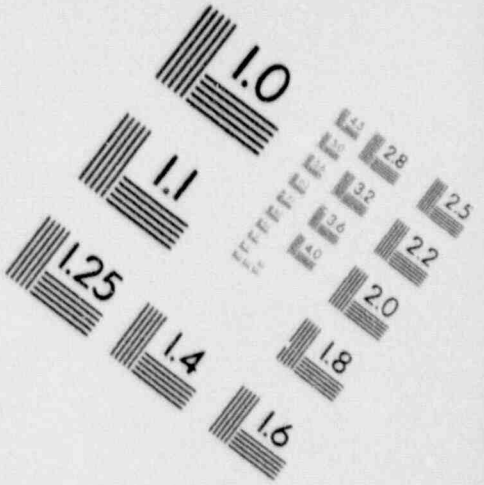


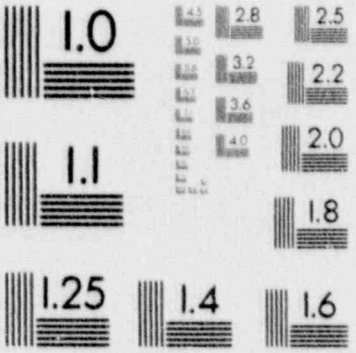
PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

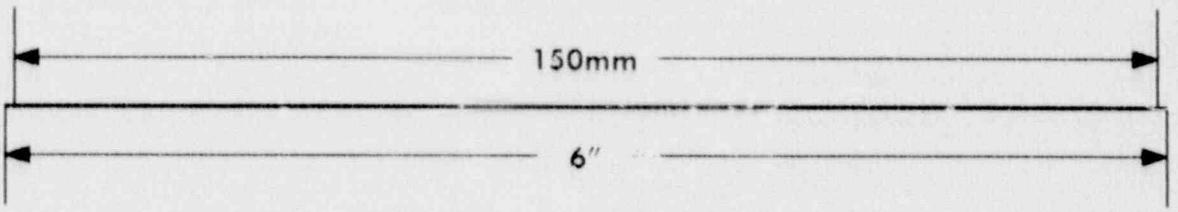
2

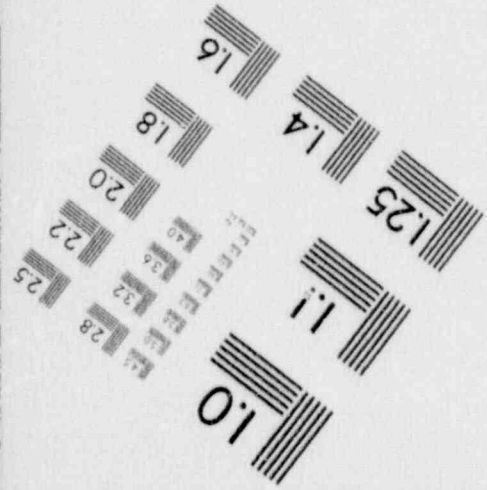
IMAGE EVALUATION TEST TARGET (MT-3)

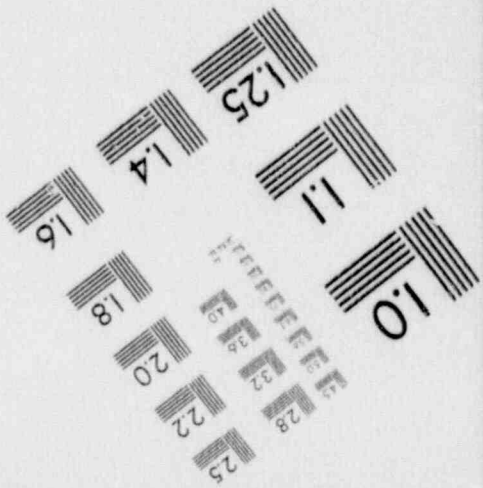












PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

A. 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.

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

1. Put on gloves to prevent hand contamination.

2. 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).

3. 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.))

4. Open the package with the following precautionary steps:

   a. Remove the packing slip.

   b. Open the outer package following the supplier's instructions, if provided.

   c. Open the inner package and verify that the contents agree with the packing slip.

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

e. If anything is other than expected, stop and notify the RSO.

5. 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.

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

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

   a. If contaminated, treat this material as radioactive waste.

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

8. Make a record of the receipt.

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

1. 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.

2. 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: 6/8/89

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: 6/8/89

SURVEY PROCEDURES

A. Types of Surveys

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

2. Waste storage areas and all other imaging areas will be surveyed weekly.

3. The weekly survey will consist of:

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

   b. A series of wipe tests to measure contamination levels. The method for analyzing wipe test samples will be sufficiently sensitive to detect 2000 dpm/100 sq.cm. Wipes taken in high background areas will be removed to a low background area for measurement. The decimal efficiency factors provided in equipment calibration reports will be divided into the net cpm reading to convert to net dpm.

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

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

2. The initials of the person conducting the survey and the date of the survey.

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

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

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

C. Areas will be cleaned if the measured levels exceed the established trigger levels for contamination or radiation exposure.

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

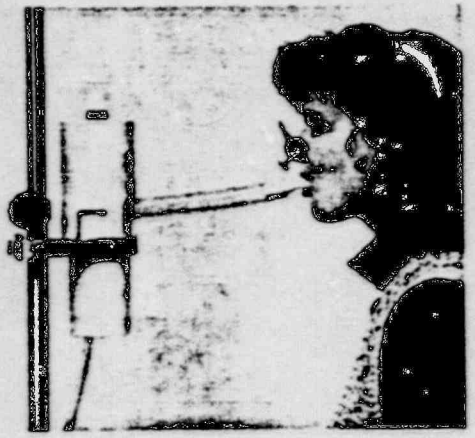
NOTE: For daily surveys where no abnormal exposures were found, only the date, identification of person performing the survey, and the survey results need be recorded.

AIR CONCENTRATION CONTROL

We use radioactive aerosol to perform pulmonary ventilation studies. We employ Atomic Products Corporation's Venti-Scan II disposable radioaerosol system and use the manufacturer's operation manual (see attachment). We will collect spent aerosol in a shielded single use device which is discarded into radioactive waste.

Item 10-19
Date: 6/8/89

STEP 9



Place the mouthpiece in the patient's mouth making sure the patient maintains a good seal. *Apply nose clip.* Instruct the patient to relax and test breathe on the system five or six times to insure proper operation and patient familiarity. Turn on the oxygen (or air) slowly, adjust the flow to 6-12 liters/minute. Instruct the patient to continue breathing through the system for 3-8 minutes to assure sufficient lung deposition. After inhalation, in order to maximize clearance of any remaining activity in the tubing and minimize possibility or inadvertant contamination of the patient or your rooms, turn off oxygen and instruct patient to continue breathing for 5 or 6 breaths before removing mouthpiece. Also to help prevent contamination, the patient may expectorate saliva in a disposable towel to be handled as normal radioactive waste. Remove nose clip and start imaging.

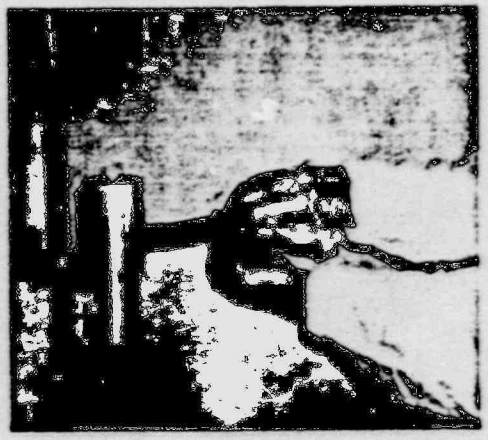
NOTE: Imaging may be performed during radio-aerosol inhalation.

CAUTION: In order to prevent inadvertant contamination of the patient or your room, use care and good radiation practice when removing the patient from the system.

CAUTION: Procedure may not be appropriate for uncooperative patients, or patients who cannot maintain a good mouthpiece seal.

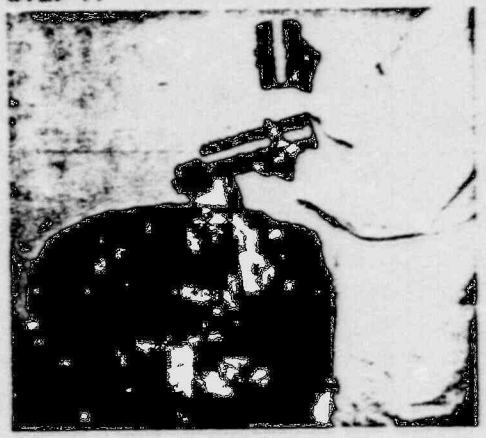
CAUTION: Federal law restricts this device to sale by or on the order of a physician.

STEP 10



Disconnect oxygen tube, remove the shielded assembly from the support stand to radioactive waste disposal/storage area.

STEP 11



Twist assembly to remove top. The nebulizer insert can be removed without handling. Use site approved procedure for disposal of radioactive and biohazardous waste.

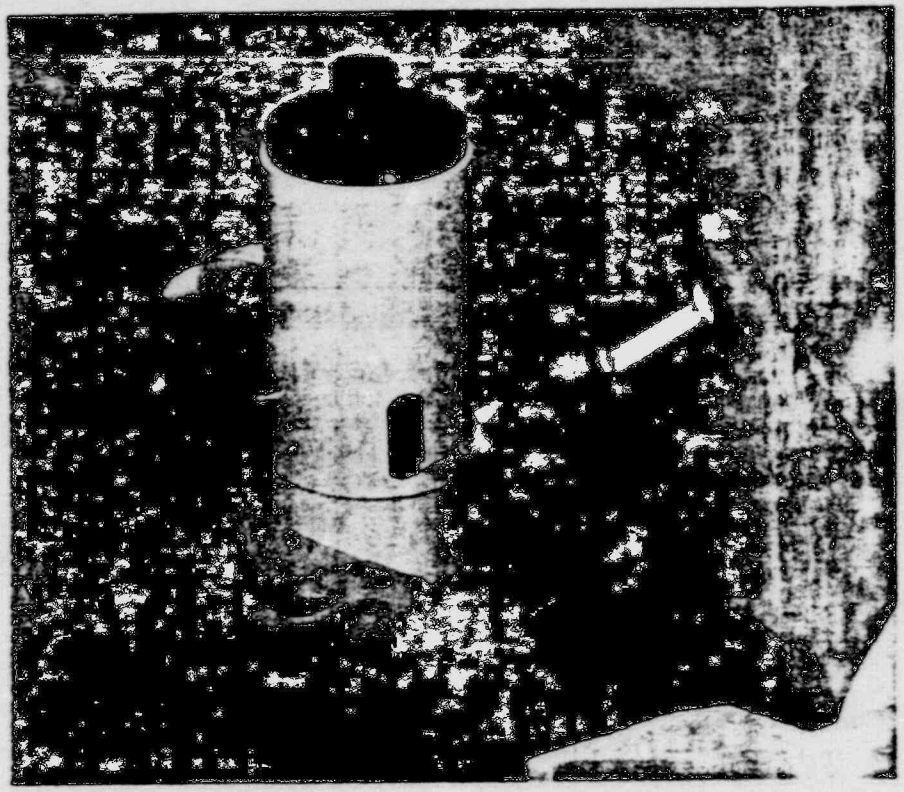
CAUTION: Do not reuse disposable nebulizer insert!

Atomic Products Corporation

ATOMLAB DIVISION • ESTABLISHED 1949

P.O. DRAWER R, SHIRLEY, NEW YORK 11967-0917 U.S.A.
TEL #: (516) 924-9000 • TELEX #: 797566 • FAX #: (516) 924-9241
TWX #: 5102280449 ATOMLAB CTCH

Operation Manual



DISPOSABLE RADIOAEROSOL SYSTEM FOR VENTILATION SCANNING STUDIES

Venti-Scan II (#177-079)

Atomic Products Corporation

ATOMLAB DIVISION • ESTABLISHED 1949

P.O. DRAWER R, SHIRLEY, NEW YORK 11967-0917 U.S.A.
TEL #: (516) 924-9000 • TELEX #: 797566 • FAX #: (516) 924-9241
TWX #: 5102280449 ATOMLAB CTCH

1/88

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with greater than 30 mCi of I-131 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material. Small items, such as telephones, doorknobs, or other items touched by the patient will be covered with plastic bags or wrappings.

2. The patient's room will be properly posted with a RADIOACTIVE MATERIALS sign.

3. The patient's room and surrounding areas will be surveyed as soon as practical after administration of therapeutic doses. Exposure rates will be measured at the patient's bedside and at three feet from the patient after administration. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times on the patient's chart and on the door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on the door.

4. The form, Doctor's Orders for Patients Who Have Received Phosphorus-32 and Iodine-131 Radionuclide Therapy, will be completed immediately after administration of the treatment dose and posted on the patient's chart. Nurses who attend the patient will be issued whole body personnel monitors. Except for a medical emergency, only personnel wearing personnel monitors will enter the patient's room.

5. Radiation levels in unrestricted areas will be maintained less than 2 mR/hr or less than 100 mR/7 days.

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

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste, will be placed in a specially designated container. The material will be held until surveyed and released by the Radiation Safety Officer or his designee.

8. Nondisposable items used for patients will be held in designated containers and checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use after verified free of contamination.

Item 10-20
Date:

9. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

10. Hospital staff personnel who routinely render medical or nursing care to the therapy patient will be provided with and required to read the special instructions on the patient's chart for handling patients with therapeutic doses of radionuclides.

11. Nurses will change surgical dressings for P-32 therapy patients only by direction of a physician. Stained dressings shall be collected in plastic bags and monitored by the Radiation Safety Officer or his designee. These dressings should be handled only with tongs or tweezers and disposable gloves worn.

12. Thyroid ablation patients will not be discharged until either the exposure rate from the patient is less than 5 mR/hr at one meter or the retained radioactivity is less than 30 mCi of I-131. The amount of activity remaining will be based on the ratio of:

$$\frac{\text{Activity Administered (mCi)}}{\text{Initial Exposure Reading at One Meter (mR/hr)}} =$$

$$\frac{\text{Activity Remaining (mCi)}}{\text{Current Exposure Reading at One Meter (mR/hr)}}$$

13. Patients may be released from the hospital with greater than 10 mCi but less than 30 mCi of activity, if instructions as enclosed are given to the patient. These instructions shall be given by the patient's physician or the Radiation Safety Officer, and a written copy shall be provided for the patient (see enclosed).

14. The Radiation Safety Officer shall be consulted before surgery is performed on a patient with therapuetic amounts of radionuclides; the Radiation Safety Officer shall also be consulted before autopsy is performed on a deceased patient with therapeutic amounts of radionuclides.

RADIATION SAFETY PROCEDURES FOR HANDLING PATIENTS WITH THERAPEUTIC DOSES OF RADIONUCLIDES

A. Purpose

The purpose of these procedures is to familiarize nursing personnel with the procedures to be followed to minimize their exposure and minimize the chance of spreading contamination when caring for patients who have received therapeutic doses of radionuclides.

B. General

1. Non-sealed radioactive sources are usually administered in liquid form, either by injection or orally. The radioactive material will remain in the patient until it is removed by radioactive decay or is excreted.

2. These procedures apply to patients who have received non-sealed radioactive sources for therapeutic purposes. They do not apply to patients who have received small amounts of radioactive material in connection with diagnostic tests such as scans.

3. Nurses who attend the patient will be issued personnel monitoring devices and must obey the designated amount of time (stay time) that they are allowed to spend near the patient.

C. Specific Procedures

1. Place the patient in a room with the bed near the outside wall of the room. A corner room is ideal. Place no other patients in the room.

2. Consistent with good care for the patient, carry out only minimal nursing procedures close to the patient. If the patient's clinical condition requires constant observation, rotate personnel required to perform adequate nursing care in order to minimize personnel exposure. The patient's bed should be approached only when required by nursing duties.

3. Nursing personnel should observe their stay time restrictions. Custodial, utility, maintenance, and food service personnel should not enter the room.

4. Unless contraindicated for other reasons, the patient may have visitors. Visitors should be instructed to stay at least 6 feet from the patient, except for short periods to deliver mail or shake hands, etc. The visitors should limit their visits to not more than 30 minutes per day, and the patient must remain in bed while visitors are in the room.

5. A television set, telephone, books, etc., may be provided to the patient. These items should not be returned to unrestricted use until they have been monitored and found to be free from radioactive contamination.

6. The food tray will be prepared entirely with disposable components. These will be disposed of as waste within the patient's room. Uneaten food will not be given to other patients or staff members.

7. Necessary contamination control measures are very similar to isolation techniques:

   a. Cover the mattress and pillow on the bed with plastic or rubber material.

   b. Wear gloves when changing bed linen, dressings, or other items that have been in contact with the patient. When done, remove gloves inside out and dispose of in radioactive waste container and wash hands.

   c. The patient must wear hospital pajamas.

   d. Place a plastic-lined wastebasket and linen hamper in the patient's room.

   e. Place waste, soiled linen, etc., in designated containers for monitoring before release or disposal.

   f. Personal items for patient care (thermometer, bedpan, etc.) will be kept in the patient's room.

   g. Ambulatory patients will use toilet in their room.

   h. Diagnostic samples of blood, urine, and feces should be obtained only when authorized by the Nuclear Medicine Department physician.

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

8. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic dose of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

9. If a nurse, attendant, or anyone else suspects that his skin or clothing is contaminated, he should notify the Nuclear Medicine Department immediately. He should remain in the patient's room until checked by the Radiation Safety Office or designee.

10. If the patient dies, notify the Radiation Safety Officer (RSO). The body will not be removed without the advice of the RSO.

11. The room will not be returned to general use until cleared by the Radiation Safety Officer or alternate.

DOCTORS ORDERS FOR PATIENTS WHO HAVE RECEIVED THERAPY DOSES OF IODINE-131 OR PHOSPHORUS-32

Patient, _____ (name), received _____ mCi of _____ (isotope)
by _____ (route) at _____ (time) am/pm on _____ (date), 19____.

EXPOSURE RATES IN MR/HR

Date/Time	at bedside	3 feet from bed	Adjacent areas

COMPLY WITH ALL CHECKED ITEMS

___ 1. No visitors.
___ 2. Assign to room with bed near outside wall.
___ 3. Patient may not leave room.
___ 4. Pregnant visitors are not permitted.
___ 5. Visitors under 18 are not permitted.
___ 6. Attendants wear personnel dosimeters.
___ 7. Visitors should stay 6 feet from patient.
___ 8. Visitors should limit visiting time to 30 minutes.
___ 9. Patient to use disposable utensils and dishes.
___ 10. Cover mattress and pillow with plastic.
___ 11. Wear gloves when changing bed linen, dressings, etc.
___ 12. Patient to wear hospital pajamas.
___ 13. Place plastic-lined waste basket and linen hamper in patient's room. Place waste, soiled linen in these containers.
___ 14. Personal items for patient to be kept in patient's room.
___ 15. Diagnostic samples of blood, urine, and feces obtained only when authorized by Nuclear Medicine Department physician.
___ 16. Ambulatory patients to use commode in their room.
___ 17. Notify Nuclear Medicine or Radiation Safety Officer in case of spillage of urine or patient who vomits.
___ 18. Hold all linens and disposable wastes in room until cleared by Nuclear Medicine or Radiation Safety Officer.
___ 19. At patient's discharge, call Nuclear Medicine to clear the room prior to admitting housekeeping personnel to room.

Special orders: _____

_____

In case of any difficulty, call the RSO or alternates:	days	nights
_____	_____	_____
_____	_____	_____

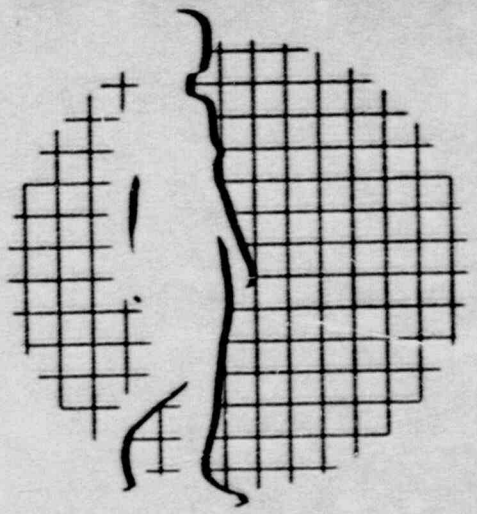
If patient dies before _____, notify the Radiation Safety Officer or alternates.

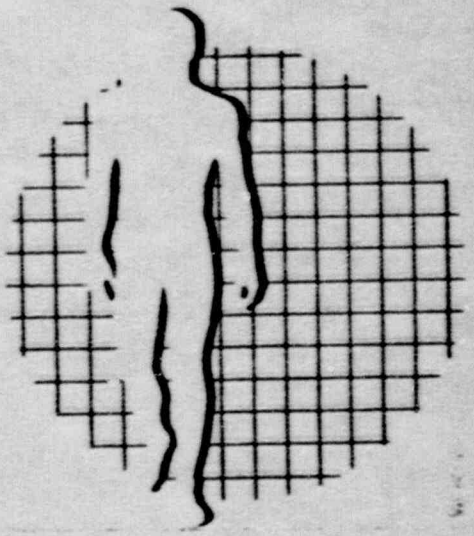
_____, M.D. _____
Attending Physician Date

Item: 10-25
Date: 6/8/89

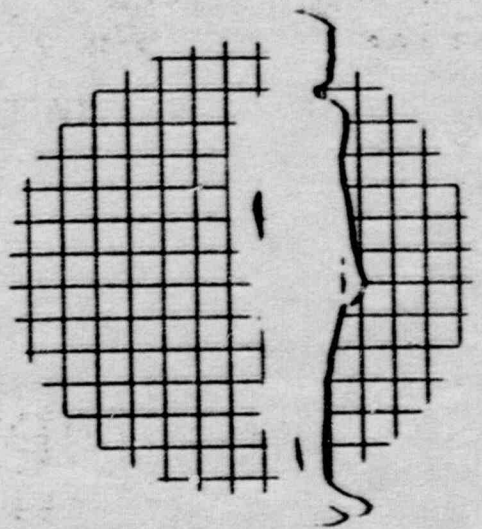
NOTES

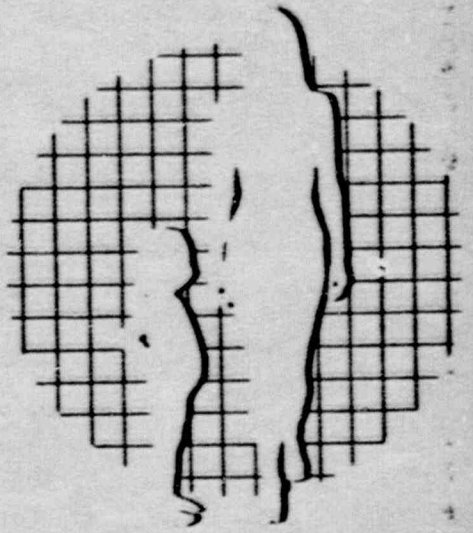
The Society of Nuclear Medicine
136 Madison Avenue
New York, NY 10016-6760
(212)889-0717





Guidelines for Patients Receiving Radioiodine Treatment





This pamphlet is for you—the patient—who will be treated with radioiodine, a radioactive form of iodine. It includes special instructions for you to follow when you go home after your treatment.

Why will you receive radioiodine treatment?

You will receive radioiodine because you and your doctor have agreed that it is the most appropriate treatment for your thyroid condition. Most of the radiation from the radioiodine will be absorbed by your thyroid gland and will interfere with the function of the thyroid cells. This is the desired and beneficial medical effect of the treatment. However, some of the radiation will leave your body, and individuals who are in close physical contact with you may be exposed to small amounts. There is no evidence that such exposure has ever caused any harm. Nevertheless, efforts should always be made to avoid unnecessary exposure to radiation.

Ask your doctor

The best source of additional information on your treatment is your doctor. This pamphlet lists some guidelines for you to follow for a short time immediately after your treatment (usually no more than 2 to 5 days, depending on your treatment and your doctor's instructions). You may decide, or your personal situation may require, that you will want to follow all or only some of the suggested guidelines. Remember, these are only suggestions to help you make more informed decisions as

This pamphlet was prepared by David V. Becker, M.D. and Barry A. Siegel, M.D. of the Publications Committee of The Society of Nuclear Medicine, Inc. in cooperation with Deborah A. Bozik, Health Physicist, and Carol A. Peabody, Technical Writer, of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission.

Important—Note that these guidelines are only carried out for the **first few days** after treatment. Your doctor will give you specific details as to how long you should follow these precautions.

A checklist for you and your doctor

Ask your doctor to help you decide which guidelines are most important for you and how long you should follow them.

	How long?
☐ Try to keep the time you spend in close contact with others to a minimum.	_____
☐ Try particularly to minimize time spent with pregnant women and young children.	_____
☐ Sleep alone, if possible.	_____
☐ Discuss how long you should wait before becoming pregnant after your treatment.	_____
☐ If you are breast feeding, ask when it may be resumed.	_____
☐ Use good hygiene habits. Wash your hands thoroughly after each toilet use.	_____
☐ Drink plenty of liquids.	_____
☐ Use separate bath linens (and launder these and underclothing separately).	_____
☐ Use separate (or disposable) eating utensils.	_____

care for your baby. However, it is preferable not to have the baby too close, such as sitting in your lap, for more than a short time during the first 2 days after treatment.

- *If you have been breast feeding* your baby, you **must** stop because radioiodine is secreted in breast milk. Discuss with your doctor when you can resume breast feeding.

- *If you are pregnant*, or think you could be, tell your doctor because radioiodine treatment should not be given during pregnancy. Also, if your are planning to become pregnant, ask your doctor how long you should wait after treatment.

- *Wash your hands* with soap and plenty of water each time after you go to the toilet.

- *Keep the toilet especially clean*. Flush it 2 or 3 times after each use.

- *Rinse the bathroom sink and tub* thoroughly after you use them. Clean bathroom practices will reduce the chances of others becoming contaminated from the radioiodine in your saliva and sweat.

- *Drink plenty of liquids* such as water or juices. This will make you urinate more frequently and help the radioiodine to leave your body more rapidly, thus lowering the amount in your body.

- *Use separate (or disposable) eating utensils* for the first few days and wash them separately. This will reduce the chance of contaminating other family members with the radioiodine in your saliva.

- *Use separate towels and washcloths*. Launder your bath towels, bed linens, and underclothing separately.

you discuss your questions and concerns with your doctor.

You and your doctor should complete the checklist at the back of this pamphlet. It will explain what steps you can take in your situation to reduce radiation exposure to others from the radioiodine you receive.

How does radioiodine work?

The thyroid gland accumulates the iodine that enters the body in food and uses this iodine to perform its normal function, which is to make thyroid hormone. Radioiodine is similarly collected by the thyroid gland. The radiation given off by this form of iodine decreases the function of the thyroid cells and inhibits their ability to grow. This is the desired medical effect and the reason you will be given this medication. Radioiodine treatment is a common, well accepted form of treatment that has been used all over the world for more than 30 years.

Most of the radiation from the radioiodine will be received by your thyroid gland. However, the other tissues in your body will receive some incidental radiation. This small amount of radiation has **not** been shown to produce any adverse effect.

How long does the radioiodine stay in your body?

The radioiodine from your treatment will remain in your body only temporarily. Most of the radioiodine not collected by your thyroid gland will be eliminated during the first 2 days after your treatment. Radioiodine leaves your body primarily in your urine, but very small amounts may leave in your saliva, sweat, and feces. The amount of radioiodine remaining in your thyroid tissue is responsible for the desired medical effect. However, this amount also decreases rapidly. This means that the possibility of radiation exposure to you and others is reduced with time. At the end of treatment, **no** radioiodine remains in your body.

How can others be exposed to radiation from the radioiodine given to you?

Exposure to radiation from the radioiodine in your body may occur if other people remain very close to you for long periods of time. The radiation received is very similar to the radiation from medical and dental X-rays, which are the most common and familiar sources of external radiation exposure.

Contamination with radioiodine can occur if it is deposited in any place where other people may have contact with it. For instance, if some of the radioiodine in your saliva gets on the bathroom sink as you brush your teeth and then on to someone's hands, contamination has occurred. If this radioiodine is then taken into someone's body from the hands or from food that has been touched, it will cause a small amount of radiation exposure to that person.

Radioiodine disappears by itself as part of the physical processes that make it radioactive. For example, it will not remain on the sink indefinitely because its quantity is reduced by one-half every 8 days. This is what is meant when it is said that the "half-life" of radioiodine is 8 days.

How can you reduce radiation exposure to others?

The amount of radioiodine in your body during the treatment is small. Although there is no evidence that the radiation from this amount of radioiodine will cause any problem, it makes sense to take steps to minimize exposure, no matter how small. If you take some simple precautions during the first few days after your treatment (as explained below), you can reduce or eliminate the possibility of radiation exposure to others.

There are three **basic principles** to remember:

1. **Distance**—the greater the distance you are from others, the less radiation they will receive. Even an increase in distance of a few feet will greatly reduce the exposure. So try not to remain in close contact with others for longer than is necessary.

2. **Time**—radiation exposure to others depends on *how long* you remain close to them. You should try to minimize the time spent in close contact with others.

3. **Hygiene**—good hygiene minimizes the possibility that other people will be contaminated with the radioiodine that leaves your body. Since most of the radioiodine leaves your body in your urine, good toilet hygiene and careful and thorough washing of your hands will reduce the possibility of contamination.

Important guidelines to help you apply these basic principles:

Your doctor can best recommend which guidelines are important for you and how long you should follow them. Do not hesitate to ask your doctor for more information.

- *Sleep alone for the first few days* after your treatment. During this period avoid kissing or sexual intercourse. Also avoid prolonged physical contact, particularly with children and pregnant women; the thyroid glands of children and fetuses are more sensitive to the effects of radioiodine than those of adults.

- *If you have a baby*, or you are taking care of one, your doctor can best instruct you on how to follow the guidelines. You probably can do all the things necessary to

PROCEDURES FOR ADMINISTERING I-131 DOSES

1. Personnel administering therapeutic doses of I-131 should wear their personnel dosimeters, including ring dosimeters, with detector towards the palm of the hand.

2. Never handle an unshielded therapuetic 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 dispoasble gloves and a lab coat or other protective clothing when administering a therapeutic dose. After the administration is complete, dispose of the gloves as waste and monitor hands and clothing for contamination.

4. Liquid doses of I-131 may release vapors to the atmosphere when they are opened. Whenever opening a liquid dose, do so in the fume hood with a face velocity of at least 100 ft/min so that vapors will be drawn away from you.

5. 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 30 mCi of liquid I-131 must have bioassays performed of their thyroid burden before and after the administration. The body burden action levels described in NRC Regulatory Guide 8.20, Applications of Bioassays for I-125 and I-131, Revision 1, September 1978, will be followed.

Item 10-26
Date: 6/8/89

PROCEDURES AND PRECAUTIONS FOR USE OF I-125 SEALED SOURCES IN BONE MINERAL ANALYZERS

A. Procedures for Ordering and Receiving Packages Containing Sealed Sources for Use in Bone Mineral Analysis Equipment

1. The Supervisor of Nuclear Medicine will place all orders for sealed sources to be used for bone mineral analysis (generally standing order) 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 sealed sources directly to the Nuclear Medicine area.

3. During off-duty hours, the security guard on duty will accept delivery of packages containing sealed sources.

4. Monitoring for contamination on packages containing sealed I-125 sources shall be performed in accordance with 10 CFR 20.205 and the facility procedures for opening packages containing radioactive material. Records of the results of the monitoring shall be kept.

5. Sealed sources will remain in lead or original shipping containers until the source is installed in the scanner.

6. Prior to disposal of the empty package and packaging materials, all labels and signs will be removed or obliterated.

7. A receipt log will be maintained and the following entries made for each source received: date of receipt, manufacturer, model number, serial number, isotope, activity and date of assay, date installed, date removed, and disposition.

B. Installation/Removal of Sealed Sources in Bone Mineral Analyzer

1. Only Authorized Users of 35.500 in 10 CFR Part 35 or personnel under the direct supervision of one (or more) of these individuals will conduct these procedures.

2. The installation/removal procedures provided by the manufacturers will be followed. These procedures will include the use of remote handling tools for any operation involving an unshielded source.

C. **Source Disposal**

1. I-125 sources too weak for use in bone mineral analyzers will be removed from the device as per manufacturer's instructions and temporarily stored in the designated long half-life decay area.

2. Sources that are no longer usable shall be either shipped back to manufacturer, shipped to a licensed waste disposal site, transferred to another licensed facility for use in an analyzer requiring a lower activity source, or held for decay. If transferred, records of certification of shipping containers shall be kept in accordance with DOT regulations. If the sealed sources are returned to the manufacturer, they will be shipped in the original shipping containers. The requirements of 10 CFR 49 shall be followed with regards to packing, labeling, marking, and surveying of the package and filling out the shipping documents. If held for decay, sources will be stored for at least 10 half-lives and surveyed with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to make sure the activity is indistinguishable from background before disposal. All radiation precaution labels will be removed before disposal into the normal trash.

D. **Radiation Safety Program - Overall**

1. A radiation survey shall be performed on the bone mineral analyzer for each new sources that is placed in the machine. The results of the survey shall be documented.

2. A radiation survey shall be performed in the storage area each time an additional source is placed in the storage area for long-term storage. The results of these surveys shall be documented.

3. Leak tests and inventories will be performed. Leak test analysis will be performed by Mid-Pacific Medical Physics using procedures set forth in NRC License No. 53-23207-01.

4. Exposures will be kept ALARA as per the license requirement and institution policy.

5. Records to be kept will include those of radiation surveys, receipt, transfer and/or disposal, leak tests, inventories, and personnel exposure.

6. An audit of the records required to demonstrate satisfaction of the requirements of this license will be made at least semiannually.

7. All personnel working with the bone mineral analyzers will wear personnel monitors.

E. **Emergency Procedure**

If the source becomes dislodged from the bone mineral analyzer, have people leave the area, close and lock the door to the room, and notify the Radiation Safety Officer. Do not reenter the room until the Radiation Safety Officer arrives with survey equipment. These emergency procedures, along with the name and phone numbers of the RSO, will be posted in all areas occupied by bone mineral analyzers.

F. **Duties and Responsibilities of the Authorized User**

1. Receipt of sources and logging in the source receipt log.

2. Storage of sources received in the radioactive materials storage area.

3. Source replacement in the bone mineral analyzers.

4. Packaging of sources for shipping and delivering to a carrier for shipment to the manufacturer.

5. Leak testing of sources in use over six months.

G. **Duties and Responsibilities of the Radiation Safety Officer**

1. Assuring that materials possessed conform to the materials listed on the license.

2. Assuring that use of the device is only by individuals authorized by the license.

3. Assuring that all users wear personnel monitoring equipment when required.

4. Assuring that the sources are properly secured against unauthorized removal at all times when not in use.

5. Serving as a point of contact to give assistance in case of an emergency, and assuring that proper authorities are notified in case of any emergency.

6. Assuring that the terms and conditions of the license are met and that required records are periodically reviewed for compliance with NRC regulations and license conditions.

Item 10-30
Date: 6/8/89

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.

Procedures 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.

A. 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.

B. 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.

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

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

1. Check your radiation detection survey meter for proper operation.

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

3. Remove any shielding from around the container.

4. Monitor all surfaces of each individual container.

5. 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.

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

Item 11-2
Date: 6/8/89

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: 6/8/89

AUG 15 1989

Docket No. : 030-31200
Control No.: 70987

Pali Momi Medical Center
98-1079 Moanalua Road
Aiea, Hawaii 96701

Attention: Mr. R. Dale Reynolds
Executive Administrator

Gentlemen:

This is in reference to your request dated June 8, 1989 for a byproduct material license. In order to complete our review, we nee' the following additional information:

1. Although the Radiation Safety Officer (RSO) may conduct a preliminary review of procedures and personnel qualifications and may lead audits, the Radiation Safety Committee (RSC) is responsible for these functions, as stated in 10 CFR 35.22(b). The RSC should be actively involved in radiation safety audits; one or more members should assist the RSO during these reviews.

   You should amend and resubmit Item 10-4, Section B., numbers 1, 2, and 3 to reflect the responsibilities of the RSC.

2. The findings of the RSO's quarterly audit of contamination and ambient radiation levels should be documented and reported to the RSC, even if all findings reflect the ALARA concept. Refer to Appendix G, page G-3, Item 3.(a)(3) of Regulatory Guide 10.8, Revision 2.

   You should amend and resubmit Item 10-4, Section B., number 6. to so indicate.

3. Although Item 10-21 specifies that hospital staff personnel will be provided with special instructions on patients receiving radiopharmaceutical therapy, it did not specify that they will have an opportunity to ask questions of the radiation safety staff.

   You should amend Item 10-21 to document the provisions which will be made to address such questions.

4. We have two comments with respect to your procedures for radiopharmaceutical therapy treatments:

   a. Although the "Doctors Orders..." form included in Item 10-25 of your application has an entry "Visitors under 18 are not permitted," it is not clear that this will always be the case. 10 CFR 35.315(a)(3) specifies that visits by minors must be approved by the RSO on a case-by-case basis.

mL5D

You should amend and resubmit your procedure to reflect this requirement.

b. Item 10-26 indicates that bioassays will be performed when liquid iodine 131 is administered. However, 10 CFR 35.315(a)(8) requires bioassays for all therapeutic (above 30 millicuries) administrations of iodine-131, including materials in capsule form.

You should amend and resubmit this item to reflect this requirement.

5. With respect to your dose calibrator procedures:

Item 9-4 indicates that sources will be within 7% of the stated activity. However, 10 CFR 35.50(b)(2) specifies that they must be within 5% of the stated activity.

You should amend and resubmit this portion of your procedure.

6. With regard to Item 10-17, "Survey Procedures":

a. In addition to the daily survey of the elution, preparation, and injection areas, 10 CFR 35.70(e) requires a weekly survey for removable contamination in these areas. It was not clear that this survey would be performed.

You should clarify and resubmit this portion of Item 10-17.

b. 10 CFR 35.70(h) specifies the content of the records of all required surveys. Therefore, the note at the end of Item 10-18 should be deleted.

You should specify that the note at the end of Item 10-18 will be deleted.

7. With respect to record-keeping:

a. Your leak test records described in Item 10-7 should also include the source model numbers as required by 10 CFR 35.59(d).

b. Your "Record of Unit Dosage and Multidose Vial" form should include the radionuclide and receipt date as specified in Appendix M, page M-2 of Regulatory Guide 10.8, Revision 2.

You should specify that these items will be added to your records.

As you noted, items possessed and used under the general license in 10 CFR 31.11 are exempt from requirements of 10 CFR 19, 20, and 21 with the exception of Mock Iodine-125 reference or calibration sources. All other limitations of 10 CFR 31.11 apply, and the area of use should be physically and administratively separate from activities which will be conducted under your NRC license.

We will continue the review of your request for a byproduct material license upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application. Please reply in duplicate, and refer to Mail Control No. 70987

Sincerely,

original signed

Beth A. Riedlinger
Health Physicist (Licensing)
Nuclear Materials Safety Section

cc:
Dr. Don Tolbert
Mid-Pacific Medical Physics
222 North School Street,
Suite 302
Honolulu, Hawaii 96817

Distribution

bcc:
License docket folder (original concurrence) (Peggy)
Inspection folder (Peggy)
Reading file (Frances)
Maurice Messier, LFMB, MNBB 4503

F.Browne	J.Montgomery	D.Skov	B.Riedlinger
/ /	/ /	/ /	8/14/89

REQUEST COPY	REQUEST COPY	REQUEST COPY	REQUEST COPY	REQUEST COPY
YES / NO	YES / NO	YES / NO	YES / (NO)	YES / NO