NRC FORM 313
(10-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 6-30-90

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS 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 HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
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
NUCLEAR MATERIALS SAFETY 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
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 21-20440-01

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

ASSOCIATED PHYSICIANS MEDICAL CENTER, INC.
24555 Haig Street
Taylor, MI 48180

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

24555 Haig Street
Taylor, MI 48180

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Tracy King, Medical Physics Consultants, Inc.

TELEPHONE NUMBER: (313) 662-3197

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 $ 580.00

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
	Paul Szilagyi	Administrator	10-12-88

9002060244 890131
REG3 LIC30
21-20440-01 PDR

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Ren	Nov 4	7C	CONTROL NO 86312	
AMOUNT RECEIVED	CHECK NUMBER			DATE
$580	23240			10/27/88

RECEIVED
OCT 27 1988
REGION III

*APPLICABILITY TABLE

Item	Topic	
8.1	Training Program	Enclosed
8.2	Other training program	N/A
9.1	Facility diagram & Equip. List	Enclosed
9.2	Survey instrument calibration	Per 10CFR35.51
9.3	Dose calibrator calibration	Enclosed
9.4	Personnel monitor program	Enclosed
9.5	Mobile Imaging equipment QA	N/A
9.6	Other equipment and facilities	N/A
10.1	Radiation Safety Committee	N/A
10.2	ALARA program	App. G, Reg. Guide 10.8, Revision 2
10.3	Leak test	Per App. H, Reg. Guide 10.8, Revision 2
10.4	Safe use of radiopharmaceuticals	Enclosed
10.5	Spill procedures	Enclosed
10.6	Ordering and receiving	Enclosed
10.7	Opening packages	Enclosed
10.8	Unit dose records	Enclosed
10.9	Multidose vial records	Enclosed
10.10	Mo-99 concentration records	Enclosed
10.11	Implant source use records	N/A
10.12	Area survey procedures	Enclosed
10.13	Air concentration control	N/A
10.14	Radiopharmaceutical therapy	Enclosed
10.15	Implant therapy	N/A
10.16	Other safety procedures	N/A
11.1	Waste disposal	Enclosed
11.2	Other waste disposal	N/A

Items 5 and 6

RADIOACTIVE MATERIAL AND PURPOSE

Material	Amount	Purpose
5a Material in 35.100	As Needed	6a Diagnostic Medical Use
5b Material in 35.200 -except radioactive gases	As Needed	6b Diagnostic Medical Use
5c Material in 35.300	As Needed	6c Outpatient Therapy Use

Associated Physicians Medical Center

Item 7

RADIATION SAFETY OFFICER AND AUTHORIZED USERS

Radiation Safety Officer: Michael Lala, M.D.

Authorized Users	Material
Michael Lala, M.D.	Sections 35.100, 35.200, 35.300
Adoph L. Melicor, M.D.	Sections 35.100, 35.200, 35.300

PERSONNEL TRAINING PROGRAM

All occupational and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Ancillary personnel may include cleaning/housekeeping personnel, security, nurses, EKG technologists, etc.

Instruction will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

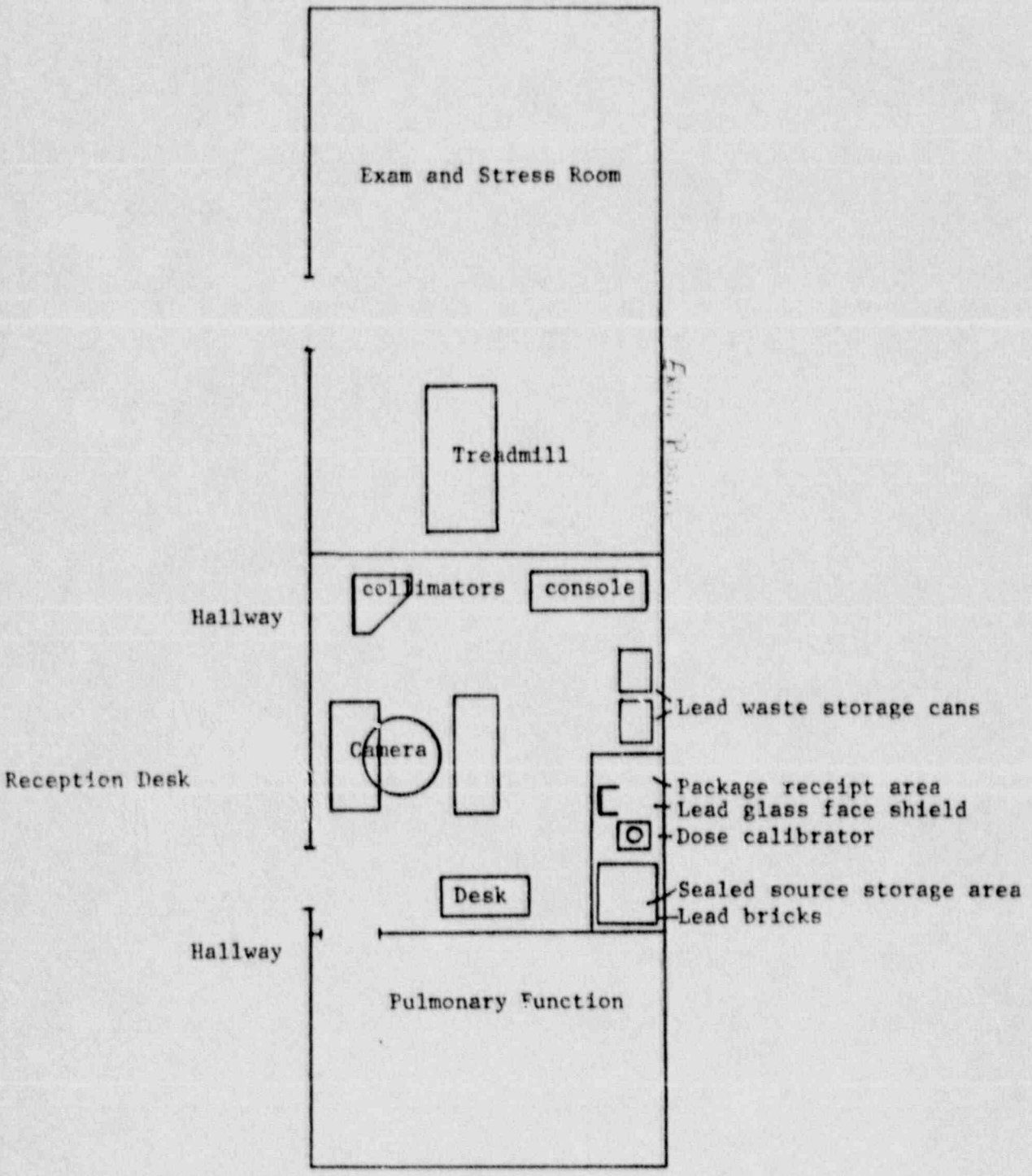
8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available, notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions, as required by 10CFR19.

Facility Diagram

Associated Physicians Med. Ctr. Inc.

21-20440-01



EQUIPMENT LIST

Associated Physicians Medical Center

Dose Calibrator
- Capintec Model CRC-5

Scintillation Camera
- Nuclear Chicago Pho/Gamma HP

GM Survey Meters
- Ludlum 14C
  - Low range: 0.0 - 0.20 mR/hr
  - High range: 0.0 - 2000 mR/Hr

Radiation Safety Equipment
- Syringe Shields
- Lead Glass Face Shield
- Lead Bricks
- Lead-lined Container
- Lead Syringe Holder
- Gloves
- Absorbent Pads
- Radiacwash
- Remote Handling Tools

Item 9.2

CALIBRATION OF SURVEY INSTRUMENTS

All survey instruments will be calibrated and checked in accordance with 10CFR35.51. Survey instruments will be calibrated by: (1) the manufacturer; or (2) Medical Physics Consultants (NRC License No. 21-20153-01).

CALIBRATION OF DOSE CALIBRATOR

In accordance with 10CFR35.50

Testing Frequency and Tolerance

a. Constancy:
   at least daily prior to the assay of patient doses
   +/- 10% tolerance
b. Linearity:
   upon installation and at least quarterly thereafter
   +/- 10% tolerance
c. Accuracy:
   upon installation and at least annually thereafter
   +/- 10% tolerance
d. Geometry dependence:
   upon installation
   +/- 10% tolerance

Following repair or adjustment, the above tests will be repeated as appropriate.

Testing Methods

a. Constancy:
   Source - 50 uCi or more of Cs-137
   1. Assay the source on the appropriate dose calibrator setting.
   2. Measure the background on the same setting, and subtract or confirm the proper operation of the automatic background subtraction circuit if it is used.
   3. Log in a book the background reading and the net activity of the source.
   4. Repeat the above procedure for a commonly used radioisotope setting.
   5. Write in the log book or post on the calibrator, action levels at which the individual performing the test will automatically notify the chief technologist or authorized user of suspected malfunction of the calibrator.

Item 9.3 cont.

b. Linearity:

Source - Tc-99m, activity at least as large as the maximum activity administered to a patient.

Decay Method

1. Assay the Tc-99m and subtract the background reading to obtain the net activity. Record the date, time, and net activity.
2. Repeat Step 1 three times daily at equally spaced intervals until the assayed activity is less than 10 uCi.
3. Pick a reading (to be used as a standard) which is near to a millicurie value that is frequently used for patient doses. Back-decay this value to obtain calculated values for all readings prior to the standard reading. Decay the standard reading to obtain the calculated values for all readings taken after the standard reading.
4. Calculate the deviation of the measured values from the calculated values.

Shield Method

If the shield or sleeve method is used, the linearity test and initial calibration of the shields or sleeves will be performed in accordance with the manufacturer's instructions.

c. Accuracy:

Sources - Cs-137 dedicated source of at least 50 uCi and
Co-57 or Ba-133 dedicated source of at least 50 uCi

1. Assay the calibrated source on the appropriate setting.
2. Remove the source from the calibrator and measure the background reading on the same setting.
3. Subtract the background reading from the measured activity to obtain the net activity.
4. Repeat this procedure for the other calibrated sources.

d. Geometry Dependence:

Source - Tc-99m between 1 and 10 mCi/ml

Syringe method - for all licensees

1. Draw 0.5 ml of Tc-99m liquid into a syringe of the size normally used for patient doses.
2. Place the syringe in the dose calibrator in a reproducible geometry.
3. Assay the syringe. Record the measured value and the volume.

4. Draw an additional 0.5 ml of non-radioactive saline or water into the syringe. Special care must be taken that none of the original radioactive liquid is released from the syringe during this process.
5. Assay and record the measured value and volume.
6. Repeat this procedure until a volume of 2.0 ml has been assayed.
7. Select as a standard the volume that is closest to that used most frequently for patient doses.
8. Divide all measured values by the standard activity. The quotient is the volume correction factor.

Vial method - for facilities using generators or radiopharmaceutical kits (in addition to the above method).

1. Begin the test with 1 ml of Tc-99m in a vial of the size most frequently used for elutions and kits.
2. Assay the vial and record the measured value and the volume.
3. Add 2.0 ml of non-radioactive saline or water to the vial.
4. Assay and record the measured activity and volume.
5. Repeat this procedure until a 19 ml volume has been assayed.
6. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits.
7. Divide all measured activities by the standard activity. This is the volume correction factor.

e. The Radiation Safety Officer must review and sign all of the above tests except the constancy tests.

Action Levels

Linearity or geometry errors in excess of 10% shall be mathematically corrected for in measurement of doses greater than 10 uCi.

Accuracy or constancy errors in excess of 10% shall be cause for repair or replacement of the dose calibrator.

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

2. All individuals who are occupationally exposed to radiation on a regular basis and may receive greater than one-tenth the quarterly permissible limits will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

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

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor when caring for those patients.

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

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA (See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

ASSOCIATED PHYSICIANS MEDICAL CENTER
(Licensee's Name)

October 31, 1988
(Date)

1. Management Commitment

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

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

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

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

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

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

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

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

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

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

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

*The NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

Table 1

Investigational Levels

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

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

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

3. Radiation Safety Officer

a. Annual and Quarterly Review

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

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

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

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

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

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

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

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

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

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

a. Personnel dose less than Investigational Level I.

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

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

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

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

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

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature

PAUL SZILAGYI

Name (print or type)

ADMINISTRATOR

Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2.

RULES FOR THE SAFE USE OF RADIOPHARMACEUTICALS

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

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

3. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.

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

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear a finger exposure montior during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

12. Assay each patient dose in the dose calibrator before administering it. Do not use a dose if it differs by more than 10 percent of the prescribed dose, except prescriptions of less than 10 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

13. Always keep radioactive material in shielded locations or containers.

14. Use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material(when practical).

EMERGENCY PROCEDURES

Minor Spills

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

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

3. CLEAN UP: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, thin-end window GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the Radiation Safety Officer who will supervise the cleanup of the spill and complete the Radioactive Spill Report.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

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

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report.

Package Order & Receipt Procedures

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that posession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

For routinely used materials

(1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

(2) The above records will be checked to confirm that material received was ordered through proper channels.

3. For deliveries during normal working hours, carriers will deliver radioactive packages directly to the nuclear medicine room.

If off-duty deliveries are necessary, the delivery personnel will be escorted to the nuclear medicine room by maintenance personnel. Maintenance will unlock the room and delivery personnel will place the package inside the room in the designated area. Maintenance will then re-lock the door to the room. At no time will maintenance personnel take possession of the radioactive materials package.

Memorandum

To: Maintenance personnel

From: Dr. Lala, Radiation Safety Officer

If radioactive package deliveries arrive before or after normal working hours, please escort the delivery person to the nuclear medicine room. Unlock the door to the room to allow the delivery person to place the package in the designated area. Re-lock the door after the delivery personnel has finished. At no time shall maintenance personnel take possession of a radioactive materials package. These packages are identified by a magenta and yellow three-bladed symbol and the words "Radioactive Materials".

Procedure for Opening Packages Containing Radioactive Material

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 and notify the RSO.

3. Measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.

4. Follow the steps listed below when opening the package.
   a. Remove the packing slip.
   b. Open the outer package following the supplier's instructions, if available.
   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 unusual is noticed, 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 with a thin-end window GM meter or a well counter to determine if there is any removable activity. If there is any contamination, notify the RSO.

6. Verify that the material received is the material ordered.

7. Monitor the packing material and the empty packages for contaminaion with a GM meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

8. Record the receipt and all readings taken.

9. For packages received under a general license in 31.11, follow the steps listed below for each package.
   a. Visually inspect the package for damage. If damage is noted, stop and notify the RSO.
   b. Verify that material received is the material ordered.

Item 10.8

Unit Dose Records shall contain:

Radionuclide
Chemical form or abbreviation
Date of receipt
Activity as recorded on the packing slip
Supplier
Lot or control number
Administration data
  time and date of administration
  measured activity
  patient name and ID number
Method of disposal and date
Initials of person recording information

Item 10.9

Multidose Vial Records shall contain:

Radionuclide
Chemical form or abbreviation
Date of receipt or preparation
Date, time, and activity of initial assay
Supplier or kit manufacturer
Administration data
  date and time dosage was drawn
  prescribed dosage
  calculated inverse concentration (cc/mCi) at drawing time
  calculated volume needed for prescribed dose
  measured activity
  patient name and ID number
Method of disposal and date
Initials of person recording information

Item 10.10

Molybdenum Concentration Records shall contain:

Date the generator was received
Date and time of elution
Measured Mo-99 activity in microcuries
Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
Measured Tc-99m activity in millicuries
Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that ratio is less than that specified in 10 CFR 35.204 (a)
Initials of the person who made the record

AREA SURVEY PROCEDURES

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed daily for ambient radiation exposure rates and weekly for removeable contamination. Special care will be taken to remove all paraphernalia from patient rooms where diagnostic administrations are occasionally made; and these rooms will not be surveyed.

2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and removeable contamination.

3. Laboratory areas where less than 200 uCi of by-product materials are used will be surveyed monthly for ambient radiation exposure rates and removeable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/hr.

5. Surveys for removeable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm.

6. The trigger level for exposure rate surveys will be rates above the normal background reading for that area.

7. The trigger level for removeable contamination surveys will be the detection of values greater than three standard deviations above background values.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to background on repeat surveys.

9. A record shall be kept of all survey results. The record will include:
   a. Location, date, and type of equipment used.
   b. Initials of the person conducting the survey.
   c. Drawing of the areas surveyed.
   d. Trigger levels keyed to the location on the drawing.
   e. Results keyed to the location on the drawing.
   f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

10. The RSO or their designat[illegible] survey results on a quarterly basis for conformance [illegible]ls.

Item 10.14

INFORMATION REGARDING RADIONUCLIDE THERAPY

All therapies will be performed on an outpatient basis only. All patients leaving the office will meet the requirements and conditions set forth in 10CFR35.75 concerning release of patients containing radiopharmaceuticals.

WASTE DISPOSAL

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer will be made in accordance with 10CFR20.303. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits enumerated in Table II of Appendix B of 10CFR20. A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay-in-Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Material will be decayed for at least 10 half-lives.

3. Prior to disposal as in-house waste, each container will be monitored as follows:

   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low-level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from background levels will be disposed of after all radioactivity labels have been defaced.

4. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low-range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/hr) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal.

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g. syringes, needles, etc.) may be returned to them in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.