

APPLICATION FOR MATERIAL LICENSE **L&L 28331**

**030-30947**

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION  
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS  
WASHINGTON, DC 20545

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  
1460 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 20-28078-01  
☐ C. RENEWAL OF LICENSE NUMBER \_\_\_\_\_

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

Advacare Management Services, Inc.  
333 Jenkintown Commons  
Jenkintown, Pa. 19046

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

233 East Lancaster Avenue  
Ardmore PA 19003  
(215-649-8394)

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Frank X. Masse

TELEPHONE NUMBER

(617) 245-6600

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 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 AMOUNT  
ENCLOSED \$ 120.00

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, 52 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

*Shirley B. Somerman*

Shirley B. Somerman

*Manager* 12-27-88

8908030325 890414  
REG1 LIC30  
37-28331-01 PDR

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

Edom Management, Inc.

DATE

APP Jan. 4 7C  
120 + 460 386/449  
S Kimbly  
110060  
1/31/89

OFFICIAL RECORD COPY **ML11**

DEC 30 1988

The following is in support of application for licensure at 233 East Lancaster Avenue, Ardmore PA.

5. Byproduct material covered in 35.200 as diagnostic radiopharmaceuticals. Calibration and reference sources authorized under 35.57 (attached is a list of sources used for dose calibration performance checks).
6. Licensed material will be used for diagnostic nuclear medicine procedures.
7. The individual to be responsible for the Radiation Safety Program will be Bruce Kornberg, DO. The training and experience of Dr. Kornberg was submitted in support of application for licensure under NRC license #37-28101-01.
8. See item 8 page 5 attached for description of training of individuals working in or frequenting restricted areas.
9. Enclosed is a diagram (item 9, page 6) of the room in which the nuclear medicine operation will be conducted. The counter adjacent to the sink will be equipped with an L-shield for shielding during preparation of the individual patient doses. Spent source containers (in their original shields) and other dry solid wastes will be stored in the cabinet under the sink for decay. The cabinet will be lined with 1/16" lead for shielding.

The following list of equipment will be purchased for proposed use:

- a. Picker Dynamo Mobile Camera
  - b. ADAC 3300 Nuclear Computer
  - c. Capintec CRC-7 Dose Calibrator
  - d. Ludlum Model 14-C with 44-7 end window probe, 0-2000 mR/hr  
(backup available during calibration or repair)
10. The following contains all aspects of the Radiation Safety Program to be initiated.
- a. Since this application proposes a clinical laboratory operation, no medical isotopes committee (radiation safety committee) is proposed. Responsibility for the safe operation of this program will rest directly with the individual users with support as necessary from F.X. Massé Associates.
  - b. ALARA Program described in detail on page 7.  
Personnel External Exposure Monitoring Program, page 12.
  - c. Calibration of survey instrumentation. As part of our survey instrument calibration program, a small dedicated check source will be affixed to each survey instrument. F.X. Massé Associates, Inc. will record the reading obtained on this source during calibration on the calibration sticker affixed to the instrument. A check of this source reading will be made by the instrument user on each day of use.

- d. Calibration of dose calibrator. ANSI Standard N42.1986 entitled "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" is followed with the noted changes.

page 9 4.6.1 Accuracy. Activity levels above 100 uCi shall be within  $\pm 5\%$ ; levels below may not fall within the  $\pm 5\%$  limits.

Linearity check. Highest dose administered down to 10 uCi level during quarterly linearity check procedures.

- e. Procedure for Leak-Testing Sealed Sources, page 22.
  - f. Procedures for Ordering and Receiving Radioactive Material, page 24.
  - g. Procedures for Safely Opening Packages Containing Radioactive Material, page 26.
  - h. General Rules for Safe Use of Radiopharmaceuticals, page 28.
  - i. Spill Procedures, page 30.
  - j. Area Survey Procedures, page 31.
  - k. Letter from Osteopathic Medical Center of Philadelphia agreeing to admit patients who have been administered radioactive materials.
11. Waste Disposal Procedures, page 35.



## CALIBRATION OF DOSE CALIBRATOR

### A. Sources Used for Linearity Test

(Check as appropriate)

N/A First elution from new Mo-99/Tc-99m generator  
 or  
 A source of Tc-99m with activity equivalent to the maximum activity assayed to clinical situations will be used.  
X Other\* (specify) \_\_\_\_\_

### B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within + 5%
Ba-133	0.1-0.5	N/A	_____
Cs-137	0.1-0.2	100 microcuries or more	within + 5%
Ra-226	1-2	N/A	_____
_____	_____	_____	_____

C. \_\_\_\_\_ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator  
 or  
X \_\_\_\_\_ Equivalent procedures are attached.

\*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

ANSI Standard N42.13 1986 entitled "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" are followed.



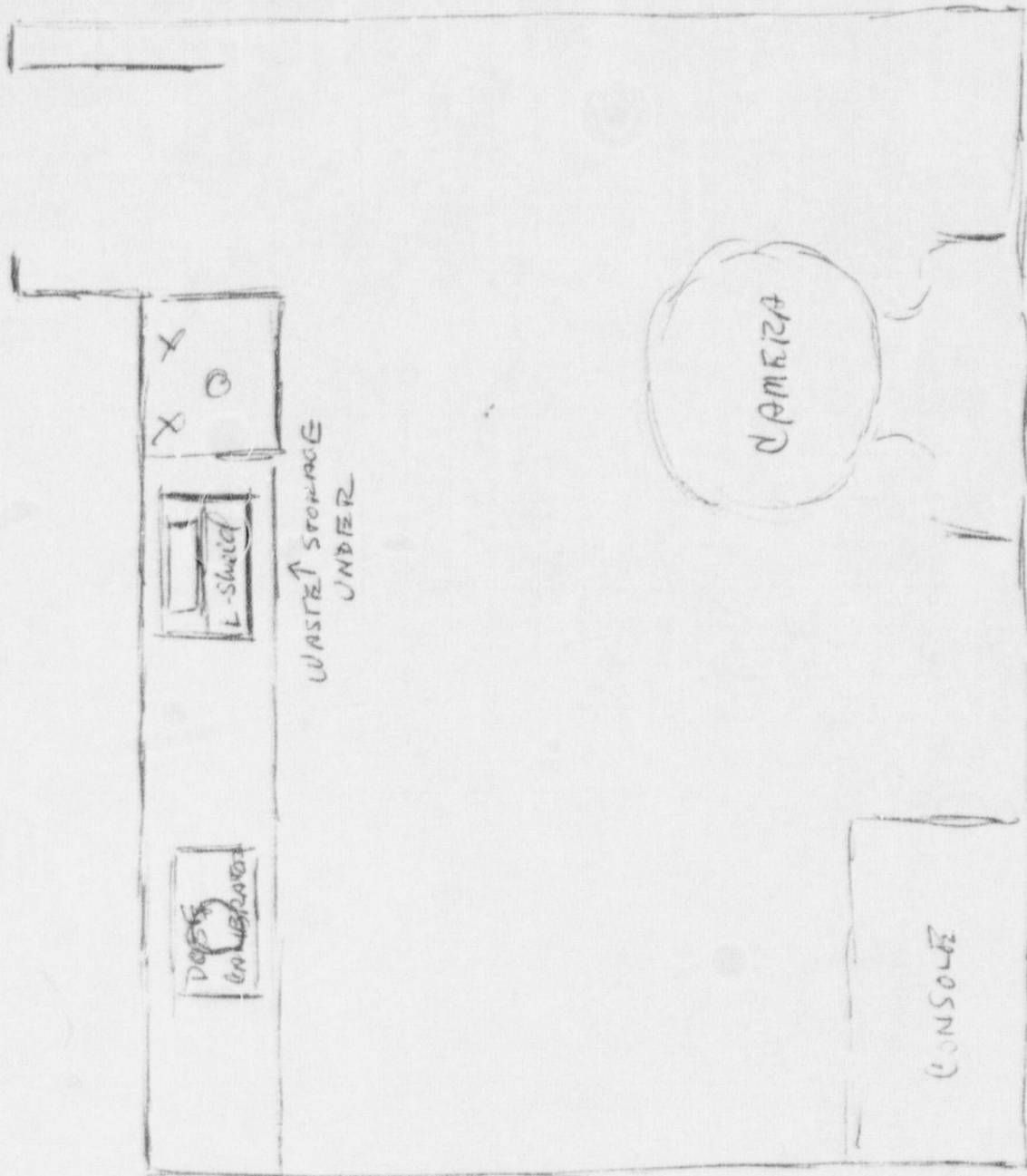
## Training Program

Personnel 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.

Instruction for individuals in attendance 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 (including applications and applicable correspondence), as required by 10 CFR Part 19.
10. Question and answer period.



ALARA PROGRAM

Advacare Management Services, Inc.

(Licensee's Name)

December, 27, 1988

(Date)

1. Management Commitment

- a. We, the management of this medical facility 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 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 Officer

a. Delegation of Authority

Authority is delegated to the RSO for enforcement of the ALARA concept.

b. Review of ALARA Program

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



- (2) The RSO 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.

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 RSO 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.

c. 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 his files.
- (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 his files.

d. 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.

e. 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.

f. 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.

3. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

- (1) The authorized user will consult with the RSO 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 occupation radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. 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.

5. 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 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. 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 RSO. The RSO 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 his records.

- 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 Investigation 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 maintained in his records.

- 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.



7. Signature of Certifying Official

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

Shirley B. Somerman  
Signature

Shirley B. Somerman  
Name (print or type)

Manager  
Title

## Personnel External Exposure Monitoring Program

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.
4. 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.
5. The supplier of whole body film badges and finger TLD, when applicable, will be R.S. Landauer, Jr. & Co. The will be exchanged monthly.

## Procedure for Leak-Testing Sealed Sources

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
  - c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.
  - d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the lead-test period.
4. The samples will be analyzed as follows:
  - a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
  - b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.



- c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
- d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified.
- g. Sign and date the list of sources, data, and calculations.

## Guidance for Ordering and Receiving Radioactive Material

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 possession 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:
  - a. 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.
  - b. For occasionally used materials (e.g., therapeutic dosages)
    - (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
    - (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.
4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair 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 appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, \_\_\_\_\_, at extension \_\_\_\_.

Name

Home Telephone

Radiation Safety Officer: \_\_\_\_\_  
Chief of Nuclear Medicine: \_\_\_\_\_  
Chief Nuclear Medicine Technologist: \_\_\_\_\_  
Nuclear Medicine Technologist on call  
(call page operator at extension \_\_\_\_)  
Nuclear Medicine Physician on call  
(call page operator at extension \_\_\_\_)



Procedure for Safely Opening Packages  
Containing Radioactive Material

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 19 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(2) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm<sup>2</sup>.
2. For packages received under the specific license, the following procedure for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; 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.
  - d. Open the package with the following precautionary steps:
    - (1) Remove the packing slip.
    - (2) Open the outer package following the supplier's instructions, if provided.
    - (3) Open the inner package and verify that the contents agree with the packing slip.
    - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
    - (5) If anything is other than expected, stop and notify the RSO.
  - e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. Take precautions against the potential spread of contamination.

- f. Check the user request to ensure that the material received is the material that was ordered.
  - g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
  - h. Make a record of the receipt.
3. For packages received under the general license in 31.11, the following procedure for opening each package will be followed:
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

## Rules for Safe Use of Radiopharmaceuticals

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
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 at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor 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. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record



the preceding information and the following pharmaceutical dosage measurement record (a) generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration date and the radionuclide; (b) patient's name, and identification number if one has been assigned; (c) prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries; (d) date and time of the measurement, and (e) initials of the individual who made the record. Syringes and unit dosages should be labeled with the radiopharmaceutical name and abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

## Spill Procedures

### Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer (RSO).
6. The RSO will follow up on the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

### Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing 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 that was released by the perspiration.
7. The RSO will supervise cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

## Procedures for Area Surveys

### Ambient Dose Rate Surveys

#### 1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of gamma-emitting radioactive materials are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
- d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurements survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

### Removable Contamination Surveys

#### 1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.
- c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedures should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm<sup>2</sup> of removable contamination (200 dpm/100 cm<sup>2</sup> for isotopes of iodine). Wipe tests are measured with a portable thin-window GM survey meter in a low background area. The calibration of this instrument is such that a 1 mR/hr reading represents a count rate of 2000 CPM. The geometry of the system for counting wipe smears is such that 10% of the activity on the wipe is detected.



Therefore, 200 dpm of removable activity on the wipe will yield a count rate increase of 20 CPM, which is readily detectable in a .02 mR/hr background which is equivalent to 40 cpm (the increase is 50%).

#### Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:
  - a. The date, area surveyed, and equipment used.
  - b. The name or initials of the person who made the survey.
  - c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO. (Recommended removable surface contamination action levels are published in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions." See Regulatory Guide 8.23 or Table N-1 for guidance in establishing action levels.)
  - d. Measured dose rate in mR/hr or contamination levels in dpm/100 cm<sup>2</sup>, as appropriate.
  - e. Actions taken in the case of excessive dose rates or contamination and followup survey information.
2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

Table N-1

Recommended Action Levels in dpm/100 cm<sup>2</sup> for Surface  
Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57 Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

Hospital Administrator  
Walter R. Brand

**Osteopathic**

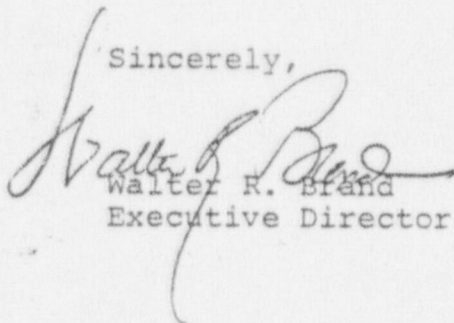
August 25, 1987

To Whom It May Concern:

This is to advise that Bruce Kornberg, D.O. and Albert D'Alonzo, D.O. are hereby approved to admit patients who have been given parenteral radioactive materials to the Hospital of Philadelphia College of Osteopathic Medicine.

In addition, be advised that Drs. Kornberg and D'Alonzo will also be responsible for radiation safety matters pertaining to patients admitted as described above.

Sincerely,



Walter R. Brand  
Executive Director



## Procedure for Waste Disposal

### Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (paragraph 20.303(d)) and generally licensed in vitro kit exemptions (paragraph 31.11(f)), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (paragraphs 30.51(a) and 20.401(c)(3).)

### General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

### Procedure for Disposal of Liquids and Gases

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

1. Regulations for disposal in the sanitary sewer appear in 20.303. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. 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 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 the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (20.306). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

#### Procedures for Disposal by Decay-In-Storage (DIS)

Short-lived material (physical half life less than 65 days) may be disposed of by DIS. Keep material separated according to half-life.

1. Use 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 be not provide any radiation shielding for the material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.
4. Prior to disposal as in-house waste, monitor each container as follows:
  - a. Check you radiation detection survey meter for proper operation;
  - b. Plan to monitor a low-level (less than 0.05 millirem per hour) area;
  - c. Remove any shielding from around the container;
  - d. Monitor all surfaces of each individual container;
  - e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.
  - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

#### Procedures for Transfer for Burial

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

#### 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.

#### Procedures for Returning Generators to the Manufacturer

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Performed the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

- 110060

Item 11  
Page 37



JAN 18 1989

Advacare Management Serv., Inc.  
ATTN: Ms. Shirley B. Somerman  
Facilities Manager  
333 Jenkintown Commons  
Jenkintown, PA 19046

Gentlemen:

This refers to your application dated December 27, 1988, for a materials license.

We received your check for \$120. Your application, however, is subject to an application fee of \$580 as specified in §170.31 (7C) of 10 CFR 170, copy enclosed. Payment of the additional \$460 should be made to the U.S. Nuclear Regulatory Commission and mailed to my attention at our Washington, D.C. address.

Your application will be processed by the Region I Licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania 19406. The additional fee, however, is required prior to issuance of the license. When submitting the fee, please refer to CONTROL NUMBER 110060.

Sincerely,

Signed by:  
Glenda Jackson

Glenda Jackson  
License Fee Management Branch  
Division of Accounting and Finance  
Office of Administration and  
Resources Management

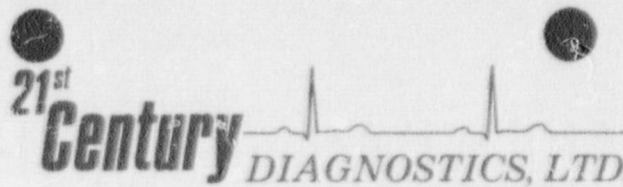
Enclosure:  
10 CFR 170

cc: Region I

DISTRIBUTION:  
Pending Fee File  
ARM/DAF R/F  
LFMB R/F (2)  
DW/RI/ADV

OFFICE: ARM/LFMB *Me*  
SURNAME: SKimberley:kb  
DATE: 01/12/89

ARM/LFMB *8*  
GJackson  
01/17/89



January 25, 1989

Ms. Glenda Jackson  
License Fee Management Branch  
Division of Accounting & Finance  
Office of Administration & Resources Management  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555

Dear Ms. Jackson,

This refers to our application dated December 27, 1988 for a materials license.

We are enclosing a check in the amount of \$460.00 to be applied to license application control number 110060.

We understand from your letter dated January 18, 1989 that our application will be processed by Region I licensing staff located at 475 Allendale Road, King of Prussia, Pennsylvania, 19406.

Thank you for your immediate attention to our application.

Sincerely,

Shirley B. Somerman  
Manager  
333 Jenkintown Commons  
Jenkintown, Pennsylvania, 19046

SBS/bf  
Enclosure

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS

PROGRAM CODE: \_\_\_\_\_  
STATUS CODE: 3  
FEE CATEGORY: \_\_\_\_\_  
EXP. DATE: 0  
FEE COMMENTS: \_\_\_\_\_

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: ADVACARE MANAGEMENT SERVICES, INC.  
RECEIVED DATE: 881233  
DOCKET NO: 3030947  
CONTROL NO.: 110060  
LICENSE NO.:  
ACTION TYPE: NEW LICENSEE

Doris: Please note: The  
letterhead on the 1/25/89  
letter is "21<sup>st</sup> Century  
Diagnostics, Ltd;" the check  
reads "Ecomanagement, Inc."  
JK

2. FEE ATTACHED

AMOUNT: \$ 120.00  
CHECK NO.: 386

3. COMMENTS

SIGNED P. J. Brown  
DATE 89-01-05

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1)

1. FEE CATEGORY AND AMOUNT: 7C \$580

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT \_\_\_\_\_  
RENEWAL \_\_\_\_\_  
LICENSE ✓

3. OTHER \_\_\_\_\_

SIGNED  
DATE

A. Kimberley  
1/31/89

A