NRC FORM 313 (10-87) 10 CFR 30, 32 33, 34, 35 and 40 APPLICATION FOR 1	U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OMB 3160-0120 Expires: 6-30-90	
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DE OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BEL	TAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES	
OF THE ENTINE COMPLETED APPLICATION TO THE NHC OFFICE SPECIFIED BEL APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: U.S. NUCLEAR REGULATORY COMMISSION DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS WASHINGTON, DC 2056 ALL OTHER PERSONS FILE APPLICATIONS & FOLLOWS, IF YOU ARE LOCATED IN: CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNBYLVANIA, HHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR ATERIALS SAFETY SECTION B 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406 ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VHIGINIA, VIRGIN ISLANDE, OR WEST VIRGINIA, SEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION I NUCLEAR BED APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION I U.S. NUCLEAR REGULATORY COMMISSION, REGION I	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, 10WA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, DR WISCONSIN, BEND APPLICATIONS TO: U.S. NUCLEAR REGULATORY COMMISSION, REGION III MATERIALS LICENSING SECTION 708 ROOSEVELT ROAD GLEN ELLYN, IL 60137 ARKANSAS, COLORADO, IDAHO, KANBAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DANOTA, 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 78011 ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:	
NUCCAR MATERIALS SAFETY SECTION NUCCAR MATERIALS SAFETY SECTION 101 MARIETTA STREET, SUITE 2900 ATLANTA, GA 30323 PERBONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION	U.S. NUCLEAR REGULATORY COMMISSION, REGION V NUCLEAR MATERIALS SAFETY SECTION 1460 MARIA LANE, SUITE 210 WALNUT CREEK, CA 94596 REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL	
1. THIS IS AN APPLICATION FOR (Check eppropriete item) A. NEW LICENSE B. AMENDMENT TO LICENSE NUMBER C. RENEWAL OF LICENSE NUMBER	2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zep Code) ADAC Laboratories 540 Alder Drive Milpitas, CA 95035	
6225 Cochran Road Solon, Ohio 44139 A NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Paul J. Early, Director, NMA Medical P SUBMIT ITEMS & THROUGH 11 ON 8% & 11" PAPER. THE TYPE AND SCOPE OF INFORMATIO	TELEPHONE NUMBER Physics Serv. Cleve, OH (216) 641-5799	
 B. RADIDACTIVE MATERIAL Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be processed 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 3P	
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THA BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF O PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 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 C TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WIT	T ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE IF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS IS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION HIN ITS JURISDICTION	
Richard M. Ferra	Asst. President Ari & General Manager x /0-17-88	
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5. Radioactive Material		6. Use	
Element	Chemical/Physical Form	Max, Amt.	<u>Use</u>
Tc-99m	Pertechnetate (liquid)	2000 mCi	Quality Control of Equipment

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CONTROL NO. 8627 1

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7. Individuals Responsible For Radiation Safety

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Jim Etzel , Radiation Safety Officer with consultation from NMA Medical Physics Services, Cleveland, Ohio. See attached resume (Item #8).

> Item #7 1 of 1 page Prepared: 10/12/88 New License

October 13, 1988

Jim Etzel

Tecmar

Qualifications:

Senior Product Safety Engineer in the Regulatory Compliance Department at Technicare Corp.

Responsible for the log in/log out of radio active sources during the time the company designated RSO was unavailable at Technicare Corp during the period from January 1980 thru March 1985.

Responsible for Product Safety and also assisted in Plant Safety inspections for compliance with Government and Industry Standards.

Instructed employees in Plant, Product, and Radiation Safety as needed.

Sources included: Cobalt 57, Technicium 99.

Training:

Radiation safety training includes 1-2 hr sessions by the RSD. Topics include basic radiation physics, source handling procedures, accident reporting, use of geiger counters, correct use of radiation film badges.

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FACILITIES AND EQUIPMENT

- 1. Survey meters
 - a. Manufacturer's name: Atomic Products
 Manufacturer's model number: 069-701
 Number of instruments available: 1
 Minimum range: 0 mR/hr to 0.5 mR/hr
 Maximum range: 0 mR/hr to 50 mR/hr
- 2. Dose Calibrator(s)

Manufacturer's name: Capintec Manufacturer's model number: CRC-7 Number of instruments available: 1

Instruments used for diagnostic procedures
 Type of Instrument Manufacturer's Name Model No.

N/A

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

N/A

5. Personnel monitoring whole body and finger badges from any company approved by <u>NAVLAP</u>.

Item #9 1 of 4 pages Prepared: 10/12/88 New License Facilities and Equipment

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Walls #2, 3 and 4 are wire cage material against an exterior wall with a ceiling and locked sliding cage door to prevent inadvertent entry.

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FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete, refrigerator) so as to not exceed 2 mR/hr at the surface of the barrier.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2 mR/hr or less.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

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PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- 1. The Radiation Safety Officer or his/her designee will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area identified in the Item #9 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.
- 2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Source Room. If this is not practical, responsible personnel will sign for packages containing radioactive materials, and immediately take them to this location. Alternatively, trained nuclear personnel will sign for and transport packages to the appropriate department.
- 3. No packages will be delivered during off-duty hours.

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PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

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- 1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours after receipt if received after working hours, in accordance with the requirements of paragraphs 20.205 (a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm² or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 1m.
- 2. For all packages, the following additional procedures for opening packages will be carried out:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect package for sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify the Radiation Safety Officer.
 - c. Measure the exposure rate at 1m from the surface of the package and record only if above background. If greater than 10 mR/hr, stop procedure and notify the Radiation Safety Officer.
 - d. Measure surface exposure rate and record. If greater than 200 mR/hr, stop procedure and notify Radiation Safety Officer.
 - e. Open the package with the following precautionary steps:
 - (1) Open the outer package (following manufacturer's directions if supplied) and remove packing slip.
 - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, packing slip, and label on bottle.

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GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

- Wear laboratory coats or other protective clothing at all times when preparing sources containing radioactive materials.
- 2. Wear disposable gloves while handling radioactive materials during source or phantom preparations.
- 3. Confirm all prepared source containers are free of contamination before releasing them from the hot lab for use.
- 4. Monitor hands and clothing for contamination on completion of source preparation or before leaving the preparation area.
- 5. Always use lead shields for routine preparation of sources.
- 6. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is prepared or stored.
 - b. Do not store food, drink, or personal effects with radioactive material.
- 7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.
- 8. Wear TLD finger badges during source preparation.
- 9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.
- Survey preparation area for contamination after each procedure or at the end of the day. Decontaminate if necessary.
- 11. Confine radioactive solutions in covered containers plainly identified and labeled with name of the radionuclide, date, time, activity, and radiation level, if applicable.
- 12. Always transport radioactive material in shielded containers.

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- (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
- (4) Check also that shipment does not exceed possession limits.
- f. When exposure levels of the surface of the package exceed background levels, wipe test the external surface of the final source container. Shield and remove the wipe to a low background area. Check the wipes with a G-M survey meter and taken precautions against the spread of contamination as necessary.
- g. Monitor the packing material and packages for contamination before discarding.
 - (1) If contaminated, treat as radioactive waste.
 - (2) If not contaminated, obliterate radiation labels before discarding in regular trash.
- 3. Maintain records of the survey results as described above for each package.

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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 tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
- 4. SURVEY: With a low-range, thin window G-M survey meter, check the area around the spill, hands and clothing for contamination.
- 5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

- 1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate room.
- 2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
- 3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
- 4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
- 5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.
- 6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: OFFICE PHONE:

HOME PHONE:

ALTERNATIVE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

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SURVEY PROCEDURE

- A. Routine preparation areas will be surveyed on each day of use with a G-M survey meter and decontaminated, if necessary.
- B. All other areas of use will be surveyed weekly.
- C. The weekly survey will consist of:
 - 1. A measurement of radiation levels
 - 2. A series of wipes

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

- D. A permanent record will be kept of the daily or weekly survey results, including negative results. The record will include:
 - 1. Location, date and type of equipment used.
 - 2. Name of person conducting the survey.
 - 3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - 4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).
 - 5. Detected contamination levels, keyed to locations on drawing.
 - 6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

Item #10 6 of 9 pages Prepared: 10/12/88 New License In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

- 1. The work bay area will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of individuals named on the license application.
- 2. Every effort will be made to hire qualified personnel to work with radioactive material. Orientation of such personnel for a day or two by the RSO named on the license and/or by the supervising technician will include the following:
 - a. Indicate areas where radioactive materials are used or stored.
 - b. Potential hazards associated with radioactive materials.
 - c. Radiological safety procedures appropriate to their respective duties.
 - d. Pertinent NRC regulations.
 - e. The rules and regulations of the license.
 - f. The pertinent terms of the license.
 - g. Their obligation to report unsafe conditions.
 - h. Appropriate response to emergencies or unsafe conditions.
 - i. Their right to be informed of their radiation exposure results.
 - j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions), as required by 10 CFR, Part 19.

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- 3. Our consulting physicists service will visit our facility quarterly to review all procedures, equipment and records. Personnel will receive refresher training relative to duties, regulations, or terms of the license during these visits or by supplementary training at least annually or more frequently, as needed.
- 4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, personnel so involved will be present under the direction of trained technicians, who will ensure that the exposure of these persons is held to the minimum required for the performance of the procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their orientation process and annually thereafter in the form of verbal instructions and/or interdepartment memos.

Item #10 8 of 9 pages Prepared: 10/12/88 New License OPERATING PROCEDURES FOR THE PREPARATION OF DOSES AND PHANTOMS

- 1. Calculate the volume that represents the required dose from bulk shipment.
- 2. Put on gloves to prevent hand contamination.

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- 3. Place empty syringe in syringe shield.
- 4. With all necessary materials placed behind loading shield, withdraw necessary volume as calculated above.
- 5. Remove from syringe shield and measure dose for accuracy in dose calibrator. If unit doses are used, put on gloves, remove unit dose from lead container and measure.
- 6. Replace syringe shield and inject into phantom that has been filled to desired level with water.
- 7. Seal phantom and agitate for even mixing, making sure that no leakage occurs.
- 8. Label phantom with "Caution Radioactive Material" tape, recording dose, volume, time and radionuclide on phantom and usage records.
- 9. After use, phantom will be returned to Source Room and stored for decay, or disposed via hot sink.

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APPENDIX J

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WASTE DISPOSAL

- 1. Liquid waste will be disposed of:
- X A. In the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.
- X B. Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.
- X C. Other (specify): Return to radiopharmacy.
- 2. Mo-99/Tc-99m generators will be:
- A. Returned to manufacturer for disposal.
- B. Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.
- C. Disposed of by commercial waste disposal service.
- D. Other (specify): Return to radiopharmacy.
- 3. Other solid waste will be:
- X A. Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.
- B. Disposed of by commercial waste disposal service.

X C. Other (specify): Return to radiopharmacy.

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