

APPLICATION FOR MATERIAL LICENSE

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

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

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

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LAKE DRIVE, 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 _____
☒ C. RENEWAL OF LICENSE NUMBER 52-21051-01

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

HECTOR R. LEON, M.D.
Carr.21 - U3, No.2 - Urb.Las Lomas
Rio Piedras, P.R. 00921

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

Carr.21 - U3, No.2 - Urb.Las Lomas
Rio Piedras, P.R. 00921

4. NAME OF PERSON TO CONTACTED ABOUT THIS APPLICATION

HECTOR R. LEON, M.D.

TELEPHONE NUMBER

(809) 781-9540

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. See Att.5.f and 6

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

See Att. 5.f and 6

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

See Att.7.1 and 7.3

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

See Att. 8 - 10 - 11

9. FACILITIES AND EQUIPMENT

See Att. 9

10. RADIATION SAFETY PROGRAM

See Att. 8 - 10 - 11

11. WASTE MANAGEMENT

See Att. 8 - 10 - 11

12. LICENSEE FEES (See 10 CFR 170 and Section 170.11)

FEE CATEGORY 7 C 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

Hector R. Leon

Hector R. Leon

M.D.

7-30-87

14. ANNUAL RECE

<\$250K	\$
\$250K-500K	\$
\$500K-750K	\$7M-10M
\$750K-1M	>\$10M

8801220257 870813
REG. LIC30
52-21051-01
PDR

15. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Labor and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit to protect confidential commercial or financial proprietary information furnished to agency in confidence)

YES

NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Ren	Aug-3-87	7C		<i>H. Leon</i>
AMOUNT RECEIVED	CHECK NUMBER			DATE
\$580	2036		251719	8/1/87

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

A T T A C H M E N T 7.1 and 7.3

(Authorized user, RSO and Radiation Physics Consultant)

- 7.1.1 Supplement A and B (Hector R. Leon, M.D. authorized user
7.3.1 and RSO)
Please see Annex to items 4 and 5 of the initial
Application for the Lic. on 1982
- 7.3.2 Supplement A and Resume (Santiago Gomez-Figueroa, Radiation
Physics Consultant)
Reference is made to NRC Broad Scope License No.
52-01946-07 of the UPR-Medical Sciences Campus, San Juan,
P.R. where Santiago Gomez-Figueroa is the Radiation
Protection Officer.

A T T A C H M E N T 9

9.1 The enclosed Layout Diagram of the Office facilities describes the location where the source will be stored. For security purposes, the Sr-90 Ophthalmic Applicator will be stored inside a keyed cabinet and keys will be kept on hand by the authorized user at his desk in the main Office.

9.2.1 Accessibility to a properly calibrated G.M. Survey Meter:

In case of emergency, during leak testing procedures, receiving the Applicator from the manufacturer, packing and delivery of the Applicator for repair or maintenance services or in any other case requiring radiation levels determination, arrangements have been made with the Radiation Physics Consultant to ensure access to a recently calibrated G.M. Survey Meter.

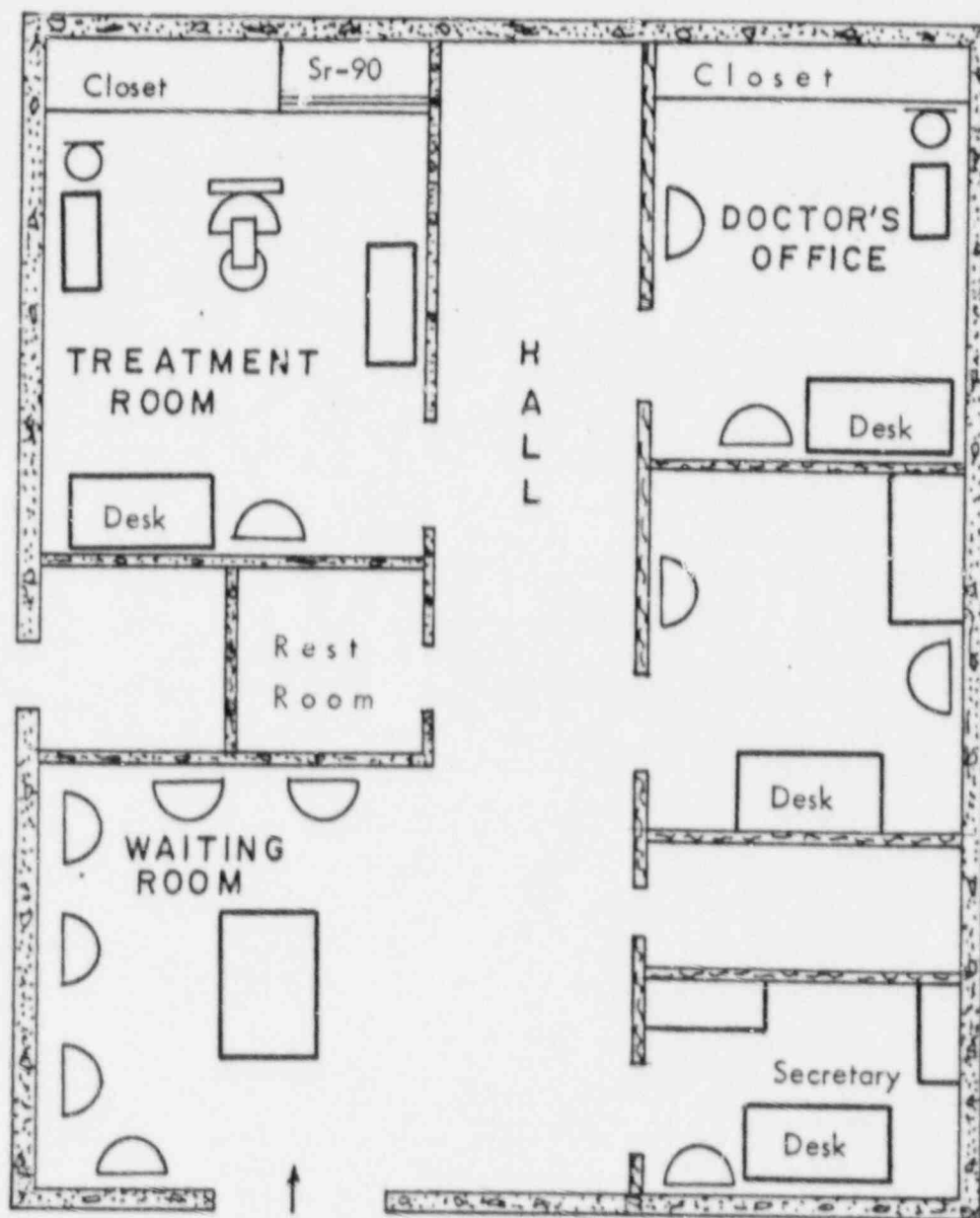
9.2.2 Calibration of the instrument:

"We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 (August, 1985)"

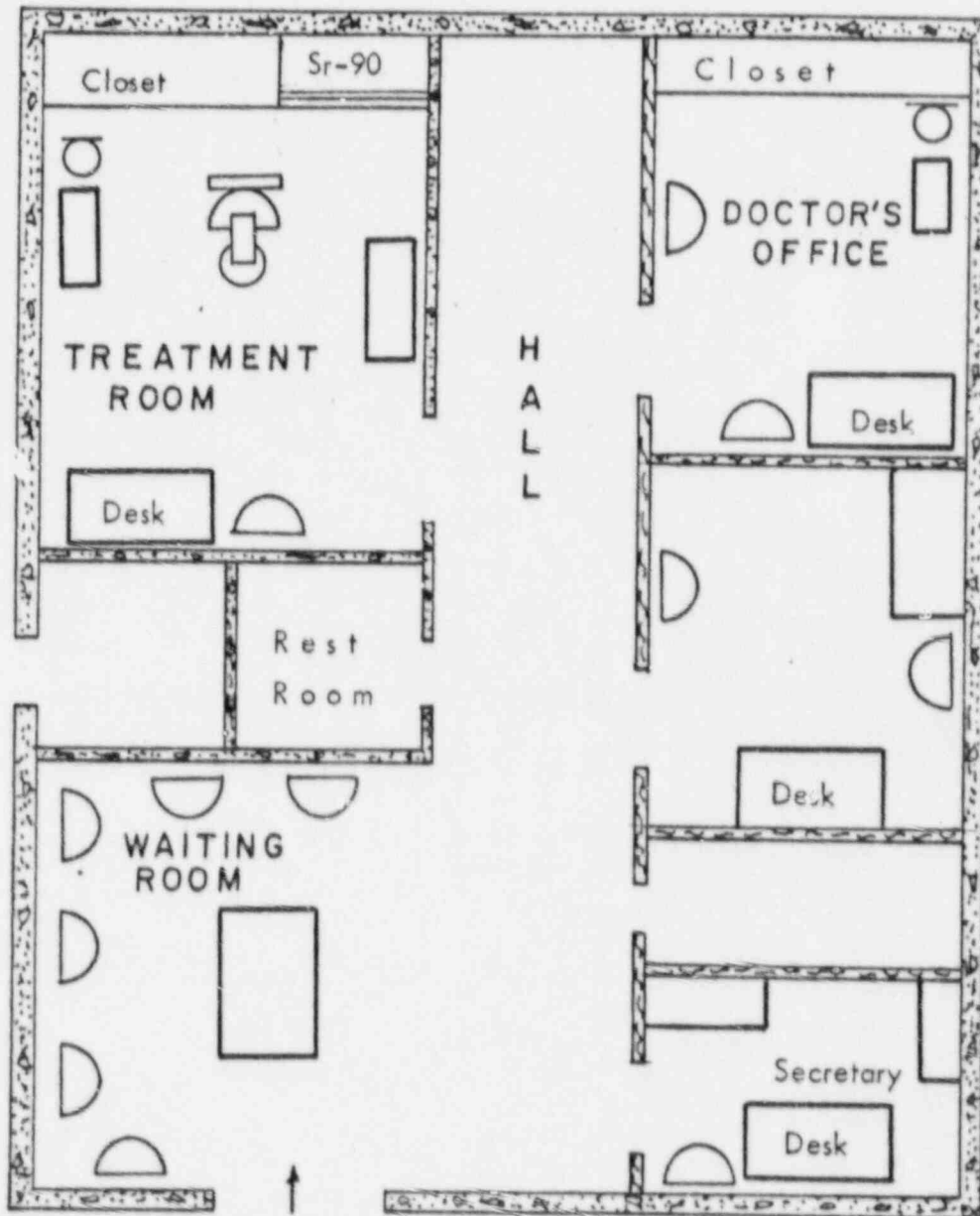
9.4 Personnel Monitor Program:

"We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2 (August, 1985)"

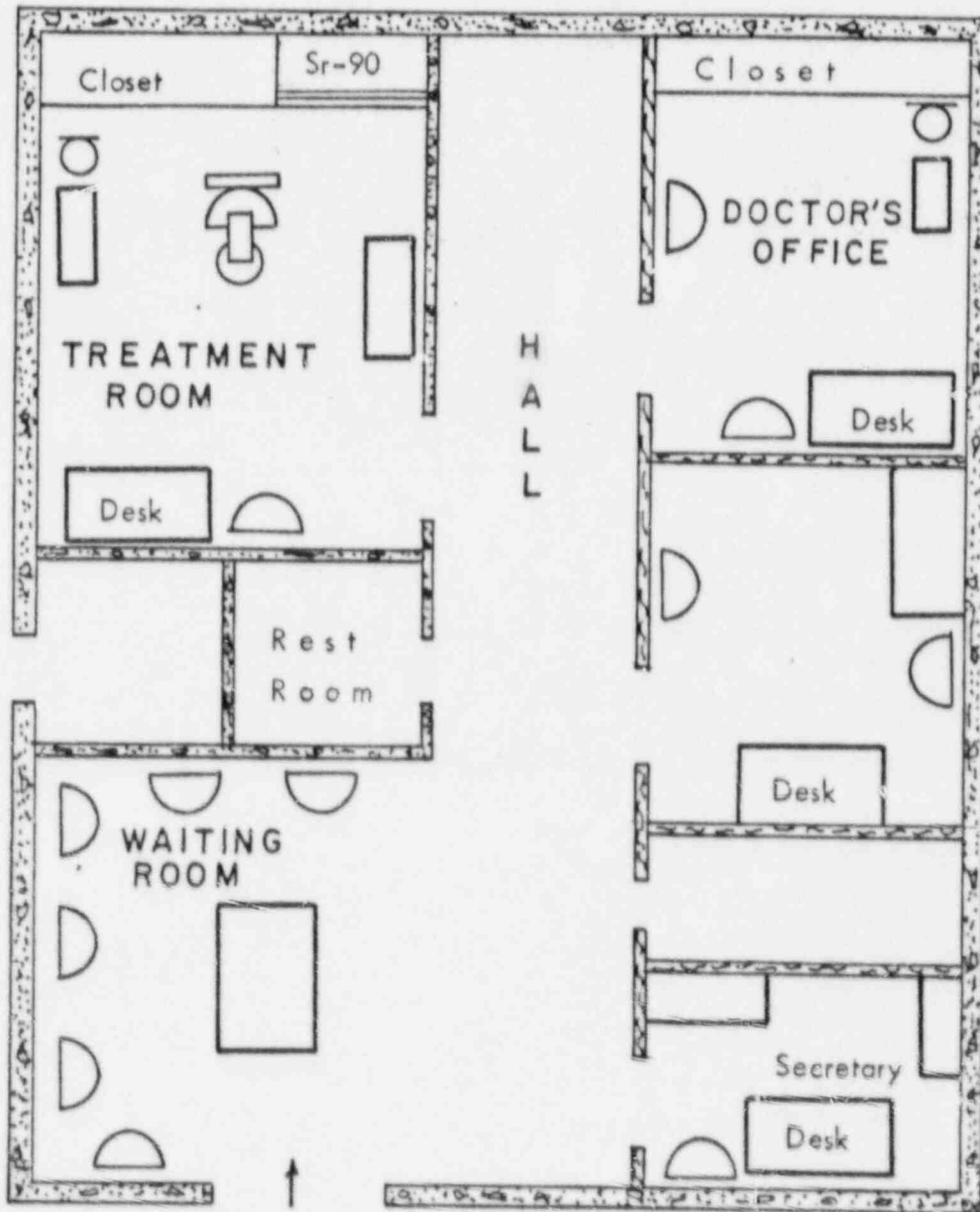
DR. HECTOR R. LEON, OFFICE
LAYOUT DIAGRAM



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LAYOUT DIAGRAM



ATTACHMENT 8 - 10 - 11

- 8.1 Personnel Training
- 10.3 Leak Tests
- 10.4 Rules for safely handling a Sr-90 Eye Applicator
- 11.1 Waste disposal

8.1 PERSONNEL TRAINING

The Beta Eye Applicator can only be handled by the authorized user when treatments are performed or by the radiation physics consultant when leak testing procedures are being made. (Please see Att. 7.1 and 7.3 for training and experience with radiation of the authorized user and the radiation physics consultant).

During treatments, paramedical personnel stay away from the source in such manner that the total dose received by any one of those employees shall not exceed the maximum permissible dose for the general public.

10.3 LEAK TESTS

Perform routine leak test at 6 - month intervals and maintain records. The source shall be withdrawn from service if leak test results indicate any increase in detectable activity from that of previous leak test. Removable contamination activity should be much less than 0.005 uCi.

Leak test shall be performed by persons specifically authorized by the Commission or an Agreement State to perform such services, and following model procedure published in Appendix H to Regulatory Guide 10.8 , Revision 2 (August, 1985).

10.4 RULES FOR SAFELY HANDLING A SR - 90 EYE APPLICATOR

1. Wear your personnel dosimeter (s) if available, whenever you handle the Sr-90 Eye Applicator.
2. Remove the Sr-90 Eye Applicator from its secured storage location just before use. Do not leave it out any longer than necessary.
3. After removing the Applicator from its storage location,
 - a. Do not touch the treatment end of the applicator with your hands or other portion of your body.
 - b. Always hold the applicator by its handle.
 - c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.
4. When the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge or gauze dampened

A T T A C H M E N T 5.f and 6

Item 5: Radioactive materials

Item 6: Purpose

Element: Sr-90/Y-90

Physical form: Sealed source in an Eye Applicator
Nuclear Associates Inc.
Model 67-850
Serial No.E-515

Max.amount: 125 mCi (August,1982)

Purpose: Therapy: treatment of superficial eye
conditions

with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge or gauze. Do not sterilize by holding the applicator or gauze in your hand.

5. During treatment, hold the patient's eye lids open with tape or other device, not with your fingers.
6. Immediately after treatment and/or resterilization, return the Sr-90 Eye Applicator to its storage container and to its secured location, i.e. keyed cabinet.
7. Do not remove any metal or plastic inserts from the manufacturer-supplied storage container. These items are generally a part of the container's shielding. Removal of these items can lead to excessive and unnecessary radiation exposures.
8. In event of apparent or probable damage to the source it shall immediately be placed into the storage container. The storage container shall be wrapped or placed into a plastic bag and secured. The cognizant radiation protection Officer, regulatory agency, or the radiation physics consultant shall be contacted immediately for consultation and action.
9. In order to ensure that radiation exposures will be as low as reasonably achievable (ALARA), in the use and handling of the Sr-90 sealed source, the authorized user, HECTOR R. LEON, M.D., enforces the following actions:
 - a. As soon as new staff members (e.g., physicians or other individuals who assist with patient treatments) report for duty and at least annually thereafter, it will be organized a refresher training in the rules for safe handling of the Sr-90 eye applicator and in the items specified in 10 CFR 19.12.
 - b. At least once each year, both the authorized user and the radiation physics consultant will review the results of personnel monitoring if available, consider ways of reducing radiation exposures and implement needed changes in procedures, equipment, etc.

11.1 WASTE DISPOSAL

It is not foreseen any waste disposal in the proposed use and handling of the Sr-90 sealed source Eye Applicator. In the event of a serious damage to the applicator, the final disposal will be performed by the manufacturer, i.e. Nuclear Associates Inc. or any other licensee specifically approved to handle and/or dispose this source.