

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 3.25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOUR 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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19408-1415

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
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:

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1460 MARIA LANE
WALNUT CREEK, CA 94596-5368

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 JURISDICTIONS.

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

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

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

Carolina Nuclear Laboratory, Inc.
P.O.Box 11665
San Juan, Puerto Rico 00910-2665

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

Carolina Nuclear Laboratory, Inc.
AC - 8 Avenida Monserrate
Valle Arriba Heights, Carolina, Puerto Rico

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. José O. Morales

(787)

TELEPHONE NUMBER

727-6060, Ext 487

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 7c AMOUNT ENCLOSED \$ 1,400

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

José O. Morales, MD

President

04/18/97

FOR NRC USE ONLY

TYPE OF FEE FEE LOG FEE CATEGORY COMMENTS

AMOUNT RECEIVED

CHECK NUMBER

257472

APPROVED BY

DATE

ITEM NO. 5 AND NO. 6

Byproduct Material	Amount	Purpose	
5.a Material in §	35.100	As needed	6.a Medical use described in 10 CFR , § 35.100
5.b Material in §	35.200	As needed	6.b Medical use described in 10 CFR, § 35.200
5.c Material in §	35.300	As needed	6.c Medical use described in 10 CFR, § 35.300

Note: We are only requesting authorization for ambulatory therapy, i.e., therapy under 30 mCi, where no hospitalization is required.

ITEM NO. 7

Authorized users:

José O. Morales, M.D. - authorized, among others, under Byproduct Materials License No. 52 - 15139 -01
Lourdes García-Alonso, M.D. - authorized, among others, under Byproduct Materials License No. 52 - 15139 - 01

Radiation Safety Officer: José O. Morales, M.D.
Alternate Radiation Safety Officer: M.M. Palacios de Lozano, M.S.
Radiological Physicist Consultant

Mrs. Lozano's training and experience are on file with NRC since 1962.

ITEM NO. 8

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2 and identify the groups of workers who will receive training and the method and frequency of training as follows:

Nuclear Medicine Technicians - lecture - once/year and as needed
secretaries, and janitors - lecture - as needed

ITEM NO. 9

9.1 Annotated drawings - (ATT 9.1)

9.2 Survey Instrument Calibration

We will use commercial laboratory services which calibrate survey instruments in accordance with the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2.

9.3 Dose Calibrator Calibration

We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2, with the exception of the shield method procedure. We will follow the procedure recommended by the shield

manufacturer. We will adopt the permissible tolerance level of $\pm 10\%$ in the regulations, rather than the recommended tolerances ($\pm 5\%$) given in Appendix C.

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. Our personnel dosimetry service is provided by Landauer, Inc., which is accredited by the National Institute of Standards and Technology.

9.5 Imaging Equipment

N/A

9.6 Other Equipment and Facilities

Refer to ATT 9.6

ITEM NO. 10 - RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

N/A

10.2 ALARA Program

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

10.3 Leak Test

We will establish and implement the procedure for leak testing sealed sources that is described in ATT. 10.3.

10.4 Safe Use of Radiopharmaceuticals

We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

10.5 Spill Procedures

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2.

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

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10.7 Opening Packages

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2.

10.8 Unit Dosage Records

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.

10.9 Multidose Vial Record

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.

10.10 Molybdenum Concentration Records

We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2.

10.11 Implant Source Use Records

N/A

10.12 Area Survey Procedures

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13 Air Concentration Control

The only procedure for which we seek authorization which would involve air concentration control is the use of Tc-99m DTPA aerosol for lung function studies. Since dispensing devices for technetium aerosols utilize traps that are to be discarded after use, we understand that an air contamination monitor is not required.

We shall follow the procedure described in Appendix O, Model Procedure 0.3, 2., 3., and 4.

10.14 Radiopharmaceutical Therapy

N/A; we are interested in requesting authorization for ambulatory therapy only, i.e., less than 30 mCi of radioiodine.

10.15 Implant Therapy

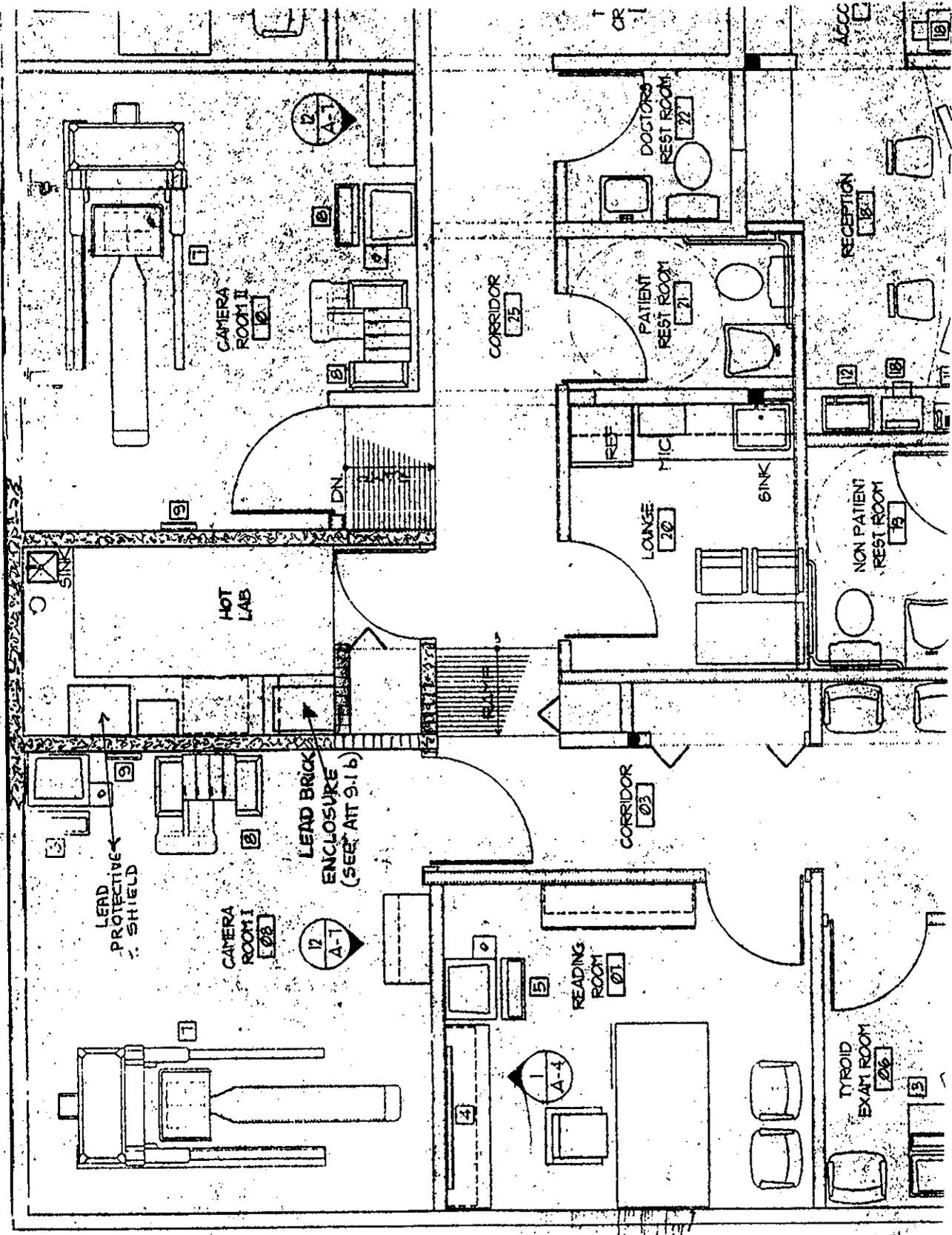
N/A

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ITEM NO.11 - WASTE MANAGEMENT

11.1 Waste Disposal

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

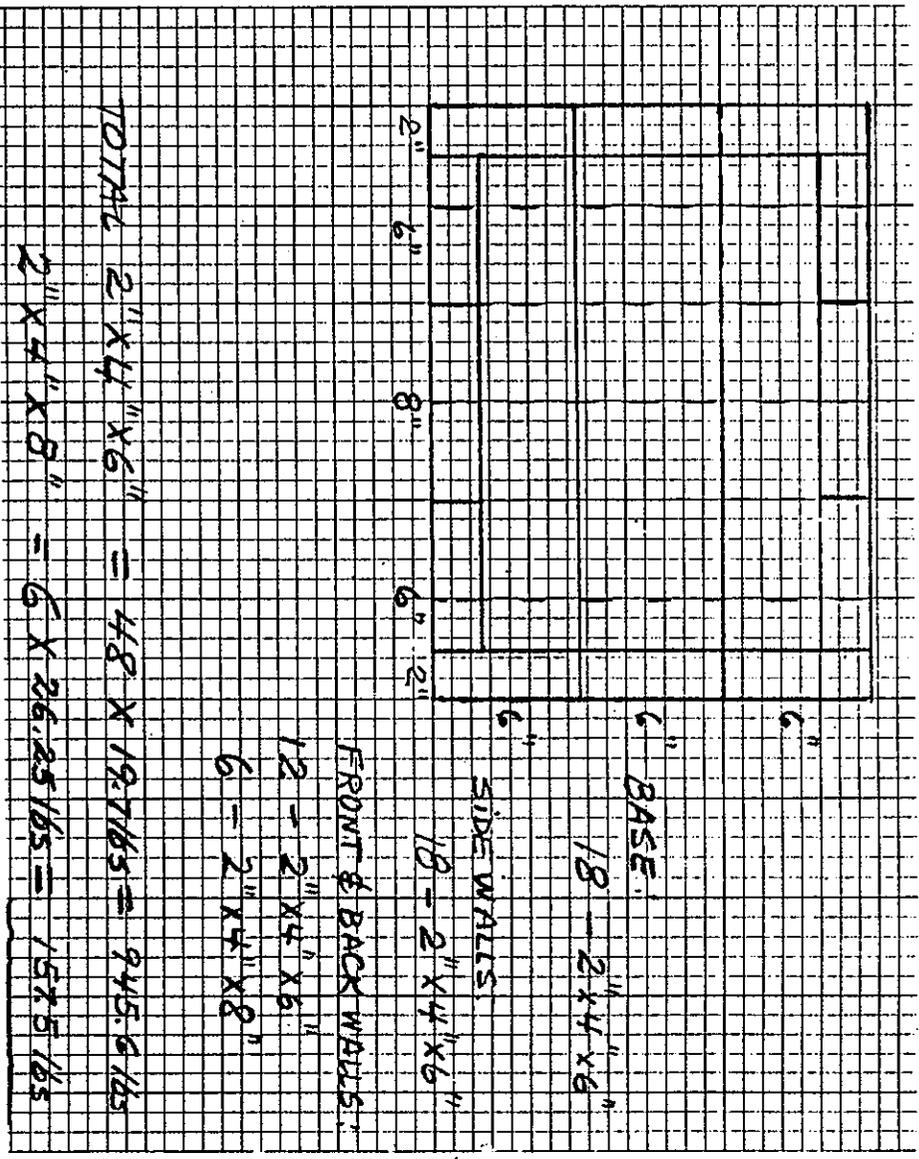


 CONCRETE

 CONCRETE BLOCK

ATT 9.1.a

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LEAD BRICK ENCLOSURE

ATT 9.1 b

ATT. 9.6

Equipment and Facilities

One single-head SPECT gamma scintillation camera with the appropriate software, UPS system, etc.

One treadmill and monitor Model Q-4500

Dose calibrator - Capintec CRC15 with printer

Set of dose calibrator standard sources - Co-57, Cs-137 and Ba-133

Uptake system Table-Top Model 950, Catalog No. 051-014 Cone Instruments Catalog

Survey meter - Ludlum Model 14-C, with 44-7 probe

Calicheck Lineator

Syringe shields - 1, 3, and 5 cc; Model Pintec, by Capintec

Lead Protective Shield - Standard, Cone Instruments Catalog No. N131176H

Two syringe holders

Vial Shield- Cone Instruments Catalog No. N070009H

Set of lead bricks to make up brick enclosure

Waste Container - Cone Instruments Catalog No. N131182H

CERTIFICATE OF SOURCE LEAK TEST

DATE: _____

Sealed Source Description:

Radionuclide: _____
 Model No.: _____
 Serial No: _____

Instrument Used:

Victoreen Deluxe Wipe Test
 Counter Model 05-578

Isotope Conversion Factors:

<u>Isotope</u>	<u>Conv. Factor</u>
Co-57	1.2
Cs-137	0.087
Co-60	0.16
Ba-133	0.83

Threshold value: $0.005 \mu\text{Ci} = \overset{11.1}{\text{kdpm}}$

Procedure:

1. Wipe all external surfaces of the source, including the source seal area, with a piece of water moistened filter paper provided with the counting instrument; place it in the corresponding glassine envelope.
2. Set the ACTIVITY to 0 nCi, just as for Tc-99 m contamination.
3. Multiply the desired THRESHOLD value (11.1 kdpm) by the CONVERSION FACTOR for the isotope, and set the resulting product value as the THRESHOLD value by pressing the THRESHOLD key and entering the value by using the CHANGE DIGIT KEYS. Press the ACTIVITY key to complete the entry. The threshold light will go out.
4. Count the wipe, in its glassing envelope, in the usual manner.
5. A PASS means that the count is less than the THRESHOLD value. A FAIL displays a kdpm value, which must be multiplied by the CONVERSION FACTOR to get the actual kdpm value for the wipe.

RESULT: _____

