

FORM NRC-313 (1-79)
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

1. APPLICATION FOR:
(Check and/or complete as appropriate)

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

X a. NEW LICENSE

b. AMENDMENT TO:
LICENSE NUMBER

c. RENEWAL OF:
LICENSE NUMBER

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

2. APPLICANT'S NAME (Institution, firm, person, etc.)

Allergan America

TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION
833-0203 809

3. NAME OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION

Edmundo Crespo

TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION
833-0203 809 16

4. APPLICANT'S MAILING ADDRESS (Include Zip Code)

P.O. Box 60

Hormigueros, Puerto Rico 00660

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED
(Include Zip Code)

P.R. Road 345 Km. 1.5

Hormigueros, Puerto Rico 00660

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL

(See Items 16 and 17 for required training and experience of each individual named below)

| NAME | TITLE |
|---------------------------------|---|
| a. Edmundo Crespo | Q.C. Manager, B.S. Chemistry |
| b. José M. Alicea | Laboratory Technician, Ass. Degree Eng. |
| c. | |
| 7. RADIATION PROTECTION OFFICER | Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15. |
| Nimia E. Irizarry | |

| LINE NO. | ELEMENT AND MASS NUMBER | CHEMICAL AND/OR PHYSICAL FORM | NAME OF MANUFACTURER AND MODEL NUMBER (If Sealed Source) | MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME |
|----------|-------------------------|-------------------------------|--|---|
| | A | B | C | D |
| (1) | Nickel 63 | Plated Part | Hewlett - Packard Electron Capture Detector #18803-60520 | 15 m ci per detector/ 2 detectors |
| (2) | | | | |
| (3) | | | | |
| (4) | | | | |

8. LICENSED MATERIAL

E

For analyzing 1,1,1 - Trichloro-2-Methyl-2 Propanol (Chlorobutanol) in our products: Liquifilm Tears and Blink-N-Clean

| | | | |
|-----|----------------------|-------------|-------|
| (1) | Applicant... | 10067 | 10178 |
| (2) | Check No. | 10067 | 10178 |
| (3) | Amount/ Fee Category | 190(3) | 20 |
| (4) | Type of Fee | Application | |
| | Date Check | MAR 1 1980 | |
| | Received By | Thom | |

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9. STORAGE OF SEALED SOURCES

| LINE NO. | CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A. | NAME OF MANUFACTURER B. | MODEL NUMBER C. |
|----------|---|----------------------------|--------------------|
| (1) | Hewlett - Packard Gas Chromatograph Series 5840 | Hewlett - Packard | 5840 |
| (2) | | | |
| (3) | | | |
| (4) | | | |

10. RADIATION DETECTION INSTRUMENTS

| LINE NO. | TYPE OF INSTRUMENT A. | MANUFACTURER'S NAME B. | MODEL NUMBER C. | NUMBER AVAILABLE D. | RADIATION DETECTED (alpha, beta, gamma, neutron) E. | SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F. |
|----------|--------------------------|---------------------------|--------------------|------------------------|---|---|
| (1) | | | | | | |
| (2) | | | N/A | | | |
| (3) | | | | | | |
| (4) | | | | | | |

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

| | |
|--|---|
| <input type="checkbox"/> a. CALIBRATED BY SERVICE COMPANY NAME, ADDRESS, AND FREQUENCY N/A | <input type="checkbox"/> b. CALIBRATED BY APPLICANT Attach a separate sheet describing method, frequency and standards used for calibrating instruments. |
|--|---|

12. PERSONNEL MONITORING DEVICES

| TYPE (Check and/or complete as appropriate.) A. | SUPPLIER (Service Company) B. | EXCHANGE FREQUENCY C. |
|---|-------------------------------------|---|
| <input type="checkbox"/> (1) FILM BADGE <input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD) <input type="checkbox"/> (3) OTHER (Specify): _____ _____ _____ | N/A | <input type="checkbox"/> MONTHLY <input type="checkbox"/> QUARTERLY <input type="checkbox"/> OTHER (Specify): _____ _____ _____ |

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).)

- ☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.-See attachments
☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

- a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED
Return detectors to supplier
- b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.
- Detectors will be returned to Hewlett - Packard Company, Route 41,
Avondale, Pennsylvania 19311

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (if needed), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
16. **FORMAL TRAINING IN RADIATION SAFETY.** Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - b. Radioactivity measurement standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
17. **EXPERIENCE.** Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

Edmundo Crespo 3-6-80

Edmundo Crespo, Q.C. Manager

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our 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.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

\$90.00

b. CERTIFYING OFFICIAL (Signature)

c. NAME (Type or print)

Nimia E. Irizarry

d. TITLE

Radiation Prot. Officer

e. DATE

March 6, 1980

(1) LICENSE FEE CATEGORY: 3.E

(2) LICENSE FEE ENCLOSED: \$ 90.00

ATTACHMENT

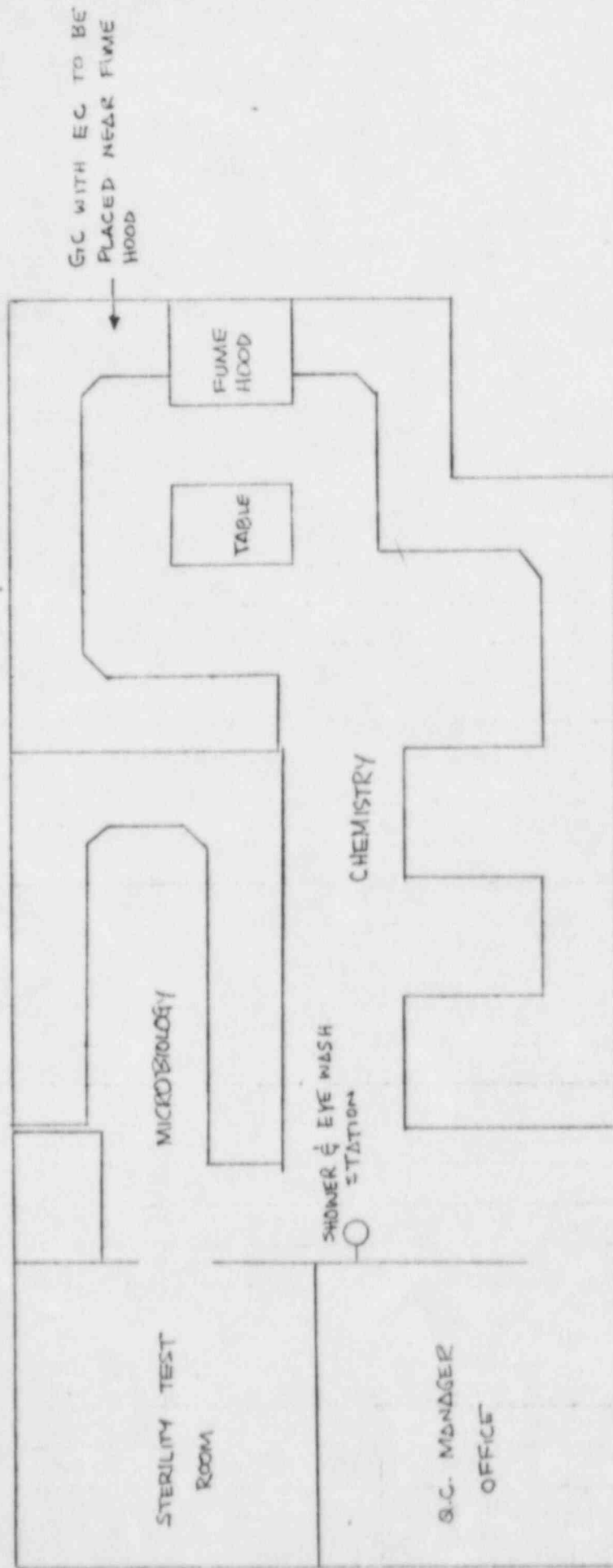
13. FACILITIES AND EQUIPMENT

- a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS
(include filtration, if any) ETC.

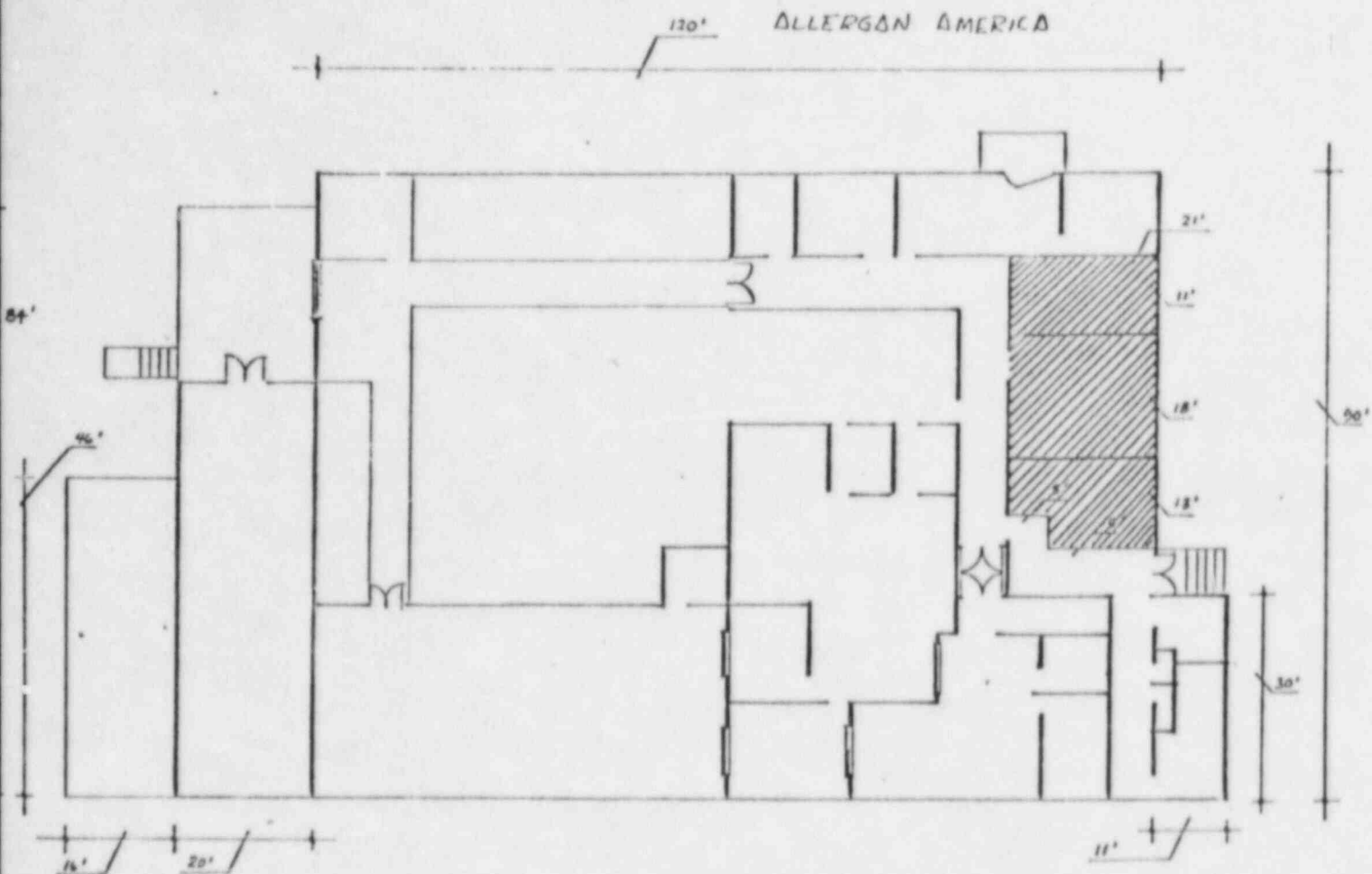
1. SHEET NO. 13.a.1. Laboratory facility
2. SHEET NO. 13.a.2. Plant facility

The gas effluents will be piped to the fume hood that
is piped to outside of the facilities.

ALLERGAN AMERICA



LABORATORY FACILITY SHEET NO. 13.2.1



PLANT FACILITY SHEET NO. 13.a.2

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ATTACHMENT

15. RADIATION PROTECTION PROGRAM

Allergan America will perform a leak test twice per year using a Hewlett-Packard No. 18713-60050 Leak Test Kit.

Nimia E. Irizarry, Head, Health & Safety Division of the Center for Energy and Environment Research, as Radiation Protection Officer, will perform two leak tests per year, and will be available for emergency calls whenever a case may arise.

Allergan America will call our Radiation Protection Officer in case that an accidental breakage occurs. Employees will be promptly evacuated from the premises.

A formal training will be undertaken by those listed on Item No. 6 so that any situation can be dealt with promptly.

ATTACHMENT

16. FORMAL TRAINING IN RADIATION SAFETY

A training course on the "Basic Concepts of Radiation" will be taken in April, 1980.

ATTACHMENT

17. EXPERIENCE

Attached to this sheet are the following:

- A. Resume of Edmundo Crespo
- B. Resume of José Manuel Alicea
- C. Resume of Nimia E. Irizarry

RESUME

PERSONAL DATA

Name: Edmundo Crespo Age: 31 Phone: 809-832-9047
Address: Urb. Villas Del Oeste Street: Tauro B 35 A
City: Mayaguez State: Puerto Rico Zip Code: 00708
Height: 5'11" Weight: 225 lbs. Date of Birth: 5-24-49
Marital Status: Married Number of Children: 3
Citizen of: U.S.A. Military Status: 1-H Disabilities: None

EDUCATION

| <u>Name of School</u> | <u>Location</u> | <u>Dates Attended</u> | <u>Degree</u> |
|-------------------------|------------------|-----------------------|------------------------|
| Boys High School | Brooklyn, N.Y. | 1965 to 1967 | Diploma |
| Ineramerican University | San German, P.R. | 1968 to 1971 | B.S. Chemistry 1972 |

BUSINESS EXPERIENCE

(present Job First) Company, Dates, Title, and Brief Summary.

Allergan America, Hormigueros, Puerto Rico * 1973 to Present *
Quality Control Manager * Responsible for all quality control
and quality assurance programs for sterile ophthalmic products.

Converse Rubber Company, Canovanas, Puerto Rico * 1971 to 1973 *
Plant Chemist and Quality Coordinator * Troubleshooting on
rubber formulations and quality assurance of processing.

BUSINESS EXPERIENCE

Colgate-Palmolive Company, Hato Rey, Puerto Rico * 1971 *
Plant Chemist * Testing of manufactured batches and in process
analysis of products.

Ineramerican University, San German, Puerto Rico * Summer of 1975 *
Laboratory Instructor of Organic Chemistry * Teach Organic
Chemistry Laboratory Technics.

Working Knowledge of: Rubber and Plastics

Problem Solving

Instrumentation

Incoming Inspection

In Process Inspection

Microbiology

FDA Regulations

DPSC Regulations

Sterile Filling Operations

Budgetting

Purchasing

Production Operations

Tabletting

Audits

Statistics

Validation/Qualification Studies

OSHA Regulations

No experience with Radio Active Substances.

As a chemistry student, nuclear, and radiation topics were
received.

RESUME

PERSONAL DATA

Name: Jose Manuel Alicea Age: 25 Phone: -
Address: Box 64 City: Guayanilla State: Puerto Rico
Zip Code: 00656
Height: 5'10" Weight: 17. lbs. Date of Birth: 5-23-54
Marital Status: Married Number of Children: None
Citizen of: U.S.A. Military Status: 1-H Disabilities: None

EDUCATION

| <u>Name of School</u> | <u>Location</u> | <u>Dates Attended</u> | <u>Degree</u> |
|--|------------------|-----------------------|------------------------|
| Francisco Rodriguez Lopez High School | Guayanilla, P.R. | 1969 to 1972 | General |
| College of Agriculture and Mechanical Arts | Mayaguez, P.R. | 1972 to 1977 | No Deg. |
| Ponce Technical Institute | Ponce, P.R. | 1977 to 1978 | Ass Deg. Chem. Eng. |

BUSINESS EXPERIENCE

(Present Job First) Company, Dates, Title, and Brief Summary.

Allergan America, Hormigueros, Puerto Rico * 1979 * Laboratory Technican * In charge of performing analysis on bulk products, final products, and raw materials using both Hand and Automated methods.

BUSINESS EXPERIENCE

Smith, Kline & French, Guayama, Puerto Rico * 1978 to 1979 *
Laboratory Technican - Odor Control * In charge of performing
all analysis in the Controlled Environment Area and laboratory
analysis of raw materials, intermediates on final bulk
substances.

PPG Industries, Guayanilla, Puerto Rico * 1978 * Laboratory
Technican * In charge of performing analysis on final products.

Working Knowledge of: Gas Chromatography
High Pressure Liquid Chromatography
Thin Layer Chromatography
Infra Red Spectrometer
UV/Visible Spectrophotometer
Melting Point Apparatus
Atomic Absorption

No experience with Radioactive Substances.

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Item 17

Radiation Protection Officer's Resumé

Nimia E. Irizarry

Training and Experience

| Type of Training | Where Trained | Duration of Training | On the Job | Formal Course |
|---|---|----------------------|------------|---------------|
| a. Principles and practices of radiation protection... | | | | |
| 1. Seminar in radiological health | Center for Energy and Environment Research (CEER), (Formerly Puerto Rico Nuclear Center), in coordination with Medical Sciences Campus U.P.R. | 5 months | Yes (No) | (Yes) No |
| 2. Radiation hazards and protection | Rio Piedras, Puerto Rico. | 5 months | | |
| 3. Laws and regulations in radiological health | | 5 months | | |
| 4. Safety in reactor operations | | 5 months | | |
| 5. Field practice | | 2 months | | |
| b. Radioactivity measurement standardization and monitoring techniques and instruments... | Same as above | | Yes (No) | (Yes) No |
| 1. Radiation detection | | 5 months | | |
| 2. Radiation dosimetry | | 5 months | | |
| 3. Decontamination and waste management | | 5 months | | |
| 4. Radioactivity of the environment | | 5 months | | |
| c. Mathematics and calculations basic to the use and measurement of radioactivity... | Same as above | | Yes (No) | (Yes) No |
| 1. Radiation physics | | 5 months | | |
| 2. Radiation chemistry | | 5 months | | |
| d. Biological effects of radiation... | Same as above | | Yes (No) | (Yes) No |
| 1. Radiation effects in mammals and humans | | | | |

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Item 17

Radiation Protection Officer's Experience with Radiation.

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| Isotope | Maximum Amount | Where Experience was Gained | Duration of Experience | Type of Use |
|--------------------|----------------|-----------------------------|------------------------|------------------------------------|
| CO-60 | 16413 Ci | Puerto Rico Nuclear Center | 4 years | Gamma irr. fac. |
| Ra-226 | 21.6 mg | Puerto Rico Nuclear Center | 4 years | Instr. and film cal. |
| Cs-137 | 20 Ci | Puerto Rico Nuclear Center | 4 years | Instr. and film cal. |
| Pu Be | 15 g Pu | Puerto Rico Nuclear Center | 4 years | Instr. and film cal. |
| TRIGA FLIP reactor | 2 MW | Puerto Rico Nuclear Center | 4 years | Radiation Protection Officer |

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Item 17

Radiation Protection Officer's Resumé

Additional Experience:

Total of 8 years working with radioisotopes.
Four years as Research Assistant I to III. Working in neutron activation and spectrometric analysis of samples.

Four years as Radiological Safety Officer, 3 of which have been as Head, Health and Safety Division, Center for Energy and Environment Research (formerly Puerto Rico Nuclear Center).