

APPLICATION FOR MATERIAL LICENSE

FORM 213
 04
 CFR 30.32.33.34
 040 80

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 20545

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

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, VERMONT, SEND APPLICATIONS TO:
 U.S. NUCLEAR REGULATORY COMMISSION, REGION III
 NUCLEAR MATERIAL SECTION B
 831 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
 700 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
 811 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 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. STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

THIS IS AN APPLICATION FOR (Check one):

A NEW LICENSE

B AMENDMENT TO LICENSE NUMBER _____

C RENEWAL OF LICENSE NUMBER _____

2 NAME AND MAILING ADDRESS OF APPLICANT (include Zip Code):

Satco Products, Inc.
 110 Heartland Blvd.
 Brentwood, N.Y. 11717

ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED:

900 N.W. 159th Drive, Miami, Fla. 33169 110 Heartland Blvd. Brentwood, N.Y. 11717
 340 Industrial Way, Brisbane, CA. 94005
 1225 East Crosby Carrollton, TX 75006

NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION: **Arnold Pepper, Executive Vice President**

TELEPHONE NUMBER: **516-243-2022**

ITEMS 1 THROUGH 11 ON THIS PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

| | |
|---|---|
| 1 RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and physical form; and c. maximum amount which will be possessed at any one time. See Appendix P. 6 & 7 | 8 PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED See Appendix p. 7 |
| 3 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE N.A. | 9 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS See Appendix p. 6 |
| 4 FACILITIES AND EQUIPMENT See Appendix p. 6 | 10 RADIATION SAFETY PROGRAM See Appendix pp. 5 & 6 |
| 5 WASTE MANAGEMENT See Appendix, p. 6 | 12 LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY: I, app. - New License AMOUNT ENCLOSED: \$ 290.00 |

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, 39, AND 60 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: *Arnold Pepper* TYPED-PRINTED NAME: **Arnold Pepper** TITLE: **Executive Vice President** DATE: _____

IS VOLUNTARY ECONOMIC DATA

| | | |
|-------------------|--|---|
| A ANNUAL RECEIPTS | B NUMBER OF EMPLOYEES (Full- or part-time) excluding outside contractors | C WOULD YOU BE WILLING TO FURNISH COST INFORMATION (labor and/or both hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to provide confidential, commercial or financial—proprietary—information furnished to the agency in confidence) |
| < \$250K | 1-10 | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| \$250K - \$500K | 11-20 | |
| \$500K - \$1M | 21-30 | |
| \$1M - \$5M | 31-40 | |
| > \$5M | > 40 | |

FOR NRC USE ONLY

| | | | | |
|--------------------------------|----------------------------|-------------------------|--|----------------------------------|
| TYPE OF FEE: APP | FEE LOG: Dec 2 1986 | FEE CATEGORY: 3I | COMMENTS: 9002050051 890126 NMSS LIC30 31-23705-01E PDR | APPROVED BY: <i>S. Kimberlin</i> |
| AMOUNT RECEIVED: \$ 290 | CHECK NUMBER: 5966 | | | DATE: 12/31/86 |

020399

REVERSE SIDE STATEMENT ON THE REVERSE

APPENDIX TO APPLICATION FOR SPECIFIC LICENSE FOR
EXEMPT BYPRODUCT MATERIAL

1. Background of Application

A. Type of Application

Satco Products, Inc. (Satco) is formally requesting a specific license to initially transfer for sale or distribution in the United States products containing exempt byproduct material. This application is made pursuant to 42 U.S. (§§ 2111 (1982) and 10 C.F.R. 30.3, 30.15 and 32.11 (1987)). The subject of this license is a compact fluorescent lamp containing an electron tube in the form of a glow starter. The electron tube is within the class of products specifically exempted from certain licensing requirements by operation of 10 C.F.R. §§ 30.15(a)(8) because it contains less than 30 microcuries of promethium-147 (Pm-147) and radiation levels do not exceed 1 millirad per hour at a distance of 1 centimeter when measured through 7 milligrams per square of centimeter absorber. Satco requests that this license encompass the electron tube itself and a self ballasted compact fluorescent lamp containing the tube, as described in Attachments 1, 2, and 2A.

B. Products to be Licensed

1. Electron Tube

The electron tube is designed to function as a glow starter in a compact fluorescent lamp. There are two electrodes in the glow starter, one is radioactive and the other is bi-metal mounted non-radioactive.

The radioactive electrode is comprised of non-radioactive iron and nickel alloy rod plated with Pm-147. That surface is in turn plated with non-radioactive Ni-58. Each radioactive electrode contains a maximum of 0.5 microcuries of Pm-147. Therefore, each electron tube contains a maximum 0.5 microcuries of Pm-147.

The outer envelope of the electron tube consists of soda-lime glass 0.43-0.55 mm thick, which is fused closed at each end. The tube is approximately 31.5 mm max. long and 10 mm max. in diameter.

The radiation from the electrode will not penetrate the glass tube, and the electron tube will not operate if the seal is imperfect or the glass envelope is cracked or otherwise compromised.

2. The Compact Fluorescent Lamp

The glow starter is permanently mounted in a compact fluorescent lamp. See Attachments 2 and 2A. The starter is completely enclosed within the lamp by a hard plastic or metal cover. These serve to protect the tube, and the glass bulb of the fluorescent lamp further protect the glow starter from physical damage and shield the user from radiation.

C. Production and Shipping

The compact fluorescent lamp is built for Satco by Toshiba Corporation (Toshiba). The glow starter is also built by Toshiba. The electrodes used in the starter are manufactured for Toshiba by Nemoto and Co., an unrelated company.

The compact fluorescent lamps are initially distributed in the United States by Satco. The company distributes the tubes only as components of the compact fluorescent lamps. Satco distributes the compact fluorescent lamps to dealers and distributors and to unrelated companies.

II. Section 32.14 --Requirements for Issuance of a Specific License for Distribution of Certain Items Containing Exempt Byproduct Material

A. Section 32.14(a)--General Requirements for Issuance of a Specific License (§§ 30.33)

1. Application for a Purpose Authorized by the Act.

The stated purpose of the Atomic Energy Act of 1954 as amended, (the Act) is to regulate the development of atomic energy so as to encourage its peaceful uses, 1/ including uses that will strengthen free competition in private enterprise, 2/ encourage the development of the atomic energy industry, 3/ and encourage maximum scientific and industrial progress. 4/ In addition, section 2111 of the Act classifies "industrial use" as a useful application. Satco's distribution of the electron tube makes effective industrial use of the byproduct material Pm-147 in a manner that facilitates efficient and effective use of energy, constitutes a peaceful application of atomic energy and strengthens competition and private enterprise, thus encouraging both the further development of the atomic energy industry and maximum scientific and industrial progress within the meaning of the Act.

1/ 42 U.S.C. §§ 2011-2023 (1982)
2/ 42 U.S.C. §§ 2011 (1982)
3/ 42 U.S.C. §§ 2012 (1982)
4/ 42 U.S.C. §§ 2013 (1982)

2. Adequate Equipment and Facilities

The applicant's electron tubes are tested individually by the manufacturer. They will not operate and are rejected unless the glass envelope is intact. The radiation emitted by the amount of Pm-147 on an electrode does not penetrate the intact glass of the starter tube, or of the compact fluorescent lamp as a whole.

The compact fluorescent lamps are packed for shipping in bubble wrap and other appropriate packing designed to protect against breakage. As previously stated, both the outer envelope of the lamp and the plastic or metal glove and cover over the starter bottle increase the protection of the tube.

A periodic random sample of compact fluorescent lamps is subjected to drop tests designed to ensure the tubes will survive the conditions of shipping and handling. No tube has been known to break during such testing.

Warehouses have in-rack sprinkler systems which are in full compliance with insurers' standards. The warehouses also incorporate modern security systems to prevent theft or tampering.

3. Training and Expertise for Handling of Compact Fluorescent Lamps

Satco has been in the lamp business for many years and employees are experienced in the proper handling shipping and storage of lamps requiring special care such as compact fluorescent lamps.

It should be noted that the Nuclear Regulatory Commission (NRC) regulations recognize that electron tubes containing less than 30 microcuries of Pm-147 are items of relatively small concern in terms of health and safety, since they are exempted from certain licensing requirements under 10 C.F.R. §§ 15(a)(8) (1987). Nevertheless all Satco personnel will be informed of the existence of byproduct material in the compact fluorescent lamps and will receive instruction in proper handling of the lamps including cleaning and disposal procedures in case of breakage. All waste disposal will meet or exceed NRC and applicable state regulations.

B. Section 32 14(b)(1) --[Application Item 5]
Radioactive Material

The radioactive material contained in the electron tube is Promethium-147. The promethium-147 is a solid plated on an electrode composed of iron and nickel alloy (non-radioactive).

A layer of non-radioactive Ni-58 is electroplated over the Pm-147. The maximum quantity per electron tube is 0.5 microcuries.

C. Section 32.14(b)(2)--[Application Item 6] Purpose for which Licensed Material Will Be Used

The licensed material will be contained in an electron tube which will function as a glow starter bottle in a compact fluorescent lamp. The compact fluorescent lamps may be imported and distributed by Satco.

D. Section 32.14(b)(2) Details of Construction

A drawing of the Glow starter is attached hereto as Attachment 1.

| | |
|-----------------|---------------------|
| Glass | Sodalime |
| Dimensions | As shown in drawing |
| Glass Thickness | 0.45-0.55 mm |

Sealing is achieved by fusing the ends of the glass of each tube together utilizing heat followed by the annealing process. The tubes are then incorporated in a compact fluorescent lamp, which itself is contained in a glass envelope sealed to a metal base.

Drawings of the compact fluorescent lamps containing the glow starter are attached as Attachments 2 and 2-4.

D. Section 32.14(b)(3) -- Method of Containment or Binding

The Pm-147 is bound to the iron nickel alloy by means of electroplating. For the details of the method of containment by means of the glass bulb, the plastic or metal starter holder, and the outer glass envelope of the compact fluorescent lamp, see Sections B and D above.

The hard plastic starter holder would minimize or prevent loss of the electrode in the extremely unlikely event of breakage of the electron tube or the glow starter.

F. Section 32.14(b)(4) -- Procedures for and Results of Prototype Testing

Toshiba subjects a random sample of the glow starter and the fluorescent lamp containing the glow starter to drop tests in the prototype stage. These tests are designed to replicate the most severe conditions likely to be encountered, i.e., shipping or handling of the product. No break in the glow starter has been experienced as a result of these tests, and consequently there has been no release of the nuclear byproduct material to the environment.

G. Section 32. 14(b)(5)--Quality Control Procedures to be Followed in the Fabrication of Production Lots

A schematic diagram showing all quality control procedures utilized by Toshiba Corporation in the fabrication of the electron tube is contained in Attachment 3.

With respect to the electrode itself, a random sample is undertaken by Nemoto and Co. of 10 in every 10,000 units to determine the amount of Promethium-147 per electrode. Toshiba test-lights every electron tube. Any electron tube not lighting, as in the case of a break, would be rejected.

Toshiba also test lights every compact fluorescent lamp before shipment to the United States. Any faulty compact fluorescent lamp will not be shipped and will be reworked or disposed of in every instance in accordance with applicable federal and/or state law.

F. Section 32.14(b)(6)--Labeling

Each individual compact fluorescent lamp will be labeled or printed as follows:

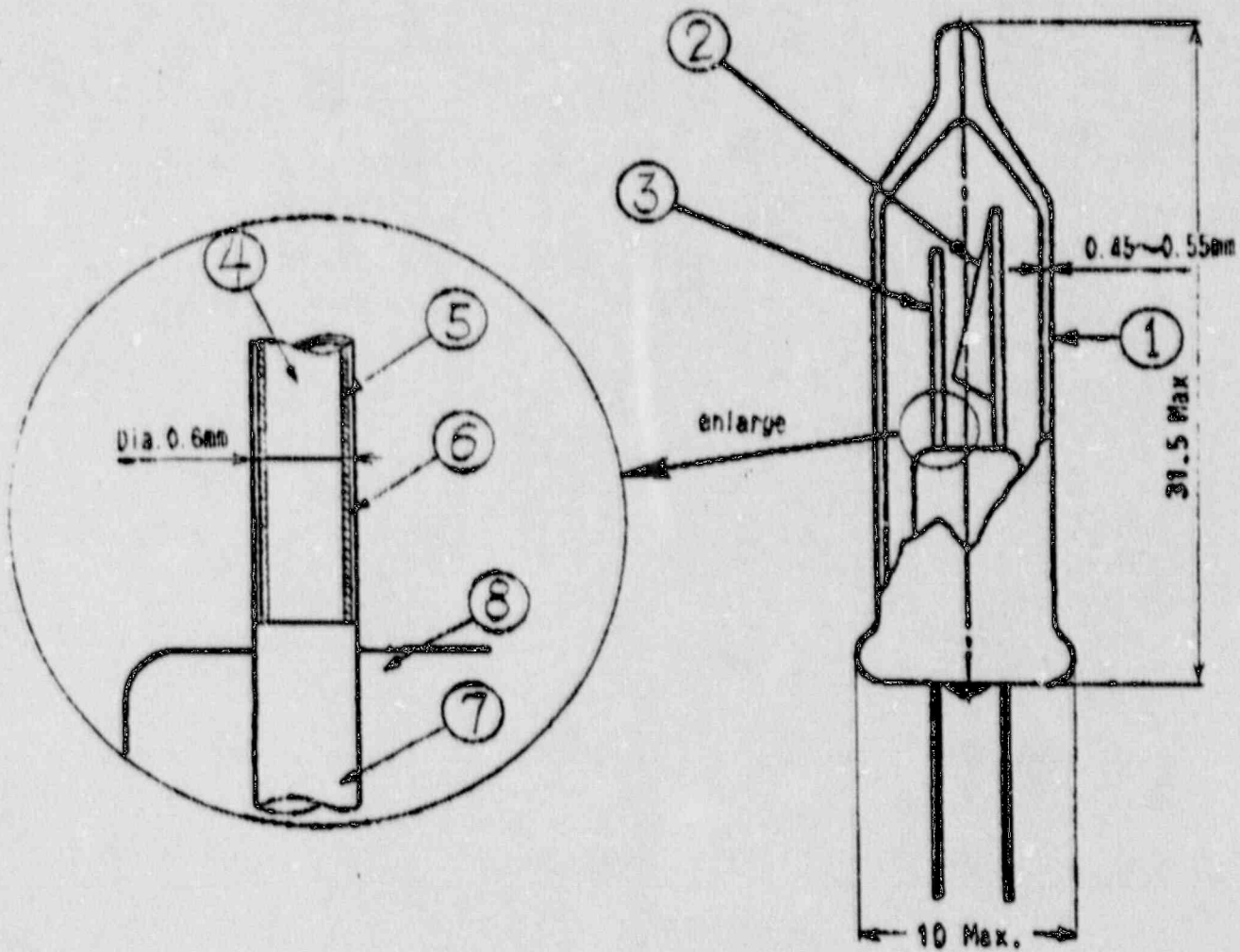
Distributed by
Satco Products, Inc.
Pm-147

I. Section 32.14(b)(7)--Radiation Level and Method of Measurement

The level of radiation from the electron tube both individually and as contained within each compact fluorescent lamp is zero.

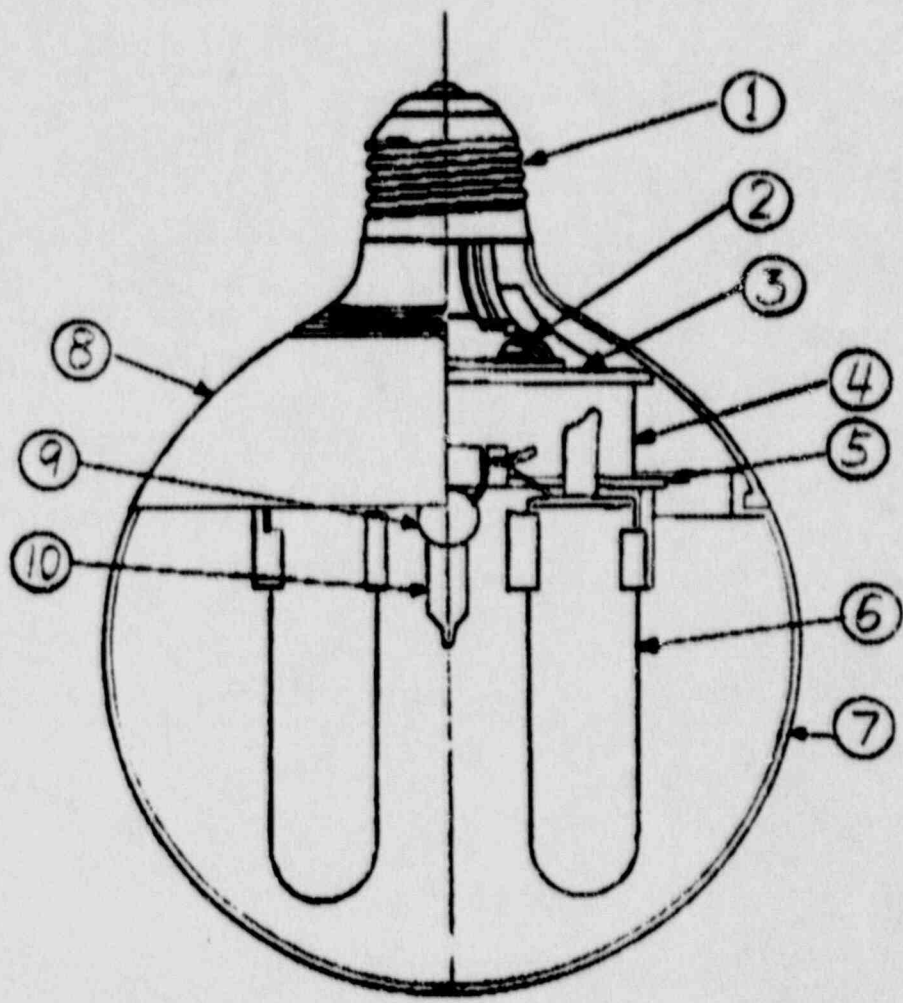
Attachment 1

GLOW STARTER BOTTLE
CONSTRUCTION



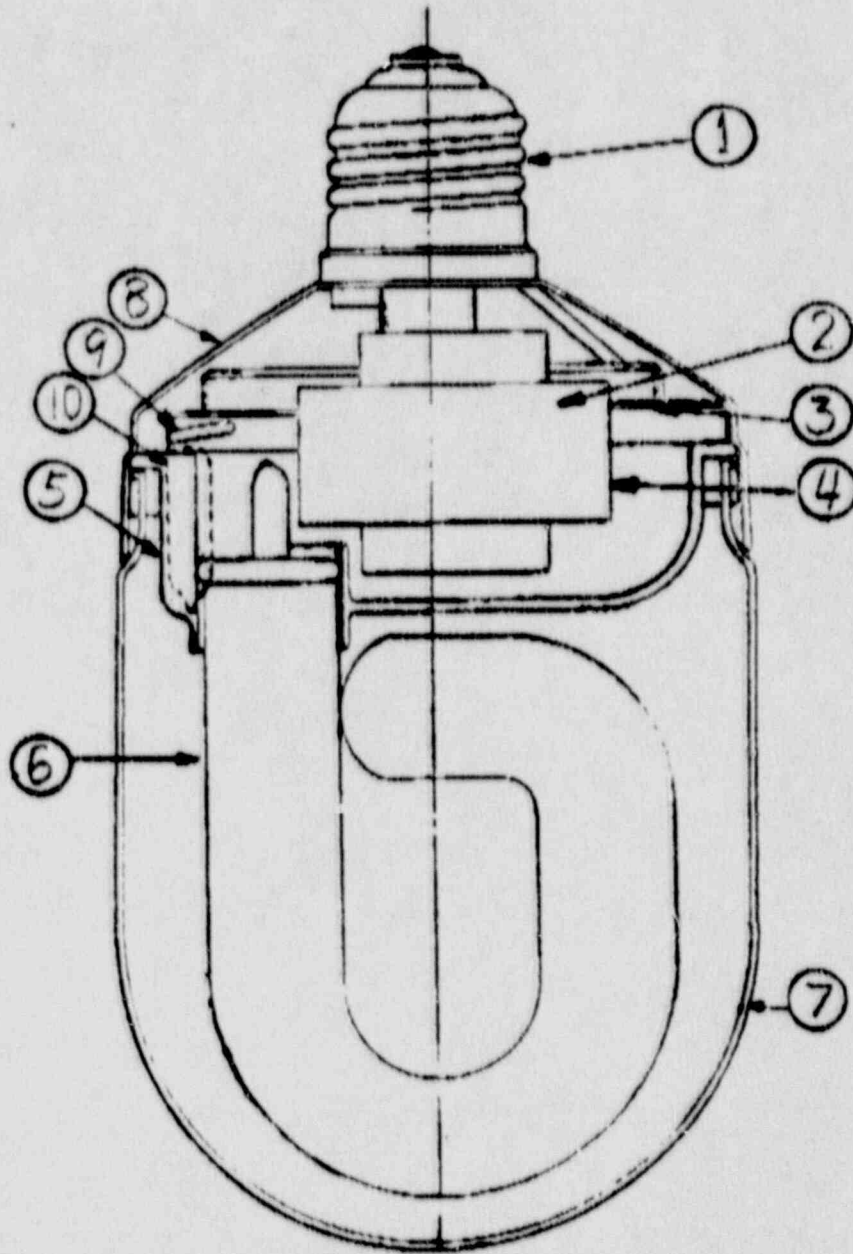
| No. | PART NAME |
|-----|---------------------------------------|
| 1. | Glow starter bottle |
| 2. | Bi-metal electrode (non-radioactive) |
| 3. | Radioactive electrode |
| 4. | Fe-Ni alloy wire (non-radioactive) |
| 5. | Pd17 (Radioactive Electroplating) |
| 6. | NiSS (non-radioactive Electroplating) |
| 7. | Dupal wire (non-radioactive) |
| 8. | Glass stop |

COMPACT FLUORESCENT LAMP
CONSTRUCTION
 (BFG-16)



| NO. | PART NAME |
|-----|---------------------|
| 1 | Screw base |
| 2 | Ballast |
| 3 | Classis |
| 4 | Ballast case |
| 5 | Starter holder |
| 6 | Inner bulb |
| 7 | Globe |
| 8 | Cover |
| 9 | Capacitor |
| 10 | Glow starter bottle |

COMPACT FLUORESCENT LAMP
CONSTRUCTION
(BFT-16)



| NO. | PART NAME |
|-----|---------------------|
| 1 | Screw base |
| 2 | Ballast |
| 3 | Chassis |
| 4 | Ballast case |
| 5 | Starter holder |
| 6 | Inner bulb |
| 7 | Globe |
| 8 | Cover |
| 9 | Capacitor |
| 10 | Glow starter bottle |

Glow Starter (Quality Control Procedure)

| Flow Chart | Manufacturing Process | Control Item | Control Object |
|---------------------|---------------------------|-------------------------------|----------------|
| | Bead Tube | | |
| | Tube Cutting | Length | Quality Check |
| | Welds | | |
| | Bimetal (Electrode) | | |
| | Mounting | | |
| | Mount Check | Electrode Gap Back Tension | Quality Check |
| | Activator | | |
| | Activator dipping | | |
| | Bulb Tube | | |
| | Tube Cutting | Length | M/C Check |
| | Bulb Making | | |
| | Sealing | | |
| | Gas Filling | | |
| | Exhausting | Gas Pressure Exhaust Level | M/C Check |
| | Discharge Check | | |
| | Aging | | |
| | Characteristic Inspection | Lamp Test | JIS |
| Packing | | | |
| Shipment Inspection | | | |
| Shipment | | | |

Attachment 4

TOSHIBA Glow Starter Quality Standard

(for Compact Self-ballasted fluorescent lamp use)

| Item | Specification | Sampling | Testing Measure |
|----------------------------------|--|-------------------------------|------------------------------|
| Starting Time (sec) (at 180V) | Max. 15 | n=20 c=0 per lot per day | Electrical Testing Device |
| Dead Time (sec) (at 108V) | 0.4~2.0 | | |
| Pre-heat Time (sec) (at 120V) | Min. 0.5 | | |
| Breakdown Voltage (V) | Min. 72 Max. 106 | | |
| Noa Re-closure Voltage (V) | Min. 72 (not reclose within 60 sec) | | |
| Life Test | Min 6000 times (25 sec. on-30 sec. off) | n=10 c=0 per lot per month | Life Tester |
| Endurance Test | Min. 5 (continuously on and off) | n=10 c=0 per lot per month | Endurance Tester |
| Appearance Inspection | start on and off normally at 108V | n=315 c=2 per lot per day | Electrical Testing Device |

Attachment 5

Compact Fluorescent Lamp (Quality Control) Procedure

| Flow Chart | Manufacturing Process | Control Item | Control Object |
|----------------------|-----------------------|---------------|----------------|
| | Bulb | | |
| | Phosphor | | |
| | Inner bulb coating | Transmission | Quality check |
| | Baking | Temperature | Quality check |
| | Mount | | |
| | Sealing | Length | Quality check |
| | Bending | Temperature | Quality check |
| | | Dimensions | Quality check |
| | Amalgam | | |
| | Filling gas | | |
| | Inner bulb exhausting | Gas pressure | Quality check |
| | | Exhaust level | Quality check |
| | Inner bulb inspection | Unlighting | Quality check |
| | | Appearance | |
| | Ballast | | |
| | Ballast case | | |
| | Chassis | | |
| | Starter holder | | |
| Glow starter bottle | | | |
| Capacitor | | | |
| Cover | | | |
| Screw base | | | |
| Globe | | | |
| Assembly | | | |
| Aging | Aging schedule | Quality check | |
| Inspection | Unlighting | Quality check | |
| | Appearance | | |
| Packing | | | |
| Out going inspection | Characteristic | JEL | |
| Out going | | | |

Attachment 6

TOSHIBA Compact Self-ballasted Fluorescent Lamp
Quality Standard (Finished Lamp)

| Item | Specification | Sampling | Testing Measure |
|--------------------------------|--|------------------------------|---|
| Starting time (sec) | Max. 7 (at 95% Rated voltage) | n=3. c=0 per lot per day | Electrical and Photometric Testing Device |
| Lamp Current (mA) | 265 ± 20 (BFG120V16) 270 ± 15 (BFI120V16) | | |
| Lamp Voltage (V) | (16) (nominal) | | |
| Luminous Flux (lm) | 570 ± 70 (BFG120V16) 750 ± 70 (BFI120V16) | | |
| Lighting Appearance Inspection | Light normally at 94% Rated voltage | n=30. c=0 per lot per day | Inspection Test Device |
| Torsion Test (N·m) | Withstand at 3.0 N·m torque | n=3. c=0 per month | Torsion Tester |
| Drop Test (Packing Case) | 70 cm height | n=30. c=0 per month | Drop Tester |
| Life (hours) | 6000 (BFG120V16) 9000 (BFI120V16) | n=3. c=0 per month | Life Tester |

November 29, 1988

Satco Products, Inc.
ATTN: Arnold Pepper
Executive Vice President
110 Heartland Boulevard
Brentwood, New York 11717

Docket No. 030-30356
Control No. 108170

Gentlemen:

SUBJECT: APPLICATION FOR MATERIAL LICENSE

This concerns your December 21, 1987 application for a material license; our letter dated March 24, 1988, in which we notified you that the application was deficient and that certain additional information was required; and your letter in response dated April 26, 1988. We also have had several telephone conversations with a representative of Hogan & Hartson concerning your application.

In your response, you note that Satco Products is only a distributor and is not involved in manufacturing or testing the Toshiba products. You also express some concern over a lengthy, complex license application process. Please be assured that we also do not wish this to be a lengthy, complex process; nor for these types of products do we believe it should be.

Nevertheless, NRC implements its responsibility for protecting the public health and safety where these products are concerned by ensuring that the products are manufactured in accordance with appropriate regulatory requirements. Because NRC can only enforce its requirements on its licensees, for foreign manufactured products the initial importer must provide information to show that these requirements are met. With this in mind, we find that we will still need information concerning the following:

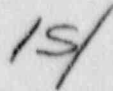
1. As indicated in our March 24 letter, paragraph 32.14(a) specifies that you must satisfy the general requirements in Section 30.33 for a license to possess licensed materials. While the possession license is not critical for issuance of the distribution license, you should note that you can neither import nor possess without that license; therefore, the distribution license provides no real authority until the possession license is issued. As discussed with the Hogan & Hartson representative, in order to reduce confusion concerning license authorizations, it is NRC's policy to not issue a distribution license prior to a possession license. However, we would issue the license based upon receipt of documentation which shows you are authorized to possess at any one of the locations listed in your application.
2. In your response to item 2 of our letter, you maintain that random testing by Nemoto of 10 in 10,000 units to verify radioactivity levels should be acceptable. Your response also provides that 100% of the lamps will be test lighted to ensure operability. While this is an acceptable quality control practice for this particular element, you provide no evidence that such tests will also ensure appropriate radioactivity quantities. As

stated in our earlier letter, paragraph 32.15(a)(2) requires that the sample size and testing be in accordance with the tables and instructions specified in Section 32.110 of 10 CFR Part 32, unless otherwise authorized pursuant to paragraph 32.15(b). If you wish to apply for the 32.15(b) alternative, you must provide information to show that the criteria of this paragraph will be met. We have enclosed additional information concerning quality control testing to help in assessing alternative procedures. You should also note that the license Toshiba holds with NRC is not for compact fluorescent lamps, but instead is for a different product. Clarification of Toshiba's quality control practices will be considered in future licensing actions with the company.

In our telephone conversations with the Hogan & Hartson representative, we suggested that Toshiba U.S.A. be contacted to help you in providing the necessary information. We have previously been contacted by a representative of Toshiba U.S.A. on other applications for these products and the representative implied that supporting information would be provided to the applicants within a short time frame. However, we still have not received the additional information.

You are hereby notified that unless within 30 days from the date of this notice we receive the additional information requested, we will consider your application as having been abandoned by you. This action is without prejudice to the resubmission of an application.

Sincerely,



J. Bruce Carrico
Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: As stated

cc: Hogan & Hartson
ATTN: Joel S. Winnik
555 Thirteenth Street, NW
Washington, DC 20004-1109

DISTRIBUTION:

IMNS Central File

NMSS r/f

IMAB r/f

BCarrico

OFC: IMAB

NAME: BCarrico

DATE: 11/27/88

OFFICIAL RECORD COPY

MAR 24 1988

Satco Products, Inc.
ATTN: Arnold Pepper
Executive Vice President
110 Heartland Boulevard
Brentwood, New York 11717

Gentlemen:

This refers to your undated application attached to letter dated December 21, 1987 from Hogan & Hartson, for a license to distribute, pursuant to Section 32.14 of 10 CFR Part 32, electron tubes in compact fluorescent lamps containing radioactive material to persons exempt from licensing pursuant to Section 30.15 of 10 CFR Part 30. We find that the following additional information is needed in support of your license request:

1. Paragraph 32.14(a) specifies that you must satisfy the general requirements in Section 30.33 for a license to possess licensed materials. In order for Satco to possess and warehouse the devices prior to distribution at the locations identified in your application you will need to obtain a license from the appropriate authorities in each state. What is the status of your license applications in these states?
2. On pages 8 and 9 of the appendix, in items F and G, you discuss procedures for quality control testing of the electron tubes by both Toshiba and Nemoto. In both of these items you indicate that only a random sample will be subjected to certain tests. You should note that paragraph 32.15(a)(2) requires that the sample size and testing must be in accordance with the tables and instructions specified in Section 32.110 of 10 CFR Part 32, unless otherwise authorized pursuant to paragraph 32.15(b). It is not apparent from the information you provided that the quality control testing procedures are in accordance with these requirements. Please clarify and/or describe procedures to show the tests will meet the requirements.
3. The information you provided concerning labeling indicates that the lamp rather than the electron tube will be labeled. The exemption provided in paragraph 30.15(a)(8) is for electron tubes. Paragraph 32.15(d) specifies that each unit (e.g., the electron tube) must be labeled. You should also note that paragraph 32.14(b)(6) provides that the applicant must submit information on its proposed method of labeling both the unit and its container. While we would consider alternative labeling provisions, such alternatives must be justified and shown to be equivalent to labeling the tube itself. You should also provide information to show that the label can be expected to remain durable and legible over the expected useful life of the product and provide a sketch or drawing to show the location of the label on the unit and package.
4. You should also note the reporting requirements specified in Section 32.16 of 10 CFR Part 32 and confirm that you understand and agree to abide by these requirements.

Mr. Arnold Pepper

- 2 -

Our review of your application will continue upon receipt of the above information. Please reply within 30 days, in duplicate, and reference Mail Control No. 020399. If you have questions, please feel free to call me at (301) 492-0634.

Sincerely,

JS
J. Bruce Carrico
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: 10 CFR Part 30
10 CFR Part 32
10 CFR Part 110
10 CFR Part 150
Agreement State List

cc: Hogan & Hartson
ATTN: Joel S. Winnik
555 Thirteenth Street, NW
Washington, DC 20004-1109

DISTRIBUTION:
NRC File Center
IMNS Central File
NMSS r/f
IMAB r/f
MLamastra
VMiller

OFC: IMAB *JS*

NAME: BCarrico/bc

DATE: 03/24/88

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20545

03030354

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

Regional License Section
Material Licensing Branch
FCMS, Office of Nuclear Material
Safety & Safeguards

LICENSE FEE TRANSMITTAL

A. REGION Age

1. APPLICATION ATTACHED

Applicant/Licensee: Satec Products, Inc

Application Dated: 12/21/87

Control No.: 020399

License No.: _____

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed _____

Date _____

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: BI \$ 290

2. Correct Fee Paid. Application may be processed for:

Amendment _____

Renewal _____

License ✓

Signed S. Kimberley

Date 12/31/87

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WRITER'S DIRECT DIAL NUMBER
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January 17, 1989

Mr. J. Bruce Carrico
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS
United States Nuclear Regulatory
Commission
Washington, D.C. 20555

Re: Docket No. 030-30356; Control No. 108170
Satco Products, Inc. Application for Material
License

Dear Mr. Carrico

Satco Product, Inc. ("Satco"), by its attorneys, hereby submits information in response to the November 29, 1988 letter from the Nuclear Regulatory Commission (NRC) requesting additional data on quality control procedures and the submission of a state possession license in order to complete the processing of Satco's material license application.

With respect to the issuance of a state possession license, we have received a response to our December 21, 1988 letter to Paul E. Vause, Jr.; a copy of this letter was sent to your office. The State of Florida considers Satco's license application complete and will issue a possession license to Satco Products, Inc. within the next few weeks. As soon as Satco receives the possession license, a copy will be forwarded to your office.

Quality control information has been provided to Satco by Toshiba America, Inc. (TAI); a copy of the information is included as attachments to this letter. TAI has supplied

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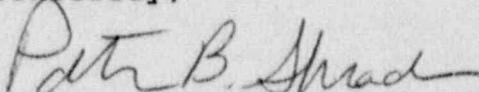
Mr. J. Bruce Carrico
January 17, 1989
Page 2

schematic drawings of the assembly and quality control procedures for the glow starter (attachment 3) and compact fluorescent lamp (attachment 4). The quality standards for the glow starter (attachment 3A) and compact fluorescent lamp (attachment 4A) are also provided.

With respect to the electrode itself, Nemoto and Company randomly samples electrodes from each inspection lot in accordance with the sampling table shown at 10 C.F.R. § 32.110(b)(6) (1988) for Lot Tolerance Percent Defective 5.0 percent, to determine the amount of Promethium-147 per electrode. This test meets the requirements of §§ 32.15(a)(2) and 30.15(a)(8)(vi), which specify that electron tubes may not contain more than 30 microcuries of Pm-147 per tube. Toshiba Corporation then test lights every compact fluorescent lamp individually, in accordance with § 32.110(a) to assure that there is no leakage and thus no unacceptable level of exposure to radioactive material. Prototype tests have shown that radiation levels on the surface of the electron tube are zero as long as the tube is properly sealed and the glass is not cracked. Thus, radiation levels do not exceed 1 millirad per hour at a distance of 1 centimeter when measured through 7 milligrams per square centimeter absorber. A final inspection is performed at a time of packing and shipment to assure that bulbs are sealed and that there is no leakage of radioactive materials.

We believe that these procedures, along with those procedures outlined in the December 21, 1987 application for a material license meet all the applicable regulatory requirements. As previously noted, we will provide a copy of the Florida possession license as soon as we receive it. We appreciate your cooperation in allowing Satco the additional time needed to complete the application process and we look forward to your response.

Sincerely,


Patricia B. Shrader

Enclosures

cc: Arnold Pepper, Satco Products, Inc.
Joel S. Winnik, Esq.

TOSHIBA Glow Starter Quality Standard

(for Compact Self-ballasted Fluorescent Lamp use)

| Item | Specification | Sampling | Testing Measure |
|----------------------------------|---|-------------------------------|------------------------------|
| Starting Time (sec) (at 180V) | Max. 15 | n=20 c=0 per lot per day | Electrical Testing Device |
| Dead Time (sec) (at 108V) | 0.4~2.0 | | |
| Pre-heat Time (sec) (at 120V) | Min. 0.5 | | |
| Breakdown Voltage (V) | Min. 72 Max. 106 | | |
| Non Re-closure Voltage (V) | Min. 72 (not reclose within 60 sec) | | |
| Life Test | Min. 6000 times (25 sec. on-30 sec. off) | n=10 c=0 per lot per month | Life Tester |
| Endurance Test | Min. 5 (continuously on and off) | n=10 c=0 per lot per month | Endurance Tester |
| Appearance Inspection | start on and off normally at 108V | n=315 c=2 per lot per day | Electrical Testing Device |

Compact Fluorescent Lamp (Quality Control Procedure)

| Flow Chart | Manufacturing Process | Control Item | Sampling | Testing Measure |
|----------------------|-----------------------------|--|-------------------------------------|--|
| | Bulb | | | |
| | Phosphor | | | |
| | Inner bulb coating | Transmission | 1 pc.per 2 Hrs | By Testing Device : Transmission Device |
| | Baking | Temperature | at Machine Operation Start | Thermo - Meter |
| | Mount | | | |
| | Sealing | Length | 5 pcs at Machine Operation Start | Scale |
| | Bending | Temperature | at Machine Start | Thermo-Meter |
| | | Dimensions | 1 pc.at Machine Operation Start | Gauge |
| | Amalgam | | | |
| | Filling gass | | | |
| | Inner bulb exhausting | Gass Pressure | 1 pc.at Machine Operation Start | By Testing Device : Pressure Gauge |
| | | Exhaust Level | at Machine Start | Vacuum Gauge |
| | Inner bulb inspection | Lighting | 3 pcs per 4 Hrs | Auto Checker (Lighting Device) |
| | | Appearance | All | Visual Check |
| | Ballast | | | |
| | Ballast case | | | |
| | Chassis | | | |
| | Starter holder | | | |
| | Glow starter bottle | | | |
| | Capacitor | | | |
| Cover | | | | |
| Screw base | | | | |
| Globe | | | | |
| Assembly | | | | |
| Aging | Aging Schedule | All | By Testing Device : Volt Meter | |
| Inspection | Lighting | All | Auto Checker (Lighting Device) | |
| | Appearance | All | Visual | |
| Packing | | | | |
| Out going inspection | (Characteristic) Appearance | AQL2.5% (For Minor Defect) AQL0.1% (For Major Defect) | Per Attachment 4A Visual & Gauge | |
| Out going | Dimensions | N=5, C=0 | Slide Calipers | |
| | Base Fixing Strength | N=5, C=0 | Torque Tester | |
| | Initial Lighting Test | N=5, C=0 | Lighting Box | |

TOSHIBA Compact Self-ballasted Fluorescent Lamp
Quality Standard (Finished Lamp)

| Item | Specification | Sampling | Testing Measure |
|--------------------------------|--|------------------------------|---|
| Starting time (sec) | Max. 7 (at 95% Rated voltage) | n=3. c=0 per lot per day | Electrical and Photometric Testing Device |
| Lamp Current (mA) | 265 ± 20 (BFG120V16) 270 ± 15 (BFT120V16) | | |
| Lamp Wattage (W) | 16 (nominal) | | |
| Luminous Flux (lm) | 670 ± 70 (BFG120V16) 750 ± 70 (BFT120V16) | | |
| Lighting Appearance Inspection | Light normally at 94% Rated voltage | n=80. c=0 per lot per day | Inspection Test Device |
| Torsion Test (N · m) | Withstand at 3.0 N · m torque | n=3. c=0 per month | Torsion Tester |
| Drop Test (Packing Case) | 70 cm height | n=30. c=0 per month | Drop Tester |
| Life (hours) | 6000 (BFG120V16) 9000 (BFT120V16) | n=3. c=0 per month | Life Tester |

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301/493-0030

April 26, 1988

J. Bruce Carrico
Medical, Academic and Commercial
Use Safety Board
Division of Industry and Medical
Nuclear Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Carrico:

This is in response to your letter to Satco Products, Inc. ("Satco") concerning its application for an exempt distribution license pursuant to Section 32.14 of the Nuclear Regulatory Commission ("NRC") regulations.

By way of background, it should be understood that Satco is one of several distributors engaged in the distribution of compact fluorescent lamps which incorporate a glow switch containing .5 microcuries of Promethium-147. These lamps are manufactured in Japan by Toshiba Corporation ("Toshiba"). Satco understands that Toshiba first became aware of the NRC licensing requirements in 1987 and immediately instituted a company wide compliance program. Satco also understands that Toshiba has attempted to notify United States distributors of products manufactured by Toshiba that contain nuclear byproducts or that may contain Toshiba manufactured parts containing nuclear byproducts of the need to comply with NRC and state licensing requirements. Toshiba also has attempted to explain those requirements to such distributors, encouraged the distributors to obtain the appropriate licenses, and made available to the distributors information necessary to file the applications.

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J. Bruce Carrico
April 26, 1988
Page 2

Having learned of the licensing requirements, Satco and the other distributors are now attempting to come into voluntary compliance.

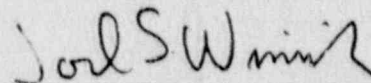
Please note that Satco and the other distributors of the compact fluorescent lamp addressed in the Satco application are relatively small companies without the resources to pursue a lengthy, complex application process. To this end, the distributors are relying on certain manufacturing and testing information supplied by Toshiba for products employing Toshiba manufactured parts, since the distributors perform no manufacturing or testing of their own. The distributors have also relied upon policies and procedures employed by the NRC in connection with the earlier Toshiba applications and applications submitted by such companies as Sharp Electronics, Inc. and an application of Osram, Inc., involving a similar product not manufactured by Toshiba.

Satco recognizes the importance of the NRC regulatory scheme in protecting the public from harmful radiation and pledges its willingness to fully cooperate with the NRC in achieving compliance.

Responses to your questions are contained in the attached amendment to the application. In order to aid in the review of these responses, the specific request or question from the March 24, 1988 letter from the NRC appears just prior to Satco's response.

If you require additional information, please contact the undersigned.

Sincerely,



Joel S. Winnik

Attachment

Responses to March 24, 1988
letter from Nuclear Regulatory Commission
to Satco Products, Inc.

1. Paragraph 32.14(a) specifies that you must satisfy the general requirements in Section 30.33 for a license to possess licensed materials. In order for Satco to possess and warehouse the devices prior to distribution at the locations identified in your application you will need to obtain a license from the appropriate authorities in each state. What is the status of your license applications in these states?

Response: Satco has currently prepared applications for possession licenses for those states in which it has warehouses: New York, Florida, California, and Texas. These applications will be submitted once training of personnel is completed.

Satco is not aware of any requirement to provide information on the status of possession licenses or to obtain state possession licenses prior to the filing of a license application with the NRC. Because Satco recognized that Toshiba's exempt distribution license was granted by the NRC prior to the time that Toshiba received state possession licenses, Satco did not provide any information on the status of state possession licenses.

2. On pages 8 and 9 of the appendix, in items F and G, you discuss procedures for quality control testing of the electron tubes by both Toshiba and Nemoto. In both of these items you indicate that only a random sample will be subjected to certain tests. You should note that paragraph 32.15(a)(2) requires that the sample size and testing must be in accordance with the tables and instructions specified in section 32.110 of 10 C.F.R. Part 32, unless otherwise authorized pursuant to paragraph 32.15(b). It is not apparent from the information you provided that the quality control testing procedures are in accordance with these requirements. Please clarify and/or describe procedures to show the tests will meet the requirements.

Response: Toshiba performs quality control testing designed to evaluate the potential radiation exposure on each lot of compact fluorescent bulbs distributed by Satco as required by § 32.14(b)(5). The quality control program consists of test lighting of 100% of the glow starters and 100% of the compact fluorescent bulbs produced. Test lighting of the glow starters is performed to demonstrate that there is no escape of byproduct material from the products. Neither the glow starters nor the bulbs will light if not properly sealed. Pm-147 will not penetrate the envelope of the

intact glow starter or compact fluorescent bulb. Therefore, the quality control test demonstrates that under normal conditions of use, no exposure to byproduct material will result from the handling of the compact fluorescent bulbs.

Because 100% of the glow starters and 100% of the compact fluorescent bulbs are test lighted, the sample quantity exceeds the requirement of § 32.110. The same quality control testing was employed in the case of the Toshiba application, previously approved by the Commission.

In addition to the strict quality control testing, Toshiba and Nemoto also utilize additional procedures to ensure compliance with Commission rules and the integrity of the product. As stated in Item G of the application, Nemoto determines the amount of Pm-147 per electrode. This testing meets the requirements of § 32.14(b)(7) and (c). The sampling frequency of 10 in every 10,000 electrodes is the same as that specified in the Toshiba application.

As described in Item F of the application, Toshiba performs drop testing in the prototype stage to assure that the byproduct material will not become detached or be released. The drop test utilizes

thirty packing cases of compact fluorescent bulbs per month, dropped from a height of 70 cm. The test was performed not only in the prototype stage, but is routinely performed in the course of production. Toshiba, Inc. performs this test for the byproduct-containing products distributed by Satco Products, as well as for its own licensed products. The number of compact fluorescent bulbs drop tested for Satco meets or exceeds the number of products that Toshiba tests in accordance with its own NRC license. Attachment 3 of the application details the procedures employed by Toshiba to ensure consistent high quality.

The quality control procedure and other test procedures described in the application and supplemental materials meet the intent of the NRC regulations and are adequate to assure that there is no potential radiation exposure resulting from the routine handling and use of the compact fluorescent bulbs. The byproduct material is electroplated onto an electron tube, which is in turn plated with nonradioactive nickel-58. This electrode and a nonradioactive electrode are contained within a soda-lime glass envelope, forming the glow starter. The glow starter itself is permanently mounted in the

compact fluorescent lamp, enclosed by a hard plastic or metal cover. Thus, the radioactive byproduct material is contained in a sealed source and the product is routinely tested to assure that no byproduct material is detectable on the outer surface of the product. Should the lamp itself break, the glow starter would probably remain intact. In the unlikely event of breakage of both the lamp and the glow starter, the radioactive material is designed to remain bound to the electrode and not to be dispersed into the environment. Moreover, the maximum exposure per electron tube, in the unlikely event of breakage of both the lamp and the glow starter, does not pose any health hazard.

3. The information you provided concerning labeling indicates that the lamp rather than the electron tube will be labeled. The exemption provided in paragraph 30.15(a)(8) is for electron tubes. Paragraph 32.15(d) specifies that each unit (e.g., the electron tube) must be labeled. You should also note that paragraph 32.14(b)(6) provides that the applicant must submit information on its proposed method of labeling both the unit and its container. While we would consider alternative labeling provisions, such alternatives must be justified and shown to be equivalent to labeling the tube itself. You should also provide

information to show that the label can be expected to remain durable and legible over the expected useful life of the product and provide a sketch or drawing to show the location of the label on the unit and package.

Response: The glow starter is sealed within an outer envelope and cannot be separately labeled by the distributor. Due to its small size and its location, it would be impossible to label the electron tube with a label that could be read by consumers. Thus, such a label would be of little value in advising consumers of the byproduct material contained therein. For that reason, Satco believes that Toshiba's placement of the label on the lamp is appropriate and justifiable. Toshiba plans to label the Satco product with a sticker on the end of the bulb, just as Toshiba labels its own electron tubes.

Satco originally understood the "container" of the unit that is required to be labeled to be the bulb itself. However, if it is required as a condition of licensing, Satco will arrange with Toshiba to begin placing a label on each lamp, on each individual lamp box and on each carton of lamp boxes. The durability and legibility of the label on the lamp, which is produced by Toshiba, is the same as Toshiba's for the purposes of this license application, since Toshiba

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uses the same materials and processes to label the compact florescent bulbs as it uses for its electron tubes.

4. You should also note the reporting requirements specified in Section 32.16 of 10 C.F.R. Part 32 and confirm that you understand and agree to abide by these requirements.

Response: Satco understands the reporting requirements contained in Section 32.16 and agrees to abide by such requirements.

84885