



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

December 1, 2017

Top Shelf LED, Inc., dba Grower's Choice  
ATTN: Leonardo Day, CEO  
1500 S. Milliken Ave., Unit B  
Ontario, CA 91761

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Day:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated August 31, 2017, requesting an exempt distribution license.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application. These questions are based on our understanding that your products consist of gas electron tubes containing no greater than 0.1 microcuries of Kr-85 per unit. If any of your products contain larger quantities of this, or contain other byproduct materials, we will ask additional questions.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Your application for a distribution license should not contain information concerning the possession and use of radioactive material because that is covered in a separate possession license.

Any correspondence regarding your amendment application should reference Control Number 601516.

L. Day

2

If you have any questions, please contact me at (301) 415-5477, or by e-mail at [Richard.Struckmeyer@nrc.gov](mailto:Richard.Struckmeyer@nrc.gov).

Sincerely,

**/RA/**

Richard K. Struckmeyer  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-39076

Enclosure:  
Request for Additional Information

L. Day

3

TOP SHELF LED, INC., REQUEST FOR ADDITIONAL INFORMATION

Date: December 1, 2017

Certified Mailing No.: 7015 3010 0000 7901 7397

**ML17306A018 (pkg.)**

**ML17333A864 (Letter)**

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Richard Struckmeyer	Deborah Weaver	Richard Struckmeyer
DATE	12/1/2017	11/30/2017	12/1/2017

OFFICIAL RECORD COPY

**TOP SHELF LED, INC., APPLICATION DATED AUGUST 31, 2017  
REQUEST FOR ADDITIONAL INFORMATION**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Top Shelf LED, Inc., application dated August 31, 2017, and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your exempt distribution license application is required by Title 10 of the *Code of Federal Regulations*, Chapter 32 (10 CFR 32), Sections 32.14 and 32.15, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses," available on the NRC public web site (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/>). Please be advised that an application for an exempt distribution license should not contain information concerning the possession of radioactive material because that is covered in your separate possession license. This includes Items 7 through 11 on Form 313. You should provide this information to the State of California in support of an application for a possession license.

Please provide the information required by each of the following regulations. You may need to obtain some of this information from your supplier(s). Note that it is the applicant's responsibility to confirm the validity of all information.

1. 10 CFR 32.14(a) requires the applicant to satisfy the general requirements specified in Section 30.33 of 10 CFR. To do so, please provide a copy of your possession and use license from the State of California. Please note that an exempt distribution license will not be issued until we receive a copy of your possession and use license.
2. 10 CFR 32.14(b)(1) requires the applicant to submit the chemical and physical form and maximum quantity of byproduct material in each product. In response to Item 5 of Form 313, you indicated that the maximum activity per item is 5 microcuries, while further down in your application you stated:

Maximum activity per arc tube:	1. Less than 0.1 microcuries
	2. Less than 0.1 microcuries

Please explain why these quantities differ, and clearly state the maximum activities of each item you plan to distribute.

3. 10 CFR 32.14(b)(2) requires the applicant to submit details of construction and design of each product. Applicants should provide a list of all models of each type of product they wish to distribute. Applicants should provide detailed engineering drawings of each basic device containing the overall dimensions, the minimum and maximum dimensions for each device, the tolerances, description or identification of the construction materials, and the source mounting configuration(s) to be used with each device. Your application appears to indicate two types of arc tubes, quartz and ceramic polycrystalline alumina. The requested information must be provided for each type of material used (such as steel, aluminum, or plastic) in each type of tube. If you plan to distribute various models of devices within groups or series (where there are similarities in the design and construction of the devices within each series), you should specify the above information for each series type.

Enclosure

4. 10 CFR 32.14(b)(3) requires the applicant to submit the method of containment or binding of the byproduct material in the product. Please describe the method by which Kr-85 gas is introduced and the glass tube is sealed.
5. 10 CFR 32.14(b)(6) requires the applicant to submit the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product. Note: 10 CFR 32.15(d)(1) requires labeling or marking of each unit and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Please provide examples of your labels in the form of drawings, copies, or photographs.
6. 10 CFR 32.14(b)(7) requires the applicant to submit the radiation level and the method of measurement for products for which limits on levels of radiation are specified in Section 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in Section 30.15 of this chapter. Section 30.15(a)(8) specifies that the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. Although you provided radiation levels, you did not state how these levels were determined. Please indicate how you made this determination; i.e., your method of measurement or calculation.
7. 10 CFR 32.14(d) requires the applicant to provide information to show that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling. This requirement could be satisfied in by conducting your own testing or by acquiring information from the manufacturer or a third party. Whether you conduct your own testing, or rely on a description from the manufacturer or a third party of methods for testing samples of the product(s) and the results of these tests to satisfy this regulatory requirement, please provide this information in your response.
8. 10 CFR 32.15(b)(1) states that no person licensed under Section 32.14 shall transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria.

Please describe how you will prevent the transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any part or product tested and found defective under the criteria and procedures specified in the license issued under Section 32.14.

The following paragraph does not require a specific response; however, you should confirm that you understand the requirement contained in the cited regulation:

9. 10 CFR 32.16(a) requires each person licensed under Section 32.14 to maintain and report records of all transfers of byproduct material.