Enclosure

Information Needed for Jelight Company
Exempt-Distribution License

A. Regulatory Requirements

Your application does not sufficiently address the requirements in Title 10, Code of Federal Regulations, Part 32, Section 32.14 (10 CFR 32.14), "Certain items containing byproduct material; requirements for license to apply or initially transfer," and 10 CFR 32.15, "Same: Quality assurance, prohibition of transfer, and labeling." Please respond to each requirement below.

1. Details of construction and design of each product are required by 10 CFR 32.14(b)(2). We note that you provided drawings of products, but no description of the details of construction and design. Please provide details of construction and design of each product, as required by 10 CFR 32.14(b)(2).

2. Please provide the method of containment or binding of the radioactive byproduct material in the product, as required by 10 CFR 32.14(b)(3).

3. As stated in 10 CFR 32.14(b)(6), each unit and its container must be labeled or marked so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. This requirement is repeated in 10 CFR 32.15(d)(1).

   For those products requiring labeling, NRC's policy is that the smallest item distributed must display the required label. If this is not possible, then the label should be placed as close as possible to the product. For example, if an electron tube is too small to label, then the label should be placed on the next smallest container, such as the bubble pack containing the electron tube.

   - Additional clarification is needed regarding your proposed method of labeling. Your application stated: "Each electron tube will be laser scribed, 'JCI Kr85'. The electron tube containers will be marked, 'Jelight Company, Inc. Kr85'." In order to determine whether your proposed method of labeling or marking each unit is adequate, you should specify whether the size of each model of electron tube permits a more complete description of the manufacturer or initial transferor. The drawings you provided appear to indicate a length of 10 inches for at least some tubes (although it is not clear whether the dimensions are inches, centimeters, or millimeters; please clarify this).

4. The radiation level and the method of measurement are required by 10 CFR 32.14(b)(7) for products for which limits on levels of radiation are specified in 10 CFR 30.15.

   You provided data (the results of calculations) in the section of your application titled "Item#6 Details" that appear to meet this requirement; however, some pertinent information is missing and/or unclear. Although each set of data appears to be correlated to a particular drawing, you have not provided any indication as to whether each of these combinations of drawings and data tables represents a particular model (or series) of electron tube.

- It is not clear whether you plan to distribute four models, as would appear to be indicated by these combinations of drawings and data tables, or whether these combinations are representative of additional, unspecified models and/or series. Please provide additional information to clarify these issues.

- We also note that the data tables are undated and have no indication of the person who performed and checked the calculations, as would typically be expected within the context of an applicant's quality assurance / quality control program. Please provide data tables that have been verified as part of your quality assurance / quality control program.

5. Please describe how 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, as required by 10 CFR 32.14(d).

6. As stated in 10 CFR 32.15(a)(1), each person licensed under 10 CFR 32.14 shall maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product. Please describe your quality assurance practices in the manufacture of the part or product, or the installation of the part into the product.

7. As stated in 10 CFR 32.15(a)(3), each person licensed under 10 CFR 32.14 shall visually inspect each unit in inspection lots. Any unit that has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit. Please describe how you shall visually inspect each unit in inspection lots for defects.

8. As stated in 10 CFR 32.15(c), no person licensed under §32.14 shall transfer to other persons for use under 10 CFR 30.15 or equivalent regulations of an Agreement State any defective part or product. Please describe how you shall prevent transfer to other persons for use under 10 CFR 30.15 or equivalent regulations of an Agreement State any defective part or product.

B. Additional information

In the section of your application titled "Item#6 Details" you provided a table that lists four drawings, namely 40-0118 rev. C, 40-0119 rev. D, 40-0120 rev. B, and 45-0016 rev. C. It does not appear that these drawings are correlated to any specific models of the products you plan to distribute. Applicants should list all models of each type of product they wish to distribute. Applicants may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the devices. Please provide additional information to specify what models and/or series of product you plan to distribute, and how these are related to the drawings provided in your application.