



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

April 19, 2018

BWGS, LLC
ATTN: Tony Bayt
1410 Hancel Parkway
Mooresville, IN 46158

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Bayt:

This letter is in response to your application, U.S. Nuclear Regulatory Commission (NRC) Form 313, dated February 22, 2018, requesting an exempt distribution license, and to your April 11, 2018, reply to our Request for Additional Information dated March 15, 2018.

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.

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 602602.

T. Bayt

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

Sincerely,

/RA/

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

Docket No. 030-39098

Enclosure:
Second Request for Additional Information

T. Bayt

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BWGS, LLC, SECOND REQUEST FOR ADDITIONAL INFORMATION

Date: April 19, 2018

Certified Mailing No.: 7015 3010 0000 7901 7489

ML18073A015 (pkg.)

ML18108A031 (Letter)

OFC	NMSS/MSST/MSLB	NMSS/MSST/MSLB	NMSS/MSST/MSLB
NAME	Richard Struckmeyer	Deborah Weaver	Richard Struckmeyer
DATE	04/19/2018	04/19/2018	04/19/2018

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BWGS, LLC APPLICATION SECOND REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the BWGS LLC, Inc., application dated February 22, 2018, and your response dated April 11, 2018, to our Request for Additional Information (RAI), and has determined that additional information is needed. In order to continue with our review, please address the issues listed below.

In your response letter dated April 11, 2018, you referred to two attachments, "Kr85 license related files-CMH" and "Kr85 license related files-MH." Some of your responses did not fully address the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 32.14. The requirements for which additional clarification is requested are enumerated below.

Please provide additional clarification for the following items, which are numbered to correspond to the items in our RAI of March 15, 2018.

1. 10 CFR 32.14(a), Possession License – No additional information is needed at this time. We will await the issuance of your possession license.
2. 10 CFR 32.14(b)(2), Construction and Design – You provided diagrams of various lamp models in the attachments to your letter; however, you should also provide a brief written description of the details of construction and design of each type of lamp. This description should include, but is not necessarily limited to, the materials used, the sequence of construction in general terms, how the bulb material, outer bulb material, and arc tube material are joined in the construction process, as well as how any of the other specifications you provided in the attachments are relevant to the manufacturing process.

10 CFR 32.14(b)(3), Method of Containment – You provided flow charts in the attachments that illustrate the sequence of construction of the lamps; however, you should also provide a brief written description of the point in these flow charts at which the Kr-85 gas is introduced, how it is transferred from the storage container, and how the glass tube is sealed following introduction. The emphasis here is not to repeat the information provided in response to 10 CFR 32.14(b)(2), but to specifically state what is done in the manufacturing process to introduce the Kr-85 gas into a tube, and how the tube is then sealed.

3. 10 CFR 32.14(b)(6) & CFR 32.15(d)(1), Method of Labeling – As stated in our RAI, these regulations require 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. Labeling may be achieved by imprinting the information on the product during the manufacturing process.

In the attachments, it does not appear that you provided examples of labels to appear on the lamps. If the lamps are too small to label, or for imprinting, you should so indicate in your written response, including a justification as to why labeling cannot be affixed or imprinted on them. As noted in our letter of March 15, 2018, the guidance in NUREG-1556, Volume 8, Section 9.3, states: "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

Enclosure

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.”

Also, the examples of labels you provided in the attachments did not appear to state the identification of the manufacturer or initial transferor of the product. Please indicate where the identification of the manufacturer or initial transferor of the product can be found. If this information is not stated on the product and container, provide examples of new labels that state this required information (unless the product is confirmed to be too small to be labeled; however, the container must state the required information).

4. 10 CFR 32.14(b)(7), Radiation Levels and Method of Measurement – this regulation 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. Your response to this question did not appear to provide the required information. Note that you must be able to demonstrate 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.
5. 10 CFR 32.14(d), Byproduct Material Containment – No additional information is needed.
6. 10 CFR 32.15(b)(1), Transfer of Defective Products or Parts – No additional information is needed.