



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 4, 2018

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

Dear Mr. Bayt:

We have reviewed your application dated March 14, 2018 for a new license. We used NUREG-1556, Volume 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution" as a guide to review your application. NUREG-1556, Volume 12 can be found on the NRC's website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/>. Before we can take further actions, we will need the following information.

- 1) Describe lamps containing radioactive material that you plan to possess (name of the manufacturer, the model of the lamp, the maximum activity of Kr-85 in each model, and the total activity of Kr-85 per model).
- 2) Title 10 of the Code of Federal Regulations (10 CFR) 20.1101(a) requires that each NRC licensee must develop, document, and implement a radiation safety program. The NRC requires its licensee to designate a person called Radiation Safety Officer (RSO) to be responsible for implementing the radiation safety program. Please name a RSO, provide a copy of the delegation of authority for the RSO (see attached sample), and provide information that the proposed RSO have completed the training as discussed in Section 8.7.1, "Radiation Safety Officer", in NUREG-1556, Vol. 12.
- 3) Please provide name of individual(s) who will use the licensed material or supervise the use of licensed material (this individual may be the RSO) and provide information demonstrating that he/she meets the training criteria discussed in Section 8.7.2, "Authorized Users" in NUREG-1556, Vol.12.
- 4) Based on 10 CFR 19.12, "Instruction to workers", the applicant must provide radiation safety training for individuals who in the course of employment are likely to receive in a year an occupational dose in exceed of 100 mR. Please provide justification that dose to your workers is likely not to exceed 100 mR a year or provide a description of the radiation safety training program that the applicant will provide to persons working in the areas where licensed material stored, including topics cover, who will provide the training and his/her qualification related to the radiation safety, the training assessment method, and the method (online, classroom, etc.) and frequency of the training (you could use information in NUREG-1556, Vol. 12, Appendix H, "Radiation Training Topics", to develop a training program).
- 5) 10 CFR 30.33(a)(2) requires the application's facility and equipment be adequate to protect health and minimize danger to life or property. Furthermore, 10 CFR 20.1801

- requires the licensee to secure from unauthorized removal or access licensed material that are stored in controlled or unrestricted areas. Additionally, 10 CFR 20.1802 requires the licensee to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Please provide a description of the access control for the licensed material storage areas; the access control must meet the requirements above. In addition, based on NUREG-1556, Vol. 12, Section 8.9, "Facilities and Equipment", please provide a facility diagram with a specified scale or dimensions and indicate the storage areas and their adjacent areas on the diagram.
- 6) 10 CFR 20.1101(c) requires the licensee to conduct a periodic review their radiation safety program content and implementation at least annually. Please provide the audit program and the frequency of the audit. You could use the topics listed in NUREG-1556, Vol 12, Section 8.10.1, "Audit Program" to prepare your response.
 - 7) 10 CFR 20.1906(b)(3) requires the licensee to monitor all packages known to contain radioactive material for radioactive contamination and radiation level if there is evidence of the degradation of package integrity, such as packages that are crushed, wet, or damaged. In addition, please note that damaged devices are considered radioactive waste and cannot be sent back to the manufacturer/vendor in other countries in accordance with 10 CFR 110.23(a)(1). Please provide quality control/quality assurance information that lamps contained Kr-85 and their packages were free of radioactive material contamination and each lamp will only contains an exempt quantity of Kr-85 before being shipped to your facility.
 - 8) Based on 10 CFR 20.1906(b)(1), the licensee is not required to monitor the external surface contamination for package or sealed sources containing only radioactive material in form of gas. However, 10 CFR 20.1906(b)(3) requires the licensee to monitor all packages known to contain radioactive material for radioactive contamination and radiation level if there is evidence of the degradation of package integrity, such as packages that are crushed, wet, or damaged. Please provide a description of the radiation monitor instrumentation and commitment as discussed in NUREG-1556, Vol. 12, Section 8.10.2, "Radiation Monitoring".
 - 9) Based on 10 CFR 20.1801, 20.1802, 20.1906(b)(3), and 20.1101(d), the applicant must develop, implement and maintain written procedures for receipt and accountability of licensed material. In accordance with NUREG-1556, Vol 12, Section 8.10.3, "Material Receipt and Accountability", please provide a statement that "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."
 - 10) 10 CFR 20.1201, "Occupational dose limits for adults" requires the licensee to control the occupational dose to their workers. Based on NUREG-1556, Vol 12, Section 8.10.4, "Occupational Dose", please provide a statement that "We have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program – Occupational Dose' in NUREG-1556, Vol. 12, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.'"
 - 11) Based on NUREG-1556, Vol. 12, Section 8.10.6, "Operating and Emergency

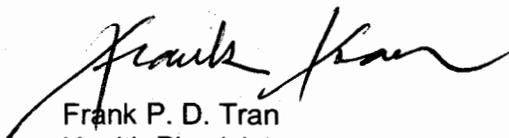
Procedures", please provide a statement that "We will develop, implement and maintain operating and emergency procedures for safe use of licensed material." The procedures should include steps to take when receiving a damage package contained licensed material or when a large quantity of lamps contained licensed material were broken and released Kr-85 gas in an enclosed areas (to prevent unnecessary inhalation of radioactive gas).

- 12) Radioactive waste can only be disposed in accordance with 10 CFR Subpart K, "Waste Disposal". Please address the disposal of defected lamps containing licensed material (such as transfer back to manufacturer/vendor or to an authorized license) and broken lamps (must be ensure that they are at background radiation level before disposal as ordinary waste).

To continue the review of your application, we request that you submit a written response to this letter by June 4, 2018. Your response must be dated and signed by a licensee's representative and please reference Mail Control Number 602699 in the response. To expedite the licensing process, you could fax your response to 630-515-1078. If you have any questions or require clarification on any of the information stated above, please do not hesitate to contact me at 630-829-9887 or frank.tran@nrc.gov.

In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390 of the U.S. Nuclear Regulatory Commission's (NRC) "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Frank P. D. Tran
Health Physicist
Materials Licensing Branch

Docket No. 030-39102
Mail Control No. 602699