**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 20, 2020

Jamie Liphard
EHS&S Leader
Nutrition & BioSciences USA 1, LLC
3400 S. Saginaw Rd., Unit 57
Midland, MI 48460

Dear Mr. Liphard:

This letter is in reference to your request dated August 28, 2020, requesting issuance of a new U.S. Nuclear Regulatory Commission (NRC) Materials License.

The NRC's guidance document for your proposed type of license, which I will be referring to below as "the guidance", is NUREG-1556, Volume 4, Rev. 1, dated July 2016, "Consolidated Guidance About Materials Licenses, Program – Specific Guidance About Fixed Gauge Licenses." This guidance is available on the NRC Web site at: https://www.nrc.gov/docs/ML1618/ML16188A048.pdf

Upon review of your request, I identified the following areas requiring additional or clarifying information:

1. The guidance states that applicants must provide information regarding the radioactive material requested. This should include the following:

   - radionuclide;
   - activity for each requested sealed source;
   - manufacturer or distributors name;
   - model number of each gauging device; and
   - number of gauging devices for each model requested.

   Your request identifies that you are seeking authorization for three cesium-137 Ohmart-VEGA Model SHLD-1-45 sealed sources. I was unable to locate this sealed source model in the National Sealed Source & Device Registry database. Your request also did not identify required information for the fixed gauging device requested.

   Please respond by providing the correct sealed source model number. In addition, please provide the following information with your response:

   - manufacturer or distributor's name;
   - device model number; and
   - number of fixed gauging devices that you are requesting.

   Please refer to Title 10 Code of Federal Regulations (10 CFR) §30.32(g)(1) and Section 8.5.1, "Sealed Sources and Device," of the guidance for additional information.

2. The guidance states that the appointed Radiation Safety Officer (RSO) must have adequate training and experience. This is necessary so that the RSO understands the hazards and is familiar with the regulations concerning the licensed radioactive material.

   Your application identified your enrollment in a Radiation Safety Officer Training course.

In your e-mail message dated October 2, 2020, you supplied a copy of your certificate of completion for this course. The certificate of completion identifies that the course was provided virtually. It is not possible to provide supervised hands-on training in a virtual or online format.

Completion of additional training and experience that includes supervised hands-on instruction is needed. It is understandable that some flexibility may be needed to allow you to complete this training during the COVID-19 Public Health Emergency. One such flexibility that might be considered is the provision of this training with the assistance of a visiting manufacturer's representative (i.e., Service Engineer) or a member of your staff who is qualified as an Authorized User of fixed gauging devices. Please submit documentation of the completion of supplemental training and experience addressing supervised hands-on instruction.

Please refer to 10 CFR §30.33(a)(3) and Section 8.7.1, "Radiation Safety Officer," of the guidance for additional information.

3. The guidance specifies that license applicants shall commit to developing and implementing procedures regarding the performance of routine maintenance and provide a commitment or procedures regarding nonroutine maintenance of fixed gauging devices.

   Nonroutine maintenance or repair (beyond routine cleaning, lubrication and calibration) refers to any maintenance or repair that involves or could affect components related to radiological safety and other activities in which personnel could receive radiation doses in excess of the U.S. NRC's regulatory dose limits.

   Nonroutine operations include activities involving:

   - components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control or shielding);
   - installation, relocation, or alignment of the gauge;
   - initial radiation surveys;
   - replacement and disposal of sealed sources;
   - removal of a gauge from service;
   - a potential for any portion of the body to come into contact with the primary radiation beam; and
   - any other activity during which personnel could receive radiation doses exceeding the U.S. NRC's regulatory dose limits.

   Your application includes conflicting statements regarding the performance of nonroutine operations. Item 7.2, "Authorized Users," of your application identifies the training and experience requirements of individuals who will be tasked with performing nonroutine maintenance. Whereas, Item 10.8, "Maintenance," states that nonroutine operations will only be performed by the gauge manufacturer, distributor, or other person licensed by the U.S. NRC or an Agreement State.

Resubmit your application with corrections made to remove the conflicting statements regarding your intent to perform nonroutine operations “in-house.” If applicable, provide the additional information related to the performance of nonroutine operations.

Please refer to Section 8.10.8, “Maintenance,” and Appendix J, “Information Needed to Support Applicant’s Request to Perform Nonroutine Operations,” of the guidance for additional information.

4. The guidance states that the license applicant shall provide a commitment or procedures regarding leak testing.

   Item 10.7 of your application included a commitment regarding the performance of leak testing. Though, your application also included a list of exceptions to leak testing. This included an exception in which you stated, “Sealed sources will not be leak tested if they are not designed to emit alpha particles.” This would allow for beta and gamma emitting radionuclides to be excepted from leak testing. This is not acceptable and must be revised.

   Resubmit your application with corrections made to remove the exception for leak testing sealed sources that are not designed to emit alpha particles. Please refer to Section 8.10.7, “Leak Tests,” of the guidance for additional information.

5. The requested license, upon approval and issuance, will be conditioned in accordance with 10 CFR §30.34(e), “Terms and Conditions of Licenses.” A license condition will be included in the license requiring the testing of the shutter mechanism and indicators, if any, at intervals not to exceed 6 months or at such longer intervals as specified in the certificate of registration issued by the U.S. NRC pursuant to 10 CFR §32.210 or the equivalent regulations of an Agreement State.

   Item 10.7 of your application states that shutter checks will be performed at least annually. This may not be acceptable if the associated certificate of registration specifies a more restrictive interval. One example that may be relevant is Ohio Sealed Source & Device Registry Sheet #OH-522-D-120-B (12-6-2018). This is the certificate of registration for the VEGA Americas Corporation Model SHLD1.xxx (previously Ohmart/VEGA Corporation Model SHLD-1). The Limitations and/or Other Considerations of Use section of this registry sheet identifies that shutter checks must be performed at least every six months.

   To ensure compliance with the regulations and the terms and conditions of the license, your statement should be revised to commit to performing the shutter checks at intervals not to exceed 6 months or at such longer intervals as specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR §32.210 or the equivalent regulations of an Agreement State.

To continue the review of your amendment request, please provide a written response to this letter by November 10, 2020. Your response must be dated and signed by a licensee’s representative and please reference Mail Control Number 622919 in the response. To expedite the licensing process, you may fax your response to (630) 515-1078. If you have any questions or require clarification on any of the information stated above, you may contact me at (630) 829-9737 or Jason.Kelly@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 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,

Digitally signed by Jason M. Kelly
Date: 2020.10.20 18:22:32 -05'00'
Adobe Acrobat version: 2020.012.20043

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

License No. 21-35600-01
Docket No. 030-39235
Control No. 622919