Ohio Lumex
Applications Dated April 12, 2019 and March 20, 2019
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Ohio Lumex applications dated April 12, 2019 and March 20, 2019 and 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 Sealed Source and Device amendment application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt-distribution license application is required by 10 CFR 32.14, 32.15, 32.16, 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, "Program-Specific Guidance About Exempt Distribution Licenses."

A. Questions related to the sealed source and device application

Description/Construction

1. Please provide detailed design and construction information for the GC-IMS devices. The information should be sufficient to allow us to fully understand the construction and operation of the device. In your response, please make sure you include the following:

   - Provide fabrication and assembly methods (e.g., welds, bolts, screws), including size and spacing, this should include the Ion Mobility Cell (IMC).

   - Materials of construction for the IMC and gas chromatograph and a discussion of whether there is a potential for corrosion between unlike materials.

   - Discuss how the sources are mounted in the IMC.

   In your application, you stated that the IMC ion generator sources manufactured by RC TRITEC AG source should be registered as part of the device. For a source to be registered as part of a device, you must submit enough information for NRC Staff to perform a complete evaluation of the sealed source. This would include the sealed source model designation, a complete description of the sealed source include assembly methods, engineering drawings, prototype testing results, etc. Please submit the source information.

Labeling

2. Please provide the materials of construction, method of attachment, dimensions, and location for the external label.

Prototype Testing/Historical Use

3. We noted that the GC-IMS gas chromatograph was drop tested while in its original packaging. Please explain why it was not drop tested without the packaging material as the device may be dropped while being moved within a laboratory environment.

4. Please describe the packaging material used in the drop test.

Radiation Profiles

5. We noted that Ohio Lumex has requested a maximum activity of 330 MBq (8.91 mCi), which includes loading tolerance. The external radiation levels provided did not identify the activity level of the GC-IMS devices that was measured. Please provide the activity level of the tritium source that was measured, if the maximum activity requested was not used in the measurement please submit external radiation levels with the maximum activity. Please note that as referenced in NUREG-1556, Volume 3, Revision 2, Section 10.6, "Radiation Profiles" the NRC may accept measured or calculated radiation levels.

Quality Assurance (QA)

6. Please provide the details of Ohio Lumex's QA program, please note that at a minimum the QA program needs to ensure that: (1) the materials of construction and the final assembly meet the design specifications; (2) the final product is leak tested; (3) a final radiation profile is performed; (4) a test is performed that verifies that the product operates as intended, including all safety functions; and (5) a visual inspection is performed of components that are considered related to safety or are expected to be susceptible to failure under extreme or unusual conditions.

7. In accordance with the guidance in NUREG-1556, Volume 3, Revision 2, Section10.7 "Quality Assurance and Quality Control," please confirm that Ohio Lumex will evaluate G.A.S. Gesellschft fur analytische Sensorsysteme mbH's QA program in Germany. Also confirm that Ohio Lumex will perform periodic audits of the facility in Germany. The audits may be conducted by a third party, but the records must be available for review in the U.S.

8. Please confirm that Ohio Lumex will maintain records in the U.S. as required by the provisions set forth by 10 CFR 110.53(b), for future regulatory review.

Accompanying Documentation

9. As described on Page 13 of 46 of Ohio Lumex's application, please provide a copy of the GC-IMS operating manual, that includes a description of the radioactive material in the gas chromatograph.

B. Questions related to the exempt-distribution license application

1. Your application provides the chemical and physical form of the byproduct material in the product but does not detail changes in chemical and physical form that may occur during the useful life of the device (approximately 8 years). As required by 10 CFR 32.30(b)(3), please provide the changes in chemical and physical form that may occur during the useful life of the device.

2. Per 10 CFR 32.30(b)(4), please provide the solubility in water and body fluids of the forms of the byproduct material (in this case, tritium). More information on this requirement can be found in NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials."

3. On page 12 of your SSD application, it is stated that a Fluke 451B ion chamber was used to determine external radiation measurements required by 10 CFR 32.30(b)(6). Upon review of the 451B Operators Manual, the instrument can only measure beta radiation above 100

keV. Tritium decays via beta particle emission releasing 18 keV of energy, therefore, this instrument is not able to determine the external radiation levels from the device. Please describe how you will meet this requirement.

4. Per 10 CFR 32.30(b)(7), your application should discuss the degree of access of human beings to the device during normal handling and use. Please provide a discussion of how access is restricted to the device.

5. Please provide the total quantity of byproduct material expected to be distributed in the devices annually as required by 10 CFR 32.30(b)(8).

6. On page 14 of the SSD application, the annual committed dose is shown as 100 mrem, however, the basis for the estimate is not provided as required by 10 CFR 32.30(b)(13). Please detail the basis for your estimation. See NUREG-1717, page 4-30, Section 4.3.4 and NUREG-1556, Volume 8, “Consolidated Guidance About Materials Licenses – Program Specific Guidance About Exempt Distribution Licenses” Appendix E for more information.

7. Per 10 CFR 32.30(b)(14), please provide a determination that the probabilities with respect to the doses referred to in 10 CFR 32.13(a)(4) meet the criteria that paragraph.

8. Per 10 CFR 32.30(c)(2), requires that the device is unlikely to be routinely used by members of the general public in a non-occupational environment. Please provide a statement that members of the general public will not routinely use the device and what types of institutions will use the device.