

May 15, 2014

Mr. Colin D'Silva, President
Chemicals and Applied Markets (CAM)
Bruker Daltonics, Inc.
3500 West Warren Avenue
Fremont, CA 94538

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. D'Silva:

This letter refers to your letter, dated February 18, 2014, Agencywide Documents Access and Management System (ADAMS) Accession No. ML14070A455, which responds to our request for additional information dated December 18, 2013 (Accession No. ML13345A265). In order to continue our review, we need clarification and additional information. In the enclosure to this letter, we have summarized the issues that need to be addressed.

We will continue our review upon receipt of this information. If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application. Any correspondence regarding your application should reference the Mail Control number specified below.

In accordance with 10 CFR 2.390 of NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC's Public Document Room or from the Publicly Available Records component of NRC's ADAMS. ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions regarding the Sealed Source and Device Registration you can contact Maria Arribas-Colon at (301) 415-6026 or by email at Maria.Arribas-Colon@nrc.gov. For questions related to the exempt distribution license, please contact me at (301) 415-7640 or email at Shirley.Xu@nrc.gov.

Sincerely,

/ra/

Shirley S. Xu
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No. 030-38672
Mail Control: 583151

Enclosure:
Request for Additional Information

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Shirley S. Xu
Licensing Branch
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Docket No. 030-38672

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Enclosure:
Request for Additional Information

ADAMS Accession No.: ML14120A305

OFFICE	FSME/LB	FSME/LB	FSME/LB	FSME/LB	FSME/LB
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DATE	04/30/2014	05/07/2014	05/07/2014	05/15/2014	05/15/2014

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Bruker Daltonics, Inc.
Chemical and Applied Markets (CAM)
030-38672

A. Additional Information Request Regarding Registration Certificate Application

1. [NRC Question 1.3 dated December 18, 2013]: "Please clarify the following statement: "The upper part of the detector kit either protrudes through a hole in the top of the cabinet or is visible immediately beneath the hole." Does this mean that there will be two variations of source assembly mounting, or two variations of the source assembly itself, or two variations of the entire instrument. Please provide drawings to show the two configurations, and clarify how the variations will be identifiable and distinguished from each other."

In your response dated January 16, 2014, you stated that: "Please see the installation manual for an explanation of the configuration of the ECD." This response is not sufficient because the installation manual refers to one configuration only. Please explain the statement made in your application dated July 29, 2013, and stated in NRC Question 1.3 dated December 18, 2013, or reference the applicable pages in the installation manual.

2. [NRC Question 1.4 dated December 18, 2013]: "Address the issue of potential corrosion of the components due to the compositions of gases to which the instrument will be exposed."

In your response dated January 16, 2014, you stated that: "Enclosed as Attachment D are comments from Chris Kellogg, one of the original design engineers of the product, regarding potential corrosion." The letter dated December 14, 2010 signed by Mr. Kellogg, indicated that the source in the ECD will not emit radiation capable of penetrating the housing and will not degrade the housing. This does not respond to our question because your answer addresses radiation issues instead of addressing the interaction of different materials regarding potential corrosion. Please address the issue of potential corrosion of the components due to the compositions of gases to which the instrument will be exposed. Specifically, list the components and the materials of these components in the vicinity of the Ni-63 foil to demonstrate that potential corrosion would not release the radioactive material.

3. [NRC Question 1.6 dated December 18, 2013]: "Provide drawings and clarification of the tamper proofing measures of the device. The application refers to Attachment I; however, the drawings do not identify the components which serve as tamper proof measures."

In your response dated January 16, 2014, regarding tamper proofing, refers to Attachment F. However, Attachment F shows disassembly of the ECD using common hand tools such as a hex wrench and a Phillips screwdriver which do not constitute tamper proofing. Please show tamperproof measures which prevent access to the Ni-63 foil.

Enclosure

4. [NRC Question 1.14 dated December 18, 2013]: "Please provide all the Gas Chromatograph Systems in which the Model 02-001972-02 will be used. Please provide this information in a similar format to the table listed in CA-662-D-101-B under the description section."

In your response dated January 16, 2014, you referred to Attachment I. Attachment I contained columns titled "Source Part #", "Foil Replacement Kit Part #", "Detector Cell Assembly Part" and "Detector Kit Part #." Please provide information on each of the different "Parts #" in relation to the ECD.

5. [NRC Question 4.1 dated December 18, 2013]: "The application referred to Attachment K as prototype tests conducted for the ECD, however, Attachment K contains only the test results for the Ni-63 Cell, drawing VZ-3212-001. Please explain how these test results are relevant to the Model 02-001972-02."

In your response dated January 16, 2014, you stated that: "For clarification, prototype testing was performed on the Ni-63 cell and not on the complete ECD. The NRC has historically accepted either mode of testing as a method of demonstrating compliance with the requirements. These tests were performed on the cell which will be used in model 02-001972-02." Please confirm that the prototype tests of temperature, pressure, and shock performed on the Ni-63 cell represent the conditions of normal use and likely accident conditions for the ECD.

B. Additional Information Request Regarding Exempt Distribution License Application

1. We will notify the State of California when we are ready to issue your NRC distribution license. Please submit a copy after you have received your California license as required under 10 CFR 30.33.
2. You have questioned that why Electron Capture Detector (ECD) can only be distributed within a Gas Chromatography (GC) system, the answer is that 10 CFR 30.22 (new regulation), along with other revisions of 10 CFR 30 and 32, was issued on July 25, 2013 (77 FR 43689). NRC NUREG-1556, Vol. 3, Revision 1 was published in April 2004. Previous guidance does not apply to the new regulation and the regulation itself governs.

Additionally, the exemption in 10 CFR 30.22 covers industrial devices containing byproduct material designed and manufactured for *the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere.* An ECD does not fulfill one of the stated purposes by itself; it is a component in a device that does. Thus, a gas chromatograph can be approved for use under this exemption and an ECD cannot.

Therefore, the model 02-001972-02 can only be distributed with gas chromatography systems. This will not prevent the licensee from replacing or repairing the ECD itself. Please provide the model number(s) of the gas chromatography systems that contain this ECD for distribution under 10 CFR 32.30.

3. You stated in your response to our question B. 4, that under normal handling and use, the user does not have access to the ECD; they are only interacting with the GC. Although you may intend on installing or servicing an exempt product, we cannot be sure that an exempt person will not do so. Please describe the degree of access of human beings to the device during normal handling and use.
4. In your letter, dated February 18, 2014, you referenced Attachment H to answer our question B. 5. The attachment H is 400-GS Series User Manual, not prototype testing for the device. You need to provide the procedures for prototype testing of the device (not the source) to demonstrate the effectiveness of the containment, shielding, and other safety features, under both normal and severe conditions of handling, storage, use, and disposal of the device.
5. Your response to our question B. 6 in your letter, dated February 18, 2014, stated that "Under the prototype testing conditions there was no release of radioactivity to the environment, and no change in external radiation levels." Your response does not satisfy 10 CFR 32.30 (b)(11) and (12). You need to provide the procedures for prototype testing (see question #4 above) and results of the prototype testing based on the procedure.
6. Question B. 7 in our letter dated, December 18, 2013, we requested you to provide quality control procedure. You referenced to Attachment K to respond to the question. The Attachment K is Production Manual that does not meet the requirement of 10 CFR 32.30. You need to provide quality control procedures to be followed in the fabrication of production lots of devices and the quality control standards the devices will be required to meet.
7. You stated in your response to our question B. 8 that our question does not reflect the required criteria specified in NUREG- 1717, Systematic Radiological Assessment of Exemptions for Source and Byproduct Material, June 2001. Please be advised that NUREG-1717, Section 4.3 Electron Capture Detectors for Gas Chromatographs applies to devices for potential use under exemption. However the criteria for the exemption in 10 CFR 30.22 were written subsequent to NUREG-1717. It is the regulation, not the NUREG, that requires the analysis of various scenarios. Bruker Daltonics applied for a license fo this device under 10 CFR 32.30. Therefore, you need to follow the regulation for gas chromatography under 10 CFR 32.30.