

December 18, 2013

Bruker Chemicals and Applied Markets  
ATTN: Mr. Colin D'Silva, President  
3500 West Warren Avenue  
Fremont, CA 94538

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. D'Silva:

This letter is in response to your application dated July 29, 2013, for a U.S. Nuclear Regulatory Commission (NRC) Exempt-Distribution Materials License and a Sealed Source and Device Registration Certificate for an exempt device. Your application lacks the required information to complete our safety review and evaluation. In the enclosure to this letter, we have summarized the issues that need to be addressed.

In your application you mentioned that you request the "registration of the Electron Capture Detector unit itself and not the associated Gas Chromatographs, which is consistent with the NRC's statements contained in NUREG-1556, Vol.3, and Revision 1." Please note, NUREG-1556 is guidance not regulation. Your application will be evaluated based on the applicable regulations. NUREG-1556, Volume 3, is currently under revision and the language you pointed out is being revised.

Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 of 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. Any correspondence regarding your application should reference the 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 Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

C. D'Silva

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

Sincerely,

**/RA/**

Maria Arribas-Colon, Project Manager  
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 No. 581468

Enclosure:  
As stated

C. D'Silva

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

Sincerely,

**/RA/**

Maria Arribas-Colon, Project Manager  
Licensing Branch  
Division of Materials Safety and  
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Docket No. 030-38672  
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Enclosure:  
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**DISTRIBUTION:** ARB/DC/CFO SSD 13-29

**ML13345A260**

<b>OFFICE</b>	LB/MSSA	LB/MSSA	ASPB/MSSA	LB/MSSA	LB/MSSA
<b>NAME</b>	MArribas-Colon	JJankovich	SPoy	SXu	MKotzalas
<b>DATE</b>	12/16/13	12/17/13	12/17/13	12/16/13	12/18/13

**OFFICIAL RECORD COPY**

Bruker Chemical and Applied Markets Application dated July 29, 2013  
Information Needed for Registration and Exempt-Distribution License  
of Electron Capture Detector (ECD) Model 02-001972-02

A. Items Regarding Registration Certificate Application Request

1. Description/Construction:

- 1.1 Please submit a full set of engineering drawings and a detailed description of the construction of the device. The design and data should be sufficient to allow the reviewer to fully understand the construction, operations of the product and its components and safety features and to allow the evaluation of the product's safety, security and integrity.

The drawings in Attachment I are not sufficient for conducting a safety evaluation. Specifically, the components are not identified and listed. You should include, as a minimum, complete annotated engineering design and/or construction drawings showing assembly of components, exterior construction of the final product for the Model 02-001972-02, location and mounting of the sources.

- 1.2 The application referred to a series of products to be manufactured. Please summarize all the differences between the various models; you may use a table to indicate the differences between Models 02-001972-00, 02-001972-01 and 02-001972-02.
- 1.3 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.
- 1.4 Address the issue of potential corrosion of the components due to the compositions of gases to which the instrument will be exposed.
- 1.5 Provide the drawings of the Model 02-001972-02, with dimensions, suitable for inclusion in the Registration Certificate. If possible, please provide electronic copies also.
- 1.6 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.
- 1.7 Attachment D provided the product flyer for the various instruments. The flyers showed a number of "injectors." Please clarify if the injectors refer to various configurations of the source assembly, i.e., the Model 02-001972-02.

- 1.8 Please provide a detailed and thorough discussion regarding how the Model 02-001972-02 electron capture detector operates within a typical gas chromatograph. Please indicate whether the device operates differently from Models 02-001972-00 and 02-001972-01.
- 1.9 Information provided in this application is inconsistent regarding vendor designation (e.g. Bruker's Netherland address vs. Bruker's California address) with information in Registration Certificate MA-1101-D-103-B. Provide justification for the apparent inconsistency.
- 1.10 The application stated that Model 02-001972-02 will be used with the Gas Chromatograph Systems SCION GC 436 GC and SCION GC 456 GC. Please discuss how the Model 02-001972-02 is mounted and operates within these systems (if possible provide diagrams and photos).
- 1.12 Please provide information regarding how users can replace the Model 02-001972-02 in a Gas Chromatograph System, or is this function for a licensed entity.
- 1.13 Please clarify your statement that the Electron Capture Detector (ECDs) are used with the SCION 436 GC or the SCION 45GC Gas Chromatograph Systems and that all other models listed on the original Varian device registration (CA-662-D-101-B) have been discontinued. Please note that SCION 436 GC and SCION 45GC Gas Chromatograph Systems are not listed in Registration Certificate CA-662-D-101-B.
- 1.14 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.

## 2. Conditions of Use:

- 2.1 Please provide statements indicating that the conditions of use of the Model 02-001972-02 with regard to maximum allowable temperature, vibration, shock, corrosion, during use, handling, storage and transport.
- 2.2 Please elaborate on the operation of the automatic shutoff unit discussed in the conditions of use section.

## 3. Radiation Profiles:

- 3.1 The application did not contain a discussion of the radiation protection measures or radiation profiles for either the source assembly or entire instrument. Please provide the relevant information in relation to background radiation.

4. Prototype Testing:

- 4.1 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.
- 4.2 The application stated: "The radioactive source is Eckert and Ziegler Model NER-004, registration no. CA-0406-S-214-S and has received an ANSI N542-1977 classification rating of 77C3211." Please confirm whether the correct classification is ISO/99/C42211.

5. Operation Manual/User Manual:

- 5.1 The application referred to Attachment P as containing the User Manual; however, the attachment was blank. Please provide the manual.
- 5.2 The application indicates that Bruker will provide servicing; please clarify whether servicing applies to any components containing radioactive material.

6. General:

- 6.1 Please provide information on whether Bruker plans to inactivate Registration Certificate MA-1101-D-103-B or keep it active.

B. Additional Information Request Regarding Exempt Distribution License Application

1. 10 CFR 30.33 requires that you apply for, and obtain, a specific license authorizing possession and use of radioactive materials from the States or NRC regional offices, wherever licensed materials are possessed. Please submit a copy of your current California license that reflects all of your radioactive material use authorization information.
2. 10 CFR 32.22 defined the purpose of industrial devices, in that, these devices are used for detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere. You indicated in your application that the product to be distributed is an Electron Capture Detector (ECD), Model 02-001972-02. Please be advised that the model 02-001972-02 ECD can only be distributed for use 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 chromatograph that contain this ECD for distribution under 10 CFR 32.30.
3. Provide details of the construction and design of the device, as related to containment and shielding of the byproduct material and other safety features, under normal and severe conditions of handling, storage, use, and disposal of the device.
4. Describe the degree of access of human beings to the device during normal handling and use.

5. 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.
6. Submit results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.
7. Provide the quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet.
8. In accordance with 10 CFR 32.31, please demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter, and those resulting in dispersal and subsequent intake of  $10^{-4}$  of the quantity of byproduct material, a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).