UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 29, 2015

Bruker Detection Corporation
ATTN: Mr. George A. Gleason
Radiation Safety Officer
40 Manning Road
Billerica, MA 01821

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION, BRUKER DETECTION CORPORATION; AMENDMENT REQUEST DATED JANUARY 2, 2015

Dear Mr. Gleason:

This letter is in response to your letter dated April 27, 2015, which provided additional information in response to the NRC's letter dated March 2, 2015, concerning your application dated January 2, 2015, which requested the addition of the TIMON and OrthoTIMON devices to your exempt distribution license 20-32465-02E and registration certificate NR-1101-D-102-E. In reviewing your request, we find that additional information is required to complete our review. In the enclosure to this letter, we have summarized the issues not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the NRC may be withheld from public disclosure. To do this, you must follow the procedures in 10 CFR 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390 (b)(1).

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 amendment request. Any correspondence regarding your application should reference the Mail Control number specified below.

In accordance with 10 CFR 2.390(a), a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Any questions regarding the sealed source and device registration should be directed to Celimar Valentin-Rodriguez at (301) 415-7124 or by email at Celimar.Valentin-Rodriguez@nrc.gov. If you have any questions related to the exempt distribution license, please contact me at (301) 415-5608 or by email at Eric.Reber@nrc.gov.

Sincerely,

/RA/

Eric H. Reber, General Engineer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-37315
Mail Control No. 585750
License No. 20-32465-02E
Registration Certificate No. NR-1101-D-102-E

Enclosure: As Stated

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Sincerely,

/RA/

Eric H. Reber, General Engineer
Materials Safety Licensing Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-37315
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License No. 20-32465-02E
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Enclosure: As Stated

Certified Mail Tracking Number: 7014 0510 0000 4426 4769

ML15133A197 (2nd RAI)

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Eric Reber	Shirley Xu	Celimar Valentin-Rodriguez	Maria Arribas-Colon
DATE	05/18/2015	05/28/2015	05/28/2015	05/28/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	
NAME	Tomas Herrera	Hipolito Gonzalez	Eric Reber	
DATE	05/28/2015	05/28/2015	05/28/2015	

OFFICIAL RECORD COPY

Bruker Detection Corporation Amendment Request dated January 2, 2015
Request for Additional Information

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Bruker Detection Corporation amendment request dated January 2, 2015, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

REQUEST FOR ADDITIONAL INFORMATION REGARDING SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE

1. Please provide the weight for the TIMON and OrthoTIMON devices.

2. Please provide an engineering drawing that shows the cross sectional view of the "measuring tube" shown in Drawing Number "OR 0100 G 003" in Attachment E of your amendment request. The drawing can be similar to the drawing of the IMS detection cell included in Attachment 4 of your current Registration Certificate NR-1101-D-102-E and should include dimensions and tolerances.

3. In your response to question 2 of NRC's RAI, dated April 27, 2015, the table provided includes the NBCD source model. Please clarify if the TIMON and OrthoTIMON devices will also use the NBC source model used by the other devices in the RAID series. If the TIMON and OrthoTIMON devices will use the NBC source model, please provide an updated table.

4. In your response to question 2, you also indicated that the ANSI/ISO Classification for source models NER-004 and NER-004P is 77C32211. However, E&Z Isotope Product Laboratories Registration Certificate CA-0406-S-214-S indicates that the ANSI/ISO classification is 99C42211. Please confirm that the ANSI/ISO classification for source Models NER-004 and NER-004P is 99C42211.

5. In your response to question 13, in row 3 column 3 of the table provided, you included an asterisk next to the Operating Temperature for the OrthoTIMON. Please clarify the meaning of this asterisk.

6. In your response to question 16, you stated that the tests performed to the TIMON and OrthoTIMON devices and also provided the tests reports. These tests do not demonstrate that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Please confirm that there is no change in the IMS cell, which has been previously approved for the other models within the RAID Series, and therefore, that the prototype testing is applicable to both TIMON and OrthoTIMON device models.

7. In questions 4 and 21, you stated that the correct dimensions of the TIMON and OrthoTIMON devices will be updated in the next version of the Operator Manual. You also committed to including the updated labels in the instrument operator manual for each device. Please provide copies of the updated Technical Data Annex for the TIMON and OrthoTIMON Operator Manuals, as well as with copies of the inserts for each Operator Manual which will include the updated labels for both devices.

REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

8. The regulation in 10 CFR 32.29(b)(3) requires that the external surface of the point-of-sale package has a legible, readily visible label or marking containing the items in 10 CFR 32.29(b)(3)(i), (ii), and (iii). The regulation in 10 CFR 32.29(b)(3)(i) requires that the label or marking contain the name of the radionuclide and quantity of activity.

   Item 25 of your letter provided a copy of the label that you stated will be attached to the point-of-sale package of the TIMON and OrthoTIMON devices. Contrary to the above, the copy of the label that you provided does not contain the name of the radionuclide and quantity of the activity.

   Please provide labels, copies of labels, or markings that meet the requirements in 10 CFR 32.29(b)(3) for point-of-sale packages. You should specifically ensure that the labels, copies of labels, or markings that you submit contain the name of the radionuclide and quantity of the activity in accordance with 10 CFR 32.29(b)(3)(i).