



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

March 2, 2015

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

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

Dear Mr. Gleason:

This letter is in response to your application dated January 2, 2015, requesting 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 listed the items that should be addressed in your response to this letter.

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).

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).

G. Gleason

-2-

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](mailto: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](mailto:Eric.Reber@nrc.gov).

Sincerely,

**/RA/**

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

Enclosure: As stated

G. Gleason

-2-

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](mailto: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](mailto:Eric.Reber@nrc.gov).

Sincerely,

**/RA/**

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

Enclosure: As stated

SSD Case: 15-13

**Certified Mail Tracking Number: 7014 0510 0000 4426 4530**

**ML15054A144 (RAI) See previous concurrence**

<b>OFC</b>	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
<b>NAME</b>	Eric Reber*	Shirley Xu*	Celimar Valentin-Rodriguez*	Maria Arribas-Colon* w/comments
<b>DATE</b>	02/23/2015	02/23/2015	02/24/2015	02/24/2015
<b>OFC</b>	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	
<b>NAME</b>	Tomas Herrera* w/comments	Hipolito Gonzalez	Eric Reber	
<b>DATE</b>	02/24/2015	03/02/2015	03/02/2015	

**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

General

1. On Page 3 of your amendment request, Section 1. *Summary Information (10.1)*, you stated that the device manufacturer is Bruker Daltonik GmbH. However, the manufacturer listed in your Registration Certificate NR-1101-D-102-E is Bruker Saxonia Analytic GmbH. Please provide us with accurate manufacturer information.

Description of Product/Construction

2. On Page 4 of your amendment request, Section 1.5 *Registration of Sources as Part of a Device*, you indicated that the sources listed in NR-1101-D-102-E would be used in the TIMON and OrthoTIMON device models. Please note that some of this information is inaccurate and be aware that Registration Certificate NR-136-S-185-S has been superseded by Registration Certificate MA-1059-S-185-S, issued by the Commonwealth of Massachusetts. Please provide an accurate list of sources with their corresponding source model, capsule designation (if applicable), source manufacturer, isotope, maximum activity, ANSI/ISO classification, and registration certificate number.
3. On Page 5 of your amendment request, Section 2. *Conditions of Use (10.2)*, you stated that TIMON and OrthoTIMON device models can detect and identify ultralow levels of toxic chemical weapon agents and critical toxic industrial chemicals, *including chlorine*. On page 6 of your request, Section 3. *Construction of the Product (10.3)*, subheading *Materials of Construction*, you stated that localized corrosion may occur if the models are exposed to halides, particularly chlorine or chlorine compounds. Please describe what effects halides and/or chloride compounds may have on the IMS detector cell and the Ni-63 source.
4. The engineering drawings titled "Basic Device TIMON" and "Basic Device OrthoTIMON" provided in Attachment E, include the dimensions of both models. However, in some instances, these dimensions do not match those provided in the TIMON and OrthoTIMON Operator Manuals in Attachments I and J of your amendment request. Some of the dimensions include accessories such as wheels, air inlets, power, and Ethernet connections, while others do not. Please provide the dimensions for both models that should be referenced in your Registration Certificate.
5. In your amendment request, you stated that the "measuring tube and source configurations" for the TIMON and OrthoTIMON device models are the same as the "measuring tube and source configurations" in the Bruker RAID Series of devices listed in your current

Enclosure

Registration Certificate. However, we noted that there are differences in dimensions between the IMS detection cell/"measuring tube" that are intended to be used in the TIMON and OrthoTIMON device models, and the IMS detection cell/"measuring tube" currently used

6. in the RAID Series. Please provide a description of the similarities and differences between the appropriate RAID Series of devices and TIMON and OrthoTIMON models, as well as similarities and differences between the TIMON/OrthoTIMON IMS detection cell/"measuring tube" and the RAID Series IMS detection cell/"measuring tube". A table format is preferred.
7. In Attachment E, you provided engineering drawings for the TIMON device model; however, you did not provide detailed engineering drawings for OrthoTIMON device model. Please provide engineering drawings with dimensions and tolerances for OrthoTIMON device model that includes the IMS detection cell/"measuring tube" and the FT-IR sensor unit.
8. 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. 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.
9. On page 6 of your amendment request, you stated that "The TIMON and OrthoTIMON devices are manufactured with Bruker machined screws in the measuring tube assembly which require a Bruker tool to dismantle." Please provide details on the tamper-proofing measures. Please note that your current Registration Certificate states that the source assembly in the RAID Series of devices contains four tamper-resistant screws; please confirm if this is also the case for the TIMON and OrthoTIMON device models. If the tamper-proofing measures are different for the TIMON and OrthoTIMON device models, please provide a description.

#### Labeling

10. On Page 7, you provided copies of the labels that will be located on the right side cabinet. Please note that the label shown in "Figure 1- Source Information Label, Cabinet Surface," contains your former distributor name "Bruker Daltonics NBC Detection Corporation." Please provide a copy of the label with the current distributor name and address.
11. On Page 8, you provided a copy of the label that will be located on the "measuring tube." Please provide the dimensions of this label.

#### Conditions of Use

12. Please provide the estimated working life of the TIMON and OrthoTIMON device models.

13. Please provide the likely environment to which the devices will be subjected to during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation. In your response please include maximum allowable temperature, vibration, shock, corrosion, etc.
14. Please describe the actions to be taken at the end of the working life of the TIMON and OrthoTIMON device models.
15. On Page 5 of your amendment request, Section 2. *Conditions of Use (10.2)*, you stated that both the TIMON and OrthoTIMON device models are permanently installed air monitoring systems. However, in the OrthoTIMON product brochure in Attachment D, you stated that OrthoTIMON device model can be mounted on a “transportable frame” to permit it to be taken to assembly rooms and other areas. Please clarify this discrepancy. If the OrthoTIMON device model is to be registered as a movable device, please (1) describe how the device is to be mounted to “the transportable frame” and (2) provide the maximum conditions of use for the OrthoTIMON device model in the case that it is mounted on a “transportable frame.”

#### Prototype Testing/Historical Use

16. On Page 9 of your amendment request, Section 5. Prototype Testing (10.5), you stated that the same “measuring tube and source configurations” have been provided in Bruker’s RAID Series devices currently listed in your Registration Certificate. However, you have not provided sufficient information about the prototype testing for the TIMON and OrthoTIMON device models, as required by 10 CFR 32.26 (b)(11) and (12) and by 10 CFR 32.210 (c). You may provide justification as to why prototype testing for the TIMON and OrthoTIMON device models is not necessary; this may include a comparison to the registered models in the RAID series. The guidance in NUREG-1556, Volume 3, Revision 1, Section 10.5, “Prototype Testing,” provides the various methods of prototype testing that are acceptable to the NRC. Alternatively, you may provide a copy of the device testing referenced in Attachment B for both the TIMON and OrthoTIMON device models.
17. The test certificates in Attachment B of your amendment request indicated that the ISO 2919 classification for the TIMON and OrthoTIMON device models is C22222. Please clarify whether this classification is for the IMS detection cell/“measuring tube”, the sensor unit, or the entire device.

#### Radiation Profiles

18. In Attachment G of your amendment request, you stated that the calibration due dates for the Ludlum Model 3 survey meter and the Ludlum Model 9DP1 survey meter are 6/30/2014 and 2/21/2014. These calibration due dates differ from those provided in the certificates of calibrations for both survey meters. Please clarify the due date discrepancy for both survey meters.

19. The radiation profiles provided in Attachment G of your amendment request identify the Model surveyed as TIMON. Please clarify if both TIMON and OrthoTIMON device models were surveyed. If only the TIMON device model was surveyed, please explain why only this model was surveyed, and how the radiation profiles are applicable to the OrthoTIMON device model. If the OrthoTIMON device model was surveyed, please provide the radiation profiles.

#### Quality Assurance

20. Please confirm that there have been no changes to the Quality Assurance program that Bruker Detection Corporation committed to in Registration Certificate NR-1101-D-102-E.

#### Accompanying Documentation

21. Figure 2-3 in Section 2.5.1 of the TIMON Operator Manual and Figure 2-5 in Section 2.6.1 of the OrthoTIMON Operator Manual identify the location of the labels that will be included on both devices. However, neither operator manual references the label required by 10 CFR 32.29, which Bruker committed to including on each device on Page 7 of 11 in the amendment request. Please provide revised Operator Manuals for both devices that include all of the labels required for distribution in the U.S.

#### REQUEST FOR ADDITIONAL INFORMATION REGARDING EXEMPT DISTRIBUTION LICENSE

22. In Item 1.5, Registration of Sources as Part of a Device, of your application you wrote that, in addition to other sources, Isotope Products Laboratories Model NER-004 or Model NER-004P sources would be used in the devices. Sealed Source and Device Registration Certificate No. NR-1101-D-102-E and License No. 20-32465-02E list the manufacturer of these source models as "Eckert & Ziegler Isotope Products, Inc."

Please confirm the name of the manufacturer of the Model NER-004 and NER-004P sealed sources.

23. 10 CFR 32.26 (b)(8) requires that applications include the total quantity of byproduct material expected to be distributed in the product annually.

Your application did not address the requirement of 10 CFR 32.26 (b)(8).

Please provide the total quantity of byproduct material expected to be distributed in the product annually.

24. 10 CFR 32.29(b)(1)(i) requires that each person licensed under 10 CFR 32.26 shall label or mark each detector so that each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing the following statement: "CONTAINS RADIOACTIVE MATERIAL."

Contrary to the above, the device labels submitted in section 4.1 of your application do not meet the requirement of 10 CFR 32.29(b)(1)(i).

Please provide labels, copies of labels, or markings that meet the requirement in 10 CFR 32.29(b)(1)(i).

25. 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).

Your application did not address the requirements in 10 CFR 32.29 (b)(3) concerning point-of-sale labeling and marking.

Please provide labels, copies of labels, or markings that meet the requirements in 10 CFR 32.29 (b)(3) for point-of-sale packages.

26. 10 CFR 32.27 requires that an applicant for a license under 10 CFR 32.26 shall demonstrate that the product is designed and will be manufactured so that the requirements of 10 CFR 32.27 are met.

In Attachment H, External and Internal Dose Calculations, of your application you provided information concerning external and internal doses that may be received by an end user of a Bruker TIMON device and also provided information concerning possible incineration of the device, but the information you provided is not oriented toward all of the specific safety criteria of 10 CFR 32.27. Furthermore, the OrthoTIMON device was not addressed within this context.

Please provide additional information for the Bruker TIMON and OrthoTIMON devices to demonstrate that these products are designed and will be manufactured so that each of the specific safety criteria in 10 CFR 32.27 are met. In preparing your response, you should address each of the specific circumstances described in 10 CFR 32.27. You may wish to consult section 2.15 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which provides guidance on meeting the safety criteria of 10 CFR 32.27.

27. In the Estimated Use Time Basis section of your application, you wrote, "63Ni is a low-energy, pure beta-emitting radioisotope. Therefore there is no radiation from the source that is detectable outside the TIMON metal cabinet Fig.1)." In the TIMON Pre-registration Survey you wrote that external dose rates were indistinguishable from background dose rates. However, in paragraph 3.a., you wrote, "Direct bremsstrahlung radiation measurements were made with the device intact, source installed. At a distance of 5 cm, the measured dose rate was 0.1 mrem per hour."

Please provide additional information that clarifies these seemingly contradictory statements with regard to external dose rates. In preparing your response, you may wish to consult section 2.15.5 of NUREG-1717, Systematic Radiological Assessment of Exemption for Source and Byproduct Materials, which addresses external dose rates from gas and aerosol detectors containing Ni-63.