

March 21, 2017

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

SUBJECT: BRUKER DETECTION CORPORATION, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR A NEW LICENSE

Dear Mr. Gleason:

This letter refers to your application dated February 28, 2017, for an exempt distribution license. In reviewing your application, we found that additional information is required.

Title 10 of the *Code of Federal Regulations* (10 CFR) 32.26 and 32.18 require the applicant to submit sufficient information regarding the product pertinent to evaluation of the potential radiation exposure. Your application did not contain all required information. Please submit the following information:

1. In your application on page 3, item number 5, "Radioactive Material: Devices," under Device Distributor and Source Distributor, you listed "Bruker Daltonics," which is different from the device distributor listed on your current Sealed Sources and Devices Registry (SSDR) Certificate NR-1101-D-102-E. Provide clarification regarding who the distributor is for your products.
2. On page 3, item number 5, "Radioactive Material: Devices," under Device Manufacturer, you listed "Bruker Saxonia Analytic GmbH," which is different from the device manufacturer listed on your current SSDR. Provide clarification regarding who the manufacturer is for your products.
3. Throughout your application, you used "Bruker Daltonics" and "Bruker Detection" interchangeably. Provide a statement to clarify who the distributor is that is applying for the exempt distribution license.
4. Throughout your application, you used "Bruker Saxonia Analytic GmbH" and "Bruker Daltonik GmbH" interchangeably. Provide a statement to clarify who the manufacturer is for these products.
5. Throughout your application, you used the model name "TIMMON" and "TIMON" interchangeably. Provide a statement to clarify which model name for the products for which you are applying.

6. Throughout your application, you used the model name "orthoTIMMON" and "orthoTIMON" interchangeably. Provide a statement to clarify which model name for the products for which you are applying.
7. Under the Exempt Check Sources, you stated "All sources are +/- 20% nominal activity." In accordance with 10 CFR 30.18, each source should not exceed the applicable quantity set forth in 10 CFR 30.71, Schedule B. Provide the maximum activity of each source you will distribute under 10 CFR 30.18 and 32.18.
8. In your application the maximum activity under "Radionuclides used in the Product: Ni-63" is 2.7 millicuries (100 MBq); however, under "Manufacturing of the Device," the source NBCB is 300 MBq which is also different from the maximum activity stated in your current SSDR. Provide a statement of the maximum activity used for the devices for which you are applying.
9. In your application, Tap N (Attachment N) does not contain "Technical Drawings of the RAID-AFM" as stated, nor any other document. Provide drawings for RAID-AFM.
10. Attachment R included an "OrthoTIMON" drawing, but not a TIMON drawing. Provide drawings for TIMON.
11. In your application under "Distribution of Exempt Check Sources," you stated that "No individual source can exceed the activity limit on our license." The maximum possession limits for isotopes listed on your Massachusetts (MA) license (License No. 38-0257), Amendment 11, are above the limits in 10 CFR 30.71, Schedule B, e.g. maximum possession limit for Carbon-14 on your MA license is 120 microcuries per source, the limit for Carbon-14 in 10 CFR 30.71, Schedule B is 100 microcuries. Provide a statement that explains how you intent to meet the requirements under 10 CFR 30.18.
12. In Attachment K, "Technical Drawings of the RAID-M100," the dimension of the device is different from the one in your current SSDR. Provide clarification on which of the two dimensions is correct for model RAID-M 100.
13. In Attachment T, "Table of Models," the model uRAID is not listed. This is different from the models provided under the section "Radioactive Material: Devices." Provide a statement to clarify for which models you are applying with this application.
14. Provide prototype testing for models RAID-XP, ARFCAM, RAID-AFM, μ RAID, TIMON and OrthoTIMON.
15. Provide radiation profiles for models ARFCAM and OrthoTIMON.
16. In Attachment Z, "Normal and accidental dose calculations" required under 10 CFR 32.27, the deep dose equivalent, lens dose equivalent, and combined doses calculations for models TIMON, IPDS-LR and μ RAID are incorrect. Provide correct dose calculations for these models. Additionally, provide the internal dose calculations for the scenario of incineration in a storage room fire for models TIMON, IPDS-LR and μ RAID.

17. In Attachment Z, "Normal and accidental dose calculations," under "Internal Dose Calculation From Incineration," you assumed that the fraction of Ni-63 vaporized and released is equal to 0.1 percent (0.001), and under "Incineration in a Storage Room Fire," you assumed the fraction of Ni-63 vaporized and released is equal to 0.01 percent (0.0001). Explain the discrepancy between the two assumptions for the same isotope vaporized and released rate.
18. In Attachment Z, in your calculation of the concentration of aerosolized Ni-63 emitted during the burn, you used radiation activity of 2.7 μ Ci for Ni-63, however, Ni-63 in each device is 2.7 mCi as stated in your application. Explain why the lower radiation activity for Ni-63 is used in this calculation.
19. Provide external and internal dose calculations for models RAID-AFM, RAID-S2 and OrthoTIMON.

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.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC 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>.

If you have any questions, you may contact me at (301) 415-7640, or by e-mail at Shirley.Xu@nrc.gov.

Sincerely,

/RA by Hipolito Gonzalez for/

Shirley S. Xu
Materials Safety License Branch
Division of Material Safety, State, Tribal,
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-39014
Mail Control No. 592491

G. Gleason

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CONCERNING APPLICATION FOR A NEW LICENSE

DATE: March 21, 2017

Certified Mailing No. 7015 3010 0000 7901 6215

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OFC	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB	MSTR/MSLB
NAME	HGonzalez for SXu	DMiller	HGonzalez	HGonzalez for SXu
DATE	3/21/17	3/20/17	3/21/17	3/21/17

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