

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

July 10, 2015

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

# SUBJECT: AMENDMENT TO EXEMPT DISTRIBUTION LICENSE AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATE FOR BRUKER DETECTION CORPORATION

Dear Mr. Gleason:

This refers to your application dated January 2, 2015, which requested the addition of the TIMON and OrthoTIMON devices to your U.S. Nuclear Regulatory Commission (NRC) exempt distribution license and to your Sealed Source and Device registration certificate. Please find enclosed the amended NRC exempt distribution license No. 20-32465-02E and Sealed Source and Device (SSD) registration certificate NR-1101-D-102-E.

During our review of your amendment request we determined that a superseded version of your SSD registration certificate (ML070090370) and a letter dated March 3, 2009 concerning a name change (ML090930388), which were previously listed in Condition 14 of Amendment No. 07 of your license, are no longer relevant to the current activities conducted under your license; therefore, reference to these items has been removed from your license. Furthermore, reference to the requirement in 10 CFR 32.20(b) to file annual reports of the distribution of exempt products under 10 CFR 32.18 had been erroneously omitted from Condition 13 of your license and this error has been corrected. Also, License Conditions 9.A, 9.B-O and 10 have been updated, and Condition 14 has been added, in accordance with standard license conditions. The changes to your license described in this paragraph do not result in changes to the requirements of your license.

Please review the enclosed documents carefully and be sure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections or answers can be provided.

Please be advised that you must manufacture and distribute the products in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your license and registration certificate. As a general rule, you must request and obtain an amendment to the license and registration certificate before you make changes or modifications to the information submitted to obtain them. You are also obligated to notify us promptly in writing should you decide to no longer distribute the product.

### G. Gleason

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the NRC, now or hereafter in effect, to include the following:

 Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

- 2. Distribute only those products containing radioactive material which are specifically authorized in your license.
- 3. Notify NRC in writing within 30 days of any change in mailing address.
- 4. In accordance with 10 CFR 30.33, 30.34 and 30.38, please file appropriate documentation with the NRC prior to any changes to your organization, change locations of distribution of products containing radioactive material, facilities, equipment, procedures, change in the contact person or the person responsible for the quality assurance program for licensed activities, or any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with the NRC.
- 5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
- 6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

G. Gleason

Please be aware that, as a holder of an NRC license and/or registration, you may be subject to the NRC's annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Accounts Receivable Branch at (301) 415-7544.

In accordance with 10 CFR 2.390(a), "Public inspections, exemptions, requests for withholding," 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 Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/NRC/ADAMS/index.html.

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

Sincerely,

## /RA/ Shirley Xu for:

Eric H. Reber 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

Enclosures: License No. 20-32465-02E SSD Certificate No. NR-1101-D-102-E G. Gleason

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Sincerely, /RA/ Shirley Xu for: Eric H. Reber 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

Enclosures: License No. 20-32465-02E SSD Certificate No. NR-1101-D-102-E

DISTRIBUTION: SSD ELicense.Resource@nrc.gov SSD Case 15-13 RI/DNMS

MSTR r/f

ML15187A204 (cover letter)

ML15187A208 (E-license)

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	Eric Reber	Shirley S. Xu	Celimar Valentin-Rodriguez	Tomas Herrera
DATE	07/09/2015	07/09/2015	07/09/2015	07/09/2015
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	
NAME	Maria Arribas-Colon	Hipólito J. González	Eric Reber	
DATE	07/09/2015	07/10/2015	07/10/2015	

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