January 7, 2014

Bruker Detection Corporation
ATTN: J. Brian Turk, Vice President
40 Manning Road
Billerica, MA 01821

Mail Control No. 581480

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Turk:

This refers to your letter dated November 4, 2013 (ML13331A871), regarding your application to amend your exempt-distribution License No. 20-32465-02E, to add 24 check sources for distribution. Your original application, dated July 31, 2013 (ML13218B124), indicated that you sought to have these sources licensed in accordance with 10 CFR 32.14; however, it was subsequently determined that these sources must be licensed in accordance with 10 CFR 32.18.

In order to ensure that all requirements of 10 CFR 32.18 are fully addressed, we sent you a Request for Additional Information (RAI), dated September 23, 2013 (ML13240A439), requesting that you resubmit your application with particular attention to specific questions contained therein. Your letter and application dated November 4, 2013, were provided in response to that RAI.

Your letter provided responses to each of the questions in our RAI, but some of these responses were not clear or did not provide sufficient information. The original questions, your responses, and our additional questions are as follows:

1. Title 10, Code of Federal Regulations, Section 32.10(a) states, in part "…any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B."

   Title 10, Code of Federal Regulations, Section 30.18(d) states: "No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State."

Your application provided a list of radionuclide sources and the activity of each source, followed by the statement "Nominal activity is +/- 20%." For some of the radionuclides in this list, an activity within the 20% upper bound would exceed the limits stated in § 30.71, Schedule B by an unacceptable amount. An example is Ba-133, 10 microcuries. An uncertainty of +/- 5 percent has been found acceptable in previous applications pursuant to 10 CFR 32.18, and it is likely that this will continue to be the case. For those radionuclides with activities equal to the Schedule B limits, please describe how you shall prevent the activity from exceeding more than 5 percent of the limit.

Response: The manufacturer states it is their policy to not ship any check source with an activity greater than that allowed by 10 CFR 30.71, Schedule B. Item closed.

Additional Question: Your response does not specifically indicate how the manufacturer will prevent the shipment of any check source with an activity greater than that allowed by 10 CFR 30.71, Schedule B. Please provide this information. As stated in the original question, an uncertainty of +/- 5 percent has been found acceptable in previous applications pursuant to 10 CFR 32.18, and it is likely that this will continue to be the case. The primary concern pertaining to this question is that the limits in 10 CFR 30.71, Schedule B not be exceeded by more than 5 percent. Your response might include information such as whether each check source will be individually measured; the uncertainty in the overall measurement process; and/or any other information that will provide assurance that the limits will not be exceeded by more than 5 percent.

2. Title 10, Code of Federal Regulations, Section 32.18(b) requires that the byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being. Please confirm that this requirement will be met.

   Response: The label and data sheet containing the verbiage required by the regulation are included in the amendment request dated November 4, 2013, as it was in the original amendment request.

   Additional Question: As the initial distributor of these sources, Bruker Detection Corporation must confirm that this requirement will be met. Please confirm that the requirement of Title 10, Code of Federal Regulations, Section 32.18(b), which requires that the byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being, will be met.

3. Title 10, Code of Federal Regulations, Section 32.18(c) requires the byproduct material to be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution. Please describe the form of the byproduct material that you intend to distribute, and confirm that this requirement will be met.

Response: The drawing from the manufacturer describing the makeup of the check source is included in the amendment request dated November 4, 2013, as it was in the original amendment request.

Additional Question: As the initial distributor of these sources, Bruker Detection Corporation must confirm that this requirement will be met. Please confirm that the requirement of Title 10, Code of Federal Regulations, Section 32.18(c), which requires the byproduct material to be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution, will be met.

4. Title 10, Code of Federal Regulations, Section 32.18(d) requires the applicant to submit copies of prototype labels and brochures and that the Commission approves such labels and brochures. Please provide copies of the labels to be used on these products, and the accompanying brochure, if any, that may be distributed along with the byproduct material.

   Response: The drawing of the label is included in the amendment request dated November 4, 2013, as it was in the original amendment. Additionally, the data sheet containing the verbiage required by the regulation is also included in the November 4, 2013, amendment request. The label is a durable label and the data sheet will be provided by the source manufacturer for each source.

   Additional Question: None.

5. Title 10, Code of Federal Regulations, Section 32.19(a) requires that no more than 10 exempt quantities set forth in Section 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Section 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity. Please describe how you shall prevent the sale or transfer of more than 10 exempt quantities in any single transaction.

   Response: The above requirements are included in Bruker procedures.

   Additional Question: Please provide a copy of the procedure(s) that describes how you shall prevent the sale or transfer of more than 10 exempt quantities in any single transaction.

6. Title 10, Code of Federal Regulations, Section 32.19(b) requires that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Section 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour. Please describe how you shall ensure that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually

packaged, with no more than 10 such packaged exempt quantities contained in any outer package for transfer, and such that the dose rate at the external surface of the outer package does not exceed 0.5 millirem per hour.

Response: The above requirements are Included in Bruker procedures.

Additional Question: Please provide a copy of the procedure(s) that describes how you shall ensure that each quantity of byproduct material set forth in Section 30.71, Schedule B of this chapter shall be separately and individually packaged, with no more than 10 such packaged exempt quantities contained in any outer package for transfer, and such that the dose rate at the external surface of the outer package does not exceed 0.5 millirem per hour.

7. Title 10, Code of Federal Regulations, Section 32.19(c) requires that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material." Please describe and provide samples or copies of the labels you plan to use in meeting this requirement.

   Response: The drawing of the durable label is included in the amendment request dated November 4, 2013.

   Additional Question: The drawing of the label provided in the amendment request dated November 4, 2013, appears to be representative of the label that will be used on the individual check sources. Title 10, Code of Federal Regulations, Section 32.19(c) requires that the immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material." Please describe and provide samples or copies of the labels you plan to use in meeting this requirement.

8. Title 10, Code of Federal Regulations, Section 32.19(d) requires, in addition to the labeling information required by paragraph (c) of this section, that the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material. Please describe and provide a sample or copy of the labels and/or brochures you plan to use in meeting this requirement.

   Response: The data sheet containing the verbiage required by the regulation is included in the amendment request dated November 4, 2013. This sheet will be ordered with every check source from the manufacturer. Included in Bruker procedures.

   Additional Question: Please provide a copy of the procedure(s) that describes how you shall meet the requirements of Title 10, Code of Federal Regulations, Section 32.19(d).

If we do not receive your reply within 30 calendar days from 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.

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.

Any correspondence regarding your amendment application should reference the control number specified above.

If you have questions regarding the Exempt-Distribution License review, please contact me at (301) 415-5477, or by email at Richard.Struckmeyer@nrc.gov.

Sincerely,

/RA/

Richard K. Struckmeyer, Health Physicist
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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If you have questions regarding the Exempt-Distribution License review, please contact me at (301) 415-5477, or by email at Richard.Struckmeyer@nrc.gov.

Sincerely,

Richard K. Struckmeyer, Health Physicist
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

DISTRIBUTION: MSSA r/f MKotzalas TKime JOHara KButler LFARB Region I/DNMS

ML13218A316 (pkg.) **ML13365A170**

OFFICE	FSME:MSSA	FSME:MSSA	
NAME	RKStruckmeyer	JJankovich for MKotzalas	
DATE	1/7/14	1/7/14	

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