

March 13, 2013

Maria Arribas-Colon, General Engineer
Agreement State Programs Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs



**Met One
Instruments**

Met One Instruments, Inc.

1600 Washington Blvd.

Grants Pass, Oregon 97526

Phone (541) 471-7111

Fax (541) 471-7116

www.metone.com

REGIONAL OFFICE

3206 Main St., Ste. 106

Rowlett, Texas 75088

Phone (972) 412-4747

Fax (972) 412-4716

Response to RAI dated March 8, 2013

Dear Maria:

This letter is in response to your RAI dated March 8, 2013. I included your questions (*italic*) with my answers (*blue*) for clarity.

1. **General**

1.1 *In your amendment request you stated that you want to amend your license and registration certificate to include BAM 1022, and also stated that BAM 1022 is essentially a rebranding of BAM 1030. Please clarify if your intent is to add BAM 1022 to your license and registration certificate and remove BAM 1030, or if your intent is to have both models listed on the license and certificate.*

1.1.1 Answer:

We intend to have both models listed on the license and certificate.

1.2 *If you are going to discontinue the manufacturing of BAM 1030, please indicate the discontinuation date.*

1.2.1 Answer: N/A

2. **Description/Construction**

2.1 *Please confirm that the overall dimensions of BAM 1022 and BAM 1030 are the same.*

2.1.1 Answer:

The overall dimensions of the BAM 1022 and BAM 1030 are the same.
10.5" (H) x 17" (W) x 16" (D)

2.2 *Confirm the all aspects previously described for the BAM 1030, such as intended use, source model and activity, etc., are the same for the BAM 1022.*

2.2.1 Answer:

All aspects previously described for the BAM 1030, such as intended use, source model and activity, etc., are the same for the BAM 1022.

3. **Labeling**

3.1 *Identify any differences in how the BAM 1022 will be labeled from the*

3.2 *models listed in the current certificate.*

3.2.1 Answer:

The BAM 1022 label/placard will be the same as the BAM 1020 and BAM 1030 (see below). The dimensions will be 3" x 1.5".

Model Number:	BAM 1022	
Serial Number:		
Isotope:	CARBON 14	○
Max. Activity:	75uCi	
Party Licensed to		
Transfer Product:	Met One Instruments, Incorporated	
○	THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH US-NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.	

3.3 *Identify the location of the label.*

3.3.1 Answer:

There will be two riveted metal placards. The locations will be the same as the BAM 1020. One placard will be located inside the front door. The second will be on the rear panel.

4. Conditions of Use

4.1 *Specify the expected useful life of the BAM 1022.*

4.1.1 Answer:

The expected useful life of the BAM 1022 is 10 years or more.

4.2 *Provide environmental conditions for the use of the device, such as the maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport) of the BAM 1022.*

4.2.1 Answer:

The BAM-1022 unit is not weatherproof. It is designed to be mounted in a weatherproof, level, low vibration, dust free, and temperature-stable environment where the operating temperature is 0° C to +40° C, and where the relative humidity is non-condensing and does not exceed 90%.

4.3 *Please confirm that the BAM 1022 meets the dose limits of 10 CFR 32.27.*

4.3.1 Answer:

The BAM 1022 meets the dose limits of 10 CFR 32.27.

5. Prototype Testing

5.1 *Address issue whether the prototype testing conducted for the in BAM 1030 also applies to the BAM 1022.*

5.1.1 Answer:

The prototype testing for the BAM 1030 also applies to the BAM 1022.

6. Installation and Instruction to Users

6.1 Please describe whether the BAM 1022 will be a fixed, portable or movable installation.

6.1.1 Answer:

Generally, BAM 1022s will be installed at a location and remain there (fixed). Occasionally, customers may move them to another site (moveable). It is not considered portable equipment.

6.2 Provide a final copy of the BAM 1022 operating manual.

6.2.1 Answer:

Manual attached.

7. Servicing

7.1 Please provide the type of services that Met One Instruments will provide to the users (i.e. installation, maintenance, leak testing, training, etc.).

7.1.1 Answer:

We will provide the same services that we provide to our BAM 1020, BAM 1030 and EBAM customers. For example,

- We manufacture these units in Grants Pass, Oregon.
- We routinely provide customer training (installation, operating and maintenance) in Grants Pass, Oregon.
- We repair customer units in Grants Pass, Oregon.
- We conduct leak tests during the manufacturing process.

8. Computer Software

8.1 Please confirm that the display and keyboard changes do not affect the integrity and the radiation protection features of the equipment safety systems.

8.1.1 Answer:

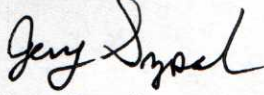
The display and keyboard changes do not affect the integrity and the radiation protection features of the equipment safety systems.

Note: The last page of your RAI for some reason was addressed to:

Dale P. Jones
Quality Manager
Thermo Fisher Scientific
27 Forge Parkway
Franklin, MA 02038

Thermo Fisher Scientific is actually a competitor. Hopefully, our information has not been sent to them. As of this date, I have not received the hard copy of the RAI via mail.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerry Szpak". The signature is written in a cursive style with a large, prominent initial "J".

Jerry Szpak
Director of Technology

Enclosures (1)