May 23, 2013

Mail Control No. 579474

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Katie Wagner
Licensing Branch
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Office of Federal and State Materials and Environmental Management Programs

Response to RAI dated May 15, 2013

Dear Katie:

This letter in in response to your RAI dated May 15, 3013. I included your questions (*Italic*) with my answers (blue) for clarity.

1. *Section 32.26(b)(8), 10 CFR 32, requires the applicant to submit information that should include total quantity of byproduct material expected to be distributed in the product annually. Please submit information on the quantity of byproduct material expected to be distributed annually as part of BAM 1022 Beta Attenuation Monitors.*

   Answer:

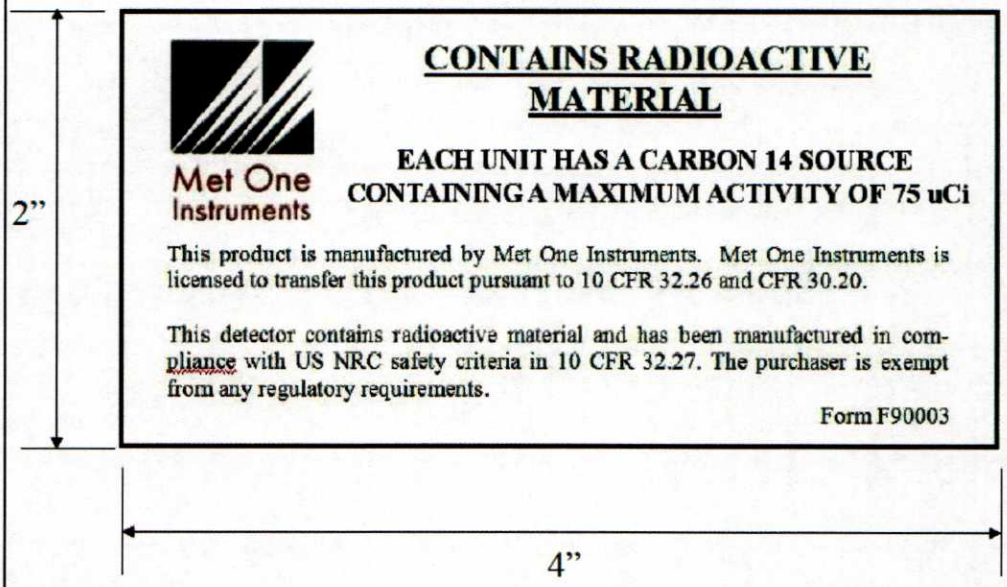
   Estimated quantity (domestic and international) for the BAM 1022 is 200 units per year. Each unit will have one beta source.

2. *Section 32.29(b)(3), 10 CFR 32, states that each licensee under 32.26 shall label or mark its point-of-sale package so that the external surface of the pointof-sale package has a legible, readily visible label or marking containing information described in 32.29(b)(3)(i-iii), 10 CFR 32. Please identify any differences in how the BAM 1022 point-of-sale packaging will be labeled from the models currently listed on your exempt-distribution materials license.*

   Answer:

   The BAM 1022 point-of-sale label will be the same as the BAM 1020, E-BAM and BAM 1030 (see below).

LABEL - Form F90003



NOTES:

1. Label above to be printed on yellow colored material.
2. Page 2 will print to 8½ X 11 shipping label sheet.

3. *In your response dated 13 March 2013, you stated that "The BAM 1022 meets the dose limits of 10 CFR 32.27." Please provide a rationale for how this conclusion was reached (e.g. provide a calculation or other information).*

Answer:

The BAM 1022, E-BAM and BAM 1030 have the same rationale since they contain the same C14 source, containment, shielding and safety components. The E-BAM / BAM 1030 have been in production since 2002 / 2004 respectively.

10 CFR 32.27 (a) In normal use and disposal of a single **BAM 1022**, and in normal handling and storage of the quantities of **BAM 1022** units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in Section 32.28.

Rationale for 32.27 (a):

Estimated annual production is 200 units per year. Each production run will be no more than 10 units. The C14 beta source produce less than .05 mR/hour at 2 cm from the nearest accessible surface of the source. The door is closed during normal operation. During this time there is no exposure to radiation (no radiation detectable on external surfaces). The door is open for less than 30 minutes during tape maintenance. This activity occurs monthly or bimonthly. Finally, the BAM 1022 normally operates unattended.

10 CFR 32.27 (b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the **BAM 1022** from wear and abuse likely to occur in normal handling and use of the product during its useful life.

Rationale for 32.27 (b):

The source is completely surrounded on all sides except one by an aluminum housing which blocks all beta emissions. The open end has limited access. Customers are instructed not to remove or access the beta source. No detectable radiation when the door is closed.

10 CFR 32.27 (c) In use and disposal of a single **BAM 1022** and in handling and storage of the quantities of **BAM 1022** units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.

Rationale for 32.27 (c):

- Low beta source activity (75 uCi max.)
- The beta source containment / safety components are aluminum.
- Limited quantity (200/year globally)
- Customers are instructed not to remove or access the beta source.
- Met One Instruments has a process for safe handling, recycling, storage and disposal of the C14 sources. Customers can return units to the factory when they reach the end of usable life.
- It is highly unlikely that even a few units would end up in any one landfill.

Sincerely,

Jerry Szpak
Director of Technology