Bruker Detection Corporation
Amendment Request dated January 2, 2015
Request for Additional Information dated May 29, 2015

1. Please provide the weight for the TIMON and OrthoTIMON devices. This information is provided in the product manuals.

   Response: *TIMON = approx. 22 kg (Product Specification Sheet)*
   OrthoTIMON = approx. 51 kg (Product Specification Sheet)

2. Please provide an engineering drawing that shows the cross sectional view of the "measuring tube" shown in Drawing Number "OR 0100 G 003" in Attachment E of your amendment request. The drawing can be similar to the drawing of the IMS detection cell included in Attachment 4 of your current Registration Certificate NR-1101-D-102-E and should include dimensions and tolerances.

   Response: *See Attachment A – TM1600G003-B1 IMS Tube and Cross Section*

3. In your response to question 2 of NRC's RAI, dated April 27, 2015, the table provided includes the NBCD source model. Please clarify if the TIMON and OrthoTIMON devices will also use the NBC source model used by the other devices in the RAID series. If the TIMON and OrthoTIMON devices will use the NBC source model, please provide an updated table.

   Response: *The TIMON and OrthoTIMON will not use the NBCD source model but will use the NBC source model.*

4. In your response to question 2, you also indicated that the ANSI/ISO Classification for source models NER-004 and NER-004P is 77C32211. However, E&Z Isotope Product Laboratories Registration Certificate CA-0406-S-214-S indicates that the ANSI/ISO classification is 99C42211. Please confirm that the ANSI/ISO classification for source Models NER-004 and NER-004P is 99C42211.

   Response: *ANSI/ISO classification for source Models NER-004 and NER-004P is, indeed, 99C42211*

5. In your response to question 13, in row 3 column 3 of the table provided, you included an asterisk next to the Operating Temperature for the OrthoTIMON. Please clarify the meaning of this asterisk.

   Response: *(*) For special applications where the environment is below 0° C, a temperature controlled enclosure can be supplied.*

6. In your response to question 16, you stated that the tests performed to the TIMON and OrthoTIMON devices and also provided the tests reports. These tests do not demonstrate that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Please confirm that there is no change in the IMS cell, which has been previously approved for the other models within the RAID Series, and therefore,

that the prototype testing is applicable to both TIMON and OrthoTIMON device models.

Response: *The Ceramic Rings are now glued into place instead of being held in place with solder. See Attachment B - IMS Tube Test Report and Test Report Translation*

7. In questions 4 and 21, you stated that the correct dimensions of the TIMON and OrthoTIMON devices will be updated in the next version of the Operator Manual. You also committed to including the updated labels in the instrument operator manual for each device. Please provide copies of the updated Technical Data Annex for the TIMON and OrthoTIMON Operator Manuals, as well as with copies of the inserts for each Operator Manual which will include the updated labels for both devices.

   Response: *See Attachment C – Operator Manual, OrthoTIMON, Annex C, Ver 1-1*

   See Attachment D - Operator Manual, TIMON, Annex C, Ver 1-1

   See Attachment E - TIMON & OrthoTIMON Operator Manuals Eratta, Labeling

8. The regulation in 10 CFR 32.29(b)(3) requires that the external surface of the point-of-sale package has a legible, readily visible label or marking containing the items in 10 CFR 32.29(b)(3)(i), (ii), and (iii). The regulation in 10 CFR 32.29(b)(3)(i) requires that the label or marking contain the name of the radionuclide and quantity of activity.

   Item 25 of your letter provided a copy of the label that you stated will be attached to the point-of-sale package of the TIMON and OrthoTIMON devices. Contrary to the above, the copy of the label that you provided does not contain the name of the radionuclide and quantity of the activity.

   Please provide labels, copies of labels, or markings that meet the requirements in 10 CFR 32.29(b)(3) for point-of-sale packages. You should specifically ensure that the labels, copies of labels, or markings that you submit contain the name of the radionuclide and quantity of the activity in accordance with 10 CFR 32.29(b)(3)(i).

   Response:

CONTIANS RADIOACTIVE MATERIAL
Ni-63, 2.7mCi (100 mBq)
Bruker Detection Corporation
40 Manning Rd. Billerica, MA 01821 USA
This device contains radioactive material and has been manufactured in compliance with U.S. NRC safety criteria in 10 CFR 32.27. The purchaser is exempt from any regulatory requirements.

1.19"

3.25"