UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

April 18, 2011

Mitchell Eppley, Senior Manufacturing Engineer
Morpho Detection
205 Lowell Street
Wilmington, MA 01887

SUBJECT: REQUEST TO AMEND LICENSE 20-23904-01E AND REGISTRATION NR-0399-D-101-E

Dear Mr. Eppley:

This letter is in response to your amendment request dated March 01, 2011, to add the MobileTrace DX, a new device, to the Morpho Detection registration certificate. In reviewing your request, we find that additional information is required to complete our review. In the enclosure of this letter, we have summarized the issues not addressed in your application letter.

Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions concerning the license, please contact Shirley Xu at (301) 415-7640 or Shirley.xu@nrc.gov. If you have any questions on the registration certificate, please contact me at (301) 415-7908 or john.odonnell@nrc.gov.

Sincerely,
/RA/
John O'Donnell
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosure: As stated

License Number: 20-23904-01E
Docket: 030-36457
Mail Control Number: 754631

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Distribution: SSD Case 11-16
Registration: NR-0399-D-101-E
E-License: 20-23904-01E
R. Jones, Fees, B. Brown, Fees, J. Foster M. Moriarty RI/DNMS/LAS

ADAMS Package: ML110750259

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NAME	JODonnell		UBhachu		JJankovich		SXu	
DATE	4/18/2011		4/18/2011		4/18/2011		4/18/2011	

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The first set of questions refers to your registration certificate amendment request dated March 01, 2011. In order to continue our review, we need the following additional information.

1. Description / Construction
   On Page 8 of 8 of your application in the Comparison of Dimensions section, the differences in the size of the MobileTrace DX relative to the Hardened MobileTrace are described. However, in the table, under System dimensions and weights, the only dimension difference is in the height. Please clarify the differences described and provide the correct dimensions.

2. Conditions of Use
   This model references both the Hardened MobileTrace and the Itemiser DX. The Hardened MobileTrace storage temperature range is -20C to +70C while the Itemiser DX storage temperature range is 0C to +50 C. Please provide the rationale for the differences in the storage temperature range (-7C to +49C) provided for the MobileTrace DX.

3. Drawings
   Please provide detail drawings for the changes in the MobileTrace DX device.

4. Prototype Testing
   Section 10.5 discusses testing of the detector cells. Please provide copies of the test results of the tests conducted in January 2010, to qualify the source/device in accordance with ISO 2919 as described in your application for our review and records. The test results, for NRC review, should indicate changes in the external radiation level and device integrity, if any.

5. Radiation Profiles
   Please provide supporting technical information (e.g., measurement data, analysis) that the MobileTrace DX does not have measureable radiation exposure to either the operator or member of the public.

6. Safety Instructions
   Please provide the safety instructions and end of life handling instructions provided to the user.

The following questions refer to your license amendment request dated March 01, 2011. In order to continue our review, we need the following additional information.

7. Maximum external radiation levels at 5 and 25 centimeters (per 10 CFR 32.26(b)(6)) or 5, 30 and 100 centimeters (per ANSI N43.8) from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

8. Degree of access of human beings to the product during normal handling and use.

9. Total quantity of byproduct material expected to be distributed in the product annually.

10. Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

11. Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

12. The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates.

13. A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph.