



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

October 2, 2014

John Harvey  
Radiation Safety Officer  
Morpho Detection, LLC  
205 Lowell Street  
Wilmington, MA 01887

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. Harvey:

This letter refers to your application dated July 10, 2014, Agencywide Documents Access and Management System (ADAMS) Accession No. ML14204A816, for your renewal of the Nuclear Regulatory Commission (NRC) Exempt-Distribution Materials License no. 20-23904-01E. In reviewing your application, we find additional information is required to complete our review. In order to continue our review, please provide the information listed below. This information is required by 10 CFR 32.26, "Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer," and described in the relevant guidance document NUREG-1556, Volume 8 titled "Program-Specific Guidance about Exempt Distribution Licenses."

1. The solubility in water and body fluids of the forms of the byproduct material.
2. Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use and disposal of the product.
3. Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.
4. Degree of access of human beings to the product during normal handling and use.
5. Total quantity of byproduct material expected to be distributed in the product annually.
6. The expected useful life of the product.
7. The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of 10 CFR 32.29.
8. 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.

9. 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.
10. The estimated external radiation doses and dose commitments relevant to the safety criteria in 10 CFR 32.27 and the basis for such estimates.
11. A determination that the probabilities with respect to the doses referred to in 10 CFR 32.27(c) meet the criteria of that paragraph.
12. The company name under your Massachusetts State materials license is Morpho Detection, Inc. Please submit a copy of the amended license with the company name Morpho Detection, LLC.

In addition we noticed that the NRC SSD Certification No. NR-0399-D-101E has Morpho Detection, Inc. as the distributor and manufacturer. Please submit an amendment requesting a change of name of the company.

Any correspondence regarding your application should reference the control number specified below. 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 assume that you do not wish to pursue your application, and we will take regulatory action to your current NRC License, 20-23904-01E.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

If you have any questions, please contact me at (301) 415-6004 or electronic mail: [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov).

Sincerely,

**/RA/**

Hector Rodriguez-Luccioni, Ph.D.  
Licensing Branch  
Division of Materials Safety and  
State Agreements  
Office of Federal and State Materials and  
Environmental Management Programs

Docket No. 030-36457  
Mail Control No. 584404  
License No. 20-23904-01E

9. 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.
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/RA/

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Licensing Branch  
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DISTRIBUTION: SSD\_ELicense Resources

Accession No. Pkg: ML14204A797 RAI: ML14267A213

OFC	FSME/MSSA/LB	FSME/MSSA/LB	FSME/MSSA/LB	FSME/MSSA/LB
NAME	H.Rodriguez	S. Xu	M.Kotzalas A. McMurtray for:	H.Rodriguez
DATE	9/24/2014	9/30/2014	10/2/2014	10/2/2014

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