



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

August 1, 2017

Smiths Detection, LLC  
ATTN: Zemei Liu, Ph.D.  
Radiation Safety Officer  
23 Frontage Road  
Andover, MA 01810

SUBJECT: SMITHS DETECTION, LLC, REQUEST FOR ADDITIONAL INFORMATION

Dear Dr. Liu:

This letter is in response to your amendment request dated April 30, 2017, requesting a name change for your Exempt Distribution License 20-23904-01E and Sealed Source and Device Registration Certificate NR-0399-D-101-E.

We do not have sufficient information to complete the review of your application. In the enclosure to this letter you will find the list of the questions and items not addressed in your application.

Please be aware that upon your request, proprietary information submitted to the U.S. Nuclear Regulatory Commission (NRC) may be withheld from public disclosure. To do this, you must follow the procedures in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b) including requesting withholding at the time the information is submitted and complying with the document marking and affidavit requirements set forth in 10 CFR 2.390(b)(1).

We will continue our review upon receipt of this information. If we do not receive your reply within 30 calendar days from the date of this letter, we will consider your application as having been abandoned by you. This action would be without prejudice to the resubmission of another application with the required information.

Any correspondence regarding your application should reference Control Number 594706.

Z. Liu

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If you have any questions, please contact Celimar Valentin-Rodriguez at (301) 415-7124, or by e-mail at [Celimar.Valentin-Rodriguez@nrc.gov](mailto:Celimar.Valentin-Rodriguez@nrc.gov), regarding the sealed source and device registration, and Shirley Xu at (301) 415-7640, or by e-mail at [Shirley.Xu@nrc.gov](mailto:Shirley.Xu@nrc.gov), regarding the exempt distribution license.

Sincerely,

**/RA/**

Celimar Valentin-Rodriguez, Ph.D.  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal,  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-36457

Enclosure:  
Request for Additional Information

SMITHS DETECTION REQUEST FOR ADDITIONAL INFORMATION

DATE: August 1, 2017

Certified Mailing No. 7015 3010 0000 7901 6567

**ML17131A254 (pkg.)**

**ML17212A816 (Letter)**

OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
NAME	CValentin-Rodriguez	DWeaver	CValentin-Rodriguez for THerrera	LSepulveda
DATE	8/1/2017	8/1/2017	8/1/2017	8/1/2017
OFC	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB		
NAME	SXu	CValentin-Rodriguez		
DATE	8/1/2017	8/1/2017		

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**Smiths Detection Amendment Request dated April 30, 2017**  
**Request for Additional Information**

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed the Smiths Detection, LLC amendment request dated April 30, 2017, and determined that additional information is needed. In order to continue with our review, please address the issues listed below.

The information related to review of your sealed source and device application is required by Title 10 of the *Code of Federal Regulations* (10 CFR) 32.210 and is described in the relevant guidance document NUREG-1556, Volume 3, Revision 2, titled "Applications for Sealed Source and Device Evaluation and Registration."

The information related to review of your exempt distribution license application is required by 10 CFR 32.22, 32.23, and 32.24, and is described in the relevant guidance document NUREG-1556, Volume 8, titled "Program-Specific Guidance about Exempt Distribution Licenses."

1. Please confirm that Morpho Detection, LLC (Morpho Detection) is requesting a name change to their Exempt Distribution License 20-23904-01E and not requesting to combine this license with Smiths Detection, Inc. Exempt Distribution License 19-24009-01E.
2. State the facility's name and location where the products are manufactured.
3. Specify the serial number of the last unit for each of the models listed in NR-0399-D-101-E that were distributed by Morpho Detection before it was acquired by Smiths Detection, LLC, and the number of completed units that were transferred by Morpho Detection to be distributed by Smiths Detection.
4. Provide change of ownership information discussing the transfer of products, records, custody, and servicing arrangements for products previously distributed by Morpho Detection.
5. Provide a new label for the devices indicating the new company name and the effective date of the label change.
6. Confirm that no changes were made to the products since the last amendment to NR-0399-D-101-E on June 11, 2015.
7. Verify that previous commitments made by Morpho Detection have not changed.
8. Provide details about the quality assurance program under the new ownership.

Enclosure