

April 10, 2012

EA-11-270

Brad Buswell  
c/o Blanca Verduzco  
Morpho Detection, Inc.  
7151 Gateway Blvd.  
Newark, CA 94560

SUBJECT: MORPHO DETECTION, INC. - NOTICE OF VIOLATION – NRC Inspection  
Report No. 03036457/2011001

Dear Mr. Buswell:

This letter provides you the U.S. Nuclear Regulatory Commission (NRC) enforcement decision for the apparent violation identified during the NRC inspection conducted between August 4, 2011, and January 9, 2012, at the Morpho Detection, Inc. (MDI) facility in Wilmington, Massachusetts. The inspection consisted of an on-site examination of your licensed activities within NRC jurisdiction as they relate to radiation safety and to compliance with NRC regulations. In addition to the on-site review, the inspection also involved in-office review of additional information provided by MDI in correspondence dated September 12, 2011, and November 9, 2011 (ML120120400 and ML12013A118, respectively<sup>1</sup>). This information related to locations within NRC jurisdiction where MDI had used and/or stored radioactive materials. The NRC discussed its findings with Mr. Aric Tillburg, MDI's Radiation Safety Officer, during a telephonic exit meeting on January 9, 2012. The findings were also described in NRC Inspection Report No. 03036457/2011001, sent to you with a letter dated January 27, 2012 (ML1203004610).

In the January 27, 2012, letter transmitting the inspection report, the NRC informed you that one apparent violation was identified and was being considered for escalated enforcement. A pre-decisional enforcement conference was held on March 7, 2012, at the NRC Region I office in King of Prussia, PA with you and members of your staff to discuss the apparent violation, its significance, root causes, and corrective actions (MDI's presentation is available at ML120740146<sup>1</sup>). Based on information developed during the inspection and information MDI presented at the conference, the NRC has determined that, in fact, two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

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<sup>1</sup> Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

The first violation involves MDI's failure to, on multiple occasions between 2007 and 2011, file for reciprocity prior to using and/or possessing licensed material in non-Agreement States. MDI is the manufacturer of explosive detection systems used in airport security and border patrol applications. The company holds an NRC license that authorizes the distribution of ion mobility spectrometer devices which are used in the explosive detection systems, and which contain radioactive material (nickel-63 foils). The NRC license is for distribution only, and does not authorize the possession or use of the radioactive material.

MDI also holds a license issued by the Commonwealth of Massachusetts that authorizes the possession and use (within the Commonwealth) of the radioactive material. However, this license does not authorize the use of the radioactive material in non-Agreement States or other areas of exclusive federal jurisdiction. Title 10 of the Code of Federal Regulations (CFR) Section 150.20 grants an NRC general license to Agreement State licensees allowing them to conduct the licensed activities authorized by the Agreement State in non-Agreement States and areas of exclusive federal jurisdiction provided, in part, that the Agreement State licensee files for reciprocity. This is accomplished by submitting to the Regional Administrator of the appropriate NRC regional office, at least three days prior to engaging in such licensed activities: 1) a copy of NRC Form-241, "Report of Proposed Activities in Non-Agreement States;" 2) a copy of the Agreement State specific license; and, 3) the appropriate fee. However, during the NRC inspection, the NRC identified that, on multiple occasions between 2007 and 2011, MDI engaged in licensed activities in non-Agreement States and within areas of exclusive federal jurisdiction without submitting the required documentation. Specifically, on these occasions, the licensee used the devices containing the radioactive material in non-Agreement States and other areas of exclusive federal jurisdiction (namely, Connecticut, Indiana, Missouri, and Washington, D.C.), to conduct product demonstrations at trade shows and to perform customer acceptance testing and laboratory certification.

The second violation is related to the first, and involves the length of time MDI used and/or stored its devices containing radioactive material in areas of NRC jurisdiction. The reciprocity regulations in 10 CFR 150.20 restrict Agreement State licensees to conducting the licensed activities authorized by the Agreement State in non-Agreement States and other areas of exclusive federal jurisdiction (other than offshore waters) for no more than 180 days in any calendar year. However, during the NRC inspection, the NRC identified that, on several occasions between 2007 and 2011, MDI used or stored its devices in Connecticut, Indiana, Missouri and Washington, D.C. for periods of up to two years.

These violations impacted the NRC's regulatory process because the NRC was not provided an opportunity to conduct inspections of licensed activities since the NRC was not informed that the activities were occurring in NRC jurisdiction on these occasions. MDI indicated to the NRC that the two violations occurred, in part, due to unclear guidance MDI had provided its staff related to the process, roles, and responsibilities for working under reciprocity. The NRC notes that during the inspection, no violations associated with safety or security activities were identified.

The NRC concluded that both violations were caused by the failure by MDI to maintain an adequate internal process framework to ensure that the appropriate regulatory requirements were followed any time material was stored or used in locations within NRC jurisdiction. Therefore, the violations have been categorized collectively as a Severity Level (SL) III Problem

in accordance with the NRC Enforcement Policy. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III Problem. Because MDI has not been the subject of escalated enforcement action within the last two years (note, this was the first NRC reciprocity inspection of your license), the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for MDI's corrective actions taken to address the violations. Those actions included: (1) limiting the circumstances under which reciprocity filings must be performed and reducing the number of demonstration shipments requiring reciprocity filings by removing radioactive material from a number of devices, and by limiting to one location where demonstration shipments may be shipped or returned; (2) creating an internal process framework under which all demonstration shipment requests are reviewed and approved by the RSO; and, (3) establishing a centralized regulatory oversight function under a new Chief Compliance Officer position.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III Problem constitutes escalated enforcement action which may subject you to increased inspection effort in the future.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is adequately addressed on the docket in this letter, in MDI correspondence dated September 12, 2011, in NRC Inspection Report No. 03036457/2011001 issued on January 27, 2012, and in the aforementioned MDI presentation material. Therefore, you are not required to respond to this letter unless the descriptions provided in the aforementioned correspondence do not accurately reflect MDI's position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure as well as your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

*/RA/*

William M. Dean  
Regional Administrator

Docket No. 03036457  
License No. 20-23904-01E

Enclosure: Notice of Violation

cc w/ Enclosure:  
Ben Mallen, Vice President, Quality  
Aric T. Tillburg, RSO  
Commonwealth of Massachusetts  
State of Missouri  
State of Indiana  
State of Connecticut  
District of Columbia

To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,  
*/RA/*  
William M. Dean  
Regional Administrator

Docket No. 03036457  
License No. 20-23904-01E

Enclosure: Notice of Violation

cc w/ Enclosure:  
Aric T. Tillburg, RSO  
Commonwealth of Massachusetts  
State of Missouri  
State of Indiana  
State of Connecticut  
District of Columbia  
Distribution:  
See next page

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\Morpho Detection NOV-III EA-11-270.docx  
ADAMS ACCESSION NUMBER: [ML121020101](#)

<input checked="" type="checkbox"/> SUNSI Review/ MMM		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive		<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available	
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NAME	ADeFrancisco/AED**	BWelling / BDW**	RLorson/ RKL**	KFarrar/KLF**	DHolody/ DJH**
DATE	03/ 22 /12	03/ 22 /12	03/26 /12	04/02 /12	04/ 03/12**
OFFICE	HQ/OE*	RI\RA			
NAME	L Sreenivas by email	WDean			
DATE	04/09/12	04/10 /12			

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\*HQ to perform a quick review. \*\* see previous concurrence page

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Enforcement Coordinators

RII, RIII, RIV (C Evans; S Orth; H Gepford)

E Hayden, OPA

H Bell, OIG

C McCrary, OI

S Titherington-Buda, OCFO

C Scott, OGC

M Williams, OCFO

W Dean, RA, RI

D Lew, DRA, RI

D Screnci, PAO-RI / N Sheehan, PAO-RI

R Lorson, DNMS, RI

D Collins, DNMS, RI

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D Janda, SAO-RI / M Orendi, SAO-RI

K Farrar, RI

D Holody, RI

M McLaughlin, RI

A DeFrancisco, RI

C ODaniell, RI

S Villar, RI

R1DNMSMailResource

Region I OE Files (with concurrences)

## NOTICE OF VIOLATION

Morpho Detection, Inc.  
Wilmington, MA

Docket No. 03036457  
License No. 20-23904-01E  
EA-11-270

During an NRC inspection conducted between August 2011 and January 2012, for which a telephonic exit meeting was held on January 9, 2012, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

10 CFR 30.3 requires, in part, that except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in 10 CFR 30.

10 CFR 150.20(a) states, in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in non-Agreement States subject to the provisions of 10 CFR 150.20(b).

- A. 10 CFR 150.20(b) requires, in part, that any person engaging in activities in non-Agreement States shall: (1) for the first time in a calendar year, at least 3 days before engaging in each such activity, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee, with the Regional Administrator of the appropriate NRC regional office; and, (2) shall file an amended NRC Form 241 or letter with the Regional Administrator to request approval for changes in work locations, radioactive material or work activities different from the information contained on the initial Form 241.

Contrary to the above, on multiple occasions between 2007 and 2011, Morpho Detection, Inc. (MDI), which is authorized for possession and use of byproduct material under a Massachusetts Agreement State license, engaged in activities in non-Agreement States (namely, Connecticut, Indiana, Missouri and Washington, D.C.), without: (1) filing a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee, with the NRC Region I Regional Administrator; or, (2) filing an amended NRC Form 241 or letter with the Regional Administrator.

- B. 10 CFR 150.20(b)(4) requires, in part, that persons engaging in activities in non-Agreement States shall not, under the general license concerning activities in non-Agreement States or in areas of exclusive federal jurisdiction within Agreement States, possess or use radioactive materials for more than 180 days in any calendar year.

Contrary to the above, on several occasions between 2007 and 2011, MDI, which is authorized for possession and use of byproduct material under a Massachusetts Agreement State license, engaged in activities in non-Agreement States (namely,

Connecticut, Indiana, Missouri and Washington, D.C.), for periods greater than 180 days in any calendar year.

These violations constitute a Severity Level III Problem (Section 6.9).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is adequately addressed on the docket in MDI correspondence dated September 12, 2011, in NRC Inspection Report No. 03036457/2011001 dated January 27, 2012, in materials presented by MDI, at the pre-decisional enforcement conference held on March 7, 2012, and in the letter transmitting this Notice of Violation (Notice). Therefore, you are not required to respond to this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description in the above correspondences does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation – EA-11-270," and send it to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 10<sup>th</sup> day April of 2012