

U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No.                   03036457/2011001  
Docket No.                     03036457  
License No.                    20-23904-01E  
Licensee:                      Morpho Detection, Inc.  
Location:                      205 Lowell Street  
                                  Wilmington, Massachusetts 01887  
Inspection Dates:             August 4, 2011- January 9, 2012

Inspector:	<b><i>/RA/</i></b>	<b><i>01/18/12</i></b>
	_____	_____
	Craig Z. Gordon	date
	Senior Health Physicist	
	Materials Security and Industrial Branch	
	Division of Nuclear Materials Safety	
Approved By:	<b><i>/RA/</i></b>	<b><i>01/18/12</i></b>
	_____	_____
	Blake Welling, Chief	date
	Materials Security and Industrial Branch	
	Division of Nuclear Materials Safety	

## EXECUTIVE SUMMARY

Morpho Detection, Inc.  
NRC Inspection Report No. 03036457/2011001

Morpho Detection, Inc. (MDI) is a manufacturer of explosive detection systems used in airport security and border control. The company is authorized by NRC to distribute ion mobility spectrometer devices containing licensed material. The NRC license does not authorize possession or use of the devices. MDI also holds a specific license issued by the Commonwealth of Massachusetts for possession and use of material, including use of the devices for promotional purposes at temporary job sites throughout the Commonwealth.

In May 2011, the MDI Radiation Safety Officer contacted the NRC to inquire about reciprocity filing for continued and upcoming work planned within NRC jurisdiction. Based on the discussion, it appeared that some required NRC reciprocity filings were not submitted for specific periods prior to 2011. On August 4, 2011, the NRC inspected the MDI Wilmington, Massachusetts facility to review the licensee's work activities and found that MDI staff was unable to present a complete set of NRC-approved documentation of reciprocity filings for activities conducted between 2007 and 2011.

MDI conducted an internal review of product shipments and uses at temporary job sites outside Massachusetts and determined that NRC reciprocity requirements had been misinterpreted by MDI staff, and that approximately 60 specifically licensed units were shipped to locations within NRC jurisdiction since 2007. Devices were used or stored in Connecticut, Indiana, Missouri, New Jersey, and Washington, D.C. for periods up to two years.

Based on the results of the inspection, the NRC determined that an apparent violation of 10 CFR 150.20(b)(1) occurred for failure to file for reciprocity, as required, on approximately 60 occasions during the period October 8, 2007 through March 28, 2011.

In response to this issue, MDI developed a summary of proposed corrective actions, and highlighted program changes that were issued to MDI personnel who perform device product demonstrations throughout the United States.

## **REPORT DETAILS**

### **I. Organization and Scope of the Program**

a. Inspection Scope (IP 87126, Section 02.06)

The inspector reviewed the organization and scope of the licensee's program as it relates to the filing of reciprocity requests for work in NRC jurisdiction.

b. Observations and Findings

Morpho Detection, Inc. (MDI) is a manufacturer of explosive detection systems used in airport security and border control. The company is authorized by NRC to distribute ion mobility spectrometer devices containing a maximum quantity of 10 microcuries of Nickel-63 foils per device. The NRC license does not authorize possession or use of licensed material. MDI also holds a specific license issued by the Commonwealth of Massachusetts for possession and use of material, including use of the devices for promotional purposes at temporary job sites throughout the Commonwealth, except for areas under exclusive Federal jurisdiction or regulated by other Agreement States.

Work activities involved transfer and use of the devices at trade shows for product demonstrations at various locations throughout the U.S. (including Agreement States). Records of reciprocity requests were maintained in a binder filed by State. Review of records verified that MDI used licensed material for product demonstrations and related activities in NRC and Agreement State jurisdiction.

c. Conclusions

No violations were identified.

### **II. Management Oversight of the Program**

a. Inspection Scope (Inspection Procedure (IP) 87126, Section 02.07)

The inspector reviewed management oversight and implementation of the radiation safety program.

b. Observations and Findings

The RSO was appointed in April 2011. He reports to the corporate RSO, located in the MDI California headquarters facility. The RSO is responsible for oversight of NRC activities at the Massachusetts site as they relate to implementation of the radiation safety program, with emphasis on distribution and use of product devices containing licensed material. The RSO receives some assistance from engineering staff for regulatory activities.

Product demonstrations for licensed material were coordinated between several other departments within the company, including staff working in the areas of sales, service, engineering, and quality assurance. From discussion with the licensee's radiation safety representatives, they were not always notified by the various departments when transfer of devices to temporary job sites for product demonstrations were planned, nor were they fully aware of locations and times when devices were used in the field. It appeared that plans to perform product demonstrations of devices containing licensed material for use at temporary job sites were not well coordinated among company departments and the RSO. As a result, radiation safety representatives could not ensure NRC reciprocity requests were filed as required.

c. Conclusions

No violations were identified. The inspector noted that product demonstrations of devices containing licensed material at temporary job sites were not always well coordinated between the licensee's departments.

### **III. Material Receipt, Use, Transfer, and Control**

a. Inspection Scope (IP 87126, Section 02.03)

The inspector reviewed the licensee's program for material use, transfer, and control during demonstration activities at temporary job sites.

b. Observations and Findings

On May 4, 2011, the newly appointed MDI RSO called the NRC to inquire about reciprocity filing for planned and continued work at temporary job sites. The proposed work involved product demonstrations at trade shows throughout the U.S., including Agreement States.

The RSO indicated that MDI had conducted similar demonstration activities for several years as part of the company's routine marketing program. He began required filing for these activities in early 2011 as part of his RSO duties, but was unable to provide complete information about the licensee's filings prior to that time. He stated that when he took over as RSO, MDI records of previous reciprocity filings were incomplete with regard to storage and use activities, or specific temporary job site locations where the licensee's product demonstrations were performed.

Based on these communications with the RSO, it appeared the NRC reciprocity filings were not completed as required for some periods prior to 2011. The RSO indicated that he had not discussed the status of the reciprocity program with the former RSO, and that he could not explain MDI's activities in this area prior to his arrival.

On August 4, 2011, the NRC inspected the MDI Wilmington, Massachusetts facility to review the licensee's work activities in areas within NRC jurisdiction. The inspector noted that, in addition to product demonstrations, devices were used for customer acceptance testing and laboratory certification. The RSO and engineering staff provided some records of NRC Form-241s filed between 2007 and 2010 under previous company ownership, but were unable to present a complete set of NRC-approved documentation of the work performed for this period. The inspector also questioned whether the licensee's program ensured that other regulatory authorities, i.e., Agreement States, received notification of proposed work activities in areas under their jurisdiction.

Following the inspection, MDI conducted an in-depth internal review of product shipments and uses at temporary job sites outside Massachusetts for calendar years 2007 – 2011. On September 12, 2011, and November 9, 2011, MDI submitted the results of this review. Information was compiled from interviews of management, sales, and technical staff, purchase orders, billing statements, customer information, and device shipments. Results of the review included, for each item, the type of unit (and serial numbers), customer, shipping date, customer address, and return date.

Based on this information, MDI determined that NRC reciprocity requirements had been misinterpreted by its staff. MDI noted that approximately 60 specifically licensed units had been shipped to locations in Connecticut, Indiana, Missouri, New Jersey, and Washington, D.C., and used or stored for periods of a few days up to two years at each location.

Additionally, for calendar year 2008, the NRC identified that no reciprocity filings were submitted and MDI did not pay the required reciprocity fees.

The inspector conducted an additional interview with the current RSO and found that after he assumed the position in 2011 and discussed reciprocity filing requirements with the NRC, he recognized that all previous filings were not submitted as required and began to file properly after that time.

Based on the results of the NRC's onsite inspection and review of the licensee's submittals dated September 12, 2011 and November 9, 2011, the inspector determined that an apparent violation of 10 CFR 150.20(b)(1) occurred for failure to file for reciprocity, as required, on multiple occasions between October 8, 2007, and March 28, 2011.

In response to this issue, MDI conducted a comprehensive review of work practices and policies associated with their reciprocity program. This resulted in the initiation of interim corrective actions and proposed corrective actions. The interim corrective actions included withholding all product demonstrations until affiliated MDI departments complied with NRC filing requirements. Proposed corrective actions included changing sales force product demonstration requests, revising shipping methods and tracking of material, clarifying the intended use of material shipments, and improving maintenance of, and access to, MDI's records.

c. Conclusions

NRC regulations require 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). Morpho Detection, Inc., which is authorized for possession and use of radioactive material only under a Massachusetts Agreement State license, failed to submit the required forms for reciprocity prior to working in NRC jurisdiction on approximately 60 occasions between October 8, 2007, and March 28, 2011.

The following apparent violation of NRC requirements was identified and is being considered for escalated enforcement:

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in non-Agreement States shall, 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.

#### **IV. Exit Meeting**

On December 12, 2011 and January 9, 2012, the inspector contacted Mr. Aric Tilberg, MDI RSO and presented the results of the inspection. The RSO was informed that an apparent violation of NRC requirements was being considered for escalated enforcement action, and that MDI would be offered the opportunity to attend a pre-decisional enforcement conference to discuss the apparent violation.

**PARTIAL LIST OF PERSONS CONTACTED**

Licensee

Mitchell Eppley, Senior Engineer  
Aric Tilberg, RSO