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Morpho Detection

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Mr. Raymond Lorson
Director – Division Nuclear Material Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

September 12, 2011

Dear Mr. Lorson,

On August 4, 2011, Mr. Craig Gordon performed an inspection of the Morpho Detection, Inc. (MDI) facility located in Wilmington, Massachusetts focusing on our implementation of U.S. Nuclear Regulatory Commission (NRC) requirements related to the use of our products in reciprocity jurisdictions. At the end of that inspection, Mr. Craig Gordon requested a listing of product uses in reciprocity jurisdictions and our indication of whether proper forms (*i.e.*, Form 241) were used. In response to that request, please find attached a list of product demonstrations that MDI has been able to determine it has performed regarding ion mobility spectrometer devices at locations falling under the NRC's jurisdiction, per your request. (Attachment 1.) The data covers the period from calendar years 2007 to 2010.

Please note that the attached list reflects MDI's good faith efforts to obtain the requested product demonstration information. MDI has endeavored to improve its maintenance of clearer, retrievable records of its various uses of its products. Because of numerous past recordkeeping methods, it is possible that some units may not be addressed on this listing. However, MDI has reasonable assurance that this list is as accurate as possible based on available records.

Five different MDI departments were involved in compiling the requested information regarding product demonstrations described above. Specifically, the Quality, Customer Service, Service, Technology and Sales departments assisted with gathering and verifying product demonstration information. In summary, data development had three key parts. First, a senior member of the Service department at the Wilmington, Massachusetts facility searched Oracle, MDI's inventory tracking system, to gather information regarding which units have been transported to other jurisdictions and for what purpose. This effort generated a listing of approximately 700 units that were shipped from the Wilmington facility for purposes of customer acceptance testing, laboratory certification or product demonstration. Second, the listing was filtered for those units

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that were sent to a location under NRC jurisdiction. This narrowed the list from approximately 700 (shipments to locations throughout the world) to approximately 60 units. Third, the Radiation Safety Officer (RSO) directly interviewed personnel from the Sales and Technology departments to better understand the reasons why some devices remained in a given location for a lengthy period of time. MDI determined that approximately 10 of the 60 units were shipped for a purpose other than product demonstration, such as customer acceptance testing or laboratory certification. These steps are discussed in more detail below:

Part 1: Initial Record Search and Review

- The initial record search was done using Oracle. Oracle is the Enterprise Resource Planning (ERP) system used by MDI. It is MDI's system of records. Oracle controls and records:
    - Bills of material (list of all components and procedures used to build MDI's devices);
    - How MDI's vendors are approved;
    - The work order process which corresponds to the way MDI manufactures devices at the Wilmington, Massachusetts facility;
    - Customers' information;
    - All customer purchase orders;
    - All shipments of products/devices (in addition to recording shipping information, all shipping requests must be submitted in Oracle).

  MDI uses an additional report writer program called "Discoverer". This program allows MDI to obtain specific details such as the name, location and address of any given shipment. In other words, *Discoverer* is a tool for accessing specific or detailed information from the Oracle database. This application was used in connection with Oracle to obtain the information contained in Attachment 1.

- MDI assigns an Account number (also known as a "customer number") to each of its customers. All transactions relating to this customer are entered into Oracle by that

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Account number. As part of this practice, there is a specific customer number assigned to MDI fixed asset demonstration units. MDI places all of MDI's fixed asset demonstration units under this number in Oracle, for the purpose of tracking each of those units.

- MDI began its review of the requested product demonstration information by searching Oracle, using the *Discoverer* program. Specifically, MDI ran the following 2 reports using MDI's assigned customer number for its fixed asset demonstration units: (1) a report of units that were shipped from MDI's Wilmington, Massachusetts facility from 2007 to 2010, and (2) a report of units returned to MDI's Wilmington, Massachusetts facility from 2007 to 2010.

- MDI used the information from the 2 Oracle reports to populate an excel spreadsheet. Information for each unit was matched through the use of Sale Order number and the Return Manufacturer Authorization (RMA). The Sale Order number is an internal classification that applies to any order for a device to be shipped, whether for sale, customer acceptance testing, laboratory certification or product demonstration.

Part 2: Filter Records to Identify Units in NRC Jurisdiction Areas (Past or Present)

Once MDI created the spreadsheet covering the approximately 700 units for the purpose of customer testing, laboratory certification or product demonstration, MDI further filtered the data to focus on those units that could have been sent to a location in an NRC jurisdiction.

- MDI first filtered the spreadsheet by units sent to locations within the United States, and then those sent to locations falling within NRC jurisdiction. This narrowed the list from approximately 700 to 60 units that were shipped to locations falling within NRC jurisdiction.

- MDI then began review of documentation to determine which of the 60 units were shipped for the purpose of product demonstrations.

- Through the above process, MDI discovered, as previously mentioned, that past recordkeeping practices did not clearly distinguish between devices shipped for customer acceptance testing, laboratory certification or product demonstration. Therefore, once the spreadsheet of approximately 60 units shipped for the purpose of product demonstrations

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was populated, MDI interviewed personnel and reviewed email communications pertaining to shipments whose records were not clear about the purpose for shipment, to confirm which devices were shipped for product demonstrations.

- After discovering inconsistent recordkeeping practices, the RSO (who was appointed in January 2011) reviewed the current practices and policies to better understand the reasons for such inconsistencies. Based on this review, the RSO determined that the inconsistencies with recordkeeping may have been due, in part, to a past misinterpretation of the regulatory requirements, and a lack of systematic distinction of whether a device is shipped for customer acceptance testing, laboratory certification or product demonstration. Corrective actions have been identified and logged into an internal database called Gensuite. In the past, MDI has used Gensuite to monitor environmental compliance. MDI is currently using Gensuite to track corrective actions addressing nuclear regulatory compliance as well. Corrective actions currently being taken are detailed in Attachment 2.

Part 3: Sales and Technology Personnel Interviews

The RSO interviewed MDI Sales and Technology personnel and managers, in person and over the phone. Based on interview results, and prior review of other documentation, MDI made a reasonable determination of which entries from the filtered report of approximately 60 units were more likely to represent devices shipped to a NRC jurisdiction location for product demonstrations from 2007 to 2010. The information in the attached spreadsheet (Attachment 1) reflects the results of this best faith determination. When MDI could not confirm whether a device was shipped for customer acceptance purposes or for a product demonstration, MDI erred on the conservative side and included the device on the attached spreadsheet as a product demonstration in an NRC jurisdiction location.

Other Issues:

MDI also discovered that from 2007 to 2010, certain devices sent to GE Homeland Protection, Inc.'s (now MDI's) offices in Washington, D.C. may have been transported to neighboring states for additional product demonstrations. MDI has been unable to obtain complete records of such activities, in part because at the time, MDI did not consistently maintain such records. After identifying the inconsistent maintenance of product demonstration records, MDI instituted a

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requirement that a product demonstration request form be systematically submitted to the RSO for each use of a device, including the proposed duration of use and the specific location proposed for a product demonstration. This requirement has been communicated to the workforce by the RSO at department meetings and via e-mail. MDI is also drafting a policy to incorporate this requirement to systematically submit a product demonstration request form for each use of a device, to the RSO. Additionally, beginning in 2011, MDI has reinforced the importance of submitting such requests with the Sales department based on the regulatory requirement to file reciprocity requests with the NRC in order to conduct a product demonstration in a Non-Agreement State or area of exclusive Federal jurisdiction in an Agreement State. MDI is also in the process of reinforcing this message with other MDI departments.

During the NRC visit to our Massachusetts facility on August 4, 2011, MDI provided a preliminary list of 4 product demonstrations held in Washington, D.C.: (1) from 03/14/2008 to 06/12/2008, (2) from 06/09/2008 to 06/12/2008, (3) from 01/13/2010 to 02/03/2010, and (4) from 02/08/2010 to 06/08/2011. Based on further investigation, MDI determined that two of the previously supplied dates should not be included in the target group and as such, were not included on the attached spreadsheet. More specifically, the product demonstrated in Washington, D.C. from 06/09/2008 to 06/12/2008 was a Street Lab Mobile device, which does not contain a sealed source. The product demonstration that occurred from 01/13/2010 to 02/03/2010 took place in New York State (an Agreement State), not Washington, D.C. This demonstration did not occur in an area of exclusive Federal jurisdiction in New York State and thus, does not fall within the NRC's jurisdiction.

Corrective Actions To-Date:

The first key corrective action involved the hiring of me as the RSO. My goal is to instill improved rigor and discipline into the MDI product line as it works within the scope of NRC and Agreement State regulatory requirements. As you can tell from this submittal, MDI has identified numerous incidents where it likely did not follow regulatory requirements in the 2007-2010 timeframe, *i.e.,* filing a Form 241 with the NRC prior to conducting certain demonstrations in NRC jurisdictions. MDI has implemented, and is implementing, numerous corrective actions to prevent recurrence of these findings as summarized in Attachment 2. The MDI Quality

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department is aware of these findings and is currently adjusting its audit/quality activities for the foreseeable future to better ensure the effectiveness of these corrective actions.

We have requested that this response, including the Attachments, be withheld pursuant to 10 C.F.R. § 2.390(a)(4). The appropriate affidavit to support this request pursuant to 10 C.F.R. § 2.390(b) is attached. This response, including the Attachments, contains no new regulatory commitments. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Aric Tillberg
Safety Specialist
Facility RSO Wilmington

Cc. Craig Gordon

AFFIDAVIT

1. My name is Darryl K. Jones and I am Vice President, Global Product Management for Morpho Detection, Inc. ("MDI").

2. The purpose of this affidavit is to support a request for withholding of information being provided to the U.S. Nuclear Regulatory Commission ("NRC") on September 12, 2011, pursuant to 10 C.F.R. § 2.390(b). MDI's September 12, 2011 letter and attachments respond to an NRC request for certain information relating to MDI's compliance with certain NRC reciprocity regulations, but also reveals MDI's business practices regarding its products. I have been delegated the function of reviewing the information that MDI requests be withheld and am authorized to execute this Affidavit on behalf of MDI.

3. MDI requests that the entire response, including Attachments 1 and 2, be withheld from public disclosure as confidential business information. The specified information constitutes confidential commercial information that should be held in confidence by the NRC pursuant to 10 C.F.R. § 2.390(a)(4) because:

a. This information is and has been held in confidence by MDI in that it involves product sales, shipping, demonstrations, volume of business and inventory.

b. This information is of a type that is customarily held in confidence by MDI, as stated above, and there is a rational basis for doing so.

c. This information is being transmitted to the NRC in confidence and is marked "Confidential" and is treated as "confidential" within MDI.

d. This information is not available in public sources and could not be gathered readily from other publicly available information.

e. Public disclosure of this information would create substantial harm to the competitive position of MDI because it would reveal valuable business information regarding the capacity of MDI to provide devices containing sealed sources, would reveal sales techniques and associated territories, and reveal strategic areas of focus by MDI regarding the sales of its products. The public disclosure of the specified information would provide MDI's competitors with free access to MDI's confidential business information, and thereby would likely cause substantial financial harm to MDI.

4. Accordingly, MDI requests that its September 12, 2011 letter, including Attachments 1 and 2, which provide NRC-requested information be withheld from public disclosure, in its entirety, pursuant to 10 C.F.R. § 2.390(a)(4).

5. The foregoing statements are true and correct to the best of my knowledge, information, and belief.

Darryl K. Jones

Subscribed and sworn before me, a Notary Public, in and for the State of Massachusetts and County of Middlesex, this 12 day of September, 2011.

Notary Public

My Commission Expires: February 17, 2017
Date

JODI MORRIS
Notary Public
Commonwealth of Massachusetts
My Commission Expires
February 17, 2017

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ATTACHMENT 2 – SUMMARY OF CORRECTIVE ACTIONS

In the March/April 2011 timeframe, Morpho Detection Inc. (MDI) began a review of the organization's radiation work practices and policies. A number of improvement areas were identified, as described below. Once the scope of issues was better understood, corresponding corrective actions were identified in the June/July 2011 timeframe. A description of the improvement areas and corresponding corrective actions follows:

1. MDI determined that additional requirements were needed for shipments of units from the Wilmington, Massachusetts facility for the purpose of product demonstrations, based in part, on potential past misinterpretation of NRC reciprocity regulations.

    a. Interim Corrective Action – while reviewing the NRC reciprocity requirements, MDI placed a hold on all product demonstrations until MDI had complete confidence in the organization's capacity to fully comply with the applicable NRC regulatory requirements. All relevant MDI departments were notified of the hold on product demonstrations, including departments such as the Customer Depot that calibrates the units, Customer Service which submits paperwork for shipments, and the Shipping department.

    b. Corrective Action – The Radiation Safety Officer (RSO) communicated a new requirement to the Sales department via email and meetings that units shipped to one location for a product demonstration must always be returned to the Wilmington facility before being sent to another product demonstration location. This requirement has facilitated a renewed understanding of the NRC reciprocity regulations and has enhanced the RSO's ability to track each device shipped for product demonstration purposes.

2. MDI determined that the product demonstration request process whereby Sales personnel submit requests for approval of product demonstrations needed to be formalized.

    a. Corrective Actions – MDI instituted a requirement that a product demonstration request form be systematically submitted to the RSO for each use of a device, including the proposed duration of use and the specific location proposed for a product demonstration. This requirement has been communicated to the workforce by the RSO at department meetings and via e-mail. MDI is also

drafting a policy to incorporate this requirement to systematically submit a product demonstration request form for each use of a device, to the RSO.

3. MDI determined that it had not maintained a clear distinction between units shipped to a location for a product demonstration or for other purposes, such as customer acceptance testing or laboratory certification. As explained in the cover letter, MDI assigned a specific Account number to MDI's fixed asset demonstration units, which was intended to indicate a shipment, or return, for the purpose of a product demonstration. However, during MDI's self-assessment, MDI determined that this number had also been used for shipments of devices for other purposes, such as customer acceptance testing, laboratory certification, and distribution to customers during maintenance of a different customer device (*i.e.,* loaners).

    a. Corrective Action – MDI is in the process of having specific numbers issued for shipments of devices for each of these other purposes (*i.e.,* customer acceptance testing, laboratory certification and loaners) to ensure the appropriate regulatory requirements are met for each use of MDI's devices.

4. MDI determined that improvements in maintenance and accessibility of records was needed.

    a. Corrective Action – MDI is in the process of determining how best to improve maintenance and accessibility of records.

5. In reviewing historical documents relating to the shipment and receipt of units, it became apparent that MDI needed to broaden the types of documents required in a shipment record to ensure sufficient information regarding the device, such as the purpose for which it was shipped, is maintained.

    a. Corrective Action – MDI has instituted a requirement that all supporting documents for a shipment be attached to, and maintained with, any shipment order.

In addition to the corrective actions discussed above, MDI is in the process of determining how best to adjust its processes to ensure compliance with both NRC and Agreement State radiological regulatory requirements. MDI has entered a corrective action in Gensuite for the Quality department to schedule and perform radiological regulatory compliance audits in 2011

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and 2012. MDI is dedicated to improving the programs, policies, and processes to ensure that they comply, in every aspect, with all applicable NRC and Agreement State regulatory requirements.