

EXECUTIVE SUMMARY

Bruker Detection Corporation
NRC Inspection Report Nos. 03037315/2012-001 and 15000020/2013-001

Bruker Detection Corporation (BDC) is a manufacturer of explosives and chemical detection systems used in airport security, border control and by first responders in emergencies. The company is authorized by the NRC to distribute ion mobility spectrometry devices containing a maximum quantity of 2.7 millicuries of Nickel-63, a licensed material, per device. The NRC license does not authorize possession or use of licensed material. BDC also holds a specific license issued by the Commonwealth of Massachusetts (Massachusetts) for possession and use of radioactive material, including use of the devices for promotional purposes at temporary jobsites throughout Massachusetts, except for areas under exclusive Federal jurisdiction or regulated by other Agreement States.

On August 28, 2012, NRC Region I inspected the BDC Billerica, Massachusetts facility and reviewed the licensee's distribution activities of exempt items authorized by NRC License No. 20-32465-02E and reciprocity activities authorized by a General License in 10 CFR 150.20. Based on interviews with the Radiation Safety Officer (RSO) and Senior Electrical Engineer, it was determined that the licensee had performed demonstrations of devices containing licensed material at 18 temporary jobsites not authorized by Massachusetts License No. 38-0257. One of the 18 temporary jobsites was located at Indianapolis, Indiana, an area under NRC jurisdiction, from April 16 through 21, 2012. The other 17 temporary jobsites were located in Agreement States, i.e., Colorado, Florida (2), Illinois, Louisiana (2), Maryland (4), Nebraska, Nevada, Oregon, Pennsylvania, Texas, Virginia, and Washington, between August 1, 2011 and November 2, 2012.

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, for one occasion during the period April 16, 2012 through April 21, 2012, for work performed in Indianapolis, Indiana, an area under NRC jurisdiction (See Section III).

In response to this issue, BDC indicated that they will contact a representative of any Agreement State in which a product demonstration is planned to determine any reciprocity requirements, and that reciprocity would be filed with the NRC prior to a trade show being performed in areas under NRC jurisdiction. Training will be provided to sales agents in reciprocity requirements in order to provide the RSO with advance notice of trade shows not conducted within the jurisdiction of the Commonwealth of Massachusetts.

REPORT DETAILS

1. **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 distribution of products as authorized by the NRC License No. 20-32465-02E and the filing of reciprocity requests for work to be performed in NRC jurisdiction as authorized by a general license specified in 10 CFR 150.20.

b. Observations and Findings

BDC is a manufacturer of explosive and chemical detection systems used in airport security, border control, and by first responders. The company is authorized by NRC to distribute ion mobility spectrometer devices containing a maximum quantity of 2.7 millicuries of Nickel-63 in foils per device. The NRC license does not authorize possession or use of licensed material. BDC 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 distribution of exempt devices, transfer and use of the devices at trade shows for product demonstrations at various locations throughout the U.S. (including Agreement States). Review of records, by the inspector, verified that BDC used licensed material for product demonstrations and related activities in NRC and Agreement State jurisdiction.

c. Conclusions

No violations were identified.

2. **Management Oversight of the Program**

a. Inspection Scope (IP 87126, Section 02.07)

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

b. Observations and Findings

The licensee's Radiation Safety Officer (RSO) reports to the Vice President of Operations. The RSO is responsible for oversight of NRC activities at the Massachusetts (MA) site as they relate to implementation of the radiation safety program, with emphasis on distribution and use of product devices containing radioactive material. The RSO receives some assistance from the senior electrical engineer in preparing the devices for transportation to and from temporary jobsites. Specifically, the engineer packs and

unpacks the devices at trade shows where the licensee performs product demonstrations. Product demonstrations were coordinated between the engineering department, of whom the RSO was a part, and staff working in the areas of sales.

c. Conclusions

No violations were identified.

3. Material Receipt, Use, Transfer, and Control

a. Inspection Scope (IP 87126 02.03)

The inspector reviewed the licensee's program for radioactive material use, transfer, and control during demonstration activities at temporary job sites; and the transfer of radioactive material under the exempt distribution license to a specific licensee.

b. Observations and Findings

The inspector was informed by the licensee that devices are manufactured overseas and distributed from the Billerica, MA facility. An examination of the devices located at the licensee's Billerica facility by the inspector determined that the devices were made in accordance with the Sealed Source and Device (SS&D) Registry and were labeled appropriately. Exempt distribution reports were filed annually as required by 10 CFR 32.29(c).

The inspector performed an inspection of the licensee's activities under the authorization of a general license as specified in 10 CFR 150.20 for reciprocity. From discussion with the licensee's RSO, the licensee had been informed by a consultant during an independent audit of the licensee's program that a representative of the NRC might have questions about reciprocity during the next inspection. The RSO informed the inspector that subsequent to the independent audit he had reviewed the regulations pertaining to reciprocity in 10 CFR 150 and the NRC exempt distribution license and mistakenly came to the conclusion that the licensee was exempt from regulations. The licensee was informed by the inspector that while the devices were in the possession of the licensee, the devices were specifically-licensed under the license issued by the Commonwealth of Massachusetts and only became exempt after the devices were distributed to an end user under the exempt distribution license issued by the NRC. The inspector informed the licensee that the requirement for filing reciprocity could be found in License Condition 10.B. of the license issued by the Commonwealth. The RSO, once informed that the regulations pertaining to reciprocity did apply, committed to contacting state representatives of Agreement States at which trade show demonstrations were scheduled to determine the state's requirements and that there were no demonstrations currently scheduled for areas within NRC jurisdiction. The Vice President of Operations also committed to providing a report to the NRC which would include all known trade shows conducted outside of the Commonwealth of Massachusetts after the licensee reviewed available records and interviewed individuals involved in the demonstrations as well as the sale of devices. The RSO stated that the licensee conducted between 10 and 15 trade show demonstrations per year.

On September 5, 2012, the inspector spoke to the licensee regarding the exempt distribution report dated December 31, 2011, which indicated that four microRAID devices had been distributed by the licensee in 2011. The inspector informed the licensee that, prior to December 31, 2011; the devices were not part of the SS&D Registry description of what constituted the "RAID Series" which was necessary for distribution of the devices. The RSO stated that he had listed the devices as being distributed as exempt devices when the devices had been transferred to a specific licensee for evaluation. The inspector contacted the RSO of the licensee that had received the devices and confirmed that the company was a broad scope licensee located in an Agreement State and provided information verifying that the licensee was authorized to receive the devices.

On September 25, 2012, the licensee submitted to the inspector by electronic mail a report listing the demonstrations conducted with devices outside the jurisdiction of the Commonwealth of Massachusetts. A review of the report by the inspector determined that between the dates of August 1, 2011, and November 2, 2012, the licensee conducted or planned to conduct 18 demonstrations of devices at trade shows across the country. One of the trade shows was located in Indianapolis, Indiana, a state under NRC jurisdiction, from April 16, 2012, to April 21, 2012. The other 17 temporary jobsites were located in Agreement States, i.e., Colorado, Florida (2), Illinois, Louisiana (2), Maryland (4), Nebraska, Nevada, Oregon, Pennsylvania, Texas, Virginia, and Washington, between August 1, 2011 and November 2, 2012. After reviewing the report, the inspector contacted the RSO who informed the inspector that research for temporary jobsites prior to August 2011 was inconclusive as records were not kept and sales agents did not recall information in sufficient detail.

On January 10, 2013, the inspector called the licensee to determine who was responsible for packaging and shipping the devices at demonstrations and to conduct an exit meeting. The RSO indicated that either he or his associate went to the demonstrations to package the devices for transport.

Based on the inspection and review of the licensee's report received September 25, 2012, the inspector determined that an apparent violation of 10 CFR 150.20(b)(1) occurred. Specifically, the licensee did not file for reciprocity, as required, on one occasion for work at a temporary jobsite in NRC jurisdiction between April 16, 2012, and April 21, 2012.

In response to this issue, BDC conducted a review of past and future work at trade shows associated with their reciprocity program. This resulted in the initiation of interim corrective actions and proposed long-term corrective actions. The interim corrective actions included contacting representatives of Agreement States at which trade show demonstrations were to be conducted. Proposed corrective actions included maintaining a list of what each Agreement State required under its reciprocity regulations and filing with the NRC immediately upon determining that a trade show demonstration is scheduled for a site under NRC jurisdiction and the training of sales agents in reciprocity requirements.

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). BDC, which is authorized for possession and use of radioactive material under a Massachusetts Agreement State license, did not submit the required forms for reciprocity prior to working in NRC jurisdiction between April 16 through 21, 2012.

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.

4. Training of Workers

a. Inspection Scope (IP87126 02.06)

The inspector interviewed personnel and reviewed training records for individuals involved in packaging of devices containing radioactive material for transport.

b. Observations and Findings

The inspector interviewed the RSO and determined that he and the senior electrical engineer were the only individuals involved in receiving and packaging the devices containing radioactive material. The licensee's radiation safety program training included HAZMAT training which is provided annually. These two individuals packaged the devices when the devices were to be transported to a trade show under a general license or distributed to an end user under the exempt distribution license. On January 10, 2013, the inspector spoke with the RSO and confirmed that either the RSO or the senior electrical engineer went to the trade show to unpack devices for use by the sales agents and repackage the devices for shipment back to the Billerica, MA facility.

Based on the inspection, the licensee decided to provide radiation safety and HAZMAT training to sales agents in case a sales agent might need to package the devices for transport at future trade shows. Also, the RSO stated that he would provide training in reciprocity requirements to the sales agents so the RSO could ensure that the NRC or an Agreement State representative was notified of the dates when a trade show demonstration was to be performed within its jurisdiction.

c. Conclusions

No violations were identified.

5. Exit Meeting

On August 28, 2012, and January 10, 2013, the inspector contacted the licensee's Vice President of Operations and presented the results of the inspection. The licensee's Vice President was informed that an apparent violation of NRC requirements had been identified.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Brian Turk, Vice President of Operations
Mark Beland Senior Electronics Engineer
George Gleason, Radiation Safety Officer

LIST OF ACRONYMS USED

BDC – Bruker Detection Corporation
Commercial and R&D Branch – Commercial and Research and Development Branch
HAZMAT – Hazardous Materials
IP – Inspection Procedures
MA – Massachusetts
NRC – Nuclear Regulatory Commission
RSO – Radiation Safety Officer
SS&D Registry – Sealed Source and Device Registry
U.S. – United States of America