



August 21 2017

U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Rd, Suite 210  
Lisle, IL 60532

RE: Response to the Apparent Violation in Inspection Report No. 03036973/2017004(DNMS);  
EA-17-096, RAM License No. 34-29200-01MD, Cardinal Health, St Louis, MO.

Dear John Giessner

This letter is in response to the U.S. Nuclear Regulatory Commission (NRC) letter dated July 25, 2017 regarding the routine inspection of the St. Louis, MO Cardinal Health Nuclear Pharmacy Services (hereafter Cardinal Health) nuclear pharmacy. The on-site inspection was conducted on June 2, 2017, and additional review by NRC occurred through July 6, 2017. Cardinal Health's response to the inspection findings are below.

In Section 2.2 of the NRC's inspection report it is stated:

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The licensee's apparent failure to secure from unauthorized removal or access licensed materials that were stored in an unrestricted area is an apparent violation of 10 CFR 20.1801

**Cardinal Health's response:**

On February 28<sup>th</sup>, 2017, a Cardinal Health driver discovered that the facility vestibule exterior door could be opened from the outside. The vestibule door had the appearance of being closed and locked, but could be opened without using the proper means of entry. The vestibule door was in this unsecured condition from approximately 5:30 pm until 10:30 pm on February 28<sup>th</sup>, 2017. During this time frame two Mo-99/Tc-99m generators were delivered by Associated Couriers and sat inside the vestibule during this period. Once found, this issue was immediately self-identified, documented, and prompt corrective actions implemented. The security alarm on the vestibule door was active and indicated that the licensed material within the vestibule remained undisturbed during this period.

**Root Cause:**

The unsecure condition of the vestibule door was directly attributed to a malfunction in the electronic solenoid mechanism that allows for the door to be locked. This directly resulted in the licensed material being held within the vestibule in an unsecured state that did not prevent unauthorized access or removal during that time frame. As noted previously, the facility's alarm system remained fully operational and would have alarmed had an unauthorized entry been made.

**Corrective Steps Taken:**

The licensed material within the vestibule was secured that same day and prior to the discovery of the failed electronic solenoid mechanism. Following this discovery, Cardinal Health contacted a company to repair the lock and by the morning of the next business day, March 1, 2017, the vestibule door lock's faulty electronic solenoid mechanism was repaired. As of March 1, 2017, the vestibule was again secure against unauthorized access.

To help mitigate future unexpected failures of the electronic solenoid mechanism, this facility instituted a procedure to periodically verify that the electronic solenoid mechanism in the lock was clean. Additionally, this facility implemented a procedure that requires closing personnel to physically test the exterior doors prior to leaving to verify the integrity of the locking mechanism and ensure that the exterior doors are latched and remain closed.

On July 18<sup>th</sup>, 2017, the facility moved the interior door of the vestibule deeper into the facility to remove packages from view by outside individuals as a method of improving passive security.

The facility RSO has developed a Memorandum of Understanding with Associated Couriers that requires their drivers test the exterior vestibule door for security prior to leaving and notify the after-hours contact (a Cardinal Health Authorized Nuclear Pharmacist) should a problem with the door be observed. If the courier tests the door and it cannot be locked, the after-hours contact will tell the courier to maintain constant surveillance of the licensed material until the ANP arrives.

Full compliance was achieved on February 28, 2017, when the licensed material was secured from unauthorized access within Cardinal Health's secure restricted area. Normal after-hours delivery processes were able to resume on the next day (March 1, 2017), following repair of the electronic solenoid mechanism on the door lock. The security alarm on the exterior door indicated that while the licensed material was unsecured, material remained undisturbed during the duration of this incident. Facility security is taken very seriously by Cardinal Health, as is compliance with all applicable Title 10, Code of Federal Regulations requirements. This incident was self-identified internally, was self-corrected and was addressed immediately and promptly.

Should you have any further questions, please contact me at 614-757-9586.

Sincerely,



Glenn P. Sullivan  
Corporate Radiation Safety Officer  
Director, Health Physics  
Quality and Regulatory Department  
Nuclear Pharmacy Services

/tc

Encl: Memorandum of Understanding

CC: NRC Consolidated License File (3)  
Location 7030 License File (3)  
Earl Robertson, RSO

# Memorandum of Understanding



CardinalHealth

Cardinal Health  
Nuclear Pharmacy Services  
1909 Beltway DR.  
Overland, MO 63114

August 17, 2017

Associated Couriers Inc.

RE: Regulatory Concern on Shipment Dated February 27, 2017  
Memorandum of Understanding – Delivery Security

Dear Associated Couriers, Inc. Manager:

The following is a report detailing a regulatory compliance issue that was discovered with regard to delivery of radioactive materials, following business hours at the address above on Monday, February 27<sup>th</sup>, 2017. A Cardinal Health Driver discovered on February 28, 2017 that the lock on the facility vestibule door had an electronic solenoid mechanism malfunction. The electronic solenoid mechanism was in apparent malfunction from approximately 5:30 pm until 10:30 pm where the exterior door could be opened without key from the outside. There were two Mo-99 / Tc-99m generators delivered by Associated Couriers during those hours, inside of the vestibule that remained unsecured during this period. The failure of the electronic solenoid mechanism and subsequent failure to notice this by your employee resulted in licensed material existing in an unsecured state that did not prevent unauthorized access or removal.

Per our contract courier agreement it is expected that each driver working in the service of Associated Couriers Inc. be trained in the procedures of maintaining the security of radioactive materials. Each driver should also have a complete understanding of the importance of maintaining the security of radioactive materials. We request your drivers test the exterior vestibule door for security prior to leaving and notifying the after hours contact (an Authorized Nuclear Pharmacist) should a problem with the door be observed. If the driver tests the door and it cannot be locked, the afterhours contact will tell the courier to maintain constant surveillance of the licensed material until the ANP arrives to take control of the delivery.

In order to continue transporting packages for Cardinal Health, Associated Couriers Inc. must follow these requirements set forth by the contract courier agreement. Cardinal Health requests that Associated Couriers addresses the item described above and sign to acknowledge receipt of this notice.

If you should have any questions, please contact Earl Robertson, 314.428.2906.

Sincerely,

Earl Robertson PharmD, BCNP  
Radiation Safety Officer  
314.428.2906 dir | 314.428.1336 fax  
CC: Tyler Cantrell Q&R, Glenn Sullivan, CRSO

Courier Signature upon receipt: \_\_\_\_\_

Date: \_\_\_\_\_