UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 25, 2017

EA-17-096

Mr. Glenn Sullivan
Radiation Safety Officer
Cardinal Health Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036973/2017004(DNMS) – CARDINAL HEALTH NUCLEAR PHARMACY SERVICES

Dear Mr. Sullivan:

On June 2, 2017 an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your St. Louis, Missouri facility, with continued in-office review through July 6, 2017. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included receipt and review of information that was unavailable during the onsite inspection including, in part, the cause of a vestibule door lock malfunction. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the licensee's apparent failure to secure licensed material during storage, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. Mr. Robert Gattone of my staff discussed the circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action with you at the inspection exit meeting on July 6, 2017.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Aaron T. McCraw at 630-829-9650 or aaron.mccraw@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03036973/2017004(DNMS); EA-17-096," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the PEC. The PEC will be open to public observation.

Because your facility has not been the subject of escalated enforcement action within the last two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Please be advised that the number and characterization of the apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Gattone if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-36973
License No. 34-29200-01MD

Enclosure:
IR No. 03036973/2017004(DNMS)
w/Attachment: Supplemental Information

cc w/encl: Mr. Earl Robertson, St. Louis Facility RSO
State of Missouri
State of Ohio

Letter to Mr. Glenn Sullivan from John Giessner, dated July 25, 2017

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036973/2017004(DNMS) – CARDINAL HEALTH NUCLEAR PHARMACY SERVICES

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-36973
License No.	34-29200-01MD
Report No.	03036973/2017004(DNMS)
EA No.	EA-17-096
Licensee:	Cardinal Health Nuclear Pharmacy Services
Facility:	1909 Beltway Dr. St. Louis, Missouri
Inspection Dates:	June 2, 2017 with continued in-office review through July 6, 2017.
Exit Meeting Date:	July 6, 2017
Inspector:	Robert G. Gattone, Jr. Senior Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Cardinal Health Nuclear Pharmacy Services
NRC Inspection Report 03036973/2017004(DNMS)

On June 2, 2017 an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the licensee's St. Louis, Missouri radiopharmacy, with continued in-office review through July 6, 2017. The purpose of the inspection was to review activities performed under the NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included receipt and review of information that was unavailable during the onsite inspection including, in part, the cause of a vestibule door lock malfunction.

The inspector reviewed the licensee's security of licensed material. The inspector noted that on February 28, 2017, a licensee driver identified that two molybdenum-99 (Mo-99)/technetium-99m (Tc-99m) generators were not secured to prevent unauthorized access or removal. The generators were in a vestibule that is used for delivery. Specifically, the driver identified that the vestibule exterior door was closed and unlocked. The two generators totaled 9,706 millicuries (mCi) of Mo-99. The material was unsecured from approximately 5:30 pm until 10:30 pm, and there were no employees on site at that time. This incident is an apparent violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801 concerning the licensee's failure to secure licensed material during storage. The licensee implemented immediate and long-term corrective actions to prevent a similar violation.

The inspector reviewed the licensee's safe use of licensed material, including use of gloves, lab coat, mask, whole body and extremity dosimeters, booties, and shielding when conducting Tc-99m labeled radiopharmaceuticals kit preparations and dispensing of unit dosages. The inspector observed a demonstration of how a licensee staff member compounded iodine-131 (I-131) capsules in a safe manner. The inspector noted that internal and external radiation doses to licensee staff and members of the public were below applicable NRC regulatory requirements limits.

Based on the inspector's review of selected transportation records including shipping papers and HAZMAT training, interviews of applicable staff members, and observation of a demonstration of how a licensee staff member would respond to a transportation scenario involving a radioactive spill, the licensee transported licensed material as required.

REPORT DETAILS

1.0 Program Overview and Inspection History

Cardinal Health Nuclear Pharmacy Services is authorized under NRC Materials License No. 34-29200-01MD to use byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days not to exceed 5 curies per facility for preparation and distribution of radioactive drugs, including compounding I-131 and redistribution of used and unused Mo-99/Tc-99m generators to authorized recipients. The licensee has four main runs between 2:30 am and 10:00 am.

During the last 2 years, the licensee was inspected by the NRC at several authorized locations of use, including Indianapolis, Indiana; Stamford, Connecticut; Highland, Indiana; Dublin, Ohio; Springfield, Missouri; Kansas City, Missouri; Jenison, Missouri; Fort Wayne, Indiana; and Kansa City, Missouri. The August 2016 Dublin, Ohio inspection resulted in a cited Severity Level IV violation of 10 CFR 30.41 (unauthorized transfer of licensed material). The May 2015 Kansas City, Missouri inspection resulted in a cited Severity Level IV violation of 10 CFR 20.1802 (failure to secure licensed material that was not in storage). The other aforementioned inspections resulted in no identification of violations of NRC regulatory requirements. As such the licensee was not the subject of escalated enforcement during the last 2 inspection cycles.

2.0 Security of Licensed Material

2.1 Inspection Scope

The inspector reviewed the licensee's security of licensed material by touring the licensee's facility, interviewing selected licensee staff members, and observing a licensee driver demonstrate how he had secured licensed material in a vehicle before he left the vehicle with licensed material inside.

2.2 Observations and Findings

The inspector noted that licensed material was properly secured in vehicles when the driver was not by the vehicle. In addition, the inspector observed that a security system sensor and a motion sensor were used to detect and alarm in the event of unauthorized access through an exterior door. The inspector noted that the licensee had no loss or theft of licensed material since the last inspection.

On February 28, 2017, a licensee driver identified that two Mo-99/Tc-99m generators were not secured to prevent unauthorized access or removal. The generators were in a vestibule that is used for delivery. Specifically, the driver identified that the vestibule exterior door was closed and unlocked. The vestibule exterior door lock's electronic solenoid mechanism malfunctioned for about five hours resulting in an unlocked state such that unauthorized individuals could have opened the door without a key to enter the vestibule from the outdoors. The two generators totaled 9,706 mCi of Mo-99. The material was unsecured from approximately 5:30 pm until 10:30 pm, and there were no employees on site at that time. The inspector noted that the vestibule exterior door was equipped to send a security alarm if during those five hours an unauthorized person would have opened the door without a key.

During after business hours there are two secure doors one must get past from the vestibule in order to access licensed material inside of the radiopharmacy. There is an additional door at the end of the vestibule that is dead bolted from the inside which is equipped with an alarm sensor. In addition, the restricted area is dead bolted at night with only authorized users having a key (i.e., 5 individuals). There is a motion sensor in the hall and in the restricted area attached to the alarm system. Based on review of packing slips and supplier order/receipt information, the two generators were accounted for and they were intact upon receipt.

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.

The licensee had the vestibule exterior door lock's electronic solenoid mechanism malfunction fixed during the morning of March 1, 2017. The vestibule exterior door lock manufacturer informed the licensee that the lock's electronic solenoid mechanism requires no preventive maintenance. In addition, the manufacturer recommended that the licensee periodically verify that the lock's electronic solenoid mechanism is clean, and to not lubricate the mechanism. The licensee implemented those recommendations.

In addition, the licensee plans to open up the vestibule area and move the interior door deeper into the facility to remove packages from view by outside individuals to improve passive security. The licensee will revise applicable procedures to require closing personnel to test exit doors prior to leaving in order to ensure they are latched and remain closed. The licensee's RSO will develop a Memorandum of Understanding with Associated Couriers related to their drivers testing the door for security prior to leaving and notifying the afterhours contact (authorized nuclear pharmacist (ANP)) if a problem with the door is observed, such that if the courier tests the door and it cannot be locked, the afterhours contact will tell the courier to maintain constant surveillance of the licensed material to prevent unauthorized access until the ANP arrives at the radiopharmacy.

2.3 Conclusions

The inspector noted that the licensee identified an apparent violation of 10 CFR 20.1801 involving failure to secure from unauthorized removal or access licensed materials that were stored in an unrestricted area. The licensee implemented immediate and long-term corrective actions to prevent a similar violation.

3.0 Safe Use of Licensed Material

3.1 Inspection Scope

The inspector reviewed the licensee's safe use of licensed material by touring the licensee's facility, and observing an ANP conduct Tc-99m labeled radiopharmaceutical kit preparations and dispensing of unit dosages. In addition, the inspector observed other selected staff members who were working with licensed material during preparation for a run to licensee clients. The inspector also reviewed selected internal radiation protection program audit records.

3.2 Observations and Findings

The inspector observed that an ANP used gloves, lab coat, mask, whole body and extremity dosimeters, booties, and shielding when he conducted Tc-99m labeled radiopharmaceuticals kit preparations and dispensing of unit dosages.

The inspector observed a pharmacy technician (PT) make a Tc-99m bulk vial. The technician used proper personal protection equipment (PPE), remote handling tools, vial shields, and dosimeter badges. In addition the inspector used an NRC owned, calibrated survey instrument to measure 0.05 milliRoentgen per hour (mR/hr) near the pharmacy technician's waist when he was preparing a vial of Tc-99m labeled macro aggregated albumin. The inspector measured a maximum of 0.4 mR/hr at selected surfaces in the unit dosage preparation area. The inspector observed the PT demonstrate how he would respond to a radioactive spill scenario posed by the inspector.

The inspector observed another PT demonstrate how he had compounded I-131 capsules. The PT used PPE, dosimeter badges, shielding, and remote handling tools.

The inspector observed a licensee staff member wrapping and packing unit dosages for delivery. The inspector noted that the individual conducted removable contamination radiation surveys on the unit dosages' shields and the individual knew how to respond if the survey result was above the action level. In addition, the individual affixed tamper-proof seals on the unit dosages.

The inspector observed a dispatcher loading unit dosages into Type A packages. The dispatcher also conducted radiation surveys of the packages that were marked and labeled as required. The dispatcher was aware of the ambient exposure rate limits for White I, Yellow II, and Yellow III labeled packages and he knew how to respond to survey results that exceed the labels' limits.

Based on the licensee's dosimetry records, the highest annual whole body and extremity doses for radiation workers from 2014 through March 31, 2017, were 503 millirem and 21,160 millirem, respectively. In addition, the inspector reviewed selected bioassay records and the results were of no concern. The inspector observed that the licensee strategically affixed dosimeters as a means of showing compliance with public dose limits.

The licensee did not have any overexposures, loss, theft, flood, or fire involving licensed material since 2014.

The inspector reviewed selected air sampling records for 2015 through June 1, 2017, and noted that the licensee's air effluent was less than the constraint on air emissions per 10 CFR 20.1101(d).

The inspector observed that the licensee's facility remodeling was about 90 percent finished, and the remaining work was primarily cosmetic. The inspector reviewed selected radiation safety training records for construction workers who remodeled the radiopharmacy. The inspector observed that the remodeled facility was as per the diagram.

The inspector observed that selected survey instruments were calibrated as required.

The inspector observed selected radiation protection program audit records and determined that the audits were as required.

3.3 Conclusions

The licensee implemented radiation safety procedures to reduce radiation exposure to licensee staff and members of the public.

4.0 Transportation of Licensed Material

4.1 Inspection Scope

The inspector reviewed transportation of licensed material by observing transportation activities, interviewing selected staff, and observing selected staff demonstrate how transportation was conducted.

4.2 The inspector reviewed a shipping paper and noted that the licensee used a company for response assistance in the event of a transportation accident involving licensed material. The inspector called the emergency phone number on the shipping paper and asked questions for the individual who answered the call. The inspector noted that the individual knew how to respond to a transportation accident involving a spill of licensed material scenario posed by the inspector.

The inspector observed a licensee driver wearing his dosimeter badges. The driver loaded packages of licensed material into a vehicle such that the packages were blocked and braced as required. The inspector observed the driver demonstrate how he secured licensed material in the vehicle when he was not near the vehicle. In addition, the driver demonstrated how he would respond to a transportation accident resulting in a radioactive spill based on a scenario posed by the inspector.

The inspector used an NRC owned, calibrated survey instrument to conduct independent ambient exposure rate surveys, including selected surfaces of a White I labeled package that was prepared for delivery, and the highest result was 0.02 mR/hr.

The inspector reviewed selected HAZMAT training records and noted that hazmat training was as required.

5.0 Exit Meeting Summary

The licensee implemented actions for safe transportation of licensed material.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONNEL CONTACTED

Dave Cedeck, Licensee Driver
Steve Collier, Radiopharmacy Technician
Scott Early, ANP
Dwayne English, Dispatcher
Tom Pagel, Radiopharmacy Technician
Earl Robertson, St. Louis Facility RSO
#Glenn Sullivan, RSO

Attended exit meeting on July 6, 2017.

INSPECTION PROCEDURES USED

87127: Radiopharmacy Programs