



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 14, 2017

EA-17-096

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

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

Dear Mr. Sullivan:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 2, 2017, 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. During the inspection, an apparent violation of NRC requirements was identified. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you during a telephone exit meeting on July 6, 2017. Details regarding the apparent violation were provided in NRC Inspection Report No. 03036973/2017004(DNMS), dated January 19, 2017. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML17206A439. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter, dated August 21, 2017, (ML17233A352) you provided a response to the apparent violation.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. The violation involved the failure to secure radioactive material from unauthorized removal or access as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1801. Specifically, on February 28, 2017, two molybdenum-99/technetium-99m generators were unsecured in your St. Louis Missouri facility's vestibule, because the vestibule's exterior door was unlocked due to a malfunction of the lock's electronic solenoid mechanism.

The failure to secure two molybdenum-99/technetium-99m generators is of safety significance to the NRC because of the potential for unauthorized individuals to gain control of the radioactive material, which could result in an unintended exposure to the public.

Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III. In accordance with the Enforcement Policy, a base civil penalty in the amount of \$7,000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that *Corrective Action* credit was warranted due to the following corrective actions: (1) securing the radioactive material that was in the vestibule; (2) having the electronic solenoid mechanism repaired; (3) periodically verifying that the electronic solenoid mechanism was clean; (4) requiring 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; and (5) developing a memorandum of understanding with the courier's drivers to test the exterior vestibule door to ensure it is locked and to notify pharmacy personnel should a problem occur with the door's locking mechanism.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03036973/2017004(DNMS) and your letter, dated August 21, 2017. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of

information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA/

Cynthia D. Pederson
Regional Administrator

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

Enclosure:
Notice of Violation

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

Letter to Glenn Sullivan from Cynthia D. Pederson dated September 14, 2017.

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

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NOTICE OF VIOLATION

Cardinal Health Nuclear Pharmacy Services
Dublin, Ohio

Docket No. 030-36973
License No. 34-29200-01MD
EA-17-096

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 2, 2017, with continued in-office review through July 6, 2017, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on February 28, 2017, the licensee did not secure from unauthorized removal or access to 9.7 Curies of molybdenum-99 located in a vestibule, that was an unrestricted area. Specifically, two molybdenum-99/technetium-99m generators were not secured in the vestibule, because the vestibule exterior door was unlocked due to a malfunction of the lock's electronic solenoid mechanism.

This is a Severity Level III violation (Section 6.7).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03036973/2017004(DNMS) and your letter, dated August 21, 2017. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-17-096)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will

Enclosure

G. Sullivan

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create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 14th day of September 2017