



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 20, 2018

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

SUBJECT: NRC REPORT NO. 03036973/2017006(DNMS) AND NOTICE OF VIOLATION –
CARDINAL HEALTH

Dear Mr. Sullivan:

From October 24, 2017, through January 31, 2018, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an in-office review of the circumstances surrounding the remodeling of your nuclear pharmacy facilities in Princeton, West Virginia, and East Hartford, Connecticut. The NRC initiated this review after becoming aware that these facilities were remodeled without first receiving written approval from the NRC. The in-office review included a review of your letter dated November 6, 2017, requesting a license amendment and your letter dated January 2, 2018, providing corrective actions for the violation. Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with you on February 15, 2018, to discuss the in-office review findings. This letter presents the results of the in-office review.

During this in-office review, 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.

Based on the results of the in-office review, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated 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 violation concerned the failure to maintain facilities under your license as approved by the NRC, in that you remodeled two nuclear pharmacy facilities without first receiving written approval from the NRC for the alterations. While you stated that you believe that the amendment request was mailed in 2014, the NRC has no record of receiving it. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because NRC staff identified it.

The inspector determined that the root cause of the violation was a lack of attention to detail in tracking amendment requests. In particular, you did not verify receipt of the NRC's approval in writing before beginning the remodeling of the two facilities. As corrective actions to restore compliance and to prevent recurrence, you submitted a letter dated November 6, 2017, requesting retroactive authorization to remodel the facilities. In your letter dated January 2, 2018, you committed to track future remodels, including dates in which facility diagrams are approved as well as when final approval is given by the NRC. You further

committed that no vendors will be contacted to initiate construction and no movement will be allowed until written approval from the NRC is received. Compliance with the terms of your license was restored on January 31, 2018, when the NRC issued Amendment No. 55 to your license retroactively authorizing the remodeling of your facilities.

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 this letter. Therefore, you are not required to respond to this letter unless the description herein 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 Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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. Warren if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure:
Notice of Violation

cc w/encl: State of Ohio

Letter to Glenn Sullivan from Aaron McCraw dated February 20, 2018

SUBJECT: NRC REPORT NO. 03036973/2017006(DNMS) AND NOTICE OF VIOLATION –
CARDINAL HEALTH

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OFFICE	RIII-DNMS	C	RIII-DNMS	C				
NAME	GWarren:ps		AMcCraw					
DATE	2/20/2018		2/20/2018					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Cardinal Health
Dublin, Ohio

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

During a U.S. Nuclear Regulatory Commission (NRC) in-office review conducted from October 24, 2017, through January 31, 2018, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition No. 25.A. of NRC License No. 34-29200-01MD requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 20, 2011.

Item 9 of the application, Figures 2 and 21 (pages 9-5 and 9-24), specifies the floor plans and layouts of the licensee's nuclear pharmacy facilities in East Hartford, Connecticut, and Princeton, West Virginia, respectively.

Contrary to the above, between approximately mid-2015 and January 31, 2018, the licensee failed to maintain its nuclear pharmacy facilities in East Hartford, Connecticut, and Princeton, West Virginia, as described in Item 9 of the application dated July 20, 2011. Specifically, the licensee remodeled these facilities without first receiving approval in writing from the NRC for the alterations.

This is a Severity Level IV violation (Section 6.3).

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 the letter transmitting this Notice of Violation. However, you are required to submit a written statement or explanation pursuant to Title 10 of the *Code of Federal Regulations* (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, IR 03036973/2017006(DNMS)" 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, within 30 days of the date of the letter transmitting this Notice.

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, U.S. 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'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.

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

Dated this 20th day of February 2018.

Enclosure