



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

May 18, 2018

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036973/2018001(DNMS) AND  
NOTICE OF VIOLATION – CARDINAL HEALTH

Dear Mr. Sullivan:

On February 23, 2018, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Honolulu, Hawaii, with continued in-office review through March 25, 2018. 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 a review of information not available at the time of the onsite inspection. The inspector discussed preliminary inspection findings with Seung Yoon Yeo, Pharm.D. at the conclusion of the onsite inspection on February 23, 2018. Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with you on May 8, 2018, to discuss the inspection findings. This letter 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, 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 licensee's failure to maintain constant surveillance of material that was not in storage, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1802. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because the inspector identified the violation.

The inspector determined that the root cause of the violation was individual error; a technician failed to ensure the door was latched. As corrective actions to restore compliance and to prevent recurrence, the pharmacy supervisor immediately fixed and tested the door so it would latch properly. The pharmacist stated that he planned to: (1) brief the staff and remind them of the importance of ensuring that the door latches firmly and (2) discuss the matter with the

Cardinal Health corporate office to see if there were any additional physical controls that could be implemented. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. 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's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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 or proprietary 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 John Giessner Acting for/***

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 Hawaii  
Jeffrey Eckerd,  
Radiation Control Program  
Director

Letter to Glenn P. Sullivan from Aaron T. McCraw, dated May 18, 2018

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036973/2018001(DNMS) AND  
NOTICE OF VIOLATION – CARDINAL HEALTH

DISTRIBUTION w/ encl:

Steven West  
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MIB Inspectors

**ADAMS Accession Number: ML18138A457**

OFFICE	RIV-DNMS	RIII-DNMS	RIII-DNMS	
NAME	JKatanic:cl <small>(via-e-mail)</small>	GWarren	AMcCraw JGiessner for	
DATE	5/17/2018	5/18/2018	5/18/2018	

**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

Cardinal Health  
Honolulu, Hawaii

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 23, 2018, at the Cardinal Health facility in Honolulu, Hawaii, with continuing in-office review through March 25, 2018, one 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) 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on February 23, 2018, the licensee failed to control and maintain constant surveillance of two packages containing a total of approximately 46 millicuries of molybdenum-99 that was in an unrestricted area and that was not in storage.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, Cardinal Health is hereby required to submit a written statement or explanation 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include, for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was or will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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.

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

Dated this 18<sup>th</sup> day of May, 2018

Enclosure