



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

March 27, 2017

Docket No. 03038331

License No. 34-32780-02

Glenn Sullivan
Director, Health Physics
Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC INSPECTION REPORT NO. 03038331/2016001, CARDINAL HEALTH 414, LLC, EAST HARTFORD, CONNECTICUT SITE AND NOTICE OF VIOLATION

Dear Mr. Sullivan:

On August 25, 2016, and December 1, 2016, Craig Gordon of this office conducted a safety inspection at the East Hartford, Connecticut site of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your letter dated October 5, 2016, to the NRC, and in e-mail correspondence dated February 7, 2017, from Mr. Evan Western of your office (ML17081A485), was also examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that a Severity Level IV problem occurred that involved violations of two NRC requirements: 1) the failure to properly survey packages before disposal; and 2) the failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

During our inspection exit meeting on March 1, 2017, you indicated have taken corrective and preventative actions to address each violation and that Cardinal Health is committed to radiation safety and to compliance with NRC regulations and licensed conditions. Further, you stated verbally and you documented in your October 5, 2016, letter and February 7, 2017, correspondence, that you have taken the following corrective and preventative actions:

- 1) all employees at the East Hartford, Connecticut were trained on the proper survey procedures of trash prior to final disposal; and
- 2) immediate response by the local PET manufacturing facility staff to recover the material is expected when an incident involving loss of control of licensed material is reported.

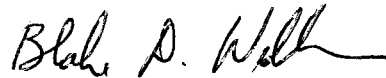
The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated October 5, 2016, and February 7, 2017. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your October 5, 2016, correspondence 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 enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Craig Gordon at 610-337-5216 if you have any questions regarding this matter.

Sincerely,



Blake D. Welling, Chief
Commercial, Industrial, R&D and
Academic Branch
Division of Nuclear Materials Safety

Enclosures:

1. Notice of Violation
2. Inspection Report No. 03038331/2016001

cc w/Encls: Beau Dugas, Manufacturing
Radiation Safety Officer
State of Ohio
State of Connecticut

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated October 5, 2016, and February 7, 2017. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your October 5, 2016, correspondence 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.

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cc w/Encls: Beau Dugas, Manufacturing
Radiation Safety Officer
State of Ohio
State of Connecticut

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OFFICE	DNMS/RI	N	DNMS/RI				
NAME	CGordon <i>CG</i>		BWelling <i>BW</i>				
DATE	3/21/17		3/21/17				

NOTICE OF VIOLATION

Cardinal Health 414, LLC
Dublin, OH

Docket No. 03038331
License No. 34-32780-02

During an NRC inspection conducted on August 25, 2016, and December 1, 2016, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

10 CFR 20.2001(a)(1) states, in part, that a licensee shall dispose of licensed material only by transfer to an authorized recipient.

Contrary to the above, on September 1, 2016, the licensee did not make or cause to be made, surveys that were necessary to ensure that licensed material was disposed of only by transfer to an authorized recipient. Specifically, the licensee did not perform a survey of a waste shipment to verify that no licensed material was contained therein. As a result, the licensee did not identify that the shipment, which went to an unauthorized trash-processing facility, included a contaminated filter cartridge, which contained Cobalt-57, Cobalt-60, and Chromium-51, as normal, non-radioactive waste.

- B. 10 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 September 1, 2016, the licensee did not control a contaminated filter cartridge, which contained 0.750 mCi of Cobalt-57, Cobalt-60, and Chromium-51, sent to a Hartford, CT, trash processing facility, which is an unrestricted area, until retrieved and returned back to the authorized location of use on September 15, 2016.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, D.C. 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Notice of Violation
Cardinal Health 414, LLC

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Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

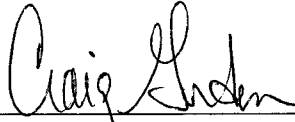
In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.


Dated This 21st day of March 2017

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03038331/2016001
Docket No. 03038331
License No. 34-32780-02
Licensee: Cardinal Health 414, LLC
Address: 7000 Cardinal Place
Dublin, OH 43017
Locations Inspected: 131 East Hartland Street
East Hartford, CT 06108
Inspection Dates: August 25, 2016, and December 1, 2016
Telephone Exit Meeting March 1, 2017
Date Followup
Information Received: October 5, 2016
February 7, 2017 (ML17081A485)

Inspector:  March 24, 2017
date
Craig Gordon
Senior Health Physicist
Commercial, Industrial, R&D and
Academic Branch
Division of Nuclear Materials Safety

Approved By:  3/27/2017
date
Blake D. Welling, Chief
Commercial, Industrial, R&D and
Academic Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Cardinal Health 414, LLC
NRC Inspection Report No. 03038331/2016001

On September 1, 2016, the NRC was notified by the Connecticut DEEP Radiation Division about their response to a radiation alarm at a waste disposal facility in the Hartford, CT area. Radiation survey by DEEP located a plastic trash bag containing a small process filter measuring up to 10 mR/hr. Contents of the trash bag indicated it had originated at Cardinal Health's Positron Emission Tomography (PET) facility located in East Hartford, Connecticut.

By letter dated October 5, 2016, the licensee notified the NRC regarding loss of control of the material, indicating the filter and associated trash were retrieved on September 15, 2016, and returned to the licensee's PET facility.

On August 25, 2016, the NRC conducted a routine safety inspection at the site, followed by another site inspection on December 1, 2016, to review the licensee's response activities to the incident. The inspection identified two violations. The first violation relates to the failure to perform a proper survey before disposing of contaminated material. The second violation relates to failure to control the material after being notified that it had been transferred to an unrestricted area. The violations and the licensee's corrective actions to achieve compliance are documented in this Inspection Report.

REPORT DETAILS

I. Organization and Scope of the Program (IP 87126)

a. Inspection Scope

The inspection included a review of licensee records, interviews with the Manufacturing (site) RSO and corporate health physics staff, and observations of PET facility office and material storage locations.

b. Observations and Findings

Cardinal Health 414, LLC (CH) is authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 34-32780-02 for production, packaging, handling, storage, and distribution of radiochemicals at the East Hartford, Connecticut PET facility. The primary operation in the PET facility involves cyclotron use for production of Carbon-11 and Fluorine-18, and calibration of instruments. The facility operates weekdays and some weekends with a small staff of health physicists and radiochemists. The MRSO manages the onsite activities for the radiation safety program. Responsibility for program implementation is assigned from the CH Ohio corporate office to the MRSO.

c. Conclusions

No violations were identified.

II. Material Receipt, Use, Transfer, and Control (IP 87103, 87126)

a. Inspection Scope

A routine safety inspection was conducted to examine licensed activities for the Cardinal Health PET operation. In response to a loss of control incident reported after the routine inspection, a second site visit was made to review the licensee's program for material control and follow up response actions.

b. Observations and Findings

The licensee is authorized for cyclotron production and use of PET material from its East Hartford, CT facility. The production and laboratory areas are located adjacent to the radiopharmacy where workers from both areas coordinate together on most shifts for distribution and offsite transportation of material.

During the routine inspection on August 25, 2016, the inspector met with the MRSO to discuss each area of the program. No major changes were noted. Required records were organized and kept up to date in a designated file drawer. These included quarterly corporate audits, leak tests, cyclotron maintenance, inventories, equipment calibrations, and area surveys. Laboratory operations and technician performance while handling material was observed to be implemented efficiently. The MRSO participated in monthly calls with counterparts from the corporate office and other CH facilities throughout the country to discuss areas of common interest. No concerns were identified.

The following week, on September 1, 2016, the NRC was notified by the Connecticut DEEP Radiation Division about their response to a radiation alarm which had activated at a local trash to energy disposal facility. The DEEP area radiation survey found a plastic garbage bag that measured up to 6 mR/hr on contact. After contents of the bag were segregated, a small process filter which measured 10 mR/hr was isolated. Papers and other records from the CH facility were also found inside the bag, indicating it had originated at the licensee's East Hartford, CT facility.

DEEP inspectors visited the CH facility to discuss the issue. From photographs, the MRSO recognized the filter as one routinely used to recover activation products during cyclotron operation. DEEP provided their site assessment and material transfer information to the NRC, and expressed concern about performance of licensee surveys before waste was sent for disposal.

The licensee did not respond immediately when notified that licensed material had been transferred from its site and identified at the disposal facility. By letter dated October 5, 2016, from the Cardinal Health Director, Health Physics (Corporate RSO), the licensee notified the NRC regarding loss of control of the material, indicating the Site MRSO retrieved the material on September 15, 2016, two weeks after being identified. The filter and associated trash was recovered and returned to the PET facility for confirmatory survey. Upon spectral analysis, the material in the filter was identified as 0.75 mCi Co-56/Co-57 and Cr-51, activated from cyclotron production.

On December 1, 2016, the inspector met with the site MRSO to discuss the licensee's response activities after DEEP notified them. During inspection of the laboratory and production areas, the MRSO demonstrated methodology for waste handling and radiation surveys. He stated that the 3.0 cm. filter apparently had dropped from a countertop unnoticed into the trash bag, but went undetected before being sent offsite because of an inadequate survey of the waste shipment.

The licensee's letter to the NRC stated their investigation determined there was insufficient training on CH policy for survey of trash prior to transfer for disposal. A violation of 10 CFR 20.1501 is identified for failure to perform a proper survey prior to disposal of contaminated material. Corrective action included retraining of site personnel on proper survey techniques for facility trash. Radiation surveys are now performed in a dedicated area of low background using detection devices with greater sensitivity. Interviews of technicians found they were retrained and understood proper survey procedures.

According to the MRSO, beginning September 2, 2016, he communicated several times with the landfill operator about control of the material until visiting the site for the first time on September 15, 2016, to perform a radiation survey. He did not retrieve the trash bag immediately after notification because landfill personnel indicated it was being held in a secure area and not accessible.

To identify causes for the delay in recovering the material from the landfill, the inspector reviewed the CH Emergency Response Plan. The ERP indicates that some incidents and events require immediate actions to reduce the potential severity of the event. The ERP provides for CH staff responses for onsite security of material in the event of an emergency, but does not include procedures related to different incident situations, i.e., for loss of control of material outside CH facilities.

When asked about the delay in response, the Corporate Manager, Health Physics, indicated in an e-mail to the NRC, dated February 7, 2017, that he expected a loss of control event should be reported and addressed as soon as possible. The licensee's failure to control the material for a period of approximately two weeks while at the disposal facility (an unrestricted area), is identified as a violation of 10 CFR 20.1802, which 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.

As corrective action after the incident, corporate office staff held discussions with CH facility MRSOs to use lessons learned from the incident to reinforce the need for immediate reporting and response to a situation which involves the loss of control of material.

c. Conclusions

Two violations were identified:

- A. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

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

III. Exit Meeting

On March 1, 2017, the inspector held a telephone exit meeting with the CH Director, Health Physics to present the findings of the inspection. The licensee was informed that two violations were identified for to failure to perform proper surveys and failure to control licensed material. The licensee acknowledged the results.

PARTIAL LIST OF PERSONS CONTACTED

LICENSEE

G. Sullivan, Director, CH Health Physics, Ohio office
E. Western, Manager, CH Health Physics, Ohio office
B. Dugas, Manufacturing (Site) Radiation Safety Officer, East Hartford, CT

SUPPLEMENTAL INFORMATION

Notice of Loss of Control Incident Report from G. Sullivan, Director, CH Health Physics, dated October 5, 2016, (ML16287A749)

INSPECTION PROCEDURES USED

Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing"

Inspection Procedure 87126, "Industrial/Academic/Research Programs"