



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

April 16, 2020

Glenn P. Sullivan, Corporate Radiation
Safety Officer
Cardinal Health 414, LLC
7000 Cardinal Place
Dublin, OH 43017

**SUBJECT: CARDINAL HEALTH 414, LLC - NRC INSPECTION NO. 030-38331/2019-001
AND NOTICE OF VIOLATION**

Dear Mr. Sullivan:

This letter refers to the inspection conducted on September 24-25, 2019 and February 19, 2020, at your East Hartford, Connecticut location. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with 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. The inspection also included review of information provided by Evan Western in discussions and by electronic mail during the period of September 25, 2019, through April 13, 2020.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also 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 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 Web site 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.

G. Sullivan

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If you have any questions regarding this matter, please contact Betsy Ullrich of my staff at (610) 337-5040 or by electronic mail to Elizabeth.Ullrich@nrc.gov .

Thank you for your cooperation.

Sincerely,

Christopher Cahill, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-38331
License No. 34-32780-02

Enclosure:
Notice of Violation

cc w/ enclosure
Arshad Mehmood, Manufacturing Radiation Safety Officer

CARDINAL HEALTH 414, LLC - NRC INSPECTION NO. 030-38331/2019-001 AND NOTICE OF VIOLATION DATED APRIL 16, 2020

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L34-32780-02.2019-001.docx

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NOTICE OF VIOLATION

Cardinal Health 414, LLC
East Hartford, Connecticut

Docket No. 030-38331
License No. 34-32780-02

During an NRC inspection conducted onsite September 24-25, 2019 and February 19, 2020 and by review of documents submitted through April 13, 2020, four 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 20.1501(c) requires the licensee to ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

In accordance with 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, as of September 1, 2017, the licensee did not make surveys to assure compliance with airborne concentrations of radioactive materials, and did not ensure that the equipment used for effluent monitoring was calibrated. Specifically,

1. The effluent monitoring system was set to alarm if effluent concentrations exceeded the action level of 1 E-7 microcuries per milliliter in a 24-hour period, which would require investigation and corrective actions be taken. However, the inspector observed the monitor display indicating that the action level was exceeded by greater than 1000% on September 24 and 25, 2019; records reviewed identified that the monitor display indicated concentrations of 1240% above the limit on February 5, 2019 and 5629% above the limit on September 3, 2019 with no investigation or corrective actions taken; this problem was identified in staff audits performed January 16, February 20, March 15, April 24, May 16, June 21, July 22, 2019 and corporate audits performed November 15, 2018 and April 11, 2019 but there was no indication if investigation and corrective actions were taken between November 15, 2018 and September 24, 2019. Some staff were unfamiliar with the action level, what it represented, and what actions were to be taken; other staff believed that other readouts indicated no effluent problem so disregarded the alarm display.
2. On December 12 through 13, 2019, as part of the NRC inspection review, the corporate health physicist determined that the calibration of the Lab Impex effluent air monitoring system was in error since 2017. The stack calibration records for 2017, 2018, and 2019 contained significantly different values for the "average ratio" determined each year from release of actual known quantities of radioactive material compared to the measured value by the stack detector; those ratios were: 0.098 in

3. 2017, 16.157 in 2018, and 0.854 in 2019. These average ratios were inconsistent from year to year, and not investigated by the licensee. As a result of the 2019 inspection, the licensee determined that the errors included: selection of the wrong peaks in the data; failure to wait for effluent levels to reach background before the next calibration release; use of an incorrect calibration factor; and false background readings caused by the cyclotron and natural background.
4. The licensee's dose assessment performed using the software "CAP88-PC" Version 4.0 contained an incorrect plume rise momentum (exit velocity) of 7.16 meters per second (m/s) instead of the correct value of 14.37 m/s. The incorrect value was used in dose assessments for 2019 dated December 20, 2019 and February 17, 2020; for 2018 dated March 15, 2019 and January 14, 2020 (correcting errors identified in December 2019 as a result of the inspection on September 24-25); and for 2017 dated March 1, 2018 and January 14, 2020 (correcting errors identified in December 2019 as a result of the inspection on September 24-25)

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

- B. Condition 10 of License No. 34-32780-02, Amendment 21, dated April 3, 2019, states "The Radiation Safety Officer (RSO) for this license is Beau Dugas."

Contrary to the above, on September 24, 2019, which was the first day of this inspection, Beau Dugas was no longer a licensee employee and was not performing the duties of the Radiation Safety Officer (RSO). Specifically, Beau Dugas left employment with the licensee at the beginning of August 2019. Although Arshad Mehmood was assigned to take over the RSO activities, the licensee did not submit a letter to the NRC until September 20, 2019, requesting approval of a new RSO. Amendment 22 was issued December 6, 2019, naming Arshad Mehmood as the new RSO.

This is a Severity Level IV violation (Section 6.3)

- C. Items 6, 7 and 8 F through L of License No. 34-32780-02 specifies that the types and maximum amounts of various radionuclides produced as incidentally activated products with half-lives greater than 120 days as follows: 10 millicuries (mCi) of hydrogen-3, 10 mCi of manganese-54, 100 mCi of cobalt-57, 15 mCi of cobalt-60, 15 mCi of zinc-65, 15 mCi of niobium-93m, and 100 mCi of niobium-94m.

Contrary to the above, as of April 9, 2020, the licensee's inventory of long-lived incidentally activated products with half-lives greater than 120 days included radionuclides not authorized on the license. Specifically, the licensee possessed 0.003 millicuries of aluminum-26, 1.9 millicuries of silver-110m, and 1.1 millicuries of cadmium-109 as incidentally activated products, but which are not listed on the license.

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

- D. Condition 17.B. of License No. 34-32780-02, Amendment 21, dated April 3, 2019, states in part that, for radioactive materials disposed of by decay-in-storage, a record of each such disposal be retained for 3 years, and that the record include information specified in the license condition.

E.

Contrary to the above, for a period from approximately November 2018 through September 25, 2019, records of radioactive materials disposed of by decay-in-storage were not maintained. Specifically, on September 25, 2019, two staff members who performed surveys for radioactive materials held for decay-in-storage stated that they were unaware of the requirement to document the disposals in the licensee's online tracking system. Although the two staff members performed surveys as required prior to disposal, the information was not documented. One of the staff members began working for the licensee in November 2018, and the other began working for the licensee in February 2019.

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

Pursuant to the provisions of 10 CFR 2.201, Cardinal Health 414, LLC is hereby required to submit a written statement or explanation 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). 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, (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 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 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 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.

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

Dated This 16th day of April 2020