Cardinal Health 414, LLC
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

cardinalhealth.com

May 12, 2020

Elizabeth Ullrich
U.S. NRC Region I
2100 Renaissance Road
King of Prussia, PA 19406

Re: Response to Notice of Violation for Radioactive Materials License number 34-32780-02, Cardinal Health PET Manufacturing Services, East Hartford, CT

Dear Ms. Ullrich:

Cardinal Health 414, LLC (Nuclear Pharmacy Services and PET Manufacturing Services, hereafter Cardinal Health) acknowledges receipt of the inspection summary and notice of violation letter dated April 16, 2020 in regard to the recent inspection at the above referenced licensed location in East Hartford, CT. Cardinal Health submits the following information in response to the violations outlined therein.

Language from the NRC letter is included for reference in italics, followed by Cardinal Health's response.

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…*
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 at effluent concentrations exceeding the action level of 1E-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; … 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 licensee determined that the errors included: selection of the wrong peaks I* (sic) *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.*
   3. (Item 3 of this section appears to be a continuation of item 2.)

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 …*

Cardinal Health acknowledges the issues with the effluent monitor described by the NRC. The calibration problems resulted from several factors, including a lack of training for the former RSO and facility cyclotron engineer, a calibration procedure that required more thorough steps and explanations, and a lack of direction over how to identify potential issues and escalate them to the corporate Quality & Regulatory group.

In December 2019, an experienced cyclotron engineer from another facility performed a new effluent monitor calibration. On December 12 and 13, the corporate health physicist from the Quality & Regulatory department visited the facility to investigate the past issues and to validate the new calibration. This investigation confirmed significant errors in the 2017 and 2018 calibrations, as described by the NRC. The health physicist also reviewed the December 2019 calibration and confirmed that it had been performed successfully, with the correct data used for the assayed and observed releases and the background subtraction settings set properly. Q&R then applied these settings to the release data dating back to the 2017 calibration to recalculate the facility's releases for 2017, 2018, and 2019. The health physicist then confirmed the alarm settings and re-trained the RSO on the meaning of this alarm and the internal policies governing the response to this alarm. The RSO has re-trained the facility staff on basic operations and functions of the effluent monitor, including the meaning of the alarm setting and corrective actions to be taken when the system is in an alarmed state. Documentation of this staff training is attached to this letter.

Following the adjustments to the release data, the health physicist determined that this facility did exceed the 10 CFR 20 Appendix B effluent concentration value for fluorine-18 at the exhaust nozzle of the fan in its average effluent concentrations for 2017, 2018, and 2019. However, dose modeling using CAP88-PC Version 4.0 combined with public dosimetry measurements from OSL dosimeters demonstrates that no member of the public received a dose exceeding 100 mrem in any of these calendar years. The facility received and installed new filters for its carbon scrubber in January 2020 and has seen a significant reduction in effluent release.

Cardinal Health acknowledges the mistake in exit velocity identified in section 4 above; this was caused by an arithmetic error in the conversion from air flow rate in cubic feet per minute to exit velocity and has been corrected for the dose modeling calculations referenced above and for all future CAP88 calculations. Using a lower exit velocity will result in a higher calculated TEDE, meaning that previous calculations were overestimates and were therefore conservative, so no doses that could have resulted in public safety concerns would have been overlooked.

Starting in January 2020, the Quality & Regulatory department began an effort to review the effluent stack monitor configurations and calibrations at every facility in the Cardinal Health PET Manufacturing network. The department visited approximately half of the 30 facilities in person prior to business travel being suspended in March 2020 due to the COVID-19 public health emergency. The other facilities have submitted their most recent annual effluent monitor calibration documents to Q&R for review.

Finally, Q&R has revised the Radiation Safety Manual section addressing the effluent monitor calibration to clarify several steps in the process and provide a more user-friendly procedure. In addition, the procedure now includes a requirement that all PET Manufacturing facilities must

submit their annual effluent monitor calibration documents to the Quality & Regulatory department for a secondary review of the data and results.

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.

As the letter notes, Cardinal Health notified the NRC of the RSO change on September 20. This notice was submitted approximately two business days following the Cardinal Health Quality & Regulatory department being notified that Mr. Dugas was no longer employed. This resulted from a communication failure between Cardinal Health's regional operations leadership and Q&R.

Cardinal Health's internal policies require operations leadership to inform the Quality & Regulatory department immediately when there is a change in RSO at the facility to ensure timely communications to the NRC or appropriate Agreement State agency. Operations leadership has reminded individuals at all levels of the leadership structure of this requirement and Q&R has also reinforced this policy to the MRSOs. Finally, Cardinal Health will add a formal requirement into the Radiation Safety Manual stating that Q&R must be notified no later than the close of the next business day following any change in RSO.

C. *Items 6, 7, and 8F 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 are as follows: …*
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.

In the past five years, Cardinal Health has decommissioned several GE PETtrace cyclotrons. *In situ* gamma spectroscopy analyses of these cyclotrons, performed by a third-party health physics consulting firm, provide a profile of the radionuclides and quantities of radioactivity produced in the fixed components of the cyclotrons.

Comparing this profile against authorized possession limits on radioactive materials licenses revealed that the nuclides mentioned by the NRC were not specifically listed on the license. Therefore, Cardinal Health submitted an amendment request letter to the NRC for license 34-32780-02 dated April 21, 2020 to correct the discrepancies by adding the unlisted nuclides to the license and adjusting the requested maximum possession activities to reflect the amounts required to operate two GE PETtrace cyclotrons. The NRC issued Amendment 26 dated May 11, 2020 to reflect these changes and the facility is in full compliance with the updated licensed limits.

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.
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.

Cardinal Health policy is to record final surveys of all decay-in-storage waste within the company's proprietary electronic recordkeeping system. When the corporate health physicist from the Quality & Regulatory department visited the facility in December 2019, he re-trained the MRSO, Arshad Mehmood, on this requirement and the process for using the system. Mr. Mehmood then re-trained his full staff on the use of the system for this purpose. A record of the site staff re-training is attached to this letter.

As a result of the corrective actions described in this letter, Cardinal Health believes that this facility has returned to full compliance with all appropriate regulations and license conditions. Thank you for your thorough review of the radiation safety program at this facility.

If you have any questions regarding this request, please contact Evan Western at 614.553.4555.

Sincerely,

Glenn Sullivan, Corporate RSO
Director, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Enclosure: Re-training documentation

cc: Arshad Mehmood, MRSO (loc. 5869)
License File 5869 (4)

ATTACHMENT

Re-training documentation

FIGURE 8.59-1

PRS-59

IN-SERVICE ATTENDANCE RECORD

LECTURE TITLE: Effluent monitoring/Logging using Lab Impact
DATE: 15 Apr 20
INSTRUCTOR: Arshad Mehmood.
ATTENDED BY THE FOLLOWING:

NAME (print)	SIGNATURE	POSITION
Conor Sutphin	Con B Tph	PET Tech II
Ade Adetola	G Tchol 9	Tech II

TOPICS COVERED:

- Daily/monthly effluent monitoring in Lab Impact system.
- Effluent needs to be entered for daily monitoring on daily effluent tracking Log on computer next to effluent computer.
- Comment needs to made and RSO notified if effluent is above 100% on any given day.

FIGURE 8.59-1

PRS-59

IN-SERVICE ATTENDANCE RECORD

LECTURE TITLE: Waste managment in Isotrac
DATE: 15 Apr 20
INSTRUCTOR: Arshad Mehmood
ATTENDED BY THE FOLLOWING:

NAME (print)	SIGNATURE	POSITION
Conor Sutphin		PET Tech II
Ade Adetoyi		Tech II
Robin Amsden		Tech I

TOPICS COVERED:

- All waste bins are to be opened in Isotrac and assigned very short lived waste.
- Biohazard signs to be pasted on every waste bin opened.
- New labels to be made and attached to each bin and initialed/dated.
- Proper entries to be made in Isotrac for date opened, closed, disposed and ~~reading~~ surface reading at time of disposal must be entered in Isotrac.