DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/15/2026-3/18/2026 FEI NUMBER 3004750502

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexander J Nemeth, Director of Operations Nuclear & Precision Health Solutions

FIRM NAME	STREET ADDRESS
Cardinal Health 414, LLC	350 W Woodrow Wilson Ave Ste 1700
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jackson, MS 39213-7627	PET Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

Your facilities are not adequate to ensure the prevention of contamination of equipment or product by substances, personnel, or environmental conditions that could reasonably be expected to have an adverse effect on product quality.

Specifically,

Equipment used for the manufacture of Positron Emission Topography (PET) drug products including (b) (4) injection, are not adequately maintained and in good state of repair. For example, during my observation of the hot cell cleaning and aseptic manipulation in the hot cell ((b) (4)) on 17Mar2026, I observed the following:

1. The interior of the hot-cell door's lead-shielded glass exhibited breakage at two corner locations (top and bottom), with sections of glass missing from each corner and a risk assessment has not been conducted to assess the impact of the missing glass sections on the identity, strength, quality, or purity of PET drug products.
2. Chipped paint and rust were observed on the hinges and surfaces of both the hot cell's main door and side door.

The missing glass sections of hot cell and its peeling surface pose a risk of contamination to the PET drug product manufactured within this hot cell. The firm has manufactured and released into commercial distribution approximately (b) (4) batches of (b) (4) injection using this equipment in the last 12

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Pearl C Ozuruigbo, Investigator Tareq W Haddad, Investigator X Tareq W Haddad Investigator Signed By: TAREQ W. HADDAD - S Date Signed: 03-18-2026 15:34:34	3/18/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/15/2026-3/18/2026
	FEI NUMBER 3004750502

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Alexander J Nemeth, Director of Operations Nuclear & Precision Health Solutions

FIRM NAME	STREET ADDRESS
Cardinal Health 414, LLC	350 W Woodrow Wilson Ave Ste 1700
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jackson, MS 39213-7627	PET Drug Manufacturer

months.

X Pearl C Ozuruigbo
Investigator
Signed By: PEARL C. OZURUIGBO -S
Date Signed: 03-18-2026 15:35:07

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Pearl C Ozuruigbo, Investigator
Tareq W Haddad, Investigator

X Tareq W Haddad
Investigator
Signed By: TAREQ W. HADDAD -S
Date Signed: 03-18-2026 15:34:34

DATE ISSUED
3/18/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."