RCRA Inspection Report

1) Inspector and Author of Report

William Kappler
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2) Facility Information

Cardinal Health – Madison DC
1240 Gluckstadt Road
Madison, Mississippi 39110
Madison County
EPA ID No.: MSR000104760

3) Responsible Officials

Mr. Allen Raynor
Manager
EHS, Maintenance and Security
Cardinal Health – Madison DC
1240 Gluckstadt Road
Madison, Mississippi 39110
allen.raynor@cardinalhealth.com
(601) 898-2239

4) Inspection Participants

Allen Raynor, Cardinal Health – Madison DC
Kyla McCoy, Cardinal Health – Madison DC
Jay Lewis, Cardinal Health – Madison DC
Selenia Werner, Cardinal Health – Madison DC
Dennis Sevin, Cardinal Health – Madison DC
Phil Thorton, Cardinal Health – Madison DC
Jarrod Jordan, Cardinal Health – Madison DC
Charlie McGhee, Cardinal Health – Madison DC
Brad Justice, Mississippi Department of Environmental Quality
William Kappler, Environmental Protection Agency, Region 4

5) Date and Time of Inspection

October 20, 2021, at 9:30 a.m.

6) Applicable Regulations

Mississippi Code of 1972, Miss. Code Ann. § 17-17-1 *et seq.* [Resource Conservation and Recovery Act (RCRA) Sections 3002, 3004, 3005, 3007 and 3008, (42 U.S.C. §§ 6922, 6924, 6925, 6927 and 6928)] and the Mississippi Department of Environmental Quality, Office of Pollution Control, Mississippi Hazardous Waste Management Regulations (MHWMR), 11 Miss. Admin. Code Pt. 3, R. 1.1-1.24, which adopts and incorporates by reference 40 C.F.R. Parts 260-270, 273, and 279 [40 Code of Federal Regulations (C.F.R.) Parts 260-270, 273, and 279].

As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.

Pursuant to 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near the point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or without having interim status, as required by Mississippi Code of 1972, Miss. Code Ann. § 17-17-27(4) [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.16(b) or §262.17(a)], except as required in 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.15(a) (hereinafter referred to as the "SAA Permit Exemption").

Pursuant to 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.17], a large quantity generator (LQG) may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 17-17-27 of the Mississippi Code of 1972, Miss. Code Ann. § 17-17-27 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.17] (hereinafter referred to as the "LQG Permit Exemption").

7) Purpose of Inspection

On October 18, 2021, MDEQ contacted Cardinal Health – Madison DC, by email to Mr. Glen J. Brown announcing the EPA and MDEQ will be conducting a RCRA compliance evaluation inspection (CEI) on October 20, 2021, at 9:00 a.m.

On October 20, 2021, EPA inspector William Kappler accompanied by MDEQ inspector Brad Justice conducted an announced CEI at Cardinal Health – Madison DC (hereinafter, "Cardinal Health" or the "facility") to determine the compliance status of the facility with the RCRA and the State of Mississippi regulations. This was an EPA-lead inspection. Inspectors arrived at Cardinal Health at approximately 9:30 a.m. and Cardinal Health Staff immediately received the inspectors. The inspectors were escorted to a meeting room for an opening conference. The inspectors introduced themselves, showed credentials, exchanged business cards, explained the purpose of the visit, the notification procedures due to the Covid-19, the EPA health and safety procedures, the general areas for inspection and the RCRA records needed for review. Cardinal Health discussed health and safety procedures, the personal protective equipment, an overview of the facility's current process operations and the RCRA records.

The EPA inspector described the anticipated use of a digital camera during the inspection and the facility's ability, pursuant to 40 C.F.R. §2.203, to assert a business confidentiality claim for information submitted to the EPA. The facility asserted a business confidentiality claim for certain records when copied for the inspectors. Cardinal Health does not appear to meet the Small Business Regulatory Enforcement Fairness Act's classification of a "small business," which is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. Health and safety protocols and required personal protective equipment were discussed.

Mr. Allen Raynor and Ms. Kyla McCoy of Cardinal Health led the inspectors on a tour of the facility's operations.

8) Facility Description

Cardinal Health is located at 1240 Gluckstadt Road, Madison, Madison County, Mississippi. The facility has been at this location since 1996 and consists of 13 acres of property. Cardinal Health owns the property. The facility employs 100 people and operates two work shifts starting on Sunday evening at approximately 6:00 p.m. and ending on Friday evening, at approximately 10:00 p.m. General operating hours are 8:00 a.m. to 5:00 p.m. There is one main building consisting of 127,190 square feet of space. Potable water and domestic waste service are provided by Bear Creek. The primary NAICS code for the facility is 424210, drugs and druggist's sundries merchant wholesalers.

Cardinal Health's most recent notification of its regulated waste activity to MDEQ was on February 24, 2021, notifying as a large quantity generator (LQG) and small quantity handler of universal waste (SQHUW).

9) General Process Description

Cardinal Health is a warehouse and distributor of approximately 30,000 pharmaceutical products consisting of prescription, over the counter (OTC), controlled substances and sundries (sunscreen, deodorant, hair spray). The facility purchases the pharmaceuticals from numerous manufacturers, consolidates the products for storage, prepares the pharmaceutical orders into site-specific deliveries to retail pharmacies, hospitals, clinics, mail-order facilities, physician offices, surgery centers, long-term care facilities, some universities and other alternate medical care facilities. The facility does not handle E-Cigarettes.

Pharmaceuticals received by the facility are sorted and stocked on shelves during the day shift. The products are stacked in flow, static, and hi-bay shelving racks. The flow and static racks contain the individual products while the case-sized bulk products are placed in the high-bay racking area. Pharmaceutical orders are processed and prepared for shipping in bulk or individual quantities during the night shift. The night shift picks the products from the shelves, packs the containers, and prepares the products to be shipped.

Pharmaceutical waste is generated from out of date, expired merchandise and from damaged goods. Pharmaceutical products between three to six months from expiration are pulled from the shelf. Cardinal Health generates a daily pull list to determine what items need to be pulled and sent to the Morgue (90-Day or Less Accumulation Area) or one of the two Drug Enforcement

Agency (DEA) cages. The records are maintained in monthly packages. The Morgue is where the returned, recalled, and expired items are managed. Pharmaceuticals can be sent out as creditable or uncreditable. Cardinal Health may make that determination using their hazardous waste contractor's (Veolia) product management system. Controlled substances (C2 through C5) may be sent to either the Primary or Secondary Vault. Each Vault is enclosed with a Cage Area. Cardinal Health has permission from the DEA to store non-C2, C3, C4, or C5 pharmaceuticals with the controlled substances. The primary vault and cage house the C3 through C5 substances and the secondary vault houses the C2 pharmaceuticals with no products stored in the secondary cage.

10) Previous Inspection History

Cardinal Health was last inspected by the MDEQ on June 8, 2017. No apparent hazardous waste violations were observed during the inspection.

Cardinal Health was last inspected by the EPA and the MDEQ on February 29, 2012. The facility was cited for failing to label or mark containers with the words hazardous waste, failing to mark containers of hazardous waste with a date, failing to keep containers of hazardous waste closed, failing to label or mark containers with the words universal waste, failing to maintain RCRA personnel training documents and records and failing to conduct weekly inspections on containers of hazardous waste.

11) Findings

The information in this RCRA inspection report is based on the EPA's October 20, 2021, RCRA CEI.

Receiving Area

Products are received and inspected for damage. Cardinal Health uses an electronic system ("WARF") to receive the products, confirm information on the products using Safety Data Sheets (SDS), process the products for stocking, process customer orders and to ship the products to the customer.

The electronic system is also used to pull the expired products from the shelf as well as determine the cleanup of any damaged or spilled pharmaceuticals. Mr. Charlie McGhee joined the inspectors in the receiving area to electronically pull the locations of epinephrine and nitroglycerine containing pharmaceuticals after a discussion where the products were located. Prescription pharmaceuticals are stocked on the first floor and over the counter pharmaceuticals are stocked on the second floor. Shift supervisors and shift leads are given training to implement the contingency plan to respond to damaged products and product spills. Solid waste generated from damaged products and spills are managed in the 90-day or less accumulation area.

Dock Area

The facility has eight docks for receiving and shipping products. Hazardous waste shipments are generally staged on docks one through seven. The inspectors did not observe hazardous waste accumulating in the docks at the time of this inspection.

Maintenance Shop

Mr. Phil Thorton is the maintenance manager. Mr. Thorton conducts maintenance and repair work on the facility mechanical systems. Mr. Thorton indicated the facility maintenance and repair operation generates spent aerosols. Mr. Thorton indicated to inspectors that the empty aerosol cans are disposed to the trash. Cardinal Health should establish an aerosol management program to properly managed possible solid waste and coordinate with the MDEQ on the Universal Waste Aerosol rule.

Morgue Area - 90-Day or Less Accumulation Area

Mr. Jarrod Jordan manages the 90-Day or Less Accumulation Area (90-Day Area). The 90-Day Area is located indoors near the back wall of the building. The 90-Day Area is constructed with a concrete floor and enclosed by a chain link fence and locked gate. Hazardous waste, universal waste, nonhazardous waste, recalled pharmaceuticals and work in progress pharmaceuticals are accumulated in this area.

The hazardous waste area is identified with a sign on the wall with the words "Hazardous Waste". The inspectors observed one 15-gallon container accumulating carbon and iron powder (D001), one 15-gallon container accumulating lindan and mitomycin C (D007, D008, D010, D011, D013, D024, U010, U035, U058, U059, U50, U188, U204-206), one 30-gallon container accumulating butene and albuterol (D001), one 30-gallon container accumulating silver nitrate and potassium nitrate (D001, D002, D011) and one 30-gallon container accumulating nitroglycerin and physostigmine (D004, P001, P012, P042, P075, P081, P188, P204). The containers were on a poly pallet with secondary containment. The inspectors observed the containers were closed, in good condition with aisle space, labeled with the words hazardous waste, marked with the words ignitable, corrosive, and toxic as hazard indicators and all containers marked with the date October 15, 2021 (Photographs 2, 3, and 4). The inspectors explained the hazard indicators on the hazardous waste labels appeared small and asked the facility to apply the words with a larger font or pictograms. Mr. Raynor agreed, and the facility placed signs with words in a larger font on the containers until the correct hazard indicator labels or pictograms could be placed on the containers.

The universal waste area is identified with a sign hanging on a line with the words "Universal Waste". The inspectors observed two 15-gallon containers and one 30-gallon container accumulating waste batteries on a poly pallet. The inspectors observed the containers were closed, in good condition, labeled with the words universal waste and marked with the date October 15, 2021 or October 18, 2021 (Photograph 5).

The nonhazardous waste area is identified with a sign hanging on a line with the words "Nonhazardous Waste". The inspectors observed two rows with several red plastic containers and cardboard boxes accumulating nonhazardous waste. Mr. Jordan uses generator knowledge of the product and safety data sheets (SDS) to determine the solid waste is nonhazardous waste. The inspectors observed the containers were closed and in good condition (Photograph 6).

The recall zone area is identified with a sign hanging on multiple shelves with the words "Recall Zone". The inspectors observed several shelves with red plastic containers and cardboard boxes accumulating recalled prescription and over the counter pharmaceuticals. The facility coordinates with the vendor to determine if the pharmaceutical can be shipped back as a product. Confirmed recalled pharmaceuticals are shipped to the vendor as products by ground

transportation services. Mr. Jordan uses generator knowledge of the product and SDS to conduct a waste determination on the solid waste that is not shipped to the vendor as product. The inspectors observed the containers were closed and in good condition (Photograph 7).

The work in progress (WIP) area is managed in a separate area of the 90-Day Area. Prescription and over the counter pharmaceutical products mistakenly sent to Cardinal Health are accumulated in the WIP area. The facility coordinates with the customer and/or the manufacturer if the pharmaceutical can be managed as product or waste. The inspector observed several blue plastic containers shrink-wrapped on a pallet accumulating pharmaceutical products which were destined for a hospital (Ochsner) in New Orleans, Louisiana (Photograph 1). Mr. Jordan explained the contract between Cardinal Health and the hospital ended and they are working with the manufacturer to return the pharmaceuticals as product. Mr. Jordan indicated the pharmaceuticals have been accumulating for approximately one week.

Primary Cage and Vault
Controlled substances are stored in these areas that have been recalled, damaged, rejected, and outdated. Controlled substance C3 through C5 are stored in the Cage Area (Photograph 9) and controlled substances C2 are stored in the Vault Area (Photograph 8). The control substances are shipped to INMAR RX Solutions, located in Grand Prairie, Texas.

Secondary Cage and Vault
Controlled substances (C2) are stored in these areas (Photographs 10 and 11). The control substances are shipped to INMAR RX Solutions, located in Grand Prairie, Texas.

12) Waste Management Practices

Cardinal Health generates out of date, expired, and damaged prescription and OTC pharmaceuticals. The facility generates C2-C5 controlled substances also regulated by the Drug Enforcement Agency. The facility conducts a monthly audit of the pharmaceutical products using an internal policy to remove the pharmaceutical product from its stock approximately five months prior to its expiration date. The facility may also use the manufacturers pharmaceutical policy to remove a pharmaceutical product from its stock approximately three to six months prior to its expiration date. Pharmaceuticals that are within the expiration date range are shipped to INMAR RX Solutions located in Grand Prairie, Texas (TXR000085217), to determine the pharmaceutical use. Cardinal Health receives credit for recalled pharmaceuticals. Nonhazardous waste pharmaceuticals are shipped to Veolia ES Technical Solutions. Pharmaceuticals that Cardinal Health determines are solid waste are accumulated in the 90-Day Area. Based on the most recent notification of its regulated waste activity the facility generates the following waste codes: D001, D002, D005-D008, D010, D011, D022, D024, P001, P042, P075, P188, P204, U002, U010, U035, U044, U058, U059, U089, U129, U132, U144, U150, U187, U188, U200, U201, U205, U206, U237, U246 and U248. The facility generates universal waste lamps and batteries.

The facility prepares the hazardous waste for packaging and on-site management, prior to shipping the hazardous waste using the manifest system to a treatment, storage, or disposal facility (TSDF). The waste pharmaceuticals are transferred to the loading dock on the day they are shipped to an offsite destination facility.

Cardinal Health used the following transporters in 2018 through 2021.
Stericycle Specialty Waste Solutions, Inc – MNS000110924
Action Resources, Inc. – ALR000007237
Freehold Cartage, Inc. – NJD054126164
Republic Environmental Systems (PA), LLC – PAD982661381
Veolia ES Technical Solutions – NJD080631369

Cardinal Health used the following TSDF in 2018 through 2021.
Republic Environmental Systems (PA), LLC – PAD085690592
Veolia ES Technical Solutions – TXD000838896
INMAR RX Solutions – TXR000085217

13) Record Review

RCRA Site Identification Form
The inspectors reviewed he most recent notification of its regulated waste activity.

Hazardous Waste Manifests Records
The inspectors reviewed hazardous waste manifests and non-hazardous waste manifests from March 2018, to October 2021. There were no hazardous waste manifests for review in EPA's E-Manifest Record System.

The inspectors observed manifest number 021302803 JJK, dated March 30, 2020, was missing the return manifest with the hand-written signature and date the hazardous waste was received by the designated treatment, storage, or disposal facility.

Pursuant to 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.40(b)], a generator of greater than 1,000 kilograms of hazardous waste in a calendar month must submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if he has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter. The Exception Report must include: A legible copy of the manifest for which the generator does not have confirmation of delivery and a cover letter signed by the generator or his authorized representative explaining the efforts taken to locate the hazardous waste and the results of those efforts.

On October 26, 2021, Mr. Raynor emailed the EPA a copy of manifest number 021302803 JJK, with the hand-written signature of the destination facility, dated April 9, 2020.

Universal Waste Records
The inspectors reviewed universal waste records from 2019 to 2021.

Waste Determination/Waste Profile
The inspectors reviewed waste determination and waste profile records for waste pharmaceuticals.

Contingency Plan
The inspectors reviewed the contingency plan (Plan). At the time of the inspection the Plan

reviewed by inspectors appeared to be last updated on April 27, 2021, Revision 2.7. The inspectors observed the Plan listed Stericycle as the emergency contractor and not updated with Veolia as the new emergency contractor. Veolia's contract began in January 2021.

Pursuant to 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.17(a)(6)], which incorporates 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.261(c)], and is a condition of the LQG Permit Exemption, the plan must describe arrangements agreed to with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, local hospitals or, if applicable, the Local Emergency Planning Committee, pursuant to § 262.256.

On October 20, 2021, Mr. Raynor emailed the EPA and MDEQ a copy of the revised Plan dated July 7, 2021, Revision 2.7. The Plan included Veolia as the emergency contractor.

Quick Reference Guide

The inspectors reviewed the Quick Reference Guide (QRG). The inspectors observed the QRG did not include the water supply flow rate at the time of the inspection. The facility revised the QRG to include the water supply flow rate (110-gallons per minute), prior to inspectors completing the inspection.

Arrangements with Local Authorities

The inspectors reviewed the arrangements with the local authorities. The inspectors observed arrangements with the local authorities were described in the contingency plan, but it appears at the time of the inspection the arrangements with the local authorities were not documented.

Pursuant to 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.17(a)(6)], which incorporates 11 Miss. Admin. Code Pt. 3, R. 1.3 [40 C.F.R. § 262.256(a)], which is a condition of the LQG Permit Exemption, the large quantity generator must submit a copy of the contingency plan and all revisions to all local emergency responders (i.e., police departments, fire departments, hospitals, and state and local emergency response teams that may be called upon to provide emergency services). This document may also be submitted to the Local Emergency Planning Committee, as appropriate.

On October 25, 2021, Mr. Raynor emailed the EPA copies of the certified mail and return receipts and the certified mail charges, sent in January 2016.

Weekly Container Inspection Records

The inspectors reviewed weekly container inspection records from October 23, 2019 to September 28, 2021.

Personnel Training

The inspectors reviewed the RCRA training records, job titles, and position descriptions. Employees handling and managing hazardous waste are given RCRA training. The job descriptions are broken down by Duty and each person responsible is listed, along with their job titles. The tasks are then also broken down into a grid for tracking responsibilities for each person – Task (R), Completed (A), Consulted (C), and informed (I). The training duties included the management of RCRA, the contingency plan, facilities maintenance, electronic wastes, hazardous waste manifests, and the central accumulation area with the person or persons listed.

Annual Report
The 2017, 2018, 2019, and 2020 annual reports were available and were reviewed.

Waste Minimization Plan
The 2020 Waste Minimization plan was reviewed.

September 2021 Pull Report
The inspectors reviewed the September 2021 Pharmaceutical Pull Report for the expired pharmaceuticals to compare the report with the hazardous waste manifests and DEA Bill of Lading. INMAR RX Solutions (INMAR), receives the pharmaceuticals from Cardinal Health, and INMAR determines whether the product is creditable or uncreditable, INMAR is a reverse distributor with the DEA Number RR0191902 located in Grand Prairie, Texas.

Land Disposal Restriction Notice

The land disposal restriction documents were reviewed.

14) Exit-Briefing

Upon conclusion of the inspection, a closing conference was conducted in the presence of Cardinal Health – Madison DC representatives. Mr. Dennis Sevin, National EHS Manager attended the closing conference by phone. The inspectors informed the facility of the preliminary conclusions at the time of the inspection.

15) Sampling Overview

Sampling was not conducted at this facility.

16) Conclusion

Based on the CEI conducted on October 20, 2021, Cardinal Health – Madison DC, was inspected as a large quantity generator of hazardous waste and a small quantity handler of universal waste.

17) Signed

WILLIAM KAPPLER Digitally signed by WILLIAM KAPPLER
Date: 2021.12.10 12:19:38 -05'00'

William Kappler — Date
Physical Scientist
RCRA Enforcement Section

18) Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ
Date: 2021.12.10 13:10:09 -05'00'

Araceli B. Chavez — Date
Chief
RCRA Enforcement Section

Cardinal Health Madison - DC
MSR000104760
October 20, 2021
RCRA CEI Photographs
Photographs by William Kappler
Camera Model: Samsung WB250F
Property Tag #: S75917

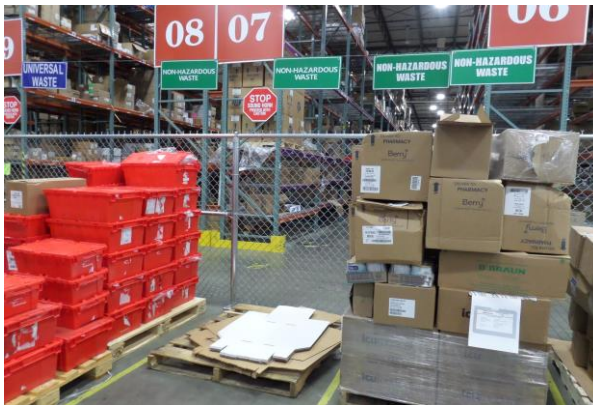
Cardinal Health Madison – DC (Cardinal Health). Morgue 90-Day or Less Accumulation Area (90-Day Area). Containers of work in progress (WIP) pharmaceuticals. Photograph 1 taken at 11:55 a.m.

Cardinal Health. 90-Day Area. Hazardous waste area. Containers closed, labeled, and dated. Photograph 2 taken at 12:06 p.m.

Cardinal Health. 90-Day Area. Hazardous waste area. Containers closed, labeled, and dated. Photograph 3 taken at 12:06 p.m.

Cardinal Health. 90-Day Area. Hazardous waste area. Containers closed, labeled, and dated. Photograph 4 taken at 12:06 p.m.

Cardinal Health. 90-Day Area. Universal waste area. Containers closed, labeled, and dated. Photograph 5 taken at 12:08 p.m.



Cardinal Health. 90-Day Area. Nonhazardous waste area. Photograph 6 taken at 12:14 p.m.

Cardinal Health. 90-Day Area. Recall zone area. Photograph 7 taken at 12:19 p.m.

Cardinal Health. Primary Cage and Vault. Vault area. Photograph 8 taken at 12:41 p.m.

Cardinal Health. Primary Cage and Vault. Cage area. Photograph 9 taken at 12:42 p.m.

Cardinal Health. Secondary Cage and Vault. Cage area. Photograph 10 taken at 12:47 p.m.

Cardinal Health. Secondary Cage and Vault. Vault area. Photograph 11 taken at 12:47 p.m.