REPORT OF RCRA COMPLIANCE EVALUATION INSPECTION

At

CAMBREX CHARLES CITY INC.
1205 11th Street
Charles City, Iowa 50616
(641) 257-5448

EPA RCRA ID No. IAD984591891

On

March 26, 2024

By

TOEROEK ASSOCIATES, INC.

For

U.S. ENVIRONMENTAL PROTECTION AGENCY
Region 7
Enforcement and Compliance Assurance Division

INTRODUCTION

At the request of the Enforcement and Compliance Assurance Division/Chemical Branch/RCRA Section of the U.S. Environmental Protection Agency (EPA) Region 7, Toeroek Associates, Inc. and its subcontractor CLAENE Group (Toeroek team) conducted a hazardous waste compliance evaluation inspection (CEI) at Cambrex Charles City Inc. (Cambrex), at 1205 11th Street, Charles City, Iowa. The CEI was conducted under the authority of Section 3007 of the Resource Conservation and Recovery Act (RCRA), as amended. The CEI covered hazardous waste generator, used oil, and universal waste requirements as applicable. This report and its attachments present the findings of the CEI.

PARTICIPANTS

Cambrex:

Eric Mayhew, Manager, Environmental & Controlled Substances
Zachary McGraw, Environmental Engineer
Brian Pickar, Environmental Technician

Toeroek Team:

John D. Dixon, Inspector, (703) 473-8717

INSPECTION PROCEDURES

Prior to the CEI at Cambrex on March 26, 2024, I conducted a drive-by visual inspection. I did not observe any areas of concern during the drive-by; however, the visual inspection was limited due to the facility's setback from public roadways. After the drive-by inspection, I approached the security station, introduced myself to the guard, and explained the purpose of the CEI. She contacted Mr. Mayhew to inform him of my arrival. The guard issued a vehicle pass to me and directed me to an administrative building. Mr. Mayhew met me upon my arrival at the administrative building. I introduced myself to Mr. Mayhew and explained the purpose of the CEI. Mr. Mayhew escorted me to a conference room where I conducted an entry briefing with him.

During the entry briefing, I presented my business card and EPA credentials to Mr. Mayhew. I explained the scope and procedures for the CEI. I explained the facility's right to make confidentiality claims and provided a Notice Regarding Proprietary/Confidential Business Information. I stated that at the conclusion of the CEI, he would be presented with a Confidentiality Notice with which he could make or not make a claim of confidentiality for the facility. I also provided Mr. Mayhew a copy of U.S. Federal Codes 1001 and 1002, concerning communication of false statements and documents to federal inspectors, and RCRA Section 3007, explaining EPA's inspection authority, both of which he read.

Messrs. McGraw and Pickar joined the CEI after the entry briefing. I provided a copy of U.S. Federal Codes 1001 and 1002 to Messrs. McGraw and Pickar, which they read prior to participating in the CEI.

A copy of each of the following documents was left with the facility during the inspection:

- RCRA Facility Access Information Sheet
- Mr. Trevor Urban's contact information (a business card was not available)
- RCRA Section 3007
- U.S. Federal Codes 1001 and 1002
- Instructions for Responding to a Notice of Preliminary Findings
- Notice Regarding Proprietary/Confidential Business Information
- U.S. EPA Small Business Resources Information Sheet
- Chemical Facility Anti-Terrorism Standards
- E-Manifest Fact Sheet: Generators
- Managing Your Hazardous Waste: A Guide for Small Businesses
- Part 279 Requirements: Used Oil Management Standards
- EPA Region 7 Emergency Response Program
- Recycling Electronics: A Guide for Businesses
- Battery Recycling/Disposal
- Management of Fluorescent Lamps for Businesses
- Incompatible Chemicals
- Universal Wastes – Including Aerosol Cans
- TCLP – Toxicity Characteristic Leaching Procedure
- Iowa Environmental Guide for Businesses

I reviewed the Notification Acknowledgement/Verification Report (Verification Report) with Mr. Mayhew (Attachment 1). I noted that the Verification Report identified Cambrex as a healthcare facility in the Other Activities section. I asked Mr. Mayhew if the Cambrex met the definition of a healthcare facility in Title 40 *Code of Federal Regulations* (40 CFR) Subpart P. He explained that Cambrex is a manufacturer of active pharmaceutical ingredients (API) and not a healthcare facility. Therefore, I changed the Other Activities section of the Verification Report to "no" for healthcare facility. Based on my interview with Mr. Mayhew and visual observations during the CEI, I made no other changes to the Verification Report.

I conducted the visual inspection and records review on March 26, 2024, accompanied by Messrs. Mayhew, McGraw, and Pickar (Cambrex Group). During the records review, I reviewed facility documentation such as waste shipping records, waste profiles, inspection logs, RCRA Contingency Plan, training records, and written job descriptions. I prepared and completed a site-specific inspection checklist to document my observations.

I conducted an exit briefing on March 26, 2024, with the Cambrex group. During the exit briefing, I provided a Receipt for Documents and Samples, which Mr. Mayhew signed, acknowledging receipt (Attachment 2). I provided Mr. Mayhew the Confidentiality Notice, which he signed indicating no confidential business information had been provided (Attachment 3). I also provided Mr. Mayhew a Notice of Preliminary Findings (NOPF), which he signed to acknowledge receipt (Attachment 4).

A map of facility was obtained during the CEI and is in Attachment 5. An aerial photograph of the facility was downloaded after the CEI and is in Attachment 6. The 82 photographs taken during the CEI are in Attachment 7; of these, 77 are discussed in this report.

FINDINGS AND OBSERVATIONS

1. Facility Description and General Information

Cambrex is a contract development and manufacturer of a wide range of API and pharmaceutical intermediates, including highly potent molecules and controlled substances. The facility consists of several production units (Chem 1, Chem 2, Pharma 1, Pharma 2, Pharma 3/4, and the Pilot Plant), as well as research and development (R&D) areas, laboratories, warehouses, administrative offices, and an onsite wastewater treatment plant (WWTP) to treat production wastewater (Attachment 5).

The facility was originally constructed in 1949 as Dr. Salsbury's Laboratories and later renamed Salsbury Laboratories, Inc. The facility was purchased by a division of Solvay America, Inc., in 1979 and renamed Solvay Animal Health, Inc. Cambrex acquired the facility in 1991. The facility consists of multiple buildings with approximately 380,000 square feet under roof on approximately 45 acres (Attachment 5 and Attachment 7, Photograph 82). Cambrex currently employs approximately 400 personnel who typically work one of two rotating 12-hour shifts. The facility operates 24 hours per day, 7 days per week.

API and pharmaceutical intermediates are generally produced by batch reactions of acids and bases with solvents. Desired products are then separated from production wastes. Bulk production wastes include spent non-halogenated solvents, spent halogenated solvents, aqueous waste with trace solvents, compound production wastes, solvent cakes (waste solids), and other hazardous waste liquids and solids. The facility has determined that each of these wastes is hazardous based on product and process knowledge. These wastes are accumulated in less-than-90-day hazardous waste aboveground storage tanks (ASTs) or less-than-90-day hazardous waste container accumulation areas (HWCAAs). Smaller volume wastes, such as spent solvents and expired chemicals generated from the laboratories, are accumulated in a dedicated less-than-90-day HWCAA in Warehouse 1 for labpack wastes. Wastes accumulated in the Warehouse 1 labpack HWCAA are processed (evaluated to make hazardous waste determinations), repackaged, and transported off site monthly. A list of the facility's less-than-90-day HWCAAs and ASTs is included as Attachment 8.

Four of the facility's 12 hazardous waste ASTs are reactor tanks (designated with an "R" in the AST name). According to Mr. Mayhew, reactor tanks are primarily used for neutralization of hazardous waste streams. Thermal treatment is not performed in the tanks. Reactor tanks are managed according to the less-than-90-day hazardous waste AST requirements.

Domestic wastewater discharges to the sanitary sewer for treatment at the Charles City publicly-owned treatment works (POTW). However, wastewater from production processes drains to an onsite WWTP for activated sludge treatment. The facility generates approximately 180,000 gallons of process wastewater per day. The wastewater treatment process includes pH adjustment/equalization, aeration, clarification, and sludge dewatering via fan press. Treated effluent is discharged to the Cedar River under a National Pollutant Discharge Elimination System (NPDES) permit. Wastewater treatment biosolids (sludge) are transported off site for landfill disposal. The facility considers wastewater treatment biosolids to be nonhazardous based on product/process knowledge and annual analytical testing.

Equipment and facility maintenance generate used oil, waste aerosol cans and aerosol can residue, used batteries, used lead-acid batteries, used lamps, and general trash. Used oil is managed according to requirements of 40 CFR Part 279. Waste aerosol cans punctured and drained upon generation. Drained aerosol cans are considered scrap metal and are collected for offsite recycling. Aerosol can residue is accumulated in a satellite accumulation area (SAA) container beneath the aerosol can puncturing device. The facility considers aerosol can residue to be hazardous based on product and process knowledge.

Used lead-acid batteries are collected for reclamation according to requirements of 40 CFR Part 266 Subpart G. Other used batteries and used lamps are managed as universal wastes according to requirements of 40 CFR Part 273. General trash, consisting of general office and non-production solid wastes, is considered nonhazardous and collected for landfill disposal.

Cambrex was previously inspected by EPA on April 24-26, 2018. The previous CEI included monitoring areas, processes, and equipment using a vapor analyzer and infrared optical gas imaging camera. The inspector left a Notice of Violation (NOV) for the following findings during the CEI:

- Failure to operate three pressure/vacuum relief vents with no detectable emissions
- Failure to monitor seven valves in contact with hazardous waste for leaks

These findings were not repeated during this CEI, but I did not repeat the field screening or imaging performed during the previous CEI.

2. RCRA Status

Cambrex was identified as a LQG of hazardous waste (generating more than 1,000 kilograms [kg] of hazardous waste per month) on the Verification Report provided by EPA (Attachment 1). During the CEI, I determined the facility's hazardous waste generator status through a review of internal waste tracking records, waste reports, uniform hazardous waste manifests, and interviews with the Cambrex group.

I obtained a copy of the facility's 2023 Hazardous Waste Biennial Report (Attachment 9). Mr. Mayhew also provided a copy of the facility's waste tracking spreadsheet for 2023 (Attachment 10). Based on these records, Cambrex generated more than 10,000,000 pounds of hazardous waste in 2023. Messrs. Mayhew and McGraw explained that the 2023 hazardous waste generation rate was representative of the current hazardous waste generation rate. I reviewed uniform hazardous waste manifests from 2021 to the date of the CEI and noted a similar rate of hazardous waste generation. Copies of a representative week of uniform hazardous waste manifests, dated March 11 through March 14, 2024, are in Attachment 11. Based on records reviewed, I confirmed that Cambrex is operating as a LQG of hazardous waste and inspected the facility as such. I also inspected Cambrex as a small quantity handler (SQH) of universal waste (accumulating less than 5,000 kg of universal waste at any time) and a used oil generator.

Cambrex manages one primary less-than-90-day HWCAA identified as the Old Flammable Storage Area, and a second less-than-90-day HWCAA in Warehouse 1 where smaller volumes of waste are accumulated prior to lab packing. I inspected both HWCAAs during the CEI. I also inspected an ad-hoc HWCAA in Pharma 1 that the facility managed as a SAA, although I determined it did not meet the requirements for a SAA outlined in 40 CFR 262.15.

Cambrex also manages hazardous waste in 12 less-than-90-day hazardous waste ASTs. A list of the AST names, capacities, and types of waste accumulated in each tank is in Attachment 12. The locations of each AST are marked on the facility map in Attachment 5. I inspected each less-than-90-day hazardous waste AST during the CEI. I also inspected SAAs in the laboratories and the North End Waste Garage. Messrs. Mayhew, McGraw, and Pickar accompanied me during the visual inspection of the facility.

3. Waste Streams

This section of the CEI report describes waste streams generated by the facility, including the facility's waste determination and waste codes, generation process and rate, management at the facility, and ultimate disposition. Based on the 2023 internal waste tracking spreadsheet (Attachment 10), the facility generates more than 100 wastes. The following discussion includes

the wastes generated in the largest quantity and wastes I observed in accumulation during the CEI. It is not a comprehensive account of all wastes generated at the facility.

Spent non-halogenated solvents include various non-halogenated solvents generated from manufacturing and laboratory testing. The facility considers the waste to be hazardous (D001, F003, F005) based on product and process knowledge. Based on 2024 uniform hazardous waste manifest records, the facility generates approximately 747,000 pounds of spent non-halogenated solvents per month. Bulk generated spent non-halogenated solvents from production areas are pumped to less-than-90-day hazardous waste ASTs T-1219, T-1257, T-2115, and T-2123. Spent non-halogenated solvents generated in the laboratories are accumulated in SAA containers and transferred to the less-than-90-day hazardous waste ASTs when the SAA containers are full. The waste is transported to Green America Recycling in Hannibal, Missouri, or Veolia ES Technical Solutions (Veolia) in Sauget, Illinois, for energy recovery.

During the CEI, I observed several 2.5- and 5-gallon SAA containers of spent non-halogenated solvents in the Chem Development Lab, Quality Control (QC) Lab, and Atomic Absorption (AA) Lab. The SAA containers were connected to analytical equipment or in dedicated areas of a fume hood. Cambrex considers each laboratory to be a separate SAA. Mr. Mayhew explained that the facility is aware of the 55-gallon limit for satellite accumulation, and frequently evaluates the number and sizes of waste accumulation containers within each laboratory SAA to ensure the 55-gallon limit is not exceeded. All SAA containers observed in laboratories were near the point of generation, under control of the operator, structurally sound, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and closed. Representative photographs of laboratory SAA containers of spent non-halogenated solvents are in Attachment 7, Photographs 72 through 79.

Full SAA containers from the laboratories are taken to a temporary staging area for addition of the waste to a less-than-90-day hazardous waste AST. According to Messrs. Mayhew and McGraw, SAA containers are emptied into an AST and returned to the laboratory within the same shift they are placed into the temporary staging area. During the CEI, I observed two 2.5-gallon SAA containers in a temporary staging area in Pharma 1 (Attachment 7, Photograph 26). Both SAA containers were structurally sound and closed. One SAA container was labeled with the words "hazardous waste" and an indication of the nature of the hazard (Attachment 7, Photographs 27 and 28). However, the other SAA container was not labeled with the words "hazardous waste," as required by 40 CFR 262.15(a)(5)(i), or an indication of the nature of the hazard, as required by 40 CFR 262.15(a)(5)(ii) (Attachment 7, Photographs 29 and 30) **(NOPF Nos. 1 and 2)**.

I provided compliance assistance regarding labeling of SAA containers. During the CEI, Cambrex personnel affixed labeling with the words "hazardous waste" and an indication of the nature of the hazard to the previously-unlabeled SAA container (Attachment 7, Photograph 31).

During the CEI, I observed a 330-gallon hazardous waste accumulation container (HWAC) in Pharma 1 actively receiving spent non-halogenated solvent from process vessel T-5403 (Attachment 7, Photograph 22). The HWAC had an open port allowing the container to vent while filling, and a vacuum hose near the open port was in place to capture volatile emissions (Attachment 7, Photograph 24). The HWAC was structurally sound, labeled with the words

"hazardous waste" and an indication of the nature of the hazard, and held approximately 75 gallons of waste. However, the HWAC was not marked with an accumulation start date, as required by 40 CFR 262.17(a)(5)(i)(C) (Attachment 7, Photographs 22, 23, and 25) **(NOPF No. 3)**.

I provided compliance assistance regarding labeling of HWACs during the CEI. I returned to the area approximately 2 hours later and observed that the HWAC was no longer actively receiving hazardous waste. The open port allowing the container to vent while filling had been closed (Attachment 7, Photograph 32). Cambrex personnel had also affixed a label to the HWAC with an accumulation start date of March 26, 2024 (Attachment 7, Photograph 36).

During the CEI, I observed hazardous waste ASTs T-1219, T-1257, T-2115, and T-2123 (Attachment 7, Photographs 10 through 12 and 16 through 18). The less-than-90-day hazardous waste ASTs were structurally sound and labeled with the words "hazardous waste" and an indication of the nature of the hazard. I determined the volume of waste in each tank by control room readings. AST T-1257 held 2,074 gallons of waste, AST T-2115 held 110 gallons of waste, and T-2123 held 6,026 gallons of waste. AST T-1219 was empty at the time of the CEI. Each of the hazardous waste ASTs had been pumped empty within the last 90 days.

Spent halogenated solvents consist of spent solvents generated from manufacturing and laboratory testing processes that include methylene chloride. The facility considers the waste to be hazardous (D001, F002, F005) based on product and process knowledge. Based on 2024 uniform hazardous waste manifest records, the facility generates approximately 38,000 pounds of spent halogenated solvents per month. Bulk generated spent halogenated solvents from production areas are pumped to less-than-90-day hazardous waste ASTs T-1243 and T-1244. Spent halogenated solvents generated in the laboratories are accumulated in SAA containers and transferred to the less-than-90-day hazardous waste ASTs when the SAA containers are full. The waste is transported to Veolia in West Carrollton, Ohio, for reclamation.

During the CEI, I observed a 2.5-gallon SAA container of spent halogenated solvents in a fume hood in the Chem Development Lab (Attachment 7, Photographs 72 and 74). The SAA container was near the point of generation, under control of the operator, structurally sound, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and closed.

I also observed hazardous waste ASTs T-1243 and T-1244 (Attachment 7, Photographs 14 and 15). The less-than-90-day hazardous waste ASTs were structurally sound and labeled with the words "hazardous waste" and an indication of the nature of the hazard. Based on control room readings, AST T-1243 held 0.5 gallons of waste, and AST T-1244 held 720 gallons. Each of the hazardous waste ASTs had been pumped empty within the last 90 days. I noted no deficiencies with accumulation of spent halogenated solvents during the CEI.

Aqueous waste with trace solvents consist of aqueous production wastes with low concentrations of non-halogenated solvents generated from manufacturing and laboratory testing processes. The facility considers the waste to be hazardous (D001, F003, F005) based on product and process knowledge. Based on the 2023 Hazardous Waste Biennial Report (Attachment 9), the facility generates approximately 62,570 pounds of aqueous waste with trace solvents per month. Bulk generated aqueous waste with trace solvents from production areas are pumped to

less-than-90-day hazardous waste ASTs T-1232 and T-1258. Spent aqueous waste with trace solvents generated in the laboratories are accumulated in SAA containers and transferred to the less-than-90-day hazardous waste ASTs when the SAA containers are full. The waste is transported to Veolia in Sauget, Illinois, for incineration.

During the CEI, I observed hazardous waste ASTs T-1232 and T-1258 (Attachment 7, Photographs 7, 8, and 15). The less-than-90-day hazardous waste ASTs were structurally sound and labeled with the words "hazardous waste" and an indication of the nature of the hazard. Based on control room readings, AST T-1232 held 3,027 gallons of waste, and AST T-1258 held 1,426 gallons. Each of the hazardous waste ASTs had been pumped empty within the last 90 days. I noted no deficiencies with accumulation of aqueous waste with trace solvents during the CEI.

Compound production wastes are compound-specific wastes generated during manufacturing. The facility has made hazardous waste determinations for each compound production waste based on product and process knowledge. Depending on the compound, applicable hazardous waste codes can include one or more characteristic or listed codes. Based on the 2023 Hazardous Waste Biennial Report (Attachment 9), the facility generates approximately 85,000 pounds of hazardous compound production wastes per month. The wastes are accumulated in 330-gallon HWACs when generated during production. The HWACs are transferred to a less-than-90-day HWCAA, and are transported to Veolia in Sauget, Illinois, West Carrollton, Ohio, or Menomonee Falls, Wisconsin, for incineration or fuel blending. I did not observe compound production wastes in accumulation during the CEI.

Other hazardous wastes include a variety of characteristic and/or listed hazardous wastes generated during manufacturing. The facility makes a hazardous waste determination for each waste based on product and process knowledge. The types and quantities of the waste vary depending on production needs, and I did not determine a generation rate during the CEI. The wastes are accumulated in various sized HWACs (typically 55-gallon containers) and are transferred to a less-than-90-day HWCAA. The wastes are transported to Veolia in Sauget, Illinois, for disposition depending on the type of waste.

During the CEI, I observed eleven 55-gallon HWACs of hazardous waste flammable liquids and four 55-gallon HWACs of hazardous waste corrosive liquids in the Old Flammable Storage Area HWCAA (Attachment 7, Photographs 37 through 41). All HWACs were structurally sound, closed, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and marked with an accumulation start date. The earliest accumulation start date was February 26, 2024. I noted no deficiencies regarding management of other hazardous wastes during the CEI.

Labpack wastes include a variety of small-volume wastes primarily generated from the laboratories or during manufacturing. The facility makes a hazardous waste determination for each waste based on product and process knowledge. The types and quantities of the waste vary depending on testing or production needs, and I did not determine a generation rate during the CEI. The wastes are accumulated in small (less than 4-liter) HWACs and are transferred to the Warehouse 1 Labpack HWCAA. Wastes accumulated in the Warehouse 1 Labpack HWCAA are sorted and evaluated, repackaged, and transported off site monthly. The wastes are transported to

Veolia in Sauget, Illinois, or Menomonee Falls, Wisconsin, for disposition depending on the type of waste.

During the CEI, I observed the Warehouse 1 Labpack HWCAA (Attachment 7, Photograph 66). The HWCAA consisted of a plastic rack that held individually-labeled containers of waste. The rack was labeled with the words "hazardous waste," an indication of the nature of the hazards, and an accumulation start date of March 21, 2024 (Attachment 7, Photographs 67 through 69). According to Mr. Mayhew, the accumulation start date indicated the date the first small container was placed on the top rack (for wastes awaiting determination). The small containers of waste on the top rack were individually closed and labeled to indicate the contents. Five 4-liter containers of hazardous waste were on the middle rack of the HWCAA (Attachment 7, Photographs 70 and 71). The 4-liter containers were closed, labeled with the words "hazardous waste," and marked with accumulation start dates. The earliest accumulation start date on the 4-liter containers was March 17, 2024. I noted no deficiencies regarding management labpack wastes during the CEI.

Solvent cakes are waste solids generated during batch production of API and pharmaceutical intermediates. The facility considers solvent cakes to be hazardous (D001 and other characteristic or listed waste codes as applicable) based on product and process knowledge. Based on the 2023 Hazardous Waste Biennial Report (Attachment 9), the facility generates approximately 5,580 pounds of solvent cakes per month. The waste is accumulated in plastic-lined 1-cubic-yard HWACs and are transferred to the Old Flammable Storage Area less-than-90-day HWCAA. The wastes are transported to Veolia in Sauget, Illinois, of Green America Recycling in Hannibal, Missouri, for incineration or fuel blending.

During the CEI, I observed four 1-cubic-yard HWACs of Pilot Plant solvent cakes in the Old Flammable Storage Area HWCAA (Attachment 7, Photographs 37 and 42 through 45). All HWACs were structurally sound, closed, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and marked with an accumulation start date. The earliest accumulation start date was February 18, 2024. I noted no deficiencies regarding management of solvent cakes during the CEI.

Hazardous solids include a variety of waste solids generated from the laboratories or during manufacturing. These solids include production waste, waste personal protective equipment (PPE), and waste vials from laboratory testing. The facility considers hazardous solids to be hazardous (D001 and other waste codes as applicable) based on product and process knowledge. The types and quantities of the waste vary depending on testing or production needs, and I did not determine a generation rate during the CEI. Hazardous solids generated in the laboratories (vials) are accumulated in 5-gallon SAA containers, and hazardous solids generated during manufacturing are accumulated in 55-gallon HWACs. Full containers are transferred to the Old Flammable Storage Area less-than-90-day HWCAA. The wastes are primarily transported to Veolia in Sauget, Illinois, or Menomonee Falls, Wisconsin, for incineration.

During the CEI, I observed a 5-gallon SAA container of waste vials in the AA Lab (Attachment 7, Photographs 80 and 81). The container was near the point of generation, under control of the operator, structurally sound, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and closed.

I also observed a 55-gallon container near the Old Flammable Storage Area HWCAA that held approximately 45 gallons of waste gas chromatogram (GC) vials from a laboratory (Attachment 7, Photograph 46). Mr. Mayhew identified the 55-gallon container as a SAA container, and explained that full SAA containers from the laboratories are emptied into the 55-gallon container near the Old Flammable Storage Area HWCAA. I explained that the 55-gallon container did not appear to meet the definition of a SAA container as it was not near the point of generation or under control of the laboratory operators. Therefore, I explained that I considered the 55-gallon container of waste GC vials to be a HWAC and inspected the container as such. The HWAC of waste GC vials was structurally sound, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and closed. However, the HWAC was not marked with an accumulation start date, as required by 40 CFR 262.17(a)(5)(i)(C) (Attachment 7, Photographs 47 and 48) **(NOPF No. 3)**.

I provided compliance assistance regarding management of HWACs during the CEI. Messrs. Mayhew and McGraw discussed the date that the 55-gallon container began accumulating waste. Based on the date of the previous waste shipment and volume of the container at the time of the CEI, they determined that the accumulation start date was mid-January 2024. Mr. Mayhew marked an accumulation start date of January 15, 2024, on the HWAC of waste GC vials (Attachment 7, Photograph 49).

In the Old Flammable Storage Area HWCAA, I observed six 55-gallon HWACs of hazardous flammable solids (Attachment 7, Photographs 37 through 39, 44, and 45). All HWACs were structurally sound, closed, labeled with the words "hazardous waste" and an indication of the nature of the hazard, and marked with an accumulation start date. The earliest accumulation start date was February 18, 2024.

Process wastewater consists of wastewater generated from API and pharmaceutical intermediates production. Process wastewater flows through gravity-fed drains directly to an onsite WWTP for activated sludge treatment. The facility generates approximately 180,000 gallons of process wastewater per day. The wastewater treatment process includes pH adjustment/equalization, aeration, clarification, and sludge dewatering via fan press. Treated effluent is discharged to the Cedar River under a NPDES permit. The facility considers the wastewater to be exempt from the definition of solid waste, per 40 CFR 261.4(a)(2).

During the CEI, I observed the WWTP components, including the equalization basin, two aeration tanks, two clarifiers, and fan press. I confirmed that process wastewater is not accumulated or stored prior to treatment at the WWTP. I noted no RCRA deficiencies with management or treatment of process wastewater.

Wastewater treatment biosolids consist of dewatered wastewater treatment sludge from the WWTP fan press. The facility generates approximately 25,000 to 30,000 pounds of wastewater treatment biosolids per week. Cambrex considers the waste to be nonhazardous based on product and process knowledge as well as annual analytical testing. Copies of the March 9, 2023, waste profile for wastewater treatment biosolids and the associated analytical testing report are included in Attachment 13. Based on the profile and analytical report, the nonhazardous waste determination appeared to be adequate.

Wastewater treatment biosolids are accumulated in two 25-cubic-yard roll-off containers in the WWTP building. The waste is transported to Glacier Ridge Landfill in Horicon, Wisconsin, for landfill disposal. During the CEI, I observed accumulation of wastewater treatment biosolids in a 25-cubic-yard roll-off container (Attachment 7, Photograph 65). I noted no deficiencies with management of wastewater treatment biosolids during the CEI.

Used oil is generated during maintenance of facility equipment. The facility manages used oil according to provisions of 40 CFR Part 279. The facility generates approximately 55 gallons of used oil per year. Used oil is accumulated in 55-gallon used oil storage containers in the North End Waste Garage and is transported Veolia in Menomonee Falls, Wisconsin, for recycling.

During the CEI, I observed two 55-gallon used oil storage containers in the North End Waste Garage (Attachment 7, Photograph 57). One container was full and the other held approximately 20 gallons of used oil. Both used oil storage containers were structurally sound and labeled with the words "used oil" (Attachment 7, Photographs 58 and 60). I noted no deficiencies with management of used oil during the CEI.

Waste aerosol cans consist of empty and unwanted aerosol cans generated during facility maintenance activities such as spot painting. I did not determine a generation rate for waste aerosol cans during the CEI. Waste aerosol cans are taken to an aerosol can puncturing device in the North End Waste Garage upon generation for puncturing and draining. After draining, waste aerosol cans are considered to be scrap metal and excluded from the definition of hazardous waste per 40 CFR 261.4(a)(13). Punctured and drained waste aerosol cans are added to the facility's scrap metal waste stream and are collected by Alter Scrap in Leroy, Minnesota, for recycling. I did not observe waste aerosol cans in accumulation during the CEI.

Aerosol can residue consists of liquids and propellant drained from waste aerosol cans in the North End Waste Garage. The facility considers aerosol can residue to be hazardous (D001) based on product and process knowledge. I did not determine a generation rate for aerosol can residue during the CEI. The waste is drained into a 55-gallon SAA container beneath an aerosol can puncturing device. Full SAA containers of aerosol can residue are transported to Veolia in Sauget, Illinois, for incineration.

During the CEI, I observed the aerosol can puncturing device and 55-gallon SAA container (Attachment 7, Photographs 61 and 62). The SAA container was at the point of generation, under control of the operator, structurally sound, labeled with the words "hazardous waste" and an indication of the nature of the hazard, closed, and held approximately 10 gallons of waste. I noted no deficiencies with management of aerosol can residue during the CEI. I provided compliance assistance regarding management of waste aerosol cans as universal waste.

Used batteries include all waste batteries generated during equipment maintenance except used lead-acid batteries. The facility manages used batteries as universal waste according to provisions of 40 CFR Part 273. Based on the facility's 2023 waste tracking records (Attachment 10), the facility generates approximately 11 pounds of used batteries per year. Used batteries are accumulated in universal waste accumulation containers in the North End Waste

Garage. Used batteries are shipped to Veolia in Port Washington, Wisconsin, through the RecyclePak program for recycling.

During the CEI, I observed a 3.5-gallon universal waste accumulation container for used batteries in the North End Waste Garage (Attachment 7, Photograph 54). The container held approximately 3 gallons of used batteries and was structurally sound, labeled with the words "universal waste-batteries," and marked with an accumulation start date of October 31, 2023 (Attachment 7, Photographs 55 and 56). I noted no deficiencies with management of used batteries during the CEI.

Used lead-acid batteries are generated during maintenance of facility equipment. The facility manages used lead-acid batteries according to provisions of 40 CFR Part 266, Subpart G. Based on the facility's 2023 waste tracking records (Attachment 10), the facility generates approximately 300 pounds of used lead-acid batteries per year. Used lead-acid batteries are accumulated in a 30-gallon container in the North End Waste Garage. Used lead-acid batteries are shipped to Veolia in Port Washington, Wisconsin, through the RecyclePak program for recycling.

During the CEI, I observed the 30-gallon container for used lead-acid batteries in the North End Waste Garage (Attachment 7, Photograph 61). The container held approximately 10 gallons of used lead-acid batteries with the terminals taped. The batteries appeared to be intact (that is, not leaking) and the 30-gallon container was structurally sound. I noted no deficiencies with management of used lead-acid batteries during the CEI.

Used lamps consist of used fluorescent and other lamps generated during facility maintenance. The facility manages all used lamps as universal waste according to provisions of 40 CFR Part 273. Based on the facility's 2023 waste tracking records (Attachment 10), the facility generates approximately 41 pounds of used lamps per year. Used lamps are accumulated in universal waste accumulation containers in Warehouse 1, and are shipped to Veolia in Port Washington, Wisconsin, through the RecyclePak program for recycling.

During the CEI, I observed a fiberboard universal waste accumulation container for used 4-foot fluorescent lamps and a 20-gallon container for smaller lamps in Warehouse 1. Both containers were empty at the time of the CEI. The containers were structurally sound, labeled with the words "universal waste-lamps" and marked with accumulation start dates of March 12, 2024 (4-foot container) and March 1, 2024 (20-gallon container). The accumulation start dates indicated the date each container was last emptied.

General trash consists of office, packaging, and other non-production refuse generated throughout the facility. The facility considers general trash nonhazardous based on product knowledge. General trash is accumulated in several containers throughout the facility and transferred to roll-off containers outside the facility. The waste is collected by LBJ Waste Solutions in Charles City, Iowa, and transported to the Floyd/Mitchell/Chickasaw County Landfill for disposal. I did not obtain a generation rate for general trash. During the CEI, I observed various containers for general trash accumulation and noted no deficiencies.

4. Required Response Equipment and Hazard Management

Per 40 CFR 262.15(a)(8) and 262.17(a)(6), a LQG must operate to minimize possibility of a fire, explosion, or spill, and must maintain emergency response equipment. During the CEI, I observed adequate aisle space for emergency response in the Old Flammable Storage Area and Warehouse 1 HWCAAs (Attachment 7, Photographs 37 and 66), and no evidence of spills or leaks. I observed sprinkler systems or fire extinguishers for fire protection, telephones for summoning emergency assistance, and spill control materials (such as granular absorbent material, brooms, and dust pans) readily available for spill response near each HWCAA, hazardous waste AST, and SAA. Representative photographs of emergency response equipment and materials are in Attachment 7, Photographs 50, 51, 63, and 64. I noted no deficiencies regarding response equipment and hazard management during the CEI.

5. HWCAAs

At the time of the CEI, the Old Flammable Storage Area less-than-90-day HWCAA held 26 HWACs (including the 55-gallon container of waste GC vials inspected as a HWAC). Wastes included hazardous solids (waste vials and flammable solids), other hazardous waste (flammable liquids and corrosive liquids), and solvent cakes. The earliest accumulation start date was January 15, 2024. The earliest accumulation start date in the Warehouse 1 Labpack HWCAA was March 19, 2024. Wastes were adequately segregated. In the Old Flammable Storage Area HWCAA, HWACs of flammable and corrosive wastes were on pallets in separate rows of the HWCAA, and the corrosive wastes observed were not concentrated. I noted no concerns with accumulation of incompatible wastes together.

I asked Mr. Mayhew if the HWCAAs are inspected. He stated that the HWCAAs and SAAs are inspected weekly and the inspections are documented. During the CEI, I reviewed inspection logs for the previous 3 years and noted no missed weeks or documented issues. Copies of the inspection logs for March 1 and 8, 2024, are included in Attachment 14 as examples.

Cambrex previously operated an additional HWCAA in the Chem 1 East Room for accumulation of containerized D002 and D021 wastes. Messrs. Mayhew and McGraw explained that the facility stopped using the Chem 1 East Room for waste storage in 2022. I asked Messrs. Mayhew and McGraw if the facility had performed any closure activities for the former HWCAA. They explained that all wastes were removed, the former HWCAA was rinsed, and the final rinse water was tested for pH to ensure adequate cleaning. Mr. McGraw stated that a memorandum documenting the location and closure of the former HWCAA was placed in the facility's operating record, as required by 40 CFR 262.17(a)(8)(i)(A). A copy of the Chem 1 East Room closure memorandum is in Attachment 15. During the CEI, I observed the Chem 1 East Room and noted storage of empty containers and products (Attachment 7, Photograph 52). No wastes were in accumulation in the Chem 1 East Room.

6. Hazardous Waste ASTs

Cambrex has 12 less-than-90-day hazardous waste ASTs. A list of the AST names, capacities, and types of waste accumulated in each tank is in Attachment 12. Four ASTs (R-3148, R-3149, R-4490, and R-4592 are reactor tanks used for neutralization and accumulation of hazardous

waste. Four ASTs (T-1219, T-1257, T-2115, and T-2123) are used for accumulation of spent non-halogenated solvents. Two ASTs (T-1243 and T-1244) are used for accumulation of spent halogenated solvents, and two ASTs (T-1232 and T-1258) are used for accumulation of aqueous waste with trace solvents. I inspected each of these ASTs during the CEI. I obtained the volume of waste in each AST by control room readings, except for ASTs R-4490 and R-4592 where I inadvertently neglected to obtain the readings.

The hazardous waste ASTs appeared to be structurally sound and were labeled with the words "hazardous waste" and an indication of the nature of the hazard (Attachment 7, Photographs 3 through 8 and 14 through 20). All hazardous waste ASTs were within secondary containment, and no structural deficiencies were noted in the secondary containment walls or floors. (Attachment 7, Photographs 9 through 11 and 21). The secondary containments serving outdoor hazardous waste ASTs were coated with an impervious protective coating. Each of the ASTs sharing a single secondary containment held compatible hazardous wastes.

I observed standing stormwater in one of the secondary containment structures (Attachment 7, Photograph 13). Charles City, Iowa, received more than 1 inch of precipitation in the 24 hours prior to the CEI. A pump within the secondary containment was actively pumping accumulated stormwater to the WWTP at the time of the CEI.

Hazardous waste AST volumes and conditions are monitored in control rooms associated with each production unit. I observed hazardous waste AST inspection reminders posted in the control rooms, as well as the accumulation start date for each AST (Attachment 7, Photographs 1 and 2). Waste transfer logs are maintained for each hazardous waste AST, documenting waste additions and removals, and the dates each AST was pumped empty. I reviewed the waste transfer logs for each AST for the previous 3 years and noted no accumulation of hazardous waste for longer than 90 days. Copies of the transfer logs for AST T-2123 in January 2024 are in Attachment 16 as examples.

I asked Mr. Mayhew if the hazardous waste ASTs are inspected. He stated that all hazardous waste ASTs are inspected daily, regardless of whether they hold waste, and inspections are documented. During the CEI, I reviewed inspection logs for all hazardous waste ASTs for the previous 3 years and noted no missed inspections. Copies of the hazardous waste AST inspection logs for AST T-2123 for the weeks of February 12 and 19, 2024, are in Attachments 17 as examples. I noted no deficiencies with management of hazardous waste ASTs during the CEI.

7. Manifests, Bills of Lading, Biennial Report

The facility generated approximately 250 to 300 uniform hazardous waste manifests over the past 3 years. I reviewed an estimated 60 manifests and associated LDR notifications during the CEI (all 2024 manifests, approximately 20 percent of the manifests from 2023, and randomly-selected manifests from 2022 and 2021). Copies of the manifests from a representative week of waste shipments, dated March 11 through 14, 2024, are in Attachment 11. I also reviewed randomly-selected nonhazardous waste manifests and bills of lading, and the 2023 Hazardous Waste Biennial Report (Attachment 9). I noted no deficiencies during my review of manifests, bills of lading, and the Biennial Report.

8. Personnel Training Requirements

Personnel training is required by LQG regulations specified in 40 CFR 262.17(a)(7) to ensure that employees are thoroughly familiar with proper waste handling procedures relevant to their responsibilities. During the CEI, I discussed personnel training requirements with Mr. Mayhew. He explained that all personnel are provided initial RCRA training upon hiring, and annual RCRA training thereafter. I reviewed the training material (slides) for the 2023 RCRA training slides, which included topics such as RCRA awareness, waste management procedures, universal waste handling, and emergency response procedures (Attachment 18). Records documenting RCRA training for all personnel in 2023, 2022, and 2021 are in Attachment 19.

I reviewed written job descriptions for several positions that handle hazardous waste, such as production area operators and laboratory positions. The written job descriptions listed duties (including management of hazardous waste), skills and requirements, and training requirements. Copies of the written job descriptions for QC Chemist, High Potency API (HIPO) Operator, and Pharma Reactor Operator are in Attachment 20 as examples. I noted no deficiencies regarding personnel training requirements during the CEI.

9. Preparedness and Prevention and Contingency Plan

As an LQG, Cambrex is required to arrange for emergency response with local emergency agencies, to designate an emergency coordinator (EC) for the facility, and maintain a Contingency Plan. During the CEI, I reviewed the facility's Contingency Plan. I noted the Contingency Plan included a description of actions needed to respond to fires, explosions, and spills, a description of arrangements with the local emergency agencies, a list of emergency response equipment (including capabilities and location), and a complete evacuation plan with a description of the signals used, as required by 40 CFR 262.17(a)(6) referencing 262.261(a, c, e, and f). The Contingency Plan also included names and telephone numbers of the primary EC (Mr. Scott Kendall, Operations Director) and alternate ECs, as required by 40 CFR 262.17(a)(6) referencing 262.261(d).

I also reviewed the facility's Quick Reference Guide, required by 40 CFR 262.17(a)(6) referencing 262.262(b). The Quick Reference Guide included a list with descriptions and maximum quantities of hazardous wastes onsite; identification of special hazards; maps showing hazardous wastes locations, overall facility location, and water supplies; identification of notification systems; and EC contact information. A copy of the facility's Quick Reference Guide, updated August 18, 2023, is in Attachment 21. I noted no deficiencies regarding preparedness and prevention or with content of the Contingency Plan and Quick Reference Guide during the CEI.

10. Air Emissions: 40 CFR Part 265 Subparts AA, BB, CC

EPA regulations in 40 CFR Part 265, Subparts AA, BB, and CC apply to LQGs. If a LQG manages hazardous waste with an organic concentration greater than 10 parts per million by weight (ppmw), the standards specified in Subpart AA apply to hazardous waste air emissions from certain process vents. A process vent used in distillation, fractionation, solvent extraction, thin-film evaporation, air stripping, or steam stripping is regulated by Subpart AA. Cambrex is

not subject to the Subpart AA regulations because the facility does not have any of the process vents listed above.

If a LQG has equipment that contains or contacts hazardous waste composed of 10 percent or greater organics by weight, the facility is subject to Subpart BB standards for inspection and monitoring of the equipment. Cambrex is subject to the Subpart BB regulations because it has equipment that contains or comes in contact with hazardous waste. According to Mr. Mayhew, all but three hazardous waste ASTs are considered to be in light liquid service and are subject to Subpart BB requirements after exceeding 300 hours of service per year. Copies of internal memorandums documenting Subpart BB applicability are in Attachment 22.

Cambrex contracts with a third party, Trinity Consultants, to perform Subpart BB monitoring. Mr. Mayhew explained that most equipment that contacts hazardous waste falls below 300-hour threshold in 40 CFR 265.1050(f). Trinity Consultants determines which equipment needs to be monitored and performs the monitoring. A copy of the January 2024 Leak Detection and Repair (LDAR) report from Trinity Consultants is in Attachment 22. I noted no deficiencies with hazardous waste per the Subpart BB air emissions requirements.

The standards found in Subpart CC apply to LQGs that manage hazardous waste in containers with organic compounds (VOC) concentration that exceeds 500 ppmw. The Subpart CC standards are applicable because the facility accumulates hazardous waste that contains VOCs in 55-gallon and 330-gallon HWACs. During the CEI, I determined that Cambrex meets the Subpart CC requirements for containers by using Container Level 1 and Level 2 controls (containers that are Department of Transportation [DOT]-approved). I noted no concerns with management of hazardous waste per the Subpart CC air emissions requirements.

11. Summary of Preliminary Findings

In summary, as part of the CEI, I made the following preliminary findings:

1. Failure to label one SAA container with the words “hazardous waste,” as required by 40 CFR 262.15(a)(5)(i) **(NOPF No. 1)**
2. Failure to label one SAA container with an indication of the nature of the hazard, as required by 40 CFR 262.15(a)(5)(ii) **(NOPF No. 2)**
3. Failure to label two HWACs with an accumulation start date, as required by 40 CFR 262.17(a)(5)(i)(C) **(NOPF No. 3)**

Other than items specifically noted in the narrative, I observed no additional issues. However, further review by EPA may change or add to my findings.

John D. Dixon

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John D. Dixon
Inspector
CLAENE Group, LLC.

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Amber Whisnant
Section Chief
ECAD/CB/RCRA, EPA Region 7

Attachments

1. Notification Acknowledgement/Verification Report (2 Pages)
2. Receipt for Documents and Samples (1 Page)
3. Confidentiality Notice (1 Page)
4. Notice of Preliminary Findings (1 Page)
5. Facility Map (1 Page)
6. Google Earth Aerial Photograph (1 Page)
7. Photographic Documentation (82 Photos and Photolog) (49 Pages)
8. List of Hazardous Waste Accumulation Areas (1 Page)
9. 2023 Biennial Report (22 Pages)
10. Waste Tracking Spreadsheet for 2023 (2 Pages)
11. Uniform Hazardous Waste Manifests for Week of March 11, 2024 (5 Pages)
12. List of Bulk Waste ASTs (2 Pages)
13. Profile with Analytical Results for Wastewater Treatment Biosolids (28 Pages)
14. Weekly Waste Container Inspection Logs (2 Pages)
15. Chem 1 East Room HWCAA Closure Memorandum (1 Page)
16. Transfer Logs for AST T-2123 in January 2024 (2 Pages)
17. Inspection Logs for AST T-2123 for Weeks of February 12 and 19, 2024 (2 Pages)
18. 2023 RCRA Training Slides (49 Pages)
19. RCRA Training Records for 2023, 2022, and 2021 (22 Pages)
20. Job Descriptions for QC Chemist, HIPO Operator, and Pharma Reactor Operator (12 Pages)
21. Quick Reference Guide (11 Pages)
22. Subpart BB Applicability Memorandums (2 Pages)
23. January 2024 LDAR Report (9 Pages)