REPORT OF RCRA COMPLIANCE EVALUATION INSPECTION

At

VALENT BIOSCIENCES LLC
2142 350th Street
Osage, Iowa 50461
847-968-4757

EPA ID Number: IAR000519736

On

May 18, 2021

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 (ECAD/CB/RCRA) of the U.S. Environmental Protection Agency (EPA) Region 7, Toeroek Associates, Inc. and its subcontractor Tetra Tech (Toeroek team) conducted a hazardous waste compliance evaluation inspection (CEI) at Valent Biosciences LLC (Valent) at 2142 350th Street, Osage, 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. This report and its attachments present the findings of the CEI.

PARTICIPANTS

Valent:

Jake Larrison, Senior Environmental Health and Safety (EHS) Specialist
Jerry Hogan, EHS Manager
Ertan Hyuseinov, Plant Manager
Carrie Halsne, Human Resources Manager
Lindsay Voight, Training Specialist

Toeroek Team:

Heather K. Wood, Environmental Consultant, (816) 412-1768

INSPECTION PROCEDURES

Due to the spread of coronavirus disease 2019 (COVID-19) at the time of the CEI, I contacted Valent via telephone 1 week prior to the scheduled inspection and spoke to Mr. Hogan. The purpose of the initial contact was to identify the appropriate facility representative, ensure the representative would be available during the CEI, and to discuss protocols, procedures, and any other requirements adopted by the facility to mitigate the spread of COVID-19.

Prior to the CEI at Valent on May 18, 2021, I conducted a drive-by inspection. I did not observe any areas of concern during the drive-by. Upon my arrival, I was met in the lobby by Mr. Larrison. He escorted me to a conference room where we were joined by Messrs. Hogan and Hyuseinov and Ms. Halsne for the entry briefing.

During the entry briefing, I presented my business card and EPA credential letter to Messrs. Larrison. Hogan, and Hyuseinov and Ms. Halsne (the "Valent group"). I explained the scope of the CEI and the data gathering procedures that would be employed (for example, interviews, visual inspection, records review, and digital photography). I then informed them of the facility's right to make confidentiality claims for any or all of the information obtained. I stated that at the conclusion of the CEI, they would be presented with a Confidentiality Notice (Notice) with which they could make or not make a claim of confidentiality for the facility. I also provided them 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 they read.

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 business card
- 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
- Managing your Hazardous Waste: A Guide for Small Businesses

- U.S. EPA Small Business Resources Information Sheet
- Industry Sector Notebooks
- Environmental Compliance Assistance Centers
- Solvent-Contaminated Wipes Final Rule Summary Chart
- IDNR Excluded Solvent-Contaminated Wipes Rule: Management Practices for Wipes, Rags, and Shop Towels
- Recycling Electronics: A Guide for Businesses
- Lead-Based Paint Activities: Handling and Disposal
- Battery Recycling/Disposal
- Management of Fluorescent Lamps for Businesses
- Incompatible Chemicals
- Universal Wastes – Including Aerosol Cans
- TCLP – Toxicity Characteristic Leaching Procedure
- RCRA Online: A Quick Reference Guide
- Security Awareness
- Chemical Facility Anti-Terrorism Standards

I reviewed the Verification Report with the Valent group (Attachment 1). Based on this review, as well as observations during the CEI, I added small quantity handler (SQH) of universal waste and used oil generator to the Type(s) of Regulated Activity section of the Verification Report; added waste codes D007 and D009; and removed waste codes F001 and F005.

I conducted the visual inspection of the facility, accompanied by Messrs. Hogan and Larrison and Ms. Halsne. I also reviewed available facility records including Safety Data Sheets (SDS), summary reports, and shipping manifests. Facility information gathered during the CEI is documented on the Data Gathering Worksheets and Checklists (Attachment 2).

At the conclusion of the CEI, I conducted an exit briefing with the Valent group. During the exit briefing, I provided a Receipt for Documents and Samples, which Mr. Hogan signed, acknowledging receipt (Attachment 3). I provided Mr. Hogan the Notice, which he signed to indicate no confidential business information (CBI) had been provided (Attachment 4). I also provided Mr. Hogan a Notice of Preliminary Findings (NOPF), which he signed to acknowledge receipt (Attachment 5).

Maps of the facility with locations of waste accumulation areas were obtained with the facility's quick reference guide (QRG) during the CEI and are in Attachment 6 (Pages 8 and 12 through 24). An aerial photograph of the facility is also included in the QRG (Attachment 6, Page 11). The 59 photographs taken during the CEI are in Attachment 7.

FINDINGS AND OBSERVATIONS

1. Facility Description and General Information

Valent formulates and produces active ingredients for "biorational" chemicals, including pesticides and soil amendments. The active ingredients are shipped to an offsite location operated by an independent company for packaging and production of final products. Raw

materials used include a variety of chemicals, enzymes, and food-related products. Production of the active ingredients involves fermentation, analysis of pesticide efficacy on insects, centrifugation, evaporation, crystal extraction, drying, and laboratory testing and analysis.

Valent began operations at this location in 2013, when the building was constructed. According to Mr. Hogan, Valent currently employs approximately 100 full-time staff. Mr. Hogan stated that the facility operates 24 hours a day, 7 days a week, with personnel spread over five shifts. The facility covers approximately 18 acres and is divided into a main building that is subdivided into production, office, and laboratory areas; a Central Utility Building (CUB) that houses maintenance and production water processing operations; and a wastewater pre-treatment plant (WWTP) that is owned by Mitchell County but operated by Valent for pretreatment of Valent's wastewater only.

The facility operates multiple laboratories in the main building. These include product testing laboratories, raw material testing laboratories, and laboratories to support the growth of insects and other test subjects. Wastes generated during laboratory operations include used isopropyl alcohol (IPA) wipes, wastes from operation of high performance liquid chromatography (HPLC) instruments, and formalin waste. The laboratories also generate waste from culture staining, which is consolidated with the HPLC waste. All of these wastes are considered hazardous. The facility also generates lab packs for off-specification or expired materials. The chemicals in the lab packs may be hazardous or nonhazardous and are evaluated on a case-by-case basis.

Production waste consists primarily of wastewater and wastes generated from the purification and treatment of feedstock process water. Process water treatment wastes include waste filter socks and used absorbent materials used to cleanup incidental spills of water treatment chemicals. Both of these wastes are considered hazardous. Wastewater is treated at the onsite pre-treatment WWTP, then discharged to the City of Osage publicly owned treatment works (POTW) for final treatment. The wastewater is considered nonhazardous. The Valent WWTP operations generate a WWTP sludge, which is also considered nonhazardous. Wastewater is tested twice weekly to ensure it meets discharge permit requirements, and the analysis of the effluent generates used chemical oxygen demand (COD) vials, which are considered hazardous.

One production process uses organic solvents as part of the Nutsche drying process. Methanol is used during liquid extraction and crystallization during the aminoethoxyvinyl glycine (AVG) recovery process. The remaining methanol is captured after the extraction process. The facility considers this used methanol to be hazardous waste. Materials used to clean up incidental spills of the waste methanol are also considered hazardous. According to Mr. Larrison, the facility has just begun testing the use of ethyl acetate as a solvent for this process. As a result, the facility has begun to generate waste ethyl acetate from Nutsche drying processes in a smaller drying unit. This waste is also hazardous.

In addition to these wastes, the facility's maintenance processes generate used oil and used oily debris including filters, both of which are managed as used oil; excluded solvent-contaminated wipes, which are considered exempt from the definition of hazardous waste; universal waste lamps, batteries, and aerosol cans; and general trash.

In October 2015, EPA conducted a CEI at Valent, when the Nutsche drying process had not come fully online and the facility was inspected as a small quantity generator (SQG). The inspector made one finding of failure to make a waste determination on solvent-contaminated wipes generated by maintenance operations. Although the facility is now attempting to manage these wipes as exempt solvent-contaminated wipes, they failed to meet all the requirements for the exemption during this inspection.

2. RCRA Status

Valent is identified as a large quantity generator (LQG) on the Verification Report provided by EPA (Attachment 1), generating more than 1,000 kilograms (kg) of hazardous waste per month. Based on my review of manifests, Valent generates approximately 6,000 kg of waste methanol alone per month. Valent is also a used oil generator and a SQH of universal waste (accumulating less than 5,000 kg of universal waste at any time).

The facility operates two less-than-90-day container central accumulation areas (CAA) in the glass washing room in the laboratory area and in the methanol room in the AVG Building. Waste methanol is accumulated in a less-than-90-day hazardous waste accumulation tank. During my inspection, I observed at least 23 SAAs across 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. The following discussion of waste streams is based on my interviews with the Valent group, the visual inspection, and my review of available documentation.

HPLC waste is generated from analytical activities in the facility's laboratories. The laboratories also generate waste from culture staining, which is consolidated with the HPLC waste. The primary solvent used by this process is methanol, and the facility considers this waste hazardous (D001, F003) waste based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 90 kg per month of this waste. HPLC waste is transported to Petro-Chem Processing (Petro-Chem) in Detroit, Michigan, or Solvent Recovery in Kansas City, Missouri, for bulking. It was last collected on May 4, 2021 (Attachment 9, Page 10).

During the visual inspection, I observed multiple SAA containers of HPLC waste in multiple laboratories. All but one of containers were identical 2.5-gallon, polypropylene quick-disconnect waste cans (Attachment 7, Photographs 2, 3, and 18). One container held used vials that contained HPLC waste (Attachment 7, Photograph 5). This container was a 5-gallon plastic bucket with a screw-top. The containers were all closed, in good condition, and labeled as "hazardous waste." They were also labeled to indicate the nature of the hazard (Class 3 flammable liquid). Each SAA container was associated with a single work station and under the control of the operator.

I also observed a 55-gallon hazardous waste accumulation container (HWAC) of HPLC waste in the glass washing CAA (Attachment 7, Photographs 9 and 11). Waste from the SAA containers in all of the laboratories is decanted into this container. According to Mr. Larrison, when this 55-gallon HWAC is full, it will be taken to the methanol room CAA, and it will be collected for disposal from there. He said that the containers are not re-dated when they are moved. The container was approximately half full. It was in good condition, securely closed, and labeled as "hazardous waste." It was also labeled to indicate the nature of the hazard (Class 3 flammable liquid). The container was dated May 4, 2021.

Used IPA wipes are generated from using IPA to clean surfaces in the laboratories. The facility considers this waste hazardous (D001) waste based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 5 kg per month of this waste. Used IPA wipes are transported to Petro-Chem in Detroit, Michigan, or Tradebe Treatment and Recycling (Tradebe) in East Chicago, Indiana, for bulking. They were last collected on May 4, 2021 (Attachment 9, Page 10).

During the visual inspection, I observed multiple SAA containers of used IPA wipes in multiple laboratories. Used IPA wipes were accumulated in 15-gallon metal containers (Attachment 7, Photographs 1, 6, and 7). The containers were all closed, in good condition, and labeled as "hazardous waste." They were also labeled to indicate the nature of the hazard (Class 4 flammable solids). Each SAA container was associated with a single work station and under the control of the operator.

I also observed a 55-gallon HWAC of used IPA wipes in the glass washing CAA (Attachment 7, Photographs 9 and 10). Used IPA wipes from the SAA containers in all of the laboratories are consolidated in this container. According to Mr. Larrison, when this 55-gallon HWAC is full, it will be taken to the methanol room CAA, and it will be collected for disposal from there. He said that the containers are not re-dated when they are moved. The container was approximately a quarter full. It was in good condition, securely closed, and labeled as "hazardous waste." It was also labeled to indicate the nature of the hazard (Class 4 flammable solid). The container was dated May 4, 2021.

Lab pack wastes are generated when expired or off-specification materials are removed from laboratory and manufacturing areas or from cleanup of chemical spills in the laboratory. The facility determines that the wastes are hazardous or nonhazardous based on product and process knowledge. Hazardous lab pack waste is manifested under a range of D, U, and P-list waste codes, and the generation rate varies widely. Based on the facility's 2019 Biennial Report, the facility has recently generated D001, D002, D003, U122, U123, and U220 lab pack wastes. The facility generated approximately 600 pounds of lab pack waste in 2019. The waste is transported to Petro-Chem in Detroit, Michigan, or Tradebe, in East Chicago, Indiana, for disposal, bulking, or recycling.

During the inspection, I did not observe any lab pack waste. According to Mr. Larrison, laboratory materials are evaluated for disposal immediately before a scheduled hazardous waste collection.

Formalin waste is generated during production of feed for insects raised in the QC laboratory. The facility considers this waste hazardous (D001, D002) waste based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 4 kg per month of this waste. Formalin waste is transported to Petro-Chem in Detroit, Michigan, or Solvent Recovery in Kansas City, Missouri, for bulking. It was last collected on May 4, 2021 (Attachment 9, Page 11).

During the visual inspection, I observed two SAA containers of formalin waste in the insectary rearing laboratory. Formalin waste was accumulated in two 4-liter glass SAA containers (Attachment 7, Photograph 8). The containers were both closed, in good condition, and labeled as "hazardous waste." They were also labeled to indicate the nature of the hazard (poison skull-and-crossbones pictograms). The containers were at the point of generation and under the control of the operator. One container was nearly full, and the other was approximately a quarter full.

Waste methanol is excess solvent remaining after the AVG crystallization process. The facility considers waste methanol to be hazardous waste (D001, F003) based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), I estimated that the facility generates approximately 5,000 gallons of waste methanol every 3 months, or 6,000 kg per month (assuming a density of approximately 3 kg per gallon). It is transported to Systech in Fredonia, Kansas, for fuel blending. It was last collected on May 3, 2021 (Attachment 9, Page 7).

During the inspection, I observed the hazardous waste accumulation tank used for waste methanol (Attachment 7, Photographs 31 through 38). Waste is piped from a valve inside the methanol room in the AVG Building. According to the tank certification report, the tank capacity is 9,422 gallons (Attachment 10). The tank is continuously monitored in the control room, including the high-level alarm. According to Mr. Larrison, at the time of the CEI, control room monitors showed that the tank held approximately 1,382 gallons of waste. I noted that the hazardous waste accumulation tank appeared to be structurally sound and was labeled with the words "hazardous waste" (Attachment 7, Photograph 31). It was also labeled to indicate the nature of the hazard (a hazard diamond with a fire hazard of 3 on the tank itself and a Class 3 flammable liquid placard on the secondary containment) (Attachment 7, Photograph 31 and 36). The tank was marked with an accumulation start date of May 3, 2021, consistent with the last waste manifest (Attachment 7, Photograph 32).

The tank itself was in secondary containment, along with the truck loadout area and all valves (Attachment 9, Photographs 32 through 36 and 38). All secondary containment was in good condition.

Methanol debris is generated during cleanup of incidental spills of waste methanol as it is piped from the methanol room into the hazardous waste accumulation tank. The facility considers this waste hazardous (D001, F003) waste based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 5 kg per month of this waste. Methanol debris is transported to Petro-Chem in Detroit, Michigan, or Solvent Recovery in Kansas City, Missouri, for bulking. It was last collected on May 4, 2021 (Attachment 9, Page 10).

During the visual inspection, I observed a SAA container of methanol debris in the methanol room. Methanol debris was accumulated in a 55-gallon metal SAA container (Attachment 7, Photograph 23). The container was closed, in good condition, and labeled as "hazardous waste." It was also labeled to indicate the nature of the hazard (Class 4 flammable solids). The SAA was adjacent to the tank fill pipe valve and under the control of the operator. The container was less than a quarter full.

Waste ethyl acetate is excess solvent remaining after the AVG crystallization process. According to Mr. Larrison, the facility is in the process of evaluating the use of ethyl acetate rather than methanol, and it just recently began generating the waste. The facility considers waste ethyl acetate to be hazardous waste (D001, F003) based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and statements by Mr. Larrison, I estimated that the facility generates approximately 10 kg of waste ethyl acetate per month. It has not yet been sent for disposal.

During the visual inspection, I observed a SAA container of waste ethyl acetate and a HWAC of waste ethyl acetate in the methanol room. Waste ethyl acetate was accumulated in 55-gallon metal container (Attachment 7, Photograph 24 through 26). The containers were closed, in good condition, and labeled as "hazardous waste." They were also labeled to indicate the nature of the hazard (Class 3 flammable liquids). The waste ethyl acetate is generated in an adjacent room. According to Mr. Larrison, the SAA container is kept in the methanol room rather than the drying room for fire safety purposes. He said that access to both rooms is limited to the equipment operators and the waste management team. I concluded that the container was near the point of generation and under the control of the operator. The HWAC, which was full, was marked with a May 7, 2021, accumulation start date. The SAA container was empty or nearly empty, based on the weight of the container.

Used water treatment chemical absorbents are generated during cleanup of incidental spills of chemicals used to purify and treat process water. The facility considers this waste hazardous (D002) waste based on product and process knowledge. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 7 kg per month of this waste. Used water treatment chemical absorbents are transported to Petro-Chem in Detroit, Michigan, for bulking. They were last collected on May 4, 2021 (Attachment 9, Page 11).

During the visual inspection, I observed three SAA containers of used water treatment chemical absorbents in the CUB. Each container was a 15-gallon metal SAA container (Attachment 7, Photographs 53 through 56). The containers were closed, in good condition, and labeled as "hazardous waste." They were also labeled to indicate the nature of the hazard (Class 8 corrosive). The SAA was adjacent to the storage area for water treatment chemicals and under the control of the operator. The SAA containers were nearly empty, based on the weight of the containers.

Used filter socks are generated during maintenance of a filter unit used to purify and treat process water. The facility considers this waste hazardous (D007) waste based on analysis. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 5 kg per month of this waste. Used filter socks are transported to

Tradebe in East Chicago, Indiana, for storage and transfer. They were last collected on April 24, 2018 (Attachment 9, Page 1).

During the visual inspection, I observed a SAA container of used filter socks in the CUB. The container was a 55-gallon plastic SAA container (Attachment 7, Photographs 57 and 58). The containers was closed, in good condition, and labeled as "hazardous waste." It was also labeled to indicate the nature of the hazard (Class 9 miscellaneous and "chromium"). The SAA was adjacent to the filtration unit and under the control of the operator.

Wastewater is generated from the facility's manufacturing operations. After fermentation and extraction of chemicals, the remaining liquid and solids are piped to the WWTP, with the exception of the waste solvents from Nutsche drying processes (waste methanol and waste ethyl acetate, described above). After pre-treatment, it is discharged to the City of Osage POTW. Wastewater is treated in the onsite pre-treatment WWTP and tested twice weekly for COD, biological oxygen demand, total suspended solids, and nitrogen. The facility considers the wastewater nonhazardous based on process and product knowledge and analytical testing. The wastewater would also be exempt from the definition of hazardous waste at the point of discharge per Title 40 *Code of Federal Regulations* (40 CFR) 261.4(a)(2). Staff at the WWTP estimated that the facility generates approximately 137,000 gallons per day of treated wastewater. During the CEI, I observed the WWTP and noted no deficiencies.

Wastewater treatment sludge is generated from treatment of wastewater and consists of the solids removed during treatment, which consist primarily of biological materials. The facility considers the wastewater treatment sludge nonhazardous based on process and product knowledge and analytical testing of the wastewater. Staff at the WWTP estimated that the facility generates approximately 10 million gallons per year of wastewater treatment sludge. Smith Agriculture of Osage, Iowa, collects the sludge for land application as fertilizer. I did not observe the wastewater treatment sludge.

Used COD vials are generated during analysis of treated wastewater under the conditions of the discharge permit. The facility considers this waste hazardous (D002, D007, D009, D011) waste based on product and process knowledge and analysis. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 1 kg per month of this waste. Used COD vials are transported to Veolia Technical Solutions (Veolia) in Port Washington, Wisconsin, for bulking. They were last collected on February 8, 2021 (Attachment 9, Page 6).

During the visual inspection, I observed a SAA container of used COD vials in the laboratory at the WWTP. The vials were accumulated in a 5-gallon plastic SAA container (Attachment 7, Photograph 59). The container was closed, in good condition, and labeled as "hazardous waste." It was also labeled to indicate the nature of the hazard (Class 8 corrosive). The SAA was at the point of generation and under the control of the operator. The container was approximately half full.

Used oil is generated during maintenance of facility hydraulic and compressor equipment. The facility manages used oil under the provisions of 40 CFR Part 279. Based on my review of shipping documents, I estimated that the facility generates approximately 55 gallons of used oil

per month. Used oil is collected for recycling by Retrofit Recycling (Retrofit) of Owatonna, Minnesota. It was last collected on February 8, 2021 (Attachment 9, Page 4).

During the inspection, I observed used oil stored in containers in maintenance areas in the AVG Building and the CUB (Attachment 7, Photographs 21 and 48 through 51). All used oil storage containers were in good condition and labeled as "used oil."

Used oily debris is generated during cleanup of oil spills. It also includes drained used oil filters. During the inspection, all the used oil filters I observed were open canister textile filters. The facility manages used oily debris under the provisions of 40 CFR Part 279. I did not determine the generation rate for used oily debris. Used oily debris is collected for incineration at Stericycle in Blaine, Minnesota. It was last collected on February 8, 2021 (Attachment 9, Page 5).

During the inspection, I observed used oily debris stored in containers in maintenance areas in the AVG Building and the CUB (Attachment 7, Photographs 19-22, 44, 45, and 52). All storage containers were in good condition and labeled as "used oil."

Excluded solvent-contaminated wipes are generated in the CUB maintenance area from cleaning equipment with mineral spirits and brake cleaning solvent (some of which may contain tetrachloroethene). The facility considers solvent-contaminated wipes to be excluded from the definition of hazardous waste according to 40 CFR 261.4(b)(18). Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 2 kg per month of this waste. Excluded solvent-contaminated wipes are collected for incineration at Systech in Fredonia, Kansas. They were most recently collected on May 4, 2021 (Attachment 9, Page 9).

The wipes are accumulated in a 55-gallon container in the maintenance shop in the CUB (Attachment 7, Photographs 44 and 46). The container was in good condition, closed, and labeled with the words "excluded solvent-contaminated wipes." It was marked with an accumulation start date of May 4, 2021, thereby documenting that the 180-day accumulation time limit in 40 CFR 261.4(b)(18)(ii) is being met, as required by 40 CFR 261.4(b)(18)(v)(B) for the exemption.

The facility retains shipping documents for excluded solvent-contaminated wipes, thereby documenting the name and address of the combustor, as required by 40 CFR 261.4(b)(18)(v)(A) for the exemption. I asked if the facility had a written procedure documenting management practices for excluded solvent-contaminated wipes. The procedure Mr. Larrison provided described container management and labeling, but not procedures regarding free liquids (Attachment 11). I concluded that the facility failed to document the process the generator is using to ensure solvent-contaminated wipes contain no free liquids at the point of being transported for disposal, as required by 40 CFR 261.4(b)(18)(v)(C) for the exemption (**NOPF No. 2**).

I provided compliance assistance regarding documentation for excluded solvent-contaminated wipes and the requirements for the exemption. NOPF No. 2 is based on my inspection of the facility as a generator of excluded solvent-contaminated wipes. If it is determined that the facility does not meet conditions of the solvent-contaminated wipes exclusion, the wipes would be solid

waste and potentially a D001 and D039 characteristic hazardous waste subject to the management requirements of 40 CFR 262.17.

Universal waste lamps are generated during facility maintenance and include both fluorescent tube lamps and high-intensity discharge (HID) lamps. The facility considers used lamps hazardous waste and manages them as universal waste according to 40 CFR 273. I did not determine the generation rate for universal waste lamps. They are consolidated in the universal waste storage area in the Maintenance/Warehouse Building. They collected for recycling by Retrofit of Owatonna, Minnesota, and were most recently collected on May 4, 2021 (Attachment 9, Page 8).

During the visual inspection, I observed two containers of universal waste lamps—one for 2-foot or U-shaped tube lamps and one for 4-foot tube lamps (Attachment 7, Photographs 39 and 40). Both containers were closed and in good condition. They were labeled as "used lamp(s)" and dated May 4, 2021. Each container held only one lamp.

Universal waste batteries are generated during facility maintenance and include nickel-cadmium, lithium ion, lead-acid, and alkaline. The facility manages all used batteries as universal waste according to 40 CFR 273. I did not determine the generation rate for universal waste batteries. They are consolidated in the universal waste storage area in the Maintenance/Warehouse Building. They collected for recycling by Retrofit of Owatonna, Minnesota, and were most recently collected on May 4, 2021 (Attachment 9, Page 8).

During the visual inspection, I observed three 5-gallon containers for universal waste batteries—one each for nickel-cadmium, lithium ion, and lead-acid (Attachment 7, Photographs 41 through 43). All were closed and in good condition. They were labeled as "used battery(ies)" and dated May 4, 2021. The containers were all empty.

Universal waste aerosol cans are generated during facility maintenance. The facility manages used aerosol cans as universal waste according to 40 CFR 273. Based on my review of the facility's waste list (Attachment 8) and manifests (Attachment 9), the facility generates approximately 55 gallons of universal waste aerosol cans per year. Universal waste aerosol cans are sent for solvent recovery to Tradebe in East Chicago, Indiana. They were most recently collected on March 10, 2020 (Attachment 9, Page 2). At that time the facility was still managing and manifesting the used aerosol cans as conventional hazardous waste. The March 2020 manifest was completed with F-list waste codes for spent solvent (F001, F003, F005). If the facility chooses to manage these materials as conventional hazardous waste again in the future, these waste codes would not be applicable, as the solvents remaining in a used aerosol can are not spent.

During the visual inspection, I observed a 55-gallon container of universal waste aerosol cans (Attachment 7, Photographs 44 and 47). It was closed and in good condition. It was labeled as "used aerosol can(s)" and dated June 24, 2020. The container was nearly full. I drew Mr. Larrison's attention to the approaching 1-year accumulation limit.

General trash is generated during facility maintenance. The facility has determined that general trash is nonhazardous, based on product and process knowledge. General trash includes, but is

not limited to, floor sweepings, paper, and packaging. I did not determine the generation rate for general trash. The facility manages the general trash in multiple roll-off containers and in a 20-cubic-yard compactor. General trash is collected by Jendro of Charles City, Iowa, for disposal at the Floyd Mitchell Chickasaw Landfill in Elma, Iowa.

4. Container CAAs

The facility maintains a CAA in the glass washing room in the laboratory area of the main building and another CAA in the methanol room in the AVG Building. Both were inspected during the CEI, and their contents are described in Section 3. The facility keeps a log of weekly inspections of CAAs and SAAs (Attachment 7, Photographs 4 and 28). I reviewed the weekly inspection checklists for the CAAs for the last 3 years and noted no missed inspections.

5. Hazardous Waste Accumulation Tank

Valent has a single hazardous waste accumulation tank. According to the certification report, it has a capacity of 9,422 gallons; it appears to have a nominal capacity of 10,000 gallons. Based on my review of manifests and statements by the Valent group, the tank is emptied every 3 months, removing approximately 5,000 gallons of waste. It was most recently emptied on May 3, 2021.

I asked Messrs. Larrison and Hogan if the hazardous waste accumulation tank is inspected. They provided 3 years of inspection logs for the tank. Copies of the logs for 2021 are in Attachment 12. During my review of the logs, I observed gaps in the recorded inspections. The tank was not regularly inspected on the weekends or holidays, even when it contained waste, and week days were often also skipped. I observed 39 days in 2021 when the tank was not inspected although it contained waste. I asked Messrs. Larrison and Hogan if the inspections had been conducted but not recorded or if they were missed. They said that the tank was not specifically inspected every day and that the gaps in the log were likely missed inspections. I concluded that the facility failed to conduct daily inspections of a hazardous waste accumulation tank, as required by 40 CFR 262.17(a)(2) referencing 265.195(a) (**NOPF No. 1**). I provided compliance assistance regarding requirements for tank inspection.

I also reviewed the tank system installation assessment, completed in 2017 when the tank was initially brought on-line (Attachment 10). It was certified by a professional engineer.

6. Manifests and Biennial Report

Hazardous wastes are collected approximately every 6 weeks at the facility. During the CEI, I reviewed the approximately 40 manifests and LDR notifications generated in the previous 3 years. I noted no deficiencies or concerns during the manifest review. Copies of manifests for recent wastes shipped are in Attachment 9.

The Hazardous Waste Biennial Report for 2019 was submitted on February 27, 2020. I reviewed a copy provided by EPA before the report and verified that the report was maintained at the facility.

I did not identify any deficiencies related to manifests or the Biennial Report.

7. Preparedness and Prevention, and Contingency Plan

LQG facilities are required by 40 CFR 262.17(a)(6) to meet the emergency preparedness, prevention, and procedures requirements outlined in 40 CFR 262 Subpart M, including preparation of a RCRA Contingency Plan and documented arrangements with response agencies. During the CEI, I reviewed the facility's RCRA Contingency Plan. The primary emergency coordinator (EC) is listed as Mr. Hogan, with Mr. Brian Lynch (Facility Manager), then Mr. Larrison as alternate ECs. During the CEI, I reviewed content of the Contingency Plan and determined that it included the following required elements:

- Response activities for fires, spills, and explosions
- Description of arrangements with emergency response agencies
- Location and capabilities of emergency response equipment
- Evacuation plan

The facility's Contingency Plan was updated in May 2021, and a QRG was prepared and submitted to emergency response agencies on May 13, 2021 (documented by Postal Service certified mail receipts). A copy of the QRG is in Attachment 6.

I did not identify any deficiencies related to preparedness and prevention or the Contingency Plan.

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. Valent provides training to employees through computer-based training administered and managed by a learning management system (LMS). Ms. Voight provided me with a copy of the facility's training plan (Attachment 13). It included a description of hazardous waste duties tied to a job title, a matrix showing what training is required for each job title, and table identifying employees by name and title. It also included a description of the content of training.

Ms. Voight also provided a print-out of the LMS documentation of training for an employee for 2020-2021 (Attachment 14). She said that employees and their supervisors receive reminders that training must be completed and that the reminders are escalated through successive administrative levels until training is completed.

Ms. Voight also provided an example of a typical job description, which supplements the description of duties in the training plan (Attachment 15).

I did not identify any deficiencies related to training.

9. 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 found 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. Valent is not subject to the Subpart AA regulations because the facility does not manage hazardous waste in equipment with 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. Valent is subject to the Subpart BB regulations because the hazardous waste accumulation tank (and associated appurtenances) contact hazardous waste with greater than 10 percent organics. Because of the nature and properties of the solvents managed, the hazardous waste accumulation tanks and appurtenances are considered to be in light liquid service.

The standards found in Subpart CC apply to LQGs that manage hazardous waste in containers and tanks with volatile organic compounds (VOC) concentration that exceeds 500 ppmw. The Subpart CC standards are applicable to a variety of wastes generated and received at the facility and managed in containers and in the tank. I determined that the facility meets the Subpart CC requirements for containers by using Container Level 1 controls (storage containers between 26 gallons and 122 gallons that are DOT-approved) for storage of hazardous wastes. Because of the capacity of the tank, vapor pressure of the waste, and lack of waste stabilization in-tank, Level 1 controls are applicable. According to Mr. Larrison, the tank has a fixed roof with a nitrogen blanket and an atmospheric valve to control overpressure.

On June 29, I contacted Mr. Hogan by email to determine what measures Valent was using to ensure compliance with the Subpart BB and CC requirements for the hazardous waste accumulation tank (Attachment 16). In his response on July 9, he stated that the tank was new when installed and inspected for leaks during its initial commissioning in 2017, which meets part of the requirements for Subpart CC. He did not provide any other confirmation that the facility was meeting the requirements for Subpart BB or CC for the tank. When I followed up on his July 9 response, he stated in a July 12 email that the facility had not been aware of the Subpart BB and CC requirements. I concluded that the facility had failed to meet the emissions controls requirements for the hazardous waste accumulation tank, as required by 40 CFR 262.17(a)(2) referencing 265 Subpart BB and CC (**NOPF Nos. 3 and 4, respectively**). I emailed the revised NOPF to the facility on July 13.

Mr. Hogan said that Trinity Consultants (Trinity), who had initially certified the tank, would be on site to complete the visual inspections and Method 21 leak detection inspections on July 12 and that Trinity would be performing a general review of the facility emissions control systems to determine what additional measures were needed for compliance.

10. Summary of Preliminary Findings

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

(1) Failure to conduct daily inspections of a hazardous waste accumulation tank, as required by 40 CFR 262.17(a)(2) referencing 265.195(a) (**NOPF No. 1**)

(2) Failure to document the process the generator is using to ensure solvent-contaminated wipes contain no free liquids at the point of being transported for disposal, as required by 40 CFR 261.4(b)(18)(v)(C) for the exemption (**NOPF No. 2**)

(3) Failure to meet all requirements for assessing emissions from equipment leaks associated with the hazardous waste accumulation tank, as required by 40 CFR 262.17(a)(2) referencing 265 Subpart BB (**NOPF No. 3**)

(4) Failure to meet all requirements for assessing emissions from the hazardous waste accumulation tank itself, as required by 40 CFR 262.17(a)(2) referencing 265 Subpart CC (**NOPF No. 4**)

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.

Digitally signed by Heather K. Wood
Date: 2021.07.15 09:37:01 -05'00'

_____ Date: _____

Heather K. Wood, Inspector
Tetra Tech

AMBER WHISNANT Digitally signed by AMBER WHISNANT
Date: 2021.07.26 19:23:49 -05'00'

_____ Date: _____

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

Attachments:

1. Hazardous Waste Site Info Verification Report (1 Page)
2. Data Gathering Worksheets and Checklists (52 Pages)
3. Receipt for Documents and Samples (1 Page)
4. Confidentiality Notice (1 Page)
5. Notice of Preliminary Findings (1 Page)
6. Contingency Plan with Quick Reference Guide (24 Pages)
7. Photographic Documentation (59 Photos and Photolog) (35 Pages)
8. List of Hazardous Wastes Generated (4 Pages)
9. Manifests and Shipping Documents (11 Pages)
10. Tank Certification Report (7 Pages)
11. Wipes Management Procedures (2 Pages)
12. Tank Inspection Logs (22 Page)
13. Training Plan (11 Pages)
14. Training Documentation (3 Pages)
15. Job Descriptions (2 Pages)
16. Email regarding Tank Air Emissions Controls (4 Pages)

NOTICE OF PRELIMINARY FINDINGS

FACILITY NAME: VALENT BIOSCIENCES LLC
ADDRESS: 2142 350TH ST
OSAGE IA 50461
EPA ID NUMBER: IAR000519736 **DATE:** 5/18/21

NOTICE: I am not an employee of the Environmental Protection Agency ("EPA"). I am a contractor for EPA retained to conduct compliance evaluation inspections. The following is a list of observations/recommendations found during this inspection which will be reported back to EPA. This is not to be construed as a complete list of observations/recommendations. The EPA will be evaluating the report prepared as a result of this inspection and making the determinations as to what violations may have occurred at your facility.

1. FAILURE TO CONDUCT DAILY INSPECTIONS OF LESS-THAN-90-DAY ACCUMULATION TANK (40 CFR 262.17(a)(2) → 265.195(a))
2. FAILURE TO MAINTAIN PROCEDURE DOCUMENT FOR PREVENTING ACCUMULATION OF FREE LIQUIDS IN EXCLUDED WIPES CONTAINERS
3. (40 CFR 261.4(b)(18)(ii)(C))
4. * FAILURE TO MEET ALL REQUIREMENTS FOR ASSESSING EQUIPMENT LEAKS FOR THE HAZARDOUS WASTE ACCUMULATION TANK (40 CFR 262.17(a)(2)
5. (HW) → 265 SUBPART BB)
6. * FAILURE TO MEET ALL REQUIREMENTS FOR ASSESSING EMISSIONS FROM THE HAZARDOUS WASTE ACCUMULATION TANK (40 CFR
7. 262.17(a)(2) → 265 SUBPART CC)

* ADDED TO NOPF ON 7/15/21 AND COMMUNICATED TO FACILITY BY EMAIL. (HW)

If you have any questions regarding these findings please contact TREVOR URBAN, EPA REGION 7

The undersigned person hereby acknowledges receipt of a copy of this document and has read the same.

PRINTED NAME: Jerald HOGAN **TITLE:** EHS Manager

SIGNATURE:

This document was prepared by HEATHER K. WOOD