

RCRA Inspection Report

1) Inspector and Author of Report

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2) Facility Information

Exela Pharma Sciences, LLC EPA ID# NCR000170803
1245 Blowing Rock Road
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3) Responsible Officials

Brian Eckert, EHS Manager
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4) Inspection Participants

Brian Eckert, Exela Pharma Sciences Ernest Lawrence, NCDEQ
April Brandon, Exela Pharma Sciences Laurie Benton DiGaetano, US EPA
Paige Lowry, Exela Pharma Sciences

5) Date of Inspection

June 16, 2022

6) Purpose of Inspection

The purpose of this inspection was to conduct an unannounced compliance evaluation inspection (CEI) to determine Exela Pharma Sciences, LLC's compliance with the applicable requirements of RCRA and the corresponding NCDEQ regulations. This was an EPA lead inspection.

7) Applicable Regulations

Resource Conservation and Recovery Act (RCRA) Sections 3002 (42 U.S. Code – Annotated U.S.C.A. 6925 and 6927), Title 15A of the North Carolina Administrative Code (NCAC), Chapter 13; and 40 Code of Federal Regulation (C.F.R.), Parts 260-270, 273, 278, & 279.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17], an LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by 130A-294(c) and (g) of the NCSWML, N.C.G.S. § 130A-294(c) and (g) [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17] (hereinafter referred to as the “LQG Permit Exemption”).

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or without having interim status, as required by 130A-294(c) and (g) of the NCSWML, N.C.G.S. § 130A-294(c) and (g) [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with 15A NCAC 13A .0107(a) [40 C.F.R. § 262.16(b) or § 262.17(a)], except as required in 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)] (hereinafter referred to as the “SAA Permit Exemption”).

8) Facility Description

Exela Pharma Sciences, LLC (Exela) was founded as a research and development organization in 2005. Today, the company develops, manufactures and supplies generic and proprietary prescription pharmaceutical products for use in the United States, Canada and Australia. The company specializes in sterile injectable products that are packaged in liquid vials, lyophilized vials, aseptic and terminally sterilized IV bags, and pre-filled syringes. Exela has approximately 600 employees who work in four buildings, which are referred to as the Max, Augusta, Michelle, and Elma buildings and are located on separate properties in Lenoir, North Carolina.

The company headquarters, laboratory activities, inspection, packaging and labeling operations, as well as some warehousing, is housed in Exela’s Max Building; product compounding and container filling operations (into vials, syringes and IV bags) are performed in Exela’s Augusta and Michelle Buildings; and additional warehousing is housed in Exela’s Elma building. Together, these four buildings make up the total Exela campus. At the time of the inspection, facility personnel indicated that the company is in the process of moving the inspection, packaging, and labeling operations from the Max Building to the Elma building. When this move is complete, most manufacturing operations will occur in the Augusta and Michelle Buildings, all supporting laboratory operations will occur in the Max Building, and all final preparation, storage and shipping operations will occur in the Elma building.

The subject of this inspection report is limited to operations observed at the Max Building, which is a three-story structure of approximately 145,000 square feet. Exela purchased the building in 2013, and this location currently houses the company headquarters, a Quality Control (Q/C) Chemistry Laboratory for Raw Materials, a Q/C Chemistry Laboratory for Finished Products, a Research and Development (R&D) Laboratory, an Active Pharmaceutical Ingredients (API) Synthesis Laboratory, two automated inspection lines, four semi-automated inspection lines, two automated labeling lines, one automated packaging line, a 13,000 square foot freezer farm, and

11,000 square feet of warehouse space. The facility is surrounded by a chain-link fence and security services are provided 24 hours per day/seven days per week through a security contract.

Exela operates the subject facility under the primary NAICS Code 325412 for Pharmaceutical Preparation manufacturing and the secondary NAICS Code 54171 for Research and Development in the Physical, Engineering, and Life Sciences. The facility has approximately 320 employees at this location, and laboratory operations are performed between 5:00 am and 11:00 pm. Personnel estimated that the laboratories have forty high-performance liquid chromatography (HPLC) machines, five gas chromatography (GC) machines, two atomic absorption (AA) spectroscopy machines, 2 inductively coupled plasma mass spectrometry (ICPMS) machines, and two Dionex ion chromatography (IC) machines. Personnel analyze approximately 5-10 raw material samples and 50-60 finished product release and stability samples every week.

Exela first notified as a large quantity generator (LQG) of hazardous waste at this location on July 30, 2018. Hazardous wastes are typically generated and accumulated in one of the hazardous waste satellite accumulation areas (SAAs) managed in the on-site laboratories. Every Monday and Thursday, laboratory personnel remove waste containers from SAAs and replace them with empty containers for continued waste accumulation. Personnel transfer the waste containers to the hazardous waste central accumulation area (CAA) shed where the contents are consolidated into larger containers for additional storage and subsequent shipment offsite. Similarly, smaller containers of waste excess or expired laboratory chemicals are also brought to the CAA where they are placed into a flammable storage cabinet until they are placed into a lab-pack and shipped off-site. Personnel stated that lab-packs are shipped offsite once every 90-days.

According to their most recent biennial report, which was submitted on February 19, 2020, the facility generated the following hazardous wastes during calendar year 2019:

- D001/D022/F002/F003 HPLC liquids
- D001/D007/D022/F002/F003 HPLC vials
- D001/F003/F005 mixed lab solvents
- D002 acid waste
- D001/F003/F005 lab solids
- D002/D011 nitric acid waste
- D002 caustic lab waste
- D001/D018/U019/U213 waste flammable liquids
- D002 waste corrosive liquid acid
- D005/D008/D011/D022/U030 waste toxic liquids
- D001/D008/D011 waste oxidizing solid
- D001/D007 waste toxic solids
- D001 waste sodium perchlorate
- P030 waste cyanides
- D009 waste mercury iodide
- D001/D002 waste flammable liquid
- D005 waste corrosive solid basic
- P105 waste sodium azide

- D001 waste corrosive solids, oxidizing
- D004/P012 waste arsenic trioxide
- D001/U058/U154 waste flammable liquids
- D001 waste oxidizing solid
- D001 waste flammable liquids
- D001/D002/D003 waste ammonium sulfide solution
- D001/P022 waste carbon disulfide
- D001/D003 waste zinc powder

9) **Previous Inspection History**

NCDEQ has conducted one RCRA compliance assistance visit and two RCRA CEIs at the subject facility since they first notified as a large quantity generator (LQG) of hazardous waste in July 2018.

On February 24, 2020, NCDEQ conducted the first RCRA CEI at the subject facility, and found apparent violations of RCRA's requirements for the contingency plan and hazardous waste training. As a result, NCDEQ issued a warning letter, and then verified that the facility had returned to compliance during a follow-up inspection on June 29, 2020.

On March 25, 2021, NCDEQ conducted the most recent RCRA CEI at the subject facility and found apparent violations of RCRA's requirements for hazardous waste training and training records and for hazardous waste container management. As a result, NCDEQ issued a warning letter, and then verified that the facility had returned to compliance during a follow-up inspection on May 18, 2021.

10) **Opening Conference**

On June 16, 2022, EPA inspector Laurie Benton DiGaetano, accompanied by NCDEQ inspector Ernest Lawrence, arrived at Exela Pharma Sciences, LLC (Exela) at approximately 10:10 a.m. Mr. Brian Eckert, EHS Manager, immediately received the inspectors. The inspectors introduced themselves, showed their credentials, and explained the purpose of the visit. Mr. Eckert and the inspectors were joined by Ms. April Brandon, Director of Compliance, and Ms. Paige Lowry, EHS Supervisor for the opening conference.

The inspectors described the anticipated use of equipment (digital camera) during the inspection and provided a request for records. The inspectors discussed the company's ability, pursuant to 40 C.F.R. §2.203, to assert a business confidentiality claim for information submitted to the EPA. The company did not assert a business confidentiality claim. The EPA inspector noted that the EPA has an information sheet that identifies available EPA resources for small businesses. The Small Business Regulatory Enforcement Fairness Act's classification of a "small business" is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees, and the EPA's Small Business Resources Information Sheet can be found at <https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf>.

Facility representatives provided an overview of the facility's history and current operations, and the inspection participants discussed health and safety protocols and personal protective equipment that are required for touring the facility operations. Following the opening conference, Mr. Eckert, Ms. Brandon and Ms. Lowry led the inspectors on a tour of the Facility operations.

11) **Findings**

Waste Profile Record Review: Exela personnel provided the inspectors with waste profile records for the following hazardous wastes:

- D002/D010 selenium lab waste
- D001/F002/F003 halogenated flammable waste
- D001/D002/F003 flammable acidic waste from API – R&D area
- D001/D022/F002/F003 HPLC liquids
- D001/F003/F005 lab solids (API)
- D001/D022/F002/F003 HPLC vials
- D001 2,3-dihydropyran lab pack
- D001/D002/F003/F005 flammable basic corrosive waste (API)
- D002/D011 nitric acid waste
- D001/F003/F005 mixed lab solvents (API)
- D001/D002/D009/F003/F005 flammable acidic corrosive waste (API)
- D002 acid waste
- D002 caustic lab waste
- D001/D002/D009 acetic solution
- D001 ethyl alcohol

Exela personnel also provided the inspectors with waste profile records for the following non-hazardous wastes:

- Nonhazardous waste liquids (API)
- Cleaners and detergent
- Nonhazardous powders (API)
- Contaminated debris
- Used oil
- Nonhazardous salt
- Empty drums

Quality Control (Q/C) Chemistry Lab for Finished Products (SAAs): Mr. Scott Nicol joined the inspection participants during the tour of the Q/C Chemistry Laboratories for Finished Products and Raw Materials. Exela manages three SAAs in the Q/C Chemistry Laboratory for Finished Products: one for accumulating hazardous waste liquids generated from HPLC machines and laboratory benches, one for accumulating used vials from HPLC, HPIC and AA machines, and one for accumulating hazardous waste liquids generated from AA machines.

The inspectors observed the following containers in the first SAA in the Q/C Chemistry Lab for Finished Products. The inspectors observed a combined storage capacity of 51.5-gallons in this SAA, which is used to accumulate D001/D022/F002/F003 hazardous waste liquids from HPLC machines and laboratory benches:

- Fifteen 2.5-gallon containers with a combined capacity of 37.5-gallons of HPLC hazardous waste liquids. The inspectors observed a series of ten racks holding a total of fifteen HPLC machines along the wall to the left inside the Q/C Chemistry Lab for Finished Products. Each rack held one or two HPLC machines, and each machine was equipped with a 2.5-gallon container for accumulating hazardous waste liquids generated by that HPLC machine. Each container was placed inside a secondary containment pan, and the inspectors observed a hazardous waste label, a flammable liquid DOT hazard placard, and a toxic DOT hazard placard on each container.
- Six flammable cans with a combined capacity of 14-gallons of hazardous waste liquids. The inspectors observed four 2.5-gallon and two 2-gallon flammable cans on a portable cart in the Q/C Chemistry Lab for Finished Products. Facility personnel explained that these containers are used to accumulate hazardous waste liquids generated at laboratory benches, and that these hazardous waste liquids are managed under the same hazardous waste profile as the hazardous waste liquids generated by the HPLC machines. The inspectors observed a hazardous waste label and a flammable liquid DOT hazard placard on each of the six containers. The inspectors also observed a toxic DOT hazard placard on each of the four 2.5-gallon containers. The 2.5-gallon containers were not marked to indicate that their contents are toxic. However, these containers were empty at the time of the inspection.

The inspectors observed the following containers in the second SAA in the Q/C Chemistry Lab for Finished Products. Facility personnel stated that used vials generated at the laboratory benches and at the AA machines would also be accumulated in the 2-gallon containers observed in the SAA for accumulating used vials in the Q/C Chemistry Lab for Finished Products. The inspectors observed a combined storage capacity of 20-gallons in this SAA, which is used to accumulate D001/D022/F002/F003 used sample vials:

- Ten 2-gallon containers with a combined capacity of 20-gallons of used vials. The inspectors observed one 2-gallon container for accumulating used HPLC vials at each of the ten racks of HPLC machines located along the wall to the left inside the Q/C Chemistry Lab for Finished Products. The inspectors observed a hazardous waste label and a flammable liquid DOT hazard placard on each container. Although D022 hazardous waste exhibits the characteristic of toxicity and F002 hazardous waste contains toxic constituents, none of the 2-gallon containers were marked to indicate that their contents are toxic.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

The inspectors observed four containers in the third SAA in the Q/C Chemistry Lab for Finished Products. The inspectors observed a combined storage capacity of approximately 11-gallons in this SAA, which is used to accumulate D002/D011 nitric acid waste:

- Two 5-gallon containers with combined capacity of 10-gallons. The inspectors observed one 5-gallon container, which was labeled as nitric acid/heavy metal waste, at each of two AA machines. The inspectors observed a hazardous waste label and a corrosive DOT hazard placard on each container. Although D011 hazardous waste exhibits the characteristic of toxicity, neither container was marked to indicate that its contents are toxic.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

- Two 2-liter containers with a combined capacity of approximately one-gallon. The inspectors observed one 2-liter container, which was labeled as nitric acid/heavy metal waste, at each of two AA machines. The inspectors observed a hazardous waste label and corrosive DOT hazard placard on one container. Although D011 hazardous waste exhibits the characteristic of toxicity, this container was not marked to indicate that its contents are toxic. The second container was not labeled as hazardous waste or marked to indicate that its contents are toxic or corrosive.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with the words “Hazardous Waste” and with an indication of the hazards of the contents.

The inspectors observed one 5-gallon yellow step-to-open can at a laboratory bench in the Q/C Chemistry Lab for Finished Products. Facility personnel indicated that this container is used to accumulate used sample vials and waste associated with a specific product. The customer for this product requested that the waste be managed separately from other wastes generated on-site. Although the container was labeled as hazardous waste, it was not marked with an indication of the hazards of its contents. The inspectors reviewed the waste profile associated with this material and confirmed that it is not a listed hazardous waste and does not exhibit a hazardous waste characteristic.

Q/C Chemistry Laboratory for Raw Materials: Mr. Scott Nicol joined the inspection participants during the tour of the Q/C Chemistry Laboratories for Finished Products and Raw Materials. Exela manages one SAA for accumulating hazardous waste liquids generated at the laboratory benches in the Q/C Laboratory for Raw Materials. The inspectors observed four 5-gallon flammable cans in this SAA. The containers were located inside two secondary containment trays at the end of the laboratory bench. Each container was labeled as hazardous waste and identified with flammable liquid and toxic DOT hazard placards.

Exela manages another SAA for accumulating hazardous waste liquids generated in two ICP units in the Q/C Chemistry Laboratory for Raw Materials. The inspectors observed one 2-gallon container connected to each ICP unit. Each container was labeled hazardous waste corrosive nitric acid/heavy metal. Although D002/D011 hazardous waste nitric acid exhibits the characteristic of toxicity, neither container was marked to indicate that its contents are toxic.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

Exela also manages one SAA for accumulating hazardous waste acids and another for accumulating hazardous waste bases in the Raw Materials Laboratory. These SAAs are located in laboratory cabinets beneath laboratory cabinets with lab hoods. Personnel explained that acid and bases generated in the R&D Laboratory are also accumulated in these SAAs. The inspectors observed thirteen containers with a combined storage capacity of approximately 20-gallons in the hazardous waste acid SAA, and two containers with a combined storage capacity of 10-gallons in the hazardous waste bases SAA.

The following containers of hazardous waste acids were observed in a cabinet beneath a laboratory hood in the Raw Materials Laboratory hazardous waste acid SAA:

- One 5-gallon container labeled as hazardous waste nitric acid and identified with a corrosive DOT hazard placard.
- One 5-gallon container labeled hazardous waste acid and identified with corrosive and toxic DOT hazard placards.
- Six approximately 1-gallon containers labeled as hazardous waste, but not identified with an indication of the hazards of their contents.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

- Five <1-gallon containers not labeled as hazardous waste or identified with an indication of the hazards of their contents.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with the words “Hazardous Waste” and with an indication of the hazards of the contents.

The following containers of hazardous waste acids were observed in a cabinet beneath a laboratory hood in the Raw Materials Laboratory hazardous waste bases SAA:

- One 5-gallon container labeled hazardous waste base waste and identified with corrosive and toxic DOT hazard placards.

- One 5-gallon container labeled hazardous waste base waste, but not marked with an indication of the hazards of its contents.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

API Synthesis Laboratory: Mr. Mo Ahmed, Director of API, joined the inspection participants during the tour of the API Synthesis Laboratory. Exela manages five SAAs in the API Synthesis Laboratory. The first SAA is used to accumulate HPLC hazardous waste liquids. The inspectors observed a total of seven containers with a combined storage capacity of 23-gallons in this SAA:

- Three of six 5-gallon cans on secondary containment trays staged in one corner of the laboratory in preparation for transfer to the CAA. These three containers were labeled HPLC hazardous waste and identified with flammable liquid and toxic DOT hazard placards.
- Four 2-gallon containers in secondary containment trays on the floor next to HPLC machines. Three of the four 2-gallon containers contained hazardous waste liquids and were connected to HPLC machines. The fourth was empty and not in use. All four 2-gallon containers were labeled HPLC hazardous waste and identified with flammable liquid and toxic DOT hazard placards.

The second SAA is used to accumulate hazardous waste mixed solvents generated in the API Synthesis Laboratory. The inspectors observed a total of four containers with a combined storage capacity of 70-gallons in this SAA, however the total volume of waste in this SAA did not appear to be in excess of 55-gallons at the time of the inspection. Although Exela may manage more than one container in the same SAA, please note that the SAA Permit Exemption limits the total volume of waste accumulated in this area at any given time to be no more than 55 gallons. Pursuant to 15A NCAC 13A .0107 [40 C.F.R. § 262.15(a)(6)], a generator who accumulates hazardous waste in excess of 55 gallons must, with respect to that amount of excess waste, comply with 15A NCAC 13A .0107 [40 C.F.R. § 262.17(a)] or remove the excess waste from the SAA within three consecutive calendar days. The inspectors observed the following containers in the SAA for accumulating hazardous waste mixed solvents generated in the API Synthesis Laboratory:

- Three of six 5-gallon cans on secondary containment trays staged in one corner of the laboratory in preparation for transfer to the CAA. Each was labeled hazardous waste mixed lab solvents and identified with a flammable liquid DOT hazard placard.
- One 55-gallon drum beneath a laboratory hood in the opposite corner of the laboratory. The drum, which was partially full, was closed, labeled hazardous waste mixed solvents, and identified with a flammable liquid DOT hazard placard. Facility personnel explained that this drum is hooked up to the analytical machine to collect hazardous waste mixed solvents that are generated when that machine is running.

The waste profile for mixed lab solvents generated in the API Laboratory indicates that these solvents are D001/F003/F005 hazardous waste. Although F005 hazardous waste contains toxic

constituents, none of the containers of hazardous waste mixed solvents in the API Laboratory were marked to indicate that their contents are toxic.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

The third SAA is used to accumulate TFA hazardous waste generated in the API Synthesis Laboratory. The inspectors observed one 5-gallon container in this SAA. The container was located in a secondary containment tray on a bench with a bench top laboratory fume hood. The container was labeled hazardous waste TFA waste and identified with a corrosive DOT hazard placard.

The fourth SAA is used to accumulate hazardous waste laboratory solids generated in the API Synthesis Laboratory. The inspectors observed two containers with a combined storage capacity of approximately 70-gallons in this SAA, however the total volume of waste in this SAA was less than 55-gallons at the time of the inspection. Although Exela may manage more than one container in the same SAA, please note that the SAA Permit Exemption limits the total volume of waste accumulated in this area at any given time to be no more than 55 gallons. Pursuant to 15A NCAC 13A .0107 [40 C.F.R. § 262.15(a)(6)], a generator who accumulates hazardous waste in excess of 55 gallons must, with respect to that amount of excess waste, comply with 15A NCAC 13A .0107 [40 C.F.R. § 262.17(a)] or remove the excess waste from the SAA within three consecutive calendar days. The inspectors observed the following containers in the SAA for accumulating hazardous waste laboratory solids generated in the API Synthesis Laboratory:

- One 55-gallon drum containing contaminated gloves and filter papers. The drum was closed with a latched flip-top lid, labeled hazardous waste solids, and identified with a flammable solid DOT hazard placard.
- One empty 15-gallon yellow container with a step-to-open lid. The container was labeled hazardous waste flammable debris and identified with a flammable solid DOT hazard placard.

The fifth SAA is used to accumulate hazardous waste chlorinated solvents generated in the API Synthesis Laboratory. The inspectors observed one 20-gallon container labeled hazardous waste DCM waste in this SAA. The drum was identified with a toxic DOT hazard placard, but it was not marked to indicate that its contents are flammable.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

Research and Development (R&D) Laboratory: Mr. Frank Moses, R&D Supervisor, joined the inspection participants during the tour of the R&D Laboratory. Exela manages two SAAs in this laboratory: one for accumulating hazardous waste liquids generated from HPLC machines and laboratory benches, and one for accumulating used sample vials from HPLC machines and laboratory benches.

The inspectors observed ten containers with a combined storage capacity of 32-gallons in the first SAA in R&D Lab. The inspectors observed six 2-gallon containers connected to HPLC machines. Each of these containers was labeled as hazardous waste HPLC liquid and identified with a flammable liquid and a toxic DOT hazard placard. The inspectors observed four additional red flammable cans in this SAA. Each of these containers was labeled hazardous waste and identified with a toxic DOT hazard placard. None of the four red flammable cans was marked with an indication that its contents are flammable.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

The inspectors observed one 15-gallon container for accumulating D001/D022/F002/F003 hazardous waste sample vials in the second SAA in the R&D Lab. The container was labeled as hazardous waste and identified with a flammable liquid DOT hazard placard. Although D022 hazardous waste exhibits the characteristic of toxicity and F002 hazardous waste contains toxic constituents, the 15-gallon container was not marked to indicate that its contents are toxic.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)(ii)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with an indication of the hazards of the contents.

Hazardous Waste Shed (CAA): Exela manages a hazardous waste CAA in a metal storage shed located just outside of the main building. The shed is equipped with a curbed concrete floor. The inspectors observed a sign that read “danger, hazardous waste” on the outside of the shed and a sign that read “no smoking” on the inside of the shed. According to facility personnel, employees carry cellular phones to alert the security officer and/or to summon emergency assistance from local police departments, fire departments, or state or local emergency response teams in the event of an emergency. The shed is also equipped with a portable fire extinguisher and emergency spill response kit.

The inspectors observed nine portable secondary containment pallets staged at intervals along the left and right walls within the storage shed. Each containment pallet is capable of holding two 55-gallon drums.

- The first pallet contained one 55-gallon drum, which was labeled D001/D022/F002/F003 hazardous waste flammable liquid/toxic (acetonitrile, chloroform), identified with DOT hazard placards for flammable liquids and toxics, and dated March 8, 2022; and one 30-gallon drum, which was empty. The empty 30-gallon drum was labeled D001 hazardous waste isopropanol, identified with a DOT hazard placard for flammable liquids, and it was bulging.
- The second pallet contained one 30-gallon drum, which was labeled hazardous waste corrosive acidic (sulfuric acid, hydrochloric acid), identified with DOT hazard placards for corrosives and toxics, and dated May 7, 2022.

- The third pallet contained one 30-gallon drum, which was labeled D002/D011 hazardous waste nitric acid waste (nitric acid, sulfuric acid), identified with DOT hazard placards for corrosives and toxics, and dated June 16, 2022.
- The fourth pallet contained two 5-gallon drums. Each drum was labeled D001 hazardous waste isopropanol, identified with a DOT hazard placard for flammable liquids, and dated June 16, 2022.
- The fifth pallet contained one 30-gallon drum, which was labeled D002 hazardous waste corrosive liquid (sodium hydroxide, potassium hydroxide), identified with DOT hazard placards for corrosives and toxics, and dated June 7, 2022.
- The sixth pallet contained one 30-gallon drum, which was labeled D001/F003/F005 hazardous waste flammable liquid (acetone, methanol), identified with a DOT hazard placard for flammable liquid, and dated April 13, 2022. This drum was not marked to indicate that its contents are toxic.

Pursuant to 15A NCAC 13A .0107 [40 C.F.R. § 262.17(a)(5)(i)(B)], which is a condition of the LQG Permit Exemption, a generator is required to mark or label containers with an indication of the hazards of the contents.

- The seventh pallet contained one empty 55-gallon drum.
- The eighth pallet contained one 55-gallon drum, which was labeled D001/D022/F002/F003 hazardous waste flammable liquid (acetonitrile, chloroform), identified with DOT hazard placards for flammable liquids and toxics, and dated June 08, 2022.
- The ninth pallet contained one 55-gallon drum, which was labeled D001/D022/F002/F003 hazardous waste flammable liquid (acetonitrile, chloroform), identified with DOT hazard placards for flammable liquids and toxics and dated June 14, 2022.

Exela stores small waste containers that will be shipped offsite in a laboratory pack in a flammable cabinet in the CAA. Facility representatives explained that personnel enter information about each container into an inventory list as the containers are placed into the flammable cabinet and mark the cabinet with the date that the first container is placed inside. Although the cabinet was dated March 18, 2022, it was empty at the time of the inspection. Facility representatives explained that the contents of the cabinet had been placed into a lab-pack and picked up earlier that day. The inspectors noted that the cabinet is already marked to indicate that the contents are flammable and recommended that it be marked with any additional indications of hazards as materials are placed into the cabinet.

The inspectors observed eleven empty 2-gallon containers on a portable cart next to two empty 20-gallon containers and one empty 15-gallon container in the middle of the CAA. Facility representatives explained that personnel use the cart to deliver empty containers to the SAAs in the laboratories and transfer full containers from the SAAs back to the CAA. The contents of the full containers are consolidated into larger containers in the CAA for further storage and subsequent transportation off-site. Personnel pick up waste from SAAs twice per week.

Contingency Plan: The actions that facility personnel should take in response to an emergency are described in the facility's Contingency Plan, which was last updated on June 10, 2022. The plan describes actions facility personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility, and it describes an evacuation plan for personnel. The plan includes a list of all emergency equipment at the facility, and the list includes fire extinguishing systems, spill control equipment, communications and alarm systems, decontamination equipment, personal protective equipment, and first aid equipment. The plan includes a map that indicates the location of emergency response equipment, and another map that identifies primary and alternate evacuation routes.

The plan lists the names and emergency telephone numbers for persons identified as emergency coordinators, and it describes arrangements agreed to with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, local hospitals, or the Local Emergency Planning Committee. Individuals who are identified as emergency coordinators are listed in the order in which they will assume responsibility as alternates.

The quick reference guide is a one-page document which includes the types/names of hazardous waste in layman's terms and the associated hazard associated with each hazardous waste present at any one time; the estimated maximum amount of each hazardous waste that may be present at any one time; and the identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff; and the identification of on-site notification systems; a street map of the facility in relation to surrounding businesses, schools and residential areas; and the locations of water supply. Although the quick reference guide included a facility diagram which identified the location of the hazardous waste CAA shed, the facility map did not identify the areas where hazardous wastes are generated and accumulated and routes for accessing these wastes. A copy of the Contingency Plan and the associated quick reference guide was most recently submitted to Frye Regional Medical Center, NCDEQ, Caldwell Memorial Hospital, the Lenoir Police Department, and the Lenoir Fire Department on June 10, 2022. However, the quick reference guide had not been updated to reflect the new emergency coordinator, who had been identified in the revised contingency plan.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17(a)(6)], which incorporates 15A NCAC 13A .0107(i) [40 C.F.R. § 262.262(b)(4)], and is a condition of the LQG Permit Exemption, the quick reference guide must include a map of the facility showing where hazardous wastes are generated, accumulated and treated and routes for accessing these wastes; and the name of the emergency coordinators and emergency telephone numbers.

Training Records: The inspectors reviewed facility job descriptions and employee names that were provided for Principal Scientist-API Synthesis (R&D), Scientist I API Synthesis (R&D), Research Scientist II, Analytical (R&D), Analytical Chemist I (Chemistry), and Analytical Chemist II (Chemistry). Each description included the requisite skill, education, or other qualifications of facility personnel assigned to that position. Exela provided a written description of the type and amount of both introductory and continuing training to be given to each person

filling the positions listed above. The inspectors reviewed employee training records and verified that annual hazardous waste training has completed by the identified personnel.

Waste Manifest Records: The inspectors reviewed available hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent since January 2022. Hazardous waste manifest records show that two or three hazardous waste shipments were sent to DART (NCD121700777) every month, and one shipment of hazardous waste was sent to Environmental Enterprises Incorporated (OHD083377010) in February 2022. Wastes shipped to DART included:

- D001/F003/F005 waste flammable liquids (acetone/methanol)
- D001/D022/F002/F003 waste flammable liquids, toxic (acetonitrile/chloroform)
- D001/D007/D022/F002/F003 waste flammable liquids, toxic (acetonitrile/chloroform)
- D002 waste corrosive liquid (sulfuric acid/hydrochloric acid)
- D002 waste corrosive liquid (sodium hydroxide/potassium hydroxide)
- D002/D011 waste corrosive liquid (nitric acid/sulfuric acid)

Wastes shipped to Environmental Enterprises Incorporated included:

- D004/D012 waste arsenic trioxide
- D001/D007 waste oxidizing solid
- U080
- D002 solid
- D001/D002 waste perchloric acid
- D001/U108 waste flammable liquid
- D009 waste mercury compounds
- D010 waste selenium compound
- D001/D003 waste sodium borohydride
- D002
- D001 waste oxidizing liquid

Manifest records also show that sixty-four 4-foot universal waste lamps were sent to SLE Processing Plant on February 2, 2022.

Inspection Records: The inspectors reviewed Exela's available records of inspections of the hazardous waste CAA since January 4, 2022. The inspection log includes a checklist to record observations about leaking containers and for deterioration of containers caused by corrosion or other factors. The checklist includes a place to record observations about the CAA being free of debris; the ground being clean and dry; the containers tops being clean; evidence of spills or leaks; containers in good condition; containers closed; containers labeled hazardous waste; hazardous waste labels containing the generator name, start date, contents, physical state and hazard properties; labels being legible; containers in storage less than 90 days; containers compatible with contents; incompatible wastes segregated; and aisle space. The records include a place to record the date of the inspection; the name of the employee conducting the inspection; and a description of corrective actions taken.

12) **Closing Conference**

The inspectors conducted the exit meeting with Mr. Eckert, Ms. Brandon, and Ms. Lowry. During this meeting, the inspectors stated their preliminary conclusions of the inspection.

13) **Inspection Findings**

Based on the observations made during the inspection, Exela was apparently deficient with the following RCRA requirements:

- Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers with the words “Hazardous Waste” and with an indication of the hazards of the contents.
- Pursuant to 15A NCAC 13A .0107 [40 C.F.R. § 262.17(a)(5)(i)(B)], which is a condition of the LQG Permit Exemption, a generator is required to mark or label containers with an indication of the hazards of the contents.
- Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17(a)(6)], which incorporates 15A NCAC 13A .0107(i) [40 C.F.R. § 262.262(b)(4)], and is a condition of the LQG Permit Exemption, the quick reference guide must include a map of the facility showing where hazardous wastes are generated, accumulated and treated and routes for accessing these wastes; and the name of the emergency coordinators and emergency telephone numbers.

14) **List of Appendices**

Appendix 1–Photo Log:

1 Photo taken on: June 16, 2022

Photos taken by: Laurie Benton DiGaetano

Photos taken with: Panasonic DMC TS-5 Digital Camera

EPA Property Tag: S09533

15) **Signed**

LAURIE DIGAETANO Digitally signed by LAURIE DIGAETANO
Date: 2022.07.15 13:37:01 -04'00'

Laurie Benton DiGaetano
Senior Enforcement and Compliance Specialist

Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ
Date: 2022.07.15 14:56:08 -04'00'

Araceli B. Chavez
Chief
RCRA Enforcement Section