

RCRA Inspection Report

1) Inspector and Author of Report

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2) Facility Information

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3) Responsible Officials

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4) Inspection Participants

Molly Darden, Alcami Corporation
Taylor Henderson, Alcami Corporation
James Hooker, Clean Harbors

Wes Hare, NCDEQ
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5) Date of Inspection

June 30, 2022

6) 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. § 262.15(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”).

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”).

7) Purpose of Inspection

The purpose of this inspection was to conduct an unannounced compliance evaluation inspection to determine Alcami Corporation’s compliance with the applicable requirements of RCRA and the corresponding NCDEQ regulations. This was an EPA lead inspection.

8) Previous Inspection History

NCDEQ’s most recent RCRA CEI at the subject facility was conducted on June 4, 2021, and NCDEQ found no apparent violations of RCRA’s requirements during that inspection. Since 2010, NCDEQ has conducted a total of ten RCRA CEIs at the subject facility and found no apparent violations during eight of those inspections. NCDEQ found one apparent violation during each of the two remaining CEIs in 2013 and 2018.

9) Facility Description

Alcami Corporation (Alcami) is a contract development and manufacturing organization serving pharmaceutical and biotechnology industries through the product development life cycle. The company operates five scientific campuses: in Wilmington, North Carolina, in Research Triangle Park, North Carolina, in Charleston, South Carolina, in St. Louis, Missouri, and in New England. The subject facility is part of the Wilmington, North Carolina, campus, which specializes in oral solid dosage forms including hard shell capsule, tablets and powders. Alcami has approximately 175 employees at the Wilmington campus, with approximately 150 of those employed at the subject facility. The facility includes a two-story building that includes laboratory operations and the company’s headquarters. This building was built by AAI Pharma in the late 1990s, and AAI Pharma later became known as Alcami in 2016. The facility operates under the NAICS Code 325412 for Pharmaceutical Preparation Manufacturing.

For more than ten years, Alcami has been operating as a large quantity generator (LQG) of hazardous waste at the subject facility under the current or former company name. In general, Alcami operates hazardous wastes satellite accumulation areas (SAAs) for accumulating hazardous wastes that discharge directly from analytical testing units into attached containers; for accumulating hazardous bench wastes generated by laboratory personnel; and for accumulating excess sample materials (vials) as hazardous waste. According to the Quick Reference Guide, hazardous wastes that are generated onsite include the following used laboratory chemicals and/or samples, excess laboratory sample materials (vials), and expired laboratory chemicals: D001, D022, D038, F003, F005 flammable and toxic liquid waste (acetonitrile, methanol, pyridine, chloroform); D001, D002, D022, D038, F003, F005 flammable, toxic and corrosive liquid waste (acetonitrile, methanol, acetic acid, sulfuric acid, pyridine, chloroform); D002 dissolution media waste (hydrochloric acid, potassium phosphate); D002, D004, D005, D006,

D007, D008, D009, D010, D011 corrosive toxic heavy metal waste (sulfuric acid, arsenic); D002, D005 strong acid corrosive liquid waste (nitric acid, hydrochloric acid); and D001 ignitable particle size waste (hexanes).

Alcami also operates two hazardous waste central accumulation areas (CAAs) on-site: one at the Mezzanine and one in the Waste Shed. A representative from Clean Harbors inspects all SAAs and the Mezzanine CAA twice each day, and transfers containers of hazardous waste from these areas to the Waste Shed CAA. The Clean Harbors employee then places expired chemicals and other lab-pack waste in a flammable cabinet at the Waste Shed CAA and consolidates like wastes from small containers into 55-gallon drums for further storage and subsequent shipment offsite. A Clean Harbors chemist transfers waste in the flammable cabinet into lab-pack containers prior to shipping it to a permitted treatment, storage or disposal facility.

The facility most recently notified as a LQG as part of the biennial report, which was submitted on February 28, 2022. In that biennial report, Alcamis reported that the following volumes of hazardous waste were shipped off-site during calendar year 2021:

Waste Description	Hazardous Waste Code(s)	Pounds Shipped Offsite
Lab Waste Flammable Liquids	D001, D022, D038, F003, F005	226,4520
Waste Flammable Liquids in Vials	D001, D022, D038, F003, F005	31,375
Labpack Organics for Incineration	D004, D008, D009, D010, D011, D022, D042, F002, U188	4,505
Labpack Flammables for Incineration	D001	2,535
Labpack Acid and Acid Compatibles for Incineration	D002	2,515
Particle Size Waste	D001	2,400
Labpack Reactive Basic and Basic Compatibles for Incineration	D002, P105	2,055
Digitub Vials Containing Standards with Heavy Metals	D002, D004, D005, D006, D007, D008, D009, D010, D011	1,925
Standards with Heavy Metals	D002, D004, D005, D006, D007, D008, D009, D010, D011	1,260
Labpack Reactive Oxidizers for Incineration	D001, D002, D003, D011	755
Labpack Basic and Basic Compatibles for Incineration	D001, D002	620
Flammable Corrosive (Bases) Liquids	D001, D002, F003	615
Flammable Corrosive (Acidic) Liquids	D001, D002, D022, D038, F003	430
Percorten in Vials	D009	125
Acid Wastewater	D002	115
Labpack Mercury Salts and Solutions for Retort	D002, D009	110

Labpack Required to be Packaged Alone per DOT	D002	101
Labpack Oxidizers for Incineration	D001, D008, D011	30
Labpack Mercury for Stabilization or Landfill	D009	20
Flammable Cylinders for Disposal	D001	20
Labpack Mercury Devices or Debris for Retort	D009	15
Toxic Cylinders for Disposal	D001	10
Labpack Reactive Flammables for Incineration	D001, D002	5

10) **Opening Conference**

On June 30, 2022, EPA inspector Laurie Benton DiGaetano, accompanied by NCDEQ inspector Wes Hare, arrived at the subject Alcam Corporation facility at approximately 9:00 a.m. Mr. Stan Harts, EHS Manager, was not available on the day of the inspection, so Ms. Molly Darden, Senior EHS Systems Specialist and Ms. Taylor Henderson, Intern, immediately received the inspectors. The inspectors introduced themselves, showed their credentials to Ms. Darden, and explained the purpose of the visit.

Ms. Darden and Ms. Henderson provided an overview of the facility's history and current operations during the opening conference. The inspectors described the anticipated use of equipment (digital camera) during the inspection and discussed the company's ability, pursuant to 40 C.F.R. §2.203, to assert a business confidentiality claim for information submitted to EPA. The company did not assert a business confidentiality claim. The EPA inspector explained that 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. The EPA has an information sheet for small businesses, and that information sheet can be found at <https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf>. The inspection participants discussed health and safety protocols and required personal protective equipment before Ms. Darden and Ms. Henderson led the inspectors on a tour of the Facility operations.

11) **Findings**

In general, containers of hazardous waste observed in SAAs throughout the facility were identified by either a yellow or white hazardous waste label that is printed with information to identify the hazardous waste inside the container. The yellow hazardous waste labels are also printed with an indication of the hazards associated with the identified waste. Alternatively, each white hazardous waste label includes the words "ignitable," "corrosive," "reactive," and "toxic" with an associated checkbox that can be marked to indicate when the contents of that container exhibit one or more of those hazardous waste characteristics.

Hazardous wastes generated by laboratory analytical equipment is routinely discharged through tubing that transfers the waste from the equipment to an accumulation container. In some cases, the accumulation container is equipped with a small filter to absorb volatile organic chemical

vapors before they can be released from the container. According to facility personnel, these filters are changed out every year and the used filters are placed into a labpack for disposal as hazardous waste. In other cases, one or more ports on the accumulation container may be left open to allow for venting during the waste transfer process. The inspectors warned against leaving any ports open on a container holding hazardous waste when the laboratory equipment is not in use, because 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption, requires a generator to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste; or when temporary venting of a container is necessary for the proper operation of equipment, or to prevent dangerous situations, such as build-up of extreme pressure.

Laboratory 232: Alcamis manages three SAAs in Laboratory 232 for managing hazardous waste generated in this laboratory. Hazardous waste flammable liquids generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed two 2-gallon safety cans in this SAA. One container was located under Fume Hood 1 and the other was located under Fume Hood 2. Each container was labeled as D001, D022, D038, F003, F005 hazardous waste flammable liquids (methanol, toluene). *Each pre-printed white hazardous waste label was only marked to indicate that its contents exhibit the characteristic of ignitability.* Alcamis personnel immediately corrected the hazardous waste labels by marking them to indicate that the contents also exhibit the characteristic of toxicity.

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 flammable liquids generated by laboratory equipment is accumulated in the second SAA in this laboratory. The inspectors observed nine containers with a combined total storage capacity of approximately thirteen gallons in this SAA:

- One 2-gallon white safety can that was connected to a UV Vis unit;
- Two 1-liter bottles that were connected to HPLC units;
- Five 2-gallon containers that were connected to HPLC units; and
- One 1-gallon container that was connected to a HPLC unit.

The 2-gallon container UV Vis container and the 2-gallon HPLC containers were each located in a secondary containment tray, labeled as hazardous waste, and marked to indicate its contents exhibit the hazardous waste characteristics of ignitability and toxicity. *The 1-liter HPLC bottles were each located in a secondary containment bucket and did not appear to be labeled as hazardous waste or marked to indicate the hazards of their contents.* However, each secondary containment bucket was labeled as hazardous waste and marked to indicate its contents exhibit the hazardous waste characteristics of ignitability and toxicity. The 1-gallon HPLC container was located in a secondary containment tray and labeled as hazardous waste. *This container was identified with the word “flammable,” but it was not marked to indicate that its contents exhibit the hazardous waste characteristic of toxicity.*

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.

Used sample vials containing hazardous waste flammable liquids are accumulated in the third SAA in this laboratory. The inspectors observed two 5-gallon buckets in this SAA, and each bucket was identified with a yellow hazardous waste label. Each pre-printed yellow hazardous waste label states that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Laboratory 233, Low Humidity Room: Alcamis manages a SAA in the Laboratory 233 for managing hazardous waste that is generated in this Low Humidity Room. The inspectors observed one 2-gallon container, one 1-gallon container and six 1-liter containers in this SAA. The 2-gallon and 1-gallon containers were located under the Fume Hood. The 2-gallon container was labeled as hazardous waste and marked to indicate that its contents are flammable. *It was not marked to indicate that its contents are also toxic.* The inspectors observed a laminated hazardous waste card sitting on top of the 1-gallon container, but *the label was not affixed to the container.* Each of the six 1-liter containers was labeled as hazardous waste and marked to indicate that its contents are flammable, but *not all of the 1-liter containers were marked to indicate that its contents are also toxic.* Alcamis personnel marked the 2-gallon container to indicate that its contents are also toxic; affixed a hazardous waste label with an indication of the hazards of the waste to the 1-gallon container; and added an indication that the contents are also toxic to 1-liter containers that were missing this information.

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 also observed one 20-gallon step can labeled for accumulating pharmaceutical waste. Alcamis personnel explained that this container is used to accumulate pharmaceutical waste that is not regulated as hazardous waste.

Laboratory 228: Alcamis manages three SAAs in Laboratory 228 for managing hazardous waste generated in this laboratory. Hazardous waste flammable liquids generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed three 2-gallon safety cans in this SAA. One container was located under Fume Hood 1, one was located under Fume Hood 2, and the third was located under Fume Hood 3. Each container was labeled as hazardous waste and marked to indicate that the contents of the container exhibit the hazardous waste characteristics of ignitability and toxicity.

Hazardous waste flammable liquids generated by laboratory equipment are accumulated in the second SAA in this laboratory. The inspectors observed eighteen containers with a combined total storage capacity of approximately thirty gallons in this SAA: thirteen 2-gallon safety cans, three 1-liter bottles, and one 1-gallon container. Each container was located in a secondary containment tray or bucket, and all but one of the containers was hooked up to one or more laboratory machines. The 1-gallon container was closed, and not hooked up to a laboratory machine.

Each of the 2-gallon safety cans, the 1-gallon container, and two of the 1-liter containers were identified with pre-printed white hazardous waste labels. However, *the label on one of the 1-liter containers was not legible because it was washed out. Although the remaining two 1-liter containers were not labeled*, each was placed inside a secondary containment bucket that was identified with a pre-printed white hazardous waste label. *Each of the white hazardous waste labels observed in this SAA was only marked to indicate that the contents of that container exhibit the characteristic of ignitability*, but Alcamí personnel immediately marked each label to indicate that the contents of the containers also exhibit the characteristic of toxicity.

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.

Used sample vials containing hazardous waste flammable liquids are accumulated in the third SAA in this laboratory. The inspectors observed two empty 5-gallon buckets in this SAA, and each bucket was identified with a yellow hazardous waste label. Each pre-printed yellow hazardous waste label states that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Laboratory 238: Alcamí manages three SAAs in Laboratory 238 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed three 2-gallon safety cans and one 1-liter container in this SAA. One 2-gallon container was located under Fume Hood 1, and another was located under Fume Hood 2. Each of these containers was labeled as hazardous waste and marked to indicate that the contents of the container exhibit the hazardous waste characteristic of ignitability, but *neither was marked to indicate that the contents of the container also exhibit the hazardous waste characteristic of toxicity*. Personnel immediately marked each container to indicate that the contents are toxic. The inspectors observed the red safety can and 1-liter container in this SAA under Fume Hood 2. The red safety can was labeled D001, D002, D022, D038, F003 hazardous waste flammable corrosive (acidic) liquids, *but it was not marked to indicate that the contents also exhibit the hazardous waste characteristic of toxicity*. The 1-liter container was labeled D002, D009 hazardous waste mixed solution loose pack pharmaceutical waste with mercury.

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 flammable liquids generated by laboratory equipment are accumulated in the second SAA in this laboratory. The inspectors observed thirty-six containers with a combined total storage capacity of approximately forty-four gallons in this SAA: sixteen 2-gallon safety cans, one 2-liter bottle, eleven 1-liter bottles, and eight 1-gallon containers. Each container was located in a secondary containment tray or bucket and hooked up to one or more laboratory machines.

Fifteen of the 2-gallon containers, one of the 1-liter containers, and two of the 1-gallon containers were identified with pre-printed white hazardous waste labels. Although *they were not labeled*, the 2-liter container and eight of the remaining 1-liter containers were each placed inside a secondary containment bucket that was identified with a pre-printed white hazardous waste label. *Each of the white hazardous waste labels observed in this SAA was only marked to indicate that the contents of that container exhibit the characteristic of ignitability*, but Alcamí personnel immediately marked each label to indicate that the contents of the containers also exhibit the characteristic of toxicity.

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.

One of the 2-gallon containers and six of the 1-gallon containers were identified with pre-printed yellow hazardous waste labels. The pre-printed yellow hazardous waste labels indicate that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Two of the 1-liter containers were not labeled as hazardous waste or marked to indicate that their contents exhibit the hazardous waste characteristic of toxicity. One of these two containers was identified with a flammable liquid hazard placard, but the other was not marked to indicate that its contents exhibit the hazardous waste characteristic of ignitability.

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.

Used sample vials containing hazardous waste flammable liquids are accumulated in the third SAA in this laboratory. The inspectors observed two empty 5-gallon buckets in this SAA, and each bucket was identified with a yellow hazardous waste label. Each pre-printed yellow hazardous waste label states that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Laboratory 150: Alcamí manages two SAAs in Laboratory 150 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed one 1-liter container and one 5-gallon container in this SAA. The 1-liter container was labeled hazardous waste FIMS waste acid with mercury and identified with a flammable liquid hazard placard. Although *the container was not marked to indicate that its contents exhibit the hazardous waste characteristics of corrosivity or toxicity*, personnel immediately added this information to the waste label. The 5-gallon container was labeled graphite furnace atomic absorption hazardous waste. Personnel stated that these containers will eventually be placed into a lab-pack for shipment off-site.

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 flammable liquids generated by laboratory equipment are accumulated in the second SAA in this laboratory. The inspectors observed two 1.5-gallon containers and two approximately ½-liter containers, which were each attached to laboratory equipment in this area. One of the 1.5-gallon and ½-liter containers were each labeled flame atomic absorption hazardous waste, and the other 1.5-gallon and ½-liter containers were each labeled graphite furnace atomic absorption hazardous waste. *The 1.5-gallon container of flame atomic absorption hazardous waste was 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.

Laboratory 150A: Alcami manages two SAAs in Laboratory 150A. Used sample vials containing hazardous waste flammable liquids are accumulated in the first SAA. The inspectors observed one 15-gallon container in this SAA. The container was labeled hazardous waste flammable liquids and it was marked to indicate that its contents exhibit the hazardous waste characteristics of ignitability and toxicity.

Alcami manages hazardous wastes that will eventually be shipped off-site in a lab-pack in the second SAA in this laboratory. The inspectors observed two ½-liter containers, two 5-gallon containers and a flammable cabinet holding approximately ten to fifteen small containers in this SAA. The first ½-liter container was located under Fume Hood 3. *This container, which was labeled as hazardous waste mercuric iodide and identified with a toxic hazard placard, was open.* The second ½-liter container was located under Fume Hood 4. This container was labeled as hazardous waste. One of the 5-gallon containers was labeled as hazardous waste corrosive acid wastewater. The other 5-gallon container was labeled as hazardous waste heavy metals lab and marked to indicate that its contents exhibit the hazardous waste characteristics of corrosivity, toxicity, and reactivity. Each container inside the flammable cabinet appeared to be marked with an indication of the hazards of its contents.

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption, a generator is required to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste; or when temporary venting of a container is necessary for the proper operation of equipment, or to prevent dangerous situations, such as build-up of extreme pressure.

Laboratory 139: Alcami manages two SAAs in Laboratory 139 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed one 2-gallon safety can under a Fume Hood in this SAA. The container was labeled as hazardous waste and marked to indicate that the contents of the container exhibit the hazardous waste characteristics of ignitability and toxicity.

Used sample vials containing hazardous waste flammable liquids are accumulated in the second SAA in this laboratory. The inspectors observed one 5-gallon bucket in this SAA. The bucket

was labeled as hazardous waste and marked to indicate that its contents exhibit the hazardous waste characteristics of ignitability and toxicity.

Laboratory 135: Alcami manages two SAAs in Laboratory 135 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed one 1-gallon container in this SAA. The container was labeled as hazardous waste and marked to indicate that the contents of the container exhibit the hazardous waste characteristics of ignitability and toxicity.

Used sample vials containing hazardous waste flammable liquids are accumulated in the second SAA in this laboratory. The inspectors observed one 15-gallon bucket in this SAA. The bucket was labeled as hazardous waste and marked to indicate that its contents exhibit the hazardous waste characteristics of ignitability and toxicity.

Laboratory 136: Alcami manages three SAAs in Laboratory 136 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed two 2-gallon safety cans, one 1-gallon container and one 1-liter container in this SAA. The 1-gallon container, which was located under Fume Hood 1, contained hazardous waste nitric acid and residual hydrogen peroxide. *The container was identified with an old hazardous waste label that had previously been used to identify another waste stream, and some information on the hazardous waste label had been crossed out.* The visible information on the label indicated that the contents of the container exhibited the hazardous waste characteristic of ignitability. Laboratory personnel marked the label to cross-out the reference to the ignitability characteristic and to indicate that the contents of the container exhibit the hazardous waste characteristics of toxicity and corrosivity. EHS personnel further requested that the laboratory personnel place a new hazardous waste label onto the container in order to clarify the communication of information related to the contents of the container.

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 1-liter container, which was labeled as halogenated hazardous waste, was located under Fume Hood 3. The 1-liter container was empty. One of the 2-gallon containers was located under Fume Hood 2, and the other was located under Fume Hood 3. Each of these 2-gallon containers was labeled as hazardous waste. The 2-gallon container under Fume Hood 3 was also marked to indicate that the contents of the container exhibit the hazardous waste characteristics of ignitability and toxicity. The 2-gallon container under Fume Hood 2 was marked to indicate that the contents of the container exhibit the hazardous waste characteristic of ignitability, but *it was not marked to indicate that the contents of the container also exhibit the hazardous waste characteristic of toxicity.* Personnel immediately marked this container 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 flammable liquids generated by laboratory equipment are accumulated in the second SAA in this laboratory. The inspectors observed thirteen containers with a combined total storage capacity of approximately seventeen gallons in this SAA: five 2-gallon safety cans, six 1-gallon containers, and two 1-liter bottles. Each container was located in a secondary containment tray or bucket and hooked up to one or more laboratory machines.

All of the five 2-gallon containers and two of the 1-gallon containers were identified with pre-printed white hazardous waste labels. Although *they were not labeled*, the two 1-liter containers were each placed inside a secondary containment bucket that was identified with a pre-printed white hazardous waste label. Each of the white hazardous waste labels observed in this SAA were only marked to indicate that the contents of that container exhibited the characteristic of ignitability, but *not marked to indicate that the contents also exhibited the characteristic of toxicity*. Alcami personnel immediately marked each label to indicate that the contents of the containers also exhibit the characteristic of toxicity.

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.

Four of the 1-gallon containers were identified with pre-printed yellow hazardous waste labels. The pre-printed yellow hazardous waste labels indicate that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Used sample vials containing hazardous waste flammable liquids are accumulated in the third SAA in this laboratory. The inspectors observed two 5-gallon buckets in this SAA. Each bucket was labeled as hazardous waste and marked to indicate that its contents exhibit the hazardous waste characteristics of ignitability and toxicity.

Laboratory 136C: Alcami manages three SAAs in Laboratory 136C for managing hazardous waste generated in this laboratory. Hazardous waste digitube vials are accumulated in the first SAA, and the inspectors observed one 20-gallon container in this SAA. The container was labeled as hazardous waste and it was marked to indicate that its contents are corrosive and toxic.

Hazardous waste standards with heavy metals are accumulated in the second SAA, and the inspectors observed one 15-gallon container, one 5-gallon container, and one ½-gallon container in this SAA. A yellow hazardous waste label on the 15-gallon container identified its contents as hazardous waste standards with heavy metals that exhibit the hazardous waste characteristics of corrosivity and toxicity. The 5-gallon and ½-liter containers were also labeled as heavy metal hazardous waste that exhibits the hazardous waste characteristics of corrosivity and toxicity. Personnel explained that the contents of the 5-gallon and ½-liter containers are routinely poured into the 15-gallon container for transfer to the Waste Shed CAA.

Particle size hazardous waste is accumulated in the third SAA. The inspectors observed one 5-gallon container under an exhaust vent in this SAA. The container was labeled as particle size hazardous waste and marked to indicate that its contents are ignitable.

Laboratory 120: Alcamis manages three SAAs in Laboratory 120 for managing hazardous waste generated in this laboratory. Hazardous waste generated by personnel working at laboratory benches is accumulated in the first SAA. The inspectors observed two 2-gallon safety cans in this SAA. One 2-gallon container was located under Fume Hood 2, and another was located under Fume Hood 3. Each of these containers was labeled as hazardous waste and marked to indicate that the contents of the container exhibit the hazardous waste characteristic of ignitability, but *neither was marked to indicate that the contents of the container also exhibit the hazardous waste characteristic of toxicity*. Personnel immediately marked each container to indicate that the 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 flammable liquids generated by laboratory equipment are accumulated in the second SAA in this laboratory. The inspectors observed twelve containers with a combined total storage capacity of approximately nineteen gallons in this SAA: nine 2-gallon safety cans, one 2-liter bottle, and two 1-gallon containers. Each container was located in a secondary containment tray or bucket and hooked up to one or more laboratory machines.

The 2-gallon and 2-liter containers were identified with pre-printed white hazardous waste labels. *Each of the white hazardous waste labels observed in this SAA was only marked to indicate that the contents of that container exhibit the characteristic of ignitability*, but Alcamis personnel immediately marked each label to indicate that the contents of the containers also exhibit the characteristic of toxicity.

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.

Each of the 1-gallon containers was identified with pre-printed yellow hazardous waste label. The pre-printed yellow hazardous waste labels indicate that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Used sample vials containing hazardous waste flammable liquids are accumulated in the third SAA in this laboratory. The inspectors observed two 5-gallon buckets in this SAA, and each bucket was labeled as hazardous waste and identified to indicate that its contents exhibit the hazardous waste characteristic of ignitability and toxicity.

Laboratory 125: Alcamis manages one SAA in Laboratory 125 for managing hazardous waste generated in this laboratory. Hazardous waste flammable liquids generated by laboratory equipment is accumulated in this SAA. The inspectors observed four containers with a combined total storage capacity of approximately six gallons in this SAA: two 2-gallon safety cans, one 2-liter bottle, and one 1-gallon container. Each container was located in a secondary containment tray or bucket, hooked up to one or more laboratory machines, and identified with pre-printed yellow hazardous waste label. The pre-printed yellow hazardous waste labels indicate that the waste exhibits the hazardous waste characteristics of ignitability and toxicity.

Laboratory 115: Alcamí manages two SAAs in Laboratory 115 for managing hazardous waste generated in this laboratory. Used sample vials containing hazardous waste flammable liquids are accumulated in the first SAA. The inspectors observed one 5-gallon bucket in this SAA, and the bucket was labeled as hazardous waste and identified to indicate that its contents exhibit the hazardous waste characteristic of ignitability and toxicity. Expired and unwanted laboratory chemicals that will be shipped off-site in lab-packs are accumulated in the second SAA. The flammable storage cabinet used to house containers of these lab-pack chemicals was empty at the time of the inspection.

Mezzanine CAA: Alcamí manages a hazardous waste CAA on the second floor of the building in an area referred to as the Mezzanine. The CAA is located in a flammable cabinet, which was identified with a “danger, hazardous waste storage” sign. The area is equipped with an emergency telephone, a portable fire extinguisher, and a spill control kit. The inspectors also observed several empty waste containers staged on a storage rack next to the flammable cabinet. Personnel explained that if the Clean Harbors employee is not available, laboratory personnel can bring full containers of hazardous waste to this CAA and retrieve an empty container for use in the laboratory. Laboratory personnel also bring expired or unwanted chemicals to this CAA so that the Clean Harbors employee can transfer those containers to the Waste Shed CAA. Hazardous waste managed in this CAA includes ignitable waste, and the cabinet was marked with the words “flammable” and “keep fire away.” Alcamí personnel immediately added a “No Smoking” sign on the door of the flammable cabinet.

The inspectors observed four 2-gallon containers of liquid hazardous waste and five trays or boxes holding small containers of lab-pack chemicals inside the flammable cabinet. Personnel noted that the inspection was being conducted on the last day of June, and laboratory personnel typically place more lab-pack waste in this CAA at the end of the month. Each lab-pack container was identified with an indication of the hazards of its contents on the original container label or an attached identification tag.

One box of 4-foot universal waste lamps was also observed in the area next to the flammable cabinet. The box was closed, labeled universal waste lamps, and dated June 27, 2022.

Waste Shed CAA: Alcamí manages a hazardous waste CAA in a Waste Shed located outside of the main building. This area is inside a shed with a metal roof, walls and a concrete floor. The area was identified with signs which read “Hazardous Waste CAA” and “No Smoking.” The Waste Shed CAA is equipped with a fire suppression system, spill control equipment, a LEL alarm system, and a vent hood for the liquid waste consolidation area. Employees working in this area carry a cellular phone, and the area is also equipped with pull alarm which will send a signal to the alert panel inside the building and call for assistance from emergency response teams.

The inspectors observed four 55-gallon drums in the area designated for liquid waste consolidation activities. Three of the drums were full and the fourth was nearly full. The full drums were closed, with the date that the drum was filled marked on the lid of each drum. The nearly full drum was also closed. Each drum was identified with flammable liquid DOT hazard placard and a yellow hazardous waste label indicating that the contents of the drum were toxic and ignitable. In addition to the date marked on top of the full drums, each drum was marked with an accumulation start date of June 17, 2022, June 22, 2022, June 23, 2022, or June 27, 2022.

The inspectors observed three additional 55-gallon drums, one 35-gallon container, one 20-gallon container, one 5-gallon container, and one box of hazardous waste in this CAA:

- Each of the three 55-gallon drums was identified with a flammable liquid DOT hazard placard and a yellow hazardous waste label indicating that the contents of the drum were toxic and ignitable. The drums were marked with an accumulation start date of June 17, 2022, June 28, 2022, or June 29, 2022. The June 29, 2022 drum was equipped with a flip-top lid, and all three drums were closed.
- The 35-gallon container was labeled as hazardous waste digitube vials containing standards with heavy metals; it was marked to indicate that the contents of the container were corrosive and toxic; and it was dated June 15, 2022.
- The 20-gallon container was labeled as hazardous waste particle size waste; it was marked to indicate that the contents of the container were ignitable; and it was dated June 21, 2022.
- The 5-gallon carboy was labeled as hazardous waste acid wastewater; it was marked to indicate that the contents of the container were corrosive; and it was dated April 20, 2022.
- The cardboard box was labeled as hazardous waste totals; it was marked to indicate that the contents of the container were toxic; and it was dated June 20, 2022.

Alcami manages smaller containers of hazardous waste inside two flammable cabinets inside the shed near the door before those containers are placed into a lab-pack container for shipment offsite. The inspectors observed approximately twenty-five containers inside one of the flammable cabinets and one container inside the other flammable cabinet. Each container was labeled hazardous waste and identified with an indication of the hazards of its contents.

The inspectors also observed the following containers of universal waste in the Waste Shed CAA:

- One 15-gallon container labeled universal waste lithium batteries and dated June 10, 2022;
- One 20-gallon fiber drum labeled universal waste compact fluorescent lamps and dated February 25, 2022;
- One 5-gallon bucket labeled universal waste lamps and dated February 8, 2022;
- One 5-gallon bucket labeled universal waste lithium batteries and dated June 27, 2022; and
- One 5-gallon bucket labeled universal waste lithium-ion batteries and dated February 17, 2022.

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 August 20, 2021. The plan describes actions facility personnel must take in response to a spill or emergency at the facility; lists the names and emergency telephone numbers for persons identified as emergency coordinators; includes a list of emergency equipment at the facility; and includes an evacuation plan for personnel. The list of emergency equipment includes fire control equipment, spill containment equipment, communication and alarm systems, and first aid equipment. The

contingency plan also includes a map showing the location of emergency response equipment and the accompanying evacuation plan includes a map showing evacuation routes for personnel.

Alcami created a Quick Reference Guide for the Contingency Plan, 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; the identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff; a map of the facility showing where hazardous wastes are generated, accumulated and treated and routes for accessing these wastes; a street map of the facility in relation to surrounding businesses, schools and residential areas; the identification of on-site notification systems; and the name of the emergency coordinator(s) and emergency telephone number(s).

Alcami has attempted to make arrangements with the local police department, fire department, other emergency response teams, and local hospital to respond in the event of an emergency. Copies of the Contingency Plan and Quick Reference Guide were provided to the City of Wilmington Police Department, the City of Wilmington Fire Department, the New Hanover Regional Medical Center, and the New Hanover County Emergency Management on June 3, 2021.

Training Records: The inspectors reviewed facility job descriptions and employee names that were provided for the Hazardous Waste Inspection Coordinator, the Chemical Waste Pick-Up Coordinator, Chemical Waste Generator and Disposal employees, and the Clean Harbors On-Site Chemist contractor. Alcamí provided a written description of the type of hazardous waste training to be given to each person filling the positions listed above, and the inspectors reviewed records of employee hazardous waste training completed in 2020 and 2021.

Waste Manifest Records: The inspectors reviewed available hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent between July 2021 and June 2022. During calendar year 2022, Alcamí initiated shipments of hazardous waste to Clean Harbors (TXD055141378) about two or three times each month. Those shipments have included one or more of the following hazardous wastes:

- waste hydrogen peroxide;
- waste corrosive and toxic liquid (sodium hydroxide, sodium thiosulfate);
- waste flammable liquid (methanol, toluene);
- waste corrosive and toxic liquid (hydrochloric acid, mercury);
- waste corrosive liquid (sulfuric acid, hydrochloric acid);
- waste corrosive liquid (sodium hydroxide, potassium hydroxide);
- waste corrosive liquid (hydrochloric acid, nitric acid);
- waste flammable and corrosive liquid (acetonitrile, acetic acid); or
- waste flammable and corrosive liquid (acetonitrile, sodium hydroxide).

During calendar year 2022, Alcamí initiated shipments of hazardous waste to Safety Kleen (KYD053348108) about two or three times each month. Those shipments have included one or more of the following hazardous wastes:

- waste hexanes; or

- waste flammable liquid (methanol, toluene)

During calendar year 2022, Alcami initiated shipments of hazardous waste to Clean Harbors (NCD000648451) about one or two times each month. Those shipments have included one or more of the following hazardous wastes:

- waste flammable liquid (alcohol, ethanol);
- waste toxic liquid (chloroform, methylene chloride);
- waste corrosive and toxic liquid (hydrochloric acid, mercury); and
- various other waste flammable liquids.

Alcami also initiated one shipment of hazardous waste sulfuric acid to Clean Harbors (OHD000724153); three shipments of hazardous waste toxic liquid (methylene chloride, cyclomethicone) to Giant Resource Recovery (SCD368275626); one shipment of hazardous waste corrosive and toxic liquid (hydrochloric acid, mercury) to Clean Harbors (TXD982290140); one shipment of hazardous waste 2-methyl 2-butene to Clean Harbors (ARD069748192); one shipment of waste corrosive liquid (hydrochloric acid) to Clean Harbors (OHD065438376); and one shipment of universal waste batteries and lamps to Clean Harbors (NCD000648451) during calendar year 2022.

Inspection Records: The inspectors reviewed Alcami's available records of inspections of the hazardous waste CAAs since June 4, 2021. Weekly inspections are recorded using an electronic inspection log, which identifies the name of the person conducting the inspection and the name of the area being inspected and records the date and time of the inspection. The inspection log includes a checklist to record observations about leaking containers and for deterioration of containers caused by corrosion or other factors. Specific items on the checklist include: security of area from unauthorized entry; presence of danger and no smoking signs; presence of telephone and/or 2-way radio communication equipment; availability of spill control equipment, fire extinguishing/control equipment, and water supply; adequacy of aisle spacing; condition of containers; labels and dates on containers; and segregation of incompatible wastes. Written records of each inspection are kept by printing and signing the completed checklist for each week.

12) Closing Conference

At approximately 3:00 pm, the inspectors conducted the exit meeting with Molly Darden and Taylor Henderson in person and with Stan Harts via teleconference. During this meeting, the inspectors stated their preliminary conclusions of the inspection.

13) Signed

LAURIE DIGAETANO Digitally signed by LAURIE DIGAETANO
Date: 2022.08.15 11:02:54 -04'00'

Laurie Benton DiGaetano
Senior Enforcement and Compliance Specialist

Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ
Date: 2022.08.15 11:06:12 -04'00'

Araceli B. Chavez
RCRA Enforcement Section