

RCRA Inspection Report

1) Inspector and Author of Report

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2) Facility Information

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EPA ID# NCD047373766

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3) Responsible Officials

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4) Inspection Participants

Natalie Brown, Patheon
Toby Holliday, Patheon
Laurie Benton DiGaetano, U.S. EPA

Andrea Stermer, NCDEQ
Jenne S. Walker, NCDEQ

5) Date of Inspection

April 7, 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; Hazardous Waste Management Permit NCD047373766-R2; 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”).

Pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17(a)(2)], which incorporates 15A NCAC 13A .0110 [40 C.F.R. § 265 Subpart BB] and is part of the LQG Exemption, equipment that contains or contacts hazardous waste with an organic concentration of at least 10 percent by weight for less than 300 hours per calendar year is excluded from the requirements of 15A NCAC 13A .0110 [40 C.F.R. §§ 165.1052 through 265.1060] if it is identified, either by list of location (area or group), as required in 15A NCAC 13A .0110 [40 C.F.R. §265.1064(g)(6)] (hereinafter referred to as the “Less than 300-hour Monitoring Exclusion”).

7) Purpose of Inspection

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

8) Previous Inspection History

NCDEQ has conducted a RCRA CEI at the subject facility nearly every fiscal year for over twenty years. The most recent NCDEQ RCRA CEI was conducted on June 15, 2021, and one apparent violation was noted for failing to conduct two months of air monitoring as required by 15A NCAC 13A .0107(a) [40 C.F.R. § 262.17(a)(2)], which incorporates 15A NCAC 13A .0110 [40 C.F.R. § 265 Subpart BB] and is part of the LQG Exemption.

The most recent joint EPA and NCDEQ RCRA CEI was conducted on July 12, 2016.

9) Facility Description

Patheon Manufacturing Services, LLC (Patheon) performs contract pharmaceutical manufacturing operations for producing over-the-counter medications, capsules, tablets, sterile injectable formulas, creams, and other pharmaceuticals at the subject facility in Greenville, North Carolina. The facility includes an approximately 1,500,000 square foot building complex on approximately 143 acres of property. The building complex houses manufacturing operations,

research and development laboratories, quality assurance and quality control laboratories, engineering facilities, environmental operations, and administrative offices. On-site research and development activities are used only to determine how formulations can be scaled up for the manufacturing process. The subject facility operates under the primary NAICS code 3254012 for Pharmaceutical Preparation Manufacturing and under the additional NAICS code 325998 for All Other Miscellaneous Chemical Product and Preparation Manufacturing. Production operations and utility services run twenty-four hours per day, seven days per week, and the company has approximately 1,900 employees (full time and temporary) at this location. Manufacturing at the subject facility is done in a batch mode, and the specific manufacturing process for each product does not change.

The facility has been operating as a large quantity generator (LQG) of hazardous waste for over 30 years, and Patheon first notified as the owner and operator on April 20, 2018. The facility has also been operating under a hazardous waste management permit for the storage of hazardous waste generated onsite. The current permit, Hazardous Waste Management Permit Number NCD047373766-R2 (the RCRA Permit), was issued to Patheon by the North Carolina Department of Environmental Quality (NCDEQ) on November 15, 2018. The facility is permitted to store up to 2,582 gallons of hazardous waste, or approximately 224 55-gallon drums, on a designated concrete pad which is divided into two curbed containment areas (East and West), surrounded by a chain link fence, and covered by a metal roof.

Patheon has also identified 70 satellite accumulation areas (SAAs) where hazardous waste is routinely managed. Most of these SAAs are located in laboratories where personnel typically accumulate hazardous waste in small containers at the initial collection point and then transfer it into a larger consolidation container before Environmental Operations personnel move it to the permitted hazardous waste container storage area. OSHA-approved laboratory solvent containers are used to transport hazardous waste liquids from the laboratories to the permitted area where it is consolidated into DOT-approved shipping containers for disposal. Hazardous waste solids are typically accumulated at the laboratories in 44-gallon fiber drums, which are transferred to the permitted storage area before they are shipped off-site for disposal. Each laboratory may also generate small amounts of other hazardous waste (i.e. outdated laboratory chemicals) that are packaged in lab packs, stored in the permitted container storage area, and shipped off-site for disposal.

The facility also manages a few SAAs in the manufacturing areas of the facility. Formulation processes involving powders are conducted under vent-hood filtering systems with a central dust collection point. Dust residues are collected in 33-gallon fiber drums. When these residues contain hazardous constituents, trained personnel remove the containers from the collection point, seal it, and place the sealed fiber drum into a 55-gallon DOT-approved metal drum. The metal drum is also sealed, marked to identify its contents, and transferred to the permitted storage area. In addition, manufacturing operations in the sterile products production area infrequently generates hazardous waste rinsate at the end of a production run. This hazardous waste rinsate is accumulated in plastic containers that are palletized, taken to the permitted storage area, and transferred to DOT-approved metal drums for on-site storage and off-site disposal.

When hazardous waste off-spec commercial chemical products (CCPs) generated in the manufacturing areas are suitable for containerization, they are drummed and sealed by the employee(s) performing the manufacturing operations. The shift supervisor (or his designee) signs a waste disposal transfer sheet which is submitted to Environmental Operations personnel in order to notify them that hazardous waste is ready for transfer to the permitted container storage area. Hazardous waste CCPs that are not suitable for containerization may be shipped off-site directly from production vessels.

Patheon has also identified four central accumulation areas (CAAs) for managing hazardous waste in areas that are not at or near the point of generation before they are transferred to the permitted container storage area:

- Hazardous waste mixed organic liquids generated in the Model Lab are accumulated and stored in two 55-gallon drums in the Storage Locker CAA;
- Hazardous waste acetone generated by cleaning equipment in Building 7 is accumulated and stored in one 55-gallon drum in the Building 7 Outside Locker CAA;
- Hazardous waste liquid generated in Building 7 is accumulated and stored in the Building 7 Inside CAA; and
- Hazardous wastes generated in other areas of the facility may be accumulated and stored in the Building 1 Inside CAA.

Environmental Operations personnel routinely pick up containers of hazardous waste from SAAs and CAAs throughout the facility and transfer those containers to the permitted container storage area. Personnel pick up waste that is identified on a waste disposal transfer sheet or is stored in one of the CAAs every Tuesday and Thursday, and they pick up waste from laboratories every Monday and Tuesday. Environmental Operations personnel attach a drum identification number to each container and verify that the container is labeled as hazardous waste and marked with an indication of the hazards of its contents before transferring the container to the permitted container storage area.

In the 2019 biennial report, which was submitted to NCDEQ on 02/24/2020, Patheon reported shipments of the following hazardous wastes during calendar year 2019:

Description of waste	EPA Hazardous Waste Code(s)	Pounds shipped in 2019
Bravecto liquid	D001	27,070
alcohols (isopropanol, ethanol, water)	D001	19,600
spent solvents	D001/D035/D038 F002/F003/F005	16,400
Flucelvax with thimerosal	D009	7,350
HPLC vials	D001	3,050
Flucelvax thimerosal contaminated	D009	2,860
thinner and rags	D001/D008/D035/F002/F003/F005	2,670

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lab scraps with melphalan	U150	1,460
spent solvents	D001/D035/F003	1,200
solvent based paint/ink debris	D001/D035/F005	910
glassware with organics	F002/F003/F005	740
lab trash/debris	F002/F003/F005	700
crushed fluorescent bulbs	D009	500
sodium hydroxide/detergent solution	D002	260
Neosporin ophthalmic solution	D009	250
alkaline batteries	D009	240
CIP 220	D002	40
mercury devices	D009	10
starch TS with mercuric iodide	D009	10
metallic mercury	D009	5
Various lab packs (44 types of lab packs, each containing one or more of the identified waste codes)	D001/D002/D003/D004/D005/D006/D007/D008/D009/D010/D011/D022/D038/D040/F003/F005/U001/U002/U003 / U006/U012/U019/U031/U044/U080/U088/U095 / U108/U112/U122/U123/U135/U138/U144/U154/U161 /U162/U168/U190/U201/ U213/U218/U219/U220/U228 /U404/P030/P048/P098/P105/P119	4,682 total (1 to 395 pounds per lab pack type)

10) Opening Conference

On April 7, 2022, EPA inspector Laurie Benton DiGaetano, accompanied by NCDEQ inspectors Andrea Stermer and Jenne S. Walker, arrived at Patheon Manufacturing Services, LLC at approximately 8:30 a.m. Natalie Brown, Senior EHS Specialist, immediately received the inspectors, and they were joined by Toby Holliday, Director of EHS for the opening conference. The inspectors introduced themselves, showed their credentials, and explained the purpose of the visit. 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 EPA. The company did not assert a business confidentiality claim. The inspection participants also discussed health and safety protocols and required personal protective equipment before Ms. Brown and Mr. Holiday led the inspectors on a tour of the Facility operations.

Ms. Brown and Mr. Holliday provided an overview of the facility's history and current operations during the opening conference. 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. Although the EPA inspector did not provide a copy of the agency's information sheet for small businesses, it can be found at <https://www.epa.gov/sites/production/files/2017-06/documents/smallbusinessinfo.pdf>.

11) **Findings**

Building 8A General Lab SAA: Patheon manages a SAA in the Metrology Mix Lab, 081F050 (Building 8, First Floor, Room 50), for managing hazardous waste liquids that are generated by the HPLC machines. The inspectors observed four 10-liter containers accumulating liquids directly from the machines, and one 5-gallon flammable can for consolidating those liquids. All of the 10-liter containers were labeled as hazardous waste. Two were marked to indicate that the contents are flammable, toxic, and corrosive, and the other two were marked to indicate that the contents are flammable and toxic. Although the 5-gallon container was empty, it was also labeled as hazardous waste and flammable in preparation for use. Laboratory personnel track the contents of the 5-gallon container by maintaining a written inventory of its contents as liquids are added to the container.

Building 8A Lab 39: No hazardous wastes were observed in Laboratory 39 in Building 8A.

Building 8A Lab 38 HPLC Lab SAAs: Patheon manages two SAAs in the HPLC Lab, 081F38. One SAA is used to manage hazardous waste liquids that are generated by the HPLC machines, and the other is used to manage used HPLC sample vials.

The inspectors observed fourteen 10-liter containers accumulating liquids directly from the HPLC machines, and four 5-gallon red flammable cans for consolidating those liquids. Each of the 10-liter containers were labeled hazardous waste and marked with an indication of the hazards of its contents (flammable, oxidizer and/or toxic). Each of the 5-gallon cans was labeled hazardous waste and marked to indicate the contents are flammable. Three of the 5-gallon cans were empty, and the total volume of hazardous waste observed in this SAA was less than 42 gallons. The inspectors observed a loose rubber tube at one of the HPLC machines where liquid hazardous waste dripping from the tube and not being accumulated in the associated 10-liter accumulation container. Patheon personnel immediately addressed the leak by connecting the rubber tube so that the liquid would flow from the HPLC machine directly into the associated 10-liter accumulation container.

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 SAA Permit Exemption.

The inspectors observed one 44-gallon fiber drum in the second SAA. The drum was labeled as hazardous waste and marked to indicate that the contents are flammable and oxidizing.

Building 8A Lab 24 SAAs: Patheon manages two SAAs in Lab 24 inside Building 8A. One SAA is used to manage hazardous waste liquids that are generated by the HPLC machines, and the other is used to manage used HPLC sample vials.

The inspectors observed five 10-liter containers accumulating liquids directly from the HPLC machines, one 4-liter container under a laboratory hood, and three 5-gallon red flammable cans for consolidating liquids from the HPLC machines. Each of the 10-liter containers was labeled hazardous waste and marked with an indication of the hazards of its contents (flammable and/or toxic); the 4-liter container was labeled as hazardous waste and marked with an indication of the hazards of its contents; and each of the 5-gallon cans was labeled hazardous waste and marked to indicate the contents are flammable. All of the 5-gallon cans were empty, and the total volume of hazardous waste observed in this SAA was less than 15 gallons.

The inspectors observed one 44-gallon fiber drum in the second SAA. The drum was labeled as hazardous waste and marked to indicate that the contents are corrosive and toxic.

Building 8A Lab A-22 SAAs: Patheon manages two SAAs in the Animal Health Lab A-22 inside Building 8A. One SAA is used to manage hazardous waste liquids that are generated by the HPLC machines, and the other is used to manage used HPLC sample vials.

The inspectors observed five 10-liter containers and one 5-gallon container accumulating liquids directly from the HPLC machines, and three 5-gallon red flammable cans for consolidating liquid hazardous waste. Each of the HPLC containers was labeled hazardous waste and marked with an indication of the hazards of its contents. Each of the 5-gallon cans was labeled hazardous waste, and two contained liquids. One was marked to indicate the contents are flammable; one was marked to indicate the contents are corrosive; and the third was empty. All of the 5-gallon cans were empty, and the total volume of hazardous waste observed in this SAA was less than 30 gallons.

The inspectors observed one 44-gallon fiber drum in the second SAA. The drum was labeled as hazardous waste and marked to indicate that the contents are corrosive and toxic.

Building 4 (041F02) SAA: Patheon conducts painting operations during routine maintenance at the facility and manages one SAA in Building 4 where paints are mixed and prepared for use. The inspectors observed one 44-gallon fiber drum and two 5-gallon flammable cans in this area. The 44-gallon drum was labeled hazardous waste alcohol and paint rags, and it was marked to indicate that the contents are flammable. Each 5-gallon can was labeled hazardous waste and marked to indicate that its contents are ignitable.

Machine Shop SAA: Patheon manages one SAA for managing used aerosol cans in the Machine Shop. The inspectors observed one 44-gallon fiber drum in this area. The drum was labeled hazardous waste HVAC aerosol cans, and it was marked to indicate its contents are flammable. Personnel stated that paint cans are not punctured on-site.

Electric Shop SAA: Patheon manages one SAA for managing crushed fluorescent bulbs in the Electric Shop. The inspectors observed one 55-gallon drum, which was equipped with a bulb crusher, in this SAA. The drum was labeled hazardous waste crushed bulbs containing mercury, and it was marked to indicate the contents are toxic. The inspectors observed broken glass that appeared to have fallen from bulb crusher onto the top of the drum rather than inside it.

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 SAA Permit Exemption.

On April 8, 2022, Ms. Brown sent an email to the inspectors in which she provided photographic evidence that Patheon has addressed this issue by cleaning the top of the 55-gallon drum and placing the broken glass into the hazardous waste container.

Forklift Truck Shop SAA: Patheon manages one SAA for managing used aerosol cans in the Forklift Truck Shop. The inspectors observed one 44-gallon fiber drum in this area. The drum was labeled hazardous waste and it was marked to indicate its contents are ignitable. The inspectors also observed one 55-gallon drum, which was labeled used oil, on a portable secondary containment pallet in this area.

Raw Materials Lab (022F014) SAA: Ms. Martina Jones, Raw Materials Supervisor, joined the inspection participants in the Raw Materials Lab. Patheon manages one SAA to accumulate hazardous wastes generated in this laboratory. The inspectors observed three 5-gallon flammable cans stationed at the end of three laboratory benches in this SAA. One can was labeled hazardous waste and marked to indicate its contents are ignitable; one can was labeled hazardous waste acid mixture only and marked to indicate its contents are corrosive; and one can was labeled hazardous waste base mixture only and marked to indicate its contents are corrosive.

The inspectors observed one 4-liter bottle labeled perchloric acid waste, two small bottles of waste sodium thiosulfate, and two boxes of waste hydranal water standard. None of these containers were labeled hazardous waste, and the container of perchloric acid was not marked to indicate that its contents are corrosive. Personnel explained that these containers, along with another 5-gallon container labeled hazardous waste flammable liquids, have been set aside to be placed in a lab pack which will be stored at the permitted storage area.

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.

On April 8, 2022, Ms. Brown sent an email to the inspectors in which she provided photographic evidence that each container had been labeled with the words “hazardous waste” and that an indication of the hazards of its contents had been added to each container where necessary. Ms. Brown also stated that additional training had been provided to the laboratory supervisor and personnel to improve container labeling procedures.

The inspectors also observed a bag which appeared to contain used PPE and paper towels under a lab hood. The bag was marked as “hazardous material” and “handle with care.” It was labeled HF waste and dated April 7, 2022. The laboratory manager stated that this bag contains single-use items contaminated with low levels of acid. She explained that the bag does not contain hazardous waste and will be disposed of in the regular trash.

Small Lab in Raw Material Lab (022F013) SAA: Patheon manages another SAA inside a smaller laboratory within the Raw Material Lab. The inspectors observed one 5-gallon container accumulating hazardous wastes generated by the AA machine. The container was labeled hazardous waste and marked to indicate its contents are toxic. The inspectors observed a second 44-gallon fiber drum to accumulate waste vials from testing for zinc, copper, iron, lead, nickel, potassium, and sodium. This container was also labeled as hazardous waste and it was marked to indicate that its contents are toxic and corrosive.

Model Lab 022F010 SAAs: Patheon manages two SAAs in the Model Lab 22 inside Building 2. One SAA is used to manage hazardous waste liquids that are generated by the Karl Fisher machine, and the other is used to manage used sample vials. The inspectors observed one 2-liter container accumulating liquids directly from the Karl Fisher machine. The container was labeled hazardous waste, but it was not marked with an indication of the hazards of its contents. No container was observed in the second designated SAA.

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.

On April 8, 2022, Ms. Brown sent an email to the inspectors in which she provided photographic evidence that an indication of the hazards had been added to the container. Ms. Brown also stated that additional training had been provided to the laboratory supervisor and personnel to improve container labeling procedures.

Sink Room in Model Lab SAA: Patheon stores solutions that are pending analysis and sample retains inside the Sink Room, which is located within the Model Lab in Building 2. When all testing is complete for a specific sample, the remaining sample material becomes a waste. The inspectors observed eight 5-gallon red flammable cans in this area. Each can was labeled

“hazardous waste” and marked to indicate that its contents are flammable. Six of the cans were empty, and the total volume of hazardous waste in this SAA was less than 10-gallons.

The Sink Room is also equipped with a sink within a laboratory hood. This sink is hard piped to the hazardous waste CAA storage locker just outside of Building 1, where liquids from the sink discharge into two 55-gallon drums. Liquid organic wastes generated in the Model Lab are poured into the sink and accumulated as hazardous waste in the 55-gallon drums in the CAA storage locker. The sink is equipped with an automatic valve, and the inspectors observed a tag on this valve identifying it as MP1.

Personnel explained that opening the door to the CAA storage locker immediately triggers signal lights and closes the automatic valve beneath the laboratory sink. Signal lights in the laboratory are also used to indicate when the 55-gallon drums in the CAA are reaching capacity and need to be changed out.

HPLC Lab 022F001 SAA: Patheon manages one SAA in the HPLC Lab within the Model Lab in Building 2. At the time of the inspection, no container was present in this SAA, which is used to manage HPLC sample vials. This HPLC Lab houses 42 HPLC units, which are lined up on three parallel laboratory benches. Each HPLC machine is connected to a solid header pipe, which runs along the length of that laboratory bench. The three header pipes tie in together and drain into one of two 55-gallon drums located in the CAA storage locker. When D001/D035/D038/F002/F003/F005 hazardous waste acetone and methylene chloride is generated by the HPLC machines, the liquid flows via gravity through the piping system into the hazardous waste containers in the CAA storage locker. The piping system does not include any pumps, and the only valves associated with the system are located in the CAA and under the sink in the Sink Room. The inspectors observed one manual control valve (MP1) in the piping just beneath the laboratory sink. The valve was tagged to distinguish it from other pieces of equipment.

Storage Locker CAA: Hazardous wastes that are transferred from the HPLC Room and Sink Room in the Model Lab through the piping system are accumulated in two 55-gallon drums inside the Storage Locker CAA. Facility personnel stated that it takes between four to six weeks to fill the drums, and that they are changed out at the same time. The inspectors observed that each of the 55-gallon drums were labeled hazardous waste mixed organics, dated March 3, 2022, and marked to indicate the contents are ignitable and toxic. The drums were equipped with secondary containment, and the CAA was equipped with a fire extinguisher and a spill kit. The inspectors also observed the piping used to transfer hazardous waste from the point of generation to this area. The piping in this area was equipped with two automatic control valves (MP2 and MP3) and two manual valves (MP4 and MP5), and each valve was tagged to distinguish it from other pieces of equipment.

Building 7 Outside Locker CAA: Patheon has designated a storage shed outside Building 7 as a CAA for managing hazardous wastes generated from cleaning the manufacturing equipment between batches. According to the Permit application, acetone is used in Building 7 to clean equipment in place, and the spent acetone is transferred from the equipment via stainless steel piping. The Permit application asserts that this piping is excluded from the requirements of 15A NCAC 13A .0110 [40 C.F.R. §§ 265.1052 through 265.1060] under the Less than 300-hour

Monitoring Exclusion. According to the Permit application, acetone is used to clean equipment in Building 7 about 35 times per year, and that the piping and equipment used to transfer the spent acetone is in contact with hazardous waste for approximately 44 minutes during each cleaning event. The piping is purged with nitrogen between uses, so that the equipment is in contact with hazardous waste acetone for a total of approximately 26 hours each year.

The Building 7 Outside Locker CAA is a flammable storage shed/locker unit with built-in secondary containment. The inspectors observed brooms, a spill kit, and a fire extinguisher in this area, and the shed is identified with signs reading “hazardous waste” and “no smoking.” Patheon representatives stated that personnel carry two-way radios when working in this area. The inspectors observed one 55-gallon drum of hazardous waste inside the CAA. The drum was labeled hazardous waste, identified as flammable, corrosive and toxic, and dated March 29, 2022.

Building 7 Inside CAA: The facility manages another CAA inside the Animal Health area at Building 7. This area is identified with signs reading “danger, hazardous waste,” and “no smoking.” It is equipped with a spill kit and fire extinguisher. The inspectors observed one 44-gallon drum in this area. The drum was labeled hazardous waste and marked to indicate the contents are flammable, toxic, and oxidizing. The drum was not marked with an accumulation start date because it was empty.

Building 1 Inside CAA: Alcohol is used to clean equipment in the Sterile Packaging and Inspection Building, and personnel use and reuse the same rags for these cleaning activities. At the end of the work shift, personnel bring the used rags to Patheon’s designated CAA closet in Building 1. The CAA was identified with signs that read “danger, hazardous waste,” and “no smoking.” It was equipped with a spill kit and fire extinguisher. The inspectors observed two 44-gallon fiber drums in this CAA. Each drum was labeled hazardous waste and marked to indicate its contents are flammable. One drum was dated 03/08/2022 and the other was dated April 5, 2022.

The inspectors observed two additional 44-gallon drums just outside of the CAA. One drum, which was labeled hazardous waste aerosol cans, was empty. The other drum was labeled hazardous waste alcohol rags and marked to indicate its contents are flammable.

Permitted Storage Area East and West: Mr. Kent Cutler, Lead Technician for Environmental Operations, joined the inspection participants at the permitted hazardous waste storage area. This area is a concrete pad that is divided into two curbed containment areas (East and West), surrounded by a chain link fence, and covered by a metal roof. Metal signs, which read “danger, hazardous waste storage” and “no smoking,” were posted on the chain link fence. The inspectors observed an emergency shower and eyewash station, fire extinguishers, shovels, and two spill kits in this area. The facility representatives stated that personnel carry cellular phones and/or two-way radios capable of calling for emergency assistance while working in this area.

Designated rows for container storage and associated aisle spacing are identified by yellow lines painted on the concrete floor in this permitted hazardous waste storage area. The inspectors observed containers in five rows, running North-South, in the East side of the area, and in four

rows, running East-West, on the West side. Among the hazardous waste containers stored in this permitted area, the inspectors observed:

- Sixteen 44-gallon fiber drums of aerosol cans awaiting puncture;
- One 55-gallon steel drum of aerosol can waste, which was equipped with an aerosol can puncture device and identified as ignitable and toxic;
- Three 44-gallon fiber drums of retains, which were identified as ignitable;
- Two 44-gallon fiber drums of empty IPA cans, which were identified as ignitable;
- Four 55-gallon drums of hazardous waste, which were identified as ignitable;
- One 44-gallon drum, which was identified as corrosive and toxic;
- One 44-gallon drum, which was identified as ignitable and toxic;
- One 55-gallon drum of coating suspension waste, which were identified as ignitable;
- Four 55-gallon drums of lab waste, which were identified as ignitable;
- One 44-gallon drum of aerosol cans, which was identified as ignitable;
- Three 44-gallon drums of alcohol rags, which were identified as ignitable;
- Eight 15-gallon containers of waste NaOH, which were identified as corrosive;
- One 44-gallon drum of empty alcohol cans, which was identified as ignitable;
- One 44-gallon drum of canisters;
- Six 44-gallon lab packs, which were identified as toxic and corrosive;
- One 44-gallon drum of waste dust, which was identified as toxic;
- One 44-gallon drum of glass / solvents, which was identified as toxic and corrosive;
- One 18-gallon container of alcohol rags, which was identified as ignitable;
- Eight 44-gallon drums of flu vaccine, which were identified as toxic;
- One 35-gallon drum and one 18-gallon container of mercury containing waste, which were each identified as toxic;
- One 44-gallon drum of hazardous waste, which was identified as toxic; and
- Thirty-six 44-gallon drums of hazardous waste, which were identified as toxic.

Each of the containers listed above was labeled as hazardous waste, identified with an indication of the hazards of its contents, and marked with an accumulation start date. The oldest container was dated September 16, 2021. The containers appeared to be closed, and no leaks or spills from these containers were observed during the inspection.

In addition to the containers described above, the inspectors also observed three 55-gallon drums that were not labeled, one 55-gallon drum of hazardous waste NaOH that was not marked with an indication of the hazardous of its contents, and one 44-gallon drum of hazardous waste media tubing that was not marked with an indication of the hazards of its contents. Personnel determined that the unlabeled drums contained a rejected nonhazardous product material. The 55-gallon drum of hazardous waste NaOH was marked to indicate that the contents were corrosive, and the 44-gallon drum of hazardous waste media tubing was marked to indicate that the contents were toxic.

Pursuant to HW Permit NCD047373766 R2, Part VI.B.2. Land Disposal Prohibitions and Treatment Standards, which incorporates 15A NCAC 13A .0112 [40 C.F.R. § 268.50(a)(2)(i)], the storage of hazardous wastes restricted from land disposal is prohibited unless an owner / operator of a hazardous waste treatment,

storage or disposal facility stores such wastes solely for the purpose of the accumulation of such quantities of hazardous waste as necessary to facilitate proper recovery, treatment or disposal and each container is clearly marked to identify its contents with the applicable EPA hazardous waste numbers, an indication of the hazards of the contents, and the date each period of accumulation begins.

On April 8, 2022, Ms. Brown sent an email to the inspectors in which she provided photographic evidence that the container labeling issues had been corrected.

The inspectors also observed a section of the permitted hazardous waste container storage area where Environmental Operations personnel consolidate hazardous waste liquids generated in the laboratories. The inspectors observed twenty-one empty 5-gallon flammable cans staged next to two 55-gallon drums in this area. Hazardous waste liquids are brought to the permitted hazardous waste container storage area in the 5-gallon flammable cans, which are poured through a funnel into a 55-gallon drum for transportation to a permitted hazardous waste treatment, storage, and disposal facility. Each 55-gallon drum was labeled hazardous waste laboratory waste and identified as ignitable. One drum was closed and dated March 28, 2022, and the other was equipped with a funnel (with a closed valve) and dated April 4, 2022. Each empty 5-gallon flammable can was labeled as hazardous waste, and ready to be returned to a laboratory for reuse.

Inspection participants discussed the standard operating procedures for accumulating and consolidating hazardous waste in the individual laboratories and transferring that waste to the 55-gallon drums in the permitted container storage area. The inspectors observed an inventory log kept with each 5-gallon flammable can where wastes are initially consolidated in the laboratories, and the facility representatives explained that laboratory personnel mark the applicable indication(s) of hazards on the container as more waste is placed into the 5-gallon can. The inspectors noted that the two 55-gallon drums and empty 5-gallon flammable cans in the permitted container storage area and almost all of the flammable cans in the laboratories were marked to indicate that the contents are flammable. It was not clear if laboratory personnel were adding an indication that the contents of the 5-gallon containers were toxic, if appropriate. Please note that, pursuant to 15A NCAC 13A .0107(a) [40 C.F.R. § 262.11(a)], a hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and that an accurate determination is required to ensure wastes are properly managed according to applicable RCRA regulations.

Contingency Plan: The actions that facility personnel should take in response to an emergency are described in the facility's Contingency Plans. The facility maintains one contingency plan for the permitted hazardous waste storage area and another for the areas where hazardous wastes are generated and stored prior to transfer to the permitted hazardous waste storage area. The plans were last updated on January 7, 2021, and the facility's quick reference guide was updated on January 6, 2020.

Both contingency plans describe 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. Each lists the names and

emergency telephone numbers for persons identified as emergency coordinators and includes a list of all emergency equipment at the facility along with a description of the equipment and its location. The contingency plan for the permitted area includes an evacuation plan for personnel in that area, and the contingency plan for the other areas includes an evacuation plan for personnel in those areas. The evacuation plans describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes. Both plans describe arrangements agreed to with Pitt County Emergency Services, the City of Greenville, the Bethel Police Department, Vidant Medical Center, Station House Fire Department, Pitt County Sheriff, Veolia, Eastern Environmental Services, and CA Lewis, Inc.

The quick reference guide 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; the identification of on-site notification systems; and the name of the emergency coordinator(s) and emergency telephone number(s). Although the quick reference guide references schematic maps, a street map and a site map, these maps are kept with the contingency plan and not included with the quick reference guide.

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)], 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; a street map of the facility in relation to surrounding businesses, schools and residential areas; and the locations of water supply.

Training Records: The RCRA Permit identifies the duties and training requirements for facility personnel with hazardous waste management duties under the following job titles: Principal/Senior Environmental Engineer, Environmental Engineer, Environmental Control Operator I, and Environmental Control Operator II. The inspectors requested hazardous waste training records for ten employees who were randomly selected due to identified hazardous waste management duties. The records indicated that each employee has completed the hazardous waste training as assigned.

Waste Manifest Records: The inspectors reviewed hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent since most recent NCDEQ RCRA CEI, which was conducted on June 15, 2021.

Inspection Records: The inspectors reviewed Patheon's available records of inspections of the East and West permitted drum storage areas, and of the CAAs at Buildings 18 and 7 for calendar year 2021, and records of inspections of the CAAs at the East Side of Building 7, the Model Labs hazardous waste locker at Building 1 and the Sterile Packaging area between May and December of 2021. The inspection logs include a checklist to record observations about leaking containers and for deterioration of containers caused by corrosion or other factors. The inspection log includes a checklist to record observations about the number of containers,

container labels and dates, age of containers, leaks or stains, closed containers, dents or corrosion, aisle space, liquid in secondary containment, gaps or cracks in secondary containment, and compatibility of containers. The records include the date of the inspection and the signature of the employee conducting the inspection.

12) Closing Conference

The inspectors conducted the exit meeting with Tommy Schornak, Site Direct VP General Manager, Toby Holliday, Director of EHS, and Natalie Brown, EHS Specialist. During this meeting, the inspectors stated their preliminary conclusions of the inspection.

13) Inspection Findings

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

- 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 SAA Permit Exemption.
- 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(a) [40 C.F.R. § 262.17(a)(6)], which incorporates 15A NCAC 13A .0107(i) [40 C.F.R. § 262.262(b)], 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; a street map of the facility in relation to surrounding businesses, schools, and residential areas; and the locations of water supply.
- Pursuant to HW Permit NCD047373766 R2, Part VI.B.2. Land Disposal Prohibitions and Treatment Standards, which incorporates 15A NCAC 13A .0112 [40 C.F.R. § 268.50(a)(2)(i)], the storage of hazardous wastes restricted from land disposal is prohibited unless an owner / operator of a hazardous waste treatment, storage or disposal facility stores such wastes solely for the purpose of the accumulation of such quantities of hazardous waste as necessary to facilitate proper recovery, treatment or disposal and each container is clearly marked to identify its

contents with the applicable EPA hazardous waste numbers, an indication of the hazards of the contents, and the date each period of accumulation begins.

14) **Signed**

LAURIE DIGAETANO Digitally signed by LAURIE DIGAETANO
Date: 2022.05.26 15:34:33 -04'00'

Laurie Benton DiGaetano
Senior Enforcement and Compliance Specialist

Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ
Date: 2022.05.26 15:45:52 -04'00'

Araceli B. Chavez
Chief
RCRA Enforcement Section