

RCRA Inspection Report

1) Inspector and Author of Report

Alan Newman
RCRA Enforcement Section
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W. (404) 562-8589
Atlanta, Georgia 30303 newman.alan@epa.gov

2) Facility Information

Aegis Sciences Corporation
501 Great Circle Road
Nashville, Tennessee 37228
Davidson County
EPA ID: TND987777638

3) Responsible Officials

Brianna Whalen, Environmental Health and Safety Coordinator
(615) 577 - 4559
Brianna.Whalen@aegislabs.com

4) Inspection Participants

Brianna Whalen	Aegis Sciences Corporation
Patrick Campbell	Aegis Sciences Corporation
Trent McKenzie	Aegis Sciences Corporation
Matthew Hardison	Aegis Sciences Corporation
Joe Gassenheimer	Aegis Sciences Corporation
Bart Marston	TDEC – Nashville Field Office
Alan Newman	EPA Region 4

5) Date and Time of Inspection

February 23, 2022, 9:30 p.m. – 4:30 p.m. C.S.T.

6) Applicable Regulations

Resource Conservation and Recovery Act (RCRA) Sections 3002 (42 U.S. Code – Annotated U.S.C.A. 6925 and 6927), and 40 Code of Federal Regulation (C.F.R.) Parts 260 - 270, 273, 278, & 279; Tennessee Hazardous Waste Management Act of 1977, Tennessee Code Annotated (Tenn. Code Ann.) § 68-212-101 *et seq.*, and Chapter 0400-12-01 of the Rules and Regulations of the State of Tennessee (Tenn. Comp. R. & Regs.).

As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10], a large quantity generator of hazardous waste (LQG) is a generator who generates greater than or equal to 1,000 kilograms (2,200 pounds) of non-acute hazardous waste in a calendar month.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h) [40 C.F.R. § 262.17], a LQG may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h) [40 C.F.R. § 262.17] (hereinafter referred to as the "LQG Permit Exemption").

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1. [40 C.F.R. § 15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near the 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 Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1. [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(g)2. or 0400-12-01-.03(1)(h)1. [40 C.F.R. § 262.16(b) or §262.17(a)], except as required in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1.(vii and viii) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in Ten Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1. [40 C.F.R. § 262.15(a)] (hereinafter referred to as the "SAA Permit Exemption").

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(1)(i) [40 C.F.R. § 273.9], a small quantity handler of universal waste (SQHUW) is a universal waste handler who does not accumulate 5,000 kilograms or more of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or aerosol cans, calculated collectively) at any time.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(d)1.(xxvi) [40 C.F.R. § 261.4(a)(26)], solvent-contaminated wipes that are sent for cleaning and reuse are not solid wastes from the point of generation, provided that the conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(d)1.(xxvi) [40 C.F.R. § 261.4(a)(26)] are met (hereinafter referred to as the "Solvent-Contaminated Reusable Wipe Exclusion").

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(d)2.(xviii) [40 C.F.R. § 261.4(b)(18)], solvent-contaminated wipes, except for wipes that are hazardous waste due to the presence of trichloroethylene, that are sent for disposal are not hazardous wastes from the point of generation, provided that the conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(d)2.(xviii) [40 C.F.R. § 261.4(b)(18)] are met (hereinafter referred to as the "Solvent-Contaminated Disposable Wipe Exclusion").

7) **Purpose of Inspection**

The purpose of this inspection was to conduct an unannounced compliance evaluation inspection to determine Aegis Sciences Corporation compliance with the applicable requirements of RCRA and the corresponding Tennessee regulations. This was an EPA lead inspection.

8) **Previous Inspection History**

The most recent TDEC RCRA CEI was conducted in 2010 at the subject facility and found no violations during that inspection. This facility recently changed to large quantity generator status.

9) **Facility Description**

Aegis Sciences Corporation is a forensic toxicology and healthcare laboratory that provides drug testing and consulting services based in Nashville, Tennessee. The facility occupies a campus that encompasses two laboratories including one found at 515 Great Circle Road (TNR000018259) (515 Laboratory) and a second biopharma laboratory that occupies the entire 1st floor of the building at 501 Great Circle Road (TND987777638) (501 laboratory or biopharma laboratory). EPA Identification number TND987777638 was originally assigned to Brown and Caldwell at this site, a consulting firm in the Nashville area. On November 17, 2020, Aegis notified as a new facility hazardous waste generator to the Division of Solid Waste Management and thereby taking ownership of this EPA identification number.

The 515 laboratory conducts analysis which are primarily related to medication compliance, substance abuse, and drug-drug interactions through definitive testing of urine, oral fluid, or blood specimens. In addition to healthcare testing services, the 515 laboratory offers anti-doping and forensic testing services to professional and amateur sports organizations and college and university athletic programs.

Aegis's biopharma laboratory (Aegis) provides molecular diagnostic services, including clinical trial services, pharmacogenetic testing, and other services. The biopharma laboratory is primarily engaged in analyzing polymerase chain reaction (PCR) tests for COVID-19. Aegis Sciences Corporation Biopharma Lab at 501 Great Circle Road (TND987777638) was the identified facility for this inspection. The facility occupies 43,000 sq. ft., employs approximately 500 people, and operates 24 hours, seven days a week. For the inspection period of November 2020 – February 2022, AEGIS Sciences Corporation (TND 98-777-7638) was classified as a Large Quantity Generator (LQG) of Hazardous Waste and a Small Quantity Handler of Universal Waste.

Aegis has notified Tennessee of two open waste streams including:

Waste Stream 8 (WS#8) – Ethyl Alcohol (D001) is generated from discarding old/expired product.

Waste Stream 9 (WS#9) – Treated COVID-19 Samples (D001/D002) are generated from COVID-19 testing.

Aegis further analyzes positive Covid-19 results to determine the specific strain/mutation that the positive test exhibits. Aegis operates under the NAICS code 621511 - Medical Laboratories.

10) **Opening Conference**

On February 23, 2022, EPA inspector Alan Newman, accompanied by TDEC inspectors Bart Marsden, arrived at Aegis at approximately 9:30 pm C.S.T. Trent McKenzie immediately received the inspectors but was not part of the environmental staff. The inspection team was introduced to Patrick Campbell, and the inspectors were later joined by Brianna Whalen who was working from home and drove in for the opening conference and inspection. The inspectors introduced themselves, showed their credentials to Patrick Campbell and Brianna Whalen 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 the 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 Brianna Whalen and Patrick Campbell led the inspectors on a tour of the Facility operations.

Aegis representatives provided an overview of the facility's history and current operations during the opening conference. The company does not appear to meet the Small Business Regulatory Enforcement Fairness Act's classification of a "small business," which is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. Therefore, the EPA inspector did not provide a copy of the agency's information sheet for small businesses, which can be found at <https://www.epa.gov/compliance/small-business-resources-information-sheet>.

11) **Findings**

In November of 2020, Aegis began analyzing samples for PCR COVID-19 tests from a variety of testing sites including chain pharmacies which make up the largest contributor of these tests. Tests are sent via FedEx overnight to Aegis in Nashville, Tennessee. The number of PRC samples can range as high as 25,000 samples per day. Aegis conducts the analysis and turns around results within 24 hours. Facility personnel stated that there were 18,000 samples processed the previous day.

- **Accessioning Area**

Tests are received at the main loading dock where they are unloaded and moved to Accessioning. Tests are then unpacked and batched. Sample information is entered into a database at the Accessioning Area. Each sample is given a unique identifier for identification. Any tests that appear to be damaged are taken to a singular table in this area. An Accessioning Tech Senior 2 will then observe the test and determine if it can be used or disposed of. Any tests that are deemed to be for disposal are taken to the Satellite Accumulation Area (SAA).

The inspection team noted one 55-gallon black poly container storing sample wastes (D001) in the SAA. The inspection team noted that the indication of the hazard on this container but was in small type and difficult to read unless you were very close to the label (Photos 1-2). The inspection team recommends including indications of hazards that are larger like other labeling

used onsite.

- Aliquot/Extraction Area

Aegis Aliquot/Extraction employees will use a sampling device to remove a representative sample from the batched test tubes into a 96 deep well plate for further processing and analysis. A disposable pipette tip is used to transfer the sample between the test tube and the plate. Pipette tips are disposed of as non-hazardous waste as medical red bag waste. These samples on plates are processed in a magnetic bead extraction prior to analysis. Aegis was storing non-hazardous waste in two 4-liter amber containers in this area (Photo 3). The labels on these containers were faded. The inspection team recommended that these containers be relabeled; and a sign be posted to indicate that these were waste containers.

Aegis was generating wipes in the process and were disposing of them into medical red bag waste containers. Aegis had not conducted a hazardous waste determination on this waste stream.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(b) [40 C.F.R. § 261.2], must determine if the waste is a hazardous waste following methods articulated in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11].

- Evo Prep/Annex

Aegis continues to prepare the sample in the 96 deep well plates and transfers smaller samples to a new plate that utilizes 384 wells. Aegis generates ethanol wastes in this prep step. Aegis was storing wastes in 4-liter amber containers in this area. There were three containers grouped in the waste storage area (Photos 4-6). One of these containers was empty, one was labeled as non-hazardous, and the third was labeled with an indication of the hazard but was not labeled as hazardous waste. This container was in good condition and closed. Facility personnel immediately labeled this container during the inspection.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1.(v)(I) [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 (I) with the words “Hazardous Waste”.

There was no waste noted in either the pre-amplification or the post amplification areas.

- Accessioning overflow

Aegis utilized the accessioning overflow area during peak sample processing. This area was smaller than the main accessioning area but set up similarly. Aegis was storing hazardous waste in one 55-gallon black poly container in this area (WS#9). The container was in good condition, closed and labeled (Photos 7-8). Similar to other containers, the indication of the hazard was in small type on the container label. Please see previous recommendation for this issue.

- Central Accumulation Area – Container Storage

Aegis was utilizing a small room for its central accumulation area (CAA). Aegis was storing hazardous waste in three 55-gallon black poly containers in this room on the day of the inspection (WS#9). These containers were labeled, closed, and in good condition (Photos 9-10). The oldest accumulation start date was February 22, 2022. The inspection team recommended that these containers be labeled with the larger indication of hazard decals from the supply area. A spill kit was located nearby; and personnel utilize cell phones for communications. The inspection team recommended that this room be marked with appropriate signage to identify the location of the CAA.

- CAA - Sample Disposal Room

Down the hall from the CAA, Aegis operates a Sample Disposal Room. Aegis accumulates post-analysis COVID-19 samples until the Center for Disease Control hold guidelines are met. Once this hold time is met, the samples are discarded. Aegis operates a second CAA in this room which consists of two 30-gallon blue poly containers (Photo 11). One container was storing ethanol wastes and the other was storing non-RCRA regulated buffer wastes. The hazardous waste container was labeled with an accumulation start date of February 8, 2022. These containers were located on a secondary containment pallet. Due reduce the potential for spills, the inspection team recommended that a locking funnel be added to the top of these containers.

- Universal Waste Lamps

Aegis was storing universal waste lamps in one 4-foot cardboard accumulation box (Photos 12-13). This box was in good condition, closed, and labeled. The accumulation start date on the box was April 19, 2021.

- Record Review

The inspection team reviewed the following records: the contingency plan, hazardous waste manifests, inspections, training records, hazardous waste reduction plan, hazardous waste determinations, annual reports, among other records.

Aegis failed to register isopropanol as a waste stream that was shipped from the facility on January 10, 2022, on hazardous waste manifest 015215384FLE. This new waste stream has not been notified to the DSWM within the 30-day requirement.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(2)(d)1.(i)(IV), which is a condition of the LQG Permit Exemption, a generator shall be responsible for maintaining an up to-date notification file by re-notifying the Commissioner of the following changes in the information submitted within 30 days after such changes by revising or submitting the appropriate notification forms, completed according to the instructions for completing the form: (IV) Generating a new hazardous waste stream.

Contingency Plan: The actions that facility personnel should take in response to an emergency

are described in the facility's ACS Integrated Contingency Plan, which was last updated on September 24, 2020. The plan describes actions facility personnel must take in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility. The plan describes arrangements agreed to with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, local hospitals, or the Local Emergency Planning Committee. The plan lists the names and emergency telephone numbers for persons identified as emergency coordinators. Brianna Whalen is listed as the primary emergency coordinator, and the other individuals are listed in the order in which they will assume responsibility as alternates. The plan includes a list of all emergency equipment at the facility. The list includes fire extinguishing systems, spill control equipment, communications and alarm systems, and decontamination equipment. The list appears to be up to date. The plan includes the location and a physical description of each item on the list, and a brief outline of its capabilities. The plan includes an evacuation plan for personnel. This plan describes signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

Training Records: The inspectors reviewed facility job descriptions and employee names that were provided for Lab Aides. Each description did not include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to that position. These job descriptions were insufficient to determine ongoing required training or duties.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)1.(vii)(IV)II. [40 C.F.R. § 262.17(a)(7)(iv)], which is a condition of the LQG Permit Exemption, a generator must maintain training records that include, among others: a written job description for each position listed under subitem I of this item. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position.

Waste Manifest Records: The inspectors reviewed available hazardous waste manifest records and land disposal restriction forms for shipments of hazardous waste sent since November 2020 through February 2022. Hazardous waste manifest records show that D001 hazardous waste ethyl alcohol and D001/D002 hazardous waste treated COVID-19 tests are routinely shipped to Clean Harbors El Dorado, Arkansas (ARD069748192). The records included signed return copies of manifests for shipments sent during this timeframe.

Inspection Records: The inspectors reviewed Aegis's available records of inspections of the hazardous waste central accumulation area (CAA) since November 2020. The inspection log includes a checklist to record observations about leaking containers and for deterioration of containers caused by corrosion or other factors. The records include the date and time of the inspection and the name, signature and initials of the employee conducting the inspection. Each week, the employee records notations of observations and necessary follow-up actions for the inspected areas. The inspection team noted records for the CCA – Container Storage but noted no inspection records were provided for the CAA – Sample Disposal Room the weeks between May 24, 2021, and June 4, 2021 (11 days) and also July 16, 2021, and July 29, 2021 (13 days). Inspections – two breaks with Sample Disposal Room CAA.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)1.(i)(V) [40 C.F.R. § 262.17(a)(1)(v)], which is a condition of the LQG Permit Exemption, a generator is required to, at least weekly, inspect central accumulation areas looking for leaking containers and for deterioration of containers caused by corrosion or other factors.

12) Closing Conference

The inspectors conducted the exit meeting at approximately 4:00 pm C.D.T. with Brianna Whalen, Patrick Campbell, and Matthew Hardison. During this meeting, the inspectors stated their preliminary conclusions of the inspection. On March 10, 2022, Brianna Whalen provided updated job descriptions and waste registration records in an email to Alan Newman.

13) Inspection Findings

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

- **Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(b) [40 C.F.R. § 261.2], must determine if the at waste is a hazardous waste following methods articulated in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11].**
- **Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(f)1.(v)(I) [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 (I) with the words “Hazardous Waste”.**
- **Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)1.(vii)(IV)II. [40 C.F.R. § 262.17(a)(7)(iv)], which is a condition of the LQG Permit Exemption, a generator must maintain training records that include, among others: a written job description for each position listed under subitem I of this item. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position.**
- **Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(2)(d)1.(i)(IV), which is a condition of the LQG Permit Exemption, a generator shall be responsible for maintaining an up to-date notification file by re-notifying the Commissioner of the following changes in the information submitted within 30 days after such changes by revising or submitting the appropriate notification forms, completed according to the instructions for completing the form: (IV) Generating a new hazardous waste stream.**
- **Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)1.(i)(V) [40 C.F.R. § 262.17(a)(1)(v)], which is a condition of the LQG Permit Exemption, a generator is required to, at least weekly, inspect central accumulation areas looking for leaking containers and for deterioration of containers caused by corrosion or other factors.**

14) **List of Appendices**

Appendix 1 – Photo Log:
13 Photos taken on: February 23, 2022
Photos taken by: Alan Newman
Photos taken with: Panasonic Lumix
EPA Property Tag: S75870

15) **Signed**

ALAN NEWMAN Digitally signed by ALAN NEWMAN
Date: 2022.03.30 14:59:12 -04'00'

Alan Newman
Environmental Engineer

Date

Concurrence

BROOKE YORK Digitally signed by BROOKE YORK
Date: 2022.03.30 14:07:57 -04'00'

for Araceli B. Chavez
Chief
RCRA Enforcement Section

Date

Photographs

Photos taken on February 23, 2022

Photos taken by Alan Newman

Camera: Panasonic Lumix

Serial Number: S75870



Photo 1: Accessioning Area SAA.

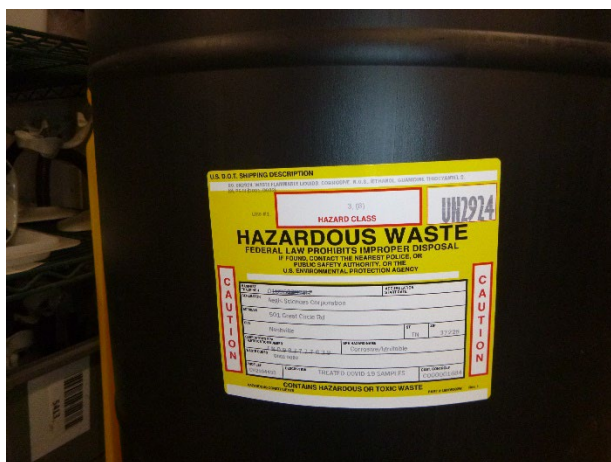


Photo 2: Accessioning Area SAA.



Photo 3: Extraction non-hazardous waste storage area.



Photo 4: Evo Prep SAA.



Photo 5: Evo Prep SAA.



Photo 6: Evo Prep SAA.

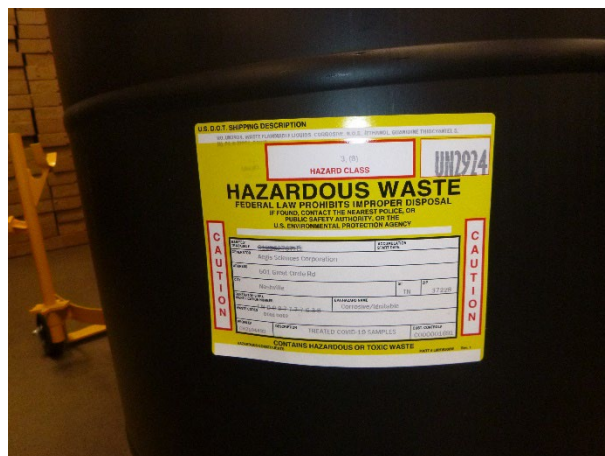


Photo 8: Accessioning overflow SAA.



Photo 7: Accessioning overflow SAA.



Photo 9: CAA – Drum Storage Room.



Photo 10: CAA – Drum Storage Room.



Photo 11: CAA – Sample Disposal Room.



Photo 12: Universal Waste Lamps Box.



Photo 13: Universal Waste Lamps Box.