US Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
Response and Remediation Branch

Resource Conservation and Recovery Act (RCRA)
Compliance Evaluation Inspection

Facility Name:	PACE Analytical, Inc.		
EPA ID Number:	PRD090235227		
Date of Inspection:	December 21, 2023		
Generator Status in Record:	LQG		
Generator Status at the time of inspection:	LQG		
RCRA Permitted:	No		
Basis for Inspection:	Core Program		
Corrective Action:	No		
Project ID	CEPD-RCRA-09-0142		
Facility Physical Location: (Municipality, PR, zip code)	El Retiro Zona Industrial Calle B & C San Germán, Puerto Rico, 00683		
Geographical Coordinates:	18° 4'31.02"N, 67° 1'37.19"W		
Facility Contact:	Ms. Nilsa Martínez, Senior Director	787-659-1137	
	nilsa.martinez@pacelabs.com		
	Mailing address: P.O Box 325 San Germán, Puerto Rico, 00683		
Facility Contact:	Mr. Hery Torres, Safety Officer	787-672-2963 787-659-0235	
	hery.torres@pacelabs.com		
	Mailing address: P.O Box 325 San Germán, Puerto Rico, 00683		
NAICS:	541380, Testing Laboratories		
Area:	Approximately 26,000 square feet		
Number Employees:	100 Full Time Employees (FTE)		
Personnel participating in inspection:			
Inspector's Name	EPA Region 2-CEPD	Enforcement Officer	{phone/email}
Eduardo Gonzalez	EPA Region 2-CEPD	Enforcement Officer	787-977-5839
			gonzalez.eduardo@epa.gov
Status:	FINAL		
Record Schedule:	1044(c) {unless landmark or precedent}		
Multi-media Checklist: ATTACHMENT # No		Referral: No	
EPA Lead Inspector Signature/Date	X Eduardo Gonzalez February 23, 2024		
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2024.02.27 09:11:39 -04'00' David N. Cuevas Miranda, Ph.D.		

1 INTRODUCTION

On December 21, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (Inspection) was conducted at PACE Analytical, Inc. (the "Facility), pursuant to Section 3007 of RCRA. The Facility is located at El Retiro Zona Industrial Calle B & C, San Germán, Puerto Rico.

As part of the Inspection, an opening meeting, walkthrough, documents review and closing meeting were conducted to evaluate Facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers and used oil generators as per RCRA. PACE Analytical, Inc. is designated in the RCRAInfo[1]database as a Large Quantity Generator (LQG). According to RCRAInfo database, PACE Analytical, Inc. was last inspected by EPA on June 26, 2019, and July 24, 2014, respectively, in the areas of general generator requirements, and no violations were found. Nevertheless, the Puerto Rico Department of Natural and Environmental Resources (former Environmental Quality Board) inspected the Facility on May 16, 2018, and violations were found pursuant to 40 Code of Federal Regulations (CFR) § 262.34(d)(5)(iii) - "Preparedness and Prevention," § 265.32(b) – "Required Equipment," and § 265.37(a)(1) "Arrangements with Local Authorities," and the Facility returned to compliance soon after the citations were issued.

2 OPENING MEETING

An opening meeting was held between Ms. Nilsa Martínez, Senior Director, Ms. Rosamarie Valle, Scientific 1, and Hery Torres, Safety Officer, all from PACE Analytical, and me. I identified myself as EPA RCRA Enforcement Officer and told the Facility representatives that the purpose of my visit was to conduct a RCRA Inspection at the Facility to evaluate its hazardous waste management practices and compliance. I discussed the objectives of my inspection, and the requirements under RCRA for a Large Quantity Generator (LQG). I asked Ms. Martínez to provide me for review PACE Analytical, Inc.'s manifests (last three years), and land disposal records regarding the handling, transportation, and final disposal of hazardous waste generated, and stored at the Facility. I also asked for review the waste analysis plan, weekly inspection records, personnel training requirements, biennial report, waste minimization plan, closure plan, contingency and emergency preparedness plan, SPCC[2] (Used Oil), and RCRA air emission requirement under 40 CFR § 265 Subparts AA, BB & CC certification reports.

Ms. Martínez stated that she needed to investigate about RCRA requirements pursuant to 40 CFR § 265 Subparts AA, BB & CC that would apply to PACE Analytical, Inc., specifically compliance with containers and drums under Subpart CC at the 90-Day Hazardous Waste Accumulation Area. She specified that containers and drums holding volatile organic wastes were provided by its hazardous waste contractor, Clean Harbors, who prepares waste profiles and specifies appropriate containers. She specified that containers holding volatile organic wastes were provided with a cover and manufactured tested seal in accordance with the Department of Transportation (DOT) (49 CFR 178 - Specifications for Packagings) requirements, and the United Nations (UN) Performance Oriented Packaging Standards. She later presented the "Containers Assembly Instructions," which describes each drum received comes with the

[1] RCRA Info and ECHO, EPA's Enforcement Compliance and History Online system
[2] Spill Prevention Control and Countermeasures Plan pursuant to 40 CFR § 112.7(a)(3) – Oil Pollution Prevention

assembly instructions, and packaging group type. As per the case of PACE Analytical, Inc., they use Packaging Group II Standard "Y" Moderate Waste and DOT container type is provided in Clean Harbor's Waste Profiles Section G – DOT Transportation of Dangerous Goods (TDG) information. According to the information provided all containers drums comply with the 40 CFR § 265.1087 for air emissions control. In addition, PACE Analytical, Inc.'s container management practices (transferring, storing, and stacking) are provided to prevent of volatile air emissions in a well vented and controlled storage area.

Based on a review of electronic manifests under the "Manifest Tracking Report," it was estimated that approximately over 2,962 to 3,307 lbs (> 2,200 lbs for LQG) of hazardous waste are generated at the Facility. I was told by Ms. Martínez that there are a 90-day hazardous waste accumulation area and various hazardous waste satellite accumulation areas (SAAs) for the management of hazardous wastes in the quality assurance/quality control laboratories.

2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION

Pace Analytical Life Sciences Puerto Rico Laboratory, known as Pace Analytical Inc., has been operated by Pace Analytical, Inc. since 2003. The laboratory was previously known as Caribbean Bio-Labs, Inc., which began operation in 1989. Pace Analytical Life Sciences is a full service, Good Manufacturing Practices (GMP) contract laboratory providing chemistry and microbiology testing services to the pharmaceutical, medical device and biopharmaceutical industries. The San German Facility includes 26,000 ft of laboratory that is equipped with state-of-the-art instrumentation. The laboratory is registered by the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) with over thirty years of FDA's audit history.

Pace Analytical, Inc. also housed a 14,000 sq ft laboratory that sits adjacent to the existing 11,000 sq ft laboratory and represents a state-of-the-art testing Facility to support the pharmaceutical and medical device manufacturing industry in Puerto Rico and in the US[3].

The Facility "Pace Analytical" comprises the following areas: Building No.1 – Microbiology which houses all microbiology laboratories and sample receiving areas, Building No. 2 – Chemistry which houses all analytical chemical laboratories, sample storge, 90-day central hazardous/non-hazardous/biohazard waste accumulation area, administration offices, parking lot, and some additional supporting utilities and facilities (i.e., chemical storage rooms, emergency generators, cafeteria, etc.).

PACE Analytical started operations approximately fifteen (15) years ago and currently employs approximately 100 people, working Monday to Saturday from 7:00 am to 10:00 pm. All buildings and property lot are under a rental contract with the Puerto Rico Industrial Development Company (PRIDCO).

[3] PACE's San German Location Holds Open House - June 29, 2017 (Ref. https://www.pacelabs.com/company/news-and-insights/life-sciences/san-german-open-house/#:~:text=Pace%20Analytical's%20Life%20Sciences%20Puerto,which%20began%20operation%20in%201989)

2.2 PHYSICAL SETTING

PACE Analytical, Inc. is located at El Retiro Zona Industrial Calle B & C, on a 1.83-acre tract of land south of State Road PR-2 within the municipality of San Germán, Puerto Rico. The topography is relatively flat, surrounded by residential houses and other factories in an industrial park that belongs to PRIDCO. The site is located at approximately 196 feet above mean sea level. ***Figure 1*** presents the site location on a portion of the US Geological Service (USGS) Topographical Map. ***Figure 2*** presents an aerial photograph of the site. The closest superficial water body is the Rio Guanajibo located approximately 0.56 miles to the north of the site (see **ATTACHMENT I)**.

2.3 SOLID AND HAZARDOUS WASTE GENERATION

PACE Analytical generates hazardous waste from their chemistry and microbiology testing services of material samples received from the pharmaceutical, medical device and biopharmaceutical industries. Most of the hazardous waste generated at PACE Analytical comes from the analytical testing, samples discarded, and chemical reagents and other solvents used during analytical tests at their laboratories. According to manifests, the Facility generates over 2,962 lbs to 3,307 lbs (> 2,200 lbs for LQG) of hazardous waste per month which is disposed of with Clean Harbors Caribe Inc. Typical solid wastes generated at the Facility include office paper, cardboard, metals, and other domestic waste from the restrooms and cafeteria areas which are disposed of with Cyclone Company in a municipal landfill. Industrial and sanitary wastewater is discharged to the Puerto Rico Aqueducts and Sewer Authority-Regional Wastewater Treatment Plant in Mayagüez.

The following chemistry and microbiology analytical testing generate hazardous wastes at PACE Analytical Facility in San German Site based on a review of the 2021 Hazardous Waste Biennial Report:

Principal hazardous waste streams generated at the Facility consist of i) vials with tetrahydrofuran, acetonitrile, dimethyl sulfoxide, and acetone (D001, U002, U003); ii) laboratory waste – acid (D002); iii) opacode and opadry ink (U031, D002); iv) raw materials waste stream (D004, D002, D007, D008, D009, D022, D028, P012, U044, U218); v) opadry ink raw materials solid samples (D001); vi) disinfectants waste stream (D002); vii) organic solvent mixture in aqueous media (D001, D018, D022, D038, F002, F003, F005, U019, U056, U239); viii) lab pack acid and acid compatibles for incineration (D002); ix) lab pack organics for incineration (D005, D008, D010); x) lab pack organics for incineration (U353); xi) lab pack organics for incineration (D036, U169); xii) pack organics for incineration (D019); xiii) pack organics for incineration (D002); xiv) lab pack flammable for incineration (D001); xv) lab pack flammable for incineration (D001, D002); xvi) lab pack require to be packaged alone per DOT (D002); xvii) lab pack oxidizer for incineration (D001, D008); xviii) lab pack oxidizer for incineration (D001, D007); xix) lab pack oxidizer for incineration (D001); xx) lab pack mercury salts and solutions for retort (D009); xxi) lab pack reactive basic and basic compatibles for incineration (D001, D002, D003); xxii) lab pack reactive organics for incineration (P030); xxiii) lab pack reactive organics for incineration (D003); xxiv) lab pack reactive organics for incineration (P098); xxv) lab pack require to be packaged alone per DOT (D002); xxvi) lab pack require to be packaged alone per DOT (P087); xxvii) lab pack reactive flammable for incineration (D003, D001); xxviii) lead acid batteries (D002, D008); xxix) lab pack basic and basic compatible for incineration (D002); xxx) lab pack basic and basic compatible for incineration (D005); and, xxxi) laboratory waste-basic (D002).

Based on the 2021 Hazardous Waste Biennial Report, the Facility is classified as a Large Quantity Generator (LQG). Based on a review of the 2023 Waste Handling Report (Safety S11) and the Emergency Contingency Procedures and Business Continuity Plan (Safety S7) the following hazardous waste streams were reported at the Facility and depicted in table below.

DOT Shipping Name	Maximum Volume on site*	EPA Hazardous Waste Code (s)
Waste Corrosive Liquid, Basic, Inorganic, N.O.S (Sodium Hydroxide, Potassium Hydroxide, Ammonium Hydroxide)	5 gallons	D002
Waste Flammable Liquids, Toxic, N.O.S., Mixture, (Methanol, Chloroform)	110 gallons	D001, D022, F002, F003, F005
Waste Corrosive Liquid, Acidic, Organic, N.O.S (Acetic Acid, Nitric Acid)	5 gallons	D002
Waste Corrosive Liquid, Acidic, Inorganic, N.O.S (Hydrochloric Acid, Sulfuric Acid)	5 gallons	D002
Waste Corrosive Liquid, Basic, Inorganic, N.O.S (Sodium Hydroxide, Potassium Hydroxide, Ammonium Hydroxide)	5 gallons	D002
Waste Flammable Liquids, Toxic, N.O.S., Mixture, (Methanol, Chloroform)	110 gallons	D001, D022, F002, F003, F005
Waste Flammable Liquids, Toxic, N.O.S, Mixture, (Methanol, Chloroform)	110 gallons	D001, D018, D022, F002, F003, F005, U019, U056, U239
Waste Flammable Liquids, Toxic, N.O.S, (Tetrahydrofuran, Acetonitrile)	55 gallons	D001, F005, U213
Waste Flammable Liquids, Toxic, N.O.S, (Tetrahydrofuran, Acetonitrile)	300 pounds	D001, U002, U003
Hazardous Waste, Solid, N.O.S, (Mercury)	50 pounds	D009
Waste Environmentally Hazardous Substances, Solid, N.O.S, (Mercury)	50 pounds	D009
Waste Arsenic Trioxide	6 pounds	D004, P012
Waste Corrosive Liquid, Acidic, Inorganic, N.O.S., (Sulfuric Acid, Hydrochloric Acid)	55 gallons	U031
Waste Flammable Solid, Inorganic, N.O.S. Mixture, (Iron Oxide Red)	500 pounds	D001
Waste Batteries, Wet Filled with Acid	20 pounds	D002, D008
Waste Batteries, Wet, Non-Spillable, Electric Storage	20 pounds	D002, D008
Waste Batteries, Wet, Filled with Acid, Electric Storage	20 pounds	D002, D008
Waste Environmentally Hazardous Substances, Solid, N.O.S, (Lead)	10 pounds	D008
Waste Batteries, Dry, Containing Potassium Hydroxide Solid	20 pounds	D006
Waste Corrosive Liquids, Toxic, N.O.S., (Hydrochloric Acid, Mercury)	40 pounds	D002, D009

Waste Toxic Liquid, Inorganic, N.O.S., (Mercury, Water)	80 pounds	D009
DOT Shipping Name	**Maximum Volume on site***	**EPA Hazardous Waste Code (s)**
Waste Toxic Liquid, Organic, N.O.S., (Chromium, Chloroform)	110 gallons	D002, D004, D007, D008, D009, D022, D028, U044, U218, P012
Waste Corrosive Liquids, Toxic, N.O.S Solution, (Chromium, Chloroform)	110 gallons	D002, D004, D007, D008, D009, D022, D028, U044, U218, P012
Biological Waste	900 pounds	Biohazard
Regulated Medical Waste	150 pounds	Biohazard

Other solid wastes generated at the Facility were Universal Waste (UW) associated with the management of spent fluorescent lamps, Biological Waste, Used Oil (small quantities), Ni-Cd batteries, and disposal of unused sanitation, maintenance, and housekeeping products.

3 FACILITY WALKTHROUGH

Ms. Martinez accompanied me during the facility walkthrough. A total of eight (8) areas were inspected: Room 2032-Gas Chromatology Area, Room 2033-High Performance Liquid Chromatography (HPLC) Area, Room 2026-Chemestry Area, Room 2029-Metals Area, Room 2011 90-day Hazardous Waste Accumulation Area (HWAA), Room 1009-Receiving Area, Room 1031 Area, and Room 2021 Area. The observations for each area are described below. Refer to Appendix 1 for pictures taken during the inspection.

3.1 ROOM 2032-GAS CHROMATOGRAPHY AREA

At the Room 2032-Gas Chromatography Laboratory Area, Ms. Martinez explained all laboratory logistics and analytical operations that generate hazardous wastes at the Satellite Accumulation Areas (SAAs). The Room 2032 is used to perform gas chromatography (GC) which is one of the most important types of chromatography used in analytical chemistry for separating and analyzing chemical organic compounds, especially volatile organic compounds. There twelve (12) GC equipment analyzers and three (3) head space equipments. At the Room 2032, there were two (2) SAAs observed: SAA-01, and SAA-02. The content of these SAAs was generated nearby the Point of Generation (POG) and under control of the operator by security access to the areas.

SAA-01

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 1**):

- One (1) 5-gallon white container with “HPLC/GC Vials,” clearly labeled with the words, “Hazardous Waste,” and identified with its hazard communication pictogram as, “Flammable Liquids & Solids.”

SAA-02

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 2**):

- One (1) 5-gallon black container with "GC Columns," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Solids & Toxic."

I strongly recommended that each laboratory container should also be labeled with its individual RCRA hazard code as an additional hazard communication and compatibility characteristics of the content as reported in the Biennial Report.

3.2 ROOM 2033-HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) AREA

I proceeded to inspect Room 2033-High Performance Liquid Chromatography (HPLC) Laboratory Area. In this area, I observed ten (10) High Performance Liquid Chromatography (HPLC) and six (6) dissolution bath continuously running different quality tests and generating spent solvent wastes (i.e., mobile phases) in its satellite accumulation areas. As discussed, HPLC is an analytical chemistry technique that separates compounds dissolved in a liquid sample and allows qualitative and quantitative analysis of what components and how much of each component are contained in the sample. It was informed by Ms. Martinez that 3 HPLCs were out of service. Most of the waste generated in the laboratory is from the mobile phases used in the equipments which may contain a mixture of Heptane (HP), Acetonitrile (ACN), Isopropyl Alcohol (IPA), Methanol (MeOH) and water (D001, F003) spent solvents.

At the Room 2032, there were four (4) SAAs observed: SAA-01, SAA-02, SAA-3, and SAA-4. The content of these SAAs was generated nearby the Point of Generation (POG) and under control of the operator by security access to the areas.

SAA-01

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Pictures 3** and **4**):

- Two (2) 5-gallon white container with "Organic Wastes" clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids & Toxic."

In this area, I observed that the mobile phase line that connects to both SAA containers was leaking throughout an oxidized metal valve. It was also observed that the base of the cabinet was containing the spill inside the metal tray. It was noted that the spill was leaking slowly such as drop-to-drop releases meaning that it has been occurring for a long period of time. It was also noted that the spill may probably be seating there for some time due to the visible stains on the metal tray. Ms. Martinez explained this incident has never happened at the laboratory, since it is the first time a connected valve has been rusted allowing its contents to be released. However, she reacted by calling and activating the emergency team of the Facility who immediately responded to attend the spill incident according to the Contingency Procedures and Business Continuity Plan (Safety S7) protocols.

I explained to Ms. Martinez that pursuant to 40 CFR § 262.17(a)(1)(ii), if a container holding hazardous waste is not in good condition (including peripherals and valves), or if it begins to leak, the large quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of a RCRA Permit. Additionally, I told Ms. Martinez that pursuant to 40 CFR § 262.17(a)(6) referring to 40 CFR § 262.251 that a large quantity generator must maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

I strongly recommended that pursuant to 40 CFR § 262.17(a)(1)(v), a large quantity generator must inspect central accumulation areas at least weekly. Although, under RCRA regulation it does not include satellite accumulation areas, it was deemed advised to include them as part of weekly inspections as a Good Laboratory Practice. During weekly inspection, the Facility must look for leaking containers and for deterioration of containers caused by corrosion or other factors and undertake remedial action if deterioration or leaks are detected.

SAA-02

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 5**):

- One (1) 5-gallon black container with “HPLC/GC Vials,” clearly labeled with the words, “Hazardous Waste,” and identified with its hazard communication pictogram as, “Flammable Liquids & Toxic.”

SAA-03

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 6**):

- One (1) 5-gallon white container with “Organic Solvent Mixture” clearly labeled with the words, “Hazardous Waste,” and identified with its hazard communication pictogram as, “Flammable Liquids & Toxic.”

SAA-04

Inside a spill contained and secured white-bone metal cabinet, I observed the following:

- One (1) 5-gallon white container with “Organic Wastes” clearly labeled with the words, “Hazardous Waste,” and identified with its hazard communication pictogram as, “Flammable Liquids & Toxic.”

I strongly recommended that each laboratory container should also be labeled with its individual RCRA hazard code as an additional hazard communication and compatibility characteristics of the content as reported in the Biennial Report.

3.3 ROOM 2026-WET CHEMISTRY AREA

I proceeded to inspect Room 2026-Wet Chemistry Laboratory Area. As explained by Ms. Martinez, most of the quality assurance and quality control analytical tests are performed in this area on samples received from pharmaceutical, medical device and biopharmaceutical industries. Wet chemical analysis includes a multitude of analytical techniques, including titration, distillation, spectrophotometry (UV/Vis/IR), nitrogen determinations, colorimetry, filtration, conductivity, turbidity, drying, weighing, pH tests, direct read with electrodes, among other analytical procedures.

At the Room 2026, there were four (4) SAAs observed: SAA-01, SAA-02, SAA-03 and SAA-04. The content of these SAAs was generated nearby the Point of Generation (POG) and under control of the operator by security access to the areas.

SAA-01

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Pictures 7** and **8**):

- One (1) 2.5-gallon red container with "Organic Wastes," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids & Solids;" and,
- One (1) 2.5-gallon white container with "Organic Solvent Mixtures," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids & Solids."

SAA-02

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Pictures 9** and **10**):

- One (1) 5-gallon white container with "Phosphoric Acid," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;"
- One (1) 5-gallon white container with "Formic Acid/Acetic Acid," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;" and,
- One (1) 5-gallon white container with "HCl, HNO_3, H_2SO_3," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic."

SAA-03

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Pictures 11** and **12**):

- One (1) 5-gallon white container with "Opadry/Opacode Ink," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;"
- One (1) 5-gallon white container with "Inorganic Waste/Raw Materials Waste Stream," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;" and,
- One (1) 5-gallon white container with "Diluted NaOH/Waste Nitrogen Equipment," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic."

SAA-04

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 13**):

- One (1) 5-gallon white container with "NaOH/Ammonium Hydroxide," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic."

I strongly recommended that each laboratory container should also be labeled with its individual RCRA hazard code as an additional hazard communication and compatibility characteristics of the content as reported in the Biennial Report.

3.4 ROOM 2029-METALS AREA

I proceeded to inspect Room 2029-Metals Laboratory Area. In this area metal analysis is performed including lead analysis, nickel absorption, mercury analyzer tests, atomic absorption spectroscopy (AA), and X-ray are a few common qualitative and quantitative methods of determining material composition of metals.

At the Room 2026, there were two (2) SAAs observed: SAA-01, and SAA-04. The content of these SAAs was generated nearby the Point of Generation (POG) and under control of the operator by security access to the areas.

SAA-01

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 14**):

- One (1) 5-gallon white container with "HCl, HNO_3, H_3PO_4," waste from atomic absorption test clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;" and,
- One (1) 5-gallon white container with "HCl, HNO_3, H_3PO_4," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic."

SAA-02

Inside a spill contained and secured white-bone metal cabinet, I observed the following (see **Picture 15**):

- One (1) 5-gallon white container with "Mercury Waste/HCl 3% in Water/Stannous Chloride STD Mercury," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic."

I strongly recommended that each laboratory container should also be labeled with its individual RCRA hazard code as an additional hazard communication and compatibility characteristics of the content as reported in the Biennial Report.

3.5 ROOM 2011 90-DAY HAZARDOUS WASTE ACCUMULATION AREA (HWAA)

I proceeded to inspect Room 2011 the 90-Day Hazardous Waste Accumulation Area (HWAA) located in Building No. 2 - Chemistry of Facility. All hazardous wastes, biohazard wastes, used oils, and universal wastes collected from all analytical testing and manufacturing processes and satellite accumulation areas (SSAs) are transferred and stored at this area. Also, all hazardous waste generated from quality assurance/quality control tests, as well as laboratory packs are transferred to this area before final disposition with Clean Harbors Caribe Inc. The area is an enclosed warehouse with reinforced concrete floor. It has an estimated storage capacity over twenty (20) 55-gallon drums. As observed, the base floor was free of cracks or gaps, and it was designed to contain leaks and spills in a collection sump. The room is well vented and provided with ambient controlled temperature in the area.

At the Room 2011 was segregated into six (6) waste characteristic areas and each area physically separated by a 6-feet tall concrete wall. Each area was identified as follows: Hazardous Waste Organic Waste, Hazardous Waste Raw Material Waste Stream, Corrosive Waste, Non-Hazardous Waste, Universal Waste, and Hazardous Waste Solids.

<u>Hazardous Waste Organic Waste Area</u>

In this area I observed the following:

- One (1) 55-gallon black drum containing "Organic Solvent Mixture in Aqueous Media-Inhibited BNA," clearly labeled with the words, "Hazardous Waste," and dated with its accumulation start date on December 17, 2023 (see **Picture 16**). The drum was clearly labeled, and identified with its hazard communication pictograms as, "Flammable Liquids," and "Toxic."
- One (1) 30-gallon blue drum containing "HPLC/GC Vial," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictograms as, "Flammable Liquids," and "Toxic." As observed by the Inspector, the drum was not dated with its accumulation start date since it was "Empty" at the time of the Inspection on December 21, 2023, (see **Picture 17**).

<u>Hazardous Waste Raw Material Waste Stream Area</u>

In this area I observed the following:

- One (1) 55-gallon white drum containing "Raw Material Waste Stream," clearly labeled with the words, "Hazardous Waste," and dated with its accumulation start date on November 27, 2023 (see **Picture 18**). The drum was clearly labeled, and identified with its hazard communication pictograms as, "Corrosive Liquids," and "Toxic."

Corrosive Waste Area

At the time of the Inspection this area was empty. Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

Non-Hazardous Waste Area

In this area I observed the following:

- Six (6) 55-gallon blue drums containing "IV Fluids/Saline Solution with Bags," and "Broken Glass," clearly labeled with the words, "Non-Hazardous Waste," (see **Picture 19**).

Universal Waste Area

In this area I observed the following:

- One (1) 5-gallon black container with "UV Lamps," clearly labeled with the words, "Universal Wastes;" and dated with its accumulation start date on September 12, 2023 (see **Picture 20**);
- One (1) 5-gallon black container with "Alkaline Batteries," clearly labeled with the words, "Universal Waste," and dated with its accumulation start date on September 11, 2023 (see **Picture 21**);
- One green/white cardboard box (1' x 1' x 2' sq ft) with "Lithium Batteries," clearly labeled with the words, "Universal Waste," and dated with its accumulation start date on April 6, 2023 (see **Picture 22**);
- One brown cylindrical cardboard box (1½ Dia, 4' height) with "Spent Fluorescent Lamp Bulbs (4-feet)," clearly labeled with the words, "Universal Waste," and dated with its accumulation start date on May 10, 2023(see **Picture 23**); and,
- One (1) 5-gallon blue drum with "Discarded Equipment," clearly labeled with the words, "E-Wastes."

Hazardous Waste Solids Area

At the time of the Inspection this area was empty. Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

As observed by the Inspector, all the drums, and containers were clearly labeled with the words, "Hazardous Waste," dated with its accumulation start dates from the date of generation and identified with its hazard communication pictograms as required by RCRA requirements. Additionally, all the

drums, containers and bottles holding hazardous waste were closed and in good conditions. No leaks were observed on the floor.

The hazardous wastes containers storage area at PACE Analytical was equipped with fire extinguishers, fire alarms, emergency system and security system.

According to Mr. Martinez, the spent fluorescent lamp bulbs are also collected and disposed of as "Universal Wastes" (D009) with Clean Harbors Caribe Inc.

3.6 ROOM 1009-RECEIVING AREA

I proceeded to inspect Room 1009 – Receiving Area. This area is in Building No.1 – Microbiology of the Facility. All sample material to be analyzed from the pharmaceutical, medical device and biopharmaceutical industries are received in this area. Some other discarded samples from compatibility testing, and validation are also managed in this area.

At the Room 1009, there was one (1) SAA observed in this room. The content of the SAA was generated nearby the Point of Generation (POG) and under control of the operator by security access to the room area.

SAA-01

Inside this room area, I observed the following (see **Pictures 24,** and **25)**:

- One (1) 5-gallon black container with "Electrodes Wastes," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Toxic Solids;" and,
- One (1) 5-gallon black container with "Dräger Waste," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Corrosive Liquids & Toxic;" and,
- One (1) 55-gallon blue drum containing "Opadry/Raw Material Solid Samples Wastes," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Solids."

I strongly recommended that each laboratory container should also be labeled with its individual RCRA hazard code as an additional hazard communication and compatibility characteristics of the content as reported in the Biennial Report.

3.7 ROOM 1031-MICROBIOLOGY AREA

I proceeded to inspect Room 1031 – Microbiology Area. This room area is used to prepare the media that will be used as part of the microbiology laboratory testing of samples.

At the Room 1031, there was one (1) SAA observed in this room. The content of the SAA was generated nearby the Point of Generation (POG) and under control of the operator by security access to the room area.

SAA-01

Inside this room area, I observed the following (see **Picture 26)**:

- One (1) 5-gallon white container with "Grain Stain Wastes," clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids and Toxic."

3.8 ROOM 2021-SOVENT STORAGE AREA

I proceeded to inspect Room 2021 – Solvent Storage Area. This area is used to store chemical reagents by characteristic compatibility and safety protocols. All raw materials, solvents, and analytical equipment devices are received and organized in cabinet shelves. It was observed that they maintain a strict inventory program in place that goes along with the analytical testing planning. Active ingredients and equipment devices are inspected and accounted for chemistry and microbiology testing services.

Observations at this area rendered no concerns regarding the generation or management of hazardous wastes.

3.9 ROOM 2033-HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) AREA

I proceeded to revisit Room 2033-High Performance Liquid Chromatography (HPLC) Laboratory Area. It was informed by Ms. Martinez that a remedial action was undertaken by the emergency team to address the leaking line of "Organic Liquid Waste." I was also informed that all lines and containers connection were replaced by new lines and valves, and the hazardous waste spill was cleaned-up with absorbent pads, and packed in hazardous waste containers for final disposition.

At the Room 2032 - SAA-01 inside a spill contained and secured white-bone metal cabinet, I observed again the following (see **Pictures 27** and **28**):

- Two (2) 5-gallon white container with "Organic Wastes" clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids & Toxic," and,
- Two (2) 5-gallon black container with "Absorbent Pads with Organic Wastes" clearly labeled with the words, "Hazardous Waste," and identified with its hazard communication pictogram as, "Flammable Liquids & Toxic."

All containers were clearly labeled as, "Hazardous Wastes," coded with its hazard, and identified with its hazard communication pictograms.

4 DOCUMENTS REVIEW

The following documents were reviewed as required by the RCRA Program after the walkthrough inspection and on a follow-up conference call on December 21. 2023:

4.1 CONTINGENCY PROCEDURES AND BUSINESS CONTINUITY PLAN (SAFETY S7)

There was a "Contingency Procedures and Business Continuity Plan (Safety S7)," dated December 15, 2023, which plan describes the types of emergencies identified by the senior leadership of the Facility that may impact the operation and what needs to be in place to prevent an interruption of the services provided by PACE Analytical, Inc. It also outlines the procedures and activities required for the prevention of, and response to, hazardous waste releases at the Facility located in San German. In general, the plan provided procedures to control of toxic and hazardous substances which may pose an unreasonable risk to health and the environment. In this respect, RCRA requires a plan to be developed by industrial facilities to minimize the risk of unplanned releases and/or spill of oil, toxic and/or hazardous substances. As reviewed the Contingency Plan was ready accessible, and so the plan was also posted and accessible to all employees and provided to emergency agencies. (i.e., Fire Department, Hospitals, Police Department, and Civil Defense). Additionally, the Facility was equipped with alarm systems, sprinkler systems, telephones, certified extinguishers nearby areas where hazardous wastes were stored at the Facility. A "RCRA Contingency Plan Quick Reference Guide RCRA" was also provided for review. All appeared to be properly maintained and in compliance.

4.2 AIR EMISSIONS STANDARD RECORDS

Pursuant to 40 CFR § 262.17(a)(1)(i) referring to 40 CFR Part § 265, all Facility record related to the RCRA air emission requirements were requested. According to Ms. Martinez, PACE Analytical, Inc. does not have to comply with Subparts AA, BB & CC of RCRA requirements except for DOT approved containers and management practices of volatile hazardous wastes. She specified that containers holding volatile organic wastes were provided with a cover and manufactured tested seal in accordance with the Department of Transportation (DOT) (49 CFR 178 - Specifications for Packagings) requirements, and the United Nations (UN) Performance Oriented Packaging Standards. She also presented the "Containers Assembly Instructions," which describes each drum received comes with the assembly instructions, and packaging group type. As per the case of PACE Analytical, Inc., they use Packaging Group II Standard "Y" Moderate Waste and DOT container type which is provided in Clean Harbor's Waste Profiles Section G – DOT Transportation of Dangerous Goods (TDG) information. According to the information provided all containers drums comply with the 40 CFR § 265.1087 for air emissions control. Therefore, all information regarding RCRA Subpart CC Air Emissions Standard controls air emissions for certain containers was reviewed and found to comply.

4.3 BIENNIAL REPORT

The Hazardous Waste Report for 2021 was submitted electronically on February 24, 2022, in RCRA Info Site. The Biennial Report described all the waste streams generated and managed by

the Facility including hazardous wastes, laboratory packs compatible for incineration, raw material waste steams (Hazardous Waste Codes: D001, D002, D003, D004, D005, D006, D007, D008, D009, D010, D011, D018, D019, D022, D028, D035, D038, F002, F003, F005, P012, P030, P098, U002, U003, U019, U031, U044, U056, U134, U135, U144, U169, U211, U213, U218, U239, U353). It appeared to be properly documented and in compliance.

4.4 MANIFEST RECORDS AND LAND DISPOSAL RESTRICTION FORMS (LDR)

Manifests and associated Land Disposal Restriction (LDRs) for all incoming and outgoing shipments for the last three years (2023, 2022, and 2021) were reviewed in hard copies and in an electronic format (i.e., Manifest Tracking Report). Most of the hazardous wastes and biohazard regulated medical waste are sent by Clean Harbors Caribe Inc. to El Dorado Arkansas, or Bartow, FL, USA. One of the most recent shipments manifested the disposal of over 1,070 kg on September 13, 2023. All appeared to be properly maintained and in compliance.

4.5 PERSONNEL TRAINING RECORDS

The Facility provided a Record of Training for the personnel associated with the management of hazardous waste. The electronic "Record of Trainings" printed on September 18, 2023, detailed the kind of training, date, and completion status taken by personnel thru computer programs or outside contractor during 2023. It appeared to be properly maintained and in compliance.

4.6 WASTE MINIMIZATION (WASTE HANDLING – SAFETY S11)

The Facility provided for review, "Waste Handling – Safety S11" as a Waste Minimization Program, dated December 15, 2023. The basic objective of the Waste Handling Plan is to operate the Facility in an effective-environmentally-sound manner by minimizing and preventing hazardous waste pollution. The Waste Handling environmental goals provide data with which PACE Analytical can operate more efficient analytical procedures, decreasing material usage and environmental impacts, and increasing quality data assurance. It is Pace Analytical policy to minimize the amount of hazardous waste it produces and to reduce the hazardous properties of those wastes whenever practical within regulatory compliance. This can be achieved by periodic auditing of all processes producing hazardous waste; reduction of sample volume delivered by the client; return of excess sample material to clients whenever practical and economical; investigation of new technologies that might require smaller volumes of sample or produce fewer or less hazardous by-products implementation at the laboratories; cleaning procedures that reduce the volume of cleaning residue; recycling of hazardous materials; and investigation of new treatment technologies that are comprehensively destructive or are effective in reducing the volume or hazardous qualities of the wastes produced. It appeared to be properly developed, executed, documented and in compliance.

4.7 WASTE ANALYSIS

A Full RCRA analysis was provided on each Profile Detail Report prepared by Clean Harbors Caribe Inc. all Toxic Characteristic Leaching Procedure (Test Method SW 1311) tests, and other analytical

methods or knowledge of the waste and quantity generated monthly. All wastestreams generated by the Facility were identified, tested, codified, and disposed of as required by the land disposal restrictions (LDRs). The Waste Analysis Plan appeared to comply.

4.8 WEEKLY LOG RECORDS

All weekly logs records for weekly inspection at the 90-Day Hazardous Waste Accumulation Area were reviewed and found to comply.

5 CLOSING MEETING

After completion of the walkthrough and document review, I met with Ms. Nilsa Martínez, Senior Director, Ms. Rosamarie Valle, Scientific 1, from PACE Analytical, Inc. to conduct a closing meeting. I indicated that the purpose of the closing meeting is to inform the Facility's representatives about the RCRA observations. I indicated to Ms. Martínez that I wanted to discuss some EPA's observations before I can reach a full compliance determination of the RCRA program as follows:

EPA's Observation No. 1: Explain the rationale for the spill incident observed at the time of the inspection in which a mobile phase line that connects to both SAA containers was leaking throughout an oxidized metal valve. It was also observed that the base of the cabinet was containing the spill inside the metal tray. It was noted that the spill was leaking slowly such as drop-to-drop releases meaning that it has been occurring for a long period of time. It was also noted that the spill may probably be seating there for some time due to the visible stains on the metal tray. the "Production Wastes" current process of hazardous waste storage and Satellite Accumulation Areas (SAAs) in the manufacturing lines.

I explained to Ms. Martinez that pursuant to 40 CFR § 262.17(a)(1)(ii), if a container holding hazardous waste is not in good condition (including peripherals and valves), or if it begins to leak, the large quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of a RCRA Permit. Additionally, I told Ms. Martinez that pursuant to 40 CFR § 262.17(a)(6) referring to 40 CFR § 262.251 that a large quantity generator must maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

I strongly recommended that pursuant to 40 CFR § 262.17(a)(1)(v), a large quantity generator must inspect central accumulation areas at least weekly. Although, under RCRA regulation it does not include satellite accumulation areas, it was deemed advised to include them as part of weekly inspections as a Good Laboratory Practice. During weekly inspection, the Facility must look for leaking containers and for deterioration of containers caused by corrosion or other factors and undertake remedial action if deterioration or leaks are detected.

6 COMPLIANCE ASSISTANCE

The EPA inspector discussed with PACE Analytical Inc.'s representatives the specific RCRA program regulations that apply to the Facility, and how to stay in compliance in case they decide to minimize or recover waste streams and implement waste minimization/pollution prevention procedures as required by RCRA.

7 CONCLUSION & FOLLOW-UP ACTIONS

As a result of the abovementioned concern, I provided the Facility a 2-day period to submit undertake corrective measures to resolve the spill incident observed at the time of the inspection in which a mobile phase line that connects to both SAA containers was liking throughout an oxidized metal valve. At the end of the Inspection, I was informed by Ms. Martínez that a remedial action was undertaken by the emergency team to address the leaking line of "Organic Liquid Waste." I was also informed that all lines and containers connection were replaced by new lines and valves, and the hazardous waste spill was cleaned-up with absorbent pads and packed in hazardous waste containers for final disposition. On January 3, 2024, PACE Analytical, Inc. provided additional information requested to complete the compliance evaluation at the Facility.

After responding to EPA's observations, inspection of regulated areas and completion of a document session, EPA determined that the hazardous waste management program at PACE Analytical, Inc. was not satisfactory since they could have prevented that spill incident if proper Good Laboratory Practice are implemented to maintain and operate its Facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

8 ATTACHMENTS

I. Figure 1- Facility Location Map and Figure -2 Aerial Photograph
II. Photolog and Camera Roll (include all pictures taken during the inspection)