

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:	Pfizer Pharmaceuticals LLC		
EPA ID Number:	PRD0911144709		
Date of Inspection:	July 05, 2023		
Generator Status in Record:	Large Quantity Generator (LQG)		
Generator Status at the time of inspection:	LQG		
RCRA Permitted:	No		
Basis for Inspection:	Core Program		
Corrective Action:	No		
Project ID	CEPD-RCRA-18-0405		
Facility Physical Location: (Municipality, PR, zip code)	689 State Road Km. 1.9 Carmelita Ward Vega Baja, Puerto Rico, 00694		
Geographical Coordinates:	18.4488625, -66.3716582		
Facility Owner:	Pfizer Pharmaceuticals LLC	787-858-2323	
	Jose Campos Figueroa	President	
	Mailing address: 689 State Road Km. 1.9 Carmelita Ward Vega Baja, Puerto Rico, 00694-4119		
Facility Operator:	Pfizer Pharmaceuticals LLC		
	Mailing address: Same as owner		
NAICS:	325412		
SIC:	N/A		
Area:	{ft2, acres}		
Number Employees:			
Personnel participating in inspection:			
Khrystian M. Vazquez	EPA Region 2-CEPD	Enforcement Officer	vazquez.khrystian@epa.gov
Jose Aleman	Pfizer	Environmental Health & Safety Manager	jose.alemanfigueroa@viatris.com
Alexandra Perez	Pfizer	Environmental Health & Safety Specialist	alexandra.perezbeltran@viatris.com
Status:	FINAL		
Record Schedule:	1044(c)		
Multi-media Checklist: ATTACHMENT #		Referral: NONE	

EPA Lead Inspector Signature/Date	X Khrystian Vazquez Environmental Scientist
Supervisor Signature/Date	X David N. Cuevas Miranda, Ph.D.

1 INTRODUCTION

On July 5, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection was conducted at Pfizer Pharmaceuticals LLC (the facility), pursuant to Section 3007 of RCRA. 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 applicable.

The Facility is located at 689 State Road Km. 1.9 Carmelita Ward Vega Baja, Puerto Rico, 00694. Refer to **APPENDIX I**, *Figure 1* for the aerial photograph and to *Figure 2* for layout of the facility.

According to EPA records, the Facility has been inspected several times between 1985 and 2016. Two EPA inspections are registered in RCRA Info 2002 & 2018. Most of the inspections registered in the system have been performed by the State and shows no violations found.

2 OPENING MEETING

I arrived at the facility around 0950 hours and met with Mr. Jose Aleman for the opening meeting. I identified myself as EPA RCRA enforcement officer and told him that the purpose of my visit was to conduct a CEI at the facility to evaluate its hazardous waste management practices and compliance. Mr. Aleman identified himself as the Environmental Health & Safety (EHS) Manager for the facility. He has been assigned in this position for the last seven years but, has been working with the facility for more than twenty-five years. Along with him, he also introduced me to Ms. Alexandra Perez. Ms. Perez is the EHS Specialist for the facility and has been assigned to this position for more than thirteen years.

I explained the facility representatives that the inspection would consist of the opening meeting, a walkthrough through the facility where hazardous waste is generated and stored, and to review the regulated documents according to their waste generation.

2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION

Following the opening meeting, I started to gather more information regarding the facility physical description and operation. Mr. Aleman stated that the facility has approximately one thousand (1,000) employees and that hours of operations are five days a week from 0800 hours to 1630 hours. The facility has been operating in Vega Baja since 1978, former Warner Lambert and then Pfizer since 2001. The facility operation consists of the manufacturing of consumer goods such as: Zithromax, Lipitor, Dilantin, Neurontin, Atorvastatin etc. in tablets and/or capsules, and final packaging of Celebrex. Product distribution goes around one-hundred forty (140) countries. They provided me with a list of all the manufacturing products generated at the facility. Ms. Aleman as well as Ms. Perez also informed that on 16, November 2020 the facility announced the creation of VIATRIS, the new name of the company. The change of name does not constitute a change of the corporate entity nor corporate control. VIATRIS legal entity name was in effect on 16, June 2023 by the Department of State.

(See **APPENDIX II** for the facility manufacturing products list)

(See **APPENDIX VIII** for documentation provided of legal transaction)

2.2 SOLID AND HAZARDOUS WASTE GENERATION

According to the facility representatives as part of their manufacturing operation they generate hazardous waste as a Large Quantity Generator (LQG) and consist mainly of solvents, lab-packs, and rags containing solvents. Also, they manage universal waste such as fluorescent lamps, used oil, scrap metals, and electronic waste.

The hazardous generated waste from their manufacturing operations comes from chemical laboratories (Lab) (Raw material, Packaging, and Finished Products), the 90-Storage Area, Manufacturing Satellite Accumulation Areas (SAA) and the lab of the Waste Water Treatment Plant (WWTP)

At this time, I asked Mr. Aleman for a facility layout to better understand where the hazardous waste areas are located and coordinate the walkthrough around the facility. The layout was provided, and the facility representatives showed me where exactly are the RCRA related areas and coordinated the walkthrough.

(See **APPENDIX I-** for Facility Layout)

3 FACILITY WALKTHROUGH

Mr. Aleman and Ms. Perez accompanied me during the facility walkthrough. During the walkthrough the following areas were inspected:

- Scrap Metal Container
- Quality Control (QC) Lab and Finished Product
- Finished Product Lab
- 90-days Storage Area
- Packaging
- Waste Water Treatment Plant (WWTP) Lab
- Manufacturing Satellite Accumulation Areas (SAA)

Refer to **APPENDIX XII** for pictures taken during the inspection.

*SAA locations descriptions were provided by the facility representatives. (See **APPENDIX II**)

3.1 SCRAP METAL CONTAINER

Walking towards the WWTP there's a designated area with cubic yard container for Scrap Metal. The opened area has a metal roof and is identified as "Solo Metales" (Metals Only). I observed the cubic yard container with different scrap metal items inside. Next to the container there's also a designated area for metal mechanics devices to dispose. Those items were store with a secondary container to catch any residues that may leak from them. The facility representative told me that they managed their Scrap Metal with "Reciclaje del Norte" company.

No concerns observed

(See **APPENDIX XII-Pictures 01-03**)

3.2 WWTP LABORATORY

The WWTP laboratory (lab) has two identified Satellite Accumulation Areas (SAA). At the time of the CEI, Mr. Jorge Pagan was the operator in charge of the lab. The observation of the two satellites areas is as follow:

- SAA1 (L047)- One (5-gallon) container identified as hazardous waste and labeled with corrosive pictogram containing metal residues containing nitrate, phosphate, ammonium, pH sampling to confirm H2O state. Waste codes are D006 and D035. Sampling is performed daily.
- SAA2 (VBL-020)- One (5-gallon) bucket identified hazardous waste and labeled with corrosive pictogram containing used COD lab-pack vials with corrosive and toxic waste codes D002/D007/D009/D011

(See APPENDIX XII-Pictures 04-11-)

No concerns observed

3.3 90-DAYS HAZARDOUS WASTE STORAGE AREA (HWSA)

The person in charge of the HWSA is Mr. Ortiz which at the time of the CEI was on vacation. During his absence, Mr. Boria was assisting the area. The HWSA consist of an independent storage building with two subdivisions. Hazardous waste is stored on the right side of the building, and non-hazardous waste is placed on the left side. The building is all constructed of concrete walls, floor, and roof. Outside the HWSA is identified as “DANGER” Hazardous Waste Storage Facility and emergency contact information including a phone system and a fire extinguisher. Inside, the building has an emergency water sprinkler system, a vapor/gas extraction system, and a dike area that could retain up to four-(4) inches thick in a spill event.

Inside, on the right side of HWSA are subdivisions for storing, Flammable, Corrosive, Other HW and Consolidation transfer area. I observed the following waste:

- First identified pallet was the **Universal Waste** storing area and it has:
 - One (15-gallon) white plastic container with used oil from the WWTP (about 1/8 full) labeled as Non-Hazardous Waste
 - One (55-gallon) blue plastic container labeled as Non-hazardous waste impregnated rags with used oil from the WWTP.

(See APPENDIX XII-Pictures 12-19)

- Second identified pallet contained **Flammable Waste**. All waste containers were properly labeled and marked as hazardous waste including their respective pictogram characteristics. Observation of the area goes as followed:
 - Four (55-gallon) plastic container with lab mixed solution, flammable liquids/dated: 06-28-23/06-30-23/06-22-23/ 06-23-23 respectively.

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- One(5-gallon) of HPLC vials finished product (dated: 06-13-23)
 - One(15-gallon) Lab packs pads with methanol and Isopropyl finished product (dated: 06-12-23)
 - One (55-gallon) Mixed solvent lab finished product (dated: 06-20-23)
 - One(55-gallon) mixed solvent lab/finished product dated: (06-13-23)
 - One(55-gallon) mixed solvent lab/finished product dated: (06-16-23)

(See APPENDIX XII-Pictures 20-30)

- Four pallet contained **Other Hazardous Waste**. All waste containers were properly marked as Hazardous waste including accumulation start date and corrosive pictograms attached. Observation of the area goes as followed:
 - One (5-gallon) white plastic container with aqueous consolidation with metals raw material (dated: 06-30-23)
 - One (55-gallon) blue plastic container pads with mixed solvents (dated: 06-21-23)

(See APPENDIX XII-Pictures 31-33)

- Fifth pallet is identified as **Consolidation and Transfer Area for Hazardous Waste**
 - One (55-gallon) white plastic container with mixed solution lab ethanol/isopropyl (dated: 07-05-23). The container was properly labeled as hazardous waste and had attached the flammable pictogram.

I also observed an area where the empty containers for flammable waste are stored. At the time of the CEI all containers were empty.

(See APPENDIX XII-Pictures 34-38)

No concerns observed

On the left side of the building structure, I observed the following Non-Hazardous Waste areas:

- Waste Consolidation Area for Universal Waste in process. All containers had universal waste label and dated accordingly. Observations described as followed:
 - One (30-gallon) blue container with lead acid batteries (dated: 06-20-23)
 - One (55-gallon) blue container with electronic batteries devices/Lithium Metals (dated: 06-15-23)
 - One (55-gallon) blue container with electronic batteries devices/Pb Special order (dated: 06-15-23)

(See APPENDIX XII-Pictures 41-45)

No concerns observed

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- Waste Consolidation Area for Non-Hazardous waste. All containers had the Non-Hazardous Waste label and dated accordingly. Observations described as followed:

- One (55-gallon) white plastic container with cooking oil (dated; 06-22-23)
- One (5-gallon) white plastic container with pads with cooking oil (dated 06-22-23)
- One (30 gallon) green container with metal empty containers of Kolliphor¹
- One (30 gallon) blue plastic container with poly/ sulfuric acids empty containers from the WWTP (dated: 06-13-23)

(See APPENDIX XII-Picture 46-52)

No concerns observed

- **Non-Hazardous waste area.** All containers had the Non-Hazardous Waste label and dated accordingly.

- One (55-gallon) blue steel container with metal empty containers of ethanol and methanol (dated: 06-23-23)
- One (30-gallon) blue plastic container with toner (dated: 06-20-23)
- **One (15-gallon) blue plastic container with pads with alcohol, ink, and grease (dated: 06-23-23)**

My observation/concern in this area was how the One (15-gallon) blue plastic container with pads containing alcohol, ink and grease was determined as Non-Hazardous. (Pic. 56)

(See APPENDIX XII-Pictures 53-56)

- SAA-VB-S-015 for aerosol destruction
- One (3-gallon) white plastic container with aerosol can collector flammable liquids (dated: 02-07-23) This container complied with the hazardous waste label and flammable pictogram.

(See APPENDIX XII-Pictures 58-61)

No concerns observed

After the observation of the 90-days storage area inventory I proceeded to test the Emergency Phone line. The sign with the emergency information read to dial Ext. 2000, I proceed to dial the mentioned number and Ms. Keila Lopez, the facility nurse, answered the call. I identified myself as an EPA enforcement officer doing a test call. I asked Ms. Lopez what is needed to be done if an emergency happens at the 90-days HW Storage Area and she proceeded to indicate step by step the facility protocol to activate the emergency personnel and identities.

¹ Kolliphor EL is a non-ionic solubilizer made by reacting castor oil with ethylene oxide in a molar ration of 1:35 used to stabile emulsions of non-polar materials in water. (source: <https://pharma.basf.com/product-families/kolliphor>)

Before leaving the area, I also proceeded to review the 90-Storage Area weekly inspection log and the hazardous waste register log. Log were updated with the last week inspection and documented on maintenance follow up.

(See APPENDIX XII-Pictures 39-40)

No concerns observed

3.4 QUALITY CONTROL (QC) LAB AND FINISHED PRODUCT

Ms. Perez introduced me to Ms. Marangely Gerena Soto, the Lab Analyst, and Mr. Wigberto Gonzalez, the Lab Manager. I visited four QC SAA: each section has a high-performance liquid chromatography (HPLC). They also use Gas Chromatography Absorption (GCA) machine to test for metals, mercury, lead, cadmium, and dissolved acids. At this area I observed the following SAA's:

- SAA 1 (VB-L013)-The HPLC generates organic aqueous non chlorinated flammable waste that is stored in a five-gallon metal container with secondary container. The area was properly identified, and container had hazardous waste label with description of waste and flammable pictogram.

(See APPENDIX XII-Pictures 62-63)

No concerns observed

- SAA 2 (VB-L038 A, B, C) These three SAAs generates the following waste:
 - A- Flammable compartment has one gallon glass bottle of toluene waste. **(Pic's 78-79)**
 - B- Corrosive waste- a two compartment door holding separately **basic waste** from **acid waste**. **The basic waste** compartment had one (1-gallon) glass container with ammonia hydroxide, one (1-gallon) glass container with nitric acid waste, one (1-gallon) glass container with hydroxide acetonitrile and two (1-pint) bottles of sodium hydroxide. **The acid waste** compartment has two (1-gallon) glass container with ethyl acetate/acetic acid and one (1-gallon) of isobutyl ketone, acetic acid, and water and one (1-gallon) of sulfuric acid solution. **(Pic's 68-77)**
 - C- Chemical Lab Packs was empty. **(Pic. 66)**

(See APPENDIX XII-Pictures 64-79)

No concerns observed

- **SAA 3 (VB- L039 A & VB- L039 B)-** This SAA is a yellow cabinet, which contained a secondary container. The waste store in here is generated from the laboratory finished products. I observed: two (15-gallon) plastic container with mixed solvents (methanol, ethanol). One was empty and the other was 1/16 full; Four (1 quart) containers of HPLC/GCA vials. **The two (15-gallon) containers had two different dates. It is labeled as effective date 31-Mar-2021 and**

Performed by/date: 08/23/22. Three of the four (1-quart) container had a Performed by/date 07/28/21.

(See APPENDIX XII-Pictures 80-88)

- SAA 4 (VB-L010)- In this SAA the waste generated comes from the finished products of Celebrex, Dilantin, Norvasc and Statin drugs. At the time of the CEI I observed the following waste:
 - One (5- gallon) steel container of flammable waste of mixed solvent from HPLC. The container was ground and labeled as hazardous waste with pictogram included.

(See APPENDIX XII-Pictures 89-91)

- SAA 5 (VB-L045)- This satellite area generates flammable waste from the ultra-performance liquid chromatography (UPLC) generated at the packing material. In this area I observed the following:
 - **One- (2-gallons) white chromatography container in a secondary container and labeled as hazardous flammable waste. On the description it also reads Performed by/date 07/28/21. The yellow hazardous waste label had also the description of the waste but, no accumulation date written.**

(See APPENDIX XII-Pictures 92-96)

- SAA 6 (VB-L008)- This laboratory refrigerator is where the hazardous waste lab packs are stored. The refrigerator is complete identified with signs of hazardous waste and compatibility storing labels. The refrigerator is designed with five shelves and six other shelves at the door. The waste stored here is only at the bottom shelf. The bottom shelf had ether waste, and acetaldehyde. **The acetaldehyde bottle has a white label indicating two dates: effective date: 31-Mar-2021 and Performed by/date: 06-16-23.**

(See APPENDIX XII-Pictures 97-101)

- SAA 7 (VB-009)- This SAA is also for raw material lab packs. Inside the laboratory cabinet there's a tray with a variety of glass bottles. Inventory of bottles was provided. **I also notice that each labeled waste has a Performed by/date.**

(See APPENDIX XII-Pictures 102-105)

- SAA 8 (VB-L040)- This SAA is for storing corrosive waste. The laboratory cabinet had four white plastic chromatography containers. One was labeled nitric acid waste, the second with sulfuric acid waste and the other two were empty. All containers were inside a secondary container and grounded.

(See APPENDIX XII-Pictures 106-107)

- SAA 9 (VB-L016)- At this satellite area I observed one white plastic container for storing aqueous waste such as chlorinated material, corrosive material, and mercury. The container was also contained in a tray and identified with hazardous waste yellow label. **This tray has a waste description in a printed paper with Effective date: 31-Mar-2021.**

(See APPENDIX XII-Pictures 108-111)

- SAA 10 (VB-L044)- This is atomic absorption unit SAA. In this area I observed a two-gallon container, half full with a printed description of acetic acid. **This printed waste description also included the Effective date: 31- Mar-2021 and Performed by/date: 02-05-22. The yellow hazardous waste label read hazardous corrosive waste.**

(See APPENDIX XII-Pictures 112-114)

Throughout the SAA's I observed the practice of some containers having two different dates (effective date and performed by/date) this practice leads to confusion on when exactly the accumulation day started.

3.5 MANUFACTURING

The manufacturing area is a big plant with subdivision that are specific to the product being manufacture.

- SAA 1 (VB-M-014)- is the manufacturing area for NORPACE, properly identified as a SAA, the area contained; one-plastic (30-gallon grounded container) with mixed of ethyl alcohol, shellac, ethyl cell (flammable liquids) the container was labeled as hazardous waste; also, a red steel (5-gallon) container with rags containing alcohol and labeled as hazardous waste as well. The SAA had spill kit adjacent to the abovementioned waste. All these containers were place in a pallet type secondary container.

(See APPENDIX XII-Pictures 115-118)

No concerns observed

- SAA 3 (VB-M060)- This area is a rail metal cage with locked gates. Inside the cage, I observed; One (55 gallon) blue plastic containers with pads containing mixed solvents and hazardous waste labeling as well as corrosive pictogram included.

(See APPENDIX XII-Pictures 119-121)

No concerns observed

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- SAA 2 (VB-M001)- This SAA stores Non-hazardous and hazardous waste. The Non-Hazardous waste area had 4 (55-gallon) white plastic container with water and Opadry Ink². All 55-gallon containers were empty. According to Mr. Perez, storing the containers in that specific SAA is an unusual activity. They are holding the empty containers because the person in charge is on vacation and left a few to have then available during his/her absent. The HW SAA stores color paint waste. The area was identified as Flammable liquid SAA and contained: one (30-gallon) steel container with flammable waste D001 with hazardous waste label and pictogram. Next to the container, a 5-gallon red container use to store rags with alcohol, it was also empty. The two containers were on a secondary container. The SAA also had a spill kit next to it.

(See APPENDIX XII-Pictures 124-127)

No concerns observed

3.6 PACKAGING

- SAA 1 (VB-P055)- This SAA is also a rail metal cage. It is subdivided in non-hazardous waste, and hazardous waste. In the non-hazardous waste I observed the following:
- **Inside I observed one (55 gallon) blue plastic container with pads containing alcohol, ink, and grease.**
 - One (15-gallon) white plastic container with used oil.

My observation/concern in this area was how one (55 gallon) blue plastic container with pads containing alcohol, ink and grease was determined as Non-Hazardous.

(See APPENDIX XII-Pictures 128-131)

- SAA 2 (VB-M031)- Is the subdivision of the rail cage of VB-P055. I observed the following:
- One (pile) plastic container with aerosol cans, labeled as hazardous waste with flammable pictogram.
 - One pile of used batteries, labeled as universal waste, and dated 04-13-23.

(See APPENDIX XII-Pictures 132-135)

No concerns observed

² Opadry is Colorcon's original, customized, one-step film coating system which combines polymer, plasticizer and pigment, as required, in a dry concentrate. Use of an Opadry film coating will result in attractive, elegant coatings on a variety of tablet cores. Opadry systems can be easily dispersed in aqueous or organic solvent solutions. (source: <https://www.colorcon.com/markets/pharmaceuticals/film-coatings/immediate-release/opadry>)

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- SAA 3 (VB-S-005) This is the Mechanical Room Warehouse (Machine Shop) the SAA is identified with hazardous and non-hazardous waste. In this area I observed the following:
 - One (55-gallon) blue plastic container with grounding lid labeled as non-hazardous waste label containing pads with oil.
 - One (15-gallon) blue plastic container with hazardous waste label as aerosol; machine shop aerosols flammable liquids; each not exceeding 1L capacity. Flammable pictogram also attached.

(See APPENDIX XII-Pictures 136-142)

No concerns observed

3.7 UNIVERSAL WASTE

- SAA (VB-W-001)- This area is for batteries and electronics components. I observed three containers in a pallet. Description goes as follows:
 - One (55-gallon) container labeled as Non-hazardous waste with pads with alcohol.
 - One (55-gallon) container labeled as Universal Waste dated; 06-09-23 with electric devices.
 - One (15-gallon container) labeled as batteries dated: 04-13-23.

(See APPENDIX XII-Pictures 143-147)

No concerns observed

4 DOCUMENTS REVIEW

After the facility walkthrough, I told the facility representatives that according to RCRA Hazardous Waste generation, the following documentation must be available for review:

- Facility Contingency Plan
- Waste Minimization Plan
- Training Documentation related to RCRA
- Job description of employees that managed hazardous waste
- Biennial Report
- Last three-year manifest
- 90-days HW Storage Weekly Log

Mr. Aleman and Ms. Perez provided the requested documents for review and stayed with me to answer any questions.

See **APPENDIXES** -for documentation provided by the facility during the review.

4.1 FACILITY CONTINGENCY PLAN

The facility representatives provided me with the RCRA Contingency Plan (Quick Reference Guide) and the Hazardous Waste Management SOP. The guide contains current contact information in an emergency event, management of hazardous waste procedures for spills and incidents. The Quick Reference Guide also included the acknowledgement receipt certification that the plan has been distributed to hospitals, police, fire department and other local authorities. Last revision was dated on Jun-01-2023.

See **APPENDIX X & XI**- for documents provided by the facility representatives.

4.2 WASTE MINIMIZATION PLAN

Facility waste minimization (August-2017) described activities of how to reduce the generation of hazardous waste and metrics of how their plan performs are included. They also provided a Summary of their Recycling Program.

See **APPENDIX V**- for documents provided by the facility representatives.

4.3 TRAINING DOCUMENTATION

Mr. Aleman and Ms. Perez provided the RCRA training certificates for the following personnel:

- Alexandra Perez (RCRA-Atlantic OSHA Training Center) September 08-09-2022/ Hazardous Material Instructor Training (Sustainable Workplace Alliance) March-08-09-2021
- Juan Aleman Figueroa (RCRA training Annual Refresher) AUGUST-2017
- The facility Representative also provided training logs for other division personnel, including training documents that contains RCRA training subjects.

See **APPENDIX VI & VII**- for documents provided by the facility representatives.

4.4 JOB DESCRIPTION

The job description evaluated from the facility described the hazardous waste obligations and responsibilities from the following positions: Alexandra Perez Senior EHS Specialist. Jose Campos, EHS Manager/Team Leader

See **APPENDIX III**- for documents provided by the facility representatives.

4.5 BIENNIAL REPORT

I reviewed the Biennial Report as required for LQG. The latest report was submitted on February 2022 (certified mail: 7013 1710 0002 1901 0487) report included the facility information, the quantity and nature of the hazardous waste and disposal date.

See **APPENDIX IX-** for documents provided by the facility representatives.

4.6 90-DAYS HW STORAGE WEEKLY LOG

Ms. Perez provided the 90 days HWSA inspection & register log. The log is consistent and well kept with the maintenance check list.

4.7 HAZARDOUS WASTE MANIFEST

I reviewed facility manifest of year 2021, 2022 and 2023. All manifests had in common the following waste codes:

F003 F005 U044 U117 U138 U044 U123 U213 D001 D038 D007 D011 D022

Facility representatives also provided the Manifest Generation Log of 2021 &2022.
(See **APPENDIX IV**)

2021

Date	Manifest # with LDR	Date	Manifest # with LDR
Jul -01-2021	001851047VES 001851048VES 001851049VES	Nov-02-2021	002065163VES 002065164VES 002065165VES
Aug-03-2021	002065003VES 002065004VES 002065005VES	Dec-10-2021	002065396VES 002065397VES 002065398VES

2022

Date	Manifest # with LDR	Date	Manifest # with LDR
Jan -14-2022	002069636VES 002069637VES 002069639VES	Jun-28-2022	002069871VES 002069869VES 002069870VES
Mar-04-2022	002065346VES 002065347VES 002065348VES 002065349VES 002065350VES	Oct-04-2022	002064285VES 002066079VES 002066080VES 002066081VES

Date	Manifest # with LDR	Date	Manifest # with LDR
Mar -01-2023	002065665VES	May-23-2023	002066389VES
Apr-05-2023	002065719VES	Jun-12-2023	002065730VES

➤ **Oil Manifest**

- 05 Apr 2023 Num. ZZ01008322 Num. Manifest T01516 65 Gal
- 03 May 2023 Num. ZZ00880896 Num. Manifest T01524 65 Gal

➤ **Universal Waste Manifest**

- 01 Feb 2023 Fluorescent Lamps and batteries Manifest Num. 002066373VES

5 CLOSING MEETING

After completion of the walkthrough and document review, I met with Mr. Aleman and Ms. Perez to conduct a closing meeting. I indicated that the purpose of the closing meeting is to inform the facility about the CEI observations. I communicated the facility the following:

A walkthrough to the facility was completed as well as the review of documents. No major concerns identified at the closure of the CEI. Nevertheless, it is always advised that at the time of the evaluation of pictures and writing report concerns may arise where more information be requested for clarification purpose.

6 POTENTIAL AREAS OF CONCERN

At the time of writing this report the following concerns arose:

- § 262.11 Hazardous waste determination and recordkeeping.
 - Determination of container with pads with alcohol, ink and grease waste located at the 90-days HWSA Non-Hazardous waste area and Packaging Area (SAA 1 /VB-P055)
- § 262.15 Satellite accumulation area regulations for small and large quantity generator
 - Practice that regulates SAA labeling shown two different dates on containers throughout the QC Laboratory and Finished Product Area.

7 FOLLOW-UP ACTIONS

A request for information will be sent for the clarification on the following concerns:

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- HW determination of the waste containing alcohol, ink, and grease generated at the 90-days HWSA Non-hazardous area and Packaging.
 - Quality Control (QC) Lab and Finished Products SAA's date labeling (effective date and Performed by/date) practice on containers.

8 ATTACHMENTS

Appendix I:	Facility Location, Aerial Picture, & Facility Layout
Appendix II:	Facility Manufacturing Products & SAA Locations
Appendix III:	Job Descriptions
Appendix IV:	Manifest Generation Log
Appendix V:	Recycle Summary
Appendix VI:	Training Certificates
Appendix VII:	Training Logs
Appendix VIII:	Change of Legal Name
Appendix IX:	Biennial Report
Appendix X:	Hazardous Waste Management SOP
Appendix XI:	RCRA Contingency Plan (Quick Reference Guide)
Appendix XII:	Pictures and Description