

Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (CEI)

Pall Life Sciences

PRD981139611

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



Resource Conservation and Recovery Act (RCRA)
Compliance Evaluation Inspection (CEI)

Facility Name:	<i>Pall Life Sciences</i>						
EPA ID Number:	<i>PRD981139611</i>						
Completion Date:	<i>March 16, 2023</i>						
Generator Status in Record:	Large Quantity Generator						
RCRA Permitted:	No						
Corrective Action:	No						
Project ID	CEPD-RCRA-09-0132						
Basis for Inspection:	Core Program (Conducted during the <i>COVID-19 pandemic</i> timeframe.)						
Facility Personnel:							
Name:	Title:	Email:	Phone:	Attend to:			
				OM ¹	FW ²	DR ³	CM ⁴
Ms. Jalixa Díaz	EHS ⁵ Manager	jalixa_diaz@pall.com	939-489-7754	√	√	√	√
Ms. Natalia Pérez	EHS Team	natalia_perez@pall.com	939-649-0026	√	-	√	√
EPA Personnel:							
Inspector's Name		EPA Region 2-CEPD	Enforcement Officer	phone/email			
Ms. Rosana Caballer-Cruz		EPA Region 2-CEPD	Enforcement Officer	787-977-5880/ caballer.rosana@epa.gov			
Status:	FINAL						
EPA Inspector Signature/Date	X ROSANA CABALLER-CRUZ Digitally signed by ROSANA CABALLER-CRUZ Date: 2023.04.27 10:14:36 -04'00'						
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2023.04.27 10:25:13 -04'00' David N. Cuevas Miranda, Ph.D.						

¹ Opening Meeting

² Facility Walkthrough

³ Documents Review. For additional information related to this item, please refer to Section 3 and 5 of this Report.

⁴ Closing Meeting

⁵ Acronym usually stands for Environmental, Health and Safety.

1 FACILITY SUMMARY

Facility Physical Location: (Municipality, PR, zip code)	194 STATE ROAD 194 KM. 0.4. FAJARDO, PUERTO RICO 00738.
Geographical Coordinates:	18.336147; -65.653368
Facility Information:	PALL LIFE SCIENCES PUERTO RICO, LLC
	939-233-5155
	Mailing address: STATE ROAD 194 KM. 0.4 FAJARDO, 00738.
NAICS:	339999 - ALL OTHER MISCELLANEOUS MANUFACTURING/ALL OTHER PLASTICS PRODUCT MANUFACTURING.
Previously inspected:	YES
Area:	THREE (3) BUILDINGS ⁶
Employees	APPROXIMATELY 806
HW ⁷ transferred via pipeline?	NO ⁸
UST ⁹ available at the facility?	NO ¹⁰
NRC ¹¹ orientation provided?	YES

2 INTRODUCTION

On March 16, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (inspection) was conducted at Pall Lifesciences Puerto Rico, LLC. (the facility), pursuant to Section 3007 of RCRA. As part of the inspection, I explained to the facility representative that an opening meeting, walkthrough, and document review, would be conducted to evaluate the facility's compliance with the requirements that govern hazardous waste generators, universal waste handlers, and used oil generators, as applicable.

According to records, the facility has been inspected by the EPA prior to this inspection. I arrived at the facility around 9:20 am and the weather conditions that remained through the CEI were a sunny day, hot temperature, and with humidity.

2.1 FACILITY PHYSICAL DESCRIPTION AND OPERATION

Pall Life Sciences has been at this location for approximately forty-five (45) years. The facility is dedicated to the manufacturing of filters for the food, beverage, medical, and pharmaceutical industries. The whole production of these filters occurs at the Fajardo Plant and then is

⁶ One (1) of the Buildings is currently being lease to another company.

⁷ Acronym stands for hazardous waste.

⁸ Information provided by the facility representative.

⁹ Acronym stands for underground storage tanks.

¹⁰ Information provided by the facility representative.

¹¹ Acronym stands for National Response Center.

distributed to their clients¹². The facility consists of three (3) buildings¹³. The buildings and the lot are owned by Pall Life Sciences. Approximately 806 employees work at this facility 24 hours, seven (7) days a week.

2.2 AERIAL PHOTOGRAPH



Figure 1: Facility Location

2.3 SOLID AND HAZARDOUS WASTE GENERATION

According to the facility representatives, they are currently generating mainly isopropyl alcohol. They informed me that two (2) 90-day hazardous waste accumulation areas are available at the facility and that Satellites Accumulation Areas (SAAs) are available in the laboratory and manufacturing areas, as well. The hauler company for their hazardous waste is Veolia ES, and the last disposal was conducted in February 2023. Also, I asked the facility representatives about their universal waste and used oil generation, handling, and/or disposal activities. They replied that they are currently generating used oil and universal waste¹⁴. Information related to any spills and/or chemical releases in their facility was asked, as well. According to them, spills nor chemical releases in their facility have occurred. Finally, I provided Pall representatives with an orientation and information related to NRC, such as but not limited to the phone number

¹² A general overview of their process as follows: raw material – manufacturing process (i.e., filters) – packaging-distribution center- clients.

¹³ According to the facility representative, one (1) of the buildings is currently under a leasing contract with Haemonetics Puerto Rico, LLC.

¹⁴ The hauler company for both wastes pick up is Veolia ES.

3 OPENING MEETING

I met at the facility with Ms. Jalixa Díaz, EHS¹⁵ Manager, and Ms. Natalia Pérez, EHS Specialist, for the opening meeting. I identified myself as an EPA RCRA enforcement officer and told the facility representatives that the purpose of my visit was to conduct a CEI at the facility to evaluate its hazardous waste, universal waste, and used oil management practices and compliance. In addition, I told them that RCRA, universal wastes, and/or used oil documents would be requested as part of this CEI. As part of the inspection, I mentioned to the facility representatives that I needed to take photos related to any RCRA-related issues. They permitted me to take photos during the inspection. Finally, I also explained that we needed to visit the waste generation areas in the facility.

4 FACILITY WALKTHROUGH

Just after the opening meeting closure, we started the facility walkthrough. The areas inspected were: (1) SLS¹⁶ Laboratory Area, Manufacturing Area (aka Acrylic Area), Syringe Area, and the 90-day Hazardous Waste Accumulation Area (HWAA). The observations for the areas inspected are described below:

4.1 SLS LABORATORY AREA

Description of the Area	This was the first area inspected. Located on the second floor of Building 3, it is used to provide laboratory services, as requested by their clients. Here, microbiology and analytical works are conducted and, according to the facility representatives SAAs are located within this area. Here, Mr. Fernando Marcellan, SLS Director, joined us at the inspection.
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For inspection purposes, this area was segregated into two (2) subareas: (a) Microbiology Lab Subarea and (b) TFF Room Subarea. In order to have access to this room, regular gowning was requested and used. At the time of the inspection, two (2) SAAs were inspected. Information on each one is as follows:

4.1.1 MICROBIOLOGY LAB SAA SUBAREA

Here, one (1) 55-gallon steel container with hazardous waste-solid waste was observed above a secondary containment. It was closed¹⁷, labeled as hazardous waste, and the area was labeled as Waste SAA, which was observed clean and without debris (Picture #1).

¹⁵ Acronym usually stands for Environmental Health and Safety.

¹⁶ Acronym stands for Scientific and Laboratory Services.

¹⁷ This container was closed and have available the Department of Transportation (DOT) lid in place.

Also, a package with information related to the components of the containers and each SDS, as well, was observed at the lid's container.

4.1.2 TFF ROOM SUBAREA

Located on the second floor of Building 3, just at the front of the Microbiology Lab Subarea, one (1) 55-gallon white plastic container with corrosive was observed labeled as hazardous waste, with a pictographic label available, closed, and above a secondary containment (Picture #2). The area was observed clean and without debris.

4.2 MANUFACTURING AREA (AKA ACRYLIC AREA)

Description of the Area	This was the second area inspected. Located on the first floor of Building 3, here is where the manufacturing process is conducted. In order to have access to this room, regular gowning was requested and used. Here, Mr. Christian Sambolin, Manufacturing Supervisor, joined us at the inspection.
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For inspection purposes, this area was segregated into two (2) subareas: (a) SAA Subarea and (b) Ink Room Subarea. Information on each one is as follows:

4.2.1 SAA SUBAREA

One (1) 14-gallon red plastic container with Paños¹⁸, filtros¹⁹, alcohol, kerosene was observed labeled as hazardous waste, with a pictographic label, and the area was observed clean (Picture #3). Inside, I observed a plastic bag that contained spent filters. It was observed approximately 1/3 full. Just at the side of this SAA, an eye wash station was available²⁰.

4.2.2 INK ROOM SUBAREA

Here, three (3) containers were observed below a metal shelf (Picture #4). Information on each one is as follows:

- (a) One (1) 25-gallon²¹ white plastic container with thinner/tinta a base de agua²²/tinta²³ TPU/etc. was observed above a base with wheels. It was labeled as hazardous waste, closed, with a hood connected at the container, with a pictographic label available, with an accumulation started date was 13/02/2023.

¹⁸ Spanish. Could be translate as "rags"

¹⁹ Spanish. Could be translate as "filters"

²⁰ The last inspection conducted to this equipment was done on 2-27-2023.

²¹ Approximately.

²² Spanish. Could be translate as "water base ink".

²³ Spanish. Could be translate as "ink"

- (b) One (1) 10-gallon red metal container with tinta/paños/guantes²⁴ was observed. This container has inside a bag. It was observed labeled as hazardous waste, nevertheless, a pictographic label and/or indication of the hazards was not observed at this container. The accumulation start date was 10/03/2022.
- (c) One (1) 10-gallon red metal container with tinta/thinner/paños/guantes was observed. This container has inside a bag. It was observed labeled as hazardous waste and with a pictographic label available.

I told the facility representatives the following:

1. Pictographic label and/or indication of the hazards - One (1) 10-gallon red metal container with tinta/paños/guantes was observed without a pictographic label and/or indication of the hazard. Hazardous waste containers must be marked or labeled its containers with an indication of the hazards or a pictogram.

4.3 SYRINGE AREA

Description of the Area	This was the third area inspected. This area is where the syringe manufacturing process is conducted. In order to have access to this room, regular gowning was requested and used.
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For inspection purposes, this area was segregated into four (4) subareas: (a) IPA 25 SAA Subarea, (b) Rintex 50 SAA Subarea, (c) IPA 50 SAA Subarea, and (d) Syringe Ink Room Subarea. Information on each one is as follows:

4.3.1 IPA 25 SAA SUBAREA

Here, a 55-gallon black steel container with isopropyl alcohol was observed closed, labeled as hazardous waste, with the pictographic label, grounded, and has a secondary containment available. Also, the subarea was observed without debris.

4.3.2 RINTEX 50 SAA SUBAREA

Here, a 10-gallon yellow plastic container with napkins and filters was observed near the equipment identified as Rintex 50. According to the facility representatives, this container is used to store the napkins and filters generated within the Rintex equipment subarea. At the time of the inspection, the container was observed closed, with a bag inside the container and

²⁴ Spanish. Could be translate to "gloves".

almost empty. The latter was labeled as hazardous waste, nevertheless, a pictographic label and/or indication of the hazard were not observed in this container. As a result, during the CEI, the facility representatives took action immediately and provided the corresponding pictographic label for the mentioned container²⁵ (Picture #5). The area where this container was placed was observed without debris.

4.3.3 IPA 50 SAA SUBAREA

Here, a 55-white plastic container with isopropyl alcohol was observed closed, half full, labeled as hazardous waste, with its pictographic label available, grounded and a secondary containment was available, as well.

4.3.4 SYRINGE INK ROOM SUBAREA

This was the last subarea inspected. Here, three (3) containers were observed (Picture #6). Information on each one is as follows:

- (a) One (1) 20-gallon white plastic container. This container was observed above a base that has available wheels. The latter has available a pictographic label, nevertheless, at the time of the inspection, it was not labeled as hazardous waste²⁶. Also, a funnel was observed connected to the mentioned container. The funnel was observed open.
- (b) One (1) 5-gallon red plastic container with napkins with alcohol and ink was observed closed. It was labeled as hazardous waste, nevertheless, a pictographic label was not available. This container had a bag inside and, at the time of the inspection, it was observed almost empty.
- (c) One (1) 10-gallon red plastic container with napkins with alcohol and ink was observed closed. It was labeled as hazardous waste and a pictographic label was observed, as well. This container had a bag inside and, at the time of the inspection, it was observed almost empty.

I told the facility representatives the following:

1. Pictographic label and/or indication of the hazards - a 10-gallon yellow plastic container with napkins and filters, and a 5-gallon red plastic container with napkins with alcohol and ink were observed without a pictographic label and/or indication of the hazard. Hazardous waste containers must be marked or labeled with an indication of the hazards or a pictogram.

²⁵ Ms. Díaz placed a flammable pictographic label to the 10-gallon yellow plastic container.

²⁶ At the time of the inspection, the information related to the content of this container was not available.

2. Hazardous waste label - One (1) 20-gallon white plastic container was observed without a hazardous waste label. Hazardous waste containers must be marked or labeled with the words "Hazardous Waste".

4.4 90-DAY HAZARDOUS WASTE ACCUMULATION AREA (HWAA)

Description of the Area	This was the fourth area inspected. Located outside Building 3, in the west part of the facility, it is aimed to store the hazardous waste generated at Building 3. It consists of metal fence walls and a galvalume ceiling and according to the facility representatives, the floor of the area is considered itself a secondary containment. Mr. Domingo Ayala, EHS Technician, was working in the area when we access the latter.
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At the time of the inspection, the area was observed open since Mr. Ayala was already working inside. Here, the emergency contact information and a no-smoking label are available, nevertheless, a hazardous waste label was not observed. I asked the facility representatives about the emergency equipment in this area. They replied that a fire extinguisher²⁷ and an eye-wash station²⁸ were available. Also, I asked him about communication devices. He replied that he has available a cell phone and a two-way radio^{29 30}. I asked them if this area has available an alarm in place and they replied that the nearest alarm is available at Building 3. I also asked if this area has available an automatic sprinklers system or water to be used in case of an emergency. They replied that a sprinkler system is not available in the area, nevertheless, a (tap) water intake is available nearby the facility's 90-day HWAA.

Inside the area, I observed eight (8) 55-gallon containers segregated in three (3) rows. Additional information on each one is as follows:

- (a) One (1) 55-gallon black steel container with filtros, paños, guantes. The container was observed closed, labeled as hazardous waste, with a flammable-solid pictographic label and dated 03-16-2023.
- (b) One 55-gallon black steel container with filtros con alcohol. The container was observed closed, labeled as hazardous waste, with a flammable solid pictographic label, and dated 03-16-2023.

²⁷ The last inspection conducted to this equipment was in February 2023.

²⁸ The last inspection conducted to this equipment was in 02-27-2023.

²⁹ Conflict information about this statement was found as part of the document review section. For additional information of this item, please refer to Section 5.2.2.

³⁰ Nevertheless, at the time of the inspection, Mr. Ayala was not carry-on the two-ways radio. For additional information of this item, please refer to Section 5.2.2 of this Report.

- (c) One 55-gallon white plastic container with diluted NaOH. The container was observed closed, labeled as hazardous waste, with a corrosive pictographic label, and dated 03-14-2023.
- (d) One (1) 55-gallon white plastic container with isopropyl alcohol. The container was observed closed, labeled as hazardous waste, with a flammable liquid pictographic label, and dated 02-02-2023.
- (e) One (1) 55-gallon white plastic container with isopropyl alcohol. The container was observed closed, labeled as hazardous waste, with a flammable liquid pictographic label, and dated 02-22-2023. A dent was observed in this container. As a result, additional information related to this observation was requested to the facility representatives³¹.
- (f) One (1) 55-gallon white plastic container with isopropyl alcohol. The container was observed closed, labeled as hazardous waste, with a flammable liquid pictographic label, and dated 03-13-2023.
- (g) One (1) 55-gallon black steel container with isopropyl alcohol. The container was observed closed, labeled as hazardous waste, with a flammable liquid pictographic label, and dated 03-13-2023.
- (h) One (1) 55-gallon black steel container with isopropyl alcohol. The container was observed closed, labeled as hazardous waste, with a flammable liquid pictographic label, and dated 01-26-2023. Dirt was observed in this lid's container.

In addition, I asked about one (1) 55-gallon white plastic container that I observed as part of the facility's 90-day HWAA. According to Mr. Ayala, this container is used as an SAA. I asked him how they handle this container, and he replied that they stored the alcohol residues of other containers stored at this 90-day HWAA. I asked Ms. Díaz about this SAA, and she replied that she was not aware of this SAA. As a result of this conflict, I told the facility representatives that additional information would be requested about this in order to properly identify this area and this container. They agreed to provide the latter at a later time.

I told the facility representatives the following:

1. Segregation of hazardous wastes – as an LQG, the facility needs to comply with waste segregation. A container identified as corrosive waste was observed near containers of flammable waste without any physical barrier or device.
2. Condition of the containers – one (1) 55-gallon white plastic container with isopropyl alcohol was observed with a dent. According to them, this condition observed was a

³¹ When I asked to the facility representatives about this observation, they replied that this occurs as a result of the heat/hot temperatures in their 90-day HWAA.

result of hot temperatures in the 90-day HWAA. In addition, dirt was observed on the lid of one (1) 55-gallon black steel container with isopropyl alcohol.

3. SAA inside the 90-day HWAA – Additional information would be requested to the facility representatives as a result of conflicting information/lack of knowledge of this area inside the 90-day HWAA.

4.5 90-DAY HAZARDOUS WASTE ACCUMULATION AREA (HWAA)

Description of the Area	This was the fifth area inspected. Located outside Building 1, on the east side of the facility, it is aimed to store the hazardous waste generated at Building 1. It consists of a fire-retardant room on which its floor is considered itself a secondary containment. Mr. Domingo Ayala, EHS Technician, opened the area for us in order to inspect this room.
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Once opened, I observed one (1) 55-gallon white plastic container with mezcla de TBA/IPA agua. It was closed, labeled as hazardous waste, with a pictographic label available and the start date was 03-15-2023. The room was observed without vegetative material. I asked Mr. Ayala about communication devices available in this area. He replied that he has available a cellphone and a two-way communication device^{32 33}. This room has available the hazardous waste label, the internal emergency response personnel contact information, and the external emergency response personnel contact information, as well. Finally, aisle space was observed inside the room and the logbook, when requested, it was available for review.

4.6 BACTERIAL CHALLENGE BUILDING 1

Description of the Area	This was the sixth area inspected. Located in Building 1's laboratory, this area is aimed to conduct filter analysis using bacteria for quality purposes. In order to have access to this room, regular gowning was requested and used. Ms. Mariangelis Santana, Laboratory Senior Lab Technician, joined us at the inspection.
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For inspection purposes, this area was segregated into two (2) subareas: (a) SAA #1 Subarea, and (b) SAA #2 Subarea. Information on each one is as follows:

³² Conflict information about this statement was found as part of the document review section. For additional information of this item, please refer to Section 5.2.2.

³³ Nevertheless, at the time of the inspection, Mr. Ayala was not carry-on the two-ways radio. For additional information of this item, please refer to Section 5.2.2 of this Report.

4.6.1 SAA #1

Here, one (1) 5-gallon black plastic container was observed with isopropyl alcohol. The latter was observed closed, labeled as hazardous waste, with a pictographic label and a secondary containment available, as well. This subarea was observed below a metal shelf. It was clean and it is currently being shared with non-hazardous waste containers (Picture #7).

4.6.2 SAA #2

Here, one (1) 20-gallon white plastic container was observed with paños/papeles/servilletas con alcohol (IPA). The container was observed closed, labeled as hazardous waste, with a pictographic label available, and inside the container, has available a bag. This subarea was observed clean and without debris (Picture #8).

4.7 MANUFACTURING AREA (CLEAN ROOM)

Description of the Area	This was the last area inspected. Located inside Building 1, to access this area, <i>full gowning</i> was requested to be used. Ms. Melissa Vega, Manufacturing Supervisor, joined us at the inspection.
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Here, one (1) 55-gallon white plastic container with mezcla de TBA/IPA Agua was observed. The container was labeled as hazardous waste, with its pictographic label, a secondary containment, was grounded, had an air filter and was observed approximately 1/3 full. A pump with soft tubes was observed and it was explained by the facility representatives that this was as a result of the connection of the latter with the Pallsol Tank #1903 equipment³⁴. At the time of the inspection, the pump was operational (Picture #9). Finally, the area where this container was placed was observed, labeled, clean, and without debris.

5 DOCUMENTS

5.1 DOCUMENT REQUEST

I explained to the facility representatives that, as part of the CEI activities, a request and evaluation of documents would be conducted. I asked them for the following documents for review: (1) biennial report (2) job description, (3) HWAA inspection information, (4) training records (5) contingency plan (6) waste minimization plan, and (7) manifests. The documents requested were available for review. Information related to each document is presented below:

³⁴ According to the facility representatives, this equipment is used to conduct the reverse bubble testing.

Documents Requested	Requested during CEI	Available during CEI?	Description
1. Biennial Report	YES	YES	The 2021 Biennial Report document was available for review. It was certified by Ms. Vivienne Henry, Plant Manager, on February 28, 2022, and submitted before the due date of March 1 st , 2022.
2. HWAA inspection information	YES	YES	The documents' timeline evaluated was from January 3, 2023, to March 13, 2023.
3. Job Description	YES	YES	Two (2) documents were provided for evaluation.
4. Training Records	YES	YES	Information related to two (2) training was provided (a) presentation identified as 2 nd -day Hazardous Waste Operations and Emergency Response (HAZWOPER) and (b) four (4) attendance sheet pages.
5. Contingency Plan	YES	YES	One (1) binder with the facility's Integrated Contingency Plan (ICP) was provided for evaluation.
6. Waste Minimization Plan	YES	YES	Three (3) pages document was provided for evaluation.
7. Manifests	YES	YES	Three (3) binders were provided for evaluation. The time frame evaluated was from 2020 to 2022.

5.2 DOCUMENTS REVIEW

5.2.1 BIENNIAL REPORT:

At the time of the inspection, the document was available for review. It was prepared by Mr. Jorge O. Guzmán Cora, P.E., and includes information related to the facility's NAICS information³⁵, the location of the facility using the GPS³⁶, and information related to the document's certification.

5.2.2 HWAA INSPECTION INFORMATION:

³⁵ For additional information, please refer to Section 1 of this Report.

³⁶ Acronym stands for Global Positioning System.

The documents evaluated were from Building #1 and Building #3, respectively. According to the information gathered, Mr. Domingo Ayala conducts these inspections at the mentioned Buildings, and he includes the following comments:

Area	Date of Comment	Comment	Action taken (if applicable)
Building #1	Comment observed in the logbook since January 2023	"needs integrity test since humidity and corrosion was observed at the ceiling and walls. Extractor fan also not operational."	According to the facility representative, the work order related to this action was conducted and the paint that will be used is almost delivered to the facility.
Building #3	Comment observed in the logbook since January 2023	Two (2) ways radio is not okay. All responses were "No" ³⁷ in the logbook.	Nevertheless, at the time of the inspection, when I ask Mr. Ayala about the communication devices, he told me that he has a two-way radio available while working at both 90-day HWAA. ³⁸

5.2.3 JOB DESCRIPTIONS:

Each document, identified as Environmental Health and Safety Technician, was evaluated. According to the information gathered, the job code of the latter is U30095, and the revision was conducted in July 2007. After evaluation, the documents provided include the hazardous waste component.

5.2.4 TRAINING RECORDS:

The HAZWOPER training was provided, and information related to RCRA, and hazardous wastes started on slide #48 of such presentation. The attendance sheet provided was related to the DOT³⁹-HAZWOPER training. Information related to each attendance sheet is as follows:

³⁷ According to the information gathered during the document review section, the response "No" in the facility logbook means that the equipment was not available nor operational during their HWAA inspection.

³⁸ For additional information related to this item, please refer to Section 4.4.

³⁹ Acronym stands for Department of Transportation.

DOT-HAZWOPER TRAINING	DATE	HOURS	EMPLOYEES
	11/11/2021	8	9
	11/12/2021	8	8
	11/16/2021	8	9
RCRA CAPACITATION	08/03/2021	2	4

5.2.5 CONTINGENCY PLAN:

The last version of the ICP was dated September 2022 and was prepared by Compliance Resource, Inc. This document includes the SPCC Plan⁴⁰, the equipment list, the map and diagrams, information related to the wastes generated, the external emergency response personnel, the emergency response equipment, the evacuation procedure narrative, and the professional engineer certification⁴¹ and it was signed by Ms. Díaz and Ms. Vivienne Henry, Plant manager, on 02/01/23. Nevertheless, it was discussed with the facility representatives the following: the quick reference guide was not available for review, the equipment location, physical description, and brief outline of its capabilities were not available, the first responder's certification/evidence and the facility's emergency contact information⁴² were not available for review. In addition, it was discussed with the facility representatives that the document still referred to the Environmental Quality Board (EQB)⁴³. Information and Regulation references were shared with the facility representatives as part of the document review section.

5.2.6 WASTE MINIMIZATION PLAN:

This document, identified as Waste Minimization and Pollution Prevention, became effective on September 9, 2015. This document includes the definition of hazardous waste, as defined by 40 CFR 261.3, the facility's procedure, responsibility, and purpose, among others.

5.2.7 MANIFESTS:

At the time of the inspection, the manifests evaluated were signed and appeared to be in compliance with the 45-day timeframe. The representatives, who signed the mentioned documents were Mr. Ayala and Ms. Pérez, respectively. Nevertheless, one (1) manifest was observed without the Certification of receipt of hazardous materials. As a result, additional

⁴⁰ Acronym stands for Spill Prevention, Control, and Countermeasure Plan (40 CFR § 112 Oil Pollution Prevention).

⁴¹ Ms. Rosario Jiménez Rivera, P.E. License No. 12812.

⁴² During the evaluation of the document, the facility representative printed this information and provided for review since it was not available at the facility's ICP. After evaluation of the document, she included the latter in the Appendix 10 of the mentioned document.

⁴³ Nowadays, the Agency has merged within the Puerto Rico Department of Natural and Environmental Resources (PR DNER). (Ley Núm. 171 de 2 de agosto de 2018).

information related to the latter was requested to the facility representatives.^{44 45}

6 CLOSING MEETING

On March 16, 2023, the closing meeting was conducted with the facility representatives, at their facility. I indicated that the purpose of the closing meeting was to inform them about the CEI observations raised. As part of the closing meeting, I told them that additional information would be sent for their reference and that additional information would be requested. The latter was sent, as agreed, on March 17, 2023⁴⁶. For more information, please refer to Section 8 and Section 9 of this Report.

7 POTENTIAL AREAS OF CONCERN

7.1 GENERATORS

On February 27, 2022, the facility notified of its hazardous waste activities as a Large Quantity Generator. Based on the observations and information gathered during the inspection, the following areas of concern were identified:

7.1.1. SUBPART A- STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

i. According to 40 CFR § 262.17(a)(1)(ii), which states that *“if a container holding hazardous waste is not in good condition, 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 this section...”*

At the time of the inspection, the facility failed to comply with this requirement in the 90-day HWAA. Here, one (1) 55-gallon white plastic container with isopropyl alcohol was observed with a dent.

ii. According to 40 CFR 262.17(a)(1)(vii)(C), which states that *“a container holding a hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.”*

At the time of the inspection, the facility failed to comply with this requirement in the 90-day HWAA. Here, one 55-gallon white plastic container with diluted NaOH, labeled as hazardous waste, was observed with a corrosive pictographic label. This container was not observed separated from the other flammable materials observed at the facility’s 90-day HWAA or was not protected from them by means of a dike, berm, wall, or other device.

⁴⁴ Manifest information is as follows: 001849286 VES, signed by Mr. Ayala on 06/16/2021.

⁴⁵ For additional information of this item, please refer to Section 7.1 of this Report.

⁴⁶ Ms. Díaz read the email on March 20, 2023.

- iii. According to 40 CFR § 262.17(a)(5)(i)(A), which states that *“A large quantity generator must mark or label its containers with the following: (A) The words “Hazardous Waste...””*.

At the time of the inspection, the facility failed to comply with this requirement in the Syringe Area. Here, one (1) 20-gallon white plastic container was observed without a hazardous waste label.

- iv. According to 40 CFR § 262.17(a)(5)(i)(B), which states that *“an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704)...”*

At the time of the inspection, the facility failed to comply with this requirement in the Manufacturing Area and the Syringe Area. At the Manufacturing Area, one (1) 10-gallon red metal container with tinta/paños/guantes was observed without a pictographic label and/or indication of the hazard while at the Syringe Area, a 10-gallon yellow plastic container with napkins and filters, and a 5-gallon red plastic container with napkins with alcohol and ink were observed without a pictographic label and/or indication of the hazard.

7.1.2 SUBPART M - PREPAREDNESS, PREVENTION, AND EMERGENCY PROCEDURES FOR LARGE QUANTITY GENERATORS

- v. According to 40 CFR 262.262(b), which states that *“A large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee...”*

At the time of the inspection, the facility failed to comply with this requirement. During the documents review section, the quick reference guide was not available for review. Although the facility provided via email, at a later date, the quick reference guide, according to the information gathered, this quick reference guide appears to be generated after amending its contingency plan. According to records evaluated during the inspection, the facility's contingency plan, aka ICP, was dated September 2022. The quick reference guide provided for review after the inspection was dated in March 2023, hence, it seems that the quick reference guide was not part of the contingency plan facility's amendment, as required by the Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators - Copies of contingency plan section.

8 FOLLOW-UP ACTIONS

As expressed in Section 6 of this Report, an email to the facility representatives was sent on

March 17, 2023. The email included direct links which provide information related to the RCRA Regulation (40 CFR §§ 260 to 265), Universal Waste (40 CFR § 273), and Used Oil (40 CFR § 279), among other direct links with specifics, such as aerosol cans, satellites accumulation areas (SAAs), aisle space, etc. In addition, the EPA Form 8700-12, and one page with additional links which provide direct links for specific items for the RCRA Regulation were sent for their future reference. The facility representative, Ms. Díaz, read the email on March 20, 2023⁴⁷.

7.1 REQUESTS

Information Requested	Reason
1. Certification evidence of Mr. Ayala (2020, 2021, 2022, and 2023, if available) 2. Certification evidence of Ms. Pérez (2020, 2021, 2022, and 2023, if available)	- This information was requested to confirm that the person who signed during the mentioned time frame was certified and willing to sign the facility's manifests.
3. Manifests	- The manifest: 001849286 VES; signed by Mr. Ayala on 06/16/2021, did not include the corresponding information at the Designated Facility Owner or Operator: Certification of receipt of hazardous materials.
4. 90-d HWAA Building #3	- Additional information about a potential Satellite Accumulation Area (SAA) subarea identified by the facility representative during the inspection was requested.
5. Contingency Plan	- Additional information was requested in order to complete the evaluation of said document.

7.2 INFORMATION PROVIDED TO THE FACILITY REPRESENTATIVE

Information Requested	Link	Enclosed
1. RCRA (Hazardous Waste)	√	

⁴⁷ For additional information related to this item, please refer to the Attachment identified as OTHER: EMAIL SENT TO FACILITY REPRESENTATIVES ON MARCH 17, 2023.

2. <i>Summary of Requirements for Very Small Quantity Generators (VSQGs)</i>	√	
3. <i>Summary of Requirements for Small Quantity Generators (SQGs)</i>	√	
4. <i>Summary of Requirements for Large Quantity Generators (LQGs)</i>	√	
5. <i>Universal Waste</i>	√	
6. <i>Used Oil</i>	√	
7. <i>Aerosol cans</i>	√	
8. <i>Satellite Accumulation Areas</i>	√	
9. <i>Condition of containers</i>	√	
10. <i>Aisle space</i>	√	
11. <i>Alternative Standards for Episodic Generation</i>	√	
12. <i>National Response Center</i>	√	
13. <i>Hazardous Waste Generator Regulations Compendium</i>	√	
14. <i>Defining Hazardous Waste</i>	√	
15. <i>P-waste</i>	√	
16. <i>EPA Form 8700-12</i>	√	√
17. <i>One page with additional links which provide direct links for specific items for the RCRA Regulation</i>	√	√

9 ATTACHMENTS

I. CAMERA ROLL

II. APPENDIX 1: SITE PICTURES

III. OTHER: EMAIL SENT TO FACILITY REPRESENTATIVES ON MARCH 17, 2023.

ATTACHMENT I: CAMERA ROLL

