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:	Patheon Puerto Rico Inc
EPA ID Number:	PRR000000836
Date of Inspection:	February 1, 2024
Generator Status in Record:	Large Quantity Generator (LQG)
Generator Status at the time of inspection:	Large Quantity Generator (LQG)
RCRA Permitted:	No
Basis for Inspection:	Core Program
Corrective Action:	No
Facility Physical Location: (Municipality, PR, zip code)	Carr. 670 Km 5.2, Manati, Puerto Rico, 00674.
Geographical Coordinates:	18.198414, -65.972756
Facility Contact:	Ms. Lorraine Afanador 787-409-5102 EHS[1] Supervisor Email: lorraine.afanador@thermofisher.com Mailing address: P.O. Box 3199 Manati, Puerto Rico, 00674
Facility Contact:	Xiomara Torres 939-438-8566 EHS Specialist II Email: xiomara.torres@thermofisher.com Mailing address: P.O. Box 3199 Manati, Puerto Rico, 00674
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[1] Acronym usually stands for Environmental Health and Safety.

NAICS:	325412 – Pharmaceutical preparation manufacturing		
Area:	Approximately 110 acres[2]		
Number Employees:	Approximately 512 employees		
Personnel participating in inspection:			
Inspector's Name	EPA Region 2-CEPD	Enforcement Officer	{phone/email}
Rosana Caballer-Cruz	EPA Region 2-CEPD	Enforcement Officer	787-977-5880 caballer.rosana@epa.gov
Status:	FINAL		
Record Schedule:	1044(c) {unless landmark or precedent}		
Multi-media Checklist: ATTACHMENT # N/A		Referral: N/A	
EPA Inspector Signature/Date	X ROSANA CABALLER-CRUZ Digitally signed by ROSANA CABALLER-CRUZ Date: 2024.03.15 10:32:44 -04'00'		
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2024.03.15 11:09:36 -04'00' David N. Cuevas Miranda, Ph.D.		

1 INTRODUCTION

On February 1, 2024, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (inspection) was conducted at Patheon Puerto Rico, Inc. (the facility), pursuant to Section 3007 of RCRA. As part of the inspection, I explained to the facility representatives that an opening meeting, walkthrough, and document review would be conducted in order to evaluate the 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 Carr. 670 Km 5.2 Manati, Puerto Rico. According to EPA records, the facility has been inspected seventeen (17) times prior to this CEI. The last inspection was conducted by the Agency on June 23, 2017, while the last inspection conducted by the State[3] was on December 5, 2011, respectively. I arrived at the facility around 9:45 a.m. A sunny day with hot temperatures, no wind and humidity were the weather conditions that remained through the CEI.

2 OPENING MEETING

I met with Ms. Lorraine Afanador, EHS Supervisor, Ms. Xiomara Torres, EHS Specialist II, and Mr. Bernardo Jaime, EHA Manager 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

[2] Due to the facility's size, a pickup truck was provided by the facility representatives in order to conduct the CEI.
[3] Inspection conducted by Department of Natural & Environmental Resources personnel.

be requested as part of this CEI[4]. As part of the inspection, I told them that I needed to take photos related to any RCRA-related issues. The facility representatives allowed me to take photos during the inspection. Finally, I also explained that we needed to visit the waste generation areas in the facility. Just after, Mr. Bruno Rossy, EHS Technician II, joined us at the opening meeting and I was notified that he would join us in order to conduct the facility's walkthrough.

2.1 Facility Physical Description And Operation

Patheon Puerto Rico Inc. is a manufacturing company located in Manati for approximately past 20 years[5]. The facility mainly manufactures a variety of OTC[6] solid doses[7] for human consumption. According to the information provided by the facility representatives, each client would determine the contract terms and necessity of their service. Additionally, it was explained that an overall summary of their manufacturing process would be from receiving the raw material to the packaging process[8]. Also, it was discussed that this facility consists of an approximately 110-acre[9] lot and their employees cover a 24/7 schedule.

2.2 Aerial Photograph

Figure 1: Patheon Puerto Rico Inc Location

[4] For additional information on this item, please refer to Section 4 of this Report.
[5] This information is accurate for Patheon. This facility was previously owned by another company.
[6] Acronym stands for Over the Counter.
[7] According to the information provided by the facility, the OTC manufacturing process (final solid tablet) would depend on each client (contract).
[8] It was explained that this process is on a case-by-case basis and would depend on the contract and terms with each client.
[9] According to information provided by the facility representatives, both buildings and lot are owned by Patheon Puerto Rico Inc.

2.3 SOLID AND HAZARDOUS WASTE GENERATION

According to the facility representatives, their main hazardous waste generation is lab waste and alcohol-related waste, and a 90-day hazardous waste accumulation area (HWAA) is available at the facility. The hauler company that provides pick-up services is Clean Harbor, and the last disposal was conducted on January 31, 2024. Also, I asked the facility representatives about their universal waste and used oil generation, handling, and/or disposal activities. According to them, they are currently generating both universal, such as fluorescent lamps, and batteries[10], and used oil. The hauler company for their universal waste is Clean Harbor, and the last disposal was conducted in the last trimester of 2023[11]. Meanwhile, for their used oil, Clean Harbor is also the hauler company that provides pickup services. According to them, the frequency of their used oil disposal activities is approximately twice per year.

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 the facility representatives with an orientation and information related to NRC, such as but not limited to the phone number.

3 FACILITY WALKTHROUGH

Just after the opening meeting, we started the facility walkthrough. Mr. Jaime and Mr. Rossy accompanied me during the facility walkthrough[12]. The areas inspected were (i) the 90-day Hazardous Waste Accumulation Area (HWAA), (ii) the Light Mechanical Shop Area, (iii) the Room M15 Washroom Area, (iv) the Maintenance Shop Area, (v) the Laboratory Area-Chemical Storage Q3 Area, (vi) the Laboratory Area – Chemical Storage 26 Area, (vii) the Laboratory Area – Chemical Storage Q5 Area, (viii) the Former Hazardous Waste Tanks Area, and (ix) the Paint Storage Area. The observations for the areas inspected are described below. Refer to Appendix 1 for pictures taken during the inspection.

3.1 90-DAY HAZARDOUS WASTE ACCUMULATION AREA (HWAA)

Description of the Area	This was the first area inspected. Located in the north area of the facility, the area was observed closed and locked. It consists of a concrete floor, which according to the facility representatives is considered a secondary containment itself[13], with a galvalume ceiling, metal columns; some of them corroded, and walls and a cyclone fence as a physical barrier. It was observed elevated from the facility's ground level[14]. In order to conduct the CEI inside, Mr. Rossy opened the area for us. Additional information is as follows.

[10] According to them, alkaline batteries.
[11] According to them, the last disposal for their fluorescent lamps was on October 19, 2023, and for the batteries, the last disposal was on December 13, 2023.
[12] Additional personnel joined us throughout the CEI.
[13] A valve was observed outside the building. At the time of the CEI, it was observed closed and locked.
[14] Approximately 1-foot ½ inches above the street level.

At the time of the inspection, this area was labeled as hazardous waste, has a no smoking label, a label that describes the PPE[15] required in order to access this area, and the emergency contact information[16]. I asked the facility representatives about the emergency equipment at this location. The emergency equipment available in this area was the following: an operational eyewash station[17], a fire extinguisher[18], a spill kit, a video surveillance system[19], and an operational alarm[20]. Additionally, a mainline phone was available. Likewise, I was notified that the personnel authorized[21] to access this area use two-way radio equipment, in addition to cell phones, that are allowed. I asked to conduct a test on their mainline phone[22]. They agreed to conduct the latter. As a result, Mr. Rossy tried to use the equipment, nevertheless, the latter was not operational. As part of the inspection of this area, we walked around the outside perimeter of the 90-day HWAA. Vegetative material was observed growing at one of the ceiling corners and a closed and locked valve was observed, as well.

At the time of the CEI, this area was almost empty[23], just two (2) containers and one (1) yellow shelf were observed. This area has available, yellow-painted squares on the floor in order to identify the container location. I asked about the area's container capacity, and Mr. Rossy told me that the maximum quantity of containers at this location is 30 containers (Picture #1). Additional information is as follows:

a. One (1) 55-gallon white plastic container with halogenado. At the time of the inspection, it was observed closed, labeled as hazardous waste, has a pictographic and/or indication of the hazard available, and was dated January 8, 2024. Also, it was observed almost empty, and the container appears to be in good condition (Picture #2).

b. One (1) 15-gallon[24] white plastic container with lab-waste basic. At the time of the inspection, it was observed closed, labeled as hazardous waste, has a pictographic and/or indication of the hazard available, and was dated January 24, 2024. The container appears to be in good condition (Picture #3).

c. Inside the yellow shelf, a 15-gallon[25] yellow plastic bag with paños HPLC[26] no halogenado was observed. At the time of the inspection, it was observed closed, labeled as hazardous waste, has a pictographic and/or indication of the hazard available, and was dated February 1, 2023 (Picture #4). I asked Mr. Rossy about this, and he confirmed that it was a typo, and

[15] Acronym usually stands for Protective Personal Equipment.
[16] The facility's emergency contact number is X 4911.
[17] Information related to the last inspection conducted on this equipment was not available. Nevertheless, during the CEI, it was provided. The last inspection was conducted on January 31, 2024.
[18] The last inspection was conducted in January 2024.
[19] They told me that they included this feature as a result of a previous robbery situation in this area.
[20] A two (2) push button alarm was observed just at the side of the facility's emergency contact information.
[21] According to the facility representatives three (3) employees are authorized to access this area.
[22] The test was conducted around 11:25 am. As a result of this test, the facility representatives knew that the equipment was out of service. Just after, they called to notify this issue and to work with the latter.
[23] The last pick-up activity was conducted the day before the CEI.
[24] Approximately.
[25] Approximately.
[26] Acronym stands for High-performance liquid chromatography.

that the correct information was February 1, 2024. As a result, he promptly changed the label in order to include the correct date information.

During the inspection of these containers, I observed that a ground system is available to be used when needed. Also, some stains throughout the 90-day HWAA were observed wet and vegetative material through the 90-day HWAA was observed, as well. Likewise, I told the facility representatives that some areas of the galvalume ceiling were observed broken. Since some areas of the floor were observed wet, I asked the facility representative what was liquid was observed[27]. I was told that the broken ceiling permitted access to the rain and, that the day before the CEI, approximately 1-in of rainfall was experienced. Finally, I asked the facility representatives if there was a log available in this area. They replied that the latter was available, and it was provided for evaluation.

I told the facility representatives the following:

- *Maintenance and good housekeeping practices* – I discussed with the facility representatives the issue with the broken galvalume ceiling, the wet stains observed throughout the 90-day HWAA, as well as the vegetative material throughout the area, and the growing vegetative material at one of the area's galvalume ceiling corners.

- *Rusted columns* – We talked about the issue related to the corroded metal columns observed in the 90-HWAA and the potential issues that they could face as a result of it.

- *Broken galvalume ceiling –* We talked about the issues related to the broken galvalume ceiling and the issues that are currently being faced as a result of it.

- *Date –* Although it was confirmed that the date included in the yellow plastic bag was a typo, we discussed the importance of the correct date on the labels.

3.2 LIGHT MECHANICAL SHOP AREA

Description of the Area	This was the second area inspected and it is located in Building 501, at the center of the facility. Although this area was not scheduled to be inspected, I asked the facility representatives to provide access to this area. They agreed to provide access to this area. At first, the latter was identified as a light mechanical shop, but throughout the area walkthrough, it was confirmed that additional activities are being conducted in this area. Due to the size, and areas found at this location, the latter was subdivided into subareas. It is important to highlight that those observations, in some cases, were general as a result of the lack of aisle space and/or crowded areas. Here, Mr. Jose Prada, Facility Supervisor, and Mr. Ricardo de Leon, Electrician, joined us at the inspection. Additional information on the findings in this area is as follows.

[27] The liquid appears to be water with vegetative material and soil.

The inspection of this area started at the outside/rear area of Building 501, which was the first area reached from the facility walkthrough's route scheduled. For inspection purposes, I segregated the latter into two general areas: Building 501-Outside Subarea and Building 501-Inside Subarea. Additional information on each one is as follows:

3.2.1 BUILDING 501-OUTSIDE SUBAREA

According to the facility representatives, this is the contractor's area. Here, light mechanical works, housekeeping-related activities, and landscaping-related activities are conducted for the site. This area consists of an open, no-ceiling subarea with a concrete floor (Picture #5). In addition, this area boasts recycling and regular waste cubic yard containers. At the time of the inspection, three (3) cubic yard containers were observed (Picture #6). Information on each one is as follows:

a. Two (2) cubic yard[28] blue metal containers with paper and cardboard. At the time of the CEI, one of them was observed open, labeled and it was full[29]. The other was observed with a lid, nevertheless, it was not labeled.

b. One (1) cubic yard[30] green metal container with plastic bags that appears to have inside regular trash. At the time of the CEI, it was observed open, and it was full[31] (Picture #7).

Also, as part of the findings at this subarea, scrap metals were observed inside containers and throughout the subarea, as well as wood pieces, and garbage. Non-operational equipment, such as two (2) forklifts and one (1) tractor were observed. At the time of the inspection, and according to the information provided by the facility representatives, the latter were not in use. Nevertheless, underneath the tractor, a spill that has been controlled using absorbent material was observed[32] (Picture #8). Just at the side, an open container, not labeled and with an unknown content was observed (Picture #9). Moreover, since the subarea did not have a ceiling, some of the concrete floor and containers observed throughout it were observed with wet spots or even with an unknown liquid[33] collected inside. I notified the facility representatives that, at least, one of the containers observed, there was what appeared to be mosquitoes' larvae[34] (Picture #10). The facility representatives confirmed this observation.

I told the facility representative the following:

- *Maintenance and good housekeeping practices* – I discussed with the facility representatives the issues observed such as, but not limited to the overflown cubic yard containers, scrap metal throughout the subarea, open containers, unlabeled containers,

[28] According to the facility representatives.
[29] Content was even going outside the container.
[30] According to the facility representatives.
[31] Content was even going outside the container.
[32] I asked about the time of this event or when occur. Information on the latter was not available at the time of the inspection. Nevertheless, the facility representatives agreed that this appears to be a controlled spill event.
[33] The liquid appears to be water.
[34] For additional information related to this item, please refer to: https://www.epa.gov/mosquitocontrol/mosquito-life-cycle

lack of maintenance of this subarea, lack of knowledge from facility personnel related to this area, among others.

3.2.2 BUILDING 501-INSIDE SUBAREA

Once inside the building, I observed that the latter was already segregated into various subareas. As an overall observation, lack of maintenance and/or housekeeping practices were observed throughout this Building. As a result, I asked the facility representatives if they knew the current conditions of this subarea (Picture #11, through Picture #14)[35]. They replied that they were not aware of the current subarea's conditions[36]. Just after, we walked through Building 501 in order to document the current conditions of it.

Overall, as part of the walkthrough, we observed various containers that, at the time of the CEI, the facility representatives did not know if these were products and/or if they would be disposed of. Also, some of the containers were not labeled. In addition, various of those containers were observed rusted, slightly opened, with dents, and with spider webs.

Spent batteries were also observed throughout the subarea, especially in one (1) location, which was a wood pallet (Picture #15). The following information is related to the ones observed in the wood panel[37].

a. Eight (8) spent batteries were observed above a wood panel. At the time of the inspection, none of them were labeled, and/or the area was identified. Some of them were not observed in good condition[38] and with materials above them.

In addition, one (1) Duracell[39] battery was observed above the batteries already described. This section of the subarea was crowded with unlabeled containers, vegetative material, scrap metal within open containers, plastic containers[40] wood panels, among others. This made it tough to conduct the inspection activity as a result of the lack of aisle space. Also, additional equipment was observed at this subarea. I asked the facility representatives about them, and they replied that some of them were not operational, while others appeared to be in use[41].

Also, I observed various sinks throughout the subarea. The conditions of these, at the time of the

[35] In important to highlight that this question was raised at the beginning of the area walkthrough. All the observations registered in this section were not made by the time this question was asked.
[36] I explained to them that the reason to ask them is that the fire extinguishers observed through this subarea state that they were inspected in January 2024. They replied that they (EHS Personnel) did not receive information related to this subarea. Facility staff, but from the utility section, are the ones that conduct the fire extinguisher and eyewash station emergency equipment inspection, not them.
[37] The observations related to this item are general as a result of the conditions of the subarea and due to the lack of aisle space during the inspection.
[38] Appears to be corroded.
[39] Small.
[40] Not labeled. Unknown if they were full or empty.
[41] Nevertheless, this statement was not confirmed or denied by the facility representatives. At the time of the CEI, their current conditions were unknown.

inspection, were dirty, with dust, and/or with rags impacted with an unknown. Aerosol cans were also observed through the walkthrough (Picture #16). I asked the facility representatives about them; and how they handled, stored, and disposed of the latter. Mr. Rossy told me that they have two (2) areas identified where aerosol cans are currently stored. Nevertheless, it was confirmed that none of these areas were located in this subarea. Hence, I asked again about the ones observed in this subarea. The facility representatives told me that they appeared to be in use.

Likewise, I observed some open containers with scrap metal (Picture #17). At the time of the inspection, those containers did not have a label. Moreover, scrap metal was observed to overflow the containers and throughout the subarea. Scrap metal was also observed in some equipment[42] throughout the subarea, as well (Picture # 18 and Picture #19).

Moving on through this subarea, another location with wood panels, additional equipment, desk, and electronic equipment was observed. Additionally, an unidentified area, with various 5-gallon white plastic containers was observed (Picture #20). I asked the facility representatives about these, and Mr. Prada told me that those containers were paint that is being used as a result of maintenance activities that currently were being conducted at the facility. Nevertheless, information related to which containers were products and which ones were not was not confirmed[43]. Additionally, just at the inside of the paint containers area, a wood panel with approximately six (6) blacktop repair bags was observed (Picture # 21). Information related to this material[44] was not able to be gathered as part of the CEI.

Another subarea was identified during the walkthrough. This one was identified by the facility representatives as the contractor's area. It consists of a wood box-like container which, according to the facility representatives, has materials inside that are used by the facility contractors' personnel. Just at the side of this subarea, additional open, corroded containers, open cardboard boxes, and plastic containers, such as power aid container, were observed (Picture #22).

By this point of the subarea walkthrough, it was confirmed that we were heading to the central location of Building 501. The facility representatives told me that they were currently using the latter as a warehouse. At the time of the inspection, I observed the following: no operational equipment; some with scrap metal inside, facility's record-keeping files, electronic equipment, air filters, and metal doors, among others. It was not clear nor confirmed by the facility representatives the purpose of this warehouse[45] (Picture # 23 and Picture #24).

Moving on to the rear part of this location, an electrical area[46] was identified. It consists of a hallway-type area with metal shelves with various materials, such as but not limited to cables, cardboard boxes

[42] The facility representatives did not know if the equipment was operational.
[43] This also includes information related to the containers: if they were empty, full, and/or in use.
[44] Information related to them, including but not limited to time at this location, current conditions, handling, storing and/or disposal activities were not able to be gathered during the CEI.
[45] The facility representatives could not be precise if the warehouse is used to store the facility's new/raw materials, to store equipment that was no longer operational, to store waste to be disposed of, and/or as a record-keeping area.
[46] This name was provided by the facility representatives.

fluorescent lamps[47], among others. I asked the facility representatives about those materials, and they replied that they were in use (Picture # 25 to Picture # 28). Just in front of the metal shelves, various open and broken card boxes were observed with what appeared to be fluorescent lamps[48]. The latter were observed to overflow the boxes (Picture #29). I asked the facility representatives about them, and they replied that those lamps would be used[49]. In this location, I also observed metal scrap in the surroundings, wood panels, chairs, and a broken desk, among others (Picture #30). In addition to that, one round cardboard box was observed. I asked the facility representatives to open it for me. Once opened, inside, I observed that it was full of spent fluorescent lamps, even broken sections of spent fluorescent lamps[50] were observed. Moreover, an additional broken fluorescent lamp[51] and three (3) additional spent fluorescent lamps were observed outside the round cardboard box (Picture # 31). At the time of the CEI, this round cardboard box was observed closed, not labeled as Universal Waste, not dated, and was not under the operator's control. As part of the electrical area, one (1) red plastic box full of spent ballast was observed below a hose (Picture #32). In addition, multiple ballasts were observed throughout all the metal shelves. Although some of them were identified by the manufacturer as "NO PCB", the facility representatives and I were unable to confirm that all of the observed[52] were, indeed, "NO PCB".

At this time, Mr. De Leon, Electrician joined us at the inspection. According to the facility representatives, he is in charge of this area. As a result, I asked him about the latter and he provided the following information:

- U-Type fluorescent lamps observed at the metal shelves – those are being used, but they are still functional. As a result, it was stored for future use (spare).

- Ballasts observed at the red plastic box and throughout the area – those are being stored for use. I asked him how long those are being stored. He replied that approximately three (3) years.

- Fluorescent lamps inside the round cardboard box and the ones outside the latter – Those have been at this location for approximately one (1) year. According to him, they were used, but they are good to be used.

- Open and broken cardboard boxes with fluorescent lamps overflown the latter – According to him, those are LED lamps, and they are new to be used.

Just after, we continued our subarea walkthrough, and we found another section that was identified as ERT Storage ENGI-47. At the time of the inspection, it was closed. The facility representatives opened it for me in order to conduct the inspection. According to them, this area is used to store the facility's

[47] Approximately five (5) U-type fluorescent lamps
[48] Various sizes. According to them, 4-foot, 6-foot and 8-foot, respectively.
[49] Various broken cardboard boxes were observed. As a result of the conditions of this area, at the time of the inspection, we are unable to identify a quantity of broken cardboard boxes available.
[50] Reference on how to handle broken spent lamps at 40 CFR 273.13(d)(2).
[51] According to the facility representatives, this broken lamp was a new one. After the observation was made, it was removed from this subarea and transferred to the disposal area.
[52] Due to the lack of aisle space in this area, I was not able to confirm that all ballasts observed were the ones available in this area.

emergency equipment. Although it appears that the materials observed here are products, due to the lack of aisle space observed, information related to hazardous waste, universal waste, and/or used oil was not able to be gathered (Picture #33).

Finally, we walked towards the Building 501 entrance and we found the Used Oil Subarea. According to the facility representative, this subarea collects the used oil generated at this location (Picture #34). Inside, I observed the following:

a. One (1) 55-gallon white plastic container with used oil. At the time of the inspection, it was open, labeled as non-hazardous waste Aceite Usado, almost half full, and it was placed above a secondary containment. Additionally, the top of the container was observed dirty. I asked the facility representatives how they determined that this used oil was a non-hazardous waste. They replied that they made the determination by knowledge.

b. A 15-gallon[53] blue plastic container was observed. It was identified as the spill kit.

c. One (1) 30-gallon[54] blue plastic container with non-hazardous waste with Pad usados. At the time of the inspection, the container was observed open, labeled as non-hazardous waste, and almost full. Inside the latter, I observed a mix of pad usados, with vegetative material, regular waste, and plastic containers, among others (Picture #35).

d. One (1) 30-gallon[55] blue plastic container with filtros usados. At the time of the inspection, it was observed open, labeled as non-hazardous waste, and almost empty.[56]

I told the facility representatives the following:

- *Maintenance and good housekeeping practices* – I discussed with the facility representatives the issues observed throughout this area. This item includes but is not limited to no-operational equipment at this subarea, scrap metal throughout the subarea, lack of information related to items observed at this subarea, and the controlled spill with absorbent material observed below the tractor, among others.

- *Universal Waste* – Lack of information about the storage time, lack of labels, lack of date, condition of the container, and the condition of the content, such as broken fluorescent lamps, among others. This item included but is not limited to the issues observed with the fluorescent lamps, aerosol cans, and electronic equipment, among others.

- *Containers requirements and containers conditions* – It was discussed during the subarea that open containers, containers rusted, with dents, unlabeled, without pictographic labels and/or indication of the hazard, without date, among others, were observed.

[53] Approximately.
[54] Approximately
[55] Approximately
[56] Approximately five (5) filters.

- *Used Oil Determination –* According to them, this determination was made by knowledge. We discussed that additional information on this item would be requested. This item also included but is not limited to the container identified as used oil rags, but the content was not the one identified at said container.

- *Paint containers –* Accurate information related to those containers was not properly gathered during the inspection.

- *Spent batteries -* Accurate information related to those spent batteries was not properly gathered during the inspection.

- *Scrap metal –* It was observed throughout the subarea in open containers and overflown containers, in non-operational equipment, among other locations.

- *Aisle space –* We discussed the aisle space issues found in the Building.

- *Additional information –* I told the facility representatives that additional information related to this subarea would be requested. They agreed to provide it at a later date.

3.3 ROOM M15 WASHROOM AREA

Description of the Area	This was the third area inspected. Located at Building 201, this area is where the manufacturing equipment is cleaned. Special gowning was needed in order to get access to this area. At the time of the inspection, two (2) employees were cleaning at the rear area of the room. Additional information in this area is as follows.

Here, two (2) yellow shelves, identified by the facility representatives as SAAs, were observed (Picture # 36). Additional information on each shelf is as follows:

a. One (1) 35-gallon[57] blue plastic container with paños con alcohol. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, has a pictographic label and/or indication of the hazard available, and grounded. Also, the container appears to be in good condition and the shelf itself was labeled as flammable and rags with alcohol (Picture #37).

b. One (1) 55-gallon white plastic container with alcohol waste 70%. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, has a pictographic label and/or indication of the hazard available, and grounded. The container appears to be in good condition and the shelf itself was labeled as desperdicio líquido de alcohol isopropilico (Picture #38).

[57] Approximately

Finally, I asked the facility representatives about both areas. According to them, both SAAs are under the operator's control, and both wastes are generated at this location.

3.4 MAINTENANCE SHOP AREA

Description of the Area	This was the fourth area inspected and it is located inside Building 201. According to the facility representatives, this area is where the universal waste and hazardous waste are stored, and it is also used as a stock room[58]. They told me that the universal and hazardous waste stored at this location was generated at the manufacturing area. Additional information on the latter is as follows.

At the time of the inspection, six (6) containers were observed (Picture #39). Information on each one is as follows:

a. One (1) 30-gallon[59] blue plastic container with aerosols. According to the facility representatives, this is a SAA. The container in this area was observed closed, labeled as hazardous waste, and has a pictographic label and/or indication of the hazard available.

b. One (1) 35-gallon[60] blue plastic container with U-Type lamps. At the time of the inspection, the container was observed closed and had the universal waste label available. Nevertheless, the date was not available.

c. One (1) cardboard box with 4-feet fluorescent lamps. At the time of the inspection, the container was observed closed and had the universal waste label available. Nevertheless, the date was not available.

d. One (1) 35-gallon[61] blue plastic container with bulbs. At the time of the inspection, the container was observed closed and had the universal waste label available. Nevertheless, the date was not available.

e. One 35-gallon[62] blue plastic container with ballasts. At the time of the inspection, the container was observed closed and had the universal waste label available. Nevertheless, the date was not available.

f. One (1) 15-gallon[63] blue plastic container with batteries. At the time of the inspection, the

[58] For manufacturing pieces that are stored in this area.
[59] Approximately.
[60] Approximately.
[61] Approximately.
[62] Approximately.
[63] Approximately.

container was observed closed and had the universal waste label available. Nevertheless, the date was not available.

Likewise, two (2) additional containers were observed in front of the containers described above. Additional information on each one is as follows:

g. One (1) 55-gallon white plastic container with Aceite usado. At the time of the inspection, the container was observed closed, labeled as non-hazardous waste, and was placed above a secondary containment (Picture #40).

h. One (1) 35-gallon blue plastic container was observed labeled as aceite usado, nevertheless, when opened, rags impacted with used oil and a hose inside a plastic bag were observed inside. I told the facility representatives about this issue. At the time of the inspection, the container was observed closed, labeled as non-hazardous waste, and above a wheel-like round base (Picture #41).

I told the facility representatives the following:

- *Date* - I explained to them that the date is required by RCRA Regulation to be available at each container. This observation was made in almost all the containers available at this location.

- *Content inside the container* – I told the facility representative about the container that, at the time of the inspection, had a different content than the one labeled in the container.

3.5 LABORATORY AREA-CHEMICAL STORAGE Q3 AREA

Description of the Area	This was the fifth area inspected and it is located at Building 401. Inside, two (2) yellow shelves were observed (Picture #42). Both were identified as flammable and Full HPLC Safety Cans with no halogenated waste. Additional information on each one is as follows.

a. One (1) yellow shelf labeled as flammable and Full HPLC Safety Cans no halogenated waste was observed. Inside, the latter had nine (9) 2.5-gallon[64] white plastic containers. At the time of the CEI, all of them were full[65], closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard, and appeared to be in good condition (Picture # 43). I asked the facility representatives where did this waste was generated. They told me that it was generated at the HPLC Laboratory Area. As a result, I asked them if this shelf was considered a SAA. They replied that is not a SAA, that is an intermediary area between the HPLC generation area and the 90-day HWAA.

[64] Approximately.
[65] According to the facility representatives.

b. One (1) yellow shelf labeled as flammable and Full HPLC Safety Cans no halogenated waste was observed. Inside, four (4) 2.5-gallon[66] white plastic containers were observed. At the time of the CEI, all of them were full[67], closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard, and appeared to be in good condition (Picture #44). I asked the facility representatives where did this waste was generated. They told me that, as previous information shared, it was generated at the HPLC Laboratory Area. As a result, I told them about the same issue, if this shelf is considered a SAA. They replied that all the containers observed are transferred daily from here to the 90-day HWAA. Mr. Rossy told me that usually, this action occurs every morning[68]. I told them that additional information on this matter would be requested. Nevertheless, during the CEI in this location, information related to the facility SOP Waste Management QC Lab document was provided. The latter considered both shelves as SAA. The document identified them as SAA Room Q3- HPLC reservoir waste.

Likewise, I asked the facility representatives how they do they store the facility's laboratory reactives. They replied that they store them by compatibility.

Additionally, I observed two (2) plastic carts with empty containers[69] [70] I asked them about the latter, and they told me that these would be recycled with Reciclaje del Norte, and they were rinsed at the hood that is located at the HPLC Laboratory Area. This subarea was identified as Empty HPLC Safety Cans (Picture #45). At the time of the inspection, five (5) 5-gallon white plastic containers were observed, where one (1) of them was empty. Also, all of them were observed labeled as hazardous waste and each one had a pictographic label and/or indication of the hazard. I asked the facility representatives about them, and they replied that, as previous containers observed on the shelves, they would also be transferred from this location to the 90-day HWAA.

I told the facility representatives the following:

- *SAAs* - During the CEI at this location, the facility representatives were not aware/properly unaware that both shelves were considered SAA, as indicated in the SOP Waste Management QC Lab document. As a result, conflicting information and/or misinformation was provided during the inspection.

3.6 LABORATORY AREA – CHEMICAL STORAGE 26 AREA

Description of the Area	This was the sixth area inspected. Located in Building 401, inside the Chemical Storage 26 room. A container was observed inside the area. Additional information on the latter is as follows.

[66] Approximately.
[67] According to the facility representatives.
[68] Mr. Rossy explained that, since he was escorting me through all the CEI, he was not able to transfer those containers to the 90-day HWAA.
[69] According to the facility representatives.
[70] General description: Cristal, Various sizes.

Here, one (1) 35-gallon[71] blue plastic container with HPLC vials was observed closed, labeled as hazardous waste, and has a pictographic label[72] and/or indication of the hazard available. Additionally, it was observed half full, the container appears to be in good condition, and the area was identified (Picture # 46). I asked the facility representatives about the hazardous waste generated at this location. They replied that the latter is generated in this room and from here is then moved to the facility's 90-day HWAA.

3.7 LABORATORY AREA – CHEMICAL STORAGE Q5 AREA

Description of the Area	This was the seventh area inspected. It is located in Building 401, inside the Chemical Storage Q5 room. According to the facility representatives, tests on raw materials are conducted at this location. Here, one (1) hood and HPLCs equipment were observed (Picture #47). At the time of the CEI, the area was undergoing construction activities[73]. Mr. William Rosario, Lab Manager, Ms. Rosa Rosario, Supervisor, Ms. Erica Roman, Supervisor, and Mr. Oscar Colón, Supervisor, joined us at the inspection. Additional information on the latter is as follows.

In this area, a hood identified as FH4 was observed[74]. Inside I observed the following:

a. One (1) 5-gallon[75] red plastic container with halogenated. At the time of the inspection, it was observed open, labeled as hazardous waste, and a pictographic label and/or indication of the hazard was available. The latter was observed above a secondary containment. I asked about the hazardous waste, and I was told that the latter is then moved from here to the 90-day HWAA.

b. One (1) 5-gallon white plastic container with no halogenated. At the time of the inspection, it was observed closed, labeled as hazardous waste, and a pictographic label and/or indication of the hazard was available. The latter was observed above a secondary containment. I asked about the hazardous waste, and I was told that the latter is then moved from here to the 90-day HWAA.

c. One (1) 2.5-gallon white plastic container with acid waste. At the time of the inspection, it was observed closed and labeled as hazardous waste. Nevertheless, a pictographic label and/or indication of the hazard was not available. It was observed above a secondary containment, and I was told that the latter is then moved from here to the 90-day HWAA.

[71] Approximately.
[72] Flammable liquid.
[73] I was told that phase 1 of this construction activity has been completed, nevertheless, they are preparing the area to continue with phase 2 construction activities.
[74] This hood additionally has available the following identification (HOD-2793).
[75] Approximately.

Likewise, in this area, I observed an eyewash station equipment. The last inspection for the latter was conducted on January 28, 2024. Additionally, I was told that approximately 28 HPLC equipment are available for Building 401. According to them, all of them are functional and operational. I observed the following:

d. Equipment identified as UPLC#LC_055 and UPLC#LC_054. At the time of the inspection, 2.5 white plastic containers were observed connected to the equipment. They were labeled as hazardous waste, a pictographic label and/or indication of the hazard was available, a secondary containment was available, and the area was observed in good condition (Picture # 48). I asked the facility representative about the hazardous waste generated at this location. They told me that from this point is moved to the yellow shelve observed in the Q3 area and then moved to the facility's 90-day HWAA.

I told the facility representatives the following:

- *Open containers –* Although during the CEI the container was closed by the facility personnel, I reminded them that if hazardous waste was not poured at the latter, the container must be closed at all times.

- *Pictographic label –* I told them that in order to comply with RCRA Regulation, at the time of the inspection, all containers identified as hazardous waste need to have a pictographic label and/or indication of the hazard in place.

3.8 FORMER HAZARDOUS WASTE TANKS AREA

Description of the Area	This was the eighth area inspected, it is located at the center area of the facility. The latter, Aka[76] the CBA[77], was observed with physical barriers that avoid access inside the area since construction activities are being conducted[78]. As a result, the CEI was visually conducted from the outside of the Former Hazardous Waste Tanks Area. Additional information on the latter is as follows.

At the time of the inspection, ongoing construction activities were not observed since construction activities were completed by the day. This area consists of a high galvalume ceiling with part concrete, and part soil floor. It was observed with a yellow band that works as a physical barrier in order to control the entrance to the latter (Picture # 49 and Picture #50). During the last inspection conducted at the facility[79], this area was identified as the Former Hazardous Waste Tanks Area and, by that time, it was explained that *their hazardous waste tanks are no longer in service since the last time those hazardous waste tanks were in operation was November-December 2020. Currently, they are not in*

[76] Acronym stands for also known as.
[77] Acronym stands for Carbon Bed Adsorption Area.
[78] At the time of the CEI, construction activities and construction workers were not observed. Nevertheless, the area was "closed" as a result of construction activities. This was around 5:32 pm.
[79] The multiple days Offsite Compliance Monitoring (OfCM) activity was finalized on February 9, 2022.

use. The latter consisted on two (2) steel hazardous waste tanks that were observed inside a dike.[80] I asked the facility representatives, in order to confirm if this was the same area inspected in 2022 and if this was the Former Hazardous Waste Tanks Area. They confirmed that this was the same area inspected. As a result, I referred to the information provided as part of the 2022 closing meeting, which discussed information related to these hazardous waste tanks, such as but not limited to the future use of the tanks[81] [82] and, if applicable, the hazardous waste tank's closure.

Finally, I told the facility representatives that additional information related to this item would be requested. They agreed to provide it at a later time.

3.9 PAINT STORAGE AREA

Description of the Area	This was the last area inspected and it is located outside Building 501. I observed a metal cage-like area identified as Paint Storage Area. Inside, two (2) containers were observed. Additional information is as follows.

At the time of the inspection, this metal-like cage area was observed closed and locked, had a cyclone fence as a physical barrier, and was located below a concrete high ceiling[83]. Mr. Rossy opened the area for me in order to conduct the inspection. Inside, two (2) containers were observed (Picture #51 and Picture #52). Additional information on each one is as follows:

a. One (1) 55-gallon white plastic container with paint (water base). At the time of the inspection, the container was closed, grounded, labeled as non-hazardous waste, approximately ½ full and the container appeared to be in good condition. I asked the facility about the non-hazardous waste determination. Mr. Rossy replied that they made the determination by knowledge and that this area is a non-hazardous waste SAA.

b. One (1) trash can-like container was observed labeled as "Desperdicio de pintura". I asked Mr. Rossy about this container, and he replied that this container is not from them, is from the contractors.

Additionally, a spill kit was available inside this area.

I told the facility representatives that additional information related to this area would be requested. They agreed to provide it at a later time.

[80] Information in italics was extracted and gathered as part of the OfCM conducted in February 2022. It was included as a past reference of the area.
[81] Letter dated and sent, via email, on February 18, 2022, provides information related to the future plans of those hazardous waste tanks. For additional information on this item, please refer to Attachment IV of this Report.
[82] This is in order to comply with 40 CFR 262.17(a)(8)(iii), which states the requirements of closure performance for container, tank systems and containment building waste accumulation units.
[83] This high ceiling is provided by the Building 501 per se.

4 DOCUMENTS REVIEW

I explained to the facility representative that, as part of the CEI activities, an evaluation of documents would be conducted. I asked them for the following documents for review: (1) biennial report (2) HWAA inspection information, (3) job description, (4) training records and presentation, (5) contingency plan, (6) waste minimization plan, and (7) manifests[84]. Ms. Afanador, Ms. Torres, Mr. Jaime, and Ms. Herrero provided the documents and stayed with me to answer any questions. This evaluation was conducted after the facility walkthrough. All the documents requested were available for review. Information related to each document is presented below:

Documents Requested	Requested during CEI	Available during CEI?	**Description**
1. Biennial Report	YES	YES	The Biennial Report document was available for review.
2. HWAA inspection information	YES	YES	The document was provided for evaluation.
3. Job Description	YES	YES	Two (2) documents were provided for evaluation.
4. Training Records	YES	YES	Training and presentation documents were available for review.
5. Contingency Plan	YES	YES	The document was provided for evaluation.
6. Waste Minimization Plan	YES	YES	One (1) document was provided for evaluation.
7. Manifests	YES	YES	The last three (3) years of manifest were available for review.

4.1 BIENNIAL REPORT

The document was provided for review. It was certified by Mr. Luis Lozada, EHS Manager[85], on February 25, 2022, and submitted before the due date of March 1st, 2022. The document includes information related to the facility's NAICS information[86], the location of the facility, and information

[84] This request was done as part of the Opening Meeting. For additional information on this item, please refer to Section 2 of this Report.
[85] Mr. Lozada is no longer working at the facility.
[86] For additional information on this item, please refer to the first page of this Report.

related to the document's certification.

4.2 HWAA Inspection Information

According to the information gathered, this inspection is usually conducted on Tuesdays[87] [88], and two (2) employees are authorized to conduct said inspections[89]. After evaluation, it seems that the facility is complying with the 7-day timeframe.

4.3 Job Description

The first document provided for review was for the EHS Technician II. The last modification date was on June 23, 2023. At the time of the inspection, the document had the hazardous waste component available. Additionally, the EHS Specialist II job description was also provided for evaluation. The last modification date was on September 26, 2023, and the hazardous waste component was available at the latter, as well.

4.4 Training Records

Information and presentation related to the RCRA Annual Refresher were provided by the facility representatives. According to the information gathered, this training was provided by Compliance Resource, Inc[90]. in May and October 2023, respectively. Ms. Afanador was certified in May 2023, while Ms. Torres, Mr. Jaime, and Mr. Rossy were certified in October 2023.

4.5 Contingency Plan

As part of the document review section, the latter was requested and confirmed that was available to be evaluated at the facility. The last revision was dated in 2024. It was certified by Mr. Juan Polanco, Senior Director and General Manager on December 14, 2023, while the last document's certification was conducted by Mr. Hector Macias, on January 11, 2024.

The document includes the distribution of the first responders plan delivery and coordination agreements narrative, the updated information related to the site emergency management team, the evacuation plan narrative with the evacuation map and routes[91], and the emergency equipment list. Additionally, although the first responders' letters[92] and a quick reference guide[93] were available for review, those letters were related to the 2020 Contingency Plan document, and the quick reference

[87] As per facility internal protocol, since September 2023, they have been conducting inspections twice per week. When occurred, usually are conducted on Tuesdays and Thursdays.
[88] According to information gathered during the CEI, only two (2) inspections were conducted in June 2023. I asked about this issue and the facility representatives told me that the lack of inspections during this month was a result of personnel turnovers.
[89] According to the information gathered, the authorized personnel are Ms. Torres and Ms. Afanador.
[90] Ms. Rosario Jimenez Rivera provided the 4.0 hours of training. The latter is provided annually and includes a 20-question test.
[91] This information was available in the Appendix D of the Plan.
[92] Additional information on this item was requested since the Plan was updated in 2024. The facility representatives would provide additional information is a later date.
[93] The document provided was dated in 2022.

guide was for a previous version (2022). I confirmed with the facility representatives that a quick reference guide is not available for the 2024 Contingency Plan version.

I told the facility representatives that, after evaluation of the documents, the document lacks the following: the 2024 first responders' letters, the quick reference guide, the facility's equipment description, location, outline, and capabilities, and emergency contact information. As part of the closing meeting discussion, it was confirmed that the facility's emergency contact information was available. Finally, I told the facility representatives that the latest document, dated 2024, needs to be reviewed since page #15 referred to the hazardous waste tanks. As part of the information gathered during the inspection conducted at the facility, it was confirmed that this area no longer exists.

4.6 WASTE MINIMIZATION PLAN

The last version of the plan was in October 2022. The latter includes information related to the general facility's background, waste minimization team, waste minimization goals, options, scope, and objectives. The latter also includes figures, flow charts, graphs, procedures, and tables with the facility's waste minimization-related information.

4.7 MANIFESTS

The timeframe evaluated was from January 19, 2021, to January 31, 2024. Mr. Rossy[94], Mr. Migdoel Perez[95], Mr. Luis Lozada[96], Mr. Justo Martinez[97], Mr. Elizomar Ramos,[98] and Ms. Yadira De Jesus[99] were the representatives who signed during the mentioned timeframe. According to the information gathered during the CEI, each representative was certified by the time each one signed the manifests. Almost all manifests evaluated were observed closed[100], signed, and appeared to comply with the 45-day timeframe. Nevertheless, it was discussed with the facility representatives that one (1) manifest, from 2023, identified as 018202446 FLE and signed on 12/13/2023, did not have the returned signed sheet available. In order to review it, the facility representatives accessed the Clean Harbor System and confirmed that the latter was signed on January 3, 2024. A copy was provided and filed in their manifest binder.

5 CLOSING MEETING

On February 1, 2024, the closing meeting was conducted with the facility representatives, at the facility. I indicated that the purpose of the closing meeting was to inform them about the CEI observations raised[101]. Also, as part of the closing meeting, additional information was requested. Additionally, I told the facility representatives that additional information would be sent, via email, for

[94] Employee Certified (2021)
[95] Employee Certified (2021)
[96] Employee Certified (2021)
[97] Employee Certified (2021)
[98] Employee Certified (2022 and until the last signature in January 2023)
[99] Employee Certified (2023)
[100] Facility's last manifest generated, identified as 018206460 FLE, was signed on January 31, 2024 (the day before the CEI) and is currently under the 45-day timeframe.
[101] The information and observations shared at this meeting were already discussed as part/during the facility walkthrough.

their reference. The latter was sent, as agreed, on February 2, 2024. For more information, please refer to Section 7 and Section 8 of this Report.

6 POTENTIAL AREAS OF CONCERN

6.1 GENERATORS

On February 25, 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:

6.1.1 HAZARDOUS WASTE DETERMINATION AND RECORDKEEPING (40 CFR § 262 Subpart A)

i. According to 40 CFR § 262.11, which states that *"A person who generates a solid waste, as defined in 40 CFR 261.2, must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable RCRA regulations…."*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, accurate determinations for various open and closed containers, materials, open and closed cardboard boxes, shelves with materials, and areas crowded with unlabeled containers and cardboard boxes were not made. This includes, but is not limited to paint containers, containers with unknown content, scrap metal, spent batteries, aerosol cans, spent lamps, and ballasts, among others.

ii. According to 40 CFR § 262.17(a)(1)(iv)(A), which states that *"A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste."*

At the time of the inspection, the facility failed to comply with this requirement in the Laboratory Area – Chemical Storage Q5 Area. Here, one (1) 5-gallon red plastic container with halogenated was not closed and hazardous waste was not being poured by the time the observation was made.

6.1.3 PREPAREDNESS, PREVENTION, AND EMERGENCY PROCEDURES FOR LARGE QUANTITY GENERATORS (40 CFR § 262 SUBPART M)

iii. According to 40 CFR § 262.251, which states 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)."*

At the time of the inspection, the facility failed to comply with this requirement in the 90-day Hazardous Waste Accumulation Area (HWAA), in the Light Mechanical Shop Area, in the Maintenance Shop Area, and in the Laboratory Area-Chemical Storage Q3 Area. Additional information on each area is as follows:

Area	Observation
90-day Hazardous Waste Accumulation Area (HWAA)	- Lack of maintenance and/or housekeeping practices. - Rusted columns. - Broken galvalume ceiling.
Light Mechanical Shop Area	- The facility personnel acknowledged that they were not aware of the current conditions of this area. - Lack of maintenance and/or housekeeping practices - Unlabeled, open, and closed containers. Some with unknown content. - Unlabeled, open, and closed cardboard boxes. Some of them were broken. - Containers without a date. - Containers without a pictographic label and/or indication of the hazard. - Paint containers: unable to know what are new, in use or to be disposed of. - Mixed waste observed inside containers. - Crowded areas with containers and other materials, restraining the CEI activity (lack of aisle space). - Scrap metal in different areas, including but not limited to non-operational equipment.
Maintenance Shop Area	- Content inside the container did not match the label in the container.
Laboratory Area-Chemical Storage Q3 Area -	- The facility personnel did not know that this area was a SAA. The latter was confirmed with a facility SOP[102].

iv. According to 40 CFR § 262.261(e), which states that *"The plan must include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities."*

At the time of the inspection, the facility failed to comply with this requirement. Although the contingency plan has available the emergency equipment list, the emergency equipment description,

[102] Acronym stands for Standard Operating Procedure.

location, and capabilities were not available.

v. According to 40 CFR § 262.262(a), which states that *"The large quantity generator must submit a copy of the contingency plan and all revisions to all local emergency responders (i.e., police departments, fire departments, hospitals and State and local emergency response teams that may be called upon to provide emergency services). This document may also be submitted to the Local Emergency Planning Committee, as appropriate."*

At the time of the inspection, the facility failed to comply with this requirement. The documents provided for evaluation were generated as a result of the 2020 contingency plan document version. Nevertheless, during the inspection, the facility representatives were not able to provide the ones related to their latest version.

vi. 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. The facility representatives were not able to provide a quick reference guide related to their latest contingency plan document.

6.1.4 PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT (40 CFR § 273)

vii. According to 40 CFR § 273.13(a), which states that *"A small quantity handler of universal waste must manage universal waste batteries in a way that prevents releases of any universal waste or component of a universal waste to the environment…"*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, spent batteries were found throughout the area. Some of them showed evidence of leakage, spillage, or damage. In addition, the facility representatives were not able to provide information related to the handling, storing, and/or disposal activities related to the latter. In addition, those spent batteries were not observed in a closed, structurally sound container.

viii. According to 40 CFR § 273.13(d), which states that *"A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment…"*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, some spent fluorescent lamps were observed outside containers or packages that are structurally sound, while others were observed in broken and/or open cardboard boxes or even overflowed. Additionally, the RCRA Regulation establishes that any lamp that is broken must be placed in a container and the containers must be closed and structurally sound. Additionally, broken spent lamps were observed inside and outside cardboard boxes.

ix. According to 40 CFR § 273.13(e)(1), which states that *"Universal waste aerosol cans must be accumulated in a container that is structurally sound, compatible with the contents of the aerosol cans, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions, and is protected from sources of heat."*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, aerosol cans were observed throughout the area and a structurally sound container in order to store them was not available.

x. According to 40 CFR 273.14(a), which states that *"Universal waste batteries (i.e., each battery), or a container in which the batteries are contained, must be labeled or marked clearly with any one of the following phrases: "Universal Waste—Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies);"".*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, each battery and/or a container was not labeled or marked clearly with the phrases required in the RCRA Regulation.

xi. According to 40 CFR 273.14(e), which states that *"Each lamp or a container or package in which such lamps are contained must be labeled or marked clearly with one of the following phrases: "Universal Waste—Lamp(s)," or "Waste Lamp(s)," or "Used Lamp(s)"".*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, each spent lamp and/or a container or package was not labeled or marked clearly with the phrases required in the RCRA Regulation.

xii. According to 40 CFR 273.14(f), which states *that "Universal waste aerosol cans (i.e., each aerosol can), or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: "Universal Waste—Aerosol Can(s)," "Waste Aerosol Can(s)," or "Used Aerosol Can(s)""*.

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, each aerosol can and/or a container was not labeled or marked clearly with the phrases required in the RCRA Regulation.

xiii. According to 40 CFR 273.15(c)(2), which states that *"A small quantity handler of universal waste who accumulates universal waste must be able to demonstrate the length of time that the universal waste has been accumulated from the date it becomes a waste or is received… "*

At the time of the inspection, the facility failed to comply with this requirement in the Maintenance Shop Area. Here, five (5) of the six (6) containers observed in this area did not were marked or labeled with the date it became a waste, each individual item was not marked or labeled, and/or an inventory system to identify the earliest date each universal waste became a waste or was received was not provided.

6.1.5 PART 279—STANDARDS FOR THE MANAGEMENT OF USED OIL (40 CFR § 279)

xiv. According to 40 CFR 279.22(d)(3), which states that *"… Clean up and manage properly the released used oil and other materials…"*

At the time of the inspection, the facility failed to comply with this requirement in the Light Mechanical Shop Area. Here, a spill that had been controlled using absorbent material was observed underneath the tractor. Nevertheless, it was not cleaned up and properly managed since the absorbent material was still on the concrete floor.

6.2. CONDITIONS FOR EXEMPTION FOR A LARGE QUANTITY GENERATOR THAT ACCUMULATES HAZARDOUS WASTE – HAZARDOUS WASTE TANKS

As expressed in Section 3.8 of this Report, during the 2022 and 2024 inspections, information related to the former hazardous waste tanks located in this area was discussed and requested. As a result of the 2022, inspection request of information, on February 18, 2022, the facility representatives sent, via email, the document identified as Uso futuro del area de los tanques de RCRA - Item 5 of 10, which is a letter providing information related to the future use and/or potential actions of the facility related to those hazardous waste tanks[103]. Since at the time of the 2024 inspection activity, those hazardous waste tanks no longer exist, this information was raised again in order to obtain additional information related to the hazardous waste tanks and what action the facility has taken in order to comply with this requirement. As a result, I told the facility representatives that additional information related to the latter would be requested.

7 FOLLOW-UP ACTIONS

As expressed in Section 5 of this Report, an email to the facility representative was sent on February 2, 2024. The email included the due date in order to submit the information requested during the closing meeting[104] and included direct links that 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 that provide direct links for specific items for the RCRA Regulation were sent for their future reference. The facility representatives provided the information, as agreed, by the due date established[105].

7.1 INFORMATION PROVIDED TO THE FACILITY REPRESENTATIVES

Information Requested	Link	Enclosed
1. RCRA (Hazardous Waste)	√	
2. Summary of Requirements for Very Small Quantity Generators (VSQGs)	√	
3. Summary of Requirements for Small Quantity Generators (SQGs)	√	

[103] For additional information on this item, please refer to Attachment III of this document, identified as Future use area 90 days RCRA bulk tanks.
[104] Due date: February 16, 2024.
[105] The information was received, via email, on February 16, 2024.

4. Summary of Requirements for Large Quantity Generators (LQGs)	√	
5. Universal Waste	√	
6. Used Oil	√	
7. Aerosol cans	√	
8. Satellite Accumulation Areas	√	
9. Condition of containers	√	
10. Aisle space	√	
11. Alternative Standards for Episodic Generation	√	
12. National Response Center	√	
13. Hazardous Waste Generator Regulations Compendium	√	
14. Defining Hazardous Waste	√	
15. P-waste	√	
16. EPA Form 8700-12	√	√
17. One page with additional links that provide direct links for specific items for the RCRA Regulation	√	√
18. Managing your Waste, English Version		√
19. Como manejar sus desperdicios peligrosos, Spanish version		√

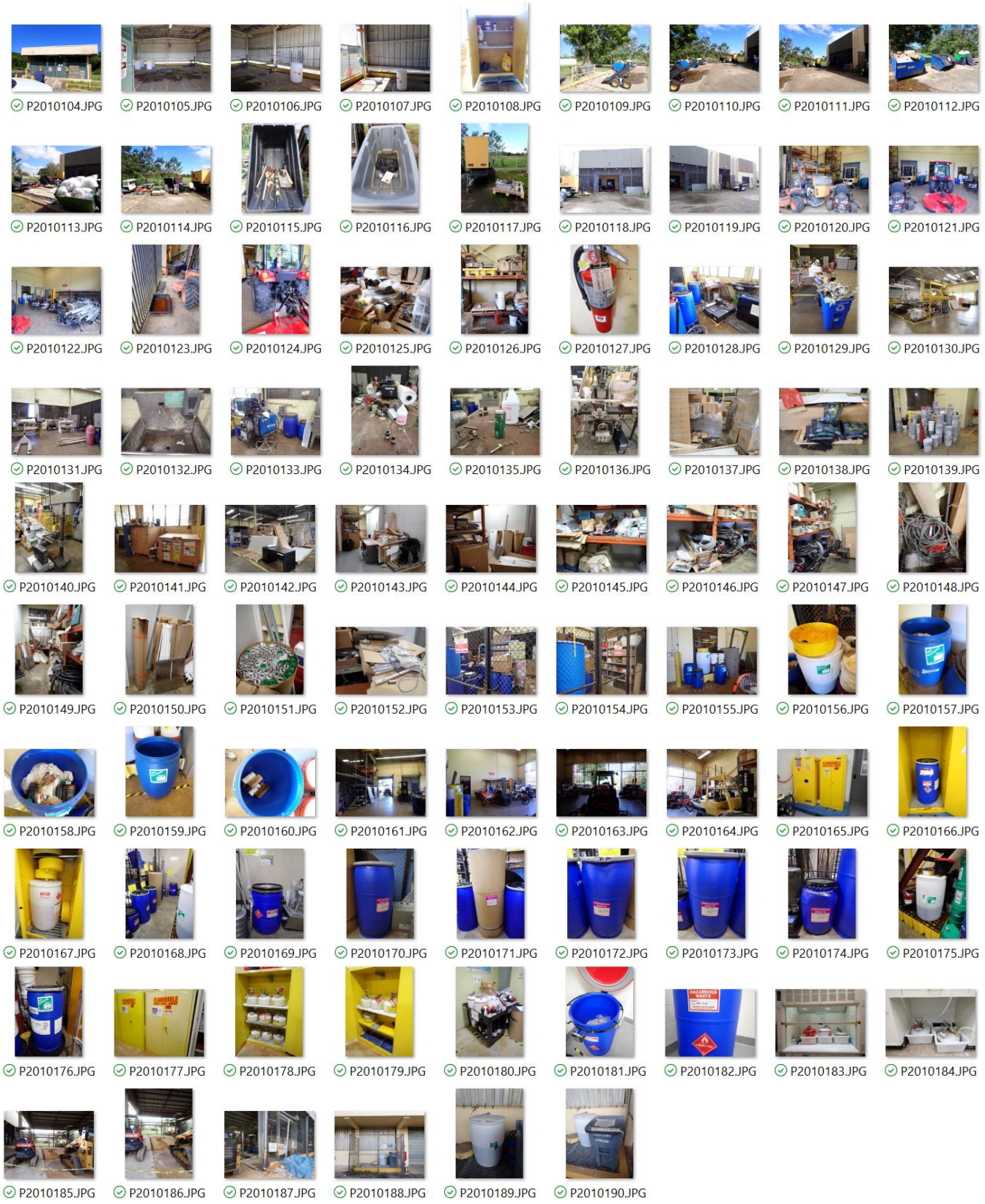
8 ATTACHMENTS

I. CAMERA ROLL

II. SITE PICTURES

III. OTHERS

ATTACHMENT I: CAMERA ROLL



ATTACHMENT III:

OTHERS

1. Email: 2024 02 02 Additional information and supporting documents related to February 1st, 2024 CEI conducted in Manatí Puerto Rico.
    a. Sent on 02/02/2024.

2. Email: 2024 02 16 Facility Response for info requested during closing meeting on 2024 02 01
    a. Sent on 02/16/2024.

3. Email 2022 02 18 Uso futuro del area de los tanques de RCRA - Item 5 of 10 (email per se)
    a. Sent on 02/18/2022.

4. Enclosure: Future use area 90 days RCRA bulk tanks (email document)
    a. Included in 02/18/2022 email.

Picture 1 — 90-day Hazardous Waste Accumulation Area (HWAA) - At the time of the CEI, this area was almost empty, just two (2) containers and one (1) yellow shelf were observed. Also, the area has available yellow-painted squares on the floor in order to identify the container location.

Picture 2 — 90-day Hazardous Waste Accumulation Area (HWAA) - One (1) 55-gallon white plastic container with halogenado. It was observed closed, labeled as hazardous waste, has a pictographic and/or indication of the hazard available, and was dated January 8, 2024.

Picture 3 — 90-day Hazardous Waste Accumulation Area (HWAA) - One (1) 15-gallon white plastic container with lab-waste basic. It was observed closed, labeled as hazardous waste, has a pictographic and/or indication of the hazard available, and was dated January 24, 2024.

Picture 4 — 90-day Hazardous Waste Accumulation Area (HWAA) - Inside the yellow shelf, a 15-gallon yellow plastic bag with paños HPLC no halogenado was observed. It was observed closed, labeled as hazardous waste, has a pictographic label available, and was dated February 1, 2023. The typo was addressed.

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	EPA ID: PRR000000836	Date: 2024-02-01	

Picture 5 — Light Mechanical Shop Area—Light mechanical works, housekeeping-related activities, and landscaping-related activities are conducted here. It is consist of an open, no-ceiling subarea with a concrete floor. In addition, this area boasts recycling and regular waste cubic yard containers.

Picture 6 — Light Mechanical Shop Area—At the time of the inspection, three (3) cubic yard containers were observed: two (2) cubic yard blue metal containers and one (1) cubic yard green metal container.

Picture 7 — Light Mechanical Shop Area— At the time of the CEI, the cubic yard green meta container was observed open, and it was full. Additionally, wood pieces, garbage and no operational equipment was observed.

Picture 8 — Light Mechanical Shop Area— At the time of the CEI, one (1) tractor was observed. According to the information provided by the facility representatives, the latter was not in use. Nevertheless, a spill that has been controlled using absorbent material was observed.

Picture 9 — Light Mechanical Shop Area— Just at the side of the tractor, an open container, not labeled and with an unknown content was observed.

Picture 10 — Light Mechanical Shop Area— Since the subarea did not have a ceiling, some of the concrete floor and containers observed throughout it were observed with wet spots or even with an unknown liquid collected inside.

Picture 11 — Light Mechanical Shop Area— Overall observation: a lack of maintenance and/or housekeeping practices throughout this Building, in addition to various containers that the facility representatives did not know if there were products and/or if they would be disposed of, some of them were not labeled, various of those containers were observed rusted, slightly opened, with dents, and with spider webs.

Picture 12 — Light Mechanical Shop Area—Overall observation: a lack of maintenance and/or housekeeping practices throughout this Building, in addition to various containers that the facility representatives did not know if there were products and/or if they would be disposed of, some of them were not labeled, various of those containers were observed rusted, slightly opened, with dents, and with spider webs.

Picture 13 — Light Mechanical Shop Area—Overall observation: a lack of maintenance and/or housekeeping practices throughout this Building, in addition to various containers that the facility representatives did not know if there were products and/or if they would be disposed of, some of them were not labeled, various of those containers were observed rusted, slightly opened, with dents, and with spider webs.

Picture 14 — Light Mechanical Shop Area—Overall observation: a lack of maintenance and/or housekeeping practices throughout this Building, in addition to various containers that the facility representatives did not know if there were products and/or if they would be disposed of, some of them were not labeled, various of those containers were observed rusted, slightly opened, with dents, and with spider webs.

Picture 15 — Light Mechanical Shop Area— Spent batteries were also observed throughout the subarea, especially in one (1) location, which was a wood pallet with eight (8) spent batteries above a wood panel.

Picture 16 — Light Mechanical Shop Area— Aerosol cans were also observed through the walkthrough.

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Picture 17 — Light Mechanical Shop Area— At the time of the CEI, some open containers with scrap metal did not have a label. Scrap metal was observed to overflow the containers and throughout the subarea, and in some equipment throughout the subarea, as well.

Picture 18 — Light Mechanical Shop Area—At the time of the CEI, some open containers with scrap metal did not have a label. Scrap metal was observed to overflow the containers and throughout the subarea, and in some equipment throughout the subarea, as well.

Picture 19 — Light Mechanical Shop Area— At the time of the CEI, some open containers with scrap metal did not have a label. Scrap metal was observed to overflow the containers and throughout the subarea, and in some equipment throughout the subarea, as well.

Picture 20 — Light Mechanical Shop Area— An unidentified area, with various 5-gallon white plastic containers was observed during the walkthrough.

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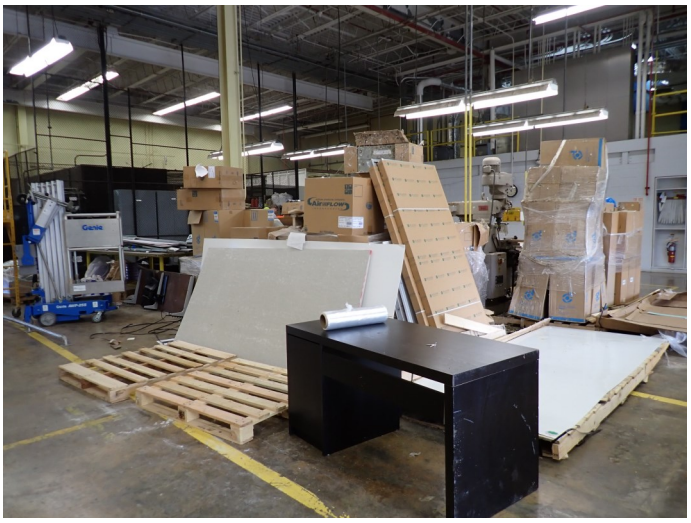
Picture 21 — Light Mechanical Shop Area—Just at the inside of the paint containers area, a wood panel with approximately six (6) blacktop repair bags was observed .

Picture 22 — Light Mechanical Shop Area—Just at the side of the contractor's subarea, additional open, corroded containers, open cardboard boxes, and plastic containers, such as power aid container, were observed.

Picture 23 — Light Mechanical Shop Area— This is the center location of Building 501. According to facility representatives, they are currently using the latter as a warehouse.



Picture 24 — Light Mechanical Shop Area—This is the center location of Building 501. According to facility representatives, they are currently using the latter as a warehouse.

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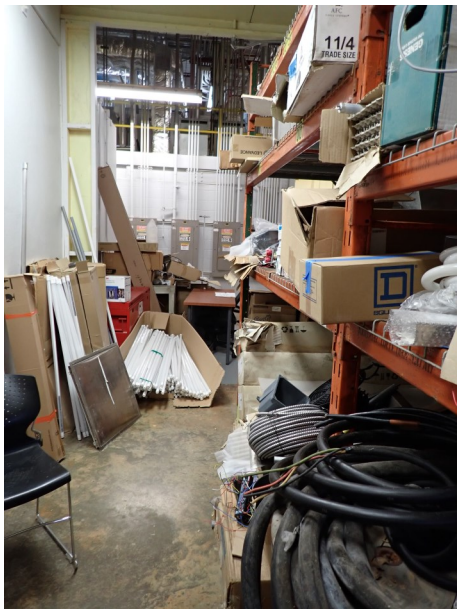

Picture 25 — Light Mechanical Shop Area— Located in the rear part of Building 501, an electrical area was identified. It consists of a hallway-type area with metal shelves with various materials, such as but not limited to cables, cardboard boxes fluorescent lamps, among others. According to the facility representatives, those materials were in use.

Picture 26 — Light Mechanical Shop Area— Located in the rear part of Building 501, an electrical area was identified. It consists of a hallway-type area with metal shelves with various materials, such as but not limited to cables, cardboard boxes fluorescent lamps, among others. According to the facility representatives, those materials were in use.

Picture 27 — Light Mechanical Shop Area—Located in the rear part of Building 501, an electrical area was identified. It consists of a hallway-type area with metal shelves with various materials, such as but not limited to cables, cardboard boxes fluorescent lamps, among others. According to the facility representatives, those materials were in use.

Picture 28 — Light Mechanical Shop Area—Located in the rear part of Building 501, an electrical area was identified. It consists of a hallway-type area with metal shelves with various materials, such as but not limited to cables, cardboard boxes fluorescent lamps, among others. According to the facility representatives, those materials were in use.

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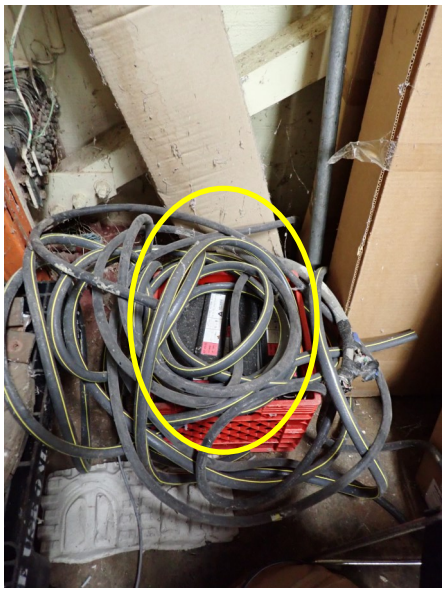
Picture 29 — Light Mechanical Shop Area— Just in front of the metal shelves, various open and broken card boxes were observed with what appeared to be fluorescent lamps. Those were observed to overflown the boxes.

Picture 30 — Light Mechanical Shop Area— In this location, I also observed metal scrap in the surroundings, wood panels, chairs, and broken desk, among others.

Picture 31 — Light Mechanical Shop Area— One (1) card board box was observed full of spent fluorescent lamps, even broken sections of spent fluorescent lamps. It was observed closed, not labeled as Universal Waste, not dated, was not under the operator's control, and did not have a pictographic label and/or indication of the hazard. Additionally, three (3) spent fluorescent lamps were observed outside the round cardboard box.



Picture 32 — Light Mechanical Shop Area— As part of the electrical area, one (1) red plastic box full of spent ballast was observed below a hose. In addition, multiple ballasts were observed throughout all the metal shelves.

Picture 33 — Light Mechanical Shop Area— This is the ERT Storage ENGI-47 subarea. According to them, this area is used to store the facility's emergency equipment.

Picture 34 — Light Mechanical Shop Area— The Used Oil subarea is located towards the Building 501 entrance. According to the facility representative, this subarea collects the used oil generated at this location.

Picture 35 — Light Mechanical Shop Area— One (1) 30-gallon blue plastic container with non-hazardous waste with Pad usados was observed. It was open, labeled as non-hazardous waste, and almost full. Inside, I observed a mix of pad usados, with vegetative material, regular waste, and plastic containers, among others.

Picture 36 — Room M15 Washroom Area - Here, two (2) yellow shelves, identified by the facility representatives as SAAs, were observed.

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Picture 37 — Room M15 Washroom Area - Here, one (1) 35-gallon blue plastic container with paños con alcohol was observed. It was closed, labeled as hazardous waste, has a pictographic label, and grounded.

Picture 38 — Room M15 Washroom Area - Here, one (1) 55-gallon white plastic container with alcohol waste 70% was observed. It was closed, labeled as hazardous waste, has a pictographic label, and grounded.

Picture 39 — Maintenance Shop Area— According to the facility representatives, this area is where the universal waste and hazardous waste are stored, and it is also used as a stock room. Six (6) containers were observed in this area.

Picture 40 — Maintenance Shop Area— Here, one (1) 55-gallon white plastic container with Aceite usado was observed. It was closed, labeled as non-hazardous waste, and was placed above a secondary containment.

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Picture 41 — Maintenance Shop Area— Here, one (1) 35-gallon blue plastic container was observed labeled as aceite usado, nevertheless, when opened, rags impacted with used oil and a hose inside a plastic bag were observed inside. It was closed, labeled as non-hazardous waste, and above a wheel-like round base.

Picture 42 — Laboratory Area-Chemical Storage Q3 Area— This area was located at Building 401. Inside, two (2) yellow shelves were observed.

Picture 43 — Laboratory Area-Chemical Storage Q3 Area— Here, one (1) yellow shelf labeled as flammable and Full HPLC Safety Cans no halogenated waste was observed. Inside, the latter had nine (9) 2.5-gallon white plastic containers.

Picture 44 — Laboratory Area-Chemical Storage Q3 Area—Here, one (1) yellow shelf labeled as flammable and Full HPLC Safety Cans no halogenated waste was observed. Inside, the latter had four (4) 2.5-gallon white plastic containers.

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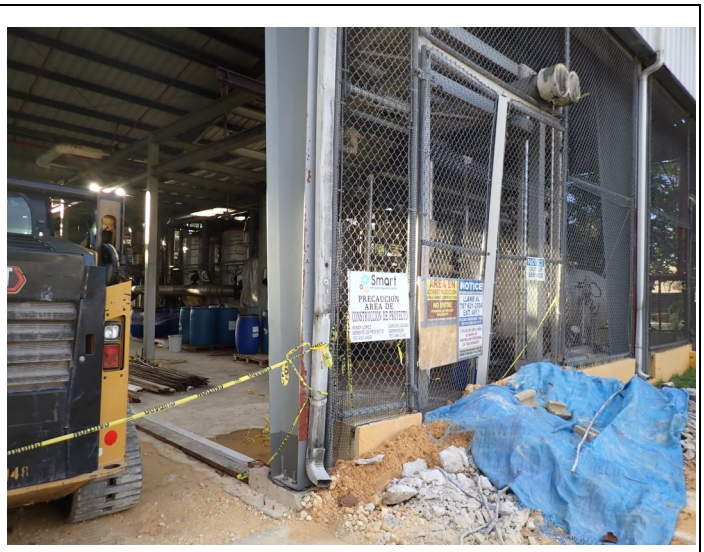
Picture 45 — Laboratory Area-Chemical Storage Q3 Area— This subarea was identified as Empty HPLC Safety Cans. It is consist of two (2) plastic carts with empty containers and five (5) 5-gallon white plastic containers, where one (1) of them was empty.

Picture 46 — Laboratory Area – Chemical Storage 26 Area— Here, one (1) 35-gallon blue plastic container with HPLC vials was observed closed, labeled as hazardous waste, and has a pictographic label available.

Picture 47 — Laboratory Area – Chemical Storage Q5 Area— Located in Building 401, here, one (1) hood and HPLCs equipment were observed.

Picture 48 — Laboratory Area – Chemical Storage Q5 Area— Here, equipment identified as UPLC#LC_055 and UPLC#LC_054 were observed. At the time of the inspection, 2.5 white plastic containers were connected to the equipment, were labeled as hazardous waste, and a had a pictographic label available.

Picture 49 — Former Hazardous Waste Tanks Area—At the time of the CEI, ongoing construction activities were not observed since construction activities were completed by the day. It consists of a high galvalume ceiling with part concrete, and part soil floor. A yellow band that works as a physical barrier in order to control access to the latter was observed.



Picture 50 — Former Hazardous Waste Tanks Area—At the time of the CEI, ongoing construction activities were not observed since construction activities were completed by the day. It consists of a high galvalume ceiling with part concrete, and part soil floor. A yellow band that works as a physical barrier in order to control access to the latter was observed.

Picture 51 — Paint Storage Area— A metal-like cage area was observed closed and locked, had a cyclone fence as a physical barrier, and was located below a concrete high ceiling. Inside, two (2) containers were observed.

Picture 52 — Paint Storage Area—Here, one (1) trash can-like container was observed labeled as “Desperdicio de pintura”. According to the facility representatives, this container is not from them, is from the contractors.

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