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:	Ethicon LLC		
EPA ID Number:	PRD982542219		
Date of Inspection:	November 29, 2023		
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. #183 Km. 8.3 Hato Industrial, San Lorenzo, Puerto Rico, 00754.		
Geographical Coordinates:	18.198414, -65.972756		
Facility Contact:	Ms. Wanda Marrero EHS[1] Manager at San Lorenzo Facility	939-225-0679 / 787-783-7070	
	wmarrer2@its.jnj.com		
	Mailing address: P.O. Box 982 San Lorenzo, Puerto Rico, 00754.		
Facility Contact:	Mr. Luis Rodriguez Senior Safety Specialist	904-566-3555	
	lrodr274@its.jnj.com		
	Mailing address: P.O. Box 982 San Lorenzo, Puerto Rico, 00754.		
Facility Contact:	Mr. Christian Reyes Senior EHS Technician	787-627-0809	
	creyes35@its.jnj.com		
	Mailing address: P.O. Box 982 San Lorenzo, Puerto Rico, 00754.		
NAICS:	339112 – Surgical and medical instrument manufacturing 339113 – Surgical appliances and supplies manufacturing		
Area:	Comprises of (6) Buildings, approximately 156,000 ft^2		
Number Employees:	Between 1,500 to 1,600[2]		
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

[1] Acronym usually stands for Environmental Health and Safety.
[2] This number is accurate by November 2023 and includes full-time and temporary jobs.

			caballer.rosana@epa.gov
Status:	FINAL		
Record Schedule:	1044(c) {unless landmark or precedent}		
Multi-media Checklist: ATTACHMENT # N/A		Referral: N/A	
EPA Lead Inspector Signature/Date	X ROSANA CABALLER-CRUZ Digitally signed by ROSANA CABALLER-CRUZ Date: 2024.01.30 11:06:17 -04'00'		
Supervisor Signature/Date	X DAVID CUEVAS-MIRANDA Digitally signed by DAVID CUEVAS-MIRANDA Date: 2024.01.30 11:37:34 -04'00' David N. Cuevas Miranda, Ph.D.		

1 INTRODUCTION

On November 29, 2023, a Resource Conservation and Recovery Act (RCRA) Compliance Evaluation Inspection (inspection) was conducted at Ethicon LLC (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. #183 Km. 8.3 Hato Industrial, San Lorenzo, Puerto Rico. Refer to *Figure 1* for the location and to *Figure 2* for an aerial photograph of the facility, **ATTACHMENT I**.

According to EPA records, the facility has been inspected thirteen (13) times prior to this CEI. The last inspection was conducted by the Agency on June 19, 2019, while the last inspection conducted by the State[3] was on June 11, 2015. I arrived at the facility around 9:15 a.m. A cloudy day with hot temperatures and humidity were the weather conditions that remained through the CEI.

2 OPENING MEETING

I met with Ms. Wanda Marrero, EHS Manager, Mr. Luis Rodríguez, Senior Safety Specialist, and Mr. Christian Reyes, Senior EHS Technician 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[4]. As part of the inspection, I told them that I needed to take photos

[3] Inspection conducted by Department of Natural & Environmental Resources personnel.
[4] For additional information of this item, please refer to Section 4 of this Report.

related to any RCRA-related issues. The facility representatives allowed me to take photos during the inspection[5]. Finally, I also explained that we needed to visit the waste generation areas in the facility.

2.1 Facility Physical Description And Operation

Ethicon LLC is a medical devices company[6] that started operations in San Lorenzo approximately 35 years ago. The facility mainly manufactures the surgeries' sutures for human use. According to the facility representatives, the manufacturing activities currently conducted are the same ones observed during the last CEI conducted[7]. Nevertheless, it was said that, as a result of their growing manufacturing activities with Stratafix and Biosurgery products, the facility is now facing an expansion. Likewise, they now have available an additional shift, for a total of four (4), and their employees cover a 24/7 schedule through all these shifts. In addition, it was told that by the time this inspection was conducted, a new Plant Manager position was being appointed, and the transition had begun. This facility consists of approximately six (6) buildings, has approximately 1,600 employees, and has a rental contract, as tenants, from PRIDCO[8] [9].

2.2 Solid And Hazardous Waste Generation

According to the facility representatives, their main hazardous waste generation is flammable waste. The facility currently has approximately six (6) SAA[10]s, and two (2) 90-day hazardous waste accumulation areas (HWAA).

The hauler company that provides pick-up services is Clean Harbor, and the last disposal was conducted between October - November 2023. 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 waste, such as spent batteries[11] and fluorescent lamps[12], and used oil. The hauler company for their universal waste is Clean Harbor, and the last disposal was conducted the week before our inspection. 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 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

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[5] The Agency camera turned off during the CEI. As a result, I was unable to take pictures beyond the Chemical Room Subarea, Section 3.1.3 of this Report. The additional pictures included in this Report were taken by an Ethicon LLC representative and were provided, via email, on a later day. For additional information of this item, please refer to Section 8 and Attachment I of this Report.
[6] For more information about the Company: https://www.jnjmedicaldevices.com/en-US/companies/ethicon
[7] The last CEI conducted at this facility was on June 19, 2019.
[8] Acronym stands for Puerto Rico Industrial Development Company.
[9] This information includes the building and the parking lot.
[10] Acronym stands for Satellite Accumulation Area.
[11] According to them, alkaline batteries.
[12] According to the facility representatives, 4 feet, and U Type.

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. Ms. Marrero, Mr. Rodríguez, and Mr. Reyes accompanied me during the facility walkthrough. The areas inspected were (i) the Building 3 Area, (ii) the QA Laboratory Area, (iii) the Main Diesel Tank Area, and (iv) the Building 3-Receiving Area[13]. The observations for the areas inspected are described below. Refer to Appendix 1 for pictures taken during the inspection.

3.1 BUILDING 3 AREA

Description of the Area	This was the first area inspected. Located on the first floor of Building 3, is one (1) of the facility's manufacturing areas. Here is where the Stratafix[14] is manufactured. Special gowning was required to be worn in order to get access to this area. For inspection purposes, I segregated this area into four (4) subareas. Additional information on each one is as follows.

3.1.1 BUILDING 3 SUBAREA

Here, a SAA was observed. Inside, a 55-gallon blue plastic container with waste solid flammable was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard and the container was observed in good condition (Picture #1). I asked the facility representatives, where the hazardous waste poured into this container is generated. They replied that this hazardous waste is generated at this subarea.

3.1.2 DERMABOND BUILDING 3A SUBAREA

This subarea is located on the second floor of Building 3. According to the facility representatives, this area is where the Dermabond product is manufactured, filled, and the packaging process occurs. At this subarea, Mr. Ernesto Sánchez, Supervisor, joined us at the CEI. Here, an SAA a 55-gallon blue plastic container with waste flammable liquid was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard and the container was observed in good condition. I asked Mr. Sánchez where the hazardous waste poured into this container was generated. He replied that is generated in this room and then is transferred to the Central 90-day HWAA, located at Building 3.

[13] The Central 90-day Hazardous Waste Accumulation Area (HWAA) was located inside this area.
[14] According to the facility representatives, these are sutures aimed for human use.

3.1.3 CHEMICAL ROOM SUBAREA

This was the third subarea inspected. The latter is located in Building 3 and has been identified as an electrically classified area[15] and in order to get access to it, you need to be authorized personnel (Picture #2). At the time of the CEI, this room had a control-access system and a fire retardant-like door. The door was observed labeled as a hazardous waste area and has a non-smoking area label. The emergency contact information was available, as well[16]. Once inside, I observed that this subarea consists of a Part washer Subarea and the 90-day HWAA Subarea. Additional information on each area is as follows.

3.1.3.1 PART WASHER SUBAREA

Here, four (4) part washer equipment were observed segregated by concrete walls. At the time of the CEI, each one was observed closed, labeled, had a pictographic label and/or indication of the hazard, and was observed in good condition. I asked the facility personnel if they were functional. They replied that the four of them were functional and operational.

3.1.3.2 90-DAY HWAA SUBAREA

Here, a concrete room with approximately 12’ high ceiling and walls was observed. I asked the facility representatives about how many employees work and/or are authorized to access this area. They replied that approximately 4 employees were authorized to access this room. In addition, I asked them about the emergency equipment available. At the time of the CEI, I observed a mainline phone[17] [18], a spill kit, two (2) fire extinguishers[19], a push station alarm,[20] and an eyewash station[21]. Likewise, the

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[15] According to the Risk Management Program (RMP) Rule, the “electrical classification" means Equipment and wiring for locations where fire and explosion hazards may exist must meet requirements based on the hazards. Each room, section, or area must be considered separately. Equipment should be marked to show Class, Group, and operating temperature or temperature range. You must determine the appropriate classification for each area and ensure that the equipment used is suitable for that classification. The equipment covered includes transformers, capacitors, motors, instruments, relays, wiring, switches, fuses, generators, lighting, alarms, remote controls, communication, and grounding. Electrical classification will be included in equipment specifications (Reference: https://www.epa.gov/rmp/what-does-electrical-classification-mean) while The National Electrical Code (NEC), NFPA (National Fire Protection Association) 70, defines hazardous (classified) areas as those where fire or explosion hazards may exist due to the presence of flammable gases, vapors, or liquids, combustible dust, or ignitable fibers. (Reference: https://www.powermag.com/practical-guidelines-for-determining-electrical-area-classification/#:~:text=The%20National%20Electrical%20Code%20(NEC,combustible%20dust%2C%20or%20ignitable%20fibers)

[16] The emergency contact number is X 2525.

[17] As part of the CEI, a test was conducted at 11:44 am. Ms. Linda Santos, Security Personnel, responded to this test.

[18] As an electrically safe classified area, the mainline phone was not located inside the Chemical Room Area, it was located at the entrance of it. It was confirmed that neither phones nor two-way radios were bit allowed in this area as well. As a result, additional information related to this item was requested to the facility representatives. For additional information on this item, please refer to Footnote 15 in Section 3.1.3, Section 7.1, and Attachment IV of this Report.

[19] According to the information gathered, the last inspection conducted on each equipment was in November 2023.

[20] This equipment is located outside the Chemical Area.

[21] According to the information gathered, the last inspection conducted on this equipment was on November 5, 2023.

room has a grounded system[22], a sprinkler system, and an extraction system is available, as well. Furthermore, the facility representatives told me that this room is considered a secondary containment itself[23] and that they are currently installing a Lower Explosion Level (LEL) equipment.

Inside the 90-day HWAA, I observed two (2) containers (Picture #3). Additional information on each one is as follows:

(a) One (1) 55-gallon metal container with waste flammable liquids-acetone/toluene. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard available, and was dated 11/14/2023.

(b) One (1) 55-gallon plastic container with waste solids flammable-rags and acetone/toluene. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard available, and was dated 11/17/2023.

I asked the facility representatives if there was a logbook available. The facility representatives replied that the latter was available and provided it. Finally, at the time of the inspection, this area was observed clean, without debris and spills/leaks.

3.1.4 Dermabond Subarea

This was the fourth subarea inspected in Building 3. AKA[24] the AmpFill area, at the time of the inspection, three (3) SAAs were observed each one connected to an AmpFill equipment, identified as AmpFill #1, AmpFill #8, and AmpFill #7, respectively. Each SAA has connected a 15-gallon red metal container with waste solids-Acetone/Toluene. At the time of the inspection, the three (3) of them were observed closed, labeled as hazardous waste, had pictograph and/or indication of the hazard available, were grounded and all SAAs were observed clean (Picture #4). Finally, I asked the facility representatives about this hazardous waste, and they replied that the hazardous waste, after being generated at these SAAs, is moved to the 90-day HWAA before moving it to its final storage at the facility's Central 90-day HWAA.

3.2 QA Laboratory Area

Description of the Area	This was the second area inspected. Located in Building 1, this area is where the facility's QA[25] Laboratory is located. This area is aimed to conduct sampling tests for the facility's manufacturing products. As requested in the previous area inspected, special gowning was required to be worn in order to get access. Here, Ms. Kiara García, QA Lab representative, joined us at the inspection.

[22] In order to be used on containers, as needed.
[23] This statement also includes the Part washer Subarea.
[24] Acronym stands for also known as.
[25] Acronym usually stands for Quality Assurance.

Here, two (2) SAAs were observed. For inspection purposes, I segregated this area into two (2) subareas. Additional information on each one is as follows:

3.2.1 Yellow Metal Shelf Subarea

At the time of the inspection, a yellow metal shelf identified as an SAA and labeled as flammable liquid was observed closed (Picture #5). I asked the facility representative to open it for me in order to conduct the inspection. Once open, inside the latter, a 5-gallon plastic container with waste flammable liquids isopropanol-acetone was observed closed, labeled as hazardous waste, and had a pictographic label and/or indication of the hazard available.

3.2.2 Blue Metal Shelf Subarea

Here, a blue metal shelf labeled as corrosive was observed closed. At the time of the inspection, the latter was observed closed. As a result, I asked the facility representatives to open it for me in order to conduct the CEI. Once open, inside the mentioned shelf, a 5-gallon plastic container with sulfuric acid waste corrosive liquid was observed closed, labeled as hazardous waste, and had it pictographic label and/or indication of the hazard available.

I asked the facility representatives about the hazardous waste handling procedures of the wastes stored at these SAAs. They replied to me that after generating, those hazardous wastes are then transferred to the facility's Central 90-day HWAA.

3.3 Main Diesel Tank Area

Description of the Area	This was the third area inspected. Located outside buildings and on the northeast side of the facility, this area contains the 10,000-gallon diesel tank. Additional information in this area is as follows.

Here, a 10,000-gallon single wall tank was observed below an open-concept building-like structure galvalume ceiling and metal columns (Picture #6). At the time of the inspection, the tank, which at the time of the inspection was labeled as flammable and had a no smoking label available, appeared to be in good condition. The latter was identified as Diesel Fuel Tank and it was placed inside a dike, which appears to be in good condition, as well. According to the facility representatives, this dike has available an epoxy treatment. Likewise, they told me that this tank feeds four (4) additional day tanks[26] via double-wall pipes. Additional information on the daily tank is as follows:

[26] Those tanks are not located at the inspected area.

Daily tank (feeds)	Capacity
Generator 101	500 gallons
Fire pumps	250 gallons
Generator 301	1,0000 gallons
GEN 401 and GEN 402	2,000 gallons

Finally, the facility representatives told me that all daily tanks have been placed inside a dike and each one has an epoxy treatment available.

3.4 BUILDING 3-RECEIVING AREA (CENTRAL 90-DAY HWAA)

Description of the Area	This was the last area inspected and it is located at Building 3's Receiving Area. According to the facility representatives, the sterilization process does not occur within this facility[27]. As a result, this area is used to prepare the products to be shipped outside the facility in order to then be sterilized to finally be delivered to their clients. In addition, it was told by the facility representatives that, in this area, is located the facility's Central 90-day HWAA (Picture #7 and Picture #8). This area was already segregated into five (5) subareas. Additional information on the latter is as follows.

This area is a room that has available a control-access system and a fire retardant-like door. The door was observed labeled as a hazardous waste area and has a non-smoking area label. Likewise, and as previous 90-day HWAA, this area was classified as an electronically safe one[28]. I asked the facility representatives about how many employees work and/or are authorized to access to this area. They replied that approximately 15 employees were authorized to access this room. In addition, I asked them about the emergency equipment available. At the time of the CEI, I observed a mainline phone[29], a spill kit, a fire extinguisher[30], a push station alarm[31] and an eyewash station[32]. Likewise, the room has a grounded system[33], a sprinkler system, and a ventilation area is available, as well. Furthermore, the

[27] According to the facility representatives, the sterilization process is for the products manufactured at this facility.
[28] For additional information of this item, please refer to Footnote 15 on Section 3.1.3 of this Report.
[29] As part of the CEI, a test was conducted around 12:35 pm. Ms. Linda Santos, Security Personnel, also responded to this test.
[30] According to the information gathered, the last inspection conducted on this equipment was in November 2023.
[31] This equipment is located near the Building 3 main entrance.
[32] According to the information gathered, the last inspection conducted on this equipment was in November 5, 2023.
[33] In order to be used on containers, as needed.

facility representatives told me that this room is considered a secondary containment itself. At the time of the inspection, I observed that this room was already segregated into five (5) subareas. Additional information on each subarea is included below.

3.4.1 FLAMMABLE SUBAREA

Here, three (3) containers were observed. Information on each one is as follows:

(a) One (1) 55-gallon blue plastic container with hydrocarbon solvent. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard available, and was dated 11/28/2023.

(b) One (1) 30-gallon blue plastic container with propylene glycol/methyl ether. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard available, and was dated 11/27/2023.

(c) One (1) 55-gallon blue plastic container with hydrocarbon solvent. At the time of the inspection, the latter was observed closed, labeled as hazardous waste, had a pictographic label and/or indication of the hazard available, and was dated 11/27/2023.

3.4.2 CORROSIVE SUBAREA

At the time of this inspection, this area was observed empty.

3.4.3 UNIVERSAL WASTE-FLUORESCENT LAMPS SUBAREA

Here, one (1) 4’cardboard box was observed above a wheel car. At the time of the inspection, the latter was observed closed, labeled as universal waste, had a pictographic label and/or an indication of the hazard available, and dated 11/26/2023.

3.4.4 UNIVERSAL WASTE-BATTERIES SUBAREA

Here, three (3) 5-gallon white containers were observed. Information on each one is as follows:

(a) One (1) 5-gallon white container with lead acid. At the time of the inspection, the latter was observed closed, labeled as universal waste, had a pictographic label and/or indication of the hazard available, and was dated 11/27/2023.

(b) One (1) 5-gallon white container with alkaline batteries. At the time of the inspection, it was observed closed, labeled as universal waste, had a pictographic label and/or indication of the hazard available, and was dated 11/27/2023.

(c) One (1) 5-gallon white container with UV lamps. At the time of the inspection, the container was observed closed, labeled as universal waste, had a pictographic label and/or indication of the hazard available, and was dated 11/26/2023.

3.4.5 USED OIL SUBAREA

Here, a 55-gallon blue plastic container was observed labeled as not regulated as hazardous waste. In addition, the latter was observed closed, labeled as used oil dated 10/18/2023. Finally, the subarea was observed clean and without any visible spill and/or leak.

I asked the facility representatives if there was a logbook available. The facility representatives replied that the latter was available and provided a hazardous waste logbook and a universal waste logbook. Finally, at the time of the inspection, this area was observed clean, without debris and spills/leaks.

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[34]. Ms. Marrero, Mr. Rodríguez, and Mr. Reyes 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	One (1) document was provided for evaluation.
4. Training Records	YES	YES	Three (3) documents were available for review.
5. Contingency Plan[35]	YES	YES	The document and attachments were sent via email for evaluation.

[34] This request was done as part of the Opening Meeting. For additional information on this item, please refer to Section 2 of this Report.
[35] This document was available at the facility for review. Nevertheless, it was requested to be sent, via email, in order to be reviewed outside the facility. The facility representatives agreed to provide the latter at a later time and to be discussed as part of the remote meeting, which was conducted, via Microsoft Teams, on December 8, 2023. For additional information on this item, please refer to Section 6.2 of this Report.

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 Ms. Wanda Marrero, EHS Manager, on February 22, 2023, and submitted before the due date of March 1st, 2022. The document includes information related to the facility's NAICS information[36], the location of the facility, and information related to the document's certification.

4.2 HWAA Inspection Information

The documents' timeline evaluated was from January 3, 2023, to November 28, 2023. According to the information gathered, this inspection is usually conducted on Tuesdays, and approximately three 3 employees are authorized to conduct said inspections[37]. After evaluation, it seems that the facility is complying with the 7-day timeframe.

4.3 Job Description

The Senior EHS Technician Job description, a six (6) page document, was provided for review. This document indicates that this employee, as part of his duties, manages hazardous waste, took RCRA-related training, such as HAZWOPER, and has RCRA certifications, as well. At the time of the inspection, the document had the hazardous waste component available.

4.4 Training Records

Information and presentation related to the RCRA EPA 40 CFR 265 were provided by the facility representatives. According to the information gathered, this training is provided, to the new hires, in person. Afterward, the training is then provided every year electronically.

4.5 Contingency Plan

As part of the document review section, the latter was requested and confirmed that was available to

[36] For additional information on this item, please refer to the first page of this Report.
[37] According to the information gathered, the authorized personnel are Mr. Christian Reyes, Mr. Luis Rodríguez, and Ms. Frances Santiago.

be evaluated at the facility. Nevertheless, it was agreed that the latter would be sent at a later date[38], via email, for evaluation outside the facility. As a result, the discussion of the document was conducted, via Microsoft Teams, on December 8, 2023[39] [40]. Additional information on the mentioned documents is as follows: The last revision was dated in 2020. It was certified by Ms. Marla E. Ciares Rivera, P.E.[41] on September 4, 2020, and approved by Mr. Francisco J. Muñíz, General Manager.

The document includes the emergency contact names, phones, and addresses, the emergency response procedures, the emergency response equipment, and the coordination agreement. In addition, the latter has available the evacuation plan narrative, which includes the evacuation procedures, and the evacuation meeting points, the quick reference guide, the environmental weekly checklist, the hazardous waste inventory generated at the facility, spill kit locations, firefighters' equipment emergency response equipment, among others. Likewise, the first responders' letter evidence was available[42] [43], which consists of five (5) Letters individually sent to the Emergency Management Office-San Lorenzo, the Police Department- San Lorenzo, the Fire Department-San Lorenzo, DRNA-San Juan Office, and the DRNA Humacao[44], respectively.

Finally, I told the facility representatives that, after evaluation of the documents, I would like to confirm if the following information is available: the evacuation routes and alternate evacuation routes signals, the facility's emergency response equipment description, and, for the quick reference guide, the requirement established in 40 CFR 262.262(b)(3)[45]. As part of the closing meeting discussion, it was confirmed that the facility's emergency response equipment description, the identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff, and the requirement established in 40 CFR 262.262(b)(3) were available. Nevertheless, the evacuation routes and alternate evacuation routes signals were not included in the document evaluated. As a result, the facility representatives told me that they would be including the latter in the upcoming contingency plan document, which will be available at a later date.

4.6 WASTE MINIMIZATION PLAN

A 14-page document was provided for evaluation. The last version of the plan was in 2019. The latter includes information related to the facility's background, waste minimization techniques, facility goals,

[38] It was agreed that the document would be sent, via email, NLT Friday, December 1st, 2023. The facility representatives complied with the due date established.
[39] For additional information on this item, please refer to Section 5, Section 6, and Section 7 of this Report.
[40] I received, via email, the following three (3) documents: (i) Distribution letters, (ii) Quick Reference Guide, and (iii) Contingency Plan.
[41] Ms. Ciares Rivera's Engineering License is #16226.
[42] This information was provided as part of the document sent by the facility representatives, via email, which consists of five (5) pages.
[43] All Distribution Letters were dated August 31st, 2020, and were received on September 8, 2020, respectively.
[44] At the time of the evaluation, this date was illegible. During the document's discussion, it was told by the facility representatives that the date received was also September 8, 2020.
[45] Citation as follows: *"The identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff…"* For Additional information on this item, please refer to Section 7 and Attachment IV of this Report.

and waste minimization options, among others. In addition, tables and figures, such as a table with the hazardous waste generated from 2017 – 2018, were included as part of the document.

4.7 MANIFESTS

The timeframe evaluated was from January 24, 2021, to November 22, 2023. Ms. Marrero and Mr. Reyes 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, signed, and appeared to comply with the 45-day timeframe. Nevertheless, it was discussed with the facility representatives that one (1) manifest, from 2022, identified as 015722033 FLE and signed on March 31, 2022, exceeds the 45-day timeframe. This manifest also included attached, an Exception Report letter, which was sent to the State Agency. As a result, I asked Ms. Marrero if this letter was also sent to the Regional Administrator, as required by the RCRA Regulation. As part of the dialogue, it was confirmed that the mentioned letter was not sent to the Agency. As a result, I explained and shared with the facility representatives the RCRA Regulatory citation, which describes what to do in case you face this situation.

5 CLOSING MEETING

5.1 WRAP-UP MEETING ON NOVEMBER 29, 2023

On November 29, 2023, around 2:37 p.m., we agreed to stop the CEI and continue with it at a later date. As part of the wrap-up activities, the contingency plan document was requested to be sent via email to be properly evaluated. In addition, we discussed the next steps and the future date/time to continue in order to conclude the CEI. As a result, we agreed to virtually meet, via the Microsoft Teams Application, on December 8, 2023, at 10:30 a.m. The latter was conducted, as scheduled, on December 8, 2023, at 10:30 a.m.

5.2 CLOSING MEETING CONDUCTED VIA MICROSOFT TEAMS APPLICATION ON SEPTEMBER 21, 2023.

On December 8, 2023, at 10:30 a.m., as scheduled, the discussion of the contingency plan and the closing meeting was conducted with the facility representatives, via Microsoft Teams Application. I indicated that the purpose of the closing meeting was to discuss the contingency plan document and to inform them about the CEI observations raised. For more information, please refer to Section 6 and Section 7 of this Report.

6 POTENTIAL AREAS OF CONCERN

6.1 GENERATORS

On February 22, 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 Recordkeeping and Reporting (40 CFR § 262 Subpart D)

i. According to 40 CFR § 262.42(a)(2), which states that *"A large quantity generator must submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if he has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter…"*

At the time of the inspection, the facility failed to comply with this requirement. Although a notification letter was generated, and the intention of the facility to communicate the issue was proven, it was confirmed with the facility representatives that such notification was sent to the State Agency, not to the EPA Regional Administrator for the Region, as requested by the Regulation.

6.1.2 Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators (40 CFR § 262 Subpart M)

ii. According to 40 CFR § 262.261(f), which states that *"The plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires)."*

At the time of the inspection, the facility failed to comply with this requirement. During the discussion of the contingency plan, it was confirmed that the signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes were not included nor available on the document provided for evaluation.

7 FOLLOW-UP ACTIONS

As described in Section 5 of this Report, as part of the Closing Meeting discussions, additional information was requested and shared with the facility representatives, such as the Regulation citations related to the concerns discussed. Specifics of the latter are presented below:

7.1 REQUESTS

Information Requested	Reason / additional information
1. *Identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff* *40 CFR 262.262(b)(3)*	- To confirm that the facility's document complies with the Regulation requirements.
2. *Evacuation Plan Map* 40 CFR § 262.261(f)	

	- To confirm that the facility's document complies with the Regulation requirements.
3. *Exception Report* 40 CFR § 262.42(a)(2)	- To confirm that the facility's action complies with the Regulation requirements.
4. *Emergency equipment in 90-day HWAA*	- Since the mainline phone location (as a result of an electronically safe classified area) was outside the 90-day HWAA, additional information was requested.

The facility representatives provided the information, as agreed, by the due date established[46]. Evaluation of the documents received, via email, was conducted and it was confirmed that the requirement established in 40 CFR 262.262(b)(3) were available. In addition, although it was confirmed that the evacuation routes and alternate evacuation routes signals were not included in the contingency plan, those that were sent via email would be included in the next contingency plan that would be generated by the facility representatives[47].

8 ATTACHMENTS

I. Figure 1- Facility Location Map and Figure -2 Aerial Photograph

II. Camera Roll

III. APPENDIX 1: SITE PICTURES

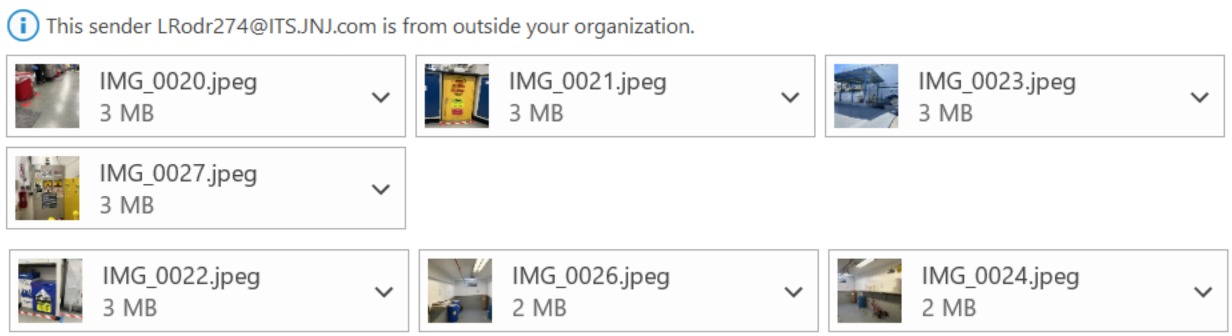
IV. Others

[46] The documents were received, via email, on December 9, 2023.
[47] For additional information on this item, please refer to Section 4.5 of this Report.

ATTACHMENT II:

CAMERA ROLL- AGENCY CAMERA

CAMERA ROLL- PROVIDED BY THE FACILITY REPRESENTATIVES



ATTACHMENT IV:

OTHERS

1. Email Fotos de inspeccion[48]
    a. Sent on 11/29/2023 – Pictures taken by the facility representative
2. Email RE: Concern regarding electrical classified areas and non-classified equipment
    a. Sent on 12/09/2023.
3. Email Ethicon LLC San Lorenzo Evacuation Plans
    a. Sent 12/09/2023.
4. Email RE: Ethicon LLC San Lorenzo Evacuation Plans
    a. Sent on 12/09/2023.

[48] Email title was written in Spanish Language and was copied just as it was sent.