

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 2

**IN THE MATTER OF:**

Patheon Puerto Rico, Inc.  
Road 670, Km 5.2  
Manatí, Puerto Rico, 00674

EPA ID. No. PRR000000836

Respondent

**Docket No. RCRA-02-2025-7201**

**EXPEDITED SETTLEMENT AGREEMENT  
AND  
FINAL ORDER**

**EXPEDITED SETTLEMENT AGREEMENT**

1. The United States Environmental Protection Agency ("EPA") is authorized to enter into this Expedited Settlement Agreement (herein alternatively referred to as "the Agreement") pursuant to Section 3008 of the Resource Conservation and Recovery Act ("RCRA") and 40 C.F.R. § 22.13(b).
2. By copy of this Agreement, EPA is providing the Commonwealth of Puerto Rico Department of Natural and Environmental Resources with notice of the referenced violations of Subtitle C of RCRA.
3. Patheon Puerto Rico, Inc. (herein alternatively referred to as "Respondent") is the owner or operator of the facility located at Road 670 Km 5.2, Manatí, Puerto Rico ("Facility"). EPA conducted a RCRA Compliance Evaluation Inspection on February 1, 2024 ("February 2024 CEI"). EPA alleges that Respondent violated the following large quantity generator ("LQG") requirements and small quantity handler requirements of the RCRA hazardous waste management program:
  - a. 40 C.F.R. § 262.11 requires that a person who generates a solid waste, as defined in 40 C.F.R. § 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. During the February 2024 CEI, the EPA inspector observed that accurate waste determinations were not made in the Light Mechanical Shop Area for various materials. These materials included, among others, paint

containers, containers with unknown content, scrap metal, spent batteries, aerosol cans, spent lamps, and ballasts.

- b. 40 C.F.R. § 262.17(a)(1)(iv)(A) requires that a container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste. During the February 2024 CEI, the EPA inspector observed open containers in the Light Mechanical Shop Area and at the Laboratory Area – Chemical Storage Q5 Area. Within the Light Mechanical Shop Area, open containers were observed at the Building 501-Outside Subarea and Building 501-Inside Subarea. At the Laboratory Area – Chemical Storage Q5 Area, one (1) 5-gallon red plastic container only identified with the word “halogenated” was open.
- c. 40 C.F.R. § 262.251 requires that a LQG 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. During the February 2024 CEI, the EPA inspector observed lack of maintenance and/or housekeeping practices to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste, in the 90-day Hazardous Waste Accumulation Area (“90-day HWAA”), the Light Mechanical Shop Area, the Maintenance Shop Area, and the Laboratory Area-Chemical Storage Q3 Area. In the 90-day HWAA, the EPA inspector observed that the roof was in bad condition. Traces of rainwater were observed on top of containers. In the Light Mechanical Shop Area, the EPA inspector observed unlabeled and open containers; cardboard boxes (some with unknown content and broken); containers without a date and their corresponding pictographic label and/or indication of the hazard; paint containers that were not characterized and the facility personnel did not know whether the material was product or waste; mixed waste observed inside containers; crowded areas with scattered containers and scrap metal, including but not limited to non-operational equipment; and lack of aisle space. In the Maintenance Shop Area, the EPA inspector observed that the contents of a container did not match its label. As to the Laboratory Area-Chemical Storage Q3 Area, the facility personnel were not aware that this area is considered a hazardous waste Satellite Accumulation Area.
- d. 40 C.F.R. § 262.261(e) requires that the contingency 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 contingency plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities. A review of the contingency plan during the February 2024 CEI revealed that although the plan

had a list of the emergency equipment, it didn't include the location and a physical description of each equipment included in the list, and a brief outline of their capabilities.

- e. 40 C.F.R. § 262.262(a) requires that a LQG 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). The contingency plan may also be submitted to the Local Emergency Planning Committee, as appropriate. During the February 2024 CEI, the EPA inspector noticed that the last version of the contingency plan was dated on January 11, 2024; however, the letters addressed to the local emergency responders were referencing the 2020 contingency plan. On February 2, 2024, the EPA inspector requested information not provided during the February 2024 CEI via electronic mail. On February 16, 2024, Respondent submitted documentation confirming that the 2024 contingency plan was submitted to the local emergency responders. However, the documentation established that the plan was provided after the February 2024 CEI was conducted.
- f. 40 C.F.R. § 262.262(b) requires that a LQG submit a quick reference guide of the contingency plan to the local emergency responders, such as police departments, fire departments, hospitals and State and local emergency response teams that may be called upon to provide emergency services, or, as appropriate, the Local Emergency Planning Committee. Additionally, 40 C.F.R. § 262.262(c) requires that generators must update, if necessary, their quick reference guides, whenever the contingency plan is amended and submit it to the 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) or, as appropriate, the Local Emergency Planning Committee. The quick reference guide available for review during the February 2024 CEI was referencing the 2022 contingency plan not the updated version of the January 2024 contingency plan. On February 2, 2024, the EPA inspector requested information not provided during the February 2024 CEI via electronic mail. On February 16, 2024, Respondent submitted to EPA documentation confirming that the 2024 quick reference guide was submitted to the local emergency responders after the February 2024 CEI was conducted.
- g. 40 C.F.R. § 273.13(a) requires 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. More specifically, 40 C.F.R. § 273.13(a)(1) requires that a small quantity handler of universal waste must contain any universal waste battery that shows evidence of leakage, spillage, or

damage that could cause leakage under reasonably foreseeable conditions in a close, and structurally sound container compatible with the contents of the batteries. During the February 2024 CEI, the EPA inspector observed that spent universal waste batteries were found scattered throughout the Light Mechanical Shop Area.

- h. 40 C.F.R. § 273.13(d) requires 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. 40 C.F.R. § 273.13(d)(1) requires small quantity handlers of universal waste to contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions. During the February 2024 CEI, the EPA inspector observed spent fluorescent lamps outside structurally sound containers or packages and also were found scattered throughout the Light Mechanical Shop Area. Additionally, other fluorescent lamps were observed broken and/or in open cardboard boxes exceeding its content capacity.
- i. 40 C.F.R. § 273.13(e)(1) requires 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. During the February 2024 CEI, the EPA inspector observed aerosol cans scattered on different locations in the Light Mechanical Shop Area.
- j. 40 C.F.R. § 273.14(a), requires 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)". During the February 2024 CEI, the EPA inspector observed that each universal waste battery and/or their containers at the Light Mechanical Shop Area were not labeled or marked clearly as required by 40 C.F.R. § 273.14(a).
- k. 40 C.F.R. § 273.14(e) requires 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)". During the February 2024 CEI, the EPA inspector observed that each spent lamp and/or a container or package at the Light Mechanical Shop Area was not labeled or marked clearly with any of the phrases required under 40 C.F.R. § 273.14(e).



7. The undersigned representative of Respondent certifies that he or she is fully authorized to enter the terms and conditions of this Expedited Settlement Agreement and Final Order and to execute and legally bind Respondent to it. Payment of the civil penalty shall constitute full settlement of the civil claims alleged herein.
8. EPA reserves all its rights to take an enforcement action for any other past, present, or future violations by Respondent of RCRA, any other federal statute or regulation, or this Agreement.
9. Each party shall bear its own costs and fees, if any.
10. This Agreement is binding on the parties signing below, and in accordance with 40 C.F.R. § 22.31(b), shall be effective upon the filing of the Expedited Settlement Agreement and Final Order with the Regional Hearing Clerk for EPA, Region 2.

Pursuant to the authority of Section 3008(a) of RCRA, 42 U.S.C. § 6938(a), and according to the terms of this Expedited Settlement Agreement and Final Order, IT IS HEREBY ORDERED THAT:

11. Respondent must pay the civil penalty of \$16,250.00 within thirty (30) calendar days after this Agreement has been filed with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, using any method provided on the following website: <https://www.epa.gov/financial/makepayment>. The payment shall identify Respondent by name and include the Docket Number assigned to this Agreement.

The effective date of this Agreement shall be the date of its filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2. This Agreement will be filed with the Regional Hearing Clerk after the signature of the Final Order by the Regional Judicial Officer.

12. Within twenty-four (24) hours of payment, email proof of payment (e.g., a copy of the check or a statement of affirmation regarding electronic funds transfer), including Respondent's name, complete address, and Docket Number to the following:

Karen Maples, Regional Hearing Clerk  
U.S. Environmental Protection Agency, Region 2  
[maples.karen@epa.gov](mailto:maples.karen@epa.gov)

and

Rosana Caballer-Cruz, Enforcement Officer  
U.S. Environmental Protection Agency, Region 2  
[caballer.rosana@epa.gov](mailto:caballer.rosana@epa.gov)

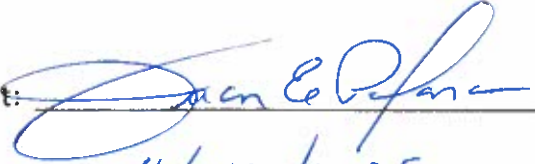
13. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of this Expedited Settlement Agreement and Final Order shall be claimed by Respondent as a deduction for federal, state or local income tax purposes.

IT IS SO AGREED,

**FOR RESPONDENT: PATHEON PUERTO RICO INC**

Name of representative of Respondent: Juan E. Polanco  
(type or print)

Title of representative of Respondent: General Manager  
(type or print)

Signature of representative of Respondent: 

Date: 4/NOV/2025

**FOR COMPLAINANT: UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

Carmen R. Guerrero Perez

DATE: December 16, 2025

Carmen R. Guerrero Pérez, Director  
Caribbean Environmental Protection Division  
United States Environmental Protection Agency  
Region 2



**FINAL ORDER**

The Regional Judicial Officer of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Expedited Settlement Agreement. This Agreement, entered into by the parties to this matter, is hereby approved, incorporated herein, and issued as an Order pursuant to Section 3008 of the Act and 40 C.F.R. § 22.18(b)(3). The Effective Date of this Order shall be the date of its filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region 2, New York, New York. 40 C.F.R. § 22.31 (b).

**IT IS SO ORDERED:**



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Dana Friedman, Regional Judicial Officer  
U.S. Environmental Protection Agency – Region 2  
290 Broadway  
New York, New York 10007-1866

Date: December 18, 2025