



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
CITY VIEW PLAZA, SUITE 7000
#48 165 RD. KM 1.2
GUAYNABO, PR 00968-8069

U.S. Environmental Protection Agency
RCRA-Reg 2
2016 SEP 28 PM 12:31
REGIONAL HEARING CLERK

6926:6

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ildefonso Vargas Feliciano
Executive Director
Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc.
PO Box 600
Mayagüez, PR 00681

**Re: In the Matter of Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc.
Docket Number RCRA-02-2016-7106**

Dear Mr. Vargas:

Enclosed is the Complaint, Compliance Order and Opportunity for Hearing in the above-referenced proceeding. The Complaint alleges violations of the Solid Waste Disposal Act, as amended, 42 U.S.C. §§ 6901 *et seq.*

You have the right to a formal hearing to contest any of the allegations in the Complaint and/or to contest the penalty proposed in the Complaint. If you wish to contest the allegations and/or the penalty proposed in the Complaint, you must file an Answer within thirty (30) days of your receipt of the enclosed Complaint with the Regional Hearing Clerk of the Environmental Protection Agency (“EPA”), Region 2, at the following address:

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

If you do not file an Answer within thirty (30) days of receipt of this Complaint and have not obtained a formal extension for filing an Answer from the Regional Judicial Officer of Region 2, a default order may be entered against you and the entire proposed penalty may be assessed.

Whether or not you request a formal hearing, you may request an informal conference with EPA to discuss any issue relating to the alleged violations and the amount of the proposed penalty. EPA encourages all parties against whom it files a Complaint to pursue the possibility of settlement and to have an informal conference with EPA. However, a request for an informal conference does not substitute for a written Answer, affect what you may choose to say in an Answer, or extend the thirty (30) days by which you must file an Answer requesting a hearing.

You will find enclosed a copy of the “Consolidated Rules of Practice,” which govern this proceeding (a

brief discussion of some of these rules appears in the later part of the Complaint). For your general information and use, I also enclose both an "Information Sheet for U.S. EPA Small Business Resources" and a "Notice of SEC Registrants' Duty to disclose Environmental Legal Proceedings" which may apply to you depending on the size of the proposed penalty and the nature of your company.

EPA encourages the use of Supplemental Environmental Projects, where appropriate, as part of any settlement. I am enclosing a brochure on EPA's Supplemental Environmental Projects. Additional information on EPA's Supplemental Environmental Projects and the complete policy can be found at <https://www.epa.gov/enforcement/supplemental-environmental-projects-seps>. Please note that these projects are only available as part of a negotiated settlement and are not available if this case has to be resolved by a formal adjudication.

If you have any questions or wish to schedule an informal conference, please contact the attorney whose name is listed in the Complaint.

Sincerely,



Carmen R. Guerrero-Pérez, Director
Caribbean Environmental Protection Division

Enclosures

cc: Karen Maples, Regional Hearing Clerk (without enclosures)

U.S. Environmental
Protection Agency-Reg 2

2016 SEP 28 PM 12:32

REGIONAL HEARING
CLERK

U.S. ENVIRONMENTAL PROTECTION AGENCY
Region 2

In the Matter of:

**Mayagüez Medical Center
Dr. Ramón Emeterio Betances, Inc.**
Respondent

Proceeding under Section 3008 of the Solid
Waste Disposal Act, as amended, 42 U.S.C. §
6928

**COMPLAINT, COMPLIANCE ORDER,
AND NOTICE OF OPPORTUNITY FOR
HEARING**

Docket No. RCRA-02-2016-7106

I. COMPLAINT

This is a civil administrative proceeding instituted pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by various laws including the Resource Conservation and Recovery Act, and the Hazardous and Solid Waste Amendments of 1984 (“HSWA”), 42 U.S.C. §§ 6901-6991 (together hereafter the “Act” or “RCRA”), for injunctive relief and the assessment of civil penalties. The United States Environmental Protection Agency (“EPA”) has promulgated regulations governing the handling and management of hazardous waste at 40 C.F.R. Parts 260-273 and 279.

This “COMPLAINT, COMPLIANCE ORDER AND NOTICE OF OPPORTUNITY FOR HEARING” (“Complaint”) serves notice of EPA’s preliminary determination that the Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc. has violated provisions of RCRA and federal regulations concerning the management of hazardous waste.

Section 3006(b) of the Act, 42 U.S.C. § 6926(b), provides that EPA’s Administrator may, if certain criteria are met, authorize a state to operate a “hazardous waste program” (within the meaning of Section 3006 of the Act, 42 U.S.C. § 6926) in lieu of the federal hazardous waste program. The Commonwealth of Puerto Rico is a “State” as that term is defined by Section 1004(31) of the Act, 42 U.S.C. § 6903(31). The Commonwealth of Puerto Rico, however, is not authorized by EPA to administer a hazardous waste program under Section 3006 of RCRA, 42 U.S.C. § 6926. Therefore, EPA retains primary responsibility for the implementation and enforcement of RCRA’s hazardous waste regulations in the Commonwealth of Puerto Rico.

The Complainant in this proceeding, the Director of the Caribbean Environmental Protection Division, EPA, Region 2, who has been duly delegated the authority to institute this action, hereby alleges upon information and belief:

JURISDICTION AND GENERAL PROVISIONS

1. This administrative Tribunal has jurisdiction over the subject matter of this action pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), and 40 C.F.R. § 22.1(a)(4).

2. RCRA establishes a comprehensive federal regulatory program for the management of hazardous waste. 42 U.S.C. § 6901 *et seq.* The Administrator of EPA, pursuant to Sections 3002(a) and 3004(a) of RCRA, 42 U.S.C. §§ 6922(a) and 6924(a), promulgated regulations for the management of hazardous waste and setting standards for generators and treatment, storage and disposal facilities. These regulations are set forth in 40 C.F.R. Parts 260 through 266 and Parts 268, 270, 273 and 279.
3. Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), authorizes the Administrator of EPA to issue an order assessing a civil penalty and/or requiring compliance for any past or current violation(s) of Subtitle C (Hazardous Waste Management) of RCRA.

Notice

4. EPA has given notice of this action to the Commonwealth of Puerto Rico.

Respondent's Background

5. The Respondent is Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc. (hereinafter the "Respondent").
6. Respondent is a for-profit corporation organized pursuant to the laws of the Commonwealth of Puerto Rico. Respondent is registered in the Puerto Rico Department of State under registration number 193888.
7. Respondent is a hospital engaged in the business of health care and emergency services, pharmacy, x-rays and other diagnostic tests and surgery procedures.
8. Respondent's business is located at Hostos Avenue #410, State Road PR-2, Sábalo Ward, Mayagüez, Puerto Rico, 00680. The geographical coordinates are 18.1804215° N, -67.1533614° E (hereinafter the "Facility").
9. Respondent has been and remains the owner and operator of the Facility.
10. Respondent is a "person" as that term is defined in Section 1004(15) of the Act, 42 U.S.C. § 6903(15) and 40 C.F.R. § 260.10.
11. Respondent's Facility constitutes a "facility," within the meaning of 40 C.F.R. § 260.10.
12. Respondent is the "operator" of the Facility as that term is defined in 40 C.F.R. § 260.10.
13. On or about March 23, 2011, Respondent provided the EPA with a Notification of Hazardous Waste Activity (the "March 23, 2011 Notification"), identifying itself as a large quantity generator of hazardous waste. In response to the March 23, 2011 Notification, EPA assigned Respondent with EPA Identification Number PRR000023630.
14. Respondent is a "generator" of "hazardous waste," as those terms are defined in 40 C.F.R. § 260.10.
15. The requirements for hazardous waste generators are set forth in 40 C.F.R. Part 262.

EPA INVESTIGATIVE ACTIVITIES

16. On or about May 7, 2015, a duly designated representative of EPA conducted a Compliance Evaluation Inspection of the Facility pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927 (hereinafter the "Inspection").

Pharmacy Area

17. At the time of the Inspection, Ms. Dianne Guzmán, Respondent's Pharmacy Director, explained to the representative of EPA that Respondent used an equipment known as Omnicell Dispensing Machine ("ODM") to dispense medicines in sealed packages.
18. Ms. Guzmán informed the EPA representative that unused medicines were collected by Respondent's pharmacy personnel and reused if the packages were intact (sealed). Otherwise, the unused medicines were discarded.
19. At the time of the Inspection, Ms. Guzmán indicated that all discarded medicines were disposed of as a biomedical waste.
20. At the time of the Inspection, Respondent had not made a hazardous waste determination for the discarded medicines.

Biomedical Waste Container Area

21. At the time of the Inspection, the representative of EPA observed a twenty cubic yards (20 yd³) biomedical waste container located at the south of the Facility.
22. During the Inspection, Mr. Luis Quintana, Respondent's Pharmacy Warehouse Supervisor in charge of collecting and placing the discarded medicines in the biomedical waste container, opened the container.
23. At the time of the Inspection, the representative of EPA observed a bag with discarded medicines inside the biomedical waste container. According to Respondent's representatives, the discarded medicines observed in the container were brought the day of the Inspection.

Biosafety Warehouse Area

24. Once in the Biosafety Warehouse Area, the representative of EPA observed five (5) boxes containing chemicals and at least one (1) of them was labeled as "corrosive."
25. According to Respondent's representatives, the boxes had been at the Facility at least since 2010 when there was a change in the operator of the Facility.
26. At the time of the Inspection, Respondent had not made a hazardous waste determination for the contents of the boxes observed in this area.

Boiler Room Area

27. At the time of the Inspection, the representative of EPA observed eleven (11) containers of various sizes, some of them rusted and with their contents leaking.

28. The representative of EPA observed that some of the eleven (11) containers had illegible labels.
29. According to Respondent's representatives, the containers in this area had been at the Facility at least since 2010 when there was a change in the operator of the Facility.
30. At the time of the Inspection, Respondent had not made a hazardous waste determination of the containers observed in this area.

EPA Request for Information

31. At the end of the Inspection, the representative of EPA held a closing meeting with Respondent's representatives in which the preliminary findings of the Inspection were discussed. The representative of EPA informed Respondent's representatives that:
 - a. Respondent needed to perform a hazardous waste determination for the Pharmacy waste.
 - b. Respondent needed to clean up and make a hazardous waste determination for the unknown containers at the Boiler Room.
 - c. Respondent needed to clean up and make a hazardous waste determination for the containers at the Biosafety Warehouse.
 - d. Respondent needed to conduct and provide to EPA the hazardous waste determinations no later than June 8, 2015.
32. On or about May 11, 2015, the representative of EPA sent Respondent an email reiterating the request for information specified in paragraph 31, above.
33. On or about June 5, 2015, Respondent submitted to EPA via email a response to the request for information made during the closing meeting and subsequent email (hereinafter the "Response").
34. In its Response, Respondent identified a total of twenty two (22) containers in the Boiler Room and Biosafety Warehouse areas as follows:
 - a. Respondent determined that the contents of three (3) containers were hazardous waste (D002, corrosive), the contents of eight (8) containers were product, and the contents of four (4) containers were non-hazardous waste.
 - b. Respondent did not make a hazardous waste determination for seven (7) other containers.
35. In its Response, Respondent provided a list of over 1,200 pharmaceutical products that are used at the Facility. The list included a hazardous waste determination for sixty (60) of the items. Respondent indicated in the Response that it was in the process of characterizing the listed products and its goal was to complete such characterization as soon as possible.

COUNT

Respondent's Failure to Make Hazardous Waste Determinations

36. Complainant repeats and re-alleges each allegation contained in paragraphs "1" through "35", inclusive, as if fully set forth herein.
37. Pursuant to 40 C.F.R. § 262.11, a person who generates a solid waste, as defined in 40 C.F.R. § 261.2, must determine if that waste is a hazardous waste.
38. At the time of the Inspection, Respondent had not made a hazardous waste determination for:
 - a. the waste generated at the Pharmacy Area;
 - b. the waste accumulated at the Biosafety Warehouse Area; and
 - c. the waste accumulated at the Boiler Room Area.
39. Respondent's failure to determine and demonstrate whether each solid waste generated at its Facility constitutes a hazardous waste is a violation of 40 C.F.R. § 262.11.
40. Respondent's failure to comply with 40 C.F.R. § 262.11 subjects it to penalties and injunctive relief pursuant to Section 3008 of the Act, 42 U.S.C. § 6928.

II. PROPOSED CIVIL PENALTY

The Complainant proposes, subject to the receipt and evaluation of further relevant information, that Respondent be assessed the following civil penalty for the violations alleged in this Complaint:

Total Proposed Penalty is **\$45,837.00**

The proposed civil penalty has been determined in accordance with Section 3008(a)(3) of the Act, 42 U.S.C. § 6928(a)(3). For purposes of determining the amount of any penalty assessed, Section 3008(a)(3) requires EPA to "take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements." To develop the proposed penalty in this complaint, the Complainant has taken into account the particular facts and circumstances of this case and used EPA's 2003 RCRA Civil Penalty Policy, a copy of which is available upon request or can be found on the Internet at the following address: <http://www2.epa.gov/sites/production/files/documents/rcpp2003-fnl.pdf>. This 2003 RCRA Civil Penalty Policy provides a rational, consistent and equitable calculation methodology for applying the statutory penalty factors to particular cases.

The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through 2015 ("Inflation Adjustment Act"), 28 U.S.C. § 246, required EPA to adjust its penalties for inflation on a periodic basis. Consistent with this, the penalty amounts in the 2003 RCRA Civil Penalty Policy have been amended to reflect inflation adjustments. The adjustments were made pursuant to the December 29, 2008 document entitled "Amendments to EPA's Civil Penalty Policies to Implement the 2008 Civil Penalty Monetary Penalty Inflation Adjustment Rule (effective January 12, 2009)"; the

November 16, 2009 document entitled “Adjusted Penalty Policy Matrices based on the 2008 Civil Monetary Inflation Rule;” the December 6, 2013 document entitled “Amendments to the U.S. Environmental Protection Agency’s Civil Penalties Policies to Account for Inflation (applicable to violations that occurred between December 7, 2013 and November 2, 2015);” and the July 27, 2016 document entitled “Amendments to the U.S. Environmental Protection Agency’s Civil Penalty Policies to Account for Inflation (applicable to violations that occurred after November 2, 2015).”

Pursuant to the Inflation Adjustment Act , the maximum statutory civil penalty under Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), is \$37,500 per day for each violation occurring after January 12, 2009 through November 2, 2015; and \$93,750 per day for each violation occurring after November 2, 2015. *See* 40 C.F.R. Part 19 and 81 Fed. Reg. 43,091 (July 1, 2016).

A penalty calculation worksheet and narrative explanation to support the penalty figure for each violation cited in this Complaint are included in Attachment I, below. Matrices employed in the determination of individual and multi-day penalties are also included in Attachment I.

III. COMPLIANCE ORDER

Based upon the foregoing, and pursuant to the authority of Section 3008 of the Act, 42 U.S.C. § 6928, Complainant herewith issues the following Compliance Order to the Respondent, which shall take effect (i.e., the effective date) thirty (30) days after service of this Order, unless by that date Respondent has requested a hearing pursuant to 40 C.F.R. § 22.15. *See*, 42 U.S.C. § 6928(b) and 40 C.F.R. §§ 22.37(b) and 22.7(c):

1. Within ten (10) calendar days of the effective date of this Compliance Order, Respondent shall, to the extent it has not already done so, clean up and properly manage any spill of hazardous waste, as that term is defined in Section 1004(5) of the Act, 42 USC § 6903(5) and 40 C.F.R. § 260.10, at the Facility.
2. Within ninety (90) calendar days of the effective date of this Compliance Order, if it has not already done so, Respondent shall make the hazardous waste determination of all the pharmaceutical waste.
3. Within thirty (30) calendar days of the effective date of this Compliance Order, Respondent shall comply with the requirements for hazardous waste generators set forth in 40 C.F.R. Part 262, and applicable state regulations.
4. Respondent shall submit a compliance certification within ninety (90) calendar days of the effective date of this Compliance Order along with any appropriate supporting documentation. If Respondent is in noncompliance with an ordered provision, the certification shall state the reasons for noncompliance and shall provide a schedule to bring its Facility into compliance.
5. All responses, documentation, and evidence submitted in response to this Compliance Order should be sent to:

Jesse Avilés
U.S. Environmental Protection Agency, Region 2
Caribbean Environmental Protection Division

Response & Remediation Branch
City View Plaza 2, suite 7000
#48 PR-165 km 1.2
Guaynabo, PR 00968-8069
787-977-5882
aviles.jesse@epa.gov

6. Compliance with the provisions of this Compliance Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all other applicable RCRA statutory or regulatory (federal and/or local) provisions, nor does such compliance release Respondent from liability for any violations at the Facility. In addition, nothing herein waives, prejudices or otherwise affects EPA's right to enforce any applicable provision of law, and to seek and obtain any appropriate penalty or remedy under any such law, regarding Respondent's generation, handling and/or management of hazardous waste at the Facility.

IV. NOTICE OF LIABILITY FOR ADDITIONAL CIVIL PENALTIES

Pursuant to the terms of Section 3008(c) of RCRA, 42 U.S.C. § 6928(c), and the Inflation Adjustment Act, a violator failing to take corrective action within the time specified in a compliance order is liable for a civil penalty of up to \$56,467 for each day of continued noncompliance. *See* 40 C.F.R. Part 19 and 81 Fed. Reg. 43,091 (July 1, 2016). Such continued noncompliance may also result in suspension or revocation of any permits issued to the violator by EPA.

V. PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

Upon receipt of a compliance order issued under Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Respondent may seek administrative review in accordance with 40 CFR Part 22. The Respondent may seek judicial review of the compliance order pursuant to Chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706, once it is final and reviewable pursuant to Section 3008(b) of RCRA, 42 U.S.C. § 6928(b), and 40 C.F.R. Part 22.

The rules of procedure governing this civil administrative litigation have been set forth in the "CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENTS OF CIVIL PENALTIES, ISSUANCE OF COMPLIANCE OR CORRECTIVE ACTION ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS," ("CROP") and which are codified at 40 C.F.R. Part 22. A copy of these rules accompanies this Complaint, Compliance Order and Notice of Opportunity for Hearing.

A. Answering the Complaint

Where Respondent intends to contest any material fact upon which the Complaint is based, to contend that the proposed penalty and/or the Compliance Order is inappropriate or to contend that Respondent is entitled to judgment as a matter of law, Respondent must file with the Regional Hearing Clerk of EPA, Region 2, both an original and one copy of a written answer to the Complaint, and such Answer must be filed within 30 days after service of the Complaint (40 C.F.R. §§ 22.15(a) and 22.7(c)). The address of the Regional Hearing Clerk of EPA, Region 2, is:

**Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th floor - Room 1631,
New York, New York 10007-1866.**

Respondent shall also then serve one copy of the Answer to the Complaint upon Complainant and the Assistant Regional Counsel mentioned in Section VI below and any other party to the action. 40 C.F.R. § 22.15(a).

Respondent's Answer to the Complaint must clearly and directly admit, deny, or explain each of the factual allegations that are contained in the Complaint and with regard to which Respondent has any knowledge. 40 C.F.R. § 22.15(b). Where Respondent lacks knowledge of a particular factual allegation and so states in its Answer, the allegation is deemed denied. 40 C.F.R. § 22.15(b).

The Answer shall also set forth: 1) the circumstances or arguments that are alleged to constitute the grounds of defense, 2) the facts that Respondent disputes (and thus intends to place at issue in the proceeding) and 3) whether Respondent requests a hearing. 40 C.F.R. § 22.15(b).

Respondent's failure to affirmatively raise in the Answer(s) facts that constitute or that might constitute the grounds of their defense may preclude Respondent, at a subsequent stage in this proceeding, from raising such facts and/or from having such facts admitted into evidence at a hearing.

B. Opportunity to Request A Hearing

If requested by Respondent, a hearing upon the issues raised by the Complaint and Answer may be held. 40 C.F.R. § 22.15(c). If, however, Respondent does not request a hearing, the Presiding Officer (as defined in 40 C.F.R. § 22.3) may hold a hearing if the Answer raises issues appropriate for adjudication. 40 C.F.R. § 22.15(c). With regard to the Compliance Order in the Complaint, unless Respondent requests a hearing pursuant to 40 C.F.R. § 22.15 within thirty (30) days after the Compliance Order is served, the Compliance Order shall automatically become final. 40 C.F.R. § 22.37.

Any hearing in this proceeding will be held at a location determined in accordance with 40 C.F.R. § 22.21(d). A hearing of this matter will be conducted in accordance with the provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551-59, and the procedures set forth in Subpart D of 40 C.F.R. Part 22.

C. Failure to Answer

If Respondent fails in its Answer to admit, deny, or explain any material factual allegation contained in the Complaint, such failure constitutes an admission of the allegation (40 C.F.R. § 22.15(d)). If Respondent fails to file a timely (i.e. in accordance with the thirty (30) day period set forth in 40 C.F.R. § 22.15(a)) Answer to the Complaint, Respondent may be found in default upon motion (40 C.F.R. § 22.17(a)). Default by Respondent constitutes, for purposes of the pending proceeding only, an admission of all facts alleged in the Complaint and a waiver of Respondent's right to contest such factual allegations (40 C.F.R. § 22.17(a)). Following a default by Respondent for a failure to timely file an Answer to the Complaint, any order issued therefore shall be issued pursuant to 40 C.F.R. § 22.17(c).

Any penalty assessed in the default order shall become due and payable by Respondent without further proceedings thirty (30) days after the default order becomes final pursuant to 40 C.F.R. § 22.27(c) as set forth in 40 C.F.R. § 22.17(d). If necessary, EPA may then seek to enforce such final order of default against Respondent, and to collect the assessed penalty amount, in federal court. Any default order requiring compliance action shall be effective and enforceable against Respondent without further proceedings on the date the default order becomes final under 40 C.F.R. § 22.27(c) as set forth in 40 C.F.R. § 22.17(d).

D. Filing of Documents Filed After the Answer

Unless otherwise ordered by the Presiding Officer for this proceeding, all documents filed after Respondent has filed an Answer should be filed with the Headquarters Hearing Clerk acting on behalf of the Regional Hearing Clerk, addressed as follows:

If filing by the United States Postal Service:

Sybil Anderson
Headquarters Hearing Clerk
Office of the Administrative Law Judges
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1900R
Washington, D.C. 20460

If filing by UPS, FedEx, DHL or other courier or personal delivery, address to:

Sybil Anderson
Headquarters Hearing Clerk
Office of the Administrative Law Judges
Ronald Reagan Building, Room M1200
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

E. Exhaustion of Administrative Remedies

Where Respondent fails to appeal an adverse initial decision to the Agency's Environmental Appeals Board ("EAB"; *see* 40 C.F.R. § 1.25(e)) pursuant to 40 C.F.R. § 22.30, and that initial decision thereby becomes a final order pursuant to the terms of 40 C.F.R. § 22.27(c), Respondent waives its right to judicial review. 40 C.F.R. § 22.27(d).

To appeal an initial decision to the EAB, Respondent must do so "[w]ithin thirty (30) days after the initial decision is served upon the parties." 40 C.F.R. § 22.30(a). Pursuant to 40 C.F.R. § 22.7(c), where service is effected by mail, "five days shall be added to the time allowed by these rules for the filing of a responsive pleading or document." Note that the forty five (45) day period provided for in 40 C.F.R. § 22.27(c) [discussing when an initial decision becomes a final order] does not pertain to or extend the time period prescribed in 40 C.F.R. § 22.30(a) for a party to file an appeal to the EAB of an adverse initial decision.

VI. INFORMAL SETTLEMENT CONFERENCE

Whether or not Respondent requests a formal hearing, EPA encourages settlement of this proceeding consistent with the provisions of the Act and its applicable regulations. 40 C.F.R. § 22.18(b). At an informal conference with a representative(s) of Complainant, Respondent may comment on the charges made in the Complaint, and Respondent may also provide whatever additional information that it believes is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged, (2) any information relevant to Complainant's calculation of the proposed penalty, (3) the effect the proposed penalty would have on Respondent's ability to continue in business and/or (4) any other special facts or circumstances Respondent wishes to raise.

Complainant has the authority to modify the amount of the proposed penalty, where appropriate, to reflect any settlement agreement reached with Respondent, to reflect any relevant information previously not known to Complainant, or to dismiss any or all of the charges, if Respondent can demonstrate that the relevant allegations are without merit and that no cause of action as herein alleged exists. Respondent is referred to 40 C.F.R. § 22.18.

Any request for an informal conference or any questions that Respondent may have regarding this complaint should be directed to:

Suzette M. Meléndez-Colón, Esq.
Assistant Regional Counsel
U.S. Environmental Protection Agency, Region 2
Caribbean Environmental Protection Division
Office of Regional Counsel-Caribbean Team
City View Plaza 2, Suite 7000, #48 PR-165 km 1.2
Guaynabo, PR 00968-8069
(787) 977-5822
melendez-colon.suzette@epa.gov

The parties may engage in settlement discussions irrespective of whether Respondent has requested a hearing. 40 C.F.R. § 22.18(b)(1). Respondent's requesting a formal hearing does not prevent it from also requesting an informal settlement conference; the informal conference procedure may be pursued simultaneously with the formal adjudicatory hearing procedure. A request for an informal settlement conference constitutes neither an admission nor a denial of any of the matters alleged in the Complaint. Complainant does not deem a request for an informal settlement conference as a request for a hearing as specified in 40 C.F.R. § 22.15(c).

A request for an informal settlement conference does not affect Respondent's obligation to file a timely Answer to the Complaint pursuant to 40 C.F.R. § 22.15. No penalty reduction, however, will be made simply because an informal settlement conference is held.

Any settlement that may be reached as a result of an informal settlement conference will be embodied in a written consent agreement. 40 C.F.R. § 22.18(b)(2). By accepting the consent agreement, Respondent waives its right to contest the allegations in the Complaint and waive its right to appeal the final order that is to accompany the consent agreement. 40 C.F.R. § 22.18(b)(2). To

conclude the proceeding, a final order ratifying the parties' agreement to settle will be executed. 40 C.F.R. § 22.18(b)(3).

Respondent's entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Respondent's entering into a settlement does not extinguish, waive, satisfy or otherwise affect its obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

VII. RESOLUTION OF THIS PROCEEDING WITHOUT HEARING OR CONFERENCE

If, instead of filing an Answer, Respondent wishes not to contest the Compliance Order in the Complaint and wants to pay the total amount of the proposed penalty within thirty (30) days after receipt of the Complaint, Respondent should promptly contact the Assistant Regional Counsel identified in Section VI.

COMPLAINANT:



Carmen R. Guerrero-Pérez, Director
Caribbean Environmental Protection Division
U.S. Environmental Protection Agency, Region 2

Date: SEPTEMBER 22 / 2014

To: Mr. Ildefonso Vargas Feliciano
Executive Director
Mayaguez Medical Center Dr. Ramón Emeterio Betances, Inc.
PO Box 600
Mayagüez, PR 00681

cc: Mr. Weldin Ortiz Franco
Executive Director
Puerto Rico Environmental Quality Board
PO Box 11488
San Juan, PR 00910

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2

In the Matter of:

Mayagüez Medical Center
Dr. Ramón Emeterio Betances, Inc.

Respondent

Proceeding under Section 3008 of the Solid Waste
Disposal Act, as amended, 42 U.S.C. § 6928

**COMPLAINT, COMPLIANCE ORDER,
AND NOTICE OF OPPORTUNITY FOR
HEARING**

Docket No. RCRA-02-2016-7106

CERTIFICATE OF SERVICE

This is to certify that on the day of 9/26/2016, I caused to be mailed a true and correct copy of the foregoing Complaint, Compliance Order and Notice of Opportunity for Hearing, bearing Docket Number RCRA-02-2016-7106, together with Attachment I, and with a copy of the "CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENTS OF CIVIL PENALTIES, ISSUANCE OF COMPLIANCE OR CORRECTIVE ACTION ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS," ("CROP"), 40 C.F.R. Part 22, by certified mail, return receipt requested, to:

Ildefonso Vargas Feliciano
Executive Director
Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc.
PO Box 600
Mayagüez, PR 00681

The original and one copy of the Complaint was filed, by certified mail, return receipt requested, with:

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2,
290 Broadway, 16th floor,
New York, New York 10007-1866.

Dated: 9/26/2016



ORC-CT, Guaynabo, Puerto Rico

Attachment I

**NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT
Penalty Computation Worksheet**

Respondent: Mayagüez Medical Center Dr. Ramón Emeterio Betances, Inc.

Facility Address: Hostos Avenue #410, PR-2, Sábalo Ward, Mayagüez, Puerto Rico, 00680

Docket No. RCRA-02-2016-7106

Requirement Violated:

40 C.F.R § 262.11, Failure to make a hazardous waste determination.

PENALTY AMOUNT FOR COMPLAINT

1	Gravity based penalty from matrix		\$37,500
	a) Potential for harm		Major
	b) Extent of deviation		Major
2	Select an amount from the appropriate multi-day matrix		\$7,090
3	Multiply line 2 by number of instances minus 1	2	\$7,090.00
4	Add line 1 and line 3		\$44,590.00
5	Percent increase/decrease for good faith	0%	\$ 0.00
6	Percent increase/decrease for willfulness/negligence	0%	\$ 0.00
7	Percent increase for history of non-compliance	0%	\$ 0.00
8	Calculate economic benefit		\$1,247
9	Add lines 4, 5, 6, 7 and 8 for penalty amount to be inserted in the complaint		\$45,837.00

Gravity Based Penalty

1. Penalty Amount Selection –The applicable cell ranges from \$28,330 to \$37,500. The high point of the range was selected.
 - a. Potential for Harm – The potential for harm for a failure to conduct a hazardous waste determination is deemed MAJOR. The RCRA Civil Penalty Policy provides that the potential for harm should be based on two factors: 1) the adverse impact of the noncompliance on the regulatory scheme; and 2) the risk of human or environmental exposure. The RCRA regulatory program is undermined when a generator fails to make a hazardous waste determination. This follows because, if the owner or operator is unaware that the facility is generating hazardous waste, there is a much greater likelihood that the owner or operator will not comply with the applicable provisions of the regulatory scheme. The hazardous waste determination is the cornerstone of the regulatory scheme. Every part of RCRA stems from the hazardous waste determination. Without a hazardous waste determination, a hazardous waste can be improperly disposed in landfills that are not adequate to contain it. RCRA comprises certain worker protections that may not be properly implemented if a determination is not made.
 - b. Extent of Deviation – The extent of deviation present in this violation was determined to be MAJOR. A duly representative of the Respondent informed during the inspection that

discarded medicines were disposed as biomedical waste. At the time of the inspection, the EPA's inspector observed discarded medicines accumulated inside a biomedical waste container. After the inspection, the Respondent provided a list of over 1,200 medicines used at the Facility. Additionally, at the time of the inspection, the EPA's inspector observed at least fifteen (15) abandoned containers for which a hazardous waste determination was not made. According to the Respondent the containers were abandoned approximately in 2010.

2. Multiple/Multi-day – A multiple was added for two groups of waste streams: waste generated as part of public health management (Pharmacy and Biosafety area); and, waste generated as part of the Facility's maintenance (Boiler room). The applicable cell ranges from \$1,420 to \$7,090. The high point of the range was selected.

Adjustment Factors

1. Good Faith – Based upon the Facility's specific factors and information available to date, no adjustment was made at this time.
2. Willfulness/Negligence – Based upon the Facility's specific factors and information available to date, no adjustment was made at this time.
3. History of Compliance – Based upon the Facility's specific factors and information available to date, no adjustment was made at this time.
4. Ability to Pay – No inability to pay evidence has been presented at this time.
5. Environmental Project – No supplemental environmental project has been considered at this time.
6. Other Unique Factors – No other factors were considered for increase or decrease of the penalty in this Count.

Economic Benefit

After the inspection, the Respondent provided a list of over 1,200 pharmaceutical products used at the Facility. A return-for-credit service was not in place at the time of the inspection. Many of the medicines included in the list were itemized in more than one dosage. After a broad assessment, the list of unique medicines is about a fourth of the original list. EPA estimated this number at 300 medicines. EPA estimated that an hour was needed to make a hazardous waste determination for each medicine. EPA then estimated that the cost per hour for the determination will be approximately \$60. Additionally, laboratory analysis were needed for the abandoned containers with little or no information to make a hazardous waste determination. EPA estimated that the onetime cost for the hazardous waste determination was \$25,000. After running the BEN model, the economic benefit for not performing the hazardous waste determination was \$1,247.

PENALTY ASSESSMENT GRAVITY MATRIX

Extent of Deviation from Requirement		Major	Moderate	Minor
Potential for Harm	Major	\$37,500 to 28,330	\$28,330 to 21,250	\$21,250 to 15,580
	Moderate	\$15,580 to 11,330	\$11,330 to 7,090	\$7,090 to 4,250

	Minor	\$4,250 to 2,130	\$2,130 to 710	\$710 to 150
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MULTI-DAY MATRIX

Extent of Deviation from Requirement		Major	Moderate	Minor
Potential for Harm	Major	\$7,090 to 1,420	\$5,670 to 1,070	\$4,250 to 780
	Moderate	\$3,120 to 570	\$2,230 to 360	\$1,420 to 220
	Minor	\$850 to 150	\$430 to 150	\$150