

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of:

BECTON DICKINSON CARIBE LTD
Medical Surgical System Facility
Road PR-31, Km. 24.3
Juncos, Puerto Rico 00777

NOE Tracking Number PRNOEC126

RESPONDENT

Proceeding pursuant to Section 309(g) of the Clean
Water Act, 33 U.S.C. § 1319(g)

REGIONAL HEARING
CLERK

2015 SEP 11 PM 12:11

U.S. Environmental
Protection Agency-Reg 2

**CONSENT AGREEMENT
AND FINAL ORDER**

**DOCKET NUMBER
CWA-02-2015-3351**

I. PRELIMINARY STATEMENT

1. This is a civil administrative proceeding for the assessment of a civil penalty instituted pursuant to Section 309(g) of the Clean Water Act ("CWA" or "the Act"), 33 U.S.C. § 1319(g).
2. The following Findings of Fact are made and Order issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by the Act, as amended, 33 U.S.C. § 1251 *et. seq.*, and in particular Section 309(g) of the Act, 33 U.S.C. § 1319(g). This authority has been duly delegated by the Administrator to the Regional Administrator of Region 2 of EPA, which authority has been duly delegated to the undersigned Director of the Caribbean Environmental Protection ("CEPD") of Region 2 of EPA.
3. EPA is initiating and concluding this proceeding for the assessment of a civil penalty, pursuant to Section 309(g) of the Clean Water Act, 33 U.S.C. § 1319(g); and 40 C.F.R. § 22.13(b) of the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits" ("CROP"), which set forth procedures for simultaneous commencement and conclusion of administrative civil penalty assessment proceedings through issuance of a consent agreement and final order pursuant to 40 C.F.R. §§ 22.18 (b)(2) and (3).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

4. Becton Dickinson Caribe Ltd. ("Respondent") is a corporation organized under the laws of the Commonwealth of Puerto Rico. Respondent is registered in the Puerto Rico Department of State under registration number 10,561.
5. Respondent is a "person" pursuant to Section 502(5) of the CWA, 33 U.S.C. § 1362(5).
6. Respondent is the owner and operator, as defined in 40 C.F.R. § 122.2, of a medical surgical system facility located at Road PR-31, Km. 24.3, Juncos, Puerto Rico (the "Facility").
7. Respondent's operations at the Facility primarily consist of the manufacture of spinal needles for anesthesia application during surgery.
8. The operations at the Facility are best described by the Standard Industrial Classification (SIC) Code 3841 (Surgical and Medical Instruments and Apparatus). SIC Code 3841 covers establishments primarily engaged in manufacturing medical, surgical, ophthalmic, and veterinary instruments and apparatus.
9. Respondent's operations at the Facility are classified as an "industrial activity," as defined in 40 C.F.R. §§ 122.26(b)(14)(xi).
10. 40 C.F.R. § 122.26(b)(14)(xi) includes those facilities identified with SIC Code 3841.
11. Respondent's Facility has a storm water runoff collection and conveyance system, which is used to discharge storm water associated with industrial activity into Valenciano River.
12. At relevant times, Respondent "discharged pollutants," as defined in 40 C.F.R. § 122.2, from the Facility into the Valenciano River.
13. Respondent's Facility is a "point source" pursuant to Section 502(14) of the CWA, 33 U.S.C. § 1362(14).
14. The Valenciano River is a water of the United States within the meaning of Section 502(7) of the CWA, 33 U.S.C. § 1362(7).
15. Section 402(p) of the Act, 33 U.S.C. § 1342(p), authorizes the Administrator of EPA to issue permits for the discharge of pollutants subject to certain requirements of the Act and conditions which the Administrator determines are necessary.
16. Section 402(p)(2)(B) of the Act, 33 U.S.C. § 1342(p)(2)(B), authorizes the Administrator of EPA to issue a permit for storm water discharges associated with industrial activity.

17. The Administrator of EPA promulgated regulations at 40 C.F.R. §§ 122.26(a)(1)(ii) and 122.26(b)(14), which require that a National Pollutant Discharge Elimination System (“NPDES”) permit shall be obtained for storm water discharges associated with industrial activity.
18. Respondent was required to apply for an NPDES permit for its storm water discharges associated with industrial activity pursuant to 40 C.F.R. §§ 122.21 and 122.26(e)(1).
19. Respondent is therefore subject to the provisions of the CWA, 33 U.S.C. § 1251 *et seq.*
20. Regulations found at 40 CFR § 122.26(e)(1) require that operators of storm water discharges associated with industrial activity that commenced operations on or before October 1, 1992 submit an individual permit application by October 1, 1992, if the operator is not authorized by a NPDES storm water general permit for industrial activities or is not participating in an approved NPDES storm water group application.
21. On September 29, 2008, EPA re-issued the NPDES Storm Water Multi-Sector General Permit for Industrial Activities (the “MSGP”).
22. The MSGP became effective on September 29, 2008, and expired on September 29, 2013. Pursuant to 5 U.S.C. § 558(c) and 40 C.F.R. § 122.6(a), the MSGP was administratively extended to those operators who obtained coverage under the MSGP prior to its expiration date.
23. The MSGP established Notice of Intent (“NOI”) requirements, development and implementation of Storm Water Pollution Prevention Plans (“SWPPP”), inspections, monitoring, reporting, recordkeeping and other special and general conditions.
24. Part 1.3.1 (How to Obtain Authorization) of the MSGP requires a facility operator who seeks coverage under the MSGP to submit a complete and accurate NOI form in order to obtain authorization to discharge storm water associated with industrial activity from its facility.
25. Part 1.3.1 and Table 1-2 (NOI Submittal Deadlines/Discharge Authorization Dates) required existing dischargers to submit a NOI no later than January 5, 2009. Upon NOI submittal, the discharge authorization became effective thirty (30) days after EPA posted the NOI in the EPA WEB-Based NOI Tracking Center database.
26. The MSGP requires the selection, design, and construction/implementation of control measures, such as non-structural and structural BMPs, to meet the non-numeric effluent limits contained in the MSGP (Section 2.1). The selection, design, installation, and implementation of the control measures must be in accordance with good engineering practices and manufacturer’s specifications.

27. Part 2.1.2.1 (Minimize Exposure) of the MSGP requires the operator to minimize the exposure of material storage areas to rain and runoff by either locating these industrial materials and activities inside or protecting them with storm resistant coverings.
28. Part 2.1.2.2 (Good Housekeeping) of the MSGP requires the operator to keep clean all exposed areas that are potential sources of pollutants.
29. Part 2.1.2.3 (Maintenance) of the MSGP requires the operator to regularly maintain and repair systems to avoid situations that may result in releases of pollutants in storm water discharged to receiving waters.
30. Part 2.1.2.9 (Employee Training) of the MSGP requires the operator to train all employees who work in areas where industrial materials or activities are exposed to storm water, or who are responsible for implementing activities necessary to meet the conditions of the MSGP, including all members of the storm water Pollution Prevention Team.
31. Part 4.1.1 (Routine Facility Inspection) of the MSGP requires the operator to conduct routine facility inspections at least quarterly by qualified personnel with at least one member of the storm water Pollution Prevention Team participating.
32. Part 4.2.1 (Quarterly Visual Assessment Procedures) of the MSGP indicates that the visual assessment must be made: of a sample in a clean, clear glass, or plastic container, and examined in a well-lit area; and on samples collected within the first thirty (30) minutes of an actual discharge from a storm event. If it is not possible to collect the sample within the first thirty (30) minutes of discharge, the sample must be collected as soon as practicable after the first thirty (30) minutes and the operator must document why it was not possible to take samples within the first thirty (30) minutes.
33. Part 4.3.2 (Comprehensive Site Inspection Documentation) of the MSGP requires operators to document the findings of each comprehensive site inspection and maintain this documentation onsite with the SWPPP. The operator must submit this documentation in an annual report, as required in Part 7.2 of the MSGP.
34. Part 5 (SWPPP) of the MSGP requires operators to review and update the SWPPP to implement all provisions of the MSGP prior to submitting the NOI.
35. Part 7.2 (Annual Report) of the 2008 MSGP requires the operator to submit an annual report to EPA that includes the findings of the comprehensive site inspection and any corrective action documentation.
36. On January 26, 2009, Respondent submitted a NOI for coverage under the MSGP for the Facility. The NOI was submitted twenty one (21) days late.
37. By letter dated January 26, 2009, EPA notified Respondent that it had received the NOI, and that coverage under the MSGP begins on February 25, 2009.

38. The MSGP Tracking Number assigned to Respondent is PRR05BL37.
39. The MSGP authorizes Respondent to discharge storm water associated with industrial activity into Valenciano River.
40. On December 10, 2014, a duly-authorized EPA enforcement officer (“Inspector”) conducted a Compliance Evaluation Inspection (“Inspection”) of the Facility. The Inspector conducted a walkthrough of the Facility, reviewed Respondent’s records and obtained copies of certain documents, relating to compliance with the MSGP.
41. As described in more detail in the Inspections Report, dated February 11, 2015, the Facility walkthrough and the review of the documents Respondent provided, revealed that Respondent did not comply with certain requirements of the MSGP, as stated below:
 - a. provide storm resistant coverings to industrial materials and equipment to minimize exposure to rain and runoff, as required by Part 2.1.2.1 of the MSGP;
 - b. clean certain areas of the Facility, which are sources of pollutants, as required by Part 2.1.2.2 of the MSGP;
 - c. provide protection to inlets and catch basins, as required by Part 2.1.2.11 of the MSGP;
 - d. review and update the SWPPP prior to filing the NOI, as required by Part 5 of the MSGP;
 - e. conduct regular inspections, cleaning and repairs of the storm water collection and discharge system, as required by Part B.5 of the MSGP;
 - f. provide employee training in years 2010, 2011, 2012, 2013, and 2014, as required by Part 2.1.2.9 of the MSGP;
 - g. conduct and document routine facility inspections in years 2009, 2010, 2011, 2012, 2013, and 2014, as required by Part 4.1 of the MSGP;
 - h. properly conduct and document quarterly visual assessments of storm water discharges for the July-September 2010, October-December 2012, January-March 2013, October-December 2013, January-March 2014, April-June 2014, and July-September 2014 periods, as required by Part 4.2 of the MSGP;
 - i. prepare comprehensive site inspection documentation for years 2009, 2010, 2011, 2012, 2013, and 2014, as required by Part 4.3.2 of the MSGP; and
 - j. provide certain information required to be submitted in the annual reports, as required by Part 7.2 of the MSGP.

42. On December 12, 2014, an EPA official reviewed the EPA NOI Processing Center database (the "EPA Review") to determine if Respondent had obtained NPDES permit coverage for the Facility.
43. The findings of the EPA Review revealed that:
- a. on January 26, 2009, Respondent filed a NOI form seeking coverage under the MSGP for its storm water discharges associated with industrial activities from the Facility into waters of the United States;
 - b. the MSGP tracking number assigned to the Facility was PRR05BL37;
 - c. the MSGP authorized Respondent to discharge storm water associated with industrial activity from the Facility into Valenciano River starting on February 25, 2009; and
 - d. the NOI was submitted twenty one (21) days late.
44. Respondent discharged pollutants without an NPDES permit from January 6, 2009 (date after deadline to file NOI form seeking coverage under the MSGP) to February 24, 2009 (date before Respondent obtained MSGP coverage), in violation of Sections 301(a) and 402(p) of the Act, 33 U.S.C. §§ 1311(a) and 1342(p).
45. On May 12, 2015, Respondent submitted a No Exposure Waiver form electronically ("eNOE") to obtain conditional exclusion from NPDES storm water permitting for the Facility. The eNOE tracking number assigned to the Facility was PRNOEC126.
46. On May 15, 2015, Respondent completed the certification of the eNOE submission.
47. The conditional exclusion coverage for the Facility obtained pursuant to 40 C.F.R. § 122.26(g) became effective on May 15, 2015, and will expire on May 15, 2020, subject to Respondent maintaining its status of conditional exclusion for no exposure of industrial activities and materials to storm water.
48. Based upon the findings of facts and conclusions of law set forth above, EPA has jurisdiction over the subject matter of this action, pursuant to Section 309(g) of the Act, 33 U.S.C. § 1319(g), and over the Respondent.

III. CONSENT AGREEMENT

49. Paragraphs 1 through 48 are re-alleged and incorporated herein by reference.
50. EPA and Respondent agree that it is in the public interest to resolve the issues alleged in this CA/FO without further litigation and the expense and effort that litigation entails.

51. Based upon the foregoing and pursuant to Section 309(g) of the Act, 33 U.S.C. § 1319(g), and the CROP, it is hereby agreed by and between EPA and Respondent, and Respondent voluntarily and knowingly agrees as follows:

IV. TERMS OF SETTLEMENT

52. For the purpose of this proceeding, Respondent:
- a. admits the jurisdictional allegations of this CA/FO;
 - b. neither admits nor denies the factual allegations contained herein;
 - c. waives its right to contest the allegations, a judicial or administrative hearing, or to appeal this CA/FO; and
 - d. consents to the payment of the civil penalty in the amount of **thirty one thousand five hundred dollars (\$31,500)**, as stated in Section V. below.

V. PAYMENT OF CIVIL PENALTY

53. No later than thirty (30) days after the Effective Date of this Order, as defined in the Final Order (at the end of this document), Respondent shall pay a civil penalty in the amount of **THIRTY ONE THOUSAND FIVE HUNDRED DOLLARS (\$31,500)**.
54. Respondent shall pay the penalty of thirty one thousand five hundred dollars (\$31,500) by check, payable to the "Treasurer of the United States of America", electronically (i.e. wire or automated clearinghouse) or on line payment.
55. Respondent shall clearly identify, regardless of the form of payment, the name and docket number of the case, set forth in the caption on the first page of this document. The payment methods are described below:
- a. If Respondent chooses to pay by cashiers' or certified check, the check shall be mailed mail to:

BY U.S. POSTAL SERVICE

United States Environmental
Protection Agency
Fines and Penalties
Cincinnati Finance Center
P. O. Box 979077
St. Louis, MO 63197-9000

BY OVERNIGHT MAIL

U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C20
ATTN Box 979077
St. Louis, MO 63101
Contact: Natalie Pearsall
Tel.: (314) 418-4087.

- b. If Respondent chooses to pay electronically, the transfer shall be made to:

BY WIRE TRANSFER
Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045.

Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency."

BY AUTOMATED CLEARINGHOUSE (ACH) (also known as REX or remittance express)

ACH for receiving US currency
PNC Bank
808 17th Street, NW
Washington, DC 20074
ABA = 051036706
Transaction Code 22 - checking
Environmental Protection Agency
Account 310006—CTX Format
Contact: Jesse White
Tel.: (301) 887-6548.

- c. On Line Payment Option is available through the Department of Treasury. This payment option can be accessed through WWW.PAY.GOV. Enter sfo 1.1 in the search field. Open form and complete required fields.

Respondent shall send prove of payment as specified in paragraph 54 above to each of the following:

José A. Rivera, BSCE
Enforcement Officer
Multimedia Permits and Compliance Branch
Caribbean Environmental Protection Agency
United States Environmental Protection Agency Region 2
City View Plaza II
48 CARR 165 STE 7000
Guaynabo, PR 00968-8073,

Héctor L. Vélez, Esq.
Lead General Attorney
Associate Regional Counsel for Caribbean Programs
Office of Regional Counsel
United States Environmental Protection Agency, Region 2
City View Plaza II
48 CARR 165 STE 7000
Guaynabo, PR 00968-8073,

and

Karen Maples
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, New York 10007.

56. Failure to pay the penalty in full according to the above provisions will result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for Collection.
57. Further, if the payment is not received on or before the due date, interest will be assessed at the annual rate established by the Secretary of Treasury pursuant to the Debt Collection Act, 31 U.S.C. § 3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of \$15.00 will be assessed for each 30-day period (or any portion thereof) following the due date in which the balance remains unpaid. A 6% per annum penalty also will be applied on any principal amount not paid within ninety (90) days of the due date.
58. In addition, pursuant to Section 309(g)(9) of the Clean Water Act, 33 U.S.C. § 1319(g)(9), if payment is not received by the due date, a quarterly nonpayment penalty will be imposed for each calendar quarter during which such nonpayment persists. The quarterly nonpayment penalty is 20% of the aggregate amount of penalties and quarterly nonpayment penalties, which are unpaid as of the beginning of such quarter. Respondent may also be required to pay attorneys fees and costs for collection proceedings in connection with nonpayment.

59. The penalty to be paid is a civil penalty assessed by the EPA and shall not be deductible from Respondent's federal or Commonwealth of Puerto Rico taxes.

VI. GENERAL PROVISIONS

60. The provisions of this CA/FO shall be binding upon Respondent, its officers, directors, agents, servants, authorized representatives and successors or assigns, including but not limited to, subsequent purchasers. No transfer of ownership or operation shall relieve Respondent of its obligation to comply with this CA/FO.

61. The Respondent waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with and to reply to any memorandum or communication addressed to the Director or the Regional Administrator where the purpose of such discussion, memorandum, or communication is to discuss a proposed settlement of this matter or to recommend that such official accept this Consent Agreement and issue the accompanying Final Order.

62. Nothing in this agreement shall be construed as prohibiting, altering or in any way limiting the ability of EPA to seek any other remedies or sanctions available by virtue of Respondent's violation of this agreement or of the statutes and regulations upon which this agreement is based, or for Respondent's violation of any applicable provision of law.

63. This CA/FO shall not relieve Respondent of its obligation to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state or local permit.

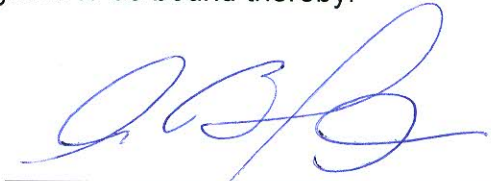
64. This CA/FO constitutes a settlement by EPA of all claims for civil penalties pursuant to the CWA for the violations by the Respondent alleged herein. Nothing in this CA/FO is intended to nor shall be construed to operate in any way to resolve any criminal liability of the Respondent. Compliance with this CA/FO shall not be a defense to any actions subsequently commenced pursuant to Federal laws and regulations administered by EPA, and it is the responsibility of Respondent to comply with such laws and regulations.

65. Each undersigned representative of the parties to this CA/FO certifies that he or she is fully authorized by the party represented to enter into the terms and conditions of this CA/FO and to execute and legally bind that party to it.

66. Each party shall bear its own costs and attorney's fees in connection with the action resolved by this CA/FO.

For Respondent: Becton Dickinson Caribe Ltd. hereby consents to the issuance of the ORDER and agrees to be bound thereby.

BY:



ALEJANDRO BLANCO

Vice President

Becton Dickinson Caribe Ltd.

P. O. Box 372860

Cayey, Puerto Rico 00737-2860

DATE:

01 July 2015

For the Complainant, the United States Environmental Protection Agency:

BY:



JOSE C. FONT

Director

Caribbean Environmental Protection Division

United States Environmental Protection Agency, Region 2

City View Plaza II

48 CARR 165 STE 7000

Guaynabo, PR 00968-8073

DATE:

Sept 5, 2015

VIII. FINAL ORDER

The Regional Administrator of the United States Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Agreement entered into by the parties is hereby approved, incorporated herein, and issued as an Order. The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2.

BY: 
JOSE C. FONT

Director
Caribbean Environmental Protection Division
United States Environmental Protection Agency, Region 2
City View Plaza II
48 CARR 165 STE 7000
Guaynabo, PR 00968-8073

DATE: Sept 5, 2015