



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
5 Post Office Square, Suite 100
BOSTON, MASSACHUSETTS 02109-3912

RECEIVED

DEC 12 2014

EPA ORC WS
Office of Regional Hearing Clerk

December 12, 2014

Wanda Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency - Region 1
5 Post Office Square, Suite 100
Mail Code: ORA18-1
Boston, MA 02109-3912

BY HAND

Re: In the Matter of Tegra Medical, LLC, Docket No. CWA-01-2011-0039

Dear Ms. Santiago,

Enclosed for filing, please find a Consent Agreement and Final Order (CAFO) both initiating and settling the matter referenced above.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Wagner".

Michael Wagner
Senior Enforcement Counsel
EPA Region 1

Enclosure

cc: Sarah H. Broughel

DEC 12 2014

EPA ORC
Office of Regional Hearing Clerk

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1**

| | | |
|-------------------------|---|------------------------------------|
| In the Matter of: |) | Docket No. CWA-01-2014-0039 |
| |) | |
| |) | CONSENT AGREEMENT AND |
| |) | FINAL ORDER FOR CLASS II |
| Tegra Medical, LLC |) | CIVIL PENALTY UNDER |
| Franklin, MA |) | |
| 9 Forge Park, Franklin, |) | |
| Massachusetts 02038 |) | CLEAN WATER ACT |
| |) | |
| Respondent. |) | |

The Regional Administrator of the United States Environmental Protection Agency, Region I ("EPA"), issues this Consent Agreement and Final Order ("CAFO") to Tegra Medical, LLC ("Respondent"). EPA alleges that Respondent violated Sections 301(a), 307(d) and 308 of the Clean Water Act ("CWA" or "Act"), 33 U.S.C. §§ 1311(a), 1317(d) and 1318. The parties agree to resolve this action by the issuance of this CAFO as provided under 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) included in EPA's "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, and the Revocation/Termination or Suspension of Permits," 40 C.F.R. Part 22 ("Part 22").

I. DESCRIPTION OF VIOLATIONS

1. EPA alleges that Respondent discharged process water to a Publicly Owned Treatment Works ("POTW") in violation of a categorical pretreatment standard in violation of Section 307(d) of the CWA, 33 U.S.C. § 1317(d), failed to comply with reporting requirements for Industrial Users of a POTW in violation of 40 C.F.R. Part 403 and Section 308(a) of the CWA, 33 U.S.C. § 1318(a), and failed to apply for or seek an exemption from a National

Pollutant Discharge Elimination System ("NPDES") permit for discharge of storm water associated with industrial activity in violation of Section 301(a) of the CWA, 33 U.S.C. § 1311(a)

II. STATUTORY AND REGULATORY AUTHORITY

2. EPA takes this action under the authority of Section 309(g) of the Act, 33 U.S.C. § 1319(g), for violation of Sections 301(a), 307(d) and 308(a) of the Act, 33 U.S.C. §§ 1311(a), 1317(d) and 1318(a). Pursuant to Section 309(g)(1) of the Act, 33 U.S.C. § 1319(g)(1), and 40 C.F.R. § 22.38(b), EPA notified the State of Massachusetts of this action, and has consulted with the Massachusetts Department of Environmental Protection ("MassDEP") on this action.

III. GENERAL ALLEGATIONS

3. Pursuant to Section 307(b) of the Clean Water Act, 33 U.S.C. § 1317(b), the Administrator promulgated the National Categorical Pretreatment Standards governing the Metal Finishing Point Source Category (the "Metal Finishing Regulations"), which appear at 40 C.F.R. Part 433.

4. Section 307(d) of the CWA, 33 U.S.C. § 1317(d), prohibits the operation of any source in violation of any applicable pretreatment standard established pursuant to Section 307(b) of the CWA, 33 U.S.C. § 1317(b).

5. Tegra Medical, LLC ("Respondent") is a person within the meaning of Section 502(5) of the Act, 33 U.S.C. § 1362(5).

6. Since February 2009, the Respondent has operated under a lease agreement a medical device manufacturing plant at 9 Forge Park, Franklin, Massachusetts ("Franklin Facility").

7. Since September 2007, the Respondent has owned and operated a medical device manufacturing plant at 8 Ledgewood Boulevard, Dartmouth, Massachusetts (“Dartmouth Facility”).

8. Between September 1, 2007 and at least January 17, 2014, Respondent discharged pollutants, as defined at Section 502(6) of the Act, 33 U.S.C. §1362(6), into a POTW, as defined at 40 C.F.R. Part 403.3(o), that is owned and operated by the City of Dartmouth, Massachusetts (“Dartmouth”), a municipality within the meaning of Section 502(4) of the Act, 33 U.S.C. §1362(4).

9. The EPA, Region I, is, and was at all times relevant to this action, the Control Authority, as defined by 40 C.F.R. §403.12(a), for the Dartmouth Facility.

IV. FINDINGS OF VIOLATION

FAILURE TO SUBMIT A TIMELY BASELINE MONITORING REPORT

10. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§ 1317(b) and 1318(a), the Administrator promulgated 40 C.F.R. §403.12(b). This regulation requires, among other things, that industrial users subject to categorical pretreatment standards submit a Baseline Monitoring Report (“BMR”) to the Control Authority.

11. The Respondent failed to submit a timely BMR to the Control Authority for the Dartmouth Facility in accordance with 40 C.F.R. §403.12(b). The Respondent did not submit a BMR until December 10, 2012, and thus violated Sections 307 and 308 of the Act, 33 U.S.C. §§ 1317 and 1318.

FAILURE TO SUBMIT A 90 DAY COMPLIANCE REPORT

12. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§ 1317(b) and 1318(a), the Administrator promulgated 40 C.F.R. §403.12(d). This regulation requires, among

other things, that new source industrial users subject to a categorical pretreatment standard submit a Report on Compliance ("90 Day Compliance Report") to the Control Authority within 90 days of the commencement of discharges. Respondent was required to submit to the Control Authority for the Dartmouth Facility a 90 day Compliance Report for the Metal Finishing Regulations.

13. In violation of Sections 307 and 308 of the Act, 33 U.S.C. §§ 1317 and 1381, the Respondent failed to submit a timely 90 Day Compliance Report to the Control Authority for the Dartmouth Facility.

FAILURE TO SUBMIT PERIODIC REPORTS ON COMPLIANCE

14. Pursuant to Sections 307(b) and 308(a) of the Act, 33 U.S.C. §§ 1317(b) and 1318(a), the Administrator promulgated 40 C.F.R. §403.12(e). This regulation requires, among other things, that industrial users subject to a categorical pretreatment standard submit Periodic Reports on Compliance ("Periodic Compliance Reports") to the Control Authority at least during the months of June and December.

15. In violation of Sections 307 and 308 of the Act, 33 U.S.C. §§ 1317 and 1318, Respondent failed to submit Periodic Compliance Reports to the Control Authority for the Dartmouth Facility from December 2007 through June 2012.

FAILURE TO ACHIEVE COMPLIANCE WITH PRETREATMENT STANDARDS

16. At all times relevant to this action, Respondent was subject to, and required to comply with, the pretreatment standards for new sources which appear at 40 C.F.R. §433.17.

17. In violation of 40 C.F.R. §433.17 and Section 307(d) of the Act, 33 U.S.C.

§307(d), on certain occasions after September 1, 2007, the Respondent exceeded the chromium pretreatment standards for new sources established under the Metal Finishing Regulations for the Dartmouth Facility.

FAILURE TO APPLY FOR STORM WATER PERMIT

18. Section 301(a) of the CWA, 33 U.S.C. § 1311(a), prohibits the discharge of pollutants by any person into navigable waters of the United States except in compliance with the terms and conditions of an NPDES permit issued pursuant to Section 402 of the CWA, 33 U.S.C. § 1342.

19. Section 502(5) of the CWA, 33 U.S.C. § 1362(5), defines "person" to include "an individual, corporation, [or] partnership." The Respondent is a person within the meaning of Section 502(5) of the CWA, 33 U.S.C. § 1362(5).

20. Section 502(12) of the CWA, 33 U.S.C. § 1362(12), defines "discharge of a pollutant" to include "any addition of any pollutant to navigable waters from any point source."

21. Section 502(6) of the CWA, 33 U.S.C. § 1362(6), defines "pollutant" to include, inter alia, dredged spoil, rock, sand and industrial waste.

22. Section 502(7) of the CWA, 33 U.S.C. § 1362(7), defines "navigable waters" as "the waters of the United States, including the territorial seas." Section 502(14) of the CWA, 33 U.S.C. § 1362(14), defines "point source" to include "any discernible, confined and discrete conveyance . . . from which pollutants are or may be discharged."

23. Section 308(a) of the CWA, 33 U.S.C. § 1318(a), authorizes EPA to require the owner or operator of any point source to provide such information as EPA may reasonably require to carry out the objectives of the CWA, including the issuance of NPDES permits pursuant to CWA section 402, 33 U.S.C. § 1342.

24. Pursuant to Sections 308 and 402 of the CWA, 33 U.S.C. §§ 1318 and 1342, EPA promulgated storm water discharge regulations at 40 C.F.R. § 122.26. Forty C.F.R. § 122.26(c) requires dischargers of storm water "associated with industrial activity" to apply for an individual permit or to seek coverage or apply for an exemption from coverage under a promulgated general permit. Forty C.F.R. § 122.26(b)(13) defines "storm water" to include storm water runoff, snow melt runoff, and surface runoff and drainage.

25. Section 402(p) of the CWA, 33 U.S.C. § 1342(p), and implementing regulation 40 C.F.R. § 122.26(a)(1)(ii), require that facilities discharging storm water "associated with industrial activity" obtain a permit or seek an exemption from coverage.

26. Forty C.F.R. § 122.26(b)(14)(xi) specifies that "storm water discharge associated with industrial activity" includes storm water discharge from facilities classified under Standard Industrial Classification ("SIC") code 34 (including 3841—surgical and medical instruments and apparatus).

27. In October 2000, EPA issued Multi-Sector General Permits for Storm Water Discharges Associated with Industrial Activities ("2000 MSGP"). The expiration date for the 2000 MSGP was set for October 30, 2005.

28. In September 2008, EPA issued Multi-Sector General Permits for Storm Water Discharges Associated with Industrial Activities ("2008 MSGP"). Although the expiration date for the 2000 MSGP was set for October 30, 2005, it was administratively extended and remained in effect until the effective date of the 2008 MSGP, which was September 29, 2008. Dischargers previously covered under the 2000 MSGP and new dischargers commencing discharges between October 30, 2005 and January 5, 2009 were required to submit a Notice of Intent to be covered

or seek an exemption from coverage under the 2008 MSGP by no later than January 5, 2009. The expiration date of the 2008 MSGP is September 29, 2013.

29. As "operator," Respondent was required to obtain a NPDES permit or seek an exemption from coverage for the industrial activity at the Franklin Facility and the Dartmouth Facility.

30. The Respondent did not apply for coverage or seek an exemption from coverage under the 2008 MSGP until April 16, 2013 for the Franklin Facility.

31. The Respondent did not apply for coverage or seek an exemption from coverage under the 2000 MSGP and did not apply for coverage or seek an exemption from coverage under the 2008 MSGP until April 28, 2013 for the Dartmouth Facility.

32. By failing to timely apply for an individual permit or apply for coverage or an exemption from coverage under the 2008 MSGP, Respondent violated Section 308(a) of the CWA, 33 U.S.C. § 1318(a), each day from at least February 1, 2009 through April 16, 2013 for the Franklin Facility. By failing to timely apply for an individual permit or apply for coverage or an exemption from coverage under the 2000 MSGP and the 2008 MSGP, Respondent violated Section 308(a) of the CWA, 33 U.S.C. § 1318(a), each day from at least September 1, 2007 and through April 28, 2013 for the Dartmouth Facility.

V. CONSENT AGREEMENT

33. EPA and Respondent agree that the above matter constitutes a disputed claim and that settlement of the above matter is in the public interest, and that entry of this CAFO without litigation is the most appropriate means of resolving this matter. Therefore, before taking any testimony, upon the pleadings, without adjudication of any issue of fact or law, and upon consent and agreement of the parties, it is hereby ordered and adjudged as follows:

34. Respondent admits the jurisdictional allegations in Section I and II above.

Respondent neither admits nor denies the specific factual allegations contained in Section III above.

VI. WAIVER OF RIGHTS

35. Respondent waives the right to a hearing under Section 309(g)(2)(B) of the Act, 33 U.S.C. § 1319(g)(2)(B), to appeal any Final Order in this matter under Sections 309(g)(8)(B) of the Act, 33 U.S.C. §§ 1319(g)(8)(B), and consents to the issuance of a Final Order without further adjudication.

VII. PENALTY

36. Complainant proposes, and Respondent consents to, the assessment of a civil penalty of fifty thousand dollars (\$50,000).

VIII. PAYMENT TERMS

37. In agreeing to the penalty described in paragraph 35 above, EPA has taken into account the statutory penalty factors at Sections 309(g)(3) of the CWA, 33 U.S.C. §§ 1319(g)(3). Respondents shall pay a total penalty of \$50,000 for violation of Sections 301, 307, and 308 of the CWA which shall be due within 15 calendar days of the effective date of this CAFO.

38. Respondent shall make payment of \$50,000 by cashier's or certified check, payable to "United States Treasurer," and referencing the title and docket numbers of the action ("In the Matter of Tegra Medical, LLC, CWA-01-2014-0039)." The payment shall be mailed via regular U.S. Postal Service mail, to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000\

39. Respondent shall note on the penalty payment checks the title and docket number of this case. Respondent shall submit copies of the checks to the following people:

Wanda Santiago
Regional Hearing Clerk (ORA18-1)
U.S. Environmental Protection Agency
Region 1
5 Post Office Square, Suite 100
Boston, Massachusetts 02109-3912

and

Michael Wagner
Office of Environmental Stewardship (OES04-)
U.S. Environmental Protection Agency
Region I
5 Post Office Square, Suite 100
Boston, Massachusetts 02109-3912

40. The penalty provided for herein is a penalty within the meaning of 26 U.S.C. §162(f) and is not tax deductible for purposes of federal, state, or local law.

IX. GENERAL PROVISIONS

41. Pursuant to Sections 309(g)(9) of the CWA, 33 U.S.C. §§ 1319(g)(9), a failure by the Respondent to pay the penalty assessed by this CAFO in full by its due date shall subject Respondent to a civil action to collect the assessed penalty, plus interest at current prevailing rates, from the date when this CAFO becomes final. The rate of interest assessed shall be at the rate set forth in 31 C.F.R. § 901.9(b), promulgated under 31 U.S.C. § 3717. Any person who fails to pay on a timely basis the amount of an assessed penalty shall be required to pay, in addition to such amount and interest, attorney's fees, costs for collection proceedings, and a quarterly nonpayment penalty for each quarter during which such failure to pay persists. Such nonpayment penalty shall be in an amount equal to twenty percent of the aggregate amount of such person's penalties and nonpayment penalties that are unpaid as of the beginning of such

quarter. In any such collection action, the validity, amount, and appropriateness of the penalty shall not be subject to review.

42. The Final Order shall be binding upon Respondent and Respondent's officers, directors, agents, servants, employees, successors, or assigns.

43. The Final Order constitutes the final Agency action in a proceeding pursuant to 40C.F.R. § 22.31 and resolves only those causes of action alleged in this CAFO. The Final Order shall not affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any other violations of law. The Final Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of the CWA and regulations promulgated thereunder.

44. The undersigned representative of Respondent certifies that he is fully authorized by Tegra Medical, LLC to enter into the terms and conditions of this CAFO and to execute and legally bind Tegra Medical, LLC to it.

FOR TEGRA MEDICAL, LLC

Date: 9/29/14

Bill Fisher
Bill Fisher
Chief Financial Officer

FOR U.S. ENVIRONMENTAL PROTECTION AGENCY:

Date: 09/30/14

Susan Studlien

Susan Studlien, Director
Office of Environmental Stewardship
U.S. EPA, Region 1

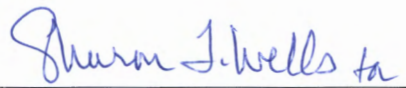
X. FINAL ORDER

1. EPA has provided a thirty-day opportunity for public notice and comment on this proposed CAFO, pursuant to Sections 309(g)(4)(A) of the CWA, 33 U.S.C. §§ 1319(g)(4)(A), and 40 C.F.R. § 22.45(b), and has not received any public comments.

2. The foregoing Consent Agreement is hereby approved and incorporated by reference into this Order.

3. Respondent is hereby ordered to comply with the terms of the above Consent Agreement, which will become final thirty (30) days from the date it is signed by the Regional Judicial Officer.

Date: 12/10/14



LeAnn Jensen
Acting Regional Judicial Officer
U.S. Environmental Protection Agency, Region 1

In the Matter of Tegra Medical, LLC, Docket No. CWA-01-2011-0039

CERTIFICATE OF SERVICE

I certify that the foregoing "Consent Agreement and Final Order" was sent to the following persons, in the manner specified, on the date below:

Two copies, hand-delivered:


Wanda Santiago
Regional Hearing Clerk
U.S. Environmental Protection Agency - Region 1
5 Post Office Square, Suite 100
Mail Code: ORA18-1

A true and correct copy, by certified mail, return receipt requested:

Sarah H. Broughel
Choate, Hall & Stewart, LLP
Two International Place
Boston, MA 02110

Date:

12/12/14


Michael Wagner
Senior Enforcement Counsel