

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 6
DALLAS, TX

FILED
2018 APR -5 AM 9:56
REGIONAL HEARING CLERK
EPA REGION VI

IN THE MATTER OF:

MED FUSION LLC

RESPONDENT
TXR 000084184

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Consent Agreement and Final Order
USEPA Docket No. RCRA-06-2018-0915

CONSENT AGREEMENT AND FINAL ORDER

I.

PRELIMINARY STATEMENT

1. This Consent Agreement and Final Order (“CAFO”) is entered into by the United States Environmental Protection Agency, Region 6 (“EPA” or “Complainant”) and Respondent, Med Fusion, LLC (“Med Fusion” or “Respondent”) and concerns the facility that is located at 2501 South State Hwy 121, Suite 1100, Lewisville, Texas 75067-8188 (the “Facility”).
2. Notice of this action has been given to the state of Texas, under Section 3008(a)(2) of the Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. § 6928(a)(2).
3. For the purpose of these proceedings, Respondent admits the jurisdictional allegations herein; however, Respondent neither admits nor denies the specific factual allegations or alleged violations contained in this CAFO.
4. Respondent explicitly waives its right to appeal the proposed final order contained in this CAFO.

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5. The CAFO resolves only those violations which are alleged herein.
6. This CAFO covers the violations alleged herein from the period of January 1, 2014 through the effective date of this CAFO.
7. Respondent consents to the issuance of the CAFO hereinafter recited, consents to the assessment and payment of the stated civil penalty in the amount and by the method set out in this CAFO, and consents to the specific stated compliance order as set forth in Section V, Compliance Order, Paragraph 52.

II.
JURISDICTION

8. This CAFO is issued by the EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928, as amended by the Hazardous and Solid Waste Amendments of 1984 and is simultaneously commenced and concluded through the issuance of this CAFO under 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3).
9. Respondent agrees to undertake and complete all actions required by the terms and conditions of this CAFO. In any action by the EPA or the United States to enforce the terms of this CAFO, Respondent agrees not to contest the authority or jurisdiction of the EPA to issue or enforce this CAFO, and agrees not to contest the validity of this CAFO or its terms or conditions.

III.
STATUTORY AND REGULATORY BACKGROUND

10. Federal regulation of hazardous waste is primarily based on RCRA, enacted on October 21, 1976 to amend the Solid Waste Disposal Act, and the Hazardous and Solid Waste Amendments (“HSWA”) enacted by Congress in 1984 to further amend the Solid Waste Disposal Act. RCRA establishes a “cradle-to-grave” program to be administered

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by the Administrator of EPA and authorized states for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste. See 42 U.S.C. § 6901 *et seq.*

11. RCRA's Subchapter III (RCRA §§ 3001-3023, 42 U.S.C. §§ 6921-6940, known as "Subtitle C") required EPA to promulgate regulations establishing performance standards applicable to facilities that generate, transport, treat, store, or dispose of hazardous wastes. Together, RCRA Subtitle C and its implementing regulations, set forth at 40 C.F.R. Parts 260 – 279, comprise EPA's RCRA hazardous waste program.
12. Pursuant to its authority under RCRA, EPA has promulgated regulations at 40 C.F.R. Parts 260 through 272 applicable to generators, transporters, and treatment, storage, and disposal facilities. These regulations include detailed requirements governing the activities of those who generate hazardous waste and those who are lawfully permitted to store, treat, and dispose of hazardous waste.
13. Pursuant to 40 C.F.R. § 261.2, a "solid waste" is any discarded material that is not otherwise excluded under 40 C.F.R. § 261.4(a), or that is not excluded by variance. A discarded material is any material which is abandoned, recycled, inherently waste-like, or a military munitions. Materials are solid waste, as defined in 40 C.F.R. § 261.2, if they are abandoned by being disposed of, burned or incinerated, or accumulated, stored, or treated (but not recycled) before, or in lieu of, being abandoned by being disposed of, burned, or incinerated.

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14. A solid waste is a hazardous waste if it is not excluded from regulation as a hazardous waste under 40 C.F.R. § 261.4(b), and it exhibits any of the characteristics of hazardous waste identified in 40 C.F.R. Part 261, Subpart C or it is listed in C.F.R. Part 261, Subpart D.
15. Characteristic hazardous wastes are assigned “D” codes in 40 C.F.R. Part 261, Subpart C, depending on the specific hazardous characteristic that the waste exhibits.
16. An ignitable hazardous waste has a flash point of less than 60 degrees centigrade (140 degrees Fahrenheit) and is assigned the D001 hazardous waste code pursuant to 40 C.F.R. § 261.21.
17. A corrosive hazardous waste has a pH of less than or equal to 2.0 or greater than or equal to 12.5 and is assigned the D002 hazardous waste code pursuant to 40 C.F.R. § 261.22 and reactive hazardous waste is assigned the D003 hazardous waste code pursuant to 40 C.F.R. § 261.23.
18. Listed waste are assigned with “F”, “K”, “P”, and “U” codes in 40 C.F.R. Part 261, Subpart D, depending on the specific waste generated from a non-specific source, a specific source, or discarded commercial chemical products, off-specification species, container residues and spill residues therefrom.
19. 40 C.F.R. Parts 264 or 265 and applies to owners and operators of facilities that treat, store and/or dispose of hazardous waste.
20. The relevant RCRA statutory and regulatory requirements to this CAFO require that generators of solid waste and hazardous waste must, among other things:
 - A. Comply with the statutory notification requirements of Section 3010 of RCRA, 42 U.S.C. § 6930;

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- B. Comply with the manifest requirements, pursuant to 40 C.F.R. § 262.20;
- C. Determine its generator status; and comply with the specific requirements set forth at 40 C.F.R. §§ 262.34 and/or 270.10.

IV.
FACTUAL ALLEGATIONS AND ALLEGED VIOLATIONS

- 21. Respondent is authorized to do business in the state of in Texas, and is headquartered in Lewisville, Texas.
- 22. Respondent is a “person” within the meaning of Section 1004(15) of RCRA, 42 U.S.C. § 6903(15); and 30 TEX.ADMIN.CODE¹ § 3.2(25), [40 C.F.R. § 260.10].
- 23. Med Fusion owns and/or operates the Facility identified in Paragraph 1 of this CAFO.
- 24. Med Fusion describes itself as an integrated clinical reference laboratory and clinical trials organization, with specialization in oncology, women’s health, and infectious disease.
- 25. During the period of October 2017 through December 2017, EPA conducted a RCRA investigation and record review of Med Fusion’s activities as a generator of hazardous waste in the state of Texas.
- 26. On or about November 13, 2017, Med Fusion provided EPA with responses to EPA’s informal request of October 17, 2017. Further, Med Fusion provided EPA with additional information on January 24 and 29, 2018.
- 27. EPA’s record review together with its receipt and review of Med Fusion responses, for purposes of this CAFO, represents the investigation conducted by EPA “Investigation”).

¹ Citations to the Texas Administrative Codes reflect the relevant period of this CAFO.

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28. From the Investigation, EPA concluded that in general and at a minimum Med Fusion generated “solid waste” within the meaning of TEX.ADMIN.CODE § 335.1(138), [40 C.F.R. § 261.2].
29. The Facility identified in Paragraph 1 of this CAFO is a “facility” within the meaning of 30 TEX.ADMIN.CODE § 335.1(59), [40 C.F.R. § 260.10].
30. EPA concluded that at all times relevant to this CAFO, the Facility identified in Paragraph 1 of this CAFO has generated “solid waste” streams that are also “hazardous waste” pursuant to 30 TEX.ADMIN.CODE §§ 335.1 (138) and (69), [40 C. F.R. §§ 261.21, 261.22, 261.23, 261.24, 261.31 and 261.33] because one or several solid waste streams:
- A. exhibited the characteristics of ignitability, corrosivity, and reactivity, respectively with the EPA’s waste codes D001, D002, and D003;
 - B. exhibited the hazardous characteristics for toxicity, specifically with the EPA waste codes, D008, D009, D011, D022; and
 - C. are listed hazardous waste, respectively with the EPA waste codes, F003, U154, U002, and U044.
31. Med Fusion is a “generator” of “hazardous waste” as those terms are defined in 30 TEX.ADMIN.CODE §§ 335.1(65) & (69), [40 C.F.R. § 260.10].
32. As a generator of hazardous waste, Med Fusion is subject to Sections 3002 and 3010 of RCRA, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth at 30 TEX.ADMIN.CODE, Chapter 335, Subchapter C, [40 C.F.R. Parts 262 and/or 270].

CLAIMS FOR RELIEF

Claim i. Failure to comply with the RCRA Notification Requirements

33. The allegations in Paragraphs 1-32 are realleged and incorporated herein by reference.
34. Pursuant to Section 3010(a) of RCRA, 42 U.S.C. § 6930(a), any person required to obtain an EPA ID Number and generating a characteristic or listed hazardous waste shall file with the Administrator a notification stating the location and general description of such activity and the identified or listed hazardous wastes handled by such person.
35. During the Investigation, EPA determined that for the periods relevant to this CAFO, Med Fusion operated as if it was a conditionally exempt small quantity generator (“CESQG”) and did not file with the Administrator a notification of hazardous waste activities for the Facility until June 16, 2017.
36. During the Investigation, EPA determined that for several instances during the periods relevant to this CAFO, Med Fusion operated the Facility without an EPA Identification Number. Further, Respondent did not describe all its waste activities, including location and general description of such activity and the identified or listed hazardous wastes generated and managed at the Facility.
37. During the Investigation, EPA determined that for the periods relevant to this CAFO, Med Fusion generated hazardous waste in the quantities that exceeded the CESQG status and triggered the small quantity generator (“SQG”), thereby requiring Med Fusion to obtain an EPA ID number and fully comply with the requirements of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

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38. Respondent violated Section 3010(a) of RCRA, 42 U.S.C. § 6930(a), for its failure to timely file the required notification(s) for the Facility during the period of 2014 through and until it received its EPA Identification Number on June 19, 2017.

Claim ii. Failure to Make an Adequate Hazardous Waste Determination

39. The allegations in Paragraphs 1-32 are realleged and incorporated herein by reference.

40. Pursuant to 30 TEX.ADMIN.CODE § 335.62, [40 C.F.R. § 262.11(c)], a person who generates a solid waste, as defined in 30 TEX.ADMIN.CODE § 335.1(138), [40 C.F.R. § 261.2], must determine if the waste is hazardous either by applying the required test method or by applying its knowledge of the hazardous characteristic of the waste in light of the materials or the processes used.

41. From the Investigation, EPA determined that during the relevant period of this CAFO, Respondent shipped at a minimum 4817 kilograms of hazardous waste.

42. Further, EPA during its Investigation did not and could not identify any contemporaneous waste determination and/or documentation of such determination made by Respondent for its waste streams.

43. Respondent violated 30 TEX.ADMIN.CODE § 335.62, [40 C.F.R. §§ 262.11 and 262.40(c)], by failing to make adequate hazardous waste determinations on all its solid waste streams and/or by failing to keep the required records for the required time period.

Claim iii. Failure to Comply with the Manifest Requirements

44. The allegations in Paragraphs 1-32 are realleged and incorporated herein by reference.

45. Pursuant to 30 TEX.ADMIN.CODE §§ 335.10(a)(1) and 335.10(c), [40 C.F.R. § 262.20(a)(1)], a generator shall not offer its hazardous waste for shipment unless it

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prepares a standard manifest form (EPA Form 8700-22) according to the instructions found in the Appendix to 40 C.F.R. Part 262.

46. Further, for manifests, 008752499FLE, 008084297FLE, and 008752501FLE, Respondent omitted to include the required waste code of D001.
47. Without EPA ID Number and appropriate waste code(s) on the required manifests, Respondent failed to completely and adequately prepare its hazardous waste manifest for several shipments of hazardous waste, during the relevant period of this CAFO, in violation of 30 TEX.ADMIN.CODE §§ 335.10(a)(1) and 335.10(c), [40 C.F.R. § 262.20(a)].

Claim iv. Failure to Comply with the Applicable Generator Conditions

48. The allegations in Paragraphs 1-32 are realleged and incorporated herein by reference.
49. For several instances during the relevant period of this CAFO, where Respondent generated hazardous waste greater than 100 kilograms but less than 1000 kilograms in a calendar month, EPA determined that for the period such hazardous waste remained onsite, Med Fusion operated as a SQG at the Facility identified in Paragraph 1 of this CAFO.
50. From the Investigation, EPA determined that Med Fusion at a minimum did not comply with certain generator exemption conditions; specifically, its personnel training program procedures, and arrangements to be made with local authorities did not fully comply, respectively with the requirements of 262.34(d)(4), (5) (i) through (iv) which incorporates by reference 40 C.F.R. Part 265, specifically 40 C.F.R. § 265.16 and 40 C.F.R. § 265.37.

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51. For the periods that Med Fusion operated as a SQG at the Facility identified in Paragraph 1, Med Fusion failed to fully meet the SQG generator exemption conditions set forth at 40 262.34(d)(4) and (d)(5), therefore violated 40 C.F.R. §§ 270.1 and 270.10.

V.
COMPLIANCE ORDER

52. Pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Respondent is hereby ordered to take the following actions, and submit any and all documents, photos, and/or other appropriate evidence, required by this compliance order, to EPA and within the time period specified below:

- A. Within ninety (90) days of the effective date of this CAFO, Respondent shall certify that it has assessed all its solid waste streams at the Facility to determine the accurate waste codes and has developed and implemented standard operating procedures (“SOPs”) for the Facility to ensure that Med Fusion is operating in compliance with RCRA and the regulations promulgated thereunder, including, but not limited to, procedures for: (a) making hazardous waste determinations; (b) managing hazardous wastes; (c) reporting, transporting, and disposing of hazardous waste; (d) preparing its manifests; and (e) meeting the requirements of the land disposal restrictions;
- B. Within ninety (90) calendar days of the effective date of this CAFO, Respondent shall certify that it has accurately and adequately complied with its RCRA Section 3010 Notification, where applicable, for the Facility and within the prescribed time period, pursuant to Section 3010 of RCRA, 42 U.S.C. § 6930; and
- C. Respondent shall provide, with its certification, a copy of Respondent’s SOPs as described in subparagraph A above.

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53. In all instances in which this CAFO requires written submission to EPA, the submittal made by Respondent shall be signed by an owner or officer of Med Fusion or a qualified designee appointed in writing by such owner or officer and shall include the following certification:

“I certify under the penalty of law that this document and all its attachments were prepared by me or under my direct supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.”

54. Copies of all documents required by this CAFO shall be sent to the following:

U.S. Environmental Protection Agency
Compliance Assurance and Enforcement Division
Waste Enforcement Branch
Waste Compliance II Section (6EN-H2)
1445 Ross Avenue, Suite 1200
Dallas, TX 75202-2733
Attn: Debra Pandak

In the alternative, documents required by this CAFO may be sent to Debra Pandak via email at Pandak.Debra@epa.gov.

VI. TERMS OF SETTLEMENT

i. **Penalty Provisions**

55. Pursuant to the authority granted in Section 3008 of RCRA, 42 U.S.C. § 6928, and upon consideration of the entire record herein, including the above referenced Factual Allegations and Alleged Violations, which are hereby adopted and made a part hereof, upon the seriousness of the alleged violations, and Respondent’s good faith efforts to comply with the applicable regulations, it is ordered that Respondent be assessed a civil

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penalty of One Hundred and Fifty-One Thousand Four Hundred and Thirteen Dollars (\$151,413.00).

56. The penalty shall be paid within thirty (30) calendar days of the effective date of this CAFO and made payable to the Treasurer United States.

57. The following are Respondent's options for transmitting the penalties:

Regular Mail, U.S. Postal Mail (including certified mail) or U.S. Postal Service Express

Mail, the check should be remitted to:

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

Overnight Mail (non-U.S. Postal Service), the check should be remitted to:

U.S. Bank
Government Lockbox 979077
US EPA Fines and Penalties
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63101
314-418-1028

Wire Transfer:

Federal Reserve Bank of New York
ABA: 021030004
Account No. 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045

58. The case name and docket number (In the Matter of Med Fusion LLC Docket No. RCRA-06-2018-0915) shall be clearly documented on or within Respondent's chosen method of payment to ensure proper credit.

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The Respondent shall send a simultaneous notice of such payment to the following:

Lorena S. Vaughn
Regional Hearing Clerk (6RC-D)
U.S. EPA, Region 6
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202-2733

Waste Compliance II Section (6EN-H2)
Waste Enforcement Branch
Compliance Assurance and Enforcement Division
U.S. EPA, Region 6
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202-2733
Attention: Debra Pandak

Adherence to this request will ensure proper credit is given when penalties are received by EPA.

59. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, unless otherwise prohibited by law, EPA will assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest on the civil penalty assessed in this CAFO will begin to accrue on the effective date of the CAFO and will be recovered by EPA on any amount of the civil penalty that is not paid within thirty (30) calendar days of the civil penalty's due date and will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11(a). Moreover, the costs of the Agency's administrative handling overdue debts will be charged and assessed monthly throughout the period the debt is overdue. 40 C.F.R. § 13.11(b). EPA will also assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) day period the penalty remains unpaid. In addition, a penalty charge of up to

six percent per year will be assessed monthly on any portion of the debt which remains delinquent more than ninety (90) days. 40 C.F.R. § 13.11(b). Should a penalty charge on the debt be required, it shall accrue from the first day payment is delinquent.

31 C.F.R. § 901.9(d). Other penalties for failure to make a payment may also apply.

ii. Cost

60. Each party shall bear its own costs and attorney's fees. Furthermore, Respondent specifically waives its right to seek reimbursement of its costs and attorney's fees under the Equal Access to Justice Act (5 U.S.C. § 504), as amended by the Small Business Regulatory Enforcement Fairness Act (P.L. 104-121), and any regulations promulgated pursuant to those Acts.

iii. Termination and Satisfaction

61. When Respondent believes that it has complied with all the requirements of this CAFO, including compliance with the Compliance Order and payment of the civil penalty, Respondent shall so certify in writing and in accordance with the certification language set forth in Section V (Compliance Order), Paragraph 53. Unless the EPA, objects in writing within sixty (60) days of EPA's receipt of Respondent's certification, then this CAFO is terminated on the basis of Respondent's certification.

62. This CAFO resolves the claims set forth in Section IV, Factual Allegations and Alleged Violations, and Med Fusion, and its officers, directors, employees, and affiliated entities are released from civil liabilities as provided in 40 C.F.R. §§ 22.18(e) and 22.31 upon the termination of this CAFO.

iv. Effective Date of Settlement

63. This CAFO shall become effective upon filing with the Regional Hearing Clerk.

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**THE UNDERSIGNED PARTIES CONSENT TO THE ENTRY OF THIS CONSENT
AGREEMENT AND FINAL ORDER:**

FOR THE RESPONDENT:

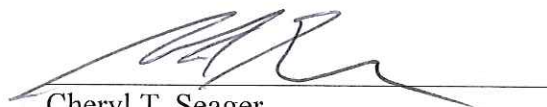
Date: 3/21/18



Med Fusion, LLC

FOR THE COMPLAINANT:

Date: MAR 30 2018



Cheryl T. Seager
Director
Compliance Assurance and
Enforcement Division

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FINAL ORDER

64. Pursuant to the Consolidated Rules of Practice Governing the Administrative

Assessment of Civil Penalties, 40 C.F.R. Part 22, the foregoing CAFO is hereby ratified.

This Final Order shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. This Final Order shall resolve only those causes of action alleged herein. Nothing in this Final Order shall be construed to waive, extinguish or otherwise affect Respondent's (or its officers, agents, servants, employees, successors, or assigns) obligation to comply with all applicable federal, state, and local statutes and regulations, including the regulations that were the subject of this action. The Respondent is ordered to comply with the terms of settlement and the civil penalty payment instructions as set forth in the CAFO. Pursuant to 40 C.F.R. § 22.31(b) this Final Order shall become effective upon filing with the Regional Hearing Clerk.

Date: _____

4/4/18



Thomas Rucki
Regional Judicial Officer

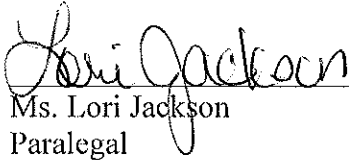
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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of April, 2018, the original of the foregoing Consent Agreement and Final Order was hand delivered to the Regional Hearing Clerk, U.S. EPA - Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, and that a true and correct copy of the CAFO was sent to the following by the method identified below:

CERTIFIED MAIL - RETURN RECEIPT REQUESTED 7005 1820000374584073

Med Fusion LLC
2501 S. State Highway 121, Suite 1100
Lewisville, TX 75067-8188
Attention: Tom Gooding
972-966-7004


Ms. Lori Jackson
Paralegal