UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

MAR 2 8 2013

CERTIFIED MAIL/ RETURN RECEIPT REQUESTED

Ms. Mary Lavin
President
Sartorius Stedim Filters, Inc.
Road 128 Int. 376 Bda. Arturo Lluberas
Yauco, Puerto Rico 00698

Re: **In the Matter of Sartorius Stedim Filters, Inc.**
Docket Number RCRA-02-2013-7102

Dear Ms. Lavin:

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 Registrant's 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 Policy. Please note that these 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,

Dore LaPosta, Director
Division of Enforcement and Compliance Assistance

Enclosures

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2

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In the Matter of

Sartorius Stedim Filters, Inc.

Respondent.

Proceeding under Section 3008 of the Solid Waste Disposal Act, as amended.

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COMPLAINT, COMPLIANCE ORDER, AND NOTICE OF OPPORTUNITY FOR HEARING

Docket Number RCRA-02-2013-7102

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 United States Code (U.S.C.) §§ 6901-6991 (together hereafter the "Act" or "RCRA"), for injunctive relief and the assessment of civil penalties.

This COMPLAINT, COMPLIANCE ORDER AND NOTICE OF OPPORTUNITY FOR HEARING ("Complaint") serves notice of the United States Environmental Protection Agency's ("EPA") preliminary determination that Sartorius Stedim Filters, Inc. (hereafter "Sartorius" or "Respondent") has violated provisions of RCRA and federal regulations concerning the management of hazardous waste at its facility in Puerto Rico.

Under Section 3006(b) of the Act, 42 U.S.C. § 6926(b), the Administrator of EPA 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 ("Puerto Rico" or "the Commonwealth") is a "State" within the meaning of this provision. Puerto Rico has not received authorization to operate a hazardous waste program pursuant to this provision. As a result, federal hazardous waste regulations remain in effect.

The Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance, EPA, Region 2, has been duly delegated the authority to institute this action. For all times relevant to this Complaint, Complainant hereby alleges:

Jurisdiction

1. This 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).

General Allegations

2. RCRA establishes a comprehensive federal regulatory program for the management of hazardous waste. 42 U.S.C. § 6901 et seq.

3. Pursuant to Sections 3002(a) and 3004(a) of RCRA, 42 U.S.C. §§ 6922(a) and 6924(a), the Administrator of EPA has promulgated regulations for the management of hazardous waste including 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 and 273.

4. 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, which includes the regulations referenced above.

5. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, required EPA to adjust its penalties for inflation on a periodic basis. The maximum civil penalty under Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), is $37,500 per day of each violation occurring after January 12, 2009. 40 C.F.R. Part 19.

Respondent

6. The Respondent is Sartorius Stedim Filters, Inc.

7. Respondent owns and operates a manufacturing plant located in Yauco, Puerto Rico. The plant produces cellulose acetate filters.

8. 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.

9. The Yauco, Puerto Rico location where Respondent conducts its manufacturing business constitutes a "facility" as that term is defined in 40 C.F.R. § 260.10 (hereinafter "facility").

10. Respondent is and has been the "owner" and "operator" of the facility as those terms are defined in 40 C.F.R. § 260.10.

11. On or about April 21, 1986, Respondent submitted a Section 3010 Notification of Regulated Waste Activity to EPA informing EPA of its hazardous waste activities at its facility. In response, EPA assigned Respondent with EPA Identification Number PRD049532807.

12. Respondent never submitted a Part A or a Part B Permit Application to EPA for its facility and never received "interim status" or a hazardous waste permit to treat, store or dispose of hazardous waste at its facility.

13. Respondent is and has been a "generator" of "hazardous waste" at its facility as those terms are defined in 40 C.F.R. § 260.10. The requirements for generators are set forth in 40 C.F.R. Part 262.

14. Respondent has generated, and continues to generate, at least 1000 kilograms ("kg") of hazardous waste in a calendar month at its facility. (Generators that generate 1000 kg or more in a month are commonly referred to as large quantity generators ("LQGs")).

15. Respondent has been holding, and continues to hold, hazardous waste generated at its facility in a hazardous waste container storage area and/or hazardous waste tank(s) for a temporary period of time, constituting "storage" as that term is defined in 40 C.F.R. 260.10. Respondent stores hazardous waste on site for a period of 90 days or less.

16. The facility operated two hazardous waste storage tanks prior to November 17, 2010. Thereafter, it has operated and continues to operate a single hazardous waste storage tank.

17. Pursuant to 40 C.F.R. § 262.34, LQGs may accumulate hazardous waste on site without interim status or a permit for 90 days or less provided that they comply with, among other things, the applicable requirements set forth in 40 C.F.R Part 265, Subparts BB and CC. Having failed to comply with certain requirements set forth in Subparts BB and CC as alleged herein, Respondent is subject to the requirements set forth in 40 C.F.R. Part 264. See 40 C.F.R. § 264.1(b).

40 C.F.R. Part 264, Subpart BB

18. Subpart BB of 40 C.F.R. Parts 264 sets forth air emission standards for "equipment," as that term is defined in 40 C.F.R. § 264.1031, that contains or contacts hazardous waste with organic concentrations of at least 10 percent by weight (hereafter referred to as "organic hazardous waste"). These requirements are set forth at 40 C.F.R. §§ 264.1050-1065.

19. Since at least April 2009, Respondent has conveyed, and continues to convey, organic hazardous waste through pipes and equipment, including pumps and valves, to an above ground storage tank(s) at its facility.

20. Pursuant to 40 C.F.R. § 264.1050(f), equipment that contains or contacts organic hazardous waste for less than 300 hours per calendar year is excluded from certain specified Subpart BB requirements provided that equipment is identified in the facility's operating log as required by 40 C.F.R. § 264.1064(g)(6).

21. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent's operating log did not identify any equipment at its facility as being subject to Subpart BB and did not identify whether any equipment subject to Subpart BB came into contact with or contained organic hazardous waste for less than 300 hours.

40 C.F.R. Part 264, Subpart CC

22. Subpart CC of 40 C.F.R. Parts 264 sets forth air emission standards for, among other things, tanks that receive hazardous waste with an average volatile organic concentration ("VOC") of at least 500 parts per million by weight ("ppmw"). See 40 C.F.R. § 264.1082(c)(1). These requirements are set forth in 40 C.F.R. §§ 264.1080-1090.

23. Since at least April 2009, Respondent has stored and continues to store hazardous waste with an average VOC of at least 500 ppmw in its hazardous waste tank(s).

EPA Investigative and Initial Enforcement Activities

24. On or about April 17, 2012, a duly designated representative of EPA conducted an inspection of the facility pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927, to determine Respondent's compliance with RCRA and its implementing regulations ("the Inspection").

25. Pursuant to Sections 3007 and 3008 of RCRA, 42 U.S.C. §§ 6927 and 6928, on or about July 18, 2012, EPA issued Respondent an Information Request Letter ("IRL") and a Notice of Violation ("NOV") regarding its management of hazardous waste at its facility.

26. On or about September 25, 2012, Respondent submitted responses to EPA's IRL/NOV. This submission was prepared by an agent of Respondent in the course of carrying out its employment or duties.

Count 1
Failure to Maintain Required Records for Equipment Subject to Subpart BB

27. Complainant re-alleges each allegation contained in the above paragraphs as if fully set forth herein.

28. 40 C.F.R. § 264.1064 sets forth the recordkeeping requirements for owners and operators subject to Subpart BB.

29. 40 C.F.R. § 264.1064(b)(1) requires owners and operators of equipment to which Subpart BB applies to record, among other things, the following information in the operating log: i) equipment identification numbers and hazardous waste management unit identification; ii) approximate locations of equipment within the facility; iii) the type of equipment (*i.e.*, valve or pump); and iv) the percentage by weight total organics in the waste stream at the equipment.

30. 40 C.F.R. § 264.1064(g) further requires owners and operators with equipment subject to the requirements set forth in 40 C.F.R. §§ 264.1052-1060 to record in the operating record, among other things, all equipment that comes into contact with organic hazardous waste for less than 300 hours.

31. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent's operating log did not contain any information regarding equipment at its facility subject to Subpart BB.

32. Respondent's failure to record and maintain requisite information regarding Subpart BB equipment in its operating log during the above referenced period is a violation of 40 C.F.R. § 264.1064.

Count 2
Failure to Conduct Required Monitoring of Pumps in Light Liquid Service

33. Complainant re-alleges each allegation contained in the above paragraphs as if fully set forth herein.

34. Pursuant to 40 C.F.R. § 264.1052(a)(1) each pump in light liquid service shall be monitored monthly to detect leaks by methods specified in 40 C.F.R. §264.1063(b).

35. Pursuant to 40 C.F.R. § 264.1063(b)(1), monitoring shall comply with Reference Method 21 in 40 C.F.R. Part 60.

36. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent had five pumps in "light liquid service," as that term is defined in 40 C.F.R. § 264.1031, at its facility.

37. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent failed to conduct monthly leak detection monitoring pursuant to Reference Method 21 on the five pumps in light liquid service at its facility.

38. Respondent's failure to conduct monthly monitoring pursuant to Method 21 on each of its five pumps in light liquid service during the above referenced time period is a violation of 40 C.F.R. § 264.1052(a)(1).

Count 3
Failure to Conduct Required Monitoring of Valves in Light Liquid Service

39. Complainant re-alleges each allegation contained in the above paragraphs as if fully set forth herein.

40. Pursuant to 40 C.F.R. § 264.1057(a), each valve in light liquid service shall be monitored monthly to detect leaks by the methods specified in 40 C.F.R. § 264.1063(b).

41. Pursuant to 40 C.F.R. § 264.1063(b)(1), monitoring shall comply with Reference Method 21.

42. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent had 27 valves in "light liquid service," as that term is defined in 40 C.F.R. § 264.1030, at its facility.

43. During the period of time between at least April 17, 2009 and April 17, 2012, Respondent failed to perform monthly leak detection monitoring pursuant to Reference Method 21 on 27 valves at its facility.

44. Respondent's failure to conduct monthly monitoring on all 27 valves in light liquid service pursuant to Reference Method 21 during the above referenced time period is a violation of 40 C.F.R. § 264.1057(a).

Count 4
Failure To Timely Determine Maximum Organic Vapor Pressure

45. Complainant re-alleges each allegation contained in the above paragraphs as if fully set forth herein.

46. Pursuant to 40 C.F.R. § 264.1084(c)(1) an owner or operator shall determine the maximum organic vapor pressure for a hazardous waste to be managed in a tank using Tank Level 1 controls before the waste is placed in the tank using the procedures referenced therein.

47. Respondent has been using Tank Level 1 Controls on its hazardous waste storage tank since on or about November 17, 2010.

48. Respondent has stored hazardous waste with VOCs of over 500 ppmw in its hazardous waste tank since on or about November 17, 2010.

49. Respondent determined the maximum vapor pressure for the hazardous waste in the tank in August 2012.

50. Respondent's failure to determine the organic vapor pressure for its hazardous waste prior to placing the waste in its storage tank is a violation of 40 C.F.R. § 264.1084(c)(1).

II. PROPOSED CIVIL PENALTY

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

Count 1:	$32,900
Counts 2 and 3:	$36,560
Count 4:	$13,455

Total Proposed Penalty for Counts 1 - 4 is **$82,915**

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://www.epa.gov/compliance/resources/policies/civil/rcra/rcpp2003-fnl.pdf***. This 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 by the Debt Collection Improvement Act of 1996, 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. These 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); and the November 16, 2009 document entitled Adjusted Penalty Policy Matrices based on the 2008 Civil Monetary Inflation Rule (with a further revision not relevant to this action on April 6, 2010).

The maximum civil penalty under Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), for violations after January 12, 2009 is $37,500 per day of violation.

The Complainant proposes, subject to receipt and evaluation of further relevant information from the Respondent, that the Respondent be assessed the civil penalty set forth above for the violations alleged in this Complaint. 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 included as Attachments II, and III, below.

COMPLIANCE ORDER

Based upon the foregoing, and pursuant to the authority of Section 3008 of the Act, Complainant issues Respondent the following Compliance Order:

1) a. Within twenty (20) days of the effective date of this Compliance Order, to the extent it has not already done so, Respondent shall comply with all applicable and appropriate provisions for the short term accumulation of hazardous waste by large quantity generators referenced in 40 C.F.R. § 262.34, including those set forth in 40 C.F.R. Part 265, Subparts BB and CC; or

b. As an alternative to compliance with the generator provisions identified in Paragraph 1.a. of this Compliance Order, obtain and comply with all the provisions of a hazardous waste storage permit from the Environmental Protection Agency, Region 2. Respondent must however comply with the appropriate requirements in 40 C.F.R. Part 264, including Subparts BB and CC, within twenty (20) days of the effective date of this Compliance Order until such permit is obtained and effective.

2) Within thirty (30) calendar days of the effective date of this Compliance Order, Respondent shall submit to EPA: a) a written statement indicating if it intends to continue its operations at its facility as a generator generating more than 1000 kilograms of hazardous waste in a calendar month (often referred to as a "large quantity generator") or as a permitted facility; and b) a statement indicating its compliance with this Compliance Order, and all documentation Respondent necessary to demonstrate such compliance. Respondent's submission may reference information already submitted to EPA. If earlier submitted information is referenced, Respondent shall indicate dates, and other identifying aspects, of these prior submissions. If Respondent is in noncompliance with a particular requirement, the notice shall state the reasons for noncompliance and shall provide a schedule for achieving prompt compliance with the requirement.

3) All responses, documentation, and evidence submitted in response to this Compliance Order should be sent to:

John Wilk, Compliance Officer
Hazardous Waste Compliance Section
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway, 21st Floor
New York 10007-1866

4) This Compliance Order shall take effect 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).

5) 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 commonwealth) provisions, nor does such compliance release Respondent from liability for any RCRA violations occurring or existing at the Sartorius facility. In addition, nothing herein waives, prejudices or otherwise affects EPA's right to enforce against Respondent 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 Sartorius facility.

IV. NOTICE OF LIABILITY FOR ADDITIONAL CIVIL PENALTIES

Pursuant to the terms of Section 3008(c) of RCRA and the Debt Collection Improvement Act of 1996, a violator failing to take corrective action within the time specified in a compliance order regarding hazardous waste violations is liable for a civil penalty of up to $37,500 for each day of continued noncompliance (73 Fed. Reg. 75340, December 11, 2008).

V. PROCEDURES GOVERNING THIS ADMINISTRATIVE LITIGATION

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 COMPLIANCE ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS." These rules are codified at 40 C.F.R. Part 22. A copy of these rules accompanies this Complaint.

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 are 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(s) to the Complaint, and such Answer(s) 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
New York, New York 10007-1866

(**NOTE:** Any documents that are filed after the Answer has been filed should be filed as specified in "D" below.)

Respondent shall also then serve one copy of the Answer(s) to the Complaint upon Complainant and any other party to the action. 40 C.F.R. § 22.15(a).

Respondent's Answer(s) 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 the Answer(s), the allegation is deemed denied. 40 C.F.R. § 22.15(b).

The Answer(s) 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 affirmatively to raise in the Answer(s) facts that constitute or that might constitute the grounds of its 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(s), a hearing upon the issues raised by the Complaint and Answer(s) may be held. 40 C.F.R. § 22.15(c). If, however, Respondent requests a hearing, the Presiding Officer (as defined in 40 C.F.R. § 22.3) may hold a hearing if the Answer(s) raises issues appropriate for adjudication. 40 C.F.R. § 22.15(c). With regard to the Compliance Order in the Complaint, unless either Respondent requests a hearing pursuant to 40 C.F.R. § 22.15 within 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 their Answer(s) 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 30-day period set forth in 40 C.F.R. § 22.15(a)) Answer(s) 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(s) 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 30 days after the default order becomes final pursuant to 40 C.F.R. § 22.27(c). 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). 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 Environmental Appeals Board 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 the right to judicial review. 40 C.F.R. § 22.27(d).

To appeal an initial decision to the Agency's Environmental Appeals Board ("EAB"), Respondent must do so "[w]ithin 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 affected 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 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.

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 they believe is relevant to the disposition of this matter, including: (1) actions Respondent has taken to correct any or all of the violations herein alleged, and/or (2) 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:

Amy R. Chester
Assistant Regional Counsel
U.S. Environmental Protection Agency
290 Broadway, 16th floor
New York, N.Y. 10007-1866

Telephone (212) 637-3213

Please note that Amy Chester will be out of the office until April 25, 2013. Requests or questions prior to that date should be made to:

Lee Spielmann
Assistant Regional Counsel
U.S. Environmental Protection Agency
290 Broadway, 16th floor
New York, N.Y. 10007-1866

Telephone (212) 637-3222

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 request for 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(s) 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 shall be embodied in a written consent agreement. 40 C.F.R. § 22.18(b)(2). In accepting the consent agreement, Respondent waives the right to contest the allegations in the Complaint and waives the 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 entering into a settlement through the signing of such Consent Agreement and its complying with the terms and conditions set forth in the such Consent Agreement terminate this administrative litigation and the civil proceedings arising out of the allegations made in the Complaint. Respondent entering into a settlement does not extinguish, waive, satisfy or otherwise affect their obligation and responsibility to comply with all applicable statutory and regulatory requirements, and to maintain such compliance.

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 30 days after receipt of the Complaint, Respondent should promptly contact the Assistant Regional Counsel identified on the previous page.

Dated: _____, 2013
New York, New York

COMPLAINANT:

_____
Dore LaPosta, Director
Division of Enforcement and Compliance Assistance
Environmental Protection Agency, Region 2
290 Broadway, 21st floor
New York, NY 10007-1866

To: Ms. Mary Lavin
President
Sartorius Stedim Filters
Road 128 Int. 376 Bda. Arturo Lluberas
Yauco, Puerto Rico 00698

CERTIFICATE OF SERVICE

This is to certify that on the day of March 29, 2013, 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-02-2013-7102, together with Attachments I and II (collectively henceforth referred to as the "Complaint"), and with a copy of the "CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENTS OF CIVIL PENALTIES, ISSUANCE OF COMPLIANCE OR CORRECTIVE ACTION COMPLIANCE ORDERS, AND THE REVOCATION, TERMINATION OR SUSPENSION OF PERMITS," 40 C.F.R. Part 22, by certified mail, return receipt requested, to each of the following addressees listed below. I also on said date hand carried the original and a copy of the Complaint to the Office of the Regional Hearing Clerk of the United States Environmental Protection Agency, Region 2, 290 Broadway, 16th floor, New York, New York 10007-1866.

Ms. Mary Lavin
President
Sartorius Stedim Filters, Inc
Road 128 Int. 376 Bda. Arturo Lluberas
Yauco, Puerto Rico 00698

Dated: March 29, 2013
New York, New York

Mildred Baez
MILDRED BAEZ

ATTACHMENT I

PENALTY CALCULATION WORKSHEET
WITH NARRATIVE EXPLANATION

Sartorius Stedim Filters, Inc.

Sartorius Stedim Filters, Inc.

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT

Penalty Computation Worksheet (Count 1)

Respondent: Sartorius Stedim Filters, Inc.

Facility Address: Route 128, Intersection 376, Yauco, PR 00698

Requirement Violated: 40 C.F.R. § 264.1064 - Respondent failed to identify equipment subject to Subpart BB in its operating log.

PENALTY AMOUNT FOR COMPLAINT-

1. Gravity based penalty from matrix	$32,900
(a) Potential for harm	MAJOR
(b) Extent of Deviation	MAJOR
2. Select an amount from the appropriate multiple matrix cell	$0
3. Multiply line 2 by number of number of days minus 1:	$0
4. Add line 1 and line 3	$32,900
5. Percent increase/decrease for good faith	0%
6. Percent increase for willfulness/negligence	0%
7. Percent increase for history of noncompliance	0%
8. Total lines 5 through 7	0%
9. Multiply line 4 by line 8	$0
10. Calculate economic benefit -- de minimis	$0
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint	**$32,900**

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT
Penalty Computation Worksheet (Count 1)

1) Gravity Based Penalty

   a) Potential for Harm - The potential for harm for failing to identify equipment subject to Subpart BB in its operating record is deemed to be MAJOR. The RCRA Civil Penalty Policy provides that the potential for harm should be based on two factors: the risk of human or environmental exposure; and the adverse impact of the noncompliance on the regulatory scheme. The RCRA regulatory program is undermined when an owner/operator of a facility subject to Subpart BB fails to identify the regulated equipment. Equipment identification is the first step in ensuring that Subpart BB requirements are complied with.

   b) Extent of Deviation - The extent of deviation present in this violation was determined to be MAJOR. Respondent failed to identify any of its Subpart BB equipment in its operating log.

      The applicable cell ranges from $28,330 to $37,500. The midpoint of the cell matrix ($32,900) was selected

   c) Multiple/Multi-day – Since Respondent only had to perform this task once, EPA has not calculated a multiple component. To the extent this violation has ongoing ramifications, the multiple day component was captured in the penalties calculated for Counts 2 and 3.

2) Adjustment Factors

   a) Good Faith - Based upon facility specific factors and available information, no adjustment has been made at this time.
   b) Willfulness/Negligence - Not applicable.
   c) History of Compliance - Based upon facility specific factors and available information, no adjustment has been made at this time.
   d) Ability to Pay - Not applicable.
   e) Environmental Project - Not applicable.
   f) Other Unique Factors - Not applicable

3) Economic Benefit - No penalty is being sought to recoup Respondent's economic benefit for this violation since Respondent and/or its employees should have been able to identify such equipment with no or low additional cost to Respondent.

Sartorius Stedim Filters, Inc.

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT

Penalty Computation Worksheet (Counts 2 and 3)

Respondent: Sartorius Stedim Filters, Inc.

Facility Address: Route 128, Intersection 376, Yauco, PR 00698

Requirements Violated: 40 C.F.R. §§ 264.1052 and 1057 - Respondent failed to perform monthly leak detection on pumps and valves in light liquid service.

PENALTY AMOUNT FOR COMPLAINT

1. Gravity based penalty from matrix		$24,790
(a) Potential for harm		MAJOR
(b) Extent of Deviation		MODERATE
2. Select an amount from the appropriate multiple matrix cell		$1,070
3. Multiply line 2 by number of number of days minus 1:	11	$11,770
4. Add line 1 and line 3		$36,560
5. Percent increase/decrease for good faith		0%
6. Percent increase for willfulness/negligence		0%
7. Percent increase for history of noncompliance		0%
8. Total lines 5 through 7		0%
9. Multiply line 4 by line 8		$0
10. Calculate economic benefit -- de minimis		$0
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint		**$36,560**

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT
Penalty Computation Worksheet (Counts 2 and 3)

1) Gravity Based Penalty

   a) Potential for Harm - The potential for harm for failing to perform monthly leak detection monitoring on pumps and valves in light liquid service subject to Subpart BB is deemed to be MAJOR. The RCRA Civil Penalty Policy provides that the potential for harm should be based on two factors: the risk of human or environmental exposure; and the adverse impact of the noncompliance on the regulatory scheme. The RCRA regulatory program is undermined when an owner/operator of a facility fails to perform requisite monitoring, which is employed to detect leaks. By failure to conduct the requisite monitoring, Respondent increased the chance of hazardous waste releases not being detected and remedied, and undermines the regulatory scheme.

   b) Extent of Deviation - The extent of deviation present in this violation was determined to be MODERATE. Respondent failed to monitor any of its Subpart BB equipment prior to EPA's inspection; however, a number of the pumps and valves were in contact with organic hazardous waste for less than 300 hours and would not have been subject to monitoring if Respondent had properly noted this in its operating log.

      The applicable cell ranges from $21,250 to 28,329. The midpoint of the cell matrix was selected ($24,790).

   c) Multiple/Multi-day – The facility failed to monitor all of its pumps and valves during at least a three year time period. EPA, however, is using its discretion and limiting the duration of violations to one year or 12 occasions, using the low end of the matrix. This is because at the time of EPA's inspection all of the valves and pumps appeared to be in good condition and the facility was conducting daily visual inspections of its tank system.

2) Adjustment Factors

   a) Good Faith - Based upon facility specific factors and available information, no adjustment has been made at this time.
   b) Willfulness/Negligence - Not applicable.
   c) History of Compliance - Based upon facility specific factors and available information, no adjustment has been made at this time.
   d) Ability to Pay - Not applicable.
   e) Environmental Project - Not applicable.
   f) Other Unique Factors - Not applicable

3) Economic Benefit - No penalty is being sought to recoup Respondent's economic benefit for this violation since Respondent and/or its employees should have been able to monitor the equipment with little additional cost.

Sartorius Stedim Filters, Inc.

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT

Penalty Computation Worksheet (Count 4)

Respondent: Sartorius Stedim Filters, Inc.

Facility Address: Route 128, Intersection 376, Yauco, PR 00698

Requirement Violated: 40 C.F.R. § 264.1084 - Respondent failed to timely determine the maximum organic pressure of the hazardous waste in the tank.

PENALTY AMOUNT FOR COMPLAINT

1. Gravity based penalty from matrix	$13,455
(a) Potential for harm	MODERATE
(b) Extent of Deviation	MAJOR
2. Select an amount from the appropriate multiple matrix cell	$0
3. Multiply line 2 by number of number of days minus 1:	$0
4. Add line 1 and line 3	$13,455
5. Percent increase/decrease for good faith	0%
6. Percent increase for willfulness/negligence	0%
7. Percent increase for history of noncompliance	0%
8. Total lines 5 through 7	0%
9. Multiply line 4 by line 8	$0
10. Calculate economic benefit -- de minimis	$0
11. Add lines 4, 9 and 10 for penalty amount to be inserted into the complaint	**$13,455**

NARRATIVE EXPLANATION TO SUPPORT COMPLAINT AMOUNT
Penalty Computation Worksheet (Count 4)

1) Gravity Based Penalty

   a) Potential for Harm - The "Potential for Harm" resulting from this violation was determined to be "Moderate." Although the Respondent failed to timely determine the organic vapor pressure of the hazardous waste being managed in the tank, Level 1 controls were in place thus limiting the potential for releases.

   b) Extent of Deviation - The extent of deviation present in this violation was determined to be MAJOR. The facility did not determine the vapor pressure in the tank until April 2012, and this determination is necessary to confirm the adequacy of Level 1 controls for a hazardous waste tank.

      The applicable cell ranges from $11,330 to $15,580. The midpoint of the cell matrix ($13,455) was selected.

   c) Multiple/Multi-day – Failure to determine the maximum organic vapor pressure of the organic hazardous waste stored in hazardous waste storage tank is considered to be a one-time event.

2) Adjustment Factors

   a) Good Faith - Based upon facility specific factors and available information, no adjustment has been made at this time.
   b) Willfulness/Negligence - Not applicable.
   c) History of Compliance - Based upon facility specific factors and available information, no adjustment has been made at this time.
   d) Ability to Pay - Not applicable.
   e) Environmental Project - Not applicable.
   f) Other Unique Factors - Not applicable

3) Economic Benefit - No penalty is being sought to recoup Respondent's economic benefit for this violation since Respondent and/or its employees should have been able to determine the vapor pressure of the hazardous waste in the tank at no or low additional cost to Respondent.

ATTACHMENT II
TABLE I - GRAVITY MATRIX

POTENTIAL FOR HARM	EXTENT OF DEVIATION FROM REQUIREMENT			
		MAJOR	**MODERATE**	**MINOR**
	MAJOR	**$37,500 to $28,330**	**$28,329 to $21,250**	**$21,249 to $15,580**
	MODERATE	**$15,580 to $11,330**	**$11,329 to $7,090**	**$7089 to $4,250**
	MINOR	**$4,250 to $2,130**	**$2,129 TO $710**	**$709 TO $150**

ATTACHMENT II
TABLE II - MULTI-DAY MATRIX

	EXTENT OF DEVIATION FROM REQUIREMENT			
POTENTIAL FOR HARM		Major	Moderate	Minor
	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

receipt of the Complaint, Respondent should promptly contact the Assistant Regional Counsel identified on the previous page.

Dated: 3/28, 2013
New York, New York

COMPLAINANT:

Dore LaPosta, Director
Division of Enforcement and Compliance Assistance
Environmental Protection Agency, Region 2
290 Broadway, 21st floor
New York, NY 10007-1866

To: Ms. Mary Lavin
President
Sartorius Stedim Filters
Road 128 Int. 376 Bda. Arturo Lluberas
Yauco, Puerto Rico 00698