

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103**



IN THE MATTER OF:)	DOCKET NO.: RCRA-03-2026-0080
)	
BioSpectra, Inc.)	EXPEDITED SETTLEMENT AGREEMENT AND
)	FINAL ORDER
Respondent,)	
)	
BioSpectra, Inc.)	Proceeding under Section
100 Majestic Way)	3008(a) and (g) of the Resource
Bangor, PA 18013,)	Conservation and Recovery Act, as
)	amended, 42 U.S.C. § 6928(a) and (g)
Facility)	
)	

EXPEDITED SETTLEMENT AGREEMENT

1. BioSpectra, Inc. (“Respondent”), and the Director, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region 3 (“Complainant”) enter into this Expedited Settlement Agreement (“Agreement”) pursuant to Section 3008(a) and (g) of the Resource Conservation and Recovery Act (“RCRA”), as amended, 42 U.S.C § 6928(a) and (g), and the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (“Consolidated Rules of Practice”), 40 C.F.R. Part 22 (with specific reference to 40 C.F.R. §§ 22.13(b), 22.18(b)(2), and (3)). The Administrator has delegated the authority to enter into this Agreement to the Regional Administrator who, in turn, has delegated it to the Complainant.
2. The U.S. Environmental Protection Agency, Region 3 (“EPA”) has jurisdiction over this matter pursuant to Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), and 40 C.F.R. §§ 22.1(a)(4) and 22.4 of the Consolidated Rules of Practice.
3. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), EPA has authorized the Commonwealth of Pennsylvania to administer a hazardous waste management program in lieu of the federal hazardous waste management program established under RCRA Subtitle C, 42 U.S.C. §§ 6921-6939g. The provisions of the current authorized Pennsylvania Hazardous Waste Management Regulations (“PaHWMR”), codified at 25 Pa. Code 260a-266a, 266b, and 268a, 270a, have thereby become requirements of RCRA Subtitle C and are enforceable by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). EPA last authorized revisions to the PaHWMR on June 29, 2009, including incorporation by reference of the federal regulations which were in effect as of October 12, 2005. The Code of Federal Regulation citations used herein are to the 2005 Federal regulations in place as of October 12, 2005, when referring to the Federal regulations incorporated by the

Pennsylvania regulations.

4. On December 12, 2025, EPA sent a letter to Pennsylvania, through the Pennsylvania Department of Environmental Protection (“PADEP”), giving prior notice of this enforcement action in accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).
5. At its facility, located at 100 Majestic Way, Bangor, PA 18013 (“Facility”), Respondent produces salts and solutions for use in pharmaceutical manufacturing. On May 14, 2024, the Respondent most recently submitted a notification to PADEP that the Facility was a large quantity generator (“LQG”) of hazardous waste (“HW”) at the Facility and has been assigned by PADEP the RCRA ID No. PAD038422036. Respondent does not have a permit for the treatment, storage (for greater than 90 days), or disposal of HW at the Facility.
6. Complainant alleges that, at all times relevant to the allegations described in this Agreement, Respondent was and continues to be a corporation and is therefore a “person,” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903(15), and PaHWMR, and at all times relevant to the allegations in this Agreement was the “operator” and the “owner” of a “facility,” described in Paragraph 5, as the terms “facility,” “owner” and “operator” are defined in 40 C.F.R. § 260.10, as incorporated by reference in PaHWMR.
7. At all times relevant to the allegations described in this Agreement, Respondent stored HW including sodium hydroxide waste, isopropyl alcohol waste, in addition to lab and scrubber water wastes with EPA HW Numbers D001, D002, D007, D008, D009, D011, D022, D038, F001, F003, F005, and P030, which are “hazardous waste(s)” at the Facility, as the terms “stored” and “hazardous waste” are defined in 40 C.F.R. § 260.10, as incorporated by reference in 25 Pa. Code 260a.10.
8. On April 23, 2025, EPA representatives conducted a Compliance Evaluation Inspection (“Inspection”) at the Facility to determine compliance with the applicable hazardous waste regulations.
9. Based on the observations during the Inspection, Complainant alleges and finds that Respondent failed to comply with specific requirements of Subtitle C of RCRA, 42 U.S.C. §§ 6921 et seq., its implementing regulations at 40 C.F.R. Parts 262, 264, 265, and the federally-authorized Pennsylvania hazardous waste management regulations set forth in the PaHWMR, 25 Pa. Code 260a-266a, 266b, and 268a-270a et seq.
10. Complainant has identified the following violations at the Facility:
 - a. Respondent violated 42 U.S.C. § 6925(a) and 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b) by operating its Facility without a permit.

(1) From April 15, 2025 to April 23, 2025, the Respondent stored HW onsite for

greater than 90 days in violation of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a). At the time of the Inspection, the Facility stored one (1), 55-gallon drum of D001, F003 isopropyl alcohol waste marked with an accumulation start date of January 15, 2025, nine (9) days in excess of 90 days.

- (2) Additionally, the following acts or omissions prevented Respondent from meeting the regulatory permit exemption conditions set forth at 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34:
 - (i) On April 23, 2025, Respondent failed to mark HW containers with an accumulation start date, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(2). At the time of the Inspection, the Respondent failed to mark the following containers with accumulation start dates: two (2) 275-gallon totes of D002 HW and three (3) bins of lab pack wastes;
 - (ii) On April 23, 2025, Respondent failed to label HW containers with the words hazardous waste, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(3). At the time of the Inspection, the Respondent failed to label the following containers as HW: two (2) 275-gallon totes of D002 HW, three (3) bins of lab pack wastes, four (4), one (1)-liter containers of methanol lab waste, and five (5) small containers of lab waste;
 - (iii) Respondent failed to conduct weekly inspections of its HW accumulation area, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) referring to 40 C.F.R. 265 Subpart I, as described in 10.c. below;
 - (iv) Respondent failed to conduct and document a 40 CFR Subpart BB applicability determination, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) referring to 40 C.F.R. 265 Subpart BB, as described in 10.d. below;
 - (v) Respondent failed to maintain adequate aisle space, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(4) in reference to 40 C.F.R. 265 Subpart C, as described in 10.e. below;
 - (vi) Respondent failed to provide copies of its Contingency Plan to local authorities, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(4) in reference to 40 C.F.R. 265 Subpart D, as described in 10.f. below; and

- (vii) Respondent failed to list HW responsibilities within job descriptions of employees with HW duties, as required by 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.34(a)(4) in reference to 40 C.F.R. § 265.16, as described in 10.g. below.

- b. On April 23, 2025, Respondent failed to make a waste determination, in violation of 25 Pa. Code § 262a.10, which incorporates by reference 40 C.F.R. § 262.11. At the time of the Inspection, five (5) 275-gallon totes were located in the Facility's HW accumulation area for which Respondent had not made a waste determination.

- c. On September 29, 2023 through October 27, 2023, Respondent failed to conduct weekly inspections of its HW accumulation area, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.174. At the time of the Inspection the inspector did not observe weekly inspection logs for three (3) weeks between September 29, 2023 and October 27, 2023 and it is the Facility's general practice to keep logs of its HW accumulation area weekly inspections.

- d. On April 23, 2025, Respondent failed to maintain an up-to-date analysis with supporting information and data used to determine whether equipment is subject to 40 C.F.R. Subpart BB, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.1064(k)(3). At the time of the Inspection, the Respondent did not make a Subpart BB applicability determination for at least one (1) pump used to transfer HW isopropyl alcohol.

- e. On April 23, 2025, Respondent failed to maintain adequate aisle space, in violation of Pa. 25 Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.35. At the time of the Inspection, Respondent did not maintain adequate aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment in an emergency in its HW accumulation area.

- f. On April 23, 2025, Respondent failed to provide copies of its Contingency Plan to local authorities, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.53. At the time of the Inspection, Respondent had not submitted its Contingency Plan to all local police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services.

- g. On April 23, 2025, Respondent failed to include HW duties within job descriptions, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.16(d)(2). At the time of the Inspection, Respondent did not include HW duties in its "Lab Tech II" and "Chemical Operator II" job descriptions.

At the time of the Inspection, the inspector also observed the following Areas of Concern:

Respondent did not have a quick reference guide for its Contingency Plan at the Facility and the Respondent submitted its 2021 biennial report for the Facility on April 14, 2022, with the due date being March 1, 2022, after working through submission difficulties with the PADEP central office.

11. Complainant and Respondent agree that settlement of this matter for a total penalty of **THIRTEEN THOUSAND SEVEN HUNDRED AND FIFTY DOLLARS (\$13,750.00)** is in the public interest. In calculating this amount, Complainant considered the statutory factors set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3).
12. Respondent agrees that, within 30 days of the effective date of this Agreement, Respondent shall make a payment of \$13,750.00 (“the Assessed Penalty”). Respondent shall pay the Assessed Penalty and any interest, fees, and other charges due using one of the electronic payment options provided on the EPA website: <https://www.epa.gov/financial/makepayment>. For additional instructions relating to electronic payment options, see: <https://www.epa.gov/financial/additional-instructions-making-payments-epa>. Respondent acknowledges that EPA has provided adequate notification that, prior to the Effective Date, in accordance with Executive Order 14247: Modernizing Payments To and From America’s Bank Account, EPA ceased accepting paper checks as a form of payment of civil penalties and EPA only accepts specific electronic methods of payments as provided on the above website.
13. Within 24 hours of payment, Respondent shall also send proof of payment (confirmation of credit card or debit card payment, confirmation of wire or automated clearinghouse transfer), by electronic mail to:

Rebecca Serfass, Sr. Inspector/Enforcement Officer (3ED22)
U.S. EPA, Region 3
Serfass.Rebecca@epa.gov

and

Regional Hearing Clerk (3RC00)
U.S. EPA, Region 3
R3_Hearing_Clerk@epa.gov

14. In signing this Agreement, Respondent: admits the jurisdictional allegations in this Agreement; neither admits nor denies the specific factual allegations in this Agreement, except as provided in the jurisdictional admission above; agrees not to contest EPA’s jurisdiction with respect to the execution of this Agreement, the issuance of the attached Final Order, or the enforcement the Agreement; expressly waives its right to a hearing on any issue of law or fact in this Agreement and any right to appeal the accompanying Final Order; consents to the issuance of the Agreement and agrees to comply with its terms;

- agrees to bear its own costs and attorney's fees; and agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.
15. By its signature below, Respondent certifies, subject to civil and criminal penalties for making a false submission to the United States Government, that (1) the alleged violations have been corrected, and (2) any documentation or information provided to EPA was true and accurate.
 16. This Agreement and the attached Final Order constitute a settlement by EPA of its claims for civil penalties for the violations alleged in this Agreement.
 17. By signing this Agreement, Respondent waives any rights or defenses that Respondent has or may have for this matter to be resolved in federal court, including but not limited to any right to a jury trial, and waives any right to challenge the lawfulness of the final order accompanying the Agreement.
 18. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Sections 22.18(c) and 22.31(a) of the Consolidated Rules of Practice. Further, EPA reserves any rights and remedies available to it under the RCRA, the RCRA regulations promulgated, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this Agreement, following its filing with the Regional Hearing Clerk.
 19. Late payment of the agreed upon penalty may subject Respondent to interest, administrative costs and late payment penalties in accordance with 40 C.F.R. § 13.11.
 20. This Agreement is effective upon filing, in accordance with 40 C.F.R. § 22.31(b).
 21. The undersigned representative certifies that she/he is fully authorized to execute this Agreement and to legally bind BioSpectra, Inc.
 22. As permitted under 40 CFR § 22.6, the Regional Hearing Clerk will serve copies of this Agreement and Final Order by e-mail to the parties at the following valid e-mail addresses: serfass.rebecca@epa.gov (for Complainant), and dora.meissner@biospectra.us (for Respondent).
 23. By signing this Agreement, Respondent acknowledges that this Agreement and Final Order will be available to the public and represents that, to the best of Respondent's knowledge

and belief, this Agreement and Final Order does not contain any confidential business information or personally identifiable information from Respondent.

For Respondent: BioSpectra, Inc.

Date: _____

By: _____

Dora Meissner
Executive Vice President of Regulated Systems

For Complainant: U.S. Environmental Protection Agency, Region 3

After reviewing the Agreement and other pertinent matters, I, the undersigned Director of the Enforcement and Compliance Assurance Division of the United States Environmental Protection Agency, Region 3, agree to the terms and conditions of this Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

[Digital Signature and Date]

Acting Director

Enforcement and Compliance Assurance Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103



In the Matter of: :
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BioSpectra, Inc. : U.S. EPA Docket No. RCRA-03-2026-0080
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Respondent. : Proceeding under 3008(a) and (g) of the
: Resource Conservation and Recovery Act, as
: amended, 42 U.S.C. § 6928(a) and (g)
: :
BioSpectra, Inc. :
100 Majestic Way :
Bangor, PA 18013 :
: :
Facility :

FINAL ORDER

Pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. Part 22 (with specific reference to Sections 22.13(b) and 22.18(b)(2) and (3)), the Consent Agreement resolving this matter is hereby ratified and incorporated by reference into this Final Order.

The Respondent is hereby **ORDERED** to comply with all of the terms of the Consent Agreement.

The effective date of the foregoing Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

By: _____
Regional Judicial and Presiding Officer
U.S. EPA, Region 3

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REGION 3
Philadelphia, Pennsylvania 19103

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Respondent.	:	
	:	
BioSpectra, Inc.	:	
100 Majestic Way	:	
Bangor, PA 18013	:	
	:	
Facility	:	

CERTIFICATE OF SERVICE

I certify that the foregoing *Expedited Settlement Agreement and Final Order* was filed with the EPA Region 3 Regional Hearing Clerk on the date that has been electronically stamped on the *Expedited Settlement Agreement and Final Order*. I further certify that on the date set forth below, I caused to be served a true and correct copy of the foregoing to each of the following persons, in the manner specified below, at the following addresses:

Copies served via email to:

Dora Meissner
Executive Vice President of Regulated Systems
BioSpectra, Inc.
Dora.meissner@biospectra.us
100 Majestic Way
Bangor, PA 18013

Rebecca Serfass
Sr. Inspector/Enforcement Officer
U.S. EPA, Region 3
Serfass.rebecca@epa.gov

[Digital Signature and Date]
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 3