

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
Philadelphia, Pennsylvania 19103**

In the Matter of:	:	
	:	
Piramal Critical Care, Inc. 3950 Shelden Circle Bethlehem, PA 18017	:	U.S. EPA Docket No. RCRA-03-2022-0053
	:	
Respondent.	:	Proceeding under Section 3008(a) and (g) of the Resource Conservation and Recovery Act, as amended, 42 U.S.C. Section 6928(a) and (g)
	:	
Piramal Critical Care, Inc. 3950 Shelden Circle Bethlehem, PA 18017	:	
	:	
Facility.	:	

CONSENT AGREEMENT

PRELIMINARY STATEMENT

1. This Consent Agreement is entered into by the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region III (“Complainant”) and Piramal Critical Care, Inc. (“Respondent”) (collectively the “Parties”), pursuant to Sections 3008(a) and (g) of the Solid Waste Disposal Act, commonly known as the Resource Conservation and Recovery Act of 1976, as amended by *inter alia*, the Hazardous and Solid Waste Amendments of 1984 (collectively referred to hereinafter as “RCRA”), 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. RCRA Section 3008(a)(1), 42 U.S.C. Section 6928(a)(1), authorizes the Administrator of the U.S. Environmental Protection Agency to assess penalties and undertake other actions required by this Consent Agreement. The Administrator has delegated this authority to the Regional Administrator who, in turn, has delegated it to the Complainant. This Consent Agreement and the attached Final Order (hereinafter jointly referred to as the “Consent Agreement and Final Order”) resolve Complainant’s civil penalty claims against Respondent under RCRA Section 3008(a)(1), 42 U.S.C. Section 6928(a)(1), (or the “Act”) for the violations alleged herein.

2. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant hereby simultaneously commences and resolves this administrative proceeding.

JURISDICTION

3. The U.S. Environmental Protection Agency has jurisdiction over the above-captioned matter, as described in Paragraph 1, above.
4. The Consolidated Rules of Practice govern this administrative adjudicatory proceeding pursuant to 40 C.F.R. § 22.1(a)(4).
5. In accordance with Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2), and by written letter dated February 25, 2021, EPA notified the Pennsylvania Department of Environmental Protection (“PaDEP”) of EPA’s intent to commence this administrative action against Respondent in response to the alleged violations of RCRA Subtitle C and the Pennsylvania Hazardous Waste Management Regulations (“PaHWMR”) that are set forth herein.

GENERAL PROVISIONS

6. For purposes of this proceeding only, Respondent admits the jurisdictional allegations set forth in this Consent Agreement and Final Order.
7. Except as provided in Paragraph 6, above, Respondent neither admits nor denies the specific factual allegations set forth in this Consent Agreement.
8. Respondent agrees not to contest the jurisdiction of EPA with respect to the execution of this Consent Agreement, the issuance of the attached Final Order, or the enforcement of this Consent Agreement and Final Order.
9. For purposes of this proceeding only, Respondent hereby expressly waives its right to contest the allegations set forth in this Consent Agreement and Final Order and waives its right to appeal the accompanying Final Order.
10. Respondent consents to the assessment of the civil penalty stated herein, and to any conditions specified herein.
11. Respondent shall bear its own costs and attorney’s fees in connection with this proceeding.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

12. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant alleges and adopts the Findings of Fact and Conclusions of Law set forth immediately below.

13. The Commonwealth of Pennsylvania has received federal authorization to administer a Hazardous Waste Management Program (the “Pennsylvania Hazardous Waste Management Program”)(“PaHWMR”) in lieu of the federal hazardous waste management program authorized under RCRA Subtitle C, 42 U.S.C. §§6921 – 6939 (g). Effective January 30, 1986, the PaHWMR was authorized by the EPA pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), and 40 C.F.R. Part 271, Subpart A and thereby became requirements of RCRA Subtitle C and enforceable by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a). *See 51 Fed.Reg. 1791* (January 15, 1986), *65 Fed. Reg. 57734* (September 26, 2000), *69 Fed. Reg. 2674* (January 20, 2004) and *74 Fed. Reg. 19453* (April 29, 2009).
14. Factual allegations or legal conclusions in this Consent Agreement that are based on provisions of federally authorized PaHWMR requirements cite those respective provisions as the authority for such allegations or conclusions.
15. When EPA last authorized the Pennsylvania hazardous waste regulations on June 29, 2009, EPA approved Pennsylvania’s incorporation by reference of the federal regulations which were in effect as of October 12, 2005, including, among other things, incorporation of 40 C.F.R. § 262.34 (Accumulation Time, which lists the requirements for the generator permit exemption). As a result, 40 C.F.R. § 262.34 (2005) is the currently federally enforceable version of that RCRA regulation in Pennsylvania. On November 28, 2016, EPA re-codified the generator permit exemption, effective on May 30, 2017. The federal requirements previously found in 40 C.F.R. §262.34 are now re-codified at 40 C.F.R. §§ 262.15 – 262.17. The Code of Federal Regulation citations used herein are to the Federal regulations in place as of October 12, 2005, when referring to the Federal regulations incorporated by the Pennsylvania regulations.
16. Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), authorizes EPA to initiate an enforcement action and issue an order requiring compliance whenever it determines that a person is in violation of any requirement of RCRA Subtitle C, EPA’s regulations thereunder, or any regulation of a state hazardous waste program which has been authorized by EPA. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), authorizes the assessment of a civil penalty against any person who violates any requirement of Subtitle C of RCRA.
17. Respondent is and was at the time of the violations alleged herein, a corporation incorporated under the law of the state of Delaware.
18. Respondent is and was at the time of the violations alleged herein, a “person” as defined in Section 1004(15) of RCRA, 42 U.S.C. § 6903, 25 Pa. Code § 260a.10.
19. Respondent is, and at all times relevant to this Consent Agreement, was the “owner” and “operator” of a “facility”, described in Paragraph 20 below, as those terms are defined in 40 C.F.R. § 260.10, as incorporated by reference in 25 Pa. Code § 260a.1, except for the term “facility” which is defined in 25 Pa. Code § 260a.10.

20. The facility referred to in Paragraph 19, above, including all of its associated equipment and structures (hereinafter the “Facility”), is a manufacturing facility located at 3950 Shelden Circle, Bethlehem, Pennsylvania, 18017.
21. Respondent was at all times relevant to this Consent Agreement and Final Order, a “generator” of, and has engaged in the “storage” in “containers” and “tanks” at the Facility of materials described below that are “solid wastes” and “hazardous wastes”, as those terms are defined in 40 C.F.R. § 260.10, as incorporated by reference by 25 Pa. Code § 260a.1, with the exception of the term “storage”, which is defined in 25 Pa. Code § 260a.10.
22. Respondent was at all times relevant to this Consent Agreement and Final Order, a large quantity generator of hazardous waste that generated more than 1,000 kilograms of hazardous waste per month at its Facility. Respondent is assigned EPA ID No. PA0000965533.
23. On October 3 - 4, 2019, representatives of EPA conducted a RCRA Compliance Evaluation Inspection (“CEI”) at the Facility.
24. At the time of the CEI, “hazardous wastes” generated by Respondent, identified below in Paragraphs 25 - 28, below, were in “storage” in containers and tanks at the Facility.
25. Respondent generates waste solvent at the Facility which is a hazardous waste (EPA Hazardous Waste Nos. D001) (it exhibits characteristic of ignitability) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. Part 261.
26. Respondent generates waste chromium at the Facility which is a hazardous waste (EPA Hazardous Waste Nos. D007) (it exhibits the characteristic of toxicity for chromium) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. Part 261.
27. Respondent generates waste selenium at the Facility which is a hazardous waste (EPA Hazardous Waste Nos. D010) (it exhibits the characteristic of toxicity for selenium) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. Part 261.
28. Respondent generates waste methanol and acetone which are listed hazardous wastes (EPA Hazardous Waste Nos. F003) within the meaning of 25 Pa. Code § 261a.1, which incorporates by reference 40 C.F.R. Part 261.

Count I

Operating a Treatment, Storage, and Disposal Facility without a Permit or Interim Status

29. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
30. 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) and (e) of RCRA, 42 U.S.C. § 6925(a) and (e), provide, in pertinent part, that a person may not own or operate a facility for the treatment, storage or disposal of hazardous waste unless such person has first obtained a permit for such facility or has qualified for interim status for the facility.
31. 25 Pa. Code § 262a.10 incorporates by reference 40 C.F.R. § 262.34, which provides, in pertinent part, that a generator that accumulates hazardous waste on site for less than 90 days in compliance with the terms of that section may do so without a permit or interim status, provided that the generator meets the conditions specified in the regulations.
32. 25 Pa. Code § 262a.10 incorporates by reference 40 C.F.R. § 262.34(a)(2) which provides, in pertinent part, that a generator may accumulate hazardous waste in containers on-site for 90 days or less without a permit or having interim status provided that, among other things, each container, while being accumulated on site, is properly labeled with the date upon which each period of accumulation began.
33. 25 Pa. Code § 262a.10 incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) and by further reference 40 C.F.R. § 265.173(a), which provides that a generator may accumulate hazardous waste in containers for 90 days or less without a permit or having interim status provided that, among other things, each container, while being accumulated on site, is kept closed except when adding or removing waste.
34. 25 Pa. Code § 262a.10 incorporates by reference the generator accumulation and permit exemption requirements and conditions of 40 C.F.R. § 262.34(a)(4) with further reference to 40 C.F.R. Part 265 Subpart D, which provides that a generator may accumulate hazardous waste in containers and tanks for 90 days or less without a permit or having interim status provided that, among other things, the facility have a contingency plan which includes a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.
35. 25 Pa. Code § 262a.10 incorporates by reference the generator accumulation and permit exemption requirements and conditions of 40 C.F.R. § 262.34(a)(1)(ii) and by further reference 40 C.F.R. § 265.192(g), which provides that a generator may accumulate hazardous waste in tanks for 90 days or less without a permit or having interim status provided that, among other things, that for new tanks, the owner or operator must obtain and keep on file at the facility written statements by those persons required to certify the

- design of the tank system and supervise the installation of the tank system in accordance with the requirements of paragraphs (b) through (f) of 40 C.F.R. § 265.192, that attest that the tank system was properly designed and installed and that repairs, pursuant to paragraphs (b) and (d) of 40 C.F.R. § 265.192, were performed. These written statements must also include the certification statement as required in 40 C.F.R. § 270.11(d).
36. 25 Pa. Code § 262a.10 incorporates by reference the generator accumulation and permit exemption requirements and conditions of 40 C.F.R. § 262.34(a)(1)(ii) and by further reference 40 C.F.R. § 265.195(a) – (c), which provides that a generator may accumulate hazardous waste in tanks for 90 days or less without a permit or having interim status provided that, among other things, requires the owner or operator of hazardous waste storage tanks inspect the tanks each operating day for the items specified in 40 C.F.R. § 265.195(a) – (c).
 37. 25 Pa. Code § 262a.10 incorporates by reference the generator accumulation and permit exemption requirements and conditions of 40 C.F.R. § 262.34(a)(1)(ii) and by further reference 40 C.F.R. § 265.195(d), which provides that a generator may accumulate hazardous waste in tanks for 90 days or less without a permit or having interim status provided that, among other things, the owner or operator of hazardous waste storage tanks document, in the operating record of the facility, an inspection of those items in 40 C.F.R. § 265.195(a) - (c).
 38. At the time of the CEI, Respondent had accumulated hazardous waste in a 55-gallon drum located in the Facility Hazardous Waste Accumulation Area Number 3 that was not marked with a start accumulation date as required by 25 Pa. Code § 262a.10 which incorporates by reference 40 C.F.R. § 262.34(a)(2).
 39. At the time of the CEI, Respondent had accumulated hazardous waste in a 55-gallon drum located in the Facility Hazardous Waste Accumulation Area Number 3 that was open and hazardous waste was not being added or removed as required by 25 Pa. Code § 262a.10 which incorporates by reference 40 C.F.R. § 262.34(a)(1)(i) and by further reference the container management requirements of 40 C.F.R. § 265.173(a).
 40. At the time of the CEI, Respondent did not specify the location of emergency equipment listed in the Facility Contingency Plan as required by 25 Pa. Code § 262a.10, which incorporates by reference of 40 C.F.R. § 262.34(a)(4) with further reference to 40 C.F.R. § 265 Subpart D.
 41. At the time of the CEI, Respondent stored hazardous waste in a new tank system, as defined in 25 Pa. Code § 260a.10 but did not have on file at the Facility written statements by those persons required to certify the design of the tank system and supervise the installation of the tank system in accordance with the requirements of paragraphs (b) through (f) of 40 C.F.R. § 265.192, that attest that the tank system was properly designed and installed and that repairs, pursuant to paragraphs (b) and (d) of 40 C.F.R. § 265.192, were performed as required by 25 Pa. Code § 262a.10 which incorporates by reference the generator accumulation and permit exemption requirements

and conditions of 40 C.F.R. § 262.34(a)(1)(ii) and by further reference 40 C.F.R. § 265.192(g).

42. From at least January 1, 2016 until the date of the EPA CEI, Respondent did not inspect or document daily inspections of the hazardous waste storage located at the Facility used to store waste HCL.
43. For the reasons and during the times set forth above at the Facility, Respondent failed to comply with the conditions for the temporary storage (*i.e.*, 90 days or less) of hazardous waste by a generator that are required pursuant to 25 Pa. Code § 262a.10, which incorporates by reference the requirements of 40 C.F.R. § 262.34, and therefore failed to qualify for an exemption from the permitting/interim status requirements provided by such section.
44. Respondent's Facility is a hazardous waste treatment, storage, or disposal "facility" as that term is defined in 25 Pa. Code § 260a.10 with respect to the storage of hazardous waste as described above.
45. Respondent does not have, and never had, a hazardous waste treatment or storage permit or interim status pursuant to 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), for the treatment or storage of hazardous waste at the Facility.
46. Respondent was required by 25 Pa. Code § 270a.1, which incorporates by reference 40 C.F.R. § 270.1(b), and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), to obtain a permit for the hazardous waste storage activities described in this count.
47. At the time of the CEI, Respondent violated 25 Pa. Code § 270a.1, 40 C.F.R. § 270.1(b) and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), by operating a hazardous waste storage facility without a permit, interim status or a valid exemption to the permit requirement.
48. In failing to comply with 25 Pa. Code § 270a.1 which incorporates by reference 40 C.F.R. § 270.1(b) and Section 3005(a) of RCRA, 42 U.S.C. § 6925(a), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count II
Failure to Maintain a Contingency Plan

49. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
50. 25 Pa. Code § 264a.1 incorporates by reference the Facility Contingency Plan requirements of 40 C.F.R. § 264.52(e). 40 C.F.R. § 264.52(e) requires that the Facility Contingency Plan include a list of all emergency equipment at the facility (such as fire

extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.

51. At the time of the CEI, Respondent's Facility Contingency did not specify the locations of emergency equipment in violation of 25 Pa. Code § 264a.1 which incorporates by reference the Facility Contingency Plan requirements of 40 C.F.R. § 264.52(e).
52. In failing to comply with 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. 262.52(e), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count III

Failure to Obtain Assessment or Certify Hazardous Waste Storage Tank

53. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
54. 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.192(g), requires facility owners and operators of new tanks obtain and keep on file at the facility written statements by those persons required to certify the design of the tank system and supervise the installation of the tank system in accordance with the requirements of paragraphs (b) through (f) of 40 C.F.R. § 264.192, that attest that the tank system was properly designed and installed and that repairs, pursuant to paragraphs (b) and (d) of 40 C.F.R. § 265.192, were performed. These written statements must also include the certification statement as required in 40 C.F.R. § 270.11(d).
55. At the time of the CEI, Respondent stored hazardous waste in a new tank system, as defined in 25 Pa. Code § § 260a.10, but did not have on file the written statements by those persons required to certify the design of the tank system and supervise the installation of the tank system in accordance with the requirements of paragraphs (b) through (f) of 40 C.F.R. § 265.192, that attest that the tank system was properly designed and installed and that repairs, pursuant to paragraphs (b) and (d) of 40 C.F.R. § 265.192, were performed, in violation of 25 Pa. Code § 264a.1, which incorporates by reference 40 C.F.R. § 264.192(g).
56. In failing to comply with 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. § 264.192, Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count IV
Failure to Keep Container Closed

57. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
58. 25 Pa. Code § 264a.1 incorporates by reference the container management requirements of 40 C.F.R. § 264.173(a) which requires that containers of hazardous waste be kept closed except when adding or removing waste.
59. At the time of the CEI, Respondent accumulated hazardous waste in a 55-gallon drum located in the Facility Hazardous Waste Accumulation Area Number 3 that was open and hazardous waste was not being added or removed in violation of 40 C.F.R. § 265.173(a).
60. In failing to comply with 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. § 264.173(a), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count V
Failure to Inspect Hazardous Waste Tanks Each Operating Day

61. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
62. 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. § 264.195(a) - (c), requires the owner or operator of hazardous waste storage tanks to:
 - (a) The owner or operator must develop and follow a schedule and procedure for inspecting overfill controls.
 - (b) The owner or operator must inspect at least once each operating day:
 - (1) Aboveground portions of the tank system, if any, to detect corrosion or releases of waste;
 - (2) Data gathered from monitoring and leak detection equipment (e.g., pressure or temperature gauges, monitoring wells) to ensure that the tank system is being operated according to its design; and
 - (3) The construction materials and the area immediately surrounding the externally accessible portion of the tank system, including the secondary containment system (e.g., dikes) to detect erosion or signs of releases of hazardous waste (e.g., wet spots, dead vegetation).
63. 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. § 264.195(d), requires the owner or operator of hazardous waste storage tanks to document, in the operating record of the facility, an inspection of those items in 40 C.F.R. § 264.195(a) - (c).

64. From at least January 1, 2016 until the date of the EPA CEI, Respondent did not inspect or document daily inspections of the hazardous waste storage located at the Facility used to store waste HCL.
65. In failing to comply with 25 Pa. Code § 264a.1 which incorporates by reference 40 C.F.R. § 264.195(a) - (c), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count VI
Failure to Obtain Signed Manifest

66. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
67. 25 Pa. Code § 262.4(a)(1) which incorporates by reference 40 C.F.R. 262.42(a)(1), requires a generator of greater than 1,000 kilograms of hazardous waste in a calendar month who does not receive a copy of a manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter, to contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste.
68. At the time of the CEI, Respondent had not contacted the designated facility with regard to two manifests lacking a designated facility signature, specifically, Manifest 001485613VES dated January 3, 2019, and Manifest 001669929VES dated February 28, 2019 in violation of 25 Pa. Code § 262.4(a)(1) which incorporates by reference 40 C.F.R. 262.42(a)(1).
69. In failing to comply with § 262.4(a)(1) which incorporates by reference 40 C.F.R. 262.42(a)(1), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

Count VII
Failure to Properly Manage Universal Waste Lamps

70. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
71. Respondent is a small quantity handler of universal waste as that term is defined at 25 Pa. Code § 266b.1.
72. 25 Pa. Code § 266b.1 incorporates by reference 40 C.F.R. § 273.13(d)(1) which requires universal waste lamps be stored in containers that are closed, structurally sound, compatible with the contents of the lamps and lack evidence of leakage, spillage or

damage that could cause leakage or releases of mercury or other hazardous constituents to the environment under reasonably foreseeable conditions.

73. At the time of the EPA CEI, Respondent stored one universal waste lamp without placing it in a container and stored universal waste lamps in two open containers, in violation of 25 Pa. Code § 266b.1 incorporates by reference 40 C.F.R. § 273.13(d)(1).
74. 25 Pa. Code § 266b.1, which incorporates by reference 40 C.F.R. § 273.14, requires a small quantity handler of universal waste to label or mark the universal waste to identify the type of universal waste as specified in 40 C.F.R. § 273.14.
75. 25 Pa. Code § 266b.1, which incorporates by reference 40 C.F.R. § 273.14(e), requires containers of universal waste lamps to be labeled with one of the following phrases: “Universal Waste -Lamp(s),” or “Waste Lamp(s)” or “Used Lamp(s).”
76. At the time of the EPA CEI, Respondent stored universal waste lamps in a container that was not labeled with one of the following phrases: “Universal Waste -Lamp(s),” or “Waste Lamp(s)” or “Used Lamp(s)” in violation of 25 Pa. Code § 266b.1, which incorporates by reference 40 C.F.R. § 273.14(e).
77. In failing to comply with § 25 Pa. Code § 266b.1 which incorporates by reference 40 C.F.R. § 273.13(d)(1) and 40 C.F.R. § 273.14(e), Respondent is subject to the assessment of penalties under Sections 3008(a) and (g) of RCRA, 42 U.S.C. §§ 6928(a) and (g).

CIVIL PENALTY

78. In settlement of EPA’s claims for civil penalties for the violations alleged in this Consent Agreement, Respondent consents to the assessment of a civil penalty in the amount of FIFTY-EIGHT THOUSAND THIRTY-ONE DOLLARS (\$58,031.00), which Respondent shall be liable to pay in accordance with the terms set forth below.
79. The civil penalty is based upon EPA’s consideration of a number of factors, including the penalty criteria (“statutory factors”) set forth in Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), including, the following the seriousness of the violation and any good faith efforts to comply with the applicable requirements. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA’s October, 1990 RCRA Civil Penalty Policy, as revised in June, 2003 (“RCRA Penalty Policy”), which reflects the statutory penalty criteria and factors set forth at Sections 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6982(a)(3) and (g). the appropriate *Adjustment of Civil Monetary Penalties for Inflation*, pursuant to 40 C.F.R. Part 19, and the applicable EPA memoranda addressing EPA’s civil penalty policies to account for inflation.
80. Payment of the civil penalty amount, and any associated interest, administrative fees, and late payment penalties owed, shall be made by either cashier’s check, certified check or electronic wire transfer, in the following manner:

- a. All payments by Respondent shall include reference to Respondent's name and address, and the Docket Number of this action, *i.e.*, RCRA-2022-03-0053;
- b. All checks shall be made payable to the "United States Treasury.
- c. All payments made by check and sent by regular mail shall be addressed and mailed to:

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

- d. For additional information concerning other acceptable methods of payment of the civil penalty amount see:

<https://www.epa.gov/financial/makepayment>

- e. A copy of Respondent's check or other documentation of payment of the penalty using the method selected by Respondent for payment shall be sent simultaneously by email to:

Joyce Howell
Sr. Assistant Regional Counsel
howell.joyce@epa.gov

and

U.S. EPA Region III Regional Hearing Clerk
R3_Hearing_Clerk@epa.gov.

- 81. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, EPA is entitled to assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the costs of processing and handling a delinquent claim, as more fully described below. Accordingly, Respondent's failure to make timely payment of the penalty as specified herein shall result in the assessment of late payment charges including interest, penalties and/or administrative costs of handling delinquent debts.
- 82. Payment of the civil penalty, in accordance with the above terms and provisions, is due and payable immediately upon Respondent's receipt of a true and correct copy of the fully executed and filed Consent Agreement and Final Order. Receipt by Respondent or Respondent's legal counsel of such copy of the fully executed Consent Agreement and Final Order, with a date stamp indicating the date on which the Consent Agreement and Final Order was filed with the Regional Hearing Clerk, shall constitute receipt of written

initial notice that a debt is owed EPA by Respondent in accordance with 40 C.F.R. § 13.9(a).

83. INTEREST: In accordance with 40 C.F.R § 13.11(a)(1), interest on the civil penalty assessed in this Consent Agreement and Final Order will begin to accrue on the date that a copy of the fully executed and filed Consent Agreement and Final Order is mailed or hand-delivered to Respondent. However, EPA will not seek to recover interest on any amount of the civil penalties that is paid within thirty (30) calendar days after the date on which such interest begins to accrue. Interest 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).
84. ADMINISTRATIVE COSTS: The costs of the EPA's administrative handling of overdue debts will be charged and assessed monthly throughout the period a debt is overdue. 40 C.F.R. § 13.11(b). Pursuant to Appendix 2 of EPA's *Resources Management Directives – Case Management*, Chapter 9, EPA will assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the first thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) days the penalty remains unpaid.
85. LATE PAYMENT PENALTY: A late payment penalty of six percent per year will be assessed monthly on any portion of the civil penalty that remains delinquent more than ninety (90) calendar days. 40 C.F.R. § 13.11(c). Should assessment of the penalty charge on the debt be required, it shall accrue from the first day payment is delinquent. 31 C.F.R. § 901.9(d).
86. Respondent agrees not to deduct for federal tax purposes the civil penalty assessed in this Consent Agreement and Final Order.

GENERAL SETTLEMENT CONDITIONS

87. By signing this Consent Agreement, Respondent acknowledges that this Consent Agreement and Final Order will be available to the public and represents that, to the best of Respondent's knowledge and belief, this Consent Agreement and Final Order does not contain any confidential business information or personally identifiable information from Respondent.
88. Respondent certifies that any information or representation it has supplied or made to EPA concerning this matter was, at the time of submission true, accurate, and complete and that there has been no material change regarding the truthfulness, accuracy or completeness of such information or representation. EPA shall have the right to institute further actions to recover appropriate relief if EPA obtains evidence that any information provided and/or representations made by Respondent to the EPA regarding matters relevant to this Consent Agreement and Final Order, including information about respondent's ability to pay a penalty, are false or, in any material respect, inaccurate. This right shall be in addition to all other rights and causes of action that EPA may have,

civil or criminal, under law or equity in such event. Respondent and its officers, directors and agents are aware that the submission of false or misleading information to the United States government may subject a person to separate civil and/or criminal liability.

CERTIFICATION OF COMPLIANCE

89. Respondent certifies to EPA, upon personal investigation and to the best of its knowledge and belief, that it currently is in compliance with regard to the violations alleged in this Consent Agreement.

OTHER APPLICABLE LAWS

90. Nothing in this Consent Agreement and Final Order shall relieve Respondent of its obligation to comply with all applicable federal, state, and local laws and regulations, nor shall it restrict EPA’s authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on the validity of any federal, state or local permit. This Consent Agreement and Final Order does not constitute a waiver, suspension or modification of the requirements of RCRA, or any regulations promulgated thereunder.

RESERVATION OF RIGHTS

91. This Consent Agreement and Final Order resolves only EPA’s claims for civil penalties for the specific violations alleged against Respondent in this Consent Agreement and Final Order. 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. This settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Section 22.18(c) of the Consolidated Rules of Practice, 40 C.F.R. § 22.18(c). EPA reserves any rights and remedies available to it under RCRA, the regulations promulgated thereunder and any other federal law or regulation to enforce the terms of this Consent Agreement and Final Order after its effective date.

EXECUTION /PARTIES BOUND

92. This Consent Agreement and Final Order shall apply to and be binding upon the EPA, the Respondent and the officers, directors, employees, contractors, successors, agents and assigns of Respondent. By his or her signature below, the person who signs this Consent Agreement on behalf of Respondent is acknowledging that he or she is fully authorized by the Respondent to execute this Consent Agreement and to legally bind Respondent to the terms and conditions of this Consent Agreement and Final Order.

EFFECTIVE DATE

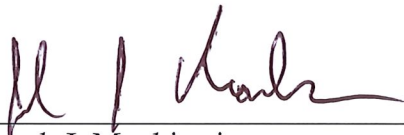
93. The effective date of this Consent Agreement and Final Order is the date on which the Final Order, signed by the Regional Administrator of EPA, Region III, or his/her designee, the Regional Judicial Officer, is filed along with the Consent Agreement with the Regional Hearing Clerk pursuant to the Consolidated Rules of Practice.

ENTIRE AGREEMENT

94. This Consent Agreement and Final Order constitutes the entire agreement and understanding between the Parties regarding settlement of all claims for civil penalties pertaining to the specific violations alleged herein and there are no representations, warranties, covenants, terms, or conditions agreed upon between the Parties other than those expressed in this Consent Agreement and Final Order.

For Respondent: PIRAMAL CRITICAL CARE, INC.

Date: 04 APR 2022

By: 

Joseph J. Monkiewicz
Environmental Health and Safety Manager

For the Complainant:

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

Date: _____

By: _____

Karen Melvin, Director
Enforcement & Compliance Assurance Division
U.S. EPA – Region III
Complainant

Attorney for Complainant:

Date: _____

By: _____

Joyce A. Howell
Sr. Assistant Regional Counsel
U.S. EPA – Region III

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103

In the Matter of:	:
	:
Piramal Critical Care, Inc.	: U.S. EPA Docket No. RCRA-03-2022-0053
3950 Shelden Circle	:
Bethlehem, PA 18017	: Proceeding under Section 3008(a) and
	: (g) of the Resource Conservation and
	: Recovery Act, as amended, 42 U.S.C.
Respondent.	: Section 6928(a) and (g)
	:
Piramal Critical Care, Inc.	:
3950 Shelden Circle	:
Bethlehem, PA 18017	:
	:
Facility.	:

FINAL ORDER

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region III, and Respondent, Piramal Critical Care, Inc., have executed a document entitled “Consent Agreement,” which I hereby ratify as a Consent Agreement in accordance with 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 22.18(b)(2) and (3)). The terms of the foregoing Consent Agreement are accepted by the undersigned and incorporated into this Final Order as if fully set forth at length herein.

Based upon the representations of the parties in the attached Consent Agreement, the penalty agreed to therein is based upon consideration of, *inter alia*, EPA’s October, 1990 RCRA Civil Penalty Policy, as revised in June, 2003 (“RCRA Penalty Policy”), which reflects the statutory penalty criteria and factors set forth at Sections 3008(a)(3) and (g) of RCRA, 42 U.S.C. §§ 6982(a)(3) and (g).

NOW, THEREFORE, PURSUANT TO Section 3008(a) and (g) of the Resource Conservation and Recovery Act, 42 U.S.C. § 6928(a) and (g) and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondent pay a civil penalty in the amount of FIFTY-EIGHT THOUSAND THIRTY-ONE DOLLARS (\$58,031.00), in accordance with the payment provisions set forth in the Consent Agreement and in 40 C.F.R. § 22.31(c) and comply with the terms and conditions of the Consent Agreement.

In Re: Piramal Critical Care, Inc.
EPA Docket No. RCRA-03-2022-0053

This Final Order constitutes the final Agency action in this proceeding. This Final Order shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief, or criminal sanctions for any violations of the law. This Final Order resolves only those causes of action alleged in the Consent Agreement and does not waive, extinguish, or otherwise affect Respondent's obligation to comply with all applicable provisions of RCRA and the regulations promulgated thereunder.

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

Date _____

Joseph J. Lisa
Regional Judicial and Presiding Officer
U.S. EPA Region III

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103**

In the Matter of:	:
	:
Piramal Critical Care, Inc.	:
3950 Shelden Avenue	:
Bethlehem, PA 15650	:
	:
Respondent.	:
	:
Piramal Critical Care, Inc.	:
3950 Shelden Avenue	:
Bethlehem, PA 15650	:
	:
Facility.	:

CERTIFICATE OF SERVICE

I certify that on _____, the original and one (1) copy of the foregoing *Consent Agreement and Final Order*, were filed with the EPA Region III Regional Hearing Clerk. 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:

Copy served via Email to:

Patrick Zaepfel
Zaepfel Law PC
200 Willow Valley Square
Suite 201
Lancaster, PA 17607-4859
pz@phzlaw.com

In Re: Piramal Critical Care, Inc.
EPA Docket No. RCRA-03-2022-0053

Joyce A. Howell
Senior Assistant Regional Counsel
ORC – 3RC40
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103

Dated: _____

Regional Hearing Clerk
U.S. Environmental Protection Agency,
Region III