

UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY REGION 2

In the Matter of:

**Datascope Corp,**

Respondent,

Proceeding Under Section 3008 of the  
Resource Conservation and Recovery  
Act as amended.

**CONSENT AGREEMENT  
AND  
FINAL ORDER**

**Docket No. RCRA-02-2023-7105**

**PRELIMINARY STATEMENT**

This is a civil administrative proceeding instituted pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by various statutes including the Resource Conservation and Recovery Act and the Hazardous and Solid Waste Amendments of 1984 ("HSWA"), 42 U.S.C. §§ 6901 *et seq.* (referred to collectively as the "Act" or "RCRA"). The United States Environmental Protection Agency ("EPA") has promulgated regulations governing the handling and management of hazardous waste at Title 40 of the Code of Federal Regulations ("C.F.R.") Parts 260-273 and 279.

Section 3006(b) of the Act, 42 U.S.C. § 6926(b), provides that EPA's Administrator 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 regulations comprising the federal hazardous waste program (the Federal Program). The State of New Jersey has been authorized by EPA to conduct a hazardous waste program ("authorized state program").

The State of New Jersey was authorized by EPA to conduct a hazardous waste program on August 2, 1999 (64 Fed. Reg. 41823). At that time, the authorized state program incorporated by reference, with some modifications, the regulations in the federal program at 40 C.F.R. Parts 260- 266, 268 and 270, as set forth in the 1993 edition. On Dec. 16, 2002 (67 Fed. Reg. 76995), New Jersey was also authorized for the hazardous waste requirements promulgated by EPA between July 2, 1993 and July 31, 1998. These changes became effective February 14, 2003. Thus, as of February 14, 2003, the authorized state program, with some modifications, essentially incorporates by reference the regulations in the 1998 edition of the same Parts of Title 40 of the C.F.R. New Jersey's regulations that comprised the original state program, and that were authorized in 1999, can be found in the New Jersey Register. See 28 N.J.R. 4606 (Oct. 21, 1996). The regulations authorized in 2002 can be found at 31 N.J.R.166 (Jan. 19, 1999). New Jersey is not authorized for any HSWA regulations adopted by EPA after July 31, 1998, for which EPA retains primary responsibility.

Section 3008(a) of the Act, 42 U.S.C. § 6928(a), authorizes EPA to enforce the regulations constituting the authorized state program, and EPA retains primary responsibility for the enforcement of certain requirements promulgated pursuant to HSWA.

Pursuant to 40 C.F.R. § 22.13(b), where the parties agree to settlement of one or more causes of action before the filing of an administrative complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a Consent Agreement and Final Order ("CA/FO") pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3). This administrative proceeding constitutes one that is simultaneously being commenced and concluded pursuant to said provisions.

The Complainant and Respondent agree, by entering into this CA/FO, that settlement of this matter upon the terms set forth in this CA/FO is an appropriate means of resolving the claims specified herein against Datascope Corp. ("Respondent") without litigation. The parties had settlement conferences on or about August 17 & 29, 2023, which led to this settlement. The findings of fact and conclusions of law set forth below, are not intended, nor are they to be construed as Respondent either admitting or denying such findings and conclusions. No adjudicated findings of fact or conclusions of law have been made.

### **EPA'S FINDINGS OF FACT AND CONCLUSIONS OF LAW**

1. EPA has given notice of this action to the State of New Jersey.
2. Respondent is Datascope Corp. ("Datascope" or "Respondent"), a for profit corporation incorporated in Delaware in 1999.
3. Respondent is located at 45 Barbour Pond Drive, Wayne, NJ 07470.
4. Respondent's facility (the "Facility") as that term is defined in 40 C.F.R. § 260.10, as incorporated by reference by New Jersey Administrative Code ("N.J.A.C") 7:26G-4.1(a) is located at 1300 MacArthur Blvd, Mahwah, NJ 07430.
5. Respondent, since at least 2000, is and has been the "owner" and "operator" of the Facility as those terms are defined in 40 C.F.R. § 260.10 as incorporated by reference in N.J.A.C. 7:26G-4.1(a).
6. 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 as incorporated by reference by the N.J.A.C. 7:26G-4.1(a).
7. Respondent has been conducting operations at its Facility since at least 2000.
8. Respondent manufactures collagen at the Facility in which it generates organic acetone hazardous waste ("Spent Acetone").
9. The Spent Acetone is transported to a 1320 gallon outdoor above-ground hazardous waste tank ("Waste Tank") through fixed piping where it is stored before being transported off-site for disposal or reclamation.

10. The Spent Acetone has a volatile organic concentration of more than 500 parts per million (“ppm”).
11. The Spent Acetone entering the Waste Tank came in contact with equipment subject to subpart BB which had an organic concentration of more than 10% by weight.
12. On July 12-13, 2022, duly designated representatives of EPA inspected Respondent's Facility pursuant to Section 3007 of the Act, 42 U.S.C. § 6927 to determine Respondent's compliance with Subtitle C of RCRA and its implementing regulations, including New Jersey’s authorized hazardous waste regulations (the "Inspection").
13. At the time of the Inspection, there was a release of Spent Acetone vapor from an open curved pipe (not the pressure relief valve which was located in a different area on the tank) attached to a pressure gauge on the roof of the Waste Tank located at the Facility.
14. Prior to and at the time of the Inspection, Respondent failed to tag and to conduct routine monitoring of valves, pumps, and connections attached to the Waste Tank and equipment subject to Subpart BB.
15. Prior to and at time of the Inspection, Respondent’s monitoring program did not adequately meet the requirements of EPA Method 21 for the monitoring of valves and pumps in light liquid service in ways:
  - a. Respondent failed to use the two required calibration gases (zero gas and a calibration gas) required for instrument calibration. Instead Respondent used 500 ppm isobutylene and ambient air as calibration gasses; and
  - b. Respondent failed to conduct required quarterly calibration precision tests on monitoring devices. Calibration tests were only performed prior to the monitoring device being placed into service. EPA Method 21 states that calibration precision tests must be completed before the monitoring device is placed into service and at subsequent 3-month intervals or at the next use, whichever is later.
16. Respondent failed to provide documentation that prior to and at the time of the Inspection it had:
  - a. conducted daily inspections of the pipes transporting the Spent Acetone to the Waste Tank;
  - b. performed initial monitoring or annual inspections on the closure devices on the Waste Tank;
  - c. determined and recorded a one-time initial vapor pressure calculation of the Waste Tank;
  - d. conducted daily inspections of the secondary containment area, Waste Tank, and associated equipment; and

- e. transmitted by certified mail or email the facility's contingency plan to the local police department, fire department, or other emergency response teams.
17. From approximately 2018 to the time of the Inspection, Respondent failed to maintain and/or repair the secondary containment area for the Waste Tank to prevent the migration/leak of hazardous wastes or accumulated liquid.
  18. Respondent failed to conduct inspections of the container storage area at the Facility from July 6, 2019 to July 22, 2019.
  19. From at least 2010 to the time of the Inspection, Respondent has been a generator of "hazardous waste" within the meaning of 40 C.F.R. 260.10 as incorporated by reference in N.J.A.C. 7:26G-4.1(a) at its Facility.
  20. From 2010 to the time of the Inspection, Respondent was classified as a large quantity generator of hazardous waste.
  21. On or about September 22, 2022, EPA issued a combined Notice of Violation ("NOV") and Request for Information ("IRL") ("NOV-IRL") to Respondent.
  22. On or about December 21, 2022, Respondent submitted a response to the IRL (the "December Response").
  23. In response to the EPA's Inspection Findings, Respondent informed EPA that it took the following measures to address the findings:
    - a. An inspection was performed on the Waste Tank on October 19, 2022;
    - b. A new acetone liner was installed for the Waste Tank secondary containment area;
    - c. Secondary containment was installed for the ancillary equipment serving both the Spent Acetone and fresh acetone tanks; and
    - d. A leak detection system was installed within the Waste Tank secondary containment area.
  24. On or about February 20, 2023, Respondent submitted an amendment to the December Response, informing EPA that it had taken the following measures to address two remaining matters ("February Response"):
    - a. Respondent made a hazardous waste determination for the contents of the Waste Tank; and
    - b. Respondent implemented a regime of yearly inspections and documentation of such inspections of the Waste Tank's roof.
  25. Based on the Inspection and Respondent's responses to EPA's Inspection Findings, EPA has determined that during varying time periods between October 18, 2018 through July 13, 2022, Respondent failed to:

a. minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents pursuant to 40 C.F.R. § 265.31, as incorporated by reference by N.J.A.C. 7:26G-9.1(a);

b. comply with RCRA requirements under 40 C.F.R. 265 Subpart BB “Air Emissions Standards for Equipment Leaks,” including failure to monitor and failure to comply with secondary containment requirements as they pertain to ancillary equipment, including the following requirements:

1. 40 C.F.R. § 265.1052(a)(1) as incorporated by reference in N.J.A.C. 7:26G-9.1(a), each pump in light liquid service shall be monitored monthly to detect leaks by the methods specified in § 265.1063(b);
2. 40 C.F.R. § 265.1057(a) as incorporated by reference in N.J.A.C. 7:26G-9.1(a), each valve in gas/vapor or light liquid service shall be monitored monthly to detect leaks by the methods specified in 40 C.F.R. § 265.1063(b) and shall comply with paragraphs (b) through (e) of this section;
3. 40 C.F.R. § 265.1063(b)(1) as incorporated by reference in N.J.A.C. 7:26G-9.1(a) leak detection monitoring, as required in 40 C.F.R. §§ 265.1052 through 265.1062, shall comply with Reference Method 21 in 40 C.F.R. Part 60.
4. 40 C.F.R. § 265.193(f)(1) as incorporated by reference in N.J.A.C. 7:26G-9.1(a), ancillary equipment must be provided with full secondary containment (e.g., trench, jacketing, double-walled piping) that meets the requirements of paragraphs (b) and (c) of this section except for aboveground piping (exclusive of flanges, joints, valves, and connections) that are visually inspected for leaks on a daily basis; and
5. 40 C.F.R. § 265.1064(a)(1) as incorporated by reference in N.J.A.C. 7:26G-9.1(a), each owner or operator subject to the provisions of this subpart shall comply with the recordkeeping requirements of this section.

c. comply with Subpart J “Tank Systems” and Subpart CC organic air emission standards applicable to hazardous waste tanks including the following requirements;

1. 40 C.F.R. § 265.193(b)(1) & (2) as incorporated by reference by N.J.A.C. 7:26G-9.1(a), secondary containment systems must be designed, installed, and operated to prevent any migration of wastes or accumulated liquid out of the system to the soil, ground water, or surface water at any time during the use of the tank system; and be capable of detecting and collecting releases and accumulated liquids until the collected material is removed;
2. 40 C.F.R. § 265.1084(a) as incorporated by reference by N.J.A.C. 7:26G-9.1(a), the average volatile organic concentration of a hazardous waste at the point of waste origination shall be determined using either direct measurement as

specified in paragraph (a)(3) of this section or by knowledge as specified in paragraph (a)(4) of this section;

3. 40 C.F.R § 265.1085(g)(3)(i-v) as incorporated by reference by N.J.A.C. 7:26G-9.1(a), the owner or operator shall inspect and monitor the air emission control equipment; and
4. 40 C.F.R § 265.195(b)(1)-(3), as incorporated by reference by N.J.A.C. 7:26G-9.1(a), the owner or operator must inspect at least once each operating day: (1) overfill/spill control equipment to ensure that it is in good working order; (2) above ground portions of the tank system, if any, to detect corrosion or releases of waste; 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).

d. conduct weekly Inspections and make arrangements with local authorities, resulting in the following violations:

1. Failure to conduct weekly container storage area inspections pursuant to 40 C.F.R. § 265.174, as incorporated by reference by N.J.A.C. 7:26G-9.1(a); and
  2. Failure to make arrangements with local authorities pursuant to 40 C.F.R. § 265.37, as incorporated by reference by N.J.A.C. 7:26G-9.1(a).
26. On June 29, 2023, EPA sent a letter to Respondent to determine its interest in pre-filing discussions regarding the violations EPA had identified.
27. On August 17 and 29, 2023, EPA and Respondent held an informal settlement conference and agreed to settle this matter as provided herein.

### **CONSENT AGREEMENT**

Pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, and 40 C.F.R. §§ 22.13(b) and 22.18 of the Consolidated Rules of Practice, it is hereby agreed by and between the parties hereto, and voluntarily and knowingly accepted by Respondent, that Respondent, for purposes of this Consent Agreement and in the interest of settling this matter expeditiously without the time, expense or uncertainty of a formal adjudicatory hearing on the merits: (a) admits the jurisdictional basis for EPA prosecuting this case; (b) neither admits nor denies EPA's Findings of Fact and Conclusions of Law; (c) consents to the assessment of the civil penalty as set forth below; (d) consents to the issuance of the Final Order; and (e) waives its right to contest or appeal that Final Order.

Pursuant to 40 C.F.R. § 22.31(b), the executed Consent Agreement and accompanying Final Order ("CA/FO") shall become effective and binding when filed with the Regional

Hearing Clerk of the Agency, Region 2 (such date henceforth referred to as the "effective date").

Based upon the foregoing, and pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, and 40 C.F.R. § 22.18, Respondent voluntarily and knowingly agrees to, and shall comply with, the following terms:

1. Respondent shall hereinafter comply with RCRA and all applicable New Jersey hazardous waste regulations relating to the generation and storage of hazardous waste at its Facility, including:
  - a. minimizing the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste, as required by 40 C.F.R. § 265.31, as incorporated by reference by N.J.A.C. 7:26G-9.1(a);
  - b. complying with RCRA requirements under Subpart BB as incorporated by reference in the N.J.A.C, including requirements to monitor and comply with secondary containment requirements as they pertain to ancillary equipment;
  - c. complying with Subpart J and Subpart CC organic air emission standards applicable to hazardous waste tanks as incorporated by reference in the N.J.A.C.; and
  - d. conducting weekly inspections and making arrangements with local authorities.
2. Respondent hereby certifies that, as of the date of its signature to this Agreement, to the best of its knowledge and belief, it is in compliance with all the RCRA requirements referenced in Paragraph 25 of EPA's Findings of Facts and Conclusions of Law of this CA/FO.
3. This CA/FO is not intended, and shall not be construed, to waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable federal, state and local laws and regulations relating to any generation, management, treatment, storage, transport or offering for transport, or disposal of hazardous waste by the Respondent.
4. Respondent shall pay a civil penalty to EPA in the total amount of **One Hundred Ninety-Two Thousand Three Hundred and Twenty dollars (\$192,320)** in one payment. Such payment shall be made by cashier's or certified check or by electronic fund transfer (EFT).

If the payment is made by check, then the check shall be made payable to the **Treasurer, United States of America**, and shall be mailed to:

**U.S. Environmental Protection Agency  
Fines and Penalties Cincinnati Finance Center  
P.O. Box 979078  
St. Louis, MO 63197-9000**

The check shall be identified with a notation thereon listing the following: *In the Matter of Datascope Corp* and shall bear thereon the **Docket No. RCRA-02-2023-7105**.

If Respondent chooses to make the payment by EFT, then Respondent shall provide the following information to its remitter bank:

- a. Amount of Payment - **\$192,320**.
- b. SWIFT address: **FRNYUS33, 33 Liberty Street, New York, NY 10045**.
- c. Account Code for Federal Reserve Bank of New York receiving payment: **68010727**.
- d. Federal Reserve Bank of New York ABA routing number: **021030004**.
- e. Field Tag 4200 of the Fedwire message should read: **D 8010727 Environmental Protection Agency**.
- f. Name of Respondent and Matter: **Datascope Corp**
- g. Docket Number: **RCRA 02-2023-7105**.

5. The payment of \$192,320 must be received at the above address (or account of EPA) on or before thirty (30) calendar days after the date of the signature of the Final Order, which is located at the end of this CA/FO.
  - a. Failure to pay the requisite civil penalty amount in full according to the above provisions may result in the referral of this matter to the United States Department of Justice or Department of the Treasury for collection or other appropriate action.
  - b. Furthermore, if payment is not made on or before the date specified in this document, interest for said payment shall be assessed at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, on the overdue amount from the date said payment was required to have been made through the date said payment has been received. In addition, a late payment handling charge of \$15.00 will be assessed for each thirty (30) calendar day period or any portion thereof, following the date any payment was to have been made, in which payment of the amount remains in arrears.
  - c. In addition, a 6% per annum penalty will be applied to any principal amount that has not been received by the EPA within ninety (90) calendar days of the deadline for any payment. Any such non-payment penalty charge on the debt will accrue from the date any penalty payment becomes due and is not paid.
  - d. The civil penalty provided for herein constitutes a "penalty" within the meaning of 26 U.S.C. § 162(f) and is not a deductible expenditure for purposes of federal or state law.
6. Complainant shall email to Respondent (to the representative designated in Paragraph 7 of this Consent Agreement, *infra*) a copy of the fully executed CA/FO. Respondent



consents to service of the CA/FO by email and consents to service upon it by an employee of EPA other than the Regional Hearing Clerk.

7. Except as the parties may agree otherwise in writing, all documentation and information required to be submitted in accordance with the terms and conditions of this Consent Agreement shall be sent both by email and hardcopy to:

William Chernes, Enforcement Officer  
Enforcement & Compliance Assurance Division  
US Environmental Protection Agency, Region 2  
290 Broadway, 21st Floor  
New York, New York 10007-1866  
[Chernes.William@epa.gov](mailto:Chernes.William@epa.gov)

a n d

Jeannie M. Yu, Assistant Regional Counsel  
Office of Regional Counsel  
US Environmental Protection Agency, Region 2  
290 Broadway, 16<sup>th</sup> Floor  
New York, New York 10007  
[Yu.Jeannie@epa.gov](mailto:Yu.Jeannie@epa.gov)

Unless the above-named EPA contacts are later advised otherwise in writing, EPA shall send any future written communications related to this matter (including any correspondence related to payment of the penalty) to Respondent either by email or United States mail to the following address:

Christopher J. McAuliffe, Esq.  
Morgan, Lewis & Bockius LLP  
502 Carnegie Center  
Princeton, NJ 08540-6289  
[Christopher.Mcauliffe@morganlewis.com](mailto:Christopher.Mcauliffe@morganlewis.com)

8. Full payment of the penalty described in Paragraphs 4 and 5 of the Consent Agreement, shall only resolve Respondent's liability for federal civil penalties for the violation(s) and facts described in Paragraph 25 of EPA's Findings of Fact and Conclusions of Law. Full payment of this penalty shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.
9. The provisions of this Consent Agreement shall be binding upon Respondent, and its successors or assigns.

10. Respondent waives its right to request or to seek any hearing in this matter including one on the terms and conditions set forth in the Consent Agreement and its accompanying Final Order and/or EPA's Findings of Fact and Conclusions of Law, above.
11. Nothing in this document is intended or construed to waive, prejudice or otherwise affect the right of EPA, or the United States, from pursuing any appropriate remedy, sanction or penalty prescribed by law against Respondent, if Respondent has made any material misrepresentations or has provided materially false information in any document submitted during this proceeding.
12. Each party hereto agrees to bear its own costs and attorney's fees in this matter.
13. The undersigned signatory for Respondent certifies that he\she is duly and fully authorized to enter into this Consent Agreement and all the terms and conditions set forth in this Consent Agreement.
14. EPA and Respondent agree that the parties may use electronic signatures for this matter.

**In the Matter of Datascope Corp**  
**Docket Number: RCRA 02-2023-7105**

**RESPONDENT:** BY: \_\_\_\_\_

NAME: Jerry Zukowsky  
(PLEASE PRINT)

TITLE: Vice President Cardiac Assist

DATE: \_\_\_\_\_

**COMPLAINANT:** \_\_\_\_\_

Dore LaPosta, Director  
Enforcement & Compliance Assurance Division  
U.S. Environmental Protection Agency, Region 2  
290 Broadway  
New York, New York 10007-1866

**In the Matter of Datascope Corp**  
**Docket Number: RCRA 02-2023-7105**

**FINAL ORDER**

The Regional Administrator of EPA, Region 2, concurs in the foregoing Consent Agreement in the case of *In the Matter of Datascope Corp* bearing Docket No. RCRA-02-2023-7105. Said Consent Agreement having been duly accepted and entered into by the parties, is hereby ratified, incorporated into and issued as this Final Order, which shall become effective when filed with the Regional Hearing Clerk of EPA, Region 2. 40 C.F.R. § 22.31(b). This Final Order is being entered pursuant to the authority of 40 C.F.R. § 22.18(b)(3) and shall constitute an order issued under authority of Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

---

Lisa F. Garcia  
Regional Administrator  
U.S. Environmental Protection Agency, Region 2  
290 Broadway  
New York, New York 10007-1866

**In the Matter of Datascope Corp**  
**Docket Number: RCRA 02-2023-7105**

**CERTIFICATE OF SERVICE**

I certify that I have this day caused to be sent the foregoing fully executed CONSENT AGREEMENT and FINAL ORDER, bearing the above-referenced docket number, in the following manner to the respective addressees below:

By email:

Office of the Regional Hearing Clerk  
Regional Hearing Clerk  
U.S. Environmental Protection Agency,  
Region 2  
290 Broadway, 17<sup>th</sup> floor  
New York, New York 10007-1866  
[Maples.Karen@epa.gov](mailto:Maples.Karen@epa.gov)

Copy by email:

Christopher J. McAuliffe, Esq.  
Morgan, Lewis & Bockius LLP  
502 Carnegie Center  
Princeton, NJ 08540-6289  
[Christopher.Mcauliffe@morganlewis.com](mailto:Christopher.Mcauliffe@morganlewis.com)

Dated: September \_\_\_\_\_, 2023  
New York, New York

\_\_\_\_\_