UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MA 02109-3912

Date: *Dated as shown on electronic signature(s)*

Subj: Evaluation Inspection Report
Clean Water Act
Arch Medical Solutions-Seabrook

From: John (Jack) Melcher, Environmental Engineer

Thru: Damian Bednarz, Life Scientist

To: File

Appendices:

Appendix A - 35 Woodworkers Way Floor Plan
Appendix B - Flow Summary Report
Appendix C – Selected Photographs
Appendix D - Monitoring and Reporting Procedures - Metal Finishing

I. Facility Information

A. Facility Name: Arch Medical Solutions-Seabrook

B. Facility Location: 15 Woodworker's Way
Seabrook, NH 03874

C. Facility Contacts: Dawn Frazer, General Manager

Craig Michaud, Director of Engineering
603.760.1532, cmichaud@archgp.com

Eola Saucier, Downstream Process Manufacturing Engineer
(603) 474-1919, eola.saucier@archgp.com

D. NPDES ID No(s).: NHPIU0022 (wastewater pretreatment)
NHNOE3304 (stormwater)

II. Background Information

A. *Date(s) of inspection:* February 14, 2023

B. *Weather Conditions:* Clear, mild

C. *US EPA Representative(s):*
John (Jack) Melcher, Enforcement and Compliance Assurance Division ("ECAD")
Damian Bednarz, ECAD
Shannon Shea, Laboratory Services and Applied Science Division ("LSASD")
Will Sommer, LSASD

D. *State/Local Representative(s):*
Mario Leclerc, Town of Seabrook

E. *Federally Enforceable Requirements Covered During the Inspection:*
40 C.F.R. Part 403 – General Pretreatment Regulations for Existing and New Sources of Pollution[1]
40 C.F.R. § 433.17 – Metal Finishing Point Source Category, Pretreatment Standards for New Sources[2]
40 C.F.R § 122.26 – National Pollutant Discharge Elimination System ("NPDES") regulation for the discharge of stormwater

F. *Previous Enforcement Actions:*
No EPA Clean Water Act enforcement actions are on record since at least June 27, 2013.

III. Type and Purpose of Inspection

EPA conducted an Industrial User ("IU") Evaluation Inspection and an IU Sampling Inspection to evaluate compliance with the General Pretreatment Regulations at 40 C.F.R. Part 403 and the Metal Finishing Point Source Category, Pretreatment Standards for New Sources at 40 C.F.R. § 433.17 ("Metal Finishing PSNSs"). The IU Sampling Inspection is documented in a separate inspection report.

EPA conducted a Compliance Evaluation Inspection to evaluate compliance with the NPDES regulation for the discharge of stormwater at 40 C.F.R § 122.26.

IV. Facility Description

Arch Medical Solutions-Seabrook ("Arch Medical" or the "Facility") manufactures small metallic and plastic medical devices and implants.

[1] Available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-N/part-403?toc=1

[2] Available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-N/part-433?toc=1

EPA's Enforcement Compliance History Online ("ECHO") website provides general environmental compliance data for Arch Medical.[3]

EPA's previous on-site inspection to evaluate Clean Water Act compliance was on May 10, 2016.

A. Wastewater Pretreatment

Arch Medical discharges to the Town of Seabrook Publicly Owned Treatment Works ("POTW"; NPDES Permit No. NH0101303). The Town has an activated-sludge wastewater treatment facility with a design flow of 1.8 million gallons per day; biosolids are sent to a composting facility. The Town's NPDES Permit does not require the Town to implement a federally-approved industrial pretreatment program. Therefore, EPA Region 1 is the pretreatment "Control Authority" for Arch Medical.

The Facility submitted a pretreatment Baseline Monitoring Report, dated June 27, 2013, stating that the Facility performs passivation of stainless-steel parts. Passivation is listed as a type of coating operation in the EPA Guidance Manual for Electroplating and Metal Finishing Pretreatment Standards.[4] Forty C.F.R. § 433.10(a) provides that plants performing coating operations are subject to the Metal Finishing Point Source Category.

The Baseline Monitoring Report states that the Facility performs two-stage neutralization treatment.

The Facility's most recent Periodic Report on Continued Compliance states that during the period of June 1, 2022, through November 30, 2022, the Facility had average daily flow of metal finishing wastewaters of 20 gallons per day and a maximum daily flow of 123 gallons per day.

B. Stormwater

The Facility submitted a No Exposure Certification for exclusion from EPA's Multi-Sector General Permit for stormwater discharges associated with industrial activity ("MSGP"), dated October 22, 2021, stating that the Facility's primary Standard Industrial Code ("SIC") Code is 3842 (Orthopedic, Prosthetic, and Surgical Appliances and Supplies). The No Exposure Certification includes an exposure checklist, where the Facility stated that none of the listed materials or activities were exposed to precipitation.

V. Inspection

I announced the inspection to the Facility on February 7, 2023.

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[3] Available at: https://echo.epa.gov/detailed-facility-report?fid=110004095265

[4] Available at: https://www.epa.gov/system/files/documents/2021-07/owm0022.pdf

Mr. Bednarz, Ms. Shea, Mr. Sommer, and I (the "EPA Inspectors") arrived at approximately 09:00 on February 14, 2023.

Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.

A. Opening Conference

An opening conference was held with Mr. Leclerc and the following Facility representatives:

- Dawn Frazer, General Manager;
- Steven Flynn, Director of Operations;
- Craig Michaud, Director of Engineering; and
- Eola Saucier, Downstream Process Manufacturing Engineer.

I presented my credentials and explained the purpose of the inspection.

The facility representatives said that Arch Medical has 22 facilities, located across the United States.

The Seabrook facility (formerly known as Seabrook International) was purchased by Arch Medical in 2018.

Approximately 165 employees work at the Arch Medical Seabrook facility. Three shifts work Monday through Friday and one shift works on weekends.

Business fell off significantly during the COVID-19 pandemic as the Facility's products are used primarily for elective surgeries.

Arch Medical manufactures medical implants and instrumentation (e.g., hammers and screwdrivers) used in orthopedic surgery. Arch Medical does not sell directly to health care providers, but to several Original Equipment Manufacturers, who design and market the products.

At the time of EPA's last inspection, the Facility occupied all of 15 Woodworker's Way and part of 35 Woodworker's Way. Since EPA's last inspection, Arch Medical began leasing the building at 130 Ledge Road, located across a parking lot from 15 Woodworker's Way.

Facility representatives described operations performed in each of their buildings.

130 Ledge Road contains some office space and a small-volume production line ("Made to Order"). Products are made by machining using either oil or an oil/water emulsion as a cutting fluid. No industrial wastewaters are discharged to the Town from 130 Ledge Road. Waste liquids are hauled by a contractor, Safety-Kleen.

15 Woodworker's Way contains office space and machining equipment, but no industrial wastewaters are discharged to the Town from 15 Woodworker's Way. A wastewater evaporator is present at 15 Woodworker's Way, but the evaporator is currently out of service.

35 Woodworker's Way contains machining equipment and the cleaning and passivation line. Wastewater from the cleaning and passivation line flows into the Facility's two-stage neutralization system and then to the Town of Seabrook's POTW. The cleaning and passivation line consists of two cleaning tanks, two rinse tanks, a nitric acid passivation tank, followed by three rinse tanks and a drier.

Facility representatives said that, although their 2013 Baseline Monitoring Report stated that an anodization line was planned, this line was never installed.

Facility representatives said that no floor drains are present in their buildings, except perhaps under a safety shower.

The Facility shares 35 Woodworker's Way with a rubber gasket warehouse and distributor ("Marco Rubber"). A floor plan for 35 Woodworker's Way is provided in Appendix A of this report.

Wastewater sampling is performed where the neutralization system discharges into a sink. Marco Rubber does not discharge to the sink. The Facility performs grab samples (and not composite samples) for metals because flows are low and there is not a convenient way to configure an automated sampler. The Facility does not collect composite samples at the manhole and pumping station outside of the building due to the presence of flows from Marco Rubber.

The Facility's 2013 Baseline Monitoring Report includes a "Flow Summary Report," provided in Appendix B of this report. The Flow Summary Report states that spent cleaning baths are discharged into the neutralization system approximately once every three months. Facility representatives said that they were not aware of any wastewater monitoring being performed while the facility is processing a spent cleaning bath. The Flow Summary Report states that rinse baths discharge continuously into the neutralization system while the cleaning and passivation line is in use. The Flow Summary Report states that the nitric acid passivation bath is not discharged into the neutralization system, but is hauled away as a waste.

B. Facility Tour

Selected photographs taken during the Facility Tour are provided in Appendix C of this report.

1. 35 Woodworker's Way

At approximately 09:45, the EPA Inspectors, Mr. Leclerc, Mr. Michaud, and Ms. Saucier began a tour of 35 Woodworker's Way.

Photo 1 shows an approximately 2-inch diameter plastic pipe and an approximately ½-inch diameter plastic pipe entering a sink in a small room in 35 Woodworker's Way. Both pipes are labeled "Treated Discharge to Town Sewer."

Ms. Shea and Mr. Sommer began collecting wastewater samples. See the report under a separate cover for wastewater sampling and analysis details.

Photo 2 shows the pipes in the wastewater treatment room entering the wall between the wastewater treatment room and the small room with the sink. Facility representatives said that the white cube on the ½-inch diameter pipe was a flow meter. An impeller meter measures flow, which is recorded electronically.

Photo 3 shows the cleaning and passivation line. Parts move from left to right across the line. A detergent, "RD-531," is used as a detergent in the ultrasonic cleaning baths.

Photo 4 shows a rinse bath with parts inside. Clean water enters the final rinse bath (number 5), then flows into rinse bath number four, then into rinse baths number 3, and then to the neutralization system. Wastewaters are pumped to the neutralization system through an overhead pipe.

Photo 5 shows a sink with a pump below. Facility representatives said that the sink is used for pH adjustments and the wastewater is sent to the neutralization system.

Photo 6 shows a secondary-containment pallet with two drums labeled, "nitric acid." Facility representatives said that the drums are product; due to supply chain issues a relatively large quantity of nitric acid is kept on-site.

Photo 7 shows a spill kit.

Photo 8 shows the inside of a flammable materials storage cabinet. Most containers are labeled "isopropyl alcohol," but there is also a container label "corrosive" and "deconex OP 164," and a container labeled "mineral spirits."

Photo 9 shows two small tumblers. Photo 10 shows the treatment system used to enable the Facility to recirculate tumbling waters. Facility representatives said that the tumbling system does not generate wastewaters.

Facility representatives said that floor cleaning wastewaters are collected and hauled away. Normally, the evaporator system is used to reduce volume prior to shipment.

Photo 11 shows the wastewater line from the cleaning and passivation room entering the neutralization system.

Photo 12 shows the Programable Logical Controller display on the neutralization system. The neutralization system has two approximately 100-gallon tanks. Wastewater is sent through the tanks in serial. Each tank has caustic and acid addition, a pH probe, and an agitator. Facility representatives said that the first tank ("10") is set to dose wastewater with caustic and/or acid to a range of 6.5 to 10 Standard Units ("S.U."), while the second tank ("20") is set to dose wastewater to a range of 7 to 9 S.U.

Photo 13 shows a routine maintenance log sheet for the neutralization system.

Facility representatives described the system by which Arch Medical diverts off-spec wastewaters. If a pH of less than 7 S.U. is detected in Tank 20, then an automated valve is closed on the discharge line. If water levels rise high enough in Tank 20, then a high-water alarm will activate, with auditory and visual signals (but no electronic communications). Upon observing the high-water alarm, a valve is opened to direct wastewaters to an open 55-gallon drum adjacent to the neutralization system (the "dump tank," Photo 14. Operators would also shut down the cleaning and passivation line upon observing the high-water alarm. If operators did not respond to the high-water alarm in time, wastewater would overflow into the secondary containment area around the neutralization system (Photo 15). Wastewaters collected in the dump tanks are hauled away as waste.

The Facility records continuous pH and flow. pH in Tank 20 is recorded on a wheel chart; wheel charts are scanned and high and low daily observations reported. Flow is logged electronically and daily flows reported.

Facility representatives said that the flow meter is checked by noting whether any flow is being measured during discharge. There is potential for solids to accumulate on the impeller, preventing it from operating.

Facility representatives said that pH measurement equipment is calibrated periodically by a contractor, "IN-CAL." I observed calibration stickers on the control panel showing that pH probes had been calibrated on February 7, 2023, and the next calibration was due on April 30, 2023.

2. Outdoor Areas

At approximately 11:00, Mr. Bednarz, Mr. Leclerc, Mr. Michaud, Ms. Saucier, and I began a tour of the perimeters of 35 Woodworker's Way, 15 Woodworker's Way, and 130 Ledge Road.

Photo 16 shows a white plastic pipe coming out from the north side of 35 Woodworker's Way. Photo 17 shows the pipe terminating onto the pavement. The pavement around the

pipe termination is dark-colored, consistent with oil staining. Facility representatives said that the pipe discharged air conditioning condensate.

Photo 18 shows a dust handling unit on the southeast side of 15 Woodworker's Way. The unit is covered by a roof. No leaked materials were observed on the ground near the unit.

An uncovered roll-off container was observed to the east of 130 Ledge Road. Photo 19 shows the interior the container; scrap metal, cardboard, and plastic were observed.

Photo 20 shows metal plates located to the east of 130 Ledge Road.

C. Records Review

At approximately 11:40, the EPA Inspectors, Mr. Leclerc, Mr. Michaud, and Ms. Saucier performed a brief review of the Facility's most recent wastewater pretreatment Periodic Report on Continued Compliance.

I provided Ms. Saucier with a copy of EPA Region 1's Monitoring and Reporting Procedures guidance document, included as Appendix D of this report.

The Facility's most recent wastewater pretreatment Periodic Report on Continued Compliance included certification language in lieu of monitoring for all Total Toxic Organics.

Ms. Saucier confirmed that the average daily flow during the reporting period includes days on which no discharge occurred.

No violations of Pretreatment Standards have been reported by the Facility.

The Facility has submitted several recent Periodic Reports on Continued Compliance late.

D. Closing Conference

At approximately 11:50, the EPA Inspectors, Mr. Leclerc, Ms. Frazer, Mr. Michaud, Ms. Saucier conducted a closing conference.

I described the potential areas of non-compliance identified during the inspection:

- Several recent wastewater pretreatment Periodic Report on Continued Compliance were submitted late.

- The Facility's uncovered roll-off container and the nearby metal plates are not consistent with the Facility's No Exposure Certification.

The EPA Inspectors departed at approximately 12:00.