



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1600 John F Kennedy Boulevard
Four Penn Center
Philadelphia, Pennsylvania 19103

Report Title: Clean Water Act Compliance Inspection Report
Inspection Date(s): 03/16/2023
Regulatory Program(s): National Pollutant Discharge Elimination System (NPDES)
Type of Activity: Pretreatment – Industrial User Inspection
Facility Name: Alcon Precision Device Manufacturing
Permittee(s): Alcon Research, Ltd.
Facility Operator: Alcon Research, Ltd.
Facility Address: 714 Columbia Avenue Building A, Sinking Spring, PA, 19608
Lat/Long: 40.32222/-76.02463
County/Parish: Berks
Permit Number: PAP128649
NAICS & SIC Codes: 339112/3841
Unique Project #: 3E23WN041A

Facility Representative(s): Ryan Johnson – HSE Site Head – Alcon
Phone: 610-927-6047 Email: ryan-1.johnson@alcon.com ☒ **Point of Contact**

EPA Inspectors: Aaron Thomson - EPA Inspector (3ED33)
Phone: 215-814-2116 Email: Thomson.aaron@epa.gov

**Report Preparer
Signature/Date**

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THOMSON

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Jessica Duffy, NPDES Section 2 Chief (3ED33)
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I. Introduction

On March 16, 2022, Aaron Thomson (hereinafter, “Inspector Thomson”, or “EPA Inspector”) an inspector from the U.S. Environmental Protection Agency (“EPA”) Region III conducted an on-site inspection of the Alcon Precision Device Manufacturing facility’s (hereinafter, “Alcon”, or “the Facility”) pretreatment program. Alcon is a surgical eye care manufacturing facility located at 714 Columbia Avenue Building A, Sinking Spring, PA 19608 and operates under the EPA pretreatment program identification number PAP12864. Alcon is permitted by the Borough of Sinking Spring to discharge to the local sewerage system leading to the Borough of Sinking Spring Wastewater Treatment Plant (**Attachment 1**).

A. Inspection Opening Conference

The EPA Inspector arrived at the facility at est. 11:00 AM for the on-site inspection. Inspector Thomson met with the following facility representatives:

Table 1: Inspection Attendee List

Name	Affiliation	Telephone	Email
EPA Region III Inspectors and Contractors			
Aaron Thomson	EPA Region III	215-814-2116	Thomson.aaron@epa.gov
Site/Facility Representatives			
Ryan Johnson	Alcon	610-927-6047	ryan-1.johnson@alcon.com

Inspector Thomson displayed their credentials to Mr. Johnson at the outset of the inspection, and explained the purpose of the inspection was to observe compliance with the Federal Pretreatment Regulations. The EPA Inspector informed Mr. Johnson that any information that the Facility deemed to be confidential business information (“CBI”) should be identified to EPA representatives during the inspection and it would be handled as CBI according to EPA’s CBI procedures.

B. Weather and Precipitation Conditions

During the inspection, the weather was sunny with a high of 62 degrees Fahrenheit. National Oceanic and Atmospheric Administration (NOAA) National Weather Service precipitation data for the date of the inspection and five days prior are provided in the Table 2 below:

Table 2. Precipitation Data

Station Name	Date	Precipitation Amount (inches) ¹
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/11/2023	0.47
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/12/2023	0.00
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/13/2023	0.01
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/14/2023	T ²
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/15/2023	T
ADAMSTOWN 2.5 SSE, PA US US1PALN0003	03/16/2023	0.00

¹ Source: NOAA National Climatic Data Center (<http://www.ncdc.noaa.gov/>).

² "T" values in the Precipitation or Snow category above indicate a "trace" value was recorded.

II. Facility Activity/Walkthrough

Based on statements by Mr. Johnson and observations made on-site, the facility is classified as a metal finishing point source Categorical Industrial User (CIU), which is subject to the Federal Pretreatment Regulations 40 CFR Part 403 and Categorical Industrial User Regulations 40 CFR Part 433.15. The facility discharges to the Borough of Sinking Spring publicly owned treatment works (POTW). Because the facility discharges into a POTW without an approved pretreatment program, EPA is designated as the Control Authority, and as such is the authority for inspections per 40 CFR Part 403.3(f).

Alcon is a surgical eye care manufacturing plant. The facility's manufacturing processes that contribute to the wastewater stream discharged to the sewage system includes process wastewater generated from two separate chemical milling process trains, identified by the Facility as "Novalite 1" and "Novalite 2". The process is identical for both trains, and includes, in order, a degreasing bath, a rinse bath, a basket drain, a deburring (acid) bath, and a series of 3 cascading baths. Wastewater from the rinse bath (second) and the first cascading bath (fifth) contribute to the wastewater stream discharged to the local wastewater treatment facility. Wastewater from the first cascading bath (fifth) will enter a reservoir tank, which will enter a neutralization tank after the previous wastewater load is neutralized. Novalite 1 produces approximately 40 gallons per discharge 24 times a day (960 gallons per day) and has a neutralization tank with a capacity of 55 gallons. Novalite 2 produces approximately 116 gallons per discharge 6 times per day (696 gallons per day). Batch neutralization occurs in the neutralization tanks, which are monitored continuously by a pH probe. Once the pH is brought within permitted discharge limits, the wastewater is discharged to a sump tank where water from the rinse bath (second) is also directly received, before being discharged to the sewer system. Sampling points are located after the neutralization tank in each process train and do not include water from the rinse bath (second). Waste from the deburring bath (fourth) is stored as hazardous waste and hauled off-site and treated by Veolia Environmental Services as hazardous waste. Overflow from the second and third cascading baths are directed back into the first cascading bath.

After the opening conference, Mr. Johnson led a tour of the processes that contribute to the wastewater discharge to the sewage system. Inspector Thomson was led to the facility's first chemical bath process train (Novalite 1), equipped with troughs to collect any spillage. Next, Inspector Thomson was led to Novalite 1's neutralization tank and the Novalite 1 sampling point. Next, Inspector Thomson was led to piping exiting the neutralization tank and leading to the "combo sump" where all wastewater streams combine before being discharged to the sewer. Inspector Thomson was then led to Novalite 2's train, including the chemical and rinse baths, the neutralization tank, and the continuous monitoring systems. At the request of Inspector Thomson, Mr. Johnson then described the location and sampling methods used for their "all effluent" sampling point.

III. Observations

A checklist was utilized during the review and is provided below. The checklist is divided into sections, with Observations listed under each section. Photographs were taken during the inspection by Facility representative Ryan Johnson but were not provided to Inspector Thomson to include in this report.

Visual Observations pertaining to each section are listed at the end of each section.

Section 1.				
General Information				
	Yes	No	N/A	Comments
General Description of Processes and Products	Surgical eye care manufacturing			
Are there any alternates to effluent monitoring conducted? (e.g., TTO/TOMP, Waiver requirements?) Describe in comments if “yes”	☒	☐	☐	“Additionally, as of 2/13/18 Alcon will only need to submit semiannual data for the following Total Toxic Organic (TTO) compounds: benzene, 1,1,2-trichlorethane, chloroform (trichloromethane), methylene chloride (dichloromethane), naphthalene, phenol, toluene and trichloroethylene (TCE).” – included on the cover page of bi-annual self-monitoring reports for 2021, 2022 (not attached) Additionally, the self-monitoring reports each include a signed letter from Alan Carl, General Manager for Alcon, verifying that “to the best of my knowledge and belief, no dumping of concentrated toxic organics into the wastewaters [h]as occurred since filing of the last discharge monitoring report.” (not attached)
Provide production rates for all processes subject to production based standards and include:	n/a			
1) Process				
2) production rate used for calculating limits				
3) production rate for last 12 months				
Any anticipated changes in processes or production rates?	☐	☒	☐	
List the production rate listed on the approval letter				
Shift information, list	Mon-fri shifts, discharge (batch) only when operating			
1) Shift #				
2) No. of Employees				

3) Hours				
4) Work Days				
Is production seasonal? If yes, describe	☐	☐	☒	
List all visual observations pertaining to this section				

Section 2.				
Categorical Industry				
	Yes	No	N/A	Comments
Categorical Industry?	☒	☐	☐	
Category(s):	40 CFR Part 433.15,			
Subcategory(s):	Subpart A: Metal Finishing.			
Regulatory New Source Date:				
New source?	☐	☒	☐	
List of categorical processes	Cascading (rinse) bath for deburring (acid) bath			
List of other operations producing wastewater	Rinse/wash bath after degreasing bath			
List all visual observations pertaining to this section				

Section 3.				
Characterization of Wastewater Discharges (CFR 433.15)				
	Yes	No	N/A	Comments
Describe the time of day discharge to sewer occurs	The discharges occur in batches during the normal operating hours of 8 AM to 5 PM			
Are discharges seasonal (if yes, describe)	☐	☒	☐	
Attach a block flow diagram of manufacturing process in the Facility Activity section of the inspection report, including: chemical storage area, and wastewater generated. Identify all regulated, unregulated and dillution wastewater discharges. Include sample location, discharge flow rates and method of disposal*. Note any recent changes. *disposal method CD - Continuous discharge to sanitary ND - Not discharged or disposed BD - Batch discharge to sanitary sewer HH - Hauled as hazardous waste OD - Other disposal - not to sanitary sewer HW - Hauled as nonhazardous waste				
List all visual observations pertaining to this section				

Section 4.
Pretreatment Facility

	Yes	No	N/A	Comments
Pretreatment installed?	☒	☐	☐	Consists of pH neutralization, measuring pH as discharged
Attach a schematic of the pretreatment facility in the Facility Activity section of the inspection report (include all units and sludge storage)				
Briefly describe treatment processes and operation.				Water from rinse bath (after acid bath) is collected, neutralized/measured and discharged
Describe sludge storage and disposal method				5 gal container → 55 gal drum → hauled as haz waste
Describe appearance of effluent at time of inspection.				n/a
List all visual observations pertaining to this section				

Section 5.				
Self Monitoring				
	Yes	No	N/A	Comments
Does facility have a sampling plan or protocol including use of 40 C.F.R. Part 136 techniques (obtain copy)?	☒	☐	☒	According to Mr. Johnson, sampling for self-monitoring of Facility is performed by the POTW's staff
Is sampling location (identified on block flow diagram) the same as in control mechanism? If no, explain.	☒	☐	☐	Outfall 1 (all wastewater streams) is labeled/sampled – also includes individual sampling of each train “N1 Effluent” and “N2 Effluent”
Is this sampling location permanently identified by a sign, painted number, or other means?	☒	☐	☐	
Is this sampling location appropriate? If no, explain...	☒	☐	☐	
Is this sampling location shown on the chain of custody form?	☒	☐	☐	“Sample: desc”
Are any parameters monitored by approved methods more frequently than required at permitted sampling location?.	☒	☐	☐	More locations that permit requires are sampled, all are reported
If yes to previous question, are all results submitted to the control authority?	☒	☐	☐	If they were sampled above frequency, all would be reported
Does facility resample and report within 30 days of discovering a violation?	☒	☐	☐	
Are sampling records maintained on site? Describe for how long.	☒	☐	☐	3 years+
Is flow determined as required by permit?	☒	☐	☐	

How is flow determined (i.e., estimated or measured)?	Calculated (based on known volume of full tank)			
Is flow measurement appropriate?	☐	☒	☐	Permit calls for “meter” in “sample type”
Is flow measurement device calibrated?	☐	☐	☒	
Does the facility have an operator's manual for its pH meters?	☒	☐	☐	
Does the facility do a proper 2-point calibration of its pH meter in accordance with the operator's manual?	☒	☐	☐	
Is other monitoring equipment (e.g. DO meter) calibrated? Describe how often if yes.	☒	☐	☐	Monthly, in-house calibration
Is sampling and analysis done in-house or by contract? If by contract, list company.	☐	☐	☐	Contract, M.J. Reider Associates, Inc.
Is QA/QC program for sampling and analysis adequate? Obtain copy of plan if available.	☐	☐	☒	contract
List all visual observations pertaining to this section				

Section 6.				
Hazardous Waste Management				
	Yes	No	N/A	Comments
Is IU aware of RCRA regulations?	☒	☐	☐	
Does facility generate any hazardous waste? If yes, indicate type of waste, method of management on site and means of disposal on a separate sheet. Describe any spillage problems or any other releases that are observed.	☒	☐	☐	5 gal container → 55 gal drums → Veolia environmental services
Has facility notified POTW and EPA of any hazardous waste discharges to the sewer?	☐	☒	☐	
List all visual observations pertaining to this section				

Section 7.				
Spill Prevention				
	Yes	No	N/A	Comments
Has the facility had any spills or been responsible for slug loads? List dates of events in comments.	☐	☒	☐	
If yes to previous question, was POTW notified?	☐	☐	☒	
Does the facility have spill notification procedures posted?	☒	☐	☐	
Has the facility evaluated its need for a spill prevention plan at least every two years?	☒	☐	☐	
If yes to previous question, was it determined that they needed one?	☒	☐	☐	Yes, also required by permit
Does the IU have a spill prevention (SP) plan to address spills to the POTW?	☒	☐	☐	Included in Integrated Contingency Plan, updated

				in 2023 and includes description of discharge practices, description of stored chemicals, procedures to notify borough of sinking spring/epa in case of discharge, procedures to prevent slug discharge and a facility flow diagram (reviewed, not attached)
If spills occurred- Did the IU follow procedures outlined in the spill plan at the time of spills?	☐	☐	☒	
If spills occurred- Were procedures effective in containing the spill?	☐	☐	☒	
Is the facility keeping records of spill events?	☐	☐	☒	
Have there been any changes in spill procedures recently. Describe if yes.	☐	☒	☐	
List all visual observations pertaining to this section				

Section 8.				
Recordkeeping Review.				
	Yes	No	N/A	Comments
Current IU control mechanism (through EPA, not a permit)	Attachment 2			
Notices and correspondence with control authority including:				
a. Self monitoring report transmittals?	☒	☐	☐	Self monitoring reports (reviewed, not attached) received by facility from MJ Reider are sent control authority
b. BMR if required?	☐	☐	☒	
c. Other?	☐	☐	☐	
Do sampling records include:				
a. Date of sampling event?	☒	☐	☐	Chain of Custody (CoC)
b. Time of sampling event?	☒	☐	☐	CoC
c. Name of sampling person and affiliation?	☒	☐	☐	CoC
d. Sample collection method?	☒	☐	☐	CoC
e. Method of sample preservation?	☒	☐	☐	CoC
f. Description of sample location?	☒	☐	☐	CoC
g. Name of person conduction analysis?	☒	☐	☐	CoC
h. Date of analysis?	☒	☐	☐	CoC
i. Time of analysis, if applicable (i.e., BOD, Cr?)	☒	☐	☐	CoC

j. Sample analyses method?	☒	☐	☐	CoC shows requested method, analysis results show method used
Is type of sample specified in control mechanism?	☒	☐	☐	CoC
Are all parameters monitored at the required frequency? Note any discrepancies in comments.	☒	☐	☐	
Analytical results?	☒	☐	☐	Analysis
Are all monitoring results sent to the Control Authority?	☒	☐	☐	
Are copies sent to the POTW?	☒	☐	☐	
Appropriate production records for production based standards?	☐	☐	☒	
Documentation of flow rates and volumes?	☒	☐	☐	
Are records maintained at least 3 years?	☒	☐	☐	
List all visual observations pertaining to this section				

Section 9.				
EPA Sampling				
	Yes	No	N/A	Comments
Were samples taken?	☐	☒	☐	
Describe sampling location, method, and time:				
List all visual observations pertaining to this section				

Section 10.				
Stormwater				
	Yes	No	N/A	Comments
Does facility have a stormwater permit?	☐	☒	☐	
If yes, describe what type of permit along with issuance and expiration dates	According to Mr. Johnson, site is contained and does not require a stormwater permit			
Does facility have a stormwater pollution prevention plan?	☐	☒	☐	
Describe any BMPs that the facility is currently implementing.				
List all visual observations pertaining to this section				

Section 11.				
Current Compliance Status				
	Yes	No	N/A	Comments
Indicate compliance with:				
a. effluent limits (indicate in comments the date range reviewed)	☒	☐	☐	
b. monitoring (indicate in comments the date range reviewed)	☒	☐	☐	

c. recordkeeping/reporting (indicate in comments the date range and records reviewed)	☒	☐	☐	
List all visual observations pertaining to this section				

IV. Records Review

Prior to the inspection, Inspector Thomson requested the following documentation, via email, to be prepared for the inspection, or by email up to two weeks after the inspection: Control mechanism, categorical status, 2 years worth of compliance monitoring reports, slug/spill prevention plan and process flow diagrams relating to the pretreatment system. During the inspection, Mr. Johnson provided the following information/documents which were reviewed by Inspector Thomson; categorical status; compliance monitoring reports from Q1 & Q2 2021, Q3 & Q4 2021, Q1 & Q2 2022 and Q3 & Q4 2022; the integrated contingency plan (slug/spill prevention plan); and process diagrams. Mr. Johnson also provided a copy of their discharge permit granted by the Borough of Sinking Spring (**Attachment 1**). At the time of the inspection, and after the inspection via telephone and email, Inspector Thomson requested Mr. Johnson provide the photographs taken during the inspection, as of writing this report no photographs were supplied by the Facility.

V. Closing Conference

After the facility inspection, the EPA Inspection Team met with the facility representatives for a closing conference. The EPA Inspection Team shared preliminary observations with the facility. The EPA Inspection Team reiterated to the facility representatives that all preliminary observations discussed were not compliance determinations. Any and all preliminary observations shared were subject to further investigation by EPA upon the additional review of records and documentation. Additional observations may be contained in this inspection report that were not identified at the time of the closing conference after EPA reviewed additional materials following the inspection.

The inspection concluded at 2:00 PM

VI. List of Attachments

Attachment 1. Alcon's Local Permit