UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Enclosure 2

Tolmar Fact Sheet

Pretreatment ICIS Number:	CO-PF00106
Facility Name and Address:	Tolmar 1201 Cornerstone Drive Windsor, CO 80550
Authorized Representative Contact:	Chris Banfield Environmental Health and Safety Manager 701 Centre Avenue Fort Collins, CO 80526 970-212-4500, chris.banfield@tolmar.com
Applicable Pretreatment Regulations:	Pharmaceutical Point Source Category, Categorical Industrial User
Categorical Reference:	40 C.F.R. Part 439, subpart D (Pretreatment Standards for New Sources at 40 C.F.R. § 439.47)
Receiving POTW/Collection System:	Windsor POTW CDPS Permit No. CO-0020320 30502 CO-257 Windsor, CO 80550
POTW Contact:	Dennis Markham, POTW Superintendent Town of Windsor Public Works 301 Walnut Street Windsor, CO 80550 970-686-2144, dmarkham@windsorgov.com

Section 1 Tolmar Process Description Operation

1.1 Facility Description

The Tolmar facility (facility) is located at 1201 Cornerstone Drive in Windsor, CO, 80550. According to the Notice of Discharge Requirements (NDR) application submitted by the facility on June 20, 2023, the facility employs about 100 production employees that work 12-hour shifts. The facility is continuously manufacturing 7 days/week, 24 hours/day throughout the year. Typically, no manufacturing occurs for 1 week in December (23rd-31st), Thanksgiving (2 to 3 days), 30 days in April/May and 30 days in September. Maintenance activities still occur. Figure 1 provides a Google Earth View of the facility. Figure 2 provides an overall site diagram of the facility.

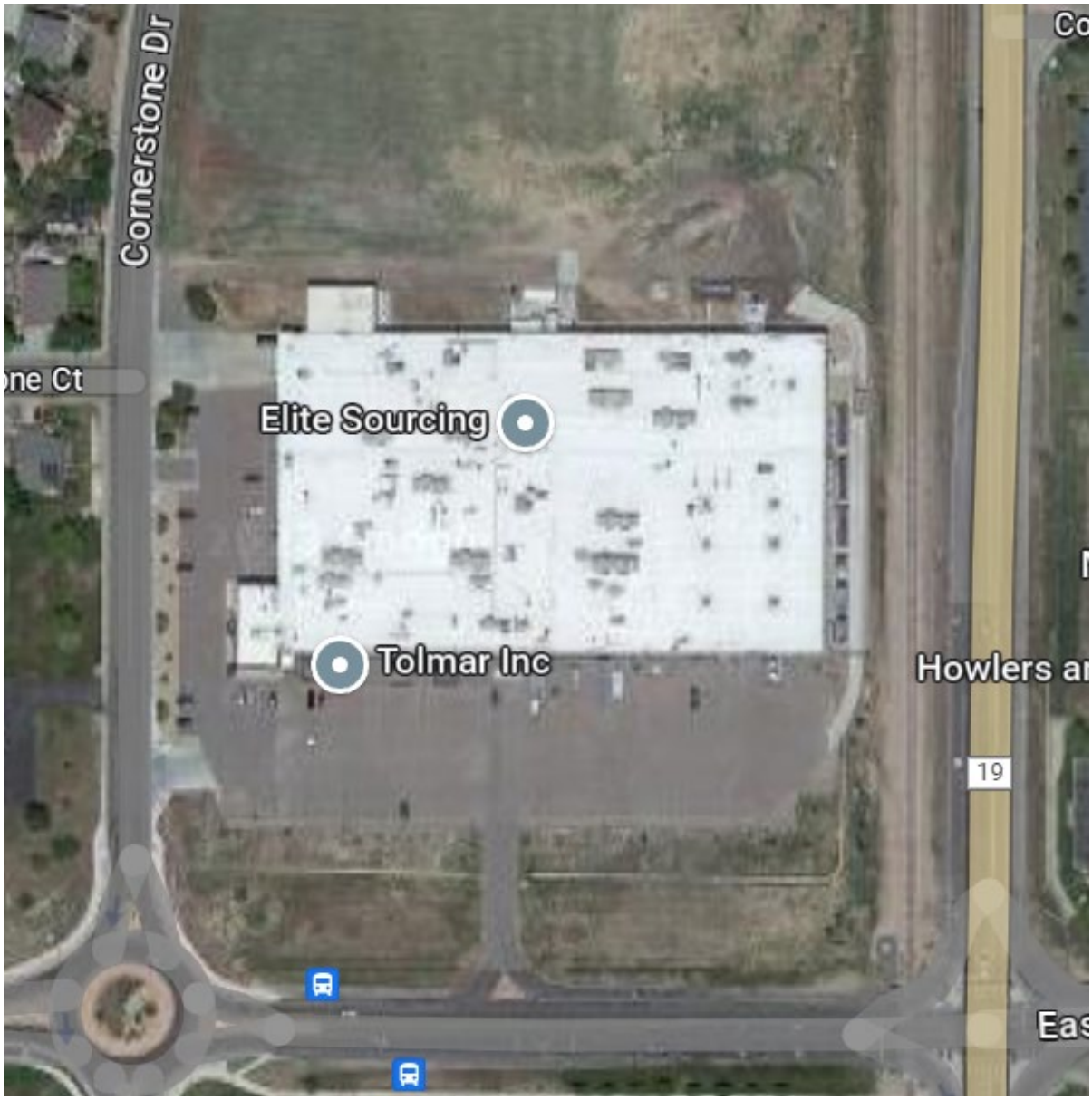


Figure 1 - Tolmar - Google Earth View

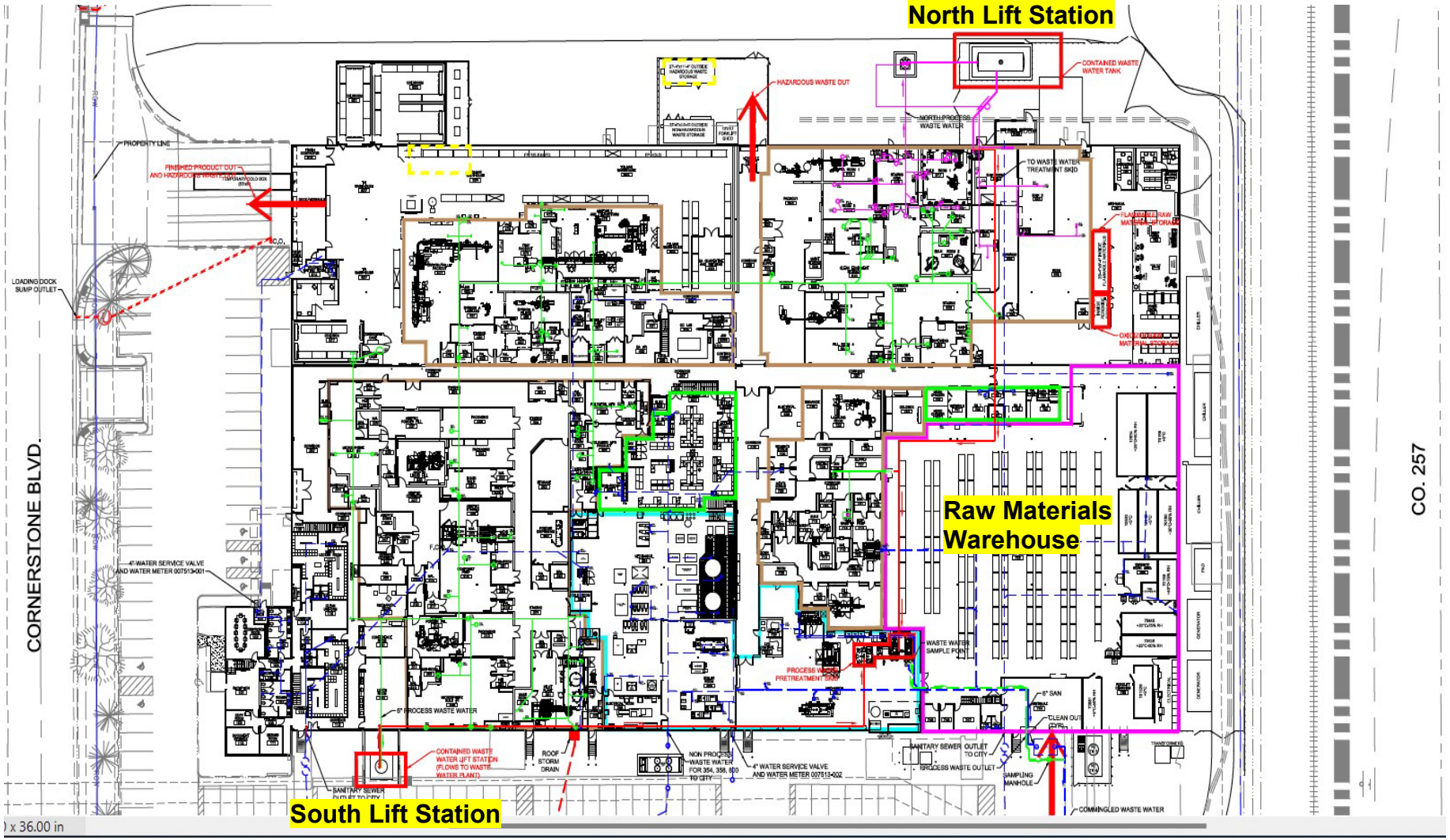


Figure 2 - Tolmar Site Layout

1.2 Raw Materials and Chemicals Storage and Spill Potential

Table 1 lists the chemicals the facility uses in its powder coating process:

Table 1 – Raw Materials and Chemicals Overview

Chemical	Volume/Mass	Storage Location	Process/Equipment Use
Flammables: (isopropyl alcohol, acetonitrile, acetone, ethanol, methanol)	Various sizes (5-gallon, 55-gallon, 250-gallon}	Raw Materials Waterhouse	Pharmaceutical manufacturing
Cleaner: (sporacide, hydrogen peroxide, para-acetic acid, Vesphene, lysol)	Various sizes	Raw Materials warehouse	Pharmaceutical manufacturing
Sulfuric acid	Two 55-gallons drums	Wastewater treatment skids in spill containment	Wastewater treatment – pH neutralization
Caustic Soda	Two 55-gallons drums	Wastewater treatment skids in spill containment	Wastewater treatment – pH neutralization
Defoamer	10-gallons	Wastewater treatment skids in spill containment	Wastewater treatment

The raw materials, active pharmaceutical ingredients (API) and chemicals are received in shipping docks located on the south side of the facility and stored in the Raw Materials warehouse. The boiler treatment and wastewater treatment chemicals are moved to the in-use areas. The raw materials are stored in the warehouse either on the floor or on shelves of large industrial storage racks. When requested by the various manufacturing areas or labs within the facility, the raw materials are staged in a pickup storage rack and issued to that area or lab.

Certain raw materials may be sampled to ensure quality control. An aliquot is taken from the raw material container and analyzed in the QA area, located in the Raw Materials warehouse. Note: the facility is decommissioning the dermatological products manufacturing (Derms East and Derms West areas) and will be moving large manufacturing equipment (mixing/bulking) and quantities of chemicals used in this larger scale manufacturing out of the facility.

1.3 Water Use and Distribution

According to the NDR application submitted on June 20, 2023, the facility receives its water from the Town of Windsor and used a total of 6,258,805 gallons in the previous 12 months or an average daily water consumption of 17,147 gallons per day (gpd). Table 2 provides information on the water usage and distribution in the facility:

Table 2 - Tolmar Water Usage and Distribution

Type	Average Water Usage (gpd)	Estimate (E) or Measured (M)
Irrigation (landscaping and lawn care)	1,150	E
Sanitary/Domestic	3,589	E
Plant and equipment sanitation and cleaning	5,108	E
Contained in product	1,459	E
Non-contact cooling water	73	E
Boiler feed water	`1,386	E
Process Water	4,378	E
Total:	17,143	E

1.4 Pharmaceutical Unit Operations

The facility organizes its pharmaceutical manufacturing of products into areas or labs within its building. As mentioned in the previous section, the raw materials, chemicals, and API are stored in the Raw Materials warehouse and are issued to the different pharmaceutical product areas when requested. The current pharmaceutical products manufactured at the facility includes the following:

- Eligard
- Fen-Solvi
- EPSS – Eligard with improved packaging.
- Polymer Manufacturing Suites
- Polymer R&D
- Note: The facility no longer manufactures dermatological products in the Derms East and West areas. The Derms East area is currently vacant, and the Derms West area is under construction for the EPSS product line.
- A general process flow diagram is included in Figure 3

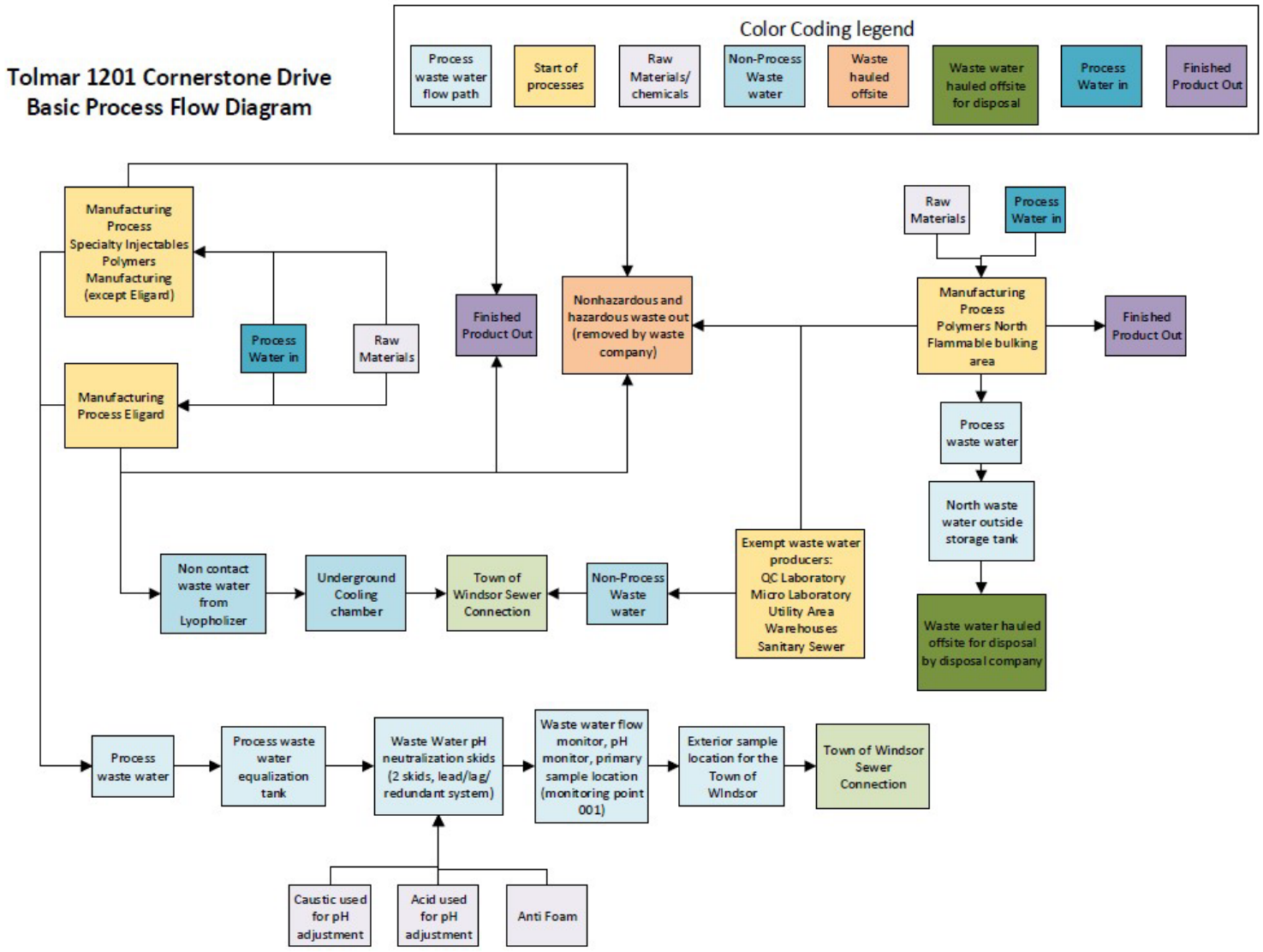


Figure 3 - Tolmar Pharmaceutical Manufacturing Process Flow Diagram

Pharmaceutical Manufacturing –

The raw materials and APIs that are issued from the Raw Materials warehouse are received in the centralized mixing or bulking lab. The bulking process occurs in one centralized area or lab within the facility. The mixing/compounding/formulating operations for each pharmaceutical product (Eligard, EPSS and Fen-Solvi) are the same, but the volumes change depending on the pharmaceutical product manufactured. The volumes for each pharmaceutical product will be identified in the narrative of the bulking operations.

The raw materials and APIs are mixed and compounded in carboys (Eligard – 10L, EPSS – 20L) using a magnetic stir plate. The mixed product is sent through an oven and then pumped through a series of filters to a media bag. The filters used during this process are single use and are collected as non-hazardous waste for disposal. The media bag is used in the filling machine designed to create dosage forms in syringe vials. The filling machine has a 5-station manifold and silicone tubing to fill syringes. The silicone tubing is single use and is disposed after every product filling run. The stainless-steel fill nozzles are rinsed in a lab sink, sterilized and reused. The facility manufactures 100 syringes per tub. The typical production runs for each pharmaceutical product are identified below:

- Eligard – 120 tubs
- EPSS – 60 to 210 tubs
- Fen-Solvi – 60 tubs

The dosage form products are freeze-dried (lyophilization) to stabilize the product in either final dosage form (EPSS) or ready for combining with the polymer syringe component.

Polymer Manufacturing –

The polymer is manufactured in two suites. The raw materials issued from the warehouse are received and mixed in an 8L helicone mixing vessel. The facility currently manufactures about two to three batches per week. The mixture is heated to dry and are extruded out of the containers into milling machines. The helicone vessel is cleaned with solvents to dissolve the residual polymer. The bottom of the container is opened to aid in cleaning. The waste solvent is collected and hauled off-site as hazardous waste.

The milled polymer powder is contained and sealed in a Syringe A bulking area/lab. According to facility representatives, the facility manufactures about 5 batches of polymer per week.

Polymer Development –

The polymer research and development are conducted in the Polymer Lab, located east of the Derms East area in the facility. The polymers developed and tested in this lab are produced in 10L batches. Acetone is used for cleaning and dissolving polymer in this lab. The waste acetone is collected and shipped off-site as hazardous waste.

Specialty Injectables –

The APIs used in specialty injectables are in powder form and are mixed in a 20L vessel, transferred to a 20L tank and are milled in a 200µ machine. The milled product is contained in a carrier container and are transferred to a 30L tank and then moved to the filling room for dosage form in vials. These products do not undergo lyophilization. The vessels used in this manufacturing operation are washed in the washrooms.

Purified Water –

The facility uses supply water that has undergone reverse osmosis (RO) for use in its manufacturing operations. Approximately 1 gallon of reject water or brine is generated for every 3 gallons of RO-treated water. The RO brine generated from the process is discharged directly to the City sewer. The RO water is first contained in a 5,400-gallon tank for facility use, with the exception of the Eligard manufacturing process. The water undergoes an additional treatment process and contained in a separate 5,400-gallon tank for use in the Specialty Injectables and Eligard manufacturing processes.

Boiler Room –

The facility boilers are blown down daily, based on conductivity and are annually evacuated for maintenance/inspection. The boilers wastewaters are discharged directly to the City sewer.

1.5 Non-Regulated Wastestreams –

According to the NDR application, non-contact steam condensate from the boilers mixes with the process wastewater throughout the facility. The volume of non-contact steam condensate is estimated to be 210 gpd discharged to the Eligard and South lift stations and to the wastewater treatment system. In addition, the facility performs cleaning of the production areas/labs, and this wastewater is discharged to the wastewater treatment system at a minimal volume. The monthly total was calculated by multiplying the daily average by 30 production days in an average month or 6,300 gallons per month.

1.6 Wastewater Collection and Lift Stations

The south lift station (Figure 4) collects regulated process wastewater from the Specialty Injectables, EPSS and old Derms East labs. The north lift station (Figure 5) collects regulated process wastewater from the H2 area within the Derms East lab. The facility does not allow the north lift station to pump to wastewater treatment but instead, the north lift station pumps to a 12,000-gallon collection tank. The valves on the pipes leading to wastewater treatment are locked. The 12,000-gallon collection tank has alarms that are triggered at about 3,500 and 6,000 gallons. The wastewater within this tank is hauled off-site and is tested for pH and flashpoint to ensure they are within the characteristic pH hazardous waste levels and a flashpoint below 140º C.

The regulated process wastewaters generated in the pharmaceutical products bulking lab are collected in the 75-gallon Eligard lift station (Figure 6) located on the west side of the Raw Materials warehouse.

Figure 4 - South Lift Station

Figure 5 - North Lift Station

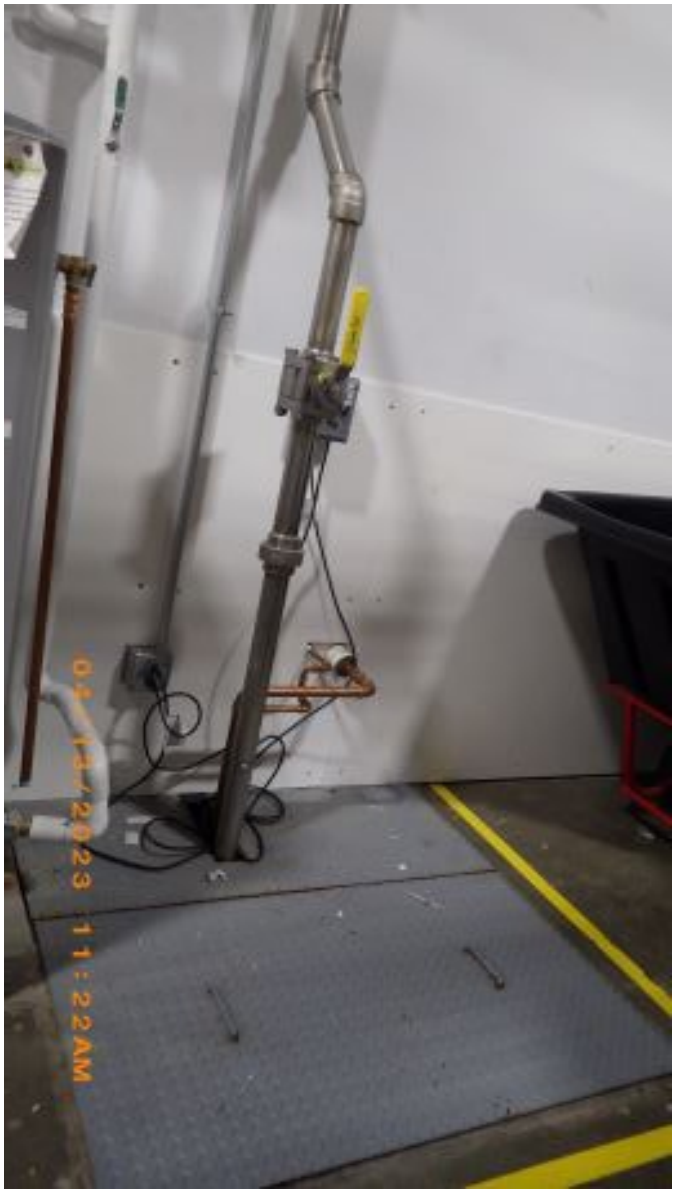


Figure 6 - Eligard 75-gallon Lift Station

1.7 Wastewater Treatment

The wastewater pumped from the Eligard and South lift stations are collected in the 2,800-gallon equalization tank (Figure 7). The facility has a larger backup overflow, in case this is needed. The contents in the 2,800-gallon equalization tank are pumped to the two waste treatment skids at about 37% capacity. The two wastewater treatment skids are identical in functionality for pH neutralization and capacity.

The wastewater enters Stage 1 (450-gallon capacity) of the pH neutralization skid and is treated for pH and defoaming agent is added if needed. The pH treatment acid/base and defoaming agent are contained in spill containment equipment (Figure 8). The treatment pH meter is set for 5.0 to 10.3. If Stage 1 wastewater is outside this range, the appropriate volume of either H2SO4 acid or caustic soda is added

to adjust the pH within the set criteria. The wastewater is moved across a weir to Stage 2 within the system and is monitored for a pH range of 7.0 to 9.0. If the pH of the Stage 2 wastewater is outside this range, then the wastewater is rerouted back to Stage 1 for additional treatment. If the Stage 2 wastewater is within range, then the contents are discharged through the discharge pipe from the treatment skid (Figure 9). The discharge pipes from the two treatment skids combine into one common discharge pipe. This is defined as outfall 001 and the facility continuously monitors for pH and flow. A monitoring point valve is also located on this discharge pipe (Figure 10). Flow and pH readings are taken on the discharge pipe of the wastewater treatment system using inline meters. The magmeter flow sensor probe is located next to the pH monitoring probe. Flow and pH data is sent to the wastewater treatment system's control panel and is recorded electronically using Tolmar's building management system (BMS). Figure 11 provides a layout of the wastewater treatment system.

According to the NDR application, the facility discharges about two to three batches per day with an average of about 630 gallons per batch. However, based on supplemental NDR application information provided by the facility on July 12, 2023, it appears that the facility only discharges one batch per day; the daily average flow for the facility from 2020 -2022 was 629 gpd and the maximum daily flow was 3,502 gallons that occurred in 2020. The 2020 to 2022 monthly average was determined by multiplying the daily average by 30 production days in an average month resulting as 18,870 gallons per month.

Figure 7 - 2,800 gallon Equalization tank and Backup Overflow Tank

Figure 8 - pH Neutralization Systems

Figure 9 - pH Neutralization Skid

Figure 10 - Discharge Pipe from the two pH Neutralization Skids

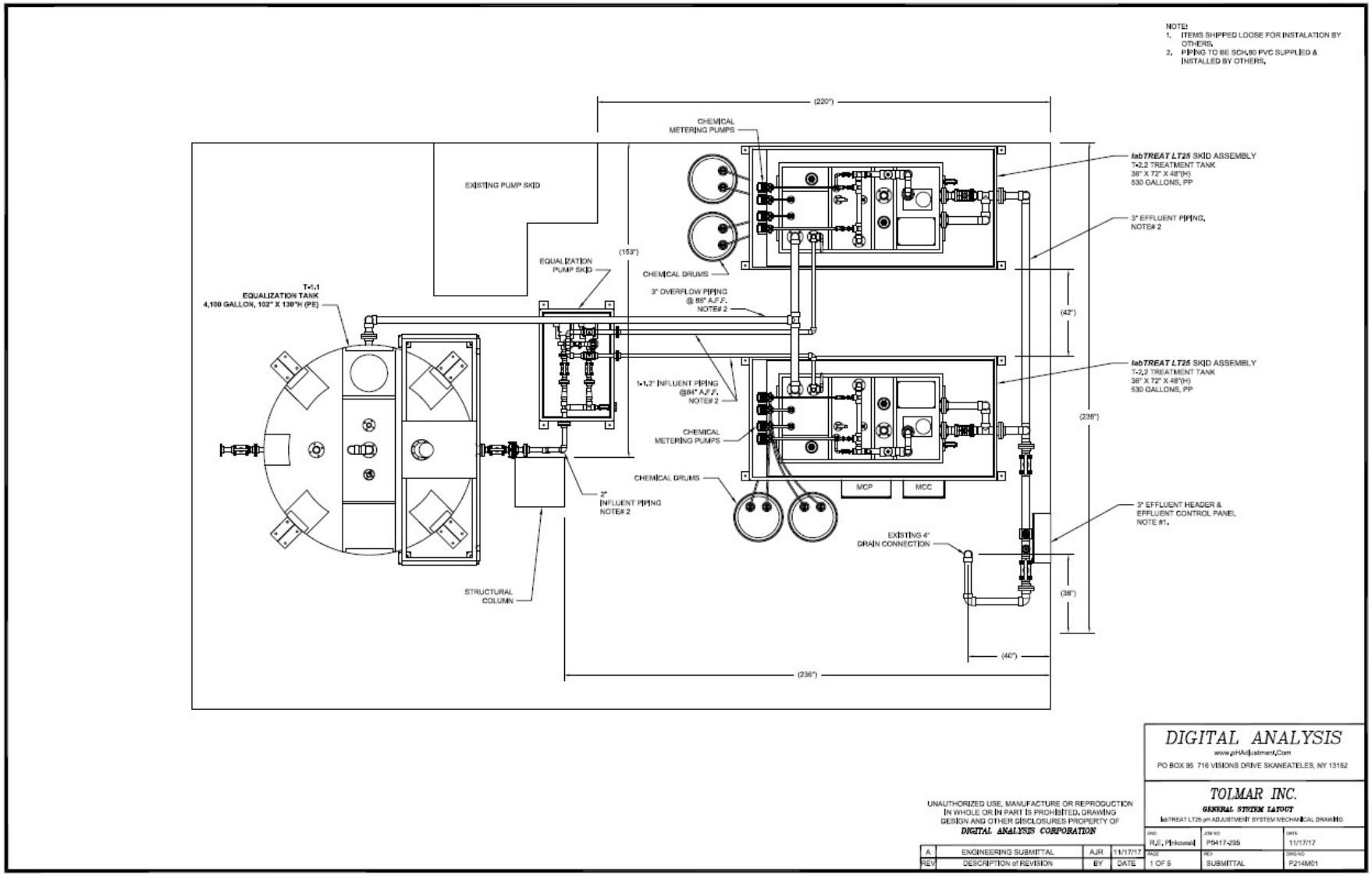


Figure 11 - Waste Treatment System Layout

1.8 Outfalls to the City Sanitary Sewer

According to the June 20, 2023 NDR application, the facility has three outfalls to the City sanitary sewer system. The outfalls are located are on the south side of the property and are shown on the facility drawings.

- 6-inch line for sanitary, non-contact process wastewater and laboratory (non-process) wastewater.
- 4-inch line for sanitary and non-process wastewater.
- 6-inch line that combines wastewater from the facility's waste treatment system and non-contact wastewater from the Eligard lyophilizer. These two waste streams get co-mingled at a junction point outside of the facility and under the parking lot. Outfall 001 defined in the NDR discharges to this 6-inch line.

Section 2 Applicable Pretreatment Regulations

Based on the information submitted in the June 20, 2023 NDR application and in an April 13, 2023, inspection conducted by the EPA, the facility is subject to Pharmaceutical Point Source Category found in 40 C.F.R. §439, Subpart D – Mixing/Compounding and Formulating. The facility's pharmaceutical manufacturing process generates wastewater that is discharged to the City of Windsor's POTW. The facility was constructed in 2014 and is determined to be a new source as defined in 40 C.F.R. §403(m)(1). As a new source to the Pharmaceutical Point Source Category (new source date = 05/02/1995), the facility is subject to the Pretreatment Standards for New Sources found in 40 C.F.R. §439.47.

The specialized definitions for Subpart D found at 40 C.F.R. §439(a) and (b), state the following:

> "For the purpose of this subpart:
>
> (a) ***Mixing, compounding, and formulating operations*** means processes that put pharmaceutical products in dosage forms.
>
> (b) ***Product*** means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions."

The Pretreatment Regulations found in 40 C.F.R. §§ 403 and 439 impose Pretreatment Requirements on the facility based on the pharmaceutical manufacturing operations and resulting discharge to the POTW. These Pretreatment Requirements include monitoring, reporting, and notification requirements found in 40 C.F.R. Sections 403.12, 403.16, and 403.17 and specialized definitions and monitoring requirements specific to the Pharmaceutical Manufacturing Point Source Category found in 40 C.F.R. §439. The applicable effluent limits are listed in the pretreatment standards for new sources at 40 C.F.R. 439.47.

2.1 Discharge Limitations

The Pharmaceutical Manufacturing, Subpart D-Mixing/Compounding and Formulating New Source Categorical Pretreatment Standards found in 40 C.F.R. § 439.47 establish the limitations for listed pollutants. Any new source subject to this subpart that introduces pollutants into a POTW must comply with 40 C.F.R. part 403 and achieve the following pretreatment standards for new sources:

Table 3 – Pharmaceutical Manufacturing, Subpart D Standards for New Source (PSNS) – 40 C.F.R. § 439.47

Pollutant	Daily Maximum (mg/L)	Monthly Average (mg/L)
Acetone	20.7	8.2
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

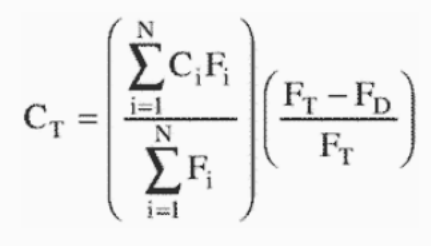
2.2 Dilution Prohibition as Substitute for Treatment

The Pretreatment Regulations at 40 CFR §403.6(d) state the following: "Except where expressly authorized to do so by an applicable Pretreatment Standard or Requirement, no Industrial User shall ever increase the use of process water, or in any other way attempt to dilute a Discharge as a partial or complete substitute for adequate treatment to achieve compliance with a Pretreatment Standard or Requirement. The Control Authority may impose mass limitations on Industrial Users which are using dilution to meet applicable Pretreatment Standards or Requirements, or in other cases where the imposition of mass limitations is appropriate."

2.3 Combined Wastestream Formula

The facility introduces unregulated/dilute wastestreams generated from non-contact steam condensate from the boilers to the regulated process wastestreams prior to the waste treatment system. These unregulated wastestreams identified in Section 1.5 generate a dilution factor that affects the regulated wastestreams when monitoring for compliance. Based on information submitted in the NDR application, the volume of non-regulated process wastewater introduced into the wastestreams regulated by the Pharmaceutical categorical Pretreatment Standards found in 40 C.F.R. § 439.47 is 210 gpd. Where process effluent is mixed prior to treatment with wastewaters other than those generated by the regulated process, fixed alternative discharge limits may be derived using a combined wastestream formula. These alternative limits shall be applied to the mixed effluent.

The combined wastestream formula for an alternative concentration limit found in 40 CFR §403.6(e)(1)(i) is expressed in Figure 12.



$$C_T = \left(\frac{\sum_{i=1}^{N} C_i F_i}{\sum_{i=1}^{N} F_i} \right) \left(\frac{F_T - F_D}{F_T} \right)$$

Figure 12 - Combined Wastestream Formula for Alternative Concentration Limits

C_T = the alternative concentration limit for the combined wastestream.

C_i = the categorical Pretreatment Standard concentration limit for a pollutant in the regulated stream i.

F_i = the average daily flow of the regulated wastestreams

F_D = the average daily flow of the non-regulated wastestreams

Based on supplemental NDR application information provided by the facility on July 12, 2023, the daily average for the facility from 2020 -2022 was 629 gpd. The monthly average was determined by multiplying the daily average by 30 production days in an average month or 18,870 gallons per month.

The volume of non-contact steam condensate is estimated to be 210 gpd discharged to the Eligard and South lift stations and to the wastewater treatment system. The monthly total was calculated by multiplying the daily average by 30 production days in an average month or 6,300 gallons per month.

The daily average flow of the regulated process wastestream is calculated by subtracting the non-regulated wastewater volume of 210 gpd from the total discharge flow of 629 gpd or 419 gpd

2.3.1 Daily Average CWF calculations

2.3.1.1 Acetone, n-Amyl acetate, Ethyl acetate and Isopropyl acetate

For purposes of the daily average CWF calculations for acetone, n-amyl acetate, ethyl acetate and isopropyl acetate the following factors were established to use in the equation:

CT = the alternative concentration limit for the combined wastestream.
Ci = 20.7 mg/L.
Fi = 419 gpd
FD = 210 gpd

$$C_T = \frac{20.7 \text{ mg/L} \times 419 \text{ gpd}}{419 \text{ gpd}} \times \frac{629 \text{ gpd} - 210 \text{ gpd}}{629 \text{ gpd}}$$

C_T = 13.8 mg/L

2.3.1.2 Methylene chloride

For purposes of the daily average CWF calculations for Methylene chloride the following factors were established to use in the equation:

CT = the alternative concentration limit for the combined wastestream.
Ci = 3.0 mg/L
Fi = 419 gpd
FD = 210 gpd

$C_T = \frac{3.0 \text{ mg/L} \times 419 \text{ gpd}}{419 \text{ gpd}} \times \frac{629 \text{ gpd-210 gpd}}{629 \text{ gpd}}$

$C_T = 2.0$ mg/L

2.3.2 Monthly Average CWF calculations

2.3.2.1 Acetone, n-Amyl acetate, Ethyl acetate and Isopropyl acetate

For purposes of the monthly average CWF calculations for acetone, n-amyl acetate, ethyl acetate and isopropyl acetate, the following factors were established to use in the equation:

CT = the alternative concentration limit for the combined wastestream.
Ci = 8.2 mg/L.
Fi = 419 gpd
FD = 210 gpd

$C_T = \frac{8.2 \text{ mg/L} \times 419 \text{ gpd}}{419 \text{ gpd}} \times \frac{629 \text{ gpd-210 gpd}}{629 \text{ gpd}}$

$C_T = 5.5$ mg/L

2.3.2.2 Methylene chloride

For purposes of the monthly average CWF calculations for methylene chloride, the following factors were established to use in the equation:

CT = the alternative concentration limit for the combined wastestream.
Ci = 0.7 mg/L
Fi = 419 gpd
FD = 210 gpd

$C_T = \frac{0.7 \text{ mg/L} \times 419 \text{ gpd}}{419 \text{ gpd}} \times \frac{629 \text{ gpd-210 gpd}}{629 \text{ gpd}}$

$C_T = 0.5$ mg/L

Table 4 - Pharmaceutical Manufacturing, Subpart D Standards for New Source (PSNS) – 40 C.F.R. § 439.47 (Alternative Concentration limits based on the Combined Wastestream Formula)

Pollutant	Daily Maximum (mg/L)	Monthly Average (mg/L)
Acetone	13.8	5.5
n-Amyl acetate	13.8	5.5
Ethyl acetate	13.8	5.5
Isopropyl acetate	13.8	5.5

Methylene chloride	2.0	0.5

2.4 Reporting, Monitoring, Notification and Record-Keeping Requirements

The reporting, monitoring, notification, and record keeping requirements are found in 40 C.F.R. Part 403 of the General Pretreatment Regulations and include the following:

- **Baseline Report and 90-Day Compliance Report Monitoring Requirements** (40 C.F.R. § 403.12(b) and (d); 40 C.F.R. § 403.12(g));
- **Periodic Compliance Report Monitoring Requirements** (40 CFR§ 403.12(e); 40 CFR§ 403.12(g))
- **Potential Problem and Slug Reporting** (40 C.F.R. § 403.12(f))
- **Effluent Violation Reporting and Resampling** (40 C.F.R. § 403.12(g)(2))
- **Notification of Changed Discharge** (40 C.F.R. § 403.12(j))
- **Hazardous Waste Discharge Notification** (40 C.F.R. § 403.12(p))
- **Upset Effect, Notification, and Reporting** (40 C.F.R. § 403.16)
- **Bypass Requirements Notification** (40 C.F.R. § 403.17)
- **Report Signatory Requirements** (40 C.F.R. § 403.12(l))
- **Retention of Records** (40 C.F.R. § 403.12(o))

2.5 Self-Monitoring Reporting Requirement

40 C.F.R. § 403.12(e) requires industrial users "subject to a categorical Pretreatment Standard" to monitor and report twice per year "unless required more frequently…by the Control Authority," which is the EPA in this case. Because daily average flows are approximately 630 gpd and non-regulated wastestreams are present, the reporting requirements for Tolmar. are established at quarterly. The quarterly reporting is established to ensure compliance with the Pretreatment Standards found in the Pharmaceutical regulations (40 C.F.R. § 439.47). In addition, Subpart D of the Pharmaceutical Manufacturing Point Source Category at 40 CFR 439.2(b) states that "Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged."

Tolmar will submit discharge monitoring reports (DMRs) through the NetDMR electronic reporting system, as described in §3.7. Table 5 lists the deadline due dates based on quarterly reporting:

Table 5 - Self-Monitoring Reporting Frequency

Compliance Monitoring Period	Due Date
January through March	April 30
April through June	July 31
July through September	October 31
October through December	January 31

2.6 Monitoring Requirements

The discharges from the facility at Outfall 001 are subject to the following monitoring requirements, listed in Table 4. Outfall 001 is defined as the monitoring point valve located on the combined discharge pipe from the two wastewater pH treatment skids and prior to discharge into the 6-inch line leading to the City sanitary sewer system.

40 C.F.R. § 403.12(g)(3) requires that periodic compliance reports "must be based upon data obtained through appropriate sampling and analyses performed during the period covered by the report, which data are representative of the conditions occurring during the reporting period." Based on the EPA's evaluation of the facility's discharge characteristics based on one batch discharged per day, a grab sample for regulated metals is representative of the discharge for the production day. In addition, the facility is required to measure for flow and pH because of the potential for fluctuations during the discharge. At a minimum, the daily discharge of every production day shall be measured for pH and flow.

All analyses shall be performed in accordance with test procedures established in 40 C.F.R. Part 136. Sampling methods shall be those defined in 40 C.F.R. Part 136, 40 C.F.R. Part 403, as further described in the Notification of Discharge Requirements.

Table 6 - Monitoring Frequency

Pollutant	Sample Type	Sampling Frequency
Flow	Continuously Measured	Every Production day
pH	Continuously Measured	Every Production Day
Acetone	Grab	Quarterly
n-Amyl acetate	Grab	Quarterly
Ethyl acetate	Grab	Quarterly
Isopropyl acetate	Grab	Quarterly
Methylene chloride	Grab	Quarterly

2.7 Additional Monitoring

The Pretreatment Regulations at 40 C.F.R. § 403.12(g)(6) requires the following:

"If an Industrial User subject to the reporting requirement in paragraph (e) or (h) of this section [compliance reports] monitors any regulated pollutant at the appropriate sampling location more frequently than required by the Control Authority, using the procedures prescribed in paragraph (g)(5) of this section [representative sampling and 40 C.F.R. § 136 analytical methods], the results of this monitoring shall be included in the report." [emphasis added]

2.8 Notification of Changed Discharges

The Pretreatment Regulations at 40 C.F.R. 403.12(j) states the following: "All Industrial Users shall

promptly notify the Control Authority (and the POTW if the POTW is not the Control Authority) in advance of any substantial change in the volume or character of pollutants in their Discharge, including the listed or characteristic hazardous wastes for which the Industrial User has submitted initial notification under paragraph (p) of this section."

This regulation requires Tolmar to promptly notify EPA, as the Control Authority, and the City of Windsor in advance of any substantial change in the volume or character of pollutants in its discharge. These substantial changes include changes that may affect the requirements contained in this notification and could include changes to the operations, wastestream generation, and/or wastewater management that may affect the status of Tolmar's current control mechanism conditions under the Pretreatment Regulations. This also includes any changes to the operation that changes the discharge of listed or hazardous wastes.

2.9 Record-keeping Requirements

40 C.F.R. § 403.12(o) establishes record-keeping requirements for any Industrial User subject to reporting requirements resulting from any monitoring (including flow monitoring), including documentation with Best Management Practices.

The facility shall be required to retain for a minimum of three years any records of monitoring activities and results and shall make such records available for inspection and copying by EPA and the POTW. This period of retention shall be extended during the course of any unresolved litigation regarding the facility or when requested by EPA.

2.10 Signatory Requirement

Pursuant to 40 C.F.R. §403.12(l), the Baseline Report, 90-day Compliance Report, and Periodic Compliance Reports (Parts III.A and B) shall include the following signed certification statement:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

The certification statement shall be signed as follows:

1. By a responsible corporate officer, if the Industrial User is a corporation. For the purpose of this paragraph, a responsible corporate officer means:
   a. A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or
   b. The manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; can ensure that the necessary

systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

2. By a general partner or proprietor if the Industrial User is a partnership, or sole proprietorship respectively.
3. By a duly authorized representative of the individual designated in (1) or (2) of this section if:
   a. The authorization is made in writing by the individual described in paragraph (1) or (2);
   b. The authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the Industrial Discharge originates, such as the position of plant manager, operator of a well, or well field superintendent, or a position of equivalent responsibility, or having overall responsibility for environmental matters for the company; and
   c. The written authorization is submitted to the EPA.
4. If an authorization under (3) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, or overall responsibility for environmental matters for the company, a new authorization satisfying the requirements of (3) of this section must be submitted to EPA prior to or together with any reports to be signed by an authorized representative.

2.11 Reporting and Notification Contacts

On October 22, 2015, the Environmental Protection Agency (EPA) published in the Federal Register the NPDES Electronic Reporting rule for all NPDES permit reporting and notification requirements (40 C.F.R. Part 127). The deadline for the electronic reporting of Periodic Compliance Reports for CIUs/SIUs in municipalities without an approved Pretreatment is December 21, 2020 (40 C.F.R. § 127.16). Upon the effective date of the NPDES Electronic Reporting Rule, the facility will be required to:

a. Establish a NetDMR account to electronically submit DMRs and notifications and must sign and certify all electronic submissions in accordance with the signatory requirements of the control mechanism. NetDMR is accessed from the internet at https://netdmr.zendesk.com/home. Additionally, the facility can contact the EPA via our R8NetDMR@epa.gov mailbox for any individual assistance or one-on-one training and support.

b. Effluent monitoring results will be summarized for each month and recorded on a DMR to be submitted via NetDMR to the EPA on a quarterly basis. If no discharge occurs during a month, it shall be stated as such on the DMR.

Until the effective date of the NPDES Electronic Reporting Rule, the facility may either submit Periodic Compliance Reports electronically, as described above, or submit hard copies to the address below. Other written reports and notifications to the EPA shall be submitted at the following address:

NPDES and Wetlands Enforcement Section (8ENF-W-NW)
US EPA Region 8
1595 Wynkoop Street
Denver, CO 80202
Attention: Pretreatment

All written reports and notifications must also be submitted to the POTW at the following address:

Dennis Markham, POTW Superintendent
City of Windsor
301 Walnut Street
Windsor, CO 80550
dmarkham@windsorgov.com

Verbal notifications required to be submitted to the EPA shall be made by calling either number below and asking to speak with NPDES Enforcement, Pretreatment.

303-312-6312 or 800-227-8917

Verbal notifications required to be submitted to the POTW shall be made by calling the number below.

970-686-2144

Section 3 Public Notice Period and Response to Comments

The proposed fact sheet and discharge requirements for Tolmar, NPDES ID # COPF00106 were public noticed on the EPA website on December 4, 2023. During the 30-day public notice period, EPA did not receive any substantive public comments.