

Pretreatment Compliance Inspection

Summary Report

Discharger: Novato Sanitary District
Novato Sanitary District Wastewater Treatment Plant NPDES No.
CA0037958
Marin County

Location: 500 Davidson Street, Novato, CA 94945

Contact: Elizabeth Falejczyk, Veolia
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Inspection Dates: January 28, 2019

Inspected By: Chuck Durham, PG Environmental
Sirese Jacobson, PG Environmental

Attachments

Attachment A Industrial User Site Visit Data Sheets

I. Inspection Summary

Upon arrival, EPA contractors Chuck Durham and Sirese Jacobson (Inspection Team) met with representatives of the District. The District contracts with Veolia to implement the pretreatment program. For the purposes of this report, Veolia contract staff members and Novato Sanitary District staff are collectively referred to as District representatives. The Inspection Team discussed the purpose and format of the pretreatment compliance inspection (PCI) and interviewed the District representatives about the District's pretreatment program and procedures.

As part of the inspection, the Inspection Team reviewed the following files:

- BioMarin – Galli Drive (categorical industrial user [CIU] subject to 40 Code of Federal Regulations [CFR] Part 439.16 pretreatment standards for existing sources [subpart A Fermentation Products]*; see Finding C.4.a)
- Optical Metal Services (non-significant CIU [NSCIU] subject to 40 CFR 433.17)

The Inspection Team conducted inspections at the following facilities:

- BioMarin – Galli Drive
- Dye Guy (non-significant industrial user)

The last review of the District's pretreatment program was a PCI performed on January 12, 2016 (2016 PCI).

*Division II, Part I of the BioMarin Pharmaceutical permit indicates that the permittee is subject to the pretreatment standards for new sources under 40 CFR 439; however, the limits in Tables A and B are the 40 CFR 439.16 (pretreatment standards for existing sources).

II. Program Description

The District manages a pretreatment program serving a population of approximately 60,000. The District operates the Novato Sanitary District Wastewater Treatment Plant (WWTP) NPDES No. CA0037958. The WWTP's design flow is 7 million gallons per day (MGD). The WWTP's average dry weather flow is approximately 3.5 MGD.

The District receives and treats wastewater from the City of Novato, as well as Atherton, Greenpoint, Blackpoint, Indian Valley, Bel Marin Keys, and Verissimo Valley. The District's 2017 annual pretreatment program report indicates that the majority of these areas are zoned very low density residential and are on septic tanks systems (except for Bel Marin Keys and Verissimo Valley) but were expected to convert to sewers in the future.

III. Industrial User (IU) Characterization		
IUs currently identified by the Control Authority (CA)*	IU Type	
3	Discharging Significant Industrial Users (SIUs)	
	2	Discharging Non-Categorical SIUs (as defined by the CA)
	1	Categorical Industrial Users (CIUs)
	0	Middle Tier CIUs
1	Zero-Discharging CIUs	
2	Non-significant CIU (NSCIU)	
17	Other Regulated IUs (e.g. permitted IUs) Describe: The District issues permits to seven non-significant dischargers and issues temporary permits to ten groundwater remediation sites.	
3	Waste Haulers Describe: The District issues permits to three waste haulers.	

IV. Findings Summary Table		
Part V Section Reference – Finding	Requirement(s)	Recommendation(s)
C.4.a - The applicable categorical subpart was not clear in the BioMarin Pharmaceutical permit.	1	
C.4.b - The permits reviewed did not require the permittees to notify the District of changes affecting the potential for a slug discharge.	2	
C.4.c - The Optical Metal Services permit includes requirements for the District.		1
C.4.d - The permits reviewed do not contain adequate language regarding notification of substantial changes in discharge.	3	
C.4.e - The permits reviewed could be better organized to clarify separate reporting requirements.		2
C.4.f - The Optical Metal Services permit does not require the facility to notify the District when it is operational.		3
E.2 - The District's sampling chain-of-custody (COC) forms did not document the sample temperature.	4	
F.1 - The District representatives were unsure if the District's enforcement response plan (ERP) was consistent with the changes made to the sewer use ordinance (SUO) in 2015.		4
Focus Topics: Dental Mercury - It was unclear whether the District intends to receive the one-time certification reports from dental facilities in its service area.		5
BioMarin Galli Site Visit Data Sheet - The facility was storing incompatible chemicals adjacent to one another and		6

not fully within the separate secondary containment pallets.		
V. Evaluation		
<p>The Inspection Team discussed the following topics regarding the District's pretreatment program with the District representatives. The Inspection Team also reviewed SIU files to assess the retention and maintenance of required program documents and to generally evaluate overall program implementation. The following sections describe program deficiencies and areas of concern identified during the inspection process along with requirements, recommendations, and associated references to 40 CFR Part 403.</p>		
A. Control Authority (CA) Pretreatment Program Modification		
<p>1. When was the last program modification? Did the CA notify the EPA of program modifications? (40 CFR 403.18)</p> <p>According to the District representatives, no changes have been made to the pretreatment program since the 2016 PCI.</p> <p>According to the District representatives, all required streamlining provisions were incorporated into the SUO in 2015. It is recommended that the District ensure that the ERP is reviewed to ensure that it is consistent with changes made to the SUO (see Finding F.1 below).</p>		
B. IU Characterization		
<p>1. Describe the CA's procedure for identifying and locating IUs that might be subject to the pretreatment program. Has the CA identified and located all applicable IUs (non-categorical SIUs, CIUs, NSCIUs, etc.)? (40 CFR 403.8(f)(2)(i))</p> <p>The District performed a formal industrial waste survey in 2014 or 2015. District staff could not definitively confirm the exact date. The District now performs drive-by inspections of industrial areas. When an industrial user is moving, District staff inquire as to where the industrial user is moving. The District staff also review water usage once per year. The District's procedures for identifying industrial users appears to be thorough and adequate.</p>		
<p>2. Has the CA identified the character and volume of pollutants contributed to the publicly owned treatment works (POTW) by IUs subject to the pretreatment program? (40 CFR 403.8(f)(2)(ii))</p> <p>The District appears to have adequate knowledge of the character and volume of pollutants discharged to the POTW. The District performs annual inspections and semi-annual sampling at its SIUs.</p>		
<p>3. Has the CA prepared and maintained a list of SIUs, as defined in 403.3(v)(1), along with the applicable SIU criteria? Does the list indicate whether the CA has made a determination that an SIU is a NSCIU, as defined in 403.3(v)(2), rather than an SIU? Have modifications to the list been submitted with annual reports? (40 CFR 403.8(f)(6))</p> <p>The District maintains a current list of SIUs and NSCIUs, which it submits with the annual pretreatment</p>		

program report.

C. Control Mechanism Evaluation

1. Has the CA issued individual or general control mechanisms to all SIUs?
(40 CFR 403.8(f)(1)(iii))

The SIU and NSCIU whose files were reviewed during the inspection had been issued an individual permit and both permits were current. The District had not issued general permits at the time of the inspection.

2. Do the applications for general control mechanism contain the following?
(40 CFR 403.8(f)(1)(iii)(A)(2))

- a. Contact info**
- b. Production processes**
- c. Types of wastes generated**
- d. Location for monitoring**
- e. Any request for waiver for pollutants not present per 40 CFR 403.12(e)(2)**

N/A. The District does not issue general control mechanisms.

3. Are general control mechanisms only issued for IUs where the following is true?
(40 CFR 403.8(f)(1)(iii)(A)(1))

- a. Involve same/substantially similar types of operations**
- b. Discharge the same type of waste**
- c. Same effluent limitations**
- d. Same or similar monitoring**
- e. There are no CIU production-based standards, CIU mass limits, combined wastestream formula, or net/gross calculations**

N/A. The District does not issue general control mechanisms.

4. Do both individual and general control mechanisms include the following, where applicable?
(40 CFR 403.8(f)(1)(iii)(B))

- a. Statement of duration (5 years max)**
- b. Statement of non-transferability**
- c. Applicable effluent limits (local limits, categorical standards, BMPs)**
- d. Self-monitoring requirements**
 - Identification of pollutants to be monitored**
 - Sampling frequency**
 - Sampling locations/discharge points**
 - Appropriate sample types**
 - Reporting requirements**
 - Record-keeping requirements**
- e. Statement of applicable civil and criminal penalties**

- f. Compliance schedules
- g. Notice of slug loading or potential problems at POTW
- h. Notification of spills, bypasses, upsets, etc.
- i. Notification of significant change in discharge
- j. 24-hour notification of effluent violation
- k. Submit resampling results within 30-days
- l. Slug discharge control plan requirement, if required by POTW
- m. Certification statements
- n. Sampling/analysis requirements (Part 136 or alternative)
- o. Reporting of additional sampling
- p. 90-day compliance report

The Inspection Team reviewed the files, including the permits, for two SIUs:

- BioMarin (CIU subject to 40 CFR 439.16; see Finding C.4.a below)
- Optical Metal Services (NSCIU subject to 40 CFR 433.17)

The permits reviewed included most of the above permit elements, where applicable, with the exception of the findings identified below.

Finding C.4.a – The applicable categorical subpart was not clear in the BioMarin Pharmaceutical permit.

Division II, Part I of the BioMarin Pharmaceutical permit indicates that the permittee is subject to the pretreatment standards for new sources under 40 CFR 439; however, the limits in Tables A and B are the 40 CFR 439.16 (pretreatment standards for existing sources).

The information in the District's 2017 annual pretreatment report identifies the permittee as a CIU subject to 40 CFR 439.16 and includes these categorical limits, but the narrative indicates that the facility is subject to pretreatment standards for new sources.

Regulatory Requirement

The federal regulations at 40 CFR 403.8(f)(2)(iii) require the control authority to notify industrial users of applicable pretreatment standards and requirements. The federal regulations at 40 CFR 439.16 provide the pretreatment standards for existing sources under the pharmaceutical manufacturing, subpart A Fermentation products category. The federal regulations at 40 CFR 439.17 provide the pretreatment standards for new sources under the pharmaceutical manufacturing, subpart A Fermentation products category.

Requirement 1

The District is required to revise the permit to clarify the applicable categorization of the CIU.

Finding C.4.b – The permits reviewed did not require the permittees to notify the District of changes affecting the potential for a slug discharge.

Regulatory Requirement

The federal regulations at 40 CFR 403.8(f)(1)(iii)(B)(4) require that permits include notification and other requirements in accordance with the general pretreatment standards in part 403. The regulations

40 CFR 403.8(f)(2)(vi) require SIUs to notify the District immediately of any changes at the facility affecting the potential for a slug discharge.

Requirement 2

The District is required to modify its SIU permits to require the SIUs to notify the District of changes affecting the potential for a slug discharge, as specified at 40 CFR 403.8(f)(2)(iv).

Finding C.4.c – The Optical Metal Services permit includes requirements for the District.

The Optical Metal Services permit states that the District will perform the monitoring in lieu of requiring self-monitoring, unless the District requires self-monitoring in writing.

Recommendation 1

It is strongly recommended that the District remove language from SIU permits that contain obligations for the District.

Finding C.4.d – The permits reviewed do not contain adequate language regarding notification of substantial changes in discharge.

The permits reviewed require the permittees to notify the District of “facility expansion, production increase, or process modifications which results in new or substantially increased discharges or a change in the nature of the discharge.” However, this language does not require the permittees to notify the District of decreases in production and discharge.

Regulatory Requirement

The federal regulations at 40 CFR 403.8(f)(1)(iii)(B)(4) require that permits include notification and other requirements in accordance with the general pretreatment standards in part 403. The regulations at 40 CFR 403.12(j) require all industrial users to promptly notify the District in advance of any substantial change in the volume or character of pollutants in their discharge.

Requirement 3

The District is required to revise the SIU permits to include the requirement for notification of substantial changes which mirrors the federal regulations at 40 CFR 403.12(j).

Finding C.4.e – The permits reviewed could be better organized to clarify separate reporting requirements.

Upon review of the permits, the inspectors noted that several reporting requirements were grouped under the same heading and may not be easily identified by permittees. The permits include information on duty to reapply for permit issuance and continuation of an expired permit under a heading called Limitation on Permit Transfer. However, these topics do not fall under the topic of limitations of permit transfer.

Recommendation 2

It is recommended that the District revise the permits to clearly identify these different reporting requirements.

Finding C.4.f – The Optical Metal Services permit does not require the facility to notify the District when it is operational.

According to the District representatives, when the District wishes to collect a sample at Optical Metal Services, they call the facility representative and ask if they are operating so the District can conduct an inspection and sampling. If the District required the facility to notify them whenever the facility is operational, the District would be able to decide whether or not to inspect and sample the facility.

Recommendation 3

It is recommended that the District revise the Optical Metal Services permit to require the permittee to notify the District any time they are operational.

D. Application of Pretreatment Standards and Requirements

1. Does the CA apply all applicable pretreatment standards? (40 CFR 403.8(f)(1)(ii) and 403.8(5))

Based on the files reviewed, the District is applying all applicable pretreatment standards to its SIUs other than as noted in Finding C.4.a above.

2. Has the CA evaluated the need for SIUs to develop slug discharge control plans? (40 CFR 403.8(f)(2)(vi))

According to District representatives, the District evaluated the need for SIUs to develop slug discharge control plans and required that two of its SIUs, BioMarin Galli and North Marin Water District, develop and implement slug discharge control plans. The slug discharge control plan for BioMarin Galli (developed August 2017) contains the required elements. The North Marin Water District plan was not evaluated as part of this inspection.

E. Compliance Monitoring

1. Has the CA inspected and independently sampled each SIU at least once a year? Middle tier CIUs at least once every two years? Sample once during term of CIU control mechanism if CIU sampling waived for pollutants not present? (40 CFR 403.8(f)(2)(v), 403.12(e)(2), 403.12(e)(2))

Yes. According to the District representatives, and based on the files reviewed, the District has been conducting inspections and sampling at least once per year. The District had not permitted any industrial users as middle tier CIUs at the time of the inspection.

According to the District representatives, when the District wishes to collect a sample at Optical Metal Services, they call the facility representative and ask if they are operating so the District can conduct an inspection and sampling (see Finding C.4.g above).

2. Has the CA used proper sampling and analysis procedures (40 CFR Part 136) and inspection procedures? Were the procedures done with sufficient care to produce evidence admissible in enforcement proceedings or in judicial actions? (40 CFR 403.8(f)(2)(v) and (vii), 40 CFR 403.12(g)(5))

Based on the files reviewed, the District appears to be using proper sampling procedures and using 40

CFR Part 136 methods, with the exception of the District's sampling procedure described in Finding E.2 below.

Finding E.2 – The District's sampling COC forms did not document the sample temperature.

Neither the District's COC form or composite sampling note sheet for a composite sample collected on November 8-9, 2018, documented the sample temperature.

Regulatory Requirement

Pursuant to federal regulations at 40 CFR 136, composite samples must be kept refrigerated at or below 6 degrees Celsius.

Requirement 4

The District is required to ensure that composite samples are refrigerated at or below six degrees Celsius during compositing and record the sample temperature on the COC form.

3. Has the CA kept records for three years including the following?

- a. Period compliance reports and other reports/notices
 - b. All monitoring records including: sample date, place, method, time, personnel; analysis date, personnel, method; results
 - c. BMP compliance documentation
 - d. Other monitoring records
- (40 CFR 403.12(o))

Based on the files reviewed, the District maintains records for at least three years.

4. Has the CA evaluated, at least once per year, whether NSCIUs continue to meet the criteria of an NSCIU?

(40 CFR 403.8(f)(2)(v)(b), 403.3(v)(2))

Yes. The District permits nondomestic dischargers as NSCIUs. Based on the NSCIU file reviewed during the inspection, the District inspects the facility annually and receives an annual report from the facility which includes a NSCIU certification, total toxic organic certification, and a summary of total monthly flows for the year.

5. Has the CA required, received, and analyzed reports and other notices from SIUs?

- a. Self-monitoring reports
- b. BMRs and 90-day compliance reports
- c. Compliance schedules reports
- d. Notice of slug loading or potential problems at POTW
- e. Notification of spills, bypasses, upsets, etc.
- f. Notification of significant change in discharge
- g. 24-hour notification of effluent violation
- h. Resampling results within 30-days
- i. Other reports/notifications required by the CA
(40 CFR 403.8(f)(2)(iv))

Based on the files reviewed during the inspection, the District has been requiring, receiving, and analyzing required reports.

6. Have SIUs monitored to demonstrate continued compliance and re-sampled after violation(s)?

(40 CFR 403.12(g)(1) & (2))

Based on the BioMarin Galli file reviewed, the SIU monitored at the required frequency. BioMarin Galli did not experience effluent violations in 2018, and therefore, did not have to perform resampling.

7. Has the CA ensured CIUs report on all regulated pollutants at least once every 6 months?
(40 CFR 403.12(e)(1) & (g)(1))

Based on the CIU files reviewed, the District is requiring these permittees to submit required reports at least once every six months. BioMarin Galli submits quarterly monitoring reports. Optical Metal Services is classified as a NSCIU and is not required to monitor. The facility submitted an annual NSCIU certification and TTO certification on January 17, 2019, and January 18, 2018.

8. Has the CA ensured non-categorical SIUs self-monitor and report at least once every 6 months with a description of the nature, concentration, and flow of the pollutants required to be reported by the Control Authority?

(40 CFR 403.12(h) & (g)(1))

The inspection team did not review a non-categorical SIU file during the inspection.

9. Has the CA required self-monitoring reports from CIUs to be signed and certified?

(40 CFR 403.12(b)(6), 403.12(l))

Yes. Based on the CIU files reviewed, all required reports were signed and certified.

10. Has the CA received notification of hazardous waste discharges?

(40 CFR 403.12(j) & (p))

According to the District representatives during the interview and based on the SIU files reviewed during the inspection, no hazardous waste discharge notifications were received, nor was there an

indication that such notifications should have been received.

F. Enforcement

1. Has the CA implemented its enforcement response plan (ERP)? (40 CFR 403.8(f)(5))

The District's ERP was last revised in 1993. In general, it appeared that the District was implementing its ERP.

Finding F.1 – The District representatives were unsure if the District's ERP was consistent with the changes made to the SUO in 2015.

Recommendation 4

It is recommended that the District review its ERP to ensure that the language is consistent with the changes made to the SUO in 2015.

2. Does the CA evaluate both numeric and narrative criteria for significant non-compliance (SNC) and annually publish a list of IUs in SNC? (40 CFR 403.8(f)(2)(viii))

Yes. The District's definition of SNC is the same as the definition at 40 CFR 403.8(f)(2)(viii). According to the District representatives, the last SNC publication took place in 2013. Based on the information included in the District's 2017 annual pretreatment program report, there were no SIUs in SNC during that year. According to the District representatives during the interview, no SIUs were in SNC in 2018. The District would publish SIUs in SNC in the *Marin Independent Journal*.

2.a Were any SIUs in SNC in the past year? Include name of industry, type of SNC, and current compliance status.

According to the District representative, no SIUs were identified as being in SNC in 2018.

3. Has the CA developed IU compliance schedules? (40 CFR 403.8(f)(1)(iv)(A))

According to the District representatives, no SIUs were on compliance schedules at the time of the PCI.

4. Has the CA ensured CIU compliance within 3 years of standards effective date (or less than 3 years where required by standard)? (40 CFR 403.6(b))

The District representatives stated that no CIUs had been allowed more than three years from the effective date of a categorical standard to achieve compliance. No new CIU regulations have been promulgated in the last three years.

**5. Has the CA ensured CIUs submit complete baseline monitoring reports and 90-day compliance reports within the required time frames?
(40 CFR 403.12(b) & (d))**

The Inspection Team did not review baseline monitoring reports or 90-day compliance reports for the facilities whose files were reviewed.

G. Additional Evaluations

1. Hauled Waste

The District accepts hauled waste from three haulers at the WWTP. The haulers must be certified by the County. The District accepts septage waste only, and only at the designated discharge point. The haulers access the discharge point by key card during business hours. The District requires the haulers to provide them with a hauled waste manifest. The District does not currently sample hauled waste.

Focus Topics

As a component of the PCI, the Inspection Team discussed the following focus topics with the District representatives.

Dental Mercury

The EPA promulgated pretreatment standards for dental offices on June 14, 2017; these standards can be found at 40 CFR Part 441. The rule became effective on July 14, 2017. The rule specifies that dental facilities are not considered SIUs or CIUs; therefore, POTWs are not required to permit or inspect dental facilities but may choose to do so. However, 40 CFR 403.8(f)(2)(b)(i) requires control authorities to identify and locate all industrial users which includes dental facilities. According to the rule, control authorities must receive the one-time certification report from dental facilities and ensure that dental facilities are implementing BMPs. Information on this rule can be viewed at <https://www.epa.gov/eg/dental-effluent-guidelines>, including the Frequently Asked Questions for Control Authorities on the Dental Rule, found at <https://www.epa.gov/npdes/frequently-asked-questions-control-authorities-dental-rule-40-cfr-part-441>.

Finding – It was unclear whether the District intends to receive the one-time certification reports from dental facilities in its service area.

According to the District representatives, the District has identified 33 dentists. According to District representatives, the Central Marin Sanitation Agency intends to accept the one-time certification reports from dental facilities throughout the county as these facilities are being inspected annually under the Central Marin Sanitation Agency's pollution prevention program (P2). The federal regulations at 40 CFR Part 441 require that control authorities receive a one-time certification report from all regulated dental facilities that discharge to the POTW.

Recommendation 5

The District is reminded that, as the control authority, it must receive the one-time certification reports, per 40 CFR Part 441.

Fats, Oils, and Grease (FOG)

The District does not issue permits to FSEs; however, they do inspect FSEs. The District pretreatment staff are in communication with the collection system crews and FSEs are inspected based on hot spots in the collection system; therefore, the District has not inspected every FSE in the service area.

Attachment A

Industrial User Site Visit Data Sheets

IU SITE VISIT DATA SHEET

INSTRUCTIONS: Record observations made during the IU site visit. Provide as much detail as possible.					
Name of industry: Norcal Dye and Dye Guy					
Address of industry: 46 Digital Dr # 3, Novato, CA 94949					
Date of visit: 1/29/2019			Time of visit: 3:07 PM – 3:49 PM		
Name of inspectors: Chuck Durham and Sirese Jacobson (PG Environmental) Liz Falejczyk, John O'Hare, and Kurt Hawkroad (Veolia) Eric Brown (Novato Sanitary District)					
Provide the name(s) and title(s) of industry representative(s)					
Name			Title		
Mark Garrison			Owner		
Mary Garrison			Manager		
IU Permit Number: 005		Exp. Date: 3/29/2019		IU Classification: non-significant IU	
Please provide the following documentation:					
1. Nature of operation: The facility dyes fabric.					
2. Number of employees:	4	Number of shifts:	N/R.	Hours of operation:	Open 8 hours on Monday and Thursday and 11 hours on Tuesday and Wednesday
3. Wastestream flow(s) discharged to the POTW: The facility discharges wastewater from the fabric wash, dye bath, fixer wash, and rinse bath.					
Sanitary:	N/R.	Process:	According to the facility representative, they use approximately 4,000-6,000 gpd. There is no effluent water flow meter.		Combined: N/R.
4. Describe any significant changes in process or flow: According to the owner, there have been no changes to the process or flow.					
5. Type of pretreatment system (Describe): The facility does not operate a pretreatment system. However, wastewater from the process flows through lint screens to two sumps. Wastewater is then discharged to the sewer. The facility also keeps a pH log and calibrates its pH meter once per month using pH 7 and 10 buffers prior to taking the reading.					
	Continuous flow			Batch	Combined
6. Process area description (identify raw materials and processes used)					
Fabric is washed with soap, then goes into a hot water bath. The fabric is then dyed (with sodium sulfate) for 10 to 15 minutes. After dyeing the fabric is placed in soda ash to fix the color. Then the fabric is rinsed and dried.					
7. Chemical storage area (identify the chemicals that are maintained on site and how they are stored): The facility does not store any liquid chemicals onsite.					
Any floor drains?		Yes		Any spill control measures? No	

8. Are hazardous wastes drummed and labeled? N/A.
9. Does the IU have hazardous waste manifests? N.A.
10. Solid waste production and disposal: N/R.
11. Description of sample location and methods: The facility collects samples from the sump.
Notes:
None.

IU SITE VISIT DATA SHEET

INSTRUCTIONS: Record observations made during the IU site visit. Provide as much detail as possible.					
Name of industry: BioMarin Pharmaceutical Inc.					
Address of industry: 46 Galli Drive, Novato, CA 94949					
Date of visit: 1/29/2019				Time of visit: 1:14 PM	
Name of inspectors: Chuck Durham and Sirese Jacobson (PG Environmental) Liz Falecyxzh, John O'Hare, and Kurt Hawkroad (Veolia) Eric Brown (Novato Sanitary District)					
Provide the name(s) and title(s) of industry representative(s)					
Name			Title		
Michael Kraus			Sr. Manager, EH & S		
Don Clark			EH & S		
Steve Miller			Maintenance		
IU Permit Number: 014		Exp. Date: September 20, 2021		IU Classification: 40 CFR 439.17 Subpart A PSNS Fermentation	
Please provide the following documentation:					
1. Nature of operation: The facility manufactures orphan drugs using continuous perfusion from genetically-modified cells. One drug is manufactured using bacterial fermentation. These pharmaceuticals are for rare diseases.					
2. Number of employees:	1 st shift: 175, 2 nd shift: 50, 3 rd shift: 25	Number of shifts:	3	Hours of operation:	24 hours/ 7 days/wk
3. Wastestream flow(s) discharged to the POTW: The wastestreams that are discharged to the POTW include reverse osmosis reject water, cooling tower blowdown, boiler blowdown, excess water from the process, and from flushing of the bioreactors process. If wastewater is high in TDS, it is sent to the diversion tanks. The facility has a tanker truck haul this wastewater to East Bay Municipal Utility District once or twice per week.					
Sanitary:	N/R.	Process:	Galli West: 33,000 gpd Galli East: 27,000 gpd	Combined:	N/R.
4. Describe any significant changes in process or flow: According to the facility representative, there have been no changes in process or flow. However, the facility representatives indicated that they are planning to install a more advance pretreatment system, but it will likely not be installed until 2021.					
5. Type of pretreatment system (Describe): The facility's pretreatment system consists of pH adjustment. The Galli West and Galli East processes both have their own pH neutralization system. The pH probes are calibrated twice per week. The facility performs a three-point calibration using pH 4, 7, and 10 buffers. The pH system will send out an email and alarm if the pH is outside the range of 5.5 to 10.5. The facility's flow meter is calibrated twice per year, in January and July.					

Continuous flow	X	Batch		Combined
<p>6. Process area description (identify raw materials and processes used)</p> <p>The facility is split into two process areas, Galli East and Galli West.</p> <p>Flow from Galli West flows to an underground 1,000-1,500-gallon tank. From there, it is pumped to a 2,000-gallon surge tank. When the surge tank is approximately 25 percent full, the wastewater is pumped to the 660-gallon pH adjustment tank. From the pH adjustment tank, wastewater flows through the sampling point or is diverted to the diversion tank. The facility has a diversion system that blends high TDS wastewater into the system.</p> <p>Flows from Galli East first enter a "hot dog" tank, then into a 4,200-gallon surge tank before entering the pH adjustment tank. Wastewater from the pH adjustment tank flows to a smaller round tank for the batch discharge through the sampling point or to the diversion tank.</p> <p>Boiler blowdown is collected in a pit and then to a 3,000-gallon holding tank.</p>				
<p>7. Chemical storage area (identify the chemicals that are maintained on site and how they are stored):</p> <p>The facility stores corrosives onsite, as well as chelation agents. The facility uses 36% sulfuric acid and 25% sodium hydroxide for pH adjustment.</p>				
Any floor drains?		Any spill control measures?		
<p>8. Are hazardous wastes drummed and labeled? In the facility's new chemical storage room, there was no accumulation start date on two drums, labeled as category 8 hazardous waste.</p>				
<p>9. Does the IU have hazardous waste manifests? Yes. The facility disposes of the following wastes: alcohols, ethanol, sodium hydroxide, peroxide, imidazole, acetonitrile, ammonia, and trifluoroacetic acid. Hazardous waste is picked up weekly by Clean Harbors. Five full-time Clean Harbors staff are onsite to handle hazardous waste.</p>				
<p>10. Solid waste production and disposal: Not reviewed.</p>				
<p>11. Description of sample location and methods:</p> <p>Galli West: sampling manhole located in front of building.</p> <p>Galli East: sampling manhole located in driveway north of the building.</p> <p>Sample analysis is performed by CalTest in Napa, CA, and Alpha Analytical, when needed.</p>				
<p>Notes:</p>				

According to facility representative, all EH&S staff have required training relating to health and safety, hazardous waste, and emergency response.

Finding – The facility was storing incompatible chemicals adjacent to one another and not fully within the separate secondary containment pallets.

In the Galli West treatment room, the facility had drums of incompatible chemicals stored adjacent to one another on secondary containment pallets. In addition, some of the drums were not fully within the secondary containment.

Recommendation 6

It is recommended that the District follow-up with the facility to ensure that incompatible chemicals are properly segregated.