



United States Environmental Protection Agency
Region 2
Water Division
290 Broadway
New York, New York 10007

NPDES NO. PR0026695

NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM PERMIT

The following Permittee is authorized to discharge subject to the requirements set forth in this permit:

Permittee (mailing address)	Facility (location address)
Amgen Manufacturing Limited LLC	Amgen Manufacturing Limited LLC Wastewater Treatment Plant
P.O. Box 4060	State Road PR-31
Juncos, PR 00777	Juncos, PR 00777
EPA has classified this discharge as a major discharge.	

The Permittee may discharge from the discharge points identified below:

Outfall	Effluent description	Outfall latitude	Outfall longitude	Receiving water name and classification
001	Treated Tertiary Effluent	18°, 14', 17" N	65°, 54', 29" W	Rio Gurabo, Class SD

Issuance date	Effective date (EDP)	Expiration date	Renewal application date
<Issuance Date>	<Effective Date>	<Enter date 5 years from EDP>	<Enter date 180 days prior to Exp. Date>

To meet the provisions of the Clean Water Act (CWA) as amended, 33 *United States Code* (U.S.C.) 1251 *et seq.* and its implementing regulations, the Permittee shall comply with the requirements in this permit.

I, **Javier Laureano Perez, Director**, do hereby certify that this permit with all attachments is a full, true, and correct copy of the permit issued by EPA and certified by the Puerto Rico Department of Natural and Environmental Resources, on **<Issuance Date>**.

Javier Laureano Perez, Director
Water Division
U.S. Environmental Protection Agency Region 2

CONTENTS

PART I. Background

PART II. Effluent Limitations and Monitoring Requirements

PART III. Reporting Requirements and Compliance Determination

PART IV. Standard and Special Conditions

Attachment A: Definitions

Attachment B: Standard Conditions

DRAFT

PART I BACKGROUND

- A. Rationale for Permit Requirements.** This permit is issued pursuant to CWA section 402 and its implementing regulations adopted by EPA. EPA developed the requirements in this permit on the basis of information submitted as part of the complete application and monitoring and reporting requirements, and other available information. This permit contains Technology-Based Effluent Limits (TBELs) based on Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category in 40 CFR Part 439 and WQBELs based on the Puerto Rico Water Quality Standards Regulation (PRWQS), as amended. The accompanying Fact Sheet contains detailed information and rationale for permit requirements.
- B. Water Quality Certificate.** Pursuant to CWA section 401(a)(1), after due consideration of the applicable provisions established in the PRWQS and CWA sections 208(e), 301, 302, 303, 304(e), 306 and 307, on June 26, 2024, the Puerto Rico Department of Natural and Environmental Resources (DNER) certified that reasonable assurance was determined that the allowed discharge will not cause violations to the applicable water quality standards for the receiving water body if the limitations and monitoring requirements in the Water Quality Certificate are met. Additional requirements could be required to comply with other sections of the CWA.
- C. Impaired Waters and Total Maximum Daily Loads (TMDLs).** This facility discharges to an impaired water. A Total Maximum Daily Load (TMDL) has not been developed for the impaired waterbody. The effluent limitations in this permit are sufficient to ensure compliance with the applicable water quality standards 40 CFR 122.44(d)(1)(vii)(A). The effluent limitations in this permit are consistent with the assumptions and requirements of any wasteload allocation (WLA) assigned to the Permittee [40 CFR 122.44(d)(1)(vii)(B)].
- D. Mixing Zone/Dilution Allowance.** DNER has not approved a mixing zone or dilution allowance for this discharge.
- E. Antidegradation and Anti-backsliding Requirements.** The discharge is consistent with the federal anti-degradation provisions at 40 CFR 131.12, 72 Federal Register 238 (December 12, 2007, pages 70517-70526), and DNER's *Anti-Degradation Policy Implementation Procedure* in Attachment A of PRWQS. In addition, some effluent limitations in this permit are less stringent than those in the previous permit and the rationale for these limitations is provided in the Fact Sheet for this permit. An anti-backsliding analysis has been conducted, and EPA has determined that these limitations are consistent with the anti-backsliding requirements at 40 CFR 122.44(l).
- F. Public Participation.** Federal regulations at 40 CFR 124 require EPA to consider all significant comments on the draft permit received during the public comment period in the development of the final permit. Any comments received will be provided in a Responsiveness Summary issued with the final permit.

PART II EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

A. Final Effluent Limitations—Outfall Number 001

The Permittee shall maintain compliance with the following effluent limitations at Outfall 001.

Effluent Limitations Table

Parameter	Units	Effluent limitations			Monitoring requirements		Footnotes
		Average monthly	Average weekly	Maximum daily	Sample type	Minimum sampling frequency	
1,2-Dichloroethane*	µg/L	--	--	5	Grab	1/Month	
2-Chlorophenol ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
2-4-Dichlorophenol ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
2,4-Dinitrophenol ^{1*}	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	(3)
2-Methyl-4,6-Dinitrophenol*	µg/L	--	--	2.0	Grab	1/Month	
Arsenic	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Benzene	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Biological Oxygen Demand (BOD ₅)*	kg/day	--	--	20	Composite	1/Month	(8)
Chemical Oxygen Demand (COD)	kg/day	228	--	86	Composite	1/Month	(8)
Cadmium*	µg/L	--	--	0.77	Grab	1/Month	
Chlorides*	mg/L	--	--	230	Grab	1/Month	
Chloroform ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Chlorobenzene ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Chromium VI*	µg/L	--	--	11	Grab	1/Quarter	

Color*	Pt-Co Units	--	--	15	Grab	1/Month	
Copper*	µg/L	--	--	9.0	Grab	1/Month	
Cyanide, Total	µg/L	--	--	4.0	Grab	1/Month	(6)
Dissolved Oxygen*	mg/L	--			Grab	1/Day	(9)
Effluent Flow	m ³ /day (mgd)	Monitor only	Monitor only	1892.71 (0.50)3.0	Metered	Continuous	(1)
Enterococci*	(colonies/100 ml)	--			Grab	2/Month	(2)
Lead*	µg/L	--	--	3.02	Grab	1/Day	
Mercury (Hg)*	µg/L	--	--	0.05	Grab	1/Month	(6)
Methylene Chloride	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Nickel ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Oil & Grease*	mg/L	--			Grab	2/Month	(10)
O-Dichlorobenzene ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Pentachlorophenol*	µg/L	--	--	0.3	Grab	1/Month	
pH*	standard units	Minimum 6.0 Maximum 9.0			Grab	1/Day	
Phenol ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Residual Chlorine*	µg/L	--	--	11	Grab	1/Day	(5)
Selenium (Se)*	µg/L	--	--	5.0	Grab	1/Month	
Silver ^{1*}	µg/L	--	--	3.75	Grab	1/Month and 1/Year	(3)
Solids and Other Matter*	µg/L	--					(11)
Sulfates*	mg/L	--	--	250	Grab	1/Month	
Sulfide* (undissociated H ₂ S)*	µg/L	--	--	2.0	Grab	1/Month	(4)
Surfactants (as MBAS)*	µg/L	--	--	100	Grab	1/Month	
Suspended, Colloidal or Settleable Solids*	mL/L	--			Grab	1/Day	(12)
Taste and Odor Producing Substances*	µg/L	--			Grab	1/Month	(13)

Temperature*	°F (°C)	--			Grab	1/Day	(14)
Toluene ¹	µg/L	Monitor Only	Monitor Only	Monitor Only	Grab	1/Month	
Total Ammonia Nitrogen (TAN)*	µg/L				Grab	1/Month	
Total Dissolved Solids*	µg/L	--	--	500	Grab	1/Month	
Total Nitrogen (NO ₃ , NO ₂ , TKN)*	µg/L	--	--	1700	Grab	1/Month	
Total Phosphorous*	µg/L	--	--	160	Grab	1/Month	
Total Suspended Solids (TSS)	kg/day	--			24-hr Composite	1/Month	(8)
Turbidity	NTU	--	--	50	Grab	1/Month	
Whole Effluent Toxicity, Acute	TU _a	--	--	--	24-hr Composite	1/Quarter	(7)
Zinc	µg/L	--	--	115.8	Grab	1/Month	

Notes, Footnotes and Abbreviations

Dashes (--) indicate there are no effluent limitations or monitoring requirements for this parameter.
 Asterisks (*) indicate that the limit was established pursuant to the Water Quality Certification (WQC).
¹ indicates a parameter that wasn't in the previous permit.

All limitations expressed in mass calculated from concentration-based limitations are calculated according to: mass (kg/day) = Flow (MGD) x concentration (mg/L) x 3.78 (kg/L)/(mg)(mgd)

- (1) All flow measurements must achieve accuracy within the range of plus or minus (±) 10%. See Special Conditions Part IV.B.5.3 *Flow*.
- (2) See Special Conditions Part IV.B.5.1 *Enterococci*.
- (3) See Special Conditions Part IV.B.5.2 *Silver*.
- (4) See Special Conditions Part IV.B.5.11 for Sulfide requirements
- (5) See Special Conditions Part IV.B.5.7 and 8 for Residual Chlorine requirements.
- (6) See Special Conditions Part IV.B.5.12 for Cyanide and Mercury requirements
- (7) See Part IV.B.1. *Whole Effluent Toxicity Testing* for monitoring and reporting requirements for acute WET.
- (8) Flow and concentration monitoring of BOD₅ is required to calculate limits in mass loading for BOD₅, COD, and TSS pursuant to 40 CFR 439.42 (existing sources). See Part D of this section for monitoring locations.
- (9) See Special Conditions Part IV.B.5.19 for narrative limits from the WQC for *Dissolved Oxygen*
- (10) See Special Conditions Part IV.B.5.19 for narrative limits from the WQC for *Oil and Grease*
- (11) See Special Conditions Part IV.B.5.20 for narrative limits from the WQC for *Solids and Other Matter*
- (12) See Special Conditions Part IV.B.5.21 for narrative limits from the WQC for *Suspended, Colloidal or Settleable Solids*
- (13) See Special Conditions Part IV.B.5.22 for narrative limits from the WQC for *Taste and Odor Producing Substances*
- (14) See Special Conditions Part IV.B.5.23 for narrative limits from the WQC for *Temperature*

B. Narrative Limitations

All narrative limitations are pursuant to the Water Quality Certificate and contained in Part IV.B.5, below.

C. Monitoring Requirements

1. Effluent monitoring and analyses shall be conducted in accordance with EPA test procedures approved under 40 CFR Part 136, *Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act*, as amended. For situations where there may be interference, refer to *Solutions to Analytical Chemistry Problems with Clean Water Act Methods* (EPA 821-R-07-002). For effluent analyses, the Permittee shall use a *Minimum Level (ML)* that is lower than the effluent limitations described in Effluent Limitations Table of this permit. If all published MLs are higher than the effluent limitations, the Permittee shall use the test method procedure with the lowest ML. The Permittee shall ensure that the laboratory uses a standard calibration where the lowest standard point is equal to or less than the ML. Priority pollutant analysis for metals shall measure *total metal*, except as provided under 40 CFR 122.45(c). EPA method 1631E shall be used for mercury analysis. Priority pollutant analysis for benzene, ethylbenzene, toluene and xylene shall employ either EPA Method 602 or 624. Effluent analysis for xylene shall measure *total xylene*.
2. The regulations at 40 CFR 122.48 require that all NPDES permits specify monitoring and reporting requirements. All monitoring shall be in accordance with Standard Condition 10. *Monitoring and records* in Attachment B of this permit.
3. Sampling point for Outfall **001** shall be located immediately after the primary flow measuring device of the effluent of the treatment system.
4. The Permittee shall develop and implement a quality assurance (QA) plan for laboratory analyses for effluent and/or receiving water monitoring.

D. Monitoring Locations

The Permittee shall establish the following monitoring locations to demonstrate compliance with the effluent limitations and other requirements in this permit:

Sampling points should be taken to determine flow and monitoring of (1) manufacturing processes, (2) laboratories, (3) warehouse, (4) cooling towers and boilers, and (5) after the wastewater treatment plant. See Attachment C: Sampling Points for a suggested sampling location map using the Permittee's provided water balance diagram.

Monitoring Locations Table

Outfall	Monitoring location	Monitoring location description
001	EFF-001	18°, 14', 17" N 65°, 54', 29" W

PART III REPORTING REQUIREMENTS AND COMPLIANCE DETERMINATION

A. Reporting Requirements

1. **Standard Conditions.** The Permittee shall comply with all Standard Conditions in section IV.A below and Attachment B of this permit related to monitoring, reporting, and recordkeeping.
2. **Monitoring data submission.** The Permittee shall either submit monitoring data and other reports to EPA in hard copy form, or report electronically using NetDMR, a web-based tool that allows Permittees to electronically submit discharge monitoring reports (DMRs) and other required reports via a secure internet connection. Specific requirements regarding submittal of data and reports in hard copy form and for submittal using NetDMR are described below:
 - a. **Submittal of Reports in Hard Copy Form.** Hard copy DMR submittals must be submitted in accordance with Standard Condition 12.d. *Monitoring reports* in Attachment B of this permit. The Permittee will report the results for all monitoring specified in this permit. The Permittee shall submit monthly DMRs including the results of all required monitoring using EPA-approved test methods or other test methods specified in this permit as required by III.A.3. below. If the Permittee monitors any pollutant more frequently than

required by the permit using test procedures approved under 40 CFR Part 136, or another method required for an industry-specific waste stream under 40 CFR subchapters N or O, the results of such monitoring must be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by EPA.

- b. **Submittal of Reports Using NetDMR.** DMRs and reports submitted electronically to EPA must be done using NetDMR at <http://www.epa.gov/netdmr>. All reports required under the permit shall be submitted to EPA as an electronic attachment to the DMR. Once a Permittee submits DMRs and reports using NetDMR, it is not required to submit hard copies of DMRs or other reports to EPA and the DNER. However, Permittees shall continue to send hard copies of reports other than DMRs to the DNER until further notice from the DNER.
- c. **Timing of submissions.** DMRs shall be submitted to EPA no later than the 28th day of the month following the completed reporting period. Monitoring results shall be summarized and reported on EPA DMR Form No. 3320-1, postmarked no later than the 28th day of the month following the completed monitoring period. The first report is due on the 28th day of the first month following EDP.
- d. **Submission Requirements.** If submitting reports in hard copy form, DMRs must be signed and certified as required by Standard Condition 11. *Signatory requirements* in Attachment B of this permit. The Permittee shall submit the original signed DMR to 3.a below and duplicate signed copies and all other reports required in this permit to 3.b below:

- i. U.S. Environmental Protection Agency, Region 2
290 Broadway, 21st Floor
New York, NY 10007-1866
Attention: Compliance Assistance and Program Support Branch
or
via electronic mail at Teitelbaum.Daniel@epa.gov
- ii. Puerto Rico Department of Natural and Environmental Resources
San Jose Industrial Park
1375 Ave. Ponce de Leon
San Juan, PR 00926
or
via electronic mail at fuentesprecisadas@drna.pr.gov

3. **Analytical Determinations.** The Permittee shall report the results on the DMR of analytical determinations for the presence of chemical constituents in a sample using the following reporting protocols:
 - a. Sample results greater than or equal to the ML must be reported as measured by the laboratory (i.e., the measured chemical concentration in the sample).
 - b. Sample results less than the ML must be reported as <ML, where the ML equals the ML reported by the laboratory.
 - c. Permittees are to instruct laboratories to establish calibration standards so that the ML value (or its equivalent if there is differential treatment of samples relative to calibration standards) is the lowest calibration standard. At no time is the Permittee to use analytical data derived from extrapolation beyond the lowest point of the calibration curve.
4. **Bacterial Monitoring.** For bacterial monitoring, the Permittee shall report on the DMR the calculated geometric mean and the percentage of individual samples that exceeded the single-sample maximum criterion. The geometric mean must be calculated on the basis of five grab samples taken within the calendar month and as described in Attachment A. *Definitions* of this permit. The Permittee shall report on an attachment to the DMR the analytical results of each of the five individual sample measurements, the calculated geometric means using these individual samples, and the percentage of individual samples that exceed the single sample maximum criterion.

B. Compliance Determination

Compliance with effluent limitations contained in this permit will be determined as specified below:

1. **General.** Compliance with effluent limitations for priority pollutants must be determined using sample reporting protocols defined in section III. A and Attachment A. *Definitions*.

2. **Average Monthly Discharge Limitation (AML).** If the average or, when applicable, the median of daily discharges that were measured in a calendar month exceeds the AML for a given parameter, this will represent a single violation, though the Permittee will be considered out of compliance for each day of that month for that parameter (e.g., resulting in 31 days of noncompliance in a 31-day month). If only a single sample is taken during the calendar month and the analytical result for that sample exceeds the AML, the Permittee will be considered out of compliance for that calendar month. The Permittee will be considered out of compliance for only the days when the discharge occurs. For any one calendar month during which no sample (daily discharge) is taken yet sampling is required, the Permittee will be considered out of compliance for that calendar month.
3. **Average Weekly Discharge Limitation (AWL).** If the average or, when applicable, the median of daily discharges over a calendar week exceeds the AWL for a given parameter, this will represent a single violation, though the Permittee will be considered out of compliance for each day of that week for that parameter, resulting in 7 days of noncompliance. If only a single sample is taken during the calendar week and the analytical result for that sample exceeds the AWL, the Permittee will be considered out of compliance for that calendar week. The Permittee will be considered out of compliance for only the days when the discharge occurs. For any one calendar week during which no sample (daily discharge) is taken yet sampling is required, the Permittee will be considered out of compliance for that calendar week.
4. **Maximum Daily Discharge Limitation (MDL).** If a daily discharge exceeds the MDL for a given parameter, the Permittee will be considered out of compliance for that parameter for that 1 day only in the reporting period. For any one day during which no sample is taken yet a sampling is required, the Permittee will be considered out of compliance for that day.

PART IV STANDARD AND SPECIAL CONDITIONS

A. Standard Conditions

1. Standard Conditions Applicable to All Facilities

- a. The Permittee shall comply with all Standard Conditions that apply to all NPDES permits in accordance with 40 CFR 122.41 (Attachment B of this permit), and additional conditions applicable to specific categories of facilities in accordance with 40 CFR 122.42.
- b. The Permittee shall comply with the Reopener Clause in Standard Condition 17. *Reopener clause for toxic effluent limitations*, in Attachment B of this permit, which applies to all NPDES permits in accordance with 40 CFR 122.44(b). EPA reserves the right to revoke and reissue or modify this permit to establish effluent limitations, additional monitoring, schedules of compliance or other permit conditions based on new information, including any changes to the final Water Quality Certificate from DNER.

2. Standard Conditions Applicable to Specific Facilities—Notification Levels

Existing manufacturing, commercial, mining, and silvicultural dischargers must notify EPA as soon as they know or have reason to believe [40 CFR 122.42(a)]:

- a. That any activity has occurred or will occur that would result in the discharge, on a routine or frequent basis, of any toxic pollutant that is not limited in this permit, if that discharge will exceed the highest of any one of the following *notification levels* [40 CFR 122.42(a)(1)]:
 - 1) 100 micrograms per liter ($\mu\text{g/L}$) [40 CFR 122.42(a)(1)(i)].
 - 2) 200 $\mu\text{g/L}$ for acrolein and acrylonitrile; 500 $\mu\text{g/L}$ for 2,4 dinitrophenol and 2 methyl 4,6 dinitrophenol; and 1 milligrams per liter (mg/L) for antimony [40 CFR 122.42(a)(1)(ii)].
 - 3) Five times the maximum concentration value reported for that pollutant in the DMR [40 CFR 122.42(a)(1)(iii)].
 - 4) The level established by EPA in accordance with 40 CFR 122.44(f) [40 CFR 122.42(a)(1)(iv)].
- b. That any activity has occurred or will occur that would result in the discharge, on a non-routine or infrequent basis, of any toxic pollutant that is not limited in this permit, if that discharge will exceed the highest of any one of the following *notification levels* [40 CFR 122.42(a)(2)]:
 - 1) 500 $\mu\text{g/L}$ [40 CFR 122.42(a)(2)(i)].

- 2) 1 mg/L for antimony [40 CFR 122.42(a)(2)(ii)].
- 3) Ten times the maximum concentration value reported for that pollutant in the DMR [40 CFR 122.42(a)(2)(iii)].
- 4) The level established by EPA in accordance with 40 CFR 122.44(f) [40 CFR 122.42(a)(2)(iv)].

B. Special Conditions

1. Whole Effluent Toxicity Testing Requirements from the WQC

1. This special condition shall not become in effect until DNER has determined the applicability to the respective facility and has notified the permittee and EPA, in writing, of the necessity comply with this special condition. No later than one hundred eighty (180) days after the Effective Date of this Special Condition (EDSC), the permittee shall conduct semiannually acute toxicity tests for a period of one (1) year, which the tests shall be performed annually, of its wastewater discharge through outfall serial number 001 in accordance with the following:
 - i) The test species should be the Fathead Minnow (*Pimephales promelas*) and Cladocera (*Daphnia magna*). The test should be static renewal type.
 - ii) The toxicity test shall be conducted in accordance with the EPA publication, EPA-821-R02-012 Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms (Fifth Edition), October 2002, or the most recent edition of this publication, if such edition is available.
 - iii) The test shall provide a measure of the acute toxicity as determined by the wastewater concentration, which causes 50 percent mortality of the test organisms over a 48-hour period. The test results shall be expressed in terms of Lethal Concentration (LC) and reported as 48-hour, LC₅₀.
 - iv) A procedure report shall be submitted within ninety (90) days after the EDSC. following information shall be included in the procedure report:
 - (1) An identification of the organizations responsible for conducting the test and the species to be tested.
 - (2) A detailed description of the methodology to be utilized in the conduct of the test, including equipment, sample collection, dilution water and source of test organisms.
 - (3) A schematic diagram, which depicts the effluent sampling location in relation to the wastewater treatment facility and the discharge monitoring point.
 - (4) If stream flow monitoring is required, the method used to obtain the stream flow data in estimating the seven-day two-year low flow (7Q2).

The results of the test conducted shall be submitted to EPA's Region 2 Clean Water Division and to the DNER's Water Quality Area, within sixty (60) days of completion of the test. Based on the review of the test results, the Regional Administrator of EPA or the DNER can require additional toxicity tests, including chronic tests and toxicity/treatability studies, and may impose toxicity limitations.

2. Whole Effluent Toxicity Testing Established by EPA

1. Acute Whole Effluent Toxicity Testing

a. **Monitoring Frequency and Sample Type.** No later than **180 days after the EDP**, the Permittee shall conduct **semiannual** acute toxicity tests on a 24-hour composite effluent sample. Acute toxicity test samples shall be collected for each point of discharge at the designated monitoring location for the effluent (i.e., downstream from the last treatment process and any in-plant flow return flows where a representative effluent sample can be obtained).

b. **Methods.** The acute toxicity tests shall be conducted in accordance with the EPA document, *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms* (EPA-821-R-02-012, Fifth Edition, 2002) and Table IA of 40 CFR Part 136. Tests shall provide a measure of the acute toxicity as determined by the effluent concentration that causes 50 percent mortality of the test organisms over a 48-hour period. The tests must be static renewal tests. The acute toxicity tests shall provide a measure of the acute toxicity as determined by the effluent concentration that represents the LC₅₀. Test results shall be expressed in terms of the LC₅₀ and reported in TU_a on the monthly DMR, where TU_a = 100 / LC₅₀.

If the acute WET test does not meet all test acceptability criteria as specified in the test method, the Permittee shall re-sample and re-test as soon as possible, not to exceed 14 days following

notification of invalid test results. Data from invalid and valid tests must be submitted in the Permittee's DMR.

- c. **Test Species.** The test species must be Cladocera (*Daphnia magna*) and Fathead Minnow (*Pimephales promelas*) species for acute WET testing.
- d. **Numeric Effluent Limitation or Trigger.** There is no acute WET effluent limitation for this discharge. *There is, however, an acute WET trigger of an LC₅₀ result less than 100%.* This permit requires additional toxicity testing if the acute WET limit or trigger is exceeded (see *Accelerated Toxicity Testing and TRE Initiation* of this part).
- e. **Dilution Allowance.** For this discharge, DNER has not authorized a mixing zone or dilution allowance for acute toxicity.

2. Chronic Whole Effluent Toxicity Testing

There are no chronic WET testing requirements applicable to this facility.

3. **WET Notification Requirements.** The Permittee shall notify EPA within 48-hours after the receipt of test results exceeding the effluent limitation or monitoring trigger during regular or accelerated monitoring.
4. **Toxicity Reduction Evaluation (TRE) Workplan.** Within 90 days after the effective date of this permit, the Permittee shall prepare and submit a TRE Workplan to EPA, which must include steps the Permittee intends to follow if toxicity is measured in the effluent. The workplan must include, at a minimum:
 - 1) A description of the investigation and evaluation techniques that would be used to identify potential causes and sources of toxicity, effluent variability, and treatment system efficiency.
 - 2) A description of methods for maximizing in-house treatment system efficiency, good housekeeping practices, and a list of all chemicals used in operations at the facility.
 - 3) Potential actions to be undertaken by the Permittee to investigate, identify, and correct the causes, and prevent the recurrence of toxicity.
 - 4) Identification of responsible persons/parties for conducting the TRE.
 - 5) Possible source reduction measures and pollution prevention measures opportunities to reduce toxicity.
5. **Accelerated Toxicity Testing and TRE Initiation.** If the discharge displays an acute or chronic toxicity result that exceeds the effluent limitation or trigger, the Permittee shall conduct six additional toxicity tests of the discharge using the same species and test method as that of the observed toxicity, every two weeks, over a 12-week period.
 - 1) Accelerated testing shall begin within 14 days of the Permittee's receipt of the test result exceeding the effluent limit or trigger. If none of the six additional toxicity tests exceeds the effluent limit or trigger, then the Permittee may return to its regular testing frequency. All accelerated laboratory test results shall be submitted to EPA and DNER within 30 days of receipt by the Permittee, as required in the Reporting of Toxicity Monitoring Results section below.
 - 2) If the result of any accelerated toxicity test for the discharge exceeds the effluent limit or trigger, the Permittee is in violation of this permit and must cease accelerated monitoring and initiate a TRE within 14 days of receipt of this test result to investigate the cause(s) of, and identify corrective actions to reduce or eliminate effluent toxicity. The TRE must use the same species and test method as that of the observed toxicity. The Permittee shall use the following EPA guidance manual to conduct the TRE: *Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations* (EPA-600-2-88-070, 1989).
 - 3) The Permittee may also use the following manuals for Toxicity Identification Evaluation (TIE) to identify and abate the causes of toxicity:
 - a) *Toxicity Identification Evaluation: Characterization of Chronically Toxic Effluents, Phase I* (EPA-600-6-91-005F, 1992).
 - b) *Methods for Aquatic Toxicity Identification Evaluations, Phase II Toxicity Identification Procedures for Samples Exhibiting Acute and Chronic Toxicity* (EPA-600-R-92-080, 1993).
 - c) *Methods for Aquatic Toxicity Identification Evaluations, Phase III Toxicity Confirmation Procedures for Samples Exhibiting Acute and Chronic Toxicity* (EPA-600-R-92-081, 1993).
 - d) *Marine Toxicity Identification Evaluation (TIE): Phase I Guidance Document* (EPA-600-R-96-054, 1996).

- 4) The Permittee shall submit accelerated test results within 30 days after the Permittee's receipt of the laboratory reports for accelerated monitoring. Test results that were conducted because of accelerated monitoring may be used to satisfy the normal **acute** Toxicity Testing requirements above, provided that all requirements (including species, test type, frequency, timing, and sample requirements) are met.
6. **Reporting of Toxicity Monitoring Results.** For any WET testing event, the Permittee shall report the WET results in TU_a or TU_c on the DMR for the month in which the toxicity test was conducted. In addition, a full laboratory report must be submitted to the addresses in Part III.A.2 of this permit as an attachment to the DMR, reported according to the test methods manual chapter on report preparation and test review, and must include, at a minimum, the following:
- The acute WET toxicity results expressed in LC₅₀ and TU_a. For tests where the IWC is 100 percent effluent that does not result in a toxic response, the result shall be reported at <0.3 TU_a.
- 1) The chronic WET toxicity results expressed in NOEC, TU_c, the Lowest Observable Effects Concentration (LOEC), the calculated inhibition concentration 25 (IC₂₅), and 100 / IC₂₅. For tests where the IWC is 100 percent effluent that does not result in a toxic response, the result shall be reported at <1.0 TU_c.
 - 2) The dates of sample collection and initiation of each toxicity test.
 - 3) The statistical methods used to calculate endpoints.
 - 4) The statistical output page, which includes the calculation of the percent minimum significant difference (PMSD).
 - 5) All results for effluent parameters monitored concurrently with the toxicity test(s).
 - 6) The results compared to the numeric toxicity effluent limitation or trigger.
 - 7) Progress reports on any TRE/TIE investigations.

Toxicity Reporting Table

Task	Due Date
Submit a TRE Workplan	90 days after EDP
Submit WET Report for quarterly monitoring	28 th day of every month following the completed monitoring
Submit WET Report for annual monitoring	28 th day of every month following the completed monitoring
Notify Toxicity in Effluent	<48 hours of receipt of test results that exceed limit or trigger
Conduct Accelerated Monitoring	≤ 14 days of exceedance of limit or trigger
Submit Accelerated Monitoring Report	≤ 30 days of receipt of test results
Initiate a TRE	≤ 14 days of accelerated test results that exceed limit or trigger

- g. **Reopener Clause for Toxicity.** In accordance with 40 CFR Parts 122 and 124, this permit may be reopened to establish additional toxicity requirements to address toxicity in the effluent or receiving water, including other toxicity/treatability studies, effluent limitations or monitoring requirements.

3. Best Management Practices and Pollution Prevention

Preventive Maintenance Plan (PMP) and Pollution Prevention

- 1) **Implementation.** The Permittee shall during the term of this permit operate the facility in accordance with the existing PMP and in accordance with subsequent amendments to the plan. The Permittee shall amend the plan to **incorporate** practices to achieve the objectives and specific requirements listed below, and a copy of the amended plan must be submitted to the addresses in Part III.A.3 of this permit within three months of the EDP. The amended plan must be implemented as soon as possible but not later than six months from the EDP.
- 2) **Purpose.** Through implementation of the PMP, the Permittee shall prevent or minimize the generation and the potential for the release of pollutants from the facility to the waters of the United States through normal operations and ancillary activities.

- 3) **Objectives.** The Permittee shall develop and amend the PMP consistent with the following objectives for the control of pollutants.
- a) The number and quantity of pollutants and the toxicity of effluent generated, discharged, or potentially discharged at the facility must be minimized by the Permittee to the extent feasible by managing each influent waste stream in the most appropriate manner.
 - b) Under the PMP, and any Standard Operating Procedures (SOPs) included in the plan, the Permittee shall ensure proper operation and maintenance of the treatment facility as required by 40 CFR 122.41(e).
 - c) The Permittee shall establish specific objectives for the control of pollutants by conducting the following evaluations:
 - i. Each facility component or system must be examined for its waste minimization opportunities and its potential for causing a release of significant amounts of pollutants to waters of the United States because of equipment failure, improper operation, and natural phenomena such as rain or snowfall, etc. The examination must include all normal operations and ancillary activities including **material storage areas, plant site runoff, in-plant transfer, process and material handling areas, spillage or leaks, sludge and waste disposal.**
 - ii. Where experience indicates a reasonable potential for equipment failure (e.g., a tank overflow or leakage), natural condition (e.g., precipitation), or other circumstances that could result in significant amounts of pollutants reaching surface waters, the program should include a prediction of the direction, rate of flow, and total quantity of pollutants that could be discharged from the facility as a result of each condition or circumstance.
- 4) **Requirements.** The PMP shall be consistent with the objectives in the Objectives section above and the general guidance contained in the publication titled *Guidance Manual for Developing Best Management Practices (BMPs)* (EPA 833-B-93-004, 1993) or any subsequent revisions to the guidance document.
- a) The PMP shall be documented in narrative form, include any necessary plot plans, drawings or maps, and be developed in accordance with good engineering practices. The PMP shall be organized and written with the following structure:
 - i. Name and location of the facility.
 - ii. Statement of PMP policy.
 - iii. Structure, functions, and procedures of the PMP Committee.
 - iv. Specific management practices and standard operating procedures to achieve the above objectives, including modifying equipment, facilities, technology, processes, and procedures; reformulating or redesigning products; substituting materials; and improving management, inventory control, materials handling or general operational phases of the facility.
 - v. Risk identification and assessment.
 - vi. Reporting of PMP incidents.
 - vii. Materials compatibility.
 - viii. Good housekeeping.
 - ix. Preventative maintenance.
 - x. Inspections and records.
 - xi. Security.
 - xii. Employee training.
 - b) The PMP shall include the following provisions concerning PMP review:
 - i. Review by plant engineering staff and the plant manager.
 - ii. Review and endorsement by the Permittee's PMP Committee.

- iii. A statement that the above reviews have been completed and that the PMP fulfills the requirements set forth in this permit. The statement must include the dated signatures of each BMP Committee member as certification of the reviews.
- c) The PMP shall establish specific BMPs to meet the objectives identified in the Objectives section above, addressing each component or system capable of generating or causing a release of significant amounts of pollutants, and identifying specific preventive or remedial measures to be implemented.
- d) The PMP shall establish specific BMPs or other measures that ensure that the following specific requirements are met:
 - i. Ensure proper management of solid and hazardous waste in accordance with regulations promulgated under the Resource Conservation and Recovery Act (RCRA). Management practices required under RCRA regulations must be referenced in the BMP plan.
 - ii. Reflect requirements for Spill Prevention, Control, and Countermeasure (SPCC) plans under CWA section 311 and 40 CFR Part 112 and may incorporate any part of such plans into the PMP by reference.
 - iii. Reflect requirements for stormwater control under CWA section 402(p) and the regulations at 40 CFR 122.26 and 122.44, and otherwise eliminate to the extent practicable, contamination of stormwater runoff.
- 5) **Documentation.** The Permittee shall maintain a copy of the PMP at the facility and must make the plan available to EPA upon request.
- 6) **PMP Modification.** The Permittee shall amend the PMP whenever there is a change in the facility or in the operation of the facility that materially increases the generation of pollutants or their release or potential release to the receiving waters. The Permittee shall also amend the plan, as appropriate, when plant operations covered by the PMP change. Any such changes to the PMP must be consistent with the objectives and specific requirements listed above. All changes in the PMP must be reported to EPA in writing.
- 7) **Modification for Ineffectiveness.** If at any time the PMP proves to be ineffective in achieving the general objective of preventing and minimizing the generation of pollutants and their release and potential release to the receiving waters and/or the specific requirements above, the permit and/or the PMP must be subject to modification to incorporate revised BMP requirements.

4. Compliance Schedules

This permit does not authorize any compliance schedules.

5. Additional Special Conditions

Water Quality Certificate Special Conditions

1. *Enterococci.* The enterococci density geometric mean and the 90th percentile shall be calculated on a monthly basis on EDP + 90 days, using the 6 points data set obtained during the previous 90-day interval. A monthly report with the calculations and the data set shall be submitted to DNER's Water Quality Area and to EPA's Region 2 Clean Water Division, beginning on EDP + 105 days and during the effectiveness of the permit.
The enterococci density, in terms of geometric mean shall not exceed 35 colonies/100 mL in any 90-day interval; neither the 90th Percentile of the samples taken shall exceed 130 colonies/100 mL in the same 90-day interval.
2. *Silver.* The Permittee shall implement a monthly monitoring program using analytical method approved by EPA with the lowest possible detection level, in accordance with Rule 1306.2(C) of the PRWQS, as amended, for one (1) year period, after which they will be conducted annually.
3. *Flow.* The flow of discharge 001 shall not exceed the limitation of 1,892.7 m³/day (0.5 MGD) as daily maximum. No increase in flow of discharge 001 shall be authorized without a recertification from the Department of Natural and Environmental Resources (DNER).

4. No changes in the design or capacity of the treatment system will be permitted without previous authorization of the DNER.
5. Prior to the construction of any additional treatment system or the modification of the existing one, the permittee shall obtain the approval from the DNER of the engineering report, plans and specifications.
6. The permittee shall install, maintain, and operate all water pollution control equipment in such a manner as to be in compliance with the Applicable Rules and Regulations.
7. No toxic substances shall be discharged, in toxic concentrations, other than those allowed as specified in the NPDES permit. Those toxic substances included in the permit renewal application, but not regulated by the NPDES permit, shall not exceed the concentrations specified in the applicable regulatory limitations.
8. The waters of Puerto Rico shall not contain any substance attributable to discharge 001, at such concentration which, either alone or as result of synergistic effects with other substances, is toxic or produces undesirable physiological responses in human, fish or other fauna or flora.
9. The discharge 001 shall not cause the presence of oil sheen in the receiving water body.
10. All sample collection, preservation, and analysis shall be carried out in accordance with Title 40 of the Code of Federal Regulations (40 CFR), Part 136. A licensed chemist authorized to practice the profession in Puerto Rico shall certify all chemical analyses. All bacteriological tests shall be certified by a microbiologist or licensed medical technologist authorized to practice the profession in Puerto Rico.
11. The permittee shall use the analytical method approved by the Environmental Protection Agency (EPA), with the lowest possible detection limit, in accordance with the 40 CFR, Part 136 for Sulfide (as S). Also, the permittee shall complete the calculations specified in Method 4500-S-2 F, Calculation of Un-ionized Hydrogen Sulfide, of Standards Methods 18th Edition, 1992, to determine the concentration of undissociated H₂S. If the sample results of Dissolved Sulfide are below the detection limit of the EPA approved method established in the 40 CFR, Part 136, then, the concentration of undissociated H₂S shall be reported as "below detection limit".
12. The samples taken for the analysis of cyanide and mercury shall be analyzed using the analytic method approved by the Environmental Protection Agency (EPA) with the lowest possible detection level, in accordance with Rule 1306.8 of the Puerto Rico Water Quality Standards Regulation (PRWQSR), as amended.
13. The flow-measuring device for discharge 001, shall be periodically calibrated and properly maintained. Calibration and maintenance records must be kept in compliance with the Applicable Rules and Regulations.
14. The sampling point for discharge 001 shall be located immediately after the primary flow-measuring device of the effluent.
15. The sampling point for discharge 001 shall be labeled with an 18 inches per 12 inches (minimum dimensions) sign that reads as follows:

"Punto de Muestreo para la Descarga 001"
16. All water or wastewater treatment facilities, whether publicly or privately owned, must be operated by a person licensed by the Examination Board of Water and Wastewater Treatment Plants Operators of Puerto Rico.
17. The solid waste such as sludge, screenings, and grit, generated due to the operation of the treatment system shall be:
 - a. Disposed in compliance with the applicable requirements established in the 40 CFR, Part 257. A semiannual report shall be submitted to the Water Quality Area and the Land Pollution Control Area

of the DNER and EPA's Region 2 Clean Water Division, notifying the method or methods used to dispose the solid waste generated in the facility. Also, a copy of the approval or permit applicable to the disposal method used shall be submitted, if any.

b. Transported adequately in such a way that access is not gained to any water body or soil. In the event of a spill of solid waste on land or into a water body, the permittee shall notify the Point Sources Permits Division of the DNER's Water Quality Area in writing within a term no longer than twenty-four (24) hours after the spill to the following electronic address: bypass@drna.pr.gov.

This notification shall include the following information:

- i) spilled material,
- ii) spilled volume,
- iii) measures taken to prevent the spilled material to gain access to any water body. This special condition does not relieve the permittee from its responsibility to obtain the corresponding permits from the DNER's Land Pollution Control Area and other state and federal agencies, if any.

18. A logbook must be kept for the material removed from the Amgen Manufacturing Limited LLC Wastewater Treatment Plant, such as sludge, screenings and grit, detailing the following items:

- i) removed material, date and source of it;
- ii) approximate volume and weight;
- iii) method by which it is removed and transported;
- iv) final disposal and location;
- v) person that performs the service.

A copy of the Non-Hazardous Solid Waste Collection or Transportation Services Permit issued by the authorized official from the DNER must be attached to the logbook.

19. *Dissolved Oxygen*. Shall not contain less than 5.0 mg/L
20. *Oil and Grease*. The waters of Puerto Rico shall be substantially free from floating non-petroleum oils and greases as well as petroleum derived oils and greases.
21. *Solids and Other Matter*. The waters of Puerto Rico shall not contain floating debris, scum or other floating materials attributable to the discharge in amounts sufficient to be unsightly or deleterious to the existing or designated uses of the water body.
22. *Suspended, Colloidal or Settleable Solids*. Solids from wastewater sources shall not cause deposition in or be deleterious to the existing or designated uses of the water body.
23. *Taste and Odor Producing Substances*. Shall not be present in amounts that will interfere with the use for potable water supply, or will render any undesirable taste or odor to edible aquatic life.
24. *Temperature*. Except by natural phenomena, no heat may be added to the waters of Puerto Rico, which would cause the temperature of any site to exceed 86°F (30°C)

6. Biosolids (Sewage Sludge) Requirements

1. General Biosolids Requirements

- i) All biosolids generated by the Permittee shall be used or disposed of in compliance with the applicable portions of the following:
 - (1) 40 CFR Part 503—for biosolids that are land applied, placed in a surface disposal site (dedicated land disposal site, monofill, or sludge-only parcel at a municipal landfill), or incinerated.
 - (2) 40 CFR Part 258—for biosolids disposed of in a municipal solid waste landfill (with other material).
 - (3) 40 CFR Part 257—for all biosolids use and disposal practices not covered under 40 CFR Parts 258 or 503.
- ii) The regulation at 40 CFR Part 503, Subpart B (land application) sets requirements for biosolids that are applied for the purpose of enhancing plant growth or for land reclamation. The regulation at 40 CFR Part 503, Subpart C (surface disposal) sets requirements for biosolids that are placed on the land for the purpose of disposal, and 40 CFR Part 503, Subpart E, sets requirements for biosolids incinerated in a biosolids incinerator.

- iii) The Permittee shall be responsible for assuring that all biosolids produced at its facility are used or disposed of in accordance with these rules, whether the Permittee uses or disposes of the biosolids itself or transfers the biosolids to another party for further treatment, use, or disposal. The Permittee shall be responsible for informing subsequent preparers, applicators, and disposers of the requirements that they must meet under these rules.
- iv) The Permittee shall assure that haulers transporting biosolids off site for treatment, storage, use, or disposal take all necessary measures to keep the biosolids contained. All haulers must have spill cleanup procedures. If a spill of biosolids on land or into a body of water occurs, the Permittee shall notify the Point Sources Permits Division of the DNER's Water Quality Area in the following manner:
 - (1) By telephone communication within a term no longer than 24 hours after the spill; (787) 767-8073.
 - (2) By letter, within a term no longer than 5 days after the spill, which must include the spill material, spill volume, and measures taken to prevent the spill material to gain access to any body of water. This special condition does not relieve the Permittee from its responsibility to obtain the corresponding permits from DNER's Solid Wastes Program and other state and federal agencies, if any.
- v) **General Biosolids Monitoring Requirements**
 - (1) The 40 CFR Part 503 requirements apply differently depending on the use or disposal practice followed by the Permittee and depends on the quality of the biosolids produced by the facility.
 - (2) Biosolids must be monitored for pollutant concentrations, pathogen reduction and vector attraction (land application and surface disposal) at the following frequency. This frequency is based on the volume of biosolids generated at the facility in dry metric tons per year:
 - (a) less than 290 1/year
 - (b) 290 to less than 1,500 1/quarter (4/year)
 - (c) 1,500 to less than 15,000 1/60 days (6/year)
 - (d) equal to or greater than 15,000 1/month (12/year)
- vi) **General Biosolids Reporting Requirements**
 - (1) **Annual Biosolids Report.** By February 19 of each year, the Permittee shall submit an annual report covering information and data collected during the previous calendar year to EPA and DNER at the address in Part d) of this section below. This report must contain the following:
 - (a) Amount of sludge generated, in dry metric tons.
 - (b) Use or disposal practices.
 - (c) Amount of sludge that goes to each use or disposal practice (amount of sludge that goes to each use or disposal site, in dry metric tons).
 - (d) Name and address of the preparer or the person who receives sludge next (name and address of each preparer or person who receives sludge next), if applicable.
 - (e) Name and address of the land applier and owner/operator of the surface disposal site, if different from the generator.
 - (f) Analytical results from monitoring pollutant concentrations in sewage sludge which should include results of all analyses performed during the reporting period using the prescribed method(s) in milligrams per kilograms (mg/kg) dry weight. Reports should also indicate which analytical methods were used, how frequently sludge was monitored, and the types of samples collected. Preparers may have to report additional information regarding pollutants if they beneficially use or dispose of the sludge themselves.
 - (g) A certification and description of how the pathogen reduction requirements were met, including a detailed description of the pathogen treatment process that specifies the type of process used, standard operating procedures, and a schematic diagram. All pathogen density laboratory results (such as fecal coliform or salmonella), if monitored for must comply with pathogen reduction requirements.
 - (h) A description of how one of the vector attraction reduction requirements was met if one of the sludge processing options was used (Options 1-8, 40 CFR 503.33(b)(1) - (b)(8)) and a certification that the vector attraction reduction requirements were met.
 - (i) A listing of all relevant environmental (federal, state, or local) permits or construction approvals applied for or received.
 - (2) **Certification Statement.** The incinerator owner/operator of the sewage sludge incinerator should submit the signed certification statement (described in section H, page 17 of the *THC Continuous Emission Monitoring Guidance for Part 503 Sewage Sludge Incinerators*) as part of the Annual Biosolids Report. Specifically, the owner/operator in conjunction with the CEM manufacturer, if appropriate, should certify that the THC/CO CEM system is installed, operated, and maintained

pursuant to the manufacturer’s written instructions and recommendations, meets performance specification criteria, and is suitable for compliance evaluation purposes. The report must include the information in 40 CFR 503.47(b) through 40 CFR 503.47(h). The incinerator owner/operator of the sewage sludge incinerator should submit the 40 CFR Part 503 site-specific metals limits that are required to be determined as per 40 CFR 503.43.

- (3) **MSW Landfill Disposal.** Preparers who send their sludge to a Municipal Solid Waste (MSW) landfill are required to submit the information indicated in 1) through 3) above, the name and address of each MSW landfill, in addition to submitting documentation that sludge quality is in compliance with 40 CFR Part 258 requirements (sludge is non-hazardous and passes the paint filter test).
- (4) **Biosolids Reporting.** All reports must be submitted to:
 - (a) U.S. Environmental Protection Agency, Region 2
 290 Broadway, 21st Floor
 New York, NY 10007-1866
 Attention: Compliance Assistance and Program Support Branch
 or
 via electronic mail at Teitelbaum.Daniel@epa.gov
 - (b) Puerto Rico Department of Natural and Environmental Resources
 San Jose Industrial Park
 1375 Ave. Ponce de Leon
 San Juan, PR 00926
 or
 via electronic mail at fuentesprecisadas@drna.pr.gov
- (5) **Biosolids Reporting Schedule.** All reports must be submitted according to the following table:

Biosolids Reporting Table

Task	Due date
If a spill of biosolids on land or into a body of water occurs	Telephone <24 hours after the spill and Letter <5 days after the spill
Annual Biosolids Report	February 19th of each year

7. Limit Removal Special Conditions

- 1. The permit requires the Permittee to achieve the same level of treatment as in the previous permit for limits that were removed due to its removal from the WQC.

ATTACHMENT A: DEFINITIONS

Acute Toxicity Test means any toxicity test designed to determine the concentration in which a response to a stimulus, such as a total effluent, specific substance or combinations of these, has sufficient severity to induce an adverse effect on a group of test organisms during a period of 96 hours or less; even if said effect is not necessarily the death of the organisms.

Acute Toxicity Unit (TU_a) means the reciprocal of the effluent concentration that causes 50 percent of the organisms to die in an acute toxicity test or induce a response halfway between the base line and maximum as defined by the following equation:

$$TU_a = 100 / (LC_{50})$$

(The LC₅₀ should be expressed in terms of the percent of effluent in the dilution water.)

Average Monthly Discharge Limitation (AML) means the highest allowable average of daily discharges over a calendar month, calculated as the sum of all daily discharges measured during a calendar month divided by the number of daily discharges measured during that month. [40 CFR 122.2]

Average Weekly Discharge Limitation (AWL) means the highest allowable average of daily discharges over a calendar week (Sunday through Saturday), calculated as the sum of all daily discharges measured during a calendar week divided by the number of daily discharges measured during that week. [40 CFR 122.2]

Best Management Practices (BMP) means the most effective practicable means of preventing or reducing the amount of pollution generated by nonpoint and point sources to a level more compatible to the water quality goals, including, but not limited to, structural and non-structural controls and operating and maintenance procedures. [40 CFR 122.2]

Biosolids means non-hazardous sewage sludge, as defined in 40 CFR Part 503.9. Sewage sludge that is hazardous, as defined in 40 CFR Part 261, must be disposed of in accordance with Resource Conservation and Recovery Act.

Bypass means the intentional diversion of waste streams from any portion of a treatment facility as discussed in 13. Bypass of Attachment B of this permit. [40 CFR 122.41(m)]

Composite means a combination of individual (or continuously taken) samples obtained at regular intervals over the entire discharge day. The volume of each sample must be proportional to the discharge flow rate. For a continuous discharge, a minimum of 24 individual grab samples (at hourly intervals) must be collected and combined to constitute a 24-hour composite sample. For intermittent discharges of more than 4 hours duration, grab samples must be taken at a minimum of 30-minute intervals.

Chronic Toxicity Test means any toxicity test designed to determine the concentration in which a response to a stimulus, such as a total effluent, a specific substance, or combination of these, has sufficient severity to induce a long-term adverse effect on a group of test organisms. A chronic effect could be lethality, reduction of growth rate, reduction of reproduction rate, etc.

Chronic Toxicity Unit (TU_c) means the reciprocal of the effluent concentration that causes no observable effect on the test organisms by the end of the chronic exposure period obtained during a chronic toxicity test as defined by the following equation:

$$TU_c = 100 / NOEC$$

(The NOEC value should be expressed in terms of the percent of effluent in the dilution water.)

Critical Initial Dilution means the minimum dilution to be determined by means of the use of a mathematical model to be approved by DNER, and according to the procedures described in the *Mixing Zone and Bioassay Guidelines*, approved by DNER.

Daily Discharge is defined as either (1) the total mass of the constituent discharged over the calendar day (12:00 a.m. through 11:59 p.m.) or any 24-hour period that reasonably represents a calendar day for purposes of sampling (as specified in the permit), for a constituent with limitations expressed in units of mass; or (2) the unweighted arithmetic mean measurement of the constituent over the day for a constituent with limitations expressed in other units of measurement (e.g., concentration).

The daily discharge may be determined by the analytical results of a composite sample taken over the course of one day (a calendar day or other 24-hour period defined as a day) or by the arithmetic mean of analytical results from one or more grab samples taken over the course of the day. For composite sampling, if 1 day is defined as a 24-hour period other than a calendar day, the analytical result for the 24-hour period will be considered as the result for the calendar day in which the 24-hour period ends. [40 CFR 122.2]

Director means the *Regional Administrator* or the *State Director*, as the context requires, or an authorized representative. Until Puerto Rico has an approved state program authorized by EPA under 40 CFR Part 123, *Director* means the Regional Administrator. Following authorization, *Director* means the State Director. Even in such circumstances, EPA may retain authority to take certain action (see, for example, 40 CFR 123.1(d), 45 *Federal Register* 14178, April 1, 1983, on the retention of jurisdiction over permits EPA issued before program approval). If any condition of this permit requires the reporting of information or other actions to both the Regional Administrator and the State Director, regardless of who has permit issuing authority, the terms *Regional Administrator* and *State Director* will be used in place of *Director*. [40 CFR 122.2]

Discharge Monitoring Report (DMR) means EPA uniform national form, including any subsequent additions, revisions, or modifications, for the reporting of self-monitoring results by the Permittee. [40 CFR 122.2]

Geometric Mean means the n th root of the product of n numbers.

Grab means an individual sample collected in less than 15 minutes.

ICIS means EPA's Integrated Compliance Information System that provides web access to enforcement and compliance assurance data to EPA and state agencies.

Inhibition Concentration 25 (IC₂₅) means a point estimate of the effluent concentration that would cause a 25-percent reduction in a non-lethal (e.g., reproduction, growth) or lethal (mortality) biological measurement.

Lethal Concentration (LC₅₀) means the concentration of effluent, specific substances or combination of these that is lethal to 50 percent of test organisms exposed during a specific period in a toxicity test.

Lowest Observable Effects Concentration (LOEC) means the lowest concentration of an effluent or toxicant that results in adverse effects on the test organisms. That is, where the values for the observed endpoints are statistically different from the control.

Maximum Daily Discharge Limitation (MDL) means the highest allowable daily discharge of a pollutant, over a calendar day (or 24-hour period). For pollutants with limitations expressed in units of mass, the daily discharge is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the arithmetic mean measurement of the pollutant over the day.

Median is the middle measurement in a set of data. The median of a set of data is found by first arranging the measurements in order of magnitude (either increasing or decreasing order). If the number of measurements (n) is odd, the median = $X_{(n+1)/2}$. If n is even, the median = $(X_{n/2} + X_{(n/2)+1})/2$ (i.e., the midpoint between the $n/2$ and $n/2+1$).

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes, and processing steps have been followed.

Mixing Zone is a limited volume of receiving water that is allocated for mixing with a wastewater discharge where water quality criteria can be exceeded without causing adverse effects on the overall water body.

Monthly means one day each month (the same day each month) and a normal operating day (e.g., the 2nd Tuesday of each month).

No Observed Effect Concentration (NOEC) means the highest tested concentration of an effluent or a toxicant at which no adverse effects are observed on the aquatic test organisms at a specific time of observation.

Not Detected (ND) are those sample results less than the ML.

Regional Administrator means the Regional Administrator of EPA Region 2 or the authorized representative of the Regional Administrator.

Severe property damage means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

Toxic pollutant means any of the pollutants listed in 40 CFR 401.15 (45 *Federal Register* 44503, July 30, 1979) and any modification to that list in accordance with CWA section 307(a)(1). [40 CFR 122.2]

Toxicity Reduction Evaluation (TRE) is a study conducted in a step-wise process designed to identify the causative agents of effluent or ambient toxicity, isolate the sources of toxicity, evaluate the effectiveness of toxicity control options, and then confirm the reduction in toxicity. The first steps of the TRE consist of collecting data relevant to the toxicity, including additional toxicity testing, and evaluating facility operations and maintenance practices, and best management practices. A Toxicity Identification Evaluation (TIE) may be required as part of the TRE, if appropriate. (A TIE is a set of procedures to identify the specific chemical(s) responsible for toxicity. These procedures are performed in three phases (characterization, identification, and confirmation) using aquatic organism toxicity tests.)

Total Maximum Daily Loads (TMDLs) are calculations of the maximum amount of a pollutant that a water body can receive and still safely meet water quality standards. TMDLs are the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background. [40 CFR 130.2(i)]

Upset is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the Permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation as discussed in 14. Upset of Attachment B of this permit. [40 CFR 122.41(n)]

Waters of Puerto Rico means all coastal waters, surface waters, estuarine waters, ground waters and wetland as defined in Puerto Rico Water Quality Standards Regulations, as amended.

Weekly means every seventh day (the same day of each week) and a normal operating day

ATTACHMENT B: STANDARD CONDITIONS

General Conditions language in this attachment for sections 1 through 14, and 17 is based on the *Code of Federal Regulations* (CFR). Reference to provisions in the *United States Code* (U.S.C.) is based on the date of permit issuance.

Table of Regulatory References for General Conditions

<u>Section</u>	<u>Section Title</u>	<u>Reference</u>
1.	Duty to comply	40 CFR 122.41(a)
2.	Duty to reapply	40 CFR 122.41(b)
3.	Need to halt or reduce not a defense	40 CFR 122.41(c)
4.	Duty to mitigate	40 CFR 122.41(d)
5.	Proper operation and maintenance	40 CFR 122.41(e)
6.	Permit actions	40 CFR 122.41(f)
7.	Property rights	40 CFR 122.41(g)
8.	Duty to provide information	40 CFR 122.41(h)
9.	Inspection and entry	40 CFR 122.41(i)
10.	Monitoring and records	40 CFR 122.41(j)
11.	Signatory requirements	40 CFR 122.41(k)
12.	Reporting requirements	40 CFR 122.41(l)
13.	Bypass	40 CFR 122.41(m)
14.	Upset	40 CFR 122.41(n)
15.	Removed substances	33 U.S.C. 1311
16.	Oil and hazardous substance liability	33 U.S.C. 1321
17.	Reopener clause for toxic effluent limitations	40 CFR 122.44(b)(1)
18.	State laws	33 U.S.C. 1370
19.	Availability of information	33 U.S.C. 1318
20.	Severability	-

1. Duty to Comply [40 CFR 122.41(a)].

- a. The Permittee shall comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.
- b. The Permittee shall comply with effluent standards or prohibitions established under section 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under section 405(d) of the Clean Water Act within the time provided in the regulations that establish these standards or prohibitions or standards for sewage sludge use or disposal, even if the permit has not yet been modified to incorporate the requirement.
- c. The Clean Water Act provides that any person who violates sections 301, 302, 306, 307, 308, 318 or 405 of the Clean Water Act, or any permit condition or limitation implementing any such sections in a permit issued under section 402, or any requirement imposed in a pretreatment program approved under sections 402(a)(3) or 402(b)(8) of the Clean Water Act, is subject to a civil penalty not to exceed \$25,000 per day for each violation (\$68,445 as adjusted by 40 CFR Part 19).
- d. The Clean Water Act provides that any person who negligently violates sections 301, 302, 306, 307, 308, 318, or 405 of the Clean Water Act, or any permit condition or limitation implementing any such sections in a permit issued under section 402 of the Clean Water Act, or any requirement imposed in a pretreatment program approved under section 402(a)(3) or 402(b)(8) of the Clean Water Act, is subject to criminal penalties of not less than \$2,500 nor more than \$25,000 per day of violation, or imprisonment of not more than 1 year, or both. In the case of a second or subsequent conviction for a negligent violation

of the Clean Water Act, a person shall be subject to criminal penalties of not more than \$50,000 per day of violation, or by imprisonment of not more than 2 years, or both.

- e. The Clean Water Act provides that any person who knowingly violates sections 301, 302, 306, 307, 308, 318, or 405 of the Clean Water Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of the Clean Water Act, or any requirement imposed in a pretreatment program approved under section 402(a)(3) or 402(b)(8) of the Clean Water Act, is subject to criminal penalties of not less than \$5,000 nor more than \$50,000 per day of violation, or imprisonment for not more than 3 years, or both. In the case of a second or subsequent conviction for a knowing violation of the Clean Water Act, a person shall be subject to criminal penalties of not more than \$100,000 per day of violation, or imprisonment of not more than 6 years, or both.
 - f. Any person who knowingly violates sections 301, 302, 303, 306, 307, 308, 318 or 405 of the Clean Water Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of the Clean Water Act, and who knows at that time that he thereby places another person in imminent danger of death or serious bodily injury, shall, upon conviction, be subject to a fine of not more than \$250,000 or imprisonment of not more than 15 years, or both. A person which is an organization, as defined at 33 U.S.C. 309(c)(3)(B)(iii), shall, upon conviction be subject to a fine of not more than \$1,000,000. In the case of a second or subsequent conviction for a knowing endangerment violation of the Clean Water Act, the maximum punishment shall be doubled with respect to both fine and imprisonment.
 - g. Any person who knowingly makes any false material statement, representation, or certification in any application, record, report, plan, or other document filed or required to be maintained under the Clean Water Act or who knowingly falsifies, tampers with, or renders inaccurate any monitoring device or method required to be maintained under this chapter, shall upon conviction, be punished by a fine of not more than \$10,000, or imprisonment for not more than 2 years, or both. In the case of a second or subsequent conviction, under this paragraph, punishment shall be by a fine of not more than \$20,000 per day of violation, or by imprisonment of not more than 4 years, or both.
 - h. Any person may be assessed an administrative penalty by the Administrator for violating sections 301, 302, 306, 307, 308, 318 or 405 of this Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of this Act. Administrative penalties for Class I violations are not to exceed \$10,000 per violation (\$27,378 as adjusted by 40 CFR Part 19), with the maximum amount of any Class I penalty assessed not to exceed \$25,000 (\$68,445 as adjusted by 40 CFR Part 19). Penalties for Class II violations are not to exceed \$10,000 per day for each day during which the violation continues (\$27,378 as adjusted by 40 CFR Part 19), with the maximum amount of any Class II penalty not to exceed \$125,000 (\$342,218 as adjusted by 40 CFR Part 19).
2. Duty to Reapply [40 CFR 122.41(b)]. This permit and the authorization to discharge shall terminate on the expiration date indicated on the first page. In order to receive authorization to discharge after the expiration date of this permit, the Permittee shall apply for and obtain a new permit. If the permit issuing authority remains the EPA, the Permittee shall complete, sign, and submit an application to the Director no later than 180 days before the expiration date. All applications must be submitted to:
- Director
Water Division
U.S. Environmental Protection Agency, Region 2
290 Broadway, 24th Floor
New York, NY 10007-1866
Attention: Clean Water Regulatory Branch
3. Need to Halt or Reduce not a Defense [40 CFR 122.41(c)]. It shall not be a defense for a Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
 4. Duty to Mitigate [40 CFR 122.41(d)]. The Permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.
 5. Proper operation and maintenance [40 CFR 122.41(e)]. The Permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the Permittee to achieve compliance with the conditions of this permit. Proper operation and

maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back up or auxiliary facilities or similar systems which are installed by a Permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

6. Permit actions [40 CFR 122.41(f)]. This permit may be modified, revoked and reissued, or terminated during its term pursuant to 40 CFR Part 122, Subpart D. The filing of a request by the Permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.
7. Property rights [40 CFR 122.41(g)]. This permit does not convey any property rights of any sort, or any exclusive privileges.
8. Duty to provide information [40 CFR 122.41(h)]. The Permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The Permittee shall also furnish to the Director, upon request, copies of records required to be kept by this permit.
9. Inspection and Entry [40 CFR 122.41(i)]. The Permittee shall allow the Director, or an authorized representative (including an authorized contractor acting as a representative of the Administrator), upon presentation of credentials and other documents as may be required by law, to:
 - a. Enter upon the Permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;
 - b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
 - c. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and
 - d. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act, any substances or parameters at any location.
10. Monitoring and records [40 CFR 122.41(j)].
 - a. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.
 - b. Except for records of monitoring information required by this permit related to the Permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by 40 CFR Part 503), the Permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement report or application. This period may be extended by request of the Director at any time.
 - c. Records of monitoring information shall include:
 - 1) The date, exact place, and time of sampling or measurements;
 - 2) The individual(s) who performed the sampling or measurements;
 - 3) The date(s) analyses were performed;
 - 4) The individual(s) who performed the analyses;
 - 5) The analytical techniques or methods used; and
 - 6) The results of such analyses.
 - d. Monitoring must be conducted according to test procedures approved under 40 CFR Part 136 and any subsequent changes to the methods contained therein unless another method is required under 40 CFR subchapters N or O.
 - e. The Clean Water Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than \$10,000, or by imprisonment for not more than 2 years, or by both. If a conviction of a person is for a violation committed after a first conviction of such person

under this paragraph, punishment is a fine of not more than \$20,000 per day of violation, or by imprisonment of not more than four years, or both. [See U.S.C. 1319(c)(4)].

11. Signatory requirements [40 CFR 122.41(k)]. All applications, reports, or information submitted to the Director shall be signed and certified. (See 40 CFR 122.22)

a. Applications. All permit applications shall be signed as follows:

- 1) For a corporation. By a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) 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 (ii) 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 initiating and directing other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or actions taken to gather complete and accurate information for permit application requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

Note: EPA does not require specific assignments or delegations of authority to responsible corporate officers identified in 40 CFR 122.22(a)(1)(i). EPA will presume that these responsible corporate officers have the requisite authority to sign permit applications unless the corporation has notified the Director to the contrary. Corporate procedures governing authority to sign permit applications may provide for assignment or delegation to applicable corporate positions under 40 CFR 122.22(a)(1)(ii) rather than to specific individuals.

- 2) For a partnership or sole proprietorship. By a general partner or the proprietor, respectively; or
 - 3) For a municipality, state, federal, or other public agency. By either a principal executive officer or ranking elected official. For purposes of this section, a principal executive officer of a federal agency includes: a) The chief executive officer of the agency, or b) a senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., Regional Administrators of EPA).
- b. All reports required by permits, and other information requested by the Director shall be signed by a person described in paragraph 11.a of Part II.B, or by a duly authorized representative of that person. A person is a duly authorized representative only if:
- 1) The authorization is made in writing by a person described in paragraph 11.a;
 - 2) The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company, (A duly authorized representative may thus be either a named individual or any individual occupying a named position.) and,
 - 3) The written authorization is submitted to the Regional Administrator, U.S. Environmental Protection Agency, Region 2, 290 Broadway, New York, NY 10007-1866, Attention: Compliance Assistance Program Support Branch, and to DNER.
- c. Changes to authorization. If an authorization under paragraph 11.b of Part II.B is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of paragraph 11.b of Part II.B must be submitted to the Director prior to or together with any reports, information, or applications to be signed by an authorized representative.
- d. Certification. Any person signing a document under paragraph 11.a or 11.b of Part II.B shall make the following certification:
- 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.

- e. The Clean Water Act provides that any person who knowingly makes any false material statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or noncompliance shall, upon conviction, be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than 6 months per violation, or by imprisonment for not more than 6 months per violation, or by both. If a conviction is for a violation committed after a first conviction of such person under this paragraph, punishment shall be by a fine of not more than \$20,000 per day of violation, or by imprisonment of not more than four years, or both. (See CWA section 309.c.4).

12. Reporting Requirements [40 CFR 122.41(l)].

- a. Planned changes. The Permittee shall give notice to the Director as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:
 - 1) The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source in 40 CFR 122.29(b);
 - 2) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under paragraph 4.a of Part I.B (40 CFR 122.42(a)(1)); or
 - 3) The alteration or addition results in a significant change in the Permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan.
- b. Anticipated noncompliance. The Permittee shall give advance notice to the Director of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.
- c. Transfers. This permit is not transferable to any person except after notice to the Director. The Director may require modification or revocation and reissuance of the permit to change the name of the Permittee and incorporate such other requirements as may be necessary under the Clean Water Act. (See 40 CFR 122.61; in some cases, modification or revocation and reissuance is mandatory.)
- d. Monitoring reports. Monitoring results shall be reported at the intervals specified in Part III of this permit.
 - 1) Monitoring results shall be reported on a Discharge Monitoring Report (DMR) or forms provided or specified by the Director for reporting results of monitoring of sludge use or disposal practices.
 - 2) If the Permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 CFR Part 136, or another method required for an industry-specific waste stream under 40 CFR subchapters N or O, the results of such monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Director.
 - 3) Calculations for all limitations which require averaging of measurements shall utilize an arithmetic mean unless otherwise specified by the Director in the permit.
- e. Compliance Schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.
- f. Twenty four hour reporting.
 - 1) The Permittee shall report any noncompliance which may endanger health or the environment. Any information shall be provided orally within 24 hours from the time the Permittee becomes aware of the circumstances to EPA Region 2, Caribbean Environmental Protection Division at (787) 977-5870 and State Director. A written submission shall also be provided within 5 days of the time the Permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and if

the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance.

- 2) The following shall be included as information which must be reported within 24 hours under this paragraph.
 - a) Any unanticipated bypass (see 13 below) which exceeds any effluent limitation in the permit. [See 40 CFR 122.41(g)].
 - b) Any upset (see 14 below) which exceeds any effluent limitation in the permit.
 - c) Violation of a maximum daily discharge limitation for any of the pollutants listed by the Director in the permit to be reported within 24 hours. (See 40 CFR 122.44(g)).
- 3) The Director may waive the written report on a case by case basis for reports under paragraph 12.f.(2) of Part II.B if the oral report has been received within 24 hours.
- g. Other noncompliance. The Permittee shall report all instances of noncompliance not reported under paragraphs 12.d, e, and f of Part II.B, at the time the monitoring reports are submitted. The reports shall contain the information listed in paragraph 12.f of Part II.B.
- h. Other information. Where the Permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Director, it shall promptly submit such facts or information.

13. Bypass [40 CFR 122.41(m)].

- a. Bypass not exceeding limitations. The Permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraphs 13.b. and 13.c of Part II.B.
- b. Notice.
 - 1) Anticipated bypass. If the Permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible at least ten days before the date of the bypass.
 - 2) Unanticipated bypass. The Permittee shall submit notice of an unanticipated bypass as required in paragraph 12.f of Part II.B (24-hour notice).
- c. Prohibition of bypass.
 - 1) Bypass is prohibited, and the Director may take enforcement action against a Permittee for bypass, unless:
 - a) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;
 - b) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and
 - c) The Permittee submitted notices as required under paragraph 13.b of Part II.B.
 - 2) The Director may approve an anticipated bypass, after considering its adverse effects, if the Director determines that it will meet the three conditions listed above in paragraph 13.b.(1) of Part II.B.

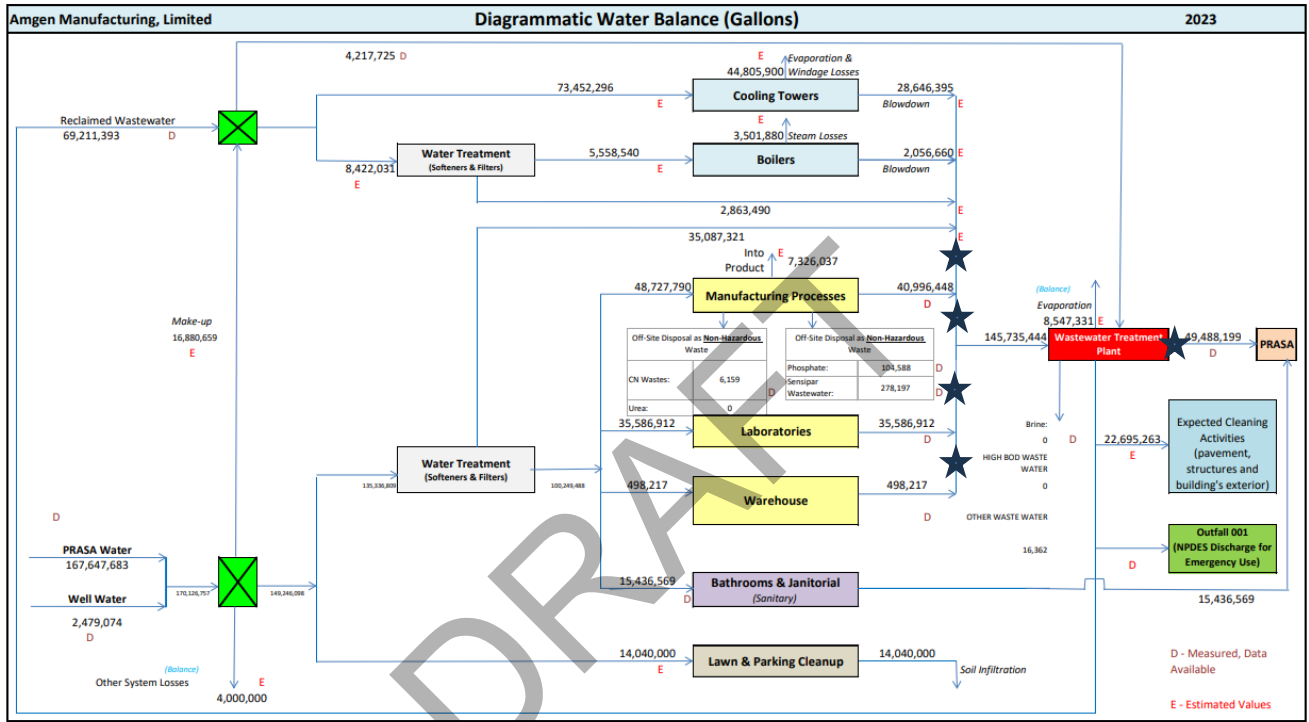
14. Upset [40 CFR 122.41(n)].

- a. Effect of an upset. An upset constitutes an affirmative defense to an action brought for noncompliance with such technology-based permit effluent limitations if the requirements of paragraph 14.(b) of Part II.B are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review.
- b. Conditions necessary for a demonstration of upset. A Permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:
 - 1) An upset occurred and that the Permittee can identify the cause(s) of the upset;

- 2) The permitted facility was at the time being properly operated;
 - 3) The Permittee submitted notice of the upset as required in paragraph 12.f.(2)(b) of Part II.B (24 hour notice); and
 - 4) The Permittee complied with any remedial measures required under paragraph 4 of Part II.B (duty to mitigate).
- c. Burden of proof. In any enforcement proceeding the Permittee seeking to establish the occurrence of an upset has the burden of proof.
15. Removed substances (33 U.S.C. 1311). Pursuant to section 301 of the Clean Water Act, solids, sludges, filter backwash or other pollutants removed in the course of treatment or control of wastewaters and/or the treatment of intake waters shall be disposed of in a manner such as to prevent any pollutant from such materials from entering navigable waters. The following data shall be reported together with the monitoring data required in paragraph 2 of Part I.B:
- a. The sources of the materials to be disposed of;
 - b. The approximate volumes and weights;
 - c. The method by which they were removed and transported; and
 - d. Their final disposal locations.
16. Oil and hazardous substance liability (33 U.S.C. 1321). The imposition of responsibilities upon, or the institution of any legal action against the Permittee under CWA section 311 shall be in conformance with regulations promulgated pursuant to Section 311 to discharges from facilities with NPDES permits.
17. Reopener clause for toxic effluent limitations [40 CFR 122.44(B)(1)]. Other effluent limitations and standards under CWA sections 301, 302, 303, 307, 318 and 405. If any applicable toxic effluent standard or prohibition (including any schedule of compliance specified in such effluent standard or prohibition) is promulgated under CWA section 307(a) for a toxic pollutant and that standard or prohibition is more stringent than any limitation on the pollutant in the permit, the Director shall institute proceedings under these regulations to modify or revoke and reissue the permit to conform to the toxic effluent standard or prohibition. See also 40 CFR 122.41(a).
18. State laws (33 U.S.C. 1370). Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the Permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable state law or regulation under authority preserved by CWA section 510. The issuance of this permit does not preempt any duty to obtain state or local assent required by law for the discharge.
19. Availability of information (33 U.S.C. 1318). (CWA section 308)
- a. NPDES permits, effluent data, and information required by NPDES application forms provided by the Director under 40 CFR 122.21 (including information submitted on the forms themselves and any attachments used to supply information required by the forms) shall be available for public inspection at the offices of the Regional Administrator and State Director.
 - b. In addition to the information set forth in subsection a., any other information submitted to EPA in accordance with the conditions of this permit shall be made available to the public without further notice unless a claim of business confidentiality is asserted at the time of submission in accordance with the procedures in 40 CFR Part 2 (Public Information).
 - c. If a claim of confidentiality is made for information other than that enumerated in subsection a., that information shall be treated in accordance with the procedures in 40 CFR Part 2. Only information determined to be confidential under those procedures shall not be made available by EPA for public inspection.
20. Severability. The provisions of this permit are severable, and if any provision of this permit, or the application of any provision of this permit to any circumstance, is held invalid, the application of such provision to other circumstances, and the remainder of this permit, shall not be affected thereby.

ATTACHMENT C: SAMPLING LOCATIONS

Suggested sampling locations to gather data for each desired flow, respectively, indicated by a five-pointed star icon.



Amgen Proprietary - For Internal Use Only