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

FACT SHEET

DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

Amgen Manufacturing Limited LLC
PERMIT No. PR0026695

This Fact Sheet sets forth the principal facts and technical rationale that serve as the legal basis for the requirements of the accompanying draft permit. The draft permit has been prepared in accordance with Clean Water Act (CWA) section 402 and its implementing regulations at Title 40 of the *Code of Federal Regulations* (CFR), Parts 122 through 124, and the final Water Quality Certificate (WQC) issued by the Puerto Rico Department of Natural and Environmental Resources (DNER) pursuant to CWA section 401 requirements.

Pursuant to 40 CFR 124.53, the Commonwealth of Puerto Rico must either grant a certification pursuant to CWA section 401 or waive this certification before the U.S. Environmental Protection Agency (EPA) may issue a final permit. On June 26, 2024**,** DNER provided in the WQC that the allowed discharge will not cause violations to the applicable water quality standards at the receiving water body if the limitations and monitoring requirements in the WQC are met. In accordance with CWA section 401, EPA has incorporated the conditions of the final WQC into the draft permit. The WQC conditions are discussed in this Fact Sheet and are no less stringent than allowed by federal requirements. Additional requirements might apply to comply with other sections of the CWA. Review and appeals of limitations and conditions attributable to the WQC were made through the applicable procedures of the Commonwealth of Puerto Rico and not through EPA procedures. No appeals were received by DNER on the WQC.

PART I. BACKGROUND

A. Permittee and Facility Description

Amgen Manufacturing Limited LLC, previously known as Amgen Manufacturing Limited (referred to throughout as the Permittee) has applied for renewal of its National Pollutant Discharge Elimination System (NPDES) permit. The Permittee is authorized to discharge pursuant to NPDES Permit No**.** PR0026695. The Permittee submitted a renewal application for the NPDES permit to discharge treated wastewater from the Amgen Manufacturing Limited LLC Wastewater Treatment Plant (WWTP) called the facility. The facility is classified as a major discharger by EPA in accordance with the EPA rating criteria. The Permittee submitted Application Form 1 and Form 2C under the cover letter dated May 30, 2023, as well as the revised line drawing and Form 2C, Table B provided via email on June 28, 2023, and July 13, 2023. EPA notified the Permittee that the application was complete on July 20, 2023.

The Permittee owns and operates an industrial facility manufacturing pharmaceutical preparations. Attachment A of this Fact Sheet provides a map of the area around the facility and a flow schematic of the facility. Process wastewater goes through tertiary pre-treatment at a wastewater treatment plant on-site before it is discharged as a pretreatment source to the nearby Puerto Rico Aqueduct and Sewer Authority (PRASA) facility, Caguas Regional Wastewater Treatment Plant.

The treatment system consists of the following: Equalization tanks, pH adjustment, Membrane Biological Reactor biological treatment, anaerobic treatment, primary reverse osmosis, and metals precipitation.

Sludge is treated through aerobic digestion and centrifugation. Sludge is held in a storing tank for no more than four days before being hauled to a landfill.

The Permittee has applied for a renewal of the direct discharge NPDES permit as a contingency for extreme circumstances that may render the PRASA facilities unavailable to accept the Permittee's pretreatment discharge. It is important to note that, to date, the facility has not discharged process wastewater from Outfall 001 as there has been no interruption in their ability to discharge to PRASA.

The facility is permitted for industrial stormwater discharges under the Puerto Rico Multi Sector General Permit (MSGP). The MSGP conditions list non-stormwater waste streams authorized to be discharged, including those from potable water, pavement wash waters, and external building and structure washdown and power wash water (Part 1.2.2.1 of the MSGP). In October 2022, Amgen submitted documentation in the Wastewater Treatment Plant Reuse Project which indicated that the results of monitoring sample analyses have confirmed treatability levels of the Amgen WWTP process not exceeding the Safe Drinking Water Act limits for potable water standards. In a letter dated April 12, 2023, EPA provided conditional approval for treated effluent from the Amgen WWTP to be used for exterior cleaning activities on pavement, structures and buildings at the facility and subsequently discharged under the MSGP. This conditional approval requires continued implementation of treatability levels at the WWTP to produce an effluent that meets potable water standards.

B. Summary of Permittee and Facility Information

Permittee	Amgen Manufacturing Limited LLC
Facility contact, title, phone	Jose F. Martinez Toledo, Environmental Health Safety & Sustainability Senior Manager, 787-916-1203
Permittee (mailing) address	P.O. Box 4060 Juncos, PR 00777
Facility (location) address	State Road PR-31, Juncos, PR 00777
Type of facility	SIC Code 2834 Pharmaceutical Preparations and SIC Code 2836 Biological Products (Except Diagnostic)
Pretreatment program	Discharges as a pretreatment source to Puerto Rico Aqueduct and Sewer Authority (PRASA) GDA-92-608-076
Facility permitted flow	0.5 MGD
Facility classification	Major

C. Discharge Points and Receiving Water Information

Wastewater is discharged from Outfall 001 to the Rio Gurabo, a water of the United States and classified as SD per Puerto Rico Water Quality Standards (PRWQS).

The draft permit authorizes the discharge from the following discharge point(s): 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

As indicated in the PRWQS Regulations, the designated uses for Class SD receiving waters include:

1. Use as a raw source of public water supply,
2. Propagation and maintenance of desirable species, including threatened or endangered species, and
3. Primary and secondary contact recreation.

CWA section 303(d) requires the Commonwealth of Puerto Rico to develop a list of impaired waters, establish priority rankings for waters on the list, and develop Total Maximum Daily Loads (TMDLs) for those waters. The receiving water has been determined to have water quality impairments for one or more of the designated uses as determined by section 303(d) of the CWA. There are impairments for: Chromium VI, Enterococci, Temperature, Total Nitrogen, Total Phosphorus and Turbidity. There are currently no TMDLs applicable to this facility.

D. Mixing Zone/Dilution Allowance

A mixing zone or dilution allowance has not been authorized for the discharger.

E. Summary of Basis for Effluent Limitations and Permit Conditions - General

The effluent limitations and permit conditions in the permit have been developed to ensure compliance with the following, as applicable:

1. Clean Water Act section 401 Certification
2. NPDES Regulations (40 CFR Part 122)
3. PRWQS (February 2023 or November 2022)
4. Technology-based limits are included based upon 40 CFR § 122.45(h)
5. Effluent Limitation Guidelines (ELG) for the Pharmaceutical Manufacturing Point Source Category based on 40 CFR § 439.42 subpart D (existing source)

PART II. RATIONALE FOR EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

CWA section 301(b) and 40 CFR 122.44(d) require that permits include limitations more stringent than applicable technology-based requirements where necessary to achieve applicable water quality standards. In addition, 40 CFR 122.44(d)(1)(i) requires that permits include effluent limitations for all pollutants that are or may be discharged at levels that cause, have the reasonable potential to cause, or contribute to an exceedance of a water quality criterion, including a narrative criterion. The process for determining reasonable potential and calculating water quality-based effluent limits (WQBELs) is intended to protect the designated uses of the receiving water and achieve applicable water quality criteria. Where reasonable potential has been established for a pollutant, but there is no numeric criterion for the pollutant, WQBELs must be established using (1) EPA criteria guidance under CWA section 304(a), supplemented where necessary by other relevant information; (2) an indicator parameter for the pollutant of concern; or (3) a calculated numeric water quality criterion, such as a proposed state criterion or policy interpreting the state's narrative criterion, supplemented with other relevant information, as provided in 40 CFR 122.44(d)(1)(vi).

The effluent limitations and permit conditions in the permit have been developed to ensure compliance with all federal and state regulations, including PRWQS. The basis for each limitation or condition is discussed below.

Previous permit issuance miscategorized the Permittee's facility as a new source, using new source performance standard (NSPS). This issuance is revising the Permittee's facility to an existing source.

A. Effluent Limitations

The permit establishes both Technology-based Effluent Limitations (TBELs) and WQBELs for several pollutants. The facility has not discharged under its stated emergency conditions from Outfall 001 so there is no available discharge data. As such, EPA has used the current PRASA Industrial Pretreatment Program industrial user (IU) permit (GDA-92-608-076) to identify pollutants which may be present in the NPDES discharge. Effluent limitations based on the WQC or monitoring requirements have been established in the permit for all parameters that have effluent limits or monitoring requirements in the PRASA IU permit. If the facility commences discharge from Outfall 001, the additional monitoring requirements will ensure that EPA

has sufficient data to evaluate whether a pollutant causes, contributes, or has the reasonable potential to contribute to an excursion of WQS. The basis for the effluent limitations and monitoring limits is discussed below.

Asterisks (*) indicate that the limits are established pursuant to the Water Quality Certification (WQC).

1. **Technology Based Effluent Limits (TBELs)**
    a. **5-Day Biochemical Oxygen Demand (BOD_5)*:** The effluent concentration and percent removal limitations are based on technology-based effluent limitation guidelines in 40 CFR 439.42 which states equivalence to 439.12(a). In the absence of data for calculating this limit, monitoring requirements have been established in Part II of the permit, and a numeric limit is set according to the WQC.
    b. **Chemical Oxygen Demand (COD):** The effluent concentration and percent removal limitations are based on technology-based effluent limitation guidelines in 40 CFR 439.42 which states equivalence to 40 CFR 439.22(c) and 40 CFR 439.22(d). In the absence of data for calculating this limit as required by 40 CFR 439.22(d), monitoring requirements have been established in Part II of the permit.
    c. **Total Suspended Solids (TSS):** The effluent concentration and percent removal limitations are based on technology-based effluent limitation guidelines in 40 CFR 439.45, which states equivalence to 40 CFR 439.12(b). In the absence of data to calculate this limit, monitoring requirements have been established in Part II of the permit, and the WQC.
2. **Water Quality Based Effluent Limits (WQBELS)**
    a. **1,2-Dichloroethane***: The effluent limit for 1,2-Dichlorethane is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(3) of PRWQS, and the WQC.
    b. **2,4-Dinitrophenol***: The effluent limit for 2,4-Dinitrophenol is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(3) of PRWQS, and the WQC.
    c. **2-Methyl-4,6-Dinitrophenol***: The effluent limit for 2-Methyl-4,6-Dinitrophenol is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(3) of PRWQS, and the WQC.
    d. **Cadmium***: The effluent limit for Cadmium is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(1) of PRWQS, and the WQC. The limit for Cadmium is less stringent than the previous permit. Per Region 2's anti-backsliding policy, this is allowable as detailed in Part II Section D.
    e. **Chlorides***: The effluent limit for Chlorides is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(k) of PRWQS, and the WQC.
    f. **Chromium (VI)*:** The effluent limit for Chromium-VI is based on the water quality criterion for SD waters as specified in Rule 1303.1(J)(1) the PRWQS, and the WQC.
    g. **Color***: The effluent limit for color is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(e) of the PRWQS, and the WQC.
    h. **Copper***: The effluent limit for Copper is based on the water quality criterion for Class SD waters as specified in Rule 1303.1(J)(1) of the PRWQS, and the WQC.
    i. **Cyanide, Total*:** The effluent limit for Cyanide, Total is based on the WQC.
    j. **Dissolved Oxygen (DO)*:** The effluent limit for Dissolved Oxygen is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(a) of PRWQS, and the WQC.
    k. **Enterococci***: The effluent limit for Enterococci is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(c) of PRWQS, and the WQC.
    l. **Flow*:** The effluent limit for flow is based on the WQC.
    m. **Lead*:** The effluent limit for Lead is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(1) of PRWQS and the WQC. The limit for lead is less stringent than the previous permit's. Per Region 2's anti-backsliding policy, this is allowable. See Part II Section D.
    n. **Mercury*:** The effluent limit for Mercury is established in the permit based on Rule 1303.1(J)(1) the PRWQS, and the WQC.
    o. **Oil & Grease***: The effluent limit for Oil & Grease is based on the water quality criterion for all waters as specified in Rule 1303.1(H) of PRWQS, and the WQC.
    p. **Pentachlorophenol*:** The effluent limit for Pentachlorophenol is established in the permit based on Rule 1303.1(2)(a) of the PRWQS, and the WQC.
    q. **pH*:** The effluent limit for pH is based on Rule 1303.2(C)(2)(d) of the PRWQS, and the WQC.

r. **Residual Chlorine***: The effluent limit for Residual Chlorine is based on the water quality criterion for Class SD waters as specified in Rule 1303.1(J)(1) of the PRWQS, and the WQC.
s. **Selenium*:** The effluent limit for Selenium is based on the water quality criterion for Class SD waters, as specified in Rule 1303.2(C)(2)(o) of PRWQS, and the WQC.
t. **Silver***: The effluent limitation for Silver is based on the water quality criterion for SD waters as specified in Rule 1303.1(J)(1) the PRWQS, and the WQC.
u. **Solids, Other Matter***: The effluent limitation for Solids and Other Matter is based on the water quality criterion for all waters as specified in Rule 1303.1(A) of the PRWQS, and the WQC.
v. **Sulfates*:** The effluent limit for Sulfates is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(j) of PRWQS, and the WQC.
w. **Sulfides (undissociated H_2S)***: The effluent limit for Sulfides is based on the water quality standards for Class SD waters as specified in Rule 1303.1(J)(1), and the WQC.
x. **Surfactants, Methylene Blue Active Substances (MBAS)*:** The effluent limit for MBAS Surfactants is based on the water quality criterion for Class SD waters, as specified in Rule 1303.2(C)(2)(i) of PRWQS, and the WQC.
y. **Suspended, Colloidal or Settleable Solids***: The effluent limit for Suspended, Colloidal or Settleable Solids is based on the water quality criterion for all waters as specified in Rule 1303.1(E) of the PRWQS, and the WQC.
z. **Taste and Odor Producing Substances***: The effluent limit for Taste and Odor Producing Substances is based on the water quality criterion for all waters as specified in Rule 1303.1(B) of the PRWQS, and the WQC.
aa. **Temperature*:** The effluent limit for temperature is based on the water quality criterion for all waters as specified in Rule 1303.1(D) of PRWQS, and the WQC.
bb. **Total Ammonia Nitrogen (TAN)*:** The effluent limit for Total Ammonia Nitrogen is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(l), and the WQC.
cc. **Total Dissolved Solids*:** The effluent limit for Total Dissolved Solids is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(g), and the WQC.
dd. **Total Nitrogen (NO_2, NO_3, TKN)*:** The effluent limit for Total Nitrogen is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(m), and the WQC.
ee. **Total Phosphorous***: The effluent limit for Total Phosphorous is based on the water quality criterion for Class SD waters as specified in Rule 1303.2(C)(2)(n), and the WQC.
ff. **Turbidity*:** The effluent limit for turbidity is based on the water quality criterion for all waters as specified in Rule 1303.1(B) and for Class SD waters as specified in Rule 1303.2(C)(2)(f) of PRWQS, and the WQC.
gg. **Zinc*:** The effluent limit for Zinc is based on the water quality criterion for Class SD waters, as specified in Rule 1303.1(J)(1) of PRWQS, and the WQC.

The following parameters have effluent limitations or monitoring requirements in the Permittee's current pretreatment permit for discharge to PRASA. In order to assess potential pollutants of concern and collect sampling data for future reasonable potential analysis and WQBEL development, monitoring requirements for these parameters have been established at Outfall 001: 2-Chlorophenol, 2,4-dichlorophenol, 2,4-Dinitrophenol, Arsenic, Benzene, Chlorobenzene, Chloroform, Methylene Chloride, Nickel, O-Dichlorobenzene, Phenol and Toluene. These monitoring conditions are only applicable in the event of a discharge from Outfall 001.

B. Effluent Limitations Summary Table

Outfall Number 001

Parameter	Units	Averaging period	Existing limits	Final limits	Basis
1,2-Dichloroethane*	µg/L	Maximum Daily	3.8	5	WQBEL
2-Chlorophenol[1]	µg/L	Maximum Daily	-	M/R	Data Collection

2-4-Dichlorophenol[1]	µg/L	Maximum Daily	-	M/R	Data Collection
2,4-Dinitrophenol[1]*	µg/L	Maximum Daily	-	M/R	WQBEL from WQC
2-Methyl-4,6-Dinitrophenol*	µg/L	Maximum Daily Average monthly	monitoring	2	WQBEL
Arsenic	µg/L	Maximum Daily	10	M/R	Data Collection
Benzene	µg/L	Maximum Daily	5	M/R	Data Collection
BOD_5*	kg/day	Average monthly Maximum Daily	18 35	M/R 20	TBEL
Chemical Oxygen Demand (COD)	µg/L	Maximum Daily Average monthly	86 228	86 228	TBEL
Cadmium*	µg/L	Maximum Daily	.26	.77	WQBEL from WQC
Chlorides*	mg/L	Maximum Daily	250	230	WQBEL
Chlorobenzene[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Chloroform[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Chromium VI (Cr^{+6})*	µg/L	Maximum Daily	11	11	WQBEL
Color*	Pt-Co Units	Maximum Daily	15	15	WQBEL from WQC
Copper*	µg/L	Maximum Daily	9.0	9.0	WQBEL
Cyanide, Free (CN)	µg/L	Maximum Daily	5.2	-	Removed from WQC
Cyanide, Total (CN)[1]*	µg/L	Maximum Daily	-	4.0	WQBEL from WQC
Dissolved Oxygen*	mg/L	Maximum Daily Average monthly	Shall not contain less than 5.0 mg/L	Shall not contain less than 5.0 mg/L	WQBEL
Effluent Flow*	m^3/day (mgd)	Average monthly Average weekly Maximum daily	Monitor only Monitor only 1892.71 (0.50)	1892.71 (0.50)	WQBEL from WQC

Enterococci*	colonies/ 100 mL	Maximum Daily Average monthly	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.	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.	WQBEL
Lead*	µg/L	Maximum Daily	3.00	3.02	WQBEL from WQC
Mercury (Hg)*	µg/L	Maximum Daily	0.05	0.05	WQBEL
Methylene Chloride	µg/L	Maximum Daily	46	M/R	Data Collection
Nickel[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Oil & Grease*	mg/L	Maximum Daily Average monthly	The waters of Puerto Rico shall be substantially free from floating non-petroleum oils and greases as well as petroleum derived oils and greases.	The waters of Puerto Rico shall be substantially free from floating non-petroleum oils and greases as well as petroleum derived oils and greases.	WQBEL
O-Dichlorobenzene[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Pentachlorophenol*	µg/L	Maximum Daily	monitoring	0.3	WQBEL
pH*	standard units	Minimum Maximum	6.0 9.0	6.0 9.0	WQBEL
Phenol[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Residual Chlorine*	µg/L	Maximum Daily	11	11	WQBEL
Selenium (Se)*	µg/L	Maximum Daily	5.0	5.0	WQBEL
Silver[1]*	µg/L	Maximum Daily	-	3.75	WQBEL

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 waterbody.	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.	WQBEL from WQC
Sulfates (SO_4)*	mg/L	Maximum Daily	250	250	WQBEL from WQC
Sulfide (undissociated H_2S)*	µg/L	Maximum Daily	2.0	2.0	WQBEL
Surfactants (as MBAS)*	µg/L	Maximum Daily	100	100	WQBEL
Suspended, Colloidal or Settleable Solids*	mL/L	-	Solids from wastewater source shall not cause deposition in or be deleterious to the existing or designated uses of the waterbody.	Solids from wastewater sources shall not cause deposition in or be deleterious to the existing or designated uses of the water body.	WQBEL
Taste and Odor Producing Substances*	-	-	Shall not be present in amounts that will render any undesirable taste or odor to edible aquatic life.	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.	WQBEL
Temperature*	°F (°C)	-	Except by natural phenomena, no heat which would cause the temperature of any site to exceed 90°F (32.2 °C) may be added to the waters of Puerto Rico	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)	WQBEL
Toluene[1]	µg/L	Maximum Daily	-	M/R	Data Collection
Total Ammonia Nitrogen (TAN)*	µg/L	Maximum Daily	monitoring	M/R	WQBEL
Total Dissolved Solids*	µg/L	Maximum Daily Average monthly	500	500	WQBEL
Total Nitrogen (NO_3, NO_2, TKN)*	µg/L	Maximum Daily	1700	1700	WQBEL

Total Phosphorous (P)*	µg/L	Maximum Daily	160	160	WQBEL
Total Suspended Solids*	kg/day	Maximum Daily Average monthly	58 31	M/R M/R	TBEL
Turbidity*	NTU	Maximum Daily	50	50	WQBEL
Whole Effluent Toxicity*	TU_a	-	-	-	WQBEL from WQC
Zinc*	µg/L	Maximum Daily	115.8	115.8	WQBEL from WQC

Notes, Footnotes and Abbreviations

Note: Dashes (-) indicate there are no effluent data, no limitations, or no monitoring requirements for this parameter.

Asterisks (*) indicate that the limits are established pursuant to the Water Quality Certification (WQC).

M/R indicates that monitoring and reporting is required.

[1] indicates a parameter that wasn't in the previous permit.

C. Monitoring Requirements

NPDES regulations at 40 CFR 122.48 require that all permits specify requirements for recording and reporting monitoring results. The Part III of the Permit establishes monitoring and reporting requirements to implement federal and state requirements. The following provides the rationale for the monitoring and reporting requirements for this facility.

1. Influent Monitoring Requirements

a. This facility is not subject to influent monitoring requirements.

2. Effluent Monitoring Requirements

a. Effluent monitoring frequency and sample type have been established in accordance with the requirements of 40 CFR 122.44(i) and recommendations in EPA's Technical Support Document (TSD). Consistent with 40 CFR Part 136 monitoring data for toxic metals must be expressed as total recoverable metal.

D. Compliance with Federal Anti-Backsliding Requirements and Puerto Rico's Anti-Degradation Policy

Federal regulations at 40 CFR 131.12 require that state water quality standards include an anti-degradation policy consistent with the federal policy. The discharge is consistent with the anti-degradation provision of 40 CFR 131.12, 72 Federal Register 238 (December 12, 2007, pages 70517-70526) and EQB's *Anti-Degradation Policy Implementation Procedure* in Attachment A of PRWQS. In addition, CWA sections 402(o) and 303(d)(4) and federal regulations at 40 CFR 122.44(l) prohibit backsliding in NPDES permits. Further, the Region 2 Antibacksliding Policy provides guidance regarding relaxation of effluent limitations based on water quality for Puerto Rico NPDES permits. These anti-backsliding provisions require effluent limitations in a reissued permit to be as stringent as those in the previous permit with some exceptions where limitations may be relaxed. The limits for 1,2-Dichloroethane, arsenic, benzene, chlorides, cyanide (total), cadmium, lead, and methylene chloride are less stringent than the previous permit. Since the changes are based on the WQC issued by DNER, Region 2's antibacksliding policy allows for relaxation. Free Cyanide and 2,4,6-Trichlorophenol limits have been removed from this current permit in accordance with their removal from the WQC. A special condition has been added to Part IV.B.7 for this removal to be allowable, as required in the policy.

PART III. RATIONALE FOR STANDARD AND SPECIAL CONDITIONS

A. Standard Conditions

In accordance with 40 CFR 122.41, standard conditions that apply to all NPDES permits have been incorporated by reference in Part IV.A.1 of the permit and expressly in Attachment B of the permit. The Permittee must comply with all standard conditions and with those additional conditions that are applicable to specified categories of permits under 40 CFR 122.42 and specified in Part IV.A.2 of the Permit.

B. Special Conditions

In accordance with 40 CFR 122.42 and other regulations cited below, special conditions have been incorporated into the permit. This section addresses the justification for special studies, additional monitoring requirements, Best Management Practices, Compliance Schedules, and/or special provisions for POTWs as needed. The special conditions for this facility are as follows:

C. Best Management Practices (BMP) Plan

In accordance with 40 CFR 122.2 and 122.44(k), BMPs are schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution to waters of the United States. The Permittee is required to develop a BMP Plan in Part IV.B.3 of the Permit to control or abate the discharge of pollutants as outlined in the WQC.

D. Special Conditions from the Water Quality Certificate

In accordance with 40 CFR 124.55, EPA has established Special Conditions from the WQC that DNER determined were necessary to meet PRWQS. Special and narrative conditions from the WQC are established in Part IV.B of the permit.

1. Whole Effluent Toxicity (WET)

a. Special conditions for WET from the WQC and EPA are established in Part IV.B.1 and Part IV.B.2 of the permit, respectively.

2. Best Management Practices (BMPs)

a. In accordance with 40 CFR 122.2 and 122.44(k), BMPs are Special conditions for BMPs are schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution to waters of the United States. The Permittee is required to develop a BMP as established in Part IV.B.3 of the permit.

3. Compliance schedules

a. A compliance schedule has not been authorized for any pollutant or parameter in the permit on the basis of 40 CFR 122.47.

4. Additional special requirements

a. In accordance with 40 CFR 124.55, EPA has established Special Conditions from the WQC in the permit that DNER determined were necessary to meet PRWQS. The additional Special Conditions established in this section are only those conditions from the WQC that have not been established in other parts of the permit.

5. Sludge

a. Special conditions for sludge are established in Part IV.B.5.17, Part IV.B.5.18 and Part IV.B.6 of the permit.

PART IV. COMPLIANCE WITH APPLICABLE PROVISIONS OF OTHER FEDERAL LAWS OR EXECUTIVE ORDERS

A. Coastal Zone Management Act

Under 40 CFR 122.49(d), and in accordance with the Coastal Zone Management Act of 1972, as amended, 16 *United States Code* (U.S.C.) 1451 *et seq*. section 307(c) of the act and its implementing regulations (15 CFR Part 930), EPA may not issue an NPDES permit that affects land or water use in the coastal zone until the Permittee certifies that the proposed activity complies with the Coastal Zone Management Program in Puerto Rico, and that the discharge is certified by the Commonwealth of Puerto Rico to be consistent with the Commonwealth's Coastal Zone Management Program. On November 20, 2024, the Puerto Rico Planning Board issued a consistency certification for the discharge that provides that the discharge complies with its Coastal Zone Management Plan.

B. Endangered Species Act

Under 40 CFR 122.49(c), EPA is required pursuant to section 7 of the Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq*. and its implementing regulations (50 CFR Part 402) to ensure, in consultation with the National Marine Fisheries Service (NMFS) and U.S. Fish and Wildlife Service (USFWS) that the discharge authorized by the permit is not likely to jeopardize the continued existence of any endangered or threatened species or adversely affect its critical habitat. No federally listed endangered or threatened species, or critical habitat, are in the vicinity of the discharge. NMFS determined that no consultation was required on August 15, 2024. USFWS provided a consistency letter on August 15, 2024, confirming no effect to any endangered species.

C. National Historic Preservation Act

Under 40 CFR 122.49(b), EPA is required to assess the impact of the discharge authorized by the permit on any properties listed or eligible for listing in the National Register of Historic Places (NRHP) and mitigate any adverse effects when necessary in accordance with the National Historic Preservation Act, 16 U.S.C. 470 et seq. EPA's analysis indicates that no soil disturbing or construction-related activities are being authorized by approval of this permit; accordingly, adverse effects to resources on or eligible for inclusion in the NHRP are not anticipated as part of this permitted action.

D. Magnuson-Stevens Fishery Conservation and Management Act

Under 40 CFR 122.49, EPA is required to ensure that the discharge authorized by the permit will not adversely affect Essential Fish Habitat (EFH) as specified in section 305(b)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA), 16 U.S.C. 1801 *et seq*. NOAA determined no EFH consultation was required on August 21, 2024 and the receiving water does not contain EFH.

E. Clean Water Act, Section 401(a)(2) Neighboring Jurisdictions

Amgen Manufacturing Limited LLC is located on the island of Puerto Rico and discharges to the Gurabo River. Puerto Rico is located in the northeast Caribbean Sea, approximately 1,000 miles southeast of Miami, Florida between the Dominican Republic and the U.S. Virgin Islands. Puerto Rico includes and eponymous main island and several smaller islands such as Mona, Culebra, and Vieques. The closest neighboring jurisdiction to Puerto Rico is the U.S. Virgin Islands, located approximately 45 miles east of Puerto Rico. The contiguous or conterminous US is approximately 1,000 miles of Puerto Rico. Pollutants in open ocean setting tend to experience rapid dilution due to high turbulence, stratification, and dispersive forces. The ocean currents move westerly from the U.S. Virgins Islands towards Puerto Rico.

Based on the nature of the discharge, physical and chemical factors prevalent in the receiving ocean waters, prevailing ocean currents, and distance to any neighboring jurisdiction, EPA has no basis to conclude that a discharge from EPA-issued CWA section 401 permitted projects in Puerto Rico may affect the water quality of Florida or the U.S. Virgin Islands.

PART V. PUBLIC PARTICIPATION

The procedures for reaching a final decision on the draft permit are set forth in 40 CFR Part 124 and are described in the public notice for the draft permit, which is published on EPA's website at https://www.epa.gov/npdes-permits/puerto-rico-npdes-permits. Included in the public notice are requirements for the submission of comments by a specified date, procedures for requesting a hearing and the nature of the hearing, and other procedures for participation in the final agency decision. EPA will consider and respond in writing to all significant comments received during the public comment period in reaching a final decision on the draft permit. Requests for information or questions regarding the draft permit should be directed to:

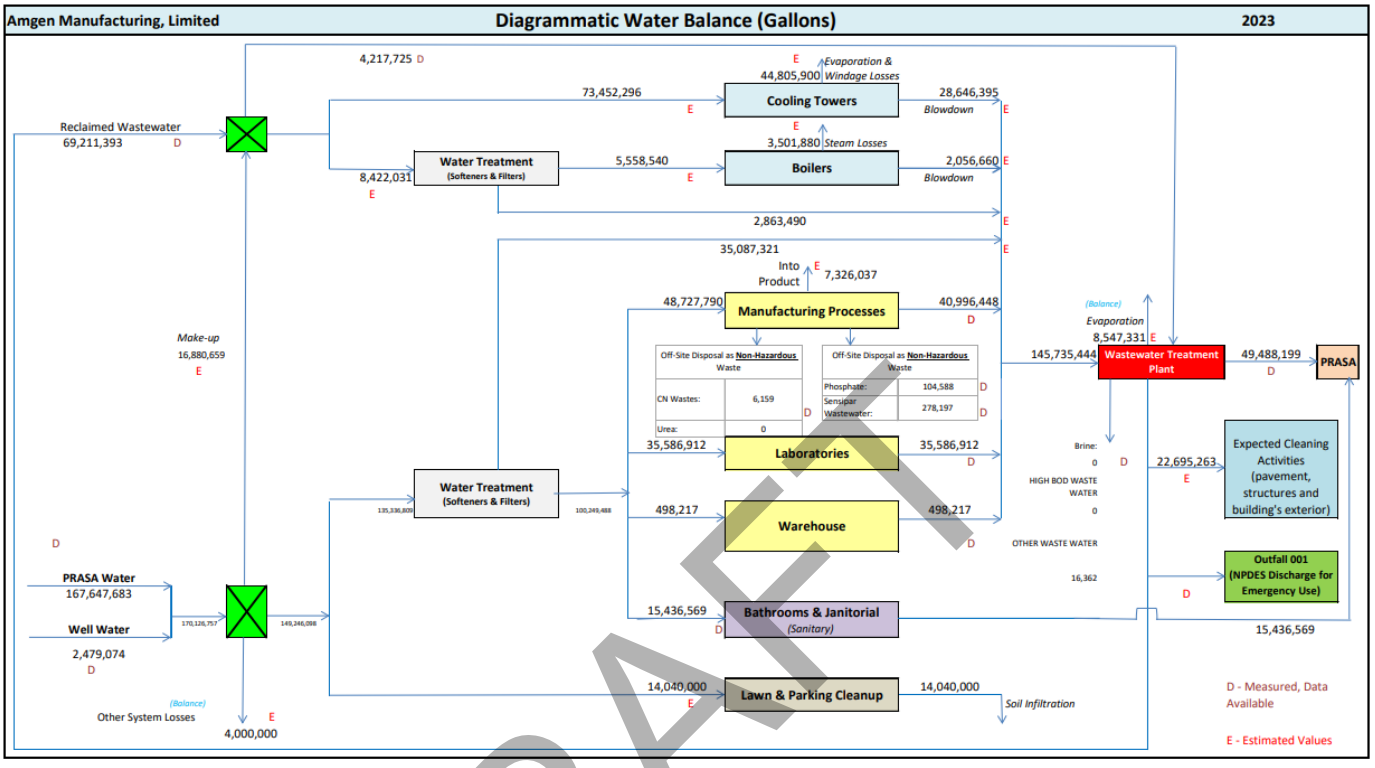
Atifa Hoque
EPA Region 2, Water Division
Permit Writer Phone: 212-637-3732
Permit Writer Email: hoque.atifa@epa.gov

ATTACHMENT A — FACILITY MAP AND FLOW SCHEMATIC

The facility map and flow schematic are attached as provided by the discharger in the application.

1. Facility location

2. Water balance diagram



ATTACHMENT B — WATER QUALITY CERTIFICATE

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GOVERNMENT OF PUERTO RICO
DEPARTMENT OF NATURAL AND ENVIRONMENTAL RESOURCES

JUN 2 6 2024

SENT VIA ELECTRONIC MAIL (mjoube01@amgen.com)

Ms. Margie Joubert
EHS Director
Amgen Manufacturing Limited LLC
P. O. Box 4060
Juncos, Puerto Rico 00777-4060

Dear Ms. Joubert:

RE: WATER QUALITY CERTIFICATE
AMGEN MANUFACTURING LIMITED LLC
WASTEWATER TREATMENT PLANT
STATE ROAD NO. 31, KM 24.6
JUNCOS, PUERTO RICO
NPDES NO. PR0026695

We have received and reviewed the application for a permit under Section 402, National Pollutant Discharge Elimination System (NPDES), of the Federal Clean Water Act, as amended (33 U.S.C. 466 *et seq.*) (the Act) for the referenced facility.

Pursuant to Section 401 (a) (1) of the Act, after due consideration of the applicable provisions established in the Puerto Rico Water Quality Standards Regulation, as amended and in Sections 301, 302, 303, 306 and 307 of the Act, it is certified that there is reasonable assurance, as determined by the Department of Natural and Environmental Resources (DNER), as successor of the Environmental Quality Board, that the allowed discharge will comply with the applicable water quality requirements if the limitations and monitoring requirements on Table A-1 are met. The conditions specified in the aforementioned table shall be incorporated into the NPDES permit in order to satisfy the provisions of Section 401 (d) of the Act.

The applicant must comply with the aforementioned special conditions. Each condition of this WQC is considered as separate. Therefore, if the applicability of any condition of this WQC is stayed due to any circumstance, the remaining conditions of this WQC will not be affected. Pursuant to the provisions of Title 40 of the Code of Federal Regulations (CFR) Part 121.11 (c), the Environmental Protection Agency shall be responsible for enforcing the WQC's conditions incorporated in the federal permit.

JUN 2 6 2024

This certification applies only to the effects that this activity may have on water quality, and not for other ecological, biological, or environmental effects that may result from the project.

The DNER reserves the right to comment at a later date concerning other environmental aspects of the discharge.

Cordially,

Anaïs Rodríguez Vega
Secretary
Department of Natural and Environmental Resources

Enclosures

c: Ms. Virginia Wong, EPA – Region 2
Eng. José F. Martínez Toledo, AML LLC
Eng. Rosario Jiménez, Compliance Resource, Inc.

G:\División de Permisos para Fuentes Precisadas\WORD\Hery Joel\CCA\WQC_AMGEN LLC_PR0026695_2024.docx

TABLE A-1 **EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS** **NPDES NO. PR0026695**

During the period beginning on the Effective Date of the NPDES Permit (EDP) and lasting through the EDP + 5 years, the permittee is authorized to discharge from outfall serial number 001 wastewater from the cooling towers, boilers, manufacturing process, laboratory, warehouse, and sanitary wastewater, treated in a tertiary wastewater treatment plant prior to be discharged. Such discharge shall be limited and monitored by the permittee as specified below:

Receiving Water Name and Classification: Río Gurabo, SD

Effluent Characteristics	Gross Discharge Limitations		Monitoring Requirements	
	Monthly Average	Daily Maximum	Measurements Frequency	Sample Type
1,2-Dichloroethane (µg/L)		5.0	Quarterly	Grab
2,4-Dinitrophenol (µg/L)		----	λ	Grab
2-Methyl-4,6-Dinitrophenol (µg/L)		2.0	Monthly	Grab
BOD_5 (mg/L)	20.0		Monthly	Composite
Cadmium (Cd) (µg/L)		0.77	Monthly	Grab
Chlorides (mg/L)		230	Monthly	Grab
Chromium VI (Cr^{+6}) (µg/L)		11	Quarterly	Grab
Color (Pt-Co Units)		15	Monthly	Grab
Copper (Cu) (µg/L)		9.0	Monthly	Grab
Cyanide, Total (CN) (µg/L) δ		4.0	Quarterly	Grab
Dissolved Oxygen (mg/L)	Shall not contain less than 5.0.		Daily	Grab

TABLE A-1 **EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS** **NPDES NO. PR0026695**

Receiving Water Name and Classification: Río Gurabo, SD

Effluent Characteristics	Gross Discharge Limitations		Monitoring Requirements	
	Monthly Average	Daily Maximum	Measurements Frequency	Sample Type
Enterococci (colonies/100 mL) σ	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.		Twice per Month	Grab
Flow m^3/day (MGD)		1,892.7 (0.50)	Continuous Recording	
Lead (Pb) (µg/L)		3.02	Quarterly	Grab
Mercury (Hg) (µg/L) δ		0.050	Quarterly	Grab
Oil and Grease (mg/L)	The waters of Puerto Rico shall be substantially free from floating non-petroleum oils and greases as well as petroleum derived oils and greases.		Twice per Month	Grab
Pentachlorophenol (µg/L)		0.3	Monthly	Grab
pH (SU)	Shall always lie between 6.0 and 9.0.		Daily	Grab
Residual Chlorine (µg/L) γ		11	Daily	Grab
Selenium (Se) (µg/L)		5.0	Quarterly	Grab
Silver (Ag) (µg/L)		----	λ	Grab

TABLE A-1 **EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS** **NPDES NO. PR0026695**

Receiving Water Name and Classification: Río Gurabo, SD

Effluent Characteristics	Gross Discharge Limitations		Monitoring Requirements	
	Monthly Average	Daily Maximum	Measurements Frequency	Sample Type
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.		----	----
Sulfates (SO_4) (mg/L)		250	Monthly	Grab
Sulfide (undissociated H_2S) (µg/L) β		2.0	Monthly	Grab
Surfactants as MBAS (µg/L)		100	Quarterly	Grab
Suspended, Colloidal or Settleable Solids (mL/L)	Solids from wastewater sources shall not cause deposition in or be deleterious to the existing or designated uses of the water body.		Daily	Grab
Taste or 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.		----	----
Temperature °F (°C)	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).		Daily	Grab
Total Ammonia Nitrogen (TAN) (mg/L)		----	Monthly	Grab
Total Dissolved Solids (mg/L)		500	Monthly	Grab

TABLE A-1 **EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS** **NPDES NO. PR0026695**

Receiving Water Name and Classification: Río Gurabo, SD

Effluent Characteristics	Gross Discharge Limitations		Monitoring Requirements	
	Monthly Average	Daily Maximum	Measurements Frequency	Sample Type
Total Nitrogen (TKN, NO_3, NO_2) (µg/L)		1,700	Monthly	Grab
Total Phosphorus (P) (µg/L)		160	Monthly	Grab
Total Suspended Solids (mg/L)	----	----	Monthly	Composite
Turbidity (NTU)		50	Monthly	Grab
Zinc (Zn) (µg/L)		115.8	Quarterly	Grab
Special Conditions	See attached sheet, which contains special conditions part of this certification.		----	----

Notes:

To comply with the monitoring requirements specified above, samples shall be taken at the sampling point for discharge 001.
All flow measurements shall achieve accuracy within the range ± 10%.

γ See Special Conditions 5 and 6.
β See Special Condition 9.
δ See Special Condition 10.

λ The permittee shall implement a monthly monitoring program using the analytical method approved by EPA with the lowest possible detection level, in accordance with Rule 1306.2(C) of the PRWQSR, as amended, for one (1) year period, after which they will be conducted annually.

Receiving Water Name and Classification: Río Gurabo, SD

σ The enterococci density geometric mean and the 90th Percentile shall be calculated on a monthly basis beginning 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.

A. SPECIAL CONDITIONS

NPDES NO. PR0026695

These special conditions are an integral part of the Water Quality Certificate (WQC) and are authorized by Article 9 of the Environmental Public Policy Act, Law No. 416-2004, as amended. Therefore, they must be incorporated into the NPDES permit in order to satisfy the provisions of Section 401(d) of the Federal Clean Water Act (CWA) as amended (33 U.S.C. 466 *et seq.*):

1. The flow of discharge 001 shall not exceed the limitation of 1,892.7 m^3/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).

2. No changes in the design or capacity of the treatment system will be permitted without the previous authorization of the DNER.

3. 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.

4. 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.

5. 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.

6. 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.

7. The discharge 001 shall not cause the presence of oil sheen in the receiving water body.

8. 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.

9. 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 H_2S. 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 H_2S shall be reported as "below detection limit".

10. 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.

11. 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.

12. The sampling point for discharge 001 shall be located immediately after the primary flow-measuring device of the effluent.

13. 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"

14. 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.

15. 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 to 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, after which the tests shall be performed annually, of its wastewater discharge through outfall serial number 001 in accordance with the following:

a. The test species should be the *Fathead Minnow* (Pimephales promelas) and *Cladocera* (Daphnia magna). The test should be static renewal type.

b. The toxicity test shall be conducted in accordance with the EPA publication, EPA-821-R-02-012 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.

c. 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, LC_{50}.

d. A procedure report shall be submitted within ninety (90) days after the EDSC. The following information shall be included in the procedure report:

i. An identification of the organizations responsible for conducting the test and the species to be tested.

ii. 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.

iii. A schematic diagram, which depicts the effluent sampling location in relation to the wastewater treatment facility and the discharge monitoring point.

iv. If stream flow monitoring is required, the method used to obtain the stream flow data in estimating the seven-day two-year low flow ($7Q_2$).

e. 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.

16. 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.

17. 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:

a. removed material, date and source of it;
b. approximate volume and weight;
c. method by which it is removed and transported;
d. final disposal and location;
e. 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.

18. The DNER, by the issuance of the WQC, does not relieve the applicant from its responsibility to obtain additional permits or authorizations from the DNER as required by law. The issuance of the WQC shall not be construed as an authorization to conduct activities not specifically covered in the WQC, which will cause water pollution as defined by the Puerto Rico Water Quality Standards Regulation, as amended.

B. CITATION AND JUSTIFICATION FOR SPECIAL CONDITIONS (40 CFR 121.7(d)(1))

Special Condition	Statement explaining why the condition is necessary (40 CFR 121.7(d)(1)(i))	Citation to federal or state law that authorizes the condition (40 CFR 121.7(d)(1)(ii))
1	These special conditions are established to assure that no changes in nature or flow of the allowed discharge occur without an evaluation of the effects of such changes in the compliance with the applicable water quality requirements set forth in the PRWQSR and in Sections 301, 302 and 303 of the CWA.	• Rule 1306.1.B of the PRWQSR • Sections 301, 302 and 303 of the CWA
2, 3	This special condition is necessary to assure that the treatment system be evaluated and authorized by the DNER, for compliance with the requirement to implement control measures to prevent adverse effects on the receiving water body.	• Rule 1306.7 of the PRWQSR
4, 11	These special conditions are necessary to require the permittee to establish control measures to prevent that the discharge coming from the facility affects or causes impairment to the applicable water quality requirements set forth in the PRWQSR and in Sections 301, 302 and 303 of the CWA.	• Rule 1306.6.A.1 of the PRWQSR • Sections 301, 302 and 303 of the CWA
5, 6	These special conditions are established to assure that the discharge coming from the facility does not affect or cause impairment to the applicable water quality requirements set forth in the PRWQSR and Sections 301, 302, 303 and 307 of the CWA.	• Rule 1303.1.J of the PRWQSR • Rule 1306.1.B of the PRWQSR • Sections 301, 302, 303 and 307 of the CWA
7	This special condition is established to assure that the discharge coming from the facility does not affect or cause impairment to the applicable water quality requirements set forth in the PRWQSR and Sections 301, 302 and 303 of the CWA.	• Rule 1303.1.H of the PRWQSR • Rule 1306.1.B of the PRWQSR • Sections 301, 302 and 303 of the CWA
8, 9	This special condition is necessary to establish source monitoring, record keeping, reporting, sampling, and testing methods requirements in the WQC, to assure that the allowed discharge will comply with the applicable water quality requirements established in the PRWQSR and in Sections 301, 302 and 303 of the CWA.	• Rule 1306.2.C of the PRWQSR • Sections 301, 302 and 303 of the CWA
10	This special condition is necessary to establish source monitoring, record keeping, reporting, sampling, and testing methods requirements in the WQC, to assure that the allowed discharge will comply with the applicable water quality requirements established in the PRWQSR and in Sections 301, 302 and 303 of the CWA.	• Rule 1306.2.C of the PRWQSR • Rule 1306.8 of the PRWQSR • Sections 301, 302 and 303 of the CWA
12, 13	These special conditions are necessary to assure proper characterization of the discharge to comply with the applicable water quality requirements established in	• Rule 1306.2.E of the PRWQSR

Special Condition	Statement explaining why the condition is necessary (40 CFR 121.7(d)(1)(i))	Citation to federal or state law that authorizes the condition (40 CFR 121.7(d)(1)(ii))
	the PRWQSR and in Sections 301, 302 and 303 of the CWA.	• Sections 301, 302 and 303 of the CWA
14	This special condition is necessary to assure that the discharge will comply with the water quality requirements established in the PRWQSR.	• Rule 1306.6.B of the PRWQSR
15	This special condition is necessary to establish source monitoring, record keeping, reporting, sampling, and testing methods requirements in the WQC, to assure that the allowed discharge will comply with the applicable water quality requirements established in the PRWQSR and in Sections 301, 302, 303 and 307 of the CWA.	• Rule 1306.9 of the PRWQSR • Sections 301, 302, 303 and 307 of the CWA.
16	This special condition is necessary to require the permittee to establish Best Management Practice to prevent solids and other pollutants coming from the facility gaining access to the water body, in such manner that the permitted activity comply with the applicable water quality requirements established in the PRWQSR, and in Sections 301, 302 and 303 of the CWA. Also, this condition is necessary to establish record keeping and reporting requirements in the WQC, to comply with water quality requirements established in the PRWQSR.	• Rule 1306.1 of the PRWQSR • Rule 1306.2 of the PRWQSR • Rule 1306.4 of the PRWQSR • Rule 1306.6.A.2 of the PRWQSR • Sections 301, 302 and 303 of the CWA
17	This special condition is necessary to establish source monitoring, record keeping, reporting, sampling, and testing methods requirements in the WQC, to assure that the allowed discharge will comply with the applicable water quality requirements established in the PRWQSR and in Sections 301, 302, and 303 of the CWA.	• Rule 1306.2.A of the PRWQSR • Sections 301, 302 and 303 of the CWA
18	These special conditions are necessary to require the permittee to establish the Best Management Practice to prevent pollutants coming from the facility gaining access to the water body, in such manner that the facility comply with the applicable requirements established in the PRWQSR concerning the conservation and protection of the natural resources that may affect the quality of water resources.	• Rule 1306.1.B of the PRWQSR
Table A-1	Table A-1 is necessary to establish the water quality-based effluent limitations and monitoring requirements in order to assure that the allowed discharge will comply with the applicable water quality requirements established in the PRWQSR and in Sections 301, 302, 303 and 307 of the CWA.	• Rule 1302 of the PRWQSR • Rule 1303 of the PRWQSR • Rule 1306 of the PRWQSR • Sections 301, 302, 303 and 307 of the CWA