



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

FACT SHEET

**DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM
AMGEN MANUFACTURING, LIMITED
WASTEWATER TREATMENT PLANT
NPDES NO PR0026695**

This Fact Sheet sets forth the principle 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 Environmental Quality Board (EQB) 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 October 31, 2017, EQB 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.

PART I. BACKGROUND

A. Permittee and Facility Description

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 discharging pursuant to NPDES Permit No. **PR0026695**. The Permittee submitted **Application Form 1 dated June 1, 2016 and Form 2C dated June 1, 2016**, and applied for an NPDES permit to discharge **treated wastewater from the Amgen Manufacturing Limited Wastewater Treatment Plant** (referred herein as "the facility"). AML updated their application with a supplement dated August 17, 2016. The facility is classified as a **major** discharger by EPA in accordance with the EPA rating criteria.

Amgen Manufacturing Limited (AML) is a biotechnology manufacturing company with one of its facilities in Juncos, Puerto Rico. AML proposes to discharge a daily maximum of 1892.71 m³ (0.5 MGD) as treated process wastewater, blowdown and other wastewaters after tertiary treatment at this wastewater treatment plant (WWTP). The facility currently discharges this treated wastewater as a pretreatment source to nearby PRASA wastewater treatment plants. AML has applied for a direct discharge NPDES permit as a contingency for extreme circumstances that may render the PRASA facilities unavailable for pretreatment discharge.

The point of discharge from the AML plant in Juncos, Puerto Rico, designated as Outfall 001, discharges to Gurabo River. The receiving water has been classified SD by the Puerto Rico Environmental Quality Board (EQB). Attachment A of this Fact Sheet provides a map of the area around the facility and a flow schematic of the facility.

The treatment system consists of Equalization tanks, pH adjustment, Membrane Biological Reactor biological treatment, solids treatment, and reverse osmosis, evaporation, and metals precipitation.

Summary of Permittee and Facility Information

Permittee	Amgen Manufacturing Limited (AML)
Facility contact, title, phone	Kerry Ingalls, Vice President, Site Operations, (787) 916-5677; kingalls@amgen.com
Permittee (mailing) address	P.O. Box 4060, Juncos, Puerto Rico, 00777
Facility (location) address	State Road PR-31, Km. 24.6
Type of facility (SIC Code)	Pharmaceuticals Manufacturing, Biological Products (2836) and Pharmaceutical Preparations (2834)
Pretreatment program	Does not receive Pretreatment Waste, does discharge as a pretreatment source to PRASA
Facility permitted flow	0.5 MGD
Facility classification	Major

B. Discharge Points and Receiving Water Information

Wastewater is discharged from Outfall **001** to the **Rio Gurabo**, a **water** of the United States classified as SD.

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	<type(s) of effluent>	18 ° , 14' , 33" N	65 ° , 54' , 15" W	Rio Gurabo, Class SD

As indicated in the Puerto Rico Water Quality Standards (PRWQS) Regulations, the designated uses for Class **SD** receiving waters include, Surface waters intended for use as a raw source of public water supply, propagation and preservation of desirable species, including threatened or endangered species, as well as 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 TMDLs for those waters. The receiving water **has not** been determined to have water quality impairments for one or more of the designated uses as determined by section 303(d) of the CWA.

D. Compliance Orders/Consent Decrees

The Permittee **does not have any compliance order or consent decrees that affect this permit action.**

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 (April 2016)
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 at 40 CFR §439.25

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.

A. Effluent Limitations

The permit establishes **both Technology-based Effluent Limitations (TBELs) and WQBELs** for several pollutants and the basis for these limitations are discussed below.

1. Water Quality Based Effluent Limits (WQBELs)

Water Quality Based Effluent Limits established through the final WQC issued by the Puerto Rico Environmental Quality Board for Effluent Flow, 1,2-Dichloroethane, 2,4,6-Trichlorophenol, 2-Methyl-4,6-Dinitrophenol, Arsenic, Benzene, Cadmium, Chlorides, Chromium VI (Cr+6), Color, Copper, Free Cyanide, Dissolved Oxygen, Enterococci, Lead, Mercury, Methylene Chloride, Oil & Grease, Pentachlorophenol, pH, Residual Chlorine, Selenium, Solids and Other Matter, Sulfates, Sulfide (undissociated H₂S), Surfactants (as MBAS), Suspended, Colloidal or Settleable Solids, Taste and Odor Producing Substances, Temperature, Total Ammonia Nitrogen (TAN), Total Dissolved Solids, Total Nitrogen (NO₃, NO₂, TKN), Total Phosphorous, Turbidity, Whole Effluent Toxicity, Zinc.

2. Technology-based Effluent Limitations (TBELs)

Technology Based effluent limits were based on Effluent Limitation Guidelines (ELG) for the Pharmaceutical Manufacturing Point Source Category, Mixing and Formulating Subcategory, at 40 CFR §439.25 for 5-day Biochemical Oxygen Demand (BOD₅), Chemical Oxygen Demand (COD), and Total Suspended Solids. Technology based limitations for BOD₅ and TSS were more stringent than the WQBELs included in the final WQC issued by the EQB. In accordance with NPDES Regulations at 40 CFR 122.44, EPA included the more stringent technology based effluent limitation.

B. 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

This facility is not subject to influent monitoring requirements.

2. Effluent Monitoring Requirements

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 TSD. Consistent with 40 CFR Part 136 monitoring data for toxic metals must be expressed as total recoverable metal

C. 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)(2) and 303(d)(4) and federal regulations at 40 CFR 122.44(l) prohibit backsliding in NPDES permits. Further, the Region 2 Antbacksliding 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. All effluent limitations in the permit are at least as stringent as the effluent limitations in the existing permit.

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. In accordance with 40 CFR 124.55, EPA has established Special Conditions from the WQC in the permit that EQB determined were necessary to meet PRWQS. The Special Conditions established in this section are only those conditions from the WQC that have not been established in other parts 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. The Permittee has indicated the outfall is not in a coastal area managed by the Commonwealth's Coastal Zone Management Program and, although nearby, EPA has determined it will not affect the coastal area. Therefore, the requirements of 40 CFR 122.49(d) do not apply to this discharge.

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.

The ESA requires the Regional Administrator to ensure, in consultation with the Secretary of the Interior or Commerce, that any action authorized by EPA is not likely to jeopardize the continued existence of any endangered or threatened species or adversely affect its critical habitat.

In a May 2000 memo to the Regions, EPA Headquarters provided guidance to the Regions in making a determination as to whether a final permit may be issued while waiting for consultation to be concluded. As part of this permit action, if consultation has not been completed by final permit issuance and EPA has concluded that permit issuance is consistent with section 7 prior to the conclusion of consultation, EPA will re-issue the final permit before consultation is concluded and will document this decision in the Administrative Record. At the time consultation is completed, EPA may decide that changes to the permit are warranted after permit issuance based on the results of the consultation. Therefore, a reopener provision to this effect has been included in the Permit Part IV.A.1.b.

E. 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.

F. 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.

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 in *El Vocero*. 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

Karen O'Brien

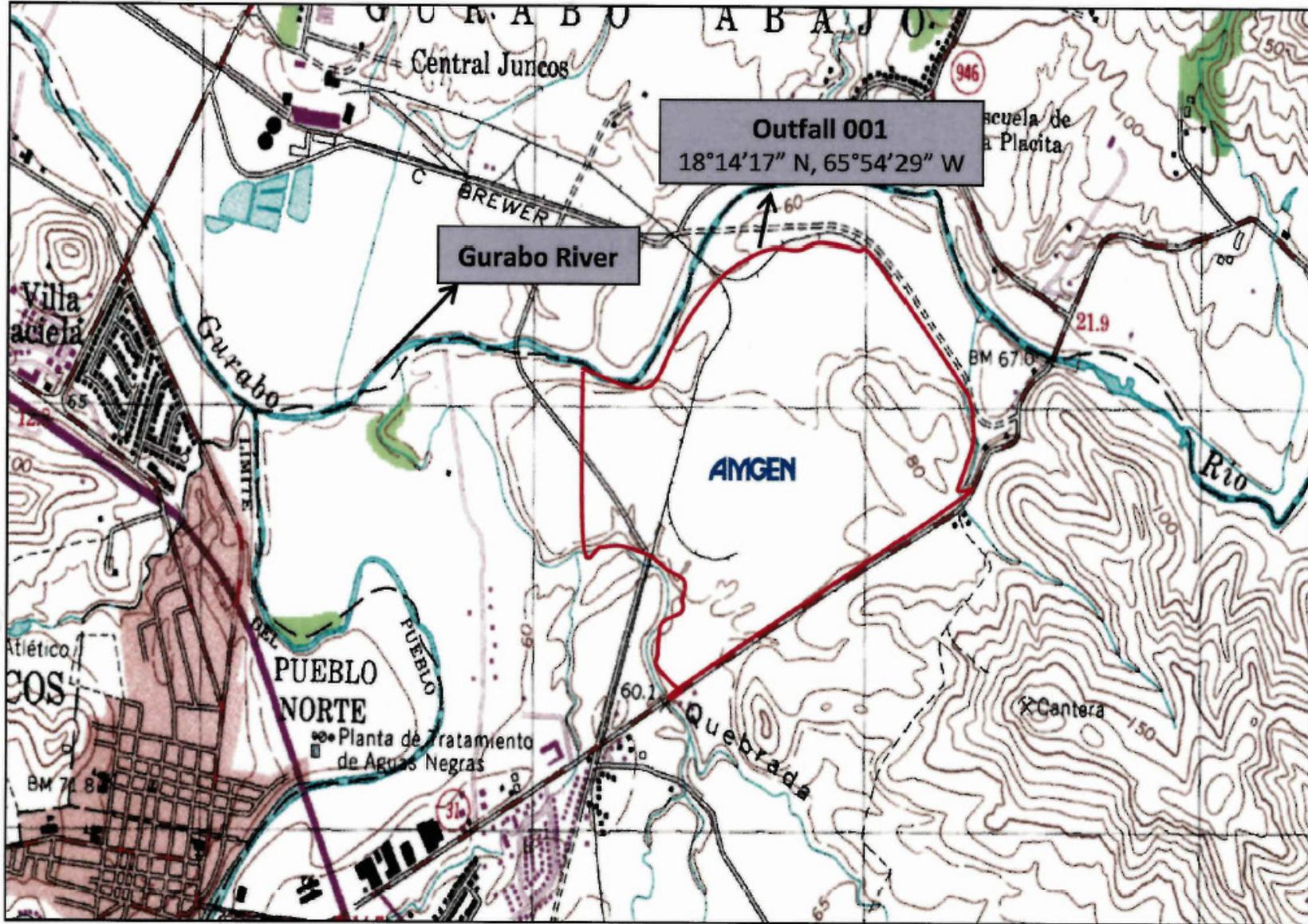
EPA Region 2, Clean Water Division
Permit Writer Phone: 212-637-3717
Permit Writer Email: obrien.karen@epa.gov

A copy of the draft permit is also available on EPA's website at

<https://www.epa.gov/npdes-permits/puerto-rico-npdes-permits>

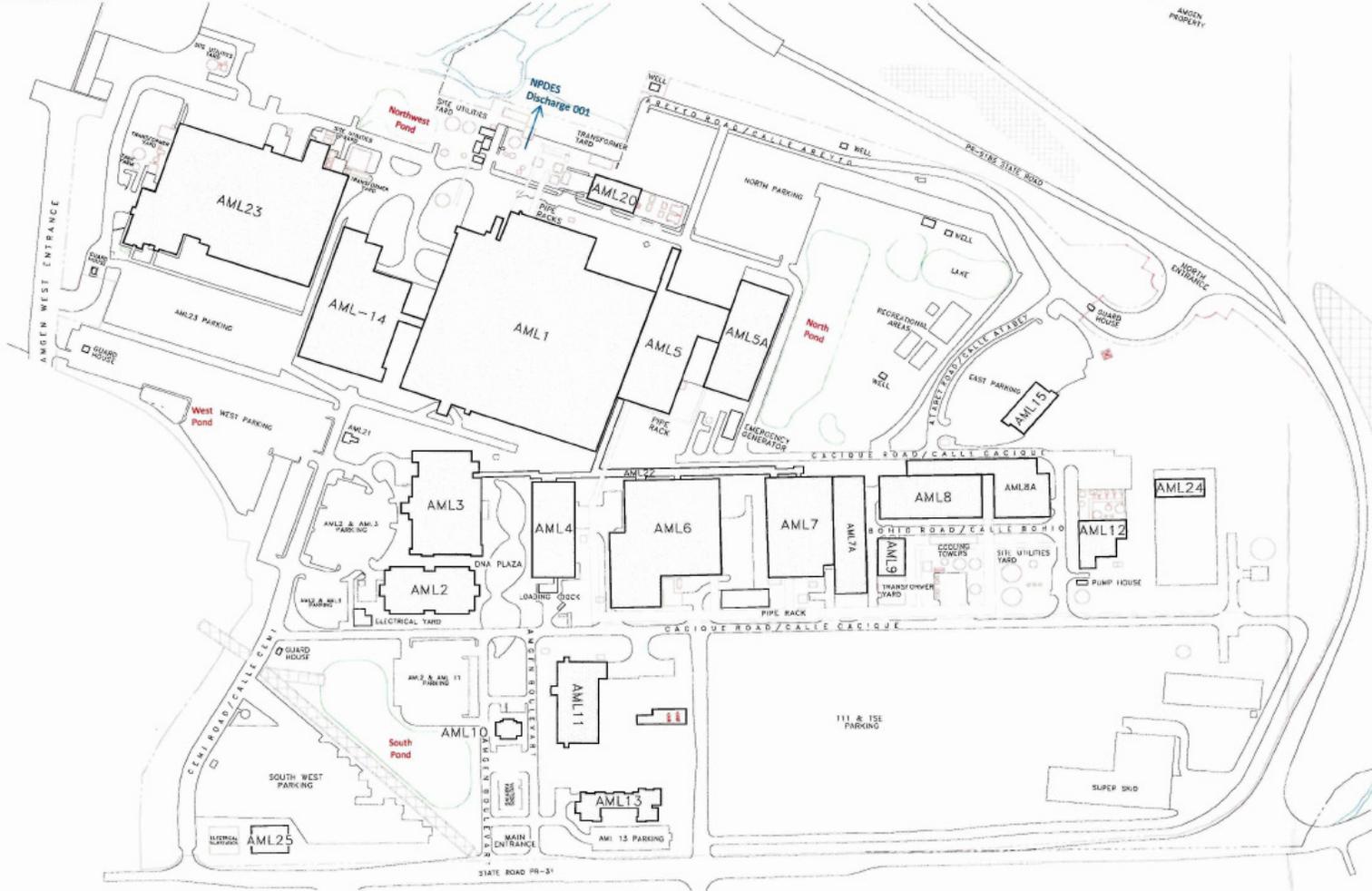
ATTACHMENT A — FACILITY MAP AND FLOW SCHEMATIC

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





General Site Diagram



- 1. Property size: 201.6 acres
- 2. Shown structures, including buildings and paved roads, account for the impervious surfaces at the site.
- 3. Wastewater Treatment Plant (WWTP) = AML-12 BUILDING

