

Statement of Basis
Modification of National Pollutant Discharge Elimination System (NPDES) Permit issued to
Amgen Manufacturing, Limited (AML) for the
AML Wastewater Treatment Facility (PR0026695)

On September 29, 2011, the U.S. Environmental Protection Agency, Region 2 (EPA) issued a final NPDES permit to Amgen Manufacturing, Limited (AML) for the AML Wastewater Treatment Facility located in Juncos, Puerto Rico. EPA specified that the Permit was to become effective on December 1, 2011.

On November 17, 2011, pursuant to 40 CFR §§124.19, AML filed a Petition appealing certain conditions (the “Contested Conditions”) included in the referenced Permit. EPA entered into the Alternative Dispute Resolution Process with AML and has since agreed to make the modifications requested in the Petition. This permit modification action memorializes EPA’s decision on the contested conditions. EPA is accepting comment solely on the modified conditions, which are explained in this Statement of Basis. All other conditions of the permit remain in effect.

EPA’s decision is based on a review of the final water quality certificate issued by the Puerto Rico Environmental Quality Board on September 30, 2010, as modified on June 6, 2011, as well as our intention to clarify the meaning of “Effective Date of Commencement of Discharge.” AML is seeking NPDES permit coverage for contingency discharges resulting from a natural disaster or other emergency which could impair their ability to discharge as a pretreatment source to facilities operated by the Puerto Rico Aqueduct and Sewer Authority.

Certain conditions of the NPDES permit require monitoring to collect data to allow EPA and EQB to calculate water quality based permit limitations. AML met with EPA and also commented on the proposed permit to express their concern that these monitoring requirements compel a discharge from this facility. It was EPA’s intention, with the establishment of the “Effective Date of Commencement of Discharge (“EDCD”)” provision, to address this concern expressed by AML and only require these monitoring conditions to be in effect when the facility was engaged in a planned, continuous discharge. In this petition, AML commented that it was not clear that this note was for planned continuous discharges and that AML would not be able to notify EPA and EQB in advance of emergency, contingency discharges. To address this concern, EPA has included a clarifying note to the ED CD provision.

The other three comments made by AML are typographical errors, which are corrected with this permit modification. All changes to the permit are summarized in the attached Table 1. Changed pages included in this modification will be substituted for those same pages in the final permit issued September 29, 2011, and shall take effect upon finalization of this modification.

Table 1: Withdrawn Permit Conditions and Proposed Modification AML Wastewater Treatment Facility (PR0026695)

Page Number	Proposed Modified Condition
6	<p>Footnote Φ to Table A-1 has been modified as follows to correct a typographical error:</p> <p>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, until the completion of twelve (12) sampling events, after which they will be conducted annually. The sampling events cannot be not more often than one event per month. The monitoring program shall commence not later than thirty (30) days after the EQB's written approval of the Quality Assurance Project Plan (QAPP). The QAPP must be submitted for evaluation and approval of EQB not later than thirty December 31, 2011. The results of the monitoring program shall be submitted to EQB and EPA-Region 2 no later than sixty (60) days of completion of the monitoring program. Based on the evaluation of the results obtained, EQB will determine if an effluent limitation is necessary for this parameter. In such case, the WQC will be reopened to include the applicable effluent limitation.</p>
6	<p>Footnote λ to Table A-1 has been modified as follows to correct a typographical error:</p> <p>The permittee shall implement a 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, until the completion of twelve (12) sampling events, after which they will be conducted annually. The sampling events cannot be not more often than one event per month. The monitoring program shall commence not later than thirty (30) days after the EQB's written approval of the QAPP. The QAPP must be submitted for evaluation and approval of EQB not later than December 31, 2011. The results of the monitoring program shall be submitted to EQB and EPA-Region 2 not later than sixty (60) days of completion of the monitoring program. Based on the evaluation of the results obtained, EQB will determine if more frequent monitoring is necessary for this parameter. In such case, the WQC will be reopened to revise the monitoring frequency for such parameter, if considered necessary.</p>
7	<p>The EPA Note to Table A-2 has been modified as follows to clarify the conditions related to Effective Date of Commencement of Discharge (EDCD):</p> <p><i>EPA Note: The Effective Date of the Commencement of Discharge (EDCD) shall be the date upon which the permittee begins planned, continuous discharge to the Gurabo River. The permittee shall notify both EPA and EQB in writing of the intent to commence planned, continuous discharge fourteen (14) days prior to the ED CD, at the addresses listed in Part I.C. In the event that the QAPPs are approved by the EQB prior to the ED CD, the monitoring programs shall commence not later than thirty (30) days after the ED CD. The ED CD does not apply to short-term discharges that are the result of emergency circumstances or contingency actions.</i></p>
31	<p>Bullet item identifier "e." has been added to identify the paragraph on Compliance Schedules to correct a typographical error.</p>