RESPONSE TO COMMENTS ON
DRAFT NPDES PERMIT FOR
AMGEN MANUFACTURING LIMITED (PR0026695)
SEPTEMBER 2011

On July 23, 2010, the United States Environmental Protection Agency (EPA) issued a draft National Pollutant Discharge Elimination System (NPDES) permit (PR0026695) to the Amgen Manufacturing, Limited (AML) Company for its pharmaceutical manufacturing facility in Juncos, Puerto Rico. Public notice of the draft permit was provided in the *Puerto Rico Daily Sun* newspaper on July 23, 2010. The public comment period for the draft NPDES permit ended on August 23, 2010.

The final water quality certifícate for this permit was issued by EQB on September 30, 2010. Amgen submitted a Petition for Reconsideration to the EQB within the 21-day appeals period in October 2010. EQB issued a decision on the Petition for Reconsideration on June 6, 2011, which included some modifications to the final water quality certifícate language. EPA has included the final water quality certificate requirements, as modified on June 6, 2011.

According to 40 Code of Federal Regulations (CFR) §124.17, at the time that any final permit decision is issued under §124.15, EPA shall issue a response to comments. This response shall: (1) specify which provisions, if any, of the draft permit have been changed in the final permit decision, and the reasons for the change; and (2) briefly describe and respond to all significant comments on the draft permit raised during the public comment period.

Comments were received from the following parties:

Ms. Glynda Harrington, Director
Environmental Health and Safety
Amgen Manufacturing, Limited

Comments on the Draft NPDES Permit No. PR0026695
Amgen Manufacturing, Limited (AML)
Juncos, Puerto Rico

The following are comments from the permittee, Amgen Manufacturing, Limited ("AML"), to the draft National Pollutant Discharge Elimination System ("NPDES") Permit, permit number PR0026695 (the "Draft NPDES Permit") issued by the United States Environmental Protection Agency ("USEPA"). After each comment, EPA Region 2 provides a response.

The permittee's comment submission began with an Introductory Section, labeled Section A, which has been omitted since it did not contain comments on the permit.

Amgen has reviewed the Draft NPDES Permit, the Fact Sheet, the PREQB Letter, the Draft WQC, PREQB Preliminary Determinations and other related documents and hereby submits its comments for the USEPA's consideration.

General Comments (Identified as "Section B. General Comments" in the Submission by AML)

1. Permitting Process

An NPDES permit is issued either by the USEPA or by a state, if the state has received permitting authority from the USEPA, pursuant to Section 402(b) of the Clean Water Act ("CWA"), 33 U.S.C. §§ 1251-1387. In the case of Puerto Rico, the USEPA is the NPDES permitting authority. Where the USEPA is the permitting authority, the state in which the discharger is located must certify that the discharge authorized in the permit will comply with state water quality standards and other requirements. CWA Section 401(a), 33 U.S.C. § 1341(a); 40 C.F.R. Part 121. In such cases, the state agency with jurisdiction over water pollution control, issues a WQC after the USEPA has deemed the application for a NPDES permit complete. The WQC shall incorporate effluent limitations and any special mechanisms requested on the application, such as the waste load allocation. Following the granting of the WQC, the USEPA will issue the Draft NPDES Permit based on the effluent limitations and conditions included in the state issued WQC. The specific procedures for the adoption of the Water Quality Standards ("WQS") and mechanisms to implement effluent limitations on the discharge are described on the PRWQSR.

The USEPA must then publish a notice of the issuance of the draft permit in a local newspaper and must accept comments from the public for at least 30 days. 40 C.F.R. §§ 124.10(c), 124.11. After accepting comments, the USEPA will evaluate the comments and issue a final permit decision, which becomes effective in 30 days, unless a later date is specified or review is requested. 40 C.F.R. §124.15.

In the case at hand, in order to accelerate the permitting process, the USEPA and the PREQB published the Draft NPDES Permit and the Draft WQC almost simultaneously. However, as required by the CWA, the USEPA cannot issue a final NPDES permit until the PREQB grants the final WQC. 40 C.F.R. §124.53. Therefore, even when AML submits to the USEPA its comments on the Draft NPDES Permit in a timely manner, the USEPA should wait for the WQC process to finalize to determine whether a revised draft NPDES Permit has to be issued to incorporate any changes made to the WQC. Since the process before the PREQB is still in its commenting phase, PREQB may continue addressing comments from any interested party, including AML, which might entail changes to the Draft WQC.[1] Following this process and as stated in the PREQB Letter, any condition adopted in the WQC will have to be incorporated into the final NPDES Permit in order to satisfy the provisions of Section 301(b)(1)(c) of the CWA.

Moreover, given certain discrepancies found between the Draft NPDES Permit and the Draft WQC, AML respectfully submits that the USEPA must reissue the Draft NPDES Permit to correct such discrepancies. See comments in items B.2 and B.4 below.

EPA Response B.1:

All conditions of the final water quality certificate have been incorporated into the final NPDES permit. EPA has not finalized the NPDES permit until the public participation process for the water quality certificate and petition for reconsideration was fully resolved between EQB and AML. EPA has reviewed the changes between the draft NPDES permit and final NPDES permit, and does not believe there are new requirements from draft to final for which AML has not had an opportunity to provide comment.

2. The Fact Sheet is Vague and Lacks Necessary Information

The CWA regulatory framework requires that the draft NPDES Permit be accompanied by a fact sheet or statement of basis explaining how the permit's terms and conditions were calculated and developed. 40 C.F.R. §§ 124.7, 124.8, 124.56. Specifically, the Fact Sheet must "set forth the principal facts and significant factual, legal, methodological and policy questions considered in preparing the draft permit". 40 C.F.R. §§ 124.6 and 124.8. For NPDES permits, the fact sheet must include calculations or other necessary explanation of the derivation of specific effluent limitations and conditions or an explanation of how the alternate effluent limitations were developed. 40 C.F.R. § 124.56(a). For USEPA-issued NPDES permits, the fact sheet must also include the State certification requirements. 40 C.F.R. § 124.56(d).

Although the USEPA did prepare the Fact Sheet to accompany the Draft NPDES Permit, the same is vague and lacks required information. Specifically, the Fact Sheet states in the last sentence of the first page that a map showing the location of the facility is found in Attachment I. In addition, the Fact Sheet states in item IV that state certification

[1] The comment period for the Draft WQC is open until September 3, 2010.

requirements are described in Attachment III. However, the Fact Sheet does not include a map in any of its pages or attachments identified either as "Attachment I" or "Attachment III". The Fact Sheet only includes one attachment identified as "Attachment II".[2]

Also, the Fact Sheet is silent on whether AML's WLA request was considered to determine the effluent limitations proposed in the Draft NPDES Permit and the Draft WQC. In regards to the proposed effluent limitations, the Fact Sheet states that "all effluent limitations and monitoring requirements of parameters listed in Table A-1 are as imposed" in the Draft WQC. However, after comparing both documents, the Draft NPDES Permit and the Draft WQC, AML has found several differences including the effluent limitation for the Phosphorus, BOD and TSS parameters.

AML understands that the PREQB developed the conditions and language related to the WLA for the Draft WQC. However, the USEPA did not include any information in the Fact Sheet that shows whether it requested information from the PREQB on the development of the WLA or any justification reached by the PREQB for the inclusion or rejection of the effluent limitations requested by AML under the WLA mechanism.

EPA Response B.2:

EPA has corrected any discrepancies between the draft NPDES permit and the final Water Quality Certificate. In the case of BOD_5, COD, and TSS additional limitations were included to meet the requirements of federal effluent limitation guidelines at 40 CFR Part 439 for the Pharmaceutical Point Source Category. EPA notes the deficiency of the map in the fact sheet and has attached a map to this responsiveness summary, which, along with the draft permit fact sheet, draft permit, and draft and final water quality certificates become part of the administrative record for this permit decision. All NPDES permit decisions are based on the administrative record, which includes the NPDES permit application, correspondence with the permittee and other documents that may not have been included as part of the draft NPDES permit and fact sheet.

3. Technical Basis for Adoption of Effluent Limitations

The primary purpose of the NPDES permit is to establish enforceable effluent limitations. In addition to effluent limitations, the NPDES permit establishes a number of other enforceable conditions, such as monitoring and reporting requirements, a duty to properly operate and maintain systems, upset and bypass provisions, recordkeeping, and inspection and entry requirements. In the adoption of the effluent limitations the PREQB uses the WQS promulgated under the PRWQSR. The actual mechanisms to apply these standards and develop the effluent limitations that will be included in the WQC are established on the PRWQSR and include alternatives such as the WLA mechanism requested by AML. The practice of PREQB is that if it determines not to grant the WLA,

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[2] The version of the Fact Sheet found on EPA's website, http://www.epa.gov/region02/water/npdes_fs_amgen.pdf, is identical to the one received by AML, which does not include an attachment identified as "Attachment III".

the discharge is defaulted to comply with the WQS at the point of discharge, not in the receiving waters.

When AML submitted the application, it requested the PREQB to adopt a WLA for thirteen (13) parameters. Of the thirteen parameters with WLA submitted by AML, none were granted. Of those requested, only Copper and Lead were given concentrations above the water quality standards. For the rest of the eleven (11) parameters the Maximum Requested Discharge Concentrations ("MRDC") were rejected and the water quality standards for surface waters, classified as SD, found in the PRWQSR were adopted. Given the foregoing, it is possible that some of the parameters included in the Draft NPDES Permit may restrict the effluent of AML's WWTP. For example, as currently operated the WWTP may have problems achieving the effluent limitations established for Chlorides, Chromium VI, Copper, free Cyanide, Selenium and Surfactants. In addition, not being able to apply the MRDCs for Total Dissolved Solids and Chlorides may limit the discharge of concentrates and brines to the water body. Neither the USEPA's Fact Sheet nor the PREQB Preliminary Determination provides information or the reasoning to support or deny AML's request for a WLA.

Although State water quality standards normally consist of a numeric level of a pollutant that cannot be exceeded in the ambient water, the PRWQSR specifically states in Rule 1306.11 that water quality standards promulgated by the regulation are not concentration limits applicable to the effluent. USEPA's regulations require permits to include water quality-based limitations for all pollutants that "are or may be" discharged at levels that cause, have a "reasonable potential to cause, or contribute to an excursion above any State water quality standard." 40 C.F.R. § 122.44(d)(1)(i). Therefore, in setting a permit limitation to meet a water quality standard, the permit writer should calculate how much of the pollutant the permittee may discharge without causing the ambient standard to be exceeded. To calculate an appropriate permit limitation based on a numerical state standard, the permit writer should take into account the dilution provided by the receiving body of water. Where mixing with the receiving water occurs rapidly, the permit writer should consider the flow of the receiving stream as compared to the flow of the outfall and develop a dilution factor. The ambient water standards should then be multiplied by this dilution factor to determine the permit limitations.

EPA Response B.3

The limitations in the final permit for the above parameters are based on the final WQC issued by EQB on September 30, 2010, as amended June 2, 2011. EQB has authority pursuant to Section 401(d) of the Clean Water Act to establish limitations which it believes are necessary to meet the applicable Commonwealth water quality standards. In exercising its authorities, EQB has chosen to establish limitations based both on standards end-of-pipe and a wasteload allocation for certain parameters, which, in its judgement, are appropriate. When certification is required under CWA Section 401(a)(1), no final permit can be issued unless the final permit incorporates the requirements specified in the certification (40 CFR 124.55(a)(2)).

Section 301(b)(1)(C) of the Clean Water Act (CWA) requires that there be achieved effluent limitations necessary to assure that a discharge will meet Water Quality Standards (WQS) of the applicable State and Federal laws and regulations where those effluent limitations are more stringent than the technology-based effluent limitations required by the CWA. Section 401(a)(1) of the CWA requires that the State certify that the discharge will comply with the applicable provisions of sections 301, 302, 303, 306 and 307 of the CWA. Pursuant to Section 401(d) of the CWA any certification shall set forth any effluent limitations and other limitations, and monitoring requirements necessary to assure that any applicant for a Federal permit will comply with any applicable effluent limitations and other limitations under section 301 or 302 of the CWA, and with any other appropriate requirement of State law set forth in such certification. Also, 40 C.F.R. 122.44(d) requires that each NPDES permit shall include requirements which conform to the conditions of a State Certification under Section 401 of the CWA that meets the requirements of 40 C.F.R. 122.53. Similarly, 40 C.F.R. 124.55 requires that no final NPDES permit shall be issued unless the final permit incorporates the requirements specified in the certification under §124.53. Concerning the certification requirements in 40 C.F.R. 124.53(e)(1), they specify that all Section 401(a)(1) State certifications must contain conditions which are necessary to assure compliance with the applicable provisions of CWA sections 208(e), 301, 302, 303, 306, and 307 and with appropriate requirements of State law.

The final WQC by EQB certified that pursuant to Section 401(a)(1) of the CWA, after due consideration of the applicable provisions established under Sections 208(e), 301, 302, 303, 304(e), 306 and 307 of the CWA concerning water quality requirements, there is reasonable assurance that the discharge will not cause violations to the applicable WQSs, provided that the effluent limitations set forth in the WQC are met by the above facility.

The effluent limitations (where more stringent than technology-based effluent limitations), monitoring requirements and other appropriate requirements of State law (including footnotes, Special Conditions, etc.) specified in the final WQC issued by the EQB were incorporated by EPA into the NPDES permit as required by Section 301(b)(1)(C) and 401(d) of the CWA and the applicable regulations. Therefore, concerns and comments regarding the WQC must be directed to EQB or to the Superior Court.

4. Reference to PREQB's Prior Water Quality Standards Regulation in the Draft NPDES Permit

Although the draft WQC issued by the PREQB includes references to the current PRWQSR, the Draft NPDES Permit makes reference to sections from the repealed version of the PRWQSR. Once again, this reflects the importance of following the required permitting process for the approval of the NPDES Permit, which requires that prior to issuing the draft NPDES Permit, a final WQC must be obtained from the state agency with jurisdiction over water pollution control, in this case the PREQB. In this

regard, AML understands that the Draft NPDES Permit should be revised to incorporate the correct legal references.

EPA Response B.4:

The limitations, conditions, and legal references of the final water quality certificate have been incorporated in the final NPDES permit.

5. Amgen's Operational Changes

Since the NPDES Permit Application was submitted more than three (3) years ago, several changes have occurred in AML's operation. Originally, the concept of the OPUS Expansion Project included the discharge of the treated effluent to the Juncos Publicly Owned Treatment Works ("POTW"), operated by the Puerto Rico Aqueduct and Sewer Authority ("PRASA") and to the Gurabo River. The discharge to the Gurabo River required the issuance of a NPDES Permit for which the NPDES Permit Application was submitted. Although the NPDES Permit Application stated that AML would discharge its treated effluent to the Juncos POTW, currently AML discharges to the Caguas POTW as authorized by PRASA by way of an Industrial Discharge Permit GDA-92-608-076 (the "PRASA Permit").

During the first years of the expansion project, the WWTP suffered several changes to optimize and troubleshoot its operation. AML includes a list of the most significant changes to the WWTP:

a. New Jet Aeration System on the equalization ("EQ") tanks, includes Jet Aeration on EQ#1 already installed and fully operational and Installation of Jet Aeration on EQ#2 in process;

b. AML-6 and AML-7 High Stream discharge process, which includes:

    1. Ethanol, Urea and HBOD waste stream from AML-6 tanks is now received in the EQ tanks. Please note that prior to the installation of the Jet Aeration system, the waste stream went directly to the pH neutralization tank;

    2. HBOD waste stream from AML-7 tank is now received in the EQ tanks. Please note that prior to the installation of the Jet Aeration system, the waste stream went directly to the pH neutralization tank;

c. Spent Brine (i.e., regeneration wastewater from AML-1 and AML-8 utilities) can now be treated on the WWTP. Prior to the installation of the Jet Aeration system, the spent brine was hauled for disposal at an offsite facility;

d. The process sump waste can now be received in the EQ tanks. Prior to the installation of the Jet Aeration system, the waste stream went directly to the pH neutralization tank;

e. Utilities wastewater stream from the new structure AML-23 building (Manufacturing) is also directed and treated in the WWTP. In the future, the process wastewater from new building AML-14 will also be directed to the WWTP;

f. Nearly 80 % of the wastewater entering the WWTP is recycled and used in AML's utilities;

g. Sanitary wastewater is not treated in the WWTP. It is discharged through segregated lines directly to the Caguas POTW.

h. The Brine generated by the WWTP (*i.e.*, rejected wastewater from reverse osmosis treatment) is being evaluated to determine whether it can be discharged through the WWTP to the Caguas POTW.

i. Fermentation processes are currently performed at manufacturing buildings AML-6 and AML-7. These processes commence with the fermentation of a cell. Afterwards, the cell seeds are inoculated in a fermentor and, then, a protein is extracted. The aqueous waste of these processes is sent to the HBOD tanks of buildings and from there to the EQ tanks to be injected for treatment at the WWTP. These waste streams are mostly constituted of organic media nutrients and buffer solutions.

Notwithstanding the above, AML understands that operational changes and the new waste streams will not affect either the performance of the WWTP, the quality of the effluent or require an increase in the proposed flow parameter included in the Draft NPDES Permit and NPDES Permit Application.

In addition to the foregoing, some of the information included in the NPDES Permit Application has changed.

a. The process description of the treatment units described in Appendix F of the NPDES Permit Application has been modified. New equipment has been installed in the WWTP and the equalization tank flow streams have experienced changes. However, the effluent is still tertiary treated effluent, as described previously, and includes all the process units presented on Appendix F of the NPDES application.

b. The septic system that had a UIC Permit in the NPDES Permit Application is closed and no longer exists. There are no septic tanks on the Facility. Therefore, there is no need to include conditions or restrictions on such units.

c. New buildings that have discharges need to be included in Appendix G, including AML-23, AML-14, as well as the potable water and other new projects. In addition, permit expiration dates should be revised.

d. The water balance included on Appendix E of the NPDES Permit Application is not current.

e. The NPDES Permit Application established that the Juncos WWTP was the receiving POTW. However, since July 7, 2009, AML's effluent was authorized and is being received by the Caguas POTW.

f. Henry McLeod and Madhaven Balachandran appear as contact persons in the NPDES Permit Application. However, due to changes in personnel, the current contact persons for this permit are Glynda Harrington and Emilio Rivera.

g. Current data obtained by GPS shows that the location of the discharge, Discharge Point 001, should be described by the following coordinates: N 18˚14.283', W 065˚54.480'.

EPA Response B.5:

EPA notes the operational changes and updates to the information submitted in the original NPDES Permit Application. In general, the changes described above have not resulted in revisions to the NPDES permit conditions specified in the draft permit. This responsiveness summary is part of the Administrative Record for this permit issuance, therefore the information above has been entered into the Administrative Record for this permit.

6. Establishing Discharge Point 001

The structure of the Discharge Point 001 to the Gurabo River consists of the following items:

a. Connection between the AML WWTP and Discharge Point 001, which is currently in place;

b. Cooling tower and Parshall flume at the Discharge Point 001 location; and

c. Discharge Point 001 to the Gurabo River.

Although AML has the foregoing equipment in place, due to the passage of time between the date when the NPDES Permit Application was submitted and the equipment was installed to the present, some of the equipment has suffered damages. In order to determine whether the equipment is still operational, several tests, repairs and/or replacement must be conducted. In view of the foregoing, AML will need to

implement a capital project plan for which a scope of work, budget and design must be approved. Therefore, AML estimates that the Discharge Point 001 and its supporting infrastructure would be fully operational in a period of approximately 6 to 9 months.

Given a preliminary evaluation of the current conditions of Discharge Point 001, some of the activities necessary to place it in operation would be:

a. The replacement of the Parshall flume at the Discharge Point 001;

b. Installation of measurement instrumentation equipment (*i.e.*, pH, Flow);

c. The reconstruction of the discharge pipe to the Gurabo River;

d. The discharge point must be fenced and identified with a sign reading "Punto de Muestreo para la Descarga 001" as per Special Condition No. 10 of the Draft NPDES Permit;

e. The utilities (*i.e.*, cooling tower, pipes, pumps) must be tested to confirm their operational status. Once tested AML will determine whether any of them require replacement or repair; and

f. Test of the complete system prior to any discharge into the Gurabo River.

Therefore, AML requests that the USEPA consider establishing the effective date of the NPDES permit ("EDP") after the completion of the above activities. To allow EPA to determine the EDP, AML will submit via letter a written confirmation to the USEPA of the completion of said activities. This confirmation also ensures that the activities described previously have been completed prior to initiating the discharge via the NPDES Outfall. Following such confirmation, the USEPA may issue a written statement establishing the EDP of the final NPDES Permit.

EPA Response B.6:

Final EPA permit decisions become effective 30 days after the service of notice unless a later effective date is specified in the decision (40 CFR §124.15). It is EPA's understanding that the facility is not currently discharging. All effluent limitations and special conditions are in effect upon the effective date of the permit. However, AML is under no obligation to commence discharging at the effective date of this permit. EPA has revised the timeframes for milestones that require discharge, such as monitoring studies in support of a waste load allocation, to the effective date of the commencement of discharge (EDCD). EPA agrees that AML should notify EPA and EQB in writing two weeks prior to the commencement of continuous discharge. Accordingly, we have made this a condition of the NPDES permit.

7. Use of Discharge 001 as an alternative to discharge to the Caguas POTW.

As mentioned in item B.5 above, currently all of AML's effluent from the WWTP is received by the Caguas POTW. Therefore, the use of the Discharge Point 001 to discharge effluent into the Gurabo River is being considered by AML as an alternative or emergency operating scenario and/or backup plan to the current discharge of effluent to the Caguas POTW. Given the foregoing, AML does not foresee a steady flow of effluent discharging at Discharge Point 001. Therefore, AML will not be able to conduct some of the monitoring and reporting requirements of the permits in a regular manner as required by the Draft NPDES Permit. Accordingly, AML requests that the USEPA consider whether the monitoring and reporting requirements may be relaxed to address this type of scenario. In addition, AML requests that any ambient monitoring studies for WLA validation and the condition of the Toxicity Reduction Evaluations and testing be relaxed or waived until actual operation of the discharge is confirmed as proposed in item B.6. This confirmation can be made in writing at least three (3) months before the actual discharge commences.

Several of the conditions of the Draft NPDES Permit require the implementation of monitoring programs for extended periods (*e.g.*, one (1) year after the Effective Date of the NPDES Permit) to validate the parameters found in the permit. Among them, the WLA sampling described in Table A-2 and the Model Calibration Monitoring Requirements described in Table A-3. Given that AML will not regularly discharge through Discharge Point 001 the implementation of such monitoring programs will not be possible. AML could, however, submit to the USEPA in lieu of the baseline sampling required by the Draft NPDES Permit: (1) historical sampling data from the WWTP to demonstrate compliance with parameters (including discharges made to the PRASA pretreatment system); or (2) conduct laboratory benchscale testing (e.g., modeling, simulation, etc.) to demonstrate compliance with specific parameters or simplified toxicity testing in lieu of the detailed static type bioassays requested under the special conditions. In any case, either alternative may be implemented once the NPDES Permit is effective and a discharge commencement date is confirmed in writing by AML.

EPA Response B.7:

It is EPA's understanding that the facility is not currently discharging. AML is under no obligation to commence discharging at the effective date of this permit. EPA has revised the timeframes for milestones that require discharge and begin at the effective date of permit (EDP) to the effective date of the commencement of discharge (EDCD). As noted above, AML will be required to notify EPA and EQB in writing two weeks prior to the commencement of discharge, which is a condition of the NPDES permit. All timeframes that are included in the draft NPDES permit from the EDP have been revised to the effective date of the commencement of discharge.

C. Specific Comments:

1. Several special conditions contained in the Draft NPDES Permit have no correlation with the Draft WQC's special conditions.

   a. The Draft NPDES Permit's Special Condition No. 13 cites Section 6.8 of the PRWQSR. However, according to the Draft WQC the applicable rule is Rule 1306.8. (See Draft WQC's Special Condition No. 9 and Draft NPDES Permit's Special Condition No. 13).

   b. The PREQB and the USEPA should clarify which reporting method is preferable when the Dissolved Sulfide is below the detection limit. According to the PREQB, the permittee should report such finding as "Below Detection Level" and the USEPA prefers the concept of "Not Detectable". (See Draft WQC's Special Condition No. 10 and the Draft NPDES Permit's Special Condition No. 12).

   c. The PREQB's Special Conditions No. 11 and 12 were combined in the Draft NPDES Permit into one Special Condition No. 9. For consistency, they should be separated, as presented on PREQB's version of the Draft WQC.

   d. The USEPA should revise Special Condition No. 11 of the Draft NPDES Permit to include the language contained in Special Condition No. 14 of the Draft WQC.

   e. Special Condition No.16 of the Draft NPDES Permit makes reference to sludge treatment, said condition needs to be updated with language of the Draft WQC, which already indicates that sludge treatment is being conducted. In addition, AML hereby clarifies that it currently does not have or operate a sludge treatment system. The sludge currently generated by the WWTP as part of its process, is de-watered (not treated) and sent for off-site disposal.

   f. Special Condition No.17 of the Draft NPDES Permit needs to be updated with language of the Draft WQC. (See Comment in item C.1.e above.)

   g. In regards to Special Condition No. 18, there are no septic tanks in the Facility. Therefore, this special condition should be deleted from the NPDES permit.

   h. Special Condition No.19 of the Draft NPDES Permit needs to be updated with language of the Draft WQC. (Special Condition No. 18 of the Draft WQC).

   i. Special Conditions of the Draft NPDES Permit are listed/ordered differently if compared with the Draft WQC. For consistency purposes, the USEPA could organize its Special Conditions in the same fashion as they appear in the Draft WQC.

EPA Response C.1:

The final NPDES permit reflects all Special Conditions of the final water quality certificate issued by EQB September 30, 2010, as amended June 6, 2011.

2. Several parameters of the Draft NPDES Permit are not supported by the parameters of the Draft WQC:

   a. A COD effluent limitation appears in the Draft NPDES Permit, but not in the Draft WQC.

   b. Effluent limitations for BOD_5 contained in the Draft NPDES Permit differ from those contained in the Draft WQC.

   c. Effluent limitations for TSS contained in the Draft NPDES Permit do not appear in the Draft WQC.

EPA Response C.2:

The effluent limitations for COD, BOD_5, and TSS were included in the draft NPDES permit as required by federal effluent limitation guidelines at 40 CFR Part 439. This facility is currently subject to pretreatment limitations included at 40 CFR Part 439. Should the facility begin discharging treated wastewater directly to the Gurabo River, the effluent limitation guidelines for the Mixing, Formulating, and Compounding Subcategory (40 CFR Part 439 Subpart D) for direct dischargers are applicable. EPA has included the concentration based limitations for COD, TSS, and BOD_5 for new sources which are outlined at 40 CFR §439.45. While this would be a new discharge, it is an existing facility. Should AML wish to apply for the mass based limitations applicable to existing dischargers, they may request a permit modification and provide the influent loading data required for calculation of mass based limitations based on percent removal outlined at 40 CFR §439.42.

3. The Draft WQC provides no basis that supports the adoption by the PREQB of the WQS as the applicable effluent limitations. Therefore, PREQB must provide a fact sheet (*e.g.*, evaluation, analysis and basis) that supports its decision not to grant the MRDCs requested in the application for the following parameters:

a. Ammonia
b. Temperature
c. Dissolved Oxygen
d. Total Phosphorous
e. Copper
f. Cyanide
g. Lead
h. Nitrate + Nitrite
i. Chlorides
j. Sulfates
k. Surfactants

EPA Response C.3:

The final NPDES permit reflects all limitations of the final water quality certificate issued by EQB September 30, 2010, as amended June 6, 2011. The Puerto Rico EQB establishes water quality based effluent limitations based on water quality standards at the end of the pipe, unless a waste load allocation has been applied for and approved by EQB. The final permit does include provisions for certain parameters (Copper, Lead, and Total Phosphorous) to utilize the assimilative capacity of the Gurabo River, based on information provided by AML after the commencement of discharge.

4. The USEPA established a monthly average for COD of 86 mg/l and a daily maximum of 228 mg/l. Assuming that both the Draft NPDES Permit's BOD and COD values are correct, then the COD/BOD ratio varies between the average conditions (4.78) and the maximum conditions (6.51). AML requests the USEPA to confirm whether this difference is intentional. If not, then AML requests that the USEPA provides the correct COD and BOD values for the final NPDES permit. AML understands that these COD and BOD values must be in agreement between the USEPA and the PREQB, since the PREQB modeled the maximum BOD limitation based on the assimilative capacity of the receiving water body. As mentioned before, the PREQB did not include a COD limitation in its Draft WQC.

EPA Response C.4

The effluent limitations for COD, BOD_5, and TSS were included in the draft NPDES permit as required by federal effluent limitation guidelines at 40 CFR Part 439. This facility is currently subject to pretreatment limitations included at 40 CFR Part 439. Should the facility begin discharging treated wastewater directly to the Gurabo River, the effluent limitation guidelines for the Mixing, Formulating, and Compounding Subcategory (40 CFR Part 439 Subpart D) for direct dischargers are

applicable. EPA has included the concentration based limitations for COD, TSS, and BOD_5 for new sources which are outlined at 40 CFR §439.45. While this would be a new discharge, it is an existing facility. Should AML wish to apply for the mass based limitations applicable to existing dischargers, they may request a permit modification and provide the influent loading data required for calculation of mass based limitations based on percent removal outlined at 40 CFR §439.42.

5. References made in parameters of Table A-1 have no correlation with the page or condition attached to such reference.

EPA Response C.5

The references have been corrected in the final NPDES permit.

6. The Waste Load Monitoring Requirements contained in Table A-2 of the Draft NPDES Permit requires monitoring on Copper, Lead and Phosphorous. The foregoing has been interpreted to mean that no additional waste load monitoring is required for Ammonia, Temperature, Dissolved Oxygen, Cyanide, Nitrate + Nitrite, Chlorides, Sulfates and Surfactants.

EPA Response C.6

EPA notes AMLs interpretation of the Waste Load Monitoring requirements, and agrees that AML must provide the information requested in the monitoring requirements of this permit, and may interpret the absence of a monitoring requirement to mean that it is not required.

7. The Draft NPDES Permit requires a waste load monitoring for "Hardness" even though such parameter was not included in the WLA application.

EPA Response C.7

A hardness value is required for calculating the water quality standard for certain parameters in freshwater streams, such as metals. In order to receive a WLA for Copper and Lead, the EQB must have a measure of the site specific hardness of the receiving stream.

8. Special Conditions contained on the Draft NPDES Permit that make reference to incorrect sections of other Special Conditions:

    a. Special Condition No. 15.g.2 (p. 14) requires AML to submit all laboratory test results to the USEPA and the PREQB within 30 days of receipt, "as required in item f.3 of this Special Condition". However, "item f.3" is related to the information that the Toxicity Reduction Evaluation ("TRE") Workplan must include. Therefore, it seems that the reference made in the fifth line of the Special Condition No. 15.g.2 is incorrect.

b. Special Condition No. 15.g.3 (p. 14) makes reference in its first line to "paragraph d.1" as the section that requires the additional toxicity tests. However, "paragraph d.1" is related to the procedure report of the quarterly toxicity tests. Therefore, it seems that the reference made in Special Condition No. 15.g.3 is incorrect.

c. Also, Special Condition No. 15.g.3 (p. 14) makes reference in its fourth line to "paragraph c" as the section related to the TRE Workplan. However, "paragraph c" provides for the measure of the acute toxicity which cause 50% mortality of organisms over a 48-hr period. Therefore, it seems that the reference made in the fourth line of Special Condition No. 15.g.3 is incorrect.

d. Special Condition No. 15.g.5 (p. 15) makes reference in its third line to "item f.3" as the section related to the reporting requirement of Special Condition 15. However, "item f.3" is related to the information that the TRE Workplan must include. Therefore, it seems that the reference made in the third line of the Special Condition No. 15.g.5 is incorrect.

e. Special Condition No. 15.i.3 (p. 16) makes reference in its fifth line to "Part I.B" of the Draft NPDES Permit. However, the Draft NPDES Permit does not include a "Part I.B".

f. Part III.A.1 makes reference to "Part II.B.10" as the part that contains the monitoring and records requirements. However, the Draft NPDES Permit does not include a "Part II.B.10".

g. Part III.A.2.a makes reference to "Part II.B.12.d" as the part that contains the discharge monitoring reports requirements. However, the Draft NPDES Permit does not include a "Part II.B.12.d.

EPA Response C.8

EPA has corrected all discrepancies in references within the Special Conditions.

9. Footnotes of page 18 of the Draft NPDES Permit should be revised to include the correct legal citation, including the reference made to the Puerto Rico Environmental Public Policy Act, Law No. 416 of September 22 of 2004.

EPA Response C.9

Footnotes are included as specified in the final water quality certificate issued by EQB on September 30, 2010, as amended June 6, 2011.

EPA Addendum to the Responsiveness Summary

EPA has added a permit reopener clause to the permit as Special Condition 19, which states that the permit may be modified or revoked and reissued based on the results of

consultation with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (referred herein as "the Services") for compliance with Section 7 of the Endangered Species Act (ESA). EPA had commenced an informal ESA consultation with the Services regarding this permit upon receiving the permit application, which was never concluded. Upon conclusion of that consultation, should modifications to the permit be necessary, EPA would reopen the permit and include the necessary modifications, subject to appropriate notice and comment procedures.