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ENVIR. APPEALS BOARD

**AMGEN®**

**Amgen Manufacturing, Limited**  
**EHS Department**  
**PO Box 4060**  
**Juncos, Puerto Rico 00777**  
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CERTIFIED MAIL: 7008 3230 0001 1813 5800

November 17, 2011

United States Environmental Protection Agency  
Environmental Appeals Board (MC-1103B)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N. W.  
Washington, D. C. 20460

Re: Comments to Final Permit  
NPDES Permit: PR0026695  
Amgen Manufacturing, Limited (AML)

To Environmental Appeals Board:

Amgen Manufacturing Limited ("AML") hereby submits its comments to the Final NPDES Permit PR0026695 (the "Permit") issued by the United States Environmental Protection Agency (the "USEPA"). AML is a biotechnology manufacturing company with its facilities located on State Road PR-31, km 24.6, Ceiba Norte Ward, in the municipality of Juncos, Puerto Rico (the "Facility").

On July, 23, 2010, the USEPA issued a draft NPDES permit (PR0026695) to AML for its 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. On August 23, 2010, AML submitted comments to the draft NPDES permit to the USEPA. Finally, on October 18, 2011, the USEPA issued a Notice of Issuance of the final NPDES permit for AML (Appendix I).

The USEPA Notice of Issuance establishes that the final permit decision shall become effective thirty (30) days from the date of service of the notice and within this 30 day period (i.e. not later than November 17, 2011), the final permit decision may be appealed for review with the Agency's Environmental Appeals Board (the "EAB"), in accordance with 40 Code of Federal Regulations (CFR) §124.19. In view of the above mentioned, AML requests that the USEPA address the comments hereby included and modify and reissue the final permit to reflect the changes requested.

United States Environmental Protection Agency  
Environmental Appeals Board  
November 17, 2011  
Page 2

Thank you in advance for your prompt attention to our comments. If you have any questions, please contact the undersigned at your convenience at 787-916-3360.

Sincerely,



Glynda Harrington  
Director EH&S

Enclosure – Final Permit Comments

cc: Barbara McGarry, Chief  
Compliance Assistance and Program Support Branch  
United States Environmental Protection Agency - Region II  
290 Broadway, 21<sup>st</sup> Floor  
New York, New York 10007-1866  
CERTIFIED MAIL: 7010 0290 0001 4896 8016

AMGEN MANUFACTURING, LIMITED  
COMMENTS TO FINAL NPDES PERMIT PR 0026695  
NOVEMBER 2011

1. Note  $\Phi$  in Table A-1, Page 6 of 37, should be corrected as:

*"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 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 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 include the applicable effluent limitation."*

2. Note  $\lambda$  in Table A-1, Page 6 of 37, should be corrected as:

*"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."*

3. In page 7 of 37, was included a EPA note that reads:

*"The Effective Date of the Commencement of Discharge (EDCD) shall be the date upon which the permittee begins discharging to the Gurabo River. The permittee shall notify both EPA and EQB in writing of the intent to commence discharging fourteen (14) days prior to the EDCD, at the addresses listed in Part I.C. In the event that the QAPP's are approved by the EQB prior to the EDCD, the monitoring programs shall commence not later than thirty (30) days after the EDCD."*

For clarification purposes, this note was discussed with Karen O'Brien, NPDES Section, USEPA Region 2, on November 8, 2011. Ms. O'Brien clarified that the Effective Date of the Commencement of Discharge ("EDCD") is the date when the facility starts a continuous discharge to the Gurabo River. This date does not include discharges under emergency circumstances. In relation to the requirement of notify both EPA and EQB in writing of the intent to commence discharging fourteen (14) days prior to the EDCD, it was clarified that this will apply only if AML is proposing to begin a continuous discharge

to the Gurabo River. This notification requirement, and the subsequent monitoring plan requirements, does not apply under emergency circumstances.

AML respectfully requests that this clarification is included in the permit note.

4. On Page 31 of 37, the final paragraph for "Compliance Schedules" does not have the corresponding numbering. It should be numbered as "e".

# **Appendix I**

**Copy of NPDES Permit PR0026695**

NPDES PERMIT NO. PR0026695

AUTHORIZATION TO DISCHARGE UNDER THE  
NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

In compliance with the provisions of the Clean Water Act, as amended, 33 U.S.C. § 1251 et. seq. (the "Act"),

Amgen Manufacturing Limited (AML)  
P.O. Box 4060  
Juncos, Puerto Rico 00777

hereinafter referred to as "the permittee" is authorized to discharge from the following facility:

AML Wastewater Treatment Plant  
State Road PR-31, Km 24.6  
Juncos, Puerto Rico 00777

to receiving water

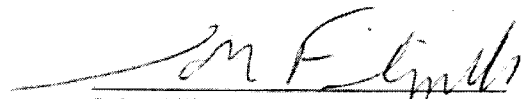
Gurabo River

in accordance with effluent limitations, monitoring requirements and other conditions set forth in Parts I and II hereof. All references to Title 40 of the Code of Federal Regulations are to regulations that are in effect on the effective date of this permit, including all amendments thereto published in the Federal Register. Unless otherwise specified herein, all terms are defined as provided in the applicable regulations under Title 40 of the Code of Federal Regulations.

This permit shall become effective on December 1, 2011.

This permit and the authorization to discharge shall expire at midnight, November 30, 2016.

Signed this 29<sup>th</sup> day of September 2011



John Filippelli, Acting Director  
Division of Environmental Planning  
and Protection  
U.S. Environmental Protection Agency  
Region II

**A. EFFLUENT LIMITATIONS AND REQUIREMENTS**

During the period beginning on December 1, 2011 and lasting through November 30, 2016 the permittee is authorized to discharge from outfall serial number 001 tertiary treated wastewaters. Such discharge shall be limited and monitored by the permittee as specified below:

TABLE A-1 EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

<u>Effluent Characteristics</u>	<u>Gross Discharge Limitations</u>	<u>Monitoring Requirements</u>		
	Monthly Average	Daily Maximum	Measurement Frequency	Sample Type
1,2-Dichlorobenzene (µg/l) <sup>2,3</sup>		420	λ	Grab
2-Methyl-4,6 Dinitrophenol (µg/l) <sup>2,3</sup>		----	Φ	Grab
2,4,6-Trichlorophenol (µg/l) <sup>2,3</sup>		----	Φ	Grab
Pentachlorophenol (µg/l) <sup>2,3</sup>		----	Φ	Grab
Arsenic (As) (µg/l) <sup>2,3</sup> φ		----	Φ	Grab
Biochemical Oxygen Demand (BOD <sub>5</sub> ) (mg/l) <sup>2,3</sup> α	18	35	Monthly	Composite
Chemical Oxygen Demand (COD) (mg/l)	86	228	Monthly	Composite
Chlorides (mg/l) <sup>2,3,4,7</sup> α		250	Monthly	Grab
Chlorine, Total Residual (mg/l) <sup>2,3</sup> *		0.50	Daily	Grab
Chromium VI (Cr <sup>+6</sup> ) (µg/l) <sup>2,3</sup>		11.43	λ	Grab

TABLE A-1 EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

<u>Effluent Characteristics</u>	<u>Gross Discharge Limitations</u>		<u>Monitoring Requirements</u>
	Monthly Average	Daily Maximum	Measurement Frequency Sample Type
Coliforms, Fecal (colonies/100 ml) <sup>1,2,3</sup>	The geometric mean of a series of representative samples (at least five samples) of the waters taken sequentially shall not exceed 200 colonies/ 100ml. Not more than 20 percent of the samples shall exceed 400 colonies/ 100 ml.		Monthly Grab
Coliforms, Total (colonies/100ml) <sup>1,2,3</sup>	The coliform geometric mean of a series of representative samples (at least five samples), of the waters taken sequentially shall not exceed 10,000 colonies/100 ml of total coliforms.		Monthly Grab
Color (Pt-Co Units) <sup>2,3</sup>	15		Monthly Grab
Copper (Cu) (µg/l) <sup>2,3,4,7</sup> α	19		Monthly Grab
Cyanide, Free (CN) (µg/l) <sup>2,3,4,7</sup> α	5.2		Monthly Grab
Dissolved Oxygen (mg/l) <sup>1, 2,3,4,7</sup> α	Shall not be less than 5.0.		Monthly Grab
Flow m <sup>3</sup> /day (MGD) <sup>1,3,5</sup>	3,028.33 (0.8)		Daily Continuous Recording
Lead (Pb) (µg/l) <sup>2,3,4,7</sup> α	8.0		Monthly Grab
Nitrate plus Nitrite (as N) (µg/l) <sup>2,3,4,7</sup> α	10,000		λ Monthly Grab







Notes:

To comply with the monitoring requirements specified above, samples shall be taken at the sampling point of discharge serial number 001.  
All flow measurements shall achieve accuracy within the range of plus or minus 10%.

- $\alpha$  Waste Load Allocation (WLA) was performed in order to develop the water quality based effluent limitation.
- $\gamma$  See Special Conditions 5 and 6.
- $\varphi$  See Special Condition 9.
- $\delta$  See Special Condition 10.
- $\phi$  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.
- $\lambda$  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.

1, 2, 3, 4 and 5 see endnotes to the special conditions.

TABLE A-2 WASTE LOAD ALLOCATION (WLA) MONITORING REQUIREMENTS

The EQB has performed a WLA pursuant to Article 10 of the PRWQSR. During the period beginning on EDCD + 60 days and lasting through one year, after which the monitoring shall be conducted annually, the permittee shall perform ambient monitoring at the immediate vicinity<sup>1</sup> of the discharge station and the background<sup>2</sup> monitoring station as specified below. The sampling events cannot be more often than one event per month. Within thirty (30) days of completion of the one year monitoring program, the permittee shall submit a report to EQB and EPA containing the ambient monitoring results obtained as well as the monthly monitoring results obtained during the same period at the sampling point for discharge 001 for the below parameters. Based on the evaluation of the results obtained, EQB shall determine if the current limitations established shall remain as is or if it is necessary to reopen the WQC to modify (increase or decrease) the effluent limitations for the following parameters:

Receiving Water Name and Classification: Rio Gurabo, SD.

Parameter

Monitoring Requirements

Parameter	Measurement Frequency	Sample Type
Hardness <sup>3</sup> (as CaCO <sub>3</sub> ) (mg/l)	Monthly	Grab
Copper (Cu) (µg/l) <sup>2,3,4</sup>	Monthly	Grab
Lead (Pb) (µg/l) <sup>2,3,4</sup>	Monthly	Grab
Temperature °F (°C) <sup>2,3,4</sup>	Monthly	Grab
Phosphorous, Total (P) (mg/l) <sup>2,3,4</sup>	Monthly	Grab

Notes

- 1 The immediate vicinity of the discharge station shall be located one hundred forty three (143) meters downstream from discharge 001.
- 2 The background sampling station shall be located five (5) meters upstream from discharge 001.
- 3 Monitoring is only required at the background sampling station.

For 2, 3 and 4, see endnotes to the Special Conditions.

*EPA Note: The Effective Date of the Commencement of Discharge (EDCD) shall be the date upon which the permittee begins discharging to the Gurabo River. The permittee shall notify both EPA and EQB in writing of the intent to commence discharging fourteen (14) days prior to the EDCD, at the addresses listed in Part I.C. In the event that the QAPPs are approved by the EQB prior to the EDCD, the monitoring programs shall commence not later than thirty (30) days after the EDCD.*

TABLE A-3 MODEL CALIBRATION MONITORING REQUIREMENTS

During the period beginning on EDCD + 60 days and lasting through one (1) year, the permittee shall implement a monitoring program to obtain the necessary data required to calibrate the MULSMP mathematical model as specified below. Sampling for all parameters shall be performed on the same day. Within thirty (30) days of completion of the one year monitoring program, the permittee shall submit a report to EQB and EPA containing the results obtained, as well as the monthly monitoring results obtained during the same time period at the sampling point of discharge 001 for the below parameters:

Receiving Water Name and Classification: Rio Gurabo, SD

Monitoring Requirements

<u>Parameter</u>	<u>Measurement Frequency</u>	<u>Sample Type</u>	<u>Location</u>
Ammonia, Total (NH <sub>3</sub> ) (mg/l)	Monthly	Composite *	A, B, C
BOD <sub>5</sub> (mg/l)	Monthly	Composite *	A, B, C
BOD <sub>u</sub> (mg/l)	Monthly	24 - Hour Composite	A
Dissolved Oxygen (mg/l)	Monthly	Grab	A, B, C
Flow (MGD, cfs)	Monthly	Instantaneous	B, D
pH (SU)	Monthly	Grab	A, B, C
Temperature (°F)	Monthly	Grab	A, B, C
Velocity, Avg. (ft/s)	Monthly	Instantaneous	B, D

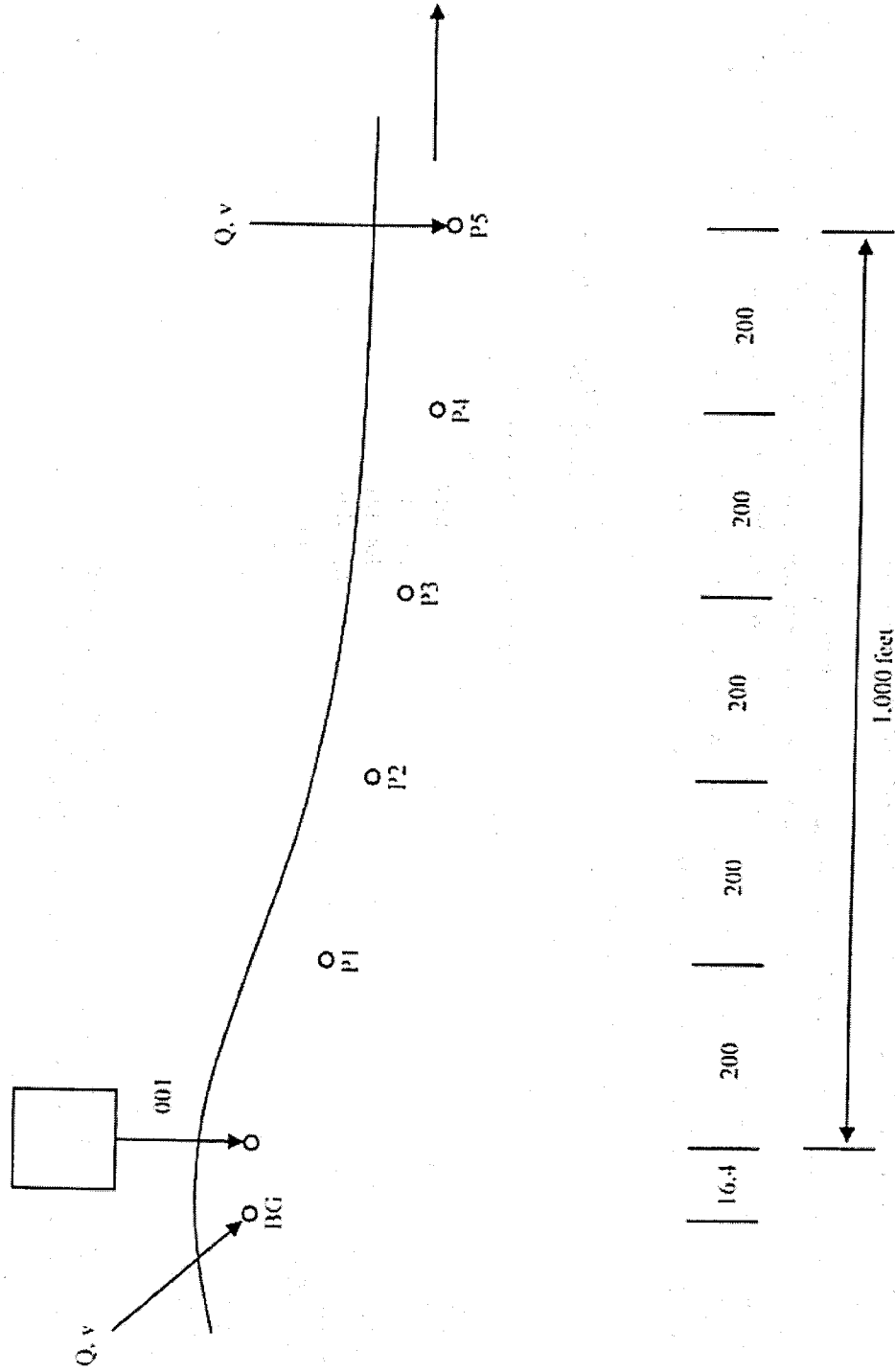
Notes

\* Samples shall be taken at (1) one hour intervals for (6) six consecutive hours. These shall be grab samples that will be mixed in equal portions to prepare a composite sample at each one of the required locations.

Sampling Locations

- A = Point of discharge 001.
- B = Background station, located five (5) meters upstream from discharge 001.
- C = Five (5) points downstream of the discharge 001 along a receiving water segment of one thousand (1000) feet, as shown in Figure 1
- D = Point # 5, located one thousand (1000) feet downstream of the discharge 001.

FIGURE - 1



## B. SPECIAL CONDITIONS

The permittee shall comply with all Special Conditions specified below in accordance Section 301(b)(1)(C) of the Act, as amended (33 U.S.C. 466 *et seq.*). Pursuant to Section 401 of the Act, EPA has established limitations, standards, and other permit conditions based on EQB's Water Quality Certificate (WQC) as part of the Special Conditions.

1. The flow of discharge 001 shall not exceed the limitation of 3,028.33 m<sup>3</sup>/day (0.8 MGD) as daily maximum. No increase in flow of discharge 001 shall be authorized without a recertification from the Puerto Rico Environmental Quality Board (EQB).<sup>1,5</sup>
2. No changes in the design or capacity of the treatment system will be permitted without the previous authorization of EQB.<sup>5</sup>
3. Prior to the construction of any additional treatment system or the modification of the existing one, the permittee shall obtain the approval from EQB of the engineering report, plans and specifications.<sup>5</sup>
4. The permittee shall install, maintain and operate all water pollution control equipment in such manner as to be in compliance with the applicable Rules and Regulations.<sup>1,3</sup>
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 application, but not regulated by the NPDES permit, shall not exceed those concentrations specified in the applicable regulatory limitations.<sup>2,3</sup>
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.<sup>2</sup>
7. The discharge 001 shall not cause the presence of oil sheen in the receiving water body.<sup>2</sup>
8. All sample collection, preservation, and analysis shall be carried out in accordance with the Title 40 of the Code of Federal Regulations (40 CFR), Part 136. All chemical analyses shall be certified by a licensed chemist authorized to practice the profession in Puerto Rico. All bacteriological tests shall be certified by a licensed microbiologist or medical technologist authorized to practice the profession in Puerto Rico.<sup>1,3</sup>
9. The samples taken for the analysis of arsenic shall be analyzed using the analytical 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.<sup>3</sup>

10. The permittee shall use the approved EPA analytical method, 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<sup>2</sup>-F, Calculation of Un-ionized Hydrogen Sulfide, of Standards Methods 18<sup>th</sup> Edition, 1992, to determine the concentration of undissociated H<sub>2</sub>S. 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<sub>2</sub>S shall be reported as "not detectable".<sup>1,3</sup>
11. The flow-measuring device for the discharge 001 shall be periodically calibrated and properly maintained. Calibration and maintenance records must be kept in compliance with the applicable Rules and Regulations.<sup>3,5</sup>
12. The sampling point for discharge 001 shall be located immediately after the primary flow-measuring device of the effluent of the treatment system.
13. The sampling point for discharge 001 shall be labeled with an 18 inches per 12 inches (minimum dimension) sign that reads as follows:

"Punto de Muestreo para la Descarga 001"

14. All water or wastewaters treatment facilities, whether publicly or privately owned, must be operated by a person licensed by the Potable Water and Wastewaters Treatment Plants Operators Examining Board of the Commonwealth of Puerto Rico.<sup>3</sup>
15. Not later than one hundred eighty (180) days after the Effective Date of the Commencement of Discharge (EDCD), the permittee shall conduct quarterly acute toxicity tests for a period of one (1) year, after which the tests shall be performed annually, of its wastewaters discharge through outfall serial number 001, in accordance with the following:<sup>3</sup>
  - a. The test species should be Fathead Minnow (*Pimephales promelas*) and Cladocera (*Daphnia magna*). The test should be static renewal type.
  - b. The toxicity tests 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 tests shall provide a measure of the acute toxicity as determined by the wastewaters concentration, which cause 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<sub>50</sub>.
  - d. A procedure report shall be submitted by February 29, 2012. The following information shall be included in the procedure report:



- 1) An identification of the organizations responsible for conducting the tests and the species to be tested.
  - 2) A detailed description of the methodology to be utilized in the conduct of the tests, including equipment, sample collection, dilution water and source of test organisms.
  - 3) A schematic diagram, which depicts the effluent sampling location in relation to the wastewaters treatment facility and discharge monitoring point.
  - 4) If stream flow monitoring is required, the method used to obtain the stream flow data in estimating the seven-day two-year low flow (7Q<sub>2</sub>).
- e. The results of the tests conducted shall be submitted to EPA Region 2 and EQB within sixty (60) days of completion of each test. Based on a review of the test results the EPA or the EQB can require additional toxicity tests, including chronic tests and toxicity/treatability studies, and may impose toxicity limitations.

f. TRE Workplan

By May 31, 2012, the permittee shall prepare and submit a Toxicity Reduction Evaluation (TRE) Workplan to EPA Region 2. This plan shall include steps the permittee intends to follow if toxicity is measured in the effluent. The plan must include, at a minimum:

- 1) A description of the investigation and evaluation techniques that would be used to identify potential causes and sources of toxicity, effluent variability, and treatment system efficiency.
- 2) A description of methods for maximizing in-house treatment system efficiency, good housekeeping practices, and a list of all chemicals used in operations at the facility.
- 3) Potential actions to be undertaken by the permittee to investigate, identify, and correct the causes, and prevent the recurrence of toxicity.
- 4) Identification of responsible persons/parties for conducting the TRE.
- 5) Possible source reduction measures and pollution prevention measures opportunities to reduce toxicity.

g. Accelerated Toxicity Testing and Commencement of TRE

- 1) If the discharge displays an acute toxicity result with an LC50 of less than 100% effluent, the permittee shall conduct six additional toxicity tests of

the discharge using the same species and test method, every two weeks, over a 12 week period.

- 2) Accelerated testing shall begin within 14 days of the permittee's receipt of test results violating the effluent limit. If none of the additional toxicity tests exceeds the chronic toxicity effluent limit, then the permittee may return to its regular testing frequency. All laboratory test results shall be submitted to EPA and EQB within 30 days of receipt by the permittee, as required in item i.3 of this Special Condition.
- 3) If one of the additional toxicity tests for the discharge (in paragraph g.1) demonstrates an LC50 of less than 100% effluent, then, within 14 days of receipt of this test result, the permittee shall initiate the TRE workplan prepared in compliance with paragraph f. of this Special Condition. The TRE shall use the same species and test method as that of the observed exceedance. The permittee shall use the following guidance manual:

*Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations* EPA/600/2-88/070, 1989).
- 4) The permittee may also use the following manuals for Toxicity Identification Evaluation to identify and abate the causes of toxicity:
  - A) *Toxicity Identification Evaluation: Characterization of Chronically Toxic Effluents, Phase I* (EPA/600/6-91/005F, 1992);
  - B) *Methods for Aquatic Toxicity Identification Evaluations, Phase II Toxicity Identification Procedures for Samples Exhibiting Acute and Chronic Toxicity* (EPA/600/R-92/080, 1993);
  - C) *Methods for Aquatic Toxicity Identification Evaluations, Phase III Toxicity Confirmation Procedures for Samples Exhibiting Acute and Chronic Toxicity* (EPA/600/R-92/081, 1993); and
  - D) *Marine Toxicity Identification Evaluation (TIE): Phase I Guidance Document* (EPA/600/R-96-054, 1996).
  - E) *Sector Notebook Project Pharmaceutical Industry: Profile of the Pharmaceutical Manufacturing Industry, September 1997* (EPA/310-R-97-005).
- 5) The permittee must submit test results within 30 days after the permittee's receipt of the laboratory reports for accelerated monitoring in order to comply with the reporting requirements of item g.3 of this Special Condition. Test results that were received by the permittee due to

accelerated monitoring may be used to satisfy the requirements of Section a. of this Special Condition, provided that all requirements of Section a. (including species, test type, frequency, timing, and sample requirements) are met.

h. Test Methods

- 1) The acute toxicity tests 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.
- 2) The tests shall provide a measure of the acute toxicity as determined by the wastewater concentration, which cause 50 percent mortality of the organisms over a 48 hour period. Test results shall be expressed in terms of *Lethal Concentration (LC)* and reported as 48 hour LC50.
- 3) The test species shall be the *Pimephales Promelas* (fathead minnow) and *Daphnia Magna* (cladocera). The tests shall be static renewal type.

i. Reporting of Toxicity Monitoring Results

- 1) A procedure report shall be submitted by February 29, 2012. The following information shall be included in the procedure report:
  - A) An identification of the organizations responsible for conducting the test and the species to be tested.
  - B) A detailed description of the methodology to be utilized in the conduct of the tests, including equipment, sample collection, dilution water and source of test organisms.
  - C) A schematic diagram which depicts the effluent sampling location. The diagram shall indicate the location of effluent sampling in relation to wastewaters treatment facility and discharge monitoring point.
- 2) For any chronic toxicity testing event, a full laboratory report shall be submitted and shall include: the toxicity test results in NOEC, LOEC, IC25, and the results reported at each effluent dilution. For any acute toxicity testing event, the results shall include the LC50 result and the results reported at each effluent dilution. The results shall be reported according to the test methods manual chapter on report preparation and test review; the dates of sample collection and initiation of each toxicity

test; all results for effluent parameters monitored concurrently with the toxicity test(s); and progress reports on TRE/TIE investigations.

- 3) Full laboratory reports of analytical results shall be submitted to EPA Region II and EQB within thirty (30) days of completion of each test. Based on a review of the test results, EPA or the EQB may require additional toxicity tests, including chronic toxicity analyses. In addition to submitting the procedures report and test results to the addresses listed in Part III.A. of this permit, results shall be submitted to:

CHIEF, CLEAN WATER REGULATORY BRANCH  
U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2  
290 BROADWAY - 24th FLOOR  
NEW YORK, NEW YORK 10007-1866

- 4) The permittee shall notify the permitting authority in writing within 14 days of results with LC50 of less than 100% effluent. This notification shall describe actions the permittee has taken or will take to investigate, identify, and correct the causes of toxicity; the status of actions required by this permit; and schedule for actions not yet completed; or reason(s) that no action has been taken.

j. Reopener Clause for Toxicity Requirements

In accordance with 40 CFR Parts 122 and 124, this permit may be reopened by EPA to include toxicity/treatability studies, chronic toxicity monitoring, additional effluent limitations, or other special conditions to address toxicity in the effluent or receiving water body.

16. The solid wastes (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 EQB and EPA notifying the method or methods used to dispose the solid wastes generated in the facility. Also, copy of the approval or permit applicable to the disposal method used shall be submitted, if any.
  - b. Transported adequately in such 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 EQB's Water Quality Area in the following manners:
    - 1) By telephone communication within a term no longer than twenty four (24) hours after the spill (787-767-8073).

- 2) By letter, within a term no longer than five (5) days after the spill.

These notifications shall include the following information:

- a) spill material,
- b) spill volume,
- c) measures taken to prevent the spill 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 EQB's Solid Wastes Program and other state and federal agencies, if any. <sup>5,8</sup>

17. A log book must be kept for the material removed from the treatment system (solids wastes 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 offers the service.

A copy of the Non-Hazardous Solid Waste Collection and Transportation Service Permit issued by the authorized official from the EQB must be attached to the log book. <sup>3</sup>

18. The EQB has performed a Waste Load Allocation (WLA) pursuant to Rule 1310 of the PRWQSR, as amended. The WLA will not be transferable and do not convey any property rights of any sort or any exclusive privileges, nor does it authorize any injury to persons or property or invasion of other private rights, or any infringement of Federal or State Laws or regulations. <sup>4</sup>
19. Reopener Clause for Endangered Species Protection

This permit may be modified or revoked and reissued based on the results of ESA section 7 consultation with the U.S. Fish and Wildlife Service and National Marine Fisheries Service.

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See next page for references 1, 2, 3, 4, 5, 6, 7 and 8 of the Special Conditions.

1. According to Rule 1301 of the Puerto Rico Water Quality Standards Regulation, as amended.
2. According to Rule 1303 of the Puerto Rico Water Quality Standards Regulation, as amended.
3. According to Rule 1306 of the Puerto Rico Water Quality Standards Regulation, as amended.
4. According to Rule 1310 of the Puerto Rico Water Quality Standards Regulation, as amended.
5. According to the Environmental Public Policy Act of September 22, 2004, Act No. 416, as amended.
6. According to the Code of Federal Regulation Number 40 (40 CFR), Part 131.36, as amended (Federal Register/Volume 57, No. 246/Tuesday, December 22, 1992).
7. According to the Title 40 of the Code of Federal Regulation (40 CFR), Part 131.42 (Federal Register/Volume 72, No. 238/Wednesday, December 12, 2007).
8. According to the Section 405 (d) (4) of the Federal Clean Water Act as Amended (33 U.S.C 466 *et seq.*).

C. **MONITORING AND REPORTING**

1. Monitoring and records. See Part II.C.10.

2. Discharge monitoring reports.

a. See Part II.C.12.d.

b. Monitoring results obtained during the previous month shall be summarized and reported on a Discharge Monitoring Report Form (EPA No. 3320-1), postmarked no later than the 28th day of the month following the completed reporting period. The first report is due on January 28, 2012. Duplicate signed copies of these, and all other reports required herein, shall be submitted to the Regional Administrator and State Director at the following addresses:

COMPLIANCE ASSISTANCE  
PROGRAM SUPPORT BRANCH  
U.S. ENVIRONMENTAL PROTECTION  
AGENCY, REGION 2  
290 BROADWAY - 21ST FLOOR  
NEW YORK, NEW YORK 10007-1866

DIRECTOR  
CARIBBEAN ENVIRONMENTAL  
PROTECTION DIVISION  
U.S. ENVIRONMENTAL PROTECTION  
AGENCY, REGION 2  
EDIF CENTRO EUROPA, SUITE 417  
1492 AVENIDA PONCE DE LEON  
SAN JUAN, PUERTO RICO 00907-4127

ENVIRONMENTAL QUALITY BOARD  
OF PUERTO RICO  
P.O. BOX 11488  
SANTURCE, PUERTO RICO 00910

3. Twenty-four hour reporting.

Pollutants for which the permittee must report violations of maximum daily discharge limitations under paragraph 12.f of Part II.B (40 CFR §122.41(1)(6)(ii)(C)) (24 hour reporting) shall be listed in the permit as included in Table A-1.

4. Additional reporting requirements.

*Existing manufacturing, commercial, mining, and silvicultural dischargers.* In addition to the reporting requirements under 40 C.F.R. §122.41(1), all existing manufacturing, commercial, mining, and silvicultural dischargers must notify the Director as soon as they know or have reason to believe:

- a. That any activity has occurred or will occur which would result in the discharge, on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":
- (1) One hundred micrograms per liter (100 ug/l);
  - (2) Two hundred micrograms per liter (200 ug/l) for acrolein and acrylonitrile; five hundred micrograms per liter (500 ug/l) for 2, 4-dinitrophenol and for 2-methyl-4, 6-dinitrophenol; and one milligram per liter (1 mg/l) for antimony;
  - (3) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or
  - (4) The level established as follows by the Director in accordance with 40 C.F.R. §122.44(f): Not Applicable
- b. That any activity has occurred or will occur which would result in any discharge, on a non-routine or infrequent basis, of a toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":
- (1) Five hundred micrograms per liter (500 ug/l);
  - (2) One milligram per liter (1 mg/l) for antimony;
  - (3) Ten (10) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or
  - (4) The level established as follows by the Director in accordance with 40 C.F.R. §122.44(f): Not Applicable



PART II

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16. "Toxic pollutant" means any of the pollutants listed in 40 C.F.R. §401.15 (45 F.R. 44503, July 30, 1979) and any modification to that list in accordance with Section 307 (a)(1) of the Clean Water Act.
17. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation.
18. "Weekly" means every seventh day (the same day of each week) and a normal operating day.

**B. GENERAL CONDITIONS**

**TABLE OF REGULATORY REFERENCES FOR GENERAL CONDITIONS**

Note: General Condition language in Part II, Sections B.1 through B.14, and B.17 is based on the July 1, 2010 Code of Federal Regulations (C.F.R.). Reference to language in the U.S.C. (United States Code) is based on the date of permit issuance.

Section	Section Title	Reference
B.1.	Duty to Comply	40 C.F.R. §122.41(a)
B.2.	Duty to Reapply	40 C.F.R. §122.41(b)
B.3.	Need to Halt or Reduce not a Defense	40 C.F.R. §122.41(c)
B.4.	Duty to Mitigate	40 C.F.R. §122.41(d)
B.5.	Proper operation and maintenance	40 C.F.R. §122.41(e)
B.6.	Permit actions	40 C.F.R. §122.41(f)
B.7.	Property rights	40 C.F.R. §122.41(g)
B.8.	Duty to provide information	40 C.F.R. §122.41(h)
B.9.	Inspection and Entry	40 C.F.R. §122.41(i)
B.10.	Monitoring and records	40 C.F.R. §122.41(j)
B.11.	Signatory requirements	40 C.F.R. §122.41(k)
B.12.	Reporting Requirements	40 C.F.R. §122.41(l)
B.13.	Bypass	40 C.F.R. §122.41(m)
B.14.	Upset	40 C.F.R. §122.41(n)
B.15.	Removed substances	33 U.S.C. §1311
B.16.	Oil and hazardous substance liability	33 U.S.C. §1321
B.17.	Reopener clause for toxic effluent limitations	40 C.F.R. §122.44(b)(1)
B.18.	State laws	33 U.S.C. §1370
B.19.	Availability of information	33 U.S.C. §1318
B.20.	Severability	-

3. Need to Halt or Reduce not a Defense

It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

4. Duty to Mitigate.

The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

5. Proper Operation and Maintenance

The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

6. Permit Actions

This permit may be modified, revoked and reissued, or terminated during its term pursuant to 40 C.F.R. Part 122, Subpart D. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.

7. Property Rights

This permit does not convey any property rights of any sort, or any exclusive privileges.

8. Duty to Provide Information

The permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit; or to determine compliance with this permit. The permittee shall also furnish to the Director, upon request, copies of records required to be kept by this permit.

9. Inspection and Entry

The permittee shall allow the Director, or an authorized representative (including an authorized contractor acting as a representative of the Administrator), upon presentation of credentials and other documents as may be required by law, to:

- a. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;
- b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- c. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and
- d. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act, any substances or parameters at any location.

10. Monitoring and records.

- a. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.
- b. Except for records of monitoring information required by this permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by 40 C.F.R. part 503), the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement report or application. This period may be extended by request of the Director at any time.
- c. Records of monitoring information shall include:
  - (1) The date, exact place, and time of sampling or measurements;
  - (2) The individual(s) who performed the sampling or measurements;

- (3) The date(s) analyses were performed;
  - (4) The individual(s) who performed the analyses;
  - (5) The analytical techniques or methods used; and
  - (6) The results of such analyses.
- d. Monitoring must be conducted according to test procedures approved under 40 C.F.R. Part 136 and any subsequent changes to the methods contained therein unless another method is required under 40 C.F.R. subchapters N or O.
- e. The Clean Water Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than \$10,000, or by imprisonment for not more than 2 years, or by both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment is a fine of not more than \$20,000 per day of violation, or by imprisonment of not more than four years, or both. (See U.S.C. §1319(c)(4)).
11. Signatory requirements. All applications, reports, or information submitted to the Director shall be signed and certified. (See 40 C.F.R. §122.22)
- a. Applications. All permit applications shall be signed as follows:
    - (1) For a corporation. By a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or (ii) the manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiating and directing other comprehensive measures to assure long term environmental compliance with environmental laws and regulations; the manager can ensure that the necessary systems are established or actions taken to gather complete and accurate information for permit application requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

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

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

- f. Twenty-four hour reporting.
- (1) The permittee shall report any noncompliance which may endanger health or the environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances to the Regional Administrator at (732) 548-8730 and State Director. A written submission shall also be provided within 5 days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance.
  - (2) The following shall be included as information which must be reported within 24 hours under this paragraph.
    - (a) Any unanticipated bypass (see 13 below) which exceeds any effluent limitation in the permit. (See 40 C.F.R. §122.41(g)).
    - (b) Any upset (see 14 below) which exceeds any effluent limitation in the permit.
    - (c) Violation of a maximum daily discharge limitation for any of the pollutants listed by the Director in the permit to be reported within 24 hours. (See 40 C.F.R. §122.44(g)).
  - (3) The Director may waive the written report on a case-by-case basis for reports under paragraph 12.f.(2) of Part II.B if the oral report has been received within 24 hours.
- g. Other noncompliance. The permittee shall report all instances of noncompliance not reported under paragraphs 12.d, e, and f of Part II.B, at the time the monitoring reports are submitted. The reports shall contain the information listed in paragraph 12.f of Part II.B.
- h. Other information. Where the permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Director, it shall promptly submit such facts or information.

13. Bypass

a. Bypass not exceeding limitations. The permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraphs 13.b. and 13.c of Part II.B.

b. Notice.

(1) Anticipated bypass. If the permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible at least ten days before the date of the bypass.

(2) Unanticipated bypass. The permittee shall submit notice of an unanticipated bypass as required in paragraph 12.f of Part II.B (24-hour notice).

c. Prohibition of bypass.

(1) Bypass is prohibited, and the Director may take enforcement action against a permittee for bypass, unless:

(a) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(b) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgement to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and

(c) The permittee submitted notices as required under paragraph 13.b of Part II.B.

(2) The Director may approve an anticipated bypass, after considering its adverse effects, if the Director determines that it will meet the three conditions listed above in paragraph 13.b.(1) of Part II.B.



- c. If a claim of confidentiality is made for information other than that enumerated in subsection a., that information shall be treated in accordance with the procedures in 40 C.F.R. Part 2. Only information determined to be confidential under those procedures shall not be made available by EPA for public inspection.

20. Severability.

The provisions of this permit are severable, and if any provision of this permit, or the application of any provision of this permit to any circumstance, is held invalid, the application of such provision to other circumstances, and the remainder of this permit, shall not be affected thereby.

**C. EFFECTIVENESS OF PERMIT**

1. This permit shall become effective in its entirety on the date indicated on the first page of this permit unless a petition has been filed with the Environmental Appeals Board to review any condition of the permit decision pursuant to the provisions of 40 C.F.R. Part 124.19. All contested conditions and any uncontested condition(s) that are inseverable from the contested conditions shall be stayed. All other conditions shall become effective thirty (30) days after the date of the notification specified in 40 C.F.R. §124.16(a)(2)(ii).
2. For purposes of judicial review under Section 509(b) of the Clean Water Act, final agency action on a permit does not occur unless and until a party has exhausted its administrative remedies under 40 C.F.R. 124. Any party which neglects or fails to seek review under 40 C.F.R. §124.19, thereby waives its opportunity to exhaust available agency administrative remedies.

PERMITTEE NAME/ADDRESS (include Facility Name/ Location if different)  
 NAME:  
 ADDRESS:

NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES)  
 DISCHARGE MONITORING REPORT (DMR)

Form Approved  
 OMB No. 2040-0004

FACILITY:  
 LOCATION:  
 ATTN:

PERMIT NUMBER \_\_\_\_\_ DISCHARGE NUMBER \_\_\_\_\_  
 MONITORING PERIOD  
 YEAR MO DAY \_\_\_\_\_ YEAR MO DAY \_\_\_\_\_  
 FROM \_\_\_\_\_ TO \_\_\_\_\_

(SUBR 001)  
 F - FINAL  
 DISCHARGE 001

\*\*\* NO DISCHARGE \*\*\*  
 Note: Read instructions before completing this form.

PARAMETER	X	QUANTITY OR LOADING			QUALITY OR CONCENTRATION			NO. EX	FREQ. OF ANALYSIS	SAMPLE TYPE
		AVERAGE	MAXIMUM	UNITS	MINIMUM	AVERAGE	MAXIMUM			
Sample Measurement										
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