

**OEPA Permit No.: 3DP00003\*GP  
Public Notice No.: OEPA 18-01-035IDM**

**Indirect Discharge Permit Program**

**PUBLIC NOTICE**

**Indirect Discharge Permit to a Publicly Owned Treatment Works (POTW)  
that does not have a State Approved Pretreatment Program**

Ohio Environmental Protection Agency  
Lazarus Government Center  
50 West Town Street.  
P. O. Box 1049  
Columbus, Ohio 43216-1049  
(614) 644-2001

Public Notice No. OEPA 18-01-035IDM

Date of Public Notice: January 30, 2018  
Date of Issuance of Proposed Modification: January 23, 2018  
Effective Date of Modification: April 1, 2018

Name and Address of Applicant: Xellia Pharmaceuticals, USA, LLC, 200 Northfield Road ,  
Bedford, OH 44146

Name and Address of Facility where Discharge Occurs: Xellia Cleveland, 200 Northfield Rd ,  
Bedford, OH, 44146 Cuyahoga County

Location of Discharge: From plant property to Receiving POTW

Receiving POTW: Bedford WWTP

Purpose of this Modification: Added reporting codes: 00340 – Chemical Oxygen Demand (High Level), 00530 – Total Suspended Solids, 03809 – Amyl Acetate, Total, Effluent, 04146 – Isopropyl Acetate, Total, Effluent, 34423 – Methylene Chloride, 71900 – Mercury, Total, 79539 – Acetone, 80082 – CBOD 5Day, 81585 – Ethyl Acetate, with monitoring and added new footnotes to final table for outfall 3DP00003002; added new final table for outfall 3DP00003003; and added Part II, Item E.

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On the basis of preliminary staff review and application of standards and regulations, the director of the Ohio Environmental Protection Agency will issue a permit for the discharge subject to certain effluent conditions and special conditions. The draft permit will be issued as a final action unless the director revises the draft after consideration of the record of a public meeting or written comments, or upon disapproval by the administrator of the U.S. Environmental Protection Agency. Any person may submit written comments on the draft permit and administrative record and may request a public hearing. A request for public hearing shall be in writing and shall state the nature of the issues to be raised. In appropriate cases, including cases where there is significant public interest, the director may hold a public hearing on a draft permit or permits prior to final issuance of the permit or permits. Following final action by the director, any aggrieved party has the right to appeal to the Environmental Review Appeals Commission.

Interested persons are invited to submit written comments upon the discharge permit. Comments should be submitted in person or by mail no later than 30 days after the date of this public notice. Deliver or mail all comments to:

Ohio Environmental Protection Agency  
Division of Water Pollution Control  
Permits Section  
50 West Town Street Suite 700  
P. O. Box 1049  
Columbus, Ohio 43216-1049

The Ohio EPA permit number and public notice numbers should appear next to the above address on the envelope and on each page of any submitted comments. All comments received no later than 30 days after the date of this public notice will be considered.

The application, fact sheets, permit including effluent limitations, special conditions, comments received, and other documents are available for inspection and may be copied at a cost of 5 cents per page at the Ohio Environmental Protection Agency at the address shown on page one of this public notice any time between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Copies of the public notice are available at no charge at the same address. Individual NPDES draft permits that are in public notice are now available on DSW's web site: <http://www.epa.ohio.gov/dsw/permits/individuals/draftperm.aspx>

Mailing lists are maintained for persons or groups who desire to receive public notice for all applications in the state or for certain geographical areas. Persons or groups may also request copies of fact sheets, applications, or other documents pertaining to specific applications. Persons or groups may have their names put on such a list by making a written request to the agency at the address shown above.

Application No. OHP000014

Modification Issue Date: January 23, 2018

Modification Effective Date: **PROPOSED**

Expiration Date: June 30, 2021

Ohio Environmental Protection Agency

Indirect Discharge Permit

In compliance with the provisions of the Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et. seq., hereinafter referred to as "the Act"), and the Ohio Water Pollution Control Act (Ohio Revised Code 6111),

Xellia Pharmaceuticals USA LLC  
Xellia Cleveland

is authorized by the Ohio Environmental Protection Agency, hereinafter referred to as "Ohio EPA," to discharge wastewater from its facility located at 300 Northfield Road, Bedford, OH 44146

into the Publicly Owned Treatment Works of the City of Bedford located at 705 Glendale Avenue, Bedford, OH 44146

in accordance with the conditions specified in Parts I, II, and III of this permit.

The permit is issued to apply and enforce pretreatment rules of the state of Ohio. The rights granted by this permit shall not supersede the primacy of the above authority in the regulation of its publicly owned treatment works.

This permit is conditioned upon payment of applicable fees as required by Section 3745.11 of the Ohio Revised Code.

This permit and the authorization to discharge shall expire at midnight on the expiration date shown above. In order to receive authorization to discharge beyond the above date of expiration, the permittee shall submit such information and forms as are required by the Ohio EPA no later than 180 days prior to the above date of expiration.

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Craig W. Butler  
Director

Total Pages: 17

Part I, A. - FINAL EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

1. During the period beginning on the effective date of this permit and lasting until its expiration date, the permittee is authorized to discharge in accordance with the following limitations and monitoring requirements from the following outfall: 3DP00003001.

Table - End of Pipe - 001 - Final

Effluent Characteristic  Parameter	Discharge Limitations						Monitoring Requirements			
	Concentration Specified Units		Loading* kg/day				Measuring Frequency	Sampling Type	Monitoring Months	
	Maximum	Minimum	Weekly	Monthly	Daily	Weekly				Monthly
00056 - Flow Rate - GPD	-	-	-	-	-	-	-	1/Quarter	24hr Total Estimate	Quarterly - Alt.
00400 - pH - S.U.	-	5.0	-	-	-	-	-	1/Quarter	Grab	Quarterly - Alt.

Footnotes for Outfall 3DP00003001:

- a. Samples shall be collected from the manhole located in the east sidewalk between Building 22 and Building 19.
- b. Samples shall be representative of the average flow discharged from the facility. If no discharge occurred during the month, enter "No Discharge" into eDMR. Quarterly monitoring shall occur during the months of March, June, September, and December of each year.
- c. This outfall is permitted only for the discharge of sanitary wastewater. Prior to discharging any wastewater associated with pharmaceutical manufacturing or processing through this outfall, the facility must apply to modify its permit (see Part II, Item D).

Part I, A. - FINAL EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

2. During the period beginning on the effective date of this permit and lasting until the expiration date, the permittee is authorized to discharge in accordance with the following limitations and monitoring requirements from the following outfall: 3DP00003002.

Table - End of Pipe - 002 - Final

Effluent Characteristic  Parameter	Discharge Limitations						Monitoring Requirements			
	Concentration Specified Units		Loading* kg/day			Measuring Frequency	Sampling Type	Monitoring Months		
	Maximum	Minimum	Weekly	Monthly	Daily				Weekly	Monthly
00056 - Flow Rate - GPD	-	-	-	-	-	-	-	1/Month	24hr Total	All
00340 - Chemical Oxygen Demand (High Level) - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
00400 - pH - S.U.	-	5.0	-	-	-	-	-	1/Month	Grab	All
00530 - Total Suspended Solids - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
03809 - Amyl Acetate, Total, Effluent - mg/l	9.82	-	-	3.89	-	-	-	1/Month	Grab	All
04146 - Isopropyl Acetate, Total, Effluent - mg/l	9.82	-	-	3.89	-	-	-	1/Month	Grab	All
34423 - Methylene Chloride - ug/l	1420	-	-	332	-	-	-	1/Month	Grab	All
71900 - Mercury, Total (Hg) - ug/l	-	-	-	-	-	-	-	1/Month	Composite	All
79539 - Acetone - mg/l	9.82	-	-	3.89	-	-	-	1/Month	Grab	All
80082 - CBOD 5 day - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
81585 - Ethyl Acetate - ug/l	9820	-	-	3890	-	-	-	1/Month	Grab	All

Footnotes for Outfall 3DP00003002:

- a. Samples shall be collected from the manhole located in the Water for Injection System Room in Building 22.
- b. Limits are based on the categorical pretreatment standards for Pharmaceutical Manufacturing, Mixing/Compounding and Formulation (40 CFR 439.46) and the combined wastestream formula [40 CFR 403.6(e)] where the ratio is equal to 0.474 (57,795 gpd process wastewater / 121,845 gpd total flow).
- c. When submitting eDMR data, the permittee shall report the estimated volume of process wastewater discharged to the sanitary sewer for each monitoring event. The process wastewater volume shall be reported under the "Comments" section of eDMR. A list of operations which generate process wastewater is included in Part II, Item E.

d. Mercury - the permittee shall use either EPA Method 1631 or EPA Method 245.1 promulgated under 40 CFR 136 to comply with the sampling requirements of this permit.

Part I, A. - FINAL EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

3. During the period beginning on the effective date of this permit and lasting until the expiration date, the permittee is authorized to discharge in accordance with the following limitations and monitoring requirements from the following outfall: 3DP00003003.

Table - End of Pipe - 003 - Final

Effluent Characteristic  Parameter	Discharge Limitations						Monitoring Requirements			
	Concentration Specified Units		Loading* kg/day			Measuring Frequency	Sampling Type	Monitoring Months		
	Maximum	Minimum	Weekly	Monthly	Daily				Weekly	Monthly
00056 - Flow Rate - GPD	-	-	-	-	-	-	-	1/Month	24hr Total	All
00340 - Chemical Oxygen Demand (High Level) - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
00400 - pH - S.U.	-	5.0	-	-	-	-	-	1/Month	Grab	All
00530 - Total Suspended Solids - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
00665 - Phosphorus, Total (P) - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
01119 - Copper, Total Recoverable - ug/l	-	-	-	-	-	-	-	1/Month	Composite	All
03809 - Amyl Acetate, Total, Effluent - mg/l	14.43	-	-	5.72	-	-	-	1/Month	Grab	All
04146 - Isopropyl Acetate, Total, Effluent - mg/l	14.43	-	-	5.72	-	-	-	1/Month	Grab	All
34423 - Methylene Chloride - ug/l	2090	-	-	490	-	-	-	1/Month	Grab	All
71900 - Mercury, Total (Hg) - ug/l	-	-	-	-	-	-	-	1/Month	Composite	All
79539 - Acetone - mg/l	14.43	-	-	5.72	-	-	-	1/Month	Grab	All
80082 - CBOD 5 day - mg/l	-	-	-	-	-	-	-	1/Month	Composite	All
81585 - Ethyl Acetate - ug/l	14430	-	-	5720	-	-	-	1/Month	Grab	All

Footnotes for Outfall 3DP00003003:

a. Samples shall be collected from the manhole located in Building 24.

b. Limits are based on the categorical pretreatment standards for Pharmaceutical Manufacturing, Mixing/Compounding and Formulation (40 CFR 439.46) and the combined wastestream formula [40 CFR 403.6(e)] where the ratio is equal to 0.697 (30,975 gpd process wastewater / 44,425 gpd total flow).

- c. When submitting eDMR data, the permittee shall report the estimated volume of process wastewater discharged to the sanitary sewer for each monitoring event. The process wastewater volume shall be reported under the "Comments" section of eDMR. A list of operations which generate process wastewater is included in Part II, Item E.
- d. Mercury - the permittee shall use either EPA Method 1631 or EPA Method 245.1 promulgated under 40 CFR 136 to comply with the sampling requirements of this permit.



Part I, A. - FINAL EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

4. During the period beginning on the effective date of this permit and lasting until its expiration date, the permittee is authorized to discharge in accordance with the following limitations and monitoring requirements from the following outfall: 3DP00003004.

Table - End of Pipe - 004 - Final

Effluent Characteristic  Parameter	Discharge Limitations							Monitoring Requirements		
	Concentration Specified Units				Loading* kg/day			Measuring Frequency	Sampling Type	Monitoring Months
	Maximum	Minimum	Weekly	Monthly	Daily	Weekly	Monthly			
00056 - Flow Rate - GPD	-	-	-	-	-	-	-	1/Quarter	24hr Total Estimate	Quarterly
00400 - pH - S.U.	-	5.0	-	-	-	-	-	1/Quarter	Grab	Quarterly

Footnotes for Outfall 3DP00003004:

- a. Samples shall be collected from Building 24 East.
- b. Samples shall be representative of the average flow discharged from the facility. If no discharge occurred during the month, enter "No Discharge" into eDMR. Quarterly monitoring shall occur during the months of March, June, September, and December of each year.
- c. This outfall is permitted only for the discharge of sanitary wastewater. Prior to discharging any wastewater associated with pharmaceutical manufacturing or processing through this outfall, the facility must apply to modify its permit (see Part II, Item D).

Part I, A. - FINAL EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

5. During the period beginning on the effective date of this permit and lasting until its expiration date, the permittee is authorized to discharge in accordance with the following limitations and monitoring requirements from the following outfall: 3DP00003005.

Table - End of Pipe - 005 - Final

Effluent Characteristic  Parameter	Discharge Limitations						Monitoring Requirements			
	Concentration Specified Units		Loading* kg/day				Measuring Frequency	Sampling Type	Monitoring Months	
	Maximum	Minimum	Weekly	Monthly	Daily	Weekly				Monthly
00056 - Flow Rate - GPD	-	-	-	-	-	-	-	1/Quarter	24hr Total Estimate	Quarterly - Alt.
00400 - pH - S.U.	-	5.0	-	-	-	-	-	1/Quarter	Grab	Quarterly - Alt.

Footnotes for Outfall 3DP00003005:

- a. Samples shall be collected from Building 24 W.
- b. Samples shall be representative of the average flow discharged from the facility. If no discharge occurred during the month, enter "No Discharge" into eDMR. Quarterly monitoring shall occur during the months of March, June, September, and December of each year.
- c. This outfall is permitted only for the discharge of sanitary wastewater. Prior to discharging any wastewater associated with pharmaceutical manufacturing or processing through this outfall, the facility must apply to modify its permit (see Part II, Item D).

## Part II, Other Requirements

A. The permittee shall comply with all applicable rules, regulations, and ordinances of the City of Bedford. If the authority to discharge is revoked by the POTW, this shall also be considered grounds for revocation of this permit.

B. In addition to the report submitted to Ohio EPA under Part III, Item 3, of this permit, a copy of each discharge monitoring report shall be submitted to the POTW at the following address:

City of Bedford  
Wastewater Treatment Plant  
165 Center Road  
Bedford, OH 44146

C. Any slug loading shall be reported to the POTW at (440) 232-1600 pursuant to requirements in Part III, Item 10. Any accidental discharge of wastewater to the waters of the state, including treated and untreated process wastewater, shall be reported to Ohio EPA at 1-800-282-9378 within 24 hours of becoming aware of the discharge.

D. A modification of this permit is required prior to discharging process wastewater from any of the outfalls in this facility. The application form (Form 4223) and instructions can be found in the Ohio EPA website  
<http://www.epa.ohio.gov/dsw/pretreatment/forms.aspx> .

The forms may also be filled out and paid electronically through Ohio EPA's eBusiness Center: <https://ebiz.epa.ohio.gov/login.html> .

Forms must be submitted no later than 180 days prior to the expected date of the process wastewater discharge.

E. Process wastewaters include all wastewaters that, during manufacturing or processing, comes into contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product.

For Xellia Cleveland, operations which generate process wastewaters include but are not limited to the following:

Clean steam generator, Terminal sterilizer, Isolators, Lyophilizers, Preparation sinks, Compounding sinks, Parts washers, Vial washers, Rack stalls, Tray washers, Tank stalls, CIP skids, Stopper washers, Autoclaves, and Quench tanks.

### Part III - GENERAL CONDITIONS

#### 1. DEFINITIONS

"Absolute Limitations" Compliance with limitations having descriptions of "shall not be less than," "nor greater than," "shall not exceed," "minimum," or "maximum" shall be determined from any single value for samples and/or measurements collected.

"Composite" means a combination of individual samples collected at periodic intervals of the entire discharge day. The composite must be flow proportional; either the time interval between each individual sample or the volume of each individual sample must be directly proportional to either the wastestream flow at the time of the sampling or the total wastestream flow since the collection of the previous sample. Samples may be collected manually or automatically.

"Grab" means an individual sample collected at such time and location as to be representative of the discharge.

"Interference" means a discharge which, alone or in conjunction with a discharge or discharges from other sources, both: 1) inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and (2) therefore, is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation) or of the prevention of sewage sludge use or disposal in compliance with the following statutory provisions and regulations or permits issued thereunder (or more stringent local regulations): Section 405 of the Clean Water Act, the Solid Waste Disposal Act (SWDA) (including Title II, more commonly referred to as the Resource Conservation and Recovery Act (RCRA), and including state regulations contained in any state sludge management plan prepared pursuant to Subtitle D of SWDA), the Clean Air Act, and the Toxic Substances Control Act.

"mg/l" means milligrams per liter.

"pass through" means a discharge which exits through the POTW to waters of the state in quantities or concentrations which, alone or in conjunction with a discharge or discharges from other sources, is a cause of a violation of any requirement of the POTW's NPDES permit.

"POTW" or "publicly owned treatment works" means a treatment works owned or operated by a public authority. This definition includes any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW treatment plant. The term also means the public authority which has jurisdiction over the indirect discharges to and the discharges from such a treatment works.

"Pollutant" means sewage, industrial waste, or other waste as defined by divisions (B), (C) and (D) of Section 6111.01 of the Revised Code.

"Reporting Code" is a five digit number used by the Ohio EPA in processing reported data. The reporting code does not imply the type of analysis used nor the sampling techniques employed.

"Slug loading" means any pollutant, including oxygen demanding pollutants, released in a discharge at a flow rate and/or pollutant concentration as to cause interference in the POTW.

"ug/l" means micrograms per liter.

## 2. GENERAL EFFLUENT LIMITATIONS

A. All users of a POTW shall comply with the requirements of 40 CFR Part 403, the Federal "General Pretreatment Regulations for Existing and New Sources of Pollution," as appropriate.

B. The permittee shall not introduce the following pollutants into a POTW

1. Pollutants which create a fire or explosion hazard in the POTW including, but not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21;

2. Pollutants which will cause corrosive structural damage to the POTW, but in no case discharges with pH lower than 5.0, unless the POTW is specifically designed to accommodate such discharges;

3. Solid or viscous pollutants in amounts which will cause obstruction to the flow in sewers, or other interference with the operation of the POTW;

4. Any pollutant, including oxygen demanding pollutants (BOD, etc.) released in a discharge at a flow rate and/or pollutant concentration as to cause interference in the POTW;

5. Heat in amounts that will inhibit biological activity in the POTW resulting in interference or causing damage, but in no case heat in such quantities that the temperature exceeds 40 Degrees C (104 Degrees F) at the POTW unless the director, upon request of the POTW, approves an alternate temperature limit;

6. Petroleum oil, nonbiodegradable cutting oil or products of mineral oil origin in amounts that will cause interference or pass through;

7. Pollutants which result in the presence of toxic gases, vapor or fumes within the POTW in a quantity that may cause acute worker health and safety problems;

8. Any trucked or hauled pollutants, except at discharge points designated by the POTW.

C. The permittee shall not achieve any effluent concentration by dilution. The permittee shall not increase the use of potable water, process water or cooling water.

## 3. REPORTING

A. Monitoring data required by this permit, including results from any sampling pursuant to paragraph 3.H.7., below, shall be reported on a semi-annual basis, unless specified otherwise in Part II - Other Requirements. Monitoring data required by this permit shall be submitted on Ohio EPA 4519 Discharge Monitoring Report (DMR) forms using the electronic DMR (e-DMR) internet application. e-DMR allows permitted facilities to enter, sign, and submit DMRs on the internet. It is accessed from the Ohio EPA eBusiness Center. The eBusiness Center can be found at the following web page:

<http://www.epa.ohio.gov/dsw/edmr/eDMR.aspx>

Alternatively, if you are unable to use e-DMR due to a demonstrated hardship, monitoring data may be submitted on paper DMR forms provided by Ohio EPA. Monitoring data shall be typed on the forms. Please contact Ohio EPA, Division of Surface Water at (614) 644-2050 if you wish to receive paper DMR forms.

B. DMRs shall be signed by a facility's Responsible Official or a Delegated Responsible Official (i.e. a person delegated by the Responsible Official). The Responsible Official of a facility is defined as:

1. For corporations - 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 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 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;
2. For partnerships - a general partner;
3. For a sole proprietorship - the proprietor; or,
4. For a municipality, state or other public facility - a principal executive officer, a ranking elected official or other duly authorized employee.

For e-DMR, the person signing and submitting the DMR will need to obtain an eBusiness Center account and Personal Identification Number (PIN). Additionally, Delegated Responsible Officials must be delegated by the Responsible Official, either on-line using the eBusiness Center's delegation function, or on a paper delegation form provided by Ohio EPA. This information can be found at the following web page:

<http://www.epa.ohio.gov/dsw/edmr/eDMRpin.aspx>

C. Reports for each sampling period shall be transmitted to Ohio EPA no later than the 20th day of January or July. Reports due by the 20th of January shall cover the sampling period of July through December of the previous year. Reports due by the 20th day of July shall cover the sampling period of January through June of the current year.

DMRs submitted on paper shall be the original signed DMR form and shall be mailed to:

Ohio Environmental Protection Agency  
Lazarus Government Center  
Division of Surface Water - PCU  
P.O. Box 1049  
Columbus, Ohio 43216-1049

D. Regardless of the submission method, a copy of the submitted Ohio EPA 4519 DMR must be signed by a Responsible Official or a Delegated Responsible Official and maintained onsite for records retention purposes (see Section 6. RECORDS RETENTION). For e-DMR users, a copy of the DMR can be printed from e-DMR.

E. If the permittee monitors any pollutant at the location(s) designated herein more frequently than required by this permit, using approved analytical methods as specified in Section 4. SAMPLING AND ANALYTICAL METHODS, the results of such monitoring shall be included in the calculation and reporting of the values required in the reports specified above.

F. Analyses of pollutants not required by this permit, except as noted in the preceding paragraph, shall not be reported to the Ohio EPA, but records shall be retained as specified in Section 6. RECORDS RETENTION.

G. A copy of each DMR shall be sent to the POTW authority as specified in Part II, Other Requirements.

H. The permittee shall report noncompliance that is the result of any violation of a daily maximum discharge limit for any of the pollutants listed by the Director in the permit by telephone within twenty-four (24) hours of discovery. The permittee shall report by telephone to the appropriate Ohio EPA district office as follows:

Central District Office: (800) 686-2330  
Southwest District Office: (800) 686-8930  
Southeast District Office: (800) 686-7330  
Northwest District Office: (800) 686-6930  
Northeast District Office: (800) 686-6330

The permittee shall include the following information in the noncompliance report required by paragraph H:

1. The limit(s) that has been exceeded;
2. The extent of the exceedance(s);
3. The cause of the exceedance(s);
4. The period of the exceedance(s) including exact dates and times;
5. If uncorrected, the anticipated time the exceedance(s) is expected to continue; and,
6. Steps taken to reduce, eliminate or prevent occurrence of the exceedance(s).
7. The permittee shall also repeat the sampling and analysis and submit the results of the repeat analysis to Ohio EPA within thirty (30) days after becoming aware of the violation. The results shall be mailed to:

Ohio Environmental Protection Agency  
Lazarus Government Center  
Division of Surface Water - Pretreatment  
P.O. Box 1049  
Columbus, OH 43216-1049

#### 4. SAMPLING AND ANALYTICAL METHODS

A. Samples and measurements taken as required herein shall be representative of daily operations. Test procedures for the analysis of pollutants shall conform to regulation 40 CFR 136, "Test Procedures For The Analysis of Pollutants" unless other test procedures have been specified in this permit. The permittee shall periodically calibrate and perform maintenance procedures on all monitoring and analytical instrumentation at intervals to ensure accuracy of measurements.

B. Unless otherwise specified in Part II - Other Requirements, samples shall be obtained through use of flow-proportional composite sampling techniques; where composite sampling is not physically possible or contrary to the approved methods set forth in 40 CFR 136, a grab sample is acceptable.

C. The permittee is responsible for providing a sampling location suitable for obtaining a representative sample.

#### 5. RECORDING OF RESULTS

For each measurement or sample taken pursuant to the requirements of this permit, the permittee shall record the following information:

- A. The exact place and date of sampling;
- B. The person(s) who performed the sampling or measurements;
- C. The date the analyses were performed on those samples;
- D. The person(s) who performed the analyses;
- E. The analytical techniques or methods used; and
- F. The results of all analyses and measurements.

#### 6. RECORDS RETENTION

The permittee shall retain all of the following records for a minimum of three years, including:

- A. All sampling and analytical records (including internal sampling data not reported);
- B. All original recordings for any continuous monitoring instrumentation;
- C. All instrumentation, calibration and maintenance records; and
- D. All plant operation and maintenance records.
- E. All reports required by this permit.
- F. Records of all data used to complete the application for this permit for a period of at least three years from the date of the sample, measurement, report or application.

#### 7. AVAILABILITY OF REPORTS

Except for data determined by the Ohio EPA to be entitled confidential status, all reports prepared in accordance with the terms of this permit shall be available for public inspection at the appropriate district office of the Ohio EPA. Both the Clean Water Act and Section 6111.05 of the Ohio Revised Code state that effluent data shall not be considered confidential. Knowingly making any false statement on any such report may result in the imposition of criminal penalties as provided for in the Ohio Revised Code Section 6111.99.

#### 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 or revoking the 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. RIGHT OF ENTRY

The permittee shall allow the director, or an authorized representative 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,
- 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. NOTIFICATION OF SLUG LOADING

A. The permittee shall notify the POTW at the telephone number provided in Part II - Other Conditions and the Ohio EPA by telephone at 1-800-282-9378 within one hour of discovery of any slug loading and provide the following:

1. A description of the discharge and the cause of the slug loading;
2. The period of slug loading including exact dates and times and, if not corrected, the anticipated time the noncompliance is expected to continue;
3. The steps taken or planned to reduce, eliminate and prevent reoccurrence of the slug loading.
4. The POTW affected by the discharge.

B. A written report containing the above information shall be filed with the POTW at the address provided in Part II - Other Conditions, and the Ohio EPA, at the address provided in Part III, Paragraph 3 entitled "REPORTING" within five business days of the day when the slug loading occurred.

#### 11. DISCHARGE CHANGES

The following changes must be reported to the Ohio EPA as soon as practicable.

A. Any significant change in character of the discharge which the permittee knows or has reason to believe has occurred or will occur which would constitute cause for modification or revocation. The permittee shall give advance notice to the director of any planned changes in the process line or treatment works from which the permitted discharge originates which may result in noncompliance with permit requirements. These changes include, but are not limited to, increases or decreases in production rates from which categorical standards are calculated, discharge flow rates, and the addition or deletion of wastestreams. Notification of permit changes or anticipated noncompliance does not stay any permit conditions.

Following this notice, modifications to the permit may be made to reflect any necessary changes in permit conditions, including any necessary effluent limitations for any pollutants not identified and limited herein. Sections 6111.44 and 6111.45, Ohio Revised Code, require that plans for treatment works or improvements to such works be approved by the director of the Ohio EPA prior to construction.

#### 12. TOXIC POLLUTANTS

The permittee shall comply with effluent standards or prohibitions under Section 307(a) of the Clean Water Act or Section 3745-3 of the Ohio Administrative Code for toxic pollutants within the time provided in the regulations that establish these standards or prohibitions, even if the permit has not yet been modified to incorporate the requirement. Following establishment of such standards or prohibitions, the director shall modify this permit and so notify the permittee.

#### 13. PERMIT MODIFICATION OR REVOCATION

A. After notice and opportunity for a hearing, this permit may be modified or revoked, by the Ohio EPA, in whole or in part during its term for cause including, but not limited to, the following:

1. Violation of any terms or conditions of this permit;
2. Obtaining this permit by misrepresentation or failure to disclose fully all relevant facts; or
3. A change in any condition that requires either a temporary or permanent reduction or elimination of the permitted discharge; or

B. Pursuant to rule 3745-36-08, Ohio Administrative Code, the permittee may at any time apply to the Ohio EPA for modification of any part of this permit. The filing of a request by the permittee for a permit modification or revocation does not stay any permit condition. The application for modification should be received by the Ohio EPA Pretreatment Unit at least ninety days before the date on which it is desired that the modification become effective. The application shall be made only on forms approved by the Ohio EPA.

#### 14. TRANSFER OF OWNERSHIP OR CONTROL

This permit cannot be transferred or assigned nor shall a new owner or successor be authorized to discharge from this facility, until the following requirements are met:

- A. The permittee shall notify the Ohio EPA Pretreatment Unit at least sixty days in advance of the proposed transfer date;
- B. The notice includes a written agreement containing a specific date for transfer of permit responsibility and coverage between the current and new permittee (including acknowledgement that the existing permittee is liable for violations up to that date, and that the new permittee is liable for violations from that date on); and
- C. The director does not exercise his right to notify the current permittee and the new permittee of his or her intent to modify or revoke the permit and to require that a new application be filed.

#### 15. STATE LAWS AND REGULATIONS

Nothing in this permit shall be construed to preclude the institution of any legal action nor relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable state law or regulation under authority preserved by Section 510 of the Act.

#### 16. 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.

#### 17. PROPERTY RIGHTS

The issuance of this permit does not convey any property rights in either real or personal property, or any exclusive privileges, nor does it authorize any injury to private property or any invasion of personal rights, nor any infringement of federal, state, or local laws or regulations.

#### 18. SIGNATORY REQUIREMENTS

A. All applications and reports submitted to the Ohio EPA must be signed by an authorized representative of the permittee. An authorized representative may be:

- 1. In the case of a corporation, by a principal executive officer of at least the level of vice president, or his duly authorized representative, if such representative is responsible for the overall operation of the facility from which the discharge originates.
- 2. In the case of a partnership, by a general partner.
- 3. In the case of a sole proprietorship, by the proprietor.

#### 19. NEED TO HALT OR REDUCE ACTIVITY

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 conditions of this permit.

#### 20. APPLICABLE FEDERAL RULES

All references to 40 CFR in this permit mean the version of 40 CFR which is effective as of the effective date of this permit.

21. AUTHORIZED DISCHARGES

All discharges authorized herein shall be consistent with the terms and conditions of this permit. The discharge of any pollutant identified in this permit more frequently than, or at a level in excess of, that authorized by this permit shall constitute a violation of the terms and conditions of this permit. Such violations may result in the imposition of civil and/or criminal penalties as provided for in Ohio Revised Code Sections 6111.09 and 6111.99.

22. DISPOSAL OF RESIDUALS

The storage and disposal of collected screenings, slurries, sludge or other solids shall be in accordance with Section 405 of the Clean Water Act and Subtitle C and D of the Resource Conservation and Recovery Act.

23. CIVIL AND CRIMINAL LIABILITY

Except as exempted in the permit conditions on unauthorized discharges, nothing in this permit shall be construed to relieve the permittee from civil or criminal penalties for noncompliance.

24. OTHER INFORMATION

A. 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.

B. ORC 6111.99 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 \$25,000 per violation.

C. ORC 6111.99 states that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or noncompliance shall, upon conviction, be punished by a fine of not more than \$25,000 per violation.

D. ORC 6111.99 provides that any person who violates Sections 6111.04, 6111.042, 6111.05, or division (A) of Section 6111.07 of the Revised Code shall be fined not more than \$25,000 or imprisoned not more than one year, or both.