John R. Kasich, Governor
Mary Taylor, Lt. Governor
Craig W. Butler, Director

6/11/2014

Certified Mail

No	TOXIC REVIEW
No	PSD
No	SYNTHETIC MINOR TO AVOID MAJOR NSR
No	CEMS
Yes	MACT/GACT
No	NSPS
No	NESHAPS
No	NETTING
No	MAJOR NON-ATTAINMENT
No	MODELING SUBMITTED
No	MAJOR GHG
No	SYNTHETIC MINOR TO AVOID MAJOR GHG

Patrick Stenski
Amylin Ohio LLC
8814 Trade Port Drive
West Chester, OH 45071

RE: FINALAIR POLLUTION PERMIT-TO-INSTALL
Facility ID: 1409040987
Permit Number: P0116675
Permit Type: Administrative Modification
County: Butler

Dear Permit Holder:

Enclosed please find a final Ohio Environmental Protection Agency (EPA)Air Pollution Permit-to-Install (PTI) which will allow you to install or modify the described emissions unit(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, we urge you to read it carefully. Because this permit contains conditions and restrictions, please read it very carefully. In this letter you will find the information on the following topics:

- **How to appeal this permit**
- **How to save money, reduce pollution and reduce energy consumption**
- **How to give us feedback on your permitting experience**
- **How to get an electronic copy of your permit**

How to appeal this permit

The issuance of this PTI is a final action of the Director and may be appealed to the Environmental Review Appeals Commission pursuant to Section 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of $70.00, made payable to “Ohio Treasurer Josh Mandel," which the Commission, in its discretion, may reduce if by affidavit you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General’s Office, Environmental Enforcement Section. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
77 South High Street, 17th Floor
Columbus, OH 43215

How to save money, reduce pollution and reduce energy consumption

The Ohio EPA is encouraging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Compliance Assistance and Pollution Prevention at (614) 644-3469. Additionally, all or a portion of the capital expenditures related to installing air pollution control equipment under this permit may be eligible for financing and State tax exemptions through the Ohio Air Quality Development Authority (OAQDA) under Ohio Revised Code Section 3706. For more information, see the OAQDA website: www.ohioairquality.org/clean_air

How to give us feedback on your permitting experience

Please complete a survey at www.epa.ohio.gov/survey.aspx and give us feedback on your permitting experience. We value your opinion.

How to get an electronic copy of your permit

This permit can be accessed electronically via the eBusiness Center: Air Services in Microsoft Word format or in Adobe PDF on the Division of Air Pollution Control (DAPC) Web page, www.epa.ohio.gov/dapc by clicking the "Search for Permits" link under the Permitting topic on the Programs tab.

If you have any questions, please contact Southwest Ohio Air Quality Agency at (513)946-7777 or the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469.

Sincerely,

Michael W. Ahern

Michael W. Ahern, Manager
Permit Issuance and Data Management Section, DAPC

Cc: U.S. EPA
SWOAQA; Indiana; Kentucky

FINAL

Division of Air Pollution Control
Permit-to-Install
for
Amylin Ohio LLC

Facility ID:	1409040987
Permit Number:	P0116675
Permit Type:	Administrative Modification
Issued:	6/11/2014
Effective:	6/11/2014

Division of Air Pollution Control
Permit-to-Install
for
Amylin Ohio LLC

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Authorization

Facility ID:	1409040987
Facility Description:	Pharmaceuticals manufacturer
Application Number(s):	M0002732
Permit Number:	P0116675
Permit Description:	Administrative Modification to the terms and conditions of P0114889 to correct previously provided information and to eliminate conditions no longer required.
Permit Type:	Administrative Modification
Permit Fee:	$100.00
Issue Date:	6/11/2014
Effective Date:	6/11/2014

This document constitutes issuance to:

Amylin Ohio LLC
8814 Trade Port Drive
West Chester Twp., OH 45071

of a Permit-to-Install for the emissions unit(s) identified on the following page.

Ohio Environmental Protection Agency (EPA) District Office or local air agency responsible for processing and administering your permit:

Southwest Ohio Air Quality Agency
250 William Howard Taft Rd.
Cincinnati, OH 45219
(513)946-7777

The above named entity is hereby granted a Permit-to-Install for the emissions unit(s) listed in this section pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Craig W. Butler
Director

Authorization (continued)

Permit Number: P0116675
Permit Description: Administrative Modification to the terms and conditions of P0114889 to correct previously provided information and to eliminate conditions no longer required.

Permits for the following Emissions Unit(s) or groups of Emissions Units are in this document as indicated below:

Emissions Unit ID:	**P001**
Company Equipment ID:	Production Line No. 1
Superseded Permit Number:	P0114889
General Permit Category and Type:	Not Applicable

A. Standard Terms and Conditions

1. Federally Enforceable Standard Terms and Conditions

a) All Standard Terms and Conditions are federally enforceable, with the exception of those listed below which are enforceable under State law only:

(1) Standard Term and Condition A.2.a), Severability Clause

(2) Standard Term and Condition A.3.c) through A. 3.e)General Requirements

(3) Standard Term and Condition A.6.c) and A. 6.d), Compliance Requirements

(4) Standard Term and Condition A.9., Reporting Requirements

(5) Standard Term and Condition A.10., Applicability

(6) Standard Term and Condition A.11.b) through A.11.e), Construction of New Source(s) and Authorization to Install

(7) Standard Term and Condition A.14., Public Disclosure

(8) Standard Term and Condition A.15., Additional Reporting Requirements When There Are No Deviations of Federally Enforceable Emission Limitations, Operational Restrictions, or Control Device Operating Parameter Limitations

(9) Standard Term and Condition A.16., Fees

(10) Standard Term and Condition A.17., Permit Transfers

2. Severability Clause

a) A determination that any term or condition of this permit is invalid shall not invalidate the force or effect of any other term or condition thereof, except to the extent that any other term or condition depends in whole or in part for its operation or implementation upon the term or condition declared invalid.

b) All terms and conditions designated in parts B and C of this permit are federally enforceable as a practical matter, if they are required under the Act, or any of its applicable requirements, including relevant provisions designed to limit the potential to emit of a source, are enforceable by the Administrator of the U.S. EPA and the State and by citizens (to the extent allowed by section 304 of the Act) under the Act. Terms and conditions in parts B and C of this permit shall not be federally enforceable and shall be enforceable under State law only, only if specifically identified in this permit as such.

3. General Requirements

a) Any noncompliance with the federally enforceable terms and conditions of this permit constitutes a violation of the Act, and is grounds for enforcement action or for permit revocation, revocation and re-issuance, or modification.

b) It shall not be a defense for the 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 federally enforceable terms and conditions of this permit.

c) This permit may be modified, revoked, or revoked and reissued, for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or revocation, or of a notification of planned changes or anticipated noncompliance does not stay any term and condition of this permit.

d) This permit does not convey any property rights of any sort, or any exclusive privilege.

e) The permittee shall furnish to the Director of the Ohio EPA, or an authorized representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying or revoking this permit or to determine compliance with this permit. Upon request, the permittee shall also furnish to the Director or an authorized representative of the Director, copies of records required to be kept by this permit. For information claimed to be confidential in the submittal to the Director, if the Administrator of the U.S. EPA requests such information, the permittee may furnish such records directly to the Administrator along with a claim of confidentiality.

4. Monitoring and Related Record Keeping and Reporting Requirements

a) Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall maintain records that include the following, where applicable, for any required monitoring under this permit:

(1) The date, place (as defined in the permit), and time of sampling or measurements.

(2) The date(s) analyses were performed.

(3) The company or entity that performed the analyses.

(4) The analytical techniques or methods used.

(5) The results of such analyses.

(6) The operating conditions existing at the time of sampling or measurement.

b) Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

c) Except as may otherwise be provided in the terms and conditions for a specific emissions unit, the permittee shall submit required reports in the following manner:

(1) Reports of any required monitoring and/or recordkeeping of federally enforceable information shall be submitted to the Southwest Ohio Air Quality Agency.

(2) Quarterly written reports of (i) any deviations from federally enforceable emissionlimitations, operationalrestrictions, andcontroldeviceoperatingparameterlimitations, excluding deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06, that have been detected by the testing, monitoring and recordkeeping requirements specified in this permit, (ii) the probable cause of such deviations, and (iii) any corrective actions or preventive measures taken, shall be made to the Southwest Ohio Air Quality Agency. The written reports shall be submitted (i.e., postmarked) quarterly, by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. See A.15. below if no deviations occurred during the quarter.

(3) Written reports, which identify any deviations from the federally enforceable monitoring, recordkeeping, andreportingrequirements contained in this permit shall be submitted to the Southwest Ohio Air Quality Agency every six months, by January 31 and July 31 of each year for the previous six calendar months. If no deviations occurred during a six-month period, the permittee shall submit a semi-annual report, which states that no deviations occurred during that period.

(4) This permit is for an emissions unit located at a Title V facility. Each written report shall be signed by a responsible official certifying that, based on information and belief formed after reasonable inquiry, the statements and information in the report are true, accurate, and complete.

d) The permittee shall report actual emissions pursuant to OAC Chapter 3745-78 for the purpose of collecting Air Pollution Control Fees.

5. Scheduled Maintenance/Malfunction Reporting

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction, i.e., upset, of any emissions units or any associated air pollution control system(s) shall be reported to theSouthwest Ohio Air Quality Agencyin accordance with paragraph (B) of OAC rule 3745-15-06. (The definition of an upset condition shall be the same as that used in OAC rule 3745-15-06(B)(1) for a malfunction.) The verbal and written reports shall be submitted pursuant to OAC rule 3745-15-06.

Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emission unit(s) that is (are) served by such control system(s).

6. Compliance Requirements

a) All applications, notifications or reports required by terms and conditions in this permit to be submitted or "reported in writing" are to be submitted to Ohio EPA through the Ohio EPA's eBusiness Center: Air Services web service ("Air Services"). Ohio EPA will accept hard copy submittals on an as-needed basis if the permittee cannot submit the required documents through the Ohio EPA eBusiness Center. In the event of an alternative hard copy submission in lieu of the eBusiness Center, the post-marked date or the date the document is delivered in person will be recognized as the date submitted. Electronic submission of applications, notifications or reports required to be submitted to Ohio EPA fulfills the requirement to submit the required information to the Director, the appropriate Ohio EPA District Office or contracted

local air agency, and/or any other individual or organization specifically identified as an additional recipient identified in this permit unless otherwise specified. Consistent with OAC rule 3745-15-03, the electronic signature date shall constitute the date that the required application, notification or report is considered to be "submitted". Any document requiring signature may be represented by entry of the personal identification number (PIN) by responsible official as part of the electronic submission process or by the scanned attestation document signed by the Authorized Representative that is attached to the electronically submitted written report.

Any document (including reports) required to be submitted and required by a federally applicable requirement in this permit shall include a certification by a Responsible Official that, based on information and belief formed after reasonable inquiry, the statements in the document are true, accurate, and complete.

b) Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Director of the Ohio EPA or an authorized representative of the Director to:

(1) At reasonable times, enter upon the permittee's premises where a source is located or the emissions-related activity is conducted, or where records must be kept under the conditions of this permit.

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit, subject to the protection from disclosure to the public of confidential information consistent with ORC section 3704.08.

(3) Inspect at reasonable times any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit.

(4) As authorized by the Act, sample or monitor at reasonable times substances or parameters for the purpose of assuring compliance with the permit and applicable requirements.

c) The permittee shall submit progress reports to the Southwest Ohio Air Quality Agency concerning any schedule of compliance for meeting an applicable requirement. Progress reports shall be submitted semiannually or more frequently if specified in the applicable requirement or by the Director of the Ohio EPA. Progress reports shall contain the following:

(1) Dates for achieving the activities, milestones, or compliance required in any schedule of compliance, and dates when such activities, milestones, or compliance were achieved.

(2) An explanation of why any dates in any schedule of compliance were not or will not be met, and any preventive or corrective measures adopted.

7. Best Available Technology

As specified in OAC Rule 3745-31-05, new sources that must employ Best Available Technology (BAT) shall comply with the Applicable Emission Limitations/Control Measures identified as BAT for each subject emissions unit.

8. Air Pollution Nuisance

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

9. Reporting Requirements

The permittee shall submit required reports in the following manner:

a) Reports of any required monitoring and/or recordkeeping of state-only enforceable information shall be submitted to the Southwest Ohio Air Quality Agency.

b) Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from state-only required emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the Southwest Ohio Air Quality Agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

10. Applicability

This Permit-to-Install is applicable only to the emissions unit(s) identified in the Permit-to-Install. Separate application must be made to the Director for the installation or modification of any other emissions unit(s)not exempt from the requirement to obtain a Permit-to-Install.

11. Construction of New Sources(s) and Authorization to Install

a) This permit does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. This permit does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the application and terms and conditions of this permit. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of this permit does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Issuance of this permit is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

b) If applicable, authorization to install any new emissions unit included in this permit shall terminate within eighteen months of the effective date of the permit if the owner or operator has not undertaken a continuing program of installation or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of

installation. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the permittee shows good cause for any such extension.

c) The permittee may notify Ohio EPA of any emissions unit that is permanently shut down (i.e., the emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31) by submitting a certification from the authorized official that identifies the date on which the emissions unit was permanently shut down. Authorization to operate the affected emissions unit shall cease upon the date certified by the authorized official that the emissions unit was permanently shut down. At a minimum, notification of permanent shut down shall be made or confirmed by marking the affected emissions unit(s) as “permanently shut down” in “Air Services” along with the date the emissions unit(s) was permanently removed and/or disabled. Submitting the facility profile update electronically will constitute notifying the Director of the permanent shutdown of the affected emissions unit(s).

d) The provisions of this permit shall cease to be enforceable for each affected emissions unit after the date on which an emissions unit is permanently shut down (i.e., emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31). All records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, must be maintained in accordance with law. All reports required by this permit must be submitted for any period an affected emissions unit operated prior to permanent shut down. At a minimum, the permit requirements must be evaluated as part of the reporting requirements identified in this permit covering the last period the emissions unit operated.

Unless otherwise exempted,no emissions unit certified by the responsible official as being permanently shut down may resume operation without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31 and OAC Chapter 3745-77 if the restarted operation is subject to one or more applicable requirements.

e) The permittee shall comply with any residual requirements related to this permit, such as the requirement to submit a deviation report, air fee emission report, or other any reporting required by this permit for the period the operating provisions of this permit were enforceable, or as required by regulation or law. All reports shall be submitted in a form and manner prescribed by the Director. All records relating to this permit must be maintained in accordance with law.

12. Permit-To-Operate Application

The permittee is required to apply for a Title V permit pursuant to OAC Chapter 3745-77. The permittee shall submit a complete Title V permit application or a complete Title V permit modification application within twelve (12) months after commencing operation of the emissions units covered by this permit. However, if operation of the proposed new or modified source(s) as authorized by this permit would be prohibited by the terms and conditions of an existing Title V permit, a Title V permit modification of such new or modified source(s) pursuant to OAC rule 3745-77-04(D) and OAC rule 3745-77-08(C)(3)(d)must be <u>obtained before</u>operating the source in a manner that would violate the existing Title V permit requirements.

13. Construction Compliance Certification

The applicant shall identify the following dates in the "Air Services" facility profile for each new emissions unit identified in this permit.

a) Completion of initial installation date shall be enteredupon completion of construction and prior to start-up.

b) Commence operation after installation or latest modification date shall be entered within 90 days after commencing operation of the applicable emissions unit.

14. Public Disclosure

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

15. Additional Reporting Requirements When There Are No Deviations of Federally Enforceable Emission Limitations, Operational Restrictions, or Control Device Operating Parameter Limitations

If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters.

16. Fees

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable permit-to-install fees within 30 days after the issuance of any permit-to-install. The permittee shall pay all applicable permit-to-operate fees within thirty days of the issuance of the invoice.

17. Permit Transfers

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The new owner must update and submit the ownership information via the "Owner/Contact Change" functionality in "Air Services" once the transfer is legally completed.The change must be submitted through "Air Services" within thirty days of the ownership transfer date.

18. Risk Management Plans

If the permittee is required to develop and register a risk management plan pursuant to section 112(r) of the Clean Air Act, as amended, 42 U.S.C. 7401 et seq. ("Act"), the permittee shall comply with the requirement to register such a plan.

19. Title IV Provisions

If the permittee is subject to the requirements of 40 CFR Part 72 concerning acid rain, the permittee shall ensure that any affected emissions unit complies with those requirements. Emissions exceeding any allowances that are lawfully held under Title IV of the Act, or any regulations adopted thereunder, are prohibited.

B. Facility-Wide Terms and Conditions

1. All the following facility-wide terms and conditions are federally enforceable with the exception of those listed below which are enforceable under state law only:

   a) None.

2. The following emissions unit contained in this permit is subject to 40 CFR Part 63, Subpart GGG: P001. The complete MACT requirements, including the MACT General Provisions may be accessed via the internet from the Electronic Code of Federal Regulations (e-CFR) website http://ecfr.gpoaccess.gov or by contacting the appropriate Ohio EPA District office or local air agency.

C. Emissions Unit Terms and Conditions

1. P001, Production Line No. 1

Operations, Property and/or Equipment Description:

Production line No. 1

a) The following emissions unit terms and conditions are federally enforceable with the exception of those listed below which are enforceable under state law only.

(1) None.

b) Applicable Emissions Limitations and/or Control Requirements

(1) The specific operation(s), property, and/or equipment that constitute each emissions unit along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures are identified below. Emissions from each unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3), as effective 11/30/01	Particulate emissions (PE) and particulate matter emissions ten microns and less in diameter (PM10) shall not exceed 0.26 tons per month averaged over a twelve-month rolling period. Organic compound (OC) stack emissions shall not exceed 91.2 pounds per month averaged over a twelve-month rolling period. Fugitive organic compound emissions shall not exceed 0.58 tons per month from pumps, valves, flanges and other fittings averaged over a twelve-month rolling period. See b)(2)a.
b.	OAC rule 3745-31-05(A)(3)(b), as effective 12/01/06	See b)(2)b.
c.	OAC rule 3745-17-07(A)(1)	Visible particulate emissions from any stack serving this emissions unit shall not exceed 20% opacity, as a six-minute average, except as specified by rule.
d.	OAC rule 3745-17-11(B)	Particulate emissions (PE) shall not exceed 0.70 pound per hour.
e.	40 CFR Part 63 Subpart GGG (40 CFR 63.1250-1261)	Uncontrolled HAP emissions from the sum of all process vents within a process

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
	In accordance with 40 CFR 63.1250 this emissions unit is a pharmaceutical manufacturing process dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP.	shall be reduced by 98 percent or greater by weight. See 40 CFR 63.1255 for equipment leak standards and 40 CFR 63.1255 for wastewater standards.
f.	40 CFR 63.1-63.15	Table 1 to Subpart GGG of 40 CFR Part 63 – Applicability of General Provisions to Subpart GGG which shows which parts of the General Provisions in 40 CFR Part 63 apply.

(2) Additional Terms and Conditions

a. The permittee has satisfied the Best Available Technology (BAT) requirements pursuant to Ohio Administrative Code (OAC) paragraph 3745-31-05(A)(3), as effective November 30, 2001, in this permit. On December 1, 2006, paragraph (A)(3) of OAC rule 3745-31-05 was revised to conform to the Ohio Revised Code (ORC) changes effective August 3, 2006 (Senate Bill 265 changes), such that BAT is no longer required by State regulations for National Ambient Air Quality Standards (NAAQS) pollutant(s) less than ten tons per year. However, that rule revision has not yet been approved by U.S. EPA as a revision to Ohio's State Implementation Plan (SIP). Therefore, until the SIP revision occurs and the U.S. EPA approves the revisions to OAC rule 3745-31-05, the requirement to satisfy BAT still exists as part of the federally-approved SIP for Ohio. Once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05, then these emission limitations/control measures no longer apply.

b. This rule paragraph applies once U.S. EPA approves the December 1, 2006 version of OAC rule 3745-31-05 as part of the State Implementation Plan.

The Best Available Technology (BAT) requirements under OAC rule 3745-31 05(A)(3) do not apply to the PE and PM10 emissions from this air contaminant source since the uncontrolled Potential to Emit (PTE) for PE and PM10 is less than 10 tons per year.

The Best Available Technology (BAT) requirements under OAC rule 3745-31 05(A)(3) do not apply to the OC emissions from this air contaminant source since the calculated annual emission rate of OC is less than 10 tons per year.

c) Operational Restrictions

(1) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall perform weekly checks, when the emissions unit is in operation and when the weather conditions allow, for any visible particulate emissions from the stack serving this emissions unit. The presence or absence of any visible emissions shall be noted in an operations log. If visible emissions are observed, the permittee shall also note the following in the operations log:

a. the color of the emissions;

b. whether the emissions are representative of normal operations;

c. if the emissions are not representative of normal operations, the cause of the abnormal emissions;

d. the total duration of any visible emissions incident; and

e. any corrective actions taken to minimize or eliminate the visible emissions.

If visible emissions are present, a visible emissions incident has occurred. The observer does not have to document the exact start and end times for the visible emissions incident under item (d) above or continue the daily check until the incident has ended. The observer may indicate that the visible emissions incident was continuous during the observation period (or, if known, continuous during the operation of the emissions unit). With respect to the documentation of corrective actions, the observer may indicate that no corrective actions were taken if the visible emissions were representative of normal operations, or specify the minor corrective actions that were taken to ensure that the emissions unit continued to operate under normal conditions, or specify the corrective actions that were taken to eliminate abnormal visible emissions.

(2) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

e) Reporting Requirements

(1) The permittee shall submit semiannual written reports that identify:

a. all weeks during which any visible particulate emissions were observed from the stack serving this emissions unit; and

b. any corrective actions taken to minimize or eliminate the visible particulate emissions.

These reports shall be submitted to the Director (the appropriate Ohio EPA District Office or local air agency) by January 31 and July 31 of each year and shall cover the previous 6-month period.

(2) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

(3) Unless other arrangements have been approved by the Director, all notifications and reports shall be submitted through the Ohio EPA's eBusiness Center: Air Services online web portal.

f) Testing Requirements

(1) Compliance with the Emissions Limitations and/or Control Requirements specified in section b) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitations:

0.26 tons per month of PE/PM10 averaged over a twelve-month rolling period.

Applicable Compliance Method:

Compliance with the monthly PE emissions limit shall be demonstrated by multiplying the maximum hours of operation of the most recent twelve months of operation by the maximum hourly emissions rate, dividing by twelve and converting to tons by multiplying by 1 ton/2000 lb.

The maximum hourly emission rate was determined to be 0.70 pound per hour based on Table I in OAC rule 3745-17-11 and a process weight rate of 142.6 pounds per hour for the process.

All PE was assumed to be PM10.

b. Emission Limitations:

91.7 pounds per month of OC stack emissions averaged over a twelve-month rolling period.

0.58 tons of OC fugitive emissions from pumps, valves, flanges and other fittings averaged over a twelve-month rolling period*

Applicable Compliance Method:

Compliance with the monthly rolling OC emissions limitation shall be determined by multiplying the maximum OC pounds per batch emissions by the maximum batches of operation (183) annually and dividing by twelve.

The pounds per batch OC emissions are calculated by multiplying the uncontrolled OC pounds per batch by one minus the 96.2% control efficiency of the cryogenic condenser required by Administrative Consent Order EPA-5-13-113(a)-OH-2, USEPA Region 5, July 17, 2013.

The uncontrolled pounds per batch of OC are 157.1 pounds. This was provided in the permit application submitted June 7, 2013 by Amylin Ohio LLC based on Detailed Emission Master Process Calculations testing done at that facility in October of 2012.

If required, the permittee shall demonstrate the accuracy of the the pounds per batch OC emissions calculation through emission tests performed in accordance with 40 CFR Part 60, Appendix A, Methods 1 through 4 and 25 or 25a.

*An additional 7 tons of fugitive OC emissions are released from pumps, valves, flanges and other fittings each year based on Detailed Emission Master Process Calculations done at the Amylin facility in October of 2012. 7 tons divided by 12 months = 0.58 tons per month.

c. Emission Limitation:

Visible particulate emissions from any stack shall not exceed 20% opacity, as a 6-minute average.

Applicable Compliance Method:

If required, compliance shall be determined through visible emissions observations performed in accordance with 40 CFR Part 60, Appendix A, Method 9.

(2) See 40 CFR Part 63, Subpart GGG (40 CFR 63.1250-1261).

g) Miscellaneous Requirements

(1) None.