



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY PROGRAM

STATE ONLY OPERATING PERMIT

Issue Date: July 16, 2018

Effective Date: July 16, 2018

Expiration Date: June 30, 2023

In accordance with the provisions of the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, as amended, and 25 Pa. Code Chapter 127, the Owner, [and Operator if noted] (hereinafter referred to as permittee) identified below is authorized by the Department of Environmental Protection (Department) to operate the air emission source(s) more fully described in this permit. This Facility is subject to all terms and conditions specified in this permit. Nothing in this permit relieves the permittee from its obligations to comply with all applicable Federal, State and Local laws and regulations.

The regulatory or statutory authority for each permit condition is set forth in brackets. All terms and conditions in this permit are federally enforceable unless otherwise designated.

State Only Permit No: 25-00918

Federal Tax Id - Plant Code: 52-1598781-1

Owner Information

Name: COSMED GROUP INC
Mailing Address: 2205 E 33RD ST
ERIE, PA 16510-2555

Plant Information

Plant: COSMED GROUP LLC/ERIE
Location: 25 Erie County 25001 Erie City
SIC Code: 3841 Manufacturing - Surgical And Medical Instruments

Responsible Official

Name: DAVID G HOWE
Title: CHIEF OPERATING OFFICER
Phone: (908) 583 - 5500

Permit Contact Person

Name: CHRISTINE RENDER
Title: DIR OF CORP QA & RA
Phone: (908) 374 - 1037

[Signature] _____
ERIC A. GUSTAFSON, NORTHWEST REGION AIR PROGRAM MANAGER

**SECTION A. Table of Contents****Section A. Facility/Source Identification**

Table of Contents
Site Inventory List

Section B. General State Only Requirements

- #001 Definitions.
- #002 Operating Permit Duration.
- #003 Permit Renewal.
- #004 Operating Permit Fees under Subchapter I.
- #005 Transfer of Operating Permits.
- #006 Inspection and Entry.
- #007 Compliance Requirements.
- #008 Need to Halt or Reduce Activity Not a Defense.
- #009 Duty to Provide Information.
- #010 Revising an Operating Permit for Cause.
- #011 Operating Permit Modifications
- #012 Severability Clause.
- #013 De Minimis Emission Increases.
- #014 Operational Flexibility.
- #015 Reactivation
- #016 Health Risk-based Emission Standards and Operating Practice Requirements.
- #017 Circumvention.
- #018 Reporting Requirements.
- #019 Sampling, Testing and Monitoring Procedures.
- #020 Recordkeeping.
- #021 Property Rights.
- #022 Alternative Operating Scenarios.

Section C. Site Level State Only Requirements

- C-I: Restrictions
- C-II: Testing Requirements
- C-III: Monitoring Requirements
- C-IV: Recordkeeping Requirements
- C-V: Reporting Requirements
- C-VI: Work Practice Standards
- C-VII: Additional Requirements
- C-VIII: Compliance Certification
- C-IX: Compliance Schedule

Section D. Source Level State Only Requirements

- D-I: Restrictions
- D-II: Testing Requirements
- D-III: Monitoring Requirements
- D-IV: Recordkeeping Requirements
- D-V: Reporting Requirements
- D-VI: Work Practice Standards
- D-VII: Additional Requirements

Note: These same sub-sections are repeated for each source!

Section E. Source Group Restrictions

- E-I: Restrictions
- E-II: Testing Requirements
- E-III: Monitoring Requirements



SECTION A. Table of Contents

- E-IV: Recordkeeping Requirements
- E-V: Reporting Requirements
- E-VI: Work Practice Standards
- E-VII: Additional Requirements

Section F. Alternative Operating Scenario(s)

- F-I: Restrictions
- F-II: Testing Requirements
- F-III: Monitoring Requirements
- F-IV: Recordkeeping Requirements
- F-V: Reporting Requirements
- F-VI: Work Practice Standards
- F-VII: Additional Requirements

Section G. Emission Restriction Summary

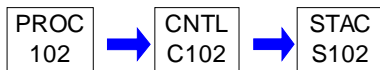
Section H. Miscellaneous



SECTION A. Site Inventory List

Source ID	Source Name	Capacity/Throughput	Fuel/Material
101	ETO STERILIZER CHAMBERS (4)	0.004 Lbs/HR	ETHYLENE OXIDE
102	AERATION ROOMS (2)	0.001 Lbs/HR	ETHYLENE OXIDE
C101	ACID SCRUBBER		
C102	ETO ABSORBENT (3 UNITS)		
S101	SCRUBBER STACK		
S102	ABSORBENT STACK		

PERMIT MAPS



**SECTION B. General State Only Requirements****#001 [25 Pa. Code § 121.1]****Definitions.**

Words and terms that are not otherwise defined in this permit shall have the meanings set forth in Section 3 of the Air Pollution Control Act (35 P.S. § 4003) and in 25 Pa. Code § 121.1.

#002 [25 Pa. Code § 127.446]**Operating Permit Duration.**

- (a) This operating permit is issued for a fixed term of five (5) years and shall expire on the date specified on Page 1 of this permit.
- (b) The terms and conditions of the expired permit shall automatically continue pending issuance of a new operating permit, provided the permittee has submitted a timely and complete application and paid applicable fees required under 25 Pa. Code Chapter 127, Subchapter I and the Department is unable, through no fault of the permittee, to issue or deny a new permit before the expiration of the previous permit.

#003 [25 Pa. Code §§ 127.412, 127.413, 127.414, 127.446 & 127.703(b)&(c)]**Permit Renewal.**

- (a) The permittee shall submit a timely and complete application for renewal of the operating permit to the appropriate Regional Air Program Manager. The application for renewal of the operating permit shall be submitted at least six (6) months and not more than 18 months before the expiration date of this permit.
- (b) The application for permit renewal shall include the current permit number, a description of any permit revisions that occurred during the permit term, and any applicable requirements that were promulgated and not incorporated into the permit during the permit term. An application is complete if it contains sufficient information to begin processing the application, has the applicable sections completed and has been signed by a responsible official.
- (c) The permittee shall submit with the renewal application a fee for the processing of the application and an additional annual administrative fee as specified in 25 Pa. Code § 127.703(b) and (c). The fees shall be made payable to "The Commonwealth of Pennsylvania - Clean Air Fund" and shall be for the amount specified in the following schedule specified in 25 Pa. Code § 127.703(b) and (c).
- (1) Three hundred dollars for applications filed during the 2000-2004 calendar years.
 - (2) Three hundred seventy-five dollars for applications filed for the calendar years beginning in 2005.
- (d) The renewal application shall also include submission of proof that the local municipality and county, in which the facility is located, have been notified in accordance with 25 Pa. Code § 127.413.
- (e) The application for renewal of the operating permit shall also include submission of supplemental compliance review forms in accordance with the requirements of 25 Pa. Code § 127.412(b) and § 127.412(j).
- (f) The permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information as necessary to address any requirements that become applicable to the source after the permittee submits a complete application, but prior to the date the Department takes action on the permit application.

#004 [25 Pa. Code § 127.703]**Operating Permit Fees under Subchapter I.**

- (a) The permittee shall pay fees according to the following schedule specified in 25 Pa. Code § 127.703(b):
- (1) Three hundred dollars for applications filed during the 2000-2004 calendar years.
 - (2) Three hundred seventy-five dollars for applications filed for the calendar years beginning in 2005.

This fee schedule shall apply to the processing of an application for an operating permit as well as the extension,

**SECTION B. General State Only Requirements**

modification, revision, renewal, and re-issuance of each operating permit or part thereof.

(b) The permittee shall pay an annual operating permit administrative fee according to the fee schedule established in 25 Pa. Code § 127.703(c).

(1) Two hundred fifty dollars for applications filed during the 1995-1999 calendar years.

(2) Three hundred dollars for applications filed during the 2000-2004 calendar years.

(3) Three hundred seventy-five dollars for applications filed during the years beginning in 2005.

(c) The applicable fees shall be made payable to "The Commonwealth of Pennsylvania - Clean Air Fund".

#005 [25 Pa. Code §§ 127.450 (a)(4) and 127.464]**Transfer of Operating Permits.**

(a) This operating permit may not be transferred to another person, except in cases of transfer-of-ownership that are documented and approved by the Department.

(b) In accordance with 25 Pa. Code § 127.450(a)(4), a change in ownership of the source shall be treated as an administrative amendment if the Department determines that no other change in the permit is required and a written agreement has been submitted to the Department identifying the specific date of the transfer of permit responsibility, coverage and liability between the current and the new permittee and a compliance review form has been submitted to, and the permit transfer has been approved by, the Department.

(c) This operating permit is valid only for those specific sources and the specific source locations described in this permit.

#006 [25 Pa. Code § 127.441 and 35 P.S. § 4008]**Inspection and Entry.**

(a) Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Department or authorized representatives of the Department to perform the following:

(1) Enter at reasonable times upon the permittee's premises where a source is located or emissions related activity is conducted, or where records are kept under the conditions of this permit;

(2) Have access to and copy, at reasonable times, any records that are kept under the conditions of this permit;

(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) Sample or monitor, at reasonable times, any substances or parameters, for the purpose of assuring compliance with the permit or applicable requirements as authorized by the Clean Air Act, the Air Pollution Control Act, or the regulations promulgated under the Acts.

(b) Pursuant to 35 P.S. § 4008, no person shall hinder, obstruct, prevent or interfere with the Department or its personnel in the performance of any duty authorized under the Air Pollution Control Act or regulations adopted thereunder including denying the Department access to a source at this facility. Refusal of entry or access may constitute grounds for permit revocation and assessment of criminal and/or civil penalties.

(c) Nothing in this permit condition shall limit the ability of the EPA to inspect or enter the premises of the permittee in accordance with Section 114 or other applicable provisions of the Clean Air Act.

#007 [25 Pa. Code §§ 127.441 & 127.444]**Compliance Requirements.**

(a) The permittee shall comply with the conditions of this operating permit. Noncompliance with this permit constitutes

**SECTION B. General State Only Requirements**

a violation of the Clean Air Act and the Air Pollution Control Act and is grounds for one or more of the following:

- (1) Enforcement action
- (2) Permit termination, revocation and reissuance or modification
- (3) Denial of a permit renewal application

(b) A person may not cause or permit the operation of a source which is subject to 25 Pa. Code Article III unless the source(s) and air cleaning devices identified in the application for the plan approval and operating permit and the plan approval issued for the source is operated and maintained in accordance with specifications in the applications and the conditions in the plan approval and operating permit issued by the Department. A person may not cause or permit the operation of an air contamination source subject to 25 Pa. Code Chapter 127 in a manner inconsistent with good operating practices.

(c) For purposes of Sub-condition (b) of this permit condition, the specifications in applications for plan approvals and operating permits are the physical configurations and engineering design details which the Department determines are essential for the permittee's compliance with the applicable requirements in this State-Only permit. Nothing in this sub-condition shall be construed to create an independent affirmative duty upon the permittee to obtain a predetermination from the Department for physical configuration or engineering design detail changes made by the permittee.

#008 [25 Pa. Code § 127.441]**Need to Halt or Reduce Activity Not a Defense.**

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

#009 [25 Pa. Code §§ 127.442(a) & 127.461]**Duty to Provide Information.**

(a) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of each source at the facility.

(b) The permittee shall furnish to the Department, in writing, information that the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Department copies of records that the permittee is required to maintain in accordance with this permit.

#010 [25 Pa. Code § 127.461]**Revising an Operating Permit for Cause.**

This operating permit may be terminated, modified, suspended or revoked and reissued if one or more of the following applies:

- (1) The permittee constructs or operates the source subject to the operating permit so that it is in violation of the Air Pollution Control Act, the Clean Air Act, the regulations thereunder, a plan approval, a permit or in a manner that causes air pollution.
- (2) The permittee fails to properly or adequately maintain or repair an air pollution control device or equipment attached to or otherwise made a part of the source.
- (3) The permittee has failed to submit a report required by the operating permit or an applicable regulation.
- (4) The EPA determines that the permit is not in compliance with the Clean Air Act or the regulations thereunder.

#011 [25 Pa. Code §§ 127.450 & 127.462]**Operating Permit Modifications**

(a) The permittee is authorized to make administrative amendments, minor operating permit modifications and

SECTION B. General State Only Requirements

significant operating permit modifications, under this permit, as outlined below:

(b) Administrative Amendments. The permittee shall make administrative operating permit amendments (as defined in 25 Pa. Code § 127.450(a)), according to procedures specified in § 127.450 unless precluded by the Clean Air Act or its regulations.

(c) Minor Operating Permit Modifications. The permittee shall make minor operating permit modifications (as defined 25 Pa. Code § 121.1) in accordance with 25 Pa. Code § 127.462.

(d) Permit modifications which do not qualify as minor permit modifications under 25 Pa. Code § 127.541 will be treated as a significant operating permit revision subject to the public notification procedures in §§ 127.424 and 127.425.

#012 [25 Pa. Code § 127.441]**Severability Clause.**

The provisions of this permit are severable, and if any provision of this permit is determined by a court of competent jurisdiction to be invalid or unenforceable, such a determination will not affect the remaining provisions of this permit.

#013 [25 Pa. Code § 127.449]**De Minimis Emission Increases.**

(a) This permit authorizes de minimis emission increases in accordance with 25 Pa. Code § 127.449 so long as the permittee provides the Department with seven (7) days prior written notice before commencing any de minimis emissions increase. The written notice shall:

(1) Identify and describe the pollutants that will be emitted as a result of the de minimis emissions increase.

(2) Provide emission rates expressed in tons per year and in terms necessary to establish compliance consistent with any applicable requirement.

(b) The Department may disapprove or condition de minimis emission increases at any time.

(c) Except as provided below in (d), the permittee is authorized to make de minimis emission increases (expressed in tons per year) up to the following amounts without the need for a plan approval or prior issuance of a permit modification:

(1) Four tons of carbon monoxide from a single source during the term of the permit and 20 tons of carbon monoxide at the facility during the term of the permit.

(2) One ton of NO_x from a single source during the term of the permit and 5 tons of NO_x at the facility during the term of the permit.

(3) One and six-tenths tons of the oxides of sulfur from a single source during the term of the permit and 8.0 tons of oxides of sulfur at the facility during the term of the permit.

(4) Six-tenths of a ton of PM₁₀ from a single source during the term of the permit and 3.0 tons of PM₁₀ at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(5) One ton of VOCs from a single source during the term of the permit and 5.0 tons of VOCs at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(d) In accordance with § 127.14, the permittee is authorized to install the following minor sources without the need for a plan approval or permit modification:

**SECTION B. General State Only Requirements**

(1) Air conditioning or ventilation systems not designed to remove pollutants generated or released from other sources.

(2) Combustion units rated at 2,500,000 or less Btu per hour of heat input.

(3) Combustion units with a rated capacity of less than 10,000,000 Btu per hour heat input fueled by natural gas supplied by a public utility or by commercial fuel oils which are No. 2 or lighter, viscosity less than or equal to 5.82 c St, and which meet the sulfur content requirements of 25 Pa. Code §123.22 (relating to combustion units). For purposes of this permit, commercial fuel oil shall be virgin oil which has no reprocessed, recycled or waste material added.

(4) Space heaters which heat by direct heat transfer.

(5) Laboratory equipment used exclusively for chemical or physical analysis.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(e) This permit does not authorize de minimis emission increases if the emissions increase would cause one or more of the following:

(1) Increase the emissions of a pollutant regulated under Section 112 of the Clean Air Act except as authorized in Subparagraphs (c)(4) and (5) of this permit condition.

(2) Subject the facility to the prevention of significant deterioration requirements in 25 Pa. Code Chapter 127, Subchapter D and/or the new source review requirements in Subchapter E.

(3) Violate any applicable requirement of this permit, the Air Pollution Control Act, the Clean Air Act, or the regulations promulgated under either of the acts.

(f) Emissions authorized under this permit condition shall be included in the monitoring, recordkeeping and reporting requirements of this permit.

(g) Except for de minimis emission increases, installation of minor sources made pursuant to this permit condition and Plan Approval Exemptions under 25 Pa. Code § 127.14 (relating to exemptions), the permittee is prohibited from making changes or engaging in activities that are not specifically authorized under this permit without first applying for a plan approval. In accordance with § 127.14(b), a plan approval is not required for the construction, modification, reactivation, or installation of the sources creating the de minimis emissions increase.

(h) The permittee may not meet de minimis emission threshold levels by offsetting emission increases or decreases at the same source.

#014 [25 Pa. Code § 127.3]**Operational Flexibility.**

The permittee is authorized to make changes within the facility in accordance with the regulatory provisions outlined in 25 Pa. Code § 127.3 (relating to operational flexibility) to implement the operational flexibility requirements provisions authorized under Section 6.1(i) of the Air Pollution Control Act and the operational flexibility terms and conditions of this permit. The provisions in 25 Pa. Code Chapter 127 which implement the operational flexibility requirements include the following:

(1) Section 127.14 (relating to exemptions)

(2) Section 127.447 (relating to alternative operating scenarios)

(3) Section 127.448 (relating to emissions trading at facilities with Federally enforceable emissions caps)

(4) Section 127.449 (relating to de minimis emission increases)

(5) Section 127.450 (relating to administrative operating permit amendments)

**SECTION B. General State Only Requirements**

(6) Section 127.462 (relating to minor operating permit modifications)

(7) Subchapter H (relating to general plan approvals and general operating permits)

#015 [25 Pa. Code § 127.11]**Reactivation**

(a) The permittee may not reactivate a source that has been out of operation or production for at least one year unless the reactivation is conducted in accordance with a plan approval granted by the Department or in accordance with reactivation and maintenance plans developed and approved by the Department in accordance with 25 Pa. Code § 127.11a(a).

(b) A source which has been out of operation or production for more than five (5) years but less than 10 years may be reactivated and will not be considered a new source if the permittee satisfies the conditions specified in 25 Pa. Code § 127.11a(b).

#016 [25 Pa. Code § 127.36]**Health Risk-based Emission Standards and Operating Practice Requirements.**

(a) When needed to protect public health, welfare and the environment from emissions of hazardous air pollutants from new and existing sources, the permittee shall comply with the health risk-based emission standards or operating practice requirements imposed by the Department, except as precluded by §§ 6.6(d)(2) and (3) of the Air Pollution Control Act [35 P.S. § 4006.6(d)(2) and (3)].

(b) A person challenging a performance or emission standard established by the Department has the burden to demonstrate that performance or emission standard does not meet the requirements of Section 112 of the Clean Air Act.

#017 [25 Pa. Code § 121.9]**Circumvention.**

No person may permit the use of a device, stack height which exceeds good engineering practice stack height, dispersion technique or other technique which, without resulting in reduction of the total amount of air contaminants emitted, conceals or dilutes an emission of air contaminants which would otherwise be in violation of 25 Pa. Code Article III, except that with prior approval of the Department, the device or technique may be used for control of malodors.

#018 [25 Pa. Code §§ 127.402(d) & 127.442]**Reporting Requirements.**

(a) The permittee shall comply with the applicable reporting requirements of the Clean Air Act, the regulations thereunder, the Air Pollution Control Act and 25 Pa. Code Article III including Chapters 127, 135 and 139.

(b) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of any air contamination source.

(c) Reports, test data, monitoring data, notifications and requests for renewal of the permit shall be submitted to the:

Regional Air Program Manager
PA Department of Environmental Protection
(At the address given in the permit transmittal letter, or otherwise notified)

(d) Any records or information including applications, forms, or reports submitted pursuant to this permit condition shall contain a certification by a responsible official as to truth, accuracy and completeness. The certifications submitted under this permit shall require a responsible official of the facility to certify that based on information and belief formed after reasonable inquiry, the statements and information in the documents are true, accurate and complete.

(e) Any records, reports or information submitted to the Department shall be available to the public except for such

**SECTION B. General State Only Requirements**

records, reports or information which meet the confidentiality requirements of § 4013.2 of the Air Pollution Control Act and §§ 112(d) and 114(c) of the Clean Air Act. The permittee may not request a claim of confidentiality for any emissions data generated for the facility.

#019 [25 Pa. Code §§ 127.441(c) & 135.5]**Sampling, Testing and Monitoring Procedures.**

(a) The permittee shall comply with the monitoring, recordkeeping or reporting requirements of 25 Pa. Code Chapter 139 and the other applicable requirements of 25 Pa. Code Article III and additional requirements related to monitoring, reporting and recordkeeping required by the Clean Air Act and the regulations thereunder including the Compliance Assurance Monitoring requirements of 40 CFR Part 64, where applicable.

(b) Unless alternative methodology is required by the Clean Air Act and regulations adopted thereunder, sampling, testing and monitoring required by or used by the permittee to demonstrate compliance with any applicable regulation or permit condition shall be conducted in accordance with the requirements of 25 Pa. Code Chapter 139.

#020 [25 Pa. Code §§ 127.441(c) and 135.5]**Recordkeeping.**

(a) The permittee shall maintain and make available, upon request by the Department, the following records of monitored information:

- (1) The date, place (as defined in the permit) and time of sampling or measurements.
- (2) The dates the analyses were performed.
- (3) The company or entity that performed the analyses.
- (4) The analytical techniques or methods used.
- (5) The results of the analyses.
- (6) The operating conditions as existing at the time of sampling or measurement.

(b) The permittee shall retain records of any required monitoring data and supporting information for at least five (5) years from the date of the monitoring, sample, measurement, report or application. Supporting information includes the calibration data and maintenance records and original strip-chart recordings for continuous monitoring instrumentation, and copies of reports required by the permit.

(c) The permittee shall maintain and make available to the Department upon request, records including computerized records that may be necessary to comply with the reporting, recordkeeping and emission statement requirements in 25 Pa. Code Chapter 135 (relating to reporting of sources). In accordance with 25 Pa. Code Chapter 135, § 135.5, such records may include records of production, fuel usage, maintenance of production or pollution control equipment or other information determined by the Department to be necessary for identification and quantification of potential and actual air contaminant emissions.

#021 [25 Pa. Code § 127.441(a)]**Property Rights.**

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

#022 [25 Pa. Code § 127.447]**Alternative Operating Scenarios.**

The permittee is authorized to make changes at the facility to implement alternative operating scenarios identified in this permit in accordance with 25 Pa. Code § 127.447.

**SECTION C. Site Level Requirements****I. RESTRICTIONS.****Emission Restriction(s).****# 001 [25 Pa. Code §121.7]****Prohibition of air pollution.**

No person may permit air pollution as that term is defined in the Air Pollution Control Act (35 P. S. §§ 4001—4015).

002 [25 Pa. Code §123.1]**Prohibition of certain fugitive emissions**

(a) No person may permit the emission into the outdoor atmosphere of fugitive air contaminant from a source other than the following:

(1) Construction or demolition of buildings or structures.

(2) Grading, paving and maintenance of roads and streets.

(3) Use of roads and streets. Emissions from material in or on trucks, railroad cars and other vehicular equipment are not considered as emissions from use of roads and streets.

(4) Clearing of land.

(5) Stockpiling of materials.

(6) Open burning operations.

(7) Not applicable

(8) Not applicable

(9) Sources and classes of sources other than those identified in paragraphs (1)-(8), for which the operator has obtained a determination from the Department that fugitive emissions from the source, after appropriate control, meet the following requirements:

(i) the emissions are of minor significance with respect to causing air pollution; and

(ii) the emissions are not preventing or interfering with the attainment or maintenance of any ambient air quality standard.

003 [25 Pa. Code §123.2]**Fugitive particulate matter**

A person may not permit fugitive particulate matter to be emitted into the outdoor atmosphere from a source specified in 123.1(a)(1) -- (9) (relating to prohibition of certain fugitive emissions) if such emissions are visible at the point the emissions pass outside the person's property.

004 [25 Pa. Code §123.31]**Limitations**

A person may not permit the emission into the outdoor atmosphere of any malodorous air contaminants from any source in such a manner that the malodors are detectable outside the property of the person on whose land the source is being operated.

005 [25 Pa. Code §123.41]**Limitations**

A person may not permit the emission into the outdoor atmosphere of visible air contaminants in such a manner that the opacity of the emission is either of the following:

(1) Equal to or greater than 20% for a period or periods aggregating more than three minutes in any 1 hour.

(2) Equal to or greater than 60% at any time.

SECTION C. Site Level Requirements**# 006 [25 Pa. Code §123.42]****Exceptions**

The limitations of 123.41 (relating to limitations) shall not apply to a visible emission in any of the following instances:

- (1) when the presence of uncombined water is the only reason for failure of the emission to meet the limitations.
- (2) When the emission results from the operation of equipment used solely to train and test persons in observing the opacity of visible emissions.
- (3) When the emission results from sources specified in 123.1(a)(1) -- (9) (relating to prohibition of certain fugitive emissions).
- (4) Not applicable

II. TESTING REQUIREMENTS.**# 007 [25 Pa. Code §123.43]****Measuring techniques**

Visible emissions may be measured using either of the following:

- (1) A device approved by the Department and maintained to provide accurate opacity measurements.
- (2) Observers, trained and qualified to measure plume opacity with the naked eye or with the aid of any devices approved by the Department.

III. MONITORING REQUIREMENTS.

No additional monitoring requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

IV. RECORDKEEPING REQUIREMENTS.

No additional record keeping requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

V. REPORTING REQUIREMENTS.**# 008 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.5]****Subpart A--General Provisions****Construction and reconstruction.**

No person may construct a new affected source or reconstruct an affected source subject to 40 CFR Part 63 Subpart O, or reconstruct a source such that the source becomes an affected source subject to the standard, without notifying the Administrator of the intended construction or reconstruction. The notification shall be submitted in accordance with the procedures in 40 CFR 63.9(b) and shall include all the information required for an application for approval of construction or reconstruction as specified in 40 CFR 63.5(d). [from 63.5(b)(4)]

009 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.9]**Subpart A--General Provisions****Notification requirements.**

An owner or operator who intends to construct a new affected source or reconstruct an affected source subject to such standard, or reconstruct a source such that it becomes an affected source subject to such standard, shall notify the Administrator, in writing, of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of the relevant standard) if the construction or reconstruction commences after the effective date of a relevant standard promulgated in this part. The notification shall be submitted as soon as practicable before startup. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in 40 CFR 63.5(d). [from 63.9(b)(5)]

**SECTION C. Site Level Requirements****VI. WORK PRACTICE REQUIREMENTS.****# 010 [25 Pa. Code §123.1]****Prohibition of certain fugitive emissions**

A person responsible for any source specified in subsections (a)(1) -- (7) or (9) [condition #001] shall take all reasonable actions to prevent particulate matter from becoming airborne. These actions shall include, but not be limited to, the following:

- (1) Use, where possible, of water or chemicals for control of dust in the demolition of buildings or structures, construction operations, the grading of roads, or the clearing of land.
- (2) Application of asphalt, oil, water or suitable chemicals on dirt roads, material stockpiles and other surfaces which may give rise to airborne dusts.
- (3) Paving and maintenance of roadways.
- (4) Prompt removal of earth or other material from paved streets onto which earth or other material has been transported by trucking or earth moving equipment, erosion by water, or other means.

011 [25 Pa. Code §129.14]**Open burning operations**

- (a) Air basins. No person may permit the open burning of material in an air basin.
- (b) Not applicable
- (c) Exceptions: The requirements of subsections (a) and (b) do not apply where the open burning operations result from:
 - (1) A fire set to prevent or abate a fire hazard, when approved by the Department and set by or under the supervision of a public officer.
 - (2) A fire set for the purpose of instructing personnel in fire fighting, when approved by the Department.
 - (3) A fire set for the prevention and control of disease or pests, when approved by the Department.
 - (4) Not applicable
 - (5) A fire set for the purpose of burning domestic refuse, when the fire is on the premises of a structure occupied solely as a dwelling by two families or less and when the refuse results from the normal occupancy of such structure.
 - (6) A fire set solely for recreational or ceremonial purposes.
 - (7) A fire set solely for cooking food.
- (d) Clearing and grubbing wastes. The following is applicable to clearing and grubbing wastes:
 - (1) As used in this subsection the following terms shall have the following meanings:

Air curtain destructor -- A mechanical device which forcefully projects a curtain of air across a pit in which open burning is being conducted so that combustion efficiency is increased and smoke and other particulate matter are contained.

Clearing and grubbing wastes -- Trees, shrubs, and other native vegetation which are cleared from land during or prior to the process of construction. The term does not include demolition wastes and dirt laden roots.

- (2) Subsection (a) notwithstanding, clearing and grubbing wastes may be burned in a basin subject to the following requirements:

SECTION C. Site Level Requirements

(i) Air curtain destructors shall be used when burning clearing and grubbing wastes.

(ii) Each proposed use of air curtain destructors shall be reviewed and approved by the Department in writing with respect to equipment arrangement, design and existing environmental conditions prior to commencement of burning. Proposals approved under this subparagraph need not obtain plan approval or operating permits under Chapter 127 (relating to construction modification, reactivation and operation of sources).

(iii) Approval for use of an air curtain destructor at one site may be granted for a specified period not to exceed 3 months, but may be extended for additional limited periods upon further approval by the Department.

(iv) The Department reserves the right to rescind approval granted if a determination by the Department indicates that an air pollution problem exists.

(3) Not applicable

(4) During an air pollution episode, open burning is limited by Chapter 137 (relating to air pollution episodes) and shall cease as specified in such chapter.

[This permit does not constitute authorization to burn solid waste pursuant to Section 610(3) of the Solid Waste Management Act, 35 P.S. Section 6018.610(3), or any other provision of the Solid Waste Management Act.]

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VIII. COMPLIANCE CERTIFICATION.

No additional compliance certifications exist except as provided in other sections of this permit including Section B (relating to State Only General Requirements).

IX. COMPLIANCE SCHEDULE.

No compliance milestones exist.

SECTION D. Source Level Requirements

Source ID: 101

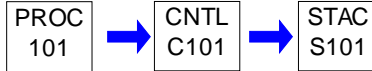
Source Name: ETO STERILIZER CHAMBERS (4)

Source Capacity/Throughput:

0.004 Lbs/HR

ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP

**I. RESTRICTIONS.****Emission Restriction(s).**

001 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Total ethylene oxide emissions from the medical equipment sterilizers shall not exceed 0.1 pound per hour (one cycle average) and 0.4 tons per year.

[From plan approval 25-399-041, as amended by plan approval 25-332-001A.]

Control Device Efficiency Restriction(s).

002 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

Ethylene oxide removal efficiency of the control equipment shall be at least 99%. This EtO removal efficiency shall be achieved on a weight basis over the entire evacuation cycle.

[From plan approval 25-399-041 and plan approval 25-332-001A.]

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

III. MONITORING REQUIREMENTS.

003 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The permittee shall install and maintain equipment to monitor gas and liquid flow rates to the scrubber.

[From plan approval 25-399-041.]

004 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The operating limit for the acid-water scrubber, established during the initial performance test required by 40 CFR Part 63.363(b)(2), is a maximum ethylene glycol concentration of 30 percent. [Requirements for the measurement and recording of this concentration are specified in 40 CFR 63.364(b)(1) and are part of this permit.]

IV. RECORDKEEPING REQUIREMENTS.

No additional record keeping requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

**SECTION D. Source Level Requirements****V. REPORTING REQUIREMENTS.**

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VII. ADDITIONAL REQUIREMENTS.

005 [25 Pa. Code §127.12b]

Plan approval terms and conditions.

The height of the (scrubber) stack shall be at least 55 feet and the stack design shall not obstruct the proper dispersion of the air toxic substances (i.e., no rain caps, elbows, etc.).

[From plan approval 25-399-041]

**SECTION D. Source Level Requirements**

Source ID: 102

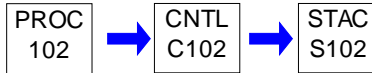
Source Name: AERATION ROOMS (2)

Source Capacity/Throughput:

0.001 Lbs/HR

ETHYLENE OXIDE

Conditions for this source occur in the following groups: ETO NESHAP

**I. RESTRICTIONS.****Emission Restriction(s).****# 001 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

The emissions of ethylene oxide from the exhaust of the 3 Safe Cell Units (controlling the aeration rooms) shall not exceed 1 ppmv. [from PA 25-918A]

II. TESTING REQUIREMENTS.**# 002 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

The facility shall perform periodic testing to determine the time to schedule reactant change-out. The testing shall be performed initially as part of the Installation Qualification, then at 6-month intervals until 0.5 ppmv is reached. The interval will then be reduced to 3 months, then monthly; and when 0.9 ppmv is reached, the reactant shall be changed out and verification testing shall be performed. [from PA 25-918A]

III. MONITORING REQUIREMENTS.**# 003 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

A magnehelic gauge or equivalent shall be permanently installed, calibrated, operated, and maintained at a conveniently readable location to indicate pressure drop across the Safe Cell Unit. The pressure drop shall be monitored to the manufacturer's specifications. [from PA 25-918A]

IV. RECORDKEEPING REQUIREMENTS.**# 004 [25 Pa. Code §127.12b]****Plan approval terms and conditions.**

The facility shall maintain a log of preventative maintenance inspections of the Safe Cell Units. The inspection log shall, at a minimum, contain the dates of the inspections, any potential problems or defects encountered, the steps to correct them, and the measured pressure drop across the control device. [from PA 25-918A]

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

VI. WORK PRACTICE REQUIREMENTS.

No additional work practice requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).



SECTION D. Source Level Requirements

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements) and/or Section E (Source Group Restrictions).

**SECTION E. Source Group Restrictions.**

Group Name: ETO NESHAP

Group Description: 40 CFR Part 63 Subpart O, Ethylene Oxide Emission Standards for Sterilization Facilities

Sources included in this group

ID	Name
101	ETO STERILIZER CHAMBERS (4)
102	AERATION ROOMS (2)

I. RESTRICTIONS.**Emission Restriction(s).**

001 [25 Pa. Code §123.13]

Processes

No person may permit the emission into the outdoor atmosphere of particulate matter from this process in a manner that the concentration of particulate matter in the effluent gas exceeds 0.04 grain per dry standard cubic foot.

Control Device Efficiency Restriction(s).

002 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.362]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities Standards.

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in § 63.360(g). The standards of this section are summarized in Table 1 of this section. [Non-applicable rows of Table 1 are omitted.]

Table 1 of Section 63.362—Standards for Ethylene Oxide Commercial Sterilizers and Fumigators

Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
>=9,070 kg (>=10 tons)	99% emission reduction (see § 63.362(c))	1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d))	No control.

(b) Applicability of emission limits. The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) Sterilization chamber vent at sources using 1 ton. Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) Aeration room vent at sources using 10 tons. Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

(e) [Reserved]

[Source: 59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55583, Nov. 2, 2001]

II. TESTING REQUIREMENTS.

003 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.365]

Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities**Test methods and procedures.**

(a) - (d) [These are procedures for initial testing and initial compliance determination which have already been met.]

(e) Determination of baseline parameters for acid-water scrubbers. The procedures in this paragraph shall be used to determine the monitored parameters established in Sec. 63.363(b), (d), or (e) for acid-water scrubbers and to monitor the parameters as established in Sec. 63.364(b).

(1) Ethylene glycol concentration. For determining the ethylene glycol concentration, the facility owner or operator shall establish the maximum ethylene glycol concentration as the ethylene glycol concentration averaged over three test runs; the

**SECTION E. Source Group Restrictions.**

sampling and analysis procedures in ASTM D 3695-88, Standard Test Method for Volatile Alcohols in Water By Direct Aqueous-Injection Gas Chromatography, (incorporated by reference--see Sec. 63.14) shall be used to determine the ethylene glycol concentration.

(f) [Reserved]

(g) [This was a one-time requirement for submission of information regarding an alternative control device. This requirement was met as evidenced by the August 2, 2000, approval letter from the EPA.]

(h) Not applicable.

[Source: 59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55584, Nov. 2, 2001; 79 FR 11283, Feb. 27, 2014]

III. MONITORING REQUIREMENTS.**# 004 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.364]****Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities****Monitoring requirements.**

(a)(1) The owner or operator of a source subject to emissions standards in Sec. 63.362 shall comply with the monitoring requirements in Sec. 63.8 of subpart A of this part, according to the applicability in Table 1 of Sec. 63.360, and in this section.

(2) Each owner or operator of an ethylene oxide sterilization facility subject to these emissions standards shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(b) For sterilization facilities complying with Sec. 63.363 (b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

(1) Sample the scrubber liquor and analyze and record once per week the ethylene glycol concentration of the scrubber liquor using the test methods and procedures in Sec. 63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated;

(2) Not applicable

(c) Not applicable

(d) For sterilization facilities complying with Sec. 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in Sec. 63.365(g). [The approval letter to Medical Manufacturing Group from the EPA dated August 2, 2000, for the alternative control technique is incorporated into the State Only operating permit. This approval specifies the monitoring parameters.]

(e) Not applicable.

(f) [Reserved]

[59 FR 62589, Dec. 6, 1994, as amended at 66 FR 55584, Nov. 2, 2001; 79 FR 11283, Feb. 27, 2014]

IV. RECORDKEEPING REQUIREMENTS.**# 005 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.10]****Subpart A--General Provisions****Recordkeeping and reporting requirements.**

(a) Applicability and general information. [See regulation for 40 CFR §63.10(a)]

(b) General recordkeeping requirements.

SECTION E. Source Group Restrictions.

(1) [See regulation for 40 CFR §63.10(b)(1)]

(2) The owner or operator of an affected source subject to the provisions of this part shall maintain relevant records for such source of—

(i) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O];

(ii) The occurrence and duration of each malfunction of operation (i.e., process equipment) or the required air pollution control and monitoring equipment;

(iii) - (v) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O]

(vi) Not applicable;

(vii) All required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, 15-minute averages of CMS data, raw performance testing measurements, and raw performance evaluation measurements, that support data that the source is required to report);

(A) - (C) Not applicable.

(viii) All results of performance tests, CMS performance evaluations, and opacity and visible emission observations;

(ix) All measurements as may be necessary to determine the conditions of performance tests and performance evaluations;

(x) - (xiii) Not applicable;

(xiv) All documentation supporting initial notifications and notifications of compliance status under § 63.9.

(3) Recordkeeping requirement for applicability determinations. [See regulation for 40 CFR §63.10(b)(3)]

(c) Not applicable.

(d) General reporting requirements.

(1) Notwithstanding the requirements in this paragraph or paragraph (e) of this section, and except as provided in § 63.16, the owner or operator of an affected source subject to reporting requirements under this part shall submit reports to the Administrator in accordance with the reporting requirements in the relevant standard(s).

(2) Reporting results of performance tests. [One-time requirement which is no longer applicable.]

(3) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O]

(4) Not applicable.

(5) Not applicable. [Ref. Table 1 of §40 CFR 63.360 of Subpart O]

(e) Not applicable.

(f) Waiver of recordkeeping or reporting requirements.

(1) - (6) See regulation 40 CFR §63.10(f)(1) - (f)(6).

[59 FR 12430, Mar. 16, 1994, as amended at 64 FR 7468, Feb. 12, 1999; 67 FR 16604, Apr. 5, 2002; 68 FR 32601, May 30, 2003; 69 FR 21752, Apr. 22, 2004; 71 FR 20455, Apr. 20, 2006]

**SECTION E. Source Group Restrictions.****# 006 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.367]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Recordkeeping requirements.**

(a) The owner or operator of a source subject to Sec. 63.362 shall comply with the recordkeeping requirements in Sec. 63.10(b) and (c), according to the applicability in Table 1 of Sec. 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) Not applicable.

(c) Not applicable.

(d) Not applicable.

[66 FR 55585, Nov. 2, 2001]

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VI. WORK PRACTICE REQUIREMENTS.**# 007 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.363]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Compliance and performance provisions.**

(a) - (e) [These are one-time requirements for initial performance testing and establishing operating limits of control devices and are no longer applicable.]

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, and malfunction, according to the methods specified in § 63.364.

[Source: 66 FR 55583, Nov. 2, 2001]

VII. ADDITIONAL REQUIREMENTS.**# 008 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.360]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Applicability.**

Refer to regulation for 40 CFR §63.360 and Table 1 of 63.360.

Table 1 of 63.360 indicates which General Provisions of Part 63 Subpart A are applicable.

**# 009 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.361]
Subpart O -- Ethylene Oxide Emissions Standards for Sterilization Facilities
Definitions.**

Refer to regulation 40 CFR §63.361 for Definitions of Subpart O.



SECTION F. Alternative Operation Requirements.

No Alternative Operations exist for this State Only facility.



SECTION G. Emission Restriction Summary.

Source Id	Source Description						
101	ETO STERILIZER CHAMBERS (4)						
<table border="1"> <thead> <tr> <th>Emission Limit</th> <th>Pollutant</th> </tr> </thead> <tbody> <tr> <td>0.100 Lbs/Hr (and 40 TPY)</td> <td>Ethylene Oxide</td> </tr> <tr> <td>0.040 gr/DRY FT3</td> <td>TSP</td> </tr> </tbody> </table>		Emission Limit	Pollutant	0.100 Lbs/Hr (and 40 TPY)	Ethylene Oxide	0.040 gr/DRY FT3	TSP
Emission Limit	Pollutant						
0.100 Lbs/Hr (and 40 TPY)	Ethylene Oxide						
0.040 gr/DRY FT3	TSP						
102	AERATION ROOMS (2)						
<table border="1"> <thead> <tr> <th>Emission Limit</th> <th>Pollutant</th> </tr> </thead> <tbody> <tr> <td>1.000 PPMV</td> <td>Ethylene Oxide</td> </tr> <tr> <td>0.040 gr/DRY FT3</td> <td>TSP</td> </tr> </tbody> </table>		Emission Limit	Pollutant	1.000 PPMV	Ethylene Oxide	0.040 gr/DRY FT3	TSP
Emission Limit	Pollutant						
1.000 PPMV	Ethylene Oxide						
0.040 gr/DRY FT3	TSP						

Site Emission Restriction Summary

Emission Limit	Pollutant
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**SECTION H. Miscellaneous.**

(a) The Capacity/Throughput numbers listed in Section A, the Site Inventory List, and provided in Section D of this permit for individual sources are for informational purposes only and are not to be considered enforceable limits. Enforceable emission limits are listed in the Restrictions section for each source and source group and in Section C. The emission limitations contained in Section G of this permit are for informational purposes and are not to be considered as enforceable limits.

(b) Abbreviations used in this permit:

Schematics:

FML: Fuel material location
 CU: Combustion Unit
 PROC: Process
 CNTL: Control device
 STAC: Stack. The stack can represent either the emission point or fugitive emissions in a permit map.

Pollutants:

CO: Carbon Monoxide
 NOx: Nitrogen Oxides
 SOx: Sulfur Oxides
 TSP: Total Suspended Particulate
 VOC: Volatile Organic Compounds
 HAP: Hazardous Air Pollutant

Source ID: Department assigned ID number for the source

Source Name: Department assigned name for the source

Capacity/Throughput: The maximum rated capacity or throughput for the source. The maximum rated capacity or throughput is not considered an enforceable limit. Enforceable limits are contained within the conditions of the permit.

Fuel/Material: The fuel/material assigned to SCC for the source

CFR: Code of Federal Regulations

CMS: Continuous Monitoring System

Department: Pennsylvania Department of Environmental Protection (the DEP)

NESHAP: National Emission Standards for Hazardous Air Pollutants (40 CFR Part 63)

NSPS: New Source Performance Standards (40 CFR Part 60)

NWRO: Northwest Regional Office of PADEP

RFD: Request for Determination of Changes of Minor Significance & Exemption from plan approval.

SCC: Source Classification Code as defined by EPA

Source: An air contamination source (25 Pa. Code § 121.1).

(c) All reports, submittals, and other communications required by this permit shall be submitted to the following office.

Bureau of Air Quality
 Department of Environmental Protection
 230 Chestnut Street
 Meadville, PA 16335
 814-332-6940 (phone)
 814-332-6121 (fax)

The address and phone number for notification is:

Bureau of Air Quality
 DEP Northwest Regional Office
 230 Chestnut Street
 Meadville, PA 16335
 Office Hours 8 a.m. - 4 p.m.
 Phone: 814-332-6945 (business hours)
 1-800-373-3398 (after hours)

(d) The address of the Regional Administrator for EPA Region III is:

EPA Region III Director
 Air Protection Division

**SECTION H. Miscellaneous.**

1650 Arch Street
Philadelphia, PA 19103.

- (e) Medical Manufacturing Corporation is deferred from submitting a Title V permit application. This is because of a change in the regulation that appears in 40 CFR §63.360 (f). It is important to note that this change specifies that the facility must "continue to comply with the provisions of this subpart applicable to area sources."
- (f) Plan Approval #25-399-041 was issued for Source 101 in Oct. 1988 and permit #25-332-001 was issued in March 1990. An approved modification was issued in July 1991 with permit #25-332-001A.
- (g) This facility has two (2) Cleaver-Brooks natural gas fired boilers rated at 1.674 MBTU. They were installed in 1988 (Model #CB-200-40, Serial #L-85189). They are used to produce steam for the sterilizers, heat for aeration and comfort heating during winter months. They were not included as sources because of the BTU rating.
- (h) The following regulations are incorporated into this permit by reference to the regulation.
- 40 CFR §63.360 -- Applicability of Subpart O, Ethylene Oxide Standards
 - 40 CFR §63.361 -- Definitions to Subpart O, Ethylene Oxide Standards
 - 40 CFR §63.2 -- Definitions to Part 63 Subpart A, General Provisions
 - 40 CFR §63.3 -- Units and abbreviations to Part 63 Subpart A, General Provisions
- (i) Incorporated into this permit is an August 2, 2000, letter from the EPA which is referenced in this permit in Section E under MONITORING REQUIREMENTS for 40 CFR §63.364(d) and under TESTING REQUIREMENTS for 40 CFR §63.365(g). The letter, dated Aug. 2, 2000, was sent from the EPA to Medical Manufacturing Corporation (MMC), the former owner of this facility. In the letter, the US EPA approved the use of an alternative control device to control EtO emissions from the Aeration Room Vent to comply with 40 CFR Part 63 Subpart O, NESHAP for EtO emissions from Sterilization Facilities
- (j) This permit was reissued on September 6, 2007.
- (k) This permit was administratively amended on June 25, 2010 to incorporate the change of responsible official from Thomas Bienias to Michael Henderson - Director, Operations.
- (l) This permit renewal effective May 8, 2013, is issued on May 8, 2013.
- (m) This permit was amended on February 10, 2014 to change the responsible official to Jennifer Walters, Corporate Controller.
- (n) This permit was amended on May 22, 2014 to change the permit contact from Paul Niemet to Nancy Rakiewicz - Site Manager.
- (o) This permit was amended on July 1, 2015 to change the ownership from MMC Sterilization to Iuvo BioScience Operations, LLC. The responsible official changed to Benjamin Burton - CEO, President. The new Tax ID is 47-3409419-1.
- (p) This permit was amended on February 9, 2017 to change the ownership from Iuvo BioScience Operations to Cosmed Group, Inc. The responsible official changed to David G. Howe - Chief Operating Officer. The permit contact changed to Christine Render - Director of Corporate QA and RA. The new Tax ID is 51-1598781-1.
- (q) This permit renewal, effective July 16, 2018, is issued on July 16, 2018.



***** End of Report *****

