TITLE V OPERATING PERMIT RENEWAL APPLICATION – 2009 REVISION

B. BRAUN MEDICAL, INC.

TVOP NO. 39-00055

Prepared in accordance with:
25 Pa. Code §127.412, 127.413, 127.414, & 127.503

County: Air Quality
APR - 1 REC'D
Facility:
Permit:
File #:

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Submitted By:

B|BRAUN
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Federal Tax ID: 23-2116774
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Allentown, PA 18103

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JUL 06 2009
Air Protection Division
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1. INTRODUCTION

B. Braun Medical Inc. (B. Braun) operates a surgical and medical instrument apparatus manufacturing facility located at 901 Marcon Blvd. (901 Marcon Blvd. facility) in Allentown, Pennsylvania. The 901 Marcon Blvd. facility currently operates pursuant to the permit application shield provisions of Title V Operating Permit Number 39-00055 (TVOP 39-00055), which expired on November 30, 2005. A timely and complete renewal application was submitted in May 2005. A final permit is still pending. This application serves as a revision to the May 2005 renewal application.

B. Braun also owns and operates an adjacent support facility located at 939 Marcon Blvd. (939 Marcon Blvd. facility) in Allentown, Pennsylvania that is currently used to house facility personnel, perform training, and store equipment. The 939 Marcon Blvd. facility currently operates pursuant to State Only Operating Permit Number 39-00038 (SOOP 39-00038), which, pursuant to a February 27, 2009 meeting between B. Braun and the Pennsylvania Department of Environmental Protection (PADEP) and a subsequent letter submitted to PADEP on March 13, 2009, B. Braun will let expire on June 30, 2009. The 939 Marcon Blvd. facility was formerly owned and operated by SureFit Inc. (SureFit). In accordance with 25 Pa. Code §§ 127.450(a)(4) and 127.464, B. Braun submitted change of ownership and administrative amendment forms in November 2006 in order to transfer the operating permit from SureFit to B. Braun. PADEP approved the transfer of ownership on November 15, 2006. The 901 Marcon Blvd. facility and the 939 Marcon Blvd. facility are considered "contiguous and adjacent" properties and may be regarded as one facility.

The purpose of the this Title V Renewal Application revision is to incorporate the regulated emissions units and applicable permit terms and conditions of SOOP 39-00038 into TVOP 39-00055, such that all of the existing sources at both facilities will be permitted under the terms and conditions of TVOP 39-00055. B. Braun will not submit a renewal application for SOOP 39-00038. Once the SOOP expires, B. Braun will operate both facilities according to the applicable terms and conditions included in this renewal application until such time as the new

Title V Operating Permit that includes both facilities is issued by PADEP. In addition, this Title V Renewal Application revision also includes changes associated with the Minor Operating Permit Modification Application that was submitted in 2007 for TVOP-39-00055, and other changes that have taken place since the submittal of the original Title V Renewal Application.

This application includes the required agency PADEP Title V application forms, report narrative, copies of municipal notification letters, and an updated Air Pollution Control Act (APCA) Compliance Review Form.

The remaining sections of this application narrative include the following:

Section 2 – FACILITY OVERVIEW
Section 3 – CHANGES REQUESTED FROM THE EXISTING TITLE V OPERATING PERMIT
Section 4 – REGULATORY REQUIREMENTS
Section 5 – COMPLIANCE ASSURANCE MONITORING (CAM) APPLICABILITY

The completed TVOP application forms are included in Appendix B.

2. FACILITY OVERVIEW

The following subsections discuss the operations at the 901 and 939 Marcon Blvd. facilities. As discussed in Section 1, the two facilities are considered "contiguous and adjacent" properties and may be regarded as one facility.

2.1 901 MARCON BLVD. FACILITY DESCRIPTION

B. Braun's 901 Marcon Blvd. facility is located in Allentown, Pennsylvania in Lehigh County. The 901 Marcon Blvd. facility manufactures surgical and medical instruments that are sterilized during the manufacturing process. The sterilization process utilizes ethylene oxide (ETO) within a sterilization chamber and is subject to 40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities. B. Braun maintains nine (9) ETO sterilization chambers (Units 101 – 109); eight (8) of which are currently operational (B. Braun is concurrently submitting a Plan Approval Application under separate cover in order to reactivate Unit 109). From the sterilization chamber, the sterilized devices are directed to an aeration chamber or room (Unit 110). The sterilization chamber and the aeration chamber are both controlled. The exhaust gases from the aeration chamber are routed to the Donaldson Catalytic Oxidizer (DCO), which utilizes a catalyst in conjunction with oxidation to control ETO emissions. ETO emissions from the sterilization chamber are routed to the Deoxx unit through the use of a vacuum pump. The Deoxx unit employs a wet scrubbing technique for treatment of ETO emissions. While controlling aeration room ETO emissions, the DCO achieves a 99% emission reduction or maintains an outlet ETO concentration of less than or equal to 1 ppmv in accordance with 40 CFR §63.362(d). While controlling sterilization chamber ETO emissions, the Deoxx unit achieves a 99% emission reduction in accordance with 40 CFR §63.362(c). A process flow diagram is provided in Figure 2-1.

In addition to the ETO sterilization processes, B. Braun operates several combustion units; including two (2) emergency generators (Units 111 and 112) and a fire pump (Unit 113) that are

identified in the current Title V Operating Permit (TVOP). In November 2007, B. Braun submitted a Minor Operating Permit Modification Application to:

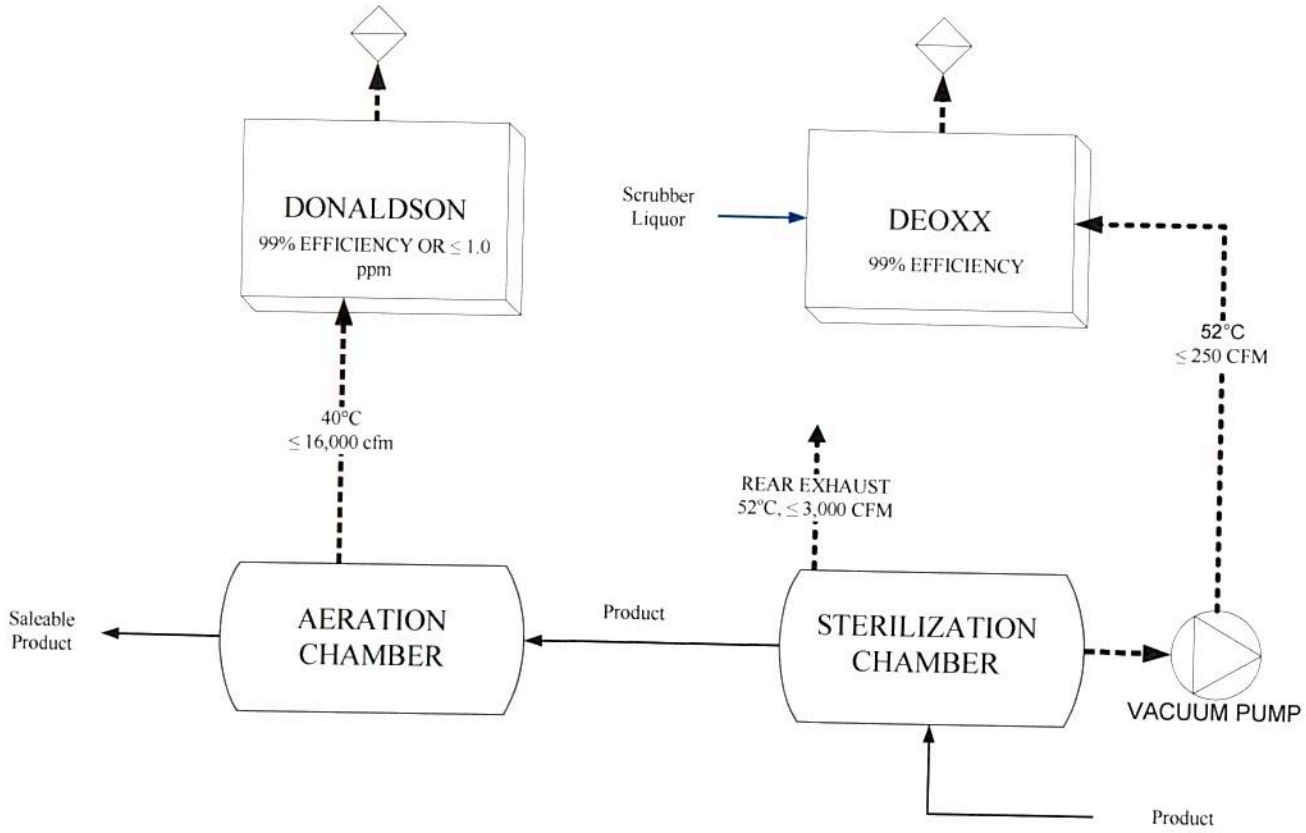
- Install several insignificant combustion sources,
- Incorporate existing insignificant combustion units into the permit, and
- Include operational restrictions in the permit for all of the emergency generators and fire pumps at the facility.

The changes addressed in the Minor Operating Permit Modification Application have been included in this permit renewal revision.

2.2 939 MARCON BLVD. FACILITY DESCRIPTION

The 939 Marcon Blvd. facility is currently used to house facility personnel, perform training, and store equipment. The facility operates two boilers that are permitted under SOOP 39-00038 as well as a 30 KW emergency generator was installed in 2006.

STERILIZATION PROCESS



LEGEND:

- PRIMARY PRODUCT
- GAS / VAPOR
- WATER / PROCESS LIQUID
- EMISSION POINT

NOTES:

Review By: _____

Date: 3/17/09

Signature: _____

FIGURE 2-1

Process Flow Diagram

B|BRAUN SHARING EXPERTISE

B. Braun Medical, Inc.
Allentown, Pennsylvania

REVISION NO	DRAWING FILE
DATE	DRAWN BY D.Dix

2.3 FACILITY LOCATION

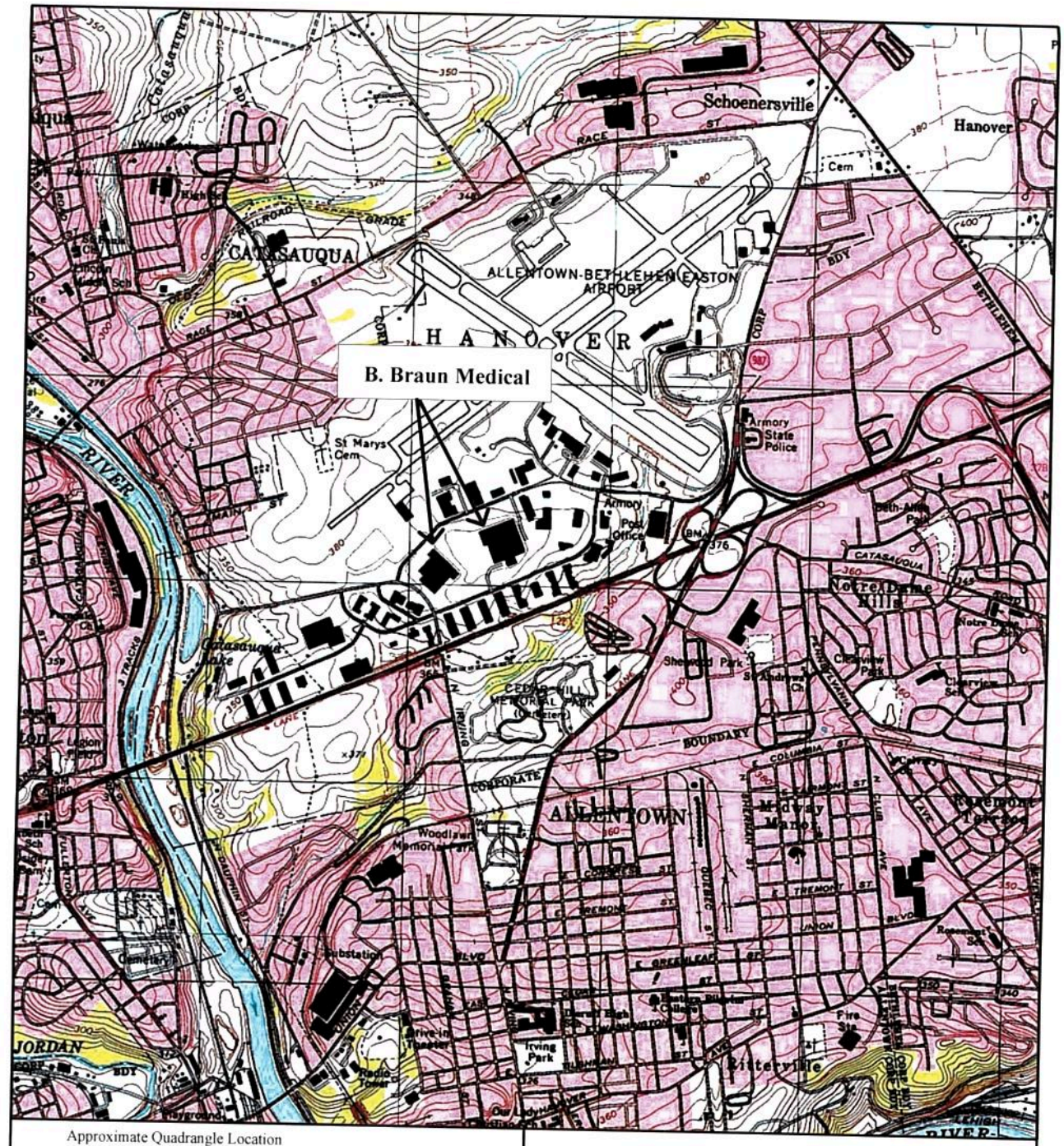
The B. Braun Facility is located adjacent to the Allentown-Bethlehem-Easton Airport outside of Allentown, PA. The facility is situated in Hanover Township, Lehigh County. A facility location map is provided in Figure 2-2.

2.4 FACILITY BACKGROUND INFORMATION

The Facility is under the jurisdiction of the following State and Federal agencies:

Pennsylvania Department of Environmental Protection – Air Quality Program
Northeast Regional Office
2 Public Square
Wilkes-Barre, PA 18711-0790

United States Environmental Protection Agency - Region 3
1650 Arch Street
Philadelphia, PA 19103



B. Braun Medical, Inc.
Allentown, Pennsylvania

Figure 2-2
Facility Location Map

G:\Client Files\B Braun Medical\USGS\B Braun Facility Location Map.wor

3. CHANGES REQUESTED FROM THE EXISTING TITLE V OPERATING PERMIT

This section summarizes changes that B. Braun is requesting from the existing Title V Operating Permit.

3.1.1 Incorporation of SOOP 39-00038 into TVOP 39-00055

B. Braun is requesting to incorporate the following sources and associated conditions from SOOP 39-00038 into TVOP 39-00055. B. Braun has included proposed new source identification numbers and names for the SOOP 39-00038 sources in order to provide clarity. In Section 4 of the attached revised application forms, B. Braun has included these sources as Group 3 (GRP3).

Source ID from SOOP 39-00038	Proposed New Source ID in TVOP 39-00055	Source Name from SOOP 39-00038	Proposed New Source Name in TVOP 39-00055	Conditions from SOOP 39-00038 to be incorporated into TVOP 39-00055 as GRP3
001	031	BOILER #1	KEWANEE - 19.5 MMBTU/HR	Section E., GRP1, Conditions 001, 002, and 003
002	032	BOILER #2	KEWANEE - 10 MMBTU/HR	Section E., GRP1, Conditions 001, 002, and 003

In addition, B. Braun is requesting that the 30 KW Kohler emergency generator installed in 2006 at the 939 Marcon Blvd. facility be included as Source 114 in TVOP 39-00055. As indicated in Section 4 of the attached revised application forms, this generator will also be included as a part of GRP2, and will have a restriction on operating hours of 242 hours during the May 1 through September 30 ozone season of each year, and no more than 500 hours during any consecutive 12-month period.

3.1.2 2007 Minor Operating Permit Modification

B. Braun has identified all of the insignificant combustion sources that were addressed in the 2007 Minor Permit Modification in Appendix C. In addition, as referenced in Section 3.1.1, the operational restrictions for all of the emergency generators and fire pumps at the facility have been included in Section 4 of the revised permit application forms. New Unit Heater 5 (018) was not included in the Minor Permit Modification but has been included in Appendix C.

3.1.3 Removal of ETO Sterilizer Chamber Exhaust Vent from ETO Control System

In accordance with the November 21, 2001 Federal Register Notice and the approved Request for Determination (RFD) that B. Braun submitted in April 2008, B. Braun removed the ETO sterilizer chamber exhaust vents for each sterilizer from the ETO sterilizer control system due to safety concerns. The revised TVOP renewal application forms indicate additional points of air emissions for each sterilizer unit to indicate this change. **

3.1.4 Proposed and Revised Permit Conditions

B. Braun has included proposed permit revisions regarding additional conditions that were included in the original Title V Operating Permit that were ***not*** included in previous Plan Approvals or Operating Permits. These were apparently new requirements that first appeared in the original Title V Operating Permit.

In addition, proposed permit language is included regarding the Section E, GRP1 requirements in the current Title V Operating Permit, which contain references to, and language from, 40 CFR Part 63, Subpart O. Since Subpart O was modified in 2001 (after the date of issuance of the original Title V Permit), the facility has proposed the conditions to be consistent with the current version of 40 CFR Part 63, Subpart O in this TVOP Operating Permit renewal application revision.

Proposed permit language is included regarding the Section E, GRP2 requirements in the current Title V Operating Permit relating to the operational restrictions for all of the fire pumps and emergency generators located at the facility.

Finally, permit language for proposed new GRP3, which would include the two boilers at the 939 Marcon Blvd. facility, is also included.

The proposed revisions are summarized below:

Section C: Site Level Requirements

III. MONITORING REQUIREMENTS

#010 ***[25 Pa. Code §127.511]***

Monitoring and related recordkeeping and reporting requirements.

The permittee shall conduct a weekly inspection during daylight hours when the plant is in production to detect visible or fugitive emissions as follows:

(a) Visible emissions in excess of the limits stated in Section C, Site Level Condition #004. Visible emissions may be measured according to the method specified in Site Level Condition #009 or alternatively, plant personnel who observe any visible emissions will report the incident of visible emissions to the Department within four hours of each incident and make arrangements for a certified observer to verify the opacity of the visible emissions.

(b) The presence of fugitive emission visible beyond the plant boundaries as stated in Section C, Site Level Condition #002.

B. Braun believes that the current daily monitoring and recording of fugitive and visible emissions is excessive based on the operations at the B. Braun Facility. B. Braun also believes that current volume of site data documenting no fugitive or visible emissions exceedances supports this position. B. Braun requests to reduce the frequency of the monitoring and recording to weekly.

Section E: Group Level Requirements (GRP1)

I. RESTRICTIONS

Emission Limitation(s)

#001 ***Request deletion as this condition is redundant with Condition #008(b)(2).***

#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.

Relevant Sections from Table 1 of Section 63.362 - Standards for Ethylene Oxide Commercial Sterilizers and Fumigators

New and Existing Sources – Source Type	Sterilization Chamber Vent	Aeration Room Vent	Chamber Exhaust Vent
≥ 9,070 kg (≥ 10 tons)	99% emission reduction (see 63.362(c))	1 ppmv 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]

Control Device Efficiency Restriction(s)

99% #003 ***Request Deletion as this condition is redundant with revised Condition #002 above.***

II. TESTING REQUIREMENTS

#004 ***Request deletion as this condition is inconsistent with revised Condition #008(b)(4).***

A Remove

#005 [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) *Performance testing.* The owner or operator of a source subject to the emissions standards in §63.362 shall comply with the performance testing requirements in §63.7 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this section.

(b) *Efficiency at the sterilization chamber vent.* The following procedures shall be used to determine the efficiency of all types of control devices used to comply with §63.362(c), sterilization chamber vent standard.

(1) *First evacuation of the sterilization chamber.* These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

(i) The amount of ethylene oxide loaded into the sterilizer (W_c) shall be determined by either:

(A) Weighing the ethylene oxide gas cylinder(s) used to charge the sterilizer before and after charging. Record these weights to the nearest 45 g (0.1 lb). Multiply the total mass of gas charged by the weight percent ethylene oxide present in the gas.

(B) Installing calibrated rotameters at the sterilizer inlet and measuring flow rate and duration of sterilizer charge. Use the following equation to convert flow rate to weight of ethylene oxide:

$$W_c = F_v \times t \times \% EO_v \times \left(\frac{MW}{SV}\right)$$

where:

W_c=weight of ethylene oxide charged, g (lb)

F_v=volumetric flow rate, liters per minute (L/min) corrected to 20 °C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68 °F and 1 atmosphere of pressure (atm)); the flowrate must be constant during time (t)

t=time, min

$\%EO_V$=volume fraction ethylene oxide

SV=standard volume, 24.05 liters per mole (L/mole)=22.414 L/mole ideal gas law constant corrected to 20 °C and 101.325 kPa (385.32 scf per mole (scf/mole)=359 scf/mole ideal gas law constant corrected to 68 °F and 1 atm).

MW=molecular weight of ethylene oxide, 44.05 grams per gram-mole (g/g-mole) (44.05 pounds per pound-mole (lb/lb-mole)), or

(C) Calculating the mass based on the conditions of the chamber immediately after it has been charged using the following equation:

$$W_c = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

P=chamber pressure, kPa (psia)

V=chamber volume, liters (L) (ft^3)

R=gas constant, 8.313 L·kPa/g-mole·(10.73 psia·ft^3/mole°R)

T=temperature, K (°R)

Note: If the ethylene oxide concentration is in weight percent, use the following equation to calculate mole fraction:

$$\%EO_v = \frac{W_{EO}}{W_{EO} + \left(W_x \times \frac{MW}{MW_x}\right)}$$

where:

W_{EO}=weight percent of ethylene oxide

W_x=weight percent of compound in the balance of the mixture

MW_x=molecular weight of compound in the balance gas mixture

(ii) The residual mass of ethylene oxide in the sterilizer shall be determined by recording the chamber temperature, pressure, and volume after the completion of the first evacuation and using the following equation:

$$W_r = \frac{MW \times \%EO_v \times P \times V}{R \times T}$$

where:

W_r=weight of ethylene oxide remaining in chamber (after the first evacuation), in g (lb)

(iii) Calculate the total mass of ethylene oxide at the inlet to the control device (W_i) by subtracting the residual mass (W_r) calculated in paragraph (b)(1)(ii) of

this section from the charged weight (W_c) calculated in paragraph (b)(1)(i) of this section.

(iv) The mass of ethylene oxide emitted from the control device outlet (W_o) shall be calculated by continuously monitoring the flow rate and concentration using the following procedure.

(A) Measure the flow rate through the control device exhaust continuously during the first evacuation using the procedure found in 40 CFR part 60, appendix A, Test Methods 2, 2A, 2C, or 2D, as appropriate. (Method 2D (using orifice plates or Rootstype meters) is recommended for measuring flow rates from sterilizer control devices.) Record the flow rate at 1-minute intervals throughout the test cycle, taking the first reading within 15 seconds after time zero. Time zero is defined as the moment when the pressure in the sterilizer is released. Correct the flow to standard conditions (20 °C and 101.325 kPa (68 °F and 1 atm)) and determine the flow rate for the run as outlined in the test methods listed in paragraph (b) of this section.

(B) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

(*1*) Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(*2*) Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \frac{MW}{SV} \times \frac{1}{10^6}$$

Where:

Wo = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide in ppmv

V = volume of gas exiting the control device corrected to standard conditions, L (ft^3)

$1/10^6$ = correction factor $L_{EO}/10^6\ L_{TOTAL\ GAS}$ ($ft^3_{EO}/10^6\ ft^3_{TOTAL\ GAS}$)

(*3*) Calculate the efficiency by the equation in paragraph (b)(1)(v) of this section.

(C) [Reserved]

(v) Determine control device efficiency (% Eff) using the following equation:

$$\%Eff = \frac{W_i - W_o}{W_i} \times 100$$

where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_o = mass flow rate out of the control device

(vi) Repeat the procedures in paragraphs (b)(1) (i) through (v) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(2) [Reserved]

(c) *Concentration determination.* The following procedures shall be used to determine the ethylene oxide concentration.

(1) *Parameter monitoring.* For determining the ethylene oxide concentration required in §63.364(e), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS–8.

(2) *Initial compliance.* For determining the ethylene oxide concentration required in §63.363(c)(2), the procedures outlined in Method 18 or Method 25 A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device.

(d) *Efficiency determination at the aeration room vent (not manifolded).* The following procedures shall be used to determine the efficiency of a control device used to comply with §63.362(d), the aeration room vent standard.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

Where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_O = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(e) *Determination of baseline parameters for acid-water scrubbers.* The procedures in this paragraph shall be used to determine the monitored parameters established in §63.363(b), (d), or (e) for acid-water scrubbers and to monitor the parameters as established in §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 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 §63.14) shall be used to determine the ethylene glycol concentration.

(2) *Scrubber liquor tank level.* For determining the scrubber liquor tank level, the sterilization facility owner or operator shall establish the maximum liquor tank level based on a single measurement of the liquor tank level during one test run.

(f) [Reserved]

(g) ***Request deletion or note that this paragraph is not applicable as B. Braun uses an acid-water scrubber to meet the sterilization chamber vent standard and a catalytic oxidizer to meet the aeration room vent standard.***

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of §63.363 or §63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

III. MONITORING REQUIREMENTS

#006 ***Request deletion as this condition is redundant with revised Condition #009(b).***

#007 ***Request deletion as Condition #008(b)(3) says for facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an***

Rg. changed Bill checking w B Braun

operating limit. As provided in Condition #008(b)(4), testing is not required each year to determine the minimum bed temperature.

#008 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.363]
Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities
Compliance and performance provisions

(a)(1) The owner or operator of a source subject to emissions standards in §63.362 shall conduct an initial performance test using the procedures listed in §63.7 according to the applicability in Table 1 of §63.360, the procedures listed in this section, and the test methods listed in §63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in §63.360(g).

(b) The procedures in paragraphs (b)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under §63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices:

(1) The owner or operator shall determine the efficiency of control devices used to comply with §63.362(c) using the test methods and procedures in §63.365(b).

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

(i) The maximum ethylene glycol concentration using the procedures described in §63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in §63.365(e)(2).

(3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices:

(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in §63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or

(ii) Once per year after the initial compliance test, analyze ethylene oxide concentration data from §63.364(e) or a continuous emission monitoring

system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or,

(iii) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

(c) The procedures in paragraphs (c)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under §63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with §63.362(d)) using the methods in §63.365(c)(2); *[Please note, the reference in §63.363 incorrectly identifies §63.365(c)(1)]* or

(3) Determine the efficiency of the control device used to comply with §63.362(d) using the test methods and procedures in §63.365(d) *[Please note, the reference §63.363 incorrectly identifies §63.365(d)(2) when all of §63.365(d) is applicable]*.

(d) [Reserved]

(e) ***Request deletion or note that this paragraph is not applicable as B Braun uses an acid-water scrubber to meet the sterilization chamber vent standard and a catalytic oxidizer to meet the aeration room vent standard.***

(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.

#009 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.364]
Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities
Monitoring requirements.

(a)(1) The owner or operator of a source subject to emissions standards in §63.362 shall comply with the monitoring requirements in §63.8 of subpart A of this part, according to the applicability in Table 1 of §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 §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 §63.365(e)(1). Monitoring is required during a week only if the scrubber unit has been operated; or

(2) Measure and record once per week the level of the scrubber liquor in the recirculation tank. The owner or operator shall install, maintain, and use a liquid level indicator to measure the scrubber liquor tank level (i.e., a marker on the tank wall, a dipstick, a magnetic indicator, etc.). Monitoring is required during a week only if the scrubber unit has been operated.

(c) For sterilization facilities complying with §63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with §63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

(1)–(3) [Reserved]

(4) The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature. The owner or operator shall verify the accuracy of the temperature monitor twice each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) ***Request deletion or note that this paragraph is not applicable as B Braun uses an acid-water scrubber to meet the sterilization chamber vent standard and a catalytic oxidizer to meet the aeration room vent standard.***

(e) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in

§63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

(f) [Reserved]

(RFD# #374) RFD approved 4/3/2008 Delete (a) Rec Cpl

#010 ***Request deletion as this condition is redundant and the language is inconsistent with the language in Condition #009(c).***

#011 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.367]
Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities
Recordkeeping requirements.

(a) The owner or operator of a source subject to §63.362 shall comply with the recordkeeping requirements in §63.10(b) and (c), according to the applicability in Table 1 of §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) ***Request deletion or note that this paragraph is not applicable to B Braun as more than 10 tons per year of ethylene oxide is used.***

(c) ***Request deletion or note that this paragraph is not applicable to B Braun as more than 10 tons per year of ethylene oxide is used.***

(d) The owners or operators complying with §63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

#012 [40 CFR Part 63 NESHAPS for Source Categories §40 CFR 63.366]
Subpart O – Ethylene Oxide Emission Standards for Sterilization Facilities

Reporting requirements.

(a) The owner or operator of a source subject to the emissions standards in §63.362 shall fulfill all reporting requirements in §§63.10(a), (d), (e), and (f) of subpart A, according to the applicability in Table 1 of §63.360. These reports will be made to the Administrator at the appropriate address identified in §63.13 of subpart A of this part.

(1) Reports required by subpart A and this section may be sent by U.S. mail, fax, or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Administrator on or before the specified date.

(2) If acceptable to both the Administrator and the owner or operator of a source, reports may be submitted on electronic media.

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per §63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see §63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in §63.10(c)(5) through (13), as applicable in Table 1 of §63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(b) *Construction and reconstruction.* The owner or operator of each source using 10 tons shall fulfill all requirements for construction or reconstruction of a source in §63.5 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this paragraph.

(1) *Applicability.* (i) This paragraph and §63.5 of subpart A of this part implement the preconstruction review requirements of section 112(i)(1) for sources subject to these emissions standards. In addition, this paragraph and §63.5 of subpart A of this part include other requirements for constructed and reconstructed sources that are or become subject to these emissions standards.

(ii) After the effective date, the requirements in this section and in §63.5 of subpart A of this part apply to owners or operators who construct a new source or reconstruct a source subject to these emissions standards after December 6, 1994. New or reconstructed sources subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b) (2) and (3) of this section and §63.5(d) (3) and (4) and (e) of subpart A of this part.

(2) After the effective date, whether or not an approved permit program is effective in the State in which a source is (or would be) located, no person may

construct a new source or reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and §63.5(d) (3) and (4) and (e) of subpart A of this part.

(3) *Application for approval of construction or reconstruction.* The provisions of paragraph (b)(3) of this section and §63.5(d) (3) and (4) of subpart A of this part implement section 112(i)(1) of the Act.

(i) *General application requirements.* (A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new source subject to these emissions standards, the reconstruction of a source subject to these emissions standards, or the reconstruction of a source such that the source becomes a source subject to these emissions standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (c)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(*1*) The applicant's name and address.

(*2*) A notification of intention to construct a new source subject to these emissions standards or make any physical or operational change to a source subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in §63.2 of subpart A of this part.

(*3*) The address (i.e., physical location) or proposed address of the source.

(*4*) An identification of the relevant standard that is the basis of the application.

(*5*) The expected commencement date of the construction or reconstruction.

(*6*) The expected completion date of the construction or reconstruction.

(*7*) The anticipated date of (initial) startup of the source.

(*8*) The type and quantity of hazardous air pollutants emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants expected to be emitted by the source reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(*9*) Other information as specified in paragraph (b)(3)(ii) of this section and §63.5(d)(3) of subpart A of this part.

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(*8*) and (ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) *Application for approval of construction.* Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior State preconstruction review.* (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and §63.5(d)(3) and (4) of subpart A of this part if the owner or operator of a new or reconstructed source who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in §63.5(e)(1) of subpart A of this part.

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in §63.5 of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) *Notification requirements.* The owner or operator of each source subject to the emissions standards in §63.362 shall fulfill all notification requirements in §63.9 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this paragraph.

(1) *Initial notifications.* (i)(A) If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month period after December 6, 1996, such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of §63.9 of subpart A of this part.

(B) Sources subject to these emissions standards may use the application for approval of construction or reconstruction under paragraph (b)(3)(ii) of this section and §63.5(d) (3) of subpart A of this part, respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed source subject to these emissions standards that has an initial startup date after the effective date and

for which an application for approval of construction or reconstruction is required under paragraph (b)(3) of this section and §63.5(d) (3) and (4) of subpart A of this part shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (b)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, 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 these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (b)(3) of this section and §63.5(d)(3) and (4) of subpart A of this part. For sources

subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of §63.9 of subpart A of this part.

(2) If an owner or operator of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (b)(3)(ii) of this section and §63.5(d)(3) of subpart A of this part, respectively, in place of the actual emissions data or control efficiencies required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) The owner or operator of any existing sterilization facility subject to this subpart shall also include the amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by §63.9(b)(2) and (3) of subpart A of this part. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

Section E: Source Group Restrictions (GRP2)

Sources included in this group:

ID	***Name***
111	*Emergency Generator #2*
112	*Emergency Generator #1*
113	*Fire Pump*
114	***30 KW Kohler Emergency Generator***
003	***New Emergency Generator – 605 HP, Diesel***
004	***New Fire Pump – 100 HP, Diesel***

I. RESTRICTIONS

Emission Limitation(s).

#001 *Processes.* The permittee may not permit the emission into the outdoor atmosphere of particulate matter, expressed as PM, from each source of this group in excess of the following rate:

(i) 0.04 grain per dry standard cubic foot, when the effluent gas volume is less than 150,000 dry standard cubic feet per minute.

#002 *General.* The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides from a source in a manner that the concentration of the sulfur oxides, expressed as SO2, from each source of this group in excess of the following rate:

(1) 500 parts per million, by volume, dry basis.

#003 ***Operating permit terms and conditions. Each source of this group shall operate no more than 242 hours during the May 1 through September 30 ozone season of each year, and no more than 500 hours during any consecutive 12-month period.***

#004 *Operating Permit Terms and Conditions.* The permittee shall record the total hours of operation for each source on a monthly basis. The data recorded shall include, but not be limited to:

(1) The name of the source which was operated.

(2) The hours of operation of each source.

Measurements, records and other data shall be maintained in accordance with General Title V Requirements Condition #020, Section B.

#005 *Operating Permit Terms and Conditions.* The sources shall be operated in accordance with the manufacturers specification and the source shall also be operated and maintained in accordance with good air pollution control practices.

Section E: Source Group Restrictions (GRP3)

Sources included in this group:

ID	*Name*
031	*KEWANEE - 19.5 MMBTU/HR*
032	*KEWANEE - 10.0 MMBTU/HR*

I. RESTRICTIONS

#001 Combustion units. The permittee may not permit the emission into the outdoor atmosphere of particulate matter from a combustion unit in excess of the following:

(1) The rate of 0.4 pound per million Btu of heat input, when the heat input to the combustion unit in millions of Btus per hour is greater than 2.5 but less than 50.

#002 Combustion units. The permittee may not permit the emission into the outdoor atmosphere of sulfur oxides, expressed as SO2, from a combustion unit in excess of the rate of 4 pounds per million Btu of heat input over any 1-hour period.

#003 Operating Permit Terms and Conditions. The type of fuel usage for each source of this source group as follow:

(1) 10.5 MMBTU/hr boiler shall be fired either with #6 oil or natural gas. The primary fuel is #6 fuel oil and the secondary fuel is natural gas.

(2) The percent (%) by weight of Sulfur content of the # 6 fuel oil shall not exceed 1%.

(3) 19.5 MMBTU/hr boiler shall be fired with natural gas only.

4. REGULATORY REQUIREMENTS

B. Braun is subject to the requirements of 40 CFR Part 63, Subpart O "National Emission Standards for Hazardous Air Pollutants, Ethylene Oxide Emission Standards for Sterilization Facilities" published in final format in the Federal Register on December 6, 1994 with an initial compliance date of December 6, 1998. Because B. Braun is subject to 40 CFR Part 63, Subpart O, they are also subject to the 40 CFR Part 70 requirements – Title V Operating Permit Program incorporated in 25 Pa. Code §127, Subchapters F. The B. Braun facility met the compliance date for 40 CFR Part 63, Subpart O and also applied for and received a TVOP from PADEP effective December 1, 2000. The TVOP was valid for five years from the effective date and B. Braun submitted a timely TVOP renewal application in May 2005. This application serves as a revision to the May 2005 application. A potential new requirement that corresponds with the TVOP renewal is compliance assurance monitoring (CAM). B. Braun has addressed the CAM requirements in Section 5 of this application narrative.

There have been no new requirements that have become effective during the life of the TVOP and B. Braun has summarized requested changes to the TVOP in Section 3 of this application narrative.

4.1 PERMIT APPLICATION SHIELD REQUEST

This is a formal request for a permit application shield. Section 503(d) of the Clean Air Act, as amended in 1990 ("CAAA") stipulates that once a timely and complete application for an operating permit has been filed, the applicant will be shielded from enforcement action for operating without a permit until the permit has been issued or other action has been taken on the application.

B. Braun believes that the information provided herein is complete and accurate and contains all of the information required by 25 Pa. Code §127.503. As discussed, the original permit application was submitted six months prior to the expiration date of the current TVOP as required by 25 Pa. Code §127.446(e). Therefore, B. Braun has satisfied the requirements of 25

Pa. Code §127.446(c) and the General Title V Requirements Condition #004 (Permit Renewal) of the existing TVOP to qualify for an application shield. B. Braun hereby requests that such a shield be granted by PADEP.

Consistent with B. Braun's February 27, 2009 meeting with PADEP, B. Braun does not intend to submit a renewal application for SOOP 39-00038 as the emissions units covered by the permit and the associated applicable requirements are now incorporated into this Title V renewal application for the combined facility. B. Braun will continue to comply with the appropriate underlying applicable requirements that govern the 901 and 939 Marcon Blvd. facilities, respectively, until a new operating permit is issued. B. Braun understands that the shield provisions will remain in effect for the joint 901 and 939 Marcon Blvd. facility until the TVOP renewal is issued.

4.2 PERMIT SHIELD REQUEST

This is a formal request for a permit shield. The Federal TVOP regulations include provisions for major sources covered under the program to request and obtain a permit shield. 25 Pa. Code §127.516 affords the same protection. Section 504(f) of the CAAA defines the permit shield provision, whereby the permitting authority is empowered to grant an applicant compliance with a Federal operating permit and other applicable provisions of the CAA as long as:

- The applicable requirements of these provisions have been identified in the permit; or
- The permitting authority determines in the course of acting on the permit that other provisions of the act are not applicable. The permit must include a list or summary of these provisions.

40 CFR § 70.6(f) provides that operating permits may include a statement indicating that a source which is in compliance with permit conditions shall be considered to be in compliance with any applicable requirements, provided that these requirements are included and specifically identified in the permit, or that other specific requirements are identified as not applicable. The operating permit must explicitly state the existence of the permit shield.

Consistent with Section B #28 of the existing B. Braun TVOP, B. Braun hereby requests a permit shield stating that compliance with the conditions of the permit shall be deemed compliance with applicable requirements specifically identified in the permit.

5. COMPLIANCE ASSURANCE MONITORING (CAM) APPLICABILITY

U.S. EPA's CAM rule is codified at 40 CFR Part 64. Section 64.2 of the CAM rule specifies the criteria for determining applicability with the CAM rule, and Table 5-1 summarizes the applicability requirements for Part 64. If an emissions unit satisfies **all** of the applicability requirements listed in Table 5-1, the emissions unit is subject to CAM. Otherwise, Part 64 does not apply to the emissions unit.

Table 5-1
CAM Applicability Requirements Summary

Part 64 Reference	Requirement
§64.2(a)	Unit is located at major source that is required to obtain a Title V Operating Permit.
§64.2(a)(1)	Unit is subject to an emission limitation or standard for an applicable pollutant.
§64.2(a)(2)	Unit uses a control device to achieve compliance with this applicable limitation or standard (See §64.1 for definition of control device).
§64.2(a)(3)	Potential pre-control emissions of the applicable pollutant from the unit are at least 100 percent of major source threshold amount (i.e., greater than 100 ton/yr).
§64.2(a),(b)	Unit is not otherwise exempt.

Based on the aforementioned criteria, 40 CFR § 64.2(b) identifies exemptions from the requirements for any emission limitation or standards proposed by the Administrator after November 15, 1990 pursuant to Section 111 or 112 of the Act (the NSPS and NESHAP requirements). ETO from the sterilization chambers and aeration room is regulated pursuant to 40 CFR 63, Subpart O and, therefore, B. Braun is exempt from the requirement to develop a CAM Plan for these units.

6. COMPLIANCE CERTIFICATION

A requirement of both the Federal and state TVOP programs is that a responsible official sign a statement attesting to the truth, accuracy, and completeness of the Title V permit application. The compilation of the large amount of information and data required to prepare this TVOP renewal application involved numerous facility personnel at all levels as well as outside consultants. Throughout the application preparation process, standard operating procedures were incorporated which involved developing the most accurate and currently available data, review of that data by competent individuals with the appropriate experience and knowledge, and preparation of accurate, factual information, for presentation in the application. The application was prepared by an independent consultant under the oversight of B. Braun. The designated B. Braun responsible corporate official charged with signing the application certification is Mr. Al Kiani, Vice President/General Manager of PA/NJ Operations. Mr. Kiani has reviewed this document and the contents with the individuals responsible for preparing the submittal. Based on information and belief formed after reasonable inquiry, he has signed the Compliance Certification in Section 12 of the PADEP Title V application forms.

APPENDIX A –
AIR POLLUTION CONTROL ACT COMPLIANCE REVIEW FORM

APPENDIX B –
TITLE V OPERATING PERMIT RENEWAL APPLICATION FORMS

2700-PM-AQ0010 12/2001

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF AIR QUALITY

County: Air Quality
Facility Permit: File #:
APR - 7 REC'D

FOR OFFICIAL USE ONLY
Title V OP Number: _____
Reviewed by: _____
Date: _____

TITLE V OPERATING PERMIT APPLICATION

Section 1 - General Information

1.1 Application Type

Type of permit for which application is made: (Check one)

☐ Initial

☒ Renewal Operating Permit No. *39-00055*

☒ Application Revision - provide date of original Title V Application or OP No.: *May 2005*

1.2 Plant Information

Federal Tax ID/Plant Code: *23-2116774* **Firm Name:** *B. Braun Medical, Inc.*

SIC Code: *3841* **Plant Name:** *B. Braun Medical, Inc.*

Description of SIC: *Surgical & Medical Instruments & Apparatus*

County: *Lehigh* **Municipality** *Hanover Township*

UTM Zone: *18* **UTM North:** *4498.5* **UTM East:** *462*

Method of Obtaining UTM: *USGS MAP – Catasauqua PA*

1.3 Contact Information

Name: *David R. Lauer* **Title:** *Environmental, Heath, and Safety Manager*

Address: *901 Marcon Blvd.*
Allentown, PA 18109

Telephone Number: *(610) 596-2584*

1.4 Certification of Truth, Accuracy and Completeness

Note: This certification must be signed by a responsible official. Applications without a signed certification will be returned as incomplete.

I certify under penalty of law that, based on information and belief formed after reasonable inquiry, the statements and information contained in this application are true, accurate, and complete.

(Signed) For Al Kiani **Date:** 3-31-09

Name (Typed): *Al Kiani* **Title:** *Vice President/General Manager of PA/NJ Operations*

Section 2 - Applicable Requirements for the Entire Site

Describe and cite all applicable requirements pertaining to the entire site.

Note: A Method of Compliance Worksheet (Addendum 1) must be completed for each requirement listed.

For renewals, only list site level requirements not included in the current Title V Operating Permit. If there are no changes, check the box to the right.

☒ No changes from current Title V Operating Permit.

Citation No.	Citation Limitation	Limitation Used

Section 3 - Site Inventory List*

site inventory list of insignificant units is included as Appendix D to this application.

Give a complete listing of all air pollution sources, control equipment, emission points and fuel material locations within this site.

For renewals, only list sources not included in current Title V Operating Permit or sources which are now subject to Compliance Assurance Monitoring (CAM) requirements of 40 CFR Part 64. If preprinted information is provided, correct and/or add any new sources as necessary. Note: one (1) of the following sections (5, 6 or 7) of the application must be completed for each new source listed here.

Unit ID	Company Designation	Unit Type	CAM (✓)
003	*New Emergency Generator – 605 HP, Diesel*	*Process*	*N/A*
004	*New Fire Pump – 100 HP, Diesel*	*Process*	*N/A*
031	*KEWANEE – 19.5 MMBTU/HR*	*Combustion*	*N/A*
032	*KEWANEE – 10.0 MMBTU/HR*	*Combustion*	*N/A*
101	*33714 – 1000 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
102	*363365 – 1000 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
103	*1124 – 1000 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
104	*J70–49 – 1000 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
105	*J78-56 – 1200 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
5	*STI-1300 – 1250 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
107	*J91-24 – 3700 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
108	*STI-150 – 130 cu. ft. - 100% ETO Sterilizer*	*Process*	*N/A*
109	*400-05 – 225 cu. ft. - 100% ETO Sterilizer [not operational]*	*Process*	*N/A*
110	*AER-001 sq. ft. - Aeration room*	*Process*	*N/A*
111	*2EG2 - Emergency generator #2*	*Process*	*N/A*
112	*1EG1 - Emergency generator #1*	*Process*	*N/A*
113	*3FP1 - Fire pump #1*	*Process*	*N/A*
114	*30 KW Kohler Emergency Generator*	*Process*	*N/A*
C001	*16,000 CFM - Catalytic oxidizer*	*Air Pollution Control Device*	*N/A*
C002	*84-186 500 CFM - Wet Scrubber Deoxx Unit*	*Air Pollution Control Device*	*N/A*
S01	*Catalytic Oxidizer Stack*	*Point of Air Emission*	*N/A*
S02	*Deoxx Unit Stack*	*Point of Air Emission*	*N/A*
S03	*1EG1 Stack*	*Point of Air Emission*	*N/A*
S04	*2EG2 Stack*	*Point of Air Emission*	*N/A*
S05	*3FP1 Stack*	*Point of Air Emission*	*N/A*
S06	*30 KW Kohler Emergency Generator Stack*	*Point of Air Emission*	*N/A*
S07	*New Emergency Generator Stack*	*Point of Air Emission*	*N/A*
S08	*New Fire Pump Stack*	*Point of Air Emission*	*N/A*

S09	*KEWANEE – 19.5 MMBTU/HR STACK*	*Point of Air Emission*	*N/A*
S10	*KEWANEE – 10.0 MMBTU/HR STACK*	*Point of Air Emission*	*N/A*
!	*33714 - Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S12	*363365 - Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S13	*1124 - Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S14	*J70–49 – Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S15	*J78-56 – Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S16	*STI-1300 – Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S17	*J91-24 – Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S18	*STI-150 – Sterilizer Chamber Exhaust Vent*	*Point of Air Emission*	*N/A*
S19	*400-05 – Sterilizer Chamber Exhaust Vent (Not Operational)*	*Point of Air Emission*	*N/A*
FML01	*Diesel Fuel Storage*	*Fuel Material Location*	*N/A*
FML02	*Natural Gas Distribution Line*	*Fuel Material Location*	*N/A*
FML03	*No. 6 Fuel Oil Storage*	*Fuel Material Location*	*N/A*

Section 4 - Source Group (optional)

Source Group Definition

This section applies to new Title V Operating Permit applications only.

Define groups of source(s) that are subject to one or more applicable requirements that apply to all source(s) in the group.

Group No.	Source ID (for source(s) in this group)
GRP1	*101-110*
GRP2	*003, 004, 111, 112, 113, and 114*
GRP3	*031-032*

4.2 Applicable Requirements for Source Groups

For renewals, only list group level requirements not included in the current Title V Operating Permit. If there are no changes, check the box to the right.

☐ No changes from current Title V Operating Permit.

Describe and cite all applicable requirements pertaining to all source groups.

Note: A Method of Compliance Worksheet (Addendum 1) must be completed for each requirement listed.

Group No.	Citation No.	Citation Limitation	Limitation Used
GRP1	*40 CFR 63.362*	*Ethylene oxide=* *Sterilization chamber vent 99% emission reduction* *Aeration Room Vent ≤ 1 ppmv Outlet or 99% emission reduction*	*N/A*
GRP2	*25 Pa. Code §127.441*	*Each source of this source group shall operate no more than 242 hours during the May 1 through September 30 ozone season of each year, and no more than 500 hours during any consecutive 12-month period.*	*N/A*
GRP3	*25 Pa. Code §123.11*	*Particulate Matter Emissions = < 0.4 LB/MMBTU*	*N/A*
GRP3	*25 Pa. Code §123.22*	*SO_2 Emissions = < 4 LB/MMBTU over any 1-hour period.*	*N/A*

GRP3	*25 Pa. Code §127.441*	*The type of fuel usage for each source of this source group shall be as follows:* *(1)KEWANEE 10.5 MMBTU/HR boiler shall be fired either with #6 fuel oil or natural gas. The primary fuel is #6 fuel oil and the secondary fuel is natural gas.* *(2)The percent by weight of sulfur content of the #6 fuel oil shall not exceed 1%.* *(3)KEWANEE 19.5 MMBTU/HR boiler shall be fired with natural gas only.*	

Section 5 - Combustion Operational Inventory

›mplete this section for each combustion source in this site. Duplicate this section as needed).

For renewals, complete this section if a new combustion source is listed in Section 3 of this application.

5.1 General Source Information

a. Unit ID: *031*

b. Company Designation: *KEWANEE – 19.5 MMBTU/HR*

c. Plan Approval or Operating Permit No.: *SOOP 39-00038*

d. Manufacturer: *Kewanee*

e. Model No.: *H35-350-G06*

f. Source Description: *Boiler – Natural Gas*

g. Rated Heat Input/Thruput: *19.5 MMBTU/HR*

h. Installation Date:

i. Exhaust Temperature *300* Units *°F*

j. Exhaust % Moisture *10*

k. Exhaust Flow Volume: ACFM

5.2 CAM Information

Yes	No	
☐	☒	Emissions unit uses a control device to achieve compliance.
☐	☒	Potential precontrol emissions of applicable pollutant are at least 100 percent of the major source ›ount.

(Addendum 3 must be completed if both boxes are checked "Yes")

5.3 Exhaust System Components

Explain how the exhaust components are configured:

From Unit ID	Unit Description	To Unit ID	Unit Description	Percent Flow	Begin Date	End Date
FML02	*Fuel Material Location*	*031*	*Combustion*	*Variable*	*1/1*	*12/31*
031	*Combustion*	*S09*	*Point of Air Emission*	*100%*	*1/1*	*12/31*

5.4 Source Classification Code (SCC) Listing for Standard Operation

Fuel/Material	Associated SCC	Max Throughput Rate	Firing Sequence
Natural Gas	*1-02-006-02*	*18.6 MSCF/HR*	*N/A*

5.5 Maximum Fuel Physical Characteristics

If taking limitations on Fuel Physical Characteristics, see instructions.

SCC/Fuel Burned	FML	% Sulfur	% Ash	BTU Content (Units)
Natural Gas	*FML02*	*Negligible*	*Negligible*	*1,050 BTU/SCF*

*FML = Fuel Material Location

5.6 Limitations on Source Operation

Complete this section if you are requesting a limitation on operational hours and/or a permit limitation on the throughput rate equal to or lower than that stated in Section 5.3 of the application.

Maximum amount of hours of source operation per year: *N/A*

Fuel/SCC	Hours/Day	Days/Week	Days/Year	Hours/Year	Max Thruput	Units/Time

5.7 Source Applicable Requirements ***This unit is part of group GRP3. Please refer to the source group applicable requirements in Section 4.2.***

Describe and cite all applicable requirements pertaining to this source.

Note: A Method of Compliance Worksheet (Addendum 1) must be completed for each requirement listed.

For renewals, only list source level requirements not included in the current Title V Operating Permit. If there are no changes, check the box to the right.

☐ No changes from current Title V Operating Permit.

Fuel/SCC	Citation No.	Citation Limitation	Limitation Used

Section 5 - Combustion Operational Inventory

omplete this section for each combustion source in this site. Duplicate this section as needed).

For renewals, complete this section if a new combustion source is listed in Section 3 of this application.

5.1 General Source Information

a. Unit ID: *032*

b. Company Designation: *KEWANEE – 10.0 MMBTU/HR*

c. Plan Approval or Operating Permit No.: *SOOP 39-00038*

d. Manufacturer: *Kewanee*

e. Model No.:

f. Source Description: *Boiler – No. 6 Fuel Oil or Natural Gas*

g. Rated Heat Input/Thruput: *10.0 MMBTU/HR*

h. Installation Date:

i. Exhaust Temperature *300* Units *°F*

j. Exhaust % Moisture *10*

k. Exhaust Flow Volume: ACFM

5.2 CAM Information

Yes	No	
☐	☒	Emissions unit uses a control device to achieve compliance.
☐	☒	Potential precontrol emissions of applicable pollutant are at least 100 percent of the major source

ıount.

(Addendum 3 must be completed if both boxes are checked "Yes")

5.3 Exhaust System Components

Explain how the exhaust components are configured:

From Unit ID	Unit Description	To Unit ID	Unit Description	Percent Flow	Begin Date	End Date
FML03	*Fuel Material Location*	*032*	*Combustion*	*100%*	*1/1*	*12/31*
032	*Combustion*	*S10*	*Point of Air Emission*	*100%*	*1/1*	*12/31*
FML02	*Fuel Material Location*	*032*	*Combustion*	*Variable*	*1/1*	*12/31*
032	*Combustion*	*S10*	*Point of Air Emission*	*100%*	*1/1*	*12/31*

5.4 Source Classification Code (SCC) Listing for Standard Operation

Fuel/Material	Associated SCC	Max Throughput Rate	Firing Sequence
No. 6 Fuel Oil	*1-02-004-01*	*66.7 GAL/HR*	*Primary Fuel*
Natural Gas	*1-02-006-02*	*9.5 MSCF/HR*	*Secondary Fuel*

5.5 Maximum Fuel Physical Characteristics

If taking limitations on Fuel Physical Characteristics, see instructions.

SCC/Fuel Burned	FML	% Sulfur	% Ash	BTU Content (Units)
1-02-004-01/No. 6 Fuel Oil	*FML03*	*< 1.0 wt%*	*<0.1 wt%*	*150,000 BTU/GAL*
1-02-006-02/ Natural Gas	*FML02*	*Negligible*	*Negligible*	*1,050 BTU/SCF*

*FML = Fuel Material Location

5.6 Limitations on Source Operation

Complete this section if you are requesting a limitation on operational hours and/or a permit limitation on the throughput rate equal to or lower than that stated in Section 5.3 of the application.

Maximum amount of hours of source operation per year: *N/A*

Fuel/SCC	Hours/Day	Days/Week	Days/Year	Hours/Year	Max Thruput	Units/Time

5.7 Source Applicable Requirements *This unit is part of group GRP3. Please refer to the source group applicable requirements in Section 4.2.*

Describe and cite all applicable requirements pertaining to this source.

Note: A Method of Compliance Worksheet (Addendum 1) must be completed for each requirement listed.

For renewals, only list source level requirements not included in the current Title V Operating Permit. If there are no changes, check the box to the right.

☐ No changes from current Title V Operating Permit.

Fuel/SCC	Citation No.	Citation Limitation	Limitation Used

Section 7 - Process Operational Inventory

›mplete this section for each process at this site. Duplicate this section as needed).

For renewals, complete this section if a new process is listed in Section 3 of this application.

7.1 General Source Information

a. Unit ID: *003*

b. Company Designation: *New Emergency Generator – 605 HP, Diesel*

c. Plan Approval or Operating Permit No.: *N/A*

d. Manufacturer: *Cummins*

e. Model No.: *400DFCE*

f. Source Description: *Emergency Generator*

g. Rated Heat Input/Thruput: *605 HP*

h. Installation Date: *2008*

i. Exhaust Temperature *995* Units *°F*

j. Exhaust % Moisture *0-5%*

k. Exhaust Flow Volume: *3,780* ACFM

7.2 CAM Information

Yes	No	
☐	☒	Emissions unit uses a control device to achieve compliance with emission limitations or standards.
☐	☒	Potential **precontrol emissions of applicable pollutant are at least 100 percent of the major source amount.**

(Addendum 3 must be completed if both are checked "Yes")

7.3 Exhaust System Components

Explain how the exhaust components are configured:

From Unit ID	Unit Description	To Unit ID	Unit Description	Percent Flow	Begin Date	End Date
FML01	*Fuel Material Location*	*003*	*Process*	*Variable*	*1/1*	*12/31*
003	*Process*	*S07*	*Point of Air Emission*	*100%*	*1/1*	*12/31*