



west virginia department of environmental protection

Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone (304) 926-0475 • FAX: (304) 926-0479

Earl Ray Tomblin, Governor
Randy C. Huffman, Cabinet Secretary
www.dep.wv.gov

ENGINEERING EVALUATION

BACKGROUND INFORMATION

Application No.: R13-2518D
Plant ID No.: 011-00037
Applicant: Alcon Research, Ltd. (Alcon)
Facility Name: Alcon - Advanced Optic Device Center (AODC) South
Location: 6065 Kyle Lane, Huntington, Cabell County, WV 25702
NAICS Code: 339113 - Surgical Appliance and Supplies Manufacturing
Application Type: Modification
Received Date: August 06, 2015
Engineer Assigned: John Legg
Fee Amount: \$1,000
Date Received: August 10, 2015
Complete Date: September 1, 2015 (Date Original Affidavit of Publication was received at the DAQ)
Due Date: December 1, 2015
Applicant Ad Date: August 13, 2015
Newspaper: *The Herald Dispatch*
UTM's: Easting: 385.7 km Northing: 4,257.6 km Zone: 17
Lat/Long Coordinates: Latitude: 38.4605 Longitude: -82.3082
Description: Add: Boilers: Four (4) boilers each rated at 2.0 MMBtu/hr heat input; One (1) boiler rated at 1.3 MMBtu/hr heat input; NG-fueled
Emergency
Generators: One (1) 27 bhp Dayton 4W117H; One (1) 67 bhp Dayton 4LM43; One (1) 201 bhp Caterpillar 3406; and One (1) 80 bhp Caterpillar G60F3.
Remove: EO Sterilizers: Two (2) rated at 3.2 lb/cycle and one (1) rated at 12 lb/cycle and all associated control devices.

DESCRIPTION OF PROCESS

The following process description came from permit application R13-2518B, Attachment G:

Alcon Research, LTD (Alcon) is an Advanced Optical Device Center (AODC) that manufactures ophthalmic products; primarily intraocular lenses and surgical delivery system accessories.

Emergency Generators (S01 - S05)

Five (5) emergency generators (S01 - S05) provide backup power to the facility:

Table 1: Alcon's Five (5) Emergency Generators (S01 - S05).					
Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device
S01	E01	Emergency Generator Natural Gas-fueled Dayton 4W117H	2002	27 hp	None
S02	E02	Emergency Generator Natural Gas-fueled Dayton 4LM43	2002	67 hp	None
S03	E03	Emergency Generator Natural Gas-fueled Caterpillar 3406	2005	201 hp	None
S04	E04	Emergency Generator Natural Gas-fueled Caterpillar G60F3	2005	80 hp	None
S05	E05	Emergency Generator Diesel-fueled Caterpillar C15	2012	619 bhp	None

The first four emergency generators (S01 - S04) have reciprocating internal combustion, spark ignition engines, fueled by pipeline quality natural gas. The natural gas is supplied by the local utility.

The fifth emergency generator, the Caterpillar C15 (S05), has a reciprocating internal combustion, compression ignition engine, fueled by #2 fuel oil supplied from an integrated 1,000 gallon tank. This generator engine was previously permitted under R13-2518C.

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Boilers (S06 - S10)

Alcon uses five (5) small industrial boilers (S06 - S10) at their facility to provide conditioning and comfort heating for the manufacturing areas.

Four (4) of the boilers (S06 -S09) are Plenum boilers, each having a design heat input of 2.0 mmBtu/hr. The fifth boiler (S10) is a Govenair Boiler having a design heat input of 1.3 mmBtu/hr.

Table 2: Alcon's five (5) Boilers (S06 -S10)					
Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device
S06	E06	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S07	E07	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S08	E08	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S09	E09	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S10	E10	Boiler – Govenair	1980	1.3 MM Btu/hr	None

Ethylene Oxide (EO) Sterilizers

Alcon removed all three (3) EO sterilizers from it facility. This was done of April 28, 2014.

Table 3: Alcon's Removed EO Sterilizers.					
Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device
Old 1S	Old 1E or 2E	Ethylene Oxide Sterilizer	1982	3.2 lb EO/Cycle	1C or 2C
Old 2S	Old 1E or 2E	Ethylene Oxide Sterilizer	1997	3.2 lb EO/Cycle	1C or 2C
Old 3S	Old 2E	Ethylene Oxide Sterilizer	2004	12 lb EO/Cycle	2C

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SITE INSPECTION

Alcon's facility is an existing source, issued it's first construction permit (R13-2518) on February 24, 2003 (+12 years ago).

The writer did not conduct a site inspection for this modification application. The location of the facility is known to the DAQ's Enforcement Group, who conducts periodic inspections of the facility.

The last full, on-site inspection was conducted by Eric Ray, DAQ Enforcement Inspector, Charleston Main Office, on October 11, 2013. The facility was given the in-compliance status code of 30.

Directions to the facility as given in the permit application (Section I. General, Item 12A, Page 2 of 4):

From I-64W, take exit 18 towards US-60/WV-2. Turn right at Merritts Creek Connector/WV-193. Go 3.2 miles to Ohio River Rd/WV-2. Turn left and go approximately 0.2 miles. Turn right onto Kyle Lane.

ESTIMATE OF EMISSIONS BY REVIEWING ENGINEER

Before Draft Permit (R13-2518D)

According to their August 6, 2015 legal notice/newspaper advertisement, Alcon estimates the potential to discharge the following regulated air pollutants on a facility-wide basis to be:

- 0.29 ton/yr (tpy) Volatile Organic Compounds (VOC)
- 0.11 tpy Hazardous Air Pollutants (HAPs)
- 4.05 tpy Carbon Monoxide (CO)
- 7.27 tpy Nitrogen Oxides (Nox)
- 0.24 tpy Particulate Matter (PM)
- 0.33 tpy Sulfur Dioxide (SO2)

Table 4: VOC, HAP, and CO Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).

Emission Source			VOC		HAP		CO		
			lb/hr	ton/yr	lb/hr	ton/yr	lb/hr	lb/day*	ton/yr
Five (5) Generators	S01	Dayton 4W117H	0.05	0.01	0.02	0.01	0.13	3.21	0.03
	S02	Dayton 4LM43	0.09	0.02	0.04	0.01	0.25	5.97	0.06
	S03	Caterpillar 3406	0.24	0.06	0.11	0.03	5.54	132.96	1.39
	S04	Caterpillar G60F3	0.09	0.02	0.04	0.01	0.23	5.58	0.06

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Table 4: VOC, HAP, and CO Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).

Emission Source			VOC		HAP		CO		
			lb/hr	ton/yr	lb/hr	ton/yr	lb/hr	lb/day*	ton/yr
	S05	Caterpillar C15	0.05	0.01	0.02	0.00	0.48	11.52	0.12
**Five (5) Boilers	S06 -S09	2.0 MMBtu/hr	0.04	0.13	0.01	0.05	0.66	15.81	2.06
	S10	1.3 MMBtu/hr	0.01	0.02	0.00	0.01	0.11	2.57	0.33
Totals			0.56	0.29	0.25	0.11	7.40	177.62	4.05

* CO daily emissions exceed the 150 lb/day trigger, i.e., a rule 13 permit is needed.

** Annual boiler emissions based on 6,240 hr/yr (24 hr/day x 5 day/wk x 52 wk/yr).

Table 5: Nox, PM, and SO₂ Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).

Emission Source			NOx			PM		SO ₂	
			lb/hr	lb/day*	ton/yr	ton/yr	lb/hr	lb/day	ton/yr
Five (5) Generators	S01	Dayton 4W117H	1.72	41.35	0.43	0.004	0.00	<0.001	<0.001
	S02	Dayton 4LM43	3.20	76.81	0.80	0.008	0.00	<0.001	<0.001
	S03	Caterpillar 3406	5.01	120.20	1.25	0.020	0.00	0.001	<0.001
	S04	Caterpillar G60F3	2.99	71.81	0.75	0.007	0.00	<0.001	<0.001
	S05	Caterpillar C15	4.80	115.20	1.19	0.050	0.01	1.270	0.317
**Five (5) Boilers	S06-S09	2.0 MMBtu/hr	0.78	18.82	2.45	0.06	0.19	0.005	0.015
	S10	1.3 MMBtu/hr	0.13	3.06	0.40	0.010	0.03	0.001	0.002
Totals			18.64	447.25	7.27	0.16	0.24	1.28	0.33

* NOx daily emissions exceed the 150 lb/day trigger, i.e., a rule 13 permit is needed.

** Annual boiler emissions based on 6,240 hr/yr (24 hr/day x 5 day/wk x 52 wk/yr).

After Draft Permit (R13-2518D)

On November 25, 2015, the DAQ submitted a draft permit to Alcon's consultant Justin Spencer for review. Upon review of that draft permit (December 7, 2015), Alcon decided to increase the hours of operation for their boilers from 6,240 hr/yr (24 hr/day x 5 day/wk x 52 wk/yr) to 8,760 hr/yr (24 hr/day x 5 day/wk x 52 wk/yr). On December 8, 2015, attachments J, L and N of the permit application were revised.

The re-calculated emissions following the increase in annual hours are detailed below and in Tables 6 and 7. DAQ's legal notice will increase emissions to the amounts calculated below.

Annual Emissions

Before Draft	After Draft	Pollutant
0.29 ton/yr (tpy)	0.35 tpy	Volatile Organic Compounds (VOC)
0.11 tpy	0.13 tpy	Hazardous Air Pollutants (HAPs)
4.05 tpy	5.01 tpy	Carbon Monoxide (CO)
7.27 tpy	8.41 tpy	Nitrogen Oxides (Nox)
0.24 tpy	0.33 tpy	Particulate Matter (PM)
0.33 tpy	0.34 tpy	Sulfur Dioxide (SO ₂)

Table 6: VOC, HAP, and CO Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).

Emission Source			VOC		HAP		CO		
			lb/hr	ton/yr	lb/hr	ton/yr	lb/hr	lb/day*	ton/yr
Five (5) Generators	S01	Dayton 4W117H	0.05	0.01	0.02	0.01	0.13	3.21	0.03
	S02	Dayton 4LM43	0.09	0.02	0.04	0.01	0.25	5.97	0.06
	S03	Caterpillar 3406	0.24	0.06	0.11	0.03	5.54	132.96	1.39
	S04	Caterpillar G60F3	0.09	0.02	0.04	0.01	0.23	5.58	0.06
	S05	Caterpillar C15	0.05	0.01	0.02	0.00	0.48	11.52	0.12
**Five (5) Boilers	S06 -S09	2.0 MMBtu/hr	0.04	0.19	0.01	0.06	0.66	15.81	2.89
	S10	1.3 MMBtu/hr	0.01	0.03	0.00	0.01	0.11	2.57	0.47
Totals			0.56	0.35	0.25	0.13	7.40	177.62	5.01

* CO daily emissions exceed the 150 lb/day trigger, i.e., a rule 13 permit is needed.

** Annual boiler emissions based on 8,760 hr/yr (24 hr/day x 7 day/wk x 52 wk/yr).

Table 7: Nox, PM, and SO₂ Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).

Emission Source			NOx			PM		SO ₂	
			lb/hr	lb/day*	ton/yr	ton/yr	lb/hr	lb/day	ton/yr
Five (5) Generators	S01	Dayton 4W117H	1.72	41.35	0.43	0.004	0.00	<0.001	<0.001
	S02	Dayton 4LM43	3.20	76.81	0.80	0.008	0.00	<0.001	<0.001
	S03	Caterpillar 3406	5.01	120.20	1.25	0.020	0.00	0.001	<0.001
	S04	Caterpillar G60F3	2.99	71.81	0.75	0.007	0.00	<0.001	<0.001
	S05	Caterpillar C15	4.80	115.20	1.19	0.050	0.01	1.270	0.317

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Table 7: Nox, PM, and SO2 Emissions as Calculated in Permit Application R13-2518D Before Alcon Commented on Draft Permit (R13-2518D).									
Emission Source			NOx			PM		SO2	
			lb/hr	lb/day*	ton/yr	ton/yr	lb/hr	lb/day	ton/yr
**Five (5) Boilers	S06-S09	2.0 MMBtu/hr	0.78	18.82	3.44	0.06	0.26	0.005	0.021
	S10	1.3 MMBtu/hr	0.13	3.06	0.56	0.010	0.04	0.001	0.003
Totals			18.64	447.25	8.41	0.16	0.33	1.28	0.34

* NOx daily emissions exceed the 150 lb/day trigger, i.e., a rule 13 permit is needed.
 ** Annual boiler emissions based on 8,760 hr/yr (24 hr/day x 7 day/wk x 52 wk/yr).

REGULATORY APPLICABILITY

Regulatory applicability information can be found in permit application R13-2518D, Attachment D:

45CSR2 - *To Prevent and Control Particulate Air Pollution From Combustion of Fuel in Indirect Heat Exchangers*

The boilers are indirect heat exchangers that combust natural gas. These units are less than 10 mmBtu/hr. Such units are subject to 10% opacity as a six-minute block average limitation, but are exempt from most other requirements in the rule aside from discretionary testing requirements.

45CSR4 - *To Prevent and Control the Discharge of Air Pollutants Into the Open Air Which Causes or Contributes to an Objectionable Odor or Odors*

The facility is subject to the requirements of 45CSR4 and shall not allow the discharge of air pollutants which cause or contribute to an objectionable odor at any location occupied by the public.

Operations conducted at Alcon are subject to this requirement, however, based on the nature of the process, the presence of objectionable odors is unlikely.

45CSR13 - *Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Administrative Updates, Temporary Permits, General Permits, and Procedures for Evaluation*

This modification application is being submitted for the operational activities associated with Alcon's production of ophthalmic products. Per 45-13-2.17.a, the change in an emission increase of more than 144 pounds per calendar day of any regulated pollutant triggers the need for this permit modification. Alcon's potential-to-emit is 177 lb/day of CO and 447 lb/day Nox.

Alcon paid the proper permitting fee, ran a legal advertisement, sent the DAQ the original affidavit of publication and were deemed to have submitted a complete application. Specific dates are detailed below:

- Modification permit submitted on 8/6/15.
- \$1,000.00 application/permitting fee received 8/10/15.
- Legal advertisement ran on 8/13/2015.
- Original affidavit of publication received at the DAQ 9/1/15.
- The application was deemed complete as of 9/1/15 via an email issued by the writer on 10/14/15.

45CSR16 - Standards of Performance for New Stationary Sources Pursuant to 40CFR60

45CSR16 incorporates by reference the standards of performance for new stationary sources (40CFR60).

- 40 CFR 60, Subpart D (Standards of Performance for Fossil Fuel Fired Steam Generators)

Boiler units are too small, i.e., less than 10mmBtu/hr.

- 40 CFR 60, Subpart Dc (Standards of Performance for Small Industrial-Commerical-Institutional Steam Generating Units)

Boilers are less than 10 mmBtu/hr.

- 40 CFR 60, Subpart IIII (Standards of Performance for Stationary Compression Ignition Internal Combustion Engines.)

Subpart IIII establishes emission standards and compliance requirements for the control of criteria pollutants from stationary compression ignition (diesel-fueled) emergency generators.

The applicable provisions and requirements of Subpart IIII were addressed for the diesel-fueled Caterpillar C15 emergency generator in R13-2518C. These requirements do not apply to the natural gas-fired reciprocating internal combustion engines.

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- 40 CFR 60, Subpart JJJJ (Standards of Performance for Stationary Spark Ignition Internal Combustion Engines): Engine manufacturer dates do not apply to this subpart.

45CSR22 - Air Quality Management Fee Program

This facility is subject to the requirements of 45CSR22. This source is a 9M source and pays an annual fee of \$200.

45CSR34 - National Emission Standards for Hazardous Air Pollutants (NESHAP)

45CSR34 establishes and adopts a program of national emission standards for hazardous air pollutants and other regulatory requirements promulgated by the United States Environmental Protection Agency pursuant to 40 CFR Parts 61, 63 and section 112 of the federal Clean Air Act, as amended.

- 40 CFR 63 Subpart ZZZZ (National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines)

The emergency generators permitted under R13-2518D are not subject to the regulations listed in 40 CFR 63 Subpart ZZZZ.

AIR QUALITY IMPACT ANALYSIS

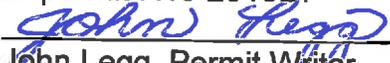
Alcon's facility is a minor source under Rule 13. For that reason no air quality impact analysis was performed.

CHANGES TO PERMIT R13-2518C

A compare file is attached to this evaluation. It details the changes made to R13-2518C to arrive at R13-2518D.

RECOMMENDATION TO DIRECTOR

The information provided in permit application R13-2518D indicates that Alcon should meet all applicable federal and state rules/regulations. It is therefore recommended that Alcon be granted modification permit R13-2518D.



John Legg, Permit Writer



December 08, 2015

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Alcon - AODC South
Huntington, WV

West Virginia Department of Environmental Protection
Earl Ray Tomblin
Governor

Division of Air Quality

Randy C. Huffman
Cabinet Secretary

Permit to Modify



R13-~~2518~~C2518D

This permit is issued in accordance with the West Virginia Air Pollution Control Act (West Virginia Code §§22-5-1 et seq.) and 45 C.S.R. 13 – Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Temporary Permits, General Permits and Procedures for Evaluation. The permittee identified at the above-referenced facility is authorized to construct the stationary sources of air pollutants identified herein in accordance with all terms and conditions of this permit.

Issued to:

Alcon Research, Ltd.
Advanced Optic Device Center (AODC) South,
Huntington Facility, WV
011-00037

John A. Benedict
William F. Durham
Director

Issued: ~~October 23, 2012~~ • Effective: ~~October 23, 2012~~ Draft

This permit will supercede and replace Permit R13-2518C.

Facility Location: Huntington, Cabell County, West Virginia
Mailing Address: 6065 Kyle Lane
Huntington, WV 25702

Facility Description: Optical Device Manufacturing Facility
NAICS Codes: 339113 - Surgical Appliance and Supplies Manufacturing

UTM Coordinates: 385.7 km Easting • 4,257.6 km Northing • Zone 17

Permit Type: Modification

Description of Change: ~~Installation of a 619 bhp #Add: Five (5) Boilers - Four (4) each rated at 2-FO-0~~
MMBtu/hr heat input;

~~- One (1) rated at 1.3 MMBtu/hr heat input;~~

Four (4) Natural Gas-fired engine

Emergency Generators - One (1) 27 bhp Dayton 4W117H;

- One (1) 67 bhp Dayton 4LM43;

- One (1) 201 bhp Caterpillar 3406; and

- One (1) 80 bhp Caterpillar G60F3.

Remove: Three (3)

Ethylene Oxide

Sterilizers - Two (2) rated at 3.2 lb/cycle;

- One (1) rated at 12 lb/cycle and

- All associated with a 400 kW emergency

generator-control devices.

(EO Sterilizers removed 4/28/14.)

Any person whose interest may be affected, including, but not necessarily limited to, the applicant and any person who participated in the public comment process, by a permit issued, modified or denied by the Secretary may appeal such action of the Secretary to the Air Quality Board pursuant to article one [§§22B-1-1 et seq.], Chapter 22B of the Code of West Virginia. West Virginia Code §§22-5-14.

This permit does not affect 45CSR30 applicability, the source is a nonmajor source subject to 45CSR30.

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CERTIFICATION OF DATA ACCURACY2319 ← **Forma**

1.0. Emission Units

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device
1SS01	1E-or 2EE01	Ethylene Oxide Sterilizer Generator – Natural Gas Dayton 4W117H	1982 <u>2002</u>	3.2 lbs Ethylene Oxide/Cycle 27 bhp; 20 kw; 0.42 MM Btu/hr	1C-or 2CNone
2SS02	1E-or 2EE02	Ethylene Oxide Sterilizer Generator – Natural Gas Dayton 4LM43	1997 <u>2002</u>	3.2 lbs Ethylene Oxide/Cycle 67 bhp; 0.78 MM Btu/hr	1C-or 2CNone
3SS03	2EE03	Ethylene Oxide Sterilizer Generator – Natural Gas Caperpillar 3406	2004 <u>2005</u>	12 lbs Ethylene Oxide/Cycle 201 bhp; 150 kw; 1.99 MM Btu/hr	2CNone
S04	E04	Generator – Natural Gas Caterpillar G60F3	2005	80 bhp; 60 kw; 0.73 MM Btu/hr	None
4SS05	4EE05	Generator (Diesel) Caterpillar Emergency Generator C15	2012	619 bhp	None
5SS06	5EE06	#2 Fuel Oil Tank Boiler – Plenum	2012 <u>2003</u>	1,000 gallons 2.0 MM Btu/hr	None
S07	E07	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S08	E08	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S09	E09	Boiler – Plenum	2003	2.0 MM Btu/hr	None
S10	E10	Boiler – Govenair	1980	1.3 MM Btu/hr	None

Forma

2.0. General Conditions

2.1. Definitions

- 2.1.1. All references to the “West Virginia Air Pollution Control Act” or the “Air Pollution Control Act” mean those provisions contained in W.Va. Code §§ 22-5-1 to 22-5-18.
- 2.1.2. The “Clean Air Act” means those provisions contained in 42 U.S.C. §§ 7401 to 7671q, and regulations promulgated thereunder.
- 2.1.3. “Secretary” means the Secretary of the Department of Environmental Protection or such other person to whom the Secretary has delegated authority or duties pursuant to W.Va. Code §§ 22-1-6 or 22-1-8 (45CSR§30-2.12.). The Director of the Division of Air Quality is the Secretary’s designated representative for the purposes of this permit.

2.2. Acronyms

CAAA	Clean Air Act Amendments	NO_x	Nitrogen Oxides
CBI	Confidential Business Information	NSPS	New Source Performance Standards
CEM	Continuous Emission Monitor	PM	Particulate Matter
CES	Certified Emission Statement	PM_{2.5}	Particulate Matter less than 2.5 μm in diameter
C.F.R. or CFR	Code of Federal Regulations	PM₁₀	Particulate Matter less than 10μm in diameter
CO	Carbon Monoxide	Ppb	Pounds per Batch
C.S.R. or CSR	Codes of State Rules	Pph	Pounds per Hour
DAQ	Division of Air Quality	Ppm	Parts per Million
DEP	Department of Environmental Protection	Ppm_v or ppmv	Parts per Million by Volume
dscm	Dry Standard Cubic Meter	PSD	Prevention of Significant Deterioration
FOIA	Freedom of Information Act	Psi	Pounds per Square Inch
HAP	Hazardous Air Pollutant	SIC	Standard Industrial Classification
HON	Hazardous Organic NESHAP	SIP	State Implementation Plan
HP	Horsepower	SO₂	Sulfur Dioxide
lbs/hr	Pounds per Hour	TAP	Toxic Air Pollutant
LDAR	Leak Detection and Repair	TPY	Tons per Year
M	Thousand	TRS	Total Reduced Sulfur
MACT	Maximum Achievable Control Technology	TSP	Total Suspended Particulate
MDHI	Maximum Design Heat Input	USEPA	United States Environmental Protection Agency
MM	Million	UTM	Universal Transverse Mercator
MMBtu/hr or mmbtu/hr	Million British Thermal Units per Hour	VEE	Visual Emissions Evaluation
MMCF/hr or mmcf/hr	Million Cubic Feet per Hour	VOC	Volatile Organic Compounds
NA	Not Applicable	VOL	Volatile Organic Liquids
NAAQS	National Ambient Air Quality Standards		
NESHAPS	National Emissions Standards for Hazardous Air Pollutants		

2.3. Authority

This permit is issued in accordance with West Virginia air pollution control law W.Va. Code §§ 22-5-1. et seq. and the following Legislative Rules promulgated thereunder:

- 2.3.1. 45CSR13 – *Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Temporary Permits, General Permits and Procedures for Evaluation;*

2.4. Term and Renewal

- 2.4.1. This permit supersedes and replaces previously issued Permit R13-2518C. This ~~Permit~~ permit shall remain valid, continuous and in effect unless it is revised, suspended, revoked or otherwise changed under an applicable provision of 45CSR13 or any other applicable legislative rule;

2.5. Duty to Comply

- 2.5.1. The permitted facility shall be constructed and operated in accordance with the plans and specifications filed in Permit Application R13-~~2518C~~2518D, and any modifications, administrative updates, or amendments thereto. The Secretary may suspend or revoke a permit if the plans and specifications upon which the approval was based are not adhered to; [45CSR§§13-5.11 and 10.3.]
- 2.5.2. The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the West Virginia Code and the Clean Air Act and is grounds for enforcement action by the Secretary or USEPA;
- 2.5.3. Violations of any of the conditions contained in this permit, or incorporated herein by reference, may subject the permittee to civil and/or criminal penalties for each violation and further action or remedies as provided by West Virginia Code 22-5-6 and 22-5-7;
- 2.5.4. Approval of this permit does not relieve the permittee herein of the responsibility to apply for and obtain all other permits, licenses, and/or approvals from other agencies; i.e., local, state, and federal, which may have jurisdiction over the construction and/or operation of the source(s) and/or facility herein permitted.

2.6. Duty to Provide Information

The permittee shall furnish to the Secretary within a reasonable time any information the Secretary may request in writing to determine whether cause exists for administratively updating, modifying, revoking, or terminating the permit or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Secretary copies of records to be kept by the permittee. For information claimed to be confidential, the permittee shall furnish such records to the Secretary along with a claim of confidentiality in accordance with 45CSR31. If confidential information is to be sent to USEPA, the permittee shall directly provide such information to USEPA along with a claim of confidentiality in accordance with 40 C.F.R. Part 2.

2.7. Duty to Supplement and Correct Information

Upon becoming aware of a failure to submit any relevant facts or a submittal of incorrect information in any permit application, the permittee shall promptly submit to the Secretary such supplemental facts or corrected information.

2.8. Administrative Update

The permittee may request an administrative update to this permit as defined in and according to the procedures specified in 45CSR13.

[45CSR§13-4.]

2.9. Permit Modification

The permittee may request a minor modification to this permit as defined in and according to the procedures specified in 45CSR13.

[45CSR§13-5.4.]

2.10 Major Permit Modification

The permittee may request a major modification as defined in and according to the procedures specified in 45CSR14 or 45CSR19, as appropriate.

[45CSR§13-5.1]

2.11. Inspection and Entry

The permittee shall allow any authorized representative of the Secretary, upon the presentation of credentials and other documents as may be required by law, to perform the following:

- a. At all reasonable times (including all times in which the facility is in operation) enter upon the permittee's premises where a source is located or emissions related activity is conducted, or where records must be kept under the conditions of this permit;
- b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- c. Inspect at reasonable times (including all times in which the facility is in operation) any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under the permit;
- d. Sample or monitor at reasonable times substances or parameters to determine compliance with the permit or applicable requirements or ascertain the amounts and types of air pollutants discharged.

2.12. Emergency

- 2.12.1. An "emergency" means any situation arising from sudden and reasonable unforeseeable events beyond the control of the source, including acts of God, which situation requires immediate corrective action to restore normal operation, and that causes the source to exceed a technology-based emission limitation under the permit, due to unavoidable increases in emissions attributable to the emergency. An emergency shall not include noncompliance to the extent caused by

improperly designed equipment, lack of preventative maintenance, careless or improper operation, or operator error.

- 2.12.2. Effect of any emergency. An emergency constitutes an affirmative defense to an action brought for noncompliance with such technology-based emission limitations if the conditions of Section 2.12.3 are met.
- 2.12.3. The affirmative defense of emergency shall be demonstrated through properly signed, contemporaneous operating logs, or other relevant evidence that:
- a. An emergency occurred and that the permittee can identify the cause(s) of the emergency;
 - b. The permitted facility was at the time being properly operated;
 - c. During the period of the emergency the permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards, or other requirements in the permit; and
 - d. The permittee submitted notice of the emergency to the Secretary within one (1) working day of the time when emission limitations were exceeded due to the emergency and made a request for variance, and as applicable rules provide. This notice must contain a detailed description of the emergency, any steps taken to mitigate emissions, and corrective actions taken.
- 2.12.4. In any enforcement proceeding, the permittee seeking to establish the occurrence of an emergency has the burden of proof.
- 2.12.5 The provisions of this section are in addition to any emergency or upset provision contained in any applicable requirement.

2.13. Need to Halt or Reduce Activity Not a Defense

It shall not be a defense for a permittee in an enforcement action that it should have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. However, nothing in this paragraph shall be construed as precluding consideration of a need to halt or reduce activity as a mitigating factor in determining penalties for noncompliance if the health, safety, or environmental impacts of halting or reducing operations would be more serious than the impacts of continued operations.

2.14. Suspension of Activities

In the event the permittee should deem it necessary to suspend, for a period in excess of sixty (60) consecutive calendar days, the operations authorized by this permit, the permittee shall notify the Secretary, in writing, within two (2) calendar weeks of the passing of the sixtieth (60) day of the suspension period.

2.15. Property Rights

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

2.16. Severability

The provisions of this permit are severable and should any provision(s) be declared by a court of competent jurisdiction to be invalid or unenforceable, all other provisions shall remain in full force and effect.

2.17. Transferability

This permit is transferable in accordance with the requirements outlined in Section 10.1 of 45CSR13. [45CSR§13-10.1.]

2.18. Notification Requirements

The permittee shall notify the Secretary, in writing, no later than thirty (30) calendar days after the actual startup of the operations authorized under this permit.

2.19. Credible Evidence

Nothing in this permit shall alter or affect the ability of any person to establish compliance with, or a violation of, any applicable requirement through the use of credible evidence to the extent authorized by law. Nothing in this permit shall be construed to waive any defense otherwise available to the permittee including, but not limited to, any challenge to the credible evidence rule in the context of any future proceeding.

3.0. Facility-Wide Requirements

3.1. Limitations and Standards

- 3.1.1. **Open burning.** The open burning of refuse by any person, firm, corporation, association or public agency is prohibited except as noted in 45CSR§6-3.1.
[45CSR§6-3.1.]
- 3.1.2. **Open burning exemptions.** The exemptions listed in 45CSR§6-3.1 are subject to the following stipulation: Upon notification by the Secretary, no person shall cause, suffer, allow or permit any form of open burning during existing or predicted periods of atmospheric stagnation. Notification shall be made by such means as the Secretary may deem necessary and feasible.
[45CSR§6-3.2.]
- 3.1.3. **Asbestos.** The permittee is responsible for thoroughly inspecting the facility, or part of the facility, prior to commencement of demolition or renovation for the presence of asbestos and complying with 40 C.F.R. § 61.145, 40 C.F.R. § 61.148, and 40 C.F.R. § 61.150. The permittee, owner, or operator must notify the Secretary at least ten (10) working days prior to the commencement of any asbestos removal on the forms prescribed by the Secretary if the permittee is subject to the notification requirements of 40 C.F.R. § 61.145(b)(3)(i). The USEPA, the Division of Waste Management, and the Bureau for Public Health - Environmental Health require a copy of this notice to be sent to them.
[40CFR§61.145(b) and 45CSR§34]
- 3.1.4. **Odor.** No person shall cause, suffer, allow or permit the discharge of air pollutants which cause or contribute to an objectionable odor at any location occupied by the public.
[45CSR§4-3.1] *[State Enforceable Only]*
- 3.1.5. **Permanent shutdown.** A source which has not operated at least 500 hours in one 12-month period within the previous five (5) year time period may be considered permanently shutdown, unless such source can provide to the Secretary, with reasonable specificity, information to the contrary. All permits may be modified or revoked and/or reapplication or application for new permits may be required for any source determined to be permanently shutdown.
[45CSR§13-10.5.]
- 3.1.6. **Standby plan for reducing emissions.** When requested by the Secretary, the permittee shall prepare standby plans for reducing the emissions of air pollutants in accordance with the objectives set forth in Tables I, II, and III of 45CSR11.
[45CSR§11-5.2.]

3.2. Monitoring Requirements

[Reserved]

3.3. Testing Requirements

- 3.3.1. **Stack testing.** As per provisions set forth in this permit or as otherwise required by the Secretary, in accordance with the West Virginia Code, underlying regulations, permits and orders, the permittee shall conduct test(s) to determine compliance with the emission limitations set forth in this permit and/or established or set forth in underlying documents. The Secretary, or his duly authorized representative, may at his option witness or conduct such test(s). Should the Secretary

exercise his option to conduct such test(s), the operator shall provide all necessary sampling connections and sampling ports to be located in such manner as the Secretary may require, power for test equipment and the required safety equipment, such as scaffolding, railings and ladders, to comply with generally accepted good safety practices. Such tests shall be conducted in accordance with the methods and procedures set forth in this permit or as otherwise approved or specified by the Secretary in accordance with the following:

- a. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with 40 C.F.R. Parts 60, 61, and 63 in accordance with the Secretary's delegated authority and any established equivalency determination methods which are applicable. If a testing method is specified or approved which effectively replaces a test method specified in the permit, the permit may be revised in accordance with 45CSR§13-4. or 45CSR§13-5.4 as applicable.
- b. The Secretary may on a source-specific basis approve or specify additional testing or alternative testing to the test methods specified in the permit for demonstrating compliance with applicable requirements which do not involve federal delegation. In specifying or approving such alternative testing to the test methods, the Secretary, to the extent possible, shall utilize the same equivalency criteria as would be used in approving such changes under Section 3.3.1.a. of this permit. If a testing method is specified or approved which effectively replaces a test method specified in the permit, the permit may be revised in accordance with 45CSR§13-4. or 45CSR§13-5.4 as applicable.
- c. All periodic tests to determine mass emission limits from or air pollutant concentrations in discharge stacks and such other tests as specified in this permit shall be conducted in accordance with an approved test protocol. Unless previously approved, such protocols shall be submitted to the Secretary in writing at least thirty (30) days prior to any testing and shall contain the information set forth by the Secretary. In addition, the permittee shall notify the Secretary at least fifteen (15) days prior to any testing so the Secretary may have the opportunity to observe such tests. This notification shall include the actual date and time during which the test will be conducted and, if appropriate, verification that the tests will fully conform to a referenced protocol previously approved by the Secretary.
- d. The permittee shall submit a report of the results of the stack test within sixty (60) days of completion of the test. The test report shall provide the information necessary to document the objectives of the test and to determine whether proper procedures were used to accomplish these objectives. The report shall include the following: the certification described in paragraph 3.5.1.; a statement of compliance status, also signed by a responsible official; and, a summary of conditions which form the basis for the compliance status evaluation. The summary of conditions shall include the following:
 1. The permit or rule evaluated, with the citation number and language;
 2. The result of the test for each permit or rule condition; and,
 3. A statement of compliance or noncompliance with each permit or rule condition.

[WV Code § 22-5-4(a)(14-15) and 45CSR13]

3.4. Recordkeeping Requirements

- 3.4.1. **Retention of records.** The permittee shall maintain records of all information (including monitoring data, support information, reports, and notifications) required by this permit recorded

in a form suitable and readily available for expeditious inspection and review. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation. The files shall be maintained for at least five (5) years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent two (2) years of data shall be maintained on site. The remaining three (3) years of data may be maintained off site, but must remain accessible within a reasonable time. Where appropriate, the permittee may maintain records electronically (on a computer, on computer floppy disks, CDs, DVDs, or magnetic tape disks), on microfilm, or on microfiche.

- 3.4.2. **Odors.** For the purposes of 45CSR4, the permittee shall maintain a record of all odor complaints received, any investigation performed in response to such a complaint, and any responsive action(s) taken.

[45CSR§4. *State Enforceable Only.*]

3.5. Reporting Requirements

- 3.5.1. **Responsible official.** Any application form, report, or compliance certification required by this permit to be submitted to the DAQ and/or USEPA shall contain a certification by the responsible official that states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- 3.5.2. **Confidential information.** A permittee may request confidential treatment for the submission of reporting required by this permit pursuant to the limitations and procedures of W.Va. Code § 22-5-10 and 45CSR31.
- 3.5.3. **Correspondence.** All notices, requests, demands, submissions and other communications required or permitted to be made to the Secretary of DEP and/or USEPA shall be made in writing and shall be deemed to have been duly given when delivered by hand, or mailed first class with postage prepaid to the address(es) set forth below or to such other person or address as the Secretary of the Department of Environmental Protection may designate:

If to the DAQ:

~~Director~~
~~Drector~~
WVDEP
Division of Air Quality
601 57th Street
Charleston, WV 25304-2345

If to the US EPA:

Associate Director
Office of Air Enforcement and Permits
Review/Compliance Assistance
(3AP123AP20)
U.S. Environmental Protection Agency
Region III
1650 Arch Street
Philadelphia, PA 19103-2029

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3.5.4. Operating Fee

- 3.5.4.1. In accordance with 45CSR22 – Air Quality Management Fee Program, the permittee shall not operate nor cause to operate the permitted facility or other associated facilities on the same or contiguous sites comprising the plant without first obtaining and having in current effect a Certificate to Operate (CTO). Such Certificate to Operate (CTO) shall be renewed annually, shall be maintained on the premises for which the certificate has been issued, and shall be made immediately available for inspection by the Secretary or his/her duly authorized representative.

- 3.5.5. **Emission inventory.** At such time(s) as the Secretary may designate, the permittee herein shall prepare and submit an emission inventory for the previous year, addressing the emissions from the facility and/or process(es) authorized herein, in accordance with the emission inventory submittal requirements of the Division of Air Quality. After the initial submittal, the Secretary may, based upon the type and quantity of the pollutants emitted, establish a frequency other than on an annual basis.

4.0. Source-Specific Requirements

4.1. Limitations and Standards

4.1.1. ~~Ethylene Oxide Sterilizer [1S]Emergency generators S01 thru S04 (Emission Point IDs: E01 thru E04) shall adhere to the following operating limits:~~

- ~~a. Ethylene oxide usage combust only natural gas and shall not exceed a maximum of 3.2 pounds per sterilization cycle performed.~~
- ~~b. The maximum number of sterilization cycles performed shall not exceed three (3) cycles per 24 hour day or 1,095 cycles per year.~~
- ~~c. Emissions released from the sterilization chamber shall be vented to DEOXX Scrubber [1C] or DEOXX Scrubber [2C].~~

~~4.1.2. Ethylene Oxide Sterilizer [2S] shall adhere to the following operating limits:~~

- ~~a. Ethylene oxide usage shall not exceed a maximum of 3.2 pounds per sterilization cycle performed.~~
- ~~b. The maximum number of sterilization cycles performed shall not exceed three (3) cycles per 24 hour day or 1,095 cycles per year.~~
- ~~c. Emissions released from the sterilization chamber shall be vented to DEOXX Scrubber [1C] or DEOXX Scrubber [2C].~~

~~4.1.3. Ethylene Oxide Sterilizer [3S] shall adhere to the following operating limits:~~

- ~~a. Ethylene oxide usage shall not exceed a maximum of 12 pounds per sterilization cycle performed.~~
- ~~b. The maximum number of sterilization cycles performed shall not exceed three (3) cycles per 24 hour day or 1,095 cycles per year.~~
- ~~c. Emissions released from the sterilization chamber shall be vented to DEOXX Scrubber [2C].~~

~~4.1.4. DEOXX Scrubbers [1C] and [2C] shall be operated and maintained so to provide a minimum guaranteed ethylene oxide emissions reduction rate of 99% or greater.~~

~~4.1.5. Emission point [1E] shall be limited to a maximum hourly ethylene oxide emission rate of 0.07 pounds per hour rates.~~

~~4.1.6. Emission point [2E] shall be limited to a maximum hourly ethylene oxide emission rate of 0.19 pounds per hour.~~

~~4.1.7. Emission points [1E] and [2E] shall be limited to a maximum total combined annual ethylene oxide emission rate of 201.48 pounds per year.~~

~~4.1.8. The permitted facility shall comply with all applicable requirements of 40CFR63, Subpart O, provided however, that compliance with any more stringent requirements set forth in Section 4.0 of this permit shall also be demonstrated. The pertinent section establishing the operating limits and standards associated with the operation of an ethylene oxide sterilization facility are as follows:~~

40CFR63.362

(a) Each owner or operator of a source subject to the provisions of this Subpart shall comply with these requirements on or after the compliance date specified in 40CFR63.360(g). The standards of this sections are summarized in Table 4.1.8.a. of this permit.

Table 4.1.8.a. Standards for Ethylene Oxide Commercial Sterilization and Fumigators

Existing and new sources Emergency Generator	Source Type		Sterilization chamber vent	NOx	Aeration room vent	VOC	Chamber exhaust vent	
	lb/hr	≥ 1 ton and < 10 tons/yr (1)	99% emissions reduction (see 40CFR63.362(e))	No control	ton/yr (1)	No control	lb/hr	ton/yr (1)
S01 (E01)	0.13	0.03	1.72	0.43	--	--	--	--
S02 (E02)	0.25	0.06	3.20	0.80	--	--	--	--
S03 (E03)	5.54	1.39	5.01	1.25	0.24	0.06	--	--
S04 (E04)	0.23	0.06	2.99	0.75	--	--	--	--

(1) Based on operating 500 hr/yr.

(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 start-up, shutdown, or malfunction.

(e) Sterilization chamber vent at sources using 1 ton. 4.1.2. Boilers S06 thru S09 (Emission Point IDs: E06 thru E09) shall combust only natural gas and shall not exceed a maximum heat input per boiler of 2.0 MMBtu/hr.

4.1.3. Boiler S10 (Emission Point ID: E10) shall combust only natural gas and shall not exceed a maximum heat input of 1.3 MMBtu/hr.

4.1.4. Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to of the atmosphere by at least 99 percent from each sterilization vent boilers (S06 thru S09; and S10).

4.1.9. Maximum emissions from emergency generator engine (4S) shall not exceed the following limit emission rates:

Source ID	Emission Source	Pollutant	Maximum Hourly Emissions (lb/hr) Each Boiler S06 thru S09 (E06 thru E09)	Maximum Emissions (tpy)

4S	Caterpillar or Emergency Generator	Nitrogen Oxide /yr ⁽¹⁾	4.8 lb/hr
		Carbon Monoxide	0.48
			0.13

(1) Based on operating 8,760 hr/yr.

4.1.4.1.5. No person shall cause, suffer, allow or permit emission of smoke and/or particulate matter into the open air from any fuel burning unit which is greater than ten (10) percent opacity based on a six minute block average. [45CSR2-3.1] (E06 thru E10)

4.1.6. No person shall cause, suffer, allow or permit the discharge of particulate matter into the open air from all fuel burning units located at one plant, measure in terms of pounds per hour in excess of the amount determined as follows:

For Type 'b' fuel burning units, the product of 0.09 and the total design heat inputs for such units in million B.T.U.'s per hour, provided however that no more than six hundred (600) pounds per hour of particulate matter shall be discharged into the open air from all such units;

[45CSR2-4.1 and 45CSR2-4.1.b.] (E06 thru E10)

4.1.7. Maximum emissions from emergency generator (S05) shall not exceed the following limits:

Source ID No.	Emission Source	Pollutant	Maximum Emissions	
			lb/hr	ton/yr ⁽¹⁾
S05	Caterpillar Emergency Generator	Nitrogen Oxides (NOx)	4.8	1.19
		Carbon Monoxide (CO)	0.48	0.12

(1) Based on operating 500 hr/yr.

4.1.8. Limit on ~~Combustion Fuels~~ #2 Fuel Oil. Emergency generator engine 4S is S05 shall be limited to combusting #2 fuel oil at the following maximum amounts of #2 Fuel Oil rates: 32 gallons/gal/hr and 15,950 hours/year/gal/yr to meet the emission limits in 4.1.7.

4.1.9.

~~4.1.11.~~ **Emergency Engine Generator Engines Requirement.** To show compliance with the emission limits listed in ~~4.1.9.1 and 4.1.7,~~ emergency generator ~~engine 4S will engines S01 thru S05 shall each~~ be operated less than 500 hours per year based on a 12 month rolling total.

~~4.1.12.~~ **10. #2 Fuel Oil Requirements.** The #2 Fuel Oil combusted in ~~4SS05~~ must meet the requirements in 40 CFR 80.510(a) and 40 CFR 80.510(b).
[45CSR§60.4207]

~~4.1.13~~ **11. Manufacturer's Requirements.** Engine ~~4SS05~~ is required to be operated and maintained to the manufacturer's written instructions or procedures over the entire life of the engine. Alcon can only change those settings approved by the manufacturer for engine ~~4SS05~~.
[45CSR§60.4206 and 45CSR§60.4211]

~~4.1.14~~ **12. Operation and Maintenance of Air Pollution Control Equipment.** The permittee shall, to the extent practicable, install, maintain, and operate all pollution control equipment listed in Section 1.0 and associated monitoring equipment in a manner consistent with safety and good air pollution control practices for minimizing emissions, or comply with any more stringent limits set forth in this permit or as set forth by any State rule, Federal regulation, or alternative control plan approved by the Secretary.
[45CSR§13-5.11.]

4.2. Monitoring Requirements

~~4.2.1.~~ For the purpose of determining compliance with the ~~limitations and standards set forth in Section opacity limit of 45CSR2-3.1 (condition 4.1.5 of this permit),~~ the permittee shall ~~comply with the applicable~~ conduct visible emission checks and/or opacity monitoring requirements set forth in ~~40CFR63.364.~~

~~(a) Per 40CFR63.364(a)(1), the owner or operator of a source and recordkeeping for all emission sources/boilers subject to emissions standards in 40CFR63.362 shall comply with the monitoring requirements established in 40CFR63.8 of Subpart A of this part, according to the applicability in Table 1 of 40CFR63.360 the opacity limit.~~

~~(b) Per 40CFR63.364(a)(2), each owner or operator of an ethylene oxide sterilization facility subject to these emission 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 operations status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.~~

~~(c) For sterilization facilities complying with 40CFR63.363(b) or (d) through the use of an acid-water scrubber, the owner or operator shall measure and record once per week, the level of the scrubber liquor in the re-circulation 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.~~

The visible emission check shall determine the presence or absence of visible emissions. At a minimum, the observer must be trained and knowledgeable regarding the effects of background contrast, ambient lighting, observer position relative to lighting, wind, and the presence of uncombined water (condensing water vapor) on the visibility of emissions. This training may be obtained from written materials found in the References 1 and 2 from 40CFR Part 60, Appendix

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A, Method 22 or from the lecture portion of the 40CFR Part 60, Appendix A, Method 9 certification course.

Visible emission checks shall be conducted at least once per calendar month with a maximum of forty-five (45) days between consecutive readings. These checks shall be performed at each source (stack, transfer point, fugitive emission source, etc.) for a sufficient time interval, but no less than one (1) minute, to determine if any visible emissions are present. Visible emission checks shall be performed during periods of normal facility operation and appropriate weather conditions.

If visible emissions are present at a source(s) for three (3) consecutive monthly checks, the permittee shall conduct an opacity reading at that source(s) using the procedures and requirements of Method 9 (E06 thru E10) as soon as practicable, but within seventy-two (72) hours of the final visual emission check.

4.2.2. **Operation time.** To demonstrate compliance with 4.1.11, ~~a non-resettable hour meter will be installed before the startup of engine 4S and the 9;~~

~~- The hours of operation will~~shall be recorded for emergency generator engines S01 thru S04.

~~- A non-resettable hour meter shall be installed before the startup of emergency generator engine S05 and the hours of operation shall be recorded.~~

[45CSR§60.4209(a)]

4.3. Testing Requirements

~~4.3.1. For the purpose of demonstrating compliance with the limitations and standards set forth in Section 4.1. of this permit, the permittee shall comply with the applicable test methods and procedures set forth in 40CFR63.365.~~

~~4.3.1.a. Performance Testing. In accordance with 40CFR63.365(a), the owner or operator of a source subject to emission standards in 40CFR63.362 shall comply with the performance testing requirements in 40CFR63.7 of Subpart A of this part, according to the applicability in Table 1 of 40CFR63.360.~~

~~4.3.1.b. Efficiency of the sterilization chamber vent. Per 40CFR63.365(b), the following procedures shall be used to determine the efficiency of all types of control devices used to comply with 40CFR63.362(e), sterilization chamber vent standard.~~

~~4.3.1.c. Determination of baseline parameters for acid water scrubbers. The procedures in this paragraph shall be used to determine the monitored parameters established in 40CFR63.363(b), (d), or (e) for acid water scrubbers and to monitor the parameters as established in 40CFR63.364(b).~~

~~(1) Scrubbing 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.~~

[Reserved]

4.4. Recordkeeping Requirements

4.4.1. **Record of Monitoring.** The permittee shall keep records of monitoring information that include the following:

- a. The date, place as defined in this permit, and time of sampling or measurements;
- b. The date(s) analyses were performed;
- c. The company or entity that performed the analyses;
- d. The analytical techniques or methods used;
- e. The results of the analyses; and
- f. The operating conditions existing at the time of sampling or measurement.

4.4.2. **Record of Maintenance of Air Pollution Control Equipment.** For all pollution control equipment listed in Section 1.0, the permittee shall maintain accurate records of all required pollution control equipment inspection and/or preventative maintenance procedures.

4.4.3. **Record of Malfunctions of Air Pollution Control Equipment.** For all air pollution control equipment listed in Section 1.0, the permittee shall maintain records of the occurrence and duration of any malfunction or operational shutdown of the air pollution control equipment during which excess emissions occur. For each such case, the following information shall be recorded:

- a. The equipment involved.
- b. Steps taken to minimize emissions during the event.
- c. The duration of the event.
- d. The estimated increase in emissions during the event.

For each such case associated with an equipment malfunction, the additional information shall also be recorded:

- e. The cause of the malfunction.
- f. Steps taken to correct the malfunction.
- g. Any changes or modifications to equipment or procedures that would help prevent future recurrences of the malfunction.

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~~4.4.4. In accordance with the requirements set forth in 40CFR63.362, the permittee shall comply with the recordkeeping requirements in 40CFR63.10(b) and (c), according to the applicability in Table 1 of 40CFR63.360. 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 two (2) years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding three (3) years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable format including, but not limited to paper, microfilm, electronic, magnetic tape, or microfiche.~~

4.4.4. The permittee shall maintain records of all monitoring data required by Section 4.2.1, documenting the date and time of each visible emission check, the emission point or equipment/source identification number, the name or means of identification of the observer, the

results of the check(s), whether the visible emissions are normal for the process, and, if applicable, all corrective measures taken or planned. The permittee shall also record the general weather conditions (i.e. sunny, approximately 80°F, 6 - 10 mph NE wind) during the visual emission check(s). An example form is supplied as Appendix A. Should a visible emission observation be required to be performed per Method 9 (E06 thru E10), the data records of each observation shall be maintained per the requirements of Method 9 (E06 thru E10). For an emission unit out of service during the normal monthly evaluation, the record of observation may note "out of service" (O/S) or equivalent.

4.4.5. The permittee shall maintain records of emergency generator engine operating times as required by Section 4.2.2. These records shall be certified by the responsible official and maintained on site for a period of no less than five (5) years, and made available to the Director of the Division of Air Quality or his/her duly authorized representative upon request.

4.5. Reporting Requirements

[Reserved]

CERTIFICATION OF DATA ACCURACY

I, the undersigned, hereby certify that, based on information and belief formed after reasonable inquiry, all information contained in the attached _____, representing the period beginning _____ and ending _____, and any supporting documents appended hereto, is true, accurate, and complete.

Signature¹ _____
(please use blue ink) Responsible Official or Authorized Representative Date

Name & Title _____
(please print or type) Name Title

Telephone No. _____ Fax No. _____

- ¹ This form shall be signed by a "Responsible Official." "Responsible Official" means one of the following:
- a. For a corporation: The president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation, or a duly authorized representative of such person if the representative is responsible for the overall operation of one or more manufacturing, production, or operating facilities applying for or subject to a permit and either:
 - (i) the facilities employ more than 250 persons or have a gross annual sales or expenditures exceeding \$25 million (in second quarter 1980 dollars), or
 - (ii) the delegation of authority to such representative is approved in advance by the Director;
 - b. For a partnership or sole proprietorship: a general partner or the proprietor, respectively;
 - c. For a municipality, State, Federal, or other public entity: either a principal executive officer or ranking elected official. For the purposes of this part, a principal executive officer of a Federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., a Regional Administrator of U.S. EPA); or
 - d. The designated representative delegated with such authority and approved in advance by the Director.

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