west virginia department of environmental protection

Division of Air Quality
601 57th Street, SE
Charleston, WV 25304-2345
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Jim Justice, Governor
Austin Caperton, Cabinet Secretary
www.dep.wv.gov

January 30, 2017

Ms. Michelle Dixon
Plant Manager
Alcon Research, Ltd
6055 Kyle Lane
Huntington, WV 25702

Re: Alcon Research, Ltd
Advance Optic Device Center North
Permit No. R13-2820D
Plant ID No. 011-000201

Dear Ms. Dixon:

Your application for a permit as required by Section 5 of 45CSR13 - "Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Temporary Permit, General Permit, and Procedures for Evaluation" has been approved. The enclosed permit R13-2820D is hereby issued pursuant to Subsection 5.7 of 45CSR13. Please be aware of the notification requirements in the permit which pertain to commencement of construction, modification, or relocation activities; startup of operations; and suspension of operations.

The Source is not subject to 45CSR30.

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.

Should you have any questions or comments, please contact me at (304) 926-0499, extension 1214.

Edward S. Andrews, P.E.
Engineer

Enclosures

c. Michelle Dixon, Michelle.dixon@alcon.com
Chad Stutler, Chad.Stutler@alcon.com
Robbie Louden, Robbie.Louden@alcon.com

West Virginia Department of Environmental Protection

Jim Justice
Governor

Division of Air Quality

Austin Caperton
Cabinet Secretary

Permit to Modify

R13-2820D

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.
Advance Optic Device Center North
011-00201

William F. Durham
Director

Issued: January 30, 2017

This permit will supercede and replace Permit R13-2820C.

Facility Location:	2 Vision Lane Lesage, Cabell County, West Virginia 25537
Mailing Address:	Same as Above
Facility Description:	Optic Device Manufacturing Facility
NAICS Codes:	339113
UTM Coordinates:	388.03 km Easting • 4,270.07 km Northing • Zone 17
Permit Type:	Modification
Description of Change:	This action is for the installation of an additional sterilizing chamber with aeration room, a 7.0 MMBtu/hr gas-fired boiler and fire water pump.

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.

The Source is not subject to 45CSR30.

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1.0. Emission Units

Emission Unit ID	Emission Point ID	Emission Unit Description	Year Installed	Design Capacity	Control Device
1S	1E	EO Sterilization Chamber #1	2011	2 Cycles/day	EO Abator (1C)
2S	1E	EO Sterilization Chamber #2	2011	2 Cycles/day	EO Abator (1C)
7S	1E	EO Sterilization Chamber #3	2017	2 Cycles/day	EO Abator (1C)
10S	1E	Aeration Room #1	2011		EO Abator (1C)
11S	1E	Aeration Room #2	2011		EO Abator (1C)
12S	1E	Aeration Room #3	2011		EO Abator (1C)
13S	1E	Aeration Room #4	2017		EO Abator (1C)
3S	2E	Generator Set	2010	250 kW	None
4S	3E	Base Fuel Tank (Belly Tank for Generator)	2010	400 gallon	None
9S	7E	Firewater Pump	2010	110 Bhp	None
5S	4E	Natural Gas Fired Boiler	2010	7.0 MMBtu/hr	None
6S	5E	Natural Gas Fired Boiler	2010	7.0 MMBtu/hr	None
8S	6E	Natural Gas Fired Boiler	2012	7.0 MMBtu/hr	None

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
CBI	Confidential Business Information
CEM	Continuous Emission Monitor
CES	Certified Emission Statement
C.F.R. *or* CFR	Code of Federal Regulations
CO	Carbon Monoxide
C.S.R. *or* CSR	Codes of State Rules
DAQ	Division of Air Quality
DEP	Department of Environmental Protection
dscm	Dry Standard Cubic Meter
FOIA	Freedom of Information Act
HAP	Hazardous Air Pollutant
HON	Hazardous Organic NESHAP
HP	Horsepower
lbs/hr	Pounds per Hour
LDAR	Leak Detection and Repair
M	Thousand
MACT	Maximum Achievable Control Technology
MDHI	Maximum Design Heat Input
MM	Million
MMBtu/hr *or* mmbtu/hr	Million British Thermal Units per Hour
MMCF/hr *or* mmcf/hr	Million Cubic Feet per Hour
NA	Not Applicable
NAAQS	National Ambient Air Quality Standards
NESHAPS	National Emissions Standards for Hazardous Air Pollutants
NO_X	Nitrogen Oxides
NSPS	New Source Performance Standards
PM	Particulate Matter
$PM_{2.5}$	Particulate Matter less than 2.5 µm in diameter
PM_{10}	Particulate Matter less than 10µm in diameter
Ppb	Pounds per Batch
Pph	Pounds per Hour
Ppm	Parts per Million
Ppm_V or ppmv	Parts per Million by Volume
PSD	Prevention of Significant Deterioration
Psi	Pounds per Square Inch
SIC	Standard Industrial Classification
SIP	State Implementation Plan
SO_2	Sulfur Dioxide
TAP	Toxic Air Pollutant
TPY	Tons per Year
TRS	Total Reduced Sulfur
TSP	Total Suspended Particulate
USEPA	United States Environmental Protection Agency
UTM	Universal Transverse Mercator
VEE	Visual Emissions Evaluation
VOC	Volatile Organic Compounds
VOL	Volatile Organic Liquids

2.3. Authority

This permit is issued in accordance with West Virginia Air Pollution Control Act 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 R13-2820C. This 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 R13-2820, R13-2820A, R13-2820B, R13-2820C, R13-2820D, 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; and

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

If to the US EPA:
Associate Director
Office of Air Enforcement and Compliance Assistance (3AP20)
U.S. Environmental Protection Agency
Region III
1650 Arch Street
Philadelphia, PA 19103-2029

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. The permittee shall employ no more than three ethylene oxidize sterilizing chambers (1S, 2S & 7S) at the facility. Such sterilizing shall be installed, operated, and maintained in accordance with the following operational and emission limitations:

a. Each chamber shall not be filled/charged with any more than 16.0 pounds of ethylene oxidized per normal production cycle.

b. Each chamber shall not be filled/charged with any more than 25.0 pounds of ethylene oxide per regulatory approval maximum parameter process cycle, cycle development cycles, special test cycles, or sensor calibration cycles.

c. The total amount of ethylene oxidized charged into these chambers shall not exceed more than 19,720 pounds per year.

d. During the sterilization operation, the entire ethylene oxidize stream from the chamber shall be vented to the EtO catalytic abator (1C).

e. Each aeration room shall be vented to EtO catalytic abator at all times when finished product is being degassed in the room.

f. The EtO catalytic abator (1C) shall be installed, operated, and maintained in such a manner that this control device shall have an ethylene oxidize reduction efficiency of no less than 99.0%. **[40CFR§§63.362(c)]**

g. Annual emissions of ethylene oxidize from emission point 1E shall not exceed 177.4 pounds per year.

h. The oxidation temperature of the abator (1C) shall not fall below 65^{0}C (149^{0}F) or the minimum oxidation temperature recommended by the abator manufacturer, while the abator is in operation.
[40CFR§§63.363(3)]

i. The catalyst bed in the abator shall be replaced with new catalyst material once every five (5) years, beginning five (5) years after the initial compliance test as required in 4.3.1. of this permit.
[40CFR§§63.363(4)(iii)]

4.1.2. The following conditions and requirements are specific to the internal combustion engines for the emergency generator set identified as 3S and the firewater pump identified as 9S:

a. The generator set and firewater pump shall be equipped with an engine or engine configuration that has been certified by the manufacturer to comply or conform with either 40 CFR §60.4205(b)(2), which referred to 40 CFR §§89.111 and 112 or 40 CFR Part 60.
[40 CFR §§60.4211(a)(3) and (c)()]

b. There is no time limit on the use of each engine in emergency situations. Each engine can operate for combined non-emergency purposes, which include emergency demand response, maintenance and testing, and other non-emergency use for a maximum of 100 hours per year. Within the 100 hours per year, the engine can only operate:

i. For periods of emergency demand response. Emergency demand response is determined by the Reliability Coordinator under the North American Electric Reliability Corporation (NERC) Reliability Standard EOP-002-3 or other authorized entity as determined by the Reliability Coordinator; and
[40 CFR §60.4211(f)(2)(ii)]

ii. 50 hours per year for non-emergency use. The non-emergency situations cannot be used for peak shaving or to generate income for the facility to supply power to an electric gird or otherwise supply power as part of a financial arrangement with another entity.
[40 CFR §60.4211(f)(3)]

c. The operating limits imposed in this condition are on a calendar year basis.
[40 CFR §60.4211(f)]

d. Each engine shall be equipped with a non-resettable hour-meter prior to start-up.
[40 CFR §60.4237(a)]

e. Each engine shall be operated and maintained in accordance with the manufacturer's written instructions. The permittee is only authorized to change only those emission-related settings that are permitted by the engine manufacturer. A copy of such instruction shall be permanently maintained on site for the life of the engine.
[40 CFR 60.4211(a)(1) and (a)(2)]

f. engine shall only consume diesel fuel meeting following requirements:

i. Maximum sulfur content of 15 ppm;

ii. Cetane index or aromatic content as follows:

1. A minimum cetane index of 40; or

2. A minimum aromatic content of 35 % by volume.

[40CFR§§80.510(b)]

4.1.3. **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. The permittee shall continuously monitor and record the oxidation temperature at the outlet of the catalyst bed using a temperature monitor. Such monitoring is required when the oxidation unit is in operation. 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.

This temperature monitor shall be install, calibrated, and maintained to be accurate to within $\pm$ 5.6^{0}C ($\pm$ 10^{0}F) to measure the oxidation temperature. The permittee shall verify the accuracy of the 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 this 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). Records the temperature data, computed daily average oxidation temperature, verification of accuracy checking, and documentation of any maintenance preformed on the monitor shall be maintained in accordance with Condition 3.4.1. of this permit.
[40CFR§§63.364(c), (c)(4) and 367(a)]

4.2.2. For the purposes of demonstrating compliance with the hours of operation limits in condition 4.1.2.c. and 4.1.2.d., the permittee shall record the time, date, length of operation and note the reason each engine operated. Such records shall be maintained in accordance with 3.4.1. of this permit.

4.3. Testing Requirements

4.3.1. After sixty (60) days after start-up of normal production cycles of the sterilizing chamber #3 (7S), the permittee shall conduct an initial compliance demonstration to determine compliance with the reduction efficiency requirement of Condition 4.1.1.d. of this permit. Such demonstration shall be conducted in accordance with the either the California Air Resources Board (CARB) Method 431 or the following procedures to determine the efficiency of the EtO catalytic abator (1C) used to comply with Condition 4.1.1.e. and 40CFR§63.362(c), sterilization chamber vent standard:

a. 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:

1. 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; or

2. 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 the ethylene oxide charged, g (lb)

F_v = volumetric flow rate, liter per minute (L/min) corrected to 20^{0}C and 101.325 kilopascals (kPa) (scf per minute (scfm) corrected to 68^{0}F and 1 atmosphere of pressure (atm); the flow rate must be constant during time (t)

t = time, min

$\%EO_v$ = volume fraction ethylene oxide

SV = standard volume, 24.05 liter per mole (L/mole) = 22.414 L/mole ideal gas law constant corrected to 20^{0}C and 101.325 kPa (385.32 scf per mole (scf/mole) = scf/mole ideal gas low constant corrected to 68^{0}F and 1 atm).

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

3. 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, litter (L) (ft^3)

R = gas constant, 8.313 L · kPa/g-mole · (10.73 psia · ft^3/mole^{0}R)

T = temperature, K (^{0}R)

Note: if the ethylene oxide concentration is in weight percent, use the following 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) as calculated in paragraph (a)(i)(3) of this section from the charged weight (W_c) calculated in paragraph (a)(i)(2) 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:

1. 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.

2. 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.

   a. 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.

   b. 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:

W_o = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide om ppmv

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

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

v. Calculate the efficiency by 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 (a)(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.

vii. Such testing shall be conducted in accordance with Condition 3.3.1. of this permit.

viii. During such testing, records of the oxidation temperature recorded during each of the test runs shall be included as part of the test report.

ix. Records of this testing shall be maintained in accordance with Condition 3.4.1 o this permit.

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.

4.4.4. The permittee shall monitor and recorders the amount of ethylene oxide used at the facility on a monthly basis and compute the facility's 12 month rolling average use of ethylene oxide. Such records shall be maintained in accordance with Condition 3.4.1. of this permit.
[40CFR§63.367(b)]

4.4.5. The permittee shall maintain on site documents noting that the engine for the generator set (3S) and Firewater Pump (9S) are certified in accordance with 40 CFR Part 89 for the same model year or the engine conform to the requirements of 40 CFR Part 60. Such records maintain on site for the life of the corresponding engine.

4.5. Reporting Requirements

4.5.1. The permittee shall submit an excess emissions and continuous monitoring system performance and summary report to the Director and the U.S. EPA Administrator for the reporting period of January 1 through June 30 and July 1 through December 31. Such reports shall be delivered or postmarked by the 30th day following the end of the reporting period. This report shall contain the following:

a. If any, deviation of the operating limit defined in Condition 4.1.1.g. of this permit (40CFR§§63.363(3)). This requires the following information to be submitted with the report:

i. The date and time identifying each period during which the CMS was inoperative except for zero (low-level) and high-level checks;

ii. The specific identification (i.e., the date and time of commencement and completion) of each time period of excess emissions and parameter monitoring exceedances, as defined in the relevant standard(s), that occurs during periods other than startups, shutdowns, and malfunctions of the affected source;

iii. The nature and cause of any malfunction (if known);

iv. The corrective action taken or preventive measures adopted;

v. The nature of the repairs or adjustments to the CMS that was inoperative or out of control;

vi. The total process operating time during the reporting period;

vii. Information of the method used during the verification check of the temperature monitor that was conducted during this reporting period (calibration test reports).

b. If no deviations occurred or monitoring equipment has not been inoperative, repaired, or adjusted during the reporting period, then such information shall be stated in the report.

c. The report shall include the name, title, and signature of the responsible official who is certifying the accuracy of the report.

[40CFR§§63.366(a)(3) and 63.10(c)(5), (8), (10-13)]

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.

Signature[1] (please use blue ink) _____ Responsible Official or Authorized Representative _____ Date

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

Telephone No. _____ Fax No. _____

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[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.