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ENGINEERING EVALUATION / FACT SHEET

BACKGROUND INFORMATION

Application No.:	R13-2820D
Plant ID No.:	011-00201
Applicant:	ALCON Research, Ltd.
Facility Name:	ALCON – Advanced Optic Device Center North
Location:	Lesage
NAICS Code:	339113
Application Type:	Modification
Received Date:	October 17, 2016
Engineer Assigned:	Edward S. Andrews, P.E.
Fee Amount:	$4,500.00
Date Received:	October 17, 2016
Completeness Date:	December 2, 2016
Due Date:	March 30, 2017
Newspaper:	*The Herald-Dispatch*
Applicant Ad Date:	October 19, 2016
UTMs:	Easting: 388.0 km Northing: 4,270.1 km Zone: 17
Description:	This action is for the installation of a third sterilizer chamber, one gas-fired boiler, and one firewater pump.

DESCRIPTION OF PROCESS

ALCON Research, Ltd. manufactures optic devices at their Kyle Lane location. Due to site limitations, ALCON has located their packaging and sterilizing operation at One Vision Lane in Lesage, WV, which is just north of their Kyle Lane location. There are no emission sources associated with ALCON manufacturing process except for sterilizing the finished optic devices. ALCON uses an ethylene oxide sterilizer to sterilize the finished product.

At the Advanced Optic Device Center North, ALCON operates two sterilization chambers (1S & 2S). These chambers will be capable of performing two complete cycles per day per chamber. A result of emission control requirements of 40CFR63 Subpart O, these chambers will be vented to a catalytic oxidizer. During the controlled sterilization cycles, six chamber purges (three with nitrogen and three with air) are performed. During these purges, the ethylene oxide gas is exhausted out of the sterilization chamber and piped to the Lesni Catalytic Abatement device, which oxidizes the ethylene oxide to less than 1 ppm.

Once the sterilization cycle is complete, the packaged lenses are removed from the chamber and placed inside one of three aeration rooms to allow for any residual ethylene oxide to be released from the packaged lenses. The sterilizer chamber is in a sealed room with a corresponding aeration room located next to the sterilizer chamber room. An automated transfer system is used to remove the lenses from the chamber and place them in the aeration room.

The Advanced Optic Device Center North has a 250-kW generator and 2 – 7 MMBTU/hr natural gas fired boilers. The generator is used to provide emergency electrical power to the facility whenever there is a disruption of electrical service provided by the local utility company. This generator set is a Caterpillar C9E01717 driven by a 400 hp diesel engine. To condition the indoor air, two – 7 MMBTU boilers are used.

Under Permit R13-2820C, Alcon limits the sterilization operation to only consume 19,720 pounds of ethylene oxide per year. This limit allows Alcon to exclude the aeration rooms as affected sources from Subpart O of Part 63. Alcon intends to continue to operate the facility under this ethylene oxide utilization limit.

For this modification application, Alcon has elected to address emission sources that were installed but not included in any previous applications, which are a firewater pump rated at 110 horsepower and a third 7.0 MMBtu/hr gas fired boiler. In addition, Alcon has proposed to install a third EtO sterilizing chamber with a corresponding aeration room.

SITE INSPECTION

November 2, 2016, the writer conducted a site visit of the facility. Ms. Robbie Louden, Health, Safety & Environmental Specialist, accompanied the writer during this visit. This visit included an in-depth explanation of the sterilization process and associated control device with a walk through of the facility. The additional third boiler and firewater pump are in place and operating at the facility and are being included in this application. Alcon's intends to locate the additional chamber and aeration room next to the other existing chambers, which will be within the footprint of the current building. The writer determined that the location is acceptable for this emission unit.

ESTIMATE OF EMISSIONS BY REVIEWING ENGINEER

The writer estimated the carbon monoxide, oxides of nitrogen and VOC emissions from boilers using factors published by the boiler manufacturer. The hourly and annual estimates provided in the table below are for a single 7.0 MMBTU/hr boiler operating 8,760 hours per year.

Table No. 1 – Emissions from One 7.0 MMBtu/hr Boiler using Natural Gas

Pollutant	Emission Factor	Hourly Rate (lb/hr)	Annual Rate (tpy)
PM Filterable/Condensable Fractions	0.0072 lb/MMBtu	0.05	0.22
PM_{10} Filterable/Condensable Fractions	0.0072 lb/MMBtu	0.05	0.22
$PM_{2.5}$ Filterable/Condensable Fractions	0.0072 lb/MMBtu	0.05	0.22
Sulfur Dioxide (SO_2)	0.0006 lb/MMBtu	0.004	0.02
Oxides of Nitrogen (NO_x)	0.093 lb/MMBtu	0.65	2.85
Carbon Monoxide (CO)	0.078 MMBtu	0.55	2.41
Volatile Organic Compounds (VOCs)	0.005 lb/MMBtu	0.04	0.18

Total Hazardous Air Pollutants (HAPs)	0.002 lb/MMBtu	0.01	0.04
Carbon Dioxide Equivalent* (CO_2e)	117.098 lb/MMBtu	819.69	3,590.24

ALCON has elected to only operate the firewater pump to a maximum of 500 hours per year. This requested limit as well as consumed diesel with a maximum sulfur content of 15 ppm were taken into consideration when determining emissions from this firewater pump. Emission estimated for this specific generator set were based on actual performance tests of an identical model engine. Sulfur dioxide emission estimates was based on AP-42 factors that considered the sulfur content of the fuel being consumed. Presented in the following table is a summary of these emission estimates from the engine for the firewater pump.

Table #2 – Emissions from the Firewater Pump Engine

Pollutant	Hourly Rate (lb/hr)	Annual Rate (tpy)
$PM/PM_{10}/PM_{2.5}$	0.073	0.02
SO_2	0.08	0.02
NO_x	1.47	0.37
CO	0.21	0.05
VOCs	0.04	0.01
Total HAPs	0.02	0.02
CO_2e	84.99	21.25

The additional sterilization chamber and corresponding aeration room were proposed in the application to be vented to the existing Leni EtO Abator system with no increase in ethylene oxide usage at the facility. Thus, ALCON proposes no change in the permitted emissions from the EtO Abator.

There is a potential for hourly emissions from the EtO Abator because there is going to be additional source venting to the control device. However, this abator uses a water balancer

(water scrubber) to absorb a slug of ethylene oxide from the chambers during their ethylene oxide purge cycles. Then the scrubber slowly (regulates) the release of ethylene oxide from the water which is sent to the catalytic oxidizer to be destroyed. An ethylene oxide monitor is located in the duct downstream of the balancer to measure the concentration of ethylene oxide being sent to the catalytic oxidizer.

The closed vent system employed at this facility to route the effluent from the sterilizer chambers and aeration room is operated under negative pressure by using vacuums pump. The fugitive from the vacuum pumps are the pump seals. These particular pumps that are used in this vent system are using water seals for the vacuum pumps with the water being routine back to the water balancer which will confined any leakage from the seals back to the EtO Abator. Thus, there is no potential for fugitive emissions from leaks of the closed vent system. In additional to this design, ALCON monitors the indoor air for ethylene oxide where this vent system is located, which includes the outer rooms where the sterilizers and aeration rooms are located within and the location of the EtO Abator.

Presented in the following table is a summary of the facility's total potential to emit:

Table #3 – Summary of Emissions Changes

Pollutant	Change in Hourly Rate (lb/hr)	Change in Annual Rate (tpy)	Facility New Annual Emission Rate (tpy)
$PM/PM_{10}/PM_{2.5}$	0.12	0.24	0.70
SO_2	0.08	0.04	0.20
NO_x	2.12	3.22	6.77
CO	0.76	2.46	14.46
VOCs	0.18	0.19	6.44
Total HAPs	0.03	0.06	0.15
CO_2e	904.59	3,611.49	10,791.25

REGULATORY APPLICABILITY

The proposed new emissions units at this facility will be subject to 45CSR2, 45CSR6, and 45CSR7. The manufacturing process at this facility does not have the potential to emit particulate matter. Therefore, the manufacturing process is exempt from the process weight standard pursuant under 45CSR§7-10.5. The manufacturing process would be subject to the visible emission standard. However, the nature of ALCON's process results in no visible emissions being emitted from the facility.

The catalytic abator does destroy or breaks down ethylene oxide into water vapor and carbon dioxide. This abator is an incinerator and is subject to the emission standard under 45CSR6. By design, this abator does not have any particulate matter just only water, carbon dioxide, trace amounts of unconverted EtO and other products of combustion (i.e. CO, NO_x). Thus, this control device will meet the particulate matter limit under this rule.

Because the modified facility will operate three sterilizers at a non-medical treatment facility, these sterilizers are subject to 40CFR63 Subpart O. ALCON plans to continue to use no more than 19,720 pounds of ethylene oxide per year. Under this subpart, the proposed facility is classified as an area source of hazardous air pollutants (HAPs) and subject to the area source provisions for sterilizers under Subpart O.

This subpart requires area source operators of EtO sterilizers that use more than one ton of EtO per year but less than 10 tons to reduce the amount of EtO emitted by 99%. To meet this emission reduction requirement, ALCON has proposed to use a catalytic abator (catalytic oxidizer). During the initial compliance demonstration, ALCON that the EtO ab abator has a destruction efficiency of 99.999% on September 22, 2012.

Regarding other requirements under Subpart O, ALCON has proposed to continuously monitoring the outlet temperature from the catalyst bed to ensure the vent stream is not falling below the minimum oxidization temperature. To comply with the work practice requirements,

ALCON has elected to replace the catalyst every five years beginning after the initial performance test, which is currently scheduled for June of 2017 to meet this requirement.

The proposed firewater pump set is driven by a compression ignition, internal combustion engine, which was manufactured after 2007. Therefore, this engine is subject to this subpart as defined in 40CFR§§60.4200(2) (Subpart IIII). The displacement of the engine is 1.13 liters per cylinder. This engine is subject to the emission standard of 40 CFR §§60.4205(b), which refers to §§60.4202(a)(2). §§60.4202(a)(2) refers to §§89.112. ALCON provided documentation from John Deere, the engine manufacturer, noting that this model engine conforms to the requirements of 40 CFR Part 60.

The applicant will be required to equip the engine with a non- resettable hour meter and sets strict fuel specifications on the type of diesel fuel to be used in this engine, which is ultra-low sulfur diesel.

Subpart IIII of Part 60 and Subpart O of Part 63 does not required ALCON to obtain an operating permit under Part 70 or 71 by being subject to either one of these regulations. This facility will remain to be classified as a minor source and not subject to 45CSR30, which West Virginia's operating permit program pursuant under Part 70. Therefore, this facility is subject to 45CSR22 and classified as a "9M" source.

TOXICITY OF NON-CRITERIA REGULATED POLLUTANTS

The new emission units will not emit any pollutants that aren't already being emitted by another emission source at the facility. Therefore, no information about the toxicity of the hazardous air pollutants (HAPs) is presented in this evaluation.

AIR QUALITY IMPACTS ANALYSIS

The writer deemed that an air dispersion modeling study or analysis was not necessary, because the proposed construction does not meet the definition as a major source as defined in 45CSR14.

MONITORING OF OPERATIONS

The writer recommends no additional monitoring than what is already required by the permit, which is summarized in the following list:

- Tracking ethylene oxide usage;
- Continuously monitoring the outlet temperature of the catalysis bed;
- Recording the hours of operation for the generator set and firewater pump and reason for such operation; and
- Replacing the catalyst bed once every five years.

The new boiler and existing boilers are less than 10 MMBtu/hr and are configured to only operate on natural gas. Rule 2 excludes these units from the Sections 4-6 and 8-9 of 45 CSR 2, which includes the section on testing, monitoring recordkeeping, and reporting for boilers. This writer does not recommend any monitoring for these boilers based on the design heat input and type of fuel being consumed.

The writer has recommended that a compliance demonstration be conducted as result adding this third sterilizer to the EtO Abator. However, this sterilizer with be required to be certified by the Federal Drug Administration (FDA). Part of this certification process will require the chamber to be operated at specific ethylene oxide loading rates to sterilize certain lenses to ensure that the chamber will sterilize the lenses to meets the FDA standards for medical devices, which would not be representative the normal operating cycles. Thus, the writer

recommends requiring within 60 days after starting normal operating cycles of the third sterilizer.

RECOMMENDATION TO DIRECTOR

The information provided in permit application R13-2820D indicate that compliance with all applicable state rules and federal regulations will be achieved. Therefore, this writer recommends to the Director a modification permit should be issued to ALCON Research, Ltd. for the proposed changes at the Advanced Optic Device Center North Plant in Lesage, WV.

Edward S. Andrews, P.E.
Engineer

Date: December 22, 2016