



**TECHNICAL REVIEW AND EVALUATION
OF APPLICATION FOR
AIR QUALITY PERMIT NO. 66030
Centurion Medical Products**

I. INTRODUCTION

This Class II air quality control renewal permit is issued to Centurion Medical Products Corporation, the Permittee, for the continued operation of their ethylene oxide (EO) sterilization facility located at 3173 East 43rd Street, Yuma, Arizona.

A. Company Information

1. Facility Name: Centurion Medical Products
2. Facility Location: 3173 East 43rd Street
Yuma, AZ
3. Mailing Address: 100 Centurion Way
Williamston, MI 48895

B. Attainment Classification

The facility is located in an area which is designated non-attainment for PM₁₀, and attainment/unclassifiable for all other criteria pollutants.

II. PROCESS DESCRIPTION

A. Process Description

Centurion Medical Products manufactures custom medical procedure kits. The manufacturing process includes assembly and packaging of these kits to customer specification; many of these kits are sterilized by exposure to Ethylene Oxide (referred to as EO). The facility is subject to NESHAP standard 40 CFR Part 63, Subpart O -Ethylene Oxide Emission Standards for Sterilization Facilities.

The sterilization process consists of three basic stages; preconditioning, sterilization, and aeration. Preconditioning is a temperature and humidity controlled pre-process and is not subject to the permitting process. Sterilization is regulated by NESHAP Subpart O; specifically, the sterilization chamber vent (SCV) and the chamber exhaust vent (CEV). Aeration is a temperature controlled post-process and is regulated by Subpart O; specifically, the aeration room vent (ARV).

B. Control Devices

Ethylene oxide emissions are controlled by one natural gas-fired thermal oxidizer and three dry-bed scrubbers. Emissions from the SCV are controlled by the thermal oxidizer at a minimum EO destruction efficiency of 99 percent. EO emissions from the ARV are controlled by the dry-bed scrubbers operating at a minimum destruction efficiency of 99 percent or to a 24-hour average concentration of EO no greater than 1 ppmv.



III. EMISSIONS

Table 1: Potential Emissions

Pollutant	Emissions (tons per year)
PM₁₀ = PM_{2.5}	0.03
NO_x	0.35
CO	0.29
SO₂	0.002
VOC	0.02
HAPs	0.43

IV. MINOR NEW SOURCE REVIEW

There are no changes to emissions for this renewal permit, thus no review of minor NSR is required.

V. APPLICABLE REGULATIONS

Table 2 displays the applicable requirements for each permitted piece of equipment along with an explanation of why the requirement is applicable.

Table 2: Verification of Applicable Regulations

Unit	Control Device	Rule	Discussion
Sterilization Chambers	Natural gas-fired thermal oxidizer	40 CFR 63 Subpart O	This standard applies to sources using at least one ton of ethylene oxide in any consecutive 12-month period.
Aeration Room	Dry-bed Scrubbers	40 CFR 63 Subpart O	This standard applies to sources using at least one ton of ethylene oxide in any consecutive 12-month period.
Fugitive dust sources	Water and other reasonable precautions	A.A.C. R18-2-Article 6 A.A.C. R18-2-702.B.1	These standards are applicable to all fugitive dust sources.
Mobile sources	None	A.A.C. R18-2-801	This standard is applicable to off-road mobile sources, which either move while emitting air pollutants or are frequently moved during the course of their utilization.



Unit	Control Device	Rule	Discussion
Abrasive Blasting	Wet blasting; Dust collecting equipment; Other approved methods	A.A.C. R-18-2-702.B.1 A.A.C. R-18-2-726	These standards are applicable to any abrasive blasting operation.
Spray Painting	Enclosures	A.A.C. R18-2-702.B.1 A.A.C. R-18-2-727	This standard is applicable to any spray painting operation.
Demolition and renovation operations	N/A	A.A.C. R18-2-1101.A.8	This standard is applicable to any asbestos related demolition or renovation operations.

VI. PREVIOUS PERMIT CONDITIONS

Permit No. 55431 was issued on February 8, 2013, for the continued operation of this facility. Table 3 below illustrates if a section in Permit No. 66030 was revised or deleted.

Table 3: Permit No. 66030

Section No.	Determination		Comments
	Revised	Delete	
Att. A.	X		General Provisions - Revised to represent most recent template language.
Att A. VII.A	X		Revised annual reporting period to match current permitting standards
Att. A. XII.B.	X		Revised reporting requirements for permit deviations other than excess emissions and upset conditions
Att. B	X		Throughout- revised to represent current template language and formatting (non-substantive changes unless listed below)
Att. B. II.D.2	X		Revised paragraph formatting of Conditions 2 and 3, with subsequent renumbering of following outline headings
Att. B. II.D.6.a	X		Added to clarify semi-annual summary report reporting periods

VII. MONITORING REQUIREMENTS

- A. The Permittee must continuously monitor and record the oxidation temperature at the exhaust point from the thermal combustion chamber using the temperature monitor. This is to ensure that the thermal oxidizer is being operated at a temperature above the required minimum oxidation temperature.
- B. The Permittee shall measure and record once per hour, the ethylene oxide concentration from the aeration room vent, before and after the dry-bed scrubbers using the gas chromatograph. The Permittee must compute and record a 24-hour average daily.
- C. Fugitive Dust sources

The Permittee is required to maintain records of the date on which any of the activities listed in Condition III.B.1.a.(3) in Attachment "B" of the permit were performed along



with the control measure that was adopted.

D. Mobile Sources

The Permittee is required to keep records of all emission related maintenance performed on the mobile sources.

E. Periodic Activities

1. The Permittee is required to record the date, duration and pollution control measures of any abrasive blasting project.
2. The Permittee is required to record the date, duration, and quantity of paint used, any applicable MSDS/SDS, and pollution control measures of any spray painting project.
3. The Permittee is required to maintain records of all asbestos related demolition or renovation projects. The required records include the “NESHAP Notification for Renovation and Demolition Activities” form and all supporting documents.

VIII. TESTING REQUIREMENTS

The Permittee must perform tests every two years on the thermal oxidizer and dry-bed scrubbers to show compliance with the applicable emission limits.

IX. COMPLIANCE HISTORY

There have been three facility inspections, two performance tests, eight compliance certification report reviews and one excess emission report for this facility during the term of the previous permit.

One case was opened as a result of the report of excess emission of ethylene oxide from the aeration room vent. The case was closed upon the source’s implementation of additional monitoring of the gas chromatograph data and establishment of an action level to replace dry-scrubber media when the ethylene oxide concentration reaches 0.8 ppmv.

No other cases or alleged violations appear to be associated with this facility or place identification number at this time

X. LIST OF ABBREVIATIONS

A.A.C.	Arizona Administrative Code
ADEQ	Arizona Department of Environmental Quality
A.R.S.	Arizona Revised Statutes
ARV	aeration room vent
CEMS	continuous emissions monitoring system
CEV	chamber exhaust vent
CFR	Code of Federal Regulations
CO	carbon monoxide
COMS	continuous opacity monitoring system
EO	ethylene oxide
EPA	Environmental Protection Agency



HAP(s)hazardous air pollutant
NAAQS..... National Ambient Air Quality Standard
NESHAP National Emission Standards for Hazardous Air Pollutants
NO_x nitrogen oxide
NSPS New Source Performance Standards
NSR..... New Source Review
Pblead
PM.....Particulate Matter with an aerodynamic diameter less than 100 microns
PM₁₀..... Particulate Matter with an aerodynamic diameter less than 10 microns
PM_{2.5}Particulate Matter with an aerodynamic diameter less than 2.5 microns
PSDPrevention of Significant Deterioration
PTE Potential-to-Emit
scfm..... standard cubic feet per minute
SCV..... sterilization chamber vent
SO₂..... sulfur dioxide
TPY.....tons per year
VOC volatile organic compound
yr year