



**TECHNICAL REVIEW AND EVALUATION
OF APPLICATION FOR
AIR QUALITY PERMIT NO. 63419**

I. INTRODUCTION

This permit is for the continued operation of W.L. Gore & Associates medical products manufacturing facility located in Flagstaff, Arizona. This permit renews and supersedes operating permit #52794.

Company Information

Facility Name: W.L. Gore & Associates, Inc.
Woody Mountain Campus

Mailing Address: 4100 West Kiltie Lane
Flagstaff, AZ 86001

Facility Location: 3250, 3450, 3650, 3750, 4000, 4100, and 4250 West Kiltie Lane
Flagstaff, AZ 86001

II. FACILITY DESCRIPTION

The facility manufactures medical devices from fluoropolymer. The basic manufacturing process takes fluoropolymer resin (powder), blends it with a liquid extrusion aid, and forms into various shapes. The fluoropolymer is then placed into a paste extruder where the material is extruded into an intermediate or final shape. Final processing or assembly steps occur after the extrusion aid is volatilized from the fluoropolymer. The facility has three ethylene oxide sterilizers for sterilizing manufactured medical equipment. There are two electro polishing lines which polish nitinol wires. Besides, there is a co-fired incinerator for the incineration of pathological and medical/infectious waste.

III. COMPLIANCE HISTORY

Inspections are being conducted on this source to ensure compliance with the permit. No cases or violations have been developed as a result of inspections.

IV. EMISSIONS

A. Potential to Emit

The facility is classified as a Synthetic Minor Source because it has accepted an emission cap of 70 tons per year of VOC. Additionally the source has accepted voluntary limitation of 7 ton per year of any single federal HAP and 18 tons per year of a combination of federal HAPs to ensure minor source status. Table 1 lists the facility wide potential emissions.

TABLE 1: FACILITYWIDE POTENTIAL TO EMIT (PTE)

Pollutant	Tons per Year
Particulate Matter (PM ₁₀)	0.99
Volatile Organic Compounds (VOC)	70*
Sulfur Dioxide (SO ₂)	0.43
Nitrogen Oxides (NO _x)	32.42
Carbon Monoxide (CO)	26.98
Federal HAPs	7 tpy for any one HAP* 18 for combination of HAPs*

* Facility accepted voluntary emission caps to stay below major source thresholds.

B. Minor NSR Applicability

Through this permit renewal, the facility is adding a new extruder (#CPE2) which is identical to the existing extruder (#7664). The extruder is electrically powered and has a potential to emit 15.53 tons per year of VOCs.

The total emission of VOCs is below the permitting exemption threshold of 20 tons per year. The facility is not requesting any changes to the currently established voluntarily accepted VOC limit. The addition of new extruder triggers new applicable requirement to add and track the emissions from the new extruder.

The increase in PTE for volatile organic components is less than the permitting exemption threshold; therefore the permit is not subject to minor NSR requirements.

V. APPLICABLE REQUIREMENTS

The Permittee has identified regulations that apply to each unit in its permit application. Table 2 summarizes the findings of the Department with respect to the regulations that are applicable to each emission unit.

TABLE 2: APPLICABLE REGULATIONS

Unit ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Production Lines	Various	N/A	<u>A.A.C. R18-2-702.B,</u> 730.A.1, B, D, F, and G	The facility is subject to A.A.C.R18-2-730 (Standards of Performance for Unclassified Sources).

Unit ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Boilers, Humidifiers, Heaters, and KP Gas Oven	Various	None	<p><u>A.A.C. R18-2-724.B, C.1, and J</u></p> <p>National Emission Standards for Hazardous Air Pollutants (NESHAP) Subpart JJJJJ</p>	<p>Fossil-fuel fired equipment is subject to A.A.C. R18-2-724.</p> <p>NESHAP Subpart JJJJJ is not applicable to gas - fired boilers. The boilers, heaters, humidifiers, and gas ovens use natural gas as fuel. Therefore NESHAP Subpart JJJJJ is not applicable.</p>
Emergency Internal Combustion Engines (ICEs)	<p>Pre NSPS, various</p> <p>2009</p>	None	<p><u>A.A.C. R18-2-719.B, C.1, E, F, H, and I</u></p> <p>New Source Performance Standard (NSPS), 40 CFR Part 60 Subpart JJJJ</p> <p>NESHAP, 40 CFR Part 63 Subpart ZZZZ</p>	<p>All emergency ICEs except the 275 kW Caterpillar ICE are subject to A.A.C. R18-2-719 (Standards of Performance for the Existing Stationary Rotating Machinery).</p> <p>The 275 KW Caterpillar ICE, natural gas fired, is subject to 40 CFR Part 60 Subpart JJJJ.</p> <p>As per 40 CFR 63.6590(c)(1), requirements of NESHAP Subpart ZZZZ are met by meeting the requirements of NSPS Subpart JJJJ.</p> <p>NESHAP Subpart ZZZZ is applicable to non-NSPS ICEs. These engines are categorized as 'existing' area source under Subpart ZZZZ.</p>

Unit ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Co-fired Incinerator	1991	None	<p><u>A.A.C. R18-2-704</u>.A, B, D, E, and F</p> <p><u>A.A.C. R18-2-732</u></p> <p>NSPS, 40 CFR Part 60 Subpart Ec</p>	<p>The incinerator is subject to A.A.C. R18-2-2-704 (Standards of Performance for Incinerators).</p> <p>This is not applicable since the facility meets the exemption criteria of handling less than 10 percent of medical and infectious waste.</p> <p>This Subpart is applicable to incinerators manufactured after June 20, 2006. This co-fired incinerator was manufactured in the year 1991; therefore NSPS Subpart Ec is not applicable.</p>
Sterilizers	2009	Acid-water Scrubber and Dry-bed Reactor	NESHAP, 40 CFR 63, Subpart O	NESHAP Subpart O is not applicable to ethylene sterilizers at the facility. Earlier the facility has installed these for use as a commercial sterilizer. In the present renewal process, the facility has indicated that these shall not be used for commercial purposes. The medical products that W.L. Gore manufactures are sterilized at outside facilities. Though NESHAP Subpart O is not applicable, still the source desires to keep the applicable testing requirements of this Subpart in the permit.
Fugitive Dust Sources	Not Applicable	Control Measures	<u>A.A.C. R18-2-602</u> , 604, 605, 606, 607, 614, and 702.B.3	The regulations listed are applicable to non point sources.
Mobile Sources	Not Applicable	Control measure	<u>A.A.C. R18-2-801</u> , 802, and 804	These regulations are applicable to all mobile sources.

Unit ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Abrasive Blasting	Not Applicable	Wet blasting, enclosures or equivalent approved by Director	A.A.C. R-18-2-726	This standard is applicable to any abrasive blasting operation.
Spray painting operations	-	Enclosed area	A.A.C. R-18-2-727	This standard is applicable to any spray painting operation.
Demolition/renovation Operations	-		A.A.C. R18-2-1101.A.8	This standard is applicable to any asbestos related demolition or renovation operations.

VI. PREVIOUS PERMITS AND CONDITIONS

A. Previous Permits

The following table lists the previous permits that have been issued to W. L. Gore & Associates.

Table 3: Previous Permits

Date Permit Issued	Permit #	Application Basis
July 19, 2011	52794	Class II Air Quality Operating Permit
February 29, 2012	54956	Minor Permit Revision
April 4, 2013	57453	Significant Permit Revision
January 28, 2014	59002	Minor Permit Revision

B. Previous Permit Conditions

Table 4: Operating Permit #52794

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
Attachment "A"	x				General Provisions - revised to represent the most recent language.
Attachment "B"					

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
I		x			Facility wide requirements
II.A		x			Applicability section
II.B.1	x				Condition for Particulate Matter and Opacity revised
II.C		x			Condition for VOCs and HAPs
II.D			x		This condition for applicability of NESHAP Subpart WWWW for Electro Polishing Lines deleted through Minor Revision #54956
III	x				This condition for Boilers, Humidifiers, and KP Gas Oven changed to Boilers, Humidifiers, Heater, and Gas-fired Ovens.
III.A	x				Applicability condition revised
III.B	x				Fuel requirement reworded to include the various types of equipment
III.C		x			Condition for Particulate Matter and Opacity
IV.A		x			Applicability condition
IV.B	x				This condition of fuel limitation revised to reflect deletion of WM Emergency Fire Pump
IV.C		x			Condition for ICEs subject to State regulations
IV.D		x			Conditions for ICEs subject to NSPS Subpart JJJ
IV.E				x	Condition for applicability streamlined by deleting the compliance date of May 3, 2013
V		x			Requirements for the co-fired incinerator
VI		x			Requirements for Ethylene Oxide Sterilization and Aeration Chambers
VII		x			Fugitive Dust Requirements.

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
VII		x			Mobile Source Requirements.
VIII		x			Other Periodic Requirements
Attachment "C" (Equipment List)	x				Equipment List has been updated to include all the emission units currently onsite.

Table 5: Minor Permit Revision #54956

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
Attachment "B"					
IV.D.1		x			Condition for ICEs subject to NSPS Subpart JJJJ.
IV.E		x			Condition for applicability streamlined by deleting the compliance date of May 3, 2013

Table 6: Significant Permit Revision #57453

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
Attachment "B"					
V.B.1.d		x			Condition for load limitation on burning of pathological waste.
V.B.3	x				Condition for testing changed for testing in the first year of the permit term.

Table 7: Minor Permit Revision #59002

Condition #	Determination				Comments
	Revised	Keep	Delete	Stream-line	
Attachment "B"					
III		x			This condition for Boilers, Humidifiers, and KP Gas Oven changed to Boilers, Humidifiers, Heater, and Gas-fired Ovens.

VII. MONITORING REQUIREMENTS

A. Production Lines

1. Opacity

The production line emission units are subject to a 20 percent opacity standard. Minimal visible emissions are expected from the production lines; therefore no opacity monitoring is required.

2. Particulate Matter

The facility is subject to A.A.C.R18-2-730.A. The emissions are expected to be significantly lower than the allowable that can be calculated from the process weight rate equation specified in A.A.C.R18-2-730.A; consequently, no monitoring is required.

3. Volatile Organic Compounds

Volatile Organic Compounds emitted from the facility are limited to a total of 70 tons per year. The mass balance equation must be used to compute VOC emissions on a semi-annual basis.

4. Hazardous Air Pollutants

The Permittee must record the mass of all HAP containing materials used and keep Safety and Data Sheets showing the mass fraction of HAPs present.

B. Boilers and Humidifiers

1. Opacity

The boilers and humidifiers are subject to a 15 percent opacity standard and are natural gas fired. Minimal visible emissions are expected from the boilers and humidifiers; therefore, no opacity monitoring is required.

2. Particulate Matter

The Permittee must keep records of fuel supplier certifications.

C. Internal Combustion Engines (ICEs)

1. Particulate Matter

The Permittee must maintain daily records of the lower heating values of the fuel.

2. Opacity

The ICEs are subject to a 40 percent opacity standard. The Permittee must conduct a quarterly survey of visible emissions by a certified EPA Reference Method 9 observer.

3. Sulfur Dioxide

The Permittee must maintain records of fuel supplier certification including the name of the fuel supplier, heating value and sulfur content of the diesel fuel, and the method used to determine the sulfur content of the diesel.

D. Co-fired Incinerator

1. The Permittee must maintain a record of the daily charging rates and hours of operation.

2. The incinerator is subject to a 20 percent opacity standard. The Permittee must conduct a quarterly survey of visible emissions by a certified EPA Reference Method 9 observer.

E. Ethylene Oxide (ETO) Sterilization and Aeration Chambers

1. Acid-water Scrubber

The Permittee must sample the scrubber liquor, analyze, and record the ethylene glycol concentration or record the level of liquor in acid-water scrubber once a week, only if the scrubber has been operated during that week.

2. Dry-bed Reactor

The Permittee must monitor the following parameters for the dry-bed reactor:

a. ETO usage in the sterilizers

Based on ETO monitoring systems and stack test results, for every pound of ETO used, 2% (at 15 ppm maximum levels) goes to the aeration chamber and then the dry-bed reactor, and the remaining 98% goes to the acid-water scrubber. The acid water scrubber on ETO has control efficiency of 99.86% before being fed to the dry-bed reactor (For calculation purposes, the control

efficiency is assumed at 99.5%).

$$360 \text{ lb} = (\text{X lb}) (0.98) (1-0.995) + (\text{X lb}) (0.02)$$

Quantity from acid- Quantity from aeration
water scrubber chamber

X lb = 14,450 lb of ETO usage before diminished efficiency.

Threshold ETO usage before dry-bed reactor media replacement at 95 % of 14,450 pound is= 14,450*0.95= 13,725 pounds

The media of the dry bed reactor must be changed each time that the ETO usage reaches 13,725 pounds.

b. Pressure drop across the dry-bed reactor

The dry-bed reactor is designed to handle an air flow rate of 2,000 acfm. At higher flow rates, the control device efficiency decreases due to decreased residence time. Lower flow rates will actually improve the performance of the control device by increasing residence time. Pressure drop across the reactor provides an indication of flow rate. Vendor information indicates that operation above 14 inches of water column across the dry bed reactor will cause an undesirable decrease in the efficiency. The dry bed reactor shall be monitored daily so that the pressure drop across the unit does not exceed 14 inches of water column.

F. Fugitive Dust

Opacity

1. The Permittee must conduct a quarterly survey of visible emissions by a certified EPA Reference Method 9 observer.
2. The Permittee must record the emission point being observed, date, time and the results of all observations made, as well as the name of the observer who conducted the test. In the event of opacity going beyond the limit, the Permittee must keep a record of the corrective action taken to bring the opacity below the standard.

VIII. TESTING REQUIREMENTS

1. Co-fired Incinerator

The Permittee must conduct a performance test for particulate matter using EPA Reference Method 5 in the first year of the permit term.

2. ETO Sterilizers

a. Acid-water Scrubber

The Permittee must conduct the performance test on the acid-water scrubber within

180 days of issuance of the permit.

b. Dry-Bed Reactor

- (1) The Permittee must conduct the performance test on the dry-bed reactor within 180 days of the ETO usage exceeds 10 tons in any 12-month period.
- (2) The Permittee must conduct subsequent testing annually there after.

IX. INSIGNIFICANT ACTIVITIES

The following includes a list of activities proposed by W.L. Gore & Associates to be insignificant. These activities have been deemed “insignificant” by the Department.

Table 8: Insignificant Activity List

S. No.	Activity	Determination	Justification
1	Central vacuum system	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.d.i
2	Fluidized beds in R & D	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e.i
3	Diesel fuel tank less than 500 gallons	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.a.i
4	Laboratory down draft tables (Formaldehyde)	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e.i
5	Laboratory slide cleaner	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e.i
6	Powder Coating equipment	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.c.iii
7	Shop grinding and machining equipment	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.c.ii
8	Shop aluminum grinder utilizing a Donaldson Torit Downflow Ultra-Web Dust Collector	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.c.ii
9	Shop plastic grinder utilizing a Donaldson Torit Cyclone Model Dust Collector	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.c.ii
10	Benchtop ETO in research laboratory	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e and f.iii
11	Formalin used at research facility for preservation of samples	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e.i

S. No.	Activity	Determination	Justification
12	Lab scale chemicals used in Research & Development	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.e.i
13	Parts washer that use 2 gallons to 20 gallons per years of parts washer fluid	Yes	Insignificant pursuant to A.A.C. R18-2-101.68.c.i

X. TRIVIAL ACTIVITIES

The following includes a list of activities proposed by W.L. Gore & Associates to be trivial. These activities have been deemed “trivial” by the Department.

Table 8: Trivial Activity List

S. No.	Activity	Determination	Justification
1	Adhesive tubes, 5-30 ml, Less than 300 lbs per year	Yes	Trivial pursuant to A.A.C. R18-2-144.b.ix
2	480 V Electric wastewater evaporator	Yes	Trivial pursuant to A.A.C. R18-2-144
3	Negligible emissions associated with dry plastic molding	Yes	Trivial pursuant to A.A.C. R18-2-144
4	Laser etching/ cutting/ trimmings on components	Yes	Trivial pursuant to A.A.C. R18-2-144.b.xiv
5	Colling towers with a pte of 27 lbs per year of particulate matter	Yes	Trivial pursuant to A.A.C. R18-2-144.b.xix to xxi

XI. LIST OF ABBREVIATIONS

- A.A.C.Arizona Administrative Code
- acfm.....Actual Cubic Feet per Minute
- ADEQ Arizona Department of Environmental Quality
- CFR.....Code of Federal Regulations
- CO.....Carbon Monoxide
- EPA..... Environmental Protection Agency
- ETO.....Ethylene Oxide
- HAP Hazardous Air Pollutants
- Hr Hour
- ICE..... Internal Combustion Engine
- Btu.....British Thermal Units
- NESHAPNational Emission Standards for Hazardous Air Pollutants
- NO_x Nitrogen Oxide
- NSPS..... New Source Performance Standards
- PM₁₀..... Particulate Matter Nominally less than 10 Micrometers

PTE Potential-to-Emit
SO₂ Sulfur Dioxide
TPY Tons per Year
VOC Volatile Organic Compound

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