

**TECHNICAL REVIEW AND EVALUATION
OF APPLICATION FOR
AIR QUALITY PERMIT NO. 47898**

I. INTRODUCTION

This renewal permit is for the operation of W.L. Gore & Associates medical products manufacturing facility located at 1500 & 1505 N. Fourth St. in Flagstaff, Coconino County, Arizona. This is a renewal of Air Quality Permit No. 28211.

A. Company Information

1. Mailing Address: W.L. Gore & Associates, Inc.
4100 West Kiltie Lane
Flagstaff, AZ 86001
2. Facility Address: W.L. Gore & Associates, Fourth Street Campus
1500 and 1505 N. Fourth Street
Flagstaff, Coconino County, AZ 86004

B. Background

Since Air Quality Permit Number 28211 was issued on December 22, 2003, there has been one facility change without revision, one minor revision and one administrative amendment issued. Facility Change without Revision #33692 was issued on August 12, 2004. Minor Revision #42706 was issued on April 30, 2007, to add a sterilizing facility consisting of two, 3-pallet production sterilizers and one, 32 cubic feet volume R & D chamber. Administrative Amendment #45380 was issued on September 19, 2007, for typographic correction in the capacity of Sterilizers #1 and #2 in the Equipment List, Attachment "C" of Significant Permit Revision #42706 to Operating Permit #28211. The sterilizing facility was moved to another location and is now part of Operating Permit #34379.

II. FACILITY DESCRIPTION

The facility manufactures medical devices from fluoropolymers. The basic manufacturing process takes fluoropolymer resin (powder), blending it with a liquid extrusion aid and forming it into a billet of the required pre-formed shape. The fluoropolymer billet 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 fluoropolymers.

III. COMPLIANCE HISTORY

No air quality cases or violations are documented for this facility.

IV. LEARNING SITES EVALUATION

In accordance with ADEQ's Environmental Permits and Approvals Near Learning Sites Policy, the Department conducted an evaluation to determine if any nearby learning sites would be adversely

impacted by the facility. Learning sites consist of all existing public schools, charter schools and private schools at the K-12 level, and all planned sites for schools approved by the Arizona School Facilities Board. The learning sites policy was established to ensure that the protection of children at learning sites is considered before a permit approval is issued by ADEQ.

There are nineteen impacted Learning Sites near the W.L. Gore & Associates Fourth Street Facility. The impacted learning sites are as follows: Montessori Charter School of Flagstaff-Campus, The Peak School, Coconino High School, Bilingual Magnet (Puente De Hozho), Continental Project, Excel Education Centers Flagstaff and LLC, John Q Thomas Elementary School, Mount Elden Middle School, Mountain English Spanish Academy of Flagstaff (M.E.S.A.), Northland Preparatory Academy, Renaissance Magnet Middle School, Sinagua High School, Thomas M Knoles Elementary School, Thomas R Weitzel Elementary School, W F Killip Elementary School, Coconino Community College-Fourth Street Campus, Kinlani Bordertown Dormitory, Peace Preschool-Kindergarten and Montessori School of Flagstaff.

The Department has reviewed the emission sources at the facility and has determined that the operation of the facility will not adversely affect the learning sites.

V. EMISSIONS

Pollutant	Emissions (tpy)
PM ₁₀	0.08
SO ₂	0.01
NO _x	1.07
VOC*	70.06
CO	0.90
Single HAP*	7.00
Total HAPs*	18.00

*Based on permit limits

VI. APPLICABLE REGULATIONS

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

Applicable Regulations

Unit ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Production Lines*	N/A	None	<u>A.A.C.</u> R18-2-702.B R18-2-702.C R18-2-730.A R18-2-730.B R18-2-730.D R18-2-730.F R18-2-730.G	The production line is subject to the opacity standards of R18-2-702.B & C and also the standards for unclassified sources in R18-2-730.
Boilers	1985	None	<u>A.A.C.</u> R18-2-724.B. R18-2-724.C.1 R18-2-724.J	The boilers are less than 250 MMBtu/hr and are used to produce steam. They are therefore subject to A.A.C. R18-2-724. The boilers are less 10 MMBtu/hr and are therefore not subject to 40 CFR60 Subparts D, Da, Db or Dc.
Fugitive Dust Sources	N/A	Water and other reasonable precautions	<u>A.A.C.</u> R18-2-2-702 Article 6	These standards are applicable to all fugitive dust sources.
Mobile Sources	N/A	Water Sprays/Water Truck for dust control	<u>A.A.C.</u> Article 8	Article 8 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 ID	Year of Manufacture	Control Equipment	Applicable Regulations	Verification
Spray Painting Operations	N/A	N/A	<u>A.A.C.</u> R18-2-727	Arizona Administrative Code R18-2-727 standard is applicable to any spray-painting operation.
Demolition/ Renovation Operations	N/A	N/A	<u>A.A.C.</u> R18-2-1101.A.8	This standard is applicable to any asbestos related demolition or renovation operations.
Abrasive Blasting	N/A	N/A	<u>A.A.C.</u> R18-2-726 R18-2-702.B	Arizona Administrative Code R18-2-726 and 702.B are standards that are applicable to any activity relative to abrasive blasting operations.

*The facility manufactures medical devices from fluoropolymers.

VII. PREVIOUS PERMIT CONDITIONS

A. Previous Permits

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

Previous Permits

Date Permit Issued	Permit #	Application Basis
12/22/2003	28211	Operating Permit
4/30/2007	42706	Minor Revision
9/19/2007	45380	Administrative Amendment

B. Previous Permit Conditions

The following are discussions on the previous permits that have been issued to the source.

CLASS II, NON-TITLE V OPERATING PERMIT NO. 28211

This operating permit was issued to W.L. Gore & Associates, Inc. on December 22, 2003, to operate a facility to manufacture medical devices.

OP #28211, References	Determination				Comments
	Revise	Keep	Delete	Stream-line	
Att. A.	X				General provisions - revised to represent most recent language
Att.B.I		X			Facility Wide Limitations—Section and language is retained.
Att B.II.A		X			Production Lines—Applicability—Section and language is retained.
Att B.II.B		X			Production Lines--Particulate Matter & Opacity Standards—Section and language is retained.
Att B.II.C		X			Production Lines—Volatile Organic Compounds (VOC) Standards—Section and language is retained.
Att B.II.D		X			Production Lines—Hazardous Air Pollutants (HAPs)—Section and language is retained.
Att B.III.A		X			Boilers—Applicability—Section and language is retained.
Att B.III.B		X			Boilers—Fuel Limitation—revised to represent most recent language Matter in accordance with A.A.C. R18-2-306.A.2.
Att B.III.C		X			Boilers—Particulate Matter & Opacity Standards—revised to represent most recent language Matter in accordance with A.A.C. R18-2-724.C.1 & -724.J.
Att B.IV		X			Non-Point Sources-Open Areas, Roadways & Streets, Storage Piles, and Material Handling—revised to represent most recent language.
Att B.V.		X			Mobile Sources—revised to represent most recent language.

OP #28211, References	Determination				Comments
	Revise	Keep	Delete	Stream- line	
Att C		X			Equipment List—revised to most updated equipment list provided

CLASS II, NON-TITLE V MINOR REVISION NO. 42706

This minor revision was issued to W.L. Gore & Associates, Inc. on April 30, 2007, to operate a facility to manufacture medical devices.

OP #42706, References	Determination				Comments
	Revise	Keep	Delete	Stream- line	
Att.B.III.A		X			Applicability—Section and language is retained.
Att.B.V.A			X		Ethylene Oxide Usage & Record Keeping—Section deleted because equipment was moved to Permit #34379.
Att B.V.B			X		Emission Limitations/Standards—Section deleted because equipment was moved to Permit #34379.
Att B.V.C			X		Air Pollution Control Requirements—Section deleted because equipment was moved to Permit #34379.
Att B.V.D			X		Testing Requirements—Section deleted because equipment was moved to Permit #34379.
Att B.V.E			X		Monitoring, Reporting, and Record Keeping—Section deleted because equipment was moved to Permit #34379.
Att B.V.F			X		Test Methods & Procedures—Section deleted because equipment was moved to Permit #34379.
Att C		X			Equipment List—revised to most updated equipment list provided

CLASS II, NON-TITLE V ADMINISTRATIVE AMENDMENT NO. 45380

This administrative amendment was issued to W.L. Gore & Associates, Inc. on September 19, 2007.

Administrative Amendment No. 45380 was issued for the typographic correction in the capacity of Sterilizers #1 and #2 in the Equipment List of Attachment "C" of Significant Permit Revision #42706 to Operating Permit #28211. The sterilizers have been deleted from the equipment list because all of the sterilization equipment has been moved to Permit #34379.

VIII. MONITORING REQUIREMENTS

A. Volatile Organic Compounds (VOC)

The Permittee must follow the monitoring, recordkeeping and reporting requirements stated below to ensure that the total emissions of VOCs from the facility do not exceed 70 tons in any 12-month period:

1. The Permittee must maintain records of all purchase orders, invoices, waste material shipped off site under manifest and Material Safety Data Sheets (MSDS) of all VOC-containing materials used at the facility.
2. The Permittee must calculate and record a 12-month total of VOC emissions at the end of each semi-annual period.
 - a. The emissions are calculated by the following equation:

$$\text{VOC}_{\text{Emitted}} = \text{VOC}_{\text{beg}} + \text{VOC}_{\text{tr}} - \text{VOC}_{\text{end}} - \text{Waste}_{\text{Facility}}$$

- b. The method of calculation is described below:

The 12-month total of VOC emissions emitted ($\text{VOC}_{\text{Emitted}}$) are calculated by adding the initial amount of VOCs at the beginning of the 12-month period (VOC_{beg}) to the amount of purchased or transferred materials containing VOCs during the 12-month period (VOC_{tr}), then subtracting all of the reportable VOC containing materials at the facility at the end of the 12-month period (VOC_{end}), and subtracting the materials removed from the facility during the 12-month period ($\text{Waste}_{\text{Facility}}$).

B. Hazardous Air Pollutants (HAP)

The Permittee must maintain records of the mass of all HAP containing materials used and the MSDS showing the mass fraction of HAP present, to demonstrate that the facility will not exceed the emission limitations of 7 tons of any single federal HAP or 18 tons of any combination of federal HAP in a 12-month period.

C. Boilers

The Permittee must keep records of fuel supplier certifications to show the heating value of the fuel. The certification must contain information about the name of fuel supplier and lower heating value of the fuel. These records must be made available to ADEQ upon request.

IX. LIST OF ABBREVIATIONS

A.A.C.....	Arizona Administrative Code
ADEQ.....	Arizona Department of Environmental Quality
AQD.....	Air Quality Division
CO.....	Carbon Monoxide
ft.....	Feet
HAP.....	Hazardous Air Pollutant
hr.....	Hour
lb.....	Pound
MMBtu.....	Million British Thermal Units
NO _x	Nitrogen Oxide
PM.....	Particulate Matter
PM ₁₀	Particulate Matter Nominally less than 10 Micrometers
PTE.....	Potential-to-Emit
s.....	Seconds
SO ₂	Sulfur Dioxide
TPY.....	Tons per Year
VOC.....	Volatile Organic Compound
yr.....	Year

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