

**MONTANA DEPARTMENT OF ENVIRONMENTAL QUALITY
OPERATING PERMIT TECHNICAL REVIEW DOCUMENT**

**Permitting and Compliance Division
1520 E. Sixth Avenue
P.O. Box 200901
Helena, Montana 59620-0901**

Specialty Surgical Products, Inc.
SW ¼ of Sec. 31, Township 7 North, Range 20 West, Ravalli County
1131 U.S. Highway 93 North
Victor, MT 59875

The following table summarizes the air quality programs testing, monitoring, and reporting requirements applicable to this facility.

Facility Compliance Requirements	Yes	No	Comments
Source Tests Required	X		Method 9
Ambient Monitoring Required		X	
COMS Required		X	
CEMS Required		X	
Schedule of Compliance Required		X	
Annual Compliance Certification and Semiannual Reporting Required	X		As applicable
Monthly Reporting Required		X	
Quarterly Reporting Required		X	
Applicable Air Quality Programs			
ARM Subchapter 7 Air Quality Permitting	X		#3237-00
New Source Performance Standards (NSPS)		X	
National Emission Standards for Hazardous Air Pollutants (NESHAPS)		X	
Maximum Achievable Control Technology (MACT)		X	
Major New Source Review (NSR)		X	
Prevention of Significant Deterioration (PSD)		X	
Risk Management Plan Required (RMP)		X	
Acid Rain Title IV		X	
Compliance Assurance Monitoring (CAM)		X	
State Implementation Plan (SIP)	X		General SIP

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SECTION I. GENERAL INFORMATION

A. Purpose

This document establishes the basis for the decisions made regarding the applicable requirements, monitoring plan, and compliance status of emission units affected by the operating permit proposed for this facility. The document is intended for reference during review of the proposed permit by the U.S. Environmental Protection Agency (EPA) and the public. It is also intended to provide background information not included in the operating permit and to document issues that may become important during modifications or renewals of the permit. Conclusions in this document are based on information provided in the original application submitted by Specialty Surgical Products, Inc. (Specialty Surgical Products) on January 9, 2003 and additional submittals on January 30, 2003, October 28, 2003, and January 14, 2004.

B. Facility Location

The Specialty Surgical Products facility is located in the SW ¼ of Section 31, Township 7, North, Range 20 West, Ravalli County, about three miles north of Hamilton. The physical address is 1131 North U.S. Highway 93, Victor, MT 59875. The Selway Bitterroot Wilderness (Class I area) is located approximately 10 miles west of the site.

C. Facility Background Information

Montana Air Quality Permit #3237-00 was issued to Specialty Surgical Products on April 12, 2003, for the operation of a manufacturing facility producing silicon-based devices used in medical procedures.

D. Taking and Damaging Analysis

HB 311, the Montana Private Property Assessment Act, requires analysis of every proposed state agency administrative rule, policy, permit condition or permit denial, pertaining to an environmental matter, to determine whether the state action constitutes a taking or damaging of private real property that requires compensation under the Montana or U.S. Constitution. As part of issuing an operating permit, the Department is required to complete a Taking and Damaging Checklist. As required by 2-10-101 through 105, MCA, the Department has conducted a private property taking and damaging assessment and has determined there are no taking or damaging implications. The checklist was completed on October 24, 2003.

E. Compliance Designation

Specialty Surgical Products was last inspected on April 23, 2003, and was found to be in compliance with all applicable requirements. A copy of the inspection report is on file with the Department.

SECTION II. SUMMARY OF EMISSION UNITS

A. Facility Process Description

The facility includes two process buildings where silicon-based devices used in medical procedures such as plastic surgery are produced. Volatile Organic Compound (VOC) emissions, primarily xylene and some ethyl benzene, result from the product manufacturing process. Xylene and ethyl benzene are listed Hazardous Air Pollutants (HAPs). Mandrels are dipped in a xylene/silicon mixture and allowed to partially dry. The process is repeated until the desired product thickness is obtained. Formed products are then placed in curing ovens to complete the drying process. Isopropyl alcohol is used to clean the products. A spray paint hood is used for product coating on an as-needed basis. Both buildings contain natural gas-fired heating equipment.

B. Emission Units and Pollution Control Device Identification

The emission units regulated by this permit are the exhaust fans at Buildings A and B. Currently, Specialty Surgical Products is not required to install or operate any air pollution control equipment.

C. Categorically Insignificant Sources/Activities

The Administrative Rules of Montana (ARM) 17.8.1201(22)(a) defines an insignificant emissions unit as one that emits less than 5 tons per year of any regulated pollutant, has the potential to emit less than 500 pounds per year of lead or any hazardous air pollutant, and is not regulated by an applicable requirement other than a generally applicable requirement. The following table lists the insignificant emission units at Specialty Surgical Products.

Emissions Unit ID	Description
IEU01	Building A Heater (F-1)
IEU02	Building A Heater (F-2)
IEU03	Building A Heater (F-3)
IEU04	Building A Unit Heater (UHA-01)
IEU05	Building A Unit Heater (UHA-02)
IEU06	Building A Comfort Heater (FCA-01)
IEU07	Building A Alcohol Fume Hood (AV-01)
IEU08	Building A Paint Hood (PH-01)
IEU09	Building A Fugitive Emissions
IEU10	Building B Boiler #1 (B-01)
IEU11	Building B Boiler #2 (B-02)
IEU12	Building B Curing Oven (CO-01)
IEU13	Building B Curing Oven (CO-02)
IEU14	Building B Fugitive Emissions
IEU15	Building A Extension Boiler (1.2 MMBtu/hr)

SECTION III. PERMIT CONDITIONS

A. Emission Limits and Standards

The VOC emissions from the facility are limited to 52.3 tons during any rolling 12-month time period. This is a combined limit for both Buildings A and B.

B. Monitoring Requirements

ARM 17.8.1212(1) requires that all monitoring and analysis procedures or test methods required under applicable requirements are contained in operating permits. In addition, when the applicable requirement does not require periodic testing or monitoring, periodic monitoring must be prescribed that is sufficient to yield reliable data from the relevant time period that is representative of the source's compliance with the permit.

The requirements for testing, monitoring, recordkeeping, reporting, and compliance certification sufficient to assure compliance does not require the permit to impose the same level of rigor for all emission units. Furthermore, it does not require extensive testing or monitoring to assure compliance with the applicable requirements for emission units that do not have significant potential to violate emission limitations or other requirements under normal operating conditions. When compliance with the underlying applicable requirement for a insignificant emissions unit is not threatened by lack of regular monitoring and when periodic testing or monitoring is not otherwise required by the applicable requirement, the status quo (**i.e., no monitoring**) will meet the requirements of ARM 17.8.1212(1). Therefore, the permit does not include monitoring for insignificant emission units.

The permit includes periodic monitoring or recordkeeping for each applicable requirement. The information obtained from the monitoring and recordkeeping will be used by the permittee to periodically certify compliance with the emission limits and standards. However, the Department may request additional testing to determine compliance with the emission limits and standards.

C. Test Methods and Procedures

The operating permit may not require testing for all sources if routine monitoring is used to determine compliance, but the Department has the authority to require testing if deemed necessary to determine compliance with an emission limit or standard. In addition, the permittee may elect to voluntarily conduct compliance testing to confirm its compliance status.

D. Recordkeeping Requirements

The permittee is required to keep all records listed in the operating permit as a permanent business record for at least five years following the date of the generation of the record.

E. Reporting Requirements

Reporting requirements are included in the permit for each emissions unit and Section V of the operating permit "General Conditions" explains the reporting requirements. However, the permittee is required to submit semi-annual and annual monitoring reports to the Department and to annually certify compliance with the applicable requirements contained in the permit. The reports must include a list of all emission limit and monitoring deviations, the reason for any deviation, and the corrective action taken as a result of any deviation.

F. Public Notice

In accordance with ARM 17.8.1232, a public notice was published in the *Ravalli Republic* on or before December 12, 2003. The Department provided a 30-day public comment period on the draft operating permit from December 12, 2003, to January 12, 2004. ARM 17.8.1232 requires the Department to keep a record of both comments and issues raised during the public participation process.

Summary of Public Comments for OP3237-00

Person/Group Commenting	Comment	Department Response
No comments received.		

G. Draft Permit Comments

Summary of Permittee Comments for OP3237-00

Permit Reference	Permittee Comment	Department Response
No comments received.		

Summary of EPA Comments for OP3237-00

Permit Reference	EPA Comment	Department Response
No comments received.		

SECTION IV. NON-APPLICABLE REQUIREMENT ANALYSIS

Specialty Surgical Products did not request a shield from any of the air quality Administrative Rules of Montana (ARM) or federal regulations (pursuant to ARM 17.8.1214). Therefore, no further analysis of non-applicable requirements is necessary.

SECTION V. FUTURE PERMIT CONSIDERATIONS

A. MACT Standards

As of December 12, 2003, the Department is unaware of any currently applicable or future MACT Standards that may be promulgated that will affect this facility.

B. NESHAP Standards

As of December 12, 2003, the Department is unaware of any currently applicable or future NESHAPS Standards that may be promulgated that will affect this facility.

C. NSPS Standards

As of December 12, 2003, the Department is unaware of any currently applicable or future NSPS Standards that may be promulgated that will affect this facility.

D. Risk Management Plan

As of December 12, 2003, this facility does not exceed the minimum threshold quantities for any regulated substance listed in 40 CFR 68.115 for any facility process. Consequently, this facility is not required to submit a Risk Management Plan.

If a facility has more than a threshold quantity of a regulated substance in a process, the facility must comply with 40 CFR 68 requirements no later than June 21, 1999; three years after the date on which a regulated substance is first listed under 40 CFR 68.130; or the date on which a regulated substance is first present in more than a threshold quantity in a process, whichever is later.