San Joaquin Valley
Unified Air Pollution Control District

Best Available Control Technology (BACT) Guideline 4.10.5*

Emissions Unit: Solvent Wipe Cleaning – Medical Devices and Pharmaceuticals

Industry Type: Multiple

Equipment Rating: All **Last Update:** March 6, 2024

Pollutant	Achieved in Practice or contained in SIP	Technologically Feasible	Alternate Basic Equipment
NOx	N/A	N/A	
SOx	N/A	N/A	
VOC	Compliance with SJVAPCD Rule 4663	1) 98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent) 2) 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent)	
PM10	N/A	N/A	

BACT is the most stringent control technique for the emissions unit and class of source. Control techniques that are not achieved in practice or contained in a state implementation plan must be cost effective as well as feasible. Economic analysis to demonstrate cost effectiveness is required for all determinations that are not achieved in practice or contained in an EPA approved State Implementation Plan.

***This is a Summary Page for this Class of Source**

Proactive Best Available Control Technology Analysis

District BACT Guideline 4.10.5

Solvent Wipe Cleaning – Medical Devices and Pharmaceuticals

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(Updated March 6, 2024)

I. Introduction

The objective of this project is to develop a Best Available Control Technology (BACT) guideline for solvent wipe cleaning associated with a manufacturing process for medical devices. For the purposes of this guideline, the following definitions from District Rule 4663 is used:

Medical Device:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar article, including any component or accessory that meets the following conditions: 1) is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or 2) is intended to affect the structure or any function of the body; or 3) is defined in the National Formulary or the United States Pharmacopeia, or any supplement to it.

Operations further up the supply chain that produce components intended for use in direct manufacturing of such devices or pharmaceuticals may be considered associated with the manufacture of such devices or pharmaceuticals and subject to this BACT guideline if they are bound by industry standards of cleanliness.

A BACT guideline exists for wipe cleaning of medical grade silicone products (guideline 4.10.5, updated 5/28/2020), however, the defined scope of this guideline is narrow and does not include solvent wipe cleaning operations of other types of medical devices. The scope will be expanded to include all solvent wipe cleaning operations for all medical devices and pharmaceuticals.

This proactive update is necessary to incorporate the most stringent emission control standards that have been achieved in practice. Furthermore, the proactive update to this BACT guideline will bring consistency in implementing the BACT standard throughout the regional offices of the District for new and modified organic solvent wipe cleaning operations triggering BACT. The discussion in this document will be limited to the following items:

- Source of emissions
- Top-Down BACT Analysis for each pollutant
- Recommendation

II. Source of emissions

Solvent wipe cleaning is used to remove contaminant material and may sterilize surfaces. For operations associated with the manufacture of medical devices or pharmaceuticals, a high degree of cleanliness is the industry standard.

Emissions are expected to result when the VOC in the solvent evaporates. The amount of VOC emitted is assumed to be the entire VOC content of the solvent used.

III. Top Down BACT Analysis for VOC Emissions

Step 1 – Identify All Possible Control Technologies

A. Survey of BACT Guidelines

The following published BACT Guidelines were reviewed to determine potential control technologies for this class and category of operation:

- The U.S. Environmental Protection Agency (USEPA) RACT/BACT/LAER Clearinghouse,
- California Air Resources Board (CARB) BACT Clearinghouse,
- South Coast Air Quality Management District (SCAQMD),
- Sacramento Metropolitan Air Quality Management District (SMAQMD),
- Bay Area Air Quality Management District (BAAQMD),
- San Diego County Air Pollution Control District (SDCAPCD),
- San Joaquin Valley Air Pollution Control District (SJVAPCD)

The EPA RACT/BACT/LAER clearinghouse[1] (RBLC) does not include general guidelines, only determinations made by individual agencies. There was no relevant data in the clearinghouse for organic solvent cleaning operations for medical devices and pharmaceuticals. A query of the RBLC for process descriptions containing "WIPE" or "MEDICAL" returned only one potentially relevant result. This result, RBLC ID CA-0597, described a process where xylene emissions resulting from silicone based medical device manufacturing were controlled by a recuperative thermal oxidizer with 95.5% efficiency. Pure xylene has VOC content of 7.3 lb-VOC/gal. As discussed below, this VOC content exceeds the VOC content limits of SJVAPCD Rule 4663, therefore, Rule 4663 would require such a control device.

The CARB BACT clearinghouse does not include general guidelines, only individual determinations made by individual air districts. The relevant data are summarized in the following Achieved in Practice BACT and Technologically Feasible BACT tables.

The BAAQMD, and SJVAPCD BACT clearinghouses include relevant guidelines. The SCAQMD, SBAPCD, and SMAQMD clearinghouse do not include any BACT requirements for wipe cleaning operations. Achieved in Practice (which is required of all subject operations) and Technologically Feasible (which may be required if cost effective) are summarized in the following Achieved in Practice and Technologically Feasible BACT tables.

[1] https://cfpub.epa.gov/rblc/index.cfm?action=Search.AdvancedSearch

Achieved in Practice (AIP) and Technologically Feasible (TF) BACT			
Air District	**Guideline#: Source Category (revision date)**	**VOC Guideline**	
		AIP	**TF**
BAAQMD	179B.1: Wipe Cleaning Operations – All Classes (revised 6/11/2015)	Minimizing use of solvents; and use of lowest practical vapor pressure solvents; and use of controlled flow solvent dispenser (e.g., squeeze bottle); and all cloths/papers and solvents not in active use kept in closed container	1) Wipe cleaning in a hood, booth, or room vented to a control device, w/ emissions controlled to overall capture/destruction efficiency >90%
SJVAPCD	4.10.5: Medical Grade Silicone Products – Wipe Cleaning Operation (5/28/2020)	Use of solvents with VOC content (less water and exempt compounds) of 7.2 lb/gal, or lower, and evaporative minimization methods, which include: - use of controlled flow dispensers (e.g. squeeze bottles) and - keeping all cloth/papers and solvent, which are not in active use, stored in closed containers	1) Capture and control using an enclosed booth and thermal/catalytic oxidation system 2) Capture and control using a hood and thermal/catalytic oxidation system

Summary of BACT Guideline Requirements:

Both existing AIP guidelines describe work practice methods to minimize evaporative loss of solvents including use of controlled flow dispensers (e.g., squeeze bottle) and keeping all cloths/papers and solvents which are not in active use in closed containers. The BAAQMD guideline, additionally, prescribes minimizing use of solvents and use of lowest practical vapor pressure solvents. The SJVAPCD guideline, which is much narrower in scope, prescribes a maximum VOC content. As discussed below, SJVAPCD Rule 4663 (and similar rules of other air districts) includes additional VOC content requirements depending on specifics of the solvent cleaning operation. These rule requirements are at least as stringent as the former BACT requirement. Therefore, it is more suitable for this BACT guideline to refer to the district rule where limits are discussed in greater context and detail. Such an incorporation of requirement by reference to the district rule is not a relaxation of requirements of this BACT guideline.

The TF options describe control devices. The BAAQMD requirement prescribes overall control efficiency of 90%. The existing SJVAPCD requirement does not specify an overall capture/control efficiency, however, the capture and control efficiency expected of fully enclosed (100% capture efficiency) operations and controlled operations is at least 98%. A variety of control device types, including, but not limited to, thermal oxidation systems and activated carbon systems are expected to be highly effective at controlling solvent vapors. Therefore, the TF option identified is:

i. VOC

- 98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent)
- 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent)

B. Survey of District Rules

District rules relevant to organic solvent cleaning are discussed individually, and then compared to each other.

SJVAPCD Rules:

Rule 4663: Organic Solvent Cleaning, Storage, and Disposal (9/20/2007)
The purpose of this rule is to limit VOC emissions from organic solvent cleaning and from the storage and disposal of solvents and waste solvent materials. This rule is applicable to the aforementioned solvent wipe cleaning operation.

This rule prescribes limits on permissible VOC content solvents. Limits relevant to solvent wipe cleaning are shown in the table below:

SJVAPCD Rule 4663: VOC limits for Solvent Cleaning Operations	
Type of Solvent Cleaning Operation	**VOC Content Limit Grams of VOC/liter of material (lb/gal)**
A. Product Cleaning During Manufacturing Process or Surface Preparation for Coating, Adhesive, or Ink Application:	
1. General	25 (0.21)
2. Electrical Apparatus Components and Electronic Components	100 (0.84)
3. Medical Devices and Pharmaceuticals	800 (6.7)
B. Repair and Maintenance Cleaning	
1. General	25 (0.21)
2. Electrical Apparatus Components and Electronic Components	100 (0.84)
3. Medical Devices and Pharmaceuticals	
3.1 Tools, Equipment, and Machinery	800 (6.7)
3.2 General Work Surfaces	600 (5.0)
C. Cleaning of Coating or Adhesive Application Equipment	25 (0.21)

As an alternative to complying with the VOC limits, this rule allows higher VOC content if the operation is controlled by an approved emission control system which limits emissions to levels which would be achieved with a compliant solvent, has at 90% capture efficiency, and has 95% control efficiency or reduces output VOC concentration to less than 50 ppm (calculated as carbon with no dilution).

Additionally, this rule includes requirements for evaporative loss minimization including requirements for cleaning methods, storage and disposal. The evaporative loss minimization requirements of this rule are at least as stringent as the previously established Achieved in Practice BACT guidelines of BAAQMD and SJVAPCD.

Other Air District Rules:

BAAQMD Regulation 8.4: General Solvent and Surface Coating Operations (10/16/2002)

The purpose of this rule is to limit emissions of volatile organic compounds from the use of solvents and surface coatings in any operation other than those specified by other BAAQMD rules. This rule does not include requirements applicable to solvent wipe cleaning associated with medical device manufacturing.

BAAQMD Regulation 8.16: Solvent Cleaning Operations (10/16/2002) [2]

The purpose of this rule is to reduce VOC emissions from solvent cleaning operations, including wipe cleaning, used to clean or dry metal and non-metal surfaces typically using a cold, vapor, or conveyorized solvent cleaner. For wipe cleaning operations, this rule only prescribes recordkeeping requirements.

SCAQMD Rule 1171: Solvent Cleaning Operations (5/1/2009)[3]

The purpose of this rule is to reduce emissions from solvent cleaning operations and activities. This rule prescribes limits on permissible VOC content solvents depending on operation type. As an alternative to complying with the VOC limits, this rule allows higher VOC content if the operation is controlled by an approved emission control system which limits emissions to levels which would be achieved with a compliant solvent, has at 90% capture efficiency, and has 95% control efficiency or reduces output VOC concentration to less than 50 ppm (calculated as carbon with no dilution). The applicable limits for operations associated with medical devices and pharmaceuticals and the alternative control system requirements coincide with SJVPACD Rule 4663.

SMAQMD Rule 466: Solvent Cleaning (10/28/2010)[4]

The purpose of this rule is to reduce VOC emissions from solvent cleaning operations and activities, and from the storage and disposal of new and spent cleaning solvents. This rule prescribes limits on permissible VOC content solvents depending on operation type. As an alternative to complying with the VOC limits, this rule allows higher VOC content if the operation is controlled by an approved emission control system which limits emissions to levels which would be achieved with a compliant solvent, has at 90% capture efficiency, and has 95% control efficiency or reduces output VOC concentration to less than 50 ppm (calculated as carbon with no dilution). The applicable limits for operations associated with medical devices and pharmaceuticals and the alternative control system requirements coincide with SJVPACD Rule 4663.

[2] https://www.baaqmd.gov/~/media/dotgov/files/rules/reg-8-rule-16-solvent-cleaning-operations/documents/rg0816.pdf?la=en&rev=1bc8308d9bba4794a6496adffa04841a
[3] http://www.aqmd.gov/docs/default-source/rule-book/reg-xi/rule-1171.pdf
[4] https://www.airquality.org/ProgramCoordination/Documents/rule466.pdf

SDAPCD Rule 66.1: Miscellaneous Surface Coating Operations and Other Processes Emitting Volatile Organic Compounds (2/10/2010)[5]

Solvent wipe cleaning operations are subject to this rule because SDAPCD Rule 67.6.1: Cold Solvent Cleaning and Stripping Operations is not applicable to wipe cleaning operations. Section (b)(xi) of this rule grants exemption for any solvent cleaning, including wipe cleaning, or surface preparation of electrical or electronic components, medical devices, laser optics or precision optics components. Additionally, Section (b)(xii) of this rule grants exemption for surface preparation or solvent cleaning, including wipe cleaning, for quality control or quality assurance purposes. The source category considered herein is solvent cleaning associated with medical devices, which may include solvent wipe cleaning of components and tooling for quality control and/or quality assurance purposes. Therefore, the requirements of this rule are not applicable to the source category of this BACT determination.

SBCAPCD Rule 321: Solvent Cleaning Machines and Solvent Cleaning (6/21/2012)[6]

The purpose of this rule is to reduce VOC emissions from solvent cleaning operations including wipe cleaning. This rule prescribes limits on permissible VOC content solvents depending on operation type. As an alternative to complying with the VOC limits, this rule allows higher VOC content if the operation is controlled by an approved emission control system which limits emissions to levels which would be achieved with a compliant solvent and with overall control efficiency of at least 85%. The applicable limits for operations associated with medical devices and pharmaceuticals and the alternative control system requirements are less stringent than those of SJVPACD Rule 4663.

Summary of Applicable Rules and Regulations:

The BAAQMD, SCAQMD, SMAQMD, SDAPCD, and SBCAPCD rulebooks were reviewed for requirements applicable to solvent wipe cleaning operations associated with medical device manufacturing. The requirements of SJVAPCD Rule 4663 at least as stringent as the requirements of other district rules.

[5] https://www.sdapcd.org/content/dam/sdapcd/documents/rules/current-rules/Rule-66.1.pdf
[6] https://www.ourair.org/wp-content/uploads/Rule321.pdf

C. Survey of Permitted Sources

The SJVAPCD currently has 2 active PTOs for a solvent wipe cleaning operations associated with medical device manufacturing[7]. Both of these operations utilize solvents which satisfy the applicable VOC content limits of Rule 4663; neither of these operations utilize control devices.

D. List of Control Options

Based on the survey of the above BACT determinations, rules and regulations, and District permitted operations, the following control options have been identified:

i. VOC

- 98% overall capture and control (full enclosure; thermal oxidation, activated carbon, or equivalent) (TF)
- 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent) (TF)
- Compliance SJVAPCD Rule 4663 (AIP)

Step 2 - Eliminate Technologically Infeasible Options

i. VOC

There are no technologically infeasible options listed in Step 1. All of the VOC emission control options under consideration are based on current BACT requirements, permitted operations, or common industrial technologies.

The VOC control options are:

- 98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent) (TF)
- 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent) (TF)
- Compliance with SJVAPCD Rule 4663 (AIP)

[7] A Permit Services database query identifying permits with Active status and equipment description containing “solvent wipe cleaning”.

Step 3 - Rank Remaining Control Technologies by Control effectiveness

i. VOC

Rank	Control Efficiency or Emission Rate	Achieved in Practice
1	98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent)	No
2	90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent)	No
3	Compliance with SJVAPCD Rule 4663	Yes

Step 4 - Cost Effectiveness Analysis

This is a proactive determination that is not part of a permitting action. Therefore, a cost effectiveness analysis is not necessary.

Step 5 - Select BACT

As discussed above, SJVAPCD District Rule 4663 is at least as stringent as SIP approved rules from other jurisdictions. Therefore, the BACT guideline proposed herein incorporates Rule 4663 requirements, by reference, for the Achieved in Practice standard. Additionally, this proposed guideline requires cost-effectiveness consideration of Technologically Feasible VOC control systems.

i. VOC

The following VOC emission control standard has been determined to be achieved in practice and is recommended as the Achieved in Practice requirement.

- Compliance SJVAPCD District Rule 4663

The following VOC emission control standards have been determined to be technologically feasible, but not achieved in practice. The described control technology is in accordance with previous BACT determinations from SJVAPCD and BAAQMD. No solvent wipe cleaning operations associated with medical device manufacturing operations were identified that satisfied the Rule

4663 VOC limits and utilized a control system. Therefore, at this time, these control technologies are recommended as a Technologically Feasible requirement.

- 98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent)
- 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent)

IV. Recommendation

Upon approval, adopt the proposed draft BACT guideline in Appendix A into the District's BACT Clearinghouse.

Appendices

Appendix A: Proposed BACT Guideline 4.10.5
Appendix B: BACT Guideline 4.10.5 (5/28/2020)

Appendix A
Proposed Draft BACT Guideline 4.7.5

San Joaquin Valley
Unified Air Pollution Control District

Best Available Control Technology (BACT) Guideline 4.10.5*

Emissions Unit: Solvent Wipe Cleaning – Medical Devices and Pharmaceuticals
Industry Type: Multiple

Equipment Rating: All **Last Update:** March 6, 2024

Pollutant	Achieved in Practice or contained in SIP	Technologically Feasible	Alternate Basic Equipment
NOx	N/A	N/A	
SOx	N/A	N/A	
VOC	Compliance with SJVAPCD Rule 4663	1) 98% overall capture and control (full enclosure (100% capture); thermal oxidation, activated carbon, or equivalent) 2) 90% overall capture and control (partial enclosure via fume hood or equivalent; thermal oxidation, activated carbon, or equivalent)	
PM10	N/A	N/A	

BACT is the most stringent control technique for the emissions unit and class of source. Control techniques that are not achieved in practice or contained in a state implementation plan must be cost effective as well as feasible. Economic analysis to demonstrate cost effectiveness is required for all determinations that are not achieved in practice or contained in an EPA approved State Implementation Plan.

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Appendix B
BACT Guideline 4.10.5 (5/28/2020)

San Joaquin Valley
Unified Air Pollution Control District

Best Available Control Technology (BACT) Guideline 4.10.5*

Last Update: 5/28/2020

Medical Grade Silicon Products - Wipe Cleaning Operation

Pollutant	Achieved in Practice or contained in the SIP	Technologically Feasible	Alternate Basic Equipment
VOC	Use of solvents with VOC content (less water and exempt compounds) of 7.2 lb/gal, or lower, and evaporative minimization methods, which include: - use of controlled flow dispensers (e.g. squeeze bottles) and - keeping all cloth/papers and solvent, which are not in active use, stored in closed containers	1) Capture and control using an enclosed booth and thermal/catalytic oxidation system 2) Capture and control using a hood and thermal/catalytic oxidation system	

BACT is the most stringent control technique for the emissions unit and class of source. Control techniques that are not achieved in practice or contained in a State Implementation Plan must be cost effective as well as feasible. Economic analysis to demonstrate cost effectiveness is required for all determinations that are not achieved in practice or contained in an EPA approved State Implementation Plan.

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