AIR AND RADIATION ADMINISTRATION
DRAFT PART 70 OPERATING PERMIT

DOCKET # 24-015-0212

COMPANY: Terumo Cardiovascular Systems

LOCATION: 125 Blue Ball Rd
Elkton, MD 21921

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MARYLAND DEPARTMENT OF THE ENVIRONMENT
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AIR QUALITY PERMITS PROGRAM

TITLE V – PART 70 OPERATING PERMIT PROGRAM OVERVIEW

Title V of the Clean Air Act (amended) requires each state to implement a federally enforceable operating permit program for major sources of air pollution. This program, the Part 70 Permit Program, also known as the Title V Permit Program, is designed to provide a comprehensive administrative document (a Part 70 Operating Permit) that identifies all air emissions sources at a given facility and the federal air quality regulations applicable to those sources. The permit establishes the methodology by which the owner/operator will demonstrate compliance, and includes testing, monitoring, record-keeping, and reporting requirements for each emissions source.

A Part 70 Operating Permit does not authorize new construction, and does not add any new emissions limitations, standards, or work practices on an affected facility. There may, however, be additional testing, record keeping, monitoring, and reporting requirements. A Part 70 Operating Permit is a five-year renewable permit. A responsible official for each facility subject to a Part 70 Operating Permit is required to annually certify compliance with each applicable requirement for that facility.

When an application for a Part 70 Operating Permit is received, the Department will complete a technical review of the application and will prepare a draft Part 70 Operating Permit and Fact Sheet. The Fact Sheet will explain the basis and technical analysis used by the Department to develop the federally enforceable permit conditions, including the required testing, monitoring, record keeping, and reporting provisions for each emissions unit at the permitted facility. The Fact Sheet will also include a description of the facility operations and the current compliance status with applicable requirements. If there are any discrepancies between the Part 70 Operating Permit application and the draft permit, the Fact Sheet will contain a discussion of the inconsistencies and the final resolution.

Public Participation Process

The Part 70 Operating Permit Program provides the public, adjacent states, and EPA the opportunity to review and submit comments on draft permits. The public may also request a public hearing on the draft permit.

The purpose of a public hearing is to give interested parties the opportunity to submit comments for the record which are germane to the draft federally enforceable permit conditions. Comments made at the hearing, or in writing to the Department during the comment period, should address errors and deficiencies in the permit such as unidentified emissions units, incorrect or deficient regulation citation, deficient record keeping, monitoring, reporting or testing requirements and unresolved compliance issues. After the public comment period has closed, the Department will review the formal testimony as part of the final review and prepare a Response to Comments document which will be sent to the EPA along with the draft Part 70 Operating Permit and Fact Sheet.

Testimony on state-only requirements will be kept on file at the Department as part of the formal record, however, state-only rules and regulations are not federally enforceable, and therefore are not within the scope of the EPA review. The Department will keep a record of the identity of the commenters, their statements, a summary of the issues raised during the public comment period, and the Response to Comments document for at least five years.

Citizen Petition to EPA to Object to Permit Issuance

Interested parties may petition the EPA to object to the Part 70 Permit if the EPA has not already objected, within 60 days after the 45-day EPA review period has ended. The petition period will be posted on the EPA website. The EPA will only consider objections to the federally enforceable provisions of the draft permit which were raised with reasonable specificity during the public comment period, unless: (1) the petitioner demonstrates that it was impractical to raise the objections within the public comment period, or (2) the grounds for the objection arose after the comment period. If the EPA agrees with the petition, the Department will reopen, revise, or revoke the permit as determined.

Applicant Objection to Permit Issuance and Recourse

If the applicant objects to the federally enforceable permit conditions contained in the issued Part 70 Operating Permit, the applicant has 15 days from receipt of the issued permit to request a contested case hearing. More information on that can be found in 40 CFR, Part 70, and COMAR 26.11.03.11.

MARYLAND DEPARTMENT OF THE ENVIRONMENT
AIR AND RADIATION ADMINISTRATION

NOTICE OF INTENT TO ISSUE PART 70 OPERATING PERMIT, OPPORTUNITY TO SUBMIT WRITTEN COMMENTS OR TO REQUEST A PUBLIC HEARING

The Maryland Department of the Environment, Air and Radiation Administration (ARA), has completed its review of the application for a renewal Part 70 Operating Permit submitted by Terumo Cardiovascular Systems Corporation. The facility includes multiple natural gas fed boilers, potting and coating processes, bonding operations, and cleaning operations.

The applicant is represented by:

Mr. Nick Begin, RSO, CSP
Manager, Environmental, Health and Safety
Terumo Cardiovascular Systems
125 Blue Ball Rd
Elkton, Maryland 21921

The Department has prepared a draft Part 70 Operating Permit for review and is now ready to receive public comment. A docket containing the application, draft permit, and supporting documentation is available for review on the Department's website, under the Air Quality Permitting Page's Title V link under "Draft Title V Permits" and may be viewed here:

https://tinyurl.com/DraftTitleV

Interested persons may submit written comments or request a public hearing on the draft permit. Written comments must be received by the Department no later than 30 days from the date of this notice. Requests for a public hearing must be submitted in writing and must also be received by the Department no later than 30 days from the date of this notice.

Comments and requests for a public hearing will be accepted by the Department if they raise issues of law or material fact regarding applicable requirements of Title V of the Clean Air Act, and/or regulations implementing the Title V Program in Maryland found in COMAR.

A Request for public hearing shall include the following:

1) The name, mailing address, and telephone number of the person making the request;

2) The names and addresses of any other persons for whom the person making the request if representing; and

3) The reason why a hearing is requested, including the air quality concern that forms the basis for the request and how this concern relates to the person making the request.

All written comments and requests for a public hearing should be directed to the attention of Ms. Shannon Heafey via email at Shannon.heafey@maryland.gov or by post at Air Quality Permits Program, Air and Radiation Administration, 1800 Washington Boulevard Suite 720, Baltimore, Maryland 21230-1720. Further information may be obtained by calling Ms. Shannon Heafey at (410) 537-4433.

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
125 Blue Ball Road, Elkton, MD 21921
PERMIT NO. 24-015-0212
PART 70 OPERATING PERMIT FACT SHEET

BACKGROUND

Terumo Cardiovascular Systems Corporation (TCVS) designs, manufactures, and sells products used during cardiac surgery. TCVS is located at 125 Blue Ball Road, Elkton, in Cecil County, Maryland. The major products produced at TCVS are the CAPIOX Oxygenators (OX), blood oxygenators used during open heart surgery. The facility operates under SIC Code 3841 (Surgical and Medical Instruments and Apparatus).

TCVS is adjacent and contiguous to Terumo Medical Corporation (TMC). The two plants are independently managed but are related entities by a common ultimate parent company, Terumo Corporation. Both facilities combined are considered an actual major source for VOC. Although both facilities are considered one emission source, each is independently managed. For this reason, both facilities are considered a separate premises by the Department and each maintains a separate Title V permit with the understanding that combined emissions from both plants must be considered when either plant is modified.

The following tables summarize the actual emissions from TMC and TCVS based on their Annual Emission Certification Reports:

Table 1: Actual Emissions – TCVS

Year	NO_x (TPY)	SO_x (TPY)	PM_{10} (TPY)	CO (TPY)	VOC (TPY)	Total HAP (TPY)
2016	1.6	0.01	0.03	1.4	25.9	8.3
2017	1.6	0.01	0.03	1.3	22.0	7.2
2018	1.7	0.01	0.03	1.4	19.6	7.5
2019	1.7	0.01	0.03	1.4	19.6	7.5
2020	1.4	0.01	0.03	1.2	25.0	7.9
2021	1.3	0.01	0.03	1.1	18.9	7.6
2022	1.4	0.01	0.03	1.2	25.5	8.3
2023	1.4	0.01	0.03	1.2	24.9	8.0

Table 2: Actual Emissions – TMC

Year	NO_x (TPY)	SO_x (TPY)	PM_{10} (TPY)	CO (TPY)	VOC (TPY)	Total HAP (TPY)
2016	1.4	0.01	0.03	1.2	15.7	0
2017	1.2	0.01	0.02	1.0	16.6	0
2018	1.8	0.01	0.03	1.5	18.6	0
2019	1.8	0.01	0.03	1.5	20.7	0

2020	1.9	0.01	0.04	1.6	21.7	0
2021	2.3	0.01	0.04	1.9	18.7	0
2022	2.7	0.02	0.05	2.2	18.3	0
2023	2.7	0.02	0.05	2.3	23.3	0

The major source thresholds for triggering Title V permitting requirements in Cecil County are 25 tons per year for VOC and NO_X, 100 tons per year for all other criteria pollutants, 10 tons per year for any single HAP, and 25 tons per year for any combination of HAPs. Since the actual VOC emissions from both plants are greater than the major source threshold, both plants are required to obtain a Title V – Part 70 Operating Permit under COMAR 26.11.03.01.

The Part 70 permit application for the facility was received by the Department on May 31, 2016. The application was deemed administratively complete on June 9, 2021. The Part 70 permit is a renewal of the current permit that expired on May 31, 2022. Since the prior Part 70 – Title V permit issued on June 1, 2017, there have been changes at the facility that required air permitting actions. Those changes are explained below.

Both plants combined are a synthetic minor source for HAP emissions. HAP emissions from both plants are limited in their respective permits. Facility wide HAP limits are required to ensure that the emissions from both plants do not exceed major source threshold levels.

APPLICABILITY OF FEDERAL REGULATIONS

TCVS maintains two (2) non-registered emergency generators (one powered by natural gas, the other propane) that are less than 500 brake horsepower. The Department does not require permits for emergency engines of this size as per COMAR 26.11.02.10E. The emergency generators will be subject to the requirements of 40 CFR Part 63 Subpart ZZZZ. The specific requirements are listed in the Insignificant Activities section of Title V – Part 70 Operating Permit.

There are no other source categories covered under NESHAP or NSPS regulations that apply to the processes at TCVS.

CAM APPLICABILITY

TCVS does not operate any control devices for emission control; therefore CAM requirements do not apply.

GREENHOUSE GAS (GHG) EMISSIONS

TCVS and TMC emit the following greenhouse gases (GHGs) related to Clean Air Act requirements: carbon dioxide, methane, and nitrous oxide. These GHGs originate from boilers and emergency generators at the premises. The facility has not triggered Prevention of Significant Deterioration (PSD) requirements for GHG emissions; therefore, there are no applicable GHG Clean Air Act requirements.

Emission certifications reports for the years 2019, 2020, 2021, 2022, and 2023, showed that the emissions of TMC and TCVS are below major source threshold (100,000tpy CO2e) for GHGs (see Tables below). The Permittee shall quantify facility wide GHG emissions and report them in accordance with Section 3 of the Part 70 permit.

The following tables summarize the actual emissions from TMC and TCVS based on Annual Emission Certification Reports:

Table 3: Summary of Greenhouse Gases Emissions – TCVS

GHG	**Conversion factor**	**2019** tpy CO_2e	**2020** tpy CO_2e	**2021** tpy CO_2e	**2022** tpy CO_2e	**2023** tpy CO_2e
Carbon dioxide CO_2	1	2065	1696	1600	1666	1650
Methane CH_4	25	0.04	0.03	0.03	0.03	0.03
Nitrous Oxide N_2O	300	0.04	0.03	0.03	0.03	0.03
Total GHG CO_{2eq}		**2078**	**1706**	**1610**	**1676**	**1660**

Table 4: Summary of Greenhouse Gases Emissions – TMC

GHG	**Conversion factor**	**2019** tpy CO_2e	**2020** tpy CO_2e	**2021** tpy CO_2e	**2022** tpy CO_2e	**2023** tpy CO_2e
Carbon dioxide CO_2	1	2135	2259	2713	3201	3246
Methane CH_4	25	0.04	0.04	0.05	0.06	0.06
Nitrous Oxide N_2O	300	0.04	0.04	0.05	0.06	0.06
Total GHG CO_{2eq}		**2148**	**2272**	**2729**	**3221**	**3266**

CHANGES AND MODIFICATIONS TO THE TITLE V PERMIT

The following emission units were removed from TCVS since the issuance of the last permit**:**

- EU-15 – One (1) Capiox Hand Assembly Area, manual bonding (ARA Registration No. 015-0212-5-0221) removed in 2019

- EU-19 – One (1) Arterial Filter Area, biopassive coating (ARA Registration No. 015-0212-6-0229) removed in 2017

- EU-31 – One (1) HB Smith natural gas-fired boiler rated at 1.3 MMBtu/hr (ARA Registration No. 015-0212-5-0133) was removed in 2020 and replaced with a like-kind unit.

The following emissions units were added/modified at TCVS since the issuance of the last permit:

- EU-31 – One (1) HB Smith natural gas-fired boiler rated at 1.30 MMBtu per hour (ARA Registration No. 015-0212-5-0207) installed in 2020.

- EU-7 – Two (2) registration updates were issued regarding the NX Oxygenator Process (ARA Registration No. 015-0212-6-0222) for an as-built change during construction and the addition of new urethane.

- EU-TBD – One (1) Centrifugal Pump Automated Assembly Machine (ARA Registration No. 015-0212-6-0374) installed in 2018.

- EU-17 and EU-25 – One (1) Capiox Reservoir Assembly Area, manual bonding (ARA Registration No. 015-0212-6-0224) and One (1) Tubing Pack Assembly Area, manual bonding (ARA Registration No. 015-0212-6-0217) modified in 2021 to allow for increased production.

EMISSION UNIT IDENTIFICATION

TCVS has identified the following emission units as being subject to Title V permitting requirements and having applicable requirements.

Emissions Unit Number	ARA Registration Number	Emissions Unit Name and Description	Date of Installation
EU-1	015-0212-5-0089	One (1) Cleaver Brooks natural gas-fired boiler rated at 2.0 MMBTU per hour used for space heat	1973
EU-30	015-0212-5-0126	One (1) Cleaver Brooks natural gas-fired boiler rated at 1.57 MMBTU per hour for process heat	2013
EU-31	015-0212-5-0207	One (1) HB Smith natural gas-fired boiler rated at 1.30 MMBTU per hour	2020
EU-7	015-0212-6-0222	One (1) Capiox Oxygenator (OX) Potting and Coating Area, biopassive coating	1997 modified in 2000 and 2017
EU-9	015-0212-6-0234	Capiox - Quick Disconnect Assembly Area, manual bonding	2000
EU-12	015-0212-6-0227	One (1) Venous Reservoir (VR) and Cardiotomy Reservoir (CR) Filter Dipping Area, biopassive coating	1997
EU-13	015-0212-6-0226	One (1) Capiox Cardiotomy Reservoir (CR) Potting/Assembly Area	1997
EU-17	015-0212-6-0224	One (1) Capiox Reservoir Assembly Area, manual bonding	1997 Modified in 2021
EU-18	015-0212-6-0228	One (1) Capiox Final Assembly Area, manual bonding and biopassive coating	1997
EU-20	015-0212-6-0216	Conducer (CON) Area with downdraft tables	2000
EU-21	015-0212-6-0231	One (1) Pump Assembly, manual bonding	2000

Emissions Unit Number	ARA Registration Number	Emissions Unit Name and Description	Date of Installation
EU-22	015-0212-6-0211	One (1) Flexible Venous Reservoir (FVR) Coating Line, manual bonding and biopassive coating	2004
EU-23	015-0212-6-0233	One (1) X-Coat Capiox/Connectors Area, biopassive coating	2001
EU-24	015-0212-6-0232	One (1) X-Coat Tubing Area, biopassive coating	2001
EU-25	015-0212-6-0217	One (1) Tubing Pack Assembly Area, manual bonding	2002 Modified in 2021
EU-26	015-0212-6-0255	One (1) CDI Assembly Area, manual bonding - HSAT	2005
EU-27	015-0212-6-0255	One (1) OPS Assembly Area, manual bonding	2005
EU-29	015-0212-6-0255	One (1) CDI Assembly Area, manual bonding - SHUNT	2005
EU-28	015-0121-6-0212	Facility Wide Cleaning Operations	1979
EU-32	015-0212-6-0312	One (1) Biological Safety Cabinet	2012
EU-33	015-0212-6-0338	One (1) SARNS 101 chemical manufacturing process	2014
TBD	015-0212-6-0374	One (1) Centrifugal Pump Automated Assembly Machine	2018

AN OVERVIEW OF THE PART 70 PERMIT

The Fact Sheet is an informational document. If there are any discrepancies between the Fact Sheet and the Part 70 permit, the Part 70 permit is the enforceable document.

Section I of the Part 70 Permit contains a brief description of the facility and an inventory list of the emissions units for which applicable requirements are identified in Section IV of the permit.

Section II of the Part 70 Permit contains the general requirements that relate to administrative permit actions. This section includes the procedures for renewing, amending, reopening, and transferring permits, the relationship to permits to construct and approvals, and the general duty to provide information and to comply with all applicable requirements.

Section III of the Part 70 Permit contains the general requirements for testing, record keeping and reporting; and requirements that affect the facility as a whole, such as open burning, air pollution episodes, particulate matter from construction and demolition activities, asbestos provisions, ozone depleting substance provisions, general conformity, and acid rain permit. This section includes the requirement to report excess emissions and deviations, to submit an annual emissions certification report and an annual compliance certification report, and results of sampling and testing.

Section IV of the Part 70 Permit identifies the emissions standards, emissions limitations, operational limitations, and work practices applicable to each emissions unit located at the facility. For each standard, limitation, and work practice, the permit identifies the basis upon which the Permittee will demonstrate compliance. The basis will include testing, monitoring, record keeping, and reporting requirements. The demonstration may include one or more of these methods.

Section V of the Part 70 Permit contains a list of insignificant activities. These activities emit very small quantities of regulated air pollutants and do not require a permit to construct or registration with the Department. For insignificant activities that are subject to a requirement under the Clean Air Act, the requirement is listed under the activity.

Section VI of the Part 70 Permit contains State-only enforceable requirements. Section VI identifies requirements that are not based on the Clean Air Act, but solely on Maryland air pollution regulations. These requirements generally relate to the prevention of nuisances and implementation of Maryland's Air Toxics Program.

REGULATORY REVIEW/TECHNICAL REVIEW/COMPLIANCE METHODOLOGY

Emission Unit (EU) EU-1 - One (1) Cleaver Brooks natural gas fired boiler rated at 2.0 MMBTU per hour used for space heat (ARA Registration No. 015-0212-5-0089)

Emission Unit (EU) EU-30 - One (1) Cleaver Brooks natural gas fired boiler rated at 1.57 MMBTU per hour for process heat. (ARA Registration No. 015-0212-5-0126)

Emission Unit (EU) EU-31 - One (1) HB Smith natural gas-fired boiler rated at 1.30 MMBTU per hour. (ARA Registration No. 015-0212-5-0207)

The boilers at the TCVS facility provide process and space heat. 40 CFR Part 60, Subpart Dc does not apply because although two of the boilers were installed after 1989 the rated heat input capacity of each boiler is less than 10 MMBtu per hour. There have been no modifications to these boilers since the initial permit issuance.

The boilers are permitted to burn only natural gas. Natural gas fired boilers are not subject to 40 CFR 63 Subpart JJJJJJ, the area source NESHAP for boilers. A permit condition limiting the boilers to burn only natural gas is included in the Title V permit.

TCVS (in combination with TMC) is a synthetic minor HAP source; therefore 40 CFR Part 63, Subpart DDDDD does not apply to the three (3) boilers. Subpart DDDDD only applies to boilers located at major sources of HAP.

Applicable Standards/Limits:

A. Visible Emissions Limitations

COMAR 26.11.09.05A(1), which limits visible emissions from any fuel burning equipment to 20 percent opacity other than water in an uncombined form.

Exceptions: COMAR 26.11.09.05A(3) establishes that “Section A(1) does not apply to emissions during load changing, soot blowing, start-up, or adjustments or occasional cleaning of control equipment if (a) the visible emissions are not

greater than 40 percent opacity; and (b) the visible emissions do not occur for more than 6 consecutive minutes in any 60 minute period."

Compliance Demonstration and Rationale for Periodic Monitoring for the Visible Emissions Limitations

To comply with these requirements, the Permittee must properly operate and maintain the boilers in a manner to prevent visible emissions. Boilers of this size that are properly maintained and operated will operate without visible emissions when burning natural gas. To verify proper operation and maintenance, the Permittee will maintain records of maintenance performed on the boilers to prevent visible emissions. However, if incidents of visible emissions are observed which are not allowable under the exceptions to COMAR visible emission regulations, then the Permittee is required under "Report of Excess Emissions and Deviations" Permit Condition 4, Section III to report the incidents. No additional periodic monitoring is necessary to demonstrate compliance.

B. Operational Requirement

The Permittee shall only burn natural gas unless the Permittee applies for and receives an approval or permit from the Department to burn an alternate fuel. **[Authority: COMAR 26.11.02.09A]**

Compliance Demonstration and Rationale for Periodic Monitoring for the Operational Requirement

To demonstrate compliance with these operational limits, the Permittee shall maintain records of the quantity and types of fuel burned in each boiler and submit the records with the required annual emissions certification report. These records are adequate to determine that the appropriate fuel was used in each boiler.

EU-7, EU-9, EU-12, EU-17, EU-18, E21 through EU-27, EU-29, EU-33, and EU-TBD

The CAPIOX product requires multiple process steps to produce the end product. These steps have been broken into separate ARA registration numbers and emission units for record keeping purposes. The majority of emissions from the production of CAPIOX oxygenators are from manual bonding and biopassive coating. The CAPIOX production processes consist of potting and biopassively coating of the parts, manual bonding the various components to the ports, potting

and biopassively coating various filters, and manual assembly of the manifold, reservoir, and final CAPIOX product (includes manual bonding).

The CAPIOX area was initially permitted under the premises-wide PTC issued on September 2, 2004 and was modified for a throughput increase under the most recent premises-wide PTC issued on April 9, 2021.

EU - 7: One (1) Capiox Oxygenator (OX) Potting and Coating Area, biopassive coating (ARA Registration No. 015-0212-6-0222)

EU - 9: One (1) Capiox - Quick Disconnect Assembly Area, manual bonding(ARA Registration No. 015-0212-6-0234)

EU - 12: Venous Reservoir (VR) and Cardiotomy Reservoir (CR) Filter Dipping Area, biopassive coating (ARA Registration No. 015-0212-6-0227)

EU - 17: One (1) Capiox Reservoir Assembly Area, manual bonding (ARA Registration No. 015-0212-6-0224)

EU - 18: One (1) Capiox Final Assembly Area, manual bonding and biopassive coating (ARA Registration No. 015-0212-6-0228)

EU - 21: One (1) Pump Assembly Area (ARA Registration No. 015-0212-6-0231). The Pump Assembly Area began initial operation in 2000. The centrifugal pump is a medical device that pumps blood during open-heart surgery. The process entails assembly of the pump, which includes manual bonding, and biopassively coating the pump and its components. The Pump Assembly was initially permitted under the premises-wide PTC issued on September 2, 2004. The Pump Assembly Area is covered under the most recent premises-wide PTC issued on April 9, 2021.

EU- 22: One (1) Flexible Venous Reservoir (FVR) Coating Line (ARA Registration No. 015-0212-6-0211). The FVR coating line began initial operation in 2004. The FVR is a medical device used to hold blood during open-heart surgery. The FVR coating line process entails manual bonding of PVC to polycarbonate ports and biopassively coating FVR molded parts. The coating line was added to the premises-wide PTC issued on September 2, 2004 and is covered under the most recent premises-wide PTC issued on April 9, 2021.

EU - 23: X-Coat Capiox/Connectors Area (ARA Registration No. 015-0212-6-0233). The X-Coat Capiox/Connectors Area began initial operation in 2001. This process entails biopassively coating Capiox connectors. The X-Coat Capiox/Connector Area was initially permitted under the premises-wide PTC issued on September 2, 2004 and is covered under the most recent premises-wide PTC issued on April 9, 2021.

EU - 24: X-Coat Tubing Area (ARA Registration No. 015-0212-6-0232). The X-Coat Tubing Area began initial operation in 2001. This process entails biopassively coating PVC tubing. The X-Coat Tubing Area was initially permitted under the premises-wide PTC issued on September 2, 2004 and is covered under the most recent premises-wide PTC issued on April 9, 2021.

EU - 25: Tubing Pack Assembly Area (ARA Registration No. 015-0212-6-0217). The Tubing Pack Assembly Area began initial operation in 2002. The tube packs are assemblies of medicals devices. The process entails manual bonding of connectors to PVC tubing. The Tubing Pack Area was initially permitted under the premises-wide PTC issued on September 2, 2004 and was modified for a throughput increase under the most recent premises-wide PTC issued on April 9, 2021.

EU – 26 and EU – 29: CDI Assembly Area, HSAT and SHUNT (ARA Registration No. 015-0212-6-0255). The CDI Assembly Area began initial operation in 2005. The CDI is a connector device with a sensor connection port used for continuous blood gas monitoring during open-heart survey. The CDI process entails manual bonding of a small magnet to the top of the unit, applying a UV curing adhesive, and curing the unit in a UV oven. Other parts are bonded using a UV curing adhesive and silicone mixture applied by an XYZ machine and cured in a second UV oven.

EU - 27: The OPS process (ARA Registration No. 015-0212-6-0255) entails lubricating the unit with silicone, bonding with a UV curing adhesive, and curing in a UV oven. The CDI/OPS Assembly Area is covered under the most recent premises-wide PTC issued on April 9, 2021.

EU - 33: One (1) SARNS 101 chemical manufacturing process (ARA Registration No. 015-0212-6-0338). This process began operation in 2014. The SARNS 101 chemical manufacturing process combines two chemicals and the finished product is used for binding plastics at an offsite location.

EU-TBD: One (1) Centrifugal Pump Automated Assembly Machine (ARA Registration No. 015-0212-6-0374) installed in 2018 and covered under the most recent premises-wide PTC issued on April 9, 2021.

Applicable Standards/Limits

A. Control of VOC

COMAR 26.11.19.31, which requires that the Permittee minimize VOC emissions from medical device manufacturing for premises that emit or have

the potential to emit, 100 pounds or more per day of VOC emissions from all medical device manufacturing installations.

Compliance Demonstration for the Control of VOC

TCVS shall do the following to demonstrate compliance with COMAR 26.11.19.31 unless the Permittee uses a Department approved alternative method of compliance or alternative control technology that achieves an equivalent or better level of VOC control:

a. Provide and maintain appropriately designed VOC impermeable covers on dip pots used for manual bonding operations when not in use;

b. Upon request of the Department, participate in the evaluation of new or innovative designs or VOC material substitutions to minimize the use of solvent bonds for medical device manufacturing;

c. Use an enclosed system to apply biopassive coating to fully assembled medical devices; and

d. Apply biopassive coating to individual medical device components only when it is not feasible to coat medical devices in assembled form.

[Authority: COMAR 26.11.19.31D]

In addition, before coating individual components under COMAR 26.11.19.31D(1)(d), the Permittee shall submit to the Department for review and approval, a report documenting the technical and economic justification for coating components individually. **[Authority: COMAR 26.11.19.31E]**

Before using an alternative method of compliance or control technology as allowed under COMAR 26.11.19.31D(2), the Permittee shall submit to the Department for review and approval, a proposal to use such an alternative method of compliance or control technology. **[Authority: COMAR 26.11.19.31F]**

The Permittee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information:

(1) Monthly records of the amount of materials used and the amount of material waste generated for each registered process area.

(2) Material Safety Data Sheets (MSDS) for all materials used.

[Authority: COMAR 26.11.03.06C and ARA Permit to Construct issued on 04/09/2021]

Rationale for Periodic Monitoring Strategy for Control of VOC

COMAR 26.11.19.31 outlines specific methods that the Permittee must perform to demonstrate compliance with this regulation. The Permittee uses covers on all dip pots used for manual bonding. Biopassive coating is applied to fully assembled devices in an enclosed system or to individual devices only when it is not feasible to coat medical devices in assembled form. No periodic monitoring is required.

Other Emission Units

EU-13, EU-20, EU-28, and EU-32 are emission units that emit little to no VOC. The emission units do not use manual bonding or biopassive coating and are not considered fixed needle syringe or hypodermic needle processes. There are not specific VOC requirements in the medical device manufacturing VOC RACT of COMAR 26.11.19.31 for these emission units. These sources are subject to the good operating practices and VOC leak requirements in COMAR 26.11.19.02I and COMAR 26.11.19.16, which apply facility wide. Therefore, the requirements for these sources are included in the General Facility emission unit table of the Title V permit.

Emission Unit (EU- General Facility)

The General Facility is subject to the good operating practices and VOC leak requirements in COMAR 26.11.19.02I and COMAR 26.11.19.16, which apply facility wide.

Applicable Standards/Limits

A. Facility Wide HAP Limitations

1. Facility wide HAP emissions shall be less than the following limits:

   a. 10 tons in any rolling 12-month period for any single HAP; and

   b. 25 tons in any rolling 12-month period for the total combination of all HAP.

2. Facility wide emissions shall include total emissions from both the TMC and TCVS combined. **[Authority: Premises-wide Permit to Construct issued on 04/09/2021]**

Compliance Demonstration for HAP Limitations

The Permittee shall keep the following records on-site:

1. Facility wide individual HAP emissions in tons per month per individual HAP and the total tons for the previous 12 months for each individual HAP.

2. Facility wide total HAP emissions in tons per month and the total tons for the previous 12 months.

[Authority: COMAR 26.11.03.06C]

Rationale for Periodic Monitoring Strategy for HAP Limitations

Required records of HAP emissions on a monthly basis and total HAP emissions for the previous 12-month period are sufficient to demonstrate that the facility wide HAP emissions are less than major source thresholds.

B. Control of VOC (good operating practices and VOC leak requirements)

1. COMAR 26.11.19.02I, which requires the Permittee to implement good operating practices to minimize Volatile Organic Compound (VOC) emissions into the atmosphere.

2. COMAR 26.11.19.16C, which requires the Permittee to minimize leaks from VOC equipment and their components, including process equipment, storage tanks, pumps, compressors, valves, flanges and other pipeline fittings, pressure relief valves, process drains, and open-ended pipes.

Compliance Demonstration for the Control of VOC

To comply with COMAR 26.11.19.02I, the Permittee shall establish “good operating practices” for the facility in writing, and implement the practices at the facility. The “good operating practices” shall include provisions for training operators on methods to minimize VOC emissions at the facility, and provisions for minimizing VOC emissions from clean-up and storage operations, including maintaining covers on containers of VOC. The Permittee shall also display the “good operating practices” documents in clear view for all operators that work with these types of VOC emitting process areas or include them in operator training.

To comply with COMAR 26.11.19.16, the Permittee shall conduct monthly VOC leak inspections of all equipment and their components that may cause leaks of

VOC. The Permittee is also required to tag any leaks discovered and repair the leak within the guidelines specified in COMAR 26.11.19.16. Logs of the leak inspections must be kept and made available to the Department upon request.

Rationale for Periodic Monitoring Strategy for the Control of VOC

COMAR 26.11.19.02I and COMAR 26.11.19.16 outline specific methods to demonstrate compliance with each of these regulations. By establishing and implementing "good operating practices" in writing and by conducting monthly VOC leak inspections, the Permittee is able to demonstrate that they are minimizing VOC emissions as required by COMAR 26.11.19.02I and COMAR 26.11.19.16. No additional periodic monitoring is required.

COMPLIANCE SCHEDULE

TCVS is currently in compliance with all applicable air quality regulations.

TITLE IV – ACID RAIN

TCVS is not subject to the Acid Rain Program requirements.

TITLE VI – OZONE DEPLETING SUBSTANCES

TCVS is subject to Title VI requirements for ozone depleting substances (40 CFR 82, Subpart F).

SECTION 112(r) – ACCIDENTAL RELEASE

TCVS is not subject to the requirements of Section 112(r).

PERMIT SHIELD

TCVS requested that a permit shield be expressly included in the Permittee's Part 70 permit. Permit shields are granted on an emission unit by emission unit basis. If an emission unit is covered by a permit shield, a permit shield statement will follow the emission unit table in Section IV - Plant Specific Conditions of the permit. In this case, a permit shield was granted for each emission unit covered by the permit.

INSIGNIFICANT ACTIVITIES

This section provides a list of insignificant emissions units that were reported in the Title V permit application. The applicable Clean Air Act requirements, if any, are listed below the insignificant activity.

(1) No. 7 Fuel burning equipment using gaseous fuels or no. 1 or no. 2 fuel oil, and having a heat input less than 1,000,000 Btu (1.06 gigajoules) per hour;

The following equipment is subject to the requirements below:

(a) One (1) natural gas fired water heater rated at 199,000 Btu/Hr.

(b) Two (2) natural gas fired space heaters rated at 800,000 Btu/Hr.

(c) Two (2) natural gas fired space heaters rated at 150,000 Btu/Hr.

(d) One (1) natural gas fired furnace rated at 625,000 Btu/Hr.

(e) One (1) natural gas fired furnace rated at 313,000 Btu/Hr

COMAR 26.11.09.05A(1), which establishes that the Permittee may not cause or permit the discharge of emissions from any fuel burning equipment, other than water in an uncombined form, which is greater than 20 percent opacity.

Exceptions: COMAR 26.11.09.05A(2) does not apply to emissions during load changing, soot blowing, start-up, or adjustments or occasional cleaning of control equipment if:

(a) The visible emissions are not greater than 40 percent opacity; and

(b) The visible emissions do not occur for more than 6 consecutive minutes in any sixty minute period.

(2) No. 2 Stationary internal combustion engines with an output less than 500 brake horsepower (373 kilowatts) and which are not used to generate electricity for sale or for peak or load shaving;

The one (1) natural gas fired emergency lighting generator rated at 241 horsepower (HP) and the one (1) propane fired emergency lighting generator rated at 240 HP are subject to the following requirements:

(a) COMAR 26.11.09.05E(2), Emissions During Idle Mode: The Permittee may not cause or permit the discharge of emissions from any engine, operating at idle, greater than 10 percent opacity.

(b) COMAR 26.11.09.05E(3), Emissions During Operating Mode: The Permittee may not cause or permit the discharge of emissions from any engine, operating at other than idle conditions, greater than 40 percent opacity.

(c) Exceptions:

(i) COMAR 26.11.09.05E(2) does not apply for a period of 2 consecutive minutes after a period of idling of 15 consecutive minutes for the purpose of clearing the exhaust system.

(ii) COMAR 26.11.09.05E(2) does not apply to emissions resulting directly from cold engine start-up and warm-up for the following maximum periods:

(a) engines that are idled continuously when not in service: 30 minutes

(b) all other engines: 15 minutes.

(iii) COMAR 26.11.09.05B(2) & (3) do not apply while maintenance, repair or testing is being performed by qualified mechanics.

The one (1) natural gas fired emergency lighting generator rated at 241 horsepower (HP) and the one (1) propane fired emergency lighting generator rated at 240 HP are subject to the following requirements of 40 CFR Part 63 Subpart ZZZZ. Some requirements are incorporated by reference.

(a) 40 CFR, §63.6603, Table 2d, which establishes maintenance, and inspection requirements for the engines as follows:
   a) Change oil and filter every 500 hours of operation or annually, whichever comes first;
   b) Inspect air cleaner every 1,000 hours of operation or annually, whichever comes first;
   c) Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary.

(b) 40 CFR, §63.6625(e), (f), (h), (j) which establish work, operation or management practices for the engines.

(c) 40 CFR, §63.6605(a) which requires continuous compliance with all applicable emission limitations and operating limitations of the subpart.

(d) 40 CFR, §63.6605(b) which requires that the engines be maintained in a manner consistent with safety and good air pollution control practices for minimizing emissions.

(e) 40 CFR, §63.6640(a) which requires that the Permittee demonstrate continuous compliance with each emission limitation and operating limitation in Table 2d of the subpart that apply according to methods specified in Table 6 of this subpart.

(f) 40 CFR, §63.6640(b) which requires that the Permittee report each instance in which you did not meet each emission limitation or operating limitation in Table 2d to this subpart that apply to you. These instances are deviations from the emission and operating limitations in this subpart. These deviations must be reported according to the requirements in 40 CFR, Part 63.6650.

(g) 40 CFR, §63.6640(f) requires that that the emergency RICE be operated according to the following requirements:

   (i) There is no time limit on the use of emergency stationary RICE in emergency situations;

(ii) You may operate your emergency stationary RICE for the purpose of maintenance checks and readiness testing, provided that the tests are recommended by Federal, State or local government, the manufacturer, the vendor, or the insurance company associated with the engine. Maintenance checks and readiness testing of such units is limited to 100 hours per year; and

(iii) You may operate your emergency stationary RICE up to 50 hours per year in non-emergency situations.

(h) 40 CFR, §63. 6655(a)(5) which requires that the Permittee keep the records of actions taken during periods of malfunction to minimize emissions in accordance with 40 CFR, Part 63.6605(b).

(i) 40 CFR, §63. 6655(d) which requires that the Permittee keep the records required in Table 6 of this subpart to show continuous compliance with each applicable emission or operating limitation.

(j) 40 CFR, §63. 6655(e) which requires that the Permittee keep records of the maintenance conducted on the stationary RICE in order to demonstrate that it was operated and maintained according to an approved maintenance plan (if applicable).

(k) 40 CFR, §63. 6655(f) which requires that the Permittee keep records of the hours of operation of the engine that is recorded through the non-resettable hour meter. The owner or operator must document how many hours are spent for emergency operation; including what classified the operation as emergency and how many hours are spent for non-emergency operation.

(l) The Permittee shall report to the Department any failure to perform the required management practice under which the risk of performing the management practice on the required schedule was deemed unacceptable. **[Authority: Footnote 2 of Table 2d in 40 CFR 63 Subpart ZZZZ]**

(m) The Permittee shall comply with all applicable requirements listed in Table 8 - General Provisions of 40 CFR part 63 Subpart ZZZZ.

(3) ✓ Space heaters utilizing direct heat transfer and used solely for comfort heat;

(4) ✓ Water cooling towers and water cooling ponds unless used for evaporative cooling of water from barometric jets or barometric condensers, or used in conjunction with an installation requiring a permit to operate;

(5) No. 1 Unheated VOC dispensing containers or unheated VOC rinsing containers of 60 gallons (227 liters) capacity or less;

The 30 gallon degreaser is subject to COMAR 26.11.19.09D, which requires that the Permittee control emissions of volatile organic compounds (VOC) from cold degreasing operations by meeting the following requirements:

(a) COMAR 26.11.19.09D(2)(b), which establishes that the Permittee shall not use any VOC degreasing material that exceeds a vapor pressure of 1 mm Hg at 20 ° C;

(b) COMAR 26.11.19.09D(3)(a—d), which requires that the Permittee implement good operating practices designed to minimize spills and evaporation of VOC degreasing material. These practices, which shall be established in writing and displayed such that they are clearly visible to operators, shall include covers (including water covers), lids, or other methods of minimizing evaporative losses, and reducing the time and frequency during which parts are cleaned;

(c) COMAR 26.11.19.09D(4), which prohibits the use of any halogenated VOC for cold degreasing.

The Permittee shall maintain on site for at least five (5) years, and shall make available to the Department upon request, the following records of operating data:

(a) Monthly records of the total VOC degreasing materials used; and

(b) Written descriptions of good operating practices designed to minimize spills and evaporation of VOC degreasing materials.

(6) Containers, reservoirs, or tanks used exclusively for:

(a) ✓ Storage of butane, propane, or liquefied petroleum, or natural gas;

(b) <700 The storage of VOC normally used as solvents, diluents, thinners, inks, colorants, paints, lacquers, enamels, varnishes, liquid resins, or other surface coatings and having individual capacities of 2,000 gallons (7.6 cubic meters) or less;

(7) ✓ First aid and emergency medical care provided at the facility, including related activities such as sterilization and medicine preparation used in support of a manufacturing or production process;

(8) ✓ Comfort air conditioning subject to requirements of Title VI of the Clean Air Act;

(9) ✓ Natural draft hoods or natural draft ventilators that exhaust air pollutants into the ambient air from manufacturing/industrial or commercial processes; and

(10) ✓ Laboratory fume hoods and vents.

STATE ONLY ENFORCEABLE REQUIREMENTS

The Permittee is subject to the following State-only enforceable requirements:

1. Applicable Regulations:

(A) COMAR 26.11.06.08 and 26.11.06.09, which generally prohibit the discharge of emissions beyond the property line in such a manner that a nuisance or air pollution is created.

(B) COMAR 26.11.15.05, which requires that the Permittee implement "Best Available Control Technology for Toxics" (T – BACT) to control emissions of toxic air pollutants.

(C) COMAR 26.11.15.06, which prohibits the discharge of toxic air pollutants to the extent that such emissions will unreasonably endanger human health.

2. Record Keeping and Reporting:

The Permittee shall submit to the Department, by April 1 of each year during the term of this permit, a written certification of the results of an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year. The analysis shall include either:

(i) a statement that previously submitted compliance demonstrations for emissions of toxic air pollutants remain valid; or

(ii) a revised compliance demonstration, developed in accordance with requirements included under COMAR 26.11.15 & 16, that accounts for changes in operations, analytical methods, emissions determinations, or other factors that have invalidated previous demonstrations.

DRAFT PERMIT

Wes Moore Serena McIlwain

Air and Radiation Administration

1800 Washington Boulevard, Suite 720
Baltimore, MD 21230

☐ Construction Permit ☒ Part 70 Operating Permit

PERMIT NO.:
24-015-0212

DATE ISSUED:
[TBD]

PERMIT FEE:
To Be Paid in Accordance with COMAR 26.11.02.19B

EXPIRATION DATE:
May 31, 202X

LEGAL OWNER & ADDRESS
Terumo Cardiovascular Systems Corporation
125 Blue Ball Rd
Elkton, Maryland 21921

Attention: Nick Begin, EHS Manager

SITE
Terumo Cardiovascular Systems Corporation
125 Blue Ball Rd
Elkton, MD 21921
AI # 13158

SOURCE DESCRIPTION

Medical device manufacturing facility consisting of assembly lines with fume hoods, coating lines and boilers.

This source is subject to the conditions described on the attached pages.

Program Manager

Director, Air and Radiation Administration

TERUMO CARDIOVASCULAR SYSTEMS
125 BLUE BALL ROAD
ELKTON, MARYLAND 21921
DRAFT PART 70 OPERATING PERMIT NO. 24-015-0212

SECTION I SOURCE IDENTIFICATION

1. DESCRIPTION OF FACILITY

Terumo Cardiovascular Systems Corporation (TCVS) designs, manufactures, and sells products used during cardiac surgery. TCVS is located at 125 Blue Ball Road, Elkton, Maryland in Cecil County. The major products produced at TCVS are the CAPIOX Oxygenators (OX), blood oxygenators used during open heart surgery. The facility operates under SIC Code 3841 (Surgical and Medical Instruments and Apparatus).

TCVS is adjacent and contiguous to Terumo Medical Corporation (TMC). The two plants are independently managed but are related entities by a common ultimate parent company, Terumo Corporation. Both facilities combined are considered an actual major source for VOC. Although both facilities are considered one emission source, each is independently managed. For this reason, both facilities are considered a separate premises by the Department and each maintains a separate Title V permit with the understanding that combined emissions from both plants must be considered when either plant is modified.

2. FACILITY INVENTORY LIST

Emissions Unit Number	ARA Registration Number	Emissions Unit Name and Description	Date of Installation
EU-1	015-0212-5-0089	One (1) Cleaver Brooks natural gas-fired boiler rated at 2.0 MMBTU per hour used for space heat	1973
EU-30	015-0212-5-0126	One (1) Cleaver Brooks natural gas-fired boiler rated at 1.57 MMBTU per hour for process heat	2013
EU-31	015-0212-5-0207	One (1) HB Smith natural gas-fired boiler rated at 1.30 MMBTU per hour	2020
EU-7	015-0212-6-0222	One (1) Capiox Oxygenator (OX) Potting and Coating Area, biopassive coating	1997 modified in 2000 and 2017
EU-9	015-0212-6-0234	Capiox - Quick Disconnect Assembly Area, manual bonding	2000

Emissions Unit Number	ARA Registration Number	Emissions Unit Name and Description	Date of Installation
EU-12	015-0212-6-0227	One (1) Venous Reservoir (VR) and Cardiotomy Reservoir (CR) Filter Dipping Area, biopassive coating	1997
EU-13	015-0212-6-0226	One (1) Capiox Cardiotomy Reservoir (CR) Potting/Assembly Area	1997
EU-17	015-0212-6-0224	One (1) Capiox Reservoir Assembly Area, manual bonding	1997 Modified in 2021
EU-18	015-0212-6-0228	One (1) Capiox Final Assembly Area, manual bonding and biopassive coating	1997
EU-20	015-0212-6-0216	Conducer (CON) Area with downdraft tables	2000
EU-21	015-0212-6-0231	One (1) Pump Assembly, manual bonding	2000
EU-22	015-0212-6-0211	One (1) Flexible Venous Reservoir (FVR) Coating Line, manual bonding and biopassive coating	2004
EU-23	015-0212-6-0233	One (1) X-Coat Capiox/Connectors Area, biopassive coating	2001
EU-24	015-0212-6-0232	One (1) X-Coat Tubing Area, biopassive coating	2001
EU-25	015-0212-6-0217	One (1) Tubing Pack Assembly Area, manual bonding	2002 Modified in 2021
EU-26	015-0212-6-0255	One (1) CDI Assembly Area, manual bonding - HSAT	2005
EU-27	015-0212-6-0255	One (1) OPS Assembly Area, manual bonding	2005
EU-29	015-0212-6-0255	One (1) CDI Assembly Area, manual bonding - SHUNT	2005

Emissions Unit Number	ARA Registration Number	Emissions Unit Name and Description	Date of Installation
EU-28	015-0121-6-0212	Facility Wide Cleaning Operations	1979
EU-32	015-0212-6-0312	One (1) Biological Safety Cabinet	2012
EU-33	015-0212-6-0338	One (1) SARNS 101 chemical manufacturing process	2014
TBD	015-0212-6-0374	One (1) Centrifugal Pump Automated Assembly Machine	2018

SECTION II GENERAL CONDITIONS

1. DEFINITIONS

[COMAR 26.11.01.01] and [COMAR 26.11.02.01]

The words or terms in this Part 70 permit shall have the meanings established under COMAR 26.11.01 and .02 unless otherwise stated in this permit.

2. ACRONYMS

ARA	Air and Radiation Administration
BACT	Best Available Control Technology
Btu	British thermal unit
CAA	Clean Air Act
CAM	Compliance Assurance Monitoring
CEM	Continuous Emissions Monitor
CFR	Code of Federal Regulations
CO	Carbon Monoxide
COMAR	Code of Maryland Regulations
EPA	United States Environmental Protection Agency
FR	Federal Register
gr	grains
HAP	Hazardous Air Pollutant
MACT	Maximum Achievable Control Technology
MDE	Maryland Department of the Environment
MVAC	Motor Vehicle Air Conditioner
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NO_x	Nitrogen Oxides
NSPS	New Source Performance Standards
NSR	New Source Review
OTR	Ozone Transport Region
PM	Particulate Matter
PM10	Particulate Matter with Nominal Aerodynamic Diameter of 10 micrometers or less
ppm	parts per million
ppb	parts per billion
PSD	Prevention of Significant Deterioration
PTC	Permit to construct
PTO	Permit to operate (State)

SIC	Standard Industrial Classification
SO_2	Sulfur Dioxide
TAP	Toxic Air Pollutant
tpy	tons per year
VE	Visible Emissions
VOC	Volatile Organic Compounds

3. EFFECTIVE DATE

The effective date of the conditions in this Part 70 permit is the date of permit issuance, unless otherwise stated in the permit.

4. PERMIT EXPIRATION

[COMAR 26.11.03.13B(2)]

Upon expiration of this permit, the terms of the permit will automatically continue to remain in effect until a new Part 70 permit is issued for this facility provided that the Permittee has submitted a timely and complete application and has paid applicable fees under COMAR 26.11.02.16.

Otherwise, upon expiration of this permit the right of the Permittee to operate this facility is terminated.

5. PERMIT RENEWAL

[COMAR 26.11.03.02B(3)] and [COMAR 26.11.03.02E]

The Permittee shall submit to the Department a completed application for renewal of this Part 70 permit at least 12 months before the expiration of the permit. Upon submitting a completed application, the Permittee may continue to operate this facility pending final action by the Department on the renewal.

The Permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall submit such supplementary facts or corrected information no later than 10 days after becoming aware that this occurred. The Permittee shall also provide additional information as necessary to address any requirements that become applicable to the facility after the date a completed

application was submitted, but prior to the release of a draft permit. This information shall be submitted to the Department no later than 20 days after a new requirement has been adopted.

6. CONFIDENTIAL INFORMATION

[COMAR 26.11.02.02G]

In accordance with the provisions of the State Government Article, Sec. 10-611 et seq., Annotated Code of Maryland, all information submitted in an application shall be considered part of the public record and available for inspection and copying, unless the Permittee claims that the information is confidential when it is submitted to the Department. At the time of the request for inspection or copying, the Department will make a determination with regard to the confidentiality of the information. The Permittee, when requesting confidentiality, shall identify the information in a manner specified by the Department and, when requested by the Department, promptly provide specific reasons supporting the claim of confidentiality. Information submitted to the Department without a request that the information be deemed confidential may be made available to the public. Subject to approval of the Department, the Permittee may provide a summary of confidential information that is suitable for public review. The content of this Part 70 permit is not subject to confidential treatment.

7. PERMIT ACTIONS

[COMAR 26.11.03.06E(3)] and [COMAR 26.11.03.20(A)]

This Part 70 permit may be revoked or reopened and revised for cause. The filing of an application by the Permittee for a permit revision or renewal; or a notification of termination, planned changes or anticipated noncompliance by the facility, does not stay a term or condition of this permit.

The Department shall reopen and revise, or revoke the Permittee's Part 70 permit under the following circumstances:

a. Additional requirements of the Clean Air Act become applicable to this facility and the remaining permit term is 3 years or more;

b. The Department or the EPA determines that this Part 70 permit contains a material mistake, or is based on false or inaccurate information supplied by or on behalf of the Permittee;

c. The Department or the EPA determines that this Part 70 permit must be revised or revoked to assure compliance with applicable requirements of the Clean Air Act; or

d. Additional requirements become applicable to an affected source under the Federal Acid Rain Program.

8. PERMIT AVAILABILITY

[COMAR 26.11.02.13G]

The Permittee shall maintain this Part 70 permit in the vicinity of the facility for which it was issued, unless it is not practical to do so, and make this permit immediately available to officials of the Department upon request.

9. REOPENING THE PART 70 PERMIT FOR CAUSE BY THE EPA

[COMAR 26.11.03.20B]

The EPA may terminate, modify, or revoke and reissue a permit for cause as prescribed in 40 CFR §70.7(g)

10. TRANSFER OF PERMIT

[COMAR 26.11.02.02E]

The Permittee shall not transfer this Part 70 permit except as provided in COMAR 26.11.03.15.

11. REVISION OF PART 70 PERMITS – GENERAL CONDITIONS

[COMAR 26.11.03.14] and [COMAR 26.11.03.06A(8)]

a. The Permittee shall submit an application to the Department to revise this Part 70 permit when required under COMAR 26.11.03.15 -.17.

b. When applying for a revision to a Part 70 permit, the Permittee shall comply with the requirements of COMAR 26.11.03.02 and .03 except that the application for a revision need include only information listed that is related to the proposed change to the source and revision to the permit. This information shall be sufficient to evaluate the proposed change and to determine whether it will comply with all applicable requirements of the Clean Air Act.

c. The Permittee may not change any provision of a compliance plan or schedule in a Part 70 permit as an administrative permit amendment or as a minor permit modification unless the change has been approved by the Department in writing.

d. A permit revision is not required for a change that is provided for in this permit relating to approved economic incentives, marketable permits, emissions trading, and other similar programs.

12. SIGNIFICANT PART 70 OPERATING PERMIT MODIFICATIONS

[COMAR 26.11.03.17]

The Permittee may apply to the Department to make a significant modification to its Part 70 Permit as provided in COMAR 26.11.03.17 and in accordance with the following conditions:

a. A significant modification is a revision to the federally enforceable provisions in the permit that does not qualify as an administrative permit amendment under COMAR 26.11.03.15 or a minor permit modification as defined under COMAR 26.11.03.16.

b. This permit does not preclude the Permittee from making changes, consistent with the provisions of COMAR 26.11.03, that would make the permit or particular terms and conditions of the permit irrelevant, such as by shutting down or reducing the level of operation of a source or of an emissions unit within the source. Air pollution control equipment shall not be shut down or its level of operation reduced if doing so would violate any term of this permit.

c. Significant permit modifications are subject to all requirements of COMAR 26.11.03 as they apply to permit issuance and renewal,

including the requirements for applications, public participation, and review by affected states and EPA, except:

(1) An application need include only information pertaining to the proposed change to the source and modification of this permit, including a description of the change and modification, and any new applicable requirements of the Clean Air Act that will apply if the change occurs;

(2) Public participation, and review by affected states and EPA, is limited to only the application and those federally enforceable terms and conditions of the Part 70 permit that are affected by the significant permit modification.

d. As provided in COMAR 26.11.03.15B(5), an administrative permit amendment may be used to make a change that would otherwise require a significant permit modification if procedures for enhanced preconstruction review of the change are followed that satisfy the requirements of 40 CFR 70.7(d)(1)(v).

e. Before making a change that qualifies as a significant permit modification, the Permittee shall obtain all permits-to-construct and approvals required by COMAR 26.11.02.

f. The Permittee shall not make a significant permit modification that results in a violation of any applicable requirement of the Clean Air Act.

g. The permit shield in COMAR 26.11.03.23 applies to a final significant permit modification that has been issued by the Department, to the extent applicable under COMAR 26.11.03.23.

13. MINOR PERMIT MODIFICATIONS

[COMAR 26.11.03.16]

The Permittee may apply to the Department to make a minor modification to the federally enforceable provisions of this Part 70 permit as provided in COMAR 26.11.03.16 and in accordance with the following conditions:

a. A minor permit modification is a Part 70 permit revision that:

(1) Does not result in a violation of any applicable requirement of the Clean Air Act;

(2) Does not significantly revise existing federally enforceable monitoring, including test methods, reporting, record keeping, or compliance certification requirements except by:

(a) Adding new requirements,

(b) Eliminating the requirements if they are rendered meaningless because the emissions to which the requirements apply will no longer occur, or

(c) Changing from one approved test method for a pollutant and source category to another;

(3) Does not require or modify a:

(a) Case-by-case determination of a federally enforceable emissions standard,

(b) Source specific determination for temporary sources of ambient impacts, or

(c) Visibility or increment analysis;

(4) Does not seek to establish or modify a federally enforceable permit term or condition for which there is no corresponding underlying applicable requirement of the Clean Air Act, but that the Permittee has assumed to avoid an applicable requirement to which the source would otherwise be subject, including:

(a) A federally enforceable emissions standard applied to the source pursuant to COMAR 26.11.02.03 to avoid classification as a Title I modification; and

(b) An alternative emissions standard applied to an emissions unit pursuant to regulations promulgated under Section 112(i)(5) of the Clean Air Act

(5) Is not a Title I modification; and

(6) Is not required under COMAR 26.11.03.17 to be processed as a significant modification to this Part 70 permit.

b. Application for a Minor Permit Modification

The Permittee shall submit to the Department an application for a minor permit modification that satisfies the requirements of COMAR 26.11.03.03 which includes the following:

(1) A description of the proposed change, the emissions resulting from the change, and any new applicable requirements that will apply if the change is made;

(2) The proposed minor permit modification;

(3) Certification by a responsible official, in accordance with COMAR 26.11.02.02F, that:

(a) The proposed change meets the criteria for a minor permit modification, and

(b) The Permittee has obtained or applied for all required permits-to-construct required by COMAR 26.11.03.16 with respect to the proposed change;

(4) Completed forms for the Department to use to notify the EPA and affected states, as required by COMAR 26.11.03.07-.12.

c. Permittee's Ability to Make Change

(1) For changes proposed as minor permit modifications to this permit that will require the applicant to obtain a permit to construct, the permit to construct must be issued prior to the new change.

(2) During the period of time after the Permittee applies for a minor modification but before the Department acts in accordance with COMAR 26.11.03.16F(2):

(a) The Permittee shall comply with applicable requirements of the Clean Air Act related to the change and the permit terms and conditions described in the application for the minor modification.

(b) The Permittee is not required to comply with the terms and conditions in the permit it seeks to modify. If the Permittee fails to comply with the terms and conditions in the application during this time, the terms and conditions of both this permit and the application for modification may be enforced against it.

d. The Permittee is subject to enforcement action if it is determined at any time that a change made under COMAR 26.11.03.16 is not within the scope of this regulation.

e. Minor permit modification procedures may be used for Part 70 permit modifications involving the use of economic incentives, marketable permits, emissions trading, and other similar approaches, but only to the extent that the minor permit modification procedures are explicitly provided for in regulations approved by the EPA as part of the Maryland SIP or in other applicable requirements of the Clean Air Act.

14. ADMINISTRATIVE PART 70 OPERATING PERMIT AMENDMENTS

[COMAR 26.11.03.15]

The Permittee may apply to the department to make an administrative permit amendment as provided in COMAR 26.11.03.15 and in accordance with the following conditions:

a. An application for an administrative permit amendment shall:

(1) Be in writing;

(2) Include a statement certified by a responsible official that the proposed amendment meets the criteria in COMAR 26.11.03.15 for an administrative permit amendment, and

(3) Identify those provisions of this part 70 permit for which the amendment is requested, including the basis for the request.

b. An administrative permit amendment:

(1) Is a correction of a typographical error;

(2) Identifies a change in the name, address, or phone number of a person identified in this permit, or a similar administrative change involving the Permittee or other matters which are not directly related to the control of air pollution;

(3) requires more frequent monitoring or reporting by the Permittee;

(4) Allows for a change in ownership or operational control of a source for which the Department determines that no other revision to the permit is necessary and is documented as per COMAR 26.11.03.15B(4);

(5) Incorporates into this permit the requirements from preconstruction review permits or approvals issued by the Department in accordance with COMAR 26.11.03.15B(5), but only if it satisfies 40 CFR 70.7(d)(1)(v);

(6) Incorporates any other type of change, as approved by the EPA, which is similar to those in COMAR 26.11.03.15B(1)—(4);

(7) Notwithstanding COMAR 26.11.03.15B(1)—(6), all modifications to acid rain control provisions included in this Part 70 permit are governed by applicable requirements promulgated under Title IV of the Clean Air Act; or

(8) Incorporates any change to a term or condition specified as State-only enforceable, if the Permittee has obtained all necessary permits-to-construct and approvals that apply to the change.

c. The Permittee may make the change addressed in the application for an administrative amendment upon receipt by the Department of the application, if all permits-to-construct or approvals otherwise required by COMAR 26.11.02 prior to making the change have first been obtained from the Department.

d. The permit shield in COMAR 26.11.03.23 applies to administrative permit amendments made under Section B(5) of COMAR 26.11.03.15 , but only after the Department takes final action to revise the permit.

e. The Permittee is subject to enforcement action if it is determined at any time that a change made under COMAR 26.11.03.15 is not within the scope of this regulation.

15. OFF-PERMIT CHANGES TO THIS SOURCE

[COMAR 26.11.03.19]

The Permittee may make off-permit changes to this facility as provided in COMAR 26.11.03.19 and in accordance with the following conditions:

a. The Permittee may make a change to this permitted facility that is not addressed or prohibited by the federally enforceable conditions of this Part 70 permit without obtaining a Part 70 permit revision if:

(1) The Permittee has obtained all permits and approvals required by COMAR 26.11.02 and .03;

(2) The change is not subject to any requirements under Title IV of the Clean Air Act;

(3) The change is not a Title I modification; and

(4) The change does not violate an applicable requirement of the Clean Air Act or a federally enforceable term or condition of the permit.

b. For a change that qualifies under COMAR 26.11.03.19, the Permittee shall provide contemporaneous written notice to the Department and the EPA, except for a change to an emissions unit or activity that is exempt from the Part 70 permit application, as provided in COMAR 26.11.03.04. This written notice shall describe the change, including the date it was made, any change in emissions, including the pollutants emitted, and any new applicable requirements of the Clean Air Act that apply as a result of the change.

c. Upon satisfying the requirements of COMAR 26.11.03.19, the Permittee may make the proposed change.

d. The Permittee shall keep a record describing:

(1) Changes made at the facility that result in emissions of a regulated air pollutant subject to an applicable requirement of the Clean Air Act , but not otherwise regulated under this permit; and

(2) The emissions resulting from those changes.

e. Changes that qualify under COMAR 26.11.03.19 are not subject to the requirements for Part 70 revisions.

f. The Permittee shall include each off-permit change under COMAR 26.11.03.19 in the application for renewal of the part 70 permit.

g. The permit shield in COMAR 26.11.03.23 does not apply to off-permit changes made under COMAR 26.11.03.19.

h. The Permittee is subject to enforcement action if it is determined that an off-permit change made under COMAR 26.11.03.19 is not within the scope of this regulation.

16. ON-PERMIT CHANGES TO SOURCES

[COMAR 26.11.03.18]

The Permittee may make on-permit changes that are allowed under Section 502(b)(10) of the Clean Air Act as provided in COMAR 26.11.03.18 and in accordance with the following conditions:

a. The Permittee may make a change to this facility without obtaining a revision to this Part 70 permit if:

(1) The change is not a Title I modification;

(2) The change does not result in emissions in excess of those expressly allowed under the federally enforceable provisions of the Part 70 permit for the permitted facility or for an emissions unit within the facility, whether expressed as a rate of emissions or in terms of total emissions;

(3) The Permittee has obtained all permits and approvals required by COMAR 26.11.02 and .03;

(4) The change does not violate an applicable requirement of the Clean Air Act;

(5) The change does not violate a federally enforceable permit term or condition related to monitoring, including test methods, record keeping, reporting, or compliance certification requirements;

(6) The change does not violate a federally enforceable permit term or condition limiting hours of operation, work practices, fuel usage, raw material usage, or production levels if the term or condition has been established to limit emissions allowable under this permit;

(7) If applicable, the change does not modify a federally enforceable provision of a compliance plan or schedule in this Part 70 permit unless the Department has approved the change in writing; and

(8) This permit does not expressly prohibit the change under COMAR 26.11.03.18.

b. The Permittee shall notify the Department and the EPA in writing of a proposed on-permit change under COMAR 26.11.03.18 not later than 7 days before the change is made. The written information shall include the following information:

(1) A description of the proposed change;

(2) The date on which the change is proposed to be made;

(3) Any change in emissions resulting from the change, including the pollutants emitted;

(4) Any new applicable requirement of the Clean Air Act; and

(5) Any permit term or condition that would no longer apply.

c. The responsible official of this facility shall certify in accordance with COMAR 26.11.02.02F that the proposed change meets the criteria for the use of on-permit changes under COMAR 26.11.03.18.

d. The Permittee shall attach a copy of each notice required by condition b. above to this Part 70 permit.

e. On-permit changes that qualify under COMAR 26.11.03.18 are not subject to the requirements for part 70 permit revisions.

f. Upon satisfying the requirements under COMAR 26.11.03.18, the Permittee may make the proposed change.

g. The permit shield in COMAR 26.11.03.23 does not apply to on-permit changes under COMAR 26.11.03.18.

h. The Permittee is subject to enforcement action if it is determined that an on-permit change made under COMAR 26.11.03.18 is not within the scope of the regulation or violates any requirement of the State air pollution control law.

17. FEE PAYMENT

[COMAR 26.11.02.16A(2) & (5)(b)]

a. The fee for this Part 70 permit is as prescribed in Regulation .19 of COMAR 26.11.02.

b. The fee is due on and shall be paid on or before each 12-month anniversary date of the permit.

c. Failure to pay the annual permit fee constitutes cause for revocation of the permit by the Department.

18. REQUIREMENTS FOR PERMITS-TO-CONSTRUCT AND APPROVALS

[COMAR 26.11.02.09.]

The Permittee may not construct or modify or cause to be constructed or modified any of the following sources without first obtaining, and having in current effect, the specified permits-to-construct and approvals:

a. New Source Review source, as defined in COMAR 26.11.01.01, approval required, except for generating stations constructed by electric companies;

b. Prevention of Significant Deterioration source, as defined in COMAR 26.11.01.01, approval required, except for generating stations constructed by electric companies;

c. New Source Performance Standard source, as defined in COMAR 26.11.01.01, permit to construct required, except for generating stations constructed by electric companies;

d. National Emission Standards for Hazardous Air Pollutants source, as defined in COMAR 26.11.01.01, permit to construct required, except for generating stations constructed by electric companies;

e. A stationary source of lead that discharges one ton per year or more of lead or lead compounds measured as elemental lead, permit to construct required, except for generating stations constructed by electric companies;

f. All stationary sources of air pollution, including installations and air pollution control equipment, except as listed in COMAR 26.11.02.10, permit to construct required;

g. In the event of a conflict between the applicability of (a.— e.) above and an exemption listed in COMAR 26.11.02.10, the provision that requires a permit applies.

h. Approval of a PSD or NSR source by the Department does not relieve the Permittee obtaining an approval from also obtaining all permits-to-construct required by (c.— g.) above.

19. CONSOLIDATION OF PROCEDURES FOR PUBLIC PARTICIPATION

[COMAR 26.11.02.11C] and [COMAR 26.11.03.01K]

The Permittee may request the Department to authorize special procedures for the Permittee to apply simultaneously, to the extent possible, for a permit to construct and a revision to this permit.

These procedures may provide for combined public notices, informational meetings, and public hearings for both permits but shall not adversely affect the rights of a person, including EPA and affected states, to obtain information about the application for a permit, to comment on an application, or to challenge a permit that is issued.

These procedures shall not alter any existing permit procedures or time frames.

20. PROPERTY RIGHTS

[COMAR 26.11.03.06E(4)]

This Part 70 permit does not convey any property rights of any sort, or any exclusive privileges.

21. SEVERABILITY

[COMAR 26.11.03.06A(5)]

If any portion of this Part 70 permit is challenged, or any term or condition deemed unenforceable, the remainder of the requirements of the permit continues to be valid.

22. INSPECTION AND ENTRY

[COMAR 26.11.03.06G(3)]

The Permittee shall allow employees and authorized representatives of the Department, the EPA, and local environmental health agencies, upon presentation of credentials or other documents as may be required by law, to:

a. Enter at a reasonable time without delay and without prior notification the Permittee's property where a Part 70 source is located, emissions-related activity is conducted, or records required by this permit are kept;

b. Have access to and make copies of records required by the permit;

c. Inspect all emissions units within the facility subject to the permit and all related monitoring systems, air pollution control equipment, and practices or operations regulated or required by the permit; and

d. Sample or monitor any substances or parameters at or related to the emissions units at the facility for the purpose of determining compliance with the permit.

23. DUTY TO PROVIDE INFORMATION

[COMAR 26.11.03.06E(5)]

The Permittee shall furnish to the Department, within a reasonable time specified by the Department, information requested in writing by the Department in order to determine whether the Permittee is in compliance with the federally enforceable conditions of this Part 70 permit, or whether cause exists for revising or revoking the permit. Upon request, the Permittee shall also furnish to the Department records required to be kept under the permit.

For information claimed by the Permittee to be confidential and therefore potentially not discloseable to the public, the Department may require the Permittee to provide a copy of the records directly to the EPA along with a claim of confidentiality.

The Permittee shall also furnish to the Department, within a reasonable time specified by the Department, information or records requested in writing by the Department in order to determine if the Permittee is in compliance with the State-only enforceable conditions of this permit.

24. COMPLIANCE REQUIREMENTS

[COMAR 26.11.03.06E(1)] and [COMAR 26.11.03.06A(11)] and [COMAR 26.11.02.05]

The Permittee shall comply with the conditions of this Part 70 permit. Noncompliance with the permit constitutes a violation of the Clean Air Act, and/or the Environment Article Title 2 of the Annotated Code of Maryland and may subject the Permittee to:

a. Enforcement action,

b. Permit revocation or revision,

c. Denial of the renewal of a Part 70 permit, or

d. Any combination of these actions.

The conditions in this Part 70 permit are enforceable by EPA and citizens under the Clean Air Act except for the State-only enforceable conditions.

Under Environment Article Section 2-609, Annotated Code of Maryland, the Department may seek immediate injunctive relief against a person who violates this permit in such a manner as to cause a threat to human health or the environment.

25. CREDIBLE EVIDENCE

Nothing in this permit shall be interpreted to preclude the use of credible evidence to demonstrate noncompliance with any term of this permit.

26. NEED TO HALT OR REDUCE ACTIVITY NOT A DEFENSE

[COMAR 26.11.03.06E(2)]

The need to halt or reduce activity in order to comply with the conditions of this permit may not be used as a defense in an enforcement action.

27. CIRCUMVENTION

[COMAR 26.11.01.06]

The Permittee may not install or use any article, machine, equipment or other contrivance, the use of which, without resulting in a reduction in the total weight of emissions, conceals or dilutes emissions which would otherwise constitute a violation of any applicable air pollution control regulation.

28. PERMIT SHIELD

[COMAR 26.11.03.23]

A permit shield as described in COMAR 26.11.03.23 shall apply only to terms and conditions in this Part 70 permit that have been specifically

identified as covered by the permit shield. Neither this permit nor COMAR 26.11.03.23 alters the following:

a. The emergency order provisions in Section 303 of the Clean Air Act, including the authority of EPA under that section;

b. The liability of the Permittee for a violation of an applicable requirement of the Clean Air Act before or when this permit is issued or for a violation that continues after issuance;

c. The requirements of the Acid Rain Program, consistent with Section 408(a) of the Clean Air Act;

d. The ability of the Department or EPA to obtain information from a source pursuant to Maryland law and Section 114 of the Clean Air Act; or

e. The authority of the Department to enforce an applicable requirement of the State air pollution control law that is not an applicable requirement of the Clean Air Act.

29. ALTERNATE OPERATING SCENARIOS

[COMAR 26.11.03.06A(9)]

For all alternate operating scenarios approved by the Department and contained within this permit, the Permittee, while changing from one approved scenario to another, shall contemporaneously record in a log maintained at the facility each scenario under which the emissions unit is operating and the date and time the scenario started and ended.

SECTION III PLANT WIDE CONDITIONS

1. PARTICULATE MATTER FROM CONSTRUCTION AND DEMOLITION

[COMAR 26.11.06.03D]

The Permittee shall not cause or permit any building, its appurtenances, or a road to be used, constructed, altered, repaired, or demolished without taking reasonable precautions to prevent particulate matter from becoming airborne.

2. OPEN BURNING

[COMAR 26.11.07]

Except as provided in COMAR 26.11.07.04, the Permittee shall not cause or permit an open fire from June 1 through August 31 of any calendar year. Prior to any open burning, the Permittee shall request and receive approval from the Department.

3. AIR POLLUTION EPISODE

[COMAR 26.11.05.04]

When requested by the Department, the Permittee shall prepare in writing standby emissions reduction plans, consistent with good industrial practice and safe operating procedures, for reducing emissions creating air pollution during periods of Alert, Warning, and Emergency of an air pollution episode.

4. REPORT OF EXCESS EMISSIONS AND DEVIATIONS

[COMAR 26.11.01.07] and [COMAR 26.11.03.06C(7)]

The Permittee shall comply with the following conditions for occurrences of excess emissions and deviations from requirements of this permit, including those in Section VI – State-only Enforceable Conditions:

a. Report any deviation from permit requirements that could endanger human health or the environment, by orally notifying the Department immediately upon discovery of the deviation;

b. Promptly report all occurrences of excess emissions that are expected to last for one hour or longer by orally notifying the Department of the onset and termination of the occurrence;

c. When requested by the Department the Permittee shall report all deviations from permit conditions, including those attributed to malfunctions as defined in COMAR 26.11.01.07A, within 5 days of the request by submitting a written description of the deviation to the Department. The written report shall include the cause, dates and times of the onset and termination of the deviation, and an account of all actions planned or taken to reduce, eliminate, and prevent recurrence of the deviation;

d. The Permittee shall submit to the Department semi-annual monitoring reports that confirm that all required monitoring was performed, and that provide accounts of all deviations from permit requirements that occurred during the reporting periods. Reporting periods shall be January 1 through June 30 and July 1 through December 31, and reports shall be submitted within 30 days of the end of each reporting period. Each account of deviation shall include a description of the deviation, the dates and times of onset and termination, identification of the person who observed or discovered the deviation, causes and corrective actions taken, and actions taken to prevent recurrence. If no deviations from permit conditions occurred during a reporting period, the Permittee shall submit a written report that so states.

e. When requested by the Department, the Permittee shall submit a written report to the Department within 10 days of receiving the request concerning an occurrence of excess emissions. The report shall contain the information required in COMAR 26.11.01.07D(2).

5. ACCIDENTAL RELEASE PROVISIONS

[COMAR 26.11.03.03B(23)] and [40 CFR 68]

Should the Permittee become subject to 40 CFR 68 during the term of this permit, the Permittee shall submit risk management plans by the date

specified in 40 CFR 68.150 and shall certify compliance with the requirements of 40 CFR 68 as part of the annual compliance certification as required by 40 CFR 70.

The Permittee shall initiate a permit revision or reopening according to the procedures of 40 CFR 70.7 to incorporate appropriate permit conditions into the Permittee's Part 70 permit.

6. GENERAL TESTING REQUIREMENTS

[COMAR 26.11.01.04]

The Department may require the Permittee to conduct, or have conducted, testing to determine compliance with this Part 70 permit. The Department, at its option, may witness or conduct these tests. This testing shall be done at a reasonable time, and all information gathered during a testing operation shall be provided to the Department.

7. EMISSIONS TEST METHODS

[COMAR 26.11.01.04]

Compliance with the emissions standards and limitations in this Part 70 permit shall be determined by the test methods designated and described below or other test methods submitted to and approved by the Department.

Reference documents of the test methods approved by the Department include the following:

a. 40 CFR 60, appendix A

b. 40 CFR 51, appendix M

c. The Department's Technical Memorandum 91-01 "Test Methods and Equipment Specifications for Stationary Sources", (January 1991), as amended through Supplement 3, (October 1, 1997)

8. EMISSIONS CERTIFICATION REPORT

[COMAR 26.11.01.05-1] and [COMAR 26.11.02.19C] and [COMAR 26.11.02.19D]

The Permittee shall certify actual annual emissions of regulated pollutants from the facility on a calendar year basis.

a. The certification shall be on forms obtained from the Department and submitted to the Department not later than April 1 of the year following the year for which the certification is required;

b. The individual making the certification shall certify that the information is accurate to the individual's best knowledge. The individual shall be:

(1) Familiar with each source for which the certifications forms are submitted, and

(2) Responsible for the accuracy of the emissions information;

c. The Permittee shall maintain records necessary to support the emissions certification including the following information if applicable:

(1) The total amount of actual emissions of each regulated pollutant and the total of all regulated pollutants;

(2) An explanation of the methods used to quantify the emissions and the operating schedules and production data that were used to determine emissions, including significant assumptions made;

(3) Amounts, types and analyses of all fuels used;

(4) Emissions data from continuous emissions monitors that are required by this permit, including monitor calibration and malfunction information;

(5) Identification, description, and use records of all air pollution control equipment and compliance monitoring equipment including:

(a) Significant maintenance performed,
(b) Malfunctions and downtime, and
(c) Episodes of reduced efficiency of all equipment;

(6) Limitations on source operation or any work practice standards that significantly affect emissions; and

(7) Other relevant information as required by the Department.

9. COMPLIANCE CERTIFICATION REPORT

[COMAR 26.11.03.06G(6) and (7)]

The Permittee shall submit to the Department and EPA Region III a report certifying compliance with each term of this Part 70 permit including each applicable standard, emissions limitation, and work practice for the previous calendar year by April 1 of each year.

a. The compliance certification shall include:

(1) The identification of each term or condition of this permit which is the basis of the certification;

(2) The compliance status;

(3) Whether the compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of each source, currently and over the reporting period; and

(5) Any other information required to be reported to the Department that is necessary to determine the compliance status of the Permittee with this permit.

b. The Permittee shall submit the compliance certification reports to the Department and EPA simultaneously.

10. CERTIFICATION BY RESPONSIBLE OFFICIAL

[COMAR 26.11.02.02F]

All application forms, reports, and compliance certifications submitted pursuant to this permit shall be certified by a responsible official as to truth, accuracy, and completeness. The Permittee shall expeditiously notify the Department of an appointment of a new responsible official.

The certification shall be in the following form:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

11. SAMPLING AND EMISSIONS TESTING RECORD KEEPING

[COMAR 26.11.03.06C(5)]

The Permittee shall gather and retain the following information when sampling and testing for compliance demonstrations:

a. The location as specified in this permit, and the date and time that samples and measurements are taken;

b. All pertinent operating conditions existing at the time that samples and measurements are taken;

c. The date that each analysis of a sample or emissions test is performed and the name of the person taking the sample or performing the emissions test;

d. The identity of the Permittee, individual, or other entity that performed the analysis;

e. The analytical techniques and methods used; and

f. The results of each analysis.

12. GENERAL RECORDKEEPING

[COMAR 26.11.03.06C(6)]

The Permittee shall retain records of all monitoring data and information that support the compliance certification for a period of five (5) years from the date that the monitoring, sample measurement, application, report or emissions test was completed or submitted to the Department.

These records and support information shall include:

a. All calibration and maintenance records;

b. All original data collected from continuous monitoring instrumentation;

c. Records which support the annual emissions certification; and

d. Copies of all reports required by this permit.

13. GENERAL CONFORMITY

[COMAR 26.11.26.09]

The Permittee shall comply with the general conformity requirements of 40 CFR 93, Subpart B and COMAR 26.11.26.09.

14. ASBESTOS PROVISIONS

[40 CFR 61, Subpart M]

The Permittee shall comply with 40 CFR 61, Subpart M when conducting any renovation or demolition activities at the facility.

15. OZONE DEPLETING REGULATIONS

[40 CFR 82, Subpart F]

The Permittee shall comply with the standards for recycling and emissions reduction pursuant to 40 CFR 82, Subpart F, except as provided for MVACs in subpart B:

a. Persons opening appliances for maintenance, service, repair, or disposal shall comply with the prohibitions and required practices pursuant to 40 CFR 82.154 and 82.156.

b. Equipment used during the maintenance, service, repair or disposal of appliances shall comply with the standards for recycling and recovery equipment pursuant to 40 CFR 82.158.

c. Persons performing maintenance, service, repairs or disposal of appliances shall be certified by an approved technician certification program pursuant to 40 CFR 82.161.

d. Persons disposing of small appliances, MVACS, and MVAC-like appliances as defined in 40 CFR 82.152, shall comply with record keeping requirements pursuant to 40 CFR 82.155.

e. Persons owning commercial or industrial process refrigeration equipment shall comply with the leak repair requirements pursuant to 40 CFR 82.156.

f. Owners/operators of appliances normally containing 50 or more pounds of refrigerant shall keep records of refrigerant purchased and added to such appliances pursuant to 40 CFR 82.166.

16. ACID RAIN PERMIT

Not applicable

SECTION IV PLANT SPECIFIC CONDITIONS

This section provides tables that include the emissions standards, emissions limitations, and work practices applicable to each emissions unit located at this facility. The Permittee shall comply with all applicable emissions standards, emissions limitations and work practices included herein.

The tables also include testing, monitoring, record keeping and reporting requirements specific to each emissions unit. In addition to the requirements included here in **Section IV**, the Permittee is also subject to the general testing, monitoring, record keeping and reporting requirements included in **Section III – Plant Wide Conditions** of this permit.

Unless otherwise provided in the specific requirements for an emissions unit, the Permittee shall maintain at the facility for at least five (5) years, and shall make available to the Department upon request, all records that the Permittee is required under this section to establish. [Authority: COMAR 26.11.03.06C(5)(g)]

Table IV – 1	
1.0	**Emissions Unit Number(s)** EU-1: One (1) Cleaver Brooks natural gas fired boiler rated at 2.0 MMBTU per hour used for space heat. (ARMA Registration No. 015-0212-5-0089) EU-30: One (1) Cleaver Brooks natural gas fired boiler rated at 1.57 MMBTU per hour for process heat. (ARMA Registration No. 015-0212-5-0126) EU-31: One (1) HB Smith natural gas-fired boiler rated at 1.30 MMBTU per hour. (ARMA Registration No. 015-0212-5-0207)
1.1	**Applicable Standards/Limits:** A. Visible Emissions Limitations COMAR 26.11.09.05A(1), which limits visible emissions from any fuel burning equipment to 20 percent opacity other than water in an uncombined form. Exceptions. COMAR 26.11.09.05A(3) establishes that "Section A(1) does not apply to emissions during load changing, soot blowing, start-up, or adjustments or occasional cleaning of

Table IV – 1	
	control equipment if (a) the visible emissions are not greater than 40 percent opacity; and (b) the visible emissions do not occur for more than 6 consecutive minutes in any 60 minute period." B. Operational Requirement The Permittee shall burn only natural gas in the boilers unless the Permittee applies for and obtains an approval from the Department to burn alternate fuels per COMAR 26.11.02.09A.
1.2	**Testing Requirements:** A. Visible Emissions Limitations See Reporting Requirements B. Operational Requirement See Record Keeping and Reporting Requirements
1.3	**Monitoring Requirements:** A. Visible Emissions Limitations See Reporting Requirements B. Operational Requirement See Record Keeping and Reporting Requirements
1.4	**Record Keeping Requirements:** a. Visible Emissions Limitations See Reporting Requirements b. Operational Requirement The Permittee shall keep annual fuel usage records including the amount and type of fuel used on site for at least five years. **[Authority: COMAR 26.11.02.19C and D]**

Table IV – 1	
1.5	**Reporting Requirements:** A. Visible Emissions Limitations The Permittee shall report incidents of visible emissions in accordance with permit condition 4, Section III, Plant Wide Conditions, "Report of Excess Emissions and Deviations." **[Authority: COMAR 26.11.03.06C]** B. Operational Requirement Annual fuel usage records including the amount and type of fuel used shall be submitted with the required annual emission certification. **[Authority: COMAR 26.11.02.19C and D]**

A permit shield shall cover the applicable requirements identified for the emissions unit(s) listed in the table above.

Table IV – 2	
2.0	**Emissions Unit Number(s)** EU - 7: One (1) Capiox Oxygenator (OX) Potting and Coating Area, biopassive coating (ARMA Registration No. 015-0212-6-0222) EU - 9: One (1) Capiox - Quick Disconnect Assembly Area, manual bonding (ARMA Registration No. 015-0212-6-0234) EU - 12: One (1) Venous Reservoir (VR) and Cardiotomy Reservoir (CR) Filter Dipping Area, biopassive coating (ARMA Registration No. 015-0212-6-0227) EU - 17: One (1) Capiox Reservoir Assembly Area, manual bonding (ARMA Registration No. 015-0212-6-0224) EU - 18: One (1) Capiox Final Assembly Area, manual bonding and biopassive coating (ARMA Registration No. 015-0212-6-0228)

Table IV – 2	
	EU - 21: One (1) Pump Assembly, manual bonding (ARMA Registration No. 015-0212-6-0231) EU - 22: One (1) Flexible Venous Reservoir (FVR) Coating Line, manual bonding and biopassive coating (ARMA Registration No. 015-0212-6-0211) EU - 23: One (1) X-Coat Capiox/Connectors Area, biopassive coating (ARMA Registration No. 015-0212-6-0233) EU - 24: One (1) X-Coat Tubing Area, biopassive coating (ARMA Registration No. 015-0212-6-0232) EU - 25: One (1) Tubing Pack Assembly Area, manual bonding (ARMA Registration No. 015-0212-6-0217) EU - 26: One (1) CDI Assembly Area, manual bonding - HSAT (ARMA Registration No. 015-0212-6-0255) EU - 27: One (1) OPS Assembly Area, manual bonding (ARMA Registration No. 015-0212-6-0255) EU - 29: One (1) CDI Assembly Area, manual bonding – SHUNT (ARMA Registration No. 015-0212-6-0255) EU - 33: One (1) SARNS 101 chemical manufacturing process (ARMA Registration No. 015-0212-6-0338) EU - TBD: One (1) Centrifugal Pump Automated Assembly Machine (ARMA Registration No. 015-0212-6-0374)
2.1	**Applicable Standards/Limits:** Control of VOC COMAR 26.11.19.31 which requires the Permittee to minimize VOC emissions from medical device manufacturing for premises that emit, or have the potential to emit, 100 pounds or more per day of VOC emissions from all medical device manufacturing installations.

Table IV – 2	
2.2	**Testing Requirements:** Control of VOC See Operating and Monitoring and Record Keeping and Reporting Requirements
2.3	**Operating and Monitoring Requirements:** Control of VOC The Permittee shall do the following unless the Permittee uses a Department approved alternative method of compliance or alternative control technology that achieves an equivalent or better level of VOC control: a. Provide and maintain appropriately designed VOC impermeable covers on dip pots used for manual bonding operations when not in use; b. Upon request of the Department, participate in the evaluation of new or innovative designs or VOC material substitutions to minimize the use of solvent bonds for medical device manufacturing; c. Use an enclosed system to apply biopassive coating to fully assembled medical devices; and d. Apply biopassive coating to individual medical device components only when it is not feasible to coat medical devices in assembled form. **[Authority: COMAR 26.11.19.31D]**
2.4	**Record Keeping Requirements:** Control of VOC The Permittee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information:

Table IV – 2	
	1. Monthly records of the amount of materials used and the amount of material waste generated for each registered process area. 2. Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS) or equivalent for all materials used. **[Authority: COMAR 26.11.03.06C and ARMA Premises Wide Permit to Construct issued on 04/09/2021]**
2.5	**Reporting Requirements:** Control of VOC Before coating individual components under COMAR 26.11.19.31D(1)(d), the Permittee shall submit to the Department for review and approval, a report documenting the technical and economic justification for coating components individually. **[Authority: COMAR 26.11.19.31E]** Before using an alternative method of compliance or control technology as allowed under COMAR 26.11.19.31D(2), the Permittee shall submit to the Department for review and approval, a proposal to use such an alternative method of compliance or control technology. **[Authority: COMAR 26.11.19.31F]**

A permit shield shall cover the applicable requirements identified for the emissions unit(s) listed in the table above.

Table IV -3	
3.0	**Emissions Unit Number: General Facility** Facility Wide Requirements
3.1	**Applicable Standards/Limits:** A. Facility Wide HAP Limitations Facility wide HAP emissions shall be less than the following limits:

	(1) 10 tons in any rolling 12-month period for any single HAP; and (2) 25 tons in any rolling 12-month period for the total combination of all HAP. Facility wide emissions shall include total emissions from both TMC and TCVS combined. **[Authority: ARMA Premises Wide Permit to Construct issued on 04/09/2021]** B. Control of VOC COMAR 26.11.19.02I, which requires the Permittee to implement good operating practices to minimize Volatile Organic Compound (VOC) emissions into the atmosphere. COMAR 26.11.19.16C which requires the Permittee to minimize leaks from VOC equipment and their components, including process equipment, storage tanks, pumps, compressors, valves, flanges and other pipeline fittings, pressure relief valves, process drains, and open-ended pipes.
3.2	**Testing Requirements:** A. Facility Wide HAP Limitations See Record Keeping and Reporting Requirements. B. Control of VOC See Monitoring, Record Keeping and Reporting Requirements.
3.3	**Monitoring Requirements:** A. Facility Wide HAP Limitations See Record Keeping and Reporting Requirements. B. Control of VOC

	In accordance with COMAR 26.11.19.02I, the Permittee shall implement "good operating practices" designed to minimize emissions of VOC to the atmosphere. 1. Where applicable, good operating practices shall, at a minimum, include the following: a. Provisions for training of operators on practices, procedures, and maintenance requirements that are consistent with the equipment manufacturers' recommendations and the source's experience in operating the equipment, with the training to include proper procedures for maintenance of air pollution control equipment; b. Maintenance of covers on containers and other vessels that contain VOC and VOC-containing materials when not in use; c. Minimize spills of VOC-containing cleaning materials; d. Convey VOC-containing cleaning materials from one location to another in closed containers or pipelines; e. Minimize VOC emissions from cleaning of storage, mixing, and conveying equipment; f. As practical, scheduling of operations to minimize color or material changes when applying VOC coating or other materials by spray gun; g. For spray gun applications of coatings, use of high volume low pressure (HVLP) or other high efficiency application methods where practical; and h. As practical, mixing or blending materials containing VOC in closed containers and taking preventative measures to minimize emissions for products that contain VOC.

2. The Permittee shall:

   a. Establish good operating practices in writing;

   b. Make the written operating practices available to the Department upon request; and

   c. Display the good operating practices so that they are clearly visible to the operator or include them in operator training.

In accordance with COMAR 26.11.19.02I, the Permittee shall take all reasonable precautions to prevent or minimize the discharge of VOC into the atmosphere when cleaning process and coating application equipment, including containers, vessels, tanks, lines and pumps.

3. Where applicable, reasonable precautions for equipment cleanup shall, at a minimum, include the following:

   a. Storing all wastes and waste materials, including cloth and paper that are contaminated with VOC, in closed containers;

   b. Preparing written standard operating procedures for frequently cleaned equipment, including when practical, provisions for the use of low VOC or non-VOC materials and procedures to minimize the quantity of VOC materials used;

   c. Using, when practical, enclosed spray gun cleaning, VOC-recycling systems and other spray gun cleaning methods that reduce or eliminate VOC emissions; and

   d. Using, when practical, detergents, high-pressure water, or other non-VOC cleaning operations to clean coating lines, containers, and process

equipment.

In accordance with COMAR 26.11.19.02I, the Permittee shall minimize VOC emissions into the atmosphere from VOC storage and transfer operations.

4. Where applicable, the Permittee shall, at a minimum:

   a. Install conservation vents or other vapor control measures designed to minimize standing losses, on all storage tanks with a capacity of 2,000 gallons or more, in VOC service; and

   b. Utilize vapor balance, vapor control lines, or other vapor control measures when VOCs are transferred from a tank truck into a stationary storage tank with a capacity greater than 10,000 gallons and less than 40,000 gallons that store VOCs or materials containing VOCs, other than gasoline, that have a vapor pressure greater than 1.5 psia.

5. In accordance with COMAR 26.11.19.16C, the Permittee shall perform the following to minimize VOC emissions from equipment leaks:

   a. Visually inspect all components on the premises for leaks at least once each calendar month.

   b. Tag any leak immediately so that the tag is clearly visible. The tag shall be made of a material that will withstand any weather or corrosive conditions to which it may be normally exposed. The tag shall bear an identification number, the date the leak was discovered, and the name of the person who discovered the leak. The tag shall remain in place until the leak has been repaired.

   c. Take immediate action to repair all observed VOC leaks that can be repaired within 48 hours.

	d. Repair all other leaking components not later than 15 days after the leak is discovered. If a replacement part is needed, the part shall be ordered within 3 days after discovery of the leak, and the leak shall be repaired within 48 hours after receiving the part. e. Maintain a supply of components or component parts that are recognized by the source to wear or corrode, or that otherwise need to be routinely replaced, such as seals, gaskets, packing, and pipe fittings. f. Maintain a log that includes the name of the person conducting the inspection and the date on which leak inspections are made, the findings of the inspection, and a list of leaks by tag identification number. Components that cannot be repaired as required by COMAR 26.11.19.16 because they are inaccessible, or that cannot be repaired during operation of the source, shall be identified in the log and included within the source's maintenance schedule for repair during the next source shutdown.
3.4	**<u>Record Keeping Requirements</u>:** A. Facility Wide HAP Limitations The Permittee shall keep the following records on-site: 1. Facility wide individual HAP emissions in tons per month per individual HAP and the total tons for the previous 12 months for each individual HAP. 2. Facility wide total HAP emissions in tons per month and the total tons for the previous 12 months. **[Authority: COMAR 26.11.03.06C and ARMA Premises Wide Permit to Construct issued on 04/09/2021]**

	B. Control of VOC Good operating practices information as required by COMAR 26.11.19.02I shall be kept on-site at all times. **[Authority: COMAR 26.11.19.02I(2)(c)]** Leak inspection logs as required by COMAR 26.11.19.16 shall be kept on-site for at least five (5) years. **[Authority: COMAR 26.11.19.16C(6)]**
3.5	**Reporting Requirements:** A. Facility Wide HAP Emissions Facility wide HAP emissions records shall be submitted with the required annual emission certification. **[Authority: COMAR 26.11.02.19C and D]** B. Control of VOC The following information shall be made available to the Department upon request: 1. Good operating practices information as required by COMAR 26.11.19.02I shall be made available to the Department upon request. 2. Leak inspection logs as required by COMAR 26.11.19.16 shall be made available to the Department upon request. **[Authority: COMAR 26.11.03.06C]**

A permit shield shall cover the applicable requirements identified for the emissions unit(s) listed in the table above.

SECTION V INSIGNIFICANT ACTIVITIES

This section provides a list of insignificant emissions units that were reported in the Title V permit application. The applicable Clean Air Act requirements, if any, are listed below the insignificant activity.

(1) No. 7 Fuel burning equipment using gaseous fuels or no. 1 or no. 2 fuel oil, and having a heat input less than 1,000,000 Btu (1.06 gigajoules) per hour;

The following equipment is subject to the requirements below:

(a) One (1) natural gas fired water heater rated at 199,000 Btu/Hr.

(b) Two (2) natural gas fired space heaters rated at 800,000 Btu/Hr.

(c) Two (2) natural gas fired space heaters rated at 150,000 Btu/Hr.

(d) One (1) natural gas fired furnace rated at 625,000 Btu/Hr.

(e) One (1) natural gas fired furnace rated at 313,000 Btu/Hr

COMAR 26.11.09.05A(1), which establishes that the Permittee may not cause or permit the discharge of emissions from any fuel burning equipment, other than water in an uncombined form, which is greater than 20 percent opacity.

Exceptions: COMAR 26.11.09.05A(2) does not apply to emissions during load changing, soot blowing, start-up, or adjustments or occasional cleaning of control equipment if:

(a) The visible emissions are not greater than 40 percent opacity; and

(b) The visible emissions do not occur for more than 6 consecutive minutes in any sixty minute period.

(2) No. 2 Stationary internal combustion engines with an output less than 500 brake horsepower (373 kilowatts) and which are not used to generate electricity for sale or for peak or load shaving;

The one (1) natural gas fired emergency lighting generator rated at 241 horsepower (HP) and the one (1) propane fired emergency lighting generator rated at 240 HP are subject to the following requirements:

(a) COMAR 26.11.09.05E(2), Emissions During Idle Mode: The Permittee may not cause or permit the discharge of emissions from any engine, operating at idle, greater than 10 percent opacity.

(b) COMAR 26.11.09.05E(3), Emissions During Operating Mode: The Permittee may not cause or permit the discharge of emissions from any engine, operating at other than idle conditions, greater than 40 percent opacity.

(c) Exceptions:

(i) COMAR 26.11.09.05E(2) does not apply for a period of 2 consecutive minutes after a period of idling of 15 consecutive minutes for the purpose of clearing the exhaust system.

(ii) COMAR 26.11.09.05E(2) does not apply to emissions resulting directly from cold engine start-up and warm-up for the following maximum periods:

(a) engines that are idled continuously when not in service: 30 minutes

(b) all other engines: 15 minutes.

(iii) COMAR 26.11.09.05B(2) & (3) do not apply while maintenance, repair or testing is being performed by qualified mechanics.

The one (1) natural gas fired emergency lighting generator rated at 241 horsepower (HP) and the one (1) propane fired emergency lighting generator rated at 240 HP are subject to the following

requirements of 40 CFR Part 63 Subpart ZZZZ. Some requirements are incorporated by reference.

(a) 40 CFR, §63.6603, Table 2d, which establishes maintenance, and inspection requirements for the engines as follows:
   a) Change oil and filter every 500 hours of operation or annually, whichever comes first;
   b) Inspect air cleaner every 1,000 hours of operation or annually, whichever comes first;
   c) Inspect all hoses and belts every 500 hours of operation or annually, whichever comes first, and replace as necessary.

(b) 40 CFR, §63.6625(e), (f), (h), (j) which establish work, operation or management practices for the engines.

(c) 40 CFR, §63.6605(a) which requires continuous compliance with all applicable emission limitations and operating limitations of the subpart.

(d) 40 CFR, §63.6605(b) which requires that the engines be maintained in a manner consistent with safety and good air pollution control practices for minimizing emissions.

(e) 40 CFR, §63.6640(a) which requires that the Permittee demonstrate continuous compliance with each emission limitation and operating limitation in Table 2d of the subpart that apply according to methods specified in Table 6 of this subpart.

(f) 40 CFR, §63.6640(b) which requires that the Permittee report each instance in which you did not meet each emission limitation or operating limitation in Table 2d to this subpart that apply to you. These instances are deviations from the emission and operating limitations in this subpart. These deviations must be reported according to the requirements in 40 CFR, Part 63.6650.

(g) 40 CFR, §63.6640(f) requires that that the emergency RICE be operated according to the following requirements:

(i) There is no time limit on the use of emergency stationary RICE in emergency situations;

(ii) You may operate your emergency stationary RICE for the purpose of maintenance checks and readiness testing, provided that the tests are recommended by Federal, State or local government, the manufacturer, the vendor, or the insurance company associated with the engine. Maintenance checks and readiness testing of such units is limited to 100 hours per year; and

(iii) You may operate your emergency stationary RICE up to 50 hours per year in non-emergency situations.

(h) 40 CFR, §63. 6655(a)(5) which requires that the Permittee keep the records of actions taken during periods of malfunction to minimize emissions in accordance with 40 CFR, Part 63.6605(b).

(i) 40 CFR, §63. 6655(d) which requires that the Permittee keep the records required in Table 6 of this subpart to show continuous compliance with each applicable emission or operating limitation.

(j) 40 CFR, §63. 6655(e) which requires that the Permittee keep records of the maintenance conducted on the stationary RICE in order to demonstrate that it was operated and maintained according to an approved maintenance plan (if applicable).

(k) 40 CFR, §63. 6655(f) which requires that the Permittee keep records of the hours of operation of the engine that is recorded through the non-resettable hour meter. The owner or operator must document how many hours are spent for emergency operation; including what classified the operation as emergency and how many hours are spent for non-emergency operation.

(l) The Permittee shall report to the Department any failure to perform the required management practice under which the risk of performing the management practice on the

required schedule was deemed unacceptable. **[Authority: Footnote 2 of Table 2d in 40 CFR 63 Subpart ZZZZ]**

(m) The Permittee shall comply with all applicable requirements listed in Table 8 - General Provisions of 40 CFR part 63 Subpart ZZZZ.

(3) ✓ Space heaters utilizing direct heat transfer and used solely for comfort heat;

(4) ✓ Water cooling towers and water cooling ponds unless used for evaporative cooling of water from barometric jets or barometric condensers, or used in conjunction with an installation requiring a permit to operate;

(5) No. 1 Unheated VOC dispensing containers or unheated VOC rinsing containers of 60 gallons (227 liters) capacity or less;

The 30 gallon degreaser is subject to COMAR 26.11.19.09D, which requires that the Permittee control emissions of volatile organic compounds (VOC) from cold degreasing operations by meeting the following requirements:

(a) COMAR 26.11.19.09D(2)(b), which establishes that the Permittee shall not use any VOC degreasing material that exceeds a vapor pressure of 1 mm Hg at 20 ° C;

(b) COMAR 26.11.19.09D(3)(a—d), which requires that the Permittee implement good operating practices designed to minimize spills and evaporation of VOC degreasing material. These practices, which shall be established in writing and displayed such that they are clearly visible to operators, shall include covers (including water covers), lids, or other methods of minimizing evaporative losses, and reducing the time and frequency during which parts are cleaned;

(c) COMAR 26.11.19.09D(4), which prohibits the use of any halogenated VOC for cold degreasing.

The Permittee shall maintain on site for at least five (5) years, and shall make available to the Department upon request, the following records of operating data:

(a) Monthly records of the total VOC degreasing materials used; and

(b) Written descriptions of good operating practices designed to minimize spills and evaporation of VOC degreasing materials.

(6) Containers, reservoirs, or tanks used exclusively for:

(a) ✓ Storage of butane, propane, or liquefied petroleum, or natural gas;

(b) <700 The storage of VOC normally used as solvents, diluents, thinners, inks, colorants, paints, lacquers, enamels, varnishes, liquid resins, or other surface coatings and having individual capacities of 2,000 gallons (7.6 cubic meters) or less;

(7) ✓ First aid and emergency medical care provided at the facility, including related activities such as sterilization and medicine preparation used in support of a manufacturing or production process;

(8) ✓ Comfort air conditioning subject to requirements of Title VI of the Clean Air Act;

(9) ✓ Natural draft hoods or natural draft ventilators that exhaust air pollutants into the ambient air from manufacturing/industrial or commercial processes; and

(10) ✓ Laboratory fume hoods and vents.

SECTION VI STATE-ONLY ENFORCEABLE CONDITIONS

The Permittee is subject to the following State-only enforceable requirements:

1. Applicable Regulations:

   (A) COMAR 26.11.06.08 and 26.11.06.09, which generally prohibit the discharge of emissions beyond the property line in such a manner that a nuisance or air pollution is created.

   (B) COMAR 26.11.15.05, which requires that the Permittee implement "Best Available Control Technology for Toxics" (T – BACT) to control emissions of toxic air pollutants.

   (C) COMAR 26.11.15.06, which prohibits the discharge of toxic air pollutants to the extent that such emissions will unreasonably endanger human health.

2. Record Keeping and Reporting:

   The Permittee shall submit to the Department, by April 1 of each year during the term of this permit, a written certification of the results of an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year. The analysis shall include either:

   (i) a statement that previously submitted compliance demonstrations for emissions of toxic air pollutants remain valid; or

   (ii) a revised compliance demonstration, developed in accordance with requirements included under COMAR 26.11.15 & 16, that accounts for changes in operations, analytical methods, emissions determinations, or other factors that have invalidated previous demonstrations.

NON-CONFIDENTIAL COPY

Part 70 Permit
Renewal Application

Terumo Cardiovascular Systems
125 Blue Ball Road
Elkton, Maryland 21921

May 2021

Terumo Cardiovascular Systems
2021 Title V Renewal
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MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 Washington Boulevard • Suite 720 • Baltimore, Maryland 21230-1720
410-537-3000 • 800-633-6101 • http://www.mde.state.md.us
Air and Radiation Administration • Air Quality Permits Program

Budget Reconciliation and Financing Act of 2003
(Commonly referred as Maryland House Bill 935)

On July 1, 2003, House Bill 935, Chapter 203 amended § 1-203 of the Environment Article, Annotated Code of Maryland, as follows:

Section 1-203(b).
(1) A license or permit is considered renewed for purposes of this subsection if the license or permit is issued by a unit of State government to a person for the period immediately following a period for which the person previously possessed the same or a substantially similar license.
(2) Before any license or permit may be renewed under this article, **the issuing authority shall verify through the office of the Comptroller (emphasis added)** that the applicant has paid all undisputed taxes and the unemployment insurance contributions payable to the Comptroller or the Secretary of Labor, Licensing, and Regulation or that the applicant has provided for payment in a manner satisfactory to the unit responsible for collection.

In order for the Maryland Department of the Environment (MDE) to verify this compliance, we would need you to provide the following information before we can process or issue your renewal license, permit, or certification:

Current MDE License/Permit No.: 24-015-0212

Name of Licensee or Permit Holder: Terumo Cardiovascular Systems

Address: 125 Blue Ball Road - Elkton, MD 21921

Contact Name: Nick Begin **Title:** EHS Manager

Contact Telephone Number: 908-616-7072

Privacy Act Notice: This Notice is provided pursuant to the Federal Privacy Act of 1974, 5 U.S.C. § 552a. Disclosure of your Social Security or Federal Tax Identification on this form is mandatory pursuant to the provisions of § 1-203 (2003) of Environment Article, Annotated Code of Maryland, which requires MDE to verify that an applicant for a permit or license has paid all undisputed taxes and unemployment insurance. Social Security and Federal Tax Identification Nos. will not be used for any purposes other than those described in this Notice.

Federal Employer Identification Number (FEIN): 52-2173764

Certification: I certify that the above information is true and correct to the best of my knowledge.

Signature 5/18/21 Date

Complete and return this form to the above address. If you have any questions, please contact our office at (410) 537-3225.

MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 Washington Boulevard Baltimore MD 21230
(410) 537-3000 1-800-633-6101 http://www.mde.state.md.us

PART 70 PERMIT APPLICATION FOR RENEWAL

AIR AND RADIATION MANAGEMENT ADMINISTRATION

Facilities required to obtain a Part 70 permit under COMAR 26.11.03.01 must complete and return this form. Applications are incomplete unless all applicable information required by COMAR 26.11.03.03 is supplied. Failure to supply additional information required by the Department to enable it to act on the application may result in loss of the application shield and denial of this application.

Owner and Operator:

Name of Owner or Operator: Terumo Cardiovascular Systems		
Street Address: 125 Blue Ball Rd.		
City: Elkton	State: MD	Zip Code: 21921
Telephone Number: 410-398-8500		Fax Number: 410-392-2415

Facility Information:

Name of Facility: Terumo Cardiovascular Systems		
Street Address: 125 Blue Ball Rd.		
City: Elkton	State: MD	Zip Code: 21921
Plant Manager: Kevin Doughty	Telephone Number: 302-530-2952	Fax Number: 410-392-7218
24-Hour Emergency Telephone Number for Air Pollution Matters: 443-252-4204		

List, on a separate page, the names and telephone numbers of other facility owners and persons with titles.

SECTION 1. CERTIFICATION STATEMENTS

1. Compliance Status with Applicable Enhanced Monitoring and Compliance Certification Requirements

The emissions units identified in this application are in compliance with applicable enhanced monitoring and compliance certification requirements.

2. Certification of Current Compliance with All Applicable Federally Enforceable Requirements

Except for the requirements identified in Section 7 of this application, for which compliance is not achieved, I hereby certify, based on information and belief formed after reasonable inquiry, that the facility is currently in compliance with all applicable federally enforceable requirements and agree that the facility will continue to comply with those requirements during the permit term.

You must complete a Section 7 form for each non-complying emissions unit.

3. Statement of Compliance with Respect to All New Applicable Requirements Effective During the Permit Term

I hereby state, based on information and belief formed after reasonable inquiry, that the facility agrees to meet, in a time ly manner, all applicable federally enforceable requirements that become effective during the permit term, unless a more detailed schedule is expressly required by the applicable requirement.

4. Risk Management Plan Compliance

I hereby certify that, based on information and belief formed after reasonable inquiry that a Risk Management Plan as required under 112(r) of the Clean Air Act:

[ ] has been submitted;

[ ] will be submitted at a future date;

or [✓] does not need to be submitted.

5. Statement of Truth, Accuracy, and Completeness

"I certify, under penalty of law, that this document and all attachments were prepared under my direction or supervision and in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person(s) who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

RESPONSIBLE OFFICIAL:

X Kevin Doughty 05/25/21

SIGNATURE DATE

Kevin Doughty
PRINTED NAME

Vice President of Operations
TITLE

SECTION 2. FACILITY DESCRIPTION SUMMARY

1. Major Activities of Facility

Briefly describe the major activities, including the applicable SIC Code(s) and end product(s).

Terumo Cardiovascular Systems (TCVS) manufactures, markets, and sells medical devices, supplies, and accessories. The facility operates under SIC SIC Code 3841.

2. Facility-Wide Emissions

A. This facility is required to obtain a Part 70 Operating Permit because it is:
Check appropriate box:

✓ Actual Major
□ Potential Major·
□ Solid Waste Incineration Unit Requiring Permit Under § 129(e) of CAA

B. List the actual facility-wide emissions below:

PM10 0.03 NOx 1.41 VOC 25.01 SOx 0.01 CO 1.19 HAPs 8.02

3. Include With the Application:

Flow Diagrams showing all emissions units, emission points, and control devices;
Emissions Certification Report (copy of the most recent submitted to the Department)

MARYLAND DEPARTMENT OF THE ENVIRONMENT

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-1 1a. Date of installation (month/year): 1973	2. MDE Registration No.: (if applicable) 015-0212-5-0089

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Cleaver Brooks natural gas fired boiler rated at 2 MMBtu per hour used for space heat.

Emissions went to atmosphere through EF-1.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.	Natural Gas		11,592,000 ft³/yr
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.580 SOx 0.003 VOC 0.032

PM10 0.044 HAPs 0.011

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-7 1a. Date of installation (month/year): 1997, modified 2000 & 2017	2. MDE Registration No.: (if applicable) 015-0212-6-0222

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

Capiox Oxygenator (OX) Potting and Coating Area, biopassive coating.

Fume hoods from EU-7 vent to EF-14.

A PTC was submitted in December 2016 for the addition of a NX Oxygenator process. This was approved by MDE in February 2017.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.070

PM10 0.000 HAPs 0.020

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-8 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0225

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in October 2016.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-9 1a. Date of installation (month/year): Relocated in 2000	2. MDE Registration No.: (if applicable) 015-0212-6-0234

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Capiox - Quick Disconnect Assembly Area, manual bonding.

Enclosures vent to atmosphere.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.150

PM10 0.000 HAPs 0.144

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-10 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0219

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in October 2016.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-11 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0223

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in October 2016.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-12 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0227

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Venous Reservoir (VR) and Cardiotomy Reservoir (CR) Filter dipping area, biopassive coating

Fume hoods vent to EF-4.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 15.550

PM10 0.000 HAPs 2.018

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-13 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0226

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Capiox Cardiotomy Reservoir (CR) Potting/Assembly Area.

Fume hoods vent to EF-3.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.290

PM10 0.000 HAPs 0.117

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-14 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0230

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in November 2016.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-15 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0221

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in December 2019.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-16 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0220

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in November 2016.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-17 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0224

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Capiox Reservoir Assembly Area, manual bonding and biopassive coating.
Fume hoods vent to EF-3.

A PTC was submitted in January 2021 to increase production in Capiox Reservoir Assembly. This was approved by MDE in April 2021.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day
_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 1.050
PM10 0.000 HAPs 0.919

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-18 1a. Date of installation (month/year): 1997	2. MDE Registration No.: (if applicable) 015-0212-6-0228

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Capiox Final Assembly Area, manual bonding

Fume hoods vent to EF-3.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.680

PM10 0.000 HAPs 0.673

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-19 1a. Date of installation (month/year): 2001	2. MDE Registration No.: (if applicable) 015-0212-6-0229

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

This source was removed in September 2017.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-20 1a. Date of installation (month/year): 2000	2. MDE Registration No.: (if applicable) 015-0212-6-0216

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

Conducer (CON) Area with fume hoods.

This area vents to EF-17.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.120

PM10 0.000 HAPs 0.001

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-21 1a. Date of installation (month/year): 2000	2. MDE Registration No.: (if applicable) 015-0212-6-0231

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Pump Assembly, manual bonding

Fume hoods vent to EF-15.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.001

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-22 1a. Date of installation (month/year): 2004	2. MDE Registration No.: (if applicable) 015-0212-6-0211

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Flexible Venous Reservoir (FVR) Coating Line, manual bonding and biopassive coating

This area vents to EF-3.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.			
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.140

PM10 0.000 HAPs 0.135

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-23 1a. Date of installation (month/year): 2001	2. MDE Registration No.: (if applicable) 015-0212-6-0233

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) X-Coat Capiox/Connectors Area, biopassive coating.

Fume hoods vent to EF-16.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 1.560

PM10 0.000 HAPs 1.548

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-24 1a. Date of installation (month/year): 2001	2. MDE Registration No.: (if applicable) 015-0212-6-0232

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) X-Coat Tubing Area, biopassive coating.

Fume hoods vent to EF-16.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 4.470

PM10 0.000 HAPs 2.355

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-25 1a. Date of installation (month/year): 2002	2. MDE Registration No.: (if applicable) 015-0212-6-0217

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Tubing Pack Assembly Area, manual bonding

Fugitive emissions.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.060

PM10 0.000 HAPs 0.048

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-26 1a. Date of installation (month/year): 2005	2. MDE Registration No.: (if applicable) 015-0212-6-0255

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) CDI Assembly Area, manual bonding - HSAT

Fugitive Emissions.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-27 1a. Date of installation (month/year): 2005	2. MDE Registration No.: (if applicable) 015-0212-6-0255

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) OPS Assembly Area, manual bonding

Fugitive Emissions.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-28 1a. Date of installation (month/year): 1979	2. MDE Registration No.: (if applicable) 015-0212-6-0212

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

Facility Wide Cleaning Operations

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.790

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-29 1a. Date of installation (month/year): 2005	2. MDE Registration No.: (if applicable) 015-0212-6-0255

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) CDI Assembly Area, manual bonding - SHUNT

Fugitive emissions.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: _____

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-30 1a. Date of installation (month/year): 2013	2. MDE Registration No.: (if applicable) 015-0212-5-0126

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

Clever Brooks NG Boiler - 1.57MMBtu (Process Heat)

Air emissions from the boiler are vented through a dedicated stack.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.	Natural Gas		9,047,000 ft³/yr
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.452 SOx 0.003 VOC 0.025

PM10 0.034 HAPs 0.009

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-31	2. MDE Registration No.: (if applicable)
1a. Date of installation (month/year): 2020	

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

HB Smith NG Fired Boiler - 1.30 MMBtu

Air emissions from the boiler are vented through a dedicated stack.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

	Types of Fuel	% Sulfur	Annual Usage (specify units)
1.	Natural Gas		7,633,000 ft³/yr
2.			
3.			

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.382 SOx 0.002 VOC 0.021

PM10 0.029 HAPs 0.007

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-32 1a. Date of installation (month/year): 2012	2. MDE Registration No.: (if applicable) 015-0212-6-0312

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) Biological Safety Cabinet. There are no emissions associated with this unit.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: EU-33 1a. Date of installation (month/year): 2014	2. MDE Registration No.: (if applicable) 015-0212-6-0338

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

One (1) SARNS 101 Chemical Manufacturing Process. Emissions from this unit are deminimus.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3A. EMISSIONS UNIT DESCRIPTIONS

1. Emissions Unit No.: TBD 1a. Date of installation (month/year): 2018	2. MDE Registration No.: (if applicable) 015-0212-6-0374

3. Detailed description of the emission unit, including all emission point(s) and the assigned number(s):

A PTC was submitted in June 2018 for the installation of a centrifugal pump automated assembly machine.

This area vents to exhaust EF-03. This was approved by MDE in August 2018.

4. Federally Enforceable Limit on the Operating Schedule for this Emissions Unit:

General Reference: N/A

Continuous Processes: _____ hours/day _____ days/year

Batch Processes: _____ hours/batch _____ batches/day

_____ days/year

5. Fuel Consumption:

Types of Fuel	% Sulfur	Annual Usage (specify units)
1.		
2.		
3.		

6. Emissions in Tons:

A. Actual Major: _____ Potential Major: _____ (note: before control device)

B. Actual Emissions: NOx 0.000 SOx 0.000 VOC 0.000

PM10 0.000 HAPs 0.000

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.06.03D

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall not cause or permit any building, its appurtenenances, or a road to be used, constructed, altered, repaired, or demolished without taking reasonable precautions to prevent particulate matter from becoming airborne.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.07

Briefly describe the Emission Standard/Limit or Operational Limitation:

Except as provided in COMAR 26.11.07.04, the Permittee shall not cause or permit an open fire from June 1 through August 31 of any calendar year. Prior to any open burning, the Permittee shall request and receive approval from the Department.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.05.04

Briefly describe the Emission Standard/Limit or Operational Limitation:

When requested by the Department, the Permittee shall prepare in writing standby emissions reduction plans, consistent with good industrial practice and safe operating procedures, for reducing emissions creating air pollution during periods of Alert, Warning, and Emergency of an air pollution episode.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.01.07 & COMAR 26.11.03.06C(7)

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall promptly report any deviations from permit requirements; all occurances of excess emissions that are expected to last for one hour or longer; report all deviations from permit conditions within 5 days when requested; submit semi-annual monitoring reports; when requested submit a written report to the Department within 10 days of receiving the request concerning excess emissions.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[✓] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference Multiple Describe: Immediate notification of the Department is required by telephone (26.11.03.06C(7)(ii)); Excess emissions expected to last for one hour or longer shall be notified orally to the Department (26.11.01.07C(1)); When requested by the Department, the Permittee shall provide a written report of deviations within 5 days of request (26.11.03.06C(7)(iii)); Permitee shall submit semi-annual monitoring reports within 30 days of each reporting period; (03.11.03.06C(7)(i); When requested by the Department, the Permitee shall provide a written report of excess emissions within 10 days of request (26.11.01.07D(1)).

Frequency of submittal of the compliance demonstration: Semi-Annual & Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.03.03B(23)

Briefly describe the Emission Standard/Limit or Operational Limitation:

Should the Permittee become subject to 40 CFR 68 during the term of this permit, the Permittee shall submit risk management plans by the date specified in 40 CFR 68.150 and shall certify compliance with the requirements of 40 CFR 68 as part of the annual compliance certification as required by 40 CFR 70.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Not Applicable

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.01.04

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Department may require the Permittee to conduct, or have conducted, testing to determine compliance with this Part 70 permit. The Department, at its option, may witness or conduct these tests. This testing shall be done at a reasonable time, and all information gathered during a testing operation shall be provided to the Department.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Not Applicable

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.01.04

Briefly describe the Emission Standard/Limit or Operational Limitation:

Compliance with the emissions standards and limitations in this Part 70 permit shall be determined by the test methods designated or other test methods submitted to and approved by the Department.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.01.05-1 COMAR 26.11.02.19C COMAR 26.11.02.19D

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall certify actual annual emissions of regulated pollutants from the facility on a calendar basis no later than April 1.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.01.05-1C Describe: Emissions statements shall be organized by premises, submitted on a Department form, and include the following information: identification of each source that discharges NOx or VOC and their daily and annual emissions; an explanation of the method used to determine emissions and operating schedules and production data; an explanation for any increases or decreases in emissions; and other relevant information as required by the Department.

Reporting: Reference COMAR 26.11.01.05-1B Describe: Submit to the Department an emissions statement for the previous calendar year that meets the recordkeeping requirements of this regulation. A person certifying that the information in the emissions statement should be familiar with each source for which the statement is submitted and responsible for the accuracy of the statement.

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.03.06G (6)&(7)

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permitee shall submit to the Department and EPA Region III a report certifying compliance with each term of this Part 70 permit including each applicable standard, emission limitation, and work practice for the previous year by April 1 of each year.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference COMAR 26.11.03.06G (6)&(7) Describe: The compliance certfication shall include: the identification of each condition of this permit which is the basis of the certification; the compliance status; whether the compliance was continuous or intermittent; the methods used for determining the compliance status of each source; any other information required to be reported to the Department.

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.02.02F

Briefly describe the Emission Standard/Limit or Operational Limitation:

All application forms, reports, and compliance certifications submitted pursuant to this permit shall be certified by a responsible official as to truth, accuracy and completeness. The Permittee shall expeditiously notify the Department of an appointment of a new responsible official.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference COMAR 26.11.02.02F Describe: The certification shall be in the following form:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalities for submitting false informaiton, including the possibility of fine and imprisonment for knowing knowing violations."

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.03.06C(5)

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall gather and retain information as specified when sampling and testing for compliance demonstrations.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.03.06C(5) Describe: Retain the following information: the location and date and time that samples and measurements are taken; all pertinent operating conditions existing at the time samples and measurements are taken; the date that each analysis is performed and the name of the person taking the sample; the identity of the entity that performed the analysis; the analytical methods; and the results of each analysis.

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.03.06C(6)

Briefly describe the Emission Standard/Limit or Operational Limitation:

The permittee shall retain records of all monitoring data and information that support the compliance certfication for a period of five years from the date that the monitoring, sample measurement, application, report or emissions test was completed or submitted to the Department.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.03.06C(6) Describe: These records and support information shall include: all calibration and maintenance records; all original data collected from continous monitoring instrumentation; records which support the annual emissions certification; and copies of all reports required by the permit.

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.26.09

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall comply with the general conformity requirements of 40 CFR 93, Subpart B and COMAR 26.11.26.09.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference 40 CFR 93.155 Describe: When a revision to the Maryland State Implementation Plan is needed, a 30-day noticed which describes the proposed action needs to be submitted.

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** 40 CFR 61, Subpart M

Briefly describe the Emission Standard/Limit or Operational Limitation:

The permittee shall comply with 40 CFR 61, Subpart M when conducting any renovation or demolition activities at the facility.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference 40 CFR 61, Subpart M Describe: Notify the Department prior to any applicable renovation or demolition activities at the facility.

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** 40 CFR 82, Subpart F

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permittee shall comply with the standards for recycling and emissions reduction pursuant to 40 CFR 82, Subpart F, except as provided for MVACs in Subpart B.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference 40 CFR 82.166 Describe: Owners/Operators of appliances normally containing 50 or more pounds of refrigerant shall keep records of refrigerant purchased and added to such appliances pursuant to 40 CFR 82.166.

Reporting: Reference None Describe:

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: EU-1, EU30, EU-31 **General Reference:** COMAR 26.11.09.05A(1)

Briefly describe the Emission Standard/Limit or Operational Limitation:

A person may not cause or permit discharge of emissions from any fuel burning equipment, other than water in an uncombined form, which is greater than 20 percent opacity.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference COMAR 26.11.03.06C Describe: The permitee shall properly operate and maintain the boilers in a manner to prevent visible emissions.

Testing: Reference None Describe:

Record Keeping: Reference None Describe:

Reporting: Reference COMAR 26.11.03.06C Describe: The permitee shall report incidents of visible emissions within 5 days of discovery of the deviation or a shorter time that the Department may specify in the permit, by submitting a written description of the deviation to the Department, including the cause and dates and times of the onset and termination of deviation.

Frequency of submittal of the compliance demonstration: As required

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: EU-1, EU-30, EU-31 **General Reference:** COMAR 26.11.02.09A

Briefly describe the Emission Standard/Limit or Operational Limitation:

The permitee shall burn only natural gas in the boilers unless the permittee applies for and obtains an approval from the Department to burn alternative fuels per COMAR 26.11.02.09A

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.02.19C & D Describe: The permitee shall keep annual fuel usage records including the amount and type of fuel used on site for at least five years.

Reporting: Reference COMAR 26.11.02.19C & D Describe: Annual fuel usage records including the amount and type of fuel used shall be submitted with the required annual emission certification.

Frequency of submittal of the compliance demonstration: Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: EU-7, EU-9, EU-12, EU-13, EU-17, EU-18, EU-21, EU-22, EU-23, EU-24, EU-25, EU-26, EU-27, EU-29 **General Reference:** COMAR 26.11.19.31

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permitee is required to minimize VOC emissions from medical device manufacturing for premises that emit or have the potential to emit 100 pounds or more per day of VOC emissions from all medical manufacturing installations.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[✓] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference COMAR 26.11.03.06C Describe: The Permittee shall do the following…provide and maintain VOC imperable covers on dip pots; upon request, participate in the evaluation of new or innovative designs or VOC material substitutions; use an enclosed system to apply biopassive coating to fully assembled medical devices; apply biopassive coating to individual medical device components only when it is not feasable to coat in assembled form.

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.03.06C Describe: The Permitee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information: (1) Monthly records of the amount of material used and waste generated for each registered process area (2) Material Safety Data Sheets (MSDS) for all materials used.

Reporting: Reference COMAR 26.11.19.31 E & F Describe: Before coating individual components under COMAR 26.11.19.31 D(1)(d), the Permitee shall submit to the Department for review and approval, a report documenting the technical and economic justification for coating components individually. Before using an alternative method of compliance or control technology as allowed under COMAR 26.11.19.31D(2), the Permitee shall submit to the Department for review and approval, a proposal to use such an alternative method of compliance or control technology.

Frequency of submittal of the compliance demonstration: Semi-Annual & Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** ARMA PTC Issued 02/22/17

Briefly describe the Emission Standard/Limit or Operational Limitation:

Facility Wide HAP emissions shall be less than the following limits: (1) 10 tons in any rolling 12-month period for any single HAP; and (2) 25 tons in any rolling 12-month period for the total combination of all HAP.

Facility wide emissions include total emissions from both TMC and TCVS Elkton, MD combined.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[✓] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference None Describe:

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.03.06C Describe: The Permitee shall keep the following records on site: 1. Facility wide individual HAP emissions in tons per month per individual HAP and the total tons for the previous 12 months for each individual HAP 2. Facility wide total HAP emissions in tons per month and the total tons for the previous 12 months.

Reporting: Reference COMAR 26.11.03.06C & D Describe: Facility wide HAP emissions records shall be submitted with the required annual emission certification.

Frequency of submittal of the compliance demonstration: Semi-annual/Annually

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.19.02I

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permitee shall implement good operating practices to minimize Volatile Organic Compound (VOC) emissions in to the atmosphere.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[✓] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference COMAR 26.11.19.02I Describe: The Permittee shall implement "good operating practices" designed to minimize emissions of VOC to the atmosphere; establish good operating practices in writing; take reasonable precautions to prevent or minimize the discharge of VOC into the atmosphere when cleaning process and coating application equipment, including containers, vessels, tanks, lines and pumps; minimize VOC emissions into the atmosphere from VOC storage and transfer operations

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.19.02I(2)c Describe: Good operating practices information shall be kept on site at all times

Reporting: Reference COMAR 26.11.19.02I Describe: Good operating practices information as required by COMAR 26.11.19.02I shall be made available to the Department upon request

Frequency of submittal of the compliance demonstration: Semi-Annual & Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.19.16C

Briefly describe the Emission Standard/Limit or Operational Limitation:

The Permitee is required to minimize leaks from VOC equipment and their components, including process equipment, storage tanks, pumps, compressors, valves, flanges and other pipeline fittings, pressure relief valves, process drains, and open-ended pipes.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report:

[✓] Annual Compliance Certification:

[✓] Semi-Annual Monitoring Report:

Methods used to demonstrate compliance:

Monitoring: Reference COMAR 26.11.19.16C Describe: The Permittee shall perform the following to minimize VOC emissions from equipment leaks: a. Visually inspect all components on the premises for leaks at least once each calendar month b. Tag any operating leak immediately so that the tag is clearly visible.

Testing: Reference None Describe:

Record Keeping: Reference COMAR 26.11.19.16C(6) Describe: Leak inspection logs shall be kept on-site for at least five (5) years.

Reporting: Reference COMAR 26.11.19.16C(6) Describe: Leak inspection logs as required shall be made available to the Department upon request.

Frequency of submittal of the compliance demonstration: Semi-Annual & Annual

SECTION 3B. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Emissions Unit No.: Emergency Generators **General Reference:** 40 CFR 63 Supart ZZZZ

Briefly describe the Emission Standard/Limit or Operational Limitation:

The emergency generators are subject to the requirements of 40 CFR, Part 63 Subpart ZZZZ and must be operated, maintained, inspected, and demonstrate continuous compliance with each emission limitation and operating limitation listed. The Permittee shall comply with all applicable requirements listed in Table 8 - General Provisions of 40 CFR 63 Subpart ZZZZ.

Permit Shield Request: Not Applicable

Compliance Demonstration:

Check appropriate reports to be submitted:

[] Quarterly Monitoring Report: _____

[] Annual Compliance Certification: _____

[] Semi-Annual Monitoring Report: _____

Methods used to demonstrate compliance:

Monitoring: Reference 40 CFR 63.6603 Describe: The Permittee must comply with the requirements set forth in Table 2d, which establishes maintenance, and inspection requirements for the engines.

Testing: Reference None Describe:

Record Keeping: Reference 40 CFR 63.6655 (d-f) Describe: The Permittee must keep the records required in Table 6 of the subpart to show continous compliance with each applicable emission or operating limitation; records of the maintenance conducted on the stationary RICE; records of hours of operation of the engine that is recorded through a non-resettable hour meter.

Reporting: Reference 40 CFR 63.6640(b) Describe: The Permittee must report each instance in which applicable emission limitations or operating limitations in Table 2d of the subpart were not met.

Frequency of submittal of the compliance demonstration: As required

SECTION 3C. OBSOLETE, EXTRANEOUS, OR INSIGNIFICANT PERMIT CONDITIONS

List permit to construct conditions which should be considered to be obsolete, extraneous, or environmentally insignificant.

Emissions Unit No.: Not Applicable **Permit to Construct No. _____**

Emissions Point No.	Date Permit Issued	Condition No.	Brief Description of Condition and Reason for Exclusion

SECTION 3D. ALTERNATE OPERATING SCENARIOS

Emissions Unit No.: Not Applicable

Briefly describe any alternate operating scenarios. Assign a number to each scenario for identification purposes.

SECTION 3E. CITATION TO AND DESCRIPTION OF APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS FOR AN ALTERNATE OPERATING SCENARIO

Scenario No.: Not Applicable

Emissions Unit No.: _____ General Reference: _____

Briefly describe any applicable Emissions Standard/Limits/Operational Limitations:

_____

_____

_____

_____

_____

_____

Compliance Demonstration

Methods used to demonstrate compliance:

Monitoring: Reference _____ Describe: _____

_____

_____

_____

Testing: Reference _____ Describe: _____

_____

_____

_____

Record Keeping: Reference _____ Describe: _____

_____

_____

_____

Reporting: Reference _____ Describe: _____

_____

_____

_____

Frequency of submittal of the compliance demonstration: _____

SECTION 4. CONTROL EQUIPMENT

1. Associated Emissions Units No. : Not Applicable	2. Emissions Point No.:
3. Type and Description of Control Equipment:	

4. Pollutants Controlled:	Control Efficiency:

5. Capture Efficiency:

SECTION 5. SUMMARY SHEET OF POTENTIAL EMISSIONS

List all applicable pollutants in tons per year (TPY) pertaining to this facility. The Emission Unit No. Should be consistent with numbers used in Section 3. Attach a copy of all calculations.

Pollutant	VOC	NO_X	PM	SO_2	CO
CAS Number					
Emissions Unit # 1	0.048	0.876	0.067	0.005	0.736
Emissions Unit # 7	2.887				
Emissions Unit # 8	Source was removed in 2016.				
Emissions Unit # 9	0.167	-	-	-	-
Emissions Unit # 10	Source was removed in 2016.				
Emissions Unit # 11	Source was removed in 2016.				
Emissions Unit # 12	17.168	-	-	-	-
Emissions Unit # 13	0.318	-	-	-	-
Emissions Unit # 14	Source was removed in 2016.				
Emissions Unit # 15	Source was removed in 2019.				
Emissions Unit # 16	Source was removed in 2016.				
Emissions Unit # 17	0.770	-	-	-	-
Emissions Unit # 18	0.750	-	-	-	-
Emissions Unit # 19	Source was removed in 2017.				
Emissions Unit # 20	0.127	-	-	-	-
Emissions Unit # 21	0.002	-	-	-	-
Fugitive Emissions					
Total	Continued on next page				

SECTION 5. SUMMARY SHEET OF POTENTIAL EMISSIONS

List all applicable pollutants in tons per year (TPY) pertaining to this facility. The Emission Unit No. Should be consistent with numbers used in Section 3. Attach a copy of all calculations.

Pollutant	VOC	NO_X	PM	SO_2	CO
CAS Number					
Emissions Unit # 22	0.150	-	-	-	-
Emissions Unit # 23	1.726	-	-	-	-
Emissions Unit # 24	4.938	-	-	-	-
Emissions Unit # 25	0.061	-	-	-	-
Emissions Unit # 26	0.003	-	-	-	-
Emissions Unit # 27					
Emissions Unit # 29					
Emissions Unit # 28	0.870	-	-	-	-
Emissions Unit # 30	0.039	0.688	0.052	0.004	0.578
Emissions Unit # 31	0.032	0.569	0.043	0.003	0.478
Emissions Unit # TBD	0.001	-	-	-	-
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Fugitive Emissions					
Total	30.057	2.133	0.162	0.012	1.792

SECTION 5. SUMMARY SHEET OF POTENTIAL EMISSIONS

List all applicable pollutants in tons per year (TPY) pertaining to this facility. The Emission Unit No. Should be consistent with numbers used in Section 3. Attach a copy of all calculations.

Pollutant	Total HAPs				
CAS Number					
Emissions Unit # 1	0.017				
Emissions Unit # 7	0.005				
Emissions Unit # 8	Source was removed in 2016.				
Emissions Unit # 9	0.143				
Emissions Unit # 10	Source was removed in 2016.				
Emissions Unit # 11	Source was removed in 2016.				
Emissions Unit # 12	0.334				
Emissions Unit # 13	0.021				
Emissions Unit # 14	Source was removed in 2016.				
Emissions Unit # 15	Source was removed in 2019.				
Emissions Unit # 16	Source was removed in 2016.				
Emissions Unit # 17	2.088				
Emissions Unit # 18	0.111				
Emissions Unit # 19	Source was removed in 2017.				
Emissions Unit # 20	0.005				
Emissions Unit # 21	0.000				
Fugitive Emissions					
Total	Continued on next page				

SECTION 5. SUMMARY SHEET OF POTENTIAL EMISSIONS

List all applicable pollutants in tons per year (TPY) pertaining to this facility. The Emission Unit No. Should be consistent with numbers used in Section 3. Attach a copy of all calculations.

Pollutant	VOC	NO_X	PM	SO_2	CO
CAS Number					
Emissions Unit # 22	0.002				
Emissions Unit # 23	0.256				
Emissions Unit # 24	0.390				
Emissions Unit # 25	0.048				
Emissions Unit # 26	-				
Emissions Unit # 27					
Emissions Unit # 29					
Emissions Unit # 28	-				
Emissions Unit # 30	0.013				
Emissions Unit # 31	0.011				
Emissions Unit # TBD	-				
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Emissions Unit #					
Fugitive Emissions					
Total	3.445				

SECTION 6. EXPLANATION OF PROPOSED EXEMPTIONS FROM OTHERWISE APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Describe and cite the applicable requirements to be exempted. Complete this Section only if the facility is claiming exemptions from or the non-applicability of any federally enforceable requirements.

1. Applicable Requirement:
Not Applicable

2. Brief Description:

_____

_____

_____

3. Reasons for Proposed Exemption or Justification of Non-applicability:

_____

_____

_____

_____

_____

SECTION 7. COMPLIANCE SCHEDULE FOR NONCOMPLYING EMISSIONS UNITS

1. Emissions Unit #	Anticipated Compliance Date
Not Applicable	
Applicable Federally Enforceable Requirement being Violated:	

2. Description of Plan to Achieve Compliance:

_____

_____

_____

_____

_____

_____

Certified Progress Reports for sources in noncompliance shall be submitted at least quarterly to the Department.

STATE-ONLY ENFORCEABLE REQUIREMENTS

Facility Information:

Name of Facility: Terumo Cardiovascular Systems	County Cecil County
Premises Number: 00212	
Street Address: 125 Blue Ball Road	
24-hour Emergency Telephone Number for Air Pollution Matters: 443-252-4204	
Type of Equipment (List Significant Units): Medical device manufacturing facility	

CITATION TO AND DESCRIPTION OF APPLICABLE STATE-ONLY ENFORCEABLE REQUIREMENTS

Registration No.: Facility Wide

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.06.08 COMAR 26.11.06.09

Briefly describe the requirement and the emissions limit (if applicable):

An installation or premises may not be operated or maintained in such a manner that a nuisance or air pollution is created.

Nothing in this regulation relating to the control of emissions may in any manner be construed as authorizing or permitting the creation of, or maintenance of, nuisance or air pollution.

A person may not cause or permit the discharge into the atmosphere of gases, vapors, or odors beyond the property line in such a manner a manner that a nuisance or air pollution is created.

Methods used to demonstrate compliance:

Any installation or premises is not operated or maintained in such a manner that a nuisance or air pollution is created.

CITATION TO AND DESCRIPTION OF APPLICABLE STATE-ONLY ENFORCEABLE REQUIREMENTS

Registration No.: Facility Wide

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.15.05

Briefly describe the requirement and the emissions limit (if applicable):

The Permitee shall implement "Best Available Control Technology for Toxics" to control emissions of toxic air pollutants.

Methods used to demonstrate compliance:

The Permittee shall submit to the Department, by April 1 of each year during the term of this permit, a written certification of the results of the an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year.

CITATION TO AND DESCRIPTION OF APPLICABLE STATE-ONLY ENFORCEABLE REQUIREMENTS

Registration No.: Facility Wide

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.15.06

Briefly describe the requirement and the emissions limit (if applicable):

The Permittee is prohibited from the discharge of toxic air pollutants to the extent that such emissions will unreasonably endanger human health.

Methods used to demonstrate compliance:

The Permittee shall submit to the Department, by April 1 of each year during the term of this permit, a written certification of the results of the an analysis of emissions of toxic air pollutants from the Permittee's facility during the previous calendar year.

CITATION TO AND DESCRIPTION OF APPLICABLE STATE-ONLY ENFORCEABLE REQUIREMENTS

Registration No.: Facility Wide

Emissions Unit No.: Facility Wide **General Reference:** COMAR 26.11.33.01-.06

Briefly describe the requirement and the emissions limit (if applicable):

No person may sell, lease, rent, install, use, or manufacture in the State, any product or equipment if it consists of, uses, or will use a listed substance for use in an end-use listed in Regulation .03B of this chapter, unless an exemption is listed in Regulation .03C of this chapter.

Methods used to demonstrate compliance:

The permittee shall obtain documentation from the manufacturer and/or service provider as to what refrigerants are being used and whether or not the material is compliant with the regulation.

Attachment 1:

Facility Diagram

Terumo Cardiovascular Systems: 125 Blue Ball Rd, Elkton MD, 21921

Attachment 2

New Process Area Flow Diagrams

(Confidential Information Omitted)

Attachment 3

RY2020 Annual Compliance Certification

yo United States Environmental Protection Agency

OMB No. 2060-0336, Expires 11/30/2022

Federal Operating Permit Program (40 CFR Part 71)
CERTIFICATION OF TRUTH, ACCURACY, AND COMPLETENESS (CTAC)

This form must be completed, signed by the "Responsible Official" designated for the facility or emission unit, and sent with each submission of documents (i.e., application forms, updates to applications, reports, or any information required by a part 71 permit).

A. Responsible Official

Name: (Last) Doughty (First) Kevin (MI) ____

Title: Vice President of Operations

Street or P.O. Box 125 Blue Ball Rd.

City Elkton State MD ZIP 21921

Telephone (800) 262 - 3304 Ext. 7403 Facsimile (410) 392 - 7218

B. Certification of Truth, Accuracy and Completeness (to be signed by the responsible official)

I certify under penalty of law, based on information and belief formed after reasonable inquiry, the statements and information contained in these documents are true, accurate and complete.

Name (signed) Kevin Doughty

Name (typed) Kevin Doughty Date: 03 / 29 / 2021

United States Environmental Protection Agency

OMB No. 2060-0336, Expires 11/30/2022

Federal Operating Permit Program (40 CFR Part 71)
ANNUAL COMPLIANCE CERTIFICATION (A-COMP)

A. GENERAL INFORMATION

Permit No: 24-015-0212

Reporting Period: Beg. 01/01/20 **End.** 12/31/20

Source / Company Name: Terumo Cardiovascular Corporation

Mailing Address (*Street or P.O. Box***):** 125 Blue Ball Road

City: Elkton **State:** MD **ZIP:** 21921

Contact person: Jennifer Johnson **Title:** Senior EHS Specialist

Telephone (800) 283-7866 ext. 7480

Continued on next page

B. COMPLIANCE STATUS

Describe the compliance status of each permit term for the reporting period. Copy this page as many times as necessary to cover all permit terms and conditions.

Emission Unit ID(s): EU-1, EU-30, EU-31

Permit Term (Describe requirements and cross-reference):

Table IV -1, Condition 1.1A
Visible Emissions Limitations

COMAR 26.11.09.05A(1) which limits visible emissions from any fuel burning equipment to 20 percent opacity other than water in an uncombined form.

Exceptions. COMAR 26.11.09.05A(3) established that "Section A(1) does not apply to emissions during load changing, soot blowing, start-up, or adjustments or occasional cleaning of control equipment if (a) the visible emissions are not greater than 40 percent opacity; and (b) the visible emissions do not occur for more than 6 consecutive minutes in any 60 minute period."

Compliance Methods for the Above (Description and Citation):

Compliance with the visible emissions limitation is met by burning natural gas and properly maintaining the boilers.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): EU-1, EU-30, EU-31

Permit Term (Describe requirements and cross-reference):

Table IV-1, Condition 1.1B
Operational Requirement

The permittee shall burn only natural gas in the boiler unless the Permittee applies for and obtains an approval from the Department to burn alternative fuels per COMAR 26.11.02.09A.

Compliance Methods for the Above (Description and Citation):

Fuel records show that only natural gas was used in the boilers.

Status (Check one): ___ **Intermittent Compliance** _×_ **Continuous Compliance**

Emission Unit ID(s): EU-1, EU-30, EU-31

Permit Term (Describe requirements and cross-reference):

Table IV-1, Condition 1.4B

The Permittee shall keep annual fuel usage records, including the type of fuel used, on site for at least five years.
[Authority: COMAR 26.11.02.19 C and D]

Compliance Methods for the Above (Description and Citation):

Fuel usage records, including the amount and type of fuel used, are maintained for at least five years.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): EU-1, EU-30, EU-31

Permit Term (Describe requirements and cross-reference):

Table IV-1, Condition 1.5A

The Permittee shall report incidents of visible emission in accordance with Permit Condition 4, Section III, Plant Wide Conditions, “Report of Excess Emission and Deviations.”
[Authority: COMAR 26.11.02.19 C]

Compliance Methods for the Above (Description and Citation):

Any incidents of visible emissions are reported according to Permit Condition 4, Section III, Plant Wide Conditions, “Report of Excess Emission and Deviations.” There were no incidents of visible emissions during this compliance period.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): EU-1, EU-30, EU-31

Permit Term (Describe requirements and cross-reference):

Table IV-1, Condition 1.5B

Annual fuel usage, including the type of fuel used, shall be submitted with the required annual emission certification.
[Authority: COMAR 26.11.02.19 C and D]

Compliance Methods for the Above (Description and Citation):

Annual fuel usage is submitted as part of the annual emissions certification report.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

---

Emission Unit ID(s): EU-7, EU-9, EU-12, EU-15, EU-17, EU-18, EU-19, EU-21, EU-22, EU-23, EU-24, EU-25, EU-26, EU-27, EU-29, EU-33

Permit Term (Describe requirements and cross-reference):

Table IV-2, Conditions 2.1 & 2.3
Control of VOC

COMAR 26.11.19.31 which requires the Permittee to minimize VOC emissions from medical device manufacturing for premises that emit, or have the potential to emit, 100 pounds or more per day of VOC emissions from all medical device manufacturing installations.

The Permittee shall do all the following unless the Permittee uses a Department approved alternative method of compliance or alternative control technology that achieves an equivalent or better level of VOC Control:

a. Provide and maintain appropriately designed VOC impermeable covers on dip pots used for manual bonding operations when not in use;
b. Upon request of the Department, participate in the evaluation of new or innovative designs or VOC material substitutions to minimize the use of solvent bonds for medical device manufacturing;
c. Use an enclosed system to apply biopassive coating to fully assembled medical devices;
d. Apply biopassive coating to individual medical device components only when it is not feasible to coat medical devices in assembled form; and
[Authority: COMAR 26.11.19.31D]

Compliance Methods for the Above (Description and Citation):

Impermeable covers for dip pots for manual bonding operations have been provided and their use is documented on departmental check sheets. Fully assembled medical devices will have the biopassive coating applied within an enclosed system where practical. Individual medical device components are only coated when it is not feasible to coat them in assembled form.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): EU-7, EU-9, EU-12, EU-15, EU-17, EU-18, EU-19, EU-21, EU-22, EU-23, EU-24, EU-25, EU-26, EU-27, EU-29, EU-33

Permit Term (Describe requirements and cross-reference):

Table IV-2, Condition 2.4

The Permittee shall maintain for at least five (5) years, and shall make available to the Department upon request, records of the following information:

(1) Monthly records of the amount of materials used and the amount of material waste generated for each registered process area.
(2) Material Safety Data Sheets (MSDS) for all materials used.

[Authority: COMAR 26.11.03.06C and ARMA Premises Wide Permit to Construct issued on 02/22/2017]

Compliance Methods for the Above (Description and Citation):

(1) Records are maintained on site for all materials used and wastes generated.
(2) MSDS are maintained on site for all materials used.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): EU-7, EU-9, EU-12, EU-15, EU-17, EU-18, EU-19, EU-21, EU-22, EU-23, EU-24, EU-25, EU-26, EU-27, EU-29, EU-33

Permit Term (Describe requirements and cross-reference):

Table IV-2, Condition 2.5

Before coating individual components under COMAR 26.11.19.31D (1) (d), the Permittee shall submit to the Department for review and approval, a report documenting the technical and economic justification for coating components individually.
[Authority: COMAR 26.11.19.31E]

Compliance Methods for the Above (Description and Citation):

Approval will be sought before individually coating components.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): EU-7, EU-9, EU-12, EU-15, EU-17, EU-18, EU-19, EU-21, EU-22, EU-23, EU-24, EU-25, EU-26, EU-27, EU-29, EU-33

Permit Term (Describe requirements and cross-reference):

Table IV-2, Condition 2.5

Before using an alternative method of compliance or control technology as allowed under COMAR 26.11.19.31D(2), the Permittee shall submit to the Department for review and approval, a proposal to use such and alternative method of compliance or control technology.
[Authority: COMAR 26.11.19.31F]

Compliance Methods for the Above (Description and Citation):

Approval will be sought before using any alternative method of compliance technology.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.1 A&B

A. Facility Wide HAP Limitations

Facility wide HAP emissions shall not exceed the following limits:

(1) 10 tons in any rolling 12-month period for any single HAP;
(2) 25 tons in any rolling 12-month period for the total combination of all HAP.

Facility wide emissions shall include total emissions from both TMC and TCVS combined.

[Authority: ARMA Premises Wide Permit to Construct issued on 02/22/2017]

B. Control of VOC

COMAR 26.11.19.02I, which requires the Permittee to implement good operating practices to minimize Volatile Organic Compound (VOC) emissions into the atmosphere.

COMAR 26.11.19.16C, which requires the Permittee to minimize leaks from VOC equipment and their components, including process equipment, storage tanks, pumps, compressors, valves, flanges, and other pipeline fittings, pressure relief valves, process drains, and open-ended pipes.

Compliance Methods for the Above (Description and Citation):

Facility wide HAP emissions are maintained on a 12-month rolling basis. Facility wide emissions did not exceed 25 tons for total HAPs and 10 tons for a single HAP in any rolling 12-month period.

Good operating practices are in place to minimize VOC emissions, including leaks from VOC equipment and their components.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Conditions 3.3B (1) & (2)
Control of VOC

In accordance with COMAR 26.11.19.02I, the Permittee shall implement "good operating practices" designed to minimize VOC emissions to the atmosphere.

1. Where applicable, good operating practices shall, at a minimum, include the following:
- **a.** Provisions for training of operators on practices, procedures, and maintenance requirements that are consistent with the equipment manufacturers' recommendations and the source's experience in operating the equipment, with the training to include proper procedures for maintenance of air pollution control equipment;
- **b.** Maintenance of covers on containers and other vessels that contain VOC and VOC-containing materials when not in use;
- **c.** As practical, scheduling of operations to minimize color or material changes when applying VOC coating or other materials by spray gun;
- **d.** For spray gun applications of coatings, use of high volume low pressure (HVLP) or other high efficiency application methods where practical; and
- **e.** As practical, mixing or blending materials containing VOC in closed containers and taking preventative measures to minimize emissions for products that contain VOC.

2. The permittee shall:
- **a.** Establish good operating practices in writing;
- **b.** Make the written operating practices available to the Department upon request;
- **c.** Display the good operating practices so that they are clearly visible to the operator or include them in operator training.

Compliance Methods for the Above (Description and Citation):

Good operating practices, equipment manufacturers' recommendations, and the source's experience in operating the equipment have been established in writing and are included in all operator training materials. The maintenance of covers on containers and other vessels that contain VOC and VOC-containing materials is verified at least monthly and recorded on a departmental check sheet. Any requested documentation is provided to the Department.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Conditions 3.3B (3)

In accordance with COMAR 26.11.19.02I, the Permittee shall take all reasonable precautions to prevent or minimize the discharge of VOC into the atmosphere when cleaning process and coating application equipment, including containers, vessels, tanks, lines, and pumps.

3. Where applicable, reasonable precautions for equipment cleanup shall, at a minimum, include the following:

a. Storing all wastes and waste materials, including cloth and paper that are contaminated with VOC, in closed containers;
b. Preparing written standard operating procedures for frequently cleaned equipment, including when practical, provisions for the use of low VOC or non-VOC materials and procedures to minimize the quantity of VOC materials uses;
c. Using, when practical, enclosed spray gun cleaning, VOC-recycling systems, and other spray gun cleaning methods that reduce or eliminated VOC emissions; and
d. Using, when practical, detergents, high-pressure water, or other non-VOC cleaning operations to clean coating lines, containers, and process equipment.

Compliance Methods for the Above (Description and Citation):

All wastes and waste materials are stored in closed containers. Low VOC materials are used when cleaning process equipment.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Conditions 3.3B (4)

In accordance with COMAR 26.11.19.02I, the Permittee shall minimize VOC emissions into the atmosphere from VOC storage and transfer operations.

4. Where applicable, the Permittee shall, at a minimum:

a. Install conservation vents or other vapor control measures designed to minimize standing losses, on all storage tanks with a capacity of 2,000 gallons or more, in VOC service; and
b. Utilize vapor balance, vapor control lines, or other vapor control measures when VOCs are transferred from a tank truck into a stationary storage tank with a capacity greater than 10,000 gallons and less than 40,000 gallons that store VOCs or materials containing VOCs, other than gasoline, that have a vapor pressure of greater than 1.5 psia.

Compliance Methods for the Above (Description and Citation):

This condition does not currently apply to this facility.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Conditions 3.3B (5)

5. In accordance with COMAR 26.11.19.16C, the Permittee shall perform the following to minimize VOC emissions from equipment leaks;

a. Visually inspect all components on the premises for leaks at least once each calendar month.

b. Tag any leak immediately so that the tag is clearly visible. The tag shall be made of a material that will withstand any weather or corrosive conditions to which it may be normally exposed. The tag shall bear and identification number, the date the leak was discovered, and the name of the person who discovered the leak. The tag shall remain in place until the leak has been repaired.

c. Take immediate action to repair all observed VOC leaks that can be repaired within 48 hours.

d. Repair all other leaking components not later than15 days after the leak is discovered. If a replacement part is needed, the part shall be ordered within 3 days after discovery of the leak, and the leak shall be repaired within 48 hours after receiving the part.

e. Maintain a supply of components or component parts that are recognized by the source to wear or corrode, or that otherwise need to be routinely replaced, such as seals, gaskets, packing, and pipe fittings.

f. Maintain a log that includes the name of the person conducting the inspection and the date on which leak inspections are made, the findings of the inspection, and a list of leaks by tag identification number.

Components that cannot be repaired as required by COMAR 26.11.19.16 because they are inaccessible, or that cannot be repaired during operation of the source, shall be identified in the log and included within the source's maintenance schedule for repair during the source shutdown.

Compliance Methods for the Above (Description and Citation):

The VOC leak checks described above are performed at least once per calendar month and recorded on a departmental check sheet and maintained in a log book. Leaks are promptly fixed and any repairs needed are kept in programs like Equipment Repair Forms (ERF) for documentation.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.4A

The Permittee shall keep the following records on-site:

1. Facility wide individual HAP emissions in tons per month per individual HAP and the total tons for the previous 12 months for each individual HAP.
2. Facility wide total HAP emissions in tons per month and the total tons for the previous 12 months.

[Authority: COMAR 25.11.03.06C and ARMA Premises Wide Permit to Construct issued on 02/22/2017]

Compliance Methods for the Above (Description and Citation):

The required HAP emission records are maintained on-site and are available for review.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.4B

Good operating practices information as required by COMAR 26.11.19.02I shall be kept on-site at all times. **[Authority: COMAR 26.11.19.02I (2)(c)]**

Compliance Methods for the Above (Description and Citation):

The required good operating practices are maintained on-site and are available for review.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.4B

Leak inspection logs as required by COMAR 26.11.19.16 shall be kept on-site for at least five (5) years. [**Authority: COMAR 26.11.19.16C (6)]**

Compliance Methods for the Above (Description and Citation):

The required leak inspection log records are maintained on-site and are available for review.

Status (Check one): ___ Intermittent Compliance _×_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.5A

Facility wide HAP emissions records shall be submitted with the required annual emission certification. [**Authority: COMAR 26.11.02.19C and D]**

Compliance Methods for the Above (Description and Citation):

Calendar year facility wide HAP emission records are submitted with the annual Emission Certification Report.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.5B (1)

Good operating practices information as required by COMAR 26.11.19.02I shall be made available to the Department upon request.

Compliance Methods for the Above (Description and Citation):

The required good operating practices records are maintained on-site and are available for review.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

Emission Unit ID(s): General Facility

Permit Term (Describe requirements and cross-reference):

Table IV-3, Condition 3.5B (2)

Leak inspection logs as required by COMAR 26.11.19.16 shall be made available to the Department upon request. **[Authority: COMAR 26.11.03.06C]**

Compliance Methods for the Above (Description and Citation):

The required leak inspection log records are maintained on-site and are available for review.

Status (Check one): ___ Intermittent Compliance _x_ Continuous Compliance

C. DEVIATIONS FROM PERMIT TERMS AND CONDITIONS

Report all deviations from permit terms (whether reported previously or not) that occurred during the permit term. Cross-reference deviations already reported in the six-month report. Indicate whether each deviation is a possible exception to compliance. Start and end period of each deviation should be in mo/day/yr, hr:min format (24-hour clock). Also specify the date when the written deviation report was submitted (if written report required, not submitted, leave the date field blank).

Permit Term for Which There was a Deviation:

There were no deviations with the Section IV conditions of the Title V Permit during the 2020 compliance reporting period.

Emission Units (unit IDs):

Deviation: Start ___/___/___ ____:____ **End** ___/___/___ ____:____

Date Written Report Submitted: ___/___/___

CERTIFICATION OF PLANT-WIDE CONDITIONS
(SECTION III OF PART 70 OPERATING PERMIT)

Indicate compliance with the following requirements of Section III of your Part 70 Operating Permit in the space provided below:

1. Particulate Matter from Construction and Demolition

   No outdoor construction or demolition occurred during the reporting period. Terumo Cardiovascular Systems (TCVS) has demonstrated compliance with this requirement.

2. Open Burning

   TCVS has not conducted any open burning during the reporting period. TCVS has demonstrated compliance with this requirement.

3. Air Pollution Episode

   The Department made no requests to TCVS regarding the preparation in writing of standby emissions reduction plans. TCVS has demonstrated compliance with this requirement.

4. Report of Excess Emissions and Deviations (All deviations from permit conditions should be clearly identified in quarterly monitoring reports.)

   There were no excess emissions and deviations during the 2020 annual reporting period. TCVS has demonstrated compliance with this requirement.

5. Accidental Release Provisions

   TCVS does not store any listed chemicals above the reporting threshold, therefore the facility is not subject to this requirement.

6. General Testing Requirements

   The Department made no request to TCVS regarding testing to demonstrate compliance with the Part 70 Permit during 2020. TCVS has demonstrated compliance with this requirement.

7. Emissions Test Methods

   No test methods were required during 2020. TCVS has demonstrated compliance with this requirement.

8. Emission Certification Report

   TCVS has submitted the Emission Certification Report following all proper directions by April 1st for the previous calendar year. TCVS has demonstrated compliance with this requirement.

9. Compliance Certification Report

   This form is part of the TCVS submittal of the compliance certification that has properly followed all directions and has been submitted by April 1st for the previous calendar year. TCVS has demonstrated compliance with this requirement.

10. Certification by Responsible Official

    Submittals that require certification from a responsible official are signed by the Vice President of Operations. TCVS has demonstrated compliance with this requirement.

11. Sampling and Emissions Testing Recordkeeping

    No testing was conducted in 2020. When TCVS conducts sampling or testing for compliance demonstration, the required information is maintained in accordance with Condition 11. TCVS has demonstrated compliance with this requirement.

12. General Recordkeeping

    All records supportive to the compliance certification have been maintained on site for a period of five years and all recordkeeping has included the required information. TCVS has demonstrated compliance with this requirement.

13. General Conformity

    Not applicable. This requirement does not apply to TCVS.

14. Asbestos Provisions (if applicable)

    No renovation or demolition activities involving asbestos containing material were performed on site during 2020. TCVS has demonstrated compliance with this requirement.

15. Ozone Depleting Regulations (if applicable)

    TCVS has complied with all maintenance, service, repairs, or disposal requirements as defined in 40 CFR 82. TCVS has demonstrated compliance with this requirement.

16. Acid Rain Permit (if applicable)

    Not applicable. This requirement does not apply to TCVS.

Attachment 4

RY2020 Emissions Certification Report

(Confidential Information Omitted)

MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 Washington Boulevard, Suite 715 ● Baltimore, Maryland 21230-1720
410-537-3000 ● 1-800-633-6101 ● http://www.mde.state.md.us
Air and Radiation Management Administration
Air Quality Compliance Program
410-537-3220

FORM 1:

GENERAL FACILITY INFORMATION
EMISSIONS CERTIFICATION REPORT **Calendar Year:** 2020

A. FACILITY IDENTIFICATION				**Do Not Write in This Space**
Facility Name: Terumo Cardiovascular Corporation				Date Received Regional
Address: 125 Blue Ball Road				Date Recived State
City: Elkton County: Cecil Zip Code: 21921				AIRS Code
B. BRIEFLY DESCRIBE THE MAJOR FUNCTION OF THE FACILITY				FINDS Code
Manufacturer of medical devices				SIC Code
				Facility Number
				TEMPO ID
C. SEASONAL PRODUCTION (%, if applicable)				Reviewed By
Winter *(Dec - Feb)*	Spring *(Mar - May)*	Summer *(Jun - Aug)*	Fall *(Sept - Nov)*	
25	25	25	25	Name Date

D. EXPLAIN ANY INCREASES OR DECREASES FROM THE PREVIOUS CALENDAR YEAR FOR EACH REGISTRATION AT THIS FACILITY.

The VOC emissions at the facility decreased as a result of an decrease in production.
The natural gas usage decreased as well, therefore the GHG and criteria source pollutant emissions decreased.

E. CONTROL DEVICE INFORMATION (for NOx and VOC sources only)

Control Device	Capture Efficiency	Removal Efficiency

I am familiar with the facility and the installations and sources for which this report is submitted. I have personally examined the information in this report, which consists of 21 pages (including attachments), and certify that the information is correct to the best of my knowledge.

Kevin Doughty	Vice President of Operations	03/29/21
Name (Print/Type)	Title	Date
Kevin Doughty		410-398-7403
Signature		Telephone

FORM 2:

CRITERIA AIR POLLUTANTS
EMISSIONS CERTIFICATION REPORT

Calendar Year: 2020

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: CO

Equipment Description/ Registration No.	SCC Number	Fuel		Actual Emissions		Operating Schedule (Actual)				TOSD	Operating Schedule			Emissions Methods
				Tons/yr	Lbs/day	Hrs/dy	Dys/wk	Wk/yr	Days/yr	Lbs/day	Hrs/dy	Start	End	
015-0212-5-0089		Natural Gas	S	0.49	2.67	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 2 mmBTU			F											
015-0212-5-0126		Natural Gas	S	0.38	2.08	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 1.57 mmBTU			F											
015-0212-5-0133		Natural Gas	S	0.32	1.76	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 1.3 mmBTU			F											
Total				1.19	6.51					NA				

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

TOSD: Typical Ozone Season Day means a typical days of that period fo the year during which conditions for photochemical conditions are most favorable, which is generally during sustained periods of direct sunligh and warm temperatures (April-September). This section needs to be completed only for VOC and NOx Sources.

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement

C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 2:

CRITERIA AIR POLLUTANTS
EMISSIONS CERTIFICATION REPORT

Calendar Year: 2020

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: NO_x

Equipment Description/ Registration No.	SCC Number	Fuel		Actual Emissions		Operating Schedule (Actual)				TOSD	Operating Schedule			Emissions Methods
				Tons/yr	Lbs/day	Hrs/dy	Dys/wk	Wk/yr	Days/yr	Lbs/day	Hrs/dy	Start	End	
015-0212-5-0089		Natural Gas	S	0.58	3.18	24	7	52	365	1.56	24	NA	NA	C3
Natural Gas Boiler - 2 mmBTU			F											
015-0212-5-0126		Natural Gas	S	0.45	2.48	24	7	52	365	1.22	24	NA	NA	C3
Natural Gas Boiler - 1.57 mmBTU			F											
015-0212-5-0133		Natural Gas	S	0.38	2.09	24	7	52	365	1.03	24	NA	NA	C3
Natural Gas Boiler - 1.3 mmBTU			F											
Total				1.41	7.75					3.81				

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

TOSD: Typical Ozone Season Day means a typical days of that period fo the year during which conditions for photochemical conditions are most favorable, which is generally during sustained periods of direct sunligh and warm temperatures (April-September). This section needs to be completed only for VOC and NOx Sources.

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement

C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 2:

CRITERIA AIR POLLUTANTS
EMISSIONS CERTIFICATION REPORT

Calendar Year: 2020

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: SO_x

Equipment Description/ Registration No.	SCC Number	Fuel		Actual Emissions		Operating Schedule (Actual)				TOSD	Operating Schedule			Emissions Methods
				Tons/yr	Lbs/day	Hrs/dy	Dys/wk	Wk/yr	Days/yr	Lbs/day	Hrs/dy	Start	End	
015-0212-5-0089		Natural Gas	S	0.003	0.019	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 2 mmBTU			F											
015-0212-5-0126		Natural Gas	S	0.003	0.015	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 1.57 mmBTU			F											
015-0212-5-0133		Natural Gas	S	0.002	0.013	24	7	52	365	NA	24	NA	NA	C3
Natural Gas Boiler - 1.3 mmBTU			F											
Total				0.008	0.047					NA				

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

TOSD: Typical Ozone Season Day means a typical days of that period fo the year during which conditions for photochemical conditions are most favorable, which is generally during sustained periods of direct sunligh and warm temperatures (April-September). This section needs to be completed only for VOC and NOx Sources.

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement
C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 2:

CRITERIA AIR POLLUTANTS
EMISSIONS CERTIFICATION REPORT

Calendar Year: 2020

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: VOC

Equipment Description/ Registration No.	SCC Number	Fuel		Actual Emissions		Operating Schedule (Actual)				TOSD	Operating Schedule			Emissions Methods
				Tons/yr	Lbs/day	Hrs/dy	Dys/wk	Wk/yr	Days/yr	Lbs/day	Hrs/dy	Start	End	
015-0212-5-0089		Natural Gas	S	0.03	0.18	24	7	52	365	0.09	24	NA	NA	C3
Natural Gas Boiler - 2 mmBTU			F											
015-0212-5-0126		Natural Gas	S	0.03	0.14	24	7	52	365	0.07	24	NA	NA	C3
Natural Gas Boiler - 1.57 mmBTU			F											
015-0212-5-0133		Natural Gas	S	0.02	0.12	24	7	52	365	0.06	24	NA	NA	C3
Natural Gas Boiler - 1.3 mmBTU			F											
015-0212-6-0121			S	0.79	5.28	24	7	50	335	5.48	24	NA	NA	C2
Facility Wide Cleaning Operations			F											
015-0212-6-0216			S	0.12	1.14	9	4	50	202	1.85	10	6:00 AM	4:30 PM	C2
Conducer Area			F											
015-0212-6-0217			S	0.06	0.54	10	4	50	206	0.53	10	6:00 AM	4:30 PM	C2
Tubing Pack Area			F											
015-0212-6-0221			S	0.00	0.00	0	0	0	0	0.00	NA	NA	NA	C2
Hand Assembly			F											
015-0212-6-0222			S	0.07	3.00	8	1	50	48	6.93	10	6:00 AM	4:30 PM	C2
Capiox - NX & OX			F											
015-0212-6-0224			S	1.05	9.15	17	5	50	229	9.26	10	6:00 AM	4:30 PM	C2
Reservoir Assembly			F											
015-0212-6-0226			S	0.29	2.58	11	5	50	223	2.57	10	6:00 AM	4:30 PM	C2
CR Potting			F											
Total				-	-					-				

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

TOSD: Typical Ozone Season Day means a typical days of that period fo the year during which conditions for photochemical conditions are most favorable, which is generally during sustained periods of direct sunligh and warm temperatures (April-September). This section needs to be completed only for VOC and NOx Sources.

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement

C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 2:

CRITERIA AIR POLLUTANTS
EMISSIONS CERTIFICATION REPORT

Calendar Year: 2020

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: VOC

Equipment Description/ Registration No.	SCC Number	Fuel		Actual Emissions		Operating Schedule (Actual)				TOSD	Operating Schedule			Emissions Methods
				Tons/yr	Lbs/day	Hrs/dy	Dys/wk	Wk/yr	Days/yr	Lbs/day	Hrs/dy	Start	End	
015-0212-6-0227			S	15.55	141.36	17	5	50	220	145.15	10	6:00 AM	4:30 PM	C2
VR/CR Filter Dipping			F											
015-0212-6-0228			S	0.68	5.86	17	5	50	232	6.08	10	6:00 AM	4:30 PM	C2
Final Assembly			F											
015-0212-6-0229			S	0.00	0.00	0	0	0	0	0.00	0	NA	NA	C2
Arterial Filter Area			F											
015-0212-6-0231			S	0.00	0.01	10	4	50	175	0.02	10	6:00 AM	4:30 PM	C2
CP Assembly			F											
015-0212-6-0232			S	4.47	30.84	24	6	50	290	32.01	24	NA	NA	C2
X-Coat Tubing Area			F											
015-0212-6-0233			S	1.56	26.05	3	3	50	120	24.76	3	6:00 AM	9:00 AM	C2
X-Coat Capiox/Connectors			F											
015-0212-6-0211			S	0.14	2.47	10	2	50	110	2.08	10	6:00 AM	4:30 PM	C2
FVR Coating Line			F											
015-0212-6-0234			S	0.15	1.40	17	4	50	216	1.31	10	6:00 AM	4:30 PM	C2
Quick Disconnect Area			F											
015-0212-6-0255			S	0.00	0.03	21	5	50	227	0.03	20	NA	NA	C2
CDI/OPS Assembly			F											
Total				25.01	230.14					238.27				

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

TOSD: Typical Ozone Season Day means a typical days of that period fo the year during which conditions for photochemical conditions are most favorable, which is generally during sustained periods of direct sunligh and warm temperatures (April-September). This section needs to be completed only for VOC and NOx Sources.

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement

C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 3: PM

EMISSIONS CERTIFICATION REPORT **Calendar Year:** 2020

Particulate Matter

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: PM

Equipment Description/ Registration No.	SCC Number	Fuel		PM - Filterable		PM 10 - Filterable		PM 2.5 Filterable		PM Condensable		Operation	Emission Methods
				Tons/yr	Lbs/day	Tons/yr	Lbs/day	Tons/yr	Lbs/day	Tons/yr	Lbs/day	Days/yr	
015-0212-5-0089		Natural Gas	S	0.011	0.060	0.011	0.060	0.011	0.011	0.033	0.181	365	C3
Natural Gas Boiler - 2 mmBTU			F										
015-0212-5-0126		Natural Gas	S	0.009	0.047	0.009	0.047	0.009	0.009	0.026	0.141	365	C3
Natural Gas Boiler - 1.57 mmBTU			F										
015-0212-5-0133		Natural Gas	S	0.007	0.040	0.007	0.040	0.007	0.007	0.022	0.119	365	C3
Natural Gas Boiler - 1.3 mmBTU			F										
Total				0.027	0.147	0.027	0.147	0.027	0.027	0.081	0.441		

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

Fuel: Include emissions for each fuel used. If more than one fuel is used, calculate and list emissions separately for each fuel.

Emission Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement
C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: Bis (2-ethylhexyl) phthalate

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0226 Capiox-CR Potting	0.090	0.817	0.074		
TOTALS	0.090	0.817	0.074		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: Dibutyl Pthalate

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0226 Capiox-CR Potting	0.016	0.144	0.013		
TOTALS	0.016	0.144	0.013		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: Dichloroethane

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0217 Tubing Pack Area	0.048	0.494	0.049		
015-0212-6-0224 Reservoir Assembly	0.919	8.201	0.482		
TOTALS	0.968	8.695	0.532		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: 4'4 - MDI

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0226 CR Potting	0.011	0.103	0.009		
015-0212-6-0222 Capiox-NX	0.020	0.859	0.107		
TOTALS	0.032	0.963	0.117		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: Methanol

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0227 VR/CR Filter Dipping	2.018	18.448	1.085		
015-0212-6-0228 Final Assembly	0.673	5.914	0.348		
015-0212-6-0211 FVR Coating Line	0.135	2.539	0.254		
015-0212-6-0233 X-Coat Capiox/Connectors	1.548	25.791	8.597		
015-0212-6-0232 X-Coat Tubing Area	2.355	16.128	0.672		
TOTALS	6.728	68.821	10.956		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 4:

TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0059 Pollutant: Trichloroethane

Equipment Description/ Registration No.	Actual Emissions			Control Device**	% Efficiency
	Tons/yr	Lbs/Day	Lbs/hr		
015-0212-6-0231 CP Assembly	0.0001	0.0010	0.0001		
TOTALS	0.0001	0.0010	0.0001		

* Please attach all calculations

* See Attachment 1 for the minimum reporting values.

** Control Device
S = Scrubber
B = Baghouse
ESP = Electrostatic Precipitator
A = Afterburner
C = Condenser
AD = Adsorbtion
O = Other

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 5:

BILLABLE TOXIC AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Facility ID: 015-0212

Chemical Name	CAS Number		Actual Emissions				Estimation Method
			Tons/yr	Lbs/Day	Lbs/hr		
carbon disulfide	75-15-0	S	-	-	-		
		F	-	-	-		
carbonyl sulfide	463-58-1	S	-	-	-		
		F	-	-	-		
chlorine	7782-50-5	S	-	-	-		
		F	-	-	-		
cyanide compounds	57-12-5	S	-	-	-		
		F	-	-	-		
hydrochloric acid	7647-01-0	S	-	-	-		
		F	-	-	-		
hydrogen fluoride	7664-39-3	S	-	-	-		
		F	-	-	-		
methyl chloroform	71-55-6	S	-	-	-		
		F	-	-	-		
methylene chloride	75-09-2	S	-	-	-		
		F	-	-	-		
perchloroethylene	127-18-4	S	-	-	-		
		F	-	-	-		
phosphine	7803-51-2	S	-	-	-		
		F	-	-	-		
titanium tetrachloride	7550-45-0	S	-	-	-		
		F	-	-	-		
TOTALS			0.000	0.000	0.000		

Emissions Estimation Method

A1-U.S. EPA Reference Method
A2-Other Particulate Sampline Train
A3-Liquid Absorption Technique
A4-Solid Absorption Technique
A5-Freezing Out Technique
A9-Other, Specify

C1-User calculated based on source test or other measurement
C2-User calculated based on material balance using engineering knowledge of the process
C3-User calculated based on AP-42
C4-User calculated by best guess/engineering judgement
C5-User calculated based on a State or local ageny emissions factor
C6-New construction, not operational
C7-Source closed, operation ceased
C8-Computer calculated based on standard

This form to include only the eleven chemicals identified.

S - Stack Emissions F-Fugitive Emissions Daily emissions (lb/day) are lbs/operating day of the source

PLEASE NOTE: Be sure to attach all data and calculations necessary to suppor the emissions figures shown above.

See attachment 1 for minimum reporting values.

01/09/08

FORM 6: Greenhouse Gases

GREENHOUSE GAS AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: CO_2*

Equipment Description/ Registration No.	Actual Emissions		
	Tons/yr	Lbs/Day	Lbs/hr
015-0212-5-0089 Natural Gas Boiler - 2 mmBTU	695	3,811	159
015-0212-5-0126 Natural Gas Boiler - 1.57 mmBTU	543	2,974	124
015-0212-5-0133 Natural Gas Boiler - 1.3 mmBTU	458	2,510	105
TOTALS	1,696	9,295	388

This form must be used to report Greenhouse gas emissions:

- carbon dioxide (CO2)
- methane (CH4)
- nitrous oxide (N20)
- hydroflurocarbons (HFCs)
- perfluorocarbons (PFCs)
- sulfur hexafluoride (SF6)

* Use a separate form for each pollutant

* Please attach all calculations

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 6: Greenhouse Gases

GREENHOUSE GAS AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Cardiovascular Systems Corporation Facility ID: 015-0212 Pollutant: CH_4*

Equipment Description/ Registration No.	Actual Emissions		
	Tons/yr	Lbs/Day	Lbs/hr
015-0212-5-0089 Natural Gas Boiler - 2 mmBTU	0.013	0.073	0.003
015-0212-5-0126 Natural Gas Boiler - 1.57 mmBTU	0.010	0.057	0.002
015-0212-5-0133 Natural Gas Boiler - 1.3 mmBTU	0.009	0.048	0.002
TOTALS	0.032	0.178	0.007

This form must be used to report Greenhouse gas emissions:

- carbon dioxide (CO2)
- methane (CH4)
- nitrous oxide (N20)
- hydroflurocarbons (HFCs)
- perfluorocarbons (PFCs)
- sulfur hexafluoride (SF6)

* Use a separate form for each pollutant

* Please attach all calculations

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

FORM 6: Greenhouse Gases

GREENHOUSE GAS AIR POLLUTANTS **Calendar Year:** 2020

EMISSIONS CERTIFICATION REPORT

Facility Name: Terumo Medical Corporation Facility ID: 015-0212 Pollutant: N_20*

Equipment Description/ Registration No.	Actual Emissions		
	Tons/yr	Lbs/Day	Lbs/hr
015-0212-5-0089 Natural Gas Boiler - 2 mmBTU	0.013	0.070	0.003
015-0212-5-0126 Natural Gas Boiler - 1.57 mmBTU	0.01	0.055	0.002
015-0212-5-0133 Natural Gas Boiler - 1.3 mmBTU	0.008	0.046	0.002
TOTALS	0.031	0.171	0.007

This form must be used to report Greenhouse gas emissions:

- carbon dioxide (CO2)
- methane (CH4)
- nitrous oxide (N20)
- hydroflurocarbons (HFCs)
- perfluorocarbons (PFCs)
- sulfur hexafluoride (SF6)

* Use a separate form for each pollutant

* Please attach all calculations

[1]Emissions must be broken down by equipment registration number (ex. 9-0076, 9-0077)

Attachment 5

Potential Emissions

(Confidential Information Omitted)

Attachment 6

Application Completeness Checklist

VI. Application Completeness Checklist

The purpose of this part is to list the information required to achieve a Part 70 application shield.

Cover Page

(✓) Name and address of owner or operator, including telephone number.

(✓) Name and address of facility, including the plant manager's name and telephone number.

(✓) A 24-hour emergency telephone number for air pollution matters.

Section 1 CERTIFICATION STATEMENTS

(✓) The certification statement completed and signed by a responsible official.

Section 2 FACILITY DESCRIPTION SUMMARY

(✓) A brief description of each of the source's process(es), including all applicable SIC codes and end products.

(✓) Flow diagrams indicating all emissions units, emission points and control devices. **(See Attachment 2)**

(✓) A plot plan of the entire facility. **(See Attachment 1)**

(✓) Emission Certification Report. **(See Attachment 4)**

(✓) General Emissions Information. **(See Attachment 5)**

Section 3 EMISSIONS UNIT DESCRIPTIONS –
This section must be completed for each emissions unit.

Part A

(✓) Emissions unit number.

(✓) Detailed description of unit, including all emission points.

(✓) Federally enforceable limit(s) on the operating schedule.

(✓) Fuel consumption information for any emissions unit that consumes fuel including the type of fuel, percent sulfur, and annual usage of fuel.

Part B

(✓) A citation and description of each federally enforceable requirement, including all emission standards, for each emissions unit.

(✓) A statement of compliance demonstration techniques for each requirement, including a description of monitoring, record keeping, reporting requirements, and test methods.

(✓) The frequency of submittal of the compliance demonstration during the permit term.

Part C – Not Applicable

( ) Emissions unit number.

( ) Permit to construct number.

( ) Emissions point number.

( ) Date(s) the permit to construct was issued.

( ) Condition number(s) as indicated on the permit to construct.

( ) Description of the permit condition(s) and the reason(s) why they are believed to be obsolete, extraneous, or insignificant.

Part D – Not Applicable

( ) Description of all alternate operating scenarios that apply to an emissions unit.

( ) Number assigned to each scenario.

( ) Emissions unit number.

( ) Description of the operating parameters for the emissions unit and other information which describes the how the operation of the unit will change under the different scenario.

Part E – Not Applicable

( ) A citation and description of each federally enforceable requirement triggered by an operating scenario, including all emission standards, for each emissions unit.

( ) As an attachment, the date and results of the most recent compliance demonstration for each emission standard and/or emissions certification report with relevant supporting documentation.

( ) A statement of compliance demonstration techniques for each requirement, including a description of monitoring, record keeping, reporting requirements, and test methods.

( ) The frequency of submittal of the compliance demonstration during the permit term.

Section 4 CONTROL EQUIPMENT – Not Applicable

( ) The type of each piece of air pollution control equipment.

( ) The capture and control efficiencies of the control equipment.

Section 5 SUMMARY SHEET OF POTENTIAL EMISSIONS

(✓) Quantity of potential emissions for criteria pollutants and HAPs emitted in tons per year for each emissions unit.

(✓) Fugitive emission estimations for the entire facility for criteria pollutants and HAPs emitted in tons per year.

(✓) Basis for all emission calculations.

Section 6 AN EXPLANATION OF PROPOSED EXEMPTIONS FROM OTHERWISE APPLICABLE FEDERALLY ENFORCEABLE REQUIREMENTS

Not Applicable

( ) An explanation of the proposed exemption.

Section 7 COMPLIANCE SCHEDULE FOR NONCOMPLYING EMISSIONS UNITS

Not Applicable

( ) Identification of emissions unit(s) not in compliance, including the requirement being violated and the effective compliance data.

( ) Detailed description of methods to be used to achieve compliance.

( ) A schedule of remedial measures, including an enforceable sequence of actions with milestones.

Attachment

(✓) Checklist of Insignificant Activities

( ) CAM Plan (If Applicable)