Engineering Evaluation
Cepheid
6601 Overlake Place, Newark, CA 94560
Plant No. 24996
Application No. 738560

Background

Yorke Engineering, LLC, on behalf of Cepheid, is submitting application for an Authority to Construct (AC) and/or Permit to Operate (PO), to operate the following:

S-2 Poly Methyl Methacrylate (PMMA) Wafer Stripping and Drying, IPA 145 gal/yr and Acetone 125 gal/yr.

Cepheid operates a diagnostic test cartridge manufacturing campus, designated as "Newark 2" at 6601 Overlake Place in Newark, CA (Facility ID: 24996). The facility's previously exempt poly methyl methacrylate (PMMA) wafer stripping and drying process is changing from research and development (R&D) to manufacturing, which will require a permit. The process utilizes isopropyl alcohol (IPA) and acetone to strip and dry the PMMA wafers, resulting in emissions of Precursor and Non-Precursor Organic Compounds (POC and NPOC).

Process and Equipment Description

The PMMA wafer stripping and drying process begins following the dicing process and serves to strip any contaminants from the wafer and then dry it before the next processing steps. Wafer dies are transferred and positioned onto a universal carrier. After inspection, the die is moved from a universal carrier to a Teflon fixture. Next, two glass dishes are prepared, adding 500 mL of acetone to one dish and 500 mL IPA to the other. The die fixture is immersed in the dish with acetone for 5 minutes, ensuring complete coverage of the die area. After 5 minutes, the die fixture is removed and immediately immersed in the dish with IPA for 2 minutes, ensuring complete coverage of the die area. After 2 minutes, the die fixture is removed and dried using nitrogen gas. Lastly, the die fixture is submerged once again in IPA for 2 minutes, before being dried using the nitrogen gun. This entire process takes place inside of a fume hood. Figure 1 shows an image of this benchtop set up.

Figure 1. A picture of the PMMA Wafer Stripping system setup.

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The acetone is swapped every two batches of die that are stripped, while the IPA is swapped very batch. One wafer is composed of 6 batches of dies, requiring a total of 3 batches of acetone and 6 batches of IPA. Leftover acetone and IPA are disposed of in dedicated waste containers.

Emission Calculations

The wafer stripping and drying process uses acetone and IPA. Acetone is NPOC, and IPA is POC and TAC (toxic air contaminant).

By conducting an evaporation study, Cepheid has determined the amount of IPA and acetone evaporated per batch of die. One wafer is composed of 6 batches of dies. Net volume evaporated per wafer is estimated to be 180 mL of Acetone (= 0.048 gallon) and 210 mL of IPA (= 0.055 gallon).

Emissions are calculated based on the volume of acetone and IPA evaporated per wafer, and number of wafers processed. Approximately 1 wafer is processed per hour for a total of 8 wafers per day, 40 per week, and 2,080 per year. A summary of the POC and NPOC emissions is provided in Table 1. Emissions were calculated more conservatively, adding 25% to the estimated net volume of the solvents evaporated per wafer.

Table 1. Emission Calculation

Solvent	Annual Usage (gal/yr)	POC/NPOC Content (lb/gal)	POC/NPOC Emissions			Annual Emissions (TPY)
			Hourly (lb/hr)	Daily (lb/day)	Annual (lb/yr)	
IPA	145	6.54	0.456	3.65	948.3	0.474
Acetone	125	6.59	0.396	3.17	823.8	0.412

Toxic Pollutants

IPA is designated toxic air contaminant (TAC) per Table 2-5-1. IPA emission is not expected to exceed Reg 2-5 toxic trigger levels (Table 2). A Health Risk Assessment (HRA) is not required.

Table 2. TAC Emission (Unabated)

Pollutant	Annual Emissions (lb/yr)	Chronic Toxic Trigger Level (lb/yr)	Hourly Emission (lb/hr)	Acute Toxic Trigger Level (lb/hr)	HRA Required? (Y/N)
IPA	948.3	2.70E+5	0.456	1.40E+00	N

Plant Cumulative Increase

The cumulative increase summary for the plant is shown below in Table 3.

Table 3. Plant Cumulative Increase (tons/year)

Pollutant	Existing	New	Total
NO_X	0.000	0.000	0.000
POC	1.373	0.474	1.847
NPOC	0.000	0.412	0.412
CO	0.000	0.000	0.000
$PM_{10}/PM_{2.5}$	0.000	0.000	0.000
SO_2	0.000	0.000	0.000

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Statement of Compliance

S-2 is subject to Regulation 8, Rule 1. Sections 320 and 321 prohibit storage of fresh or spent VOC and VOC-containing cloth or paper in open containers. The facility will store fresh and spent VOCs and VOC-laden cloths and paper in closed containers.

S-2 is subject to the requirements of Regulation 8, Rule 4. Per Section 8-4-116, S-2 is not subject to the surface preparation standards in Section 8-4-313 because S-2 involves surface preparation associated with medical device manufacturing operations. S-2 is subject to Section 8-4-302, which limits uncontrolled volatile organic compound (VOC) emissions to no more than 5 tons per year (TPY). The VOC from S-2 is not expected to exceed 0.886 TPY (POC+NPOC) which complies with this emission limit. (Total VOC permitted for the plant = 2.259 TPY.) Also, the recordkeeping requirements in Section 8-4-501 apply. These recordkeeping requirements will be included in the permit conditions. Lastly, the owner/operator of S-2 shall comply with the solvent evaporative loss minimization requirements in Section 8-4-312. This section requires the use of closed containers for the storage of solvent and any solvent-impregnated cloth and paper.

Stripping operations, as defined under Reg. 8-16-225, are exempt from Reg. 8-16, pursuant to Reg. 8-16-120. These operations are subject to the requirements of Regulation 8, Rule 4. Wafer striping and drying in this application is therefore exempt from rule 8-16. Nevertheless, this operation is in compliance with Reg. 8-16 as discussed below.

The stripping and drying process falls under solvent cleaning operations as defined by this rule. In accordance with Section 115, except for the requirements in subsections 8-16-303.1, 303.3.1, and 303.3.2, the requirements of this Rule shall not apply to equipment or operations that use unheated solvent and that contain less than 3.785 liters (1 gal) of solvent, including volume in any remote reservoir, or have an evaporative area of less than 929 cm2 (144 in2 or 1 ft2). [1]

The stripping and drying process uses unheated solvent, the dishes contain only 1 liter of solvent per batch, and the evaporative area is less than 929 cm^2. Therefore, the process qualifies for the limited exemption detailed in Section 8-16-115.

Section 8-16-303.1 General Operating Requirements:

- 1.1 The solvent cleaning equipment and emission control shall be operated and maintained in proper working order.
- 1.2 Liquid solvent leaks shall be repaired immediately or the equipment shall be shut down.
- 1.3 Solvent, including waste solvent, shall not be stored or disposed of in a manner that will cause or allow evaporation into the atmosphere.
- 1.4 Waste solvent residues shall be disposed of by one of the following methods:
  - a. Where residues are treated prior to further offsite treatment such residues shall be stored in covered containers to minimize evaporation prior to service pick-up.

[1] According to the applicant, "There is no "remote reservoir" for this process. The team uses a Pyrex looking glass bowl with 1 L of solvent in the fume hood to strip and dry the wafer, then the "dirty" solvent is discarded as hazardous waste. Only the 1L of solvent is used per batch. And, "The only evaporative area is from the glass dishes - area of less than 929 cm2 (1 ft2)."

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b. Where residues are treated prior to final disposal at an appropriate waste disposal facility, such residues shall not contain more than 10 percent solvent by volume and shall be stored in covered containers.

1.5 Devices designed to reduce solvent evaporation shall not be removed except to process work or to perform maintenance. Where a compound with low volatility or a VOC content that does not exceed 50 g/l (0.42 lb/gal) is being used, enclosed (remote) reservoirs are deemed equivalent equipment to closed covers.

1.6 If a solvent flow is utilized, only a continuous fluid stream shall be used (not a fine, atomized, or shower type spray), unless an approved emission control device is used with a control efficiency of 90 percent or more on a mass basis, or unless the solvent spray is totally enclosed during the washing, rinsing and drying process.

The following subsections in Section 8-16-303.3 Cold Cleaner General Equipment Requirements apply:

3.1 A container for the solvent and the articles being cleaned.

3.2 An apparatus, cover, or enclosed (remote) reservoir which reduces solvent evaporation when not processing work in the solvent cleaner. If a compound with low volatility or a VOC content that does not exceed 50 g/l (0.42 lb/gal) is not being used or the solvent is agitated or heated, the cover must be designed so that it can be operated with one hand.

The facility is expected to comply with the applicable requirements of Regulation 8 Rule 16.

CEQA: The project is considered to be ministerial under the District's CEQA Regulation 2-1-311 and therefore is not subject to CEQA review. The engineering review for this project requires only the application of standard permit conditions and standard emissions factors in the District's Permit Handbook Chapter 6.1, Cold Solvent Cleaning, and therefore is not discretionary as defined by CEQA.

Public Notice: The public notification requirements of Regulation 2-1-412 apply to applications which result in an increase in toxic air contaminants or hazardous air contaminant emissions at facilities within 1,000 feet of the boundary of a K-12 school, or a new or modified source located within an Overburdened Community for which a Health Risk Assessment (HRA) is required.

The project is not located within an Overburdened Community and does not require HRA. However, it is within 1000 feet of the outer boundary of a K-12 school [2]. Therefore, it is subject to the public notification requirements of Regulation 2-1-412, and a school public notice will be conducted.

Best Available Control Technology (BACT): In accordance with Reg. 2-2-301 (Best Available Control Technology Requirement), BACT is triggered for any new or modified source with the

[2] The nearest school to the Cepheid Newark 2 building is Challenger School Ardenwood, a private K-8 school, approximately 700 feet east of the Cepheid building, as measured to the school's closest property boundary (an open grass playfield).

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potential to emit 10 pounds or more per highest day of POC, NPOC, NOx, CO, SO_2 PM_{10}, or $PM_{2.5}$. Based on the emission calculations in Table 1, BACT is not triggered since the daily POC or NPOC emissions are less than 10 pounds per day for each pollutant.

***Offsets**:* Offsets must be provided for any new or modified source at a facility that emits more than 10 tons/yr of POC or NOx per Regulation 2-2-302. The facility has only one other permitted source, S-1, Wipe Cleaning Operation, and S-1's Potential to Emit (PTE) of POC is 1.373 TPY as permitted in AN 31192. As shown in Table 1, S-2's PTE of POC will be 0.474 TPY. The facility's PTE of POC will be 1.847 TPY. Because the facility's PTE of POC will be less than 10 TPY after this project, POC offset is not required.

Prevention of Significant Deterioration (PSD): A new or modified source is considered a PSD project if the proposed project results in a significant emissions increase for a PSD pollutant at a Major PSD facility. A Major PSD facility is one that has a potential to emit 250 tons or more per year of any PSD pollutant or that is one of the 28 categories listed in Section 169(1) of the Clean Area Act and emits 100 tons or more per year. Cepheid's permitted emissions, summarized in Table 3, are significantly less than 100 tpy. Therefore, the facility is not a Major PSD facility and PSD does not apply.

New Source Performance Standards (NSPS): There is no New Source Performance Standard for the medical devices manufacturing. [3] This operation is not subject to NSPS.

National Emission Standards for Hazardous Air Pollutants (NESHAP): NESHAP may apply and would impose additional requirements for those cold cleaners using any combination of the following six halogenated solvents at a total concentration of 5 percent or more by weight: methylene chloride, perchloroethylene, trichloroethylene, 1,1,1-trichloroethane, carbon tetrachloride and chloroform (EPA 40 CFR 63 subpart T). None of these solvents are used at S-2, therefore this NESHAP does not apply to S-2.

Permit Conditions

Permit Condition #100979 will apply to S-2.

1. The owner/operator of S-2 shall not exceed the following net solvent usage limits during any consecutive twelve-month period:
   a. Isopropanol Alcohol 145 Gallons
   b. Acetone 125 Gallons
   [Basis: Cumulative Increase]

2. The owner/operator may use an alternate solvent(s) other than the materials specified in Part 1 and/or usages in excess of those specified in Part 1, provided that the owner/operator can demonstrate that all of the following are satisfied:
   a. Total POC emissions from S-2 do not exceed 948 pounds in any consecutive twelve-month period,
   b. Total NPOC emissions from S-2 do not exceed 824 pounds in any consecutive twelve-month period,
   c. The use of these materials does not increase toxic emissions above any risk screening trigger level of Table 2-5-1 in Regulation 2-5.

[3] https://www.epa.gov/stationary-sources-air-pollution/new-source-performance-standards

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[Basis: Cumulative Increase; Regulation 2, Rule 5]

3. To determine compliance with the above parts, the owner/operator shall maintain the following records and provide all of the data necessary to evaluate compliance with the above parts, including the following information:
   a. Quantities of each type of solvent used at this source on a monthly basis,
   b. If a material other than those specified in Part 1 is used, POC/NPOC and toxic component contents of each material used; and mass emission calculations to demonstrate compliance with Part 2, on a monthly basis,
   c. Monthly usage and/or emission calculations shall be totaled for each consecutive twelve-month period,
   d. Demonstration that any toxic air contaminants in alternate material(s) in Part 2.c. do not exceed the acute and chronic trigger levels by calculating toxic air contaminant emissions on a pound per hour and pound per year basis, respectively.

   All records shall be retained on-site for two years, from the date of entry, and shall be made available for inspection by District staff upon request. These recordkeeping requirements shall not replace the recordkeeping requirements contained in any applicable District Regulations.
   [Basis: Recordkeeping; Cumulative Increase; Regulation 2, Rule 5]

Recommendation

The Air District has reviewed the material contained in the permit application for the proposed project and has made a preliminary determination that the project is expected to comply with all applicable requirements of Air District, State, and Federal air quality-related regulations. I recommend that the Air District initiate public notice and consider any comments received prior to taking final action on issuance of an Authority to Construct/Permit to Operate for the following source:

S-2 Poly Methyl Methacrylate (PMMA) Wafer Stripping and Drying, IPA 145 gal/yr and Acetone 125 gal/yr.

Prepared by: _____ **Date:** _____
Sadegh Sadeghipour 6/29/2026
Air Quality Engineer

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