SACRAMENTO METROPOLITAN
AIR QUALITY MANAGEMENT DISTRICT

STATEMENT OF REASONS

Proposed Amendments to Rule 464 – Organic Chemical Manufacturing Operations

and

Proposed Repeal of Rule 455 – Pharmaceuticals Manufacturing

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RULE JUSTIFICATION – HEALTH IMPACTS

Ground level ozone is a secondary pollutant formed from photochemical reactions of nitrogen oxides (NOx) and volatile organic compounds (VOC) in the presence of sunlight. Ozone is a strong irritant that adversely affects human health and damages crops and other environmental resources. As documented by the U.S. Environmental Protection Agency (EPA) in the most recent science assessment for ozone[1], both short-term and long-term exposure to ozone can irritate and damage the human respiratory system, resulting in:

- reproductive and developmental effects, such as low birth weight from long-term exposure to ozone;
- decreased lung function;
- development and aggravation of asthma;
- increased risk of cardiovascular problems such as heart attacks and strokes;
- central nervous system affects, such as memory and sleep patterns;
- increased hospitalizations and emergency room visits; and
- premature deaths.

RULE JUSTIFICATION – BACKGROUND

Section 182(b)(2) of the federal Clean Air Act (CAA) requires air districts in ozone nonattainment areas to implement Reasonably Available Control Technology (RACT) for VOC sources covered by a Control Technique Guidelines (CTG) issued by EPA. One source category covered by a CTG is pharmaceutical manufacturing operations[2].

<u>CTG: Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products</u>

This CTG document contains RACT recommendations for the manufacture of pharmaceutical products through chemical synthesis. Synthesized pharmaceutical products are manufactured by following specific processes, usually in the order of reactions, production separations, purification and drying. During each process step, VOC emissions may be released. This CTG recommends techniques to reduce these emissions. Specifically, this CTG recommends reducing emissions from reactors, distillation operations, crystallizers, centrifuges, vacuum dryers, air dryers, production equipment exhaust systems, storage tanks (liquid transfer and tank storage) by using emission control devices. In-process tanks should be covered to reduce solvent evaporation and all leaks of VOC-containing material from process equipment should be repaired as soon as is practical.

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[1] "Integrated Science Assessment for Ozone and Related Photochemical Oxidants." U.S. EPA, February 2013, Table 2-1.

[2] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978.

Rule 455 – Pharmaceuticals Manufacturing

Rule 455 was last amended on September 5, 1996, and was intended to meet the federal RACT requirements by limiting the emissions of VOCs from pharmaceutical manufacturing operations. This amended version of Rule 455 was submitted to EPA for approval into the State Implementation Plan (SIP), but EPA did not take immediate action to approve or disapprove the rule. In 2015, EPA re-evaluated the rule as part of its review of the District's 2006 RACT SIP[3], and concluded that Rule 455 does not meet the requirements of federal Clean Air Act section 110(a)(2) because it lacks test methods, recordkeeping, and monitoring requirements that are necessary to ensure that the rule is enforceable[4]. In January 2016, EPA formalized that decision in a partial approval and partial disapproval of the 2006 RACT SIP[5]. For Rule 455 to be SIP-approved, EPA is requiring that the rule be amended to include these enforceability elements. In addition, EPA suggested areas in which the District could improve the rule:

- Definitions: The rule defines four terms: cosmetics manufacturing plant, in-process tanks, pharmaceutical manufacturing plant, and volatile organic compound (VOC). EPA suggested that the District include additional definitions for relevant terms, including production equipment exhaust system and leaks, in order to clarify rule interpretation and to make rule enforcement easier.
- Equivalent or More Effective Control Device/Method: The rule allows the use of an equivalent or more effective control device or method that is approved by the Air Pollution Control Officer (APCO) as an alternative to comply with the rule's control requirements. According to the Guidance Document for Correcting Common VOC & Other Rule Deficiencies[6], APCO discretion is not appropriate in provisions related to the applicability, emission limits, operating requirements, recordkeeping, monitoring, test methods, and alternative compliance. EPA expressed concerns that the use of equivalent control device/method approved by the APCO should also require EPA approval or the provision in the rule should be very specific as to how the District will determine equivalency.
- Leaks: The rule specifies that a leak repair should be completed the first time the equipment is off-line for a period of time long enough to complete the repair. EPA noted that the section for leaks needs to specify a time limit for completing the repair in order for this provision to be enforceable.

Rule 464 – Organic Chemical Manufacturing Operations

Rule 464 was adopted on July 23, 1998 and amended on September 25, 1998. The rule limits VOC emissions from organic chemical manufacturing operations, including pharmaceutical and

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[3] "Analysis of Reasonably Available Control Technology for the 8-Hour Ozone State Implementation Plan (RACT SIP)," Sacramento Metropolitan Air Quality Management District, September 26, 2006.

[4] "Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan – EPA's Evaluation of Sacramento Metropolitan Air Quality Management District, Ozone State Implementation Plan Revision Reasonably Available Control Technology as Applicable to the 8-hour Ozone Standard - Adopted 26, 2006 ("2006 RACT SIP TSD")." November 2015.

[5] "Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Proposed Rule." 81 Federal Register (January 15, 2016), pp. 2136 – 2140.

[6] "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," U.S. EPA Region IX, Revised August 21, 2001.

cosmetic manufacturing operations. The Board Letter for the July 1998 adoption stated that Rule 464 would replace Rule 455 because both rules imposed similar requirements on the same source category[7]. Rule 464 does not have the SIP approvability issues as discussed above for Rule 455 because Rule 464 established monitoring and recordkeeping requirements and test methods. Rule 464 also includes definitions for "production equipment exhaust system" and "leak." It does not allow sole APCO discretion on equivalent or more effective control device or method, except for the requirements for storage tanks that will be amended as a part of this rulemaking process. Leak requirements were not specified in the rule but sources subject to Rule 464 were also required to comply with the leak requirements in Rule 443 – Leaks from Synthetic Organic Chemical and Polymer Manufacturing.

The District had intended to repeal Rule 455 after Rule 464 was approved by EPA into the SIP. Although EPA approved Rule 464 on April 19, 2000, Rule 455 was never repealed.

Proposed Actions

Rule 455 remains in effect. As previously discussed, EPA has informed the District that Rule 455 is inadequate to meet RACT requirements for pharmaceutical manufacturing because it does not have all enforceable elements that are necessary for inclusion in the SIP. EPA also noted that certain requirements in Rule 464 are not as stringent as the requirements established in the CTG for pharmaceutical manufacturing operations. Consequently, the District has not met the RACT requirements for the source category of pharmaceutical manufacturing operations.

To meet the federal RACT requirements and eliminate duplication, Staff is proposing to repeal Rule 455 and amend Rule 464. If approved by the District's Board, Rule 464 will be submitted to EPA for inclusion in the SIP. If approved into the SIP, the requirements will be subject to federal enforcement and citizen civil legal actions under the CAA Sections 113 and 304. Rule 455 will be removed from the SIP. In addition, Staff is proposing changes to Rule 464 that will meet the state requirements for Best Available Retrofit Control Technology (BARCT) and all feasible measures that are applicable to pharmaceutical and cosmetic manufacturing operations.

RULE JUSTIFICATION – LEGAL MANDATES

Federal Mandates:

The District is designated as a "severe" nonattainment area for the 1997 and 2008 federal 8-hour ozone standards[8,9]. Federal Clean Air Act section 172(c)(1) specifies that SIPs for

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[7] Board Letter, Subject Regulation 4 – Prohibition, Proposed New Rule 464, Organic Chemicals Manufacturing Operations, from Norm Covell to SMAQMD Board of Directors, July 23, 1998.

[8] "Air Quality Designations and Classifications for the 8-Hour Ozone National Ambient Air Quality Standards; Early Action Compact Areas with Deferred Effective Dates, Final Rule." 69 Federal Register (April 30, 2004), pp. 23857 – 23951.

[9] "Implementation of the 2008 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications Approach, Attainment Deadlines and Revocation of the 1997 Ozone Standards for Transportation Conformity Purposes, Final Rule." 77 Federal Register (May 21, 2012), pp. 30160 – 30171.

nonattainment areas must include "reasonably available control measures" (RACM), including "reasonably available control technology," for sources of emissions. Section 182(b)(2)(A) of the CAA provides that for nonattainment areas classified as "moderate" or worse, states must revise their SIPs to include RACT for all VOC sources covered by any CTG issued before November 15, 1990. EPA defines RACT as "the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility"[10]. Pursuant to CAA Sections 108(b) and (c), EPA periodically publishes information regarding available controls. In developing CTGs, EPA evaluates, among other things, the sources of VOC emissions and the available control approaches for addressing these emissions, including the costs of such approaches. CTG documents establish the presumptive minimum recommendations for RACT.

Rule 455 was amended in 1996 to meet the federal RACT requirements for the pharmaceutical manufacturing operation source category, but the rule did not establish all necessary enforceable elements to be SIP-approved. Rule 464 was adopted to replace Rule 455 and to meet the RACT requirements, and although EPA testified in support of Rule 464, some requirements in Rule 464 were not as stringent as the requirements in Rule 455 or the CTG for pharmaceutical manufacturing operations. These less stringent requirements are discussed in detail in the "Summary of Proposed Amendments to Rule 464 and Repeal of Rule 455" section. For a complete comparison, see the table in Appendix A, which compares all standards in the CTG for pharmaceutical manufacturing operations with the current standards in Rule 455 and Rule 464. The proposed amendments will ensure that the requirements in Rule 464 are as stringent as the requirements in the CTG for pharmaceutical manufacturing operations and will satisfy the federal RACT requirements.

Following a repeal of Rule 455, Staff will request that EPA remove the rule from the SIP. Section 110(l) of the CAA prevents EPA from approving a plan revision if the action would interfere with any applicable requirement concerning attainment and reasonable further progress. In addition, Section 193 of the CAA requires a rule in effect before November 15, 1990 to remain in effect except when revised by EPA, and any control requirement in effect before November 15, 1990 may not be modified unless the modification insures equivalent or greater emission reductions. Rule 455 was in the SIP before the 1990 CAA amendments. Although Staff is proposing to repeal Rule 455, the requirements for pharmaceutical and cosmetic manufacturing operations will be no less stringent because these requirements are already in Rule 464 or are incorporated in these proposed amendments to Rule 464. The proposed action to repeal Rule 455 also will not interfere with the District's progress to meet the air quality standards. See Appendix C to compare the requirements between Rule 455 and Rule 464 with the proposed amendments.

State Mandates:

The District is designated "serious" nonattainment for the state ozone standard. The California Clean Air Act requires areas designated as "serious" to adopt certain control measures, including:

- California Health and Safety Code (CHSC) Section 40919 requires districts designated serious nonattainment for ozone to adopt Best Available Retrofit Control Technology

[10] 44 FR 53761, September 17, 1979.

(BARCT) for all existing permitted sources. BARCT means an emission limitation that is based on the maximum degree of reduction achievable, taking into account environmental, energy, and economic impacts by each class or category of sources[11].

- CHSC Section 40914 requires a district to adopt "all feasible measures" if it is unable to achieve at least a 5% annual reduction in district wide emissions.
- Transport Mitigation Emission Control Requirements: Title 17, Section 70600 of the California Code of Regulations requires that districts within the areas of origin of transported air pollutants, as identified in Section 70500(c), include sufficient emission control measures (including all feasible measures and BARCT) in their attainment plans for ozone to mitigate the impact of pollution sources within their jurisdictions on ozone concentrations in downwind areas commensurate with the level of contribution. An upwind district must comply with the transport mitigation planning and implementation requirements set forth in this section regardless of its attainment status, unless the upwind district complies with the requirements of Section 70601.

Staff is proposing amendments to meet BARCT and all feasible measures requirements for pharmaceutical and cosmetic manufacturing operations. A starting point for determining BARCT and all feasible measures is to evaluate the most stringent emission standards established in other districts' rules for feasibility in Sacramento County. The evaluation of other districts' rules included the rules from South Coast AQMD (Rule 1103), Bay Area AQMD (Rule 8-24), Yolo-Solano AQMD (Rule 2.35), and San Diego APCD (Rule 67.15). The other districts' rules were not more stringent than the CTG for pharmaceutical manufacturing operations except where noted below:

- In YSAQMD, the emission applicability thresholds for pharmaceutical manufacturing operation and equipment at pharmaceutical manufacturing operation are lower than the thresholds in the CTG;
- In SDAPCD, the control efficiency of alternative controls for reactors, distillation columns, crystallizers, evaporators and centrifuges are higher than the control efficiency in the CTG; and
- In BAAQMD, SDAPCD, and YSAQMD, the emissions standards for air dryers and other production equipment are more stringent than the emission standards in CTG.

Staff has determined that the most stringent standards from other air district's rule are feasible for application in Sacramento County. Their inclusion in the proposed amendments to Rule 464 will meet the BARCT and all feasible measures requirements. Discussions of the most stringent standards from other district's rules are presented in the "Summary of Proposed Amendments to Rule 464 and Repeal of Rule 455" section.

SUMMARY OF PROPOSED AMENDMENTS TO RULE 464 AND REPEAL OF RULE 455

Currently, the District has two rules that apply to pharmaceutical and cosmetic manufacturing operations. Rule 455 – Pharmaceuticals Manufacturing applies only to pharmaceutical and cosmetic manufacturing operations. Rule 464 – Organic Chemical Manufacturing Operations applies more generally to organic chemical manufacturing operations, which include

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[11] California Health and Safety Code Section 40406.

pharmaceutical and cosmetic manufacturing operations. Staff is proposing to repeal Rule 455 to eliminate the duplication of requirements for pharmaceutical and cosmetic manufacturing operations.

Staff is proposing to amend Rule 464 to meet RACT, BARCT, and all feasible measures requirements for pharmaceutical and cosmetic manufacturing operations. The proposed amendments will ensure that the requirements in Rule 464 are as stringent as the requirements in the CTG for pharmaceutical manufacturing operations and in other air districts' rules. In addition, the proposed amendments ensure that the requirements of Rule 464 are not less stringent than those of Rule 455, which will be repealed. The significant proposed amendments for Rule 464 are summarized below. For a detailed list of changes, see Appendix B.

Decreases in Exemption Thresholds: The proposed amendments will lower the VOC emission exemption thresholds from 15 pounds per day to 10 pounds per day for:

- An entire pharmaceutical or cosmetic manufacturing plant with emissions less than 10 pounds per day; or
- Any individual vent stream from any reactor, distillation column, evaporator, crystallizer or centrifuge with emissions less than 10 pounds per day at a pharmaceutical or cosmetic manufacturing plant.

The proposed changes to the exemption thresholds are consistent with YSAQMD Rule 2.35. The exemption thresholds for other organic chemical manufacturing plants or for equipment at other organic chemical manufacturing plants will not change.

Changes to Equipment Standards: The proposed amendments will change the standards for the following equipment or operations at pharmaceutical and cosmetic manufacturing plants.

- Reactors, Distillation Columns, Crystallizers, Evaporators or Centrifuges: Rule 464 currently requires emissions from any of the listed equipment greater than 15 pounds per day be vented to a control system with a combined system efficiency of at least 85% and a control efficiency of at least 90%. This requirement is more stringent than the CTG for pharmaceutical manufacturing operations, which requires that the emissions from the listed equipment be vented to a surface condenser or equivalent device. An equivalent device must achieve at least as much VOC emission reduction as using a surface condenser. According to an EPA letter dated April 30, 1980, the outlet gas temperature established for surface condenser in the CTG for pharmaceutical manufacturing operations were based on control levels of approximately 70%[12]. Therefore, an equivalent device must reduce emissions by at least 70%, which is less stringent than the current requirement in Rule 464.

  For the purpose of meeting BARCT and all feasible measure requirements, Staff reviewed the requirements in other air districts. YSAQMD Rule 2.35, which applies to pharmaceutical and cosmetic manufacturing, requires emissions from any of the listed equipment of 10 pounds per day or more to be vented to control device with a combined system efficiency of at least 85% or to a surface condenser. SDAPCD Rule 67.15,

[12] Letter from Tom Williams, EPA, to Viney Aggarwal, Division of Air, New York State Department of Environmental Conservation, dated April 30, 1980.

which also applies to pharmaceutical and cosmetic manufacturing, requires emissions from any of the listed equipment of 15 pounds per day or more to be vented to a surface condenser or as an alternative, a control device with a combined system efficiency of at least 90%. To incorporate these more stringent levels of control into Rule 464, Staff is proposing to lower the threshold at which control is required to 10 pounds per day at a pharmaceutical or cosmetic manufacturing plant and require that the control system have a combined system efficiency of at least 90%. For equipment that emits more than 10 pounds per day but not more than 15 pounds per day, the emissions from the equipment may be vented to a condenser as an alternative to using a control system. The condenser must be operated in a manner that the condenser outlet gas temperature will not exceed the following for specific ranges of vapor pressure:

Absolute Vapor Pressure of VOC at 20°C	**Maximum Condenser Outlet Gas Temperature (°C)**
0.5 psi to 1.0 psi	25
Greater than 1.0 psi to 1.5 psi	10
Greater than 1.5 psi to 2.9 psi	0
Greater than 2.9 psi to 5.8 psi	-15
Greater than 5.8 psi	-25

The proposed amendments are more stringent than the requirements in the CTG for pharmaceutical manufacturing operations and are consistent with requirements in YSAQMD Rule 2.35 and SDAPCD Rule 67.15. This proposed standard will be effective 18 months after the date of adoption.

- Dryers or Production Equipment Exhaust Systems: Rule 464 currently requires that the emissions from dryers or production equipment systems greater than or equal to 330 pounds per day be vented to a control system with a combined system efficiency of at least 85% and a control efficiency of at least 90%. This requirement is not as stringent as the requirements in the CTG for pharmaceuticals manufacturing operations and in Rule 455; both require emissions from air dryers and production equipment exhaust systems greater than or equal to 330 pounds per day to be reduced by 90%. Staff is proposing to require emissions greater than or equal to 330 pounds per day from air dryers or other production equipment exhaust systems at a pharmaceutical or cosmetic manufacturing plant to be vented to a control system with a combined system efficiency of at least 90%. This proposed standard will be effective on the date of adoption to avoid a relaxation of the current requirement in Section 310.1 of Rule 455.

  YSAQMD Rule 2.35 requires the use of a control device with a combined efficiency of 85% if the emissions from dryers are 10 pounds per day or more, and both SDAPCD Rule 67.15 and BAAQMD Rule 8-24 require the use of a control device with a combined efficiency of 90% if the emissions from dryers and production equipment systems are greater than or equal to 33 pounds per day. The current Rule 464 requires emissions from dryers or production equipment systems less than 330 pounds per day to be reduced to less than 33 pounds per day. Staff is proposing to require emissions less than 330 lb/day from air dryers or other production equipment exhaust systems at a pharmaceutical or cosmetic manufacturing plant to be vented to a control system with a combined system efficiency of at least 90%, effective 18 months after the date of adoption. The proposed amendments are more stringent than the requirements in the CTG for pharmaceutical manufacturing operations and are consistent with requirements in YSAQMD Rule 2.35, SDAPCD Rule 67.15 and BAAQMD Rule 8-24.

- Liquid Transfer: Rule 464 currently requires the use of one of three methods to reduce emissions from the transfer of VOC-containing liquids: a vapor balance system, a VOC capture and control system, or a floating roof tank. If a VOC capture and control system is used, it must have a combined system efficiency of at least 85% and a control efficiency of at least 90%. This requirement is not as stringent as the requirements in the CTG for pharmaceutical manufacturing operations, which requires that for the transfer of VOC from truck/rail car deliveries to all tanks greater than 2,000 gallons capacity, the transfer process must not release more than one liter of displaced vapor for every ten liters transferred (i.e. 90% effective vapor balance or equivalent). This requirement is also not as stringent as the requirement in Section 310.3 of Rule 455, which requires the VOC emissions during transfer are reduced by 90% by weight. Therefore, Staff is proposing to increase the required combined system efficiency to 90% to be consistent with the CTG for pharmaceutical manufacturing operations and Rule 455. The proposed standard will be effective upon the date of adoption to avoid relaxation of current requirements.

Leak Requirements: The CTG for pharmaceutical manufacturing operations requires all leaks in which liquid can be observed running or dripping from vessels and equipment to be repaired as soon as is practical. In a communication to Staff, EPA noted[13] that the requirements for leaks (Section 310.5 of Rule 455) need to specify a time limit for completing the repairs after detection. Although Rule 464 does not specify leak requirements, except from wastewater, leak requirements for organic chemical manufacturing operations (including pharmaceuticals and cosmetics) are already established in Rule 443 – Leaks from Synthetic Organic Chemical and Polymer Manufacturing. To clarify that Rule 443 applies to operations that are subject to Rule 464, Staff is proposing to add language to Rule 464 stating that an organic chemical manufacturing facility must comply with the requirements of Rule 443. One of the requirements in Rule 443 specifies that leaks must be repaired within 2 working days after detection.

Petition of Exemption: Rule 464 requires a petition of exemption for an organic chemical plant or process vent that is exempt from meeting the rule standards. One of the proposed amendments is to lower the exemption threshold for pharmaceutical or cosmetic manufacturing plants and process vents at pharmaceutical or cosmetic manufacturing plants to 10 pounds per day of maximum uncontrolled VOC emissions. For process vents that are exempt, Staff is proposing to require the facility to submit a new petition of exemption to identify the process vents that are below the proposed exemption threshold of 10 pounds per day. The petition of exemption must be submitted to the District within 6 months after date of adoption of the proposed amendments.

Authority to Construct Application: For process vents that are no longer exempt, these process vents must comply with the proposed rule requirements by using an emission control device. If an existing emission control device that already has a District permit is used to comply with the rule requirement without modification to the device, then a permit application is not required. A permit application is required when the facility installs a new or modifies an existing emission control device to comply with the proposed rule requirements for existing process vents. An application for an Authority to Construct must be submitted within 6 months after the date of adoption.

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[13] Email from Nancy Levin, EPA, to Kevin J. Williams, SMAQMD, "Rule 455 Pharmaceuticals Manufacturing," February 25, 2014.

EMISSIONS IMPACT

There are no cosmetic manufacturing operations in the District, and there is a single pharmaceutical manufacturing facility. Staff has worked with this facility to determine the impact of the amendments. The information reviewed by Staff included all permits for the pharmaceutical operations, as well as emission summaries and evaluations provided by the facility. Staff's review of the documentation is summarized below.

There are several vents from reactors or centrifuges at the facility that emit between 10 and 15 pounds per day. These vents will become newly subject to the control requirements of Rule 464. Review of each of these emission points indicates that the emissions are controlled either by an emission control system or condenser that has a combined system efficiency of at least 90%, or by a condenser with an outlet gas temperature that meets the temperature requirement corresponding to the VOC vapor pressure.

Currently, Rule 464 requires the emissions from reactors and centrifuges that emit 15 pounds per day or more be vented to a VOC capture and control system with a combined system efficiency of at least 85% and a control efficiency of at least 90%. At the facility, the emissions from the vents are conveyed to the control devices through sealed pipes, resulting in essentially 100% capture efficiency. A capture and control system at the facility that has a control device efficiency of at least 90% (as currently required) will also have a combined system efficiency of at least 90%. Therefore, the amendment to Rule 464 that increases the required combined system efficiency to 90% is not expected to achieve any emission reductions from the facility.

There are dryers at the facility that emit more than 10 pounds per day. The amendments will require emissions from these dryers to be vented to a VOC capture and control system with a combined system efficiency of at least 90%. From the emission summaries, Staff identified the dryers that emit more than 10 pounds per day of uncontrolled emissions. The uncontrolled emissions from dryers are vented to emission control devices and most emissions are reduced by a combined system efficiency of at least 90%. There is one dryer that does not meet the proposed requirement of at least 90% emission reduction. Further review of this process showed that the dryer is used in several steps, and the duration of the process is more than 24 hours. In any 24-hour period, the emissions from the dryer are less than 10 pounds per day; therefore, the dryer will not require further control.

Based on the permit records and the information provided by the facility, Staff has determined that the facility already meets the proposed requirements. No emissions impact is expected as a result of the proposed amendments.

The repeal of Rule 455 will not increase emissions because pharmaceutical and cosmetic manufacturing operations are also subject to Rule 464. The proposed amendments to Rule 464 will ensure that the requirements in Rule 464 are at least as stringent as the requirements in Rule 455.

ECONOMIC IMPACT – COST

Section 40703 of the CHSC requires that the District consider and make public its findings relating to the cost-effectiveness of implementing an emission control measure.

There are no cosmetic manufacturing operations in the District. There is one pharmaceutical manufacturing facility in the District, and it is already in compliance with the proposed changes. No changes are proposed to the requirements for other types of organic chemical manufacturing plants. As a result, no facilities in the District will be required to modify their operations, and no additional compliance costs will be incurred.

ECONOMIC IMPACT – INCREMENTAL COST-EFFECTIVENESS

Health and Safety Code Section 40920.6(a)(3) requires the District to perform an incremental cost-effectiveness (ICE) analysis prior to adopting requirements for BARCT or all feasible measures. The ICE is calculated by the difference in the dollar costs divided by the difference in the emission reduction potentials between each progressively more stringent potential control option as compared to the next less expensive control option[14].

Based on the 2014 emission inventory, the annual VOC emissions for the one pharmaceutical manufacturing facility subject to Rule 464 are 3,202 pounds[15]. The proposed amendments to Rule 464 require that emissions from all process equipment greater than 10 pounds per day be vented to a control system with a combined system efficiency of at least 90%. The facility is already in compliance with the proposed changes, and the proposed amendments will not result in any emission reductions. For the purpose of this analysis, Staff assumed that the emissions from the facility are reduced by 90%, and the alternative compliance options for process equipment, where provided in the proposed rule, were not accounted for in the ICE analysis.

The next most stringent control option, Option 1, is to increase the control efficiency to at least 95%. According the CTG for pharmaceutical manufacturing operations, the use of a carbon adsorption system can meet the control efficiency of at least 95%[16]. The CTG for pharmaceutical manufacturing operations estimates the annualized cost of a carbon adsorption system to be approximately $113,000 (in 2014 dollars) per year, assuming that the facility is small and operates 8,064 hours per year[17]. The emission reduction potential compared to the proposed option is 1,601 pounds per year. The ICE of Option 1 compared to the proposed amendments is calculated to be $70.31 per pound of VOC reduced.

Another option, Option 2, is to require control efficiency higher than Option 1 or a control efficiency of at least 99%. According to the CTG for pharmaceutical manufacturing operations, a thermal incinerator has a control efficiency that ranges from 90% - 99%[18]. For this analysis, the control efficiency of thermal incinerator is assumed to be at least 99%. The CTG for pharmaceutical manufacturing operations estimates the annual cost of the thermal incinerator to be approximately $102,000 (in 2014 dollars) per year, assuming that the facility operates 8,064 hours per year[19]. The emission reduction potential compared to the proposed option is 2,882 pounds per year. The ICE of Control Option 2 compared to Control Option 1 is calculated to be

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[14] California Health and Safety Code Section 40920.6(a)(3).
[15] 2014 Emission Inventory Survey submitted by AMPAC Fine Chemicals on May 13, 2015.
[16] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978, Page 5-2.
[17] Ibid, Page 5-22. The system cost was estimated assuming no cost credit from product recovery.
[18] Ibid, Page 5-2.
[19] Ibid, Page 5-25.

-$8.50 per pound of VOC reduced. Note that if the ICE of Control Option 2 is compare to the proposed amendments, the ICE will be $35.28 per pound of VOC reduced.

The incremental cost-effectiveness of the Options 1 and 2 are shown in the table below. See Appendix D for the detailed calculations.

More Stringent Option	Less Stringent Option	Difference in Annualized Cost*	Difference in Emission Reduction Potentials** (lb/year)	Incremental Cost-Effectiveness***
Option 1	Proposed Option	$112,559	1,601	$70.31
Option 2	Option 1	-$10,893	1,281	-$8.50
Option 2	Proposed Option	$101,666	2,882	$35.28

*Annualized cost of the more stringent option minus annualized cost of the less stringent option
**Emission reduction potential from the more stringent option minus emission reduction potential from the less stringent option
***Difference in annualized cost divided by difference in emission reductions

To estimate the lowest potential ICE, the above analysis assumed the facility needed only one emission control system to control the VOC emissions from all process vents. The facility will likely require multiple emission control systems because the pharmaceutical manufacturing processes are located in multiple locations and buildings. As a result, the ICE is likely to be much greater than the cost presented in the above table.

In addition, Health and Safety Code Section 40920.6(a)(4)(b) requires the District to consider and review the cost-effectiveness for each proposed control option assessed in the ICE analysis. The cost-effectiveness is the cost, in dollars, of the potential control option divided by emission reduction potential, in tons, of the potential control option[20]. The cost-effectiveness of Option 1 and Option 2 are calculated to be $70.31 per pound of VOC reduced and $35.28 per pound of VOC reduced, respectively, as shown in the following table:

Control Option	Emission Reduction Potential (lb/year)	Annualized Cost in 2014 dollars ($/year)	Cost-Effectiveness ($/lb)
Option 1	1,601	$112,559	$70.31
Option 2	2,882	$101,666	$35.28

ECONOMIC IMPACT – SOCIOECONOMIC

CHSC Section 40728.5 requires a district to perform an assessment of the socioeconomic impacts before adopting, amending, or repealing a rule that will significantly affect air quality or emission limitations. The District Board is required to actively consider the socioeconomic impacts of the proposal and make a good faith effort to minimize adverse socioeconomic impacts. Although the proposed actions to amend Rule 464 and repeal Rule 455 will not significantly affect air quality or emission limitations, Staff has nevertheless analyzed the socioeconomic impacts.

[20] California Health and Safety Code Section 40920.6(a)(2).

CHSC Section 40728.5 defines "socioeconomic impact" to mean the following:

1. The type of industry or business, including small business, affected by the proposed rule or rule amendments.
2. The impact of the proposed rule or rule amendments on employment and the economy of the region.
3. The range of probable costs, including costs to industry or business, including small business.
4. The availability and cost-effectiveness of alternatives to the proposed rule or rule amendments.
5. The emission reduction potential of the rule or regulation.
6. The necessity of adopting, amending, or repealing the rule or regulation to attain state and federal ambient air standards.

Type of industry or business, including small business, affected by the proposed rule: Rule 464 applies to any person/business that operates an organic chemical manufacturing plant, including a pharmaceutical or cosmetic manufacturing plant. Changes to the emission limits for pharmaceutical manufacturing and cosmetic manufacturing are proposed; however, there are no cosmetic manufacturing facilities in the District and the lone pharmaceutical manufacturing operation is already in compliance with the proposed changes. No small businesses are affected.

Impact on employment and economy in the District of the proposed rule: No additional compliance costs will be incurred by businesses as a result of the proposed changes; therefore, no impact on employment or the economy is expected.

Range of probable costs, including costs to industry or business, including small business of the proposed rule: No additional compliance costs will be incurred by industries or businesses subject to Rule 464.

Availability and cost-effectiveness of alternatives to the proposed rule: An alternative to the proposed amendments to Rule 464 is not to adopt them. However, the District is required by Section 182(b)(2) of the Clean Air Act to revise the SIP to include RACT for source categories covered by a CTG document. In addition, the proposed amendments will satisfy state mandates for BARCT and all feasible measures requirements. If the proposed amendments to Rule 464 are not adopted, the District will not fulfill the RACT, BARCT and all feasible measures requirements for pharmaceutical and cosmetic manufacturing operations.

Another alternative is to adopt more stringent emission control standards than proposed. In the Economic Impact – Incremental Cost-Effectiveness section, two options with greater control efficiencies than the proposal were presented. Option 1 would increase the required control efficiency to 95%, and compared to proposed amendments, would reduce VOC emissions by an additional 1,601 pounds per year at a cost-effectiveness of $70.31 per pound of VOC reduced. Option 2 would increase the required control efficiency to 99%, and compared to the proposed amendments, would reduce VOC emissions by an additional 2,882 pounds per year at a cost-effectiveness of $35.28 per pound of VOC reduced.

In conclusion, the alternatives are not recommended at this time because the first alternative, not adopting the amendments, does not meet state and/or federal laws and regulations, and the

second alternative, to increase the required control efficiency, is significantly higher in cost than the proposed amendments.

Emission reduction potential of the proposed rule: The proposed amendments to Rule 464 are not expected to achieve emission reductions.

Necessity of adopting the rule: Staff finds that proposed amendments to Rule 464 are necessary to satisfy the requirements of Section 182(b)(2) of the federal Clean Air Act, which requires the District adopt RACT for CTG source categories. In addition, the proposed amendments will satisfy Health and Safety Code Sections 40914 and 40919, which require the District to meet BARCT and all feasible measures requirements.

PUBLIC OUTREACH/COMMENTS

Staff held a public workshop on March 16, 2016, to discuss the proposed amendments to Rule 464 and the proposed repeal of Rule 455. A public notice for the workshop was sent (either by U.S. Mail or email) to all interested parties, including the two sources subject to Rule 464 and all persons who have requested to receive rulemaking notices. The notice was published in the Sacramento Bee on February 26, 2016, and posted on the District's website. The draft Rule 464 and Statement of Reasons were available for public review prior to the public workshop.

Staff received questions concerning Rule 464 at the public workshop. No oral or written comments from the public or affected parties were received. CARB and EPA reviewed the proposed amendments. CARB had no comments. EPA had two comments, which stated that the proposed requirements in Sections 303 and 306 of Rule 464 should become effective upon adoption to avoid relaxation of current requirements. Staff revised the proposed effective dates consistent with EPA's comments. This change was discussed at the public workshop. All questions, comments and responses are included in Appendix E.

ENVIRONMENTAL REVIEW

California Public Resources Code Section 21159 requires an environmental analysis of the reasonably foreseeable methods of compliance. Proposed actions to repeal Rule 455 and amend Rule 464 are not expected to require any source within the District to change its operations to comply. Therefore, Staff has concluded that no environmental impacts will be caused by compliance with the proposed amendments.

Staff finds that the proposed action to repeal Rule 455 and amend Rule 464 are exempt from the California Environmental Quality Act as an action by a regulatory agency for the protection of the environment (Class 8 Categorical Exemption, Section 15308 State CEQA Guidelines) and because it can be seen with certainty that there is no possibility that the activities in question may have a significant adverse effect on the environment (Section 15061(b)(3), State CEQA Guidelines).

FINDINGS

The California Health and Safety Code (CHSC), Division 26, Air Resources, requires local districts to comply with a rule adoption protocol as set forth in Section 40727 of the Code. This section contains six findings that the District must make when adopting, amending, or repealing a rule. These findings and their definitions are listed in the following table.

Rule 455 – PHARMACEUTICALS MANUFACTURING
Required Findings

Finding	Finding Determination
Authority: The District must find that a provision of law or of a state or federal regulation permits or requires the District to adopt, amend, or repeal the rule.	The District is authorized to repeal Rule 455 and remove it from the SIP by California Health and Safety Code (CHSC) Sections 40702, 40726, and 40727, and CAA Sections 110, 172, 182 and 193, 40 CFR Parts 51 and 52, and related statutory and regulatory requirements. [CHSC Section 40727(b)(2)].
Necessity: The District must find that the rulemaking demonstrates a need exists for the rule, or for its amendment or repeal.	It is necessary to repeal Rule 455 to eliminate the duplication of requirements for pharmaceutical and cosmetic manufacturing. Rule 455 and Rule 464 both set requirements for these source types. [CHSC Section 40727(b)(1)].
Clarity: The District must find that the rule is written or displayed so that its meaning can be easily understood by the persons directly affected by it.	Staff is proposing to repeal Rule 455, which will remove the entire text of the rule. [CHSC Section 40727(b)(3)].
Consistency: The rule is in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or state or federal regulations.	The proposed repeal of Rule 455 will not cause a conflict with, and is not contradictory to, existing statutes, court decisions, or state or federal regulations. [CHSC Section 40727(b)(4)].
Non-Duplication: The District must find that either: 1) The rule does not impose the same requirements as an existing state or federal regulation; or (2) that the duplicative requirements are necessary or proper to execute the powers and duties granted to, and imposed upon the District.	In repealing Rule 455, the District will eliminate the duplication of District requirements for the same source categories. [CHSC Section 40727(b)(5)].
Reference: The District must refer to any statute, court decision, or other provision of law that the District implements, interprets, or makes specific by adopting, amending or repealing the rule.	Pharmaceutical Manufacturing is a CTG category. In repealing Rule 455 and amending Rule 464, the District is implementing the RACT requirements of Sections 172(c)(1) and 182(b)(2)(A) of the federal Clean Air Act. [CHSC Section 40727(b)(6)].
Additional Informational Requirements: In complying with CHSC Section 40727.2, the District must identify all federal requirements and District rules that apply to the same equipment or source type as the proposed rule or amendments.	Rule 464 applies to the same source types that are covered under Rule 455, which is proposed for repeal. Appendix C includes a comparison of Rule 464 with federal requirements [CHSC Section 40727.2].

Rule 464 – ORGANIC CHEMICAL MANUFACTURING

Required Findings

Finding	Finding Determination
Authority: The District must find that a provision of law or of a state or federal regulation permits or requires the District to adopt, amend, or repeal the rule.	The District is authorized to adopt amendments to Rule 464 by California Health and Safety Code (CHSC) Sections 40001, 40702, and 41010, and CAA Sections 110, 172, and 182 and related statutory and regulatory requirements. [CHSC Section 40727(b)(2)].
Necessity: The District must find that the rulemaking demonstrates a need exists for the rule, or for its amendment or repeal.	It is necessary to amend Rule 464 to comply with the RACT requirements of the federal Clean Air Act Sections 172(c)(1) and 182(b)(2)(A), and all feasible measure and BARCT requirements of CHSC Sections 40914(b)(2) and 40919(a)(3). [CHSC Section 40727(b)(1)].
Clarity: The District must find that the rule is written or displayed so that its meaning can be easily understood by the persons directly affected by it.	Staff has reviewed the proposed rule and determined that it can be understood by the affected parties. In addition, the record contains no evidence that people directly affected by the rule cannot understand the rule. [CHSC Section 40727(b)(3)].
Consistency: The rule is in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or state or federal regulations.	The proposed rule does not conflict with, and is not contradictory to, existing statutes, court decisions, or state or federal regulations. [CHSC Section 40727(b)(4)].
Non-Duplication: The District must find that either: 1) The rule does not impose the same requirements as an existing state or federal regulation; or (2) that the duplicative requirements are necessary or proper to execute the powers and duties granted to, and imposed upon the District.	The proposed amendments to the rule do not duplicate any existing state or federal regulations. [CHSC Section 40727(b)(5)].
Reference: The District must refer to any statute, court decision, or other provision of law that the District implements, interprets, or makes specific by adopting, amending or repealing the rule.	Pharmaceutical Manufacturing is a CTG category. In adopting the proposed amendments to Rule 464, the District is implementing the RACT requirements of Sections 172(c)(1) and 182(b)(2)(A) of the federal Clean Air Act and CHSC Sections 40914(b)(2) and 40919(a)(3). [CHSC Section 40727(b)(6)].
Additional Informational Requirements: In complying with CHSC Section 40727.2, the District must identify all federal requirements and District rules that apply to the same equipment or source type as the proposed rule or amendments.	Appendix C includes a comparison with federal requirements. [CHSC Section 40727.2]

REFERENCES

1. Bay Area Air Quality Management District, Regulation 8 – Organic Compounds, Rule 24 – Pharmaceutical and Cosmetic Manufacturing Operations, June 15, 1994.

2. Board Letter from Norm Covell, Air Pollution Control Officer, Sacramento Metropolitan Air Quality Management District to Sacramento Metropolitan Air Quality Management District Board of Directors. Subject: Regulation 4 – Prohibition, Proposed New Rule 464, Organic Chemical Manufacturing Operations. Dated July 23, 1998.

3. Bureau of Labor Statistics. "CPI Detailed Report Data for July 2015," July 2015.

4. Letter from Tom Williams, EPA, to Viney Aggarwal, Division of Air, New York State Department of Environmental Conservation, dated April 30, 1980.

5. San Diego Air Pollution Control District, Regulation IV, Rule 67.15 – Pharmaceutical and Cosmetic Manufacturing Operations, May 15, 1996.

6. South Coast Air Quality Management District, Rule 1103 – Pharmaceuticals and Cosmetics Manufacturing Operations, March 12, 1999.

7. U.S. Environmental Protection Agency. "Air Quality Designations and Classifications for the 8-Hour Ozone National Ambient Air Quality Standards; Early Action Compact Areas with Deferred Effective Dates, Final Rule." 69 Federal Register (April 30, 2004), pp. 23857 – 23951.

8. U.S. Environmental Protection Agency. "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products" (EPA-450/2-78-029). December 1978.

9. U.S. Environmental Protection Agency. "Implementation of the 2008 National Ambient Air Quality Standards for Ozone: Nonattainment Area Classifications Approach, Attainment Deadlines and Revocation of the 1997 Ozone Standards for Transportation Conformity Purposes, Final Rule." 77 Federal Register (May 21, 2012), pp. 30160 – 30171.

10. U.S. Environmental Protection Agency. "Integrated Science Assessment for Ozone and Related Photochemical Oxidants." February 2013.

11. U.S. Environmental Protection Agency. "Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Proposed Rule." 81 Federal Register (January 15, 2016), pp. 2136 – 2140.

12. U.S. Environmental Protection Agency. "Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan – EPA's Evaluation of Sacramento Metropolitan Air Quality Management District, Ozone State Implementation Plan Revision Reasonably Available Control Technology as Applicable to the 8-hour Ozone Standard - Adopted 26, 2006 ("2006 RACT SIP TSD")." November 2015.

13. U.S. Environmental Protection Agency. Clean Air Technology Center – RACT/BACT/LAER Clearinghouse, http://cfpub.epa.gov/rblc/index.cfm?action=Results.PermitSearchResults. Accessed on September 1, 2015.

14. U.S. Environmental Protection Agency, Region IX. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies ("Little Blue Book")." Revised August 21, 2001.

15. Yolo-Solano Air Quality Management District, Regulation II, Rule 2.35 Pharmaceutical Manufacturing Operations, May 14, 2008.

APPENDIX A

Pharmaceutical and Cosmetic Manufacturing Operation Standards in CTG, Current Rule 455, and Current Rule 464

Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)	Rule 455 – Pharmaceuticals Manufacturing	Rule 464 – Organic Chemical Manufacturing Operations
Each vent from a reactor, distillation operation, crystallizer, centrifuge, or vacuum dryer that emits 15 lb/day or more VOC requires a surface condenser or equivalent control. If a surface condenser is used, the condenser outlet should not exceed a specific temperature when condensing VOC of vapor pressure greater than a specific pressure. EPA memo dated April 30, 1980, indicated the CTG for pharmaceutical manufacturing operations expected condensers to achieve approximately 70% control. Equivalent control results when emissions are reduced at least as much as they would have been by using a surface condenser.	Shall not use reactors, distillation columns, crystallizers, or centrifuges emitting more than 15 lb/day of VOC for each permit unit unless the vents are equipped with surface condensers or equivalent control devices. - Shall not use surface condensers unless the condenser outlet gas temperature is controlled as listed in the table (same as CTG for pharmaceutical manufacturing operations). - Equivalent control devices may be used with the approval of the APCO. Equivalent control is achieved when VOC emissions are reduced by at least as much as would have been achieved using a surface condenser.	Shall use any reactor, distillation column, crystallizer, evaporator or enclosed centrifuge which emits more than 15 lb/day of maximum uncontrolled VOC unless such emission is vented to a VOC capture and control system which has combined system efficiency of at least 85 percent and a control efficiency of at least 90% by weight.
Enclose all centrifuges, rotary vacuum filters, and any other filters having an exposed liquid surface where the liquid contains VOC. The CTG for pharmaceutical manufacturing operations notes that one method to control the emissions from these equipment types is to vent the emissions to a control system, such as a carbon adsorber.	Shall not use centrifuges, rotary vacuum filters, or devices having exposed liquid surface where the liquid contains VOC having a total VOC vapor pressure of 0.5 psi or more at 20°C, unless such devices incorporate a hood or enclosure with a delivery system or ductwork to collect VOC emissions, exhausting to a carbon adsorber, or equivalent control method.	Shall not use centrifuges, rotary vacuum filters, or other devices which has an exposed liquid surface where the liquid contains VOC having a VOC composite partial vapor pressure of 26 mm Hg (0.5 psi) or more at 20°C, unless it incorporates a hood or enclosure with a delivery system or ductwork to collect VOC emissions, exhausting to a carbon adsorber, or equivalent control method.
All in-process tanks shall have covers. Covers should be closed when possible. The CTG for pharmaceutical manufacturing operations notes that emissions from tanks may be reduced through the use of control systems, such	Shall not use in-process tanks for material containing VOC unless an apparatus or cover, which prevents VOC evaporation, is provided for the tank. The cover shall be closed or in in place on the tank at all times except while loading or	Shall not use any process tanks containing material with a VOC composite partial pressure of greater than 26 mm Hg at 20 C, unless it is a closed container, which is kept tightly covered at all times except when accessing the container

Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)	Rule 455 – Pharmaceuticals Manufacturing	Rule 464 – Organic Chemical Manufacturing Operations
as vapor balance system, conservation vent, vent condenser, pressurized tank or carbon adsorber.	unloading the tank.	Shall not use any process tank which contains material with VOC composite partial vapor pressure of greater than 26 mm Hg at 20 C and which emits more than 15 lb/day of maximum uncontrolled VOC unless such emission is vented to a VOC capture and control system which has combined system efficiency of at least 85% percent by weight, and a control efficiency of at least 90% by weight
For air dryers and production equipment exhaust systems that emit 330 lb/day or more of VOC, require 90% emission reduction.	Shall not use air dryers or production equipment exhaust systems that emit 330 lb/day or more of volatile organic compounds for each basic permit unit unless the emission of such organic materials has been reduced by at least 90% by weight.	Shall not use any dryer or other production equipment exhaust system which emits 330 lb/day or more of maximum uncontrolled VOC unless such emission is vented to a VOC capture and control system which has a combined system efficiency of at least 85% by weight and a control efficiency of at least 90% by weight
For air dryers and production equipment exhaust systems that emit less than 330 lb/day, require emission reduction to 33 lb/day.	Using air dryer or production equipment exhaust systems that emit less than 330 lb/day of VOC shall reduce the emissions to less than 33 lb/day.	Shall not use any dryer or production equipment exhaust system which emits less than 330 pounds on any day of maximum uncontrolled VOC unless such emissions is reduced to less than 33 lb/day.
For storage tank storing VOC with a vapor pressure greater than 4.1 psi at 20C, allow one liter of displaced vapor to be released to the atmosphere for every 10 liters of liquid transferred (90% effective vapor balance or equivalent) on truck/rail car delivery to all tanks greater than 2000 gallons capacity, except when tanks are equipped with floating roofs, vapor recovery or equivalent.	Shall not transfer VOC having a vapor pressure greater than 4.0 psi at 20C, from any truck or rail car into any storage tank of a 2,000 gallons capacity or greater, unless VOC emission during transfer are reduced by 90% by weight.	Shall not transfer material with a VOC composite partial vapor pressure of greater than 26 mm Hg at 20 C in to any tank truck, trailer, railroad tank car, or storage tank of 2000 gallons capacity or greater unless VOC emissions during the transfer are controlled with one of the following system: -A vapor balance system -A VOC capture and control system which has a combined system efficiency of at least 85% by weight, and a control efficiency of at least 90% by weight -An internal or external floating roof which complies with 40 CFR63.119 and 63.120.

Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)	Rule 455 – Pharmaceuticals Manufacturing	Rule 464 – Organic Chemical Manufacturing Operations
For tanks storing VOC liquids with a vapor pressure greater than 1.5 psi at 20C, require pressure/vacuum conservation vents set at ±0.2 kPa, except where more effective air pollution control is used.	Shall install pressure/vacuum vents set at 0.03 psig on all storage tanks than store VOC with a vapor pressure greater than 1.5 psig at 20C, unless a more effective control system, approved by the APCO is used.	Shall install pressure/vacuum valve with a minimum pressure setting of 0.03 psi and a minimum vacuum setting of 0.03 psi, or equivalent control on all vents of any storage tank greater than 55 gallons and less than or equal to 40,000 gallons that stores material with a VOC composite partial vapor pressure of greater than 78 mm Hg at 20 C. Storage tank with capacity of less than 55 gallons or less that stores material with a VOC composite partial vapor pressure of greater than 78 mm Hg at 20 C shall be closed container which kept tightly covered at all times except when accessing the container.
For liquids containing VOC, all leaks in which liquid can be observed to be running or dripping from vessels and equipment should be repaired as soon as is practical.	Shall repair all leaks from which a liquid, containing VOC, can be observed to be running or dripping. The report shall be completed the first time the equipment is off-line for a period of time long enough to complete repair.	

APPENDIX B

SUMMARY OF PROPOSED RULE AMENDMENTS

Rule 464 – Organic Chemical Manufacturing Operations

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
Where applicable	Where applicable	Removed the ambiguous term "shall" and replaced it with "must," "may," "do," "does," "will," "is," or "are," as appropriate, to retain the intent of the provision.
Where applicable	Where applicable	Replaced "which" with "that," where appropriate, to eliminate nonstandard usage.
102	102	Clarified that leaks from process equipment are subject to Rule 443 – Leaks from Synthetic Organic Chemical and Polymer Manufacturing. This is consistent with the applicability of Rule 443.
110	110	Separated the section into two subsections. The first subsection lowers the exemption threshold for pharmaceutical manufacturing plants and cosmetic manufacturing plants from 15 lb/day to 10 lb/day. This is consistent with YSAQMD Rule 2.35. The second subsection maintains the exemption threshold for other chemical manufacturing plants at 15 lb/day.
111	111	Separated the section into two subsections. The first subsection lowers the exemption threshold for vents at pharmaceutical manufacturing plants and cosmetic manufacturing plants from 15 lb/day to 10 lb/day. This is consistent with YSAQMD Rule 2.35. The second subsection maintains the exemption threshold for vents at any other chemical manufacturing plant at 15 lb/day.
112	112	Reworded to clarify that the exemption applies to an organic chemical plant that is not a pharmaceutical manufacturing plant or a cosmetic manufacturing plant.
114	114	Moved "at a stationary source" to clarity it refers to cumulative emissions at a stationary source. Replaced "into" with "of" to be grammatically correct.
115	115	Removed the reference to Section 308.5 due to renumbering and deletion of expired solvent cleaning requirements.
116	116	Moved "at a stationary source" to clarity it refers to cumulative VOC emissions at a stationary source. Combined "record" and "keeping."
201	201	Removed "s" on "systems" to correct grammatical error.
203	203	Removed "and pharmaceuticals" from the definition because the definition of organic chemicals manufacturing operations already includes pharmaceutical manufacturing operations. Removed "s" on "solvents" since solvent is an example of a material.
205	205	Corrected grammatical error.
206	206	Added "A" at the beginning of the sentence.
207	207	Replaced "plant" with "stationary source."
208	208	Added "air pollution" before "control device" to be consistent with the term "air pollution control device" that is defined in Section 201. Removed "s" on "rates" since it is one emission rate. Rephrased "test data collected" to "collected test data."

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
211	211	Specified that the definition of "leak" applies only to Section 305, WASTEWATER. Leaks from process equipment covered by Rule 443 – LEAKS FROM SYNTHETIC ORGANIC CHEMICAL AND POLYMER MANUFACTURING are defined in that rule. Added "s" to "part" to correctly refer to the methane reading of 500 parts per million.
213	213	Added "in an Authority to Construct that has been or will be incorporated" into the definition to clarify that the maximum quantity of VOC emissions includes the limitations in the Authority to Construct in cases where the Permit to Operate has yet to be issued.
214	214	Added "air pollution" before "control device" to be consistent with the term "air pollution control device" that is defined in Section 201.
215	215	Replaced "drugs" with "pharmaceuticals." Added "and" before re-refining.
216	216	Replaced "plant" with "stationary source."
218	218	Added "air pollution" before "control device" to be consistent with the term "air pollution control device" that is defined in Section 201. Added that the potential to emit includes both directly emitted and fugitive emissions. This addition is consistent with the definition of "potential to emit" in Rule 202.
221	221	Replaced "oil and water separator" with more commonly used term "oil-water separator." Grammatical errors corrected.
222	222	Reworded to clarify that a process vent is a vent that releases or has the potential to release a VOC –containing gas stream into the atmosphere.
228	228	Added wastewater tanks to the list to clarify that wastewater tanks should not be included as storage tanks. Wastewater tanks have their own requirements (Sections 305.1 and 305.2) and are not subject to the storage tank requirements (Section 307).
301.1	N/A	Added the current and proposed requirements for reactors, distillation columns, crystallizers, evaporators or enclosed centrifuges that emit more than 15 lb/day of uncontrolled VOC emissions at a pharmaceutical manufacturing plant or a cosmetic manufacturing plant. The current requirement for these types of equipment requires the emission be vented to an emission control device with a combined system efficiency of 85 percent and a control efficiency of 90 percent. This requirement will sunset 18 months after the date of adoption. Thereafter, the emissions must be vented to an emission control device with a combined system efficiency of 90%. This standard is consistent with YSAQMD Rule 2.35 and SDAPCD Rule 67.15.
301.2	N/A	Added the requirement that a person cannot use reactors, distillation columns, crystallizers, evaporators or enclosed centrifuges that emit more than 10 lb/day but no more than 15 lb/day of uncontrolled VOC emissions at a pharmaceutical manufacturing plant or a cosmetic manufacturing plant unless the emissions are vented to an emission control device with a combined system efficiency of 90%. This requirement is effective 18 months after the date of adoption. This section is consistent with YSAQMD Rule 2.35 and SDAPCD Rule 67.15.
301.3	N/A	Added an alternative to Section 301.2 to allow the use of a condenser to control emissions from reactors, distillation columns, crystallizers, evaporators or enclosed centrifuges that emit more than 10 lb/day but no more than 15 lb/day. Added a table that specifies the condenser outlet temperatures for specific ranges of VOC vapor pressure. This section is consistent with YSAQMD Rule 2.35. The vapor pressure/temperature requirements are the same as Rule 455 (which is proposed to be repealed).

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
301.4	301.1	Clarified that this section applies to an organic chemical manufacturing plant that is not a pharmaceutical manufacturing plant or a cosmetic manufacturing plant. Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Added a provision to use applicable method specified in Section 410. Referenced section renumbered.
301.5	301.2	Clarified that this section applies to an organic chemical manufacturing plant that is not a pharmaceutical manufacturing plant or a cosmetic manufacturing plant. Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Added reference to a specific section for control requirement. Replaced "appropriate" with "applicable" and added "specified" after "method" when referencing to the method in Section 410. Removed "or unless" to indicate subsection (b) is an alternative to subsection (a). Referenced sections renumbered.
302.1	302.1	Clarified that this section applies to separation operations at pharmaceutical manufacturing plants and cosmetic manufacturing plants. Added "filter" after "other" to include any other filters, as suggested by EPA. Referenced section renumbered. Added "U.S." before EPA.
302.2	302.2	Clarified that this section applies to separation operations at an organic chemical plant that is not a pharmaceutical manufacturing plant or a cosmetic manufacturing plant. Added "filter" after "other" to include any other filters. Deleted "other organic chemical plant" to eliminate redundancy. Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Replaced "appropriate" with "applicable" and added "specified" after "method" when referencing to the method in Section 410. Referenced section renumbered.
303	303	Separated the section into two subsections to reflect new applicability thresholds and control efficiencies. Section 303.1 applies to pharmaceutical manufacturing plants and cosmetic manufacturing plants. Section 303.2 applies to organic chemical manufacturing plants that are not pharmaceutical manufacturing plants or cosmetic manufacturing plants.
303.1	N/A	Added section that shows the current and proposed requirements for dryers or production equipment exhaust systems at pharmaceutical manufacturing plants and cosmetic manufacturing plants. Currently, the rule requires that a person may not operate dryers or production equipment exhaust systems that emit 330 lb/day or more unless the emission are vented to an emission control device with a combined system efficiency of 85 percent and a control efficiency of 90 percent. However, Rule 455 requires the emission from dryer or production exhaust systems are reduced 90%. To avoid a relaxation of Rule 455 requirement, Staff is changing the combined system efficiency to 90%. This change is proposed to be effective upon the date of adoption. For these types of equipment that emit less than 330 lb/day, the emission must be reduced to less than 33 pounds per day. These requirements are proposed to sunset 18 months after the date of adoption. After 18 months after the date of adoption, this section will require that any dryers or production exhaust systems with uncontrolled emissions of more than 10 lb/day be vented to a control device with a combined system efficiency of at least 90%. This requirement is consistent with YSAQMD Rule 2.35.

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
303.2	303.1-303.2	Modified sections to maintain current requirements for dryers or other production equipment exhaust systems located at organic chemical manufacturing plants that are not pharmaceutical manufacturing plants or cosmetic manufacturing plants. Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Replaced "appropriate" with "applicable" and added "specified" after "method" when referencing to the method in Section 410. Referenced section renumbered.
304	304	Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Replaced "appropriate" with "applicable" and added "specified" after "method" when referencing to the method in Section 410. Referenced sections renumbered.
305	305	Section 305 applies to all wastewater equipment, including wastewater tanks and containers. Container is defined in Section 205 as portable waste management unit, and it has its own requirements (Section 305.3). As such, a wastewater tank that is not portable is a stationary waste management unit. Added "s" to "part". Added "stationary" before wastewater tanks in Sections 305, 305.1 and 305.2 to clarify that these sections apply only to stationary wastewater tanks. Replaced "and" with "or". Referenced sections renumbered. Replaced "can not" with "cannot". Added "A" or "An" to beginning of the sentences in Sections 305.2(b), 305.6(a) or 305.6(b). Replaced "appropriate" with "applicable" and added "specified" after "method" when referencing to the method in Section 410. Added "air pollution" before "control device" to be consistent with the term "air pollution control device" that is defined in Section 201.
306	306	Referenced section renumbered.
306.2	306.2	Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201. Separated the section into two subsections. Section 306.2.a applies to pharmaceutical manufacturing plants and cosmetic manufacturing plants. This section changes the current requirement for a VOC capture and control device to have a combined system efficiency of 85% to 90%. This change is effective upon the date of adoption because this requirement already exists in Rule 455. Section 306.2.b applies to organic chemical manufacturing plants that are not pharmaceutical manufacturing plants or cosmetic manufacturing plants. The current requirements for capture and control systems for liquid transfer are maintained. Referenced section renumbered.
307.1	307.1	Added "approved in writing by the Air Pollution Control Officer and U.S. EPA and" to eliminate sole APCO discretion and include EPA in the process to approve an equivalent control method. According to EPA guidance, APCO discretion is not appropriate in SIP rule provisions related to alternative compliance[21]. Referenced section renumbered.
308.3	308.3	Replaced "VOC capture and control system" with "air pollution control device" to be consistent with term defined in Section 201.

[21] "Guidance Document for Correcting Common VOC & Other Rule Deficiencies (a.k.a, The Little Bluebook)," U.S. EPA Region IX, Revised August 21, 2001, p. 17.

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
N/A	308.4	Removed the section that is no longer in effect.
308.4	308.5	Removed the past effective date. Added "and in-line solvent cleaning as provided in Section 308.3" to specify that this section does not apply to in-line solvent cleaning. Requirements for in-line solvent cleaning are specified in Section 308.3.
401	401	Added "maximum uncontrolled VOC" to clarify that the emission rate is the maximum uncontrolled VOC emission. Replaced "below" with "less than or equal to" to be consistent with the exemption thresholds in Sections 110, 111, 112, 113, 114, and 116.
401.1	401.1	Updated this section to specify that existing plants or process vents are those in existence before the date of adoption for these proposed amendments. Also, updated the timeframe to 6 months after the date of adoption to submit a petition of exemption. A petition of exemption for existing plant or process vents will be required because the exemption thresholds are proposed to be lower than before the proposed amendments.
401.2	401.2	Revised the timeframe to submit a petition of exemption for a new or modified plant or process vent to align with the timeframe for an Authority to Construct permit specified in Rule 201 – General Permit Requirements. The petition of exemption will be evaluated as part of the permit application review process.
402	402	Updated this section to require a permit application if a facility installs a new or modifies an emission control device to control an existing process vent. The facility has 6 months after the date of adoption to submit an application for an Authority to Construct. The facility must be in compliance with the emissions requirements within 18 months after the date of adoption. An application is not required if an existing control device already has a permit and the use of the air pollution control device, without modification, results in compliance with the rule. Replaced "emission control equipment" with "air pollution control device" to be consistent with the term that is defined in Section 201.
403	403	Deleted "approved" from "approved emission control device" to ensure that the emission control device and the Operation and Maintenance Plan for the emission control device are evaluated and approved at the same time. Replaced "emission control device" or "emissions control equipment" with "air pollution control device" to be consistent with the term that is defined in Section 201. Removed the January 1, 1999 submission date because this date has passed. Specified that the facility must implement the Operation and Maintenance Plan if the operation commences before the plan is approved by the APCO.
N/A	404	Deleted this section that describes the procedure for approving an O&M plan, which removes the timeframe to approve the plan. The procedure to approve a plan will follow the procedure to approve or deny an application for Authority to Construct in Section 403. This is consistent with other District Rules (Rule 450, 451, 452, and 463).
404	405	Section renumbered. Removed the January 1, 1999 submission date because this date has passed and revised this provision to state that an annual wastewater report is due by February 1 of each year. This allows sufficient time to prepare a report covering the previous calendar year.
405	406	Revised variables in the text to be consistent with the variables in the equation. Added "U.S." before EPA.

NEW SECTION NUMBER	EXISTING SECTION NUMBER	PROPOSED CHANGES
406	407	Added "U.S." before EPA. Updated the version of the wastewater emissions model from WATER8 to WATER9. There is no impact from this change because the one facility that is required to use this model is currently using the WATER9 version. Referenced sections renumbered.
407	408	Sections and referenced sections renumbered.
408	409	Sections and referenced sections renumbered. Add "s" to "hour" to correct grammatical error.
409	410	Added "air pollution" before "control device" to be consistent with the term "air pollution control device" that is defined in Section 201.
410	411	Replaced "capture and control devices" with "air pollution control devices" and added "air pollution" before "control device" to be consistent with the term "air pollution control device" defined in Section 201. Deleted "and control efficiency" to remove redundant phrase. Added "s" to "contain" to correct grammatical error.
411	412	Section renumbered.
501	501	Combined "RECORD" and "KEEPING." Replaced "emission control system" with "air pollution control device" to be consistent with the term defined in Section 201. Replaced "on-site" with "on site."
501.1	501.1	Referenced section renumbered.
501.2	501.2	Added "combined system efficiency" and "efficiency" after capture and control to clarify that this section applies to a person who uses a control device that must meet a specified efficiency.
501.3	501.3	Referenced section renumbered.
501.4	501.4	Removed the emission threshold of 15 lb/day from the section heading because the emissions thresholds will be different for pharmaceutical and cosmetic manufacturing plants and for any other organic chemical manufacturing plants.
501.5	501.5	Removed the emission threshold of 15 lb/day from the section heading because the emission thresholds will be different for pharmaceutical and cosmetic manufacturing plants and for any other organic chemical manufacturing plants. Thresholds are specified in the referenced sections. Added "SEPARATION OPERATION" after "NON-COSMETIC" to be consistent with Section 112.
502	502	Added "methods" after "following." Added "U.S." before EPA. Replaced "collection" with "capture" because "capture efficiency" is used consistently in the rule.

APPENDIX C

Matrix to Meet the Requirements of CHSC Section 40727.2 and CAA Sections 110(l) and 193

Repealing Rule 455 – Pharmaceuticals Manufacturing and Amending Rule 464 – Organic Chemical Manufacturing Operations

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
Applicability		- Manufacture of pharmaceutical and cosmetic products by chemical processes - Production and separation of medicinal chemicals - Manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials and animal tissues - The formulation of pharmaceuticals into various dosage forms that can be taken by patient immediately and in accurate	-Equipment located at organic chemical plants which emit VOC -Transfer and storage of VOC at organic chemical plants	Existing plants synthesizing pharmaceutical products	Pharmaceutical operation that is a major source or is located at a major source of HAP.	Pharmaceutical manufacturing plant[22]

[22] Based on BACT determination IN-0146 (10/06/2009), in EPA's RACT/BACT/LAER Clearinghouse, http://cfpub.epa.gov/rblc/index.cfm?action=Results.PermitSearchResults.

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
		amount - The formulation of cosmetics into configurations intended for consumer use				
Conclusion: Rule 464 applies to organic chemical plants, which includes pharmaceutical and cosmetic manufacturing plants. Therefore, the applicability of Rule 464 covers the sources that are subject to Rule 455.						
Exemptions		Facilities that emit 15 lb/day or less.	-Pharmaceutical or cosmetic manufacturing plants that emit 10 lb/day or less and any other organic chemical plant that emits 15 lb/day or less -Reactor, distillation column, evaporator, crystallizer or centrifuge that emits 10 lb/day or less at a pharmaceutical or cosmetic manufacturing plant or 15 lb/day or less at any other organic chemical plant. -Non-pharmaceutical/non-cosmetic separation operation that emits 15 lb/day or less -Process tank that emits 10 lb/day at		-Research and development facilities	No specific exemption.

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
			pharmaceutical and cosmetic manufacturing operation and 15 lb/day or less at any other organic chemical manufacturing plant -Research and development operations that emit 15 lb/day or less -Lab equipment solvent cleaning or solvent cleaning operation regulated by the Food and Drug Administration			
Conclusions: The exemptions in Rule 464 are at least as stringent as the exemptions in Rule 455.						
Averaging Provisions		None	None	None	Except for specific conditions, emission averaging provisions may be allowed for any storage tank or process.	None.
Conclusion: There are no averaging provisions in Rule 455 or Rule 464.						
Emissions Limits/ Standards		Vents from reactors, distillation columns, crystallizers, centrifuges emitting more than 15 lb/day equipped with a surface condensers or equivalent control device. Emissions from	<u>Reactors, distillation columns, crystallizers, evaporators, or centrifuges</u>: -At pharmaceutical and cosmetic manufacturing plants that emit more than 10 lb/day, emissions vented to a control system with combined efficiency of	Each vent from reactors, distillation operations, crystallizers, centrifuges, and vacuum dryers that emit 15 lb/day or more of VOC must be vented to a surface condenser or equivalent controls. Emissions from air dryers and production	Uncontrolled HAP emissions from process vents shall be reduced by 93% by weight. If uncontrolled HAP from a process vent exceeds 25 tons per year, emission must be reduced by 98%. Actual HAP emissions from all process vents within a process shall not	Emission control device with 98% control or no more than 20 ppmv (24-hr average).

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
		centrifuges, rotary vacuum filters, or devices having exposed liquid surface collected by a hood or enclosure and exhausted to a carbon adsorber, or equivalent control method Dryers or production equipment exhaust systems that emit 330 lb/day or more of volatile organic compounds must reduce emissions by at least 90% by weight Dryers or production equipment exhaust systems that emit less than 330 lb/day of VOC must reduce the emissions to less than 33 lb/day Transfer of VOC having a vapor pressure greater than 4.0 psi at 20 °C, from any truck or rail car into any storage tank of a 2,000 gallons capacity or greater,	90%. As an alternative for equipment that emits more than 10 lb/day but not more than 15 lb/day, facility may use a surface condenser. -At any other organic chemical plant that emits more than 15 lb/day, emissions vented to a control system with combined efficiency of 85% and control efficiency of 90%. <u>Separation Operations:</u> -At pharmaceutical and cosmetic manufacturing plant, emissions collected and vented to a carbon adsorber or equivalent device. -At any other organic chemical plant, emissions vented to a control system with combined efficiency of at least 85% and control efficiency of at least 90%. <u>Dryer and production equipment exhaust system:</u>	equipment exhaust systems that: -Emit 330 lb/day or more of VOC, require to reduce emissions by 90%. -Emit less than 330 lb/day of VOC, require to reduce emissions to 33 lb/day. For storage tanks greater than 2,000 gallons, require emissions from transferring VOC materials to be reduced by 90% except where the tank is equipped with floating roofs, vapor recovery, or equivalent. For storage tanks, require pressure/vacuum conservation vents except where more effective air pollution control is used.	exceed 900 kg. Total HAP from all processes shall not exceed 1800 kg. For storage tank with capacity greater than 38 m^3 but less than 75 m^3, the owner shall equip the tank with a fixed roof with internal floating roof, or a closed-vent system with a control device that reduce inlet emissions of total HAP by 90% by weight or greater, reduces emissions to outlet concentration to less than 20 ppmv of TOC, is a combustion device or flare, or a control device. For storage tanks greater than 75 m3, the owner shall equip the tank with a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal roof, or a closed vent system with a control device that reduces emissions by 95%, reduces emissions to outlet concentration to less than 20 ppmv of TOC, is a combustion	

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
		must be reduced by 90% by weight. Install pressure/vacuum vents set at 0.03 psig on all storage tanks than store VOC with a vapor pressure greater than 1.5 psig at 20C, unless a more effective control system, approved by the APCO is used	-At pharmaceutical and cosmetic manufacturing plants, units that emit more than10 lb/day must be vented to a control system with a combined system efficiency of at least 90%. -At any other organic chemical plant, units that emit 330 lb/day or more must be vented to a control system with combined efficiency of 85% and control efficiency of 90%. Emissions of less 330 lb/day must reduce emissions to less than 33 lb/day. Process Tanks: Emissions more than 15 lb/day must be vented to control system with a combined system efficiency of at least 85% and 90% control. Liquid transfer; Various control options. Storage tanks: For tanks capacity greater than 55		device or flare, or a control device.	

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
			gallons and less than or equal to 40,000 gallon, required to install a pressure/vacuum valve <u>Wastewater:</u> Requirements specific to wastewater. Solvent cleaning: For in-line solvent cleaning, emissions are vented to emission control system or the VOC is limited to no more than 200 g/l For maintenance cleaning, the VOC is limited to 25 g/l			
Conclusion: The emission standards in Rule 464 are at least as stringent as the emission standards in Rule 455.						
Work Practice Requirements		In-process tanks for material containing VOC must use an apparatus or cover which prevents VOC evaporation. The cover shall be closed or in place on the tank at all times except while loading or unloading the tank. Repair all leaks from which a liquid can be observed to be running	Process tank containing material and storage tanks with capacity less than or equal to 55 gallons shall be covered except when accessing the container Leaks shall comply with Rule 443 Closed containers for the storage of disposal of cloth, paper, or sponges	Enclose all centrifuges, rotary vacuum filters, any other filters having an exposed liquid. In-process tanks shall have covers. Covers should be closed when possible. All liquid leaks observed to be running or dripping from vessels and equipment should be	Opening of safety device is allowed at any time to avoid unsafe conditions. Specifies leak detection and repair requirement, including appropriate timeline to repair detected leaks. See 40 CFR63. 1255.	Leak detection and repair program for fugitive VOC emissions.

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
		or dripping. The repair shall be completed the first time the equipment is off-line for a period of time long enough to complete repair	Store fresh or spent cleanup material in closed containers	repaired as soon as is practical.		
Conclusion: Operations subject to Rule 464 are also subject to Rule 443, Leaks from Synthetic Organic Chemical and Polymer Manufacturing. The requirements in Rule 443 specify time limits for repairing leaks. Therefore, the work practice requirements in Rule 464 are at least as stringent as the work practice requirements in Rule 455.						
Monitoring/ Records	Recordkeeping	None	For any control system, daily records required by the Operation and Maintenance Plan. Current list of organic compounds in use including the vapor pressure of each compound. For continuous process, daily records of the types and amounts of organic compounds used and produced by each organic chemical manufacturing process unit. For batch process, records of each production batch step Maintain annual		-Each measurement of a control device operating parameter of a treatment process parameter. -Records of consumption, production and the rolling average values of production-indexed HAP and VOC consumption factors. -For continuous monitoring system, records documenting calibration check and maintenance. -For annual mass limits, daily records of rolling annual total emissions. -Uncontrolled and controlled emissions from each process. -Number of batches per year -Number of storage tank turnovers per year	Determined by permit.

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
			wastewater reports Daily records for the exemption for small source, process vent, process tank, non-pharmaceutical and non-cosmetic separation operation, research and development operations, solvent cleaning operation regulated by the FDA. Monthly records of the total applied volume of material used for cleanup. Source test report kept on-site Records maintained on site for five years		-Records of equipment leak detection and repair programs. Additional recordkeeping requirements specified in 40 CFR 63.1259.	
	Frequency	None	Daily or monthly		Daily or annually.	Determined by permit.
Conclusion: There are no recordkeeping requirements in Rule 455. Therefore, Rule 464 is more stringent.						

Comparative Requirements						
Elements of Comparison	**Specific Provisions**	**Rule 455 (To be repealed)**	**Proposed Amendments to Rule 464**	**Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (CTG)**	**40 CFR Part 63, Subpart GGG – National Emission Standards for Hazardous Air Pollutants - Pharmaceuticals Production**	**Best Available Control Technology (BACT)/Lowest Achievable Emission Rate (LAER)**
Monitoring/ Testing	Test Methods	None	VOC emission rate or control efficiency with EPA Method 18, 25, or 25A, EPA Method 1 or 1A, EPA Method 2, 2A, 2B, or 2C, EPA Method 3 and EPA Method 4, whichever combination is most applicable Collection efficiency by EPA Method 204, 204A, 204B, 204C, 204D, 204E or 204F, or SCAMQD Protocol for determining VOC capture efficiency, or any method approved by EPA , CARB and the APCO. Vapor pressure by ASTM Method D2879-97 (2007) Leak detection measured using portable gas detector as prescribed in U.S. EPA Method 21.		Test methods and calculations specified for each process and device. See 40 CFR Part 63.1257.	Determined by permit.
	Frequency	None	As needed.			Determined by permit.
Conclusion: There are no test methods in Rule 455. Therefore, Rule 464 is more stringent.						

APPENDIX D

Incremental Cost-Effectiveness Calculations

As specified in California Health and Safety Code Section 40920.6(a)(3), the incremental cost-effectiveness (ICE) is calculated by the difference in the dollar costs divided by the difference in the emission reduction potentials between each progressively more stringent potential control option as compared to the next less expensive control option, and is expressed as:

$$ICE = \frac{AC_2 - AC_1}{ER_2 - ER_1}$$

where: *ICE* = Incremental cost-effectiveness ($/lb)
AC_1 = Annualized cost of the less stringent control ($/year)
AC_2 = Annualized cost of the more stringent control ($/year)
ER_1 = Emission reduction potential from the less stringent control (lb/year)
ER_2 = Emission reduction potential from the more stringent control (lb/year)

The emission reduction potential is the additional emission reduction achieved when a more stringent control option is implemented. It is calculated as the difference between the emission reduction achieved from a control option and the emission reduction from the current requirements in Rule 464. The current emission reduction is the difference between the uncontrolled VOC emissions and the current controlled VOC emissions. The current controlled VOC emissions of 3,202 pounds per year were calculated from the 2014 Emission Inventory Survey submitted by the facility[23]. Rule 464 requires emissions from all process equipment be vented to a VOC capture and control device with a combined system efficiency of 85% and a control efficiency of 90%. At the one pharmaceutical manufacturing facility that is subject to Rule 464, the emissions from the vents are conveyed to the control devices through sealed pipes, resulting in essentially 100% capture efficiency. As a result, the capture and control system that have a control device efficiency of at least 90% will also have a combined system efficiency of at least 90%. Assuming that the emissions from the facility are controlled by 90%, the uncontrolled VOC emissions were calculated to be 32,020 pounds per year. The current emission reduction is calculated to be 28,818 lb/year.

Uncontrolled VOC emissions = (Controlled VOC Emissions)/(1 – Control Efficiency)
= (3,202 lb/year)/(1-0.90)
= 32,020 lb/year

Current Emission Reduction = Uncontrolled VOC Emissions – Controlled VOC Emissions
= 32,020 lb/year – 3,202 lb/year
= 28,818 lb/year

This ICE analysis evaluated three control options, and each option is discussed below.

1. Proposed Option – The Proposed Option is to require emissions from all process vents greater than 10 pounds per day to be vented to a control system with a combined system efficiency of at least 90%. Although there are provisions that allow other

[23] 2014 Emission Inventory Survey submitted by AMPAC Fine Chemicals on May 13, 2015.

compliance options, for this analysis it is assumed that the emissions from the facility are controlled by 90%. The annualized cost and emission reduction for the Proposed Option are discussed below.

a. Annualized Cost: The one pharmaceutical manufacturing facility subject to this rule is already in compliance with the proposed amendments. Therefore, the annualized cost for this option is $0.
b. Emission Reduction Potential: The one facility subject to this rule is already in compliance with the proposed requirement. Therefore, the emission reduction potential for this option is 0 lb/day.

2. Option 1 – Option 1 is to increase the required control efficiency to be at least 95%. According to the CTG for pharmaceutical manufacturing operations, the emission control device that achieves this control efficiency is a carbon adsorption system[24]. The annualized cost and emission reduction for Option 1 are discussed below.

   a. Annualized Cost: The CTG for pharmaceutical manufacturing operations provided an annualized cost of a carbon adsorption system in 1978 dollars to be $31,000 per year[25]. The system cost was estimated assuming no cost credit from product recovery. The cost was adjusted to 2014 dollars using the consumer price index (CPI)[26]:

      Annualized Cost (2014 dollars) = Annualized Cost (1978 dollars) x (CPI for 2014/ CPI for 1978)
      = $31,000 per year x (236.736/65.2)
      = $112,559 per year

   b. Emission Reduction Potential: The emission reduction potential is calculated by the emission reduction achieved from this control option (multiplying the uncontrolled emissions by the control efficiency of 95%) minus the current emission reduction:

      Emission Reduction Potential = (Uncontrolled VOC Emissions x Control Efficiency) – Current Emission Reduction
      = (32,020 lb/year x 0.95) – 28,818 lb/year
      = 1,601 lb/year

3. Option 2 – Option 2 is to increase the required control efficiency to be at least 99%. According to the CTG for pharmaceutical manufacturing operations, a thermal incinerator has control efficiency between 90%-99%[27]. For this analysis, the control efficiency for a thermal incinerator is assumed to be at least 99%. The annualized cost and emission reduction for Option 2 are discussed below.

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[24] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978, Page 5-2.
[25] Ibid, Page 5-22.
[26] "CPI Detailed Report Data for July 2015," Bureau of Labor Statistics, July 2015, Page 71. The most recent year for which the annual average CPI is available is 2014.
[27] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978, Page 5-2.

a. Annualized Cost: The CTG for pharmaceutical manufacturing operations provided an annualized cost of a thermal incinerator in 1978 dollars to be $28,000 per year[28]. The cost was adjusted to 2014 dollars using the CPI:
Annualized Cost (2014 dollars) = Annualized Cost (1978 dollars) x (CPI for 2014/ CPI for 1978)
= $28,000 per year x (236.736/65.2)
= $101,666 per year

b. Emission Reduction Potential: The emission reduction potential is calculated the emission reduction achieved from this control option (multiplying the uncontrolled emissions by the control efficiency of 99%) minus the current emission reduction:

Emission Reduction Potential = (Uncontrolled VOC Emissions x Control Efficiency) – Current Emission Reduction
= (32,020 lb/year x 0.99) – 28,818 lb/year
= 2,882 lb/year

The following table summarizes the emission reduction potential and annualized cost for each control option.

Control Option	Control Efficiency	Emission Reduction Potential (lb/year)	Annualized Cost in 2014 dollars ($/year)
Proposed Option	90%	0	$0
Option 1	95%	1,601	$112,559
Option 2	99%	2,882	$101,666

The table below shows the results of the ICE calculations. The ICE for Option 1 compared to the Proposed Option is $70.31. The ICE for Option 2 compared to Option 1 is -$8.50; the negative value indicates that Option 2 achieved more emission reduction than Option 1 at a lower cost. The ICE for Option 2 compared to the Proposed Option is $35.28.

More Stringent Option	Less Stringent Option	Difference in Annualized Cost*	Difference in Emission Reduction Potentials (lb/year)**	Incremental Cost-Effectiveness***
Option 1	Proposed Option	$112,559	1,601	$70.31
Option 2	Option 1	-$10,893	1,281	-$8.50
Option 2	Proposed Option	$101,666	2,882	$35.28

*Annualized cost of the more stringent option minus annualized cost of the less stringent option ($AC_2 - AC_1$)
**Emission reduction potential from the more stringent option minus emission reduction potential from the less stringent option ($ER_2 - ER_1$)
***Difference in annualized cost divided by difference in emission reduction potentials ($AC_2 - AC_1$)/ ($ER_2 - ER_1$)

[28] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978, Page 5-25. Assume lowest flow rate to be most conservative.

APPENDIX E
Comments and Responses

Public Workshop for Rules 455 and 464
March 16, 2016, 1:30 PM

Attendees: Ella Iott, AMPAC Fine Chemicals
John Levitt, AMPAC Fine Chemicals
Tim Kelly, AMPAC Fine Chemicals

Oral Questions from the Public Workshop

Question #1: How many facilities are affected by Rule 464?

Response: Two facilities are subject to Rule 464: AMPAC Fine Chemicals and Proctor and Gamble. AMPAC Fine Chemicals is the only facility affected by the amendments.

Question #2: Why was the rule cited by EPA and why now?

Response: In 2015, EPA re-evaluated the rule as part of its review of the District's 2006 Reasonably Available Control Technology demonstration (known as the RACT SIP[29]), a demonstration required by the Clean Air Act. EPA concluded that Rule 455 does not meet the requirements of Clean Air Act section 110(a)(2) because it lacks test methods, recordkeeping, and monitoring requirements that are necessary to ensure that the rule is enforceable[30]. In January 2016, EPA formalized that decision in a partial approval and partial disapproval of the 2006 RACT SIP[31]. To meet RACT, we are proposing to consolidate all requirements for pharmaceuticals manufacturing into Rule 464 and adopt requirements that are at least as stringent as the RACT recommendations in the CTG. We are also proposing to repeal Rule 455.

Question #3: Is Rule 464 updated online?

Response: The current version of Rule 464 on our website is the rule in effect until the proposed amendments are adopted by the Board of Directors. If the proposed amendments to Rule 464 are adopted, we will update the rule on the website with the most up-to-date version of the rule.

Question #4: Is it your impression that AMPAC is in compliance with the proposed rule?

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[29] "Analysis of Reasonably Available Control Technology for the 8-Hour Ozone State Implementation Plan (RACT SIP)," Sacramento Metropolitan Air Quality Management District, September 26, 2006.
[30] "Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan – EPA's Evaluation of Sacramento Metropolitan Air Quality Management District, Ozone State Implementation Plan Revision Reasonably Available Control Technology as Applicable to the 8-hour Ozone Standard - Adopted 26, 2006 ("2006 RACT SIP TSD")." November 2015.
[31] "Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Proposed Rule." 81 Federal Register (January 15, 2016), pp. 2136 – 2140.

Response: We reviewed the permits, inspection reports, and emission summaries that AMPAC provided. Based on that review, we concluded that the facility already complies with the proposed amendments.

Question #5: Are you familiar with the simulation program?

Response: Emission Master is simulation software that calculates emissions from unit operations in chemical processes. Although we have not run the model, we are familiar with its capabilities and the emissions summaries it generates. AMPAC provides Emission Master output with their permit applications.

Question #6: AMPAC is planning to add new processes that will add more equipment. What would this involve?

Response: An application for an Authority to Construct would be required. For a new process, it would be subject to Rule 202 – New Source Review, which includes a requirement to meet Best Available Control Technology. At a minimum, AMPAC would be required to meet the requirements in Rule 464.

Written Comments from EPA (March 7, 2016)

Comment #1: Section 303.1a, Dryers or Production Equipment Exhaust Systems at Pharmaceutical and Cosmetic Manufacturing Plants, provides for a VOC capture and control system that has a combined system efficiency of at least 85% by weight, and a control efficiency of at least 90% by weight, to be used prior to 18 months after date of adoption. Section 303.1c requires a combined efficiency of 90% effective 18 months after date of adoption. The previous SIP-approved Rule 455, Pharmaceuticals Manufacturing (50 FR 3338, 1/24/85), Section 310.1, requires the reduction of the emission of organic materials by at least 90% by weight. To avoid a rule relaxation, and to be consistent with other air district RACT rules (e.g., SCAQMD Rule 1103(d)(1)), we recommend removing the 18 month allowance and instead requiring 90% combined capture and control system efficiency to be effective immediately.

Response: Staff has changed the proposed language in Section 303.1a so that the requirement to achieve a combined capture and control efficiency of at least 90% will be effective upon adoption.

Comment #2: Section 306.2a, Liquid Transfer, provides for a VOC capture and control system that has a combined system efficiency of at least 85% by weight, to be used prior to 18 months after date of adoption. Section 306.2b requires a combined efficiency of 90% effective 18 months after date of adoption. The SIP-approved Rule 455, Section 310.3, requires that VOC emissions during transfer be reduced by 90% by weight. To avoid a rule relaxation, and to be consistent with other air district RACT rules (e.g. SCAQMD Rule 1103(d)(3)), we recommend removing the 18 month allowance and instead requiring 90% combined capture and control system efficiency to be effective immediately.

Response: Staff has changed the proposed language in Section 306.2 so that the requirement to achieve a combined capture and control efficiency of at least 90% will be effective upon adoption.