

Response to Comments

Joint Outfall System (JOS)
Pomona Water Reclamation Plant
Tentative Amended NPDES Permit

This Table describes all significant comments received from interested persons with regard to the above-mentioned tentative permit. Each comment has a corresponding response and action taken.

Commenter	#	Comment	Response	Action Taken
Comments received from JOS (formerly County Sanitation District of Los Angeles County) on June 8, 2015				
Joint Outfall System (JOS)	C-1	The Sanitation Districts incorporate by reference all previous written comments associated with the Pomona and Whittier Narrows WRP tentative NPDES permits submitted by the Sanitation Districts to the California Regional Water Quality Control Board, Los Angeles Region (Regional Board) (i.e., those dated October 10, 2014); the Sanitation Districts' testimony provided at the Pomona and Whittier Narrows WRP NPDES permit adoption hearing on November 6, 2014; and the written comments contained in the petition for review filed with the State Water Resources Control Board (State Water Board) on December 8, 2014 by the Sanitation Districts, the California Association of Sanitation Agencies (CASA), Southern California Alliance of POTWs (SCAP), and the Bay Area Clean Water Agencies (BACWA) related to the adopted Pomona and Whittier Narrows WRP NPDES permits.)	<p>Comment noted, however, the instructions in the letter transmitting the Tentative Amendment Order clearly informed the public that "the Board will accept comments only with respect to the proposed changes to the tentative amended requirements in underline and strikeout format." In addition, Finding D of the Fact Sheet on page F-4 explains the reason for the permit amendment, as follows:</p> <p>"On May 8, 2014, the Regional Water Board adopted Order No. R4-2014-0212 for the Pomona WRP, which included chronic toxicity requirements using a two-concentration test design, based upon USEPA's Alternative Test Procedure (ATP) approval letter dated March 17, 2014. However, on February 11, 2015, USEPA withdrew its ATP approval. On April 9, 2015, the Regional Water Board adopted NPDES permits for the Joint Outfall System San Jose Creek WRP and other POTWs with revised chronic toxicity requirements consistent with the USEPA ATP withdrawal letter. Order R4-2014-0212 is being amended to update the chronic toxicity requirements, consistent with those included in the San Jose Creek WRP permit, and to correct other reporting requirements. All other permit requirements will remain unchanged and in effect." (Refer to Attachment C)</p> <p>As such, only those comments pertaining to language that appears in underline and strikeout format will be accepted in the context of this narrow NPDES permit amendment.</p>	Corrected typographic error w/r/t the date of adoption..

Commenter	#	Comment	Response	Action Taken
			However, the typographical error with respect to the date of adoption mentioned in Finding D of the Fact Sheet was corrected to "November 6, 2014." Subsequently, a revised tentative Order was emailed to interested persons on June 11, 2015 transmitting the correction.	
JOS	C-2	<p>Furthermore, the Tentative Amendments incorporate additional elements that were not originally incorporated into the tentative or adopted Pomona and Whittier Narrows WRP NPDES permits, but were included in, <i>inter alia</i>, the tentative or adopted San Jose Creek, Long Beach, and Los Coyotes WRP NPDES permits.</p> <p>Therefore, the Sanitation Districts also incorporate by reference all written comments associated with the San Jose Creek, Long Beach, and Los Coyotes WRP tentative NPDES permits, including, but not limited to, the written comments submitted by the Sanitation Districts to the Regional Board in letters dated January 16, 2015 (San Jose Creek WRP tentative NPDES permit) and May 4, 2015 (Long Beach and Los Coyotes WRP tentative NPDES permits); the Sanitation Districts' testimony provided at the San Jose Creek WRP permit adoption hearings held on March 12, 2015 and April 9, 2015; and the written comments submitted by the Sanitation Districts, CASA, SCAP, and the National Association of Clean Water Agencies (NACW A) in the petition for review submitted to the State Water Board on May 11, 2015 related to the San Jose Creek WRP adopted NPDES permit</p>	Please see response to Comment C-1.	None necessary.
JOS	C-3	In particular, the Sanitation Districts would like to highlight several issues related specifically to the Tentative Amendments, which were not submitted as part of our comments, testimony, and appeal of the Whittier Narrows and Pomona WRP NPDES permits, but were included in our comments and testimony associated with the San Jose Creek, Long Beach, and Los Coyotes WRP NPDES permits, as follows:	It is USEPA's position that applying EPA's 2000 concentration-response pattern review guidance and/or inapplicable NOEC/LOEC variability criteria (i.e., PMSDs) to the TST – an unrelated statistical approach – prior to reporting compliance will undercut the transparency of the reported toxicity result, shroud a potentially non-compliant result prior to reporting, and diminish the reliability and enforceability of the permit and its toxicity limits.	None necessary.

Commenter	#	Comment	Response	Action Taken
		<p>The Tentative Amendments prohibit the Permittee from conducting concentration-response relationship evaluations as mandated by the promulgated method. (See USEPA, <i>Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms</i>, Fourth Ed., Oct. 2002 (2002 Methods), incorporated by reference into 40 C.P.R. § 136.3(a), Table IA, footnote 27; see also 67 Fed. Reg. 69955, 2002, ("these methods, including the modifications in today's rule, are applicable for use in NPDES permits.")).</p>	<p>USEPA's Method Guidance addressing concentration-response evaluations, states that an "evaluation of the concentration-response relationship generated for each sample is an important part of the data review process that should not be overlooked." This guidance was promulgated in 2002, well before development of the TST statistical approach. The guidance assumes that either NOEC-LOEC hypothesis testing or a point estimation analysis will be used to evaluate multi-concentration WET test data. In that circumstance, evaluation of the concentration-response relationship is important to determine whether the assumptions underlying these statistical approaches are reflected in the data. As previously discussed, these same assumptions are not relied upon by the TST statistical approach. A WET test is validated by reviewing the test acceptability criteria and quality assurance/quality control (QA/QC) measures, such as:</p> <ul style="list-style-type: none"> • Performing and evaluating reference toxicant tests. • Evaluating various test condition components, such as water quality measurements (temperature, pH, DO, light intensity, etc.) to ensure that they are within the typically accepted range. • Examining effluent sampling and handling. • Plotting control charts to track the lab's control performance and reference toxicant performance over time. 	
	C-4	<p>The Tentative Amendments limit the full application of available, scientifically defensible, concentration-response evaluation tools thereby reducing the reliability of the whole effluent toxicity tests. (See 2002 Methods at Sections 8.1 0.1, 1 0.2.6.2, and Tables 1, 3 and 4 (labeled as 3) on pages 76, 165, and 211.)</p>	<p>Please see response to comment C-3.</p> <p>The Order is consistent with the letter dated February 11, 2015, from USEPA to the State Water Board withdrawing approval of the alternate test procedure using a two-concentration test design. The Order requires the test methods described in <i>Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms</i> (October 2002) (EPA-821-R-02-013), including a multi-concentration test design, when required, and review of the concentration-response pattern.</p> <p>The State permitting authority, here, the Regional Water Board, has the discretion to select the statistical approach for analyzing WET test data that is most appropriate for use in a particular permit. (See Section 9.4.1.2 of <i>Short-term Methods</i>, October</p>	None necessary.

Commenter	#	Comment	Response	Action Taken
			<p>2002, EPA-821-R-02-013 (“[T]he statistical methods recommended in the manual are not the only possible methods of statistical analysis.”)) The Regional Water Board has selected the TST statistical approach for use in this Order.</p> <p>The Method Guidance and Recommendations for Whole Effluent Toxicity (WET) Testing (40 CFR part 136), July 2000, identifies common patterns of WET test data and provides guidance on using the concentration-response relationship to review WET test results. Some of these response patterns were identified as requiring further review if a toxic result is obtained depending on the statistical approach used. Since the statistical approach is based on assumptions concerning the data set, if the concentration response pattern of the data set does not comply with those assumptions, then the calculated NOEC/LOEC endpoints may not be valid. But these anomalous results would not occur with the TST statistical approach because the results of the instream waste concentration are compared directly to the control, and do not rely upon the same statistical assumptions as the NOEC-LOEC hypothesis testing and point estimation approaches. The TST statistical approach will produce reliable results in these circumstances.</p> <p>The remaining concentration-response patterns identified in the guidance as warranting further review suggested evaluation of factors such as test acceptance criteria, test conditions, and reference toxicant testing. These factors can and should be evaluated and are accounted for in the draft permit. Evaluation of these factors and application of the TST approach, which accounts for the inherent variability in WET test data, will produce reliable test outcomes for purposes of permit compliance.</p> <p>USEPA’s Variability Study referenced by the commenter appropriately applied the concentration-response relationship guidance to data analyzed with the NOEC-LOEC hypothesis testing and point estimation approaches to reduce the false positive error rate. Consideration of the concentration-response relationship is not necessary when analyzing WET test data using the TST approach, and would not be expected to reduce the error rate. Instead, evaluation of test acceptance criteria, test conditions, and reference toxicant testing are appropriate to</p>	

Commenter	#	Comment	Response	Action Taken
			<p>identify anomalous data prior to analysis using the TST approach.</p> <p>The TST statistical approach for use in the statistical analysis of WET test data has undergone an extensive external peer review process by both the USEPA and the State Water Board. The approach was published in <i>Environmental Toxicology and Chemistry</i> (Denton et al. 2011). Data from over 2,000 WET tests were used to develop and evaluate the TST approach. The TST was tested for nine different WET test methods with 12 biological endpoints (e.g., reproduction, growth, survival) representing most, if not all of the different types of WET test designs currently in use. Over one million computer simulations were also used to select error rates meeting EPA's RMDs (Regulatory Management Decisions) for the TST approach.</p> <p>The TST statistical approach has been shown to perform as well or better than the NOEC-LOEC statistical analysis of multi-concentration data. The results of TST statistical analysis was compared to analysis using the NOEC-LOEC approach in a "Test Drive Analysis" conducted in California. The results of the test drive are provided in a report dated December, 2011 and published in <i>Environmental Toxicology and Chemistry</i> (Diamond et al. 2013) The findings of the peer-reviewed journal article by Diamond et al, 2013, found that the TST statistical analysis improves understanding of the discharge condition by correctly identifying toxic and non-toxic samples more often than when using the NOEC-LOEC statistical approach.</p>	
JOS	C-5	The Tentative Amendments specifically disallow application of the method-required Percent Minimum Significant Difference (PMSD) criteria. (See 2002 Methods at Section 1 0.2.8.2.)	<p>USEPA's position is that applying its 2000 concentration-response pattern review guidance and/or inapplicable NOEC/LOEC variability criteria (i.e., PMSDs) to the TST – an unrelated statistical approach – prior to reporting compliance will undercut the transparency of the reported toxicity result, shroud a potentially non-compliant result prior to reporting, and diminish the reliability and enforceability of the permit and its toxicity limits. Page F-51 of the Fact Sheet references audit correspondence from the State Water Board and USEPA.</p> <p>The preamble to the WET Test Method (Federal Register/ Vol. 67, No. 223, p. 69952 (November 19, 2002)) provides valuable insight into what USEPA intended when it was updating its WET</p>	None necessary.

Commenter	#	Comment	Response	Action Taken
			<p>Test Method. From the underlined language below, it is clear that the PMSD was only intended for permits that had limits in terms of NOEC or LOEC.</p> <p>“Variability Criteria</p> <p>Today’s action incorporates mandatory variability criteria for five chronic test methods. USEPA recommends the use of point estimation techniques over hypothesis testing approaches for calculating endpoints for effluent toxicity tests under the NPDES Permitting Program. <u>However, to reduce the within-test variability and to increase statistical sensitivity when test endpoints are expressed using hypothesis testing rather than the preferred point estimation techniques, variability criteria must be applied as a test review step when NPDES permits require sublethal hypothesis testing endpoints (i.e., no observed effect concentration (NOEC) or lowest observed effect concentration (LOEC) and the effluent has been determined to have no toxicity at the permitted receiving water concentration.</u> These variability criteria must be applied for the following methods: Fathead minnow Larval Survival and Growth Test: Selenastrum capricornutum Growth Test: Mysidopsis bahia Survival, Growth and Fecundity Test: and Inland Silverslide Larval Survival and Growth Test. <u>Within test variability, measured as the percent minimum significant difference (PMSD), must be calculated and compared to upper bounds established for test PMSDs...</u>” (p. 69957)</p> <p>It is reasonable and appropriate for the Regional Board to conclude that the PMSD tool for evaluating test variability is not applicable to this permit because it does not include chronic toxicity limits expressed as TUc or NOEC.</p> <p>While section 10.2.8.2 of the WET Test Method specifies that “When NPDES permits require sublethal hypothesis testing endpoints from Methods 1000.0, 1002.0, or 1003.0 (e.g., growth or reproduction NOECs and LOECs), within-test variability must be reviewed and variability criteria must be applied as described in this section (10.2.8.2)” (emphasis added), the WET Test Method section does not require the use of the PMSD.</p>	

Commenter	#	Comment	Response	Action Taken
			<p>Subsection 10.2.8.2.1 describes how to calculate the PMSD and subsequent subsections describe how to compare the PMSD to see if the PMSD falls within an acceptable range; i.e. if PMSD is within the upper and lower bounds.</p> <p>Subsection 10.2.8.3 states:</p> <p>“To assist in reviewing within-test variability, EPA recommends maintaining control charts of PMSDs calculated for successive effluent tests (USEPA, 2000b). A control chart of PMSD values characterizes the range of variability observed within a given laboratory, and allows comparison of individual test PMSDs with the laboratory’s typical range of variability. Control charts of other variability and test performance measures, such as the MSD, standard deviation or CV of control responses, or average control response, also may be useful for reviewing tests and minimizing variability. The log of PMSD will provide an approximately normal variate useful for control charting.” (emphasis added)</p> <p>USEPA recommends use of PMSD when the hypothesis test has endpoints expressed in terms of growth or reproduction NOECs and LOECs. However, the Pomona WRP permit does not have endpoints expressed as NOEC/LOEC, but in terms of Pass or Fail and Percent Effect. In addition, under this permit, within-test variability of the WET test data utilized for the TST statistics will be reviewed and variability criteria will be applied by using control charts and coefficient of variation, as allowed by Subsection 10.2.8.3 of the WET Test Method.</p> <p>Therefore, the permit disallows the PMSD approach to evaluate variability of the WET test data because that approach is applicable to the NOEC/LOEC statistical analysis and not the TST statistics required by the permit.</p>	
	C-6	To address these concerns, as well as concerns previously transmitted in testimony and written comment letters, the Sanitation Districts request that the toxicity provisions in the Tentative Amendments be modified as requested in the December 8, 2014 and May 11, 2015 petitions for review.	<p>Please see response to Comment C-1.</p> <p>Consistent with the public notice that was distributed for this item, the issue about whether the chronic toxicity final effluent limit should be numeric or a trigger, and other issues raised in the petition, will not be considered at the July 9, 2015 Board hearing,</p>	None necessary

Commenter	#	Comment	Response	Action Taken
			<p>since that is outside of the scope of the proposed NPDES permit amendment.</p> <p>Moreover, these issues were addressed on October 30, 2014 in response to JOS's comment letter dated October 10, 2014, in the Response to Comments Table prepared by Water Board staff and included in the Board agenda package for the adoption of NPDES Order No. R4-2014-0212 for the Pomona WRP.</p>	
Comments received from Heal the Bay June 8, 2015				
Heal the Bay	1	Numeric Chronic Toxicity Effluent Limits Must be Included	Thank you for your comment in support of this permit.	None necessary.
	2	Additional Self-Monitoring Report Requirements Will Help the Regional Board Track and Assess Permittees Chronic Toxicity Testing	Thank you for your comment in support of the reporting requirements.	None necessary.
	3	<p>Regional Board Should Approach Issuance of Time Schedule Orders for Chronic Toxicity Exceedances Cautiously</p> <p>The Tentative Amendments would allow Permittees to submit a request for a time schedule order upon an exceedance of an effluent limitation for chronic toxicity. Although the Regional Board has included assessment criteria when determining if a time schedule order is appropriate (e.g. facility compliance with effluent limitations for chronic toxicity, magnitude and duration of exceedance, history of past TIE/TRE processes, efforts of Permittee to achieve compliance with effluent limitations for chronic toxicity), these criteria are extremely broad and lack clear guidance. The Tentative Amendments do not include information or guidance for determining the duration of time schedule orders. In addition, the Tentative Amendments do not address how chronic toxicity effluent limit exceedances occurring during time schedule orders, separate from the initial event, will be enforced; if these exceedances are included in time schedule orders, their inclusion would contradict</p>	<p>During the March 2015 Board meeting there was much discussion over a change sheet that offered language, proposed by the Discharger for the San Jose Creek WRP, that would have suspended enforcement action by the Board for chronic toxicity exceedances. The Board did not accept this proposal but instead directed staff to work with the Permittee and USEPA to consider alternative language and return to the Board in April 2015. The following language was considered by the Board during the April 2015 hearing and adopted into the San Jose Creek WRP NPDES permit. The same language is being incorporated into the NPDES permit for the Pomona WRP facility, on page F-48 of the Fact Sheet, for consistency:</p> <p>The Permittee may submit a request for a time schedule order upon an exceedance of the effluent limitations for chronic toxicity in this Order. In determining whether a time schedule order is appropriate, and the conditions and duration of such an order, the Regional Water Board or Executive Officer will consider the following factors among other relevant considerations: the facility's history of compliance with effluent limitations for chronic toxicity, including the magnitude and duration of any</p>	None necessary.

Commenter	#	Comment	Response	Action Taken
		<p>previous Regional Board positions on chronic toxicity exceedance enforcement during TIE/TRE processes. The Regional Board has the discretion to enforce effluent limitation exceedances – it is unclear why the issuance of chronic toxicity time schedule orders are being considered at this time. We believe this is a slippery slope. Further, issuance of time schedule orders are resource intensive for Regional Board staff, time that may be better suited for other programs and projects. Because of these reasons, we believe the Regional Board should approach issuing time schedule orders for chronic toxicity effluent limitation exceedances cautiously as the criteria and requirements for crafting these enforcement actions are not clearly identified by the Regional Board at this time.</p>	<p>exceedances; history of and information acquired from past TIEs or TREs conducted for the facility; and the efforts of the Permittee to achieve compliance with effluent limitations for chronic toxicity.</p> <p>In addition to submitting a request for a TSO, the Permittee will need to provide adequate justification before the Executive Officer or the Regional Water Board would issue the TSO. Information submitted may include, but is not limited to, a proposed schedule with tasks for achieving compliance and milestone dates for completing such tasks. The duration of the TSO should be as short as practicable. However, if information is lacking, then the TSO would not be issued.</p>	
Comments received from United States Environmental Protection Agency (USEPA) on June 4, 2015				
USEPA	1	<p>USEPA strongly support adoption of the chronic toxicity requirements in this permit.</p> <p>USEPA is pleased that the draft permits plainly require effluent limits on chronic whole effluent toxicity (WET), where there is reasonable potential.</p> <p>USEPA agrees with the Regional Water Board's decision to use numeric chronic WET WQBELs for these POTW permits, which are feasible to calculate for the discharges.</p> <p>USEPA supports the inclusion of both monthly and daily WQBELs for chronic toxicity, as the Regional Water Board has determined that such limits are necessary to protect against highly toxic short-term peaks of acute or chronic toxicity that exceed the applicable toxicity water quality standard.</p> <p>USEPA commented that the draft permits are consistent with the nine POTW permits this Board has</p>	Thank you for your comment in support of this permit.	None necessary.

Commenter	#	Comment	Response	Action Taken
		<p>adopted over the past 12 months, which express both monthly and daily chronic toxicity WQBELs numerically.</p> <p>USEPA commented that it is critical that permitting authorities explicitly choose and identify the statistical approach that will be used to protect their narrative toxicity water quality standard and interpret toxicity test results required by NPDES permits. The Los Angeles Regional Water Board has chosen to measure chronic toxicity for compliance reporting with the Test of Significant Toxicity (TST) bioequivalence statistical t-Test approach used to determine if two sets of observations - made for the effluent's instream concentration (IWC) and the control concentration - are different. The proposed modifications ensure that the subject permits, reissued over the past year, contain standardized transparent, clearly expressed, enforceable requirements for chronic WET.</p> <p>It is with that strong context that USEPA strongly supports the permit language updating Order section VII.J and associated fact sheet language, to result in consistency across all non-ocean POTW permits with chronic toxicity WQBELs expressed in terms of the TST. This provision specifies compliance evaluation and reporting requirements for chronic toxicity data expressed in terms of the TST and assures compliance with the multi-concentration test design requirement for NPDES effluents found in EPA's 2002 toxicity test methods. Also, it assures that - following EPA's 2002 toxicity test methods - the concentration-response pattern will be reviewed, as appropriate. On this point, USEPA notes that the National Organization of Clean Water Agencies (NACWA) has previously submitted comments critical of some of the POTW permits the Regional Water Board has recently issued. Bearing this in mind, we wish to draw your attention to a January 2006 white paper by NACWA, page 10, which states: "The [toxicity]</p>		

Commenter	#	Comment	Response	Action Taken
		<p>methods do not specifically state that a permittee may invalidate a [toxicity] test purely on the basis of the concentration-response relationship. However, NACWA believes that, in context of a full Data Quality Objectives program, the testing laboratory and the clean water agency should consider a test invalid if an adequate relationship is not present.” This position places NACWA and its member agencies holding this position squarely at odds with EPA’s 2002 toxicity test methods rule and preamble regarding the proper role of concentration-response pattern reviews. After statistical analysis of the biological data, concentration-response pattern review specified by EPA plays a role limited to specific instructions for determining that particular endpoints - NOECs, LC50s, and IC25s - are interpreted appropriately.</p> <p>It remains EPA’s position that the determination of toxicity is not based on achieving a specified concentration-response pattern. As a result, we concur with the proposed modifications to permit fact sheets, which correctly state that the appropriate interpretation of effluent (or receiving water) sample measurement results from the TST statistical approach is, by design, independent from the concentration-response patterns of the toxicity tests for those samples. When using the TST, we agree that the application of EPA’s 2000 concentration-response pattern review guidance will not improve the appropriate interpretation of a TST result, as long as your permits require use of EPA’s toxicity test methods by which good QA/QC is demonstrated through ongoing evaluation and tracking of reference toxicant testing and measures (i.e., mean, standard deviation, and coefficient of variation) of control concentration performance.</p> <p>Also, EPA commented that provision VII.J takes good steps to effectively address our concern that a laboratory’s Standard Operating Procedures for</p>		

Commenter	#	Comment	Response	Action Taken
		<p>chronic toxicity test data analysis and review can be used to improperly disqualify a test result. It is EPA's position that applying EPA's 2000 concentration-response pattern review guidance and/or inapplicable NOEC/LOEC variability criteria (i.e., PMSDs) to the TST – an unrelated statistical approach – prior to reporting compliance will undercut the transparency of the reported toxicity result, shroud potentially non-compliance result prior to reporting, and diminish the reliability and enforceability of the permit and its toxicity limits. The three POTW permits adopted in April 2015 took a large step toward addressing EPA's ongoing observation that providing too much WET method flexibility on specific procedures has been a way for some NPDES permit holders to improperly disqualify test results. EPA supports the inclusion of the proposed generic permit condition and fact sheet language that takes steps to ensure such practices will not be used for the proposed modified permits.</p>		

Attachment A

USEPA Washington D.C. Memo dated June 18, 2010

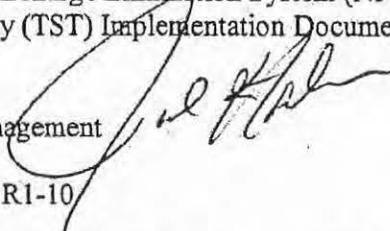


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 18 2010

OFFICE OF
WATER

SUBJECT: Final National Pollutant Discharge Elimination System (NPDES)
Test of Significant Toxicity (TST) Implementation Document

FROM: James Hanlon, Director
Office of Wastewater Management 

TO: Water Division Directors, R1-10

The purpose of this memorandum is to transmit to you a copy of the final guidance document, "National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document" (EPA 833-R-10-003). This document provides an additional recommended statistical approach for analyzing WET test data used for whole effluent toxicity (WET) reasonable potential determinations and NPDES permit compliance.

EPA developed the TST approach to provide an additional scientifically valid, statistical application for assessing WET hypothesis test data. The TST assesses the measurement of toxic impacts from effluent on specific test organisms' ability to survive, grow, and reproduce and is based on research and peer-reviewed publications. The TST examines whether there is a biologically significant difference defined as the measured difference which has a detrimental effect on aquatic organisms to thrive and survive when compared against the normal condition (i.e., a control). Using a WET test, this biologically significant difference is the comparison between an effluent's in-stream waste concentration (IWC), as specified in the permit, and the control. The TST recommendations advance the applied science of the NPDES WET Program by addressing both the false negative and false positive error rates which have been a concern for both permitting authorities and permittees. We believe the TST approach addresses these false negative and positive concerns and provides an incentive to NPDES permittees to provide valid, high quality WET test data to enhance NPDES WET reasonable potential and permit compliance determinations.

The TST document was externally peer reviewed according to EPA's requirements and after addressing the peer review comments the document was sent out to EPA Regions and States for their review. Comments received from EPA Regions and States were addressed and, where appropriate, revisions were incorporated into the final document.

The TST approach does not preclude the use of existing recommendations for assessing WET data provided in EPA's 1991 Water Quality-based Technical Support Document (TSD) which remain valid for use by EPA Regions and the States.

To compliment your understanding of the attached final TST document, we have scheduled a second webcast on Wednesday, July 14, 2010, from 1:00 to 2:00 P.M. (EST). This webcast will provide an introduction to TST, including an overview of its scope and context; how the TST should be implemented; advantages of the TST over other statistical approaches; and conceptual examples demonstrating the TST application. Please watch for an E-mail with additional details about how to participate in the webcast. If you have questions, please contact Laura Phillips (phillips.laura@epa.gov, 202-564-0741) of my staff.

Attachment (1)

Cc: Mark Pollins, WED/OCE/OECA
Debra Denton, R9
Regional Branch Chiefs, R1-10
EPA WET Coordinators, R1-10

Attachment B

**State Water Resources Control Board Letter
on 40 CFR 136 WET Method
dated May 14, 2015**



EDMUND G. BROWN JR.
GOVERNOR



MATTHEW RODRIGUEZ
SECRETARY FOR
ENVIRONMENTAL PROTECTION

State Water Resources Control Board

May 14, 2015

Water Docket, Environmental Protection Agency
Attention: Docket ID # EPA-HQ-OW-2014-0797
Mail code: 4203M, 1200 Pennsylvania Ave. NW.
Washington, DC 20460

State Water Resources Control Board (State Water Board) staff would like to thank the United States Environmental Protection Agency (U.S. EPA) for the opportunity to comment on the "Clean Water Act Methods Update Rule for the Analysis of Effluent." This letter will focus exclusively on the proposed revisions to *Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, Fifth Edition, Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, Fourth Edition*, and *Methods for Measuring the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms, Third Edition* (collectively: toxicity method manuals).

State Water Board staff supports the clarifying edits and updates proposed for the toxicity method manuals. In addition, State Water Board staff is requesting a revision to the five-concentration minimum required for all toxicity test methods in order to comport with the U.S. EPA's newest statistical approach, the Test of Significant Toxicity (TST), as it statistically compares only the instream waste concentration and a control.

The benefits of the TST approach have been lauded by numerous academicians. The five peer reviewers selected in a blind fashion for U.S. EPA's peer review process agreed that the TST's bioequivalence approach is sound, and that the results of TST analyses are reasonable and defensible. The State Water Board also initiated a peer review focusing on the use of the TST approach in the draft *Policy for Toxicity Assessment and Control*. The two researchers, Dr. Gerald A. Le Blanc and Dr. Michael C. Newman, concluded that the TST is a "...major advance from the currently compromised No Observed Effects Concentration (NOEC) approach," and "...is statistically sound, reduces burden associated with the assays, and, by structuring the assay around a hypothesis of significant toxicity, provides incentive for precision in assay performance." In addition, four individual articles examining the TST approach have been published in two respected, peer-reviewed toxicological journals (Denton et al. 2011, Diamond et al. 2011, Zheng et al. 2012, Diamond et al. 2013), while the State Water Board published a report comparatively analyzing the results of over 3,000 toxicity tests using both the TST and "traditional" hypothesis approaches (State Water Board, 2011). Although this "Test Drive" analysis showed that the results of the NOEC and TST are generally the same, it is important to note that the TST correctly identified truly non-toxic samples more often than the NOEC did. Moreover, the NOEC failed to identify more truly toxic samples than the TST approach.

ELLICIA MARCUS, CHAIR | THOMAS HOWARD, EXECUTIVE DIRECTOR

The TST approach is currently being used to implement Tribal and Territory NPDES permits issued by U.S. EPA Region 9, as well as the U.S. EPA Region 9 offshore oil and gas general permit (No. CAG280000). The State Water Board has included provisions requiring the use of the TST approach in the Caltrans general permit for storm water discharges (Order No. 2012-0011-DWQ), the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064), the San Diego Regional Water Quality Control Board's general permit for discharges from boatyards and boat maintenance and repair facilities (Order No. R9-2013-0026), and the NPDES permit issued to the US Department of the Navy's San Diego Naval base (Order No. R9-2013-0064). The TST approach has also been incorporated into several NPDES permits in Hawaii.

It is worth noting that the toxicity method manuals clearly state that the statistical approaches featured therein are merely recommendations. As such, requiring the use of five concentrations for TST analyses is inherently contradictory. Therefore, State Water Board staff is suggesting the addition of the following language (in red) to the "Test Concentration" requirement in the toxicity method manuals' "Summary of Test Conditions" tables:

Effluents:	5 and a control (required minimum for LOEC and NOEC endpoints, and point estimates) 1 and a control (required minimum for TST)
Receiving Water:	100% receiving water (or minimum of 5) and a control (recommended)

In addition to the inclusion of the *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document* in the "Cited References" section, State Water Board staff believes it would also be helpful to update the sections of the toxicity method manuals that discuss "pass/fail" tests with the following language (in red):

With the exception of the Test of Significant Toxicity (TST), use of pass/fail tests consisting of a single effluent concentration (e.g., the receiving water concentration or RWC) and a control is not recommended. If the NPDES permit has a whole effluent toxicity limit for acute toxicity at the RWC, it is prudent to use that permit limit as the midpoint of a series of five effluent concentrations for the LOEC and NOEC endpoints, and for point estimates. This will ensure that there is sufficient information on the dose-response relationship. For example, the effluent concentrations utilized in a test may be: (1) 100% effluent, (2) $(RWC + 100)/2$, (3) RWC, (4) $RWC/2$, and (5) $RWC/4$. More specifically, if the RWC = 50%, appropriate effluent concentrations may be 100%, 75%, 50%, 25%, and 12.5%. Guidance for the TST approach is provided in the *National Pollutant Discharge Elimination System Test of Significant Toxicity Implementation Document* (USEPA 2010).

These minor revisions will eliminate the extremely wasteful practice of utilizing five test concentrations for TST analyses while greatly improving regulatory interpretation.

Sincerely,



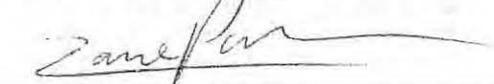
 Greg Gearheart, Director
 Office of Information Management and Analysis



 Rik Rasmussen, Chief
 Total Maximum Daily Load Section



 Rich Breuer, Assistant Deputy Director
 Office of Information Management and Analysis



 Zane Poulson, Chief
 Inland Planning Standards and Implementation Unit

References:

Denton DL, Diamond JM, Zheng L. 2011. Test of Significant Toxicity: A Statistical Application for Assessing Whether an Effluent or Site Water is Truly Toxic. *Environmental Toxicology and Chemistry*. DOI: 10.1002/etc.493.

<http://onlinelibrary.wiley.com/doi/10.1002/etc.493/full>

Diamond JM, Denton DL, Roberts Jr. JW, Zheng L. 2013. Evaluation of the Test of Significant Toxicity for Determining the Toxicity of Effluents and Ambient Water Samples. *Environmental Toxicology and Chemistry*. DOI: 10.1002/etc.2166.

<http://onlinelibrary.wiley.com/doi/10.1002/etc.2166/full>

Diamond J, Denton D, Anderson B, Phillips B. 2011. It is time for changes in the analysis of whole effluent toxicity data. *Integrated Environmental Assessment and Management*.

DOI: 10.1002/ieam.278.

<http://onlinelibrary.wiley.com/doi/10.1002/ieam.278/full>

Regional Water Quality Control Board, San Diego Region. 2013. General Waste Discharge Requirements for Discharges from Boatyards and Boat Maintenance and Repair Facilities Adjacent to Surface Waters within the San Diego Region. Order No. R9-2013-0026.

http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0026.pdf

Regional Water Quality Control Board, San Diego Region. 2013. Waste Discharge Requirements for the United States Department of the Navy Naval Base, San Diego Complex, San Diego County. Order No. R9-2013-0064.

http://www.waterboards.ca.gov/sandiego/board_decisions/adopted_orders/2013/R9-2013-0064.pdf

State Water Resources Control Board. 2011. Effluent, Stormwater, and Ambient Toxicity Test Drive Analysis of the Test of Significant Toxicity (TST).

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/final_testdrive.pdf

State Water Resources Control Board. 2012a. Policy for Toxicity Assessment and Control, Public Review Draft.

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/draft_tox_policy_0612.pdf

State Water Resources Control Board. 2012b. National Pollutant Discharge Elimination System (NPDES) Statewide Storm Water Permit Waste Discharge Requirements (WDRS) for State of California Department of Transportation. Order No. 2012-0011-DWQ.

http://www.swrcb.ca.gov/board_decisions/adopted_orders/water_quality/2012/wqo2012_0011_dwq.pdf

State Water Resources Control Board peer review:

Gerald A. LeBlanc, PhD

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/gerald_leblanc_review.pdf

Michael C. Newman, PhD

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/michael_newman_review.pdf

U.S. Environmental Protection Agency. 2010. National Pollutant Discharge Elimination System Test of Significant Toxicity Technical Document. EPA 833-R-10-004.

<http://www.epa.gov/npdespub/pubs/tst-techdoc.pdf>

U.S. Environmental Protection Agency. 2012. Authorization to Discharge Under The National Pollutant Discharge Elimination System for Oil and Gas Exploration, Development, and Production Facilities. General Permit No. CAG280000.

<http://www.epa.gov/region9/water/npdes/pdf/ocs-general-permit2012.pdf>

U.S. Environmental Protection Agency peer review:

http://www.waterboards.ca.gov/water_issues/programs/state_implementation_policy/docs/tst_peerreview.pdf

Zheng L, Diamond JM, Denton DL. 2012. Evaluation of whole effluent toxicity data characteristics and use of Welch's t-test in the Test of Significant Toxicity analysis.

<http://www.ncbi.nlm.nih.gov/pubmed/23172744>

Attachment C

**USEPA Region IX
ATP Withdrawal Letter dated February 11, 2015**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105

February 11, 2015

Renee Spears
Senior Environmental Scientist Specialist-QA Officer
Office of Information Management & Analysis
State Water Resources Control Board
1001 I Street, 16-39D- Sacramento, CA 95814
P.O. Box 100- Sacramento, CA 95812

Dear Ms. Spears:

This letter addresses the EPA Region 9 Quality Assurance Office's March 17, 2014 approval of the State of California's request to use an Alternate Test Procedure (ATP), authorizing the use of two concentrations in lieu of the five concentrations plus a control specified in the WET test methods, when using the Test of Significant Toxicity (TST) statistical approach. EPA is withdrawing the approval of the Limited Use ATP, effective immediately, for a number of reasons. Please note that at this time, California's February 12, 2014 ATP request is no longer pending before EPA and should the State wish to pursue such an ATP, a new ATP application would be required.

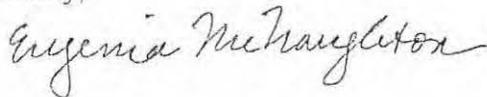
As you may know, the March 17, 2014 Limited Use ATP approval was challenged in the U.S. Eastern District Court of California in June 2014 by the Southern California Alliance of Publicly Owned Treatment Works (SCAP) and Central Valley Clean Water Association (CVCWA). As a result of the litigation, EPA has become aware of issues related to the State of California's February 12, 2014 request as well as EPA Region 9's approval. First, we note that the State's request cited 40 C.F.R. § 136.4, which describes the process for *nationwide* ATP approvals, rather than 40 C.F.R. § 136.5 for a Limited Use ATP. While we continue to believe this was a simple error, we acknowledge that it has created uncertainty and confusion among the regulated community.

Second, there is currently pending a proposed rulemaking to revise the ATP regulations at 40 C.F.R. Part 136. Please see <http://water.epa.gov/scitech/methods/cwa/mur2015.cfm>. The EPA Administrator signed a proposed rule on February 5, 2015, relevant portions of which are attached. One element of that rulemaking is a proposal to correct an inadvertent error in the 40 C.F.R. § 136.5 regulatory language regarding Limited Use ATPs. In revising 40 C.F.R. § 136.5 in 2012, EPA had inadvertently included the phrase "or permitting authority" after each instance that the phrase "Regional Alternate Test Procedure Coordinator" or "Regional ATP Coordinator" appears in Section 136.5. The effect of this inadvertent inclusion was to authorize State

permitting authorities to approve ATPs. This was not EPA's intention, and EPA has now proposed to delete the phrase "or permitting authority" from Section 136.5. It is EPA's position that the inadvertent error is not implicated in its approval decision here, but plaintiffs have raised arguments regarding the phrase "permitting authority" in Section 136.5. To the extent this error has created uncertainty in regards to the appropriateness of the March 17, 2014 ATP approval, EPA believes it is appropriate to withdraw that approval. However, withdrawal of the approval does not affect any aspect of the regulations at 40 C.F.R. Part 136 but concerns only the State's February 12, 2014 ATP request.

Third, plaintiffs have raised concerns with respect to the administrative record for the ATP approval. In light of some of the issues raised by plaintiffs, EPA has concluded that it is appropriate to withdraw its ATP approval. If you have any questions regarding this action, please contact me at (415) 972-3411.

Sincerely,

A handwritten signature in cursive script that reads "Eugenia McNaughton".

Eugenia McNaughton, Ph.D.
Manager, Quality Assurance Office

Cc: Rich Breuer

J. Clarifications/Corrections to ATP Procedures in 40 CFR 136.4, 136.5 and Allowed Modifications in 136.6

40 CFR 136.4 and 136.5 describe EPA procedures for obtaining approval to use an alternate test procedures either on a national basis, or for limited use by dischargers or facilities specified in the approval. In the 2012 Method Update Rule, EPA made several clarifying changes to the language of these sections. At the same time, however, in many places in 40 CFR 136.4 and 136.5 where the phrase “Regional Alternate Test Procedures Coordinator” or “Regional ATP Coordinator” appears, EPA inadvertently also inserted the phrase “or permitting authority” following the phrase. This error resulted from the use of the “search and replace” function on the computer. The effect of the change was to inadvertently authorize *State* permitting authorities to approve ATPs for limited use within the State. EPA never intended this result as is demonstrated by two facts. First, in its proposal for the 2012 Update, EPA did not propose to authorize State NPDES permitting authorities to approve limited use ATPs. Second, the rule states that the approval may be restricted to specific dischargers or facilities, or to all dischargers or facilities “specified in the approval *for the Region.*” (emphasis added). This language evidences EPA’s intent that the Region – not the state – would be authorized to issue any such limited use ATP approval. Finally, as further evidence of EPA’s intent, in several places, the text of the rule makes more sense if read to authorize only the Regional ATP Coordinator, and not the State permitting authority, to approve limited use ATPs. For example, 40 CFR 136.5(d)(1) provides as follows:

“After a review of the application by the Alternate Test Procedure Regional ATP Coordinator or permitting authority, the Regional ATP Coordinator or permitting

authority notifies the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure....”

As currently written, if the State is acting on a request for approval, the regulation would require the State to inform itself of its own action in approving or rejecting the ATP, a somewhat superfluous requirement.

Consequently, EPA proposes to delete all instances of “or permitting authority” from 40 CFR 136.4 and 136.5 to correct this error and revise the rule text to its original intent. Based on this revision, EPA and EPA alone would have the authority to approve limited use ATPs.

EPA also proposes changes to 40 CFR 136.4 and 136.5 to clarify the process for nationwide approval and the Regional ATP Coordinator’s role in limited use ATP approvals. These changes do not significantly change the process, the intent is to make wording simpler and clearer.

Finally, EPA proposes to add language to 40 CFR 136.6(b)(1) to clarify that if a method user is uncertain whether or not a modification is allowed under 40 CFR 136.6, the user should contact either its Director or EPA Regional ATP Coordinator.

K. Changes to Appendix B to 40 CFR part 136 - Definition and Procedure for the Determination of the MDL

EPA proposes revisions to the procedure for determination of the MDL primarily to address laboratory blank contamination and to better account for intra-laboratory variability. EPA’s consideration of revisions to the MDL procedure for this rulemaking is specific to these revisions, and other changes to the procedure are outside the scope of this action. The proposed changes originated from The National Environmental Laboratory Accreditation Conference

5. Section 136.4 is amended by revising paragraphs (a) introductory text, (b), and (c) to read as follows:

§ 136.4 Application for and approval of alternate test procedures for nationwide use.

(a) A written application for review of an alternate test procedure (alternate method) for nationwide use may be made by letter via email or by hard copy in triplicate to the National Alternate Test Procedure (ATP) Program Coordinator (National Coordinator), Office of Science and Technology (4303T), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460. Any application for an ATP under this paragraph (a) shall:

* * * * *

(b) The National Coordinator may request additional information and analyses from the applicant in order to evaluate whether the alternate test procedure satisfies the applicable requirements of this part.

(c) Approval for nationwide use.

(1) After a review of the application and any additional analyses requested from the applicant, the National Coordinator will notify the applicant, in writing, of whether the National Coordinator will recommend approval or disapproval of the alternate test procedure for nationwide use in CWA programs. If the application is not recommended for approval, the National Coordinator may specify what additional information might lead to a reconsideration of the application and notify the Regional Alternate Test Procedure Coordinators of the disapproval recommendation. Based on the National Coordinator's recommended disapproval of a proposed alternate test procedure and an assessment of any current approvals for limited uses for the

unapproved method, the Regional ATP Coordinator may decide to withdraw approval of the method for limited use in the Region.

(2) Where the National Coordinator has recommended approval of an applicant's request for nationwide use of an alternate test procedure, the National Coordinator will notify the applicant. The National Coordinator will also notify the Regional ATP Coordinators that they may consider approval of this alternate test procedure for limited use in their Regions based on the information and data provided in the application until the alternate test procedure is approved by publication in a final rule in the Federal Register.

(3) EPA will propose to amend 40 CFR part 136 to include the alternate test procedure in §136.3. EPA shall make available for review all the factual bases for its proposal, including the method, any performance data submitted by the applicant and any available EPA analysis of those data.

(4) Following public comment, EPA shall publish in the FEDERAL REGISTER a final decision on whether to amend 40 CFR part 136 to include the alternate test procedure as an approved analytical method for nationwide use.

(5) Whenever the National Coordinator has recommended approval of an applicant's ATP request for nationwide use, any person may request an approval of the method for limited use under §136.5 from the EPA Region.

6. Section 136.5 is amended by revising paragraphs (a), (b), (c), and (d) to read as follows:

§136.5 Approval of alternate test procedures for limited use.

(a) Any person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.

(b) When the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (i.e., permitting authority). The Director will forward the application to the Regional ATP Coordinator with a recommendation for or against approval.

(c) Any application for approval of an alternate test procedure for limited use may be made by letter via email or by hard copy. The application shall include the following:

(1) Provide the name and address of the applicant and the applicable ID number of the existing or pending permit(s) and issuing agency for which use of the alternate test procedure is requested, and the discharge serial number.

* * * * *

(d) Approval for limited use. (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. The approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator, to all dischargers or facilities (and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.

(2) The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National Alternate Test Procedure Coordinator.

7. In Section §136.6:

Clean Water Act Methods Update Rule for the Analysis of Effluent

List of Subjects in 40 CFR part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Test procedures, Water pollution control.

Dated:

FEB 05 2015



Gina McCarthy, Administrator.