

## SETTLEMENT AGREEMENT

This Settlement Agreement, dated this 24th day of July, 1998, is made and entered into by and between Edison Electric Institute, et al., and Western Coalition of Arid States (collectively "Petitioners") and the U.S. Environmental Protection Agency ("EPA").

WHEREAS, on October 26, 1995, the U.S. Environmental Protection agency promulgated a final rule under the Clean Water Act ("CWA") that, inter alia, adds whole effluent toxicity testing methods to the list of nationally-applicable methods in 40 C.F.R. Part 136 (60 Fed. Reg. 53,529) (the "Final Rule");

WHEREAS, Edison Electric Institute, et al. (No. 96-1062) and Western Coalition of Arid States (No. 96-1124) filed petitions for review of the Final Rule, which are now pending in the U.S. Court of Appeals for the District of Columbia Circuit;

WHEREAS, EPA acknowledges the goal of conducting interlaboratory variability studies for the whole effluent toxicity testing methods in the Final Rule as resources allow;

WHEREAS, EPA commits itself to continue to address issues unique to arid ecosystems in cooperation with Petitioner Western Coalition of Arid States ("WestCAS"), primarily through the Arid West Water Quality Research Project;

WHEREAS, in the context of pending EPA efforts to establish procedures for the development and approval of alternate test procedures under 40 C.F.R. Part 136, EPA intends to develop guidance describing procedures for the development of whole effluent toxicity methods using test organisms that are

indigenous to receiving waters, including waters in the Arid and Semi-Arid West;

WHEREAS, EPA invited public comment on the need for and the appropriate forms of water quality-based effluent limitations for storm water discharges in a rulemaking pursuant to Clean Water Act section 402(p)(6) proposed on January, 7, 1998, and shall further consider such issue in the context of whole effluent toxicity implementation discussions;

WHEREAS, EPA acknowledges that test methods manuals incorporated by reference in the Final Rule distinguish between requirements (by use of the compulsory terms "must" and "shall") and recommendations and guidance (by use of the discretionary terms "should" and "may") so as to indicate the instances when the analyst has flexibility to optimize successful test completion and when standardization is necessary to assure the predictability of the methods to provide reliable results;

WHEREAS, EPA acknowledges that provisions of this Settlement Agreement, which focus primarily on test methodology and, to a lesser extent, interpretation of test results, do not address all of the Petitioners' concerns regarding applicability of the whole effluent toxicity testing requirements to particular waterbodies (with specific reference to intermittent or effluent dependent waterbodies located in the Arid West) and do not address many of Petitioners' concerns regarding regulatory implementation of whole effluent toxicity control programs (e.g., toxicity identification evaluation requirements, toxicity reduction

evaluation requirements, compliance determinations, and trigger thresholds);

WHEREAS, EPA acknowledges that the Inhibition Concentration Percentage (“ICP”) statistical procedure may not always generate confidence intervals, but that the inability to generate a confidence interval does not indicate a confidence interval of zero, and EPA addresses data confidence concerns elsewhere in the Final Rule (including the test methods manuals incorporated by reference) and under this Agreement;

WHEREAS, EPA has committed to expeditiously resolving an issue identified by Petitioners regarding Discharge Monitoring Report (DMR) certification of WET test results, with specific reference to what is intended in certifying the “accuracy” of such results, per 40 C.F.R. § 122.22(d), through a clarification memorandum or other interpretive document to be issued independently of the provisions of this Settlement Agreement;

WHEREAS, EPA acknowledges that the Final Rule, which incorporates the WET test methods in dispute, does not specify means to adjust for the frequency, duration, or magnitude of instream exposure conditions, and that such decisions are to be made by the regulatory authority in the context of water quality standard setting and/or NPDES permitting decisions;

WHEREAS, the parties wish to settle this matter without further litigation; and

WHEREAS, settlement of all issues is in the public interest.

NOW, THEREFORE, without admission of any issues of fact or law, or waiver of any claim or defense, either factual or legal, the parties agree as follows:

Specific Provisions

1. EPA shall prepare a guidance document describing procedures to be utilized by permitting authorities for taking analytical variability into account in determining the need for, the derivation of, and any adjustment to an effluent limitation for whole effluent toxicity (“WET”). This guidance shall be consistent with the description set forth on Exhibit A to this Agreement and performed in accordance with the schedule set forth on Exhibit A. EPA shall publish notice of issuance of the guidance in the Federal Register.

2. EPA shall conduct additional interlaboratory variability studies to evaluate several of the WET methods contained in the Final Rule. These studies (the “Interlaboratory Variability Studies”) shall be conducted consistent with the outline and schedule attached as Exhibit B to this Agreement.

3. EPA shall evaluate results from the Interlaboratory Variability Studies in accordance with the criteria for evaluating the adequacy of biological methods described in “Availability, Adequacy, and Comparability for the Analysis of Pollutants Established Under Section 304(h) of the Federal Water Pollution Control Act,” EPA/600/9-87/030 (September 1988), and, to the extent applicable, the “Data Quality Objectives” guidance (from EPA’s Permit Writers’ Guide dated November 1990 and Guidance for Planning for Data Collection, EPA/QA/G-4). Based on

the Interlaboratory Variability Study results or any peer review recommendations, EPA shall also identify which additional performance characteristics, if any, are appropriate for describing and assessing the adequacy of the test methods in the Final Rule. No later than 3 months after completion of the peer review of the Interlaboratory Variability Studies, EPA will publish a notice of results of the Interlaboratory Variability Studies in the Federal Register (the "FR Notice"). This FR Notice shall, for each WET method evaluated in the Interlaboratory Variability Studies, summarize the results for the WET method. The FR Notice also shall contain, based upon the test results arising from work performed under Exhibit B: (1) reference to the data and equations used to calculate the coefficient of variation (or other applicable estimate of precision) for each test endpoint; (2) a chart of any new coefficients of variation for the various WET methods derived from the results of the Interlaboratory Variability Studies; (3) the rate at which participating laboratories completed tests initiated; and (4) the percentage of tests performed on "blanks" that produced results showing a toxic response. In addition, EPA shall, in the FR Notice, propose to either withdraw or retain each of the WET methods evaluated in the Interlaboratory Variability Studies. In the alternative, for those methods that EPA might otherwise propose to withdraw, EPA may withdraw a WET method without prior notice and opportunity for public comment upon a finding of good cause, as provided in 5 U.S.C. § 553(b). For any WET methods EPA proposes to withdraw, Petitioners may

file a motion with the Court requesting a stay of those portions of the Final Rule containing the methods proposed to be withdrawn until EPA takes final action on the proposal. For those WET methods EPA proposes to withdraw and which Petitioners seek to judicially stay, Petitioners may argue and EPA shall concede that prior application to EPA for the relief sought is not practicable because, by proposing to withdraw any method, EPA would have implicitly found that the good cause exemption of 5 U.S.C. § 553(b) would not apply. EPA shall not oppose any such motion for stay. If EPA proposes to retain a method while at the same time proposing to modify such method, EPA shall explain the reasons why such method should be retained pending final action on the proposal to modify.

4. EPA shall solicit and accept public comments on the FR Notice described in paragraph 3 for a period of at least 60 days. No later than one year after publication of the FR Notice described in paragraph 3, EPA will take final action on the proposals in the FR Notice. This final action shall include a determination to either withdraw or retain each of the WET methods evaluated in the Interlaboratory Variability Studies. The final notice shall also contain any modifications to the applicable interim coefficients of variation identified on Exhibit A, paragraph 2 (or other applicable estimate of precision) based upon the public comments received.

5. EPA shall sign a notice of final rulemaking for publication in the Federal Register on or before 6 months from the settlement date to correct technical and/or formatting errors

in the test methods manuals, including but not limited to deletion of section 8.3.4.1.2 of the chronic toxicity test manuals, but only to the extent that EPA determines that the Administrative Procedure Act does not require the Agency to provide an opportunity for public comment on the corrections.

6. On or before 18 months after settlement agreement, EPA shall sign and forward to the Office of the Federal Register for prompt publication a notice of proposed rulemaking to:

(A) Amend Method 1002 to require that test organisms be allocated among test replicates so that offspring of each female are evenly distributed among test replicates (“blocking-by-parentage”). In the development of such amendment, EPA may consider recommending an additional statistical analysis of variance which would recognize the parent as a blocking factor;

(B) Revise each of the test method manuals to incorporate objective and readily understandable requirements for the demonstration of a valid concentration-response relationship as a prerequisite for the determination of a valid test result. The proposed rulemaking would also identify the circumstances under which retesting would be required (as compared to a finding of no toxicity) due to the lack of a valid concentration-response relationship despite the satisfaction of all other test acceptance criteria; and

(C) Revise each of the test method manuals to incorporate a specific methodological procedure or procedures to control

upward pH drift that may occur during the renewal of samples during the test (causing pH shock).

EPA shall sign and forward to the Office of the Federal Register for prompt publication a notice taking final action on such proposed rulemaking on or before 30 months after settlement agreement.

7. On or before 18 months after settlement agreement, EPA shall prepare guidance, sign and forward to the Office of the Federal Register for prompt publication a notice of availability to:

(A) Revise Agency guidance and recommendations in the chronic toxicity test methods manuals to clarify that a nominal error rate of either 0.05 or 0.01 is acceptable and to identify those circumstances and conditions under which the recommended nominal error rate would be 0.01. Such circumstances and conditions shall include, but not necessarily be limited to, the use of enforceable sublethal endpoints for Ceriodaphnia dubia and fathead minnows or where there is little or no available dilution in the receiving waters and where the permitting authority would derive a limit without consideration of dilution. Based on the results from the Interlaboratory Variability Studies, any recommendations of the peer review panel, and other pertinent information, EPA shall also identify those circumstances or conditions, if any, in which the Agency recommends that the number of test replicates be increased to ensure adequate statistical power;

(B) Clarify the circumstances under which confidence intervals are not generated (and/or are not capable of generation) when using point estimation techniques, including, at a minimum, the Inhibition Concentration Percentage (ICP) procedure. In addition, prior to renewing existing supplies of EPA test method statistical software, the Agency shall incorporate into such software appropriate information to indicate when confidence intervals are not generated (and/or not capable of generation). At that time, EPA shall also make available any resulting new software specifications for manufacturers of commercial software packages.

When EPA takes final action on the rulemaking proposed in paragraph 6 to amend the Final Rule, including the test methods manuals incorporated by reference, EPA shall also modify the test manuals to incorporate the revised guidance and recommendations in this paragraph, as well as guidance and recommendations regarding application of pH shift control procedures, which would not be limited to circumstances where ammonia is present.

8. On or before 18 months after the settlement date, EPA shall prepare guidance, sign and promptly forward to the Office of the Federal Register for prompt publication a notice of availability to:

(A) Explain the concept of the valid concentration-response relationship by identifying forms of concentration-response relationships which would and would not constitute acceptable concentration-response relationships;

(B) Identify the circumstances where the number of dilutions in a series and/or the dilution sequence itself may be modified to assist in determining the existence of a concentration-response relationship. Such guidance may subsequently be modified to reflect information developed during the conduct of the Interlaboratory Variability Studies described in Exhibit B;

(C) Revise the test manuals to clarify what EPA considers to be acceptable dilution water (i.e., to clarify that the test method manuals, e.g., section 7.1.1.1 of the chronic toxicity test manual, do allow for the use of standardized control waters of other than moderate hardness when the objective of the test is to estimate the toxicity of effluent), with specific reference to matching control water hardness to ambient water hardness and including a discussion about ionic balance and strength. EPA shall provide additional recommendations regarding evaluations of data generated when the test is conducted with dual controls (i.e., controls using synthetic dilution water and controls using ambient dilution water) so as to ensure that results are interpreted using the most appropriate control waters. EPA shall further clarify that test organisms may be cultured in waters that resemble ambient receiving water chemistry, with specific reference to water hardness and ionic balance.

When EPA takes final action on the rulemaking proposed in paragraph 6 to amend the Final Rule, including the test methods

manuals incorporated by reference, EPA shall also modify the test manuals to incorporate the revised guidance and recommendations in this paragraph.

#### Procedural Matters

9. Upon execution of this Agreement by the parties, Petitioners and EPA shall file a joint motion requesting that the Court extend the stay of this proceeding pending completion of the items set forth in paragraphs 1 through 8 above. This Agreement shall be appended to that joint motion.

10. Except as provided in paragraph 11, if EPA issues the guidance documents specified in paragraphs 1, 7, and 8, completes the Interlaboratory Variability Studies referenced in paragraph 2, and publishes the Federal Register notices referenced in paragraphs 3 through 8, by the dates set forth in each of those paragraphs and associated Exhibits, Petitioners and EPA will file a joint motion for dismissal with prejudice of the two petitions, Case Nos. 1062 and 1124. That motion shall be filed no later than thirty days after publication of the latest of the final actions referenced in paragraphs 3 through 8.

#### Petitioners' Remedies

11. If EPA does not issue the guidance documents specified in paragraphs 1 and 7, complete the Interlaboratory Variability Studies referenced in paragraph 2, or publish the Federal Register notices referenced in paragraphs 3 through 7 by the dates set forth in each of those paragraphs and associated Exhibits, Petitioners' sole remedy shall be the right to revive the petitions for review and to seek imposition of a schedule for

briefing in order to obtain judicial review of the Final Rule. Petitioners will give EPA ten days notice prior to exercising their rights under this paragraph. If one petitioner gives notice to EPA exercising its rights under this paragraph, EPA may move to lift the stay as to all petitions for review, and all other petitioners shall not oppose such a motion.

12. If EPA does not issue the memorandum described in paragraph 8 by 18 months from settlement or if the memorandum does not include the information described in that paragraph, WestCAS may revive its petition for review and seek imposition of a schedule for briefing in order to obtain judicial review of the Final Rule on the limited issue of whether EPA acted arbitrarily and capriciously, abused its discretion or acted in a manner otherwise inconsistent with applicable law by not including in the Final Rule the information described in paragraph 8.

13. Petitioners may exercise their right under section 509(b)(1) of the Clean Water Act, 33 U.S.C. § 1369(b)(1), to file a new petition for review of any final action taken pursuant to paragraph 4 following completion of the Interlaboratory Variability Studies. If Petitioners decide to exercise their right to file a new petition for review, EPA will not oppose a request by Petitioners for an expedited litigation schedule in such proceedings, provided any such schedule allows EPA at least 60 days to file its response brief.

## General Provisions

14. Nothing in the terms of this Settlement Agreement shall be construed to limit or modify the discretion accorded EPA by the CWA or by general principles of administrative law.

15. Nothing in this Settlement Agreement shall be interpreted so as to (1) foreclose the ongoing or future examination, by EPA, of any additional test performance characteristics which are not specifically or completely addressed by the actions taken under this Settlement Agreement, but not limited to, the development of a detection limit or its equivalent for biological testing or (2) prohibit the use of other appropriate statistical methods and procedures to interpret test data as may be found acceptable to EPA following appropriate peer review and public notice.

16. Nothing in this Settlement Agreement shall be construed to limit or modify EPA's discretion to subsequently modify, amend, or revise the guidance documents identified in Paragraphs 1, 7, and 8, or any final action referenced in paragraphs 4 and 6, or to promulgate superseding guidance, rules, or regulations.

17. No provision of this Settlement Agreement shall be interpreted as or constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. 1341, or any other applicable law or regulation.

18. This is the entire Settlement Agreement between the parties with respect to the issues raised by Edison Electric Institute et al. v. EPA, No. 96-1062 (D.C. Cir.) and Western Coalition of Arid States v. EPA, No. 96-1124 (D.C. Cir.). All

prior conversations, meetings, discussions, drafts and writings of any kind are specifically superseded by this Settlement Agreement and may not be used by the parties to vary or contest the terms of this agreement, or as evidence of the parties' intent in entering into this Settlement Agreement.

19. The parties may agree in writing to modify any provision of this Settlement Agreement.

20. This Settlement Agreement is being entered into so as to avoid further litigation. Nothing in this settlement agreement shall be construed to constitute an admission of any issue of fact, law or liability by any of the parties. Except as expressly provided in this Agreement, none of the parties waive or relinquish any legal rights, claims or defenses they may have.

21. Each party shall bear its own costs, including attorneys' fees, in this litigation, including attorneys' fees and costs associated with monitoring, overseeing, or implementing this Settlement Agreement, and including participation in any administrative proceedings contemplated by this Agreement.

22. The undersigned representatives of each party certify that they are fully authorized by the party or parties they represent to bind the respective parties to the terms of this Agreement. This Agreement will be deemed to be executed and shall become effective when it has been signed by the representatives of the parties set forth below.

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## Exhibit A - Guidance Document

1. EPA shall prepare a guidance document directed to permitting authorities describing statistical and/or other procedures for taking WET analytical method variability into account in (1) the determination of whether an effluent limitation for whole effluent toxicity is needed, i.e., whether a discharge causes or has the reasonable potential to cause, or contributes to an instream excursion above a criterion within a State water quality standard and (2) in the derivation of a whole effluent toxicity limit.

2. The guidance document shall identify an estimate of precision, including, at a minimum, an applicable interim “coefficient of variation” for each whole effluent toxicity test method published (and incorporated by reference) at 40 CFR Part 136.

3. EPA shall make the draft guidance available in a public docket on or before 12 months after settlement date. EPA shall also include the “charge” to the peer review panel in the docket, and shall provide an opportunity for public comment on the charge. EPA shall amend the charge in response to such comments to the extent that EPA deems that amendment is necessary to ensure that the charge is objective, accurate, and complete. EPA shall submit the guidance for technical review by the peer review panel on or before 13 ½ months after the settlement date and request that the peer review panel provide comments within 4 months after receipt. EPA shall inform the peer review panel of the existence of a public docket available for their review and

the full range of regulatory uses applicable to the draft guidance undergoing peer review, including but not limited to, the potential use of results from a single test to assess compliance with a  $1TU_c$  or  $0.3TU_a$  permit limit at end-of-pipe in instances involving little or no dilution. EPA shall also provide the peer reviewers such additional pertinent information as they may request. EPA shall solicit comment from the peer review panel upon whether the draft guidance is scientifically acceptable within the context (40 C.F.R. Part 136) of the intended regulatory use.

4. The peer reviewers shall be selected in accordance with the selection criteria in EPA's current peer review policies.

5. Reviewers shall include experts in the field of aquatic toxicology and biological statistics as demonstrated by publication in scientific journals or known research. Such experts shall also be familiar with water quality-based permitting and whole effluent toxicity. The peer review panel for review of the guidance document may differ in composition from the peer review panel for the interlaboratory variability studies described in Exhibit B. For the purposes of the peer review described in this Settlement Agreement, the peer review panel shall not include any expert associated with the generation of the whole effluent toxicity methods in the Final Rule either directly by substantial contribution to the development or indirectly by consultation during the development of the methods in the Final Rule. The peer review panel, thus, can be objectively judgmental. If any expert has potential conflicts of

interest (real or perceived), such conflicts shall be fully identified to ensure credible peer review.

6. Communications between any peer review panel member and EPA's authorized representative regarding the technical aspects of the guidance document or the studies shall be subject to public disclosure to the same extent such information is available to EPA (except for business information entitled to confidential treatment under Agency regulations at 40 CFR Part 2 and any applicable provisions of the Federal Acquisition Regulation, and EPA's supplement thereto, at Title 48 of the CFR).

7. EPA shall evaluate comments from the peer review panel and any comments submitted to the public docket, revise the guidance document as appropriate, and issue the guidance document within 4 months after receipt of comments and/or recommendations from peer review panel members, but in no event later than 21 months after settlement date. Upon issuance, EPA shall promptly forward to the Office of the Federal Register a notice of availability of the guidance document.

## Exhibit B - Interlaboratory Variability Studies

1. EPA (and/or EPA's authorized representatives) shall conduct interlaboratory variability studies to evaluate several of the whole effluent toxicity test methods using the specific test protocols promulgated at 40 CFR Part 136, including, as appropriate, reference to EPA guidance entitled "Clarifications Regarding Flexibility in 40 CFR Part 136 Whole Effluent Toxicity (WET) Test Methods" dated April 10, 1996 from Tudor T. Davies to EPA Water Management Division Directors and EPA environmental Services Division Directors, except that test organisms shall (as opposed to may) be randomly allocated among test solutions. In addition, Method 1002.0, which would otherwise be terminated after 3 broods according to section 13.12.1 of that Method, shall be conducted for 8 days (through to completion), with endpoints (including number of young per day and number of broods at each recording interval) noted at the end of the sixth, seventh and eighth day (specifically, at 144 hours, at 168 hours, and at 192 hours, respectively, from test initiation), in order to assess the effect of that test acceptance criterion on test results. No test shall be terminated prior to the eighth day for any reason, including a failure to meet test acceptance criteria. Finally, in the conduct of Method 1002.0, test organisms shall be allocated among test replicates so that the offspring of each female are evenly distributed among test replicates ("blocking-by-parentage").

2. EPA shall design the interlaboratory variability studies to, among other things, quantify interlaboratory

variability, i.e., to determine an estimate of precision, including, at a minimum, a coefficient of variation, for each test endpoint, as well as to determine the rate at which participating laboratories successfully completed tests initiated and the rate at which the tests indicate toxicity is present when measuring reagent water, also known as "blanks."

3. EPA shall establish a public docket for the interlaboratory variability studies on or before one month after the settlement date. At that time, EPA shall include the "charge" to a peer review panel for peer review on the design of the interlaboratory variability studies. On or before 75 days after the settlement date, EPA shall submit the study design which shall include the laboratory qualification criteria, for peer review and request that the peer review panel provide comments within 2 months after receipt. EPA shall inform the peer review panel of the existence of a public docket available for their review and the full range of regulatory uses applicable to the Interlaboratory Variability Studies undergoing review, including but not limited to, the potential use of results from a single test to assess compliance with a  $1TU_c$  or  $0.3TU_a$  permit limit at end-of-pipe in instances involving little or no dilution. EPA shall also provide the peer reviewers such additional pertinent information as they may request. EPA shall solicit comment from the peer review panel upon whether the Interlaboratory Variability Studies are scientifically acceptable within the context (40 C.F.R. Part 136) of the intended regulatory use.

4. EPA (and/or EPA's authorized representative) shall select a least 9 laboratories to conduct each test method to be evaluated in the Interlaboratory Variability Studies. EPA shall assure that all of the laboratories selected for participation in the interlaboratory studies are representative of laboratories throughout the United States that routinely conduct WET testing for permittees and shall attempt to maximize the number of qualifying laboratories participating in the Studies. A laboratory may participate in a study for the evaluation of more than one toxicity test method. EPA (and/or EPA's authorized representative) shall identify laboratories qualified for participation in the studies. Subject to such adjustment in qualifications as may result from recommendations of the peer review panel examining the Interlaboratory Variability Study design, laboratories participating in the Interlaboratory Variability Studies must demonstrate satisfactory quality assurance and quality control (QA/QC) based on QA/QC procedures in the test manuals. The QA/QC prequalification requirements shall include, at a minimum, the development of acceptable control charts (i.e. cusum charts) using reference toxicants, meeting of test conditions and test acceptability criteria, and the application of appropriate statistical analyses for each test and test endpoint for which the laboratory would participate in an Interlaboratory Variability Study.

5. Petitioner laboratories which meet the qualifications referenced in paragraph 4 of this Exhibit shall be allowed to participate in the Interlaboratory Variability Studies, provided

that the costs of the analysis associated with such participation shall be the sole obligation of the Petitioners. In order to assist Petitioners in the expeditious identification of additional laboratories and to afford EPA (and/or EPA's authorized representative) an opportunity to determine such laboratories' demonstrated ability to participate, EPA shall incorporate the laboratory qualification criteria into the Interlaboratory Variability Study design, and Petitioners shall submit to EPA a list of candidate laboratories within 30 days after EPA establishes the public docket in paragraph 3 of this Exhibit. For each candidate laboratory identified on the list, Petitioners shall identify each WET test method for which the laboratory would seek to participate in an interlaboratory study.

6. For each method evaluated, EPA or EPA's authorized representative shall randomly distribute three "blind" samples to each laboratory for evaluation. The samples distributed shall include some combination of: reference toxicants (of known chemical composition); industrial and/or municipal wastewater effluent (of unquantified chemical composition); ambient receiving water; and method "blanks," i. e., moderately hard reagent water as explained in the test method manuals. The combinations of blind samples may include more than one sample ampule of any given sample type. At least six sample ampules of each sample type shall be evaluated for each method. Neither EPA nor EPA's authorized representative shall disclose the nature, number, or composition of any of the various samples distributed to laboratories participating in the studies. Data generated by

all qualified participating laboratories shall be considered in the evaluation of the test methods.

7. EPA (or EPA's authorized representative) shall provide each participating laboratory with specific instructions to perform the testing in accordance with their routine laboratory practices using the applicable test method in the Final Rule. Each participating laboratory, however, shall be required to report all data obtained during the course of testing, including the response of control samples.

8. Petitioners, like any member of the public, shall be provided full access to the uncensored database available to EPA that arises from the variability studies to be performed. EPA shall announce the availability of such data in the Federal Register as described in Paragraph 3 of the Settlement Agreement.

9. EPA shall conduct the interlaboratory variability studies on the following toxicity test methods:

- a. from the freshwater chronic toxicity manual (3d ed.)
  - i. Method 1000: Pimephales promelas (fathead minnow), Larval Survival and Growth Test
  - ii. Method 1002: Ceriodaphnia dubia (cladoceran), Survival and Reproduction Test
  - iii. Method 1003: Selanastrum capricornatum (green alga), Growth Test (with and without EDTA)
- b. from the marine chronic toxicity manual (2d ed.)
  - i. Method 1004: Cyprinodon variegatus sheepshead minnow), Larval Survival and Growth Test

- ii. Method 1006: *Menidia beryllina* (inland silverside), Larval Survival and Growth Test
  - iii. Method 1007: *Mysidopsis bahia* (mysid shrimp), Survival, Growth, and Fecundity Test
  - iv. Method 1009: *Champia parvula* (red macroalga), Reproduction Test
- c. from the acute toxicity manual (4th ed.)
- i. *Ceriodaphnia dubia*
  - ii. *Pimephales promelas*
  - iii. *Cyprinodon variegatus*
  - iv. *Menidia beryllina*
  - v. *Holmesimysis costata* (using the test procedures to measure acute toxicity on *Mysidopsis bahia*).

10. EPA shall complete such interlaboratory variability studies and make the results of the studies available in a public docket on or before 17 ½ months after the settlement date. EPA shall also include the “charge” to the peer review panel in the docket and shall provide an opportunity for public comment on the charge. EPA shall amend the charge in response to such comments to the extent that EPA deems that amendment is necessary to ensure that the charge is objective, accurate, and complete. EPA shall submit the results of the interlaboratory validation studies for peer review on or before 19 months after the settlement date and request that the peer review panel provide comments within 4 months after receipt. EPA shall inform the peer review panel of the existence of a public docket available for their review and the full range of regulatory uses applicable

to the Interlaboratory Variability Studies undergoing review, including but not limited to, the potential use of results from a single test to assess compliance with a  $1TU_c$  or  $0.3TU_a$  permit limit at end-of-pipe in instances involving little or no dilution. EPA shall also provide the peer reviewers such additional pertinent information as they may request. EPA shall solicit comment from the peer review panel upon whether the results and report from the Interlaboratory Variability Studies are scientifically acceptable within the context (40 C.F.R. Part 136) of the intended regulatory use.

11. The peer review shall be conducted according to current Agency peer review policies and the Office of Water's standard operating procedures for peer review.

12. Peer reviewers shall include experts in the field of aquatic toxicology and biometrics as demonstrated by publication in scientific journals or known research. The peer review panel for review of the interlaboratory variability studies may differ in composition from the peer review panel for the guidance document described in Exhibit A. For the purposes of the peer review described in this Settlement Agreement, the peer reviewers shall be selected in accordance with the selection criteria found in EPA'S current peer review policy. Specifically, the peer review panel shall not include any experts associated with the generation of the whole effluent toxicity methods in the Final Rule either directly by substantial contribution to the development or indirectly by consultation during the development of the methods in the Final Rule. The peer review panel, thus,

can be objectively judgmental. If any expert has potential conflicts of interest (real or perceived), such conflicts shall be fully identified to ensure credible peer review.

13. Communications between any peer review panel member and EPA's authorized representative regarding the technical aspects of the guidance document or the studies shall be subject to public disclosure to the same extent such information is made available to EPA (except for business information entitled to confidential treatment under Agency regulations at 40 CFR Part 2 and any applicable provisions of the Federal Acquisition Regulation, and EPA's supplement thereto, at Title 48 of the CFR).