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September 15, 1998

VIA FAX

Stephen J. Sweeney, Esquire
U. S. Environmental Protection Agency
401 M St., N.W.
Washington, D.C.

Utilities' Comments:
Charge to Reviewers: Interlaboratory Study of WET Test Methods

Dear Mr. Sweeney:

On behalf of the utility petitioners (the "Utilities"), I wish to thank you for the opportunity to review the above-referenced study design and charge to the peer reviewers. While the Utilities appreciate the effort EPA has made in preparing these documents, considerable additional work will be necessary to make both the study design and the charge to the peer reviewers consistent with the WET settlement agreement and otherwise technically sound. Following are our specific concerns and questions.

Study Design

1. The qualifying requirements for participating laboratories are excessive and contradictory to the interlaboratory study objective in the settlement agreement. The agreement says:

> 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. Settlement Agreement, Ex. B, ¶ 4.

Contrary to that commitment, the proposed study design would restrict participation by many qualified laboratories. Unless modified, the study would be performed primarily by

laboratories that are not representative of those actually conducting NPDES work. Consequently, the study results would compromise the parties' clear objective to evaluate the expected performance of WET tests in the NPDES program. If EPA considers a laboratory good enough to perform compliance monitoring, that laboratory should qualify for the interlaboratory study. Permittees will use those laboratories in practice unless EPA establishes a system to disqualify them from performing compliance monitoring. Thus, the performance of those laboratories, and not the performance of a select group of "superior" laboratories, must serve as the basis for the forthcoming study. Following are the Utilities' specific concerns.

a. A prequalification sample is excessive. Ample performance information with which to evaluate a laboratory's performance already is available. The cost of performing a prequalification test will effectively reduce the number of laboratories willing to participate on a voluntary basis. EPA has agreed to "maximize" participation, not restrict it.

b. The EPA is requiring the laboratories to provide a narrative explanation of the **width** of the control limits for each laboratory. This is not required by the test manuals, which already provide a narrative description of control limit width. According to the test manuals, a laboratory is in control as long as its reference toxicant test data fall within the mean $\pm$ 2S. Any laboratory with a control chart meeting this criterion can perform NPDES compliance testing, regardless of the width of the control limits. EPA therefore should not use the width of the control limits as a screening tool to disqualify laboratories.

c. A laboratory will be disqualified if it did not pass the most recent DMR-QA study. There should be a qualifier associated with this requirement so that a laboratory may be included if it did not pass the most recent DMR-QA study, but (1) provided a satisfactory explanation for having not passed the study, (2) had passed the DMR-QA study for that test in previous years, and/or (3) was able to pass the retest of the sample used in the DMR-QA study. It also should be pointed out that the pass fail criterion is set at the 95% level, so a certain number of "normal" values would be expected to routinely fail (i.e., simply failing the DMR-QA study should not be grounds for disqualifying a lab).

d. After Part I Prequalification, will all laboratories which demonstrate acceptable WET Testing Experience and Proficiency (i.e., pass the 7 rejection criteria) be asked to participate in Part II Prequalification? If not, what criteria will EPA use to select laboratories for Part II Prequalification?

2. The study design refers to "special instructions" to be provided to participating laboratories. The settlement agreement explicitly requires that, except for the method changes agreed to by the parties and described in the settlement agreement, the study must be performed "using the specific test protocols promulgated at 40 CFR Part 136." Settlement Agreement, Ex. B, ¶ 1. The agreement also states that "EPA . . . 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." Id. ¶ 7. Any "special instruction" other than the above would introduce a fundamental flaw in the study and contravene the settlement agreement.

If EPA wishes to revise a test protocol (i.e., modify it in any way, or restrict the flexibility currently provided), it needs either to (1) explicitly acknowledge that the forthcoming proposed and final Part 136 rule will focus exclusively on the revised protocol (and the existing protocol will be withdrawn in the Final Rule) or (2) evaluate both the existing and revised protocols and address both in the forthcoming proposed and final Part 136 rule.

When EPA evaluates the study results, it should determine the overall variability for each test protocol as well as the influence that each major flexibility option (e.g., choice of dilution water) has on variability (i.e., a sensitivity analysis to determine where flexibility introduces additional variability).

3. EPA should make absolutely clear that the study design is intended to quantify the variability of WET test methods, not to minimize that variability. Once variability has been quantified, the Agency can and should take action to minimize it.

4. The study design must be more specific regarding the "test samples" to be used. For example, the study design says that the samples will "represent a range of toxicity." It does not specify that the samples will include blanks, which are a key component of the study. That same deficiency appears in the charge to the peer reviewers.

5. Referee laboratories will be conducting WET testing for each method in the study. What will the results of these tests be used for? To ensure that the study's objectivity is not compromised, care should be used in interpreting the results of these tests, and a decision will need to be made as to how, or if, these results are to be included. Since the referee labs will be preparing the test samples, care should be used to ensure that whoever analyzes the samples at the referee lab is not privy to what the samples contain or to the study design in general. Also, toxicity testing of the samples by the referee lab should include testing of samples subjected to the same shipping and handling as the samples tested by the other participating laboratories.

6. Based on the description provided, it seems that EPA is planning to collect a **single** effluent sample that will be used throughout the testing period (which may be eight days in duration). However, EPA protocols require the collection of at least three individual samples for test solution renewals during a chronic test period. If an effluent's actual toxicity varies over the six to eight-day chronic test period, this may be reflected in an increase in the variability of test results determined by the individual laboratories. So that the tests are reflective of "real-world" conditions, at least three individual "real-world" effluent samples should be prepared for use in each chronic toxicity test.

7. It appears that EPA intends to send each matrix separately to the laboratories, over a period of time. That approach could compromise the integrity of the study. Each laboratory would know what sample all the other laboratories were analyzing at that time. While none of the laboratories would know what the specific sample was, they conceivably might communicate about the results they are getting from that particular common matrix.

8. Other than "bid cost," it is not clear if EPA will use any other criteria for selecting its nine participant laboratories once a list of prequalified laboratories is generated. Cost can represent a significant bias in terms of laboratory test sensitivity. A study quality objective should be set to include a representative range of laboratories that meet the minimum quality objectives, based on data generated from the prequalification reference toxicant tests, laboratory QA/QC control charts, and from EPA's DMR-QA data base. It is more important that this study be based on the entire range of laboratories performing acceptable testing for NPDES compliance, than using a test-cost criterion to determine what laboratories will be selected. Laboratories should be selected that have endpoints (e.g., from DMR-QA results) that lie in the low, mid, and high range of acceptable results. If all 9 laboratories' endpoints fall in only the high, mid, or low acceptable range, that would not be acceptable for this study. This same consideration should be given to selecting other laboratories who agree to participate at their own costs. This study MUST include the full range of variability from laboratories performing acceptable testing.

9. Titles for chronic tests (Tables 9, 11, 12, 16, 18, and 19) specify an IC_{25} point-estimate endpoint for growth or reproduction. Although the EPA freshwater chronic methods identify the IC_{25} as the preferred NPDES compliance test endpoint, this study should evaluate variability based on both point estimation and hypothesis testing, because both are included in the EPA methods (EPA-600-4-91-002).

10. When interlaboratory variability is evaluated for Round 1 testing, EPA should combine results from laboratories using both dissolved mineral water (DMW) and moderately-hard synthetic freshwater (MHSF), since both water types are being utilized as a diluent for effluent compliance testing. EPA should not stratify data and report variability separately for each

source (as they do for DMR-QA evaluations). A choice of either water type is included in the EPA Study Plan (Tables 8, 9, 10, 11, and 12).

11. The Round 1 Freshwater Fathead Minnow, Pimephales promelas, Acute Test is listed as a 96-hour test. Yet most NPDES permit biomonitoring requirements for evaluating acute toxicity to P. promelas require the 48-hour test (no food provided during the exposure period). Also, EPA's DMR-QA studies do not include the 96-hour test. Test results should be analyzed separately for the 48-hour (no food provided) and the 96-hour (food provided) scenarios.

12. How should laboratories handle IC_{25} point estimate data where a dose response is "significantly" non-linear (not monotonic)?

Charge to Peer Reviewers

1. The charge is unacceptably narrow and inconsistent with the settlement agreement. The charge states repeatedly that the "purpose" of the study is to evaluate test precision. It fails, however, to mention the other two purposes stated in Exhibit B, ¶ 2:

> 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."

EPA needs to add the other two purposes of the study every place in the charge that discusses "purpose."

2. EPA also agreed to "inform the peer review panel of the . . . full range of regulatory uses applicable to the Interlaboratory Variable Studies undergoing review. . . ." Settlement Agreement, Ex. B., ¶ 3. The charge fails to inform the peer reviewers that the study results will be used in the guidance being prepared in accordance with Exhibit A.

3. EPA uses language that is inaccurate, confusing, or unnecessary. Specific concerns include the following:

a. It is unnecessary to inform the peer reviewers of the Agency's view that "accuracy" is not appropriate for biological systems. (See page 2). Most significantly, that statement is false and inconsistent with the settlement agreement. Accuracy can be determined on WET tests, particularly with respect to tests performed on reagent water (i.e., blanks).

b. Also on page 2, the charge says that "Toxicity is *relative*, rather than *absolute* . . ." Again, the Utilities take issue with that conclusion and the need to raise it in the charge. The interlaboratory study is being conducted to evaluate how WET tests will perform in the NPDES process. In many cases, WET test results are used to evaluate compliance with enforceable NPDES permit limitations. In that critical respect, toxicity (i.e., the WET test results) is absolute, rather than relative. In deriving the WET limitation, the permit writer makes certain judgments that eliminate the relativity of toxicity. Once the limit has been imposed, WET test results are used as is for determining whether or not the limit has been violated. It therefore is entirely misleading to instruct the peer reviewers that toxicity is "relative."

4. EPA's questions for the peer reviewers need revision, as follows:

a. The first question needs to focus on whether the study is adequate for producing data with which to accomplish all three of the study purposes, not just precision.

b. As to the second question regarding the number of replicates, that can only be answered if EPA specifies an acceptable criterion or error rate to the peer reviewers.

c. The third question should be phrased in a manner consistent with the settlement agreement:

> Are the laboratory prequalification conditions and procedures appropriate to ensure that the study will be performed by laboratories representative of those that routinely conduct WET testing for permittees throughout the United States?

d. The fourth question raises a concern. Permittees have to ship samples based on the procedures in the guidance manuals. Therefore, the study design must not specify any different requirements.

The Utilities urge EPA to give consideration to the above comments and to make changes accordingly. Please feel free to call me if you have any questions.

Sincerely,

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Steven J. Koorse

cc: Ms. Angela Grooms
Mr. Alan Gaulke
Mark Pifher, Esquire
Ms. Barbara Potter

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