Association of
Metropolitan
Sewerage Agencies

September 24, 1998

Ms. Florence Fulk (642)
U.S. Environmental Protection Agency
National Exposure Research Laboratory
Ecosystems Exposure Research Division
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

RE: AMSA Comments on WET Interlaboratory Study Design

Dear Ms. Fulk:

AMSA is pleased to provide the following comments on the *"EPA Charge to Peer Reviewers:Interlaboratory Study of Whole Effluent Toxicity Test Methods."* We appreciate the additional review time as per the conversation between Steve Sweeney of the Office of General Counsel and myself. The additional review time provided an opportunity for AMSA to reach out to its members. This is particularly important because the study plan was not available through traditional avenues such as the Federal Register or EPA Web site.

Page 1:
The charge to the peer reviewers should be modified as follows:

> *"The charge to the Peer Review Panel is to objectively review whether the Interlaboratory Study design (Appendix A) effectively assesses method precision as it relates to the use of a single test result to judge whether an effluent has a reasonable potential to cause or contribute to receiving stream impacts or violate a NPDES permit limit and thereby subject a permittee to the legal penalties contained in the Clean Water Act."*

The changes underlined above are designed to provide peer reviewers with a clearer understanding of what the tests are designed to accomplish. A clear understanding of how a method is used is critically important when setting up a study to evaluate a method.

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AMSA also believes that all peer review comments should be provided to the peer reviewers as well as the docket. Allowing the panel to review the comments would assist the peer review panel by providing a clear understanding of the issues.

EPA should provide a more detailed discussion of how and what data was used to accomplish the tasks identified in the following sentence:

> *"The integration of the effluent effects and receiving water exposure measurements resulted in the development of effluent hazard assessment approaches."*

This detailed discussion should include what data and assumptions were used in this integration and a discussion of the uncertainties of the hazard assessment.

The discussion on how WET results are used in the permitting program is wholly inadequate and needs considerable expansion. The discussion should include discussions of beneficial uses and how a single test could be used to make a determination that a water body does not meet the "fishable" standard, reasonable potential discussions and uncertainties, as well as a clearer understanding of permit compliance and the potential enforcement consequences of permit violations, including citizen suit provisions. The peer review panel will not be able to function effectively if they are not fully aware of all the technical issues and how those issues affect the WET program and the associated legal implications of NPDES permit compliance. AMSA urges EPA to consider a format which would allow EPA and a representative of the litigants to address the peer review panel during its first meeting. These presentations would help properly frame the issues for the panel and insure that they fully understand the WET program.

Page 2:
The EPA incorrectly states that there is no way to measure the accuracy of the toxicity tests. There is a way to partially measure accuracy and that is through the use of non-toxic dilution water. This measure, while different from that used in chemical measurements, can be used to determine accuracy at the level at which the EPA program is designed to reach "zero toxicity". If the test is not accurate at the zero level, we will never be able to measure when we meet the goal.

EPA correctly admits that:

> *"Interlaboratory variance may be dependent upon how a variety of laboratories follow a specific test protocol."*

In fact one of the purposes of this study should be to evaluate how well laboratories follow the test

protocol. This would provide data to determine if a large number of laboratories do follow the protocol. Assuming that a large number deviate from the protocol, this may provide indications that the method manuals need to be more specific to insure that the protocols are followed.

Page 3:
EPA in the study design is correct in assuring:

> *"The laboratories selected by EPA should typify laboratories that routinely conduct WET testing for permittee."(emphasis added)*

However as our comments will show, the study design is flawed in that it will exclude laboratories from the study, even though those laboratories are performing the tests, permittees are submitting the data from those laboratories and regulatory agencies are accepting the data from those laboratories. EPA needs to modify the study design to allow laboratories to participate in the study as long as they are performing WET tests for NPDES permits and certify that they are using the methods as outlined in the manuals.

EPA states that they will provide specific instructions to each participating laboratory to insure that the are using the applicable promulgated method. These types of instructions are unnecessary and will negate the "blind" aspect of the study by highlighting the samples as special. The only specific instructions should be the dilution factor and to direct the laboratory to follow the method explicitly. The data can be judged later in the data review to insure that the methods were followed and to document the incidence of method deviation. EPA will need to know for future actions exactly how prevalent the problem is of method deviation. The study as currently envisioned will not provide that information, nor will it provide an opportunity to determine what the impacts of that deviation on the program.

Page 4:
The questions for the peer reviewers with respect to additional parameters for either the study or prequalifications must insure that:

- the study must be “double blind” so that laboratories do not know they are participating in this type of study;

- the requirements do not go beyond the mandatory requirements of each method and that the non-mandatory parts of the methods do not become mandatory;

- that laboratories which are actively performing compliance monitoring for permittees are not precluded from participating; and

- with respect to charge five, that the document is revised to provide the peer reviewers with sufficient information that they truly understand the concept of *"within the context of the intended regulatory use."* This was elaborated earlier in these comments.

Page A3 of the study design:
There is no discussion of using blanks as one of the test samples. This is a serious omission which undermines the study itself. The study omits an evaluation of NOEC/LOEC as reliable endpoints in the methods. This is a serious omission due to the fact that majority states use these endpoints in their regulatory programs. While it is not possible to evaluate NOEC/LOEC through traditional statistics, there are other ways to measure the degree of agreement/disagreement in split samples. This type of data is needed to evaluate the acceptability of these endpoints in the regulatory program. The charge to the peer review panel should be revised to address this area of concern.

Page A4:
The use of the clarifying memo in judging the acceptability of the tests is inappropriate given that many states do not recognize the validity of this as a requirement. The only way this can be accepted is if EPA agrees in advance that, as a minimum, the methods will be opened and this memo added as a requirement.

Page A5:
The acceptability of tests based upon meeting test requirements is acceptable, however, it is imperative that the laboratory submit the data and indicate that it does meet the requirements. EPA should then review and report the number of false or incorrect reports submitted by the laboratories. AMSA sees this submission of reports by laboratories as meeting test requirements when in fact it does not, as a national problem which needs quantification and resolution.

In Section 3, EPA discusses voluntary laboratory participation, however, how can the study be blind when you are asking for volunteers to participate? It is imperative that the study be truly "double blind" and take advantage of AMSA members offer to pay for the analyses if the samples are shipped blind as routine samples.

Page A6:
The prequalification requirements undermine the initial intent of the study which was stated earlier in the document:

> *"The laboratories selected by EPA should typify laboratories that routinely conduct WET testing for permittee."(emphasis added)*

AMSA urges EPA to consider using laboratories which certify that they follow the methods and then evaluate the test to insure that they do indeed adhere. This type of study would allow EPA to evaluate the effect that method deviation has on data and the regulatory program, and to direct efforts to fix this if it is found to be a national problem.

The addition of a prequalification test appears to be unnecessary because the data is not used, nor should it be, for screening out laboratories. It seems to be a redundant effort to insure that the laboratories are not lying about following the methods. If EPA is concerned that many laboratories are not following the methods, then it reinforces our earlier comments about the need to quantify this problem and fix it at the national level.

Page A7:
Once again EPA, in requiring laboratories to participate at their own cost, undermines the blind aspect of the study. AMSA urges EPA to use the approach where POTWs pay for the laboratories to participate with the samples sent blind to represent routine samples for testing and not some special EPA program. EPA must recognize that by now most everyone in the business knows about this effort.

Page A12:
EPA is proposing that additional requirements, such as specifying dilution and control water (bullet 5) be specified for each test. This is inappropriate, if the methods allow for different dilution waters, then those should be allowed. If EPA wants to evaluate the effect of dilution water selection on variability, then the study should ask each laboratory to use a standard water in addition to their routine water.

Page A13:
Item 14 once again is restricted to IC25 for the chronic tests and not NOEC. This should be expanded as per our comments on this issue noted earlier in our comments.

Page A28:
Item 4 requests laboratories to provide data charts with both IC25 and NOEC. This would require many laboratories to recalculate their charts over the last couple of years. This is inappropriate. Furthermore, the item asks for the laboratories to explain why they use one over the other. For many laboratories, particularly POTW laboratories, it is because the states favor one over the other and, therefore, there is no reason to use both. Once again it is imperative that the study evaluate the NOEC endpoint.

Page A29:
Rejection criteria, item 7, states that a laboratory must pass the DMR QA/QC study in order to participate. While this generally is understood, there are flaws in the study which precludes its utility. This study favors laboratories which show toxic effects. Given that it is possible only to induce toxicity with poor

techniques and not inhibit toxicity, failure to show toxicity in the DMR QA/QC study

should not be grounds for a laboratories rejection. This requirement should be modified to reject laboratories that fail because they report toxicity greater than the acceptable range. Part II on data evaluation should, once again, be expanded to include NOEC.

Thank you for the opportunity to comment. If you have any questions, please call me at 757/460-4243.

Sincerely,

Norman E. LeBlanc
Chair, AMSA Water Quality Committee

cc: Steve Sweeney, EPA Office of General Counsel
Bill Telliard, EPA Office of Science and Technology