



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

EPA-SAB-EHC-89-011

October 21, 1988

OFFICE OF
THE ADMINISTRATOR

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Science Advisory Board's review of the Analytical Methodology relating to the regulation of drinking water contaminants involved in the Phase II draft regulations.

Dear Mr. Thomas:

The Drinking Water Subcommittee of the Science Advisory Board's Environmental Health Committee has completed its review of the issues pertaining to analytical methodology of drinking water contaminants involved in Phase II proposed regulations from the Office of Drinking Water at its meeting in Cincinnati, Ohio, June 2-3, 1988.

The major recommendations of the Subcommittee include: 1) giving special attention to the potential dangers of matrix and intercompound interactions and interferences, 2) using real world samples in the development of new methods and in certifying laboratories with concern for accuracy and not simply precision, 3) considering the use of higher factors for setting the PQL above the MDL if methods demonstrate bias or interference problems, 4) certifying methods that cover several compounds not just individual compounds, 5) continuing the onsite inspection program, 6) using blind samples in evaluating laboratories, and 7) considering third party certification programs.


We appreciate the opportunity to conduct this particular scientific review. We request that the Agency formally respond to the scientific advice provided herein.

Sincerely,

A handwritten signature in dark ink, appearing to read "Norton Nelson".

Norton Nelson
Chairman, Executive Committee

Richard A. Griesemer
Chairman,
Environmental Health Committee


Gary P. Carlson
Chairman
Drinking Water Subcommittee

SUBJECT: SCIENCE ADVISORY BOARD'S REVIEW OF ISSUES RELATING TO ANALYTICAL METHODOLOGY IN THE REGULATION OF DRINKING WATER

SCIENCE ADVISORY BOARD COMMITTEE: DRINKING WATER SUBCOMMITTEE OF THE ENVIRONMENTAL HEALTH COMMITTEE

DATE OF REVIEW: JUNE 2-3, 1988

PLACE OF REVIEW: EPA LABORATORY, CINCINNATI, OHIO

The Drinking Water Subcommittee met to review the analytical methodology involved in the development of drinking water regulations and in part to consider those methods that are part of the Phase II regulations being proposed by the Office of Drinking Water. The primary issue under consideration was how to determine whether or not a laboratory is performing adequately without the laboratory's knowing of the examination. Other issues were brought up by the Subcommittee and are discussed here. This report was one of four developed at the two day meeting in which the Subcommittee divided into subgroups which discussed and developed each of the reports before sharing their recommendations with the full Subcommittee.

I. Analytical Concerns in Phase II of SDWA Regulation

A. General

There are a large number of methods which must be developed for the phase II compounds in drinking water and water supplies. Given the problem of the number of compounds and the short time available, the Environmental Monitoring and Support Laboratory approach of developing broad spectrum methods with as wide a variety of analytes and media as possible is commendable. This approach, however, has intrinsic problems. Broad spectrum methods inherently are less selective for specific compounds of interest. The Subcommittee recommends that the Agency give special attention to the potential dangers of matrix and intercompound interactions and interferences as outlined below.

B. Bias or accuracy versus reproducibility or precision

Bias errors are usually produced by matrix and intercompound interactions and interferences. Errors of this type are most often associated with complex or real world samples. Bias errors are difficult to identify since the same inaccurate value may be found each time replicate samples are analyzed. Satisfactory performance, both accurate means and low standard deviations, with reagent water and pure samples may also be found. The best and often the only way to test for bias errors is to gather data on a variety of real-world samples. Data provided the Committee so far for the new methods being developed for Phase II compounds in water were generally satisfactory for laboratory samples prepared with distilled water. However, there are few data on

complex natural waters for many of the compounds. Interferences are therefore not yet evaluated for these methods. It is recommended that the Phase II compound methods be tested with concern for accuracy, not simply precision, by using real world samples.

This testing can be done by a single operator obtaining precision and accuracy measurements with split, real-world samples spiked with a mixture of standards into a variety of matrices. Half of the split sample is used to measure the background level of the standards naturally present. The concentrated level of the standard addition above background is measured and must be a minimum level above background to be valid. There are many different procedures that can be followed here including the one from EPA's Handbook for Analytical Quality Control in Water and Wastewater Laboratories.

C. Practical quantitation limit ("PQL")

PQL is a reasonable concept. It is based on the lower precision and accuracy available in the practical application of a method. The difference between the minimum detectable level ("MDL") and a PQL depends not only on laboratory and equipment differences and the variety of technical skill levels found in practice, but also on the interference or bias error problem discussed in B above. It is recommended PQL be a value based on round robin, multiple laboratory testing using real-world samples. For those methods and compounds which show interference problems in the testing done in Section B above, the spike or standard addition method discussed above or some other procedure capable of evaluating bias errors must be used to define PQL. If several methods show bias error problems, the short time available for such testing may make it impossible to define statistically valid PQL values in a timely fashion. If such a circumstance occurs, it is recommended that at a minimum higher factors than those commonly used be selected on the basis of the few data available be used to set PQL values above method detection limits for methods with bias or interference problems.

D. Health hazards of diazomethane

The use of diazomethane for derivatization is not recommended. The laboratory health hazard of diazomethane may be as large as the drinking water hazard being regulated. The Subcommittee recommends that alternative derivatization methods should be used such as those described in more detail in the paper; Simple Device for Preparing Ethereal Diazomethane, by H.M. Fales, T.M. Jorine and J.F. Babashek in Analytical Chemistry, 45:2301 (1973).

II. Laboratory Certification

A. Method, not compound, certification

The large number and variety of compounds needing to be measured under the new phases of the SDWA make it mandatory that laboratories be certified by method rather than compound. It is recommended the compounds used to provide method certification be chosen from those most likely to provide accuracy and detection limit problems consistent with choosing compounds likely to be commonly found in water samples. More than one compound should be used and these should be rotated to provide the maximum challenge to the laboratories being certified.

B. Continue on-site inspection program

It is recommended that the on-site inspection program be continued at least at its present level as the program appears adequate.

C. Increase number of performance evaluation (PE) samples

The Subcommittee recommends that an increased frequency of performance evaluation samples should be used, where the exact frequency needs to be determined based on the specific details and needs of the situation. To the extent practical these samples should be blind samples. It is recommended that a set of protocols be developed for samples sent for submission by municipalities using commercial laboratories and that the results should be relayed from municipalities to the Agency. If blind samples are not possible, use split samples measured both by municipal laboratories and certifying agency (state, third agency or EMSL) laboratory. More details on certifying agencies can be found in Appendix D of the Office of Drinking Water's Manual for the Certification of Laboratories Analyzing Drinking Water.

E. Establish third party certification program

The Subcommittee recommends that EPA further consider the establishment of third party certification programs. Many advantages appear to be available through third party certification programs including the ability to provide an expanded program through the ability to charge for the certification service and the ability to provide more representative and blind samples. Since this program is new the Agency should follow it closely and monitor the results.

U.S. Environmental Protection Agency
Science Advisory Board
Drinking Water Subcommittee

CHAIRMAN AND VICE CHAIRMAN

Dr. Gary Carlson [CHAIR], Department of Pharmacology and Toxicology, School of Pharmacy, Purdue University, West Lafayette, Indiana 47907 (317) 494-1412

Dr. Robert Tardiff, [VICE-CHAIR], Principal, Environ Corporation, 1000 Potomac St., N.W., Terrace Level, Washington, DC 20007 (202) 337-7444

MEMBERS AND CONSULTANTS

Dr. Julian B. Andelman, Graduate School of Public Health, 130 Desoto Street, Parran Hall - Room A-711, University of Pittsburgh, Pittsburgh, PA 15261

Dr. Rose Dagirmanjian, Professor, Department of Pharmacology and Toxicology, University of Louisville, Louisville, Kentucky 40292 (502) 588-5160

Dr. William Glaze, Director, School of Public Health, University of California, Los Angeles, 650 Circle Drive South, Los Angeles, CA 90024 (213) 206-1278

Dr. J. Donald Johnson, Professor, School of Public Health, University of North Carolina, Chapel Hill, NC 27514 (919) 966-3856

Dr. David Kaufman, Department of Pathology, University of North Carolina, Rm. 515 Brinkhous-Bullitt, Chapel Hill, North Carolina 27514 (919) 966-1396

Dr. Nancy Kim, Director, New York Department of Health, Bureau of Toxic Substance Assessment, Room 359, Tower Building, Empire State Plaza, Albany, New York 12037 (518) 474-2084

Dr. Verne Ray, Medical Research Laboratory, Pfizer, Inc. Groton, Connecticut, 06340 (203) 441-3564

Dr. Harold Schechter, Professor, Chemistry Department, Ohio State University, 140 West 18th Avenue, Columbus, Ohio 43201 (614) 292-6300

Dr. Thomas Tephly, Professor, Department of Pharmacology, The Bowen Science Bldg., University of Iowa, Iowa City, Iowa 52242 (319) 335-7979

EXECUTIVE SECRETARY

Dr. C. Richard Cothorn, Executive Secretary, Science Advisory Board
[A-101F] U.S. Environmental Protection Agency, Washington, D.C. 20460
(202) 382-2552