



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4


Science and Ecosystem Support Division
980 College Station Road
Athens, Georgia 30605-2720

FEB 22 2005

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MEMORANDUM

SUBJECT: Policy notice for use of discreet analyzers under the Clean Water Act (CWA) Regulations including National Pollution Discharge Elimination System (NPDES), Storm Water Regulations, Pretreatment for Publicly Owned Treatment Works and to State Water Quality Standards where referenced to NPDES requirements

FROM: Michael V. Peyton 
Director

TO: All EPA Region 4 State Environmental Departments and Environmental Laboratories in Region 4.

A memorandum from the Office of Water dated January 27, 2005, was received in the Regions which outlined the recommendations for use of discreet analyzers with approved methods under the CWA. EPA Region 4 staff have reviewed these recommendations and endorsed these recommendations as a measure for consistency across the Region. Because of the variability among the various manufactures, it is necessary for state and regional auditors to have the information which is outlined in the memorandum prior to going on site. This is needed in order to properly assess the discreet analyzers use in the various laboratories. The information outlined in the memorandum is the minimal information needed. State and EPA Regional auditors may request additional supporting documentation as needed.

A copy of the EPA Office of Water memorandum is attached.

This letter constitutes the Region 4 policy for the use of discreet analyzers for analyses performed on samples that originated in any of the states in Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee). Laboratories analyzing samples from other EPA Regions should contact the Quality Assurance Manager in those Regions for specific policy or requirements. If you need additional information or assistance with this document contact Wayne Turnbull at 706-355-8554 or by e-mail at Turnbull.Wayne@epa.gov

Attachment



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

OFFICE OF
WATER

JAN 27 2005

MEMORANDUM

SUBJECT: Guidance on the Use of Discrete Analyzers Under EPA Clean Water Act Programs

FROM: Geoffrey H. Grubbs, Director
Office of Science and Technology

Geoffrey H. Grubbs

TO: Water Division Directors
Quality Assurance Managers
ATP Coordinators
NPDES Coordinators

We have received some inquiries from several instrument manufacturers about our position on the use of discrete analyzers as an alternative to the use of test procedures (i.e., analytical methods) approved under 40 CFR Part 136. This memorandum provides recommendations on the use of discrete analyzer instrumentation for permitting and compliance monitoring under EPA's Clean Water Act (CWA) programs. This memorandum does not address laboratory certification requirements that states have mandated. The recommendations contained in this memorandum are applicable to the use of discrete analyzers under CWA programs only.

Background

For purposes of this memorandum, a "discrete analyzer" is defined as "an instrument that automates an analysis performed by a method approved at 40 CFR Part 136, and produces results equivalent to results produced by the approved method." As such, discrete analyzers are capable of improving laboratory efficiency and reducing laboratory waste.

In principle, if a method employing a discrete analyzer simply automates the chemistry in the corresponding approved method, then the method employing a discrete analyzer should produce results equivalent to those produced by the approved method. EPA's Office of Science and Technology (OST) has reviewed information submitted by manufacturers, dischargers, and laboratories regarding the application of discrete analyzers in environmental analyses and has determined that discrete analyzers can produce results equivalent to results produced by methods approved at 40 CFR Part 136.

Recommendations on the Use of Discrete Analyzers

Under the National Pollutant Discharge Elimination System (NPDES) permits program, monitoring must be conducted according to test procedures approved under 40 CFR Part 136 for the analyses of pollutants having approved methods under that part, and according to a test procedure specified in the permit for pollutants with no approved methods [See 40 CFR § 122.44(i)(1)(iv)]. The responsibility for generating acceptable compliance data rests with the discharger and its laboratory. Therefore, the discharger and its laboratory are responsible for demonstrating that the results obtained when employing a discrete analyzer are equivalent to the results produced by the approved method. We recommend that permitting authorities specify in the NPDES permit that the discharger and its laboratory ensure that methods using discrete analyzers produce results equivalent to those produced by the approved methods (see criteria below on equivalency demonstration). To ensure equivalency, we recommend that Regions and permitting authorities use the following items when evaluating a discharger or its laboratory for using a discrete analyzer instrument:

- The discharger or its laboratory should notify the appropriate state regulatory/control authority prior to use of a discrete analyzer instrument and the applicable parameter(s).
- Regions and permitting authorities should allow use of a discrete analyzer only if there is an equivalent method approved at 40 CFR Part 136 and the requester clearly identifies the approved method. All other sample preparation requirements including sample distillation and digestion must be adhered to as stated in 40 CFR Part 136.
- The method employing a discrete analyzer should use the same reagents and chemical reactions as the promulgated method. Any changes, such as use of surfactants or slight pH changes, that do not affect the chemical reaction should be documented and justified.
- Final chemical ratios in the method employing a discrete analyzer that affect the result of the determination should be the same as the ratios in the approved method.
- The discrete analyzer instrument should use the same measurement technology as the approved method (e.g., colorimetric or spectrophotometric).
- The analytical range of the method employing a discrete analyzer should be similar to the analytical range of the approved method and must meet the requirements of the permit.
- The number and range of calibration standards in the method employing a discrete analyzer should be equal to or greater than the number and range of calibration standards in the approved method.
- The precision, recovery, and method detection limit (MDL) obtained with the method employing a discrete analyzer should be equal or superior to the precision, recovery, and MDL in the promulgated method. In cases where the approved method does not contain quality control (QC) acceptance criteria for precision, recovery, and MDL, we recommend

that the laboratory use QC acceptance criteria in the alternate test procedure (ATP) protocol. (see <http://www.epa.gov/waterscience/methods/EPA821B98003.pdf>).

- Details of the method employing a discrete analyzer should be consistent with details of the approved method including: preservation and holding time requirements (40 CFR Part 136, Table II), interferences, and required QC measures, as specified in the approved method or otherwise required by EPA.
- The discharger and its laboratory should keep documentation on file that demonstrates that the method employing a discrete analyzer provides equivalent results to the approved method. The instrument manufacturer may provide the equivalency demonstration documentation [and may collect it as specified in the ATP protocol or the EPA National Environmental Research Laboratory-Cincinnati (NERL-Ci) side-by-side protocol (<http://old.lib.ucdavis.edu/govdoc/EPA/atpnpdes.pdf>).] However, the laboratory should also keep on file the results of laboratory performance tests (e.g., MDL data, initial precision and accuracy data) demonstrating that the discrete analyzer is capable of producing results equivalent or superior to results produced by the approved method.

If the discharger and its laboratory meet the above recommendations, then OST believes that a method employing a discrete analyzer is an acceptable version of the approved method and does not require an application and approval through EPA's ATP program at 40 CFR §§ 136.4 and 136.5.

Attached is a checklist of the information that laboratories should maintain on file for use of methods employing a discrete analyzer. If you have questions or comments regarding this memorandum, please contact William Telliard at (202) 566-1061.

cc: Mary T. Smith
Herb Brass
Robin K. Oshiro

Attachment

Attachment A

Discrete Analyzers Equivalency

Use of discrete analyzers for certain of the EPA methods may be used if:

1. The manufacturer provides a written certification that the use of the technology with the manufacturer's accompanying technical notes is equivalent* to the cited EPA method and
2. The following supporting information is provided

Two-Column Comparison:

EPA Reference Method
Scope & Application
 Applicable Range
Method Summary
Equipment
Reagent & Standard Preparation
Final Ratios
Method Performance
 Precision
 MDL
 Accuracy'

Technical notes:

Must discuss or cite:

- Acceptability by specific EPA Programs
- Interferences
- Safety
 - Support and Analytical Equipment and Supplies
 - Reagent preparation, storage and handling
 - Most recent sample handling and/or preservation requirements
 - Quality Control measurements and acceptance criteria
 - Calibration and standardization
- Sample preparation (digestion, distillation, etc) as required by the cited method or Federal Register
- Detailed procedure using the manufacturer's instrument
- Data Analysis and Calculations
- Pollution Prevention and Waste Management

Supporting Information:

Typical Calibration Curve, using recommended number of calibration points

Method Detection Limit Study (meeting EPA requirements for number, and concentration level)

Precision and Accuracy Studies (at approximately 10X the MDL)

*equivalent means that the manufacturer's method uses the same reagents (surfactants excluded) as the cited method; the determinative instrumentation, and the final chemical ratios are the same; the range of use and the number and concentration of the recommended calibration standards are equivalent; and the precision, accuracy and method detection limit for the manufacturer's method is equal to or better than the cited method