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

MEMORANDUM

SUBJECT: Update on Allowed Use of Modified CWA Methods

OFFICE OF WATER

FROM: Richard Reding, Chief
Engineering & Analytical Support Branch, EAD, OST

TO: Quality Assurance Managers
ATP Coordinators
NPDES Coordinators

DATE: June 5, 2007

I am writing to you about my Discrete Analyzer (DA) memorandum of April 2, 2007 in which I explained that Clean Water Act methods modified for use as discrete analyzers fall under the allowed flexibility of 40 CFR 136.6, and therefore need not and will not be reviewed under our Alternate Test Procedure (ATP) program. I am clarifying that it is the responsibility of the method developer or instrument manufacturer, not the user, to conduct the side-by-side comparison of the DA method with an approved Part 136 method.

We also are expanding the scope of these allowable modifications to methods modified to include the use of Segmented Flow Analyzer (SFA), Flow Injection Analyzer (FIA) or self-filling reagent vials (e.g.,Vacu-vials™ or Auto-Test™ Cuvettes) that contain the same reagents as those used in the approved methods provided that these methods meet the requirements of Section 136.6. We have returned all ATP applications noting that approval is not required, and that we will not review such modifications in the future. This allowance applies only to the CWA program.

We recommend that authorities ensure that methods using these modified methods produce results equivalent to those produced by the approved methods by requiring the following documentation: Each DA, SFA, FIA or self-filling reagent vials manufacturer should provide:

- a side-by-side method comparison demonstrating similarities to and differences from the approved method(s), and
- all data comparing the performance of the modified methods to the performance of the approved methods for all the requested procedures.

The laboratory should notify the regulatory authority and/or certification program in writing of the intent to use the SIA, FIA, DA technology or reagent filling vials method for reporting data. The laboratory need not conduct a side-by-side comparison, but before using the modified method the laboratory should demonstrate proficiency by:

- making a detailed SOP available,
- performing and documenting an initial demonstration of capability,
- checking the modified method on seven separate days on the plant effluent,
- using the same reagents, reactions and determinative step as the approved method,
- demonstrating proficiency by meeting the QC specifications of the method, In cases where the reference method does not provide quality control information, the targets listed in the December 1996 Streamlining Guide (http://www.epa.gov/waterscience/methods/guide/flex.html) or the QC found in the ATP Protocol (http://www.epa.gov/waterscience/methods/EPA821B98002.pdf) should be used.
- maintaining all manufacturer's method/data and the laboratory's documentation should be available for review.

I appreciate your interest and support of our efforts to streamline the methods approval process to allow timely introduction of useful compliance technologies. If you have any questions regarding the ATP program please contact Lemuel Walker at walker.lemuel@epa.gov.

cc Lemuel Walker, CWA ATP Coordinator
Steve Wendelken, SDWA ATP Coordinator