



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

MEMORANDUM

SUBJECT: Quality Assurance and Quality Control Requirements in Methods Not Published by EPA OFFICE OF WATER

FROM: Richard Reding, Chief RR
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TO: Regional Quality Assurance Managers

DATE: May 7, 2009

Auditors, our co-regulators, laboratory personnel, and the regulated community have noted the different amount and type of quality assurance (QA) and quality control (QC) procedures practiced by laboratories that use 40 C.F.R. Part 136 methods. Some of these methods are published by voluntary consensus standard bodies, such as "Standard Methods for the Examination of Water and Wastewater", and the ASTM, International compendiums, 11.01 and 11.02. These compendiums can be in print, electronic or web-based media, and have unique structures.

The subject of this memorandum is to address problems encountered in conducting analyses, or auditing laboratory practices when the:

- QA/QC requirements are sufficient, but published in other parts of an organization's compendium rather than within the Part 136 method, or
- QA/QC instructions in a Part 136 method are insufficient.

For example, the Standard Methods Committee consolidates general QA/QC requirements for all methods in Part 1000 of their compendiums. Other Parts (and Sections) may contain additional QA/QC requirements that are relevant to the pollutants (e.g., metals, nutrients, organic solvents) measured by the methods in that Part or Section. In ASTM methods, the QA/QC requirements are specified in the method's Referenced Documents section, and in the pollutant method. Both organizations publish QA/QC instructions so that analysts can achieve acceptable results. Consequently, EPA expects that an analyst using these consensus body methods for reporting under the CWA will also comply with the quality assurance and quality control requirements listed in the appropriate sections in the consensus body compendium. EPA's approval of use of these voluntary consensus standard body methods clearly contemplated that any analysis using such methods would also meet the quality assurance and quality control requirements prescribed for the particular method. As a result, neither an analysis using a specific 40 C.F.R. Part 136 method or one using a voluntary consensus body standard approved for

Part 136 that failed to meet the applicable quality assurance and quality control requirements of the respective methods would comply with EPA's NPDES regulations requirements to monitor in accordance with the procedures of 40 C.F.R. Part 136 for analysis of pollutants.

In subsequent editions of their compendiums, the Standard Methods Committee has modified their QA/QC sections to strengthen the procedures, and conform more to the QA/QC procedures in methods published by EPA. In rules published March 12 and 26, 2007, EPA approved use of the Part 136 methods published in the most recent edition of Standard Methods, but did not withdraw approval of previous editions of these compendiums. This has allowed analysts to choose which edition to follow, and in some cases has led to significant differences in the amount or type of QA/QC used. In some cases, analysts have disregarded some procedures with the rationale that the compendium QA/QC procedures are not sufficiently prescribed within the approved method.

Regardless of the publisher, edition or source of an analytical method approved for CWA compliance monitoring, QA and QC procedures are to be employed whether they are specified in the Part 136 method, or referenced by other means. For a method that is approved in more than one edition of a compendium an analyst should, at a minimum, follow the QA/QC in that edition. To improve consistency, labs should consider phasing-in and adopting the QA/QC procedures specified in the most recent, approved editions of that compendium.

An internal or external lab auditor or regulatory authority may identify Part 136 methods or laboratory standard operating procedures (SOPs) with insufficient QA/QC instructions. For example, some Part 136 methods that were developed before EPA and other organizations standardized QA/QC practices and method formats have insufficient instructions. For these methods analysts have three options:

- a) Refer to and follow the QC published in the "equivalent" EPA method that has such QC; or
- b) Refer to National Environmental Laboratory Accreditation Conference (NELAC) 2003 Standard as outlined in chapter 5 and appropriate appendices, or any update of the Standard; or
- c) Refer to the appropriate sections of the 40 CFR listed consensus body methods.

The following twelve quality control checks are to be considered essential and must be incorporated into the laboratory's documented quality system unless a written rationale is provided that indicates why these controls are inappropriate for a specific analytical method. These essential QC checks are:

1. Demonstration of Capability (DOC),
2. Method Detection Limit (MDL),
3. Reagent blank (also referred to as method blank),
4. Laboratory fortified blank (LFB, also referred to as a spiked blank, or laboratory control sample (LCS)),

5. Matrix spike (MS), matrix spike duplicate (MSD), or laboratory fortified blank duplicate (LFBD) for suspected difficult matrices,
6. Internal standard/s, surrogate standard/s (for organic analysis) or tracer (for radiochemistry),
7. Calibration (initial and continuing),
8. Control charts (or other trend analyses of quality control results), and
9. Corrective action (root cause analyses),
10. Specific frequency of QC checks,
11. QC acceptance criteria, and
12. Definitions of a batch (preparation and analytical).

Please share this memo with your co-regulators, and other appropriate parties, and contact me with any questions or suggestions at reding.richard@epa.gov. Your ATP coordinators or QA staff may contact Lemuel Walker at walker.lemuel@epa.gov.

cc: Regional QA Coordinators
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