



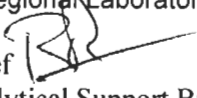
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JUN 27 2007

MEMORANDUM

OFFICE OF  
WATER

To: Gerry Sotolongo, Quality Assurance Manager  
EPA New England Regional Laboratory

From: Richard Reding, Chief   
Engineering and Analytical Support Branch  
EAD, OST, Office of Water

Topic: Regional Approval of Limited Use Methods

I am responding to your request for a follow-up to your conference call with our water law attorney, and other Regional Quality Assurance Managers about clarification of the Regional role in the alternate test procedure (ATP) approval process under 40 C.F.R. §136.5. The Water Law Office has reviewed this memorandum and concurs in its legal conclusions. In addition to clarifying Regional roles, I also describe our efforts (and a March 2007 regulation) to streamline approval of modified Clean Water Act (CWA) test procedures (methods.)

As you know, Section 136.5 provides for approval of ATPs in two circumstances. First, the Regional Administrator may approve the request of an individual NPDES discharger for use of test procedures other than those specified in Table I of Section 136.3. Second, an ATP may be approved for nationwide use, if the Administrator proposes to incorporate the new method into Section 136.3 and, after public comment, publishes a final decision to approve the method.

In the first circumstance, applicants may ask a Region to review and approve use of a new method or a modified Part 136 method at their facility. Sometimes we are consulted on these regional reviews and decisions. While we would appreciate being copied on limited use ATPs that the Regions review and approve, we do not need to see the applicant's data.

In the case of methods for which nationwide approval has been requested and Headquarters review has been completed, the regulations would allow limited use before EPA completes the process of national approval via rulemaking. Under EPA's Clean Water ATP program, a developer seeking nationwide approval of an ATP must first complete a multi-laboratory study of the method in representative circumstances that is reviewed by the Office of Water's Office of Science and Technology (OST). If OST determines that the method is both technically acceptable relative to other Part 136 methods, and applicable to CWA programs, the ATP coordinator writes the ATP applicant about this. These letters indicate that EPA should consider rulemaking for nationwide approval and that Regions approve the method under the limited use provisions of 136.5.

For the future, this Office in our ATP letters may indicate when we might conduct a rulemaking. In addition, for the sake of clarity, we also will stress that an ATP method with "interim" approval may be used for compliance monitoring by a facility only after limited use is approved by an EPA Region under Section 136.5, or if EPA has approved it for nationwide use through rulemaking. As you may know, we use the phrase "interim approval" in our ATP letters

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because the regulated community wants to see the word "approved" before considering compliance use of a non-part 136 method.

At the time method developers are notified of favorable action on their methods, we also will notify the Regions and note your authority to issue limited use approvals on a facility by facility basis under 136.5 without further individual review of the discharger's performance data. While Section 136.5 does not specifically provide the basis on which to approve a limited use ATPs -- the "scientific and technical" reasons or basis must be provided for approval or rejection (Section 136.5(b) & (d)) -- the application requirements in Section 136.4 indicate that the applicant must provide "justification" for using test procedures other than Part 136 methods (Section 136.4(c)(3) and explain why the ATP is applicable to the effluents in question (Section 136.4(c)(4)). We see no policy or legal basis for requiring individual applicants to duplicate OST's already thorough review. OST's "interim" determination of the applicability and comparability of the ATP to approved test procedures certainly provides appropriate justification for such approval. In the circumstances, allowing Regional applicants to simplify the approval process by "piggy-backing" on OST's conclusions is legally defensible and, at the least, minimally consistent with reducing unnecessary roadblocks to EPA regulatory action.

We recommend adoption of a simplified approach under Section 136.5 to approving use of ATP methods for individual NDPEs dischargers. After the first Regional limited use approval letter, the process for subsequent approval may be much streamlined because the application requirements of Section 136.4(c) (3) and (4) may be met by reference to the Region's earlier approval action. For the reasons explained above, a potential user need not submit lab data to receive a limited use ATP approval letter because a multi-laboratory validation study is a condition precedent to obtaining a favorable ATP letter from OST.

Following Regional approval of its use, an ATP method becomes like any other method used for compliance.<sup>1</sup> Users execute the initial and ongoing demonstration of capability instructions in the method, and document that they routinely run the method correctly. This data is kept on file for inspection at accreditation audits, or submitted if a client requests it. Although Regions or States have authority to request additional data for their limited use determination, such requests generally would not be necessary and are inconsistent with EPA's desire to promote the introduction and use of more effective or accurate methods. We expect that Regions will need to request additional performance data only if there is a significant concern that a specific ATP method would not work for a particular matrix, facility or industry.

I also want to inform you of the new CWA method flexibility amendment (40 CFR Part 136.6) that describes modifications one may make to a Part 136 method without EPA oversight. This amendment was promulgated on March 12, 2007 (72 FR 11200). We believe this action will significantly decrease the number of modifications submitted for ATP review. We recently eliminated about half of our ATP backlog by closing out discrete analyzer modifications that simply automated a manual Part 136 method. When combined with judicious and expedited approval of limited use ATPs, this flexibility should speed the introduction of better technologies. This decrease in the routine ATP burden allows regional and program chemists to focus on new or modified methods that clearly fall outside the scope of 136.6, and therefore justify review under ATP guidelines. Method developers benefit by use of ATP methods without the delay of national rulemaking.

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<sup>1</sup> Should the Regionally-approved method subsequently be proposed for inclusion in 40 CFR Part 136, and receive adverse comment requiring significant revision or withdrawal of the method, Regional approval may need to be reevaluated and possibly withdrawn.

My thanks to you and your Regional colleagues for your cooperation and support as we continue to streamline the methods approval program, and strengthen our partnerships with Regional and State ATP and quality assurance programs.

cc:

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