



Expedited Method Approval of Alternate Test Procedures for the Analysis of Contaminants under the Safe Drinking Water Act

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Safe Drinking Water Act (SDWA)

- SDWA defines three criteria for regulation of a contaminant in drinking water:
 - Adverse health effect
 - Occurrence
 - Regulation provides a meaningful opportunity for health risk reduction
- Primary Drinking Water Regulation for each contaminant specifies either a maximum contaminant level (MCL) or treatment technique

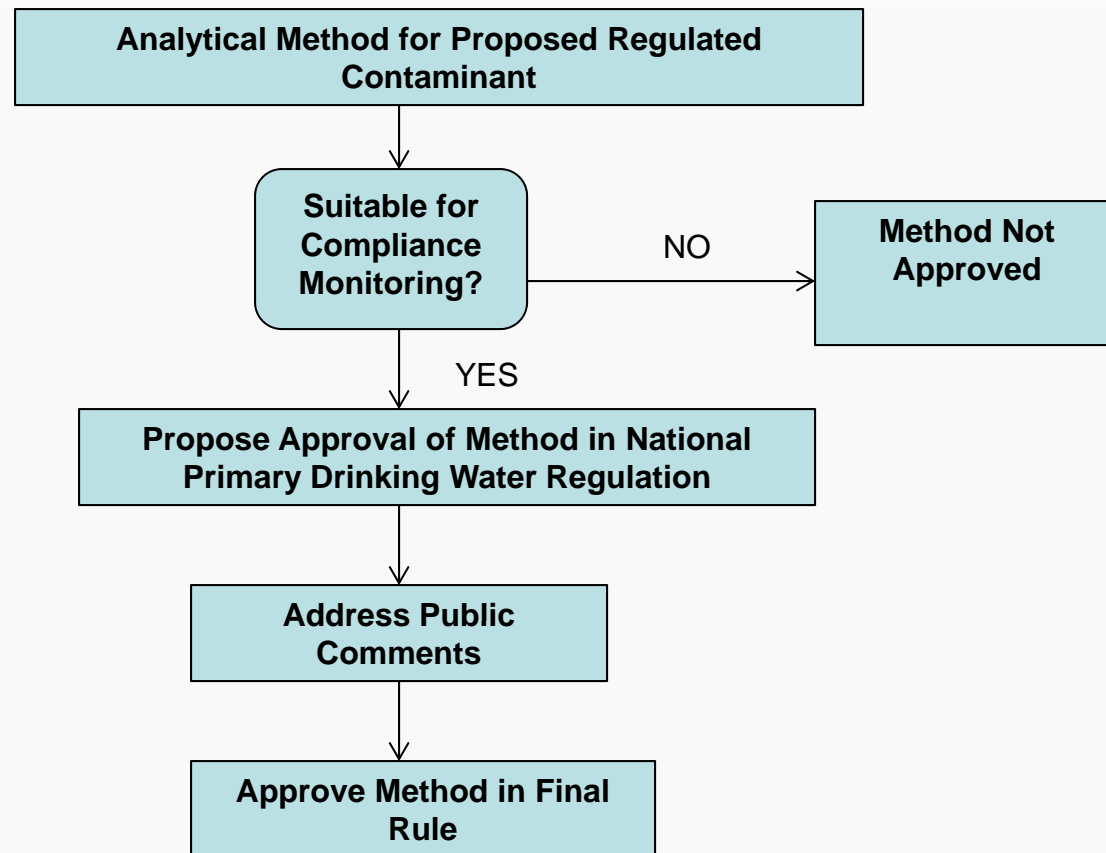


Safe Drinking Water Act (SDWA)

- Compliance with MCLs requires EPA to specify “accepted methods for quality control and testing procedures” with each Primary Drinking Water Regulation
 - With each MCL that is established, at least one analytical test method must be available and promulgated with the regulation
- SDWA also allows addition of “equally effective quality control and testing procedures” after promulgation of a regulation by publication of a *Federal Register* notice.



Regulatory Method Approval





Approved Methods are Listed in the *Code of Federal Regulations*

- Inorganic Methods: 40 CFR 141.23
- Organic Methods: 40 CFR 141.24
- Method for Radioactivity: 40 CFR 141.25
- Lead and Copper: 40 CFR 141.89
- Disinfection By-Products: 40 CFR 141.131



Drinking Water Alternate Test Procedure (ATP) Program

- ATP program does not have authority to approve alternate testing procedures
- ATP program evaluates modified or new testing methods (alternative testing procedures)
- Methods must undergo sufficient validation to support their use at the national level (multi-lab/multi-DW matrices)
 - Single laboratory approvals are not allowed
 - Regional approvals are not allowed

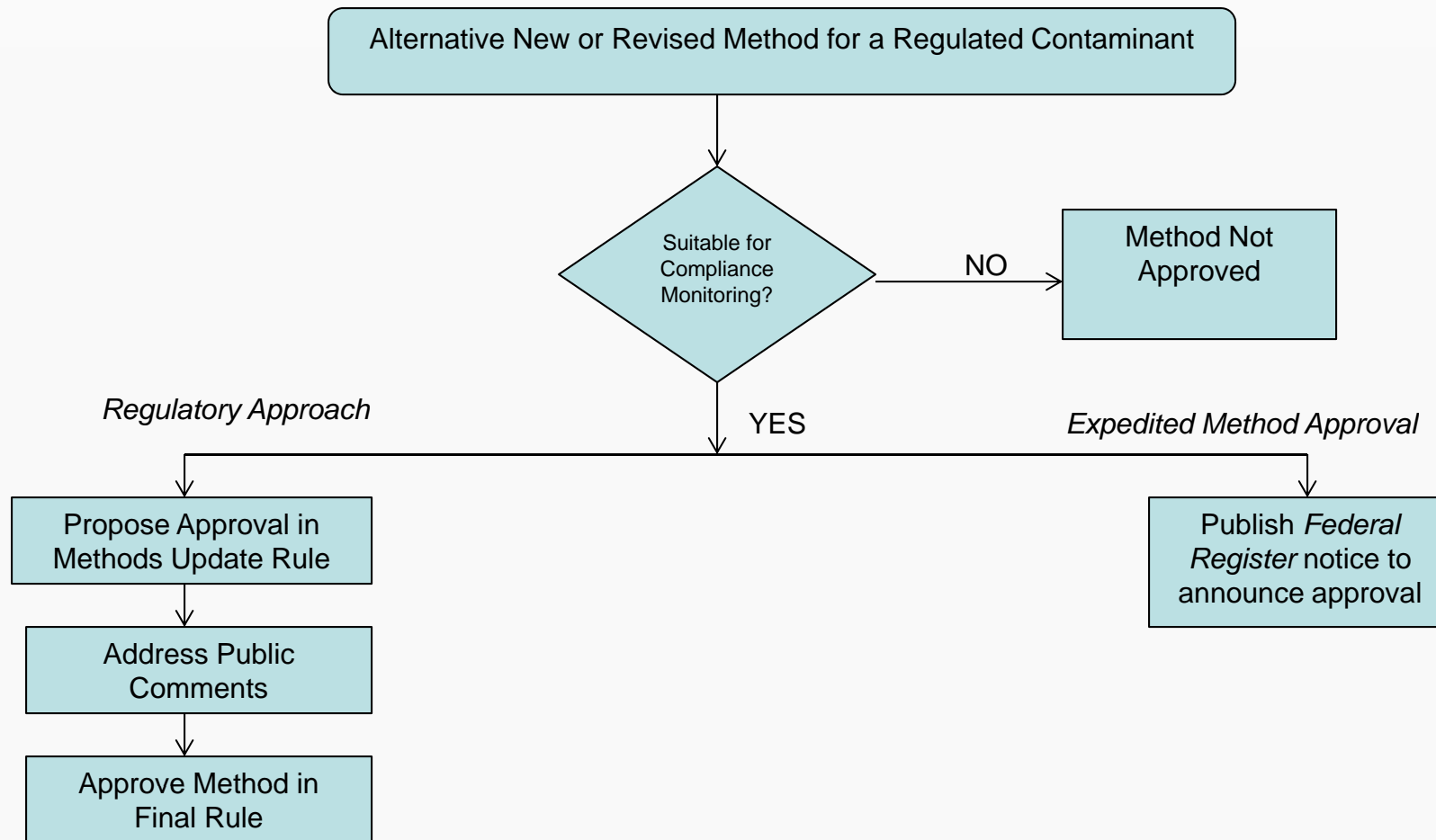


Drinking Water Alternate Test Procedure (ATP) Program

- Validation study compares method performance of modified or new method with method performance of approved method
 - Must be able to demonstrate the modified or new method is “equally effective” relative to the approved method
- Method approval can take two paths:
 - Promulgation through notice-and-comment rulemaking
 - Expedited method approval



Approval of Alternative Test Methods





Expedited Method Approval Process

Remember SDWA allows addition of “equally effective” methods through publication of a FR notice after promulgation of approved methods?

The Expedited Method Approval Process was proposed in April, 2007 (72 FR 17902) and the first action published June 3, 2008 (73 FR 31616).



Expedited Method Approval Process (cont.)

- Used to approve alternative test methods that are “equally effective” relative to method(s) cited in the regulations
- Approval decision is published in a *Federal Register* notice
- Methods are treated the same as those approved through the rulemaking process:
 - Data are acceptable for compliance monitoring & reporting
 - State adoption of alternative test methods is optional; however, if these methods are used, laboratory certification requirements extend to the use of methods approved through the expedited process



Expedited Method Approval Process (cont.)

- Non-regulatory process means:
 - Time required for approval is shortened
 - Notice-and-comment rulemaking takes 2-3 years on average for a rule to become final
 - Expedited method approval process allows alternative test methods to be available through preparation and publication of a FR notice within as little as 6-8 months
 - Methods are listed in the CFR
 - Not included in the regulation tables
 - Established Appendix A to Subpart C of Part 141 to list the methods approved through the expedited process



Expedited Method Approval Process (cont.)

- Method approvals include:
 - Methods evaluated through the drinking water ATP program
 - Voluntary Consensus Standard Body methods (Standard Methods and ASTM)
 - New or revised EPA methods
- Frequency of approvals
 - Anticipate publishing FR notices on an annual basis



Expedited Method Approvals

- Expedited method approval *Federal Register* notices published since June 2008:
 - 73 FR 31616 (June 3, 2008)
 - 74 FR 38348 (August 3, 2009)
 - 74 FR 57908 (November 10, 2009)
 - 75 FR 32295 (June 8, 2010)
 - 76 FR 37014 (June 24, 2011)
 - 77 FR 38523 (June 28, 2012)
- Over 100 optional, alternative methods have been approved



Expedited Method Approvals

Methods approved using the expedited process include:

- New and revised EPA methods
 - 334.0 - online free/total chlorine analyzers
 - 557 - direct inject IC-MS/MS for HAAs, bromate, and dalapon
 - 524.3 - VOCs. Changed preservation, flexible operating parameters, SIM analysis for EDB & DBCP
 - 525.3 - SOCs. Changed preservation, multiple SPE media & GC/MS options, improved guidance for data reduction of multi-component contaminants (e.g. toxaphene)
 - 1623.1 - *Cryptosporidium*. Addition of sodium hexametaphosphate improves accuracy/precision



Expedited Method Approvals

- Updates to Voluntary Consensus Standard Body methods:
 - ASTM International. Updated versions of methods approved in the regulations
 - *Standard Methods for the Examination of Water and Wastewater*. Updated versions of methods approved in the regulations, including the 21st edition as well as on-line versions. *The 22nd edition was published earlier this year and methods are under review for an upcoming expedited approval action.



Expedited Method Approvals

- Methods evaluated through the Drinking Water ATP Program
 - Chemistry methods
 - Turbidity (Mitchell Methods 5272, 5331; Orion AQ 4500; AMI Turbiwell)
 - Free/total chlorine analysis using disposable sensors (Chlorosense)
 - Nitrate/nitrite or nitrate only (Systea Easy 1-Reagent; Hach TNTplus)
 - Cyanide by Headspace GC/MS (ME 355.01)
 - Microbiological methods
 - Modified Colitag for Total Coliform and Ground Water Rules
 - Colilert 18, ReadyCult, Chromocult for Ground Water Rule



Expedited Method Approvals

- Expedited methods approval web page:
http://water.epa.gov/scitech/drinkingwater/labcert/analyticalmethods_expedited.cfm
 - FR notices
 - Current Appendix A to Subpart C of Part 141
- To find the specific methods:
 - Public docket associated with each FR notice (except copyright protected VCSB methods)
 - Drinking water methods web page:
http://water.epa.gov/scitech/drinkingwater/labcert/methods_index.cfm



Summary

- Expedited method approval process shortens the time between evaluation and approval of optional, alternative drinking water methods
 - Provides laboratories with access to newer technology sooner
- Established Appendix A to Subpart C of Part 141 to provide a central location in the CFR to find and cite methods approved using the expedited process
- Provides a standardized pathway between ATP evaluation and method approval