



# **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

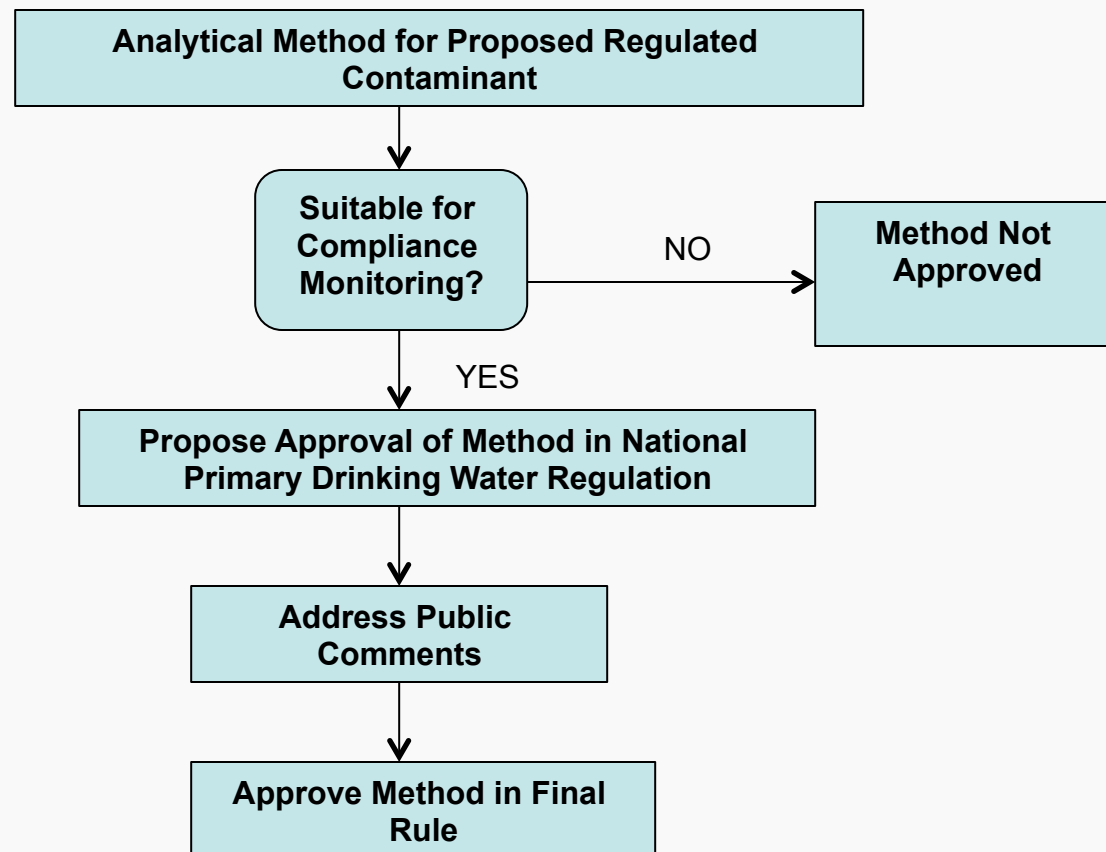


## Safe Drinking Water Act (SDWA)

- 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

([water.epa.gov/scitech/drinkingwater/labcert/alternatemethods.cfm](http://water.epa.gov/scitech/drinkingwater/labcert/alternatemethods.cfm))

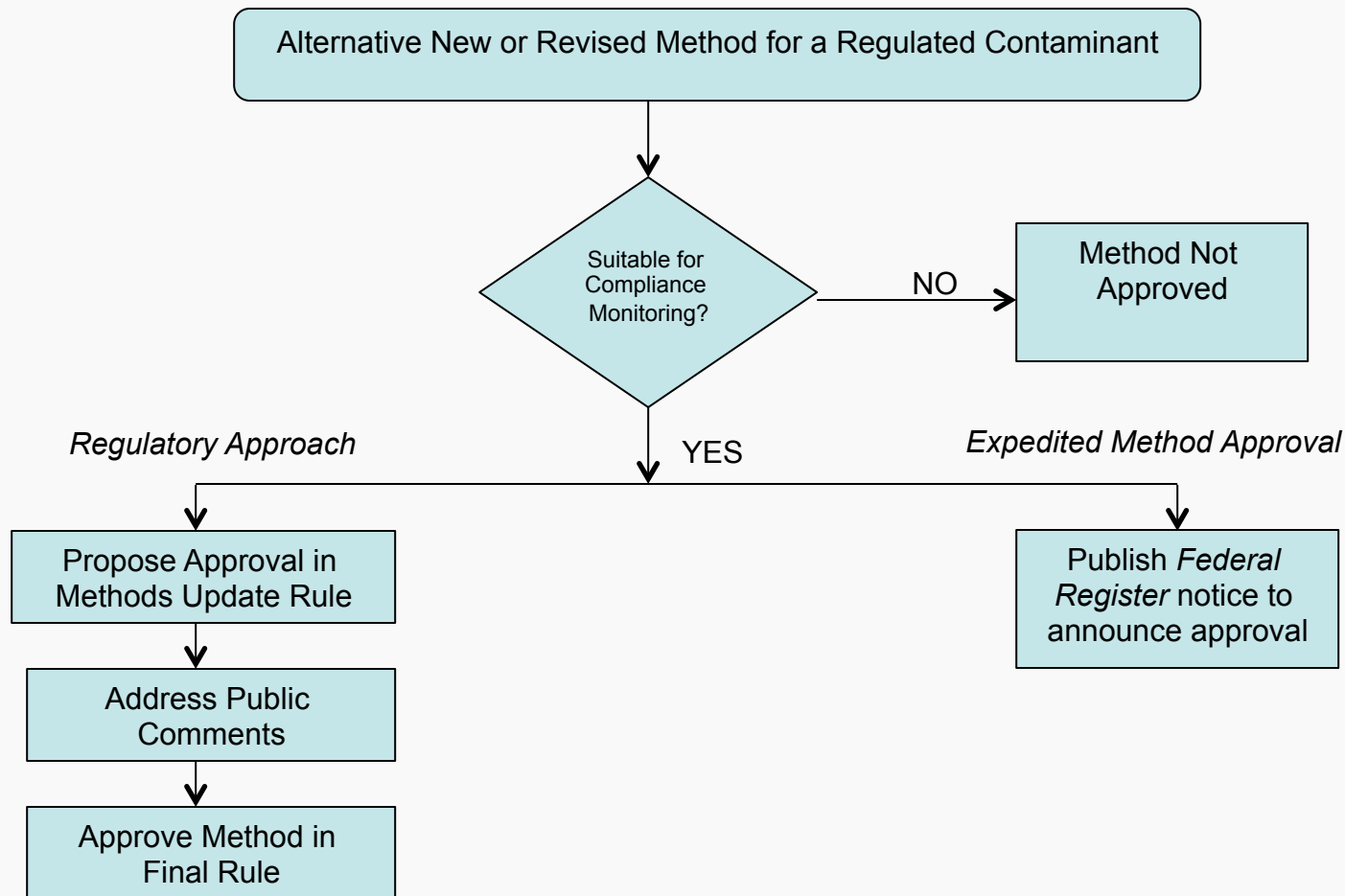


## Drinking Water Alternate Test Procedure (ATP) Program

- 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 approximately on an annual basis



## Expedited Method Approvals

- Expedited method approval *Federal Register* notices published since June 3, 2008 (73 FR 31616):
  - 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)
  - 78 FR 32558 (May 13, 2013)
  - 79 FR 35081 (June 19, 2014)
- Over 150 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
  - 524.3 - VOCs. Changed preservation, flexible operating parameters, SIM analysis for EDB & DBCP
  - 524.4 – VOCs. Same flexible parameters as 524.3; allows use of nitrogen as purge gas
  - 525.3 - SOCs. Changed preservation, multiple SPE media & GC/MS options, improved guidance for data reduction of multi-component contaminants (e.g. toxaphene)



## 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 21<sup>st</sup> and 22<sup>nd</sup> editions as well as on-line versions.



## Expedited Method Approvals

- Methods evaluated through the Drinking Water ATP Program
  - Chemistry methods
    - 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)
    - Chlorine dioxide/chlorite using disposable sensors for amperometric detection (Palintest ChlordioX Plus)
  - Microbiological methods
    - Charm Sciences, Inc. Fast Phage for coliphage detection (GWR)
    - IDEXX Laboratories Inc. Colilert 18 for total coliforms/*E. coli* (RTCR)
    - Veolia Tecta EC/TC for total coliforms/*E. coli* (TCR, RTCR, GWR)





## ATP/Expedited Collaborative Effort

- AWWA expressed concerns about radiochemical methods used for drinking water compliance
  - Methods have not been updated in over 30 years
  - Minimal QC (if any)
  - Inherent deficiencies (e.g., no pH check specified for a pH-dependent step)
- Revisions requested for
  - EPA Method 900.0 (Gross alpha and beta)
  - EPA Method 903.0 (Alpha-emitting radium isotopes)
  - EPA Method 903.1 (Ra-226 by radon emanation)
  - EPA Method 904.0 (Ra-228)



## Radiochemistry Methods Revisions

- Incorporate QC consistent with EPA DW laboratory certification manual
- Improve consistency relative to equivalent ASTM and Standard Methods
- Add detailed procedural steps to improve performance and comparability among laboratories
- Obtain input from radiochemistry methods experts
- Approve via expedited methods approval process



# Expedited Method Approvals

- Expedited methods approval web page:  
[http://water.epa.gov/scitech/drinking\\_water/labcert/analyticalmethods\\_expedited.cfm](http://water.epa.gov/scitech/drinking_water/labcert/analyticalmethods_expedited.cfm)
  - FR notices
  - Current Appendix A to Subpart C of Part 141
- To find 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](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