



Safe Drinking Water Act Methods and Current Collaborative Activities

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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.



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)
- Drinking Water 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 performance of modified or new method with 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



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 on average 2-3 years
 - 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)
 - 81 FR 46839 (July 19, 2016)
- Over 150 optional, alternative methods have been approved



Expedited Method Approvals

Most recent approvals (July 2016):

- ASTM International. Updated versions of methods approved in the regulations:
 - ASTM D 1253-14 – free, combined, and total chlorine
 - ASTM D 1125-14 A - conductivity
 - ASTM D 511-14 A,B – calcium, magnesium
 - ASTM D 1688-12 A,C – copper
 - ASTM D 3697-12 - antimony



Expedited Method Approvals

- Methods evaluated through the Drinking Water ATP Program and recently approved (July 2016)
 - Hach Method 10241 (Rev. 1.2) – free chlorine
 - Hach Methods 8026 (Rev. 1.2) and 10272 (Rev. 1.2) – copper
 - Hach Methods 10261 (Rev. 1.2) and 10267 (Rev. 1.2) – total organic carbon
 - Hach Method 10258 (Rev. 1.0) – turbidity
 - Nitrate Elimination Company, Inc. – nitrate reductase method for nitrite plus nitrate nitrogen
 - Thermo Fisher Discrete Analyzer Method – orthophosphate
 - Mitchell Method M5331 (Rev. 1.2) - turbidity



Radiochemistry Method Collaborative Efforts

- *AWWA et al.* expressed concerns about EPA 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 Method Collaborative Efforts

- 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
- Obtaining peer review input from radiochemistry methods experts
- Expect to recommend to OGWDW Office Director for future expedited methods approval action



Radiochemistry Methods Collaborative Efforts

- Standard Methods/ASTM International
 - Newer Techniques
 - Communication with Drinking Water ATP program
 - Multi-laboratory validation



Inter-Office Collaborative Efforts

- Office of Science & Technology Part 136 Method Update Rule
 - Participate in MUR Workgroup
 - Provided input on revisions to CWA 600-series methods and MDL procedure
- EPA 900-series radiochemistry method revisions
 - Add non-drinking water provisions (e.g. detection limits) so methods apply to other programs



Expedited Method Approvals

- Expedited methods approval web page:
<https://www.epa.gov/dwanalyticalmethods/expedited-drinking-water-analytical-method-approval-requirements>.
- To find specific methods:
 - Public docket associated with each FR notice (except copyright protected VCSB methods)
 - Drinking water methods web page:
<https://www.epa.gov/dwanalyticalmethods/approved-drinking-water-analytical-methods>.



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
- OGWDW seeks to work collaboratively with stakeholders and other agency offices