Drinking Water Analytical Method and Program Requirements: Roles and Responsibilities, Analytical Method Approval, and Effective Oversight

National Environmental Monitoring Conference
July 13, 2015

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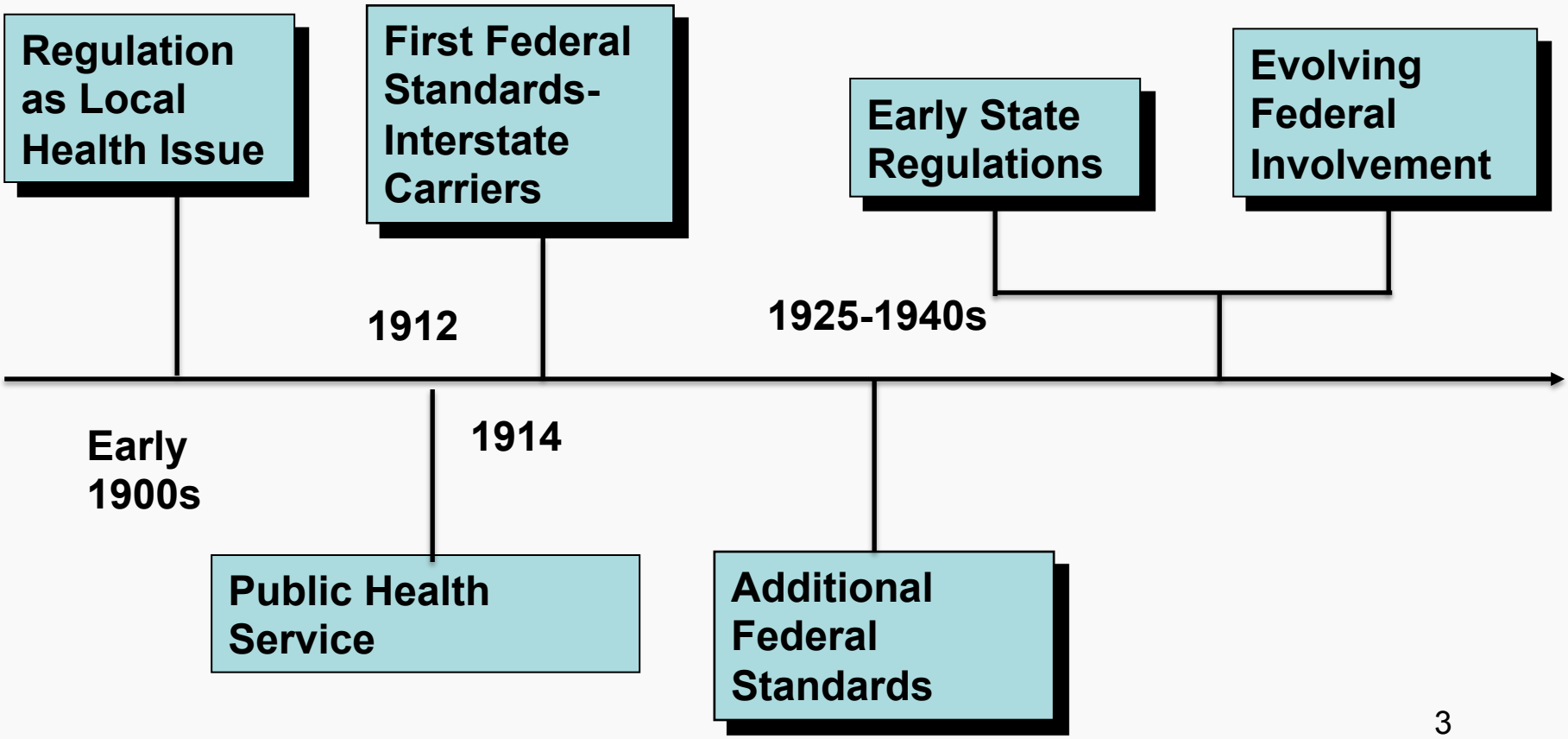
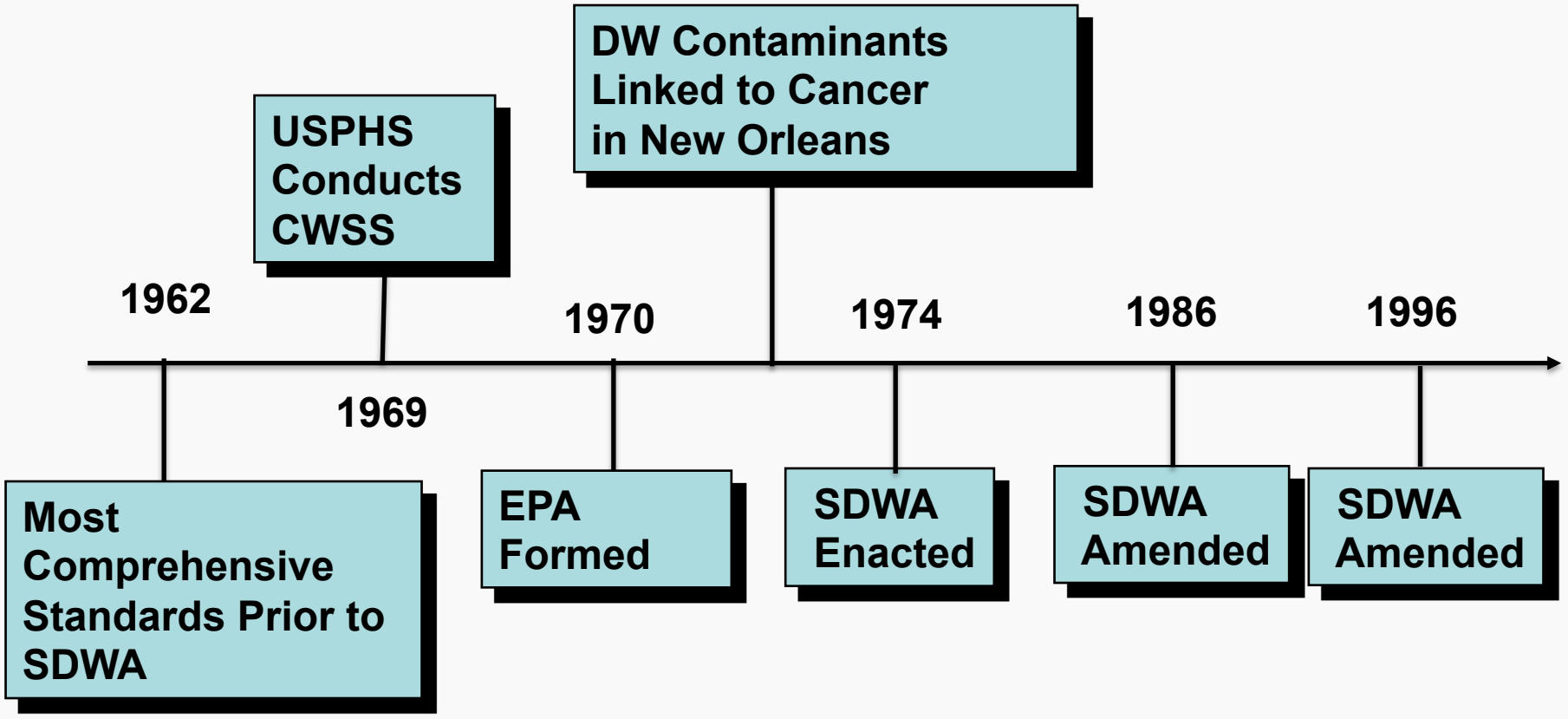
Presentation Overview

- SDWA history
- Oversight: roles and responsibilities
- EPA method approval
- Basic method QC elements
- Data integrity and inappropriate practices

History of Drinking Water Regulations



Evolving Federal Role



1970 - EPA Established

- Federal Drinking Water Program moved from U.S. PHS to U.S. EPA
- Surveys conducted in the early 1970s
  - 36 chemicals detected in finished water in LA.
  - Other surveys showed contamination on a national scale, particularly with synthetic organic chemicals.
- The increased awareness and concern prompted Congress to enact the Safe Drinking Water Act (SDWA)

1974 Safe Drinking Water Act Landmark Legislation

- Authorized EPA to set enforceable health standards for contaminants in drinking water
- Affects all PWS (15 service connections or average of 25 persons at least 60 days per year)
- Required that National Primary Drinking Water Regulations (NPDWR) be developed

Provisions of 1974 SDWA

- Established the public water system supervision (PWSS) program
- Underground injection control (UIC) program
- Sole source aquifer (SSA) programs
- Provided for State implementation -primacy

1986 SDWA Amendments

- Established regulations for 83 specific contaminants
- Required disinfection for most public water supplies
  - Filtration for most surface water systems
- Developed programs to protect ground water
- Established monitoring requirements for unregulated contaminants
- Banned lead in distribution systems
- Specified a “best available technology” for each contaminant

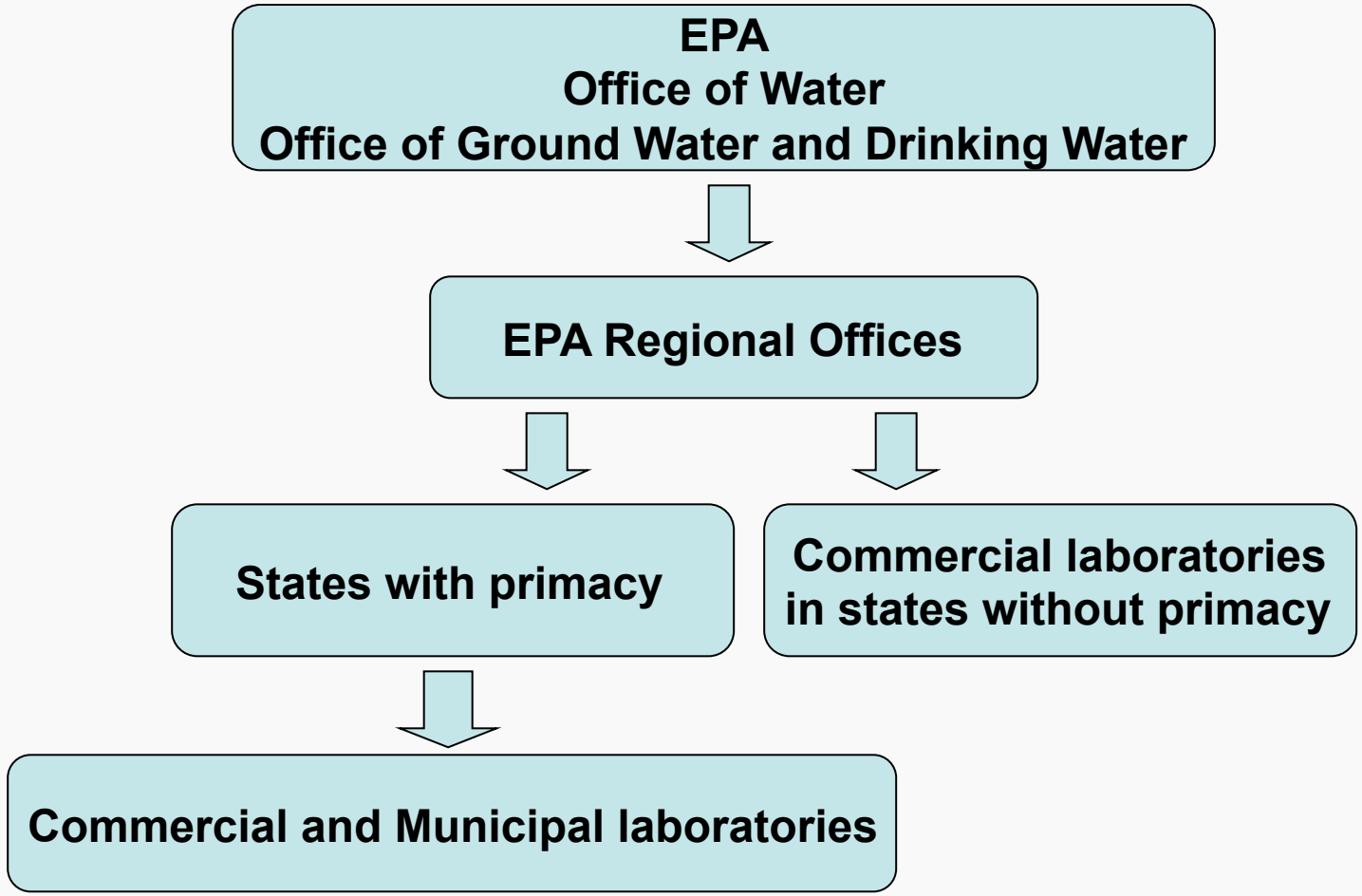
1996 SDWA Amendments

- Improved existing regulatory framework
  - Contaminant regulation priorities based on
    - Adverse health effects
    - Occurrence
    - Estimated reduction of health risk
    - Cost benefit analysis
  - Greater flexibility for State implementation
    - State Drinking Water Revolving loan Fund
    - Source water assessment and protection program
    - Special considerations for small water systems
    - Operator certification revisions

NPDWRs – Title 40 of the Code of Federal Regulations (CFR)

- Part 141 – PWS requirements
  - Certification of labs (40 CFR 141.28)
  - MCLs & Best Available Technology (BAT)
  - (40 CFR 141.60-141.66)
  - TT/Action Level for Lead & Copper (40 CFR 141.80)
  - Monitoring Requirements
  - Analytical Requirements
    - Methods are part of the NPDWR!
    - Must be followed as written
- Part 142 – Implementation & Enforcement
  - EPA & State requirements
- Part 143 – Secondary DWRs

Oversight: Roles and Responsibilities



Responsibilities - OGWDW

- Establishes drinking water regulations:
  - Ensures availability of methods to support regulations.
  - Sets criteria for Proficiency Testing.
  - Develops technical and administrative certification criteria in support of regulations.
- Oversees national drinking water laboratory certification program:
  - Reviews EPA regional certification programs.
  - Conducts training of Certification Officers.
  - Revises Manual for the Certification of Laboratories Analyzing Drinking Water.
- Provides technical assistance to EPA Regions and states.

OGWDW CO Training

- Attended by potential Regional and State Certification Officers
- Topics covered:
  - EPA regulations
  - Promulgated methods
  - Certification criteria from the lab cert manual
  - Auditing skills
- Mock laboratory evaluation
- Final examination

Responsibilities - EPA Regions

- Determines the certification status for PSLs.
- Oversight of state certification programs.
  - Assesses the scope, staffing, policies, procedures, and effectiveness
  - Observes state on-site evaluations of commercial labs.
- Hosts meetings for state certification officers.
  - Discuss program implementation issues and provide current information on regulations and methods.
- Provides technical assistance to states and certified laboratories.
- Manages the certification program and certifies laboratories in the non-primacy states, territories and Tribal Nation lands.

Responsibilities - Primacy States

- Implements regulatory compliance program to meeting National Primary Drinking Water Standards (NPDWS)
- Establishes a laboratory certification program

  (40 CFR 142.10)
  - Designate Certification Officers (COs).
    - COs review laboratory applications, conduct on-site audits of laboratories, and reviews laboratory PT data.
    - COs provide technical assistance to laboratories.
- Ensures the availability of certified laboratory facilities.
- Establishes public water system operator certification program.

State Role - Qualifications of COs and Auditors

- Experienced professionals who hold at least a bachelor's degree or equivalent education/experience in the discipline (chemistry, radiochemistry, microbiology or a related field) for which they certify.
- Have recent laboratory experience.
- Have experience in laboratory evaluation and quality assurance.
- Be familiar with the drinking water regulations and data reduction and reporting techniques.
- Technically conversant with the analytical techniques being evaluated.
- Able to communicate effectively, both orally and in writing.
- Successfully complete the appropriate EPA laboratory certification course.

What must a laboratory do to be certified?

- Comply with all federal regulations.
  - MUST follow promulgated methods.
- Meet criteria when specified in regulations.
  - Detection limit criteria.
  - Should meet minimum criteria as specified in Drinking Water Laboratory Certification Manual.
- Must successfully analyze at least one Proficiency Testing (PT) sample per year for each analyte using each approved methods they wish to employ.
- Must be able to meet acceptance criteria in methods.
- Must successfully pass an onsite evaluation.

Proficiency Testing

- EPA Sets PT Criteria in CFR
  - USEPA National Standards for Water Proficiency Testing Studies Criteria Document
- PT Provider Accreditors
  - A2LA, ANAB
- PT Providers
  - Accredited by TNI PTPA or any acceptable to the State
- Laboratories
  - One PT per method/analyte per year for certification
- Certification Officers
  - Track PT studies for labs

Other Considerations for Certification

- Are personnel qualified and sufficient?
  - Laboratory Director
  - Quality Assurance Manager
  - Laboratory Personnel
- Are promulgated/approved methods being used and requirements of those methods met?
- Are appropriate quality systems in place?
- Are laboratory facilities, equipment and supplies adequate?
- Are records adequate?

Why Certified Labs?

- Protects public health.
  - Ensures samples are consistently analyzed by the promulgated methods.
  - Ensures that results obtained are accurate.
    - The more variables that are controlled for, the more repeatable results become.
    - Data used for future regulatory development.
- Helps to protect laboratory, provides some defensibility.

EPA Method Approval

- Under 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.

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
- Appendix A to Subpart C of Part 141

Drinking Water Alternate Test Procedure (ATP) Program

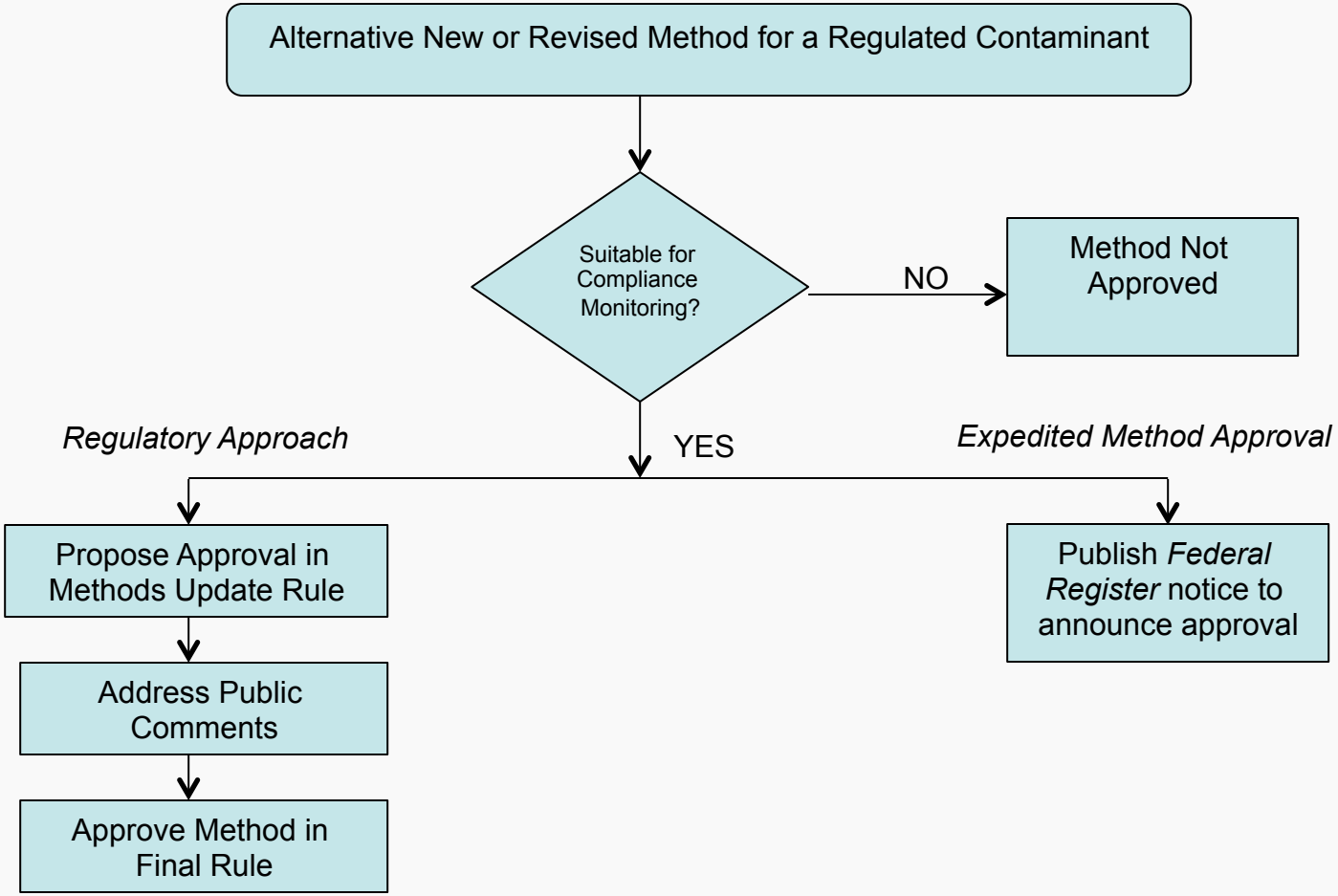
- ATP program does not have authority to approve alternate testing procedures
- ATP program evaluates modified or new testing methods (alternative testing procedures)
- Methods must undergo sufficient validation to support their use at the national level (multi-lab/multi-DW matrices)
  - Single laboratory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

(water.epa.gov/scitech/drinkingwater/labcert/alternatemethods.cfm)

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 Test Methods



more about…Expedited Method Approval Process

- Only applicable to drinking water – SDWA authority
- 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

Basic Method QC
(not an all inclusive list!)

- Calibration verification
- Lab Reagent Blanks/Method Blanks
- Lab Fortified Blanks
- Matrix Spikes & Spike Duplicates
- Surrogates and Internal Standards

Data Integrity and Inappropriate Practices

- Laboratory fraud is the deliberate falsification of analytical and/ or quality assurance results by making data appear acceptable though it fails regulatory, method or contractual requirements.
- Conditions that can increase risk for laboratory fraud:
  - Ineffective oversight,
  - Competitive market where production takes priority over quality, and
  - "One size fits all" approach to meeting requirements.

Examples of Lab Fraud

- Fabricating data
- Improper clock settings to meet holding times – “Time Travel”
- Misrepresenting quality control samples
- Modifying samples to alter characteristics
- Substituting samples, files, or data
- Falsifying records of analytical equipment readings
- Intentional deletion of non-compliant data
- Improper handling of data errors, non-compliant data, or QC outliers
- Lack of reporting unethical behavior

Questions?