

CA ELAP Expert Review Panel Meeting

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EPA Perspective: Effective Laboratory Certification Program Implementation

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Overview

- Statutory basis for lab certification
- Hierarchy: Roles and responsibilities
- Effective program elements
- Continuous improvement and communication



Why Certified Labs?

- Protects public health
 - Samples consistently analyzed by qualified labs using approved/promulgated methods.
 - Results obtained are accurate and comply with current standards.
- Maintain public confidence
 - Generate defensible data



Statutory Authority for Drinking Water

- 1974 Safe Drinking Water Act (SDWA)
 - Authorizes EPA to set National Standards for Drinking Water
 - National Primary Drinking Water Regulations
- Code of Federal Regulations: 40 CFR Part 141
 - Subpart C of Part 141: Monitoring and Analytical Requirements
 - 141.28 Certified Laboratories
 - “For the purpose of determining compliance... samples may be considered only if they have been analyzed by a laboratory certified by the State...”

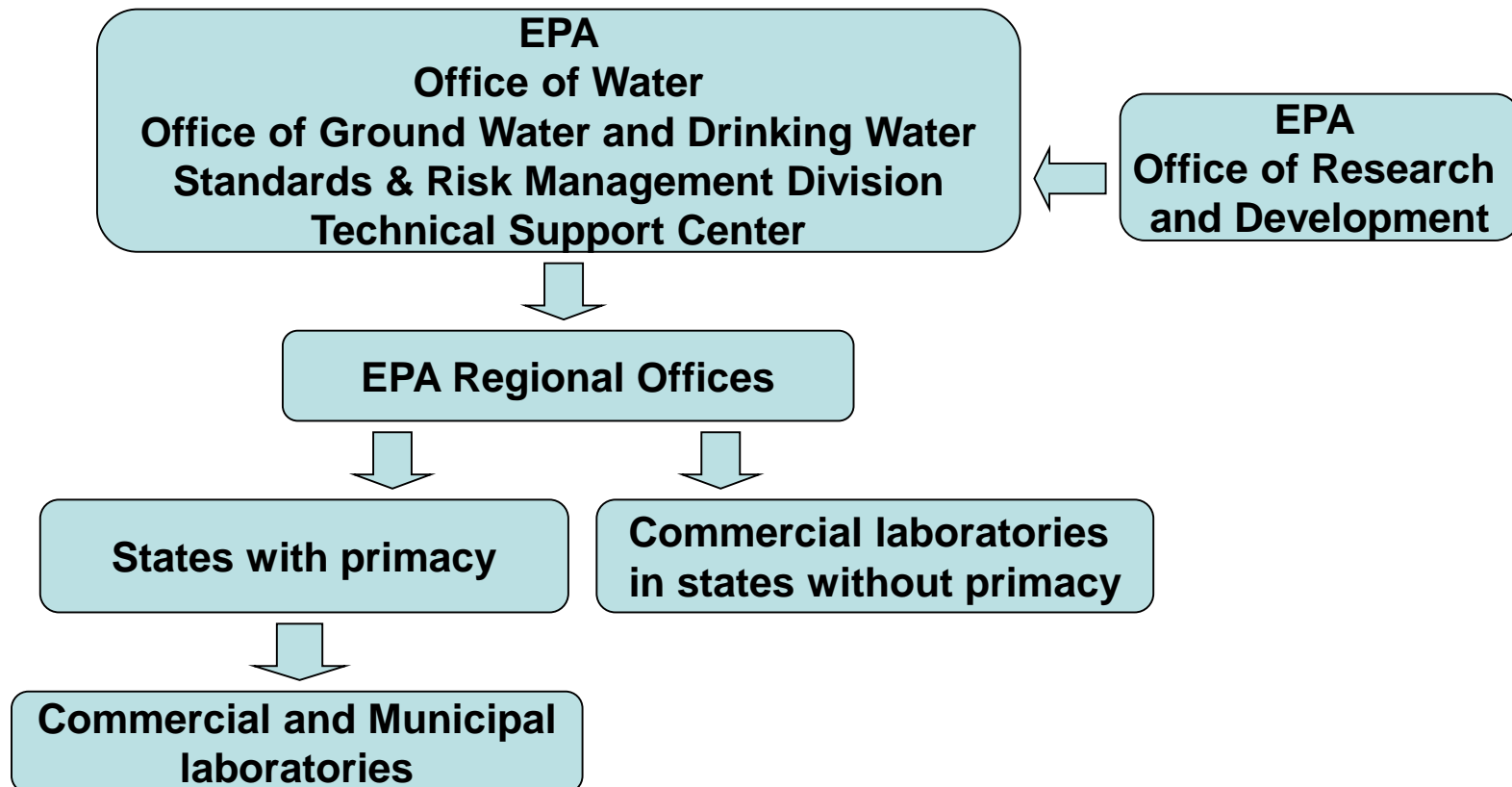


State Primacy

- 40 CFR 142.10: States have primary enforcement responsibility (primacy) for Public Water Systems.
 - Must adopt drinking water regulations *at least* as stringent as NPDWRs.
 - Must implement adequate procedures for the enforcement of State regulations, including:
 - Establish and maintain a program for the certification of laboratories conducting analyses of compliance samples.
 - Assurance of the availability to the State of laboratory facilities certified by the Administrator and capable of performing analytical measurements of all contaminants specified in the State primary drinking water regulations.



National Drinking Water Program Hierarchy





Responsibilities - OGWDW

- Establish 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.
- Oversee 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.
- Provide technical assistance to EPA Regions and states.



OGWDW Certification Officer Training

- Attended by prospective 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 (WY), territories and Tribal Nation lands.



Responsibilities - Primacy States

- Establish a laboratory certification program.
 - Designate Certification Officers.
 - COs evaluate laboratory applications, conduct on-site audits of laboratories, and review laboratory PT data.
 - COs provide technical assistance to laboratories.
- Ensure the availability of laboratory facilities capable of performing analytical measurements of all contaminants specified in the drinking water regulations.



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.



Third Parties

- Certification programs may use third parties.
 - Third Party auditor:
 - Must meet all of the qualifications of a CO.
 - Expertise in the field of auditing.
 - Attend CO training.
 - Third Party expert:
 - Utilized when expertise does not exist within audit team.
 - Must be accompanied by a CO.
- Certification Decisions Always Remain With The Certifying Authority!



Continuous Improvement, Cooperation and Communication

- Monthly conference calls between OGWDW and regional personnel.
- OGWDW offers annual training course, state/regional personnel attend.
- Regions encouraged to hold meetings with state COs; OGWDW personnel attend when possible.
- States encouraged to hold meetings/training with laboratory management/staff.



Plans for Certifying Laboratories

- Certification Program Managers should develop a written plan including:
 - Documentation of education and experience of the certification officers.
 - Maintain a schedule of laboratories to audit.
 - Specify the types of analytes to be examined.
 - Audit protocol to be followed.
 - Strategy for assessing lab performance between on-sites.



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 Certification Manual.
- Must successfully analyze one Proficiency Testing (PT) sample each 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.



WEB SITES

- Laboratory Certification/Analytical Methods:
 - <https://www.epa.gov/dwlabcert>
 - Methods listed by rule and links to EPA methods
 - State Certification Programs
 - Lab Cert Manual and supplements
- CFR and Federal Register
 - <http://www.ecfr.gov>
- Drinking Water Regulations:
 - <https://www.epa.gov/your-drinking-water/table-regulated-drinking-water-contaminants>