

“The Future of the Drinking Water Laboratory Certification Program”

Environmental Measurement Symposium
NEMC/TNI
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Greg Carroll
Director, Technical Support Center
U.S. Environmental Protection Agency
Office of Ground Water and Drinking Water

“EPA’s Drinking Water Laboratory Certification Program: History, Status, Direction”

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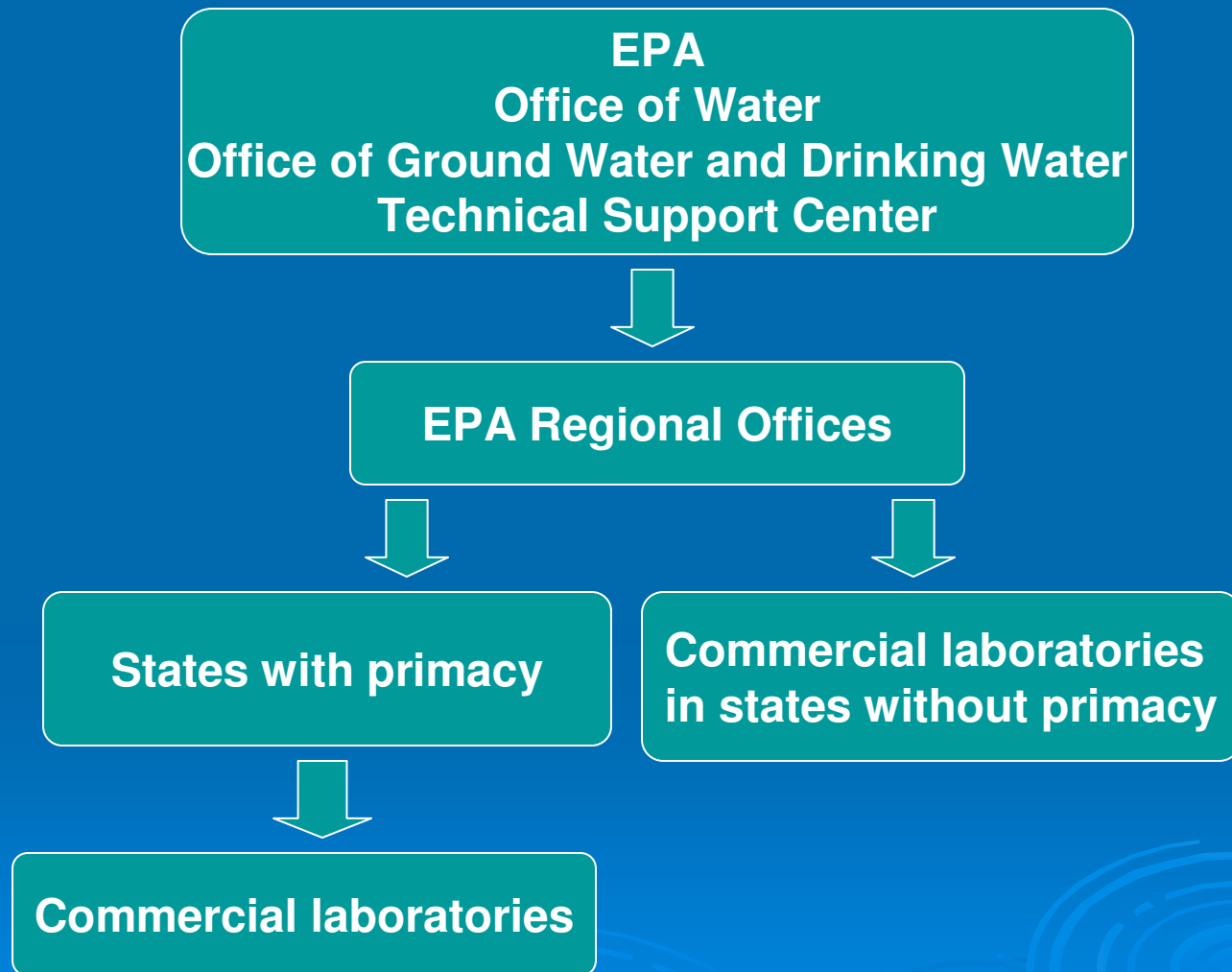
Background

- 1943 - US Public Health Service began to survey water bacteriology laboratories.
- 1974 - Safe Drinking Water Act (SDWA)
 - Authorized EPA to set enforceable health standards for contaminants in DW; National Primary Drinking Water Regulations
- 1978 – Drinking Water program implemented Certification Program, published “Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies”

Background (cont'd)

- Code of Federal Regulations: 40 CFR
 - Subpart C- 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...”
- Goal is to improve public health protection by providing more consistent, accurate, defensible results

Hierarchical Program Structure



EPA Role -- OGWDW

- Office of Ground Water and Drinking Water oversees all aspects of drinking water regulation in the US.
 - Responsible for establishing regulations and approval of methods to support regulation.
 - Oversees national drinking water laboratory certification program.
 - Reviews Regional programs
 - Conducts training of state and Regional Certification Officers
 - Maintains/updates Laboratory Certification Manual
 - Facilitates monthly conference calls with Regional COs/QAOs
 - Provides technical support regarding program, regulations, methods
 - Maintains a database of laboratory ID codes

EPA Role -- ORD

- Office of Research and Development
 - (Originally) responsible for certification of Regional laboratories
 - (Originally) responsible for audits of state radiochemistry laboratories
 - (Originally) responsible for Performance Evaluation/Proficiency Test Program.
 - Support Certification Officer Training
 - Provide technical support regarding methods
 - Develop/evaluate analytical methods to support drinking water program (shared responsibility with OGWDW)

EPA Role -- Regional Offices

- Monitor state certification programs for adequacy.
 - assess the scope, staffing, policies, procedures, and effectiveness.
- Certify principal state laboratories
- Host meetings of state certification officers
 - discuss program/implementation issues and provide current information on regulations and methods.
- Observe state on-site evaluations of local labs.
- Manage certification program and certify laboratories in the non-primacy states/territories.
- Provide technical assistance to states and certified laboratories.

State Role

- As conditions of primacy, states:
 - maintain capability to analyze regulated contaminants (in-house or via contractual arrangements)
 - manage certification program for commercial laboratories analyzing DW compliance monitoring samples
- State-designated COs review laboratory applications, conduct on-site audits of laboratories, and review laboratory PT data.
- COs provide technical assistance to laboratories.
- States may certify laboratories outside of their state through direct evaluation or reciprocity.
- Other program elements per state

Laboratory Responsibilities

- Comply with all federal regulations, including using approved methods.
- Successfully analyze Proficiency Testing (PT) samples (initial + annual)
- Successfully pass an onsite audit (initial + triennial)

Significant Program Developments

- 1978-2005 - Periodic updates to Laboratory Certification Manual
- 1997 - EPA transferred PE/PT program to private sector, with evaluation/accreditation of providers by NIST NVLAP program
- 1997 - OGWDW (Cynthia Dougherty memo) regarding NELAP accreditation as alternative to certification
 - *“....I support the use of the NELAC standards in the certification of laboratories...and encourage use of the standards based on the increased opportunity for national consistency...”*
 - *“....One of the Agency’s primary goals has been to encourage states to recognize certification of laboratories by other states...(reciprocity)...”*

Significant Program Developments (cont'd)

- 1999 - Lead responsibility for Regional laboratory audits transferred from ORD to OGWDW (with ongoing ORD audit support)
- 2002 - Renewal of OGWDW (Cynthia Dougherty) support for NELAP accreditation
 - *“I continue to support the use of the NELAC standards in the certification of laboratories...”*
 - *“...I encourage future reviews...to allow continued assessment of equivalency and promote greater consistency in the program...”*
 - *“...I reiterate that the drinking water program will benefit nationwide through state participation in the accreditation program...”*

Significant Program Developments (cont'd)

- 2002 (?) - EPA decision that Regional laboratories will be accredited by NELAP.
- 2006 - NIST announced its termination of their evaluation/accreditation program for PT providers
- 2006 – OGWDW statement of support for NELAC PTOB/PTPA process to help “assure the quality of commercially-provided PTs” (i.e., in lieu of NIST-based process)

Significant Program Developments (cont'd)

- 2004-07 – Retirement of core OGWDW laboratory certification team members (Ed Glick, Carol Madding, Pat Hurr); hiring/reassignment of new team members (Jennifer Best, Michella Karapondo, Judy Brisbin)
- 2005-07 – OIG review/report re drinking water laboratory integrity (Report 2006-P-00036), OGWDW response/action plan

Lab Cert Program - Direction

- Implement OGWDW Action Plan per OIG review
 - Integrate fraud awareness into CO training
 - Promote data validation training, techniques
 - Enhance radiochemistry training/technical support
 - Review sample collection requirements/vulnerabilities
- Strengthen the Quality Systems component of the Lab Cert Program/Lab Cert Manual

Lab Cert Program – Direction (cont'd)

- Incorporate new/modified methods into program
 - OGWDW implementation of Expedited Method Approval approach
 - Continued OGWDW progress towards Agency's/FEM's method flexibility/ "Performance Approach" goals
 - New standards resulting from CCL/Regulatory Determination processes

Lab Cert Program – Direction (cont'd)

- Resolve long-term responsibility for Criteria Document
- Investigate longer-term options for LT2 (*Cryptosporidium*) lab approval
- Continue/strengthen collaboration with TNI (e.g., participate in forum/symposium, PT Board, Regional Evaluator meetings; consultation regarding Standard; networking with DW stakeholders [?])

Lab Cert Program – Key Elements of Approach to Future

- Adapting to change
- Collaboration
- Balancing stakeholder interests
- Commitment to public health protection
- Tech support
- Managing with limited/declining resources

For More Information

- Greg Carroll
 - 513-569-7948
 - carroll.gregory@epa.gov
- Jennifer Best
 - 513-569-7012
 - best.jennifer@epa.gov
- Michella Karapondo
 - 513-569-7141
 - karapondo.michella@epa.gov
- Judy Brisbin
 - 513-569-7883
 - brisbin.judy@epa.gov
- epa.gov/ogwdw/labcert
- Drinking Water Hotline: 800 426 791