“The Future of the Drinking Water Laboratory Certification Program”

Environmental Measurement Symposium
NEMC/TNI
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“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
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
Office of Water
Office of Ground Water and Drinking Water
Technical Support Center

EPA Regional Offices

States with primacy

Commercial laboratories in states without primacy

Commercial laboratories
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
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