

**Joint Commission on
Administrative Rules:
Hearing on 1 VAC 30-45/46
Environmental Laboratory
Regulations**

**December 12, 2007
Jim Pearson, Director
DCLS**

Introduction

- Legislative History
- Regulatory History
- Concerns
- Cost

Legislative History

- **1997 Session**
 - SB1039 passed after conference committee deliberations. Chapter 652 of the Acts of Assembly, §2.1-429.01 directed DCLS to establish a program to certify environmental laboratories that “conduct any tests, analyses, measurements, or monitoring required pursuant to” Virginia’s air, waste or water laws.
- **1999 Session**
 - HB1827 to exempt local, state and federal laboratories – No Action
- **2000 Session**
 - HB1217 to repeal DCLS authority to establish a program - Continued

Legislative History

- 2000 Session (continued)
 - HB881 to exempt municipal treatment facilities serving less than 20,000 people and owned by political subdivisions - Continued
 - SB712 to repeal DCLS authority to establish the program – continued
- 2001 Session
 - HB1217 stricken at request of patron
 - HB881 tabled in CNR
 - SB712 left in AC and NR

Legislative History

- 2001 Session (continued)
 - HB2002 to modify §2.1-429.01 and require two programs – Engrossment refused
 - HB2002H1 to limit certification of local government laboratories to those serving more than 15,000 – Engrossment refused
 - HB2455 to exempt local, state and federal laboratories from DCLS regulations – Tabled
 - Chapter 844 changed citation from §2.1-429.01 to §2.2-1105

Legislative History

- 2003 Session
 - SB1275 to exempt Treatment, Storage, or Disposal of hazardous waste permittees under RCRA – bill was modified to authorize DCLS director to approve variances, provide an effective date, and included language in subsection B to require that data must come from certified laboratories only after the effective date – Statute revised: Chapter 580 of the Acts of Assembly

Regulatory History

- 1998
 - DCLS requested laboratory and environmental advocacy organizations to nominate members to represent them in the development of the regulations
 - *Ad hoc* advisory group formed to assist with the drafting of regulations
 - Twenty members including 6+ from municipal waste water agencies
- 1999
 - Group met 11 times during the first 6 months and drafted the first regulation
 - Draft regulation was submitted

Regulatory History

- 2000
 - Proposed regulatory package returned to DCLS
 - Representatives from organizations were asked to re-engage to work on revisions
 - Held 2 public meetings to discuss the regulation and to gather comments on changes
 - Met with individuals and organizations when requested to solicit additional comments
- 2001 – 2003
 - Rules on hold pending review by DPB, AG, Secretary and Governor's office

Regulatory History

- 2004
 - Formally proposed draft 1 VAC 30-45 covering municipal laboratories and 1 VAC 30-46 covering commercial laboratories for public comment
 - DEQ expressed concern that the QC requirements of 1 VAC 30-45 as proposed could not be audited – recommended adding Appendix D of the National Environmental Laboratory Accreditation Conference (NELAC) standards
 - Additional 30 day comment period
 - Final regulatory package produced

Regulatory History

- 2005
 - Director, Department of General Services signed, Department of Planning and Budget and Secretary of Administration approved the regulation package
 - Secretary Bowen received 24 similar/identical letters, 22 from VAMWA members, 1 letter from a town and one from an industrial company
 - Governor's policy office chose not to act on the regulations

Regulatory History

- 2006
 - 1 VAC 30-45 and 1 VAC 30-46 returned to Secretary of Administration
- 2007
 - 1 VAC 30-45 and 1 VAC 30-46 approved by Secretary Baskerville and submitted to Governor's Office

Issues Raised

- **Quality Control Requirements**
 - Quality Controls are procedures/activities used to measure and control data quality during laboratory analysis.
 - EPA Laboratory Methods required for waste water analysis prior to 2007 did not incorporate specific quality control procedures into the testing process

Issues Raised

- **NELAC**

- ~1988 EPA convened CNAEL to address inconsistencies in laboratory accreditation programs in the US
- ~1996 NELAC was organized based on the Council of Weights and Measures structure: Board, Delegates, Representatives, Committees
- 1999 Approved first National Consensus Standard for Environmental Laboratories
- <http://www.nemc.us/epa12/nelac.html>

Issues Raised

- NELAC (continued)
 - ISO Guides Incorporated into Standards
 - EPA reduced then eliminated funding for program staff
 - INELA contracted with EPA to assume management of the program.
INELA/NELAC merged.
 - Name was changed to The NELAC Institute, or TNI
 - TNI committees have developed updated “Draft Interim Standards” that are posted at <http://www.nelac-institute.org/>

Cost Estimates

- §2.2-1105 requires the program be self-supported
- Estimated annual program cost is \$1,150,250 for personnel, travel and *per diem*, supplies, etc.
- Program fee based on test menu
 - Simple test procedures: Maximum \$300/yr
 - Full-service laboratories: Maximum of \$2600/yr

Cost Estimates

- Proficiency Tests – 2 rounds/yr
 - Simple test procedures: \$644/yr
 - Average non-commercial lab: \$756/yr
 - Average commercial lab: \$1020/yr
- Compliance Cost
 - No estimate available
 - No lab should have to add personnel to meet the regulatory requirements
 - Most will need to develop auditable QA/QC materials to ensure they meet the requirements

Summary

- Draft Regulations are waiting for Governor's approval
- 1 VAC 30-45 and 1 VAC 30-46:
 - Are the product of several years of collaborative effort by representatives of all of the stakeholders involved in the regulation of environmental laboratories
 - Were developed through a consensus process
 - Balance the concerns of the regulated laboratories and environmental advocacy groups with the requirements of the governing statute through the application of measurable standards
- Local government laboratories are not uniformly opposed to the draft regulations
- Many municipal laboratories are actively preparing to meet the program requirements

Summary

- 1 VAC 30-46 as proposed is intended to regulate commercial laboratories and incorporates the 2003 NELAC standards by reference
- 1 VAC 30-45 as proposed is intended to regulate noncommercial laboratories and uses some NELAC language such as Appendix D, QC
- Laboratories that participate in DMRQA can substitute one PT for the DMRQA requirement
- EPA modifications to 40CFR136 have eliminated the water methods without QC requirements and replaced them with methods that have defined QC. All laboratories doing testing required by the Clean Water Act must use the new methods. Adhering to those methods satisfies the QC requirements of 1 VAC 30-45

QUESTIONS?

Dr. Jim Pearson, Director
Division of Consolidated Laboratory Services
Department of General Services
804-648-4480
Jim.Pearson@DGS.Virginia.gov