



Let's Go, ISO!

Applicable Standards and Improvement Efforts

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Outline - Questions

- What standards apply to governmental testing laboratories?
- What types of laboratory work are included in these various standards? Which are not?
- What are the differences among the standards?
- How does ISO tie in with LEI, CQI, and LEAN efforts?







Governmental Testing Labs

- Agriculture Laboratories
- Environmental Laboratories
- Feed Laboratories
- Food Laboratories
- Forensic Laboratories
- Occupational Health Laboratories
- Public Health Laboratories
- Others . . .

. . . One Laboratory's Story
State Hygienic Laboratory at the University of Iowa




State Hygienic Laboratory

Iowa's Environmental and Public Health Laboratory

- Established by the Iowa State Legislature in 1904
- 263.7 State hygienic laboratory - investigations.
- The state hygienic laboratory shall be a permanent part of the state university of Iowa. It shall make or cause to be made microbiological and chemical examinations and other necessary investigations by both laboratory and field work in the determination of the causes of disease, shall suggest methods of overcoming and preventing the recurrence of the disease, and shall evaluate environmental effects and scientific needs, whenever requested to do so by any state agency, state institution, or local board of health when the investigation or evaluation is necessary in the interest of environmental quality and public health and for the purpose of preventing epidemics of disease.

State Hygienic Laboratory

- Three laboratories

Ankeny Laboratory

Lakeside Laboratory - Milford

Coralville Laboratory

2010 - New Coralville Laboratory

State Hygienic Laboratory

- Disease Control Division
Prenatal, Maternal and Newborn Screening Program
- Environmental Health Division



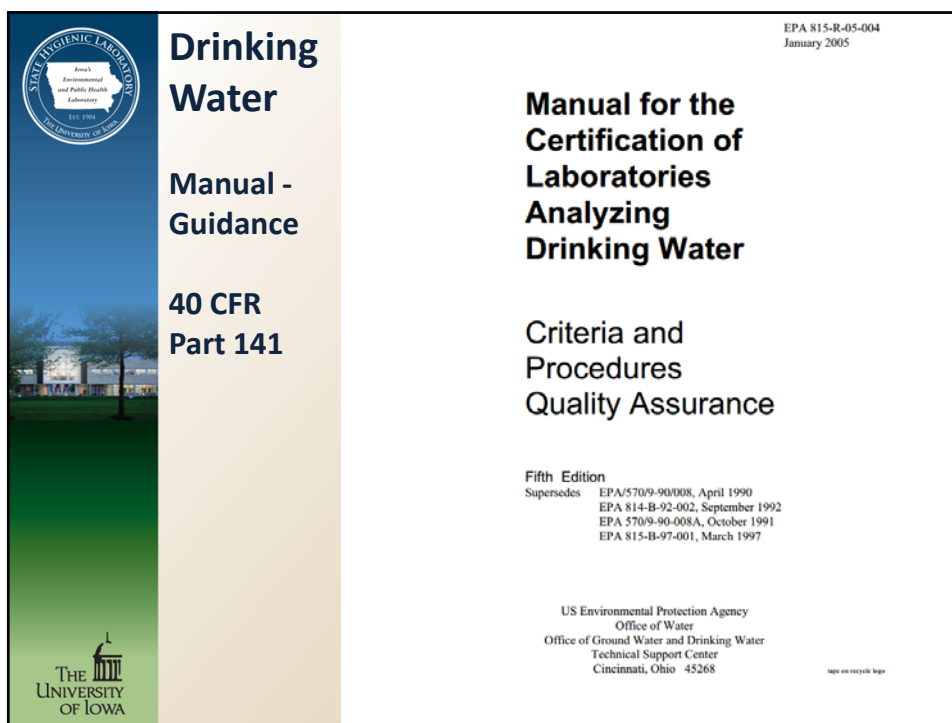
State Hygienic Laboratory (SHL)

- In the beginning . . .
 - The Safe Drinking Water Act (SDWA) - EPA Region VII Certification
 - Occupational Safety and Health Act (OSHA) - American Industrial Hygiene Association (AIHA)
 - Clinical Laboratory Improvement Act / Amendments (CLIA)



SHL – Drinking Water Certification

- National Primary Drinking Water Regulations – 40 CFR Part 141
- The Safe Drinking Water Act (SDWA) – 1974
- 1986 and 1996 Amendments
- EPA Region VII Certification
- NELAP Accreditation Accepted by Region VII



SHL - AIHA Accreditation

AIHA's Lab Accreditation Program Celebrates 40 Years of Excellence

AIHA Laboratory Accreditation Programs, LLC (AIHA-LAP, LLC) celebrates its 40th anniversary. AIHA® initially began its laboratory accreditation program working with NIOSH in 1972.

In July 1974, the AIHA Board of Directors announced the accreditation of 26 labs, fully launching the Industrial Hygiene Laboratory Accreditation Program (IHLAP).

<https://www.aiha.org/publications-and-resources/TheSynergist/AIHANews/Pages/AIHA's-Lab-Accreditation-Program-Celebrates-40-Years-of-Excellence.aspx>



SHL - AIHA Accreditation

- SHL accredited by AIHA for industrial hygiene testing with that first group of 26 laboratories
- 101048 State Hygienic Laboratory at the University of Iowa (Des Moines/Ankeny)
- 102530 State Hygienic Laboratory at the University of Iowa (Iowa City/Coralville)





SHL - AIHA Accreditation

AIHA Laboratory Accreditation Programs, LLC

- Full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory of the ILAC Mutual Recognition Arrangement (MRA)
- International Organization for Standardization (ISO) Standard ISO/IEC 17025:2005

- Ankeny**
 - Industrial Hygiene (IHLAP)
 - Environmental Lead (ELLAP)
- Coralville Laboratory**
 - Industrial Hygiene (IHLAP)

<http://www.aihaaccreditedlabs.org/2013PolicyModules/Documents/RevisedPolicyModules%20-%20CLEAN%20VERSION.pdf>



SHL – CLIA Certification

- Clinical Laboratory Improvement Act (CLIA) 1967
 - Regulated hospitals and independent laboratories
- CLIA 88 Amendments
 - Congress passed CLIA in 1988 establishing quality standards for all clinical laboratory testing to ensure the accuracy, reliability and timeliness of patient test results
- Code of Federal Regulations - 42 CFR 493



SHL – CLIA Certification

- Centers for Medicare & Medicaid Services (CMS) CLIA website – www.cms.gov/CLIA
- SHL Registration, September 1992
- SHL Compliance, September 1993





State Hygienic Laboratory (SHL)

- Since . . . the long and winding road
 - EPA Contract Laboratory Program (CLP)
 - State of Iowa (and other states)
 - National Environmental Laboratory Accreditation Program (NELAP)
 - CDC Laboratory Response Network (LRN)
 - FDA Food Emergency Response Network (FERN)
 - EPA Environmental Response Laboratory Network (ERLN)
 - FDA ISO/IEC 17025 ? . . . *In process*





SHL - Accreditations

- AIHA (The American Industrial Hygiene Association)
- CLIA (Clinical Laboratory Improvement Amendments) – Ankeny and Coralville
- SDWA - EPA (Safe Drinking Water Act - Environmental Protection Agency)
- State of Iowa - DNR (Department of Natural Resources) - Coralville – Ankeny and Lakeside
- NELAP - (National Environmental Laboratory Accreditation Program) – Ankeny, Coralville and Lakeside
- State of Nebraska - Department of Environmental Protection – Ankeny and Coralville
- State of New Hampshire - Department of Environmental Protection – Ankeny and Coralville
- Kansas Department of Health and Environment, Environmental Laboratory Accreditation – Ankeny and Coralville




State of Iowa – Environmental Laboratory Certification

- Iowa Department of Natural Resources Laboratory Certification - 567 IAC 83
 - Drinking Water/Safe Drinking Water Act
 - 567—Chapters 40, 41, 42, and 43
 - Clean Water Act (Wastewater)
 - 567—Chapters 63, 67, and 69
 - Underground Storage Tanks
 - 567—Chapter 135
 - Solid Waste
 - 567—Chapters 100 through 130
 - Contaminated Sites
 - 567—Chapters 133 and 137




SHL – NELAP Accreditation

- The NELAC Institute (TNI) Laboratory Accreditation Standards - 2009
 - Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis
 - Field Activities Standards - Volume 1: General Requirements for Field Sampling and Measurement Organizations
- Some of the TNI accreditation standards contain language from ISO/IEC 17025 and 17011



EPA Policy Directive

**POLICY TO ASSURE THE COMPETENCY OF ORGANIZATIONS
GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER
AGENCY-FUNDED ASSISTANCE AGREEMENTS OR INTERAGENCY
AGREEMENTS**

Agency Policy Directive Number FEM-2012-02

PURPOSE

This document establishes the U.S. Environmental Protection Agency's (U.S. EPA's or the Agency's) policy requiring organizations generating or using environmental data under Agency-funded assistance agreements or interagency agreements (if applicable) to submit documentation of their competency prior to award of the agreement. This includes organizations performing environmental sampling, field measurements, and/or laboratory analyses under Agency-funded agreements. Required documentation is detailed below.

EFFECTIVE DATE

This Policy is effective for 2 years from December 12, 2012. The Policy shall be reviewed at the end of 2 years and will either be reissued without revision, reissued with revisions or rescinded.

<http://www.nelac-institute.org/docs/comm/nefap/competency-policy-aaia.pdf>





SHL - Testing

- Iowa/NELAP – Environmental Testing
 - ✓ Drinking water, Non-potable water and Solids and Chemicals
- Ankeny
 - ✓ Inorganic Chemicals*, Physical Properties*, Microbiology and Whole Effluent Toxicity
- Coralville
 - ✓ Inorganic and Organic* Chemicals, Physical Properties, Microbiology and Radio Chemicals
- Lakeside
 - Inorganic Chemicals, Physical Properties and Microbiology

*Testing for Solids and Chemicals





Standard Differences

- Ms. Wangsness Crosswalk Chart*

Standards Compared	
ISO 17025:2005	AIHA 2010
ISO 15189:2007	TNI 2009
EPA Drinking Water Manual	9 CFR 318 and 381
CLIA 1988	40 CFR 140 (SDWA)

*Project was supported by the APHL Innovations in Quality Public Health Laboratory Practice Grant and Cooperative Agreement Number #U60/CD303019 from Centers for Disease Control and Prevention (CDC).



	ISO 17025	ISO 15189	EPA DW	CLIA 1988	AIHA 2010	TNI 2009	40 CFR 141
Scope	✓	✓	✓	✓	✓	✓	✓
References	✓	✓	✓		✓	✓	✓
Terms and Definitions	✓	✓	✓	✓	✓	✓	✓
Management System	✓	✓	✓	✓	✓	✓	✓
Document Control	✓	✓	✓	✓	✓	✓	✓
Contracts	✓	✓	✓	✓	✓	✓	✓
Sub-contracting	✓	✓	✓	✓	✓	✓	✓
Purchasing	✓	✓	✓	✓	✓	✓	✓
Customer Service	✓	✓	✓	✓	✓	✓	✓
Complaints	✓	✓	✓	✓	✓	✓	✓

Differences							
	ISO 17025	ISO 15189	EPA DW	CLIA 1988	AIHA 2010	TNI 2009	40 CFR 141
Complaints	✓	✓		✓	✓	✓	
Non Conformities	✓	✓	✓	✓	✓	✓	
Laboratory Improvement	✓	✓	✓	✓	✓	✓	
Corrective Actions	✓	✓	✓	✓	✓	✓	✓
Preventive Actions	✓	✓	✓	✓	✓	✓	
Control of Records	✓	✓	✓	✓	✓	✓	✓
Internal Audits	✓	✓	✓	✓	✓	✓	
Management Reviews	✓	✓			✓	✓	

Differences							
	ISO 17025	ISO 15189	EPA DW	CLIA 1988	AIHA 2010	TNI 2009	40 CFR 141
Technical Requirements	✓	✓			✓	✓	
Personnel	✓	✓	✓	✓	✓	✓	
Facilities	✓	✓	✓	✓	✓	✓	
Methods and Method Validation	✓	✓	✓	✓	✓	✓	✓
Equipment	✓	✓	✓	✓	✓	✓	
Traceability	✓	✓	✓	✓	✓	✓	
Sampling	✓	✓	✓	✓	✓	✓	✓
Handling of Test and Calibration Items	✓	✓	✓	✓	✓	✓	



Differences

	ISO 17025	ISO 15189	EPA DW	CLIA 1988	AIHA 2010	TNI 2009	40 CFR 141
Assurances	✓	✓	✓	✓	✓	✓	✓
Reporting Results	✓	✓	✓	✓	✓	✓	✓
Safety		✓	✓	✓	✓		
Integrity and Ethics		✓	✓	✓	✓	✓	

Note: New AIHA Checklist Effective May 13, 2014 not included in these tables

... the long and winding road continues – new ISO 15189:2012




LEI, CQI and LEAN and ISO

A story for another day . . .

- LEI or Laboratory Sustainability – accreditation / certifications must be considered particularly in relation to specific state requirements
- CQI/LEAN – many laboratory processes evaluated, improvements identified and implemented to meet specifications of the various standards

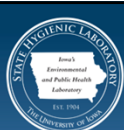
http://www.nist.gov/baldrige/publications/upload/Issue_Sheet_SS.pdf





SHL – Why GO ISO?

- Occupational Health Program – Accredited to ISO 17025 Standard
- Environmental Lead Program – Accredited to ISO 17025 Standard
- NELAP – aligned with ISO 17025
- FDA Processed Food Program Requirement
- Quality System will improve services and products provided to clients
- Diversify testing services



Questions?
Thank you!



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