


Voluntary Accreditation Program for Public Health Laboratories


Karen Breckenridge, MBA, MT(ASCP)
Director of Quality Systems
Association of Public Health Laboratories



APHA Presenter Disclosure


The following personal financial relationships with commercial interests relevant to this presentation existed within the past twelve months:

NO RELATIONSHIPS TO DISCLOSE



Objectives

- Explain the steps in the process of developing standards for laboratory accreditation based in part on APHL's L-SIP
- Describe the benefits of voluntary accreditation to the Public Health Laboratories
- Discuss the work of APHL with PHAB to include the laboratory in the public health accreditation process



Association of Public Health Laboratories (APHL)

- **Vision**
A healthier world through quality laboratory practice



Association of Public Health Laboratories (APHL)

- **Mission**
To promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.



APHL and Accreditation

- **Workgroup Formed 2009**
 - Pros and cons of accreditation
- **Introductory Discussions with PHAB**
 - How do PHLs fit into process?
- **Standards Development**
 - Role of ISO and other guidelines



Workgroup

- Accreditation Pros
 - Visibility with other parts of PHL system
 - Standards for operations in PHLs
 - Be more related to PHL structure and function, not federal regulations
 - Highlighting successes of the laboratory



Workgroup

- Accreditation Cons
 - Duplication of federal and state requirements
 - Resources – financial and staff
 - No definition of the purpose of accreditation, need marketing plan



Workgroup

- Questions to Be Answered
 - How will it be recognized?
 - What impact will a negative result have?
 - Who will assess the laboratory?
 - How to interpret the standards?
 - How to obtain sustainable funding?



Development of Standards

- Currently developing standards
 - Based on ISO and CLSI QSE
 - Crosswalk of Essential Services and Laboratory Core Functions
- Recommendation that assessment of laboratory system be included (L-SIP)



Laboratory System Improvement Program (L-SIP)

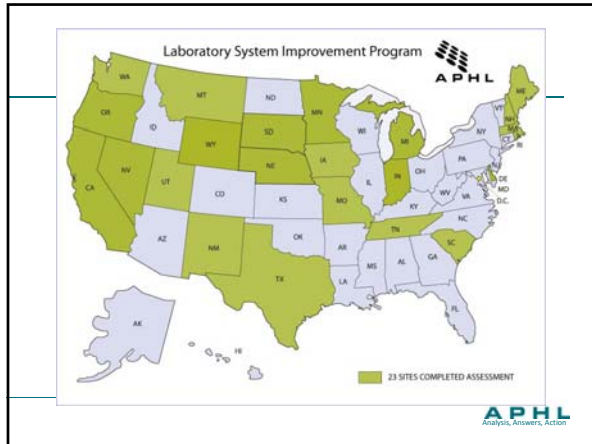
- Based on Essential Services
- NPHPSP
- CAST-5



L-SIP Goals

- Brings together key partners to determine system performance
- Measures capacity and performance of the state system in addressing national standards
- Provides results for system improvement





Essential Services	Laboratory Core Functions
1. Monitor Health Status to Identify Community Health Problems	1. Disease prevention, control, and surveillance
2. Diagnose and Investigate Health Problems and Health Hazards in the Community	2. Integrated data management 3. Reference and specialized testing 4. Environmental health and protection 5. Food safety 8. Emergency response
3. Inform Educate and Empower People About Health Issues	10. Training and education 11. Partnerships and communication
4. Mobilize Partnerships to Identify and Solve Health Problems	11. Partnerships and communication
5. Develop Policies and Plans that Support Individual and Community Health Efforts	7. Policy development


APHL

Essential Service	Lab Core Function
6. Enforce laws and regulations that protect health & safety	6. Laboratory improvement and regulation
7. Link people to needed personal health services & assure provision of health care when unavailable	3. Reference and specialized testing
8. Assure a competent public and personal health care workforce	10. Training and education
9. Evaluate effectiveness, accessibility, & quality of personnel & population-based services	3. Reference and specialized testing 6. Laboratory improvement and regulation
10. Research for new insights and innovative solutions to health problems	9. Public health-related research

APHL

Guidelines Crosswalk

QSEs	ISO 15189:2007 ¹	ISO 17025:2005 ²	ISO 9001:2008 ³
Facilities and Safety	5.2 Accommodation and environmental conditions	5.3 Accommodation and environmental conditions	6.3 Infrastructure 6.4 Work environment




Sample Standards

Standard	Required Documentation	Interpretation and Guidance
A. Facility Design		
1) The laboratory shall have space allocated commensurate with the operations conducted and suitable for the tasks undertaken. 2) Facility design shall include all of the following, as applicable: <ul style="list-style-type: none"> a. Adequate energy sources b. Lighting c. Ventilation d. Water e. Noise mitigation f. Waste disposal (hazardous and biohazardous) g. Refuse disposal (nonhazardous) 	<ul style="list-style-type: none"> • Current floor plan, with all areas labeled as to function 	The laboratory needs to have enough space to conduct its operations without compromise to the quality of its processes and test results. The layout and flow of work activities should not hamper the timeliness or quality of service provision. When possible, there should be a unidirectional flow of work through the laboratory to increase efficiency (ie, time and resources used) and effectiveness (ie, meeting requirements). The facility design needs to meet all applicable national, state, and local design requirements. Resource CLSI guideline GP18: Laboratory Design Stanford University Laboratory Standard and Design Guidelines:


APHL and PHAB

- Exploratory Meetings
- Think Tank
- Laboratory Director Debriefing
- Next Steps



Think Tank Results

- Short term goal
 - APHL to develop a few discreet and specific standards, and suggest additional measures and documentation for laboratories, to improve and enhance the existing PHAB accreditation standards.




Think Tank Results

- Long term goal
 - To develop a more comprehensive set of standards and measures for public health laboratories



Laboratory Director Debrief

- PHAB Beta site visits to 10 state health departments
- Various levels of laboratory involvement
- Laboratory tours in some
- List of requested laboratory documents shared
- Positive experiences



Next steps

- Continue development of laboratory standards
- Maintain dialog with PHAB
- Educate APHL members on value of voluntary laboratory accreditation
- Develop marketing plan



For additional information...

Karen Breckenridge, MBA, MT(ASCP)
Director of Quality Systems
Association of Public Health Laboratories
240-485-2756
karen.breckenridge@aphl.org
www.aphl.org



Thank you