April 2010

Prepared by: APHL

Association of Public Health Laboratories and Public Health Accreditation Board

- PUBLIC HEALTH LABORATORY ACCREDITATION
- Think Tank Report
EXECUTIVE SUMMARY

In response to a national movement to develop a voluntary accreditation program for public health agencies, the Association of Public Health Laboratories (APHL) has taken a lead in evaluating the need for a voluntary accreditation program for public health laboratories. APHL and the Public Health Accreditation Board (PHAB) have partnered to explore incorporating laboratory specific standards into the PHAB accreditation process to ensure that accreditation standards address the specific needs and challenges of Public Health Laboratories.

On April 29, 2010, APHL and PHAB co-sponsored a Public Health Laboratory Accreditation Think Tank in Arlington, VA to discuss the possibility of incorporating laboratory related standards (to be developed by a separate APHL workgroup) with the PHAB program. A total of 23 individuals participated in the one day session, representing APHL, PHAB, CDC, ASTHO and NALBOH.

Objectives of the APHL – PHAB Accreditation Think Tank were:

- To discuss the roles of public health laboratories within the public health agency
- To explain the importance of merging the proposed laboratory standards into the PHAB process
- To discuss ways APHL and PHAB can work together to educate APHL members on the benefits of participating in the PHAB accreditation section for laboratories.
- To outline a draft plan for merging the proposed APHL standards into the PHAB process and include a time frame
- To develop actionable recommendations to the PHAB Board of Directors concerning the outcomes of the Think Tank meeting.

The day’s discussions resulted in establishing two goals:

1. A short-term goal (by the end of this calendar year) would be for 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.
2. The long term goal (by 2013), the work group will develop a more comprehensive set of standards and measures for public health laboratories.

In addition a list of recommendations and actions items are listed on page 8.
**Purpose of Meeting**

Discuss incorporation of laboratory-related standards (to be developed by a separate APHL workgroup) into the Public Health Accreditation Board (PHAB) process. Discussions will explore how such a combined accreditation program should look, be structured, and what elements should be included in such a partnership.

**Background**

Currently, there is no accreditation process for public health agencies at the State and Local levels. In response, PHAB is developing a national voluntary accreditation program for State, Local, Territorial and Tribal public health departments. The goal of the accreditation program is to improve and protect the health of every community by advancing the quality and performance of public health departments.

Public health laboratories are subject to regulation for diagnostic testing through the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and from other Federal and State regulatory programs (i.e. environmental testing required by the U.S. Environmental Protection Agency [EPA], dairy testing and vaccine production by the U.S. Food and Drug Administration [FDA]). However, there is no accreditation process that takes into consideration the functional and operational features that link the public health laboratory to its parent agency and the public health system. Various organizations and other stakeholders have been exploring how best to proceed in this area.

- A workgroup of experts and representatives from all levels and disciplines within the public health system was convened in 2006 to explore the feasibility and desirability of a voluntary accreditation program or to determine some other systematic approach for public health improvement. This effort was funded by CDC and the Robert Wood Johnson (RWJ) Foundation and supported by the Association of State and Territorial Health Officials (ASTHO), the National Association of City and County Health Officials (NACCHO), the National Association of Local Boards of Health (NALBOH) and the American Public Health Association (APHA). The workgroup recommended a model for voluntary public health accreditation, which resulted in the establishment of PHAB.

- While initially it seemed that the broader health department accreditation initiative would have little effect on public health laboratories, as the process evolved it became apparent to APHL and others that the involvement of laboratories would strengthen the overall accreditation process and laboratories would also benefit from their involvement in the process. To date, public health laboratories have not been fully considered within the scope of the broader PHAB accreditation model. The purpose of PHAB is to measure performance of a health department. Since the laboratory plays a critical role in a health department’s ability to provide services and respond to the needs of the community, especially in emergency situations, APHL would like to explore ways to incorporate laboratories into the PHAB process and align the PHAB process with any future voluntary accreditation processes that address laboratory systems and administration.

### Expected Meeting Objectives

- Discuss the roles of public health laboratories within the public health agency.
- Explain the importance of merging the proposed laboratory standards into the PHAB process.
- Discuss ways APHL and PHAB can work together to educate APHL members on the benefits of participating in the PHAB accreditation section for laboratories.
- Outline a draft plan for merging the proposed APHL standards into the PHAB process and include a time frame.
- Develop actionable recommendations to the PHAB Board of Directors concerning the outcomes of the Think Tank meetings.
PHAB Update

The goal of PHAB’s voluntary national accreditation program is to improve and protect the health of the public by advancing the quality and performance of State, Local, Tribal and Territorial public health departments. In academia, the accreditation process provides an opportunity for various interests within the institution to work together and look at their processes and systems. PHAB intends to bring about a similar process in health departments. It is expecting to launch the accreditation program in 2011.

To develop the standards, PHAB convened a workgroup comprised of State and Local health department leaders and BOH members. The process was based on science and best practices and facilitated by a consultant with standards development expertise. Specifically, the standards and measures development process focused on:

- Development of standards and measures specific for Local, State, and Tribal health departments;
- Guidance for documentation and demonstration of department performance on meeting standards and measures;
- Scoring and weighting methodology; and
- Vetting by the public health community.

There is a great deal of flexibility built into the PHAB accreditation process—the standards provide a framework for what a health department should be. However, this flexibility can be unsettling for health departments. For example, the format of the strategic plan that health departments must develop is not prescribed but it is likely that PHAB will identify the essential components that must be included in the strategic plan. Some health departments may be looking for a specific structure or stronger guidance.

The accreditation process consists of seven steps. These include:

- Pre-application (applicant prepares and assesses readiness, receives additional training if necessary);
- Application;
- Self-assessment (applicant gathers documentation);
- Site visit (conducted by a team, including representatives from other health departments);
- Accreditation decision (PHAB Board awards accreditation status);
- Appeals (procedures for appeals and complaints);
- Reports and reaccreditation (department reports progress and reapply).

Various tools have been developed as part of the accreditation process. These tools are also being evaluated.

Currently, 30 health departments (8 State, 19 Local, and 3 Tribal) are participating in beta testing. The participants vary in organizational size and governance and come from across the country. The beta test is being evaluated by the National Opinion Research Center.
PHAB anticipates having a 5-year accreditation cycle, with health departments required to submit a progress report at the half-way point. Accreditation will stress quality improvement. It is expected that new measures will be added over time—the bar will continue to rise.

An additional form of input into the development of the accreditation program is the Think Tank Process. PHAB is using this process to explore areas critical to the national accreditation program development. Examples of areas explored by Think Tanks include: centralized States; governance; environmental public health; public health laboratory; emergency preparedness; and large city health departments.

An important consideration in the process of shaping what PHAB accreditation should look like has been how to accommodate smaller health departments in the process. While a tiered approach was considered, ultimately PHAB decided to develop a set of standards that will apply to the majority of health departments. There is also an issue with very large health departments—is the bar too low for them? It is likely that PHAB will need to re-visit this issue. There may come a point when smaller health departments are not eligible for accreditation. However, there are potential alternatives such as using a regional approach to accredit a group of small health departments.

**Other Considerations to Explore in PHAB Accreditation**

**Recognizing Tribal and Territorial Health Departments**
- Tribal and Territorial health departments will have unique issues to consider in the accreditation process. While three Tribal health departments are included in the beta test, there are no Territorial health departments involved.

**Contracted Services**
- How to measure the relationship for contract services (and services where there are no contracts)? Looking at memoranda of understanding (MOUs) and contracts that document the arrangement—do these pass the rigor test?

**Working with other State Agencies**
- Can relationships with other State agencies be reflected in the accreditation process? For example, in public health events, other State Agencies often have specific roles and responsibilities and must work with the health department. In the PHAB accreditation process, health departments must identify their various partners and how they work with them.

**Benefits of PHAB Accreditation Process**
- Increases communication across health department – people must talk to each other to assess systems and processes
- Involves laboratories in discussions within the health department (i.e., a seat at the table)
- Necessitates strategic planning (i.e., States must have a strategic plan) that can institutionalize key processes within a system
- Drives quality (e.g., need for written policies, preparedness plans, etc.)
- Results in meaningful action (i.e., address weaknesses)
- Helps to ensure the continuation of service (i.e., policymakers will not cut key services that are crucial to the accreditation process)
Information is provided in the health department’s profile and site visit teams may interview partners. Including partners in this process can benefit health departments as they will have to assess these relationships from a quality perspective.

Focus on Outcomes

• As the accreditation process moves the health department toward more quality-related activities, there should be a focus on public health outcomes. There can be a tendency to focus on business aspects (e.g., contracts, granting, purchasing) and not on the impact of the health department’s activities.

Marketing Accreditation to Health Department Leadership

• In marketing PHAB accreditation, the importance of the laboratory and its services and the involvement of the laboratory in the accreditation process should be emphasized.

Recommendations for APHL’s involvement in PHAB Process

The APHL workgroup should explore the following areas.

• Identify opportunities for laboratory involvement across the domains (e.g., administration/governance section).
• Identify programmatic areas where increased laboratory involvement could strengthen the program.
• Consider the documentation examples—are they appropriate, can some laboratory examples be added or substituted?
• Frame the role of the public health laboratory in a high performing health care system.
• Define the safety-net function, look at regional special need (e.g., Border States), etc.
• Health departments should include a laboratory example in the accreditation process

APHL Accreditation Update

It is apparent that while public health laboratories are committed to quality assessment and evaluation, they have not had the opportunity of measuring how laboratories function and support the work of the health department.

APHL developed and published Core Functions and Capabilities of State Public Health Laboratories in 1997, which were designed to define the role of public health laboratories. These recommendations have since become an essential resource, both in the United States and abroad, in the evaluation of laboratories. The Core Functions and Capabilities identify the responsibilities, capacities, and functions at the heart of the public health mission.

From the State perspective, the core functions document is seen as a description of what public health laboratories should be responsible for but it is not necessarily a description of the functions of every public health laboratory. It does however identify key tasks and while a laboratory may not perform the task, the laboratory leadership should know who provides each task.

<table>
<thead>
<tr>
<th>Core Functions and Capabilities</th>
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<tbody>
<tr>
<td>• Disease Prevention, Control and Surveillance</td>
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<td>• Integrated Data Management</td>
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<td>• Reference and Specialized Testing</td>
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<td>• Environmental Health and Protection</td>
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<td>• Food Safety</td>
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<td>• Laboratory Improvement and Regulation</td>
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<td>• Policy Development</td>
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<td>• Emergency Response</td>
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<td>• Public Health Related Research</td>
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<td>• Training and Education</td>
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<td>• Partnerships and Communication</td>
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To assess the performance of the laboratory systems within a State, APHL and CDC initiated the Laboratory System Improvement Program (L-SIP). The L-SIP process brings together internal and external stakeholders to assess the laboratory systems and identify areas for improvement. The results provide a road map to guide improvement activities. To date, approximately 21 States have participated in the L-SIP process. That so many States have engaged in this voluntary and rigorous process is a strong indication that laboratories are ready to move forward with a voluntary accreditation process.

In 2008, APHL began exploring the feasibility of developing the first stage of a voluntary accreditation process. In particular, it viewed accreditation as an opportunity to address what was seen as a gap in how laboratories measure their effort and how they work within the larger health department system. Through accreditation, laboratories will be able to demonstrate that they are an active partner within the health department. In addition, such a process could help laboratories focus on efficiency, effectiveness, and accountability. APHL recognizes that any movement toward additional accreditation activities—either increased laboratory involvement in the PHAB process or a laboratory-focused voluntary process—will require significant marketing to APHL members as laboratories are already subject to multiple required accreditation processes. In addition, any accreditation process should take into consideration existing accreditation programs—new standards should not be developed in a vacuum or duplicate what is currently available. For example, the International Standards Organization (ISO) has standards covering clinical and analytical testing, as well as standards that address management and operational functions of laboratories. These can be used to assist in defining the framework of new standards. APHL has crosswalked ISO Standards to determine how best they can be utilized for laboratory standards development.

**Accreditation of Public Health Laboratories Discussion Points**

Accreditation can provide a “playbook” for laboratory directors that defines the role of the laboratory in the overall system. Many health directors do not have a background in public health and the playbook could serve to define the laboratory’s role and assist the laboratory director in advocating for the laboratory.

However, it is also important to recognize that laboratories already face a significant accreditation burden. Accreditation can be an expensive process and also require significant staff resources. Laboratories may not have the available funding and staff resources to participate in an additional voluntary accreditation program. In addition, there may be other voluntary accreditation processes, such as ISO, which is better known in the laboratory community.

One of the challenges is creating an accreditation processes for health departments and public health laboratories is the great diversity across these organizations—how do you conduct a standard assessment when there are such huge disparities in terms of size, services offered, capacity, staffing, and resources. To address this, accreditation would need to explore what each entity does and how well it does it (e.g., scale, capabilities, and capacities). Size should not be a detriment in the process, nor a reason for relaxing standards. However, there would need to be an accommodation in the scoring process for instances when the standards are not applicable to the applicant.
Conceivably, there are some laboratories with extremely limited functions where accreditation may not be appropriate—it would not be worth applying the standards to these laboratories given their extremely limited scope of work.

Because of the diversity across laboratories, identifying specific measures will be a challenge and there will need to be an evaluation of the accreditation process to determine if the measures are appropriate. The measures will evolve as evidence becomes available.

Issues related to the accreditation of laboratories are listed below.

*Accommodating Small Laboratories*

- Small laboratories often make arrangements to have essential services provided elsewhere. Would they be eligible for accreditation? Could there be various accreditation categories, based on size or must a single set of standards be applied to all?
- The accreditation of smaller laboratories, especially if the process addresses service linkages (e.g., the providers of other essential services), could help to raise the quality of the laboratory.
- It is necessary to balance the role of the laboratory within the health department. Small laboratories could be accredited for the diagnostic testing they do. However, they may not be able to meet the standards related to functioning effectively within the overall health department.
- Accreditation can be a demoralizing process for small laboratories if they are unable to meet the standards. Thailand has addressed this by developing a set of standards that establishes a baseline for each laboratory. Once accredited, laboratories are expected to improve.

*What Services to Assess*

- How to assess the role of reference laboratories and point-of-care testing—the laboratories are not directly providing these services but have a role in their delivery.
- There is a need to identify core services for public health laboratories (i.e., what a public health laboratory should be). Consolidation and outsourcing are becoming increasingly prevalent. The laboratory must not be divested of its core services.
- States have looked at laboratory core functions at the State level. This needs to be done at the Local level. At the same time, it is necessary to identify what others can do better (e.g. STD testing). However, even when things are outsourced, the laboratory still has an assurance function. APHL is hoping to take State-based documents (that include core functions) and identify a set of core function for the Local levels. In addition, there is an established system of Local laboratories (in states like NY, TX, and CA) that must be considered.
**“Marketing” Accreditation**

Given that public health laboratories are already subject to a high level of accreditation, it is likely that there may be push back from a new accreditation process. APHL will need to convince members of the benefits of participating in these voluntary accreditation processes. In addition to APHL members, additional marketing activities will need to target health officials and health department staff and academia (e.g., schools of public health).

- Big city health departments will need to be educated about the process and how it “fits” with their capacity, resources, and responsibilities. Partnering with NACCHO may be an effective way to reach these health departments.
- Reach out to academic programs (e.g., schools of public health). They are educating the public health workforce of the future. Students need an understanding of the laboratories in the public health system.
- People need to understand the role of the laboratories in the health department system. APHL/PHAB accreditation focuses on this role and other accreditations do not address it (i.e., how is this accreditation different from others).
- Focus on “value added.” For example, involvement in the PHAB process will help those in the broader public health system understand the importance of the laboratories. It provides an opportunity to stress that the laboratory is an equal partner, not simply supporting other health department programs.
- Involve laboratories in the PHAB pilot test (e.g., provide heads up that it is taking place, invite to observe site visit, etc.).
- Stress the emphasis on quality. Accreditation is a way to set expectations. If the vast majority of laboratories are accredited, laboratories will need to do it, even if it is “voluntary.”
- Accreditation can help health departments and laboratories get systems in place to address the increased demand for services that is likely to result from health care reform (e.g., billing services, IT systems, etc.).
- With the growing emphasis on quality, involvement of a laboratory with its expertise in quality improvement programs in the PHAB accreditation process could position it to take the lead in quality-related activities within the health department (e.g., laboratory leading a quality team that infuses quality throughout the agency).
- Accreditation can serve to bring additional resources to laboratories. If accreditation standards specify that laboratories must have certain facilities, equipment, and other resources, then the laboratory must have them and maintain them in order to retain accreditation status.
Recommendations to APHL/PHAB

Think Tank participants identified the following recommendations to APHL and PHAB.

- Continue collaborations with APHL and PHAB in strengthening partnerships with the goal of including public health laboratories in the public health accreditation process
  - Continue to build communication between PHAB and APHL on progress

- Develop laboratory specific standards
  - APHL accreditation workgroup develop plan on developing standards
  - Discussions to continue on how to incorporate or partner the APHL-developed laboratory standards with the PHAB process

- Review the PHAB guidelines for opportunities to use models from the public health laboratory or laboratory testing as examples in the guidelines
  - Especially look at laboratory influence in Part A

- Develop Tribal guidelines and standards under the PHAB process.
  - Include laboratory representation on the PHAB Tribal workgroup

- Develop guidelines and standards for large metropolitan health departments under the PHAB process.
  - Include laboratory representation on the PHAB workgroup addressing this issue

- APHL should explore possible ways to have an organizational liaison to the PHAB Board
  - Currently, there are two openings on the Board and a call for nominations will be released in the near future
  - Explore other ways that laboratories can be represented in the PHAB process (e.g., through current PHAB Board members involved in the Think Tank process, by involving laboratorians in the site visit process, etc.)

- Explore the concept of the Quality Team—laboratorians bringing their experience in quality improvement to the larger health department.

Action Items

- Develop a process to plan the laboratory accreditation process
  - Look at other models (e.g., CAP)
  - Consult with other organizations such as ASTHO and NACCHO to determine how they prepare their members for accreditation

- Explore opportunities for presentations at ASTHO and NACCHO meetings
  - APHL, PHAB and CDC will be conducting an accreditation session at APHA in November 2010
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<th>Time</th>
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<td>8:00-9:00am</td>
<td>Continental Breakfast</td>
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<td>9:00-9:15am</td>
<td>Welcome, Overview and Purpose of Meeting</td>
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<td>Scott Becker, APHL Executive Director</td>
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<td>9:15-9:45am</td>
<td>Public Health Accreditation Board Update</td>
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<td>Kaye Bender, PHAB President and CEO</td>
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<td>9:45-10:00am</td>
<td>Association of Public Health Laboratories Accreditation Update</td>
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<td>Eric Blank, APHL Accreditation Workgroup Chair</td>
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<td>10:00-10:15am</td>
<td>Break</td>
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<td>10:15-10:30am</td>
<td>Review key components of PHAB and Opportunities for Collaboration</td>
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<td>Eric Blank/ Kaye Bender</td>
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<td>10:30-12:00pm</td>
<td>Group Discussion</td>
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<td>- Discuss the roles of public health laboratories within the public health agency</td>
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<td>- Explain the importance of merging the proposed laboratory standards into the PHAB process</td>
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<td>- Outline a draft plan for merging the proposed APHL standards into the PHAB process and include a time frame</td>
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<td>- Develop actionable recommendations to the PHAB Board of Directors concerning the outcomes of the Think Tank meeting</td>
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Appendix B

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