

Guide

A Practical Guide to Public Health Laboratories for State Health Officials

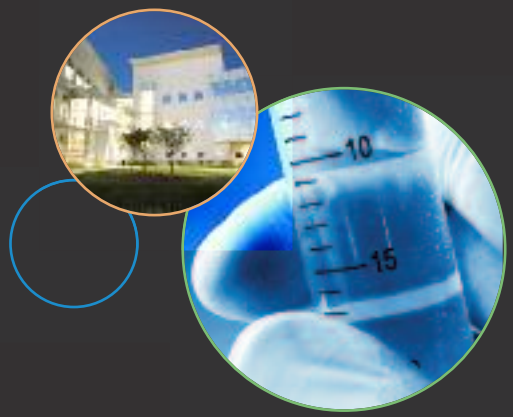


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About This Publication

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Acknowledgments

How We Created This Guide

Representatives from the Association of State and Territorial Health Officials (ASTHO) and the Association of Public Health Laboratories (APHL) saw future issues looming—primarily funding issues, but also IT, biosecurity, and emerging health threats—that could affect the relationship between state health officials and public health labs. The time to forge strong and flexible connections was now, they decided, and they convened a group of SHOs, Senior Deputies and lab directors, colleagues from the CDC and facilitators. The group, armed with an agenda of questions and issues contributed by SHOs and lab directors from around the nation, held several conference calls, information exchanges and a day-and-a-half-long face-to-face meeting to determine what information should be included—and what was most urgent.

As the process took place, the ongoing pandemic H1N1 crisis continued—and continued to yield valuable insights about relationships among SHOs, state health departments, programs, federal entities and public health labs of all kinds. The group shared a sense that the crisis was fueling a new interconnectiveness that would benefit public health into the future—an acknowledgment that each institution and each person held an essential role in containing the virus and its effects, and therefore in saving lives. We hope this guide works to expand this understanding and valuing of all contributions.

APHL and ASTHO wish to thank the following expert panelists and other consultants and staff who contributed their thoughts and experiences and gave of their valuable time:

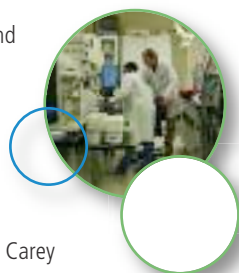
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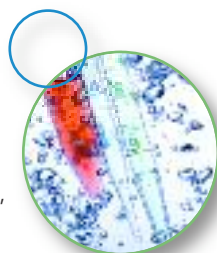
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Why You Need This Guide

Just a few days into a state health official's new job, the sudden news arrived: The public health laboratory was being shut down by federal order. Not just the lab, but every associated function had been decertified—all because of an inadvertent violation of a Clinical Laboratory Improvement Amendment (CLIA) specification. And, says the SHO, "we didn't know what to do."

"The penalty was equivalent to being executed for stealing a loaf of bread," as one SHO put it. Consequences extended far beyond the shutdown. The order triggered an investigation that identified almost 100 problems in the lab that would need to be remedied, as well as the merging and un-merging of two state departments, recertification, sanctions and penalties.



Most agree these consequences aren't really the intention of the law. Yet the story demonstrates the broad and far-reaching effect of having just one element amiss in the public health lab.

This guide is intended to help SHOs and others avoid this kind of situation, by improving communication, enhancing awareness and showing SHOs where to get information. Not knowing what to do is perhaps the worst aspect of such a situation.

SHOs recognize public health labs as a rich resource; running a health department would be impossible without one. Data, training, expertise, leadership, connections to federal issues and policymaking—the benefits SHOs can pull from the public health lab and its staff cover a wide range. Perhaps most important, a SHO can count on the lab to be objective and unaffiliated and to maintain high standards.

"We want to know from the lab where we have discretion versus what's mandatory. We want to minimize unknown, potential liabilities."

Dr. Paul Halverson, SHO, Arkansas Department of Health

But this confidence in the degree of regulatory and certification compliance the lab requires can lead to an "out of sight, out of mind" attitude. Many SHOs don't realize, or don't take into account, the extent to which the lab is intertwined with other public health functions and institutions. When something goes wrong, the lab is suddenly on everyone's radar.

It's not exactly an apples and oranges situation, but some of the differences between health department and lab culture can contribute to less-than-effective interactions. Most SHOs are political appointees; their median tenure is three years. As agency chiefs, they're pressed for time, must work quickly and are called to respond to multiple constituencies, of which the labs are just a small part. Lab directors are usually scientists of long tenure; their culture values careful, methodical approaches over innovation and flexibility. Public health laboratories need to serve many constituencies as well—programs, enforcers of federal requirements and more—a fact that isn't always well-communicated by labs or understood by SHOs.

There are certainly exceptions, but some truisms bear out. Lab staff have a strong sense of their role in serving the community and the public and in saving lives. They know their work provides critical data used by health programs and the medical community to implement appropriate prevention and control measures. In fact, the labs can be a good place for SHOs to look to regain perspective and determination when politics threaten to taint public health decisions.

“When it comes to public health, no one likes surprises. Let the SHO know—for instance, there’s an epidemiological survey coming out, and it may be a bit controversial.”

***Dr. Paul Kimsey, Director, California State Public Health Laboratory,
California Department of Public Health***

However, communication can be a point of conflict. Lab leaders most often communicate as scientists first. SHOs may want to know more, but they're wary of being inundated with nonessential information (information that people in the labs may find absolutely fascinating). This guide does not provide pat answers but directs SHOs toward knowing what to ask their labs to get the information and communication they need to strengthen their departments and the health of their states' residents.

As health reform becomes a more pressing issue, necessitating more data and activities in prevention, population-based issues and IT efficiencies, everyone in public health will likely see an increase in duties and responsibilities. Better relationships now will better position us for this future.

How to Use This Guide

Material was selected on the basis of what would be most important to SHOs today and into the future. Incoming SHOs will find material that helps them get a handle on what's going on in the lab and on how the lab contributes to the missions of the health department and the state. However, even veterans may want to check portions such as the prevailing Core Functions to determine whether lab needs and responsibilities are being met.

Often, of course, direct communication does not always occur between the lab director and the SHO—nor does it need to on every issue. Lab directors or staff members usually contact the SHO legal, communications or budgetary staff, and information filters back and forth as needed.



“At times, we’re trying to fix an adaptive cultural problem with technical solutions. This is why we so often see the problems persist.”

Dr. David R. Gifford, SHO, Rhode Island Department of Health

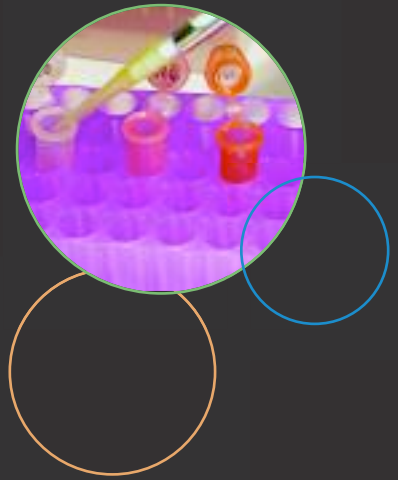
But sometimes, this filtering can get in the way. Health department staff without scientific training may not understand a message or its urgency; lab staff may lack political savvy, to give just two examples. This guide points to some of the places where a SHO does need to make direct contact and looks at ways to make overall communication more effective. We recommend sharing this guide with all staff you believe would benefit from a richer understanding of public health labs.

What Does a SHO Need to Know About the Public Health Lab?

This gives an overview of what the guide addresses in greater depth:

- Ask questions. Then ask again, until you understand the answers and can explain them to others. Request clarification on unusual or unfamiliar scientific terms from the lab director.
- Seek out vulnerabilities and gaps—in equipment, in functions (are they automated or manual?), in interactions, in accountability, in reliability, in accuracy, in timeliness, in public health relevancy.
- Determine the extent of the lab's activities, both inside and outside of the health department. Drill down to get the full breadth.
- Tap into the lab director's expertise to find out which certifications and licenses are required to keep the lab running smoothly.

Quick Answers to FAQs



Frequently Asked Questions

The following are talking points and fodder for quick answers on issues SHOs identified as being most asked or most urgent. The answers can be used as a foundation for communications or adapted for individual needs.

Why Do We Need a Public Health Lab?

No one in your state should be making decisions without appropriate data. In the world of public health, the public health lab is the provider of hard data—such as scientific evidence, test results and accurate measures of whether a health issue, from HIV/AIDS to *Salmonella*, is a containable problem or a dire crisis. Is the health department meeting its mission, strategically serving public health needs, fulfilling program mandates? With its certified processes for infectious disease testing, newborn screening and environmental analyses, and specialized, highly educated workers, your public health lab can provide results: information everyone can use, from the legislature to community workers.

Find Success Stories Real stories of lives saved, disasters averted and progress made can be found at the APHL website (www.aphl.org) and the ASTHO website (www.astho.org).

The public health lab is also a first responder—and communicating its role this way can be a strong argument for adequate lab funding. Influenza, anthrax, drug-resistant tuberculosis—it's all in the news, and an emergency involving any one of these can slow a state's economy to a crawl. Without a public health lab, which has specialized equipment and workers trained in emergency procedures, the state won't know how to analyze the extent of the threat, answer the public's questions or take appropriate action.

Lab PR Opportunity Veteran SHOs recommend National Medical Laboratory Week, the last week in April, as a good time to hold open houses, introduce the lab to general staff and showcase achievements.

Public health labs demonstrate their value through what they achieve. A public health lab's newborn screening program, for instance, can detect certain critical inborn disorders that can be successfully treated in the first days after birth—a lifesaving effect. Labs have a key role in disasters, emergencies and terrorism threats. They can act on a very local level—investigating dangerous methicillin resistant *Staphylococcus aureus* (MRSA) bacteria in a high school, for instance. Getting these success stories out can go a long way in communicating the value of the lab.

Why Do We Need That Expensive Piece of Specialized Equipment?

That's an excellent question—and it reinforces the point that SHOs should ask questions like this. Answering is the lab director's responsibility, but until you get an answer in a way you can easily explain to others, the question isn't truly answered.

Flexibility and Innovation If you get the impression that a lab is resistant to change, find out why. It may be that the lab process is so highly specialized that there really is only one way to do the job. A closer look into public health labs can reveal many areas in which they are flexible and innovative: Newborn screening programs, for instance, incorporate sophisticated instrumentation with high through-put processes to meet tough time demands—as strong a showing as any comparable activity in a private sector lab.

The question also brings up issues of budgeting, due diligence and special requests. Problems are not always a case of a SHO or legislator not understanding the need for resources. Some SHOs get too much information or information in the wrong place during the budgeting process. For instance, a SHO may get questions on basics in the last days before a grant request needs to be submitted; or an expensive, non-routine purchase may catch a budget director's attention.

Develop a Lab-Specific Budget Justification Process Use some of the questions here to create a process for the lab, or have a lab director or a senior staff member develop it.

Some lab directors don't realize they need to be able to justify requests. To help them in this area, ask the lab directors:

- Why is this request necessary?
- Are there other options?
- What are potential consequences of not having the equipment?
- Upon what assumptions are you basing this request? That is, will this be necessary only if a certain health situation or program continues? Your perspective can help them determine if their assumptions are correct.



“Often, there’s no systematic way to replace equipment, no depreciation funds. Does the state think a magic fairy comes to replace failing equipment?”

Veteran SHO

It helps to acknowledge to the department and to the public that, indeed, some functions of the lab may not be cost-effective. The low-frequency, high-intensity nature of some investigations, such as analysis of chemical threats in the environment, means certain equipment or procedures aren’t brought out of the cabinet, so to speak, too often. But when they’re needed, time is of the essence, and testing can be a lifesaving matter. Further, no other way or place usually exists to get these functions done. The consequences of not being prepared are serious.

Can We Privatize the Lab?

This question pops up with some regularity. It is hard for those determining funding not to look at the numbers attached to the public health lab and wonder. But in comparing the value of services with those of the private sector, it's essential to consider all the costs—not only the obvious ones.

A hard concept to grasp from the political side of the fence is that some lab functions and programs are not cost-effective. That's not their intent. They can be made efficient, but the benefits conveyed by biological threat preparation, for instance, may not be quantifiable.

Improvement Without Privatization Ways to reach the goals touted in privatization while minimizing the hazards:

- Partner with academic institutions in your community where viable
- Establish a business office or management function for the lab
- Explore successful business models and see how these can apply to the lab
- Use proven techniques or assessments to improve efficiency and quality
- Keep existing relationships with clinical labs strong and work on partnerships

There are two basic arguments for the privatization of the lab:

- Private sector labs do much of the same kind of testing public health labs do, so privatization could be in the interest of smaller government.
- Privatization can save money, based on the assumption that the private sector will provide the same services at a lower cost.

However, neither argument bears out practically. Here's why:

The overriding concern is that the missions are different—public health laboratories have a service mission, private labs have a mission to shareholders or owners, and academic labs have a research mission.

Other problems with privatization include:

- Public health emergency response capability and capacity would be lost.
- Short-term savings may not last. No one can guarantee private lab services will always be available at a lower cost. But it's certain that the cost of trying to re-establish lost services will be high.

“Since public health labs have a service and surveillance mission, managing the expectations of the general public and media for test results can be difficult.”

*Kathy Vincent, Staff Assistant to the SHO,
Alabama Department of Public Health*

- Private labs may be unable or unwilling to conduct testing for rare, low-incident public health threats, resulting in loss of this essential public health function. Again, if private labs abandon these functions, bringing them back into the public sector may be impossible or, if it can be done, costly.
- Does the cost comparison include the value of data management, consultative costs, institutional knowledge? Public health labs will likely come out ahead because private labs don't have to include those items.
- Continual biological and chemical surveillance for public health threats is essential—and expensive. Who picks up the tab? Private labs can't charge individuals or third parties—surveillance is a public service.
- The inherent risk of decreased communication among the private lab, epidemiologists and programs could compromise health and safety.
- The state could lose control of privacy and security specifications, resulting in costly security compromises.
- The state could lose access to valuable specimens, data and scientific innovation.
- Spinning off selected services to private labs can further complicate the already complex network of lab, organization, department and program interactions.
- Logistical challenges would grow. For instance, testing may take longer due to distances, and private labs taking samples from multiple states may compromise state regulations for reporting and compiling data.

But what's the real aim of privatization? To limit costs, increase efficiencies and improve quality? To be able to establish standards, measure performance and/or establish accountability? These are all goals a public health lab can and should meet—and the above arguments make it clear that privatization may not be a goal in itself to achieve these aims. It will be more effective to focus first on improving the public health lab operation, quality and efficiency, before considering privatizing services. For instance, one SHO established a business office in the lab to make procurement and other procedures more efficient.

Some labs have worked out other, “semi-private” measures to gain resources and efficiencies, such as contracting with academic institutions to share services and equipment. However, academic institutions are research-focused and not certified for diagnostic testing; they cannot take the place of the public health lab.

Strong leadership must be present on both sides for collaboration with academic institutions to work to the health department's advantage. Veteran SHOs warn that when public health labs contract with academic institutions to provide services or allow the use of equipment, you should watch carefully for mission interference.



Why Do We Need So Many Specialized Workers?

Legislators can find the lab workforce shortage difficult to understand. One SHO said she was asked: “Can’t you just cross-train those microbiologists and get three instead of eight?”

Of course, it’s not that simple. Because the workforce crisis extends through all facets of public health, SHOs are well aware of the overall problem, and many have put measures in place or are working with ASTHO to cultivate future leadership, scientists and more.

Cross-training is in fact one strategy being used to deal with the need for specialized workers in labs. Labs also are reducing workforce expenditures through furloughs, salary cuts and outsourcing some functions. However, each solution comes with drawbacks:

- Personnel licensure requirements, personnel regulations or union involvement may limit cross-training.
- Training takes a long time.
- Getting new or returning scientists up to speed on changing equipment, policies and procedures uses critical time and can contribute to error—especially dangerous in a crisis.
- Outsourcing, i.e., sending some lab testing to other labs, carries with it the same risks as does privatization.

Lab Staffing Strategies

- Conduct a cost-benefit analysis on personnel needs
- Assess compensation plans
- Institute long-term recruitment best practices

No one is suggesting lab worker positions are sacrosanct; however, SHOs should weigh carefully the risks against any cost advantages posed by changing personnel. In a public health lab, the nature of the work offers little tolerance for a “plug-and-play” approach. Keeping staff can be more cost-effective in the long run. SHOs should also be prepared for lab directors to advocate aggressively for needed staff.

At this writing, the workforce issue is probably the most serious one facing labs and could continue to be a problem for a decade or more. Data on workforce issues can be found at APHL and ASTHO websites; the organizations perform regular surveys.

Get Up-to-Date Salary Data APHL can provide model job descriptions and salaries as well as tips on working with human resources.

Here are some of the reasons for the workforce shortage and some ways SHOs can help:

- **The field is graying:** New laboratorians are not entering the field. Shortages also extend to private labs.
- **Again, training takes a long time:** This makes losing workers even more costly—factor in the training time on the worker that leaves and that of an incoming worker.
- **Public health labs can't recruit competitively:** The need to make salaries more competitive is one issue. Also, the competition for qualified staff is strong. SHOs can help cultivate the lab professionals for the future by encouraging directors and other management staff to keep their eyes open for talent and by connecting lab workers with the training they need to become leaders. APHL can help as a resource—it offers an Emerging Leaders Program and succession programs. Universities and other labs in the region can also be resources.
- **A thoughtful lab review can result in staff efficiencies:** However, keep in mind that new certification or licensure could be required for staff people changing duties or cross-training. Any changes should be based on a larger analysis of workload and needs, not simply rearranging the organizational boxes.

“There’s a diminished workforce in the clinical sector, too—and sometimes there’s an expectation that the public health labs will pick up the slack.”

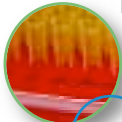
*Dr. Roberta B. Carey, Acting Director,
Division of Laboratory Systems, CDC*

How Does the Lab Work With Other Organizations and Agencies—From the CDC to the FBI to the Department of Agriculture?

This depends on the lab. A diagram on page 27 and a list of core functions on page 26 can help you pin down specifics.

The important point for SHOs to remember is that public health labs serve many agencies and perform diverse functions. These range from everyday duties, such as testing private well water, to first-responder testing for a novel strain of influenza virus.

The danger lies in resource overload. If the FBI calls about a bioterrorism threat, the lab may not be able to fulfill its duties for a state program. Of course, the workforce shortage has an impact here as well.



Invest in a Communication Plan Starting a communication plan, using techniques such as SMART (Strategic, Measurable, Reasonable and Targeted), can help with the mission of having agencies talk to each other.

Lab management should be able to assure that even while dealing with an emergency, urgent lab work, where a patient's or the public's health is at immediate risk, gets done—and other work is completed within technically acceptable limits.

To stay on top of these surge conditions, it helps to invest in communication and institutional interactivity. When labs can easily interact, they can make arrangements; one may be able to pick up the work when another is overwhelmed in a crisis or by a call from an outside agency. Labs nationwide are actively building such capacity—and a SHO can be supportive of that work.

“It's important to understand the public health laboratory system and how the pieces fit together. It's not just about them versus us, the clinical labs versus the public health labs.”

Dr. Tom Hearn, Acting Director, NCPDCID/CDC

Why Is [X] Taking So Long/Costing So Much?

SHOs with scientific backgrounds know that testing is not as fast, easy and predictable as it is made out to be; they also fully understand the difficulty of explaining this well. The answer to this question is simple: complex science takes time, special equipment and specialized knowledge to acquire and interpret reliable results.

Lab directors and staff are driven never to have a false test result, yet they are under constant pressure to produce data more quickly. In addition, the necessary communication and information exchange with federal agencies, other labs and the CDC can add time to processes.

When a delay or a cost spike occurs, SHOs would rather hear about it from the lab director than from the community, the media or the legislature. How can you open up and improve communication so you'll be the first to know?

- Encourage the lab director to let the executive office know if undue pressure is being applied (the epidemiology department pushing for results, for instance).
- Have a weekly meeting with the lab director, or periodic meetings with the lab director and program directors.
- Ask the lab director to develop or improve a lab strategic plan that aligns with the health department and state strategic plans. It should cover financial systems, IT, replacement of equipment, staff recruitment and more. This will help avoid surprises. Make sure the plan is focused on the community and the mission, not on political agendas.



How Well Is the Lab Performing?

Some public health labs have come late to performance measurement practice, largely because the degree of regulation and performance necessary for certification has provided a type of built-in quality assurance.

SHOs would generally like to have concrete performance measures and indicators of improvement to help them make decisions and the case for funding. Other divisions and programs can do it—why not labs?

You Need a Performance Evaluation Plan While many alternatives exist for this, APHL and ASTHO can also help you or your lab develop workable performance evaluation.

Public health labs have, in fact, been working to establish best practices in performance measurement. Regarding laboratory systems, APHL has provided leadership through its Laboratory System Improvement Program (L-SIP), and training programs (see Resources) also provide evaluative tools and techniques for the lab itself. If you would like to bring your lab into the performance measurement era, here are some insights and lessons learned by APHL, lab directors and other SHOs:

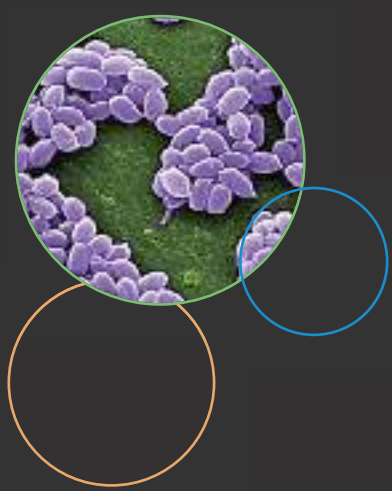
- Try customer satisfaction surveys—despite the differences among the kinds of customers you serve, the surveys can provide valuable feedback and can boost staff morale.
- Differences among labs make it difficult to collect comparative performance data. At this writing, APHL is developing a comparative database, as well as a scorecard.
- In addition to L-SIP, APHL conducts site visits with state and local lab partners and stakeholders to explore efficiency; however, while very helpful, this is a subjective assessment with no comparative data.

Get a Baseline on Strategy When you first come in, veteran SHOs recommend, ask for the lab's strategic plan. Check in on the plan every two or three years.

- To determine the lab's cost-effectiveness, you must research comparative costs of tests. APHL is developing and will pilot in 2010 a laboratory metrics tool. The CDC can also help here.
- Encourage an L-SIP assessment—it can help improve staff, department and community communication and yield insights.

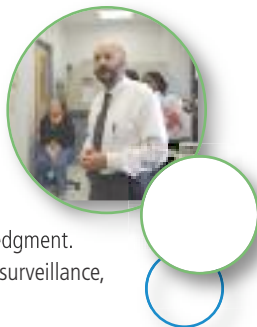


Know Your Lab's Core Functions



You Can Get a Lot Out of Your Lab

The public health lab may do more than people know or expect. To give public health labs a practical and complete framework, APHL in 2002 formalized a list of core functions. The list expanded the thinking about labs in many cases; in others, it recognized functions labs had performed without much acknowledgment. Core functions that may be of particular interest to SHOs include surveillance, furnishing data products and helping to formulate policy.



Because every lab is different, yours may not perform each of these core functions. You can use this list as a launch pad to create a list of all that your lab does. Also, because no lab exists in a vacuum, your lab may share responsibilities or spin off functions to other parts of the health department, private labs or external entities. It may also answer to these other entities and be responsible for performing functions on their behalf. The accompanying diagram shows many different places—above and beyond the SHO and state health department—with which a public health lab may interact in fulfilling its public health functions.

“The Public Health Laboratory is in the same building as the health department, so interactions occur frequently. We meet with the SHO every Monday, and I update the SHO on issues facing our Laboratory Response Network (LRN) partners. He is invited to LRN meetings on a regular basis.”

Dr. Christine Bean, Director, New Hampshire State Public Health Laboratories

The important factors for a SHO to analyze—with essential help from the lab director—are:

- Core functions: Use the APHL list to help determine these. Look for:
 - Core functions actually performed by your lab.
 - Core functions on the list performed by other means.
 - Core functions currently not covered.
 - Any core functions you feel are lacking from the list but which your state needs.
- Interactivity: Use the diagram to help determine these. Look for:
 - Activities your lab must perform for other institutions (environmental, agriculture) or programs (PulseNet); to whom does the lab report in each?
 - Activities your lab must perform for federal entities (biosecurity, CDC); to whom does the lab report in each?
 - Activities your lab performs for programs; to whom does the lab report in each?

Eleven Core Functions of State Public Health Labs

1. **Disease prevention, control and surveillance** by providing diagnostic and analytical services to assess and monitor infectious, communicable, genetic and chronic diseases and exposure to environmental toxicants.
2. **Integrated data management** to capture, maintain and communicate data essential to public health analysis and decision-making.
3. **Reference and specialized testing** to identify unusual pathogens, confirm atypical laboratory results, verify results of other laboratory tests and perform tests not typically performed by private sector laboratories.
4. **Environmental health and protection**, including analysis of environmental samples and biological specimens to identify and monitor potential threats and ensure regulatory compliance.
5. **Food safety assurance** by testing specimens from people, food and beverages implicated in foodborne illnesses and monitoring radioactive contamination of foods and water.
6. **Laboratory improvement and regulation**, including training and quality assurance.
7. **Policy development**, including developing standards and providing leadership.
8. **Emergency response** via provision of rapid, high-volume laboratory support as part of state and national disaster preparedness programs.
9. **Public health related research** to improve the practice of laboratory science.
10. **Training and education** for laboratory staff in the private and public sectors in the United States and abroad.
11. **Partnerships and communication** with public health colleagues at all levels and with managed care organizations, academia, private industry, legislators, public safety officials and others, to participate in state policy planning and to support the core functions outlined here.



Information Technology



What to Ask in IT

Information technology (IT) is a key component of today's state-of-the-art public health laboratory, being essential for data management and transfer. While purchasing lab IT is often out of a SHO's direct control, IT can still cause headaches: What technology will align with given architecture? What are the vendors and bidding processes used by the state? Here are a few points and considerations to take into account as you survey IT and the effect it may have on public health lab operations and capacity:

- Choose a laboratory information management system (LIMS) that offers maximum interoperability. (This is easier said than done, but it should factor into your decisions.)
- Public health labs are very dependent on vendors for modifications. Whenever new equipment or services are added, the lab must pay for new interfaces and versions.
- Interoperability of systems across the health department is important, especially in the area of epidemiology. IT used by programs and stakeholders should align.
- The federal funds often used in the past to pay for IT systems may not be available in the future—so labs need to plan for alternative sources now.
- IT systems should accommodate other lab operations, such as billing and procurement.
- Consider opportunities to benefit from economies of scale, such as jointly bidding with other states for IT.
- Data privacy is a top SHO concern. Security of information must be planned into any IT changes.



Public Health Laboratory Interoperability Project

The lab's IT must be able to "talk" to federal agencies, primarily the CDC. To work toward this alignment and others, APHL has developed an online community of LIMS users and is conducting the Interoperability Project, which "aims to establish reliable laboratory data exchange between state public health laboratories and the CDC by fostering collaboration in IT and laboratory science."

The benefits of this collaboration are intended to extend to all relevant public and private entities. Stated aims include the goal to “develop, pilot and deploy viable IT architecture options and tools for the exchange of electronic laboratory data at all levels of public health laboratories.” Raising capability to a national business standard and reducing overhead and expenses for all partners are other goals.

“You need to consider business continuity. You can sometimes move people working in cubicles in other departments. You can’t do that with the lab.”

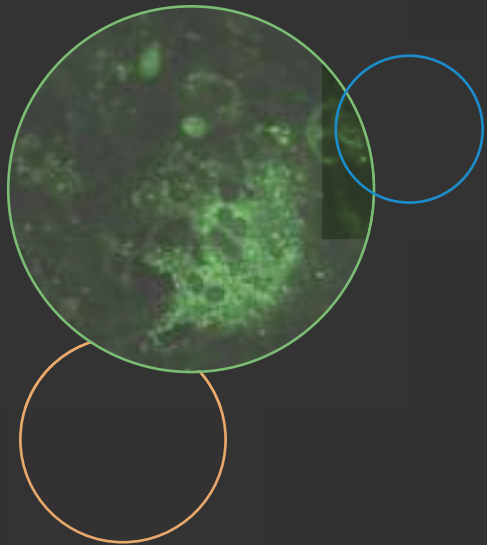
Dr. David R. Gifford, SHO, Rhode Island Department of Health

Requirements and Logical Design for PHL Information Management Systems

Also in response to the critical need for efficient LIMS, APHL collaborated with the Public Health Informatics Institute (PHII) and with state and local public health laboratories to develop universal requirements.

The resulting list identifies the 16 essential business processes of a public health lab that provided the framework for defining workflows and outputs that a LIMS should logically provide. The full document can be downloaded at www.aphl.org/aphlprograms/informatics/Pages/requirementslims.aspx.

Preparedness and Response



Capacity and Communication

As a first responder, the public health laboratory plays a critical role in national public health preparedness and response issues. For SHOs, this means that the lab will have increased demands on its capacity, not only during emergencies but also in training, exercises, planning and preparation. What are some of the points and questions to keep top of mind about your lab's involvement in security issues?

Capacity and Communication Checklist

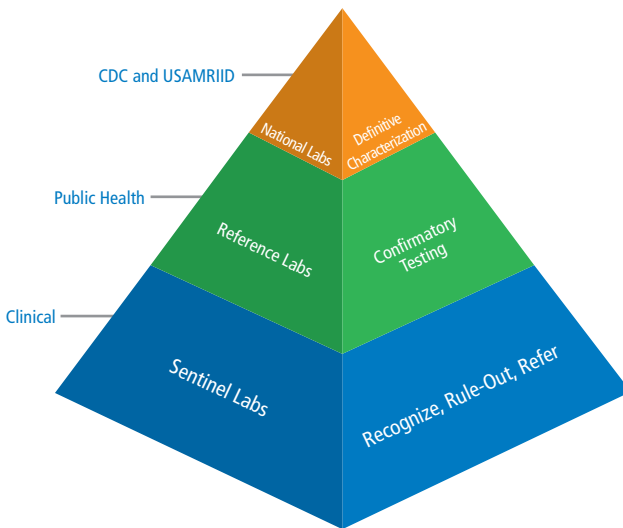
The public health lab continually faces demands from multiple agencies. In an emergency, these demands escalate.

- How are the lab and epidemiology working together—has the lab made clear what epidemiology can expect in terms of testing, turnaround and capacity? Has epidemiology worked to “protect” the lab for being inundated with unnecessary testing?
- Consider the balance of public health and patient care needs—will there be sufficient capacity and communication? The health department will be working with many types of labs in a crisis situation, including hospital and private labs.
- How does the lab fit into the public communication plan during a crisis: Can the lab director work with your communications officers to get the right messages across and explain its role? Can the lab provide the answers your department needs to shape appropriate communications?



- Is the lab technology aligned with the Health Alert Network communications needs?
- Does the lab have a continuity of operations plan aligned with the agency-wide plan that takes into account time-sensitive lab activities, such as newborn screening?
- Does legal preparation for emergencies (multiple jurisdictions, cross-state communication) include the lab?
- Is the lab supported in giving training to clinical labs in detecting agents?

The LRN and the Sentinel Laboratory Role



In an emergency, the state public health lab will put on yet another hat and get to work as an essential reference laboratory, working as a key component of the nation's Laboratory Response Network (LRN). Founded by APHL, CDC and the FBI in 1999 to improve U.S. readiness for bioterrorism, the LRN is equipped to respond to acts of biological or chemical terrorism, emerging infectious disease, natural disasters and other public health threats.

The system was in place just before the anthrax events of 2001, where it proved its value: state and local public health labs tested 125,000 samples and conducted more than a million tests. Over a period of three months, these laboratories tested approximately 70 percent of anthrax specimens and conducted more than 84,000 environmental workups.

In the LRN system, every state public health lab is an official reference laboratory (see chart above). The LRN operates through an integrated network of public and private sector laboratories. State and local public health laboratories support the network with advanced diagnostics and disease monitoring. Hospital and clinical laboratories officially serve as sentinel labs and immediately refer suspicious specimens to their nearest LRN reference public health lab. The public health lab is responsible for developing a state and local network of these sentinel clinical labs and providing them with staff training on how to use standardized tests to attempt to rule out suspicious specimens.



The CDC provides support to LRN member reference laboratories in several ways:

- Developing and sharing standardized tests used to detect and confirm biological and chemical agents.
- Enabling secure communications on emerging and emergency issues.
- Developing training curricula.
- Implementing a quality assurance program.
- Providing vaccines to protect laboratory workers against dangerous agents.

The LRN first tackled biological threats. Radiological threats, followed by chemical threats, are the latest issue, with the EPA, CDC and other federal agencies bringing gaps in radiological preparedness to the federal legislature's attention. SHOs should be aware of these efforts and the increased requirements they may put upon public health labs and environmental labs alike.

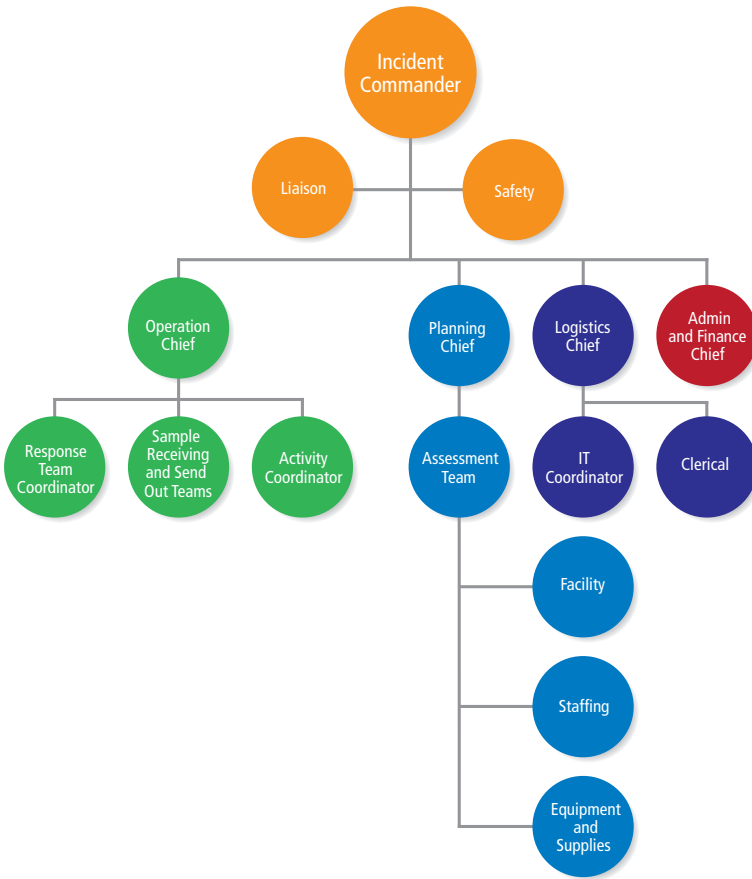
Incident Command System: How's Yours?

While the Incident Command System (ICS), which allow various agencies and jurisdictions to work together in an emergency, has operated in many states during both emergencies and exercises, SHOs may discover gaps in their ICS plan. For instance, some labs may not have all staff trained in ICS.

- SHOs are the leaders in assuring effective use of ICS within their agency. And depending on the nature of the emergency, the health department may be the lead agency for the state's overall incident command.
- ICS requires a special level of interdependence among functional components within the health agency: infectious disease epidemiology, the public health laboratory, environmental health, and emergency preparedness and response. On top of this, it requires interdependent interactions among state and local agencies—as well as federal agencies including the Department of Homeland Security, FBI, CDC and others.
- Top challenges include control issues and making certain that lab resource needs are accommodated. SHOs may find they are working under a misperception that ICS implementation interferes with each group's established operational procedures; correcting this should be a top priority.

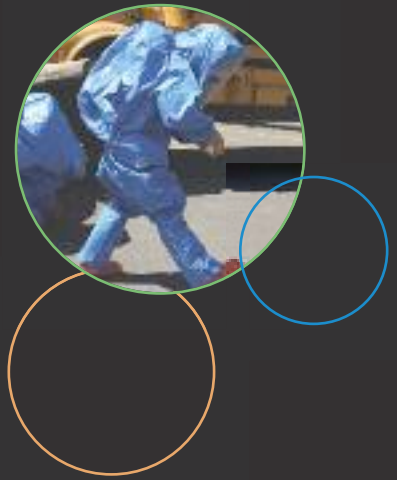


Sample ICS Chart for the Laboratory



This is one example of an Incident Command Structure (ICS) for a public health laboratory. The chart provided should be modified to meet the needs of the particular institution. The most important thing is to make sure that the structure you put in place is National Incident Management System (NIMS) compliant.

Checklists

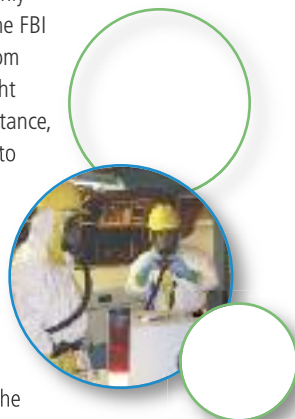


Sentinel Events Checklist

What's a Crisis?

When is it critical to talk to your public health lab director? Here is a checklist you can share, citing examples of circumstances when you or your staff need to know what's happening in the lab:

- “Highly suspect” terrorist activity testing requests:** Labs get dozens of requests to test white powders and other environmental samples; for most of these, SHOs don't need to get involved. However, if a request labeled “highly suspect” comes in from a public safety office, such as the FBI or local law enforcement, you'll want to be informed from the beginning of the investigation. Because the lab might be the first place contacted about a highly suspect substance, make sure your lab director understands that you need to know if such a request comes in.
- A positive lab result for an unexpected public health threat:** This would include a novel influenza virus or one not usually encountered in the region.
- If a lab gets a direct request for state public health information:** Ideally, these requests would go through the SHO communication staff. However, members of the media, citizens, legislators or other interested parties may not realize or follow this procedure. The SHO can be blindsided if the lab director doesn't share information about such a request.
- A request to the lab from a legislator:** Again, this would usually be handled by the SHO policy office. Legislative requests are particularly sensitive—anything from a result misinterpreted by the public to a lab needing more time to fulfill a request can undermine the SHO office's accomplishments in the legislature. The SHO will want to be in the loop on what the nature of the request is and what type of information is going to be provided.
- A request to the lab from the governor's office:** Unusual, but it can happen—and because the SHO is serving the governor, the SHO will need to know.



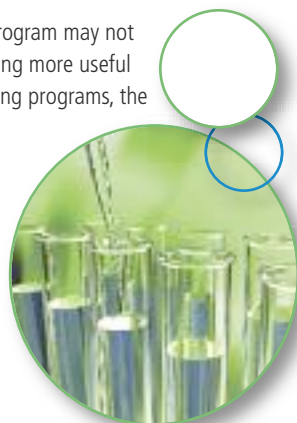
- **Critical lab workforce or budgetary issues:** Not the kind that come around with every legislative action, but rather something sudden that disrupts the lab's ability to perform. Examples would be losing a portion of the workforce or a major piece of analytic equipment.
- **Challenges to lab certification:** The regulatory agency will contact the SHO with such problems, but it will likely contact the lab first. If the lab director lets you know immediately, you'll have a chance to understand the challenge and prepare a response.
- **Challenges or conflicts with the private sector:** Some state public health labs have regulatory power over some private labs, such as environmental labs. At times, the public health lab needs to take action against a private health lab. Occasionally, the private lab takes issue with the action and starts a challenge process, at which point a SHO needs to be informed. A private lab might take its complaint directly to the governor—a situation that any SHO wants to avoid.
- **A serious personnel difficulty:** This would usually be handled by the lab's human resources manager; if the matter involves unions or could compromise the lab's activities in some ways, the director should inform the SHO.
- **Legal challenges:** Anything that happens in the lab can result in a legal challenge, and SHOs should be aware of the possibilities—and be informed if a legal challenge occurs. Examples include certification issues, a question over a lab result or the lab being required to give a legal opinion.
- **Challenges to continuity of operations:** This includes power and equipment failures, fires, floods—anything that interrupts lab operations or causes safety issues.
- **Crisis burnout:** In a crisis, labs can quickly become overwhelmed. A SHO needs to be aware in a crisis and advocate to limit testing to only that which is truly necessary. If a lab is overwhelmed, this could interfere with other lab responsibilities and could even have an effect on the quality and accuracy of testing. The lab director needs to know from the SHO that he or she can tell you when the lab is overwhelmed—without fear of repercussions. If this understanding isn't clear, you risk not hearing from the lab director—and you'll be hearing from the public if lab performance falters.

Program Changes Checklist

Programs and Public Health Labs: Managing the Mutual Impact

An epidemiologist wants to start a new study. A group within your department wants to launch a hepatitis awareness program. A legislator wants to move an initiative to a different office to save funds. Every program change has the potential to affect the public health laboratory—and the right input is essential for success. Here are some things to be aware of when changing or beginning new programs:

- Ask the lab, not the program:** Those in epidemiology or environmental health may not understand the ramifications of changes for the lab, but the lab will know.
- Ask the lab for better ideas:** Lab staff may know of more efficient or effective ways to handle the change than those proposed.
- Ensure that the necessary workforce is in place at the lab before launching or changing a program:** More people with different or specialized skills may be needed.
- Ensure needed equipment is in place at the lab before launching or changing a program:** Changing program requirements, location or operating methods may make testing more complicated and delay results.
- Ask if they really need that test:** Testing planned in a program may not always be needed, or a different kind of testing could bring more useful results. With input from the lab and communication among programs, the SHO office and the lab can help save time and money.
- Examine how program changes will affect other lab activities:** What are you willing to give up or change in the lab to get the program done? With states facing budget problems, program cuts and lab cuts should align when possible. If labs must make cuts, but programs aren't cut, the lab director will have to ask for guidance: The decision to cut certain kinds of testing can't be made unilaterally.



- **Results talk:** Set up ways to share results of programs with the lab. This gets stronger buy-in from the lab on program activities, improves communication and keeps the lab thinking of ways to improve contributions to programs.
- **Get the lab director and program directors communicating:** Once all stakeholders understand how the public health lab supports their work, program staff can even become advocates for the lab, both internally and externally.

Positive Visibility



“Why Don’t I Ever Hear About the Good Stuff?”

The answer to this question is often that the lab director doesn’t know what you most want to know. What is newsworthy?

When you’re able to communicate the accomplishments of the lab to the wider world, you gain trust in public health’s ability to protect state residents, and you develop stronger employee relations. This, of course, also can be key to getting and retaining funding for sustained lab operations.

To get there, the lab can create a marketing plan. Here are some ways you can work with the lab director or set processes in place to gain more positive recognition for the lab.

- **The quick email (with links):** Ask for a weekly email from the lab—and stipulate how long it should be. Ask for links to information instead of explanations. Ask the person responsible to limit the communication to three talking points or reports of events. This can protect you from being overwhelmed with information.
- **The basic elevator speech:** This guide answers some of the pressing and frequently asked questions about public health laboratories. But your state’s labs are unique. One way to stay on top of the details is to talk with the lab director to pin down the top three issues of the lab, create an elevator-speech answer to deal with them and then set up a calendar reminder to check in on these issues occasionally, to see if they have changed.
- **Updates on relevant topics:** SHOs want real-time updates on relevant topics. How does the lab’s work tie in with current health concerns? Ask the lab director to keep you informed on how the lab is involved in critical developments in current outbreaks or emerging threats. The media wants to know about these, as well as about activities that are unique, funny or have an “ick” factor. Ask a lab director to think in terms of what would get his or her attention on a news crawl.
- **Encourage good story telling:** Brief, interesting stories are powerful tools for demonstrating and communicating what the lab does and why it is important in protecting the public.



- **Give a glimpse into the future:** Communications on what's emerging—not simply diseases but issues, challenges, technology, discoveries—are always welcome. People look to science for innovation, novelty and hope.
- **You can and should brag about lives saved:** Newborn screening, preventing spread of foodborne illnesses, help during disasters—the lab plays a role in these life- and health-preserving activities. Just keep information credible, well-sourced and focused.
- **Give pats on the back:** Meaningful recognition of exceptional achievement is important and communicates not only the accomplishment but the department's values. Ask the lab director to communicate when staff members participate in advisory committees, work groups and standing committees for organizations such as the CDC and APHL. This should be acknowledged, and it can also aid you in networking and in giving you access to more resources.

Try Out New Media

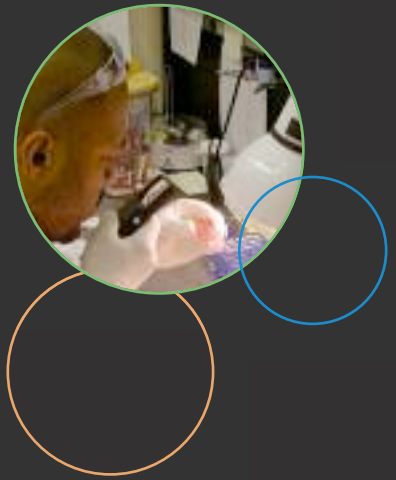
Some labs and health departments have found success using new media to get their stories out. **Caveat:** Publicly available media can backfire, so make sure content is vetted, of acceptable quality, meets confidentiality standards and transmits the right messages. (One health department's video, for instance, a humorous but educational short piece on H1N1, included a disclaimer that it was made on employees' own time and involved no department funds.) Options include:

- A Twitter feed with good news from the lab (be selective).
- Pre-made slides SHOs, staff or lab directors could use in conference and legislative presentations.
- Host Webinars on current public health issues.
- Videos showing lab workers in crisis response mode, working on a new program or featuring success stories.
- Posts about news, new techniques and learning opportunities on secure social networking sites.

- **Tout your experts:** The public health lab is home to scientific experts who can help your department and help bring positive public visibility. Lab staff can serve on advisory committees and work groups (such as the newborn screening advisory council and emergency preparedness and response work group).
- **The lab is good for business:** Many health departments overlook the role they and the public health lab play in economic strength and growth in the state. Who inspects dairy and/or shellfish to keep these industries healthy? Who ensures consumers are protected, from restaurant health problems, for instance? This is an area where you can get “good press” for your department and the lab.
- **Enjoy and preserve your reputation for accuracy:** Scientists care about facts. So do members of the media, and so do legislators, who hear many stories daily from advocacy groups and lobbyists. Ensuring the stories that come out of the lab’s work are accurate and providing fact sheets can make your office a reliable go-to source in a crisis.



Conclusion and Resources



Snapshot of What's Ahead

Because SHOs must look toward the future in their planning, here are some of the major issues on the horizon. The good news is that the basic information here, along with the ASTHO and APHL resources, can help you get prepared.

- **Information technology:** Improving interoperability, global LIMS.
- **Health reform:** Surveillance, establishment of comprehensive medical records (from newborn screening on); increasing use of rapid, point-of-care testing in the healthcare setting (how such testing impacts public health lab surveillance activities).
- **New duties for labs:** These could include biomonitoring, the direct measurement of people's exposure to environmental contaminants by measuring substances or their metabolites in blood, urine or other specimens; more research; more active role in strategic planning; a broader role in national security.

"As laboratory communication between our external and internal customers becomes more web-based, integration of the laboratory's products into other public health services becomes easier to achieve. The challenge now becomes maintaining adequate security."

*Dr. Stephanie Mayfield Gibson, Director,
Division of Laboratory Services,
Kentucky Department for Public Health*



Certification, Accreditation and Licenses: Know the Differences and Requirements

An incoming SHO should find out what is needed and what is optimal for the lab to operate and get a list of certifications and licenses.

Meeting the requirements of the Clinical Laboratory Improvement Amendments (CLIA) for clinical testing and the U.S. Environmental Protection Agency for environmental testing are essential for public health laboratory operation. Establishing stringent criteria about how the lab does its testing are justified and important. These criteria represent the lab's basic capabilities, and establishing them must be done correctly and well.



Some labs also use the College of American Pathologists accreditation system. It uses similar standards, but takes a different approach than CLIA. Labs say using it helps build teamwork and establish a culture of quality.

One recommended strategy is to invite colleagues to conduct a pre-inspection to identify potential problems. Such peer inspections can be very valuable, as accreditation inspections may not provide all of the necessary information and feedback to increase efficiency.

"I would say to a SHO, before the next major laboratory accreditation inspection, visit the lab before and during the inspection. Meeting the lab team and inspectors will send the message that your laboratory is important to you."

*Dr. Stephanie Mayfield Gibson, Director,
Division of Laboratory Services,
Kentucky Department for Public Health*

But beyond regulatory compliance is an issue especially important to public health labs supporting a larger system: How well is the lab performing as an entity? Are the labs doing what they say they're doing, and how effectively and efficiently are they doing it? No accreditation program specifically applies to public health. This has sparked a movement for public health lab accreditation. To avoid reinventing the wheel, APHL and others in the field are looking at ways to establish public health laboratory accreditation, including using L-SIP as a take-off point and exploring the possibility of implementing rigorous international standards for lab operations.

Resources in Certification, Licensing and Accreditation

- The Public Health Accreditation Board, www.phaboard.org: Developing a national voluntary accreditation program.
- CLIA certification: www.cms.gov/clia.
- College of American Pathologists, Accreditation and Laboratory Improvement information:
http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accreditation.
- National Environmental Laboratory Accreditation Program:
<http://www.nelac-institute.org/>.

Additional Resources and Terms to Know:

BioWatch

This surveillance system tests ambient air for biological terrorism agents at air-quality monitoring stations in select metropolitan areas. Air filters from the monitoring stations are routinely collected and sent to designated LRN reference laboratories for testing. The program is administered by the Department of Homeland Security (DHS) in partnership with the Environmental Protection Agency (EPA) and the Department of Health and Human Services (HHS): www.dhs.gov/xoig/assets/mgmtrpts/OIG_07-22_Jan07.pdf.

Clean Water Act

The Federal Water Pollution Control Act Amendments of 1972 is today commonly known as the Clean Water Act. This law established the basic structure for regulating the discharge of pollutants into U.S. waters, gave the EPA the authority to implement pollution control programs and continued requirements to set water quality standards for all contaminants in surface waters: www.epa.gov/lawsregs/laws/cwa.

Clinical Laboratory Improvement Amendments of 1988

Congress passed CLIA legislation in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. A laboratory is defined as any facility that performs testing on specimens derived from humans to provide information to diagnose, prevent or treat disease/impairment or to assess health status. Although all clinical laboratories must be CLIA certified to receive

Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

Final CLIA regulations, published in 1992, are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three categories of tests have been established: waived complexity, moderate complexity and high complexity. CLIA specifies quality standards for proficiency testing, patient test management, quality control, personnel qualifications and quality assurance for laboratories performing moderate and/or high complexity tests. [Laboratories performing tests that are exempt from CLIA requirements (i.e., waived tests) must enroll in the CLIA program, pay the applicable fee and follow manufacturers' instructions.] Because problems in cytology laboratories were the impetus for CLIA, there are also specific cytology requirements.

The Centers for Medicare & Medicaid Services is charged with CLIA implementation, including laboratory registration, laboratory surveys, development of surveyor guidelines, surveyor training, CLIA enforcement and approval of proficiency test providers, accrediting organizations and exempt states. The CDC is responsible for CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAAC) and providing scientific and technical support/consultation to CMS. The Food and Drug Administration is responsible for test categorization.

Those laboratories that must be surveyed routinely (i.e., those performing moderate and/or high complexity testing) can choose whether they wish to be surveyed by CMS or by a private accrediting organization. Since CLIA is funded through user fees, all costs of program administration are covered by the regulated facilities, including certificate and survey costs: www.cms.gov/clia.

Health Alert Network (HAN)

This national funding program establishes guidelines and standards for communications hardware that can electronically communicate public health and laboratory-related information and disseminate health alerts, prevention guidelines and distance learning programs to state and local health workers. When complete, HAN will ensure that all local health agencies have high-speed, secure Internet connections by funding the initial purchase and installation of electronic communications equipment, as well as user training. HAN is overseen by the National Center for Infectious Diseases: www2a.cdc.gov/han/Index.asp.

Laboratory Response Network (LRN)

This integrated, multi-tiered network includes state and local public health laboratories; national laboratories at the CDC, FDA, FBI, Department of Defense and a few other federal agencies; and private clinical laboratories, along with select veterinary and agricultural laboratories that may be among the first laboratories to detect microbial agents of terrorism.

The LRN was officially established by APHL, CDC and FBI in 1999 to assure availability of the most accurate and rapid testing methods closer to the location of a biological or chemical terrorism attack. Importantly, all LRN public health labs with a reference function receive proficiency testing and use the same standardized, validated test protocols and reagents to identify and confirm the presence of terrorism agents.

LRN members were originally grouped into four classes (Levels A through D) based on technical capabilities. But as the network has matured, LRN nomenclature has evolved toward more descriptive laboratory classifications. Thousands of sentinel laboratories operate nationwide with the expertise to watch for and apply standard methods to rule out possible agents of bioterrorism in clinical specimens or environmental samples. About 170 reference or confirmatory laboratories, including all state public health laboratories, have the ability to isolate and definitively identify (rule in) select biothreats.

Federal LRN laboratories—at the CDC and Department of Defense—conduct highly sophisticated forensic and epidemiological investigations, provide technical oversight and training to confirmatory laboratories and introduce new technology throughout the system. In the event of a confirmed biological attack, state public health laboratories are recognized as first-responder laboratories within the LRN. That is, they are the first point of contact to arrange for analytical testing on behalf of public safety officials.

While the original focus of the LRN was on biological terrorism, it now includes resources and expertise for chemical terrorism response as well. The chemical component of the LRN, known as the chemical LRN or LRN-C, consists of more than 60 public health laboratories, each classified as Level 1, 2 or 3. Level 3 is able to collect and ship specimens and train hospitals on these procedures. Level 2 laboratories are able to detect a limited number of toxic chemical agents in human blood or urine, and Level 1/ Surge Capacity labs function as surge laboratories when needed for CDC and are able to detect an expanded number of toxic chemical agents in human blood or urine.

The LRN is supported by the National Center for Preparedness, Detection and Control of Infectious Diseases, Laboratory Response Branch, Bioterrorism Preparedness and Response Program. www.bt.cdc.gov/lrn. The Chemical program is also supported by the National Center for Environmental Health: www.cdc.gov/nceh/.

APHL has a list of Sentinel Clinical Laboratory Resources, including definitions, guidance and protocol: www.aphl.org/aphlprograms/ep/lrn/Pages/SentinelLabResources.aspxGlossary.

Public Health Information Network

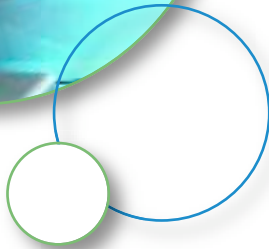
The CDC and partner organizations are continuing to build the Public Health Information Network (PHIN). The PHIN's purpose is to enable the secure transmission of population-based healthcare data across a patchwork of public health related data streams for the purposes of surveillance and detection of emerging national health threats. These streams—which include FoodNet, PulseNet and eLEXNET—currently function in isolation. Awareness of the vital importance of healthcare related information flow has been increasing in all levels of government. The Department of Health and Human Services established the National Health Information Network (NHIN) in 2004 to improve the quality and efficiency of transmission of all healthcare data—both personal and population based. It is a goal of the NHIN to promote the adoption of electronic medical record technology across the nation so ultimately every American can have unfettered access to healthcare information. The PHIN works in collaboration with the NHIN to ensure that responders to the nation's population-based healthcare have access to and are providing appropriate data to protect the public's health. www.cdc.gov/phin.

Safe Drinking Water Act

The Environmental Protection Agency, through the Safe Drinking Water Act (SDWA), is responsible for drinking water quality. The EPA sets standards for over 80 contaminants that may occur in drinking water and that may pose a potential risk to human health. Working in collaboration with the EPA, state environmental laboratories protect the public's drinking water by conducting regular water sampling and water quality analysis. State drinking water programs that implement the SDWA ensure that water systems test for contaminants, review plans for water system improvements and conduct on-site inspections and sanitary surveys. These programs also provide training and technical assistance and take action against water systems not meeting standards. www.epa.gov/safewater/sdwa/index.html.

Select Agent Program (SAP)

There are actually two select agent programs: one run by CDC and one by USDA. Both are designed to restrict and regulate the possession of so-called select agents—biological agents and toxins that could be used as biological weapons against humans or animals. Both programs require registration of facilities that possess, use or transfer any substance classified as a select agent. As part of this process, each participating facility must designate a responsible official (RO) and an alternate (ARO), who are required to undergo a Department of Justice risk assessment (i.e., FBI screening), along with any other laboratory employees who will have access to select agents. www.selectagents.gov.



Cover photo of lab courtesy Indiana Public Health Laboratory
Photos courtesy of APHL



Association of Public Health Laboratories
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www.aphl.org

The Association of Public Health Laboratories (APHL) is a national nonprofit dedicated to working with its members to strengthen governmental laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of U.S. residents and to prevent and control disease globally.



The Association of State and Territorial Health Officials
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ASTHO is the national nonprofit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 120,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice.

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