A Practical Guide for

Public Health Laboratory Leaders

Association of Public Health Laboratory

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APHL

"When I look at everything I do, I think my job title should be *magician*."

Debra Horensky
Chief, Biological Sciences Bureau
New Mexico Department of Health

"In the public health laboratory, every day is a new day. You have to assume that you don't know what's going to happen today, despite what's on your calendar."

Susan Neill
Chief, Bureau of Laboratories
Texas Department of Health

Table of Contents

Introduction

Audience for this Guide and a Note on Terminology

This is a resource for those in leadership positions within public health laboratories and those who are soon to be. It is intended to be of use whether the current or emerging leader is working in a state or local public health laboratory. It is also intended to be of use for individuals coming from diverse backgrounds, either having been promoted from the ranks, coming from a private setting to a governmental position, or coming from a local to a state position.

The audience for this document encompasses all laboratory leaders, including directors, section chiefs, deputy directors, and other high-level managers whose titles may vary. Undoubtedly, however, the *Practical Guide* will be particularly relevant for new laboratory directors, who constitute a core segment of our audience. For this reason, and as a convenience, throughout the balance of this document we have used the term *laboratory leader* or simply *director* to imply the full range of senior laboratory positions described above.

Finally, although the text is directed to laboratorians, the authors hope that this guide will be of some value to health officers and other officials outside the laboratory to whom laboratory directors may report and for whom a glimpse of the complex laboratory management environment may be useful.

A Focus on the 'Early Days'

The *Practical Guide* will be particularly helpful during the early days of tenure in a new leadership position. These early days represent a critical period for the new laboratory director. It is during this period that the new director will be measured and graded by the laboratory staff, his peers and supervisors within the organization, and those external to the organization who have influence and authority over it. It is during these first days that the new director will be branded for good or ill with regard to leadership, professionalism, character, and management skills. While a poor first impression can be overcome with time, it can happen that the events leading to that first impressions may not allow for the time to overcome it.

Since the new laboratory director must have had some working experience within a lab, it is presumed that she knows how laboratories work, formally and informally. Consequently, there should be some comfort level in assuming management responsibility of the laboratory, even though it may be a new organization to the new director.

"I started out at the bench doing newborn screening. From there I moved to laboratory improvement, and then to microbiology. Now I'm the lab director. I stay because I've been able to make a difference in North Carolina and within the APHL. I think I can make a difference. I think I've made a difference. I'm proud to say I'm in public health and this is what I've contributed."

Lou Turner, Director
North Carolina State Laboratory
of Public Health

The Importance of the External Environment

In the final analysis, the external environment seems to present the greatest challenges to all laboratory directors, new and experienced. It is this environment that must be mastered. To laboratory staff, the new director is not just a manager, but an advocate and spokesperson to the world-at-large. To health officials and policy-makers, the laboratory director is part of the *administration* or part of the organization's *management team* and, always, a representative of the science and technology that they may not understand, but have come to rely upon for much of their decision-making.

With these points in mind, much of this document focuses on elements external to the laboratory. The authors expect this document will provoke thought and, where appropriate, stimulate attention or action. We hope it gives guidance to those who will undoubtedly be pulled and pushed in several directions at once, who will experience the tension of competing priorities imposed from within and without, and who may at times feel one short step away from being overwhelmed by conflicting demands. Ultimately, it is intended to provide a framework that will enable the new director to successfully meet those challenges and make the good impression that will enable him to capably and effectively lead the laboratory over the course of his career.

Organizational Structure

- Determine the laboratory's location within its governmental department or university system.
- Evaluate the laboratory's formal and informal organizational structures, including lines of authority and decision-making processes.
- Determine whether and how the laboratory serves agencies and customers other than those in the health agency.
- Determine what, if any, public health testing is performed outside the laboratory.
- Assemble a leadership team to assess the current organizational structure of the laboratory and to begin to consider what changes, if any, should be instituted.

There is a saying common among public health laboratorians that "when you've seen one public health laboratory; you've seen *one* public health laboratory." Certainly this saying applies to the overall laboratory bureaucracy and its position within state government.

The Big Picture

The new laboratory director needs to ascertain as soon as possible the laboratory's placement within the parent organization because that dictates how much autonomy it has and how much real and perceived authority the laboratory director has. This is true even when the public health laboratory is part of an agency other than the health department, or part of a university. Moreover, the laboratory's organizational placement may not be apparent in the hiring process if one is unfamiliar with government bureaucracies. The simplest way to determine such placement is to see where the laboratory sits within the parent agency's organizational chart.

> [There is no one organization model for a state public health laboratory. On a general level, there are three: the laboratory may be either a) part of the state health agency, b) associated with a state university, or c) situated within state government, but outside the health agency.
>
> Even in the most common situation, in which the state laboratory is part of the state department of health, there is no standard location for the laboratory within the departmental structure. The laboratory director may be one of the health director's cabinet-level advisors, the laboratory may comprise a technical division of the department, or the laboratory may be part of the agency's business or support services office. Needless to say, there are advantages and disadvantages to each location; probably the decision was made long ago for an organizational reason that may or may not be pertinent today. In any case, the laboratory's location within the state bureaucracy should not be questioned in the short term, but can be part of an organizational evaluation in the long term.]

The next thing to learn is the chain-of-command within the parent agency and where the laboratory director fits within that chain. The director's position within existing lines of authority is directly related to the laboratory's placement with-

in the parent organization, and is also influenced by organizational culture. However, formal and perceived authority will change with time as the new director establishes working relations with his peers and supervisors. At this point in time, it may be useful for the new director to learn:

- What kinds of decisions can I make without prior approval from supervisors?
- What processes are available for discussing pending decisions that may have an impact beyond the laboratory?
- What information do I need from other parts of the parent organization, and are there processes in place to acquire that information?
- Can I go directly to a program manager or unit manager/director to discuss issues of mutual concern and interest?

"No one organizational structure will solve everyone's problems."

Norman Crouch, Director
Public Health Laboratory
Minnesota Department of Health

In effect, the new director needs to learn the boundaries of her authority within the parent organization, realizing that these boundaries may not be accurately reflected in an organizational chart. At the same time, the new director should not confuse her legislatively-conferred responsibilities—as enumerated in federal and possibly some state laws and regulations—with the authority delegated to her by the parent organization. There is an important distinction between the two. And if the laboratory director finds that his authority does not allow him to meet his legal responsibilities under prevailing laws, he should take immediate action to remedy this situation.

Finally, the director should be aware that, wherever it is located, the public health laboratory occupies a unique niche within the state government as it serves many health department programs, and possibly other state and local agencies, as well as private customers. The new director should quickly learn these external relationships.

Closer to Home

The organization of services under the control of the laboratory director should also be among the first priorities. All organizations reflect the logic and comfort of the director or his predecessor, and the new director should make no attempt to institute wholesale changes to this structure during the early days of tenure. Fine tuning, such as arranging the organizational location of new services, is permissible. But changes in the span of control of incumbent supervisors should not be taken without study of the virtues and weaknesses of each change. Similarly, all new managers need to understand the informal relationships that have developed among the staff to effectively execute their job responsibilities within the formal organization, and the new laboratory leader should study these relationships before making changes.

At some point early on, it is advisable to assemble a leadership team comprised of key section directors, managers, supporting administrative staff and others of central importance to laboratory operations to review both the formal and informal organizational structure and to begin to consider what changes, if any, might be beneficial over time. Of course, situations may arise that call for immediate structural changes, and in fact, they may have been a reason for the hiring of the new director. In such cases, the director must make the changes in accordance with his best judgment, recognizing that in all likelihood additional managerial challenges will result.

Core Functions—More than Just Testing

- Determine which core functions the laboratory directly provides.
- Determine which core functions the laboratory does not directly provide, where those functions *are* provided and *how* the public health laboratory can assure their provision.
- Become familiar with the laboratory's regulatory responsibilities and authorities related to laboratory improvement.

"The public health laboratory is the keystone of public health. If you pull out that piece, the rest of the system is not going to be viable."

Kit Johnson
Administrative Director
Alberta Provincial Laboratory for Public Health

The *core functions* of public health laboratories were published in the September 20, 2002, issue of *Morbidity and Mortality Weekly Report*. This formal publication was the culmination of an extended effort by the Association of Public Health Laboratories to define and describe the activities and policies that are the domain of public health laboratories. (See Table 1.)

One of the first things that a new laboratory director should do is familiarize herself with the core functions—enumerated both in the *MMWR* report and in a white paper available from APHL. These functions provide a practical and complete framework for evaluating the specific functions and services provided by the laboratory. By using this framework, the new director can:

- Determine which services and activities the laboratory directly provides.
- Determine which services and activities the laboratory does not directly provide.
- Determine which of the core functions are not accounted for within the l aboratory and where those functions are carried out.

Once this assessment is complete, the new director will have a substantive basis to understand how the public health laboratory relates to the parent agency, its programs and its plans. In other words, why, in this particular setting, the laboratory does the things it does. This assessment also provides the basis for strategic planning; that is, for integrating short-term transitional actions into the long-term planning and direction of the laboratory.

"In a hospital lab, you treat one person at a time. In a public health laboratory, you are a link with thousands of people, treating the entire community."

Bob Martin, Director
Division of Public Health Partnerships, CDC

Of note, both core functions documents state that not every public health laboratory will directly provide all essential public health laboratory services or perform all essential public health laboratory activities within a given jurisdiction. Few, if any, existing public health laboratories—at any level of government—do. However, just as emphatically, the core functions documents assign responsibility to the public health laboratory director for *assuring* that all those services, activities and functions are available within the jurisdiction. This means, for example, that if the public health laboratory does not perform the chemical testing for drinking or waste water, the director should know which agency or laboratory within the political sub-division or jurisdiction does that work.

This so-called *assurance* role has practical implications for the new laboratory director. First, it compels a thorough review of the laboratory's regulatory responsibilities and authorities related to laboratory improvement; a review that will undoubtedly provide insight into the reasons for the current structuring of laboratory services and activities. Second, it provides a basis for prioritizing thinking about possible changes that might be beneficial to the laboratory (e.g., outsourcing clinical tests or bring core functions in-house) and for determining which changes (that may have initially come to mind) are probably not feasible because of regulatory mandates. Third, it requires the new director to look beyond custom or tradition or other superficial explanations for the structuring of laboratory services to concrete laws, regulations, and executive or legislative policies. This kind of research, in turn, can help the new director get the "feel" for the political environment in which she will be working (meaning the whole process of jurisdictional policy development and implementation, the interaction between executive and legislative bodies, etc.)

"Public health laboratories don't just do testing, they save lives."

Mary Gilchrist, Director
University of Iowa Hygienic Laboratory

Ultimately, at a basic and human level—especially for a newly appointed laboratory director with minimal experience working in a government bureaucracy—the core functions provide a sound, pragmatic rationale for what the laboratory does, and serve as a resource to determine and explain what it doesn't do and why. In other words, for the new director, there is a document (two, actually) that says, *"Your lab doesn't have to be all things to all people,"* with the qualifier that the new director needs to know where all those things all those people want can be found. And, the core functions documents can be a resource to address pressures or concerns about the laboratory and the services it provides, easing the perceived need to make hasty judgments or to act on instinct alone. When it finally *is* time to make well-considered changes, the core functions can be a resource to justify those changes as well.

Table 1. State Public Health Laboratory Core Functions*

- ***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. SPHLs must assure that specialized tests can be performed for low-incidence, high-risk diseases, such as rabies and plague; be able to detect emerging pathogens; perform tests to meet the needs of public health programs; and provide screening services for conditions of interest to the public health community.
- ***Integrated data management*** to capture, maintain and communicate data essential for public health analysis and decision-making. State public health laboratories (SPHLs) are key links in several national database systems that monitor diseases of national and global concern.
- ***Reference and specialized testing*** to identify unusual pathogens, confirm atypical laboratory test results, verify results of other laboratory tests, and perform tests that are not typically performed by private sector laboratories.
- ***Environmental health and protection*****,** including analysis of environmental samples and biological specimens to identify and monitor potential threats to human health and ensure compliance with environmental regulations.
- ***Food safety assurance*** by testing specimens from people, food and beverages implicated in foodborne illness and monitoring radioactive contamination of water, milk, shellfish, and other foods.
- ***Laboratory improvement and regulation*****.** State laboratories are responsible for laboratory regulation and training in both the clinical and environmental areas and oversee statewide quality assurance programs.
- ***Policy development*****.** State laboratorians participate in the development of standards for all health-related laboratories and provide scientific and managerial leadership to aid the formulation of state and federal public health policy.
- ***Emergency response*** via provision of rapid, high-volume laboratory support as part of state and national disaster preparedness programs. State public health laboratories must be equipped to handle unknown samples that may contain infectious, toxic, radioactive, and/or explosive materials.
- ***Public health related research*** to improve the practice of laboratory science.
- ***Training and education*** for laboratory staff in the private and public sectors in the US and abroad.
- ***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 above.

*Defined as essential roles in support of public health activities. Adapted from *MMWR* 51(RR-14): 1-8, posted at www.cdc.gov/mmwr/preview/mmwrrhtm1/rr5114a1.htm.

Communication—An Essential Leadership Skill

- Speak in a non-technical language that will be understood throughout the organization.
- Understand what information your supervisors need and find the most effective way of providing it.
- Build communications skills via a structured course or other means.
- Based on a core functions assessment, begin a dialogue with laboratory clients to ascertain how well the laboratory is meeting their needs. (And then formulate a plan to address deficiencies.)
- Become the major source of information for the laboratory staff and develop your managers to be the same.
- Establish a regular schedule to communicate with your staff—as a whole, as well as with smaller subgroups.
- Communicate regularly with the broad sweep of laboratory stakeholders.
- Consult with your public information officer to learn the rules for communicating with the media.
- Sign up for a risk communication and/or media workshop.

Understanding and being understood is an achievement sought by many with varying degrees of success. Ultimately, the effectiveness and efficiency of communication within the laboratory and between the laboratory and others will determine its success or failure.

Speak in a Language That Will Be Understood Throughout the Organization

In one sense, public health departments are a gathering of specialists, each with his own professional language, be it political science, accounting, nursing, solid waste management, or laboratory science. Health officers and executive directors form their teams with a mixture of these specialists, and they are successful when team members respect one another and communicate effectively. The new director needs to be part of that team. And to do so, she must think of herself as a public health professional with expertise in laboratory science. This change-in-thinking is sometimes difficult when the new director's professional identity up to this point may have been as a *microbiologist* or a *clinical chemist*.

As noted in the introduction, laboratory staff regard the director as their representative and advocate to those outside the facility, just as officials within the parent agency or even the larger local or state jurisdiction consider her to be the *face* of the laboratory. Consequently, the communication challenge for the new director is to be conversant in the technical language used by the staff and by certain other disciplines—epidemiology, environmental health, etc.—represented within the parent agency, *and* to articulate complicated science and technology in plain English for everyone else.

Regardless of the size of the organization, it is likely that the individual to whom the laboratory director reports—whether health officer or other cabinet-level official, division or bureau director, medical officer, or university administrator—will not share his educational background or professional experiences. While precision is the natural tendency of the scientist, it is not the most effective way to achieve communication goals with health officials and others. Remember that upper-echelon officials have broader policy and administrative responsibilities; while occasionally they may need details, in the end they are most interested in the general substance of the information you have. Thus, regardless of the means of communication, the content should be concise and without technical embellishment. If elaboration is needed, it will be requested.

Establishing an effective communication style will be useful in many areas. While necessary to communicate with people from different backgrounds, it is also essential to develop effective working relationships with officials within the parent organization and with other partners and customers. One way to increase awareness of your communication style and to develop the skills needed to master the particular communication challenges of a public health laboratory leader is to participate in a communication workshop. This sort of training is definitely something to consider in the early days of tenure.

Begin a Dialogue with Laboratory Clients

A priority in the early days of tenure should be for the laboratory director to spend time learning about the overall agency and the various disciplines represented there. Then, using the core functions assessment, he should make a point of talking to the directors of the programs that utilize laboratory services and programs. There are several key questions to ask:

- Are the laboratory services meeting programmatic needs?
- How and how well is laboratory information communicated to the program?
- What would the program like to get from the laboratory that it hasn't gotten and, conversely, what does the laboratory provide that the program has no need for?
- Are there immediate *hot button* laboratory or programmatic issues that demand immediate attention?
- Is there any planning done by program and laboratory staff to determine future directions and needs of each?

This conversation needs to be held with the managers of all the programs that the laboratory supports. Such managers likely include the state or local epidemiologist, veterinarian, maternal and child health director, nursing director, environmental health director and several others. In addition, a *get acquainted* conversation should eventually take place with managers of all of the categorical programs, such as STD, TB, WIC or family planning, genetics/children with special health care needs programs, drinking or waste water programs, clean air programs, food and dairy programs, and even law enforcement or penal agencies if the laboratory provides services for them.

The new laboratory director needs to be as inclusive as possible in opening lines of communication. While it may be obvious to talk with the epidemiologists because of the natural link between the laboratory and disease control, the dialogue cannot end there. Even if the public health laboratory *only* supports infectious disease control activities, it probably provides services for the TB, STD, veterinary/zoonotic, immunization, disease control, and water, food and dairy programs. As with any high-level manager, the epidemiologist who may be in charge of these programs may not be aware of as many programmatic details as the categorical program managers are. Furthermore, these programs rely on and interrelate with other major public health programs such as nursing services, local health agencies, and targeted population-based programs for minorities or women and children that are also the *customers* or *clients* of laboratory services. Thus, even in the situation where services are focused on communicable diseases, the necessary communication needs to go well beyond the epidemiologists.

Of course, after communicating with the broad sweep of laboratory stakeholders, the director will need to formulate a plan to address any problem areas cited and particularly those cited by multiple customers.

Communicate with the Entire Laboratory Staff; Not Just a Select Few

Communication within the laboratory staff should be more comfortable for the new director than communication with those outside the facility. However staff at all levels will tend to defer to the director to guide discussions. This tendency can lead to the director dominating laboratory staff meetings, which in turn may undermine their value. Consequently, the new director must *conscientiously* provide opportunities for staff of all education and training levels to voice their opinions on laboratory business, even if this process does not always seem the most efficient way to accomplish objectives.

Staff meetings are generally meant to serve as a conduit of information; information is passed down from department leaders and up from lower echelon staff. But often staff meetings lose this focus over time. While some mechanism must exist to collect information from various sources within the laboratory, in practice, this mechanism (whether a staff meeting or other device) should be continually re-examined and refined so that it is always relevant to current staff and the current modus operandi. Again, laboratory leaders must find a way to make all parties feel that they have a stake in a collective enterprise, with continual opportunities to contribute to projects and develop ideas. It is generally a good idea to establish a regular schedule to communicate with your staff—as a whole, as well as with smaller subgroups.

The new laboratory director also needs to become familiar with, and familiar to, the entire laboratory staff. There are many ways to do this depending on one's personal style. A short general staff meeting within the first few weeks of assuming the directorship is one way. *Managing by wandering around* is another. Many directors do both. Regardless of personal style and preference, mutual familiarization is vital to build good will and earn the respect of the laboratory staff.

Learn the Rules for Communicating with the Media

Unauthorized communication with the media is almost certain to elicit hand-slapping in an administration that is sensitive to the press. As one laboratory directory said during an APHL media workshop, "You only make that mistake once."

Government or departmental policies regarding media communication are likely to change with a change in leadership. Sometimes these policies are only verbal; they are real nonetheless. Your organizational public information officer (PIO) can orient you to the prevailing rules. In fact, it is probably a good idea to consult your PIO before each and every time you feel a need to speak to a media representative. It is also extremely helpful to participate in a risk communication and/or media workshop to hone these particular communication skills. A poor public performance will likely come back to haunt you.

Communication Builds Relations, Reaps Rewards in Minnesota

When terrorists sent anthrax through the mail in 2001, Norman Crouch, director of the Minnesota state laboratory, said the laboratory's most important asset was "our relationship with epi." Throughout the crisis, epidemiologists handled all related phone calls. State epidemiologists and laboratorians met with first responders to set out a triage scheme that reduced SPHL testing to only about 30 specimens. "Having those relations in place beforehand allowed that to happen quickly and easily," says Crouch.

Today, Minnesota SPHL staff and epidemiologists meet briefly every morning to discuss current news and calls fielded the previous night. The relationship is bolstered by a mutual understanding of each partner's role. "The lab is not just a place where epidemiologists get data," Crouch reports. Laboratorians and epidemiologists share an emergency response mentality. With the application of new molecular methods "we're looking all the time for something that might signify an outbreak."

The Minnesota state laboratory also enjoys good communications with clinical labs thanks to a state rule requiring all labs to send isolates of certain reportable disease organisms to the SPHL. "We try to keep our epidemiologists from interacting with the clinical labs; that's our job," Crouch says. "And if you have a close relationship with epi you can do that."

The Political Process

- Get a copy of your state's annual legislative guidebook (if there is one) and (even if there isn't one) familiarize yourself with the various committees, advisory committees, and individual legislators who have authority over public health and laboratory programs.
- Find out if the laboratory director is allowed to attend legislative sessions uninvited.
- Learn the behavioral protocols that must be followed during legislative sessions.
- Find out if there are any bills pending that might impact the laboratory.
- Establish a relationship with the legislative liaison for health-related issues in the state governor's (or city mayor's) office. If permitted, work directly with legislative members and/or staff.
- Consider hosting science-based workshops to educate government officials about public health laboratory business and its implications for public health.
- Cast the laboratory as a non-partisan, science-based resource for legislators.
- Make the *laboratory story* compelling and relevant to non-scientists.

"In most states, labs are subject to overall state processes. Our success in securing resources gets back to how we define our role, who understands our importance. The dilemma is how to make lab work too important to be subject to normal state budget cuts."

Dennis Flynn
Acting Assistant Commissioner
New Jersey Public Health
Laboratories/Environmental Laboratories

Few laboratory leaders who have qualified to become a laboratory director under federal regulations are prepared to participate in the political processes related to the executive branch of government. Nevertheless, political acumen is part of the job of a laboratory leader and should be recognized as such. For purposes of this section, we will limit ourselves to the relationships between the laboratory and the governmental bodies that legislate and appropriate funding. Other political activities are discussed in those sections where pertinent.

The ability to affect legislation in government varies widely across the country, but a general rule of thumb is that most jurisdictions permit only invited involvement, and some permit *no* involvement between government employees and elected officials or political appointees, be they county commissioners, state legislators or boards of health. Such restrictions do not mean that the political process is outside the domain of the laboratory leader. You will be asked or required to become involved in the political process related to appropriations and also possibly in areas of public policy directly related to laboratory services such as newborn screening and genetics, public safety and emergency response, communicable disease surveillance and control authority, and any regulatory program for which the laboratory is responsible.

In the near term, you should find out if your state produces an annual legislative guidebook (as many do) and, if so, get one and become familiar with it. For example, make a point to learn something about the legislators who serve on health and budget committees—i.e., those who can most directly impact the laboratory for better or worse. In many states, different legislative committees will have jurisdiction over different public health programs, such as epidemiology, sexual transmitted disease programs and genetics and newborn screening. You should know these lines of political authority. You should also know something about government advisory committees—such as the genetics advisory committee—as you may be asked to attend one advisory committee meeting or another. Are these committees *strictly* advisory or can they make policy?

Some states prohibit laboratory directors from attending legislative sessions uninvited. Others don't. Find out which category your state falls into at the moment. And make sure you know the protocols for proper behavior in a legislative session; if these are violated, you will be escorted out. Finally, find out if there are any bills currently pending that might impact the laboratory—such as annual appropriations—and, if so, whether you need to become involved in the political process right away.

The new director must see herself as a source of information for lawmakers—and perhaps the only source representing laboratory interests. Depending on the policy of the laboratory's parent organization, you may be asked or required to provide written information to the health officer or their designees, a departmentally assigned lobbyist or legislative liaison, a legislative staff member, or directly to a lawmaker. If the parent organization is sponsoring legislation with a laboratory component, the director should be the person putting the fiscal needs and policy statements into the bill. If the organization is asked to comment on legislation with a laboratory component, the laboratory director should be prepared to draft the response.

Some public health laboratories take a proactive approach to public policy by hosting periodic science-based workshops to educate government officials about laboratory business and its implications for public health and—in the post-9/11 world—national security. Laboratory leaders will find that laboratory issues are most compelling to lawmakers when framed within a larger public health context and linked to concrete health and economic outcomes.

Do not be surprised if you are expected to be available 24/7 during the legislative session to provide written or oral briefings to those representing the department, to provide back-up responses during committee hearings, and/or to interact with legislative staff members in response to questions. The events of fall, 2001, elevated awareness of the public health laboratory in the minds of the public and its elected leadership. As a result, there is greater acknowledgement of the laboratory's role in public health and public policy deliberations, especially related to public safety and security and emergency response.

"It was interesting to be part of APHL Hill day. But what happened was that I ended up having my own handler. The mayor's legislative liaison for health-related issues interviewed me to know what my issues were so he could advise me as to how to best communicate those issues. This was the first time this liaison dealt with anyone from the lab. He became so pumped up about public health and lab issues that he communicated with me for months. He made arrangements for all the folks from the appropriations committee to come up to the lab. And what I learned was that many of the people I talked to found our message compelling."

Sara Beatrice
Assistant Commissioner
New York City Public Health Laboratories

Human Resource Management

- Foster the leadership aspirations of your staff.
- Establish a management team.
- Become familiar with formal personnel processes (e.g., filling vacancies, creating new positions, disciplining staff, etc.)
- Become familiar with any existing personnel problems, such as high position turnover rates, outstanding vacancies, issues leading to grievances within the laboratory, etc.
- Become familiar with the names, backgrounds, job functions, and performance reviews of individual staff members.
- Assure that existing position descriptions are up-to-date and that routine performance evaluations are being conducted.
- Plan to conduct a workflow analysis at some point in the future if an analysis was not already completed in the not-too-distant past.
- Begin or continue a long-term program for staff development.
- Learn the dress code.

With the possible exception of budget preparation and oversight, the amount of time devoted to all other issues will pale relative to the hours and days consumed by staff relations.

Dealing with Friends and Competitors (Sometimes One and the Same)

Any new leader moving into the director's position either by promotion from within or from without will need to address this issue, albeit in slightly different ways. Those who have been a director in one state or local laboratory will argue that *lateral* movement in the public health laboratory system is as dramatic as being promoted.

If you are promoted from within, pay particular attention to issues involving those left behind in the trenches. One of the most awkward adjustments results from the realization by you and your closest friends that they now work *for* you, not *with* you. Try as you may, you cannot support them in the manner you were accustomed to in the past. The professionals you hired and nurtured have not changed, but you have. In fact, some of your peers may have competed for your current leadership spot; you must pay them special attention and allow them to retain leadership aspirations.

If you were hired from another organization into your current position, you must also deal with internal competitors, although your professional relationship with them will begin within the new hierarchy.

In either case, you now have responsibility for the total working of the organization and need to spend much more time with key supervisors than with the individuals with whom you have greatest rapport.

The Pace of Change

Slow Down!

Unless you have been instructed to address specific deficiencies by your supervisors, try not to make major changes in the formal laboratory structure and processes during the first few months of tenure. The time span is, of course, arbitrary and the reverberations of changes will be no less later on, but after several months you should have the advantage of greater respect and understanding from your staff, especially if you communicate with them along the way. Just don't wait too long, for the window of opportunity for major change will be increasingly narrow as you establish your place in the organization.

When the time is right, your staff will expect you to initiate change and will be ready to accept change—if you solicit their input, listen to their concerns, and communicate effectively every step of the way. Because change is difficult for those who work in a structured world like the laboratory—and it's all too easy for people to slip back to *the way it was*—change must be embraced and championed by senior management if it is to occur. Once you begin the process, monitor it closely, celebrate milestones, and keep the pressure on if you hope to have lasting success.

(Of course, it is important to distinguish between changes in the *formal* and *informal* operation of the laboratory. Every organization—large or small—has its own institutional culture. The new director will invariably influence this culture by the tone she sets for the facility—for example, easy-going, but with zero tolerance for whiners. In general, it is best not to try to force changes in institutional culture regarding matters that do not have a direct bearing on staff safety, performance or morale as it will surely be resented.)

"Human resource management is gaining a lot of attention as we enhance and refine our emergency response strategies, which depend upon highly skilled, often cross-trained staff who are dedicated to the public health laboratory mission. To sustain our current level of laboratory practices and ensure future improvements, long-term, quality employees are essential."

Bonna Cunningham
Director, Division of Microbiology
North Dakota Department of Health

Establish a Management Team

Another priority for the new director is to establish a functional, trustworthy management team or group that can be relied upon for sound advice, complete and accurate information, and candor. At the outset it is not unusual for the new director to have one or two people who fill that role. This is natural and important since the new director does need someone he can rely upon in the face of sometimes daunting demands from within and without the laboratory. However, the director needs to take the time and make the effort to broaden this group over time to eventually include all appropriate managers as part of a management team.

Having said that, one will find over time that there will be a few people in whom one places more trust, and looks to for more candor, and can be relied upon to willingly and competently take on any task. This has nothing to do with organizational charts. It has more to do with personality and character. These individuals are valuable resources to develop because they will contribute to your success as director throughout your tenure.

Learn the Personnel Ropes

Finally, the new director needs to understand the personnel system that dictates hiring, discipline, salaries, and promotions. Get a copy of the laboratory personnel manual and any other relevant personnel policies (e.g., health department and/or state personnel policies). There are several key questions for consideration:

- What is the process for filling vacant positions and how long does it normally take?
- Does your state have its own licensure laws for laboratory scientists? If so, what are they?
- What is the process for creating a new position or reclassifying an existing position?
- How are salaries ranges established?
- What are the rules for promotion?
- What are the steps in progressive discipline? Are there policies that cover immediate actions that may be needed to assure the safety of staff or to defuse a potentially volatile situation?
- What workplace policies are particular to the laboratory and what policies are applicable to all employees within the governmental entity?

The new director should make a point of meeting with and opening a line of communication with the personnel director. If some of the laboratory staff are part of a collective bargaining unit, the new director must also develop a similar relationship with the shop steward or other union delegates. (However there is an important caveat here: Before initiating a relationship with union officials, review current union contracts, learn something of the history of union activities in your jurisdiction and find out if there is any union strife ongoing. The new laboratory director should be alert to the possibility that the shop steward or other senior union delegates may try to use their positions to unduly influence or press an advantage if they perceive that the new director is inexperienced in labor management or uninformed of the local labor situation.)

Here are some general questions to begin a dialogue with personnel officials:

- What are position turnover rates?
- Have there been problems filling vacancies in the laboratory, and, if so, what are they (i.e., salary, recruitment, etc.)? Is there a particular classification that has been problematic?
- How many current vacancies are there and what are they?
- Have there been persistent personnel management issues in the laboratory? What are they and what has been done in the past to resolve them?
- What have been the issues leading to grievances within the laboratory?
- Are there negotiated work rules or policies that affect routine laboratory operations and, if so, what are they? What are the effects of negotiated work rules or polices on emergency response operations?

At a deeper level, it is critical that the new director understand who her staff members are, their job functions, skills, backgrounds, and where in their performance review cycle they are. A first step to gather this information is a review of current position descriptions and performance evaluations. If position descriptions do not accurately reflect job duties or if routine meetings are not being conducted between supervisors and their subordinates to discuss performance, these problems must be rectified. An item to add to your list for future planning is a workflow analysis to determine whether staffing levels are appropriate and whether or not positions are effectively aligned with laboratory services and core functions.

Begin or Continue a Long-Term Program for Staff Development

Staff training is a broad issue addressed in other materials. If your predecessor valued training and staff development, rejoice in your good luck. In any case, you should become familiar with policies, if any, on remedial training, emerging technology training, supervisory training, continuing education, university educational opportunities, etc.

Some laboratories have placed training categories in some sort of priority order. In general, however, staff development is a long-term project, best addressed slowly and logically with fiscal planning as part of the process.

If your laboratory has a designated training officer you are on a productive path. If you do not have access to a training officer, you may wish to contact the regional representative of the National Laboratory Training Network, a quality resource. NLTN professionals have laboratory backgrounds and can help you begin the training process using a variety of aids, including organized workshops.

Learn the Dress Code

The dress code may seem a minor matter compared to recruitment, union relations, staff development and employee grievances. Be assured that to many it is not. Learn it and follow it.

Budgeting—A Matter of Dollars and Sense

- Study the current fiscal year budget to learn how much money is available for laboratory operations and where it comes from.
- Become familiar with systems for tracking expenditures and monitoring budgets, the various budget and expenditure reports available to you, cost accounting systems and the fiscal calendar.
- Find out if the laboratory has legal authority to charge fees for services and, if so, the process for doing so.
- Find out how payments for services provided to federally funded categorical programs are negotiated or otherwise charged (if the laboratory provides such services).
- Acquaint yourself with the parent organization's budget director (especially important if the laboratory budget is rolled into the parent budget).
- Always prepare a budget backed by sound—and complete—fiscal data that fully captures all laboratory expenses.
- To prepare for possible funding shortfalls—in case the laboratory budget is not fully funded—explore alternate funding options and develop a contingency plan to prioritize services.
- Develop a *wish list* of items for the laboratory in case the laboratory is asked to help programs spend un-obligated funds at the end of the fiscal year.
- Explore federal grant opportunities to fund projects affecting community health that might not otherwise be funded.

Budgeting and fiscal management are a challenge to all laboratory directors, both new and not so new. Gone are the days when the laboratory received a significant amount of its funding from a single source, usually general revenue appropriated through legislative action. Today, government laboratories have numerous funding streams, including appropriated state or local revenue, direct federal funding, indirect federal funding (through other departmental grant recipients), fees or other earned income, and third party reimbursement such as Medicaid. The fiscal management of a public health laboratory is not only more complex than in days past, but with increased focus on public accountability it is also subject to greater scrutiny.

There are as many stories about the budget process as there are states and laboratory directors. But at national gatherings of laboratory leaders, there will be no presentations on budgeting. If you walk up to several laboratory directors chatting during a break, they will likely be discussing science or the dinner that evening; never budgeting. However, if you listen in on two lone laboratory directors sitting off in a corner, invariably one will be describing how he lost 20 percent of his state funds, or was required to hold 15 positions vacant or to drop a service, start processing layoffs or postpone a building upgrade . . . *He* is speaking of budgeting.

Among the highest priorities for the new director is to review the current budget to determine how much money is available for laboratory operations, where the money is being spent (budgeted), and where it comes from (revenue streams). Then, find answers to the following questions:

- Is the SPHL budget rolled into the parent agency's budget or is it a separate line-item in the executive budget?
- What systems are in place for tracking expenditures and monitoring budgets? Does the laboratory have its own accounting process or does it depend on agency processes? Do state agencies use a common accounting system or does each agency have a unique system? If there are multiple systems, are differences reconciled? How?
- What kind of budget and expenditure reports does the laboratory receive? Who generates those reports and how frequently? Who in the laboratory reviews those reports? If problems or inconsistencies are noted, how are they reconciled, and who is responsible for the process?
- What cost accounting systems are in place? How are procurement, capital expenses, personnel costs (including fringe and indirect costs), and facility costs documented and recorded? By whom? Does the cost accounting system include all appropriate costs? Does the laboratory do its own cost accounting or is it done externally or both? If both, how are differences reconciled?
- What is the fiscal year of the parent governmental entity? Is the budget an annual budget or biennial budget? How much input does the laboratory/laboratory director have in developing the budget request? Is there a *budget adjustment window* after the budget has been approved? If so, what is it?
- Does the laboratory have the legal authority to charge fees for services? If so, what is the process for doing so? Does that money come back to the laboratory or does it go into a larger governmental revenue fund?
- If the laboratory supports federally funded categorical programs, does it receive some portion of federal grant money directly or does it contract with the state programs for specific laboratory services? If the laboratory receives grant dollars directly, does it have a negotiated indirect expense rate, and who gets the indirect funding? If the laboratory does not receive funds directly from the granting agency, does the laboratory receive a portion of the indirect funding? If it receives some portion of the grant money, how is that negotiated? Does the laboratory participate in the preparation of grant requests?

At the heart of consideration of budget and finance is the issue of who really controls the laboratory budget. Some laboratory directors do not know what their budgets are and do not hear from the parent agency until there is a budget shortfall or the laboratory is overspending. If that is the case, the laboratory director, regardless of his position in the organizational chart, does not control the laboratory budget.

If your laboratory budget is rolled into the parent organization's budget, you can still exercise control by requesting timely and complete budget reports. Get to know your organization's budget director and the analyst assigned to oversee the laboratory budget, and ask the questions listed above. Even if you are not directly responsible for the process, you need to become intimately familiar with it.

Submitting a budget through the appropriations process is actually a negotiation. By its nature, it will be subject to numerous and often conflicting political dynamics and forces. The final, legal budget appropriation probably will not provide for everything you want, but it will, except in the most dire of circumstances, provide for what is needed in the laboratory operation.

The Laboratory Advantage

When it comes to budgeting, the laboratory has an advantage over many other governmental units and programs: it produces a product, specifically laboratory data. Boiled down to even simpler terms, tangible products (i.e., laboratory test results) are produced in relation to the dollars expended. Other programs and work units have less tangible *products* or *outcomes*, such as *reducing the prevalence or incidence of disease 'X'*, which may or may not come about, and which may or may not be related to expenditures.

But, the only way to appreciate, and benefit from the laboratory advantage is to be as accurate and precise as possible when someone asks how much it will cost to perform test 'X', or how much to analyze so many specimens for disease 'X'. To calculate a precise dollar amount, you need to understand existing cost accounting systems and make sure that those systems fully capture *all* of the costs related to testing and laboratory operations. This is also the starting point for developing an accurate budget.

The only way to deal with the process is to prepare a budget that documents the complete cost of operating the laboratory. This budget must be based on accurate, defensible information. If your cost accounting is good, you won't underestimate your budget needs, and backed with sound fiscal data, you can show that you aren't *padding* your budget either. Then, follow your budget through the entire process, being prepared to immediately provide supporting documentation through the appropriate channels if changes are contemplated. If cuts need to be made, they can be made more rationally, or at least you can show the effects of the cuts more clearly.

The laboratory director must recognize that policy makers will make policy decisions. It's the laboratory director's responsibility to manage policy decisions. In this regard, it is always helpful to have a contingency plan for budget shortfalls. That is, the director should prioritize what will and will not be done if the laboratory budget is not fully funded, and should explore other funding options in advance.

Finally, as a new laboratory director, be prepared to spend someone else's money. Quite often as grant years and fiscal years come to an end the laboratory will be approached to help programs spend un-obligated end-of-year money. Cultivate a strong relationship with the programs that receive grant funds. And work with your management team to develop a prioritized *wish list* of items for the laboratory, with current cost estimates, vendor quotes or even purchase orders so these opportunities can be acted upon within the short window of opportunity. Year-end funds are one-time money that should be used for non-recurring expenses.

Grants Can be Used to Fund Projects Affecting Community Health—Even When the State Doesn't Consider the Project a High Priority

Grant money (which is distinct from federal funding that flows from services provided to categorical programs), can be used to supplement other laboratory income to accomplish your public health mission. These funds come to the laboratory in myriad forms: block grants, research grants, etc. Your hope is that the state sees these dollars as a means to keep the laboratory active and technologically current without using state funds, rather than *replacing* state funds.

A string that sometimes comes attached to federal funds is a requirement for a match of state dollars. The match can be an in-kind contribution or straight-forward allocation of state funds to the project. In the first case, it is possible that work performed using other funds may meet the federal requirement. In the latter case it is a legislative decision.

The bottom line is that federal grants can provide money for equipment that otherwise won't be funded, and also pay for operating and personnel expenses for the duration of the grant.

To take full advantage of federal and other grant opportunities, the laboratory director should find someone within the organization who specializes in grant-writing (and is familiar with requirements for matching funds) as a source of information.

> Fiscal reports, deficits, rescission, procurement bids. How many people working in the public laboratory community today are really prepared to deal with the financial side of business? And the public laboratory *is* a business. The director no longer has the luxury of focusing on science and thinking great thoughts. Follow the money. Where did it come from, and where did it go? The saying, *knowledge is power,* couldn't be truer when struggling for financial support for your laboratory.
>
> James Pearson, Director
> Virginia Division of Consolidated Laboratory Services

Assuring Quality Through Laboratory Regulatory Oversight

As a regulated agency:

- Compile a list of all the licenses, certificates and permits the laboratory possesses and request the most recent evaluation associated with each.
- Make an early appointment with the quality control officer(s) to get his perspective on the overall quality of laboratory services and strengths and weaknesses in operations and documentation.
- Seek the counsel of laboratory managers on the successes and challenges they face providing quality service and clearly articulate to managers your expectations for quality assurance and improvement.

As a regulator of laboratory services:

- Learn the laboratory's responsibilities reviewing and assuring the quality of laboratories outside the worksite and department and the specific organization and fiscal relationships involved.
- If the state laboratory does not presently have this responsibility, adopt a long term goal to take on this role.

The Value of Being the Best

Laboratory leaders must recognize early in their tenure that the public health laboratory, especially at the state level, is—or should be—perceived to provide the highest quality service available and is often seen as the technological standard-setter. If the public health laboratory is not presently seen in this light, the director has an immediate goal to orient the staff to become the "best there is." No operational or service enhancements will be respected without accurate and timely laboratory testing—measured both internally and externally. Similarly, no marketing efforts, negotiations or proposals for service expansion or contracting will be fruitful if the laboratory is not seen to offer top-quality service.

Assessing Quality Through Regulatory Compliance

One quick indicator of laboratory standards is compliance with all relevant laws and regulations (e.g., Clean Water Act, Interstate Milk Shippers Act, etc.,) including possession of all licenses, permits and certificates pertinent to testing. Among the first things the new laboratory director needs to do is review the current CLIA license, state license if applicable, Select Agent registration, any EPA certificates and any correspondence related to these licenses and certificates. These will tell the new director what specialties and activities the laboratory can legally engage in, and assure her that the laboratory has met the minimum applicable requirements to operate.

Several national agencies regulate various aspects of public health laboratory testing, and three are especially significant:

Centers for Medicare and Medicaid Services regulates testing performed on specimens of human origin in accord with the requirements of the Clinical Laboratory Improvement Amendments of 1988.

US Environmental Protection Agency, through the Safe Drinking Water Act, oversees public drinking water. The state drinking water program assumes primacy for enforcement of the act in the state, including designation of the "principle state laboratory," which is usually the state public health laboratory.

US Food and Drug Administration oversees testing of milk that will be transported across state lines.

If the laboratory has a quality assurance officer (QAO), the new director should make a point very early on to discuss the laboratory's quality, performance and related issues. If the laboratory does not have a single designated QAO, then the subject of quality assurance practices, policies, procedures and performance has to be addressed in one of the first management staff meetings. The new laboratory director needs to set his expectations regarding quality assurance and improvement and clearly articulate them to the managers who are responsible for meeting those expectations.

Assessing Quality Beyond the SPHL

If the laboratory is also a regulatory authority, i.e., acts as an evaluator of other laboratories in the state, the director should determine what these regulatory responsibilities are, their statutory basis, the resources dedicated to those functions, and the mechanism for funding them.

For example, the state public health laboratory may hold a multiple-site CLIA license that covers all or a portion of the local public health laboratories within the state. It may be responsible for licensure of private clinical laboratories statewide. And it is generally responsible for the quality of testing within the state Laboratory Response Network (certainly among other reference-level laboratories).

If the authority to regulate laboratories is not with the public health laboratory, the new director should acquaint himself with the staff in the government agency that is responsible for this activity. The purpose here is to look for ways in which the public health laboratory can assist or support the efforts of the regulatory agency through training and outreach programs, development of a jurisdictional laboratory response network, or simply facilitating coordination among different public sector laboratories, or between the private and public sectors.

Statewide laboratory improvement and regulation can be one of the most important and most satisfying duties of the public health laboratory. If the state laboratory does not presently have this responsibility, laboratory leaders should adopt a long term goal to take on this role. Statewide laboratory oversight develops the state laboratory and its staff as leaders in the field and guardians of laboratory quality.

- Register the new *responsible official* under the federal Select Agent Program.
- Familiarize yourself with the laboratory's and the jurisdiction's emergency response plan and other key documents to identify key emergency contacts within the laboratory's parent organization (including the person to whom you report during an emergency), laboratory responsibilities during an emergency (especially vis-à-vis local, state and federal authorities), the sites of sensitive military or industrial installations, the laboratory resources available in your region, specific testing arrangements with other jurisdictions and mechanisms for specimen transport.

"Our laboratory actively cultivates an image as the Michigan reference laboratory—the state CDC."

Frances Downes, Director
Michigan Public Health Laboratoy

- Contact key emergency response personnel outside the laboratory to verify their roles and their expectations of the laboratory.
- Assure that emergency personnel policies; emergency protocols for pre-analytical, analytical and post-analytical tasks (e.g., emergency purchasing procedures, surge protocols, etc.) and appropriate safety measures are in place within the laboratory.
- We hope that you have a long stretch of time before your emergency response capabilities are tested, but sooner or later they will be. And you never know when.

First Item of Business

Register the new *responsible official* under the federal Select Agent Program. Each participating laboratory has a responsible official and an alternate. Find out if you are the responsible official. If so, you may need an FBI security screen.

Position the Laboratory to Work Seamlessly with Partners

Everything related to emergency response has to be a high priority. Among your first tasks as a new director should be to familiarize yourself with the laboratory's emergency response plan, the state or local emergency response plan, the jurisdiction's BioWatch plan (if applicable), memoranda-of-understanding with other jurisdictions, and any other emergency response documents. Based on a careful review of these materials and conversations with the laboratory's BT and CT coordinators, determine the following:

- Emergency contacts within the laboratory's parent organization and the specific individual to whom you report during an emergency. Find out how to reach these people 24/7.
- Laboratory responsibilities during an emergency. For example, is the laboratory an LRN reference laboratory? What is its level of CT response (1, 2 or 3)? What are its responsibilities under the federal BioWatch program or the US Postal Service's Biohazard Detection System (BDS), if any?
- The respective (and possibly overlapping) roles of local, state and federal

authorities during an emergency. For example, under what circumstances would laboratory samples be routed to federal facilities?

- Whether (and where) there are nuclear power plants and/or other sensitive industrial or military sites within the laboratory's jurisdiction. (Buy a state or local map and put it on your office wall with these sites marked. Even if the sites are never compromised, the map will come in handy.)
- The laboratory resources available in your region (possibly including Mexico or Canada). Such resources include sentinel, veterinary, agricultural, environmental and academic/research laboratories, in addition to surrounding public health laboratories. (Establish laboratory partner lists with contact information.)
- Arrangements with other jurisdictions for surge testing and/or testing under BioWatch or the BDS. Under what circumstances do you perform testing for other jurisdictions and under what circumstance might they perform testing for you?
- How samples are moved within the laboratory's jurisdiction—i.e., courier systems or other transport arrangements.

Once you have covered the basics, it is time to contact key emergency response personnel outside the laboratory: the state homeland security officer, the local FBI WMD coordinator, state or local HAZMAT officials, local Federal Emergency Management Agency (FEMA) staff, state civil support teams, state or local emergency operations center staff, the state postal inspector, the state or local police chief and local Department of Defense (DOD) officials, if any. (The laboratory may have DOD responsibilities if federal weapons or chemical stockpiles are located in the state.) Assess the laboratory's relationship with each of these individuals and clarify their role in an emergency and their expectations of the laboratory. If their expectations of the laboratory are unrealistic, you may need to do some educating. Finally, ask if there are existing working issues or problems that need to be addressed, such as sample turnaround time. (But don't make any promises unless you are sure the laboratory can deliver.)

"Something can happen at any time. It's your responsibility to be prepared."

Bill Whitmar, Assistant Director
Missouri State
Public Health Laboratory

Prepare Your Staff

Within the laboratory, walk through the laboratory's emergency response plans with your BT and CT coordinators to identify any gaps or problem areas. Assure that the following items are in place:

- List of phone extensions, e-mail addresses, and emergency contact information for essential personnel, including laboratory supervisors and analytical experts.
- Security clearances for designated staff.
- Flex-time policy.
- Overtime policies (encompassing pay and/or compensation time).
- Weekend call schedule or duty roster.
- Built-in redundancy in testing expertise. (This may require a cross-training program.)
- Appropriate safety measures for testing unknown or high-risk samples.
- Policies outlining who reports test results and how (i.e., e-mail, other electronic reporting systems, etc.)
- Chain-of-custody forms and procedures.
- Emergency purchasing procedures.
- Surge capacity protocols and procedures for outsourcing testing.
- State and laboratory policies on the use of volunteers (e.g., retired or private sector laboratory scientists) to perform testing in the laboratory during crises.
- Description of the services provided by branch laboratories, if applicable.
- Triage procedures or special policies for sample/specimen submission during emergencies.

"If the president of the United States ever comes to your state, you should know that the secret service will call you."

Kati Kelley, Director
Connecticut Division of Laboratories

These considerations may seem a dramatic shift from the routine, but emergencies require dramatic shifts. If you have a clinical background, do not believe that a *stat* test approaches the demands of emergency testing; the sheer volume of specimens/samples submitted during a crisis can overwhelm the most organized laboratory staff.

The APHL *Emerging Infectious Diseases Framework Checklist*—available from the APHL Web site or from infectious disease program staff—is a useful resource designed to help public health laboratories prepare for outbreaks and bioterrorism threats.

APHL—Your Laboratory Resource

- Get a copy of the *APHL Member Handbook.*
- Consider joining an APHL committee.
- Attend a new director orientation program, the annual meeting and other association-sponsored gatherings.
- Send staff to NLTN training programs.
- Call if you need help.

As a public health laboratory leader, APHL is *your* professional association. Its founding members are directors of state and territorial public health laboratories, and members today include laboratory leaders representing public health laboratories at all levels (local, state, national and international), as well as food safety and environmental laboratories.

During its half century of service, APHL's broad mission has remained unchanged: to safeguard the public's health via leadership-through-science. To this end, the association works to advance laboratory systems and practices and to promote policies that will strengthen its members' ability to carry out core functions such as disease surveillance and emergency response.

In addition to providing specific services (such as "wet" workshops) for laboratory staff, APHL is your link to the policy world. The association conducts research on the status of public health laboratories and disseminates its findings in reports, briefs and Web articles. It issues statements on pending legislation and regulations, provides expert testimony, comments on proposed rulemaking and disseminates educational materials on priority issues. APHL offers policy makers, the media, health organizations, government agencies and others authoritative information on public health laboratories and related issues, plus the expert opinion of members and staff.

The *APHL Member Handbook*: Your Key to the Association

If you don't already have one, get a copy of the *APHL Member Handbook*. It describes all of the association's activities in some detail. Sections of particular note are "Member Services" and "Affecting Change." The first explains what APHL can do for you; the second explains how you can help set association priorities and policy goals.

This brief section of the *Practical Guide* does not attempt to duplicate the *Member Handbook*. Rather, it highlights items that may be of particular relevance to new laboratory leaders.

APHL Committees: A Breeding Ground for New Ideas

Much of the association's work—special studies, policy statements, international technical assistance, etc.—is initiated through its 12 committees. Committee membership offers the opportunity to advance issues of particular importance to members, to network with peers and to gain a measure of national recognition.

Committee appointments are for one year, from July 1 to June 30. Each spring, APHL notifies all members of the open application period, during which members can apply to serve on one or two committees. All appointments—including that of committee chairs—are made by the incoming association president.

In addition to the standing committees, short-term, ad hoc task forces and workgroups are sometimes established during the year when a special need arises. Again, appointments are made by the president (or in some cases through the association board of directors). Finally, the president may appoint members to serve as liaisons with external organizations.

APHL Standing Committees

Emergency Preparedness & Response

Environmental Health

Food Safety

Global Health

Infectious Disease

Informatics

Knowledge Management

Laboratory Systems & Standards

Membership & Recognition

Newborn Screening & Genetics in Public Health

Public Policy

Workforce

Yearly Events

While APHL offers numerous member events throughout the year—from technical conferences and colloquia to training programs—three are worth special mention here.

The association's ***annual meeting*** is held in a different city each June. This meeting provides a regular opportunity for members to meet face-to-face with one another and with national and private laboratory personnel. It features a keynote session, member-planned general sessions, exhibits and a business meeting over the course of two-and-a-half days.

Most years, APHL's National Center for Public Health Laboratory Leadership hosts an ***orientation program*** for new public health laboratory directors. This program is designed to acquaint new directors with the resources available from APHL and the CDC, to foster ties among those in the incoming cohort of new directors and to link new directors with experienced public health laboratory leaders.

APHL's annual spring ***Hill Day*** is a key element of a broader effort to educate lawmakers about the value of public laboratories as Congressional and national resources. Members are invited to visit members of Congress who serve on the committees most directly responsible for programmatic and appropriations decisions affecting public laboratories (and are briefed by the association's public policy director on key messages to deliver).

A Very Brief Overview of APHL Activities

Leadership Development

APHL directs the ***National Center for Public Health Laboratory Leadership*** (NCPHLL), established in 2002 to develop leaders and expand knowledge of public health laboratory administration. Activities include a risk communications workshop, an orientation program for new laboratory directors (described above) and leadership forums on timely issues. NCPHLL laboratory assessments bring a team of experts on-site to evaluate the effectiveness of laboratory activities relative to core public health laboratory functions and to document operational changes and enhancements that will improve the laboratory's overall performance. The center has sponsored teams of laboratory directors at the University of North Carolina's Public Health Leadership Institute and produced this guide.

Laboratory Training

In collaboration with the CDC, APHL sponsors the ***National Laboratory Training Network*** (NLTN), a unique resource for low-cost, laboratory-specific continuing education via traditional "wet" workshops, distance learning programs, workshops-in-a-box and an online lending library. Training topics range from molecular diagnostic techniques to foodborne disease investigations. Most NLTN programs confer CE credits. (The association also offers laboratory-based fellowships and traineeships for beginning and mid-level professionals.)

Member Recognition

APHL's ***national awards program*** recognizes leaders for lifetime achievement and for specific contributions to promote excellence in the field.

Technical Assistance

APHL is both a member resource center and a liaison among member laboratories, federal officials and other partners. The association researches and responds to inquiries, represents members at national forums, and provides guidance on federal protocols and directives. Additionally, APHL advises federal agencies on development and implementation of national health initiatives that involve public health laboratories.

"Whenever I've called for help, APHL has been there."

Barbara Jepson, Interim Director
Utah Division of Epidemiology &
Laboratory Services

Call if You Need Help

If you have a problem and need a solution, APHL is a good place to look for one. (And when in doubt, a good first point-of-contact within the association is the membership manager.) If staff can't provide an answer, they can often identify other resources. Remember, as a public health laboratory leader, APHL is *your* professional association. Use us.

APHL's Half Century of Service

APHL's predecessor organization, the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD), was formed in 1951. ASTPHLD provided a forum for state public health laboratory directors to meet annually to discuss scientific and administrative issues. CDC supported the association by hosting the majority of meetings, providing speakers for the program, and giving financial and administrative support.

Just as CDC was transformed into a more comprehensive agency, with the infectious disease and laboratory sections comprising only a portion of its organization, so did ASTPHLD change. This change resulted from the CDC decision to outsource part of its mission to support state public health laboratories. The mechanism was a cooperative agreement, developed in 1989, whereby CDC provided financial support for an APHL headquarters, thus permitting the organization to carry out many functions not possible with the limited administrative support available to ASTPHLD. Through the years, APHL has become a recognized and contributing authority in the realm of public health practice; a role reflected in its mission statement:

> "To promote the role of public health laboratories in support of national and global objectives, and to promote policies and programs that assure continuous improvement in the quality of laboratory practice."

To increase its effectiveness, the association has gradually welcomed additional individuals and entities as members, including public health laboratorians below the level of director, food safety laboratory leaders, environmental laboratory leaders, student members, industry representatives and organizational associate members.

Glossary

Biohazard Detection System (BDS)

This US Postal Service (USPS) system—developed in consultation with commercial vendors and the scientific community—uses proven technology designed exclusively for the USPS to enable early detection of anthrax.

The BDS unit consists of an air-collection hood, a cabinet where the collection and analysis devices are housed, a local computer network connection and a networked computer. All BDS processes are automated. The air collection hood is installed over the mail canceling equipment at the first pinch point in the mail processing operation. It absorbs and concentrates airborne particles into a sterile water base, creating a liquid sample that is injected into a cartridge. An automated polymerase chain reaction (PCR) test is performed on the liquid sample and results compared to a template to detect the presence of *Bacillus anthracis*. The system concentrates air samples for a one hour period followed by the PCR test that takes approximately 30 minutes. While the PCR test is performed the BDS is simultaneously concentrating particles for the next sample. In the future, BDS may be adapted to test for other biological threats.

If there is a BDS "alert," the postal inspector collects the cartridge containing the suspected sample and sends it to the designated public health laboratory for confirmatory testing. If there are additional environmental samples, these too are forward to the public health laboratory for testing.

BioWatch

A surveillance system that 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 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).

Capability

An activity that supports core laboratory functions.

Capacity

Output of laboratory services within a defined period of time.

Centers for Medicare and Medicaid Services (CMS)

CMS—and specifically, the Division of Laboratory Services within the Survey and Certification Group, under the Center for Medicaid and State Operations—regulates all laboratory testing (except research) performed on humans in the US through the Clinical Laboratory Improvement Amendments. See CLIA below for more information.

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 US 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. For more information see www.epa.gov/region5/water/cwa.

Clinical Laboratory Improvement Amendments of 1988 (CLIA)

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 which 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 were published in 1992 and 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 (CLIAC) and providing scientific and technical support/consultation to CMS. The Food and Drug Administration is responsible for test categorization.

Those laboratories which 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.

For more information, go to www.cms.hhs.gov/clia.

Core Functions

Essential roles in support of public health activities. Core SPHL functions are listed on page 9.

Electronic Laboratory Exchange Network (eLEXNET)

The Electronic Laboratory Exchange Network is a seamless, integrated Web-based information network that facilitates real-time sharing of food safety laboratory data among federal, state, and local agencies. All federal, state, and local food safety laboratories are eligible to participate in the network at no cost. More information is available at www.elexnet.com.

Epi-X

An Internet-based communications tool available to public health workers designated by health agencies. It allows for secure communication and discussion of preliminary health surveillance information and can be used to actively notify users of breaking health events as they occur. The software has functionality that can be customized by health agencies to contact designated individuals via phone, fax, pagers, and/or email during an emergency. Overseen by the National Center for Infectious Diseases.

Health Alert Network (HAN)

A national funding program with a set of guidelines and standards for communications hardware that can serve as a vehicle for electronic communication of laboratory-related information and for the dissemination of 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. Overseen by the National Center for Infectious Diseases.

Healthy People 2010

Healthy People 2010 is the name of both an initiative and a document. The document—posted at www.healthypeople.gov—identifies national objectives to improve health and sets targets to monitor the nation's progress through the year 2010. It contains 28 focus areas with a total of 467 specific objectives, several of which relate to laboratory services. (Many states have developed their own state-based health objectives, using the national document as a guide.)

The overall initiative is managed by the US Department of Health and Human Services with two major goals: 1) to increase quality and years of life for all and 2) to reduce health disparities.

Laboratory Response Network (LRN)

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

The LRN was officially established by the CDC and APHL in 1999 to move the most accurate and rapid testing methods closer to patients. Importantly, all LRN members receive proficiency testing and use the same standardized, validated test protocols and reagents.

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 the standard methods to rule out possible agents of bioterrorism in clinical specimens or environmental samples. Between 200 and 300 *reference* or *confirmatory* laboratories, including all state public health laboratories, have the ability to isolate and definitively identify (rule in) select biothreats. And *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 LRN was originally begun with a focus on biological terrorism, it is increasingly expanding resources and expertise for chemical terrorism response as well. The chemical component of the LRN (chemical LRN or LRN-C) consists of more than 60 public health laboratories, each classified as either Level 1 (able to collect and ship specimens), Level 2 (able to detect a limited number of toxic chemical agents in human blood or urine) or Level 3 (able to detect an expanded number of toxic chemical agents in human blood or urine).

The LRN is supported by the National Center for Infectious Diseases, Laboratory Response Branch, Bioterrorism Preparedness and Response Program. For more information go to www.bt.cdc.gov/lrn.

National Cooperation for Laboratory Accreditation (NACLA)

A not-for-profit corporation established in 1998 by representatives of public and private-sector organizations to provide coordination and focus for US laboratory accreditation programs. NACLA's primary mission is to evaluate US laboratory accreditation bodies and to grant recognition to those in compliance with NACLA procedures and relevant international standards. (NACLA does not itself accredit laboratories.) NACLA also provides educational and training opportunities to individuals interested in laboratory accreditation. See www.nacla.net for more info.

National Electronic Disease Surveillance System (NEDSS)

A CDC initiative to create integrated surveillance systems capable of transferring public health, laboratory, and clinical data efficiently and securely over the Internet. More information is available at www.cdc.gov/nedss. See also the APHL publication *Advancing the National Electronic Disease Surveillance System: An Essential Role for Public Health Laboratories* (January 2002).

National Laboratory System (NLS)

A CDC-directed initiative to achieve a seamless public-private laboratory system that will speed referral of unusual or suspicious lab findings from clinical or so-called *sentinel* labs to public health laboratories capable of confirmatory testing and other sophisticated analyses.

There are four CDC-funded demonstration projects (in Michigan, Minnesota, Nebraska, and Washington) with full time program advisors who serve as liaisons between the public health and clinical laboratory communities. The initiative is overseen by the Division of Laboratory Systems within CDC's Public Health Practice Program Office.

Public Health Information Network (PHIN)

A framework being developed by the CDC and partner organizations to define specifications for the coding and secure transmission of health-relevant data across a patchwork of data streams that now function in isolation. (For example, FoodNet, PulseNet and eLEXNET are all used to transmit laboratory food safety data, but information cannot be exchanged easily between systems.) In-house state laboratory information management systems will eventually conform to PHIN standards, facilitating data exchange among laboratories and among public health data reporting systems. Challenges will remain however, since the data systems used by non-traditional public health partners, such as the FBI and other law enforcement agencies, are not likely to be revamped to comply with PHIN standards. PHIN is overseen by the National Center for Public Health Informatics.

PulseNet

A network of public health laboratories, including all 50 state public health laboratories, that performs pulsed-field gel electrophoresis (PFGE) on foodborne bacteria. The network permits rapid comparison of DNA *fingerprints* through an electronic database, providing critical data for the early recognition and timely investigation of outbreaks. More information about PulseNet is available at www.cdc.gov/pulsenet.

Select Agent Program (SAP)

There are actually two select agent programs: one run by the CDC and one by the 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.

Abbreviations and Acronyms

AIDS	Acquired immunodeficiency syndrome
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
ASTPHLD	Association of State and Territorial Public Health Laboratory Directors
BDS	Biohazard Detection System
BT	Biological terrorism
BW	BioWatch
CDC	Centers for Disease Control and Prevention
CE	Continuing education
CLIA	Clinical Laboratory Improvement Amendments
CLIAC	Clinical Laboratory Improvement Amendments Committee
CMS	Centers for Medicare and Medicaid Services
CSTE	Council of State and Territorial Epidemiologists
CT	Chemical terrorism
DHHS	Department of Health and Human Services
eLEXNET	Electronic Laboratory Exchange Network
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	US Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FTE	Full time equivalent
HAN	Health Alert Network
HAZMAT	Hazardous materials
LITS	Laboratory Information Tracking System
LRN	Laboratory Response Network for Bioterrorism
LRN-C	Laboratory Response Network for Chemical Terrorism
MMWR	*Morbidity and Mortality Weekly Report*
NACLA	National Cooperation for Laboratory Accreditation
NCPHLL	APHL's National Center for Public Health Laboratory Leadership
NEDSS	National Electronic Disease Surveillance System
NELAC	National Environmental Laboratory Accreditation Conference
NLS	National Laboratory System
NLTN	APHL's National Laboratory Training Network
PHIN	Public Health Information Network
PIO	Public Information Officer
QAO	Quality assurance officer
RCRA	Resource Conservation and Recovery Act
SAP	Select Agent Program
SDWA	Safe Drinking Water Act
SPHL	State public health laboratory
WHO	World Health Organization
WMD	Weapons of mass destruction
WSLH	Wisconsin State Laboratory of Hygiene

Add Your Organization-Specific Acronyms Here

Learning idiosyncratic state or local acronyms is a necessary part of the job. Often this information can be gleaned from an administrative assistant, the person to whom you report (or that person's assistant), or another administrator who has been with the organization for a while.

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