A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes

Laboratory Efficiencies Initiative 2012

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

LEI LABORATORY EFFICIENCIES INITIATIVE

Transforming to a Sustainable Public Health Laboratory System

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

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“Public health laboratories are critically important to the health of their communities and the entire nation. We must do all we can to ensure that the public health laboratory system maintains its capacity to address today’s health threats and those of the future. This guide will be a valuable resource for public health laboratory directors as they explore service models and management practices that can strengthen their laboratories. I commend the many public health laboratory leaders who have contributed to the guide and am very pleased that CDC has been able to play a role in its creation.”

Thomas R. Frieden, MD, MPH, Director, Centers for Disease Control and Prevention

“Public health laboratories operate in a constantly changing scientific and political environment. Diminished resources, rapidly evolving technologies, and struggles to hire and retain technical staff must be addressed to ensure that essential public health laboratory services are available to support local, state and national public health programs. The sustainability of public health laboratories requires enhanced operating efficiencies, sharing limited resources and greater collaboration among all public health laboratories. APHL and CDC have undertaken the Laboratory Efficiencies Initiative to help laboratory directors identify and implement new ways to provide critical laboratory services. This guide is a wonderful resource for assessing and planning laboratory changes to strengthen the public health laboratory system.”

Charles D. Brokopp, DrPH, MT(ASCP), President, Association of Public Health Laboratories

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EXHIBITS

1. INTRODUCTION

1.1 Purpose of This Guide

Public health laboratories play invaluable and indispensable roles in protecting America's health. They perform the vast majority of public health reference tests, monitor community health conditions, help shape population-based interventions and advise healthcare providers on appropriate patient care. Of special note is the critical role public health laboratories play in detecting the onset of disease threats at the front line and helping deal with the high volume of tests required during public health emergencies.

Public health laboratories are integral members of the nation's public health laboratory system, along with environmental, food safety, agricultural, forensic, occupational health and other laboratories that perform tests to protect the health of the public. The Centers for Disease Control and Prevention (CDC) is the principal federal member of the nation's public health laboratory system.

This guide is a resource that directors and managers of public health laboratories can use as they assess and, if they so choose, implement changes in the models of their laboratories' testing services. The guide's target audience includes directors and managers of all laboratories that conduct tests of public health significance. The Association of Public Health Laboratories (APHL) and CDC's Laboratory Science, Policy and Practice Program Office (LSPPPO) cosponsored preparation of the guide. Its focus and contents reflect the contributions of many public health laboratory directors and their colleagues, APHL and CDC staff members, and others who shared the goal of making the guide as useful and practical as possible.

1.2 The Public Health Laboratory Efficiencies Initiative

Public health laboratory directors work in a highly dynamic environment. In recent years, most public health laboratories have experienced serious financial pressures, driven largely by state and local governments' responses to the economic recession. Many public health laboratories' budgets and staffing have been cut substantially. As a result, some have stopped performing certain tests, posing potential risks to the public's health.

APHL and CDC are concerned that many public health laboratories are in danger of losing the capacity to perform critically needed tests and services. This has the potential to impair the ability of public health authorities to respond effectively to conventional health risks as well as public health emergencies caused by such emerging and reemerging health threats as influenza pandemics and other threats.

CDC and APHL inaugurated the Laboratory Efficiencies Initiative (LEI) in early 2011 to help address these concerns. Additional LEI partners include public health department directors and epidemiologists, public health and laboratory associations, leaders in clinical laboratory practice and representatives of private industry.

LEI helps public health laboratories achieve long-term sustainability by adopting management practices that can improve their operating efficiency and strengthen their resilience in the face of financial and other challenges. Its strategic goal is to help build a sustainable public health laboratory system for the nation.

Laboratory Efficiencies Initiative Goals

- Improve public health laboratories' operating efficiency.
- Improve public health laboratories' sustainability.
- Maintain a sustainable public health laboratory system for the nation.

This guide is one of the practical resources created through the LEI.

One approach to improving efficiency is to adopt any of a number of different models for conducting testing services. The guide refers to these as service changes. Examples of service changes include:

- Sharing testing services with public health laboratories in other states and jurisdictions.
- Combining the services of regional or substate laboratories.
- Merging public health with environmental or other types of laboratories.
- Contracting for testing services.

Multiple states have considered or have adopted such service changes. Public health laboratory directors have taken the initiative in certain cases; in others, the initiative has come from the state's executive branch or elected officials. Uncertainty about future state or even federal programmatic funding might give additional impetus to consideration of service changes and additional high-efficiency management practices. In many cases, public health laboratories are likely to adopt combinations of such practices that best support their goals.

1.3 Background and Overview of This Guide

Public health laboratory directors have expressed interest in learning from colleagues' experience with service changes, including why the changes were considered, what processes were used in exploring and adopting them, and what benefits have accrued from them. This guide responds to their interest.

CDC and APHL developed the concept for the guide early in 2011 after a series of teleconferences with state and local public health laboratory directors. In June 2011, LSPPPO received an intramural CDC award allowing it to engage a consulting firm to gather information about service changes that have been implemented.

In December 2011, a group of state and local public health laboratory directors endorsed the idea of a service change guide and provided valuable commentary on a preliminary outline of the guide. In March 2012, LSPPPO and APHL convened a review team of five state public health laboratory directors who had not been engaged in the project earlier. The team reviewed and critiqued a working draft of the guide and made helpful recommendations for improvements. LSPPPO and APHL staff revised the guide accordingly, and the final version was released at the May 2012 APHL annual meeting.

1.3.1 Case examples

The information presented in the guide is based primarily on service changes adopted in recent years by the Michigan, New Hampshire, North Dakota, South Dakota, Oregon and Wyoming state public health laboratories and by the New Mexico and Alaska newborn screening programs. Additional sources include observations offered by other public health laboratory directors and public health administrators with related experiences, members of the review panel, APHL officials and CDC laboratory professionals.

Public Health Laboratory Service Change Examples

- Merger of Programmatically Distinct Laboratories: In 2011, as directed by the state legislature and the governor's office, the New Hampshire state environmental laboratory was merged into the state public health laboratory (see Section 4.1 for an account of this service change).
- Closure of Substate Public Health Laboratories: In 2010, the Michigan Bureau of Laboratories closed a regional branch laboratory and transferred its infectious disease testing to the central state laboratory. Water testing formerly conducted by the branch laboratory was assumed by private laboratories in that region (Section 4.2).
- Redirection of Testing Among Public Health Laboratories: In 2011, to achieve cost savings in testing for chlamydia and gonorrhea, the Michigan Bureau of Laboratories reduced the number of laboratories that conducted those tests from five to two (the central state public health laboratory and one metropolitan public health laboratory) (Section 4.3).
- Multistate Sharing of Testing Services: The public health laboratories of Montana, North Dakota, South Dakota and Wyoming formed the Northern Plains Consortium to facilitate sharing of testing services as well as training and communications materials and other efforts (Section 4.4).
- Centralization of Testing Across Jurisdictions: As of early 2012, the Oregon State Public Health Laboratory contracted to perform newborn screening tests for Alaska, Hawaii, Idaho, Nevada, New Mexico, the Marshall Islands, Guam, Saipan, a military base in California and birthing centers of the Navajo Nation (Section 4.5).

In all these cases, laboratory directors focused on changing their laboratories' testing service models to achieve cost-savings and to improve operating efficiency.

1.3.2 Organization of this guide

The guide has six sections, including this introduction (Section 1):

- Section 2, **Assessing a Potential Service Change**, presents a series of topics that public health laboratory directors and their colleagues might find helpful as they explore and assess the potential benefits of a given service change, determine its feasibility and, if they wish, move toward implementation. Points for consideration are presented under each topic to stimulate discussion and identification of action steps. Specific consideration is given to such topics as the potential benefits and costs of a proposed service change, focusing on the probable impacts of the change on the laboratory's operating efficiency and long-term sustainability, its implications for the public health department and other clients, the resources needed and transaction costs involved in actual implementation of a service change,

the extent of support from key stakeholders and other factors. The goals of the assessment phase are to:

  - Determine the advantages and disadvantages of the service change.
  - Gauge the feasibility of implementing the change successfully.
  - Decide whether to adopt the service change.

- Section 3, **Planning To Implement a Service Change**, addresses steps that occur between deciding to adopt a service change and actually making the change. In this section, the guiding questions and points for consideration focus on such challenges as developing an action plan and impact measures, revising or adopting new laboratory policies and practices as needed, mobilizing financial and other resources, and monitoring and reporting on the progress and impacts of implementation. The goals of this phase are to:
  - Develop an implementation and evaluation plan.
  - Ensure that adequate support is available for successful implementation and evaluation.
  - Initiate implementation and monitoring of its impact.

- Section 4, **Case Examples**, presents detailed accounts of service changes that have been instituted. These were provided by public health leaders who generously allowed their service change experiences to be documented for this guide — the directors of the Michigan, Montana, North Dakota, South Dakota, Wyoming, New Hampshire and Oregon public health laboratories, as well as the newborn screening coordinators for Alaska and New Mexico. Guide users can refer to these materials for a deeper understanding of the goals each laboratory team had for service change and factors they took into consideration in assessing and implementing their service changes.
- Section 5, **Resources**, contains selected materials that public health laboratory directors and their colleagues can use, or modify for use, during assessment and implementation of a service change:
  - Resources that were used during the previously described service change projects.
  - References to additional resources for use in shaping laboratory service change projects and linking them with other related initiatives.

- Section 6, **Acknowledgments,** recognizes the public health laboratory professionals, APHL and CDC staff, and other colleagues who contributed to the guide.

1.4 Using This Guide

Public health laboratories are complex scientific and service enterprises. Each director in the referenced cases crafted an approach that suited his or her unique goals and settings. A director who is considering, or who might be required to consider, a substantial change in the laboratory's service model similarly will work toward specific goals and operate within unique parameters.

This guide was designed to be a flexible resource that supports systematic analyses of factors related to laboratory service changes. The topics and considerations it presents are relevant to service changes in general and are not limited to the specific types illustrated in the case examples. Public health laboratory directors and their staff can use the guide at the beginning of a service change project or, alternatively, during various stages in the implementation of a service change. Although the guide is not designed specifically as a checklist, it can be used in that

manner. Most importantly, laboratory directors should modify the procedures outlined in the guide to meet their particular needs and purposes. Reading the case examples in Section 4 as background for Sections 2 and 3 might be helpful.

1.5 The Guide, Strategic Plans and the Laboratory System Improvement Program

APHL and CDC recommend that public health laboratory directors and their service change teams use this guide in conjunction with their existing planning and management tools. In this context, a laboratory's strategic plan can articulate the laboratory's long-term goals, supporting objectives, strategies and broad action plans. Adopting a service change might further support or, in certain cases, conflict with the strategic plan. The laboratory director and other team members will want to consider the interaction between a proposed service change and the laboratory's existing plans. Also relevant are the strategic plan and program priorities of the health department that the laboratory supports.

As of early 2012, more than half of all state public health laboratories had used the Laboratory System Improvement Program (L-SIP) Performance Measurement Tool to assess the extent to which their state public health laboratory system supports the 10 Essential Public Health Services and performs the 11 core functions and capabilities of public health laboratories. State laboratory directors who have completed L-SIP projects will want to mine the findings for information that can be applied to this guide.

As its name implies, L-SIP takes a comprehensive view of the public health laboratory system, inclusive of all stakeholders. The public health laboratories that have conducted L-SIP assessments have found the process to be extremely valuable. Among other benefits, L-SIP assessments help laboratory directors understand which laboratory services their stakeholders value. They can use that information as they review their laboratories' strengths and potential areas for improvement, including potential adoption of service changes. APHL and CDC urge all public health laboratories to have strategic plans and to conduct L-SIP performance assessments.

2. ASSESSING A POTENTIAL SERVICE CHANGE

Public health laboratory service changes might be initiated by the laboratory director or prescribed by health department administrators or other officials. As in the case examples (see Section 4), even when the decision to adopt a service change is directed by authorities outside the laboratory, directors find it helpful to take a systematic approach in shaping the details of the service change and implementing it. Doing so can illuminate the potential impacts that a service change might have on the public health department programs the laboratory supports (e.g., the crucial emergency preparedness programs that rely heavily on the laboratory) and on other key stakeholders, flag concerns related to the feasibility of implementing the service change, and generate valuable information to support successful implementation.

The approach you take in assessing the merits of a potential service change for your laboratory should reflect your goals and other factors unique to your setting. Certain topics and considerations suggested in this section will be more relevant than others in your specific context. This section presents a general approach to assessing the advantages and disadvantages of a potential service change. This approach is largely based on experiences of the state public health laboratories that have implemented the service changes described in the Section 4 case examples. It can be used independently or, ideally, in conjunction with Section 3, which presents an approach to planning the implementation of a service change.

The recommended starting point for assessing a potential service change is to ask the following three questions:

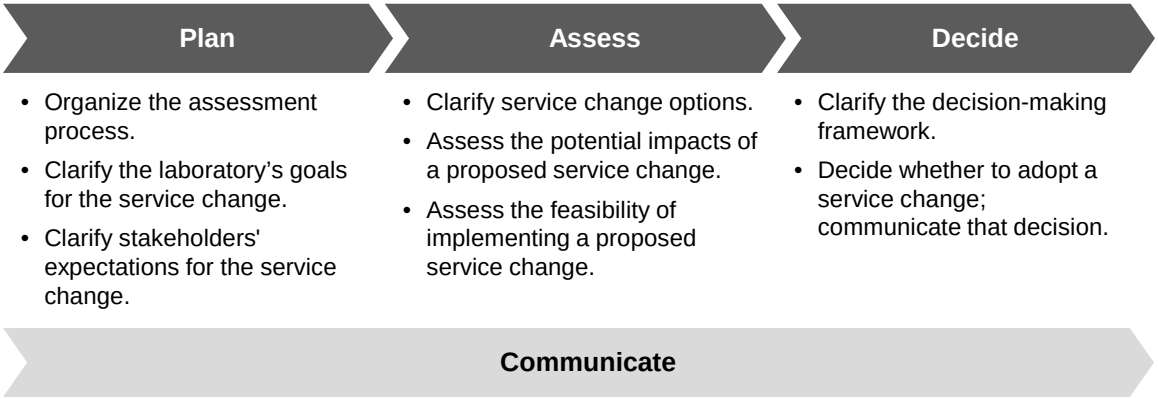
- What will be the priorities of the health department that your public health laboratory serves during the foreseeable future?
- What laboratory-based information and testing services will be required to support those health priorities?
- Which of the projected information and testing service needs should your laboratory provide?

These questions frame the assessment in the context of the public health department's goals and the critical services the laboratory must provide in the future.

2.1 Framework

Exhibit 2.1-1 presents a general framework for assessing a potential service change and separates the assessment process into three sequential phases: Plan, Assess and Decide. Topics and points for consideration are suggested for each phase. Because communicating is critically important throughout the assessment process, the framework treats communications as a topic that spans all three phases.

Exhibit 2.1-1: Framework for Conducting an Assessment



Activities conducted during the planning phase can help establish a solid foundation for the entire assessment. This is the time to think about how the assessment activities should be organized and to set out both the goals you have for the service change under consideration and the expectations that key stakeholders have.

The first focus of the assessment phase is on determining the range of service change options that are available — noting that variations might be available even within a given type of service change. After one or more service change options are identified, the focus shifts to analyzing their advantages and disadvantages, comparing the merits of alternative service changes, and determining the practicality and feasibility of implementing them.

After you have determined that a specific service change is desirable, practicable and feasible, you enter the decision phase where attention focuses on the principles, participants, and procedures involved in deciding whether to proceed to adoption and implementation of the change.

2.2 Communicate

Having a communications plan can help win support for the assessment process and for the ultimate decision to adopt or not to adopt a service change (see resources 1 and 2 in Section 5.1). Ideally, the plan should cover both the assessment and the implementation planning stages. Because the communications function is so pervasive, related suggestions appear in multiple parts of Section 2 and Section 3 of this guide.

One of the most important steps in developing a communications plan is to identify the stakeholders with whom you want to communicate. Thinking broadly about stakeholders is crucial in developing a communications strategy. Your employees almost certainly are core stakeholders. Some might fear a service change threatens their employment. Others might welcome it as opening new opportunities for professional growth. The epidemiologists and public health program staff who rely on your test results might fear loss of crucial information, as might other state and local agencies that count on the laboratory for tests that no other laboratory performs. Vendors might be concerned about loss of revenue or, alternatively, might see a business opportunity. Senior executives and elected officials might have concerns or believe you have an obligation to keep them informed about the assessment and its potential implications. CDC and other federal agencies might want to know of any implications for the effectiveness of disease reporting and other key activities.

Considerations:

- Have you decided on your key messages to stakeholders?
- Which stakeholders need to know about the assessment and potential service change?
- How will you communicate with these stakeholders (e.g., through all-hands meetings, in-person briefings, group e-mails or newsletter updates)?
- Have you considered the timing of communications with stakeholders? Do some need earlier or more frequent information than others?
- If your laboratory does not have its own communications officer, have you engaged the communications office of the health department to help in developing your communications plan?

2.3 Plan

Planning a service change assessment helps ensure that the approach taken is systematic, that key expertise and perspectives are represented, and that the assessment generates practicable, usable findings for decision makers. Planning has additional benefits as well, for example, by spotlighting concerns that need resolution before proceeding to later stages of service change consideration. The primary goals of the planning phase are to:

- Organize the assessment process.
- Clarify the laboratory's goals for a potential service change.
- Clarify stakeholders' expectations for the service change.

2.3.1 Organize the assessment process

Organizing is a first step in developing the assessment plan. This section outlines key points you might want to consider regarding who to involve in developing the plan and how decisions will be made as the assessment process moves forward.

2.3.1.1 Decide who to involve

In the case examples presented in Section 4, most of those who participated in the assessment and service change processes were drawn from the leadership and workforce of the public health laboratories. They brought two complementary perspectives to bear. On one hand, subject-matter experts conducted technical assessments of the impacts a service change might have on laboratory operations, client service and sustainability. On the other hand, clients and other stakeholders articulated the implications a service change would have for their access to the laboratory-based information they need to conduct their own activities and programs (see resources 3 and 4 in Section 5.1).

Your decision on the range of laboratory professionals and other stakeholders to involve in conducting a service change assessment will be driven by factors unique to your setting. The participation of other stakeholders, in addition to the laboratory staff, will be helpful because they have valuable technical expertise or because the service change being assessed might affect their interests. Engaging stakeholders with such interests also might help secure their endorsement and support for ultimate adoption of a specific service change.

Among the stakeholders to consider are:

- Public health laboratory scientists and technical staff.
- Public health laboratory administrative and support staff.
- Their counterparts in other laboratories that conduct tests of public health significance.
- Directors of the state and local health department programs the laboratory supports.
- Clinical laboratories that rely on the public health laboratory's testing services.
- Health care providers that rely on those services.
- Such decision makers as the state health commissioner and other senior policymakers.
- Organizations with which your laboratory has interagency or other agreements.

A related point is the important contribution that a champion can make to the assessment process and to later planning for a service change implementation. A champion brings special energy and dedication to a change initiative and can help influence and secure stakeholder support by communicating why the service change is necessary. Often the public health laboratory director serves effectively as the champion. In other cases, the role can be filled by a prominent laboratory scientist, the head of a public health program that can benefit from a potential service change, or a senior executive of the laboratory's parent agency.

Considerations:

- Have you mapped the functions of your laboratory to identify which ones the proposed service change will affect?
- Have you identified employees whose work and interests the service change will affect?
- Have you mapped implications that adoption of the potential service change will have on stakeholders outside the laboratory and identified those who can make useful contributions to planning the assessment?
- Have you designated a champion to catalyze the assessment effort?

Examples from the Field

- In the Michigan State Laboratory Redirection of Testing for Chlamydia and Gonorrhea case example, the director relied on her existing management staff to assess the redirection of testing to fewer laboratories.
- In the Northwest Regional Newborn Screening Program case example, the Oregon public health laboratory director relies on his newborn screening section manager and Oregon Health & Science University specialists to determine if the laboratory can provide services to new clients.

2.3.1.2 Decide on governance

Governance establishes the roles and responsibilities of key players in the assessment process. Governance also defines how decisions will be made as the assessment process moves forward. Decisions about governance do not have to be complicated, especially for a relatively limited service change, but these deserve attention early in the planning phase.

In most of the case examples, a small group of colleagues, including laboratory directors, laboratory program heads and managers, led the assessment efforts. Existing decision-making procedures typically were used and tended to not be formalized. Nonetheless, you might find adopting specific governance provisions helpful in clarifying roles and decision-making processes

for the assessment phase. Participants in one case example agreed that having a written charter is helpful when large-scale service changes are under review (see resource 5 in Section 5.1).

Considerations:

- Have roles and responsibilities for the assessment phase been defined?
- Do participants understand and agree to their roles and responsibilities?
- Has the decision-making process for the assessment phase been clarified?
- Will having a formal governance charter be helpful?

2.3.2 Clarify the laboratory's goals for the service change

In the current context of severe and prolonged financial pressures, a central purpose for considering service changes is to improve public health laboratories' operating efficiency, cost-effectiveness and long-term sustainability. Additional goals might be to improve (or maintain) testing services for public health programs and other clients, improve test quality and maintain testing capacity to address emerging disease threats, among others.

Establishing your laboratory's goals is one of the most important steps in making plans to assess a potential service change. This is true both when the laboratory director initiates consideration of a service change and when the impetus comes from a more senior executive or legislative body. Even if such a directive specifies that a particular type of service change must be adopted or sets other parameters, the laboratory director probably will want to consider making the laboratory's goals explicit for at least four reasons:

- Most importantly, they serve as beacons the director can use in guiding the assessment in a purposive and transparent manner.
- They can serve as criteria in weighing the advantages and disadvantages of a proposed service change. For example, if one of your goals for a service change is to reduce the cost per test or the cost per reportable test result, analysis of a proposed service change can probe its potential to achieve that goal.
- They help establish an outcome-oriented frame of reference for evaluating the impact of the service change after implementation. For example, if a goal is to ensure that your laboratory will maintain capacity to perform high volumes of tests during public health emergencies that can be a standard for measuring the laboratory's actual performance after its adoption.
- They can mobilize key partners to support the assessment and potential implementation of the service change. For example, stating that the laboratory will ensure uninterrupted testing for vaccine-preventable diseases is meaningful to, and readily understood by, elected officials, parents and healthcare providers alike.

A useful starting point for articulating your laboratory's goals might be to review its existing strategic plan; the findings of the laboratory's L-SIP performance assessment, if one has been completed; and the health department's strategic and programmatic plans (see resources 6 and 7 in Section 5.1).

Ideally, the officials who hold the laboratory accountable for its performance should endorse the goals and see them as supportive of their own expectations.

Considerations:

- Who should participate in exploring potential goals for the service change?
- How and by whom should the laboratory's goals be established? (Note the relevance of the governance challenges reviewed previously.)
- How can key stakeholders be encouraged to support the laboratory's goals as supportive of their own priorities?
- After goals are identified, how are they best communicated to laboratory staff and to external stakeholders?

2.3.3 Clarify stakeholders' expectations for the service change

Senior policymakers and the health programs the public health laboratory serves all have expectations for a potential service change. For example, a legislative appropriations committee might expect the laboratory to reduce its operating budget by a specific amount and by a specific time. In contrast, communities in the state might expect that the laboratory will continue to conduct free, on-demand drinking water testing.

Clarifying the expectations of each major stakeholder can help determine, at a minimum:

- If they are realistically attainable.
- If they are supportive of the laboratory's goals or conflict with them.
- If individual stakeholders' expectations are mutually consistent or in conflict.

Each public health laboratory works with a unique set of stakeholders. Exhibit 2.3-1 lists selected external stakeholders, and Exhibit 2.3-2 lists public health programs you might find relevant to your service change assessment.

Exhibit 2.3-1: Examples of External Stakeholders for Consideration

Local, State, National and Private-Sector Stakeholders	
• Health officials • Elected officials • Additional policymakers • Healthcare providers • Hospital and clinical laboratories • Private laboratories	• Public agencies engaged in public health activities (e.g., environmental, agricultural, law enforcement, public safety) • Public submitters (e.g., local residents who provide individual samples for testing) • Business submitters (e.g., well drillers, veterinarians, water treatment facilities) • Federal agencies

Exhibit 2.3-2: Examples of Public Health Programs for Consideration

Communicable Disease Control	Environmental Health	Maternal and Child Health	Disaster Preparedness
• Tuberculosis • STD and HIV • Influenza and other respiratory diseases • Vectorborne diseases	• Drinking water • Lead • Radiation • Air monitoring • Food safety	• Newborn screening • Cervical cancer screening	• Biological • Chemical • Radiological • Natural disasters

Considerations:

- Have you identified the stakeholders most likely to be affected by the service change under review?
- What is the best way to learn about and discuss their expectations?

2.4 Assess

The goal of the assessment phase is to determine, as fully as possible, whether the probable benefits of a proposed service change, weighed against any liabilities, justify its adoption. (The decision to adopt or not to adopt is addressed in Section 2.5 of this guide.) The assessment focuses on both technical concerns and the laboratory's relationships with its clients or customers and other organizations. Many of the former are amenable to quantitative analyses, whereas the latter involve qualitative review.

The primary activities of the assessment phase are to:

- Clarify service change options.
- Assess the potential impacts of a proposed service change.
- Assess the feasibility of implementing a proposed service change.

All the service changes that public health laboratories have adopted in recent years have been complicated, multifaceted undertakings. Therefore, a written work plan can be an invaluable resource during the assessment process.

Laboratory professionals are skilled in preparing structured action plans, reflecting in part the systematic approach they take to conducting laboratory tests and other activities. This guide therefore does not offer detailed suggestions for developing an assessment work plan. Typically, a work plan for assessing a potential service change contains objectives, work activities, timelines, deliverables and other elements as a roadmap for directing and reporting on progress during the assessment phase. The process of developing the plan itself can provide new insights and lead to formation of supportive connections among the assessment participants.

2.4.1 Clarify service change options

If public health laboratory leaders have the necessary latitude, exploring ways to fine tune a recommended service change can be helpful. In the Michigan case example related to chlamydia and gonorrhea testing, the laboratory proposed service change options both to achieve budget savings and to provide the required public health testing. This allowed the director to assess the advantages and disadvantages of different options and to conclude which option was most attractive.

Even when a specific service change is mandated, the laboratory director might consider alternative ways or options for implementing the service change within the boundaries of the mandate.

Considerations:

- What flexibility do you have to tailor or fine-tune a proposed service change?
- Which alternative approaches should be assessed for impact and feasibility?

Example from the Field

- In the Michigan State Laboratory Redirection of Chlamydia and Gonorrhea Testing case example, multiple service change options were identified and subsequently assessed, including consolidating all testing in the state public health laboratory or sharing testing between the state public health laboratory and 1–4 county public health laboratories. The state public health laboratory staff conducted cost and volume analyses for the five scenarios (see resource 8 in Section 5.1). These analyses identified the most cost-efficient and operationally sound scenario, which was to conduct testing in the state public health laboratory plus one county laboratory to ensure surge capacity. The state public health laboratory shared findings from the analyses with all four county laboratories, who agreed, on the basis of these findings, with the state public health laboratory's conclusion.

2.4.2 Assess the potential impacts of a proposed service change

This section presents a series of questions that can help in assessing the impact of a proposed service change. The areas of impact addressed here include:

- The laboratory's operations and viability.
- The health department the laboratory serves.
- The laboratory's other clients and partners.

These are core areas of impact. You might address additional areas as well. Most public health laboratories engage with partner organizations that do not fall readily into the client or customer categories. Many, for example, have ongoing research programs with academic partners. Some work with private foundations and businesses on projects of mutual interest. Any substantial service change can affect those partnerships, and those implications warrant careful analysis.

2.4.2.1 Assess the impact the proposed service change will have on your laboratory's operations and its viability

The service changes discussed in this guide typically are proposed and adopted primarily to save money, help the laboratory cope with reduced funding by becoming more efficient and, ultimately, strengthen its long-term operating sustainability. The first purpose of the assessment phase, therefore, is to answer the following questions:

- Would the proposed service change, if implemented, generate the desired budget savings?

  In most cases, savings can be estimated on the basis of such factors as the number of staff positions reduced, new revenues generated by billing for reimbursement, and reduced procurement costs. In contrast, savings might be offset by new expenses entailed by adoption of the service change (e.g., the cost of new testing equipment).

- Would the laboratory become more efficient and cost-effective?

  Answers to this question can come, in part, from analysis of operating elements similar to those in Exhibit 2.4-1. For example, sharing testing services with other states might save on personnel and reagent costs while maintaining the same volume and quality of tests as before.

- Would the proposed service change strengthen the laboratory's operating sustainability?

  Assessing the impact on the laboratory's ability to continue operating during the long term involves, first, understanding the factors that drive its revenues and costs; second, analyzing how adoption of a proposed service change will affect those factors; and third, projecting their impact on revenues and costs into the future (see resource 10 in Section 5.1).

Exhibit 2.4-1: Selected Elements of Laboratory Operations To Assess

Personnel	Processes		Resources	
• Scientific and technical staff • Administrative and support staff • Management staff	• Testing • Reporting • Quality assurance and safety • Shipping, receiving and storage • Laboratory support	• Procurement and billing • Client consultation • Document retention • Epidemiological data support	• LIMS[1] and IT[2] systems • Testing platforms • Facilities and utilities • Vendor contracts • Revenue sources	• Compliance, regulations and licensures • Computers and equipment • Memoranda-of-understanding and other agreements

[1] Laboratory Information Management Systems.
[2] Information Technology.

Considerations:

- Do you have detailed baseline information about the laboratory's revenues and costs?
- Has an analysis been conducted of the impacts that the proposed service change might have on the laboratory's operations, budget and long-term sustainability?
- Will implementing the proposed service change require any new employee certifications or modifications in the way the laboratory complies with federal or state regulations?

Examples from the Field

- In both the Michigan case examples, the public health laboratory compared its costs before the service change to the costs after the service change to demonstrate the financial impact on the laboratory.
- In the Northern Plains Consortium case example, state public health laboratory directors estimated the cost of conducting the testing in-house (including, for example, equipment, reagents, proficiency testing and additional training) given the expected volume of samples, to determine keeping testing within the state public health laboratory was cost effective.

2.4.2.2 Assess the impact the proposed service change will have on your health department

A public health laboratory's principal client or customer is the health department that serves its state, county, city or other jurisdiction. One of a laboratory director's highest priorities when assessing a potential service change is to ensure that the laboratory will continue to provide the testing and related services the health department and its individual programs require.

As a framework for assessing the impact a proposed service change can have on your health department, you might consider:

- Its implications for the health services the department and its programs currently provide.
- Its implications for the department's priorities in the longer term.

In the near-term scenario, your assessment might identify any of your health department's critically important laboratory services that will cease or be interrupted if the proposed service change were implemented. For example, if a laboratory decides that certain testing should be

performed by private or contracted laboratories, will the department's epidemiology program continue to receive the test results it requires?

In contrast, the long-term assessment might focus on the department's future priorities. Many health departments are experiencing financial and other pressures similar to those affecting public health laboratories. In addition, many are entering into new arrangements with healthcare providers (e.g., Accountable Care Organizations) and are rethinking their own service delivery models. A foundation for the long-term assessment can be laid by working with health department leaders to explore the following questions:

- What programs will be the health department's highest priorities in the coming years?
- What laboratory-based services will the health department require to address these priorities?
- Of those services, which ones should the public health laboratory provide?

Even tentative answers to these questions — and especially to the third question — can help create a frame of reference for assessing the long-term impact of a proposed laboratory service change.

Near-Term Considerations:

- Will the service change reduce, detract from or terminate the laboratory's services to current health department programs?
- If the service change is unavoidable, what can laboratory leaders do to help mitigate such effects?

Long-Term Considerations:

- Will the proposed service change enable the laboratory to support the health department's expressed longer-term priorities?
- Will it support the laboratory's ongoing need to maintain the required capacity and resilience for addressing future health department priorities that cannot be predicted now?

Example from the Field

- During January 2011, the state legislature notified the New Hampshire Department of Environmental Services (DES) that DES would have to reduce $2.6 million from its 2012–2013 general fund budget. DES leadership suggested to the governor's office that the DES Laboratory Services Unit (LSU) could be closed to meet that target. The governor's office recognized the importance of water testing in the state and recommended consolidating the DES LSU with the public health laboratory instead.

2.4.2.3 Assess the impact the proposed service change will have on other clients and partners

Many public health laboratories work with clients and partners outside the health department. These include, for example, environmental and agricultural laboratories, other state and federal agencies, hospitals and other healthcare providers, commercial laboratories and academic institutions. You might want to assess the implications a service change will have, both on the laboratory's continued ability to provide services those clients value and on the benefits the laboratory gains from such relationships.

Considerations:

- Have you mapped all of your laboratory's clients and partners, the services they receive and the reciprocal benefits to the laboratory?
- Are your clients' needs and priorities likely to change in the foreseeable future?
- Will the proposed service change affect your ability to serve clients now and in the future?

2.4.3 Assess the feasibility of implementing a proposed service change

Concluding that the merits of a potential service change outweigh its liabilities — the purpose of impact assessment — is alone not a sufficient reason for adopting it. Another essential factor in that decision is the feasibility of implementing the service change successfully in the real world.

This section includes considerations for analyzing the feasibility of a laboratory service change in the following four areas:

- Stakeholder support.
- Finance.
- Operations.
- Legal and policy implications.

2.4.3.1 Assess stakeholder support for the service change

Most public health laboratory service changes touch on the interests of multiple stakeholders. Five groups are especially salient to your feasibility assessment:

- Elected and appointed officials who shape the policies that govern the laboratory's activities and make decisions about its funding.
- Federal officials who provide financial and technical assistance to your laboratory or administer regulations that are binding on the laboratory.
- Public health department leaders and program directors who rely on the laboratory's services and influence its operations.
- Clinical laboratories and health care providers that rely on the public health laboratory's testing services.
- Academic, commercial and philanthropic foundation groups with projects that benefit from the laboratory's services.

These officials have the authority to extend or withhold support that might be critical to the laboratory's success as it implements certain types of service changes. Determining, in advance, if they have concerns regarding any of the impacts of a proposed service change and, conversely, if they are willing to support it actively is worthwhile and can open up new partnership opportunities.

Considerations:

- Have you explored whether senior officials might interpret the proposed service change as inconsistent with existing legal authorizations or appropriations policy?
- Might federal officials be concerned about compliance, for example, with the state's Medicaid plan, Clinical Laboratory Improvement Amendments (CLIA) standards or the terms of current funding awards?
- What steps can be taken to address such concerns?

2.4.3.2 Assess financial support

It takes money to initiate a service change. Even if adopting a service change ultimately results in reductions in the laboratory's budget, the initial cost of converting from the previous model of operations might be significant if it requires, among other expenditures, new equipment, staff training or new courier delivery services. For example, if a service change involves starting to bill healthcare insurance carriers for tests, thereby creating a new revenue stream, budgeting for a new administrative system might be necessary.

Your feasibility assessment should determine whether financial resources will be adequate to introduce and maintain the laboratory's new service model.

Considerations:

- Have you calculated the resources needed to initiate implementation of the service change?
- Have you estimated the resources needed for long-term operation?
- Have you identified funding sources?
- How confident are you that the required funding actually would be available?

2.4.3.3 Assess operational resources

In addition to funding, other resources are needed for a successful service change. Depending on the type of service change, these might include having adequate numbers of professional staff who have completed new training courses, new testing platforms and supplies, and new or upgraded LIMS. Many such resources appear to be mundane but can prove critically important to the real-world feasibility of making a service change.

Considerations:

- Has an inventory been completed of all the operating resources the laboratory will need to support implementation of the proposed service change?
- If the existing resources are inadequate, can affordable new resources be acquired in a timely manner (keeping in mind your agency's procurement procedures)?

Example from the Field

- In the Northwest Regional Newborn Screening Program case example, the Oregon public health laboratory provides newborn screening testing for a number of states and other jurisdictions. When the Oregon laboratory considers whether to add a new client, it assesses the impact that the volume of additional samples might have on its existing operations, including staff scheduling and equipment usage.

2.4.3.4 Assess legal and policy implications

Service changes are likely to prompt questions about their legal and policy implications. This is especially true for service changes that result in public health laboratories exchanging services across state lines. Maryland, for example, enacted legislation in 2007 specifically to authorize its public health laboratory to join a multistate mutual aid agreement and exchange testing services with other member laboratories. At the local level, Napa County and Solano County in California used a joint powers agreement to consolidate their public health laboratories (see Example from the Field: Two California County Public Health Laboratories).

In some cases, implementing a service change might require executing a new interagency agreement or modifying an existing one. Even a laboratory director who is contemplating merging a substate, regional laboratory into the central public health laboratory might want legal counsel to review the state's laws for assurance that the merger can withstand a legal challenge.

Examples from the Field

- In the Michigan State Public Health Laboratory Consolidation case example, as part of the assessment of closing the Houghton laboratory, the director researched existing laws to determine if they mandated that a public health laboratory be located within a predefined geographic area.
- In the same case example, concerns arose about "personnel bumping" regulations when closing a branch laboratory and moving staff members to the state laboratory. The director was able to prevent "bumping" by keeping vacancies unfilled at the state laboratory so it could receive displaced personnel from the branch laboratory.
- In the Northwest Regional Newborn Screening Program, when a state decides to send its newborn screening samples to the Oregon public health laboratory, the state often uses the interstate agreement process, which is easier to implement and often does not require competitive renewal.

Considerations:

- Has your legal counsel reviewed existing laws and policies to identify any obstacles to implementing the proposed service change?
- Will the service change require new legal authority or agreements with other states or jurisdictions? Will it require new or revised interagency agreements?
- Might implementation of the service change pose legal problems related to your state's human resources and collective bargaining laws and policies?

Example from the Field: Two California County Public Health Laboratories[1]

- During the late 1990s, California's Napa and Solano counties' public health laboratories faced serious budget problems and difficulties hiring staff. The counties' public health administrators and laboratory directors decided to consolidate the laboratories as a cost-saving measure. Following Napa County's decision to close its laboratory, the two boards of county supervisors approved a joint powers agreement (JPA) authorizing the Solano County laboratory to serve Napa County, thus ensuring continuity in services there (see resource 12 in Section 5.1). The JPA was the basis for creation of the joint Napa–Solano County Public Health Laboratory. JPAs are contracts between a city, county or a special district in which one agrees to perform services for, cooperate with or lend its powers to the other.
- Among other provisions, the Napa–Solano JPA:
  - Authorized use of the joint name, which cannot be granted under a contract or a memorandum-of-understanding.
  - Authorized the joint laboratory to use any funds Napa County provides for public health laboratory purposes.
  - Established shared responsibility for the laboratory; the counties jointly operate the laboratory.
  - Empowered the two counties' health officers to serve in an advisory capacity on decisions involving the public health laboratory. This provides assurance to Napa County that Solano County will not make changes to the laboratory without Napa's involvement.

[1] For additional information, please see Hsieh, Kristina (2011). "California's Public Health Laboratories: Inter-organizational cooperation models to bolster laboratory capacity". Accessible at: http://digitalassets.lib.berkeley.edu/etd/ucb/text/Hsieh_berkeley_0028E_11865.pdf.

2.5 Decide

The results of your impact and feasibility assessments are part of the basis for deciding whether to adopt a proposed service change. The decision phase is the time for systematic weighing of the evidence, specification of decision criteria and clear communication of the outcome.

The primary activities of this phase are to:

- Clarify the decision-making framework.
- Decide whether to adopt a service change and communicate the decision.

2.5.1 Clarify the decision-making framework

Two critical elements of the decision-making framework include the:

- Locus of final authority to decide whether to adopt a service change (i.e., who is empowered to make that decision).
- Criteria that are used as the basis for a decision.

2.5.1.1 Authority

Who has the authority to make a service change decision — whether the laboratory director, a more senior official or another person — is one aspect of the broader governance concerns outlined earlier in Section 2.3.1.2 and should be addressed as part of your governance discussion.

Considerations:

- Is it clear which official, committee or other entity has authority to decide on a service change?
- Has the identity of the decision maker been communicated to the laboratory staff and the stakeholders who will be most affected by the decision?

Example from the Field

- In the Michigan State Public Health Laboratory Consolidation case example, the state legislature directed the laboratory to reduce its general fund budget by 20%. After examination of different scenarios for reducing costs and assessing the related implications for public health, the laboratory and the provision of testing services, the laboratory director submitted written documentation in support of consolidation by closing the state branch laboratory in Houghton and moving its testing services to the state laboratory in Lansing. This written documentation was submitted to the state legislature for its ultimate review and approval.

2.5.1.2 Decision criteria

The criteria used in deciding on adoption include, but are not limited to, the findings of the assessment phase. Overriding budget constraints, senior officials' policy preferences, and pressures exerted by affected groups also bear on the decision. Nonetheless, advantages exist to establishing explicit decision-making criteria to help guide the process. These criteria help focus discussions about adopting a service change and, when communicated to laboratory staff and stakeholders, show that the final decision was reached through a systematic, deliberative process. This helps in both building support for the decision and ensuring its long-term success.

Considerations:

- Do you want to establish explicit decision-making criteria?
- Has the laboratory leadership used decision-making criteria in other settings that are adaptable for this purpose?
- What is the best approach to developing decision-making criteria?

Example from the Field

- In the case of the Northwest Regional Newborn Screening Program, the Oregon State Public Health Laboratory applies two main decision criteria when a state requests that Oregon's laboratory become its newborn testing provider: (1) Is the client willing to conform to Oregon's standardized testing menu? (2) Can the Oregon laboratory and medical consultants support the additional testing volume from the new client without compromising the quality of services to others? These criteria help ensure that the quality of testing and follow-up consultation is maintained and that unit cost per test remains low.

2.5.2 Decide whether to adopt a service change; communicate that decision

In a sense, deciding to adopt or not to adopt a proposed laboratory service change is a *pro forma* step after the assessment findings are in hand and the decision-making framework has been established. Each laboratory director knows best how to make such a decision or, alternatively, how to assist the officials authorized to make it.

Other important points are documenting the decision that is reached and communicating the decision to staff and stakeholders. Communicating the rationale for a service change can help build support for the decision and commitment to implementing the service change. Key communications objectives are to maintain transparency, encourage open dialogue and ensure prompt follow-up to questions and concerns that are not immediately addressed.

Considerations:

- How will the decision be recorded, including its rationale and any guidance provided to the laboratory leadership on steps to implement the decision?
- How should the decision and its implications be communicated to laboratory managers and staff?
- How should the decision and its implications be communicated to the health programs and external stakeholders the laboratory serves?

Examples from the Field

- In the New Hampshire case example, the environmental laboratory staff had specific questions regarding the new dress code, time sheets and other topics. Certain questions could not be answered at the initial announcement of the service change. The public health laboratory director documented the questions and worked with the human resources staff to obtain answers.
- In the same case example, after announcing the service change, the laboratory director invited both groups of laboratory staff to a social gathering to provide an informal opportunity to introduce them to each other. In addition, the Environmental Services Department hosted a formal ceremony to transfer its Laboratory Services Unit to the public health laboratory. This official recognition was meaningful to the environmental laboratory staff because it formally recognized their years of service at the time of their transition to the public health laboratory.

2.6 Summary

Section 2 of this guide presents a framework for use in assessing potential changes to a public health laboratory's service model. (Section 3 presents a similar framework for planning the implementation of a service change after the decision is made to adopt it.)

Exhibit 2.6-1 summarizes the activities and considerations presented in this section for ready reference.

Exhibit 2.6-1: Summary of Phases, Activities and Considerations in Assessing Potential Public Health Laboratory Service Changes

Phase: Plan	
Activities	Considerations
• Organize the assessment process. – Decide who to involve.	• Have you mapped the functions of your laboratory to identify which ones the proposed service change will affect? • Have you identified employees whose work and interests the service change will affect? • Have you mapped implications that adoption of the potential service change will have on stakeholders outside the laboratory and identified those who can make useful contributions to planning the assessment? • Have you designated a champion to catalyze the assessment effort?
– Decide on governance.	• Have roles and responsibilities for the assessment phase been defined? • Do participants understand and agree to their roles and responsibilities? • Has the decision-making process for the assessment phase been clarified? • Will having a formal governance charter be helpful?
• Clarify the laboratory's goals for the service change.	• Who should participate in exploring potential goals for the service change? • How and by whom should the laboratory's goals be established? • How can key stakeholders be encouraged to support the laboratory's goals as supportive of their own priorities? • After goals are identified, how are they best communicated to laboratory staff and to external stakeholders?
• Clarify stakeholders' expectations for the service change.	• Have you identified the stakeholders most likely to be affected by the service change under review? • What is the best way to learn about and discuss their expectations?

Phase: Assess	
Activities	Considerations
• Clarify service change options.	• What flexibility do you have to tailor or fine tune a proposed service change? • Which alternative approaches should be assessed for impact and feasibility?
• Assess the potential impacts of a proposed service change. – Assess the impact the proposed service change will have on your laboratory's operations and its viability.	• Do you have detailed baseline information about the laboratory's revenues and costs? • Has an analysis been conducted of the impacts that the proposed service change might have on the laboratory's operations, budget and long-term sustainability? • Will implementing the proposed service change require any new employee certifications or modifications in the way the laboratory complies with federal or state regulations?
– Assess the impact the proposed service change will have on your health department.	• Will the service change reduce, detract from or terminate the laboratory's services to current health department programs? • If the service change is unavoidable, what can laboratory leaders do to help mitigate such effects? • Will the proposed service change enable the laboratory to support the health department's expressed longer-term priorities? • Will it support the laboratory's ongoing need to maintain the required capacity and resilience for addressing future health department priorities that cannot be predicted now?
– Assess the impact the proposed service change will have on other clients and partners.	• Have you mapped all of your laboratory's clients and partners, the services they receive and the reciprocal benefits to the laboratory? • Are your clients' needs and priorities likely to change in the foreseeable future? • Will the proposed service change affect your ability to serve clients now and in the future?
• Assess the feasibility of implementing a proposed service change. – Assess stakeholder support for the service change.	• Have you explored whether senior officials might interpret the proposed service change as inconsistent with existing legal authorizations or appropriations policy? • Might federal officials be concerned about compliance, for example, with the state's Medicaid plan, Clinical Laboratory Improvement Amendments (CLIA) standards or the terms of current funding awards? • What steps can be taken to address such concerns?
– Assess financial support.	• Have you calculated the resources needed to initiate implementation of the service change? • Have you estimated the resources needed for long-term operation? • Have you identified funding sources? • How confident are you that the required funding actually would be available?
– Assess operational resources.	• Has an inventory been completed of all the operating resources the laboratory will need to support implementation of the proposed service change? • If the existing resources are inadequate, can affordable new resources be acquired in a timely manner (keeping in mind your agency's procurement procedures)?
– Assess legal and policy implications.	• Has your legal counsel reviewed existing laws and policies to identify any obstacles to implementing the proposed service change? • Will the service change require new legal authority or agreements with other states or jurisdictions? Will it require new or revised interagency agreements? • Might implementation of the service change pose legal problems related to your state's human resources and collective bargaining laws and policies?

Phase: Decide	
Activities	Considerations
• Clarify the decision-making framework. – Authority. – Decision criteria.	• Is it clear which official, committee or other entity has authority to decide on a service change? • Has the identity of the decision maker been communicated to the laboratory staff and the stakeholders who will be most affected by the decision? • Do you want to establish explicit decision-making criteria? • Has the laboratory leadership used decision-making criteria in other settings that are adaptable for this purpose? • What is the best approach to developing decision-making criteria?
• Decide whether to adopt a service change; communicate that decision.	• How will the decision be recorded, including its rationale and any guidance provided to the laboratory leadership on steps to implement the decision? • How should the decision and its implications be communicated to laboratory managers and staff? • How should the decision and its implications be communicated to the health programs and external stakeholders the laboratory serves?

All Phases: Communication
Considerations
• Have you decided on your key messages to stakeholders? • Which stakeholders need to know about the assessment and potential service change? • How will you communicate with these stakeholders (e.g., through all-hands meetings, in-person briefings, group e-mails or newsletter updates)? • Have you considered the timing of communications with stakeholders? Do some need earlier or more frequent information than others? • If your laboratory does not have its own communications officer, have you engaged the communications office of the health department to help in developing your communications plan?

3. PLANNING TO IMPLEMENT A SERVICE CHANGE

A public health laboratory service change might be initiated by the laboratory director or be prescribed by health department administrators or other officials. As in the case examples (see Section 4), even when a service change is instigated by authorities outside the laboratory, careful planning and monitoring of implementation efforts can increase the likelihood of achieving its goals.

The approach you take to planning and implementing a service change will reflect your goals and the factors unique to your setting. Some of the topics and considerations suggested here will be more relevant than others. In addition, although this section covers elements you might consider when planning to implement a service change, it cannot cover the full range of challenges you will encounter.

This section presents a general approach to planning and implementing a service change. This approach is based largely on experiences of the state public health laboratories that have implemented the service changes described in the Section 4 case examples. It can be used independently or, ideally, in conjunction with Section 2, which presents an approach to assessing the merits of a potential service change.

As with assessment, the recommended starting point for planning implementation of a service change is to ask the following three questions:

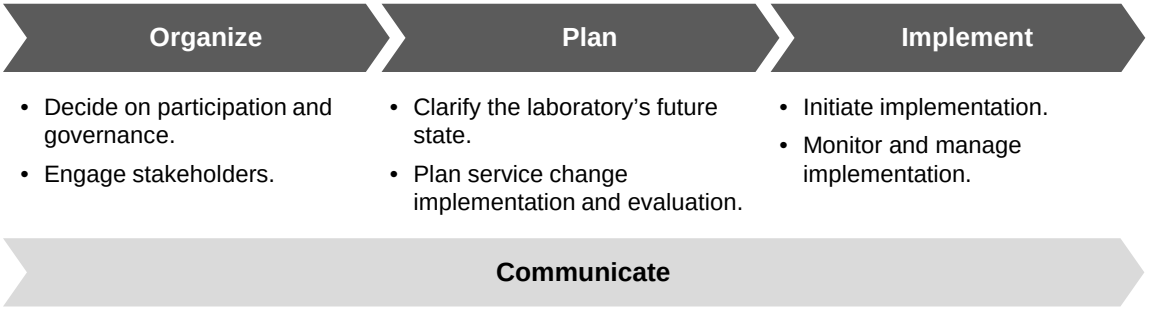
- What will be the priorities of the health department that your public health laboratory serves during the foreseeable future?
- What laboratory-based information and testing services will be required to support those health priorities?
- Which of the projected information and testing service needs should your public health laboratory provide?

These questions frame the implementation planning effort in the context of the public health department's goals and the critical services the laboratory must provide in the future.

3.1 Framework

Exhibit 3.1-1 presents a general framework for planning implementation of a service change and separates the process into three sequential phases: Organize, Plan and Implement. The body of this section of the guide suggests topics and points for consideration related to each phase. Because communications is critically important throughout the implementation process, the framework treats it as a topic that spans all three phases.

Exhibit 3.1-1: Framework for Planning To Implement a Service Change



Activities conducted during the organizing phase help establish a foundation for the entire implementation effort. This is the time to give thought to who should participate, what their roles will be and how decisions will be made.

The planning phase is the principal focus of Section 3. Work in this phase aims to develop a plan for implementing a service change. A starting point is to prepare a comprehensive description of the laboratory's operations after the selected service change is implemented and to compare that future state with the laboratory's current operation. This will help clarify implications that the service change — for example, sharing certain testing services with other states' public health laboratories — will have for the laboratory's operations and highlight concerns that should be addressed during the implementation plan (see Exhibit 3.4-1 for examples).

The implementation phase begins with transitioning from the current-state service model and continues into ongoing operation of the new future-state service model, including monitoring to identify any needed adjustments to the implementation process and evaluating the impact of the change on the laboratory's efficiency, cost-effectiveness and long-term sustainability.

Effective communication is key throughout the planning and implementation process and thus spans all three phases.

3.2 Communicate

As noted in Section 2, a first step in developing a communications strategy is to identify the stakeholders with whom you want to communicate (see resources 1, 2 and 3 in Section 5.2). Because even relatively modest service changes might affect many people within the laboratory and externally as well, it is helpful to think broadly about stakeholders. Your employees almost certainly are core stakeholders. Some might fear that a service change threatens their employment. Others might welcome it as opening new opportunities for professional growth. The epidemiologists and public health program staff who rely on your test results might fear loss of crucial information, as might other state and local agencies that count on the laboratory for tests unavailable in the marketplace. Vendors might be concerned about loss of sales or, alternatively, might see a business opportunity. Senior executives and elected officials might have concerns or believe that you have an obligation to keep them informed about the assessment and its potential implications.

Considerations:

- Have you decided on your key messages to stakeholders?
- Which stakeholders need to know about planning for implementation of the service change?
- How will you communicate with these stakeholders (e.g., through all-hands meetings, in-person briefings, group e-mails or newsletter updates)?
- Have you considered the timing of communications with stakeholders? Do some need earlier or more frequent information than others?

Example from the Field

- When the New Mexico newborn screening program decided to contract with the Oregon State Public Health Laboratory to conduct its newborn screening tests, New Mexico hospitals, birthing centers, midwives and other providers were concerned the service change might increase turnaround time and take jobs away from the state. To address this concern, the New Mexico newborn screening coordinator visited all the providers to explain that the program would send samples to Oregon by express courier, that results would be available online, and that the cost of continuing to do tests in the New Mexico laboratory could not be justified given the state's small number of births. This communication helped alleviate concerns and gain providers' support for the change.

3.3 Organize

Giving thought to organizing for implementation of a service change can help ensure that people with the needed expertise and perspectives participate in planning the implementation. The primary goals of this phase are to:

- Decide on participation and governance.
- Engage stakeholders.

3.3.1 Decide on participation and governance

Regardless of its scope, successful implementation of a service change is likely to require extensive support from the laboratory staff. This underscores the importance of determining the technical expertise needed to develop the implementation plan and manage its execution.

In this context, technical experts probably will include laboratory scientists and technicians, bioinformaticians, information technology managers, trainers, and human resources specialists and other administrative staff.

The membership and organization of the team or groups charged with implementing the service change will depend on factors related to the scope and implications of the service change and the organizational structure of the laboratory, among many other factors. Public health laboratory directors who have experience with service changes have emphasized the importance of having adequate staffing to support the implementation process. This can be a challenge because, in many cases, the responsible staff must continue to perform their original duties while participating in implementation planning.

As noted in Section 2, having a prominent and dynamic person serve as a champion for the initiative can be helpful. The laboratory director often is the best person for this role, but a more senior health official or a prominent member of the laboratory's scientific staff could also be a good choice in certain situations.

Deciding on governance is part of the organization phase. In this context, governance relates to the processes through which decisions will be made regarding the implementation plan and its execution. Especially in the case of large-scale service changes, you might consider adopting a formal charter that documents governance decisions (see resource 4 in Section 5.2). In the Section 4 case examples, laboratory directors tended to use existing laboratory governance structures in planning and implementing service changes.

Considerations:

- Has the expertise needed to develop and execute the implementation plan been defined?
- Does the team or working group responsible for planning and implementing the service change have the needed expertise? Will it have adequate support for its work?
- Have roles and responsibilities for the implementation phase been defined?
- Has the decision-making process been clarified? Will having a formal charter for the project be helpful?

Example from the Field

- In the New Hampshire Public Health Laboratory and Environmental Screening Laboratory Consolidation case, the implementation team included the managers of each laboratory program (e.g., microbiology, virology, chemistry.) Each was tasked with overseeing specific aspects of the implementation process within her or his program. Members of the state information technology and human resources departments were consulted as well.

3.3.2 Engage stakeholders

This guide refers to stakeholders as the people and organizations whose interests are affected by a service change or who believe they have standing to participate in implementing a service change. Your choice of stakeholders to engage will be driven by your service change goal and by additional factors unique to your setting.

Stakeholders who participate in assessing a potential service change might also be helpful during the implementation stage. Additional perspectives are valuable, especially because moving toward actual implementation might heighten stakeholders' appreciation of the service change or, in certain cases, their concern about its implications for them (see resources 5 and 6 in Section 5.2).

In addition to the laboratory's own staff, potential stakeholder groups might include:

- Health department program staff who rely on your laboratory's testing services.
- Laboratories in other government agencies that conduct tests of public health significance (e.g., environmental, food safety, agricultural, and forensic laboratories).
- Clinical laboratories and health care providers who rely on your laboratory's test results.
- The state health commissioner and other senior policymakers.
- Organizations with which your laboratory has interagency or other agreements.

Considerations:

- Which stakeholders' participation is crucial for successful implementation of the service change?
- How should each stakeholder be engaged?
- How will you communicate with key stakeholders about planning and implementing the service change?

Example from the Field

- In the Michigan State Public Health Redirection of Testing for Chlamydia and Gonorrhea case, the laboratory director communicated with the four local laboratories that had conducted such tests, sharing details about the cost savings and other study results that led to the decision to fund testing in only one local laboratory. This communication helped build support for the service change.

3.4 Plan

The goal of this phase is to develop a plan the laboratory director can use to implement the selected service change. The principal goals of work in this phase are to:

- Clarify the laboratory's future state.
- Plan service change implementation and evaluation.

3.4.1 Clarify the laboratory's future state

As noted earlier, one approach to developing your implementation plan is to compare the planned operations of the laboratory after the service change has been implemented — the laboratory's future state — with its present operations — the laboratory's current state. This before-and-after analysis can illuminate changes that will occur in the laboratory's operations, resources and organization. That information, in turn, can be a basis for identifying the detailed steps that will be required to implement the new service mode, determining who should be responsible for taking those steps, and determining the appropriate timeline for implementing the new service model.

At the highest level, analysis of the laboratory's current and future states asks the following three questions:

- Will the service change result in the laboratory serving different clients than before?
- Will the laboratory perform different tests (or a different mix of tests) than before?
- What changes in its operating capacity will the laboratory need to ensure it can conduct the future-state tests?

The laboratory's capacity to serve its clients' future needs will be a function of its operating elements and resources. Exhibit 3.4-1 presents a framework of such elements (e.g., the laboratory's test menu, workforce, support systems) and poses questions that can be asked to help describe and characterize the salient features of each element in the future state.

Exhibit 3.4-1: Framework of Operating Elements in the Laboratory's Future State

Operating Elements	Considerations
• The test menu	• Will current tests continue in the future? • Will new types of tests be performed as well? • Will testing volume change?
• Testing priorities, protocols and processes	• Will current testing priorities change? • Will current protocols and processes continue to be used? • Will new protocols and processes be added?
• Testing equipment	• Will current testing equipment be retained? • Will new types of testing equipment be added?
• Reagents	• Will current reagents continue to be used? • Will new types of reagents be used?
• Data management, LIMS and IT systems	• Will data management needs change? • Will access to laboratory records change? • Will the current LIMS be retained, modified or replaced? • Will IT systems and software be retained, modified or replaced? • Will existing equipment have to be modified or replaced because of changes in the LIMS or IT systems?
• Workforce	• Will current staffing patterns be retained or modified? • Will new expertise, positions or employees be added? • Will current employees need training? • Will changes be required in employee bargaining agreements?
• Sample ownership, transport and storage	• Will ownership of samples change? • Will current transport and storage systems be retained, revised or replaced?
• Administrative systems	• Will current administrative systems (e.g., personnel, procurement, records management/retention) be kept or modified? • Will new administrative systems be required, for example, systems to bill for test services?
• Quality assurance	• Will current quality assurance systems be retained, modified or replaced?
• Accreditation, certification and licensure	• Will changes be required in the laboratory's accreditation or certification? • Will employees require new licensure?
• Laboratory organization	• Will the laboratory's organizational structure change? • Will executive, management and technical functions remain the same or change?
• Facilities	• Will current facilities suffice or will modified or new facilities be required? • Will current utility services suffice or require change?
• Vendors	• Will current contracts with vendors and suppliers be retained or modified? • Will the laboratory need new vendors and suppliers?
• Partners	• Will current partnerships with other laboratories (e.g., environmental, food safety, agricultural, occupational), health department programs and other organizations continue or require modification? • Will partnerships be formed with additional organizations? • Will memoranda-of-agreement or other formal instruments be required?

Operating Elements	Considerations
• Laws and policies	• Will the laboratory's current legal authorities be adequate or will new authorities be needed? • Will current administrative policies be adequate or need revision?

3.4.2 Plan service change implementation and evaluation

The case examples that appear in Section 4 of this guide attest to the important contribution planning makes to the success of a public health laboratory's service change. One obvious purpose is to establish clear goals, objectives, work plans and timelines for implementation of any service change. Further, laboratory staff who participate actively in developing the plan are more likely to feel a sense of shared purpose and support for the service change.

This section outlines steps for consideration in developing two companion plans:

- A plan for implementing the service change.
- A plan for evaluating it.

3.4.2.1 Plan for implementation

Exploring the questions posed in Exhibit 3.4-1 will generate information you can use in outlining the implementation plan:

- Suggesting which operating elements of the laboratory's current state will support the new service model.
- Identifying gaps between current-state resources and those required for the future state.
- Identifying implementation plan priorities to address those gaps.

The team or working groups responsible for preparing the implementation plan can use the same information as they develop the more detailed, individual components of the implementation plan (see resources 7, 8 and 9 in Section 5.2). Exhibit 3.4-2 presents standardized questions to stimulate thinking about the activities, assignments, deliverables, timelines and other components of the implementation plan.

Exhibit 3.4-2: Framework for Planning to Implement a Service Change

Operating Elements	Considerations
• The test menu	• What steps are required to modify the laboratory's test menu? • Who should participate in making modifications? • What should the timeline be?
• Testing priorities, protocols and processes	• What steps are required to modify testing priorities, protocols and processes? • Who should participate in making modifications? • What should the timeline be?
• Testing equipment	• What steps are required to modify existing testing equipment or add new equipment? • Who should participate in making modifications? • What should the timeline be?
• Reagents	• What steps are required to add new types of reagents? • Who should participate in implementing decisions about reagents? • What should the timeline be?
• Data management, LIMS and IT systems	• What steps are required to modify data management? • What steps are required to modify access to laboratory records? • What steps are required to modify or replace the existing LIMS and other supporting IT system? • Who should participate in executing these steps? • What should the timeline be?
• Workforce	• What steps are required to revise current staffing patterns, acquire new expertise, deliver training and modify employee bargaining agreements? • Who should participate in executing these steps? • What should the timeline be?
• Sample ownership, transport and storage	• What steps are required to address changes in sample ownership? • What steps are required to modify or create new sample transport and storage systems? • Who should participate in executing these steps? • What should the timeline be?
• Administrative systems	• What steps are required to modify or replace existing administrative systems? • Who should participate in executing these steps? • What should the timeline be?
• Quality assurance	• What steps are required to modify or replace existing quality assurance systems? • Who should participate in executing these steps? • What should the timeline be?
• Accreditation, certification and licensure	• What steps are required to secure new types of accreditation, certification or licensure? • Who should participate in executing these steps? • What should the timeline be?
• Laboratory organization	• What steps are required to modify the laboratory's current organizational structure and executive, managerial and technical functions? • Who should participate in executing these steps? • What should the timeline be?

Operating Elements	Considerations
• Facilities	• What steps are required to modify or add new facilities and utilities? • Who should participate in executing these steps? • What should the timeline be?
• Vendors	• What steps are required to modify existing contracts with vendors and suppliers or to add new contracts? • Who should participate in executing these steps? • What should the timeline be?
• Partners	• What steps are required to modify existing partnerships or establish new partnerships? • Who should participate in executing these steps? • What should the timeline be?
• Laws and policies	• What steps are required to modify existing legal authorities and administrative policies or to add new ones? • What steps are required to ensure the laboratory complies with relevant regulations? • Who should participate in executing these steps? • What should the timeline be?

Analysis of all these operating elements and considerations must take budget matters into account. All of them will have implications for the laboratory's spending, and some might have implications for the laboratory's revenues, whether from state appropriations, fees, reimbursement, federal funds or grants.

This framework should be adapted to address the challenges most important to developing your laboratory's plan for implementing a service change.

3.4.2.2 Plan for evaluation

Well-designed evaluations can help the laboratory director:

- Determine the extent to which a service change produces intended outcomes.
- Identify ways to improve processes to better attain those outcomes.
- Generate empirical information for use in reporting to senior officials, clients and others on the impacts of the service change.

Ideally, evaluation plans should be developed in tandem with development of the service change implementation plan. This will make it more likely that evaluation will focus directly on the goals of the service change and that important baseline data will be collected before the change is implemented.

Evaluation plans vary widely, and yours should be tailored to the goals and organization of your laboratory's service change. Exhibit 3.4-3 describes typical sections of an evaluation plan and suggests steps to address them (see resources 10, 11, 12 and 13 in Section 5.2).

Exhibit 3.4-3: Typical Sections of an Evaluation Plan

Element	Description
• Evaluation purpose	• Describe succinctly what you hope to accomplish with this evaluation. – For example, "This plan is intended to determine the impacts of the service change (e.g., its impact on operating efficiency and long-term sustainability of the laboratory)."
• Users of the evaluation results	• Consider the public health programs and other clients and stakeholders who might use the evaluation findings. – For example, the tuberculosis control program might need to know if the service change reduces the time required to report positive test results. – For example, the laboratory management might use the results to inform key decision makers about the overall financial effects of this service change.
• Description of the service change	• Describe the essential features of the service change and its intended outcomes. • Consider using a logic model to describe how the service change is expected to generate the intended outcomes (see resource 13 in Section 5.2).
• Evaluation questions	• Specify the questions that will be answered through the evaluation. • For example, "To what extent has the service change reduced the laboratory's cost per test?"
• Data collection and analysis strategy	• Describe the data sources and measures that will be used to answer the evaluation questions. • Describe how the data will be analyzed (i.e., qualitative or quantitative methods). • Prepare a work plan or table that includes tasks related to data collection and analysis, timelines, and roles and responsibilities.
• Communications strategy	• Create an evaluation-specific communications plan. This might include the intended audiences, communication purpose, frequency or timing of communications, model of delivery and roles and responsibilities.

Considerations:

- Does the evaluation plan address both intended outcomes of the service change (i.e., greater operational efficiency and cost-effectiveness) and the contributions that specific implementation processes make to those outcomes?
- Does the plan address both intended and unintended consequences?
- Is the evaluation, as planned, likely to generate findings that can be used to determine if the laboratory's testing services should be modified further to better achieve the service change goals?

Example from the Field

- Northern Plains Consortium member laboratories have been building strong working relationships since 1999. They are interested in evaluating the benefits of having access across the four states to expertise spanning many laboratory science disciplines and of being able to consult with colleagues in other states on management and administrative concerns. Other benefits included leveraging resources for services beyond testing (e.g., sharing educational materials developed by other members, creating a shared marketing campaign). These are examples of objectives that can be integrated with evaluation plans beyond those directly related to the efficiency of the laboratory's operations.

3.5 Implement

In this phase, laboratory leaders and their staff take steps to implement and evaluate the service change.

This guide does not attempt to address the multitude of concerns that implementation of even a relatively small-scale service change can entail. Even when two public health laboratories implement the same type of service change, their approaches will differ on the basis of variation in their different current capacities and practices, levels of staffing and funding, and the priorities of the health departments and other clients they serve.

This section therefore only addresses two key points relevant to the early stages of service change implementation:

- Initiating implementation.
- Monitoring and managing implementation.

3.5.1 Initiate implementation

Launching implementation of a service change often involves activating new operating practices and forging new working relationships within the laboratory and with external partners. Those relationships can be crucial to the success of the new service model. Particularly in the early stages of implementation, the laboratory director might want to monitor the effectiveness of the individuals and groups responsible for its success. Forming a committee specifically charged with overseeing the initial stages and flagging problems in technical areas and in new roles and relationships can be helpful (see resources 14, 15 and 16 in Section 5.2).

Implementing a service change typically results in changes to the services that health department programs and other clients receive from the laboratory. Your implementation plan probably addressed those changes explicitly, and laboratory leaders or staff probably discussed them with the affected clients in advance. Nonetheless, the potential remains for unintended and possibly serious disruption in the laboratory's services to its clients as implementation begins. Laboratory leaders might want to establish ways to deal with such possibilities, for example, by designating members of their staff to serve as liaisons with clients during transition to the new model of conducting testing services.

Communication is a common thread throughout service change assessment and implementation, but it might be especially important at the beginning of implementation, given the many challenges associated with transition to a new service model. Effective communication with the laboratory staff, public health department programs, and other clients your laboratory serves can help ensure successful implementation of the service change. As part of your communication strategy, you might consider:

- How to communicate these changes to your staff, clients and other stakeholders.
- How to engage stakeholders in answering questions, addressing concerns and making changes in their processes.

Considerations:

- What is the best way to ensure that key actors understand the new roles and working relationships related to implementing the service change?
- What can you do to ensure that health department programs and other clients understand, in advance, the implications service change will have for them? How can continuity in services best be ensured during transition to the new service model?

3.5.2 Monitor and manage implementation

Separate from matters related to transitioning to a new service model, the laboratory director and managers need reliable sources of information they can use to monitor implementation — which often is phased in during a period of months or even years — and its consequences.

Monitoring can focus on both operating processes (e.g., timely sample submission or correct routing of samples through the laboratory or between laboratories) and their anticipated outcomes (e.g., reduced turnaround time, cost savings, or improved client satisfaction). Monitoring information supports ongoing management of the implementation process. More specifically, monitoring generates information the laboratory director and others can use to determine whether the goals, objectives and timelines spelled out in the implementation plan are being met, to identify best practices that can be applied more widely and to identify problems that must be investigated further.

Laboratory management and staff might elect to include questions in a new or existing evaluation plan that ask why or how problems detected through monitoring efforts are arising. Findings from these evaluations can be used to take specific corrective actions to improve the service change implementation process (e.g., conduct further training of staff regarding procedures for routing samples through the laboratory).

Considerations:

- What information do the public health laboratory director and managers need to monitor progress in implementing the new service model and to determine its impacts?
- What is the best approach to collecting and analyzing that information to monitor progress?
- What information do the director and managers need to identify potential disruption in the laboratory's services to its clients during transition to the new service model?

3.6 Summary

Section 3 of this guide presents a framework for use in planning implementation of a service change for a public health laboratory, following an assessment of the merits and feasibility of a given service change. (Section 2 presents a similar framework for assessing the advantages and disadvantages of a potential service change.) Exhibit 3.6-1 summarizes the activities and considerations presented in this section for ready reference.

Exhibit 3.6-1: Summary of Phases, Activities and Considerations in Planning Implementation of a Public Health Laboratory Service Change

Phase: Organize	
Activities	Considerations
• Decide on participation and governance.	• Has the expertise needed to develop and execute the implementation plan been defined? • Does the team or working group responsible for planning and implementing the service change have the needed expertise? Will it have adequate support for its work? • Have roles and responsibilities for the implementation phase been defined? • Has the decision-making process been clarified? Will having a formal charter for the project be helpful?
• Engage stakeholders.	• Which stakeholders' participation is crucial for successful implementation of the service change? • How should each stakeholder be engaged? • How will you communicate with key stakeholders about planning and implementing the service change?

Phase: Plan	
Activities	Considerations
• Clarify the laboratory's future state.	• See Exhibit 3.4-1: Framework of Operating Elements in the Laboratory's Future State.
• Plan service change implementation and evaluation. – Plan for implementation. – Plan for evaluation.	• See Exhibit 3.4-2: Framework for Planning to Implement a Service Change. • Does the evaluation plan address both intended outcomes of the service change (i.e., greater operational efficiency and cost-effectiveness) and the contributions that specific implementation processes make to those outcomes? • Does the plan address both intended and unintended consequences? • Is the evaluation, as planned, likely to generate findings that can be used to determine if the laboratory's testing services should be modified further to better achieve the service change goals?

Phase: Implement	
Activities	Considerations
• Initiate implementation.	• What is the best way to ensure that key actors understand the new roles and working relationships related to implementing the service change? • What can you do to ensure that health department programs and other clients understand, in advance, the implications service change will have for them? How can continuity in services best be ensured during transition to the new service model?
• Monitor and manage implementation.	• What information do the public health laboratory director and managers need to monitor progress in implementing the new service model and to determine its impacts? • What is the best approach to collecting and analyzing that information to monitor progress? • What information do the director and managers need to identify potential disruption in the laboratory's services to its clients during transition to the new service model?

All Phases: Communicate
Considerations
• Have you decided on your key messages to stakeholders? • Which stakeholders need to know about planning for implementation of the service change? • How will you communicate with these stakeholders (e.g., through all-hands meetings, in-person briefings, group e-mails or newsletter updates)? • Have you considered the timing of communications with stakeholders? Do some need earlier or more frequent information than others?

4. CASE EXAMPLES

The following case examples are included in Section 4:

4.1 New Hampshire Public Health Laboratories and Environmental Services Laboratory Consolidation

4.1.1 Case summary

This case example gives an overview of the approach that state public health laboratory leaders in New Hampshire took following the decision by elected officials to merge the state environmental services laboratory into the state public health laboratory. This service change began in 2011, and its implementation was under way at the time this case example was written.

4.1.2 Workshop discussion participants

The information presented here primarily is based on the proceedings of a workshop sponsored by New Hampshire public health laboratory leadership in February 2012. Participants included:

- Christine Bean, PhD, MBA, MT(ASCP) — Director, New Hampshire Public Health Laboratories.
- Patricia Bickford, MS — Administrator, Laboratory Information Management System, New Hampshire Public Health Laboratories (former Director, Environmental Services Laboratory).
- Fengxiang Gao, MD, MS — Manager, Molecular/Virology Program, New Hampshire Public Health Laboratories.
- Sally Hartman, MA — Manager, Chemistry Program, New Hampshire Public Health Laboratories.
- Mary Holiday, MBA, MT(ASCP) — Manager, Finance, New Hampshire Public Health Laboratories.
- Jill Power, MS, M(ASCP), CMQ/OE, CQA(ASQ) — Manager, Quality Assurance and Laboratory Support, New Hampshire Public Health Laboratories.
- Daniel Tullo, MS, SM(ASCP) — Manager, Microbiology Program, New Hampshire Public Health Laboratories.

4.1.3 Laboratory characteristics

The New Hampshire state public health laboratory is a unit of the Division of Public Health Services (DPHS) within the state's Department of Health and Human Services (DHHS) and is the only public health laboratory in the state. It is located in Concord, the state capital.

Before the service change — in which the Laboratory Services Unit (LSU) of the state Department of Environmental Services (DES) was merged into the public health laboratory—the public health laboratory offered three major testing services (chemistry, microbiology, and molecular diagnostics/virology) and the LSU provided testing on environmental matrices. The two laboratories were located in the same building but on different floors. They had little interaction besides a monthly lunch meeting for the three state laboratory directors of DES, DPHS and the state's Department of Safety. Exhibit 4.1-1 displays key characteristics of the two laboratories before the service change.

Exhibit 4.1-1: Characteristics of the New Hampshire State Public Health and Environmental Laboratory Services Unit Before the Service Change (FY 2010)

Characteristic	Public Health Laboratory	Laboratory Services Unit
No. of personnel[1]	50	23 FTEs: 18 filled, 5 vacancies
No. of samples tested	~83,000 samples	~26,000 samples; ~69,000 tests
Estimated annual budget	~$ 7.8 million (FY 2012)	~$ 2.2 million (FY 2011)
Population served (2007)	1.2 million	

[1] Personnel include technical and clerical categories

4.1.4 Context and drivers

The principal driver for the service change was the state government's need to reduce its 2012–2013 biennial budget in light of economic trends that had weakened state revenues. In January 2011, the state legislature notified DES leadership that an additional $2.6 million of general funds had to be cut from the 2012–2013 budget. DES leadership suggested closing the LSU to meet that target. The governor's office, however, recognized the importance of water testing and recommended that LSU be merged into the public health laboratory. The director of the public health laboratory and the LSU were asked to identify the consequences of consolidation. They later met with the DPHS and DES finance administrators and were given half an hour to propose a minimum of $200,000 in staffing cuts and construct a new organizational chart reflecting the merger.

Following advice from senior officials, the two laboratory directors informed their staffs that a merger was likely if the state budget were enacted with the funding cut in place. This was not the first budget reduction for the two laboratories. During the preceding 4 years, vacant public health laboratory positions had been eliminated; the lead testing program had been eliminated; and the laboratory's courier service had ended, which reduced the number of laboratory samples it received. The public health laboratory alone had experienced a 25% reduction in staff and a 20% reduction in its budget since 2007. Similarly, 13% of staff positions were vacant in the LSU.

4.1.5 Assessment process

Consolidation of the two laboratories was the only option presented for consideration. Other strategies for enhancing efficiencies and reducing spending were not entertained.

Although the two laboratories were not officially merged until the state budget was enacted in July 2011, the two directors considered it essential to prepare for that possibility. In addition to assessing the advantages and disadvantages of a merger based on information they possessed, they consulted with the Rhode Island public health department, which had long operated a consolidated public health and environmental laboratory.

The process of systematically assessing implications of the consolidation was fruitful in multiple ways. For example, it became clear that both laboratories could benefit in ways that would help mitigate the broad impact of the budget reduction. Exhibit 4.1-2 presents some of the potential impacts identified during the assessment process (see resource 10 in Section 5.1).

Exhibit 4.1-2: Potential Impacts of New Hampshire Public Health Laboratories and Environmental Laboratory Services Consolidation

Type of Impact	Impacts Considered
Costs incurred by Division of Public Health Services (DPHS)	• Increase in general fund budget ~$2.3 million (offset by revenues generated from fees collected from testing services). • Increase in staffing and program responsibility. • Potential future cost increases for maintenance and service contracts because of elimination of multiagency contracts.
Cost avoidances	• Salary and benefits for two full-time and two part-time positions. • Cost of supplies and reagents attributable to economies of scale. • Cost of a LIMS administrator position and other duplicate staff positions. • Preparation of standard operating procedures, emergency response plans, memoranda-of-understanding, continuity of operations plan. • Possible limited reduction in rent if sample receipt areas combined. • Minimal reduction in IT costs caused by fewer number of PCs.
Potential program benefits	• Strengthen and expand the public health laboratory's chemistry section. • Expand testing menu. • Incorporate new testing methods (e.g., molecular water testing). • Expand LIMS capability. • Expand hours of operation. • Enhance opportunity for federal funding (e.g., for Biomonitoring and the Food Emergency Response Network).
Laboratory operations efficiencies	• Optimized instrument usage and decreased duplication of testing. • Enhanced surge capacity as a result of staff cross-training. • Improved incident management because emergency responders would interact with only one laboratory. • Duplication of critical instruments to improve surge capacity and minimize effects of equipment failure. • Coordinated functions, including the newsletter, safety, training and QA committees.

4.1.6 Implementation process

In June 2011, the two directors and laboratory management staff conducted coordinated planning activities in anticipation of the consolidation (see resource 9 in Section 5.2). These included:

- Public health laboratory program managers met with LSU supervisors and staff to discuss potential functions and activities to merge.
- The DHHS human resources office met with LSU personnel to discuss changes to their benefits packages, compensation, timesheets and other concerns.
- The public health laboratory and LSU business offices met to assess the merger of such business functions as billing and invoicing, inventory, contracts, copy rentals and personnel files.
- Laboratory staff met with state IT personnel to start planning for the transition of all IT functions from the DES to the DHHS domain, given that the public health laboratory and LSU had operated on different IT systems. Considerations included necessary changes to networks, PCs, printers, file and print setups, e-mail and LIMS. Though both laboratories used ChemWare LIMS, the configuration of each system differed; therefore, merging them was not practicable.
- DES and DHHS commissioners and directors presented LSU staff with certificates of service, formally recognizing the transition of LSU from DES to DHHS.

The budget was signed on July 1, 2011, making the laboratory consolidation official. A social event held later that month helped staff of the newly merged laboratories get acquainted. Throughout July, public health laboratory program managers, LSU supervisors and staff met to share information about roles and responsibilities. Discussions during these meetings resulted in a decision to delay the merger of the laboratories until after LSU's peak summer testing season.

4.1.7 Status as of February 2012

As of February 2012, the combined laboratories had 66 FTE positions. Exhibit 4.1-3 compares staffing before and after consolidation. The entire public health laboratory staff was retained. One person from the LSU was laid off, one was hired into a public health laboratory vacancy, two retired and three vacant positions were eliminated.

Exhibit 4.1-3: New Hampshire Laboratory Personnel Profile Pre- and Postconsolidation

Characteristic	Public Health Laboratory	Environmental Health Laboratory
FTE before consolidation	50	23
FTE after consolidation	50	16
	Consolidated Laboratory	
Total FTEs	66	

Purchasing and service contracts had been integrated, former LSU personnel had begun reporting to public health laboratory managers and the safety and training committees had merged. The public health and environmental testing programs used separate IT systems and conducted media preparation and sample intake separately. The public health laboratory quality assurance/ laboratory support manager had conducted a Lean assessment for media preparation in December 2011 and January 2012 with staff members from the public health laboratory, and the LSU was assessing sample intake to aid in consolidating these processes.

Among the cultural factors that surfaced during the merger process were differences in the two laboratories' practices in billing for services and in the frequency of their staff meetings. The LSU had charged statutory fees for all tests, whereas the public health laboratory billed for few tests. The public health laboratory convened staff meetings more frequently than did the environmental laboratory, reflecting differences in scale and in the management–staff model of interaction. DPHS meetings also included many more laboratory staff than the LSU meetings had included.

Laboratory leaders began drafting a strategic plan for the integrated laboratories in September 2011, anticipating that the planning process would help facilitate the full implementation of the merger.

4.2 Michigan State Laboratory Consolidation

4.2.1 Case summary

This case example gives an overview of the approach that public health laboratory leaders in Michigan took, beginning in 2010, to closing a branch laboratory located in the state's Upper Peninsula in response to state government budget cuts. Some of the public health testing conducted there, along with some of the branch laboratory staff, was assumed by the central laboratory. Water testing that the branch laboratory had conducted for the state's Department of Environmental Quality was transferred to both public and private laboratories in the Upper Peninsula.

4.2.2 Workshop discussion participants

The information presented here is primarily based on the proceedings of a workshop sponsored by Michigan Bureau of Laboratories leadership in February 2012. Participants in the workshop included:

- Frances Pouch Downes, DrPH — Director, Bureau of Laboratories, Michigan Department of Community Health.
- George Krisztian — Laboratory Director, Michigan Department of Environmental Quality.
- Jeffrey Massey, DrPH — Manager, Quality Assurance Section, Bureau of Laboratories, Michigan Department of Community Health.
- Kirsten White, MT(ASCP) — Microbiologist, Microbiology Section, Bureau of Laboratories, Michigan Department of Community Health.

4.2.3 Laboratory characteristics

The Michigan state public health laboratory, the Bureau of Laboratories (BOL), is a unit of the Michigan Department of Community Health (MDCH). The BOL has two divisions — the Chemistry and Toxicology Division and the Infectious Disease Division — and two sections — Quality Assurance and Laboratory Systems. It is located in Lansing, the state capital, and employs approximately 120 people. Most of the approximately 6.5 million tests conducted there each year are devoted to newborn screening. The laboratory receives funds from three primary sources: state general funds, fees (mostly for newborn screening), and grants and cooperative agreements. Before December 2010, a branch laboratory located in Houghton (approximately 500 miles from Lansing) provided a limited set of testing services in the Upper Peninsula. The branch laboratory employed a staff of eight who performed water testing as well as testing for rabies, gonorrhea, syphilis, and chlamydia, and DNA fingerprinting for *Staphylococcus aureus*. The vast majority of tests (60–80%) were of water, followed by STD tests (20-40%). Exhibit 4.2-1 provides information about the Lansing and Houghton laboratories.

Exhibit 4.2-1: Characteristics of the State Public Health Laboratory in Lansing and the Houghton Branch Laboratory Before Consolidation

Characteristic	Lansing Laboratory[1]	Houghton Laboratory
No. of personnel[2]	120	8
No. of samples tested/year	> 6.5 million tests	~10,000 samples
Annual state funding budget	$6,405,175 (FY 2010)	$649,246 (FY 2010)
Population served (2010)	9,883,640	

[1] Represents characteristics of the laboratory as of 2012.
[2] Personnel include technical and clerical categories.

4.2.4 Context and drivers

The principal driver for the service change was the state government's need to reduce the FY 2011 budget in light of economic trends that had weakened state revenues. In 2010, the state legislature notified BOL that it had to cut the general funds component of its budget by 20%, of which $300,000 was removed from the Houghton laboratory's budget. Recognizing the gravity of the state's budget crisis and reflecting on experiences from previous years when she had argued to keep the Houghton laboratory open, the BOL director was required to consider its closure, along with additional large reductions in the Lansing laboratory's budget.

4.2.5 Assessment process

The directors of the central and branch laboratories carefully examined existing laboratory data, considered alternative scenarios for reducing the branch laboratory's cost, and assessed the implications of closure.

Examination of testing volume at the branch laboratory indicated a decrease in volume during recent years. One approach the directors considered was to eliminate all but water testing. Other scenarios included shedding services and consolidating testing (e.g., an earlier approach in Lansing had successfully disseminated molecular biology testing to the Microbiology and Virology Sections). Ultimately, however, they determined that sufficient cost reductions would not result from such intermediate solutions.

Staffing levels were also considered during the assessment, which revealed that multiple Houghton staff would be eligible for retirement within the next 3–5 years. Recruiting new staff was expected to be challenging because of the laboratory's rural location. When the reality of closing the branch laboratory became apparent, the state laboratory director kept positions open at the Lansing laboratory for staff who would have to be transferred, thereby eliminating the need to "bump" employees at the Lansing laboratory to accommodate more senior laboratory scientists from the Houghton laboratory.

The culture of the Upper Peninsula, defined by close relationships and tight-knit communities, was also was considered in the assessment. The Houghton laboratory, which had operated for 96 years, was tightly integrated with the community. Residents depended on the laboratory for residential water tests, and local public health agencies relied on the laboratory for clinical testing.

Additional steps in the assessment included examining the state's public health code and the public health mission. The Michigan public health code did not require a public health laboratory in each county and allowed flexibility in laboratory location. Also, each testing service (e.g., providing free clinical cultures) was examined relative to the public health mission and considered for removal if it did not align with that mission.

After examining the available data and assessing the potential implications of closing the laboratory, the decision was made to close the Houghton laboratory and remove it from the FY 2011 executive budget proposal. Exhibit 4.2-2 provides a summary of the primary topics and questions that were considered during the assessment phase.

Exhibit 4.2-2: Selected Topics Considered During the Assessment of Lansing and Houghton Laboratory Consolidation

Topic	Types of Questions Asked
Test volume	• What are recent patterns in testing volume at the branch laboratory? Is demand for its test services growing or declining? • Will the testing volume increase greatly at the central laboratory to which the branch tests will be moved? If so, does it have the capacity to accommodate greater volume?
Costs	• What does it cost to keep the branch laboratory in operation? How do costs change under different potential scenarios (e.g., service shedding)? Do these possible scenarios lead to sufficient reductions in operating costs to keep this laboratory open?
Staff projections	• What is the likelihood of retaining current branch laboratory staff in the future? Are near-term retirements planned? How easy or difficult will filling vacancies in this laboratory be? Might central laboratory staff be "bumped" to accommodate more senior scientists from Houghton who are transferred?
Potential community impact	• What is the culture of the community that the laboratory serves? How reliant are private citizens and businesses on its services?
Public health code	• Does the state public health code require services that can be provided only by the branch laboratory? Does the code mandate that laboratories be located in specific areas?
Public health mission	• How do the services performed by this laboratory align with the mission of the state public health agency?

4.2.6 Implementation process

While awaiting a signature from the governor's office on the proposed budget bill, the laboratory director notified the staff of the Houghton laboratory of the potential closure; at the same time, she also investigated the possibility of developing a memorandum-of-understanding (MOU) with a local Upper Peninsula public health department to continue offering water testing services to the community. This arrangement would have transferred water testing equipment and supplies from the Houghton laboratory to the local health department. Testing personnel already trained and approved by the state's water testing laboratory regulatory program would be rehired by the local public health department. However, implementation of the MOU ultimately proved to be infeasible, and water testing services were shed to other testing facilities.

The state budget was enacted on October 1, 2010, marking the official decision to close the branch laboratory. The laboratory continued to operate until mid-December, allowing time to plan and implement the closure. Planning and implementation efforts largely occurred in parallel. Staff first outlined the considerable number of activities that had to occur to close the laboratory and then developed a checklist to help ensure that tasks were not overlooked. Items were added to this checklist as new activities were identified (see resource 8 in Section 5.2).

To prepare for the move, the laboratory staff inventoried equipment and chemicals; determined the disposition of equipment, chemicals, media and cultures; packed and archived data and records; packed other items; obtained bids for movers; and acquired bids from insurance companies for valuation of items that were to be moved. To determine the ultimate disposition of equipment, the staff first identified the items that could be used in the Lansing laboratory or by other state agencies. They determined that most equipment could not be used by the state; therefore, it was largely sold after the Houghton laboratory closed. Similarly, laboratory chemicals, media and cultures were inventoried and decisions were made to move, distribute or dispose of them. Records were sent to the state archive or disposed of in accordance with state

record retention policies. The building itself had been leased, and certain repairs were required to restore it to its original condition because modifications had been made to support laboratory equipment (e.g., plumbing to install an autoclave). In some instances, the building repairs to restore the space to its original condition were more costly than the value of the equipment; therefore, selected equipment was left behind. Finally, the laboratory had to be cleaned and disinfected.

Notifying clients, vendors and contractors, and laboratory certification and accreditation bodies occurred as part of the laboratory closure (see resource 3 in Section 5.2). The BOL human resources staff was also notified and engaged in the process. Four of the branch laboratory staff retired, one moved to a private employer and two relocated to the Lansing laboratory; one other staff member was already working at the Lansing laboratory. After the transfer was complete, few additional efforts were needed to integrate the staff beyond providing training and issuing new badges.

4.2.7 Status as of February 2012

As of February 2012, the testing services formerly performed by the Houghton branch laboratory had been redistributed. Clinical testing (e.g., sexually transmitted diseases, rabies, pulsed-field gel electrophoresis for *Staphylococcus aureus*) was moved to the central laboratory in Lansing. Water testing continued to be performed primarily by multiple small laboratories in the Upper Peninsula. Although the Houghton laboratory had been closed for more than a year, a number of recent requests came in to the state laboratory staff (within MDCH and DEQ) for results of testing performed earlier by the branch laboratory and for details about the required efforts to end previous contracts or vendor services. The record retention procedures employed during the laboratory closure enabled timely responses to such requests.

As of February 2012, laboratory leadership had not had the opportunity to conduct formal evaluations of the Houghton laboratory closure's impact. However, closing the laboratory was estimated to have saved approximately $700,000. Integration of experienced staff from the branch laboratory into the central laboratory was recognized as potentially beneficial because it resulted in filling positions for which new or less-experienced staff might have otherwise been hired. The impact on water and rabies testing and the timeliness of testing during public health emergencies had not been determined as of February 2012.

4.3 Michigan State Laboratory Redirection of Testing for Chlamydia and Gonorrhea

4.3.1 Case summary

This case example gives an overview of the approach that Michigan public health laboratory leaders took, beginning in 2011, to redirect certain testing services for chlamydia (CT) and gonorrhea (GC) from four substate laboratories to one substate laboratory; the central state laboratory would continue to perform a portion of these tests as well.

4.3.2 Workshop discussion participants

The information presented here is primarily based on the proceedings of a workshop sponsored by Michigan public health laboratory leadership in February 2012. Participants in the workshop included:

- Frances Pouch Downes, DrPH — Director, Bureau of Laboratories, Michigan Department of Community Health.
- Jeffrey Massey, DrPH — Manager, Quality Assurance Section, Bureau of Laboratories, Michigan Department of Community Health.
- James Rudrik, PhD — Manager, Microbiology Section, Bureau of Laboratories, Michigan Department of Community Health.

4.3.3 Laboratory characteristics

Michigan's state public health laboratory, the Bureau of Laboratories (BOL), is a unit of the Michigan Department of Community Health (MDCH). The BOL is organized into two divisions — the Chemistry and Toxicology Division and the Infectious Disease Division — and two sections — Quality Assurance and Laboratory Systems. It is located in Lansing and employs approximately 120 staff who conduct approximately 6.5 million tests per year, most devoted to newborn screening. The laboratory receives funds from three primary sources: state general funds, fees (mostly for newborn screening) and grants and cooperative agreements. Michigan also has a Regional Laboratory System (RLS) that serves local jurisdictions. As of February 2012, this network included three regional laboratories in Kent, Saginaw, and Kalamazoo counties (each of which have multiple partners) and three associate members — Oakland County Health Division Laboratory, City of Detroit Department of Health Laboratory, and Genesee County Health Department.

Testing for CT and GC is performed by laboratories within the RLS through a fee-for-service contract with the state laboratory, prepaid voucher systems and billing Medicaid and submitters. Before the service change, CT and GC testing was performed at the state laboratory in Lansing and at laboratories in Kent, Kalamazoo and Saginaw counties and the city of Detroit. Testing was supported by federal funds administered through a master contract (comprehensive agreement) between the state and local public health agencies. Funding provided to the regional laboratories conducting CT and GC testing supported reagent purchasing and shipping, disposables, labor and proficiency testing. Exhibit 4.3-1 compares the CT and GC testing conducted by Lansing and the RLS before redirection of those services.

Exhibit 4.3-1: Michigan Chlamydia (CT) and Gonorrhea (GC) Testing Profile (FY 2010)

Characteristic	Lansing Laboratory	Regional Laboratories Previously Conducting CT and GC Tests
No. of CT and GC tests performed/year (pre-paid)	19,222	39,895
No. of CT and GC tests performed/year (fee-for service)	4,087	8,740

4.3.4 Context and drivers

The primary driver for redirection emerged from within the Michigan BOL. James Rudrik, the microbiology section manager, understood the potential cost savings that might result from increasing efficiencies associated with CT and GC testing.

4.3.5 Assessment process

Rudrik conducted a detailed cost analysis with existing data to estimate the potential cost savings from decreasing the number of laboratories performing these tests statewide (see resource 8 in Section 5.1). He analyzed five alternative scenarios for distributing testing for CT and GC across laboratories. The base scenario assumed that all testing would be conducted at the central state public health laboratory in Lansing. Four other scenarios were analyzed, each adding a substate laboratory. The scenarios used multiple cost variables (e.g., the reimbursement rate per unbilled test, data entry time, number of controls per day, reagent costs, testing volumes, shipping costs).

Centralizing all CT and GC testing at the Lansing laboratory resulted in the largest estimated cost savings, slightly more than $165,000 per year. Adding one substate laboratory resulted in savings of approximately $100,000. Cost savings were primarily associated with decreased quality-control costs for larger test batches, decreased proficiency testing costs, decreased disposable costs and increased automation. BOL leaders discussed the findings from the report with representatives of the regional laboratories to better understand the potential drawbacks from implementing this service change. The final decision to redirect testing to only one regional laboratory (in addition to the central laboratory) was based on the consensus reached during those discussions that few negative impacts would arise, whereas substantial cost savings were likely to result, turnaround time was likely to improve and the continuity of operations was unlikely to be disrupted. Although locating all CT and GC testing at the Lansing laboratory produced the highest estimates of savings, sharing testing with another laboratory would preserve surge capacity and continuity of operations in the event of a closure at either testing site.

4.3.6 Implementation process

In July 2011, the state issued a request for proposal for a laboratory that could perform 20,000–25,000 prepaid and 5,000–10,000 fee-for-service CT and C nucleic acid amplification tests annually (see resource 11 in Section 5.1). Four laboratories were eligible to apply and all four submitted applications. An expert panel reviewed the applications, and the award was made to the Saginaw County Health Department. After the award, BOL worked with submitters to inform them of the change, and each was assigned a laboratory for testing purposes (i.e., Lansing or Saginaw County). The general process for submitting samples for testing remained the same.

4.3.7 Status as of February 2012

As of February 2012, Saginaw County Health Department and the state laboratory in Lansing received federal funds and fee revenues for CT and GC testing. Other regional laboratories continued to perform low numbers of these tests to support local testing needs, but did not receive state funds.

Reported benefits of this service change included cost savings, as outlined in the cost analysis report, a decrease in the Lansing laboratory's workload related to sample handling and shipping, and reductions in the labor associated with quality control (given the reduction in the number of participating laboratories). The procedures for submitting samples and the turnaround time in producing test results reportedly were largely unaffected by the service change.

The laboratories not re-funded for CT and GC testing were concerned that their laboratories might have to close as a result, but innovative approaches to funding appeared to be under way. At least one laboratory had developed a business plan proposing different ways to increase the number of services they offer (e.g., fee-based testing for prison populations).

Unanticipated problems emerged early in the implementation process. Some submitters that previously had access to the state-laboratory–supported courier now bore additional shipping costs. Separately, some submitters initially were confused about why they were required to submit samples to the Lansing or Saginaw laboratories when their local laboratories were continuing to perform CT and GC tests.

4.4 Northern Plains Consortium: Multistate Service Sharing

4.4.1 Case summary

This case example gives an overview of the approach that public health laboratory leaders in Montana, North Dakota, South Dakota and Wyoming took, beginning in 1999, to share testing services for certain low-volume tests and to exchange related knowledge and expertise. Examples of tests shared include HIV multispot, 16S ribosomal bacterial identification, hantavirus serology and immunoglobulin M testing for vaccine-preventable viral diseases such as measles and mumps.

4.4.2 Workshop discussion participants

The information presented here is primarily based on the proceedings of a workshop sponsored by Montana public health laboratory leadership in February 2012. Participants included:

- Susanne Zanto, MPH, MLS, SM — Deputy Director/Acting Director, Montana Laboratory Services Bureau.
- Richard Harris, PhD — Director, Wyoming State Public Health Laboratory.
- Myra Kosse — Director, North Dakota Division of Laboratory Services.
- Mike Smith — Director, South Dakota Public Health Laboratory.
- Anne Weber, MS — Laboratory Logic (former Director, Montana Laboratory Services Bureau).
- Bonnie Barnard, MPH, CIC — Coordinator, Healthcare Associated Infection Prevention Program, Montana Communicable Disease and Prevention Bureau.
- Debbie Gibson, MT(ASCP) — Manager, Microbiology and Molecular Laboratory, Montana Laboratory Services Bureau (former Coordinator, Montana National Laboratory System).
- Eric Hieb, MS, MT(ASCP) — Supervisor, Information Technology and Compliance, North Dakota Division of Laboratory Services.
- Karl Milhon, CPM — Supervisor, Communicable Disease Epidemiology, Montana Communicable Disease and Prevention Bureau.
- Janet Stetzer, BS, MT(ASCP) — Coordinator, Laboratory System Improvement, Montana Laboratory Services Bureau.
- Jan Trythall, BS, M(ASCP) — Supervisor and State Trainer, Microbiology and Bioterrorism, North Dakota Division of Laboratory Services.

4.4.3 Laboratory characteristics

The Montana, North Dakota, South Dakota and Wyoming state public health laboratories are members of the Northern Plains Consortium (NPC).These laboratories are relatively small in scale and serve small populations distributed across widespread geographic areas. The NPC laboratories vary in their sources of funding and in the types of services they provide. Exhibit 4.4-1 displays selected characteristics of the four laboratories.

Exhibit 4.4-1: Selected Characteristics of State Public Health Laboratory Members of the Northern Plains Consortium as of Early 2012

Characteristic	Montana	North Dakota	South Dakota	Wyoming
No. of personnel[1] (FTE)	39	36	28	29
No. of samples tested/year	56,150	72,642	62,742	72,600
No. of tests performed/year	247,588	278,617	180,000	340,000
Type of testing conducted	• Public health[2] • Environmental	• Public health • Environmental	• Public health • Environmental • Forensic	• Public health • Toxicology
Budget (FY 2011)	$5,000,000	$4,500,000	$5,300,000	$3,300,000
Budget from general fund (%)	7	44	0	51
Budget from fees (%)	65	15	60	20
Budget from grants	28	41	40	29

[1] Personnel include technical and clerical categories.
[2] Montana is the only state of the four that does not contract out all of its newborn screening tests. Traditional newborn screening is conducted in-house, mass spectrometry and some additional testing is performed by the Wisconsin State Laboratory of Hygiene.

4.4.4 Context and drivers

Leaders of the four states' public health laboratories conceptualized and developed the NPC on their own initiative. The four collaborated beginning in 1999 (e.g., Montana performed hantavirus testing and viral isolation for Wyoming), building relationships among the laboratory directors. Recognizing the common challenges the laboratories faced and the similarities in their states' demographics, Anne Weber (then director of the Montana Laboratory Services Bureau) in 2006 encouraged her North Dakota, South Dakota and Wyoming colleagues to join in applying for a 3-year grant from CDC's Initiative to Integrate Clinical Laboratories into Public Health Testing. The directors established the NPC in January 2007 during their first face-to-face meeting after grant approval.

4.4.5 Assessment process

Participants in the February 2012 workshop identified considerations in determining if supportive conditions exist for multistate sharing of laboratory services or, alternatively, if certain tests should be completely outsourced:

- Volume of testing: in-house testing might not be cost-effective if the number of tests performed is limited and labor-intensive.
- Testing proficiency: this includes both the proficiency of the personnel performing the tests and the laboratory's ability to conduct proficiency testing. A public health laboratory considering whether to conduct tests for another laboratory should determine if its staff need training for the purpose — especially if new types of tests will be performed — and, if so, the cost training would entail.
- Capacity: a director who is considering adding to the laboratory's testing volume or menu — to conduct testing for other states — needs to balance the cost of acquiring new equipment and staff training against the benefits of conducting tests in-house.
- Funding: whether the laboratory has adequate, reliable sources of funds for its current and future testing services can be a decisive factor in concluding whether to share services with other laboratories.

- Impact on public health: laboratory directors might prefer to conduct tests in-house if they are of high public health significance or align closely with the health department's mission and priorities. These might include, for example, tests that generate time-sensitive information for infectious disease outbreak surveillance, but not tests whose results are used primarily by clinicians in treating individual patients for low-incidence diseases.

NPC members also noted they benefit from being able to consult with each other while exploring potential changes in testing practices and service models and on other challenges. As the coordinator of the Montana Healthcare Associated Infection Prevention Program explained, the four-state partnership is "similar to getting an expert panel together. . . .These are all very experienced people who have been doing this a long time."

4.4.6 Implementation process

Each laboratory director retains the ability to decide whether to perform tests for one or more of the other state laboratories. The low volume of testing typically shared between these states and the small related costs usually do not require formalization of the laboratories' relationships in contracts or memoranda-of-understanding. Examples of tests shared between one or more states during 2011–2012 include HIV multispot, 16S ribosomal bacterial identification, hantavirus serology, and immunoglobulin M testing for vaccine-preventable viral diseases such as measles and mumps.

Joint projects conducted by the NPC laboratories have created an environment where mechanisms to transport samples, order tests, and report test results are largely already in place. Implementation of NPC test sharing has shown that when samples are sent to another NPC state for testing, staff training regarding test sharing procedures is critical. The NPC state laboratories are committed to having customers' tests performed in a timely, high-quality manner and to providing their in-state customers with consultation and interpretation services. When an NPC state laboratory sends a sample for testing by another member, it tries to ensure the testing services provided to the public appear seamless. The NPC states keep communication lines open.

Sharing services among states in the NPC extends beyond shared testing. An important component of the consortium's activities is working together on projects to accomplish shared goals (e.g., workforce assessment and development initiatives, cross-state educational campaigns). The NPC laboratories also collaborate in applying for funding opportunities. The Montana state public health laboratory serves a convening role for the consortium. The NPC laboratories use different technologies to communicate, including teleconferencing and Web conferencing. Of particular importance, however, are the NPC's face-to-face meetings, held at least once each year, where laboratory leaders and staff, epidemiologists and other professionals from all four state laboratories discuss shared interests and future priorities (see resource 9 in Section 5.1).

4.4.7 Status as of February 2012

As of February 2012, the NPC member laboratories shared low-volume testing and were exploring high-priority projects for the region. Among other activities, the members were developing a comprehensive database of all their testing menus as a basis for identifying additional opportunities to share testing services. They also were considering new collaborative foci, including opportunities to increase efficiencies in procurement and laboratory information systems. In addition, the NPC members were seeking a stable source of funding for their periodic, in-person meetings. The consortium members explained that they greatly value their in-person meetings and therefore continue to find innovative ways to leverage funding opportunities in support of this meeting time. However, they hope that a consistent funding source will emerge

that supports and encourages this type of collaborative effort. NPC members reported that the benefits they derived from the consortium included, among others, the ability to draw on the knowledge of a broad group of subject-matter experts, build on the work of others (i.e., not "reinventing the wheel"), share ideas for effective management practices, adopt other laboratories' approaches to specific problems, and identify ways to leverage shared resources (e.g., through purchasing as a group or sponsoring invited speakers or trainings).

4.5 Northwest Regional Newborn Screening Program

4.5.1 Case summary

This case example gives an overview of the approach taken by the Northwest Regional Newborn Screening Program (NWRNSP), operated by the Oregon State Public Health Laboratory (OSPHL), to provide fee-based newborn screening services for multiple states, territories and tribal authorities in the western United States. Services include laboratory testing as well as educational sessions and materials, short-term follow-up and medical consultation. Although OSPHL conducts tests for 15 clients, this case example focuses primarily on its relationships with the Alaska and New Mexico newborn screening programs.

4.5.2 Workshop discussion participants

The information presented here is based on an in-person workshop sponsored by the Oregon public health laboratory leadership and a set of telephone conversations that occurred during February–March 2012. Participants in these efforts included:

- Michael R. Skeels, PhD, MPH — Director, Oregon State Public Health Laboratory.
- Janis Gonzales, MD, MPH, FAAP — Medical Director, Children's Medical Services, New Mexico Department of Health.
- Cheryl Hermerath, MBA, DLM(ASCP), RR(NRCM) — Manager, Newborn Screening Program, Oregon State Public Health Laboratory.
- Brenda Romero, RN, BSN — Coordinator, New Mexico State Genetics, New Mexico Department of Health/Family Health Bureau/Children's Medical Services.
- Thalia Wood, MPH — Manager, Children's Health Unit, Women's Children's and Family Health, Alaska Division of Public Health.

4.5.3 Laboratory characteristics

OSPHL is a unit within the Oregon Health Authority. It comprises five sections: general microbiology, virology/immunology, newborn screening (NBS), laboratory operations and laboratory compliance. The laboratory is located in Hillsboro, Oregon. Oregon relies primarily on the OSPHL for testing because no branch laboratories exist and only one large county public health laboratory is available in Multnomah County. As seen in Exhibit 4.5-1, approximately 50% of the OSPHL budget comes from NBS fees. Oregon was one of the first U.S. states to legislate universal NBS for phenylketonuria in 1962. The screening panel now includes endocrine, hemoglobin and metabolic conditions and cystic fibrosis.

The OSPHL currently performs NBS for Oregon, Alaska, Hawaii, Idaho, Nevada and New Mexico; birthing centers of the Navajo Nation; and medical centers in Guam, Saipan, the Marshall Islands and a military base in California. New Mexico is the most recent addition to the NWRNSP, joining in 2007. NWRNSP services are based on contracts or purchase orders between the Oregon Health Authority and each participating state's health department. Each state coordinates its own NBS program, which interacts with its own birthing centers and providers and maintains its own identity. Oregon bills the participating state health departments, rather than providers, for the NBS services. Each state health department determines the fees it charges its submitters.

OSPHL provides testing and a suite of other services to NWRNSP members. These services include providing educational materials and sessions for parents[1] and healthcare practitioners,[2] short-term follow-up and expert medical consultation from specialty physicians located at the Oregon Health & Science University (OHSU).

Exhibit 4.5-1: Characteristics of Three State NBS Programs That Participate in the Northwest Regional Newborn Screening Program

Characteristic	Oregon	Alaska	New Mexico
No. of personnel in NB screening program (FTE)	21	<1	—
Total no. of samples tested/year (2011)	296,500	21,503	49,165
No. of Oregon NB samples tested/year (2011)	89,514	—	—
Population served (2010)	3,831,074	710,231	2,059,179

4.5.4 Context and drivers

The NWRNSP was established in the northwestern United States in the mid- to late 1970s. The primary drivers for program establishment were the small population, low birth numbers, and lack of subspecialty medical consultation in the region. Conducting NBS testing in areas with low test volumes can be cost-prohibitive because purchasing equipment and recruiting qualified personnel can be expensive. Also, specialized medical expertise for metabolic disorders was not available in certain western states at that time. NWRNSP continues today for many of the same reasons.

4.5.5 Assessment process

Two perspectives are worth considering when examining the NWRNSP assessment processes: that of the service supplier — the OSPHL — and that of those who receive the services — the NBS program members. Currently, the assessment process consists of gathering information to determine whether to provide services for a new or existing client and to determine whether to contract with the service provider.

4.5.5.1 Service provider perspective

The OSPHL typically acquires new clients in one of two ways:

- By submitting a proposal in response to a request for proposals published by a state (or other entity's) NBS program.
- By contracting with a NBS program that requests its services directly.

OSPHL uses contracts as the mechanism for engaging with state and other governmental newborn screening programs. It uses purchase orders with nongovernmental partners.

OSPHL considers multiple factors when deciding whether to contract with a client (see Exhibit 4.5-2). An early consideration is whether the client's needs align with OSPHL's existing testing model. OSPHL tests for a specific set of conditions and uses standard testing protocols and processes. OSPHL also considers its available resources — including staff (medical consultants and laboratory staff), technology and equipment. OSPHL leaders typically pose the question to themselves, "How big is too big?" Finding the right balance between the number of clients and aggregate testing volume and OSPHL's capacity is an important assessment criterion.

[1] Parent pamphlet: http://public.health.oregon.gov/LaboratoryServices/NewbornScreening/Documents/ptpmph.pdf
[2] Practitioner's manual: http://public.health.oregon.gov/LaboratoryServices/NewbornScreening/Documents/nbspract/manual.pdf

4.5.5.2 Client perspective

Alaska joined the program in the mid-1970s and New Mexico in 2007. Both state NBS programs primarily considered the costs associated with conducting NBS in their own state laboratories before joining NWRNSP.

New Mexico's state public health laboratory staff conducted analyses to examine the costs associated with conducting NBS in-house and determined that conducting testing on approximately 29,000 births each year would be cost-prohibitive. They therefore initiated a process of outsourcing testing. Factors beyond cost were considered in selecting a service provider. For example, New Mexico considered the experience level of potential service providers as well as their testing menus and relationships with current clients (summarized in Exhibit 4.5-2). New Mexico and Alaska both concluded that OSPHL offered supporting services beyond laboratory testing, including access to medical specialists and short-term follow-up for positive test results.

Exhibit 4.5-2: Selected Points Considered During the Assessment Phase by Service Provider and Client

Service Provider — OSPHL	Clients
• Can our public health laboratory offer what is being requested by the client? • Is the client willing to adopt the Oregon State public health laboratory model? • Do our medical consultants have the capacity to accommodate the number of positive results that are likely to come from adding this client? • Do we have adequate staff resources to perform this work successfully? • Do we have adequate technology and equipment resources to accommodate this request? • Will the level of services needed compromise the quality of our work?	• Do the potential revenues associated with conducting newborn screening in-house offset the costs? – What is our birth rate? – What would equipment and other resources cost if screening is conducted in-house? Can the program provide follow-up services to hospitals and other sample submitters? – What will recruiting and retaining technicians to conduct tests cost? – What are the costs associated with acquiring and maintaining the staff to conduct these tests? • What is the value added of the services beyond costs (e.g., follow-up consultation, provision of data for quality assurance)? • Can the service provider screen for all conditions mandated by our laws? • What quality-assurance process is used? • What is the quality (e.g., as indicated by the provider's performance under the CDC newborn screening proficiency testing program, or by expected turnaround times) of the services?

4.5.6 Implementation process

The implementation process can be viewed from the service provider and client perspectives. When engaging a new client, OSPHL follows the procurement procedures used by the state requesting its services.

4.5.6.1 Service provider perspective

In situations where OSPHL applies for and receives funds through a request for proposal, the formal contract is routed for review through both the Oregon Health Authority's Office of Contracts and Procurement and the attorney general's office. The attorneys general of the two parties typically negotiate details of the contract language. While the contract is being routed

through these review processes, OSPHL requests a list of all sample submitters from the client to add to OSPHL's information system. OSPHL also requests the names and contact information of staff who will serve as the client's NBS coordinator and primary contact.

After a contract is in place, OSPHL works with the client's NBS coordinator to send testing kits (typically prepaid by the submitter to the client) to sample submitters and to ensure that the client's procedures align with those used by the NWRNSP (e.g., that the client will discard testing kits provided by former test suppliers). If requested, OSPHL also works with the client's coordinator to provide education, tailoring it to the client's needs and resources. OHSU medical consultants occasionally visit the client site and conduct grand rounds for specific disorders. Additionally, Oregon's education coordinator might visit individual facilities to present program information and address concerns. The education generally relates to the medical rationale for screening for a specific disorder. Travel funds are included in the contract to allow for visits by the medical consultants and education coordinator. After these preparatory steps, a start date is established and OSPHL initiates testing.

The implementation process also includes face-to-face meetings among NWRNSP members. Each spring, they meet to share information with each other and with OSPHL. Funds for this annual meeting are provided by the participating NBS programs as part of their contracts with OSPHL.

4.5.6.2 Client perspective

Both Alaska and New Mexico have state-to-state agreements with Oregon. In New Mexico, a competitive application process was initiated in 2006 and Oregon was selected; Alaska had used a similar process in earlier years. When these agreements come up for renewal, the states' procurement offices often do not require they be rebid competitively, substantially reducing the administrative burden.

Both Alaska and New Mexico conducted educational sessions on the need for NBS and the processes involved in obtaining and sending samples to Oregon. Challenges related to courier services have surfaced in both of these states. For example, because New Mexico has many rural areas, a first step in the implementation process was getting United Parcel Service (UPS) to visit each pick-up location at least once a day rather than weekly, as it had earlier. The state's NBS coordinator worked closely with UPS to identify all the pick-up locations, conducted educational efforts to make sure all sites were set up with electronic UPS labeling systems, and worked to improve communications. UPS helped facilitate this process by sending its personnel to each site to help set up the electronic system. The New Mexico NBS program trained an internal staff member as the point of contact for hospitals that had questions about UPS labels or other procedures related to the courier system. It took approximately 6 months for the system to be fully operational.

Both states communicate with OSPHL (1) about the submitters that should be sending samples and those that actually submit samples (looking for hospitals that fail to submit samples) and (2) to obtain information about the quality of the procedures (e.g., timeliness) and samples provided by the submitters. Each state NBS program bills submitters directly; OSPHL does not collect fees from the submitters.

4.5.7 Status as of February 2012

As of February 2012, OSPHL had provided a standard set of NBS testing and programmatic services to a wide variety of clients. Although a formal evaluation had not been conducted, both OSPHL's clients and OSPHL itself reported multiple benefits from this arrangement.

From the provider's perspective, an advantage of the regional approach is that it might lead to greater testing proficiency because having higher sample volume and greater population diversity likely increases the possibility that laboratory personnel will encounter rare conditions more frequently. In addition, this regional approach provides greater purchasing power with vendors. Oregon benefits because the unit cost of screening is reduced through economies of scale and a limited amount of extra revenue from the other regional states.

The arrangement of Oregon's laboratory services also might yield benefits for members of the NWRNSP and the populations they serve. Staff who perform short-term follow-up work and laboratory tests in Oregon are co-located and share the same manager. Such an arrangement can create a more collaborative, team-based approach than might otherwise occur, likely leading to service improvements. The standardization of protocols and processes across all clients served by Oregon is thought to result in greater efficiencies than would otherwise occur. However, this standardization also could exclude entities that might benefit from participation.

OSPHL's clients report that they benefit from the tests OSPHL performs and from its additional services. Both Alaska and New Mexico value the subject-matter expertise that is offered by OHSU medical specialists, as do the healthcare providers in their states. Both states noted the importance of the annual NWRNSP face-to-face meeting. This provides them time to meet with the medical specialists as well as discuss common concerns and problem-solve with colleagues from similar states. Clients also appreciate working with a state that is aware of and heavily engaged in the most recent developments in the area of NBS.

Another advantage of participation in the NWRNSP is receiving the monthly practice profiles that OSPHL provides to each client. States can use these profiles in their continuous quality-improvement efforts, for example, to see how quickly samples reach OSPHL or if errors occur in the samples provided. One of the metrics provided in the profiles involves samples that take longer than 5 days to reach OSPHL. Alaska noticed locations where this was a problem and worked with the submitters to improve their courier service. The Alaska and New Mexico NBS programs share the practice profiles with submitters. The New Mexico NBS program reported that submitters are receptive to these profiles and that it has witnessed improvements in submitters' performance levels across time. New Mexico noted that approximately 65% of the samples submitted were adequate before it contracted with OSPHL for testing services but that 90% or more of the samples are adequate after implementation of this service change.

As a region, this group is thought to have greater influence with vendors because it brings in a larger volume of business. As a result, vendors want the region to be aware of their new products, and they often welcome opportunities to discuss the laboratory's needs.

5. RESOURCES

This section presents resources you may find helpful as you assess and plan implementation of a public health laboratory service change. All of them are cited in the texts of Sections 2, 3 and 4 of this guide. They include contributions from the directors of the state public health laboratories whose service change experiences appear in the Section 4 case examples. Others come from APHL or CDC and from other recognized sources. URLs are included for online resources and were accessed as of publication of this guide.

Each public health laboratory director should feel free to adapt these resources for her or his own purposes.

5.1 Resources for Section 2: Assessing a Potential Service Change

- Resources for Section 2.2 — Communicate
  1. *CDC Unified Processes Practice Guide – Communication Management*: http://www2.cdc.gov/cdcup/library/practices_guides/CDC_UP_Communication_Management_Practices_Guide.pdf
  2. Communication plan template — refer to Section 5.1.1.
- Resources for Section 2.3 — Plan
  3. RACI matrix adapted from the Project Management Institute's Project Management Body of Knowledge — refer to Section 5.1.2.
  4. Association of Public Health Laboratories. *Laboratory System Improvement Program User's Guide*. Identifying and Recruiting Stakeholders, pages 11–13: http://www.aphl.org/aphlprograms/lss/performance/Documents/L-SIP-Users-Guide.pdf
  5. *CDC Unified Processes Practice Guide – Project Charter*: http://www2.cdc.gov/cdcup/library/practices_guides/CDC_UP_Project_Charter_Practices_Guide.pdf
  6. A brief, interactive training on developing SMART objectives from CDC's Division of Adolescent and School Health: http://www.cdc.gov/healthyyouth/tutorials/writinggoal/index.htm
  7. Laboratory System Improvement Program from APHL: http://www.aphl.org/aphlprograms/lss/performance/pages/default.aspx
- Resources for Section 2.4 — Assess
  8. Michigan's *Cost Analysis of Gen Probe testing in the Regional Laboratory System* from case example 4.3 — refer to Section 5.1.3.
  9. Northern Plains Consortium annual meeting agenda from case example 4.4 — refer to Section 5.1.4.
  10. New Hampshire Public Health Laboratories and Environmental Services Laboratory consolidation — *Effects of Consolidating the DES and PHL Laboratories* from case example 4.1 — refer to Section 5.1.5
  11. Michigan state laboratory redirection of testing for chlamydia and gonorrhea — request for proposal from case example 4.3 — refer to Section 5.1.6
  12. Napa and Solano counties' joint powers agreement — refer to Section 5.1.7

5.1.1 Communication plan template[1]

Stakeholder To Contact	Date To Start	Date Completed	Method of Communication	Owner	Topic of Message	Comments
Identify stakeholders to contact	Determine when stakeholders will be contacted	List when communication with stakeholder occurs	Determine communication method for stakeholder	Identify person responsible for contacting stakeholder	Determine message to convey to stakeholder	Additional comments on communication progress with stakeholder

[1] Adapted from a communication plan template contributed by a state public health laboratory

5.1.2 RACI matrix[1]

Type of Stakeholder	Description of Stakeholder
Responsible	This is the person or role responsible for performing the task (i.e., the actual person doing the work to complete the task).
Accountable	This is the person who is ultimately accountable for the task being done in a satisfactory manner. Essentially, the accountable person must sign off on the work that the responsible person produces. Only one person can be accountable for a task.
Consulted	Those people whose input is used to complete the task; thus, communication with this group will be two-way in nature.
Informed	Those people who are informed as to the status of the task; thus, communication with this group is one-way in nature.

[1] Adapted from Project Management Institute Project Management Body of Knowledge

5.1.3 Michigan's *Cost Analysis of Gen Probe Testing in the Regional Laboratory System* from case example 4.3

Cost Analysis of Gen Probe testing in the Regional Lab System

Background: Testing for sexually transmitted infections caused by *Chlamydia trachomatis* and *Neisseria gonnoroheae* are performed by nucleic acid amplification testing at regional laboratories located in Lansing, Houghton, Kent County, Saginaw County, Kalamazoo County, and the City of Detroit Health Department. The Family Planning and STD Programs provide support to the Regional Laboratory System to conduct this testing. The programs support the salary for one FTE at the Lansing laboratory to conduct testing, administer the program, and provide data analysis. The remaining regional laboratories in Kent, Kalamazoo, Saginaw, and Detroit receive financial support to perform testing. This support consists of $1,090 or $929 per 85 reportable results for CT/GC or CT only testing respectively. The funding includes the costs of reagents, disposables, shipping of reagents, $2.55 labor per test, and $350 per lab for proficiency testing.

The goal of this analysis is to look at the potential cost savings associated with decreasing the number of laboratories performing Gen Probe testing. The analysis will look at performing all testing at one centralized laboratory, at two laboratories, at three laboratories, at four laboratories, at five laboratories, and at five laboratories plus adding Oakland County to perform the testing from Macomb County.

Assumptions: To make the analysis simple and straight-forward several assumptions were made:

1. Analysis was performed using the actual test volumes from fiscal year 2010. All of the regional laboratories including Houghton are covered by the analysis.
2. Each laboratory performs CT only and Combo2 testing on a daily basis as described in the CPBC agreement.
3. Each regional laboratory (Lansing and Houghton excluded) is reimbursed $2.55 per non-billed test.
4. Data entry time for accessioning specimens is 1 minute/specimen. This is the time determined in a previous study using EPIC. The time for StarLims is probably longer.
5. Each laboratory performs environmental testing on a weekly basis. This consists of 6 samples per week.
6. Each laboratory runs a minimum of 5 controls per day. This includes 2 for Combo2, 2 for CT only and 1 positive external control.
7. Assume that each lab gets the maximum number of reportable tests per kit and specimen volume is equal each day. Since neither of these is true, the actual cost at each laboratory will be higher because entire kits are not used each day and on some days additional controls will be necessary when a partial kit and a new kit are needed for testing.
8. Shipping costs will remain the same regardless of the number of laboratories performing testing.
9. Reagent costs per test are $8.46 for a Combo2 and $6.89 for a CT only.
10. Testing volume for fiscal year 2010 is representative of past and future years.

11. Based on the manufacturer's model, the Tirgis can perform 350 tests in an 8 hour shift. This is equivalent to 87,500 tests annually.

Testing volume for the Regional Laboratory System for FY10

Test type	# Tests
Combo 2 non-billed	49,522
CT only non-billed	11,883
Combo 2 billed	9,314
CT only billed	4,689
Total	**75,408**

Non-billed testing performed at the Regional Labs (excluding Lansing and Houghton) in FY10

Test type	# Tests
Combo 2	31,427
CT only	8,468
Total	**39,895**

Billed testing performed at the Regional Labs (excluding Lansing and Houghton) in FY10

Test type	# Tests
Combo 2	5,971
CT only	2,778
Total	**8,749**

Cost saving associated with testing performed in Lansing only

Labor cost savings = $2.55 x 39,895	$101,732
Environmental swabs = 6/week x 50 weeks x $8.46/test x 5 labs (Houghton, Kent, Kalamazoo, Saginaw, Detroit)	$12,690
PT costs = $350 x 5 labs	$1,750
Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day Annual cost = $39.16 x 5 days/week x 50 weeks/year x 5 labs	$48,950
Total	**$165,122**

Cost saving associated with testing performed in two labs only

Lansing + 1 DTS 800

Testing volumes (2:1 ratio, Lansing:Lab A)

	Combo2 non-bill	Combo2 bill	CT only non-bill	CT only bill	Total
Lansing	33,022	6,214	7,922	3,128	**50,287**
Lab A	16,500	3,100	3,960	1,560	**25,120**

Daily testing volume

	Combo2	CT only	Total
Lansing	157	34	**191**
Lab A	79	22	**101**

Labor cost savings = $2.55 x (39,895 – 20,460)	$49,559
Environmental swabs = 6/week x 50 weeks x $8.46/test x 4 labs	$10,152
PT costs = $350 x 4 labs	$1,400
Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day	
Annual cost = $39.16 x 5 days/week x 50 weeks/year x 4 labs	$39,160
Total	**$100,271**

Cost saving associated with testing performed in three labs

Lansing + 2 DTS 800

Testing volumes (2:1:1 ratio, Lansing:Lab A:Lab B)

	Combo2 non-bill	Combo2 bill	CT only non-bill	CT only bill	Total
Lansing	24,922	4,714	5,883	2,289	**37,808**
Lab A	12,300	2,300	3,000	1,200	**18,800**
Lab B	12,300	2,300	3,000	1,200	**18,800**

Daily testing volume

	Combo2	CT only	Total
Lansing	119	33	**152**
Lab A & B	58	17	**75**

Labor cost savings = $2.55 x (39,895 – 30,600)	$23,702
Environmental swabs = 6/week x 50 weeks x $8.46/test x 3 labs	$7,614
PT costs = $350 x 3 labs	$1,050

Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day	
Annual cost = $39.16 x 5 days/week x 50 weeks/year x 3 labs	$29,370
Total	**$61,736**

Cost saving associated with testing performed in four labs

Lansing + 3 DTS 800

Testing volumes (2:1:1:1 ratio, Lansing:Lab A:Lab B:Lab C)

	Combo2 non-bill	Combo2 bill	CT only non-bill	CT only bill	Total
Lansing	19,822	3,734	4,758	1,899	**30,213**
Lab A	9,900	1,860	2,375	930	**15,065**
Lab B	9,900	1,860	2,375	930	**15,065**
Lab C	9,900	1,860	2,375	930	**15,065**

Daily testing volume

	Combo2	CT only	Total
Lansing	94	27	**121**
Lab A & B & C	47	13	**60**

Labor cost savings = $2.55 x (39,895 – 36,825)	$7,828
Environmental swabs = 6/week x 50 weeks x $8.46/test x 2 labs	$5,076
PT costs = $350 x 2 labs	$700
Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day	
Annual cost = $39.16 x 5 days/week x 50 weeks/year x 2 labs	$19,580
Total	**$33,184**

Cost saving associated with testing performed in five labs

Lansing + 4 DTS 800

Testing volumes (2:1:1:1:1 ratio, Lansing:Lab A:Lab B:Lab C:Lab D)

	Combo2 non-bill	Combo2 bill	CT only non-bill	CT only bill	Total
Lansing	16,522	3,114	3,963	1,569	**25,168**
Lab A	8,250	1,550	1,980	780	**12,560**
Lab B	8,250	1,550	1,980	780	**12,560**
Lab C	8,250	1,550	1,980	780	**12,560**
Lab D	8,250	1,550	1,980	780	**12,560**

Daily testing volume

	Combo2	CT only	Total
Lansing	79	22	**101**
Lab A & B & C & D	39	11	**50**

Labor cost savings = $2.55 x (39,895 – 1,025)	$2,613
Environmental swabs = 6/week x 50 weeks x $8.46/test x 1 labs	$2,538
PT costs = $350 x 1 labs	$350
Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day	
Annual cost = $39.16 x 5 days/week x 50 weeks/year x 1 labs	$9,790
Total	**$15,291**

Cost saving associated with testing performed in five labs plus Oakland County

Lansing + 5 DTS 800

Testing volumes (2:1:1:1:1 ratio, Lansing:Lab A:Lab B:Lab C:Lab D, Macomb County testing to Oakland County)

	Combo2 non-bill	Combo2 bill	CT only non-bill	CT only bill	Total
Lansing	14,662	3,061	3,363	1,156	**22,242**
Lab A	8,250	1,550	1,980	780	**12,560**
Lab B	8,250	1,550	1,980	780	**12,560**
Lab C	8,250	1,550	1,980	780	**12,560**
Lab D	8,250	1,550	1,980	780	**12,560**
Oakland	1,860	53	600	413	**2,926**

Daily testing volume

	Combo2	CT only	Total
Lansing	71	18	**89**
Lab A & B & C & D	39	11	**50**
Oakland[1]	75	24	**99**

Based on Oakland County's reported testing volume for 2010 (16,898) + Macomb County

Labor cost savings = $2.55 x (39,895 – 43,380)	($8,886)
PT costs = $350 x 1 additional lab – Houghton lab	$0
Controls = 3 Combo2 @ $8.46 + 2 CT only @ 6.89 = $39.16/day	
Annual cost = $39.16 x 5 days/week x 50 weeks/year x 0 labs	
Replaces Houghton with Oakland County	$0
Total	**($8,886)**

Implications for Lansing

Cost increases for Lansing (non-billed testing only)	
DASH accessioning = 39,895 specimens x 1 minute/specimen =	
684.25 hours @ $30/hour =	$19,447
Opening samples (estimate 300 hr) @ $30/hr =	$9,000
Total	**($27,447)**
Cost increases for Lansing (billed testing only)	
DASH accessioning = 8,749 specimens x 1 minute/specimen =	
146.8 hours @ $30/hour =	$4,404
Opening samples (estimate 66 hr) @ $30/hr =	$1,980
Total	**($6,384)**

Increased revenue[1]

5,971 Combo2 tests @ $36/test =	$214,956
2,778 CT only tests @ $32/test =	$88,896
Reagent cost for 8,749 tests =	($87,490)
Additional controls (4 Combo2 and 4 CT only/day)	
(4 @ $8.46 + 4 @ $6.89) x 5 days/week x 50 weeks/year	($15,350)
Total	**$201,012**

1 Assumes cost recovery for all testing

5.1.4 Northern Plains Consortium annual meeting agenda from case example 4.4

Northern Plains Consortium
Montana, North Dakota, South Dakota, Wyoming
Regional Roundtable
March 1, 2012
Crowne Plaza Hotel - Billings, Montana

Proposed Agenda

8:00 – 8:30	• Breakfast (provided), Meet and Greet
8:30 – 9:30	• Welcome • Review of Competence Assessment workshop held on Feb 29 • Review of 2011 NPC goals and achievements • Review of Deloitte draft summary of Consortium model
9:30 – 10:30	LEI and Current Status of Northern Plains Consortium Shared Services • Testing Services • Antimicrobial Resistance Initiatives, including HAI • TB NAAT Initiative
10:30 – 10:45	Break (provided)
10:45 – 12:00	Other Possible Shared Services • Procurement of supplies and instrumentation-APHL meeting • Equipment maintenance contracts-South Dakota • Healthpac and Contracted Billing Services-South Dakota
12:00 – 1:00	Lunch (provided)
1:00 – 1:30	Epidemiology and Laboratory Capacity Awards • Program Component Cooperative Agreement • ACA Cooperative Agreement
1:30 – 2:30	Electronic Laboratory Reporting • South Dakota new LIS for both EL and Microbiology Labs • Nebraska Hub for connectivity with clinical laboratories • Working with states' designated HIE organizations • North Dakota bidirectional exchange with prison • PHLIP
2:30	Break (provided)
2:30 – 3:00	Miscellaneous Topics • Preparedness Initiatives • Workforce Development Initiatives • Certification of Chemists for clinical testing
3:00-3:30	Establish Goals for 2012-13 • Outline major objectives and timelines • Funding?
3:30 – 3:45	Wrap Up and Next Steps

5.1.5 New Hampshire Public Health Laboratories and Environmental Services Laboratory consolidation — *Effects of Consolidating the DES and PHL Laboratories* from case example 4.1

Effects of Consolidating the DES and PHL Laboratories

Costs Incurred by DPHS

1. DPHS will incur a budget increase of approximately $2.4 million each year though this is offset by revenues of approximately $357,000.
2. DPHS will incur increased staffing and program responsibility.
3. PHL has little expertise in environmental testing and will rely on DES scientists to be the experts on the science and regulations.

Cost Avoidances

1. Salary and benefits for one DES position.
2. Salary and benefits for two PHL positions.
3. Small reduction of salary and benefits from possible reclassification of one Admin position.
4. Small reduction in rent to DAS after combining sample receipt areas (593 sq. ft.)
5. Possibility of a reduction in cost of rent to DAS by renting out some office space to other programs (requires security clearance).
6. Minimal reduction in costs to DOIT as result of a fewer number of PCs
7. Small reduction of costs DPHS currently pays annually to DES for water testing and DES pays to DPHS for radiological licensing
8. Small reduction in costs by economies of scale for supply inventory management, media preparation, sample kit preparation and safety supplies
9. Eliminate costs of duplicated staff efforts between laboratories in areas such as:
    a. Preparing required training sessions and essential committee work (safety, quality improvement, ethics, hazardous waste)
    b. Coordinated infectious waste and hazardous waste removal
    c. Coordinated facilities management
    d. Preparation of documents such as some Standard Operating Procedures (SOPs), Emergency Response Plans, COOP Plans, MOUs
10. Small reduction in costs for performing invoicing and other financial functions as result of LIMS and combined staff responsibilities
11. Shared cost of LIMS administrator

New Program Initiatives

1. Strengthen PHL chemistry section especially including expansion of radiochemistry laboratory.
2. Expand radiological testing capabilities to meet Safe Drinking Water Act requirements, respond to nuclear power plant emergencies and prepare for possible all-hazard events.
3. Provide new testing offerings related to public health not currently available in NH including at private labs:
    a. Giardia in drinking water
    b. Cryptosporidium in drinking water
    c. Cyanobacteria in drinking water
    d. Paralytic Shellfish Toxins testing
    e. Pharaceuticals and Personal Care Products testing

4. Coordinate Laboratory Information Management System (LIMS) administration and expand the capability to use data to perform studies on and make assessments about environmental and health issues.
5. Allow the expansion of DES testing for those procedures requiring the use of BLS-3 facilities and molecular testing of water pathogens
6. Improve customer service by expanding hours of sample receipt
7. Enhance opportunities for future federal funding of Biomonitoring and/or FERN Radiological Grants

Strategies

1. Coordinate testing efforts in other areas to make efficient use of instrumentation and staffing and offer expanded testing capability not currently available in NH.
2. Eliminate duplication of fecal coliform bacteria testing in water for shellfish program by combining State shellfish testing into one State Agency.
3. Duplication of some critical equipment from both DES and PHL to act as backups and reduce/eliminate down time in case of equipment failure or for surge capacity.
4. Cross training of staff to provide expertise and staffing for emergency responses and decrease the impact on labs as the result of seasonal fluctuations in workloads.
5. A consolidated lab structure would ease communications with emergency responders and improve incident management.
6. New structure would be in line with other state public health laboratories. Having both laboratory functions in one lab is the current structure in Connecticut, Maine and Rhode Island.

Maintain Current Efficiencies

1. Multi agency, multiyear contracts currently in effect for:
    a. Instrument and equipment maintenance agreements
    b. Chemical procurement
    c. Laboratory supplies and small equipment procurement
    d. Gas procurement
    e. Hazardous waste removal
2. Both DES and PHL use the same LIMS and share one server

5.1.6 Michigan state laboratory redirection of testing for chlamydia and gonorrhea — request for proposal from case example 4.3

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
Bureau of Laboratories

Request for Proposal (RFP)

Required Letter of Intent Due:

Friday, May 13, 2011

Full Proposal Due:

June 17, 2011

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

Request for Proposal

PART I: GENERAL GUIDELINES AND INFORMATION

A. INTRODUCTION/BACKGROUND

Chlamydia (CT) and gonorrhea (GC) are the most reported communicable diseases in Michigan. Historically, the Michigan Regional Laboratory System (RLS) has provided testing for these agents at up to six state, county, and city labs. Each laboratory provided testing on both a fee-for-service and a pre-paid voucher system. Annual testing volumes consist of 60,000 to 70,000 pre-paid tests and an additional 15,000 to 30,000 fee-for-service tests. Funds for the pre-paid voucher system were distributed through the Comprehensive Grant Agreement and consisted of state and federal funds provided through the Family Planning, STD, and Adolescent Health Programs at the Michigan Department of Community Health (MDCH). Each laboratory was repsonsible for billing functions associated with fee-for-service testing.

A cost analysis of the nucleic acid amplification testing (NAAT) currently performed by the RLS showed potential cost saving of $165,000 if all the testing was centralized to a single laboratory and savings of approximately $100,000 if testing were conducted at only two laboratories. Most of the projected savings is associated with decreased quality control costs for larger test batches, decreased proficiency testing costs, decreased disposable costs, and increased automation.

Beginning in FY 2012, NAAT testing will be performed at two laboratories within the current RLS. Cost savings, along with turnaround time for testing and continuity of operations were the basis for this decision. Under this Request for Proposal, applicants are invited to apply for funding to perform 20,000 to 25,000 pre-paid tests and 5,000 to 10,000 fee-for-service tests. The exact test volumes will be determined based on the location of the laboratory selected and the availability of funding.

B. AVAILABLE FUNDS

MDCH intends to provide financial support activities by way of the Comprehensive Grant Agreement with the local public health agency selected. The laboratory selected will be paid based on their quality assurance plan and proposed cost per reportable result. The initial award will be based on estimated test volumes for agencies assigned to submit specimens to the contracted lab. Adjustments to the award will be made quarterly based on actual test volume. A total of one award is expected to be made in response to this RFP. MDCH reserves the right to not make an award as a result of this RFP process if it is deemed in the best interest of the Infertility Prevention Project and the Department.

Funding awarded under this RFP will be planned for a 12 month (one year) period, based on availability of funding. Successful applicants will be issued a one year award for the period

October 1, 2011 - September 30, 2012. The award will be extended annually for up to three additional years based on successful implementation of program objectives and continued availability of funds.

C. APPLICANT ELIGIBILITY

It is the intent of MDCH to fund an existing Regional Laboratory with proven experience providing nucleic acid amplified testing (NAAT) for the STD, Family Planning, and Adolescent Health programs. Only Regional Laboratories currently providing GC and CT testing services are eligible to apply.

Eligible applicants include:

- Detroit Department of Health and Wellness
- Kalamazoo County Health and Community Services
- Kent County Health Department
- Saginaw County Health Department

D. SCOPE OF WORK

The successful bidder will provide CT/GC testing using a NAAT specified by MDCH. The bidder will purchase all reagents and obtain necessary equipment based on contract pricing available through the State of Michigan. The applicant must demonstrate an ability to perform high quality, cost-efficient testing within the specified timeframe as well as maintain appropriate records associated with quality control, equipment maintenance and quality assurance. The successful bidder will follow testing procedures provided by MDCH.

Applicants will perform fee-for-service testing for providers that submit specimens billed to Medicaid, Plan First, or to the submitter. The successful bidder will be responsible for packaging and shipping collections kits for all billed and non-billed tests for all submitters assigned to their laboratory.

D.1 PERFORMANCE STANDARDS

All applicants awarded funding by MDCH for CT/GC testing must:

1. Perform testing use the Gen Probe APTIMA Tigris system.
2. Maintain CLIA certification.
3. Subscribe to and successfully participate in proficiency testing for CT/GC.
4. Enter all specimens and report results in StarLIMS. Data entry should include all fields associated with race, ethnicity, date of collection, gender, specimen type, provider type, reason for test and all other fields required for regulatory compliance.

5. Initiate testing on the day the specimen is received by the laboratory and no later than one calendar day after the specimen is received.

6. Perform testing Monday – Friday, except for State Of Michigan holidays.

7. Participate in quarterly Michigan Infertility Prevention Program Alliance (MIPP) meetings held in Lansing.

8. Provide a quarterly report that include test volumes, turn around times, and a summary of any quality assurance issues encountered and action taken to resolve them. Average turn around times shall not exceed 4 days, including weekends.

9. Work with MDCH staff to resolve data integrity issues that are found when quarterly IPP reports are prepared for the Centers for Disease Control and Prevention (CDC).

10. Maintain an adequate inventory of reagents and disposables to insure no interruptions in testing.

11. Establish reimbursement agreements with relevant Medicaid Managed Care Provider Networks to secure third party reimbursement for billed tests submitted for eligible Medicaid patients.

12. The laboratory will test appropriately collected specimens from Medicaid Provider Networks even in the absence of a reimbursement agreement with that provider. The STD, Family Planning, or Adolescent Health Programs will reimburse the testing laboratory the comprehensive agreement cost per reportable test for rejected charges as funding permits.

13. Follow a quality system plan equivalent to the Department's plan including but not limited to quality control intervals, occurrence management, personnel assessment (education, training, and competency),

PART II: APPLICATION PROCESS

A. NOTICE OF INTENT TO APPLY

It is ***required*** that applicants submit an *Intent to Apply* form (*Appendix A*) by 5:00 p.m. Eastern Standard Time (EST) on **Friday, May 13, 2011.** Submission of an "Intent to Apply" form is non-binding but will be used by MDCH to adequately prepare for the review of submitted proposals. Applicants who do not submit this form or miss the deadline set above, **ARE NOT** eligible to submit a complete application. Forms may be submitted via fax or email.

Submit to: James Rudrik, Ph.D.
Michigan Department of Community Health
Bureau of Laboratories
3350 N. ML King Jr Blvd

Lansing, MI 48906

(517) 335-9631 (fax) or rudrikj@michigan.gov

Receipt of *Intent to Apply* forms will be confirmed via email within two business days of receipt. If confirmation is not received in this time period, contact Dr. Rudrik at (517) 335-9641 immediately.

B. QUESTIONS REGARDING THE RFP

All questions about this RFP **MUST** be submitted in writing. **Questions will be accepted via fax (517) 335-9631, or email rudrikj@michigan.gov.** Final questions and requests for clarifications must be received by 3:00 pm, Thursday, May 26, 2011. Questions will be responded to within three business days of receipt. Additionally, MDCH will collate all questions and answers and an Frequently Asked Questions (FAQ) Document will be posted to the MDCH web site (http://www.michigan.gov/mdch-request for proposals link). Questions that have not been submitted in writing will not be answered.

C. SUBMISSION/ REVIEW REQUIREMENTS AND TIMELINE

1. Submission

Proposal packages must be RECEIVED by **3:00 p.m. Eastern Standard Time, on Tuesday, June 17, 2011. LATE APPLICATIONS WILL NOT BE ACCEPTED OR REVIEWED.** Faxed, or e-mailed proposals WILL NOT be accepted.

Applicants are required to submit the signed original and four (4) copies of the proposal package. Submit proposals to:

James T. Rudrik, Ph.D.
Microbiology Section Manager
Michigan Department of Community Health Bureau of Laboratories
3350 N. ML King Jr Blvd
Lansing, MI 48906

Phone – if required for express delivery – (517) 335-9641

2. Rejection of Proposals

MDCH reserves the right to reject any and all proposals received as a result of this RFP. All timely proposals will undergo a technical review to determine compliance with the minimum requirements outlined in the Checklist for a Complete Proposal (Appendix E). Incomplete proposals may not be reviewed and notification will be provided.

3. Review of Proposals

Proposals submitted in response to this RFP will be reviewed and evaluated by a panel of individuals who have expertise/experience in relevant areas. All proposals will be scored by reviewers according to pre-established criteria. Scoring criteria will be responsive to the requirements of this RFP. The relative weight that each component of the proposal will receive in the review process is described in the narrative specifications.

4. Notice of Award

Notices of Award are expected to be made by July 8, 2011.

5. Incurring Costs

All awards are contingent on the availability of funds and approval by the State Administrative Board. MDCH is not liable for any costs incurred by applicants prior to issuance of a contract signed by all required parties.

III. FORMAT REQUIREMENTS

A. CONTENT OF PROPOSAL PACKAGE

A complete proposal package will consist of:

1. Proposal Cover Sheet *(Appendix B)*, signed by authorized agency representative(s)
2. Narrative Proposal
3. Budget Rationale

Applicants are encouraged to refer to the Proposal Checklist (*Appendix C*) in preparing their proposal package, and order the document according to this guideline.

B. FORMATTING/PACKAGING

1. Sequentially number all pages, including attachments and appendices
2. Include a table of contents for the entire package submitted
3. Do not staple or bind any of the copies submitted to MDCH. (Rubber bands or binder clips are acceptable)
4. Use 8 ½" by 11" paper
5. 12 point font; budgets, figures, charts, tables, figure legends, and footnotes may be smaller in size, but must be readily legible.
6. Use 1" margins (top and bottom, left and right)
7. Write on single side of page only
8. The narrative section is not to exceed 10 pages (Sections 1-6)
9. The structure and lay out of the proposal must follow the format outlined in this RFP.

Part V: PROPOSAL OUTLINE

The proposal should provide the following information using these headings and subheadings.

A. PROPOSAL COVER SHEET

Complete the Proposal Cover Sheet (*Appendix B*)

B. TABLE OF CONTENTS

Attachments must be paginated and listed in the Table of Contents.

C. PROPOSAL NARRATIVE (75 POINTS TOTAL)

The following outline must be adhered to for development of the proposal narrative.

1. Organizational Capacity (10 points)

Provide an organizational chart (as **Attachment A**) that clearly shows individuals responsible for management oversight (including laboratory manager and CLIA laboratory director), billing, data entry, and testing for this project. Include contact information (telephone and e-mail) for each individual. In the narrative, outline key staff, their credentials, experience relevant to this RFP, and reporting lines. Identify any new positions that will be necessary to complete the work outlined in this contract or vacant positions that will be filled. Describe your facility's staffing plan to expand testing from its current volume to approximately 30,000 annually. Include a description of the quality system and safety programs for the laboratory.

2. Equipment (10 points)

MDCH will arrange to have a Gen Probe APTIMA Tigris instrument available for the successful applicant. This instrument performs automated specimen testing with a minimum of hands-on time required by laboratory. This instrument is quite large (68"W x 72"H x 36"D plus Gen Probe requires a minimum of 36" service space on all sides of the instrument), weighs approximately 1,500 pounds and requires a 220V outlet for operation. It is anticipated that the equipment could be ready for installation as soon as the award is made. Please provide the following information:

- Provide a floor plan (as **Attachment B**) showing your proposed location for the instrument. MDCH is not responsible for any construction or renovation costs associated with the installation of this instrument.
- Within the narrative, provide a proposed timeline for installation, training, and verification studies on the new instrument. Since exact information about instrument availability from Gen Probe is not available, the timeline can use a scale of weeks rather than specific dates.

- Provide a detailed plan on how your laboratory will continue to test specimens using the current DTS 800 system until the new instrument is ready for use.

3. Training (5 points)

- Gen Probe provides Tigris training for two individuals in San Diego, CA at no charge. The training and travel time require a one week commitment from each individual. Please identify the two individuals who will be sent for training, and express a commitment to their participation. Explain how testing will be performed while these individuals attend training.

4. Reagent Storage (5 points)

- In order to contain shipping costs, reagents and other disposables are usually ordered on a quarterly basis. Describe your facility's ability to provide storage for this volume of materials. This includes both refrigerated and room temperature storage. Please indicate storage locations of the floor plan required for item #2.

5. Past Performance (15 points)

- Provide a copy of proficiency testing results for the last two calendar years (as **Attachment C**).
- The CPBC contract requires that laboratories perform testing every business day the facility is opened. Test results guide treatment decisions and program performance is judged based on the number of individuals treated within 14 and/or 30 days of specimen collection. To demonstrate your facilities testing turn around time, please provide turn around time reports for specimens received during the following time periods: April 5 – 9, 2010; July 5 – 9, 2010; November 8 – 12, 2010; and December 27 – 31, 2010. Turn around time is defined as the number of days from and including the date received to the date the result is validated (EPIC) or released by panel (StarLIMS). The report should include number of specimens tested. For simplicity, weekend days ARE included in the calculation.
- Discuss any changes your facility can/will make to enhance turn around time.

6. Continuity of Operations (5 points)

- Describe your plan to continue to provide testing if a natural or intentional event makes your facility unusable for any time period greater than 24 hours.
- Describe you plan to continue testing if the Tigris requires repairs that take longer than 48 h.
- The successful applicant will be expected to back-up the Lansing laboratory in the event of instrument or facility failure. Describe what steps your facility would take to manage this increased volume if such an event occurs.

7. Budget Preparation (25 points)

Provide a copy of your budget proposal as **Attachment D.**

Payment for testing will be based on a cost per reportable result. Please submit a budget that provides a final cost per reportable result. Provide a detailed narrative that justifies and fully describes each item for the figure you provide. Items that may be taken into consideration include, but are not limited to: reagent costs (see Appendix D for current contract pricing), disposables (pipette tips), consumables (paper, paper towels, bleach), labor (data entry, testing, inventory), administrative time (result checking, turn around time reports, QA/QC review and reports, attending MIPP meetings), waste disposal, record storage, specimen tracking, overhead expenses. MDCH will not cover construction or remodeling expenses. The cost per test figure should cover the initial budget period from October 1, 2011 to September 30, 2012.

APPENDIX A

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

INTENT TO APPLY FORM

Applicant Agency

Address

City State Zip Code

Phone Fax

Contact Person Title

Email

Signature of Authorized Representative Date

Please Print Name and Title

Please fax or email to:

James Rudrik, Ph.D.

(517) 335-9631 (fax)

rudrikj@michigan.gov

APPENDIX B

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

PROPOSAL COVER SHEET

Legal name of organization applying: _____

Authorized Agent: _____ Phone: _____

Contact Person for this application: _____ Phone: _____

Address: _____ Fax: _____

City/State/Zip: _____

E-Mail Address: _____ Website: _____

1. Cost per reportable result: _____

_____ _____

Signature, Authorized Representative Date

_____

Typed Name and Title

APPENDIX C

Proposal Checklist

- ❑ Cover Sheet
- ❑ Proposal Checklist (this form with each item checked off as completed)
- ❑ Table of Contents
- ❑ Proposal Narrative
- ❑ Budget Narrative
- ❑ Required Attachments
  - ❑ A. Organizational Chart
  - ❑ B. Floor plan
  - ❑ C. Copy of proficiency testing results for calendar years 2009 & 2010
  - ❑ D. Budget proposal

Have you followed the required format?

- ❑ ALL pages are sequentially numbered, including attachments
- ❑ Narrative (Sections 1-6) does not exceed 10 pages
- ❑ 12 point font is used throughout (budgets, figures, charts, tables, legends and footnotes may be smaller in size, but must be readily legible)
- ❑ 8½" x 11" paper is used
- ❑ Margins are 1" on all sides
- ❑ The proposal is written on one side of the page only
- ❑ The proposal is not bound or stapled

- ❑ Have you prepared the **original and fours copies** for submission?

5.1.7 Napa and Solano counties' joint powers agreement

Napa/Solano County Joint Powers Agreement

NAPA COUNTY AGREEMENT NO. 4092
SOLANO COUNTY AGREEMENT NO. 064092

JOINT EXERCISE OF POWERS AGREEMENT
(NAPA-SOLANO COUNTY PUBLIC HEALTH LABORATORY)

THIS AGREEMENT is made and entered into as of this 1st day of July, 2010 by and between the COUNTY OF NAPA, a political subdivision of the State of California, hereinafter referred to as "Napa County", and the COUNTY OF SOLANO, a political subdivision of the State of California, hereinafter referred to as "Solano County."

RECITALS

WHEREAS, on or about July 1, 2000, by that joint powers agreement known as Napa County Agreement No. 4092/Solano County Agreement No. 064092, subsequently amended on four occasions, Napa and Solano created a joint public health lab known as the Napa-Solano Public Health Laboratory; and

WHEREAS, the joint powers agreement will be expiring on June 30, 2010; and

WHEREAS, Napa and Solano wish to continue to operate the joint public health lab pursuant to a new joint powers agreement, on the terms and conditions set forth below:

TERMS

NOW, THEREFORE, IT IS HEREBY AGREED by Solano County and Napa County as follows:

1. DESIGNATION AND FUNCTION OF JOINT LABORATORY.

A. Name. During the term of this Agreement, Solano County and Napa County shall continue to operate the joint public health testing laboratory created on July 1, 2000, which shall continue to be known as the Napa-Solano County Public Health Laboratory.

B. Address. Testing shall occur at the Napa-Solano County Public Health Laboratory site (the existing Solano County Public Health Laboratory site) located at 2201 Courage Drive, Fairfield, California 94533 or at such other location as mutually agreed to by the parties in writing.

C. Submission and delivery of specimens, Napa County specimens submitted for testing shall continue to be received at Napa County Public Health, a division of the Napa County Health and Human Services Agency, at 2344 Old Sonoma Rd., Bldg. G, Napa, California 94559. Solano County specimens submitted for testing shall be received at the Napa-Solano County Public Health Laboratory and/or at any existing or future intake locations designated by the Director of the NapaSolano County Public Health Laboratory. Solano County shall be responsible for

providing courier services to pick up and deliver to the Napa-Solano County Public Health Laboratory all Napa County specimens submitted to the Napa County Public Health Department as well as any Solano County specimens submitted at designated intake locations in Solano County other than the Napa-Solano County Public Health Laboratory.

2. OVERSIGHT OF NAPA COUNTY HIV/AIDS PROGRAMS. In accordance with the funding Napa receives from the California Department of Public Health, Office of AIDS, both counties agree, for their mutual benefit, that Solano County will provide oversight of the following Napa County AIDS programs:

A. Ryan White CARE Act Title II ("HIV Care"): Napa currently contracts with the Queen of the Valley Medical Center for case management services for this program. Solano County shall provide subcontractor oversight, conduct site visits, prepare biannual reports and the renewal application for funding for submission to the State Office of AIDS, and interface with the state consultant regarding the program.

B. Housing Opportunities for People with AIDS (HOPWA): Napa currently contracts with Queen of the Valley Medical Center for implementation of this program. Solano shall provide subcontractor oversight, conduct site visits, prepared biannual reports, and the renewal application for funding for submission to the State Office of AIDS, and interface with the state consultant regarding the program.

3. TERM OF AGREEMENT. The term of this Agreement shall be 36 months, beginning on July 1, 2010 and ending on June 30, 2013 except that either party may terminate this Agreement at any time for the convenience of that party upon giving the other party no less than six (6) months prior written notice**.**

4. PERIODIC REVIEWS.

A. Monthly statistical reports. During the term of this Agreement, the Napa-Solano County Public Health Laboratory shall prepare monthly statistical reports of the services provided (by county) in relation to specimens originating in Solano County and Napa County.

B. Annual performance evaluations. Evaluation of the performance of the services provided and other obligations required of the parties under this Agreement shall be conducted annually, during the Agreement. The annual evaluations shall include, but not be limited to, evaluation of the following: quality of performance, turnaround time and reporting of tests; timely submission of test and patient information to and from each county; billing procedures and collections results; and satisfaction level of the respective Health Officers of Solano and Napa counties with the services provided by the Napa-Solano County Public Health Laboratory.

C. Annual Fiscal review. Fiscal review of this Agreement shall be performed annually. Such review shall include review and recommendations for update of the third-party testing fee schedules adopted by the governing boards of each party to this Agreement.

D. Renewal review. All aspects of the Agreement shall be reviewed for purposes of negotiating renewal beginning during the 18th month of the Agreement, with the

results included in the performance evaluation completed during the 24th month.

5. FISCAL ASPECTS. As consideration for the benefits conferred on each party by this Agreement, the parties agree to share responsibility for the costs of operation of and to allocate any revenues collected by the Napa-Solano County Public Health Laboratory, as follows:

A. Compensation. Napa County shall provide Solano County $115,360 annually to support the general operational costs of the Napa-Solano Public Health Laboratory and $11,545 in salary support for Solano County personnel providing program oversight of Napa County AIDS programs. In years 2 and 3 the annual compensation to support the general operational costs of the Napa-Solano Public Health Laboratory will increase by an amount equal to the Consumer Price Index (CPI).

B. Cost of facilities, equipment supplies and support services. Solano County shall be solely responsible for all costs of providing and maintaining the facilities (including utility costs), equipment, supplies, and support services (including specimen courier services) necessary to operate the Napa-Solano County Public Health Laboratory for the benefit of both counties in a manner which does not reduce in scope, timeliness, or quality the public health testing services separately provided by each county prior to the original creation of the Napa-Solano County Public Health Laboratory. Napa County agrees to enter into discussions with Solano County if, at any time during the term of this Agreement, it becomes necessary to re-evaluate the facilities used by the Napa-Solano County Public Health Laboratory.

C. Billing for tests requested by Health Officers of Solano and Napa Counties. Solano County shall be responsible for the costs of all testing by the Napa-Solano County Public Health Laboratory when such tests are requested by either the Solano County Health Officer or the Napa County Health Officer.

D. Billing for tests requested by third parties, fee schedules. Solano County shall be responsible for billing third parties (public or private) for the costs of conducting at the Napa-Solano County Public Health Laboratory any tests requested by such third parties. Solano County and Napa County shall each be responsible for ascertaining and forwarding to the Napa-Solano County Public Health Laboratory at the time of specimen submission all information necessary to bill such third parties and for providing any necessary follow-up information upon request by the Napa-Solano County Public Health Laboratory. The amounts billed to such third parties shall be determined in accordance with fee schedules adopted by resolution of the governing board of Napa County (for specimens originating in Napa County) and Solano County (for specimens originating outside Napa County) which shall be updated periodically to reflect the operational costs of the facility as a whole as well as any specific expenses unique to the particular test billed. All amounts received from such third party billing shall be deposited in the treasury of Solano County for the support of the operations of the Napa-Solano County Public Health Laboratory.

6. TESTING PROCEDURES. Testing shall be performed in accordance with methods

approved by the following agencies:

A. State of California, Department of Health Services, Laboratory Field Services, State of California approved Public Health Laboratory #1349

B. Department of Health and Human Services, Health Care Financing Administration, Clinical Laboratory Improvement Amendments (CLIA)/CLIA ID#: 05D0601 176

C. State of California, Department of Health Services, Environmental Laboratory Certification (ELAP), Certificate #2396.

7. LIABILITY.

A. Hold harmless/Indemnification by Solano County. Solano County shall hold harmless and indemnify Napa County for any liability arising from the acts or omissions of the Director, and subordinate personnel of the Napa-Solano County Public Health Laboratory, any employee of Solano County involved with preparation or handling of specimens of Solano County origin at the intake location, or any courier employed or retained by Solano County to transport specimens from either county to the Napa-Solano County Public Health Laboratory, or from any defects in the facilities, equipment and supplies provided by Solano County under this Agreement. It is expressly acknowledged by the parties that any property transferred by Napa County to Solano County pursuant to this Agreement for use in the Napa-Solano County Public Health Laboratory is conveyed "as is", and Solano County shall be solely responsible and defend, indemnify, and hold harmless Napa County for any liability arising subsequent to the conveyance from defects in or use of such property. In support of this obligation of Solano County, Napa County hereby transfers to Solano County any warranties or guarantees acquired by Napa County in connection with such transferred property.

B. Responsibility for test result follow-up activity. Nothing in this Agreement shall be construed to require the Health Officers of Solano County or Napa County to provide follow-up services relating to information regarding communicable diseases and public health conditions reported to such Health Officers by the Napa-Solano County Public Health Laboratory except for information relating to specimens originating in each Health Officer's employing county.

8. PROCEDURES MANUAL. The Director shall maintain, in accordance with standards agreed to by the Health Officers of Napa County and Solano County, a written Procedures Manual to govern the operations of the Napa-Solano County Public Health Laboratory. The Procedures Manual shall prescribe the laboratory testing methodologies and schedules, test turnaround times, reporting procedures, courier schedules, requirements for designated off-site specimen intake locations, requisition forms, billing instructions, contact phone numbers, and the most current testing fee schedules adopted by the governing boards of Napa and Solano counties.

9. ACCESS TO AND RETENTION OF RECORDS. Solano County and Napa County or the duly authorized representatives of either, including their respective Health

Officers, shall have access to the records of the Napa-Solano County Public Health Laboratory for the purpose of audit and review. In exercising such access rights, the parties shall comply with all applicable laws and regulations pertaining to confidentiality of specific health records and individual privacy rights, including the Health Insurance Portability and Accountability Act ("HIPAA"). Except where longer retention is required by any federal or state law, the Napa-Solano County Public Health Laboratory shall maintain all required records for no less than seven (7) years after the date of creation of the records.

10. INSURANCE. Solano County and Napa County shall each obtain and maintain in full force and effect throughout the term of this Agreement, and thereafter as to matters occurring during the term of this Agreement, the following insurance coverage or equivalent self-insurance, satisfactory evidence of which shall be provided to each party upon request by the other party:

A. Workers' Compensation Insurance. To the extent required by law, workers' compensation insurance covering the respective performance of the obligations of each party and its employees under this Agreement, including but not limited to, workers' compensation and disability.

B. Liability Insurance.

1. General Liability. Commercial or comprehensive general liability insurance (or self-insurance) coverage (bodily injury and property damage) of not less than One Million Dollars ($1,000,000) combined single limit per occurrence, covering liability for any personal injury, including death, to any person and/or damage to the property of any person for which that party is obligated to defend, indemnify and hold the other party harmless under Paragraph 7 of this Agreement.
2. Professional Liability. Professional liability insurance (or self–insurance) coverage for all activities of each party's employees who are providing services under this Agreement as licensed professionals, in an amount not less than One Million Dollars ($1,000,000) combined single limit per claim.
3. Comprehensive Automobile Liability Insurance. Comprehensive automobile liability insurance (or self-insurance) coverage (Bodily Injury and Property Damage) on owned, hired, leased and non-owned vehicles used by the party's employees in conjunction with the performance of that party's obligations under this Agreement, in an amount not less than Three Hundred Thousand Dollars ($300,000) combined single limit per occurrence.

C. Certificates of insurance. Where the foregoing obligations are satisfied with insurance rather than self-insurance the insured party shall obtain, maintain in its files, and provide to the other party upon request, certificate(s) of insurance which shall name the other party, its officers, employees, and agents as additional insureds; provide that the other party shall be given no less than thirty (30) days prior written notice of any non-renewal, cancellation, other termination, or material change; provide that the insurance provided is primary coverage to the other party with respect to any insurance or self-insurance programs maintained

by the other party, and provide that the inclusion of more than one insured shall not operate to impair the rights of one insured against another insured the coverage afforded applying as though separate policies had been issued to each insured, but the inclusion of more than one insured shall not operate to increase the limits of the company's liability.

D. Deductibles/Retentions. Upon request by either party, any deductibles or selfinsured retentions applicable to the coverage obtained by the other party shall be declared to, and approved by the requesting party and, upon request by that party, shall be reduced, eliminated, or other security provided for the amounts involved, including amounts relating to the costs of investigations, claims administration, and defense expenses.

11. NO WAIVER. Waiver by either party of any breach or violation of any requirement of this Agreement shall not be deemed to be a waiver of any such breach in the future, or of the breach of any other requirement of this Agreement.

12. NOTICES. Except where otherwise specified in this Agreement, all notices to either party required or authorized by this Agreement shall be in writing and shall be delivered in person or by deposit in the United States mail, by certified mail, postage prepaid, return receipt requested. Any mailed notice, demand, request, consent, approval or communication that either party desires to give the other party shall be addressed to the other party at the address set forth below. Either party may change its address by notifying the other party of the change of address. Any notice sent by mail in the manner prescribed by this paragraph shall be deemed to have been received on the date noted on the return receipt or five days following the date of deposit, whichever is earlier.

SOLANO COUNTY NAPA COUNTY
Solano County Napa County
Health & Social Services Department Health & Human Services
275 Beck Avenue, MS 5-240 2261 Elm Street
Fairfield, CA 94533 Napa, CA 94559-3721

13. AMENDMENT/MODIFICATION. Except as otherwise provided herein, this Agreement may be modified or amended only in writing with the prior written consent of the governing boards of both parties.

14. INTERPRETATION. The headings used herein are for reference. The terms of the Agreement are set out in the text under the headings. This Agreement shall be governed by the laws of the State of California. The venue for any legal action filed by either side in state court to enforce any provision of this Agreement shall be the County of Solano, California. The venue for any legal action filed by either side in federal court to enforce any provision of this Agreement lying within the jurisdiction of the federal courts shall be the Eastern District of California.

15. SEVERABILITY. If any provision of this Agreement, or any portion thereof, is found by any court of competent jurisdiction to be unenforceable or invalid for any reason, such provision shall be severable and shall not in any way impair the enforceability of any

other provision of this Agreement.

16. AUTHORITY TO CONTRACT. Solano County and Napa County each warrant to the other that they are legally permitted and otherwise have the authority to enter into and perform this Agreement.

17. THIRD PARTY BENEFICIARIES. Nothing contained in this Agreement shall be construed to create any rights in third parties and the parties to do not intend to create such rights.

18. ATTORNEY'S FEES. In the event of legal action by either party to enforce the provisions of this Agreement or to obtain damages for breach thereof, each party shall be responsible for its own costs and attorney's fees incurred in connection with such action.

19. ENTIRETY OF CONTRACT. This Agreement constitutes the entire agreement between the parties relating to the subject of this Agreement and supersedes all previous agreements, promises, representations, understandings and negotiations, whether written or oral, among the parties with respect to the subject matter hereof.

IN WITNESS WHEREOF, this Agreement was executed by the parties hereto as of the date first above written.

COUNTY OF NAPA, a political subdivision of the State of California

By _____
DIANE DILLON, Chair of the Napa , County Board of Supervisors

"County of Napa"

ATTEST: GLADYS I. COIL ATTEST:
Clerk of the Napa County Board of Supervisors

By _____

APPROVED AS TO FORM: ROBERT WESTMEYER, Napa County Counsel

By P.Tyrrell (by e-signature)

APPROVED BY THE NAPA COUNTY

COUNTY OF SOLANO, a political subdivision of the State of California

By _____
Chair of the Solano County Board of Supervisors

"County of Solano"

ATTEST: MICHAEL D. JOHNSON
Clerk of the Solano County Board of Supervisors

By _____

APPROVED AS TO FORM:
DENNIS BUNTING, Solano County Counsel Counsel

By _____

5.2 Resources for Section 3: Planning To Implement a Service Change

- Resources for Section 3.2 — Communicate
  1. *CDC Unified Processes Practice Guide – Communication Management*: http://www2.cdc.gov/cdcup/library/practices_guides/CDC_UP_Communication_Management_Practices_Guide.pdf
  2. Communication plan template — refer to Section 5.1.1.
  3. Michigan laboratory closure letters of notification from case example 4.2 — refer to section 5.2.1.
- Resources for Section 3.3 — Organize
  4. *CDC Unified Processes Practice Guide – Project Charter*: http://www2.cdc.gov/cdcup/library/practices_guides/CDC_UP_Project_Charter_Practices_Guide.pdf
  5. RACI matrix adapted from the Project Management Institute's Project Management Body of Knowledge — refer to Section 5.1.2.
  6. Association of Public Health Laboratories. *Laboratory System Improvement Program User's Guide*. Identifying and Recruiting Stakeholders, pages 11 – 13: http://www.aphl.org/aphlprograms/lss/performance/Documents/L-SIP-Users-Guide.pdf
- Resources for Section 3.4 — Plan
  7. CDC Unified Processes web page. Project management guide, practice guides, templates, checklists and process guides: http://www2.cdc.gov/cdcup/default.htm
  8. Michigan laboratory closure checklist developed for Houghton laboratory closure from case example 4.2 — refer to Section 5.2.2.
  9. New Hampshire Public Health Laboratories and Environmental Services Laboratory consolidation checklist from case example 4.1 — refer to Section 5.2.3.
  10. *Framework for Program Evaluation in Public Health* from CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm
  11. Program evaluation resources from CDC: http://www.cdc.gov/eval/resources/index.htm
  12. Sample evaluation plan template — refer to Section 5.2.4.
  13. Logic models web page from the University of Wisconsin Extension Program: http://www.uwex.edu/ces/pdande/evaluation/evallogicmodel.html
- Resources for Section 3.5 — Implement
  14. Sample status reporting template — refer to Section 5.2.5.
  15. Sample issue log template — refer to Section 5.2.6.
  16. CDC Unified Processes templates for project management web page: http://www2.cdc.gov/cdcup/library/templates/default.htm

5.2.1 Michigan laboratory closure letters of notification from case example 4.2

Bureau of Laboratories
3350 N. Martin Luther King, Jr. Blvd.
P. O. Box 30035
Lansing, MI 48909
(517) 335-8063

September 30, 2010

Dear Public Health Laboratory Submitter:

After decades of public service to the residents of Michigan's Upper Peninsula, the Michigan Department of Community Health will be discontinuing clinical laboratory testing services as of October 4, 2010 due to lack of funding. As of this date, clinical specimens, including gonorrhea and chlamydia, should be submitted to the DCH laboratory in Lansing. Please check the Laboratory Users Guide (www.michigan.gov/mdchlab) for Lansing specimen acceptability requirements as they differ in some cases from the services previously provided by the Houghton laboratory. To avoid delays in specimen transport and testing, immediately replace mailing labels for the Houghton laboratory with the enclosed Lansing labels to assure expedient shipment to the Lansing laboratory.

For hours of operation, technical consultation, test interpretation, specimen collection directions and Lansing laboratory contacts are listed on the laboratory website. Copies of results and test status inquiries can be directed to DASH Unit at (517)335-8059. Other inquiries can be directed to Dr. Jeffrey Massey at masseyj@michigan.gov or (517) 335-8074.

Water testing and rabies testing services will continue at the same address and will be transferred to the Western Upper Peninsula District Health Department.

We appreciate your patience and understanding during this transition period as we attempt to continue to provide you with the high quality public health laboratory testing services that you were accustomed to receiving from the Houghton laboratory.

Sincerely,

Frances Pouch Downes, Dr.P.H.
Laboratory Director
Bureau of Laboratories

Bureau of Laboratories
3350 N. Martin Luther King, Jr. Blvd.
P. O. Box 30035
Lansing, MI 48909
(517) 335-8063

October 29, 2010

Dear Public Health Laboratory Submitter:

After decades of public service to the residents of Michigan's Upper Peninsula, the Michigan Department of Community Health will be discontinuing water and rabies testing services as of November 19, 2010 due to lack of funding.

Rabies specimens should be immediately submitted to the DCH laboratory in Lansing. To avoid delays in specimen transport and testing, immediately replace mailing labels for the Houghton laboratory with the enclosed Lansing labels to assure expedient shipment to the Lansing laboratory.

Instructions on accessing alternate water testing services will be forthcoming from your local public health agency.

For rabies and other non-water testing services hours of operation, technical consultation, test interpretation, specimen collection directions and Lansing laboratory contacts are listed on the laboratory website. Copies of results and test status inquiries can be directed to DASH Unit at (517)335-8059. Other inquiries can be directed to Dr. Jeffrey Massey at masseyj@michigan.gov or (517) 335-8074.

We appreciate your patience and understanding during this transition period.

Sincerely,

Frances Pouch Downes, Dr.P.H.
Laboratory Director
Bureau of Laboratories

5.2.2 Michigan laboratory closure checklist developed for Houghton laboratory closure from case example 4.2

Task	Person Responsible	Date To Complete
Notify hospitals that BT specimens come to Lansing		
Notify CT/GC submitters that specimens come to Lansing		
Send Lansing CT/GC mailing labels to submitters		
Notify other clinical specimen submitters to access other lab		
Letter notifying submitters		
Supply inventory- non-water, non-office		
Equipment inventory		
Schedule salvage pick up		
Schedule DMB move equipment and supplies to be kept		
Notify MTU of lease termination		
Schedule records center pick up		
Records to be destroyed - service pick up?		
Cancel PO's and service contracts for FY11		
CLIA certificate cancelation		
Select Agent certificate decommission		
Update web page		
PTRs for staff bumping/transferring		
MOU with WUP		
Water testing media inventory		
Accreditation files		
Change owner address on umbrella certificate		
Water testing requisition		
Rabies testing requisition		
Bacterial isolates: Subculture for Lansing		
Bacterial isolates: MTA for MTU		
Bacterial isolates: Subcultures prepared for MTU		
Bacterial isolates: Destroy		
Contact MGH regarding emergency transport services		
Storage unit - keep or store materials at lab or WUP building		

5.2.3 New Hampshire Public Health Laboratories and Environmental Services Laboratory consolidation checklist from case example 4.1

Laboratory Consolidation

Strategic Issues

1. Organization, reporting duties and accountabilities of DES Lab Staff especially of supervisory staff
2. Staff Orientation into DHHS; Meet & Greet for all lab staff – advantages of working together
3. DES staff orientation
4. Staff need to get off some DES committees (green team, website, etc.)
5. What is DHHS/DPHS organization structure?
6. Staff member X – does she physically move to 2nd or 3rd floor and can she meet her supervisor prior to July 1st?
7. Decide which programs/tests to keep and what goes as result of merge (asbestos)
8. Possible amendment to subcontract to add additional parameters
9. Replacing 2 vacant positions as result of recent retirements
10. Use of Lab Equipment Fund (immediate need of Ammonia instrument, GC/MS and PC replacements)
11. Sample Receiving consolidation – a Lean team project
12. What is new lab's official name?
13. May need to provide assistance to lab staff with new assignments (EAP)

Letters to be written

1. Notify EPA, NH ELAP, FDA
2. Notify customers including state agencies (DOA and DRED, etc.); who signs letter?
3. Primacy – need approval from EPA Regional Administrator
4. Notify DHHS on Radiological license – anything else needed to be in compliance with Rads?
5. Notify Attorney General's office
6. Pesticide standards – free ones – need letter to vendor from DHHS to continue

Questions for DES

1. Resource Lab subcontract – does this need to be amended?
2. Limnology's portion of the rent
3. ARD storage in B24
4. Billing the PSP project for time and supplies – propose just invoice periodically

Finance Issues

1. Financial transfers – accounts, contracts
2. Contracts to consolidate: Agilent/Varian, ChemWare, Millipore, Spectro, Perkin Elmer – timing
3. Consolidate Fisher, VWR, Thermo and other contracts and open POs
4. Are maintenance agreements transferable to new owner without penalty?
5. Who does cash receipts?
6. Dealing with checks received from other DES programs – Pool inspections?
7. How to order supplies and chemicals?
8. Need new postal code for letters and packages

9. Comp time – is there a max? How to complete?
10. Equipment inventory list DES accounting to provide list to DHHS

Computer Related

1. Need new Lab Report but cannot do without new logo and PO Box # for address
2. E-mail – Lotus notes; need training
3. Instrument and printer networking
4. Moving files to DPHS network – need new lab drive and personal drives
5. LIMS consolidation
6. LIMS developer
7. Archived databases
8. Cognos and SQL Plus
9. MOU with EMD and DWGB to transfer data daily
10. Website update – ordering containers and lab presence

General Issues

1. Change all paper template including lab reports (need logo and PO Box)
2. Consolidate hazardous waste license (DPHS now a large quantity generator)
3. Consolidate safety, ethics, training and other programs/committees
4. Any security changes? Access cards and cards for other DES employees
5. New picture IDs
6. Move phone accounts
7. Pesticide QAAP need updating to reflect new agency
8. Work with DWGB to revise all DES and PHL Fact Sheets
9. Receiving mail and packages internally
10. Postal issues
    a. Water sample delivery
    b. Express mail
    c. How to receive afternoon packages
11. PSP grant – can a DES employee work in PHL to analyze samples?
12. Access to Knowledge Center
13. Scrubs

5.2.4 Sample evaluation plan template[1]

5.2.4.1 Introduction

This resource is a template that can be used in developing a plan for evaluating a public health laboratory service change. Many approaches can be taken to developing and documenting these types of plans. To suggest the topics that an evaluation plan can include, this generalized, condensed template is based on a hypothetical service change that involves creation of a multistate service-sharing consortium.

5.2.4.2 Purpose and intended use and users of the evaluation

This section provides a general introduction to the evaluation, including its purpose and how the information it generates will be used. Some questions to address include:

- What stimulated the development of an evaluation plan for this service change?
- What is the purpose of this evaluation?
- Who might use the information that is generated through this evaluation and how might they use it?

Sample Purpose and Intended Use Section for Hypothetical Multistate Service Sharing Evaluation

This document describes the major components and rationale for an evaluation that will be conducted during the period [insert dates]. This evaluation was commissioned to promote a better understanding of the implementation and effects of multistate service sharing recently put into place by [insert state names]. Specifically,

> The purpose of this evaluation is to learn about the extent to which staff in submitting laboratories understand new procedures for submitting laboratory samples and are able to maintain proficiency in interpreting test results. Findings will be used to improve the process for implementing shared testing services across the four participating states.

The primary intended users of this evaluation are the directors and managers of the laboratories that belong to the multistate consortium. It is anticipated that they will review the findings from this evaluation, discuss potential action steps for improving the service-sharing process, and document and monitor the implementation of those action steps.

5.2.4.3 Description of the service change

Describing the service change itself and presenting its rationale are both important. Questions to consider include:

- What need does this service change respond to?
- What resources are available to support this service change?
- What activities will be conducted during the service change?
- What will result from the effective implementation of this service change?
- When did this service change begin? What is the history behind it?
- What is the context in which this service change is being implemented? Do any external factors affect its implementation (positively or negatively)?

[1] Content based on: Centers for Disease Control and Prevention. Learning and Growing through Evaluation: State Asthma Program Evaluation Guide. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Environmental Hazards and Health Effects, Air Pollution and Respiratory Health Branch, April 2010. Russ-Eft D. and Preskill H. (2001). Evaluation in Organizations: A Systematic Approach to Enhancing Learning, Performance, and Change. Basic Books: New York.

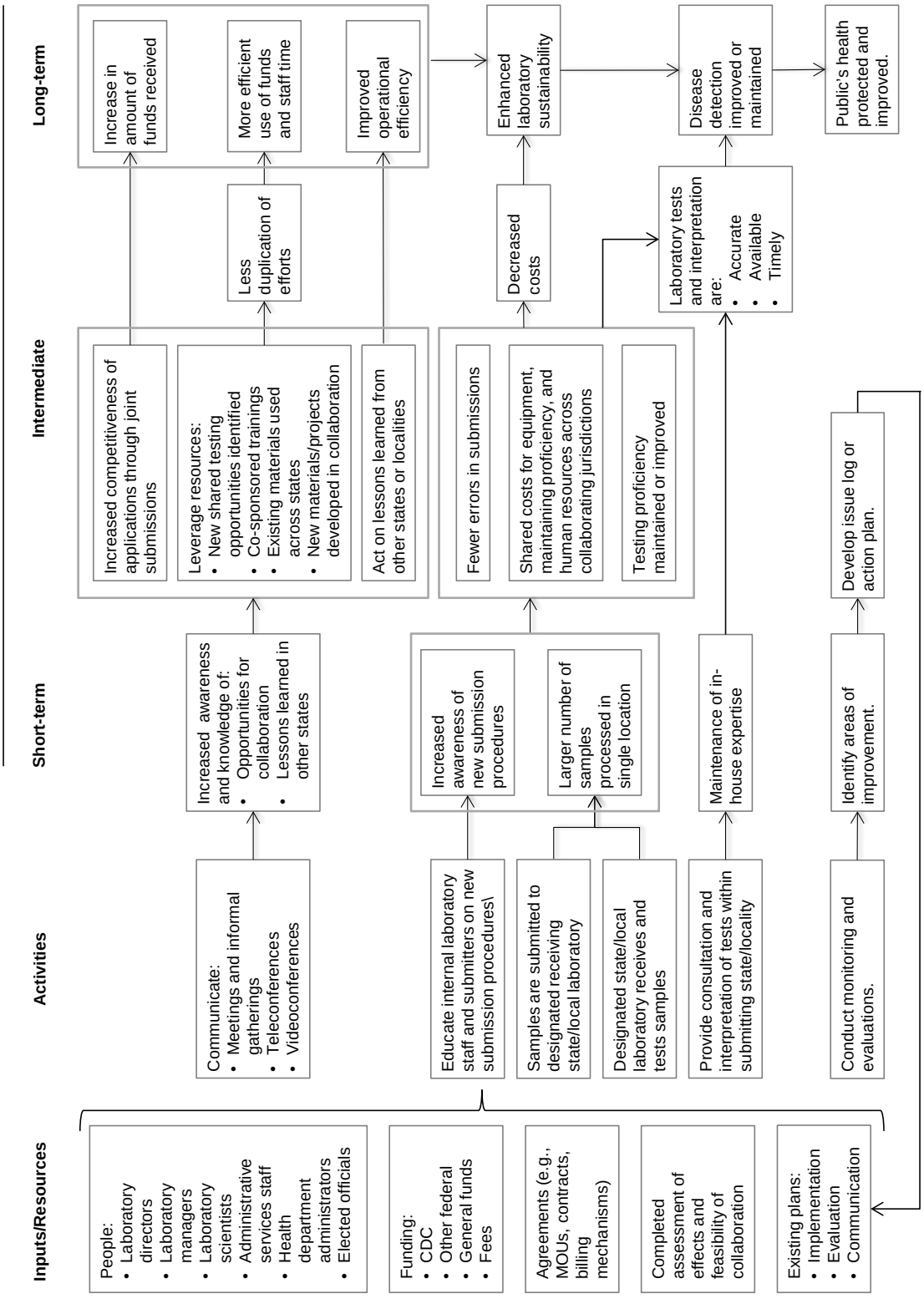
You might also find it helpful to draft a logic model for the service change. Using an illustration, you can describe the resources needed or available to implement a service change, the key activities that will be conducted during the service change, and what you hope will result from the service change if it is implemented well. Logic models are intended to reflect how the new service models will operate.

Logic models often contain the following elements:

- Resources/inputs: These are the resources that can be used to implement the activities associated with the service change.
- Activities: Efforts that are undertaken as part of implementing the service change. You can find these in your implementation plan.
- Outputs: This is the evidence that your activities actually occurred. Outputs may be reflective of tangible products (e.g., materials such as new training protocols) or processes (e.g., trainings conducted).
- Outcomes: These are the effects of implementing the service-change activities well. Frequently outcomes can be presented in a logic model in time sequence (i.e., short-term, intermediate, or long-term outcomes) to demonstrate the progression of results that are expected to be produced.

A simplified example of a logic model for a hypothetical multistate service sharing effort is provided in Exhibit 5.2-1.

Exhibit 5.2-1: Example Logic Model for Hypothetical Multistate Service Sharing Effort



5.2.4.4 Guiding questions, data collection and analysis

This section of the evaluation plan describes the questions you intend to answer during the evaluation, how the data will be collected to help answer the questions, and how these data will be analyzed. Many activities can be evaluated in any service-change effort; therefore, refining and prioritizing the questions to answer is important. In selecting your evaluation questions and the methods for answering them, you might consider the following four program evaluation standards included in the *CDC Framework for Program Evaluation in Public Health*[1]

- Utility: How useful is the answer to this evaluation question? Is taking action in response to the answers that are likely to be obtained possible?
- Feasibility: Which evaluation questions are feasible to answer given the available resources? Are the proposed data collection and analytic methods feasible within the allotted time frame? Is the necessary expertise available?
- Propriety: Are any ethical problems associated with collecting or maintaining the data needed to answer these evaluation questions? Are additional steps required to collect and store these data (e.g., informed consent, institutional review board approvals)?
- Accuracy: How accurate are the data that can be obtained? Will the intended users of the evaluation results consider the proposed methods credible?

After the evaluation questions have been prioritized and methods for collecting and analyzing data have been identified, the questions can be linked to the data and associated analyses in a single table, as displayed in Exhibit 5.2-2, which draws on the hypothetical example presented in Exhibit 5.2-1. The questions assume that the multistate service-sharing effort depicted in Exhibit 5.2-1 is in the early stages of implementation and therefore focus on answering evaluation questions about how well the implementation process is occurring and the extent to which early outcomes are being realized.

Exhibit 5.2-2: Example Evaluation Questions, Data Collection, and Analysis Strategy

Evaluation Question	Data Collection Method(s)	Data Source	Proposed Analysis
How aware is the staff of the new procedures for submitting samples to other states in the consortium? Where does a lack of clarity exist?	Document/record review	Existing logs of lag time between sample receipt and shipment to testing laboratory	• Frequency analyses of lag time data to identify abnormally long lag times • Thematic analysis of interviews with staff members
	Interviews (formal or informal)	Staff responsible for submitting samples that have abnormally long lag times	
To what extent are internal staff maintaining the proficiency necessary to interpret and provide consultation on tests that are being conducted by other states in the consortium?	Structured telephone interviews	Random sample of persons who have submitted samples for testing within the past quarter	• Content analysis of interviews and meeting notes • Triangulation of information from both sources to identify potential proficiency concerns
	Document review	Notes from past year's staff meetings	

[1] MMWR 1999;48 [No. RR-11]; http://www.cdc.gov/mmwr/PDF/rr/rr4812.pdf.

In addition to using the example in Exhibit 5.2-2, having a work plan for the evaluation tasks is helpful. An excerpt from a hypothetical evaluation work plan is provided in Exhibit 5.2-3, which describes the evaluation tasks that must be performed, who is responsible and the timeline for completing the task. Evaluation tasks can be broken down at different levels of resolution; considering what is most useful for the team conducting the evaluation is crucial.

Exhibit 5.2-3: Example Excerpt from Evaluation Data Collection and Analysis Work Plan

Evaluation Task	Individuals Responsible	Timeline
Develop draft of semistructured, in-person interview protocol for evaluation question 1 (EQ1).	J. Smith (Coordinator)	1/27/13–1/30/13
Send semistructured, in-person interview protocol for EQ1 out for comment.	J. Smith Reviewer A Reviewer B	2/1/13–2/7/13
Compile feedback for semistructured, in-person interview protocol for EQ1 and revise.	J. Smith	2/8/13–2/28/13
Schedule interviews.	M. Barnes	2/12/13–2/18/13
Conduct interviews.	J. Smith	3/1/13–3/15/13
Conduct thematic analysis.	J. Smith M. Barnes	3/16/13–4/1/13
Conduct data interpretation meeting with evaluation team and other stakeholders as appropriate.	J. Smith	4/2/13
Develop brief report of findings and disseminate it to primary intended users per communications strategy.	J. Smith	4/1/13–4/15/13
Develop action plans based on evaluation results.	J. Smith	4/15/13–4/30/13

5.2.4.5 Communications strategy

An activity that you might find helpful is to describe who will be interested in receiving information about the progress that is being made on the evaluation as well as in learning about the findings (interim and final) from the evaluation. You might choose to have a separate communications plan specific to evaluation, or to integrate plans for communicating about evaluations within an overarching communications plan for your assessment and implementation efforts. The plan could address such points as:

- The target audiences interested in learning about the evaluation.
- The purposes of communicating with them.
- The media for communicating with them.
- Roles and responsibilities for ensuring effective communication.

5.2.5 Sample status reporting template[1]

Date	Status
Date of status report	Describe current status of activity.
Issues / Risks	
List issues or risks identified that require discussion and resolution. Consider cross-referencing with the Issue Log.	
Completed Tasks	**Next Steps**
Lists tasks completed between previous status report and current status report.	List tasks to be completed between current status report and next status report.

5.2.6 Sample issue log template[1]

Issue #	Issue Status	Assigned To	Issue	Resolution	Due Date	Close Date
1, 2, 3, etc.	Status types: New, In Progress, Cancelled, Completed	Identify staff responsible for resolving issue.	Describe issue and additional information.	Describe how issue was resolved.	List date issue must be or is resolved by.	List date issue is resolved and closed.

[1] Adapted from the Project Management Institute's Project Management Body of Knowledge

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