Project Abstract:
State public health labs perform vital testing services that are essential to protecting the health of the population. Moreover, they face the unique challenge of being prepared to address testing needs for all diseases whether rare, endemic or imported. Maintaining expertise as well as cost effectiveness for all testing is difficult; thus, it is essential that regional consortiums be established to investigate ways to cooperate and share relevant services. The Northeast Environmental and Public Health Lab Directors (NEEPHLD) group with participating members from the states of New York (NY), New Jersey (NJ), Rhode Island (RI), Connecticut (CT), Massachusetts (MA), Vermont (VT), Maine (ME), and New Hampshire (NH) was established in the 1980's and is ideally suited to facilitating interstate cooperation and sharing. A number of NEEPHLD members have already established individual test sharing agreements and have worked through some of the barriers to interstate testing. These pilot projects are proven successful examples of interstate test sharing, but have highlighted numerous issues that need to be addressed before expanding in scope. For example, the electronic data communication needs to be improved to provide maximum efficiency and enable direct linking of Laboratory Information Management Systems. Thus, in order to move forward, a detailed assessment of legal, fiscal, technical and IT issues is critical to expanding the NEEPHLD shared services model. In order to facilitate the expansion and implementation of broader shared services, the NEEPHLD consortium proposes to work with an independent contractor through the Association of Public Health Laboratories. The contractor will work with each NEEPHLD member state to gather necessary information about their public health services. The NEEPHLD consortium and contractor also will meet formally five times during the year to decide what testing is sharable, what obstacles are present, how to overcome them, each state's testing strengths and weaknesses, and overall IT capabilities. Based on this assessment, the consortium will determine an achievable means to sharing laboratory services. All member states are committed to this proposal and for logistical reasons New York state lab will hire the consultant. We expect that the consultant and NEEPHLD will provide a framework where we can better enhance our current test sharing into a sustainable and efficient program. After this process, the implementation phase will be initiated with the sharing of at least one reportable disease. As is detailed in Section 1, the Massachusetts Department of Public Health, Bureau of Laboratory Sciences is considering several candidate tests and one service. The candidate tests include Rabies virus PCR (offered by New York), LaCrosse virus serology (offered by New Jersey) and Hepatitis C virus PCR and sequencing (offered by New Hampshire). The one service being considered at this point is the Biosafety Officer being a shared service. The NEEPHLD consortium, with their established relationships and pilot shared services, is an excellent model to form a strong evidence-based model for sharing among members as well as providing a framework of shared services for other states to utilize.

Project Narrative:

1. **Statement of consortium participation and scope of shared services.**

a. The Northeast Environmental and Public Health Laboratory Directors (NEEPHLD), if funded through this grant opportunity, will expand its state public health laboratory group to evaluate shared testing as it currently exists with this eight state consortium (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont) and the potential of increasing shared testing and other services. The consortium will be guided by the NPHII's Laboratory Efficiencies Initiative (LEI) and the 2012 -1015 LEI Strategic Plan goals and objectives. Tools available through the CDC or APHL will be utilized to include the Informatics Self-Assessment Tool and resources available on the APHL website for cost per test and return on investment determinations. NEEPHLD members have worked together since the mid 1980's when the group began as Environmental Laboratory Directors only and then expanded over the years to include Public Health Laboratory Directors. The NEEPHLD workgroup meets quarterly and rotates the chairing of these meetings annually to different states. For 2013 the state of Connecticut is responsible for planning and hosting these meetings. Meetings include state updates, current issues in laboratory response and an annual continuing education (CE) meeting in the fall. The recent CE meetings have focused on LEI in Environmental Laboratories hosted by the Region I EPA in fall 2012 and a meeting on Radiologic Laboratory Response in fall of 2011 which included Robert Jones from CDC presenting updates. NEEPHLD is an example of regional collaboration and the agendas from meetings have been requested from other states for their consideration of adopting a similar kind of work group. To create a NEEPHLD Consortium is a logical next step in the development and expansion of the collaboration in the Northeast region. The state of New Jersey will join the seven states as a new member.

The National Public Health Improvement Initiative (NPHII) of 2010 was developed towards achieving three goals: accelerating public health accreditation readiness activities; implementing performance and improvement management practices and systems; and implementing and sharing practice-based evidence. NEEPHLD supports these goals. Awardees of the 2010 funding were expected to measure outcomes that aligned with these goals and included increased efficiencies measured through time and/or money savings; using evidence-based policies and practices to improve health outcomes and quality of service in addition to increasing the service reach of the programs and customer satisfaction. The third measured outcome was to increase health departments' readiness to meet national Public Health Accreditation Board standards for accreditation. An important awardees activity was and continues to be establishing cross-jurisdictional collaboration with one or more other health departments.

It is well recognized and acknowledged that the US public health laboratories, state, territorial, and local, provide critically necessary and needed services which protect the health of the public and support individual patient treatment and public health prevention strategies. The pressure on these laboratories has increased in recent years most notably due to profound budget cuts which have adversely affected these laboratories' resilience and capabilities. Laboratories have been forced to reduce testing capacity, eliminate certain types of tests and in some cases there is

reduced support for outbreak investigations, surveillance, and emergency response. These deep financial cuts have affected staffing levels as well as continual staff training and education and laboratory operations in general.

The LEI co-sponsors along with contributions from public health and laboratory partners are exploring management practices that make the most of the resources available to the public health laboratories. The practices under consideration are:

* Sharing of testing services across states

* Adoption of standardized testing platforms

* Optimized models of service organization

* Generation of new revenue sources

* Application of informatics solutions and

* Procurement cost-savings

2012 was primarily a year for development and planning the direction of the LEI. The public health laboratory directors, APHL, CDC, and partners focused on three areas in addition to creating a three year Strategic Plan.

The 2012 – 2015 LEI Strategic Plan Goals are:

I. Implement and sustain innovative laboratory management practices.

II. Assure that public health laboratories have full informatics capability to participate in electronic information exchanges.

III. Identify and address institutional, legal and policy barriers to greater efficiency.

IV. Assure that resources, infrastructure and partnerships are sufficiently adequate to meet the LEI mission.

V. Communicate, inform and educate on the critical purpose of public health laboratories and the value of LEI in sustaining them.

VI. Transform the continuum of public health laboratories to a culture of efficiency.

VII. Develop a comprehensive public health laboratory workforce strategy.

The LEI 2012 Year in Review and the LEI 2012 – 2015 Strategic Plan goals and details of objectives and metrics are found at www.APHL.org. For the purpose of this funding opportunity NEEPHLD will focus on Goal I objectives and tactics.

Goal I is to implement and sustain innovative laboratory management practices. To this end there are seven objectives. The first objective is to collect data and develop models to expand sharing of test services. Data is to be provided on the extent of current sharing of services and highlight the best practices. Current model descriptions, with pros and cons, are to be made available by the end of 2013 through APHL and CDC.

The second objective of Goal I is to collect and publish data on what tests are performed by federal, state, and local public health laboratories. This information will allow all public health laboratories to explore sharing services through the 'Directory of Test Services'. All states in the NEEPHLD Consortium will complete the PHL management database when it becomes available.

Objective three evaluates current approaches to sharing test services, both within states and between states. NEEPHLD has demonstrated its commitment to cross-jurisdictional collaboration as well as resource sharing (see table 1). On a state level, the Massachusetts Bureau of Laboratory Sciences has felt the pressure on the laboratory has increased in recent years, most notably due to profound budget cuts which have adversely affected the laboratory's resilience and capabilities. All of the NEEPHLD Consortium's laboratories have been forced to reduce testing capacity, eliminate certain types of tests and in some cases there is reduced support for outbreak investigations, surveillance, and emergency response. Deep funding cuts have affected staffing levels as well as continuing staff training, education and laboratory.

This evaluation also considers the most effective solutions, including pilot projects for a consortium or region.

Objective four is identifying what tests are 'core' to each state. It is expected that by 2014 the majority of public health laboratories, following discussions with their epidemiology programs, have identified their core testing needs and have worked towards or completed referral mechanisms.

Objective five pursues cost efficiency measures, primarily under CDC/APHL leadership standardizing testing platforms.

The sixth objective is assisting public health laboratories in revenue generation by exploring billing practices. By reviewing success stories such as those from Michigan, South Dakota, Tennessee and Colorado, provide best practices as models.

The seventh and final objective under the Goal of implementing and sustaining innovative laboratory management practices provides tools, resources and information for the public health laboratory community which may assist in decision making and implementing of efficiency initiatives. An important tactic is the development of a common methodology or guideline for determining cost per test. This would allow for cost comparison models and provide public health laboratory directors as well as other state health department officials, with information on the range of cost among public health laboratories.

Proposed Consortium Guiding Principles: The Northeast Environmental and Public Health Laboratory Directors group support the goals of the National Public Health Improvement Initiative (NPHII) to accelerate public health accreditation readiness activities; implement performance and improvement management practices and systems, and implement and share evidence-based practices.

Roles and Responsibilities of Consortium Members

Each state member of the NEEPHLD Consortium who has applied for funding under this FOA is required to send representatives to the five consortium meetings to be held periodically over the 12 month funding period as indicated in the plan. Those not applying for funding, but requesting to be part of the Consortium are also expected to attend and participate in these meetings. A Point of Contact person will be named from each state to coordinate communications within the consortium and act as the liaison to the consultant group. At the point, New York State Public Health Lab will take the lead and work to hire the consultant. Connecticut will host the first of five meetings. Massachusetts will host the remaining four meeting and will use most of the funds it requests for the support of the meetings. The responsibility for keeping minutes of meetings will be rotated between each member of the consortium. The consortium will determine the lead lab for managing the informatics and collecting performance data as the project moves forward.

Consortium members will be required to submit all data required by the consultants in a timely manner and in the formats requested. Each consortium member will assess their informatics capabilities through completing the APHL Informatics Self-Assessment tool for any and all of their testing software programs and engage their respective Information Technology divisions or departments in the assessment process. Members are to ensure that their respective Legal and Regulatory Compliance offices within their department are participatory and involved in the consortium's efforts to meet the goals and objectives of their plan and that of the larger LEI strategic plan. Representatives of each member state as well as staff not attending the consortium meetings are expected to fully participate in Work Groups determined to be necessary to address specific issues identified by the Consortium and the Consultant. Each Consortium member agrees to adopt and implement the Public Health Laboratory Management database. Consortium members will collaborate and develop methods to assess performance of shared services and to create the Final Report on findings, lessons learned, and a next steps plan.

The consortium states have developed a table of tests that are currently shared among them (see table 1). Recently at the last quarterly meeting of NEEPHLD on July 24, 2013, the meeting participants discussed LEI and agreed to create a list of currently shared tests as well as begin to generate ideas for expanding shared services.

b. The letter of support from Commission Bartlett is attached.

c. Identification of proposed public health tests and/or services.

The NEEPHLD group has long recognized the importance of shared services and has explored the concept on a limited basis. The table below describes some of the services that have informally shared between various members of the proposed consortium at various times. This table will serve as the starting point for further evaluation of potential shared.

Table 1: Summary of testing services shared/ available amongst NEEPHLD Consortium states

State laboratory providing services	State(s) receiving services	Sample type (C/E/Vr/ Vc/F/A)*	Test description	Status	Notes
CT DPH	MA, NH, ME, RI, VT	E	Radiochemistry testing for drinking water	On-going	CT DPH lab serves as primacy lab under SWDA
CT DPH	RI, MA, NH, ME, VT	E	Asbestos testing for drinking water	On-going	Test
MA DEP	VT, RI, NH	E	Ambient air testing- Particulate Matter (PM2.5)	2011-2012; on-going for NH	The need arose when Hurricane Irene rendered the DEC VT lab not useable.
MA DEP	NH	Fish	Mercury	Completed 2005	Samples collected and submitted by the EPA
MA DEP		Fish	Mercury, PCBs, other pollutants	Available	
MA DEP		E	Testing for markers of human sewage pollution in ambient water	Available	Genetic markers in two groups of bacteria, caffeine, and fluorescent whitening agents by used to identify illicit and other sewage sources in watersheds
MA DEP		E	Petroleum, Cyanide and other hazardous waste methods	Available	MADEP VPH MADEP EPH, MADEP PAC, total cyanide, oil and grease/TPH (1664A) and by other SW-846 Methods.
MA DPH	MA,ME, RI, VT	C	PFGE, MLVA	On-going	Regional PFGE lab capabilities supported by CDC ELC grant
MA DPH	NH, others?	C	EEE (PCR, serology, culture, PRNT)	On-going	Sporadic requests
MA DPH	RI	C	Measles, Mumps, Rubella (PCR, serology, culture)	On-going	
NH DHHS	VT	C/V	Human IgM for EEE, WNV and SLE	On-going	
NH DHHS	VT	Veterinary	EquineWNV and EEEv IgM	On-going	
NH DHHS	VT	Veterinary	WNV and EEEv Duplex RT-PCR	On-going	
NH DHHS	VT	Mosquitoes	WNV and EEEv	2011-2012	
NH DHHS		C	HCV qualitative	Available	

State laboratory providing services	State(s) receiving services	Sample type (C/E/Vr/ Vc/F/A)*	Test description	Status	Notes
			PCR and Sequencing		
NJ PHEL		E	Organic, Inorganic, Microbiology	Available	NJ PHEL Environmental and Chemistry Laboratory Services serves as the primacy laboratory under SDWA for NJ & NJDEP
NJ PHEL		E	Radiochemistry, Radium 224, 226, & 228	Available	
NJ PHEL		E	EPA 525.2 styrene acrylonitrile trimer	Available	
NJ PHEL		E	low level metal analyses in drinking & non-potable water by ICP/MS	Available	
NJ PHEL		C	GC/Chlamydia NAAT	Available	
NJ PHEL		Mosquitoes	WNV,EEE, SLE, LAC	Available	
NJ PHEL		Avian	WNV	Available	
NYSDOH	NJ, VT, MS, MI, DE, MA, RI, PA	C	measles, mumps, VZV, and rubella detection and genotyping; rotavirus detection	On-going	Funding provided by a contract with APHL/CDC
NYSDOH	multiple	C	Influenza virus pyrosequencing for antiviral resistance	On-going	Contract with APHL/CDC
NYSDOH	RI, ME, CT	C	Norovirus PCR and genotyping	On-going	Contract with APHL/CDC
NYSDOH		C	Viral encephalitis – special requests – especially arboviruses	Available	
NYSDOH		C	Adenovirus and enterovirus subtyping by sequence analysis; sequence characterization of other viruses (PIV, hMPV, RSV)	Available	

State laboratory providing services	State(s) receiving services	Sample type (C/E/Vr/ Vc/F/A)*	Test description	Status	Notes
NYSDOH	VT	C	WNV and EEEV Multiplex qRT-PCR	On-going	
NYSDOH	RI, NJ, VT, NH	Veterinary	Rabies - monoclonal antibody panel antigenic analysis and PCR	On-going	
RI DOH	MA	C	HIV NAAT confirmation	On-going	
RI DOH	MA	E	Ambient air carbonyl	2003-2008	
RI DOH	MA	E	Ambient air toxics	On-going	
RI DOH		C	4th generation HIV	Available	
RI DOH		C	Hepatitis A, B, C serology	Available	

*C '(C) , Environmental (E), Veterinary (Vy), Vector (Vc), Avian (A)

d. **Massachusetts existing informatics capabilities including ETOR and capabilities supportive of implementation of ETOR, such as electronic messaging capability for influenza and vaccine preventable disease testing.**

MAPHL has greatly enhanced its informatics capacity and capabilities over the past several years. MAPHL developed and implemented a flexible and practical laboratory information management system (LIMS) infrastructure that allows it to send and receive data among public health systems, hospitals, public health agencies and private reference labs. The LIMS infrastructure includes an electronic laboratory reporting (ELR) system, as well as three distinct LIMS that support specimen processing, testing, and resulting functions for three different laboratory testing areas. Interoperability between the LIMS and ELR is achieved with the use of standard Order Message (ORM) messaging and Rhapsody Integration Engine. ORM messaging is a subset of HL7, developed by the MAPHL to facilitate exchange of structured data (orders, tests and results) in various data formats between the three LIMS systems and ELR.

Having three LIMS components provides the flexibility needed to accommodate rapid changes and specific requirements of a given laboratory or type of testing. These components include a system that supports all serological, immunological and molecular testing, (2) an in-house developed system that supports all microbiology testing, and (3) the Perkin Elmer Labworks LIMS that supports all chemical testing. All three LIMS components are secure and internal to BLS and support testing and reporting processes, instrument interfacing, rapid order entry, and result messaging. Additional functions include registration of patient information via barcoding, test and quality control documentation, result verification and release for reporting in ELR, internal management reports, and generation of a standard ORM (see figure 1 below).

The Electronic Laboratory Reporting and Communications (ELR) System was deployed October 2004. It is a secure web-based system that is utilized by both MAPHL and Massachusetts Bureau of Infectious Disease (BID). ELR provides laboratories and other health care partners with electronic test ordering and reporting (ETOR) capabilities. ELR allows providers send HL7 orders and retrieve HL7 results. The ETOR capability is currently used for TB testing, but supports other infectious disease and vaccine preventable diseases that MAPHL performs. Electronic orders for TB are sent from health care providers to ELR in HL7 v2.31 format. The ELR System then converts the HL7 e-order into the ORM format to allow the LIMS to accept the incoming test orders. The ELR system also health care partners to view the status of their tests electronically and print single and batch file reports by simply logging on to the secure portal. Over 120 providers log on to the system to get their reports electronically and view the status of their test orders.

MAPHL is one of the leading public health laboratories in data standardization and sharing capabilities. The trained MAPHL Informatics Division generates multiple data formats, including CSV, XML and HL7 message formats for various external systems. HL7 messaging is handled by Rhapsody, which is also used to map LIMS local codes to message-specific vocabularies, including LOINC and SNOMED coding vocabularies required by each messaging recipient (LRNB, PHLIP, LRNC and hospitals). Data is sent to the CDC using PHINMS. MAPHL has continued to expand its use of PHINMS since 2008. Data format differences for file type are handled by each respective LIMS. The Folder based pooling method is used to centralize data for PHINMS transfer. PHINMS supports PHLIP Influenza, LRNB and LRNC messaging. MAPHL has recently completed the development of the LRNC HL7 message and passed structural validation. MAPHL is one of two state public health labs to successfully develop the LRNC message and was one of the first three states to successfully deploy LRNB messaging to the CDC.

The Informatics Division supports all of the Massachusetts Public Health Laboratory (MAPHL) applications. The highly trained staff provides onsite application development and support for MAPHL Microsoft and Java based application platforms. The technical staff consists of on-site certified MS SQL and Oracle Database Administrators (DBAs) and certified Microsoft and Java developers. The MAPHL Informatics Director is a certified PMP and provides oversight at the programmatic level and acts as a liaison between the MAPHL application support group and business units. NEEPHLD's informatics capability and the contribution that Massachusetts will make will be determined in collaboration with the consultant.

e. A detailed description of Massachusetts' informatics systems and capabilities including specification of the capability to receive laboratory test orders and send test results using HL7-compliant systems.

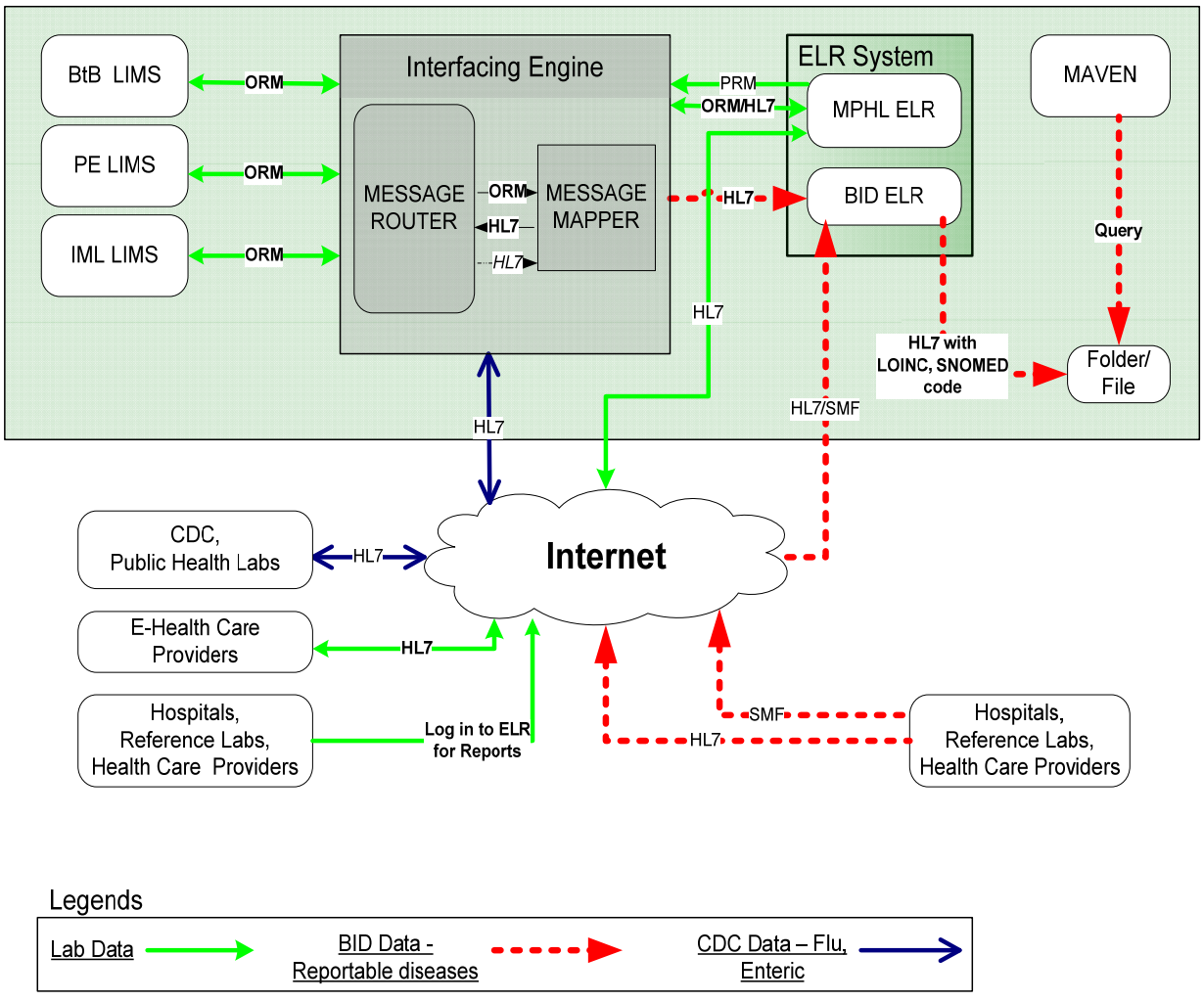
MAPHL's existing informatics capacity can support the implementation of data exchange with participating public health laboratories. To fulfill this objective, MAPHL could utilize existing HL7 messaging produced by the Rhapsody Integration Data Engine (IDE) to enable the transmission of test orders from MAPHL to one or more public health laboratories or testing sites to facilitate mutual assistance in surge capacity situations. Messaging will comply with the CDC ETOR standards for message mapping and standardized terminology implementation. Data

transformation and data brokering for state to state test orders and test results will be handled by the IDE, such as Rhapsody.

This will be based on the development of policies and procedures for data exchange with neighboring laboratories to meet surge capacity and continuity of operation needs. The New England Environmental and Public Health Laboratory Director (NEEPHLD) Consortium will facilitate the development of a Memorandum of Understanding (MOU) to share public health-related laboratory testing services and establish a system of mutual laboratory testing support that can be drawn upon as needed in the event of significant interruptions in testing operations. MAPHL plans on including the intrastate data exchange capabilities emphasized in such a proposal to support surge capacity among state public health laboratories.

MAPHL
Figure 1

SLIS DATA FLOW to CD, CDC



Legends

Lab Data — BID Data - Reportable diseases — CDC Data – Flu, Enteric

2. Plan

The NEEPHLD Consortium will conduct both individual and joint activities during the funding period. The Consortium will develop a sole-source contract with the Association of Public Health Laboratories (APHL) to provide consultancy services that will be pivotal to achieving the goal of developing a plan for sharing both testing services and other public health functions. The APHL, which possesses an un-matched understanding of how public health laboratories (PHLs) operate, is a national organization to which all members of the Consortium belong. Bringing in APHL as an external service will provide a third-party, un-biased approach to analyzing the potential for sharing services within the Consortium. The list of Consultant activities will include each of the categories indicated.

Scope of Work for Consultant

The consultant will work with all members of the Consortium to analyze, amongst other factors:

1. Legal issues:

- Review the Public Health Law in each state in the Consortium to determine if there are limitations or restrictions on how state PHLs may contract or share services.
- Analyze and propose a solution as to how the issues of liability and indemnity would be resolved under shared testing service agreements between states.
- Determine whether any state has regulatory oversight statutes which will be impacted by sharing of testing services.
- Determine the most appropriate form that test sharing agreements between states will take e.g. MOU, LOA, contract, or a regional compact option.

2. Fiscal issues:

- Build on the list of shared services that has already been assembled to compile a comprehensive list of services, both testing and non-testing that Consortium members propose as having potential for sharing. This effort will be aided by each member of the Consortium being able to implement the Public Health Laboratory Management Database.
- Use this comprehensive list to develop a comparative cost-analysis for the performance of the tests in each of the member laboratories willing to participate in test sharing. Several tools are available for this including the Iowa State Hygienic Laboratory FY2011 Test Cost Algorithm Template 2011 available on the APHL website. All states may not wish to share all tests on the proposed list. The final plan will include test sharing across the Consortium.
- Develop cost analyses under at least two different scenarios. For example, test sharing could be performed on a fee-for-service basis or on an “equal exchange” basis in which one state tests for Pathogen A in exchange for the second state testing for Pathogen B.

3. Impact on quality and sustainability of service:

- Develop a comprehensive analysis of the impact of a longer turn-around-time for the tests that the consortium proposes to share.
- Work with members of the Consortium to determine staffing levels that will be necessary to maintain quality and turn-around -time for the proposed test sharing.
- Assess the feasibility of sharing federal grant funding for position(s) to support the shared services.
- Analyze the impact that localized loss of capability in specific areas may have on emergency preparedness.
- Analyze the impact of potential loss of surge capacity on emergency preparedness

4. Information Technology issues

- Analyze the collective results of each state's performance of the LEI Informatics Self-Assessment Tool. Develop a summary document encompassing gaps, challenges and proposing next steps. It is possible that interim steps can be taken to facilitate electronic communication between states before a solution can be found.
- Communicate with and be informed by national committees currently working on standards for electronic communication. The standards for HL7 codes and messages developed by these committees will drive the Consortium's ability to develop Laboratory Information Management Systems that support interoperability and are consistent with "meaningful use" guidance to effectively communicate with each other and with multiple laboratories at CDC.

Scope of work for Consortium Members

The members of the Consortium will work with the Consultant to:

- Provide a state-specific Point-of-Contact to the Consultant and to all Consortium members to co-ordinate communications within the group.
- Identify key staff who will have the responsibility of providing necessary information.
- Communicate with their respective Department of Legal Affairs to make sure there is participation and input from an attorney in all relevant discussions.
- Assess the informatics capability of their state PHL by using the LEI Informatics Self-Assessment Tool. Report back to the Consultant and other Consortium Members on this assessment.
- Communicate with their respective Information Technology (IT) departments to make sure there is participation and input in all relevant discussions.
- Adopt and implement the Public Health Laboratory Management database.
- Provide accurate cost, staffing and test volume data to the Consultant.
- Attend five regional meetings with members of the Consortium that will be arranged at two to three month intervals to assess progress, discuss challenges and propose solutions.

The Consultant will attend all meetings and may bring in legal or IT expertise when necessary.

- Participate fully in Work Groups to address specific issues identified by the Consortium and the Consultant.

Joint activities for both Consortium Members and Consultant

- Develop an assessment of sharing testing or other services to improve efficiency, cost-effectiveness and quality of the services provided by PHLs. This assessment will be conducted in the last quarter of the funding period after all data has been collected. Factors that will be included are the expected fiscal (gain/loss/neutral) outcomes for individual laboratories, turn-around-time for results, staffing issues, IT challenges, sustainability over the long-term, impacts on preparedness due to potential loss of local capability and also estimates of surge capacity in an emergency. Other factors to be taken into consideration include overall enhancement of the public health system by the potential regionalization of expensive high technology services that may not be needed in each individual laboratory.
- Develop a plan and time-line for steps to be taken to implement sharing of testing services.
- Develop a method to assess performance of shared services.
- Develop a Final Report encompassing both the assessment and plan of next-steps.

Reporting and Dissemination of information

- The Final Report will be provided to the CDC at the conclusion of the funding period.
- The Consortium will propose to APHL that the Final Report will be posted on the APHL website so that it is available to other member states.
- The Consortium will also propose that a session at the APHL Annual Meeting be scheduled where states participating in the funded proposal can present experiences and results to date.
- Given a national audience, it is possible that other US states will be interesting in participating in shared services offered by the NEEPHLD Consortium.

3. Methods

A consultant will assist the consortium members in its decision to assess and develop a shared service list of test(s) and/ or service(s). Selection of the shared service(s) or test(s) will be based on information and considerations related to the following areas:

- Collection volume statistics for a specific shared service test (s) and/ or service(s) will be determined for each member of the consortium, from the test requests received or the service volume in each state in the consortium and will assist in the decision to make the test/service a shared test/service.
- The consortium will develop and agree on a cost analysis tool to assess performance. To ensure that comparisons are accurately made, each laboratory will employ the same cost analytic tool. The cost analysis of sharing the test/service will be evaluated against the cost of having this test/service in-house in each laboratory. The cost of shipping specimens to another facility will also be calculated.
- Members of the consortium will gather data to determine the impact on turnaround time for entering into a shared service agreement as compared to individually performed

testing or provision of a service. The test/service will be evaluated against the turnaround time at each individual laboratory for performance of the selected test. Expected delays in turnaround time will be considered. Potential causes for delays in turnaround time, to name a few, are: delays in shipping, testing volume exceeding instrumentation capacity, shortage of available staff, and delays in reporting results.

- By surveying the public health program staff and the consortium member laboratory staff in each member's jurisdiction, the satisfaction with the shared test/service concept will be determined.
- A gap analysis of each consortium member's existing laboratory informatics capabilities will be performed to identify limitations that will impede the rapid communication of information between the members of the consortium.
- Assessment of each consortium member's existing processes for specimen handling and shipping will be performed to identify the impact on turnaround time and determine if rapid transit of the specimen between members of the consortium can be achieved with the current staffing levels.

The decision making framework will be clarified through the accumulation of the data listed above to aid the consortium members in the selection of shared tests and services. This will give justification to the options of decision points considered by the consortium members.

4. Objectives with timelines

Communication will be crucial to the success of the NEEPHLD Consortium and formal meetings will be planned with all Consortium members. Each meeting will be a two-day session at rotating state locations. Attendees will travel to the meeting and will require 1-2 overnight stays depending on the meeting location. Five meetings will take place during the grant year. Contractor will attend meetings in October and December, 2013 and February, May and August, 2014. Meeting attendees will include Laboratory Director and key staff members plus legal representative for a minimum of one of the meetings.

Objective 1: Develop and produce a signed contract between Health Research Inc. and APHL.

HRI will work with APHL to develop, within the available funds, a sole source contract to provide consultancy services for the Consortium for the duration of the funding period. The first meeting between Consortium members and Consultant will be arranged to closely define, within allowable funding, the actual Scope of Work. An Implementation Plan will be developed.

Deliverable 1: Signed contract between Health Research Inc.

Deliverable 2: A document produced by the Consultant and finalized by the Consortium describing the agreed-upon Scope of Work and Implementation Plan.

Timeline: The contract will be in place within 45 days of the award. The Scope of Work and Implementation Plan will be finalized at the first Consortium meeting October 30-31, 2013 in Rocky Hill, CT.

Objective 2: Attend and participate in state-specific Consortium meetings to compile data into a summary document.

Consultant will arrange five state-specific two day meetings with key staff in each state to obtain critical test services, cost, volume, and staffing information. Consultant will compile the information collected from each state, looking for commonalities, technical strengths, gaps and challenges and develop a presentation for the second meeting of the Consortium. The presentation should summarize legal, fiscal, quality and IT areas.

Deliverable 3: Completion of consultant's meetings with Consortium members and submission of a draft document to the Consortium Members prior to presentation at the second meeting.

Deliverable 4: Presentation and discussion of draft findings at a second meeting of Consortium Members.

Timeline: The Consultant will visit as many of the member states as possible prior to the second Consortium meeting in December 4-5, 2013.

Objective 3: Form Work Groups to focus in on selected issues.

At the second Consortium Meeting, internal Work Groups will be formed that will focus on specific issues that have been identified by the Consultant's initial analyses. The charge to these Work Groups will be to hold regular Conference Calls to discuss potential solutions.

Deliverable 5: Formation of multiple smaller Work Groups with specific Charges.

Timeline: The second Consortium meeting will be in December 4-5, 2013.

5. Timeline for NEEPHLD Consortium Grant Project Period September 30, 2013 through September 29, 2014 (Timeline for objectives are listed above.)

NEEPHLD Meetings: Each meeting will be a two-day session at a state location outlined below. Attendees will travel to the meeting and will require 1-2 overnight stays depending on the meeting location. Five meetings will take place during the grant year. Funds are expected to be awarded September 2013. Contract to be in place within 45 days of award. First NEEPHLD meeting will be held to discuss plans for the grant year and the contract. Contractor will attend meetings in October, December, February, May and August. Meeting attendees will include lab director and key staff members plus legal representative for a minimum of one of the meetings.

Meeting date	Meeting location
October 30-31, 2013	Connecticut State Public Health Laboratory 395 West Street

	Rocky Hill, CT 06067Rocky Hill, CT
December 4-5, 2013	Massachusetts Medical Society Headquarters 860 Winter Street Waltham Woods Corporate Center Waltham, MA 02451-1411
February 4-5, 2014	Massachusetts Medical Society Headquarters
May 7-8, 2014	Massachusetts Medical Society Headquarters
August 6-7, 2014	Massachusetts Medical Society Headquarters

By the end of the third meeting in February 2014, the Consultant will have completed meetings with each state laboratory. It is expected that these meetings will take place 2-3 states per visit at the scheduled NEEPHLD meeting either before or after the two day meeting.
Final report prepared September 2014

6. Staff (name/position/role/responsibility)

a.

Name:	Michael Pentella, PhD D(ABMM)
Position:	Director, MA Public Health Laboratory
Role:	Project Leader; NEEPHLD Consortium MA Member
Responsibility:	PH Laboratory Director
Name:	Dina Caloggero
Position:	Division Director, MA Public Health Laboratory
Role:	Director, Division of Informatics
Responsibility:	Public Health Informatics and LIMS integration
Name:	Sandra Smole, PhD
Position:	Division Director, MA Public Health Laboratory
Role:	Director, Division of Molecular Diagnostics and Virology
Responsibility**:**	Laboratory diagnostic testing

b. Curriculum vitae (attached)

c. Organizational Charts (attached)

a. Massachusetts Bureau of Laboratory Sciences Organization Chart is attached
b. NEEPHLD Consortium

7. Challenges to sustainability and how project could contribute to sustainability.

In the current environment of affordable and care and diminishing federal and state resources, the Massachusetts State Public Health Laboratory faces a significant number of challenges to assure our sustainability. The most critical resource at risk is staffing, which impacted by all these factors. A reduced workforce also compromises our capability to support the public health priorities of Massachusetts and our capability to contribute to a national public health laboratory system. Some examples of this are by increasing testing turnaround time and limiting development and use of new technologies, many of which originate from federal agencies. A loss of technical expertise often accompanies a reduction in staffing levels. This has a profound impact on providing improved methods for public health testing.

Massachusetts has a number of regulations that make it difficult or not possible to charge testing fees for isolates, specimens or samples submitted by local health departments, state agencies, law enforcement or from reportable diseases as specified by the department. Massachusetts also has restrictions on both charging and accepting fees for testing services from other states. This could have a significant impact on our ability to participate in a national public health laboratory system or regional consortium. Massachusetts will need assistance in evaluating how to best overcome this barrier.

A regional consortium for test sharing would provide a forum for Massachusetts and the participating states to make their operations more efficient by distributing certain public health tests to designated state laboratories based on skill and expertise, and willingness to assume testing responsibilities for the region. The best candidates for shared testing or services at this point seem to be low volume testing, for example, arbovirus serology. Another candidate category would be testing that requires a high degree of expertise, for example, whole genome sequencing. Participating states would no longer have the burden of acquiring the instrumentation, maintaining reagents, controls or proficiency testing for tests performed by the designated consortium member.

8. Performance Measures

To monitor progress and evaluate the impacts of this project, the consortium will maintain, and circulate minutes of meetings and conference calls and require the consultant to issue a written report of activities on a regular basis. The following metrics will be utilized to ensure the completion of grant deliverables as well as the overall success of the project.

8. a Performance measures to be used in assessing progress in implementing the project:
Has an agreed upon scope of work been established with the contractor?
Has the contract been signed by the contractor?
Have dates been set for all five NEEPHLD meetings.
How many states attended each of the NEEPHLD Consortium meetings?
Has the contractor met with appropriate staff at each of the member states to gather information?
Has the contractor produced a report of the data collected at the state laboratories and presented it to the NEEPHLD Consortia?
Have internal Work Groups been formed and assigned to Focus Areas?
Have Work Groups completed Interim Reports?
Has the Final Report been completed and reviewed by the NEEPHLD Consortium?

Has the final report been provided to the CDC and posted to the APHL web-site?

8. b Metrics to be used to evaluate the impact of the project.

The following metrics will be applied to assess the impact of each proposal's test and /or service:

Efficiency

Cost per reportable test result have been determined by each state performing the testing.
Cost-savings for shared tests at each participating state have been determined.
How many services are now being shared that previously were performed at all labs?
For each test, how many states are participating in the shared service?
Was it necessary to hire additional staff to take on the shared service? How many staff and how were they funded?
Were major investments necessary to upgrade the Electronic Reporting System? How much was spent?

Effectiveness and Service

Turnaround time statistics per test will be used to determine the effectiveness of the test service.
For examples, has there been an increase, or decrease and by how much?
If yes, has the increased turnaround time required by specimen transport had any negative implications for patient care?
Have there been delays in transport of specimens?
Have there been issues with the quality of testing performed? Have these been satisfactorily resolved?
Status of electronic laboratory reporting ability per test is to receive and send HL-7 compliant messages consistent with "meaningful use" guidance.

Sustainability

Indicators that a shared test or service will be maintained through calendar year 2018:
Have enough funds been saved that staff and supply money can be used to address shortages in other parts of the lab?
Did test sharing continue beyond the grant period?
Have there been issues with prioritization of testing when outbreaks occur in multiple states in the region covered by the Consortium?
Have issues of liability and indemnity been resolved?
Are there additional proposals for sharing of tests between member states?
Are staff from all eight member states continuing to attend NEEPHLD meetings?
Have any agreements been put in place between member states for Emergency Support?