APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Association of Public Health Laboratories
Peer Review Report
Pennsylvania Department of Environmental Protection Bureau of Laboratories
September 2011

The Association of Public Health Laboratories (APHL) was contracted to perform a peer review of the Department of Environmental Protection Bureau of Laboratories (DEPBL) to evaluate the facility and its capacity within identified priority areas. A three member APHL team, consisting of Dr. Eric Blank, APHL Senior Director, Public Health Systems; Dr. Michael Wichman, Associate Director at the University of Iowa – Environmental Health Programs; and Ms. Pandora Ray, APHL Director of the National Center for Public Health Laboratory Leadership conducted the site review.

The primary objective of this review was to identify organizational strengths and weaknesses that may have been impacted by budget deficits and staff reductions as well as identify core laboratory functions and policies to assure public health, environmental protection, and fiscal responsibility to the Commonwealth of Pennsylvania, the Department of Environmental Protection, and other laboratory clients served.

The on site assessment was conducted on September 28-30, 2011 and entailed an entrance interview, facility tour, staff interviews and discussion period, and presentation of preliminary findings during the exit conference.

A. **Efficiency Assessment** - Assure alignment of analytical services with the mission of the laboratory and proficiency of services. Evaluate the use of laboratory resources for optimization.

Observations: Customer/program driven – mission of laboratory aligned with customer needs or regulatory requirements. Lab has maintained or increased proficiency of services despite significant loss of staffing over past 5-7 years (101 FTEs to 76 FTEs or ~ 25% decrease). Cross training has been implemented to effectively utilize staff resources. The laboratory appears to have sufficient space for current activities with some space available for limited expansion if needed. The laboratory is clean and well organized. Analytical instruments are interfaced directly to laboratory information management system (LIMS) wherever possible and practicable.

Recommendations: The laboratory could realize limited efficiency improvement by installing gas manifolds to more than two cylinders which would result in some time savings and reduce frequency of changing gas cylinders. Interface program for data review may be at risk as TARGET application is unsupported and more than 10 years old.

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Developing a process for the laboratory to send out barcoded labels with testing information, e.g., client, tests, etc. would be beneficial and streamline sample accessioning upon receipt at the laboratory. A barcoded label would also assist in streamlining sample preparation and analysis.

B. **Laboratory Staff Workload Assessment** - Review environmental program needs for analytical services compared to FTEs and use of staffs' time when sample loads change. Review turnaround time for reporting results.

Observations: The laboratory has extensively cross-trained staff and successfully implemented a process to utilize staff time as sample load dictates across sections. The laboratory has established turnaround times should be based upon customer needs and expectations and not based upon EPA established holding times. Turnaround time is reasonable, 2-weeks for inorganics and 28 days for organics which is meeting client/program expectations. The laboratory is utilizing automated solid phase extraction techniques to assist in reducing organic method turn around times.

Recommendations: The 28 days for organics is a potential vulnerability for the laboratory if a customer is considering utilizing the commercial sector for services. The laboratory may want to develop strategies to reduce turnaround time for organics if the laboratory wants or needs to be competitive with the commercial sector

C. **Organizational Structure Assessment** - Review organizational structure with scope of technical, administrative, and management duties. Optimize efficiency with cross training and emergency response preparedness.

Observations: The current revised organizational structure has led to improved communication and ability to effectively cross train staff to meet sample load requirements.

Recommendations: . The proposed organization structure is functionally in place at the current time. To reduce span of control, the laboratory should consider consolidating some of the sections that report to the Director under Management Support. Once revisions have been considered and decided upon, the organizational structure needs to be formally approved. Be prepared to justify requested/anticipated changes in salary and grade regarding the Technical Director position so that compensation is appropriate for the position and its responsibilities

The laboratory needs to formally develop continuity of operations plan (COOP). Consider further developing relationships and partnerships with other state agency laboratories as part of the COOP development.

D. **Critical Support Functions** - Review of Quality Assurance Program and relationship to critical functions as well as quality assurance management for leadership.

Observations: The laboratory is accredited through the National Environmental Laboratory Accreditation Program (NELAP) by the New Jersey Department of Environmental Protection. The laboratory has developed an effective and operational quality management plan. Leadership has adopted and is committed to quality management. The laboratory is open to innovation and actively seeks opportunities to improve relationships and communication with environmental programs within the state and DEP.

Recommendations: Continue to assess operations in terms of continuous quality improvement. Develop process to communicate services that the laboratory provides through strategic or operational planning and consider implementing a laboratory system improvement program (LSIP) within the commonwealth. Evaluate key quality indicators and develop dash board/scorecard to track and communicate activities and status.

E. **Courier Transport Services** - Review sample transport which has a critical impact on the quality of services provided.

Observations: Commonwealth is to be commended for having and funding a system to rapidly transport samples to the laboratory.

Recommendations: The courier system appears to be working but requires constant oversight from the laboratory to ensure that client samples and coolers are delivered as needed. Performance clauses included in the courier contract may need to be enacted, as failure to deliver samples in a timely manner is impacting data quality and hindering laboratory's ability to meet program requirements and/or expectations. A timely resolution to courier issues is necessary to meet customer and public needs particularly during emergency situations and is critical to ensure quality laboratory services.

F. **Information Systems** - Review LIMS, SIS and data interoperability for reporting data to federal agencies in the event of an emergency.

Observations: The laboratory has installed and implemented a LIMS system which includes instrument interfaces that meets laboratory needs.

Recommendations: Data interoperability for transmitting data to federal, state and local agencies is a national issue. Continue involvement with APHL to address lack of consistent, rapid and secure system to electronically transmit data.

G. **Revenue Limitations** - Review the fee for service budget process and external revenue sources.

Observations: Key to fiscal success is the fact that state agencies and DEP programs utilize Bureau of Laboratories (BOL) for laboratory services.

Recommendations: The laboratory must continue to work with programs to ensure that the laboratory is funded to provide services necessary to meet regulatory requirements. Programs should consult with laboratory before making decisions on laboratory services needed to meet regulatory requirements. Laboratory costs are influenced by program use of the laboratory. The greater the use of the laboratory will lower ultimately lower unit costs which in turn will lower the testing costs to programs.

The laboratory should evaluate services and consider seeking grant opportunities to diversify revenue to reduce its vulnerability and reliance on program support. New work, e.g., tritium in urine, 1,4-dioxane and recent opportunities to work with the Department of Agriculture laboratory to determine pesticides in plant tissue are identified areas to increase diversity of services. However, this process of diversifying funding sources should be done within some business or strategic planning framework to assure that developing the technical capabilities in these areas of potential growth are linked to the laboratory's essential mission.

H. **Fiscal and Administrative Functions** - Review billing and laboratory accreditation revenue processing.

Observations: The laboratory has dealt well with revenue and staffing reductions. The laboratory is a recognized National Environmental Laboratory Accreditation Program (NELAP) Accrediting Body (AB). The laboratory accreditation is self-sustaining and growing. The laboratory is in the process of revising the Minnesota Department of Health Environmental Laboratory Data-Online (ELDO) system to meet Pennsylvania Commonwealth environmental laboratory accreditation regulations. A line item appropriation for services could reduce staff time in developing and processing billing; however, existing system is in place and appears to be working effectively.

Recommendations: The hourly rate system to assess costs is unique in our experience but appears to be functional and acceptable to the programs and fiscal administrators of the department. However, it is difficult to assess how competitive the laboratory's rates are relative to other local, state or commercial laboratories. If price competitiveness with other laboratories in any sector is a factor to be considered in the future, we recommend implementing a cost accounting system to determine cost per test. Investigate off-the-shelf programs or templates for this cost accounting process. Complete the revision and implementation of the environmental laboratory accreditation ELDO system to further streamline and realize efficiencies in the accreditation program.

I. **Technical Training and Workforce Development including Management and Leadership** - Evaluate the level of technical, management, and leadership training.

Observations: The laboratory has a developed a supportive and communicative organizational structure. The laboratory created a well-designed sampling manual to provide training to clients. The laboratory brought in Commonwealth human resources (HR) staff to train laboratory staff to improve staff teaching and outreach efforts.

Recommendations: Optimize HR training resources for staff training. Support training opportunities from national resources. Invest in staff exposure/participation in additional national training programs (get best training available regardless of location) for technical, management and leadership development. Develop a system to provide leadership and management opportunities for staff to develop workforce and address succession planning. Working with human resource staff, explore the possibility of a two-track career path. One path would lead to supervision and management; the other track would lead to highly skilled, trained and knowledgeable technical specialists.

J. **Instrumentation** - Determine availability and condition of laboratory equipment.

Observations: The laboratory is well equipped and automated systems have been installed for some analyses to optimize sample processing. Rapid techniques to assess potential exposure to biological contaminants at beaches utilize polymerase chain reaction (PCR) techniques. The laboratory is in the process of evaluating, implementing and validating these methods to provide these testing services. The laboratory has some funding to replace aging equipment and instruments. There are some areas of weakness in terms of instrumentation that restrict their ability to respond to client requests.

Recommendations: The laboratory has received requests for the determination of polychlorinated biphenyl (PCB) congeners which is best determined by gas chromatography coupled to a high resolution mass spectrometer system (GC/HRMS). To perform this testing the laboratory will need to acquire a GC/HRMS.

The laboratory has one, relatively recent Symbiosis PICO high pressure liquid chromatograph (HPLC) coupled to an Applied BioSystems Sciex 3200Q Trap tandem mass spectrometer (MS/MS) liquid chromatography tandem mass spectrometer (LC/MS/MS) instrument. LC/MS/MS is essential for the determination of emerging contaminants such persistent organic pollutants, pesticide degradates, pharmaceuticals, hormones, perflourinated compounds, etc. The laboratory may need to obtain additional, and more sensitive MS/MS instruments, such as the Applied BioSystems Sciex API 4000 or 5000 instruments, which are considerably more expensive than the 3200QTrap, but may be necessary to meet program needs and expectations in the future and also to provide the sensitivity needed to detect low levels of these compounds in the environment. Many biomonitoring methods for the detection of environmental contaminants or their human metabolites to assess actual exposure or dose utilize LC/MS/MS techniques.

Complete the implementation and validation of PCR methods as needed to meet program and regulatory requirements.

Although the laboratory has some funding to replace aging equipment and instruments, the funds may not be adequate, and the laboratory should develop a formal instrument replacement plan to evaluate and obtain new analytical instruments as needed.

K. **Client/Communications Services** - Review outreach to meet client needs, technical consulting and data reporting.

Observations: Customer outreach and breaking down barriers between programs is performed exceptionally well. They set up a facilitated planning session with programs and meet quarterly with DEP program offices to promote laboratory capabilities. Weekly reports are provided to executive staff. Internal communication seems effective. The laboratory director sets a very good example.

Recommendations: Develop an annual laboratory report to "tell the story" of the activities that the laboratory is involved in to share with programs, laboratory advisory committee, and state and federal legislators. Develop fact sheets or issue briefs to engage the public and legislature.

The laboratory advisory committee meetings are not well attended or effective. Consider performing an LSIP assessment to assess laboratory system within the Commonwealth. Consider strengthening the relationship with state and local laboratories to increase system understanding.

L. **Research/Development** - Review current efforts, impacts of budget deficits, and fit for strategic planning.

Observations: The Commonwealth DEP provided a Special Assistant to Laboratory Operations to help research, identify and implement additional activities that are beneficial to the Commonwealth. Programs have requested that the laboratory develop methods to determine specific contaminants such as PCB congeners and 1,4-dioxane. The laboratory is seeking to establish biomonitoring/bioassay testing which may require Clinical Laboratory Improvement Amendments (CLIA) certification in order to analyze clinical specimens.

Recommendations: Optimize resources to implement applied research program to meet client requests and pending regulations. Research activities need to be aligned to the mission of the laboratory (see our comments under "Revenue Limitations"). The special assistant to laboratory operations could be tasked with leading research activities of the BOL.

Evaluate and develop plan to implement testing services requested by the programs, e.g., PCR testing, isotopic methane, PCB congeners, 1,4-dioxane in environmental samples and tritium in urine and other testing as needs arise.

Exploring additional testing services, especially biomonitoring programs, may require CLIA licensing or review of study protocols by an Institutional Review Board. We recommend consulting with the Commonwealth's CLIA authority and the Commonwealth's State Public Health Laboratory (SPHL) to better understand the

requirements and to establish a working relationship with these entities to be better prepared to meet the requirements should they become applicable.

Conclusion:

The Department of Environmental Protection, Bureau of Laboratories is overall, a well managed, efficient, and highly functional laboratory. It is driven by a culture of customer service and appears to meet customer needs despite significant reductions in staff over the past several years. The laboratory facility is modern and capable of meeting the physical, mechanical and electrical needs of a highly automated and sophisticated analytical laboratory. It is one of the cleanest laboratories we have visited in our professional experience. We were impressed as well by the organizational culture which has enabled a very broad use of cross-training staff to meet seasonal or emergency situations that may result in a surge of samples. Their quality management system is embedded in their work and operational processes which assures a high degree of proficiency and quality of the work output and is reflected in their accreditation status under NELAP. They developed and implemented a sustainable, active accreditation program for environmental laboratories in the Commonwealth.

In general our recommendations are not "fixes" but rather a call for the laboratory organization to take the next step up from quality management to quality improvement of their organization. They have the leadership, the highly trained and motivated staff, and the facility and equipment to take that next step.

The APHL review team would like to thank the leadership team and staff of the laboratory for their time and participation in our review.

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