Bridges
Issue 9: Summer 2012
Connecting the Nation's Environmental Laboratories

Public Health and the Economy: Rhode Island's Water Microbiology Laboratory

By Henry Leibovitz, chief, Environmental Sciences, Rhode Island State Health Laboratories

Across America, public health and environmental programs rely on government laboratories to support their environmental protection and public health efforts. Program managers use laboratory results to make key decisions necessary to carry out their mission. The Water Microbiology Laboratory (WML) in the Rhode Island State Health Laboratories is an example of the impact one environmental laboratory has on public health and the state's economy.

With a staff of full and part-time scientists, the WML performs microbiological examination of water, shellfish, and dairy samples regulated by EPA and FDA. In 2011 alone, the laboratory performed analyses on more than 2,570 drinking water, 2,450 shellfish water, 2,720 beach water, and 2,230 dairy samples. These results are critical to the health and livelihood of the public, dairy farmers, the shellfish industry, and state tourism—a leading driver of the Ocean State's economy. When the WML reports its findings to the supported programs, it is providing the data necessary to determine if public and private well water, shellfish, beaches, and dairy products are safe. The state's public health and environmental management programs are quick to praise the role of the WML.

According to John Mullen, supervising environmental health food specialist in the Office of Food Protection, "Consumers and the state shellfish industry rely on safe shellfish harvested from certified harvest areas. These areas cannot be properly classified without reliable, accurate and timely results from the WML.

Left to right: Kerry Patterson, supervising clinical laboratory scientist; Rhodora Lafountain, clinical laboratory scientist; Terry Canulla, clinical laboratory scientist; Sonia Frias, senior technician; Emma Phillips, microbiology intern, WML

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Without the services of the lab, two shellfish wet storage business facilities dependent on the lab for mandatory, weekly verification testing would not exist, along with the 50-80 jobs and millions of dollars in revenue that they create."

Cindy Hannus, senior environmental scientist in the Rhode Island Department of Environmental Management, explained "the state's Shellfish Program is responsible for the sanitary condition and classification of all Rhode Island shellfish waters as one element of the statewide shellfish safety and sanitation program. In order to meet this obligation, the program routinely samples shellfish waters and submits those samples for analysis to the WML, the state's only US FDA certified laboratory. This laboratory service is an essential aspect of the state's shellfish program, without which the state's interstate shellfish industry could not operate."

Opening and closing public beaches in Rhode Island is also a decision based on the WML's findings. Amie Parris, beach monitoring program coordinator for the Department of Health, explained "the Ocean State has over 400 miles of coastline and hundreds of beaches, which are vital to the state's tourism and economy." Through a strong partnership and open communication with the WML, the program pursues its goal to protect public health, find and eliminate sources of contamination, and show the public that Rhode Island is a beautiful and pristine state in which to live or visit. Ms. Parris goes on to state "the WML provides the Beach Program with the most rapid testing methods available, automated electronic data entry, and a team of knowledgeable scientists always there to help. In turn, the Beach Program is able to open and close beaches within minutes of a sample result, protecting public health and ensuring beaches can reopen as soon as testing determines the water is safe."

Without the WML, there would be no opportunity to ensure a variety of products and activities are safe for the public. The laboratory works to maintain the public's trust while supporting the local economy.

EPA Grant Promotes Data Exchange in Alabama

By Jack Krueger, APHL informatics consultant

To address the public's growing interest in water contamination data, the Alabama Department of Public Health's Bureau of Clinical Laboratories (BCL) received EPA grant funding to promote environmental data exchange in their state. The BCL received this prestigious award through the 2011 National Information Exchange Network Grant Program.

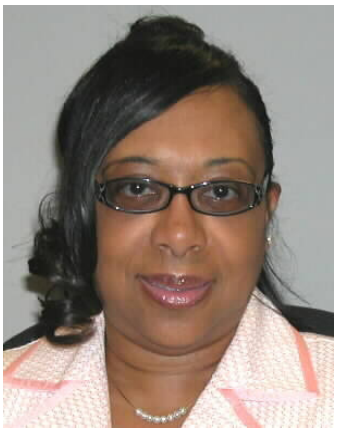
The BCL and the Bureau of Information Technology (IT) are using this funding to design and implement an electronic file transfer schema to facilitate data transfer from the BCL to the Alabama Department of Environmental Management (ADEM).

This system will be compatible with data requirements for both the Safe Drinking Water Information System (SDWIS) and the eBeaches data exchanges. The project's goals include:

- Reducing paperwork;
- Automating manual tasks;
- Simplifying accessibility to information; and
- Automating electronic data exchange of comprehensive laboratory data from a new Laboratory Information Management System (LIMS) to public health partners.

"This grant represents the forward thinking of the BCL to address not only standardized electronic data exchange but also the ability to link additional laboratory data to results."

-Dr. Mary McIntyre, assistant state health officer, acting state epidemiologist, Disease Control and Prevention, Alabama Department of Health



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In its project, ADEM is utilizing the Electronic Drinking Water Report (eDWR) format to support data transfer. The eDWR schema is broad enough to accommodate all types of water data, and allows states to customize implementation.

Current EPA reports seek only a small number of data elements from the laboratory. BCL envisions the ability to exchange linked quality control data elements, such as the date of the laboratory test, field-generated or laboratory-generated samples, target and nontarget substances, and important batching information, allowing data reviewers to verify and validate results.

The BCL is working closely with APHL to ensure that Alabama's efforts are also consistent with national goals to improve interoperability between laboratories. Interoperability allows multiple public environmental laboratories to network and support each other. Utilizing standardized data exchange, APHL seeks to build an environmental public health laboratory interoperability project (E-PHLIP) to network environmental laboratories, similar to the existing infectious disease laboratories.

Alabama's grant also reflects the importance of a strong partnership between the laboratory leadership, IT leadership, and the ADEM's Division of Drinking Water and Division of Coastal Programs. Dr. Sharon Massingale, the project manager and BCL director, has assembled a team that includes an IT manager, LIMS administrators, and an environmental laboratory team. Alabama's multi-disciplinary approach is an effort to increase transparency, accountability and increased efficiency in data reporting.

Pictured from left to right: Keith Higginbotham, IT systems manager; Angelica Webb, director of Water Division/Montgomery; Sharon Massingale, director of Bureau of Clinical Laboratories; Neelima Vundela, IT programmer; Marian Woodman, health services administrator; Ron Howard, senior microbiologist/LIMS administrator

WebEDR Delivers Time Critical High Quality Data

By Schatzi Fitz-James, EPA Office of Emergency Management, and Henry Leibovitz, chief, Environmental Sciences, Rhode Island State Health Laboratories

The collection and assessment of environmental data are increasingly complex tasks. EPA's Office of Emergency Management (OEM) maintains the Environmental Response Laboratory Network (ERLN) and coordinates with other EPA offices, whose networks, such as the Water Laboratory Alliance, actively participate in the ERLN. The purpose of the ERLN is to provide federal, state and local decision-makers with reliable, high quality analytical data used to identify chemical, biological, and radiological contaminants collected in support of response and cleanup activities.

APHL Training Alert

"Using WebEDR for Data Delivery and Review"
Course Number: 588-937-12
Access this free, archived course:
www.aphl.org/courses/Pages/100-937-12.aspx

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One of the challenges that laboratories face is the critical need to provide quality data under time-sensitive conditions. ERLN's answer to this challenge is the Web-based Electronic Data Review (WebEDR) tool, which automates the assessment of Electronic Data Deliverables (EDDs). WebEDR provides a web-based system for laboratories to upload data and for project personnel to review results. It uses a suite of user-customized tests to review data and provide results almost instantaneously. Once the automated assessment is complete, qualified results can be reviewed, edited, and downloaded in a variety of formats.

Most public and environmental health programs admit they do not have the resources or the training necessary to review, verify, or validate the laboratory data on which they base their decisions. WebEDR's flexibility and accuracy provides an efficient approach for laboratories to verify that their data meet the requirements of various programs, without investing additional resources. The verification that WebEDR provides gives program managers greater confidence in the decisions they make.

WebEDR's ability to assess EDDs accurately and efficiently has been tested during laboratory response exercises.

In the last two years, WebEDR activity included 87 laboratories participating in 11 different exercises. Exercise participants generated standardized data for a variety of methods and matrices and submitted data to WebEDR. These simulations tested the ability of WebEDR to incorporate and manage data from multiple sources and formats, and familiarized many state and federal laboratories with how to support data entry from their systems to WebEDR. This experience also guided next steps in WebEDR implementation and training. Consequently, many state and federal laboratories incorporated WebEDR into their internal processes with the goal of improving their efficiency and preparation for future events.

APHL and the ERLN created a free, publically available webinar about why data quality is important and how WebEDR manages the generation and review of quality environmental data. The training is available until March 9, 2013.

For access to the webinar, *Using WebEDR for Data Delivery and Review*, visit: www.aphl.org/courses/pages/100-937-12.aspx.

For more information, contact Schatzi Fitz-James at 202.564.2521 or fitz-james.schatzi@epa.gov.

Accreditation of State Environmental Laboratories

By Kenneth W. Jackson, program manager, The NELAC Institute

Most major commercial, environmental laboratories in the United States are accredited to a standard that includes all applicable clauses of ISO 17025. Despite international acceptance of ISO 17025 for quality systems in testing laboratories, few state environmental laboratories are accredited as such.

Many state primacy drinking water laboratories rely on the EPA Regions for certification. This article discusses why government laboratories might consider accreditation to one specific ISO-based standard: the National Environmental Laboratory Accreditation Program (NELAP).

NELAP Accreditation

The NELAP accredits environmental laboratories to The NELAC Institute's (TNI) 2009 standard, which incorporates ISO 17025 language plus requirements specific for environmental laboratories. Currently, 14 state governments serve as NELAP accreditation bodies. Collectively, they accredit over 1,600 commercial, state, and municipal (drinking water and waste water) laboratories. Of these NELAP-accredited facilities, 11 are state public health laboratories and 5 are state environmental laboratories. In addition, several hundred municipal laboratories have NELAP accreditation, with over 250 in New York alone.

EPA Regions are authorized to accept NELAP accreditation for drinking water primacy laboratories in lieu of EPA drinking water certification. However, NELAP accreditation involves fees, while EPA drinking water certification is provided at no cost. While EPA accreditation is the fiscally advantageous option, TNI argues that NELAP accreditation ensures a higher level of laboratory quality.

States are always permitted to exceed EPA standards, and NELAP provides an opportunity "to go above and beyond" through:

- Quality Manual and Quality System requirements using ISO 17025 as its basis;
- Detailed data integrity and ethics requirements;
- More frequent on-site assessments;
- Stricter Technical Director qualifications;
- A Quality Manager who reports directly to laboratory management;
- The Technical Director being responsible for data review;
- Requiring the laboratory to measure its uncertainty; and
- Providing accreditation for drinking water, waste water, solid waste, and air.

A joint TNI and APHL task force reviewed barriers identified by state principle laboratories related to NELAP accreditation. The group submitted some recommendations to TNI; including options to reduce accreditation costs as well as outreach efforts to overcome perceptions that the standards are complex and expensive.

Conclusion

State laboratories should remain aware of accreditation options. One opportunity is to obtain accreditation to a standard incorporating the ISO 17025 requirements (such as the TNI standard) for all testing performed, not only drinking water, but also waste water, solid waste, and air. For more information on NELAP accreditation, contact Kenneth Jackson at *518.899.9697, ken.jackson@nelac-institute.org or visit*: http://www.nelac-institute.org/newnelap.php.

2012 APHL ANNUAL MEETING &
6TH GOVERNMENT ENVIRONMENTAL LABORATORY CONFERENCE
May 20–23, 2012
Westin Hotel
Seattle, WA

Recap of the Laboratory Data Assessment Course

By Jack Krueger, APHL informatics consultant

On October 20, 2011, in Minneapolis, Minnesota, administrators, engineers, and scientists around the country gathered for a course on Laboratory Data Assessment. Sponsored by APHL's Environmental Laboratory Subcommittee, this one-day workshop provided participants with two consecutive sessions: (1) an overview of laboratory data, validation, and review and (2) a demonstration of WebEDR, EPA's web-based electronic data review tool. In partnership with the Association of State Drinking Water Administrators (ASDWA), the course was held at the conclusion of their annual meeting.

Led by Jack Krueger, an APHL informatics consultant and retired lab director, the first session covered topics about laboratory quality control and quality assurance, quality documentation (including accountability with certification to assure quality data), and components of data review and validation.

This session segued into the topic of electronic delivery and how the inclusion of measurement quality objectives supports automated data review. Gavin Gollehon, of CSC, demonstrated the ability of WebEDR to upload an electronic data deliverable and provide rapid automated data review of the data package in a live presentation. Mr. Gollehon demonstrated how both the laboratory and reviewer can submit data in different formats, validate data, change the review measurement quality objectives, edit qualifiers, and even export data in multiple formats.

Participant feedback from the course was very positive. Several commented on the importance of examples and stories to illustrate the complex details associated with documenting laboratory quality control and quality assurance. Particularly beneficial was the interaction between the presenters and audience. Attendees represented a wide range of backgrounds, which often resulted in the instructors "pausing" the presentation for 5-10 minute increments to allow dialogue between and among the attendees and instructors.

For more information on future environmental laboratory programs, visit http://www.aphl.org/training/teleconf/Pages/default.aspx.

2012 EPA Water Laboratory Alliance Forum

May 23, 2012, 1-4 pm
Westin Hotel, Seattle, WA

APHL is hosting the 2012 EPA WLA Forum following the Annual Meeting in Seattle, WA. We would like to invite you to learn more about the WLA. Attendees can expect to hear about WLA programmatic elements and laboratory tools developed to assist with responding to emergencies.

Registration for the Forum is free. See forum registration link on the Annual Meeting website, http://www.aphl.org/conferences/2012AM/Pages/default.aspx

Questions? Contact Michael Heintz, APHL environmental laboratory senior specialist, michael.heintz@aphl.org, or 240.485.2786.

Environmental Continuing Education and Training

Visit www.aphl.org/training to access all courses listed below and to search for more

Laboratory Ethics & Data Integrity: An Auditor's Perspective

Need annual environmental ethics training? This year, we will be looking at ethics training through an auditor's perspective. The program will focus on what an auditor looks for when evaluating data integrity and proper ethical conduct, tools that an auditor uses to uncover problems and how lab management can "think like an auditor" to evaluate their laboratory's practices and procedures.
Available: 4/3/12-9/20/12
Event Code: 909-12

LIMS Requirements for an Environmental Data Exchange Template

Environmental Data Exchange has become a cross cutting field that includes LIMS implementation, standardization of the multi-agency data collection requirements and the inclusion of quality control data in the submittal. Many laboratories are finding the creation of the electronic data message as time consuming as the actual analysis. This presentation will describe a recently proposed APHL Requirements Document for Electronic Data Exchange that defines a template for environmental data exchange. The requirements discussed are both matrix and programagnostic and are a recommended component for all environmental LIMS RFPs and data exchanges.
Available: 4/24/12-10/10/12
Event Code: 912-12

Traceability Series

The series is divided into three one-hour sessions to present the requirements for traceability for standards, reagents, samples, data, equipment, software and methods used in the laboratory. This series will review techniques for traceability and the elements needed for documentation as required by the TNI standard and recommended to provide efficient laboratory operation.

Standards and Reagents

Available: 3/20/12-9/6/12
Event Code: 907-12

Samples and Data

Available: 4/26/12-10/12/12
Event Code: 918-12

Equipment, Software and Methods

Original Program Date: 5/29/12
Available: 6/12/12-11/29/12
Event Code: 920-12

Contribute Today—Member Resource Center

The APHL Member Resource Center (MRC) provides an extensive range of resource materials designed to provide technical assistance within the public health and environmental laboratory sector. Created by and for the APHL member community, the MRC provides a virtual clearinghouse of documents designed to exchange practices, communications, protocols, state newsletters and more. The MRC assists APHL members in accessing timely, peer-contributed, public and environmental health information—rapidly and easily. These resources are not necessarily endorsed by APHL.

For more information, visit the MRC, http://www.aphl.org/MRC/Pages/default.aspx, and send questions/feedback to memberresources@aphl.org.

Examples of MRC resources include:

- Promising laboratory practices
- Media relations procedures
- Laboratory newsletters
- Human relations processes
- Laboratory testing protocols and guidelines
- Local fact sheets
- Energy management practices, and more

The APHL Member Resource Center is a vital instrument for the environmental laboratory community to remain knowledgeable in meeting today's challenges. To submit a resource item, please visit http://www.aphl.org/MRC/Pages/Submit.aspx.

Join APHL—an Association for Environmental Laboratory Leaders

APHL serves as a focal point for environmental laboratory communication, training, policy and interactions with the federal government.

An Associate Institutional membership with the Association of Public Health Laboratories offers environmental laboratory directors and their staff opportunities to connect with their counterparts from across the country to address shared issues and strengthen relationships with other health decision makers at the local, state and federal level.

Membership benefits include:

- Networking and laboratory linkages
- Professional development and training
- Policy and regulatory updates
- Technical assistance
- Unlimited access to APHL's Member Resources Center

For an application, visit www.aphl.org/becomemember.

New Associate Institutional members receive a discount of 50% their first year of membership.
Questions? Contact Drew Gaskins, associate specialist member services, at 240.485.2733 or drew.gaskins@aphl.org

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Contacts

Michael Heintz, environmental laboratory senior specialist
michael.heintz@aphl.org,
240.485.2786

Drew Gaskins, associate specialist member services
drew.gaskins@aphl.org,
240.485.2733

APHL

The Association of Public Health Laboratories is a national non-profit located in Silver Spring, MD, that is dedicated to working with members to strengthen governmental laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

8515 Georgia Avenue
Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
Web: www.aphl.org