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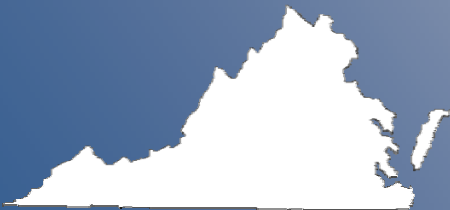


Commonwealth of Virginia

Virginia Laboratory Information Management System (LIMS)

Category

Government to Government



Nomination Submitted by

Samuel A. Nixon Jr.
Chief Information Officer
Commonwealth of Virginia
Virginia Information Technologies Agency

2010 Commonwealth of Virginia NASCIO Award Submission
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Project: Virginia Laboratory Information Management System (LIMS)

Executive Summary

The *Division of Consolidated Laboratory Services (DCLS)*, a division of the Virginia Department of General Services (DGS), was the first consolidated public health lab in the nation. DCLS scientists and staff provide laboratory support services for local, state and federal law enforcement; emergency response; health; and environmental protection programs. DCLS is at the core of the Commonwealth's public health system, linking the health infrastructure including food safety, disease control and prevention, and maternal and child health.

Previously, over 6 million annual scientific tests were performed without coordination. Requests were received on 40+ multi-part paper forms, each containing 45 pieces of metadata. Data was entered manually into a hundred disparate legacy systems. Lab results were reported on multi-part paper forms. Data standards were not enforced; there was no ability to query across applications. A technology scan identified numerous functional and technical gaps and opportunities for business process efficiencies.

An integrated, interoperable and comprehensive Laboratory Information Management System (LIMS) was fully implemented in September 2009 and now is used to process all samples. Orders are submitted electronically; results are delivered daily to public health agencies, hospitals, physicians and law enforcement agencies using a standard reporting format. Public health entities and regulatory agencies now easily use this data for outbreak management, disease treatment and prevention, surveillance, emergency response, and to satisfy legal and forensic inquiries. Data standards were adopted and system interoperability implemented. Ability to rapidly and securely disseminate lab results allows key decision makers in Virginia and nationally to act upon data to protect and improve population health, as recently observed during the H1N1 pandemic.

Enhancements include direct data transfer from lab instrumentation to LIMS, reducing data entry errors and allowing staff to focus on testing. Quality control and validation ensure compliance with best lab practices and regulatory requirements. Bar code technology pervasively tracks samples. Highly complex workflows and event-driven notification processes improve turn-around times and responsiveness. Maintenance and support are simplified through a common architecture. All data resides in a database configured for high availability and zero data loss in a secure server environment. Data now is securely exchanged for mapping, brokering and integration.

Multiple government entities collaborated based upon common business need. LIMS allowed DGS to realize a one-time savings of \$260,000; a 30% reduction in ongoing support costs is enabled. The agency also was able to reduce its operating budget by \$672,144 annually – critical in the current fiscal environment. Most importantly, technology wisely has been used to better enable the business of government.

Description of the business problem and solution

Multiple Paper-Based Forms: As the Commonwealth's state public health lab, DCLS performs analytical tests for a diverse customer base. One of the lab's largest customers is the Virginia Department of Health (VDH). VDH administers programs for disease prevention, surveillance, containment, treatment, pandemic response, and tracking of communicable and infectious disease outbreaks. Each program within VDH has its own unique data reporting requirements. As a result of this diversity, VDH was submitting over 40 different multi-part paper forms to request a clinical test. On average, over 1,200 multi-part forms were received and processed daily by the lab. Each form contained over 45 pieces of demographic information that was manually entered and then verified in the various legacy systems. This paper-based exchange of patient demographic and result data was cumbersome, inefficient, error prone, labor intensive, and required significant manual data entry by both the lab and VDH.

Multiple Disparate Systems: Within each lab at DCLS, there were over 100 disparate legacy systems used for sample tracking and result reporting. Systems were built on various technology platforms that were non-standards based, non-integrated, not secure, and maintained by non-IT staff who worked within the lab. Lack of a comprehensive, integrated LIMS posed many challenges for the DCLS Application IT support group. There was no ability to reuse common system components, cross-train developers on a common tool-set, audit transaction level events, monitor data and system access, ensure data security and integrity across the enterprise, or provide a proactive and cost-effective maintenance and support process or disaster recovery strategy. For laboratory users, there were no options for querying across the lab enterprise, developing instrument interfaces, automating quality control checks or implementing e-mail notifications.

Lack of Data and Technology Standards: Due to lack of data and technology standards across the multiple legacy systems, receiving or transferring data internally and externally required a manual translation of data to a format that could be consumed by each separate system.

Business Technology Solution

Leverage Existing Resources: Rather than gather and pass requirements to a vendor, a decision was made to train in-house developers and build a customized LIMS. This training allowed IT staff to gain critical knowledge of laboratory practices and workflow processes. This knowledge transfer not only saved time and money; it positioned the team to provide on-site support and ensure continuity of operations for a mission-critical application.

Create the Right Team: With strong project support from DGS management and user buy-in, the LIMS Project Team was created, comprised of highly skilled IT professionals and DCLS subject matter experts (SME). To undertake such a large and specialized

project, Information Systems Services (ISS) needed to understand the business aspect and requirements of the lab. Therefore, the DGS ISS team was co-located at DCLS where they worked closely with SMEs to develop customized workflows for analysis performed by the microbiology, immunology, molecular detection and tuberculosis laboratories.

Define Requirements; Engage Users: While assessing system requirements, it became obvious no two labs handled or tested samples the same way. However, by engaging users, DCLS was able to find areas of commonality, including processes such as receiving samples in the lab and approving results. Analytical workflows were developed based on lab-specific algorithms and Good Laboratory Practices (GLP). Quality control checks were defined and implemented to ensure compliance with regulatory requirements, such as Clinical Laboratory Improvement Amendments (CLIA).

Implement Business Process Efficiencies: With patience and planning, DCLS consolidated 40 different multi-part forms into two sample submission forms, and as many different reporting formats into two standardized reports. Electronic test order submissions significantly reduce data entry and error handling. Bar code technology is used to uniquely identify each specimen and facilitate sample receiving, tracking, storage, and retrieval. Worksheets and reports also are bar-coded to prevent data entry errors and allow scanning of sample data into instruments. Sophisticated integration processes allow users to directly import data from instruments into the LIMS. Standard and ad hoc query reporting capabilities, from a single LIMS system, has improved management and performance measurement of operational activities at DCLS.

Implement Data and Technology Standards: Adoption of data and technology standards in the LIMS enhanced interoperability with other applications and external partner agencies to expand information sharing and electronic messaging capabilities. DCLS eliminated redundant data entry through use of bar code technology and integration with Web applications, and improved overall efficiency of business processes through automation of common workflows and instrument integration.

Use the Right Tool for the Job: In 2005, DCLS purchased the Rhapsody tool to advance the lab's electronic data exchange capabilities and provide accurate and secure exchange of electronic data. Rhapsody is comprised of three core components: message broker, data integration engine, and a mapping tool. Its use allowed DCLS to move toward standards-based messaging with external public health partners, where data is mapped from the LIMS to message formats using industry-accepted vocabulary and coded value sets. These actions promoted system interoperability with public health partners, such as the Centers for Disease Control and Prevention (CDC) and VDH, and also provided a foundation for expanding the lab's messaging capabilities.

Enhance Pandemic and Emergency Response Capabilities: DCLS and VDH collaborated to develop a framework for exchanging critical and sensitive information for state-declared communicable disease and food-borne outbreaks. This data previously was communicated to the laboratory via phone call or paper submission form from VDH.

Now, VDH electronically sends outbreak notifications to the lab. This data is parsed, validated, and loaded by Rhapsody into the LIMS. An e-mail notification is sent from Rhapsody to all members of the lab outbreak team informing them of the new outbreak. At the end of an outbreak, a summary of all samples and the associated results is generated and electronically sent to VDH. This process has become a key tool in the Commonwealth's ability to rapidly respond to pandemics, such as H1N1, and has assisted the state epidemiologist in the rapid identification of food borne illnesses, such as Salmonellosis and *E. coli* infection.

Adopt Enterprise Architecture: The application architecture facilitates the development and ongoing maintenance and support of the LIMS. All workflow processes within the LIMS are built using the same development and reporting tool set, share a common data integration engine and data mapper, employ enterprise application architecture and reside in a common database. The LIMS was developed using the v9 version of the StarLIMS development tool, which is proprietary to the vendor and runs from within a single CITRIX environment. The database schemas reside within a common Oracle RAC database which is configured for high availability, no data loss, and advanced security options. This configuration also facilitates and simplifies the laboratory's continuity of operations plan in case there is a need to switchover/failover to a COOP CITRIX farm and standby database server.

Significance

Supporting multiple customized software solutions for similar applications can prove challenging and costly. By leveraging new technology, every facet of lab operations has been incorporated into a single comprehensive LIMS. The new LIMS is founded on a common framework and uses nationally recognized data and technology standards, which promote system integration and interoperability with both internal and external partners. Numerous business process efficiencies were attained throughout the lab by harmonizing analytical workflow processes, integrating instrumentation with the LIMS, expanding electronic data exchange capabilities, and building application-level validation that enforces regulatory compliance and the use of laboratory best practices.

As the LIMS evolved, DCLS adopted nationally-recognized data and technology standards for public health IT messaging. In March 2008, DCLS was the first state public health lab in the nation to electronically send Influenza surveillance data to the CDC using nationally adopted data and vocabulary standards in an HL7 compliant message format. The data was then used by CDC epidemiologists and partner pharmaceutical companies to develop a vaccine for H1N1.

Based on current technical and analytical capabilities, DCLS was selected by the federal government as one of the first state public laboratories to test human specimens for evidence of exposure to chemical weapons. DCLS serves as Virginia's confirmatory laboratory for CDC's national Laboratory Response Network and is the PulseNet Regional Laboratory for the Central Atlantic states. DCLS is a member of the Food Emergency Response Network and the Radiation Emergency Analytical Laboratory

Network and provides emergency analytical support for Virginia, neighboring states and other federal agencies in response to public health and environmental threats.

The LIMS project closely aligns with each of five goals of the [Commonwealth Strategic Plan for Information Technology](#). It also closely aligns with NASCIO's State CIO priorities, including *strategies* of consolidation, shared services, budget and cost control, security and e-discovery and *priority technologies* including content management, unified communications, identity and access management and business intelligence.

Benefit of the project

Enhanced Professional Development of IT Staff: The DGS IT Application Support team was trained on the LIMS application development toolset and on how to code using the vendor's proprietary language. This training resulted in a highly skilled IT staff not only knowledgeable about the applications they support, but also educated in laboratory practices and terminology. By shifting a significant portion of the application development work to trained in-house staff, a one-time project cost savings of \$260,000 was realized. This savings was attributable to the difference in the vendor's billable hourly rate of \$250 versus an actual bill rate for the DGS IT application support team of \$58 per hour.

Automated Paper-Based Processes: DCLS worked closely with VDH to reduce the number of paper-based forms and automate the electronic submission of laboratory test orders. As of December 2009, approximately 85% of the Commonwealth's 100+ local health departments are electronically transmitting nightly test orders to DCLS. Rhapsody serves as the data integration engine and is used to parse, validate, and load test order data into the LIMS. This automated process eliminates data entry by the lab and facilitates specimen receipt by pre-logging samples into the LIMS. Error handling is also built into this process, which is used to provide electronic notification for samples that have not been received and/or contain missing or erroneous data. Reduction in data entry efforts resulted in an annual cost savings of \$390,000 for contractual services. The savings are reflected in the lab's operating budget for this fiscal year.

Improved Sample Turn Around and Result Reporting: DCLS partnered with VDH epidemiologists, environmental health specialists, and over 30 animal control officers across the Commonwealth to establish a process within the LIMS to generate an e-mail notification when positive rabies results are detected. Using the new process, within 24 hours of sample submission, an automated e-mail notification is generated from the LIMS and sent to VDH Rabies Control for corrective action. Previously, rabies results were not available for at least 48 hours. Improvements in the sample turnaround time have allowed primary care physicians to more rapidly treat patients exposed to rabies.

Reduced Sample Analysis Time: Prior to the new LIMS, it took an average of 35 minutes per instrument run to enter and verify sample test results. Now, instrumentation integration is used to automatically load these results into the LIMS. This eliminates data entry errors and allows lab staff to focus on the science related to

their testing and not data entry tasks. This equates to a savings of 18 man hours per day, or \$147,600 annually. This savings has been realized and is reflected in the lab's operating budget for this fiscal year.

Enhanced Lab Capacity and Capabilities During an All Hazards Event: IT staff now can develop a new analytical workflow in the LIMS within eight hours. This capability is required to process and report samples of unknown origin that are received from public health outbreaks, biological or chemical terrorist attacks or natural disasters. Past efforts required over 40 development hours to implement new test workflows and reports. During the H1N1 pandemic, the DGS Application IT support team leveraged this ability and developed a highly configurable workflow in less than eight hours. This new workflow facilitated high volume processing of influenza samples, was integrated with instrumentation, and provided for the timely reporting of results to the Commonwealth's Pandemic Response Team and CDC.

Facilitated Maintenance and Support: By standardizing application architecture, co-locating all data into a single database, employing CITRIX for application access, adopting commonly used development tools, using Rhapsody as the data broker and data mapping tool, enforcing development standards and adopting the Commonwealth's security standards, DCLS has reduced the level of effort and ongoing support costs by over 30%.

Improved Quality Control and Assurance: New technology enhanced the lab's error detection capability by storing pertinent quality control data in the LIMS and alerting laboratories when results fall outside a pre-defined limit. This capability reduced the number of man hours previously spent reviewing spreadsheets to detect errors and document corrective actions. These enhancements resulted in a savings of 1,642 man hours or \$52,544 annually. This savings has been realized and is reflected in the lab's operating budget for this fiscal year.

Enhanced Ability to Monitor Performance Metrics: Enhanced query capability allows management to readily calculate work time units, sample turn around times, perform capacity planning, forecast revenues, track projects, and monitor quality control checks to ensure compliance with regulatory requirements. This new capability represents an annual savings of \$82,000 in management time spent gathering data and compiling results for monthly and quarterly reporting. This savings has been realized and is reflected in the lab's operating budget for this fiscal year.