

National Voluntary Laboratory Accreditation Program (NVLAP)  
Workshop on Development of a Health Information Technology Accreditation Program

April 26, 2011

Meeting Summary

**Welcome**

Sally Bruce, NVLAP Chief, welcomed all attendees to the workshop and provided a few opening remarks. Dr. Larry Knab served as the moderator for the meeting and provided a brief overview of the day's agenda of events.

**Office of the National Coordinator**

Dr. Carol Bean, Director of Certification and Testing with the Office of the National Coordinator, gave a brief overview of the temporary program for testing and certification of health information technology. As of December 2010, six authorized testing and certification bodies are presently recognized in the temporary program. It was also noted that there are 600+ products listed on the Certified Health IT Products List (CHPL).

The Office of the National Coordinator has requested that the National Voluntary Laboratory Accreditation Program develop an accreditation program for the testing laboratories recognized within the permanent program. It was noted that the temporary program would remain in effect until such time as the permanent program was developed and laboratories were accredited through this permanent program.

**NVLAP Program Development Process**

Dana Leaman, Program Manager for NVLAP in the Information Technology Security Testing area, gave a presentation on the program development process that NVLAP is required to follow per Part 285 of Title 15 of the U.S. Code of Federal Regulations. The intent of the workshop was conveyed as an opportunity for those in attendance to share their comments and/or concerns with NVLAP regarding the development of the accreditation program. The importance of open participation was stressed to the attendees as the comments collected would be used in the development of the overall Health Information Technology (HIT) Laboratory Accreditation Program (LAP) and its associated documents.

The next steps in the development of the accreditation program were outlined regarding the development of a program-specific handbook and application materials for the HIT LAP. Tentatively, NVLAP expects to announce opening the program with the acceptance of applications beginning January 1, 2012.

**NIST Technical Program**

Lisa Carnahan, NIST Computer Scientist, gave a presentation on the development of the "ONC Approved Test Method" (set of all test procedures, test data, and test tools) as well as application of the method for the testing of electronic health record technology. The Approved

Test Procedures, version 1.1, are the currently approved test procedures. These procedures are noted as Stage 1 procedures, are the basis of the NVLAP HIT LAP, and are available on line at: [http://healthcare.nist.gov/use\\_testing/effective\\_requirements.html](http://healthcare.nist.gov/use_testing/effective_requirements.html)

## **Overview of NVLAP**

Dana Leaman presented topics on accreditation and NVLAP. NVLAP was established in 1976 as a U.S. Government entity administered by the National Institute of Standards and Technology (NIST). NVLAP is a fee-supported program that operates in accordance with *ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*. The NVLAP accreditation requirements for its programs are set forth in *NIST Handbook 150:2006: Procedures and General Requirements*. This document incorporates the requirements found in Sections 4 and 5 of *ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories*.

## **Details of NVLAP Accreditation Process**

Topics on the NVLAP Accreditation Process were presented by Dana Leaman outlining the steps in the general accreditation process. Additional details will be developed for the HIT LAP; however, much of the general information presented is applicable. The topics included the application process including definition of the scope of the accreditation, the activities prior to the on-site assessment, the on-site assessment, any proficiency testing activities and the accreditation decision process.

As part of the application process, the fees associated with the program were reviewed. Presently, these fees would include an application fee, an administrative technical fee and an on-site assessment fee. General amounts were discussed; however, all were reminded that these fees are evaluated on an annual basis and are subject to change each fiscal year. Any fee changes are communicated to all laboratories in the NVLAP system once the need for changes is known.

Also discussed were the accreditation periods. A period of one year is granted with the accreditation of a laboratory. Prior to the expiry date issued on the laboratory's scope of accreditation during the first year of accreditation, a laboratory is required to undergo another complete on-site assessment. This on-site assessment is to evaluate the on-going system in place at the accredited laboratory to build confidence in the laboratory's ability to maintain the management system as well as the technical competence to perform the tests on the scope of accreditation. Upon successful completion of this on-site assessment process, the on-site assessment visits are then conducted every two years unless other visits are deemed necessary due to significant changes at the accredited laboratory. Any need for additional on-site assessment visits are reviewed on a case-by-case basis.

## **Review of Scope of the Program - Larry Knab**

Dr. Larry Knab reviewed the current methods being considered for inclusion on the HIT LAP scope of accreditation. It was noted that the technical criteria for NVLAP HIT LAP is being developed from the Approved Test Procedures, version 1.1 which are based on the meaningful

use technical requirements found in §170.302, §170.304, and §170.306 of 45 CFR Part 170, dated July 28, 2010.

Currently, NVLAP will establish a scope of accreditation that will include nine **mandatory** security testing procedures which include Sec 170.302 (o, p, q, r, s, t, u, v, and w). All nine will be required on the scope of accreditation for any laboratory applying in the HIT LAP and the applicant laboratory must demonstrate competence to perform these testing procedures.

Other listings being considered for the scope of the accreditation in the HIT LAP are EHR testing encompassing all test procedures, ambulatory EHR testing, inpatient EHR testing, and modular EHR testing. Some concerns with the terminology of “complete” EHR testing were shared and it was determined that additional consideration would be needed on how to capture the breadth of this testing on an applicant’s scope of accreditation. Suggestions of “ambulatory and inpatient” and “combined ambulatory and inpatient” were noted. Further review of the information is needed prior to the development of the formats for the scope and test procedure selection list..

#### **Overview of Sections 4 and 5 of NIST Handbook 150**

An overview of Sections 4 and 5 of NIST Handbook 150 was provided. These sections cover the general requirements for accreditation of testing and calibration laboratories. Section 4 is specific to Management requirements and Section 5 is specific to Technical requirements. In each clause area, concerns that might require more specific requirements related to the HIT program were discussed.

Of particular importance were topics on appropriate separations for laboratories performing both testing and certification, any subcontracting of the testing activities, retention period for records, completed internal audit prior to accreditation, completed management review prior to accreditation, testing being performed in the “cloud” and any additional security measures that might be necessary, use of contractors, working from remote locations, use of equipment outside of the testing laboratory’s control, monitoring of feedback to detect trends, and a standard reporting format.

Further review of these topics will be considered with the development of the HIT program specific handbook.

#### **Open Discussion**

No additional topics were introduced.

## Attendees List:

Name	Organization
Alderman, David	NIST/SSG
Bean, Carol	HHS/ONC
Bean, Nina	Federal Working Group
Beth Thomas, Beth	NVLAP
Bruce, Sally	NVLAP
Carnahan, Lisa	NIST/SSG
Clay, Chad	Deloitte Consulting LLP
Emard, Ellen	NIST/SSG
Figueiredo, Reinaldo	ANSI
Gebhart, Ken	NIST/ITL
Glickman, Mike	NVLAP Assessor
Hammond, Bob	Federal Working Group
Horlick, Jeffrey	NIST/SSG/NVLAP Contractor
Jariwala, Aditi	Surescripts
Johnson, Asara	HHS/ONC
Kalina, Larry	Surescripts
Kennemore, Wes	Association of Public Health Labs
Knab, Larry	NVLAP Contractor
Leaman, Dana	NVLAP
Mapps, Traci	SLI Global Solutions
McBrearty, John	Precision Measurements
Moon, Joony	Deloitte Consulting LLP
Moore, Brad	NVLAP
Morrow, Beth	Drummond Group Inc
Phelps, Amy	NIST/ITL
Quan, Ross	ANSI
Ray, Alisa	Certification Commission for HIT
Remala, Srinath	The St John Group, Consultant to APhL
Richmond, Hazel	NVLAP
Rose, Bambi	Certification Commission for HIT
Shin, Mark	InfoGard
Trivedi, Amit	ICSA Labs
Yencha, Bob	NVLAP Assessor