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NVLAP Health Information Technology Testing

Bradley Moore
National Voluntary Laboratory Accreditation Program
Standards Coordination Office
Laboratory Programs

Asara Clark
Health IT Certification Program
The Office of the National Coordinator for Health Information Technology (ONC)
Health and Human Services (HHS)

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personnel exercising use of the ONC-approved test tools either under the assessors' direct observation or through a written exam.

c) Demonstration of correct use and/or development of test data for use in testing. The laboratory shall demonstrate that all appropriate personnel, including those performing testing, understand test data use and operation. This shall be demonstrated by laboratory personnel exercising use and/or development of test data either under the assessors' direct observation or through a written exam.

d) demonstration of an understanding and correct interpretation of all data and test results reported by the test tools or reported in the course of implementing appropriate test procedure(s). This shall be demonstrated by laboratory personnel during an assessment under the assessors' direct observation or in response to a request from NVLAP.

e) demonstration of report generation of accurate results in an approved format. This shall be demonstrated by laboratory personnel exercising use of the laboratory's report generation process either during the assessment under the assessors' direct observation or by written request from NVLAP.

3.4.3 Proficiency testing analysis and reporting

Information regarding proficiency testing (PT) analysis and reporting may be found in section 3.4.3 of NIST Handbook 150.

3.4.4 Proficiency testing nonconformities

Information regarding proficiency testing (PT) nonconformities may be found in section 3.4.4 of NIST Handbook 150.

3.5 Accreditation Decision

There are no requirements additional to those set forth in NIST Handbook 150.

3.6 Granting Accreditation

It is important to note that the laboratory is granted initial accreditation after it has effectively implemented the management system, produced appropriate records of all management system activities, including conducting at least one internal audit and one management review, and successfully completed the initial Proficiency Testing (PT) exam/activity.

3.7 Renewal of accreditation

There are no requirements additional to those set forth in NIST Handbook 150.

3.8 Monitoring visits

There are no requirements additional to those set forth in NIST Handbook 150.

3.9 Changes to the scope of accreditation

There are no requirements additional to those set forth in NIST Handbook 150.

3.10 Adverse accreditation actions (suspension, revocation)

3.10.1 Reasons for suspension or revocation of a laboratory's accreditation may include, but are not limited to:

a) Failure to appropriately address and resolve complaints from customers or other interested parties.

b) Loss of key personnel without immediate adequate replacement;

c) New personnel prove to be unqualified for authorized testing;

d) The facilities become inadequate to support testing;

e) Failure to demonstrate continued competence to perform Health IT conformance testing.

3.10.2 All issues surrounding the need to suspend and/or revoke a laboratory's accreditation are reviewed on a case-by-case basis by NVLAP.

NOTE Laboratories are subject to the provisions of the "ONC Health IT Certification Program: Enhanced Oversight and Accountability" Final Rule.

4 General requirements

4.1 Impartiality

There are no requirements additional to those set forth in ISO/IEC 17025.

4.2 Confidentiality

There are no requirements additional to those set forth in ISO/IEC 17025.

NOTE See 3.1.2 for information related to ONC access to laboratory accreditation records.

5 Structural requirements

There are no requirements additional to those set forth in ISO/IEC 17025.

6 Resource Requirements

6.1 General

There are no requirements additional to those set forth in ISO/IEC 17025.

6.2 Personnel

6.2.1 The testing laboratory shall retain responsible, competent personnel who are knowledgeable and capable of demonstrating competencies in the ONC Health IT Certification Program regulations and test methods listed in section 1.4.

6.2.2 The testing laboratory shall have staff members with at least a bachelor's degree in computer science, information systems, or similar technical discipline or equivalent experience – such as three years experience – in the area of health IT testing, health IT interoperability, health IT standards and technologies, and events relevant to health IT.

6.2.3 The laboratory's training program shall be relevant to health IT testing, health IT standards, technologies, and events relevant to health IT testing. The laboratory shall document its training program including, at a minimum, the ONC Health IT Certification Program regulations and test methods listed in section 1.4 of this handbook.

In addition, the laboratory shall also participate in required training as directed by the ONC Health IT Certification Program. (§ 170.524(b)).

6.3 Facilities and environmental conditions

Where there are no physical testing locations, the laboratory shall ensure that the requirements of ISO/IEC 17025, section 6.3 shall be met when conducting testing of health IT.

6.4 Equipment

The laboratory may install and maintain a locally controlled installation of the ONC-approved testing tool(s) to produce test results. Local instantiations shall be validated in accordance with section 7.2 and demonstrate that they achieve the same results as the ONC-designated hosted tools.

6.5 Metrological traceability

The testing laboratory shall ensure:

a) management system documentation is in place to trace localized test scripts and test data back to the ONC-Approved Test Method.

b) local installations of the test tools are documented and traceable back to the ONC-Approved Test Method.

c) where permitted, laboratory or developer-supplied test data meet the functional and interoperable requirements identified in the certification criteria and can be adequately evaluated for conformance.

NOTE For health IT testing, traceability is interpreted to mean that the ONC-Approved Test Method (test procedures, test tools, and required test data) shall be traceable back to the underlying requirements of the ONC health IT certification criteria requirements in the applicable section(s) of 45 CFR Part 170.

6.6 Externally provided products and services

There are no requirements additional to those set forth in ISO/IEC 17025.

7 Process Requirements

7.1 Review of requests, tenders and contracts

There are no requirements additional to those set forth in ISO/IEC 17025.

7.2 Selection, verification and validation of methods

There are no requirements additional to those set forth in ISO/IEC 17025.

7.3 Sampling

There are no requirements additional to those set forth in ISO/IEC 17025.

7.4 Handling of test or calibration items

There are no requirements additional to those set forth in ISO/IEC 17025.

7.5 Technical records

There are no requirements additional to those set forth in ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

There are no requirements additional to those set forth in ISO/IEC 17025.

7.7 Ensuring the validity of results

7.7.1 Laboratories shall demonstrate and document on-going activities to maintain their proficiency in health IT to ensure no methods are compromised during execution.

7.2.2 The laboratory shall have satisfactorily participated in all required proficiency testing (PT) during its previous accreditation period or prior to accreditation being granted, if initial accreditation.

NOTE Required PT will be identified on the program page on the NVLAP website. If the laboratory performs unsatisfactorily in any proficiency test, the laboratory shall take corrective action to investigate and resolve nonconformities in a timely manner according to the requirements of ISO/IEC 17025 for the control of nonconforming work. (See also section 3.5 of this handbook).

7.8 Reporting of results

7.8.1 Common requirements

Testing laboratories shall document the specific laboratory or developer-supplied test data utilized for testing, when applicable.

7.8.2 Reporting opinions and interpretations

7.8.2.1 Whenever test procedures are such that an analysis of the observations is required in order to interpret the results before stating them in a test report, the laboratory shall have a defined process to ensure that the repeatability, reproducibility, and objectivity of the test results can be maintained.

7.8.2.2 The testing laboratory shall have and maintain a policy for handling interpretations of test results.

7.9 Complaints

There are no requirements additional to those set forth in ISO/IEC 17025.

7.10 Nonconforming work

The laboratory's procedure shall ensure that when nonconforming work is identified and recalled for an ONC-ACB (Authorized Certification Body) certified product that is listed on the Certified Health IT Product List (CHPL), the laboratory shall immediately notify NVLAP, ONC, and any associated certification bodies, as well as the developer, in writing.

7.11 Control of data and information management

There are no requirements additional to those set forth in ISO/IEC 17025.

8 Management system requirements

8.1 Options

There are no requirements additional to those set forth in ISO/IEC 17025.

NOTE No distinction is made during the assessment of laboratory management systems under §8.1.2 Option A or §8.1.3 Option B for conformance to the Health IT LAP; laboratory management systems under Option B must, at a minimum, meet all the requirements of Option A and this handbook.

8.2 Management system documentation (Option A)

The laboratory shall create a cross-reference document that facilitates verification that all program requirements, including scheme (regulatory) requirements, have been addressed by the management system, which includes clauses 4 through 8 of ISO./IEC 17025, annexes A, B, and E of NIST Handbook 150, and NIST Handbook 150-31.

8.3 Control of management system documents (Option A)

There are no requirements additional to those set forth in ISO/IEC 17025.

8.4 Control of records (Option A)

The laboratory shall retain all records as defined in 170.524(f) Records retention.

8.5 Actions to address risks and opportunities (Option A)

There are no requirements additional to those set forth in ISO/IEC 17025.

8.6 Improvement (Option A)

There are no requirements additional to those set forth in ISO/IEC 17025.

8.7 Corrective actions (Option A)

Should a nonconformity(s) be identified regarding a product tested within the laboratory, the laboratory shall initiate its corrective action process to investigate the validity of the test results issued. If further actions are warranted as a result of this investigation process (e.g., it was determined that the test results are not correct or the laboratory deviated from its testing process), those actions shall be taken in accordance with the laboratory's management system.

8.8 Internal Audits (Option A)

There are no requirements additional to those set forth in ISO/IEC 17025.

8.9 Management Review (Option A)

There are no requirements additional to those set forth in ISO/IEC 17025.

Annex A

(informative)

Acronyms and abbreviations

The following acronyms and abbreviations are used throughout this handbook:

CFR	Code of Federal Regulations
CHPL	Certified Health Information Technology Products List
EHR	Electronic Health Record
HHS	Department of Health and Human Services
Health IT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	Information Technology
LAP	Laboratory Accreditation Program
MRA	Mutual/Multilateral Recognition Arrangement
NIST	National Institute of Standards and Technology
NPRM	Notice of Proposed Rulemaking
NVLAP	National Voluntary Laboratory Accreditation Program
ONC	Office of the National Coordinator for Health Information Technology
RWT	Real World Testing

Annex B

(normative)

Additional conditions for accreditation in the Health Information Technology (Health IT) Laboratory Accreditation Program (LAP)

The National Voluntary Laboratory Accreditation Program (NVLAP) established and is conducting its laboratory accreditation program for health information technology testing laboratories in support of the responsibilities for NVLAP-accredited testing under the final rule published in 45 CFR Part 170 dated January 7, 2011.

Under the NVLAP Healthcare Information Technology Laboratory Accreditation Program (Health IT LAP), NVLAP evaluates the competence of laboratories to test the services and/or products related to electronic health information (health IT) products and systems. In support of its regulatory program, the Office of the National Coordinator (ONC) has determined access to review the accreditation records for laboratories in this accreditation program is needed.

As the Authorized Representative for _____(*laboratory's name)*, Lab Code _____, I grant NVLAP permission to the sharing of my application for accreditation information, as well as any records collected by NVLAP in support of my laboratory's accreditation activities. The laboratory information shared by NVLAP with the ONC representatives will be limited to access to the laboratory's information that is maintained at the NVLAP offices at NIST in accordance with NVLAP policies and procedures for record retention.

Signature _____ Date _____

Printed Name _____