

## Withdrawn NIST Technical Series Publication

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#### Withdrawn Publication

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<b>Latest revision of the attached publication</b>	
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**NIST HANDBOOK 150-31**  
2017 Edition

**National  
Voluntary  
Laboratory  
Accreditation  
Program**

**HEALTH  
INFORMATION  
TECHNOLOGY  
TESTING**

Dana Leaman  
Brad Moore

This publication is available free of charge from:  
<https://doi.org/10.6028/NIST.HB.150-31-2017>

**NIST**  
**National Institute of  
Standards and Technology**  
U.S. Department of Commerce



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**HEALTH  
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Dana Leaman  
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*National Voluntary Laboratory Accreditation Program  
Standards Coordination Office  
Laboratory Programs*

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July 2017



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National Institute of Standards and Technology  
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## Foreword

The NIST Handbook 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series is comprised of the following publications:

- NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;
- NIST Handbook 150-xx program-specific handbooks, which supplement NIST Handbook 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP laboratory accreditation programs (LAPs).

The program-specific handbooks are not stand-alone documents, but rather are companion documents to NIST Handbook 150. They tailor the general criteria found in NIST Handbook 150 to the specific tests, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-31, *NVLAP Health Information Technology Testing*, presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Health Information Technology (HIT) LAP. The handbook is intended for use by accredited laboratories, assessors conducting on-site visits, laboratories seeking accreditation, laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under this program. All statements in this handbook are meant to supplement NIST Handbook 150 and by no means contradict it. If any ambiguity unintentionally arises, the NIST Handbook 150 requirements are to be followed.

The July 2017 edition of NIST Handbook 150-31 was developed with the participation of technical experts in the field of health information technology testing and is approved by NVLAP. This handbook incorporates the information and requirements found in ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, NIST Handbook 150, the Office of the National Coordinator (ONC) Health IT Certification Program, and test procedures, test tools and test data associated with this program. The requirements of NIST Handbook 150, the interpretations and specific requirements of NIST Handbook 150-31, and requirements set forth by technical standards have been combined to produce the criteria for accreditation in the NVLAP HIT LAP.

The July 2017 edition of the NIST Handbook 150-31 supersedes and replaces the November 2011 edition.

This handbook is also available on the NVLAP web site, <<https://www.nist.gov/nvlap>>.

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: [nvlap@nist.gov](mailto:nvlap@nist.gov).

## Introduction

NIST Handbook 150-31 augments NIST Handbook 150, *NVLAP Procedures and General Requirements*, by gathering technical requirements of the laboratory accreditation program (LAP) for functional and conformance testing of health IT capabilities to regulatory requirements of the ONC Health IT Certification Program. Technical requirements are explained to indicate how NVLAP criteria are applied for accreditation under the HIT LAP.

Any domestic or foreign laboratory (including commercial; manufacturer; academic; and federal, state or local government laboratories) that performs testing covered by the HIT LAP may apply for NVLAP accreditation. Accreditation will be granted to a laboratory that complies with the conditions for accreditation as defined in NIST Handbook 150. Accreditation does not imply a guarantee of laboratory performance or of test results; it is a finding of laboratory competence and proficiency in conducting testing.

The testing services related to this health IT accreditation program are defined by the “Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology,” Title 45 *Code of Federal Regulations*, Part 170, 2010 ed. (see 1.4 for related references).

This publication is available free of charge from: <https://doi.org/10.6028/NIST.HB.150-31-2017>

# 1 General information

## 1.1 Scope

**1.1.1** This handbook specifies the technical requirements and provides guidance for the accreditation of laboratories under the NVLAP Health Information Technology (HIT) LAP. It supplements the NVLAP procedures and general requirements found in NIST Handbook 150, by tailoring the general criteria found in NIST Handbook 150 to the specific tests and/or types of tests covered by the HIT LAP.

**1.1.2** NIST Handbook 150, this handbook, Office of the National Coordinator for Health Information Technology (ONC) certification regulations, and ONC approved test procedures, test tools and test data associated with this program constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation for the HIT LAP.

**1.1.3** Any interpretive comments and additional requirements contained in this handbook complement the general NVLAP criteria for specific application in the HIT LAP.

## 1.2 Organization of handbook

The numbering and titles of the first five clauses of this handbook are patterned after NIST Handbook 150 to allow easy cross-reference. The primary subclauses in clauses 4 and 5 (e.g., 4.1, 4.2, etc.) are also numbered and titled to correspond with those of NIST Handbook 150, even when there are no additional requirements to those in NIST Handbook 150.

Annex A (informative) provides a list of acronyms and abbreviations used in this handbook. Annex B (normative) contains provisions to which it is necessary to conform in order to claim compliance with the handbook requirements.

## 1.3 Program description

**1.3.1** In response to the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, the U.S. Department of Health and Human Services along with ONC requested establishment of the Health Information Technology (HIT) LAP by NVLAP to accredit laboratories that perform technical and conformance testing of health information technology to ONC regulatory requirements. See 1.4, References, for a complete list of currently accepted standards.

**1.3.2** NVLAP reserves the right to expand the HIT LAP and offer to interested laboratories additional testing not listed in this handbook. Laboratories are advised to review the HIT LAP's website for the most current information, <<https://www.nist.gov/nvlap/hit-lap.cfm>>.

**1.3.3** The HIT LAP offers accreditation for all active editions of ONC Certification Criteria. Depending on the breadth of its testing capabilities, the applicant laboratory may select a scope of accreditation to an entire certification edition (e.g., 2014 Edition, 2015 Edition), or to a subset of a certification edition.

For additional information regarding the scope of accreditation available for selection in this program, please contact [nvlap@nist.gov](mailto:nvlap@nist.gov).

## 1.4 References

### Publications referenced in this handbook

The following documents are referenced in this handbook. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) shall apply within one year of publication or within another time limit specified by regulations or other requirement documents.

- “Certified Health IT Product List (CHPL),” Office of the National Coordinator for Health Information Technology; available online at <<https://healthit.gov/chpl>>.
- “Establishment of the Permanent Certification Program for Health Information Technology; Final Rule,” *Federal Register* (7 January 2011): 1262-1331 (to be codified at 45 CFR Part 170); available online at <<https://www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf>>.
- “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule,” *Federal Register* (28 July 2010): 44590-44654 (codified at 45 CFR Part 170); available online at <<https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17210.pdf>>.
- “Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology,” Title 45 *Code of Federal Regulations*, Part 170 (2010 ed.): 873-890; available online at <<https://www.gpo.gov/fdsys/pkg/CFR-2010-title45-vol1/pdf/CFR-2010-title45-vol1-part170.pdf>>.
- “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology; Final Rule,” *Federal Register* (4 September 2012): 54163-54292 (codified at 45 CFR Part 170); available online <<https://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>>.
- “Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule,” *Federal Register* (28 July 2010): 44314-44588 (codified at 42 CFR Parts 412, 413, 422, and 495); available online at <<https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf>>.
- NIST Handbook 150: 2016, “NVLAP Procedures and General Requirements”; available online at <<https://www.nist.gov/nvlap>>.
- ONC-Approved 2014 Edition Test Method (effective December 14, 2012); available online at <<https://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>>.
- ONC-Approved 2015 Edition Test Method (effective Jan 29, 2016); available online at <<https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method>>.
- ONC Health IT Certification Program: Enhanced Oversight and Accountability (effective December 19, 2016); available online at <<https://www.federalregister.gov/documents/2016/10/19/2016-24908/onc-health-it-certification-program-enhanced-oversight-and-accountability>>.

- “2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange”, *Federal Register* (11 September 2014): 54430-54480 (codified at 45 CFR Part 170); available online <<https://www.gpo.gov/fdsys/pkg/FR-2014-09-11/pdf/2014-21633.pdf>>.
- “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule”, *Federal Register* (16 October 2015): 62602-62759 (codified at 45 CFR Part 170); available online <<https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25597.pdf>>.

## 1.5 Terms and definitions

For the purposes of this handbook, the terms and definitions given in NIST Handbook 150 apply unless a term is redefined in this handbook. The definitions provided in this handbook are specific to the HIT LAP, and when applicable, they supersede the definitions given in NIST Handbook 150. For a list of acronyms, see Annex A.

### 1.5.1

#### test data

data used to verify that a given set of inputs to a given function produces the expected result.

### 1.5.2

#### test method

the set of ONC-approved test procedures, test tools, and test data used for evaluating conformance of health IT to regulatory requirements, technical requirements, and standards as approved by ONC.

### 1.5.3

#### test procedure

the ONC-approved testing document used to guide testing laboratories as they conduct health IT testing in the ONC Health IT Certification Program, to provide traceability from the certification criterion or criteria to testing activities, and to ensure consistency throughout the certification process.

### 1.5.4

#### test tool

A software tool used to perform automated testing of specific functionality or conformity to requirements.

## 1.6 Program documentation

### 1.6.1 General

This handbook details the HIT-program-specific requirements and technical procedures, while interpreting, detailing, and expanding portions of NIST Handbook 150 for HIT LAP use. Both the NIST Handbook 150 checklist and the NIST Handbook 150-31 checklist are used in conducting an assessment in the HIT LAP. Assessor use of the NVLAP checklists is to ensure that each laboratory receives an assessment comparable to that received by other laboratories. Checklists assist assessors in documenting the assessment to NVLAP requirements found in NIST Handbook 150 and in this handbook. Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation, and form part of the on-site assessment report (see NIST Handbook 150). The current version of each checklist is available upon request or on the NVLAP website, <<https://www.nist.gov/nvlap>>.

## **1.6.2 NIST Handbook 150 Checklist**

All NVLAP programs use the NIST Handbook 150 Checklist, which contains the requirements published in NIST Handbook 150. The checklist items are numbered to correspond to clauses 4 and 5 and Annexes A, B, and E of NIST Handbook 150. The current version of the checklist is available from NVLAP upon verification of ownership of ISO/IEC 17025.

## **1.6.3 NIST Handbook 150-31 Checklist**

The NIST Handbook 150-31 Checklist (also referred to as the HIT program-specific checklist) addresses the requirements specific to health information technology testing given in NIST Handbook 150-31. The checklist contains the requirements provided in this handbook, including testing requirements, and additional details and notes for the assessors (e.g., the names of the key personnel), with an emphasis on observing test performance, accuracy, instrumentation, calibration, personnel competency, and reporting. The current version of the checklist is available from the HIT LAP website, <<https://www.nist.gov/nvlap/nvlap-checklists.cfm>>.

## **1.6.5 NVLAP Lab Bulletins**

NVLAP Lab Bulletins are issued to laboratories and assessors, when needed, to clarify program-specific requirements and to provide information about program additions and changes.

# **2 LAP establishment, development, and implementation**

## **2.1 Basis for establishment**

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

## **2.2 Development of technical requirements**

All technical requirements mandated for a laboratory under accreditation tailor the requirements discussed in clauses 4 and 5 which are derived from the elected scope of accreditation and associated testing for which a candidate requests accreditation.

## **2.3 Announcing the establishment of a LAP**

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

## **2.4 Adding to or modifying a LAP**

Upon identifying the need for additional tests or test types, NVLAP reserves the right to add or modify the HIT LAP either by adding new subsidiary programs or new test procedures to existing programs, or modifying the existing test procedures. All changes will be published in a timely manner in a NVLAP Lab Bulletin and will be reflected on the NVLAP website, <<https://www.nist.gov/nvlap>>.

## **2.5 Termination of a LAP**

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

### 3 Accreditation process

#### 3.1 General

An overview of the laboratory accreditation process is provided in NIST Handbook 150, clause 3, and includes general information pertaining to application for accreditation; activities prior to on-site assessment; on-site assessment; proficiency testing; accreditation decision; granting accreditation; renewal of accreditation; changes to scope of accreditation; monitoring visits; suspension, denial, and revocation of accreditation; voluntary termination of accreditation; and appeals.

The flowchart in Figure 1 describes the accreditation process for a laboratory seeking accreditation for the HIT LAP.

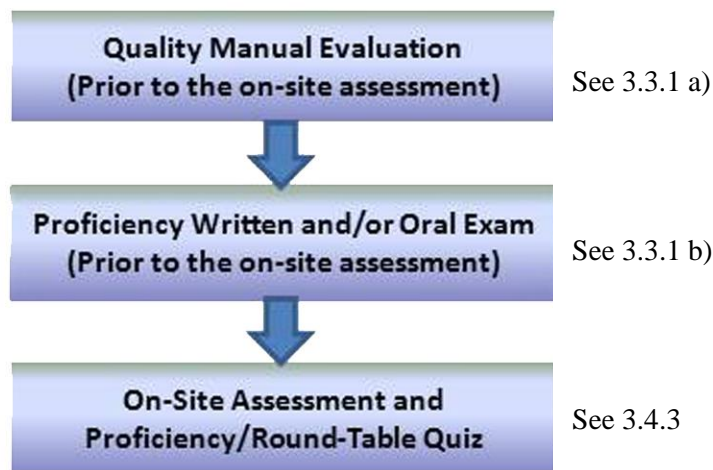


Figure 1. Accreditation process flowchart.

#### 3.2 Application for accreditation

**3.2.1** The accreditation process begins with the submission of the laboratory's application, including supporting documents, and payment of fees. A laboratory interested in accreditation for any type of test offered under the HIT LAP shall review and become familiar with the requirements listed in NIST Handbook 150 and this handbook, review the HIT LAP website at <https://www.nist.gov/nvlap/hit-lap.cfm>, and contact NVLAP for the most current updates on the requirements and application process.

**3.2.2** Prior to applying to NVLAP, the laboratory shall have a fully implemented quality management system. The quality manual and related documentation shall contain or refer to documentation that describes and details the implementation of procedures covering all of the technical requirements in NIST Handbook 150 and this handbook. A copy of the quality manual and related documentation shall be sent to NVLAP with the application forms.



### 3.3 Activities prior to on-site assessment

**3.3.1** Once NVLAP determines that an application is complete, the next steps are evaluation of the laboratory's quality manual and associated documentation and administration of the proficiency written/oral exam, as needed.

a) *Quality manual evaluation*

NVLAP reviews the laboratory quality manual and associated documentation and determines whether the quality management system meets requirements. Nonconformities and recommendations for quality management system enhancements will be discussed during the on-site assessment. However, if the quality manual and documentation are evaluated as unsatisfactory, the on-site assessment will be postponed.

b) *Proficiency written and/or oral exam*

For an initial accreditation, after it is determined that the quality manual meets the minimum requirements of NIST Handbook 150 and this handbook, a written exam may be provided to the applicant laboratory depending upon the intended scope of accreditation. This exam evaluates the laboratory personnel's technical expertise and knowledge of the standards and test procedure(s) applicable to the scope of accreditation for which the laboratory is applying. In some instances, an oral exam may be necessary to demonstrate proficiency. A technical assessor(s) and/or expert(s) from the associated technical program conducts this exam via a teleconference with the laboratory personnel prior to the on-site assessment.

**3.3.2** It is important to note that a laboratory applying for initial accreditation cannot proceed to the on-site assessment phase of the accreditation process until successful completion of the quality manual evaluation and the proficiency written and/or oral exam. For all applicants, the on-site assessment is not scheduled until it is determined that the quality management system meets the requirements found in NIST Handbook 150 and this handbook.

### 3.4 On-site assessment

#### 3.4.1 General

**3.4.1.1** The on-site assessment is scheduled by NVLAP at a mutually agreed-upon date and time at the laboratory facility. The time span for the assessment is dependent upon the applicant's scope of accreditation. Typically, the assessment will span two to three days and will be performed by two or more NVLAP assessors. All observations made by the assessors during the assessment are held in the strictest confidence.

**3.4.1.2** In addition to the NIST Handbook 150 checklist, the assessors will use the HIT program-specific checklist (NIST Handbook 150-31 Checklist), which is derived from the technical criteria contained in this handbook.

**3.4.1.3** Additionally, the assigned assessors shall evaluate any new or updated requirements that are documented in a NVLAP lab bulletin and on the HIT LAP's website, <<https://www.nist.gov/nvlap/nvlap-healthcare-information-technology-lap>>, but are not yet incorporated into the checklist.

### 3.4.2 On-site assessment activities

The on-site assessment activities include:

- a) an evaluation of the laboratory staff's understanding of relevant experience and competence to apply the health IT conformance testing methodology;
- b) an evaluation of the exercised quality management system and associated records of all quality management system activities;
- c) a demonstration, for the selected test(s), that the required set of tools and test procedures are available and the testing environment is adequate (e.g., space, security, separation, and storage); and
- d) a demonstration, if required, of the competence of the laboratory staff to prepare and use test tools, which will include loading, configuring, and running of the tools; preparing test reports; and performing updates, if necessary.

During the on-site visit, the laboratory's personnel will be evaluated and team dynamics observed for proficiency and expertise in the technical area(s)/specific criterion(a) for which the laboratory is applying for accreditation. Staff member interaction and knowledge distribution among team members are key factors that will be monitored by the technical assessors and/or technical expert(s). Laboratory staff shall provide satisfactory evidence and responses that demonstrate sufficient knowledge to support the scope of accreditation.

### 3.4.3 Agenda

The agenda for a typical on-site assessment is given below.

- a) *Opening meeting:* During the on-site visit, the assessors conduct an entry briefing with laboratory management and supervisory personnel to explain the purpose of the on-site assessment and to discuss the schedule for assessment activities. Information provided by the laboratory on the accreditation application form may be discussed during this meeting. At the discretion of the laboratory manager, other staff may attend this meeting.
- b) *Staff interviews, discussions, quizzes:* The assessors will ask the laboratory manager to assist in arranging times for individual interviews with laboratory staff members and/or proficiency evaluation of staff. While it may not be necessary for the assessors to talk to all staff members if individual interviews are requested, they may select staff members representing all different aspects of the laboratory. If proficiency evaluations are to be conducted on-site, all members of the relevant staff shall be scheduled to participate. Also, after the completion of the evaluation and/or individual interviews, further interviews may be requested.
- c) *Records review:* During the on-site visit, the assessors will also review the laboratory's documentation, including, but not limited to:
  - organizational structure;
  - contract review records;
  - purchasing records;
  - equipment and maintenance records;
  - laboratory test records/reports;

- personnel competency evaluation records;
- personnel training records including, but not limited to, training plans, areas of training, and training materials; and
- version of the test tools and/or other test program-specific software.

Laboratory staff shall be available to answer questions; however, the assessors may wish to review the documents alone. Under some circumstances, the assessors may remove some documents from the laboratory during the assessment. Specifically, the assessors may remove for review documents related to the quality management system, such as a revised quality manual or new procedures. The material will be returned or destroyed at the laboratory's direction.

The assessors will check personnel information for job descriptions, resumes, training records, and technical performance reviews. The assessors shall not be given information that violates individual privacy such as salary, medical information, or individual performance reviews outside the scope of the laboratory's accreditation. At the discretion of the laboratory, a member of its human resources department (or equivalent) may be present during the review of personnel information.

- d) *Internal audit and management review:* The laboratory shall perform a complete internal audit and management review of its quality management system and related management system records prior to the full on-site assessment visit. The assessors will review and discuss the laboratory's internal audit and management review activities with the laboratory staff. The discussion will include all aspects of those activities including the quality management system procedures, the audit findings, the results of the management review, and the actions taken to resolve any problems identified.
- e) *Equipment:* The assessors will examine test procedure-specific computer hardware, software, supporting test equipment, and facilities for appropriateness, capability, adherence to specifications, etc.
- f) *Laboratory walk-through:* The assessors will inspect the laboratory in the following areas during a walk-through:
  - physical layout of the laboratory including entrance and exit points;
  - all test equipment and tools, including computer hardware, servers used for records retention, and physical storage areas;
  - work environment in regard to providing adequate testing work space (including adequate separation of work activities as appropriate or by programmatic requirement), heating, lighting, etc.; and
  - physical security including access control procedures and records.
- g) *Proficiency evaluations:* Although a written examination may be provided prior to the initial on-site assessment, any group evaluations and/or individual interviews/demonstrations conducted during an on-site assessment are considered part of the proficiency evaluation.
- h) *Closing meeting:* At the end of the on-site visit, a closing meeting is held with the laboratory manager and staff to discuss any nonconformities documented by the assessors during the visit. See NIST Handbook 150, 3.3.3 for more information regarding the assessment report, nonconformities, and the final resolution.

### **3.4.5 On-site assessment report**

The assessors complete the on-site assessment report that summarizes the findings. Copies of the completed checklists are attached to the report at the closing meeting. The report is signed by the assessors and the laboratory's authorized representative. The original report and checklists are forwarded to NVLAP as required by NIST Handbook 150, 3.3.2.3. A copy of the report and a copy of the checklists are given to the laboratory representative for retention. The decision to grant or renew accreditation is not made by the assessment team but is made by NVLAP in accordance with the procedures described in NIST Handbook 150.

### **3.4.6 Nonconformities, comments, and recommendations**

**3.4.6.1** A nonconformity that has been corrected during the on-site assessment by the laboratory using its corrective action process and any recommendations will be specifically noted on the on-site assessment report by the assessors. The assessors will also note how the nonconformity was resolved and attach a copy of the objective evidence supporting the actions taken.

**3.4.6.2** Comments in the report should be given serious consideration by the laboratory, but no action is mandated and changes are made at the laboratory's discretion. Comments are those areas of concern where a nonconformity may arise; however, no objective evidence is available to support citing a nonconformity. Historically, it has been noted that comments often rise to the level of nonconformities on subsequent assessments. As such, comments noted in the assessment will be reviewed at the next on-site assessment to ensure that these issues have not risen to the level of nonconformities since the previous on-site visit.

**3.4.6.3** Positive feedback will also be recorded in the on-site assessment report.

**3.4.6.4** Upon completion of the on-site assessment and corrective action responses to nonconformities, if any, the accreditation process ends with NVLAP's decision regarding the laboratory's accreditation.

## **3.5 Proficiency testing**

### **3.5.1 General**

**3.5.1.1** Proficiency testing for this program may include written examinations, oral examinations, and evaluation of artifacts. Generally, proficiency testing may be expected when a change in the certification criteria is published.

**3.5.1.2** The laboratory will be informed of any proficiency testing schedules developed for the HIT LAP. When a proficiency testing schedule is published, participation in the proficiency testing is mandatory for laboratories accredited in the program.

### **3.5.2 Types of proficiency testing**

NVLAP follows ISO/IEC 17043 for the types of proficiency testing used within the HIT LAP, therefore, the LAP's proficiency testing may consist of, but not be limited to, one or more of the following exercises:

- a) Demonstration of a solid background, knowledge, and technical expertise in the area of the test procedures for the scope of accreditation. For this demonstration, the laboratory shall be provided

with a proficiency evaluation exam to be completed by appropriate personnel including all those performing testing.

- b) Demonstration of correct identification and use of any ONC-approved test tools. The laboratory shall demonstrate that all appropriate personnel, including those performing testing, understand the test tools and/or component use and operation. This shall be demonstrated by laboratory 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 on-site 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 on-site assessment under the assessors' direct observation or by written request from NVLAP.

### **3.5.3 Analysis and reporting**

When a proficiency test is initiated, the pre-defined criteria for the test will be communicated to all laboratories participating in the test. Results of the proficiency testing will be reviewed and analyzed by appropriate technical experts based on pre-defined criteria for the proficiency test. Analysis of results as well as scoring will be conducted using a rubric model that will be developed when proficiency test is initiated. Upon completion of scoring, results are reported to laboratories by NVLAP.

### **3.5.4 Proficiency testing nonconformities**

Problems resulting from the outcome of any proficiency testing will be discussed with appropriate laboratory personnel responsible for developing and implementing plans for resolving the problems. For nonconformities identified through proficiency testing, the laboratory shall resolve the nonconformities in order to attain and/or maintain accreditation.

## **3.6 Suspension of accreditation**

**3.6.1** Failure to appropriately address and resolve complaints from customers or other interested parties may result in a NVLAP surveillance activity and/or suspension or revocation of accreditation.

**3.6.2** Significant changes in a laboratory's key technical personnel or facilities may result in a NVLAP monitoring visit(s), and/or suspension of accreditation of the affected testing on the scope of accreditation if the new personnel prove inadequately prepared or unsuited for the job or if the facilities are inadequate

to support the testing. Loss of key personnel without immediate adequate replacement may result in suspension of the laboratory's accreditation for the testing affected by the loss of key personnel.

**3.6.3** If the laboratory does not demonstrate continued competence to perform HIT conformance testing, NVLAP may suspend or revoke the laboratory's accreditation.

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

## **4 Management requirements for accreditation**

### **4.1 Organization**

If any services are offered by the laboratory other than the testing defined in the HIT scope of accreditation, the laboratory shall have a policy and procedure for maintaining separation of those services from its testing activities. The procedure shall describe how separation is maintained. As an important example, if testing and certification are conducted in the same organization, the organization shall develop and implement policies and procedures to maintain separation of these functions.

### **4.2 Quality management system**

The laboratory shall create and maintain a cross reference document mapping clauses 4 and 5, annexes A, B, and E of Handbook 150 and clauses 4 and 5 of NIST Handbook 150-31 to the laboratory's management system documentation.

### **4.3 Document control**

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

### **4.4 Review of requests, tenders, and contracts**

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

### **4.5 Subcontracting of tests and calibrations**

Subcontracting of testing is the use of laboratory testing services outside of the HIT laboratory's quality management system to perform the tests. When unforeseen circumstances occur, any subcontracted tests (within the laboratory's scope of accreditation) shall be performed by a laboratory accredited under the NVLAP HIT LAP and recognized by the ONC.

### **4.6 Purchasing services and supplies**

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

#### **4.7 Service to the customer**

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

#### **4.8 Complaints**

The laboratory shall maintain a log of all complaints received regarding its testing activities. The log shall include information regarding the content of the complaint as well as activities for resolution of the complaint.

This log shall be provided to NVLAP and ONC at least on an annual basis or upon request.

#### **4.9 Control of nonconforming testing and/or calibration work**

If any nonconforming work is identified and recalled for an ONC-ACB (Authorized Certification Body) certified product which 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 vendor, in writing.

#### **4.10 Improvement**

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

#### **4.11 Corrective action**

Should a violation(s) be issued from ONC regarding a product tested within the laboratory, the laboratory shall exercise 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 quality management system.

#### **4.12 Preventive action**

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

#### **4.13 Control of records**

All records shall be maintained for the life of the certification edition plus a minimum of five years, unless other regulatory requirements specify a longer retention period.

#### **4.14 Internal audits**

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

#### 4.15 Management reviews

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

## 5 Technical requirements for accreditation

### 5.1 General

The quality manual shall contain or refer to documentation that describes and details the testing laboratory's implementation of the procedures covering all of the technical requirements in this handbook.

### 5.2 Personnel

**5.2.1** The testing laboratory shall retain responsible personnel and competent technical staff who are knowledgeable and capable of demonstrating competencies in the following (see the list in 1.4 for complete citations):

- “Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology,” 45 CFR Part 170: In relation to health IT standards including transport, privacy, security, messaging, ePrescribing, quality, content-related standards as well as vocabularies and code sets found in sections §170.202, §170.204, §170.205, §170.207, and §170.210 of 45 CFR Part 170;
- Active editions of certification criteria found in sections §170.314 and §170.315 of 45 CFR Part 170;
- Development of test data in accordance with the ONC-Approved Test Method objectives, as applicable; and
- ONC-Approved Test Method including the associated test procedures, tools, and data.

**5.2.2** The laboratory's training program shall be relevant to health IT testing, health IT standards, and technologies, and events relevant to health IT testing.

The laboratory shall have a detailed, documented description of its training program for new and current staff members. Current staff members shall receive additional training when test procedures are modified or developed, when responsibilities have changed, or when technical requirements within the certification criteria have been modified or expanded. The training shall include applying the new test procedures, performing required tests, and developing any test data needed for a given test procedure. The training shall be conducted through either on-the-job training, formal classroom training, or another appropriate training mechanism.

The testing laboratory shall ensure adequate training for laboratory staff as identified below. Personnel shall possess knowledge of, or be trained prior to accreditation in the following areas as appropriate to their role and the requirements in the scope of accreditation (see the list in 1.4 for complete citations):

- All requirements of the ONC-Approved Test Method(s);
- Related health IT standards including: Health Level Seven (HL7) Version 2 messaging and associated implementation guides; HL7 C-CDA and required document templates; direct specification;



- Health IT standards and interoperability concepts and requirements in accordance with 45 CFR Part 170;
- Health IT security and privacy concepts and requirements in accordance with 45 CFR Part 170;
- Health IT terminology in accordance with 45 CFR Part 170;
- Health IT standards found in sections §170.205, §170.207, and §170.210 of 45 CFR Part 170; and
- Operation of ONC-approved test tool(s), and the interpretation of the associated test results from the tool(s) used for testing in accordance with the ONC-Approved Test Method.

**5.2.3** The testing laboratory shall maintain a list of the key personnel designated to satisfy the technical requirements within this document, including their assigned roles and a brief summary of their latest training qualifications. The list shall include, but is not limited to:

- Authorized representative;
- Laboratory director;
- Approved signatories; and
- Key technical personnel in the laboratory (including team leaders and testers).

The list shall also identify the individual(s) knowledgeable and deemed competent in the following areas: HL7 V2, HL7 C-CDA and document templates, privacy/security, general health informatics domain, and ePrescribing.

All testing laboratory staff having an effect on the outcome of testing shall be treated as personnel regardless of their employment status. This includes, but is not limited to, full-time employees, temporary employees, and contracted subject matter experts.

**5.2.4** The testing laboratory shall identify a staff member as quality manager with overall responsibility for quality assurance and maintenance of the quality manual. An individual may be assigned to serve in more than one position; however, to the extent possible, the laboratory director and the quality manager positions should be independently staffed.

The quality manager shall be knowledgeable in all aspects of ISO/IEC 17025.

**5.2.5** 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.

The laboratory shall have a competency review program and procedures for the evaluation and maintenance of competency of each staff member for the specific test procedure(s) the staff member is authorized to conduct. The evaluation shall be conducted annually by the immediate supervisor or designee appointed by the laboratory director. A record of the evaluation shall be dated and signed by the employee.

Changes to key personnel shall be reported to NVLAP within 30 days. Notification of a personnel change shall include an up-to-date copy of the person's resume. NVLAP reserves the right to require a reassessment if considered necessary.

### **5.3 Accommodation and environmental conditions**

**5.3.1** The testing laboratory shall have adequate facilities to meet the requirements for accreditation. This includes facilities for conformance testing, record-keeping, document storage, and software storage.

If a testing laboratory conducts conformance testing at the customer site or other locations outside of the laboratory facility, the environment shall conform, as appropriate, to the requirements for the laboratory site.

**5.3.2** The testing laboratory shall provide a secure environment capable of safeguarding proprietary software, test data, electronic and paper records, and other materials. This environment/system shall protect all proprietary materials and information from laboratory personnel not authorized to perform conformance testing and result reporting, and/or visitors to the laboratory.

**5.3.3** If the testing laboratory is conducting multiple simultaneous tests, a process of total separation of products from different customers and conformance testing activities shall be maintained.

**5.3.4** The testing laboratory shall have Internet access for obtaining the most current documentation and test tools from the ONC certification program and secure e-mail capabilities for communication with the ONC certification program, the certification body, NVLAP, and the laboratory's customers.

### **5.4 Test and calibration methods and method validation**

**5.4.1** Tests may be conducted at the testing laboratory or other mutually agreed upon site. When testing is performed outside the laboratory, all requirements pertaining to the test environment shall apply. The laboratory shall have a policy and procedure regarding any conformance testing conducted outside of the laboratory facility. The personnel of the recognized testing laboratory shall conduct the tests and record the results including the loading, compiling, configuring, and execution of any of the mandated testing tools.

**5.4.2** A laboratory shall use the ONC-Approved Test Method(s) applicable to its scope of accreditation.

**5.4.3** The testing laboratory shall ensure procedures and instructions are in place to trace localized test scripts and test data back to the ONC-Approved Test Method. 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 of 45 CFR Part 170.

**5.4.4** Testing laboratories shall use the ONC-Approved Test Method (test procedures, test tools, and required test data). The testing laboratory shall have policies and procedures for exceptions that are deemed necessary for technical reasons, such as departures from the test data. When exceptions are deemed necessary, the customer and the certification body shall be informed and details shall be described in the test report.

**5.4.5** The laboratory shall have a policy and procedure for the development of test data to be used in testing.

**5.4.6** The testing laboratory shall ensure a secure electronic communication channel exists for remote testing to protect the confidentiality and integrity of the testing process.

The testing laboratory shall have its internal networks protected from unauthorized access by external entities, as well as protection against malicious software, worms, viruses, etc.

5.4.7 The testing laboratory shall ensure that, where applicable, the correct version of the test tools per the ONC-Approved Test Method are used and that the tools have not been altered in any way that might lead to incorrect results.

The testing laboratory shall have policies and procedures to reset the system under test to a prior known state.

## 5.5 Equipment

5.5.1 The testing laboratory shall have a local installation of the ONC approved testing tool(s) available, as appropriate, and produce test results.

5.5.2 Records shall be maintained of each item of equipment and test tool(s) significant to the tests performed. The records shall include:

- The identity of the item of equipment and testing tool(s);
- The test tool name, type, and version number or other unique identification;
- Checks that the equipment complies with the specifications;
- The current location of the testing tool or equipment, where appropriate; and
- The instructions or reference to their location.

5.5.3 Whenever updates are made to any testing tool, the testing laboratory shall have procedures to assure the accurate execution and correct performance of the test tool.

5.5.4 The testing laboratory shall document and follow appropriate procedures whenever a test tool is suspected to contain errors. These procedures include establishing that there is a genuine error, reporting the error to the appropriate maintenance authority, and withdrawing the test tool or test case(s) from service. If the conformance testing results differ from the original testing results for the system under test after correcting the test tool, the information shall be transmitted to the customer and certification body.

## 5.6 Measurement traceability

Testing laboratories shall ensure that any instantiation of the test tools are documented and traceable back to the ONC-Approved Test Method. Testing laboratories that locally instantiate the ONC-Approved Test Method shall have documented traceability back to the ONC-Approved Test Method.

## 5.7 Sampling

Testing laboratories shall ensure that input test data meet the functional and interoperable requirements identified in the certification criteria and can be adequately evaluated for conformance. Testing laboratories shall document the specific vendor-supplied test data utilized for testing, when applicable.

## **5.8 Handling of test and calibration items**

**5.8.1** Testing laboratories shall protect all products under testing and test tools from modifications of any kind.

**5.8.2** Before the testing laboratory begins conducting a test, the laboratory shall ensure that the ONC-Approved Test Method and any associated test tool(s) have not been corrupted, that the test data is correct, and that the laboratory is using the appropriate tool.

**5.8.3** The testing laboratory shall ensure that a configuration management plan is in place for the system under test to prevent inadvertent modifications. This configuration management shall uniquely identify each system under test, as well as control and document modifications to any of the software components.

## **5.9 Assuring the quality of test and calibration results**

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

## **5.10 Reporting the results**

**5.10.1** The testing laboratory shall issue test reports that accurately, clearly, and unambiguously present the test conditions and the test setup, including test data, when they vary from the standard protocol. Any deviations from the standard protocol shall be clearly indicated.

**5.10.2** Whenever test procedures are such that an analysis of the observations by the testing staff is required in order to interpret the results before stating them in a test report, the testing laboratory shall have objective procedures to be followed by the test operators performing the analysis, sufficient to ensure that the repeatability, reproducibility, and objectivity of the test results can be maintained.

**5.10.3** The testing laboratory shall create a test report that includes information necessary to describe the relevant criteria/health IT capabilities being tested and shall ensure policies and procedures exist to meet the testing documentation requirements of the certification body or the ONC.

Testing outcomes and report information collected during testing of each certification criterion shall be maintained by the laboratory per records retention requirements.

**5.10.4** A testing laboratory may submit either a printed or an electronic report as instructed by the certification body. The electronic version shall have the same content as the printed report and shall be generated using a software application that is acceptable to the certification body. A controlled copy of the report shall be placed in the testing laboratory's records.

**5.10.5** The testing laboratory shall maintain a policy for handling interpretations of test results.

**5.10.6** For test reports created for validation purposes and submitted to the certification body, the testing laboratory shall issue corrections or additions to a test report only by a supplementary document that is suitably marked and that meets the requirements reporting of test results.

**5.10.7** The laboratory shall have a procedure to upload the C-CDA files into the ONC repository in accordance with ONC instructions.

## **6 Additional requirements**

There are no additional requirements beyond NIST Handbook 150 and its associated normative annexes, and any other normative references cited in this handbook.

**Annex A**  
**(informative)**

**Acronyms and abbreviations**

The following acronyms and abbreviations are used throughout this handbook:

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

## Annex B

(normative)

### **Additional conditions for accreditation in the Health Information Technology (HIT) 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 (HIT 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 sharing of laboratory information 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 \_\_\_\_\_