NIST HANDBOOK 150-31
2011 Edition

National
Voluntary
Laboratory
Accreditation
Program

HEALTHCARE
INFORMATION
TECHNOLOGY
TESTING

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National Voluntary Laboratory Accreditation Program
Standards Coordination Office

November 2011

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 NVLAP ®	**DEPARTMENT OF COMMERCE** National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	**ISSUE DATE:** February 12, 2015
	LAB BULLETIN	**NUMBER:** LB-84-2015
		LAP: Healthcare IT LAP
SUBJECT: Addition of the 2014 Edition Release 2 Certification Criteria for EHR Technology to the HIT LAP		

On September 11, 2014, the 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange; Final Rule was published. As stated by the Office of the National Coordinator (ONC), this rule "introduces regulatory flexibilities and general improvements for certification to the 2014 Edition EHR certification criteria (2014 Edition)." Approved Test Procedures regarding these revisions in criteria were released on January 26, 2015.

Based on this rule and the release of approved test procedures, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the additional 2014 Edition Release 2 EHR certification criteria for testing of EHR technology. For laboratories currently accredited in the NVLAP HIT LAP, addition of these methods to the scope of accreditation must be requested in writing (e-mail is a sufficient form of written request). With the written request, a signed self-declaration regarding implementation of the new test procedures within the laboratory's management system (attached to this bulletin) is required. (Note: The declaration must be signed by the Laboratory's Authorized Representative as designated in the NVLAP records.) Each applicant laboratory must also supply a detailed description of how this additional testing has been added into its management system and communicated to its testers.

Once this information is received, NVLAP will proceed with a review of the information and a decision regarding the addition of the new criteria to the scope of accreditation. A revised scope of accreditation will be issued to each applicant that meets the requirements within the HIT program and this bulletin.

Questions should be directed to Dana S. Leaman at 301-975-4679, or dana.leaman@nist.gov.

Attachment:
Self-Declaration of Implementation

NVLAP-Accredited Testing Laboratory
Healthcare Information Technology Laboratory Accreditation Program

Self-Declaration of Implementation:

45 CFR 170, Health Information Technology: 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange, Final Rule and its associated ONC-approved 2014 R2 Test Procedures, Test Data and Test Tools.

Laboratory Name:	Lab Code:

As the laboratory's Authorized Representative, I attest that this criteria and its associated test procedures, data and tools have been implemented into our laboratory's quality management system. The appropriate training to conduct this testing to the 2014 R2 criteria has also been performed and documented as required in our system. These statements are correct to the best of my knowledge and are made in good faith.

Signature_____   Date_____

Printed Name_____

2015-02-09

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	**ISSUE DATE:** November 22, 2013
NVLAP®	**LAB BULLETIN**	**NUMBER:** LB-79-2013
		LAP: Healthcare IT LAP

SUBJECT: Addition of Test Reporting Requirements to the HIT LAP

The purpose of this bulletin is to publish a minor revision to NIST Handbook 150-31 for the subclause noted below. This bulletin becomes a part of NIST Handbook 150-31, *NVLAP Healthcare Information Technology Testing,* until such time as the next edition of the handbook is published.

Overview and background

On September 4, 2012, the 2014 Edition Standards and Certification Criteria (S&CC) final rule was published outlining the Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, updates to Stage 1, and other program modifications. Under Section 170.523(f)(8), publication of the test results used to make the certification decision is required. To ensure consistency among the Accredited Test Laboratories (ATLs), NVLAP, with input from the ATLs, supplied information to the Office of the National Coordinator (ONC) on a test report summary template.

In September 2013, ONC released the 2014 EHR Test Results Summary Template for immediate implementation and use. Based on the release of this template, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the required use of the ONC-approved template for reporting test results.

Implementation of changes

Effective upon the issuance of this bulletin, the first paragraph of NIST Handbook 150-31, subclause 5.10.3 is revised as shown in the italicized text:

5.10.3 *For test report information that is being generated by the testing laboratory for use by the certification body to make the certification decision, the laboratory shall use the ONC-approved test report summary template.* The testing laboratory ~~shall~~ *may also* create ~~a~~ *an additional* test report template *for its own use* that includes other information necessary *for reporting* to ~~describe the system/module being certified and shall ensure policies and procedures exist to~~ meet the requirements of the *vendor, the* certification body*,* or the ONC.

The second paragraph of subclause 5.10.3 is deleted.

Questions regarding the changes to the NVLAP HIT LAP requirements should be directed to Dana Leaman, NVLAP Program Manager, at dana.leaman@nist.gov, or 301-975-4679.

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	**ISSUE DATE:** January 2, 2013
NVLAP®	**LAB BULLETIN**	**NUMBER:** LB-71-2013
		LAP: Healthcare IT LAP

SUBJECT:	Amendments to NIST Handbook 150-31, *NVLAP Healthcare Information Technology Testing*

The purpose of this NVLAP Lab Bulletin is to publish revisions to the Healthcare Information Technology laboratory accreditation program (HIT LAP) handbook to reflect the addition of the 2014 certification criteria for EHR technology to the program. NVLAP is now accrediting testing applicants to the 2014 Edition Test Method. This is in support of the Office of the National Coordinator (ONC) requirements published in the *Federal Register* on September 4, 2012.

The following method has been added to the HIT LAP Test Method Selection List:

31/2014   Testing based on criteria in 45 CFR Part 170, 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 (September 4, 2012).

Effective immediately, NIST Handbook 150-31, *NVLAP Healthcare Information Technology Testing,* sections 1.4, 5.2, and 5.3 are amended as follows:

1.4   References

1.4.1   Publications referenced in this handbook

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— "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 at 45 CFR Part 170); available online <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>.

— ONC-Approved 2014 Edition Test Method (effective December 14, 2012); available online at <http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>.

5.2   Personnel

5.2.1   The testing laboratory shall maintain responsible personnel and competent technical staff who are knowledgeable of the following (see documents list in 1.4 for complete citations):

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— "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 at 45 CFR Part 170); available online <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>.

— ONC-Approved 2014 Edition Test Method (effective December 14, 2012); available online at <http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>.

5.3   Accommodation and environmental conditions

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5.3.2   (second paragraph is revised to add the words, "where necessary.")

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

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This bulletin should be maintained with your copy of NIST Handbook 150-31 until the next edition of the handbook is released, at which time these changes will be incorporated into the handbook.

Questions regarding the changes to the HIT program should be directed to Dana S. Leaman, NVLAP Program Manager, at 301-975-4679, or dana.leaman@nist.gov.

Contents

Acknowledgments

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 Healthcare Information Technology Testing*, presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Healthcare Information Technology (HIT) LAP. The handbook is intended for information and 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 2011 edition of NIST Handbook 150-31 was developed with the participation of technical experts in the field of healthcare information technology testing and was approved by NVLAP. The handbook incorporates the information and requirements found in the latest editions of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, NIST Handbook 150, and the test procedures associated with this program. The requirements of NIST Handbook 150, the interpretations and specific requirements in NIST Handbook 150-31, and the requirements set forth by the technical standards have been combined to produce the criteria for accreditation in the NVLAP HIT LAP.

This handbook is also available on the NVLAP web site, <http://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.

Introduction

NIST Handbook 150-31 augments NIST Handbook 150, *NVLAP Procedures and General Requirements*, by gathering the technical requirements of the Laboratory Accreditation Program (LAP) for functional and conformance testing of electronic health record products to nationally recognized meaningful use requirements for healthcare IT products. Technical requirements are explained to indicate how the 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 test methods 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 services and/or products related to electronic health information products and systems referred to within this 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 1.4.1).

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 Healthcare Information Technology Testing (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, and the test procedures 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.

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 the Office of the National Coordinator for Health Information Technology (ONC) requested establishment of the Healthcare Information Technology (HIT) Testing LAP by NVLAP to accredit laboratories that perform functional and conformance testing of electronic health record (EHR) technology products to meaningful use requirements as defined in the nationally recognized EHR products testing standards.   See 1.4, References, for a complete list of the currently accepted standards.

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

1.3.3   The HIT LAP offers a set of test procedures for accreditation. Depending on the breadth of its testing capabilities, the applicant laboratory may select test(s) from the list of offered test procedures.
For additional information regarding the test procedures available for selection, refer to the Test Procedure Selection List available on the HIT LAP website, <http://www.nist.gov/nvlap/hit-lap.cfm>.

1.4   References

1.4.1   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 <http://healthit.hhs.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 <http://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 <http://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 <http://www.gpo.gov/fdsys/pkg/CFR-2010-title45-vol1/pdf/CFR-2010-title45-vol1-part170.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 <http://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf>.

— NIST Handbook 150: 2006, "NVLAP Procedures and General Requirements"; available online at <http://www.nist.gov/nvlap>.

— ONC-Approved Test Method, "Approved Test Procedures Version 1.1," with each associated erratum, where applicable (effective October 24, 2010); available online at <http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__certification_program/2884>. (Click on NIST link under *Additional Information*.)

1.4.2   Informative references

The following documents contain information intended to assist the reader with the understanding and use of this handbook.

— "Electronic Health Records and Meaningful Use," Office of the National Coordinator for Health Information Technology; available online at <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2>.

— "Proposed Establishment of Certification Programs for Health Information Technology; Proposed Rule," *Federal Register* (10 March 2010): 11328-11373; available online at <http://www.gpo.gov/fdsys/pkg/FR-2010-03-10/pdf/2010-4991.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 method
The set of test procedures, test data, and test tools to ensure compliance with the meaningful use technical requirements and standards as approved by ONC.

1.5.2
test procedure
The document used to determine conformance to a specific criterion within the ONC Rule.

1.5.3
test tool
A software tool used to perform automated testing of specific functionality.

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 assessor(s) in documenting the assessment to the 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, <http://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 and B of NIST Handbook 150. The current version of the checklist is available from the NVLAP website, <http://www.nist.gov/nvlap>

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 Healthcare 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 assessor(s) (e.g., the names of the key personnel), with an emphasis on

observing and performing tests, testing accuracy, instrumentation, calibration, personnel competency, and test reporting. The current version of the checklist is available from the HIT LAP website, <http://www.nist.gov/nvlap/nvlap-checklists.cfm>.

1.6.4   HIT Template for Oral Quizzing

The assessor(s) use(s) the HIT Template for Oral Quizzing as a means to document the information gathered during the oral quizzing conducted during the on-site assessment. The template captures the questions asked, the laboratory personnel participating in the quiz and any assessor(s) comments regarding the responses provided by the laboratory personnel. The current version of the checklist is available from the NVLAP LAP website, <http://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 test procedures 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, <http://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.
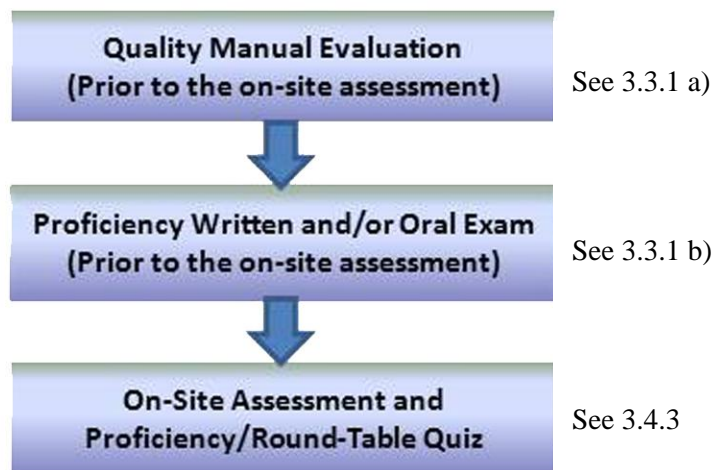
Figure 1. Accreditation process flowchart.

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 <http://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 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 initial 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.

a) *Quality manual evaluation*

   NVLAP reviews the laboratory quality manual and associated documentation and determines whether the management system meets the requirements. Nonconformities and recommendations for 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, when 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 conduct(s) 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 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 about two to three days and will be performed by two or more NVLAP assessors. All observations made by the assessor(s) during the assessment are held in the strictest confidence.

3.4.1.2 In addition to the NIST Handbook 150 checklist, the assessor(s) 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 assessor(s) shall evaluate any new or updated requirements that are documented in a NVLAP Lab Bulletin and on the HIT LAP's website, <http://www.nist.gov/nvlap/hit-lap.cfm>, but are not yet incorporated into the checklist.

3.4.2 On-site assessment activities

The on-site assessment activities include:

a) a proficiency/round-table quiz (see 3.4.3);

b) an evaluation of the laboratory staff's understanding of and competence to apply the HIT conformance testing methodology;

c) an evaluation of the exercised management system and associated records of all management system activities;

d) 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

e) a demonstration, if required, of the competence of the laboratory staff to prepare and use test tools, which will include loading, configuring and running the tools; preparing the test reports; and performing updates, if necessary.

3.4.3 On-site assessment and proficiency/round-table quiz

During the on-site visit, the laboratory's personnel will be quizzed and team dynamics observed for proficiency and expertise in the technical area 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 assessor(s) and/or technical expert(s). The laboratory staff shall provide satisfactory responses that demonstrate sufficient knowledge to support competence for the scope of accreditation.

3.4.4 Agenda

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

a) *Opening meeting:* During the on-site visit, the assessor(s) conduct(s) an entry briefing with laboratory management and supervisory personnel to explain the purpose of the on-site assessment and to discuss the schedule for the 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 assessor(s) will ask the laboratory manager to assist in arranging times for individual interviews with laboratory staff members and/or proficiency/round-table quizzes of staff. While it may not be necessary for the assessor to talk to all staff members if individual interviews are requested, he/she may select staff members representing all different aspects of the laboratory. If proficiency/round-table quizzes are to be conducted on-site, all members of the relevant staff shall be scheduled to participate. Also, after the completion of the round-table quizzing and/or individual interviews, further interviews may be requested.

c) *Records review:* During the on-site visit, the assessor(s) 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 assessor(s) may wish to review the documents alone. Under some circumstances, the assessor(s) may remove some documents from the laboratory during the assessment. Specifically, the assessor(s) may remove for review documents related to the quality system, such as a revised quality manual or new procedures. The material will be returned or destroyed at the laboratory's direction.

The assessor(s) will check personnel information for job descriptions, resumes, training records and technical performance reviews. The assessor(s) shall not be given information which 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 management system and related management system records prior to the full on-site assessment visit. The assessor(s) 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 management system procedures, the audit findings, the results of the management review, and the actions taken to resolve any problems identified.

e) *Equipment:* The assessor(s) 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 assessor(s) 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 area;
- 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 the written examination is provided prior to the initial on-site assessment, the group round-table quizzes and individual demonstrations conducted during the initial and renewal on-site assessments are considered part of the proficiency evaluations.

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 assessor(s) 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 assessor(s) completes 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 assessor(s) 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 assessor 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 assessor(s). The assessor(s) 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 on 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

Proficiency testing for this program may include written examinations, oral examinations, and evaluation of artifacts. The laboratory will be informed of proficiency testing schedules.

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 test procedure(s) 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 test procedure(s) 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 demonstrate 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 those functions.

4.2 Management system

The laboratory shall create and maintain a cross reference document mapping clauses 4 and 5, annexes A and B 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 tests is the use of laboratory services outside of the HIT laboratory's management system to perform tests. When unforeseen circumstances occur, any subcontracted tests (from 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 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 approved product listed on the CHPL, the laboratory shall immediately notify NVLAP, ONC, and any associated certification body(s), 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

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

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 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 maintain responsible personnel and competent technical staff who are knowledgeable of the following (see documents 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;

- "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);

- health IT standards including security, messaging, ePrescribing, quality, content-related standards as well as vocabularies and code sets found in sections §170.205, §170.207, and §170.210 of 45 CFR Part 170;

- health IT terminology, ONC certification criteria as well as security and privacy requirements found in sections §170.302, §170.304, and §170.306 of 45 CFR Part 170;

- ONC-Approved Test Method;

- using testing tools per the ONC-Approved Test Method; and

- "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).

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 and electronic health record (EHR) 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 developed. The training shall include applying the new test procedures and performing required tests. 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 the laboratory staff as identified below. The personnel shall possess knowledge of, or be trained prior to accreditation in the following areas (see documents list in 1.4 for complete citations):

- requirements of the ONC-Approved Test Method;

- health IT standards and interoperability concepts in accordance with 45 CFR Part 170;

- health IT security and privacy concepts and requirements in accordance with 45 CFR Part 170;

- familiarity with 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 test tools found in 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).

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 procedures 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. The laboratory shall have a policy and procedure regarding any conformance testing conducted outside of the laboratory facility.

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.

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.

5.3.3 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.

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.

5.4   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 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 applicable to the test procedures listed on its scope of accreditation along with any associated ONC-Approved testing tool(s).

5.4.3 For electronic health record testing, traceability is interpreted to mean that the testing tools shall be traceable back to the underlying requirements of the normative health IT standards found in sections §170.205, §170.207, and §170.210 of 45 CFR Part 170. Each test procedure is traceable to a specific electronic health record test criterion listed in accordance with 45 CFR Part 170, and the test procedures are achieved via the assertions and associated derived test requirements in the testing tools in use.

The testing laboratory shall ensure procedures and instructions are in place to trace localized test procedures back to the ONC-Approved Test Method.

5.4.4 Testing laboratories shall use the test methods described in the program's specific derived testing requirements. 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.

5.5   Equipment

5.5.1 For conformance testing, the testing laboratory shall load and run a copy of the testing tool(s) and produce test results using the tool(s), as appropriate.

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

- the identity of the item of equipment and testing tool(s);
- testing tool name, type, and version number or other unique identification;
- checks that the equipment complies with the specifications;
- the current location, 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, enhancements, or modifications to 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 the ONC-Approved Test Method and any associated testing tool(s) have not been corrupted, 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 which accurately, clearly, and unambiguously present the test conditions and the test setup 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 template that includes information necessary to describe the system/module being certified and shall ensure policies and procedures exist to meet the requirements of the certification body or the ONC.

Test report information collected during testing of each test procedure shall be maintained by the laboratory. The outcome of each test procedure shall be contained in the test report.

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 of the test method.

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:

CFR   Code of Federal Regulations

CHP   Certified Health Information Technology Products List

EHR   Electronic Health Record

HHS   Department of Health and Human Services

HIT   Healthcare 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