

Enter Date:

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NIST HANDBOOK 150-31 CHECKLIST HEALTHCARE INFORMATION TECHNOLOGY TESTING

Instructions to the Assessor: This checklist addresses specific accreditation requirements prescribed in NIST Handbook 150-31, *Healthcare Information Technology Testing*.

- All items on this checklist shall be addressed.
- Select “X” for each item that represents a nonconformity.
- Select “C” for each item on which you are commenting for other reasons.
- Select “OK” for each item you observed or verified as compliant at the laboratory.
- Record the item number and the nonconformity explanation and/or comment on the appropriate comment sheet.

Note: The numbering of the checklist items correlates to the numbering scheme in NIST Handbook 150-31, clauses 4 and 5.

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.

4.5 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.

4.8 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.

4.13 Control of records

— All records shall be maintained for a minimum of five years, unless other regulatory requirements specify a longer retention period.

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 Handbook 150-31, Section 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 Handbook 150-31, Section 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.

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- 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.

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- ___ 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 sites. 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.

5.10 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.

The electronic version 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.

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- ___ 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.

