NIST HANDBOOK 150-31 CHECKLIST
HEALTHCARE INFORMATION TECHNOLOGY TESTING PROGRAM

Instructions to the Assessor: This checklist addresses specific accreditation requirements prescribed in NIST Handbook 150-31 (2017), *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(2017) 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 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   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.

NIST HANDBOOK 150-31 CHECKLIST
COMMENTS AND NONCONFORMITIES

Instructions to the Assessor: Use this sheet to document comments and nonconformities. For each, identify the appropriate item number from the checklist. Identify each comment with a "C" and each nonconformity with an "X." If additional space is needed, make copies of this page or use additional blank sheets.

Item No.	*C or X*	*Comments and/or Nonconformities*

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