**Date:** **NVLAP Lab Code:** Click or tap here to enter text.

**NIST HANDBOOK 150-31 CHECKLIST (ISO/IEC 17025:2017)**

**(Health Information Technology)**

**Instructions to the Assessor:** This checklist addresses specific accreditation criteria prescribed in NIST Handbook 150-31, Health Information Technology. Included also are instructions and comments sheets used for observing actual demonstrations of the performance of selected test methods. These criteria do not supersede the *Criteria for Accreditation* based on ISO/IEC 17025:2017, which are addressed in the NVLAP General Criteria Checklist.

Place an "X" beside each checklist item that represents a nonconformity. Place a "C" beside each item on which you are commenting for other reasons. Record the nonconformity explanation and/or comment in assessment report created in the assessor portal under the laboratory’s assessment record. Place "OK" beside all other items you observed or verified as compliant at the laboratory.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Requirement** | | | **Compliance**  **(OK, X, or C)** | **Management System Reference** | **Objective Evidence** |
| **6** | **Resource requirements** | | | | |
|  | **6.2** | **Personnel** |  |  |  |
|  | **6.2.1** | The testing laboratory shall retain responsible, competent personnel who are knowledgeable and capable of demonstrating competencies in the ONC Health IT Certification Program regulations and test methods listed in section 1.4. | Choose an item. |  |  |
|  | **6.2.2** | The testing laboratory shall have staff members with at least a bachelor’s degree in computer science, information systems, or similar technical discipline or equivalent experience – such as three years experience – in the area of health IT testing, health IT interoperability, health IT standards and technologies, and events relevant to health IT. | Choose an item. |  |  |
|  | **6.2.3** |  |  |  |  |
|  | **a)** | The laboratory’s training program shall be relevant to health IT testing, health IT standards, technologies, and events relevant to health IT testing. | Choose an item. |  |  |
|  | **b)** | The laboratory shall document its training program including, at a minimum, the ONC Health IT Certification Program regulations and test methods listed in section 1.4 of this handbook. | Choose an item. |  |  |
|  | **c)** | In addition, the laboratory shall also participate in required training as directed by the ONC Health IT Certification Program. (§ 170.524(b)). | Choose an item. |  |  |
|  | **6.3** | **Facilities and environmental conditions** | |  |  |
|  |  | Where there are no physical testing locations, the laboratory shall ensure that the requirements of ISO/IEC 17025, section 6.3 shall be met when conducting testing of health IT. | Choose an item. |  |  |
|  | **6.4** | **Equipment** |  |  |  |
|  |  | The laboratory may install and maintain a locally controlled installation of the ONC-approved testing tool(s) to produce test results. Local instantiations shall be validated in accordance with section 7.2 and demonstrate that they achieve the same results as the ONC-designated hosted tools. | Choose an item. |  |  |
|  | **6.5** | **Metrological traceability** |  |  |  |
|  |  | The testing laboratory shall ensure: |  |  |  |
|  | **a)** | management system documentation is in place to trace localized test scripts and test data back to the ONC-Approved Test Method. | Choose an item. |  |  |
|  | **b)** | local installations of the test tools are documented and traceable back to the ONC-Approved Test Method. | Choose an item. |  |  |
|  | **c)** | where permitted, laboratory or developer-supplied test data meet the functional and interoperable requirements identified in the certification criteria and can be adequately evaluated for conformance. | Choose an item. |  |  |
|  |  | **NOTE** *For health IT testing, traceability is interpreted to mean that the ONC-Approved Test Method (test procedures, test tools, and required test data) shall be traceable back to the underlying requirements of the ONC health IT certification criteria requirements in the applicable section(s) of 45 CFR Part 170.* |  |  |  |
| **7** | **Process requirements** | | | | |
|  | **7.7** | **Ensuring the validity of results** |  |  |  |
|  | **7.7.1** | Laboratories shall demonstrate and document on-going activities to maintain their proficiency in health IT to ensure no methods are compromised during execution. | Choose an item. |  |  |
|  | **7.7.2** | The laboratory shall have satisfactorily participated in all required proficiency testing (PT) during its previous accreditation period or prior to accreditation being granted, if initial accreditation. | Choose an item. |  |  |
|  | **7.8** | **Reporting of results** |  |  |  |
|  | **7.8.1** | **Common requirements** |  |  |  |
|  |  | Testing laboratories shall document the specific laboratory or developer-supplied test data utilized for testing, when applicable. | Choose an item. |  |  |
|  | **7.8.2** | **Reporting opinions and interpretations** | |  |  |
|  | **7.8.2.1** | Whenever test procedures are such that an analysis of the observations is required in order to interpret the results before stating them in a test report, the laboratory shall have a defined process to ensure that the repeatability, reproducibility, and objectivity of the test results can be maintained. | Choose an item. |  |  |
|  | **7.8.2.2** | The testing laboratory shall have and maintain a policy for handling interpretations of test results. | Choose an item. |  |  |
|  | **7.10** | **Nonconforming work** |  |  |  |
|  |  | The laboratory’s procedure shall ensure that when nonconforming work is identified and recalled for an ONC-ACB (Authorized Certification Body) certified product that is listed on the Certified Health IT Product List (CHPL), the laboratory shall immediately notify NVLAP, ONC, and any associated certification bodies, as well as the developer, in writing. | Choose an item. |  |  |
| **8** | **Management system requirements** | | | | |
|  | **8.2** | **Management system documentation (Option A)** | |  |  |
|  |  | The laboratory shall create a cross-reference document that facilitates verification that all program requirements, including scheme (regulatory) requirements, have been addressed by the management system, which includes clauses 4 through 8 of ISO/IEC 17025, annexes A, B, and E of NIST Handbook 150, and NIST Handbook 150-31. | Choose an item. |  |  |
|  | **8.4** | **Control of records (Option A)** |  |  |  |
|  |  | The laboratory shall retain all records as defined in [170.524(f) Records retention](https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-E/section-170.524#p-170.524(f)). | Choose an item. |  |  |
|  | **8.7** | **Corrective actions (Option A)** |  |  |  |
|  |  | Should a nonconformity(s) be identified regarding a product tested within the laboratory, the laboratory shall initiate its corrective action process to investigate the validity of the test results issued. If further actions are warranted as a result of this investigation process (e.g., it was determined that the test results are not correct or the laboratory deviated from its testing process), those actions shall be taken in accordance with the laboratory’s management system. | Choose an item. |  |  |