Health IT Certification Program Overview

1. Introduction

The Office of the National Coordinator for Health Information Technology (ONC) operates the ONC Health IT Certification Program (Program) under the authority granted by section 3001(c)(5) of the Public Health Service Act (PHSA) and as defined in the Health Information Technology for Economic and Clinical Health (HITECH) Act. The Program is run as a third-party product conformity assessment scheme for health information technology (health IT) based on the principles of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) framework. ONC does not perform conformance testing or issue certifications itself.   Rather, ONC collaborates with other organizations that it evaluates, approves, and authorizes to perform these functions on its behalf. The Program is a voluntary health IT testing and certification scheme with requirements including, but not limited to, capabilities related to the recording, security, and interoperable sharing of health information. The Program defines the technical requirements for health IT and the process by which health IT may become certified and maintain its certification.

ONC launched the Program in 2010 to support the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) administered by the Centers for Medicare & Medicaid Services (CMS). While the EHR Incentive Programs continue to require the use of certified health IT, the use of certified health IT has expanded to other government and non-government programs. Similarly, the Program has evolved and now also supports other health IT adoption, interoperability, and care quality improvement initiatives.   This evolution has been demonstrated as the Program has released several editions of certification criteria and expanded program requirements. These new editions of certification criteria include more robust technical and interoperability requirements, ONC-Authorized Certification Body (ONC-ACB) in-the-field surveillance expectations, and cost transparency and disclosure requirements for health IT developers' certified health IT. These additional disclosure requirements have been adopted to ensure users of certified health IT are fully informed about certain types of limitations and additional costs associated with the ability to implement or use certified health IT in a manner consistent with its certification.

The Enhanced Oversight and Accountability final rule (81 FR 72404) updates the Program to provide enhanced oversight and health IT developer accountability.   Specifically, the final rule stands up a focused ONC direct review regulatory framework, aligns the testing lab oversight with the existing processes for ONC-ACBs, and makes a more comprehensive set of ONC-ACB surveillance results publicly available.   The rule emphasizes the importance of protecting public health and safety while also strengthening transparency and accountability in the Program. It will also enable the Program to better support providers and hospitals – the vast majority of whom use health IT.

2. Program Participants

ONC works with the following agencies and entities as part of Program operations:

- **NIST** (National Institute of Standards and Technology): Per the HITECH Act, NIST, a federal agency within the Department of Commerce, and ONC collaborated to establish the voluntary certification program and continue to work together to develop the necessary functional and conformance testing requirements, test cases, and test tools in support of the Program.
- **NVLAP** (National Voluntary Laboratory Accreditation Program): Administered by NIST, the Program specifies that only test results from a NVLAP-accredited testing laboratory could be used as the basis for a certification determination by an ONC-ACB.
- **ONC-ATL** (ONC-Authorized Testing Laboratory): A NVLAP-accredited testing laboratory that performs health IT testing to determine conformance with ONC's standards and certification criteria according to the ONC-approved test method.
- **ONC-AA** (ONC-Approved Accreditor): Selected by ONC to serve a three-year term to accredit and oversee ONC-ACBs under the Program requirements.
- **ONC-ACB** (ONC-Authorized Certification Body): Certifies health IT based on test results supplied by ONC-ATLs; posts results on the Certified Health IT Product List (CHPL); and is responsible for conducting surveillance of certified health IT.
- **Health IT Developer**: Presents health IT to be tested and certified under the Program.

3. Policy Making, Certification Criteria, and Standards Adoption

ONC manages the rulemaking process for the development and issuance of policy and regulations for the Program. Through the rulemaking process, ONC establishes the Program requirements, capabilities, standards, and implementation specifications for certified health IT. This process includes review and input from within the federal government as well as public and private stakeholders.

The most common rulemaking process begins with ONC issuing a notice of proposed rulemaking (NPRM) and requesting public comments on the NPRM, which is followed by a review of the comments. ONC then drafts the final rule with consideration of public comment and issues a final rule on behalf of the Department of Health and Human Services (HHS) Secretary. Through this rulemaking process, ONC establishes Program requirements as well as requirements for health IT, referred to as "certification criteria." Based on these certification criteria, ONC develops a test method (to include test procedures and test tools (including associated test data)) that is approved by the National Coordinator for Health Information Technology (National Coordinator). Only test procedures and test tools approved by the National Coordinator may be used to test health IT under the Program for the purposes of certification. Test procedures and test tools developed outside ONC may be submitted to the National Coordinator, as outlined in 75 FR 36168, for review and approval.

4. Operations

Program Structure

The Program's operational structure is informed by ISO/IEC 17067 and operated within the ISO framework and concepts for third-party conformity assessment programs. The requirements defined in the adopted regulations are built on these concepts and are implemented as described in this section.

ONC has collaborated with NVLAP to develop and maintain the Healthcare Information Technology Testing Laboratory Accreditation Program administered by NVLAP. NVLAP, in accordance with ISO/IEC 17025, Handbook 150 and 150-31, and other requirement documents, accredits and oversees testing laboratories that perform functional and conformance testing. Once NVLAP accredits a testing laboratory, the testing laboratory must submit an application to become authorized by ONC, through a formal application process, to begin testing health IT under the Program. Upon authorization, an accredited testing laboratory becomes an "ONC-ATL". ONC specifies the processes and requirements for retaining, suspending, or revoking ONC-ATL status under the Program. ONC-ATLs operate under a three-year authorization cycle and must remain in good standing by adhering to the Principles of Proper Conduct and requirements under subpart E of Part 170.

For certification of health IT under the Program, through an application process, ONC selects an ONC-AA to accredit and oversee the Program's certification bodies. Similar to testing laboratory requirements, certification bodies must be accredited by the ONC-AA to ISO/IEC 17065 and the ONC-AA accreditation program requirements to perform certification activities for health IT tested and determined to be conformant by an ONC-ATL. Once the ONC-AA accredits the certification body, the certification body submits an application to become authorized by ONC to begin certifying health IT under the Program in accordance with the process set forth at 76 FR 1327. Upon authorization, an accredited certification body becomes an "ONC-ACB". ONC-ACBs operate under a three-year authorization cycle and must remain in good standing by adhering to the Principles of Proper Conduct and other requirements under subpart E of Part 170.

Surveillance of Certified Health IT Products

Health IT certified under the Program is subject to surveillance activities as a condition of certification. Surveillance of certified health IT ensures the continued maintenance of the functionalities required by certification. Surveillance is also a requirement set forth in ISO/IEC 17065 and must be performed by ONC-ACBs to maintain their accreditation and ONC authorization. The purpose of surveillance is to ensure that certified products and capabilities meet certification requirements, not just in a controlled testing environment, but also when they are used "in the field" (for example, in a clinician's office or a hospital). Surveillance requirements include randomized and reactive surveillance activities.

When an ONC-ACB determines that a product does not comply with certification requirements, the product is considered non-conformant. Developers must work with their ONC-ACB on an appropriate corrective action plan (CAP) to cure the identified deficiency(ies) that lead to the finding(s) of non-conformity and bring the product back into compliance. All CAPs must include certain required elements per 45 CFR § 170.556(d)(3), including:

- A description of the non-conformities or deficiencies;

- How widespread the problem may be across the developer's other customers and users;
- How the developer will address the problem for all potentially affected customers and users;
- How the developer will ensure that all potentially affected customers and users are alerted and that their issues are resolved;
- The timeframe in which all corrective action will be completed; and
- An attestation by the developer that it has completed all elements of the approved CAP.

Under ONC's 2015 Edition final rule (80 FR 62601), ONC will post a finding of a non-conformity and aspects of CAPs on the CHPL **weekly**. Because the developer will resolve many non-conformities quickly, the CHPL also will reflect updated information—including the date and a description of how the non-conformity was resolved. If the developer does not resolve the non-conformity(ies) and fulfill the terms of the CAP, an ONC-ACB will follow its procedures to suspend and withdraw the product's certification.

Visitors to the CHPL should exercise care and consider relevant factors as they evaluate the certified health IT products that have (or have not) been placed under corrective action. A few points to consider:

- Non-conformities can take many forms and differ in their extent and severity. *It is important to keep in mind that just because a product has been found to be non-conforming does not automatically indicate that a product is "defective."*
- Even when a non-conformity has been identified, a developer's CAP can demonstrate commitment to the quality of technology, the user experience, and patient safety. Remember, *many non-conformities or deficiencies are resolved quickly.*
- The fact that a product has no listed non-conformities does not mean that it is free of non-conformities or other deficiencies. For example, the product may not have been surveilled recently or it may be undergoing surveillance for which a final disposition is still pending. Remember that randomized surveillance is only performed on a subset of products each year. For these reasons, it is important to *immediately report any potential issues that may warrant surveillance and to check the CHPL regularly for the latest information about a product's performance.*

To provide more complete information that illuminates good performance and continued conformity with Program requirements for certified health IT, ONC-ACBs are now required to make identifiable surveillance results (those NOT resulting in a CAP) publicly available on the CHPL on a quarterly basis. This will further enhance transparency and provide customers and users of certified health IT with valuable information about the overall conformity of certified health IT to Program requirements. This information will also benefit health IT developers that perform well.

Users of certified health IT should be familiar with the ONC recommended process for filing complaints concerning certified health IT.

ONC Direct Review of Certified Health IT Products

The Enhanced Oversight and Accountability final rule articulates a regulatory framework for ONC to directly review certified health IT if there is a reasonable belief that: (1) the certified health IT may present a serious risk to public health or safety; or (2) a review of certified health IT could present practical challenges for ONC-ACBs, such as when a suspected non-conformity presents issues that may

require access to certain confidential or other information that is unavailable to an ONC-ACB; may require concurrent or overlapping reviews by multiple ONC-ACBs; or may exceed the scope of an ONC-ACB's resources or expertise. This review will be complementary to surveillance conducted by ONC-ACBs and will promote health IT developer accountability for the performance, reliability, and safety of health IT.

5. Program Structure
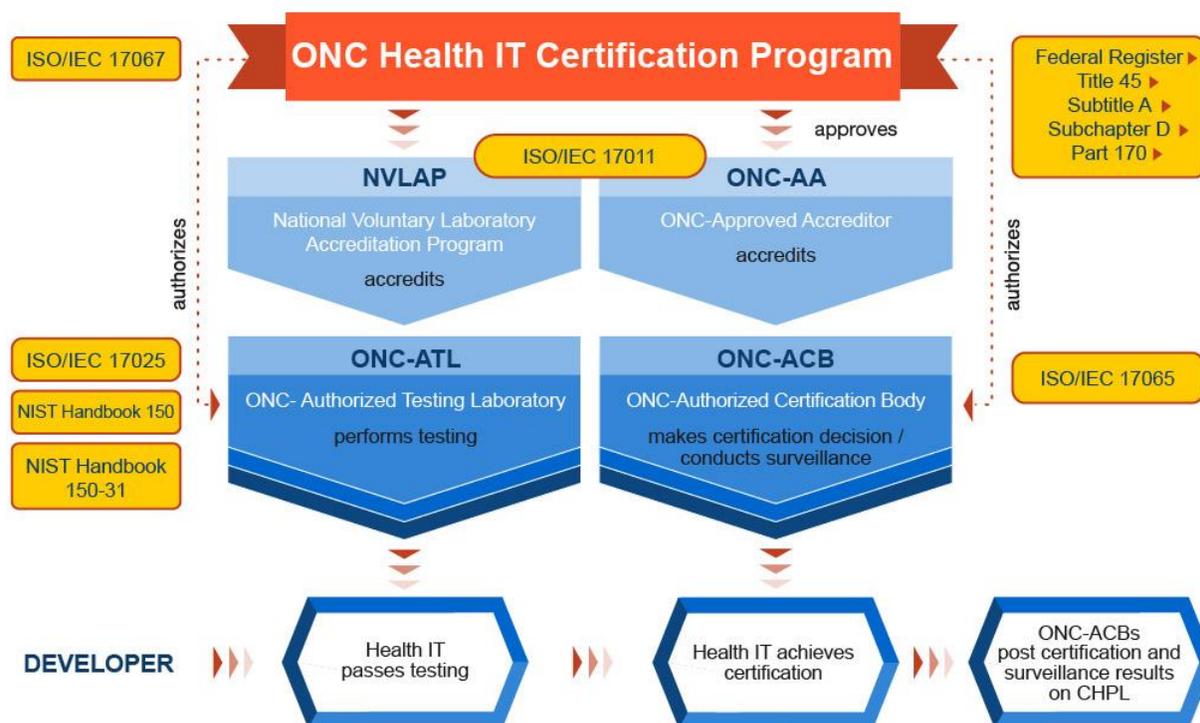
The labels alongside each entity are the ISO/IEC specifications to which that entity must be accredited. The Federal Register reference is the adopted regulation to which ONC operates the Program. Operation of the Program incorporates concepts within ISO/IEC 17067.

Document History

Version	Description of Change	Date
1.0	Initial Version	September 19, 2016
1.1	Updated after ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule published	January 30, 2016
1.2	Updated diagram	April 3, 2017