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 Standards Organization (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 functional and interoperability requirements, 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.

2 Program Participants

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

- **NIST** (National Institute for 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.

- **ATL** (Accredited Testing Laboratory)[1]: 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 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 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 requests public comments on the NPRM 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 HHS Secretary. Through this rulemaking process, Program requirements are established as well as requirements for health IT, referred to as "certification criteria." Based on these certification criteria, a test method (to include test procedures and test tools (including associated test data)) is developed and 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 by interested parties may be submitted to the National Coordinator, as outlined in 75 FR 36168, for review and approval.

4 Operations

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.

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[1] The ONC Health IT Certification Program: Enhanced Oversight and Accountability proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program. Once the rule becomes final, ATLs will be required to seek authorization from ONC to become ONC-Authorized Testing Laboratories (ONC-ATLs) to perform conformity testing under the Program. https://www.federalregister.gov/articles/2016/03/02/2016-04531/onc-health-it-certification-program-enhanced-oversight-and-accountability

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 requirements documents, accredits and oversees testing laboratories that perform functional and conformance testing.

Through an application process, ONC selects an ONC-AA to accredit and oversee the Program's certification bodies. 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 ATL. Once the ONC-AA accredits the certification body, it 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.

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. Surveillance requirements include randomized and reactive surveillance activities. Users of certified health IT should be familiar with the ONC recommended process for filing complaints concerning certified health IT.

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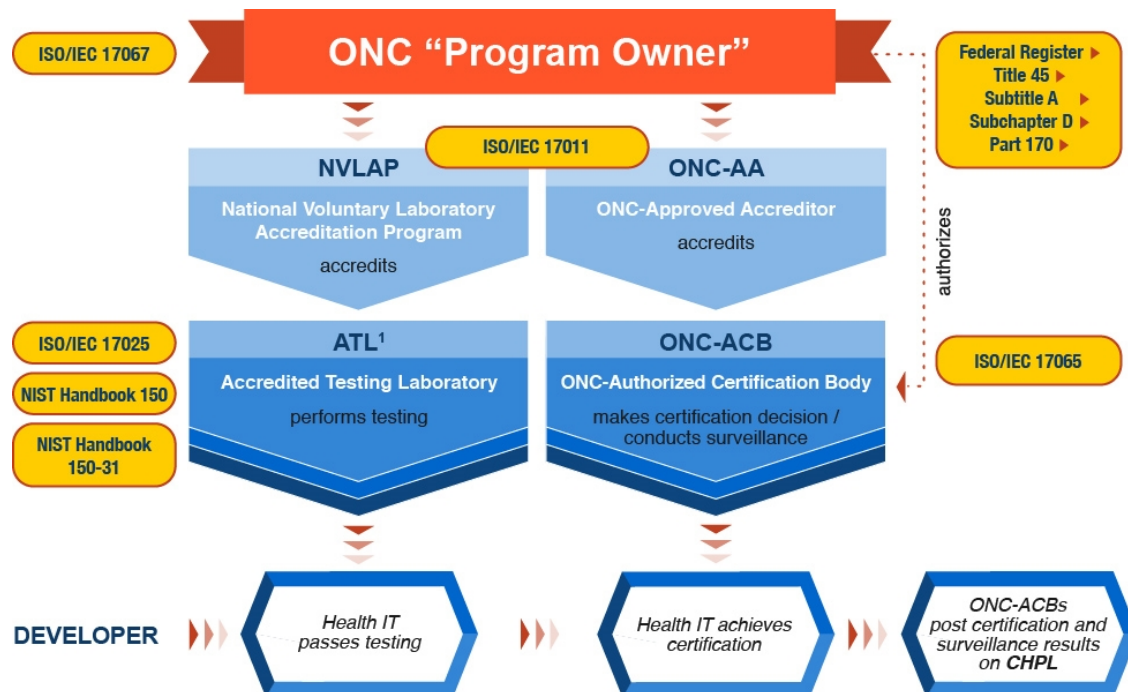
The labels alongside each entity are the ISO/IEC specifications to which that entity must be accredited. The Federal Register reference is the adopted regulation to which ONC operates the Program. Operation of the Program incorporates ISO/IEC 17067.

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Document History

Version	Description of Change	Date
1.0	Initial Version	September 19, 2016