



CONFORMANCE METHOD - ATTESTATION
Program Guidance #17-04-A
Issued and Effective Date: September 15, 2021

Attestation Approach for ONC-Approved Conformance Methods

This guidance summarizes responsibilities of health IT developers and ONC-Authorized Certification Bodies (ONC-ACBs) for implementing a new flexibility in the process of demonstrating conformance to the 2015 Edition and 2015 Edition Cures Update certification criteria¹ in which the health IT developer attests conformance directly to the ONC-ACB. The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Final Rule added this flexibility to address a previous ONC Health IT Certification Program (Certification Program) construct limitation of ONC-ACB certification only being permissible for health IT that has been tested previously by an ONC-Authorized Testing Laboratory (ONC-ATL) with ONC-approved test procedures. In addition to ONC-ACBs certifying Health IT Modules that have been tested by an ONC-ATL, using test tools and test procedures approved by the National Coordinator, ONC-ACBs may now also certify Health IT Modules that they evaluate for conformance for a set of certification criteria that includes attestation for the conformance method, which bypasses ONC-ATL review. All methods to determine conformity, including attestation, must first be approved by the National Coordinator.

In some instances, such as the previously used test procedures allowing for developer self-declaration, there is no testing required to satisfy the conformance method. By adopting this flexibility, ONC may approve conformance methods that rely solely on ONC-ACB evaluation, and not ONC-ATL testing, when appropriate [45 CFR 25711]. This additional flexibility has been added to the ONC-ACB Principles of Proper Conduct (§ 170.523 (h)(2)) Certification decision, which states ONC-ACBs can certify Health IT Modules that have been:

- (1) Tested, using test tools and test procedures approved by the National Coordinator, by an:
 - (i) ONC-ATL;
 - (ii) ONC-ATL, National Voluntary Laboratory Accreditation Program-accredited testing laboratory under the ONC Health IT Certification Program, and/or an ONC-ATCB for the purposes of performing gap certification; or
- (2) Evaluated by it for compliance with a conformance method approved by the National Coordinator.

Attestation as a Conformance Method to Replace Self-Declaration Test Procedures

In an effort to standardize terminology across the 2015 Edition and the 2015 Edition Cures Update, ONC has made some modifications to a set of the 2015 Edition Certification Criteria that were previously satisfied by a self-declaration as part of the test procedure. Test procedures that were formerly satisfied by self-declaration, will now be referenced as conformance methods. In addition, what was formerly referred to as “self-declaration” as a method of demonstrating conformity within the test procedure will



now be referred to as “attestation.” Self-declaration is a type of attestation, and while the inherent meaning of the term does not change for the purposes of this type of conformance, the certification terminology has been updated to indicate that health IT developers attest directly to the ONC-ACB.

For all 2015 Edition and 2015 Editions Cures Update certification criteria that include attestation as a conformance method, health IT developers are required to assess their health IT against the full scope of the product’s required capabilities, including but not limited to regulatory/conformance expectation clarifications and interpretations set forth in the applicable Certification Companion Guides and other issued guidance. If the health IT developer has determined from the outcome of its own assessment that its product meets the required capabilities of the certification criteria, the next step is to submit an attestation to the ONC-ACB.

The health IT developer’s attestation is submitted to satisfy requirements adopted by the federal government under the Certification Program. Health IT developers are expected to perform their due diligence in assessing products for compliance with the required capabilities and should understand that they will be expected to comply with all ONC and ONC-ACB surveillance requirements should there be end-user concerns about continued conformity in the implementation setting. ONC-ACBs may consider incorporating language into their contracts to ensure a shared understanding of these expectations.

ONC-ACB Attestation Requirements

For the 2015 Edition and 2015 Edition Cures update certification criteria that require health IT developer attestation, ONC-ACBs must define elements and/or documentation specific to the individual criterion that must be present in the attestation so that they may evaluate health IT developers’ submissions against those requirements.

In support of ONC’s intent to reduce burden on health IT developers³, ONC-ACBs shall not require information that would add more rigor than what was previously required for certification criteria that have been modified to implement the attestation approach. For certification criteria for which the conformance method requires attestation, the minimum necessary requirements for the developer’s attestation document shall ensure complete CHPL reporting by the ONC-ACB. Although ONC-ACBs are not permitted to request additional documentation other than the developer’s attestation, ONC-ACBs may require the developer to list or reference their evidence/documentation from which the health IT developer has based their attestation of conformity.

ONC-ACBs must, as always, continue to perform surveillance on the full scope of these criteria and all certification criteria, and as part of these surveillance activities may request additional documentation/evidence of conformity and in the field testing, if necessary, at that time.

¹ Please refer to the [2015 Edition Test Method](#) and the 2015 Edition test procedures.

² See 45 CFR 170.523(h)

³ See [Certification Program Updates to Support Efficiency & Reduce Burden](#)



Version	Description	Date Published
1.0	Initial Publication	November 22, 2017
2.0	Revised to remove reference to the thirty certification criteria initially modified to implement the developer self-declaration approach.	March 1, 2019
3.0	Revised to update language, shifting all references of “self-declaration” to “attestation” to align with language used in the broader Certification Program and to include the new flexibility outlined in § 170.523(h)(2).	September 15, 2021