SELF-DECLARATION APPROACH
Program Guidance #17-04-A
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Self-declaration Approach for ONC-Approved Test Procedures

This guidance summarizes the process for implementing ONC-Approved test procedures for the 2015 Edition certification criteria[1] in which the testing approach is constrained to health IT developer self-declaration and specifies responsibilities of health IT developers, ONC-Authorized Test Labs (ONC-ATLs), and ONC-Authorized Certification Bodies (ONC-ACBs).

ONC-Approved Test Procedures

ONC-ACBs shall only certify health IT tested by an ONC-ATL using ONC-Approved test procedures[2]. For 2015 Edition test procedures that require health IT developer self-declaration, ONC-ATLs, with input from ONC-ACBs, must define elements that must be present in the self-declaration and evaluate health IT developers' submissions against those requirements. Only if the ONC-ATL accepts the self-declaration as compliant with its requirements will the self-declaration be submitted to the ONC-ACB as part of the test report to be evaluated for certification. For these criteria, ONC considers the health IT developer's self-declaration document the attestation that will be provided for evaluation per the test procedure.

It is important for health IT developers and ONC Health IT Certification Program (Program) stakeholders to note that health IT certified under the Program must conform to the **full scope** of the product's required capabilities, including regulatory/conformance expectation clarifications and interpretations set forth in the applicable Certification Companion Guides and elsewhere. Materials prepared by ONC to support pre-certification testing, such as the 2015 Edition Test Method, should be read and understood on the basis that they have been prepared with the express purpose of evaluating a **limited subset** of the product's required capabilities in a controlled environment. As such, the 2015 Edition Test Method is not determinative of the full scope of a product's required capabilities.

Requirements for Developer Self-declaration

In support of ONC's intent to reduce burden on health IT developers[3], ONC-ATLs shall not require information that would add more rigor than what was previously required for criteria that have been modified to implement the self-declaration approach. For certification criteria for which the test procedure requires self-declaration, the minimum necessary requirements for the developer self-declaration document shall ensure complete CHPL reporting by the ONC-ACB. Although ONC-ATLs and ONC-ACBs are not permitted to request additional documentation other than the developer's self-declaration, ONC-ATLs may require the developer to list or

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[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

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reference their evidence/documentation from which the health IT developer has based their declaration of conformity.

Similar to ONC-ATL processes for evaluating documentation for the 170.315(g)(4) "quality management system" criterion (§ 170.315(g)(4)), the ONC-ATL must evaluate the documentation for compliance against its defined requirements for the 2015 Edition certification criteria with the self-declaration testing approach prior to submitting to the ONC-ACB for certification. 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.

Health IT Developer Self-declaration

For the 2015 Edition certification criteria that require self-declaration, 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 criterion's test procedure, the next step is to submit its self-declaration to the ONC-ATL. The ONC-ATL must accept the health IT developer's self-declaration in order for it to be considered by an ONC-ACB for certification.

The health IT developer's self-declaration is an attestation made to satisfy requirements adopted by the federal government under the U.S. Department of Health and Human Services, ONC Health IT 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 and ONC-ATLs may consider incorporating language into their contracts to ensure a shared understanding of these expectations.

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