

APPLICABILITY OF INHERITED CERTIFIED STATUS AND GAP CERTIFICATION

PROGRAM GUIDANCE #16-01-A

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INTRODUCTION

Background and Purpose

Under the ONC Health IT Certification Program (Certification Program), inherited certified status (ICS) and gap certification are flexibilities available for the certification of previously certified health IT. The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) issues resources to clarify when ICS and/or gap certification are available for certification to health IT developers with previously certified products.

Disclaimer

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this guide is not a legal document. The official requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the “companion resources” listed below.

The scenarios provided in this resource are for illustrative purposes only. The certification criteria used in these examples may reflect past requirements and are intended solely to offer ideas and context. They do not represent current or official certification scenarios. Always refer to the latest guidelines and requirements for up-to-date information.

Companion Resources and Other Relevant Materials

This resource should be read and understood in conjunction with the following companion resources, which describe in detail relevant Certification Program requirements referenced in this resource.

- [Real World Testing Resource Guide](#)
- [Real world Testing Enforcement Discretion](#)

Certified Health IT developers should also review the following regulatory materials, which establish the policies for ICS and gap certification under the Certification Program.

- [45 CFR 170.550](#) Health IT Module certification
- [45 CFR 170.523](#) Principles of proper conduct for ONC-ACBs
- [45 CFR 170.502](#) Definitions
- [45 CFR 170.405\(b\)\(2\)\(ii\)](#) Real World Testing results reporting

OVERVIEW

What is Inherited Certified Status and Gap Certification?

ICS and gap certification are two approaches for the certification of health IT under the Certification Program that allow an ONC-Authorized Certification Body (ONC-ACB) to apply the certified status of the previously

certified Health IT Module to a newer version without requiring the newer version to be retested and recertified.

ICS and gap certification may provide efficiencies and reduce the costs of testing and certification by permitting ONC-ACBs to consider prior test results as evidence of conformity for a new certification request. Both flexibilities allow ONC-ACBs to make certification decisions based on previous test results that support the previously certified health IT's continued conformance to certification requirements. Each can be used for different circumstances when adding a new version of a developer's certified Health IT Module and are discussed below.

Testing Requirements for Previously Certified Health IT

Updated certification criteria are one possible reason for developers to seek certification to newer versions of their previously certified Health IT Modules. ASTP/ONC considers revised certification criteria to be certification criteria previously adopted by the Secretary that are modified to add, remove, or otherwise alter the specified capabilities and/or the standard(s) or implementation specification(s) referred to by the certification criteria ([76 FR 1302](#)). Revised certification criteria may require testing depending on the type of update that has been adopted in regulation.

Types of updates vary from minimal updates (e.g., newer version of a vocabulary standard) to heavily revised updates (e.g., new functionality, standard or non-standard based). Minimal updates may not require testing as updates such as new vocabulary code sets may not impact the functionality required by the certification criterion. ASTP/ONC specifies in regulation what conformance method will be approved to demonstrate fulfilment of certification requirements for each certification criterion. When appropriate, the availability of ICS or gap certification will be offered as an approach for developers to maintain certified status when updating their previously certified health IT to meet updated certification requirements.

While minimal updates, such as newer versions of vocabulary code sets, may not require testing, more substantial updates such as newer versions of an implementation guide/specification and additional functionalities will likely require developers to retest their previously certified health IT Modules with an ONC-Authorized Test Lab (ONC-ATL). New certification criteria with testing requirements must undergo testing with an (ONC-ATL) and/or follow any other conformance method required for certification.

Unchanged certification criteria are managed in accordance with ONC-ACB processes and require no change or additional action by the health IT developer to maintain certification status.

INHERITED CERTIFIED STATUS

The ICS process reduces burden to streamline the certification process for Certified Health IT developers seeking certification to a newer version of a previously certified Health IT Module. It permits ONC-ACBs to grant certified status to a newer version of previously certified health IT by using the previously issued certificate's scope as the basis for the new certificate.

ICS:

- (1) Applies to newer versions of previously certified health IT;
- (2) Available only for a certification criterion or criteria to which the Health IT Module(s) was previously certified that have not been revised (i.e., unchanged certification criteria);
- (3) Requires no further testing of the certified capabilities included in the previously certified health IT if the ONC-ACB determines that they have not been adversely affected.

ICS is only available for unchanged certification criteria for which the product is already certified if the product has not undergone changes or modifications since its initial certification that adversely impact the certified capabilities. This flexibility is available to health IT developers to accommodate routine changes

and product maintenance without the need for full recertification of each updated version of a previously certified Health IT Module.

ONC-ACBs must consider a health IT developer's request for ICS. However, the granting of ICS is at the discretion of ONC-ACBs ([45 CFR 170.550\(k\)](#); see also [76 FR 1306](#)). ONC-ACBs have procedures in place, consistent with ASTP-issued guidance, for processing ICS requests. It is up to the ONC-ACB to determine whether the capabilities for which certification criteria have been adopted have not been adversely affected.

ICS Process

When submitting an ICS request, the health IT developer must submit an attestation in the format specified by the ONC-ACB explaining the changes that were made and the reasons for those changes, as well as other information and supporting documentation that would be necessary for the ONC-ACB to evaluate the potential effects of the changes on previously certified capabilities. Similarly, upon receipt of an ICS request, an ONC-ACB must review the attestation to determine (in its judgment) whether the modifications described could have adversely affected any certified capabilities (and that retesting may be necessary) or whether to issue a certification to the newer version of the previously certified health IT that is supported by the reuse of test results from previous certification. An ONC-ACB may grant certified status to a newer version of a previously certified Health IT Module(s) only if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

ICS Requests and Surveillance

ONC-ACBs are encouraged to conduct surveillance on certified health IT for repeated ICS requests. As outlined in the [ONC-ACB Surveillance Resource](#), developers that request ICS more than three times on a Health IT Module may be subject to ONC-ACB surveillance. To clarify, if a health IT developer requests ICS for a Health IT Module three times, after the initial certification, there is no obligation for an ONC-ACB to conduct surveillance on that product. However, if the developer submits a fourth request for ICS for the same Health IT Module, the ONC-ACB may conduct surveillance on that product. The specific approach to conducting surveillance on a product associated with multiple ICS requests is at the discretion of the ONC-ACB. However, the ONC-ACB is responsible for ensuring that the product maintains its conformity to certification requirements and standards. To that end, ONC-ACBs may choose to conduct various types of surveillance activities to assess conformance, such as testing, documentation review, and site visits, among others, to determine if the certification still adheres to the Certification Program requirements.

ICS and Real World Testing

Health IT developers with Health IT Module(s) certified to certification criteria outlined in § 170.405(a) must successfully test the real world use of the technology for interoperability in the type(s) of setting(s) in which such technology would be marketed. On June 30, 2025, we issued the "[Real World Testing Condition and Maintenance of Certification Requirements Enforcement Discretion Notice](#)" stating that for the calendar year 2025, a developer with a Health IT Module(s) certified to one or more of the criteria referenced in 45 CFR 170.405(a) is not expected to submit an annual real world testing plan to its ONC-ACB for the 2026 real world testing year. For calendar year 2026, ASTP/ONC only expects a developer with a Health IT Module(s) certified to the (g)(7) through (10) certification criteria, as of August 31, 2024, will submit a CY 2025 real world testing results report to its ONC-ACB by March 2026.

When a developer leverages ICS after the August 31st deadline for Real World Testing eligibility and gets a newer version of a Real World Testing-eligible product certified, then withdraws the previous listing, the newer version of that product inherits the Real World Testing requirement along with its certification. As outlined in § 170.405(b)(2)(ii), developers that update Health IT Modules using ICS after August 31st of the

year in which the plan is submitted must include the newer version of the certified Health IT Module(s) in its annual Real World Testing results report. Including the updated, newer ICS version(s) of a product required for Real World Testing will ensure that the developer does not inadvertently fail to meet the Real World Testing results reporting requirement for a given Real World Testing cycle. Thus, developers that choose to update via ICS should apply the newer version(s) to their results report and include details on how they managed the various ICS versions of their product required for Real World Testing.

GAP CERTIFICATION

Gap certification of health IT is available for specified criteria, identified by ASTP/ONC, for which a developer must meet updated requirements to maintain certification in the Certification Program. The Certification Program includes the option of gap certification to streamline the certification process for previously certified health IT.

Gap certification:

- (1) Applies to previously certified health IT;
- (2) Available for certification criteria that were adopted through rulemaking at different points in time;
- (3) Available for certification criteria that requires testing for initial certification but has been revised with updated requirements that require developer attestation to an ONC-ACB and do not require retesting to maintain certification; and
- (4) Requires no further testing of the certified capabilities included in the previously certified health IT if the ONC-ACB determines that they have not been adversely affected.

[[45 CFR 170.502](#); see also [76 FR 1307-1308](#), [80 FR 62608-62609](#), and [81 FR 72446](#)]

Gap certification is only available for certification criteria that require testing for initial certification, have been revised with new requirements adopted through rulemaking at a later point, and require only developer attestation to the ONC-ACB for conformance with the updated requirements. ASTP/ONC will identify certification criteria that are eligible for gap certification. Availability of gap certification considers whether the standard(s) associated with a certification criterion or criteria changed and whether additional certification criteria changed in such a way that they affected other previously certified capabilities of the previously certified health IT ([76 FR 1307](#)).

The option to provide and grant gap certification is at the discretion of ONC-ACBs ([76 FR 1308](#)). Gap certification is permitted based on the use of test results from previous certification. ASTP/ONC expects, however, that an ONC-ACB would have considered the temporal nature of test results and other relevant changes in the health IT brought forward for gap certification when determining whether to grant gap certification (see [81 FR 72447](#)).

Gap Certification Process

When ASTP/ONC adopts a revised version of a certification criterion or criteria, the conformance method for the updated requirement(s) will be specified. If conformance to the update requires developer attestation directly to the ONC-ACB (where testing was previously required for said criterion(a)) to maintain certification, gap certification will be used as the conformance method to grant certification for the updated requirements. The developer must submit an attestation, in the format specified by the ONC-ACB, and follow the ONC-ACB processes and procedures for gap certification requests. Upon review of the developer attestation, the ONC-ACB may grant certified status to a newer version of a previously certified Health IT Module(s) only if it determines that the capabilities for which certification criteria have been adopted have not been adversely impacted.

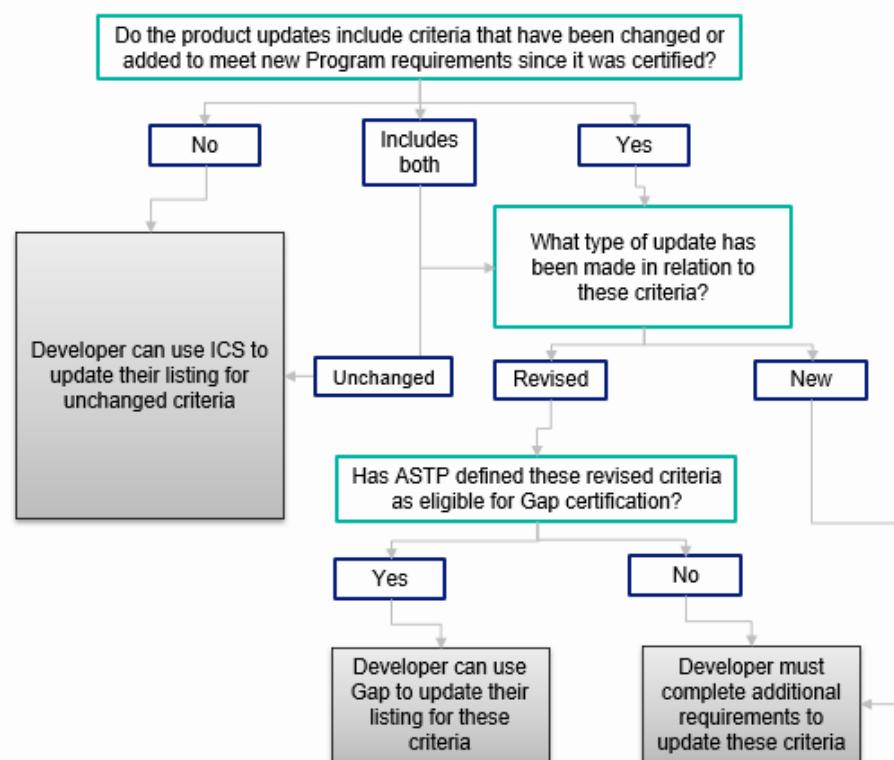
Can a listing utilize gap certification and ICS in one version update?

A scenario can arise where a Health IT Module is updated leveraging both gap certification and ICS. This can occur if a developer is updating to a newer version of a previously certified Health IT Module and includes both criteria that have not undergone changes since initial certification and criteria that have minimal revisions that must be adopted for continued conformance with certification requirements. If the developer seeks a new version of their Health IT Module to meet these requirements, the developer will utilize ICS for the unchanged criteria and gap certification for the minimally revised criteria. See below for some scenarios that may require utilization of ICS, gap certification, both or neither approach to update a certified listing.

Potential Paths for Updates to Previously Certified Health IT

Type of Criteria Updates	Path for Continued Certification
Criteria have NOT been updated with new certification requirements (i.e., unchanged criteria)	ICS
Criteria have been updated with new certification requirements (i.e., revised criteria)	Gap certification via attestation, or Additional testing/evidence needed

The following workflow outlines the approaches available for developers with previously certified health IT when updating their product to maintain certification under the Certification Program.



Scenarios

ICS	A health IT developer is requesting ICS to update to a newer version of its previously certified health IT to align it with internal upgrades unrelated to the functionalities required for certification. The listing is certified to seven certification criteria that do not have upcoming updates required for continued conformance in the Certification Program. The ONC-ACB determines that the certified capabilities have not been adversely affected by the developer's version upgrade. The ONC-ACB grants ICS based on the original scope of certification and a new listing is create in CHPL.
Gap Certification	A health IT developer is certified to three certification criteria, all of which have been revised and require updates under a recent final rule. One of the criteria requires retesting to demonstrate conformance with the updated requirements. The other two were approved by ASTP/ONC for gap certification via an attestation of conformity to their ONC-ACB for the updated requirements. The health IT developer retests the one criterion and requests gap certification for the other two criteria to maintain conformance with updated certification requirements for their listing.
Both ICS and Gap Certification	A health IT developer is certified to ten certification criteria for a health IT product. Three of those certification criteria were updated in a recent final rule. One criterion requires retesting while the other two can be updated via gap certification. The other criteria are unchanged and will be unaffected by the updates being made to the listing. The developer will use a combination of three methods to update their listing: 1) retesting for the one revised certification criterion that requires retesting; 2) if approved by the ONC-ACB, gap certification for the two revised certification criteria eligible for gap certification; and 3) if approved by the ONC-ACB, ICS for the unchanged criteria.
Neither ICS nor Gap Certification	A health IT developer is certified to three certification criteria that have been revised under a recent final rule. As outlined in the final rule, the developer will have to retest all three criteria to ensure ongoing conformance with certification requirements. Because retesting is required for all three, the listing is not eligible for gap certification or ICS to update to a newer version.

CERTIFIED HEALTH IT PRODUCT LIST (CHPL)

If the ONC-ACB issues a certification to a newer version of a previously certified Health IT Module via the gap certification and/or ICS flexibilities, the ONC-ACB must include this certification in its weekly report to the National Coordinator. For the purposes of associating a certification with a given product, this policy is appropriate regardless of the software development/release approach employed by a health IT developer.

Certification represents a snapshot (a fixed point in time) where it has been confirmed by an ONC-ACB that a Health IT Module has met all requirements of the applicable certification criteria adopted by the Secretary. Thus, if a different version of a Health IT Module is made available and the health IT developer leverages gap certification for the newer version, the ONC-ACB must report the certification of the newer version to the National Coordinator for listing on the CHPL.

For ICS, if a newer version of a previously certified Health IT Module inherits the prior version's certification, the prior version's certification needs to be formally associated with this newer version and subsequently reported to the National Coordinator for listing on the CHPL. Without this association, a health IT developer would not be able to assert that the updated health IT was "certified," nor would health care providers be able to verify on CHPL that the health IT is certified.