PRODUCT IDENTIFICATION & VERSIONING
Program Guidance #17-05
Issued and Effective Date: December 1, 2017

Subject: Product Identification & Versioning

This guidance emphasizes the significance of an ONC-ACB's assessment of a health IT developer's product identification scheme. Product identification schemes must be used to accurately identify certified health IT for which results are reported, evaluated and reviewed, and certification is granted. In the event there are modifications to, or multiple iterations of, certified health IT that affect one or more certification criteria, there is an implicit requirement to unambiguously identify each instance with traceability to that modification's/iteration's certificate.

An ONC-ATL and an ONC-ACB must be able to identify an instance when certification is granted for health IT such that:

- Installed certified health IT can be unambiguously traced to a certificate;
- End users of health IT can determine if their Health IT Module is a certified or non-certified Health IT Module;
- End users of certified health IT can distinguish between modifications and/or multiple iterations of a certified Health IT Module;
- Where multiple certificates exist for versions of certified Health IT Modules with different scopes, evaluation of the installed certified Health IT Module can identify which version is in use and can be traced to that specific certificate.

Supporting Regulatory and Standard Requirements

45 CFR 170.523 Principles of proper conduct for ONC-ACBs

(f) Provide ONC, no less frequently than weekly, a current list of Health IT Modules, Complete EHRs, and/or EHR Modules that have been certified that includes, at a minimum:

(1) For the 2015 Edition health IT certification criteria and subsequent editions of health IT certification criteria:

(i) The Health IT Module developer name; **product name**; **product version**; developer Web site, physical address, email, phone number, and contact name [emphasis added].

45 CFR 170.545 Complete EHR certification

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified product to inherit the certified status of the previously certified criteria without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified product, an ONC-ACB must review an attestation submitted by the developer of the certified product to determine whether any change in the newer version has adversely affected the certified capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified product if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

45 CFR 170.550 Health IT Module certification.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified Health IT Module(s).

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(k) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified Health IT Module(s) to inherit the certified status of the previously certified Health IT Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Health IT Module(s), an ONC-ACB must review an attestation submitted by the developer(s) of the Health IT Module(s) to determine whether any change in the newer version has adversely affected the Health IT Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified Health IT Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

By inclusion/reference:

IS0/IEC 17065

- *45 CFR 4.1.2 Certification agreement*, specifically 45 CFR 4.1.2.2(e), (f), (g), (h), (i), and (k)
- *45 CFR 4.1.3 Use of license, certificates and marks of conformity*
  a. ISO/IEC Guide 23 Methods of indicating conformity with standards for third-party certification systems
- 45 CFR *7.10 Changes affecting certification*, specifically 45 CFR7.10.3

IS0/IEC 17025

- *45 CFR 5.10.3 Test reports,* specifically 45 CFR 5.10.3.1(e), 5.10.3.2(a) and (b)

Previous and Related Guidance

Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark, December 2015, Version 3

Implementation Requirements

An ONC-ATL and an ONC-ACB must meet the requirements of their respective accreditations and provide accurate records related to the health IT being tested and certified, as well as the additional requirements of the ONC Health IT Certification Program (Program) as noted in 45 CFR 170.523(f)(1)(i). ONC-ACBs are required to assess the client's product identification scheme and make a determination as to the sufficiency of the scheme to meet the needs of the Program.

The Certified Health IT Product List (CHPL) ID scheme incorporates inherited certified status (ICS) increments and version. They, along with the product name, are the components of the ID that provide for the most traceability to the health IT developer's product ID scheme. Accurately updating and incrementing these components of the CHPL ID will minimize confusion.

Further, the Program is silent on the product identification or versioning scheme a health IT developer may take, and the determination of "fitness for use" of the client's scheme is at the discretion of the ONC-ACB. Thus, an ONC-ACB may impose additional requirements (specific to that health IT developer) necessary to fulfill their obligations within the Program to clearly associate a certified Health IT Module with its CHPL listing and to make an informed certification decision. However, the ONC-ACB cannot dictate or demand a particular product versioning approach or require overly detailed version listings on the CHPL beyond what the health IT developer intends to market. For example, if the health IT developer intends to market "Version 5.1" and used a developer-assigned "build number" associated with that product version to track the patches its customers have implemented, the ONC-ACB would not be expected to require that the "build number" be listed on the CHPL and would treat any Version 5.1 product, regardless of the build number, as the CHPL-listed product.

Implementation Recommendations and Guidelines

The fundamental requirements of product identification must be satisfied in all situations where modifications have occurred. Note that the requirements of 45 CFR 170.523(f)(1)(i) define the information that is reported and displayed on the CHPL and does not negate nor diminish these product identification and traceability requirements.

Beyond the ISO/IEC requirements, the Program does not establish any specific method, scheme, or approach for product identification, thus providing health IT developers with latitude in defining schemes that meet the requirements for unambiguous identification of released code. Such schemes must be acceptable to an ONC-ACB and be constructed such that it can be:

- Traceable to the certification decision and subsequent certificate; and
- Accessed and verified by end users and purchasers of the certified health IT.

Mutual understanding and acceptance of health IT developers' product identification schemes should be established between an ONC-ACB and the developer on a case-by-case basis. Alternately, an ONC-ACB may articulate specific requirements they believe are necessary to establish uniformity of reporting and identification of a product.

Incremental Approach to Testing and Certification and Modifications Outside Current Scope of Certification

The following guidelines are intended to inform health IT developers and ONC-ACBs of Program expectations for establishing and enforcing these requirements when health IT has been modified to broaden a scope of certification. A health IT developer may seek to broaden the scope of its health IT's certification due to taking a waved, incremental approach to testing; to incorporate certification criteria that were not previously available for testing and certification (e.g., delayed availability of test method); or when modifications to the health IT are unrelated to certification criteria and/or Program requirements.

Iterative development and testing of health IT may result in a single certificate at the end of all waves of testing or a new certificate at the end of each wave. In situations where health IT is tested and certified incrementally, the requirements of gap certification and ICS per 45 CFR 170.545(c) and (d) and 170.550(c) and (k) for Complete EHR and Health IT Module certifications may apply.

The choice of path is determined by many factors outside the scope of this guidance and at the sole discretion of the health IT developer, but must comply with all requirements of the Program set forth in the scope of certification with an ONC-ACB. Below are some examples and recommendations for ONC-ACBs working with their clients on product identification requirements:

I. ONC encourages ONC-ACBs to establish a clear understanding upfront of health IT developers' marketing intent and strategy. Prior to granting certification, an ONC-ACB may seek the following information:
   a. Is the health IT developer requesting incremental certification (certification in waves)? If so:
      i. Test results may be withheld and submitted as a final "package" for full scope of certification.
      ii. Test results may be submitted incrementally and certification is granted for each individual wave of testing.
         1. As new criteria are certified they would be added to the existing CHPL listing when the product version on the CHPL does not increment between the testing waves. Change in product version will result in new a CHPL listing.
         2. ONC expects that the ONC-ACB will carefully assess the product identification scheme to ensure traceability to the certificate.
         3. The CHPL will still record the addition of new criteria in the product history.
         4. ONC-ACBs are encouraged to provide guidance upfront to the health IT developer that addresses considering withdrawing all

previous certificates once the full scope of certification sought has been granted

II. For an incremental approach to testing as a result of delayed release of testing requirements for certification:

   a. *Option 1* – Change in product version, will result in new a CHPL listing

      i. The ICS component of the CHPL ID should be updated by increments as well (e.g., the original product is 0, the next version is 1, the version after that is 2, and so on).

   b. *Option 2* – No change in version but the product certifies to the new criteria/requirements that are now available

      i. As new criteria are certified they would be added to the existing listing on the CHPL.

      ii. The CHPL will still record the addition of new criteria in the product history.

Corrected Non-Conformities and Modifications within Current Scope of Certification

The following guidelines are intended to inform health IT developers and ONC-ACBs of Program expectations for establishing and enforcing these requirements when modification are made within the current scope of the health IT's certification. These requirements apply when: (1) modifications are made within the existing scope of certification; (2) modifications are made to correct a non-conformity; and (3) a non-conformity is related to requirements for attestation, reporting, or other non-code requirements of the Program that are resolved without modification to the Health IT Module or Complete EHR itself.

Health IT developers and ONC-ACBs are responsible for defining and agreeing on the specific requirements for addressing a modification for a non-conformity. When non-conformities are mitigated through non-code activities, there are no expectations that a health IT developer will exercise its approved product identification scheme as no change to the actual code has occurred. For example, when a non-conformity is related to usability testing and reporting, mitigation may require uploading a corrected report with no modification to the code base. Customer notifications, CHPL updates, and other activities may be required as determined by the corrective action plan (CAP).

Modifications to the product's software code may result in a change to the previous certificate such that instances of the corrected certified health IT can be distinguished from instances of the non-conforming certified health IT. An ONC-ACB must maintain confidence in its ability to identify products that have been modified under a CAP. Likewise, ONC-ACBs are responsible for ensuring that health IT developers have an effective plan to communicate the approved/accepted scheme to their customers. There is no program requirement for health IT developers to change the version of a Health IT Module or Complete EHR that has been modified to correct a non-conformity. However, in the event a health IT developer opts to not change the version of its corrected Health IT Module or Complete EHR, it must be made otherwise distinctly identifiable to the ONC-ACB and its customers from its previously non-conformant state. For example, a health IT developer may change the product's build number or

sub-minor version number (e.g., 3.1.1 to 3.1.2) to make the corrected Health IT Module or Complete EHR distinguishable.

ONC expects that ONC-ACBs will implement best practices to eliminate market confusion such as, but not limited to, the following:

1. Close out CAPs on the CHPL
    a. Note the identification method applied to the modified (corrected) Health IT Module or Complete EHR
2. Ensure that the health IT developer has an effective communication plan to customers
3. Consider adding to products in queue for upcoming surveillance [for non-cloud based Health IT Modules or Complete EHRs]

Use of Numbering Scheme for Versioning

Versioning schemes by health IT developers vary widely and the ONC-ACBs and ONC-ATLs have an obligation to ensure they are sufficient to allow for unambiguous identification of the system under testing, what is certified, and what will be surveilled. Thus, the version number that is documented on the health IT developer's application is the version number that will be on the certificate issued (unless there is an approved/accepted documented change during the testing and/or certification process). That version on the certificate is reported to and listed on the CHPL.

When health IT developers report changes to the product as required by the Program, the typical approach is to note these changes as extensions to the "baseline" version that indicate a patch or maintenance release, unless the developer is seeking to have a new "baseline" certified. For example, if a product is certified as version 5.2.0, it can be updated to version 5.3.0 and both versions can be listed on the CHPL. However, if the product updates are minor and the health IT developer wants to maintain the original "baseline" version scheme of 5.2.0, the developer should note that the actual version number that will be visible within the product to end-users will be 5.2.0.x. In this example, the baseline is stable and the ".x" represents a patch or maintenance update that the health IT developer is claiming does not affect the certified functions. Ultimately, the ONC-ACB has discretion to determine whether it agrees with the health IT developer's assessment of the effect on the certified capabilities. If the ONC-ACB agrees with the assessment, they should document evidence of this decision and that they will not alter the certificate or CHPL listing. In the above example, the version number listed on the CHPL of 5.2.0 should be considered to encompass all 5.2.0.x updates. If the ONC-ACB disagrees with the assessment (e.g., confirms there are changes in certified functions through additional testing), they will disallow the claim. The health IT developer has the option to seek a new certificate. If the health IT developer chooses to do so, they should indicate the precise version based on their versioning scheme.

It is important to clarify the proper use of a "placeholder" value (e.g., .0). When health IT developers submit their applications, they cannot change any part of the "baseline" version that relates to certified capabilities and claim the product is still certified. In other words, in the above

example, the "0" in 5.2.0 cannot be used as a placeholder for patch updates. The 5.2.0 is the "baseline" version and the health IT developer can use any numbering scheme after that ".0" to reflect updates that do not affect the certified capabilities.

Version Examples:

I.   The health IT developer has an existing certified product (version 5.2.0) and notifies the ONC-ACB they have a patch release that does not affect certified functionality. The developer's versioning scheme identifies this patch release (and is verifiable from within the application) as version 5.2.0.1, where the 4th digit indicates the patch/maintenance that has been applied to the baseline version.

    a.   If the ONC-ACB agrees, then there is no change to the certificate or CHPL listing and this decision is traceable through an evidence trail; the certificate and CHPL will show version 5.2.0 and the internal representation viewable to end-users within the software will show version 5.2.0.1.

    b.   If the ONC-ACB disagrees, they will not allow the 5.2.0.1 version to be marketed as a certified product and will discuss alternatives with the health IT developer.

Alternatives available will lead to a new certificate and CHPL update:

I.   Establish a new baseline version, e.g., from 5.2.0 to 5.3.0

    a.   The ONC-ACB will issue a new certificate and update the CHPL to this new "baseline" version – 5.3.0.

    b.   The prior 5.2.0 version will be withdrawn unless the health IT developer elects to maintain both versions.

II.   Extend the ID to unambiguously identify the product, e.g., from 5.2.0 to 5.2.0.1

    a.   The ONC-ACB will issue a new certificate and update the CHPL to this new "baseline" ID.

      i.   Note that in this example the versioning scheme is altered making the baseline x.x.x.x from x.x.x.

    b.   The prior 5.2.0 version will be withdrawn unless the health IT developer elects to maintain both versions.

In all cases, the ONC-ACB's records shall provide traceability from 5.2.0 to 5.2.0.1 or to 5.3.0 as required by the scheme.

The end result in all cases is that the product tested, certified, and marketed is unambiguously identified and non-impactful (to certified capability) changes are pushed to end users without affecting their claims of use of certified health IT. This can be verified through the ONC-ACB's records and by inspection of the system in use or under review.

Summary

In support of the requirements of 45 CFR 170.523, Principles of proper conduct for ONC-ACBs, an ONC-ACB must be able to identify certified products. To that end, ONC-ACBs may require health IT developers to implement and maintain a clearly documented product identification scheme that allows for unambiguous traceability of certification to installed products. ONC expects that an ONC-ACB will implement best practices (as noted in II.a.i and II.b.ii of the "Incremental Approach to Testing and Certification and Modifications Outside Current Scope of Certification" section above) to eliminate market confusion and ensure that end users are able to verify the scope of their certified Health IT Module or Complete EHR. The CHPL ID scheme incorporates ICS increments and version. The ICS increments and version, along with the product name, are the components of the ID that provide for the most traceability to the health IT developer's product ID scheme. Accurately updating these components of the CHPL ID will minimize confusion. In all cases, certificates issued will be subject to the full scope of Program requirements (e.g., surveillance, marketing, and transparency, et al.).