Test Procedure for §170.314(g)(4) Quality management system

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*.)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERION

This Certification Criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012. All EHR technology certified to the 2014 Edition EHR certification criteria would need to be certified to this certification criterion.

§170.314(g)(4) Quality management system**.** For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.
(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this Certification Criterion is classified as new. This Certification Criterion meets at least one of the two factors of new certification criteria: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or (2) the certification criterion was previously adopted as mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

2014 Edition Preamble Language

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the quality management system certification criterion is discussed:

- "We stated that, working with other Federal agencies, we intended to publish a quality management document that would be customized for the EHR technology development lifecycle and express similar principles to those included in ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR part 820…this document would provide specific guidance to EHR technology developers on best practices in software design processes in a way that mirrors established quality management systems, but would be customized for EHR technology development."
- "We stated that we understood that some EHR technology developers already have processes like these in place, but did not believe, especially in light of the IOM recommendation, that the EHR technology industry as a whole consistently follows such processes."
- "We emphasized that this certification criterion would not require EHR technology developers to comply with all of the document's quality management principles and processes in order to be certified. Rather, to satisfy the certification criterion, EHR technology developers would need to review their current processes and document how they do or do not meet the principles and processes specified in the document (and where they do not, what alternative processes they use, if any)."
- "We have adopted a certification criterion that accounts for the fact that we did not publish the quality management document as we had proposed. The certification criterion we have adopted is more general and provides more flexibility. The certification criterion expresses that for each capability an EHR technology includes and for which that capability's certification is sought, the use of a QMS in the development, testing, implementation and maintenance of that capability must be identified. Unlike our proposal, any QMS may be used to meet this certification criterion and even an indication that no QMS was used for particular capabilities for which certification is requested is permitted."
- "We understand that some EHR technology developers have several teams who work on different functional components of EHR technology. In the case where the whole development

organization uses the same QMS (or not at all) across all teams, then this certification criterion may be met with one report. Where there is variability across teams, the EHR technology developer will need to indicate the individual QMS' followed for the applicable certification criteria for which the EHR technology is submitted for certification."

- "We encourage EHR technology developers to choose an established QMS, but developers are not required to do so, and may use either a modified version of an established QMS, or an entirely "home grown" QMS. We also clarify that we have no expectation that there will be detailed documentation of historical QMS or their absence. As specified above, we believe that the documentation of the current status of QMS in an EHR technology development organization is sufficient."

2011 Edition Preamble Language

None included

Informative Test Description

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

The Tester shall verify that the developer has identified QMS system(s) used in the development, testing, implementation and maintenance of each capability submitted for certification.

The Vendor provides the documentation for this procedure.

This test procedure is organized into 1 section:

- Identify - Verifies that for each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability is identified.
  - The Vendor identifies the QMS used or indicates that no QMS was used in the development, testing, implementation and maintenance of each capability being certified
  - The Tester verifies that for each capability for which certification is sought, the Vendor has
    - Identified an industry-standard QMS by name (for example, ISO 9001, IEC 62304, ISO 13485, ISO 9001, and 21 CFR, Part 820…)
    - Identified a modified or "home-grown" QMS and an outline and short description of the QMS, which could include identifying any industry-standard QMS upon which it was based and modifications to that standard
    - Indicated that no QMS was used for applicable capabilities for which certification is requested

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.g.4 – 1: Identify the use of a QMS for each capability for which certification is sought

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Required Vendor Information

DTR170.314.g.4 – 1.01: Vendor shall identify QMS used in the development, testing, implementation, and maintenance of each capability for which certification is sought

DTR170.314.g.4 – 1.02: Vendor shall provide a report that

- If standard QMS (for example, (for example, ISO 9001, IEC 62304, ISO 13485, ISO 9001, or 21 CFR, Part 820…) was used, identifies standard QMS used in the development, testing, implementation, and maintenance of applicable criteria
- If modified or "home-grown" QMS was used, provides an outline and short description of modified or "home-grown" QMS used in the development, testing, implementation, and maintenance of applicable criteria
- If no QMS was used, indicates that no QMS was used for particular criteria

Required Test Procedure

TE170.314.g.4 – 1.01: Tester shall review the Vendor report to confirm that a QMS (or lack of QMS) has been identified and, if necessary, described, for each capability for which certification is sought

TE170.314.g.4 – 1.02: Using the Inspection Test Guide (below), Tester shall verify QMS report provided by the Vendor

Inspection Test Guide

IN170.314.g.4 – 1:01: Tester shall verify that

- If a single QMS was used for capabilities for which certification is sought, it was identified and, if necessary, described
- If different QMS were applied to specific capabilities for which certification is sought, each QMS applied was identified and, if necessary, described
- If no QMS was applied to all or some capabilities for which certification is sought, this was indicated

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description of Change	Date
1.0	For Public Comment	November 6, 2012