

# 2015 Edition Certification Companion Guide

## Quality Management System - 45 CFR 170.315(g)(4)

[FR preamble](#) – [Test Procedure](#)

Version 1.0 – Last Updated 10/26/2015

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
Revised	Not Eligible	No	Not Included	N/A

### Certification Requirements

This certification criterion was adopted at § 170.315(g)(4). There are no associated privacy and security certification requirements for this criterion.

### Regulation Text

Quality management system.

- (i) For each capability that a 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 that satisfies one of the following ways:
- (A) The QMS used is established by the Federal government or a standards developing organization.
  - (B) The QMS used is mapped to one or more QMS established by the Federal government or standards developing organization(s).
- (ii) When a single QMS was used for applicable capabilities, it would only need to be identified once.
- (iii) When different QMS were applied to specific capabilities, each QMS applied would need to be identified.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• All Health IT Modules certified to the 2015 Edition must be certified to the 2015 Edition QMS criterion “quality management system” (QMS) criterion.</li> <li>• This criterion is applicable to self-developed and open source software as well.</li> </ul>	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	<p>Technical Outcome – The specific QMS used in the development, testing, implementation and maintenance for each criteria/capability that certification is being sought must be identified.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• The QMS must be established by the Federal government or a standards developing organization (SDO); or mapped to one or more quality management systems established by the Federal government or standards developing organization(s). [see also <a href="#">80 FR 62672</a>]</li> <li>• Existing QMS standards may not explicitly state support for agile development methodologies. [see also <a href="#">77 FR 54191</a>] As such, documented agile development methodologies may be used in meeting the mapping provision of this criterion.</li> </ul>	N/A
(i)(A)	<p>Technical Outcome – Identify the specific QMS used that was established by the Federal government or an SDO.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• Potential QMS standards as suggested in ONC’s rules [see also <a href="#">80 FR 62672</a>, <a href="#">80 FR 16858</a>, <a href="#">77 FR 54190</a>]: <ul style="list-style-type: none"> <li>○ FDA's quality system regulation in <a href="#">21 CFR part 820</a>, so long as the developer cites their compliance with FDA's Quality System regulations for certification [see also <a href="#">77 FR 54191</a>]</li> <li>○ ISO 9001</li> <li>○ ISO 14971</li> <li>○ ISO 13485</li> <li>○ IEC 62304</li> <li>○ ISO 12207</li> <li>○ IEEE 730</li> <li>○ ISO 14764</li> <li>○ ISO 80001.</li> </ul> </li> </ul>	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(B)	<p>Technical Outcome – If <u>not using</u> a specific Federal government or SDO established QMS, the developer must map the QMS to one or more specific Federal government or SDO established QMS.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• Developers can illustrate how their QMS (including “home grown” QMS) maps to one or more QMS established by the Federal government or SDO through documentation and explanation that links the components of their QMS to an established QMS and identifies any gaps in their QMS as compared to an established QMS. [see also <a href="#">80 FR 62672</a>]</li> </ul>	N/A
(ii)	<p>Technical Outcome – If a single QMS was used <u>for all applicable capabilities/criteria</u> for which certification is being sought, it would only need to be identified once.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• In the case where the whole development organization uses the same QMS across all teams, then this certification criterion may be met with one report. [see also <a href="#">77 FR 54191</a>]</li> </ul>	
(iii)	<p>Technical Outcome – If <u>different QMS</u> were applied to specific capabilities/criteria, <u>each QMS applied would need to be identified</u> for the respective capability/criteria.</p> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• Where there is variability across teams working on different functional components of the health IT, the health IT developer will need to indicate the individual QMS' followed for the applicable certification criteria for which the technology is submitted for certification. [see also <a href="#">77 FR 54191</a>]</li> </ul>	N/A

**Note:** This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

**Version History**

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 26, 2015