

2015 Edition §170.315(g)(4) Quality Management System					
Testing Components:					
Test Procedure Version 1.1 – Last Updated 10/28/15					

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(g)(4) Quality Management System

Optionality Notes: - (i) Only one of the ways ((i)(A),(i)(B)) to demonstrate the use of a Quality Management System (QMS) is required.

(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.

Additionally Health IT Modules must meet either (i)(A) or (i)(B).

(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)(SDO).

Standard(s): None, but recognized list of Federal Government or SDO established QMSes:

21 CFR part 820: [TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES PART 820 QUALITY SYSTEM REGULATION](#)

ISO 9001: [ISO 9000 - Quality management](#)

ISO 14971: [ISO 14971:2007 Medical devices -- Application of risk management to medical devices](#)

ISO 13485: [ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes](#)

IEC 62304: [IEC 62304:2006 Medical device software -- Software life cycle processes](#)

Criteria ¶	System Under Test	Test Lab Verification
(i)(A)	<p>The Health IT developer identifies the QMS used in the development, testing, implementation, and maintenance of applicable criteria from among one of the recognized Federal Government or SDO established QMSes, including: 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304.</p> <p>The Health IT developer may demonstrate the QMS used by supplying evidence of QMS accreditation.</p>	The tester verifies that the QMS used is one of those established as per FDA's quality system regulation in 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304.
(i)(B)	The Health IT developer illustrates how their QMS maps to one or more recognized Federal Government or SDO established QMSes through documentation and explanation linking the components of their QMS to an established QMS, identifying any gaps.	The tester verifies that the QMS used is one that was established by the Federal Government or an SDO. The tester verifies that any identified gaps have been documented and explained.

(ii) When a single QMS was used for applicable capabilities, it would only need to be identified once:

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(ii)	The Health IT developer identifies the single QMS used for all applicable capabilities.	The tester verifies that the one QMS identified is used for all applicable capabilities.

(iii) When different QMS were applied to specific capabilities, each QMS applied would need to be identified.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(iii)	The Health IT developer identifies each QMS applied to the specific corresponding capability.	The tester verifies that each QMS applied to a specific capability is identified for that capability.

Document History

Version Number	Description of Change	Date
1.0	Released for Public Comment	March 31, 2015
1.1	Released for Public Comment	October 28, 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).