§170.315(g)(4) Quality management system

2015 Edition Test Procedure

Version 1.0 Updated on 01-20-2016

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016

Regulation Text

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§170.315 (g)(4) *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.

Standard(s) Referenced

None

Additional Resources

Recognized list of Federal Government or SDO established QMSes:

21 CFR § 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

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.

Testing components

Testing must be conducted for one of the Alternatives outlined below to satisfy the requirements for this criteria.

Paragraphs (g)(4)(i)(A)–(B) (Alternative)

System Under Test
A. The health IT developer identifies the QMS used in the development, testing, implementation, and maintenance for all criteria, for which certification is being sought, from among one of the recognized Federal Government or SDO established QMSes, including, but not limited to: 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304.
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.

Test Lab Verification

A. The tester verifies that the QMS used is one of those that have been established by the Federal Government or an SDO, including, but not limited to: FDA's quality system regulation in 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304.
B. The tester verifies that the QMS is mapped to one or more of the standards established by the Federal Government or an SDO. The tester verifies that any identified gaps have been documented and explained.

Paragraph (g)(4)(ii) (Alternative)

System Under Test

The health IT developer identifies the single QMS used for all criteria for which they are seeking certification.

Test Lab Verification

The tester verifies that the one QMS identified is used for all criteria for which the health IT developer is seeking certification.

Paragraph (g)(4)(iii) (Alternative)

System Under Test

The health IT developer identifies each QMS applied to the specific corresponding criteria, for which certification is being sought.

Test Lab Verification

The tester verifies that each QMS applied to a specific criteria for which certification is being sought, is identified.

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