# Test Criteria: 170.315.g.4 – Quality Management System

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| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(g)(4)_–_Quality)
* [Test Procedures](#_1.1_Quality_Management)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)
* [Appendix C: (g)(4) Attestation Template](#_Appendix_C:_G.4)

### Version of ONC Test Method

1.0

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT Developer or Participant under Test is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

|  |  |
| --- | --- |
| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Not applicable. | |
| **Test Data:**  Not applicable. | |
| **Test Tools:**  Not applicable. | |

# Demonstrate Standards Support

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** The use of a Quality Management System (QMS) must be identified in the development, testing, implementation, and maintenance for each capability certification is sought: | |

|  |  |  |
| --- | --- | --- |
|  | **Standard** |  |
|  | 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 |
|  | IEC 62304 | IEC 62304:2006 Medical Device Software – Software life cycle processes |
|  | IEEE 730 | IEEE 730 Standard on Quality Assurance |
|  | ISO 9001 | ISO 9000 – Quality Management |
|  | ISO 12207 | ISO 12207 – Systems and Software Engineering – Software life cycle processes |
|  | ISO 13485 | ISO 13485 – Medical Devices- Quality Management Systems |
|  | ISO 14764 | ISO 14764 – Software Life Cycle Processes - Maintenance |
|  | ISO 14971 | ISO 14971:2007 Medical Devices – Application of risk management to medical devices |
|  | ISO 80001 | ISO 80001 – Application of risk management for IT – Networks incorporating medical devices |
|  | ISO/IEC 12207:2008 | ISO 12207:2008 – Systems and Software Engineering – Software life cycle processes |
|  | Modified QMS/Mapped | Modified QMS that is mapped to existing QMS Standard |
|  | Other | Other QMS established Federal or SDO not listed above |

# 170.315(g)(4) – Quality Management System

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Identify single QMS or each QMS applied to capabilities in which certification is sought. | |
| **Expected Test Result:**  Health IT Developer must select one method:   * Identify the QMS used in the development, testing, implementation, and maintenance is established by the Federal Government or a standards developing organization (SDO)   **OR**   * Identify how QMS is mapped to one or more QMS established by the Federal Government or SDO(s). | |
| **Points to Remember:**   * If a single QMS was used, it would only need to be identified once. * If different QMS were applied, each QMS applied would need to be identified. * Health IT Developers are encouraged to choose an established QMS, but are permitted to use a modified version of an established QMS. In these cases, the developer must illustrate how their QMS maps to one or more QMS established by the federal government or SDO. * All Health IT modules certified to the 2015 edition will need to be certified to the §170.315(g)(4) QMS criterion. * To verify compliance to §170.315(g)(4), health IT developers must submit the following two documents:  1. **QMS Attestation Letter** (template in [Appendix C](#_Appendix_C:_G.4)) identifying QMS used. If multiple QMS or modified/mapped QMS are used, descriptions should be submitted within this attestation. 2. The “**2015 Edition Quality Management System Template**” spreadsheet can be downloaded from Zendesk or inquire with your Test Proctor for a copy. The information submitted within this template should be a very brief overview of your QMS. This discrete data will be made public on the ONC CHPL website so trade secrets or propriety information should not be disclosed. | |

**Test Procedures**

### Quality Management System (select one method for certification):

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| --- | --- |
|  | **Method #1:** Identify one of the following recognized federal government or SDO QMS standards used in the development, testing, and implementation and maintenance for all criteria for which certification is being sought.   * FDA’s QMS Regulation in 21 CFR part 820 * ISO 9001 * ISO 14971 * ISO 13485 * IEC 62304 * ISO 12207 * IEEE 730 * ISO 14764 * ISO 80001 * Other QMS established Federal or SDO not listed above |
|  | **Method #2:** Describe how QMS is modified or mapped to one or more QMS established by the Federal Government or SDO established QMSes including explanation(s) linking the components of QMS to an established QMS and identifying any gaps. |
|  | The selected method will require the following two documents to be submitted to the Test Proctor for verification:   1. QMS Attestation Letter (see [Appendix C](#_Appendix_C:_170.315(g)(4)) below) 2. “*2015 Edition Quality Management System Template*” spreadsheet |

<INSERT LINK to QMS Attestation and 2015 Edition QMS Template spreadsheet>

# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-Feb-2016 Additions

* <NONE>

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§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 is:

(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) If a single QMS was used for applicable capabilities, it would only need to be identified once.

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

### Appendix C: 170.315(g)(4) Attestation Template

*This appendix contains a template for submitting the* §*170.315(g)(4) attestation requirements. The attestation letter should be returned on company letterhead addressing the required functionality.*

[Name of Authorized Senior Company Representative]

[Title of Company Representative]

[Company Contact Information]

[Company Name] attests that in accord with ONC criteria §170.315(g)(4), the following Quality Management System was used in the development, testing, implementation, and maintenance for the criteria in which certification is being sought as outlined below:

*When completing this attestation, select the applicable option (either “a” or “b”) for these two sections:*

*Identify Standard:*

* + 1. *Federal or SDO standard QMS (for example, ISO 9001, IEC 62304, ISO 13485, ISO 9001, or 21 CFR, Part 820, etc.) was used.*
    2. *Modified/mapped Federal or SDO standard QMS was used. If so, provide an outline and short description of modified/mapped QMS used in the development, testing, implementation, and maintenance of applicable criteria.*

*Identify if standard declared above is applicable to:*

* + 1. *If a single QMS was used for* ***all*** *criteria in which certification is being sought, please specify.*
    2. *If different QMS were applied to specific criteria, list each criteria module that each QMS applies to.*

**I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.**

[Signature]

[Signature Block of Authorized Senior Company Representative]

[Date signed]

# Change Log

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| --- | --- |
| Revision | Change Description |
| 01-Nov-2016 | Added Appendix C for g4 attestation template. Added instructions for completing attestation along with QMS template. |
| 01-Oct-2016 | Updated QMS Standards list. |
| 01-Apr-2016 | Removed Appendix C containing letter templates. Added reference to the “2015 Quality Management System Template” spreadsheet. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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