

2015 Edition §170.315(c)(1) Clinical Quality Measures – Record and Export				
Testing Components:				
				ONC Supplied Test Data
Test Procedure Version 1.0 – Last Updated June 8, 2016				

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

(c)(1)(i) Record For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”

Standard(s): None

Test Data: [“Cypress Gold Standard Test Data” instructions created using the Cypress Test Tool User](#)

Test Tool: [Cypress Test Tool User Interface](#)

Criteria ¶	System Under Test	Test Lab Verification
(i)	<p>Setup</p> <ol style="list-style-type: none"> The Health IT Module provides the following information in order to enable the creation of the (c)(1)(i) “Cypress Gold Standard Test Data” which includes instructions to enable the recording of CQM data within patient record(s): <ul style="list-style-type: none"> Name of the health IT developer; Name of the Product; List of CQMs to be certified; and Data format. <p>Manual Entry</p> <ol style="list-style-type: none"> Using the instructions provided by the Cypress software, a user demonstrates that they can manually record the specified data needed for each of the certified CQMs, using codified entries for data required for CQM exclusions or exceptions, including but not limited to support for codified: <ul style="list-style-type: none"> patient reason; system reason; and medical reason. <p>Batch Entry</p> <ol style="list-style-type: none"> Using the “Cypress Gold Standard Test Data” instructions provided by the Cypress software, a user demonstrates the automated recording of data needed for each of the certified CQMs, using codified entries for data required for CQM exclusions or exceptions, including but not limited to support for codified: <ul style="list-style-type: none"> patient reason; system reason; and medical reason. 	<p>Setup</p> <ol style="list-style-type: none"> The tester creates the “Cypress Gold Standard Test Data” based upon the Health IT Module provided information using the Cypress Test Tool User Interface to create a new (c)(1) test instance. <p>Manual Entry</p> <ol style="list-style-type: none"> Through Visual Inspection, the tester verifies that the test data in step 2 of the SUT that is denoted for manual entry, can be manually recorded in a patient record within the Health IT Module, using the health IT developer identified data entry functions. <p>Automated Entry</p> <ol style="list-style-type: none"> The tester verifies that the test data recorded in step 3 of the SUT can be batch recorded in a patient record within the Health IT Module, using the health IT developer identified automated entry functions through Visual Inspection. The tester verifies that all of the test data that will be used to calculate each CQM has been recorded in a patient record within the Health IT Module for each of the CQMs to be certified using Visual Inspection. The tester verifies that the data required for CQM exclusions or exceptions within the Health IT Module are codified entries using Visual Inspection.

(ii) **Export** A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:

- (A) Formatted in accordance with the standard specified in § 170.205(h)(2)
- (B) Ranging from one to multiple patients, and
- (C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

Standard(s): §170.205(h)(2) – [HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I\(QRDA I\), DTSU Release 3 \(US Realm\)](#)

Test Tool: [Cypress Test Tool User Interface](#)

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<ol style="list-style-type: none"> 1. The health IT developer submits documentation that demonstrates that a user has the ability to export a file at any time the user chooses and without subsequent developer assistance. 2. Based upon the patient records updated in section (i), a user exports, at any time and without any developer assistance, a data file formatted in accordance with the standard specified at § 170.205(h)(2), HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I(QRDA I), DTSU Release 3 (US Realm) for one or multiple patients. 	<ol style="list-style-type: none"> 1. Via documentation submitted by the health IT developer, the tester verifies that a QRDA I data file can be exported at any time (on-demand) and without any developer assistance for one or more CQMs associated with one or more patients. 2. Using the Cypress Test Tool User Interface, the tester <ul style="list-style-type: none"> • uploads the data file submitted by the Health IT Module; and • reviews the QRDA validation report for warnings or errors. 3. The tester verifies that the data file is formatted according to the standard specified at §170.205(h)(2) for one or multiple patients correctly and without omission, using the Cypress Test Tool and the QRDA validation report. 4. The tester verifies that a QRDA I data file can be exported for each and every CQM to which technology was certified under (c)(1)(i) by repeating steps 1 and 2 for each CQM to be certified. <p>Alternative: Cypress Certification API</p> <ol style="list-style-type: none"> 5. A user may use the the Cypress Certification API to perform step 3 of the SUT. The tester can verify the results in Cypress as normal, however the tester should manually perform verification steps 1-3 for at least one CQM to ensure this functionality is present.

Document History

Version Number	Description of Change	Date
1.0	Final Test Procedure	June 8, 2016

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