

Test Procedure for §170.314(c)(1) – (c)(3) Clinical quality measures

This document describes the test procedure for evaluating conformance of electronic health record (EHR) technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document¹ is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at <http://www.healthit.gov/certification> (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program², is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERION

These certification criteria are from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012. These certification criteria are included in the definition of a Base EHR.

§170.314(c) Clinical quality measures.

(1) Clinical quality measures – capture and export.

(i) Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for

¹ Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

² Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

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.”

(ii) Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

(2) Clinical quality measures – import and calculate.

(i) Import. EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i)

(ii) Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

(3) Clinical quality measures – electronic submission. Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at § 170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of these certification criteria are classified as revised from the 2011 Edition. These certification criteria meet at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as “optional” for a particular setting and is subsequently adopted as “mandatory” for that setting.

2014 EDITION PREAMBLE LANGUAGE

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012) where the clinical quality measures certification criteria are discussed:

- "For the 2014 Edition EHR certification criteria, we proposed to revise previously adopted CQM certification criteria for the ambulatory and inpatient settings to more explicitly specify the capabilities EHR technology would need to include. These revisions focused on:"
- "Data capture—the capability of EHR technology to record the data that would be required in order to calculate CQMs."
- "Export—the capability of EHR technology to create a data file that can be incorporated by another EHR technology which could be used to calculate CQMs."
- "Calculate—the capability of EHR technology to incorporate data (from other EHR technology where necessary) and correctly calculate the result for CQMs."
- "Report—the capability of EHR technology to create a standard data file that can be electronically accepted by CMS."
- "We noted that by explicitly proposing separate CQM certification criteria focused on these discrete capabilities user experiences relative to CQMs could be enhanced, the burden of capturing data elements necessary for CQMs could be reduced, and ultimately, EPs, EHs, and CAHs would be better positioned to assess in real-time the quality of care they provide."
- "In the Proposed Rule, we explained that the CQM lifecycle in the EHR starts with the determination of data to be captured and the subsequent capture of clinical or demographic data. Thus, the first specific capability we proposed for CQM certification (§ 170.314(c)(1)(i)) focused on the capability of EHR technology to electronically record all of the data elements that are represented in the QDM. More specifically, we stated that EHR technology would need to be able to record data in some representation that can be associated with the categories, states, and attributes represented by the QDM."
- "We explained that because the QDM is agnostic to health care settings (e.g., ambulatory and inpatient settings) and all of the CQMs ultimately adopted by CMS in a final rule would be based on the QDM, we did not believe that it would be necessary or possible to propose specific separate ambulatory and inpatient setting certification requirements as we have with other proposed certification criteria. Thus, we stated that all EHR technology regardless of the setting for which it is designed would need to meet § 170.314(c)(1)(i) if it is presented for certification to this certification criterion."
- "We recognized in the Proposed Rule that the gap between the data defined by the QDM and the data traditionally captured in EHR technology is, in some areas, broad." "We also acknowledged that some specialty-focused EHR technologies may not need to capture all of the data that the QDM describes and requested public comment on how certification could accommodate specialty EHR technology developers so that they would not have to take on development work (solely to get certified) for functionality that their customers may not require."
- "In addition to being able to capture data elements for CQMs, we proposed that EHR technology presented for certification must be able to export this data in the event that an EP, EH, or CAH chooses to use a different certified EHR Module to perform the calculation of CQM results."
- "We acknowledged that we were unaware of the existence of a widely adopted standard to export captured CQM data."
- "Finally, we requested comment on whether any standards (e.g., QRDA category I or III, or Consolidated CDA) would be adequate for CQM data export as well as whether Complete EHRs

(that by definition would include calculation and reporting capabilities) should be required to be capable of data export."

- "We discussed that we previously adopted at § 170.304(j) the CQM certification criterion for EHR technology designed for an ambulatory setting and expressed that it was treated as a threshold."
- "We proposed a separate certification criterion at § 170.314(c)(2) for the calculation of CQMs in anticipation that, in many cases, the calculation of CQMs could be performed by an EHR technology that is different from the one that was certified to capture the CQM data."
- "We expressed our expectation that EHR technology certified to this criterion would be capable of accurately, and without errors, calculating CQMs and that the accuracy of these calculations would be verified through testing."
- "We proposed a certification criterion at § 170.314(c)(3) to require EHR technology to enable a user to electronically create for transmission CQM results in a data file defined by CMS."
- "We noted our expectation that this capability would require EHR technology to generate an eXtensible Markup Language (XML) data file with aggregate CQM calculation results in the format CMS would have the capacity to accept."

2011 EDITION PREAMBLE LANGUAGE

None referenced

CHANGES FROM 2011 TO 2014 EDITION

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2014) where the clinical quality measures certification criteria are discussed:

- "We agree that capture of the entirety of the QDM as a requirement for certification is not appropriate, and we know of no systematic constraints to the QDM, including a distinction between "core" and "optional" measures that would meet the needs of our certification program for 2014." "We will therefore require EHR technology submitted for certification to § 170.314(c)(1)(i) to be capable of capturing the data elements specified in the standard adopted at § 170.204(c) (Data Element Catalog) 24 as required for each and every CQM for which the technology is to be certified (the "CQM-by-CQM Data Capture" option discussed in our Proposed Rule (77 FR 13851))."
- "Also included in the standard adopted at § 170.204(c) is a list of "supplemental" data elements required for CQM data submission to CMS. The list of supplemental data elements will be required for capture and transmission in each and every CQM report and includes (but is not limited to) race, ethnicity, sex, payer, Medicare HIC number, and where appropriate, NPI, CCN and TIN."
- "EPs, EHs, and CAHs may employ many methods to capture the information required by CQMs and we do not intend for this criterion to imply that technology submitted for certification would be

required to demonstrate manual data entry through a user interface (such as form fields or templates). Rather, the technology must be capable of capturing the information in some manner, and this includes information transferred from other systems (such as a practice management system, PHR, portal or kiosk)."

- "We agree that all data elements needed for CQM calculation should be discrete and codified. We don't believe that exclusions and exceptions must be captured to the granular level of detail described by a CQM that was developed for manual chart abstraction, but agree that where this granular data is available in coded form, it can and should be employed. In light of these comments, we will not require free text, but will permit that free text be captured and made available in addition to a codified entry. Codified entries may include specific terms as defined by each CQM, or may include codified expressions of the three global concepts: "patient reason," "system reason" or "medical reason.""
- "In addition, we appreciate the comments regarding linkage of CDS to CQM, and agree that this should not be an explicit requirement for 2014 certification, as we have not formally defined how CDS and CQM should be "linked" or how this would be tested. We do not intend to require a 1:1 requirement of CDS interventions to CQM. Rather, we suggest that EHR technology developers incorporate CDS interventions for the clinical areas in which they have selected to submit CQMs for certification."
- "We appreciate the comments on export of clinical quality data, and after careful review of these comments, we have decided to require this functionality for certification at § 170.314(c)(1)(ii)."
- "QRDA Category I has now been successfully balloted through HL7, has been selected by CMS as an accepted form of quality data reporting, and will therefore be required for certification to § 170.314(c)(1)(ii)."
- "Notably, we have modified our proposal for § 170.314(c)(2) to finalize a more specific and clear certification requirement that EHR technology be able to import a QRDA category I file that has been generated by the "export" capability in § 170.314(c)(1)(ii) specified above. Unlike for the 2011 Edition EHR certification criteria for CQMs, EHR technology will be tested and certified for conformance with this capability."
- "Finally, consistent with other terminology changes we have made, we changed the term "incorporate" to "import" in this certification criterion to provide more clarity regarding the action that is required to be demonstrated for certification. "
- "We referred to this capability as "reporting" in the Proposed Rule, but now refer to this capability as "electronic submission" in this final rule and in regulation. This renaming more accurately reflects the required capability, which is the ability to create a file in a particular format and be capable of submitting that file to CMS in a manner that CMS is able to accept."
- "In this regard, we believe that EHR technology should be capable of creating CQM data files that would support the forms of electronic submission that CMS makes available to EPs, EHs, and CAHs. Therefore, we have adopted both the HL7 QRDA Category I standard to support a patient level data submission approach and HL7 QRDA Category III to support an aggregate level data submission approach."
- "In general, we expect that providers who choose to submit aggregate reports will use the standard specified at § 170.205(k) (HL7 QRDA Category III), and providers who choose to submit patient-level reports will use the standard specified at § 170.205(h) (HL7 QRDA Category I). We

require that EHR technology, regardless of the setting (inpatient or ambulatory) for which it was designed, be certified to produce CQM data that could be submitted by an EP, EH, or CAH according to either standard."

ADDRESSING THE CERTIFICATION CRITERIA

This plan outlines a testing procedure that addresses §170.314(c) by utilizing the CQM testing software Cypress as the principal means for conducting and facilitating the testing of electronic health record software systems' capability to meet the CQM certification criteria. While the Cypress software does provide some automated functions for testing CQMs, it is expected that trained Testers will be administering the tests and performing the manual steps necessary to complete the tests both from within the Cypress software workflow and outside of it.

The test procedure described in this document specifically addresses the certification criteria in the following ways:

- Clinical quality measures – capture and export
Test data is provided by the Cypress software that references all of the necessary quality data model elements for each of the CQMs for which the EHR technology is being certified. This test procedure calls for the capture of this data in either a manual or automated fashion and for this test data to be exported for upload and inspection from the EHR system during the test. The inspection will happen within the Cypress user interface with automated feedback displayed to aid the Tester in their evaluation. The Cypress software does not explicitly test the capture capability as required of an EHR system under test by the certification criteria, however, this test procedure describes the inspection process that should be taken by the trained Tester to ensure the capability is met using the Cypress provided test data.
- Clinical quality measures – import and calculate
This test procedure uses test data provided by the Cypress software in various electronic formats (including the standard recognized at §170.205(h)) and calls for the presentation of this data to an EHR for processing and as input into the EHR technology during the test. This procedure then calls for the trained Tester to perform an inspection of the functions described by the EHR vendor for calculating each CQM the EHR system is being tested for and to validate that electronic calculation is performed on the test data provided by the Cypress software.
- Clinical quality measures – electronic submission
As part of this test procedure, the EHR technology exports the results of the calculation performed during the calculate portion of the test in both of the formats described in the certification criteria (§170.205(h) and (k)). The Tester uploads the QRDA Category III aggregate summary report via the Cypress user interface and receives comparison feedback on both the expected calculation results and the expected structure and format of the document in accordance with the QRDA Category III data standard specification.

The detailed descriptions of the expected Tester workflow and interaction with the EHR system under test can be found in the Informative and Normative test procedure sections of this document.

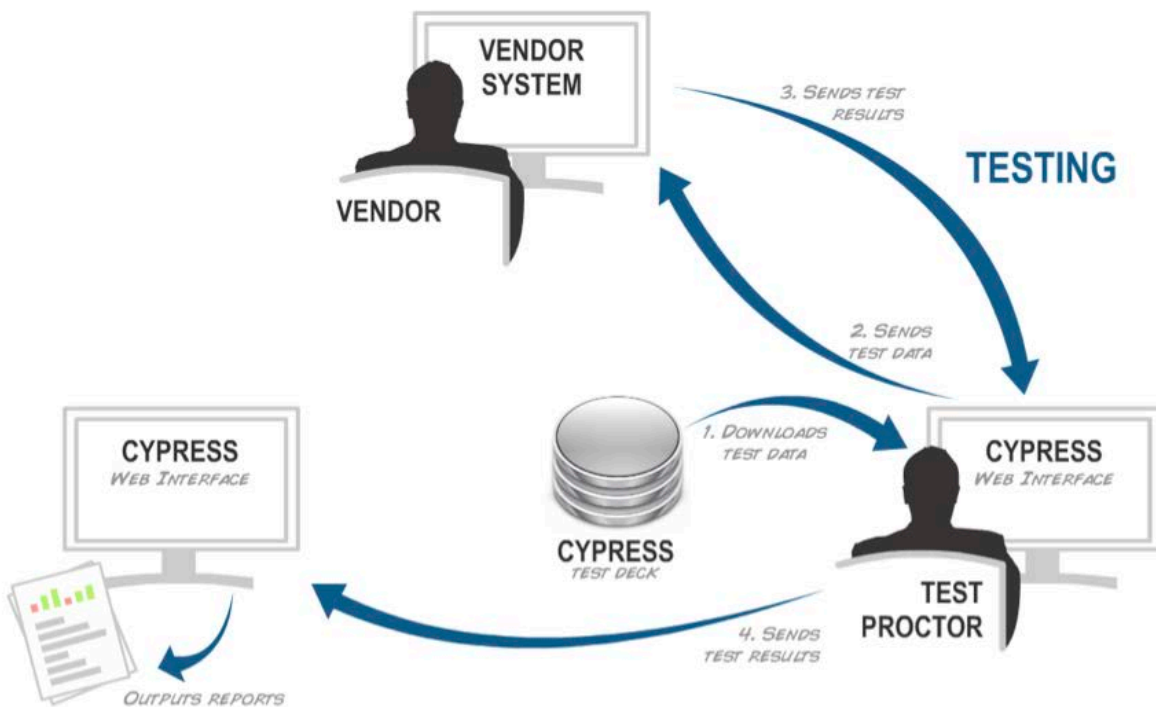
A number of terms are used in this test plan. This section enumerates those terms and defines how they are used in the context of this document.

- Cypress – A software-testing tool developed by The MITRE Corporation and funded by the Office of the National Coordinator for Health Information Technology (ONC) to test the calculation, export and electronic submission of CQMs. The web site for the project is <http://projectcypress.org/>.
- EHR Module – A component of an EHR System that only supports a subset of the CQM certification criteria contained in §170.314(c).
- EHR System – A complete EHR that is capable of all three of the CQM certification criteria contained in §170.314(c).
- EHR Technology – This term can refer to either an EHR System or an EHR Module in situations where the distinction between the two is not relevant, or the topic being discussed is common to both types.
- Gold Source Scorecard – The expected results of the Gold Source Test Data for each of the Stage 2 CQMs specified in the Medicare and Medicaid Programs: Electronic Health Record Incentive Program – Stage 2.
- Gold Source Test Data – Cypress includes a set of patient test data that has been specifically developed for testing the Eligible Professional (EP) and Eligible Hospital (EH) CQMs.
- System Under Test (SUT) – The EHR technology that is being tested for compliance with the certification criteria contained in §170.314(c) and the procedures contained elsewhere in this document.

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements. This test procedure is based on the ONC approved and the National Institute of Standards and Technology (NIST) published procedure, version 1.1, for Stage 1 – 170.304(j) and augmented to include Cypress as a software tool for testing the accurate calculation, submission and degree of correctness of the CQMs. Figure 1 shows the expected general workflow of a test performed with Cypress.

Figure 1: Sample Authorized Testing Lab Workflow



This test procedure is centered on the open source software tool, Cypress. Cypress is capable of performing the following types of tests in support of CQM certification:

- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category 1 standard for individual patient-level data used for CQM calculation
- XML Data conformance testing of the Quality Reporting Document Architecture (QRDA) Category III standard for aggregate reporting of CQM calculation
- Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Professional (EP) CQMs
- Accuracy calculation testing of the Meaningful Use Stage 2 Eligible Hospital (EH) CQMs

The principle mechanism for testing the accurate calculation of the clinical quality measures is the Cypress Gold Source Test Data. The Gold Source Test Data was designed to exercise all of the Stage 2

MU Eligible Professional (EP) and Eligible Hospital (EH) CQMs and is used to produce the Cypress Gold Source Scorecards of results by which EHR systems are evaluated.

Based on an EHR Vendor's software system capabilities, Cypress will provide either all or a subset of the Gold Source Test Data for this test procedure. It is anticipated that test scripts developed by ONC-Authorized Testing and Certification Bodies (ONC-ATCB) will determine the specifics on how the Cypress Gold Source Test Data is used and presented during a test. The Tester provides the Cypress Gold Standard Test Data to the Vendor for this procedure using one of the following methods:

- Manual entry - If manual entry is preferred by the vendor, Cypress can generate a formatted Hypertext Markup Language (HTML) page containing the test patient data for printing and human entry into the EHR SUT. It should be pointed out that manual entry of test patient data is considered the least desirable of all possible options for data entry due to a) the amount of time required to enter each patient (limiting the number of test patients that can be used and the rigor of the test); and b) the higher probability of data entry errors which could cause discrepancies in the calculated results generated by the SUT.
- Automated entry - Quality Reporting Document Architecture (QRDA) Category I XML format

This test procedure evaluates the capability of an EHR technology to calculate the CQMs (ambulatory or inpatient) for which it is being certified; and to electronically submit CQM data in accordance with the standard and implementation specified in §170.205(h) and (k). In addition to these capabilities, this test is intended to verify the degree of correctness of the implemented algorithms and resulting calculations of the quality measures based on the Cypress Gold Standard Test Data.

The test procedure is organized into two distinct phases to facilitate a workflow that supports performing a full test of the Clinical quality measures criteria as well as a subset of the criteria (as may be the case for EHR module testing and some complete EHR system testing scenarios). Each phase focuses on a specific subset of the criteria outlined in §170.314(c)(1) – (c)(3).

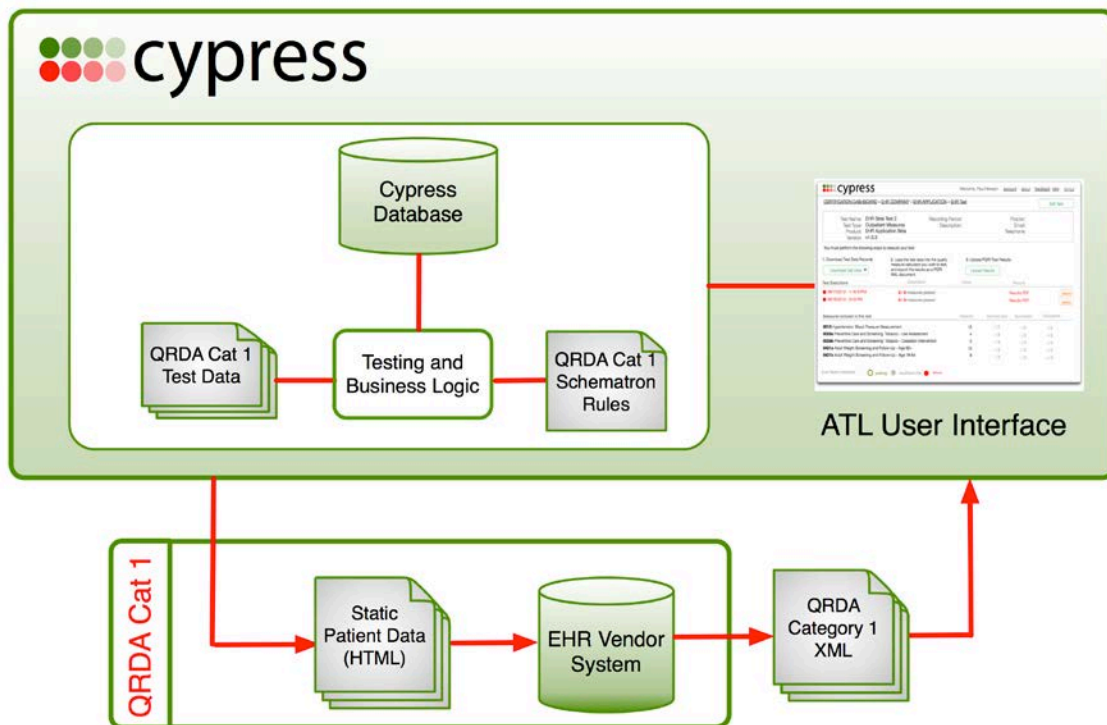
- Phase 1 – Verification of Capture and Export
 - §170.314(c)(1)(i) Capture [Only if manual entry or an electronic formats other than QRDA Category I is used to load test patient data]
 - §170.314(c)(1)(ii) Export
- Phase 2 – Verification of Import, Calculate, and Electronic Submission
 - §170.314(c)(2)(i) Import [Optional for complete EHR systems]
 - §170.314(c)(2)(ii) Calculate
 - §170.314(c)(3) Electronic submission

PHASE 1: VERIFICATION OF CAPTURE AND EXPORT

The basic concept for Phase 1 of the certification testing is shown in Figure 2. The primary purpose of this phase is the verification of the EHR technologies' ability to export data in the proper format, and with the proper Quality Data Model (QDM) data elements. In this phase, Cypress produces static patient data

for each of the CQMs that are to be tested, and exports the relevant patients in either QRDA Category I or HTML formats. This data is then loaded into the EHR SUT. The EHR is then commanded to export the patient test data in accordance with 170.314(c)(1)(ii) to produce a set of QRDA Category I files containing the proper elements from the QDM that are required to calculate the CQMs that are being tested. These QRDA files are loaded back into Cypress where they are tested for validity (valid QRDA Category I XML documents) and correctness (contain only the elements required to calculate the CQMs, and no more).

Figure 2: Verification of Capture and Export



PHASE 2: VERIFICATION OF IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

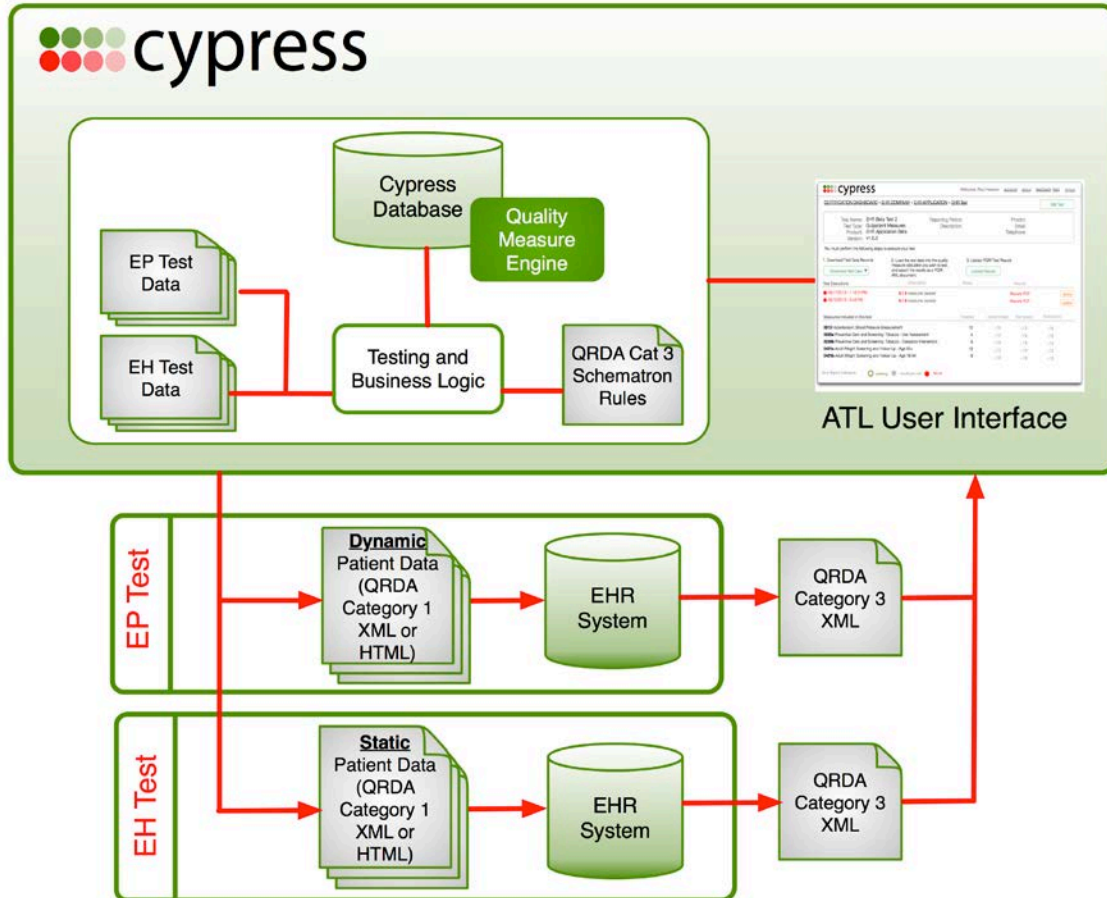
The basic concept for Phase 2 of the certification testing is shown in Figure 3. This test operates in two modes; for Eligible Professional (EP) CQM testing and Eligible Hospital (EH) testing. The EP testing will generate dynamic patient-level data with some level of randomization to guard against gamesmanship by EHR systems, but the initial plans for Cypress will include only static testing of the EH CQMs. This static EH testing will be enhanced and replaced over time with the eventual inclusion of dynamic EH CQM testing.

The purpose of this phase is verification that the EHR SUT can:

- Import properly formatted QRDA Category I documents (though complete EHR systems are exempt),
- Calculate the CQM results for the quality measures being certified, and

- c) Generate a properly formatted report that could be electronically submitted to the Centers for Medicare & Medicaid Services (CMS) using either QRDA Category I or QRDA Category III.

Figure 3: Verification of Import, Calculate and Electronic Submission



DETAILED TEST DESCRIPTION

Each phase of the test procedure is organized into four sections:

- Prepare
 - **Create the test data set for the EHR SUT** – create the test patient data using Cypress for the CQMs on which the EHR system is expected to report.
 - The Tester uses the Cypress user interface to add the EHR vendor and product being tested.
 - The Tester creates a new test using the Cypress user interface and specifies the measures that will be tested, the format and the method to use for loading the test patients into the SUT.

- Execute
 - **Electronically generate clinical quality measure artifacts** – evaluates the capability of the EHR SUT to electronically generate the proper CQM artifacts for the CQMs being certified.
 - The Tester provides Cypress Gold Standard Test Data for the clinical quality measures that the EHR system will be tested in the format selected to the EHR vendor.
 - The Vendor manually inputs or electronically imports the test data into their EHR system.
 - The Tester examines the CQMs implemented in the EHR.
 - The Tester validates that the proper CQM artifacts for the test being performed are electronically generated by the EHR SUT.

- Submit
 - **Electronically submit and verify generated CQM artifacts** – evaluates the capability of EHRs to electronically submit a) calculated quality measures in accordance with the standard and implementation specifications; and b) exported patient data sufficient to allow external calculation.
 - The Tester commands the EHR SUT to generate and electronically submit an aggregate report in the QRDA Category III format of the clinical quality measures calculated in the Execute test.
 - The Tester commands the EHR SUT to generate and electronically submit the patient-level export in the QRDA Category I format for the clinical quality measures being tested.
 - The Tester validates that the calculated clinical quality measures are submitted in accordance with the QRDA Category III standard and implementation specifications by uploading the QRDA Category III XML via the Cypress User Interface and the Cypress supplied XML Schema validation.
 - The Tester validates that the exported patient-level CQM data are submitted in accordance with the QRDA Category I standard and implementation specifications by uploading the QRDA Category I XML via the Cypress User Interface and the Cypress supplied XML Schema validation.

- Verify
 - **Verify electronic and accurate generation of clinical quality measure artifacts** – evaluates the capability to electronically and accurately generate CQM artifacts appropriate for each phase of the test procedure.
 - After the Tester validates the submission of the QRDA Category III, the Tester evaluates and displays the accuracy of the submitted clinical quality measure results via the Cypress User Interface.

- The Tester generates a test artifact bundle containing all test data used for this test execution, all products generated and submitted by the EHR SUT, and any other additional notes or information that the Tester deems relevant into a single archive file that is cryptographically signed. This artifact bundle is what the Tester makes available to the EHR SUT.

REFERENCED STANDARDS

§170.204 Functional standards	Regulatory Referenced Standard
The Secretary adopts the following functional standards:	
(c) <u>Clinical quality measure-by-measure data</u> . Data Element Catalog, (incorporated by reference in § 170.299).	
§170.205 Content exchange standards and implementation specification for exchanging electronic health information	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(h) <u>Clinical quality measure data import, export, and electronic submission</u> . Standard. HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, (incorporated by reference in § 170.299).	
(k) <u>Clinical quality measure aggregate electronic submission</u> . Standard. Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES – PHASE 1: VERIFICATION OF CAPTURE AND EXPORT

Derived Test Requirements

- DTR170.314.c – 1.1: Create the Gold Standard Test Data Set
- DTR170.314.c – 1.2: Export Patient Data from the EHR SUT
- DTR170.314.c – 1.3: Submit Exported Patient Data
- DTR170.314.c – 1.4: Verify Validity and Correctness of Exported Patient Data

DTR170.314.c – 1.1: Create the Gold Standard Test Data Set

Required Vendor Information

- VE170.314.c – 1.1.01: Vendor shall provide sufficiently detailed information about the EHR SUT such that the setup may be recreated in the future. Examples would be: product version number, the name and version of any optional modules installed in the product at the time of the test, and the operating system (and version) on which the EHR SUT is running.

VE170.314.c – 1.1.02: Vendor shall identify the clinical quality measures for which their EHR system is being certified.

Required Test Procedure

TE170.314.c – 1.1.01: Tester logs into the Cypress application and checks if the vendor of the EHR technology under test is listed on their Testing Dashboard. If the vendor is listed, testing proceeds to **TE170.314.c – 1.1.03**.

TE170.314.c – 1.1.02: Tester clicks on the “Add EHR Vendor” button and fills out the vendor information form shown in Figure 4, then clicks the “Create” button. The Tester is returned to the dashboard and the new vendor appears in the list (see Figure 5 for an example).

Figure 4: Create new vendor information form

The screenshot shows the Cypress application interface. At the top left is the Cypress logo. At the top right, it says "Welcome, Tim" followed by links for "account", "about", "feedback", "help", and "logout". Below the header, the breadcrumb "CERTIFICATION DASHBOARD » CREATE NEW VENDOR" is visible. The main content area is titled "Vendor Information" and contains the following fields:

- Vendor Name: (with a red asterisk indicating a required field)
- Vendor ID:
- Url:
- Address:
- State:
- ZIP:
- EHR POC:
- Email:
- Phone:
- Fax:

Below the "Vendor Information" section is a section titled "alternate POCs" with the following fields:

- Main EHR POC:
- Technical POC:
- Press POC:
- Email: (under Main EHR POC)
- Phone: (under Main EHR POC)
- Email: (under Technical POC)
- Phone: (under Technical POC)
- Email: (under Press POC)
- Phone: (under Press POC)

A "Create" button is located at the bottom left of the form area.

Figure 5: New vendor displayed in dashboard

The screenshot shows the Cypress Certification Dashboard. At the top left is the Cypress logo. At the top right, it says "Welcome, Michael" followed by links for "account", "about", "feedback", "help", and "logout". Below the header, there are two buttons: "Master Patient List" and "Add EHR Vendor". A welcome message states: "Welcome to Cypress! This is the Certification Dashboard that displays the names of the EHR vendors and the status of their products being tested. You can begin by adding an EHR vendor or simply explore the complete Cypress Test Deck by clicking on 'Master Patient List' above." Below this is a table with the following columns: "EHR VENDOR NAME", "PRODUCTS TESTED", "PASSING", "NOT PASSING", and "DATE OF LAST TEST". The table contains one row for "EHR Vendor Company" with "0 / 0 products" in the "PRODUCTS TESTED" column, "0 products" in the "PASSING" column, "0 products" in the "NOT PASSING" column, and a "delete" button in the "DATE OF LAST TEST" column. At the bottom, there are "Error Report Indicators" for "passing" (green circle), "insufficient info" (grey circle), and "failing" (red circle).

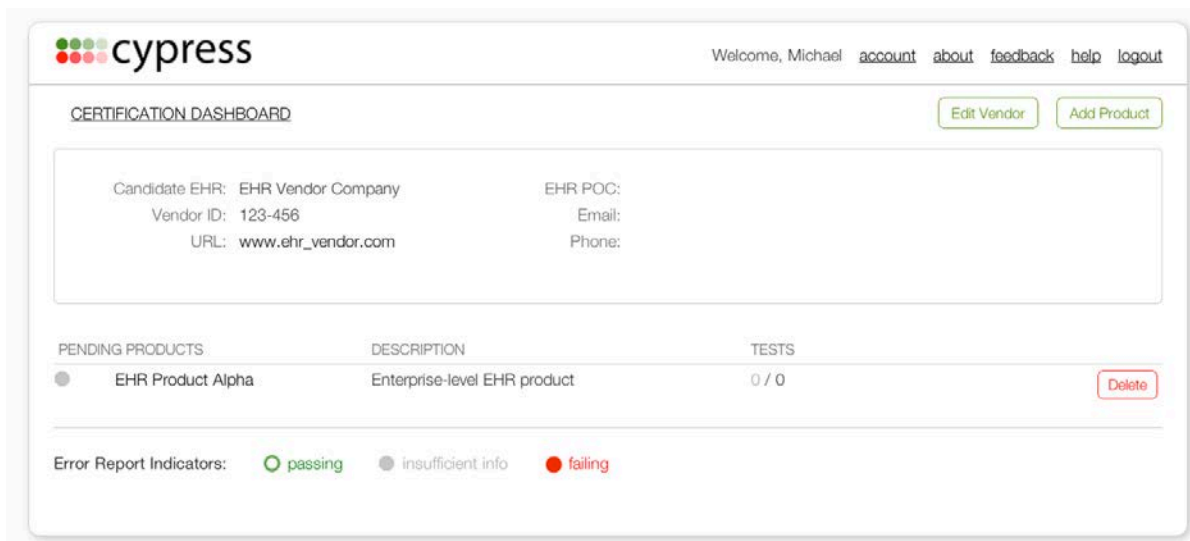
TE170.314.c – 1.1.03: Tester clicks on the EHR vendor whose product is under test and checks if the EHR product is listed on the page. If the product is listed, testing proceeds to **TE170.314.c – 1.1.05**.

TE170.314.c – 1.1.04: Tester clicks on the “Add Product” button and fills out the product information form shown in Figure 6. In the description field, enter the detailed information about the product provided in VE170.314.c – 1.1.01, then click the “Create” button. The Tester is returned to the vendor page and the new product appears in the list. An example vendor page with one product added is shown in Figure 7.

Figure 6: Create a new product form

The screenshot shows the "Create a new product form" in the Cypress dashboard. The breadcrumb trail is "CERTIFICATION DASHBOARD > EHR VENDOR COMPANY > CREATE NEW PRODUCT". The form is titled "Product Information" and contains three input fields: "Product Name:" (with a red asterisk indicating it is required), "Description:", and "Version:". A green "Create" button is located at the bottom left of the form area.

Figure 7: Vendor with one product added



- TE170.314.c – 1.1.05: Tester clicks on the EHR product being tested on the vendor page and is presented with the product page which lists all of the tests that this Tester has created for this product. A sample of the product dashboard for a newly added product that does not have any defined tests is shown in Figure 8. Tester clicks on either of the “Add Test” buttons to begin a new test sequence. This begins a test creation wizard which allows the Tester to define the parameters for the test.
- Tester provides a name, description and test type (in this phase, select QRDA Category I) for the test using the form shown in Figure 9 and clicks the “Next” button.
 - Tester selects all of the clinical quality measures that will be tested using the form shown in Figure 10 and clicks the “Done” button.
 - Tester is returned to the product dashboard with the newly created test listed under the heading “Incomplete Tests” (see Figure 11).
 - Tester clicks on the title of the test to be executed and is displayed a screen similar to Figure 12.
 - Tester moves the mouse over the “Test Data” button and clicks on the mechanism and data format that will be used to load the test patients into the SUT.
 - If the Tester chose one of the “Download ...” options, a dialog box will be displayed that will allow the zip file that contains the test data to be saved somewhere on the Tester’s computer.

TE170.314.c – 1.1.06: Tester provides the test data saved in TE170.314.c – 1.1.05(f) to the Vendor for import into the EHR SUT. The format of the test data will depend on the capabilities of the EHR SUT. The Cypress provided test data should not be loaded into the EHR SUT at this time.

Figure 8: Product dashboard with no tests

The screenshot shows the Cypress application interface. At the top left is the Cypress logo. The top right navigation bar includes 'Welcome, Michael', 'account', 'about', 'feedback', 'help', and 'logout'. The main content area is titled 'CERTIFICATION DASHBOARD » EHR VENDOR COMPANY' and contains two buttons: 'Edit Product' and 'Add Test'. Below this is a summary box with 'Product: EHR Product Alpha' and 'Description: Enterprise-level EHR product'. A table with columns 'TESTS', 'TYPE', 'DESCRIPTION', and 'EXECUTIONS' is shown, with a message 'There are no tests for this product.' and an 'Add Test' button. At the bottom, 'Error Report Indicators' are listed: 'passing' (green circle), 'insufficient info' (grey circle), and 'failing' (red circle).

Figure 9: Create new test step 1 - Basic Information

The screenshot shows the 'Create new test step 1 - Basic Information' form in the Cypress application. The breadcrumb trail is 'CERTIFICATION DASHBOARD » EHR VENDOR COMPANY » EHR PRODUCT ALPHA » CREATE NEW TEST'. The form has 'Back', 'Step 1 of 2', and 'Next' buttons. The 'Describe the test...' section includes: 'Test Name: EHR Alpha Outpatient Test', 'Reporting Period: from 09/30/2010 to 12/30/2010', and 'Description: Testing outpatient CQM behavior'. The 'Test Type' section has three radio button options: 'Outpatient - to test quality measures for Eligible Professionals (EP)' (selected), 'Inpatient - to test quality measures for Eligible Hospitals (EH)', and 'QRDA Category I - to test using the QRDA Category I format'.

Figure 10: Create new test step 2 - CQM selection

The screenshot shows the Cypress system interface for creating a new test. The breadcrumb trail is: CERTIFICATION DASHBOARD > TEST VENDOR > TEST PRODUCT > CREATE NEW TEST. The user is logged in as Rob. The current step is 'Step 2 of 2'. The main instruction is: 'Identify at least one quality measure to test from the list of available measures for this product...'. There are two checkboxes: 'all quality measures' (unchecked) and 'all Cancer measures' (unchecked). A list of quality measures is shown, with three selected: '0384 - Oncology: Medical and Radiation – Pain Intensity Quantified', '0387 - Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer', and '0389 - Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients'. A sidebar on the left lists various medical categories, with 'Cancer' selected and a count of '2'.

Figure 11: New test creation complete

The screenshot shows the Cypress system interface after a new test has been created. The breadcrumb trail is: CERTIFICATION DASHBOARD > EHR VENDOR COMPANY. The user is logged in as Michael. There are 'Edit Product' and 'Add Test' buttons. The product information is: Product: EHR Product Alpha, Version: v1.0, Description: Enterprise-level EHR product. Below this is a table of 'INCOMPLETE TESTS':

INCOMPLETE TESTS	TYPE	DESCRIPTION	EXECUTIONS
● EHR Alpha Test	QRDA Cat I	Testing EHR Product Alpha with latest code updates.	0

At the bottom, there are 'Error Report Indicators': passing (green circle), insufficient info (grey circle), and failing (red circle). A 'Delete' button is visible next to the test entry.

Figure 12: Test dashboard with no test executions

The screenshot shows the Cypress test dashboard. At the top left is the Cypress logo. The top right shows a user greeting: "Welcome, Michael" with links for "account", "about", "feedback", "help", and "logout". Below this is a breadcrumb trail: "CERTIFICATION DASHBOARD > EHR VENDOR COMPANY > EHR PRODUCT ALPHA" and an "Edit Test" button. The main content area is divided into three columns of test details: Test Name (EHR Alpha Test), Test Type (QRDA Cat 1), Product (EHR Product Alpha), and Version (v1.0); Reporting Period (09/30/2010 - 12/30/2010) and Description (Testing EHR Product Alpha with latest code updates); and Proctor (Michael Nosal), Email (mnosal@mitre.org), and Telephone. Below the details, a section titled "You must perform the following steps to execute your test:" lists three steps: 1. Download Test Data (with a "Test Data" button), 2. Load Test Data into your quality measure calculator, and 3. Upload Results (with an "Upload Results" button). A "Notes:" section has a text input field and an "add note" button. At the bottom, there is a table header for "TEST EXECUTIONS" with columns for "DESCRIPTION" and "RESULTS", and a message "There are no test executions". A legend for "Error Report Indicators" shows "passing" (green circle), "insufficient info" (grey circle), and "failing" (red circle).

DTR170.314.c – 1.2: Export patient data from the EHR SUT

Required Vendor Information

VE170.314.c – 1.2.01: Vendor shall identify the EHR function(s) that are available to export patient test data in QRDA Category I format.

Required Test Procedure

TE170.314.c – 1.2.01: Tester provides test data from Cypress generated in **DTR170.314c – 1.1** to the Vendor that is relevant to the CQMs that the EHR will be tested on in QRDA Category I and/or HTML format.

TE170.314.c – 1.2.02: The test data from the previous step is electronically imported or manually entered into the EHR SUT, based on the capabilities of the product being tested.

TE170.314.c – 1.2.03: Using the EHR function(s) identified in **VE170.314.c – 1.2.01**, the Vendor shall electronically export the patient test data in QRDA Category I format for the CQMs being tested while observed by the Tester and provide this data to the Tester.

DTR170.314.c – 1.3: Verify validity and correctness of exported patient data

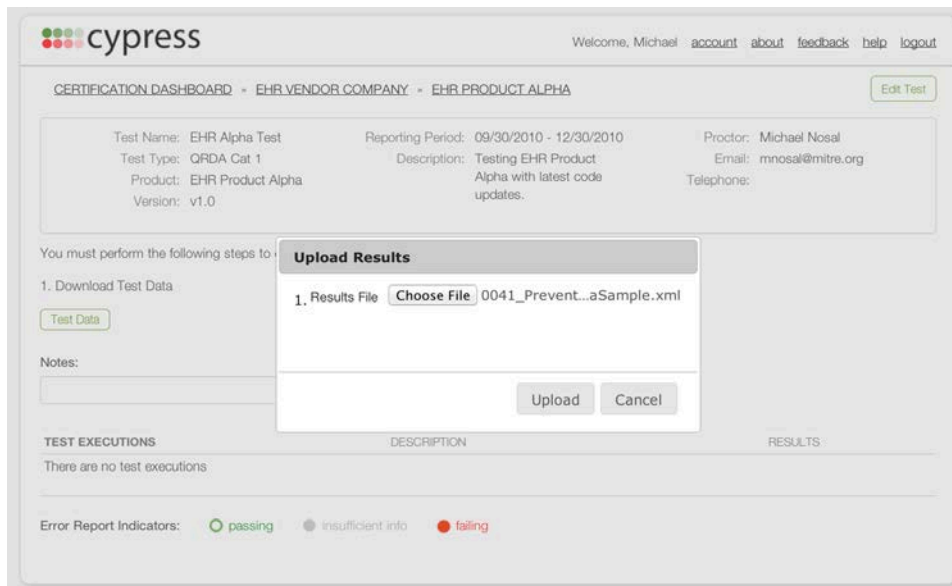
Required Vendor Information

VE170.314.c – 1.3.01: The exported QRDA Category I documents generated and provided to the Tester in **TE170.314.c – 1.2.03**.

Required Test Procedure

TE170.314.c – 1.3.01: Tester displays the Product Test dashboard page in Cypress (log in, click on vendor, click on product, and click on test name). Tester then clicks on the “Results” button. In the dialog that appears the Tester clicks on the “Browse...” button next to the “1. Results File” input box and selects the file received from the Vendor in **TE170.314.c – 1.2.03**, then clicks the “Upload” button (see Figure 13).

Figure 13: Upload test execution results



TE170.314.c – 1.3.02: Once the upload of the QRDA Category I documents is finished, validation will be performed on the uploaded documents. The Tester shall review any QRDA validation warnings or errors that are displayed at the top of the test details page. Examples of a test execution with validation errors can be seen in Figure 14 and Figure 15.

TE170.314.c – 1.3.03: The Tester downloads the Cypress test report by clicking the “Download” button at the top of the test details page, and selecting the “Report as PDF” option. The Tester should choose to save the generated PDF report in a location on their local system designated for the artifacts from this complete test (Phase 1 and Phase 2).

TE170.314.c – 1.3.04: The Tester shall collect all of the artifacts that resulted from testing this EHR system into the same location. This includes the following:

- Cypress test patient data provided to the Vendor in TE170.314.c – 1.1.06.
- The QRDA Category I export submitted by the Vendor in DTR170.314.c – 1.3.
- A copy of the manifest for the Cypress test tool instance that was used to generate the test data and create the test report. This file contains the version number of each of the subcomponents used by the particular Cypress instance. It is named CypressManifest.txt and is located in the root directory of the Cypress installation.
- The PDF report generated by Cypress in TE170.314.c – 1.3.03.
- Any additional files containing notes generated by the Tester during the execution of this test procedure.
- Any other files that the Tester deems relevant for this test execution.

TE170.314.c – 1.3.05: The Tester shall bundle the entire set of test artifacts collected in the previous step into a pkzip-compatible archive (zip archive) using utilities appropriate for the computer system the Tester is using.

Figure 14: Test execution with validation errors

The screenshot displays the Cypress certification dashboard for a specific test. The page header includes the Cypress logo and user navigation links. The main content area shows test details for 'EHR Alpha Test' and provides instructions for execution. A table lists test executions, with the most recent one showing validation errors. The bottom section provides a summary of the test results, including the number of XML validation errors and warnings.

TEST EXECUTIONS	DESCRIPTION	RESULTS
2012-10-11 02:51:53 UTC		Results

TEST RESULTS

Summary | XML Errors | XML Warnings | Content Inspection

Test Date: 2012-10-11 02:51:53 UTC
Inspection ID: EHR Vendor Company
Document Type: ** document type **
Version: ** document version **

XML Validation Errors: **49**
XML Validation Warnings: **48**
Content Inspection Errors: ** content inspection errors **

Notes

In this test, a successful test execution is one in which there are no XML validation errors. XML validation warnings are allowed, and will not result in a test failure. However, the Tester should review the warnings generated and record any relevant observations that they can make about the reasons for the warnings in the **Notes** field on the Product Test details page.

Figure 15: Details of test execution with errors

The screenshot shows the Cypress web interface for a test execution. At the top, the Cypress logo is on the left, and user information 'Welcome, Michael' with links for 'account', 'about', 'feedback', 'help', and 'logout' is on the right. Below this is a breadcrumb trail: 'CERTIFICATION DASHBOARD > EHR_VENDOR_COMPANY > EHR_PRODUCT_ALPHA' and an 'Edit Test' button.

The main content area displays test details in a grid:

- Test Name: EHR Alpha Test
- Reporting Period: 09/30/2010 - 12/30/2010
- Proctor: Michael Nosal
- Test Type: QRDA Cat 1
- Description: Testing EHR Product Alpha with latest code updates.
- Email: mnosal@mitre.org
- Product: EHR Product Alpha
- Telephone:
- Version: v1.0

Below the details, a section titled 'You must perform the following steps to execute your test:' lists three steps:

- Download Test Data (with 'Test Data' button)
- Load Test Data into your quality measure calculator
- Upload Results (with 'Upload Results' button)

A 'Notes:' section has a text input field and an 'add note' button.

A table titled 'TEST EXECUTIONS' has columns for 'TEST EXECUTIONS', 'DESCRIPTION', and 'RESULTS'. One entry is shown: '2012-10-11 02:51:53 UTC' with a 'Results' button.

The 'TEST RESULTS' section has tabs for 'Summary', 'XML Errors', 'XML Warnings', and 'Content Inspection'. The 'Summary' tab is active, showing:

- Test Date: 2012-10-11 02:51:53 UTC
- Inspection ID: EHR Vendor Company
- Document Type: ** document type **
- Version: ** document version **
- XML Validation Errors: **49**
- XML Validation Warnings: **48**
- Content Inspection Errors: ** content inspection errors **

A 'Validation Notes:' section contains a paragraph of text explaining content discrepancies and validation rules.

The 'Vendor Generated XML' section shows a code block with XML headers and a disclaimer:

```
<?xml version="" encoding="" ?>
<?xml-stylesheet type="text/xsl" href="cda.xsl"?>
<!-- Disclaimer: The QRDA samples generated by the system are designed to provide a general idea about the content, structure and parts of QRDA using hypothetical patient data; however, in this phase of the project, the content of the QRDA sample documents may not have "clinically" consistent data. Additionally, in this first phase of the project, some QRDA documents may not have all of the required Quality Data Elements and/or may not be completely error-free (i.e. there may be QRDA schema conformance issues). -->
```

NORMATIVE TEST PROCEDURES – PHASE 2: VERIFICATION OF IMPORT, CALCULATE AND ELECTRONIC SUBMISSION

Derived Test Requirements

DTR170.314.c – 2.1: Create the Gold Standard Test Data Set

DTR170.314.c – 2.2: Electronically Calculate Clinical Quality Measures

DTR170.314.c – 2.3: Electronically Submit Calculated Clinical Quality Measures

DTR170.314.c – 2.4: Verify Electronic and Accurate Calculation of Clinical Quality Measures

DTR170.314.c – 2.1: Create the Gold Standard Test Data Set

Required Vendor Information

VE170.314.c – 2.1.01: Vendor shall provide sufficiently detailed information about the EHR SUT such that the setup may be recreated in the future. Examples would be: product version number, the name and version of any optional modules installed in the product, and the operating system (and version) on which the EHR SUT is running.

VE170.314.c – 2.1.02: Vendor shall identify the clinical quality measures for which their EHR system is being certified.

Required Test Procedure

TE170.314.c – 2.1.01: Tester logs into the Cypress application and checks if the vendor of the EHR technology under test is listed on their Testing Dashboard. If the vendor is listed, testing proceeds to **TE170.314.c – 2.1.03**.

TE170.314.c – 2.1.02: Tester clicks on the “Add EHR Vendor” button and fills out the vendor information form shown in Figure 4, then clicks the “Create” button. The Tester is returned to the dashboard and the new vendor appears in the list (see Figure 5 for an example).

TE170.314.c – 2.1.03: Tester clicks on the EHR vendor whose product is under test and checks if the EHR product is listed on the page. If the product is listed, testing proceeds to **TE170.314.c – 2.1.05**.

TE170.314.c – 2.1.04: Tester clicks on the “Add Product” button and fills out the product information form shown in Figure 6. In the description field, enter the detailed information about the product provided in **VE170.314.c – 2.1.01**, then click the “Create” button. The Tester is returned to the vendor page and the new product appears in the list. An example vendor page with one product added is shown in Figure 7.

TE170.314.c – 2.1.05: Tester clicks on the EHR product and is presented with the product page which lists all of the tests that this Tester has created for this product. A sample of the product dashboard for a newly added product that does not have any defined

tests is shown in Figure 8. Tester clicks on either of the “Add Test” buttons to begin a new test sequence. This begins a test creation wizard, which allows the Tester to define the parameters for the test.

- a) Tester provides a name, description and test type (in this phase, select either Inpatient or Outpatient depending on whether the SUT is being certified against EH or EP CQMs respectively) for the test and clicks the “Next” button.
- b) Tester selects all of the clinical quality measures that will be tested using the form shown in Figure 10 and clicks the “Done” button.
- c) Tester is returned to the product dashboard with the newly created test listed under the heading “Incomplete Tests” (see Figure 11).
- d) Tester clicks on the title of the test to be executed and is displayed a screen similar to Figure 12.
- e) Tester moves the mouse over the “Test Data” button and clicks on the mechanism and data format that will be used to load the test patients into the SUT.
- f) If the Tester chose one of the “Download ...” options, a dialog box will be displayed that will allow the zip file that contains the test data to be saved somewhere on the Tester’s computer.

TE170.314.c – 2.1.06: Tester provides the test data saved in TE170.314.c – 2.1.05(f) to the Vendor for import into the EHR SUT. The format of the test data will depend on the capabilities of the EHR SUT. The Cypress provided test data should not be loaded into the EHR SUT at this time.

DTR170.314.c – 2.2: Electronically Calculate CQMs

Required Vendor Information

VE170.314.c – 2.2.01: Vendor shall import the Cypress Gold Standard test data supplied by Tester.

VE170.314.c – 2.2.02: Vendor shall describe the calculations for the specified clinical quality measures for which the EHR product is to be tested.

VE170.314.c – 2.2.03: Vendor shall identify the EHR function(s) that are available to: 1) electronically calculate the CMS clinical quality measures 2) electronically submit calculated clinical quality measures.

VE170.314.c – 2.2.04: Using the EHR function(s), the Vendor shall electronically calculate the specified clinical quality measures while observed by the Tester.

Required Test Procedure

TE170.314.c – 2.2.01: Tester provides test data from Cypress generated in **DTR170.314c – 2.1** to the Vendor that will assess the clinical quality measures that the EHR will be tested on in QRDA Category I, and/or HTML format.

TE170.314c – 2.2.02: The Vendor will electronically import or manually enter the test data from the previous step into the EHR SUT, based on the capabilities of the product being tested. An EHR module must use the electronic import of test data in QRDA Category I format.

TE170.314c – 2.2.03: Using the EHR functions identified in **VE170.314.c – 2.2.03**, the vendor shall electronically calculate the CQMs that are being tested.

TE170.314.c – 2.2.02: Using the Inspection Test Guide below, Tester shall verify that the clinical quality measures are electronically calculated in **VE170.314.c – 2.2.04**.

Inspection Test Guide

IN170.314.c – 2.2.01: Using the specified clinical quality measures, Tester shall verify that these clinical quality measures are calculated as described by the Vendor in **VE170.314.c – 2.2.02**.

DTR170.314.c – 2.3: Verify Electronic and Accurate Calculation of CQMs

Required Vendor Information

VE170.314.c – 2.3.01: The electronically submitted QRDA Category I and Category III quality measure reports generated in **DTR170.314.c–2.2**.

Required Test Procedure

TE170.314.c – 2.3.01: Tester displays the Product Test dashboard page in Cypress (log in, click on vendor, click on product, and click on test name). Tester then clicks on the “Results” button. In the dialog that appears the Tester clicks on the “Browse...” button next to the “1. Results File” input box and selects the file received from the Vendor in **VE170.314.c – 2.3.01**, then clicks the “Upload” button (see Figure 13).

TE170.314.c – 2.3.02: Once the upload of the QRDA is finished, validation will be performed on the uploaded documents. The Tester shall review any QRDA validation warnings or errors that are displayed at the top of the test details page. Examples of a test execution with validation errors can be seen in Figure 14 and Figure 15.

TE170.314.c – 2.3.03: The Tester reviews the Cypress test details page (see Figure 16), which will display a dashboard of the denominator, numerator, and exclusions for each tested CQM. The values are displayed in the form **x / y** where **x** is the reported value obtained from the EHR SUT and **y** is the value Cypress expects based on the test data created for this particular test. The CQM for which the reported numerator, denominator, and exclusion values match the expected values are listed under the heading of “PASSING MEASURES.” If there are any

discrepancies between the reported values and the expected values, the affected CQM will be listed under the heading of “FAILING MEASURES” and the reported values that differ will be highlighted in a red and bold font. *Cypress is only capable of validating the correct calculation of CQMs for reports submitted in the QRDA Category III format. QRDA Category I formatted reports will be checked for validity only.*

Figure 16: Comparison of SUT calculated results against expected results

Test Name: EP Measure Test 1	Reporting Period: 10/01/2010 - 01/01/2011	Proctor: ff
Test Type: EP	Description:	Email: bobd@mitre.org
Product: asdfasdf		Telephone:
Version:		

You must perform the following steps to execute your test:

1. Download Test Data 2. Load Test Data into your quality measure calculator 3. Upload Results

Test Data
Upload Results

Notes:

add note

TEST EXECUTIONS	DESCRIPTION	RESULTS
2012-10-12 21:02:25 UTC		Results

TEST RESULTS

PASSING MEASURES

MEASURES INCLUDED IN THIS TEST	PATIENTS	DENOMINATOR	DEN. EXCLUSIONS	NUMERATOR	NUM. EXCLUSIONS	EXCEPTIONS
Diabetes: Foot Exam	1/1	1 / 1	- / -	1 / 1	- / -	- / -
Diabetes: Urine Protein Screening	1/1	1 / 1	- / -	1 / 1	- / -	- / -
Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	0/0	0 / 0	- / -	0 / 0	- / -	- / -
Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0/0	0 / 0	- / -	0 / 0	- / -	- / -
Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	0/0	0 / 0	- / -	0 / 0	- / -	- / -
ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range	0/0	- / -	- / -	0 / 0	- / -	- / -
Use of Appropriate Medications for Asthma - Population 1	1/1	1 / 1	- / -	1 / 1	- / -	- / -
Use of Appropriate Medications for Asthma - Population 2	0/0	0 / 0	- / -	0 / 0	- / -	- / -
Use of Appropriate Medications for Asthma - Population 3	1/1	1 / 1	- / -	1 / 1	- / -	- / -
Use of Appropriate Medications for Asthma - Population 4	0/0	0 / 0	- / -	0 / 0	- / -	- / -
Use of Appropriate Medications for Asthma - Population 5	0/0	0 / 0	- / -	0 / 0	- / -	- / -
Diabetes: Eye Exam	1/1	1 / 1	- / -	1 / 1	- / -	- / -

FAILING MEASURES

MEASURES INCLUDED IN THIS TEST	PATIENTS	DENOMINATOR	DEN. EXCLUSIONS	NUMERATOR	NUM. EXCLUSIONS	EXCEPTIONS
Colorectal Cancer Screening	1/2	2 / 1	- / -	1 / 1	- / -	- / -
Breast Cancer Screening	0/1	1 / 0	- / -	0 / 0	- / -	- / -
Cervical Cancer Screening	1/2	2 / 1	- / -	0 / 0	- / -	- / -

Error Report Indicators: ● passing ● insufficient info ● failing

TE170.314.c – 2.3.04: The Tester downloads the Cypress test report by clicking the “Download” button at the top of the test details page, and selecting the “Report as PDF” option. The Tester should choose to save the generated PDF report in a location on their local system designated for the artifacts from this complete test (Phase 1 and Phase 2).

TE170.314.c – 2.3.05: The Tester shall collect all of the artifacts that resulted from testing this EHR system into the same location. This includes the following:

- Cypress test patient data provided to the Vendor in **TE170.314.c – 2.1.06**.
- The QRDA Category I and/or Category III reports submitted by the Vendor in **VE170.314.c – 2.3.01**.
- A copy of the manifest for the Cypress test tool instance that was used to generate the test data and created the test report. This file contains the version number of each of the subcomponents used by the particular Cypress instance. It is named **CypressManifest.txt** and is located in the root directory of the Cypress installation.
- The PDF report generated by Cypress in **TE170.314.c – 2.3.04**.
- Any additional files containing notes generated by the Tester during the execution of this test procedure.
- Any other files that the Tester deems relevant for this test execution.

TE170.314.c – 2.3.06: The Tester shall bundle the entire set of test artifacts collected in the previous step into a pzip-compatible archive (zip archive) using utilities appropriate for the computer system the Tester is using.

Notes

In this phase, the criteria used to determine a successful test outcome depends on whether the EHR product is being certified against the EP CQMs or the EH CQMs.

For EP CQMs, a successful test outcome is one in which the following conditions are true:

1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
2. All of the CQM results calculated and submitted by the EHR SUT exactly match the values that Cypress was expecting.

For EH CQMs, a successful test outcome is one in which the following conditions are true:

1. There were no XML validation errors in neither the QRDA Category I submitted data nor the QRDA Category III submitted data.
2. All of the CQM results calculated and submitted by the EHR SUT for discrete measures exactly match the values that Cypress was expecting.
3. The CQM results calculated and submitted by the EHR SUT for continuous variable tests are within a defined delta of the value that Cypress was expecting.

For both types of EHR technologies, it is acceptable for there to be XML validation warnings that are generated by Cypress' validation process. These warnings will not constitute a test failure. However, the Tester should review the warnings generated and record any relevant observations that they can make about the reasons for the warnings in the Notes field on the Product Test details page.

TEST DATA

ONC-supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Any departure from the provided test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

Cypress – The MITRE Corporation provides Cypress to test the calculation, export and electronic submission of clinical quality measures. The tool is available at <http://projectcypress.org/>.

ACRONYMS

ONC-ACB	ONC Authorized Certification Body
ONC-ATCB	ONC Authorized Testing and Certification Body
ASTM	American Society for Testing and Materials
CAH	Critical Access Hospital
CCHIT	Certification Commission for Healthcare Information Technology
CCR	Continuity of Care Record
CMS	Centers for Medicare & Medicaid Services
CQM	Clinical Quality Measures
EH	Eligible Hospital
EHR	Electronic Health Record
EP	Eligible Professional
GUI	Graphical User Interface
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	Hypertext Markup Language
MU	Meaningful Use
NIST	National Institute of Standards and Technology
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
QDM	Quality Data Model
QRDA	Quality Reporting Document Architecture
SUT	System Under Test
XML	Extensible Markup Language
XSD	XML Schema Document

Document History

Version Number	Description of Change	Date
1.0	Released for public comment	November 2, 2012
1.1	Delivered for National Coordinator Approval	December 4, 2012
1.2	Posted Approved Test Procedure	December 14, 2012