

Test Procedure for §170.314(a)(12) Image results

This document describes the test procedure for evaluating conformance of 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 CRITERIA

This certification criterion is 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.

§170.314(a)(12) Image results. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

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,

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.

2012), the 2014 Edition of this certification criterion is classified as new. This certification criterion meets at least one of the two factors of new certification criteria: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or (2) the certification criterion was previously adopted as mandatory” for a particular setting and subsequently adopted as “mandatory” or “optional” for a different 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 image results certification criterion is discussed:

- “Commenters requested a clear definition of “image” as well as “narrative interpretation.” Commenters asked whether both cardiology and pathology images are included or whether images were limited to radiology...It is outside the scope of this rulemaking to define the scope of images and narrative interpretations.”
- “We clarify that we did not propose nor are we requiring that EHR technology has to be able to store images to meet this certification criterion. EHR technology can meet this certification criterion by demonstrating a capability to directly link to images stored in the EHR system or providing a context-sensitive link to an external application which provides access to images and their associated narrative. By “context sensitive link” we mean that the link to the image will ideally include parameters that enable access to the images themselves rather than access to a system – which would require login, patient search, image selection, and (finally) image viewing.”
- “We clarified that the phrase “immediate electronic access” was intended to mean that a user should be able to electronically access images and their narrative interpretations directly and without, for example, having to login to a separate electronic system or repository. We stated that this access could be provided by multiple means, including, but not limited to, “single sign-on” and “secure identity parameter passing.”
- “We...do not explicitly require that this link provide “immediate access”...”
- “Finally, we emphasize that access to both narrative and imaging data must available to the user. In cases where there is no narrative data (for example when a radiographic image has not yet been interpreted by a radiologist) there will obviously be no narrative available. Nonetheless, the EHR technology must be capable of retrieving and displaying the narrative information in order to meet this certification criterion.”

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.

The Vendor supplies the test data for this test procedure.

This test procedure is organized into two sections:

- **Indicate** – evaluates the capability for the EHR to electronically indicate to a user the availability of a patient’s images and associated narrative interpretations relating to radiographic or other diagnostic test(s)
 - The Vendor creates a patient record in their EHR and populates that patient record with Vendor-supplied narrative interpretations and associated images (or links to associated images) for two or more radiographic or other diagnostic test(s)
 - The Tester signs on to the EHR and validates that availability of the patient’s images and associated narrative interpretations is indicated by the EHR to the user electronically (this may be accomplished via a link(s) that indicate that images and narrative interpretation are available)

- **Access** – evaluates the capability for the user to electronically access and display the patient’s images and narrative interpretations
 - Using the Vendor-identified EHR technology function(s), the Tester accesses and displays the patient’s images and narrative interpretations during the Indicate test for each of the radiographic or other diagnostic test(s)
 - The Tester validates that the displayed images and narrative interpretations are accurate and complete
 - The Tester validates that the images and associated narrative interpretations are accessed without requiring additional patient lookup or selection or test/study selection (additional provider login is acceptable)
 - The images must be accessible for display within the EHR, but are not required to be stored within the EHR and may be contained within another application from the EHR or within another application from the narrative interpretation

PACS capabilities, whether third party or integrated, are not intended to be included in this certification criterion. The EHR technology must have the capability to access images via a link (or other method) which would direct the user to a third party application.

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(a)(12) – 1: Electronically Indicate

DTR170.314(a)(12) – 2: Electronically Access

DTR170.314(a)(12) – 1: Electronically Indicate

Required Vendor Information

VE170.314(a)(12) – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314(a)(12) – 1.02: Vendor shall populate the existing patient’s record with imaging result information for two or more radiological or other diagnostic tests, each including both images and an associated narrative interpretation:

- Stored within the EHR, OR
- Access to images and narrative interpretation via a link to a Vendor-supplied 3rd party system, OR
- Access to images via a link to a Vendor-supplied 3rd party system, with narrative interpretation stored within the EHR

VE170.314(a)(12) – 1.03: Vendor shall populate the existing patient’s record with imaging result information for one or more radiological or other diagnostic tests, including a test with images but without associated narrative interpretation(s):

- Stored within the EHR, OR
- Access to results via a link to a Vendor-supplied 3rd party system that contain images but no narrative interpretation, OR
- Access to images via a link to a Vendor-supplied 3rd party system, without a narrative interpretation stored within the EHR

VE170.314(a)(12) – 1.04: Vendor shall identify a user who has the ability to access and view radiological or other diagnostic tests result information

VE170.314(a)(12) – 1.05: Vendor shall identify the EHR function(s) that are available to 1) electronically indicate the availability of a patient’s images and associated narrative interpretations, and 2) electronically access a patient’s images and associated narrative interpretations for radiological or other diagnostic tests

Required Test Procedure

TE170.314(a)(12) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall log in to the EHR as a user who has the ability to view images and narrative interpretations

TE170.314(a)(12) – 1.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the EHR indicates the availability of the Vendor-supplied image(s) and associated narrative interpretations for the Vendor-supplied radiological or other diagnostic tests for the Vendor-identified patient

TE170.314(a)(12) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the EHR indicates the availability of the images and narrative interpretations

TE170.314(a)(12) – 1.04: Using the Vendor-identified EHR function(s), the Tester shall verify that the EHR indicates the availability of the Vendor-supplied image(s) with no narrative interpretations for the Vendor-supplied radiological or other diagnostic tests for the Vendor-identified patient

TE170.314(a)(12) – 1.05: Using the Inspection Test Guide, the Tester shall verify that the EHR indicates the availability of the images for a radiological or other diagnostic tests for which no narrative interpretation is available

Inspection Test Guide

IN170.314(a)(12) – 1.01: Using the Vendor-supplied test data, the Tester shall verify that the EHR electronically indicates the availability of the images (may be accomplished by the presence of a link to a 3rd party system or an indication of images stored within the EHR) and electronically indicates the availability associated narrative interpretations (for tests with narrative interpretations available)

DTR170.314(a)(12) – 2: Electronically Access

Required Vendor Information

- Information as defined in DTR170.314(a)(12) – 1, no additional information is required

Required Test Procedure

TE170.314(a)(12) – 2.01: Using the Vendor-identified EHR function(s), the Tester shall log in to the EHR as a user who has the ability to access and view patient images and associated narrative interpretations for radiographic or other diagnostic tests

TE170.314(a)(12) – 2.02: Using the Vendor-identified EHR function(s) and the test patient used for the DTR170.314(a)(12) – 1: Electronically Indicate test, the Tester shall select the patient's record

TE170.314(a)(12) – 2.03: Using the Vendor-identified EHR function(s), the Tester shall access and display the images and narrative interpretations (where available) as tested for DTR170.314(a)(12) – 1: Electronically Indicate test for the selected patient

TE170.314(a)(12) – 2.04: Using the Inspection Test Guide, the Tester shall verify that the images and narrative interpretations are accessed without requiring additional patient lookup/selection or test/study selection

TE170.314(a)(12) – 2.05: Using the Inspection Test Guide, the Tester shall verify that the images are accessed without requiring additional patient lookup/selection or test/study selection for a test without a narrative interpretation with images available

Inspection Test Guide

IN170.314(a)(12) – 2.01: Using the Vendor supplied test data, the Tester shall verify that the patient's images and narrative interpretations (where available) are accessed and displayed to the user and that this radiographic or other diagnostic tests information is accurate and complete

IN170.314(a)(12) – 2.02: The Tester shall verify 1) that the images and narrative interpretations (where available) are accessible to the user within the EHR system OR via a context-sensitive link to an external application that provides access to images and their associated narrative interpretations, OR via a context-sensitive link to an external application that provides access with narrative interpretations stored within the EHR; and 2) that the user accesses these images and narrative interpretations without requiring additional patient lookup or imaging test selection (additional provider login for a 3rd party application is permitted)

TEST DATA

The Vendor shall supply the test data for this test procedure.

Vendor supplied test data shall 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.

For Vendor supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the requirements identified in the criterion can be adequately evaluated for conformance.
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support.
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing.

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Posted Updated Approved Test Procedure Updates: In Informative Test Description, added "PACS capabilities, whether third party or integrated, are not intended to be included in this certification criterion. The EHR technology must have the capability to access images via a link (or other method) which would direct the user to a third party application."	February 22, 2013