Test Procedure for §170.314(d)(3) Audit report(s)

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 document[1] 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 Program[2], 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. This certification criterion is included in the definition of a Base EHR.

§170.314(d)(3) Audit report(s). Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at §170.210(e).

[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

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), the 2014 Edition of this certification criterion is classified as revised from the 2011 Edition. This certification criterion meets 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 where the audit report(s) certification criterion is discussed:

- "This certification criterion expresses the capability that EHR technology must enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the elements specified in the standards at § 170.210(e). Anything beyond that requirement is beyond the scope of certification and likely depends upon organizational policy."

2011 Edition Preamble Language

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule (July 28, 2010) where audit log certification criterion is discussed:

- "While we believe that in most cases a user will be a health care professional performing an action using Certified EHR Technology, it is also possible that a device or another software process or program could perform any one of these actions. We do not intend to preclude EHR technology developers from including these and other types of specific features."

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 4,2010) where the audit reports certification criterion is discussed:

- "We proposed two revised certification criteria at § 170.314(d)(2) and (3) – one focused on the capability to record auditable events and another focused on the capability to create audit reports – in place of the single 2011 Edition EHR certification criterion for audit logs adopted at § 170.302(r)."
- "We made these proposals based on HITSC recommendations as well as stakeholder feedback that indicated splitting the 2011 Edition certification criterion into two separate certification criteria would permit a wider variety of EHR technologies to be certified as EHR technology."
- "Previously the 2011 Edition EHR certification criterion required that EHR technology demonstrate both the recording of auditable events and the report generation in order to be certified. With this separation EHR technology can be separately certified to perform these two capabilities. A stand-alone EHR technology for audit log reporting would not need to certify with each and every source EHR technology that may send it auditable events."

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 evaluates the capability for an EHR technology to:

- Enable a user to generate an audit report for a specific time period, and
- Sort entries in the audit log according to the data elements specified in the audit log content standard

The Vendor supplies the test data for this test procedure.

This test procedure is organized into two sections:

- Create Audit Report—evaluates the capability of the EHR technology to enable a user to generate an audit report for a specific time period
  - The Vendor provides the Tester with audit log information generated by the EHR technology that contains the minimum number of entries needed to perform actions required of the audit log content standard
    - The audit log information that is provided should contain the minimum number of entries needed to perform all required actions (additions, deletions, changes, queries, print, copy) and should include all required data elements
  - Using the Vendor-provided audit log information and reporting functions, the Tester generates an audit report for a time period that includes the time at which the entries in the audit log information were recorded and verifies that the audit report is successfully created

- Sort Audit Log Entries—evaluates the capability of the EHR technology to enable a user to sort entries in the audit log or in an audit report

- The Vendor provides the Tester with audit log information that was generated by the EHR technology. This could be provided through access to the audit log itself or audit reporting functions.
  - The audit report used in the previous test procedure step can be used for this test procedure step as long as the audit report entries contain the following data elements, as stated in ASTM E2147-01 in the audit log content standard:
    - Date and time of event (either presented in a single combined field or in separate fields)
    - Patient identification
    - User identification
    - Type of action (additions, deletions, changes, queries, print, copy), specifying any changes made (with pointer to original data state) and a delete specification (with a pointer to deleted information)
    - Identification of the patient data that is accessed
- The Vendor identifies the EHR function(s) that are available to sort the audit log information by the previously described data elements
- The Tester uses the Vendor-provided audit log information, sorts the audit log entries by each of the data elements listed above, and verifies that the entries were correctly sorted

REFERENCED STANDARDS

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.	Regulatory Referenced Standard
The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:	
(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices. (1)(i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use. (ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g).	
(2)(i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed. (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g).	

(3)The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).	
170.210(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).	
170.210(h) Audit log content. ASTM E2147-01 (Reapproved 2009), (incorporated by reference in § 170.299)	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(d)(3) – 1: Generate an Audit Report

DTR170.314(d)(3) – 2: Sort Audit Log

DTR170.314(d)(3) – 1: Generate an Audit Report

Required Vendor Information

VE170.314(d)(3) – 1.01: The Vendor shall have audit log information generated by the EHR technology that contains, at a minimum, the number of entries required to complete the test; the audit log information should include the following data elements:

- Date and time of event
- Patient identification
- User identification
- Type of action (additions, deletions, changes, queries, print, copy), specifying inquiry, any changes made (with pointer to original data state), and a delete specification (with a pointer to deleted information)
- Identification of the patient data that is accessed

VE170.314(d)(3) – 1.02: The Vendor shall identify the EHR function(s) that are available to allow a user to generate an audit report for a specific time period

Required Test Procedures

TE170.314(d)(3) – 1.01: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall generate an audit report for the time period during which the entries in the Vendor-provided audit log information were recorded

Inspection Test Guide

IN170.314(d)(3) – 1.01: The Tester shall verify that the Vendor-provided audit log or report contains the number of entries required to complete the test and includes the data elements listed in VE170.314(d)(3) – 1.01

IN170.314(d)(3) – 1.02: The Tester shall verify that the audit report has been created for the specified time period

DTR170.314(d)(3) – 2: Sort Audit Log

Required Vendor Information

- The audit log information provided by the Vendor in VE170.314(d)(3) – 1.01 shall be used in DTR170.314(d)(3)–2

VE170.314(d)(3) – 2.01: The Vendor shall identify the EHR function(s) that are available to sort the audit log entries by:

- Date and time of event
- Patient identification
- User identification
- Type of action (additions, deletions, changes, queries, print, copy), specifying inquiry, any changes made (with pointer to original data state), and a delete specification (with a pointer to deleted information)
- Identification of the patient data that is accessed

Required Test Procedures

TE170.314(d)(3) – 2.01: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall sort the audit log information according to date and time of event

TE170.314(d)(3) – 2.02: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall sort the audit log information according to patient identification

TE170.314(d)(3) – 2.03: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall sort the audit log information according to user identification

TE170.314(d)(3) – 2.04: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall sort the audit log information according to type of action (additions, deletions, changes, queries, print, copy)

TE170.314(d)(3) – 2.05: Using the Vendor-identified EHR function(s) and Vendor-provided audit log or report, the Tester shall sort the audit log information according to identification of the patient data that is accessed

Inspection Test Guide

IN170.314(d)(3) – 2.01: The Tester shall verify that the audit log or report being used is the audit log or report provided by the Vendor in VE170.314(d)(3) – 1.01

IN170.314(d)(3) – 2.02: The Tester shall verify that the audit log information has been successfully sorted by each element or set of elements

TEST DATA

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

Vendor 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.

Any test data provided 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	Post-public comment draft	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	In the Informative Test Description • Added “specifying inquiry, any changes made (with pointer to original data state), and a delete specification (with a pointer to deleted information)” to maintain consistency with ASTM E2147-01 requirements In the Normative Test Procedure, for DTR170.314(d)(3) – 1: Generate an Audit Report In Required Vendor Information • Added “specifying inquiry, any changes made (with pointer to original data state) and a delete specification (with a pointer to deleted information)” to fourth bullet point in VE170.314(d)(3) – 1.01 to maintain consistency with ASTM E2147-01 requirements In the Normative Test Procedure, for DTR170.314(d)(3) – 2: Sort Audit Log In Required Vendor Information • Added “specifying inquiry, any changes made (with pointer to original data state) and a delete specification (with a pointer to deleted information)” to fourth bullet point in VE170.314(d)(3) – 2.01 to maintain consistency with ASTM E2147-01 requirements	May 8, 2013