Test Procedure for §170.302 (r) Audit Log

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] 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://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The 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. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010*.)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302(r) Audit log.

(1) Record Actions. Record actions related to electronic health information in accordance with the standard specified in 170.210(b).

[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

(2) Generate audit log. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at 170.210(b).

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 where the 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 Complete EHR and EHR Module developers from including these and other types of specific features."

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 a Complete EHR or EHR Module to:

- Record actions related to electronic health information. Information to be recorded includes the date, time, patient identification, user identification, an indication of which actions occurred, and by whom to be recorded when electronic health information is created, modified, accessed, or deleted; and
- Enable a user to generate an audit log based on specific time parameters, and sort entries in the audit log according to the elements specified in the standard.

The Vendor supplies the data for this test procedure.

This test procedure consists of four sections:

- Record Actions – evaluates the capability to record actions related to electronic health information into the EHR.
  - The Tester shall enter electronic health information
  - The Tester shall record into the log the action taken (automatic function based on the action of entering electronic health information)
  - The Tester shall verify that the data elements have been recorded in the log

- Modify Actions – evaluates the capability to record an update/correct or otherwise modify action related to electronic health information into the EHR.
  - The Tester shall select the electronic health information entered during the Record Actions test, display the electronic health information, and correct/update the electronic health information

- The Tester shall record into the log the action taken (automatic function based on the action of entering electronic health information)
- The Tester shall verify that the data elements have been recorded in the log

- Generate Audit Log – evaluates the capability to generate an audit log for a specific time period
  - The Tester shall generate an audit log for a specified time period that will result in the audit log containing entries for the actions taken in the record and modify tests
  - The Tester shall verify that the audit log has been generated

- Sort Audit Log Entries – evaluates the capability to sort entries in the audit log
  - The Tester shall generate an audit log for the specified time period and sort audit log entries according to the specified elements
  - The Tester shall verify that the audit log entries have been sorted

REFERENCED STANDARDS

§170.210(b)	Regulatory Referenced Standard
Record actions related to electronic health information. The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.r – 1: Record actions
DTR170.302.r – 2: Modify actions
DTR170.302.r – 3: Generate audit log
DTR170.302.r – 4: Sort audit log entries

DTR170.302.r – 1: Record actions

Required Vendor Information

VE170.302.r – 1.01: The Vendor shall identify the EHR function(s) that are available to create, modify, access and delete electronic health information

VE170.302.r – 1.02: The Vendor shall identify the EHR function(s) that are available to record actions related to electronic health information. (These will be automatic functions used to create log entries.)

VE170.302.r – 1.03: The Vendor shall identify a patient with an existing record in the EHR to be used for this test and a set of electronic health test data for the patient

VE170.302.r – 1.04: The Vendor shall identify the EHR function(s) that are available to enable a user to generate an audit log for a specific time period and to sort the audit log entries according to elements specified in the standard at 170.210(b)

Required Test Procedure

TE170.302.r – 1.01: Using the EHR function(s) and test data identified by the Vendor, the Tester shall enter electronic health information. The Tester shall exercise this Record test for each action: create access and delete

TE170.302.r – 1.02: Tester shall record data elements, including:

- Date
- Time
- Patient identification
- User identification
- The action(s) taken

This will be an automatic function(s) used to generate the log entry

TE170.302.r – 1.03: Tester shall record the action that occurred in the system. (This will be an automatic function(s) used to create log entries.)

TE170.302.r – 1.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that a log entry has been correctly generated related to the action taken and the test data used

Inspection Test Guide

IN170.302.r – 1.01: Tester shall verify that the electronic health information test data is entered into the system

IN170.302.r – 1:02: Tester shall verify that the data elements generated in the log entry for the action include

- Date
- Time
- Patient identification
- User identification
- The action(s) taken

IN170.302.r – 1:03: Tester shall verify that a log entry has been correctly generated related to each action taken and the test data used

DTR170.302.r – 2: Modify actions

Required Vendor Information

- As defined in DTR170.302.r – 1, no additional information is required

Required Test Procedure

TE170.302.r – 2.01: Using the EHR function(s) and test data identified by the Vendor, the Tester shall select the electronic health information used for the Record actions test, shall display the electronic information entered during the Record actions test, and shall correct/update or otherwise modify the electronic health information

TE170.302.r – 2.02: Tester shall record data elements, including

- Date
- Time
- Patient identification
- User identification
- The action(s) taken

This will be an automatic function(s) used to generate the log entry

TE170.302.r – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that a log entry has been correctly generated related to the action taken and the test data used

Inspection Test Guide

IN170.302.r – 2.01: Tester shall verify that the electronic health information is entered into the system

IN170.302.r – 2:02: Tester shall verify that the data elements generated in the log entry for the action include

- Date
- Time
- Patient identification
- User identification
- The action(s) taken

IN170.302.r – 2.03: Tester shall verify that a log entry has been correctly generated related to the action taken and the test data used

DTR170.302.r – 3: Generate audit log

Required Vendor Information

- As defined in DTR170.302.r – 1, no additional information is required

Required Test Procedure

TE170.302.r – 3.01: Using the EHR function(s) and test data used in the previous record and modify tests, the Tester shall generate an audit log for a specified time period that will result in the audit log containing entries for the actions taken in the record and modify tests

TE170.302.r – 3.02: Using the NIST-supplied Inspection Test Guide, The Tester shall verify that the audit log has been generated

Inspection Test Guide

IN170.302.r – 3.01: Tester shall verify that the audit log has been generated for the time period specified by the test data

- The audit log encompasses the time period specified
- The audit log contains an entry(ies) for all of the actions taken in the record and modify tests
- Each entry of the audit log contains:
  - Date
  - Time
  - Patient identification
  - User identification
  - The action(s) taken

DTR170.302.r – 4: Sort audit log

Required Vendor Information

- As defined in DTR170.302.r – 1, no additional information is required

Required Test Procedure

TE170.302.r – 4.01: Using the EHR function(s) and test data identified by the Vendor, the Tester shall generate an audit log for a specified time period and sort audit log entries according to the following elements specified in the standard at 170.210(b):

- Date
- Time
- Patient identification
- User identification
- The action(s) taken

The Tester may use the audit log generated in the Generate Audit Log test, or the Vendor may provide the Tester with a new audit log that is populated with entries containing elements according to the standard. The Tester shall verify that the audit log contains entries sufficient to sort on each of the data elements required by the standard.

TE170.302.r – 4.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the audit log entries have been sorted

Inspection Test Guide

IN170.302.r – 4.01: Tester shall verify that the audit log entries have been sorted according to the specified elements in the standard and for each of the specific actions taken.

TEST DATA

This Test Procedure requires the vendor to supply the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional and interoperable 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
0.2	Original draft version	April 8, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove “Pending” from header	August 13, 2010