

## Test Procedure for §170.302 (r) Audit log

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules to the certification criteria defined in 45 CFR Part 170 Subpart C of the Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. The document 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](http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf). These test procedures will be updated to reflect the certification criteria defined in the ONC Final Rule.

Note: This test procedure is scoped only to the criteria defined in 45 CFR Part 170 Subpart C of the Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. This test procedure will be updated to reflect updates to the criteria and standards as published in the ONC Final Rule. Questions about the criteria and standards should be directed to ONC.

### CERTIFICATION CRITERIA

#### §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).
- (2) Alerts. Provide alerts based on user-defined events.
- (3) Display and print. Electronically display and print all or a specified set of recorded information upon request or at a set period of time.

### 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<sup>1</sup> to:

- Record actions related to electronic health information. Information includes the date, time, patient identification, and user identification to be recorded when electronic health information is created, modified, deleted, or printed;
- Provide alerts based on user-defined events;
- Electronically display and print all or a specified set of recorded information upon request or at a set period of time.

The Vendor supplies the data for this test procedure.

This test procedure consists of four sections:

- Record Actions – evaluates the capability to enter actions related to electronic health information into the EHR.

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<sup>1</sup> Department of Health and Human Services, 45 CFR Part 170 Proposed Establishment of Certification Programs for Health Information Technology, Proposed Rule, March 10, 2010.

- The Tester shall enter electronic health information
- The Tester shall record the action taken
- The Tester shall verify that the data elements have been recorded
  
- Modify Actions – evaluates the capability to update/correct actions 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 the action taken
  - The Tester shall verify that the data elements have been recorded
  
- Provide Alerts - evaluates the capability to provide alerts based on user-defined events
  - The Tester shall create a user-defined event requiring an alert
  - The Tester shall verify that the alert was provided in response to the user-defined event
  
- Display and Print – evaluates the capability to display and print all or a specified set of recorded information upon request or at a set period of time
  - The Tester shall select the recorded electronic health information used for the Record Actions test and display and print all or a set of recorded information entered during the Record and Modify Actions tests
  - The Tester shall verify that the electronic health information display and print correctly

## 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, deleted or printed; and an indication of which action (s) occurred 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: Provide alerts
- DTR170.302.r – 4: Display and print

## **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, delete, and display and print 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.
- VE170.302.r – 1.03: The Vendor shall identify a patient with an existing record in the EHR to be used for this test.

### 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
- TE170.302.r – 1.02: Tester shall record data elements, including
- Date
  - Time
  - Patient identification
  - User identification
- TE170.302.r – 1.03: Tester shall record the action that occurred in the system
- TE170.302.r – 1.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic information has been entered correctly

### Inspection Test Guide

- IN170.302.r – 1.01: Tester shall verify that the electronic health information is entered into the system
- IN170.302.r – 1.02: Tester shall verify that the data elements entered during the test are stored in the system, including
- Date
  - Time
  - Patient identification
  - User identification
- IN170.302.r – 1.03: Tester shall verify that action taken has been recorded

## **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 the electronic health information

- TE170.302.r – 2.02: Tester shall record the action that occurred in the system, including
- Date
  - Time
  - Patient identification
  - User identification

- TE170.302.r – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic information entered in the Modify actions test have been entered correctly

#### 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 action occurred has been recorded, including
- Date
  - Time
  - Patient identification
  - User identification

#### **DTR170.302.r – 3: Provide alerts**

##### Required Vendor Information

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

##### Required Test Procedure

- TE170.302.r – 3.01: The Tester shall test the mechanism implementing the EHR function (s) available to provide alerts based on user-defined events.
- TE170.302.r – 3.02: Using the EHR function(s) identified by the Vendor, the Tester shall create a user-defined event requiring an alert
- TE170.302.r – 3.03: The Tester shall verify that the alert was provided in response to the user-defined event
- TE170.302.r – 3.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the alert has been provided

#### Inspection Test Guide

- IN170.302.r – 3.01: Tester shall verify that the alert has been provided in response to the user-defined event

#### **DTR170.302.r – 4: Display and print**

##### 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) identified by the Vendor, the Tester shall select the recorded electronic health information used for the Record actions test and shall display and print all or a set of the recorded information entered during the Record and Modify actions tests, including
- Date
  - Time
  - Patient identification
  - User identification
- TE170.302.r – 4.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic health information display and print correctly

### Inspection Test Guide

- IN170.302.r – 4.01: Tester shall verify that the recorded electronic health information can be displayed online and printed as an electronic file
- IN170.302.r – 4.02: Tester shall verify that the action occurred has been recorded, including
- Date
  - Time
  - Patient identification
  - User identification

## TEST DATA

Test data for this test procedure is supplied by the Vendor.

## CONFORMANCE TEST TOOLS

None