# Test Criteria: 170.315.d.10 Auditing Actions on Health Information

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| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(d)(10)(i)_Record_actions)
* [Test Procedures](#_Test_Procedures_1)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.0

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT developer or Participant Under Test is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

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| --- | --- |
| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Not applicable. | |
| **Test Data:**  The Test Proctor may rely on data entered for other modules during the test event. If unavailable, or at the Proctor’s discretion, new test data may be required to be entered while testing this module. | |
| **Test Tools:**  Not applicable. | |

# Demonstrate Standards Support

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Record actions related to electronic health information, audit log status, and encryption of end-user devices according to the specified sections of the ASTM E2147-01 standard using the NTP standard for date and time. | |

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|  | **Standard** |  |
|  | §170.210(e)(1) | 1. 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) and changes to users privileges when health IT is in use. 2. The date and time must be recorded 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](http://www.rfc-editor.org/info/rfc1305), (incorporated by reference in §170.299) or [(RFC 5905) Network Time Protocol Version 4](http://www.rfc-editor.org/info/rfc5905), (incorporated by reference in §170.299). |
|  | §170.210(h) | Audit log content [ASTM E2147-01 (Reapproved 2009)](http://www.astm.org/Standards/E2147.htm), (incorporated by reference in §170.299). |

# 170.315(d)(10)(i) Record actions

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **P&S applies to all criteria:** | YES:  NO: |
| **If not, list applicable criteria:** |  |
| **Instructions:** Health IT module demonstrates synchronization to a configured NTP server. The audit log records actions related to electronic health information, audit log status, and encryption status. | |
| **Expected Test Result:**   * Record actions related to electronic health information in accordance with the standard specified in §170.210(e)(1). * All actions recorded by the audit log shall include:  1. Date and Time (utilizing a system clock synchronized following the NTP or NTP v4); 2. Patient Identification; 3. User Identification; 4. Action(s) taken, specifying inquiry and any changes made (with pointer to original data state). If EHR technology permits user to delete electronic health information, action(s) taken should include a delete specification (with a pointer to deleted information).  * Health IT module system time is synchronized within five seconds of the NTP configured ITS server. * If applicable, the EHR time is within five seconds of the health IT module system time or the NTP configured ITS server. | |
| **Points to Remember:**   * Actions and information are intended to be captured in a manner that supports the forensic reconstruction of the sequence of changes to a patient’s chart. * Only those sections specified from section 7 of ASTM E2147-01 are the minimum required for certification * “Copy” can encompass a variety of actions, including extracting data from the health IT. Copy actions originating from within the health IT interface (e.g., exporting or downloading a copy of electronic health information from the health IT) are required to be tracked in the audit log. * The certification criterion requires actions initiated by the user from within the health IT interface to be tracked in the audit log. The copy and paste functions of Microsoft Windows originate outside of the health IT environment and are thus outside the scope of certification. * Demonstration of the ability to use NIST time servers is required for certification, however vendors are not required to use NIST servers post certification. * A Health IT Module presented for certification to the “API” criteria, depending on the capabilities it included for certification, could be certified to either §170.315(d)(2) or (d)(10) as part of the 2015 Edition P&S certification framework. * Testing assumes the operating system synchronizes to the NTP server and the Health IT Module then synchronizes to the operating system; however, the Heath IT Module could synchronize directly to the NTP server. The Health IT Module may use either method to demonstrate that the synchronization has occurred. Use of internal NTP servers are allowed, but the Health IT Module must demonstrate that the internal servers are synced to a NIST timeserver for accuracy. * See “[EHR Test-128] Privacy and Security Framework” document provided by Drummond Group to verify instructions on submitting required P&S attestation. | |

### Test Procedures

**1.1 NTP Test**

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|  | Configure the HIT module’s operating system NTP server to an ITS server:  NIST Timer Server: <NIST Time Server> |
|  | Synchronize the HIT module operating system NTP server to the ITS server. |
|  | Verify that NTP server never queries the time server more than once every 4 seconds. |
|  | The HIT module operating system display time is accurate within 5 seconds of the NIST time server. |
|  | HIT module display time is accurate within 5 seconds of the operating system time. (Alternative)  HIT module display time is accurate within 5 seconds of the NIST time server. (Alternative) |
|  | Time Service (ITS):  NTP version:  NTPv3  NTPv4 |

<INSERT SCREEN SHOTS - NTP Configuration>

<INSERT SCREEN SHOTS - NTP Logs>

**1.2 Record Actions**

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|  | Health IT developer selects a patient record and performs each action listed to generate an audit log entry in accordance with standard §170.210(e)(1):   * **Additions** * **Deletions** * **Changes** * **Queries** * **Print** * **Copy** * **Changes to user privileges** * **Access to patient information, including emergency access events** |
|  | For all permissible actions, the audit log function records the following data:   * **Date and time of event**, synchronized according to NTPv3 or NTPv4 in accordance with the standard specified in §170.210(g); * **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 are accessed**. |

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**1.3 Privacy and Security Attestation**

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|  | Health IT Developer submits Privacy and Security Framework document attesting to the approach used for certification testing. Additionally, attestation must specify if the criteria demonstrated in this test event applies to *all* certified modules or only specific modules. See the “[EHR Test-128] Privacy Security Framework” document provided by Drummond Group. |
|  | For any action not supported by the health IT module, developer attests to the inability to demonstrate and is not subject to testing. Refer to framework document above for attestation template. |

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# 170.315(d)(10)(ii) Disabling Audit Functions (Conditional)

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** The audit log records the audit log status and/or the encryption status. | |
| **Expected Test Result:**   * If the audit log can be disabled, the health IT module records audit log status changes in accordance with standard specified at §170.210(e)(2). * If disabling of the audit log and/or encryption status is permitted, health IT module shall log the status change by recording:  1. Date and time, synchronized according to NTPv3 or NTPv4 in accordance with the standard specified in §170.210(g); 2. User identification; and 3. Actions that occurred  * Where the health IT module permits disabling, the capability to do so is restricted to a limited set of users for each auditing function:  1. Record actions; 2. Record the audit log status; and 3. Record encryption status. | |
| **Points to Remember:**   * This section should be tested only if the audit log can be disabled and/or the encryption can be disabled. * If the health IT module does not permit disabling of the audit log or encryption status, the health IT developer will submit documentation attesting to these inabilities and will not be subject to testing this section. Refer to the “[EHR Test-128] Privacy Security Framework” document provided by Drummond Group for attestation template. | |

### Test Procedures

**2.1 Audit Log Status (Conditional) – Cannot be disabled**

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|  | If audit log cannot be disabled, health IT developer submits documentation attesting to these inabilities and will not be subject to testing this section. Refer to “[EHR Test-128] Privacy Security Framework” provided by Drummond Group for attestation template. |

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**2.2 Audit Log Status (Conditional) – Can be disabled**

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|  | If audit log can be disabled, authorized user disables audit log. Health IT module records the change in audit log status from ‘enabled’ to ‘disabled’ (and vice versa) and logs the status change in accordance with standard specified in §170.210(e)(2), by recording:   * **date and time**, synchronized according to NTPv3 or NTPv4 in accordance with the standard specified in § 170.210(g); * **user identification**; and * **which action(s) occurred.** |
|  | If audit log can be disabled, an unauthorized user attempts to disable audit log status but is unable to do so. |

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**2.3 Encryption Status (Conditional) – Cannot be disabled**

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|  | If encryption status cannot be disabled, or if electronic health information cannot be stored locally by the technology, health IT developer submits documentation attesting to these inabilities and will not be subject to testing this section. Refer to “[EHR Test-128] Privacy Security Framework” provided by Drummond Group for attestation template. |

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**2.4 Encryption Status (Conditional) – Can be disabled**

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|  | If encryption status can be disabled, authorized user disables encryption status. Health IT module records the change in encryption status from ‘enabled’ to ‘disabled’ (and vice versa) and logs the status change in accordance with standard specified in §170.210(e)(2), by recording:   * **date and time**, synchronized according to NTPv3 or NTPv4 in accordance with the standard specified in § 170.210(g); * **user identification**; and * **which action(s) occurred.** |
|  | If encryption status can be disable, an unauthorized attempts to disable audit log status but is unable to do so. |

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# 170.315(d)(10)(iii) Protect Audit Log

# 170.315(d)(10)(iv) Detection of Audit Log Alteration

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Health IT developer provides documentation describing how the health IT module protects the audit log and how alterations to the audit log are detected. | |
| **Expected Test Result:**   * Submit signed attestation documents to the Test Proctor describing how the health IT module protects the audit log and how alterations to the audit log are detected. | |
| **Points to Remember:**   * See “[EHR Test-128] Privacy and Security Framework” document provided by Drummond Group to verify instructions on submitting required P&S attestation. * Protect audit log (d)(10)(iii) would not prohibit an organization from making a policy decision to delete or purge audit logs after a legal retention period. Rather it focuses only on the prohibition of health IT to delete an audit log as a condition of certification. * Detection of Audit Log Alteration (d)(10)(iv) requires health IT to be able to determine whether activity outside of its control has in some way altered the audit log (e.g., that the operating system was exploited to modify the health IT’s database). * The use of hashing algorithms with strength equal or greater than SHA-2 as specified in FIPS 180-4 (Secure Hash Standard) to determine whether the audit log has been altered is strongly recommended. | |

### Test Procedures

**3.1 Protection Audit Log and Detection of Audit Log Alteration**

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|  | Using the framework document referenced above, the health IT developer attests how the audit log is protected from having the following data elements from being changed, overwritten, or deleted by the health IT module:   * + Recording of actions related to electronic health   + information;   + Recording of audit log status; and   + Recording of encryption status. |
|  | Health IT developer attests how alterations to an audit log are detected. |
|  | Proctor reviews attestation document and verifies the health IT module protects the outlined items from being changed, overwritten, or deleted from the audit log and that alterations to an audit log are successfully detected. |

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# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-Mar-2016 Additions

* Demonstration of the ability to use NIST time servers is required for certification, however vendors are not required to use NIST servers post certification.
* A "pointer to original data state" is a means of identifying original information that has been changed by a user. Similarly, a "pointer to deleted information" is a means of identifying information prior to deletion. A description of a change or deletion is acceptable as long as the type of action is specified and both the original and modified data states are able to be identified. For example, an audit log could include a link to an original document and provide a description of the modified state. Conversely, it could include a description of the original data state and provide a link to the modified document. The certification criterion is not prescriptive of how the requirement should be achieved. Demonstrating the ability to view the original document prior to a change or deletion is an acceptable method of meeting the certification requirement, however it is not required during testing.
* Information related to the required actions (additions, deletions, changes, queries, print, and copy) must be recorded in the audit log, however the certification criterion is not prescriptive to the method by which this is achieved and does not place limitations on the format in which this information is presented in the audit log.
* Only those sections specified from section 7 of ASTM E2147-01 are the minimum required for certification.

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§****170.315(d)(10) Auditing Actions on Health Information.**

(i) By default, be set to record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1).

(ii) If technology permits auditing to be disabled, the ability to do so must be restricted to a limited set of users.

(iii) Actions recorded related to electronic health information must not be capable of being changed, overwritten, or deleted by the technology.

(iv) HIT module must be able to detect whether the audit log has been altered.

**§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.**

1. Record actions related to electronic health information, audit log status, and encryption of end-user devices.
   * 1. 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.
     2. The date and time must be recorded in accordance with the standard specified at §170.210(g).
2. *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).
3. *Audit log content.* ASTM E2147-01(Reapproved 2009), (incorporated by reference in §170.299) Sections 7.2 through 7.4, 7.6, and 7.7 of ASTM E2147-01, when support, the following actions should be recorded related to health care information:
4. Additions
5. Deletions
6. Changes
7. Queries
8. Print
9. Copy
10. Changes to user privileges
11. Access to patient information, including emergency access events

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 01-July-2016 | Re-numbered sections. Added sections for Privacy and Security attestations. Removed Appendix C and moved template to “[EHR Test-128] Privacy Security Framework” document. |
| 01-Jun-2016 | Added text boxes to indicate if this P&S module applies to all certified criteria and reference to the attestation based on “Privacy and Security Framework” document. |
| 01-May-2016 | Added NTP test (section 1.1). |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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