

## Test Procedure for §170.314 (b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries

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<sup>1</sup> 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<sup>2</sup>, 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](mailto: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(b)(1) Transitions of care – receive, display, and incorporate transition of care/referral summaries.

- (i) Receive. EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:

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<sup>1</sup> Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

<sup>2</sup> 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.

- (A) The standard specified in § 170.202(a).
- (B) Optional. The standards specified in § 170.202(a) and (b).
- (C) Optional. The standards specified in § 170.202(b) and (c).
- (ii) Display. EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3).
- (iii) Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:
  - (A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient
  - (B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):
    - (1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(2);
    - (2) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
    - (3) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2)
  - (C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3)

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, 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 transitions of care – receive, display, and incorporate transitions of care/referral summaries certification criterion is discussed:

- “We acknowledged that care plan, additional care team members, referring or transitioning provider’s name and contact information as well as certain hospital discharge information are not explicitly required to be captured by separate certification criteria, unlike most other data included in the summary care record. We noted that the ability to capture these data elements is both

implicit and necessary to satisfy this certification criterion (as well as the other certification criteria that rely on the same data).”

- “We have revised the final certification criterion to require that EHR technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to each of the transition of care/referral summary standards we have adopted (i.e., CCD/C32; CCR; and Consolidated CDA).”
- “...commenters expressed concern regarding hospitalizations with large volumes of data such as lab results and how this information would display in a summary document of considerable length. ... This certification criterion expresses that EHR technology must be able to display transition of care/referral summaries received ... It does not, however, dictate how that information is displayed to a user. Those design decisions are fully within an EHR technology developer’s discretion.”
- “... we intended for the term “incorporate” to mean that EHR technology would be able to process the structured data contained in those three Consolidated CDA sections (medications, problems, medication allergies) such that it could be combined (in structured form) with data already maintained by EHR technology and would subsequently be available for use, such as to be used as part of the clinical information reconciliation capabilities (expressed in the certification criterion adopted at (§ 170.314(b)(4)).”
- “... we believe that there is clinical value to the extraction and individual display of the individual sections of the Consolidated CDA ... we have added to this certification criterion a specific capability that EHR technology be able to extract and allow for individual display each additional section or sections (and the accompanying document header information (i.e., metadata)) that were included in a transition of care/referral summary received and formatted in accordance with the Consolidated CDA.”
- “... EHR technology would need to provide the user with a mechanism to select and just view those [Consolidated CDA] sections without having to navigate through what could be a lengthy document.”
- “We intend for testing and certification to verify that the document header information can be displayed with whatever individual sections are selected, but leave the ultimate quantity of header data to be displayed through implementation up to the EHR technology developer and its customers’ preferences.”
- “... this certification criterion does not necessarily require that it [the incorporate capability] be fully automated. ... it was implied by the certification criterion, that some form of matching would occur when a transition of care/referral summary is received in order to correctly determine that the document as a whole ... was attributed to the right patient.”
- “... upon receipt of a transition of care/referral summary is the appropriate point at which to verify that the transition of care/referral summary is being attributed to the correct patient.”
- “...we have revised this certification criterion to include a general statement that the EHR technology must be able to demonstrate that a transition of care/referral summary received is or can be properly matched to the correct patient. ... we have intentionally left this requirement flexible to permit many different ways for this capability to be designed.”

## 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 where the transitions of care – receive, display and incorporate transitions of care/referral summaries certification criterion is discussed:

- “...we proposed to adopt the Consolidated CDA for this certification criterion because its template structure can accommodate the formatting of a summary care record that includes all of the data elements that CMS proposed be available for inclusion in a summary care record.”
- “We proposed that EHR technology would need to be capable of transmitting a summary care record according to both of the Direct Project’s specifications for secure transport. We also proposed to adopt as an optional standard at § 170.202(a)(3) the SOAP-Based Secure Transport RTM version 1.0<sup>3</sup> which was developed under the nationwide health information network Exchange Initiative and to which we stated EHR technology should be able to be certified...”
- “We have revised the final certification criterion to require that EHR technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to each of the transition of care/referral summary standards we have adopted (i.e., CCD/C32; CCR; and Consolidated CDA).”
- “We recognize this certification criterion is more rigorous than the 2011 Edition EHR certification criterion, but believe that it is necessary to continue to introduce more demanding certification requirements for interoperability in order to advance our policy objectives for widespread electronic health information exchange.”

## 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.

**Version 1.3 Note:** All text with strikethrough represents test procedure steps that include functionality not currently available for testing with the Transport Testing Tool (TTT) at the time of release of version 1.3 of this test procedure. However these test procedure steps will be required for certification as soon as these capabilities are available, at which point an updated version of the test procedure will be released that aligns with available Transport Testing Tool functionality.

This test evaluates the capability for an EHR Technology to electronically receive, display in human readable format, and incorporate transition of care/referral summaries. The transition of care/referral summary (summary care record) must be received using the Applicability Statement for Secure Health Transport standard. ~~The vendor may optionally elect to be evaluated for the capability to receive transition of care/referral summaries using the Applicability Statement for Secure Health Transport standard and the ONC XDR and XDM for Direct Messaging Specification standard. The vendor may also optionally elect to be evaluated for the capability to electronically receive transition of care/referral summaries using~~

<sup>3</sup> <http://modularspecs.siframework.org/NwHIN+SOAP+Based+Secure+Transport+Artifacts>

~~the ONC XDR and XDM for Direct Messaging Specification standard and the ONC Transport and Security Specification.~~

This test evaluates the capability for an EHR technology to electronically display a received transition of care/referral summary; and to match the correct patient, incorporate Problems, Medications, and Medication allergies data, and incorporate (and display) individual sections of the received transition of care/referral summary. Both ambulatory EHR technology and inpatient EHR technology presented for certification should be able to receive, display, and incorporate both ambulatory and inpatient summary care records (transition of care/referral summary). The incorporation of medications, medication allergies, and problems data, provides the ability for the data to be available for reconciliation (as evaluated in §170.314(b)(4) clinical information reconciliation). Incorporation, as evaluated in this test procedure, followed by clinical information reconciliation (§170.314(b)(4)) provides the ability for the medications, medication allergies, and problems received from a transition of care/referral summary to be available for triggering of clinical decision support interventions (as evaluated in §170.314(a)(8)).

ONC provides the test data for this test procedure. This test procedure is organized into three required sections (and two optional sections):

- Receive – Evaluates the capability of EHR technology to electronically receive a transition of care/referral summary for a test patient from both ambulatory and inpatient care settings:
  - The Tester verifies that the EHR can correctly host address-bound or domain-bound certificates in either DNS CERT records or LDAP servers that are discoverable by other parties<sup>4</sup>
  - Using the Vendor-identified function(s), the Tester causes the health information in C-CDA, HITSP/C32, and ASTM CCR formats to be transmitted from the Transport Testing Tool to the EHR using the Direct transport standard (ONC Applicability Statement for Secure Health Transport standard), based on ONC-supplied test information
  - The Tester verifies successful receipt of C-CDA conformant documents using the Direct transport standard for unwrapped messages or RFC-5751 wrapped messages; If the vendor offers the capability to accept both wrapped and unwrapped messages, the tester will verify successful receipt of a Direct message using both capabilities
  - ~~○ The Tester verifies that the EHR rejects receipt of Direct messages when sent an invalid trust anchor~~
  - ~~○ The Tester verifies that the EHR rejects receipt of Direct messages when sent using an invalid, expired, or revoked certificate or sent using an invalid trust store~~
  - ~~○ The Tester verifies successful receipt of the health information by the EHR, and that the health information can be successfully decrypted and that a Message Delivery Notification (MDN) is sent by the EHR to the Transport Testing Tool~~

<sup>4</sup> Section 5.0 of the ONC Applicability Statement for Secure Health Transport v1.1: “STAs MUST be able to discover certificates using both the DNS as specified in this section and LDAP as described by the S&I Framework Certificate Discovery for Direct Project Implementation Guide. To achieve universal certificate discovery, STAs MAY elect to publish certificates in the DNS or using LDAP through the capabilities detailed in this section and in the S&I Framework Certificate Discovery for Direct Project Implementation Guide respectively”

- ~~○ Optional: Using the Vendor identified function(s), the Tester causes the health information in C-CDA format to be transmitted from the Transport Testing Tool to the EHR using Direct and the Cross-Enterprise Document Reliable Interchange (XDR) and Cross-Enterprise Document Media Interchange (XDM) for Direct Messaging Specification, based on ONC-supplied test information~~
- ~~○ Optional: Using the Vendor identified function(s), the Tester causes the health information in C-CDA format to be transmitted from the Transport Testing Tool to the EHR using the SOAP-Based Secure Transport RTM version 1.0 and XDR, based on ONC-supplied test information~~
- Display – Evaluates the capability of the EHR technology to electronically display, in human readable format, the transition of care/referral summary that was received in the “Receive” step
  - The Tester logs in to the EHR technology as a provider
  - The Tester causes the EHR to display the transition of care/referral summary transmitted to the EHR in the “Receive” step
  - The Tester validates that the transition of care/referral summary received by the EHR system is electronically displayed in a human readable format for all three acceptable document conformance types: C-CDA, HITSP/C32, and ASTM CCR
  - The Tester verifies that the individual sections of the C-CDA conformant document for both the inpatient summary and ambulatory transition of care/referral summary records formatted to the C-CDA standard can be displayed in a human readable format
  - The Tester evaluates that the EHR technology individually displays all sections and accompanying document header information from the transition of care/referral summary received in the “Receive” step using the C-CDA standard and that the individual sections and header information is complete and accurate
  - The Tester verifies that the transition of care/referral summary information is accurate and complete, and verifies that the Common MU Data Set data are displayed in their English representation if they associate with a vocabulary/code set:
    - 1) Patient name
    - 2) Sex
    - 3) Date of birth
    - 4) Race
    - 5) Ethnicity
    - 6) Preferred language
    - 7) Smoking status
    - 8) Problems
    - 9) Medications
    - 10) Medication Allergies
    - 11) Laboratory test(s)
    - 12) Laboratory value(s)/result(s)
    - 13) Vital signs – height, weight, blood pressure, BMI
    - 14) Care plan field(s), including goals and instructions
    - 15) Procedures
    - 16) Care team member(s)

- For ambulatory transition of care/referral summary C-CDA: encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider's name and contact information
  - For inpatient transition of care C-CDA: encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions
- **Incorporate data** – Evaluates that the EHR technology electronically incorporates medication, problem, and medication allergy list data from the transition of care/referral summary received in the “Receive” step:
  - Using Vendor-identified functions, the Tester evaluates that the inpatient and ambulatory transition of care/referral summary received in the “Receive” step using the C-CDA standard is properly matched to the correct patient
  - Using Vendor-identified function(s) the Tester verifies that the expected information is able to be incorporated into the patient's health record, including available for clinical information reconciliation:
    - Medications according to RxNorm standard at a minimum,
    - Problems according to the SNOMED CT standard at a minimum, and
    - Medication allergies according to the RxNorm standard at a minimum

## REFERENCED STANDARDS

§170.202 Transport standards.	Regulatory Referenced Standard
The Secretary adopts the following transport standards:	
(a) <u>Standard</u> . ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).	
(b) <u>Standard</u> . ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).	
(c) <u>Standard</u> . ONC Transport and Security Specification (incorporated by reference in § 170.299).	
§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(a) <u>Patient summary record</u> . (1) <u>Standard</u> . Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). <u>Implementation specifications</u> . The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).	
(a) (2) <u>Standard</u> . ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299).	

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- (a)(3) Standard. HL7 Implementation Guide for CDA<sup>®</sup>  
Release 2: IHE Health Story Consolidation,  
(incorporated by reference in § 170.299). The use of the  
“unstructured document” document-level template is  
prohibited.

**§170.207 Vocabulary standards for representing  
electronic health information.**

**Regulatory Referenced Standard**

The Secretary adopts the following code sets, terminology,  
and nomenclature as the vocabulary standards for the  
purpose of representing electronic health information:

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- (a)(3) Standard. IHTSDO SNOMED CT<sup>®</sup> International  
Release July 2012 (incorporated by reference in §  
170.299) and US Extension to SNOMED CT<sup>®</sup> March  
2012 Release (incorporated by reference in § 170.299).
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- (d) Medications. (2) Standard. RxNorm, a standardized  
nomenclature for clinical drugs produced by the United  
States National Library of Medicine, August 6, 2012  
Release (incorporated by reference in § 170.299).
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## NORMATIVE TEST PROCEDURES

### Derived Test Requirements

DTR170.314(b)(1) – 1: Receive Summary Care Record Using Direct

~~DTR170.314(b)(1) – 2: Receive Summary Care Record Using Direct and XDM Validation (Optional)~~

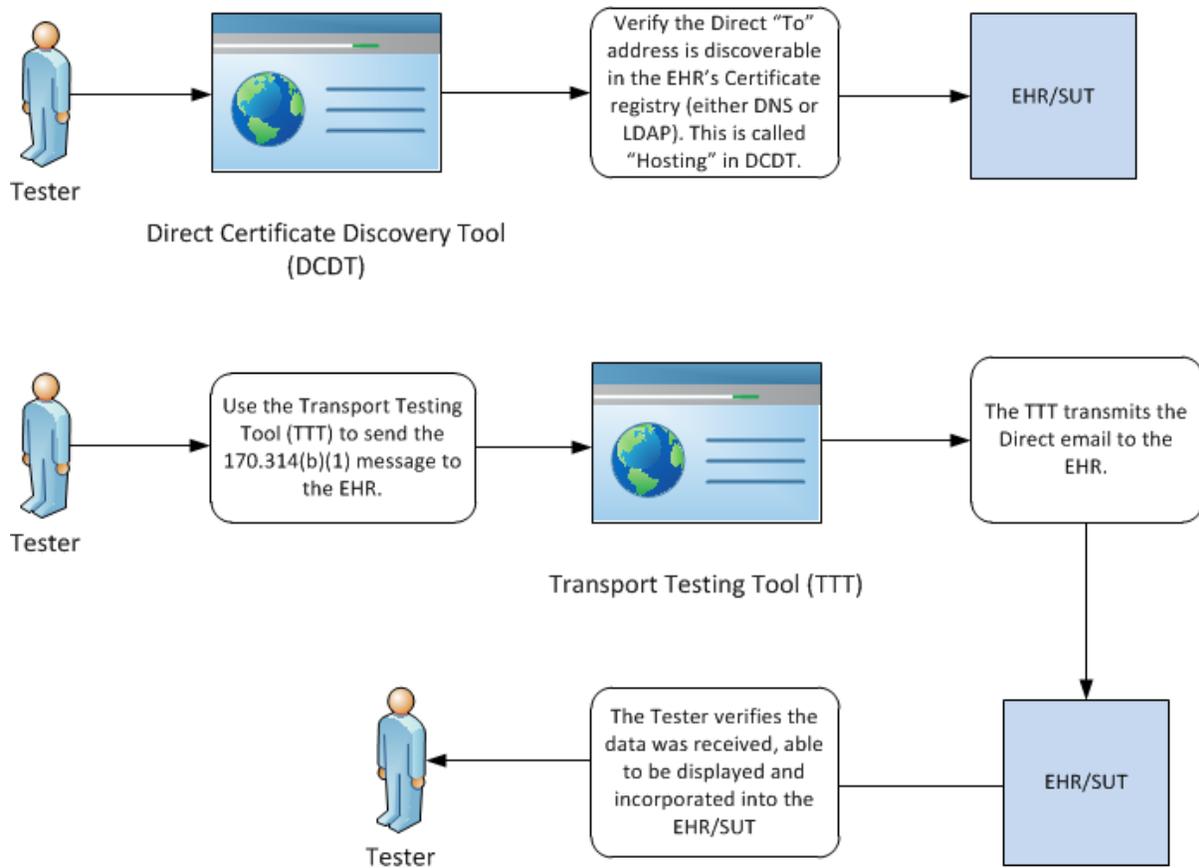
~~DTR170.314(b)(1) – 3: Receive Summary Care Record Using SOAP Protocols (Optional)~~

DTR170.314(b)(1) – 4: Display Summary Care Record

DTR170.314(b)(1) – 5: Incorporate Summary Care Record Data

### DTR170.314(b)(1) – 1: Receive Summary Care Record Using Direct

Figure 1



### Required Vendor Information

- VE170.314(b)(1) – 1.01: The Vendor shall identify whether the EHR stores certificates as address-bound or domain-bound certificates and whether the EHR hosts certificates in DNS or LDAP servers
- VE170.314(b)(1) – 1.02: The Vendor shall identify the Direct address for Test Cases within the Direct Certificate Discovery Tool and Transport Testing Tool
- VE170.314(b)(1) – 1.03: The Vendor shall install the Valid Trust Anchor available from Transport Testing Tool homepage
- VE170.314(b)(1) – 1.04: The Vendor shall identify the Transport Testing Tool's public certificate for use by the EHR to decrypt messages sent from the Transport Testing Tool
- VE170.314(b)(1) – 1.05: The Vendor shall create and identify certificate(s) for Direct receive address(es) to be used for digital signing of the Direct message(s) to be sent by the Transport Testing Tool to the EHR
- VE170.314(b)(1) – 1.06: The Vendor shall identify the EHR's Public Key (certificate) for encryption of the Direct message(s) to be uploaded to the Transport Testing Tool for sending of messages from the tool to the EHR
- VE170.314(b)(1) – 1.07: Using ONC-supplied test data, the Vendor shall create test patients with existing records in the EHR to be used for this test as indicated in TD170.314(b)(1) – 1 and TD170.314(b)(1) – 2
- VE170.314(b)(1) – 1.08: The Vendor shall identify a provider with authorized access to the test patients' records
- VE170.314(b)(1) – 1.09: The Vendor shall identify the EHR function(s) that are available for a provider to receive Summary Care Records from Third Parties using the Direct standard
- VE170.314(b)(1) – 1.10: The Vendor shall identify whether the EHR offers the capability to accept unwrapped messages, RFC-5751 wrapped messages, or both

### Required Test Procedures

- TE170.314(b)(1) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the provider
- TE170.314(b)(1) – 1.02: The Tester shall execute all test cases using the Direct Certificate Discovery Tool for address or domain-bound certificates hosted in DNS or LDAP servers based upon the Vendor's certificate hosting methods identified in VE170.314(b)(1) – 1.01 and the Direct address specified in VE170.314(b)(1) – 1.02
- TE170.314(b)(1) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the EHR technology is able to correctly host either address-bound and domain-bound certificate(s) hosted in either DNS or LDAP servers that is discoverable by others
- TE170.314(b)(1) – 1.04: As indicated in VE170.314(b)(1) – 1.08, the Tester shall utilize the Transport Testing Tool to transmit either an unwrapped message (that does not use the Direct RFC-5751 wrapper) or wrapped message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for an Ambulatory Summary of Care Record in

- C-CDA format to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02 (tested for both ambulatory EHR and inpatient EHR settings)
- TE170.314(b)(1) – 1.05: As indicated in VE170.314(b)(1) – 1.08, the Tester shall utilize the Transport Testing Tool to transmit an unwrapped message (that does not use the Direct RFC-5751 wrapper) or wrapped message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for an Inpatient Summary of Care Record in C-CDA format to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02 (tested for both ambulatory EHR and inpatient EHR settings)
- TE170.314(b)(1) – 1.06: As indicated in VE170.314(b)(1) – 1.08, the Tester shall utilize the Transport Testing Tool to transmit an unwrapped message (that does not use the Direct RFC-5751 wrapper) or wrapped message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for HITSP/C32 document to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02
- TE170.314(b)(1) – 1.07: As indicated in VE170.314(b)(1) – 1.08, the Tester shall utilize the Transport Testing Tool to transmit an unwrapped message (that does not use the Direct RFC-5751 wrapper) or wrapped message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for an ASTM CCR document to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02
- TE170.314(b)(1) – 1.08: Using the Inspection Test Guide, the Tester shall verify that the Ambulatory and Inpatient Summary of Care documents, HITSP/C32 document, and ASTM CCR document are successfully received, ~~and the Transport Testing Tool receives a successful Message Delivery Notification (MDN) from the EHR for each message~~
- TE170.314(b)(1) – 1.09: If the Vendor offers the capability to receive both Direct RFC-5751 wrapped and unwrapped messages as specified in VE170.314(b)(1) – 1.08, the Tester shall utilize the Transport Testing Tool to transmit a Direct message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for a C-CDA document to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02 using the capability (wrapped/unwrapped) that was not tested in TE170.314(b)(1) – 1.04 to TE170.314(b)(1) – 1.07
- TE170.314(b)(1) – 1.10: If the Vendor offers the capability to receive both Direct RFC-5751 wrapped and unwrapped messages as specified in VE170.314(b)(1) – 1.08, using the Inspection Test Guide, the Tester shall verify that the C-CDA conformant document transmitted in TE170.314(b)(1) – 1.09 is successfully received, ~~and the Transport Testing Tool receives a successful Message Delivery Notification (MDN) from the EHR for the wrapped message~~
- TE170.314(b)(1) – 1.11: ~~The Vendor shall download and install an invalid Trust Anchor available from the Transport Testing Tool~~

- ~~TE170.314(b)(1) – 1.12: The Tester shall utilize the Transport Testing Tool to transmit a C-CDA conformant document using an invalid Trust Anchor to the EHR using the Direct transport standard~~
- ~~TE170.314(b)(1) – 1.13: Using the Inspection Test Guide, the Tester shall verify that the EHR rejects receipt of the Direct message transmitted in TE170.314(b)(1) – 1.12~~
- ~~TE170.314(b)(1) – 1.14: The Vendor shall remove the invalid Trust Anchor and reinstall the valid Trust Anchor as in VE170.314(b)(1) – 1.03~~
- ~~TE170.314(b)(1) – 1.15: The Tester shall utilize the Transport Testing Tool to transmit a C-CDA conformant document using an invalid certificate to the EHR using the Direct transport standard~~
- ~~TE170.314(b)(1) – 1.16: The Tester shall utilize the Transport Testing Tool to transmit a C-CDA conformant document using a revoked certificate to the EHR using the Direct transport standard~~
- ~~TE170.314(b)(1) – 1.17: The Tester shall utilize the Transport Testing Tool to transmit a C-CDA conformant document using an expired certificate to the EHR using the Direct transport standard~~
- ~~TE170.314(b)(1) – 1.18: The Tester shall utilize the Transport Testing Tool to transmit a C-CDA conformant document using a certificate with an invalid trust relationship to the EHR using the Direct transport standard~~
- ~~TE170.314(b)(1) – 1.19: Using the Inspection Test Guide, the Tester shall verify that the EHR rejects receipt of the Direct messages using certificates that are invalid, revoked, expired, or have an invalid trust relationship to the NIST trust store stored in the EHR~~

#### Inspection Test Guide

- ~~IN170.314(b)(1) – 1.01: Using the Direct Certificate Discovery Tool, the Tester shall verify that the EHR's hosted certificates are discoverable for the selected test cases~~
- ~~IN170.314(b)(1) – 1.02: Tester shall verify that all messages wrapped, unwrapped, or both were received. This may be accomplished by reviewing log files (or other equivalent methods) or by viewing all received messages within DTR – 4 Display Summary Care Record~~
- ~~IN170.314(b)(1) – 1.02: Using the Transport Testing Tool, the Tester shall verify that Message Delivery Notifications were sent by the EHR to indicate successful receipt of messages sent in: TE170.314(b)(1) – 1.04, TE170.314(b)(1) – 1.05, TE170.314(b)(1) – 1.06, TE170.314(b)(1) – 1.07, and TE170.314(b)(1) – 1.09~~
- ~~IN170.314(b)(1) – 1.03: Using the Transport Testing Tool, the Tester shall verify that Message Delivery Notifications were not received for messages sent in: TE170.314(b)(1) – 1.12, TE170.314(b)(1) – 1.15, TE170.314(b)(1) – 1.16, TE170.314(b)(1) – 1.17, and TE170.314(b)(1) – 1.18 and inspect that the messages were rejected and not received by the EHR (e.g. inspecting audit logs to verify rejections)~~

#### **DTR170.314(b)(1) – 2: Receive Summary of Care Record Using Direct and XDM Validation (Optional)** Required Vendor Information

- ~~VE170.314(b)(1) – 2.01: As defined in DTR170.314(b)(1) – 1, no additional information is required~~

#### Required Test Procedures

~~TE170.314(b)(1) – 2.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the provider~~

~~TE170.314(b)(1) – 2.02: The Tester shall utilize the Transport Testing Tool to transmit an unwrapped message (that does not use the Direct RFC-5751 wrapper) digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for a C-CDA conformant document to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02 using ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation~~

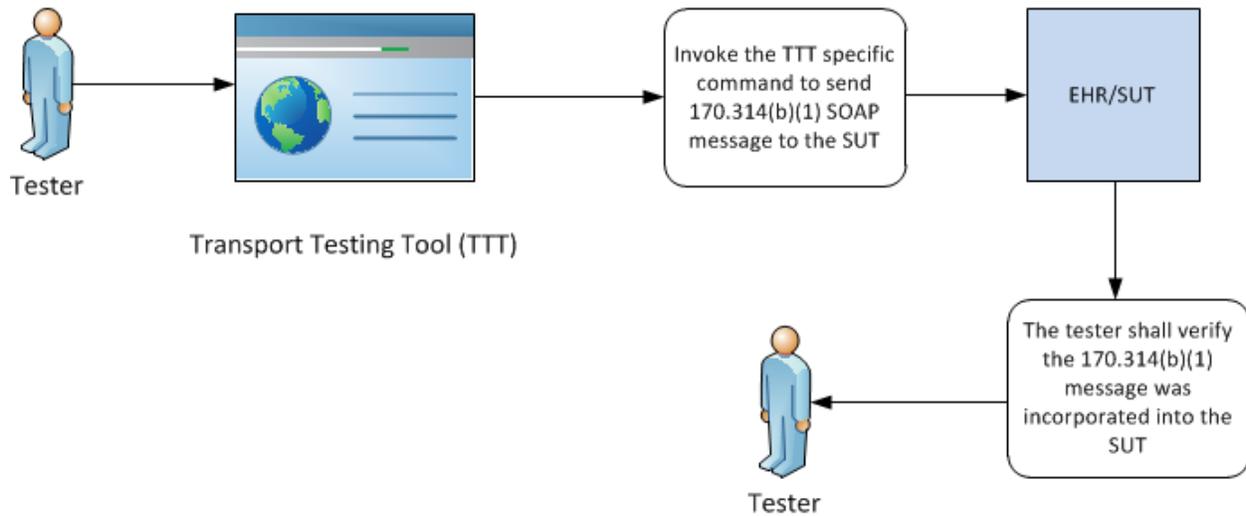
~~TE170.314(b)(1) – 2.03: If the Vendor offers the capability to receive Direct RFC-5751 wrapped messages as specified in VE170.314(b)(1) – 1.08, The Tester shall utilize the Transport Testing Tool to transmit a Direct RFC-5751 wrapped message digitally signed using a valid certificate and public key for the Vendor's EHR (provided in VE170.314(b)(1) – 1.03 and VE170.314(b)(1) – 1.04) for a C-CDA conformant document to the Vendor's Direct address specified in VE170.314(b)(1) – 1.02 using ONC Applicability Statement for Secure Health Transport (Direct) standard with XDM Validation~~

#### Inspection Test Guide

~~IN170.314(b)(1) – 1.02: Using the Transport Testing Tool, the Tester shall verify that Message Delivery Notifications were sent by the EHR to indicate successful receipt of messages sent in: TE170.314(b)(1) – 2.02 and TE170.314(b)(1) – 2.03~~

#### **~~DTR170.314(b)(1) – 3: Receive Summary of Care Record Using SOAP Protocols (Optional)~~**

#### **Figure 2**



#### Required Vendor Information

VE170.314(b)(1) — 3.01: The Vendor shall identify a SUT receiving email address to be used for receipt of the validation report generated by the Transport Testing Tool

#### Required Test Procedures

TE170.314(b)(1) — 3.01: The Tester shall cause the Transport Testing Tool transmit a Summary of Care C-CDA conformant document using SOAP Protocols with XDR Validation to the EHR's SOAP endpoint

TE170.314(b)(1) — 3.02: Using the Inspection Test Guide, the Tester shall verify that the Summary of Care Record transmitted in TE170.314(b)(1) — 3.01 is successful

#### Inspection Test Guide

IN170.314(b)(1) — 3.01: Using the Transport Testing Tool, the Tester shall verify that the transmitted C-CDA conformant document has been received successfully by the EHR according to SOAP Protocols with XDR Validation

## **DTR170.314(b)(1) – 4: Display Summary of Care Record**

### Required Vendor Information

VE170.314(b)(1) – 4.01: Vendor shall identify the EHR function(s) that are available for a provider to display Summary Care Records received electronically by third parties

### Required Test Procedures

TE170.314(b)(1) – 4.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC supplied test patient's record, created in VE170.314(b)(1) – 1.05, as the provider

TE170.314(b)(1) – 4.02: Using the Vendor-identified EHR function(s), the Tester shall display the Ambulatory Summary Care Record received in TE170.314(b)(1) – 1.04 (If the EHR technology requires additional users that are not the provider to receive the message, view message header information, and match the summary care record to the patient prior to being available for the provider, this is permitted)

TE170.314(b)(1) – 4.03: Using the Inspection Test Guide, the Tester shall verify that the information displayed for the Ambulatory Summary of Care record is complete and accurate and all sections are displayed individually

TE170.314(b)(1) – 4.04: Using the Vendor-identified EHR function(s), the Tester shall display the Inpatient Summary Care Record received in TE170.314(b)(1) – 1.05 If the EHR technology requires additional users that are not the provider to receive the message, view message header information, and match the summary care record to the patient prior to being available for the provider, this is permitted)

TE170.314(b)(1) – 4.05: Using the Inspection Test Guide, the Tester shall verify that the information displayed for the Inpatient Summary of Care record is complete and accurate and all sections are displayed individually

TE170.314(b)(1) – 4.06: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to select individual sections (not all) for display for either the Inpatient or Ambulatory received C-CDA conformant Summary Care record

TE170.314(b)(1) – 4.07: Using the Vendor-identified EHR function(s), the Tester shall display the HITSP/C32 document received in TE170.314(b)(1) – 1.06

TE170.314(b)(1) – 4.08: Using the Inspection Test Guide, the Tester shall verify that the HITSP/C32 document can be successfully displayed

TE170.314(b)(1) – 4.09: Using the Vendor-identified EHR function(s), the Tester shall display the ASTM CCR document received in TE170.314(b)(1) – 1.07

TE170.314(b)(1) – 4.10: Using the Inspection Test Guide, the Tester shall verify that the ASTM CCR document can be successfully displayed

### Inspection Test Guide

IN170.314(b)(1) – 4.01: Using the ONC-provided test data, the Tester shall verify that the content of the received C-CDA conformant Ambulatory Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements:

- 1) Encounter diagnoses

- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Reason for referral
- 6) Referring or transitioning provider's name
- 7) Provider name
- 8) Provider office contact information
- 9) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
  - 1) Patient name
  - 2) Sex
  - 3) Date of birth
  - 4) Race
  - 5) Ethnicity
  - 6) Preferred language
  - 7) Smoking status
  - 8) Problems
  - 9) Medications
  - 10) Medication Allergies
  - 11) Laboratory test(s)
  - 12) Laboratory value(s)/result(s)
  - 13) Vital signs – height, weight, blood pressure, BMI
  - 14) Care plan field(s), including goals and instructions
  - 15) Procedures
  - 16) Care team member(s)

IN170.314(b)(1) – 4.02: Using the ONC-provided test data, the Tester shall verify that the content of the received C-CDA conformant Inpatient Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements

- 1) Encounter diagnoses
- 2) Immunizations
- 3) Cognitive status
- 4) Functional status
- 5) Discharge instructions
- 6) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
  - 1) Patient name
  - 2) Sex
  - 3) Date of birth
  - 4) Race
  - 5) Ethnicity
  - 6) Preferred language
  - 7) Smoking status

- 8) Problems
- 9) Medications
- 10) Medication Allergies
- 11) Laboratory test(s)
- 12) Laboratory value(s)/result(s)
- 13) Vital signs – height, weight, blood pressure, BMI
- 14) Care plan field(s), including goals and instructions
- 15) Procedures
- 16) Care team member(s)

IN170.314(b)(1) – 4.03: Using the ONC-provided test data, the Tester shall verify the EHR provides the individual section information contained within the Summary Care Record C-CDA conformant documents

IN170.314(b)(1) – 4.04: Using the ONC-provided test data, the Tester shall verify the EHR accurately displays header information and only the selected sections in TE170.314(b)(1) – 4.05 without having to view or navigate the entire document

IN170.314(b)(1) – 4.05: Using the ONC-provided test data, the Tester shall verify that the content of the received HITSP/C32 document displays completely and accurately and coded information displays in its English representation if associated with a vocabulary/code set

IN170.314(b)(1) – 4.06: Using the ONC-provided test data, the Tester shall verify that the content of the received ASTM CCR document displays completely and accurately and coded information displays in its English representation if associated with a vocabulary/code set

#### **DTR170.314(b)(1) – 5: Incorporate Summary Care Record Data**

##### Required Vendor Information

VE170.314(b)(1) – 5.01: Vendor shall identify the EHR function(s) that are available for a provider to match patient identifying information from documents received electronically using Direct, ~~Direct with XDM, and SOAP~~ transport protocols with patient records within the EHR

VE170.314(b)(1) – 5.02: Vendor shall identify the EHR function(s) that are available to save documents received electronically from third parties within a patient's record

VE170.314(b)(1) – 5.03: Vendor shall identify the EHR function(s) that are available to incorporate medication list, problem list, and medication allergy list data from C-CDA conformant documents as structured data within the EHR

VE170.314(b)(1) – 5.04: Vendor shall identify the EHR function(s) that are available to incorporate medication list, problem list, and medication allergy list data from C-CDA conformant documents for clinical information reconciliation

### Required Test Procedures

- TE170.314(b)(1) – 5.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient’s record, created in VE170.314(b)(1) – 1.05, as the provider
- TE170.314(b)(1) – 5.02: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to match and display the received Ambulatory Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.04 with the correct patient’s record within the EHR
- TE170.314(b)(1) – 5.03: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to display that the Ambulatory Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.04 is stored as a C-CDA conformant document within the EHR
- TE170.314(b)(1) – 5.04: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to display the medication list, problem list, and medication allergy information within the Ambulatory Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.04 as structured data, available for clinical information reconciliation
- TE170.314(b)(1) – 5.05: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to match and display the received Inpatient Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.05 with the correct patient’s record within the EHR
- TE170.314(b)(1) – 5.06: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to display that the Inpatient Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.05 is stored as a C-CDA conformant document within the EHR
- TE170.314(b)(1) – 5.07: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to display the medication list, problem list, and medication allergy information within the Inpatient Summary Care Record C-CDA conformant document received in TE170.314(b)(1) - 1.05 as structured data, available for clinical information reconciliation

### Inspection Test Guide

- IN170.314(b)(1) – 5.01: Using the ONC-provided test data, the Tester shall verify that the documents received electronically are matched with the correct patient record and are stored as part of the patient record created in VE170.314(b)(1) – 1.05
- IN170.314(b)(1) – 5.02: Using the ONC-provided test data, the Tester shall verify that medication list, problem list, and allergy list data is incorporated as structured and coded data for the received C-CDA conformant Summary Care Records
- IN170.314(b)(1) – 5.03: Using the ONC-provided test data, the Tester shall verify that medication list, problem list, and allergy list data for received C-CDA conformant Summary Care Records displayed for clinical information reconciliation are complete and accurate

## TEST DATA

ONC 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-Accredited Testing Laboratories (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.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor-selected message format requires some modification to the test data.
- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Test data for §170.314(b)(1) Receive Display Incorporate is available through the conformance tool (reference Conformance Tool Section for tool access).

Any departure from the provided test data shall strictly 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. For additional information on changes to the test data, refer to the Transport Test Tool documentation.

The test procedures require that the Tester enter the 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.

## CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- Direct Certificate Discovery Tool (DCDT) – ONC provides a web application certificate discovery testing tool to support this test procedure. This tool was created to support automated testing of systems that plan to enact the Certificate Discovery and Provider Directory Implementation Guide, approved as normative specification by the Direct community, as of July 9, 2012. It is based on the written test package and requirement traceability matrix created by the Modular Specifications project.
  - This application can be installed and deployed locally.
  - The Direct Certificate Discovery Tool, User's Guide, configuration instructions, and other documentation are available at: <http://code.google.com/p/direct-certificate-discovery-tool/>

Support for the Direct Certificate Discovery Tool is available at the DCDT user group:

<https://groups.google.com/forum/#!forum/directtestsupport> or by contacting:

Avinash Shanbhag ([Avinash.Shanbhag@hhs.gov](mailto:Avinash.Shanbhag@hhs.gov))  
Director, Nationwide Health Information Network Division  
Office of Standards and Interoperability  
Office of the National Coordinator for Health IT, HHS

- Transport Testing Tool (TTT) – the Transport Testing Tool is designed to support this test procedure. The Transport Testing Tool includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using transport standards (e.g., Direct, Direct + XDM, SOAP).
  - The Transport Testing Tool (TTT) is available at: <http://transport-testing.nist.gov>

Support for the Transport Testing Tool is available by submitting questions to the Transport Testing Tool user group at: <https://groups.google.com/d/forum/transport-testing-tool>.

Inquiries may also be sent to this user group via email: [transport-testing-tool@googlegroups.com](mailto:transport-testing-tool@googlegroups.com)

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The Transport Testing Tool uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

## 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 (to align with TTT functionality): <ul style="list-style-type: none"><li>• Changed RFC 8222 to RFC 5751 in Informative Test Description and Normative Test Procedure</li><li>• Strikethrough of DTR 170.314(b)(1) – 2 and 170.314(b)(1) – 3 in Normative Test Procedure and reference to functionalities tested in Informative Test Description</li><li>• Modified Informative Test Description and Normative Test Procedure to allow for testing of receipt of wrapped, unwrapped, or both wrapped/unwrapped Direct messages</li><li>• Strikethrough of negative test of invalid, revoked and expired certificates in Normative Test Procedure and references to this test in the Informative Test Description</li><li>• Inserted notation in Informative Test Description clarifying purpose of strikethrough text</li><li>• Inserted test data reference in Normative Test Procedure</li></ul>	February 1, 2013