Test Procedure for §170.314(g)(3) Safety-enhanced design

This document describes the 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 Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. 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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*.)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(g)(3) Safety-enhanced design. User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(16); § 170.314(b)(3); and § 170.314(b)(4).

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

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this Certification Criterion is classified as new from the 2011 Edition. This certification criterion meets at least one of the two factors of new certification criteria: (1) The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria, or (2) The certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

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 safety-enhanced design certification criterion is discussed:

- "…we provided an overview of the ISO definition of usability as "[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.""
- "The IOM recommended that "[t]he Secretary of HHS should specify the quality and risk management process requirements that health IT vendors must adopt, with a particular focus on human factors, safety culture, and usability.""
- "We proposed that a significant first step toward improving overall usability would be to focus on the process of user-centered design (UCD)."
- "We acknowledged and expected that EHR technology developers who have already followed UCD in previous development efforts for the identified certification criteria would be performing a retrospective analysis."
- "We proposed that testing[3] to this certification criterion would entail EHR technology developers documenting that their UCD incorporates all of the data elements defined in the Customized Common Industry Format Template for EHR Usability Testing (NISTIR 7742)… that this information would need to be available to an ONC-ACB for review, but that the form and format for how the data would presented for testing would not necessarily need to be according to NISTIR 7742 (i.e., an EHR technology developer could capture information specified in NISTIR 7742)."
- "To demonstrate compliance with this certification criterion, UCD must have been applied to each capability of an EHR technology that is associated… only those eight certification criteria specified in this certification criterion and for which certification is sought."
- "…if an EHR technology had never applied UCD to the capabilities to which this certification criterion applies then UCD would need to be completed before that EHR technology could be certified. However, if UCD had been applied to an EHR technology for the capabilities relevant to this certification criterion, UCD would not need to be redone and an EHR technology developer could provide the required information specified by NISTIR 7742 that reflects the UCD that they had previously completed."

[3] The National Voluntary Laboratory Accreditation Program, as administered by NIST, is responsible for accrediting testing laboratories (who perform EHR technology testing) under the permanent certification program ("ONC HIT Certification Program") (76 FR 1278).

- "The method(s) that could be employed for UCD (e.g., ISO 9241-11, ISO 13407, ISO 16982, and NISTIR 7741) and that were listed in the Proposed Rule are examples of resources that EHR technology developers may choose to review in order to select a UCD. We agree that ISO/IEC 62366 and ISO 9241-210 are also acceptable alternatives."
- "Any UCD process selected by an EHR technology developer is appropriate, and it need not be listed in the examples we provided in order to be acceptable. We do, however, strongly advise EHR technology developers to select an industry standard process because compliance with this certification criterion requires submission of the name, description, and citation (URL and/or publication citation) of the process that was selected."
- "In the event that an EHR technology developer selects a UCD process that is not an industry standard (i.e., not developed by a voluntary consensus standards organization (VCSO)), but is based on one or more industry standard processes, the developer may name the process(es) and provide an outline of the process in addition to a short description."
- "Submission of the information specified in the NISTIR 7742 template will need to be submitted for each and every one of the applicable eight certification criteria specified in this certification criterion and for which certification is sought. This information will become part of the EHR technology's test report that is required to be made publicly available."
- "The following information/sections in NISTIR 7742 are required for submission:
    - Name and version of the product
    - Date and location of the test
    - Test environment
    - Description of the intended users
    - Total number of participants
    - Description of participants: their experience and demographic characteristics
    - Description of the user tasks that were tested
    - List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction
    - Data scoring
    - Results of the test and data analysis
    - Major test findings
    - Identified area(s) of improvement(s)"
- "…all of the sections specified above must to be completed, including "major findings" and "areas for improvement.""
- "…the submission that is ultimately provided for testing and certification may be the expression of a final iteration in which few areas for improvement would be identified. We do not expect EHR technology developers to include trade secrets or proprietary information in these reports."
- "The NISTIR 7742 includes several sections: Executive Summary, Introduction, Method, Results, and Appendices. In each of these sections, there are required data elements – and some of these elements call for the expression of the number of study participants, their level of experience with EHR technology, and other pertinent details. Regarding comments about the participants of usability testing, many UCD processes incorporate involvement of end-users in formative and summative testing. The cohort of users who are selected as participants will of course vary with the product and its intended users."

- "…at a minimum, only lab-based summative testing is necessary to be performed in order to demonstrate compliance with this certification criterion."

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 apply user-centered design for each EHR technology capability submitted for testing and specified in the following certification criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only - electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

The Vendor provides the documentation for this test procedure.

This test procedure is organized into two sections:

- Submit User-Centered Design Practice– evaluates Vendor-supplied documentation of referenced UCD practice to ensure the Vendor has applied user-centered design (UCD) process(es) for each EHR technology capability submitted for testing and specified in the following certification criteria:
  - § 170.314(a)(1) Computerized provider order entry
  - § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
  - § 170.314(a)(6) Medication list
  - § 170.314(a)(7) Medication allergy list
  - § 170.314(a)(8) Clinical decision support
  - § 170.314(a)(16) Inpatient setting only - electronic medication administration record
  - § 170.314(b)(3) Electronic prescribing
  - § 170.314(b)(4) Clinical information reconciliation

    - The Tester shall verify that for each EHR technology capability submitted for testing and specified in the above-listed certification criteria, the Vendor has chosen a user-centered design (UCD) process that is either:
      A) UCD industry standard (e.g.; ISO 9241-11, ISO 9241-210, ISO 13407, ISO 16982, and ISO/IEC 62366); and submitted the name, description, and citation (URL and/or publication citation)
      OR

B) Not considered an industry standard (i.e. may be based upon one or more industry standard processes); and submitted the named the process(es) and provided an outline and short description of the process(es)

- The UCD practice may incorporate different UCD process(es) for each capability an EHR technology includes that is submitted for testing and specified in the above-listed certification criteria

- Submit Summative Testing Results for Select Certification Criteria – evaluates Vendor-provided NISTIR 7742 (Customized Common Industry Format Template for Electronic Health Record Usability Testing) for usability test report(s) to ensure the Vendor has conducted summative usability testing and recorded the results for each EHR technology capability submitted for testing and specified in the following certification criteria:
  - § 170.314(a)(1) Computerized provider order entry
  - § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
  - § 170.314(a)(6) Medication list
  - § 170.314(a)(7) Medication allergy list
  - § 170.314(a)(8) Clinical decision support
  - § 170.314(a)(16) Inpatient setting only - electronic medication administration record
  - § 170.314(b)(3) Electronic prescribing
  - § 170.314(b)(4) Clinical information reconciliation
    - The Vendor may provide one single NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing report that includes a separate chapter for each EHR technology capability submitted for testing and specified in the above-listed certification criteria or a separate NISTIR 7742 Customized Common Industry Format report for each capability.
    - The Vendor may provide additional information regarding testing on earlier versions or releases of the product an optional basis
    - The Tester shall examine each Vendor-provided report to ensure the existence and adequacy of the test report(s) submitted by the manufacturer. The Tester shall verify that the report(s) conform to the information specified in NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing.
    - The Tester shall inspect the acceptability of the following reporting areas (which are marked (grayed out) in the CIF for completion), including but not limited to:
      - Name and version of the product
      - Date and location of the test
      - Test environment
      - Description of the intended users
      - Total number of participants
      - Description of participants: their experience and demographic characteristics
      - Description of the user tasks that were tested
      - List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction
      - Data scoring

- Results of the test and data analysis
- Major test findings
- Identified area(s) of improvement(s)

- The Tester shall verify that Vendor-provided report(s) conform(s) to the content and completion requirements of the Common Industry Format (CIF) per NISTIR 7742.
  - The Tester shall verify that the demographic characteristics of the subject pool meet the specifications of the particular requirement (NISTIR 7742 3.1 "Participants"); where use conditions and population of the users are analyzed
  - The Tester shall verify that the user tasks employed in the study are prioritized in accordance with the risk associated with user errors (NISTIR 7742 3.3 "Tasks")
  - The Tester shall verify how effectiveness and efficiency were evaluated (NISTIR 7742 3.9 "Usability Metrics")
  - The Tester shall verify that test results provided a risk analysis of the use, tested performance and error rates (NISTIR 7742 4. "Results")
  - The Tester shall verify that all major test findings and the identified area(s) of improvements are reported
  - The Tester shall verify that the name and version of the product are the final version (release) of the product for which the Vendor seeks certification
- The Tester shall verify that the report contains – all required (at a minimum) test scenarios for each of the EHR technology capabilities submitted for testing and specified in the following criteria:
  - § 170.314(a)(1) Computerized provider order entry
  - § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
  - § 170.314(a)(6) Medication list
  - § 170.314(a)(7) Medication allergy list
  - § 170.314(a)(8) Clinical decision support
  - § 170.314(a)(16) Inpatient setting only - electronic medication administration record
  - § 170.314(b)(3) Electronic prescribing
  - § 170.314(b)(4) Clinical information reconciliation
- For the EHR capabilities submitted for testing specified in § 170.314(a)(8) clinical decision support, the Tester shall verify that the test scenarios included in the NISTIR 7742 Customized Common Industry Format report for clinical decision support are inclusive of the test scenarios or functionality the Vendor provided for testing to the certification criterion § 170.314(a)(8) clinical decision support

REFERENCED STANDARDS

None

REFERENCED CERTIFICATION CRITERIA

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:	
(a) Clinical. (1) Computerized provider order entry. Enable a user to electronically record, change, and access the following order types, at a minimum: (i) Medications; (ii) Laboratory; and (iii) Radiology/imaging.	
(a)(2) Drug-drug, drug-allergy interaction checks. (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list. (ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted. (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.	
(a)(6) Medication list. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history: (i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of an entire hospitalization.	
(a)(7) Medication allergy list. Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history: (i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of an entire hospitalization.	

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
(a)(8) Clinical decision support. (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs. (ii) Linked referential clinical decision support. (A) EHR technology must be able to: (1) Electronically identify for a user diagnostic and therapeutic reference information; or (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at §170.204(b)(1). (B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the following data referenced in paragraphs (a)(8)(i)(A) through (F) of this section. (iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section; (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology. (v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources: (A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section: (1) Bibliographic citation of the intervention (clinical research/guideline); (2) Developer of the intervention (translation from clinical research/guideline); (3) Funding source of the intervention development technical implementation; and (4) Release and, if applicable, revision date(s) of the intervention or reference source. (B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).	§170.204204 Functional standards The Secretary adopts the following functional standards: b) Reference source. Standard. HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299). (1) Implementation specifications. HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, (incorporated by reference in § 170.299).

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
(a)(16) Inpatient setting only—electronic medication administration record. (i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s): (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered. (B) Right medication. The medication to be administered matches the medication ordered for the patient. (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient. (D) Right route. The route of medication delivery matches the route specified in the medication order. (E) Right time. The time that the medication was ordered to be administered compared to the current time. (ii) Right documentation. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.	§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged. The Secretary adopts the following standard to protect electronic health information created, maintained, and exchanged: (g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299).
(b)(3)Electronic Prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with: (i) The standard specified in § 170.205(b)(2); and (ii) At a minimum, the version of the standard specified in § 170.207(d)(2).	§170.205 Content exchange standards and implementation specifications for exchanging electronic health information. The Secretary adopts the following content exchange standards and associated implementation specifications: (b) Electronic prescribing. (2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in §170.299). §170.207 Vocabulary standards for representing electronic health information. The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information: (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).

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
(b)(4) §170.314(b)(4) Clinical information reconciliation. Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type: (i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date. (ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems. (iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.g.3 – 1: Submit User-Centered Design

DTR170.314.g.3 – 2: Submit Summative Testing Results for Select Certification Criteria

DTR170.314.g.3 – 1: Submit User-Centered Design

Required Vendor Information

VE170.314.g.3 – 1.01: The Vendor shall provide a documented and referenced UCD practice that specifies use of the following user-centered design (UCD) processes:
1) UCD industry standard; and shall submit the name, description, and citation (URL and/or publication citation)
OR
2) A process that is based on one or more industry standard processes; and shall name the process(es); and provide an outline and short description of each of the process(es)

for each EHR technology capability submitted for testing and specified in the following certification criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only - electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

Required Test Procedures

TE170.314.g.3 – 1.01: Using the Inspection Test Guide, the Tester shall examine the Vendor-provided user-centered design (UCD) process(es) to ensure the documentation exists and includes all references according to the listed requirements

Inspection Test Guide

IN170.314.g.3 –1.01: The Tester shall verify that the UCD practice contains UCD process(es) for each of the EHR technology capabilities submitted for testing and specified in the following criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only - electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

IN170.314.g.3 –1.02: The Tester shall verify the UCD processes used are:

1) a UCD industry standard (e.g. ISO 9241-11, ISO 9241-210, ISO 13407, ISO 16982, and ISO/IEC 62366); and that the Vendor submitted the name, description, and citation (URL and/or publication citation)

OR

2) process(es) are based on one or more industry standard processes); and the that the Vendor named the process(es); and provided an outline and short description of the process

DTR170.314.g.3 – 2: Submit Summative Testing Results for Select Certification Criteria

Required Vendor Information

VE170.314.g.3 – 2.01: The Vendor shall provide NISTIR 7742 (Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing) for usability test report(s) that address the application of the documented and referenced UCD process(es) specified in 'DTR170.314.g.3 – 1 Apply User-Centered Design' to each EHR technology capability submitted for testing and specified in the following certification criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only- Electronic medication administration record

- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

The Vendor may provide one single NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing report that includes a separate chapter for each capability an EHR technology includes that is specified in the above-listed certification criteria or a separate NISTIR 7742 Customized Common Industry Format report for each capability. The Vendor may provide additional information regarding testing on earlier versions or releases of the product an optional basis

Required Test Procedures

TE170.314.g.3 – 2.01: Using the Inspection Test Guide, the Tester shall examine each Vendor-provided NISTIR 7742 (Customized Common Industry Format Template for Electronic Health Record Usability Testing)) for usability test report(s) to ensure the report(s) exist and the Vendor has applied the documented and referenced UCD process(es) specified in 'DTR170.314.g.3 – 1 Apply User-Centered Design' to each capability submitted for testing and included in the EHR technology

Inspection Test Guide

IN170.314.g.3 – 2.01: The Tester shall verify that the report(s) contain (at a minimum) all required test scenarios for each of the EHR technology capabilities submitted for testing and specified in the following criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only- Electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

IN170.314.g.3 – 2.02: The Tester shall inspect the acceptability of the following reporting areas (they all are marked/grayed out in CIF for completion), including but not limited to:

- Name and version of the product
- Date and location of the test
- Test environment
- Description of the intended users
- Total number of participants
- Description of participants: their experience and demographic characteristics
- Description of the user tasks that were tested

- List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction
- Data scoring
- Results of the test and data analysis
- Major test findings
- Identified area(s) of improvement(s)

IN170.314.g.3 – 2.03: The Tester shall verify that Vendor-provided report(s) conform(s) to the content and completion requirements of the Common Industry Format (CIF) per NISTIR 7742 for each of the EHR technology capabilities submitted for testing and specified in the above criteria

- The Tester shall verify that the demographic characteristics of the subject pool meet the specifications of the particular requirement (NIST IR 7742 3.1 "Participants"); where use conditions and population of the users are analyzed.
- The Tester shall verify that the user tasks employed in the study are prioritized in accordance with the risk associated with user errors (NIST IR 7742 3.3 "Tasks").
- The Tester shall verify how effectiveness and efficiency were evaluated (NIST IR 7742 3.9 "Usability Metrics").
- The Tester shall verify that test results provided a risk analysis of the use, tested performance and error rates (NIST IR 7742 4. "Results").
- The Tester shall verify that all major test findings and the identified area(s) of improvements are reported
- The Tester shall verify that the name and version of the product are the final version (release) of the product for which the Vendor seeks certification.

IN170.314.g.3 – 2.04: The Tester shall verify that the report contains – all required (at a minimum) test scenarios for each of the EHR technology capabilities submitted for testing and specified in the following criteria:

- § 170.314(a)(1) Computerized provider order entry
- § 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- § 170.314(a)(6) Medication list
- § 170.314(a)(7) Medication allergy list
- § 170.314(a)(8) Clinical decision support
- § 170.314(a)(16) Inpatient setting only - electronic medication administration record
- § 170.314(b)(3) Electronic prescribing
- § 170.314(b)(4) Clinical information reconciliation

IN170.314.g.3 – 2.05: For EHR capabilities submitted for testing specified in § 170.314(a)(8) clinical decision support, the Tester shall verify that the test scenarios included in the NISTIR 7742 Customized Common Industry Format report for clinical decision

support are inclusive of the test scenarios or functionality the Vendor provided for testing to the certification criterion § 170.314(a)(8) clinical decision support.

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 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	Date Published
1.0	Released for public comment	September 28, 2012