

2015 Edition §170.315(g)(3) Safety-Enhanced Design					
Testing Components:					
					
Test Procedure Version 1.1 – Last Updated 10/29/15					

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(g)(3)(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (9) and (14), (b)(2) and (3) of this section.

- § 170.315 (a)(1) Computerized Provider Order Entry (CPOE) – medications
- § 170.315 (a)(2) CPOE – laboratory
- § 170.315 (a)(3) CPOE – diagnostic imaging
- § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
- § 170.315 (a)(5) Demographics
- § 170.315 (a)(6) Problem List
- § 170.315 (a)(7) Medication List
- § 170.315 (a)(8) Medication Allergy List
- § 170.315 (a)(9) Clinical Decision Support
- § 170.315 (a)(14) Implantable Device List
- § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- § 170.315 (b)(3) Electronic Prescribing

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(i)	User-centered design (UCD) process(es) are applied to all of the UCD Required Criteria, implemented by the Health IT Module.	<p>The tester verifies that for each of the following UCD Required Criteria submitted for testing, user-centered design (UCD) process(es) have been documented:</p> <ul style="list-style-type: none"> § 170.315 (a)(1) Computerized Provider Order Entry (CPOE) – medications § 170.315 (a)(2) CPOE – laboratory § 170.315 (a)(3) CPOE – diagnostic imaging § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE § 170.315 (a)(5) Demographics § 170.315 (a)(6) Problem List § 170.315 (a)(7) Medication List § 170.315 (a)(8) Medication Allergy List § 170.315 (a)(9) Clinical Decision Support § 170.315 (a)(14) Implantable Device List § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation § 170.315 (b)(3) Electronic Prescribing

(ii) Number of test participants. A minimum of 10 test participants must be used for the testing of each capability identified in paragraph (g)(3)(i) of this section.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(ii)	The Health IT Module is subjected to summative usability testing with a minimum of 10 test participants.	The tester verifies that at least 10 test participants, representative of the intended user population, participated in summative usability testing for each capability.

(iii) One of the following must be submitted on the user-centered design process used:

(A) Name, description, and citation (URL and/or publication citation) for an industry or federal government standard.

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(iii)	<p>The Health IT developer submits documentation outlining the user-centered design (UCD) process used for each of the UCD Required Criteria (specified in (g)(3)(i)) submitted for testing that includes the following:</p> <ul style="list-style-type: none"> • Where one of the industry or federal government standards is used: <ul style="list-style-type: none"> ○ Name ○ Description ○ Citation (ULR and/or publication citation) • Where an industry or federal government standard is NOT used: <ul style="list-style-type: none"> ○ Process(es) Name ○ Outline of the process ○ Short description of the process(es) ○ Explanation of the reason(s) why use of any of the existing UCD standards was impractical. 	<p>The tester verifies user-centered design (UCD) process(es) have been documented for each of the UCD Required Criteria either by:</p> <ul style="list-style-type: none"> • The name, description, and citation (URL and/or publication citation) reference of the UCD industry standard (e.g. ISO 9241-210, ISO 13407, ISO 16982, ISO/IEC 62366, and NISTIR 7741); OR • The name, outline and short description of the process(es) used, and rationale for not using a UCD industry or federal standard is provided for non-industry standard UCD process(es).

(iv) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

- (A) Name and product version; date and location of the test; test environment; description of the intended users; and total number of participants;
- (B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;
- (C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;
- (D) The specific metrics captured during the testing of each user tasked performed in (g)(3)(iv)(C) of this section, which must include: task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy), or an alternative acceptable user satisfaction measure;
- (E) Test results for each task using the metrics identified above in paragraph (g)(3)(iv)(D) of this section; and
- (F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

Standard(s): [NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing](#)

Criteria ¶	System Under Test	Test Lab Verification
(iv)	<p>The Health IT developer conducts summative usability testing and provides the required documentation for each of the UCD Required Criteria (specified in (g)(3)(i)) submitted for summative usability testing using:</p> <ul style="list-style-type: none"> • The NISTIR 7742 (Customized Common Industry Format (CIF)Template for Electronic Health Record Usability Testing) content report for usability test report(s) that address the application of the documented and referenced UCD process(es) <p>The Health IT developer may provide a NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing content report in any format, provided that the necessary information is included, and documentation may combine the results for summative usability test scenarios which incorporate more than one capability technology</p> <p>The Health IT developer may optionally provide additional information regarding summative usability testing on earlier versions or releases of the product or additional critical use risks that exceed minimum requirements (per NISTIR 7804 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records (EUP),).</p>	<p>The tester verifies the existence and adequacy of the test report(s) for each UCD Required Criteria (specified in Section (g)(3)(i)) submitted for summative usability testing. At a minimum, testing results for the information/sections listed above must be present.</p> <p>The tester verifies that the report(s) conform to the information requirements specified in NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing.</p> <p>The tester verifies that the name and version of the product are the final version (release) of the product for which the Health IT developer seeks certification.</p>
(iv)(A)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <ul style="list-style-type: none"> • Date and location of the test • Test environment • Description of the intended users • Total number of participants 	

Criteria ¶	System Under Test	Test Lab Verification
(iv)(B)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <ul style="list-style-type: none"> • Description of participants (Gender, Age, Education, Occupation/role, Professional experience, Computer experience, Product experience) 	<p>The tester verifies 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.</p>
(iv)(C)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <ul style="list-style-type: none"> • Description of the user tasks (task scenarios) that were tested and association of each task to corresponding certification criteria 	<p>The tester verifies 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”).</p>
(iv)(D)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <ul style="list-style-type: none"> • The specific metrics captured during the summative testing of each user tasked performed in (g)(3)(iv)(C) of this section (Task Success (%), Task Failures (%), Task Standard Deviations (%), Task Performance Time, User Satisfaction Rating (Scale with 1 as very difficult and 5 as very easy)) 	<p>The tester verifies that the specified metrics are captured in the report.</p>
(iv)(E)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <ul style="list-style-type: none"> • Test results for each task using metrics listed above 	<p>The tester verifies that test results are provided for each task using the specified metrics.</p>

Criteria ¶	System Under Test	Test Lab Verification
(iv)(F)	<p>The summative usability testing report includes NISTIR 7742 information/sections:</p> <p>Results and data analysis narrative (Major test finding, Effectiveness, Efficiency, Satisfaction, Areas for improvement). Measures of satisfaction may include task-based satisfaction measures, post-session satisfaction measures and other industry-standard or literature-recognized satisfaction measures (e.g. the Single Ease-of-use Question, System Usability Scale, Software Usability Measurement Inventory, etc.).</p>	<ol style="list-style-type: none"> 1. The tester verifies that all major test findings and the identified area(s) of improvements are reported. 2. The tester verifies how effectiveness and efficiency were evaluated (NIST IR 7742 3.9 “Usability Metrics”). 3. The tester verifies that test results provided an analysis of the use, tested performance and error rates in order to identify risk prone errors -- with a potential likelihood of occurrence and adverse consequences (NISTIR7742. results). 4. The tester verifies that the following NISTIR 7742 measures of effectiveness, efficiency and satisfaction were collected for each participant: <ul style="list-style-type: none"> • Number of tasks successfully completed within the allotted time without assistance; • Time to complete the tasks; • Number and types of errors; • Path deviations; • Participant’s verbalizations; and • Participant’s satisfaction ratings of the system.

(v) Submit test scenarios used in summative usability testing.

Standards: None, but reference to recommended standard: [NISTIR 7804-1 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety-Enhanced Usability Guidelines for Standardization](#)

Criteria ¶	System Under Test	Test Lab Verification
(v)	<p>The Health IT developer supplies the test scenarios used for the summative usability testing conducted on each of the UCD Required Criteria (specified in Section (i)) submitted for testing so that readers of the Summative Test findings can examine the effectiveness of protections against patient harm for critical use risk areas.</p> <p>In accordance with NISTIR 7804 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records (EUP) (page 8) it is recommended that the test scenarios be based upon an analysis of critical use risks for patient safety, which can be mitigated or eliminated by improvements to the user interface design. In support of this recommendation, the Health IT developer conducts a pre-emptive risk assessment, a post hoc discussion of the quality and quantity of risk due to error, and includes a report of expected remediation.</p> <p>The test scenarios used in the summative testing should reflect prioritized use cases based upon a risk analysis. It is recommended that the vendor follow the EUP protocol and NIST use cases, to ensure consistency, as this should improve safety-related usability outcomes. If the developer uses the NIST use cases, they will not need to perform the prioritization.</p> <p>It is recommended that where the test scenarios used for summative usability testing do not use NIST use cases to validate safety related usability and that do not to perform risk analysis from the EHR Usability Protocol (EUP), the Health IT developer also supplies a short explanation of why these are not used.</p>	<ol style="list-style-type: none"> 1. The tester verifies the existence of the report, containing at a minimum, test scenarios to cover all of the UCD Required Criteria (specified in Section (i)) submitted for summative usability testing. 2. The tester verifies that the test scenarios are prioritized in accordance with the risk associated with user errors (NIST IR 7742 3.3 "Tasks"). The developer can refer to the standard tests. If choose to use the tests. 3. The tester verifies how effectiveness and efficiency were evaluated (NISTIR 77423.9 "Usability Metrics").

Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 31, 2015
1.1	Released for Comment - FR	October 29,2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).