

§170.315(g)(3) Safety-enhanced design

2015 Edition Test Procedure

Version 1.1 Updated on 07-25-2016

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016
1.1	Added reference to the SED CHPL reference document at the beginning.	07-25-2016

Regulation Text

Regulation Text

§170.315 (g)(3) *Safety-enhanced design*—

- (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.
- (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.
- (iii) One of the following must be submitted on the user-centered design processed 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.
- (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 task 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.

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

Standard(s) Referenced

Paragraph (g)(3)(iv)

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

Additional Resources

[NISTIR 7804](#)

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.

Testing components



The ONC Health IT Certification Program requires that a limited set of quantitative data elements related to the safety-enhanced design (SED) testing be reported and displayed to the public via the new Certified Health Product List. Reporting instructions to the CHPL, including data elements and their definitions, formats, and allowable values, may be found at [CHPL SED Guide](#).

Paragraph (g)(3)(i)

System Under Test

The health IT developer submits documentation demonstrating that user-centered design (UCD) process(es) were applied to all of the safety-enhanced design referenced certification criterion for which these corresponding capabilities are being presented for certification.

Test Lab Verification

The tester verifies that the submitted documentation outlines user-centered design (UCD) process(es) to each capability for any of the following safety-enhanced design criterion submitted for certification:

- § 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

Paragraph (g)(3)(ii)**System Under Test**

The Health IT Module must have conducted summative usability testing with a minimum of 10 test participants for each safety-enhanced design criterion capabilities for which certification is being sought.

Test Lab Verification

The tester verifies that at least 10 test participants, representative of the intended user population, participated in summative usability testing for each safety-enhanced design criterion and the associated capabilities.

Paragraph (g)(3)(iii)**System Under Test**

The health IT developer submits documentation outlining the user-centered design (UCD) process used for each of the safety-enhanced design criteria (specified in (g)(3)(i)) submitted for testing that includes one of the following:

1. Where one of the industry or federal government standards is used:
 - Name;
 - Description;
 - Citation (URL and/or publication citation).

OR

2. Where an industry or federal government standard is NOT used:
 - Name & citation (URL and/or publication citation) of the industry standard Process(es) that formed basis of the “custom” process;
 - 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.

Test Lab Verification

The tester verifies user-centered design (UCD) process(es) have been documented for each of the safety-enhanced design either by:

1. 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

2. The name and citation (URL and/or publication citation) of the industry standard process(es) that formed the basis of the “custom” process, outline of the process, short description of the process(es) used, and explanation of the reason(s) why use of any of the existing UCD industry or federal government standards was impractical.

Paragraph (g)(3)(iv)

System Under Test

The health IT developer must have conducted summative usability testing and provides the required documentation for each of the safety-enhanced design criteria (specified in (g)(3)(i)) submitted for summative usability testing, using:

- 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)

The health IT developer may provide the required information/sections from NISTIR 7742 in any format, provided that the required information is included.

Test Lab Verification

The tester verifies the existence and adequacy of the summative usability test report(s) for each safety-enhanced design criterion (specified in (g)(3)(i)) capability being presented for testing/certification. The tester verifies that the report(s) conform(s) to the content and completion requirements of the required information/sections of NISTIR 7742. 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 is seeking certification.

Paragraph (g)(3)(iv)(A)**System Under Test**

The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:

- Date and location of the test
- Test environment
- Description of the intended users
- Total number of participants

Test Lab Verification

The tester verifies the existence and adequacy of the required NISTIR 7742 information/sections.

Paragraph (g)(3)(iv)(B)**System Under Test**

The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:

- Description of participants (i.e., Sex, Age, Education, Occupation/role, Professional experience, Computer experience, Product experience)

Test Lab Verification

The tester verifies 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 to ensure participant characteristics reflect the audience of current and future users.

Paragraph (g)(3)(iv)(C)**System Under Test**

1. The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:
 - Description of the user tasks (task scenarios) that were tested and association of each task to corresponding certification criteria

Test Lab Verification

1. The tester verifies that the user tasks employed in the study are prioritized in accordance with the risk associated with user errors (NISTIR 7742 3.3 “Tasks”).
2. The tester verifies that the test scenarios included in the NISTIR 7742 content report for each of the UCD Required Criteria are inclusive of the tasks or functionality the health IT developer provided for testing to the certification criterion.

Paragraph (g)(3)(iv)(D)

System Under Test

The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:

- The specific metrics captured during the summative testing of each user task performed in (g)(3)(iv)(C) of this section (Task Success (%), Task Failures (%), Task Standard Deviations of Task Performance Time (%), Task Performance Time, User Satisfaction Rating (Scale with 1 as very difficult and 5 as very easy) or an alternative acceptable user satisfaction measure.)

Test Lab Verification

The tester verifies that the specified metrics are captured in the report.

Paragraph (g)(3)(iv)(E)

System Under Test

The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:

- Test results for each task using metrics listed above in (g)(3)(iv)(D).

Test Lab Verification

The tester verifies that test results are provided for each task using the specified metrics in (g)(3)(iv)(D).

Paragraph (g)(3)(iv)(F)**System Under Test**

1. The summative usability testing report includes NISTIR 7742 Customized Common Industry Format (CIF) Template for Electronic Health Record Usability Testing information/sections:
 - Results and data analysis narrative (i.e., 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.).

Test Lab Verification

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 (NISTIR 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 (NISTIR 7742. results).
4. The tester verifies that the following NISTIR 7742 measures of effectiveness, efficiency, and satisfaction were collected for each participant:
 - 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.

Paragraph (g)(3)(v)**System Under Test**

1. The health IT developer supplies the test scenarios used for the summative usability testing conducted on each of the safety-enhanced design criteria (specified in (g)(3)(i)) submitted for testing. The test scenarios used in the summative testing should reflect prioritized use cases based upon a risk analysis.

Test Lab Verification

1. The tester verifies the existence of the test scenarios used for the summative usability testing, containing at a minimum, test scenarios to cover all of the safety-enhanced design criteria and associated capabilities (specified in (g)(3)(i)) submitted for testing/certification.
2. The tester shall verify that the name and version of the product are the final version (release) of the product for which certification is being sought.

Content last reviewed on September 24, 2018