# Test Criteria: 170.315.g.3 – Safety-Enhanced Design

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

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(g)(3)_Safety-Enhanced_Desig)
* [Test Procedures](#_1.1_User-centered_Design)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing_2)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC_1)
* [Appendix C: User-Centered Design Process Letter Template](#_Appendix_C:_User-Centered)
* [Appendix D: Usability Veracity Attestation Letter Template](#_Appendix_D:_Usability)

### Version of ONC Test Method

1.1

### Scope of Proctoring Sheet

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

# Robustness and Reliability Requirement

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

# Test Data and Tools

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| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**   * User-Centered Design process(s) must be applied during the design and development of the capabilities/associated criteria. * Two weeks prior to scheduled test date, submit: * Usability Test Report (NISTIR 7742); * Letter identifying User-Centered Design Process; * Authenticity and veracity letter signed by company representative; and * “Safety-Enhanced Design Checklist” (provided by Drummond Group and available for download in Zendesk) | |
| **Test Data:**   * Not applicable. | |
| **Test Tools:**   * Not applicable. | |

# Demonstrate Standards Support

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| Instructions: User-center design process(s) must be applied during development and summative testing to each capability that is associated with this certification criterion and for which certification is sought. Health IT Developer must document and submit sections from NISTIR 7742 for each capability which user-centered design processes were applied. | |

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| **User-Centered Design (UCD) Process** | | |
|  | ISO 9241-11 | Guidance on Usability |
|  | ISO 13407 | 1999: Human-Centered Design for Interactive Systems |
|  | ISO 16982 | Usability Methods Supporting Human-centered Design |
|  | ISO/IEC 62366 | Application of Usability Engineering to Medical Devices |
|  | ISO 9241-210 | 2010: Human-centered Design for Interactive Systems |
|  | NISTIR 7741 | NIST Guide to Processes Approach for Improving the Usability of Electronic Health Records |
| **Summative Usability Testing** | | |
|  | NISTIR 7742 | [NISTIR 7742: Customized Common Industry Format Template for Electronic Health Record Usability Testing](http://www.nist.gov/customcf/get_pdf.cfm?pub_id=907312) |
|  | NISTIR 7804-1 | RECOMMENDED: Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records: Empirically Based Use Cases for Validating Safety-Enhanced Usability Guidelines for Standardization |

# 170.315(g)(3) Safety-Enhanced Design

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** User-centered design (UCD) processes must be applied to each capability implemented by the health IT module that is specified in the following certification criteria:   * 170.315(a)(1) 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 * 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 | |
| **Expected Test Result:**   * UCD process(s), based on industry or federal standard, must be applied during development and summative testing for each of the capabilities above that health IT module is seeking certification for. * Two weeks prior to scheduled test date, health IT developer submits: * Report based on NISTIR 7742 is submitted for each capability to which UCD was applied * Letter attesting to which UCD process(s) was applied * Signed letter attesting to veracity and authenticity of UCD testing * DG-supplied “Safety-Enhanced Design Checklist” | |
| **Points to Remember:**   * SED “User Tasks” provided in [Appendix A](#_Appendix_A:_Testing_2) below. * Minimum of 10 test participants (representative of the intended user population) must be used for the testing of each capability listed above. * Product name and version are the final version (release) of the product for which the Health IT developer seeks certification. * All UCD documentation submitted will be made public on the ONC CHPL website so trade secrets or proprietary information should not be disclosed. * Drummond Group EHR Test Lab requires a two week window for reviewing submitted usability test reports. Usability test reports submitted within the two week window prior to the scheduled test data will delay the submission of the test results to the ONC-ACB certification body. * 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 (CHPL). Reporting instructions to the CHPL, including data elements and their definitions, formats, and allowable values, may be found in the [CHPL SED Guide](https://www.healthit.gov/sites/default/files/CHPL_SED_Guide_v5.pdf). | |

**Test Procedures**

### 1.1 User-centered Design Process Letter

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|  | UCD processes must be documented in a letter which is signed and on company letterhead. For each of the capabilities listed above that are presented for certification, one of the following methods should be used *(see* [*Appendix C*](#_Appendix_C:_User-Centered) *for letter template):*   1. ***Industry Standard*:** Name, description, and citation (URL and/or publication citation) of an industry or federal government standard (*see* [*Appendix A*](#_Appendix_A:_Testing_1) *for a list of standards*). 2. ***“Custom” Standard*:** Name and citation (URL and/or publication citation) of the industry standard process(s) that formed the basis of the “custom” process, provide an outline of the process(s), short description of the process(s) used, and an explanation of the reason(s) why use of any of the existing UCD standards was impractical. |

### 1.2 User-centered Design Report – NISTIR 7742

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|  | Sections from NISTIR 7742 must be submitted for each of the capabilities listed above that are presented for certification. Health IT Developer provides the completed “**Drummond Group Safety-Enhanced Design Checklist**” identifying and verifying completion of usability test report including:   1. Name and product version; date and location of the test; test environment; description of the intended users; and total number of participants 2. Description of participants. Demographic characteristics of the user pool must meet specifications of the particular requirement (NIST IR 7742 3.1 “Participants”). These should include:  * Sex * Age * Education * Occupation/role * Professional experience * Computer experience, and; * Product experience  1. Description of the user tasks (**see list of required user tasks in** Appendix A) that were tested and association of each task to corresponding certification criteria. User tasks must be prioritized in accordance with the risk associated with user errors (NIST IR 7742 3.3 “Tasks”) 2. Specific metrics captured during the summative testing of each user task performed for each capability listed above. These 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  1. Test results for each task using the (5) specific metrics listed above 2. Results and data analysis narrative including:  * Major test findings * Areas for improvement * Effectiveness (NIST IR 7742 3.9 “Usability Metrics”) * Efficiency (NIST IR 7742 3.9 “Usability Metrics”) * 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 (NIST IR 7742 results) * Measures of effectiveness, efficiency, and satisfaction collected for each participant including: * Number of tasks successfully completed within the allotted time without assistance; * Time to complete tasks; * Number and types of errors; * Path deviations; * Participant’s verbalizations; and * Participant’s satisfaction ratings of the system |
|  | Health IT developer supplies test scenarios used for summative usability testing, containing at a minimum, test scenarios to cover all of the safety-enhanced design criteria and associated capabilities. |
|  | OPTIONAL: Health IT developer may 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)). |

### 1.3 User-centered Design Veracity and Authenticity Letter

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|  | A signed letter from a representative of the Health IT developer attesting to the veracity and authenticity of the usability report and usability design standard/process *(see* [*Appendix D*](#_Appendix_D:_Usability) *for letter template).* |

### 1.4 Safety-Enhanced Designed Checklist

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|  | Health IT developer completes the DG-supplied “**Drummond Group Safety-Enhanced Design Checklist**” spreadsheet. *Spreadsheet can be downloaded from the Zendesk portal or ask your Test Proctor for a copy.* |

### 1.5 Proctor Review and Verification

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|  | Proctor verifies the name and version of the product are the final version (release) of the product for which certification is being sought. |
|  | Proctor verifies the required four documents are submitted and complete:   * User-Centered Design Process Letter * User-Centered Design Report (NISTIR 7742) * Signed letter attesting authenticity and veracity * “Drummond Group Safety-Enhanced Design Checklist” spreadsheet |

<ATTACH or INSERT LINK TO DOCUMENTATION>

# Appendix A: Testing Guide

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

Rev 15-Sept-2017 Additions

**Required User Tasks for (g.3) SED Testing**:

* (a.1) CPOE –Meds
  + Record medication via CPOE
  + Change medication via CPOE
  + Display changed CPOE medication order
* (a.2) CPOE – Labs
  + Record Lab order via CPOE
  + Change Lab order via CPOE
  + Display changed CPOE Lab order
* (a.3) CPOE – Diagnostic Imaging
  + Record Imaging order via CPOE
  + Change Imaging order via CPOE
  + Display changed CPOE Imaging order
* (a.4) Drug-drug, drug-allergy interaction checks for CPOE
  + Using CPOE, trigger a drug-drug interaction by entering a new medication order
  + Using CPOE, trigger a drug-allergy interaction by entering a new medication order
  + Adjust the severity level of a displayed drug-drug interaction
* (a.5) Demographics
  + Record a patient’s preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
  + Change the patient’s preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
  + Display the patient’s changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity, preliminary cause of death (inpatient only), and preliminary date of death (inpatient only)
* (a.6) Problem List
  + Record a problem to the problem list
  + Change a problem on the problem list
  + Display the active problem list
  + Display the historical problem list
* (a.7) Medication list
  + Record a medication to the medication list
  + Change a medication on the medication list
  + Display the active medication list
  + Display the historical medication list
* (a.8) Medication allergy list
  + Record a medication allergy
  + Change a medication allergy
  + Display the active medication allergy list
  + Display the historical medication allergy list
* (a.9) Clinical Decision support
  + Add a CDS intervention and/or reference resource for each of the required elements
    - Problem list
    - Medication list
    - Medication Allergy List
    - At least one Demographic
    - Laboratory Test
    - Vital Signs
    - And a combination of at least 2 of the elements listed above
  + Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements
  + View the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics
  + Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary
  + Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date
* (a.14) Implantable Device List
  + Record UDI
  + Change UDI Status
  + Access UDI, device description, identifiers, and attributes
* (b.2) Clinical Information Reconciliation and Incorporation
  + Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient’s record
  + Generate a new CCDA with reconciled data
* (b.3) e-Prescribing
  + Create new prescription
  + Change prescription (dosage or duration)
  + Cancel prescription
  + Refill prescription
  + Receive fill status notification
  + Request and receive medication history information

Rev 01-Mar-2016 Additions

* Refer to the Drummond Group “Safety-Enhanced Design Checklist” spreadsheet for a list of the basic capabilities to test in a usability report per associated criteria.
* The ISO definition of usability is “[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 documentation required by this “safety-enhanced design” criterion will become a component of the publicly available testing results on which a certification is based. Trade secrets or proprietary information are not expected to be included as part of these reports.
* ONC-Authorized Certification Bodies (ONC-ACBs) should be notified when changes to user-interface aspects occur. ONC-ACBs are required to obtain a record of all updates to certified Health IT Modules affecting the capabilities in certification criteria to which this “safety-enhanced design” criterion applies on a calendar quarterly basis.
* Examples of industry standard resources that technology developers may choose to review in order to select a UCD:
  + - ISO 9241-11
    - ISO 13407
    - ISO 16982
    - ISO/IEC 62366
    - ISO 9241-210
    - NISTIR 7741
* Any UCD process selected by a technology developer is appropriate, and it need not be listed in the examples we provided in order to be acceptable.
* In the event that a 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.
* 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.)

# Appendix B: ONC Criteria and Standards

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

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

1. 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) through (3) of this section.
2. *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.
3. 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.

# Appendix C: User-Centered Design Process Template

*This appendix contains a template for submitting usability-design standard/process attestation. Attestation letter should be returned on company letterhead addressing the required functionality signed by company representative and scanned as a PDF document.*

[Name of Organization]

[HIT System Product Name-Version]

[Name of Authorized Senior Company Representative]

[Title of Company Representative]

[Company Contact Information]

For public release:

[Name of Organization] used the following usability design [industry standard / process] in developing and designing their health IT module, [HIT System Product Name]: [usability design standard or process].

*[Identify the industry standard(s) used, include name(s), description(s) and citation (URL and/or publication citation).]*

*[If using a customized processes used, include industry standard name(s), description(s) and citation (URL and/or publication citation) that formed the basis of the “custom” process, provide an outline of the process(s), short description of the process(s) used, and an explanation of the reason(s) why use of any of the existing UCD standards was impractical.]*

[Signature]

[Signature Block of Authorized Senior Company Representative]

[Date signed]

# Appendix D: Usability Veracity Attestation

*This appendix contains a template for submitting usability-design standard/process attestation. Attestation letter should be returned on company letterhead addressing the required functionality signed by company representative and scanned as a PDF document.*

[Name of Organization]

[HIT System Product Name-Version]

[Name of Authorized Senior Company Representative]

[Title of Company Representative]

[Company Contact Information]

For public release:

[Name of Organization] attests that the usability standard/process and usability report submitted for the certification of [HIT System Product Name] is accurate and complete per the requirements of the ONC criterion 170.315(g)(3).

[Signature]

[Signature Block of Authorized Senior Company Representative]

[Date signed]

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 15-Sept-2017 | Added list of SED User Tasks. |
| 01-Aug-2016 | Added reference to “CHPL SED Guide” under “Points to Remember”. |
| 01-Apr-2016 | Updated Test Data section and added references to “Safety-Enhanced Design Checklist”. Clarified and listed all required UCD documentation. Added Appendix C for attestation templates. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

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

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