The Office of the National Coordinator for Health Information Technology

Certified Health IT Product List (CHPL)

SAFETY ENHANCED DESIGN (SED) / USABILITY TEST RESULTS

CHPL Reporting Instructions

Version Number	Description of Change	Date
1.0	Final SED Guidance	July 21, 2016
1.1	Updated 2015 Edition Certification Companion Guide: Safety-enhanced design – 45 CFR 170.315(g)(3) Removed the word 'Mean' from Task Time Deviation – Mean Observed Seconds and Task Time Deviation – Mean Optimal Seconds	February 8, 2019
1.2	Removed reference to criteria § 170.315(a)(6), (a)(7), and (a)(8), which were removed in ONC's 21st Century Cures Act Final Rule.	January 8, 2020

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Overview

The ONC Health IT Certification Program requires that information related to the safety-enhanced design (SED) criterion (§ 170.315 (g)(3)), user-centered design, and summative usability testing for all applicable 2015 certified health IT modules be uploaded and displayed to the public via the Certified Health IT Product List (CHPL). The SED criterion is required for health IT modules certified to the following certification criteria: § 170.315(a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(9), (a)(14), (b)(2), (b)(3). For more information, please refer to the 2015 Edition Certification Companion Guide: Safety-enhanced design – 45 CFR 170.315(g)(3). Data elements to be reported can be found in the NISTIR 7742: Customized Common Industry Format Template for Electronic Health Record Usability Testing. In order to present information pertaining to a limited set of test results in a granular, standardized, and parse-able manner, the ONC Health IT Certification Program requests that some of this data is reported with pre-defined standard formats and allowable values. This document provides definitions for each of these elements and outlines the allowable values and formats for each field.

Please note that the full SED requirements and summative usability report will still be required to be posted/hyperlinked in the CHPL, as only a limited set of data will be discretely reported on the CHPL.

Furthermore for those developers that have already conducted the required summative usability testing, this document provides additional guidance on how to translate values from existing test results into values allowable for the CHPL input. In these limited instances, ONC and NIST are happy to work with the ONC-ACB and developer as needed.

SED / Usability Fields

GENERAL

SED Report Hyperlink

Field Name	SED / Usability Report Hyperlink
Description of Field	Hyperlink to FULL Usability Test Report meeting all the SED requirements
Value Type	<url>
Allowable Values/Formats	Fully qualified URL which is reachable via web browser validation and verification.
Character Limit	255
Notes and Examples	For example, an allowable value would be http://www.sedreport.com

Description of the Intended Users

Field Name	Description of the Intended Users
Description of Field	For SED testing, a description of the intended users
Value Type	<string>
Allowable Values/Formats	No restrictions on formatting or values are in place
Notes and Examples	For example, “Ambulatory physicians and nurses”

Date SED Testing was Concluded

Field Name	Date SED Testing was Concluded
Description of Field	The date on which all SED/Usability testing was concluded for all the related certification criteria for the certified health IT product
Value Type	<date>
Allowable Values/Formats	The date must be in the format YYYYMMDD
Notes and Examples	• For example, if SED testing was concluded on July 5, 2016, the corresponding CHPL input would be 20160705 • Please note per the NISTIR 7742, the full report should list all dates for which summative usability testing was conducted

PARTICIPANT-RELATED FIELDS

Participant Gender

Field Name	Participant Gender
Description of Field	Self-reported gender of the corresponding SED participant
Value Type	<string>
Allowable Values/Formats	The following are allowable values for the 'Participant Gender' field: • Male • Female • Unknown
Notes and Examples	N/A

Participant Age

Field Name	Participant Age
Description of Field	The age range for the corresponding SED participant
Value Type	<string>
Allowable Values/Formats	The following are allowable values for the 'Participant Age' field: • 0-9 • 10-19 • 20-29 • 30-39 • 40-49 • 50-59 • 60-69 • 70-79 • 80-89 • 90-99 • 100+
Notes and Examples	N/A

Participant Education

Field Name	Participant Education
Description of Field	Highest education level attained by corresponding SED participant
Value Type	<string>
Allowable Values/Formats	The following are allowable values for the 'Participant Education' field: • No high school degree • High school graduate, diploma or the equivalent (for example: GED) • Some college credit, no degree • Trade/technical/vocational training • Associate degree • Bachelor's degree • Master's degree • Doctorate degree (e.g., MD, DNP, DMD, PhD)
Notes and Examples	N/A

Participant Occupation/Role

Field Name	Participant Occupation/Role
Description of Field	Occupation or role of corresponding SED participant
Value Type	<string>
Allowable Values/Formats	No restrictions on formatting or values are in place
Notes and Examples	Sample values include: Clinical Assistant, Physician's Assistant, MD, RN, Triage Coordinator

Participant Professional Experience

Field Name	Participant Professional Experience
Description of Field	Professional experience of the corresponding SED participant, in **number of months**
Value Type	<integer>
Allowable Values/Formats	Only positive integers (i.e. no decimals) are allowed
Notes and Examples	For a participant with 2 years and 5 months of professional experience, the corresponding CHPL input would be '29' (i.e. 29 months)

Participant Computer Experience

Field Name	Participant Computer Experience
Description of Field	The corresponding SED participant's experience with computers (in general), in **number of months**
Value Type	<integer>
Allowable Values/Formats	Only positive integers (i.e. no decimals) are allowed
Notes	For a participant with 10 years and 6 months of computer experience, the corresponding CHPL input would be '126' (i.e. 126 months)

Participant Product Experience

Field Name	Participant Product Experience
Description of Field	The corresponding SED participant's experience with the certified product / health IT capabilities (SED criterion) being tested, in **number of months**
Value Type	<integer>
Allowable Values/Formats	Only positive integers (i.e. no decimals) are allowed
Notes and Examples	For a participant with 1 year and 6 months of experience with the given certified product, the corresponding CHPL input would be '18' (i.e. 18 months)

Participant Assistive Technology Needs

Field Name	Participant Assistive Technology Needs
Description of Field	Any assistive technology needs as identified by the corresponding SED participant
Value Type	<string>
Allowable Values/Formats	No restrictions on formatting or values are in place
Notes and Examples	Example values include: "Yes, used VoiceOver" or "No"

TASK-RELATED FIELDS

Task Description

Field Name	Task Description
Description of Field	Brief description of task performed during SED testing
Value Type	<string>
Allowable Values/Formats	No restrictions on formatting or values are in place
Notes and Examples	Example: “Update the problem list with a new problem based on physical exam results” Example: “Ordering a follow-up test or diagnostic based on a physical finding or test result”

Task Success – Mean (%)

Field Name	Task Success – Mean (%)
Description of Field	The mean, as a percentage, for the task success rate of the corresponding SED task
Value Type	<percentage>
Allowable	Only positive decimal numbers are allowed

Field Name	Task Success – Mean (%)
Allowable Values/Formats	Only positive decimal numbers are allowed
Notes and Examples	Decimals are allowed. For example, an allowable CHPL input would be 35.7

Task Success – Standard Deviation (%)

Field Name	Task Success – Standard Deviation (%)
Description of Field	The standard deviation, as a percentage, for the task success rate of the corresponding SED task
Value Type	<percentage>
Allowable Values/Formats	Only positive decimal numbers are allowed
Notes and Examples	Decimals are allowed. For example, an allowable CHPL input would be 9.8

Task Path Deviation – Observed

Field Name	Task Path Deviation – Observed #
Description of Field	Observed number of steps taken for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Path Deviation – Optimal

Field Name	Task Path Deviation – Optimal #
Description of Field	Optimal number of steps for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Time – Mean (seconds)

Field Name	Task Time – Mean (seconds)
Description of Field	Average time, in seconds, of completion for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Time – Standard Deviation (seconds)

Field Name	Task Time – Standard Deviation (seconds)
Description of Field	Standard deviation, in seconds, for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Time Deviation – Observed Seconds

Field Name	Task Time Deviation – Observed Seconds
Description of Field	Observed task time deviation, in seconds, taken for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Time Deviation – Optimal Seconds

Field Name	Task Time Deviation – Optimal Seconds
Description of Field	Optimal task time deviation, in seconds, for the corresponding SED task
Value Type	<integer>
Allowable Values/Formats	Only positive integers are allowed
Character Limit	Value must be an integer between 0 to +2147483647
Notes and Examples	Decimals are **not** allowed. If a decimal is given, round up from >= 0.5 and round down from <0.5. For example, an allowable CHPL input would be 10

Task Errors – Mean (%)

Field Name	Task Errors – Mean (%)
Description of Field	The mean, as a percentage, for the task error rate for the corresponding SED task
Value Type	<percentage>
Allowable Values/Formats	Only positive decimal numbers are allowed
Notes and Examples	Decimals are allowed. For example, an allowable CHPL input would be 9.8

Task Errors – Standard Deviation (%)

Field Name	Task Errors – Standard Deviation (%)
Description of Field	The standard deviation, as a percentage, for the task error rate for the corresponding SED task
Value Type	<percentage>
Allowable Values/Formats	Only positive decimal numbers are allowed
Notes and Examples	Decimals are allowed. For example, an allowable CHPL input would be 9.8

Task Rating – Scale Type

Field Name	Task Rating – Scale Type
Description of Field	The type of scale that was used to rate the usability of the corresponding SED task
Value Type	<string>
Allowable Values/Formats	System Usability Scale is preferred. Likert Scale is also accepted
Notes and Examples	For the System Usability Scale, a scale of 1-100 should be used. If a Likert Scale is used, a scale of 1-5 should be used, with 5 being the easiest and 1 being the most difficult

Task Rating

Field Name	Task Rating
Description of Field	Mean usability rating of the corresponding SED task, based on the specified scale type
Value Type	<float>
Allowable Values/Formats	If the scale type is System Usability Scale, only positive integers between 1- 100 are allowed. If the scale type is the Likert scale, positive decimal numbers are allowed
Notes and Examples	Example: System Usability Scale: 88 Example: Likert Scale: 3.8

Task Rating – Standard Deviation

Field Name	Task Rating – Standard Deviation
Description of Field	Standard deviation of the mean usability rating of the corresponding SED task, based on the specified scale type
Value Type	<float>
Allowable Values/Formats	Only positive decimal numbers are allowed
Notes and Examples	Example: 4.52

GUIDANCE ON CONVERTING OTHER FIELDS

For those developers that have already conducted the required summative usability testing, this document provides additional guidance on how to translate values from existing test results into values allowable for CHPL input. In these limited instances, ONC and NIST are happy to work with the ONC-ACB and developer as needed.

Participant Age

Scenario	Conversion Guidance	Example Input	Example CHPL Reporting Value
Age is given as an integer	If a participant's age is given as an integer, please map the integer to the corresponding allowable age range	23	20-29
Age is given as a range that does not match CHPL discrete reporting/normalized values	Take the integer midpoint for the given range (rounding up from >= 0.5 and rounding down from <0.5) and map the resulting integer to the corresponding allowable age range	23-39 *The midpoint of this range is 31	30-39

Participant Education

Example Input	Corresponding CHPL Reporting Value
Other (explain)	No high school degree
High school graduate/GED	High school graduate, diploma or the equivalent (for example: GED)
Some college	Some college credit, no degree
Other (explain)	Trade/technical/vocational training
Other (explain)	Associate degree
College graduate (RN, BSN)	Bachelor's degree
Postgraduate (MD/PhD)	Master's degree
Other (explain)	Doctorate degree (e.g., MD, DNP, DMD, PhD)

Participant Experience (e.g. Computer Experience, Professional Experience, Product Experience)

Scenario	Conversion Guidance	Example Input	Example CHPL Reporting Value
Experience is given in number of years	If a participant's experience is given in terms of years, please multiply the number of years by 12 and add any additional number of months, as necessary to get the participant's experience in months	10 years 5 months	125
Experience is given as an approximate value	Report the approximate value given, and convert to months by multiplying by 12, as necessary	Approximately 20 years	240
Experience is given as a numerical range	Take the integer midpoint for the given range (rounding up from >= 0.5 and rounding down from <0.5). If the original input was in years, multiply the resulting integer by 12 to get the participant's experience in months	8-11 years *The midpoint of this range is 9.5 so round up to 10.	120
Experience is given as a "greater than" range	Use the first integer that meets the given criteria. If the original input was in years, multiply by 12 to get the participant's experience in months	Greater than 8 years, > 8 years, or 8+ years *Use the integer '8' for the years	96
Experience is given as a "less than" range	Use the first integer that meets the given criteria. If the original input was in years, multiply by 12 to get the participant's experience in months	Less than 8 years or <7 years *Use the integer '7' for the years	84