Accessibility-centered design | HealthIT.gov

§170.315(g)(5) Accessibility-centered design

- Certification Companion Guide (CCG)
- Test Procedure

Updated on 03-11-2024

Regulation Text

Regulation Text

§ 170.315 (g)(5) *Accessibility-centered design—*

For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

1. When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.
2. When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.
3. When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Standard(s) Referenced

None

Certification Dependencies

Design and Performance: This certification criterion was adopted at § 170.315(g)(5), and is required for all developers seeking certification to any certification criteria. When a single accessibility-centered design standard is used, the standard only needs to be identified once.

Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

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Standard(s) Referenced

None

Certification Dependencies

Design and Performance: This certification criterion was adopted at § 170.315(g)(5), and is required for all developers seeking certification to any certification criteria. When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.

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1.0	Initial publication	03-11-2024

This Test Procedure illustrates the test steps required to certify a Health IT Module to this criterion. Please consult the most recent ONC Final Rule on the Certification Regulations page for a detailed description of the certification criterion with which these testing steps are associated. ONC also encourages developers to consult the Certification Companion Guide in tandem with the test procedure as it provides clarifications that may be useful for product development and testing.

Note: The test step order does not necessarily prescribe the order in which the tests should take place.

Testing components

Paragraph (g)(5)(i) Single accessibility-centered design standard (Alternative)

System Under Test

The health IT developer identifies a single accessibility-centered design standard or law used in the development, testing, implementation, and maintenance of capabilities for which certification is being sought.

Test Lab Verification

The tester verifies the health IT developer used one accessibility-centered design for each capability for which the Health IT Module is seeking certification.

Testing must be conducted for one of the Alternatives outlined below to satisfy the requirements for this criteria.

System Under Test	Test Lab Verification
The health IT developer identifies a single accessibility-centered design standard or law used in the development, testing, implementation, and maintenance of capabilities for which certification is being sought.	The tester verifies the health IT developer used one accessibility-centered design for each capability for which the Health IT Module is seeking certification.

Paragraph (g)(5)(ii) Different accessibility-centered design standards (Alternative)

System Under Test

The health IT developer identifies each accessibility-centered design standard or law used in the development, testing, implementation, and maintenance of each capability for which certification is being sought.

Test Lab Verification

The tester verifies the health IT developer used accessibility-centered design for each capability for which the Health IT Module is seeking certification.

System Under Test	Test Lab Verification
The health IT developer identifies each accessibility-centered design standard or law used in the development, testing, implementation, and maintenance of each capability for which certification is being sought.	The tester verifies the health IT developer used accessibility-centered design for each capability for which the Health IT Module is seeking certification.

Paragraph (g)(5)(iii) No accessibility-centered design standard (Alternative)

System Under Test

If no accessibility-centered design standard or law is used in the development, testing, implementation, and maintenance of capabilities for which certification is being sought, the health IT developer indicates that no accessibility-centered design standard or law was used for particular criteria.

Test Lab Verification

The tester verifies if no accessibility-centered design standard or law was applied to all or some capabilities for which certification is sought, that this was indicated.

System Under Test	Test Lab Verification
If no accessibility-centered design standard or law is used in the development, testing, implementation, and maintenance of capabilities for which certification is being sought, the health IT developer indicates that no accessibility-centered design standard or law was used for particular criteria.	The tester verifies if no accessibility-centered design standard or law was applied to all or some capabilities for which certification is sought, that this was indicated.

Updated on 03-11-2024

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For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

1. When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.
2. When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.
3. When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Standard(s) Referenced

None

Certification Dependencies

Design and Performance: This certification criterion was adopted at § 170.315(g)(5), and is required for all developers seeking certification to any certification criteria. When a single accessibility-centered design standard is used, the standard only needs to be identified once.

Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.

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Standard(s) Referenced

None

Certification Dependencies

Design and Performance: This certification criterion was adopted at § 170.315(g)(5), and is required for all developers seeking certification to any certification criteria. When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.

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Certification Companion Guide: Accessibility-centered design

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product certification. The CCG is not a substitute for the requirements outlined in regulation and related ONC final rules. It extracts key portions of ONC final rules' preambles and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the Certification Regulations page for links to all ONC final rules or consult other regulatory references as noted. The CCG is for public use and should not be sold or redistributed.

The below table outlines whether this criterion has additional Maintenance of Certification dependencies, update requirements and/or eligibility for standards updates via SVAP. Review the Certification Dependencies and Required Update Deadline drop-downs above if this table indicates "yes" for any field.

Base EHR Definition	Real World Testing	Insights Condition	SVAP	Requires Updates
Not Included	No	No	No	No

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Technical outcome – This certification criterion requires health IT developers to identify relevant standards or laws; or, alternatively, permits a health IT developer to state that its health IT product presented for certification does not meet any accessibility-centered design standards or any accessibility laws.

Clarifications:

- The option to certify that health IT products do not meet any accessibility design standards or comply with any accessibility laws does not exempt them from their independent obligations under applicable federal civil rights laws that require covered entities to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services. [see also 80 FR 62673]

- The accessibility standards and laws listed below are examples. [see also 80 FR 16862] Because this list is not exhaustive, health IT developers may use accessibility standards not included in this list. However, in all cases the accessibility standard or law, and the standards development organization(s) or government entity recognizing the standard or law must be identified. Additional example accessibility standards and laws will be identified as appropriate. [see also 80 FR 62673]
    - ETSI ES 202 076—Human Factors (HF); User Interfaces; Generic spoken command vocabulary for ICT devices and services;
    - ETSI ETS 300 679—Terminal equipment (TE); Telephony for the hearing impaired; Electrical coupling of telephone sets to hearing aids;
    - ETSI TR 102 068 (2002) Human Factors (HF): Requirements for assistive technology devices in ICT;
    - ETSI TS 102 511 (2007) Human Factors (HF): AT commands for assistive mobile device interfaces;
    - IEEE 802.11IEEE standard for Information Technology; Telecommunications and information: Exchange between systems; local and metropolitan area network; specific requirements—Part 11: Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY) Specification;
    - ISO 13406-1 (1999) Ergonomic requirements for work with visual displays based on flat panels. Part 1—Introduction;
    - ISO 13406-2 (2001) Ergonomic requirements for work with visual displays based on flat panels. Part 2—Ergonomic requirements for flat panel displays;
    - IEC 80416-1 (2001) Basic principles for graphical symbols for use on equipment —Part 1: Creation of symbol originals;
    - ISO 80416-2 (2002) Basic principles for graphical symbols for use on equipment —Part 2: Form and use of arrows;
    - IEC 80416-3 (2002) Basic principles for graphical symbols for use on equipment —Part 3: Guidelines for the application of graphical symbols;
    - ISO 80416-4 (2005) Basic principles for graphical symbols for use on equipment. Part 4—Guidelines for the adaptation of graphical symbols for use on screens and displays;
    - ISO 9241-151 (2008) Ergonomics of human-system interaction—Part 151: Guidance on World Wide Web user interfaces;
    - ISO 9355-1 (1999) Ergonomic requirements for the design of displays and control actuators. Part 1: Human interactions with displays and control actuators;
    - ISO 9355-2 (1999) Ergonomic requirements for the design of displays and control actuators. Part 2: Displays;
    - ISO 9999 (2007) Assistive products for persons with disability—Classification and terminology;
    - ISO/CD 24500 Guidelines for all people, including elderly persons and persons with disabilities—Auditory signals on consumer products;
    - ISO/IEC 15411 (1999) Information technology—Segmented keyboard layouts;

- ISO/IEC 15412 (1999) Information technology—Portable keyboard layouts;
- ISO/IEC 24755 (2007) Information technology—Screen icons and symbols for personal mobile communication devices;
- ISO/IEC CD 24786-1 Information Technology—User interfaces—Accessible user interface for accessibility setting on information devices—Part 1: General and methods to start;
- ISO/IEC TR 15440 (2005) Information Technology—Future keyboards and other associated input devices and related entry methods;
- ISO/IEC TR 19765 (2007) Information technology—Survey of icons and symbols that provide access to functions and facilities to improve the use of IT products by the elderly and persons with disabilities;
- ISO/IEC TR 19766 (2007) Information technology—Guidelines for the design of icons and symbols accessible to all users, including the elderly and persons with disabilities;
- ITU-T E.902 (1995) Interactive services design guidelines;
- ITU-T P.85 (1994) A method for subjective performance assessment of the quality of speech voice;
- Section 504 of the Rehabilitation Act;
- Section 508 of the Rehabilitation Act;
- ISO 9241-20 (2008)—Ergonomics of Human-System Interaction—Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services;
- ISO 9241-171 (2008)—Ergonomics of Human-System Interaction—Part 171: Guidance on software accessibility; and
- ISO/IEC 40500 (2012)—Web Content Accessibility Guidelines (WCAG) 2.0.

Technical outcome – This certification criterion requires health IT developers to identify relevant standards or laws; or, alternatively, permits a health IT developer to state that its health IT product presented for certification does not meet any accessibility-centered design standards or any accessibility laws.

Clarifications:

- The option to certify that health IT products do not meet any accessibility design standards or comply with any accessibility laws does not exempt them from their independent obligations under applicable federal civil rights laws that require covered entities to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services. [see also 80 FR 62673]

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    - ISO 13406-2 (2001) Ergonomic requirements for work with visual displays based on flat panels. Part 2—Ergonomic requirements for flat panel displays;
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- ISO/IEC 40500 (2012)—Web Content Accessibility Guidelines (WCAG) 2.0.

Paragraph (g)(5)(i) Single accessibility-centered design standard

Technical outcome – When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

Clarifications:

No additional clarifications.

Technical outcome – When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

Clarifications:

No additional clarifications.

Paragraph (g)(5)(ii) Different accessibility-centered design standards

Technical outcome – When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

Clarifications:

No additional clarifications.

Technical outcome – When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

Clarifications:

No additional clarifications.

Paragraph (g)(5)(iii) No accessibility-centered design standard

Technical outcome – When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Clarifications:

No additional clarifications.

Technical outcome – When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Clarifications:

No additional clarifications.

Was this page helpful?

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