

**2015 Edition Certification Companion Guide**  
**Accessibility-Centered Design - 45 CFR 170.315(g)(5)**  
[Final Rule Preamble – Test Procedure](#)  
 Version 1.1 – Last Updated 03/24/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	In Scope for Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
New	No	No	No	N/A

**Certification Requirements**

This certification criterion was adopted at § 170.315(g)(5), and is required for all developers seeking certification to any 2015 Edition certification criteria. There are no associated required privacy and security criteria for this criterion at § 170.315(g)(5). 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.

**Regulation Text**

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.

- (i) When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.
- (ii) 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.
- (iii) When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<ul style="list-style-type: none"> <li>Technical Outcome - This certification criterion requires health IT developers to <u>identify</u> relevant standards or laws; <u>or</u>, 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.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>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 <a href="#">80 FR 62673</a>]</li> <li>The accessibility standards and laws listed below are examples [<a href="#">80 FR 16862</a>]. Because this list is not exhaustive, health IT developers may use accessibility standards not included in this list, but in all cases the accessibility standard or law and the standards developing organization(s) recognizing the standard or government entity recognizing the standard or law must be identified. Additional example accessibility standards and laws will be identified as appropriate. [<a href="#">80 FR 62673</a>]</li> </ul>	N/A

<b>Criterion Subparagraph</b>	<b>Technical Explanations and Clarifications</b>	<b>Standard(s) Referenced</b>
Applies to entire criterion	<ul style="list-style-type: none"> <li>○ ETSI ES 202 076—Human Factors (HF); User Interfaces; Generic spoken command vocabulary for ICT devices and services;</li> <li>○ ETSI ETS 300 679—Terminal equipment (TE); Telephony for the hearing impaired; Electrical coupling of telephone sets to hearing aids;</li> <li>○ ETSI TR 102 068 (2002) Human Factors (HF): Requirements for assistive technology devices in ICT;</li> <li>○ ETSI TS 102 511 (2007) Human Factors (HF): AT commands for assistive mobile device interfaces;</li> <li>○ IEEE 802.11 IEEE 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;</li> <li>○ ISO 13406-1 (1999) Ergonomic requirements for work with visual displays based on flat panels. Part 1—Introduction;</li> <li>○ ISO 13406-2 (2001) Ergonomic requirements for work with visual displays based on flat panels. Part 2—Ergonomic requirements for flat panel displays;</li> <li>○ IEC 80416-1 (2001) Basic principles for graphical symbols for use on equipment—Part 1: Creation of symbol originals;</li> <li>○ ISO 80416-2 (2002) Basic principles for graphical symbols for use on equipment—Part 2: Form and use of arrows;</li> <li>○ IEC 80416-3 (2002) Basic principles for graphical symbols for use on equipment—Part 3: Guidelines for the application of graphical symbols;</li> <li>○ 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;</li> <li>○ ISO 9241-151 (2008) Ergonomics of human-system interaction—Part 151: Guidance on World Wide Web user interfaces;</li> <li>○ ISO 9355-1 (1999) Ergonomic requirements for the design of displays and control actuators. Part 1: Human interactions with displays and control actuators;</li> <li>○ ISO 9355-2 (1999) Ergonomic requirements for the design of displays and control actuators. Part 2: Displays;</li> <li>○ ISO 9999 (2007) Assistive products for persons with disability—Classification and terminology;</li> <li>○ ISO/CD 24500 Guidelines for all people, including elderly persons and persons with disabilities—Auditory signals on consumer products;</li> </ul>	See list in middle column (Technical explanations and Clarifications)

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Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion, continued	<p><i>Continued from previous page</i></p> <ul style="list-style-type: none"> <li>○ ISO/IEC 15411 (1999) Information technology—Segmented keyboard layouts;</li> <li>○ ISO/IEC 15412 (1999) Information technology—Portable keyboard layouts;</li> <li>○ ISO/IEC 24755 (2007) Information technology—Screen icons and symbols for personal mobile communication devices;</li> <li>○ 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;</li> <li>○ ISO/IEC TR 15440 (2005) Information Technology—Future keyboards and other associated input devices and related entry methods;</li> <li>○ 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;</li> <li>○ 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;</li> <li>○ ITU-T E.902 (1995) Interactive services design guidelines;</li> <li>○ ITU-T P.85 (1994) A method for subjective performance assessment of the quality of speech voice;</li> <li>○ Section 504 of the Rehabilitation Act; and</li> <li>○ Section 508 of the Rehabilitation Act.</li> <li>○ ISO 9241-20 (2008)—Ergonomics of Human-System Interaction—Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services</li> <li>○ ISO 9241-171 (2008)—Ergonomics of Human-System Interaction—Part 171: Guidance on software accessibility</li> </ul>	<p><i>Continued from previous page</i></p> <p>See list in middle column (Technical explanations and Clarifications)</p>

**Note:** This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

## Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 28, 2015
1.1	Added example accessibility standards that were identified in the proposed rule	March 24, 2016