Usability Guidance Document Referenced

In an update to the list of recognized standards (Recognition List #43) FDA-CDRH included references to the recent Guidance Document on human factors and usability engineering. The guidance, issued on February 3, 2016, is *Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff.*

The guidance is listed for ISO 14971:2007, IEC 60601-1-6:2013, IEC 60601-1-8:2006, IEC 62366:2014, IEC 62366-1:2015, and AAMI/ANSI HE75:2009/(R)2013. It also includes any corresponding US versions of international standards.

Standard	Action	Guidance	Transition
ISO 14971 Second edition. 2007-03- 01 Medical devices— Application of risk management to medical devices	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016	N/A
AAMI/ANSI/ISO 14971:2007/(R) 2010 (Corrected 4 October 2007) Medical devices-- Application of risk management to medical devices	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016	N/A
ISO 16142-1 First edition 2016-03-01 Medical devices-- Recognized essential principles of safety and performance of medical devices--Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	New	N/A	N/A
IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment-- Part 1-6: General requirements for basic safety and essential performance--Collateral standard: Usability	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016.	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment-- Part 1-6: General requirements for basic safety and essential performance--Collateral standard: Usability

Standard	Action	Guidance	Transition
IEC 60601-1-8 Edition 2.0. 2006-10 Medical electrical equipment-- Part 1-8: General requirements for basic safety and essential performance--Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016	
AAMI/ANSI/IEC 60601-1-8:2006 & A1:2012 Medical electrical equipment--Part 1-8: General requirements for basic safety and essential performance-- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016	
ISO TR 16142 Second edition. 2006-1-15 Technical information report: Medical devices--Guidances on the selection of standards in support of recognized essential principles of safety and performance of medical devices	Withdrawn Replaced by ISO 16142-1 First edition 2016-03-01	N/A	N/A
IEC 62366 Edition 1.1 2014-01 Medical devices--Application of usability engineering to medical devices	Transition period	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016 AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management	FDA recognition of IEC 62366 Edition 1.1 2014-01 [Rec#5-87] will be superseded by recognition of IEC 62366-1 Edition 1.0 2015-02 [Rec#5-95]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-87] until January 31, 2018. After this transition period, declarations of conformity to [Rec#5-87] will not be accepted.

Standard	Action	Guidance	Transition
AAMI/ANSI/IEC 62366:2007/(R) 2013 Medical devices--Application of usability engineering to medical devices	Transition period	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016 AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management	FDA recognition of ANSI/AAMI/IEC 62366:2007/(R)2013 [Rec#5-67] will be superseded by recognition of ANSI/AAMI/IEC 62366-1:2015 [Rec#5-96]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-67] until January 31, 2018. After this transition period, declarations of conformity to [Rec#5-67] will not be accepted.
IEC 62366-1 Edition 1.0 2015-02 Medical devices--Part 1: Application of usability engineering to medical devices	Transition period, Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016. AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management.	FDA recognition of IEC 62366 Edition 1.1 2014-01 [Rec#5-87] will be superseded by recognition of IEC 62366-1 Edition 1.0 2015-02 [Rec#5-95]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-87] until January 31, 2018. After this transition period, declarations of conformity to [Rec#5-87] will not be accepted.
AAMI/ANSI/IEC 62366-1:2015 Medical devices--Part 1: Application of usability engineering to medical devices	Transition period, Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016. AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management.	FDA recognition of ANSI/AAMI/IEC 62366:2007/(R)2013 [Rec#5-67] will be superseded by recognition of ANSI/AAMI/IEC 62366-1:2015 [Rec#5-96]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec#5-67] until January 31, 2018. After this transition period, declarations of conformity to [Rec#5-67] will not be accepted.

Standard	Action	Guidance	Transition
AAMI/ANSI HE75:2009/(R)2013 Human factors engineering--Design of medical devices	Relevant guidance	Applying Human Factors And Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff. Document Issued On February 3, 2016 AAMI TIR50:2014 Post-Market Surveillance Of Use Error Management	