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
		Applying Human Factors	
		And Usability	
ISO 14971 Second		Engineering To Medical	
edition. 2007-03- 01		Devices - Guidance For	
Medical devices—		Industry And Food And	
Application of risk		Drug Administration	
management to medical		Staff. Document Issued	
devices	Relevant guidance	On February 3, 2016	N/A
AAMI/ANSI/ISO			
14971:2007/(R) 2010		Applying Human Factors	
(Corrected 4 October		And Usability	
2007)		Engineering To Medical	
		Devices - Guidance For	
Medical devices		Industry And Food And	
Application of risk		Drug Administration	
management to medical		Staff. Document Issued	
devices	Relevant guidance	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			
devicesPart 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		Applying Human Factors	IEC 60601-1-6 Edition
		And Usability	3.1 2013-10 Medical
Medical electrical		Engineering To Medical	electrical equipment
equipment Part 1-6:		Devices - Guidance For	Part 1-6: General
General requirements for		Industry And Food And	requirements for basic
basic safety and essential		Drug Administration	safety and essential
performanceCollateral		Staff. Document Issued	performanceCollateral
standard: Usability	Relevant guidance	On February 3, 2016.	standard: Usability

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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		Applying Human Factors	
performanceCollateral		And Usability	
standard: General		Engineering To Medical	
requirements, tests and		Devices - Guidance For	
guidance for alarm		Industry And Food And	
systems in medical		Drug Administration	
electrical equipment and		Staff. Document Issued	
medical electrical systems	Relevant guidance	On February 3, 2016	
AAMI/ANSI/IEC 60601-	Trese vant garantee	011100100115 0, 2010	
1-8:2006 & A1:2012			
1-0.2000 & A1.2012			
Medical electrical			
equipmentPart 1-8:			
General requirements for			
basic safety and essential		Applying Human Factors	
performance Collateral		And Usability	
standard: General		Engineering To Medical	
requirements, tests and		Devices - Guidance For	
guidance for alarm		Industry And Food And	
systems in medical		Drug Administration	
electrical equipment and		Staff. Document Issued	
	Polovent guidence		
medical electrical systems ISO TR 16142 Second	Relevant guidance	On February 3, 2016	
edition. 2006-1-15			
edition. 2006-1-13			
Tankai saliu famoati sa			
Technical information			
report: Medical devices Guidances on the			
selection of standards in			
support of recognized	W. d. d		
essential principles of	Withdrawn		
safety and performance of	Replaced by ISO 16142-1	NT/A	NT/A
medical devices	First edition 2016-03-01	N/A	N/A
			FDA recognition of IEC
			62366 Edition 1.1 2014-
			01 [Rec#5-87] will be
			superseded by recognition
		Applying Human Factors	of IEC 62366-1 Edition
		And Usability	1.0 2015-02 [Rec#5-95].
		Engineering To Medical	FDA will accept
		Devices - Guidance For	declarations of
TO 600 66 TO 11 1		Industry And Food And	conformity, in support of
IEC 62366 Edition 1.1		Drug Administration	premarket submissions, to
2014-01		Staff. Document Issued	[Rec#5-87] until January
		On February 3, 2016	31, 2018. After this
Medical devices			transition period,
Application of usability		AAMI TIR50:2014 Post-	declarations of conformity
engineering to medical		Market Surveillance Of	to [Rec#5-87] will not be
devices	Transition period	Use Error Management	accepted.

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Standard	Action	Guidance	Transition
			FDA recognition of
			ANSI/AAMI/IEC
			62366:2007/(R)2013
			[Rec#5-67] will be
			superseded by recognition
		Applying Human Factors	of ANSI/AAMI/IEC
		And Usability	62366-1:2015 [Rec#5-
		Engineering To Medical	96]. FDA will accept
		Devices - Guidance For	declarations of
		Industry And Food And	conformity, in support of
A AMI/ANGL/IEC		Drug Administration	premarket submissions, to
AAMI/ANSI/IEC 62366:2007/(R) 2013		Staff. Document Issued	[Rec#5-67] until January 31, 2018. After this
Medical devices		On February 3, 2016	transition period,
Application of usability		AAMI TIR50:2014 Post-	declarations of conformity
engineering to medical		Market Surveillance Of	to [Rec#5-67] will not be
devices	Transition period	Use Error Management	accepted.
GC 11005	Transition period	ose Error Management	FDA recognition of IEC
			62366 Edition 1.1 2014-
			01 [Rec#5-87] will be
			superseded by recognition
		Applying Human Factors	of IEC 62366-1 Edition
		And Usability	1.0 2015-02 [Rec#5-95].
		Engineering To Medical	FDA will accept
		Devices - Guidance For	declarations of
		Industry And Food And	conformity, in support of
IEC 62366-1 Edition 1.0		Drug Administration	premarket submissions, to
2015-02		Staff. Document Issued	[Rec#5-87] until January
		On February 3, 2016.	31, 2018. After this
Medical devicesPart 1:			transition period,
Application of usability	m :: 1	AAMI TIR50:2014 Post-	declarations of conformity
engineering to medical	Transition period,	Market Surveillance Of	to [Rec#5-87] will not be
devices	Relevant guidance	Use Error Management.	accepted.
			FDA recognition of ANSI/AAMI/IEC
			62366:2007/(R)2013
			[Rec#5-67] will be
			superseded by recognition
		Applying Human Factors	of ANSI/AAMI/IEC
		And Usability	62366-1:2015 [Rec#5-
		Engineering To Medical	96]. FDA will accept
		Devices - Guidance For	declarations of
		Industry And Food And	conformity, in support of
		Drug Administration	premarket submissions, to
AAMI/ANSI/IEC 62366-		Staff. Document Issued	[Rec#5-67] until January
1:2015 Medical devices		On February 3, 2016.	31, 2018. After this
Part 1:			transition period,
Application of usability		AAMI TIR50:2014 Post-	declarations of conformity
engineering to medical	Transition period,	Market Surveillance Of	to [Rec#5-67] will not be
devices	Relevant guidance	Use Error Management.	accepted.

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

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