

Document number: SG1(PD)/N044:2007 Title: Role of Standards in the Assessment of Medical Devices of July 10, 2007

Comment Number	Affiliation (e.g. FDA)	Page / Section / Line	Editorial or Technical	Comment and rationale	Proposed revised text	SG Decision (& date)
1	COCIR/ EUROMVI	General	Ed	Use of s or z in words such as “harmoni(s/z)e” is inconsistent	Choose a letter and make text consistent	Agreed
2	COCIR/ EUROMVI	Section 1, Introduction	Ed	There is no design paragraph in this whole document; don’t promise it ...	Delete “both during the design of a medical device and subsequently”	Agreed
3	COCIR/ EUROMVI	Section 1 3rd paragraph	Ed	Write present tense; it is still an existing and valid document	Write “applies” iso “applied”	Agreed
4	COCIR/ EUROMVI	Section 1 paragraph 4	Ed	Improved language	Write “1999 guidance, which” iso “previous version. It”	Not Agreed; prefer existing text
5	COCIR/ EUROMVI	Section 1 paragraph 4	Ed	There are no examples of standards applicable to IVD medical devices	Delete second bullet	Agreed
6	COCIR/ EUROMVI	Section 1 paragraph 8	Ed	Better wording	Write “are available” iso “may be found”	Agreed
7	COCIR/ EUROMVI	Section 2.1 paragraph 1	Ed	There is no design paragraph in this whole document; don’t promise it ...	Delete “when designing a medical device and, subsequently,”	Agreed
8	COCIR/ EUROMVI	Section 2.2	Ed	Section number format	Bold	Agreed
9	COCIR/ EUROMVI	Section 2.2 paragraph 1	Ed	Better wording	Write “This document intends to”: iso “To”	Not Agreed; prefer existing text
10	COCIR/ EUROMVI	Section 2.3	Ed	The term IVD has been defined	Write “this definition includes IVD medical	Not Agreed;

				before; why not use it ?	devices” iso “ including those use for the <i>in vitro</i> examination of specimens derived from the human body	prefer existing text
11	COCIR/ EUROMVI	Section 4 Last paragraph	Ed	Singular is better	Write “ Recognized Standard ” iso Recognised Standards	Agreed
12	Elke Lehmann	Footnotes Pp7	Ed	Number 1 is missing		Agreed
13	COCIR/ EUROMVI	Section 4 Last paragraph	Ed	Where is footnote 1?	Either delete footnote or put text in footnote	Agreed
14	COCIR/ EUROMVI	Section 4 Last paragraph	Ed	Singular is better	Write “Standard” iso Standards	Agreed
15	COCIR/ EUROMVI	Section 4 Last paragraph	Ed	Essential Principles have been defined before; no need to write part of the full description	Delete “of Safety and Performance”	Not Agreed; this definition is used in documents other than this so clarity could be important.
16	COCIR/ EUROMVI	Section 5 First bullet	Ed	Essential Principles have been defined before; no need to write part of the full description	Delete “of Safety and Performance of medical devices (referred to hereafter as the Essential Principles”	Agreed
17	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Text more consistent with (3 rd) bullet in 5.0	Write “provide a method” iso have, or should develop, procedures	Agreed
18	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Improved language	Write “the recognition” iso “recognition”	Agreed
19	COCIR/ EUROMVI	Footnote 2	Ed	Improved language	Write “This includes situations” iso “These include standards”	Agreed
20	CBER	Page 8, Section 5.1	Tech	Add a statement that use of standards may be a requirement	The use of standards by the manufacturer is voluntary, unless a specified standard is	Not agreed. Could encourage

					identified as a requirement by a RA as identified by regulations/rule.....	RAs to mandate the use of standards
21	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Consistency with bullet text in 5.0	Write “The method” iso “These procedures”	Agreed
22	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Better wording	Write “periodic” iso “regular”	Agreed
23	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	I don’t think we should bother with local standards; national standards are fine	Write “nationally” iso “locally”	Agreed
24	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Prefer “may” over “should” since a fully up to date website is preferable over a periodic (or even a-periodic ...) publication	Write “may” iso “should”	Agreed
25	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Simplify language	Write “of” iso “, updated to identify existing voluntary”	Agreed
26	COCIR/ EUROMVI	Section 5.1 paragraph 1	Ed	Essential Principles do the job; it is confusing to use different wording and there is no need for it	Write “Essential Principles” iso “Specific premarket or postmarket requirements”	Agreed
27	COCIR/ EUROMVI	Section 5.1 paragraph 2	Ed	Better wording	Delete “any”	Agreed
28	COCIR/ EUROMVI	Section 5.1 paragraph 2	Ed	Footnote 4: This footnote not here; better to previous section?	Connect footnote to the end of 1 st par. in 5.1	Agreed
29	COCIR/ EUROMVI	Section 5.1 paragraph 3	Ed	Refer to section on voluntary standards	Insert “See also 5.7.”	Agreed
30	CBER	Page 8, Section 5.2	Tech	Add a statement to identify version and date of recognized standard – because Standards Development		Statement added at end of Section 5.1

				Organizations are considering dropping version and dates when specifying or identifying standards in normative and informative references.		
31	Elke Lehmann	Pp8 Sec 5.2	Tech	The addition of an example that has been revised to reflect changes in the state of technology and/or accepted practice is unnecessary		Agreed
32	Secretary	Pp8 Sec 5.2	Tech	Add EITHER a reference to standards for anaesthetic machines where technology has evolved significantly with time; OR to the IEC EMC standard	Add the example EITHER EN 60601-2-13:2006 Medical electrical equipment. Particular requirements for the safety and essential performance of anaesthetic systems OR IEC 60601-1-2:2002 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests	Not Agreed
33	COCIR/ EUROMVI	Section 5.3 Par. 3, line 2	Ed	Better wording	Write “has been” iso “is”	Agreed
34	COCIR/ EUROMVI	Section 5.3 paragraph 3	Ed	Text approved by SC should be included in this paragraph	Incorporate text: “The transition period should be adequate to allow manufacturers to respond in an appropriate manner. In normal circumstances, the transition period should be 3 years and should not exceed 5 years unless there are exceptional circumstances that justify a longer transition period.”	Not Agreed; text already addresses what happens in normal circumstances.
35	COCIR/ EUROMVI	Section 5.6 Par. 1, line 3	Ed	Use present tense	Write “that are” iso “were”	Agreed

36	COCIR/ EUROMVI	Section 5.8 Last paragraph	Ed	Change order in sentence; makes more sense	Place “may be included in the Summary Technical Documentation (STED)” later in the sentence	Agreed in principle. Text modified to clarify.
37	COCIR/ EUROMVI	Section 5.8 Last paragraph	Ed	Essential Principles have been defined before; no need to write the full description	Delete “of Safety and Performance of Medical Devices”	Agreed
38	COCIR/ EUROMVI	Section 5.8 Last paragraph	Ed	Delete last line; is beyond scope of this document and too unspecific	Delete “The format of the declaration of conformity may vary from country to country but it is desirable that a common format be developed.”	Agreed
39	Michael Gropp	Pp10 footnote	Ed	Delete footnote. Reference already given in Section 3.0		Agreed
40	COCIR/ EUROMVI	Section 5.8 Last paragraph	Ed	This section is called “Technical Documentation”, yet no word is spent on TD. Suggest adding one paragraph on technical documentation.	Add separate paragraph as follows: “While GHTF does not provide guidance on how a manufacturer should organize his technical documentation, it is suggested for the purpose of efficient conformity assessment inspection of technical documentation, to use the STED approach as template.”	Not Agreed. Any such insert belongs in guidance on the STED, not here.
41	Elke Lehmann and others	Appendix A Pp11	Ed	Delete Annex		Agreed; Annex deleted.