

SG1 Work Plan of March 2011

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
SG1 IVD Medical Devices Subgroup – New Document				
Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices	SG1/N063(PD)	Comments from the SC have been considered and the document modified where agreed. It has been resubmitted to the SC for advancement as a Final Document.	1	Final Document 2011/Q1 (Subject to endorsement by the Steering Committee during its March Teleconference)
Revision of SG1 Final Documents by SG1 and IVD MD Subgroup				
Label and Instructions for Use for Medical Devices	SG1/N070(PD)	Comments reviewed and document modified where agreed. Submitted to SC as a Proposed Final Document in February for consideration at the May SC meeting.	1	Final Document 2011/Q2
Essential Principles of Safety and Performance of Medical Devices	SG1/N068 Proposed Document	Document submitted to SC for endorsement as a Proposed Document for public comment.	1	Proposed Document 2011/Q1
Information Document Concerning the Definition of the Term “Medical Device” (revised)	SG1/N071 Proposed Document	Document submitted to SC for endorsement as a Proposed Document for public comment.	1	Proposed Document 2011/Q1
Pending Revisions of SG1 Final Documents				

Principles of Medical Devices Classification	SG1/N015 Working Draft	All bookmarked comments have been discussed. One remaining item to work on at June 2011 meeting	2	Proposed Document 2011/Q3
Principles of Conformity Assessment for Medical Devices	SG1/N040 Working Draft	More than half bookmarked comments have been discussed. Remainder of comments will be completed at June 2011 meeting.	3	Proposed Document 2011/Q3

The publication of the proposed Definition of the Term Medical Device and Essential Principles of Safety and Effectiveness for comments would take place from April to September and would be the focus of the fourth quarter 2011 meetings for both the IVD subgroup and SG1 group.

The publication of the proposed principles of medical devices classification and principles of conformity assessment for medical devices would occur in the fourth quarter 2011 and the comments would be reviewed in the second/third quarter 2012.

For the IVD subgroup, there are currently draft documents for 3 guidance documents related to clinical evidence. The subgroup will be able to finalize at least 2 documents at the May 2011 meeting for forwarding to SG5 to go forward as a public document. Publication would occur in third/fourth quarter and the IVD subgroup would need to work on the comments in 1st or 2nd Quarter of 2012.

The 3rd document on Clinical Evidence would be worked on at the May 2011 meeting as time permits and fourth quarter of 2011 and forward to SG5. Publication for public comment would occur in first quarter 2012 and the subgroup would need to meet in 2012 to work on comments received to finalize the document.