

<b>Comm ent #</b>	<b>Page/Section/ Line</b>	<b>Editori al or Technic al</b>	<b>Comment and Rational</b>	<b>Proposed revised text</b>	<b>SG Decision (and date)</b>
1.	Table of Contents 6.0	Ed	Text not in line with other main headings.	Justify left in line with 'Conformity Assessment Elements' (5.0)	Accepted
2.	1.0 para 2	GE	Way in which GHTF achieves its goals – wording is different to Classification document; should be consistent.	Choose most appropriate & apply to both documents	Rejected – The document for conformity assessment for Medical Devices and IVD Medical Devices should have the same wording. Subnote : the para 2 of the introduction in IVD Medical Device classification need to be aligned with the text in the Medical Device classification document.
3.	1.0 para 4	Ge	Intro should state that CA document should be read in conjunction with IVD Classification document (Ref 2.1 par 6 & Classification doc 1.0 par 4)	Add statement to say that CA doc should be read in conjunction with classification doc.	Accepted – used similar wording as in the IVD Medical Device classification document
4.	1.0 para 1	ED		Change "...encourage convergence at the global level..." to "...encourage global convergence..."	Rejected – consistent with all GHTF documents already published

5.	1.0 para 1	ED	Decreases complexity as well as cost	Change "...decreases the cost of gaining..." to "...decreases the cost and complexity of gaining...."	Rejected – consistent with all GHTF documents already published
6.	1.0 para 2 2 <sup>nd</sup> sentence	ED		Change "...establishing in a consistent way, an economic..." to "...establishing a consistent, economic...."	Rejected – consistent with all GHTF documents already published
7.	2.1 Parta 4 1 <sup>st</sup> sentence	Gramar		Change "...Devices...." to either "Device's" or "Device"	Accepted
8.	2.1 Parta 4 2 <sup>nd</sup> sentence	ED		Change "...it is done in..." to "...it is performed in..."	Rejected
9.	2.1 Par 3	GE/TE	Why is CA necessary after an IVD is placed on market? Isn't 'after' covered in postmarket surveillance?	Remove 'and after' from 1 <sup>st</sup> line.	Rejected – sometimes the conf assessment check is done after the product has been placed on the market
10.	2.1 Par 3	Ed	'Devices in actual use' – why 'actual'? (redundant)	Remove 'actual'.	Accepted
11.	2.1 para 3 last sentence		a. Section 2.1, paragraph 3 last sentence b. Add the words" these complementary elements" at the beginning of the sentence and "and" following safety- for clarity c. These complementary elements are intended to provide the objective evidence of safety and performance, and benefits and risks, to maintain public confidence.		Accepted – remove also and between performance and benefits
12.	2.1 Par 3	Ed	"Conformity assessment, conducted before and <b>after</b> an IVD Medical Device is placed on the market, ..."		Rejected – sometimes the conf assessment check

			<b>Does “after an IVD is placed on the market” imply random/targeted/mandatory post market audits similar to the Level 1 and Level 2 Audits currently applied to Medical Devices by TGA? If so, for clarity and transparency, clear reference should be made to the types of pre- and post- market audits in the body of the text and not be confined to the tables in Section 6.2 (pp 12 – 15)</b>		is done after the product has been placed on the market
13.	2.2 2 <sup>nd</sup> , 3 <sup>rd</sup> , 4 <sup>th</sup> bullet	Ed		Add semi-colon to end of 2 <sup>nd</sup> and 3 <sup>rd</sup> bullet and change semi-colon to period at end of 4 <sup>th</sup> bullet	Accepted
14.	2.2 Pt 1	Ed	‘the available’ seems redundant & implies a wider scope than this doc	Remove ‘the available’ --> An overview of conformity assessment elements...	Rejected – refer to 5.0 RA may include in a conf assessment.....
15.	2.2	Te	Reference should be made to Recognized Voluntary International Standards and/or National Standards as the basis for Regulatory Authority’s confirmation that conformity assessment elements are properly applied by the manufacturer. This would both lend transparency to RA’s assessment process and aid manufacturer in meeting the essential safety and performance criteria.  <i>Although the SG1/N041: 2000 Role of Standards in the Assessment of Medical Devices document is cited under Section 3.0 References, a direct link to the potential existence of a list of recognized international/national</i>		Accepted with modification – added paragraph in the rationale after paragraph 3 and a footnote to the role of standards document

			standards document should be made in Section 2.2.		
16.	2.3 1 <sup>st</sup> para	Ed		Change "...definition of an IVD Medical Device as defined in..." to "...definition of an IVD Medical Device stated in..."	Accepted
17.	3.0 Pt1	Ed	Extra blank line after this point	Remove	Accepted
18.	3.0 Public comment	GE	Reference missing - STED	Add ' <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)</i> ' under the GHTF documents available for public comment heading.	Accepted – will be added once IVD STED document available
19.	4.0 Pt 4	GE	CAB definition unclear	'CAB is authorised by RA to undertake specified CA activities, including procedures for determining whether relevant requirements in technical regulations or standards are fulfilled. RA ensures CAB performance is maintained and, if necessary, withdraws CAB designation.'	Accepted – All definitions in GHTF documents will be aligned – currently an effort is being done to work on a consolidated definitions document.
20.	4.0 Pt 6	Ge	IVDs are not mentioned by name in discussion of RA control	2 <sup>nd</sup> line: "sale of medical devices, including IVDs, within its jurisdiction..."	Rejected – definition needs to remain general for all medical devices including IVD Medical Devices.
21.	4.0 Audit	Format	Para is justified; all other para's are not		Accepted
22.	4.0 Conformity Assessment	ED	Abbreviation "RA" not yet defined	Change "...by a RA that..." To "... By a Regulatory Authority that..."	Accepted but modified in section 2.2 last para by

	Body				adding (RA)
23.	4.0	ED	Please add a definition for 'manufacturer'. Is manufacturer the legal entity which put the device on the market or the 'producer'. This may be different and has influence on different parts of the document e.g. in 10/5.4./L12, 10/5.5.	Add manufacturer definition acc. European IVDD.	Accepted – NWIP submitted to the Steering Committee on behalf of SG1.
24.	4.0 Line 34		How to demonstrate the compliance to EPs is task of the manufacturer.	Omit '...normally an output of the quality management system'. This wording doesn't explain anything and is useless.	Accepted – All definitions in GHTF documents will be aligned – currently an effort is being done to work on a consolidated definitions document.
25.	4.0		a. Section 4.0, definition of AR b. In first sentence, change the wording for clarification c. Means any person explicitly designated by a manufacturer to represent it within a country or jurisdiction where it is not itself established, with respect to matters raised by the relevant Regulatory Authority.....		Accepted – All definitions in GHTF documents will be aligned – currently an effort is being done to work on a consolidated definitions document.
26.	4.0		a. Section 4.0, definition of CAB b. Is this consistent with the definition in the MRA?		Accepted – All definitions in GHTF documents will be aligned – currently an effort is being done to work on a

					consolidated definitions document.
27.	4.0		<p>a. Section 4.0, definitions of Summary Technical Documentation and Technical Documentation</p> <p>b. Aren't these definitions in the GHTF STED guidance document?</p>		Accepted – All definitions in GHTF documents will be aligned – currently an effort is being done to work on a consolidated definitions document.
28.	4.0	Ed	Acronym (STED) should be assigned to Summary Technical Documentation as it is used throughout the document.		Accepted
29.	5.0		<p>a. Section 5.0 “All five elements are required for each of the device classes.”</p> <p>b. This is guidance for regulatory authorities, and should not establish requirements for individual countries.</p> <p>c. Either delete the sentence or replace “required for” with “applicable to.”</p>		Accepted
30.	5.0 Par 1	Ge/Ed	<ul style="list-style-type: none"> <li>• Lacks introductory sentence</li> <li>• Document discusses GHTF position on CA, do not need to cover RA options</li> <li>• CAEs would be clearer in bullet list</li> </ul> <p>‘IVD’ is missing from ‘medical device’ registration</p>	<p>Change 1<sup>st</sup> sentence to “CA requirements are comprised of 5 elements, all of which are required for each of the device classes. The elements of conformity assessment are:</p> <ul style="list-style-type: none"> <li>• <i>Quality management system</i></li> </ul>	Partially accepted – elements made into bullet points

				<ul style="list-style-type: none"> <li>• <i>System for post-market surveillance</i></li> <li>• <i>Summary technical documentation</i></li> <li>• <i>Declaration of conformity</i></li> <li>• <i>Registration of manufacturers and their IVD medical devices by the RA</i></li> </ul> <p><i>These are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.”</i></p>	
31.	5.0 General	Ge	Justification for classification (as required by SG1/N045R10 – Principles of IVD Medical Devices Classification, section 6.0 point 6) should be part of CA somewhere.	Include requirement for justification of classification as part of conformity assessment, per comment (left).	Accepted but covered through comment 3 – link to the classification document and section 6.1 describes the relationship between conformity assessment and device classification
32.	5.1		<ol style="list-style-type: none"> <li>a. Section 5.1</li> <li>b. After quality management system, add “(QMS).”</li> <li>c. QMS is used later in the document, but not defined upfront.</li> </ol>		Accepted
33.	5.1		a. Section 5.1, first paragraph, first		Rejected –

			<p>sentence</p> <p>b. Remove the words "requirements for" and replace with "elements of" ; remove "accepted by RAs for regulatory purposes and"; removed "combines" and replace with "along"- clarity</p> <p>c. The elements of a quality management system that is based on internationally recognized standards, along with the other conformity assessment elements, are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.</p>		<p>requirements and not elements - not any quality system based on intern recognized standards are suitable for regulatory purposes</p>
34.	5.1		<p>. Section 5.1, last paragraph, 2nd sentence</p> <p>b. Add "The QMS established by"; remove should have a quality management system also; however, the procedures incorporated within it may not include design and development activities" and replace with "may not necessarily include procedures for design and development activities" - clarity</p> <p>d. The QMS established by manufacturers of Class B devices may not necessarily include procedures for design and development activities.</p>		<p>Partially accepted – decided on this wording after substantial discussion during the development of the document, added the word necessarily</p>
35.	5.1	Te	<p>I think that it is important to add a reference to the ISO 13485 standard for medical devices. It is a pertinent</p>	<p>Add a reference to the ISO 13485 standard for medical devices.</p>	<p>Rejected – section 5.1 makes a reference to</p>

			definition when referring to section 5.1, Quality management system.		requirements for a QMS system based on international recognised standards
36.	5.1 Line 2	Tech	Is the a definition or a list of items in SG3 guidance document that defines/clarifies full QMS including design and development, QMS with out the design and development elements, and QMS with Basic Elements only?	If not, we need to define/list them in this document	Accepted – need to check with SG3 if they can provide appropriate wording
37.	5.1 Line 26	Edit	...the IVD Medical Device, its complexity	Add the word “and” after the coma.	Accepted – same comment as 52
38.	5.1 Par 1	Ed	2 <sup>nd</sup> half of sentence should be combined with intro, it is a general statement.	Change first sentence to “ <i>A quality management system that is accepted by RAs for regulatory purposes and based on international recognised standards needs to be established by a manufacturer to demonstrate its ability to provide...</i> ” (and continue with 2 <sup>nd</sup> paragraph).	Rejected – tables define the roles and responsibilities for the parties involved
39.	5.1 Par 4-8	Te	<ul style="list-style-type: none"> <li>From 2<sup>nd</sup> sentence of paragraph 4 – why is QMS certification by accepted auditor insufficient evidence? (?is this a breakdown of harmonization?)</li> <li>Can ISO 13485 be referenced here? It is the standard generally accepted by regulatory authorities as evidence of QMS (some RAs may specify auditing bodies)</li> <li>Making extra RA/CAB</li> </ul>	<ul style="list-style-type: none"> <li>Add ISO 13485 (recent version)</li> <li>Make RA/CAB audit/review of manufacturer QMS optional part of postmarketing surveillance, to discretion of RA/CAB instead of making it a conformity assessment requirement</li> </ul>	Rejected – section 5.1 makes a reference to requirements for a QMS system based on international recognised standards - 4 <sup>th</sup> paragraph addresses supplier audits

			involvement of manufacturers' existing audited QMS is extra burden on RA and manufacturer		
40.	5.1 line 37		Only RAs should have the right to consider certifications from CABs not sufficient. As CABs are private organizations they are tending to not recognizing the certificates from other CABs despite the fact that the standards they used for e.g. auditing the QMS are the same (e.g. ISO 13485)	Cancel 'or CAB' in this line or define clearly when a CAB will have the option to consider the existing certification as not sufficient (which is indeed an unclear wording).	Rejected – default position is that existing certification will be considered except under specific circumstances as the examples given
41.	5.1 Par 1	Ed	Abbreviation “QMS” is used subsequently in section without definition in this document	Change “..for a quality management system that...” to “... for a quality management system (QMS) that...”	Accepted
42.	5.2 Par 2	Te	It is unclear when this is to take place (ref 1 <sup>st</sup> sentence, 'prior to placing on the market...'). Postmarket surveillance checks should be verified after the device has been placed on the market.	Change to: “ <i>The RA or CAB will confirm that such a process is in place at any interval following the placement of the device on the market, at the discretion of the RA/CAB.</i> ” (also suggest minimum and maximum intervals, depending on device class)	Rejected – post market surveillance systems are normally checked as part of the quality management systems audit which takes place at the premarketing stage.
43.	5.2		<ul style="list-style-type: none"> <li>a. Section 5.2</li> <li>b. Replace “through the post-marketing phase” with “throughout the IVD medical device lifecycle.”</li> <li>c. Use terminology that is consistent with earlier document terminology focusing on IVD lifecycle.</li> </ul>		Accepted

44.	5.2	Ed	Need to expand on this statement by explaining/clarifying the QMS audit mechanism (desktop or on-site evaluation; random or mandatory) and timing (pre-market or post-market) for each class of IVD. Section 5.1 does not make this clear. Alternatively, this could be expanded on in Section 5.1.		Rejected – 5.2 second paragraph addresses this-further discussion will take place on the need for more detailed guidance
45.	5.3 Par 2	Ed	Some of the wording gives unclear meaning.	<ul style="list-style-type: none"> <li>Line 1: ‘...manufacturer will <i>develop a summary</i> of ...’</li> <li>Line 2/3: delete ‘A description of that subset’, replace with ‘<i>Content requirements of this summary</i>’ will be provided...</li> <li>Line 5/6: delete ‘is likely to’, replace with ‘<i>will</i>’ increase with the class...</li> </ul>	<p>Rejected – it is explaining what the STED is, namely a subset of the technical documentation –</p> <p>It is not always the case so ‘likely’ provides for this flexibility</p>
46.	5.3 par3	Te	<ul style="list-style-type: none"> <li>Can authorised representatives (AR) be included in the STED evidence reviewers? This would reflect current European IVD regulations. This is a convenient and successful arrangement that should be continued. Failure to include this will increase regulatory complexity for no gain in compliance.</li> </ul>	<ul style="list-style-type: none"> <li>Add ‘AR (Authorized Representative)’; ‘The RA, CAB or AR determines...’</li> </ul>	Rejected – an AR represents the manufacturer and not the RA or CAB
47.	5.3 Par 3	Ed	Last sentence has unclear meaning.	Change to ‘The depth and	Accepted with

				<i>duration</i> of the review is likely to be influenced... Device.’ (delete ‘its complexity’).	modification – this is meant to be the point in time of the review
48.	5.3 2 <sup>nd</sup> para		Section 5.3, second paragraph, last sentence b. Change "is" to "generally" and add "risk" in front of class - clarity c. The extent of evidence in that STED generally increases with the risk class of the IVD Medical Device and its complexity.		Rejected, similar comment as 46 It is not always the case so “likely” provides for this flexibility
49.	5.3 last para		a. Section 5.3, last paragraph, last sentence b. Add "and/or" in front of its - clarity c. The depth and timing of the review is likely to be influenced by the risk class of the IVD Medical Device and/or its complexity.		Accepted similar comment as 38 and 52
50.	5.3	Ed	Difficult to comment on this section as the referenced IVD-specific GHTF document <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)</i> is not accessible. Additionally, the actual document number, not just the title, should also be referenced.		Accepted – similar comment as 18
51.	5.3 Para 3	Grammar		Change “...risk class of the IVD Medical Device, its complexity.” to “... risk class of the IVD	Accepted

				Medical Device and its complexity.”	
52.	5.4 2 <sup>nd</sup> para		<ul style="list-style-type: none"> <li>a. Section 5.4, second paragraph, first sentence</li> <li>b. remove "as" and replace with "at"</li> <li>c. At a minimum, this declaration should contain the following information....</li> </ul>		Accepted
53.	5.4 1 <sup>st</sup> bullet		<ul style="list-style-type: none"> <li>a. Section 5.4, first bullet</li> <li>b. Change to read " a statement that each device that is the subject of the declaration::</li> </ul>		Accepted
54.	5.4 3 <sup>rd</sup> bullet	Te	The GMDN code is still not broadly accepted or required as an EU standard. Therefore, it should be listed here as optional	List GMDN here as optional.	Accepted with modification
55.	5.4 4 <sup>th</sup> main bullet	Ed	Footnote is the same as ‘6’.	Change footnote ‘7’ to ‘6’ and delete footnote ‘7’ from bottom of page.	Accepted
56.	5.4 5 <sup>th</sup> main bullet	Te	N/A, depends on classification, classification should be enough. Having to state this would be burdensome on industry for no real added regulatory gain.	Delete this bullet point (‘Which of the CA procedures described in Section 6.2 have been applied’).	Rejected – need to be part of the Declaration
57.	5.4 7 <sup>th</sup> main bullet	Te	Should include AR (authorised representative) if applicable.	Add ‘ <i>and AR if applicable</i> ’ after ‘manufacturer’.	Rejected – the AR is region and country specific – could be included in the country/region registration
58.	5.4 Last para	Te/Ed	Please can ‘AR’ be included as	Change to ‘The RA, CAB <i>or</i> AR	Rejected – similar

			reviewer of declaration of conformity? This would reflect current European IVD regulations. This is a convenient and successful arrangement that should be continued. Failure to include this will increase regulatory complexity for no gain in compliance.  'documents' would sounds better as 'documentation'	may review and confirm... ...supporting <i>documentation</i> or other evidence.'	comment as 47
59.	5.4 para 1	Ed		Change "...for IVD Medical Devices is that the manufacturer attests that..." to "...for IVD Medical Devices requires that the manufacturer attest that..."	Accepted
60.	5.4 para 1	Ed		Change "...and <i>Performance</i> and draws up a written..." to "...and <i>Performance</i> as documented in a written..."	Accepted
61.	5.4 line 9	Ed	References 6 and 7 are identical	Change number 7 to 6	Accepted – same comment as 56
62.	5.4		There should be an acknowledgement of already established declarations as e.g. the European Declaration of Conformity. Otherwise there is the potential that for each country we will have to issue a separate declaration of conformity.	Add: Declarations of Conformity acc. national laws should be accepted.	Acknowledged but cannot be implemented Note : Today existing declarations of conformity can be amended to encompass different regulations
63.	5.4 Line 3		This is an unnecessary line as it is covered by line 1. If the device is not meeting the applicable conformity assessment elements it's not confirming to line 1.	Cancel	Rejected – the requirements in line 1 and 3 are different

64.	5.4 Line 6		There is worldwide confusion about the usage of this code. This point should be kept out of 5.4 in general as different RAs may have different systems.	Cancel	Accepted – same comment as 55
65.	5.5		Please clarify what is meant: 'Registration of Manufacturers' or 'Registration of the medical devices of a manufacturer'. This is quite different.	Rephrase in general to 'Registration of IVD Medical Devices by the Regulatory Authority'.	Accepted with modification
66.	5.5 1 <sup>st</sup> para		<p>a. Section 5.5, first paragraph, last sentence</p> <p>b. Add "communications" in front of activity</p> <p>c. This registration system will identify the IVD medical device/s and the party responsible for the IVD medical device/s within the particular jurisdiction, thereby facilitating and regulatory communication activity.</p>		Rejected – regulatory activity is going beyond communication
67.	6.1 Para 1	Ed	2 <sup>nd</sup> line – should reference where 'set of rules' comes from.	Add ' <i>defined in Principles of IVD Medical Devices Classification</i> ' after 'using a set of rules'.	Accepted
68.	6.1 Para 1	Ed	4 <sup>th</sup> line – meaning unclear	Delete 'requirements': → ' <i>level of scrutiny, evidence that the IVD MD meets the Essential...</i> '	Accepted with modification
69.	6.1 Para 1	Ed	First sentence wording could be improved; the entire document is guidance, it should not suggest that the guidance only begins hereafter. Suggest saying 'guidance tables' instead.	Change as follows: 'illustrated in the guidance <i>tables</i> that follow. <i>They identify</i> available conformity..... that may be applied to <i>the</i> different classes...'	Accepted with modification
70.	6.1 Para 1 4 <sup>th</sup> sentence	Grammar		Change "The level of scrutiny, evidence requirements that the IVD Medical Device..." to "The level of scrutiny and evidence	Accepted – same comment as 73

				demonstrates that the IVD Medical Device...”	
71.	6.1 para 1 4 <sup>th</sup> sentence	Grammar		Change “... proportional to the risk class of devices.” to “...proportional to the risk class of the device.”	Accepted with modification
72.	6.1 1 <sup>st</sup> para		<ul style="list-style-type: none"> <li>a. Section 6.1, first paragraph, last line.</li> <li>b. Add "and" in front of evidence</li> <li>c. The level of scrutiny and evidence requirements that the IVD Medical Device meets the Essential Principles for Safety and Performance and conformity assessment procedures should be proportional to the risk class of the device.</li> </ul>		Accepted – same comment as 71
73.	6.2 Class A Device table	Ed	Under Manufacturer Responsibility/Conformity Assessment of QMS, we disagree with the statement “Or a QMS without design and development controls”	Remove “Or a QMS without design and development controls.”	Rejected – no rationale provided
74.	6.2 Class A Device table	Ed	Under RA/CAB Responsibility/Conformity assessment of device safety & performance, change “Normally not requested to be submitted” to “On file with Manufacturer; available upon request	Change “Normally not requested to be submitted” to “On file with Manufacturer; available upon request”	Accepted
75.	6.2 Class A Device table		Declaration of Conformity – table section RA / CAB Responsibility: <b>Will Declaration of Conformity be requested as part of post-market audit? If so, a statement to that effect should be included.</b>	Addition of statement “May/will be required to be submitted as part of post-market audit.”	Accepted with modification – available upon request covers both pre and post market
76.	6.2 Class A & B table	Ed	Change in 3 <sup>rd</sup> row dealing with technical documentation in both places	Change “Prepare STED and have available...” to “Prepare	Rejected –current wording is more

				STED that is available...”	clear
77.	6.2 Table Headings	Ed	Headings may lack clarity, suggest adding classification descriptors.	e.g. ‘Class ‘A’ Device – <i>Lowest risk devices</i> ’	Rejected – para 6.1 first paragraph describes the risk classes
78.	6.2 All tables	Ge	Table layout – far left column of all tables: This is the first time these terms are introduced. Does not add to clarity but could cause confusion.	Remove far left column from each table.	Accepted
79.	6.2 all tables RA/CAB column	Te	There is no mention of AR (Authorised Representative). AR should be included, at least for STED and Declaration of Conformity review / verification.	Add ‘/AR’ to column heading after ‘RA/CAB/.	Rejected – an AR represents the manufacturer and not the RA or CAB Same comment as 47 and 59.
80.	6.2 Class A – RA/CAB column	Ge	QMS row – add ‘N/A’ to signify no RA/CAB responsibility. PMS row – it is unclear who the responsibility lies with for initiating this decision (RA/CAB). STED row – use of the word ‘normally’ detracts from clarity. Should use more definite language. DC row - use of the word ‘normally’ detracts from clarity. Should use more definite language.	Add ‘N/A’. Add ‘RA’ (+CAB if applicable) prior to ‘May audit...’  Delete ‘normally’ (→ submission of STED not required). Add ‘May be requested post-market by RA’.  Delete ‘normally’. Change to ‘Not required to be submitted pre-market.’	Rejected, there is a RA/CAB responsibility Rejected – refer to definition of CAB Accepted with modification  Accepted with modification
81.	6.2 Class b – RA/CAB column	Ge	<ul style="list-style-type: none"> <li>Body of responsibility should be marked, i.e. QMS and PMS should have ‘(RA/CA)’ at the end to make it clear that RA/CAB is responsible for verifying QMS.</li> <li>PMS row – first line seems</li> </ul>	<ul style="list-style-type: none"> <li>Add (RA/CA)’ to QMS and PMS boxes.</li> <li>Delete first line ‘At the time of QMS audit’, start sentence</li> </ul>	Rejected – different columns define the manufacturer and the RA/CAB responsibilities

			<p>inappropriate; QMS audit may not be necessary but still need to be satisfied PMS is in place.</p> <ul style="list-style-type: none"> <li>STED row – use of the word ‘normally’ detracts from clarity. Should use more definite language. Receipt of STED is incidental, hence superfluous here (if manufacturer makes STED available upon request and RA requests STED from manufacturer, RA receives it). Also, ‘pre-market’ might be out of place here as request may be post-market. Lastly, RA/CAB/AR does not determine conformity – manufacturer determines, reviewers evaluate the determination.</li> </ul>	<p>with ‘Be satisfied...’</p> <ul style="list-style-type: none"> <li>Delete ‘normally’ in 2<sup>nd</sup> line, delete ‘receive and’ from 3<sup>rd</sup> line, delete ‘pre-market’ from 4<sup>th</sup> line and change ‘determine’ in 6<sup>th</sup> line to ‘<i>evaluate</i>’: submission not required but <i>may be requested</i>. If requested, conduct a review of the STED sufficient to evaluate conformity to Essential...’</li> </ul>	<p>Accepted</p> <p>Reject but we deleted normally in class A table</p>
82.	6.2 Class B Device table	Ed	Under Manufacturer Responsibility/Conformity Assessment of QMS, we disagree with the statement “Or a QMS without design and development controls.	Remove “Or a QMS without design and development controls”	Rejected – no rationale provided
83.	6.2 class C & C Manufacturer column	Ed	<ul style="list-style-type: none"> <li>Delete ‘a’</li> </ul>	<ul style="list-style-type: none"> <li>‘submit STED for review’.</li> </ul>	Accepted
84.	6.2 Class C&D RA/CAB column	Ge	<ul style="list-style-type: none"> <li>Body of responsibility should be marked, i.e. QMS and PMS should have ‘(RA/CA)’ at the end to make it clear that RA/CAB</li> </ul>	<ul style="list-style-type: none"> <li>Add (RA/CA)’ to QMS and PMS boxes.</li> </ul>	Rejected – different columns define the manufacturer and the RA/CAB responsibilities



			<p>responsibility for QMS</p> <p>b. Add the word "full" in front of the first QMS</p> <p>c. Establish and maintain a full QMS or....</p>	
87.	6.2		<p>a. Table class "A", under RA/CAB Responsibility for conformity assessment</p> <p>b. Replace the word "requested" with the word "required"</p> <p>d. Normally not required to be submitted.</p>	Accepted but modified wording entirely
88.	6.2		<p>a. Table class "B" RA/CAB Responsibility – Conformity assessment of the QMS</p> <p>b. Delete "conduct a QMS audit prior to marketing authorization"</p> <p>c. Requiring an audit prior to marketing authorization seems excessive for Class B IVDs, which appear to be the equivalent to 510(k) IVDs in the US.</p> <p>d. The same comment applies to Class C devices. What IVDs fall into Class C? Again, if 510(k) devices, requiring a QMS audit prior to marketing authorization seems excessive.</p>	Rejected – QMS is required for Class B, C and D and only if not enough evidence provided by the manufacturer an audit might be needed

89.	6.2		<ul style="list-style-type: none"> <li>a. Table class “B”</li> <li>b. For DOC add “upon request” after “prepare, sign and make available for review.” For DOC, add “if requested” before “review and verify compliance with requirements.”</li> <li>c. It seems as, if the DOC is submitted only on request, but this is not reflected in the wording</li> </ul>	Rejected – with modification
90.	6.2		Clear reference to QMS audit mechanism (desktop or on-site) should be made for each class of IVD.	Rejected – 5.2 second paragraph addresses this- further discussion will take place on the need for more detailed guidance Same comment as 45
91.	6.2		. What is the difference between Class C device requirement for a premarket review and a class D device requirement for an in-depth premarket review? This implies there is a difference. If so, what is the difference?	Rejected – is addressed in the document in para 5.1 The depth and the point in time of the review is likely to be influenced by the risk class of the IVD Medical Device and its

					complexity.
92.	6.3		<ul style="list-style-type: none"> <li>a. Section 6.3</li> <li>b. Delete bullet point three “the device is new to the manufacturer”</li> <li>c. This item is not risk-based. A manufacturer of high risk Class D IVDs, could be subject to more rigorous controls if manufacturing a “new” Class A or B device.</li> </ul>		Accepted with modification
93.	6.3 Par 1		Point refers to “internationally recognized standards” reinforcing the comment made in Comment Number 2 above.		Accepted with modification – added paragraph in the rationale after paragraph 3 and a footnote to the role of standards document – same comment as 15
94.	6.3 Par 2	Ed	<p>The wording of the statement “ For example, the RA or CAB may be exempt... to a device of that class...” appears misleading because the manufacturer is never <b>exempt</b> from conformity assessment, but may be permitted to undergo a modified conformity assessment process if the device fulfills the criteria cited in the example that follows.</p> <p>The section should be rephrased to make the requirement clear to the reader. Additionally, it should clearly specify if this clause applies to all</p>		Accepted with modification – added clarifying wording to para 1 of 6.3 and modified the examples

			classes of IVDs or only Class 3, cited in the section.		
95.	6.3 15 + 16		<p>What is the meaning of this chapter?  Do we have a clear process how to make conformity assessments or not?  The process described in the document before gives the opportunity to act appropriate in both ways. How to review a STED is not described in detail. So RA and CABs are pretty free to act appropriately. Although we will provide further detailed comment we question the need for this section at all.</p>	<p>Cancel. For each RA it is possible to classify a product into a higher or lower class as the classification document only gives rules which can be adjusted productwise by the RA. So I don't see a need in this chapter which in my opinion only exists to give a reason for such an adjustment from the RA. This is unnecessary as it is given in the classification document anyway. (see page 11 of the SG1/N045R1, 8.0 Note).</p>	<p>Rejected – it adds more clarity on the paragraph included in the Classification document</p>
96.	6.3 Footnote	Ed	<p>References section 3.0 has SG1/N012:2000 – Role of standards in the assessment of medical devices. Is the standard listed different (code is different)? If so, this should be added to 3.0 list of references.</p>	<p>Add reference to 3.0 list or remove if standard is already referred to, and correct footnote 8 entry (as appropriate).</p>	<p>Accepted – changed to 012 however will be revised to 044 when the revised version of the role of standards document will be finalized</p>
97.	16/L 10		<p>What meant 'new' to the manufacturer?  New concerning design or new concerning production? Change of the manufacturing site even the legal manufacturer is experienced with such products will lead to higher activities of CABs?</p>	<p>Cancel</p>	<p>Accepted with modification – same comment as 94</p>
98.	Preface	Ed	<p>Change “The document herein was....”  To “This document was....”</p>		<p>Accepted</p>
99.	Whole Document		<p>Harmonize the document acc. the scope to avoid misunderstandings</p>	<p>Replace in general the term 'Medical Device' by 'IVD Medical Device'</p>	<p>Accepted</p>

100.	12 following		Registration of manufacturers and their devices (see point 08)	Change to: Registration of the IVD Medical Devices	Accepted
101.	General		Appears to be very high level overview of conformity assessment. Good as initial guidance, but not for further regulatory alignment		Accepted – details will be further addressed in another document (most likely the STED document)
102.	General		No inclusion of possible methods of fulfilling the Conformity Assessment elements. For example, the EU annexes, or the Australian pathways for conformity assessment		Rejected – tables include different requirements for the different classes
103.	General		No details regarding the way in which IVDs can be assessed to meet the conformity assessment elements.		Rejected – section 5.1 makes a reference to requirements for a QMS system based on international recognised standards

