Consolidated comments on SG1(PD)/N040 **Document Title: Principles of Conformity Assessment for Medical Devices**

ISSUE 2 of 22 March 2006 with outcome of discussion added on 30 to 31 March

Comment Number	Page / Section Line	Editorial or Technical	Comment and rationale	Proposed revised text	SG1 Decision (& date)
1.		General	Overall, document SG1(PD)N040 seems to provide useful guidance on the general principles of conformity assessment.		Noted
2.	Pages 5, 9, 12, 13, 14, 15 (twice) & 16	Editorial	Consistent use of hyphen in pre-market (what about post-market?)	Substitute "pre-market" for "premarket"	Accept that consistency is required using "premarket" and "post-market"
3.	Page 4 /Section 1.0 /Paragraph 4	Editorial	Comment: Recommend the addition of a statement for industry to consult with their local RA regarding their requirements. Rationale: The current text only alludes to the need to consult with local RA. This should be made explicit for efficiencies and post-market surveillance requirements.	Add to 4th paragraph "Industry is reminded to consult with local regulatory authority (RA) for local regulatory requirements and the application of this guidance document to their regions."	Not accepted. Other language in GHTF guidance documents makes this clear (e.g. Rationale paragraph 4).
4.	Page 5 Para 4 L 14 to 16	Technical	Add "in the markets where the device is sold" after requirements.	However, it is done in the context of the established regulatory requirements and both the process and conclusions are subject to further review by the regulatory authority and/or conformity assessment body in the countries and regions where the device is sold.	Accept Add:- in the countries and regions where the device is sold

5.	Page 5 L 22 to 24	Technical	Change "regulator" to "Regulatory Authority" Add " Conformity Assessment Body" Delete "alike"	A perceived failure of the conformity assessment process, even if related only to a small number of specific devices, jeopardizes the credibility of Regulatory Authority, Conformity Assessment Body and manufacturer.	See comment 6
6.	Page 5 para 6	Technical	Statement does not add to the technical content of the document – experience shows that the majority of recalls occur as a consequence of production issues, something that would never be picked up in the context of a conformity assessment process	Delete	Accepted
7.	Page 6 / Section 2.3 Scope	Editorial	We understood that this guidance document applies to the medical device, but we consider who should use the document not to become clear.	<u>We suggest adding the following text;</u> "where manufacturer, RA or CAB demonstrate and confirm the conformity for the medical devices on the pre-market."	Add and the activities of the medical device manufacturer
8.	Page7 / Section 3.0 References : International Standards	Editorial	We remove the description for clinical evaluation from this guidance document. We think that their standards are not referred in this guidance document.	<u>We suggest deleting the following reference;</u> ISO 14155-1:2003 Clinical investigation of medical devices for human subjects – Part 1: General requirements ISO 14155-2:2003 Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans	Accepted
9.	Page 7 / Section 4.0	Technical	The definition of "Audit" is referenced to ISO 8402 (which has been replaced by ISO 9000:2000). In fact, ISO 9000:2000	Substitute: The definition of "Audit" from ISO	Verify and use the definition used by SG4 in document GHTF/SG4/N28:1999.

	Definitions		(and not ISO 8402) is listed under International standards on page 6.	9000:2000.	
10.	Page 7	Technical	Add a definition for manufacturer, as the term manufacturer has a different meaning for each regulator. A common understanding of this term is required.	A separate document with regards to a definition for manufacturer should be prepared.	The definition of the term "manufacturer" has far reaching consequences and will need considerable discussion. **Bookmark** as a future work item.
11.	Definitions Page 7, Section 4	Technical	Add definition of manufacturer	The manufacturer of a medical device is the person who accepts responsibility for the design, production, packaging and labeling of a device, before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out these operations. Source: TGA Regulations.	See comment 10.
12.	Page 7 / Section 4.0 Definitions	Editorial	Comment: Recommend the addition of the definition of "Manufacturer". Rationale: Within Canada and other regions, there is the requirement to have the manufacturer of a device (as per product labelling) to be a legal entity (and not a branded division or trademark) that assumes the ISO 13845 QS responsibilities.	Add: "Manufacturer: The legal name or identifier of an individual or organization that assumes the Quality Management System and associated design and fabricating responsibilities for a medical device. It is to this individual or organization that applicable Quality System Certification and/or Regulatory Authorization is issued."	See comment 10.
13.	Page 7 / Section 4.0 Definitions	Editorial/ technical	Recommend that a definition for manufacturer be added to the definitions section. The term is used in several GHTF documents and it would be appropriate to have a harmonized definition in each document where relevant.	GHTF documents with reference to a definition for a manufacturer can be found in the SG4 QS documents and in SG3 Manufacturers Trend Reporting document.	See comment 10.
14.	Page 7	Editorial	Use "Regulatory Authority" in place of	"A CAB is authorized to undertake	Accept

	/ Section 4.0 / Line 17		"RA" Since the abbreviation (RA) has not yet been introduced into the document at this point (it is only introduced on line 21) the full title should be used in place of RA.	specified conformity assessment activities by a Regulatory Authority that will ensure performance of the CAB….."	
15.	Page 8 / Section 5.0 / line 4	Technical	Quality management systems is not the single way to show evidence of design, safety and performance conformity.	Modify paragraph as follows: As a general rule, a medical device is subject to conformity assessment during both design and manufacture <u>which may also include product testing and/or final control on each product or by sampling method.</u>	Paragraph not accepted as suggested but addressed in part through new language on type examination inserted into Section 5.1.1. **Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
16.	Page 8 L 17 to 18	Editorial	There appears to be some inconsistency in the use of a number of terms in Section 5. The existing text suggests that the RA may make available 3 conformity assessment procedures that relate to : 1) Design and performance of the product, 2) Manufacture of the product, and 3) Both "design and performance" and "manufacturer" of the product. However, in the remainder of Section 5 and in the tables on page 12, 13 and 14 the term "Design and performance" is not used nor is a conformity assessment procedure related to "design and performance" discussed.	Review and reword all of Section 5.0 to make it consistent with terms used in other parts of the document like the tables for Class A, B, C and D devices.	Replace performance with "design and development" Change "procedures" to "elements" Action by Secretary

17.	Page 8 / Section 5.1 QMS / 2nd Paragraph	Editorial	We think that 2nd paragraph is described the scope of this documents. Therefore, we think that such description remove into "Scope".	We suggest deleting this paragraph from Section 5.1 and inserting it into Section 2.3 ; "A manufacturer needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to those medical devices. Manufacturers demonstrate compliance through an established and effectively implemented quality management system that meets the regulatory requirements."	Not accepted. Scope modified already.
18.	Page 8 L 29 to 31	Technical	Because of the present use of more than one type of quality management system model by regulatory authorities § 5.1 does not purposefully identify or call for the use of one type of quality management system. However, to reduce the chances of a manufacturer adopting a system that would not be appropriate like ISO 9001:2000 or the soon to be retired ISO 13485/88:1996 suggest adding following text as guidance: "a quality management system that is accepted by regulatory authorities for regulatory purposes like ISO 13485:2003, QSR 21 CFR Part 820, or the Japanese QMS Regulations"…	The requirements for a quality management system that is accepted by regulatory authorities for regulatory purposes and based on international recognized standards, combined with the other conformity assessment elements are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.	Accepted Insert as first paragraph of 5.1.1. Reference the definition of recognized standard from Role of Standards
19.	Page 8 /Section 5.1 /Line 32	Technical	Remove "premarket". As written, this could imply on-site auditing by RA or CAB may be required post marketing.	"The QMS for manufacturers of Class A devices is normally not subject to on-site audit by the RA or CAB."	Not accepted.
20.	Page 9 / Section 5.1 QMS	Editorial	Comment: Recommend adding a statement that despite the QMS exemptions for Class A and B device manufacturers, there is the	Add: "Manufacturers of Class A and B	Not accepted. This is covered in GHTF guidance as a whole where it is clear that all devices

	/4th paragraph.		expectation that non-clinical, clinical and/or post-market surveillance data be collected, analyzed and reviewed to confirm the quality, safety and efficacy or performance of the devices. Rationale: To remind Class A and B manufacturers that there is a requirement to still have established safety and performance data to support label claims.	devices are expected to have documented non-clinical, clinical and post-market surveillance information supporting and maintaining the quality, safety and efficacy/performance of their medical devices."	must meet relevant Essential Principles. Also, new language in Paragraphs 6 to 8 of Section 5.1.1 add clarity. The Tables in Section 6.2 make it clear that post-market surveillance procedures are required for all Classes of device.
21.	Page 9 Section 5.1 paragraph 5. And Page 14 – Table Class C - Note	Technical	We are all (SG1) in agreement that the review of the STED must take place, and in particular for C and D devices. In jurisdictions that permit the exclusion of design control in quality systems, this happens in a particular way (type examination or other) due to the absence of a certified design control system. But nevertheless there is a review of the STED (A rose by any other name…, so to speak) These are the 'alternative arrangements' as stated in section 5.1 paragraph 5. Type examination is only one example of an alternative arrangement to normal STED review (or design dossier review in Europe). So the proposal would be to enhance the text on the alternative arrangements and delete the note under the table for Class "C" Devices and to include text in section 5.1 paragraph 5. Also delete reference to part of the quality system as it has to be	Section 5.1 paragraph 5: If regulatory requirements permit exclusion of design and development controls, this can be used as a justification for their exclusion from the quality management system. Some country or regional regulations can allow for alternative arrangements <u>when undertaking a review of the STED to address this exclusion.</u> ~~and that must be carried out as part of the quality management system.~~	Accepted in principle but not as written. Addressed through new text on type examination (See Section 5.1.1.). Accept that the NOTE should be deleted.

			part of the quality system in any case (redundant phrase).		
22.	Page 9 / Section 5.1 / 5th Paragraph	Technical	Replace lines 3-6. See NEMA comment below for rationale	Modify: Some regulatory requirements permit exclusion of design and development controls for low risk devices. This should not be used as justification for their exclusion from the quality management system	Accepted in principle but not as written. Addressed through new text on type examination (Section 5.1.1.).
23.	Page 9 / Section 5.1 / Line 28	Technical	The FDA believes there should be no difference between the type of QMS system applied by manufacturers of Class B, C or D devices and that all should operate a QMS that includes design and development activities.	Insert new 7th paragraph :- Manufacturers of Class B devices should have a quality management system that should include design and development activities.	Addressed through changes made to the text of the document and the discussion on type examination (Section 5.1.1.).
24.	Page9 / Section 5.1 / 8th paragraph, 2nd sentence	Editorial	We suggest a change of a wording to be easy to understand that we get together.	We suggest replacing the text; Current text Manufacturers of Class B devices should have a quality management system that need not include design and development activities. Revised text; →Manufacturers of Class B devices should have a quality management system, however it not necessarily includes design and development activities.	Accept in principle Modify text to read: 'Manufacturers of Class B devices should have a quality management system, however, the procedures incorporated within it may not include design and development activities.'
25.	Page 9 / Section 5.1 / 8th Paragraph	Technical	The way to demonstrate evidence about design and development must give the manufacturer the option of its most appropriate organizational structure	….includes design and development. However evidence about design and development may also be obtained by product testing and control of each manufactured product or by statistical sampling.	Not accepted. New language inserted to address type examination (Section 5.1.1.). **Bookmarked** for discussion of product

					verification when this document is first revised. Comment will be carried over.
26.	Page 9 / Section 5.2 / Line 6	Technical	Add "for Class B, C & D devices" To make the requirement consistent with expected practice.	"For Class B, C & D devices, the RA or CAB will confirm that such a process is in place, usually at the time of the quality management system audit…."	Addressed through edit to Section 5.0 that refers to the Tables.
27.	Page 9	Technical	At the Gaithersburg meeting of SG1, the situation with regard to type examination (TE) has not been clarified to satisfaction. Wording should be introduced that indicates that TE should be available, but only at the choice of the manufacturer. No need or reason to restrict this to a particular risk class, except for class "D".	Insert a new section 5.3 after existing Section 5.2: "5.3 Type examination The manufacturer may choose to ask the RA or CAB to conduct a type examination to verify compliance to some or all of the relevant Essential Principles. Type examination involves evaluation and testing of representative sample(s) of the device, preferably according to the requirements of applicable recognized standards. Generally, a manufacturer will only opt for type examination when other methods are excessively cumbersome or expensive. If the manufacturer chooses to use type examination to verify compliance with some or all of the relevant Essential Principles, this will be indicated as such in the STED. The use of type examination does not replace the need to establish and maintain a QMS." Delete note under the table for Class "C". Modify the reference numbers in the tables of 6.2 accordingly.	Accepted in principle but not as written. Addressed through new text on type examination.

28.	Page 9 / Section 5.3 Summary technical documentation / 2nd paragraph	Editorial	Comment: Recommend to not restrict the use and application of a pre-market review to the STED. Rationale: Although harmonization is ideal, by making specific reference to the STED, then "obligates" RAs and industry to either reject or apply both GHTF initiatives (i.e. an "all or nothing" effect).	Recommend replacing all direct reference to STED with "STED or an equivalent quality, safety and performance summary dossier". AND Same recommendation for the Tables for Class B, C & devices on pages 13 to 15	Not accepted. The guidance on the STED is part of SG1's documents and is supported by them
29.	Page 10 / Section 5.4 / 8th indent	Editorial	Comment: recommend providing a rationale for the designation of "the responsible person …… ……. upon the manufacturer's behalf" Rationale: in the absence of instruction the manufacturers may designate this task inappropriately.	Recommend replacing the word "appropriate" before "the responsible person …… ……. upon the manufacturer's behalf" and provide clarification of who this would be.	Not accepted.
30.	Page 10 / Section 5.4 / Line 20	Technical	Nothing in Declaration of Conformity makes a statement that the Declaration of Conformity or contents of the STED are truthful and accurate.	Add bullet: The information contained Declaration of Conformity and STED are truthful and accurate.	Accepted with modified wording as follows:- Substitute "……an attestation that " with "…… a statement that"
31.	Page 10 L 40 to 41 Para 2 of 5.3	Technical	Add "to a Regulatory Authority or Conformity Assessment Body " after "submitted".	For the purposes of conformity assessment, the manufacturer will establish a subset of technical documentation to be held or submitted to a Regulatory Authority or Conformity Assessment Body as required by the class of the device.	Accepted
32.	Page 11 / New Section		While it establishes rules for when a Quality Management System (QMS) is required and rules for when and how extensively a regulatory authority (RA) or		This subject has been designated as a work item for GHTF Study Group 5 rather than SG1. They have started working on the task and will publish documents on the

			a conformity assessment body (CAB) must review a premarket submission, the document does not specify what level of clinical evidence is required. Nor, as we read them, do the STED document or the document on "Essential Principles of Safety and Performance of Medical Devices."		GHTF web site when such become available. The future revision of SG1 document on the STED document will address this subject, too.
33.	Pages 8 to10 / Sections 5.1 to 5.5	Editorial	We think that we had better fit the construction for clause with table in clause 6.2. Therefore, we suggest revising them.	We suggest replacing the construction for clause. Current 5.1Quality System 5.2 System for post market surveillance 5.3Summary technical documentation 5.4 Declaration of conformity 5.5 Registration/…… Our proposal 5.1Quality System 5.1.1 Quality System 5.1.2 System for post market surveillance 5.2 Device Safety and performance 5.2.1Summary technical documentation 5.2.2 Declaration of conformity 5.3 Registration/……	Accept since it will better align with the tables.
34.	Page 11, 6.1/lines 1+2	Editorial	For consistency, only the term "risk class" should be used; remove the term "group"	…be allocated to one of four risk classes….	Accept
35.	Page 11 / 6.1 Line 21	Technical		….believes to be most suitable. As part of conformity assessment elements, product testing and/or final control of manufactured products or of statistical	**Bookmarked** for discussion of product verification when this document is first revised. This comment will be carried over.

				samplings may constitute an alternative to full QMS.	
36.	Page 11 L 24 In Declaration of Conformity bullet 3	Technical	Add web reference to GMDN agency (www.gmdnagency.com) at end of bullet as new footnote	• The Global Medical Device Nomenclature (GMDN) code and term for the device < ***insert new footnote*** >	Accept.
37.	Page 11 All tables in the document	Editorial	Remove inverted comma's from table headings, viz. CLASS "A"		Accept
38.	Page 12 Class A Device	Technical	To be consistent with text used in §5.1 add "controls" after "design and development" in column 3 row 2	Establish and maintain a QMS **or** a QMS without design and development controls	Accept
39.	Class A Page 12/ declaration of conformity/ RA/CAB responsibility	Editorial		"may be required for market surveillance" instead of " normally not requested"	Agreed to use the following text in the table: "Submission normally not requested"
40.	Page 13 Class B Devices	Technical	To be consistent with text used in §5.1 add "controls" after "design and development" in column 3 row 2	Establish and maintain a QMS **or** a QMS without design and development controls	Accepted
41.	Page13 / Table B / Line 2	Technical	Establish and maintain a QMS or a QMS without design and development.	Delete:- "or a QMS without design and development"	Addressed through the modification to the text of Section 5.1.1.
42.	Class B		As an element of the quality system the verification of products is useful for small	Add in the Conformity Assessment Element column : - verification of	**Bookmarked** for discussion of product verification when this document is first

	Page 13 / QMS		manufacturers or for manufacturers producing a limited number of products	manufactured devices Add in column manufacturer responsibility : " or have a verification process by testing device individually or on a statistical method to demonstrate conformity to safety and performance requirements. For AC / CAB : "Assess the verification of devices."	revised. Comment will be carried over.
43.	Page 13, Table "Class B device"	Technical	Product verification (testing of the manufactured products, either of all products or on a statistical basis where appropriate) should be added as an alternative to the "product realization" part of the QMS. This conformity assessment procedure has shown its value in the EU in cases where a quality system is not or not yet effective, or where only small numbers of devices are produced.	In first column, new line: Alternatives to QMS/QMS sections In column "CA element": Product verification In column "Manufacturer responsibility": Get manufactured products tested (all or on a statistical basis where appropriate) by the RA or CAB for showing compliance with the Essential Principles of Safety and Performance. In column "RA/CAB Responsibility": Perform the necessary tests on manufactured products (all or on a statistical basis where appropriate) to show compliance with the Essential Principles of Safety and Performance.	**Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
44.	Page 13 and 14, Notes to Table for CLASS B And CLASS	Technical	See paper on Rationale for Type Examination – Type examination plus statistical assessment	Amend the text associated with the Conformity Assessment table for Class C Medical Devices to read:- Quality Management Systems may implement a full cycle of design and	Accepted in principle but not as written. Addressed through new text on type examination in Section 5.1.1.

	C DEVICES			development controls to ensure that medical devices comply with functional, performance and safety requirements, and the Essential Principles, as appropriate for the intended use. For products that are in existence at the time of imposition of a quality management system and Essential Principles by a regulator, a manufacturer would need to retrospectively generate technical documentation to satisfy each stage of the design and development cycle. In these circumstances, the manufacturer ***may*** request a RA or CAB, in jurisdictions where such is permitted, to conduct a type examination to verify conformity with the relevant Essential Principles and to establish a baseline for entry into the design and development cycle. Future increments to a design, or changes to product, originally assessed for conformity by Type Examination, or a new product, must be subject to the full design and development cycle of the Quality Management System.	
45.	Page 13 / Table C / Note under table	Technical	Note: At the option of the manufacturer, the manufacturer of Class C devices may ask the RA or CAB, in jurisdictions where such is permitted, to conduct a type examination to verify compliance to some of the relevant Essential Principles. The use of type examination does not replace the need to establish and maintain a QMS.	Establish and maintain a QMS Or Note: At the option of the manufacturer, the manufacturer of Class C devices may ask the RA or CAB, in jurisdictions where such is permitted, to conduct a type examination to verify compliance to some of the relevant Essential Principles. The use of type examination does not replace the need to establish and	Accepted in principle but not as written. Addressed through new text on type examination in Section 5.1.1. NOTE deleted.

			SG1 recognises that some Founding Members have permitted the use of type examination. In an effort to support harmonization, to discourage the inclusion of mandatory type examination in future regulations and to support other GHTF guidance documents, SG1 anticipates that type examination may not be offered as an option in future revisions of this guidance document.	maintain a QMS. SG1 recognises that some Founding Members have permitted the use of voluntary type examination by a manufacturer. In an effort to support harmonization, to discourage mandatory type examination by RA/CAB in future regulations and to support other GHTF guidance documents, SG1 anticipates that type examination may not be offered as an option in future revisions of this guidance document.	
46.	Page 14 – Table Class C - Note	Technical	See comment above re. Page 9 Section 5.1 paragraph 5.		Accepted - NOTE deleted.
47.	Page 14, Note to Table for CLASS C DEVICE	Technical	See paper from TGA – Rationale for Type Examination		Addressed through new text on type examination in Section 5.1.1.
48.	Page 14 / Note to Table C	Technical	Although the note attempts to somehow recognize that type examination may not be offered as an option in future documents, we recommend that reference to it should be eliminated entirely. One of the purposes of the GHTF is to design an appropriate harmonized regulatory system of the future—not to develop guidance documents that capture all the practices of current regulatory systems of the founding members. The GHTF has been a strong proponent of quality management systems (QMS) and the idea	Delete the note in its entirety.	Accepted - NOTE deleted.

			of mandatory type examination would seem to obviate the need for a QMS.		
49.	Page 14 / Note to Table C	Technical	Extensive argument offered for the retention of Type Examination as an option in future issues of the document	Nothing specific offered but it appears to be: delete the second paragraph of the Note to the Table for Class C devices	NOTE deleted entirely.
50.	Class C Page 14/ QMS	Technical	As an alternative to full QMS two elements may be used to demonstrate conformity to design, safety and performance requirements: - devices type examination - verification of manufactured devices	Add in the Conformity Assessment Element column : - devices type examination - verification of manufactured devices Add in manufacturer responsibility column: Have submitted device to a type examination complementary to a product or production quality system or complementary to a verification process obtained by testing device individually or on a statistical method to demonstrate conformity to design, safety and performance requirements. For AC / CAB : "Assess the devices type examination and the verification of devices."	Addressed through new text on type examination in Section 5.1.1. **Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
51.	Page 16 Class C Devices	Technical	The note for Class C devices has given the option to the manufacturer in jurisdictions where it is permitted to conduct a type examination to verify compliance to some of the relevant Essential principles.		Accepted - NOTE deleted

			It is recommended to remove this note because this document is being prepared with a view of where the GHTF would like to go in the future rather than reflect what is currently in the Regulations of the Five Founding Members of GHTF.		
52.	Class D	Technical	As an alternative to full QMS two elements may be used to demonstrate conformity to design, safety and performance requirements: - devices type examination - verification of manufactured devices	Add in the Conformity Assessment Element column : - devices type examination - verification of manufactured devices Add in manufacturer responsibility column : Have submitted device to a type examination complementary to a production quality system or complementary to a verification process obtained by testing device individually or on a statistical method to demonstrate conformity to design, safety and performance requirements. For AC / CAB : "Assess the devices type examination and the verification of devices."	Addressed through new text on type examination in Section 5.1.1. **Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
53.	Page 14, Table "Class C device"	Technical	Type examination by the RA or CAB should be added as an alternative to the "design and development part" of the QMS.. Type examination has proven its ability to	In first column, new line: Alternatives to QMS/QMS sections In column "CA element": Type examination	Addressed through new text on type examination in Section 5.1.

			show compliance of a product with all the design requirements long in history in various European and other countries.	In column "Manufacturer responsibility": If the QMS excludes design and development, get the products type examined by the RA or CAB In column "RA/CAB Responsibility": If the QMS excludes design and development, perform type examination to show compliance of the product design with the Essential Principles of Safety and Performance.	
54.	Page 14, Table "Class C device"	Technical	Product verification (testing of the manufactured products, either of all products or on a statistical basis where appropriate) should be added as an alternative to the "product realization part" of the QMS. This conformity assessment procedure has shown its value in the EU in cases where a quality system is not or not yet effective, or where only small numbers of devices are produced.	In first column, new line: Alternatives to QMS/QMS sections In column "CA element": Product verification In column "Manufacturer responsibility": Get manufactured products tested (all or on a statistical basis where appropriate) by the RA or CAB for showing compliance with the Essential Principles of Safety and Performance. In column "RA/CAB Responsibility": Perform the necessary tests on manufactured products (all or on a statistical basis where appropriate) to show compliance with the Essential Principles of Safety and Performance.	**Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
55.	Page 14, Table "Class	Technical	Product verification (testing of the manufactured products, either of all	In first column, new line: Alternatives to QMS/QMS sections	**Bookmarked** for discussion of product verification when this document is first

	C device"		products or on a statistical basis where appropriate) should be added as an alternative to the "product realization part" of the QMS. This conformity assessment procedure has shown its value in the EU in cases where a quality system is not or not yet effective, or where only small numbers of devices are produced.	In column "CA element": Product verification In column "Manufacturer responsibility": Get manufactured products tested (all or on a statistical basis where appropriate) by the RA or CAB for showing compliance with the Essential Principles of Safety and Performance. In column "RA/CAB Responsibility": Perform the necessary tests on manufactured products (all or on a statistical basis where appropriate) to show compliance with the Essential Principles of Safety and Performance.	revised. Comment will be carried over.
56.	Page14 6.2	Technical	<u>Rational 1</u> We think the GHTF regulatory model is intended the harmonized model based on QMS. We think that type examination is national deviation, and such deviation should not be described in the convergent regulatory system. We think that the possibility for the type examination as mandatory should be reduced. <u>Rational 2</u> National deviation is described in the final sentence of clause 7.0 "The Determination of Device Class using this Rules-based System" in SG1/N15 "Where special national rules are applied, resulting in a device class other than that	<u>We suggest deleting the note of the table for class C.</u>	Accepted – NOTE deleted.

			suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out." We should adjust to description for them.		
57.	Section 6.2, tables	Technical	There appears not to be a clear shared vision among Competent Authorities with regard to the concept of STED and its implementation. Therefore it is considered premature to prescribe to what extent premarket review is supposed to take place. Until the fundamental solution to this issue is reached, we propose to more carefully word the text in the relevant section of the tables, especially for devices of class B and class C.	In table for class "B" device, change "If submission is requested, receive and conduct a pre-market review of the STED sufficient to determine conformity to Essential Principles." into "If submission is requested pre-market, receive the STED and review it to determine if the Essential Principles have been considered sufficiently. A detailed review of the STED is normally not performed pre-market." In table for class "C" device, change "Conduct a review, normally premarket, of the STED sufficient to determine conformity to Essential Principles." into "Review STED to determine if the Essential Principles have been considered sufficiently. A detailed review of the STED is normally not performed pre-market."	Not accepted Current text was the outcome of much discussion to accommodate various views.

58.	Page 14/ Section 6.2/ Line not numbered	Editorial and Technical	JIRA believes the appropriate use of Type Examination is by independent private commercial bodies providing information for a manufacturers master file or design portfolio, which will eventually be reviewed and evaluated by Quality System. The GHTF should not advance in any fashion the use of Type Examinations by Regulatory Authorities or suggest Regulatory Authorities to require Type Examinations	Delete the "Note" under Class "C " Device on page 14.	Accepted – NOTE deleted.
59.	P 14, Note:	T	The National Electrical Manufacturers Association (NEMA) does not support the Note under the table for class "C" Device, page 14 of the document for type examination and recommends that it be completely removed. In making this recommendation, NEMA believes it should not be within the purview of a regulatory authority (RA) or its delegate to perform type examinations (T.E.). This procedure is tantamount to a RA providing design and functionality approval of a medical device to its manufacturer. This in itself encumbers a heavy legal, or if not legal, political burden on the RA. In some jurisdictions this might be viewed as a conflict of interest. NEMA believes the GHTF should be advancing the preferred procedures for regulating medical devices e.g., QS, STED, post market activities and etc. and not advancing procedures	Eliminate the note on Pg 14	Accepted – NOTE deleted.

			deemed archaic in most advanced regulatory systems. It is understood that the EU allows for T.E. by notified bodies. It does not necessarily follow that the EU would have to abandon T.E. if it approves SG1 (PD) N40 without the note. Nor would it follow that the U.S. would abandon a three-class for a four-class system if it approves SG1 (PD) N15. It is preferable the GHTF be silent on this point rather than advance a position contrary to the larger global harmonization model. NEMA does not disapprove of the use of T.E. It is done commercially extensively. Most manufacturers do not have EMC measuring capabilities at their plants, for example, and must have an EMC T.E. performed by a private commercial laboratory. These results would become part of the master file or design portfolio. Therefore, NEMA believes the appropriate use of T.E. is by independent private commercial bodies providing information for a manufacturers master file or design portfolio, which will eventually be reviewed and evaluated by an RA. The GHTF should not advance in any fashion the use of T.E. by RAs or suggest RAs to require T.E.s.		
60			we recommend that the note on page 14 of the conformity assessment document in regard to type testing be deleted. We do not believe it is appropriate for regulatory		NOTE deleted.

			authorities to conduct such testing.		
61	Page 15, Table "Class D device"	Technical	Type examination by the RA or CAB should be added as an alternative to the "design and development part" of the QMS (see table "class C device"). Type examination has proven its ability to show compliance of a product with all the design requirements long in history in various European and other countries.	See table "class C device"	Addressed through new text on type examination in Section 5.1
62	Page 15, Table "Class D device"	Technical	Product verification (testing of the manufactured products, all products or on a statistical basis where appropriate) should be added as an alternative to the "product realization part" of the QMS. This conformity assessment procedure has shown its value in the EU in cases where a quality system is not or not yet effective, or where only small numbers of devices are produced.	See table "class C device"	**Bookmarked** for discussion of product verification when this document is first revised. Comment will be carried over.
63			We suggest that it be made very clear in the conformity assessment document that for medical devices with a significant market history of safe performance (i.e. a large number of devices supplied over a number of years with low incidence of adverse events), manufacturers should not be required to undertake additional preclinical and/or clinical testing unless it can be demonstrated that the potential risks have not been adequately addressed by the market history of the device in question or by the market history of a device from another manufacturer to which equivalence can be shown.		The subject of clinical testing/evaluation has been designated as a work item for GHTF Study Group 5 rather than SG1. They have started working on the task and will publish documents on the GHTF web site when such become available. There is already reference to market history in Section 6.3