

**REPORT OF THE SG1 MEETING HELD ON
28/31st MARCH 2006 IN SYDNEY**

Attendees

Chair: Ginette Michaud
Vice-Chair: Benny Ons
Secretary: Alan Kent

North America

Mark Melkerson – FDA, USA
Michael Gropp – AdvaMed, USA
Nancy Shadeed - Health Canada, Canada
Brenda Murphy – MEDEC, Canada

Europe

Elke Lehmann – European Commission
Carl Wallroth – EUROM VI/EMIG
Johann Rader – European Commission

Asia/Australasia

Masaaki Tsukano – MHLW, Japan
Naoki Morooka – JFMDA/JIRA, Japan
Mike Flood – TGA, Australia
Johan Brinch - MIAA, Australia

Apologies

John Brennan – European Commission
Fred Halverson – AdvaMed, USA
Peter Linders – COCIR/EMIG

Observers

Shelley Tang – TGA, Australia
Rainer Voelksen – TGA, Australia (31 March)
Jorge Garcia – TGA

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 attendees and described the arrangements for the week. The meeting was held at the offices of Standards Australia. She thanked both the TGA for organising the venue for the meeting and MIAA for its contribution.

Mike Flood described arrangements for the meeting and thanked Johann Brinch/Cochlear Limited for the firms' Wednesday evening dinner invitation to mark Mr. Brinch's resignation from Study Group 1.

Apologies were reported as shown above.

2 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was noted. The meeting times on Friday will be from 8:00 to 16:00.

Additional items for the agenda are:

- Membership of SG1.
- Discussion of the GHTF Plenary Meeting in Lubeck.

- 3 Review of the notes of the meeting held in 13/15th September 2005 in Gaithersburg. (Document GHTF. SG1. NO57).

The meeting report was accepted without change.

- 4 To note the latest version of *Status of Active GHTF Study Group Work Programme SG1/N034R21 of 20 March 2006*

A latest revision SG1/N034 was circulated prior to the meeting.

The Secretary will update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) before the next meeting and reissue to members.

Action: Secretary

- 5 Review of comments received on *Principles of Medical Devices Classification SG1(PD)/N015 of September 15, 2005*

After the last meeting, the GHTF Steering Committee endorsed SG1's request to place this version of the document on the GHTF website and seek public comment. 81 comments were received and have been consolidated into a single list to aid discussion.

The meeting discussed each comment in turn. The outcome of the discussion is noted on the table of consolidated comments (originally dated 22 March 2006) and SG1/N015 will be modified as agreed by SG1 at the meeting in Sydney.

Action: Secretary

The following items were **bookmarked** for discussion when this document is first revised, rather than being incorporated at this time:

- The classification of contact lenses with respect to their long-term influence on the eye (comment 17).
- The development of a procedure for later reclassification of a device type (see comments 20, 33, 39 & 79).
- The classification issues that affect combination products (comment 41).
- Consider moving away from the current tabular presentation of the rules currently used in Section 8.0 if such would aid understanding (comment 46).
- Consider whether evidence has accumulated to support the downwards classification of absorbable sutures from Class D to C.
- Consider whether evidence has accumulated to support the downwards classification of diagnostic X-Ray devices (comment 61).
- Consider the classification of viable and non-viable tissues of either animal or human origin (comments 68 & 70)

- Consider the classification of cleaners of medical devices.
- Consider the classification of devices used in reproductive technologies.
- Consider the classification of devices intended for recording diagnostic images (comment 77).

The following item was **bookmarked** for discussion when GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term “Medical Device”* is first revised:

- The treatment of accessories (comment 26).
- Assisted reproductive technologies.

The only area where consensus was not achieved was the comment from JFMDA (and earlier from other manufacturers of such equipment) calling for the down-classification of X-Ray imaging devices. There was considerable discussion on this topic, as there has been at previous meetings, and views were explored in depth. JFMDA and COCIR do not agree with the outcome of the discussion, i.e. these devices remain in Class C, but agreed that the revised document should be moved forward to the Steering Committee. For her part, the Chair undertook to update the Steering Committee regarding the different viewpoints that remain.

Action Chair

It was agreed that the *Principles of Classification* document will be forwarded to the Steering Committee as a Proposed Final Document. The representative of Japanese industry continued to have reservations with some parts of the document (see above) and wished these to be reported but, none-the-less, would not stand in the way of this action.

Action Chair

To provide feedback to those who had commented on this document, the updated consolidated list of comments will be posted on the GHTF web site as an attachment to the meeting report, having removed the attribution to the source of each comment.

Action: Secretary

6 Review of comments received on *Principles of Conformity Assessment for Medical Devices, SG1(PD)/N040 of September 15, 2005*

After the last meeting, the GHTF Steering Committee endorsed SG1's request to place this version of the document on the GHTF website and seek public comment. 63 comments were received and have been consolidated into a single list to aid discussion.

The meeting discussed each comment in turn. The outcome of the discussion is noted on the table of consolidated comments (originally dated 22 March 2006) and SG1/N40 will be modified as agreed by SG1 at the meeting in Sydney.

Action: Secretary

21 of the 63 comments relate to type examination or product verification and varied between suggesting the elimination of the concept of type examination

from the document completely, to extending the concept beyond Class C to Class D devices. The discussion of this topic started with an analysis of type examination (what it is, where used, pros and cons) resulting in the following outcome:

- Type examination is a means of demonstrating compliance with relevant *Essential Principles of Safety and Performance of Medical Devices*. It is often confused with type, product or qualification testing of a device where the device is tested against the particular requirements of a technical standard.
- You need one or more representative units of the device to be examined (final prototype, representative of the production configuration, chosen by the manufacturer) and the relevant technical documentation which is likely to be more extensive than that required in the STED (e.g. electrical circuit diagrams) but does not include information on design features that were explored during product development but not incorporated into the final design.
- The documentation is examined for adequacy and the representative unit (the “type”) compared with the documentation to ensure there is consistency between unit and documents, using multi-disciplinary staff with relevant expertise (e.g. clinical staff to evaluate clinical evidence).
- The adequacy of any software validation and verification procedures would be examined, if relevant.
- The manufacturer has a responsibility to have the type examination repeated if the product’s design subsequently changes such that the examined “type” does not represent production units. Type examination becomes prohibitively expensive if the design of the medical devices changes regularly.
- Type examination does not exist on its own. The manufacturer has to operate a quality system within manufacturing to ensure production units continue to be represented by the “type” that was examined.
- Devices where some manufacturers choose type examination as their conformity assessment route include: stereo-tactic surgical equipment, fixation devices, vascular grafts, robotic surgical devices, angioplasty balloon catheters, uterine ablation catheters, dialysis machines, electrical stimulators, defibrillators, pacemakers. Some are significant manufacturers; some make this choice even though they operate a full QMS system that includes design control throughout their manufacturing facilities and consider this an additional assurance and, they are located within a variety of countries, not only Australia and the EU.
- Type examination should never be the only choice to demonstrate compliance of the device and should never be imposed on a manufacturer by a regulator but can be made available by the regulator as one of the options that the manufacturer may choose to demonstrate compliance.
- PROS proposed by discussants: third-party examination of the representative “type” and its documentation; access to technical and clinical competence within the Conformity Assessment Body; perceived value in the eyes of the public as a validation of the device by a third-party organisation; knowledge transfer between the industry and CAB.

- CONS proposed by discussants: absence of formally assessed design control; less suitable for software driven devices; not keeping up with regulatory trends towards using QMS with design controls rather than type examination; higher costs for the manufacturer because re-examination of the type is required when the design changes; limited expansion for the manufacturer to other devices placed on the market as each device requires type examination; limits the manufacturer to place devices into the markets that allow type testing; safety or performance problems identified during type examination are expensive to rectify since they occur late in the design and development cycle.

Johann Rader said that the EU Commission has revisited recently the conformity assessment options offered to manufacturers of medical devices, such as type examination, and decided these will be retained in the next version of the Medical Device Directive.

New language was agreed on type examination to be inserted into Section 5.1. It was accepted widely as an acceptable compromise between the different views expressed during discussion.

Dr. Carl Wallroth, the SG1 member representing European industry, expressed himself very satisfied with the new language.

The following items were **bookmarked** for discussion when this document is first revised, rather than being incorporated at this time:

- Definition of the term ‘manufacturer’ (comments 10, 11, 12 & 13).
- Product verification (comments 15, 25, 35, 43, 50, 52, 54, 55 & 62). The representatives of European industry and European and Australian regulators accepted this decision but would have preferred the subject to have been dealt with at this time.
- The conformity assessment of procedure packs.
- The conformity assessment of in-house manufactured devices.
- The conformity assessment of custom made devices.

It was noted that the sterility of Class A devices supplied sterile is addressed in the relevant table in Section 6.2.

JFMDA wanted to remove reference to type examination (comment 56) but accepted the modifications included into the document, including the insertion of new text: “Type examination should never be imposed on a manufacturer by a regulator”.

It was agreed that the *Principles of Conformity Assessment* document will be forwarded to the Steering Committee as a Proposed Final Documents.

Action Chair

To provide feedback to those who had commented on this document, the updated consolidated list of comments will be posted on the GHTF web site as an attachment to the meeting report, having removed the attribution to the source of each comment.

Action: Secretary**7 SG1 Membership**

The Chair described her strategy for identifying members of SG1 such that SG1 documents could be moved forward in an efficient manner. This had required membership numbers to be limited somewhat while remaining regionally representative of industry and regulators.

The representative of European industry suggested the Study Group should mirror Steering Committee membership. This would lead to an increased membership of SG1.

The representative of Japanese industry supported this suggestion and explained that one representative from industry could not cover the interests of all medical devices.

The representative of US industry said AdvaMed believed limiting the industrial representation to one per region was over restrictive.

The Chair made note of these views.

8 Report on the work of Study Group 5 (Clinical Evaluation)

Johan Brinch gave a report on the work of Study Group 5, of which he is a member, and progress to date.

A copy of his slides will be circulated to SG1.

Action: Secretary**9 Document Priorities and Timetable**

Four SG1 documents are posted on the GHTF web site as Final Documents:

- SG1/N012 *Role of Standards in the Assessment of Medical Devices* (18 November 1999)
- SG1/N29:2005 *Information Document Concerning the Definition of the Term "Medical Device"*
- SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*
- SG1/N43:2005 *Labelling for Medical Devices*

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	PRIORITY	TARGET FOR COMPLETION
<i>Principles of Medical Devices Classification</i>	SG1/N015	Proposed document, under consideration by the Steering Committee for	1	Final Document 2006 / Q3

		advancement as a Final Document.		
<i>Principles of Conformity Assessment for Medical Devices</i>	SG1/N040	Proposed document, under consideration by the Steering Committee for advancement as a Final Document.	1	Final Document 2006 / Q3
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N011	Proposed Document, under revision.	1	Final Document 2007 / Q2
<i>Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012</i>	SG1/N044	Proposed Document, under revision.	1	Final Document 2007/ Q2
<i>Principles of Classification of In Vitro Diagnostic Medical Devices</i>	SG1/N045	Working draft	2	Proposed document 2007 / Q2
<i>Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices</i>	SG1/N046	Working draft	2	Proposed document 2007 / Q2

Johan Brinch is stepping down from his involvement with SG1 since he has recently joined the GHTF Steering Committee. The Chair thanked Johan for his significant contribution to SG1 over the past few years.

Elke Lehmann was offered the congratulations of SG1 on climbing the Sydney Harbour Bridge.

The Chair closed the meeting by thanking participants for their constructive efforts in moving these documents forward.

10 Date and place of next meeting

- The GHTF Plenary Meeting will be held in Lubeck on June 29-30, 2006. There will be a meeting of the IVDD sub-group and the ad hoc working group on the Role of Standards on Sunday 25th. SG1 will meet on the 26th and 27th (9:00 to 17:00). The GHTF conference is on the 28/29/30th.
- Future meeting: 3rd to 6th October in Europe – details to be confirmed.
- Future meeting: 5th to 9th February 2007.
- Future meeting: April/May 2007 (joint SG meeting LA)
- Future meeting: September 2007 GHTF Plenary Washington DC

SUMMARY OF ACTIONS

For the Secretary

- To update *Status of Active GHTF Study Group Work Programme* (SG1/NO34) before the next meeting and reissue to members.
- To incorporate agreed comments within *Principles of Medical Devices Classification SG1/015* and reissue as a Final Document for endorsement by the Steering Committee.
- To incorporate agreed comments within *Principles of Conformity Assessment for Medical Devices, SG1/N40* and reissue as a Final Document for endorsement by the Steering Committee.
- To provide feedback to those who had commented on *Principles of Medical Devices Classification SG1/015* and on *Principles of Conformity Assessment for Medical Devices, SG1/N40*, the updated consolidated list of comments for both will be posted on the GHTF web site as an attachment to the meeting report, having removed the attribution to the source of each comment.
- A copy of the slides showing the work of Study Group 5 will be circulated to SG1.

For the Chair

- To update the Steering Committee regarding the discussion by SG1 of the proposed down-classification of X-Ray imaging devices.
- To seek the endorsement of the Steering Committee to *Principles of Medical Devices Classification SG1/015* as a Final Document.
- To seek the endorsement of the Steering Committee to *Principles of Conformity Assessment for Medical Devices, SG1/N40* as a Final Document.

Items bookmarked for discussion when *Principles of Medical Devices Classification SG1/N015* is first revised in about 2009,

- The classification of contact lenses with respect to their long-term affect on the eye (comment 17).
- The development of a procedure for later reclassification of a device type (see comments 20, 33, 39 & 79).
- The classification issues that affect combination products (comment 41).
- Consider moving away from the current tabular presentation of the rules currently used in Section 8.0 if such would aid understanding (comment 46).
- Consider whether evidence has accumulated to support the downwards classification of absorbable sutures from Class D to C.
- Consider whether evidence has accumulated to support the downwards classification of diagnostic X-Ray devices (comment 61).
- Consider the classification of viable and non-viable tissues of either animal or human origin (comments 68 & 70)
- Consider the classification of cleaners of medical devices. Consider the classification of devices intended for recording diagnostic images (comment 77).

- Consider the classification of cleaners of medical devices.
- Consider the classification of devices used in reproductive technologies.

Items bookmarked for discussion when GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term “Medical Device”* is first revised in about 2009:

- The treatment of accessories (comment 26).
- Assisted reproductive technologies.

Items bookmarked for discussion when *Principles of Conformity Assessment for Medical Devices, SG1/N40* is first revised in about 2009,

- Definition of the term ‘manufacturer’ (comments 10, 11, 12 & 13).
- Product verification (comments 15, 25, 35, 43, 50, 52, 54, 55 & 62). The representatives of European industry, and European and Australian regulators accepted this decision but would have preferred the subject to have been dealt with at this time.
- The conformity assessment of procedure packs.
- The conformity assessment of in-house manufactured devices.
- The conformity assessment of custom made devices.