

**SUMMARY REPORT OF THE SG1 MEETING HELD ON
5/6th OCTOBER 2004 IN LISBON**

Attendees

Europe

Maurice Freeman - Chairman
Alan Kent – Secretary
John Brennan – European Commission
Elke Lehmann – BfArM, Germany
Benny Ons – EDMA/EMIG
Peter Linders – COCIR/EMIG
Carl Wallroth – EUROM VI/EMIG
Johann Rader - TUV PS, European Conformity Assessment Body

North America

Ginette Michaud – FDA, Office of IVD Evaluation & Safety, USA
Nancy Shadeed - Medical Devices Bureau, Health Canada (Chair of IVDD sub-group)
Maria Carballo – Device Evaluation Division, Medical Devices Bureau, Health Canada
Brenda Murphy – SciCan/MEDEC, Canada
Fred Halverson – AdvaMed, USA
Michael Gropp – AdvaMed, USA

Asia/Australasia

Atsushi Kawahara – MHLW, Japan
Katsuhisa Ide – PMDA, Japan
Naoki Morooka – JFMDA/JIRA, Shimadzu Corp.
Michiko Masaka – JFMDA, Japan
Masaaki Naito – JFMDA, Japan
Hiroshi Ishikawa – JFMDA, Japan
Tsuneo Ohaku – JACR, Abbott, Japan (invited expert on IVDDs)
Yoko Ikeda – JACR, Japan (invited expert on IVDDs)
Hideki Asai – Hitachi, Japan (invited expert on IVDDs)
Mike Flood – TGA, Australia

Apologies

Johan Brinch - MIAA, Australia
Shelley Tang – TGA, Australia
Petra Kaars-Wiele - EDMA/EMIG, Abbott (invited expert on IVDDs)
Masato Yoshida – JFMDA, Japan

Observers

Robert Britain - NEMA, USA
Ronda Balham – FDA, International Affairs

1 Welcome to the meeting and introduction of delegates

The Chairman welcomed attendees to the meeting and thanked INFARMED for offering their facilities in Lisbon for the meeting.

Apologies were reported as shown above.

2 Review of the notes of the meeting held in Canberra on 18/19th February 2004. (Document GHTF SG1. NO54 of 23rd Feb 2004).

The minutes were accepted without change.

3 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was noted.

4 To note the latest version of Status of Active GHTF Study Group Work Programme SG1/N034R18 of 25 September 2004

A latest revision SG1/N034 was circulated prior to the meeting. There were no comments upon it.

5 Report of outcomes from Steering Committee meeting held on 28th – 29th of June 2004 in Paris.

The Chairman reported briefly on the meeting.

Dr Graham Harris of TGA was asked to chair a new GHTF Study Group 5 to focus on clinical evidence.

The appointment of Study Group chairs was reviewed and Maurice Freeman will retire from SG1 Chair during May 2005 to be replaced by Ginette Michaud of the FDA. Two of the other Study Groups will have new Chairmen during 2005. The proposal for a new SG1 work item on Registration and Listing was deferred.

SG1 asked for its congratulations to be passed to Dan Schultz on his recent promotion to Centre Director at CDRH.

The next full meeting of the GHTF Steering Group is during May 2005 in Seville. In November 2004 there will be a telephone conference.

6 Summary by In Vitro Diagnostic devices sub-group of discussions at meeting held on 4th October 2004.

The chairperson of the sub-group, described progress made during the meeting. The latest draft *Principles of IVD Medical Devices Classification (SG1/NO45R4 of February 17th 2004)* was discussed and revised. It will be sent to SG1 members when it has been updated.

The next subject to be worked on is IVD Conformity Assessment.

7 Discussion on Comments Received on document *Labelling for Medical Devices SG(PD)/N043R6 of February 19th 2004*

The Secretary described changes to the Introduction, most of which were to bring it into alignment with other SG1 documents. Similar changes have been introduced to other documents which will be discussed later in the meeting.

Comments from the European Commission, BfArM, FDA, Canadian Industry and EDMA were discussed and, where agreed, incorporated into the Labelling document which was revised to SG(PD)/NO43R7.

Editorial comments regarding sub-division of Section 5.2 will be considered outside the meeting.

The new text referring to the use of electronic labelling will be prepared by a sub-group and circulated to SG1.

The IVDD sub-group will consider the BfArM comment on the language used in Section 5.2(ab).

FDA will provide a definition of 'reprocessed device' for consideration.

A highlighted copy of the revised document was circulated to attendees.

8 Review comments on *Medical Devices Classification - SG1/N015R22*

Comments from BfArM, Japanese Industry, AdvaMed, the Cooke Group, NEMA, MDMA, Abbott and the FDA were discussed and, where agreed, incorporated into the Classification document which was revised to SG(PD)/N015R23.

Since many of the comments referred to the classification of X-Ray diagnostic devices, there was a long discussion on the subject.

The Australian Regulator emphasized that TGA's concerns was that, in its opinion, the conformity assessment procedures for a Class B device were inadequate for X-Ray diagnostic devices.

The Chairman pointed out that the lack of agreement on this subject is delaying progress of this document. The Chairman proposed a note be added to Rule 10 of the document explaining that classification of these devices will be reconsidered after SG1 has made progress with conformity assessment.

It was suggested that having introduced the concept of using historical knowledge and experience to justify a different risk class (higher or lower) for a device from that suggested by the rules, that the existence and use of standards was one factor to be taken into account. A paragraph explaining this concept will be drafted for inserting into the document

SG1 documents use two definitions for 'intended use'. There was discussion about which was better. A request for this to be discussed at the next meeting of TC210 will be sent to industry and FDA representatives.

The meeting discussed FDA's comment on the use of the term 'risk'. Others were not convinced by the argument put forward and remained convinced that classification was 'risk-based'.

The GHTF Steering Committee will be asked whether the new revision of this document can be put onto the GHTF Web Site in order to demonstrate progress on other aspects.

9 Review comments on Information Document on "Definition of the term Medical Device" – SG1/N029R13

Comments from AdvaMed, NEMA and FDA were discussed and, where agreed, incorporated into the Classification document which was revised to SG(PD)/N029R14.

The need for a definition of 'finished medical device' will be considered under conformity assessment.

There was considerable discussion of whether components should be referenced within the document. A note was added to cover this subject.

A revised copy of the document will be circulated.

Unless there is a significant disagreement to the new revision by 6 November 2005, the document will be forwarded to the GHTF Steering Committee as a Final Document.

10 Review comments on SG1/N041R6 Essential Principles (including IVD's)

Comments have been received from AdvaMed and the FDA. These will be considered by the Chairman and Secretary outside this meeting and a revised document circulated to SG1.

11 Report by SG1 sub-group and discussion of comments on Summary Technical Documentation (STED) - SG1/N11R17.

Peter Linders reported on the outcome of the sub-group meetings. He did not believe many manufacturers were using the STED. Was that because the text was inadequate and should be revised or was it because manufacturers would not use a document of this type, whatever it said? The sub-group was thanked for its work.

Relatively few comments have been received on the STED e.g. those from AdvaMed, Michiko Masaka and the FDA.

In July, the FDA announced they were extending their pilot scheme to 'test' the adequacy of the STED for a second year.

Japanese guidance on the use of the STED will be circulated.

12 Review comments on *SG1/N044R4 – Role of Standards*

Comments have been received from COCIR, ASTM and the FDA. These will be considered by the Chairman and Secretary outside this meeting and a revised document circulated to SG1.

13 Discussion of the revised document: *Principles of Conformity Assessment for Medical Devices (SG1 / NO40 R10 of MAY 18th 2004)*

Comments from Japan were discussed.

The first suggestion was that the option of using type testing should be deleted (Section 6.2). The proposal was supported by the FDA but not supported by TGA or European regulators. The latter said that although this technique was applied rarely, it was acceptable to regulators because the outcome was similar to products designed under a full quality management system.

It should be noted that European regulations were the outcome of a successful harmonization process across many independent National States and the acceptance of Type Testing as an alternative to design control within a quality management system had helped to achieve consensus. Regulators from countries that were unfamiliar with type testing, such as the UK, had found that medical devices following a type-testing route to conformity assessment were as satisfactory as those using full quality management systems.

The Chair thanked Japan for its document which was valuable, but indicated that the table indicating the differences between the appropriate level of assessment for each of the four classes, was no longer indicating such steps and instead indicated unanimity of requirement for all classes except for Class A.

After discussion it was agreed that there were many other concepts not addressed in the table and which should be included as part of the identification of the appropriate level of documentation needed in relation to differing classes of device, and as affected by other factors such as historical knowledge, particular internationally acceptable standards, similarity to other devices which might preclude the need for new clinical investigations.

It was perceived that this created a clear association with matters needed similarly in applying the STED document. There is clearly a cross reference needed between documents on Risk Class, Conformity Assessment and STED.

The Chair indicated that he will discuss this with others and offer suggestions, and others were invited to input to this discussion. The value of a pictorial representation by using an improved table was considered to be important when interpreting needs.

14 Document Priorities and Timetable

SG1 has prepared three final documents:

- SG1/N020 *Essential Principles of Safety and Performance of Medical Devices* (30 June 1999)
- SG1/N009 *Labelling for Medical Devices* (18 November 1999)
- SG1/N012 *Role of Standards in the Assessment of Medical Devices* (18 November 1999)

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 - comments reviewed.	1	Further progress awaits advancement of Conformity Assessment document.
<i>Principles of Conformity Assessment for Medical Devices</i>	SG1/N040	Revised Working Draft to incorporate comments from SG1 membership.	1	2005 / Q4
Pilot testing of <i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N011	Pilot started 2002 Q1 in some regions. Extended to mid-2005 in USA	1	2005 / Q3
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N011	Proposed Document - comments reviewed.	2	2005 / Q2
<i>Information Document Concerning the Definition of the Term "Medical Device"</i>	SG1/N029	Proposed Document - comments reviewed.	2	2005 / Q1
<i>Labelling for Medical Devices - Revision of SG1/N009</i>	SG1/N043	Proposed Document - comments reviewed.	3	2005 / Q3
<i>Essential Principles for Safety and Performance of Medical Devices – Revision of SG1/N020</i>	SG1/N041	. Proposed Document - comments reviewed.	3	2005 / Q2
<i>Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012</i>	SG1/N044	Proposed Document - comments reviewed.	3	2005 / Q2
<i>Classification of In Vitro Diagnostic Devices</i>	SG1/N045	Working Draft circulated to	4	2005 / Q4

		SG1		
<i>Premarket Conformity Assessment for In Vitro Diagnostic Devices</i>	SG1/N046	Sub-group preparing first draft	4	2005 / Q4

15 Date and place of next meeting

SG1 will meet on 21/22/23/24 February 2005 in Europe. Exact date and venue to be confirmed.

There is a meeting of all the Study Groups in Washington during September 2005.