REPORT OF THE SG1 MEETING HELD ON 21/24th FEBRUARY 2005 IN MORGES

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
Barbara Staehelin - EDMA/EMIG, Abbott (invited expert on IVDDs)

North America
Ginette Michaud – FDA, USA
Mack Melkerson – FDA, USA
Nancy Shadeed - Medical Devices Bureau, Health Canada (Chair of IVDD sub-group)
Brenda Murphy – SciCan/MEDEC, Canada
Fred Halverson – AdvaMed, USA

Asia/Australasia
Atsushi Kawahara – MHLW, Japan
Tomonori Nakayama – PMDA, Japan
Naoki Morooka – JFMDA/JIRA, Shimadzu Corp.
Michiko Masaka – JFMDA, Japan*
Masaaki Naito – JFMDA, Japan
Mike Flood – TGA, Australia
Johan Brinch - MIAA, Australia

Apologies

Michael Gropp – AdvaMed, USA
Tsuneo Ohaku – JACR, Abbott, Japan (invited expert on IVDDs)
Shelley Tang – TGA, Australia
Maria Carballo – Device Evaluation Division, Medical Devices Bureau, Health Canada, (invited expert on IVDDs)
Petra Kaars-Wiele - EDMA/EMIG, Abbott (invited expert on IVDDs)

Observers

Yoko Ikeda – JACR, Japan (invited expert on IVDDs)

1 Welcome to the meeting and introduction of delegates

The Chairman welcomed attendees to the meeting and thanked Fred Halverson for making MEDTRONIC's facilities in Morges, Switzerland available for the meeting.

Apologies were reported as shown above.

2 Review of the notes of the meeting held in Lisbon on 5/6th October 2004. (*Document GHTF SG1. NO55 of 28th Oct 2004*).

The minutes (meeting reference X1) were accepted after noting that 4 attendees shown as members of SG1 were actually observers; they were Hiroshi Ishikawa, Tsuneo Ohaku, Yoko Ikeda and Hideki Asai.

3 Adoption of Agenda and discussion of procedures for this meeting

The Agenda (meeting reference X2) was noted.

4 To note the latest version of *Status of Active GHTF Study Group Work Programme SG1/N034R19 of 27 January 2005*

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

5 Summary of status of work items from In Vitro Diagnostic devices sub-group and identification of documents to be discussed later in the meeting.

The Chairperson of the sub-group, described progress made during a recent meeting of the IVD sub-group. The latest draft *Principles of IVD Medical Devices Classification (SG1/NO45R7 of February 1st 2005*) has been revised and circulated. It will be discussed later in this meeting.

The continuing development, by the IVDD Expert Subgroup, of the Working Draft document, *"Principles of Conformity Assessment for IVDDs"*, was noted.

6 Review edited version of *Principles of Medical Device Classification – SG1(PD)/N015R23 dated 19th December 2004*

It was reported that a European Experts Group had rejected a proposal from industry to modify the European Directive by changing the classification of diagnostic X-Ray equipment in a manner similar to that discussed at previous SG1 meetings.

Comments on SG1(PD)/N015R23 have been received from JFMDA and from MIAA.

The former was an editorial change that was accepted and will be incorporated in the next revision.

The comment from MIAA concerning the definition of "central circulatory system" was discussed. The objective was to seek a more harmonised definition world-wide. It was agreed that the RA representatives will check with their medical experts as to whether the revised definition is acceptable to them for use in a GHTF document. They will report the outcome to the Secretary and Chair by 1 May 2005 and, if agreed, the suggested changes will be incorporated into the document

The suggested revised definition is:

> **Central circulatory system:** For the purpose of this document, `central circulatory system' means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aortic arch and the thoracic and abdominal aorta, inferior and superior vena cava.

It is proposed to ask the GHTF Steering Committee whether the revised document could be placed on the web-site as an "Edition 2" for public comment.

Whatever the decision, it was agreed that the next stage was to review SG1(PD)/N015 in conjunction with the Conformity Assessment document, to assess how these two guidelines, in combination, direct the premarket oversight of medical devices.

It was noted that this document does not provide for a process to modify classification rules, other than the general amendment possibility for any GHTF publication. It was agreed that a proposal to address this problem will be developed by a representative of US industry (possibly also applicable to the IVD classification document (SG1 N045)) and circulate to SG1 by end July 2005, for discussion at the meeting in Washington scheduled for September 2005. It was suggested that the use of different Conformity Assessment procedures be proposed, rather than changes to the rules under which the subject devices are classified.

7 Information document *"Definition of the term Medical Device" SG1(PD)/ N029R15 dated 3rd December 2004*

A comment has been received from MIAA. This was discussed but not accepted.

Editorial changes were made to the text to assist understanding.

It was noted that this document had been submitted to the Steering Committee as a Final Document. The edited version will be substituted for it.

A copy of the revised document was circulated at the meeting and will be e-mailed to attendees, too.

8 Review edited version of *Labelling for Medical Devices (revised) – SG1/ N043R7 dated 14th October 2004*

The meeting reviewed the suggested changes submitted by the IVDD sub-group and modified the document as appropriate.

A highlighted copy of the revised document was circulated to attendees as a "work-in-progress" item.

FDA has provided a definition of 'reprocessed device' that will be incorporated within the document.

It was agreed that the document be sent to the GHTF Steering Committee as a proposed Final Document.

9 Discuss revised document *Principles of Conformity Assessment for Medical Devices – SG1/N040R11 dated 28th January 2005* – Document edited by Chair/Sec as agreed at last meeting

The comment submitted by JFMDA that suggested the Tables in Section 8.3 be deleted was discussed. Other SG1 members believed the presence of the table 8.3 was essential to this document.

In response to the Japanese delegation's request to substitute Section 8.3 for more detailed guidelines for each device class, it was decided that such guidance would more appropriately appear in a revised STED guideline.

The FDA and Health Canada submitted an alternative version of Section 8.3 to that circulated prior to the meeting (meeting reference X9). This was seen as an improvement and was the subject of detailed discussion. During the meeting a revised version of the tables was circulated and further changes incorporated.

The rest of Section 8 was discussed and the document modified as agreed. A revised copy was handed out to attendees.

Further changes were made with respect to some editorial points and a change to the Tables in Section 8.3 in respect of Technical Documentation for Class B, C and D devices.

Whether or not the document was sufficiently advanced to be subject to public comment was discussed. or whether that should be delayed until after the next meeting. However, since the Steering Committee require 6 weeks to consider a proposed document before it is placed on the web-site for 3 months, there is insufficient time to ready the Conformity Assessment guidelines for Steering Committee review in advance of its next meeting. The Secretary will circulate an updated electronic version of this document.

A subgroup of SG1 will meet in advance of the September meeting to further refine the Conformity Assessment document. The revised document will be

circulated for comment to the full Study Group 1 as well as the other GHTF study groups prior to the September meeting in Washington.

10 Review revised document *Role of Standards in the Assessment of Medical Devices (revised) – SG1(PD)/ N044R5 dated 3rd December 2004*

An SG1 sub-group will compare the document with a recent draft document from ISO (*TR 16142:2004 Medical Devices – Guidance on the Selection of Standards in Support of the Recognized Essential Principles of Safety and Performance of Medical Devices*)and suggest changes to bring them closer together. The subgroup will also develop recommendations for marketed devices previously developed in accordance with a recognized standard, which has since been withdrawn or replaced by a newer version of the standard. The sub-group's comments will be circulated to SG1 prior to the next meeting.

The 5th comment from the FDA, tabled before the last meeting, will be incorporated.

Editorial comments from Japan will be incorporated.

The Secretary will e-mail a revised version of the document to SG1.

11 Review the document *Essential Principles of Safety and Performance of Medical Devices (revised) – SG1/N041R7 dated 3rd December 2004*

The only comment received on the latest document has been received from a representative of US industry who questioned the definition of intended use / intended purpose.

FDA requested that, for consistency, the same definition of "intended use/purpose" appear in the Essential Principles, Classification and Labelling documents. It was further proposed and agreed that the definition which appears in the Essential Principles document be retained as the definition in all three guidelines.

The latest version of the document was discussed and the document modified as agreed.

It was agreed that the document be sent to the GHTF Steering Committee as a proposed Final Document.

The revised definition of "intended use" will be sent to TC 210 for their consideration.

12 To note edited document *Summary Technical Documentation for Demonstrating Conformity to the Essential Performance of Medical Devices – SG1/N11/R18 dated 1st October 2004*

Draft guidance on the use of the STED in Japan will be circulated since it will become mandatory shortly.

The USA pilot project will be extended for a further 12 months. The FDA receives few applications that use the STED.

Industry representatives are urged to promote the STED through their Associations.

13 Compilation of Definitions used by SG1

This document (SG1/N047R5) will be updated by the Secretary before the next meeting and shared with other Study Groups to ensure consistency of definitions within GHTF.

14 Review Progress of *The Principles of IVD Medical Devices Classification – SG1/N045/R7 of 1 February 2005*

The latest revision was discussed by SG1. Suggested changes will be discussed at the next sub-group meeting and incorporated if agreed.

The Chairman congratulated the IVD sub-group on the progress made with this document.

15 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
Principles of Medical Devices Classification	SG1/N015	Further progress awaits advancement of Conformity Assessment document.	1	2006/Q1
Principles of Conformity Assessment for Medical Devices	SG1/N040	Revised Working Draft completed should be available for public comment after September meeting.	1	2006 / Q2
Pilot testing of *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)*	SG1/N011	Pilot started 2002 Q1 in some regions. US pilot extended for a further year.	1	2006 / Q2
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)	SG1/N011	Proposed Document.	2	2005 / Q4
Information Document Concerning the Definition of the Term "Medical Device"	SG1/N029	Proposed to Steering Committee as Final document	2	2005 / Q3
Labelling for Medical Devices - Revision of SG1/N009	SG1/N043	Proposed to Steering Committee as Final document	3	2005 / Q3
Essential Principles for Safety and Performance of Medical Devices – Revision of SG1/N020	SG1/N041	Proposed to Steering Committee as Final document	3	2005 / Q3
Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012	SG1/N044	Proposed Document - comments reviewed.	3	2005 / Q4
Classification of In Vitro Diagnostic Devices	SG1/N045	Working Draft discussed by SG1	4	2006 / Q2
Premarket Conformity Assessment for In Vitro Diagnostic Devices	SG1/N046	Sub-group preparing first draft	4	2006 / Q4

16 Retirement of Maurice Freeman as Chairman of SG1

This meeting marked the handing over of the Chairmanship of SG1 from Maurice Freeman to Ginette Michaud. Ginette paid tribute to the patience and skill Maurice had demonstrated while leading the work of SG1 and said the quality of the documents written by the Study Group would stand as a tribute to his considerable accomplishments. A presentation was made to mark the occasion.

Maurice Freeman thanked SG1 members for the support they had given him and wished them well with their future work programme.

17 Date and place of next meeting

The IVD sub-group will meet in Washington on 12 and 13th September and the full SG1 on 14 and 15th September with joint Study Group meetings on 16th September.

The GHTF Plenary Meeting will be held in Lubeck on June 29-30, 2006. SG1 meetings could be held from Sunday 25 June to 28th (to be confirmed).

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