

**REPORT OF THE SG1 MEETING HELD FROM 7<sup>th</sup> TO 10<sup>th</sup> FEBRUARY, 2011  
IN LONDON, UK**

**Attendees**

Chair - Nancy Shadeed  
Vice-Chair - Benny Ons  
Secretary - Alan Kent

**North America**

Mark Melkerson – FDA, USA  
Brenda Murphy – MEDEC, Canada  
Michael Morton – AdvaMed, USA

**Europe**

Peter Bischoff-Everding – European Commission  
Peter Linders – COCIR/EMIG  
Alan Green – EUROM VI/COCIR

**Australia/Japan**

Atsushi Tamura – PMDA, Japan  
Naoki Morooka – JFMDA, Japan  
Tomomichi Nakazaki – JFMDA, Japan  
Kentaro Azuma – MHLW, Japan  
Gary Burgess – TGA, Australia  
Cliff Spong – MIAA, Australia

**AHWP**

Meshal Al Amri – Saudi Food and Drug Authority, KSA  
Lindsay Tao – J&J, China

**Apologies**

Daphne Yeh – AHWP, Industry representative, Chinese Taipei/AHWP  
Huifen Bai – AHWP, Health Sciences Authority, Singapore  
Gert Bos – EU Notified Body Group (Observer)

**Observer**

Jun Kitahara - PMDA, Japan

**1 Welcome to the meeting and introduction of delegates**

Nancy Shadeed, Chair of SG1, welcomed SG1 members to the meeting in London and thanked ABHI for hosting the meeting.

Mike Kreuzer welcomed SG1 to the ABHI offices and described the purpose and structure of ABHI.

The Chair welcomed Alan Green to his first meeting and Jun Kitahara as an observer from Japan.

Apologies of absence have been received from Daphne Yeh, Huifen Bai and Gert Bos.

2 **Adoption of Agenda and discussion of procedures for this meeting**

The Agenda was approved after adding an opportunity to update SG1 on any significant changes to the regulations in GHTF Founding Member jurisdictions

3 **Review of the report of the SG1 meeting held from 5<sup>th</sup> to 8<sup>th</sup> October, 2010 in Santa Rosa (Document GHTF. SG1. N81 of 8<sup>th</sup> November 2010) and review of action items**

The Santa Rosa Meeting Report was circulated prior to the meeting. It was approved without change.

Meeting actions were reviewed. All actions have been completed.

4 **Review of SG 1 accomplishments**

**GHTF/SG1/N063:2011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)*** still awaiting Steering Committee endorsement as described in the IVD subgroup report to the meeting

**SG1(PD)/N068R04 *Essential Principles of Safety and Performance of Medical Devices (revised)*** has been forwarded to the Steering Committee for endorsement as a Proposed Document for public comment.

**SG1(PD)/N070R08 *Label and Instructions for Use for Medical Devices (revised)*** will be discussed later in this meeting.

**SG1(WD)/N071R02 *Information Document Concerning the Definition of the Term "Medical Device" (revised)*** has been forwarded to the Steering Committee for endorsement as a Proposed Document for public comment.

**SG1/N077R01 *Principles of Medical Device Classification (revised)*** will be discussed later in this meeting.

**SG1/N034 *Status of GHTF Study Group 1 Work Programme*** and the **SG1 Work Plan** will be updated before the next meeting.

**Action: Secretary**

5 **Report from the In Vitro Diagnostic Medical Devices Subgroup (IVD MD Subgroup)**

A report on the activities of the sub-group was circulated prior to the meeting. The Chair described the discussions between the Steering Committee and the subgroup regarding the unresolved aspects of GHTF/SG1/N063:2011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)*.

A draft document entitled *Procedure for the Movement of Documents between the IVD Subgroup and Study Group 1* was circulated prior to the meeting. It was reviewed briefly and

some modifications suggested. These will be incorporated and the revised document circulated to SG1 and the IVD subgroup for comment.

**Action: Secretary and Shelley Tang to the IVD subgroup**

SG1 and subgroup members will review the document and send any further comments to the Secretary with a copy to the Chairs of both SG1 and the IVD subgroup by 1<sup>st</sup> May.

**Action: SG1 & IVD subgroup**

## 6 Update on the Work of the Steering Committee

A report on the activities of the Steering Committee was circulated prior to the meeting.

In addition, it was reported that SG4 has been disbanded and transferred to 'maintenance mode'.

The Steering Committee next meets - 11 March 2011 (telecom) & 11/13 May 2011 Brisbane & 4/6 October Tokyo. Any SG documents must be submitted 60 days earlier than these dates.

## 7 Regulatory Update

### USA

- FDA have a large change programme for 2011 (link through Ctrl + click to: [CDRH Plan of Action for 510\(k\) and Science and Related Documents](#)).
- Some movement towards GHTF guidance documents.
- User Fee negotiations are in progress. Mark to provide a link to website.

### EU

- The major task for 2011 is the revision of the 3 medical device directives.
- Adoption of proposal by Commission target Q1 2012.
- Issues same as in Santa Rosa. Working on e-labelling guidance for Instructions for Use on certain devices.
- Modifying IVD Annex to add 'CJD assays'.
- Aim to publish guidance on software by end May.

### Australia

- Consultation on modifying the medical device regulations to reclassifying certain partial and whole orthopaedic joints has been taken. Surgeons and industry appear supportive. The reclassification will be in line with action taken in the EU previously.

### Canada

- New User Fees may be implemented in April 2011.

- Published document entitled *Electronic Labelling (e-labelling) of certain medical devices sold or imported into Canada* on 9 November 2010.
- Published *Software Regulated as a Medical Device - Frequently Asked Questions* on 24 January 2011.

#### **Japan**

- No significant change

#### **8 Report from the Asian Harmonization Working Party**

A report on the activities of the AHWP was circulated prior to the meeting.

Meshal and Lindsay updated the meeting further on progress within the AHWP and the jurisdictions it represented by way of a presentation. The presentation will be circulated to SG1.

**Action: Secretary**

#### **9 GHTF/SG1(PD)/N070 Label and Instructions for Use for Medical Devices (January 29, 2010)**

The version of the document incorporating changes made by the IVD subgroup together with editorial changes was circulated to SG1 prior to the meeting. Three further matters were discussed.

- a) Clarification of the text which refers to the situation where the Instructions for Use are supplied in a medium other than paper.
- b) The requirement to indicate the method of sterilisation, where relevant.
- c) Providing labelling information to support UDI.

The document was modified as agreed. The revised version and updated comments template will be forwarded to the Steering Committee for endorsement as a Final Document.

**Action: Chair**

The revised version will be copied to SG1 and the IVD subgroup.

**Action: Secretary**

#### **10 SG1(PD1)/N077R01 Principles of Medical Devices Classification (revised)**

Prior to the meeting, a document with revised text for Section 5.0 was circulated to SG1. This was discussed at some length. While many seemed to accept the principle of using 'potential for causing harm' rather than 'risk', some of SG1 appeared uncomfortable with this change. It was agreed to add an introductory sentence to 'link' new text to the concepts described in the previous document.

**Action: Chair / Vice Chair / Secretary**

Any written comments/suggestions on the revised text for Section 5.0 should be forwarded to the Secretary.

**Action: SG1**

Classification of diagnostic X-ray devices

An 'evidence-based' justification for the 'down-classification' from C to B of diagnostic X-ray devices was made by the Japanese industry representative. During the discussion that followed, SG1 asked for additional information on 'worst case' situations for both patients and operators. It was noted that the regulators present appeared reluctant to agree to the change.

**Action: Peter Linders / Naoki Morooka**

Classification of orthopaedic implants

The comment from the TGA requesting the upward classification of orthopaedic implants was discussed. The Australian proposal covers hip, knee and shoulder replacement implants, whether total or partial. Reclassification would result in the product being subject to premarket design evaluation by the RA/NB; also, design changes would be subject to regulatory review.

It was reported that while Health Canada has not reclassified such devices, it does subject them to additional conformity assessment controls. MHLW would not support the change.

After discussion, the comment was not agreed.

Classification of disinfectants and disinfecting equipment

The review of comments on Rule 15 led to a long discussion on the classification of different devices.

It was agreed that the text should differentiate between sterilisation and disinfection in line with professional publications on this subject.

The difficulty of removing prions from contaminated medical devices was noted.

When SG1's guidance document was originally drafted it followed EU legislation and the majority of disinfection devices were Class B. However, in response to a comment from the TGA, the classification was raised to Class C and this change was incorporated into the Final Document GHTF/SG1/N15:2006. Subsequently the EU has modified its classification to differentiate between the disinfection of invasive and non-invasive medical devices, using the words:

*All devices intended specifically to be used for disinfecting medical devices are in Class IIa [i.e. GHTF Class B] unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb [i.e. GHTF Class C].*

After further discussion the text of SG1's document was modified.

The Secretary will ensure the diagrams are modified as required to match the revised text. The edited version of the guidance document will be circulated to SG1 for final review noting that the decision on the classification of diagnostic X-Ray devices will be made at the next meeting.

**Action: Secretary**

SG1 members are asked to review the document and email any comments to the Secretary and Chair by end April.

**Action: SG1**

#### 11 **Revision of SG1/N40:2006 Principles of Conformity Assessment for Medical Devices**

Prior to the meeting the guidance document was circulated together with comments bookmarked in 2006 for discussion when it was first reviewed.

After discussion it was agreed there was no need to take particular account of either 'custom-made' or 'in-house' devices.

Text will be drafted with respect to conformity assessment of procedure packs.

**Action: Gary Burgess**

The text in Section 5.1.1 on type examination was reviewed. While there was no agreement to delete all reference to type examination at this stage, it was agreed to add a 'Request for Public Comment' to the document as follows:

**REQUEST FOR PUBLIC COMMENT** - While acknowledging that some GHTF Founding Member jurisdictions currently permit alternatives to a full QMS, GHTF recommends a manufacturer incorporates its design and development activities into its QMS rather than relying on type examination, control of each manufactured product, or statistical sampling, to demonstrate conformity with relevant regulatory requirements. One justification for this preference is that experience has shown that regulators in jurisdictions introducing regulations for the first time mistakenly interpret the availability of such alternatives as encouragement for the mandatory testing of medical devices by the RA. Given this situation, *should the option of using type examination to demonstrate compliance with relevant Essential Principles, rather than a QMS, be removed from this guidance document?*

Consider alternative definition of CAB, currently defined as follows:

***Conformity Assessment Body (CAB):** a body engaged in the performance of procedures for determining whether the relevant technical or regulatory requirements are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a Regulatory Authority that will ensure performance of the CAB is monitored and, if necessary, withdraw designation.*

Definition from GMDN is

*A Conformity Assessment Body is an organization recognised by a national Regulatory Body for the purposes of medical device testing, certification or approval, e.g., European Notified Body, FDA Inspectorate, etc. [Source: GMDN Agency]*

**Action: SG1**

The document will be modified to align the introductory text with previous documents and circulated before the next meeting.

**Action: Secretary**

12 **Document Priorities and Timetable**

Work in progress is as follows:

DOCUMENT TITLE	REFERENCE	STATUS	PRIORITY	TARGET FOR COMPLETION
<b>SG1 IVD Medical Devices Subgroup – New Document</b>				
<b>Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices [</b>	<b>SG1/N063(PD)</b>	<b>Comments from the SC have been considered and the document modified where agreed. It has been resubmitted to the SC for advancement as a Final Document.</b>	<b>1</b>	<b>Final Document  2011/Q1  (Subject to endorsement by the Steering Committee during its March Teleconference)</b>
<b>Revision of SG1 Final Documents by SG1 and IVD MD Subgroup</b>				
<b>Label and Instructions for Use for Medical Devices</b>	<b>SG1/N070(PD)</b>	<b>Comments reviewed and document modified where agreed. Will be submitted to SC as a Proposed Final Document in February.</b>	<b>1</b>	<b>Final Document  2011/Q2</b>
<b>Essential Principles of Safety and Performance of Medical Devices</b>	<b>SG1/N068  Proposed Document</b>	<b>Document submitted to SC for endorsement as a Proposed Document for public comment.</b>	<b>1</b>	<b>Proposed Document  2011/Q1</b>
<b>Information Document Concerning the Definition of the Term “Medical Device” (revised)</b>	<b>SG1/N071  Proposed Document</b>	<b>Document submitted to SC for endorsement as a Proposed Document for public comment.</b>	<b>1</b>	<b>Proposed Document  2011/Q1</b>
<b>Pending Revisions of SG1 Final Documents</b>				

<b>Principles of Medical Devices Classification</b>	<b>SG1/N015 Working Draft</b>	<b>All Comments have been addressed except re-classification of X-ray machines which will be discussed in June 2011.</b>	<b>2</b>	<b>Proposed Document 2011/Q3</b>
<b>Principles of Conformity Assessment for Medical Devices</b>	<b>SG1/N040 Working Draft</b>	<b>More than half of the bookmarked comments have been discussed, Work will continue in June</b>	<b>3</b>	<b>Proposed Document 2011/Q4</b>

13 **Any Other Business****Date and location of next meetings**

- **In Beijing, China** starting on Monday 6<sup>th</sup> to Saturday 11<sup>th</sup> June 2011. The meeting will include a training workshop on GHTF SG1 guidance documents on Wednesday and Thursday. Lindsay will provide details of hotels and provide an invitation letter that is required for obtaining visas.

**Action: Lindsay Tao**

- Further information on who will make the presentations on SG1s behalf will be circulated later.

**Action: Chair**

- The Chair of the Steering Committee will be informed of our participation.

**Action: Chair**

- **In San Jose, California** during the week of 5<sup>th</sup> December.

**Action: meeting details to be confirmed**

## SUMMARY OF ACTIONS

### For the Chair

- The revised version of SG1/N070 *Label and Instructions for Use for Medical Devices*, the updated comments template and the document history sheet will be forwarded to the Steering Committee for endorsement as a Final Document.
- To inform the Steering Committee that SG1 is next meeting in Beijing and that a training session will be provided.
- To inform SG1 who will make presentations in Beijing.

### For the Secretary

- To send the GHTF Secretariat an updated SG1 Work Plan, Meeting Dates and Meeting Reports for posting on the GHTF website before the next meeting.
- To update *Status of GHTF Study Group 1 Work Programme* (SG1/NO34) and SG1 Work Plan before the next meeting and reissue to members.
- To circulate the presentations made during the meeting to SG1.
- To forward the revised Final Document of SG1/N070 *Label and Instructions for Use for Medical Devices* and the updated comments template to SG1 and the IVD subgroup.
- Incorporate agreed changes to the document entitled *Procedure for the Movement of Documents between the IVD Subgroup and Study Group 1* and circulate to SG1 and the IVD subgroup (through Shelley Tang) for comment by 1<sup>st</sup> May.
- To incorporate agreed changes into GHTF/SG1(PD)/N077R01 *Principles of Medical Devices Classification (revised)*, including to the diagrams, and circulate to SG1 for comment by end April.
- To incorporate agreed changes into GHTF/SG1/N078R02 *Principles of Conformity Assessment for Medical Devices* and circulate to SG1 for continuing discussion in Beijing.

### For Chair / Vice-Chair / Secretary

- To further revise the text for Section 5.0 of GHTF/SG1(WD)/N077R01 *Principles of Medical Devices Classification (revised)* and circulate to SG1 for comment.

### For SG1 Members

- **Peter Linders / Naoki Morooka** - to prepare a revised version of an 'evidence-based' justification for the 'down-classification' of diagnostic X-ray devices, for discussion at the next meeting.
- To provide comments on GHTF/SG1(WD)/N077R01 *Principles of Medical Devices Classification (revised)*, to the Secretary and Chair by end April.
- **Lindsay Tao** to provide further details on SG1's next meeting in Beijing.
- **Gary Burgess** draft revised text with respect to conformity assessment of procedure packs.