

**REPORT OF THE SG1 MEETING HELD ON  
3/6th OCTOBER 2006 IN GHENT**

**Attendees**

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

**North America**

Mark Melkerson – FDA, USA  
Nancy Shadeed - Health Canada  
Brenda Murphy – MEDEC, Canada  
Fred Halverson – AdvaMed, USA

**Europe**

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

**Asia/Australasia**

Naoki Morooka – JFMDA, Japan  
Tomomichi Nakazaki – JFMDA, Japan  
Shinichi Takae – MHLW, Japan  
Mike Flood – TGA, Australia

**Apologies**

John Brennan – European Commission  
Peter Linders – COCIR/EMIG  
Johann Rader – European Commission (alternate)  
Michael Gropp – AdvaMed, USA (alternate)

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed SG1 members to the SG1 meeting. The meeting was held at Beckton Dickinson's offices in Erembodegem, near Ghent. She thanked Benny Ons and his assistant for organising the venue for the meeting and dinner.

Apologies were reported as shown above.

2 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed with the following additions:

- Membership of SG1.
- Workflow.
- Outreach to AHWP and PACME.

3 Review of the notes of the meeting held in 26/27 June in Lubeck (*Document GHTF. SG1. N059*).

The Lubeck meeting report was accepted after modifying the document reference number from N058 to N059.

In future, draft minutes will be circulated by e-mail to all of SG1, for comment within 2 weeks.

**Action: Secretary**

4 Review of Study Group 1 accomplishments and work plan

Prior to the meeting, the Secretary had circulated the most recent version of the *Status of Active GHTF Study Group Work Programme* (SG1/N034R23) dated 23 September 2006. The document was noted.

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

**Action: Secretary**

The Secretary reported that the Steering Committee is writing a document that lists all the definitions that appear in GHTF Final Documents. The work is being undertaken by Mr Hiroshi Ishikawa. The Secretary has provided SG1's document on the subject (SG1 N047 of 15 June 2006) which Mr Ishikawa has used as a basis for the document he is developing. Subsequently, the Secretary has commented on Mr Ishikawa's first draft document.

5 Discussion of the Proposed Document SG1(PD)/N44 (September 12, 2006): *Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)*:

The revised document was discussed by meeting attendees.

One definition was modified:-

**Basic standards (also known as horizontal standards):** Standards indicating fundamental concepts, principles and requirements with regard to general safety aspects applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk assessment, clinical investigation and the quality management system for the manufacture of medical devices).

SG1 members agreed that the newly revised document (dated 3 October 2006) needs to be exposed to public comment. In particular, the attention of readers should be called to Section 5.2 *Revision or replacement of recognized standards* by adding a cover document. Therefore it will be sent to the Steering Committee (through Susanne Hoeke of the EU Commission) for endorsement as a Proposed Document.

**Action: Secretary/Chair**

## 6 New Work Item Proposals

Four proposals for new work items were discussed and modified as agreed.

Namely:

- The definition of the term “manufacturer” and related entities.
- Registration of Manufacturers and their Medical Devices by the Regulatory Authority
- Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices.
- Procedure to determine the appropriate regulatory path for combination products and subsequent regulatory management of those products that have been deemed a medical device.

They will be sent to the Steering Committee for discussion and a request for approval at its November meeting.

**Action: Secretary**

The Secretary will complete a first draft of the document on the definition of a “manufacturer” if the work item is approved by the Steering Committee.

**Action: Secretary**

## 7 SG1/N011R17 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED): revision of proposed guideline.

SG1 members offered views on the strengths and weaknesses of the current document. The following documents were tabled:

- Mike Flood spreadsheet listing documents that may be generated during the design and development of a new medical device.
- Mark Melkerson’s comparison of the elements incorporated a STED and a 510(k).
- MHLW PowerPoint presentation on their experience with the STED in Japan together with other MHLW and JFMDA guidance documents and a draft of a STED for an actual device.

It was decided to develop the spreadsheet generated by Mike Flood and, as a first step, see whether the understanding of the terms used, was agreed.

Issues raised during the discussion:

- ISO 13485 para 7.5.2.1 no longer uses the term “special processes” but instead refers to “processes where the output can not be verified by subsequent monitoring or measurement”. The current version of the STED includes specific recommendations for the control of medical devices that are placed on the market in a sterile condition since RAs acknowledge sterilisation to be a process where the output can not be verified by subsequent monitoring or measurement. However, guidance on other processes which fall within this definition, e.g. wave soldering, are not included within the STED and SG1 is not inclined to change its

approach on these matters. SG3 is likely to have a view on this when it is asked to comment on the revised STED.

- Whether initial marketing documents should be held in the STED for submission if requested (the alternative view was that they should not be part of the STED at all).

**Japanese delegates** described the experience they have had with the STED pilot scheme (over 300 submissions in 2005). JFMDA have produced a template for some categories of device (differentiated according to the GMDN system) to describe the amount of information required in a STED for such classes of device. They tabled a template for a CT X-Ray scanner. Also, they provided a presentation of the role of the STED in the Japanese regulations which depends, in part, on whether or not a technical standard exists for the device that is the subject of the documentation. To some extent, the existence of a technical standard provides “presumption of conformity” and, if absent, additional evidence has to be provided. To address the shortcomings of the GHTF STED, the Japanese delegation proposed that the revised document should provide:

- More guidance on level of detail to be included in each section of the STED.
- A rationale for the above decisions.

Mike Flood presented a description of **TGA experience**. He described experience under both the old and current medical device regulations. About 600 audits have been completed under the new regulations that uses a “STED-like” document as the source information. TGA have written a guidance document to describe what is required in the submitted document. To address shortcomings in the GHTF STED, the TGA delegate proposed that the revised STED document should provide:

- More guidance on level of detail to be included in each section of the STED.
- Information on clinical evidence requirements.

The **European** regulations do not prescribe the format of the technical documentation examined by the CAB. CABs should welcome the use of the STED which aligns well with their documentation requirements.

**Health Canada** issued guidance on using a STED for submissions but there has been little interest by manufacturers since most companies are selling only to their local market. One STED for a high risk device has been reviewed and the experience was positive.

**The FDA STED Pilot has drawn the interest of few manufacturers**, probably because of their familiarity with current 510(k) requirements and the perceived lack of advantage in using the STED format. From the FDA’s perspective, the STED calls for closely similar information to that required for a 510(k) submission. None of the large US manufacturers have “tested” the system by producing a single STED and submitting it to all Founding Member countries.

It was noted that the equivalent document for use by the pharmaceutical industry had been enthusiastically accepted, i.e., ICH CTD.

It was agreed the STED should be formatted in a manner that is convenient for review by a Regulatory Authority should such be required. A list of section headings was drawn up on this basis. During this process it was compared with

- a table showing the documents that made up a STED for the different classes of device;
- the Japanese documentation; and
- the latest version of the AHWP document entitled Common Submission Dossier Template, dated 14 September 2006. This has just appeared on the AHTP web site (via [www.AHWP.org](http://www.AHWP.org) / Technical Committee / call for comments).

It was agreed by the Japanese representatives that the content of this list agreed broadly with their regulations although there was some difference in order.

The STED should summarize or reference or contain (e.g. whether submitted or according to the option selected by the manufacturer in Section 6.2) documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.

The list of proposed section headings for the STED will be circulated and the associated spread sheet will be e-mailed to SG1.

**Action: Secretary**

Nancy Shadeed will contact SG5 to understand details on the information they will provide that is relevant to SG1's STED.

**Action: Nancy Shadeed**

8 Report from the SG1 IVDD Subgroup – Ms. Nancy Shadeed.

The sub-group will meet for 2 days at the end of this month.

**Conformity Assessment document:** an annotated list of comments, with outcome decisions, will be ready for the SG1 meeting in February 2007.

**Action: Nancy Shadeed**

The two documents on conformity assessment and classification for IVDDs should, subject to the agreement of SG1, be ready for forwarding to the Steering Committee as Proposed Documents after the SG1 meeting in February 2007.

SG5 have asked SG1's IVDD sub-group for input to aspects of their work concerning performance evaluation for IVDDs. The precise mechanism has yet to be discussed.

**Action: Nancy Shadeed**

The EU GHTF Secretariat will be asked whether this topic is the subject of a New Work Item or not.

**Action: Nancy Shadeed**

As reported in Section 6, above, the IVDD subgroup proposes to develop a STED for IVD Medical Devices as a new work item.

9 Development of outreach strategy for soliciting comments on draft documents, workflow and SG1 membership.

**OUTREACH:** Unfortunately, the pre-meeting with representatives of the AHWP, planned for the 2<sup>nd</sup> October, did not take place since they could not join SG1 in Ghent. The solution may be to either hold a meeting close to their jurisdiction or to see whether the US Department of Commerce could fund attendees at a training session on the STED.

The Steering Committee will discuss liaison with the AHWP at its November meeting.

A letter will be sent to Dr M S Pillay – AHWP Chair, MoH Malaysia, summarising SG1 discussions on the STED and inviting him, or a nominated substitute, to join us at our next meeting in February when we will further revise the text of the STED document and would welcome AHWP input.

**Action: Chair**

**NEW WORK:** Members discussed how we progress our new work (assuming the Steering Committee endorse the proposals) while retaining “ownership” but fulfilling our responsibility to collaborate with other Study Groups.

**REPRESENTATION AT SG1:** Shinichi Takae of MHLW asked whether the size of the Japanese delegation could be increased to 4 people since it would help them better contribute to the meeting when working in the English language.

**Action: Chair to consider request**

It was agreed that alternates would be included on the document distribution list (e.g. Johann Rader).

**Action: Secretary**

10 SG1 Contact List

To improve the effectiveness of the process by which SG1 receives comments on Proposed Documents, or communicates the presence of a new Final Document, it has been decided to draw up a list of appropriate organisations. As a first step, the Secretary will prepare a template of required information and e-mail to SG1 (plus alternates) asking for names of those organisations that should be contacted.

**Action: Secretary**

Following that, the Secretary will prepare a single list of such organisations prior to SG1’s meeting in February 2007.

**Action: Secretary**

11 Document Priorities and Timetable

Six SG1 documents (two agreed during the most recent meeting of the Steering Committee) 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*
- SG1/N015:2006 *Principles of Medical Devices Classification*
- SG1/N040:2006 *Principles of Conformity Assessment for Medical Devices*

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	PRIORITY	TARGET FOR COMPLETION
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance ( STED)</i>	SG1/N011	Proposed Document, under revision.	1	Proposed Document 2007 / Q4
<i>Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012</i>	SG1/N044	Submitted to the Steering Committee for endorsement as a Proposed Document.	1	Final Document 2007/ Q3
<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

## 12 Date and place of next meeting

- Next meeting of SG1: 5<sup>th</sup> to 9<sup>th</sup> February 2007 in Japan.
- Joint meeting with other Study Groups: May 7<sup>th</sup> to 11<sup>th</sup>, 2007 (joint SG meeting, LA)
- 2007 GHTF Plenary, Washington DC: September 30 to October 2 with the conference on 3<sup>rd</sup> & 4<sup>th</sup> October. AdvaMed will hold its conference on 5<sup>th</sup> & 6<sup>th</sup>. It is possible that SG1 will meet before this at the same venue, possibly at the AdvaMed offices. **NOTE: All these dates are tentative.**

- Following SG1 meeting: 4 to 8<sup>th</sup> February 2008, maybe in Bonn. **NOTE:**  
**All these dates are tentative.**

## 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 revise SG1(PD)/N44: *Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)* as agreed during the meeting and send to the Steering Committee secretariat for endorsement as a Proposed Document, together with a covering note regarding feedback on Section 5.2.
- To send the new work item applications to the Steering Committee secretariat for discussion by them during its November meeting.
- To complete a first draft of the document on the definition of a “manufacturer” if the work item is approved by the Steering Committee.
- To include alternates on the document distribution list.
- The list of proposed section headings for the STED will be circulated and the associated spread sheet.

### For the Chair

- To send a letter to Dr M S Pillay – AHWP Chair, MoH Malaysia, summarising SG1 discussions on the STED and inviting him, or a nominated substitute, to join us at our next meeting in February when we will further revise the text of the STED document and would welcome AHWP input.
- To consider the request from Japanese delegates to increase their representation by one person (2 industry + 2 government).
- To arrange for N009 to be archived on the GHTF web site.
- Co-ordinate with other SGs on
  - ❖ Definition of a manufacturer
  - ❖ Combination products
- Provide feedback to Jean Olsen on the current GHTF meeting schedule.
- Investigate whether the proposed GHTF Regional Meetings include the SGs.
- To discuss with the US Department of Commerce whether their training money can help fund AHWP delegates to attend SG1 outreach meetings.

### For the Vice-Chair

- To remind members of SG1 re. the action on the AHWP “STED Template” and subsequently prepare a formal response from SG1.

### For Nancy Shadeed

- SG5 have asked SG1’s IVDD sub-group for input to aspects of their work concerning performance evaluation for IVDDs. The precise mechanism will be the subject of discussion with the SG5 Chair.
- The EU GHTF secretariat will be asked whether this is the subject of a New Work Item or not.

### All SG1 Members

- To provide views to the organisations they represent concerning:
  - The current schedule for GHTF outreach/training meetings where, both will be held in the Americas.

- That the GHTF meeting in the Spring of 2007 does not include liaison with AHWP and PACME.
- That, at present, SG5 does not include experts with knowledge of IVDD.
- To read the AHWP “STED template” and send comments to Benny Ons by 31 December 2006.

**For Fred Halverson**

- To establish the contact details for a representative of Latin America industry.

**For Mike Flood**

- To establish the status of an SG1 representative from Australian industry.

**For Naoki Morooka**

- To establish whether SG1’s February meeting will be held in Japan.