

**REPORT OF THE SG1 IVD subgroup MEETING HELD ON
June 7-10 , 2010 – Sydney, Australia**

Attendees

Nancy Shadeed – Chair
Secretary – Benny Ons

North America

Francis Kalush – FDA, USA
Matt Gee – Medec, Canada

Europe

Marie-Lise Miguères – Affsapps, Europe
Celine Bourguignon – EU Commission, Europe
Petra Kaars Wiele – EDMA
Michael Thein - EDMA

Asia/Australasia

Shelley Tang, TGA Australia
Coles Jillianne – IVD Australia, Australia
Peter Harman – IVD Australia - Australia
Yoko Ikeda – JACRI, -Japan
Masaki Sugiura – PMDA, Japan
Kazutoshi Yamagishi - JFMDA – Japan

Observer

Irena Prat – WHO,Switzerland

Apologies

Maria Carballo – Health Canada
Jeffrey Chern – AHWP, Taiwan
Essam Mohammed Y. Al-Mohandis – AHWP, Saudi Arabia
Regina O’Meara – Advamed, USA

1 Welcome to the meeting and introduction of delegates

Nancy welcomed the members and observer to the SG1 IVD subgroup meeting..
The meeting was held at the Siemens Healthcare facilities in Sydney, Australia
and hosted by IVD Australia. Peter Harman welcomed the group on behalf of
IVD Australia.

Apologies were reported as shown above.

2 Approval of the meeting minutes of November 2009 and March 2010

Meeting minutes of the November 2009 meeting were approved and the March 2010 meeting were briefly reviewed with a comment period of 14 days after the June meeting.

3 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed as attached.

4 STED Document.

The revised document that was produced in March based on the public comments received was discussed by the main SG1 during its May meeting. A few suggested changes were tabled for re-discussion in the IVD subgroup.

The IVD subgroup was briefed on the discussion that took place in the main study group and reviewed the suggested changes.

The IVD subgroup agreed that the document was now final and could move to the SC for endorsement as a final document.

5 Update on the revision of the document definition of the term medical device

The Chair provided an update to the IVD subgroup of the discussion in the main study group 1 on the document “definition of the term medical device”

Contrary to the current published version the suggested revision will have a definition of an IVD medical device which is taken from the definition included in the document “Classification of IVD medical devices”. This is in line with the comments from the IVD subgroup.

The IVD subgroup was also informed about the work that was undertaken on the definition of accessory in this document.

6 Essential Principles of safety and Performance for medical devices

This document had been reviewed by the main study group and was awaiting review by the IVD subgroup.

The first question to be resolved for this document is whether the IVD subgroup want to split this document also in two sections, one for the medical devices and

one for the IVD medical devices, similarly to what has been done for the labelling document. Previous discussions had demonstrated that there are different opinions around the table.

It was agreed to do an analysis of all the essential requirements as currently listed in the SG1 revised MD version and indicate whether

- the EP could be used as is for IVD,
- whether it could be used but needed modification or
- whether the EP was not applicable to IVD medical devices.

The outcome of this analysis clearly demonstrated that there were many EP that needed modifications while others were not found to be applicable. Based on this outcome there was a consensus in the IVD subgroup that it would be better to split the EP document into 2 separate sections.

Similarly to the labelling document a general principles section will cover both medical devices and IVD medical devices followed by a section for medical devices and one for IVD medical devices. Some discussion took place on how to best number the sections – based on the recommendations from the IVD subgroup a numbering system will be proposed to the main study group.

A large portion of the meeting was devoted to the work on creating the IVD section for this EP document.

7 Clinical evidence for IVD medical devices – work undertaken by the IVD subgroup for Study Group 5

It was previously agreed with the IVD subgroup that there would be two rounds of comments on the first two documents (“key concepts and definitions” and “what is clinical evidence”). The first round of comments would include SG5 and other direct stakeholders – the IVD subgroup would look to the comments during its fall meeting of 2010. Then the documents would be going to SG5 for approval to move them to the SC for approval as a proposed document. Upon agreement by the SC the documents would then be posted as a proposed document for public comments. The meeting of SG5 will happen September 14-15 in Toronto, Canada.

The IVD subgroup worked on the third document for which a draft had been provided by Matt Gee.

A lot of discussion took place on the description of common diagnostic functions for IVD medical devices – the descriptions for the various terms were discussed and clear examples for each of the functions were added to the table. The table now includes the following diagnostic functions : Diagnosis, aid to diagnosis, physiological status, screening, monitoring, predisposition, prognosis and prediction.

The IVD subgroup decided that the completed table should be included in the definitions and key concepts document rather than keeping it in the current document.

The remainder of this third document will be discussed during the IVD subgroup's meeting in December.

8 Document in progress and timetable

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	TARGET FOR COMPLETION
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N063	Proposed document	Final document 2010 /
<i>Essential Principles of Safety and Performance for medical devices</i>	SG1/N045	Working draft Revision	Proposed document 2010 / Q4
<i>Labelling of Medical Devices.</i>	SG1/N046	Working draft	Final document 2011 / Q2
<i>Clinical Evidence for IVD medical devices</i>	SG5/XXX	Working draft	Proposed document 2011/Q2

9 Date and place of next meeting

- The fall meeting will be from December 6-9 and will be hosted by Beckman Coulter at their facility in Brea.