



DITTA GRP WG for Vietnam, tcon on 18<sup>th</sup> May 2018, Minutes

Attendees:

Patricia Gehrlein/Siemens; Yes  
Ha Pham Thi Thu/Siemens Vietnam; Yes  
Le Thi Van Thu/Philips; Yes  
Michael Schmit/GE; Yes  
Atsushi Habara/Canon; Yes  
Susumu Uchiyama/secretary for GRP WG, JIRA; Yes

Markus Braun/Siemen; Absent  
Shoji Toyofuku/Siemens; Absent  
Hanh Nguyen-Thi-Ngoc/Siemens Vietnam; Absent  
Jeroen van Nistelrooij/Philips; Absent  
Masami Tanaka/Canon; Absent

Chaired:

Chaired by Patricia Gehrlein/Siemens

Agenda,

1. Anti-Trust declaration
2. Approval of the agenda
3. Confirmation of the last meeting minutes
4. IEC TC62 London meeting summary (The progress of IEC 63077)
5. AHWP 2018
6. Update the Decree 36
7. Letter to the MoH
8. World Health Assembly
9. Any other topics

Discussion:

1. Welcome and approval of agenda

Addition of "Update the Decree 36" was proposed and the revised agenda was approved.





**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

2. Declaration of compliance with Antitrust rules

DITTA's Anti-trust rules was declared.

3. Confirmation/Approval of the last tcon's minutes

There was no comment forwarded. Additional comments will be accepted by May 25.

4. IEC TC62 London meeting summary (The progress of IEC 63077)

The result of the IEC TC62 London meeting was explained by Uchiyama.

- Scope inclusion of Gamma Camera and PET covered by SC62C was approved by SC62C.
- Skipping CD and circulate as CDV was approved by IEC SC62B.
- The potential conflict between the IEC 63120 being developed by SC62A WG20 was confirmed and it was assigned to both conveners to provide a joint resolution to SC62A, SC62B and TC62 by the end of May.
- The officers of SC62A, 62B and TC62 were requested to work together to avoid future conflict.

Summary;

- The development of the IEC 63077 will be delayed until the resolution of the scope overlap approved in TC62.
- The next step CDV and the inclusion of the device covered by SC62 were accepted.

5. AHWP 2018

Below communication result was reported by Uchiyama.

- GRP session at the AHWP 2018 was proposed to AHWP TC chair Ali Al Dalaan by DITTA chair Patrick.
- AHWP TC chair replied that there was no interest by TC leaders.
- GRP WG can provide slides reporting the progress of GRP WG to be presented at DITTA update session which will be programmed in the plenary of AHWP 2018.
- The AHWP 2018 is scheduled from 22 to 25 October in Kuala Lumpur, Malaysia.

Summary

- To prepare slides of GRP for DITTA update session in AHWP 2018 plenary.
- Patricia to talk with Nicole in Geneva next week to get an advice, what we would need to do for AHWP 2019.





## 6. Update the Decree 36

Below information was provided by Vietnam colleague.

Ha provided below information.

- Ministry of Health is revising the Decree 36 after 2 years of implementation.
- And revising mainly about IVD drug registration and management of IVD product, especially for drug abuse testing.
- Adding more requirement for post market surveillance.
- There were a lot of problems with temporary importation and re-exportation of demonstration instrument and training instrument.
- We want to take this opportunity for revising and would like to propose to add importation and re-exportation of used instrument for demonstration and training. It seems like they are not rejecting strongly compared to the past.
- They are going to take this requirements into the revised Decree 36.
- If the MoH approve the temporally importation of used instruments for the purpose, they will talk with Ministry of Trade. And once it is accepted/approved, it will be our starting point of escalating to importation of used medical imaging equipment processed under GRP.
- The 1<sup>st</sup> draft of Decree 36 will be forwarded to the government in June and it will be approved by the end of 2018.

## Summary

- The Decree 36, which is a general medical device law, is being revised mainly for the IVD but also include the temporal import and re-export of used instrument for training and demonstration. MoH is responsible but also Ministry of Trade are involved in the revision.
- Once the revision, allowing temporal import and re-export of used instrument is accepted/approved, it will be our starting point of GRP for Vietnam.
- The key stake holders are MoH and Ministry of Trade, and we need the 1<sup>st</sup> talk with MoH.
- The letter should be forwarded to MoH.

## 7. Letter to the MoH

A draft letter to MoH was provided by Patrica.

What way should we revise? Implement Decree 36?

From whom? To whom, Minister or vice minister?

Every members to review and comment by written format to Patricia and Susumu by May 25.





And discuss on the next tcon on May 31.

8. World Health Assembly

Patricia will participate the WHA in Geneva next week and will provide update at next tcon.  
What way we could use WHA for our objective in 2019.

9. Any other topics

Non.

7. Next tcon,

Time/Date; 14:00-15:00 CET, May 31

