FINAL DOCUMENT

Title: Amendment 5 to the Asian Harmonization Working Party House Rules

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1. **Purpose**

   This document proposes to make amendment to the Asian Harmonization Working Party (AHWP) & House Rules (hereafter as “AHWP House Rules”) as detailed in section 3 below under “Proposed Amendments to the AHWP House Rules”.

2. **Background**


   2.2. To clarify the roles and responsibilities of AHWP members, and AHWP TC WGs and STG membership.

   2.3. The amendments to AHWP House Rules in section 3 of this document are prepared to facilitate the aforementioned purposes.

   2.4. AHWP & AHWP TC Terms of Reference can override AHWP House Rules when there is any discrepancy.

3. **Proposed Amendments to the AHWP House Rules**

   3.1. The below new clause 18 Roles and Responsibilities of Technical Committee is proposed to be added in AHWP House Rules after the current clause 17 Advisor to AHWP:--

   **Clause 18 Roles and Responsibilities of Technical Committee**

   **A. Role and Responsibility of AHWP TC Chair**
   
i. The AHWP TC Chair shall conduct the decision-making on the overall WG work plan.
   
   ii. The AHWP TC Chair shall designate a TC secretary who can dedicate his/her time and effort for AHWP, especially for WI and Guidance document management.
   
   iii. The AHWP TC Chair shall conduct the final approval on WG members, WG advisors, Capacity Building trainers/leaders.
   
   iv. The AHWP TC Chair shall designate TC advisors.
   
   v. The AHWP TC Chair shall assign tasks to TC advisors.
   
   vi. The AHWP TC Chair shall make the overall confirmation of TC workshop program and In-country training.
   
   vii. The AHWP TC Chair shall sign communication letter with international partners, e.g. IMDRF, ISO, etc., for technical related subjects.
   
   viii. The AHWP TC Chair shall conduct the overall approval on AHWP and WG member’s nomination for representing AHWP in international organization, e.g. ISO, IMDRF, etc.
   
   ix. The AHWP TC Chair shall make the overall confirmation of speaker on behalf of AHWP or AHWP TC.

   **B. Role and Responsibility of AHWP TC Co-chair (Regulatory Authority)**
   
i. The AHWP TC Co-chair shall conduct the overall coordination of program of AHWP workshop.
   
   ii. The AHWP TC Co-chair shall be the contact person for important international organizations, e.g. IMDRF, WHO, APEC, PAHO, etc.
   
   iii. The AHWP TC Co-chair shall take over AHWP Chair’s responsibilities in case of absence.
   
   iv. The AHWP TC Co-chair shall recommend AHWP WG member’s nomination for representing AHWP in international organizations.
   
   v. The AHWP TC Co-chair shall recommend speaker on behalf of AHWP or AHWP TC.
C. Role and Responsibility of AHWPTC Co-chair (Industry)
i. The AHWPTC Co-chair shall be the contact person for Industry Liaison Members, i.e. APACMed, DITTA and GSI.
ii. The AHWPTC Co-chair shall conduct the overall coordination of Joint-workshop program of AHWPTC workshop with Liaison Members.
iii. The AHWPTC Co-chair shall recommend AHWPTC WG member nomination for representing AHWP in international organizations.
iv. The AHWPTC Co-chair shall recommend speaker on behalf of AHWP or AHWPTC.

D. Role and Responsibility of WG Chairs and Co-chairs
i. The WG Chairs and Co-chairs shall conduct the management of WG members and updates.
ii. The WG Chairs and Co-chairs shall designate member with the confirmation by AHWPTC Chair.
iii. The WG Chairs and Co-chairs shall make progress report to AHWPTC Chair every 3 months.
iv. The WG Chairs and Co-chairs shall set up prior or post side-meeting to AHWP Meeting to avoid any influences on AHWP main meetings.

E. Additional Role and Responsibility of AHWPTC Advisors
i. The AHWPTC Advisors shall designate a leader of AHWPTC Advisors
ii. The AHWPTC Advisors shall report assignment to AHWPTC Chair.

3.2. The below new clause 19 AHWPTC WGs and STG Membership is proposed to be added in AHWP House Rules after the proposed clause 18 Roles and Responsibilities of Technical Committee:

Clause 19 AHWPTC WGs and STG Membership
A. Only members of AHWP member economies can be accepted as WGs or STG members.
B. In case of absence of WG chair, AHWPTC Chair can assign one of the WGs or STG regulatory members with the most expertise along with AHWPTC Co-chairs agreement.
C. Members of non-AHWP member economies can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.
D. All WGs and STG members need to be confirmed by TC Chair.

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