



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

**PROPOSED FINAL DOCUMENT**

**Title:** Working Group Technical Document Endorsement  
Mechanism

**Authoring Group:** AHWP SECRETARIAT

**Date:** 27 September 2016

**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**

- 2.1. The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F001:2014 resolved in the 19<sup>th</sup> AHWP Meeting and announced on 21 November 2014.
- 2.2. Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- 2.3. To facilitate the acceleration of process for WG technical document endorsement.
- 2.4. The amendments to AHWP House Rules in section 3 of this document are prepared to facilitate the aforementioned purposes.
- 2.5. AHWP & AHWPTC Terms of Reference can override AHWP House Rules when there is any discrepancy.

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

- 3.1. The current clause on Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat in AHWP House Rules:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*A. Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions.*

is proposed to be replaced by:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*A. Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions/endorsements.*

- 3.2. The current clause on Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat in AHWP House Rules:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*D. Documents prepared for resolutions and/or approvals shall be labeled "PROPOSED FINAL".*

is proposed to be replaced by:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*D. Documents prepared for resolutions/endorsements and/or approvals shall be labeled "PROPOSED FINAL".*

- 3.3. The current clause on Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat in AHWP House Rules:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*E. Documents accepted, approved and/or prepared for already passed resolutions shall be labeled "FINAL".*

is proposed to be replaced by:-

***Clause 14 Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat***

*E. Documents accepted, approved, and/or prepared for already passed resolutions/endorsements shall be labeled "FINAL".*

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