



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Working Group Technical Document Endorsement
Mechanism

Authoring Group: AHWP SECRETARIAT

Date: 26 November 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 19th 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".

----- End -----