



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

# The 4-Step Procedure for Preparing AHWP Official Documents

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# Content

- ◆ The 4-step Procedure of going through Drafting, Call for Comment, Discussion, Approval and/or Resolutions of AHWP Official Documents at AHWP Meetings
- ◆ The Process for Documenting AHWP Reference Documents

# The 4-step Procedure with 4-Type of Doc

## AHWP Final Documents (including Guidance Documents)

Step 4

### FINAL

- Documents accepted, approved and/or passed resolutions
- Available at AHWP web as AHWP official documents

Step 3

### PROPOSED FINAL

- Documents prepared for approvals and/or resolutions
- Post on AHWP website + circulations → Call for Comments

Step 2

### PROPOSED

- Documents discussed in AHWP and/or TC Meetings
- Post on AHWP website + circulations → Call for Comments

Step 1

### DRAFT

- Initialed by: Chairs of Committees/WGs / STGs / Secretariat
- Documents discussed within group members

## Example:

# Endorsing a GHTF Guidance Doc as an AHWP Guidance Doc (4-step Procedure)

## AHWP Guidance Documents

Step 4

- a. Label as “(doc name)\_FINAL”
- b. Secretariat post on AHWP website under Final Document & Guidance Document
- c. **AHWP Guidance Document (as a kind of Final Doc) will bind to all AHWP members**

Step 3

- a. Necessary revision → Label as “(doc name)\_PROPOSED FINAL”
- b. WG Chair/Co-chair present in AHWP Annual Meeting for resolutions, and/or approvals
- c. After the meeting: Post on AHWP website + email circulations → Call for Comments
- d. Further revision

Step 2

- a. Necessary revision → Label as “(doc name)\_PROPOSED”
- b. WG Chair/Co-chair present in the TC Meeting
- c. After the meeting: Post on AHWP website + email circulations → Call for Comments

Step 1

- a. Convert to an AHWP document and label as “(doc name)\_DRAFT” (please quote the reference)
- b. Discussed within WG members

# Procedure for Documenting an AHWP Reference Document (no need to go through the 4-step Procedure)

1. Initialed by:TC/WGs/STGs
2. Discussed within group members
3. Endorsed by Chair & Co-chair
4. Discussed and Endorsed in TC Meeting
5. Post on AHWP website under Reference Doc

**AHWP Reference Documents are NOT binding to all AHWP members**

## Example:

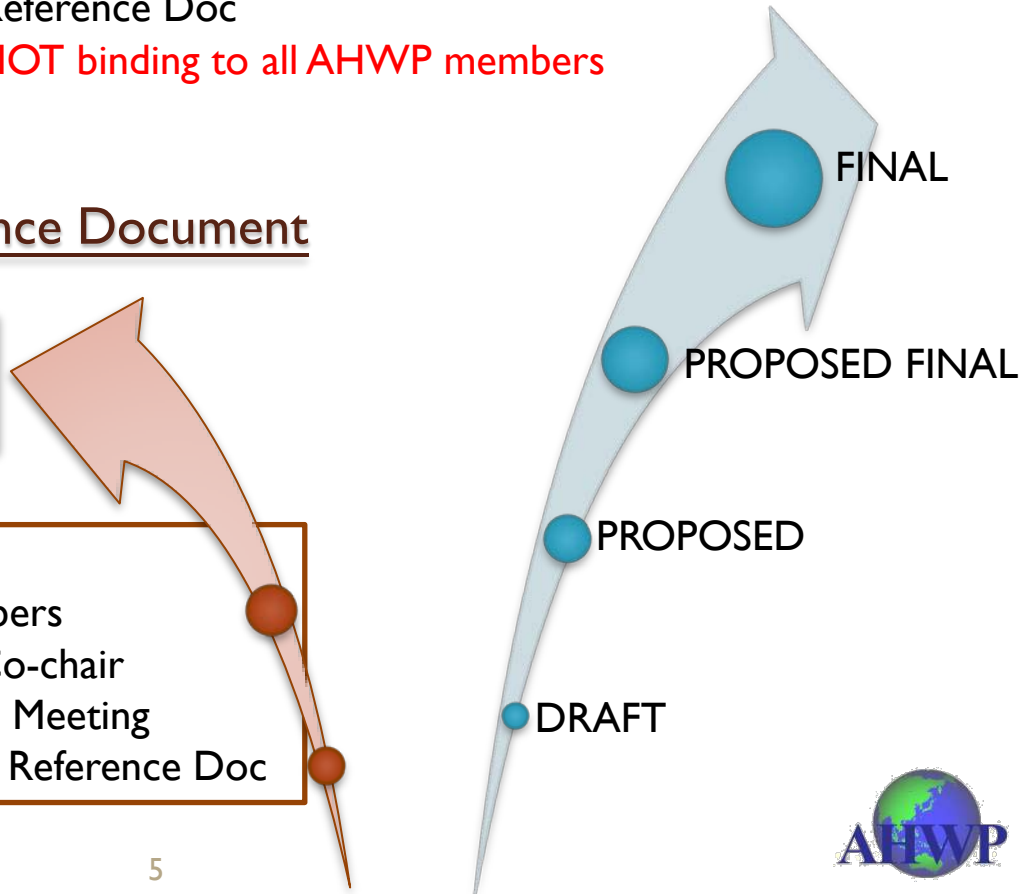
### Endorsing an AHWP Reference Document

**AHWP**  
**Reference Documents**

#### Mapping table of STEP and CSDT

1. Discussed within WG01 members
2. Endorsed by WG01 Chair & Co-chair
3. Discussed and endorsed at TC Meeting
4. Post on AHWP website under Reference Doc

**AHWP**  
**Final & Guidance Documents**



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## Guidance Documents

**Adoption of "The Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers"**

Updated: Wed, 02/11/2011 - 16:25

[Read more](#)

**Final Documents on Safety Alert Dissemination System (SADS) and Survey Post Market Surveillance System**

Updated: Sun, 02/11/2008 - 15:40

[Read more](#)

**GUIDANCE for Member Economy hosting the Meetings of AHWP or its Technical Committees**

Updated: Fri, 24/11/2006 - 16:20

[Read more](#)

Please forward your enquiries, comments and suggestions to Bryan SO / Carol LIU of the AHWP Secretariat  
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Thank You!