

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General Recommendation - Procedure 10NOV2005

Title: General Recommendation - Procedure

Background:

The Expert Working Group (EWG) of ICH M2 (ESTRI) has determined that some of their activities should result in Recommendations while others will be subjected to the ICH Step process. These are called Specifications. Recommendations will primarily apply to infrastructure standards. Due to the information technology (IT) nature of the topic, these recommendations may be subject to frequent change as both science and technologies change. Therefore, it is proposed that the M2 Recommendations be approved and distributed within the three regions in a manner which will facilitate periodic updates.

Recommendation:

The M2 EWG proposes that the following procedure relating to recommendations made to the ICH Steering Committee be adopted by the Steering Committee:

The recommendations:

- Are written according to the attached template
- Are prepared according to the major categories
 - General
 - Physical Media
 - File Format
 - Information Transfer
 - Secure messaging
 - Secure, structured transfer
 - Secure, unstructured transfer

Note: Other categories will be identified and added as needed

- Are an agreed product from the entire EWG
- Are published on the ICH-ESTRI web site
- Are presented as a new version of the M2 Recommendations (in person or writing) to the Steering Committee for approval and sign off
- Are implemented by coordinating among the Regulatory Authorities to ensure compatibility

Conditions:

- Each recommendation will be written using the attached template
- The header contains the EWG approval date of the recommendation
- The footer contains version number (to be updated with each revision) and page number

Remarks:

None

Attachment - Recommendation Template

**EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
“Category” Recommendation – “title”** DDMMYYYY

Title:

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Recommendation:

Conditions:

Remarks:

ICH-ESTRI VV_R - #