# EWG M2 Recommendation to the ICH Steering Committee
# Electronic Standards for the Transfer of Regulatory Information (ESTRI)
# File Format Recommendation – DOCX

Version 1.0 - 11JUNE2015

**Title:** DOCX (ISO/IEC 29500)

**Background:** It is recognized that there is a need to exchange regulatory documents in a common interchange format. The Expert Working Group (EWG) has defined a set of file format criteria in a publication entitled "ICH M2 File Format Criteria" which describes required and desirable functionality for various regulatory document types (e.g., narrative text, data, video). Narrative documents vary in size and complexity from simple correspondence to more complex documents containing tables, graphics, etc.  The ICH M2 Expert Working Group has previously recommended ISO-32000 (PDF) with restrictions, PDF/A and XML to meet these needs.

**Recommendation:**  The EWG has identified Office Open XML (ISO/IEC 29500) as a standard interchange format for electronic transfer of documents that meets the requirements set forth in this publication. Specifically, for narrative documents, the format known as "DOCX" (a subset of ISO/IEC 29500) is recommended. This recommendation is for an additional file format and is not intended as a replacement for ISO-32000 (PDF) or PDF/A.
The EWG recommends that regulators develop an implementation plan which specifies:

- if they can accept DOCX files
- the version(s) they are able to accept
- for which kinds of regulatory documents they are able to accept DOCX files

**Conditions:**
This recommendation is for the following 2 versions of the ISO 29500 standard as follows:

- ISO/IEC 29500:2008 (Transitional)
- ISO/IEC 29500:2012 (Strict)

It is the intention of the EWG to standardize on ISO/IEC 29500:2012 (Strict) at some point in the future.

The EWG recommends regional testing for specific use cases of DOCX before implementation. Refer to regional guidance for such details.

**Remarks:**
In addition to meeting the requirements of "ICH M2 File Format Criteria", we note the following:

- DOCX is a file format based on XML
- DOCX is already in common daily use in the industry (e.g. for word-processing and internal review)
- Free viewers are available
- The specifications are available from the ISO web site: http://www.iso.org/