

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

05APR2011

Title: ISO 32000-1 / PDF

Date: 5 April 2011

Background:

It is recognized that there is a need to exchange various regulatory documents in a common interchange format. These documents may vary in size and complexity from simple correspondence to compound documents that include tables, graphics, etc.

This standard interchange format should fulfill the following requirements:

- allows the transfer of documents whose contents do not need to be modified or extracted into functional databases;
- is both device and resolution independent;
- is designed for viewing and/or printing;
- enables paper based information to be scanned into electronic format;
- allows the use of a viewer whose specifications are in the public domain;
- retains the *content* and the *layout* of the original document.

Recommendation:

- The Expert Working Group has identified ISO 32000-1:2008 Document management -- Portable document format -- Part 1: PDF 1.7 as a standard interchange format for electronic transfer of documents that meets the above requirements;
- This common interchange format will apply to submissions by sponsors for regulatory approval of medicinal products (eCTD) and also to other types of regulatory information exchange in general.

Conditions:

The recommended standard is ISO 32000-1 without extensions and with the following restrictions. PDF files must not contain:

- JavaScript
- dynamic content which can include audio, video or special effects and animations
- attachments
- 3D content

Remarks:

- In addition to meeting the requirements for the standard interchange format, we note the following:
 - It is a low cost solution which has become an open standard (ISO);
 - Several free viewers are available;

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- Many low cost plug-ins from numerous software providers are available to help sponsors create PDF format, hyperlinks, bookmarks etc., and reviewers to develop assessment reports with features like copy and paste, post-it notes, full text search etc.;
 - Inclusion of hyperlinks and bookmarks facilitates browsing of documents;
 - Certain information are not currently appropriate for PDF transfer (e.g. X-rays)
 - Adobe, Inc. has already implemented extensions to PDF 1.7 in its latest version of the Acrobat product. This recommendation is for PDF 1.7 only without extensions.
 - Extensions to ISO 32000-1:2008 (such as those from Adobe) have been submitted to ISO for approval. As these are approved as ISO standards, they may be considered for recommendation by ICH M2.
 - The specification is available from the ISO web site: <http://www.iso.org/>