

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

2 June 2014

Title: PDF/A

Date: 2 June 2014

Background:

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

This standard electronic 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.

The ICH M2 Expert Working Group has previously recommended ISO-32000 (PDF) with restrictions to meet the above requirements. The PDF/A-1 and PDF/A-2 standards were developed to be suitable for long term preservation (archiving) . The following recommendation is in addition to the ISO-32000 (PDF) recommendation. .

Recommendation:

- The Expert Working Group has identified PDF/A-1 (ISO 19005-1:2005) and PDF/A-2 (ISO 19005-2:2011) as standard interchange formats for electronic transfer of documents that meet the above requirements;
- In addition to ISO-32000 as defined in ESTRI Recommendation “ISO-32000/PDF” these common interchange formats will apply to submissions by sponsors for regulatory review of medicinal products (eCTD) and also to other types of regulatory information exchange in general.

Conditions:

These standards restrict various types of content and features of PDF, including, but not limited to:

- JavaScript

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- 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:
 - This is not a recommendation for regulators to use PDF/A for archiving
 - PDF is a low cost solution which has become an open standard (ISO);
 - Several free viewers are available;
 - 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)
- The specifications are available from the ISO web site: <http://www.iso.org/>