

OnTrack PDF Validation Services

This specification lists the verification items of OnTrack PDF Validation Services. It provides a description of PDF problems that are verified by the verification items and defines the corresponding eCTD Validation errors of FDA eCTD Validation Criteria or FDA PDF Specification.

Version 1.0.0
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ID	Verification Item	FDA Number*	Problem Description
	Prerequisite		
PDF.TEXT.1	Text is searchable	5057	Document is empty or contains scanned image only and doesn't contain searchable text (scanned document without OCR).
PDF.PROP.1	PDF file size doesn't exceed configured limit	1238	File size exceeds the configured max. size (in MB). Default value: 100 MB
PDF.PROP.2	PDF contents can be processed successfully	3102	Document's content cannot be processed, e.g. a corrupted or invalid PDF document.
PDF.SEC.2	PDF is not protected by open password	5050	Document has password protection and cannot be opened.
PDF.SEC.3	No certificate protection	5050	Document has certificate protection and cannot be opened.
	PDF Properties		
PDF.PROP.3	Description is free of default metadata	N/A	Attributes are not empty under Properties / Description in File menu.
PDF.PROP.5	PDF version is correct	5035	PDF version of document is incorrect. Correct PDF versions are listed in configuration. Default values: 1.4,1.5,1.6,1.7
PDF.PROP.6	"Fast Web View" option is activated	5040	PDF has been created without "Fast Web View" active.
	Security		
PDF.SEC.1	No security (document access) restriction is set	5020	PDF has been created with security settings that limit the ability to select text or graphics, or make other changes. This prevents agencies from copying text and taking other action with submitted documents.
	Font Embedding		
PDF.FONT.1	All used fonts have been embedded	5005	Non-standard font is used but not embedded. Result is N/A if no fonts can be detected in document (e.g. images only).
	Initial View		
PDF.VIEW.1	Navigation Tab Setting	5045	The initial view is not set as Bookmarks and Pages in the Navigation Panel nor it is not set to Pages only if there are no bookmarks
PDF.VIEW.2	Page Layout is set to Default	5045	Page Layout is not set to "Default."
PDF.VIEW.3	Magnification is set to Default	5045	Magnification is not set to "Default."
PDF.VIEW.4	Document open to page 1 or TOC	N/A	Document does not open to first page or TOC.
	Page Orientation		
PDF.ORI.1	First page orientation is portrait	N/A	First page orientation is not portrait.

Page Size and Margins			
PDF.PAGE.1	PDF contains only pages with the configured sizes	N/A	PDF contains one or more pages with different size than the configured. Default values: LETTER,A4 Valid configuration values: A0, A1, A2, A3, A4, A5, A6, LEGAL, LETTER
Bookmarks			
PDF.BMRK.1	Bookmarks are expanded until level <1>	N/A	Bookmarks are not expanded until the defined level or over expanded. Default value: 1 Result is N/A if there are no bookmarks in the PDF.
PDF.BMRK.2	Number of bookmark levels doesn't exceed maximum limit	N/A	Number of bookmarks level is deeper than the defined level. Default value: 5 Result is N/A if there are no bookmarks in the PDF.
PDF.BMRK.3	Bookmark nesting is correct	PDF Spec	Nesting of bookmarks doesn't follow their natural, ascending order. E.g. section no. 2.1 should be nested under section no. 2, etc.
PDF.BMRK.7	No corrupted bookmarks	5102, 5110	Document with one or more bookmarks pointing to a named destination or page that does not exist. <u>A bookmark is considered to be corrupt if</u> - it has no action or destination defined - it points to a non-existing page - target page doesn't contain the bookmark title (optional) Optional check is activated by default. Bookmark titles that are excluded from check can be listed in configuration. Following bookmark titles are excluded by default: "Appendices, Post-text figures, Post-text tables, Signatures, Signature Page, Tables" Result is N/A if there are no bookmarks in the PDF.
PDF.BMRK.8	Magnification of the bookmarks is set to inherit zoom	5117	Document with one or more bookmarks that are not set to 'Inherit Zoom'. Result is N/A if there are no bookmarks in the PDF.
PDF.BMRK.9	No multiple action bookmark	5103	Document with one or more bookmarks containing multiple actions Result is N/A if there are no bookmarks in the PDF.

PDF.BMRK.10	There are bookmarks	PDF Spec	<p>There are no bookmarks in the document which contains more pages than the configured page number.</p> <p>Passed - if there are bookmarks Failed - if there are no bookmarks and number of document pages > configured value NA - if there are no bookmarks and number of document pages <= configured value</p>
PDF.BMRK.11	Provide bookmarks for each item listed in TOC	PDF Spec	<p>There are no bookmarks for each item listed in the table of contents.</p> <p>Passed - if bookmarks match the TOC Failed - if there is a TOC, but no bookmarks or only partial bookmark structure N/A - if there is no TOC in the PDF</p>
Hyperlinks			
PDF.HLNK.2	Internal hyperlinks blued	N/A	<p>There is not blued internal hyperlink. Invisible hyperlinks are also reported by default (optional).</p> <p>Result is N/A if there is no hyperlink in the PDF.</p>
PDF.HLNK.3	No broken links	5202	<p>Document contains one or more broken hyperlinks.</p> <p>A hyperlink is broken if:</p> <ul style="list-style-type: none"> - it has no action or destination defined - it points to a non-existing page - it belongs to a TOC item and it points to a different page than page number at TOC item or target page doesn't contain the TOC item's title - it is a literature reference and References section doesn't contain it - it is not a TOC item nor a lit ref, but target page doesn't contain link's text - it points to a remote destination (optional) <p>Result is N/A if there is no hyperlink in the PDF. Configured names of the Reference section by default: "Reference, References, References List"</p>
PDF.HLNK.4	Relative paths are used in hyperlinks	5215, 5115	<p>Document contains one or more non-relative (absolute) hyperlinks.</p> <p>Result is N/A if there is no hyperlink in the PDF.</p>

PDF.HLNK.5	No external hyperlinks to websites	5205, 5105	Document makes reference to one or more web references in a hyperlink (e.g. web links, email links). Result is N/A if there is no hyperlink in the PDF.
PDF.HLNK.6	Magnification of the hyperlinks is set to inherit zoom	5217	Document contains one or more links that are not set to 'Inherit Zoom'. Result is N/A if there is no hyperlink in the PDF.
PDF.HLNK.7	No multiple action hyperlink	5203	Document contains one or more hyperlinks containing multiple actions. Result is N/A if there is no hyperlink in the PDF.
PDF.HLNK.8	No blue texts without hyperlinks	PDF Spec	Document contains one or more blue texts that are not hyperlinks. Result is N/A if there is no blue text in the PDF.
PDF.HLNK.9	Hypertext linked TOC is included	PDF Spec	There is no hypertext linked TOC in the document which contains more pages than the configured page number. Maximum 10 pages - from first page - are checked for TOC by default. Configured names of TOC by default: "Table of Contents, Contents"
Annotations			
PDF.ANNO.1	No comments	N/A	Document contains one or more comments.
PDF.ANNO.2	No annotations	5055	Document contains one or more annotations. Only "Link" annotation is allowed by default. Configurable annotation types: FileAttachment, Line, Link, Popup, Stamp, Text, Widget, FreeText, Square, Circle, Underline, Squiggly, StrikeOut, Caret, Ink, Sound

* Error number FDA eCTD Validation Criteria