

Seznam validacijskih kriterijev

Kriteriji so oblikovani na podlagi rezultatov validacijskega poročila orodja eValidator podjetja Lorenz.

Kriteriji za vloge v obliki eCTD

Vloga je pripravljena v skladu z zadnjimi veljavnimi specifikacijami	
Fizični nosilec (CD/DVD) je ustrezno označen (v skladu z navodili, objavljenimi na spletni strani JAZMP)	
Spremeni dopis je ustrezno označen (v skladu z navodili, objavljenimi na spletni strani JAZMP)	
Številka mape sekvence je pravilna (npr. številka mape sekvence še ni bila uporabljena pri eni od predhodnih oddaj dokumentacije)	
Prisotna je "sledilna tabela" (angleško tracking table)- (le za vloge v MRP/DCP postopkih)	
File and Folder Security	Files or folder with restricted access permission; folders and files being readable. Note that any issues found here normally prevent the eValidator from proceeding with the validation properly (even for folders and files that might not be affected directly). So make sure to solve those issues and then restart validation before analyzing any other issues reported.
PDF Documents, corrupted	Checks for PDF documents which cannot be opened. Also checks for PDF document with a page count of 0.
PDF Protection: Commenting	Checks for PDF documents, which do not allow adding comments.
PDF Protection: Copy or extract content	Checks for PDF documents, which do not allow copying or extracting content.
PDF Protection: Printing	Checks for PDF documents, which do not allow printing.
PDF Protection: User password	Checks for PDF documents, which require a password upon opening.

Life Cycle Management Semantics	For leaves with operation "new", the eValidator verifies that: modified file must not exist / title is given / href must exist. For leaves with operation "replace", the eValidator verifies that: modified file must exist / title is given / href must exist. For leaves with operation "append", the eValidator verifies that: modified file must exist / title is given / href must exist. For leaves with operation "delete", the eValidator verifies that: modified file must exist / title is not required / href must not exist. The eValidator verifies that for initial submissions all leaves have the operation "new". The eValidator checks modified files in LCM: leaf in previous sequence must exist. It also verifies that when the attribute "modified-file"/"modified-leaf" has been used for a leaf document then the referenced document exists in the previous submission. It is recognized that this attribute is invalid when used for submission sequence number 0000.
MD5 Checksum	The eValidator regenerates the MD5 checksums for all referenced files and compares the checksums to the values provided in the backbone file.
Naming Syntax	Checks the syntax all referenced file names (path length, illegal characters, etc.).
Relative References	Checks that only relative references (href and modified file) are used. Also, only forward slashes "/" are allowed (no backslashes). Do the file references in the index files (ICH, Regional, STF) use relative paths? Absolute (i.e. rooted) paths are not allowed.
Unreferenced Files	Searches for files not referenced in an index file (ICH, Regional or STF). For non eCTD applications, this will list all files that are not reachable through a bookmark or hyperlink in any of the PDF files.
DTD Checksum (comparing content)	The DTDs and mod files found in the util/dtd folder will be compared to the corresponding DTDs and mod files located in the eValidator's configuration folder (subfolder DTDs). The comparison is performed byte for byte, ignoring white space.
MD5 for Index files	MD5 checksums for index files will be calculated and compared against the MD5 checksums provided in the MD5 text files.
Validate against delivered DTD	Performs XML validation for ICH Backbone and Regionals backbones. Uses the DTD or Schema given in the application folder (util/dtd).
Validate against stored DTD	Performs XML validation for ICH Backbone and Regionals backbones. Uses DTD or Schema given in the eValidator's configuration subfolder DTDs. This check always uses the DTD/Schema according to the version in the index file.
Attribute checksum-type	The checksum-type attribute must have the value md5 or MD5.
Country specific leaf - file naming	This rule verifies the file and folder naming for country specific leaf elements.
Element must have leaf	Checks for elements not having any leaf child nodes. This only affects elements with a name that starts with 'm'.
Element related-sequence 4 digits	The related-sequence value must be a 4-digit value.
Element sequence-number 4 digits	The sequence-number value must be a 4-digit value.

Element sequence-number matches folder name	The value of the sequence-number element must match the sequence folder name.
Envelope for centralised procedure	There must be a single eu-envelope with the country attribute value of emea if the procedure type is centralised.
Envelopes for country specific leaf elements	There is an eu-envelope element with a matching country attribute value for every country specific leaf included in Module 1 (i.e. there must no country specific leafs without a country matching envelope eu-element)
eu-regional.xml file exists	The regional backbone eu-regional.xml file must exist in folder m1\eu.
Leaf title must not be empty	For operations other than 'delete', all leafs must have a 'title' child. The title must exist.
Node Extension title must not be empty	For node extensions, the title child must be present (value must exist).
Attribute checksum-type	The checksum-type attribute must have the value md5 or MD5.
Element must have leaf	Checks for elements not having any leaf child nodes. This only affects elements with a name that starts with 'm'.
File index.xml exists	The index.xml file must exist.
File index-md5.txt exists	The MD5 checksum file index-md5.txt must exist.
Folder m1 exists	The m1 folder must exist.
Folder util exists	The util folder must exist.
Leaf title must not be empty	For operations other than 'delete', all leafs must have a 'title' child. The title must exist.
No other files in root	The root folder (the application sequence root) must not have any other files in addition to the files explicitly allowed by the rules above.
Regional backbone(s) referenced operation	All regional backbone files must be referenced. And the referenced regional backbone files should have 'new' operation attribute.
Regional backbone(s) referenced	All regional backbone files must be referenced.

Kriteriji za vloge v obliki NeeS

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Spremní dopis je ustrezno označen (v skladu z navodili, objavljenimi na spletni strani JAZMP)	
File and Folder Security	This rule's implementation performs checks for: Files or folder with restricted access permission; folders and files being readable. Note that any issues found here normally prevent the eValidator from proceeding with the validation properly (even for folders and files that might not be affected directly). So make sure to solve those issues and then restart validation before analyzing any other issues reported.
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Naming Syntax	Checks the syntax all referenced file names (path length, illegal characters, etc.).
Unreferenced Files	Searches for files not referenced in an index file (ICH, Regional or STF). For non eCTD applications, this will list all files that are not reachable through a bookmark or hyperlink in any of the PDF files.
ctd-toc.pdf exists	
Invalid file extension used	According to NeeS_0004, only the following file types are allowed: pdf, jpeg, png, svg, gif, sas, xml, rtf.
No other files in root	The root folder (the application sequence root) must not have any other files in addition to the files explicitly allowed by the rules above.