

Validation Criteria Set

Version 3.0

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2 Common Validation Criteria Sets within EXTEDO Products

General

Several **EXTEDO's** products such as **EURSvalidator**, **EURS is Yours eCTDmanager**, and **PlantOS.xml** support the validation of medicinal and veterinary eSubmissions. This is possible by using a *Validation Component*, which is implemented within each application and is used by the majority of *European National Authorities*, including EMA, to ensure eCTD and NeeS compliance. The *Validation Component* is a *CORE* component, with a general validation engine that executes the validation rules. The rules are defined in separate product-specific validation packages. Thus the *Validation Component* can be adapted to multiple products (see above) by user-definable extensions, to validate submissions according to product-specific standards.

Current *Validation Criteria Sets* are included in each of the mentioned **EXTEDO** products. If one of the products is installed, the *Validation Criteria Sets* is automatically placed in a local common folder of the computer and can be used by other products as well. This guarantees a high level of consistency in eSubmission validation.

Common Description

The *Validation Component* consists of the following parts:

- Validation engine
- GUI elements to display the progress and the results of the validation
- Validation packages: Separate sub-modules with product-specific rules

The validation component and the validation packages are configured by a set of XML and INI files.

Usability

The validation process can be complex and may take some time. Therefore the module provides a mechanism for monitoring progress. This can, for example, be used for a progress bar or a process monitor. The module can be opened from a worker thread to allow background processing.

3 EU eCTD 3.1

General

The following document contains a technical description of features implementation within the release cycle 1.0 of ValidationSets for the EU Region eCTD Validation Criteria Version 3.1.

Common Features Implementation

Validation Set Name

Validation Sets will be displayed in tool and reports as follows:

Other eCTD Context

Name	EU-eCTD v3.1 (DTD 1.4) – Other eCTD Context
Version	EU validation criteria for EU M 1.4 release 3.1
Description	eCTD 3.2 with EU M 1.4 regional part with related sequences

Context of Other eCTDs

eCTD submissions may contain references to previous sequences of application using life cycle operations *append*, *replace* and *delete* and/or using direct *document references* into the previous sequence. Validation will be possible in 2 modes of operation:

- Validate submission in context of other eCTDs

Implementation of rules will depend on this. Thus there will be a validation set for each mode. Optionally both modes can be merged into one validation set, if validation component and applications will be extended to use a parameter to switch the mode and to display the selected mode in validation reports.

To discover the other eCTD sequences the following procedure will be used:

1. Read index XML and EU regional XML files of the current sequence.
2. Get a list of all path values of attributes *xlink:href* and *modified-file* from the 2 index files.
3. Select from list all path values with a target outside the current sequence but inside the application (i.e. *../0002/* will be selected, *../app2/0002/* will not be selected).
4. Get the sequence numbers from list as the other eCTD sequences to use for the rules.

If not defined in another way for the individual rule, only the sequences discovered with the procedure will be included in checks. Other eCTD sequences will be ignored.

Later: *AutoselectDTD* can be extended to find previous sequences as described above and to select the validation set for eCTD context if previous sequences have been found and the validation set for submission only if a previous sequence has been found.

Rules Implementation

Validation Start Object

Current validation sets and validation component are implemented to start the validation for a sequence folder like /0000 or the root folder /root for vNeeS. Some checks will have a different implementation for the two methods:

Start with folder	Checks get direct access to the folder provided and search there for the start file if required (<start-folder>/index.xml or <start-folder>/ctd-toc.pdf).
Start with file	Checks get direct access to the file provided and use the folder where the file is stored as the sequence folder (sample: starting with app2/0002/index.xml will use app2/0002 as sequence folder).

Other files than the selected one to start validation (sample: eu-regional.xml or m2-toc.pdf) are selected by the checks using the folder in both cases. Therefore the *Start with file* method will result with some asymmetric implementations of checks. Sample: Start with /XXXX/xyz.xml ignoring if there is also an index.xml in folder, but require the file /XXXX/m1/eu/eu-regional.xml for another check.

Rules Implementation

Details of test rules implementation are given in next chapters.

The specified text elements for *Number*, *Validation Criterion*, *Severity*, *Problem Message* and *Hint Message* are presented to user in Validation GUI as follows:

Number	No. in Results Grid
Validation Criterion	Description in Results Grid
Severity	Severity in Results Grid
Problem Message	Test Result in Details Area (upper left text box)
Hint Message	Hint in Details Area (upper right text box)

Option: Number of checks will be formatted as XX.XX or XX.BPXX for numeric sorting in *results grid*. Samples:

- 1.1 to 01.01
- 16.BP3 to 16.BP03

Test Object Level

Submission level	The check will be started once for the sequence. The test object may be the sequence folder or the index XML file.
Index XML + EU regional XML	The check will be started twice for the sequence – for the index XML file and the EU regional XML file each with separated results for the index file.
Files	The check will be started for each individual file. This may be any file or a file selected by a pattern as *.pdf for the PDF checks.

Lifecycle Context

Other eCTD context	The check is implemented in context with all other sequences, referenced within the test submission.
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eCTD Validation Criteria Overview

The following table displays an overview about all EU eCTD validation set criteria, **version 3.1**.

Category	No. — Validation Criterion
01 ICH DTD	01.01 — Specified Filename
	01.02 — Correct File Placement
	01.03 — Acceptable DTD Version
	01.04 — Valid DTD Version
02 ICH Style Sheet	02.01 — Specified Filename
	02.02 — Correct File Placement
	02.03 — Acceptable Style Sheet Version
	02.04 — Valid Style Sheet Version
03 EU M1 DTD	03.01 — Specific Filename
	03.02 — Correct File Placement
	03.03 — Acceptable DTD Version
	03.04 — Valid DTD Version
04 EU M1 Leaf MOD File	04.01 — Specific Filename
	04.02 — Correct Folder Placement
	04.03 — Acceptable EU Leaf Version
	04.04 — Valid EU Leaf Version
05 EU M1 Envelope MOD File	05.01 — Specific Filename
	05.02 — Correct Folder Placement
	05.03 — Acceptable EU Envelope Version
	05.04 — Valid EU Envelope Version
06 EU M1 Style Sheet	06.01 — Specific Filename
	06.02 — Correct Folder Placement
	06.03 — Acceptable Style Sheet Version
	06.04 — Valid Style Sheet Version
7 Index XML	07.01 — File in Correct Folder
	07.02 — Correct Filename
	07.03 — Well Formed XML
	07.04 — Valid to DTD
08 Index MD5 txt	08.01 — File Placement
	08.02 — Correct Filename
	08.03 — Index File Checksum
09 EU Regional XML	09.01 — File Placement
	09.02 — Correct Filename
	09.03 — Well Formed XML
	09.04 — Valid to DTD



Category	No. — Validation Criterion
10 Submission Structure	10.01 — Leaf Check
	11.01 — Checksum Type Attribute
11 Leaf Attributes	11.02 — Checksum Value
	11.03 — Leaf Title Attribute
	11.04 — xlink:href Attribute Value
	11.05 — No xlink:href Attribute Value
	11.06 — xlink:href Target
	11.07 — Modified-File Attribute
	11.08 — No Modified-File Attribute
	11.09 — Modified-File Attribute Target
	12 Node Extensions
13.01 — Sequence Number Format	
13 Sequence Number	13.02 — Sequence Number Check
	13.03 — Sequence Folder Name
14 Envelope Attributes	14.01 — EU Envelope with EMEA Country Attribute Value
	14.02 — EU Envelope with Every Country Attribute Value
	14.BP01 — Related Sequence Attribute Value
	14.BP02 — No Related Sequence Attribute Value
15 Files / Folders	15.01 — File Format for Module 1
	15.02 — File Format for Module 2-5
	15.03 — Path Length
	15.04 — File Name Length
	15.05 — Folder Name Length
	15.06 — File Name Characters
	15.07 — Folder Name Characters
	15.08 — Un-referenced Files
	15.09 — Files in Sequence Folder
	15.10 — No Empty Folders
	15.11 — Tracking Table File Location
	15.12 — Tracking Table File Name
	15.BP01 — File Size
15.BP02 — Folder Name	
15.BP03 — File Name	

Category	No. — Validation Criterion
16 PDF Files	16.01 — PDF Version 1.4 or Later
	16.02 — Security Setting to Open
	16.03 — Other Security Settings
	16.BP01 — PDF Version 1.4
	16.BP02 — Current Sequence Hyperlink Targets
	16.BP03 — Current Sequence Bookmark Targets
	16.BP04 — Valid Sequence Hyperlink Targets
	16.BP05 — Valid Sequence Bookmark Targets
	16.BP06 — Inherit Zoom
	16.BP07 — Fast Web View
	16.BP08 — PDF Document Properties
16.BP09 — Relative Hyperlinks	
16.BP10 — Relative Bookmarks	
16.BP11 — Bookmarks Pane Visibility	

01 - ICH DTD

No. 01.01 Specified Filename




Basics

Number	01.01
Category	ICH DTD
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ich-ectd-3-2.dtd

Summary



Problem Message	/XXXX/util/dtd/ich-ectd-3-2.dtd not found
Hint Message	/XXXX/util/dtd/ich-ectd-3-2.dtd shall exist

Details

 fail-01.01.01	Looking for the file ich-ectd-3-2.dtd in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-01.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Ich-ectd-3-2.dtd or ich-ectd-3-2.DTD)
 pass-01.01.01	The filename there must be ich-ectd-3-2.dtd . The filename check is performed in folder /XXXX/util/dtd only .

No. 01.02 Correct File Placement




Basics

Number	01.02
Category	ICH DTD
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/ich-ectd-3-2.dtd not found.
Hint Message	/XXXX/util/dtd/ich-ectd-3-2.dtd shall exist

Details

 fail-01.02.01	Investigate folder /XXXX/util/dtd to find ich-ectd-3-2.dtd . There is no file present. No other folders are checked.
 fail-01.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file ich-ectd-3-2.dtd cannot be checked.
 fail-01.02.03	The spelling of the requested filename ich-ectd-3-2.dtd in folder /XXXX/util/dtd is incorrect (e.g. ich-ectd-3-2.DTD or ich-ectd-3-2.DTD). The correct placement of the file ich-ectd-3-2.dtd cannot be checked.

No. 01.03 Acceptable DTD Version






Basics

Number	01.03
Category	ICH DTD
Validation Criterion	A currently acceptable version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/ich-ectd-3-2.dtd not found
Hint Message	Version of /XXXX/util/dtd/ich-ectd-3-2.dtd shall not be older than the version in a previous sequence

Details

 fail-01.03.01	The version of the DTD in /XXXX/util/dtd/ich-ectd-3-2.dtd is older than the version in the previous sequence(s): {0}
 pass-01.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-01.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-01.03.03	Validate submission in context of other eCTDs: A DTD in a former sequence is not available or is misspelled.
 pass-01.03.04	Validate submission in context of other eCTDs: The DTD version number must be higher or equal to the highest DTD version number in the previous sequence.

No. 01.04 Valid DTD Version





Basics

Number	01.04
Category	ICH DTD
Validation Criterion	The valid version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v3.2 is 1d6f631cc6b6357f0f4fe378e5f79a27

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v3.2 is 1d6f631cc6b6357f0f4fe378e5f79a27



Details

 fail-01.04.01	The file /XXXX/util/dtd/ich-ectd-3-2.dtd cannot be found.
 fail-01.04.02	The provided checksum of the file ich-ectd-3-2.dtd is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-01.04.03	The invalid /util/dtd folder prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.
 fail-01.04.04	The invalid filename of ich-ectd-3-2.dtd prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.

02 - ICH Style Sheet

No. 02.01 Specified Filename

Basics



Number	02.01
Category	ICH style sheet
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ectd-2-0.xsl

Summary

Problem Message	/XXXX/util/style/ectd-2-0.xsl not found
Hint Message	/XXXX/util/style/ectd-2-0.xsl shall exist



If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.01.01	Looking for the file ectd-2-0.xsl in folder /XXXX/util/style . File is not found. Spelling cannot be checked.
 fail-02.01.02	The spelling of the present filename (in folder /XXXX/util/style) is incorrect (e.g. Ectd-2-0.xsl or ectd-2-0.XSL)

No. 02.02 Correct File Placement

Basics




Number	02.02
Category	ICH style sheet
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/style

Summary

Problem Message	/XXXX/util/style/ectd-2-0.xml not found
Hint Message	/XXXX/util/style/ectd-2-0.xml shall exist



If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.02.01	Investigate folder /XXXX/util/style to find ectd-2-0.xml . There is no file present. No other folders are checked.
 fail-02.02.02	The spelling of the folder (e.g. /XXXX/util/STYLE) is incorrect. The correct placement of the file ectd-2-0.xml cannot be checked.
 fail-02.02.03	The spelling of the requested filename ectd-2-0.xml in folder /XXXX/util/style is incorrect (e.g. Ectd-2-0.xml or ectd-2-0.XSL). The correct placement of the file ectd-2-0.xml cannot be checked.

No. 02.03 Acceptable Style Sheet Version

Basics






Number	02.03
Category	ICH stylesheet
Validation Criterion	A currently acceptable version of the stylesheet is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary

Problem Message	Acceptable version of /XXXX/util/style/ectd-2-0.xml not found
Hint Message	Version /XXXX/util/style/ectd-2-0.xml shall not be older than the version in a previous sequence



If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.03.01	The version of the stylesheet in /XXXX/util/style/ectd-2-0.xml is older than version in the previous sequence(s): {0}
 pass-02.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-02.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-02.03.03	Validate submission in context of other eCTDs: A style sheet in a former sequence is not available or is misspelled.
 pass-02.03.04	Validate submission in context of other eCTDs: The style sheet version number must be higher or equal to the highest style sheet version number in the previous sequence.

No. 02.04 Valid Style Sheet Version

Basics





Number	02.04
Category	ICH style sheet
Validation Criterion	The valid version of the style sheet is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v3.2 is 3a07a202455e954a2eb203c5bb443f77

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v3.2 is 3a07a202455e954a2eb203c5bb443f77

If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.



Details

 fail-02.04.01	The file /XXXX/util/style/ectd-2-0.xsl cannot be found.
 fail-02.04.02	The provided checksum of the file ectd-2-0.xsl is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-02.04.03	The invalid /util/style folder prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.
 fail-02.04.04	The invalid filename of ectd-2-0.xsl prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.

03 - EU M1 DTD

No. 03.01 Specific Filename



Basics

Number	03.01
Category	EU M1 DTD
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named eu-regional.dtd

Summary



Problem Message	/XXXX/util/dtd/eu-regional.dtd not found
Hint Message	/XXXX/util/dtd/eu-regional.dtd shall exist

Details

 fail-03.01.01	Looking for the file eu-regional.dtd in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-03.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Eu-regional.dtd or eu-regional.DTD)

No. 03.02 Correct File Placement




Basics

Number	03.02
Category	EU M1 DTD
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/eu-regional.dtd not found
Hint Message	/XXXX/util/dtd/eu-regional.dtd shall exist

Details

 fail-03.02.01	Investigate folder /XXXX/util/dtd to find eu-regional.dtd . There is no file present. No other folders are checked.
 fail-03.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file eu-regional.dtd cannot be checked.
 fail-03.02.03	The spelling of the requested filename eu-regional.dtd in folder /XXXX/util/dtd is incorrect (e.g. Eu-regional.dtd or eu-regional.DTD). The correct placement of the file eu-regional.dtd cannot be checked.

No. 03.03 Acceptable DTD Version






Basics

Number	03.03
Category	EU M1 DTD
Validation Criterion	A currently acceptable version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/eu-regional.dtd not found
Hint Message	Version of /XXXX/util/dtd/eu-regional.dtd shall not be older than version in a previous sequence

Details

 fail-03.03.01	The version of the DTD in /XXXX/util/dtd/eu-regional.dtd is older than the version in the previous sequence(s): {0}
 pass-03.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-03.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses “validate submission in context of other eCTDs
 pass-03.03.03	Validate submission in context of other eCTDs: A DTD in a former sequence is not available or is misspelled.
 pass-03.03.04	Validate submission in context of other eCTDs: The DTD version number must be higher or equal to the highest DTD version number in the previous sequence.

No. 03.04 Valid DTD Version





Basics

Number	03.04
Category	EU M1 DTD
Validation Criterion	The valid version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 91654e96e3bafc5e89df7f892477b246

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 91654e96e3bafc5e89df7f892477b246



Details

 fail-03.04.01	The file /XXXX/util/dtd/eu-regional.dtd cannot be found.
 fail-03.04.02	The provided checksum of the file eu-regional.dtd is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-03.04.03	The invalid /util/dtd folder prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.
 fail-03.04.04	The invalid filename of eu-regional.dtd prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.

04 - EU M1 Leaf MOD File

No. 04.01 Specific Filename



Basics

Number	04.01
Category	EU M1 leaf MOD file
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named eu-leaf.mod

Summary



Problem Message	/XXXX/util/dtd/eu-leaf.mod not found
Hint Message	/XXXX/util/dtd/eu-leaf.mod shall exist

Details

 fail-04.01.01	Looking for the file eu-leaf.mod in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-04.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Eu-leaf.mod or eu-leaf.MOD)

No. 04.02 Correct Folder Placement




Basics

Number	04.02
Category	EU M1 leaf MOD file
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder <code>/XXXX/util/dtd</code>

Summary



Problem Message	<code>/XXXX/util/dtd/eu-leaf.mod</code> not found
Hint Message	<code>/XXXX/util/dtd/eu-leaf.mod</code> shall exist

Details

 fail-04.02.01	Investigate folder <code>/XXXX/util/dtd</code> to find eu-leaf.mod . There is no file present. No other folders are checked.
 fail-04.02.02	The spelling of the folder (e.g. <code>/XXXX/util/DTD</code>) is incorrect. The correct placement of the file <code>eu-leaf.mod</code> cannot be checked.
 fail-04.02.03	The spelling of the requested filename eu-leaf.mod in folder <code>/XXXX/util/dtd</code> is incorrect (e.g. Eu-leaf.mod or eu-leaf.MOD). The correct placement of the file eu-leaf.mod cannot be checked.

No. 04.03 Acceptable EU Leaf Version






Basics

Number	04.03
Category	EU M1 leaf MOD file
Validation Criterion	A currently acceptable version of the eu-leaf.mod file is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/eu-leaf.mod not found
Hint Message	Version of /XXXX/util/dtd/eu-leaf.mod shall not be older than the version in a previous sequence

Details

 fail-04.03.01	The version of the MOD file in /XXXX/util/dtd/eu-leaf.mod is older than the version in the previous sequence(s): {0}
 pass-04.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-04.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-04.03.03	Validate submission in context of other eCTDs: A MOD file in a former sequence is not available or is misspelled.
 pass-04.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 04.04 Valid EU Leaf Version





Basics

Number	04.04
Category	EU M1 leaf MOD file
Validation Criterion	The valid version of the eu-leaf.mod file is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 2e976bc60658a964affa5026369a371e

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 2e976bc60658a964affa5026369a371e



Details

 fail-04.04.01	The file /XXXX/util/dtd/eu-leaf.mod cannot be found.
 fail-04.04.02	The provided checksum of the file eu-leaf.mod is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-04.04.03	The invalid /util/dtd folder prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.
 fail-04.04.04	The invalid filename of eu-leaf.mod prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.

05 - EU M1 Envelope MOD File

No. 05.01 Specific Filename



Basics

Number	05.01
Category	EU M1 envelope MOD file
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named eu-envelope.mod

Summary



Problem Message	/XXXX/util/dtd/eu-envelope.mod not found
Hint Message	/XXXX/util/dtd/eu-envelope.mod shall exist

Details

 fail-05.01.01	Looking for the file eu-envelope.mod in folder /XXXX/util/dtd. File is not found. Spelling cannot be checked.
 fail-05.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Eu-envelope.mod or eu-envelope.MOD)

No. 05.02 Correct Folder Placement




Basics

Number	05.02
Category	EU M1 envelope MOD file
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/eu-envelope.mod not found
Hint Message	/XXXX/util/dtd/eu-envelope.mod shall exist

Details

 fail-05.02.01	Investigate folder /XXXX/util/dtd to find eu-envelope.mod . There is no file present. No other folders are checked.
 fail-05.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file eu-envelope.mod cannot be checked.
 fail-05.02.03	The spelling of the requested filename eu-envelope.mod in folder /XXXX/util/dtd is incorrect (e.g. Eu-envelope.mod or eu-envelope.MOD). The correct placement of the file eu-envelope.mod cannot be checked.

No. 05.03 Acceptable EU Envelope Version






Basics

Number	05.03
Category	EU M1 envelope MOD file
Validation Criterion	A currently acceptable version of the eu-envelope.mod file is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/eu-envelope.mod not found
Hint Message	Version of /XXXX/util/dtd/eu-envelope.mod shall not be older than the version in a previous sequence

Details

 fail-05.03.01	The version of the MOD file in /XXXX/util/dtd/eu-envelope.mod is older than the version in the previous sequence(s): {0}
 pass-05.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-05.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-05.03.03	Validate submission in context of other eCTDs: A MOD file in a former sequence is not available or is misspelled.
 pass-05.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 05.04 Valid EU Envelope Version





Basics

Number	05.04
Category	EU M1 envelope MOD file
Validation Criterion	The valid version of the eu-envelope.mod file is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 664a76e3f31a9553d3375d3b21815904

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 664a76e3f31a9553d3375d3b21815904



Details

 fail-05.04.01	The file /XXXX/util/dtd/eu-envelope.mod cannot be found.
 fail-05.04.02	The provided checksum of the file eu-envelope.mod is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-05.04.03	The invalid /util/dtd folder prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.
 fail-05.04.04	The invalid filename of eu-envelope.mod prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.

06 - EU M1 Style Sheet

No. 06.01 Specific Filename



Basics

Number	06.01
Category	EU M1 stylesheet
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named eu-regional.xsl

Summary



Problem Message	/XXXX/util/style/eu-regional.xsl not found
Hint Message	/XXXX/util/style/eu-regional.xsl shall exist

Details

 fail-06.01.01	Looking for the file eu-regional.xsl in folder /XXXX/util/style . File is not found. Spelling cannot be checked.
 fail-06.01.02	The spelling of the present filename (in folder /XXXX/util/style) is incorrect (e.g. Eu-regional.xsl or eu-regional.XSL)

No. 06.02 Correct Folder Placement




Basics

Number	06.02
Category	EU M1 stylesheet
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/style

Summary



Problem Message	/XXXX/util/style/eu-regional.xml not found
Hint Message	/XXXX/util/style/eu-regional.xml shall exist

Details

 fail-06.02.01	Investigate folder /XXXX/util/style to find eu-regional.xml . There is no file present. No other folders are checked.
 fail-06.02.02	The spelling of the folder (e.g. /XXXX/util/STYLE) is incorrect. The correct placement of the file eu-regional.xml cannot be checked.
 fail-06.02.03	The spelling of the requested filename eu-regional.xml in folder /XXXX/util/style is incorrect (e.g. Eu-regional.xml or eu-regional.XSL). The correct placement of the file eu-regional.xml cannot be checked.

No. 06.03 Acceptable Style Sheet Version






Basics

Number	06.03
Category	EU M1 style sheet
Validation Criterion	A currently acceptable version of the style sheet is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/style/eu-regional.xml not found
Hint Message	Version of /XXXX/util/style/eu-regional.xml shall not be older than the version in a previous sequence

Details

 fail-06.03.01	The version of the stylesheet in /XXXX/util/style/eu-regional.xml is older than the version in the previous sequence(s): {0}
 pass-06.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-06.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-06.03.03	Validate submission in context of other eCTDs: A stylesheet in a former sequence is not available or is misspelled.
 pass-06.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 06.04 Valid Style Sheet Version





Basics

Number	06.04
Category	EU M1 stylesheet
Validation Criterion	The valid version of the stylesheet is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 54f9889822e1d08cc23b902fc6a66aaa

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 54f9889822e1d08cc23b902fc6a66aaa



Details

 fail-06.04.01	The file /XXXX/util/style/eu-regional.xsl cannot be found.
 fail-06.04.02	The provided checksum of the file eu-regional.xsl is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-06.04.03	The invalid /util/style folder prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.
 fail-06.04.04	The invalid filename of eu-regional.xsl prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.

07 - Index XML

No. 07.01 File Placement

Basics

Number	07.01
Category	Index XML
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The root folder /XXXX

Summary



Problem Message	Index XML file is not stored in root folder /XXXX
Hint Message	The root folder shall be /XXXX

Details

No content yet

No. 07.02 Correct Filename

Basics

Number	07.02
Category	Index XML
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named index.xml

Summary



Problem Message	File is not named index.xml
Hint Message	File must be named index.xml

Details

No content yet

No. 07.03 Well Formed XML

Basics

Number	07.03
Category	Index XML
Validation Criterion	The file is well formed
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Well formed with respect to the rules of the XML specification

Summary



Problem Message	The index XML file is not well formed
Hint Message	The index XML file must be well formed

Details

No content yet

No. 07.04 Valid to DTD

Basics

Number	07.04
Category	Index XML
Validation Criterion	The file is valid
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Valid with respect to the ICH eCTD DTD file included in the util/dtd folder

Summary

Problem Message	The index XML file is not valid
Hint Message	The index XML file must be valid according to the DTD



Details

No content yet

08 - Index MD5 Txt

No. 08.01 File Placement





Basics

Number	08.01
Category	Index MD5 txt
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The root folder /XXXX

Summary


Problem Message	Index- md5.txt file is not stored in root folder /XXXX
Hint Message	The file must be placed in the root folder /XXXX

Details

 fail-08.01.01	Investigate folder /XXXX/ to find index-md5.txt . The file is missing. The correct placement of the file cannot be checked.
 fail-08.01.02	The root folder is not a 4 digit number. The validation of the folder cannot be checked.
 pass-08.01.01	If both or one of them (7.1 and / or 7.2) failed.
 pass-08.01.02	The user selects a folder /XXXX with file index-md5.txt . The root folder is a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]

No. 08.02 Correct Filename





Basics

Number	08.02
Category	Index MD5 txt
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The file is named index-md5.txt

Summary



Problem Message	/XXXX/index-md5.txt not found
Hint Message	The file must be named index-md5.txt

Details

 fail-08.02.01	Investigate folder /XXXX/ to find index-md5.txt . There is no file present. The correct name of the file cannot be checked.
 fail-08.02.02	The spelling of the present filename is incorrect (e.g. INdex-md5.txt or index-md5.TXT)
 pass-08.02.01	The user selects a folder /XX with file index-md5.txt : The root folder is <i>not</i> a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]
 pass-08.02.02	The user selects a folder /XXXX with file index-md5.txt : The root folder is a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]

No. 08.03 Index File Checksum



Basics

Number	08.03
Category	Index MD5 txt
Validation Criterion	The regenerated checksum for the index.xml matches the value in the file index-md5.txt
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable !

Summary

Problem Message	The regenerated checksum for the index.xml does not match the value in the file index-md5.txt
Hint Message	The regenerated checksum for the index.xml must match the value in the file index-md5.txt



Details

 fail-08.03.01	The regenerated checksum of index.xml does not match the checksum stored in index-md5.txt . Checksum stored in {0} is {1}. The recalculated checksum of the index.xml is {2}.
 pass-08.03.01	If both or one of them (8.1 and / or 8.2) failed.

09 - EU Regional XML

No. 09.01 File Placement



Basics

Number	09.01
Category	EU regional XML
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The folder /XXXX/m1/eu

Summary

Problem Message	EU regional XML file is not stored in folder /XXXX/m1/eu
Hint Message	EU regional XML must be stored in /XXXX/m1/eu

Details

 fail-09.01.01	Investigate folder /XXXX/m1/eu to find eu-regional.xml . The file is missing. The correct placement of the file cannot be checked.
 fail-09.01.02	The spelling of the folder /XXXX/m1/eu is incorrect. The validation of the folder cannot be checked.

No. 09.02 Correct Filename



Basics

Number	09.02
Category	EU regional XML
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named eu-regional.xml

Summary



Problem Message	/XXXX/m1/eu/eu-regional.xml not found
Hint Message	The file must be named eu-regional.xml

Details

 fail-09.02.01	Investigate folder /XXXX/m1/eu to find eu-regional.xml . There is no file present. The correct name of the file cannot be checked.
 fail-09.02.02	The spelling of the present filename (in folder /XXXX/m1/eu) is incorrect (e.g. Eu-regional.xml or eu-regional.XML)

No. 09.03 Well Formed XML



Basics

Number	09.03
Category	EU regional XML
Validation Criterion	The file is well formed
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Well formed with respect to the rules of the XML specification

Summary



Problem Message	The EU regional XML file is not well formed
Hint Message	The EU regional XML file must be well formed

Details

 fail-09.03.01	The eu-regional.xml is not well formed. XML parser error: {0}
 pass-09.03.01	If both or one of them (9.1 and / or 9.2) failed.

No. 09.04 Valid to DTD




Basics

Number	09.04
Category	EU regional XML
Validation Criterion	The file is valid
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Valid with respect to the EU Module 1 DTD file included in the util/dtd folder

Summary

Problem Message	The EU regional XML file is not valid
Hint Message	The EU regional XML file must be valid according to the DTD



Details

 fail-09.04.01	The eu-regional.xml is not valid. XML parser error: {0}
 pass-09.04.01	If the DTD is missing or located in a wrong path (incl. incorrect spelling or capital letter of DTD)
 pass-09.04.02	If both or one of them (9.1 and / or 9.2) failed.

10 - Submission Structure

No. 10.01 Leaf Check

Basics

Number	10.01
Category	Submission Structure
Validation Criterion	All the lowest level heading elements in the XML (including node-extensions) included in the submission contain at least one leaf
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!



Summary

Problem Message	XML element without leaf found
Hint Message	All lowest level elements must contain at least one leaf

11 - Leaf Attributes

No. 11.01 Checksum Type Attribute


Basics

Number	11.01
Category	Leaf Attributes
Validation Criterion	The leaf attribute checksum-type has a value of md5 or MD5
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Note that this value is not case sensitive

Summary



Problem Message	One or more leaf elements with invalid or missing checksum-type attribute found
Hint Message	The checksum-type attribute must have the value md5 or MD5

Details

 fail-11.01.01: The checksum-type attribute is present but empty.

No. 11.02 Checksum Value


Basics

Number	11.02
Category	Leaf Attributes
Validation Criterion	The regenerated checksum for each file matches the value in the leaf attribute checksum
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Note that if the content file is in an earlier sequence within the same eCTD application then the checksum can only be regenerated if access to this file is available. The MD5 checksum is not case sensitive.

Summary



Problem Message	One or more referenced files have the wrong checksum
Hint Message	The regenerated checksum for every referenced file is the same as each associated checksum provided in the index file

Details

-  fail-11.02.01: The checksum-type attribute is present but empty.

No. 11.03 Leaf Title Attribute

Basics



Number	11.03
Category	Leaf Attributes
Validation Criterion	For every leaf the attribute is not empty
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary

Problem Message	Not all leafs have a title
Hint Message	Every leaf must have a non-empty 'title' attribute

No. 11.04 xlink:href Attribute Value

Basics

Number	11.04
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of new, replace or append must have a value for xlink:href
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary



Problem Message	Not all leafs have a xlink:href value for operations new, replace or append
Hint Message	If operation is new, replace or append, then xlink:href value should exist

Details

 fail-11.04.01: The attribute entry **xlink:href** is missing. Invalid leafs are found: {0}

No. 11.05 No xlink:href Attribute Value

Basics



Number	11.05
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of delete must have no value for xlink:href
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	The attribute does not need to be included, or can be declared but with a null value

Summary

Problem Message	Not all xlink:href entries are blank
Hint Message	xlink:href must be blank to execute the operation delete

No. 11.06 xlink:href Target


Basics

Number	11.06
Category	Leaf Attributes
Validation Criterion	The file referenced by the xlink:href must exist in the same or a previously submitted sequence within the same eCTD application
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	No conten available

Summary



Problem Message	Not all xlink:href entries are linked with a document
Hint Message	xlink:href should point to a document.

Details

 fail-11.06.01: The file referenced by **xlink:href** is missing or not accessible. Invalid leafs are found: {0}

No. 11.07 Modified-File Attribute

Basics

Number	11.07
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of replace, delete or append must have a value for modified-file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	Not all leafs have a modified-file value for operations replace, delete or append
Hint Message	A modified file value is needed to execute the operations replace , delete or append .

Details

 fail-11.07.01: The attribute entry modified-file is missing. Invalid leafs found: {0}

No. 11.08 No Modified-File Attribute

Basics



Number	11.08
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of new must have no value for modified-file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The attribute does not need to be included, or can be declared but with a null value

Summary

Problem Message	Not all modified-file entries are blank
Hint Message	The modified file must be blank to execute the operation new

No. 11.09 Modified-File Attribute Target


Basics

Number	11.09
Category	Leaf Attributes
Validation Criterion	The leaf referenced by the modified-file must exist in a previously submitted sequence within the same eCTD application
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary

Problem Message	Not all modified-file entries are linked with a leaf
Hint Message	Modified-file should point to a leaf



Details

 fail-11.09.01: The file referenced by modified-file is missing or not accessible. Invalid leafs found: {0}

12 - Node Extensions

No. 12.01 Node Extension Title

Basics

Number	12.01
Category	Node extensions
Validation Criterion	For every node-extension the title attribute is not empty
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!



Summary

Problem Message	Not all node extensions have a title
Hint Message	Every node extension must have a non-empty title attribute.

13 - Sequence Number

No. 13.01 Sequence Number Format

Basics



Number	13.01
Category	Sequence number
Validation Criterion	The sequence number is 4 digits
Type of Check	 Success  Error
Other Submissions Required	no
Comment	i.e. numbers between 0000 and 9999

Summary

Problem Message	The sequence number has an incorrect format
Hint Message	The sequence number is 4 digits (i.e. numbers between 0000 and 9999).

No. 13.02 Sequence Number Check




Basics

Number	13.02
Category	Sequence number
Validation Criterion	The sequence number has not already been used
Type of Check	 Success  P/F
Other Submissions Required	yes
Description	Not applicable!

Summary



Problem Message	The sequence number has been used already
Hint Message	Another sequence number has to be used

Details

 fail-13.02.01	No content yet
 pass-13.02.01	If 13.03 fails.
 pass-13.02.02	If one or more of the sequences is missing (e.g. MRP comprehensive model?)

No. 13.03 Sequence Folder Name




Basics

Number	13.03
Category	Sequence number
Validation Criterion	The sequence folder name matches the sequence number in the envelope in eu-regional.xml
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	The sequence folder does not match the envelope sequence number
Hint Message	The sequence folder name matches the sequence number in the eu-envelope in eu-regional.xml



Details

 fail-13.03.01	The sequence folder does not match the envelope sequence number
 pass-13.03.01	The file eu-regional.xml is missing.
 pass-13.03.02	The file eu-regional.xml is not readable or empty.

14 - Envelope Attributes

No. 14.01 EMEA Country Attribute Value



Basics

Number	14.01
Category	Envelope Attributes
Validation Criterion	There is a single envelope with the country attribute value of emea if the procedure type = centralised
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This should still be "emea"

Summary



Problem Message	There is no single eu-envelope for procedure type centralized.
Hint Message	There is a single eu-envelope with the country attribute value of emea if the procedure type = centralized.

Details

 fail-14.01.01	The centralized procedure allows only the single envelope element ' emea '. There is more than one envelope element.
 fail-14.01.02	The centralized procedure allows only the single envelope element ' emea '. The following was found: {0}

No. 14.02 Every Country Attribute Value

Basics


Number	14.02
Category	Envelope Attributes
Validation Criterion	There is a envelope element with a matching country attribute value for every country specific leaf (except "common") included in Module 1
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If all content is common, then you will still need to include separate envelopes for every country receiving the sequence. However, note that there is not a test for this scenario.

Summary

Problem Message	Some leafs donot match envelope country
Hint Message	There is an envelope element with a matching country attribute value for every country-specific leaf (except "common") included in Module 1

No. 14.BP01 Related Sequence Attribute Value


Basics

Number	14.BP01
Category	Envelope Attributes
Validation Criterion	If the submission type is supplemental-info or corrigendum then the related-sequence attribute must have a value
	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	Related-sequence attribute required
Hint Message	If the submission type is supplemental info or corrigendum, then the relatedsequence attribute must have a value

Details

-  fail-14.bp01.01: The '**related sequence number**' is only required for submission type '**supplemental-info**' or '**corrigendum**'. The related sequence number is not found for: {0}

No. 14.BP02 No Related Sequence Attribute Value




Basics

Number	14.BP02
Category	Envelope Attributes
Validation Criterion	If the submission type is not supplemental-info or corrigendum then there must not be related-sequence attribute
	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Related sequence attribute not required
Hint Message	If the submission type is not supplemental info or corrigendum, then there must not be related sequence attribute



Details

 fail-14.bp02.01	The ' related sequence number ' is only required for submission type ' supplemental-info ' or ' corrigendum '. The used submission type does not allow a ' related sequence number '. There is a related sequence number found for: {0}
 pass-14.bp02.01	The related sequence attribute is absent.
 pass-14.bp02.02	The related sequence attribute is present, but empty.

15 - Files / Folders

No. 15.01 File Format for Module 1






Basics

Number	15.01
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 1 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to table in EU Module 1 specification RTF will be removed from the list of acceptable formats to be referenced by leafs in the eu-regional.xml

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-15.01.01	The file does not have a valid format.
 pass-15.01.01	m1/eu/13-pi/131-pim-a-0000.zip.
 pass-15.01.02	m1/eu/13-pi/131-PIM-a-0000.ZIP.
 pass-15.01.03	m1/eu/13-pi/0000.pdf.
 pass-15.01.04	m1/eu/13-pi/0000.PDF.

No. 15.02 File Format for Module 2-5

Basics

Number	15.02
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 2-5 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to ICH eCTD specification

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-15.02.01: The file does not have a valid format.

No. 15.03 Path Length

Basics



Number	15.03
Category	Files / Folders
Validation Criterion	Total file folder path length must not exceed 180 characters
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Counting starts from the first digit of the sequence number in the sequence number folder name.

Summary

Problem Message	The total path length exceeds 180 characters
Hint Message	Total folder/file path must not exceed 180 characters, starting at the top level folder of the submission

No. 15.04 File Name Length


Basics

Number	15.04
Category	Files / Folders
Validation Criterion	File names, including the extension, must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a file name exceeds 64 characters
Hint Message	File names may not exceed 64 characters

Details

-  fail-15.04.01 : The maximum number of characters in a file name including the extension is 64. A file name with {0} characters was found: {1}

No. 15.05 Folder Name Length


Basics

Number	15.05
Category	Files / Folders
Validation Criterion	Folder names must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a folder name exceeds 64 characters
Hint Message	Folder names may not exceed 64 characters

Details

 fail-15.05.01: The maximum number of characters in a folder is 64. Folder name with {0} characters found: {1}

No. 15.06 File Name Characters





Basics

Number	15.06
Category	Files / Folders
Validation Criterion	Only valid characters are used in file names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The file name contains invalid characters
Hint Message	All characters used in file names must be valid. File names may only contain the characters a-z, 0-9 and '-'. File names must have exactly one extension with the same characters.

Details

 fail-15.06.01	A file name with invalid characters was found: {0}
 fail-15.06.02	A file with missing file extension was found: {0}
 fail-15.06.03	A file with multiple file extensions was found: {0}
 fail-15.06.04	A file with empty file name or empty extension is found: {0}

No. 15.07 Folder Name Characters


Basics

Number	15.07
Category	Files / Folders
Validation Criterion	Only valid characters are used in folder names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The folder name contains invalid characters
Hint Message	All characters used in folder names must be valid. Folder names may only contain the characters a-z, 0-9 and '-'

Details

 fail-15.07.01: A folder with invalid characters was found: {0}

No. 15.08 Un-referenced Files

Basics



Number	15.08
Category	Files / Folders
Validation Criterion	There are no unreferenced files in M1, M2, M3, M4 and M5 folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Including all subfolders within the m1-m5 folders but excluding util folder and sub-folders

Summary

Problem Message	Un-referenced files found
Hint Message	There cannot be un-referenced files in M1, M2, M3, M4 and M5 folders.

No. 15.09 Files in Sequence Folder

Basics



Number	15.09
Category	Files / Folders
Validation Criterion	The only files in the sequence folder (/XXXX/...) are the index.xml and index-md5.txt
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Unexpected files in sequence folder found
Hint Message	The only files in the sequence folder (/XXXX/...) should be the index.xml and index-md5.txt

No. 15.10 No Empty Folders

Basics



Number	15.10
Category	Files / Folders
Validation Criterion	There are no empty folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all folders contain at least one file
Hint Message	There shall be no empty folders

No. 15.11 Tracking Table File Location



Basics

Number	15.11
Category	Files / Folders
Validation Criterion	The tracking table file is present in the correct location
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The folder <code>/XXXX/m1/eu/10-cover/common</code>

Summary



Problem Message	Folder <code>/XXXX/m1/eu/10-cover/common</code> not found
Hint Message	The folder shall be <code>/XXXX/m1/eu/10-cover/common</code>

Details

 fail-15.11.01	The tracking table is mandatory for submission type 'MRP' or 'DCP' . The tracking table folder was missing: {0}
 pass-15.11.01	The tool validates the folder <code>/XXXX/m1/eu/10-cover/common</code> <i>only</i> . If folder is found, the rule is passed.

No. 15.12 Tracking Table File Name




Basics

Number	15.12
Category	Files / Folders
Validation Criterion	The tracking table file is correctly named
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named common-cover-tracking.pdf or common-cover-tracking.xml

Summary


Problem Message	File common-cover-tracking.pdf or common-cover-tracking.xml not found
Hint Message	File should be named common-cover-tracking.pdf or common-cover-tracking.xml

Details

 fail-15.12.01	The tracking table is mandatory for submission type ' MRP ' or ' DCP '. The tracking table file cannot be found: {0}
 fail-15.12.02	The tracking table is not named correctly and contains invalid characters: {0}
 pass-15.12.01	The tool validates the folder /XXXX/m1/eu/10-cover/common <i>only</i> for a tracking table. If a file named common-cover-tracking.pdf or common-cover-tracking.xml is found, the rule is passed.

No. 15.BP01 File Size

Basics


Number	15.BP01
Category	Envelope Attributes
Validation Criterion	Individual files do not exceed 100 MB in size
	 Best Practice
Other Submissions Required	no
	Any deviation should always be reported by the validating tool.
Comment	Files larger than 100 MB should be avoided. If there is a need to exceed this limit, this should be explained in the cover letter.

Summary

Problem Message	The file size exceeds 100 MB
Hint Message	Individual files should not exceed 100 MB in size

No. 15.BP02 Folder Naming


Basics

Number	15.BP02
Category	Files / Folders
Validation Criterion	The recommended folder structure and folder names in the ICH and EU specifications are used
Other Submissions Required	 Best Practice
Comment	Any deviation, including additional subfolders, should always be reported by the validating tool.

Summary


Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and EU specifications should be used

Details

 fail-15.bp2.01	The provided folder name does not follow the recommended ICH or EU folder name convention.
--	--

No. 15.BP03 File Naming



Basics

Number	15.BP03
Category	Files / Folders
Validation Criterion	The recommended file names from the ICH and EU specifications are used for all files
Other Submissions Required	 Best Practice no
Comment	<p>Any deviation should always be reported by the validating tool.</p> <p>Note that the components of the file names in italics in Appendix 4 of the ICH eCTD specification are to be specified by the applicant (i.e. this is variable text).</p> <p>In EU Module 1 the variable (VAR) part of the file name can include hyphens. Note: a change request has been raised to allow hyphens in the Variable part of the file names</p> <p>Applicants using the eCTD for ASMF or for MAAs including an ASMF are reminded that the EU guidance recommends the use of ap and rp prefixes for content in the applicants part and restricted part, respectively. eCTD validation tools should accept these prefixes in Modules 1, 2 and 3.</p> <p>The CC code of the filename should not be checked against the CC of the leaf attribute or the folder name</p>

Summary

Problem Message	File with unexpected name found
Hint Message	The recommended file names from the ICH and EU specifications should be used for all files



Details

 fail-15.bp3.01	The provided file name does not follow the recommended ICH or EU file name convention.
 fail-15.bp3.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

16 - PDF Files

No. 16.01 PDF Version 1.4 or Later




Basics

Number	16.01
Category	PDF Files
Validation Criterion	No PDF has been created and saved as version 1.3 or earlier
Type of Check	 Success  Error
Other Submissions Required	no
Comment	PDF 1.3 or earlier is not acceptable for technical reasons. No exceptions will be made. For example, if a literature reference is received in PDF 1.3 or earlier, then the applicant must provide it in PDF 1.4, even if this means getting a paper copy and scanning it. Further guidance may be provided about the best ways to check the PDF version.

Summary



Problem Message	PDF version 1.3 or earlier found
Hint Message	No PDF should be created and saved as version 1.3 or earlier

Details

 fail-16.01.01	The PDF version of the provided document is {0}. PDFs in version {1} and lower are not allowed.
 pass-16.01.01	PDF is version 1.4.
 pass-16.01.02	PDF is version 1.5

No. 16.02 Security Setting to Open


Basics

Number	16.02
Category	PDF Files
Validation Criterion	There is no security setting to open any individual file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This includes passwords, certificate security, adobe policy server settings, etc.

Summary



Problem Message	Security setting to open file found
Hint Message	No individual file should have a security setting

Details

-  fail-16.02.01 The PDF file is protected by a security setting and cannot be opened. Security settings are not allowed.

No. 16.03 Other Security Settings


Basics

Number	16.03
Category	PDF Files
Validation Criterion	There are no further security settings applied to any individual file (except for files in Modules 3.3, 4.3 and 5.4)
Type of Check	 Success  Error
Other Submissions Required	no
Comment	All restrictions should be allowed when viewing the Document Preferences > Security settings.

Summary


Problem Message	Security setting found
Hint Message	No further security settings should be applied to any individual file

Details

 fail-16.03.01	The PDF file can be opened but is protected by a restriction. Security restrictions are not allowed.
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No. 16.BP01 PDF Version 1.4




Basics

Number	16.BP01
Category	Envelope Attributes
Validation Criterion	Files have been created and saved as PDF 1.4
Type of Check	 Best Practice
Other Submissions Required	no
Comment	<p>If the use of later versions of PDF is unavoidable then the applicant should check that the files do not use features specific to later PDF versions than 1.4 that may be lost or not viewable based on PDF 1.4 and thus potentially could change the visual appearance of the document.</p> <p>Further guidance may be provided about the best ways to check the PDF version.</p>

Summary


Problem Message	File is not PDF 1.4
Hint Message	Files must be PDF 1.4

Details

 fail-16.bp1.01	PDF is version 1.3
 fail-16.bp1.02	PDF is version 1.5
 pass-16.bp1.01	PDF is version 1.4

No. 16.BP02 Current Sequence Hyperlink Targets


Basics

Number	16.BP02
Category	PDF Files
Validation Criterion	Hyperlinks within documents, or between documents within the same sequence, have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Links to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken hyperlinks to current sequence found
Hint Message	Hyperlinks within documents, or between documents within the same sequence, must have a valid target

Details

-  fail-16.bp2.01 : Some hyperlinks of a PDF with destinations INSIDE this eCTD sequence are broken. The number of broken hyperlinks is {0}.

No. 16.BP03 Current Sequence Bookmark Targets


Basics

Number	16.BP03
Category	PDF Files
Validation Criterion	Bookmarks to destinations within the same sequence have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Bookmarks to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken bookmarks to current sequence found
Hint Message	Bookmarks to destinations within the same sequence must have a valid target

Details

-  fail-16.bp3.01 : Some bookmarks of a PDF with destinations INSIDE this eCTD sequence are broken. The number of broken bookmarks is {0}.

No. 16.BP04 Valid Sequence Hyperlink Targets


Basics

Number	16.BP04
Category	PDF Files
Validation Criterion	Hyperlinks to targets within documents in a different sequence in the same application have a valid target
Type of Check	 Best Practice
Other Submissions Required	yes
Comment	Links to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary

Problem Message	PDF with broken hyperlinks to previous sequence found
Hint Message	Hyperlinks to targets within documents in a different sequence in the same application must have a valid target

Details

-  fail-16.bp4.01 : Some hyperlinks from a PDF with destinations OUTSIDE this eCTD sequence are broken. The number of broken hyperlinks is {0}.

No. 16.BP05 Valid Sequence Bookmark Targets

Basics

Number	16.BP05
Category	PDF Files
Validation Criterion	Bookmarks to destinations in a different sequence in the same application have a valid target
Type of Check	✘ Best Practice
Other Submissions Required	yes
Comment	Bookmarks to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken bookmarks to previous sequence found
Hint Message	Bookmarks to destinations in a different sequence in the same application must have a valid target

Details

- ✘ fail-16.bp5.01 : Some PDF bookmarks with destinations OUTSIDE this eCTD sequence are broken.
: The number of broken bookmarks is {0}.

No. 16.BP06 Inherit Zoom


Basics

Number	16.BP06
Category	PDF Files
Validation Criterion	All bookmarks and links are set to "inherit zoom"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with hyperlinks or bookmarks not using inherit zoom found
Hint Message	All bookmarks and links must be set to "inherit zoom"

Details

 fail-16.bp6.01: The document contains {0} hyperlinks or bookmarks not set to inherit zoom.

No. 16.BP07 Fast Web View

Basics


Number	16.BP07
Category	PDF Files
Validation Criterion	PDFs must have "Fast Web View" active
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	"Fast Web View" option not found
Hint Message	PDFs must have "Fast Web View" active

No. 16.BP08 PDF Document Properties


Basics

Number	16.BP08
Category	PDF Files
Validation Criterion	PDF document properties for the initial view are set for "Page Layout = Default" and "Magnification = Default"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with open actions not using inherit zoom found
Hint Message	PDF Document Properties for the Initial View must be set for "Page Layout = Default" and "Magnification = Default"

Details

-  fail- 16.bp08.01 : {0} incorrect settings found. The initial view settings of the PDF are incorrect. Page layout and magnification are not set to default.

No. 16.BP09 Relative Hyperlinks


Basics

Number	16.BP09
Category	PDF Files
Validation Criterion	All PDF hyperlinks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks must be relative

Details

 fail-16.bp09.01: The PDF file contains {0} absolute hyperlinks. Hyperlinks should be relative.

No. 16.BP10 Relative Bookmarks


Basics

Number	16.BP10
Category	PDF Files
Validation Criterion	All PDF bookmarks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks must be relative

Details

 fail-16.bp10.01: The PDF file contains {0} absolute bookmarks. Bookmarks should be relative.

No. 16.BP11 Bookmarks Pane Visibility

Basics

Number	16.BP11
Category	PDF Files
Validation Criterion	The bookmarks pane should be visible if bookmarks are included within a PDF document
Type of Check	✘ Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	PDF with invalid bookmarks pane visible setting found
Hint Message	The bookmarks pane should be visible if bookmarks are included within a PDF document

Details

✘ fail-16.bp11.01	The document contains one or more bookmarks. The bookmark pane is not open.
✘ fail-bp11.02	The document does not contain any bookmark. The bookmark pane is open and empty.

4 HR eCTD 3.1

General

The following document contains a technical description of features implementation within the release cycle 1.0 of ValidationSets for the HR Region eCTD Validation Criteria Version 3.1.

Common Features Implementation

Validation Set Name

Validation Sets will be displayed in tool and reports as follows:

Other eCTD Context

Name	HR-eCTD v3.1 (DTD 1.4) – Other eCTD Context
Version	HR validation criteria for HR M 1.4 release 3.1
Description	eCTD 3.2 with HR M 1.4 regional part with related sequences

Context of Other eCTDs

eCTD submissions may contain references to previous sequences of application using life cycle operations *append*, *replace* and *delete* and/or using direct *document references* into the previous sequence. Validation will be possible in 2 modes of operation:

- Validate submission in context of other eCTDs

Implementation of rules will depend on this. Thus there will be a validation set for each mode. Optionally both modes can be merged into one validation set, if validation component and applications will be extended to use a parameter to switch the mode and to display the selected mode in validation reports.

To discover the other eCTD sequences the following procedure will be used:

1. Read index XML and HR regional XML files of the current sequence.
2. Get a list of all path values of attributes *xlink:href* and *modified-file* from the 2 index files.
3. Select from list all path values with a target outside the current sequence but inside the application (i.e. *../0002/* will be selected, *../app2/0002/* will not be selected).
4. Get the sequence numbers from list as the other eCTD sequences to use for the rules.

If not defined in another way for the individual rule, only the sequences discovered with the procedure will be included in checks. Other eCTD sequences will be ignored.

Later: *AutoselectDTD* can be extended to find previous sequences as described above and to select the validation set for eCTD context if previous sequences have been found and the validation set for submission only if a previous sequence has been found.

Validation Start Object

Current validation sets and validation component are implemented to start the validation for a sequence folder like /0000 or the root folder /root for vNeeS. Some checks will have a different implementation for the two methods:

Start with folder	Checks get direct access to the folder provided and search there for the start file if required (<start-folder>/index.xml or <start-folder>/ctd-toc.pdf).
Start with file	Checks get direct access to the file provided and use the folder where the file is stored as the sequence folder (sample: starting with app2/0002/index.xml will use app2/0002 as sequence folder).

Other files than the selected one to start validation (sample: *hr-regional.xml* or *m2-toc.pdf*) are selected by the checks using the folder in both cases. Therefore the *Start with file* method will result with some asymmetric implementations of checks. Sample: Start with /XXXX/xyz.xml ignoring if there is also an index.xml in folder, but require the file /XXXX/m1/eu/hr-regional.xml for another check.

Rules Implementation

Details of test rules implementation are given in next chapters.

The specified text elements for *Number*, *Validation Criterion*, *Severity*, *Problem Message* and *Hint Message* are presented to user in Validation GUI as follows:

Number	No. in Results Grid
Validation Criterion	Description in Results Grid
Severity	Severity in Results Grid
Problem Message	Test Result in Details Area (upper left text box)
Hint Message	Hint in Details Area (upper right text box)

Option: Number of checks will be formatted as *XX.XX* or *XX.BPXX* for numeric sorting in *results grid*. Samples:

- 1.1 to 01.01
- 16.BP3 to 16.BP03

Test Object Level

Submission level	The check will be started once for the sequence. The test object may be the sequence folder or the index XML file.
Index XML + EU regional XML	The check will be started twice for the sequence – for the index XML file and the EU regional XML file each with separated results for the index file.
Files	The check will be started for each individual file. This may be any file or a file selected by a pattern as *.pdf for the PDF checks.

Lifecycle Context

Other eCTD context	The check is implemented in context with all other sequences, referenced within the test submission.
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eCTD Validation Criteria Overview

The following table displays an overview about all HR eCTD validation set criteria, **version 3.1**.

Category	No. — Validation Criterion
01 ICH DTD	01.01 — Specified Filename
	01.02 — Correct File Placement
	01.03 — Acceptable DTD Version
	01.04 — Valid DTD Version
02 ICH Style Sheet	02.01 — Specified Filename
	02.02 — Correct File Placement
	02.03 — Acceptable Style Sheet Version
	02.04 — Valid Style Sheet Version
03 HR M1 DTD	03.01 — Specific Filename
	03.02 — Correct File Placement
	03.03 — Acceptable DTD Version
	03.04 — Valid DTD Version
04 HR M1 Leaf MOD File	04.01 — Specific Filename
	04.02 — Correct Folder Placement
	04.03 — Acceptable EU Leaf Version
	04.04 — Valid EU Leaf Version
05 HR M1 Envelope MOD File	05.01 — Specific Filename
	05.02 — Correct Folder Placement
	05.03 — Acceptable EU Envelope Version
	05.04 — Valid EU Envelope Version
06 HR M1 Style Sheet	06.01 — Specific Filename
	06.02 — Correct Folder Placement
	06.03 — Acceptable Style Sheet Version
	06.04 — Valid Style Sheet Version
07 Index XML	07.01 — File in Correct Folder
	07.02 — Correct Filename
	07.03 — Well Formed XML
	07.04 — Valid to DTD
08 Index MD5 txt	08.01 — File Placement
	08.02 — Correct Filename
	08.03 — Index File Checksum
09 HR Regional XML	09.01 — File Placement
	09.02 — Correct Filename
	09.03 — Well Formed XML
	09.04 — Valid to DTD



Category	No. — Validation Criterion
10 Submission Structure	10.01 — Leaf Check
	11.01 — Checksum Type Attribute
	11.02 — Checksum Value
	11.03 — Leaf Title Attribute
11 Leaf Attributes	11.04 — xlink:href Attribute Value
	11.05 — No xlink:href Attribute Value
	11.06 — xlink:href Target
	11.07 — Modified-File Attribute
	11.08 — No Modified-File Attribute
	11.09 — Modified-File Attribute Target
12 Node Extensions	12.01 — Node Extension Title
	13.01 — Sequence Number Format
13 Sequence Number	13.02 — Sequence Number Check
	13.03 — Sequence Folder Name
	14.01 — EU Envelope with EMEA Country Attribute Value
14 Envelope Attributes	14.02 — EU Envelope with Every Country Attribute Value
	14.BP01 — Related Sequence Attribute Value
	14.BP02 — No Related Sequence Attribute Value
	15.01 — File Format for Module 1
15 Files / Folders	15.02 — File Format for Module 2-5
	15.03 — Path Length
	15.04 — File Name Length
	15.05 — Folder Name Length
	15.06 — File Name Characters
	15.07 — Folder Name Characters
	15.08 — Un-referenced Files
	15.09 — Files in Sequence Folder
	15.10 — No Empty Folders
	15.11 — Tracking Table File Location
	15.12 — Tracking Table File Name
	15.BP01 — File Size
	15.BP02 — Folder Name
15.BP03 — File Name	

Category	No. — Validation Criterion
16 PDF Files	16.01 — PDF Version 1.4 or Later
	16.02 — Security Setting to Open
	16.03 — Other Security Settings
	16.BP01 — PDF Version 1.4
	16.BP02 — Current Sequence Hyperlink Targets
	16.BP03 — Current Sequence Bookmark Targets
	16.BP04 — Valid Sequence Hyperlink Targets
	16.BP05 — Valid Sequence Bookmark Targets
	16.BP06 — Inherit Zoom
	16.BP07 — Fast Web View
	16.BP08 — PDF Document Properties
16.BP09 — Relative Hyperlinks	
16.BP10 — Relative Bookmarks	
16.BP11 — Bookmarks Pane Visibility	

01 - ICH DTD

No. 01.01 Specified Filename




Basics

Number	01.01
Category	ICH DTD
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ich-ectd-3-2.dtd

Summary



Problem Message	/XXXX/util/dtd/ich-ectd-3-2.dtd not found
Hint Message	/XXXX/util/dtd/ich-ectd-3-2.dtd shall exist

Details

 fail-01.01.01	Looking for the file ich-ectd-3-2.dtd in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-01.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Ich-ectd-3-2.dtd or ich-ectd-3-2.DTD)
 pass-01.01.01	The filename there must be ich-ectd-3-2.dtd . The filename check is performed in folder /XXXX/util/dtd only .

No. 01.02 Correct File Placement




Basics

Number	01.02
Category	ICH DTD
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/ich-ectd-3-2.dtd not found.
Hint Message	/XXXX/util/dtd/ich-ectd-3-2.dtd shall exist

Details

 fail-01.02.01	Investigate folder /XXXX/util/dtd to find ich-ectd-3-2.dtd . There is no file present. No other folders are checked.
 fail-01.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file ich-ectd-3-2.dtd cannot be checked.
 fail-01.02.03	The spelling of the requested filename ich-ectd-3-2.dtd in folder /XXXX/util/dtd is incorrect (e.g. ich-ectd-3-2.dtd or ich-ectd-3-2.DTD). The correct placement of the file ich-ectd-3-2.dtd cannot be checked.

No. 01.03 Acceptable DTD Version






Basics

Number	01.03
Category	ICH DTD
Validation Criterion	A currently acceptable version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/ich-ectd-3-2.dtd not found
Hint Message	Version of /XXXX/util/dtd/ich-ectd-3-2.dtd shall not be older than the version in a previous sequence

Details

 fail-01.03.01	The version of the DTD in /XXXX/util/dtd/ich-ectd-3-2.dtd is older than the version in the previous sequence(s): {0}
 pass-01.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-01.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-01.03.03	Validate submission in context of other eCTDs: A DTD in a former sequence is not available or is misspelled.
 pass-01.03.04	Validate submission in context of other eCTDs: The DTD version number must be higher or equal to the highest DTD version number in the previous sequence.

No. 01.04 Valid DTD Version




Basics

Number	01.04
Category	ICH DTD
Validation Criterion	The valid version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v3.2 is 1d6f631cc6b6357f0f4fe378e5f79a27

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v3.2 is 1d6f631cc6b6357f0f4fe378e5f79a27



Details

 fail-01.04.01	The file /XXXX/util/dtd/ich-ectd-3-2.dtd cannot be found.
 fail-01.04.02	The provided checksum of the file ich-ectd-3-2.dtd is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-01.04.03	The invalid /util/dtd folder prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.
 fail-01.04.04	The invalid filename of ich-ectd-3-2.dtd prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.

02 - ICH Style Sheet

No. 02.01 Specified Filename

Basics



Number	02.01
Category	ICH style sheet
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ectd-2-0.xsl

Summary

Problem Message	/XXXX/util/style/ectd-2-0.xsl not found
Hint Message	/XXXX/util/style/ectd-2-0.xsl shall exist



If file has been found, check that all characters of folder names and file name are valid (**0-9**, **a-z**, **dot** and **hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.01.01	Looking for the file ectd-2-0.xsl in folder /XXXX/util/style . File is not found. Spelling cannot be checked.
 fail-02.01.02	The spelling of the present filename (in folder /XXXX/util/style) is incorrect (e.g. Ectd-2-0.xsl or ectd-2-0.XSL)

No. 02.02 Correct File Placement

Basics




Number	02.02
Category	ICH style sheet
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/style

Summary

Problem Message	/XXXX/util/style/ectd-2-0.xml not found
Hint Message	/XXXX/util/style/ectd-2-0.xml shall exist



If file has been found, check that all characters of folder names and file name are valid (**0-9**, **a-z**, **dot** and **hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.02.01	Investigate folder /XXXX/util/style to find ectd-2-0.xml . There is no file present. No other folders are checked.
 fail-02.02.02	The spelling of the folder (e.g. /XXXX/util/STYLE) is incorrect. The correct placement of the file ectd-2-0.xml cannot be checked.
 fail-02.02.03	The spelling of the requested filename ectd-2-0.xml in folder /XXXX/util/style is incorrect (e.g. Ectd-2-0.xml or ectd-2-0.XSL). The correct placement of the file ectd-2-0.xml cannot be checked.

No. 02.03 Acceptable Style Sheet Version

Basics






Number	02.03
Category	ICH stylesheet
Validation Criterion	A currently acceptable version of the stylesheet is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary

Problem Message	Acceptable version of /XXXX/util/style/ectd-2-0.xml not found
Hint Message	Version /XXXX/util/style/ectd-2-0.xml shall not be older than the version in a previous sequence



If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.

Details

 fail-02.03.01	The version of the stylesheet in /XXXX/util/style/ectd-2-0.xml is older than version in the previous sequence(s): {0}
 pass-02.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-02.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-02.03.03	Validate submission in context of other eCTDs: A style sheet in a former sequence is not available or is misspelled.
 pass-02.03.04	Validate submission in context of other eCTDs: The style sheet version number must be higher or equal to the highest style sheet version number in the previous sequence.

No. 02.04 Valid Style Sheet Version

Basics





Number	02.04
Category	ICH style sheet
Validation Criterion	The valid version of the style sheet is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v3.2 is 3a07a202455e954a2eb203c5bb443f77

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v3.2 is 3a07a202455e954a2eb203c5bb443f77

If file has been found, check that all characters of folder names and file name are valid (**0-9, a-z, dot and hyphen**). If another character has been found, result is **Failure**.



Details

 fail-02.04.01	The file /XXXX/util/style/ectd-2-0.xsl cannot be found.
 fail-02.04.02	The provided checksum of the file ectd-2-0.xsl is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-02.04.03	The invalid /util/style folder prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.
 fail-02.04.04	The invalid filename of ectd-2-0.xsl prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.

03 - HR M1 DTD

No. 03.01 Specific Filename



Basics

Number	03.01
Category	HR M1 DTD
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named hr-regional.dtd

Summary



Problem Message	/XXXX/util/dtd/hr-regional.dtd not found
Hint Message	/XXXX/util/dtd/hr-regional.dtd shall exist

Details

 fail-03.01.01	Looking for the file hr-regional.dtd in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-03.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Hr-regional.dtd or hr-regional.DTD)

No. 03.02 Correct File Placement




Basics

Number	03.02
Category	HR M1 DTD
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/hr-regional.dtd not found
Hint Message	/XXXX/util/dtd/hr-regional.dtd shall exist

Details

 fail-03.02.01	Investigate folder /XXXX/util/dtd to find hr-regional.dtd . There is no file present. No other folders are checked.
 fail-03.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file hr-regional.dtd cannot be checked.
 fail-03.02.03	The spelling of the requested filename hr-regional.dtd in folder /XXXX/util/dtd is incorrect (e.g. HR-regional.dtd or hr-regional.DTD). The correct placement of the file eu-regional.dtd cannot be checked.

No. 03.03 Acceptable DTD Version






Basics

Number	03.03
Category	HR M1 DTD
Validation Criterion	A currently acceptable version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/hr-regional.dtd not found
Hint Message	Version of /XXXX/util/dtd/hr-regional.dtd shall not be older than version in a previous sequence

Details

 fail-03.03.01	The version of the DTD in /XXXX/util/dtd/hr-regional.dtd is older than the version in the previous sequence(s): {0}
 pass-03.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-03.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses “validate submission in context of other eCTDs
 pass-03.03.03	Validate submission in context of other eCTDs: A DTD in a former sequence is not available or is misspelled.
 pass-03.03.04	Validate submission in context of other eCTDs: The DTD version number must be higher or equal to the highest DTD version number in the previous sequence.

No. 03.04 Valid DTD Version





Basics

Number	03.04
Category	HR M1 DTD
Validation Criterion	The valid version of the DTD is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 91654e96e3bafc5e89df7f892477b246

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 91654e96e3bafc5e89df7f892477b246



Details

 fail-03.04.01	The file /XXXX/util/dtd/hr-regional.dtd cannot be found.
 fail-03.04.02	The provided checksum of the file hr-regional.dtd is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-03.04.03	The invalid /util/dtd folder prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.
 fail-03.04.04	The invalid filename of hr-regional.dtd prevents the calculation of the DTD MD5 checksum. The validity of the DTD version cannot be checked.

04 - HR M1 Leaf MOD File

No. 04.01 Specific Filename



Basics

Number	04.01
Category	HR M1 leaf MOD file
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named hr-leaf.mod

Summary



Problem Message	/XXXX/util/dtd/hr-leaf.mod not found
Hint Message	/XXXX/util/dtd/hr-leaf.mod shall exist

Details

 fail-04.01.01	Looking for the file hr-leaf.mod in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-04.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Hr-leaf.mod or hr-leaf.MOD)

No. 04.02 Correct Folder Placement




Basics

Number	04.02
Category	HR M1 leaf MOD file
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder <code>/XXXX/util/dtd</code>

Summary



Problem Message	<code>/XXXX/util/dtd/hr-leaf.mod</code> not found
Hint Message	<code>/XXXX/util/dtd/hr-leaf.mod</code> shall exist

Details

 fail-04.02.01	Investigate folder <code>/XXXX/util/dtd</code> to find hr-leaf.mod . There is no file present. No other folders are checked.
 fail-04.02.02	The spelling of the folder (e.g. <code>/XXXX/util/DTD</code>) is incorrect. The correct placement of the file hr-leaf.mod cannot be checked.
 fail-04.02.03	The spelling of the requested filename hr-leaf.mod in folder <code>/XXXX/util/dtd</code> is incorrect (e.g. Hr-leaf.mod or hr-leaf.MOD). The correct placement of the file hr-leaf.mod cannot be checked.

No. 04.03 Acceptable HR Leaf Version






Basics

Number	04.03
Category	HR M1 leaf MOD file
Validation Criterion	A currently acceptable version of the hr-leaf.mod file is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/hr-leaf.mod not found
Hint Message	Version of /XXXX/util/dtd/hr-leaf.mod shall not be older than the version in a previous sequence

Details

 fail-04.03.01	The version of the MOD file in /XXXX/util/dtd/hr-leaf.mod is older than the version in the previous sequence(s): {0}
 pass-04.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-04.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-04.03.03	Validate submission in context of other eCTDs: A MOD file in a former sequence is not available or is misspelled.
 pass-04.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 04.04 Valid HR Leaf Version





Basics

Number	04.04
Category	HR M1 leaf MOD file
Validation Criterion	The valid version of the hr-leaf.mod file is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 2e976bc60658a964affa5026369a371e

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 2e976bc60658a964affa5026369a371e



Details

 fail-04.04.01	The file /XXXX/util/dtd/hr-leaf.mod cannot be found.
 fail-04.04.02	The provided checksum of the file hr-leaf.mod is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-04.04.03	The invalid /util/dtd folder prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.
 fail-04.04.04	The invalid filename of hr-leaf.mod prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.

05 - HR M1 Envelope MOD File

No. 05.01 Specific Filename



Basics

Number	05.01
Category	HR M1 envelope MOD file
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named hr-envelope.mod

Summary



Problem Message	/XXXX/util/dtd/hr-envelope.mod not found
Hint Message	/XXXX/util/dtd/hr-envelope.mod shall exist

Details

 fail-05.01.01	Looking for the file hr-envelope.mod in folder /XXXX/util/dtd . File is not found. Spelling cannot be checked.
 fail-05.01.02	The spelling of the present filename (in folder /XXXX/util/dtd) is incorrect (e.g. Hr-envelope.mod or hr-envelope.MOD)

No. 05.02 Correct Folder Placement




Basics

Number	05.02
Category	HR M1 envelope MOD file
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/dtd

Summary



Problem Message	/XXXX/util/dtd/hr-envelope.mod not found
Hint Message	/XXXX/util/dtd/hr-envelope.mod shall exist

Details

 fail-05.02.01	Investigate folder /XXXX/util/dtd to find hr-envelope.mod . There is no file present. No other folders are checked.
 fail-05.02.02	The spelling of the folder (e.g. /XXXX/util/DTD) is incorrect. The correct placement of the file hr-envelope.mod cannot be checked.
 fail-05.02.03	The spelling of the requested filename hr-envelope.mod in folder /XXXX/util/dtd is incorrect (e.g. Hr-envelope.mod or hr-envelope.MOD). The correct placement of the file hr-envelope.mod cannot be checked.

No. 05.03 Acceptable HR Envelope Version






Basics

Number	05.03
Category	HR M1 envelope MOD file
Validation Criterion	A currently acceptable version of the hr-envelope.mod file is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/dtd/hr-envelope.mod not found
Hint Message	Version of /XXXX/util/dtd/hr-envelope.mod shall not be older than the version in a previous sequence

Details

 fail-05.03.01	The version of the MOD file in /XXXX/util/dtd/hr-envelope.mod is older than the version in the previous sequence(s): {0}
 pass-05.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-05.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-05.03.03	Validate submission in context of other eCTDs: A MOD file in a former sequence is not available or is misspelled.
 pass-05.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 05.04 Valid HR Envelope Version





Basics

Number	05.04
Category	HR M1 envelope MOD file
Validation Criterion	The valid version of the hr-envelope.mod file is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 664a76e3f31a9553d3375d3b21815904

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 664a76e3f31a9553d3375d3b21815904



Details

 fail-05.04.01	The file /XXXX/util/dtd/hr-envelope.mod cannot be found.
 fail-05.04.02	The provided checksum of the file hr-envelope.mod is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-05.04.03	The invalid /util/dtd folder prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.
 fail-05.04.04	The invalid filename of hr-envelope.mod prevents the calculation of the MOD file MD5 checksum. The validity of the MOD file version cannot be checked.

06 - HR M1 Style Sheet

No. 06.01 Specific Filename



Basics

Number	06.01
Category	HR M1 stylesheet
Validation Criterion	The specified filename is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named hr-regional.xsl

Summary



Problem Message	/XXXX/util/style/hr-regional.xsl not found
Hint Message	/XXXX/util/style/hr-regional.xsl shall exist

Details

 fail-06.01.01	Looking for the file hr-regional.xsl in folder /XXXX/util/style . File is not found. Spelling cannot be checked.
 fail-06.01.02	The spelling of the present filename (in folder /XXXX/util/style) is incorrect (e.g. Hr-regional.xsl or hr-regional.XSL)

No. 06.02 Correct Folder Placement




Basics

Number	06.02
Category	HR M1 stylesheet
Validation Criterion	The correct placement is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX/util/style

Summary



Problem Message	/XXXX/util/style/hr-regional.xml not found
Hint Message	/XXXX/util/style/hr-regional.xml shall exist

Details

 fail-06.02.01	Investigate folder /XXXX/util/style to find hr-regional.xml . There is no file present. No other folders are checked.
 fail-06.02.02	The spelling of the folder (e.g. /XXXX/util/STYLE) is incorrect. The correct placement of the file hr-regional.xml cannot be checked.
 fail-06.02.03	The spelling of the requested filename hr-regional.xml in folder /XXXX/util/style is incorrect (e.g. Hr-regional.xml or hr-regional.XSL). The correct placement of the file hr-regional.xml cannot be checked.

No. 06.03 Acceptable Style Sheet Version






Basics

Number	06.03
Category	HR M1 style sheet
Validation Criterion	A currently acceptable version of the style sheet is used
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Currently acceptable with reference to any transition guidance (for example, not going back to an earlier version when a newer version has already been used for that eCTD)

Summary



Problem Message	Acceptable version of /XXXX/util/style/hr-regional.xsl not found
Hint Message	Version of /XXXX/util/style/hr-regional.xsl shall not be older than the version in a previous sequence

Details

 fail-06.03.01	The version of the stylesheet in /XXXX/util/style/hr-regional.xsl is older than the version in the previous sequence(s): {0}
 pass-06.03.01	Some of the previous sequences (earlier versions) are not present if user chooses validate submission only before.
 pass-06.03.02	Validate submission in context of other eCTDs: Some of the previous sequences (earlier versions) are not present if user chooses validate submission in context of other eCTDs .
 pass-06.03.03	Validate submission in context of other eCTDs: A stylesheet in a former sequence is not available or is misspelled.
 pass-06.03.04	Validate submission in context of other eCTDs: The MOD file version number must be higher or equal to the highest MOD file version number in the previous sequence.

No. 06.04 Valid Style Sheet Version





Basics

Number	06.04
Category	HR M1 stylesheet
Validation Criterion	The valid version of the stylesheet is used
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The checksum for v1.4 is 54f9889822e1d08cc23b902fc6a66aaa

Summary

Problem Message	Valid version of file not found
Hint Message	The checksum shall match the published value. The checksum for v1.4 is 54f9889822e1d08cc23b902fc6a66aaa



Details

 fail-06.04.01	The file /XXXX/util/style/hr-regional.xsl cannot be found.
 fail-06.04.02	The provided checksum of the file hr-regional.xsl is invalid. The correct checksum for version {0} is {1}. The checksum of the provided file is {2}.
 fail-06.04.03	The invalid /util/style folder prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.
 fail-06.04.04	The invalid filename of hr-regional.xsl prevents the calculation of the stylesheet MD5 checksum. The validity of the stylesheet version cannot be checked.

07 - Index XML

No. 07.01 File Placement

Basics

Number	07.01
Category	Index XML
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The root folder /XXXX

Summary



Problem Message	Index XML file is not stored in root folder /XXXX
Hint Message	The root folder shall be /XXXX

Details

No content yet

No. 07.02 Correct Filename

Basics

Number	07.02
Category	Index XML
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named index.xml

Summary



Problem Message	File is not named index.xml
Hint Message	File must be named index.xml

Details

No content yet

No. 07.03 Well Formed XML

Basics

Number	07.03
Category	Index XML
Validation Criterion	The file is well formed
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Well formed with respect to the rules of the XML specification

Summary



Problem Message	The index XML file is not well formed
Hint Message	The index XML file must be well formed

Details

No content yet

No. 07.04 Valid to DTD

Basics

Number	07.04
Category	Index XML
Validation Criterion	The file is valid
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Valid with respect to the ICH eCTD DTD file included in the util/dtd folder

Summary

Problem Message	The index XML file is not valid
Hint Message	The index XML file must be valid according to the DTD



Details

No content yet

08 - Index MD5 Txt

No. 08.01 File Placement





Basics

Number	08.01
Category	Index MD5 txt
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The root folder /XXXX

Summary



Problem Message	Index- md5.txt file is not stored in root folder /XXXX
Hint Message	The file must be placed in the root folder /XXXX

Details

 fail-08.01.01	Investigate folder /XXXX/ to find index-md5.txt . The file is missing. The correct placement of the file cannot be checked.
 fail-08.01.02	The root folder is not a 4 digit number. The validation of the folder cannot be checked.
 pass-08.01.01	If both or one of them (7.1 and / or 7.2) failed.
 pass-08.01.02	The user selects a folder /XXXX with file index-md5.txt . The root folder is a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]

No. 08.02 Correct Filename





Basics

Number	08.02
Category	Index MD5 txt
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The file is named index-md5.txt

Summary



Problem Message	/XXXX/index-md5.txt not found
Hint Message	The file must be named index-md5.txt

Details

 fail-08.02.01	Investigate folder /XXXX/ to find index-md5.txt . There is no file present. The correct name of the file cannot be checked.
 fail-08.02.02	The spelling of the present filename is incorrect (e.g. INdex-md5.txt or index-md5.TXT)
 pass-08.02.01	The user selects a folder /XX with file index-md5.txt : The root folder is <i>not</i> a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]
 pass-08.02.02	The user selects a folder /XXXX with file index-md5.txt : The root folder is a 4 digit number and the file is named correctly. [The check is only performed on the selected folder/ folder of the selected file]

No. 08.03 Index File Checksum



Basics

Number	08.03
Category	Index MD5 txt
Validation Criterion	The regenerated checksum for the index.xml matches the value in the file index-md5.txt
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable !

Summary

Problem Message	The regenerated checksum for the index.xml does not match the value in the file index-md5.txt
Hint Message	The regenerated checksum for the index.xml must match the value in the file index-md5.txt



Details

 fail-08.03.01	The regenerated checksum of index.xml does not match the checksum stored in index-md5.txt . Checksum stored in {0} is {1}. The recalculated checksum of the index.xml is {2}.
 pass-08.03.01	If both or one of them (8.1 and / or 8.2) failed.

09 - HR Regional XML

No. 09.01 File Placement



Basics

Number	09.01
Category	HR regional XML
Validation Criterion	The file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The folder /XXXX/m1/eu

Summary



Problem Message	HR regional XML file is not stored in folder /XXXX/m1/eu
Hint Message	HR regional XML must be stored in /XXXX/m1/eu

Details

 fail-09.01.01	Investigate folder /XXXX/m1/eu to find hr-regional.xml . The file is missing. The correct placement of the file cannot be checked.
 fail-09.01.02	The spelling of the folder /XXXX/m1/eu is incorrect. The validation of the folder cannot be checked.

No. 09.02 Correct Filename



Basics

Number	09.02
Category	HR regional XML
Validation Criterion	The file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named hr-regional.xml

Summary



Problem Message	/XXXX/m1/eu/hr-regional.xml not found
Hint Message	The file must be named hr-regional.xml

Details

 fail-09.02.01	Investigate folder /XXXX/m1/eu to find hr-regional.xml . There is no file present. The correct name of the file cannot be checked.
 fail-09.02.02	The spelling of the present filename (in folder /XXXX/m1/eu) is incorrect (e.g. Hr-regional.xml or hr-regional.XML)

No. 09.03 Well Formed XML



Basics

Number	09.03
Category	HR regional XML
Validation Criterion	The file is well formed
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Well formed with respect to the rules of the XML specification

Summary



Problem Message	The HR regional XML file is not well formed
Hint Message	The HR regional XML file must be well formed

Details

 fail-09.03.01	The hr-regional.xml is not well formed. XML parser error: {0}
 pass-09.03.01	If both or one of them (9.1 and / or 9.2) failed.

No. 09.04 Valid to DTD




Basics

Number	09.04
Category	HR regional XML
Validation Criterion	The file is valid
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Valid with respect to the HR Module 1 DTD file included in the util/dtd folder

Summary

Problem Message	The HR regional XML file is not valid
Hint Message	The HR regional XML file must be valid according to the DTD



Details

 fail-09.04.01	The hr-regional.xml is not valid. XML parser error: {0}
 pass-09.04.01	If the DTD is missing or located in a wrong path (incl. incorrect spelling or capital letter of DTD)
 pass-09.04.02	If both or one of them (9.1 and / or 9.2) failed.

10 - Submission Structure

No. 10.01 Leaf Check

Basics

Number	10.01
Category	Submission Structure
Validation Criterion	All the lowest level heading elements in the XML (including node-extensions) included in the submission contain at least one leaf
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!



Summary

Problem Message	XML element without leaf found
Hint Message	All lowest level elements must contain at least one leaf

11 - Leaf Attributes

No. 11.01 Checksum Type Attribute


Basics

Number	11.01
Category	Leaf Attributes
Validation Criterion	The leaf attribute checksum-type has a value of md5 or MD5
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Note that this value is not case sensitive

Summary



Problem Message	One or more leaf elements with invalid or missing checksum-type attribute found
Hint Message	The checksum-type attribute must have the value md5 or MD5

Details

 fail-11.01.01: The checksum-type attribute is present but empty.

No. 11.02 Checksum Value


Basics

Number	11.02
Category	Leaf Attributes
Validation Criterion	The regenerated checksum for each file matches the value in the leaf attribute checksum
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Note that if the content file is in an earlier sequence within the same eCTD application then the checksum can only be regenerated if access to this file is available. The MD5 checksum is not case sensitive.

Summary



Problem Message	One or more referenced files have the wrong checksum
Hint Message	The regenerated checksum for every referenced file is the same as each associated checksum provided in the index file

Details

-  fail-11.02.01: The checksum-type attribute is present but empty.

No. 11.03 Leaf Title Attribute

Basics



Number	11.03
Category	Leaf Attributes
Validation Criterion	For every leaf the attribute is not empty
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary

Problem Message	Not all leafs have a title
Hint Message	Every leaf must have a non-empty 'title' attribute

No. 11.04 xlink:href Attribute Value

Basics

Number	11.04
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of new, replace or append must have a value for xlink:href
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary

Problem Message : Not all leafs have a xlink:href value for operations new, replace or append



Hint Message : If operation is new, replace or append, then **xlink:href** value should exist

Details

 fail-11.04.01 : The attribute entry **xlink:href** is missing. Invalid leafs are found: {0}

No. 11.05 No xlink:href Attribute Value

Basics



Number	11.05
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of delete must have no value for xlink:href
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	The attribute does not need to be included, or can be declared but with a null value

Summary

Problem Message	Not all xlink:href entries are blank
Hint Message	xlink:href must be blank to execute the operation delete

No. 11.06 xlink:href Target


Basics

Number	11.06
Category	Leaf Attributes
Validation Criterion	The file referenced by the xlink:href must exist in the same or a previously submitted sequence within the same eCTD application
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	No conten available

Summary



Problem Message	Not all xlink:href entries are linked with a document
Hint Message	xlink:href should point to a document.

Details

 fail-11.06.01: The file referenced by **xlink:href** is missing or not accessible. Invalid leafs are found: {0}

No. 11.07 Modified-File Attribute

Basics

Number	11.07
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of replace, delete or append must have a value for modified-file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	Not all leafs have a modified-file value for operations replace, delete or append
Hint Message	A modified file value is needed to execute the operations replace , delete or append .

Details

 fail-11.07.01: The attribute entry modified-file is missing. Invalid leafs found: {0}

No. 11.08 No Modified-File Attribute

Basics



Number	11.08
Category	Leaf Attributes
Validation Criterion	All leafs with an operation attribute value of new must have no value for modified-file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The attribute does not need to be included, or can be declared but with a null value

Summary

Problem Message	Not all modified-file entries are blank
Hint Message	The modified file must be blank to execute the operation new

No. 11.09 Modified-File Attribute Target


Basics

Number	11.09
Category	Leaf Attributes
Validation Criterion	The leaf referenced by the modified-file must exist in a previously submitted sequence within the same eCTD application
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Not applicable!

Summary

Problem Message	Not all modified-file entries are linked with a leaf
Hint Message	Modified-file should point to a leaf



Details

 fail-11.09.01: The file referenced by modified-file is missing or not accessible. Invalid leafs found: {0}

12 - Node Extensions

No. 12.01 Node Extension Title

Basics

Number	12.01
Category	Node extensions
Validation Criterion	For every node-extension the title attribute is not empty
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!



Summary

Problem Message	Not all node extensions have a title
Hint Message	Every node extension must have a non-empty title attribute.

13 - Sequence Number

No. 13.01 Sequence Number Format

Basics



Number	13.01
Category	Sequence number
Validation Criterion	The sequence number is 4 digits
Type of Check	 Success  Error
Other Submissions Required	no
Comment	i.e. numbers between 0000 and 9999

Summary

Problem Message	The sequence number has an incorrect format
Hint Message	The sequence number is 4 digits (i.e. numbers between 0000 and 9999).

No. 13.02 Sequence Number Check




Basics

Number	13.02
Category	Sequence number
Validation Criterion	The sequence number has not already been used
Type of Check	 Success  P/F
Other Submissions Required	yes
Description	Not applicable!

Summary



Problem Message	The sequence number has been used already
Hint Message	Another sequence number has to be used

Details

 fail-13.02.01	No content yet
 pass-13.02.01	If 13.03 fails.
 pass-13.02.02	If one or more of the sequences is missing (e.g. MRP comprehensive model?)

No. 13.03 Sequence Folder Name




Basics

Number	13.03
Category	Sequence number
Validation Criterion	The sequence folder name matches the sequence number in the envelope in hr-regional.xml
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	The sequence folder does not match the envelope sequence number
Hint Message	The sequence folder name matches the sequence number in the hr-envelope in hr-regional.xml



Details

 fail-13.03.01	The sequence folder does not match the envelope sequence number
 pass-13.03.01	The file hr-regional.xml is missing.
 pass-13.03.02	The file hr-regional.xml is not readable or empty.

14 - Envelope Attributes

No. 14.01 EMEA Country Attribute Value



Basics

Number	14.01
Category	Envelope Attributes
Validation Criterion	There is a single envelope with the country attribute value of emea if the procedure type = centralised
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This should still be "emea"

Summary



Problem Message	There is no single hr-envelope for procedure type centralized.
Hint Message	There is a single hr-envelope with the country attribute value of emea if the procedure type = centralized.

Details

 fail-14.01.01	The centralized procedure allows only the single envelope element ' emea '. There is more than one envelope element.
 fail-14.01.02	The centralized procedure allows only the single envelope element ' emea '. The following was found: {0}

No. 14.02 Every Country Attribute Value

Basics


Number	14.02
Category	Envelope Attributes
Validation Criterion	There is a envelope element with a matching country attribute value for every country specific leaf (except "common") included in Module 1
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If all content is common, then you will still need to include separate envelopes for every country receiving the sequence. However, note that there is not a test for this scenario.

Summary

Problem Message	Some leafs donot match envelope country
Hint Message	There is an envelope element with a matching country attribute value for every country-specific leaf (except "common") included in Module 1

No. 14.BP01 Related Sequence Attribute Value


Basics

Number	14.BP01
Category	Envelope Attributes
Validation Criterion	If the submission type is supplemental-info or corrigendum then the related-sequence attribute must have a value
	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	Related-sequence attribute required
Hint Message	If the submission type is supplemental info or corrigendum, then the relatedsequence attribute must have a value

Details

-  fail-14.bp01.01: The '**related sequence number**' is only required for submission type '**supplemental-info**' or '**corrigendum**'. The related sequence number is not found for: {0}

No. 14.BP02 No Related Sequence Attribute Value




Basics

Number	14.BP02
Category	Envelope Attributes
Validation Criterion	If the submission type is not supplemental-info or corrigendum then there must not be related-sequence attribute
	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Related sequence attribute not required
Hint Message	If the submission type is not supplemental info or corrigendum, then there must not be related sequence attribute



Details

 fail-14.bp02.01	The ' related sequence number ' is only required for submission type ' supplemental-info ' or ' corrigendum '. The used submission type does not allow a ' related sequence number '. There is a related sequence number found for: {0}
 pass-14.bp02.01	The related sequence attribute is absent.
 pass-14.bp02.02	The related sequence attribute is present, but empty.

15 - Files / Folders

No. 15.01 File Format for Module 1






Basics

Number	15.01
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 1 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to table in HR Module 1 specification RTF will be removed from the list of acceptable formats to be referenced by leafs in the hr-regional.xml

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-15.01.01	The file does not have a valid format.
 pass-15.01.01	m1/eu/13-pi/131-pim-a-0000.zip.
 pass-15.01.02	m1/eu/13-pi/131-PIM-a-0000.ZIP.
 pass-15.01.03	m1/eu/13-pi/0000.pdf.
 pass-15.01.04	m1/eu/13-pi/0000.PDF.

No. 15.02 File Format for Module 2-5

Basics

Number	15.02
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 2-5 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to ICH eCTD specification

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-15.01.01: The file does not have a valid format.

No. 15.03 Path Length

Basics



Number	15.03
Category	Files / Folders
Validation Criterion	Total file folder path length must not exceed 180 characters
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Counting starts from the first digit of the sequence number in the sequence number folder name.

Summary

Problem Message	The total path length exceeds 180 characters
Hint Message	Total folder/file path must not exceed 180 characters, starting at the top level folder of the submission

No. 15.04 File Name Length


Basics

Number	15.04
Category	Files / Folders
Validation Criterion	File names, including the extension, must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a file name exceeds 64 characters
Hint Message	File names may not exceed 64 characters

Details

-  fail-15.04.01 : The maximum number of characters in a file name including the extension is 64. A file name with {0} characters was found: {1}

No. 15.05 Folder Name Length


Basics

Number	15.05
Category	Files / Folders
Validation Criterion	Folder names must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a folder name exceeds 64 characters
Hint Message	Folder names may not exceed 64 characters

Details

 fail-15.05.01: The maximum number of characters in a folder is 64. Folder name with {0} characters found: {1}

No. 15.06 File Name Characters





Basics

Number	15.06
Category	Files / Folders
Validation Criterion	Only valid characters are used in file names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The file name contains invalid characters
Hint Message	All characters used in file names must be valid. File names may only contain the characters a-z, 0-9 and '-'. File names must have exactly one extension with the same characters.

Details

 fail-15.06.01	A file name with invalid characters was found: {0}
 fail-15.06.02	A file with missing file extension was found: {0}
 fail-15.06.03	A file with multiple file extensions was found: {0}
 fail-15.06.04	A file with empty file name or empty extension is found: {0}

No. 15.07 Folder Name Characters


Basics

Number	15.07
Category	Files / Folders
Validation Criterion	Only valid characters are used in folder names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The folder name contains invalid characters
Hint Message	All characters used in folder names must be valid. Folder names may only contain the characters a-z, 0-9 and '-'

Details

 fail-15.07.01: A folder with invalid characters was found: {0}

No. 15.08 Un-referenced Files

Basics



Number	15.08
Category	Files / Folders
Validation Criterion	There are no unreferenced files in M1, M2, M3, M4 and M5 folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Including all subfolders within the m1-m5 folders but excluding util folder and sub-folders

Summary

Problem Message	Un-referenced files found
Hint Message	There cannot be un-referenced files in M1, M2, M3, M4 and M5 folders.

No. 15.09 Files in Sequence Folder

Basics



Number	15.09
Category	Files / Folders
Validation Criterion	The only files in the sequence folder (/XXXX/...) are the index.xml and index-md5.txt
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Unexpected files in sequence folder found
Hint Message	The only files in the sequence folder (/XXXX/...) should be the index.xml and index-md5.txt

No. 15.10 No Empty Folders

Basics



Number	15.10
Category	Files / Folders
Validation Criterion	There are no empty folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all folders contain at least one file
Hint Message	There shall be no empty folders

No. 15.11 Tracking Table File Location



Basics

Number	15.11
Category	Files / Folders
Validation Criterion	The tracking table file is present in the correct location
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The folder <code>/XXXX/m1/eu/10-cover/common</code>

Summary



Problem Message	Folder <code>/XXXX/m1/eu/10-cover/common</code> not found
Hint Message	The folder shall be <code>/XXXX/m1/eu/10-cover/common</code>

Details

 fail-15.11.01	The tracking table is mandatory for submission type 'MRP' or 'DCP' . The tracking table folder was missing: {0}
 pass-15.11.01	The tool validates the folder <code>/XXXX/m1/eu/10-cover/common</code> <i>only</i> . If folder is found, the rule is passed.

No. 15.12 Tracking Table File Name




Basics

Number	15.12
Category	Files / Folders
Validation Criterion	The tracking table file is correctly named
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named common-cover-tracking.pdf or common-cover-tracking.xml

Summary


Problem Message	File common-cover-tracking.pdf or common-cover-tracking.xml not found
Hint Message	File should be named common-cover-tracking.pdf or common-cover-tracking.xml

Details

 fail-15.12.01	The tracking table is mandatory for submission type ' MRP ' or ' DCP '. The tracking table file cannot be found: {0}
 fail-15.12.02	The tracking table is not named correctly and contains invalid characters: {0}
 pass-15.12.01	The tool validates the folder /XXXX/m1/eu/10-cover/common <i>only</i> for a tracking table. If a file named common-cover-tracking.pdf or common-cover-tracking.xml is found, the rule is passed.

No. 15.BP01 File Size

Basics


Number	15.BP01
Category	Envelope Attributes
Validation Criterion	Individual files do not exceed 100 MB in size
	 Best Practice
Other Submissions Required	no
	Any deviation should always be reported by the validating tool.
Comment	Files larger than 100 MB should be avoided. If there is a need to exceed this limit, this should be explained in the cover letter.

Summary

Problem Message	The file size exceeds 100 MB
Hint Message	Individual files should not exceed 100 MB in size

No. 15.BP02 Folder Naming


Basics

Number	15.BP02
Category	Files / Folders
Validation Criterion	The recommended folder structure and folder names in the ICH and HR specifications are used
Other Submissions Required	 Best Practice
Comment	Any deviation, including additional subfolders, should always be reported by the validating tool.

Summary


Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and HR specifications should be used

Details

 fail-15.bp2.01	The provided folder name does not follow the recommended ICH or HR folder name convention.
--	--

No. 15.BP03 File Naming



Basics

Number	15.BP03
Category	Files / Folders
Validation Criterion	The recommended file names from the ICH and HR specifications are used for all files
Other Submissions Required	 Best Practice no
Comment	<p>Any deviation should always be reported by the validating tool.</p> <p>Note that the components of the file names in italics in Appendix 4 of the ICH eCTD specification are to be specified by the applicant (i.e. this is variable text).</p> <p>In HR Module 1 the variable (VAR) part of the file name can include hyphens. Note: a change request has been raised to allow hyphens in the Variable part of the file names</p> <p>Applicants using the eCTD for ASMF or for MAAs including an ASMF are reminded that the HR guidance recommends the use of ap and rp prefixes for content in the applicants part and restricted part, respectively. eCTD validation tools should accept these prefixes in Modules 1, 2 and 3.</p> <p>The CC code of the filename should not be checked against the CC of the leaf attribute or the folder name</p>

Summary

Problem Message	File with unexpected name found
Hint Message	The recommended file names from the ICH and HR specifications should be used for all files



Details

 fail-15.bp3.01	The provided file name does not follow the recommended ICH or HR file name convention.
 fail-15.bp3.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

16 - PDF Files

No. 16.01 PDF Version 1.4 or Later




Basics

Number	16.01
Category	PDF Files
Validation Criterion	No PDF has been created and saved as version 1.3 or earlier
Type of Check	 Success  Error
Other Submissions Required	no
Comment	PDF 1.3 or earlier is not acceptable for technical reasons. No exceptions will be made. For example, if a literature reference is received in PDF 1.3 or earlier, then the applicant must provide it in PDF 1.4, even if this means getting a paper copy and scanning it. Further guidance may be provided about the best ways to check the PDF version.

Summary



Problem Message	PDF version 1.3 or earlier found
Hint Message	No PDF should be created and saved as version 1.3 or earlier

Details

 fail-16.01.01	The PDF version of the provided document is {0}. PDFs in version {1} and lower are not allowed.
 pass-16.01.01	PDF is version 1.4.
 pass-16.01.02	PDF is version 1.5

No. 16.02 Security Setting to Open


Basics

Number	16.02
Category	PDF Files
Validation Criterion	There is no security setting to open any individual file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This includes passwords, certificate security, adobe policy server settings, etc.

Summary



Problem Message	Security setting to open file found
Hint Message	No individual file should have a security setting

Details

-  fail-16.02.01 The PDF file is protected by a security setting and cannot be opened. Security settings are not allowed.

No. 16.03 Other Security Settings


Basics

Number	16.03
Category	PDF Files
Validation Criterion	There are no further security settings applied to any individual file (except for files in Modules 3.3, 4.3 and 5.4)
Type of Check	 Success  Error
Other Submissions Required	no
Comment	All restrictions should be allowed when viewing the Document Preferences > Security settings.

Summary


Problem Message	Security setting found
Hint Message	No further security settings should be applied to any individual file

Details

 fail-16.03.01	The PDF file can be opened but is protected by a restriction. Security restrictions are not allowed.
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No. 16.BP01 PDF Version 1.4




Basics

Number	16.BP01
Category	Envelope Attributes
Validation Criterion	Files have been created and saved as PDF 1.4
Type of Check	 Best Practice
Other Submissions Required	no
Comment	<p>If the use of later versions of PDF is unavoidable then the applicant should check that the files do not use features specific to later PDF versions than 1.4 that may be lost or not viewable based on PDF 1.4 and thus potentially could change the visual appearance of the document.</p> <p>Further guidance may be provided about the best ways to check the PDF version.</p>

Summary


Problem Message	File is not PDF 1.4
Hint Message	Files must be PDF 1.4

Details

 fail-16.bp1.01	PDF is version 1.3
 fail-16.bp1.02	PDF is version 1.5
 pass-16.bp1.01	PDF is version 1.4

No. 16.BP02 Current Sequence Hyperlink Targets


Basics

Number	16.BP02
Category	PDF Files
Validation Criterion	Hyperlinks within documents, or between documents within the same sequence, have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Links to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken hyperlinks to current sequence found
Hint Message	Hyperlinks within documents, or between documents within the same sequence, must have a valid target

Details

-  fail-16.bp2.01 : Some hyperlinks of a PDF with destinations INSIDE this eCTD sequence are broken. The number of broken hyperlinks is {0}.

No. 16.BP03 Current Sequence Bookmark Targets


Basics

Number	16.BP03
Category	PDF Files
Validation Criterion	Bookmarks to destinations within the same sequence have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Bookmarks to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken bookmarks to current sequence found
Hint Message	Bookmarks to destinations within the same sequence must have a valid target

Details

-  fail-16.bp3.01 : Some bookmarks of a PDF with destinations INSIDE this eCTD sequence are broken. The number of broken bookmarks is {0}.

No. 16.BP04 Valid Sequence Hyperlink Targets


Basics

Number	16.BP04
Category	PDF Files
Validation Criterion	Hyperlinks to targets within documents in a different sequence in the same application have a valid target
Type of Check	 Best Practice
Other Submissions Required	yes
Comment	Links to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary

Problem Message	PDF with broken hyperlinks to previous sequence found
Hint Message	Hyperlinks to targets within documents in a different sequence in the same application must have a valid target

Details

-  fail-16.bp4.01 : Some hyperlinks from a PDF with destinations OUTSIDE this eCTD sequence are broken. The number of broken hyperlinks is {0}.

No. 16.BP05 Valid Sequence Bookmark Targets

Basics

Number	16.BP05
Category	PDF Files
Validation Criterion	Bookmarks to destinations in a different sequence in the same application have a valid target
Type of Check	✘ Best Practice
Other Submissions Required	yes
Comment	Bookmarks to destinations outside the eCTD (Web links, e-mail addresses, etc.) should not be tested.

Summary


Problem Message	PDF with broken bookmarks to previous sequence found
Hint Message	Bookmarks to destinations in a different sequence in the same application must have a valid target

Details

- ✘ fail-16.bp5.01 : Some PDF bookmarks with destinations OUTSIDE this eCTD sequence are broken.
: The number of broken bookmarks is {0}.

No. 16.BP06 Inherit Zoom


Basics

Number	16.BP06
Category	PDF Files
Validation Criterion	All bookmarks and links are set to "inherit zoom"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with hyperlinks or bookmarks not using inherit zoom found
Hint Message	All bookmarks and links must be set to "inherit zoom"

Details

 fail-16.bp6.01: The document contains {0} hyperlinks or bookmarks not set to inherit zoom.

No. 16.BP07 Fast Web View

Basics


Number	16.BP07
Category	PDF Files
Validation Criterion	PDFs must have "Fast Web View" active
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	"Fast Web View" option not found
Hint Message	PDFs must have "Fast Web View" active

No. 16.BP08 PDF Document Properties


Basics

Number	16.BP08
Category	PDF Files
Validation Criterion	PDF document properties for the initial view are set for "Page Layout = Default" and "Magnification = Default"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	PDF with open actions not using inherit zoom found
Hint Message	PDF Document Properties for the Initial View must be set for "Page Layout = Default" and "Magnification = Default"

Details

-  fail- 16.bp08.01 : {0} incorrect settings found. The initial view settings of the PDF are incorrect. Page layout and magnification are not set to default.

No. 16.BP09 Relative Hyperlinks


Basics

Number	16.BP09
Category	PDF Files
Validation Criterion	All PDF hyperlinks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks must be relative

Details

 fail-16.bp09.01: The PDF file contains {0} absolute hyperlinks. Hyperlinks should be relative.

No. 16.BP10 Relative Bookmarks


Basics

Number	16.BP10
Category	PDF Files
Validation Criterion	All PDF bookmarks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks must be relative

Details

 fail-16.bp10.01: The PDF file contains {0} absolute bookmarks. Bookmarks should be relative.

No. 16.BP11 Bookmarks Pane Visibility

Basics

Number	16.BP11
Category	PDF Files
Validation Criterion	The bookmarks pane should be visible if bookmarks are included within a PDF document
Type of Check	✘ Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	PDF with invalid bookmarks pane visible setting found
Hint Message	The bookmarks pane should be visible if bookmarks are included within a PDF document

Details

✘ fail-16.bp11.01	The document contains one or more bookmarks. The bookmark pane is not open.
✘ fail-bp11.02	The document does not contain any bookmark. The bookmark pane is open and empty.

5 EU NeeS 2.1

Nees Validation Criteria Overview



The following table displays an overview about all EU eCTD validation set criteria, version 3.1.

Category	No. — Validation Criterion
01 Tables of Contents	01.01 — Specified Filename
	01.02 — Correct File Placement
	01.03 — Acceptable DTD Version
	01.04 — Valid DTD Version
	01.05 — ToC File Hyperlinks
	01.06 — ToC File Hyperlink Functions
	01.07 — Toc File Referenced Documents
02 Files / Folders	02.01 — Specified Filename
	02.02 — Correct File Placement
	02.03 — Acceptable Style Sheet Version
	02.04 — Valid Style Sheet Version
	02.05 — File Name Length
	02.06 — Folder Name Length
	02.07 — No Empty Folders
	02.08 — File Name Characters
	02.09 — Folder Name Characters
	02.10 — Folder Structure / Naming for Module 1 - 5
	02.11 — File Naming for Module 1 - 3
03 PDF Files	02.BP01 — Top Folder Naming
	02.BP02 — File Size
	02.BP03 — File Naming for Module 4 - 5
	03.01 — Specific Filename
	03.02 — Correct File Placement
	03.03 — Acceptable DTD Version
	03.04 — Valid DTD Version
	03.BP01 — PDF Version 1.4
	03.BP02 — Hyperlink Targets within Nees
	03.BP03 — Current Sequence Bookmark Targets
	03.BP04 — Inherit Zoom
03.BP05 — Fast Web View	
03.BP06 — PDF Document Properties	
03.BP07 — Relative Hyperlinks	
03.BP08 — Relative Bookmarks	

01 - Tables of Contents

No. 01.01 ToC File Availability



Basics

Number	01.01
Category	Table of Contents
Validation Criterion	The main CTD TOC file is present
Type of Check	 Success  Error
Other Submissions Required	no
Comment	There must be a file called ctd-toc.pdf for the NeeS to be considered a valid submission.

Summary



Problem Message	File ctd-toc.pdf is not found.
Hint Message	There must be a file called ctd-toc.pdf for the NeeS to be considered a valid submission.

Details

 fail-01.01.01	Investigate folder /XXXX/ to find ctd-toc.pdf . There is no file present. The correct name of the file cannot be checked.
 fail-01.01.02	The spelling of the present filename is incorrect (e.g. cTD-toc.pdf or ctd-toc.PDF)

No. 01.02 ToC File Name



Basics

Number	01.02
Category	Table of Contents
Validation Criterion	The main CTD TOC file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ctd-toc.pdf

Summary



Problem Message	The main CTD TOC file is not named correctly.
Hint Message	File shall be named ctd-toc.pdf.

Details

 fail-01.02.01	Investigate folder /XXXX/ to find ctd-toc.pdf . There is no file present. The correct name of the file cannot be checked.
 fail-01.02.02	The spelling of the present filename is incorrect (e.g. cTD-toc.pdf or ctd-toc.PDF)

No. 01.03 ToC File Location



Basics

Number	01.03
Category	Table of Contents
Validation Criterion	The main CTD TOC file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX

Summary



Problem Message	The main CTD TOC file is not stored in root folder /XXXX
Hint Message	The file shall be placed in the root folder /XXXX

Details

 fail-01.03.01	Investigate folder /XXXX/ to find ctd-toc.pdf. The file is missing. The correct placement of the file cannot be checked.
 fail-01.03.02	The root folder is not a 4 digit number. The correctness of the folder cannot be checked.

No. 01.04 ToC File Naming


Basics

Number	01.04
Category	Table of Contents
Validation Criterion	If module ToC files are present, each and every module folder (/m1, /m2, etc.) contains the correctly named module ToC file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If module ToCs are used then every module present must have a ToC file. Files are named mX-toc.pdf , where mX= the folder name. The Module ToC files are placed in the module level folders, i.e. /XXXX/mX..

Summary



Problem Message	Module TOCs are used, but not all modules have a module TOC.
Hint Message	If module TOCs are used then every module present must have a TOC file. Files are named mX-toc.pdf, where mX= the folder name. The Module TOC files are placed in the module level folders, i.e. /XXXX/mX.

Details

 fail-01.04.01 : Module TOCs are used, but not all modules have a module TOC: {0}

No. 01.05 ToC File Hyperlinks




Basics

Number	01.05
Category	Table of Contents
Validation Criterion	The expected hyperlinks are present and functioning in the main CTD TOC file.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If module ToC files (mx-toc.pdf) exist, then links must only be to mx-toc.pdf; if no mx-toc.pdf exist, then links to all individual files are required.

Summary



Problem Message	There are not all hyperlinks present and functioning in the main CTD TOC file.
Hint Message	If Module ToC files (mx-toc.pdf) exist, then links must only be to mx-toc.pdf ; if no mx-toc.pdf exist, then links to all individual files are required.

Details

 fail-01.05.01	Module TOCs are used, but the Main CTD TOC also contains other hyperlinks. These are not allowed. Invalid hyperlinks found: {0}
 fail-01.05.02	Not all hyperlinks in the Main CTD TOC are functioning. Broken hyperlinks found: {0}
 fail-01-05-03	The Main CTD TOC shall contain at least one hyperlink. There have been no hyperlinks found.

No. 01.06 ToC File Hyperlink Functions



Basics

Number	01.06
Category	Table of Contents
Validation Criterion	The expected hyperlinks are present and functioning in the module ToC files, if present.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If Module ToC files (mx-toc.pdf) exist, then links to all individual files within the respective mX-folder are required. The use of a return bookmark from the module ToC back to the CTD TOC is acceptable, but not specifically checked under this criterion.

Summary



Problem Message	There are not all hyperlinks present and functioning in the module ToC files.
Hint Message	If Module ToC files (mx-toc.pdf) exist, then links to all individual files within the respective mX-folder are required. The use of a return bookmark from the module ToC back to the CTD TOC is acceptable, but not specifically checked under this criterion.

Details

 fail-01.06.01	Module TOCs are used, but hyperlinks from a module TOC to another module are not allowed. Invalid hyperlinks found: {0}
 fail-01.06.02	Module TOCs are used, but not all hyperlinks are functioning. Broken hyperlinks found: {0}

No. 01.07 ToC File Referenced Documents


Basics

Number	01.07
Category	Table of Contents
Validation Criterion	All documents in the submission are referenced using a hyperlink in a ToC, either the main ctd-toc.pdf or in a module-specific ToC, as appropriate.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Unreferenced files result in an error and technical validation will fail.

Summary

Problem Message	There are unreferenced files.
Hint Message	Unreferenced files result in an error and technical validation will fail.



Details

 fail-01.07.01	Not all documents are referenced by the Main CTD TOC or a module TOC. Unreferenced files found: {0}
---	---

02 - Files / Folders

No. 02.01 File Format for Module 1

Basics

Number	02.01
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 1 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to table in HR Module 1 specification RTF will be removed from the list of acceptable formats to be referenced by leaves in the HR-regional.xml

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-02.01.01: The file does not have a valid format.


No. 02.02 ToC File Folder Naming

Basics

Number	02.02
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 2-5 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to ICH eCTD specification



Summary

Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

 fail-02.02.01: The file does not have a valid format.

No. 02.03 ToC File Location

Basics



Number	02.03
Category	Files / Folders
Validation Criterion	The folder in which ctd-toc.pdf is placed exists and is named with a four digit number.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	For example, 0000. This number is not required to be unique or sequential for the NeeS submission. However, it is appreciated if a sequential number system is used where possible and if so, a tracking table would be helpful.

Summary

Problem Message	The sequence folder has an incorrect name.
Hint Message	The folder in which ctd-toc.pdf is placed shall be named with a four digit number. For example, 0000. This number is not required to be unique or sequential for the NeeS submission. However, it is appreciated if a sequential number system is used where possible and if so, a tracking table would be helpful.

No. 02.04 Path Length

Basics



Number	02.04
Category	Files / Folders
Validation Criterion	Total file folder path length must not exceed 180 characters
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Counting starts from the first digit of the four digit folder name in which ctd-toc.pdf is placed.

Summary

Problem Message	The total path length exceeds 180 characters
Hint Message	Total folder/file path must not exceed 180 characters, starting at the top level folder of the submission

No. 02.05 File Name Length


Basics

Number	02.05
Category	Files / Folders
Validation Criterion	File names, including the extension, must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a file name exceeds 64 characters
Hint Message	File names may not exceed 64 characters

Details

-  fail-02.05.01 : The maximum number of characters in a file name including the extension is 64. A file name with {0} characters was found: {1}

No. 02.06 Folder Name Length


Basics

Number	02.06
Category	Files / Folders
Validation Criterion	Folder names must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a folder name exceeds 64 characters
Hint Message	Folder names may not exceed 64 characters

Details

 fail-02.06.01	The maximum number of characters in a folder is 64. Folder name with {0} characters found: {1}
---	--

No. 02.07 No Empty Folders

Basics



Number	02.07
Category	Files / Folders
Validation Criterion	There are no empty folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all folders do contain at least one file
Hint Message	There shall be no empty folders

No. 02.08 File Name Characters





Basics

Number	02.08
Category	Files / Folders
Validation Criterion	Only valid characters are used in file names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The file name contains invalid characters
Hint Message	All characters used in file names must be valid. File names may only contain the characters a-z, 0-9 and '-'. File names must have exactly one extension with the same characters.

Details

 fail-02.08.01	A file name with invalid characters was found: {0}
 fail-02.08.02	A file with missing file extension was found: {0}
 fail-02.08.03	A file with multiple file extensions was found: {0}
 fail-02.08.04	A file with empty file name or empty extension is found: {0}

No. 02.09 Folder Name Characters


Basics

Number	02.09
Category	Files / Folders
Validation Criterion	Only valid characters are used in folder names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The folder name contains invalid characters
Hint Message	All characters used in folder names must be valid. Folder names may only contain the characters a-z, 0-9 and '-'

Details

 fail-02.09.01: A folder with invalid characters was found: {0}

No. 02.10 Folder Structure / Naming for Module 1 - 5


Basics

Number	02.10
Category	Files / Folders
Validation Criterion	For Modules 1-5: The folder structure and names must follow the EU or ICH defined structure and names.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Please see attached worksheet identifying the fixed and variable folder names. The fixed names must match the published values. Only these folders will be accepted.

Summary



Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and EU specifications shall be used

Details

-  fail-02.10.01 The provided folder name does not follow the recommended ICH or EU folder name convention.

No. 02.11 For Root and Module 1 - 3



Basics

Number	02.11
Category	Files / Folders
Validation Criterion	For Root and Modules 1-3: The file names must follow the EU or ICH defined names.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	<p>Please see attached worksheet identifying the fixed and variable parts of the file names. In module 1, the file name may include a country code prefix, as defined in the HR Module 1 eCTD specification. The fixed parts must match the published values.</p> <p>Note - the presence of hyphens in the variable part will not be checked.</p> <p>Applicants using NeeS for ASMF or for MAAs including an ASMF are recommended to add "ap" or "rp" as a suffix to the file name for content in the applicants part and restricted part, respectively. Note that this is not the same recommendation as for the eCTD but is acceptable under the NeeS file naming as it is part of the variable portion of the file name.</p> <p>The CC code of the filename should not be checked against the CC of the folder name.</p>

Summary


Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and EU specifications shall be used

Details

 fail-02.11.01	The provided file name does not follow the recommended ICH or EU file name convention.
 fail-02.11.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

No. 02.BP01 Top Folder Naming


Basics

Number	02.BP01
Category	Files / Folders
Validation Criterion	The folder above the folder named with four digits exists and is named appropriately.
Other Submissions Required	 Best Practice no
Comment	This folder will be part of the submitted NeeS. In a NeeS the top level folder is named with an identification of the product concerned (i.e. abbreviation of the product name or procedure number). It is recommended but not required that the name of this folder is consistent from one NeeS submission to the next.

Summary


Problem Message	The folder above the folder named with four digits does not exist.
Hint Message	The folder above the folder named with four digits shall exist and be named appropriately. This folder will be part of the submitted NeeS. In a NeeS the top level folder is named with an identification of the product concerned (i.e. abbreviation of the product name or procedure number). It is recommended but not required that the name of this folder is consistent from one NeeS submission to the next.

Implementation

 fail-02.bp01.01 The folder above the folder named with four digits does not exist.

No. 02.BP02 File Size

Basics


Number	02.BP02
Category	Files / Folders
Validation Criterion	Individual files do not exceed 100 MB in size
Other Submissions Required	 Best Practice no
Comment	Any deviation should always be reported by the validating tool. Files larger than 100 MB should be avoided. If there is a need to exceed this limit, this should be explained in the cover letter.

Summary

Problem Message	The file size exceeds 100 MB
Hint Message	Individual files should not exceed 100 MB in size

No. 02.BP03 File Naming for Module 4 - 5



Basics

Number	02.BP03
Category	Files / Folders
Validation Criterion	For modules 4 and 5: The file names should follow the ICH defined names.
Other Submissions Required	 Best Practice
Comment	no Please see attached worksheet identifying the fixed and variable parts of the file names. In Modules 4 and 5, most of the file names are entirely variable. However, the fixed parts must match the published values, when applicable. Note - the presence of hyphens in the variable part will not be checked.

Summary

Problem Message	File with unexpected name found
Hint Message	The recommended file names from the ICH and EU specifications shall be used for all files in module 4-5.



Details

 fail-02.bp3.01	The provided file name does not follow the recommended ICH or EU file name convention.
 fail-02.bp3.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

03 - PDF Files

No. 03.01 PDF Version 1.4 or Later




Basics

Number	03.01
Category	PDF Files
Validation Criterion	No PDF has been created and saved as version 1.3 or earlier
Type of Check	 Success  Error
Other Submissions Required	no
Comment	PDF 1.3 or earlier is not acceptable for technical reasons. No exceptions will be made. For example, if a literature reference is received in PDF 1.3 or earlier, then the applicant must provide it in PDF 1.4, even if this means getting a paper copy and scanning it. Further guidance may be provided about the best ways to check the PDF version.

Summary



Problem Message	PDF version 1.3 or earlier found
Hint Message	No PDF shall be created and saved as version 1.3 or earlier

Details

 fail-03.01.01	The PDF version of the provided document is {0}. PDFs in version {1} and lower are not allowed.
 pass-03.01.01	PDF is version 1.4
 pass-03.01.02	PDF is version 1.5

No. 03.02 Security Setting for Opening Files


Basics

Number	03.02
Category	PDF Files
Validation Criterion	There is no password protection to open any individual file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This includes passwords, certificate security, adobe policy server settings, etc.

Summary



Problem Message	Security setting to open file found
Hint Message	No individual file should have a security setting

Details

-  fail-03.02.01 The PDF file is protected by any security setting and cannot be opened. Security settings are not allowed.

No. 03.03 Security Settings to Individual Files


Basics

Number	03.03
Category	PDF Files
Validation Criterion	There are no further security settings applied to any individual file (except for files in Modules 3.3, 4.3 and 5.4)
Type of Check	 Success  Error
Other Submissions Required	no
Comment	All restrictions should be allowed when viewing the Document Preferences > Security settings.

Summary



Problem Message	Security setting found
Hint Message	No further security settings should be applied to any individual file

Details

-  fail-03.03.01 : The PDF file can be opened but is protected by any other restriction. Security restrictions are not allowed.

No. 03.04 Other Security Settings


Basics

Number	03.04
Category	PDF Files
Validation Criterion	All TOC PDF hyperlinks are relative
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The hyperlinks should be made to first page in the PDF.

Summary


Problem Message	Not all TOC PDF hyperlinks are relative.
Hint Message	All TOC PDF hyperlinks shall be relative.

Details

-  fail-03.04.01 The TOC PDF files contain {0} absolute hyperlinks. Hyperlinks in TOC PDF files must be relative.

No. 03.BP01 PDF Version 1.4

Basics


Number	03.BP01
Category	PDF Files
Validation Criterion	Files have been created and saved as PDF 1.4
Type of Check	 Best Practice
Other Submissions Required	no
Comment	<p>If the use of later versions of PDF is unavoidable then the applicant should check that the files do not use features specific to later PDF versions than 1.4 that may be lost or not viewable based on PDF 1.4 and thus potentially could change the visual appearance of the document.</p> <p>Further guidance may be provided about the best ways to check the PDF version.</p>

Summary

Problem Message	File is not PDF 1.4
Hint Message	Files shall be PDF 1.4

No. 03.BP02 Hyperlink Targets within NeeS



Basics

Number	03.BP02
Category	PDF Files
Validation Criterion	Hyperlinks within documents, or between documents within the same NeeS, have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Links to destinations outside the NeeS (Web links, e-mail addresses, etc.) should not be tested. There should be no hyperlinks to destinations outside the NeeS.

Summary


Problem Message	PDF with broken hyperlinks within the same NeeS found.
Hint Message	Hyperlinks within documents, or between documents within the same NeeS, shall have a valid target.

Details

 fail-03.bp2.01	Some hyperlinks of a PDF with destinations INSIDE this NeeS are broken. The number of broken hyperlinks is {0}.
 fail-03.bp2.02	Some hyperlinks of a PDF have destinations OUTSIDE this NeeS. This is not valid. The number of invalid hyperlinks is {0}.

No. 03.BP03 Current Sequence Bookmark Targets



Basics

Number	03.BP03
Category	PDF Files
Validation Criterion	Bookmarks to destinations within the same NeeS have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Bookmarks to destinations outside the NeeS (Web links, e-mail addresses, etc.) should not be tested. There should be no bookmarks to destinations outside the NeeS.

Summary


Problem Message	PDF with broken bookmarks to current sequence found
Hint Message	Bookmarks to destinations within the same sequence shall have a valid target

Details

 fail-03.bp03.01	Some bookmarks of a PDF with destinations INSIDE this NeeS are broken. The number of broken bookmarks is {0}.
 fail-03.bp03.02	Some bookmarks of a PDF have destinations OUTSIDE this NeeS. This is not valid. The number of invalid hyperlinks is {0}.

No. 03.BP04 Inherit Zoom


Basics

Number	03.BP04
Category	PDF Files
Validation Criterion	All bookmarks and links are set to "inherit zoom"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with hyperlinks or bookmarks not using inherit zoom found
Hint Message	All bookmarks and links shall be set to "inherit zoom"

Details

-  fail-03.bp04.01 : The document contains {0} hyperlinks or bookmarks not set to inherit zoom.

No. 03.BP05 Fast Web View

Basics

Number	03.BP05
Category	PDF Files
Validation Criterion	PDFs must have "Fast Web View" active
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	"Fast Web View" option not found
Hint Message	PDFs shall have "Fast Web View" active

No. 03.BP06 PDF Document Properties

Basics

Number	03.BP06
Category	PDF Files
Validation Criterion	PDF document properties for the initial view are set for "Page Layout = Default" and "Magnification = Default"
Type of Check	✘ Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with open actions not using inherit zoom found
Hint Message	PDF Document Properties for the Initial View shall be set for "Page Layout = Default" and "Magnification = Default"

Details

- ✘ fail-03.bp06.01 : The initial view settings of the PDF are incorrect. Page layout and magnification are not set to default. {0} incorrect settings found.

No. 03.BP07 Relative Hyperlinks


Basics

Number	03.BP07
Category	PDF Files
Validation Criterion	All PDF hyperlinks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Note that criterion number 3.4. concerning ToCs is a P / F check.

Summary


Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks shall be relative

Details

 fail-03.bp07.01 : The PDF file contains {0} absolute hyperlinks. Hyperlinks should be relative.

No. 03.BP08 Relative Bookmarks


Basics

Number	03.BP08
Category	PDF Files
Validation Criterion	All PDF bookmarks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks shall be relative

Details

 fail-03.bp08.01 : The PDF file contains {0} absolute bookmarks. Bookmarks should be relative.

6 HR NeeS 2.1

Nees Validation Criteria Overview



The following table displays an overview about all EU eCTD validation set criteria, version 3.1.

Category	No. — Validation Criterion
01 Tables of Contents	01.01 — Specified Filename
	01.02 — Correct File Placement
	01.03 — Acceptable DTD Version
	01.04 — Valid DTD Version
	01.05 — ToC File Hyperlinks
	01.06 — ToC File Hyperlink Functions
	01.07 — Toc File Referenced Documents
02 Files / Folders	02.01 — Specified Filename
	02.02 — Correct File Placement
	02.03 — Acceptable Style Sheet Version
	02.04 — Valid Style Sheet Version
	02.05 — File Name Length
	02.06 — Folder Name Length
	02.07 — No Empty Folders
	02.08 — File Name Characters
	02.09 — Folder Name Characters
	02.10 — Folder Structure / Naming for Module 1 - 5
	02.11 — File Naming for Module 1 - 3
03 PDF Files	02.BP01 — Top Folder Naming
	02.BP02 — File Size
	02.BP03 — File Naming for Module 4 - 5
	03.01 — Specific Filename
	03.02 — Correct File Placement
	03.03 — Acceptable DTD Version
	03.04 — Valid DTD Version
	03.BP01 — PDF Version 1.4
	03.BP02 — Hyperlink Targets within Nees
	03.BP03 — Current Sequence Bookmark Targets
	03.BP04 — Inherit Zoom
03.BP05 — Fast Web View	
03.BP06 — PDF Document Properties	
03.BP07 — Relative Hyperlinks	
03.BP08 — Relative Bookmarks	

01 - Tables of Contents

No. 01.01 ToC File Availability



Basics

Number	01.01
Category	Table of Contents
Validation Criterion	The main CTD TOC file is present
Type of Check	 Success  Error
Other Submissions Required	no
Comment	There must be a file called ctd-toc.pdf for the NeeS to be considered a valid submission.

Summary



Problem Message	File ctd-toc.pdf is not found.
Hint Message	There must be a file called ctd-toc.pdf for the NeeS to be considered a valid submission.

Details

 fail-01.01.01	Investigate folder /XXXX/ to find ctd-toc.pdf . There is no file present. The correct name of the file cannot be checked.
 fail-01.01.02	The spelling of the present filename is incorrect (e.g. cTD-toc.pdf or ctd-toc.PDF)

No. 01.02 ToC File Name



Basics

Number	01.02
Category	Table of Contents
Validation Criterion	The main CTD TOC file is named correctly
Type of Check	 Success  Error
Other Submissions Required	no
Comment	File is named ctd-toc.pdf

Summary



Problem Message	The main CTD TOC file is not named correctly.
Hint Message	File shall be named ctd-toc.pdf.

Details

 fail-01.02.01	Investigate folder /XXXX/ to find ctd-toc.pdf . There is no file present. The correct name of the file cannot be checked.
 fail-01.02.02	The spelling of the present filename is incorrect (e.g. cTD-toc.pdf or ctd-toc.PDF)

No. 01.03 ToC File Location



Basics

Number	01.03
Category	Table of Contents
Validation Criterion	The main CTD TOC file is placed in the correct folder
Type of Check	 Success  Error
Other Submissions Required	no
Comment	In the folder /XXXX

Summary



Problem Message	The main CTD TOC file is not stored in root folder /XXXX
Hint Message	The file shall be placed in the root folder /XXXX

Details

 fail-01.03.01	Investigate folder /XXXX/ to find ctd-toc.pdf. The file is missing. The correct placement of the file cannot be checked.
 fail-01.03.02	The root folder is not a 4 digit number. The correctness of the folder cannot be checked.

No. 01.04 ToC File Naming


Basics

Number	01.04
Category	Table of Contents
Validation Criterion	If module ToC files are present, each and every module folder (/m1, /m2, etc.) contains the correctly named module ToC file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If module ToCs are used then every module present must have a ToC file. Files are named mX-toc.pdf , where mX= the folder name. The Module ToC files are placed in the module level folders, i.e. /XXXX/mX..

Summary



Problem Message	Module TOCs are used, but not all modules have a module TOC.
Hint Message	If module TOCs are used then every module present must have a TOC file. Files are named mX-toc.pdf, where mX= the folder name. The Module TOC files are placed in the module level folders, i.e. /XXXX/mX.

Details

 fail-01.04.01 Module TOCs are used, but not all modules have a module TOC: {0}

No. 01.05 ToC File Hyperlinks




Basics

Number	01.05
Category	Table of Contents
Validation Criterion	The expected hyperlinks are present and functioning in the main CTD TOC file.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If module ToC files (mx-toc.pdf) exist, then links must only be to mx-toc.pdf; if no mx-toc.pdf exist, then links to all individual files are required.

Summary



Problem Message	There are not all hyperlinks present and functioning in the main CTD TOC file.
Hint Message	If Module ToC files (mx-toc.pdf) exist, then links must only be to mx-toc.pdf ; if no mx-toc.pdf exist, then links to all individual files are required.

Details

 fail-01.05.01	Module TOCs are used, but the Main CTD TOC also contains other hyperlinks. These are not allowed. Invalid hyperlinks found: {0}
 fail-01.05.02	Not all hyperlinks in the Main CTD TOC are functioning. Broken hyperlinks found: {0}
 fail-01-05-03	The Main CTD TOC shall contain at least one hyperlink. There have been no hyperlinks found.

No. 01.06 ToC File Hyperlink Functions



Basics

Number	01.06
Category	Table of Contents
Validation Criterion	The expected hyperlinks are present and functioning in the module ToC files, if present.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	If Module ToC files (mx-toc.pdf) exist, then links to all individual files within the respective mX-folder are required. The use of a return bookmark from the module ToC back to the CTD TOC is acceptable, but not specifically checked under this criterion.

Summary



Problem Message	There are not all hyperlinks present and functioning in the module ToC files.
Hint Message	If Module ToC files (mx-toc.pdf) exist, then links to all individual files within the respective mX-folder are required. The use of a return bookmark from the module ToC back to the CTD TOC is acceptable, but not specifically checked under this criterion.

Details

 fail-01.06.01	Module TOCs are used, but hyperlinks from a module TOC to another module are not allowed. Invalid hyperlinks found: {0}
 fail-01.06.02	Module TOCs are used, but not all hyperlinks are functioning. Broken hyperlinks found: {0}

No. 01.07 ToC File Referenced Documents


Basics

Number	01.07
Category	Table of Contents
Validation Criterion	All documents in the submission are referenced using a hyperlink in a ToC, either the main ctd-toc.pdf or in a module-specific ToC, as appropriate.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Unreferenced files result in an error and technical validation will fail.

Summary

Problem Message	There are unreferenced files.
Hint Message	Unreferenced files result in an error and technical validation will fail.



Details

 fail-01.07.01	Not all documents are referenced by the Main CTD TOC or a module TOC. Unreferenced files found: {0}
---	---

02 - Files / Folders

No. 02.01 File Format for Module 1


Basics

Number	02.01
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 1 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to table in HR Module 1 specification RTF will be removed from the list of acceptable formats to be referenced by leaves in the HR-regional.xml

Summary



Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

Details

 fail-02.01.01: The file does not have a valid format.


No. 02.02 ToC File Folder Naming

Basics

Number	02.02
Category	Files / Folders
Validation Criterion	The files provided in the folders for Module 2-5 are in acceptable formats
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Refer to ICH eCTD specification



Summary

Problem Message	The file does not have a valid format
Hint Message	The format must be one of: PDF, XML, JPEG, PNG, SVG, GIF. This rule checks the file extension only, not the file content

 fail-02.02.01: The file does not have a valid format.

No. 02.03 ToC File Location

Basics



Number	02.03
Category	Files / Folders
Validation Criterion	The folder in which ctd-toc.pdf is placed exists and is named with a four digit number.
Type of Check	 Success  Error
Other Submissions Required	no For example, 0000.
Comment	This number is not required to be unique or sequential for the NeeS submission. However, it is appreciated if a sequential number system is used where possible and if so, a tracking table would be helpful.

Summary

Problem Message	The sequence folder has an incorrect name.
Hint Message	The folder in which ctd-toc.pdf is placed shall be named with a four digit number. For example, 0000. This number is not required to be unique or sequential for the NeeS submission. However, it is appreciated if a sequential number system is used where possible and if so, a tracking table would be helpful.

No. 02.04 Path Length

Basics



Number	02.04
Category	Files / Folders
Validation Criterion	Total file folder path length must not exceed 180 characters
Type of Check	 Success  Error
Other Submissions Required	yes
Comment	Counting starts from the first digit of the four digit folder name in which ctd-toc.pdf is placed.

Summary

Problem Message	The total path length exceeds 180 characters
Hint Message	Total folder/file path must not exceed 180 characters, starting at the top level folder of the submission

No. 02.05 File Name Length


Basics

Number	02.05
Category	Files / Folders
Validation Criterion	File names, including the extension, must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a file name exceeds 64 characters
Hint Message	File names may not exceed 64 characters

Details

-  fail-02.05.01 : The maximum number of characters in a file name including the extension is 64. A file name with {0} characters was found: {1}

No. 02.06 Folder Name Length


Basics

Number	02.06
Category	Files / Folders
Validation Criterion	Folder names must not exceed 64 characters
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary



Problem Message	The length of a folder name exceeds 64 characters
Hint Message	Folder names may not exceed 64 characters

Details

 fail-02.06.01 The maximum number of characters in a folder is 64. Folder name with {0} characters found: {1}

No. 02.07 No Empty Folders

Basics



Number	02.07
Category	Files / Folders
Validation Criterion	There are no empty folders
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all folders do contain at least one file
Hint Message	There shall be no empty folders

No. 02.08 File Name Characters





Basics

Number	02.08
Category	Files / Folders
Validation Criterion	Only valid characters are used in file names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The file name contains invalid characters
Hint Message	All characters used in file names must be valid. File names may only contain the characters a-z, 0-9 and '-'. File names must have exactly one extension with the same characters.

Details

 fail-02.08.01	A file name with invalid characters was found: {0}
 fail-02.08.02	A file with missing file extension was found: {0}
 fail-02.08.03	A file with multiple file extensions was found: {0}
 fail-02.08.04	A file with empty file name or empty extension is found: {0}

No. 02.09 Folder Name Characters


Basics

Number	02.09
Category	Files / Folders
Validation Criterion	Only valid characters are used in folder names
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

Summary



Problem Message	The folder name contains invalid characters
Hint Message	All characters used in folder names must be valid. Folder names may only contain the characters a-z, 0-9 and '-'

Details

 fail-02.09.01: A folder with invalid characters was found: {0}

No. 02.10 Folder Structure / Naming for Module 1 - 5


Basics

Number	02.10
Category	Files / Folders
Validation Criterion	For Modules 1-5: The folder structure and names must follow the HR or ICH defined structure and names.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	Please see attached worksheet identifying the fixed and variable folder names. The fixed names must match the published values. Only these folders will be accepted.

Summary



Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and HR specifications shall be used

Details

-  fail-02.10.01 The provided folder name does not follow the recommended ICH or HR folder name convention.

No. 02.11 For Root and Module 1 - 3



Basics

Number	02.11
Category	Files / Folders
Validation Criterion	For Root and Modules 1-3: The file names must follow the HR or ICH defined names.
Type of Check	 Success  Error
Other Submissions Required	no
Comment	<p>Please see attached worksheet identifying the fixed and variable parts of the file names. In module 1, the file name may include a country code prefix, as defined in the HR Module 1 eCTD specification. The fixed parts must match the published values.</p> <p>Note - the presence of hyphens in the variable part will not be checked.</p> <p>Applicants using NeeS for ASMF or for MAAs including an ASMF are recommended to add "ap" or "rp" as a suffix to the file name for content in the applicants part and restricted part, respectively. Note that this is not the same recommendation as for the eCTD but is acceptable under the NeeS file naming as it is part of the variable portion of the file name.</p> <p>The CC code of the filename should not be checked against the CC of the folder name.</p>

Summary


Problem Message	Folder with unexpected name found
Hint Message	The recommended folder structure and folder names in the ICH and HR specifications shall be used

Details

 fail-02.11.01	The provided file name does not follow the recommended ICH or HR file name convention.
 fail-02.11.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

No. 02.BP01 Top Folder Naming


Basics

Number	02.BP01
Category	Files / Folders
Validation Criterion	The folder above the folder named with four digits exists and is named appropriately.
Other Submissions Required	 Best Practice no
Comment	This folder will be part of the submitted NeeS. In a NeeS the top level folder is named with an identification of the product concerned (i.e. abbreviation of the product name or procedure number). It is recommended but not required that the name of this folder is consistent from one NeeS submission to the next.

Summary


Problem Message	The folder above the folder named with four digits does not exist.
Hint Message	The folder above the folder named with four digits shall exist and be named appropriately. This folder will be part of the submitted NeeS. In a NeeS the top level folder is named with an identification of the product concerned (i.e. abbreviation of the product name or procedure number). It is recommended but not required that the name of this folder is consistent from one NeeS submission to the next.

Implementation

 fail-02.bp01.01 The folder above the folder named with four digits does not exist.

No. 02.BP02 File Size

Basics


Number	02.BP02
Category	Files / Folders
Validation Criterion	Individual files do not exceed 100 MB in size
Other Submissions Required	 Best Practice no
Comment	Any deviation should always be reported by the validating tool. Files larger than 100 MB should be avoided. If there is a need to exceed this limit, this should be explained in the cover letter.

Summary

Problem Message	The file size exceeds 100 MB
Hint Message	Individual files should not exceed 100 MB in size

No. 02.BP03 File Naming for Module 4 - 5



Basics

Number	02.BP03
Category	Files / Folders
Validation Criterion	For modules 4 and 5: The file names should follow the ICH defined names.
Other Submissions Required	 Best Practice no
Comment	Please see attached worksheet identifying the fixed and variable parts of the file names. In Modules 4 and 5, most of the file names are entirely variable. However, the fixed parts must match the published values, when applicable. Note - the presence of hyphens in the variable part will not be checked.

Summary

Problem Message	File with unexpected name found
Hint Message	The recommended file names from the ICH and HR specifications shall be used for all files in module 4-5.



Details

 fail-02.bp3.01	The provided file name does not follow the recommended ICH or HR file name convention.
 fail-02.bp3.02	The file naming convention in 23-qos is not followed. The file name is valid but not allowed together with {0} in the same folder.

03 - PDF Files

No. 03.01 PDF Version 1.4 or Later




Basics

Number	03.01
Category	PDF Files
Validation Criterion	No PDF has been created and saved as version 1.3 or earlier
Type of Check	 Success  Error
Other Submissions Required	no
Comment	PDF 1.3 or earlier is not acceptable for technical reasons. No exceptions will be made. For example, if a literature reference is received in PDF 1.3 or earlier, then the applicant must provide it in PDF 1.4, even if this means getting a paper copy and scanning it. Further guidance may be provided about the best ways to check the PDF version.

Summary



Problem Message	PDF version 1.3 or earlier found
Hint Message	No PDF shall be created and saved as version 1.3 or earlier

Details

 fail-03.01.01	The PDF version of the provided document is {0}. PDFs in version {1} and lower are not allowed.
 pass-03.01.01	PDF is version 1.4
 pass-03.01.02	PDF is version 1.5

No. 03.02 Security Setting for Opening Files


Basics

Number	03.02
Category	PDF Files
Validation Criterion	There is no password protection to open any individual file
Type of Check	 Success  Error
Other Submissions Required	no
Comment	This includes passwords, certificate security, adobe policy server settings, etc.

Summary



Problem Message	Security setting to open file found
Hint Message	No individual file should have a security setting

Details

-  fail-03.02.01 The PDF file is protected by any security setting and cannot be opened. Security settings are not allowed.

No. 03.03 Security Settings to Individual Files


Basics

Number	03.03
Category	PDF Files
Validation Criterion	There are no further security settings applied to any individual file (except for files in Modules 3.3, 4.3 and 5.4)
Type of Check	 Success  Error
Other Submissions Required	no
Comment	All restrictions should be allowed when viewing the Document Preferences > Security settings.

Summary



Problem Message	Security setting found
Hint Message	No further security settings should be applied to any individual file

Details

-  fail-03.03.01 : The PDF file can be opened but is protected by any other restriction. Security restrictions are not allowed.

No. 03.04 Other Security Settings


Basics

Number	03.04
Category	PDF Files
Validation Criterion	All TOC PDF hyperlinks are relative
Type of Check	 Success  Error
Other Submissions Required	no
Comment	The hyperlinks should be made to first page in the PDF.

Summary


Problem Message	Not all TOC PDF hyperlinks are relative.
Hint Message	All TOC PDF hyperlinks shall be relative.

Details

-  fail-03.04.01 The TOC PDF files contain {0} absolute hyperlinks. Hyperlinks in TOC PDF files must be relative.

No. 03.BP01 PDF Version 1.4

Basics


Number	03.BP01
Category	PDF Files
Validation Criterion	Files have been created and saved as PDF 1.4
Type of Check	 Best Practice
Other Submissions Required	no
Comment	<p>If the use of later versions of PDF is unavoidable then the applicant should check that the files do not use features specific to later PDF versions than 1.4 that may be lost or not viewable based on PDF 1.4 and thus potentially could change the visual appearance of the document.</p> <p>Further guidance may be provided about the best ways to check the PDF version.</p>

Summary

Problem Message	File is not PDF 1.4
Hint Message	Files shall be PDF 1.4

No. 03.BP02 Hyperlink Targets within NeeS



Basics

Number	03.BP02
Category	PDF Files
Validation Criterion	Hyperlinks within documents, or between documents within the same NeeS, have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Links to destinations outside the NeeS (Web links, e-mail addresses, etc.) should not be tested. There should be no hyperlinks to destinations outside the NeeS.

Summary


Problem Message	PDF with broken hyperlinks within the same NeeS found.
Hint Message	Hyperlinks within documents, or between documents within the same NeeS, shall have a valid target.

Details

 fail-03.bp2.01	Some hyperlinks of a PDF with destinations INSIDE this NeeS are broken. The number of broken hyperlinks is {0}.
 fail-03.bp2.02	Some hyperlinks of a PDF have destinations OUTSIDE this NeeS. This is not valid. The number of invalid hyperlinks is {0}.

No. 03.BP03 Current Sequence Bookmark Targets



Basics

Number	03.BP03
Category	PDF Files
Validation Criterion	Bookmarks to destinations within the same NeeS have a valid target
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Bookmarks to destinations outside the NeeS (Web links, e-mail addresses, etc.) should not be tested. There should be no bookmarks to destinations outside the NeeS.

Summary


Problem Message	PDF with broken bookmarks to current sequence found
Hint Message	Bookmarks to destinations within the same sequence shall have a valid target

Details

 fail-03.bp03.01	Some bookmarks of a PDF with destinations INSIDE this NeeS are broken. The number of broken bookmarks is {0}.
 fail-03.bp03.02	Some bookmarks of a PDF have destinations OUTSIDE this NeeS. This is not valid. The number of invalid hyperlinks is {0}.

No. 03.BP04 Inherit Zoom


Basics

Number	03.BP04
Category	PDF Files
Validation Criterion	All bookmarks and links are set to "inherit zoom"
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with hyperlinks or bookmarks not using inherit zoom found
Hint Message	All bookmarks and links shall be set to "inherit zoom"

Details

-  fail-03.bp04.01 : The document contains {0} hyperlinks or bookmarks not set to inherit zoom.

No. 03.BP05 Fast Web View

Basics

Number	03.BP05
Category	PDF Files
Validation Criterion	PDFs must have "Fast Web View" active
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	"Fast Web View" option not found
Hint Message	PDFs shall have "Fast Web View" active

No. 03.BP06 PDF Document Properties

Basics

Number	03.BP06
Category	PDF Files
Validation Criterion	PDF document properties for the initial view are set for "Page Layout = Default" and "Magnification = Default"
Type of Check	✘ Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary


Problem Message	PDF with open actions not using inherit zoom found
Hint Message	PDF Document Properties for the Initial View shall be set for "Page Layout = Default" and "Magnification = Default"

Details

- ✘ fail-03.bp06.01 : The initial view settings of the PDF are incorrect. Page layout and magnification are not set to default. {0} incorrect settings found.

No. 03.BP07 Relative Hyperlinks


Basics

Number	03.BP07
Category	PDF Files
Validation Criterion	All PDF hyperlinks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Note that criterion number 3.4. concerning ToCs is a P / F check.

Summary

Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks shall be relative

Details

 fail-03.bp07.01 : The PDF file contains {0} absolute hyperlinks. Hyperlinks should be relative.

No. 03.BP08 Relative Bookmarks


Basics

Number	03.BP08
Category	PDF Files
Validation Criterion	All PDF bookmarks are relative
Type of Check	 Best Practice
Other Submissions Required	no
Comment	Not applicable!

Summary

Problem Message	Not all PDF hyperlinks are relative
Hint Message	All PDF hyperlinks shall be relative

Details

 fail-03.bp08.01 : The PDF file contains {0} absolute bookmarks. Bookmarks should be relative.

7 Validation Criteria References - Medicinal

Swissmedic (CH) eCTD Validation Criteria

The CH eCTD Validation Criteria Version 1.0 / 1.0.1/1.1 can be found at

<http://www.swissmedic.ch/zulassungen/00933/00935/01018/index.html>

(V1.0 and V1.0.1 / Oct. 2009)

and at

<http://www.swissmedic.ch/...>

(V1.1 / May 2010)

See also: [Severity Prioritisation Keys](#)

French (FR) eCTD Validation Criteria

Refer to **European (EU) eCTD Validation Criteria** specification details. The validation result differs only in rule **0037**. There, severity B is altered to severity A.

See also: [European \(EU\) eCTD Validation Criteria](#)

Croatia (HR) eCTD Validation Criteria

The HR eCTD Validation Criteria Version 2.1 can be found at

HR-eCTD v2.1 (DTD 1.4): <http://www.almp.hr/>

FDA (US) eCTD Validation Criteria

The FDA eCTD Validation Criteria Version 1.0 can be found at

FDA-eCTD v1.0 (DTD 2.01): <http://www.fda.go/...>

Severity Prioritisation Keys

European Union / Croatia

Prioritisation Key	Summary	Additional Hints
Severity A (Serious): Compliance is mandatory. Failure to comply results in an error message in the validation report, no load of eCTD into the review tool, and a replacement sequence should be requested.	A = reject sequence (applicant must submit a replacement)	-
Severity B (Medium): Compliance is preferred. Failure to comply results in a warning being displayed. A degree of discretion should be applied by the agency to the feedback given to the applicant. It may be requested that the issue is resolved in a subsequent sequence.	B = accept but may request corrections (fix with a subsequent sequence)	Apply a degree of discretion. For example, if one study report is 105 MB, it will not be in the interests of either the agency or the applicant to make changes. However, if the submission consists of 200 scanned reports, all over 500 MB, then the agency

Severity Prioritisation Keys

Prioritisation Key	Summary	Additional Hints
		would have every reason to request changes.
Severity C (Low): Compliance is preferred. Failure to comply results in advice being displayed. Report to the applicant for future consideration. Resolution may result in the eCTD being easier to handle.	C = accept but will flag errors so that they are not repeated in subsequent sequences/submissions (no fix needed)	I.e advisory only

Switzerland

Severity Error	Error Level	Effects on the eSubmission	Example
Severity A	Serious: The sequence is rejected, the applicant must send a replacement. Compliance is mandatory.	An error classified as 'serious' is one that will stop the loading process. Should a 'serious' error occur during technical validation, the submission cannot and/or will not be uploaded into the review system. The entire submission will be rejected. A replacement submission (including the paper documents) will be requested by Swissmedic. The submission will be treated as not received . The validation clock will not be started.	The eCTD DTD is not present or cannot be read.
Severity B	Medium: The submission is accepted, but may request correction in subsequent submission/sequences. Compliance is preferred, but a degree of discretion should be applied.	Failure to comply will result in a warning. Swissmedic might ask for corrective actions to be carried out in future sequences. If the corrections do not suffice, Swissmedic may reject the submission. Swissmedic may also reject a submission that has some 'Medium' errors which, as a whole, make it difficult to review the submission. Swissmedic will request a replacement sequence. The validation clock will not be started.	If the submission contains a one page document that is not set to fast web access, it will not be in the interests of either Swissmedic or the applicant to make changes. However, if the submission has many large documents that are not set to fast web access, then the agency may decide to request changes.
Severity C	Low: The submission is accepted, but the errors are flagged to prevent their repetition in subsequent submissions/sequences. Compliance is preferred.	A failure to comply will result in an advice. Swissmedic might issue a report to the applicant for future considerations.	When the magnification setting 'Inherit Zoom' is not used in PDF-Files, Swissmedic prefers that the applicant does not repeat this omission in subsequent submissions. The applicant has not to send a replacement submission.

United States of America (FDA)

The severity levels outline the impact on the official receipt of your submissions, when FDA processes eCTD submissions.

Severity	Description
High	The error is a serious technical error which prevents the processing of the submission and will require resubmission. The submission is considered not received by FDA.
Medium	The error may impact the reviewability of the submission but cannot be determined without further inspection by the review staff. The submission might be considered received by FDA.
Low	The error is a technical error which may or may not impact the reviewability or the integrity of the sub-

7 Validation Criteria References - Medicinal

Severity	Description
	mission. The submission will likely be considered received by FDA.
Ignore	Error is a technical error which has no impact on the processing of the submission or the integrity of the submission. The submission will be considered received by FDA

European (EU) eCTD Validation Criteria

European (EU) eCTD Validation Criteria

The EU eCTD Validation Criteria Version 2.0 / 2.1 / 3.1 can be found at

<http://esubmission.emea.europa.eu/EU%20Validation%20Criteria%20v2.0%20-%20July%202008.xls>

(V2.0 / July 2008),

at

<http://esubmission.emea.europa.eu/doc/EU%20Validation%20Criteria%20v2.1%20-%20April%202009.pdf>

(V2.1 / April 2009),

and at

http://esubmission.emea.europa.eu/doc/newdocs/newesub%20docs/eCTD%20Validation%20Criteria_2011-02-11%20v3-1.xls

(V3.1 / February 2011)

See also: [Severity Prioritisation Keys](#)

Croatia (HR) NeeS Validation Criteria

The HR NeeS Validation Criteria Version 1.0 can be found at

HR-NeeS v1.0: <http://www.almp.hr/>

European (EU) NeeS Validation Criteria

The EU NeeS Validation Criteria Version 1.0 / 2.1 can be found at

EU-NeeS v1.0: <http://esubmission.emea.europa.eu/doc/EU%20NeeS%20validation%20Criteria%20v1.0.pdf>

and at

EU-NeeS v2.1:

http://esubmission.emea.europa.eu/doc/newdocs/newesub%20docs/NeeS%20Validation%20Criteria_2011-02-11%20v2-1.xls

Description of Type of Check

P / F - Pass / Fail

These are validation criteria that can either be passed or failed. eCTDs / NeeS that fail to meet one or more of these criteria will be returned to the applicant for fixing and resubmission as the same sequence number.

The pass / fail category has been introduced for the possibility of future automation of eCTD / NeeS validation.

BP - Best Practice

Any deviation from the criterion should always be reported by the validating tool.

It is considered good practice to ensure that these validation criteria are correct in the submitted eCTD / NeeS. The applicant should make every effort to address these areas before the eCTD is submitted to the agency. The applicant should be prepared to include justification for any *best practice* criteria not met in the submission cover letter/reviewer's guide.

eCTDs / NeeSs that fail to meet one or more of these criteria will still be accepted by the agency during technical validation and it is possible that agencies may not even check these criteria during technical validation.

7 Validation Criteria References - Medicinal

These criteria assess factors that affect the overall ease of use of the eCTD / NeeS. All tool vendors should include these criteria in their validation tools so that applicants can produce eCTDs / NeeSs that are easier to use. Users of the validation tool should also be able to check the eCTD / NeeS without checking for the *best practice* criteria.

8 Validation Criteria References - Veterinary

eNTA Validation Criteria

The VMD eNTA Validation Criteria can be found at

VMD-eNTA (immunological product) DTD 0.9:

http://www.ma.uropa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp

and at

VMD-eNTA (pharmaceutical product) DTD 0.9:

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp

European (EU) vNeeS Validation Criteria

The EU vNeeS Validation Criteria Version 1.0 can be found at

EU-NeeS v1.0: <http://esubmission.emea.europa.eu/...>

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10 Glossary

B

BP

Best Practice

P

P/F

Pass / Faile