Release Notes for the EU eCTD Validation Criteria version 6.0 and 6.1

The changes in the validation criteria relates mainly to the updated EU Module 1 eCTD Specification v.3.0 to come into force 1 July 2016 and being mandatory from 1 October 2016.
The changes in the validation criteria only affect the tab sheet "eCTD Validation Criteria" with the exemption of only additional recommendation for file naming rules in Module 1.2 for application forms and appendices and due to addressing ICH eCTD Q&A #81 for control strategy summary documents..

The published EU M1 eCTD specification version 3.0 has been subsequently updated to version 3.01 when errors were detected in the checksums. The eCTD validation criteria 6.0 are updated into version 6.1 to reflect the change.

Comparison of the new major version (6.0) with the current version (5.0)

Criterion Number in version 6.0	Criterion Number in version 5.0	Changes
Tab sheet "eCTD Validation Criteria":		
3.3 4.3 5.3 6.3	3.3 4.3 5.3 6.3	Updated md5 checksum value for EU M1 DTD in 'Comments', to reflect v.3.0
9.3	9.3	No changes in the text as such, however, please notice that the additional elements in the envelope (UUID, submission-unit) and related sequences being changed to mandatory in the new specification will be covered by the requirement of a well formed XML being submitted
9.7	-	The conformity with the recommended ISO Standard on UUID to be checked
9.8	-	The consistency of UUID across sequences to be checked (requires access to previous submitted sequences)
9.9		The identity of the UUIDs in all envelopes of a sequence is required.
11.9	11.9	Modified criterion to exclude some files with specific country attribute in Module 1 from this check. The attributes 'common', 'ema', or 'edqm' are not considered to be country specific attributes. At the same time exactly these files will be checked as well but only indicating mismatches as a warning (Criterion 11.BP1).
11.10	11.10	Modifying the existing criterion, leaves within node extension within the same CTD section will now be exempted For those leaves the existence of the file to be modified still need be checked but compliance is considered to be best practice, see 11.BP2.
11.BP1	-	See above, 11.9
11.BP2		Newly added criterion to address issues occurring with 11.10 cheks.
-	11.BP2 11.BP3	Deleted as the checks are not necessary on leaf attributes
14.1		The submission type 'cep' has been added as an excluded submission type from this case where a single envelope is expected.

Criterion Number in version 6.0	Criterion Number in version 5.0	Changes
14.5		This criterion has been added to define the additional case of a single envelope for submission type 'cep'. The term 'centralised' is recommended to be used in this case as well. This criterion has been added as a consequential change to the more precise definition of criterion 14.1
14.BP1 14.BP2	-	New criterion where the envelope is checked whether related sequence is either completed with the current sequence number (in case of submission unit type 'initial' or 'reformat') or with the sequence number the regulatory activity has been started with. If the element is always #REQUIRED, then a missing related sequence is P/F; applicants can no longer fail to supply a related sequence for a lifecycle submission and get only a BP error. It makes it easier for review tools to come up with a regulatory activity view. The logic now is 'everything with the same related sequence', rather than sequence = xxxx and find other submissions where related sequence also = xxxx
14.BP4 14.BP5 14.BP6	-	New criteria to assure consistency between the stated submission mode and the eCTD envelope of the Number element/ procedure tracking and the high-level numbers for grouped applications and worksharing applications. However, the criteria are set to be BP as not in all cases such numbers will be available in advance.
15.BP1	15.BP1	Changes so that only files larger than 200 MB will be indicated
15.BP4 15.BP5	-	New criterion to check whether the country code has been used consistently in the leaf, the folder and the file specifically in m1-0-cover, m1-2-form, m1-3-1-spc, m1-3-2-mockup, m1-3-3-specimen, m1-3-4-consultation, m1-3-5-approved, m1-responses and m1-additional-data, completing the criteria 11.9 and 11.BP1.
16.BP5	16.BP5	The comment is extended to more clearly state that for eAF PDF files the 'Fast Web View' cannot be set.
Line 33	12-form	Recommended usage of the variable part of the file name in this section has been added: 'cc-form-eaf-var.pdf' and 'cc-form-annex-var.pdf'
Line 160	32s4-contr-drug-sub	Refer to ICH eCTD Q&A 81, additional files are now allowed for control strategy summary document.
Line 205	32p5-contr-drug-prod	Refer to ICH eCTD Q&A 81, additional files are now allowed for control strategy summary document.