

Release Notes for the EU eCTD Validation Criteria version 6.0

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 Mandatory from 1 October 2016.

The changes in the validation criteria only affect the tab sheet “eCTD Validation Criteria”

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
<i>Tab sheet “eCTD Validation Criteria”:</i>		
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)
11.9	11.9	Modified criterion to exclude some files with specific country attribute in Module 1 from this check. At the same time exactly these files will be checked as well but only indicating mismatches as a warning (Criterion 11.BP1).
11.BP1	-	See above, 11.9
-	11.BP2 11.BP3	Deleted as the checks are not necessary on leaf attributes
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 electronic application form (eAF) 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. In addition, the test will indicate whether an eAF has been used. The check will fail in case an eAF has not been used although it is mandatory.

Criterion Number in version 6.0	Criterion Number in version 5.0	Changes
15.BP1	15.BP1	Changes so that only files larger than 500 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.