

Release Notes for the EU NeeS Validation Criteria version 4.0

Comparison of the new major version (4.0) with the current version (3.0)

Criterion Number in version 4.0	Criterion Number in version 3.0	Changes
<i>TabSheet "NeeS Validation Criteria":</i>		
There is no change to the validation criteria		
<i>TabSheet "File-Folder Structure & Names":</i>		
Row 32	Row 32	Changed "cc-cover-tracking- var .pdf" to "cc-tracking- var .pdf"
-	Row 191	Newly added the file name " excipients.pdf " as a response to ICH eCTD Q&A73 (options 1&2, file name entirely variable, multiple files allowed).
-	Row 242	Added optional folder for section 3.3 (for consistency with 5.4)
-	Row 345	Added optional folder for section 4.3 (for consistency with 5.4)
-	Row 413	Added optional folder for section 5.3.6. (to align with "Files and Folders Q&A")
-	Row 419	Added optional folder for section 5.4. (to align with "Files and Folders Q&A")
<i>TabSheet "Files and Folders Q&A":</i>		
Row 10		Removed specific reference to EU M1, v1.4 and ICH v.3.2.2
Row 14		Added that for section 3.3 additional folders are optional as well (for consistency with 4.3 and 5.4)
Row 18		Clarified that for m5.2 additional folders are not allowed and that for m5.3.6 and m5.4 additional folders are optional.
<i>TabSheet "Picklist Values":</i>		
Country		Changed "emea" to "ema" and "EMEA" to "EMA"
Country		Added "hr" and "Croatia"
Language		Added "hr" and "Croatian"