EU NeeS Validation Criteria
v1.0 August 2009

ID	CATEGORY	VALIDATION CRITERION	PRIORITY	SOURCE	NOTES
NeeS_0001	Files/folders	Table of Contents (TOC): There is a general TOC document situated within the NeeS folder structure, named 'ctd-toc.pdf'.	A	TIGes	No location specified (i.e. root folder) as NeeS guidance is not consistent witn NTA as regards placement of main TOC - either location should therefore be acceptable.
NeeS_0002	Files/folders	Table of Contents (TOC): 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 if appropriate.	A	TIGes	Module-specific TOCs are not mandatory but should be provided as necessary - (i.e. not required for modules with little or no content, required if a module contains sufficient content to necessitate a navigation aid).Naming convention for module-specific TOCs removed as was not consistent with NTA.
NeeS_0003	Files/folders	If both ctd-toc.pdf and module-specific toc documents are used, then: ● For each existing module in the submission, a dedicated module TOC is provided ● The ctd-toc.pdf has hyperlinks to all existing module TOCs ● The ctd-toc.pdf does not have any other hyperlinks ● Each module TOC does not have hyperlinks to content documents in other modules. ● Each module TOC must be located in the respective m* folder.	A	TIGes	
NeeS_0004	Files/folders	File/Directory Structure: The eCTD file/directory structure is followed, (with the addition of TOC(s) as appropriate).	A	TIGes	The eCTD file/directory structure does not include TOC documents, as navigation in the eCTD is provided by the XML backbone, (which is not present in a NeeS hence the need for a additional TOC(s)).

NeeS_0005	Files/folders	File/Directory Structure M1: The EU M1 folder and file naming convention is observed for 100% of M1 folders/files. The file naming convention consists of a country code, a fixed mandatory part, and an optional variable part (i.e. (i.e. CC-FIXED-*VAR.EXT*): - Lower case characters only are used - Accepted file extensions are used - No illegal characters are used - The variable part, if used, does not include hyphens.	A	TIGes	
NeeS_0006	Files/folders	File/Directory Structure M2 - M5: The ICH highly-recommended naming convention (detailed in ICH eCTD specification v3.2.2, Appendix 4) is observed for at least: 95% of folder names, and 85% of file names.	A	TIGes	Percentages added as 100% compliance for all modules is not required by all MS. EU M1 and M2 - M5 filenaming criteria combined. A lower percentage of adherence to the file/folder naming convention is accepted for modules 2 - 5, as a finer granularity could be used, according to the granularity rules, with additional folders/files inserted beyond the specified CTD/eCTD structure. These additional folders and files are allowed: (i) Within the fixed eCTD folder structure (ii) With the recommended filenaming convention (i.e. a variable part can be added to fixed filenames) The folder/file names can only be checked in terms of consistency with the naming convention in terms of allowed characters, lower-case characters, and accepted file extensions.
NeeS_0007	Files/folders	Folder/File Path Length: Total folder/file path does not exceed 180 characters	A	ICH Specification/ EU Q&A 13	Reduced from 230 characters - EU regional decision.
NeeS_0008	File Format	File Format: The file format is one of the following: PDF, JPEG, PNG, SVG, GIF, SAS*, XML (*SAS files are accepted by some MS only, by arrangement. The validation tool should report the existence of a SAS file, and business validation must then be performed to ascertain whether or not the file was requested by the receiving agency.)	A	TIGes	Removed RTF/DOC as Word files must be outside the structure consistent with eCTD. Previous criterion *'If DOC or RTF file formats exist, the corresponding PDF file should also exist, with the same filename but with extension .pdf instead of .doc or .rtf.'* removed, as tools cannot check for the existence of files located outside the NeeS structure.
NeeS_0009	Security	Security Settings: There is no password protection, encryption or security setting preventing the opening of any file	A	ICH Q&A 36/TIGes	This is for all modules.

NeeS_0010	Security	Security Settings: There is no security setting on any file in the submission, (does not apply to files located in 4.3 and 5.4)	A	TIGes	Some references taken from journals and other publications may not be able to be stripped of all security settings (e.g. preventing the copying of text from the article) without violating copyright rules. These files must then be exempt from a validation criterion regarding security settings. There should be no security setting on any file in Module 2, however. The technical validation should report all files with any type of protection set, and it is up to the agency to check on a case by case basis whether the protection is acceptable or not.
NeeS_0011	File Format	File Format: PDF version is v1.4 (apart from MHRA application form and EMEA paediatric application form, where PDF version must be v1.6)	A	ICH Q&A 36/TIGes	There are some national exceptions to the PDF v1.4 rule - these must be specified, and business validation applied if the technical validation reports PDF file in versions other than v1.4.
NeeS_0012	Hyperlinks	PDF Quality: 100% of hyperlinks in the TOC(s) are functional, and at least 85% of hyperlinks and bookmarks in other files in the submission are functional. (Absolute/rooted hyperlinks and bookmarks are considered as non-functional.)	A	ICH Q&A 36/TIGes	Added following review - absolute hyperlinks and bookmarks included in this criterion as they are considered broken links and should be counted as such.

Prioritisation Key:	SUMMARY
A: Compliance is required. Failure to comply results in an entry in the validation report, and no load of NeeS into any review tool. The receiving agency should assess any entries in the report, and a replacement submission should be requested if necessary.	A = reject submission (applicant must submit a replacement)