

Technical validation checklist¹ for veterinary electronic submission²

Validation checklist for VNeS submissions, approved by the veterinary subgroup of the Telematics Implementation Group for e-Submission (TIGes vet). Any deviations from the requirements of the e-submission guideline, should be discussed with the NCA e.g. changes pending finalisation of the revision of the NtA Vol. 6B.

ID	Validation Criterion	Comments on Validation Check
VNeS_001	<u>Security settings</u> No type of security on the media or individual folders	It is not permitted to apply password protection to either the media carrying the files or any folder. Hard media - If the hard media cannot be read then validation failed. Folders - all folders must be able to open. If not then validation failed.
VNeS_002	<u>Security settings</u> No type of security on individual files	Individual files should not be password protected so as to prevent access.
VNeS_003	<u>Virus free</u>	Ensure that suitable antivirus software is installed that automatically recognises infected files once they are accessed or copied. To avoid false positive results as potential cause of a rejection of a submission a confirmation of the finding may need to be requested from the antivirus software provider.
VNeS_004	<u>Folder structure:</u> Follows folder structure defined in guideline. ³	Any folder-structured submission that follows the full or parts of the NtA dossier structure - Initial MAAs or Extension Applications - ASMF - Variations For these submissions, additional folders which are <u>not specified</u> in the guidance result in validation failure. Issues not resulting in validation failure: - The absence of a 'root' folder for single file submissions. - Missing level 1, 2 and 3 folders, as empty / not relevant folders should be deleted by the applicant. If during scientific validation it is noticed that folders are missing it will be dealt with at this stage. - Use of different folder structures for PSUR submissions, renewal applications, dossiers for referral procedures and other submissions.

¹ Note that this is a maximum list of validation criteria

² See Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product
<http://www.ema.europa.eu/tiges/vetesub.htm>

ID	Validation Criterion	Comments on Validation Check
VNeeS_005	Folder structure: Follows names defined in guideline. ⁴	If (part of) the NtA structure applies (VNeeS_004), naming convention should be observed for all folder names.
VNeeS_006	Folder Path Length: Total length does not exceed 180 characters.	Path starting from the "root" folder and including all folder names, file name and file name extension (e.g. "root-mydrug\p1\1a-admin-info\applicationform.pdf").
VNeeS_007	General Table of Contents (GTOC): A General TOC file is situated within the root folder of the VNeeS structure.	General table of contents (GTOC) is present in the root directory (LEVEL 1). In case of very small submissions consisting of only a single PDF file, no separate GTOC needs to be created.
VNeeS_008	Table of Contents (TOC): A TOC file is situated within the folder for each part of the dossier.	A TOC should be present for submission spanning multiple media components. In other cases it is acceptable to only include a GTOC referring directly to all content documents. If a TOC is present it is located in the top level folder of each dossier part (LEVEL 2). In case of immunological products, the contents of Part 3E 'Assessment for products containing or consisting of GMOs' may be covered by a separate TOC for this subpart (LEVEL 3).
VNeeS_009	Table of Contents: Naming convention	Naming convention for general table of contents (GTOC): gtoc.pdf Naming convention for TOC in the top level folder of each part: p1-toc.pdf, p2-toc.pdf, p3-toc.pdf and p4-toc.pdf TOC in Part3E of immunological products: p3e-toc.pdf Only files following this naming convention can be checked by the VNeeS checker tool.
VNeeS_010	Table of Contents: The GTOC should be a complete index to the whole dossier either referring directly to content documents or via the part-specific TOCs.	The GTOC should be a complete index of the whole dossier, either directly to individual files or to the part-specific TOCs, with the exception of files located in the folder "add info" which need not to be included.

³ See: <http://www.ema.europa.eu/tiges/vetesub.htm>, Table 1 for pharmaceuticals, Table 2 for immunologicals and Table 3 for MRL applications.

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ID	Validation Criterion	Comments on Validation Check
VNeeS_011	Table of Contents: GTOC and TOC include navigation features for efficient electronic navigation	The GTOC should use hyperlinks directly to documents or to part-specific TOCs. The GTOC should be hyperlinked to any part-specific TOCs. TOCs of each part provide hyperlinks to all indexed documents. ⁵
VNeeS_012	Table of Contents: Hyperlinks in the GTOC and TOC are functional	Hyperlinks must be relative, and functional. In the GTOC/TOC this should be observed for all hyperlinks. Hyperlinks should only be made to documents inside the same VNeeS submission and not to external sources.
VNeeS_013	File format: <u>File format is PDF</u>	PDF format for all files (with exception of any editable files in the folder "add-info" which are out of scope of technical validation).
VNeeS_014	File format: No PDF documents should be in version PDF 1.3 or earlier	
VNeeS_015	File names: No prohibited characters used	The file name should not contain any 'special' characters; in particular the following characters are known to give problems and are not allowed: ' ' (SPACE, use Hyphen '-' instead); '.' (FULL STOP, except to separate files extension from rest of the file name); ':' (COLON); '/' or '\' (SLASH, BACKSLASH); '*' (ASTERISK); '?' (QUESTION MARK); '"' ''' (QUOTATION MARK), '<' (LESS THAN), '>' (GREATER THAN), ' ' (PIPE), '&' (AMPERSAND) Use of <u>upper case characters</u> would not lead to invalidation.
VNeeS_016	File names: Files use proper extension	File names should have the proper extension (e.g.".pdf")

⁵ Alternative methods (such as the use of bookmarks within one document or hyperlinks between specific documents, e.g. from reports to annexes) should be encouraged, as they assure equivalent efficiency of navigation, but these may not be supported by the VNeeS checker.