EU veterinary e-submission - Change Requests										
CR#	**Affected Document**	**Document section**	**Category**	**Description of CR**	**Justification of Requestor**	**CCG / TIGes vet Recommendation**	**Status**	**CCG decision on**	**TIGes vet decision on**	**Implemented on**
CR#-VNeeS-0001	VNeeS GL - Rev.1 (corr Feb 2010)	**1. Introduction**	Editorial	reads "... EMEA and industry. All National Competent Authorities should adopt this guidance as the basis for their acceptance of electronic submissions for marketing authorisations from applicants" change to "… EMA and industry. All National Competent Authorities and EMA should adopt this guidance as the basis for their acceptance of electronic submissions for marketing authorisations from applicants"	Correction of acronym. Guidance is valid for NCAs and the agency.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0002	VNeeS GL - Rev.1 (corr Feb 2010)	**1. Introduction**	Editorial	Include "**2. Background**" into "**1. Introduction**." **Move** paragraph "Answers to questions, variations, line extension, and renewal applications can be submitted in electronic format, i.e. as PDF files with no additional paper copies. The same basic principles apply except dossier structure, which may not be relevant for all these procedures." **to a new section "Scope"**	Clearer structure through introduction of chapter on "scope".	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0003	VNeeS GL - Rev.1 (corr Feb 2010)	**New "2. Scope"**	Content	Amend "**Scope**" section as follows: "This guidance covers all types of initial applications for marketing authorisation made in the Centralised, Mutual Recognition, Decentralised and National procedures." to "This guidance covers all types of initial applications for marketing authorisation made in the Centralised, Mutual Recognition, Decentralised and National procedures including updates provided during the assessment phase (validation updates and responses to questions)."	Clarification of guidance text. More logical as "responses" are not a "procedure" like variations or extensions. Further details as regards applicability of folder structure are discussed in section 8.	Accept change.	Accepted	NA	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0004	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Add sentence: "Several VNeeS submissions for the same medicinal product may be provided on a single media component. Grouped variations or variations submitted in a worksharing procedure should preferably be submitted on the same media component."	Further clarification especially for variations.	Accept change.	Accepted	NA	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0005	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Current text reads: "Submission of product information (SPC, label, leaflet) in an editable format as an addition to a read-only file within the e-submission is encouraged." change to: "Product information (SPC, label, leaflet) should be submitted in addition to a read-only file in an editable format."	Adaptation to already existing requirements.	Accept change. Refer also to **CR#-VNeeS-0011,** text deleted with **CR#-VNeeS-0044**	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0006	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Add clarification whether GTOC / TOC needs to be present on each optical medium if the submissions is spanning more than one CD/DVD.	See recommendation	The general table of contents should be present only on the first hard medium. On other media navigation is possible via part-specific TOCs. Amend section for clarification.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0007	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Editorial	Current text reads: "(to enable reading the beginning of a file while the rest of the file is still being accessed)" change to "(to enable viewing of any page whether or not the entire file has finished downloading)."	Technically more precise.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0008	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Content	Add sentence: "Embedding of common standard fonts should be verified, after the file has been optimised for fast web view."	Standard fonts" might not be embedded by software creating PDF renditions that has limitations similar to earlier versions of Acrobat. In this case common standard fonts are not embedded under the assumption that such fonts will always be available to the PDF viewer.	Accept change. Text deleted with **CR#-VNeeS-0092** as fast web view no longer requested.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011

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CR#-VNeeS-0009	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(b) Electronic source documents**	Content	Current text reads: "When embedding fonts, all characters for the font should be embedded, not just a subset of the fonts being used in the document. " Change to: "When setting options for font embedding, choose options that indicate that (1) all fonts should be embedded and (2) fonts should not be subsetted."	The part in the guidelines about not subsetting fonts can be confusing. That is the option that should be set -- "Embed all fonts" / DO NOT select "Subset embedded fonts..." However, it is not correct to state it in this way, "When embedding fonts, all characters for the font should be embedded, not just a subset of the fonts being used in the document." With TrueType and OpenType fonts, this simply does not happen, regardless of the options selected. TrueType and OpenType fonts may contain as many as 32,768 characters compared to PostScript Type 1 fonts' 256 characters. So, Acrobat automatically subsets TT and OT fonts into subsets of characters that are actually used, subsets that contain a maximum of 256 characters per subset.	Accept change. Text deleted as requirements to embed fonts were reduced acc.**CR#-VNeeS-0093**	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0010	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(b) Electronic source documents**	Editorial	Current text reads: "Embedding fonts requires additional computer storage space." Change to: "Embedding fonts will increase the size of the PDF file."	Clearer wording.	Accept change. Text deleted as requirements to embed fonts were reduced acc.CR#-VNeeS-0093	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0011	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(c) Documents to be edited**	Content	Current text: "In the case that product information (such as SPC, labels and leaflet) are intended for frequent exchange, editable formats like Microsoft WORD might be supplied to facilitate transfer of documents with the ability to track changes." can be deleted.	Text can be deleted as same information is already available elsewhere in the guidance.	Accept change	Accepted	NA	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0012	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(c) Documents to be edited**	Editorial	Current text reads: "It is preferable for these documents to be included in a separate folder at the level of the root folder" Change to: "It is preferable for these documents to be included in a separate folder called "additional-information" located in the top level folder ("root folder") of each VNeeS submission "	Include folder name "additional-information" for clarification. Clarify concept of root folder (physical top level folder of each single submission)	Accept change. Text deleted with **CR#-VNeeS-0034**	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0013	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	Add following passage after the first paragraph: "The name of the top level folder ("root folder") of each VNeeS folder structure should allow appropriate identification of the submission, especially in cases where more than one VNeeS structure is located on a single hard medium. For reasons of automated identification and technical validation of e-submissions with tools like the VNeeS checker each root folder name must start with the letters "root", followed by a specific identification of the submission which can be defined by the applicant. A hyphen ("-" character) should be used as separator. It is recommended to use as specific identification • the product (invented) name and/or • the procedure number (if known), especially if more than one procedure is included on the same CD, and /or • the submission date or day of procedure, to allow tracking of updates during the procedure For example root-mydrug root-mydrug-dk-v-0123-001 root-ema-v-c-0123 root-dk-v-0123-002-1a-003 root-mydrug-ema-v-c-0123-2oct11"	Further clarification and guidance on use of "root" folder of each VNeeS submission. Define naming conventions for root folder names to allow unambiguous identification of submissions. Standardize naming to ensure that a validation tool can recognize roots of submission structures.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0014	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Current text reads: "The folder structure includes a folder in the root folder for documents such as editable versions of the SPC and literature and documents which need to be provided at a local level (e.g. by a local affiliate of a centrally organised regulatory affairs department). Including additional folders within the structure of the e-submission in not permitted. " Change to: "The folder structure includes a folder called "additional-information" located in the root folder for working documents such as editable versions of the SPC, labels and package leaflet and documents which need to be provided at a local level (e.g. by a local affiliate of a centrally organised regulatory affairs department). Including additional folders within the structure of the e-submission is not permitted. "	Include folder name "additional-information" for clarification. Change "literature" to "product literature" for clarification. Correction of typographical error in last sentence ("in"). Clarify scope for "working documents" (i.e. Word renditions of PL or other files, present as PDF files in the NtA folder structure.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0015	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Current text reads: "The electronic submission must include a well-structured (preferably PDF format and hyperlinked) general table of contents (GTOC) in the root directory as well as a TOC in each folder for each part of the dossier. The GTOC should be a complete index to the whole dossier while the TOC for each part of the dossier should be a complete index for that part of the dossier." Change to: "The electronic submission must include a well-structured general table of contents (GTOC) in the root directory as well as a TOC in the top level folder of each part of the dossier. The GTOC should be a complete index to the whole dossier, while the TOC for each part of the dossier should be a complete index for that part of the dossier. All documents in the submission should be referenced in a TOC using a hyperlink. The general TOC should always be hyperlinked to any part-specific TOCs. Hyperlinks to the documents in each dossier part should be present either in the GTOC or the part-specific TOCs. The GTOC should be named "gtoc.pdf". The files containing the part-specific TOCs should be named "p1-toc.pdf", "p2-toc.pdf", "p3-toc.pdf" and "p4-toc.pdf"."	Revise and further clarify guidance on the use of Table of contents: - Delete "preferably PDF format and hyperlinked" as PDF format is a requirements and all documents in the submission should be referenced in a TOC using a hyperlink. Only efficiently navigable submissions like dossiers with hyperlinked TOCs ensure acceptance of assessors. - Clarify location of TOCs (in the top level folder of each part of the dossier) - Define standardized names for TOCs / GTOC that ensure that a validation tool can recognize and check TOCs. Currently not yet a mandatory validation criterion.	Accept change. Further amended by **CR#-VNeeS-0077**	Accepted	NA	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0016	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Amend text as follows: In the case of small dossiers (especially post-authorisation submissions) it is acceptable to only include a GTOC referring directly to the content documents. GTOC may either refer directly to content documents or via the part-specific TOCs.	For small submissions it is acceptable to have a GTOC only The general TOC should always be hyperlinked to any part-specific TOCs. Hyperlinks to the documents in each dossier part should be present either in the GTOC or the part-specific TOCs (if present).	Accept change. Further amended by **CR#-VNeeS-0077**	Accepted	16/ Jul/ 2010	23/ Sep/ 2010	1/ Sep/ 2011
CR#-VNeeS-0017	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Include guidance that "excessively long file names should be avoided."	Based on experience gained during initial phase additional guidance that discourages the use of excessively long file names should be added.	Accept change.	Accepted	16/ Jul/ 2010	23/ Sep/ 2010	1/ Sep/ 2011
CR#-VNeeS-0018	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Editorial	Correct to file name example to "part 2e3 identification and assay of excipient components.pdf"	Correction of typographical error.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0019	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Delete following requirement "In the case that filenames use codes to identify the document an index must be supplied in each directory of the folder structure."	Requirement for index in each directory deleted. Should rather be covered by a hyperlinked TOC.	Accept change.	Accepted	16/ Jul/ 2010	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0020	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Include clarification on the use of lower and upper case characters: "Files should have the proper extension (e.g. PDF), and file names should only b made up of characters 'a ' to 'z' (preferably lower case only) and '0' to '9' plus '-	Clarification on the use of upper and lower case characters. Preference for lower case characters but "hard" requirement for lower case seen as being too inflexible.	Accept change.	Accepted	16/ Jul/ 2010	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0021	VNeeS GL - Rev.1 (corr Feb 2010)	**10. Technical validation**	Editorial	Revise wording to "exceptions are: editable versions of the SPC and product literature;"	Change "literature" to "product literature" for clarification.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0022	VNeeS GL - Rev.1 (corr Feb 2010)	**11. Glossary**	Editorial	Change EMEA acronym to EMA	Editorial correction.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011

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CR#-VNeeS-0023	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Editorial	Include in first line reference to further guidance on root folder.	Delete "root" in table 1 and give further guidance and examples for root folder names in the text of the guideline.	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0024	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Content	Correct the following folder names: Pharmaceuticals: 2c1-active substances 2d-control–tests-at intermediate-process-stages 2e2-identification-and-assay-of-active-substance(s) 2f1-active-substances(s) Immunologicals: 2e2-identification-of-active-substance(s) to Pharmaceuticals: 2c1-active-substances 2d-control–tests-at-intermediate-process-stages 2e2-identification-and-assay-of-active-substances 2f1-active-substances Immunologicals: 2e2-identification-of-active-substances	Correction of folders names to be in compliance with the naming conventions (deletion of blanks or brackets, replacement of long hyphen with standard hyphen)	Accept change.	Accepted	NA	24/ Jun/ 2010	1/ Sep/ 2011
CR#-VNeeS-0025	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Editorial	Insert text from paragraph "Product information (SPC, label, leaflet) should be submitted in addition to a read-only file in an editable format. The location of these documents within the e submission is set out in section 6.(c). It is also acceptable to submit these documents via e-mail." from section **3. Media used for submission and its identification** Reword paragraph as follows "Product information (SPC, label, leaflet) should be submitted in addition to a PDF file in an editable format like Microsoft Word, normally on the same CD/DVD."	Paragraph does not address media but file format and thus should appear in section 5. The wording "PDF file" appears to be clearer than "read-only file". Clarification of "editable format" ("like MS Word"). Usual procedure will be to submit editable files on the same CD/DVD. Submission via email and location in the VNeeS structure are sufficiently addressed elsewhere.	Accept change. Note: paragraph was deleted in section 3 by **CR#-VNeeS-0044**	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0026	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Revise "The hierarchical structure of folders within a root folder gives three levels of granularity" to "The hierarchical structure of folders gives up to three levels of granularity"	Clarification that "root folder" is not counted and that levels may be less than three.	Accept change.	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0027	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Text reading: "As discussed in the Introduction to this guideline this folder structure should be used to prepare a dossier in a basic electronic format (a VNeeS. The folder structure also forms the basis for preparation of an electronic submission using a bespoke software package (eNTA). An agreed technical specification for the eNTA will be developed at a later date.)" should be deleted.	Correction as referred text is now contained in the same section. Same text on eNtA already in introduction, thus no need to repeat.	Accept change. Additionally eNtA may rather be part of a roadmap document.	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0028	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Editorial	Include explanation on the use of standardized file names for table of contents: "File naming conventions for the table of contents should be followed to allow validation tools to easily identify and check GTOC and TOCs, including the functionality of inserted hyperlinks."	Clarifies the restrictions to specific file names and the benefit received from that.	Accept change. Further amended by **CR#-VNeeS-0076**	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011

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CR#-VNeeS-0029	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Revise text as follows: "The name of the files should be in English. They should be descriptive and unambiguous especially if more than one PDF is included in a particular section. Any information that may help identify the contents of the file is encouraged to be included in the file name. Preferably the file name should include the part of the dossier where the document is located. In these cases file names should be based on the naming convention for dossier parts used in the folder structure as defined in Tables 1 and 2. However, excessively long file names should be avoided. The length of a path including file name, and extension should not exceed 230 characters. Examples of valid file names are: administrative-information.pdf p1c2-critical-summary-safety.pdf part-2e3-identification-and-assay-of-excipient-components.pdf p3a2-report-no-12345.pdf part-3a6-era.pdf If one document has to be split over more than one PDF because it is larger than 100 MB then the files should be numbered as "1ofx", "2ofx" for example: carcinogenicity-rat-1of4.pdf"	Inclusion of dossier section and subsection in file name is described as option to ease identification of the file. File names always need to be descriptive and unambiguous (no random names). Information on the dossier part is already contained in the folder path and it is expected that navigation is usually via TOCs not via folders. This helps to reduce length of file names, if necessary. The naming convention was not mandatory (validation criterion) anyhow before. Where more than one file is being present in a folder any sequential numbering (sequential file numbers, reference numbers) in the file name is discouraged as one insertion would cause renumbering of a subsequent files and change of hyperlinks throughout the dossier, a situation easily leading to errors. The example given for this case should be deleted, as file names should be anyhow descriptive and unambiguous. Additional, editorial changes (more logical order, replacement of long hyphens by standard hyphen).	Accept change. Maximum path length changed to 180 characters by **CR#-VNeeS-0071**, shorter examples introduced by **CR#-VNeeS-0105**	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0030	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Editorial	Delete sentence "Files should have the proper extension (e.g. PDF), and file names should not contain spaces or other characters which are known to give problems ."	Sentence may be deleted as it is just repeating the following requirements in the following sentence as regards file extension and allowed characters.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0031	VNeeS GL - Rev.1 (corr Feb 2010)	**9. Security**	Editorial	Include sentence "The feasibility of a secure electronic transfer of regulatory submissions, e.g. via a common portal, is currently evaluated."	As concerns regarding the secure transfer of optical media persist, it is proposed to mention the on-going activities by EMA and HMA.	Accept change but suggest "currently under evaluation"	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0032	VNeeS GL - Rev.1 (corr Feb 2010)	**New "6. Requirements for creating files for electronic submission"**	Editorial	**First level heading for chapter 6 is missing. Proposal "6. Requirements for creating files for electronic submission"**	Editorial amendment, more logical structure of the document.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0033	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Editorial	Change reference for location of editable documents to from section 6(c) to 8(a)	Appears to be more logical as section 6 covers aspects during creation of documents and section 8 covers the structure of the submission.	Accept change. However this text is deleted with **CR#-VNeeS-0025**	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0034	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(c) Documents to be edited**	Content	Following section should not appear under 6(c) as it is rather discussing structure than file specificities and can be deleted as either addressed elsewhere or no longer applicable: It is preferable for these documents to be included in a separate folder called "additional-information" located in the top level folder ("root folder") of each VNeeS submission (see section 8.(a)). However, it is also acceptable to include these in the folder for Part IB of the dossier. In the case of submissions of the same document in multiple formats (e.g. PDF and WORD at the same time), it should be clear which format is intended for which purpose. This clarification could be achieved by including a descriptor of the file types in the Table of Contents (TOC) for that part of the dossier."	More logical order of requirements. Avoid duplication as it is currently mentioned at two places. It should not be acceptable to include editable versions of the SPC and product literature in the folder for Part IB. Better to have one clear way of structure. Additionally, Word copies may not needed to be archived so should be separated from the NtA structure. The requirement to include a descriptor of the file types in the Table of Contents (TOC) to make clear which format is intended for which purpose can be deleted as other formats should ONLY go into additional information folder outside the core NtA folder structure.	Accept change. Complete section 6.(c) thus can be deleted.	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0035	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Editorial	Insert standardized files into folder structure	Very convenient way to show structure conventions to user.	Accept change. Include term "standard files" into title of table.	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0036	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Content	Delete substructure of Part 2A	Unnecessary low degree of modularity. Usually applicants will roll-up the substructure of this section as only a few pages are submitted to cover this requirement and often a single-page document covers more up to three of these subsections. Only Part 2a4 is composed of several pages. Thus all can be easily covered in one short document under 2a.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011

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CR#-VNeeS-0037	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Content	Delete substructure of Part 2E	Mandated degree of modularity by folder structure would usually lead applicants to roll-up the substructure of this section as established document modularity is different. Usually tests are rather described in one file of several pages summarising all the tests done and are not separated by e.g. general characteristics vs. assay. Further files would describe details of the tests, Thus the current subdivision is not necessary in practice (and is often not used by applicants)	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0038	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 2**	Content	Delete substructure of Part 3B	Keep 3b but delete the sub-sections which are not suitable for vaccines dossiers. Safety studies almost always cover several subsections to limit the number of animals used. In addition, vaccines can be inactivated (no need for 3b2 and 3b6), for young animals (no need for 3b4), for pets (no need for 3b8), etc… almost all applications will have to justify the absence of one or more subsections, although the relevant contents required in subsections will be covered in the part 3b. These subsections for the e-dossier are thus useless and confusing. For the part 4, the 4b section is not divided in onset of immunity, duration of immunity, etc. therefore the same rules should apply for 3b.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0039	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 2**	Content	Include option for a separate TOC for part3e and a subfolder for documentation. Name of folder for part 3e could be substantially shortened to "gmo" in order to the overall path length still short.	For Part 3e, a subsection for annexes could be usefully added because this part is often composed of a core technical document + specific TOC + many (up to 100) files: studies reports, bibliography, etc. Moreover, it is sent separately to the "GMO" agencies Those will not have the full content of the dossier with the hyperlinks from GTOC. They have to open the section 3e and it may be difficult for them to find their way to the 3e-toc in such a jungle of files. Here a subsection is fully relevant for the annexes (compared to the 2a, or 3b).	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0040	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1**	Content	Delete folder for 4b1	As the concept foresees only one subfolder there appears to be no need for this additional level of granularity.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0041	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Clarify instructions for labelling of optical media as follows: - procedure number (if known in advance by the applicant), - name of company, - target species (if necessary to avoid confusion of products), - indication as to whether multiple media components are used (and if so, these should be numbered, e.g. 1/2, 2/2).	Only minor change for clarification of existing requirements: - Application number may not be known in advance. - It was unclear what "if applicable" means for inclusion of target species. It appears to be necessary only if otherwise confusion with other products may be caused that are used for different species. - Clarification that name of the company being the applicant/MAH is sufficient. - Include example of numbering	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0042	VNeeS GL - Rev.1 (corr Feb 2010)	**NEW "2. Scope"**	Content	Text reads "The same basic principles apply except dossier structure, which may not be relevant for all these procedures." Change to "It applies also to active substance master files (ASMF), MRL applications, and post-authorisation submissions (i.e. variations and extensions, PSUR submissions, renewal applications and dossiers for referral procedures)."	Clearly state that these procedures are in scope. Add active substance master files, MRL applications and referral procedures to scope of guidance. The term "basic principles" is considered to be too vague, details should only be considered in the following sections of the guidance.	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0043	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Amend text as follows (underlined): "If accepted by the competent authority Eudralink may be used for email communication with the authorities,for submission of smaller applications and responses and for the exchange of editable versions of the product information (SPC, label, leaflet).."	We should also be able to accept variations renewals and responses by this route. Text just makes clear. Applicant should however confirm acceptance by regulatory agency.	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0044	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Editorial	Delete following paragraph: "Product information (SPC, label, leaflet) should be submitted in addition to a read-only file in an editable format. The location of these documents within the e submission is set out in section 8.(a). It is also acceptable to submit these editable documents via e-mail."	Paragraph is not needed here as it is repeated in section 5 which may be a more logical place for it as this section is talking about the submission as a whole.	Accept change. Submission via email is already addressed elsewhere in this section (see **CR#-VNeeS-0043**).	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011

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CR#-VNeeS-0045	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	**Adaptation of folder structure:** **Amend c**urrent text as follows (underlined text) "Including additional folders within the structure of the e-submission is not permitted with the exception of the folder "additional-information" where subfolders could be constructed. However, the total number of folder levels of the submission should never exceed three levels."	The granularity of the submission is limited to three levels which means that subfolders of "additional information" could be constructed.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0046	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	**Adaptation of folder structure:** Current text reads "However, if there are empty folders in the submission these may be deleted as the folder structure should reflect only what actually is submitted. " Revise to "If there are empty folders in the submission these should be deleted as the folder structure should reflect only what actually is submitted. "	Editorial change to be consistent as regards the requirement that the submission "should" reflect only what is actually submitted.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0047	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Add the following sentence: "In case of very small submissions consisting of only a single PDF file, no separate GTOC or TOC files need to be created."	The previous text appears to prevent just providing a single PDF as a submission. Some applications (variations) are so small that a GTOC is not necessary, thus we could amend text so a single PDF is allowed.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0048	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Editorial	Delete following sentences: "The lowest level of granularity of the dossier structure shown in Table 1 and Table 2 should include at least one PDF file. However, it is recognised that for some types of application no information is required in some parts of the dossier and in this situation the advice in section 8.(a) above should be followed."	Two sentences not necessary as already addressed above in section 8(a).	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0049	VNeeS GL - Rev.1 (corr Feb 2010)	**10. Technical validation**	Content	Delete limit for folder name convention.	If applicants can shorten folder names then it becomes subjective as to whether a shortened name follows 'naming convention'.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0050	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	Insert subtitles to structure 8(a) (Root folder, additional information, adaptation of folder structure, folder names),	Better structure of text.	Accept change	Accepted	NA (written consultation)	23/ Sep/ 2009	1/ Sep/ 2011
CR#-VNeeS-0051	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Editorial	Move text "As a general rule, exchange of electronic files can be made on finalised optical media such as CD or DVD." to the beginning of the section.	Appears more logical to start with this sentence stating the main requirement for media instead of labelling media.	Accept change	Accepted	3/ Nov/ 2010	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0052	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Amend requirement "All documents in the submission should be referenced in a TOC using a hyperlink" as follows "Hypertext links in GTOC or TOCs are essential for efficient navigation through any larger submission. Therefore all documents in the submission should be referenced in a GTOC or TOC using a hyperlink. … The diagrams below illustrate the recommended use of features for navigation. Alternative methods (like use of bookmarks in the (G)TOCs or hyperlinks between specific documents, e.g. from reports to annexes) can be used if they assure equivalent efficiency of navigation, but these features may not be supported by the VNeeS checker."	Request that appropriate navigation features are used in the GTOC/TOCs as this is an essential feature during assessment. Hyperlinking may be via either GTOC or TOC, as applicable.	Accepted	Accepted	NA	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0053	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Add the following paragraph: Bookmarks and hyperlinks (outside the GTOC or TOC) Navigation is significantly enhanced by appropriate use of bookmarks and hyperlinks in PDF files. The inclusion of bookmarks / hyperlinks into PDF files aids in the navigation around the document content. Hyperlinks in key documents of the submission (e.g. detailed and critical summaries or written summaries of the applicant) to related files like references, or appendices are helpful and greatly improve navigation efficiency through a VNeeS submission.	Does not add new requirement, but should encourage applicants to an intelligent use of bookmarks and hyperlinks to easy navigation during review.	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0054	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Include on hard media label: "• Format and version of specification (currently: VNeeS 1.1)"	For staff doing technical validation it should be clear what is the basic format. After a revision of the VNeeS guidance also the VNeeS version is important to know as this affects how the submission has to be validated.	Appears not to be necessary during an implementation phase also taking into account limited space on media. Applicant are requested to observe implementation timelines of a revised VNeeS guidance and agencies to be flexible where needed.	Rejected	3/ Nov/ 2010	24/ Nov/ 2010	NA
CR#-VNeeS-0055	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Revise current wording how to label media "Appropriate labels/identification should be attached to the hard medium on whic the e submission is presented. " to "Each hard medium on which the e submission is presented. ..... This informatio should preferably be printed directly onto the hard media as hand-written or self adhesive labels may compromise the disc or peel-off in time."	Promote quality of media labelling.	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0056	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	**Folder "Additional Information":** Revise "... product literature and documents which need to be provided at a local level (e.g. by a local affiliate of a centrally organised regulatory affairs department)." to "... product literature. Where the applicant still has to fulfil any specific national requirements, related country-specific documents should be provided in this folder."	The current wording can be understood in a way that the position in the folder structure is different when a document is created by a local affiliate. The revised statement clarifies that it rather applies to national requirements of NCAs.	Accept change	Accepted	3/ Nov/ 2010	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0057	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Rename section title to "8.(a) Folder structure for initial Marketing Authorisation Application" Reword first sentence as follows: "The folder structure (granularity) for an electronic submissionof an initial application for marketing authorisationis shown "	Clarification that this section is primarily applicable for initial MAAs. Subsequent submissions are discussed elsewhere.	Accept change. Structure of section should also be changed to clarify what are general requirements, see **CR#-VNeeS-0084**	Accepted	3/ Nov/ 2010	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0058	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	Amend section as follows: "If publicly announced by the competent authority, the applicant may also optionally submit the chemical, pharmaceutical and biological / microbiological information for the finished product (Part 2) in a CTD structure using the format for Non-eCTD electronic Submissions (NeeS) for human medicinal products for Module 3 of the CTD. In this case, a correlation table should be provided showing which CTD chapter corresponds to which veterinary NtA chapter."	Address option to submit Part 2 documentation also in CTD format. (As regards ASMF see **CR#-VNeeS-0061**)	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0059	VNeeS GL - Rev.1 (corr Feb 2010)	**10. Technical validation**	Content	revise criterion for functionality of hyperlinks in GTOC/TOCs from 95% to 100% functional. Proposed wording "• Hyperlinks in the GTOC and TOC are functional"	As GTOC/TOC file names are now standardized this can be easily checked by applicant and staff responsible for technical validation with the automatic validation tool. Thus this increased requirement should be acceptable for both applicants and regulators and it very much facilitates review.	Accept change	Accepted	3/ Nov/ 2010	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0060	VNeeS GL - Rev.1 (corr Feb 2010)	**8 Structure of the electronic submission**	Content	Include sections for updates during assessment phase and post-authorisation submissions (new section 8(c) and 8(e))	Additional guidance is needed for these submissions. See draft guidance for full text.	Accept change, but change order of text within section for variations/extensions.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0061	VNeeS GL - Rev.1 (corr Feb 2010)	**8 Structure of the electronic submission**	Content	Include sections for ASMF (new section 8(d))	Additional guidance is needed for these submissions. See draft guidance for full text.	Accept change. Revised text based on QWP recommendation.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0062	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Content	Add new subfolder "1-responses" in Part 1	See **CR#-VNeeS-0060**	Accept change	Accepted	3/ Nov/ 2010	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0063	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	**Bookmarks and hyperlinks** Add the following sentence: "Especially in case of submissions consisting of only a single PDF file, without separate GTOC or TOC files, or single PDF files containing several references, bookmarks should be included for efficient navigation."	Should be best practice to allow efficient review of files containing multiple documents	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011

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CR#-VNeeS-0064	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Add the following sentence: "Folder-structured submissions via Eudralink have to be submitted as a zip file."	Additional guidance to clarify how folder-structured submissions can be transferred via e-mail (Eudralink).	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0065	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	**Adaptation of folder structure** Revise section "However, if there are empty folders in the submission these may be deleted as the folder structure should reflect only what actually is submitted. The relevant TOC should indicate in such cases that no data are being submitted for these sections of the dossier and that the respective folders have been deleted. When little or no information is presented for a number of folders at the same level of granularity it is acceptable to include all the information in a single PDF at the higher level of the granularity. Again this should be indicated in the TOC" as follows: "If there are empty folders in the submission because no data is provided these should be deleted as the folder structure should reflect only what actually is submitted. Corresponding positions in the relevant table of contents (TOC) should also be deleted. When only little information is presented for a number of folders at the same leve of granularity it is acceptable to include all the information in a single PDF at the higher level of the granularity. This should be indicated in the TOC."	Clarification of existing guidance in case folders are deleted due to the presence of no or limited data. TOCs should not list corresponding dossier chapters if no data is submitted.	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0066	VNeeS GL - Rev.1 (corr Feb 2010)	**1. Introduction**	Content	Delete the following part: "The guideline also introduces the option to prepare an electronic submission using a bespoke software package of which there are a number on the market. This type of submission is identified as an eNTA submission and is based on an XML backbone. An agreed technical specification for the eNTA will be developed at a later date."	Should be rather part of an e-submission roadmap document not of the VNeeS guidance	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0067	VNeeS GL - Rev.1 (corr Feb 2010)	**11. Glossary**	Content	Delete the following part: "eNTA: an electronic application prepared using a bespoke software package which contains an XML backbone and which follows the structure set out in Tables 1 and 2."	No longer necessary as to be addressed in a roadmap document.	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0068	VNeeS GL - Rev.1 (corr Feb 2010)	**9. Security**	Content	Delete the following sentence: "The feasibility of a secure electronic transfer of regulatory submissions, e.g. via a common portal, is currently under evaluation."	Should be rather part of an e-submission roadmap document not of the VNeeS guidance	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0069	VNeeS GL - Rev.1 (corr Feb 2010)	**6. Requirements for creating files for electronic submission**	Editorial	Amend title of section as follows: 6 Requirements for creating PDF files for electronic submission	For clarification as only PDF files are currently addressed in this section.	Accept change	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0070	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Editorial	Replace CD/DVD in the following sentence by "media component" or similar wording: "If more than one CD or DVD is needed, the dossier should be split at a logical point within the granularity such that the integrity of the granularity is maintained."	To be consistent with the rest of the section as the use of optical media such as CDs is best practice, but as technology is evolving other types of optical media may be used.	Accept change	Accepted	NA	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0071	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Revise text as follows: "The length of a path including file name, and extension should not exceed 180 characters."	The current limit of 230 characters lead to problems when copying dossiers to a file system both on the side of regulators and applicants.	Accept change. Due to the reduction technical validation issues regarding abbreviated folder names would be expected Therefore a need is seen to define abbreviated file names for Tables 1 and 2. See **CR#-VNeeS-0072** and **CR#-VNeeS-0073**.	Accepted	NA (written consultation)	24/ Nov/ 2010	1/ Sep/ 2011
CR#-VNeeS-0072	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	**Folder names:** Delete: Folder names created by the applicant may be abbreviated (e.g. in order to meet the maximum character limit for path length) as long as names are self explanatory and allow unambiguous identification according to the NTA structure given in Table 1 and Table 2 below.	Reduces ambiguity for the applicants as regards technical validation also taking into account that the reduction of acceptable path length would increase the need for abbreviations. Instead standard (abbreviated) folder names should be given in Table 1 / Table 2.	Accept change.	Accepted	NA	24/ Nov/ 2010	1/ Sep/ 2011

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CR#-VNeeS-0073	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1 / TABLE 2**	Content	Introduce standardized abbreviated folder names	Reduces ambiguity for the applicants as regards technical validation also taking into account that the reduction of acceptable path length would increase the need for abbreviations.	Accept change.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0074	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Replace folder name "additional-information" with "add-info".	Folder names in Table 1 and Table 2 have been changed to abbreviated versions.	Accept change.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0075	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	Insert foot note: "The VNeeS Checker tool is a standard non-commercial, and publically available tool for technical validation of VNeeS submissions. For further details please refer to section 10 of this guidance."	To give further explanation as regards use and availability of automated technical validation tool:	Accept change	Accepted	NA	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0076	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Editorial	Insert reference to the VNeeS checker: "File naming conventions for the table of contents should be followed to allow automated validation tools like the VNeeS checker to easily identify…"	Just for clarification and easier reference.	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0077	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Revise the following sentence: "The electronic submission must include a well-structured general table of contents (GTOC) in the root directory as well as a TOC in the top level folder of each part of the dossier. In the case of small dossiers (especially post-authorisation submissions) it is acceptable to only include a GTOC referring directly to the content documents." as follows: "The electronic submission must include a general table of contents (GTOC) in the root directory. A part-specific table of contents (TOC) in the top level folder of each part of the dossier may be added where this improves the navigation within the dossier. If more than one media component is needed (e.g. several DVDs), TOCs must be provided. In this case, the GTOC should be present only on the first hard medium; part-specific TOCs must be available on the media component where the files covering that part of the dossier are located."	A GTOC only would be acceptable, if it is a complete index to the submission. A part-specific table of contents (TOC) may be added to improve navigation efficiency (e.g. for large dossier parts). Where a submission has to be split over several media components, TOCs should be provided to allow access of files on hard media via TOCs. Each file of a submission including GTOC/TOCs should be present only once in the complete VNeeS submission.	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0078	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	Include diagrams to clarify recommended navigation features.	Just to explain more clearly.	Accept change.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0079	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Add the following sentences "Applicants should provide the electronic submission on the smallest number of media components possible, e.g. if the VNeeS submission spans several CDs, the provision of a DVD is recommended. … Where possible, individual dossier parts (Part 1, Part 2 etc.) should be kept together and not be split over multiple media components."	To allow easier handling and navigation of hard media submissions.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0080	VNeeS GL - Rev.1 (corr Feb 2010)	**10. Technical validation**	Content	Delete validation criteria: ("• Virus free • No type of security on the CD/DVD or on individual files or folders (with exception noted in section 9) • Follows the folder structure described in this guideline • Follows the naming convention for folders described in this guideline • Files not >100 MB • A GTOC file in the root directory and a TOC file in the folder for each part of the dossier • Hyperlinks in the GTOC and TOC are functional • All documents should be in PDF 1.4 format (exceptions are: editable versions o the SPC and product literature; the application form where an agency may require a later version) ")	Based on a TIGes vet decision Validation criteria are handled in a separate table and should not be repeated here but only referenced.		Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0081	VNeeS GL - Rev.1 (corr Feb 2010)	**10. Technical validation**	Content	Amend text as follows to insert cross-reference to the separate validation checklist and the VNeeS checker tool: "In order to be accepted as valid, an electronic VNeeS submission has to comply with the common set of technical criteria defined in the 'Technical validation checklist for veterinary electronic submission' as published on the TIGes veterinary eSubmission website. The criteria included in this checklist should be considered as a maximum set of criteria. Authorities should not enlarge the list as this will result in a non-unified approach to the validation. Submissions that fail to comply with these technical validation criteria may be rejected and a replacement submission can be requested by the receiving authority (if necessary). VNeeS submissions can be checked against the technical validation criteria using the VNeeS checker tool. The VNeeS Checker tool can be used as point of reference for technical validity of a submission by both applicants and agencies. It is available for free download e.g. on the websites of the French agency ANMV and the Belgian agency FAGG-AFMPS. The tool will be updated in line wi	Based on a TIGes vet decision Validation criteria are handled in a separate table and should not be repeated here but only referenced. Explanation on the use of these criteria is needed. A reference to the VNeeS checker should be included to point out that applicants and agencies can easily check pass/fail criteria with that tool and can use the tool as reference point for a validity check.	Accept change.	Accepted	NA	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0082	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Editorial	Insert the following sentence at the end of the paragraph: "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, named "p3e-toc.pdf"."	For clarification of an existing requirement according table 2.	Accept change.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0083	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Revise sentence addressing folder names slightly as follows: "Folder names should be in English and where the VNeeS structure defined in this guidance is applicable follow exactly the conventions given in Table 1 for pharmaceutical products and Table 2 for immunological products."	The wording should be amended, as the revised guidance would no longer allow any deviation from the folder naming convention for all submissions where this structure is applicable.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0084	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	Introduce new section 8(a) General considerations. Move considerations on initia submissions to following section. Reword new section slightly: "The folder structure (granularity) for an electronic submission is based on the Notice to Applicants Volume 6B as amended by Directive 2009/9/EC (Annex I to Directive 2001/82/EC as amended). This hierarchical structure of folders within a root folder gives, depending on the type of submission, up to three levels of granularity. The complete VNeeS folder structure is shown in Table 1 for pharmaceutical products and Table 2 for immunological products and should be used where applicable to prepare any electronic submission consisting of more than a single file."	Correction / clarification of the revised guidance structure as the revised text did apply to all procedures and not only to initial submissions. Text that did apply to initial submissions only, should be moved to the following (new) section 8(b). Clarify that folder structure applies to multiple-file submissions.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0085	VNeeS GL - Rev.1 (corr Feb 2010)	**1. Introduction**	Content	Delete the following part: "The guideline builds on the specifications agreed in the TIGes-Vet Sub Group guideline of September 2007 by the addition of a specification for the folder structure (the granularity) to be used in a basic electronic submission to be known as VNeeS. In 2005 the Heads of Medicines Agencies (HMA) agreed that all Member States would be able to accept electronic-only submissions by the end of 2009. The benefits of moving to e working were seen as: • reduction of (internal) paper-flow (logistics and administrative burden) • reduction of physical archiving space • product lifecycle management • facilitation of the assessment and review process" Move reference to VNeeS standard deleted with above paragraph to first paragraph as follows: "It specifies the basic parameters required for an acceptable electronic submission to be known as Veterinary NeeS (VNeeS), the name being inspired by the established NeeS standard for Human medicinal products" and add the following sentence at the end of the revised section: "The work will continue to achieve a harmonised way of electronic working by all	The first paragraph to be deleted addresses a previous revision of guidance and is no longer applicable (introduction of term "VNeeS" moved to previous paragraph). The following paragraph does only contain very general statements on the history of esubmission that appear no longer to be necessary. The last sentence was added to clarify that after the 2009 deadline a harmonized implementation of esubmission across all NCAs has not been reached by today.	Accept change.	Accepted	##########	16,2,2011	1/ Sep/ 2011

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CR#	**Affected Document**	**Document section**	**Category**	**Description of CR**	**Justification of Requestor**	**CCG / TIGes vet Recommendation**	**Status**	**CCG decision on**	**TIGes vet decision on**	**Implemented on**
CR#-VNeeS-0086	VNeeS GL - Rev.1 (corr Feb 2010)	**11. Glossary**	Content	Insert definition of "hard medium" Hard medium: Any type of physical media used for storage and transfer of electronic data (e.g. optical media like CDs or DVDs) in contrast to a purely electronic transfer e.g. via Eudralink or any web portal.	Just for clarification.	Accept change.	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0087	VNeeS GL - Rev.1 (corr Feb 2010)	**New "0. Title page"**	Editorial	Insert title page with administrative data	Document should show approval date by TIGes veterinary and date for coming into effect.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0088	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Add the following sentence: "Applicants should ensure that the correct e-mail addresses intended for submission via Eudralink are used."	Applicants should use only those email addresses that are specifically agreed to be used for Eudralink submissions.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0089	VNeeS GL - Rev.1 (corr Feb 2010)	**3. Media used for submission and its identification**	Content	Add the following sentence "Electronic submissions should be accompanied by a cover letter when submitte via hard media.."	Added for clarification as agencies still face hard media submissions without any accompanying letter.	Accept change.	Accepted	1/ Feb/ 2010	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0090	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Content	Replace the following wording "... should be compatible with the baseline format PDF 1.4. The applicant should however check in cases where later versions are used that files do not use features specific to later PDF versions than 1.4 that may be lost or not viewable based on PDF 1.4 and thus potentially could change the visual appearance of the document. Applicants may offer, and agencies may request newer file formats but neither should be constrained to supply or accept anything other than files compatible with PDF 1.4 (or as updated by the ISO norm). All PDF files should be created using software that allows reading and printing using a version that is available to companies and authorities." by "... should be legible with Acrobat Reader, version 5.0 or higher. Files should be compatible with PDF 1.4 (or as updated by the ISO norm). No PDF documents should be in version PDF 1.3 or earlier."	Easier to understand. Streamlines and harmonises requirements with those established for NeeS. Compatibility with PDF 1.4 is best practice, versions of 1.3 or earlier should be rejected.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0091	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Content	Replace the wording as follows "... To ensure that PDF files can be accessed efficiently, PDF files should preferably be no larger than 100 MB."	File size limit should be best practice but no pass/fail validation criterion.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0092	VNeeS GL - Rev.1 (corr Feb 2010)	**5. File Format & Source**	Content	Delete the following passage "PDF files should be optimized for fast web view (to enable viewing of any page whether or not the entire file has finished downloading). Embedding of common standard fonts should be verified, after the file has been optimised for fast web view."	Based on the facts that value of "fast web view" appears to be limited, specific software is needed for conversion to "fast web view" and conversion may trigger a need for further corrections, this criterion can be deleted.	On the Human side fast web view is kept as best practice rather for historical reasons and is not an important criterion. No agency currently would reject files that do not fulfill this. Complexity should be reduced and CCG supports deletion of this best practice criterion for VNeeS. In case an applicant decides to keep this as internal best practice this can be done	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0093	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(b) Electronic source documents**	Content	Delete the following passage "All fonts used in the document should be embedded in the (PDF) files to ensure that those fonts will always be available to the reviewer. All classical fonts are acceptable as well as True Type or Adobe Type 1 fonts in the case of PDF. It is recommended not to use proprietary fonts and to avoid customized fonts. When setting options for font embedding, choose options that indicate that (1) all fonts should be embedded and (2) fonts should not be subsetted. Embedding fonts will increase the size of the PDF file. To help limit the storage space taken by embedding fonts, applicants are encouraged to limit the number of fonts used in each document." and insert instead "Agencies cannot guarantee the availability of any fonts except Times New Roman, Arial and Courier, and fonts supported in the Acrobat product itself. Therefore, all additional fonts used in the PDF files should be embedded to ensure that those fonts would always be available to the reviewer. "	Delete requirement to embed all fonts for regulatory review of electronic files. This is in line with the human guideline. Instead ICH M2 EWG text is included. Reduction of requirements, in case applicant only uses recommended standard fonts, no file embedding will be necessary for the purpose of VNeeS submissions. Therefore detailed technical guidance for font embedding is no longer deemed necessary.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0094	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	In the new subchapter **8.(a) General considerations** include for inclusion of national requirements: "If so, subfolders should be included named with the country code of the country concerned as per Table 4."	It should be easily recognisable in the structure where national requirements are located and which county is affected.	Accept change.	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0095	VNeeS GL - Rev.1 (corr Feb 2010)	**TABLE 1/TABLE 2**	Content	Add country-specific subfolder for national requirements in folder for additional information.	Based on **CR#-VNeeS-0094**	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0096	VNeeS GL - Rev.1 (corr Feb 2010)	**New TABLE 4**	Content	List recommended country codes for naming of country-specific folders.	Based on **CR#-VNeeS-0094**	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0097	VNeeS GL - Rev.1 (corr Feb 2010)	**New TABLE 3**	Content	Add table (TABLE 3) defining folder structure and standard files for an electronic MRL application. References in the text to the tables defining the folder structure should be amended accordingly from "Table 1 and 2" to "Tables 1 to 3".	Folder structure needs to be defined as MRL application were added to the scope of the guidance (**CR#-VNeeS-0042**)	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0098	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	In the new subchapter **8.(a) General considerations** include a requirement to submit single file within a root folder as zipped file.	Inclusion of single files in a root folder makes automatic upload and automatic validation of single file submissions easier.	Additional complexity for single file submissions is considered not to outweigh the potential benefits as other solutions can be found for automation.	Rejected	##########	16/ Feb/ 2011	NA
CR#-VNeeS-0099	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	New subchapter **8.(a) General considerations:** The folder additional information (add-info) should be located outside the root folder. The structure in table 1 and 2 should be changed accordingly.	The folder is not part of the core dossier (NtA structure) and not subject to technical validation. Moving the folder outside the root folder would allow a handling similar to that for Human medicinal products.	Currently for veterinary products no folder structure above the root folder is defined as it is common practice on the Human side. If the proposal was accepted such a structure would be needed in case more than one submission is located on a hard medium. Adding additional levels to the structure as a general rule is however not supported	Rejected	##########	16/ Feb/ 2011	NA
CR#-VNeeS-0100	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Editorial	New subchapter 8.(a) General considerations: Add underlined part to section "Adaptation of folder structure" "Where the structure defined in Table 1 to Table 3 applies, including additional folders within the structure of the e-submission is not permitted, "	Just added for clarification.	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0101	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(a) Folder structure**	Content	New subchapter **8.(a) General considerations:** In section "Folder "add-info" (additional information)" add the following information: "Any files submitted voluntarily for information only, like validation results of tools like the VNeeS checker or user instructions for the reviewer, should also be placed in the folder "add-info". Files and subfolders in the folder "add-info" are not subject to technical validation."	Added for further clarification.	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0102	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(b) Indexing**	Content	(now Subchapter 8.(f)) Include guidance on inclusion of files in folder "add-info" into index as follows: "Files being present in the folder "add-info" need not be included in to the GTOC."	Files are not in the core dossier structure and not subject to technical validation. Including these in the index should not be a validation criterion.	Accept change	Accepted	##########	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0103	VNeeS GL - Rev.1 (corr Feb 2010)	**6.(b) Electronic source documents**	Content	Revise text "Where practicable, PDF documents should be created (rendered) directly from their electronic source documents. This allows functionality such as text searching, copying and pasting into editable formats." as follows "To allow functionality such as text searching, copying and pasting into editable formats, PDF documents should be created (rendered) directly from their electronic source documents, except where the applicant has no access to the electronic source document or where the document requires a signature. Where only signature pages need to be scanned, applicants should consider providing signatures on separate pages not containing other information key to the understanding of the submission.."	The term "where practicable" leads to disharmonised interpretations and should be clarified. PDFs should be rendered from the electronic source wherever possible, stating acceptable exemptions. Brief guidance on handling of signature pages should be included.	Accept change	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0104	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Include restriction for length of file names to 64 characters.	Discourage use of excessively long file names.	Reject change as this appears to be sufficiently covered by path length restriction.	Rejected	1/ Feb/ 2011	16/ Feb/ 2011	NA
CR#-VNeeS-0105	VNeeS GL - Rev.1 (corr Feb 2010)	**8.(c) Files**	Content	Use shorter examples for valid filenames, e.g. : admin-info.pdf p1c2-dacs-safety.pdf part-2e3-ident-assay-excip.pdf	Discourage use of excessively long file names. Current examples show up to more than 60 characters.	Accepted	Accepted	1/ Feb/ 2011	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0106	VNeeS GL - Rev.1 (corr Feb 2010)	**11. Glossary**	Content	Amend explanation of VNeeS: "Veterinary NeeS (the name being inspired by the established NeeS standard for Human medicinal products), an electronic application prepared using standard software and which follows the structure set out in Table 1 to Table 3."	Correction as regards table references to new table 3. Explanation of name consistent with introduction.	Accept change	Accepted	NA	16/ Feb/ 2011	1/ Sep/ 2011
CR#-VNeeS-0107	VNeeS GL - Rev.2 (Feb 2011)	**8.(f) Indexing**	Editorial	Add sentence " Hyperlinks should only be made to documents within the same VNeeS submission and not to external sources."	Editorial correction. The same sentence was already published in the 'Technical validation checklist for veterinary electronic submission' but had by mistake not been included in the guideline being the basis for the checklist.	Accept change	Accepted	NA	27/ Mai/ 2011	1/ Sep/ 2011
CR#-VNeeS-0108	VNeeS GL - Rev.2 (Feb 2011)	**TABLE 2**	Content	Add a foot note to table 2 allowing the optional inclusion of two further level 1 folders: "Immunological dossiers may also be presented with two additional folders in the root directory (LEVEL 1), named "p5" and "p6"."	The update of NtA Vol 6B based on the latest revision of the Annex to Directive 2001/82/EC is still pending. Therefore the question whether immunological dossiers should be presented in 4 parts rather than 5 or 6 parts is not yet finally clarified. On paper currently a dossier structure based on 5 or 6 parts is accepted whereas the current table 4 in this guidance foresees only 4 parts. In order to align this approach, an alternative VNeeS structure with two additional folders in the root directory (LEVEL 1), named "p5" and "p6" should be accepted on an interim basis until final clarification of this issue.	Basically accepted by TIGes vet on 18 May 2011. Final wording of footnote to be agreed in a written procedure.	Accepted	NA	27/ Mai/ 2011	1/ Sep/ 2011
CR#-VNeeS-0109	VNeeS GL - Rev.2 (Feb 2011)	**3. Media used for submission and its identification**	Content	Update the maximum size for EudraLink messages from 40 to 80 MB	Technical change of Eudralink, text needs to be aligned	Accept change	Accepted	NA	1/ Sep/ 2011	1/ Sep/ 2011

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CR#-VNeeS-0110	VNeeS GL - Rev.2.1 (Sep 2011)	**9. Security**	Content	Change following text: "It is not permitted to apply password protection to either the media carrying the files or the files themselves", into: "It is permitted to apply password protection to the media carrying the files but not the files themselves."	EMA/HMA Draft Guidance on the identification of commercially confidential information (CCI) and protection of personal data (PPD) within the structure of the marketing-authorisation dossier acknowledges the need to protect sensitive and confidential information. An applicant should be allowed to protect its sensitive and confidential information during transmission of this information. Unsecured data transmission cannot ensure the integrity of information to remain intact during transmission. Therefore an applicant cannot guarantee that the information is unaltered or virus free after receipt of an unsecured transmission by the Regulatory Authority nor can be held responsible for any damage caused by a virus from an unsecured transmission.	An applicant has the right to protect its company's interests. It is the experience of several agencies that this interest of the applicant can better be served when using existing secure ways of transmission (e.g. Eudralink and in the future the central portal). Password protected submissions are very resource intensive for the agencies, slowing down processing of submissions, which is also not in the interest of the applicant. Where better and faster secure ways exist, as mentioned above, these should be used. Additionally, for the moment electronic submission is based on voluntary choice of the applicant by which the applicant accepts implicitly to take potential risks of submitting electronically.	Rejected	NA	15/ Dez/ 2011	NA