

Release Notes for EU NeeS Guidance – Comparison of version 3.0 with 2.0

Section	Previous section number (version 1.0)	Changes
Front page	-	Changed the name of the document
1. Introduction	1	Removed background on and benefits of moving to e-working. Added that eCTD submissions is regarded as the principal electronic submission format in EU. Emphasized that this guidance is not applicable for NeeS submitted to EMA as they do not accept this type of electronic compilation.
2.1.1 Types of Product	2.1.2	Section 2.1.2 moved up and is now 2.1.1. Indicated that small molecules, biotech products, herbals, vaccines, homeopathics and blood products are included in the product type. Added EEA in the scope for NCA's.
2.1.2 Types of Submission	2.1.3	Section 2.1.3 moved up and is now 2.1.2 Reworded text.
2.1.3 Types of procedures	2.1.1	Section 2.1.1 moved down and is now 2.1.3. Reworded text.
2.1.4 Exceptions	2.1.4	Included Orphan drug designations and PIP submissions as exceptions. Indicated that the guidance is not applicable for Centralised Procedure submissions.
2.2.1 Dossier Structure	-	Inserted a heading for existing text on structure of NeeS submissions. Changed example of a procedure number. Added the need for communicating changes to the structure with the agencies. Included requirement to continue to use a structure for all subsequent NeeS once a structure has been submitted.
2.2.2 Table of Contents and bookmarks	2.2.1	Reworded. Included a figure of a NeeS folder structure (fig.1). Updated figure on use of hypertext links in TOC (is now fig.2). Changed the location of the ctd-toc.pdf from the 'toplevel folder of the NeeS' to the 'four digit named folder for the NeeS'. Indicated that the four digit number folder comes next to the root or top level folder. Recommended a consistent use of the name of the top level folder from one NeeS submission to the next. Removed text on document TOCs.
2.3 Moving to NeeS format applications	2.4	Included an example on when it could be beneficial to reformat a whole dossier into NeeS, when switching from paper to NeeS. Included reference to eCTD guidance for general principles on format changes.
2.4.1 File and folder structure	2.4.1	Included reference to 'File-Folder Structure & Names' work sheet included in the NeeS validation criteria. Clarified that for defining the maximum folder/file path length, counting starts from the first digit of the four digit folder.

Release Notes for EU NeeS Guidance – Comparison of version 3.0 with 2.0

Section	Previous section number (version 1.0)	Changes
2.4.2 Submission numbering	2.3	Reworded and moved section down.
2.4.3 File Naming	2.5.2	Changed 'file naming conventions should be followed' to 'must be adhered to for files in modules 1-3 and are highly recommended for files in modules 4-5'. Include reference to File-Folder Structure & Names' work sheet included in the NeeS validation criteria. Included criteria for file names and folder names to not exceed 64 characters.
2.5 Correspondence	2.6	Rewritten partially to clarify which information should and which information should not be included in the NeeS.
2.6 Paper requirements	2.7	Minor change of text, included description of the general need for original signed application form and cover letter.
2.8 File formats	2.9	Moved part of text in 2.9.1 up to 2.9. Indicated that files in MS Word or RTF format should not be included in the NeeS structure. Added information on the use of XML for application forms.
2.8.1 PDF	2.9.1	Reworded. Changed the requirement that only PDF version 1.4 should be used to 'version 1.4 or 1.7 should normally be used'. Added information on PDF version 1.3 not being acceptable and the need to explain the use of versions other than 1.4 or 1.7 in the cover letter/explanation note. Updated the information on scanning of wet signatures for the cover letter and application form and changed reference to 'Annex 1' into 'national guidance'.
2.8.2 Extensible Mark-up Language (XML)	2.9.2	Removed XML information. Removed PIM as initiative to use XML structured information.
2.8.3 Other File Formats	2.9.3	Extended the information on organization and format of working documents. Updated the example of a folder structure to reflect the situation where working documents need to be submitted to multiple NCA's (fig.3). Added information on translations being provided outside the NeeS. Added information on format requirement when using e-Mail or Eudralink to send information.
2.9 Bookmarks and hypertext links	2.10	Removed text that each document needs to be referred to from a TOC, as this is covered in section 2.2.2. Add reference to 2.2.2 for details of hypertext links in TOCs.

Release Notes for EU NeeS Guidance – Comparison of version 3.0 with 2.0

Section	Previous section number (version 1.0)	Changes
2.10 Technical validation of NeeS submissions	2.11	Fully rewritten to provide detailed information on new validation criteria (valid as of 01 Sept. 2011).
2.11.2 Security Settings	2.12.2	Changed heading from 'Password Protection' to 'Security Settings'. Included more information on restriction of applying security settings to open any individual file. Removed the exception to apply security for some documents.
2.11.3 Protection against Malware	2.12.3	Changed heading from 'Virus protection' to 'Protection against Malware'. Minor textual changes to use broader term 'malware' instead of 'viruses'. Removed the need to include confirmation of testing in the cover letter.
2.11.4 Electronic Signatures	2.12.4	Reworded and removed reference to CMDh website for guidance on the need of signed paper copies .
2.11.5 Transmission Media	2.12.5	Combined section 2.12.5 & 2.12.7 and reorganized the information.
2.11.6 Procedure for Sending Electronic Information	2.12.7	Included Eudralink and portals as transmission media. Included information on how to use Eudralink and zipped files. Included preference to provide submissions for workshare /grouping variations together on one CD/DVD. Replaced figure on CD containing grouping and worksharing variations with two figures, with and without sequential sequencing. Indicated not to include previously submitted sequences to the same agency on a CD.
2.11.7 Labelling of Media	2.12.6	Included instruction on how to handle too many submission numbers to list on the CD/DVD label
2.11.8 Number of Media Requested	2.12.8	Changed heading from 'Archiving and working copies' to 'Number of Media Requested'.
2.11.9 Technical Baseline Applications	-	New section to provide information on the use of technical baseline applications.
3.1 Module 1.0 Cover Letter and Tracking Table	-	New section.
3.3 Module 1.3.1: Product Information	3.2	Included instruction to provide RTF or Word files in working documents folder. Indicated there is no need to provide the tracked changes version in PDF, if it is submitted as Word file. Included instruction to manage national translations outside of the eCTD lifecycle.

Release Notes for EU Nees Guidance – Comparison of version 3.0 with 2.0

Section	Previous section number (version 1.0)	Changes
3.4 Module 1-responses	3.3	Rewritten to expand information on the management of responses. Indicated that for MRP/DCP the location of response documents should be 'm1/eu/responses/common', regardless of which member state raised the question.
3.5 ASMF	-	New section
Annex 1	Annex 1	Added prefix 'A1-' to section numbers, e.g. '1.' is now 'A1-1.'
A1-2. Documents that Must Always Be Text Searchable	Annex 1; section 2	Removed all bullets on 'This also covers similar documents provided in non-MAA submissions'.
Annex 2	Annex 2	Reduced the information to illustrate the principle only. Removed the 'not applicalbe' documents in the Module 1 example.