Release Notes for
Harmonised Technical Guidance
for NeeS Submissions in the EU v4.0

This document highlights the changes made in version 4.0 in comparison with version 3.0 of the "Harmonised Technical Guidance for Non-eCTD electronic Submissions (NeeS) for human medicinal products in the EU" published in November 2013.

Section	Previous Section No. in v3.0	Changes
General Changes throughout the document	NA	References to TIGes (Telematics Implementation Group – Electronic Submissions) have been removed
		Updated hypertext links to point to current versions of documents or relevant webpage
Cover Page	NA	Changed the title of the Document, version number, and date.
1 Introduction	1	Reworded information on creation and adoption of the document
2.10	2.10	Aligned text with the current validation criteria
2.1.2 Types of Submissions	2.1.2	Added withdrawals to submission types enumerated
2.1.3 Types of Procedures	2.1.3	Added reference to guidance to be used for MRP and DCP submissions
		Added that the NeeS dossier used for MRP/DCP should preferably be identical in all RMS/CMSs, i.e. a single common EU dossier in line with how eCTD is managed.
2.1.4 Exceptions	2.1.4	Added a general statement at the end of the section that this guidance does not apply to dossier content explicitly excluded from the commonly maintained electronic dossier.
2.3 Moving to NeeS format applications	2.3	Reworded 'application' to 'submission' to reflect difference between the full dossier and an individual submission.
2.4.3 File Naming	2.4.3	Changed reference to specific version of NeeS validation criteria to a general reference and included hypertext link.
2.6 Paper requirements	2.6	Minor editorial changes to improve readability
2.7 Hardware	2.7	'zip drive' was changed to 'external hard drives'

Section	Previous Section No. in v3.0	Changes
2.8 File Formats	2.8	Deleted 2nd paragraph on the use of XML for application forms
2.8.1 Portable Document Format (PDF)	2.8.1	Added the document title for the ISO Standard for PDFs Added PDF versions 1.5 and 1.6 as versions normally to be used Deleted 4th bullet point in previous version, which mentioned how to handle when it is unavoidable to use other PDF versions Differentiated key requirements and requirements to consider Added the requirement that fonts used in PDF should be embedded where possible and that rendition to PDF should preferably create documents which are "tagged" Added reference to ICH M2 recommendations at the end of the section.
-	2.8.2	Removed section "Extensible Mark-up Language (XML)"
2.8.2 Other File Formats	2.8.3	Only numbering changed
2.10 Technical Validations of NeeS Submissions	2.10	Minor editorial changes to improve readability
2.11.4 Signatures	2.11.4	Removed 'Electronic' from section title Minor editorial changes to improve readability Added reference to CMDh guidance for requirements on wet or scanned signatures Added references to EMA websites regarding electronic submissions
-	2.10.5	Removed section 'Transmission Media' as the information is already covered by other sections
2.11.5 Procedure for Sending Electronic Information	2.11.6	Completely rewritten to improve readability Removed detail on size limit for EudraLink Included CESP and eSubmission Gateway information Included information on current standards for burning CDs/DVDs
2.11.6 Labelling of Media	2.11.7	Minor editorial changes to improve readability Changed "full application number(s) (if known)" to "full procedure number(s) (if known) (e.g. UK/H/1234/001-005/II/0034)"

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2.11.7 Number of Media Requested	2.11.8	Minor editorial changes to improve readability Moved information on current standards for burning CDs/DVDs to section 2.11.5
2.11.8 Technical Baseline Applications	2.11.9	Minor editorial changes to improve readability
3.1 Cover Letter	3.1	Added requirement that content of cover letter submitted in paper must be identical to the one submitted in NeeS. Added instruction that a clarification note may be provided when resubmitting content due to technical validation or sequences missing at NCA side and that the original cover letter in the NeeS should not be changed
3.4 Module 1-responses	3.4	Replaced generic text on recommendations for management of responses with specific text and examples (conform Q&A36)
3.5 Modules 2-5	-	Included section to include reference for information on structure of Modules 2-5
3.6 ASMF	3.5	Minor changes to further clarify text on ASMFs