

Change requests for NeeS checker 1.12.2012

Owing to an update on 1.12.2012 of the NeeS validation rules (v3.0) of the EU harmonization group <http://esubmission.emea.europa.eu/tiges/tigesdocuments.html>, the following changes are done for our stand alone agency NeeS Checker:

- The version of the NeeS Checker is now 3.0, also the version mentioned in the report
- In m4 all study folders are now optional
- In m5 the study folders are still mandatory, moreover additional subfolders below the study folders are allowed
- Optional folders in 32a1-fac-equip, 32a2-advent-agent, 32a3-excipt-substance and 32r-reg-info are allowed from now on
- The checker will be able to read the PDF version from the PDF following the new NeeS requirements. (sometimes one PDF file stores the version number at two places. Although exceptionally, these 2 version numbers can be different. Now we read the PDF version as specified in the ISO 32000-1 PDF specification. It is expected that this will be fully transparent for almost all submissions.
- The checker will be able to report corrupted PDFs
- The checker will accept multiple hyphens in 32a3-excipt-substance folder name

The checker in Mesea will be adapted in identical way, except for the PDF technical related issues (PDF version and corruption), as these are not verified on line for performance reasons.