



**Nees Checker – Change requests – part IV**

**07/07/2011**



## I. CHECKER – New rules effective on 1/9/2011

The new version of the NeeS checker will be based on all current errors and warnings. Moreover, extra errors & warnings will be added, in order to comply to the actual EU requirements applicable starting on 1 september 2011. These are listed here below:

- The best report will be automatically stored outside the folder selected by the user to run the checker validation. The best report will be named “NeeS report.html”

Example: folder ‘0000’ is selected to run through the checker, after the checker run is finalized you will find:



- Within modules 1 and 2 in some filenames optional variable parts have been foreseen, to have all details on these new filenames please go to:

<http://esubmission.emea.europa.eu/tiges/tigesdocuments.html>

## TIGes Documentation

### TIGes Harmonised eCTD Guidance

- The TIGes has agreed on a [final draft of a harmonised guidance document for t](#) submission to any agency for any procedure should follow the recommendation comments are actively sought, with a view to updating the document as necess
- The BPG for the use of eCTD in MRP/DCP can be found [here](#)
- [Current Validation criteria v2.1 \(valid until 31 August 2011\)](#)
- [eCTD New validation criteria v3.1 \(effective 1 September 2011\)- NEW](#)
  - [Release Notes - NEW](#)
  - [Implementation information - NEW](#)

Click on the document marked in purple on the webpage: eCTD New validation criteria v3.1, an excel file will be opened. Select the third tab ‘File-Folder Structure & Names’

You will find the complete set of eCTD structure filenames in which the variable parts are marked in red. The new version of the checker will be based on the full set of filenames mentioned in the document.



- A new section called 'Other criteria' will be added at the bottom of the actual NeeS Report (Best report), three criteria will be verified within this section. As soon as 1 file within the submission fails one of the criteria below, the file will be rejected:

1. password protection to open on pdf files is not allowed
  2. the pdf version should be 1.4 or higher, files in PDF 1.3 or lower are not allowed
  3. the path length (for complex and groupings etc starting from the top (grouping/worksharing/complex and for single submissions starting at root folder '0000' and ending with the file extension included) of the file might not exceed 230 characters (the warning for files with pathlength between 180 and 230 characters remains valid for the new version of the checker as far as no groupings, worksharings or complex dossiers are concerned). Other agencies might be more strict and implement pathlengths exceeding 180 chars as an error, meaning rejection of the submission.
- The "working document" file which contains word versions of AMM, SPC, PIL, .... Will be allowed outside the '0000' root folder, OR within the '0000' root folder: for a grouping of variations, this means that both options below are possible, however FAMHP likes to underline that option 1 is preferred!



Option 1:

- 0000-working-documents
- FR-H-1122-05
- FR-H-1234-01
- FR-H-2132-01
- FR-H-3312-02
- FR-H-4321-01
- FR-H-4321-02
- FR-H-4321-03
- FR-H-4321-04
- FR-H-4321-05

Option 2:

- FR-H-1122-05
  - 0000
  - 0000-working-documents
- FR-H-1234-01
  - 0000
  - 0000-working-documents
- FR-H-2132-01
  - 0000
  - 0000-working-documents
- FR-H-3312-02
  - 0000
  - 0000-working-documents
- FR-H-4321-01
  - 0000
  - 0000-working-documents
- FR-H-4321-02
  - 0000
  - 0000-working-documents
- FR-H-4321-03
  - 0000
  - 0000-working-documents
- FR-H-4321-04
  - 0000
  - 0000-working-documents
- FR-H-4321-05
  - 0000
  - 0000-working-documents

Option 1: 1 overall working documents folder for the complete grouping  
 Option 2: 1 working documents folder per '0000' folder

Please be aware when the applicant submits a NeeS when BE is RMS in the MRP/DCP, then all validation criteria have to apply: This means that here the FAHMP checker may not be used but that the NeeS validation set of either Lorenz (actual version) or Extedo (actual version) must be used and the NeeS validation report must be put with the submission as is the case for the eCTD. Absence of a valid NeeS validation report leads to rejection of the submission.