

Comments on Revisions of Document Procedural Advice Automatic Validation of MR /Repeat-use /DC Procedures

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Comments on Proposed Process

Revision of the procedure to include RMS technical validation phase is in principal welcomed by AESGP because it should simplify and streamline the validation process.

- Validation tools should test in the same way and report deviations in identical fashion regardless of tool used.
- Application form/cover letter should include e-mail address for applicant regarding communications concerning technical validation
- Suggested additional text: *Prior to sending an electronic submission to the RMS, the applicant is advised to ensure compliance with the latest criteria for technical validation as published on the competent authority website of the RMS.*
- For the system to work, CMSs should mutually recognise validation procedures of the RMS no matter what tools have been used.



Comments on Process Continued

- Process not entirely clear! Should the applicant send
 - all CD/ DVD discs (for RMS and CMSs) to the RMS who then distributes them following technical acceptance
 - just the one relevant disc to the RMS and following notification of a technical acceptance, then applicant distributes discs to the CMSs
 - all locally required paper-based documents directly to RMS for distribution?
- Applicant companies will need to adapt existing processes
 - Send identical CD/ DVD discs to all involved NCAs (i.e. containing all working documents as specified by the involved NCAs plus NCA specific administrative docs)
 - Obtain proof of payment to all involved NCAs prior to publishing final version of e-submission
- The AESGP supports having short timelines and contends that these should be respected
- Distribution of submission from applicant to RMS and then further to CMSs will be much easier when the CESP is functioning

Comments on Document Layout

- A short explanatory introduction merited now that the document is larger and covers more complexity
- It would improve the document readability to put the standard text for confirming technical validity into an Appendix
- It might be best not to name the validators in the template text because they are supplied by external vendors, who may either withdraw these products or rename them, or better products may become available from competitors



Thank you for your attention
