

Memo

Working Group: Document Management System

Date of Resolution: April 24, 2020

Members involved: GSK (Tosin Sule), Trans Sped (Cezar Ignat), McDougall Scientific (Daniel McKenna)

Memorandum ID: DMSWG001

Problem statement/challenge to be addressed:

- Document flattening exercised by certain document management systems and its impact on digitally signed documents. It was discovered that document flattening is not consistent with what the meaning of that term is, because there are a number of different interpretations of how it works.
 - Document flattening means the removal of any interactive form fields inside of a PDF, where a user enters information. When a document is flattened, that interactive form field is removed and turns whatever is in that field into text, which is a material change to the PDF. Because of this, a new version of the PDF must be signed or wipe out the old signature so the user can re-sign it again.
 - Document flattening can also involve removing the existing signature, changing the PDF, and then signing it again. There are two ways to address this type of document flattening: (1) Create a new version of the PDF and sign that while leaving the old signature intact or; (2) Verify the old signature first and then remove the old signature, make changes, and sign it again.
 - Another case for document flattening is that it is a type of a visual component, meaning there is no change to the PDF at all. This is probably the easiest interpretation within SharePoint. This scenario involves signing a PDF document that is in SharePoint, and then opening the document in the web browser within SharePoint. When this happens, the web browser doesn't show any evidence of a signature within the PDF, and it doesn't display a validation status. Therefore, the document appears to be unsigned. However, the document is not flattened, though it appears to be. The signature data is still present inside of that PDF, but not recognized within the web browser.

Proposed Options and/or Discussions:

- Guidance on what is expected to happen. There were different requirements proposed.

- Requirement #1. Before flattening the document, the PDF processing software should validate and report the validity of digital signatures inside of the PDF documents. After flattening, the software can ask the user if they want to re-sign the document.
- Requirement #2. Update the existing file by adding a new version to it.
- Discussion about interactive form fields. Is there is value in keeping the interactive form fields in one version of the PDF, and then have a separate re-signed version of the PDF with those form fields removed? This happens within the same file, but one of them obtains the interactive form fields with one signature, and then a newer version within the same PDF is created, and then signed over without those interactive fields.
 - Trans Sped / Romanian Use Case: Romania's government agencies send out digital forms signed by the agency, so that the recipient will know that it's from them and that it is the correct version to use. When the recipient (citizen) fills the form and sends it back to the agency, it is signed using his/her digital certificate and the agency's signature is removed prior to applying the citizen's signature. In this use case, there is no need to preserve the version of the signed document prior to flattening. It still requires signature validation and reporting of its result, of the pre-flattened document.
 - GSK: At GSK, signed documents are saved in the DMS repository to serve as template for new signed documents to be created. The initial signature is from someone authorized to approve such templates. It allows GSK to revisit that document, update it, and then have it signed again. This use case is somewhat similar to the Romanian use case since here again there is no need to save the previous signature. The previous version of the document remains saved in the repository and serves as a template for new versions to be signed in future. For each new version, the previous signature is removed, document is modified as needed and then re-signed. The previous signature simply attests that the document is a valid template to use (very much like the Romanian use case where it allows the user to ensure it came from the agency and is the right version).
- Discussion about PDF versioning: GSK and McDougall Scientific both concurred that it was not desirable to keep both the original signed version and the new flattened version with the 2nd signature in the same PDF file. They prefer to use the underlying version control of the DMS to manage the various versions of the signed documents and not use the built in PDF versioning.

Resolution/Decision:

- SAFE Identity will add a test case that ensures that the product verifies the digital signature and notifies the user of its status before it is removed.
- SAFE Identity will make the PDF versioning test optional as it not a requirement of the working group attendees.
- SAFE Identity will consider adding a test case addressing the requirement that there must be some way to archive the original document and kept completely integral, prior to flattening, and that the product has an option to configure the system in this way. This test case would be further discussed within the working group in the near future in association with testing for 21 CFR Part 11 compliance. Since the archival requirement is not directly associated with digital signature and PKI, it is better to address it along with other 21 CRF Part 11 requirements.

- It was noted that the ability to include an audit trail within the document management system varies widely between implementations. Same was true about whether such audit trails were digitally signed, electronically signed or just had a field in the underlying database as some kind of indication for its integrity (for example a timestamp and/or a checksum). SAFE Identity's recommendation is that the audit trails be digitally signed by the system making them tamper resistant.

Links to Artifacts associated with the Resolution:

N/A