



INTRODUCTION

This report summarizes the remarks of Organon on the "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records". The document represents the questions and suggestions of representatives of different Quality Assurance and Quality Management departments.

SUGGESTED COMMENTS FOR CONSIDERATION

- 1) In general, we suggest to extend every guideline topic with (a summary of) the FDA goals for the described requirements of the specific topic.
- 2) In section 5.5 the guideline states that 'the ability to process information should not diminish' and "*..... you should be able to process information in a like manner for the electronic record over the entire records retention period.*". Unclear is what is meant by 'to process'. Does this mean that you must always be able to reprocess data during the required retention period? Does it mean that if you archive your data, that the system must have all the re-processing capabilities of all the individual systems that originally collected / created the data?

As 'processing' is not mentioned in the FDA legislation, we think that only basic automation functionality (select, sort, find, and etceteras) is intended. Therefore we suggest that 'process' should be deleted and be replaced with 'read and display ... in a for inspection, review and copying suitable way...'

In the second paragraph of section 5.5 we have additional remarks to two items:

- the sentence 'perform the same kinds of processing on information in the maintained record' is unclear. Referred is to something that is not specified. We presume that inspection and review is intended.
- In the example in the draft it is mentioned that the ability to perform calculations in a spreadsheet should be retained. We suggest to delete this as the example suggests that it should be possible to re-process data. FDA legislation states that only the used algorithm and end results should be stored. We refer for this to 21 CFR 211.68 and 211.194.

Section 6.2.1.4. This section should only be applicable during the operational use of the system: In case of retirement of a system it is practically impossible to maintain automated reprocessing capabilities. We suggest that transformed data should only be available for inspection or review purposes in the retired system. In case reprocessing capability is required, this is still possible through manual processing of the stored data.

00D-1539

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- 3) Section 6.1. The guideline states that during the retention period no changes should be made to the computing environment. In case a company chooses to leave the particular system connected to the operational environment, they could be forced to make changes as a result of changes in other parts of the IT-infrastructure. We suggest that it should be possible to make these changes under the condition that the system that is retired will be kept in a validated state.
- 4) Section 6.2.1.3 indicates that the creation of a new e-record should also be included in the audit trail. Take for example the situation that you are migrating a million files for which part 11 is applicable. Would it be sufficient to:
- record the correct migration of all the files once in one main audit trail file?
 - or should all migration events be recorded in their corresponding 'hard linked' audit trail file?

We suggest that it would be sufficient to log the correct migration of files once, as long as the migration process is a validated process. In that case, the entry would provide the same level of assurance as one million separate audit trail files with the corresponding entry

- 5) In section 6.2.1.5 an example is illustrated about a qualified way to perform a migration. The suggestion that an external party would be required in this process is to our opinion contradictory to the FDA guideline on conspiracy, which states that companies should take measures to prevent misuse to the level of individuals.

We suggest deleting or adapting the example and removing the involvement of an external party. In case involvement is required, we suggest that this should be restricted to cases where documents from a certain level of value are migrated.

In general, the example applies to a particular solution of electronic signature with a TTP. A guidance should in our view be applicable for every solution (if the solution is in compliance with regulation), not for just one particular solution.





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Comments on draft Guidelines for Industry

*21 CFR Part 11; Electronic Records; Electronic Signatures,
Maintenance of Electronic Records*

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*On behalf of the N.V. Organon International 21 CFR Part 11 Compliance Platform
(PCP)*

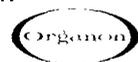
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