Commentary

21 CFR Part 11: Electronic Records; Electronic Signatures:

Questions and Answers

The agency does not believe Part 11 needs to require recording the reason for record changes because such a requirement... is already in place...

by
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The following question and answer commentaries were taken from the General Session at **IVT**'s *Computer and Software Validation and Electronic Records and Signatures Conference*, held on April 22-25, 2002.

Q: Does the system need to comply to Part 11 since the electronic record is not used, only the printed result?

A: The system does need to comply with 21 CFR Part 11. From the question, one assumes that the printed record results from electronic records. If this is true, then the printed results are generated from electronic records using a computerized system of some sort. 21 CFR Part 11.1 (i.e., the Scope) indicates the following: "This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted..." This section has only one limitation, and that is "...paper records that are, or have been, transmitted by electronic means." This refers to a fax process. Faxing doesn't seem to be the issue in this scenario. Therefore, electronic records are in fact used in the process, and this means that the system needs to comply with the regulation.

Q: Do I correctly interpret audit trail requirements for Part 11 to not require a reason for the change, as is required by the Good Laboratory Practice (GLP) audit trail?

A: Strictly speaking, this is correct. Part 11 does not in itself specify the need for a reason for change. In the preamble to the regulation, the FDA indicates, "The agency does not believe Part 11 needs to require recording the reason for record changes because such a requirement... is already in place in existing regulations and pertain to the records themselves." Given this wording, however, it is my opinion that the requirement is there nonetheless if the predicate regulations (e.g., GLP) require it. That's where the Agency will look.

Q: Is a manual audit trail acceptable for the short-term until the system is remediated technologically for the long-term?

A: The answer is "yes," but let us emphasize "short-term" here. In *Compliance Policy Guide 7153.17*, one of the determinants in the decision whether to pursue regulatory actions is the following:

> ***Adequacy and timeliness of planned corrective measures...*** *Firms should have a reasonable timetable for promptly modifying any systems not in compliance (including legacy systems) to make them Part 11 compliant, and should be able to demonstrate progress in implementing their timetable. FDA expects that Part 11 requirements for procedural controls will already be in place. FDA recognizes that technology based controls may take longer to install in older systems.*

Developing the remediation plan and then implementing it should be a priority.

Q: How much testing is required for Microsoft Excel® calculations/equations?

A: The answer to this question has to be provided in terms of "quality" rather than "quantity" of testing. Referring to the language in 21 CFR Part 11.10(a), your testing has to be robust enough to confirm that all calculations and the resulting data are accurate and reliable (i.e., the formulas work properly and the correct data is used), procedures (e.g., security, backup, and recovery) are in place to help ensure that the software will operate consistently, and an audit trail is provided to allow for identification of invalid or altered records. So the way to determine if your testing is robust enough is to measure it against your requirements for the respective spreadsheet. Therefore, you need to document those requirements (a functional requirements document), and then confirm through a traceability matrix or other appropriate tool that all requirements are met. A functional requirements document does not have to be large and complex, but it should specify what the spreadsheet is being used for. To summarize then, there is no "quantity" measure to determine how much testing is required. There is, however, a "quality" measure: are your requirements adequately tested? ❑

About the Author

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