



**DATATRAK Comments**  
Guidance for Industry: 21 CFR Part 11; Electronic Records;  
Electronic Signatures Validation  
Draft Guidance – August 2001  
Docket No. 00D-1538 FEB 13 2002

Date: 2002-02-06

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Subject:

Docket No. 00D-1538: Draft Guidance for Industry; Electronic Records; Electronic Signatures – Validation

Comments on: Audit Trail functionality in electronic data collection systems.

Dear Sir or Madam:

DATATRAK International Inc appreciates the opportunity to review and comment on FDA Guidance on Validation. We understand that this process is extremely important and required to assist industry in complying with Federal Regulations. We have reviewed the draft Guidance document in detail and are submitting specific comments, which are contained in the attached table.

We are also submitting comments and position statements respectfully for consideration in the drafting and/or revision of future regulations in 21 CFR Part 11, specifically pertaining to Audit Trail functionality in electronic data collection systems.

Please contact me with any questions regarding these comments.

Sincerely,

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Date: 2/6/2002

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Section	Paragraph/Line Number	Proposed Change	Comments
General	General Terminology	The documents states "We", Proposal: FDA or Agency	Terminology will be more appropriate for guidance documents.
2.1	18-21	Proposed Change: This draft guidance focuses on validation of computer systems used for creation of electronic records and signatures regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Services Act and any FDA regulation.	Should stay consistent with the "Scope" of this guidance document. Refer to Line 13-14 under Scope: "This draft guidance focuses on validation of computer systems."
2.2	29-34	Delete the "Audience" section or merge with the "Purpose" statement.	It is clearly stated in Purpose paragraph of the guidance documents. Refer to Paragraph 1; line 4-6.
5.1	47--51	Proposed Change: "Regardless of whether the computer system is developed in-house, developed by a contractor, or purchased off-the-shelf, establishing documented end- user requirements is extremely important."	It should be made clear that it is absolutely necessary to have a set of documented end-user requirements for a meaningful computer system validation. The guidance should be focused on the workflow/tasks rather than the person who should accomplish the task.

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5.1	51-54	Proposed Change: Once you have established end-user / product requirements you should obtain appropriate evidence that the computer system performance is consistent with respect to the pre-defined end-user / product requirements, and that they are traceable to the system requirements and specifications.	It might not be feasible, in some instances, to trace certain requirements due to system environment, etc. Also, in the case of COTS products might be very difficult to obtain a tractability matrix due to proprietary/confidentiality issues, hence it is recommended that the statement "As Appropriate" be used.
5.2	80-81	Proposed Change: Documentation of all Validation tasks is extremely important to the success of your validation efforts.	This statement adequately raises the importance of thorough and well-written documentation.
5.2.1	Validation Plan	Proposal: "Master Test Plan or Validation Plan."	Master Test Plan traditionally states the scope, and approach for testing and validation activities. It also covers the how, when and by whom testing will be done.
5.2.3	92-93	Proposed Change: The validation report should consist of a detailed analysis of the validation efforts which includes test results.	Inclusion of all details in a Validation Report may become too cumbersome. All details of the validation efforts should be categorized as evidence of documentation / quality-related records.

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5.3	Equipment Installation	Clarification required: Is this Installation Qualification for equipment used for production or for testing?	Activities to be performed are not consistent; equipment installation should be performed after the Program, Structural and Function testing.
5.4	106-109	Proposed Change: Simulation tests: These tests are normally performed using tools to simulate environments under actual operating conditions	A more detailed explanation for Simulation testing and the environment tested under is recommended.
5.4.2	Software Testing should include	Proposed Change: Minimum Software Testing should include	It is recommend to qualify the minimum then more testing can be performed as necessary.
5.4.2	Software Testing should include	Proposed Change: <ul style="list-style-type: none"><li>• Bullet point #1 Program build testing (Unit/module testing)</li><li>• Bullet Point #2 Structural Testing,</li><li>• Bullet Point #3 Functional Testing</li></ul>	Logically, the Program Build Test should occur before Structural Testing. Functional Testing occurs after the Structural testing.

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5.5	129-137	Proposed Change: Dynamic testing is an important part of the validation; however when and where possible static verification techniques should be incorporated to fully demonstrate complete and correct system performance. Static verification techniques include...	It is recommended for qualification that those static verification techniques should be performed as appropriate and to the effect where possible. With COTS products one can perform dynamic Testing but conducting any sort of static verification would almost impossible, as most COTS suppliers would never provide source code or other proprietary information to perform Code Review or "Walk Through".
5.7	149-151	Proposed Change: Two approaches to ensure an objective review are: (1) Engaging a third party or (2) Dividing the work within an organization such that people who review the system (or a portion of the system) are not the same people who built it.	Use of "OR" instead of "and" which could be confusing.
5.8	153-154	Proposed Change: Documented processes must be in place to control changes and evaluate the extent of revalidation that the changes would necessitate.	Systems in this context could be misleading.

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Section	Paragraph/Line Number	Proposed Change	Comments
6.1	181-182	Proposed Change: End-users should also be able to validate off-the-shelf software by performing the following as appropriate.	Based on the application being validated, the level and efforts of Validation should be appropriately determined. Hence stating "All" will not make logical and optimal sense.
6.1.1	185-186	Proposed Change: To delete the sentence "If possible, the end-user should obtain a copy of the developer's Requirement Specifications for comparison."	It is an ambiguous statement. The probability of getting Developer Requirements Specification is next to impossible. Software/Hardware development requirement specifications are generally highly proprietary since most Requirement Specifications contain features comprising the foundation for future features/products and platforms, making it highly unlikely that end-users will be provided with requirement specifications
6.1.2	187-188	Where source code is not available for examination, end-users should infer the adequacy of software Structural Integrity by performing the following tasks as appropriate.	The scope of software Structural Integrity must be determined by the application under review. Hence, stating "All" will not make logical and optimal sense.
6.2	206-207	Proposed Change: Agency recognizes the expanding role of the internet in the context of part 11.	Statement should be expanded with more detail.

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Section	Paragraph/Line Number	Proposed Change	Comments
6.2.1	209-213	Proposed Change: Deleting the entire paragraph.	The current statement presents concerns that the Internet cannot be validated due to its dynamic nature. We recommend giving guidance to the fact that due diligence must be performed in the event of validating the dynamics of the Internet.
6.2.1	224-225	Bullet point two: Our general comments	The statement to send acknowledgements or receipts through the use of other media besides the Internet would invalidate the currently existing technological environment and lead to procedural and administrative nightmares. Technologies deployed correctly today enable the user to be confident that the data received is, in fact, the data that was sent. If an interested third party has sufficient resources, technology and power to defeat today's secure technology, it will most probably also have the ability to intercept and fake receipts sent through other media.
6.2.1	Internet Validation	Proposal: This section should give more guidance pertaining to VPNs (Virtual Private Networks), Data Encryption	Agencies definition of VPN, WAN is recommend in these sections.

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6.2.1	Internet Validation	Proposal: This section should also include Internet Validation in terms of ASP (Application Service Provider) business model.	Extent of validation required regarding the use of ASP where the client machine is a verified fit for use to access the application hosted on a validated server over the Internet.