

Certified Software Solutions, Inc.

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February 5, 2002

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Dear Mr. Murray,

The following comments are provided for the General Principles of Software Validation: Final Guidance for Industry and FDA Staff, January 11, 2001. I find this guidance to be very complete and a good reference for developers of software for medical devices and also for development of software in general. However, I do have some comments concerning this guidance.

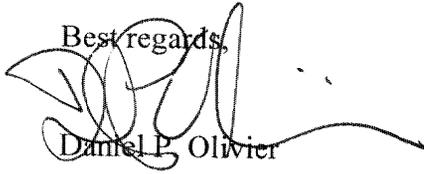
There are several references in section 5 to traceability including traceability of requirements to design, traceability of design to coding, traceability of unit tests to detailed design, and traceability of integration tests to high-level design. Although these multiple levels of traceability are academically interesting and may be applicable for many smaller/embedded applications, they are inappropriate for large existing systems and large new development applications. These traceability requirements are inconsistent with current industry design methods that encourage functional requirements definition models and object oriented design techniques that render traceability impractical and not beneficial. This mandate for multiple levels of traceability is also impossible to achieve for off-the-shelf-software, embedded hardware code, and fourth generation languages. Although traceability is appropriate during initial development stages to ensure required functions are implemented, maintaining traceability from requirements to design to code is impractical to maintain in long lived software programs. I suggest that this is impractical as a result of ten years of auditing hundreds of medical device software programs (many of whom claim they maintain these levels of traceability) and never once having seen this level of traceability as correct after years of maintenance. One would also have to ask why would this traceability be requested, as there is no direct benefit for having a traceability matrix? The benefit would be if this traceability table would conclusively show where the impacts of any change to the software might be affected. However, based on the architecture of the majority of large programs that exist today in the medical industry, I know of no developers that would rely on such a traceability table to be used as the definition for the extent of testing even if such a traceability table did exist. I recognize the criticality to mandate functional requirements to functional test procedure traceability but suggest that traceability to lower levels of design documentation not be required.

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I once again commend you on a very good guidance document. Please contact me at my e-mail address dolivier@certifiedsoftware.com or at (858) 675-8200 if you have any questions concerning these comments,

Best regards,

A handwritten signature in black ink, appearing to read 'D. Olivier', with a long horizontal flourish extending to the right.

Daniel P. Olivier

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