

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

RE: Docket No. 00D-1538

Dear Sir or Madam:

December 18, 2001

In response to the FDA's publication in the Federal Register of its Proposed Guidance, "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Validation", Becton Dickinson (BD) submits the following comments. BD is a worldwide manufacturer of medical devices whose corporate headquarters is located in Franklin Lakes, New Jersey.

In general, the guidance document is needed as there is some misunderstanding of 21 CFR Part 11 software validation requirements. The reference section is very in-depth which is helpful for the users that will be performing the validations.

Section 5.2.1, 5.2.2 and 5.2.3 state the review and approval should be by designated management. It is unnecessary and not practical in smaller firms for someone in management to review and approve validation plans, procedures and reports for software. We believe an alternative approach of independent review and approval from a knowledgeable person(s) within the organization may yield a better review. Software validation plans, procedures and reports are technical documents that require expertise in the subject area that a management person may not possess.

Under section 5.2.3, Validation Report, the report rather than including all test results may either reference the locations of the actual tests results or summarize the results. Software testing can be hundreds if not thousands of pages. Therefore, the validation report may be easier to understand if the results are summarized and compared to expected results to obtain the disposition.

Section 6.1.2, Software Structural Integrity, places a considerable and unrealistic burden upon the industry. It is impossible to obtain accurate and reliable information regarding the known limitations, other users experiences and known software problems and their resolution. An alternative may be to start this section with the limiting phrase "where possible and where reliable information is available, as deemed by the end user" or completely eliminate the first bullet point. It may be possible to obtain software problems from the software manufacturer but it is not likely with commercial off-the-shelf software. Testing the software for the end users purposes would provide a better means of accurate information on the software's limitations. Furthermore, the next bullet should begin with the limiting phrase "where possible".

The section 6.1.3, Functional Testing of Software, requires testing of all functions of the program that the end user will use. We suggest also to document those portions of the program that the end user will *not* use and to disable those portions if possible.

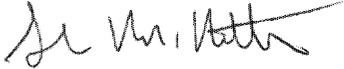
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One last general comment is that software validation for 21 CFR Part 11 be tied into the users overall Validation Program. The guidance is written as a stand alone document when it probably should be part of a Validation Master Plan.

We thank the agency for the opportunity to comment on this important document.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Mattei". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Glenn M. Mattei, Esq.
Director of Validation Services
BD