

April 28, 2003

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1060
Rockville, MD 20852

Re: Docket No. 03D-0060, Draft Guidance for Industry on Part 11, Electronic Records, Electronic Signatures – Scope and Application

Taratec Development Corporation welcomes the opportunity to comment on the FDA document titled "*Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application.*"

Taratec supports FDA's intention to provide guidance on the scope and application of Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures to enable consistency of interpretation across industry.

Taratec's comments and observations have been divided into two distinct categories: 1) general observations on the document as a whole and 2) specific comments relating to particular areas of text contained within the draft guidance. All of the comments are based on Taratec's experience in providing regulatory compliance consulting services to the life sciences industry for the past 15 years.

General Observations

Overall, Taratec found the guidance document to be clear and appreciate the emphasis being placed on predicate rule requirements in order to focus the scope of 21 CFR Part 11 (Part 11). Taratec also supports the Agency's recommendation to utilize a risk assessment approach, based on product quality and safety and record integrity, when determining the scope of Part 11 requirements.

However, it is Taratec's opinion that the following general areas could benefit from additional clarification:

- The term "enforcement discretion" is used throughout the document although a clear definition is not obvious. As such, it is not clear whether the decision to enforce Part 11 requirements will be made by individual investigators or whether all decisions will be reviewed by the appropriate FDA Center. Additional clarification of "enforcement discretion" would be beneficial in the final version of the guidance.
- The guidance states that the Agency will not "normally" take regulatory action to enforce compliance regarding the Part 11 requirements for validation, audit trail, record retention, and record copying. Taratec is of the opinion that including validation in this list is misleading as any system that contains Part 11 records as defined in Section B.2 would need to be validated. As stated in lines 126-137, the Agency intends to enforce all other provisions of Part 11 and since validation is the mechanism for proving that these other provisions are addressed, validation would be

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required. For example, in the draft guidance FDA provides the case of a word processor used only to generate SOPs (lines 209-219). If this was an electronic SOP system, the functionality of the word processor would need to be considered as part of the overall system validation to ensure that unauthorized users could not alter the approved SOPs via the word processor, as required by 11.10(g). As such, Taratec suggests that validation be excluded from this list and further clarification be provided on where validation is required.

- Taratec has noted that some in the industry are mistakenly interpreting the Agency's comments in this guidance as a statement that it is no longer necessary to validate computer systems. It is Taratec's understanding that the validation of computer systems has been an FDA expectation for many years even though it is not explicitly stated in the predicate rules apart from 21 CFR 820.70(i). Additional clarification by the Agency of this expectation in the Introduction to the guidance would be beneficial.
- Throughout the document, the Agency states that Part 11 will be interpreted narrowly and fewer records will be considered subject to Part 11. One of the areas mentioned is legacy systems, i.e., systems that were operational prior to August 20, 1997. However, a majority of these systems have not been static for the past six years. Depending on the criteria used to determine if a system is legacy or not, the relief for industry in this area may be much less than the agency is anticipating. As such, Taratec recommend further clarification be provided on the definition of legacy systems.

Specific Comments

Lines 41-44, 236-240

Lines 41-44 state that the agency will not normally take regulatory action to enforce Part 11 for legacy systems. However, lines 236-240 state that these systems must have met predicate rule requirements prior to August 20, 1997. Taratec suggests adding the additional clarifier regarding predicate rule requirements to lines 41-44 to avoid any confusion.

Lines 90-102

FDA has withdrawn all of the draft guidances on Part 11 plus CPG 7153.17. However, the Guidance for Industry on Computerized Systems Used in Clinical Trials was not withdrawn. Since this guidance is based almost entirely on 21 CFR Part 11 requirements, Taratec recommends that it also be withdrawn for consistency.

Lines 151-156

The agency states that “the *merely incidental* use of computers ... would not trigger Part 11.” Taratec suggests including additional information about the criteria used to determine if the system was merely incidental to the creation of a paper record. For example, if the information on a paper record created by a computer system was verified 100% by an expert and the paper record was always used from that point forward, it could be argued the computer system that generated it would be incidental and therefore not subject to Part 11.

Lines 242-261, 263-281

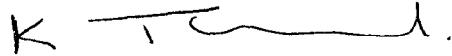
The section on Copies of Electronic Records implies that records should be available in an electronic format for inspection, review, and copying. However, the section on Records Retention states that the Agency does not intend to object if electronic records are archived to

nonelectronic media. Since no time period is stated, records could be archived to nonelectronic media immediately and the electronic record deleted. As it is not clear whether such a scenario would be acceptable to the Agency, Taratec is suggesting further clarification be provided.

Lines 242-261, 263-281

It is not clear whether sections C.4 and C.5 also apply to metadata, i.e., data about the records, such as audit trail information. As such, Taratec suggests providing clarification in the final version of the guidance.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Townsend", with a horizontal line extending from the end of the name.

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