

Comment Form

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Date May 15, 2002	Document Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Time Stamps Draft Guidance
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Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
Baxter Healthcare Corporation	5.1.1 Synchronization	99-101	Modify the existing wording to: Computer clocks should be set correctly and continue to be set correctly. Procedures should be established and followed to ensure that computer clocks are set properly.	Clarification of intent.
		101-103	Modify the existing wording to: For example, computers on a network should automatically synchronize their internal clocks with that of a designated source, for example a network server or external official time source. Synchronization should be part of a normal system operation (e.g., as part of the process of logging on to the network or on a timed schedule).	Clarify the type of clocks. Also, include allowance to synchronize with an outside source, such as the naval clock.
	5.2 Systems Clock Security	109-111	Modify the existing wording to: Inappropriate changes to computer clocks should be able to be detected through assessments and inspection. Procedures should be established and followed to detect and deter inappropriate changes to computer clocks.	(1) Clarification of intent. (2) Modified wording ensures consistency with the guidance requirements that are stated in the remainder of section 5.2 (lines #113-126).
	5.3 Time Zones	128-132	Delete the word "in" on line #128. Delete the word "we" on line #129. The sentence then reads as follows: The preamble to the final rule for part 11, entitled "21 CFR Part 11 Electronic Records; Electronic Signatures," stated: "[R]egarding systems that may span different time zones, the agency advises that the signer's local time is the one to be recorded." (See comment paragraph 101 in 62 Fed. Reg. 13430, at 13453 (March 20, 1997).	Clarification of intent.

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		132-136	Modify the two sentences to state: This position has been reconsidered and the guidance presented here reflects current thinking, and supersedes the position in comment 101 with respect to the time zone that should be recorded. Time stamps should be implemented with a clear understanding of what time zone reference is used.	Clarification of intent.
		144-148	Delete the wording "In our view," The sentence then reads: This procedure would help to ensure the authenticity and integrity of the electronic record (as well as the electronic audit trail) because it potentially eliminates confusion with respect to the timing of a particular event or action that could be attributed to different time zones.	Clarification of intent.
		149-151	Modify this sentence to state: It is recognized, however, that industry might not elect to include the time zone reference in the time stamp itself or as part of the human readable form of the time stamp.	Clarification of intent.
		151-155	Delete the wording "We believe". The sentence then reads: This approach can be potentially problematic if records are copied or transferred within (or accessed from) different organizations, or different components of an organization, that use different time zone references. In such cases, the reader could easily become confused as to exactly what time zone reference was used.	Clarification of intent.

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		155-160	Modify the two sentences to state: Nonetheless, if this approach is adopted systems documentation should be readily available that clearly explains what time zone references apply. Mechanisms should be established to ensure that the reader has a clear and accurate understanding of the correct time zone reference. For example, a record might be flagged with a code that could be used to determine the time zone referenced.	Clarification of intent.
	5.4 Expression of Date and Time	170-176	Modify this section to state: Steps should be taken to ensure that date and time expressions are clearly understood throughout an organization. As discussed in section 5.3, "Time Zones," the reader might become confused and draw erroneous conclusions about when events took place if different parts of an organization elect to express date and time differently. It is important for people who read the time stamp to have a clear understanding of what date and time expressions apply, especially where records in a collection express date and time differently.	Restructure sentence for clarity. Remove the word "very" since it's subjective and adds no value.
	6. Other Uses of Time Stamps In Electronic Recordkeeping	183-203	Delete this entire section.	This section is outside the Purpose and Scope of this Guidance Document. As this section is currently written, the content adds no value and creates potential confusion.