

**AdvaMed Comments
Guidance for Industry
21 CFR Part 11;
Electronic Records; Electronic Signatures**

				Date 6/26/02	Document Part 11 Time Stamps Guidance
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
AdvaMed	4.0	71-75	Change the sentence starting with "to satisfy this requirement..." to "To satisfy this requirement industry must employ procedures and controls regarding the use of computers and time stamps	Putting in words like "among other things" adds no value as a definition for guidance.	
AdvaMed	5.1	92-95	Change the statement beginning with "Accordingly" to "Accordingly, procedures and controls should be implemented to ensure time stamps are accurate and reliable." Remove the following sentence that starts with "It is extremely."	(1) The guidance fails to provide any insight as to what suffices for accuracy and reliability. Either need to add the word 'reasonably' before 'accurate' or indicate 'as specified by local specifications.' (2) The last sentence in this paragraph is redundant.	
AdvaMed	5.1.1	99-101	Revise to read: To ensure that they continue to maintain the correct time, computer clocks should be set correctly and checked or reset at defined time intervals or on the occurrence of system events.	E.g. local procedures should specify: When connected to a network, system date/time information must be synchronized from a designated external source. System date/time information must be reset at the end of each scheduled maintenance period.	
AdvaMed		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.	
AdvaMed	5.1.1	105	Change the sentence beginning with "Computers not connected to the network..." to read, " For computers not connected to the network, reasonable and appropriate care should be taken to ensure that their clocks are synchronized to a standard clock."	This should be commensurate with the criticality of the records created on or by the system. It allows the individual to determine if the system requires an audit or not, rather than implying one is always mandatory.	
AdvaMed	5.2	109-111	Modify the existing wording to: Inappropriate changes to computer clocks should be detectable through assessments and inspection. Procedures should be established and followed to detect and deter inappropriate changes to computer clocks.	(1) Clarification of intent. Modified wording ensures consistency with the guidance requirements that are stated in the remainder of section 5.2 (lines #113-126).	

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AdvaMed	5.2	109-126	Replace lines 111-128 with the following wording: "Where appropriate, The company should establish procedures or technical controls to ensure that the time stamp of an electronic document or electronic signature is accurate. Where computer systems lack technical controls, procedures and training are required to ensure accuracy of clocks.	The proposed wording highlights on the positive intent of the regulation. The cost of monitoring and detecting unauthorized changes would be disproportionately high relative to the value of a system designed to track these changes. Individuals creating and approving records, document or signatures can be trained to check time stamps for accuracy.	
AdvaMed	5.3	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.	
AdvaMed	5.3	135-148	Replace with the following: "Time stamp references should clearly indicate the time zone to which they refer. System and User documentation should explain time zone references, acronyms, or other naming conventions employed. References should clearly distinguish whether the time stamp is based on: (1) a site-independent time like Greenwich Mean Time (GMT), (2) a remote server running the current application, or (3) the local computer workstation.	The statement is overly lengthy for the value added. The current wording is awkward and does not clearly distinguish the three primary sources of time stamp information to be applied to a computer event/record.	
AdvaMed	5.3	135 – 137	Replace with the following: "Time stamp formats, including time zone references should be implemented in a manner not subject to conversion errors in transferring, archiving, or restoring electronic records."	This makes the sentence more concise with focus on the facts, allowing it to be more understandable.	
AdvaMed	5.4	165-168	Replace first sentence with: "System date and time information must be displayed in an unambiguous form.	Current sentence is awkward	
AdvaMed	5.4	174		Remove the word "very" since it's subjective and adds no value.	
AdvaMed	5.4	171-176	Omit the balance of this paragraph beginning with "As we discussed in section 5.3..."	The facts were already stated in section 5.3	

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AdvaMed	5.5	178-182	Change the paragraph to read "Different systems warrant different degrees of precision. Precision of the date and time stamp used should be appropriate to the sequencing requirements of the business process to which the record it is related."	This makes it a more comprehensive document to help include the requirements for manufacturing processes into one's guidance	
AdvaMed	6.	183-203	Delete this entire section.	<p>This section is outside the Purpose and Scope of this Guidance Document.</p> <p>As this section is currently written, the content adds no value and creates potential confusion.</p>	