SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

21 CFR Part 11 Memory Jogger

28-Feb-03

Subpart A-General Provisions	Subpart B-Electronic Records	Subpart C-Electronic Signatures
11.1 Scope***	**11.10 Controls for closed systems**	**11.100 General requirements**
a. – criteria for reliability	a. – validation***	a. - uniqueness
b. –created under records requirements	b. – copies of records***	b. – verification of individual's identity
c. - electronic signatures meet requirements	c. – protection and retention of records***	c. – certification to FDA
d. – electronic records meet requirements	d. – limited access	**11.200 Electronic signature components and controls**
e. – computer systems	e. – computerized audit trails***	a. – non-biometric
	f. – operational system checks	1. – two components
11.2 Implementation	g. – authority checks	i – one reentered for each signing in a session
a. – maintained records	h. – device checks	ii – both reentered for first signing of each session
b. – submitted records	i. – trained users	2. Use by genuine owner only
	j. – written policies to hold signature users accountable	3. Collaboration by two or more
11.3 Definitions	k. – controls over system documentation	b. – biometric
		11.300 Controls for Identification Codes and Passwords
	11.30 Controls for open systems	a. – maintaining uniqueness of ID/password combination
	Confidentiality and additional measures for data integrity	b. – periodic checks/revision
		c. – loss management
	11.50 Signature manifestations	d. – transaction safeguards
	a. –name, date/time, meaning	e. – token testing
	b. – human readable	
	11.70 Signature/record linking	
	Controls to avoid falsification, copying, and assure link integrity	

The items highlighted and asterisked are those directly affected by FDA's Federal Register Notice and Draft Part 11 Scope and Application Guidance issued Feb 2003 when all prior guidance and the compliance policy guide were withdrawn. FDA indicated it will exercise enforcement discretion on these items significantly reducing the burden on industry of this rule while it reexamines it as part of a modernization effort. Detailed explanations are available in a separate training aide to subscribers of SoftwareCPR.com.

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