Performance PerSPECtives

Using Millennium^{®32} Software to Help Comply with the FDA Electronic Records and Signature Rule (21 CFR Part 11)

The FDA Electronic Records and Signature Rule was established by the United States Food and Drug Administration (FDA) and went into effect on August 20, 1997 (See **www fda.gov/ora/compliance_ref/Part11**). The ruling is designed to assist laboratories in the areas of improved data management, simplified regulatory compliance, and increased data security and integrity. A summary of the ruling and suggested action items are presented in Waters[®] Performance PerSPECtive WPP 51 entitled: "FDA Electronic Records and Signature Rule (21 CFR Part 11)".

Waters believes that chromatography management software should provide a complete implementation of the rule in a way that improves rather than reduces laboratory productivity.

This Performance PerSPECtive is designed to summarize how Waters Millennium³² software version 3.2 assists in the creation of an operating environment that helps users comply with FDA Rule 21 CFR Part 11 directives for Electronic Records and Electronic Signatures. For full details, see the Waters white paper "Using Millennium^{®32} software to Help Comply with the FDA Electronic Records and Signature Rule (21 CFR Part 11)" on our Website, and read the Electronic Records and Signature Rule.

Step 1: Setting Millennium³² Software User Account Policies:

Millennium³² software helps users select and use system operating parameters that are necessary for the FDA Rule 21 CFR Part 11 compliance. When implementing the Electronic Records rule, Waters recommends enabling the options marked "(ER)". If implementing the Electronic Signatures rule, Waters recommends enabling the options marked "(ES)". (See Figure 1). This tool eliminates the confusion in configuring and operating the data system to satisfy the FDA's rulings.

Figure 1: Recommended Account Policy Settings for Electronic Record (ER) and Electronic Signature (ES) Implementation

Millennium ²² System Policies ? 🗙			
User Account Policies New Project Policies Other Policies			
Accounts and Passwords			
(ES) 🔽 Enforce Unique User Account Names			
(ES) 🔽 Enforce Unique User Passwords			
(ER/ES) 🔽 Passwords Expire every: 365 days			
(ER/ES) ☑ Limit # of Entry Attempts to: 3 tries			
(ER/ES) 🔽 Enforce Minimum Password Length of: 4 characters			
Login Window Policies			
Don't allow applications to stay running after logging off			
Don't allow <u>m</u> ultiple logons			
(ES) 🗹 Don't allow Auto-Logon			
(ES) I Don't allow use of <u>D</u> S username logon			
If you are implementing FDA Electronic Records, Waters recommends setting the options marked with (ER). If you are implementing FDA Electronic Signatures, Waters recommends setting the options marked (ES).			



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Step 2: Setting Millennium³² Software New Project Policies:

The FDA ruling requires "use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify or delete electronic records". Also, "use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand". Millennium³² software helps users operate in compliance with the FDA ruling.

Step 3: Setting Millennium³² Software Controls for Identification Codes:

The FDA ruling requires that "persons who use Electronic Signatures, based upon use of identification codes in combination with passwords, shall employ controls to ensure their security and integrity". Again, Millennium³² software helps users operate in compliance with FDA Rule 21 CFR Part 11.

Summary:

- 1. FDA Rule 21 CFR Part 11 is designed to improve the quality of manufactured products while preserving the FDA's charter to protect the public.
- Chromatography data management software should assist users in the complete implementation of the rulings in a way that improves rather than reduces laboratory productivity.
- 3. To fully comply with Rule 21 CFR Part 11, organizations that use Electronic Records and Electronic Signatures must possess and adhere to established Standard Operating Procedures (SOPs) that are supported and complemented by the flexibility and functionality of Millennium³² software version 3.2.

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Figure 2: Recommended Project Policies for Electronic Record (ER) and Electronic Signature (ES) Implementation

/lillennium ³² Syst	em Policies		?
User Account Policies	New Project Policies	Other Policies	İ
Full Audit Tra	il Policies		
Default F	ull Audit Trail Settings		
(ER/ES)	Eull Audit Trail Sup	port	
Req	uire User Comments O	n:	
(ER	/ES) 🔽 Method Cha	nges	
(ER	/ES) 🔽 <u>R</u> esult Chan	ges	
(ER	/ES) 🔽 <u>S</u> ample Infor	mation Changes	
(ER/ES) 🔽	Don't allow user to c Trail Support setting	hange <u>d</u> efault Full	Audit
(ER/ES) 🔽	Don't allow user to c User Comments On'		quire
	ng FDA Electronic Rec vith (ER). If you are im		
	ecommends setting the		
	OK	Cancel	Help
	-		_

Figure 3: Additional Policies for Electronic Record (ER) and Electronic Signature (ES) Implementation

Millennium ²² System Policies				
User Account Policies New Project Policie Other Policies				
Data Processing Policies				
Use v3.0X Style Peak Width and Threshold Determination				
Use v2.XX Style Retention Time Calculations				
Prompt User to Save manual changes made in Review				
Result Sign-Off Policies				
(ES) ▼ Sign-Off Inactivity <u>D</u> elay: 10 minutes				
(ES) 🔽 Clear password after Sign-Off				
(ES) 🔽 Enforce Single Logon for Sign-Off				
(ES) 🔽 Allow 'Lock Channels' after <u>Sign</u> -Off 2				
Other Policies				
Use "long" date formats, e.g. Friday, September 10, 1999				
If you are implementing FDA Electronic Records, Waters recommends setting the options marked with (ER). If you are implementing FDA Electronic Signatures, Waters recommends setting the options marked (ES).				
OK Cancel Help				