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)".

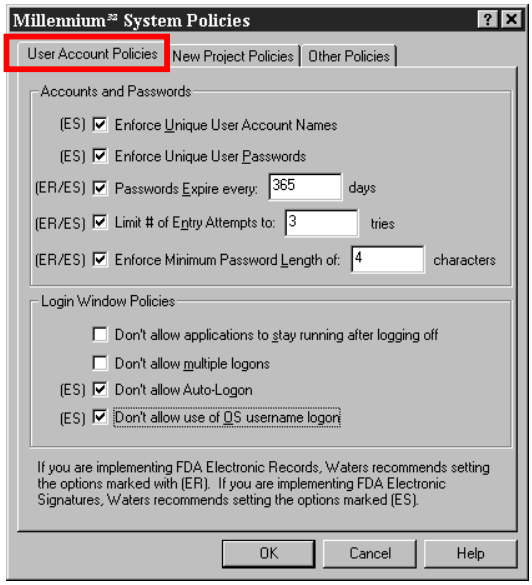
**Waters believes that chromatography management software should provide a complete implementation of the rule in a way that improves rather than reduces laboratory productivity.**

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**




Waters

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**Step 2: Setting Millennium[32] Software New Project Policies:**
The FDA ruling requires "use of secure, computer-generated, time-stamped 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". Millennium[32] software helps users operate in compliance with the FDA ruling.

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

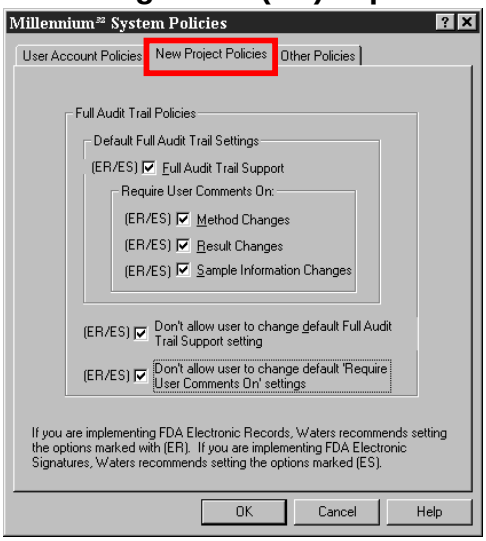
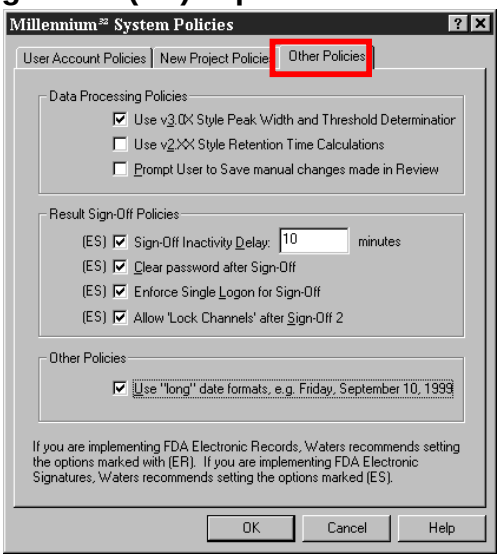



**Figure 3: Additional Policies for Electronic Record (ER) and Electronic Signature (ES) Implementation**




**Step 3: Setting Millennium[32] 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, Millennium[32] 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.
2. 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 Millennium[32] software version 3.2.

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