

# 21 CFR PART 11

## PRODIGY DELIVERS THE COMPLIANCE TOOLS YOU NEED

In 1997, the FDA issued regulations originally designed to qualify the electronic submission of data. These regulations were designed to provide criteria for acceptance of electronic records as equivalent to paper records. Since that time the scope of the regulation has expanded to include most instruments that can maintain an electronic record of results. Similarly, the EPA has introduced CHROMERR (Cross-Media Electronic Reporting and Record keeping Rule) into environmental analyses.



Login

Site Name:  User:  Password:

**User Login Administration**

Add Users

Site Name:

User Name:

Pass Word:

Pass Word Verify:

Level:

Modify Users

User:

Change Pass Word

User:

Pass Word:

Pass Word Verify:

**21 CFR part 11 requires that the instruments employed be able to track the active operators, control their access to sensitive operations and record their activities at the instrument.**

Prodigy satisfies this requirement by demanding the active operators log into the software with a valid password before any further action is permitted.

Further, the system administrator alone has the authority to add new users, de-activate obsolete users, and assign specified user permission levels.



The log-in icon is available at all times after successful login and allows easy transition between active operators.

*Authorized personnel (other than the system administrator) may access the "User Login Administration" panel only to change their password.*

## Audit Trail

**Audit Trail**

Method Selection:	Creation Date	Modify Date	Notes
Test 10	11/07/02	11/07/02	
Hg Lamp	11/06/02	11/11/02	
NaFlies	11/05/02	11/11/02	
GC Test	10/29/02	11/11/02	
Beta 1	07/24/02	11/11/02	Enter notes here
presentation	11/11/02	11/11/02	Here are the notes.

Date	Time	User	Type	Action
10:00:57		Modifier Name	METHOD	Axial Integration Time Axial Peaking Line.
10:06:26		Modifier Name	METHOD	Axial Peaking Line Num of Method Standards.
10:07:02		Modifier Name	METHOD	Update Time Axial Peaking Line.
10:07:07		Modifier Name	METHOD	Axial Peaking Line.
10:09:40		Modifier Name	METHOD	Axial Peaking Line.
10:14:40		Modifier Name	METHOD	Axial Peaking Line.
10:18:56		Modifier Name	METHOD	Axial Peaking Line.
10:22:35		Modifier Name	METHOD	Axial Peaking Line.
10:24:55		Modifier Name	METHOD	Axial Peaking Line.
10:32:28		Modifier Name	METHOD	Axial Peaking Line.
10:41:52		BA	METHOD	
10:43:20		Dave	METHOD	
10:53:54		Dave	METHOD	Sample Integrations
10:53:02		Dave	METHOD	
10:57:55		Dave	METHOD	
11:02:00		Dave	METHOD	
11:06:00		Dave	METHOD	
11:11:40		Dave	METHOD	
11:30:47		Dave	METHOD	
12:25:20		Dave	METHOD	
12:59:50		Dave	METHOD	
13:10:25		Dave	METHOD	
13:43:53		Dave	METHOD	
20:49:27		Dave	METHOD	

Parameter	Value	Parameter	Value
Pump	1.0	Peak X	542
Flow	5.0	Peak Y	494
Coil	18	Align	true
Prob	32	Width	15
Power	1.1	Height	3
Axial Time	60.0	LB(X)	3
Extra Name Time	0	LB(Y)	1
Flow Rate	300	Peak	8
Update Time	30	Peak W	3
Logging	true	RB(X)	13
Cal Status	1	RB(Y)	1
Axial Peaking Line	Mn		
Stds	4		
Std Repts	1		
Emp Repts	+3		
Lines	7		
Method Line:	Cu 324.7		
Method Line:	As 193.0		
Method Line:	Co 214.4		
Method Line:	Fe 253.8		
Method Line:	Mn 257.6		
Method Line:	Zn 213.8		
Method Line:	Ba 454.4		

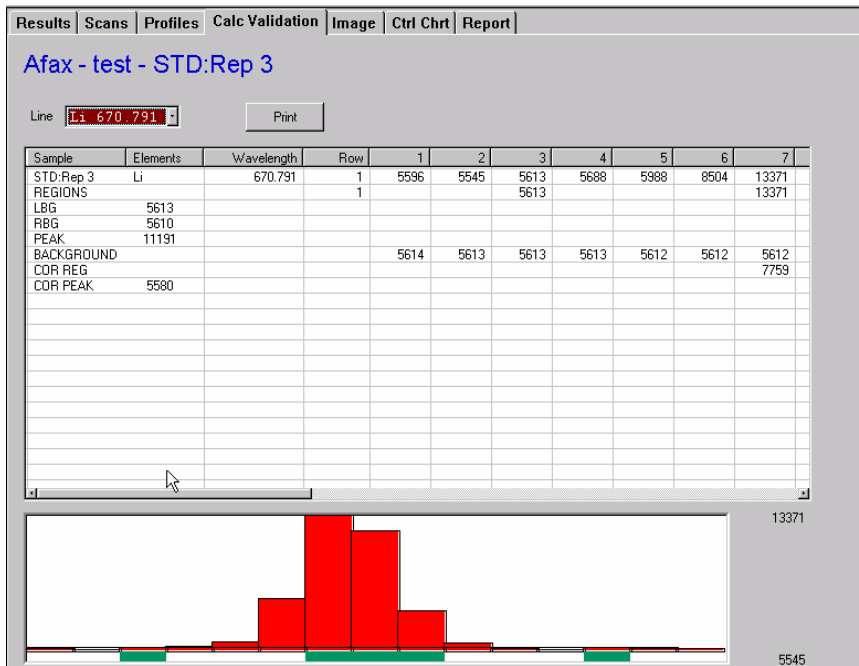
*Recent changes are identified with asterisks for easy recognition.*

**All actions and instrument conditions must be recorded in an audit trail.**

Prodigy offers an audit trail sorted by method.

- Once a method name is selected, all of the analyses for that method appear chronologically.
- Highlighting an analysis block (see highlight to left) displays a snapshot of all of the method parameters active at that time.
- Subsequently, selecting an analytical line reveals all of the information for the data acquired at that line.

# Calculation Validation



**21 CFR part 11 requires that the ability to regenerate reported data from the raw data**

Prodigy software offers a Calculation Validation display for every analytical reading.

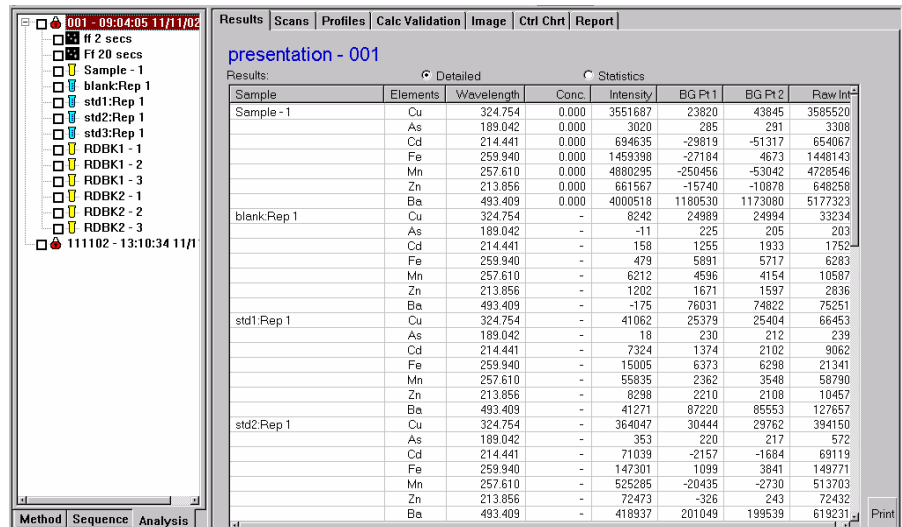
- This display shows the raw data for each analytical wavelength.
- The peak and background locations.
- Peak and background intensities.
- Background correction.

**21 CFR part 11 requires that results not be deleted.**

Prodigy automatically saves the results for every analytical measurement.

- Each measurement name is added to an analysis tree which documents the chronological order of events.
- Replicate details appear in the results display.
- Removal of results is not permitted.

Prodigy CFR Part 11 software provides all the tools necessary to keep your electronic records in compliance.



**For more information on regulatory compliance tools, please contact us at 603-886-8400 or visit [www.LeemanLabs.com](http://www.LeemanLabs.com).**