

XLReporter Security Features for 21CFR Part11

Overview

21CFR Part11 is a FDA regulation on electronic records and electronic signatures. This defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records.

The following document highlights the security features of **XLReporter** that can help satisfy this regulation.

Security Features

The following security features are available:

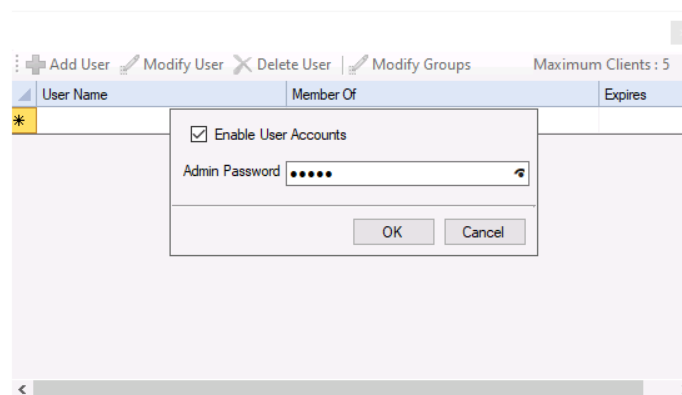
- User Accounts
This restricts the capabilities of specific users.
- Access Security
This restricts access to templates and reports.
- Audit Trail
This maintains a log of user activity including configuration changes and electronic signatures.
- File Version Control
This archives configuration files when changes are made. Versioning is applied and rollback is available.
- Electronic Signatures (eSignatures)
This applies electronic signatures to completed reports.

User Accounts

User accounts can be used to restrict the capability of a user based on credentials.

User accounts can be defined as part of the project, in the **Project Explorer**, under the **Project** tab by selecting **User Accounts**.

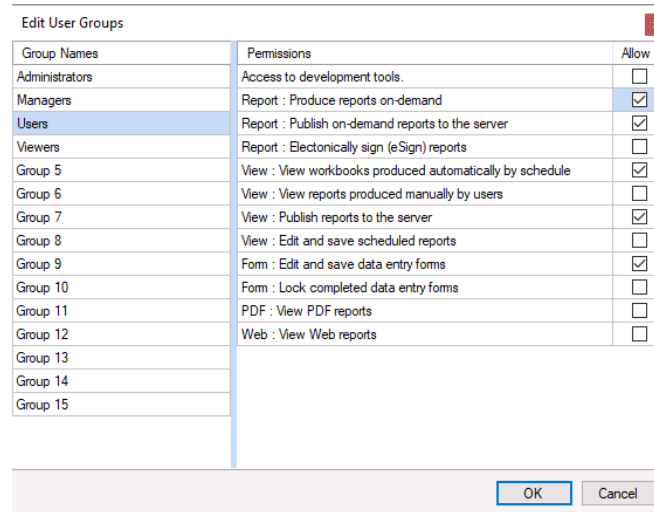
By default user accounts are not enabled so the first time this is accessed, you are prompted to **Enable User Accounts** and to set an **Admin Password**.



Once enabled, whenever this application is opened you will be prompted for the **Admin Password**.

User Groups

Each user belongs to a group. The group defines the capabilities for each user belonging to it. Click **Modify Groups** to access groups.



Group Names	Permissions	Allow
Administrators	Access to development tools.	<input type="checkbox"/>
Managers	Report : Produce reports on-demand	<input checked="" type="checkbox"/>
Users	Report : Publish on-demand reports to the server	<input checked="" type="checkbox"/>
Viewers	Report : Electronically sign (eSign) reports	<input type="checkbox"/>
Group 5	View : View workbooks produced automatically by schedule	<input checked="" type="checkbox"/>
Group 6	View : View reports produced manually by users	<input type="checkbox"/>
Group 7	View : Publish reports to the server	<input checked="" type="checkbox"/>
Group 8	View : Edit and save scheduled reports	<input type="checkbox"/>
Group 9	Form : Edit and save data entry forms	<input checked="" type="checkbox"/>
Group 10	Form : Lock completed data entry forms	<input type="checkbox"/>
Group 11	PDF : View PDF reports	<input type="checkbox"/>
Group 12	Web : View Web reports	<input type="checkbox"/>
Group 13		
Group 14		
Group 15		

By default the following groups are defined:

- Administrators
- Managers
- Users
- Viewers
- Group 5 – Group 15

Except for **Administrators**, the name of every other group listed can be changed by double-clicking on the name and entering the name you want.

Each available permission is listed on the right with a checkbox to allow or disable the permission for the group.

Users

There is no limit to the number of users that can be configured for the project. To define a new user, click the **Add User** button.

The **Member of** setting defines what **Group** the user belongs to.

If **eSignature** is enabled for the user, the **Signature Name**, **Title** and **Signature Image** will appear on any report when signed by this user. Please note that this option is only enabled if the user is a member of a group that has the **Report: Electronically sign (eSign) reports** privilege.

The **Pin Code** is used to verify the user when they attempt to electronically sign a report.

When electronic signatures are applied to a report one or more roles can be defined for the process. A user can be assigned a specific role or assigned **All** roles. The following roles are available:

- Accept
- Review
- Approve

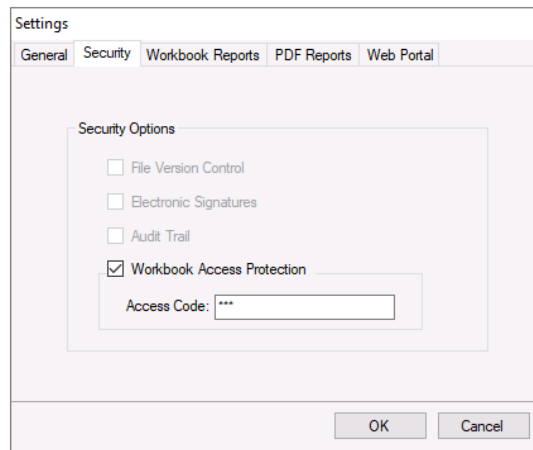
Log On/Off

Once user security is enabled you will have to log in to the **Project Explorer** otherwise virtually no application will be accessible.

Access Security

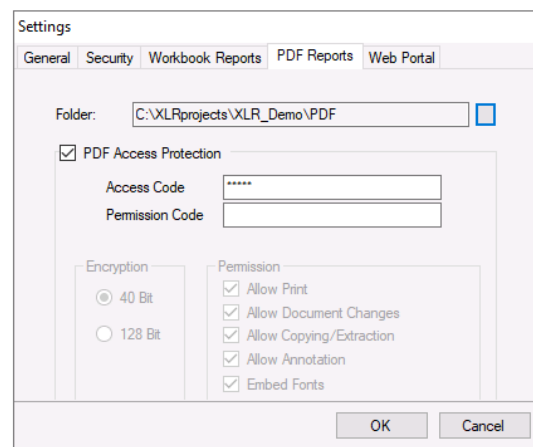
Access security is used to protect templates and the reports that are generated from them. By default there is no restriction on opening templates and reports for viewing and editing. Once access security is enabled, users will be prompted to enter a password to access.

Access security is enabled in the **Project Explorer** under the **Project** tab by clicking **Security**.



To enable, check **Workbook Access Protection** and enter an **Access Code**. This code will now be required to open either a template or a report.

To protect PDF reports, select the **PDF Reports** tab.



Check the **PDF Access Protection** option and apply an **Access Code**.

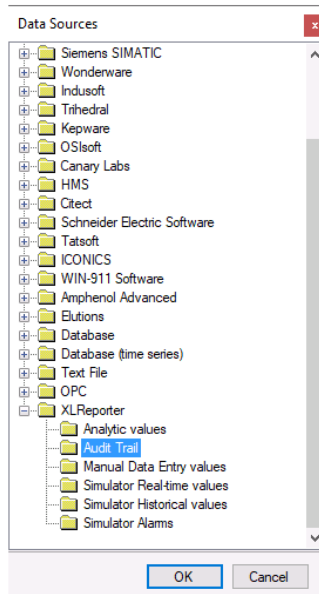
Audit Trail

The audit trail maintains a log of user activity on configuration changes and electronic signatures. This requires the Audit Trail connector to be defined in the project.

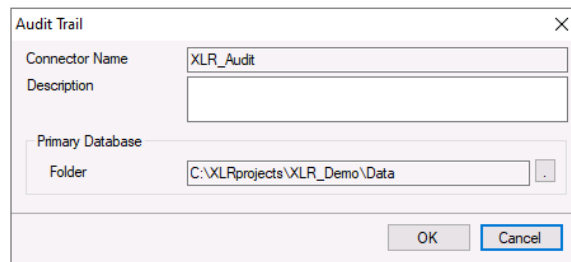
Audit Trail Connector

Connectors are accessed in the **Project Explorer**, under the **Data** tab by clicking **Connectors**.

A new connector is created by clicking the **Add** button.



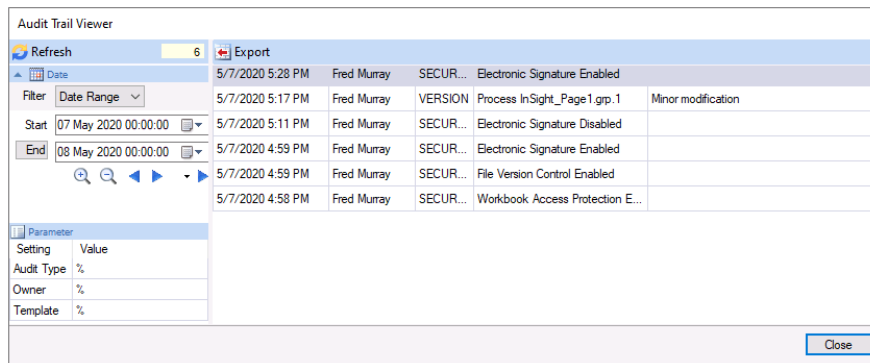
The **Audit Trail** connector is available under the **XLReporter** folder.



The **Folder** defines where the audit trail database will be stored. By default this is set to the *Data* folder of the project and in most cases should not be changed.

Viewing the Audit Trail

The audit trail can be viewed at any time from the **Project Explorer**, under the **Home** tab by clicking **Audit**.

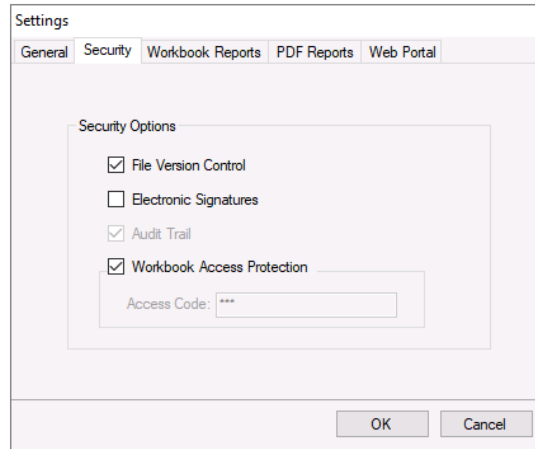


To view, specify a time period and some filters and then click **Refresh** to view items recorded in the audit trail.

File Version Control

File version control archives configuration files with versioning and the option to rollback. This also provides an audit trail of configuration changes along with the user who made the change.

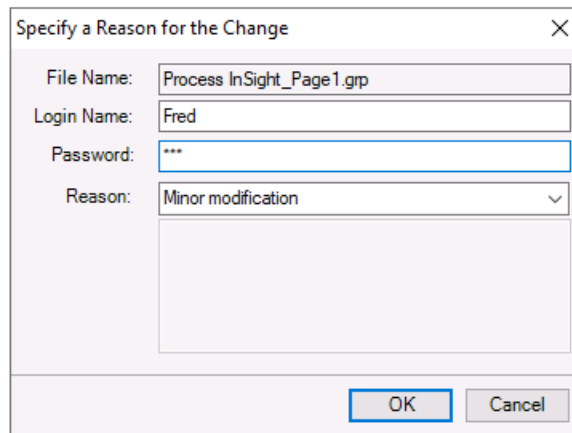
Version control is enabled from the **Project Explorer** under the **Project** tab by clicking **Security**.



Check **File Version Control** to enable.

Apply Version Control

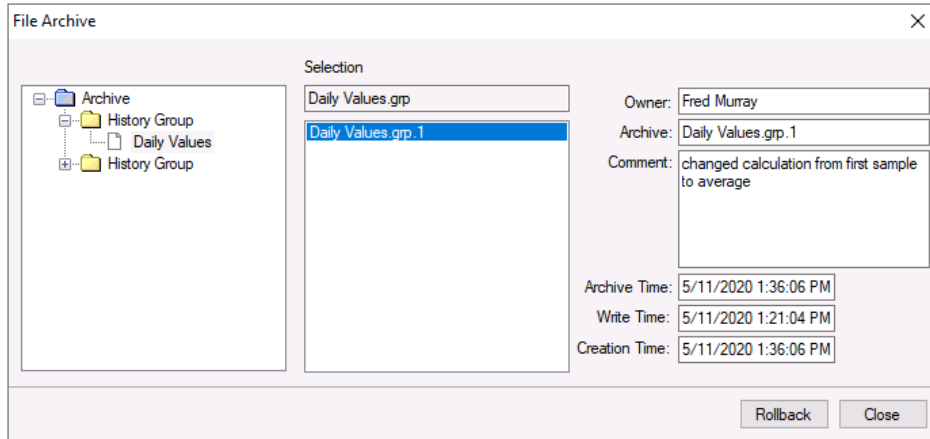
Once enabled, whenever the configuration of a template, data group or schedule is changed, a prompt appears to specify a reason as to why this change is happening.



This action is now stored in the audit trail.

View the File Archive

The file archive can be viewed with the **File Archive** viewer which can be opened from the Project Explorer under the Tools tab by clicking File Archive.



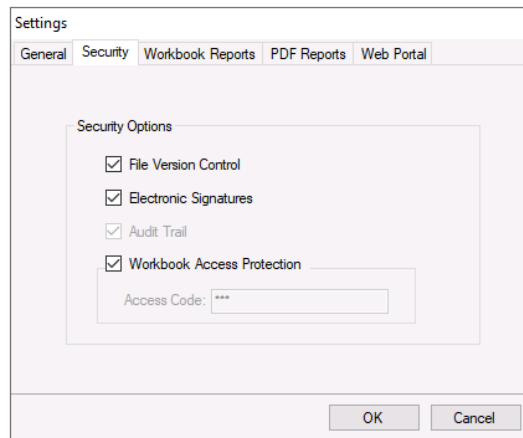
On the left side is a list of all the configuration files that have been archived. Once selected, the archived versions of that file are listed in the middle. When a specific archive is selected, the details from the audit trail when that file was archived are displayed on the right.

To rollback to an archived version of the file, click the **Rollback** button.

Electronic Signatures

Electronic signatures are a mechanism that allows users to review and accept completed reports by applying one or more eSignatures to report documents.

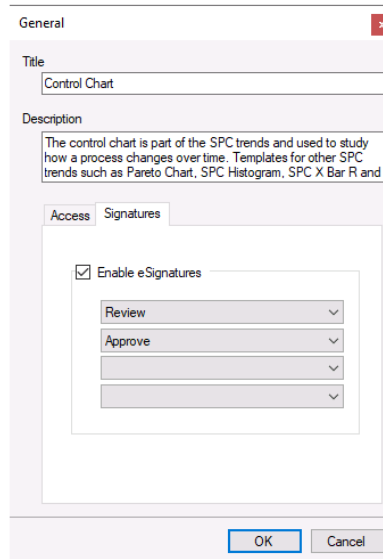
Electronic signatures are enabled in the project by accessing **Security** from the **Project Explorer** under the **Project** tab.



Check **Electronic Signatures** to enable.

Add Electronic Signatures to a Template

Electronic Signatures are added to a template in the **Template Design Studio** by clicking **General**.



Under the **Signatures** tab, check **Enable eSignatures**. Up to four roles can be added for the template.

Now any report automatically generated from the template through the schedule will now require electronic signatures.

Sign a Report

Reports are signed using the **Workbook Report Viewer** either on the local machine or on a Windows Team client.

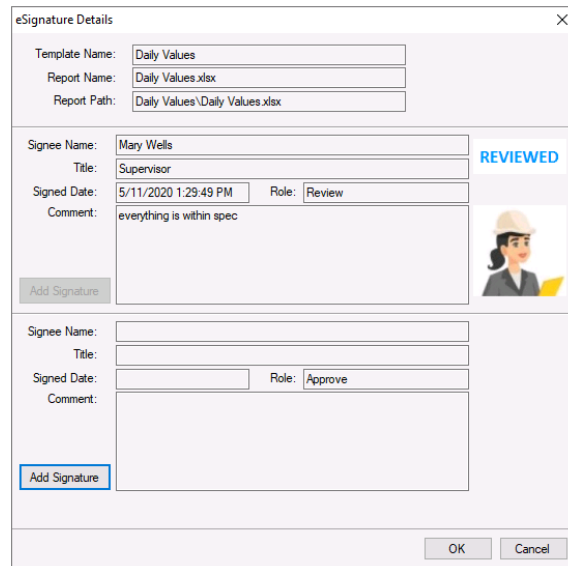
When the report is selected to view, the signature banner appears at the top indicating the current state of the signatures for the report.

Date/Time	Mixer zone 1 temperature	Mixer zone 2 temperature	Mixer speed (RPM)	Mixer ram pressure	Extruder zone 1 temperature	Extruder zone 2 temperature	Extruder speed pellets
5/10/20 0:00	75.52	75.52	30.52	82.93	55.51	75.52	70.52
5/10/20 1:00	77.75	83.47	41.81	73.69	57.16	87.47	82.94
5/10/20 2:00	78.82	89.03	41.19	64.92	59.77	93.03	71.96
5/10/20 3:00	22.00	35.00	43.57	59.66	45.00	77.41	81.24
5/10/20 4:00	76.00	77.23	43.20	59.77	56.46	78.02	80.87
5/10/20 5:00	77.41	77.41	45.47	65.19	55.86	82.87	83.13
5/10/20 6:00	70.00	79.78	43.99	74.04	57.63	85.24	81.66
5/10/20 7:00	76.00	79.44	49.59	83.23	59.49	84.90	76.71
5/10/20 8:00	76.85	82.34	56.59	89.54	50.00	87.80	83.72
5/10/20 9:00	77.34	81.96	55.88	90.77	59.15	87.42	83.01
5/10/20 10:00	40.00	78.33	53.87	86.49	57.99	78.16	81.00
5/10/20 11:00	78.26	78.75	41.00	78.20	57.81	78.58	75.78
5/10/20 12:00	16.00	90.04	42.78	68.79	57.58	89.87	77.56
5/10/20 13:00	80.24	89.62	49.77	61.55	56.56	89.45	84.55
5/10/20 14:00	78.50	76.92	44.74	59.01	57.02	77.88	79.52
5/10/20 15:00	78.54	86.48	49.23	62.05	55.99	87.44	84.01
5/10/20 16:00	76.38	88.53	51.00	69.62	57.44	89.48	70.71
5/10/20 17:00	76.00	81.58	41.48	79.07	56.60	82.53	76.45
5/10/20 18:00	76.68	82.18	42.42	87.09	56.61	83.14	77.39
5/10/20 19:00	76.85	91.10	44.26	90.90	58.51	92.05	79.23
5/10/20 20:00	22.00	04.22	62.62	89.15	60.70	22.00	77.70

The banner states are:

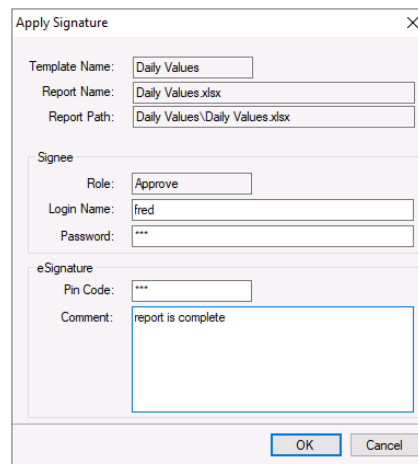
- Red no signatures have been applied
- Yellow signatures have been partially applied
- Green signatures are complete

To add a signature to the report, in the banner, click **Details**.



The 'eSignature Details' dialog box is divided into two main sections. The top section shows a completed signature for 'Mary Wells', a Supervisor, who reviewed the report on 5/11/2020 at 1:29:49 PM. A 'REVIEWED' badge and a small profile picture of Mary Wells are visible. The bottom section is for adding a new signature, with fields for Signee Name, Title, Signed Date, Role (set to 'Approve'), and Comment. An 'Add Signature' button is highlighted in blue. At the bottom right are 'OK' and 'Cancel' buttons.

This dialog shows all the signature roles required and which signatures have already been applied. Click **Add Signature** to add.



The 'Apply Signature' dialog box contains fields for Template Name, Report Name, and Report Path, all pre-filled with 'Daily Values'. Below this is a 'Signee' section with 'Role' set to 'Approve', and fields for 'Login Name' (filled with 'fred') and 'Password' (filled with '***'). The 'eSignature' section has a 'Pin Code' field (filled with '***') and a 'Comment' field (filled with 'report is complete'). 'OK' and 'Cancel' buttons are at the bottom right.

If the user logged in has the role indicated then the **Login Name** and **Password** are filled in. Otherwise they are not so a user name with this role must be specified.

The **Pin Code** must be specified to verify the user and a comment can be added.

Publish a Report

Any time after the report is signed, it can be published as a PDF file. This is done in the **Workbook Report Viewer** by clicking the **Publish Report** button.

The report is published with a signature certificate included. The signature certificate can be customized to fit your needs.

To do so, open certificate.xlsx from the *_library* folder of the installation (e.g., *C:\XLReporter*).

When published, the **Signatures** worksheet from this workbook is copied to the report workbook. The eSignature information is written as a single row in the named cell **Certificate_Data** which by default is $SB\$39$.