Create Project With 21 CFR 11 Compliance

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES).

Overview

Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records.

Listed below are described some security-related features available in the product:

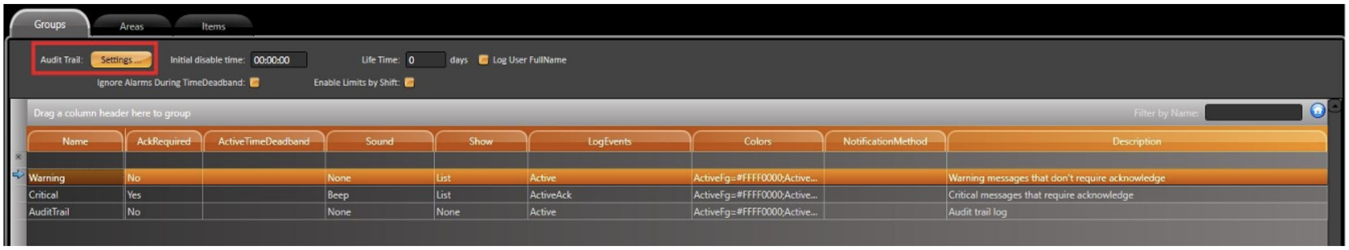
- **Access Control**: Security technique that regulates who or what can view or use resources in a computing environment.
- **Password Encryption**: System administrator does not possess access to the user. They are encrypted before being stored.
- **Maximum and Minimum Age for Password**: A feature that imposes a minimum password age before allowing it to change and a maximum age before expiring.
- **Required Password changing**: Forces the user to alter his password after the first login has been made.
- **User Name and Password Minimum Length**: Defines username and the password's minimum length.
- **Block on Invalid Login Attempt**: Blocks User if maximum number of invalid login attempts have been made.
- **Store Password History**: A range of the last 0-5 passwords can be stored to make sure the user does not repeat an already used one.
- **Auto Log Off**: User is logged off the system for inactivity or expiration date.
- **Audit Trail Data**: Security-relevant chronological record or set of records that provide documentary evidence of the sequence of activities that have affected at any time a specific operation.

Project Configuration

Audit Trail

Audit trails should be generated independently of the operator and include the local date and time of the actions that alter the record. They cannot overwrite the old data, and they must be stored as long as the record itself is stored.

To use the Audit Trail function, you must enable it. Go to **Edit** > **Alarms** > **Groups**, and click on the Settings button.



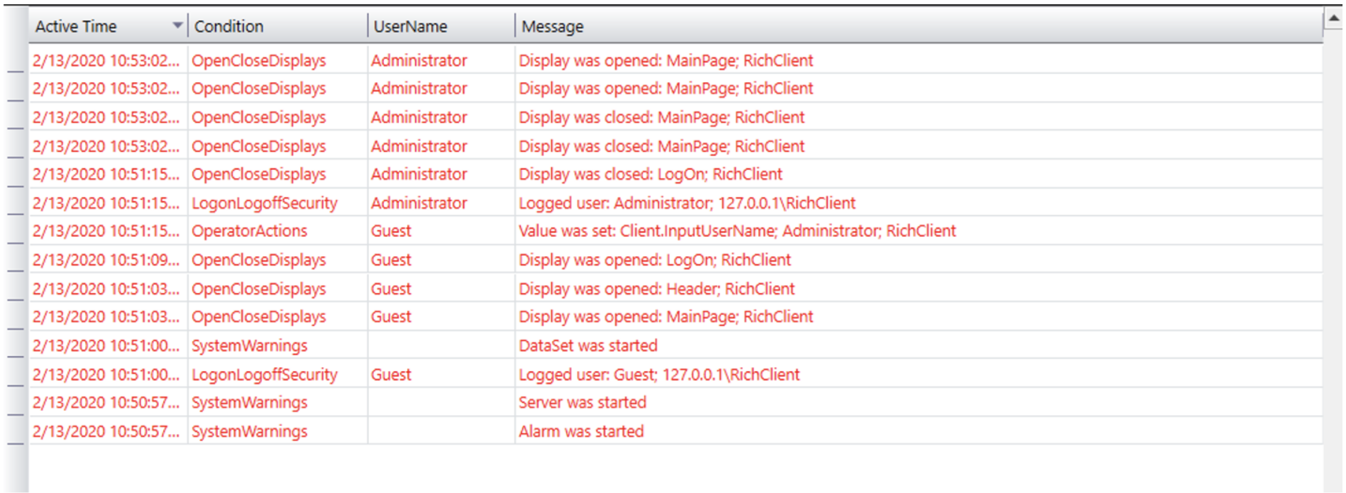
Audit Trail: Settings ... Initial disable time: 00:00:00 Life Time: 0 days Log User FullName
Ignore Alarms During TimeDeadband: Enable Limits by Shift:

Name	AckRequired	ActiveTimeDeadband	Sound	Show	LogEvents	Colors	NotificationMethod	Description
Warning	No		None	List	Active	ActiveFg=#FFFF0000;Active...		Warning messages that don't require acknowledge
Critical	Yes		Beep	List	ActiveAck	ActiveFg=#FFFF0000;Active...		Critical messages that require acknowledge
AuditTrail	No		None	None	Active	ActiveFg=#FFFF0000;Active...		Audit trail log

A popup display will open with many checkboxes. Besides the Enable option, you can choose which actions will be stored in the Audit Trail database. The options are as follows:

- **User Logon/Logoff**: Stores informational data on user login/logout.
- **Open/Close Displays**: Stores informational data when displays are open or closed.
- **Remote Connections**: Stores information on remote client connections (Smart/Rich Clients).
- **Custom Messages**: Stores added custom messages.
- **Tag Changes**: Stores informational data of every tag change.
- **Datasets (Insert/Updates or All Commands): Stores information on datasets.**
- **Operator Actions**: Stores information on operator actions.
- **Save Reports**: Stores information when the save command is executed.
- **System Warnings**: Stores information related to the system.

For every project update indicated above, crucial information is stored alongside the event info in the Alarm Historian database columns:



Active Time	Condition	UserName	Message
2/13/2020 10:53:02...	OpenCloseDisplays	Administrator	Display was opened: MainPage; RichClient
2/13/2020 10:53:02...	OpenCloseDisplays	Administrator	Display was opened: MainPage; RichClient
2/13/2020 10:53:02...	OpenCloseDisplays	Administrator	Display was closed: MainPage; RichClient
2/13/2020 10:53:02...	OpenCloseDisplays	Administrator	Display was closed: MainPage; RichClient
2/13/2020 10:51:15...	OpenCloseDisplays	Administrator	Display was closed: LogOn; RichClient
2/13/2020 10:51:15...	LogonLogoffSecurity	Administrator	Logged user: Administrator; 127.0.0.1\RichClient
2/13/2020 10:51:15...	OperatorActions	Guest	Value was set: Client.InputUserName; Administrator; RichClient
2/13/2020 10:51:09...	OpenCloseDisplays	Guest	Display was opened: LogOn; RichClient
2/13/2020 10:51:03...	OpenCloseDisplays	Guest	Display was opened: Header; RichClient
2/13/2020 10:51:03...	OpenCloseDisplays	Guest	Display was opened: MainPage; RichClient
2/13/2020 10:51:00...	SystemWarnings		DataSet was started
2/13/2020 10:51:00...	LogonLogoffSecurity	Guest	Logged user: Guest; 127.0.0.1\RichClient
2/13/2020 10:50:57...	SystemWarnings		Server was started
2/13/2020 10:50:57...	SystemWarnings		Alarm was started

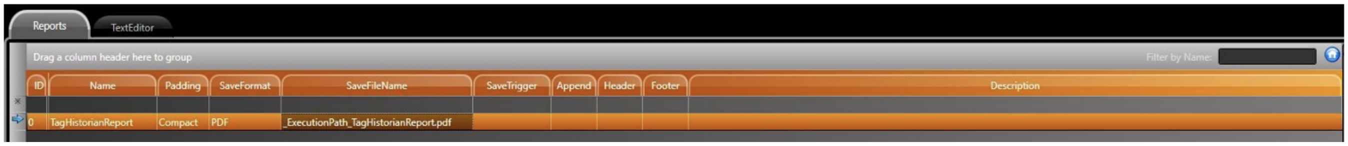
- **UserName**: Indicates the user that was logged in at the time an event happened.
- **ActiveTime Ticks**: Date and time in which the event happened. It’s worth mentioning that despite this data being stored as Ticks in the database, the product is smart enough to automatically convert it to DateTime when it shows on a Display.
- **Message**: Detailed information on the event. It changes according to the event.
- **Condition**: Indicate which Audit Trail selection field the event came from.

Exporting Reports

To comply with the regulation, the software must be able to export digital and physical copies of Reports.

To create or edit a report:

- Go to **Edit** > **Reports** > **Reports**
- Select a report name or select the insert row (first row)
- Enter or select information, as needed



ID	Name	Padding	SaveFormat	SaveFileName	SaveTrigger	Append	Header	Footer	Description
0	TagHistorianReport	Compact	PDF	_ExecutionPath_TagHistorianReport.pdf					

- **Name**: Enter a name for the report. The system will let you know if the name is not valid.
- **Padding**: Use padding when replacing a tag name with its value (the field starts with enough space for the same number of characters as the tag name):
  - Compact — Removes any extra characters and displays only the tag
  - PadRight — Adds an extra space for each character to the right of the tag
  - PadLeft — Adds an extra space for each character to the left of the tag
- **SaveFormat**: Selects the report format: XPS, HTML, Unicode, ASCII, PDF
- **SaveFileName**: Enter a string with *{*ObjectProperties*}*. Use the full path
- **SaveTrigger**: Enter an object property as the trigger
- **Append**: Enter the file that appends the report
- **Size**: The size of the report
- **EditSecurity**: Check which user groups can edit the report
- **Header**: Choose another report as the Header
- **Footer**: Choose another report as the Footer
- **Legacy**: Read-only. Shows if the report is a legacy
- **Description**: Enter a description of the report

It is possible to add several runtime objects to a Report. Some examples are:

- Tag values and properties.
- Client and Server property information.
- Symbols (TrendCharts are added as a symbol).
- Tables and DataGrids can be dynamically colored and translated according to the project’s localization setting.

The Report is saved using one of the following methods:

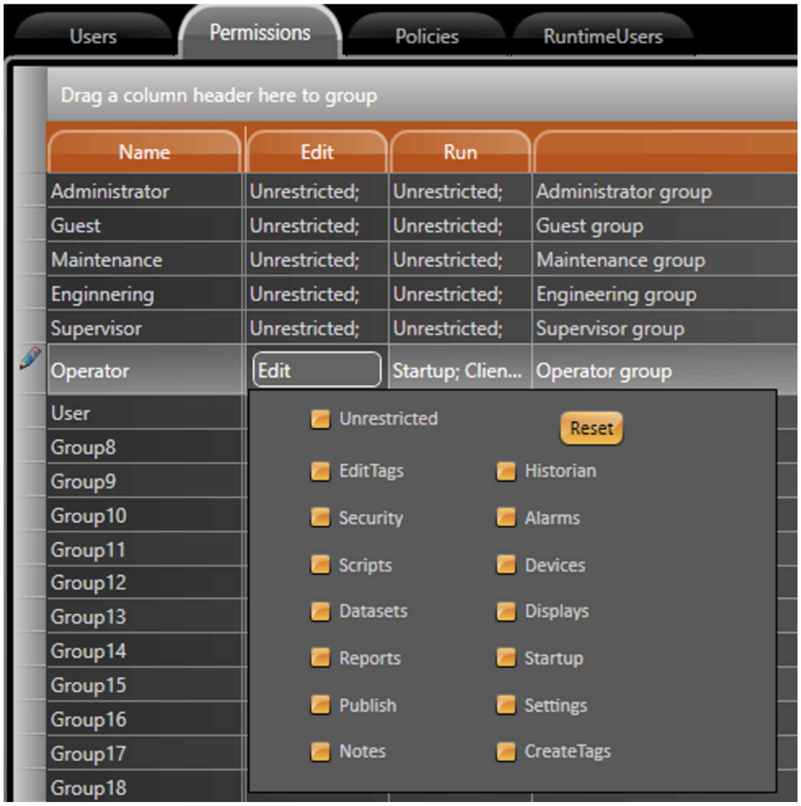
```
@Report.<ReportName>.Save
// Property used to trigger the save report action

@Report.<ReportName>.SaveCommand(int Orientation)
// Orientation = 0 or blank -- Portrait Mode
// Orientation = 1 -- Landscape Mode
// saves the selected report into the path indicated by the SaveFileName property
```

Security

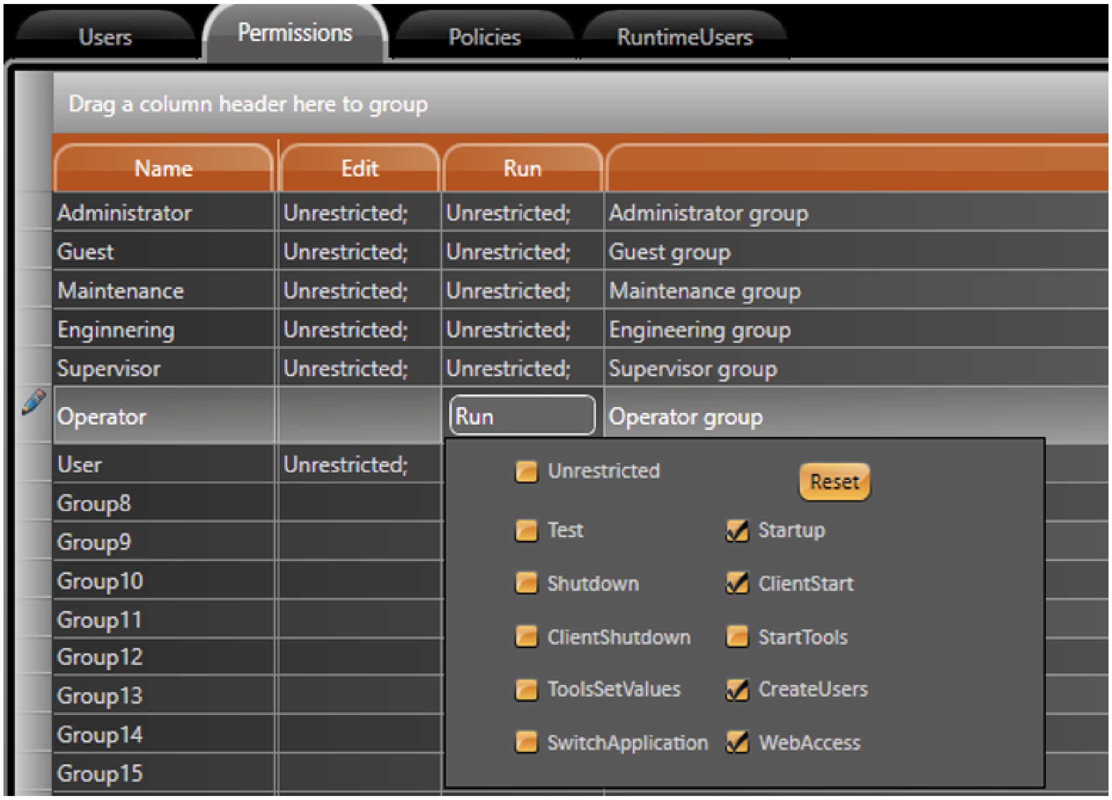
User Permissions

Under ***Security*** > ***Permissions***, it is possible to allow/disallow a user to edit different project tabs in the Engineering Environment. The available options are shown in the image below.



Name	Edit	Run	
Administrator	Unrestricted;	Unrestricted;	Administrator group
Guest	Unrestricted;	Unrestricted;	Guest group
Maintenance	Unrestricted;	Unrestricted;	Maintenance group
Enginnering	Unrestricted;	Unrestricted;	Engineering group
Supervisor	Unrestricted;	Unrestricted;	Supervisor group
Operator	Edit	Startup; Clien...	Operator group
User			
Group8			
Group9			
Group10			
Group11			
Group12			
Group13			
Group14			
Group15			
Group16			
Group17			
Group18			

It is also possible to allow/disallow a user to perform different actions during Runtime.



Name	Edit	Run	
Administrator	Unrestricted;	Unrestricted;	Administrator group
Guest	Unrestricted;	Unrestricted;	Guest group
Maintenance	Unrestricted;	Unrestricted;	Maintenance group
Enginnering	Unrestricted;	Unrestricted;	Engineering group
Supervisor	Unrestricted;	Unrestricted;	Supervisor group
Operator		Run	Operator group
User	Unrestricted;		
Group8			
Group9			
Group10			
Group11			
Group12			
Group13			
Group14			
Group15			

☐ Unrestricted

☐ Test ☑ Startup

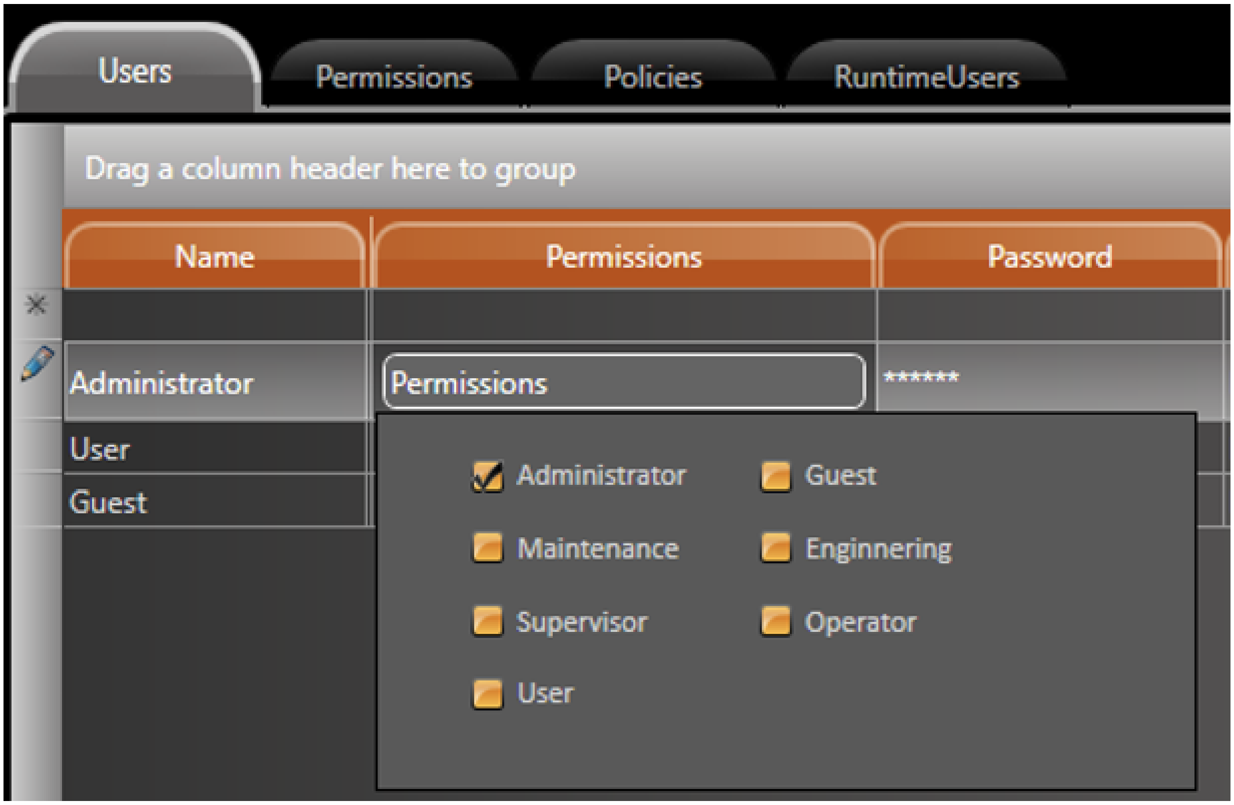
☐ Shutdown ☑ ClientStart

☐ ClientShutdown ☐ StartTools

☐ ToolsSetValues ☑ CreateUsers

☐ SwitchApplication ☑ WebAccess

To apply a created permission to a user, go to ***Security*** > ***Users (Permissions Columns)***, and select the desired option.



Name	Permissions	Password
Administrator	Permissions	******
User		
Guest		

☑ Administrator ☐ Guest

☐ Maintenance ☐ Enginnering

☐ Supervisor ☐ Operator

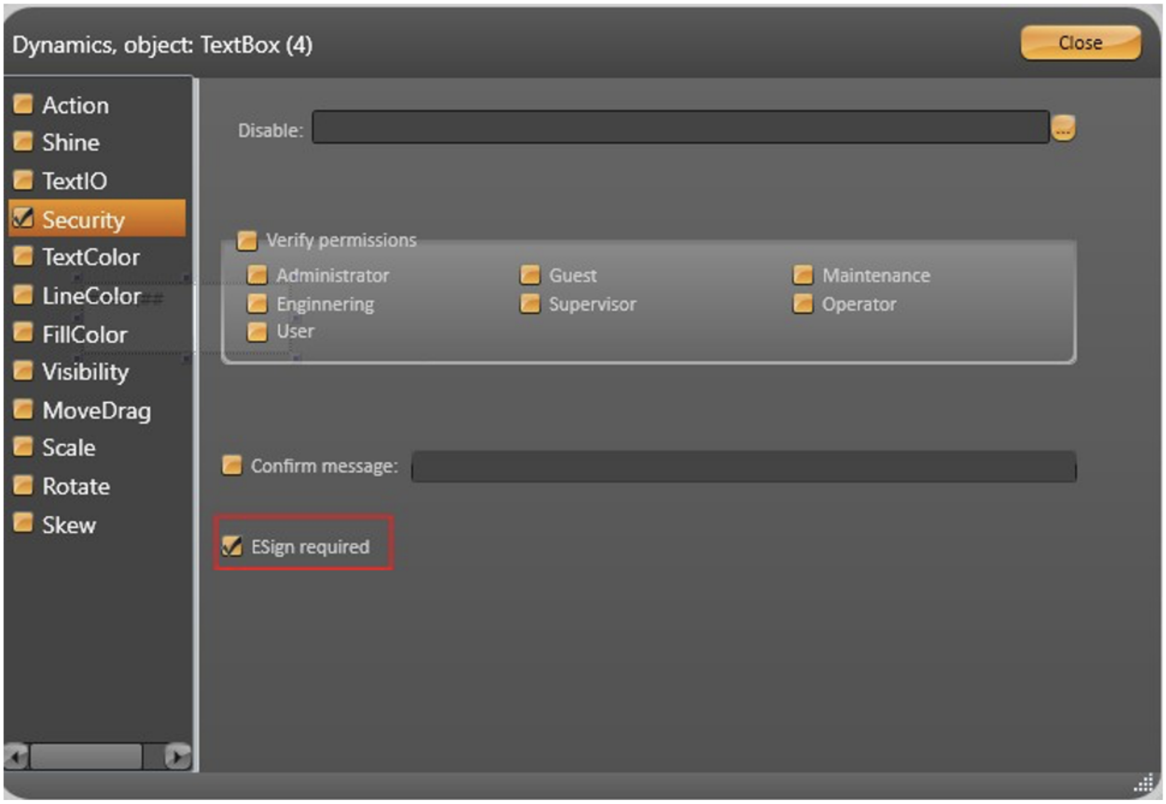
☐ User

2.3.1 User Policies

Under ***Security*** > ***Policies***, there are three main configuration columns that can be important for CFR 11 compliance.

- **Identification**: Contains several password configuration options, detailed below:
  - **Allow Password Change**: Indicates if a user, other than an administrator, can change its own password.
  - **Password Min Length**: Minimum character length for password (0 means no restrictions).
  - **Block On Invalid Attempts**: Maximum number of login attempts before blocking user (0 means no restrictions).
  - **Allow Share User**: Indicates if user can be shared between stations.
  - **UserName Min Length**: Minimum character length for username (0 means no restrictions).
  - **Password History**: Remember last passwords (Range: 0-5).
  - **Min Password Age**: Minimum password age in hours (0 means no restrictions).
  - **Max Password Age**: Maximum password age in hours (0 means no restrictions).
  - **Block Aging**: Maximum blocking age in hours (0 means no restrictions).

- **ESign**: When enabled, a password will be requested for Action Dynamics with eSign. The password remains valid for a specified timeout time (in minutes).



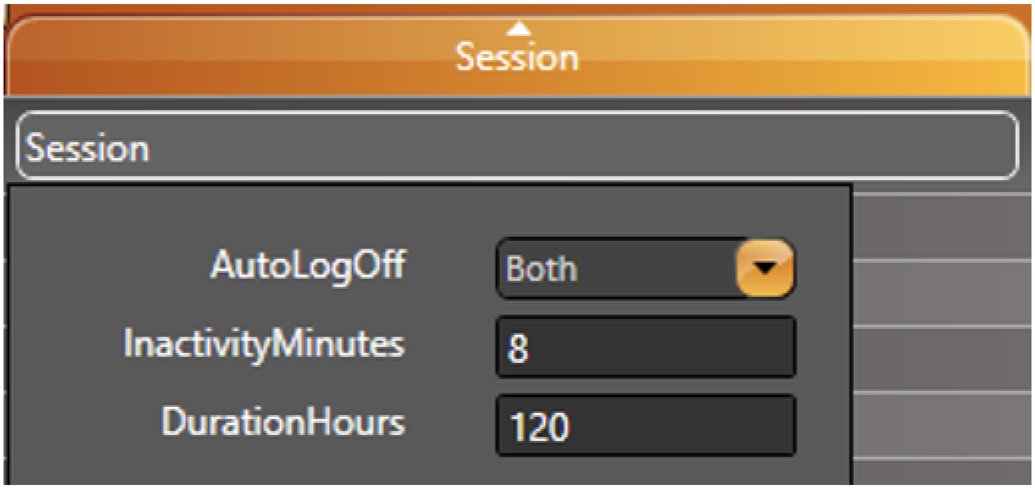
Disable:

□ Verify permissions
□ Administrator □ Guest □ Maintenance
□ Enginnering □ Supervisor □ Operator
□ User

□ Confirm message:

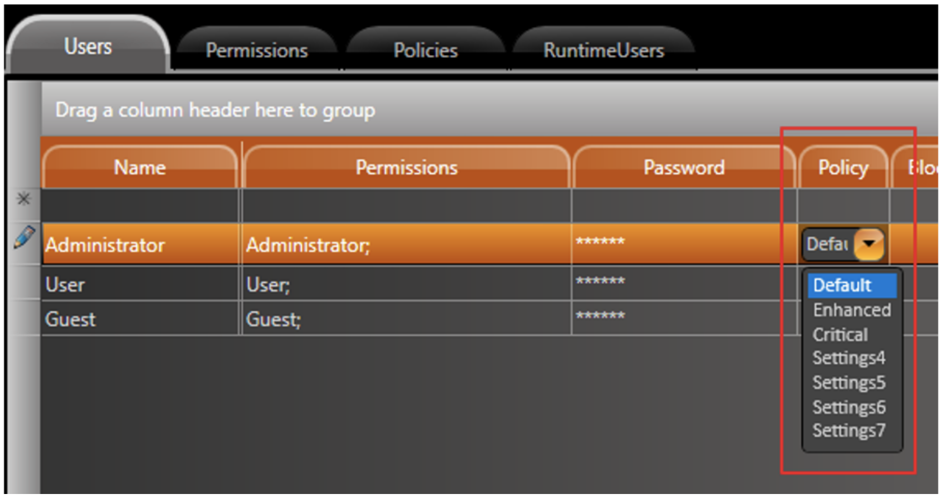
☑ ESign required

- **Session**: User can be logged off according to a determined Inactivity Time (in minutes) and/or after a maximum session duration (in hours).



AutoLogOff: Both
InactivityMinutes: 8
DurationHours: 120

To apply a created session configuration to a User, go to ***Security*** > ***Users (Policies Columns)***, and select the desired option.



Name	Permissions	Password	Policy	Bloc
Administrator	Administrator;	******	Defau	
User	User;	******		
Guest	Guest;	******		

Runtime Users

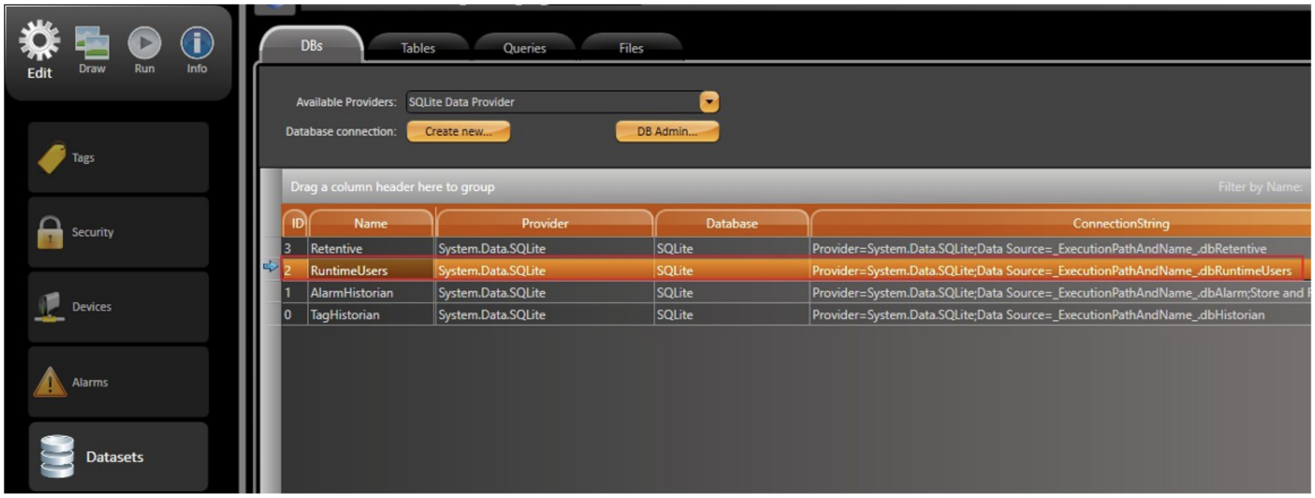
This is a type of user that exists only during an application's Runtime period. The user can be created during the Engineering process (in ***Security*** > ***RuntimeUsers***) or during runtime (via code).

Below you can find more details regarding the available RuntimeUser methods in the Security namespace.

```
@Security.NewRuntimeUser(string name, out int errorCode)
// Creates a new RuntimeUser
//  name:  User  Name
// errorCode: Error code (output)
// Returns: String containing the error message (if error) or empty (if not error)

@Security.AddRuntimeUser(string name, string permissionsStr, string password, string passwordHint, string
policyStr, string profilePhone, string profileCompleteName, bool oneTimePassword)
// Add Runtime User
//  name:  User  Name
// permissions Str: Permissions
// password: Password
// passwordHint: Password hint
// policyStr: Policy
// profileEmail: Profile email
// profilePhone: Profile phone
// profileCompleteName: Profile complete name
// oneTimePassword: flag (true or false) to set a One Time Password setting. If true, a password change is
required after first login
// Returns: String containing error message (if error) or empty (if not error)
```

The RuntimeUsers are stored in its own database found at ***Databases*** > ***DBs***.



Available Providers: SQLite Data Provider

Database connection:

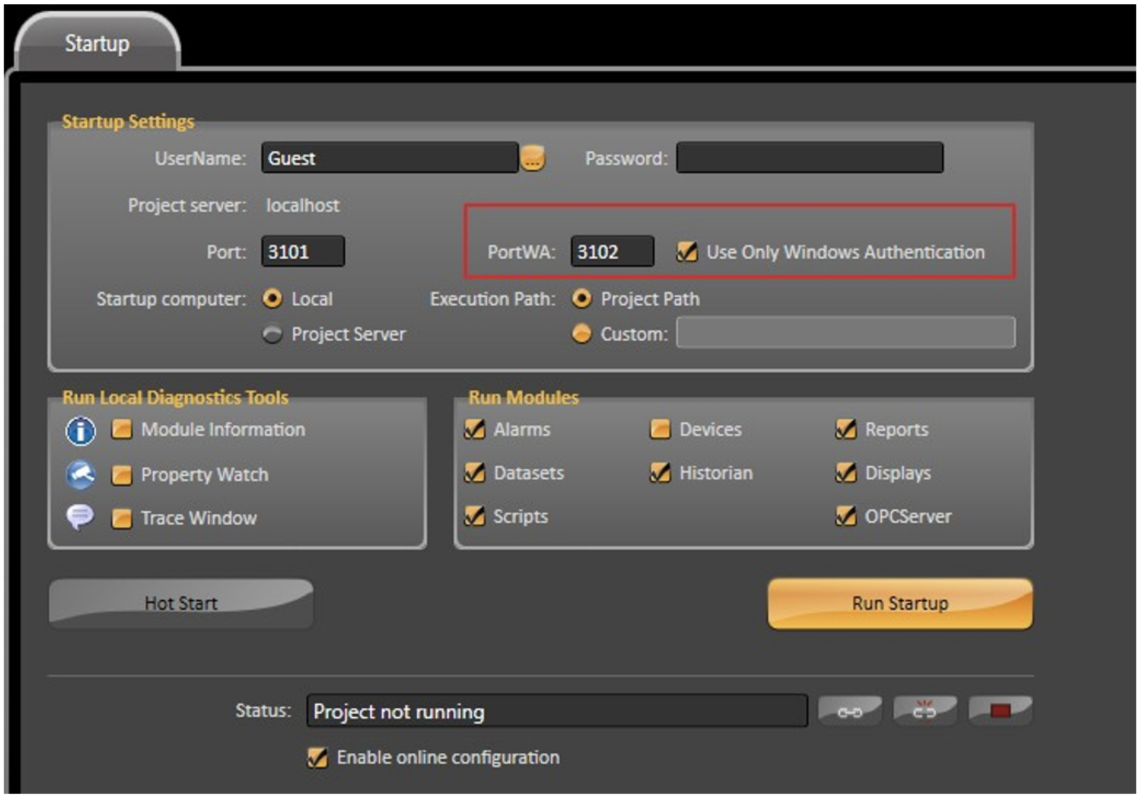
Drag a column header here to group

Filter by Name:

ID	Name	Provider	Database	ConnectionString
3	Retentive	System.Data.SQLite	SQLite	Provider=System.Data.SQLite;Data Source=_ExecutionPathAndName_.dbRetentive
2	RuntimeUsers	System.Data.SQLite	SQLite	Provider=System.Data.SQLite;Data Source=_ExecutionPathAndName_.dbRuntimeUsers
1	AlarmHistorian	System.Data.SQLite	SQLite	Provider=System.Data.SQLite;Data Source=_ExecutionPathAndName_.dbAlarm;Store and F
0	TagHistorian	System.Data.SQLite	SQLite	Provider=System.Data.SQLite;Data Source=_ExecutionPathAndName_.dbHistorian

Windows Authentication

To use Windows Authentication, select the checkbox '***Use only Windows Authentication***' in ***Run*** > ***Startup*** and configure which port will be used for authentication in PortWA.



Startup Settings

UserName: Guest Password:

Project server: localhost

Port: 3101 PortWA: 3102 ☑ Use Only Windows Authentication

Startup computer: ● Local ○ Project Server

Execution Path: ● Project Path ○ Custom:

Run Local Diagnostics Tools

□ Module Information
□ Property Watch
□ Trace Window

Run Modules

☑ Alarms ☐ Devices ☑ Reports
☑ Datasets ☑ Historian ☑ Displays
☑ Scripts ☑ OPCServer

Status: Project not running

☑ Enable online configuration

In this case, you will use the configured users for the Active Directory login. If the windows OS has the same name that was created in ***Security*** > ***Permission***, the application will use the permissions configured for this user. Otherwise, it will use the permissions for the Guest user.