Meeting FDA CFR Part 11 Requirements using QW6

Quality Window 6
The continuous improvement software

The US Federal Drug Administration (FDA) requirements under the regulation 21 CFR part 11 states all manufacturers of regulated brands must comply to these standards. Meeting these requirements for Quality Window Applications involves employing several features available in the standard version of the product.

They are:

- Use of the Protected setting for a variable when data is coming from a measuring device like a scale or automation data sources like PLC's.
- Creating a Security Database based on User Id's and Passwords for assigning individual user capabilities.
- Controlled access to the QWAdmin module to restrict access to Application maintenance and User security settings.
- Setting access restrictions for functions like Add, Edit, Delete of data for individual users and applications.
- Enabling Transaction Logging for all changes to application data (add, Edit, Inset, Copy and Delete) as well as all updates to Application templates such as Limit and Control Rule changes, addition, movement, and deletion individual variables. These transaction logs include User Identification, Workstation, Module as well as data and time of the action.
- Provide Transaction Log Viewers to review all updates to applications especially for regulated applications.

Use of a Protected setting for a Variable:

This is a very useful setting when the data should not be changed once collected. This could be data coming from a device like a scale and having the data unaltered is important for tracking the data such as in the case of a regulated brand.

Variable Details	
Variable Number	11
Variable Name	Weight_Lane 1_(gm)
Field Type	Numeric
Length	4
Decimals	1
Maximum Value	99.9
Upper Specification Limit	☐ Calc
Upper Control Limit	🟥 Fixed 7.7
Upper Warning Limit	☐ Calc
Target	🟩 Fixed 6
Lower Warning Limit	☐ Calc
Lower Control Limit	🟥 Fixed 4
Lower Specification Limit	☐ Fixed 2.05
Minimum Value	-9.9
Calculate Limits Based On	Population
Limits Centered On	Fixed Target
Active Rules	USL,LSL,UCL,LCL,3dn,3up,5up,5dn,7up,7dn
Required	No
Protected	Yes

To set a variable as Protected it is done using the QWAdmin Maintain Applications feature. On the Variable definition screen there is a setting for Required? Select Yes and the option is enabled. Once enabled the value for this variable cannot be changes in the Add or Edit screens. Using the Input/Output files feature is how the value can be placed in a variable. The value of the Input file would be set based on the source of the data Example a Scale or PLC tag value.

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Limiting access to the QWAdmin module:

Access to the QWAdmin module as well as individual functions can be set for Admin type users. These are:

- Access to Admin module
- Managing Security
- Manage Applications
- Access to the QWSpecManager

Creating a Security Database:

This is done in the QWAdmin by selecting the Security Administrator Icon. Using this module, you can define and edit Users including their individual permissions and Authentication requirements. The User ID Identifier will be used to log any actions performed in the transaction log.

Note: Passwords are encrypted and can not be viewed or recovered once set.
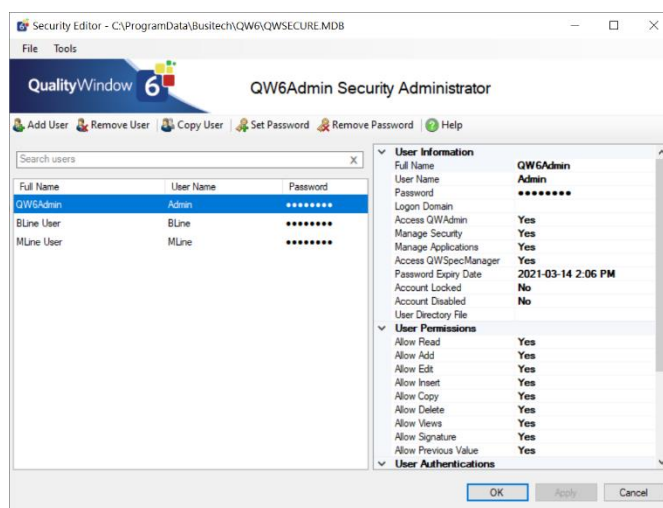
Setting access restrictions for functions like Add, Edit, Delete of data:

Using the QWAdmin Maintain Applications then selecting the General Inforamtion tab the Security restrictions can be set for individual Applications. Once set here it will require a User to enter a valid user Id and password to perform that function.

The Views setting will limit access to the Views Manager in the application which would mean a user would not be able to change or create Views without a valid User Id and Password.

In addition, there is an option to select a variable in the application to store the User Id that performed the
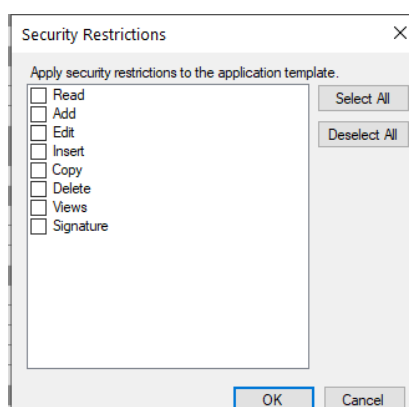
action that security was set for.

The User Id will also be stored in in the transaction log for the application.
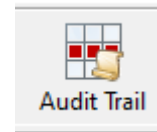
Transaction logs in QW6

A very important requirement to meet the 21 CFR part 11 requirements is to document every time the data has been updated. In QW6 Transaction Log are automatically created for each application.

The transaction log file name is assigned in the QWAdmin – Maintain Applications – General Screen. By default, it is the name of the application with a .LOG extension.

If you do not define a location for the file it will be placed in the same directory as the QW Application resides in.

Viewing the Application Data Audit Trial:

There is an Icon on the top of the QW6 Workstation screen for selecting to view the Audit trail for an application.

The Transaction Log Viewer listing the transactions recorded for each Add, Edit, and Delete action that were made to the data in chronological order. The date and time at the start of record is when the record was originally created and the date and time at the right end of the record is when the transaction was processed.

QWLogView - Process Monitoring Example

File   Edit

WARNING: Items listed in the Transaction Log window are constrained by the current Filter settings for this View.

	Date	Time	Auto Shift Id	Shift	Team	Team Leader	Batch Number	Batch Viscosity	Conveyor Speed (fpm)	Oven Temp. (F)	Weight Lane 1 (gm)	Weight Lane 2 (gm)
	YYYY-MM-DD V1	hh:mm:ss V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12
⊞	2020-03-16	20:13:22	20	3:30p to 11:30p	30-C Team	Ray	1325		141	387	6	6.1
⊞	2020-03-16	21:11:41	20	3:30p to 11:30p	30-C Team	Ray	1325	966	144	370	6	5.9
⊞	2020-03-16	22:12:01	20	3:30p to 11:30p	30-C Team	Ray	1325		140	345	6.6	6
⊞	2020-03-16	23:12:21	20	3:30p to 11:30p	30-C Team	Ray	1325	803	127	407	5.8	6.4
⊞	2020-03-17	08:14:28	10	7:30a to 3:30p	10-A Team	Fred	1327		135	357	6.1	6.5
⊞	2020-03-17	09:14:40	10	7:30a to 3:30p	10-A Team	Fred	1328	859	135	357	6.1	6.5
⊞	2020-03-17	10:15:24	10	7:30a to 3:30p	10-A Team	Fred	1328		143	377	6.7	6.1
⊞	2020-03-17	11:15:44	10	7:30a to 3:30p	10-A Team	Fred	1328	927	155	319	6	7.2

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In Addition to the data the log also contains:

- Action
- Source Module
- Computer Name
- Username
- Process Id
- Version of QW6.

The **Application Change Transaction log** can be viewed in QWAdmin - Maintain Applications - Open an Application and selecting the Change Log Tab (.LOG)

There is also a **Message Log** for each application that is Editable but the user who makes changes to an application. Update the QWAdmin generated changes to be a more readable format and outline the changes made and what important items to note like Specification changes or new variables added. (.QWM)