38. Administrative Tool & Part 11

38.1 Introduction

Historically, QC-CALC Real-Time has been used within an individual inspection machine as a single copy of software. Each person controlled and adjusted QC-CALC's operation individually. As networks became more prevalent, the inspection devices were connected to the network making data movement easier. This created the need to control the individual copies of QC-CALC running throughout the shop from a central location.

The **Administrative Tool** helps the Quality Department set up and control every copy of QC-CALC within the entire company. This tool can be activated and used from any of the QC-CALC copies on the network.

In addition, the medical supply companies must satisfy FDA title 21 Code of Federal Regulations (CFR21 Part 11) Electronic Records; Electronic Signatures, as it applies in a medical manufacturing environment. A special section has been added to this document which describes how QC-CALC can be configured to help you meet the requirements of Part 11.

38.2 Setup and Installation Instructions

38.2.1 Introduction

There are several installation options for QC-CALC. You can install the standard QC-CALC.You can use a System Management Server such as **Microsoft's** SMS or **Altiris'** Service-Oriented Management solution. Both of these programs can be used to install multiple copies of QC-CALC throughout your company at the same time. By using our batch file commands, you can run these installations in silent mode or allow the user to see the installation on their local screen.

38.3 Silent Install

The installation of QC-CALC (Administrative Copy) can be automated to a point where no questions are asked. Optionally, you can run the install in a silent mode where no screens are displayed. This type of installation requires a batch file that contains instructions to tell QC-CALC what to do and how to do it.

Normally, this type of automated installation is used in companies where the IT department "rolls out" the installation from a central server. This type of install reduces time and increase control in physically large companies.

You can use a System Management Server such as **Microsoft's** SMS or **Altiris'** Service-Oriented Management solution. Both programs can be used to install multiple copies of QC-CALC throughout your company at the same time. By using our batch file commands, you can run these installations in silent mode or allow the user to see the installation on their local screen.

Note: In all cases, an installation screen will appear briefly during the installation process. Following this, a progress bar will be displayed. This is meant as a visual cue that the install is taking place.

38.4 Setup Batch File

38.4.1 The Batch File Location

The batch file needed to automate QC-CALC's installation should be located on a shared server that is accessible to all shop floor PCs.

38.4.2 The Batch File Contents

The batch file consists of one line starting with the server path and the install .exe followed by optional arguments. The following shows the contents of an example file called QCCALC41.BAT. Keep in mind this is one long command even though it appears on multiple lines. All arguments are separated by (;) semi-colons with no extra <spaces>.

If you omit any of the arguments below, the corresponding installation screen will appear asking the user to provide this information.

```
S:\Prolink_Install\QCCALCDemo41.EXE /silent;
destinationpath=C:\Program Files (x86)\Prolink\QC-CALC 4.1\;
adminpath=H:\SPC\Admin\;usergroup=Operator;username=Bruce;
companyname=My Co.;plsserver= Prolink1;plsport=5928;
plspassword=;theme=Office 2010 Style;activationpref=RT
```

Batch File Command Item	Comments
S:\Prolink_Install___.EXE	Name of the install file downloaded from the Prolink website. Must be followed by a <space> and /silent.
/silent;	If this switch is present, the installation process is not visible on the target PC. If this switch is omitted, the InstallShield screen is displayed and someone will have to click the installation wizard's **Next >** button to continue the setup. The answers to the wizard's questions would be filled in by the contents of the batch file but you should include the **/silent** switch.
destinationpath=____;	This is the installation path where QC-CALC will be installed in the CMM or gaging station. You can change it to whatever path you desire. The default path is: `C:\Program Files (x86)\Prolink\QC-CALC 4.1\`

adminpath=H:\SPC\Admin\;	This is the folder used to control all QC-CALCs in your facility. All common settings are stored here. You should standardize on the location by using a batch file like this one.
usergroup=Operator;	This command sets the active user group when the installation is complete. This command will work if you set up one copy of QC-CALC on your desktop PC and created this user groups first.
username=Bruce;	Sets the user name into QC-CALC. This name appears on some reports.
companyname=My Co.	Sets the company name into QC-CALC. This name appears on some reports.
plsserver=Prolink1	This is the server name where Prolink License Server (PLS) is installed. No slashes or drives, just the server name.
plsport=5928	This is an internal value and is defaulted to 5928.
plspassword=	An optional password set in the PLS program. The passwords must match. This prevents uncontrolled installations.
theme=	You can specify the Theme to be used by QC-CALC. The value entered here must exactly match an item from the list in the **Tools > Options > Global > Themes** area.
activationpref=RT e.g. activationpref=CALC activationpref=RT activationpref=SPC activationpref=GS	QC-CALC has an additional activation preference flag called **activationpref**. Possible values for the activationpref are: QC-CALC Enterprise (SPC & RT) QC-CALC Real-Time only QC-CALC SPC only GageStation (QC-CALC Real-Time & QC-Gage)

Note: adminpath and **usergroup** only apply to QC-CALC and QC-Gage installations.

38.5 Manage User Groups

For simplicity reasons, QC-CALC does not save administrative settings at the user level. Instead, groups are created with default settings and locked from being changed. Copies of QC-CALC are then assigned to these groups. It is not necessary to log in as a particular user in order to obtain your group settings since groups are assigned at the PC level. It is assumed that all users using a particular PC are in the same group. This form of security was chosen because QC-CALC runs without human intervention. It is critical not to interrupt data collection due to login errors.

Note: Individual user id/password combinations are assigned to individual persons for Part 11 related activities such as auditing and the digital signing of reports. Please see the CFR21 Part 11 Considerations section on page 259 for details.

38.6 Create User Groups

After enabling the **Administrative Tools** menu, **User Groups** need to be created.

1. To access the **User Group Manager**, select the **Administrative Tools > Manage User Groups** menu and enter your password
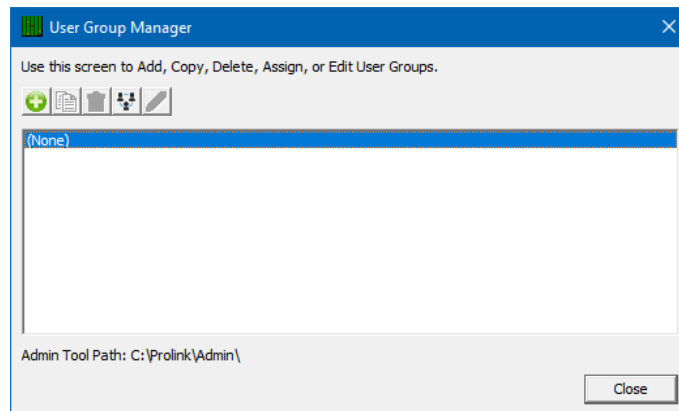
2. To create a new user group, click the **Add** button. The screen below will appear describing the process involved in the screens following.
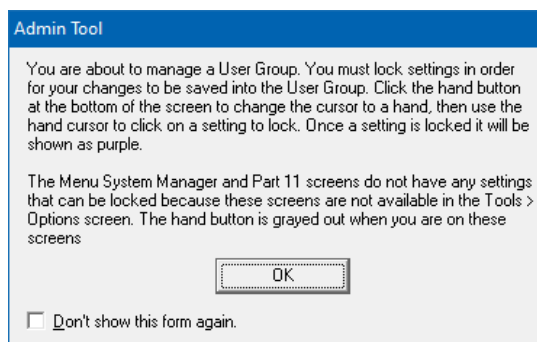
3. Enter a name for the User Group you want to create. For our examples below we entered **CMM Users**.
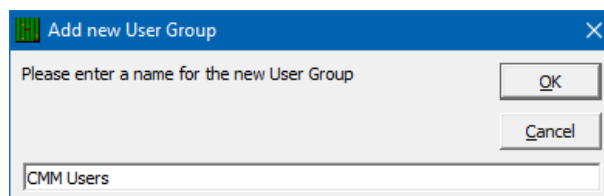
4. To configure the settings that you want the computers in your group to follow, select your group from the list and click the **Manage Group** button.
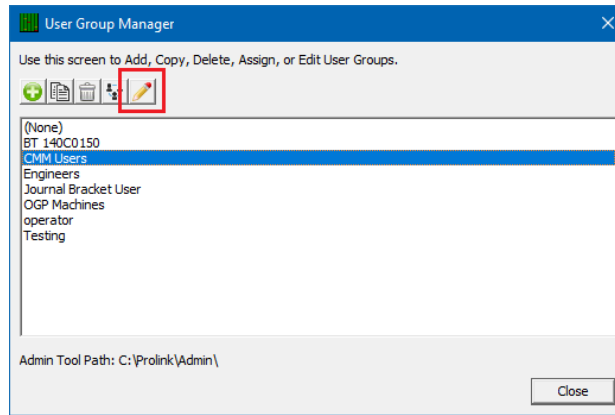

38.6.1 Manage Group

The **Manage Group** button is used to set the configurations applied to all computers within a group and therefore establish the look and feel of each QC-CALC in the group.

Select Common Settings

The **Settings** screen when managing user groups is similar to the **Tools** > **Options** screen. There is an additional **Hand** button at the bottom of the window and two additional items in the list on the left labeled **Menu System Manager** and **Part 11**. To lock a setting, change any option to the desired value, click the Hand button, and click the option. The option becomes purple which indicates it cannot be changed by the user.
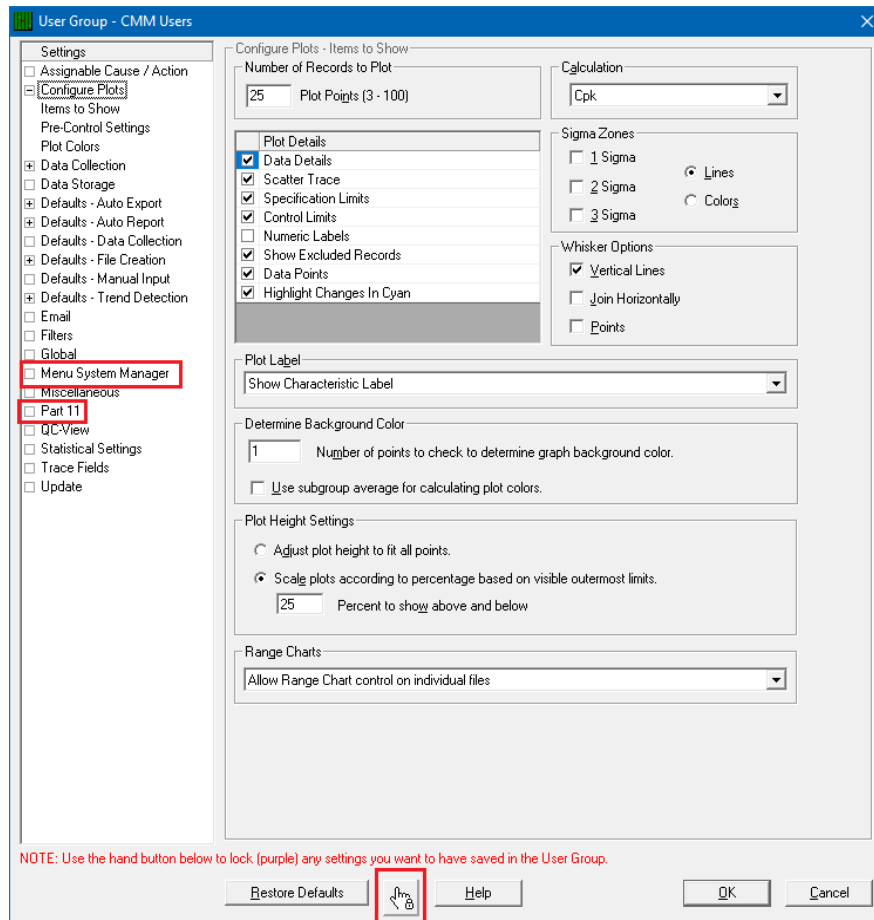
Lock the Settings

When the **Hand** button is depressed and you float the mouse over any option, the item is temporarily outlined with a purple square. Clicking on the item while the purple square is shown causes the item to turn fully purple indicating it is locked.
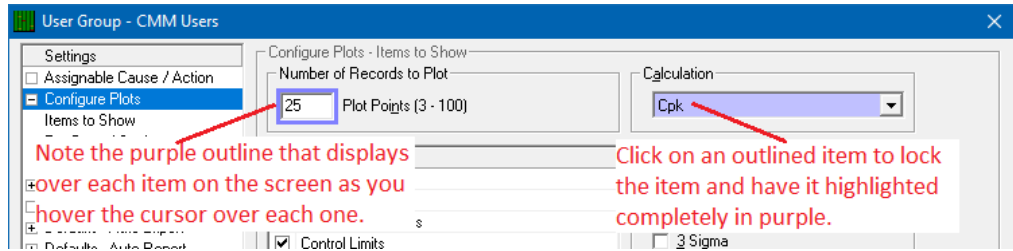

Note: Any file settings needing global access such as Assignable Causes, Corrective Actions, Filters, and the Update location should be set so that all computers use the same files. This ensures the entire company uses the same settings. You set these items in this configure window.

The Hand Button

Change all settings to values that make sense for your company and use the **Hand** button to lock all values you want restricted from the Group.
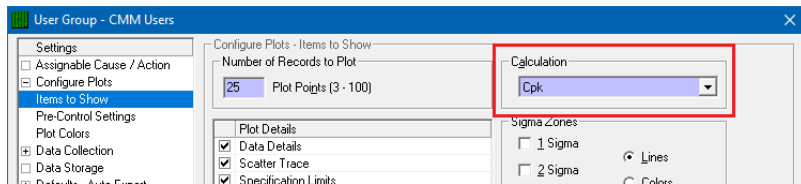
In this example the **Calculation** was set to **Cpk** and then locked so all computers in the group display the Cpk value in the lower left corner of each plot. The computers in the Group cannot change this setting since you locked it.

TIP: By default, the **Hand** button stays depressed allowing you to select many items until you click the Hand button again.

Menu System Manager

All menus can be disabled and/or checked from the **Menu System Manager** in the **Manage Options** screen. There is no need to use the Hand button on this particular screen. Simply check the box in the **Disabled** column for the menus you want to disable for the particular group you're currently editing.

You may also disable or enable an entire subcategory of menu items by checking the box on lines for main categories such as File, Properties, View, etc.
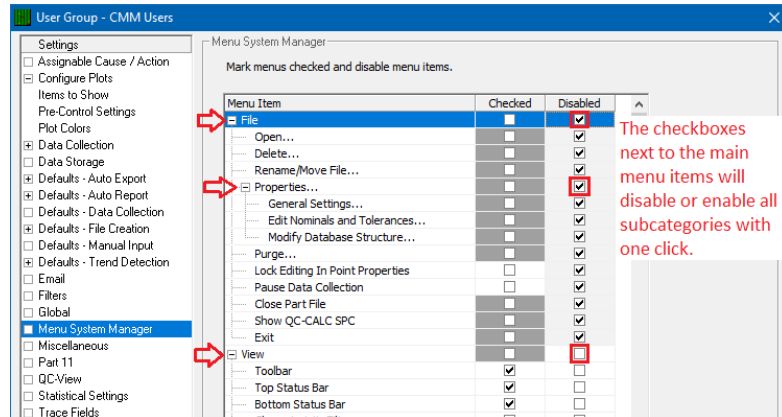
In the picture below, the **File > Exit** menu was disabled. With this setting, a user hitting the X button will be prompted to enter a password to exit the program. Additionally **View > Bottom Status Bar** was checked (so that status bar will be displayed), and **View > Point Properties** was checked to be displayed and disabled so no one can shut it off.
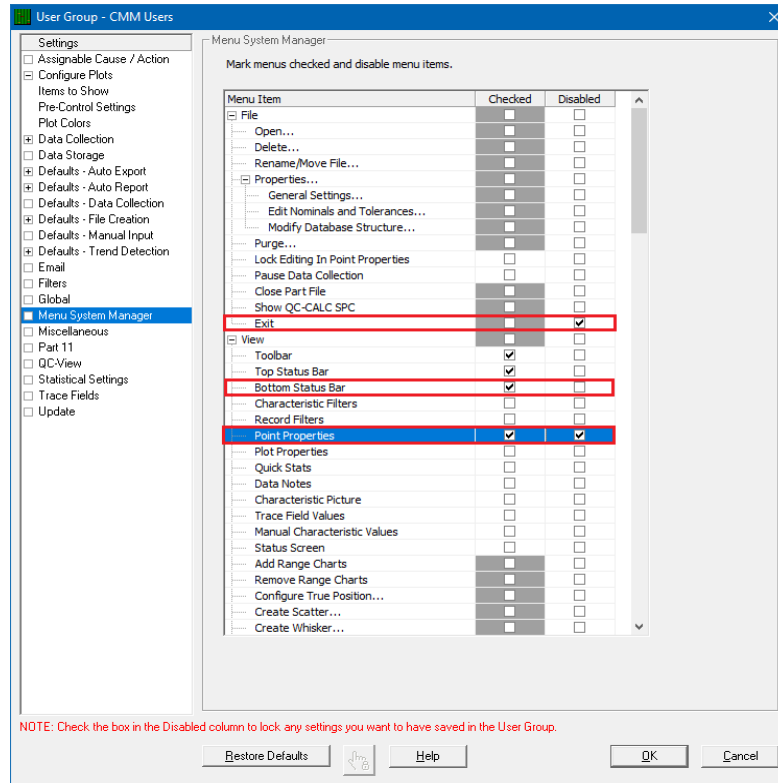
38.7 Edit Application Defaults

The **Edit Application Defaults** selection gives the administrator the ability to modify the default values for QC-CALC Real-Time. Normally, these values do not need to be modified but they can be under certain conditions. The most commonly changed default values are surrounded with red.

Choose the **Administrative Tools** > **Edit Application Defaults** menu to display this window.
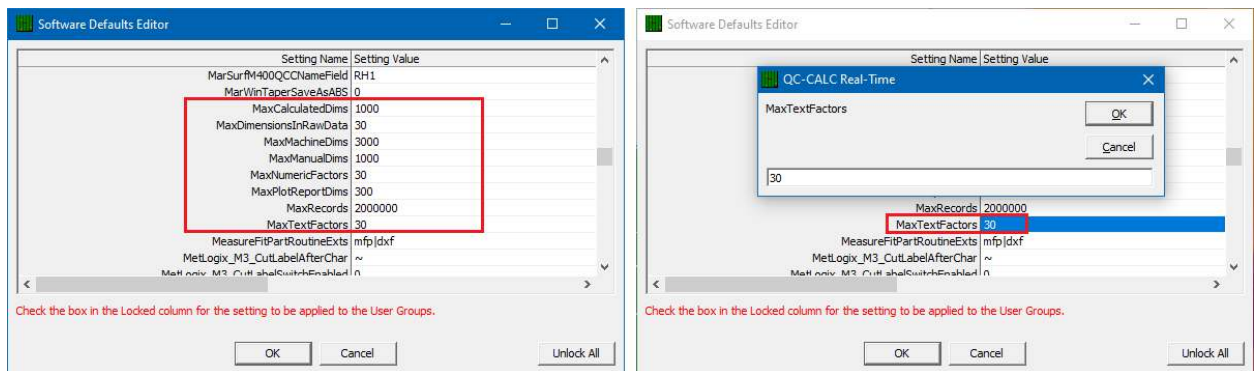
To modify the values in the boxes simply double click on the item on the right side in the grid you wish to change. This displays a dialog box with the current value that can be changed.

Be sure that you follow the current format in the box, for example if it is a number you can only change it to another number. If it is a folder path you can only change it to a new path and so on. If the format changes and you click **OK**, you will get an error message saying **An Invalid Input value was entered** and you will have to change it.

Note: Changing default values that are numbers is much simpler than changing the paths (C:\QVSI\BasicX\Config\) or any of the values that have pipes (|) in them. You have to be very careful because you can change those values, and QC-CALC may not know your value is invalid.

38.8 Set Current User Group

Once the User Groups are created and the options are locked for each group, you activate the group by selecting it from the User Group list and clicking **Set Group**. This should be a one-time change and QC-CALC will remain with this active user group.

38.9 Logout

When you enter your password to modify anything in the **Administrative Tools,** there is a checkbox saying **Keep me logged in**. Once you check this you can modify multiple settings without re-typing your password each time. If you clicked the checkbox to stay logged in, the **Logout** feature under the **Administrative Tools** menu is used to cancel the edit feature. Closing QC-CALC and restarting it will also logout the admin account.

38.10 Disconnecting from Admin Path

The **Disconnect from Admin Path** menu allows you to leave the Administrative settings you're currently connected to. You will be prompted to enter your admin password before you can disconnect the path. This will also remove the **Administrative Tools** menu until reconnected as an admin.

If you need to reconnect to the admin path, click **Tools > Enable Administrative Tools** which will take you back through the **Administrative Tools Setup**. This will also re-enable the **Administrative Tools** menu upon setup completion.

38.11 Troubleshooting

Administrative Tools Menu Not Visible

If you do not see the Administrative Tools menu when you start QC-CALC, it means QC-CALC no longer has access to the central admin settings folder. If QC-CALC was installed correctly then check the following:

- Check to make sure the local Windows user currently logged in has access to the central administrative folder.
- If you are using mapped drive letters, make sure the drive letter originally specified is still pointing to the same shared directory on the network.

The **User Group Path** is shown at the top of the **User Group Manager** window.
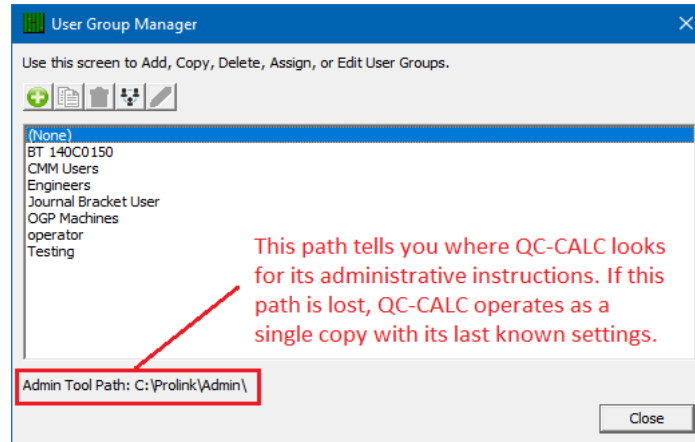
38.12 CFR21 Part 11 Considerations

38.12.1 Introduction

This section describes QC-CALC's operation as it pertains to the FDA title 21 Code of Federal Regulations (21CFR Part 11) requirements. It discusses how QC-CALC is configured to meet the high-level requirements of Part 11.

In order to run QC-CALC in Part 11 Mode, you must enable Administrative Tools due to the control nature of the Part 11 requirements. Part 11 settings are stored at the group level, so you will find the settings screen for Part 11 in the **Manage Options** window of each group.

38.12.2 Trackable Changes

The Part 11 Auditing features track all changes made to data after it is collected. Each time a change is made, the user making the change is required to enter their username, password, and select a **Reason Code** indicating the reason for that change. These changes require authentication:

1. Changes to the actual value measured
2. Changes to the measure date or time of the measurement
3. Changes to the value of any trace field
4. Deletions/un-deletions of individual points
5. Deletions/un-deletions of records (parts)
6. Re-measurement of a part
7. Additions or removals of assignable causes
8. Additions or removals of corrective actions

### 38.12.3 The Setup

The setup of Part 11 Auditing requires you to:

-
-
-
-
-

Begin the Part 11 setup by selecting the **Administrative Tools** > **Manage User Groups** menus. Add as many user groups as necessary. You will see (None) as the default until other named user groups are added.
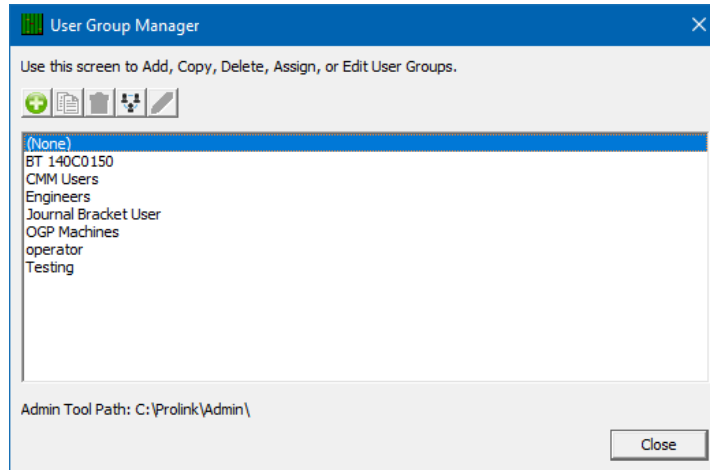
Select the user group before clicking the **Manage Group** button. Set and lock the common options for each group as discussed in the previous section.

To setup the Part 11 options, choose the **Part 11** option on the left side to see the following screen:
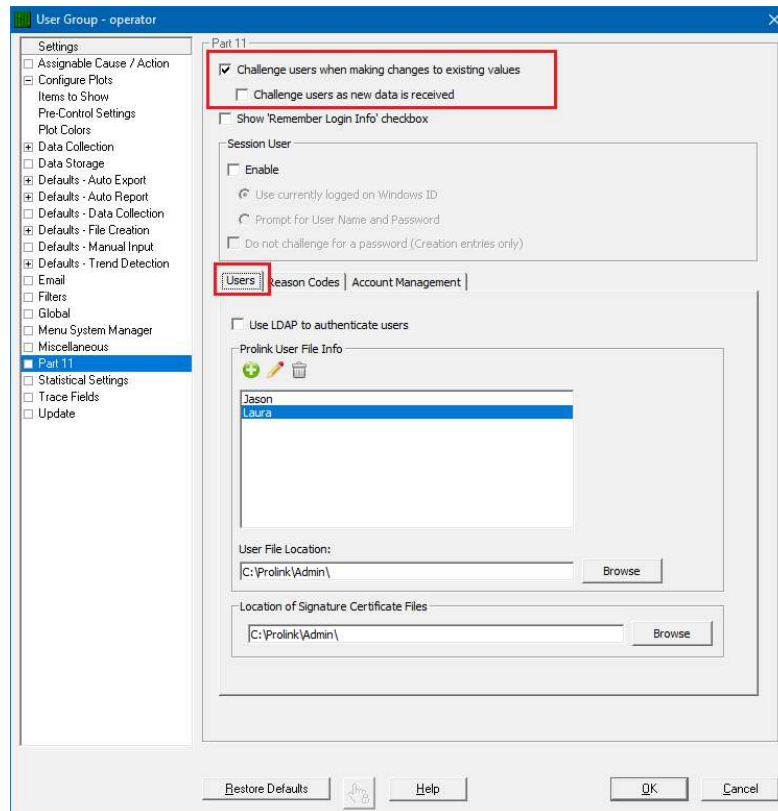
38.12.4 Adding Users to the Group

You use the **User** tab and the **Add** button to add individual people to your groups. Each person requires a name and password. You may also add a graphic signature file to the user record. This is optional and can be placed on digitally signed PDF reports.

Note: Graphic signature files are digitally stored within QC-CALC for security reasons. As such, there is a 100K byte size limit to each uploaded image.

Users are not group specific and are shared across all groups.

38.12.5 LDAP

You cannot add Users if you choose LDAP as discussed in the LDAP (Lightweight Directory Access Protocol) section on page .

38.12.6 Account Management

The **Account Management** tab has options for account deactivation, failed login attempts, and managing active and inactive accounts. If you are using LDAP to authenticate users these options do not apply and will be disabled.

Account Deactivation Notification

If this box is checked, an email will be sent to the address specified whenever an account is deactivated

Account Deactivation

Deactivate Account after exceeding authentication attempts

If this box is checked, an account will be activated after a certain number of failed attempts to access it. You can set the number of attempts in the box immediately below

Log failed authentication attempts

If this box is checked, all failed authentication attempts will be logged and can be reported on with other audit trail records.

Enforce password expiration

This allows you to set up password expiration for all accounts at the same time instead of needing to do it individually.

Adding Reason Codes to the Group

Along with authenticating username and password, users must select a **Reason Code** when making changes to existing data. Reason Codes cannot be added at the time of authentication.
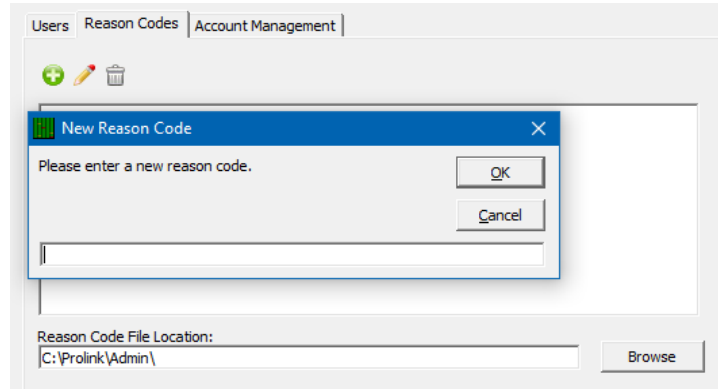
Reason Codes are shared across all groups. The maximum length of a reason code is 64 characters.

38.12.7 Challenge Users

The top section of the Part 11 area controls how users are challenged when collecting or editing values.
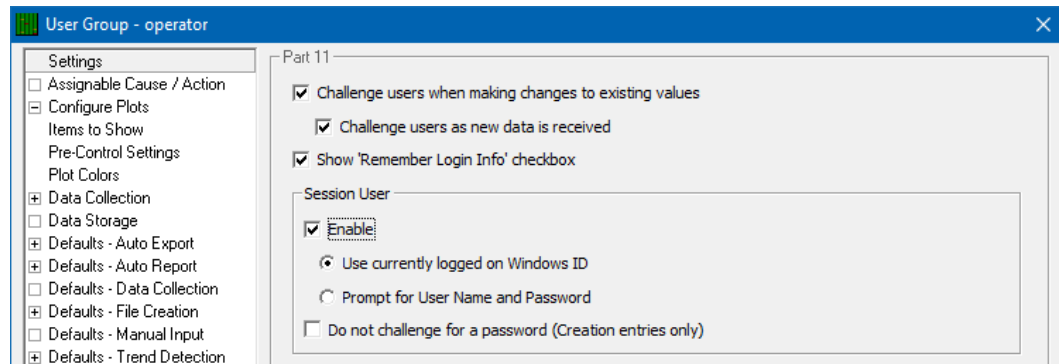
Challenge users when making changes to existing values

This option enables the auditing system in general. Users will be required to provide a username, password, and reason code when attempting any of the trackable changes. See the Trackable Changes section on page 259 for more details.

Challenge users as new data is received

Checking this option will require users to provide a username and password as new data is collected.

Show 'Remember Login Info' checkbox

This option enables users to enter their username and password once and have it remembered.

Session User

The **Session User** area enables settings that change based on the user that logs in to the software. As **Users** are being configured, they are added to specific **User Groups** and then when QC-CALC is launched the user will be asked to enter their User Name and Password. QC-CALC will use this information to determine which User Group should be loaded and the appropriate settings will be applied to that session.

Use currently logged on Windows ID

This option will automatically use the Windows ID, but that ID MUST match a User Name in the list of Users in the Admin Tool.

Prompt for User Name and Password

As QC-CALC launches the operator will be asked to enter their User Name and Password and the appropriate settings will be loaded based on that user information. This User Name will also be entered into the challenge screen so the user will only have to enter their password.

Do not challenge for a password

With this option checked the operator will not be asked to enter any information as new data is received. The value entered during the QC-CALC loading process will be used for all challenge answers.

Note: The **Enable Auditing** setting is NOT shared across all groups and must be set for each group that requires it.

38.12.8 Editing the Data

Editing tools were added to QC-CALC to help you fix bad readings. Please recognize Prolink makes a distinction between bad readings vs. bad parts. When a gage saves a reading that must be changed due to gaging errors, the Part 11 tools described here help control the "who, what, and why" of the change that was made.

Right-clicking on a point in QC-CALC Real-Time yields the familiar pop-up menu shown below.
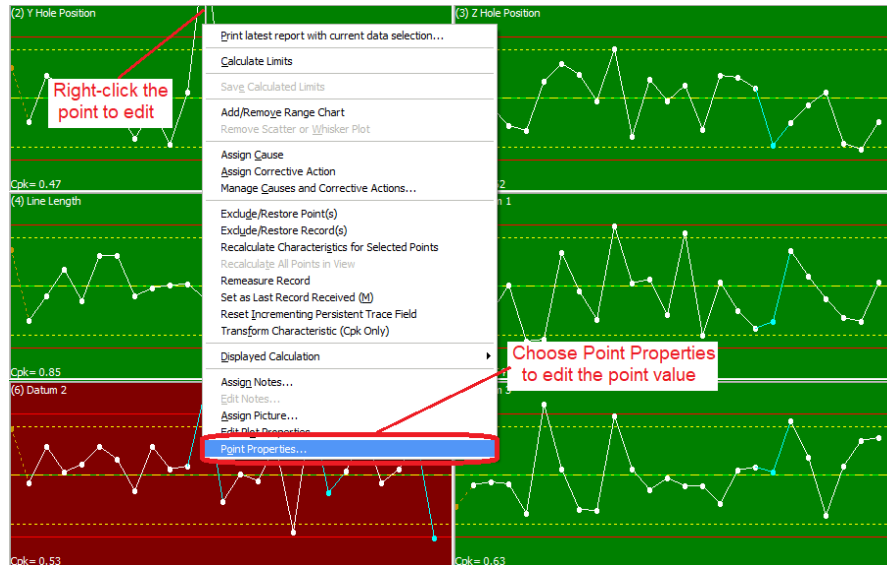
Selecting **Point Properties** allows you to edit the value as shown.
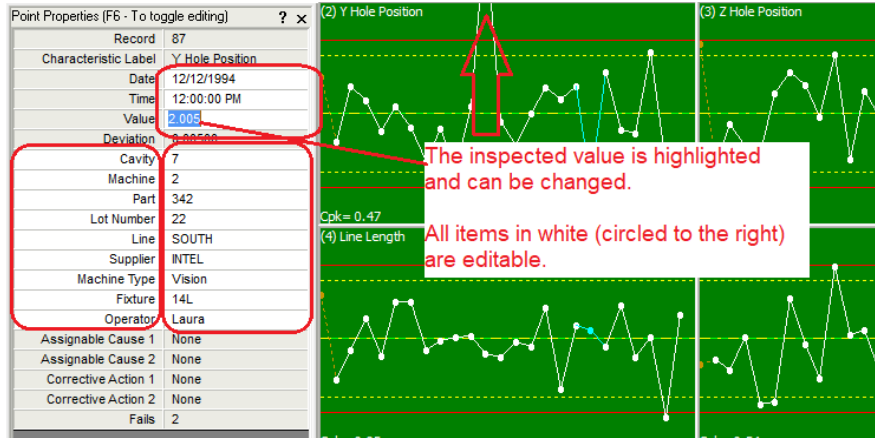
38.12.9 Documenting the Change

When you finish changing the value, press the ENTER key or the F6 key, or close the **Point Properties** panel. At this point the Part 11 Audit box appears requesting information. You must complete this dialog or your changes are discarded!

Select your name from the **User Name** list, enter your **Password**, and select a **Reason Code** from the list. Click **OK** and your changes are saved. If you do not complete this sequence or press Cancel, your changes are discarded.
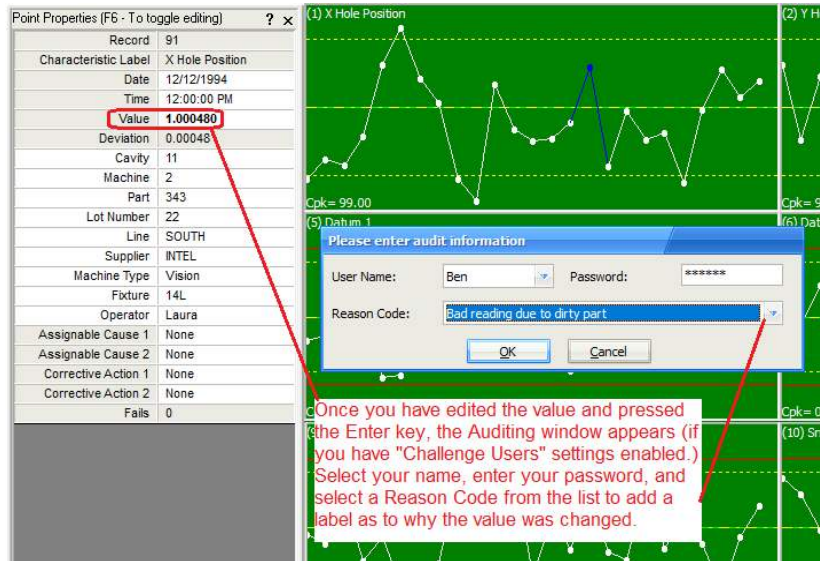
Once the challenge is answered, the edited point turns navy blue and is bold in the **Point Properties** panel. This is your visual clue the value has been edited.

38.12.10 CFR Part 11 Audit Report

You can generate a report containing all changes made to a part file by printing a special report included in the Real-Time report list called the "CFR Part 11 Audit Report." This report is generated the same as all other Real-Time reports, but it contains the pertinent audit trail information as required by Part 11. To open the **Manual Report Settings** menu, click **Report** > **Print Report**, and from here you can edit and save the settings required for your CFR Part 11 Audit Report.

Signed Reports PDF Only

You must print signed reports to **File** and select a **File Type** of **Adobe PDF Format Signed** in order to see your signature. If the file has been tampered with, it will say so. Change the File Name and location to the appropriate name and click **OK**. The PDF file has properties that you can review.

PDF File Signature Properties

The tamper proof signature is found in the signature section of the final PDF file. Clicking the Signature button reveals the status of the file. QC-CALC adds the password protected username to the document and includes the Reason Code they chose. If the file is modified in any way, the signature property indicates it is a tampered file.
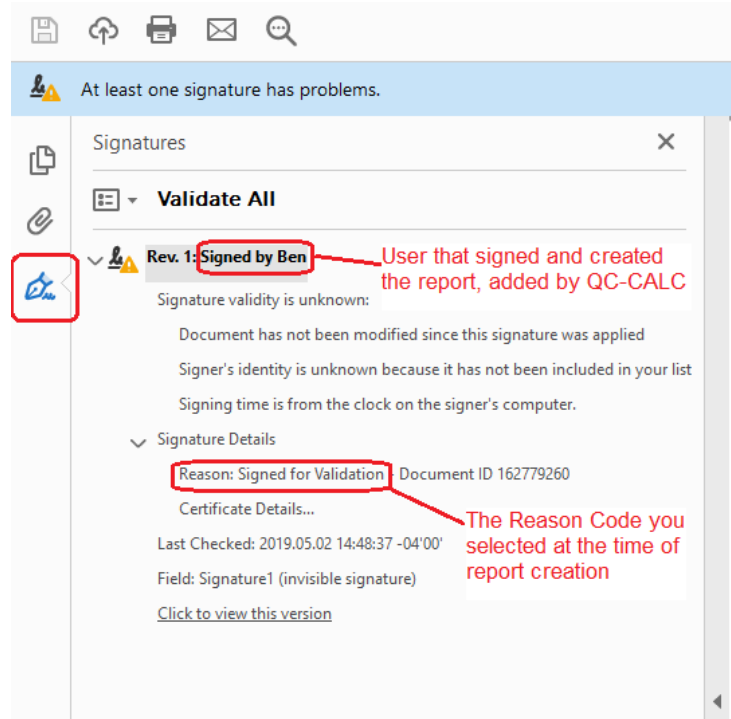
38.12.11 Sample Audit Report

This sample audit report shows the detail necessary to trace any changes to any QC-CALC database. It includes the original value before the edit and the new value. All editable items in the database are added to this report. You can print this report for an individual point by **right-clicking** on the point and selecting the **Print Report** menu. A history of that one point (part) is printed.

38.12.12 LDAP (Lightweight Directory Access Protocol)

QC-CALC has a built-in **User** > **Password** system but some organizations require these account names be stored and managed at the company level instead. The chosen standard is an LDAP server. For such organizations, QC-CALC provides a simple interface.

When the **Use LDAP to authenticate users** option is checked, the contents of the **Users** tab changes to reflect the LDAP settings instead. You will need to contact your IT department to setup the required "connection string". When changes are made or new data is collected you are asked for your **User Name** and **Password**. You must enter your company logon name and password instead of any identification you may have entered into the QC-CALC system.
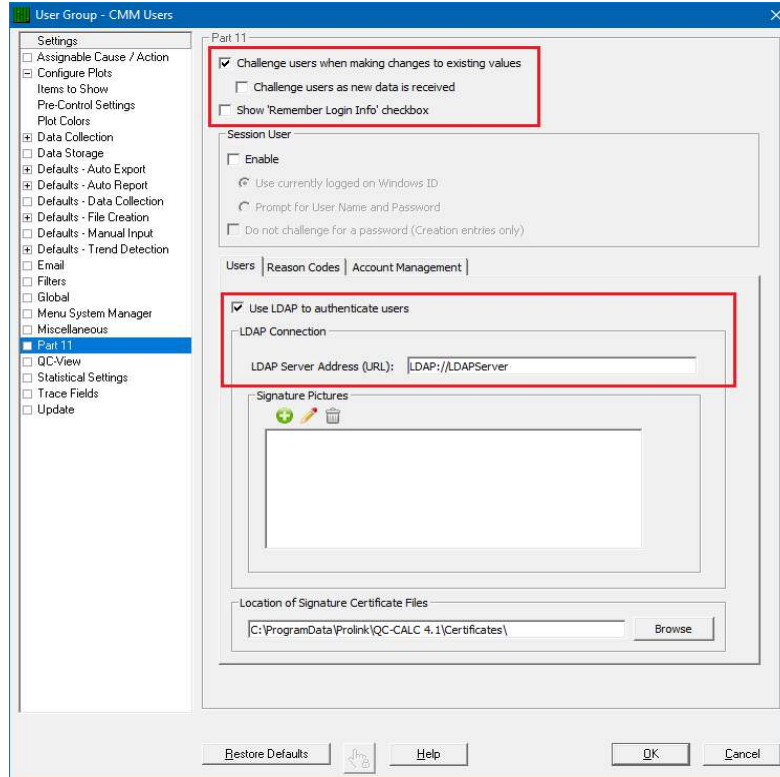
Signature Pictures can be added within the QC-CALC system by adding the LDAP user name and the picture to associate with that user.