



## *New Features 5.0 User Guide Companion*

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This *User Guide* accompanies release 5.0 of *SQCpack EZ*.

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# SQCpack EZ

## New features user guide for release 5.0

Several new features have been added to SQCpack with the release of version 5.0.

If you are currently using SQCpack 4.6 or 4.5, you will find that the basic structure and day-to-day operation of SQCpack is unchanged.

In order to make the new features available as soon as possible, PQ Systems has decided to continue shipping the SQCpack 4.6 user guide with SQCpack 5.0. The information in the guide remains relevant for learning how to use the software. We are also shipping this document, describing only the new features in SQCpack 5.0.

Over time, the information in this *New Features User Guide* will be integrated into the standard user guide. The guide will be made available to all *current* maintenance release customers.

We hope you enjoy the new features in SQCpack 5.0 and look forward to your continued patronage.



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# Contents

<b>Section 1 Send Chart as e-mail .....</b>	<b>3</b>
<b>Section 2 Save Chart as Web Page .....</b>	<b>5</b>
<b>Section 3 Control Chart Improvements .....</b>	<b>7</b>
Data above the chart .....	7
Extralines .....	9
Data values near points .....	12
Sigma zone lines,percent within 1, 2, 3 sigma .....	13
Three way control charts .....	14
<b>Section 4 Group Level Charts .....</b>	<b>15</b>
Multi-line charts .....	15
Scatter diagrams .....	19
<b>Section 5 New Out-of-control Test Rules .....</b>	<b>22</b>
<b>Section 6 Six Sigma Cpk .....</b>	<b>25</b>
<b>Section 7 Three Dimensional Bars on Pareto and Histograms ....</b>	<b>27</b>
<b>Section 8 Short-run SPC .....</b>	<b>28</b>
<b>Section 9 CFR 11.1 .....</b>	<b>35</b>
Compliance .....	35
User log-inmanagement .....	36
User log-in option 1 .....	37
User log-in option 2 .....	39
Adding a user .....	41
User privileges .....	43
User password management .....	44
Database password management .....	45
Database audit trail .....	49
Audit trail reporting .....	53
Summary .....	57



# Send Chart Image as e-mail

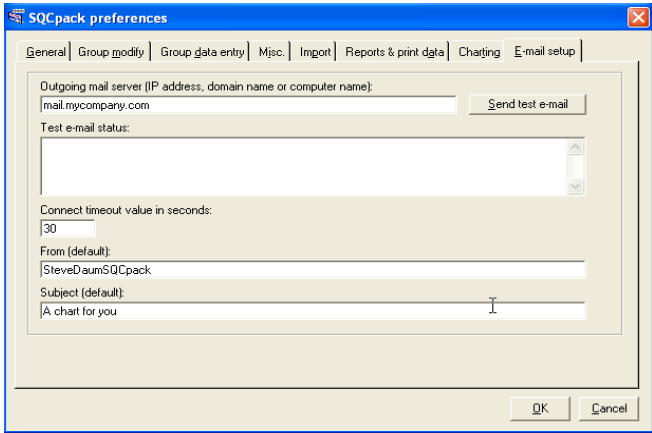
When any chart is displayed in SQCPack, there is a new option under the File menu named *Send chart image as e-mail*. This allows you to send a graphical image of the chart to one or more e-mail recipients. You can invoke this feature by:

1. Selecting *File/Send chart image as e-mail* while viewing any chart
2. Right clicking on any chart you are viewing and select *Send chart image as e-mail*
3. On the data entry form, charts/limits tab, right clicking on the chart name and select *Send chart image as e-mail*
4. From the main form, selecting the chart browser button from the toolbar to display a list of charts, select any chart, then click the *E-Mail* button.

Before you can send a chart via e-mail, you must configure SQCPack for your e-mail system. Please follow these steps:

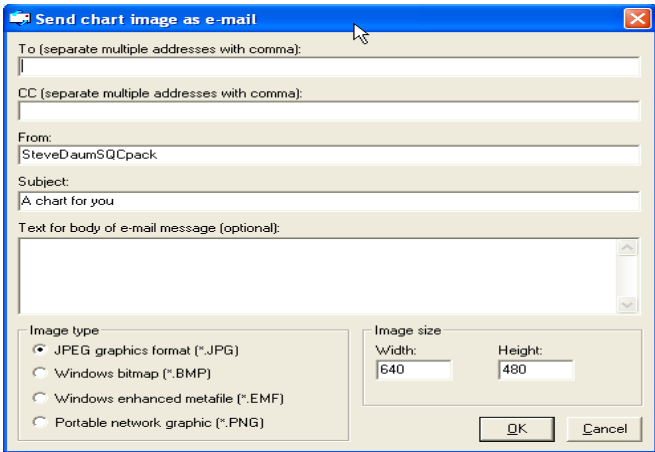
1. Start SQCPack
2. Select *Setup/Preferences*
3. Click on the *E-mail* setup tab. Enter your e-mail server name. You may have to get this information from your internal systems staff. This might be a name such as *mail.mycompany.com* or it might be an IP address made up of several numbers.
4. Send a test message to your own e-mail address using the *Send test e-mail* button. Once this works, SQCPack will be ready to send charts as e-mail.

Preferences/E-mail setup form:



SQPack supports SMTP for sending e-mail. Many popular e-mail programs support this standard. If you are unable to set up SQPack so that a test message will work, please contact your IT staff or PQ Systems, Inc. technical support.

Each chart in SQPack has a default image type and image size. You can modify these settings on the chart definition form. While viewing any chart, select *Edit chart definition* from the menu. Next, click on the *Misc.* tab. This will allow you to select an image format and a size for the chart. If you are uncertain about which image format to select, the .JPG format is recommended. It is readable on most computers. It is also a compressed format that makes e-mail transfers faster. Whenever you send a chart as e-mail, these settings will be displayed as the *default* settings, but you may change them before you send the e-mail.



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When you send a chart as e-mail, SQCpack makes a snapshot of the chart *right now* and sends this as an attachment to the e-mail. Remember that if you add or change data after you send the chart, your chart may look different from the one you sent in e-mail.

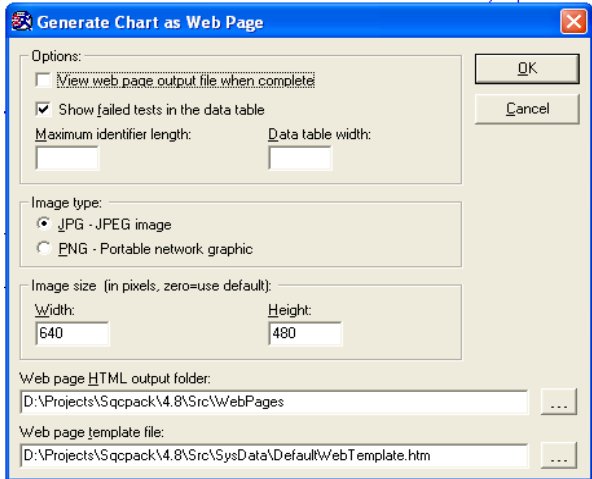


# Save Chart as Web Page

When any chart is displayed in SQCPack, there is a new option under the *File* menu named *Save chart as web page*. This allows you to save the current chart as an image within a web page. There are several different ways you can invoke this feature:

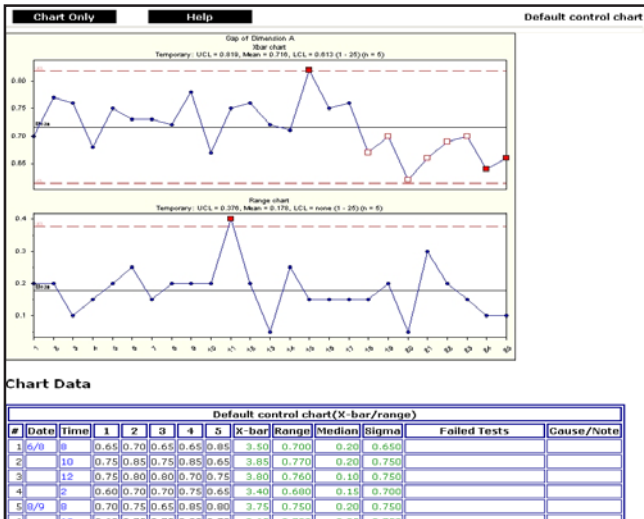
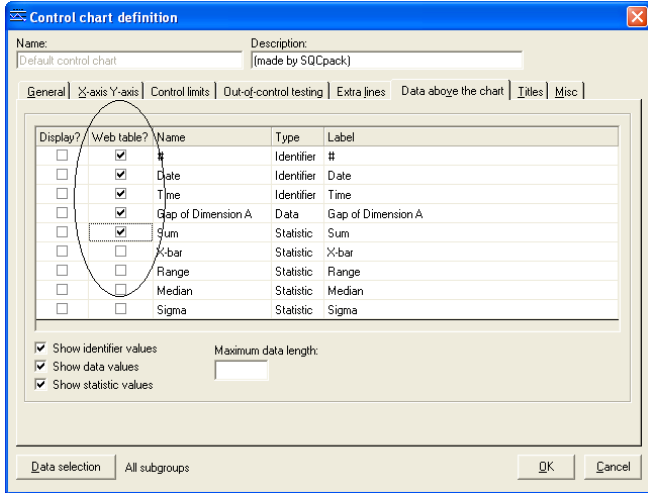
1. Select *File/Save chart as web page* while viewing any chart
2. Right click on any chart you are viewing and select *Save chart as web page*
3. On the data entry form, charts/limits tab, right click on the chart name and select *Save chart as web page*
4. From the main form, select the chart browser button from the toolbar to display a list of charts, select any chart, then click the *Web page* button.

When you ask to *Save a chart as a web page*, the following form will be displayed:



Select your options and then click *OK* to generate the web page. Notice the options at the bottom of the form. You control where the web page is saved. You may also set a web page template file. SQCPack provides you with one template, but you may alter this to your own needs. However, carefully review the HTML source code and be sure to leave the tags that tell SQCPack where to put the chart and data on the page. If you decide to modify the SQCPack template, be sure to save a backup copy of the original template.

When you save a chart as a web page, you have additional options for displaying the data from the chart as a table on the web page. To select the contents of this table, you must edit the chart definition. On the *Data above the chart* tab, check the boxes for data you wish to include on the web page. Here is an example of the setup form and a partial output page:

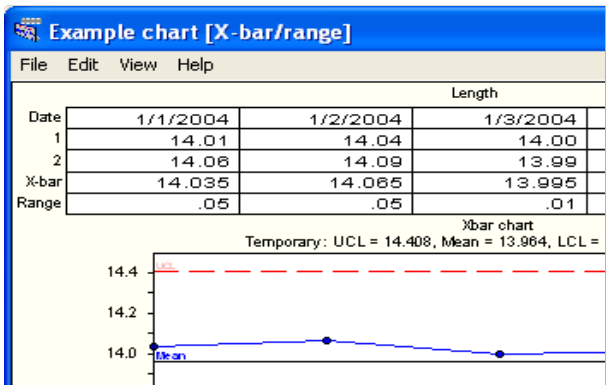


# Control Chart Improvements

## Data above the chart

SQCpack gives you options for displaying information that appears in a *grid* above control charts. This is true for both measurement (*variables*) and count (*attributes*) control charts. Options include identifiers, raw data, and statistics. New features give you more control over how this information is displayed above the chart.

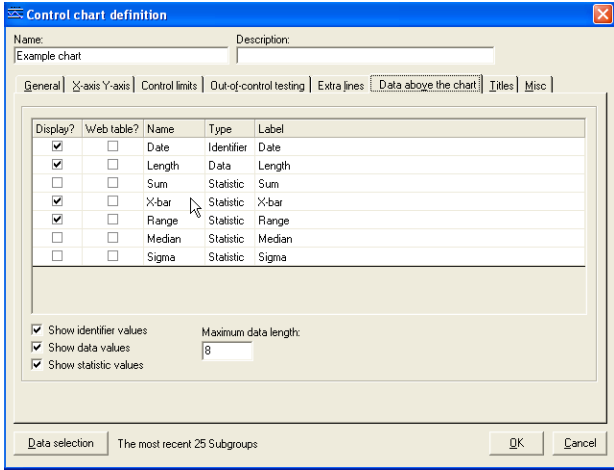
*Partial chart example showing data grid above:*



In this example, there are five rows of information in a grid above the control chart. The first row shows a *Date* identifier. The second and third rows show the raw data. The subgroup size is two, so there are two rows of data. If the subgroup size is five, there will be five rows of data. Finally, the X-bar and the Range are shown in the last two rows of the grid. These represent the X-bar and Range for the current *subgroup* or the current *column* within the data grid.

You have options to display or not display this entire grid. Additionally, if you decide to display this grid, you have control over which rows are included in the grid and how each row is labeled at the left.

A new tab named *Data above the chart* is available on the chart definition form:



The *Data above the chart* tab contains a matrix where you can select data that you want displayed above the chart. The contents of this matrix vary, based on the current group. Each identifier, the characteristic name, and some set of statistics options will be available. The statistics vary based on the characteristic type (*measurement or count*), the chart type, and subgroup size for the characteristic.

In the *Display* column, check each row you want to include above the chart.

The *Web table* column affects how the data grid appears when this chart is saved as a web page. See the section Save chart as a web page for details.

The *Name* column is read-only and contains the name of the identifier, characteristic, or statistic for this row.

The *Type* column is read-only and tells you what type of information this row contains.

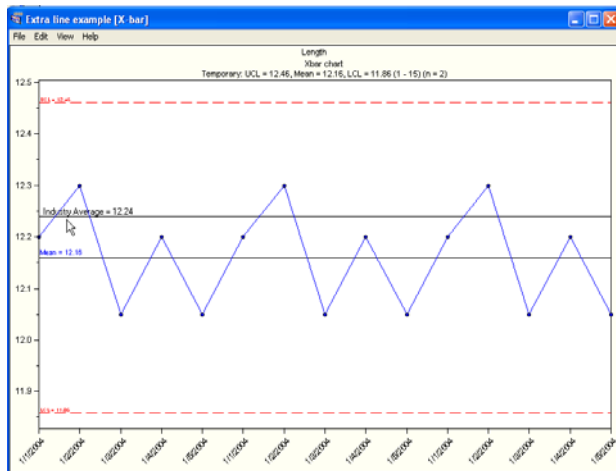
The *Label* column will default to the same text as the *Name* column; however, you may type in your own label. If you type your own label, this will appear at the left side of the data grid for this row.

The checkboxes that appear below are useful when you are printing blank control charts. Uncheck these to print a chart with an empty data entry grid above.

Use the *Maximum data length* field to limit the length of text appearing in any grid cell.

## Control Chart Improvements–Extra Lines

SQCpack allows you to customize control charts and run charts with *extra lines*. In the following chart, *Industry Average* is an example of an *extra line*:



The *extra line* features have been improved to allow for more lines and greater control of how the lines look. To define or modify the *extra lines* on a chart, you must bring up the chart definition form and/or then click on the *extra lines* tab. While viewing any control chart, select *Edit/Chart definition* from the menu. Here is an example:

Type	Line label	Value	Apply to	Label with	Which chart?	Color	Width	Style
1	Extra line	Industry Average	12.24	All	Name and value	1	Black	Regular Solid
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

---

Each row in the matrix on the *extra line* tab represents one extra line that will appear on the chart. In each row, you set or select information in each column. Following is a description of what each of these columns does:

### Type

Select a *type* for the extra line from the drop down list in this column. The options vary based on chart type. The most basic type is *extra line*. Depending on your chart type, you may also see options like mean line, median line, or spec lines. Once you select an extra line *type*, several default values for the other columns will be filled in automatically. You may accept these defaults or customize them to your liking.

### Line label

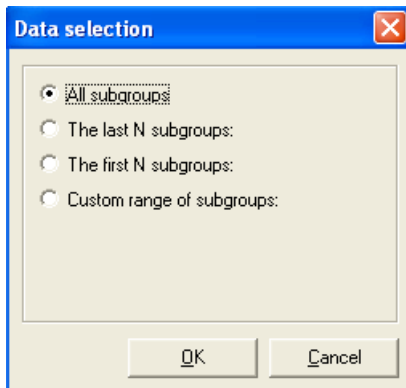
This is the text that will appear on the chart to tell the viewer what this line represents. Once you select a line type, there will be some *default* text in this cell; however, you may type in your own text if you prefer.

### Value

All extra lines are horizontal lines that appear at some value on the y-axis scale. Enter the value where you want the line to appear in this column. Note that some extra lines, such as the mean line or the median line, will not allow you to type a value. Instead, you see the word *Calculated* in this position. The placement of these lines on the y-axis is based on the mean or the median of the data so there is no need for you to enter a value.

### Apply to

In most cases, an extra line will extend from the left side all the way to the right side of the chart. You may wish to *apply* the extra line to only a portion of the chart. For example, if you are trying to demonstrate the impact of some system change, you may want two extra lines – one showing the mean before the change and another showing the mean after the change. In this case, you need to set the *Apply to* column appropriately. Clicking in the *Apply to* column allows you to make your selections on this form:



---

## Label with

You may select one of the following options for applying the *Line label* to an extra line:

Nothing	(show the line only)
Name	(show the line label text on the line)
Value	(show the numeric value on the line)
Name and value	(show both the line label and the value)

## Which chart

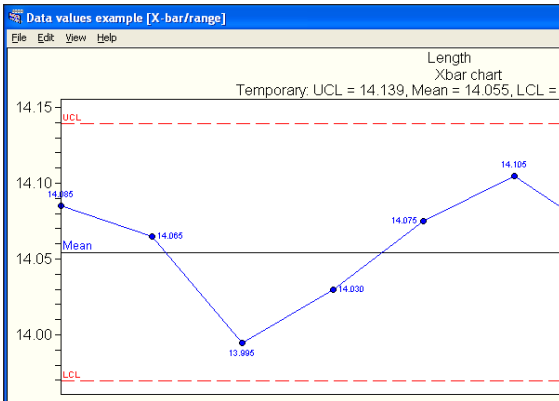
Some charts are actually two or even three charts shown together. For example, an X-bar and Range chart is actually two charts. Set the *Which chart* column to either 1, 2, or 3 to let the software know where to put the line. On an X-bar and Range chart, if you want the line on the X-bar chart, enter 1; if you want the line on the Range chart, enter 2.

## Style

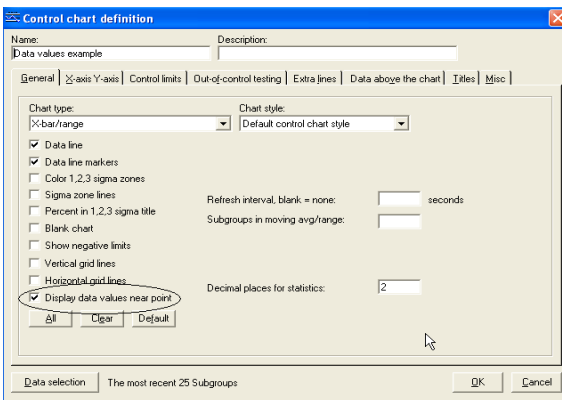
Use the style columns to set the color, line thickness, and line style for your extra line. Note that the color you select will apply both to the line and to any label you might define for the line. To change the size of the font for extra line labels, you must edit the control chart style being used on the current chart. While viewing the chart, select *Edit/Chart style* from the menu.

# Control Chart Improvements–Data Values Near Points

On control charts and run charts, you have the option to display the data values near each plotted point on the chart. Notice the data values in the following example:



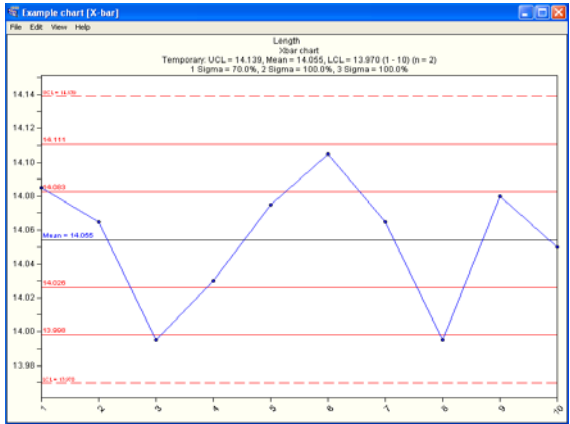
While viewing the chart, select *Edit/Chart definition*. On the *General* tab, you will see a checkbox option named *Display data values near point*. Check this box to display the data values.



# Control Chart Improvements - Sigma Zone Lines, Percent Within 1,2,3 Sigma

On the control chart definition form, a new checkbox named *Sigma zone lines* is available. This allows you to add horizontal lines to mark the 1, 2, and 3 sigma zones around the mean line. The related feature that displays the sigma zones in three different colors can be enhanced by these lines. The lines are helpful when printing on a black and white printer and they also give emphasis to the color sigma zones. Both the *Sigma zone lines* and the *Color sigma zones* depend on control limits you have on the chart. If you configure the chart without control limits, these options have no impact.

Another new check box is named *Percent in 1, 2, 3 sigma title*. If you select this, a title will be added above the chart plot area that tells you what percentage of the subgroups fall within the 1, 2, and 3 sigma zones around the centerline. The following example shows both the Sigma zone lines and the Percent in 1, 2, 3 sigma title:



Since upper and lower control limit lines traditionally fall at the mean plus or minus three sigma when you request *Sigma zone lines*, the three-sigma zone lines are not shown separately. The sigma lines are labeled based on your setting for *How to label limit and sigma lines*, which is found on the control limits tab.

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## Control Chart Improvements–Three-Way Control Charts

For measurement characteristics with subgrouped data, that is, with a subgroup size of two or more, SQCPack allows you to create and display *Three-way control charts*. A *Three-way control chart* consists of three charts looking at the same set of data.

The first chart plots the subgroup averages as if they were individual readings. Control limits are calculated as they would be for an individuals chart.

The second chart is a moving range chart of the subgroup averages plotted in the first chart.

The third chart is a traditional range chart plotting the range (max minus min) of each subgroup.

*Three-way* control charts are useful in situations where you take readings that are *auto-correlated*. This means that each reading is likely to be close to or exactly equal to the previous reading. Imagine that you inspect *blanks* that will be used to make coins. Your sampling plan calls for you to measure thickness in three different spots on each blank. In this case, thickness readings will be nearly identical.

A traditional X-bar and Range chart of this data is likely to show narrow control limits on the X-bar chart. This is because control limits are based on the range, and in this case the range is very small. In situations like this a *Three-way* control chart is a better solution than a traditional X-bar and range chart.

To create a *three-way* control chart follow these steps:

1. From the main form, select the group that contains your data.
2. Right click on the group then select *Open (data entry)*
3. Click on the charts/limits tab then click on the measurement characteristic
4. Right click and select *New control chart*
5. Give the chart a name, then select *Three way* from the *Chart type* combo box
6. Save the chart definition and then display the chart.

If *Three-way* is not an option in the *Chart type* combo box, your characteristic may have a subgroup size of one. *Three-way* charts are available only when subgroup size is two or higher.

## Section 4

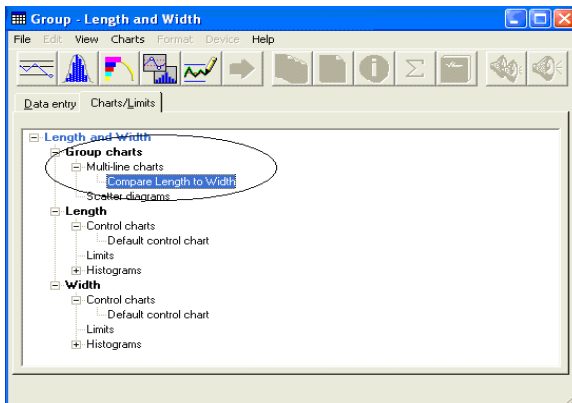
# Group Level Charts

## Multi-line Charts

Control charts and run charts plot a single data line. With *Multi-line* charts, SQCpack allows you to define charts with up to ten different data lines. These can be useful for comparing the performance of two or more characteristics on a single chart.

Most charts in SQCpack are *owned by* characteristics. If you have a group with two measurements named *Length* and *Width*, you can define one or more charts for *Length* and one or more charts for *Width*. These charts show up in the software as *children* of Length or Width; in other words, the charts are *owned by* either Length or Width.

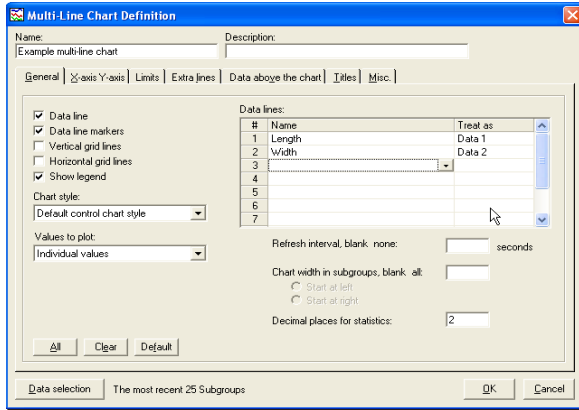
When you define a *Multi-line* chart that compares *Length* to *Width*, the chart will be *owned by* the *group* rather than either of the characteristics. In the following screen, notice the new section named *Group charts*:



Multi-line charts may be defined to compare different characteristics within a group where each characteristic is plotted as one data line.

To create a multi-line chart, follow these steps:

1. On the main form, select a group and open it for data entry.
2. Click on the Charts/Limits tab.
3. Find *Group charts* in the outline and click once on *Multi-line charts*.
4. Either right click or select the *Charts* pull-down menu.
5. Click on *New Multi-line chart*.
6. The multi-chart definition form will be displayed:



Many of the options for defining a multi-line chart are the same as they are for defining control charts. The *General* tab is where the differences lie, so this will be our focus. When setting up the chart, you must tell SQCPack where to get the data for each line you want in the multi-line chart. In the example above, there will be two data lines: one for Length and one for Width. You see this in the *Data lines* matrix.

The *Name* column in the *Data lines matrix* contains a drop-down choice list. The contents of this list are based on the current group. There will be one item in this list for each *column* of data in the group that might be plotted as a line on the chart. If your group has only one measurement characteristic named *Length* with a subgroup size of three, the *Data lines* choice list will contain these items:

- Length (1)
- Length (2)
- Length (3)

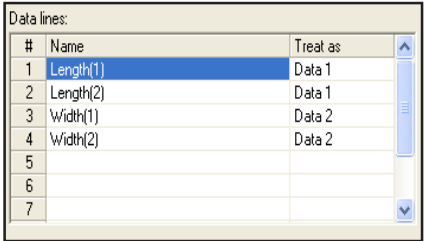
If your group has more characteristics, the *Data lines* choice list will contain more items. If you think about the data entry form for your group, consider that any column that contains count, measurement, or calculated data is a candidate for use as one line on a multi-line chart.

The *Treat as* column of the *Data lines matrix* also contains a drop-down choice list. It has a list of items as follows:

- Data1
- Data2
- ...
- To Data10

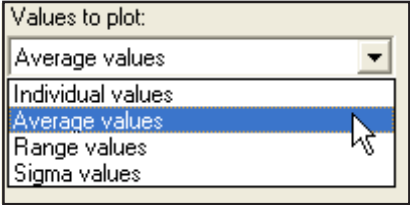
For each item you select in the *Name* column, use the *Treat as* column to assign it to a specific data line. In the previous example, Length will be Data1 or the *first* data line. And Width will be Data2 or the *second* data line.

There is a drop-down choice list for *Values to plot*. The choices available here depend on how you have set up the *Data lines matrix*. If each data line is assigned to a single column, your only option in *Values to plot* will be *Individual values*. However, consider the following case:



#	Name	Treat as
1	Length(1)	Data 1
2	Length(2)	Data 1
3	Width(1)	Data 2
4	Width(2)	Data 2
5		
6		
7		

In this example, *Data1* has been used twice and *Data2* has been used twice. When you map multiple columns to a single data line, you have additional options in the *Values to plot* choice list. For example:

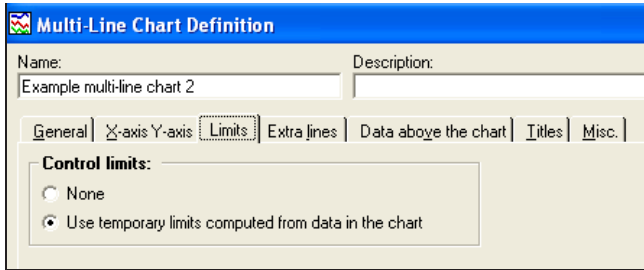


If you select *Average values* in the example above, your chart will have two data lines: Data1 will plot averages of Length(1) and Length(2); Data2 will plot averages of Width(1) and Width(2).

---

## Multi-line Charts and Control Limits

When defining a multi-line chart, you have an option to use temporary control limits on the chart. You make this selection on the *Limits* tab as in the following example:



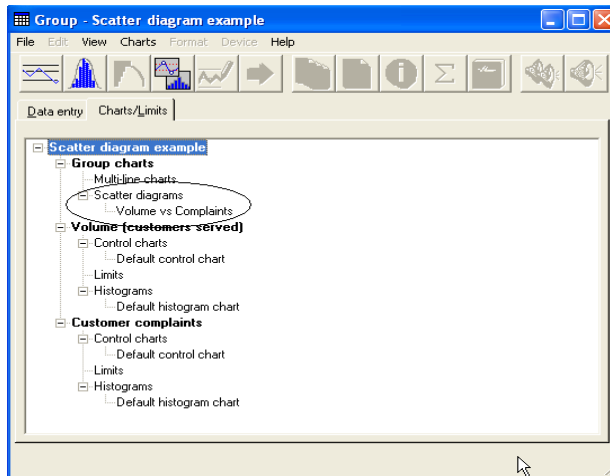
This will cause the chart to calculate a set of temporary control limits *for each* data line in the chart. As you can imagine, if you have more than two data lines, this chart will become cluttered and difficult to interpret. This option is provided simply as an analytical tool to give you a feel for how two or more control charts might compare visually. If your intention is to control a process, a single control chart of a single characteristic is a much better choice and you will have many more options for computing and using control limits.

## Multi-line Charts and Data Types

When you define a multi-line chart, you might have one data line from a measurement characteristic (variables) and another data line from a count characteristic (attributes). Once the data is plotted in a multi-line chart, SQCpack is treating this as measurement (variables) data. If you use the temporary limits option, the limits will be computed assuming variables data. The formulas will be for the Individuals, moving range,  $\bar{X}$ -bar, or Range control limits.

# Scatter Diagrams

A scatter diagram is useful for examining a possible relationship between two different variables. For example, you may want to test the hypothesis that as volume increases, the number of customer complaints also increases. SQCpack allows you to create scatter diagrams as *group level charts*. This means that the charts are *owned by* the group rather than being *owned by* any characteristic within the group. The following screen demonstrates:



To create a scatter diagram chart, follow these steps:

1. On the main form, select a group and open it for data entry.
2. Click on the Charts/Limits tab.
3. Find *Group charts* in the outline and click once on *Scatter diagrams*.
4. Either right click or select the *Charts* pull-down menu.
5. Click on *New Scatter diagram*.

The scatter diagram definition form will be displayed:

**Scatter Diagram Definition**

Name: Volume vs complaints Description:

General | X-axis, Y-axis | Titles | Misc.

Draw line of best fit  
 Show line of best fit equation and R value  
 Vertical grid lines  
 Horizontal grid lines

Chart style: Default control chart style

Dependent variable: Volume (customers served)

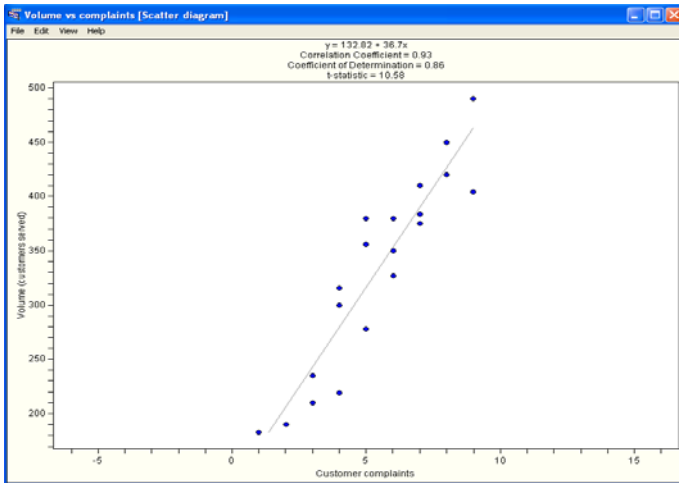
Independent variable: Customer complaints

Refresh interval, blank none: seconds  
Decimal places for statistics: 2

All Clear Default

Data selection All subgroups OK Cancel

Set the *Dependent variable* and the *Independent variable* by selecting from the drop-down list. The contents of these lists will vary, based on how your group is defined. Select other options to customize your scatter diagram, then click *OK* to save it. When you display a scatter diagram, it will look similar to this:





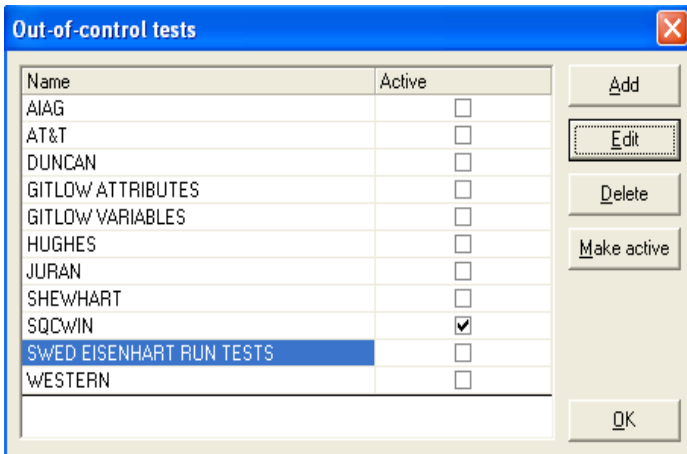
## Section 5

# New Out-of-Control Test Rules

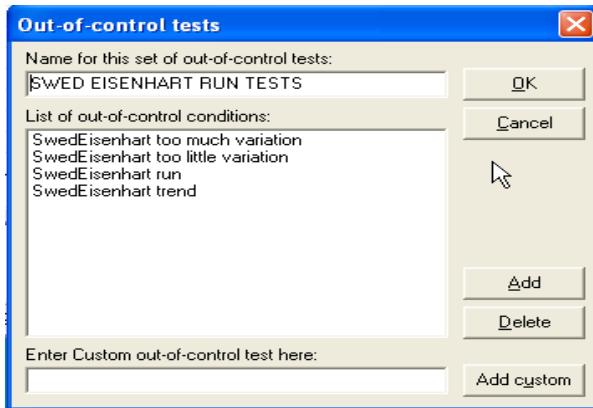
Out-of-control test rules are used to evaluate data on control charts. If a data point fails an out-of-control test rule, the data point is said to be “out-of-control.” In SQCpack, out-of-control data points are traditionally plotted with a solid red square data marker. Here are some example out-of-control test rules:

- 7 data points ascending
- 7 data points descending
- Data points beyond limits

Most out-of-control test rules are used on control charts in conjunction with a set of control limits. A **new set of rules** has been added that are specific to run charts. Run charts do not have control limits, so the test rules are slightly different. The new run chart rules can be seen in the *Swed Eisenhart run tests*. From the main form, select the *Setup/Out-of-control tests* menu and you will see this form:



Click once on *Swed Eisenhart run tests* and then click on the *Edit* button. You will see these new tests:



The *Swed Eisenhart run tests* look for trends, runs, and patterns of variation. These are often used with health-care related data, but can be informative with any run chart. For a discussion of these tests related to healthcare, consult the following book:

*Improving Healthcare with Control Charts*, Raymond G. Carey, PhD, 2003.

Another improvement to out-of-control test rules is a qualifier that applies the rule based on the total number of data points evaluated. For example:

6 above centerline ( $n < 20$ )

This rule can be read as follows:

Six data points above the centerline – when there are fewer than 20 data points – is considered an out-of-control condition. Here are some other examples:

8 above centerline ( $n > 20$ )

9 ascending ( $n > 30$ )

7 ascending ( $n \leq 30$ )

Test rules like this are added to an existing set of out-of-control test rules by typing the rule, then using the *Add custom* button on the out-of-control test form.

Test rules may also be written so they apply only to a specific type of chart. For example:

8 beyond 1 sigma [ $\bar{x}$ ]

This rule will be applied only to X-bar charts.

---

Recent additions also allow for rules to test against specifications. For example:

7 data points above target

Points beyond specifications [xbar]

7 data points below target

1 data point above spec

1 data point below spec

1 data point beyond specifications (this will test against upper and lower specifications)

When testing for runs as in the rule 7 *ascending*, what if you have two data points that are the same value? Depending on how the rule is written, you will get different results as follows:

7 ascending (duplicate values are counted in the run)

7 ascending only (duplicate values are **not** counted in the run)

Alternating values that go up and down can indicate non-natural variation. New test rules allow for this. For example: 10 *alternating*.



## Section 6

# 6 Sigma CPK

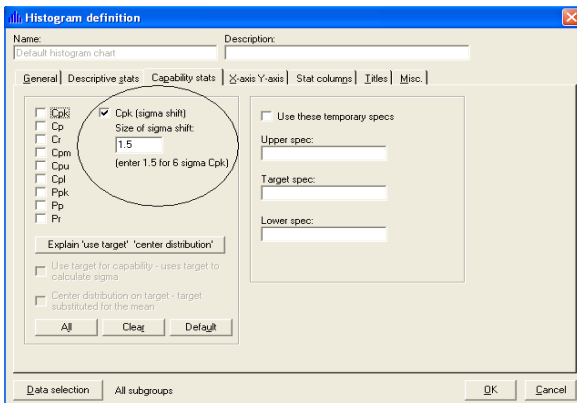
SQCpack will calculate and display several different Capability statistics. These are optional selections for all histogram charts. On the histogram definition form under the *Capability* statistics tab, you will find several check boxes related to these statistics.

Cpk, also known as the *Capability Index*, is a common statistic for describing how *capable* a process is of producing most results within customer specifications. A process is said to be *capable* if the Cpk statistic is 1.0 or higher.

Many organizations today are using various *Six Sigma* techniques. Within this discipline, a higher goal is set for Cpk; the idea is to get as close to perfection as possible. The calculation for Cpk is altered. This new statistic is often called *six sigma Cpk*. The formula for *six sigma Cpk* builds in a 1.5 sigma shift. Think of it like this: your process has to be *so good* that even if you have a shift from the mean of 1.5 sigma it will *still* be capable of producing almost zero defects.

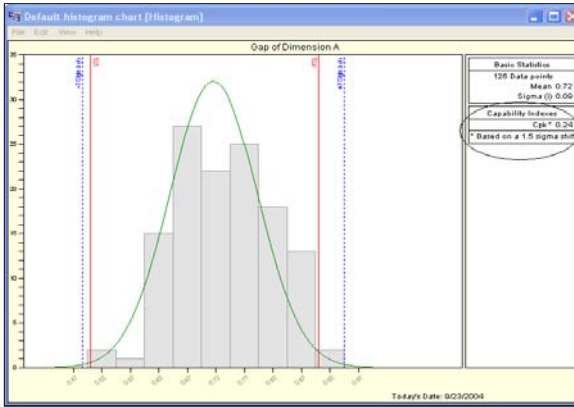
Follow these steps if you want to include *six sigma Cpk* on your histogram:

1. Display any histogram
2. Select *Edit/Chart definition*
3. Check the box *Cpk (sigma shift)*
4. Enter 1.5 into the box named *Size of sigma shift*
5. Click OK to save the histogram



You may enter a sigma shift other than 1.5; however, you must enter 1.5 if you want the traditional *CPK* for *six sigma*.

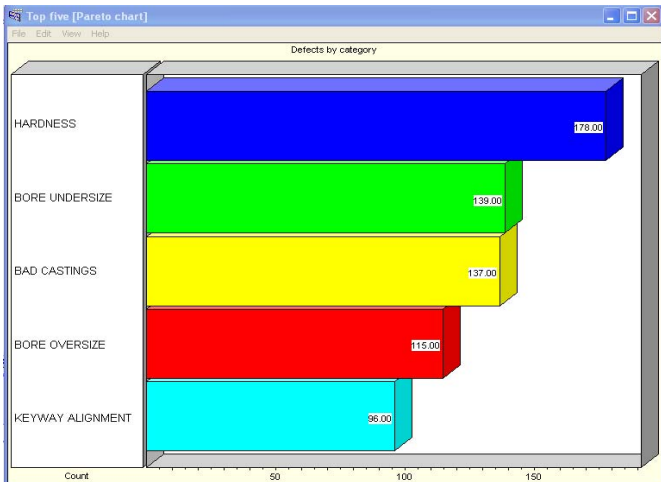
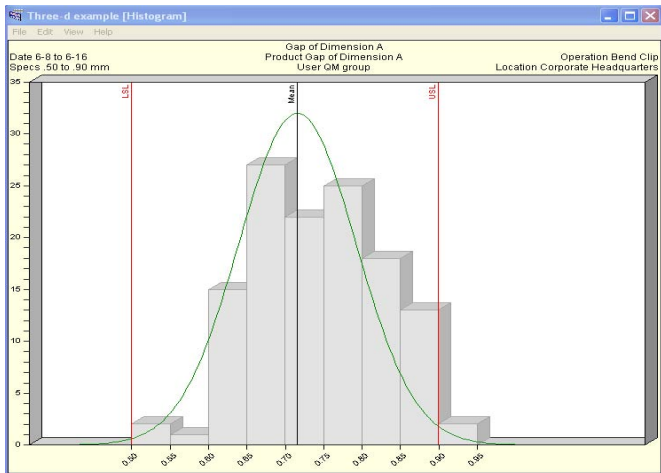
Here is what  $Cpk$  for six sigma looks like on the histogram:



## Section 7

# Three Dimensional Bars on Pareto and Histograms

New check boxes on the Pareto chart definition form and on the Histogram definition form allow you to display three-dimensional bars on these charts. Here are some examples of the output:



7



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## Section 8

# Short-run SPC

In some applications, control charts are not practical. One example of this is in manufacturing operations where small lots of many different products are produced. Since each product has different specifications, monitoring this with traditional control charts can be cumbersome.

In *Short-run SPC*, special control charts allow you to chart differences from a target value. Sometimes the absolute difference from target is plotted. In other cases, a *normalized* difference from target is plotted. The idea is that a zero difference from target is good and any deviation away from zero is bad.

A common example used to demonstrate short-run SPC is that of a machine set up to cut bar stock into different lengths. The operator may cut 6 inch bars for an hour and then switch to 12 inch bars for a few hours. Rather than keep one control chart for 6 inch bars and a different chart for 12 inch bars, short run SPC allows the operator to monitor 6 inch, 12 inch, and any other size bars, all on a single chart. You might think of the chart as monitoring “How well we are cutting bars?” rather than “How well are we cutting 6 inch bars?”

This guide will show how to set up SQCpack for short-run SPC. For more detailed information on short-run SPC, please refer to:

Donald J. Wheeler, PhD, *Short Run SPC*, (Chattanooga, TN: SPC Press; 1991)

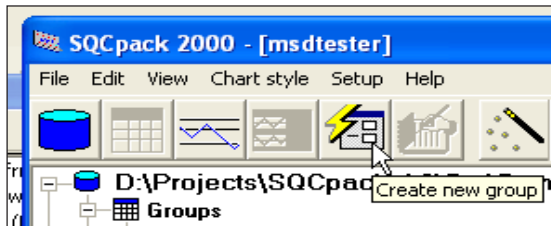
## Defining a group for short-run SPC

In SQCpack, a *group* is the basic data entry object. You may have many groups in an SQCpack database. Each group is a collection of identifiers and characteristics that together make up a data entry form and a collection of charts.

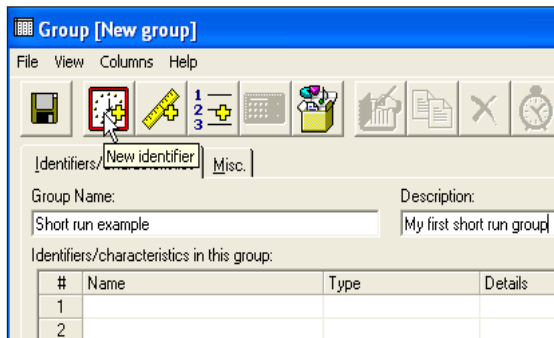
When you define a *short-run SPC* group, you will also define a *product*. Think of a *product* as a special type of identifier. During data entry, the user will select a product from a choice list much like he or she might select some other identifier from a choice list. The difference is that with each *product* in the list, we also know the *target specification*.

The next several steps guide you in setting up a group for *short-run SPC*:

1. From the main form in SQPack, click on the *Create new group* button:



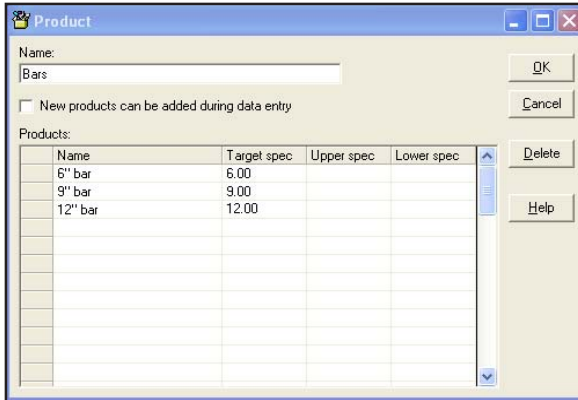
2. When the group definition form is displayed, enter a group name and description.
3. Create one *date* identifier by clicking on the *new identifier* button:



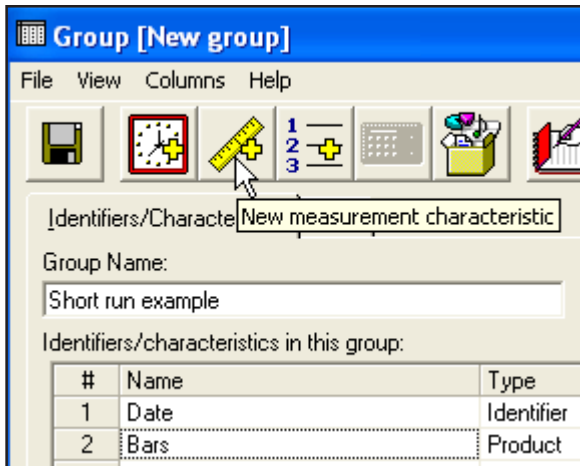
4. Set up and save the *date* identifier. Next, click on the button to add a *product* to the group definition. This is what will distinguish this group as a *short-run SPC* group:



- When the *product* definition form is displayed, enter the information for *6 inch bars*, *9 inch bars*, and *12 inch bars* as you see in the example below:



- Click *OK* to save the *product* with the bar information.
- Next, define a measurement characteristic by clicking on the *new measurement characteristic* button:



- Set up the measurement characteristic. Enter *Bar length* for the characteristic name, enter a subgroup size of 1, and to make this a *short-run* measurement, select *Bars* from the *Product* choice list. Once the form has been set up as in the example below, click *OK* to save the measurement (which is now a *short-run measurement*):

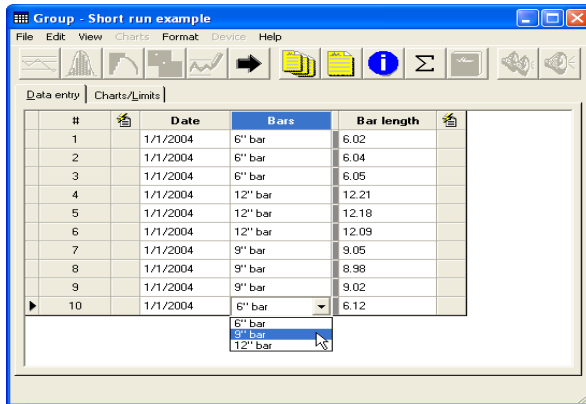
- At this point, you are ready to save the group. Click on the *Save group* button.

#	Name	Type	Details
1	Date	Identifier	Date
2	Bars	Product	
3	Bar length	Measurement	n=1 (Short run)

- Answer *Yes* when you are prompted for data entry. Next, you will see the data entry form for the new short run SPC group.

## Data Entry for Short-run SPC

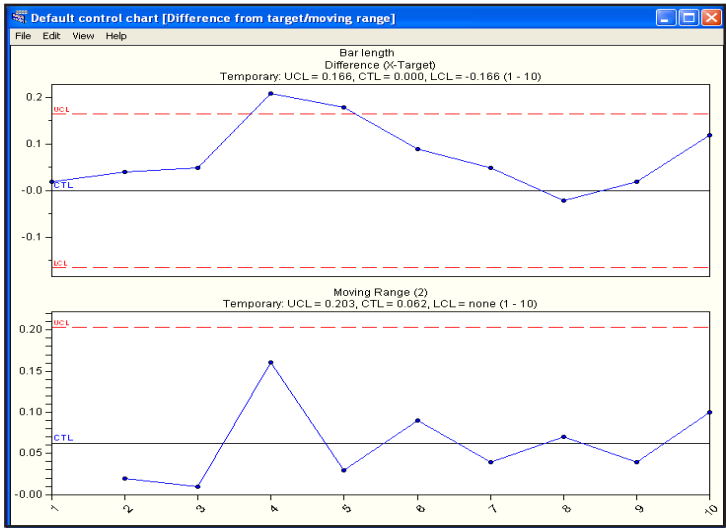
To continue with the example, enter data into the short-run group just created as shown in the screen below:



#	Date	Bars	Bar length
1	1/1/2004	6" bar	6.02
2	1/1/2004	6" bar	6.04
3	1/1/2004	6" bar	6.05
4	1/1/2004	12" bar	12.21
5	1/1/2004	12" bar	12.18
6	1/1/2004	12" bar	12.09
7	1/1/2004	9" bar	9.05
8	1/1/2004	9" bar	8.98
9	1/1/2004	9" bar	9.02
10	1/1/2004	6" bar	6.12

Here are some things to notice. The *Bars* column looks and acts like any other *identifier* column. The *Bar length* column contains data that is *mixed*. That is, the data is for three different products: 6" bars, 9" bars, and 12" bars. Remember that for each *product*, we also defined a target value. This will be important as we move into charting because short-run charts generally plot differences from a target value.

Once you have entered this data, click on the first button in the toolbar. This button displays the default control chart. You will see a chart like this:



The first chart is a *Difference* chart. Each point plots the absolute difference from the target value regardless of which product the point represents. The second chart plots a moving range of these differences. As with a traditional control chart, you can use these two charts to monitor both the central tendency (Differences) and the spread (Moving range). Notice that the target is represented as zero on the Differences chart.

The management of control limits for short-run SPC charts is the same as it is for all other control charts in SQCPack. Charts are initially drawn with *Temporary* control limits. At some point, you will compute an *official* set of control limits that will be extended into the future. Control limits are computed by selecting subgroups on the chart display, right clicking, and selecting *Compute control limits*. See the SQCPack user guide for a more detailed explanation

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# Short-run Chart Types

Here is a complete list of the short-run chart types. Notice that the options differ based on subgroup size of one vs. subgroup size larger than one.

Subgroup size is 1	Subgroup size greater than 1
Difference from target, moving range	Difference from target (X-bar), Range
Zed, W	Zed bar, W
Zed*, W*	Zed bar*, W*
Mean Ranges	Mean Ranges

The *Mean Ranges* chart is unique to short-run SPC. It will help you decide which type of chart you need for your specific data set. Consider these two scenarios:

### Scenario 1:

You are making products that have similar target values and similar variation around the mean. In our example, the 6" bars and 9" bars might qualify as *similar*.

### Scenario 2:

You are making products where both the target values and the variations are different. For example, the first product might have a target of 675 and vary from 650 up to 700. Another product might have a target of 1.1 and vary between .98 and 1.3.

The important question is, *How different are your products in terms of the mean and the variation?* If your products are *similar*, you will use the *Difference* chart. (*There is an interesting sentence!*) If your products are not *similar*, you will use the *Zed* charts.

If you display a *Mean Ranges* chart and all the points (products) fall within the control limits, use a *Difference from target* chart.

If you display a *Mean Ranges* chart and points are outside the control limits, select one of the *Zed* charts.

## Difference vs. Zed

A *Difference* chart plots the difference from target in absolute units. A *Zed* chart takes the difference from target, *normalizes* this difference in units of *sigma*, and plots this *normalized* value as the difference.



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## Section 9

# CFR 11.1 Compliance

The United States Code of Federal Regulations lists a set of regulations known as **21 CFR 11.1**. This set of regulations applies to many organizations in food and drug-related industries. The regulations cover the management of electronic records, electronic signatures, and other aspects of data and user management for computer systems and controls.

Several recent additions to SQCPack will support your efforts to comply with these regulations. To get the most from these features, you must understand and use all of the following:

- User login management
- User privileges
- User password expiration management
- Database password management
- Database audit trail management
- Audit trail reporting

Some of these are new features and some are features that have been recently enhanced. This guide will discuss each feature. Taken together, these will help you use SQCPack in a manner compliant with the regulations.

Please be aware that SQCPack does not comply with the regulations out of the box. For full compliance, you must understand, enable, and use the set of features listed above.

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# CFR 11.1 User Login Management

Whenever you start SQCpack, it is in the context of some *User*. If you have not enabled the user login features, you will be running SQCpack as the *SUPERVISOR* user. The *SUPERVISOR* user has no privilege limitations. He or she can add and delete any kind of SQCpack record, including other users, at will.

## **Important caution:**

No user should run SQCpack on a day-to-day basis as the *SUPERVISOR* user. The *SUPERVISOR* user has several unique and powerful privileges. For example, the *SUPERVISOR* may set and clear database level passwords. Features such as this rarely need to be used. Ideally, *all* of your users will run with far fewer than *SUPERVISOR* privileges. A limited number of people, perhaps no more than three, should know the *SUPERVISOR* password. Additionally, even the people who know the *SUPERVISOR* password should not run SQCpack day-to-day as *SUPERVISOR* users. Imagine that you log in as the *SUPERVISOR*, then get called away from your computer. A bystander might accidentally damage important data.

The *SUPERVISOR* user is the only user who can enable or disable the login requirement. When this is enabled, anyone who tries to start SQCpack must log in with a user name and password. When this is not enabled, anyone who tries to start SQCpack will be able to do so. It is important to note that when you first install SQCpack, user login is **not** enabled, so any user who tries to start the software will be able to do so.

When the user login requirement is enabled, two options are available to store user records:

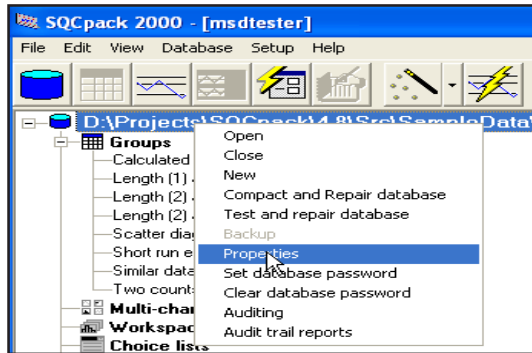
1. Users may be stored as user records in your SQCpack databases. We will call this a *regular database*.
2. Users may be stored in a stand-alone database that contains only user records. We will call this a *user database*.

The advantage of option 1 is that you have a single database file on the disk that contains both your data and the set of users who may manipulate the data.

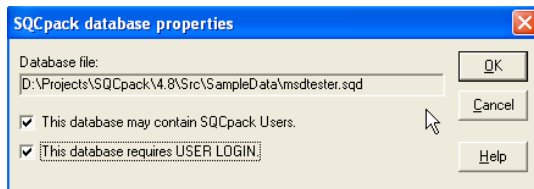
The advantage to option 2 is that a user database might be shared on a network drive. This way, many SQCpack workstations can share a common set of user records even though they may operate on different databases.

# CFR 11.1 User Login Option 1

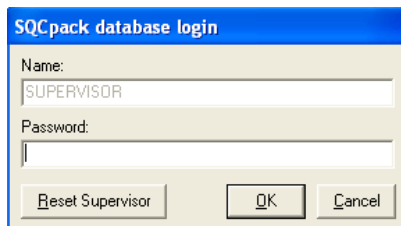
1. Start SQCpack.
2. If your database is not open, select *File/Open a SQCpack database* from the menu, browse for and select your database.
3. The database name will appear as the top *node* of the *tree* (outline) on the main form. Right click on this top node and select *Properties* from the menu as in this screen shot:



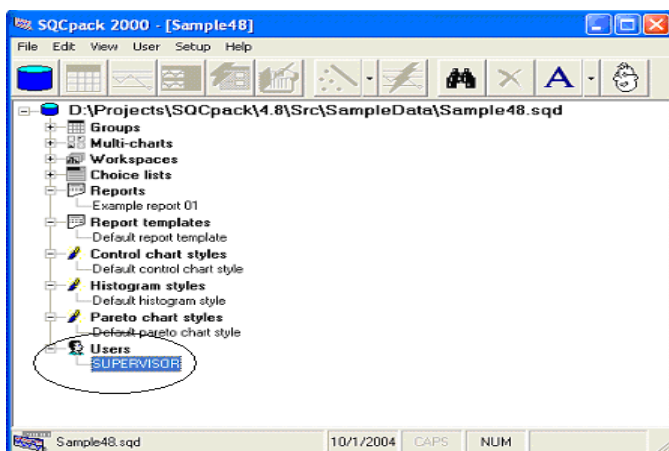
4. This will display the following dialog box. Check the boxes as you see below:



5. Click OK and you will be prompted to *login* with the following dialog:



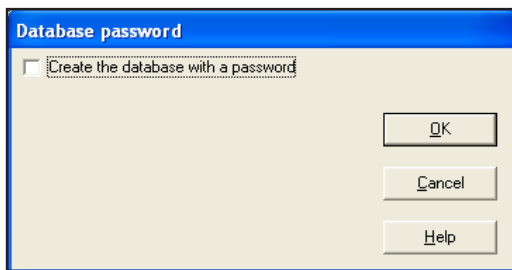
6. The first time you do this, the password is SUPERVISOR but you should change this as soon as possible.
7. From now on, each time you start SQCpack, you will be prompted to log in with a name and password. In addition, you will see a new section for *Users* in the outline on the main form as shown below:



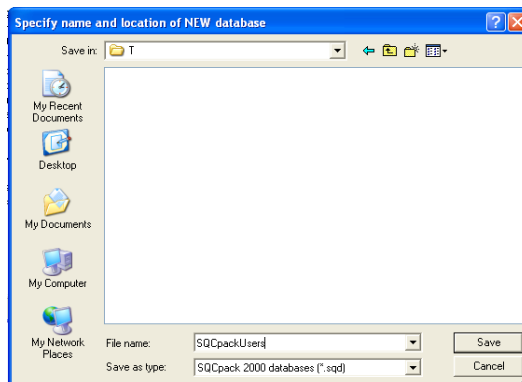
---

## CFR 11.1 User Login Option 2

1. Start SQCpack.
2. Create a new/empty *User* database: select *File/Utilities/New global user database* from the pull-down menu.
3. You will be prompted for a database password as shown below. We will discuss database passwords in another section. For now, just click OK to create the database with no database password:

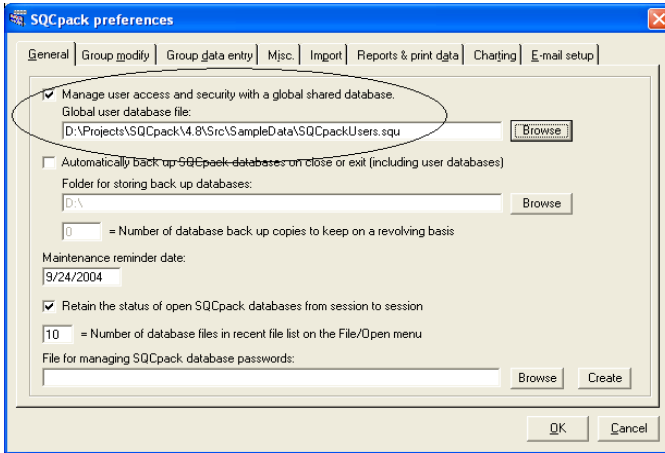


4. Browse for a folder and enter a name for your *User* database. If you plan to use a common database for SQCpack users that will be shared among many different workstations, be sure to save this *User* database on a network drive that all the workstations may access.

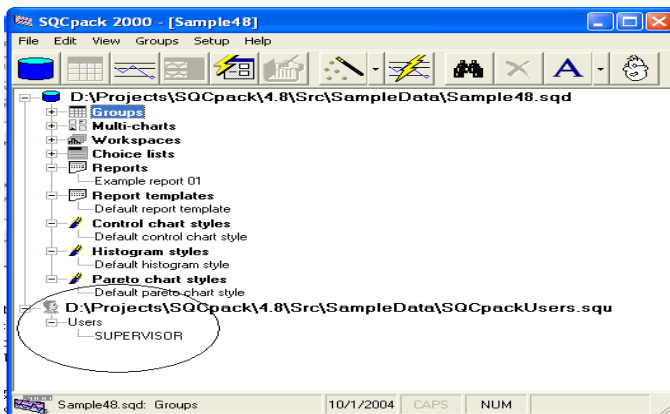


5. You will be prompted to enter a password for the *SUPERVISOR* user. Enter *SUPERVISOR* and click *OK*. At this point, all we have done is *created* the user database. The next step is to tell SQCpack to **use** this user database.

- From the main form in SQCpack, select *Setup/Preferences* and the following dialog will be displayed:



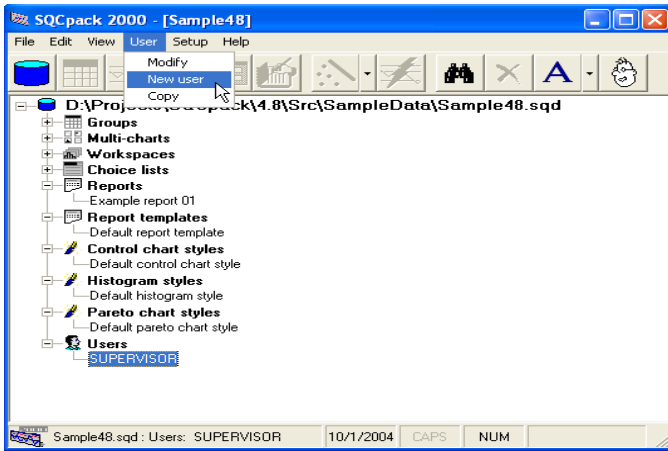
- Set up the form as shown. Use the first *Browse* button to find the specific database you created above. Click *OK* to save this information. You will be prompted again for the *SUPERVISOR* password. Enter *SUPERVISOR* for this, but realize that you need to change this *default SUPERVISOR* password as soon as possible.
- SQCpack is now set up to use a global user database. Each time you start SQCpack, you will be prompted to log in with a user name and password. Additionally, you will see a new section in the outline on the main form related to user records as shown below:



# CFR 11.1 Adding a User

Once you have established where you will store your SQCpack user records, using either option 1 or option 2, you are now able to add and modify user records. A user record defines a name, a password, and set of privileges for one person who is able to use SQCpack.

Highlight any user in the outline on the main form and then select the *User* menu:



Select *New user* from the menu and you will see the user definition form:

	Add	Modify	Delete	View
Groups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Users	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Charts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Choice Lists	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Out of Control Tests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Chart Styles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Limits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Report Templates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Fill in the information on the user form. Be sure to review all three *tabs* of the form. A good rule of thumb is to minimize user privileges. Give a user the smallest number of privileges that will allow him or her to do the job. Even if you do not have malicious users, it is a good idea to minimize privileges. Doing so will reduce the chance of data loss due to innocent mistakes.

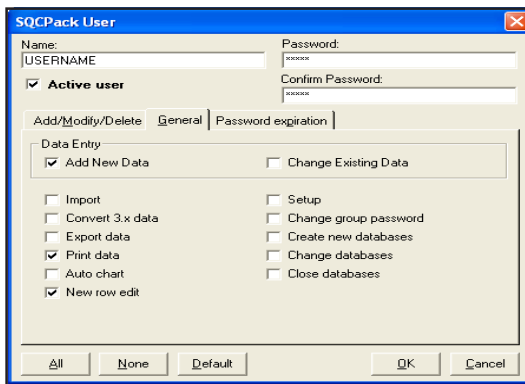
# CFR 11.1 User Privileges

On the *Add/Modify/Delete* tab of the user definition form (shown above), check each box where you want the user to have the privilege. Typical users will need only two privileges here: 1) *View charts* and 2) *View reports*. The ability to *Delete* any of the SQCpack objects should be given to very few users. This can eliminate cases where data is accidentally deleted.

The privileges related to creating, modifying, and deleting SQCpack *Users* should be given to a user only after careful consideration. The power to create user definitions, and decide what privileges they have, allows someone to do almost anything within SQCpack. Minimizing the number of people with this capability is prudent.

On the *General* tab of the user definition form (shown below) there are three privileges related to data entry:

1. Add new data
2. Change existing data
3. New row edit



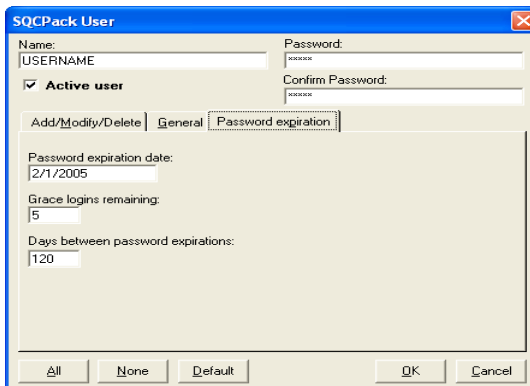
For data entry users, the recommendation is to give the user *Add new data* and *New row edit* privileges. This allows a user to add new rows of data and also change any rows that are added during this session. However, it does not allow the user to change data that was entered *before* the current session. The *Change existing data* privilege should be given only to users who frequently edit data entered during previous sessions. In many environments, SQCpack can be used with no user having the *Change existing data* privilege.

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# CFR 11.1 User Password Management

The *Password expiration* tab on the user definition form (shown below) is accessible only by the *SUPERVISOR* user. A regular user, even one with *all* privileges, will not be able use the password expiration features. Use these settings to make a password expire after a certain amount of time.

For the best security, you must have users reset their passwords occasionally. It is common practice to require that passwords be changed every 90 or 120 days. A user will be *warned* as the password expiration date approaches. When a user changes a password, the *password expiration date* will be reset, based on the setting for *Days between password expirations*.



The screenshot shows a dialog box titled "SQCpack User" with a close button in the top right corner. The dialog is divided into several sections. At the top, there are two input fields: "Name:" containing "USERNAME" and "Password:" containing "\*\*\*\*\*". Below these is a checked checkbox labeled "Active user" and a "Confirm Password:" field with "\*\*\*\*\*". A tabbed interface is visible with three tabs: "Add/Modify/Delete", "General", and "Password expiration", with the latter being the active tab. The "Password expiration" tab contains three input fields: "Password expiration date:" with "2/1/2005", "Grace logins remaining:" with "5", and "Days between password expirations:" with "120". At the bottom of the dialog are buttons for "All", "None", "Default", "OK", and "Cancel".

Once a password expires, users will be given some number of *grace logins*. If they do not change their password before they log in this many times, their password will expire and they will not be able to log in to SQCpack. When this occurs, a *SUPERVISOR* user must edit the user record and set the *grace logins* to some number. This will allow the user to log in and immediately change the password.

Users are never *Deleted* from the system. Instead, they are set to *Inactive* by un-checking the *Active user* checkbox. An *inactive* user may not log in and use SQCpack.

Since User records can be associated with *Audit Trail* records (discussed in a later section), they must be unique. No two users may have the same login name, and user records are never deleted.

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## CFR 11.1 Database Password Management

SQCpack works with two types of databases: 1) *regular* databases and 2) *user* databases. A *regular* database contains group definitions, subgroup data, charts, limits and the other SQCpack objects you are familiar with. A *user* database contains only SQCpack user definitions. Both types of databases are stored on the disk as Microsoft Access databases. A *regular* database has a .SQD file extension and a user database has a .SQU file extension.

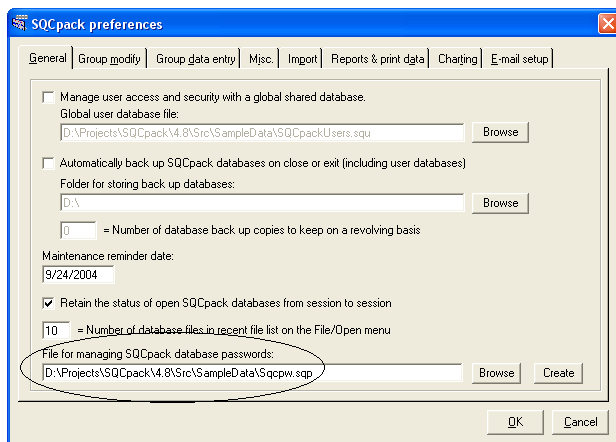
Microsoft Access typically opens files with an .MDB file extension. However, you can also open any SQCpack database. You might try this to see that it is possible. How do you feel about a Microsoft Access user opening a SQCpack database via Access? This might be done on purpose or as an innocent accident. In either case it could mean loss or damage of valuable SQCpack data. Using database passwords can minimize this possibility.

SQCpack allows you to set a password for any SQCpack database. Once this password is set, a casual user of Microsoft Access will not be able to open the database without the password. The password will also protect against other programs that might try to open a SQCpack database.

Passwords are helpful, but they can also be inconvenient. For example, if your SQCpack users routinely open and close several different databases, they will not be happy if they are constantly prompted for various passwords. SQCpack provides a special database to help with this issue.

## The database for passwords

Under *Setup/Preferences*, there is a setting available only to the *SUPERVISOR* user: *File for managing SQCpack database passwords*. Use the *Create* button to create a special file for managing SQCpack database passwords. See the *Preferences* form below:



This file is also an Access database. Each time you set a password for *any* SQCpack database, the information will be recorded in this database. Once this file is established, it will be used internally by SQCpack to find a password when trying to open *all* SQCpack databases. This file is also password protected to discourage casual users of Microsoft Access who might try to open this file.

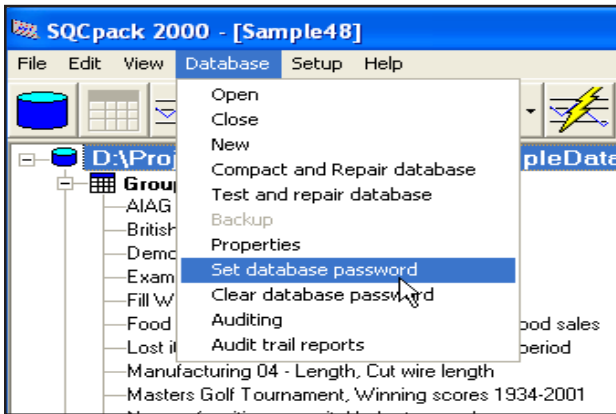
Please note that setting the *File for managing SQCpack database passwords* is optional. If you do not set this, you may still have passwords on your SQCpack databases; however, users will be prompted for the password each time the database is opened.

---

## Setting a Database Password on One of Your Existing SQCpack Databases

To password protect a SQCpack database follow these steps:

1. Start SQCpack
2. Use *File/Open* to open an SQCpack database
3. Click once on the database name to select it.
4. From the *Database menu*, select *Set database password* as shown below:



5. Enter and confirm the database password on the following form:

A screenshot of the "Database password" dialog box. It has a blue title bar and a light beige background. There are two text input fields. The first is labeled "New password:" and contains several asterisks. The second is labeled "Confirm new password:" and also contains several asterisks. To the right of the input fields are three buttons: "OK", "Cancel", and "Help".

6. When you click *OK*, the database will be password protected. From now on, when anyone tries to open this database using Microsoft Access or any other program, it will not work without the password.

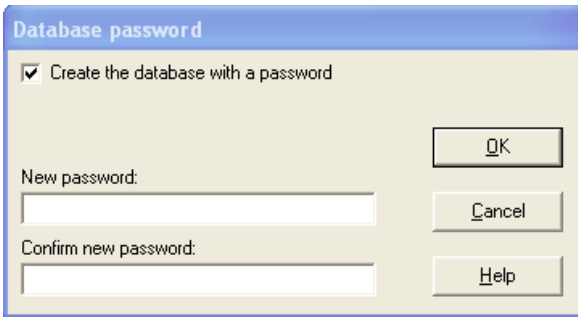
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When SQCPack tries to open any database that is password protected, it will first try to find the password in the *database for passwords* (see previous section). If it does not find this database or the password, the user will be prompted for the password. If the user does not know the password, the database will not be opened.

Keep in mind that if you are using a *database for passwords*, users will **not** be prompted for the database password because the software will find and use this automatically.

Also remember that both *regular* SQCPack databases and *user* databases may be password protected following the steps above.

When you create a *new* SQCPack database, you have the option of setting the password from the start. On the main form, if you select *File/New SQCPack database*, you will see a form like this:



If you check the box, then enter and confirm a password, the database will be password protected from the start.

Remember that SQCPack databases are not password protected by default. You must follow the steps described above.

Depending on how you configure SQCPack, you may never be prompted for a database password. However, it is still important that you remember these passwords using some technique that works for you and is secure. A yellow sticky on the edge of the monitor is generally not considered secure.

### Group level passwords

When you define a group within a SQCPack database, you have the option to set a password that is specific for the group. This feature is documented in the user guide. A group level password is *above and beyond* the passwords that protect a database. Use group level passwords when you need to limit access to specific groups within a database.

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## CFR 11.1 Database Audit Trail

An audit trail allows you to track activity that occurs within SQCpack databases. This is done by appending audit trail records to a special table stored within the database. Each record in this *audit* table contains information such as the date, time, current user, record type, record identifier, and what was changed.

Enabling the audit trail causes SQCpack to store additional information in the database. A SQCpack database that has auditing enabled will generally be larger (on the disk) than the same database without auditing. However, as described below you do have control over the level of detail you want to track in the audit trail.

When auditing is enabled, SQCpack does more work. In most cases, you will not perceive a performance difference. However, on some older and slower workstations, enabling the auditing features may cause slight delays during some activities.

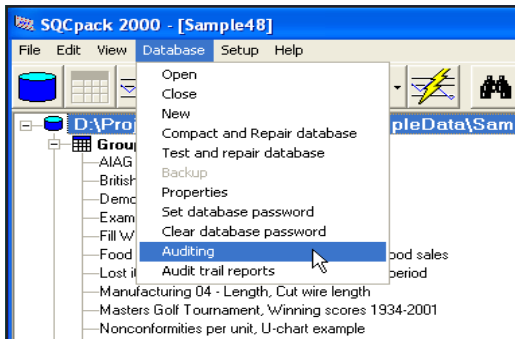
### **Auditing must be *enabled***

Auditing features are enabled or disabled *per database*. For each SQCpack database where you want to keep an audit trail, you must enable the auditing features. This includes regular databases and user databases. By default, auditing is *not* enabled on any SQCpack database until you decide to enable it.

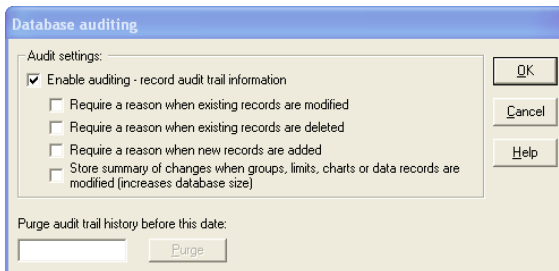
## Enabling the Audit Trail Features on a Database

To enable the audit trail for a SQPack database, follow these steps:

1. Start SQPack and log in as SUPERVISOR. Only the SUPERVISOR may enable auditing
2. Use *File/Open SQPack database* to open a database.
3. Click once on the database name (top of outline) then select *Auditing* from the *Database* menu as shown below:



4. The auditing dialog box will be displayed. Check the box for *Enable Auditing* as shown below:



5. Before you click *OK*, study each of the other check boxes and see if you want to select these options. Use caution on any of the *Require a reason...* options. End users can become discouraged when they are constantly being prompted for a reason. However, some actions such as *deleting* may warrant that you ask the user for a reason. This reason will be recorded in the audit trail.
6. When you click *OK*, auditing will be enabled. From now on, when any SQCpack user is working with this database, auditing trail information will be recorded.

If you are working with a global user database (see earlier section), you can enable auditing on this user database by following the same steps described above. Just highlight the user database instead of a regular database. Remember that only the SUPERVISOR user may enable and/or disable auditing.

### **Auditing – what gets recorded?**

When auditing is enabled, one record will be added to the audit table when any of the following events occur within the software:

User Login	Create group
Modify data record	Modify group
Delete data record	Delete group (mark for delete)
Insert data record	Delete group (permanent delete)
Create chart	Create limit
Modify chart	Modify limit
Delete chart	Delete limit
Create report	Create style
Modify report	Modify style
Delete report	Delete style
Create user	Change active OOC
Modify user	Create OOC test set
Deactivate user	Modify OOC test set
Create choice list	Delete OOC test set
Modify choice list	Open group for data entry
Delete choice list	Open group for real-time charting

---

Each audit trail record contains the following information:

Date/Time

User name

User database (where current user record is defined)

Type of event (from list above)

Reason for event (if reasons are required)

Summary of changes (if change summary is enabled)

Record ID (id of the affected record)

### **Store summary of changes**

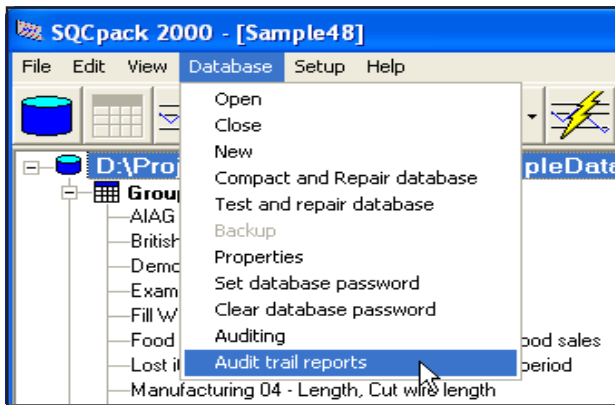
When you enabled auditing (as described above), one of the check box options is *Store summary of changes when groups etc. are modified*. Enabling this option will cause detailed text descriptions of changes to be stored when important records are modified. If you ever need to *revert* a record to a previous *state*, this information can be quite useful.

# CFR 11.1 Audit Trail Reporting

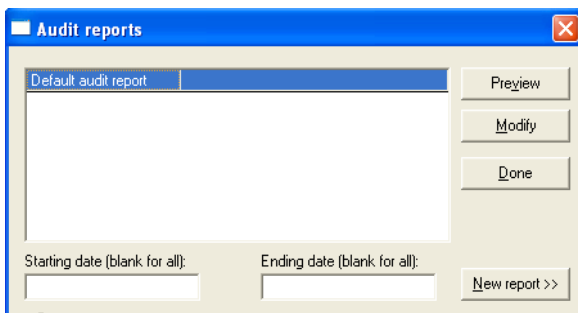
Once you have enabled the audit trail features, you may occasionally need to review audit information that has been recorded. The *Audit trail reporting* features allow the SUPERVISOR user to preview and print reports containing audit trail information.

To produce an audit trail report, follow these steps:

1. Start SQPack and log in as SUPERVISOR.
2. Use the *File/Open SQPack database* menu to open a database.
3. Click once on the database name (top of outline), then select *Audit trail reports* from the *Database* menu as shown below:

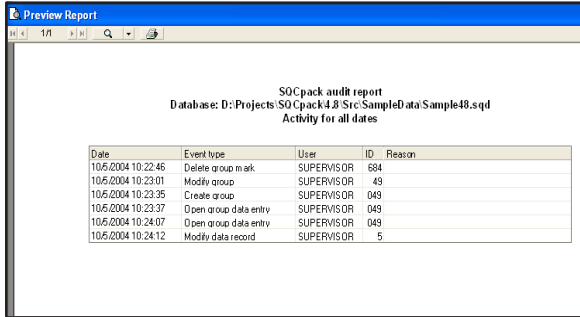


4. The following dialog box will be displayed:



5. By default, every database contains one audit trail report named *Default audit report*. You may create your own reports using the *New report* button but we will look only at the standard report for all dates.

- Click on the *Preview* button to see the standard report for *all* records. Note that if you have just enabled auditing, there may not be any audit records yet. If you have audit records, you will see a print preview screen similar to this:



The screenshot shows a window titled "Preview Report" with a standard toolbar. The main content area displays the following text:

**S0Cpack audit report**  
Database: D:\Projects\S0Cpack43\Sic\SampleData\Sample48.sqd  
Activity for all dates

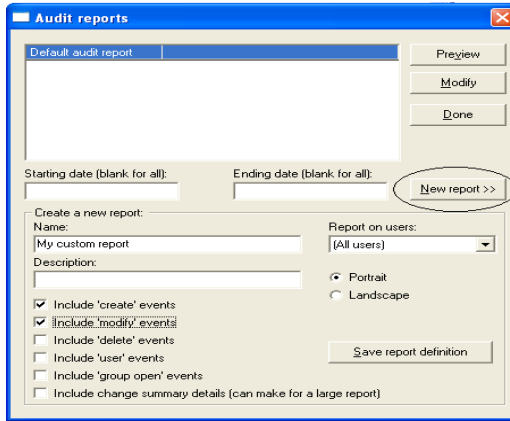
Date	Event type	User	ID	Reason
10.6.2004 10:22:46	Delete group mark	SUPERVISOR	684	
10.6.2004 10:23:01	Modify group	SUPERVISOR	49	
10.6.2004 10:23:35	Create group	SUPERVISOR	049	
10.6.2004 10:23:37	Open group data entry	SUPERVISOR	049	
10.6.2004 10:24:07	Open group data entry	SUPERVISOR	049	
10.6.2004 10:24:12	Modify data record	SUPERVISOR	5	

- Click on the print icon to send this audit trail report to a printer.

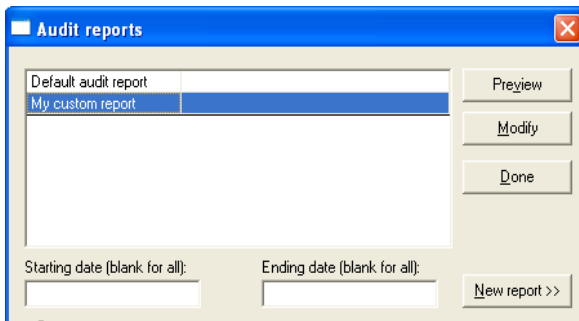
Note that you may set a range of dates when previewing any audit trail report. If you are trying to understand something that has happened during the last two weeks, enter the appropriate *Starting date* and *Ending date* before clicking on the *Preview* button. This will limit the specific audit trail records that are included in the report to your range of dates.

## Creating your own audit trail reports

Clicking on the *New report* button will expand the *Audit reports* dialog box with additional options to create your own audit trail reports. In the following example, a new report named *My custom report* has been defined:



When you define your own audit trail reports, you select types of audit trail information you want included in the report. When you click on *Save report definition*, the report will be stored in the database and it will appear as an option within the audit report list as shown below:



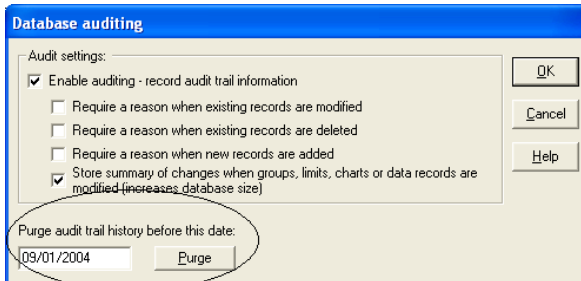
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## Purging audit trail history

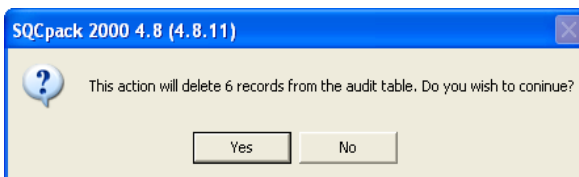
When you enable auditing, additional records are continuously added to the SQCpack database. Over time, the database can become quite large. Occasionally you may wish to archive a copy of your SQCpack database (for historical purposes) and then delete some of the previously recorded audit information. Only the SUPERVISOR user has access to this capability.

Follow these steps to purge audit trail history:

1. Start SQCpack and log in as the SUPERVISOR user.
2. Use the *File/Open SQCpack database* menu to open a database.
3. Click once on the database name (top of outline) then select *Auditing* from the *Database* menu.
4. On the *Database auditing form*, enter a date as shown below:



5. When you enter a date, keep in mind that you will be purging all audit trail records that were recorded *before* that date.
6. Click on the *Purge* button. You will be asked to confirm the deletion with a message box like this:



7. Click *Yes* to purge the audit trail records.

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## CFR 11.1 Summary

The last several sections of this guide have described features that will help you comply with the **21 CFR 11.1** regulations. Listed below is a brief summary of the steps you must take in your efforts to use SQCPack in a manner compliant with these regulations:

1. Enable and use the *User login* features of SQCPack
2. Minimize the software privileges you give to SQCPack users
3. Enable the password expiration feature which forces users to change passwords on a regular basis – every 90 or 120 days.
4. Set up every SQCPack database with a database level password.
5. Enable, understand, and use the audit trail features of SQCPack

In addition to these steps, please be sure to implement a **system of regular backups** for each of your SQCPack databases. The least-favorite technical support call we ever get is one where the user answers *no* to the question, “Do you have a backup copy of the database?”