Camco Quality Systems Elements

11. Control of Inspection, Measuring, and Test Equipment: Our calibration procedures define how we control, calibrate, and maintain those gauges, test equipment, fixtures and software that we use to make quality decisions or measure product specifications. This includes gauge identification, calibration frequency, and records thereof.

12. Inspection and Test status: Parts, components, materials & Products are identified per the quality plan so that inspection/test status is known & only good product released.

13. Control of Nonconforming Material: Our procedures define how we identify, evaluate, segregate, and disposition nonconforming product. ie.Identified, reworked, repaired,Rejected.

14. Corrective and Preventive Action: Corrective action includes handling Customer feed back through SCR/CMI/MWR, product & process corrective action to determine Root Cause and insure CA taken is effective. GB/BB projects also address many actions that Prevent customer complaints and potential causes of nonconformities. These are reviewed by site management during the Six Sigma reviews.

15. Handling, Storage, Packaging, Preservation, and Delivery: Our written procedures describe how we accomplish each of the preceding so that the product gets to our customers/ consumers without damage.

Camco Quality System Elements

An overview of our ISO 9000 based Quality System elements

1. Mgmt Responsibility: Quality Policy Implemented and understood at all levels and the Plant Mgr. must review the effectiveness of the Quality System per plan.(Op Ex)

2. Quality System:: Site Quality Manuals define all elements of the quality system with procedures effectively implemented & Quality Planning identified. CTQ's incorporated in quality plans, Drawings include measurements and controls to maintain, Capability maintained (Zlt),etc..

3. Contract Review: Before we accept an order, we understand the requirements and resolve differences with the customer. We review that we have the capability to meet the order (Price/Schedule/Delivery), Define how we amend the contract if necessary and keep records of the reviews.

4. Design Control: Documented procedures which explain our NPI process. Design & Development planning; Organizational Charts ; Marketing input into the Design Specification; Engineering output via Drawings and specifications; P & T Reviews; Evaluation and product testing , and the ECN Process. CTQ's are linked to QFD/FMEA's, Capability understood (Zst), 1st Piece dispositioned. Part qualification includes 1st piece, capability, and completed Quality Plan.

5. Document & Data Control: Explains how we control documents and data through approval and issue, and make changes to insure only current information is used. ie. All documents numbered, appproved, have an issue date and revision number.

Variables Control Chart Formulas

Average & Range Control Chart

$$\overline{\overline{X}} = \frac{(\overline{X}_1 + \overline{X}_2 + \ldots + \overline{X}_k)}{k}, \text{where } \overline{X} = \sum_{i=1}^{n} \frac{X_i}{n}$$

$$\overline{R} = \frac{(R_1 + R_2 + \ldots + R_k)}{k}$$

Central Lines

$$UCL_{\overline{x}} = \overline{\overline{X}} + A_2\overline{R} \text{ and } LCL_{\overline{x}} = \overline{\overline{X}} - A_2\overline{R}$$

$$UCL_R = D_4\overline{R} \text{ and } LCL_R = D_3\overline{R}$$

Individual X & moving Range Control Chart

$$\overline{X} = \frac{(X_1 + X_2 + \ldots + X_k)}{k}$$

Central Lines

$$R_m = |(X_{i+1} - X_i)|, \text{ and}$$

$$\overline{R}_m = \frac{(R_1 + R_2 + \ldots + R_{k-1})}{k-1}$$

$$CL_x = \overline{X} \pm E_2\overline{R}_m$$

$$UCL_{R_m} = D_4\overline{R}_m \text{ and } LCL_{R_m} = D_3\overline{R}_m$$

Control Chart Reference Texts

Statistical Quality Control Handbook, 1956. Available from I.D.C. Commercial Sales, Western Electric Company, P.O. Box 26205, Indianapolis, IN 46226

Statistical Quality Control by Eugene L. Grant and Richard S. Leavenworth, McGraw-Hill, Inc. Fifth Edition 1980

Understanding Statistical Process Control by Donald Wheeler and David S. Chambers, SPC Inc., 1986

Fundamental Statistical Process Control (Reference Manual) by A.I.A.G. ph: (313) 358-3570

Key Concepts: Control Tools

- Statistical Process Control is an excellent upstream process control tool. Control charts are ideally suited for monitoring and controlling your "Vital Few" independent X variables.

- Control charts monitor the process variation and generate a signal when the process variation is influenced by special cause variation.

- SPC Control charts can be used to monitor:
  - Continuous Variables Control Charts -
    - Xbar & Range
    - Xbar & s
    - Individuals & Moving Range (XmR)
  - Discrete Variable (Attribute) Control Charts -
    - p Chart
    - np Chart
    - c Chart
    - u Chart

Class Exercise: Catapult Control Plan

3) Anticipated potential problems -
   - Spend some time thinking about what could possibly go wrong. Add procedures to ensure that nothing else goes wrong.

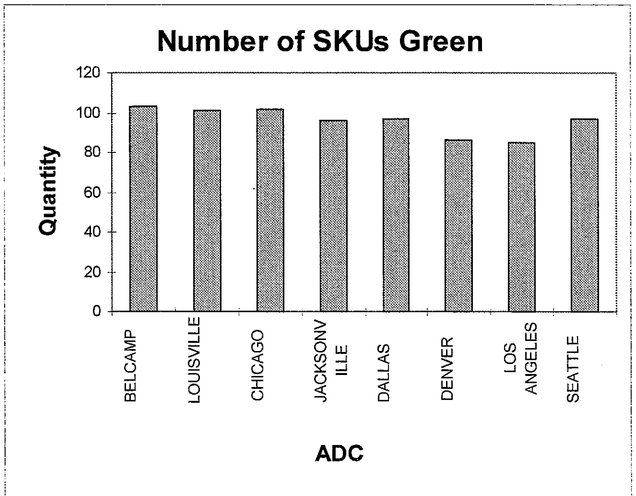
4) Re-baseline the process with the process improvements
   - For this example, collect 10 subgroups with 3 samples per subgroup. (In your project, you will likely need more subgroups. Collect subgroups over a long enough period of time and over a wide enough conditions to ensure that you capture all sources of variation.)
   - Check normality of the re-baseline data. Calculate Z.st and Z.lt for this data.
   - Use Minitab to plot a control chart.

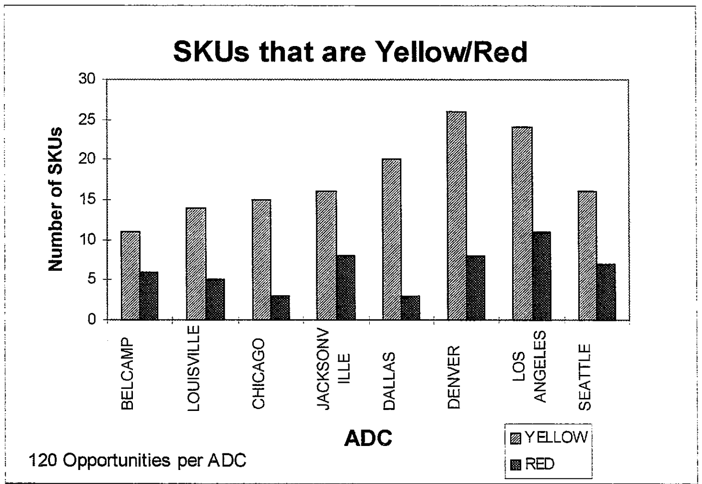
5) Monitoring plan (SPC on X's, and maybe on Y)
   - Develop a sampling plan including:
     - How often subgroups are collected
     - How many samples are collected in each subgroup
     - Who does the collection and measurement
   - Develop a data management plan. How and where are the data stored and retrieved? (SETCIM, SPQ, etc)
   - Out-of-control rules (trends, number above mean, etc.). Ensure that these are understood by all.

Dashboard - Tool # 10

100 x 120 Hot Sheet - page 2

ADC Information





	GREEN	YELLOW	RED
BELCAMP	103	11	6
LOUISVILLE	101	14	5
CHICAGO	102	15	3
JACKSONVILLE	96	16	8
DALLAS	97	20	3
DENVER	86	26	8
LOS ANGELES	85	24	11
SEATTLE	97	16	7
TOTAL	767	142	51
960 OPPORTUNITY	80%	15%	5%

Dashboard - Tool # 10

A dashboard tracks quantitative measurements.

Example: 100 x 120 Hot Sheet

Description:

This report was created as a result of the 100 x 120 availability project for Home Products and Services. The project focused on providing 100% availability on 120 key SKU's. The hot sheet shows the status of the 120 SKU's at each of the 8 ADC's for the Manufactured Housing (OEM), Single Family (SF) and Multi-family (MF) segments. The report is distributed weekly by the PSI team and they decide on the appropriate action if the data is out of control . The first page summarizes by manufacturing site and includes PSI action plans. The second page summarizes by ADC.

Internal Audits - Tool # 8

Project Title: Factory Service Scheduling

Internal Audit Process (con't):

Frequency (Cont'd):

Trend data is recorded and reported to the ASI VP-Factory Services, for discussion monthly at the Factory Service Call-Taking Council.

Definition of "Out -of-Control":

Center Average falls below 88% minimum.

Responsibility for action:

The center manager is responsible to take appropriate action to stay above minimum requirements weekly. The ASI-VP responsible for Factory Service is responsible to raise issues monthly at the Call-Taking Council.

Job Descriptions - Tool # 7

Project: AP5 Formed Liner Thickness Improvement

To control variation in the thickness of a formed plastic liner in a refrigerator, it was found through DOE analysis, that the cure time of the extruded plastic sheet needed to be a minimum of 3 days (a Vital X). If a sheet cured less than 3 days needs to be used, the controlmen on the thermoformers need to be notified so they could adjust the heater settings on the equipment (another Vital X) to continue to control the variability in the thickness.

Job Description:

The job description for the material handlers (jitney drivers) in the liner area needed to be modified to assure that a minimum of 3 day cured extruded plastic sheet is loaded into the thermoformers. The job description was modified and documented in the AP5 quality system:

Training Elements - Jitney Drivers

I. Co-extrusion

B. Sheet temperature normalization

The jitney driver takes sheet from the storage area on a first-in, first-out basis. If the sheet has not cooled for a minimum of 3 days, the driver is to take sheet directly from the co-extruders and notify the rotary (thermoforming) control person that "hot sheet" is being loaded so the thermoformer heats can be adjusted......

Document No. D7118004

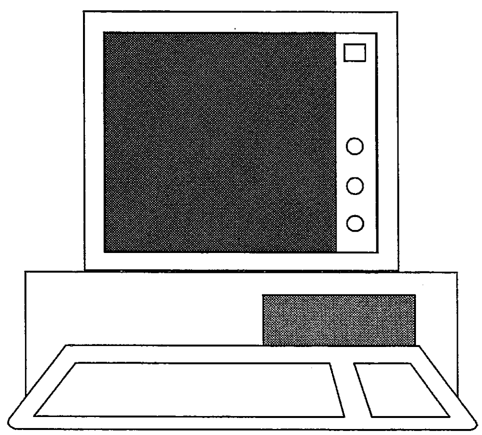
System Changes - Tool # 5

Project: Contract Channel Order Placement

Objective: Improve efficiency on incoming calls at the Forum by reducing call time with unprepared customers.

System Change: Added "customer prepared" field to order screen for tracking. The call taker must put yes or no in the field to complete order. The Forum can then track which customers are consistently unprepared and address the issue.

System changes have sustainability



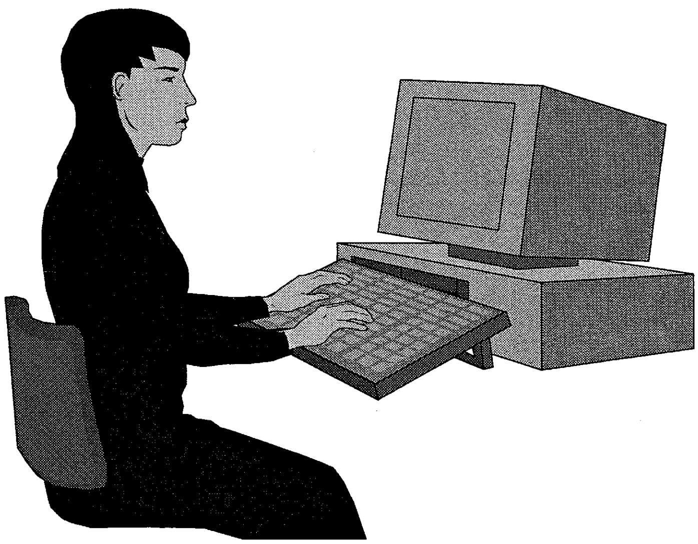
SPQ - Tool # 4

Supplier **P**rocess **Q**uality

GE process owner "sets up" the parts for data entry. The **Supplier** enters the data daily, weekly, monthly, or quarterly via the **internet**.

SPQ:

- Checks **validity** (internal consistency) of the data as it is entered.
- **Alarms** if data are not entered on time or is outside of acceptable limits.
- Creates **control charts** and reports.
- **Stores** data in a warehouse for later retrieval.



SPQ does most of the work.

Elements of ISO

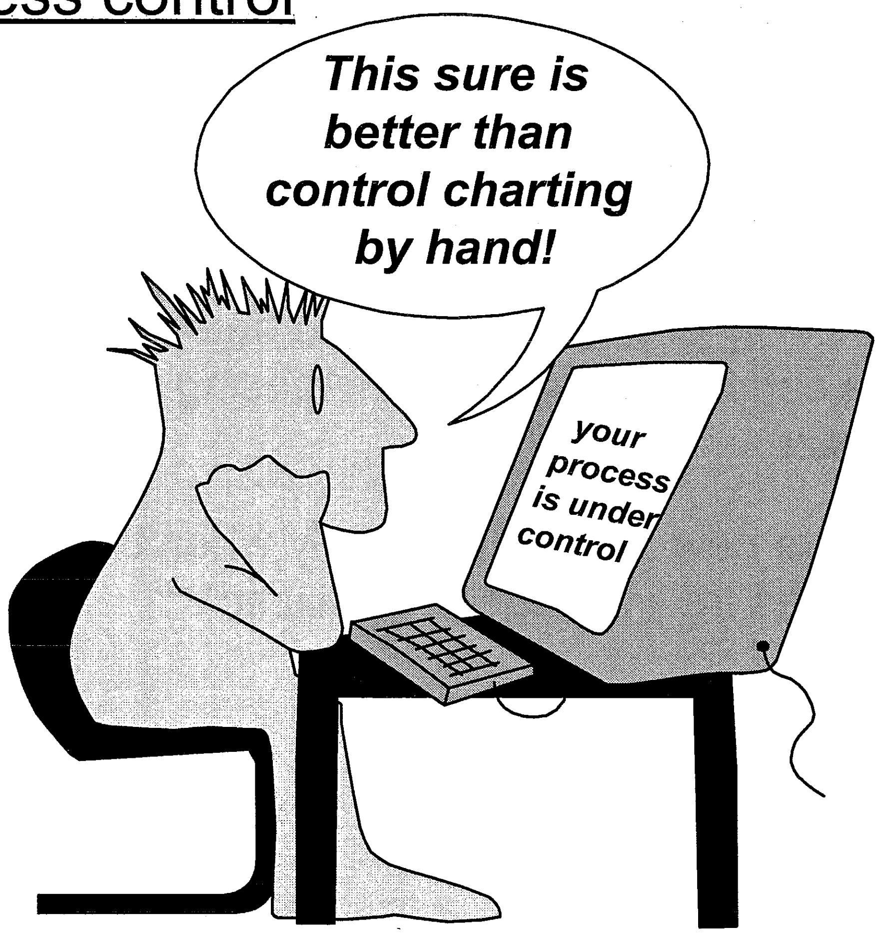
1. Management Responsibility
2. ***Quality System***
3. Contract Review
4. ***Design Control***
5. ***Document & Data Control***
6. Purchasing
7. Customer Supplied Product
8. Product Identification and Traceability
9. ***Process Control***
10. ***Inspection and Test***
11. ***Control of Inspection, Measuring, and Test Equipment***
12. ***Inspection and Test Status***
13. Control of Nonconforming Material
14. Corrective and Preventive Action
15. Handling, Storage, Packaging, Preservation, and Delivery
16. ***Control of Quality Records***
17. ***Internal Quality Audit***
18. ***Training***
19. Servicing
20. Statistical Techniques

More details shown in the Appendix.

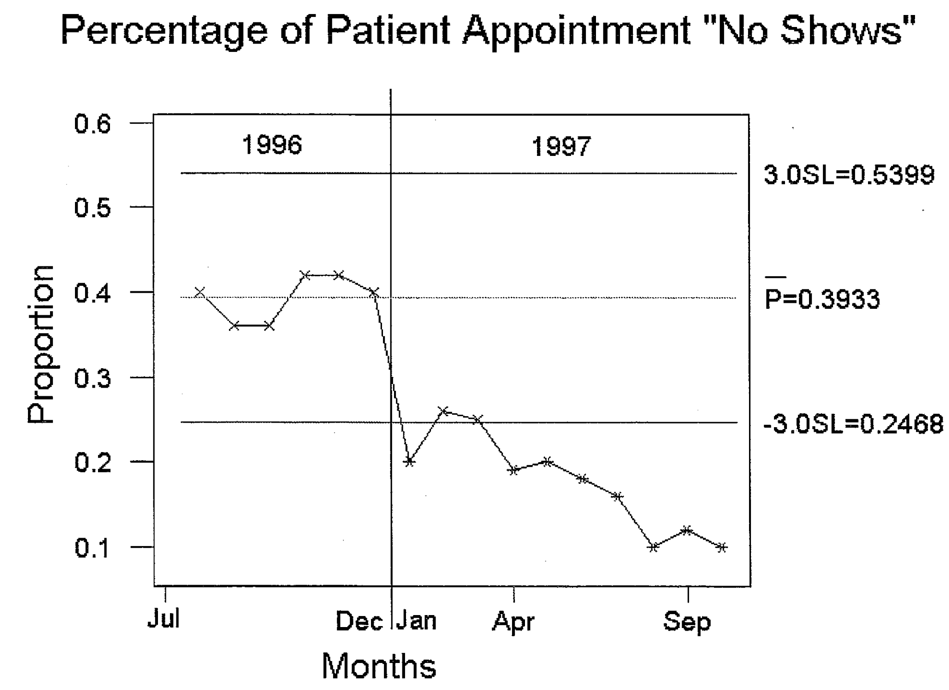
SETCIM - Tool #2

What is it? A sophisticated GEA database (customized in-house) that provides an astonishing variety of information for both reporting and troubleshooting. SETCIM offers many benefits, but two stand out:

- numerous means of data entry
- process control



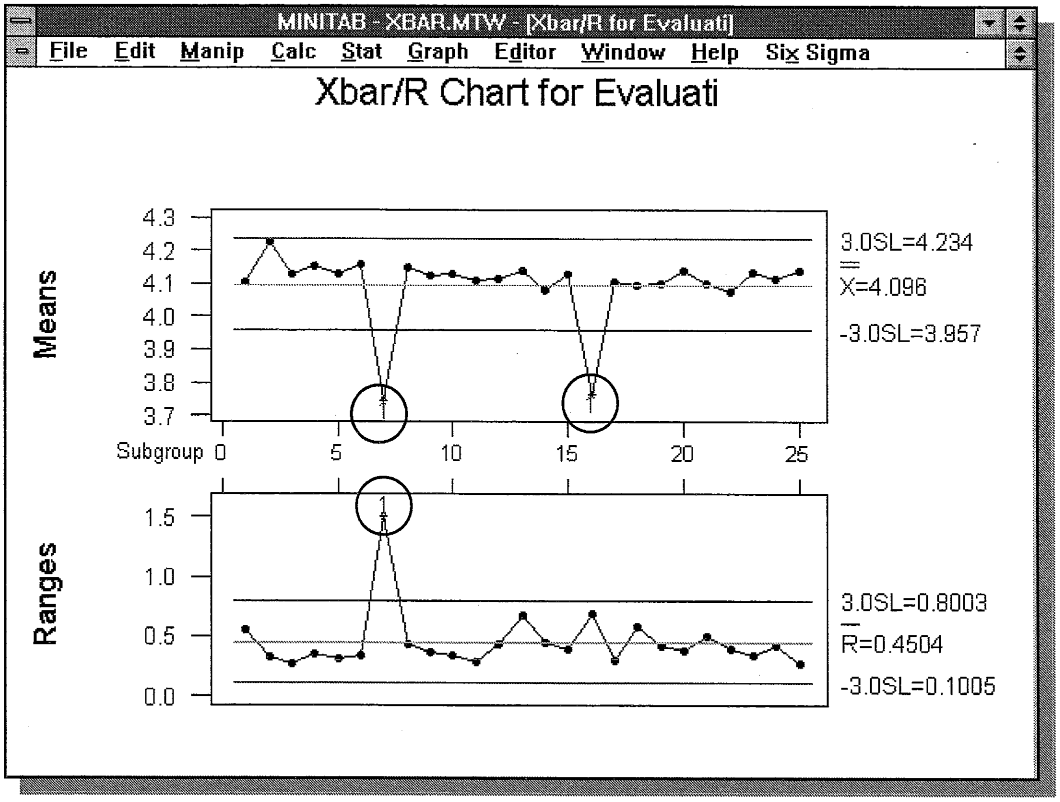
The p Chart shows that the process has improved over time...



(Control Limits based on 1996 data)

- Control limits were established from the 1996 “no show” data.
- The advocacy team examined and prioritized the various reasons why patients were missing their appointments.
- The team determined that providing flex-time for patients resulted in fewer missed appointments.
- A new flexible appointment policy was adopted in January 1997.
- The control chart shows a dramatic reduction in the number of missed appointments after the implementation of the flex-time policy.
- By adopting the new appointment policy, the team was able to reduce the average percentage of “no shows” from 39% to 18% (18% is the new average for 1997 data only).

Minitab generates the Xbar-R chart . It automatically calculates the control limits. The out-of-control points are shown on the graph and summarized in the session window. These are the same points shown on page 3.21.



MINITAB - XBAR.MTW - [Session]

File Edit Manip Calc Stat Graph Editor Window Help Six Sigma

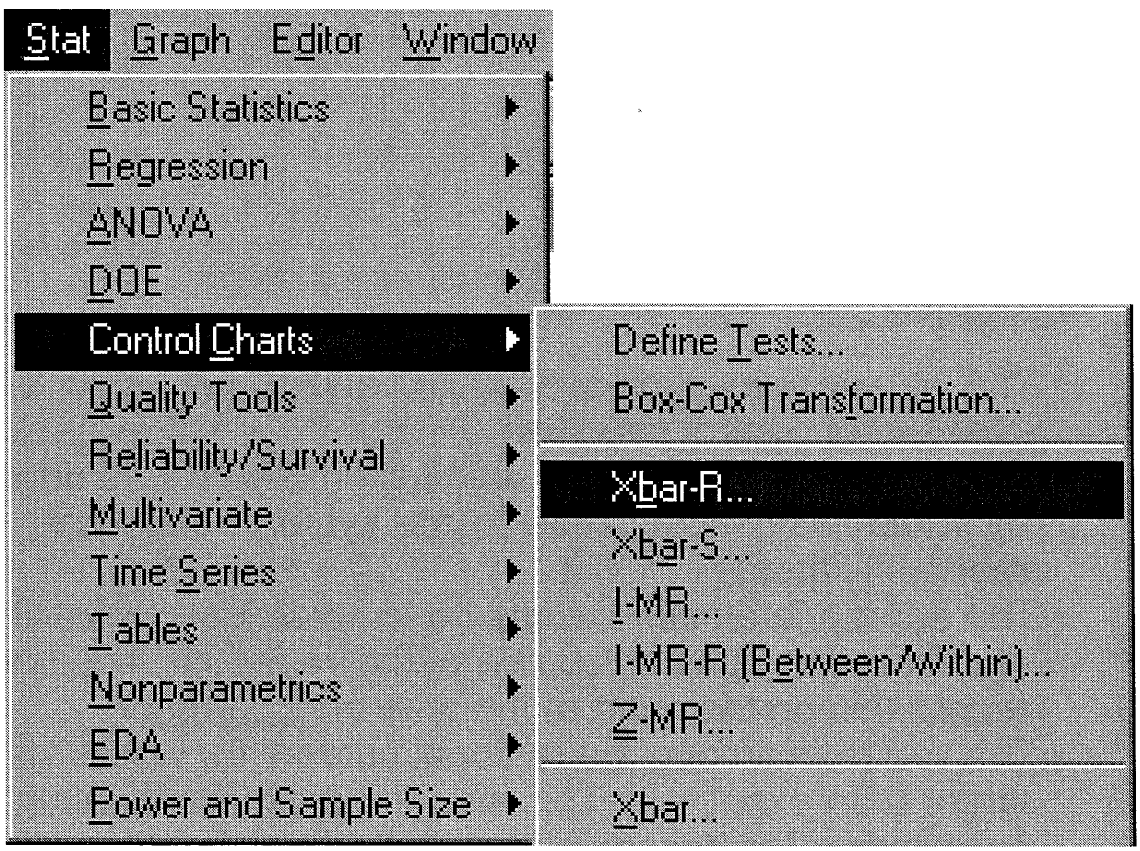
```
Worksheet size: 100000 cells


Retrieving worksheet from file: A:\XBAR.MTW
Worksheet was saved on  2/16/1998
Macro is running ... please wait
Test Results for Xbar Chart
TEST 1. One point more than 3.00 sigmas from center line.
Test Failed at points: 7 16

Test Results for R Chart
TEST 1. One point more than 3.00 sigmas from center line.
Test Failed at points: 7
```

To make a Xbar-R control chart using Minitab...

Restart Minitab.
Open **XbarR.mtw** located in the Phase3 training directory.
Select **Stat** > **Control Charts** > **Xbar-R**



Control Chart Constants

The following table contains the various constants that are used for constructing SPC control charts.

Variables Control Chart Control Limit Constants

n	A2	A3	D3	D4	B3	B4	*d*2	*c*4
1	2.660	3.760	-	-	-	-	-	-
2	1.880	2.659	0	3.267	0	3.267	1.128	0.7979
3	1.023	1.954	0	2.575	0	2.568	1.693	0.8862
4	0.729	1.628	0	2.282	0	2.266	2.059	0.9213
5	0.577	1.427	0	2.115	0	2.089	2.326	0.9400
6	0.483	1.287	0	2.004	0.03	1.970	2.534	0.9515
7	0.419	1.182	0.076	1.924	0.118	1.882	2.704	0.9594
8	0.373	1.099	0.136	1.864	0.185	1.815	2.847	0.9650
9	0.337	1.032	0.184	1.816	0.239	1.761	2.970	0.9693
10	0.308	0.975	0.223	1.777	0.284	1.716	3.078	0.9727

From the previous $\overline{\overline{X}}$ and R control chart example:

The A2 constant for a subgroup size of 10 is 0.308. This constant was calculated as follows:

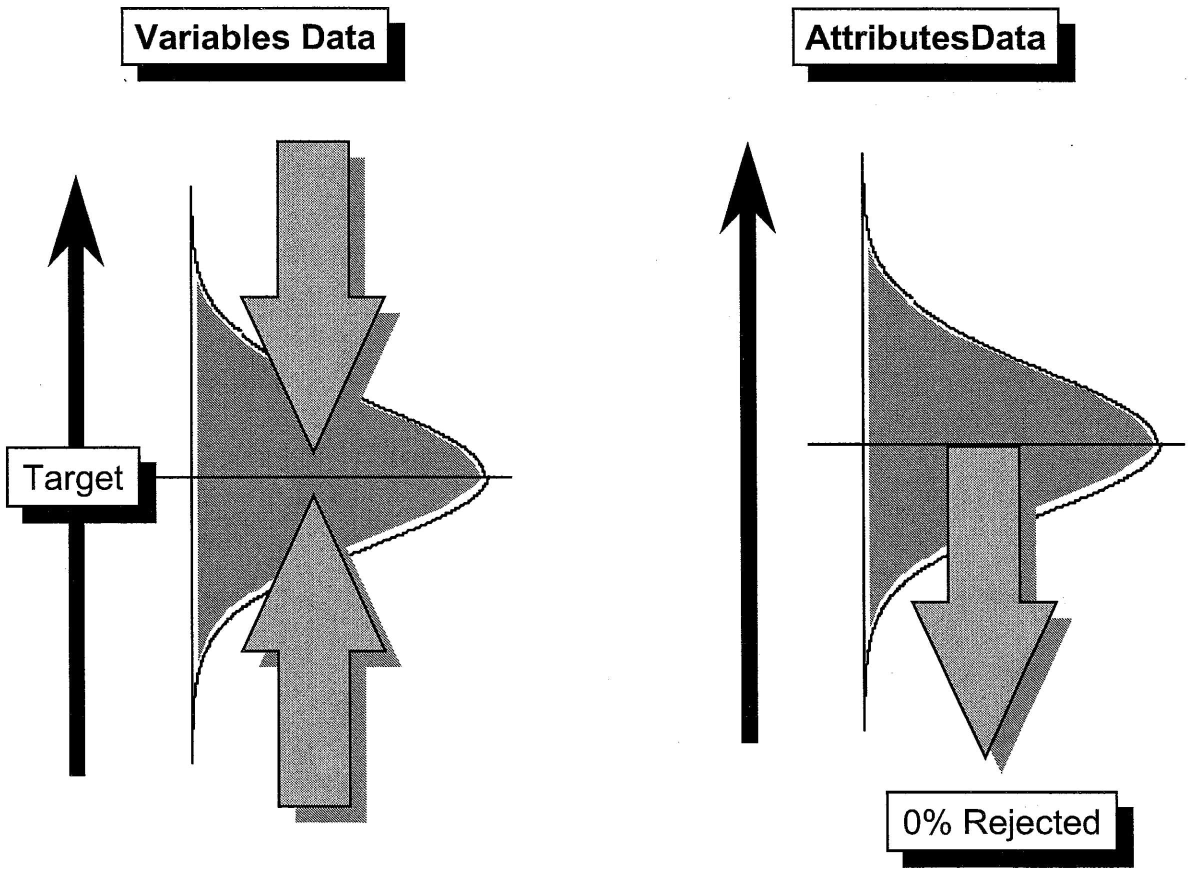
$\sigma_{\overline{X}} \cong \frac{\overline{R}}{d_2}$ and $d_2 = 3.078$ for a subgroup, $n = 10$

$\sigma_{\overline{X}} = \frac{\sigma}{\sqrt{n}}$, $\sigma =$ sigma for individual values and

$\sigma_{\overline{X}} =$ sigma for subgroup averages. Generically the control limits are plus and minus 3σ, then

$$CL = \overline{\overline{X}} \pm 3\left(\frac{\overline{R}}{3.078}\right) \times \frac{1}{\sqrt{10}} = \overline{\overline{X}} \pm 0.308 \times \overline{R} = \{4.235,\ 3.957\}$$

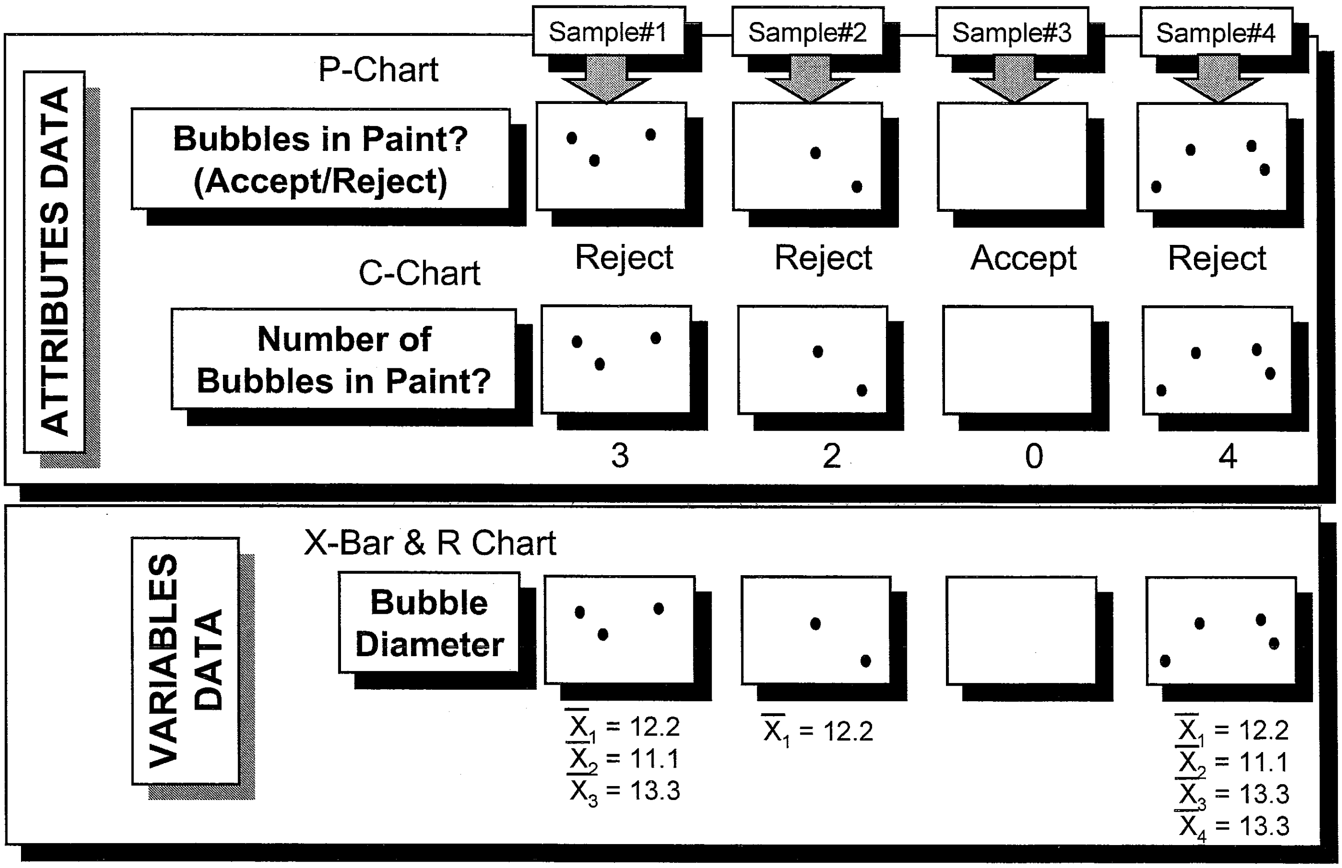
SPC Chart Goals



Remember your basic goal for using the SPC control chart. SPC for continuous variables is used to steer a process towards a target. Attribute SPC charts are used to minimize defects.

Three Families of Control Charts

There are three basic categories of control charts that are used for monitoring continuous and discrete data.

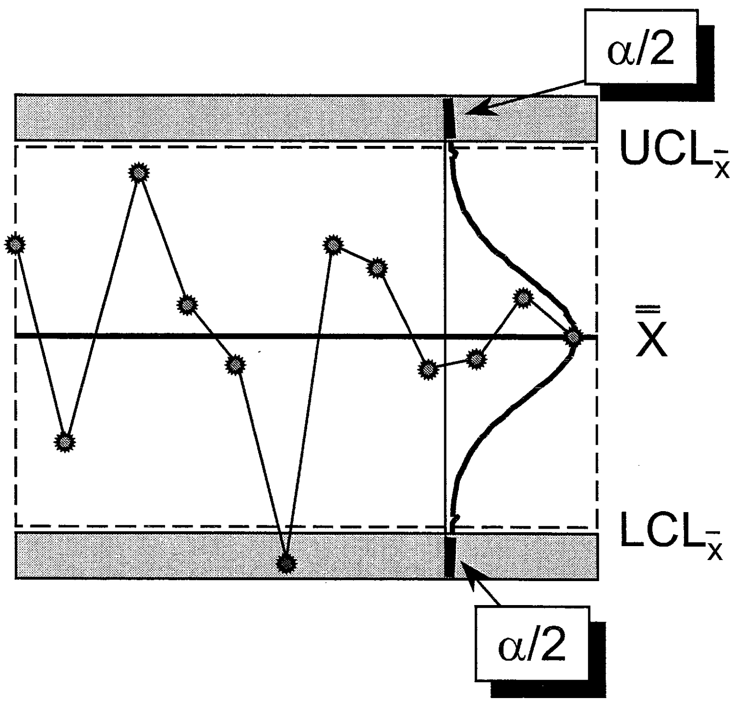


If you want to monitor a fraction or percentage, use the p-chart. For monitoring the number of defects in a unit, a c-chart would be appropriate. The Xbar/R chart is best for monitoring continuous data.

How do Control Charts work?

- The Empirical Rules emphasized that when a subgroup average falls outside of the 3 sigma limits, it is a rare event. Process stability is defined in terms of these three sigma limits.
- Another way of visualizing how control charts work: A control chart performs a sequential hypothesis test for each new subgroup.

In this case, $\alpha/2 = 0.00135$



H_o: $\mu_i = \mu$

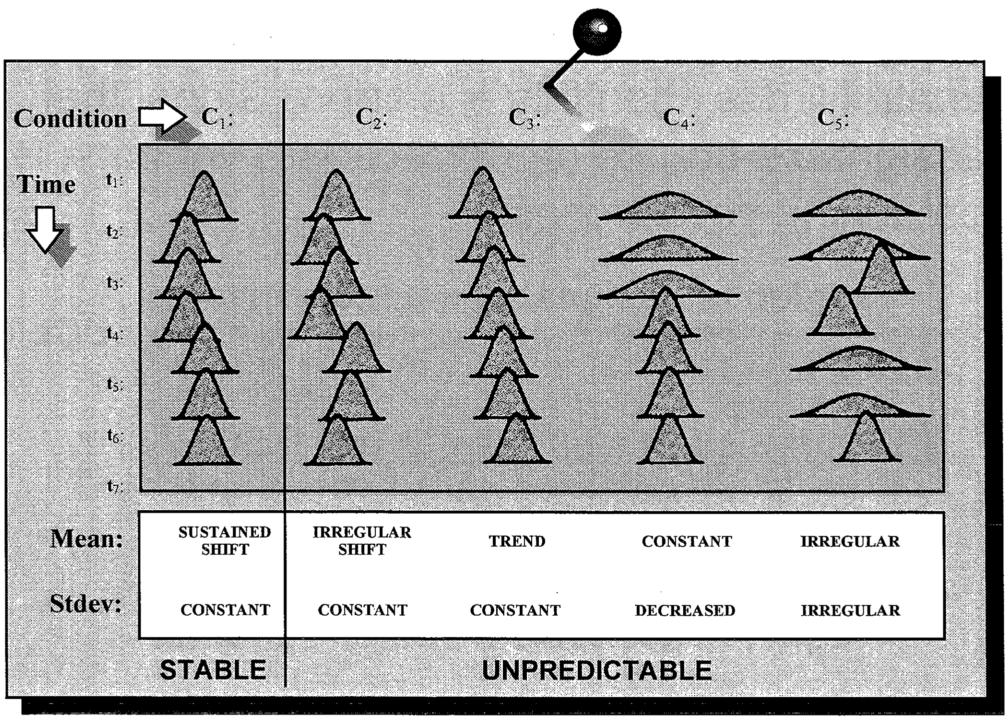
H_a: $\mu_i \neq \mu$

The hypothesis test provides the criteria for determining if a difference exists between the subgroup mean and the process average

The control limits are variation limits, not acceptance limits! Specification limits do <u>not</u> appear on SPC charts!

Importance of Process Stability

Capability studies involve forecasting the future state of the process output. This is an impossible task if past process performance doesn't provide a sound basis for prediction. Thus, before any type of meaningful capability study can be undertaken, the process being studied must be stable. A process with a sustained shift and constant standard deviation within the control limits is considered stable as shown in C1 below.



An unstable process has no predictable behavior. Stability is a necessary requirement for determining the **capability** of a process.

Why Not Six Sigma Limits?

Q: Why don't control charts use six sigma limits?

A: Six sigma limits relate to product or process specifications. Control charts graphically depict over time the shift and drifts of the process mean and standard deviation relative to the three sigma statistical limits (99.73% confidence limits) for the process mean and standard deviation.

Two errors in Control Chart application:

- Putting specifications limits on a control chart
- Treating Upper Control Limit (UCL) and Lower Control Limit (LCL) as a specification limit

We are using Control Charts to detect a change in the process to enable corrections before the process is out of specification. Placing specification limits on a control chart makes it just another inspection tool. It is no longer a **control chart**. Remember, the UCL and LCL are not directly tied to customer defects!

Determining the Control Limits

To determine the value of the control limits, you must first calculate the **Central Line**:

$$\bar{\bar{X}} = \frac{\left(\bar{X}_1 + \bar{X}_2 + \ldots + \bar{X}_k\right)}{k}$$

Overall Process Average

where k = the # of subgroup averages

The generic formula for the **Upper Control Limit**:

$$UCL_{\bar{X}} = \bar{\bar{X}} + 3\sigma$$

The formula for the **Lower Control Limit**:

$$LCL_{\bar{X}} = \bar{\bar{X}} - 3\sigma$$

The **Control Limits** are plus and minus three sigma units away from the overall process average or central line, $\bar{\bar{X}}$.

SPC is a powerful graphical process control tool

Developed in the 1920s by Dr. Walter Shewhart of the Bell Laboratories, statistical process control charts provide a graphical comparison of a measured process characteristic against statistically computed "control limits".

Control Chart Characteristics

- Plot variation over time, and help us distinguish between the two causes of variation through the use of control limits.
- The control limits serve as a probability based decision making tool for managing the process variation like a running t or F test.
  (Signals when action should be taken in a process)
- Control Charts are used in pairs. One chart characterizes the variation of subgroup averages, and the other chart characterizes the variation of the spread of the subgroups.
- The primary function of a control chart is to detect the presence of assignable causes that affect the process average or variance.

Tool #1: Statistical Process Control (SPC)

Statistical --

Statistical methods are used to monitor and analyze process variation from sample data.

Process --

Any repetitive (manual or automatic) task or steps

Control --

Provides an early warning signal that a process has changed. The warning allows you to make decisions about the process while there is still time to correct the problem before it can be seen in the final output.

Six Sigma Quality focuses on moving control upstream in a process to leverage the input characteristics for the Y response. We can not guarantee control of the Y response unless we measure and control the Vital Few X's.

Statistical **P**rocess **C**ontrol -- Enables us to control our process using statistical methods to signal when process adjustments are needed.

Control Tools

PURPOSE:

Discuss and give examples of control tools.

OBJECTIVES:

- Become familiar with some of the tools available to assist with the control phase.
- Develop the ability to use Statistical Process Control (SPC) as one effective tool to sustain process quality improvements.
- Create, interpret and maintain SPC charts for making process management decisions.
- Understand the benefits of SETCIM and the Supplier Process Quality (SPQ) system.
- Learn how to use ISO as a tool.
- See examples of other control tools.
- Be familiar with the pitfalls of each tool.
- Understand that there is no "cookbook" solution to controlling a process