

Step 5:

ISO9001:2015 -Risk Based Planning Risk Controls

Introduction

In this fifth workshop module we will look at risks controls.

By the end of this module you will be able to

- Define what is a control classification
- Identify key elements in controlling a process.
- Create a run chart for process data
- Maintain and interpret a control chart
- Document a control plan

Risk Control Classification

Controls are classified as **Preventive** or **Detection**.

A **Preventive** control is designed to avoid errors or irregularities from occurring initially.

- An error proofing design system
- Yoka-Poke put into the process at the planning stage
- RFID threshold sensors

A **Detection** control is designed to identify an error or irregularity after it has occurred. –

- Taking an annual physical inventory to check items on asset listing
- Run and control charts
- SPC
- Audit

Control Accountability

When we have identified the key input risk and output impacts and the cause and effect relationships between them.

We now specify how we are going to control them:

What - What is to be measured

Why - Reason why we need to measure.

How - Type of measurement sensor, instrument or analytical method

Definition to assure consistent results

Where and how samples will be taken

How frequently the measurement will be made

Who - Will make the measurement

Visible Measures and Standards

The most important part of any risk controls is they are visible at all times - Visible Measures and Visible Standards

- Visible Measures - Run (Trend) Chart – see slide 7
- Visible Standards - Control Charts – see slide 8
- Visible Standards - Standard Deviations – see slide 9
- Visible Standards - Control limits showing unusual conditions – see slide 10
- Visible Standards - Adding Stakeholder Standards – see slide 11
- Visible Standards Additional Tests for Unusual Events – see slide 12

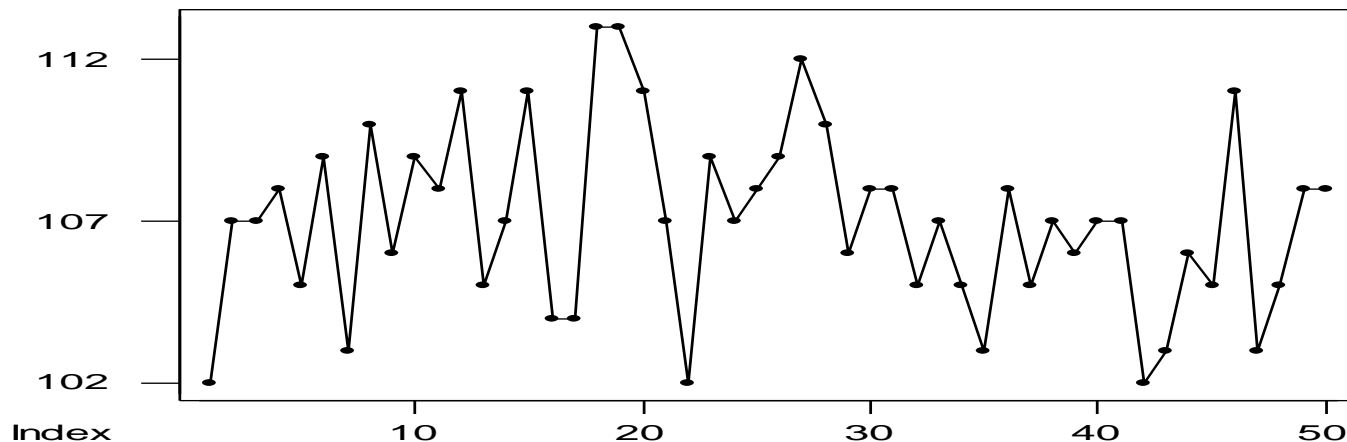
Visible Measures Run (Trend) Chart

Definition

- A display of measurements over time (or sequence)

Purpose:

- Shows trends, shifts or cycles in the process
- Focuses attention on major changes
- Allows team to display the effect of any changes it makes



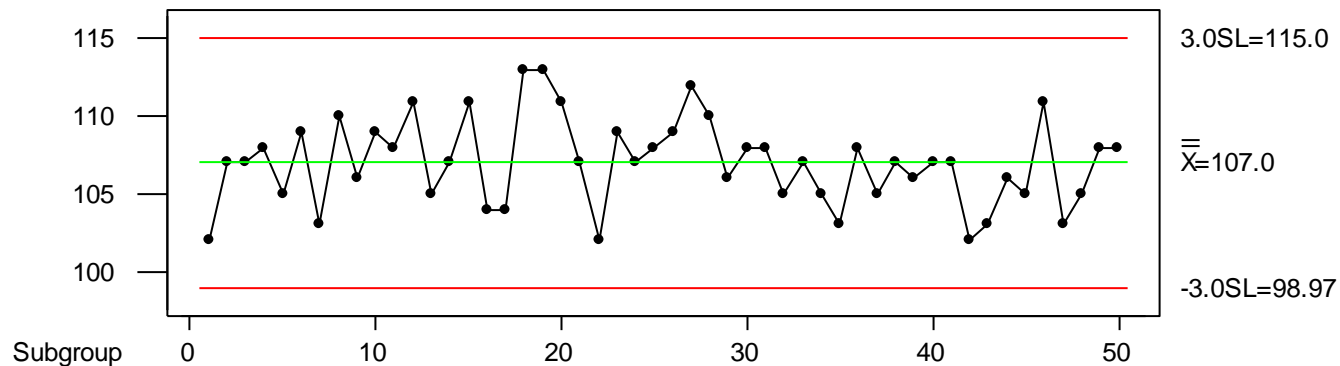
Visible Standards Control Charts

Definition:

- Run chart with addition of control limits
- May also show customer or other stakeholder specifications

Purpose:

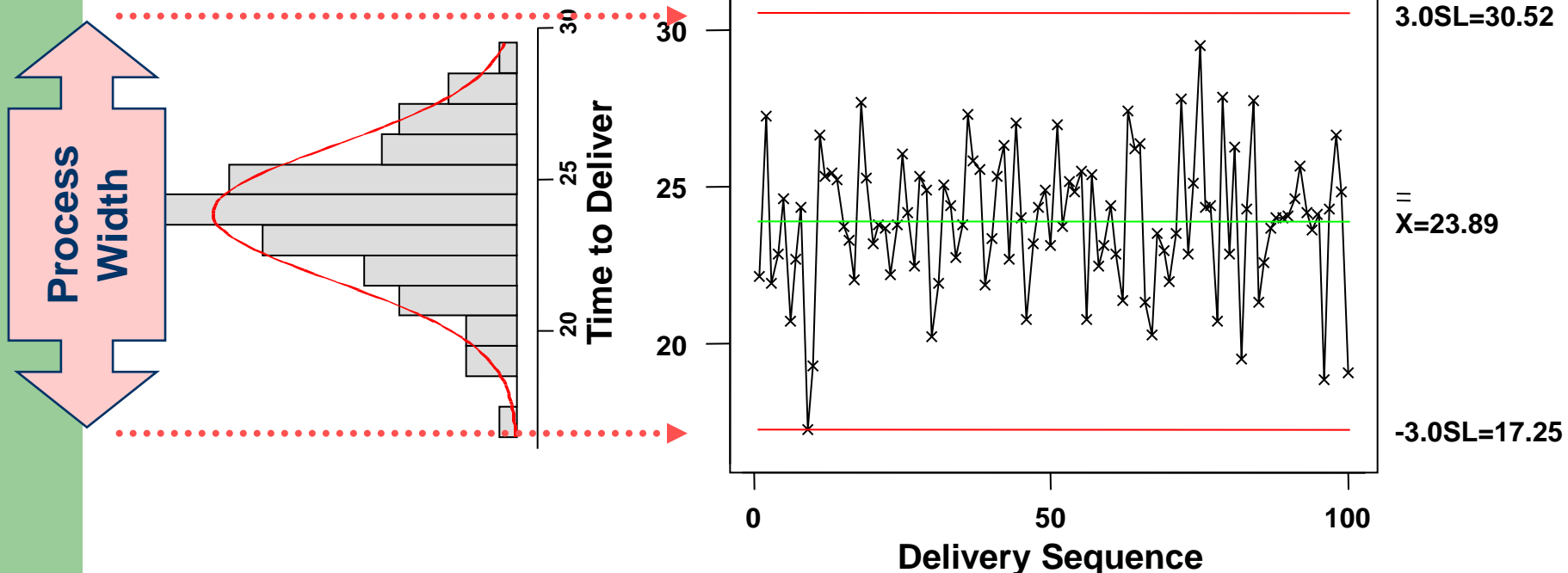
- Shows whether the process is stable and capable of the requirements
- Allows identification of unusual events



Visible Standards

Is the Process in Control?

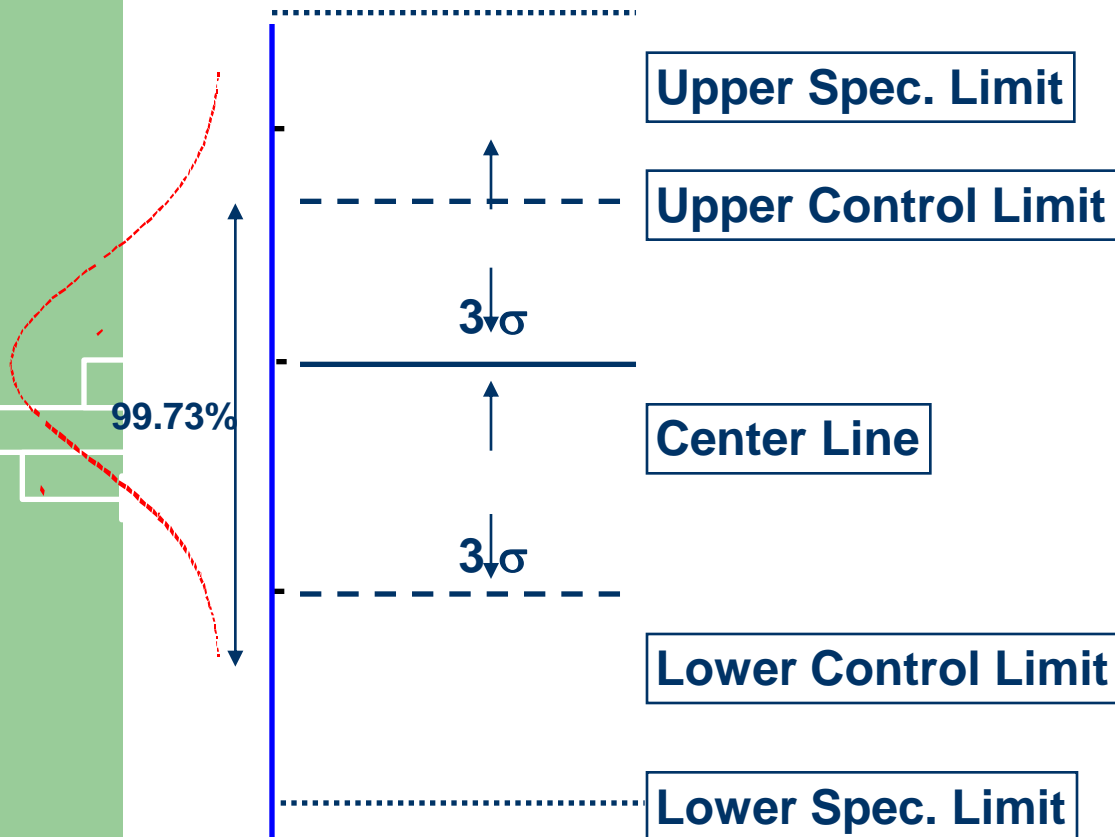
- Stable means that improbable events do not occur.
- The probability of an event depends on its distance from the mean
- An event 3 Standard Deviations from the mean will occur _____ % of the time



Visible Standards:

VOC (Voice Of Process)

VOC (Voice of Customer)



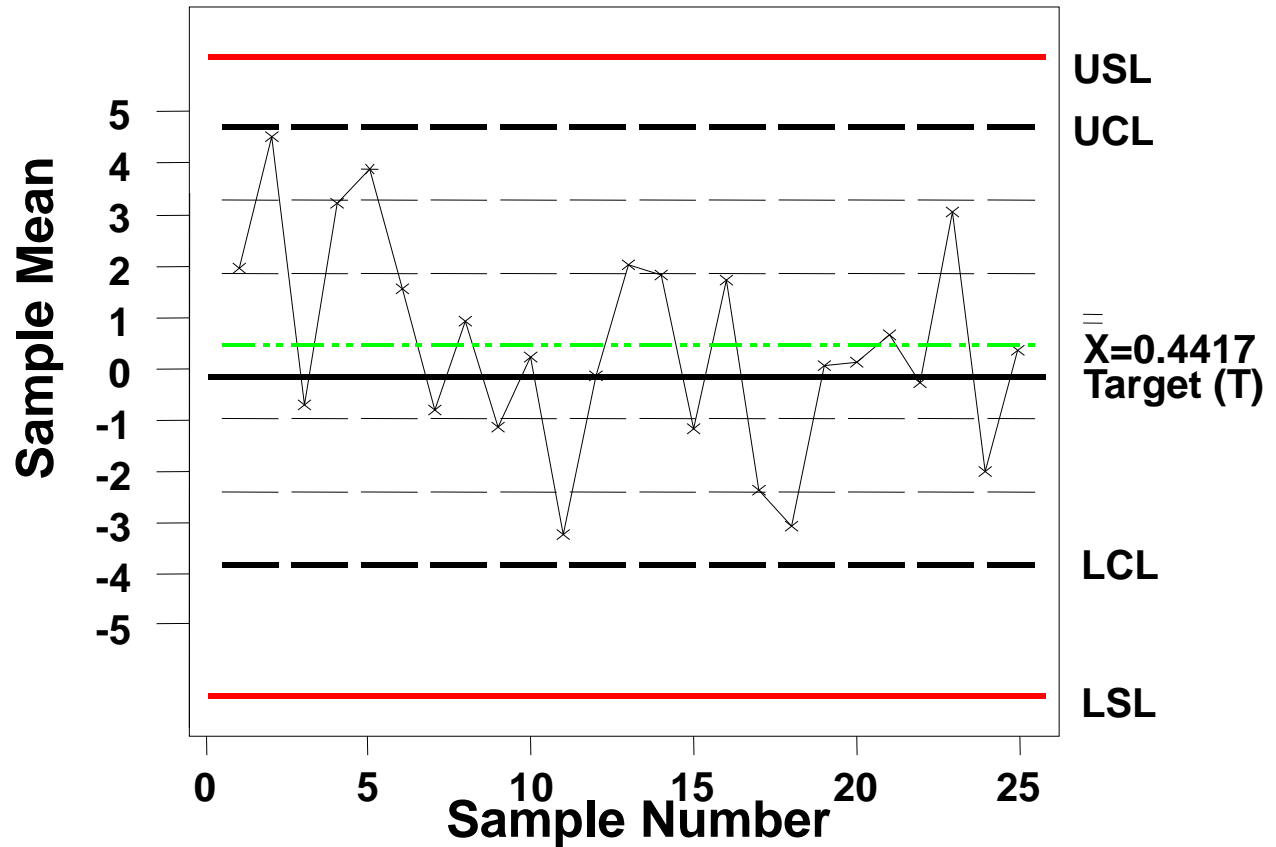
Control Limits:
“Voice of the Process”
Depend on variation
in our process

Specification Limits:
“Voice of the Customer”
Set by Contract
Ideally, to meet
customer process

Visible Change

Tests for Unusual Events

- Any point outside Control Limit
- 2 of 3 points in this area
- 4 of 5 points in this area or above
- 8 in a row in this area or above
- 8 in a row in this area or below
- 4 of 5 points in this area or below
- 2 of 3 points in this area
- Any point outside Control Limit



Control Plans

There are a multitude of different control plans that are used, however they all must contain the following

- What is being controlled?
- How is it measured?
- Instrument or method
- Guidelines
- How is the measurement interpreted?
- What action is to be taken when the process goes out of control?

Designing a Control Plan

- Step 1: Define and write the control subject.
- Describe the critical “x” that is going to be controlled, this comes from the Highest RPN Cause in the FMEA
- Step 2: Select the right measurement unit.
- Step 3: Define the control boundary values.
- Step 4: Define the sensor in terms of method or instrument.
- Step 5: Determine and record either the method or instrument capability.
- Step 6: Record the measurement - Determine who will take the actual measurement.
- Step 7: Determine the measurement frequency (daily, weekly, monthly, etc.).
- Step 8: Define the sample size (100%, 25%, etc.). Use the confidence level as a guideline
- Step 9: Define the tool or chart to transform the information (i.e. control chart).
- Step 10: Interpret the signal
- Step 11: Make recommendations and identify responsible party for the actions.

Measurement Method (Sensor Information)



Sensor

Describe the method or instrument used to detect the value of the control subject on a scale for the unit of measure. The sensors key attributes must be accuracy and precision. The sensor which is best to use is identified from the control field within the FMEA.

Method examples:

- Set of Questions answered on scale
- Number of preventative maintenance actions
- Counting of defects

Instrument examples:

- Pressure Gage
- Micrometer
- Voltage meter
- RFID



Risk Sensor Innovation



A new sensor control, which I have been developing is RFID Critical

RFID has been around for years within the retail and supply chain sectors to track and control goods.

With a team of RFID experts I have developed a new risk based critical RFID asset sensor which is linked to a FMEA database.

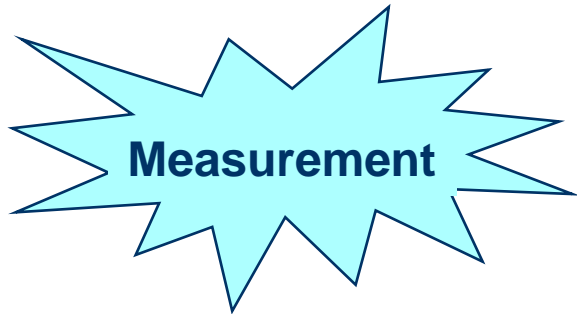
I can track and control any critical asset and a change to a critical asset (Process, product, jig, tool and equipment)

Anyone who wants to know more or discuss this new risk control innovation please contact me.



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Measurement Method (Guidelines)



Describe the point of measurement, frequency, and sample size contained in the measurement.

Interpretation Information



Interpretation

Define the graphical methods used to analyze your measurement, the results of the measurement, and the signals that need attention when they occur.

Graphical method examples

- Box Chart
- Pareto Chart —
- Control charts IMR, XR, C, u

Result examples

- Number of defects - ppm
- Mean - \bar{u} , s
- Process capability - C_p , C_{pk}
- Process stability - in-control, out-of-control

Signal examples

- out of spec
- excessive variation
- out of control

Plans and Guidelines

Action or Reaction plans: provide an outline of recommended actions for the define signal and the assignment of responsibility for the action to the appropriate individual.

Action Guidelines

- Align with the nature of control (out of control determine cause and fix, in control fix control system)
- Keep it simple

Responsible Guidelines

- Align with the process and organization structure
- Person assigned has :
 - 1) knowledge of what they control
 - 2) knowledge of their performance
 - 3) have skill and ability to regulate

11 Steps to Designing a Control plan

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Control Plan Example

Control Plan Number			Key Contact/Phone					Date (Orig.)		Date (Rev.)		
123			T. W. SMITH 3161 Ext 111					99/99/9999				
Part Number/Latest Change Level			Core Team					Customer Approval		Date (If Req'd.)		
Various			Tom, Henry and Richard									
PART OPEARTION	PROCESS NAME	DEVICE,JIG, TOOLS	CHARACTERISTICS			SPECIAL CHAR CLASS	METHODS					REACTION - PLAN
			NO.	PRODUCT	PROCESS		SPECIFICATION/T OLERANCE	EVALUATION/ MEASUREMENT/T ECHNIQUE	SAMPLE SIZE	FREQ.	CONTROL METHOD	
Op10	Stores receipt	Driver Docs	1	Inventory	Receipt of goods	N/A	Check Drivers Docs	Visual	100%	100%	Goods in supervisor	Refer to WI 25XY
Op 10	Stores receipt	Driver Docs	2	Inventory	Receipt of goods	N/A	Check Number of Items	Visual	100%	100%	Goods in supervisor	Stores receipt reaction plan 1
Op 10	Stores receipt	Parts	3	Inventory	Receipt of goods	Safety	To check condition of packaging	Visual	100%	100%	Goods in supervisor	Refer to WI 25XY
Op 20	Stores receipt	Parts	4	Inventory	Receipt of goods	Safety	Check suitable space to store the parts	Visual	100%	100%	Goods in supervisor	Check SAP

Look forward

Step 6

In the sixth and final workshop step.

We will construct a documented risk based planning management procedure.