

How to integrate FMEA, Control Plan, SPC and CAPA

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Quality systems like TS 16949 and Six Sigma require the use of FMEA and SPC. Many text books and consultants advocate the use of these techniques to control and improve processes. Hardly any text book explains how FMEA, Control Planning and SPC can be logically integrated and how to setup these different techniques in an efficient and effective way to get the best of both worlds without large amounts of engineering time to support these methods. In this article we will make an attempt to explain how you can setup FMEA, Control Planning, SPC and CAPA in an efficient and effective but more important a practical way which is easy to implement in any organization.

In this article we will use the SPC simulation of the tennis ball launcher in the Wizard training module to explain how FMEA, Control Planning and SPC come together in DataLyzer. The tennis ball launcher fires tennis balls and this process can have special causes of variation influencing the result.

FMEA and Control Plan

The start of process improvement is creating the flow chart and FMEA for the process. Because we only have one process step we don't show the flow chart. The FMEA for the process is shown in figure 1.

| Product No: Example tennis ball launcher - Rev 1 (Draft) | | | | | | | | | | | | | |
|--|---------------------------|----------------------------------|---|-------|--|---------------------------------|---------------------|-------|--------------------|-------|--------------------|---|--------------------------|
| File New Edit Delete | | | | | | | | | | | | | |
| Process Step / Function | Requirement | Potential Failure Mode | Potential Effect(s) of Failure | S E V | C L A S S | Potential Cause(s) / of Failure | Current Process | | | | Recommended Action | Responsibility / Target Completion Date | |
| | | | | | | | Controls Prevention | D C C | Controls Detection | D E T | | | |
| 010 / Fire Launcher | Balls should be on target | Too much variation between shots | Tennis lesson not effective, no way to proceed with lesson | 8 | | Debris on the floor | Cleaning | 4 | SPC | 5 | 160 | Change cleaning procedure | Marc Schaeffers 8-9-2011 |
| | | Average incorrect | Adjustments required during lessons making customer unhappy | 3 | Temperature change | | 3 | SPC | 5 | 45 | | | |
| | | | | | Supplier of balls changed | | 5 | SPC | 5 | 75 | | | |
| | | | | | Spring is wearing and requires maintenance | Maintenance | 3 | SPC | 5 | 45 | | | |

Figure 1: FMEA of tennis ball launcher

In the FMEA we see that there are 4 causes of problems given in the FMEA:

- Debris on the floor
- Temperature change
- Supplier of balls
- Wear of the spring.

Actions can be taken to reduce critical RPN numbers. The FMEA in this screen can be linked to a control plan. In the control plan we establish what we need to control on the shop floor, how we control it and what actions we need to take in case the process is out of control.

In figure 2 we see the control plan for this process

- Rev 1 (Draft)

File New Edit Delete

| Part / Process Number | Process Name / Operation Description | Machine, Device, Jig, Tools For Mfg. | Characteristics | | | Char Class | Product/Process Specification/ Tolerance |
|-----------------------|--------------------------------------|--------------------------------------|-----------------|---------|---------|------------|--|
| | | | No. | Product | Process | | |
| 010 | Fire Launcher | Launcher | 010 | Length | | | 300 - 700 |

| Product/Process Specification/ Tolerance | Evaluation / Measurement Technique | Methods | | Control Method | Reaction Plan |
|--|------------------------------------|-------------|---------------|----------------|---------------|
| | | Sample Size | Frequency | | |
| 300 - 700 | Scale | 5 | Once per hour | SPC | OCAP 102 |

Figure 2: Control Plan for launcher process.

The control plan describes what needs to be measured. In addition to the control plan you need to provide the operator with detailed instructions for the control method because there is not enough room to include it in the control plan layout. You also need to provide a method to enter the measurement results. Detailed instructions and entry of measurement results can be implemented using a SPC system.

So you need to have a link between the control plan and the SPC setup. This is shown in figure 3.

| Machine, Device, Jig, Tools For Mfg. | Characteristics | | | Char Class | Product/Process Specification/ Tolerance | Evaluation / Measurement Technique | Methods | | Control Method | Reaction Plan |
|--------------------------------------|-----------------|---------|---------|------------|--|------------------------------------|-------------|---------------|----------------|---------------|
| | No. | Product | Process | | | | Sample Size | Frequency | | |
| Launcher | 010 | Length | | | 300 - 700 | Scale | 5 | Once per hour | SPC | OCAP 102 |

Tennis ball launcher : Length

File Part Characteristic Options Preferences

Characteristic Description:
Plant/Department: _____ Part Number: _____ Resp engineer: M Schaeffers

Characteristic: _____ Special Field Title: _____
Length _____ Special Field Contents: _____

Comment: _____

Operator Information:
Control Plan Reference: _____
Measuring Instructions: Make sure the launcher is exactly on the correct position when taking a subgroup
If the balls don't land in the range of the measurement area reposition the launcher and perform the test again

☐ Critical Characteristic

Attachments: _____

Frequency: 60 ☐ Hide characteristic on network status screens ☐ Last characteristic

Specifications:
Upper Spec: 700.0
Lower Spec: 300.0
Target: 500
Units: M
Subgroup Size: 5

Natural Limits:
☐ Upper Spec: _____
☐ Lower Spec: _____

Reasonable Limits:
Upper Limit: 1000
Lower Limit: 100

Figure 3: Relation between Control Plan and SPC chart setup

The field reaction plan in the Control Plan is referring to what actions should be taken to correct the process and make sure incorrect products are reworked or rejected. A reaction plan is also often referred to as an out of control action plan (OCAP). Again there is not much

space in the control plan to include the full reaction plan so often a reference is made to another document.

The most effective reaction plan is an OCAP in a flow chart format. An example is given in figure 4.

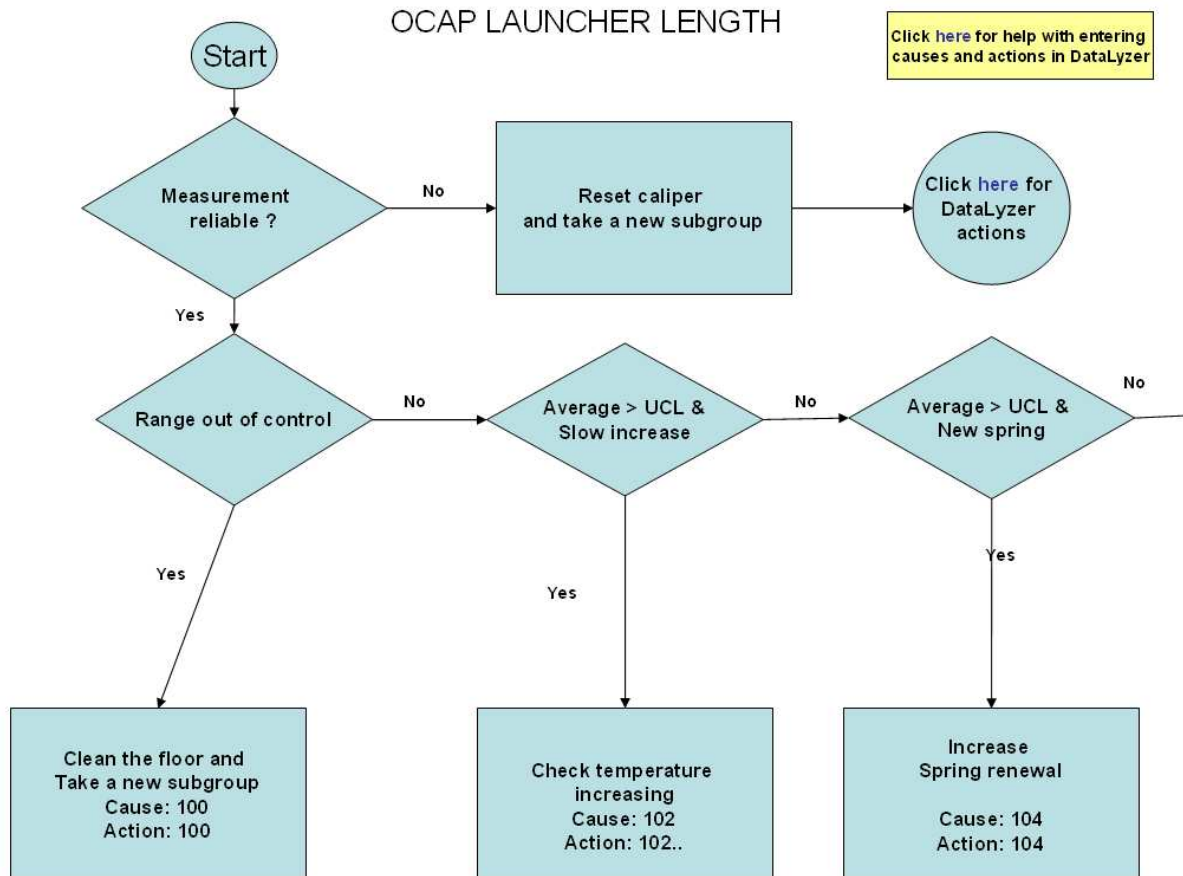


Figure 4: Out of control action plan Launcher

This OCAP gives the operator clear instructions what to do in case of an out of control. In the Control Plan we need to refer to this flow chart by indicating the document number – in this example OCAP 102. So it is important the OCAP document is instantly available in case of an out of control. This is done by linking the OCAP document to the out of control operator window (see figure 5).

'Length' Subgroup #53 7-2-2011 17:40:13 A cause note is required.

Causes:

Actions:

User Note:

OK Cancel CAPA Remeasure More...

OCAP Document 1: Launcher.doc

OCAP Document 2: OCAP Launcher.ppt

Figure 5: Out of control operator window

What you clearly see that in the OCAP document that for every step where you exit the OCAP flow chart you see a reference to a cause- and action number. These numbers are available in the out of control window and must be selected by the employee handling the out of control. This is shown in figure 6.

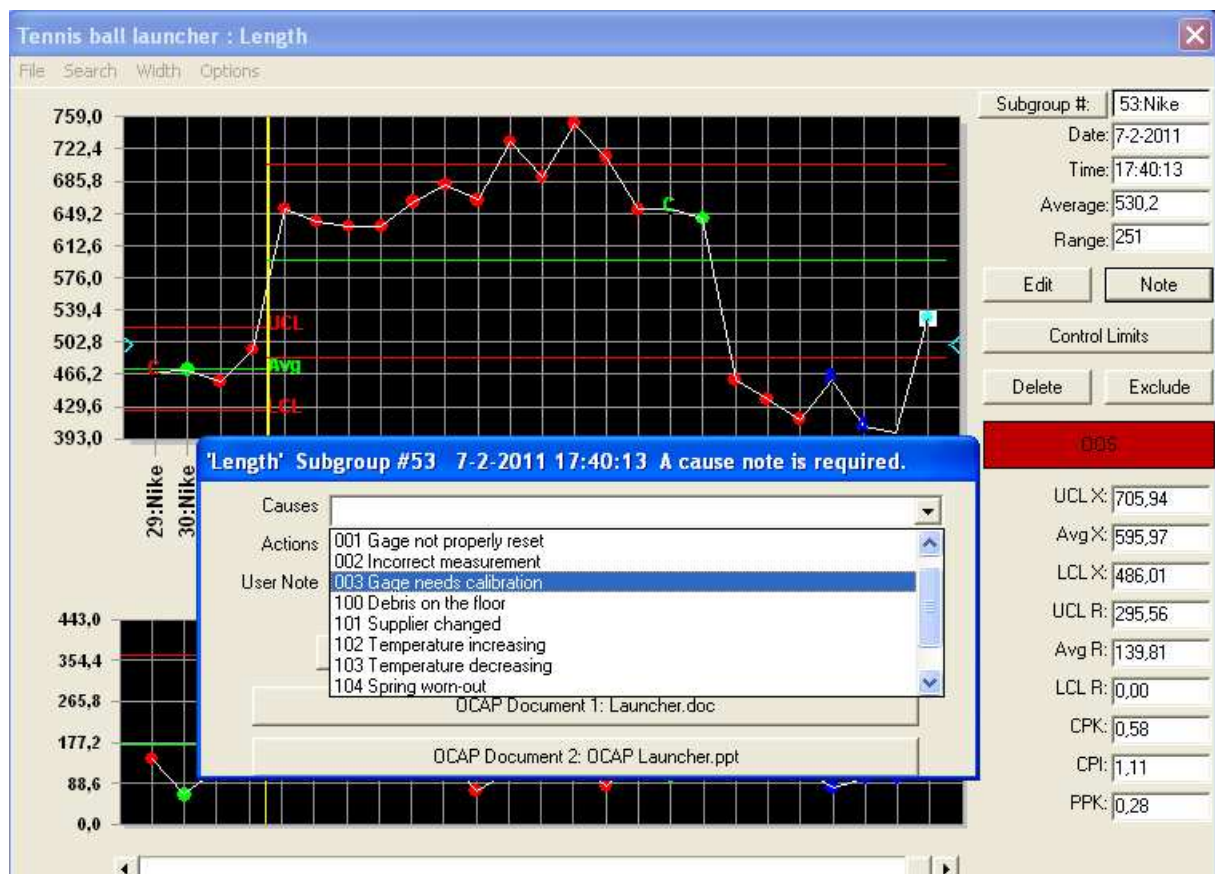


Figure 6: Handling out of control according to OCAP in DataLyzer

So when a subgroup is out of control the operator can view the OCAP, find the cause of the out of control and take the correct action and register the applicable cause and action.

In some cases problems will appear which have not been included in the FMEA and Control Plan process. In our example process the operator faced a problem that a door was open and the wind was severely impacting the process. The chart was out of control and the operator could not select the corresponding cause in the OCAP document.

In that case the operator can make a note in DataLyzer like shown in figure 7.

The screenshot shows a software window titled "'Length' Subgroup #53 7-2-2011 17:40:13". Inside the window, there are three input fields: "Causes", "Actions", and "User Note". The "Causes" and "Actions" fields are empty dropdown menus. The "User Note" field contains the text "The large front doors were open". Below these fields are five buttons: "OK", "Cancel", "CAPA", "Remeasure", and "Less...". At the bottom of the window, there are two document paths: "OCAP Document 1: Launcher.doc" and "OCAP Document 2: OCAP Launcher.ppt".

Figure 7: Example of free form note if the cause list is not providing the exact cause

When a problem occurs we need to consider if a Corrective and Preventive Action (CAPA) procedure needs to be started. If we want to start a CAPA we click the CAPA button and a new CAPA is created. The CAPA in DataLyzer has a 8D format and the information is linked back to a FMEA.

In figure 8 you see the screen when we start a new CAPA. When the CAPA is started also the status of control and the capability is registered so you can monitor if the CAPA process will lead to an improvement in control and capability.

CAPA - Launcher door open

File Reports

Characteristic: Length LSL: 300 USL: 700
 Part: Tennis ball launcher Target: 500 Units:
 Line: Starting date: 12-6-2014
 FMEA Ref: PF004 Launcher Starting Cpk: 0.68 Starting Ppk: 0.34
 Control Plan Reference: CP004 Launcher Starting OOC%: 18.0 Total Subgroups: 47
 Related Chars:
 Status
 Current Status: Open Planned Closed Date: 12-7-2014 Closed Date:
 Team:
 Team: Team 1 Members: Marc S
 Team Leader: John H E-Mail Members:
 Documentation
 Problem - Description: Add Edit
 12-6-2014 13:13 By: Marc S
 When the door is open we get unpredictable results
 The door may not be open longer than 15 seconds
 Containment
 Cause
 Corrective Action
 Implementation
 Prevention
 Conclusion
 Status Comment

Figure 8: CAPA system in DataLyzer

With this integration you will achieve 2-way communication between production and engineering and the FMEA and Control Plan really become a living document as intended.