

How to integrate FMEA, Control Plan, SPC and CAPA

By M. Schaeffers

Quality systems like IATF 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, SPC and CAPA come together in DataLyzer software suite. 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)													
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	Controls Prevention	Current Process			R P N	Recommended Action	Responsibility / Target Completion Date
								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)							
Part / Process Number	Process Name / Operation Description	Machine, Device, Jig, Tools For Mfg.	Characteristics			Char Class	Product/Process Specific Tolerances
			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				Methods						Reaction Plan
	No.	Product	Process	Char Class	Product/Process Specification/ Tolerance	Evaluation / Measurement Technique	Sample		Control Method		
							Size	Frequency			
Launcher	010	Length			300 - 700	Scale	5	Once per hour	SPC	OCAP 102	

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.

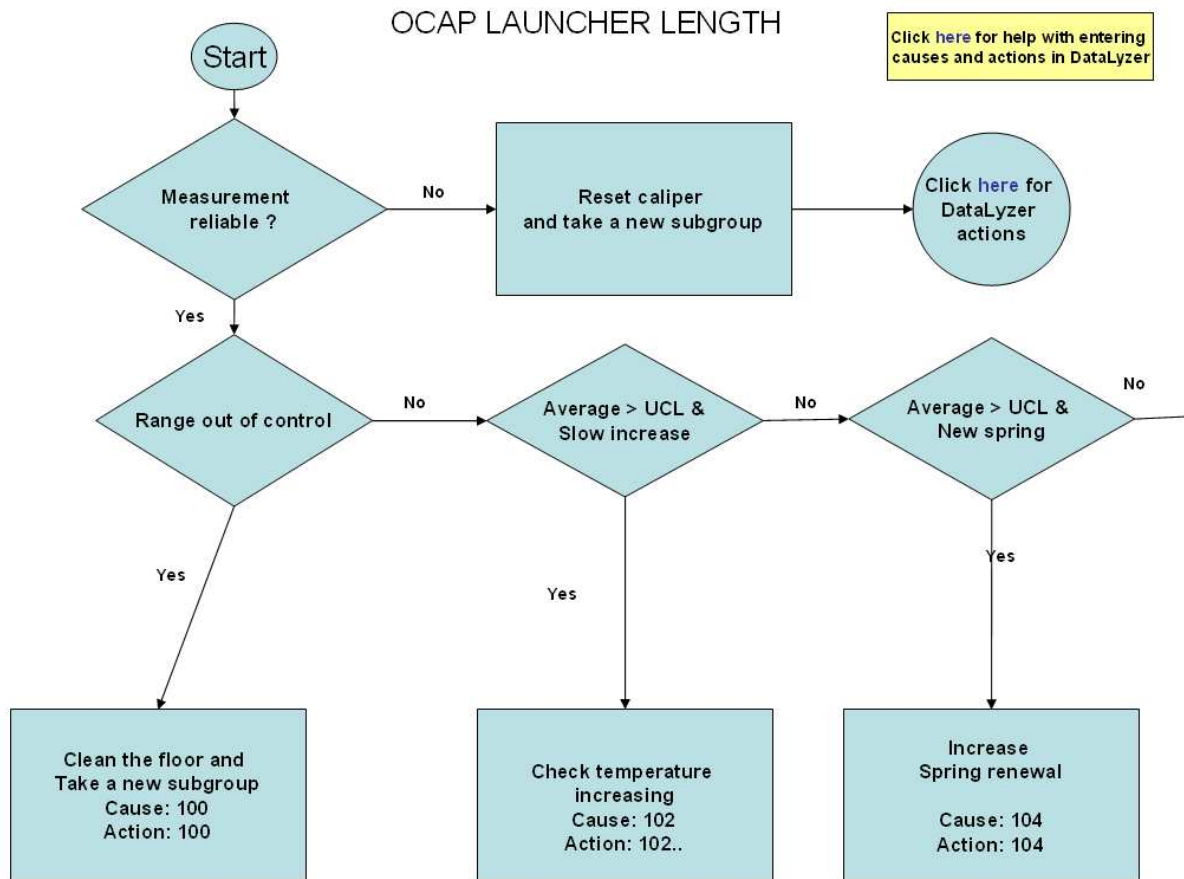


Figure 4: Out of control action plan Launcher

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).

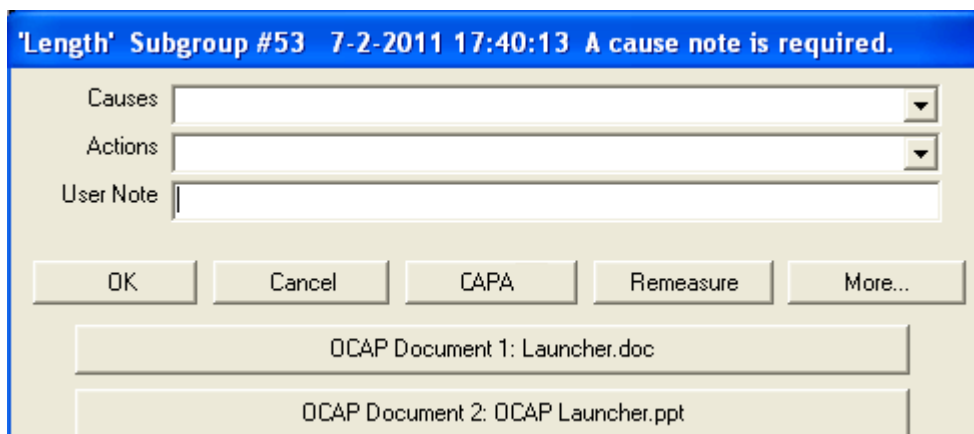


Figure 5: Out of control operator window

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.

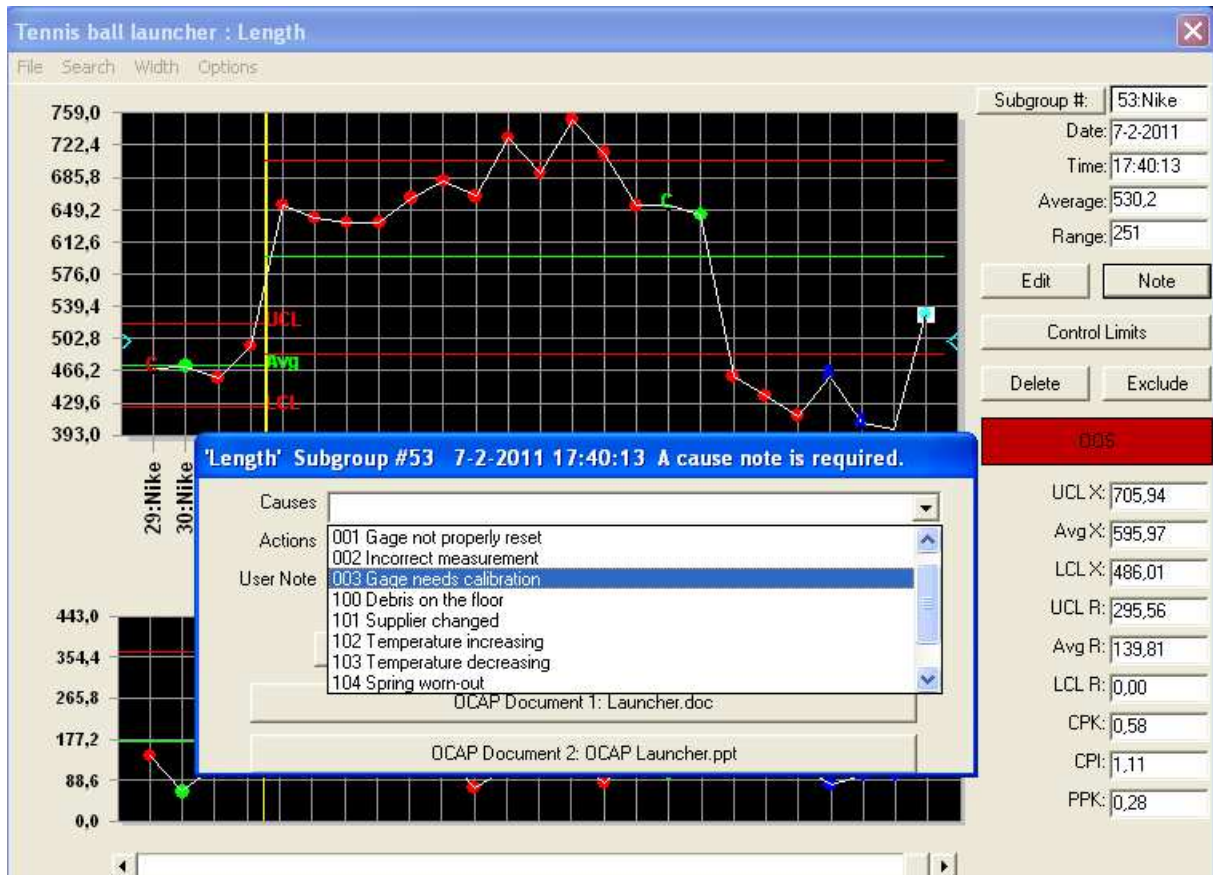


Figure 6: Handling out of control according to OCAP in DataLyzer

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.

'Length' Subgroup #53 7-2-2011 17:40:13

Causes [dropdown]

Actions [dropdown]

User Note
The large front doors were open

OK Cancel CAPA Remeasure Less...

OCAP Document 1: Launcher.doc

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 can have any format but in this example we use a 8D format..

In figure 8 you see the screen when we start a new CAPA. The CAPA system is a workflow system where actions are planned and monitored. One of the actions is to verify the FMEA document.

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.

WORKFLOW CAPA: [SAMPLE STANDARD CAPA- 2]LAUNCH DOOR OPEN

ESTABLISH THE TEAM
 DESCRIBE THE PROBLEM
 PROBLEM CONTAINMENT
 VERIFY ROOT CAUSE
 CHOOSE AND VERIFY PERMANENT CORRECTIVE ACTIONS
 IMPLEMENT PERMANENT CORRECTIVE ACTIONS
 PREVENT RECURRENCE
 CONGRATULATE THE TEAM

CAPA Reference Code: Sample Standard CAPA- 2

Additional Fields

CAPA Summary: Launch door open

PartName (*)

Creator Name: John

Location (*)

Team: Production

PartNumber (*)

CAPA Owner: John

CustomerVisitDate (*)

Creation Date: 5/15/2017

Due Date

Closed Date

CAPA Status: Open Workflow

HEADERS

Description: When the door is open we get unpredictable results
 The door may not be open longer than 15 seconds

Step Owner

Step Status: Open Workflow

Additional Fields

TeamMeeting (*)

Profile (*)

ok cancel

Figure 8: DataLyzer CAPA software