Core Tools: The Alphabet Soup of APQP, PPAP, FMEA, SPC and MSA

Jd Marhevko – Accuride Corporation, SVP QLMS

Shainin Medalist, ASQ Fellow, CSSBB, CMQ/OE, CQE, STEP Awardee

ASQ World Conference – Session T12 – May 1, 2018

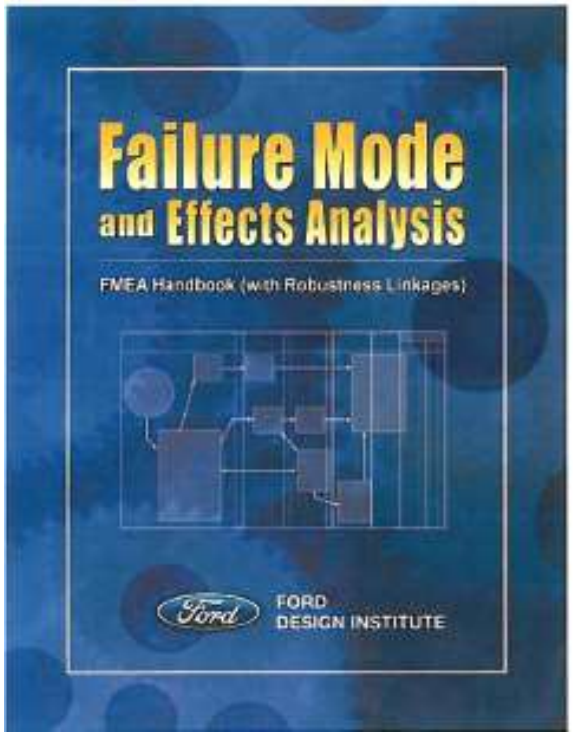
ASQ
The Global Voice of Quality

The FIVE Core Tools

1. **APQP: Advance Product Quality Planning:** Guidelines for a product quality plan to develop a product or service that satisfies the customer
2. **FMEA: Failure Modes and Effect Analysis:** Methodology used to ensure potential problems have been considered and addressed throughout the product and process development process (Ex. APQP). Traditionally includes the Control Plan (CP)
3. **PPAP: Production Part Approval Process:** Ensures product consistently meets customer engineering specification requirements during production run at the quoted production rate
4. **MSA: Measurement Systems Analysis:** Guidelines for assessing the quality of a measurement system where readings are replicated
5. **SPC: Statistical Process Control:** Basic graphing statistical tools that enable process control and capability for continual improvement

ASQ

Other Sample Manuals



ASQ

Core Tool *inferences* in ISO/IATF 16949:2016

Core Tool	ISO 9001:2015 (Core Tools NOT Specified)	IATF 16949:2016 (Core Tool Inferred/Referenced)
APQP	8.1 Operational Planning and Control 8.2 Requirements for Products and Services 8.3 Design and Development of Products and Services 8.4 Control of Externally Provided Processes, Products and Services	8.1.1 Operational Planning and Control 8.2 Requirements for Products and Services 8.3 Design and Development of Products and Services 8.4 Control of Externally Provided Processes, Products and Services
FMEA	6.1 Actions to Address Risks and Opportunities 8.3.5 Design and Development Output 9.1. Monitoring, Measurement, Analysis and Evaluation General	4.4.1.2 Product Safety 6.1 Actions to Address Risks and Opportunities 8.3 Design and Develop of Products and Services [8.3.3.3, 8.3.5.1, 8.3.5.2] 8.5 Production and Service Provision [8.5.1.1, 8.5.6.1.1] 8.7 Control of Non-Conforming Outputs [8.7.1.4, 8.7.1.5] 9.1 Monitoring, Measurement, Analysis and Evaluation General 9.2.3 Manufacturing Process Audit 10.2 Non-Conformity and Corrective Action [10.2.3, 10.2.4] 10.3.1 Continual Improvement

ASQ

Core Tool *inferences* in ISO/IATF 16949:2016

Core Tool	ISO 9001:2015 (Core Tools NOT Specified)	IATF 16949:2016 (Core Tool Inferred/Referenced)
CP*	8.3.5 Design and Development Outputs 8.5.1 Control of Production and Service Provision 8.6 Release of Products and Services 8.7 Control of Non-Conforming Outputs	8.3.5.2 Manufacturing Process Design Output 8.5 Production and Service Provision [8.5.1.1, 8.5.1.3, 8.5.6.1.1] 8.6 Release of Products and Services 8.7 Control of Non-Conforming Outputs 9.1.1.2 Identification of Statistical Tools 9.2.2.3 Manufacturing Process Audit 10.2.3 Problem Solving Annex A. Control Plan
PPAP	8.3.4 Design and Development Control	8.3.4.3 Prototype Program 8.3.4.4 Product Approval Process

***The Control Plan is not considered a "stand alone" Core Tool. Usually paired with the P-FMEA**

ASQ

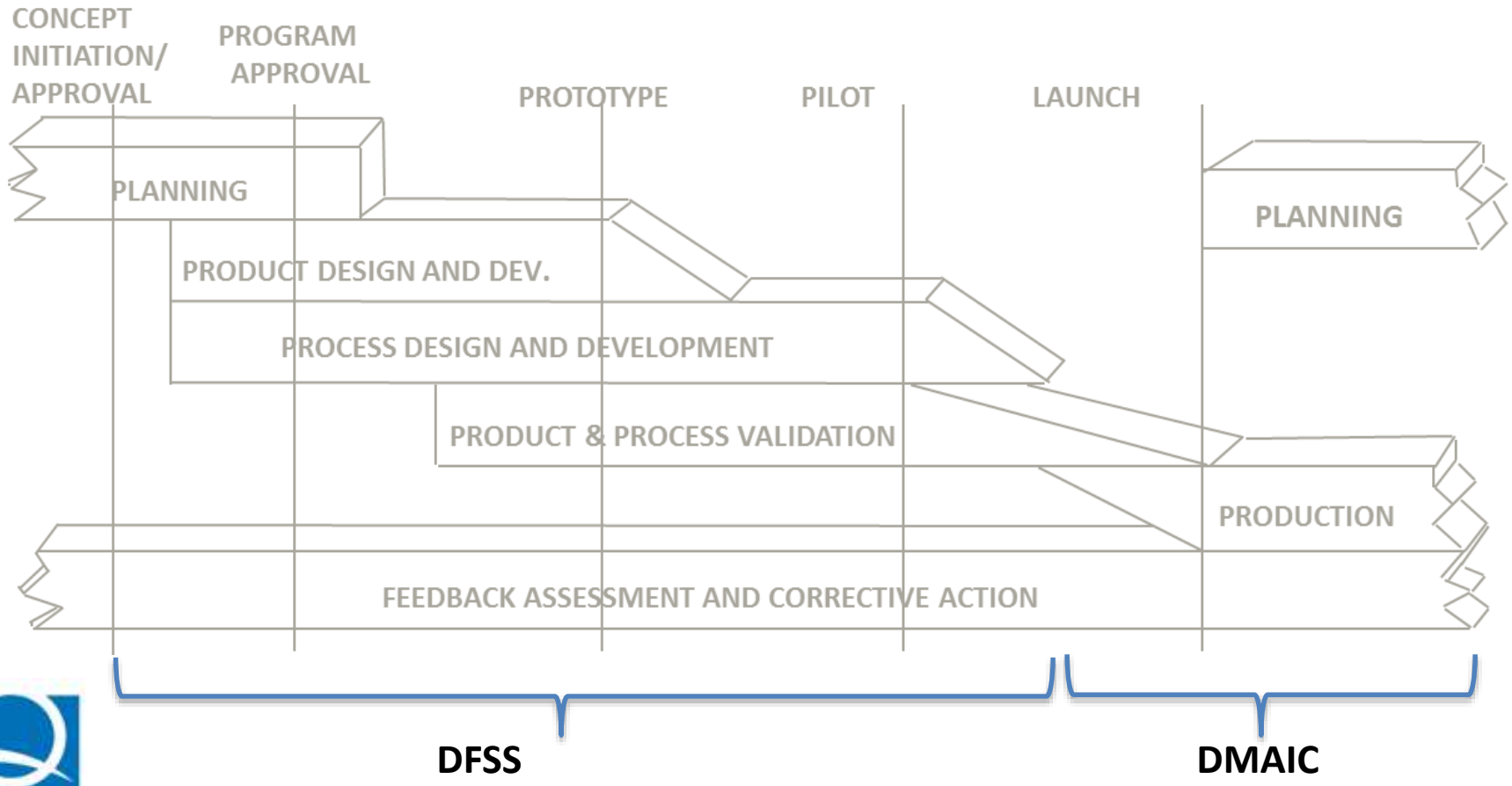
Core Tool *inferences* in ISO/IATF 16949:2016

Core Tool	ISO 9001:2015 (Core Tools NOT Specified)	IATF 16949:2016 (Core Tool Inferred/Referenced)
SPC	9.1 Monitoring, Measurement, Analysis and Evaluation	8.3.5.2 Manufacturing Process Design Output 8.6.4 Verification & Acceptance of Conformity… 9.1 Monitoring, Measurement, Analysis and Evaluation
MSA	7.1.5 Monitoring and Measurement Resources	7.1.5 Monitoring and Measuring Resources 7.1.5.1.1 MSA 7.1.5.2.1 Calibration/Verification Records 7.1.5.3 Laboratory Requirements 8.6.3 Appearance Items (inference)

ASQ

APQP

Advanced Product Quality Planning



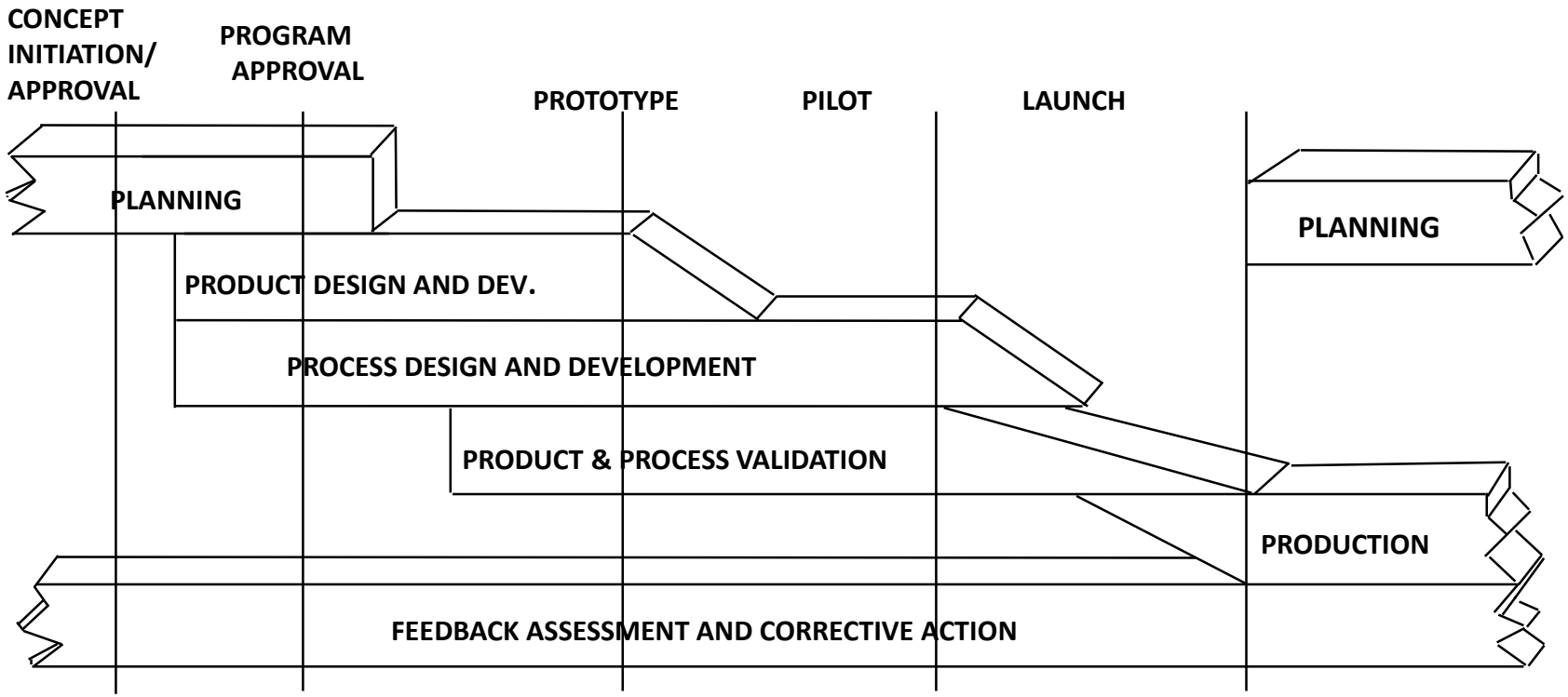
APQP

What is it: The management of **Product Development**

Why do we need it: To understand what our customer wants and to fulfill those wants

How is it done: Across a prescriptive “Five-Stage”, “Gated” or “Phased” approach. Other iterations exist and are also used so long as the foundational five are in place. The process is required to be cross-functional in its development and execution

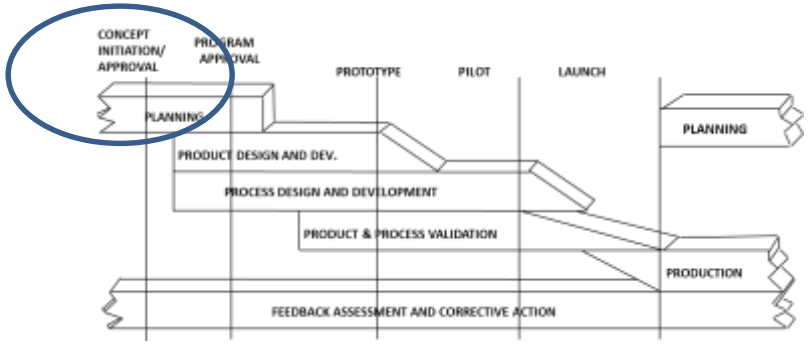
The Typical APQP Stages/Phases



Planning INPUTS	Product Design & Development INPUTS	Process Design & Development INPUTS	Product & Process Validation INPUTS	Feedback, Assessment & CAPA INPUTS
Planning OUTPUTS	Product Design & Development OUTPUTS	Process Design & Development OUTPUTS	Product & Process Validation OUTPUTS	Feedback, Assessment & CAPA OUTPUTS

APQP Plan & Define Phase

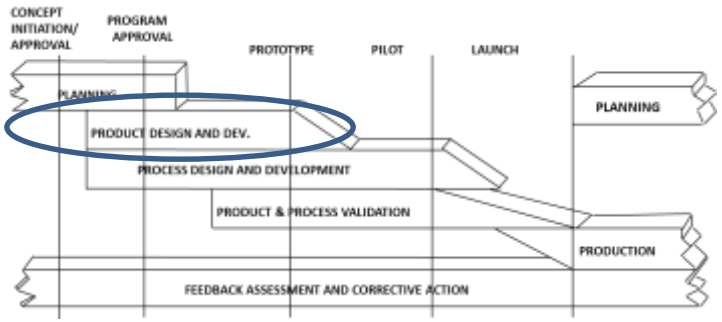
Typical Inputs	Typical Outputs
VOC Data	Design goals
Marketing Strategy	Reliability/Quality Goals
Product/Process Assumptions	Preliminary Critical Characteristics
Customer Inputs	Preliminary Process Flow
Compliance Criteria	Preliminary BOM
Etc.	Etc.



APQP Product Design & Development Phase

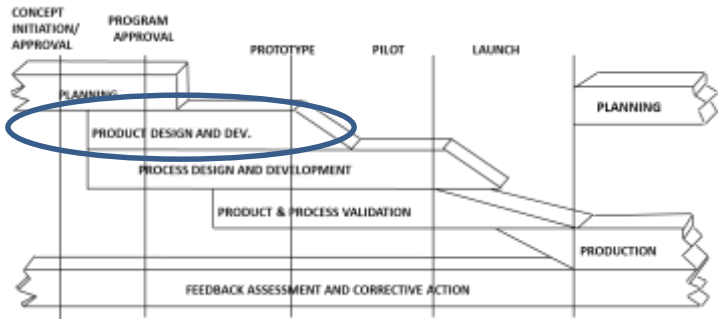
Program Approval

Design Outputs	APQP Outputs
DFMEA	New Equipment/Tooling
Design for Mfg/Asm	New Facility Needs
Design Verification	Gage/Test Requirements
Prototype Built	Final Critical Characteristics
Eng Drawings/Specs	Etc.
Etc.	



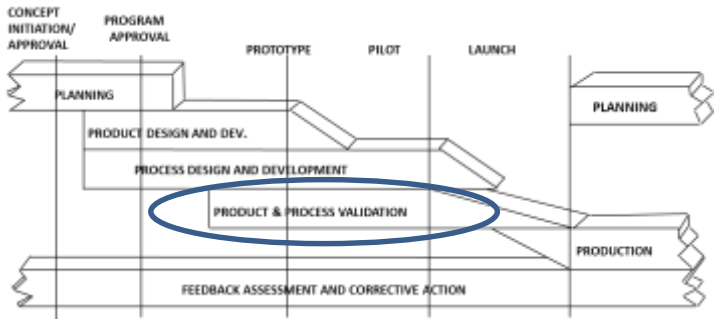
APQP Product Design & Development Phase

Prototype Outputs	
Pkg Standards/Specs	MSA/AAA
Product/Process Review	Management Support
Process Flow Chart	Cp/Cpk Plan
Floor Plan	Work Instructions
PFMEA/DCP	Etc.



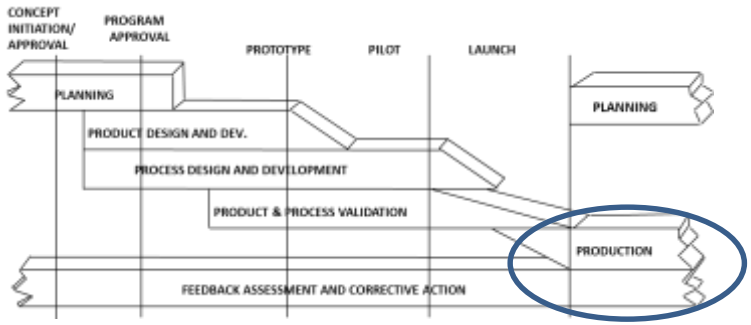
APQP Product & Process Validation Phase

Pilot. Sample Outputs	
Significant Production Run	Packaging/Preservation
MSA/AAA	Production Control
Cp/Cpk Studies	Quality Sign-Offs
PPAP Completion	Management Support
Product Validation Testing	Etc.



APQP Feedback, Assessment & CAPA Phase

Launch Outputs
Reduced Variation
Improved Customer Satisfaction
Improved Delivery/Service
Lessons Learned
Standard Work Updates
Etc.



2a

Design FMEA

Design Failure Mode Effects Analysis

FMEA Example from SEMATECH

Failure Mode and Effects Analysis (FMEA): System FMEA

System: Automated Wafer Defect Detection
Subsystem: Video Display
Reference Drawing: XYZ-1234567890

Date: MM, DD, YYYY
Sheet: X of XX
Prepared by: Mr. Example

Subsystem/ Module & Function	Potential Failure Mode	Potential Local Effect(s) of Failure	Potential End Effect(s) of Failure	SEV	CR	Potential Cause(s) of Failure	OCC	Current Controls/ Fault Detection	DET	RPN	Recommended Action(s)	Area/ Individual Responsible & Completion Date(s)	Actions Taken	SEV	OCC	DET	RPN
16-inch Color Monitor	Loss of video	Unable to display operator's input	Loss of text and graphical data representation	6		CRT component failure	2	Loss of video	1	12	Recommend the 14-inch monitor be used as a backup to provide operator interface. However, graphical data representation will become degraded due to the loss of high resolution.	Mr. X (electrical) and Mr. Y (software) will evaluate suggested configuration by MM/DD/YY.	Not accepted by the Reliability Review Team. See report ABC-XX1.	6	2	1	12
				6		Graphics PCB failure	3	System alert	3	54	Recommend a 16-inch monitor be replaced for the existing 14-inch monitor, so that complete redundancy will exist.	Mr. X (electrical) and Mr. Y (software) will evaluate proposed configuration by MM/DD/YY.	Not accepted by the Reliability Review Team. See report ABC-XX2.	6	3	3	54
				6		Power supply failure	5		5	150	Recommend multiplexing the two CRT power supplies so that power failures be almost eliminated.	Mr. X (electrical) has already reviewed this option. Report is available through Xxxxx. Date of completion MM/DD/YY.	Due to cost and time this option has been accepted by the Reliability Team. An Engineering Change will occur on MM/DD/YY for the field units S/N ### and higher.	6	1	1	6

ASQ

ALL Products & Processes Fail

Failure is **ALWAYS** a Design Requirement/Criteria

Determining **HOW** the design will fail, **WHEN** it will fail, and **WHY** it will fail will allow a designer to incorporate failure as an acceptable design constraint

Failure as an ACCEPTABLE design constraint =
Customer Satisfaction =
Design Quality

FMEA: Design (D) & Process (P)

What is it: A risk analysis of a part or process

Why do we need it: To identify the functions of a process and the associated potential failure modes, effects and potential causes. The vision is to prevent problems from occurring so that defects are not incurred and no one gets hurt. It is used to evaluate if the current planned actions are sufficient and effective

How is it done: Via the utilization of a cross-functional team approach. Multiple iterations exist across industry. Within IATF, the process is required to be cross-functional in its development and execution. It is considered a “Risk-Based Thinking” (RBT) tool. It often incorporates results from other methods such as SPC, MSA, Fault Tree Analysis, etc.

FMEAS for Products & Processes

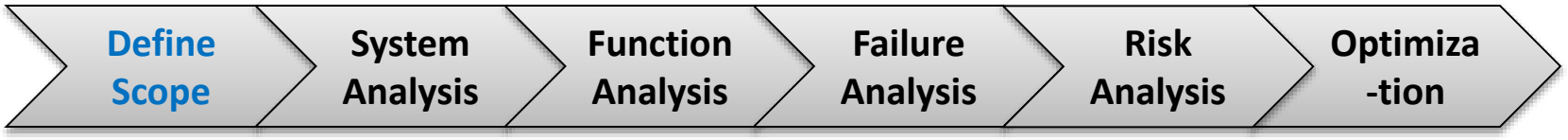
There are three (3) basic cases in which an FMEA is applied:

1. New designs, new technology or new process
2. New application of existing design or process
3. Changes to an existing design or process

- Design FMEA: A technique which analyzes system functions within a defined boundary to address possible design weakness and potential risks of failure. DFMEA data is used in the creation of the PFMEA
- Process FMEA: A technique which analyzes processes that can impact quality. These processes may be: Receiving, Handling, Manufacturing, Assembly, Storage, Transportation, Maintenance, Repair and Communication

ASQ

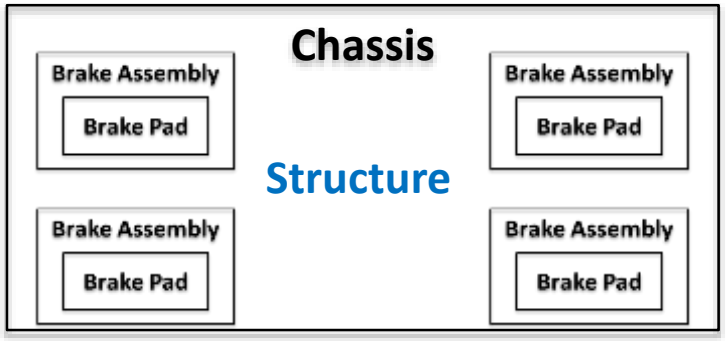
Six (6) Steps of an FMEA (D or P)



1. **Define Scope.** Identify what is to included in the evaluation. (System, Sub-system, Component). Include relevant Lessons Learned (LL) and reference materials. Manage the five (5) T's:
   1. **Team:** Who will constitute the core team
   2. **Timing:** When is it due. Gantt, lay-out timing plan
   3. **inTent:** Why is the team there; Ensure skills/training
   4. **Tool:** What reporting methodology will be used? Excel, Software, etc
   5. **Task:** What work needs to be done across the six steps. Consider inclusion of effective documentation for auditing and customer review

ASQ

2. **Conduct System Analysis:** Define the customer(s) wrt End Users, Assembly, Manufacturing, etc.
   1. **Identify and break down the design** into system, sub-system, component and parts for functional risk analysis. Note: A component FMEA is a subset of a system FMEA. Ex. A brake pad is a component of a brake assembly which is a sub-system of the chassis
   2. **Visualize the system** via block (boundary) and/or structure tree diagrams



ASQ

3. Conduct Function Analysis: Insures that the specified and required functions are appropriately allocated to the system elements. A function describes WHAT the item/ system element is intended to do.

1. Associates functions with the pertinent system elements
2. Overviews the functionality of the product
3. May describe functions in detail. May need to consider interfaces and clearances wrt physical connections, material exchange, energy transfer and data exchange
4. Allocates requirements/characteristics to individual functions
5. Cascades internal/external customer functions with associated requirements for intended use

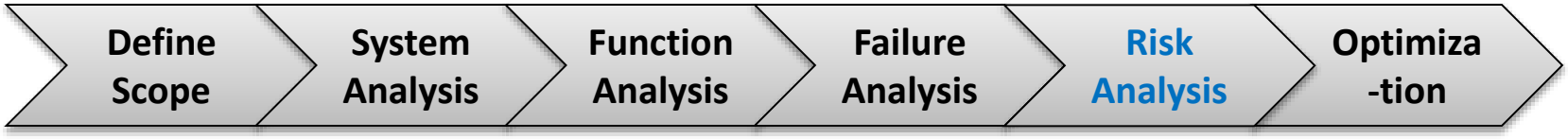
ASQ

4. **Conduct Failure Analysis:** Identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

Failure effects are the consequence of a failure mode

1. Identification of potential failures assigned to functions in structural elements
2. Visualize failure relationships (FMEA spreadsheet)
3. Collaborate between the customer and suppler on effects

Consider "Failure Chain" approach. AKA the Golden Circle



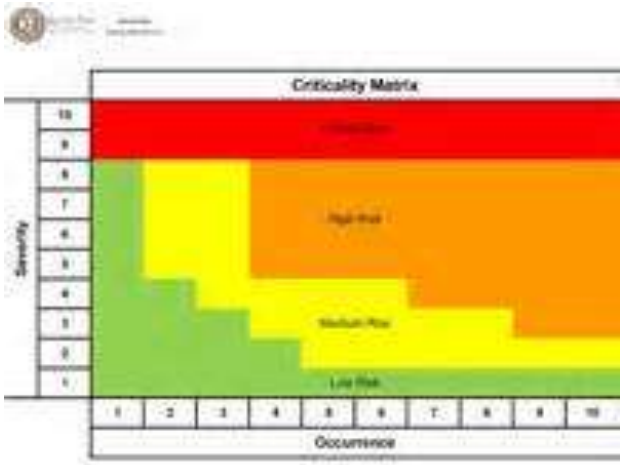
5. **Conduct Risk Analysis.** Prioritize the risks by evaluating Severity (how bad), Occurrence (how often) and Detection (how well can we find it). Aka SOD. Each is on a scale of 1-10. The multiplication of S x O x D is the RPN
   1. A Risk Priority Number (RPN) is determined
   2. Based on the RPN, assign preventive controls which provide information/guidance as an input to the design
   3. Assign detective controls to verify and validate procedures previously demonstrated to detect the failure
   4. Completed SOD assessment
   5. Collaboration between customer and supplier on Severity

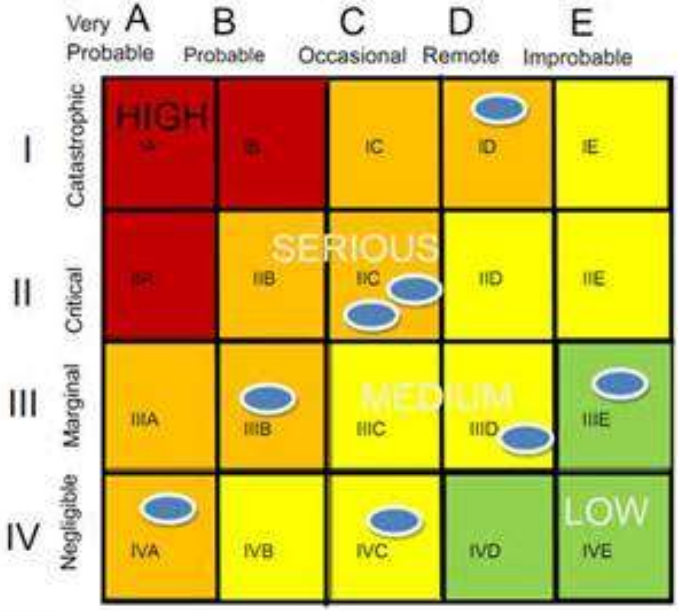
ASQ

RPN, Criticality or Prioritization

Each method of evaluation has pros and cons. There is a change in process towards an “Action Prioritization” (AP) matrix which may incorporate Criticality (S*O). **RPN will be eliminated as a method of risk evaluation (AIAG, 2018)**

AIAG currently references the SOD tables found in the FMEA “Blue Book”. Many organizations have evolved to their own form of prioritization tables based on their own logic



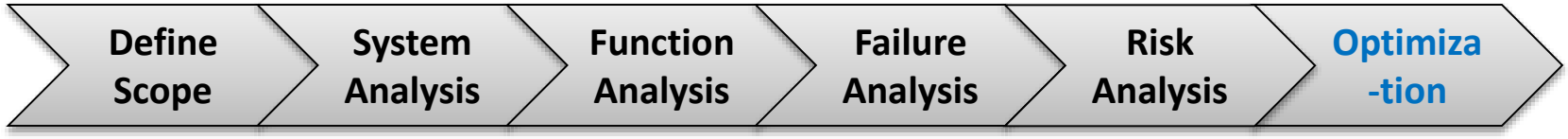


4th Ed SOD Summary for Design FMEA

NOTE: OEs & Other businesses often use their own SOD tables. This is a MODEL

#	Severity Criteria	Occurrence Criteria	Opportunity for Detection
10	Failure to meet safety and/or regulatory requirements. Potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation without warning	Very high. New technology/new design with no history. >= 1 per 10	No detection opportunity: No current design control. Cannot detect or is not analyzed. Detection is almost impossible
9	Failure to meet safety and/or regulatory requirements. Potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation with warning	High. Failure is inevitable with new design, new application or change in duty cycle/operating conditions. 1 in 20	Not likely to detect at any stage. Design analysis/detection controls have a weak detection capability. Virtual analysis is not correlated to expected actual operating conditions. Detection is very remote
8	Loss or degradation of primary function. Loss of primary function	High. Failure is likely with new design, new application or change in duty cycle/operating conditions. 1 in 50	Post design freeze and prior to launch. Product verification/validation after design freeze and prior to launch with pass/fail testing. Detection is remote
7	Loss or degradation of primary function. Degradation of primary function	High. Failure is uncertain with new design, new application or change in duty cycle/operating conditions. 1 in 100	Post design freeze and prior to launch. Product verification/validation after design freeze and prior to launch with test to failure testing. Detection is very low
6	Loss or degradation of secondary function. Loss of secondary function	Moderate. Frequent failures associated with similar designs or in design simulation and testing. 1 in 500	Post design freeze and prior to launch. Product verification/validation after design freeze and prior to launch with degradation testing. Detection is low
5	Loss or degradation of secondary function. Degradation of secondary function	Moderate. Occasional failures associated with similar designs or in design simulation and testing. 1 in 2,000	Prior to design freeze. Product verification/validation after design freeze and prior to launch with pass/fail testing. Detection is moderate
4	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%)	Moderate. Isolated failures associated with similar designs or in design simulation and testing. 1 in 10,000	Prior to design freeze. Product verification/validation after design freeze and prior to launch with test to failure testing. Detection is moderately high
3	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (>50%)	Low. Only isolated failures associated with almost identical design or in design simulation testing. 1 in 100,000	Prior to design freeze. Product verification/validation after design freeze and prior to launch with degradation testing. Detection is high
2	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%)	Low. No observed failures associated with almost identical design or in design simulation testing. 1 in 100,000,000	Virtual analysis correlated. Design analysis/detection controls have a strong detection capability. Virtual analysis is highly correlated with actual or expected operating conditions prior to design freeze. Detection is very high
1	No discernable affect	Very low. Failure is eliminated through preventive control	Detection not applicable; failure prevention. Failure cause or failure mode can not occur because it is fully prevented through design solutions. Detection is almost certain

PFMEA 4th Edition. 2008. Chrysler LLC, Ford Motor Company, General Motors Corporation



6. **Evaluate for Optimization.** The planning and execution of actions to mitigate risk and assess the effectiveness of those actions

    1. Identify necessary actions
    2. Assign responsibilities and timing
    3. Confirmation of effectiveness of the actions taken
    4. Continuous improvement of the design

Multiple other types of FMEA applications: System, Concept, Environmental/Safety, Machinery, Software, etc.

ASQ

DFMEA Sample Format

DFMEA formats vary widely based on OE criteria and independent company expectations…Even though the AIAG will add ~8-10 more columns to the current standard, the general approach and intent will be the same; mitigate risk through failure analysis

2. SYSTEM ANALYSIS			3. FUNCTION ANALYSIS	4. FAILURE ANALYSIS				5. RISK ANALYSIS					6. OPTIMIZATION						
Item	Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity (S)	Class	Potential Causes of Failure	Controls (Prevention)	Occurrence (O)	Controls (Detection)	Detection (D)	RPN	Recommended Action	Responsibility & Target Date	Actions Taken Completion Date	Severity (S)	Occurrence (O)	Detection (D)	RPN
Marker	Write	1,000 ft of continuous drawing	Cap Falls Off	Marker dries out	4	N/A	Barrel ID too small	Spec for interference fit	4	Instron pull test ABC	2	32	None at this time						
						N/A	Cap ID too large	Spec for interference fit	4	Instron pull test ABC	2	0	None at this time						
						N/A	Felt insert too long	Use felt material with low CTE	2	CTE lab test XYZ	3	0	None at this time						

Other DFMEA Sources…

- http://quality-one.com/fmea/design-fmea/
- http://www.isixsigma.com/dictionary/dfmea/
- http://www.qmii.com/LT-133%20ISO%209001_2015%20Risk%20Based%20Thinking.pdf
- http://www.iso.org/iso/home/standards/iso31000.htm (ISO Risk Management)
- 86 Minute Video…very detailed http://www.isixsigma.com/tools-templates/design-of-experiments-doe/mark-kiemele-interview/
- AIAG APQP for DFMEA Checklist (2nd ed)

2b

Process FMEA & CP

PFMEA + Control Plan = Dynamic Control

FMEA Example from SEMATECH

Failure Mode and Effects Analysis (FMEA): System FMEA

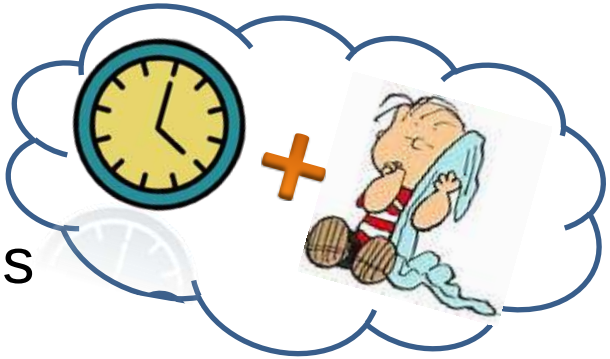
System: Automated Wafer Defect Detection
Subsystem: Video Display
Reference Drawing: XYZ-1234567890

Date: MM, DD, YYYY
Sheet: X of XX
Prepared by: Mr. Example

Subsystem/ Module & Function	Potential Failure Mode	Potential Local Effect(s) of Failure	Potential End Effect(s) of Failure	SEV	CR	Potential Cause(s) of Failure	OCC	Current Controls/ Fault Detection	DET	RPN	Recommended Action(s)	Area/ Individual Responsible & Completion Date(s)	Actions Taken	SEV	OCC	DET	RPN
16-inch Color Monitor	Loss of video	Unable to display operator's input	Loss of text and graphical data representation	6		CRT component failure	2	Loss of video	1	12	Recommend the 14-inch monitor be used as a backup to provide operator interface. However, graphical data representation will become degraded due to the loss of high resolution.	Mr. X (electrical) and Mr. Y (software) will evaluate suggested configuration by MM/DD/YY.	Not accepted by the Reliability Review Team. See report ABC-XX1.	6	2	1	12
				6		Graphics PCB failure	3	System alert	3	54	Recommend a 16-inch monitor be replaced for the existing 14-inch monitor, so that complete redundancy will exist.	Mr. X (electrical) and Mr. Y (software) will evaluate proposed configuration by MM/DD/YY.	Not accepted by the Reliability Review Team. See report ABC-XX2.	6	3	3	54
				6		Power supply failure	5		5	150	Recommend multiplexing the two CRT power supplies so that power failures be almost eliminated.	Mr. X (electrical) has already reviewed this option. Report is available through Xxxxx. Date of	Due to cost and time this option has been accepted by the Reliability Team. An Engineering	6	1	1	6

ASQ

What is a DCP



A DCP is a blended format of a PFMEA and CP. It leverages the common columns in both tools and enables “linear” thinking across the analysis of an individual process step

It saves time and increases the security of the system

- A PFMEA defines, identifies, prioritizes, and eliminates known and/or potential process failures from reaching the customer. The goal is to eliminate Failure Modes and reduce their risks
- A CP follows the PFMEA steps and provides details on how the "potential issues" are checked for in the process
- A DCP is a living document which helps to prevent problems
- It saves time and increases process security

A DCP

A DCP lists a sequence of tasks used to produce a product or provide a service by combining the PFMEA and CP. It:

1. Identifies process related **Failure Modes** before they occur
2. Determines the **Effect & Severity** of these failure modes
3. Identifies the **Causes** and probability of **Occurrence** of the failure modes
4. Identifies the **Controls** and their **Effectiveness**
5. Quantifies the **Risks** associated with the failure modes
6. Develops and documents **Action Plans** to reduce the risks
7. Identifies the **Type & Effectiveness** of the **Gaging** system
8. Determines the necessary **Inspection Frequency**

ASQ

FMEA & CP in One Format

Plant	Part/Product Name		Customer PN		Customer PN/Revision/Date	
Site Address	XXX		XXX		XXX	01/01/00
Site Address	Process		PN:	Flow Chart #	PN/Revision/Date	
Site Address	XXX		XXX	XXX	XXX	01/01/00
	Prototype (X)	Pre-Launch (X) Production (X)				

Product/Process Characteristics				Potential Failures and Effects			Causes of Failure		Current Controls					
No.	Char. or Process Desc	Characteristic	SC Class	Failure Mode	Effects of Failure	SEV	Cause	OCC	Control - Detect Failure Mode	Control Method to Prevent Cause	DET	RPN	Recommendations	Responsible Person/Timing
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
												0		
A	B	C	D	E	F	G	H	I	J	K	L	M	N	O

The format is completed linearly from A – AA. This ensures inclusion of a gaging system review and eliminates the need to manage 2 forms

**Many sites modify the format to fit their own needs

CP "Side" P - AA

Dynamic Control Plan (DCP) Revision/Date	Core Team:	
"C" 01/01/00	XXX Design Eng	XXX Other
"B" 01/01/00	XXX Mfg Eng	XXX Other
"A" 01/01/00	XXX Prod Mgr	XXX Other
(Rolling top 3 levels)	DCP File Number: XXX	

Orig SEV	New OCC	New DET	New RPN	Ctrl Fctr	OWI#	Tool Fxt #	Gage Desc/ Gage No.	GRR & Date	Insp Freq	Cpk & Date	Reaction Plans
0			0	**	**	**		**		**	
0			0								
0			0								
0			0								
0			0								
0			0								
0			0								
0			0								
P	Q	R	S	T	U	V	W	X	Y	Z	AA

A Practice DCP

The fit of a marker cap…

1. Look at the cap and barrel of a writing marker
2. Review the step of assembling the cap onto the barrel
3. Complete relevant lines of the DCP wrt assembly
4. There can be two general failure modes:
    a. The cap fits with an audible “click” and stays firmly in place. It does NOT easily pull off
    b. The cap does not stay secure and falls off
5. Each failure mode will have its own “DCP Stream” of information
6. Follow across the format and complete the information
7. Work in teams across the format

ASQ

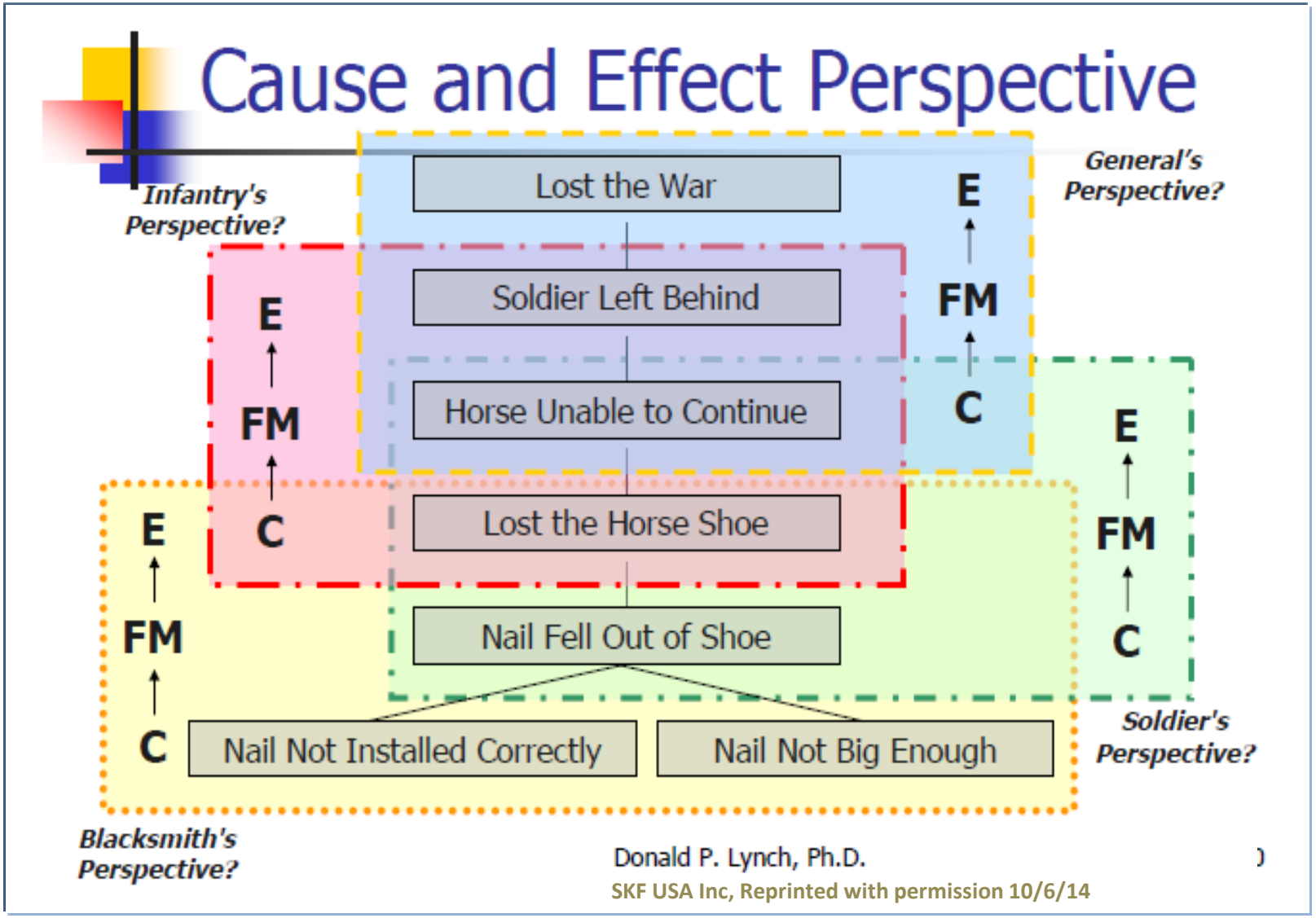
4th Ed SOD Summary for Process FMEA

NOTE: OEs & Other businesses often use their own SOD tables. This is a MODEL

#	Severity Criteria (Customer Effect)	Occurrence	Opportunity for Detection
10	Failure to meet safety and/or regulatory requirements. Potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation without warning	Very high. >= 1 per 10	No detection opportunity: No current process control. Cannot detect or is not analyzed. Detection is almost impossible
9	Failure to meet safety and/or regulatory requirements. Potential failure mode affects safe vehicle operation and/or involves non-compliance with government regulation with warning	High. 1 in 20	Not likely to detect at any stage. Failure mode and/or Cause is not easily detected. Detection is very remote
8	Loss or degradation of primary function. Does not affect safe vehicle operation	High. 1 in 50	Problem detection post processing. Failure mode detection post processing by operator through visual, tactile, or audible means. Detection is remote
7	Loss or degradation of primary function. Degradation of primary function. Vehicle operable at reduced level of performance	High. 1 in 100	Problem detection at source. Failure mode detection in-station by operator through visual, tactile, or audible means or post-processing through attribute gaging. Detection is very low
6	Loss or degradation of secondary function. Vehicle operable but convenience/comfort functions inoperable	Moderate. 1 in 500	Problem detection post processing. Failure mode detection post-processing by operator through use of variable gaging or in-station by operator through use of attribute gaging. Detection is low
5	Loss or degradation of secondary function. Vehicle operable but convenience/comfort functions at reduced levels of performance	Moderate. 1 in 2,000	Problem detection at source. Failure mode or error detection in-station by operator through use of variable gaging or by automated controls in–station that will detect issue and notify operator. Gaging performed on setup and 1st pc check. Detection is moderate
4	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by most customers (>75%)	Moderate. 1 in 10,000	Problem detected post processing. Failure mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing. Detection is moderately high
3	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by many customers (>50%)	Low. 1 in 100,000	Problem detection at source. Failure mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing. Detection is high
2	Annoyance. Appearance or audible noise, vehicle operable, item does not conform and noticed by discriminating customers (<25%)	Low. 1 in 100,000,000	Error detection and/or problem prevention. Error cause detection in station by automated controls that will detect error and prevent discrepant part from being made. Detection is very high
1	No discernable affect	Very low. Failure is eliminated through preventive control	Detection not applicable; error prevention. Error cause prevention as a result of fixture/machine/part design. Discrepant parts cannot be made due to error proofing. Detection is almost certain

PFMEA 4th Edition. 2008. Chrysler LLC, Ford Motor Company, General Motors Corporation

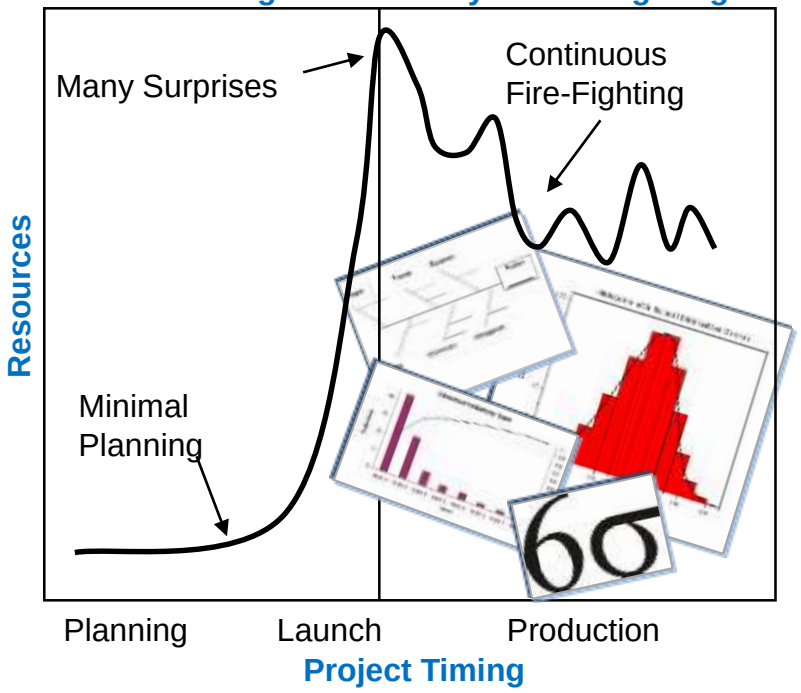
For Want of A Horse



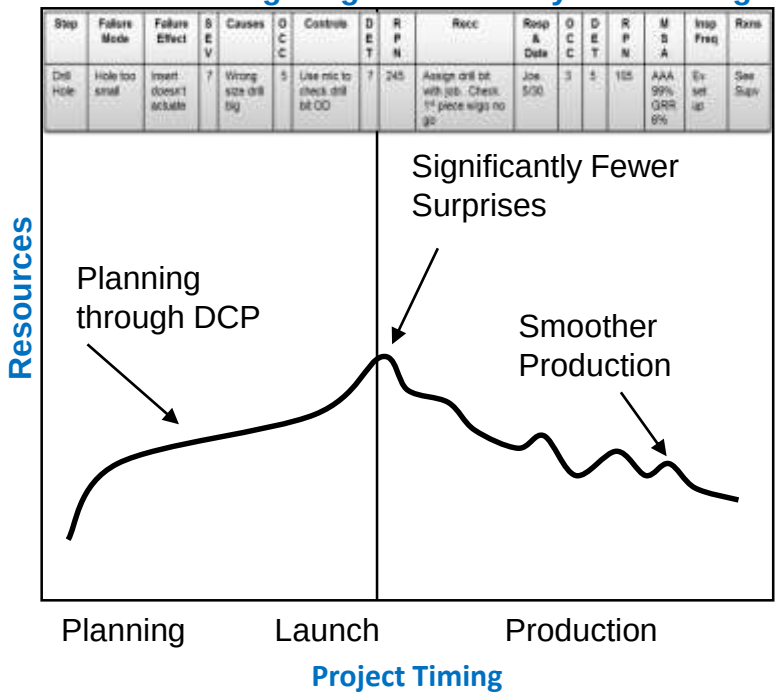
DCP or Fire-Fight?

Planning vs Fire-Fighting

When Planning is Secondary to Fire-Fighting



When Fire-Fighting is Secondary to Planning

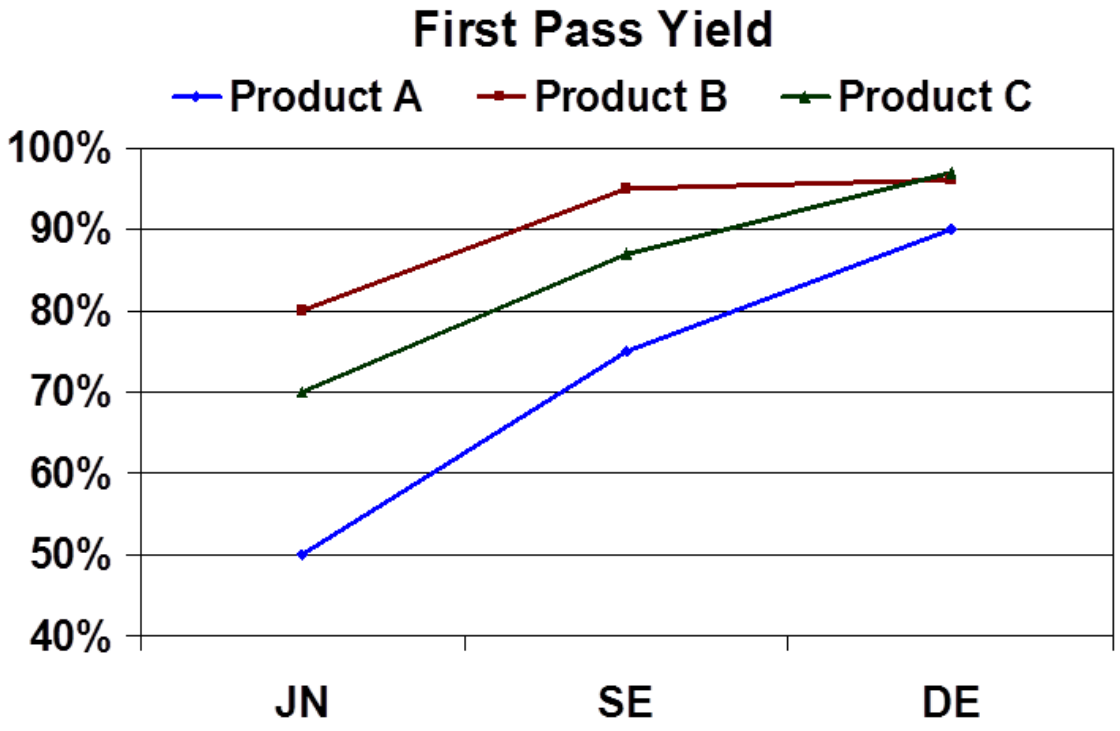


Total time is *area under the curve*…Estimated monies are 7:1 with OT, Freight, Material/Equipment changes, T&E, etc. Leverage the DCP to minimize fire-fighting after release. Partner with functional teams

Case Study: Before/After DCP

Initial release and after DCP implementation of 3 products. Was planning secondary to firefighting? What kinds of losses were likely incurred? Was it worth it?

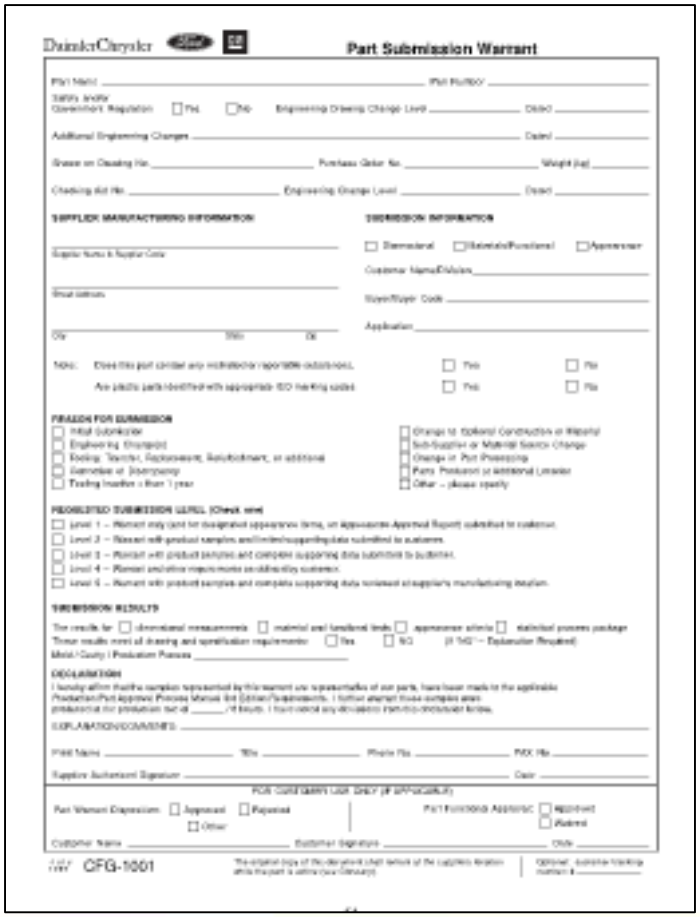
> June: Before DCP
> Sept: After DCP
> December:
Current Performance



3

PPAP

Production Part Approval Process



DaimlerChrysler

Part Submission Warrant

CFG-1001

ASQ

PPAP

What is it: Requirements for approval of production parts

Why do we need it: To make sure that we understand all of the customer requirements, and that we can meet them under actual production conditions

How is it done: Based on customer direction, there are 5 levels of PPAP to secure product approval. An application “cover sheet” is called a Product Sample Warrant (PSW) which lists 18-20 different types of evidence that may be required for submission. These can be customer and/or product/process dependent. It is typical for a customer to witness a launch and review PPAP records when on-site

PPAP Levels per AIAG 4th ed.

1. Warrant only for appearance items
2. Warrant with product samples and limited supporting data
3. Warrant with product samples and complete supporting data
4. Warrant with other requirements specified by the customer
5. Warrant with product samples and complete supporting data reviewing at the supplier's manufacturing location

PPAP level details are typically arranged in advance with the supplier and customer and will often depend on whether the product is a new design or another revision of a tried and true process

ASQ

PPAP Components

1. Design records
2. Authorized Engineering Change documents
3. Customer engineering approval
4. Design FMEA
5. Process flow diagrams
6. Process FMEA
7. Control Plan
8. MSA Studies
9. Dimensional results
10. Material/performance test results
11. Initial process study
12. Qualified lab documentation
13. Appearance approval report
14. Sample production parts
15. Master samples
16. Checking aids
17. Customer specific requirements (CSR) records
18. PSW
19. Bulk material requirements checklist
20. Special process audit results

PPAP Prep…All Hands on Deck

1. TAKES TIME and attention to DETAIL
2. Requires a cross-functional team
3. Insure a good understanding of the Customer Specific Requirements (CSRs) in advance
4. Do WELL on the Appearance Approval Reports (AARs). While the easiest “up front”, these are often the most expensive later on. Take the time to develop boundary samples and conduct Attribute Agreement Analysis (AAAs) to ensure skill
5. Attend to the full Measurement System Analysis (MSA) on variables metrics. Include calibration, resolution and GRR
6. Enable sufficient lead time for the DFMEA, FMEA and CP
7. Insure statistical control of significant characteristics
8. Etc.

How to Organize

1. Many customers will dictate submission formats
2. Some companies establish binders/books
3. Some use formal organizing software

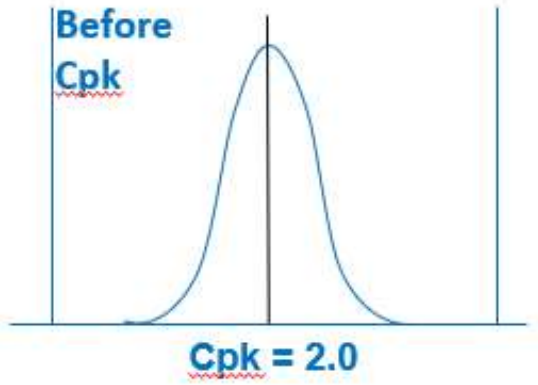
It is critical that:

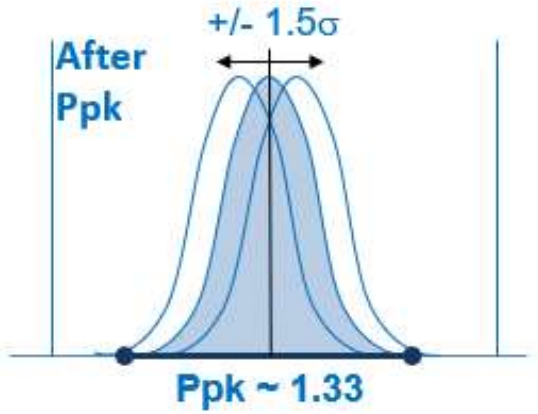
1. More than 1 person has access/passwords
2. Proper security is enabled across those individuals
3. Proper revisions are sustained/maintained

Cpk

Cp/Cpk/Pp/Ppk

Process Capability Primer





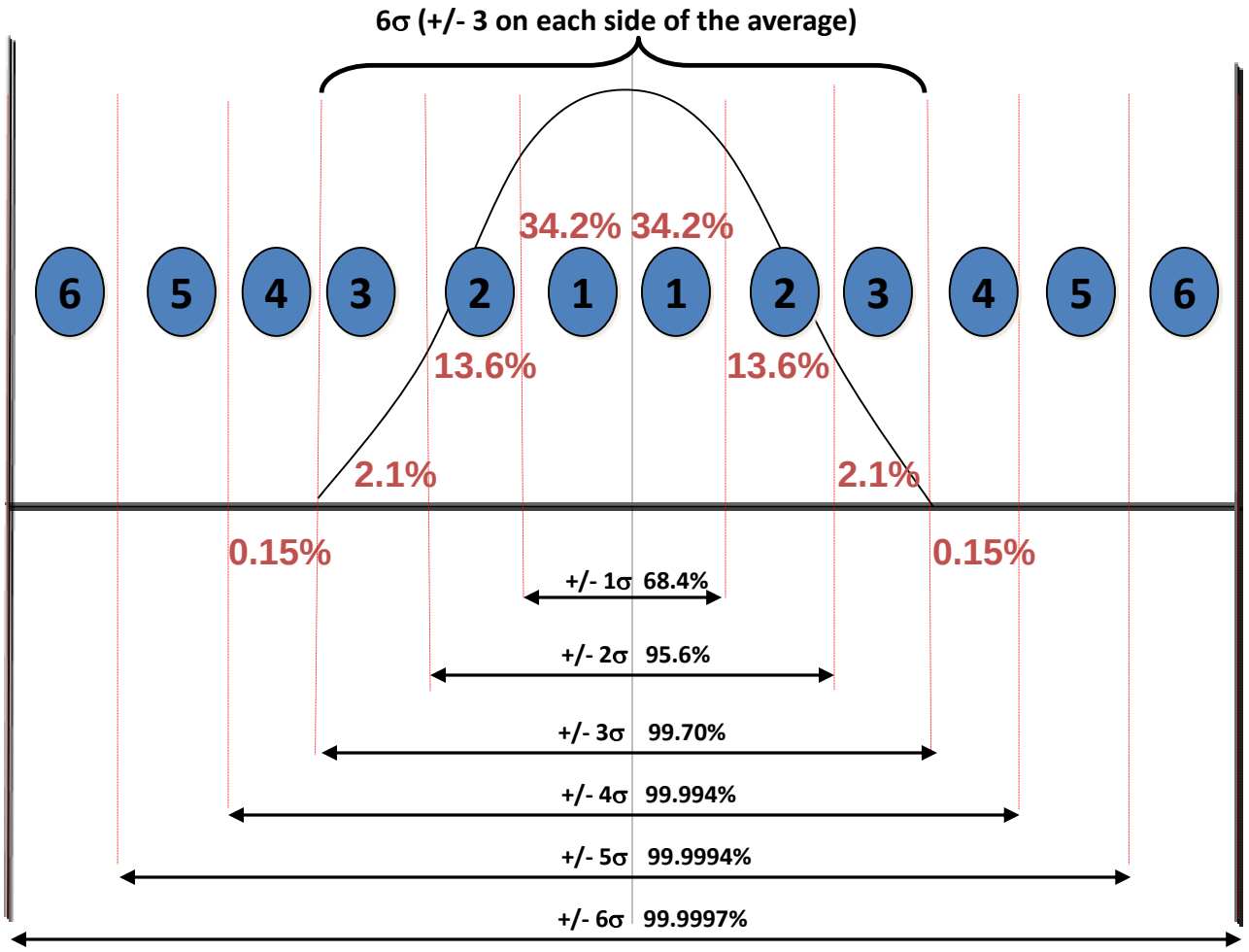
ASQ

Process Capability 101

- **Cp/Cpk**: Also called “short term” capability which is used to reliably determine if a process is yielding good **initial** results by taking a representative sample size.
  - Cp is based on the whole breadth of the process
  - Cpk is based on “half” of the process
- **Pp/Ppk**: Also known as “**long term**” process capability. The key difference is that there is much more data on hand for Pp/Ppk. AIAG notes “90 shifts, 90 days”

Dissecting the Bell

*When there is **ROOM*** for 6 sigma's on ***EACH*** side of the average before the closest target is hit…



THEN **you have "6σ quality!"**

ASQ

Calculating Capability

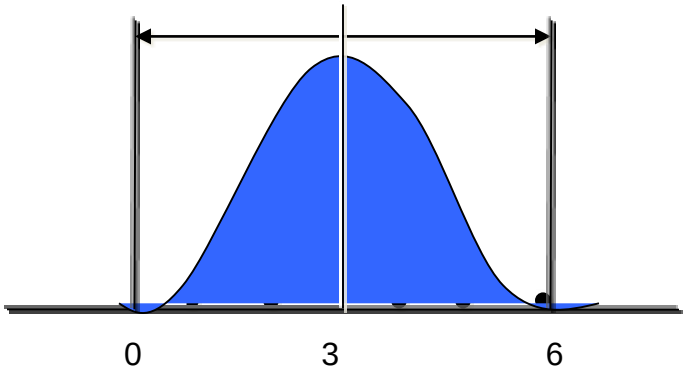
Cp (Pp). Measures the ability of the WHOLE bell to fit within the target limits

If the whole bell (6 sigmas) fit within the target limits a total of 1 time, then the Cp = 1.

Ideally, 2 is preferred.

$Cp = (USL – LSL) / (6 \times \sigma)$

USL = 6, LSL = 0, $\sigma = 1$



Cpk (Ppk). Measures the ability of HALF of a bell (3 sigmas) to fit within the average and the closest target limit

$Cpk_U = (USL – Average) / (3 \times \sigma)$

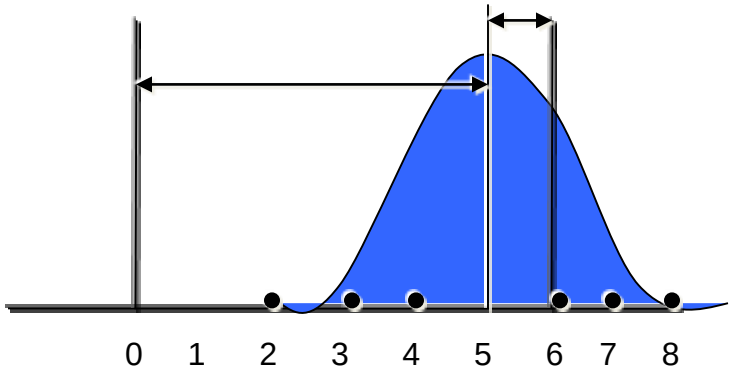
$Cpk_L = (Average – LSL) / (3 \times \sigma)$

USL = 6, LSL = 0, $\sigma = 1$

$Cp = (6 – 0) / (6 \times \sigma) = 1$

$Cpk_U = (6 – 5) / (3 \times \sigma) = 1/3\ (0.33)$

$Cpk_L = (5 – 0) / (3 \times \sigma) = 1\ 2/3\ (1.67)$

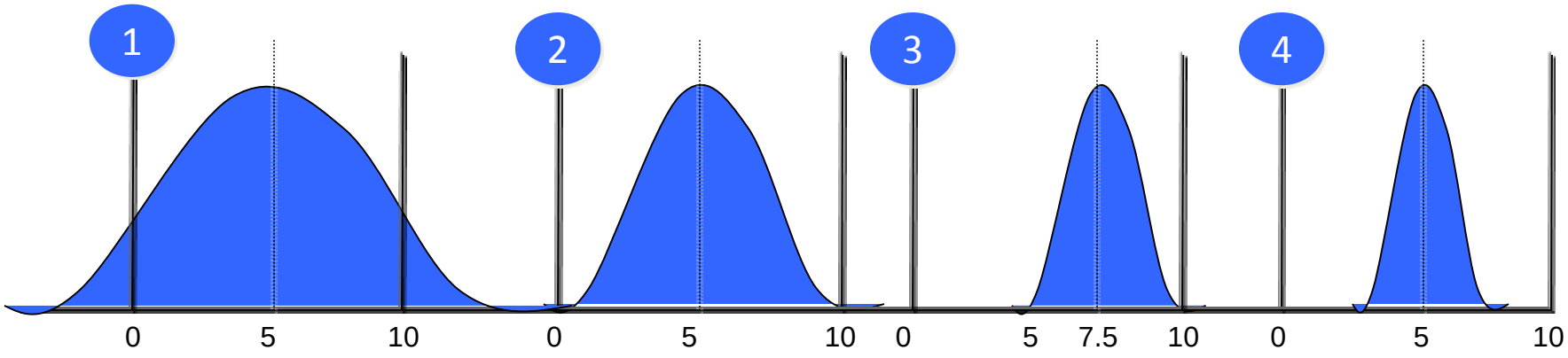


Cpk Worksheet

Determine the Cp and Cpk for each situation…Remember, if the process is NOT shaped like a bell, then sigma cannot be used (without special consideration) and the Cp/Cpk cannot be properly determined

In each case either the average or sigma may or may not change… only the specifications remain the same

#	Avg	σ	Cp	Cpk_U	Cpk_L	%Non-Conf
1	5.0	2.50				
2	5.0	1.67				
3	7.5	0.83				
4	5.0	0.83				

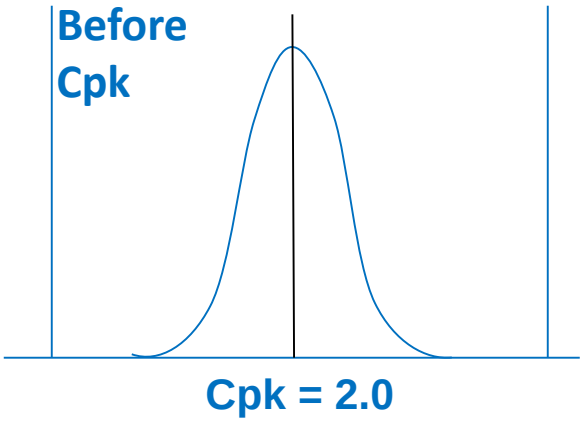


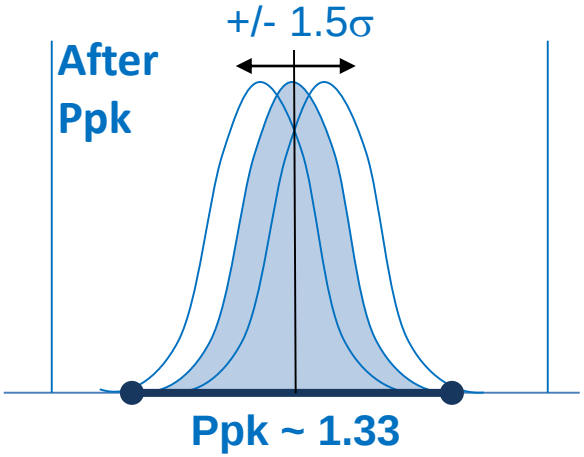
Shift Happens

Cpk of 2 is desired for *initial* capability

Long term capability is Ppk. This is the capability after the process experiences "life" via multiple material lot changes, set up and operator variation, seasonality, etc. Ppk is usually calculated after "90 days" (or with a significant quantity) of process data. It is the type of product results that the *long term* process will represent

It is estimated that a process will "shift" by +/- 1.5σ in response to those changes. As such, if a process started ideally with a Cpk of 2.00, then it is estimated that the resultant Ppk would be 1.33 to accommodate these types of affects





4

MSA (GRR & AAA)

Measurement Systems Analysis

ASQ

Measurement System Analysis

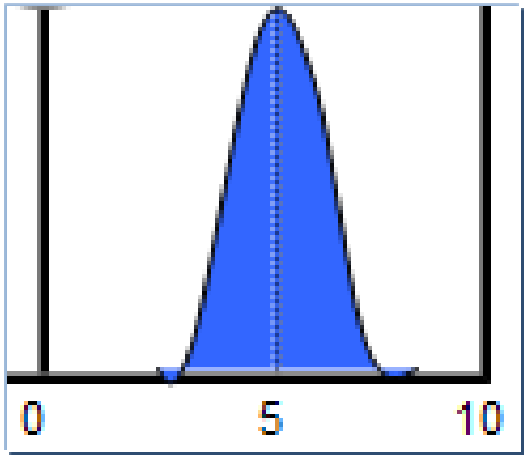
When we measure or make an assessment of the goodness of an item, we need to be sure that our result is correct. If it is not correct, we take two risks:

- **Alpha α Risk**: We may inadvertently discard or rework a good item (Aw, darn)
- **Beta β Risk**: We may inadvertently pass on a bad item (Boy, that was Bad)

Why Do We Need to Know?

We need to know how much error there is in our measurement processes for several reasons:

- Prevent α and β errors
- Reduce scrap/rework
- Understand what process Cp/Cpk we need our processes to have
- It is our **JOB** to ensure that our people are enabled to make the right pass/fail decision **EVERY** time



- And of course…it is an inherent part of PPAP
- **NOTE**: *EVERY* item called out for measure or inspection on a control plan is **REQUIRED** to have an MSA analysis conducted.

MSA Types: Variable & Attribute

Humans usually believe what they see and do not question a value shown on an instrument. There are ***two typical types*** of variables MSA used to determine the percentage of results error:

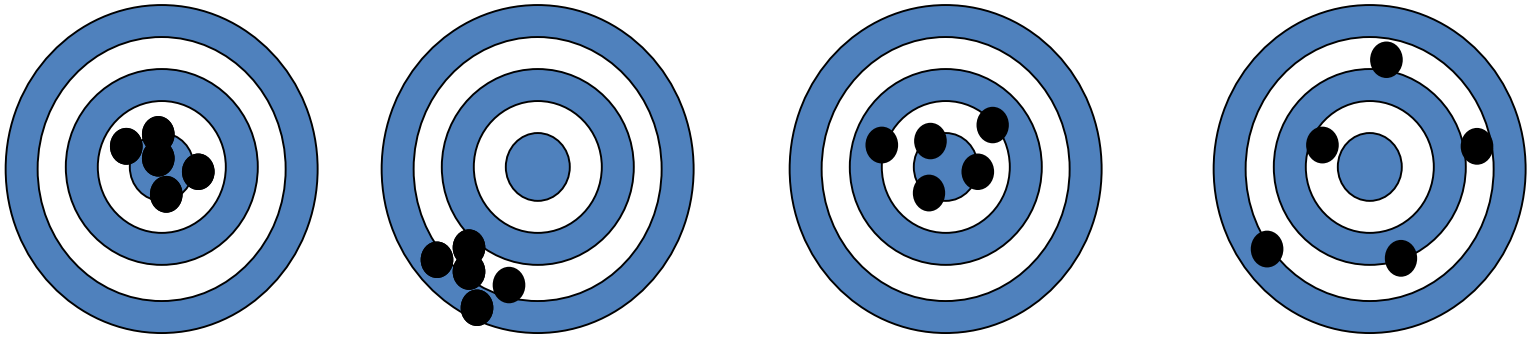
- **Crossed Gage R&R** (Repeatability & Reproducibility): One instrument, multiple operators and multiple part samples
- **Nested GR&R**. Used for gage error in destructive testing

There is ***generally one type*** of Attribute MSA to determine HOW right or wrong we are in our results:

- **Attributes Agreement Analysis (AAA)** is used for items we assess visually or by go/no go or needs to be categorized

Is this window broken? It still opens. The wooden frame is in place

How Data Varies



Accurate & Precise | Inaccurate but Precise | Accurate but Imprecise | Inaccurate & Imprecise

Accuracy: Generally managed by **calibration** includes bias (how far off), linearity (across the breadth of the measured range) and stability (holding a measure over time)

Precision: Generally managed by Repeatability (gage) and Reproducibility (human) aka **GR&R**

ASQ

General MSA Notes

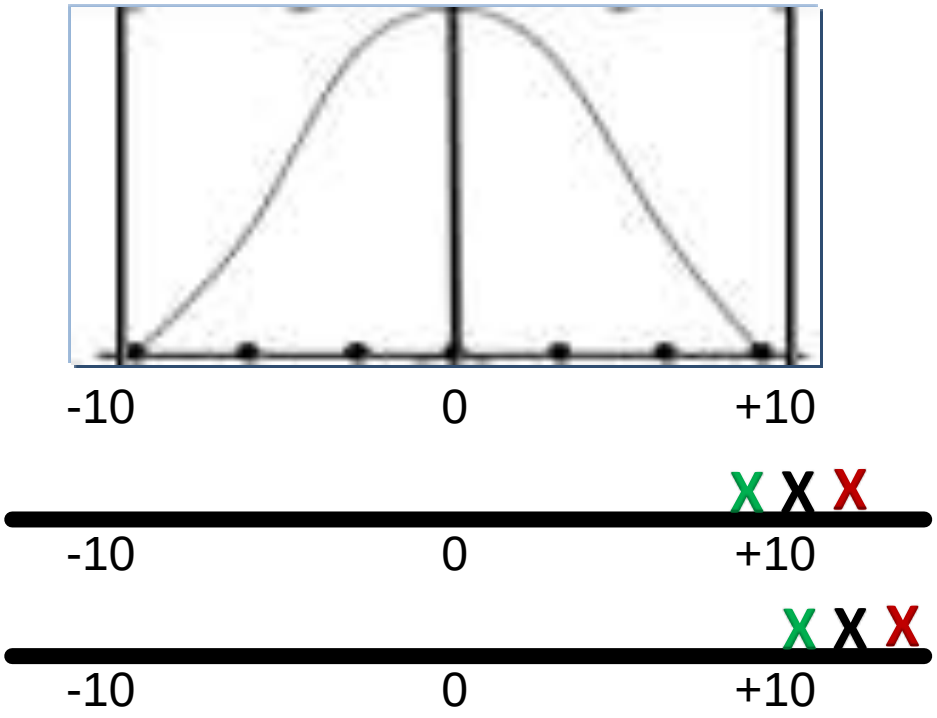
For a variables Measurement System to work, three features are ***equally*** needed:

- **Resolution:** Ability to read the gage. (Discrimination). Resolution needs to be at least 10% of the tolerance (If not at 10% or better, additional actions are needed)
- **Calibration:** A check of bias, linearity and stability (performed on a regular basis)
- **GR&R:** Amount of error in human and gage performance. Typical GR&R <= 10% error on safety features. Included in PPAP, it insures that the gage system will work as intended **BEFORE** the process is launched. After that, it is conducted on an as needed basis (verification of process, gage system change, qualification of personnel)

ASQ

Resolution and Cpk

What does Resolution do for you?



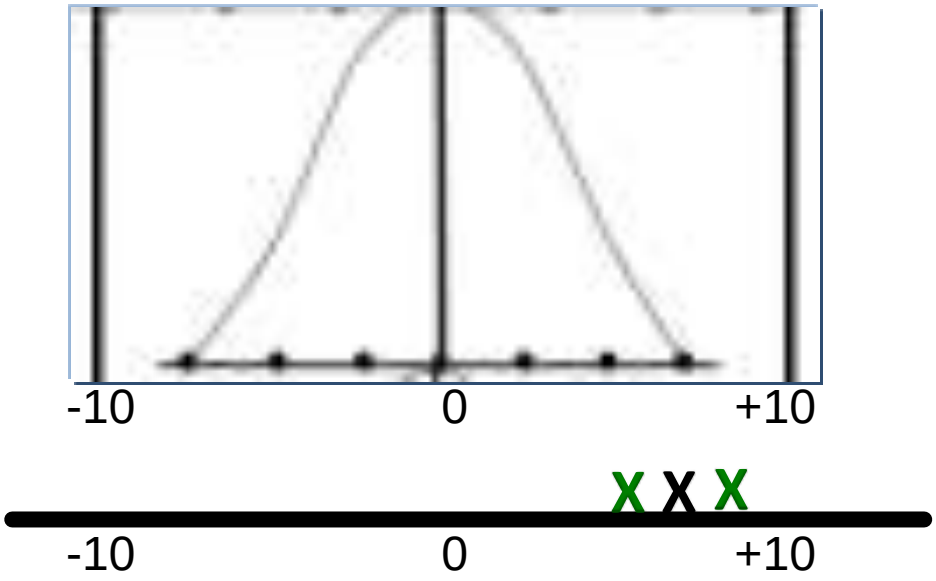
With a “10% resolution gage”, we would accept a unit that reads 10. But…it could be a 9 or an 11. We are at risk 1/3 of the time for a β error…**IF the Cp/Cpk is 1**

We would also reject an 11, (it could be a 10 or 12). We could have an α error 1/3 of the time...Again, **IF the Cp/Cpk is 1**

This is one of several reasons why a Cp/Cpk of 1 isn’t good enough for safety features

Resolution With Cpk >1.33

Resolution with better process capability



With a more capable process, if we still have a “10% gage”, the process is not likely to generate any units measuring a “10”. As such, if we read an 8, it could still be a 7 or 9. However, there is now minimal risk for either an α or β error. In this case, the **Cp/Cpk is 1.33**

This is one of several reasons of why a minimum Cp/Cpk of 1.33 is required for safety features

Attribute Agreement Analysis

AAA Checks for the chances of 100% agreement on three features:

- **Within** "myself"; Did I repeatedly call it good or bad in a consistent manner (even if I was wrong)
- **Between** both me and "my peer"; Did both my peer and I repeatedly call it good or bad in a consistent manner (even if we were both wrong)
- Compared to "**Standard**"; Did I/we get it right

Known Population		Operator #1		Operator #2		Operator #3		Y/N	Y/N
Sample #	Attribute	Try #1	Try #2	Try #1	Try #2	Try #1	Try #2	Agree	Agree
1	pass	pass	pass	pass	fail	fail	fail	N	N
2	pass	pass	pass	pass	pass	fail	fail	N	N
3	fail	fail	fail	fail	pass	pass	pass	N	N
4	fail	fail	fail	fail	fail	fail	fail	Y	Y
5	fail	fail	fail	fail	fail	fail	fail	Y	Y
6	pass	pass	pass	pass	pass	pass	pass	Y	Y

AAA Quick Notes

An AAA needs many Pass/Fail "***Samples***"; Preferably 50 or more (pass/fail/borderline).
NOTE: One unit might have several samples on it

An AAA is a check for accuracy in human performance. The target for "Statistical Agreement" is >= 85%. Another form of Agreement is called Kappa (K). AIAG calls out for K >= 75%. AAA is done as a part of PPAP to ensure that the review process will work as intended; ***before*** the process is launched. It should be treated as a "maintenance" action with regular review to keep human assessors "calibrated". Usually quarterly

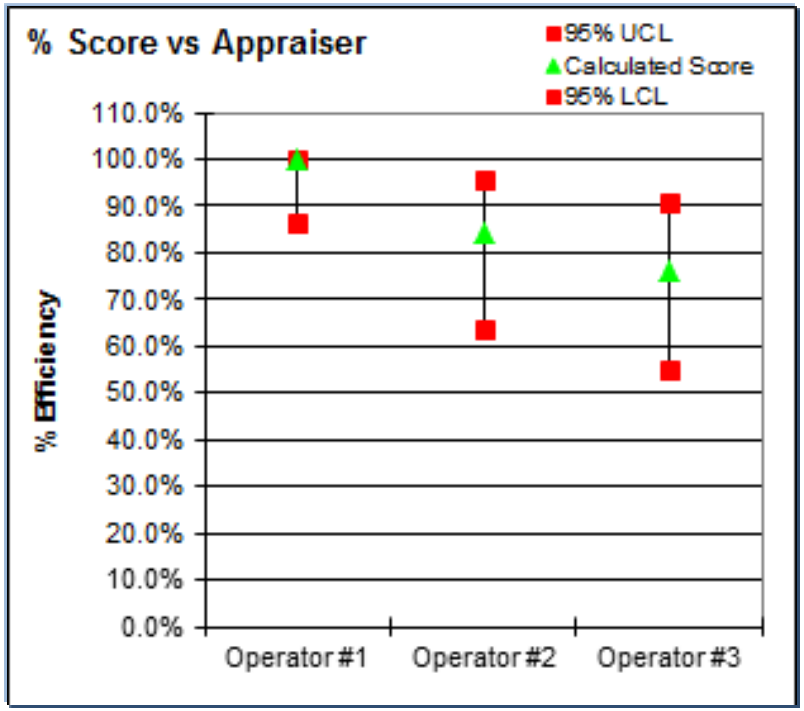
AAA: What It Looks Like

AAA Gives a series of graphs to show how the operators perform in general. While 100% agreement is not feasible, (like 0% GRR Error), industry norm is 85% for **Statistical Agreement**

Screen % Effective Score vs Attribute[4]	
Total Inspected	25
# in Agreement	17
95% UCL	85.1%
Calculated Score	**68.0%**
95% LCL	46.5%

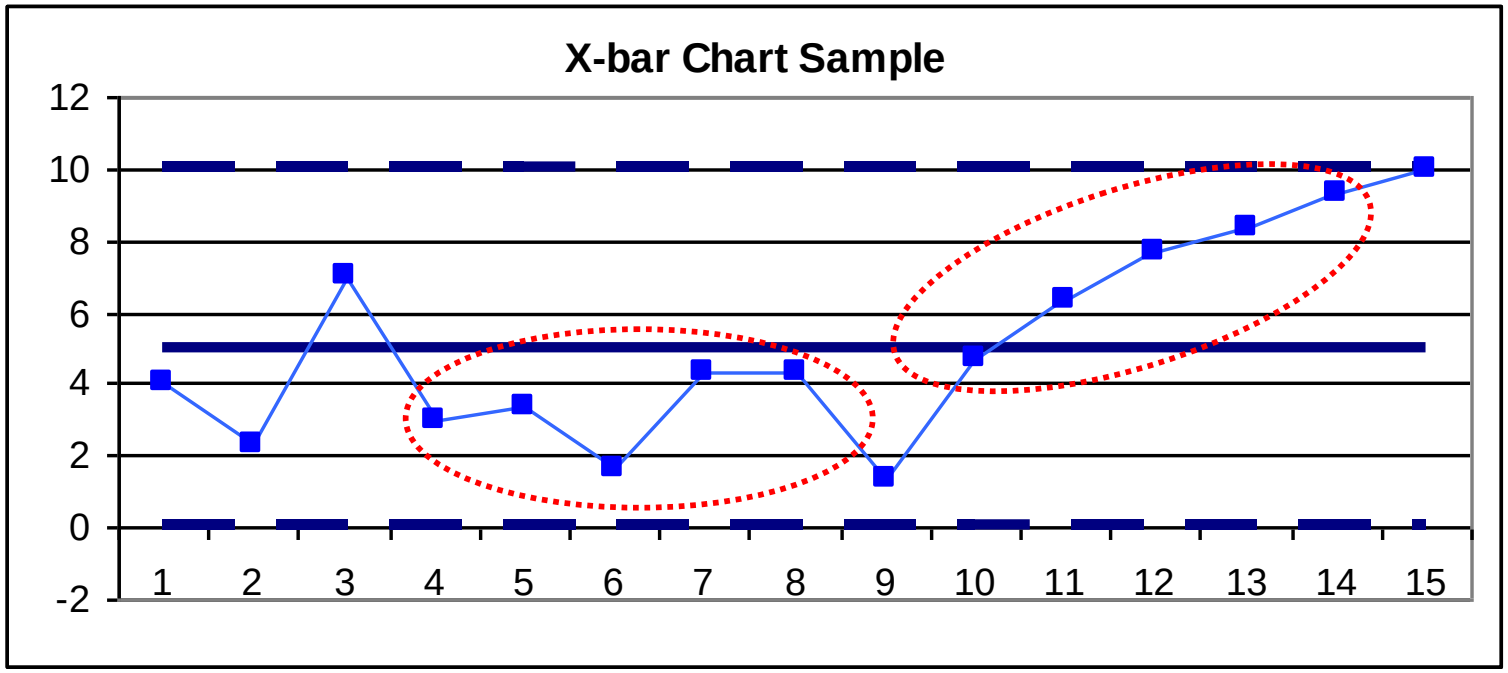
Not an effective Statistical Agreement at < 85%
This team will be in statistical agreement about 68% of the time.

However, 95% of the time, they will likely range from 47% in agreement to 85%



SPC

Statistical Process Control

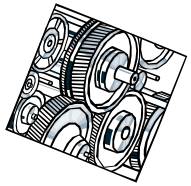


What's Normal?

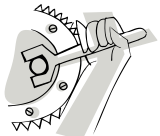
There are 6 main causes of Normal Variation for almost any type of process…

This is *NORMAL*. Hence the "normal" or Gaussian distribution.

Ma npower
Ma chine
Ma terial


Me thod
Me asurement




E nvironment

SPC; High Level Guidelines

1. SPC applies to both variables and attributes. It is a graph-based statistical method to analyze and control a process
2. First step is to **insure MSA effectiveness**; whether for variables (GRR) or attributes (AAA)
3. For variables, must **insure that the process is capable** FIRST, prior to establishing a control chart (Cpk >= 1.33)
4. Determine any key patterns (common sense control) that are meaningful to your process and train to those conditions. These typically include: Shifts, Trends, Points outside of the limits
5. After that, **it's a go/no go chart**. The graphs help you to know when the processes change (whether desired or not)

ASQ

After GRR & Cpk; ***Now*** We Can Chart

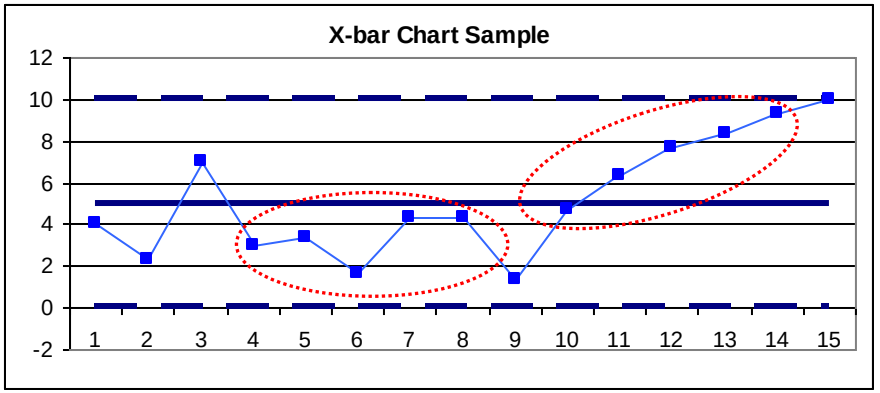
Moving X and Range chart plots data across time along with its corresponding ranges. Patterns are reviewed for prevention purposes.

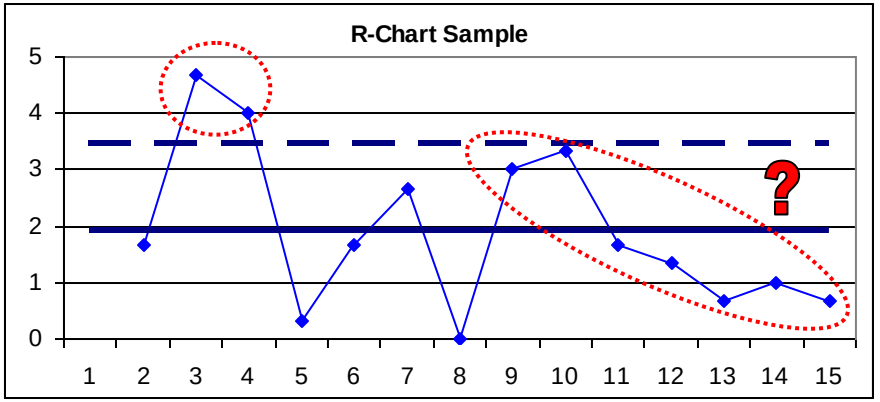
Most Common Signals:

- 5 or more points above or below the average line is considered a shift (bell has moved)
- 5 or more points continuously increasing or decreasing is considered a trend
- Any point outside of the control limits.

These are considered non-normal patterns and the process spread has likely increased

NOTE: Different references call out varying control criteria

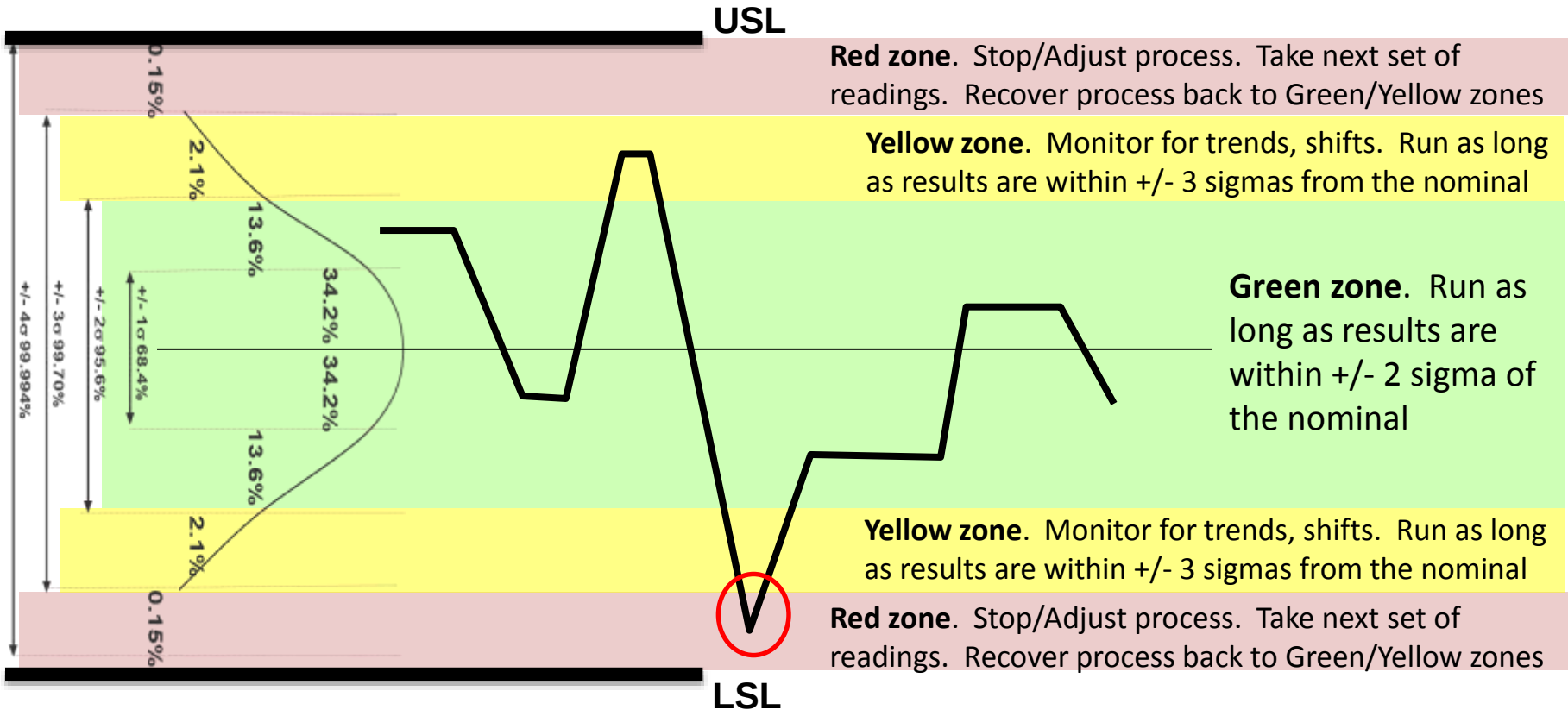




X-bar and R charts are PREVENTIVE and PREDICTIVE forms of process management. They give an advanced warning enabling proactive actions

Pre-Control: No “Limits”

SPC is powerful and effective. Pre-Control is a step before that. It “forces” a 1.33 Cpk by requiring the process to “**pre-act**” when data signals are in-spec but outside of the +/- 3 sigma range. While no control limits need to be calculated, careful communication of **WHY** a person needs to react and adjust the process for an in-spec part



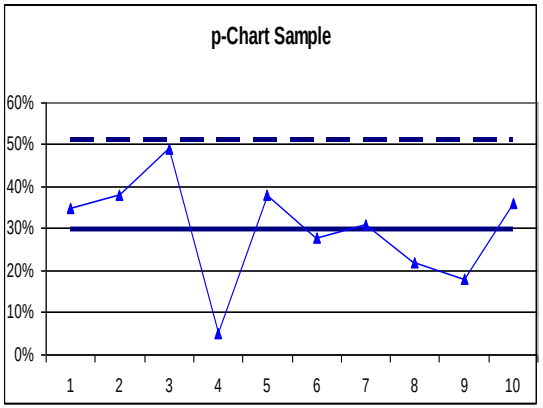
Attribute Charts; With a Good AAA

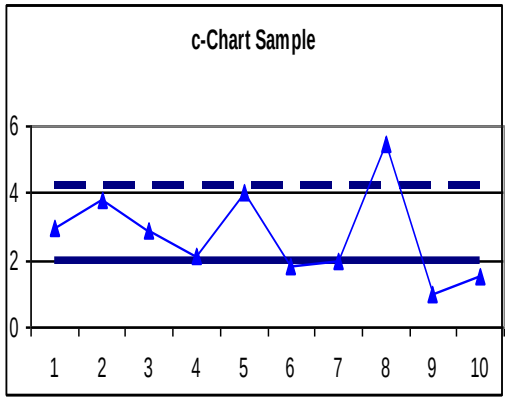
p-chart. A trend-based percentage chart. Must be paired with a Pareto or checksheet to execute fixes. A p-chart typically follows a Weibull distribution because either 0 or 100 is optimal and a “half bell” is developed with bias towards one end or the other.

c-chart. This “counts” defects per unit. Ex. A application may have 3 typos, 2 smudges and 2 areas not filled out for 8 defects on 1 item. The next one may be perfect. The c would equal 4 defects per unit. This is a highly effective method that captures detailed data. It is powerful when paired with a Pareto. Again, checksheets are often used. There is usually a high cost to capture this data. c-charts are usually “turned on/off” to capture a timeframe of data and then rechecked later to verify the effectiveness of the fixes

Trends:

- 5 or more points above or below the average line is considered a shift
- 5 or more points continuously increasing or decreasing is considered a trend
- Any point outside of the control limits. Spread has likely increased



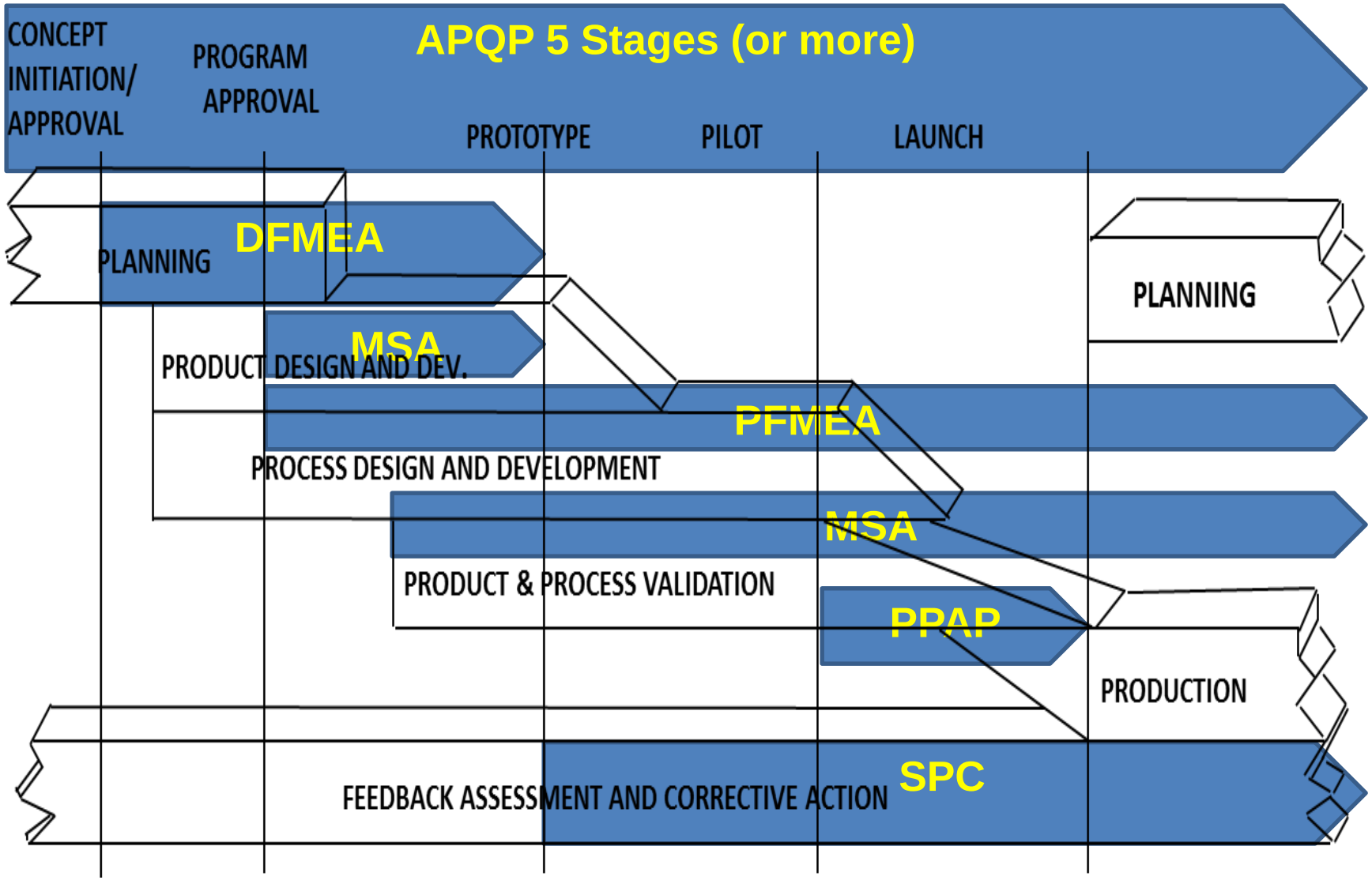


p and c Charts describe what happens **AFTER** the process has occurred. (identifying either scrap/rework). Losses are incurred. **The intent of these charts is to see if the corrective actions are working**

Common Types of SPC Charts

Chart Type	Primary Usage	What is Charted	Typical Sample Size
X-Bar & R	Routine monitoring of high volume manufacturing processes	Plots the average of the data set and its range	~3 to 6
Individual & Moving Range (IMR)	Used when only sample is possible. Common for transactional (monthly) processes	Plots the value and the moving range of the current and preceding values	One
p-Chart	Routine monitoring of high volume processes where scrap/rework trends are critical	Plots the percent non-conforming	Variable
c-Chart	Used for deeply analyzing non-conformities in a product	Plots the average number of non-conformities in a single unit	Variable

Where The Alphabets Fit…



The FIVE Core Tools

1. **APQP: Advance Product Quality Planning:** Guidelines for a product quality plan to develop a product or service that satisfies the customer
2. **FMEA: Failure Modes and Effect Analysis:** Methodology used to ensure potential problems have been considered and addressed throughout the product and process development process (Ex. APQP). Traditionally includes the Control Plan (CP)
3. **PPAP: Production Part Approval Process:** Ensures product consistently meets customer engineering specification requirements during production run at the quoted production rate
4. **MSA: Measurement Systems Analysis:** Guidelines for assessing the quality of a measurement system where readings are replicated
5. **SPC: Statistical Process Control:** Basic graphing statistical tools that enable process control and capability for continual improvement

ASQ

Questions?

Jd Marhevko
Phone: (419) 704-5603
Email: JdMarhevko@AccurideCorp.com