How to Build-in Quality

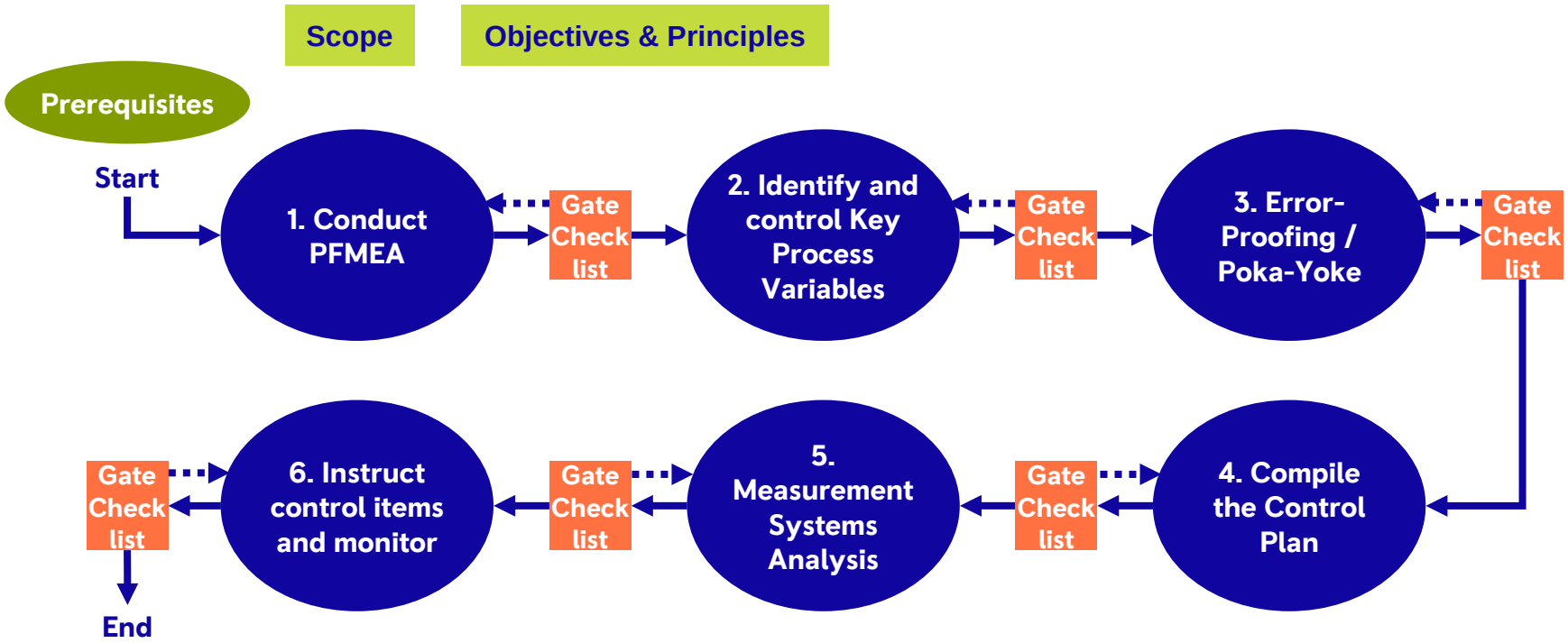
Value Chain Competitiveness (VCC)

Version: 2

February 2020

How to Build-in Quality

BACK Map NEXT



Scope

This ‘How To’ will enable you to:

- Understand the key principles behind the ‘Build-In Quality’ (BIQ) approach
- Join-up key activities to deploy a robust Quality Assurance System
- Familiarise yourself with typical ‘Build-In Quality’ tools and their use
- Focus on Prevention vs. Detection
- Design, implement and continuously improve the ‘Built-In’ Quality Assurance System

Objective and Principles

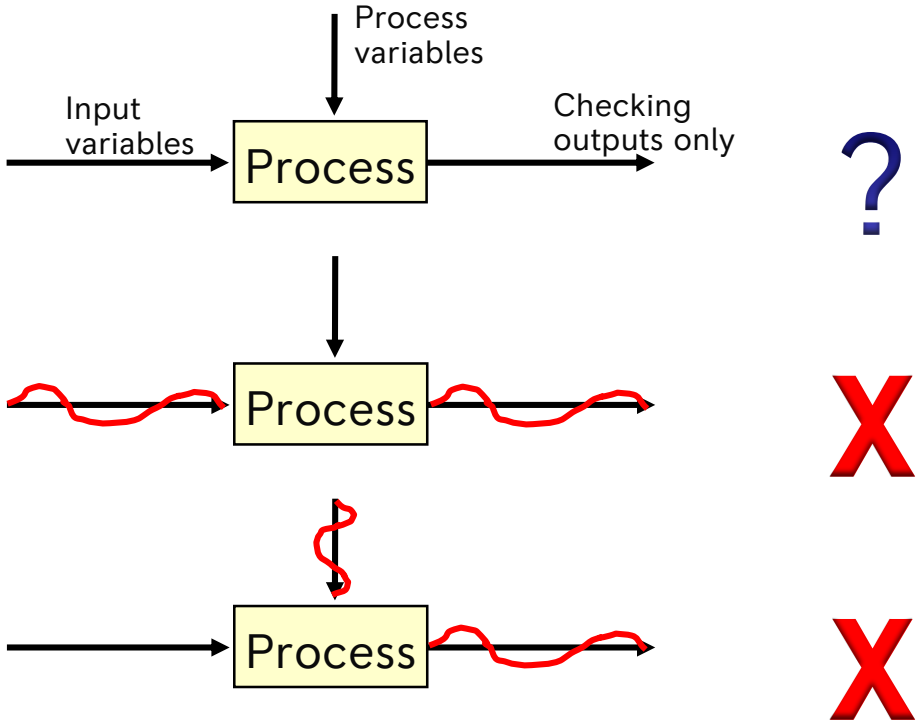
To ensure that process outputs meet or exceed Customer requirements

- ‘Zero Defects’
- ‘Right-First-Time’

A joined-up approach where the following are known and understood:

- Product or service related risk - Design Failure Mode & Effects Analysis (DFMEA)
- Process related risk - Failure Mode & Effects Analysis (PFMEA)
- Necessary controls for materials, equipment and process (Control Plan)
- Measurement System capability
- Effective instruction and deployment of the above (Work Instructions)

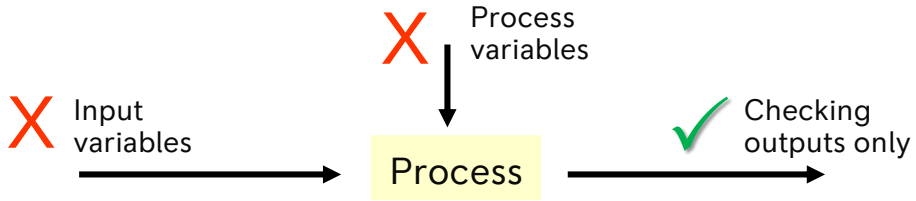
Objectives and Principles – BIQ through effective process control



X Designing a process and checking its outputs will at best highlight non-conformance and *possibly* help us to protect our customers.

Objective and Principles – the essence of BIQ

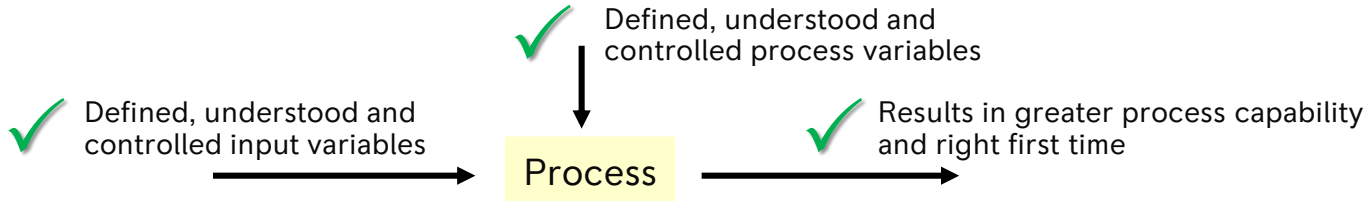
✗ Designing a process, and checking the output of the product, will only permit rework and scrap.



✓ Designing a process that has all the controls built-in to assure quality of inputs and process variables will permit the supply of good product to the customer, right-first-time.

The priority in BIQ is to prevent non-conformance by error proofing. If not practical, then by detecting the causes of non-conformance and stopping the process before a defect occurs. As a minimum, any non-conformance that may occur should be detected early and near to the point of cause.

✓ These controls must be developed at the earliest possible stage in process and product development to allow all the equipment, tooling, fixturing and measurement devices to be specified such that they contain or effect these controls.



Objective and Principles - the Need for BIQ

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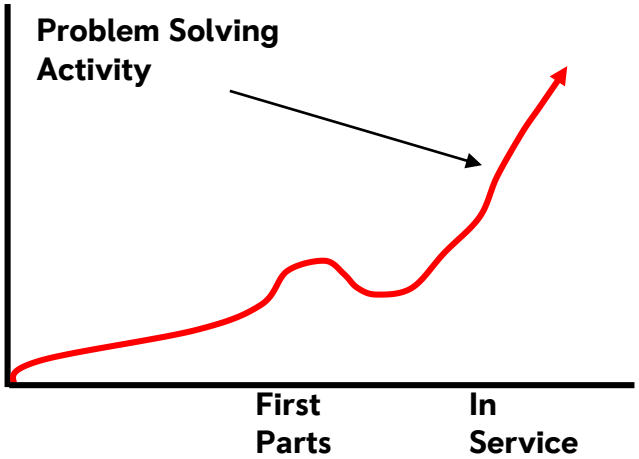
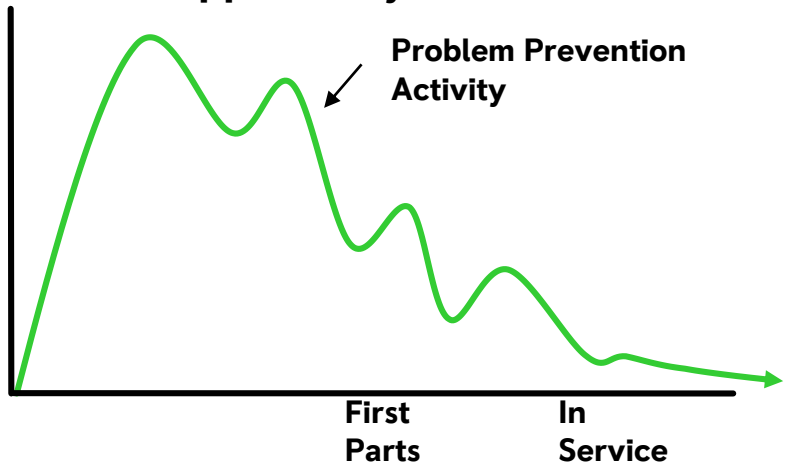
Current State



- ✗ Lack of a process for identifying and resolving potential and actual problems early results in the need to develop the process and hence product during full production
- ✗ Effort is expended on returning to standard, not in cost reduction or improvement

Opportunity



- ✓ **Build in Quality** identifies the need for process control before parts are made
- ✓ Actively seeks out potential problems using **PFMEA**
- ✓ **Error-proofs** the process
- ✓ Controls the process using measures documented in a **Control Plan**

Prerequisites

Knowledge of:

- Existing or proposed manufacturing process (for current / new product)
- Key product features including control features specified by Design Engineering
- Any available DFMEA output studies to support process risk assessment (PFMEA)
- Current / other quality performance data / history

1. Conduct PFMEA

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Gather the required information & understand risk rankings

Required for an effective PFMEA activity:

- Agreed scope for activity
- Cross-functional team (knowledge / experience as appropriate)
- Completed process map or SIPOC diagram
- Team Go-Look-See observation opportunity
- Associated Work Instructions
- Component / assembly drawings and / or other related specifications
- PFMEA template and risk ranking guidelines (1~10)

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see PFMEA standard AS13004 from SAE website

Risk rankings scored between 1 (no / least risk) and 10 (highest risk)**:**

Failure Mode Effect **SEVERITY**
- Relate the criteria to downstream customers, internal and external
- Relate to impact on product / service quality, function, delivery / cost
- Effects on safety, regulatory or legal requirements will produce high severity ranking scores

Failure Cause **OCCURRENCE** Probability
- Relate scores to the likelihood of the failure cause happening based on past experience or prediction
- ranking is related to the probability of occurrence of the failure cause; lower frequency = lower score

Control Method **DETECTION** Effectiveness
- Relates to the probability of either preventing the cause from happening, or the probability of detecting the failure mode before it escapes and causes the effect.

The **Risk Priority Number (RPN)** = **Severity** x **Occurrence** x **Detection**

Note. RPN is used for analysis to guide/ influence action priority

1. Conduct PFMEA

BACK Map NEXT

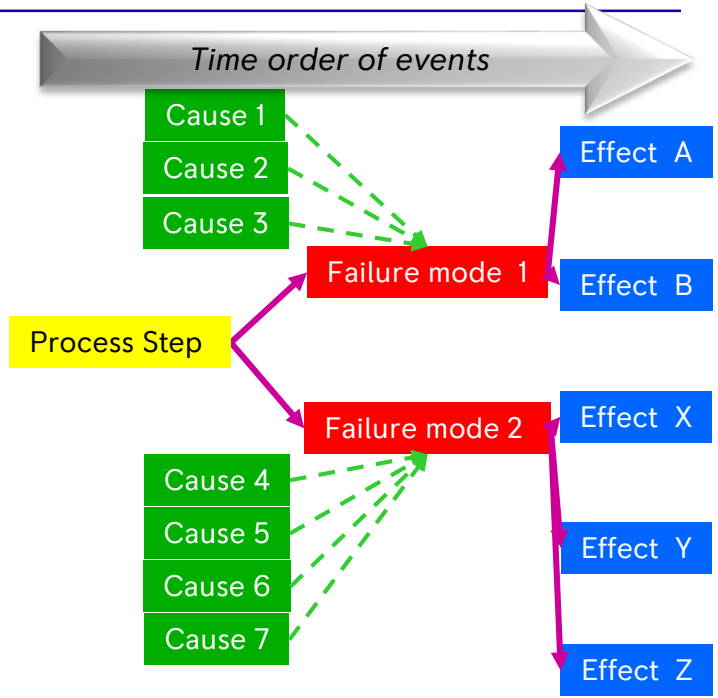
Identify Failure Modes, Effects and Causes

The first step of the Process FMEA is to identify how something can go wrong (potential *failure mode*), the consequences of this happening (*effect*) and how this could be triggered (*cause)*

The process flow of the PFMEA activity steps is counter-intuitive, as it doesn't follow the time order of events, i.e. *cause*, *failure mode* then *effect*

The order for the PFMEA activity is usually (unless otherwise decided by the IPT:

- Go-Look-See / walk the process
- potential failure mode brainstorm
- determine potential effects / impacts on the customer (internal / external)
- propose potential causes of the failure mode and implement countermeasures on a priority basis based on the criticality, or *Risk Priority Number (*RPN)



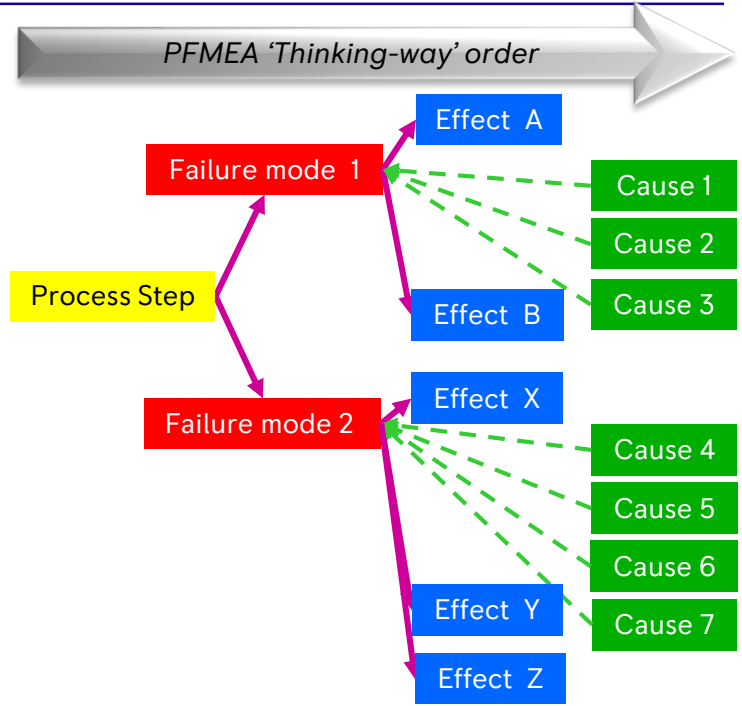
Note: The above example shows **7 different causes** for **2 different process failure modes** having **5 different effects,** all of which may have different levels of impact on the process customer…

1. Conduct PFMEA

BACK Map NEXT

Identify Failure Modes, Effects and Causes

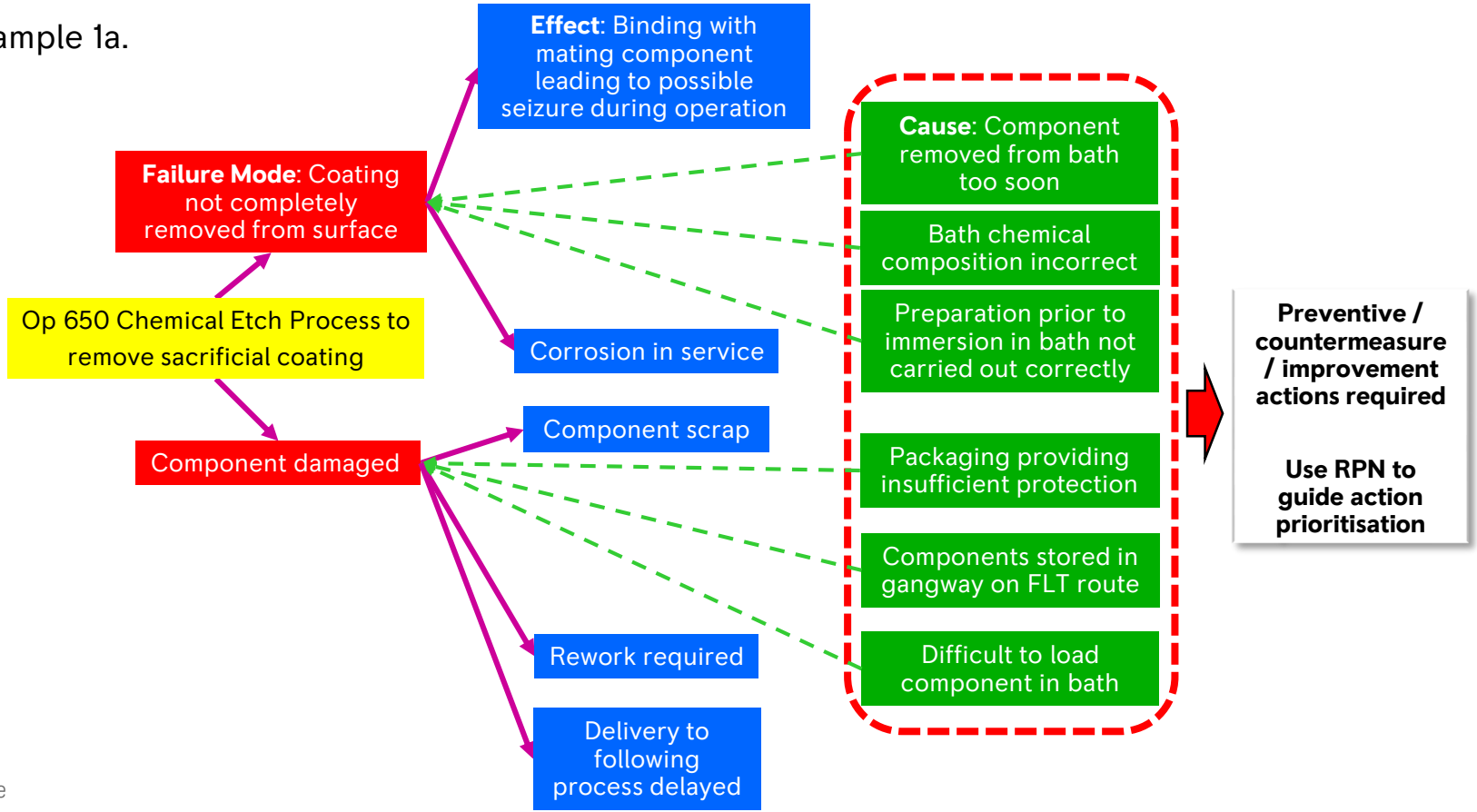
- Map the process out and break down into elemental steps, describing each step in the template under “Process Details”
- Take each process step as defined in the SIPOC diagram / detailed process map in turn, and brainstorm all the possible ways that they could fail to produce the desired outcome; these are the potential Failure Modes
- For each potential Failure Mode identify all of their potential effects, i.e. the things that could happen. Note: there are often multiple effects from each potential failure mode
- Identify the events that switch the failure modes on; the potential causes



Note: The above example shows **7 different causes** for **2 different process failure modes** having **5 different effects,** all of which may have different levels of impact on the process customer…

1. Conduct PFMEA

- Example 1a.



1. Conduct PFMEA

Assess each failure mode for action

- RPN numbers are generated from ordinal scales (1, 2, 3…10) so when we multiply them to obtain the RPN, the result is not a true *variable* scale
- An RPN of 400 may not be twice the risk of RPN 200
- **Severity 8** x Occurrence 6 x Detection 5 = RPN 240
  but
  Severity 4 x Occurrence 6 x Detection 10 = RPN 240

Options...' box above, then click here. *To enable the live **Help Box**, first enable macros in 'Options...' box above*

					Current Process Controls for:			
Potential Failure Mode Effect	SEV	Potential Failure Mode Cause	7M's / Fishbone cause category	OCC	Prevention of Potential Failure Mode Cause	Detection of potential Failure Mode occurrence	DET	RPN
kinlkaxnln nalain	3	ISDNCNLNCL	Method	5	UUA; Hw	uj udnfildnfl	7	105
ijxais'poaK[klnoain d'lnxli'k	4	KNNCSACO'	Maintenance	2	lEJHAOIHihos uhfuaebabfk	ofp pojpsfe	3	24
ki# jcfoefwaom klnalksnxpoQ[P	8	ohnOnbJK	Measurement	6	jdvjbv; fnn f	lihf l ahioahfoi	3	144
kinlkaxnln nalain	2	JKJABLJXAI	EnvironMent	3	idsfhoinip uibsuba uibfiuebfoiuwb	lihs\ofhifhon ijhoiasgihgois	9	54
PqpupQMSQ[#D; JKSOIAHOi jsnono	5	lluedunasiJND UANHDOIUho ubhuW;U;K	Man	4	ugshdupiWIOHC	UHDUHO; OIUNIOINAOU ndvnsebn	6	120

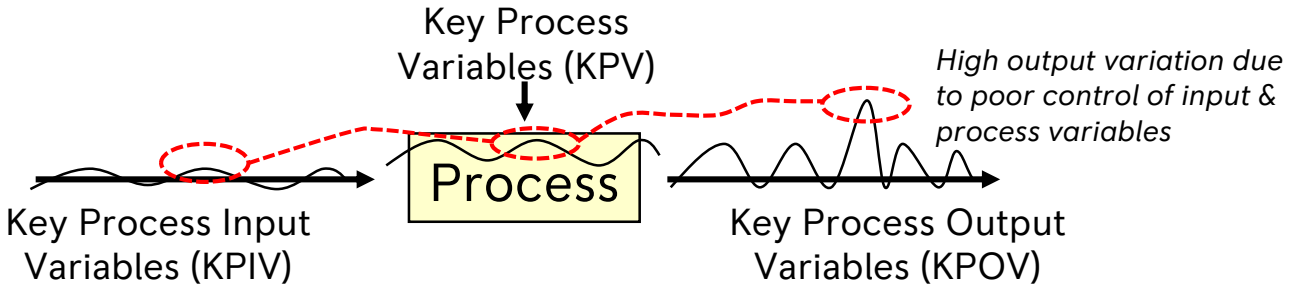
- The action taken from the first example would be different from that for the second
- Do not assume that the three failure mode indices (S, O & D) are all equally important
- Initial focus should always be on **SEVERITY**, followed by **SEVERITY x OCCURRENCE** as a general rule
- Focus on **preventing** the defect from being made in the first place, this puts the emphasis on **minimising the probability of occurrence** rather than improving the ability to capture the defect after the event
- Remember, **detection is not a solution**, it is the 'last chance saloon'…

Gate checklist 1: Conduct PFMEA

- ☑ The reason for completing the PFMEA is understood
- ☑ The process has been broken down into process steps
- ☑ All relevant documentation and quality / service history is available
- ☑ The scoring for Occurrence, Severity and Detection are defined and agreed
- ☑ Preventive and reactive controls have been evaluated and understood
- ☑ The initial phase of the PFMEA has been completed using ‘go-look-see’, and scores determined for the severity, occurrence and detection rankings
- ☑ High RPN scores have been identified for action
- ☑ High scores in ‘Severity’ and ‘Severity x Occurrence’ are focal points for action
- ☑ Actions have been verified and recorded and visual controls updated

2. Identify and control Key Process Variables

- Identify the input and process variables, which determine whether the outputs conform



Inputs

- Reduce the input variation by defining the required set of inputs and how to operate the process in a standardised way
- Define required escalation for non conformance
- Monitor to ensure compliance

Process

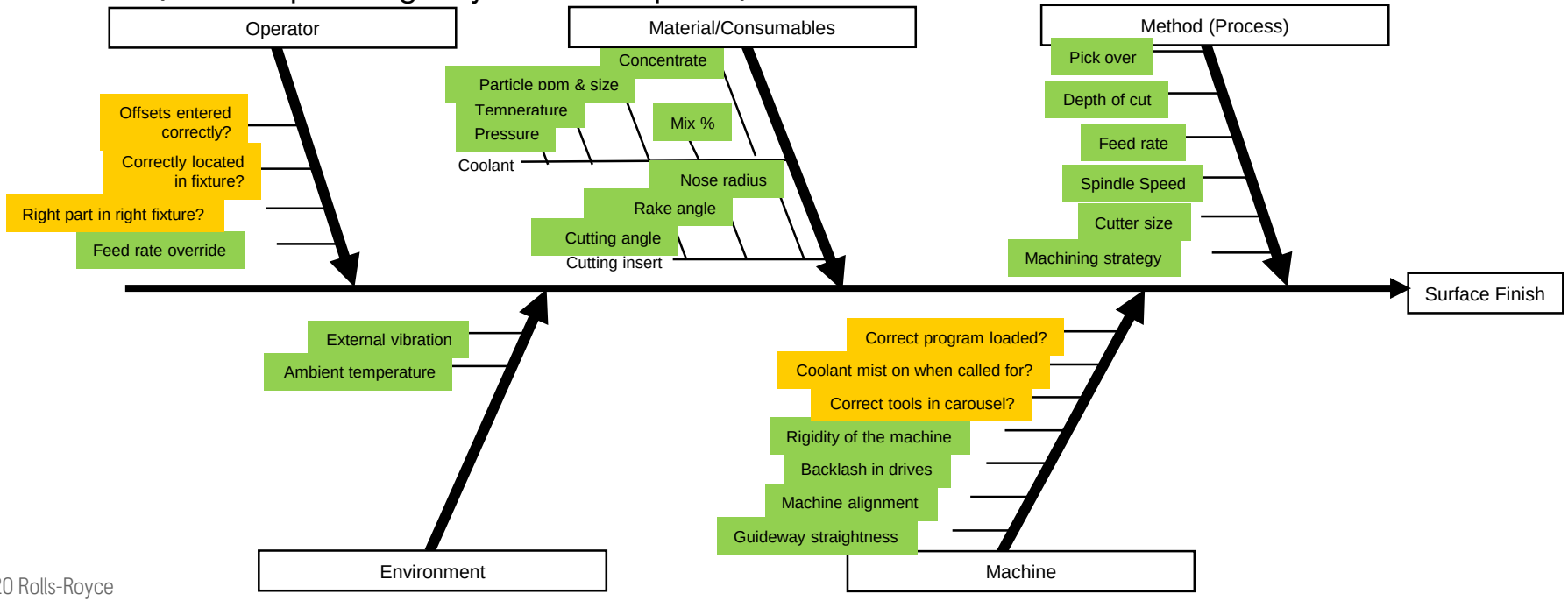
- Define the Key Process Variables, parameters, inspection, record and confirmation methods in Control Plans
- Record the process KPV data and react in accordance with escalation plans i.e. stop the process and contain
- Monitor to ensure compliance

Outputs

- By standardising and recording KPIV data the occurrence of KPOV going out of control should reduce, but more importantly the ability to trace the problem back to point of cause and then root cause will increase

2. Identify and control Key Process Variables

- On an Ishikawa diagram, each process input variable can be categorised as:
  - discrete – managed with error-proofing using Poka-Yoke
  - or continuous – managed using set-points, tolerancing & SPC confirmed using experiments (mistake-proofing may also be required)



2. Identify and control Key Process Variables

Document the KPVs on the Control Plan

CONTROL PLAN

Plant:	Project:	Who	ME	Team Ldr.	MEM	Who	Operator	Cap. Owner	Plant Ldr.
Process:		ManEng	▲	■	●	Operations	△	□	○

Process			Control Characteristics				Quality Control System							
							Inspection System				Record System			
Op. No.	Name	Work Element	Key Process Variable (KPV)	Process Generic/Part Specific (PG/PS)	Set point & Tolerance +/-	CCF reference (if any)	Inspection Method	Known Capability (Red/Amber/Green)	Frequency	Responsibility (Who)	Check Sheet #	Confirmation level & Frequency	Work Instruct #	Escalation Procedure
010	Mill	Mill top surface	Speed	PG	200 +/-10	Surface Finish	Controlled in process	Green	Every part	△	N/A	N/A	N/A	▲
010	Mill	Mill top surface	Feed Rate	PG	60 +0, -2	Surface Finish	Controlled in process	Green	Every part	△	N/A	N/A	N/A	▲

- The Control Plan shows how, when and by whom each KPV is measured, and if it goes out of tolerance, what happens (e.g. stop the process and escalate)
- In this example the KPVs are managed within the CNC program and the “Feed rate override” KPV has been eliminated by disabling the control on the machine

Gate checklist 2: Identify and control Key Process Variables

☑ Key variables identified

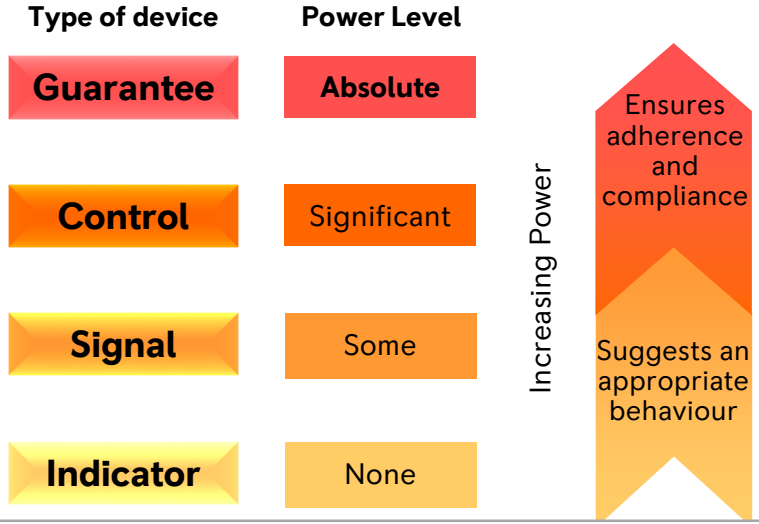
- Key Process Output Variables (KPOVs)
- Key Process Variables (KPVs)
- Key Process Input Variables (KPIVs)

☑ Set points and tolerances determined for each KPIV & KPV

☑ Variable controls documented in the Control Plan and Poka-Yoke / error-proofing methods identified

3. Error-Proofing / Poka-Yoke

Different controls have different effects on human behaviour. The level the device operates at must be determined



The control device capability should match the severity of the failure mode cause being prevented

An error-proofing (poka-yoke) device prevents failure mode occurrence. Their aim is to ensure only one method of operation – the correct one

A **Guarantee** has 'absolute' power; prevention is 'built-in'

- guarding interlock / 3-pin plug / USB connector
- the process can only be followed with compliance
- process stops when non-compliance detected

A **Control** device limits decision-making opportunities; non-compliance options are limited

- car parking barriers
- scheduling boards (provides direction, quantity, size, so the risk of non-compliance is 'obvious')

A **Signal** device draws attention to a condition to prompt a decision, but compliance again remains 'optional'

- traffic lights / Andon lights / shadow boards
- tells me what I should do

An **Indicator** device shows what could happen, but compliance is voluntary

- road signs / road markings
- tells me what, where, how many…

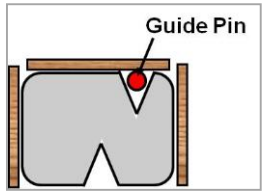
3. Error-Proofing / Poka-Yoke

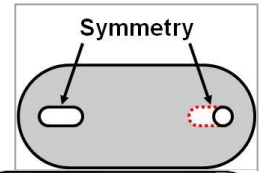
BACK Map NEXT

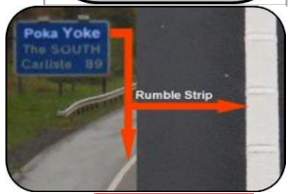
Basic error-proofing device examples

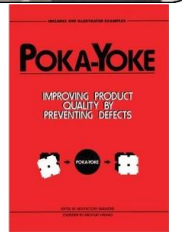
- Guide rods or pins
- Limit switches
- Counters
- Sequence enforcers
- Proximity sensors
- Optical/photoelectric sensors
- Symmetry/asymmetry
- Visual indicators
- Sorting devices

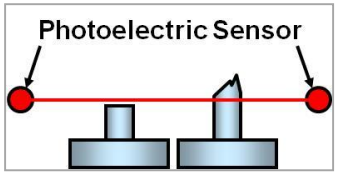
Determined from PFMEA, operation and control requirements









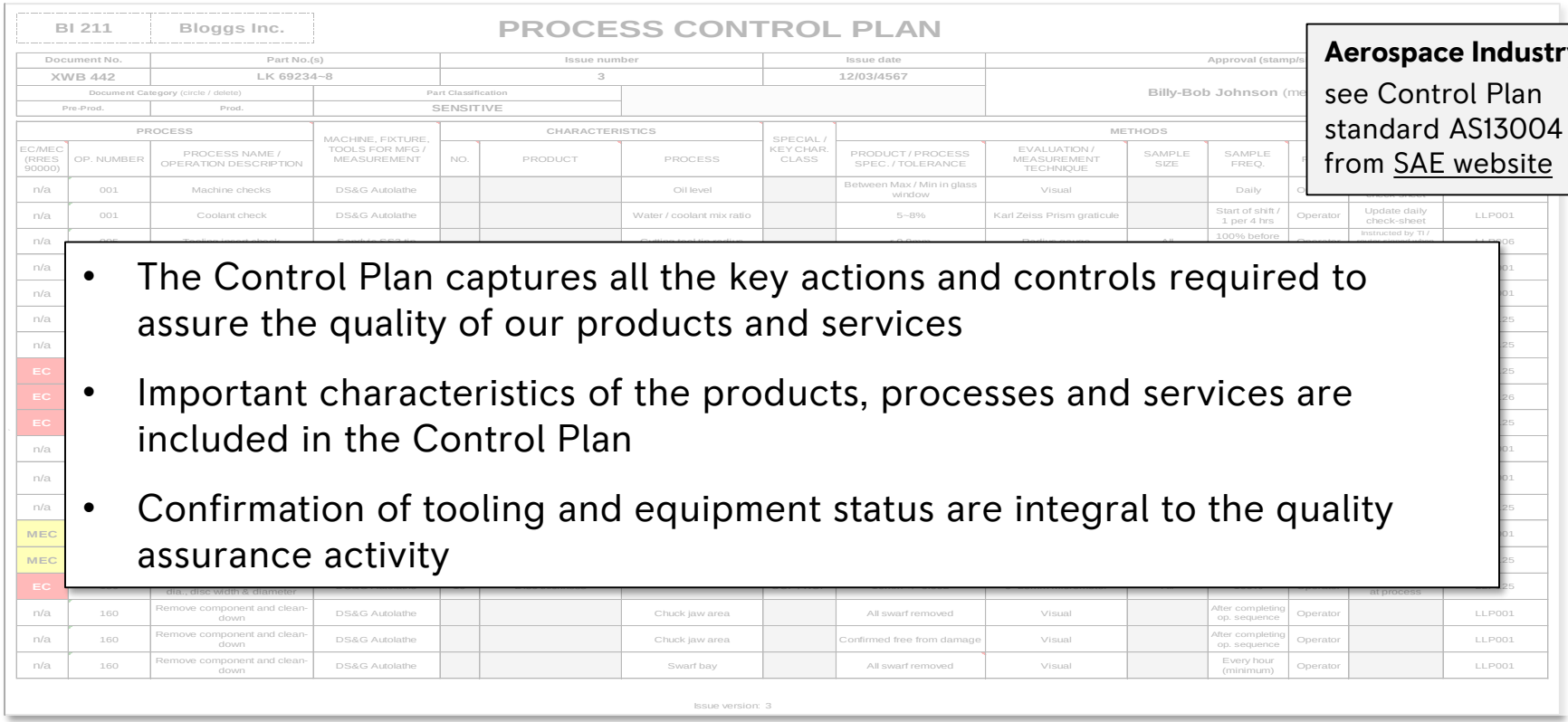


Gate checklist 3: Error-Proofing / Poka-Yoke

BACK Map NEXT

- ☑ Levels of Error-Proofing / Poka-yoke understood
- ☑ Opportunities for implementing error-proofing devices have been determined from the PFMEA and process variable control requirements
- ☑ Error-Proofing / Poka-yoke devices implemented
- ☑ BIQ documents updated (eg. work instructions, control plan) and control confirmed as effective

4. Compile the Control Plan



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PROCESS CONTROL PLAN

Document No.	Part No.(s)	Issue number	Issue date	Approval (stamp/s
XWB 442	LK 69234~8	3	12/03/4567	Billy-Bob Johnson (me

Document Category (circle / delete)		Part Classification
Pre-Prod.	Prod.	SENSITIVE

PROCESS			MACHINE, FIXTURE, TOOLS FOR MFG / MEASUREMENT	CHARACTERISTICS			SPECIAL / KEY CHAR. CLASS	METHODS						
EC/MEC (RRES 90000)	OP. NUMBER	PROCESS NAME / OPERATION DESCRIPTION		NO.	PRODUCT	PROCESS		PRODUCT / PROCESS SPEC. / TOLERANCE	EVALUATION / MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.			
n/a	001	Machine checks	DS&G Autolathe			Oil level		Between Max / Min in glass window	Visual		Daily			
n/a	001	Coolant check	DS&G Autolathe			Water / coolant mix ratio		5~8%	Karl Zeiss Prism graticule		Start of shift / 1 per 4 hrs	Operator	Update daily check-sheet	LLP001
n/a											100% before		Instructed by TI /	
n/a														01
n/a														01
n/a														25
n/a														25
EC														25
EC														26
EC														25
n/a														01
n/a														01
n/a														25
MEC														01
MEC														25
EC														25
n/a	160	Remove component and clean-down	DS&G Autolathe			Chuck jaw area		All swarf removed	Visual		After completing op. sequence	Operator		LLP001
n/a	160	Remove component and clean-down	DS&G Autolathe			Chuck jaw area		Confirmed free from damage	Visual		After completing op. sequence	Operator		LLP001
n/a	160	Remove component and clean-down	DS&G Autolathe			Swarf bay		All swarf removed	Visual		Every hour (minimum)	Operator		LLP001

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see Control Plan standard AS13004 from SAE website

- The Control Plan captures all the key actions and controls required to assure the quality of our products and services
- Important characteristics of the products, processes and services are included in the Control Plan
- Confirmation of tooling and equipment status are integral to the quality assurance activity

4. Compile the Control Plan

CHARACTERISTICS			SPECIAL / KEY CHAR. CLASS	b.	METHODS c.	d.		e.	f.	g.
NO.	PRODUCT	a. PROCESS		PRODUCT / PROCESS SPEC. / TOLERANCE	EVALUATION / MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.	RESP.	CONTROL METHOD	REACTION PLAN / REFERENCE
		Tight to datum location		Zero gap to datum location	Visual / feeler gauge	Each tool installed	100% before use	Operator	Instructed by TI / router signed when changed	LLP001
03	Location diameter	Calculation of cutting-tool off-set for finish cut	MCF	(measured dia. - 60) / 2	50~75mm micrometer	All	100%	Operator	SPC chart visual at process	LLP125
		KPV: 90~95% feed-rate	MCF			All	100%		SPC chart visual	

a. All product, processes and services Characteristics for control are listed

b. Specification / tolerance for each characteristic is entered

c. For each check item the evaluation / verification technique is entered

d. Confirm the verification plan e.g. for multiple machines, all components, sample as defined. Note the sample check frequency should be defined using process capability data

e. Define appropriate responsibility for undertaking the inspection / verification activities

f. Instruct the method by which process control is done - usually a Work Instruction or Standard Operation that details how to undertake the check / verification / inspection activity

g. Define the reaction plan / escalation procedures to be applied in the event of an abnormality from the checks. Escalation for non-conformance to standard should be clearly understood

Gate checklist 4: Compile the Control Plan

BACK Map NEXT

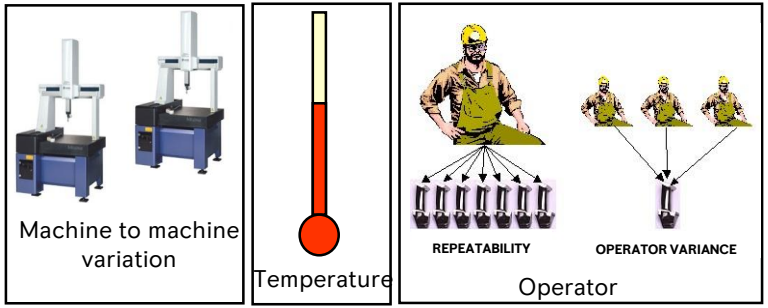
- ☑ Control characteristics and associated checks and tolerances have been included in the Control Plan
- ☑ Verification actions including inspection items, specifications / tolerances, sample frequency, responsibility, method have been defined in the Control Plan
- ☑ ‘Confirmation of checks’ process is in place
- ☑ An appropriate escalation process has been defined for non-conformance and other abnormality management

5. Measurement Systems Analysis

- Measurement System Analysis (MSA) is a structured procedure used to assess the ability of a measurement system to provide accurate data

- The measurement system should be capable of detecting variation in the process and be able to distinguish between a conforming part and a non-conforming part

- There are potential sources of variation that may influence the measurement system, eg.
  - Measurement equipment capability
  - Equipment variation
  - Temperature
  - Operator technique
  - Fixturing
  - Gauge inaccuracy / wear

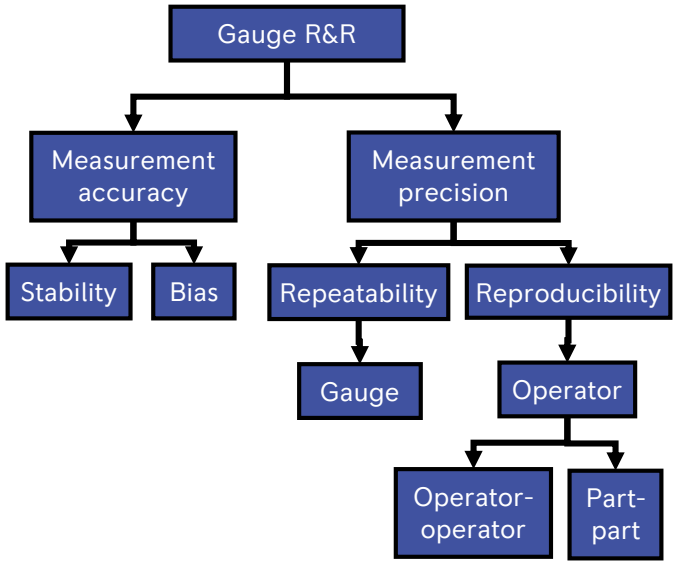


- If measurement error is not acceptable the measurement system requires either improving, or an alternative measurement system should be used with an acceptable level of measurement error

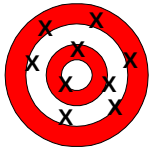
5. Measurement Systems Analysis

BACK Map NEXT

- Gauge Repeatability and Reproducibility (R&R) is a MSA method for continuous data systems
- Repeatability assesses whether each person can measure the same item multiple times with the same device and get the same value
- Reproducibility assesses whether different people can measure the same item multiple times with the same measurement device and get the same average value
- Steps to a Gauge R&R study
    - Plan the study
    - Conduct the study
    - Interpret results
    - Taking action if results are unacceptable
    - Maintain improvements
- A calibration process should ensure that measurement equipment has suitable resolution and range that is stable over time



Precise but not accurate



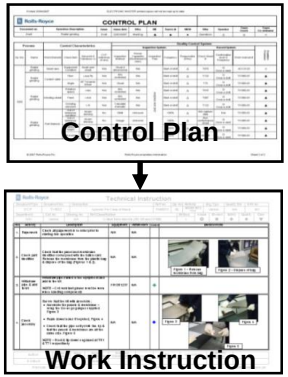
Accurate but not precise

Gate checklist 5: Measurement Systems Analysis

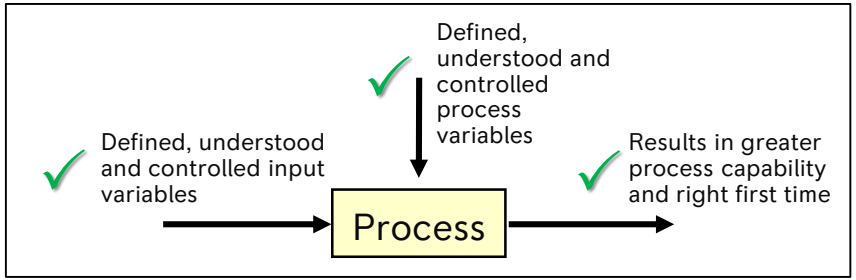
- ☑ Measurement systems are capable of detecting variation in the process and are able to distinguish between a conforming part and a non-conforming part
- ☑ Appropriate calibration process is in place to maintain measurement equipment
- ☑ There is a good understanding of Gauge R&R and its application
- ☑ Gauge R&R study is applied to improve measurement capability

6. Instruct control items and monitor

- Work Instructions contain work elemental steps and should cover all process control activities as defined in the Control Plan
  - Include the method for measurement, data capture (manual / electronic) and monitoring (eg. SPC charts)



- Work Instructions are updated to reflect any change in the Control Plan



- During ongoing production, all 'Build-In Quality' documents should be live and part of the continuous improvement process. BIQ documents:
  - Are used for future product introduction planning
  - Assists root cause analysis and problem resolution

Gate checklist 6: Instruct control items and monitor

BACK Map

- ☑ Quality assurance system effected through the Work Instructions
- ☑ Build-in quality process and documents monitored and continuously improved
- ☑ Build-in quality facilitates for effective problem solving