OMNEX - TECHNICAL PRESENTATIONS

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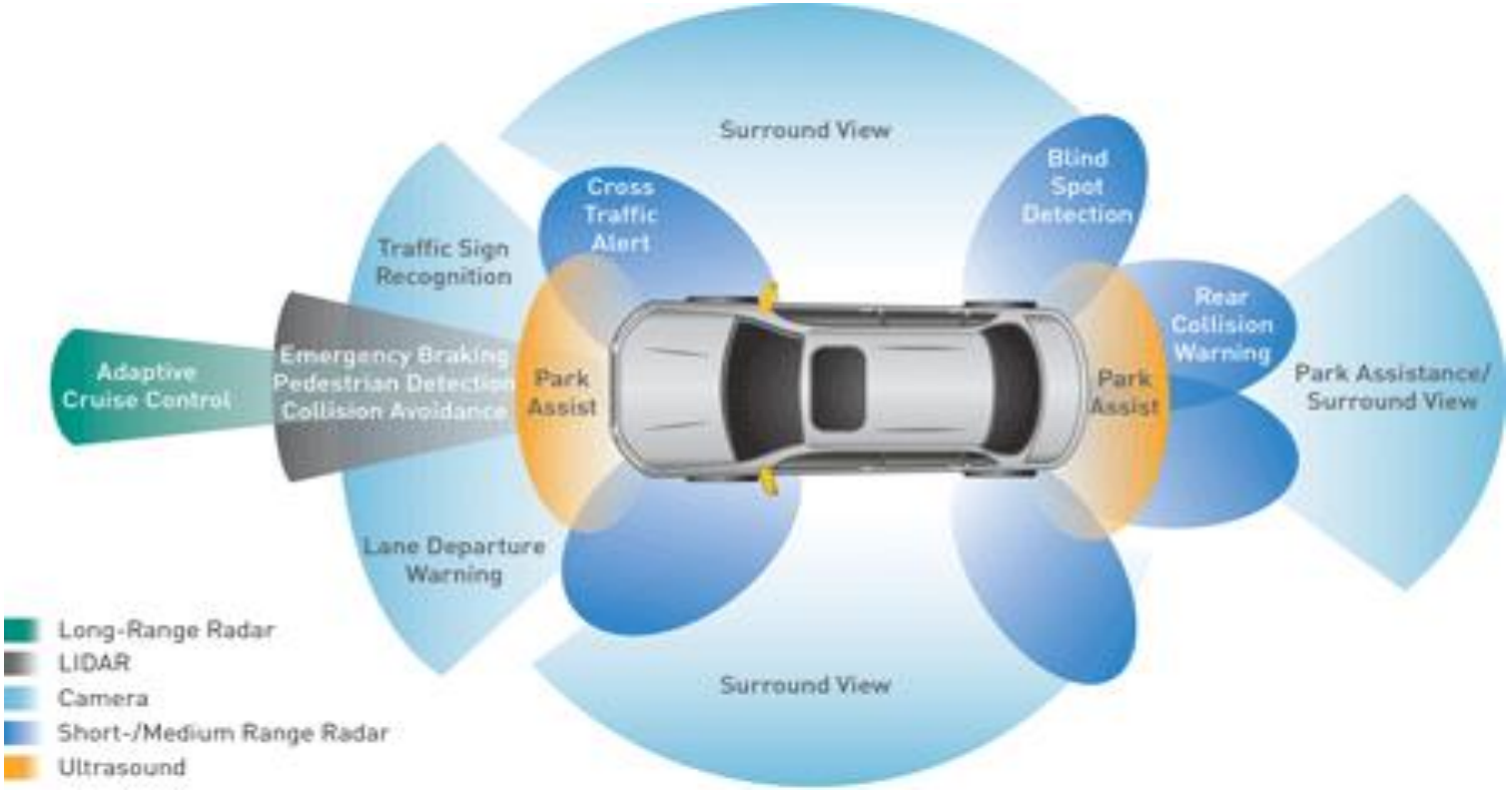
DRIVING WORLDWIDE
BUSINESS EXCELLENCE

Contents

PRESENTATION - 1

IATF 16949:2016 Product Safety
With
ISO 26262: Functional Safety Management System



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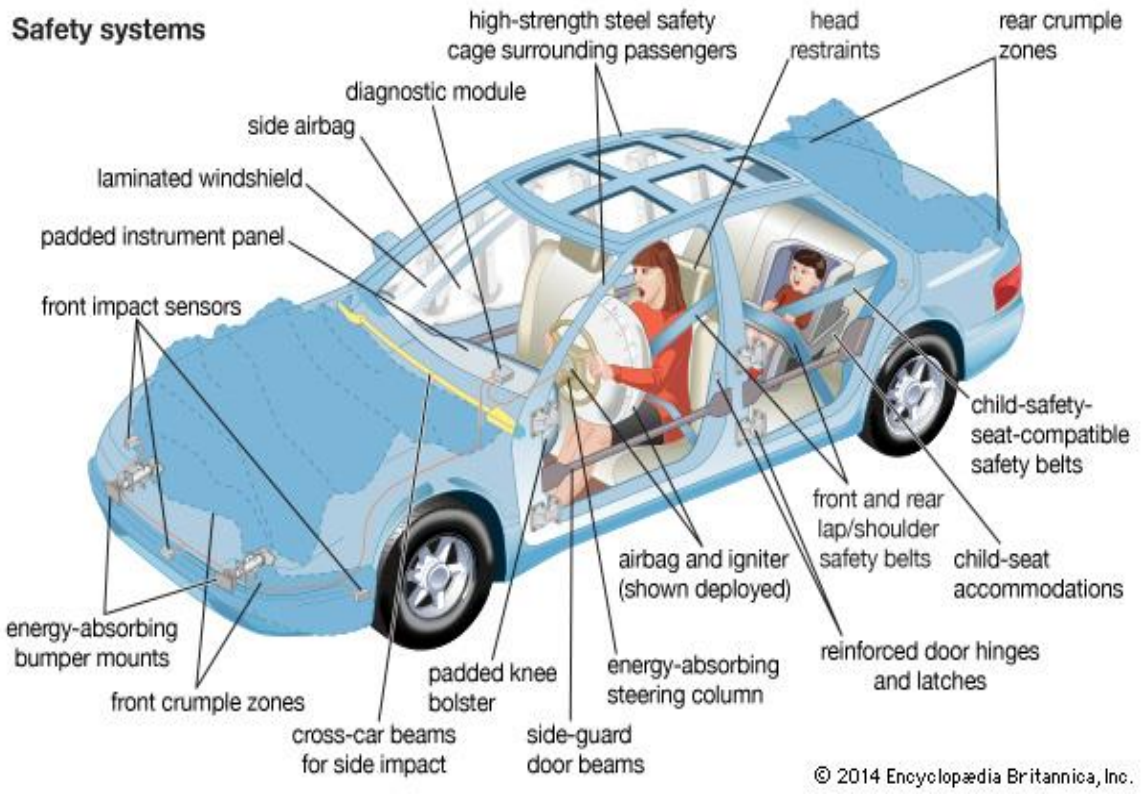

1. Introduction product safety – IATF16949

4.4.1.2 Product safety

The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable:

a) identification by the organization of statutory and regulatory product-safety requirements;
b) customer notification of requirements in item a);
c) special approvals for design FMEA;
d) identification of product safety-related characteristics;
e) identification and controls of safety-related characteristics of product and at the point of manufacture;
f) special approval of control plans and process FMEAs;
g) reaction plans (see Section 9.1.1.1);
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6);
k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1);
l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1);
m) lessons learned for new product introduction.

NOTE: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.

1. Introduction product safety – IATF 16949

- The new clause titled Product Safety requires a documented process for the management of product safety.
- This clause defines 13 normative elements that must be included in the documented product safety process.
- These 13 requirements include identification of product safety characteristics, inclusion of safety characteristics with approvals in design and process FMEA's, control of safety characteristics at the point of manufacturer with documentation in control plans with specific reaction plans, and defined responsibilities for product safety management including the definition of an escalation process and flow of information, including top management, and customer notification. Additionally, those personnel involved in product safety related processes will have specific training.

1. Introduction product safety – IATF 16949

- When determining whether the product is safe, following shall be taken into account:
  - **the characteristics of the product**,
  - including its composition,
  - packaging,
  - instructions for assembly and for installation and maintenance **the effect on other products**,
  - where it is reasonably foreseeable that it will be use with other products **the presentation of the product**,
  - the labelling, any warnings and instructions for its use and disposal and
  - any other indication or information regarding the product

1.a. BASIC CONCEPTS – Product Safety

- Why to regulate safety?
- How much safety?
- What to regulate?
- Who should regulate?
- How to regulate?
- How to control?
- Who should control?

1.b. WHY TO REGULATE SAFETY?

- End user safety - first objective of customer protection policy
- Perils to customers
  - New and sophisticated products
  - Competitive markets
  - Mass-production
- Preventive function of the safety regulation

1.c. HOW MUCH SAFETY?

- Absolute safety or optimal safety?
- No risk or acceptable risk?
- Optimal safety – acceptable risk system
  - Elements of product regulation:
    - Safety, performance, efficiency, quality, price
  - Risk-utility test
    - Acceptability of the product assessed against its utility

1.d. WHAT TO REGULATE?

- (Producers)
- Design of the product
- Manufacturing/performance process
- Instructions, warnings and information

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1.e. WHO SHOULD REGULATE?

- Private regulation
  - Individual manufacturer
  - Manufacturers' associations
  - Private regulators
- Public regulation
  - Government
  - Regulatory agencies (technocrats, experts)

1.f. HOW TO REGULATE?

- Compulsory regulation
  - laws, regulations, administrative provisions
- Voluntary regulation
  - standards
- Mixed regulation
  - compulsory laws supplemented by voluntary standards

1.g. HOW TO CONTROL?

- Pre-market control
  - Imposition of safety requirements
  - Approval to market the product
- Post-market control
  - Conformity assessment after the product is put on the market

1.h. WHO SHOULD CONTROL?

- Conformity assessment
  - self-declaration by the manufacturer
  - quality assessment procedures supervised and controlled by a third party
  - third party certification

1.i. NEW APPROACH

- Distinction is drawn between:
  - **Essential safety requirements**
    - Imposed by harmonising legislation (regulations and directives)
  - **Design/Manufacturing specifications**
    - Set out by voluntary standards
- Safety is achieved through mandatory legislation and voluntary standards

1.j.ESSENTIAL SAFETY REQUIREMENTS

- They are safety objectives which must be met
- A directive should contain a description of the safety which products covered by it must satisfy
- It should be worded precisely enough
- Sometimes vague objectives:
  - to minimise risks
  - to reduce risks as far as possible
  - to insure temperatures do not cause burning

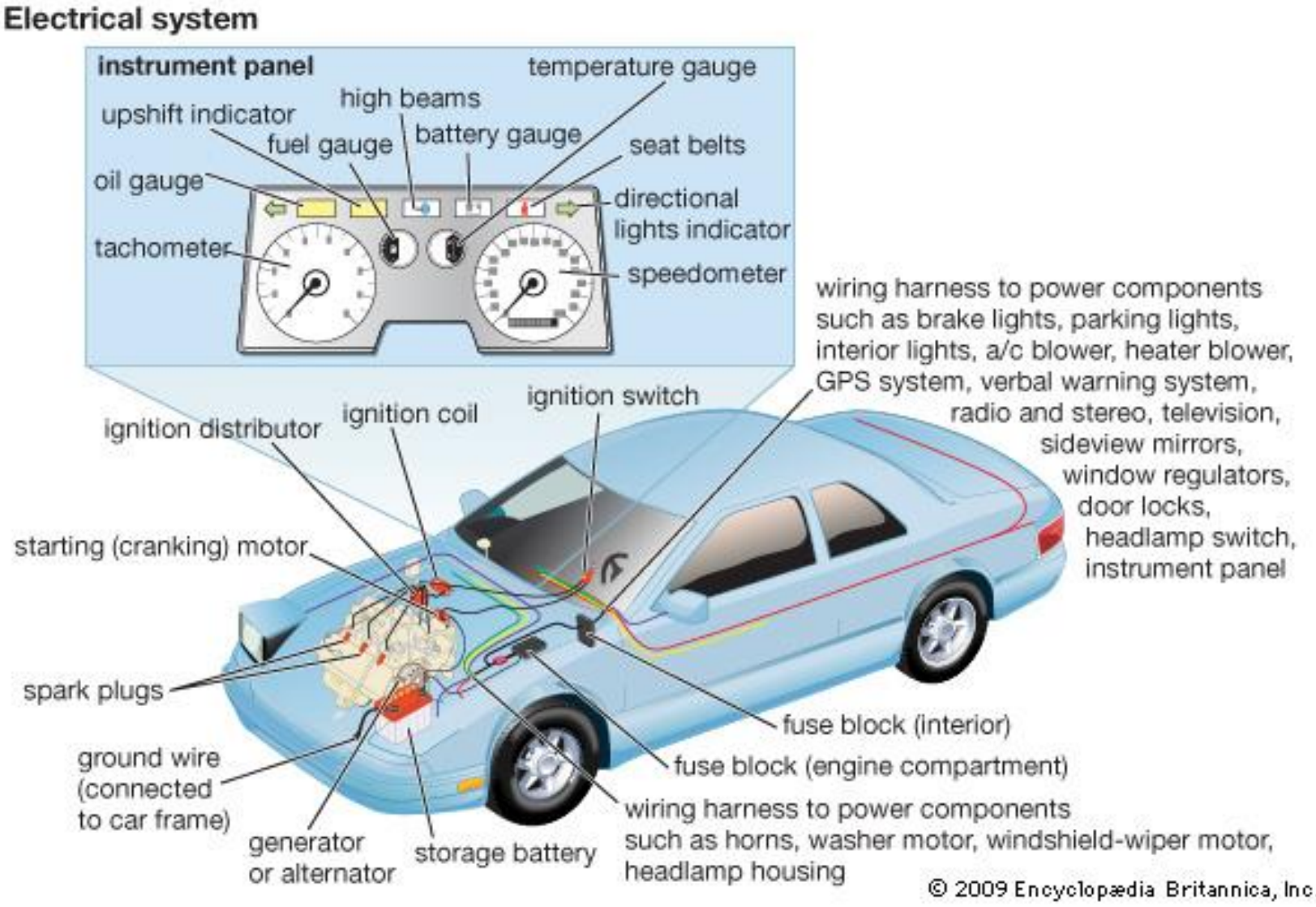
1.k. STANDARDS

- Technical specification approved by a recognised standardisation body for repeated and continuous application with which compliance is not compulsory and which is adopted by an international, regional or national standardization body and made available to the public
- Detailed technical (design and manufacturing) specifications
- Define how to reach the level of safety envisaged by essential safety requirements **in a manner acceptable to industry**
- Voluntary in nature
- Produced by professional public and independent standardisation bodies

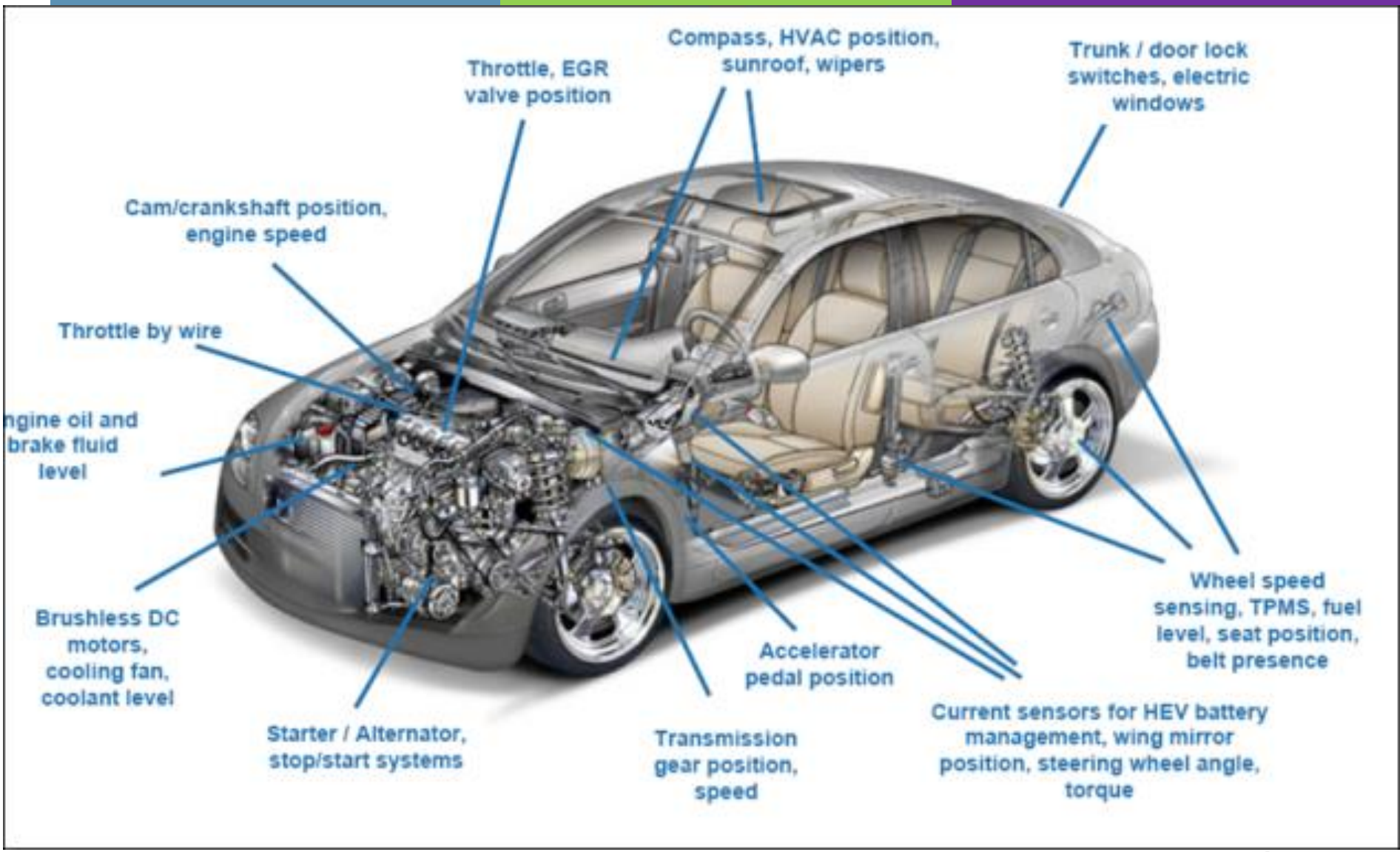
1.l. Introduction and over view – ISO 26262

- Adaptation of IEC 61508 to comply with the specific needs of E/E systems within road vehicles
- Specifies a functional safety life-cycle for automotive products
- Applies to all activities during the safety lifecycle of safety-related systems comprised of electrical, electronic, and software components
- ISO 26262 talks about disciplined methodology in engineering
- ISO 26262 DIS is going to be FDIS early next year
- ISO 26262 is not an auditable standard. By implementing this standard we are only reducing the risk.

1.m. Introduction and over view – ISO 26262



1.n. Introduction and over view – ISO 26262



1.o. Introduction and over view – ISO 26262

The Google Car is constantly predicting and updating the most likely path of every object. It's software has gone through 1.7 million miles of real life testing since 2009 and 3 million miles per day of computer simulations.

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2. Scope – ISO 26262

Functional safety is the part of the overall safety of a system or piece of equipment that depends on the system or equipment operating correctly in response to its inputs, including the safe management of likely operator errors, hardware failures and environmental changes

3. Objective – ISO 26262

- ✓ The objective of functional safety is freedom from unacceptable risk of physical injury or of damage to the health of people either directly or indirectly (through damage to property or to the environment).

- ✓ Functional safety is intrinsically end-to-end in scope in that it has to treat the function of a component or subsystem as part of the function of the whole system.

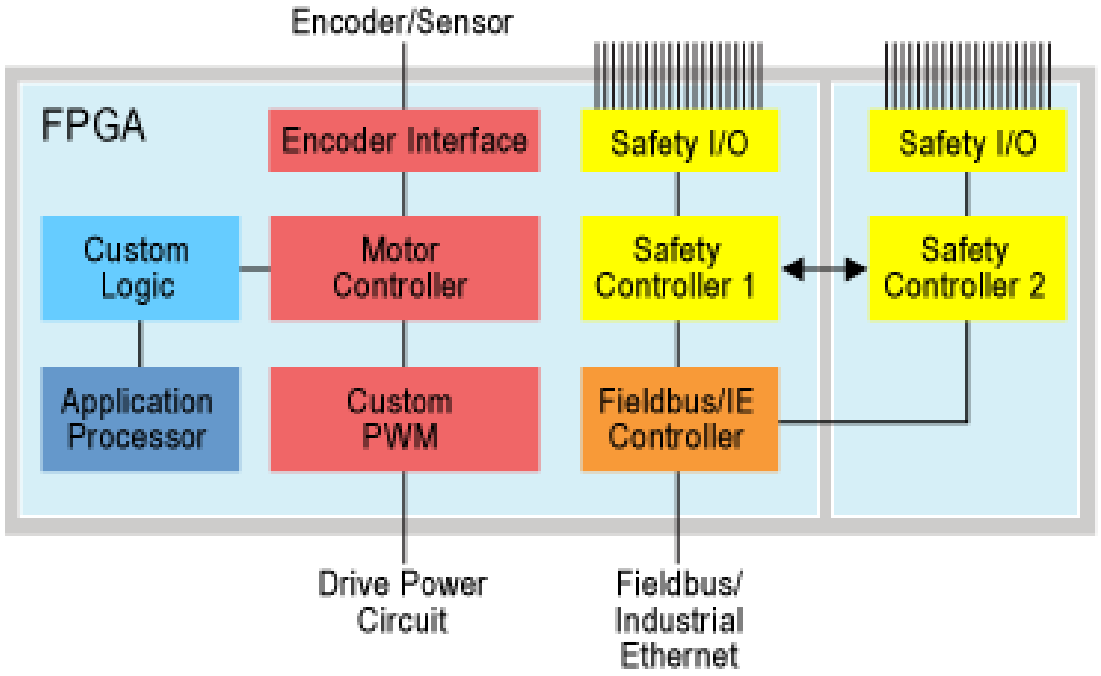
- ✓ This means that whilst functional safety standards focus on electrical, electronic, and programmable systems (E/E/PS), the end-to-end scope means that in practice functional safety methods have to extend to the non-E/E/PS parts of the system that the E/E/PS actuates, controls or monitors.

4. Purpose – ISO 26262

- Safety is a key issue of automobile development
- New functionalities and increasing content in electrical, electronics (E/E) and software requires increased focus on interface issues.
- With the increase in technological complexity, software content and mechatronic implementations there is an increase in systematic and random failures
- Applied to safety related systems that include one or more E/E systems and that are installed in series production passenger card with a maximum gross vehicle mass upto 3,500kg.
- New standard is going to be expanded to trucks also.

4. Purpose – ISO 26262

- Motorcycles will also have importance in new standard
- Trucks requirements also is applicable for bus industry too
- The new scope of standard will cover passenger cars, trucks, buses, motorcycle
- For semi conductor industries the new standard has many requirements.



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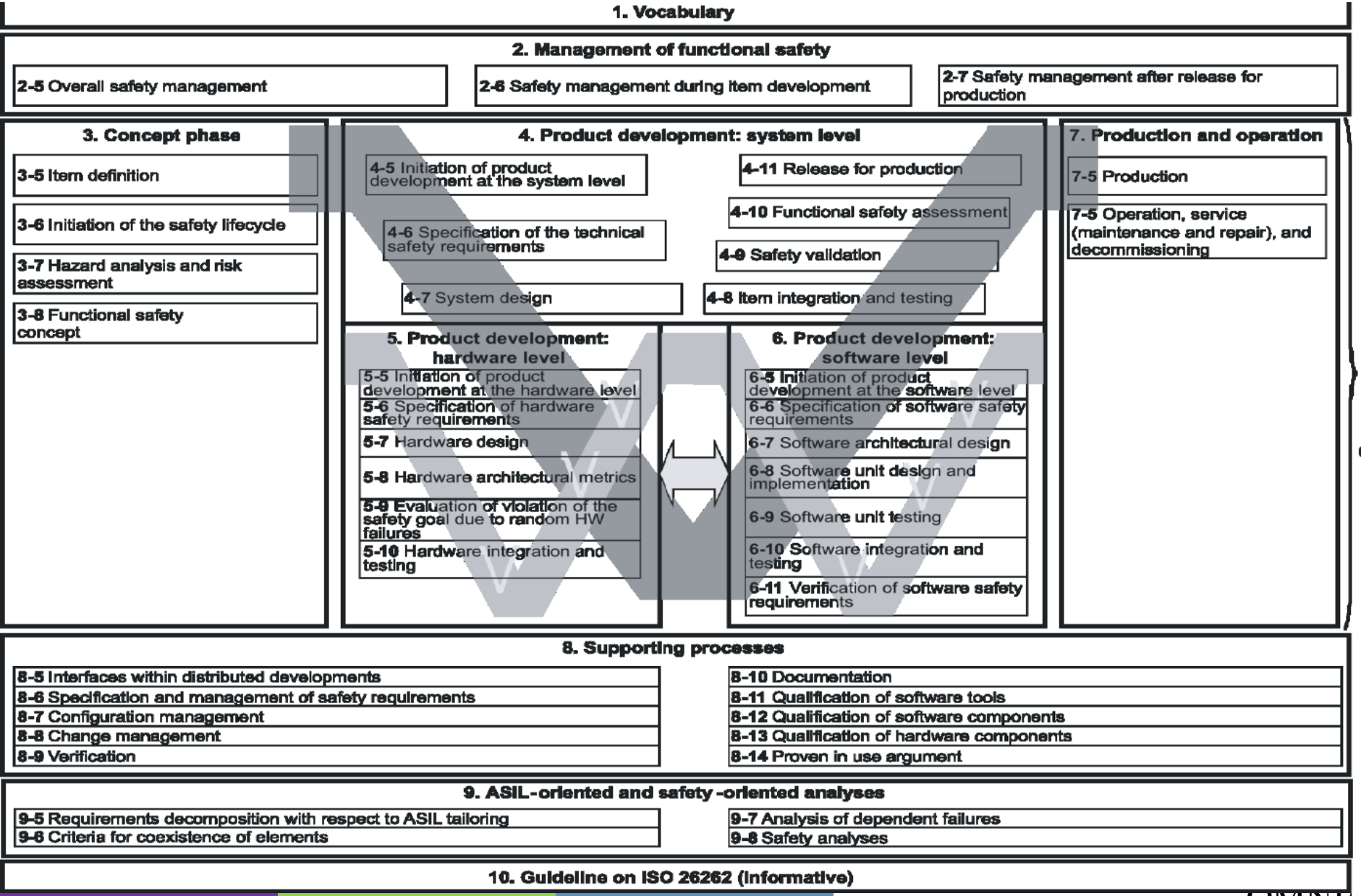
5. ISO 26262 – Framework

- Provides an automotive lifecycle that can be customized for organizations that adopt it
- Provides an automotive specific risk based approach for determining safety integrity levels (Automotive Safety Integrity Levels (ASILs)) – tier 1 to tier-n ISO 26262 can be implemented.
- From OEM product design to component level ASIL must be cascaded to child part supplier level
- Provides requirements of validation and confirmation measures to ensure a sufficient and acceptable level of safety is being achieved.
- Organization that manufacture semi conductor device can implement ISO 26262. Minimum the organization must be certified for either ISO 9001:2015 or IATF 16949.
- For organizations whose scope is design on semiconductor devices IATF cannot be obtained but ISO 9001:2015 with ISO 26262 can be implemented.

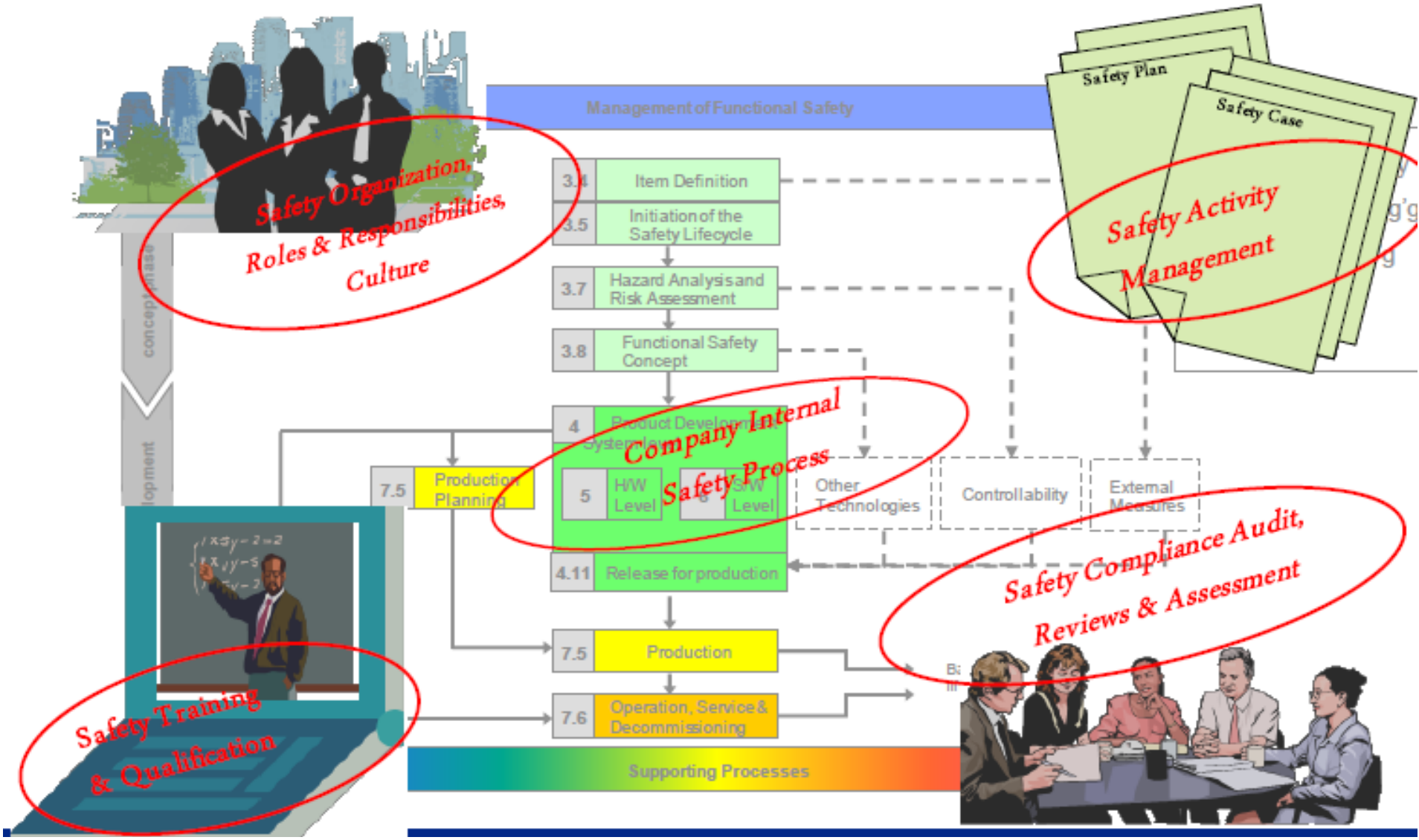
5. ISO 26262 – Framework

- Focus is on possible hazards caused by malfunctioning behaviour of E/E safety-related systems
- Failures or unintended behaviours of an item with respect to its design intent
- Includes interactions between E/E safety-related systems
- Process Framework includes the following process steps/deliverables:
- Safety plan & safety goals
- Safety case & documentation
- Bidirectional traceability
- Safety lifecycle
- Validation, verification and independent assessment
- Corresponds to automotive product lifecycle
- Development, validation, release for production vs. development, installation and commissioning, validation in IEC 61508
- Supports distributed development
- Hazard analysis corresponds to automotive use cases

6. ISO 26262 – 10 Parts



13. Management of functional safety



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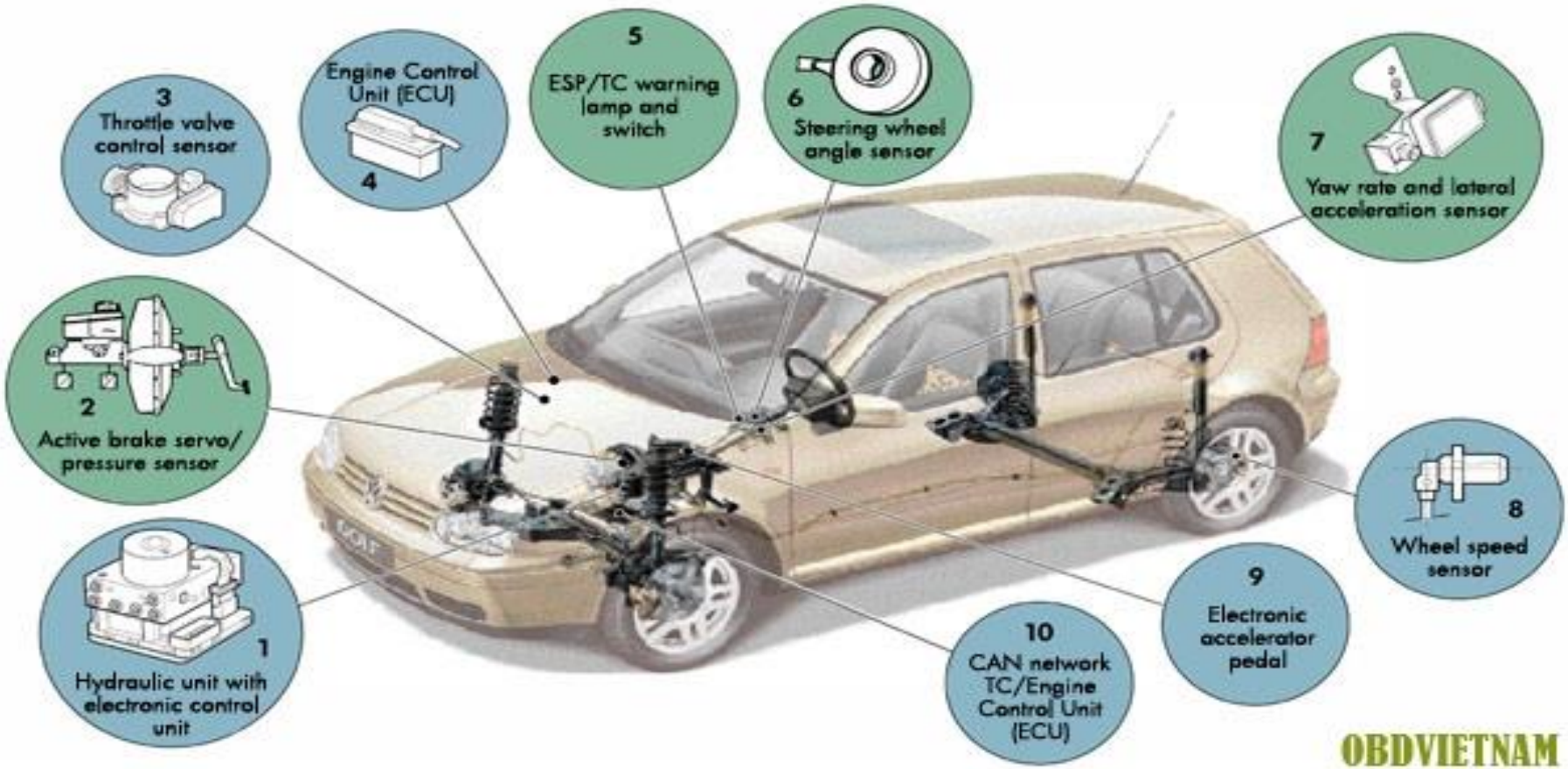
14. TYPICAL PROCESSES / DOCUMENTS REQUIREMENTS FOR ISO 26262

1) Competency And Training
2) Organizational Chart And Responsibilities
3) Hazard Analysis
4) Functional Safety Concept
5) Safety Planning And Project Planning
6) Safety Case
7) Confirmation Measures – Review , Audit And Assessments
8) After Sales Field Monitoring And Recall Processes
9) Hazard Analysis And Risk Assessment
10) Safety Goals, ASIL Determination, And Architectural Assignments
11) New Product Launch Process (Safety Systems) – System, Hardware And Software
12) Distributed Interface Agreement Development And Execution
13) Capability Analysis And Reporting Of Safety Characteristics During PPAP
14) Process Control Of Safety Characteristics In Production
15) Maintenance, Repair And End Of Life Of Product (Safety Related)
16) Specification And Management Of Safety Requirements
17) Configuration Management
18) Document Control
19) Test Plan Or Design Verification Plan And Report
20) Qualification Of Software Tool
21) Supplier Management Of Safety Related Products

Electronic Stability Program (ESP)



Thank You

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PRESENTATION - 2

Process Validation & Qualification (Technical Review Meeting)

Talk Points

- Definition - Process Validation & Qualification
- Objectives – Process validation & Qualification
- Link with APQP phases
- Sequences of Process validation.
- Methods –PV & Q
- Weld Process – PV & Q (PQR)

Definition - Verification & Validation

Process Validation means confirmation by examination and provision of objective evidence that the particular requirements for specific indented use can be consistently fulfilled

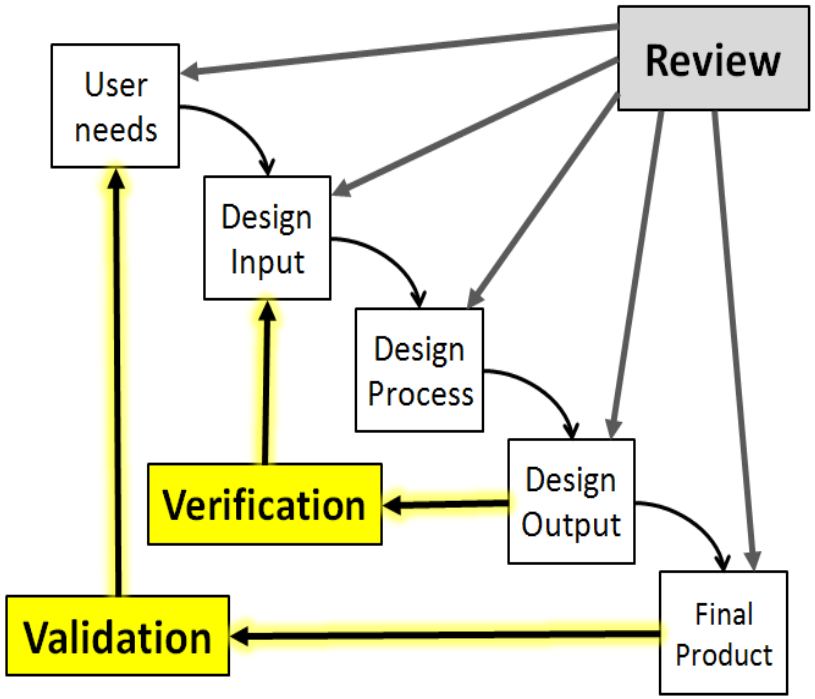
(Example – Process validation, Test method validation, Software validation) --Dynamic

Process Verification means confirmation by examination and provision of objective evidence that specified requirement fulfilled.

(Example – Design Verification & Process Verification)---- Static

Process Performance Qualification establishing confidence that process effective and reproducible.

Product Performance Qualification establishing confidence appropriate testing that finished product produced by a specified process meet all release requirements for functionality and safety



Objectives PV&Q

Process Validation & Qualification

WHY

To avoid risk in safety and product Quality
To reduce Excess variation during mass production.
To meet CSR
To Improve Efficiency
To investigate escape points
#Cost saving

WHAT

Collection & Evaluation of data from the process design stage throughout the production
Establishes scientific evidence for a process capable for consistently delivering product quality

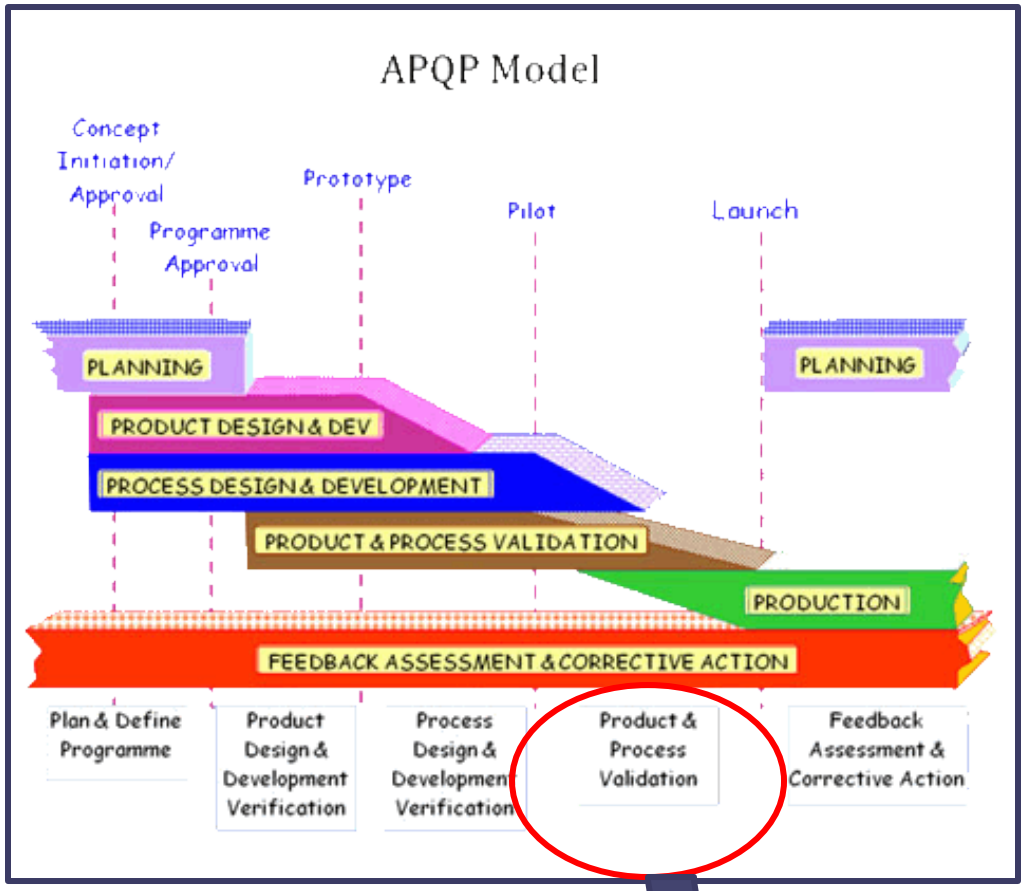
WHERE

APQP – PHASE 4
DMAIC – Improvement phase
8D – 6th Discipline

WHEN

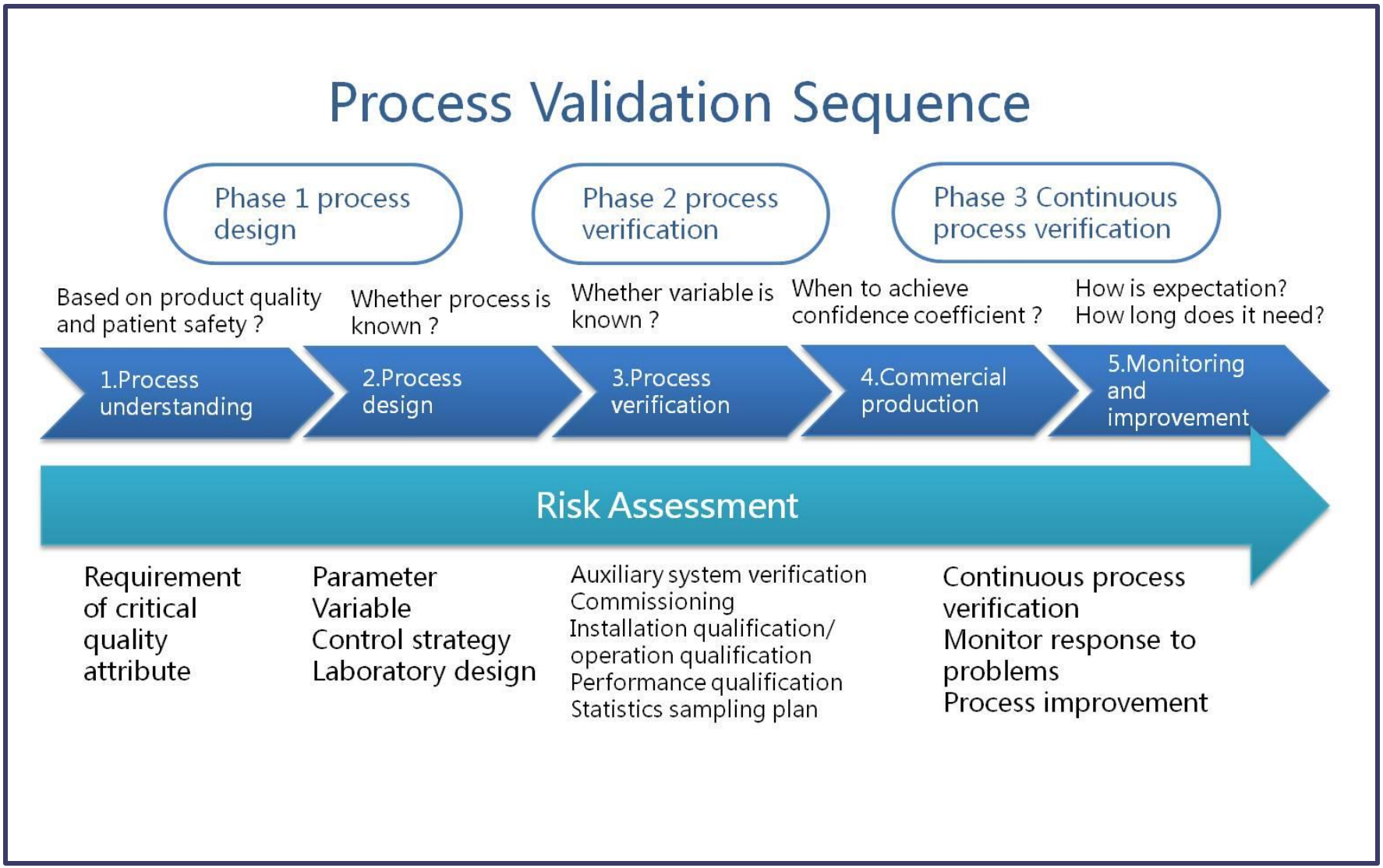
New part development
Customer complaints (external)
Increasing Internal issues.
Change Management or improvements

Link with APQP phases



Plan and Define Program	Product Design and Development Verification	Process Design and Development Verification	Product & Process Validation
• Design Goals • Reliability & Quality Goals • Preliminary Bill of Materials • Preliminary Process Flow • Preliminary Listing of Special Product & Process Characteristics • Product Assurance Plan	• Design FMEA • DFMA • Design Verification • Design Reviews • Prototype Build • Engineering Drawings • Engineering Specifications • Material Specifications • Drawing & Specification Changes • New Equip., Tooling & Facilities Reqmts. • Special Product & Process Characteristics • Prototype Control Plan • Gages/Testing Equip. Requirements	• Packaging Standards • Product/Process Quality System Review • Process Flow Chart • Floor Plan Layout • Characteristics Matrix • Process FMEA • Pre-Launch Control Plan • Process Instructions • Measurement Systems Analysis Plan • Preliminary Process Capability Study Plan • Packaging Specifications	Production Trial Run • Measurement Systems Evaluation • Preliminary Process Capability Study • Production Part Approval • Production Validation Testing • Packaging Evaluation • Production Control Plan • Quality Planning Sign-Off

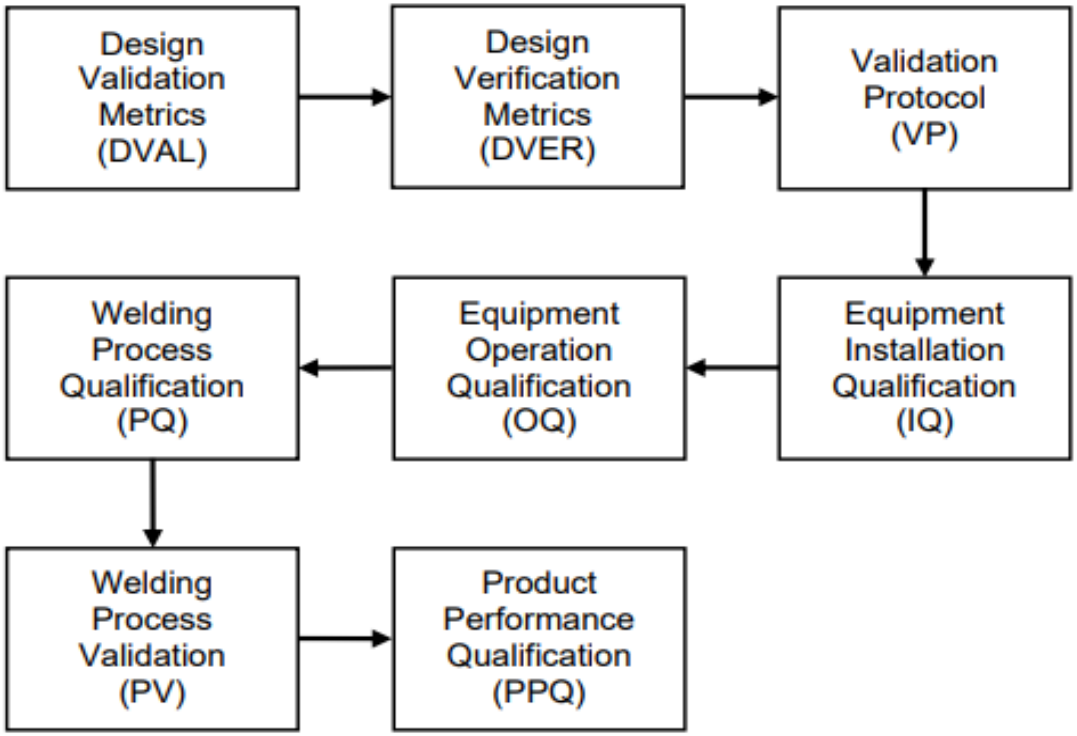
Sequence of PV



Components-PV&Q

Validation Components

The validation process consists of eight main components, beginning with the design process and ending with the product performance validation.



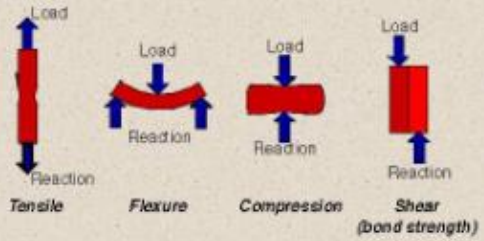
DVAL – Spot Weld

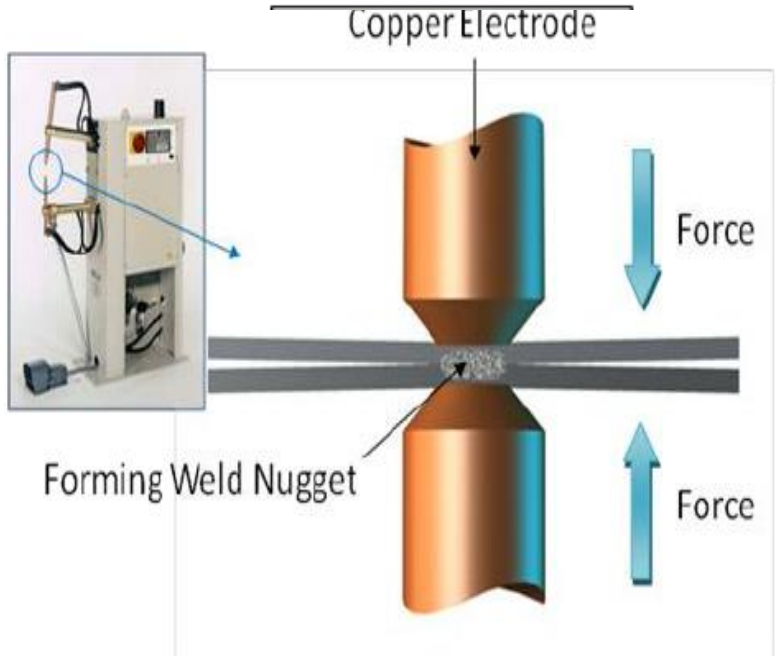
Design Validation (DVAL)

DVAL process begins with selecting the design validation metrics[6]. Design validation metrics should represent the stresses subjected on the final product by the end user. For example, a rechargeable power tool battery pack contains multiple parallel gap spot welds connecting individual battery cells together using nickel or nickel plated steel connecting straps to form a complete battery pack.

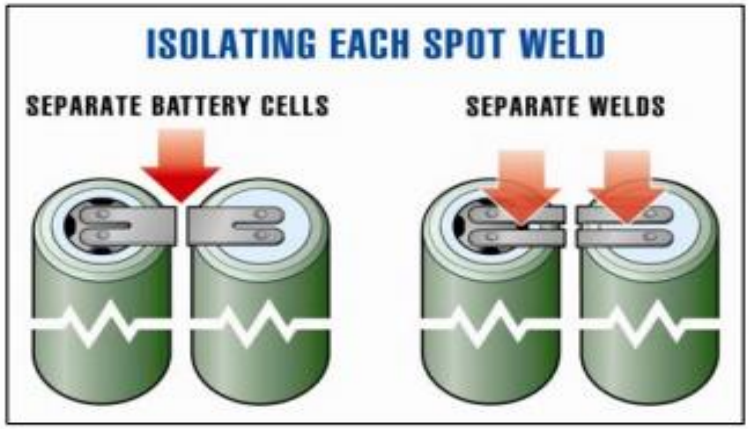
Destructive Examinations (DE)

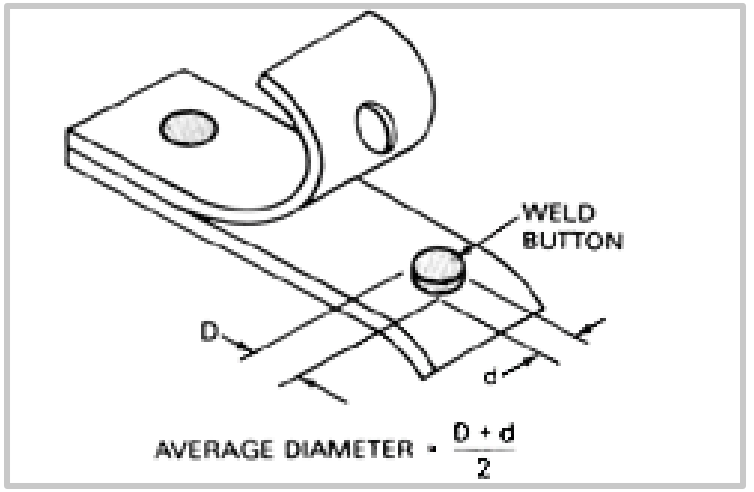
- Tensile test,
- Bend test,
- Fillet test,
- Hardness test,
- Impact test,
- Peel test (for spot welds),
- Tensile shear test (for spot welds),
- Pressure test.





DVER- Spot weld





Carefully bend one cut section 90°, protecting the two spot welds with a metal bar so the two welds will not be stressed during the bending process. See Figure-4. Peel testing each weld separately provides quantitative weld strength information for optimizing and verifying each weld compared to peel testing both welds simultaneously. The PV validation step will determine the minimum 90° peel test magnitude necessary to ensure a successful resistance welding process validation.

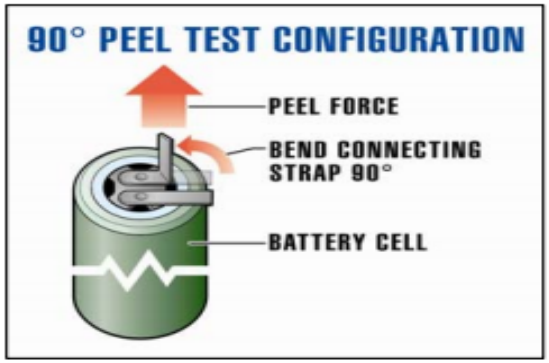
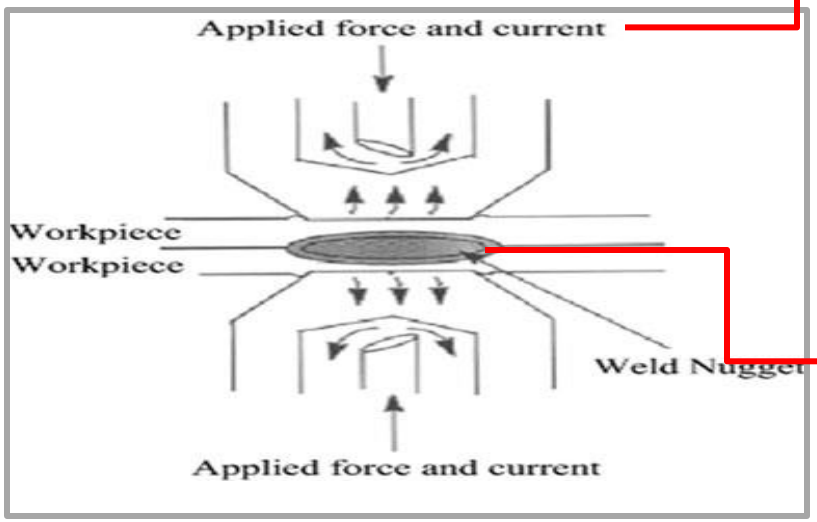


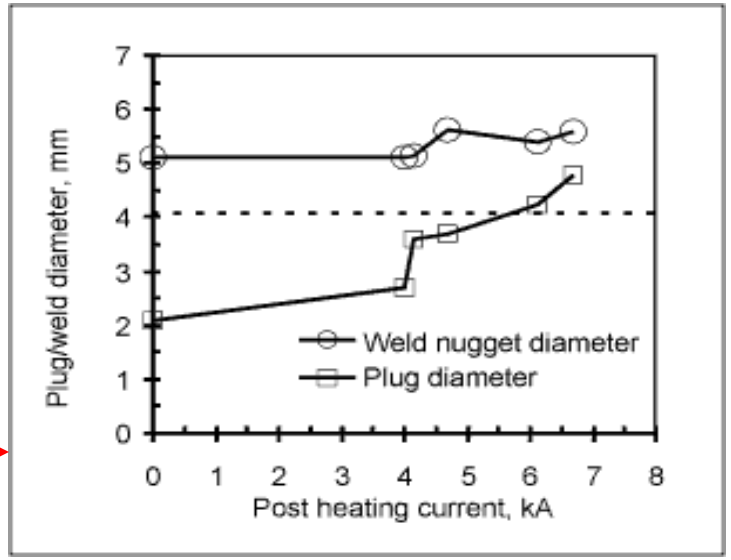
Figure-4

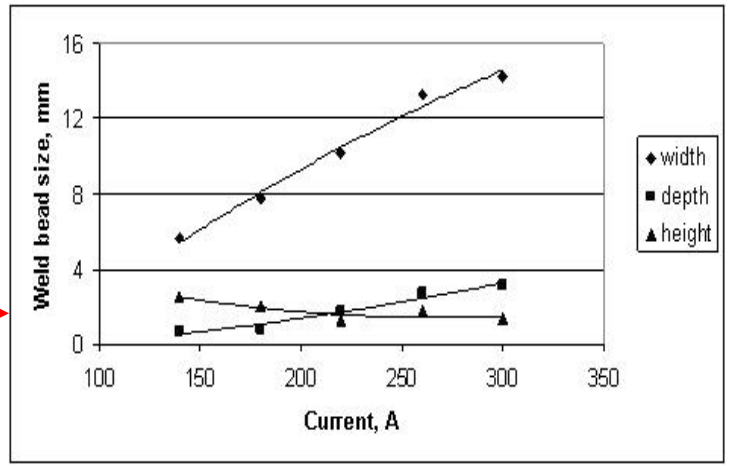
IQ & OQ

Operating Qualification (OQ)

OQ establishes manufacturing procedures and records for equipment calibration, cleaning, operation, and maintenance. The OQ also includes operator training procedures and records. Identify important welding equipment parameters that can affect the weld. The OQ does NOT qualify or validate the welding process. For a resistance weld, the most important welding equipment parameters are weld energy, time, and force. Verify that the entire welding system produces the programmed welding parameter magnitudes over their projected operating ranges on a repeatable basis and append the data to the OQ procedure. In the automotive sensor industry, the OQ may also involve operating an automatic welding station without weld energy or parts for a 24-hour "dry run".





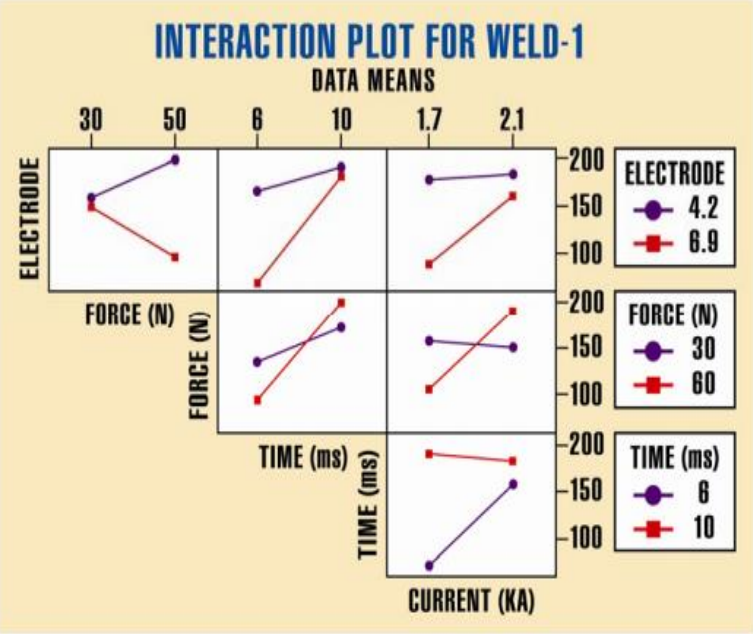


PQ

Process Qualification (PQ)

PQ involves discovering the important welding parameters, optimizing the welding parameters, choosing the lot run and sample sizes, and conducting a series of confirmation runs.

Discovery – Conduct a Taguchi L9, L12, or L18 Design of Experiment (DoE) to find out which welding parameters affect the chosen DVER weld verification metrics[8]. The Taguchi DoE method quickly identifies the most important welding parameters with minimal parts.



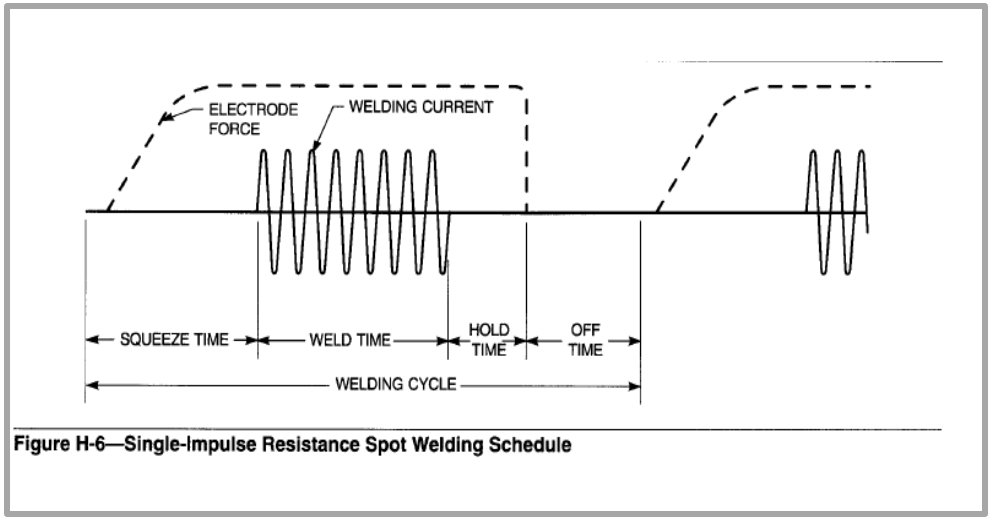


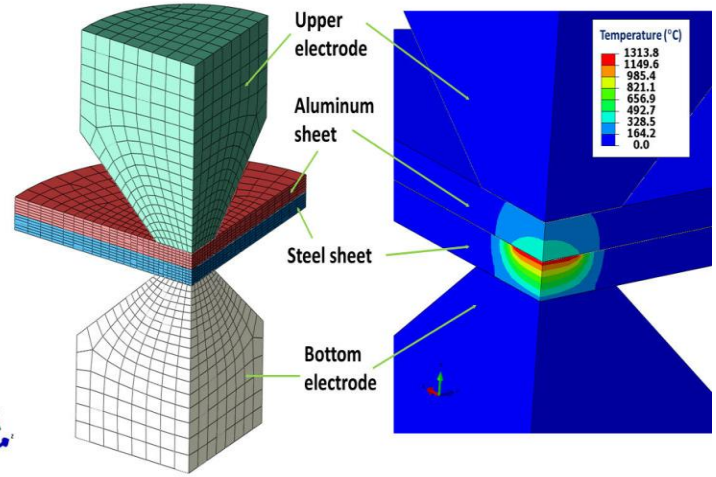
Figure H-6—Single-Impulse Resistance Spot Welding Schedule

Microsoft Excel 97-2003 Worksheet

Microsoft Excel 97-2003 Worksheet

Process Validation (PV)

PV establishes that the welding process consistently produces a part or product meeting its predetermined specification. PV involves correlating the PQ data with the PV data. In the case of the battery pack example, look for correlations between the PQ weld voltage, current, force, displacement, and the 90° peel test data with the PV data, comprising battery pack electrical parameters and tumbling cycles.



	area	maximum axis	minimum axis	output	peel test diameter	weld quality	result
weld 78	31.0	6.7	5.5	good	5.65	setup	match
weld 81	42.0	7.3	6.3	good	5.5	setup	match
weld 82	38.0	7.6	6.0	good	5.5	setup	match
weld 86	24.0	6.0	4.5	good	5.5	setup	match
weld 88	22.0	5.8	4.3	good	4.45	nominal	match
weld 90	21.0	5.9	4.0	good	4.0	minimum	match
weld 92	21.0	5.7	4.3	good	3.65	minimum	match
weld 94	19.0	5.6	4.0	bad	3.5	less than	match
weld 96	19.0	5.7	3.8	bad	2.24	less than	match
weld 98	17.0	5.6	3.8	bad	2.2	less than	match
weld 100	15.0	5.2	3.8	bad	0	stick	match
weld 102	14.0	5.2	3.8	bad	0	stick	match
weld 104	0.0	0.0	0.0	bad	0	stick	match

PRESENTATION - 3

Conformance of Products and Processes

INTRODUCTION

Clause 4.4.1.1 – Conformance of Products ad Processes (New IATF Requirement)

The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced , to all applicable customer, statutory, and regulatory requirements.

Its an overall statement telling us that's the GOAL of QMS and its processes.

SCOPE - 4.4.1.1

This clause is applicable to all products and processes carried out by the Customer, its Outsourced organization and Service Organization . This include service parts and all outsourced products and processes.

Applicable Clauses

Clause 4.4.1.1 – Conformance of Products ad Processes

1) 4.3.2 - Customer Specific Requirements.

2) 5.3.1 - Organizational roles, responsibilities, and authorities.

3) 7.1.5.2.1 - Calibration & Verification records.

4) 7.1.5.3.1 - Internal Laboratory.

5) 7.2.1 - Competence.

6) 7.2.2 – Competence (On the Job Training).

7) 7.2.3 – Internal Auditor competency.

8) 7.2.4 – Second Party auditor competency

9) 7.3.1 - Awareness

Applicable Clauses

Clause 4.4.1.1 – Conformance of Products ad Processes

10) 8.3.3.1 - Product design input
11) 8.3.3.2 - Manufacturing Process design input
12) 8.3.3.3 - Special Characteristics
13) 8.3.4.2 - Design and development Validation
14) 8.3.5.1 - Design and development Outputs
15) 8.3.5.2 - Manufacturing Process design Output
16) 8.3.6.1 - Design and Development changes.
17) 8.4.2.1 - Type and Extent of control
18) 8.4.2.2 - Statutory and Regulatory requirements

Applicable Clauses

Clause 4.4.1.1 – Conformance of Products ad Processes

19) 8.4.2.4 - Supplier Monitoring
20) 8.4.3.1 - Information for External providers
21) 8.5.1.1 - Control Plan
22) 8.5.2.1 - Identification and Traceability.
23) 8.5.6.1 – Control of changes
24) 8.6.5 – Statutory and regulatory conformity

Implementation of this requirement - Example

CUSTOMER REQUIREMENT – MINIMUM 70HRS. OF SALT SPRAY TEST TO BE MET, WITH NO STRUCTURAL DETRIMENTAL EFFECT TO NORMALLY VISIBLE SURFACES.

This requirement is implemented in the organization through capturing in Process Flow Diagram, Process Failure Mode Effects Analysis & Control Plan and check sheet .

OMNEX

4.4.1.1 – An Umbrella Clause

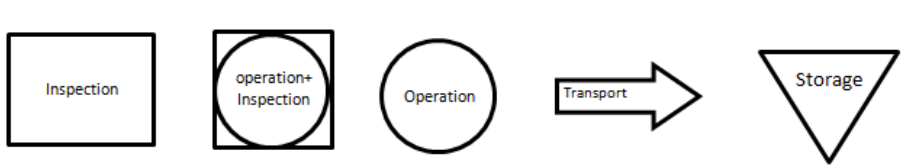
There are around 24 IATF requirements that can be linked to Clause 4.4.1.1 .Therefore this clause can be called as an Umbrella Clause.

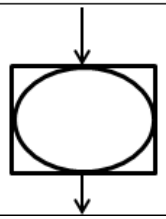
OMNEX

Implementation of this requirement in PFD

Requirement Captured in PFD

Microsoft Office Excel Worksheet



Sl. No.	Operation no.	Process / Operation Description	Incoming Source of variation	Process Flow	Product Characteristics	Process Characteristics
9	90	ED Coating	1. Unclean Surface. 2. Chemichal composition not as per ED Coating requirement.		70 Hours of Salt Spray test to be met.	1. Curing Temp - 60 °c 2. Curing time - 30 Minutes

OMNEX

Implementation of this requirement in PFMEA

Requirement Captured in PFMEA

Microsoft Office Excel Worksheet

PFMEA

Process no.	Process Name	Product Requirements	Potential Failure mode		SEV	CLAS	Potential Cause(s) / Mechanism(s) of Failure	Current Process Prevention	OCCU	Current Process Detection	DET	RPN	Recommended Action (s)	Responsibility & Target completio	Action results	SEV	OCC	DET	RPN
9	ED Coating	70 Hours of Salt Spray test to be met.	Part Corroded before 70 hours of Salt Spray.less than	**Next operation :** Part rejection **Subsequent operation**: No clearence for despatch **Operator safety:** Nil **Customer:** Issue at customer paintshop **End user** Part corrosion when pait	8		Coating Thickness less than 60 microns	Nil	3	Inprocess Inspection	5	120							

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Implementation of this requirement in CP

Microsoft Office Excel Worksheet

Requirement Captured in CP

CONTROL PLAN

Part / Process Number	Process Name/Operation Description	Machine,Device,Jigs,Tools for MFG	Product	Process	Special Char. Class	Product/Process Specification / tolerance	Evaluation / Measurement Technique	Size	Frequency	Control methods	Reaction Plan / Corrective action	Resp.
90	ED Coating	Plant 1 , ED Coating Tank 1 - 7	70 Hours of Salt Spray test to be met.		SC	70 +/- 10 Microns	DFT Meter	50%	Every lot	Inprocess Inspection Check sheer	Stop the process and Inform Coating supervisor and	Quality inspector

OMNEX

Implementation of this requirement in Check sheet

Requirement Captured in Check sheet

Microsoft Office
I 97-2003 Worksl

DATE- 22.06.16	ED COATING - INPROCESS REPORT									
CUSTOMER NAME		Mishra Industries								
PART NAME		Plate								
PART NUMBER		xyz								
REV NUMBER		1								
SL#	PARAMETER	SPEC	TOL	ACTUALS					METHOD OF INSPECTION	OK / NOT OK
I	IDENTIFICATION #			1	2	3	4	5	VISUAL	OK
1	ED Coating Thickness	70	± 10	70.2	68.9	74.2	78.1	76.2	DFT	OK

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Conclusion

Clause 4.4.1.1 – Conformance of Products ad Processes

This clause is generic and can be linked to a number of other IATF requirements which are related to applicable customer legal requirements. The IATF interprets this to mean that the organization takes a proactive approach to assess and address risk and move away from inspection.

PRESENTATION - 4

Introduction to Statistical Process Control

R Ganesh Kumar

OMNEX

DRIVING WORLDWIDE BUSINESS EXCELLENCE

Introduction to Continual Improvement and Statistical Process Control

- To prosper in today's economic climate, we – automotive manufacturers, suppliers and dealer organizations – must be dedicated to continual improvement.
- We must constantly seek more **efficient ways to produce products and services**. These products and services must continue to improve in value.
- We must focus upon our customers, **both internal and external, and make customer satisfaction a primary business goal**.
- To accomplish this, everyone in our organizations must be **committed to improvement and to the use of effective methods**. These basic statistical methods helps to make our efforts at improvement more effective.
- **Different levels of understanding are needed** to perform different tasks. The basic statistical methods addressed in this manual include those associated with **statistical process control and process capability analysis.**
- **IATF goal – To continually improve, Defect Prevention & reduce variations**
- IATF requirement (Clause: Monitoring & measurement of manufacturing processes 9.1.1.1)

What is SPC

Statistical Process Control (SPC). The term has multiple meanings, but in most companies it is considered to include basic data collection; analysis through such tools as frequency distributions, Pareto principle, Ishikawa (fish bone) diagram, Shewhart control chart, etc.; and application of the concept of process capability. Advanced tools, such as design of experiments and analysis of variance, are a part of statistical methods but are not normally considered to be a part of statistical process control.

The use of statistical techniques such as control charts to analyze a process or its output so as to take appropriate actions to achieve and maintain a state of statistical control and to improve the process capability.

Note: ISO 11462-1 Guidelines for Implementation of Statistical Process Control (SPC)

Continual Improvement and Statistical Process Control – 6 Points

- 1) Gathering data and using statistical methods to interpret them are not ends in themselves. It is very easy to become technique experts without realizing any improvements. **Increased knowledge** should become a basis for action.
- 2) **Measurement systems** are critical to proper data analysis and they should be well understood before process data are collected. When such systems lack statistical control or their variation accounts for a substantial portion of the total variation in process data, inappropriate decisions may be made
- 3) The basic concept of **studying variation and using statistical signals to improve performance** can be applied to any area. Such areas can be on the shop floor or in the office. Some examples are machines (performance characteristics), bookkeeping (error rates), gross sales, waste analysis (scrap rates), computer systems (performance characteristics) and materials management (transit times).
- 4) SPC stands for Statistical Process Control. Historically, statistical methods have been routinely applied to parts, rather than processes. **Application of statistical techniques to control output (such as parts) should be only the first step. Until the processes that generate the output become the focus of our efforts, the full power of these methods** to improve quality, increase productivity and reduce cost may not be fully realized.
- 5) **Real understanding of the subject involves deeper contact with process control situations**. The study of actual cases from the reader's own job location or from similar activities would be an important supplement to the text. There is no substitute for hands-on experience.
- 6) Need for practitioners **to increase their knowledge of statistical methods and theory**. Readers are encouraged to pursue formal statistical education. Where the reader's processes and application of statistical methods have advanced beyond the material covered here, the reader is also encouraged to consult with persons who have the proper knowledge and practice in statistical theory as to the appropriateness of other techniques. In any event, the procedures used must satisfy the customer's requirements.

Data Types

Variable Data

- Quantitative data, where measurements are used for analysis. Examples include the diameter of a bearing journal in millimeters, the closing effort of a door in Newtons, the concentration of electrolyte in percent, or the torque of a fastener in Newton-meters. and R , and s , median and range, and individuals and moving range control charts are used for variables data.

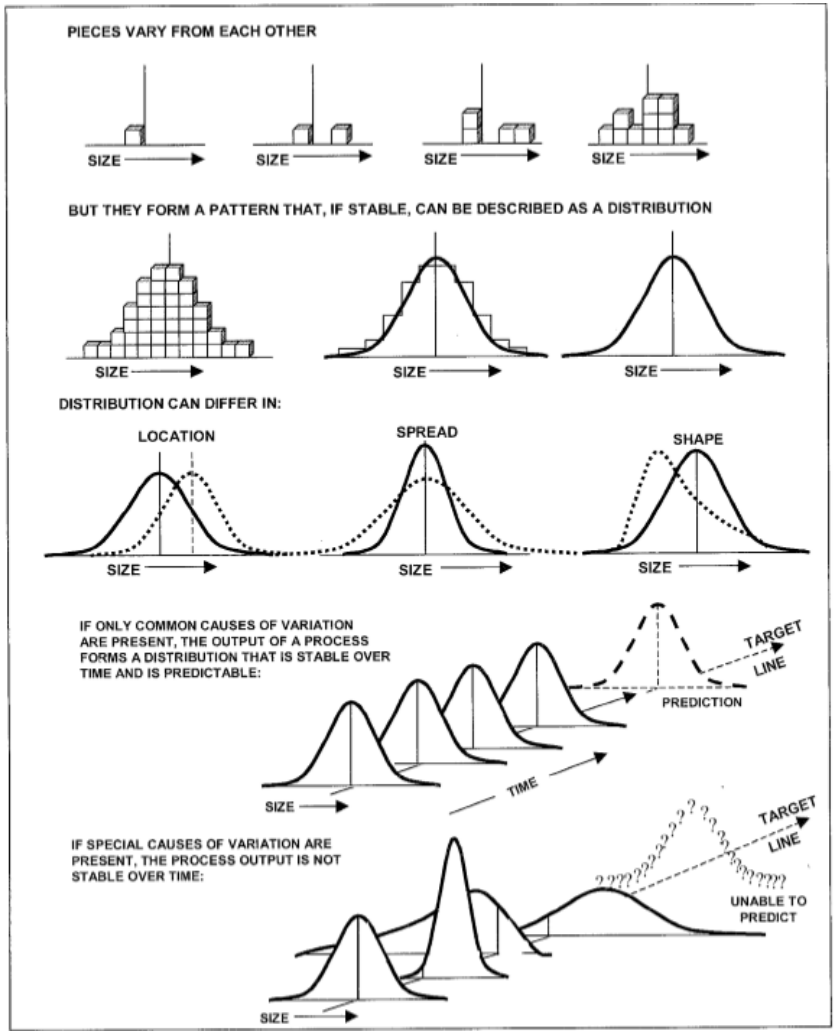
Attribute Data

- Attributes data have discrete values and they can be counted for recording and analysis. With attribute analysis the data are separated into distinct categories (conforming/nonconforming, pass/fail, go/no-go, present/absent, low/medium/high). Examples include the presence of a required label, the continuity of an electrical circuit, visual analysis of a painted surface, or errors in a typed document.

Distribution study

While individual measured values may all be different, as a group they tend to form a pattern that can be described as a distribution which can be characterized by:

- **Location** (typical or "central" value)
- **Spread** (span or "width" of values from smallest to largest)
- **Shape** (the pattern of variation whether it is symmetrical, skewed, etc.)



Variations

Common cause & Special cause Variation

- **Common causes** refer to the many sources of variation that consistently acting on the process. Common causes within a process produce a stable and repeatable distribution over time. This is called "in a state of statistical control. “in statistical control,” or sometimes just "in control." Common causes yield a stable system of chance causes. If only common causes of variation are present and do not change, the output of a process is predictable.

- **Special causes** (often called assignable causes) refer to any factors causing variation that affect only some of the process output. They are often intermittent and unpredictable. Special causes are signalled by one or more points beyond the control limits or non-random patterns of points within the control limits. Unless all the special causes of variation are identified and acted upon, they may continue to affect the process output in unpredictable ways. If special causes of variation are present, the process output will not be stable over time.

LOCAL ACTIONS AND ACTIONS ON THE SYSTEM

Local Actions
- Are usually required to eliminate special causes of variation
- Can usually be taken by people close to the process
- Can correct typically about 15% of process problems

Actions on the System
- Are usually required to reduce the variation due to common causes
- Almost always require management action for correction
- Are needed to correct typically about 85% of process problems

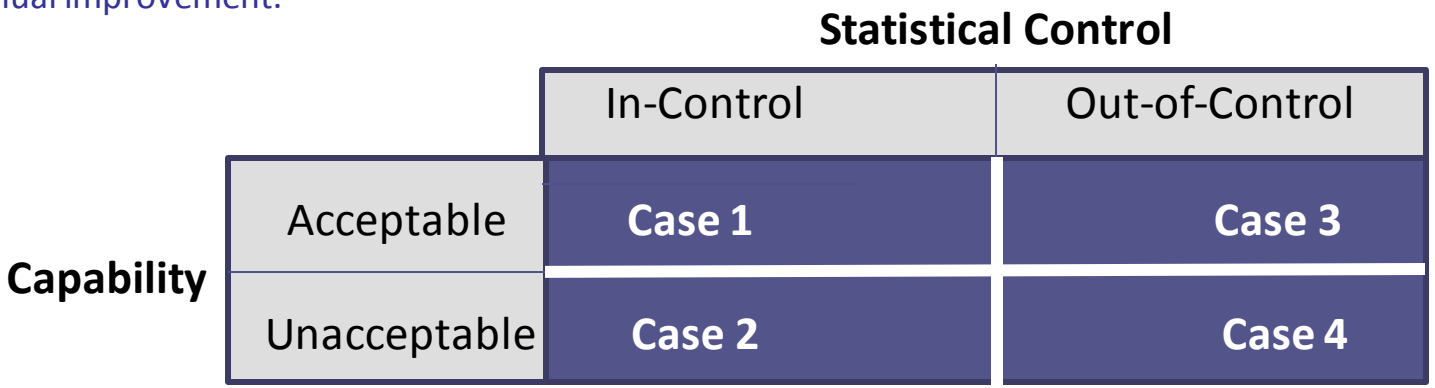
Control vs. Capability

- When discussing process capability, two somewhat contrasting concepts need to be considered:
- Process capability
- Process performance

Process capability is determined by the variation that comes from common causes. It generally represents the best performance of the process itself. This is demonstrated when the process is being operated in a state of statistical control regardless of the specifications.

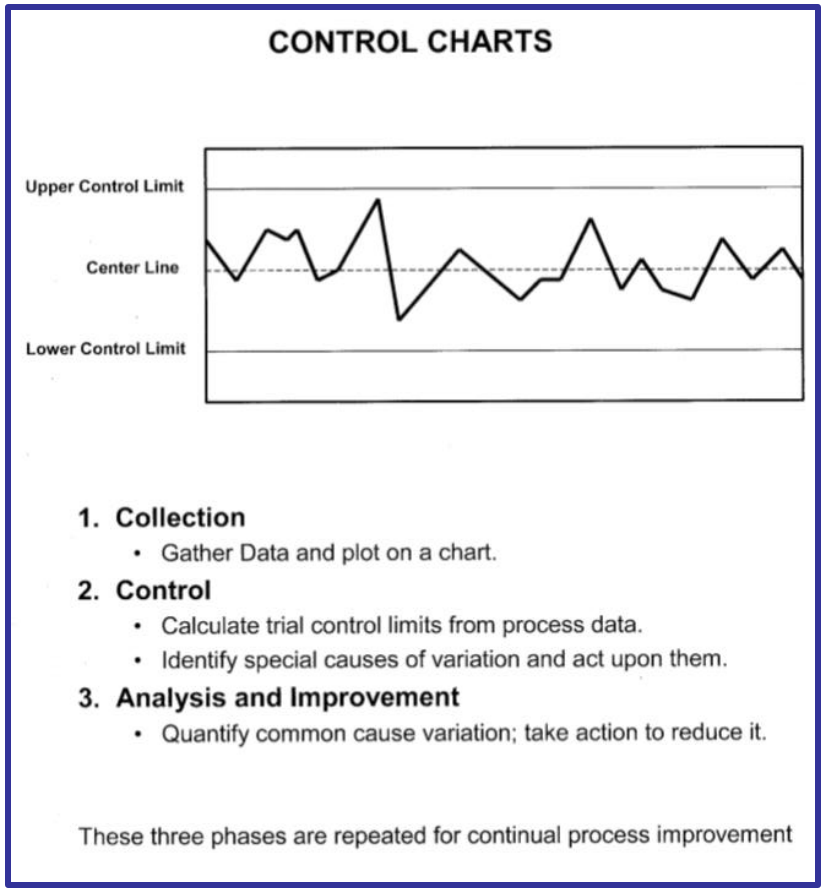
Customers, internal or external, are however more typically concerned with the process performance; that is, the overall output of the process and how it relates to their requirements (defined by specifications), irrespective of the process variation.

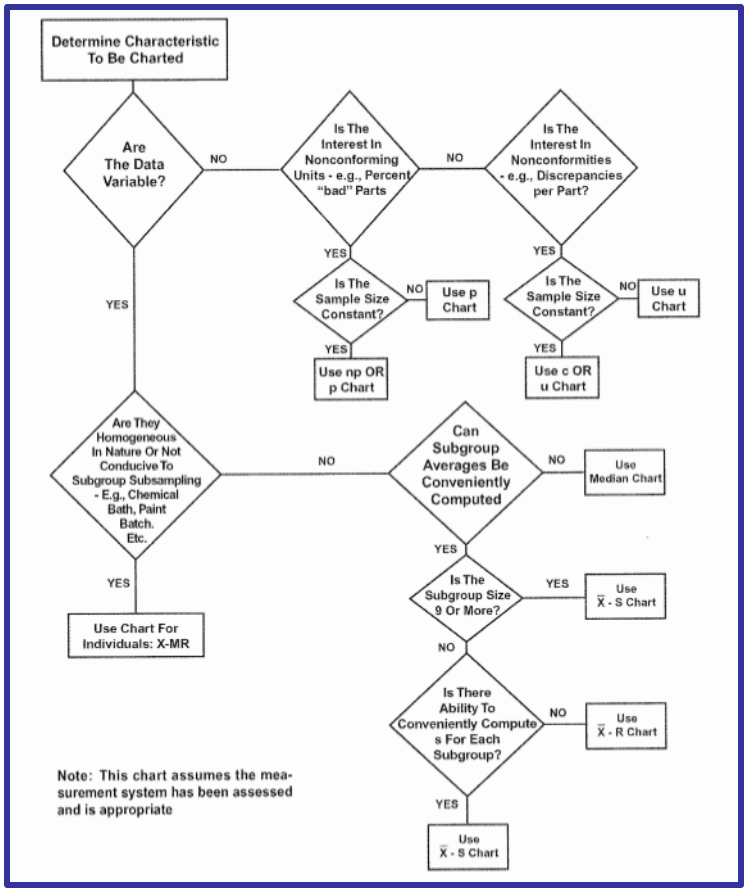
The process must first be brought into statistical control by detecting and acting upon special causes of variation. Then its performance is predictable, and its capability to meet customer expectations can be assessed. This is a basis for continual improvement.



Control Charts Application

- Control charts can be used to monitor or evaluate a process.





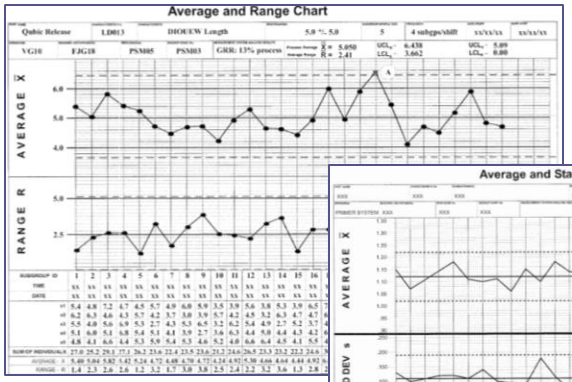
Variable Control Chart

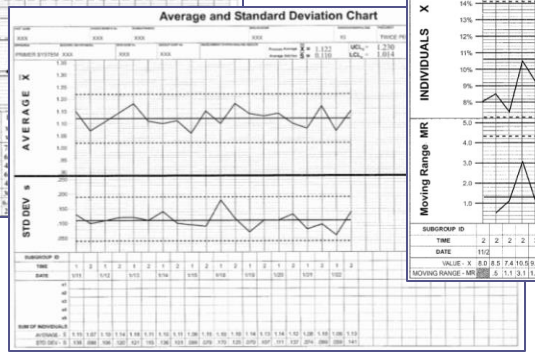
If the data derived from the process are of a continuous nature (e.g., diameter, length) then a variables type of chart would be used. Within each chart type there are several chart combinations that can be used to further evaluate the process. Some of the more common chart types, Average(X bar) and Range (R) charts, Individuals (I) chart, Moving Range (MR) chart, etc., belong to the variables chart family.

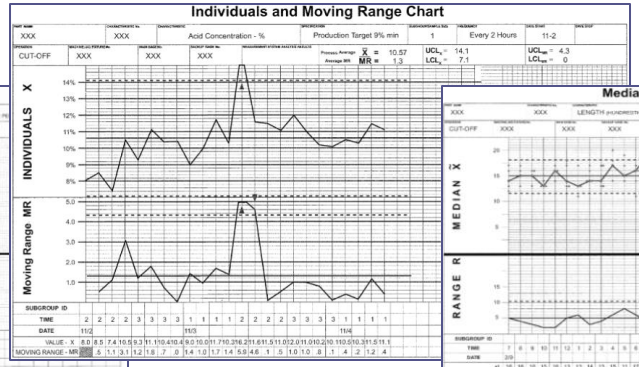
Outcome Example	Control Chart Examples
• Shaft O.D. (inches) • Hole distance from reference surface (mm) • Circuit resistance (ohms) • Railcar transit time (hours) • Engineering change processing time (hours)	$\bar{X}$ for the Average of the Measurement R Chart for the Ranges of the Measurement

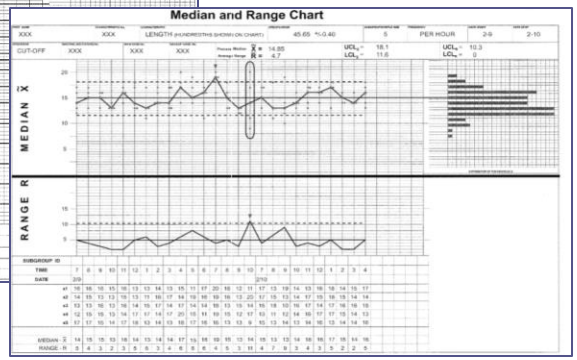
	Centerline	Control Limits	
$\bar{X}$ and R Charts	$CL_{\bar{X}} = \bar{\bar{X}}$	$UCL_{\bar{X}} = \bar{\bar{X}} + A_2\bar{R}$	$LCL_{\bar{X}} = \bar{\bar{X}} - A_2\bar{R}$
	$CL_R = \bar{R}$	$UCL_R = D_4\bar{R}$	$LCL_R = D_3\bar{R}$
$\bar{X}$ and s Charts	$CL_{\bar{X}} = \bar{\bar{X}}$	$UCL_{\bar{X}} = \bar{\bar{X}} + A_3\bar{S}$	$LCL_{\bar{X}} = \bar{\bar{X}} - A_3\bar{S}$
	$CL_s = \bar{s}$	$UCL_s = B_4\bar{s}$	$LCL_s = B_3\bar{s}$

	Centerline	Control Limits	
Median Charts	$CL_{\tilde{X}} = \bar{\tilde{X}}$	$UCL_{\tilde{X}} = \bar{\tilde{X}} + \tilde{A}_2\bar{R}$	$LCL_{\tilde{X}} = \bar{\tilde{X}} - \tilde{A}_2\bar{R}$
	$CL_R = \bar{R}$	$UCL_R = D_4\bar{R}$	$LCL_R = D_3\bar{R}$
Charts for Individuals	$CL_X = \bar{X}$	$UCL_X = \bar{X} + E_2\bar{R}$	$LCL_X = \bar{X} - E_2\bar{R}$
	$CL_R = \bar{R}$	$UCL_R = D_4\bar{R}$	$LCL_R = D_3\bar{R}$









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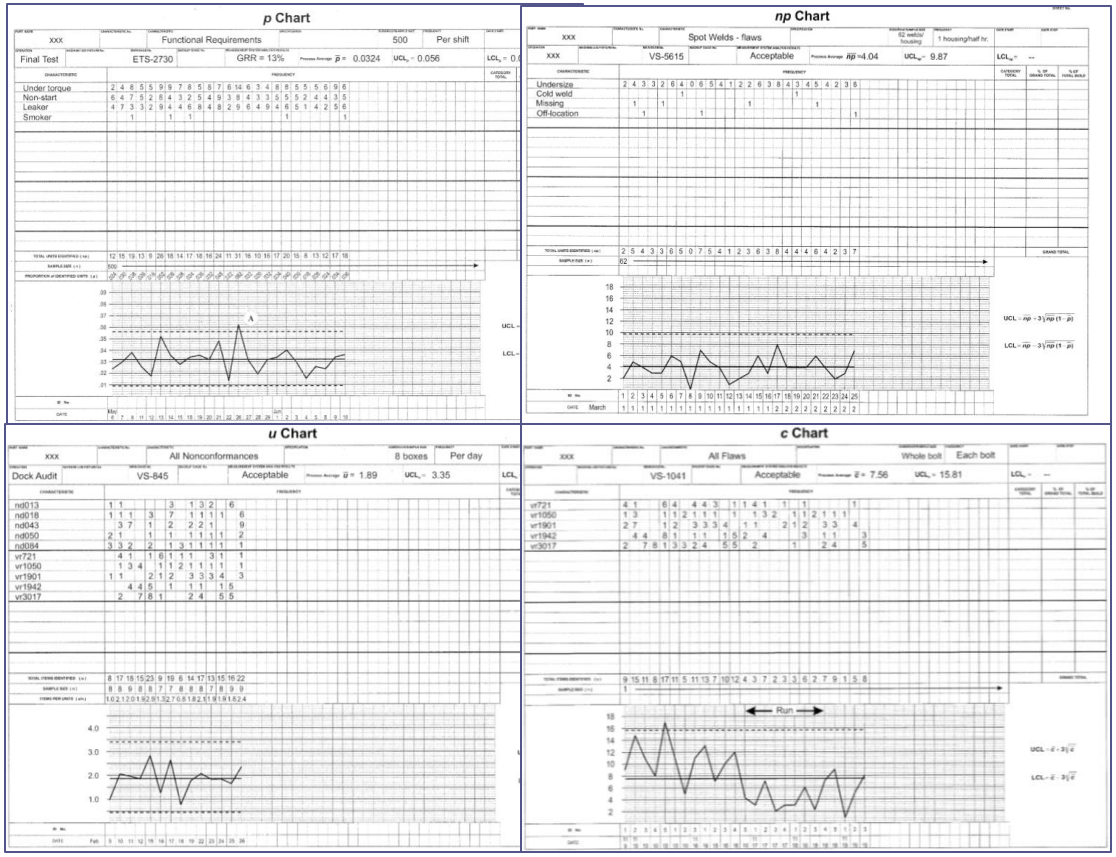
Attribute Control Chart

If the data derived from the process are of a discrete nature (e.g., go/no-go, acceptable/not acceptable) then an attributes type of chart would be used. Charts based on count or percent data (e.g., p, np, c, u) belong to the attributes chart family.

Outcome Example	Control Chart Examples
Vehicle does not leak Lamp lights does not light Hole diameter undersized or oversized (evaluated using a go/nogo gage) Shipment to dealer correct or incorrect	*p* Chart for Proportion of Units Nonconforming *np* Chart for Number of Units Nonconforming
Bubbles in a windshield Paint imperfections on door Errors on an invoice	*c* Chart for Number of Nonconformances per Unit *u* Chart for Number of Nonconformities per Unit

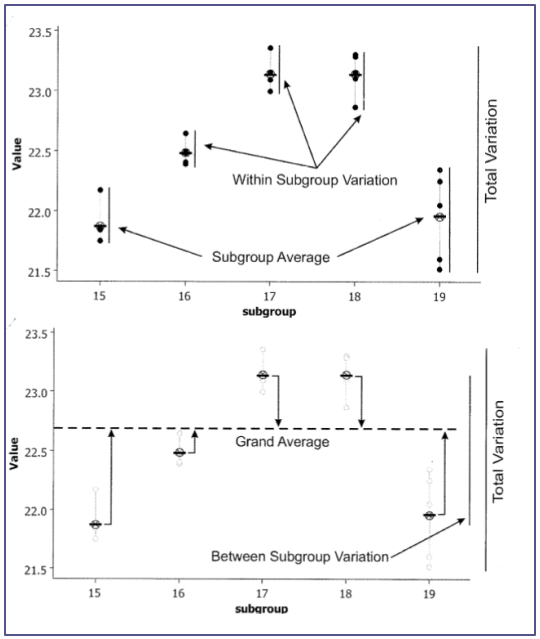


Attributes Charts

	Centerline	Control Limits	
		Samples not necessarily of constant size	
***p* chart** for proportions of units in a category	$CL_p = \bar{p}$	$UCL_{p_i} = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$	$LCL_{p_i} = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n_i}}$
		If the sample size is constant (n)	
		$UCL_p = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$	$LCL_p = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$
***np* chart** for number/rate of units in a category	$CL_{np} = \overline{np}$	$UCL_{np} = \overline{np} + 3\sqrt{\overline{np}(1-\frac{\overline{np}}{n})} = \overline{np} + 3\sqrt{\overline{np}(1-\bar{p})}$	$LCL_{np} = \overline{np} - 3\sqrt{\overline{np}(1-\frac{\overline{np}}{n})} = \overline{np} - 3\sqrt{\overline{np}(1-\bar{p})}$
c chart for number of incidences in one or more categories	$CL_c = \bar{c}$	$UCL_c = \bar{c} + 3\sqrt{\bar{c}}$	$LCL_c = \bar{c} - 3\sqrt{\bar{c}}$
***u* chart** for number of incidences per unit in one or more categories	$CL_u = \bar{u}$	Samples not necessarily of constant size	
		$UCL_{u_i} = \bar{u} + \frac{3\sqrt{\bar{u}}}{\sqrt{n_i}} = \bar{u} + 3\sqrt{\frac{\bar{u}}{n_i}}$	$LCL_{u_i} = \bar{u} - \frac{3\sqrt{\bar{u}}}{\sqrt{n_i}} = \bar{u} - 3\sqrt{\frac{\bar{u}}{n_i}}$
		Using average sample size	
		$UCL_u = \bar{u} + \frac{3\sqrt{\bar{u}}}{\sqrt{\bar{n}}} = \bar{u} + 3\sqrt{\frac{\bar{u}}{\bar{n}}}$	$LCL_u = \bar{u} - \frac{3\sqrt{\bar{u}}}{\sqrt{\bar{n}}} = \bar{u} - 3\sqrt{\frac{\bar{u}}{\bar{n}}}$
		If the sample size is constant (n)	
		$UCL_u = \bar{u} + \frac{3\sqrt{\bar{u}}}{\sqrt{n}} = \bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	$LCL_u = \bar{u} - \frac{3\sqrt{\bar{u}}}{\sqrt{n}} = \bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$

Control Chart Mechanics

- **Subgroup Frequency** — The subgroups are taken sequentially in time, e.g., once every 15 minutes or twice per shift. The goal is to detect changes in the process over time. Subgroups should be collected often enough, and at appropriate times so that they can reflect the potential opportunities for change. The potential causes of change could be due to work-shift differences, relief operators, warm-up trends, material lots, etc. Number of Subgroups — The number of subgroups needed to establish control limits should satisfy the following criterion: enough subgroups should be gathered to assure that the major sources of variation which can affect the process have had an opportunity to appear. Generally, 25 or more subgroups containing about 100 or more individual readings give a good test for stability and, if stable, good estimates of the process location and spread. This number of subgroups ensures that the effect of any extreme values in the range or standard deviation will be minimized.
- **Sampling Scheme** — If the special causes affecting the process can occur unpredictably, the appropriate sampling scheme is a random (or probability) sample. A random sample is one in which every sample point (rational subgroup) has the same chance (probability) of being selected. A random sample is systematic and planned; that is, all sample points are determined before any data are collected. For special causes that are known to occur at specific times or events, the sampling scheme should utilize this knowledge. Haphazard sampling or convenience sampling not based on the expected occurrence of a specific special cause should be avoided since this type of sampling provides a false sense of security; it can lead to a biased result and consequently a possible erroneous decision.
- Whichever sampling scheme is used all sample points should be determined before any data are collected.



Special Cause Criteria

- There are several criteria for identifying special causes. The most commonly used are discussed above. The decision as to which criteria to use depends on the process being studied/controlled.
- Summary of Typical Special Cause
- **Criteria** 1: 1 point more than 3 standard deviations 21 from center line
- **Criteria** 2: 7 points in a row on same side of center line
- **Criteria** 3: 6 points in a row, all increasing or all decreasing
- **Criteria** 4: 14 points in a row, alternating up and down
- **Criteria** 5: 2 out of 3 points > 2 standard deviations from center line (same side)
- **Criteria** 6: 4 out of 5 points > 1 standard deviation from center line (same side)
- **Criteria** 7: 15 points in a row within 1 standard deviation of center line (either side)
- **Criteria** 8: 8 points in a row > 1 standard deviation from center line (either side)

Process Capability Index

- Cp: This is a capability index. It compares the process capability to the maximum allowable variation as indicated by the tolerance. This index provides a measure of how well the process will satisfy the variability requirements. Cp is not impacted by the process location. This index can be calculated only for two-sided (bilateral) tolerances.
- Cpk: This is a capability index. It takes the process location as well as the capability into account. For bilateral tolerances Cpk will always be less than or equal to Cp. Cpk ≤ Cp Cpk will be equal to Cp only if the process is centered. Cpk is calculated as the as minimum of CPU or CPL.

- Cpk and Cp should always be evaluated and analyzed together. A Cp value significantly greater than the corresponding Cpk indicates an opportunity for improvement by centering the process.

$$C_p = \frac{USL - LSL}{6\sigma_C} = \frac{USL - LSL}{6\left(\bar{R}/d_2\right)}$$

$$CPU = \frac{USL - \bar{\bar{X}}}{3\sigma_C} = \frac{USL - \bar{\bar{X}}}{3\left(\bar{R}/d_2\right)}$$

$$CPL = \frac{\bar{\bar{X}} - LSL}{3\sigma_C} = \frac{\bar{\bar{X}} - LSL}{3\left(\bar{R}/d_2\right)}$$

- Pp: This is a performance index. It compares the process performance to the maximum allowable variation as indicated by the tolerance. This index provides a measure of how well the process will satisfy the variability requirements. Pp is not impacted by the process location.
- Ppk: This is a performance index. It takes the process location as well as the performance into account. For bilateral tolerances Ppk will always be less than or equal to PP. Ppk will be equal to Pp only if the process is centered. Ppk ≤ Pp

$$P_p = \frac{USL - LSL}{6\sigma_p} = \frac{USL - LSL}{6s}$$

$$PPU = \frac{USL - \bar{\bar{X}}}{3\sigma_p} = \frac{USL - \bar{\bar{X}}}{3s}$$

$$PPL = \frac{\bar{\bar{X}} - LSL}{3\sigma_p} = \frac{\bar{\bar{X}} - LSL}{3s}$$

Application

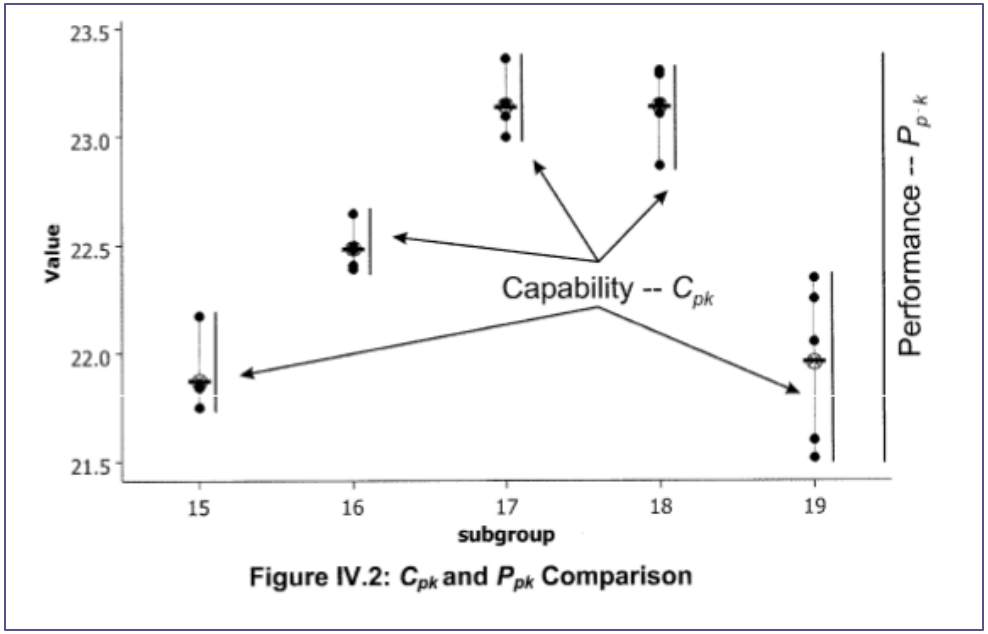
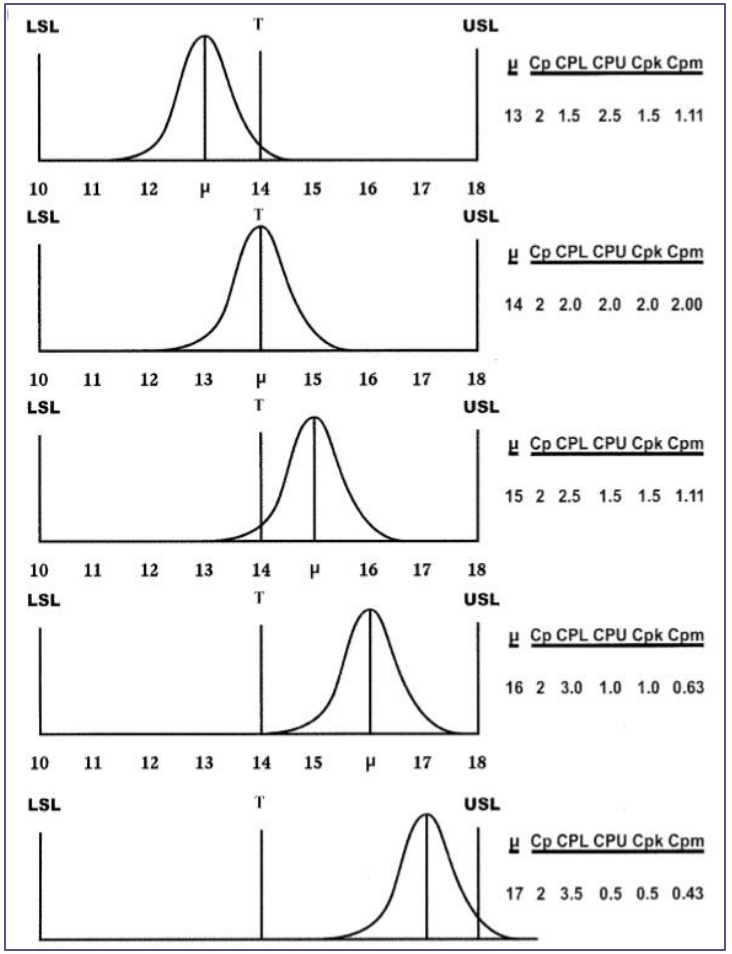


Figure IV.2: C_{pk} and P_{pk} Comparison



PRESENTATION - 5

Integrating CSR With QMS

What is CSR?

Customer Specific Requirement

Interpretation of or supplemental requirements linked to specific clause(s) of this automotive QMS standard.

Customer Requirement

All the requirement specified by the customer (e.g. technical, commercial, product and manufacturing process related requirements, general terms and conditions, customer specific requirements, etc.)

Introduction

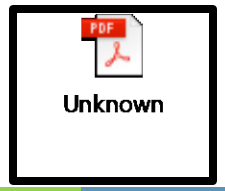
4.3.2 Customer – Specific Requirement (New requirement)

Customer-specific requirement shall be evaluated and included in the scope of the organization's quality management system.

This mean that the supplier would need some sort of process to evaluate each of their customer's customer specific requirements and determine exactly how it applies to their organization's QMS , as applicable.

CSR Matrix?

Customer Specification Requirements			
Sl No	**IATF 16949 Clause No:**	**Topics**	**Customer Ford India (Ford Spec Requ – IATF 16949:2016)**
	4	**CONTEXT OF THE ORGANIZATION**	
	4.1	**UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT**	*No Ford customer specific requirement for this section*
	4.2	**UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES**	*No Ford customer specific requirement for this section*
	4.3	**DETERMINING THE SCOPE OF THE QMS**	*Evidence of IATF 16949 Certification Verification.* *Organization shall record evidence of their certification to IATF 16949 in GSDB online available through Ford Supplier Portal.* *Notification of IATF 16949 Registration Status change.*
	4.3.1	Determining the scope of Quality management system - Supplemental	*No Ford customer specific requirement for this section*
	4.3.2	Customer Specific Requirements	*No Ford customer specific requirement for this section*
	4.4	**QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES**	*No Ford customer specific requirement for this section*
	4.4.1	**Quality Management System and its processes**	*No Ford customer specific requirement for this section*
	4.4.1.1	Conformance of product and processes	*No Ford customer specific requirement for this section*

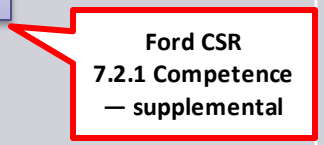


Implementation of CSR into QMS -Example

IAFT Requirement - 7.2.1 Competence- Supplemental	Ford Requirement - 7.2.1 Competence- Supplemental
The Organization shall establish and maintain a documented process(es) for identifying training needs including (see section 7.3.1) and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks shall be qualified , as required , with particular attention to the satisfaction of customer requirements.	Training shall include the appropriate Ford System. Ford training opportunities are available through Ford supplier learning institute https://fsp.covisint.com log into ford supplier portal and then go to the ford supplier learning institute (FSLI) application. Additional training is available through https://www.lean.ford.com/cqdc/

Implementation of CSR into QMS -Example

Input	Job Resp	Activity	Out Put	Document generated
Skill Matrix	Dep HOD	Start → Capture the skill matrix of the operators from the Head of department	Training requirement	
Training requirement	Dep HOD	Determine the training need for the operator for next level of skill	Training requirement sheet	
Training requirement sheet	HR	Provide training to operator that include the appropriate Ford System → Stop	Trained operator as per the requirement	Ford technical plan Doc No: HR/TP/FR/007



Implementation of CSR into QMS -Example

Ford Technical Training Plan			DOC: HR/TP/FR/007
PRODUCT: TIME FORECAST: TRAINER:	VERSION:	REVISION:	PRODUCT CHANGE #

TO BE COMPLETED BY THE QUALITY CONTROL DEPARTMENT:

TECHNICIANS TO BE TRAINED:	PROPOSED DATE:	ALTERNATE DATE	MEDIUM

TRAINING CONTENT:

* **NEW FEATURES:**
* **CORRECTED BUGS:**
* **NEW BUGS:**
* **SERVICE AND INSTALLATION ISSUES:**

Customer specific requirement

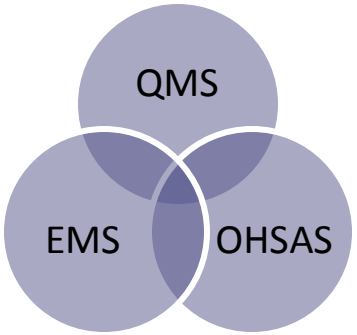
Customer Specific requirement is included in the scope of QMS through which it is integrated into the processes of the organization thereby ensures conformance of its product and services.

PRESENTATION - 6

Integrated Management System

What is it?

- QMS + EMS + OHSMS + EnMS + FSMS + ISMS + etc
- Enables an organisation to work as a single unit with unified objectives.



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Why is it required ?

- Annex SL :
  - 5. Leadership
  - 5.1 Leadership and commitment
  - Top management shall demonstrate leadership and commitment with respect to the XXX management system by
    - **ensuring the integration of the XXX management system requirements into the organizations business processes**
- **To ensure achievement of intended outcomes**

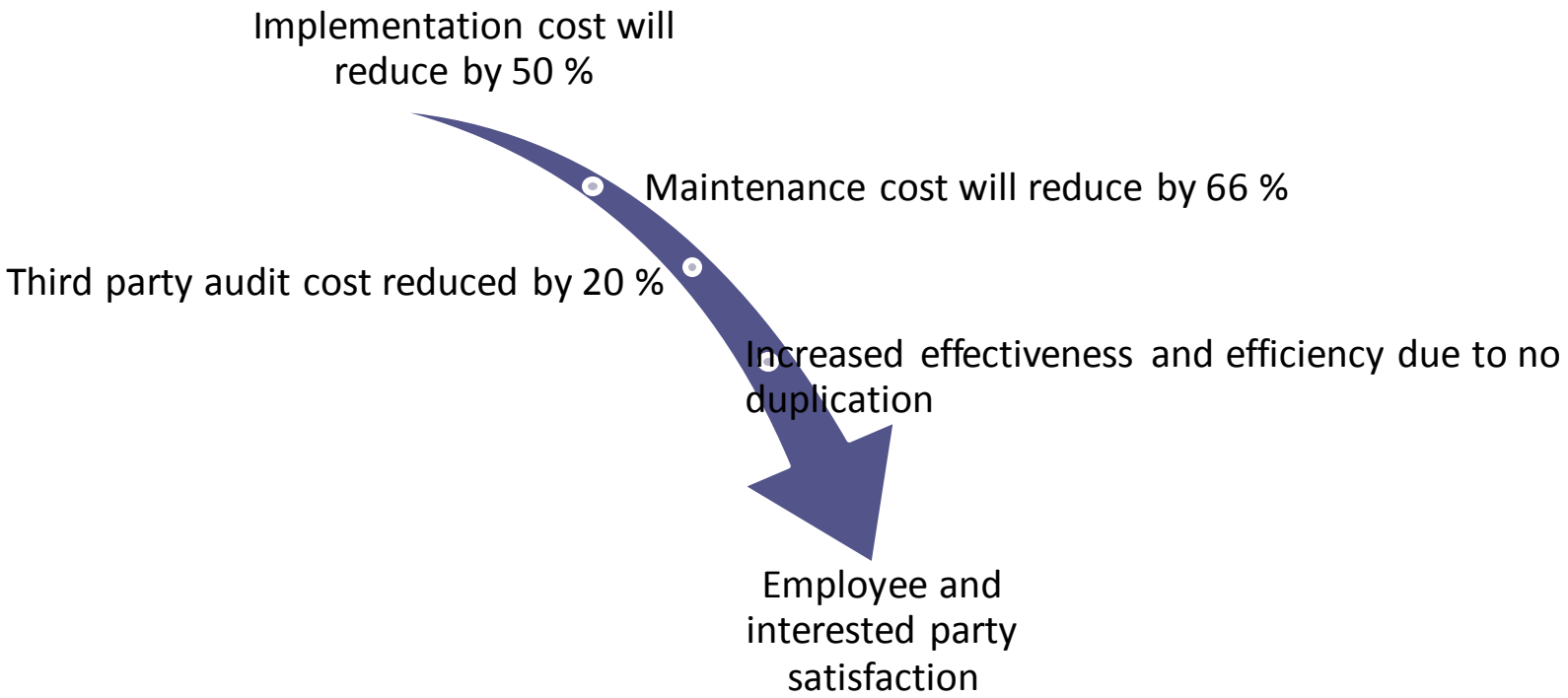
OMNEX

Drivers

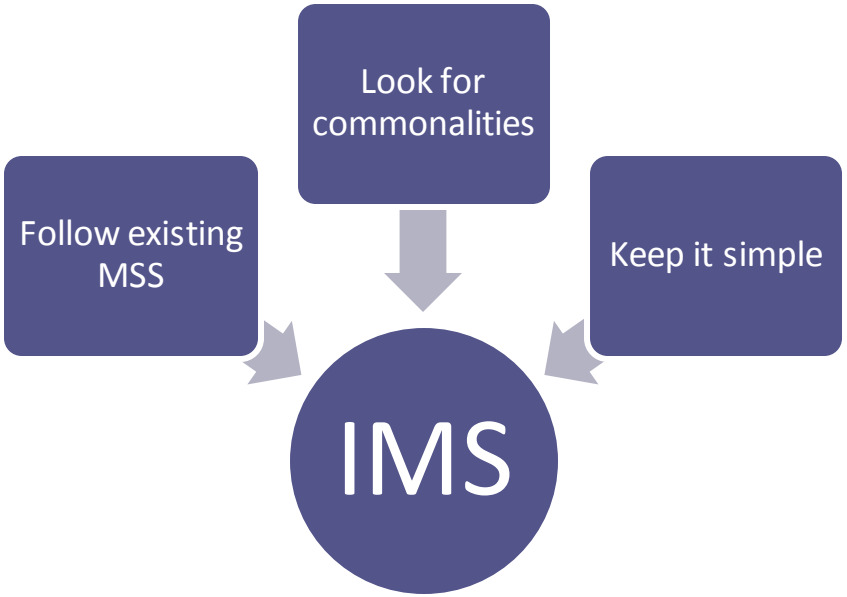
- High Level Structure
- Multiple standards implementation
- Implementation and maintenance costs
- Employees dis-satisfaction

OMNEX

Benefits

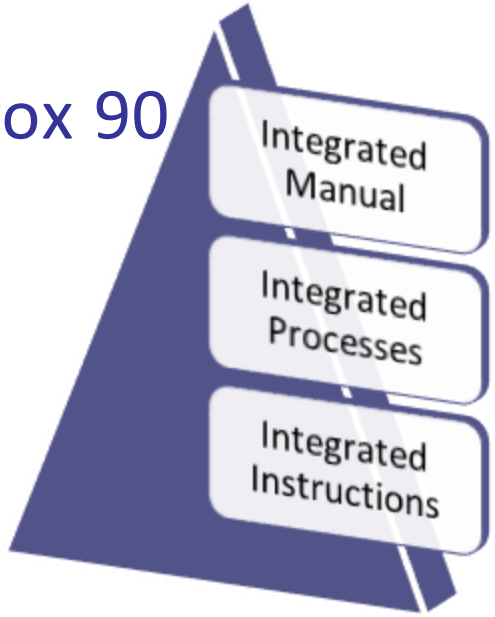

Implementation cost will reduce by 50 %
Maintenance cost will reduce by 66 %
Third party audit cost reduced by 20 %
Increased effectiveness and efficiency due to no duplication
Employee and interested party satisfaction

Key factors to success



How ?

- Level 1 : IMS Integration @ 95 %
  - Integrated manual
  - Integrated Policy (es)
  - Integrated objectives
- Level 2 : Process Integration @ Approx 90
  - Integrated processes (documented)
  - Integrated risk assessment
  - Integrated audits
  - Integrated management reviews
  - Etc
- Level 3 : Integration @ Approx 75 %
  - Work Instructions



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Steps

1. Determine the standards to integrate
2. Prepare integration matrix
3. Determine the processes, sequence & process map
4. Document and implement
5. Review effectiveness
6. Continually improve

PRESENTATION - 7

Measurement Systems Analysis

OMNEX

DRIVING WORLDWIDE
BUSINESS EXCELLENCE

Agenda

1. Measurement System Analysis
2. Measurement and Measurement system
3. Statistical Properties
4. Determining and Assessing Stability
5. Determining and Assessing Linearity
6. Determining and Assessing Repeatability
7. Determining and Assessing Reproducibility
8. Determining and Assessing GRR
9. Determining and Assessing Repeatability and Reproducibility
10. General Concepts for Assessing Measurement Systems
11. General guidelines for measurement system acceptability
12. The Gage Repeatability and Reproducibility calculations
13. Variable data study & GRR calculation

Measurement System Analysis

- The combined study of part to part variation and measurement variation is called measurement system analysis.
- The output of the process when measured has two kind of variation.

I. Part to part variation

II. Measurement System variation

Measurement & Measurement System

MEASUREMENT

- Is defined as “the assignment of numbers [or values] to material things to represent the relations among them with respect to particular properties.”
- The process of assigning the numbers is defined as the measurement process, and the value assigned is defined as the measurement value

GAUGE

- Gauge is any device used to obtain measurements; frequently used to refer specifically to the devices used on the shop floor; includes go/no-go devices

MEASUREMENT SYSTEM

- Is the collection of instruments or gages, standards, operations, methods, fixtures, software, personnel, environment and assumptions used to quantify a unit of measure or fix assessment to the feature characteristic being measured; the complete process used to obtain measurements.

Statistical Properties

- Location variation

1. Accuracy
2. Stability
3. Linearity
4. Bias

- Width variation

1. Precision
2. Repeatability
3. Reproducibility
4. GRR or Gage R&R
5. Measurement System Capability
6. Measurement System Performance
7. Sensitivity
8. Consistency
9. Uniformity

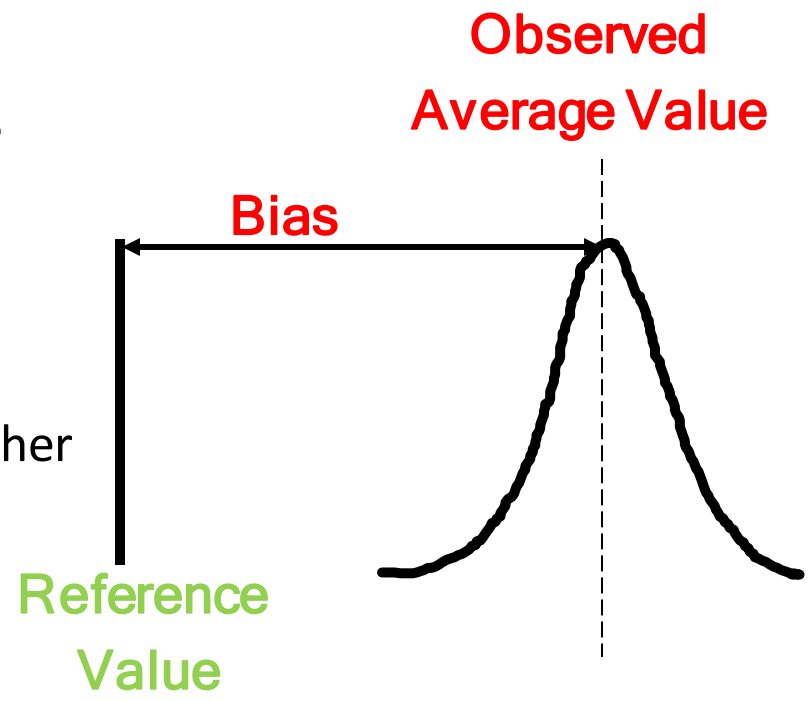
- System variation

1. Capability
2. Performance
3. Uncertainty

Statistical Properties

BIAS

- Is the difference between the observed average of measurement and the reference value.
- The reference value, also known as the accepted reference value or master value
- A reference value can be determined by averaging several measurements with a higher level of measuring equipment.



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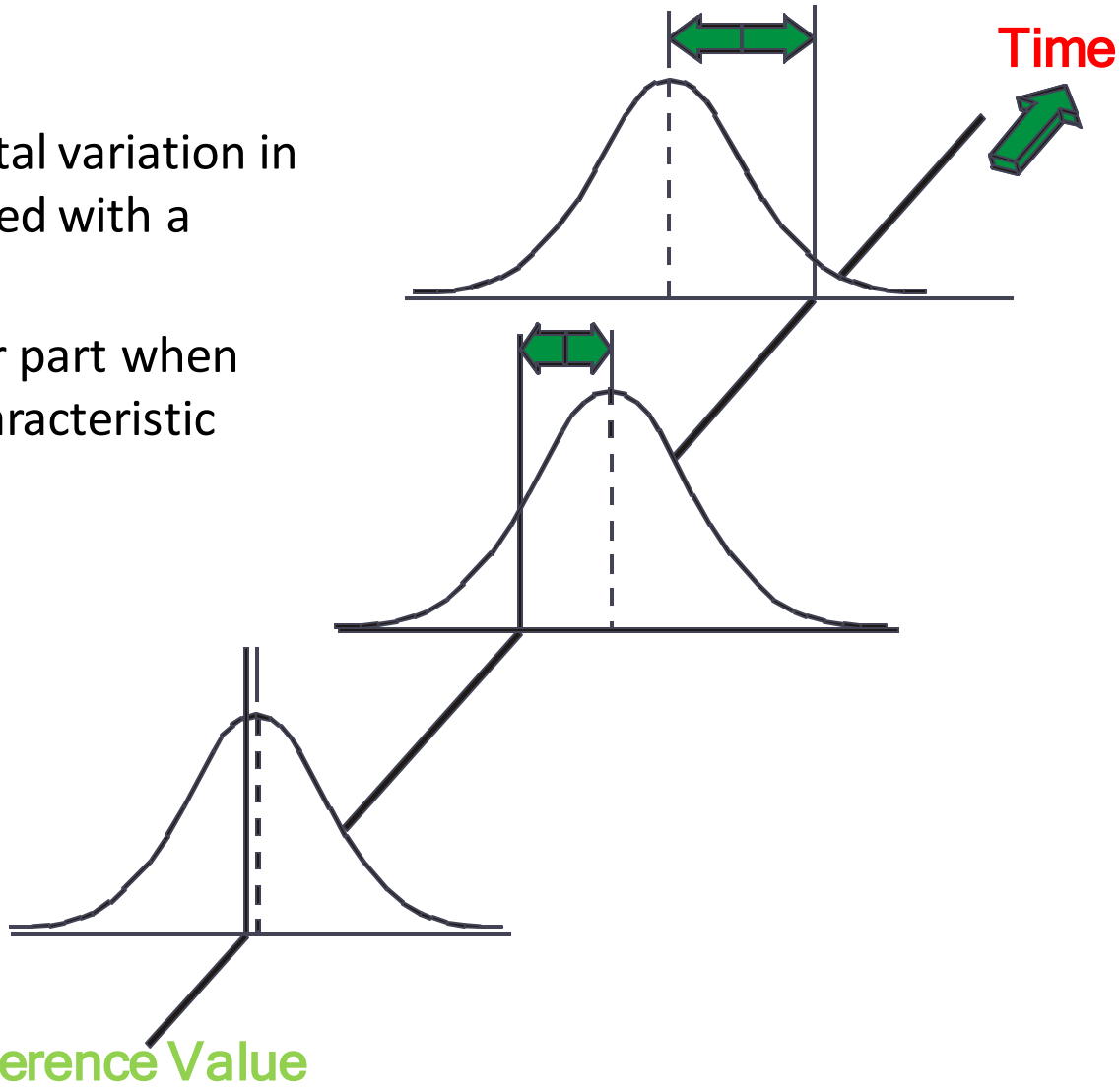
Determining and Assessing Stability

STABILITY

- Stability (or drift) is the total variation in the measurements obtained with a measurement system
  - on the same master or part when measuring a single characteristic
  - over an extended time period



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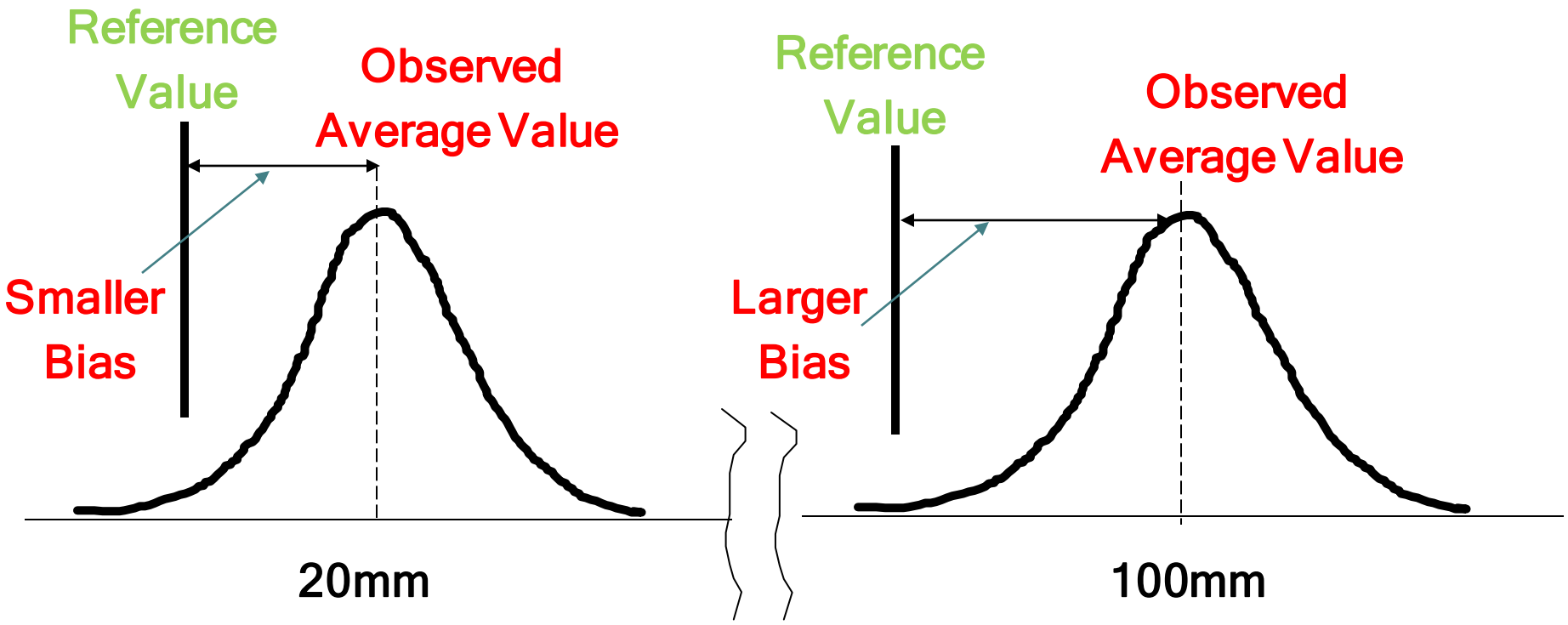
Determining and Assessing Linearity

- Linearity is the difference in the bias values through the expected operating range of the gauge.

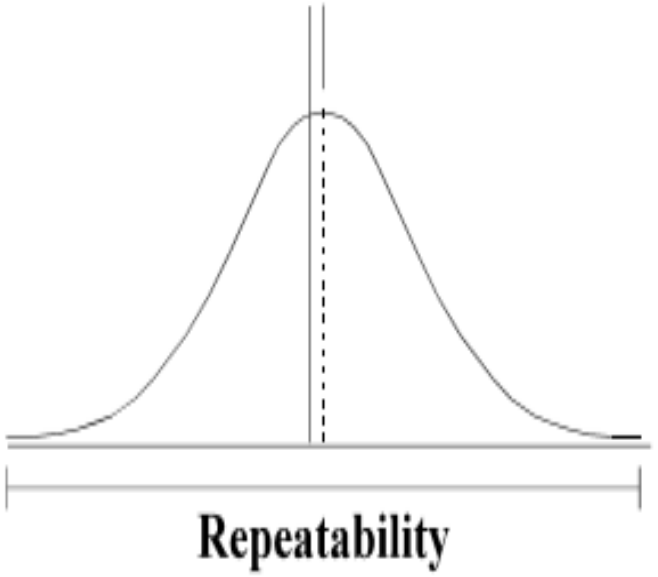


OMNEX

Determining and Assessing Repeatability

Repeatability

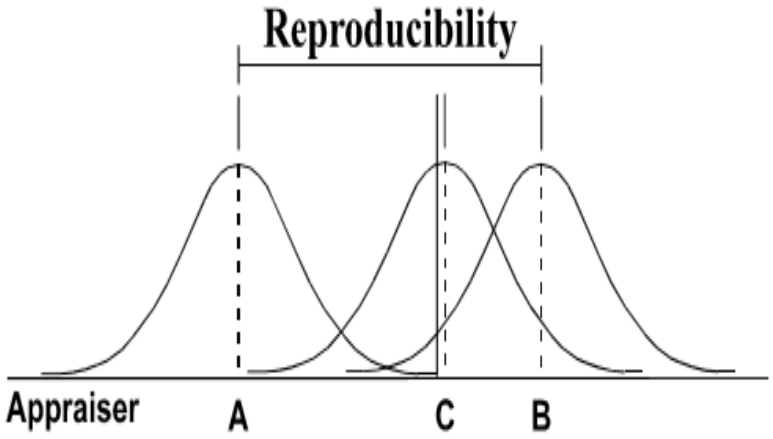
- Variation in measurements obtained with one measuring instrument when used several times by an appraiser while measuring the identical characteristic on the same part
- Within-system variation
- Commonly referred to as E.V. – Equipment Variation



Determining and Assessing Reproducibility

Reproducibility

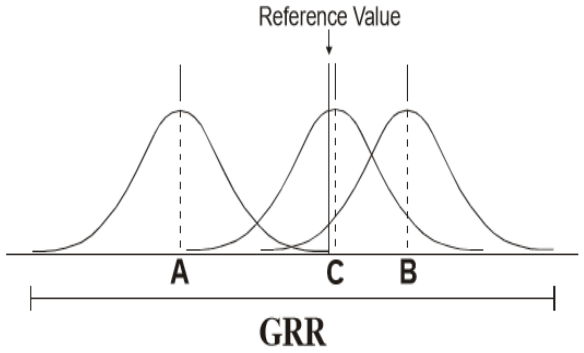
- Variation in the average of the measurements made by different appraisers using the same gage when measuring a characteristic on one part
- For product and process qualification, error may be appraiser, environment (time), or method
- Commonly referred to as A.V. – Appraiser Variation
- Between-system (conditions) variation



Determining and Assessing GRR

GRR or Gage R&R

- Gauge repeatability and reproducibility: the combined estimate of measurement system repeatability and reproducibility
- Gage R&R or GRR is an estimate of the combined variation of repeatability and reproducibility. Stated another way, GRR is the variance equal to the sum of within-system and between-system variances.



$$\sigma^2_{GRR} = \sigma^2_{reproducibility} + \sigma^2_{repeatability}$$

SENSITIVITY

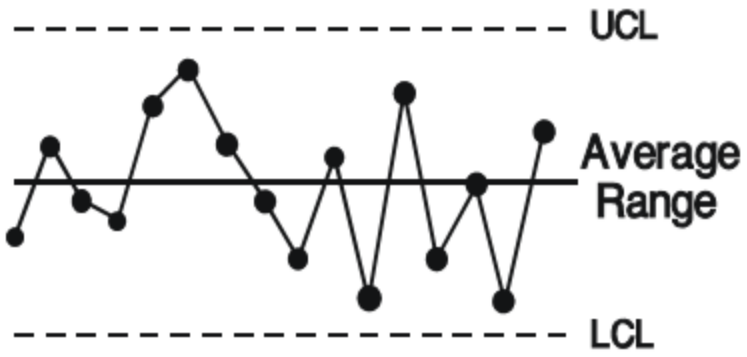
- Sensitivity is the smallest input that results in a detectable (usable) output signal.
- Sensitivity is determined by gauge design (discrimination), inherent quality (OEM), in-service maintenance, and the operating condition of the instrument and standard.

Factors that affect sensitivity include:

i. Ability to dampen an instrument
ii. Skill of operator
iii. Repeatability of the measuring device

CONSISTENCY

- Consistency is the difference in the variation of the measurements taken over time. It may be viewed as repeatability over time.



- Factors impacting consistency are special causes of variation such as: Temperature of parts
- Warm up required for electronic equipment.
- Worn equipment

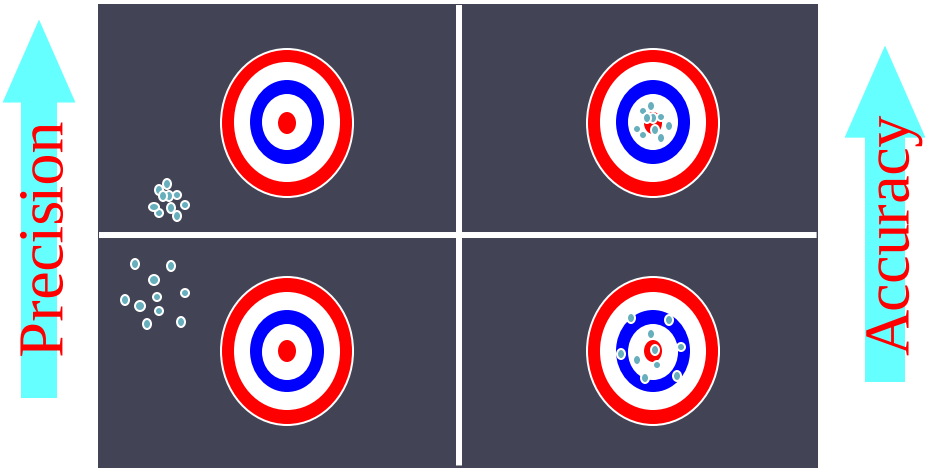
PRECISION

“Closeness” of repeated readings to each other

A random error component of the measurement system

ACCURACY

“Closeness” to the true value, or to an accepted reference value



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Determining and Assessing Repeatability and Reproducibility

- There are three methods:

- Range Method
- Average and Range Method
- Analysis of Variation Method

Range Method

- Gives a quick approximation of measurement variability. It does not decompose the variability into repeatability and reproducability.
- Conducted with 2 appraisers and 5 parts;
- Each appraiser measures each part once;
- Evaluate the range at each part;
- Estimate the variation between the measurement results over the average Range (R/d2);
- Gauge R&R = 99%-area under the normal distribution curve.

Average and Range Method

- Evaluates Repeatability and Reproducibility separately;
- Conducted typically with three appraisers and 10 parts;
- Each appraiser measures each part three time in a random order;
- Evaluation graphical or numerical;
- EV (equipment variation)
- AV (appraiser variation)
- R&R $(R\&R)^2 = EV^2 + AV^2$
- Part Variation PV
- Total Variation $TV^2 = (R\&R)^2 + PV^2$

Analysis of Variation Method

- Evaluates Repeatability and Reproducibility separately;
- Evaluates Interaction between appraiser and part;
- Conducted typically with three appraisers and 10 parts;
- Each appraiser measures each part three time in a random order;
- Evaluation graphical or numerical;
- EV (equipment variation)
- AV (appraiser variation)
- R&R (repeatability, reproducibility and interaction (I)
- R&R $(R\&R)^2 = EV^2 + AV^2 + I^2$
- Part Variation PV
- Total Variation $TV^2 = (R\&R)^2 + PV^2$

Assessing Repeatability and Reproducibility

- If repeatability is large compared to reproducibility, the reasons may be:
- The instrument needs maintenance;
- The gauge should be redesigned to be more rigid;
- The clamping or location for gauging needs to be improved;
- There is excessive part variation.

- If reproducibility is large compared to repeatability, then possible causes could be:
- The appraiser needs to be better trained in how to use and read the gauge instrument;
- Calibrations on the gauge dial are not clear;
- A fixture of some sort may be needed to help the appraiser use the gauge more consistently.

General Concepts for Assessing Measurement Systems

1. Background
2. Selecting/Developing Test Procedures
3. Preparation for a Measurement System Study
4. Analysis of the Results

Background

Two important areas need to be assessed:

1. Verify the correct variable is being measured at the proper characteristic location. Verify fixturing and clamping if applicable.

i. Also identify any critical environmental issues that are interdependent with the measurement.

ii. If the wrong variable is being measured, then no matter how accurate or how precise the measurement system is, it will simply consume resources without providing benefit.

2. Determine what statistical properties the measurement system needs to have in order to be acceptable.

Selecting/Developing Test Procedures

- General issues to consider when selecting or developing an assessment procedure include:
- Should standards, such as those traceable to NIST, be used in the testing and, if so, what level of standard is appropriate
- The cost of testing.
- The time required for the testing.
- Any term for which there is no commonly accepted definition should be operationally defined. Examples of such terms include accuracy, precision, repeatability, reproducibility, etc

Preparation for a Measurement System Study

Typical preparation prior to conducting the study is as follows:

- The approach to be used should be planned.

For instance, determine by using engineering judgment, visual observations, or a gage study, if there is an appraiser influence in calibrating or using the instrument.

- The number of appraisers, number of sample parts, and number of repeat readings should be determined in advance. Some factors to be considered in this selection are:

(a) Criticality of dimension

(b) Part configuration

(c) Customer requirements.

- Selection of appraisers
- Selection of the sample parts is critical for proper analysis and depends entirely upon the design of the MSA study, purpose of the measurement system, and availability of part samples that represent the production process.

Analysis of the Results

- Acceptability Criteria – Gage Assembly and Fixture Error :

An improperly designed fixture or poorly assembled gage will increase measurement error.

- Acceptability Criteria – Location Error : Location error is normally defined by analysing bias and linearity.
- Acceptability Criteria – Width Error : The criteria as to whether a measurement system's variability

General Guidelines for Measurement System Acceptability

Sl	GRR (%)	Decision	Comments
1	**Under 10 percent**	Generally considered to be an acceptable measurement system.	Recommended, especially useful when trying to sort or classify parts or when tightened process control is required
2	**10 percent to 30 percent**	May be acceptable for some applications	Decision should be based upon, for example, importance of application measurement, cost of measurement device, cost of rework or repair. Should be approved by the customer.
3	**Over 30 percent**	Considered to be unacceptable	Every effort should be made to improve the measurement system. This condition may be addressed by the use of an appropriate measurement strategy; for example, using the average result of several readings of the same part characteristic in order to reduce final measurement variation

The Gage Repeatability and Reproducibility calculations

$\bar{\bar{R}} = ([\bar{R}_a = \quad] + [\bar{R}_b = \quad] + [\bar{R}_c = \quad]) / [\#\ OF\ APPRAISERS = \quad] =$

$\bar{X}_{DIFF} = [Max\ \bar{X} = \quad] - [Min\ \bar{X} = \quad] =$

$^{*} UCL_R = [\bar{\bar{R}} = \quad] \times [D_4 = \quad] =$

Equipment Variation (EV)

$$EV = \bar{\bar{R}} \times K_1$$

Appraiser Variation (AV)

$$AV = \sqrt{(\bar{X}_{DIFF} \times K_2)^2 - (EV^2 / (nr))}$$

Repeatability & Reproducibility (GRR)

$$GRR = \sqrt{EV^2 + AV^2}$$

Part Variation (PV)

$$PV = R_p \times K_3$$

Total Variation (TV)

$$TV = \sqrt{GRR^2 + PV^2}$$

The percentage equipment variation (%EV)

$$\%EV = 100\,[EV/TV]$$

The percentage Appraiser Variation

$$\%AV = 100\,[AV/TV]$$

The percentage GRR

$$\%GRR = 100\,[GRR/TV]$$

The percentage Part Variation (PV)

$$\%\,PV = 100\,[PV/TV]$$

number of distinct categories
(This is the number of non-overlapping 97% confidence intervals that will span the expected product variation.)

$$\boldsymbol{ndc} = 1.41\left(PV/GRR\right)$$

- VARIABLE DATA STUDY AND GRR CALCULATION

Microsoft Excel
Worksheet

PRESENTATION - 8

KNOWLEDGE SHARING

ON

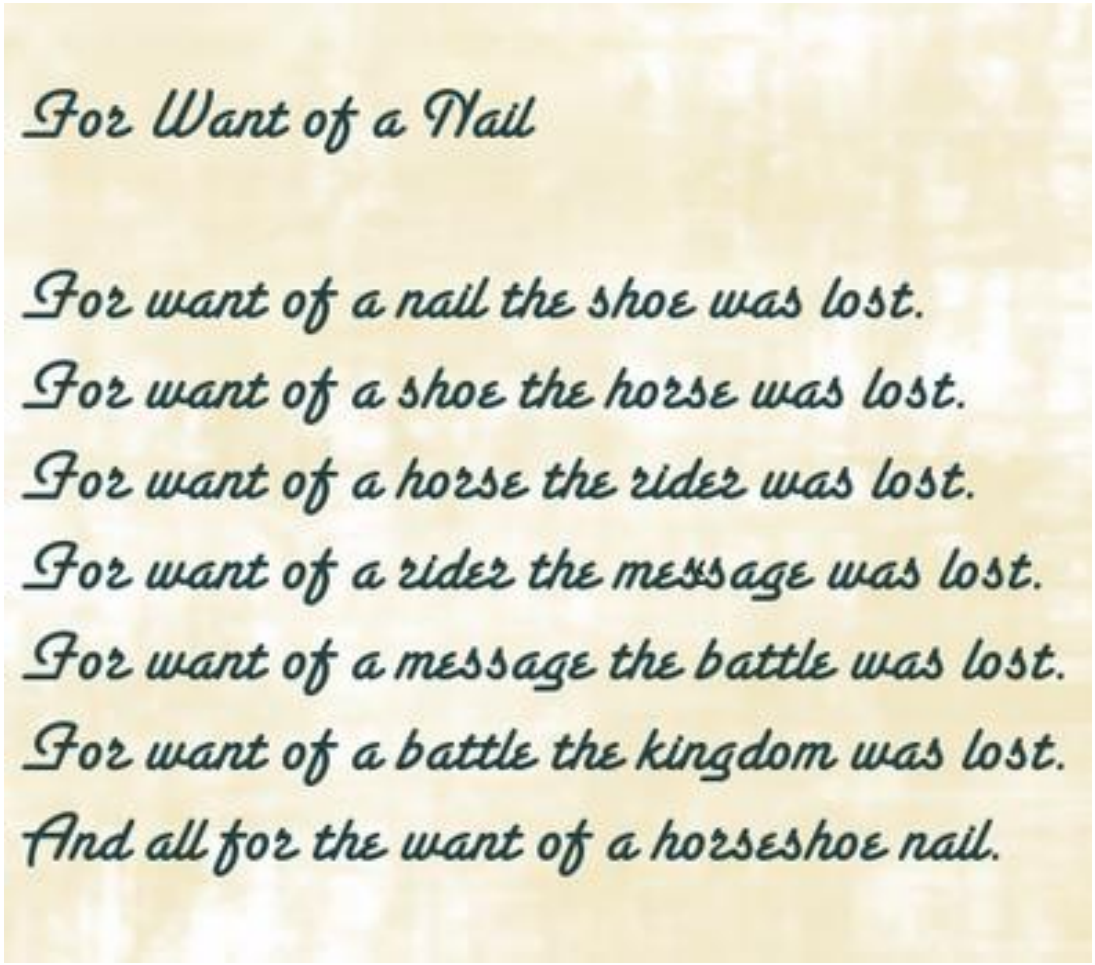
ROOT CAUSE ANALYSIS

AT

MAMALA BEACH RESORT

INDEX

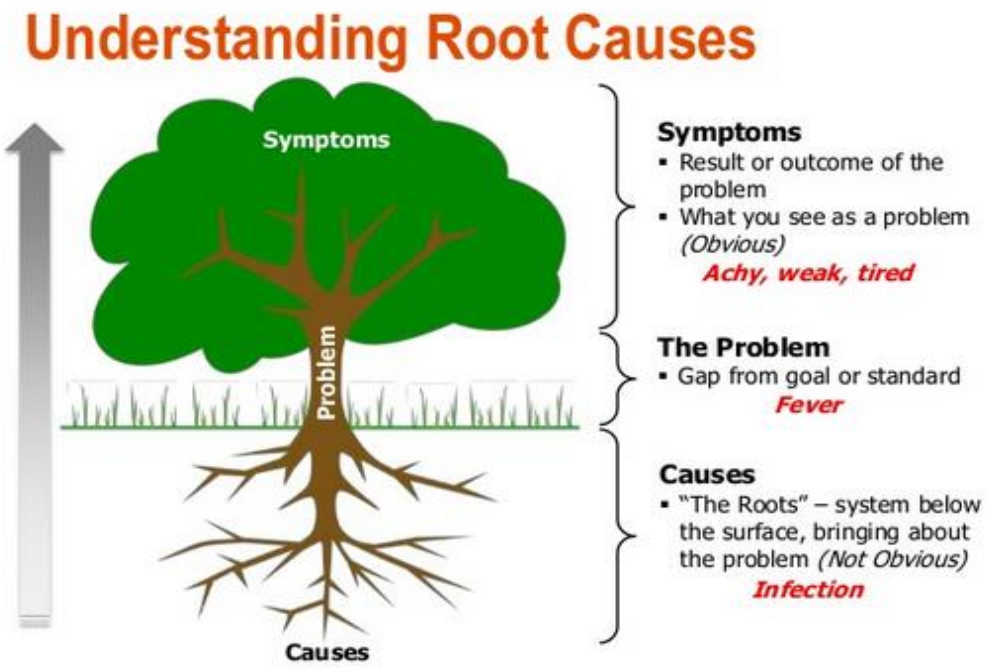
1.For want of a nail



2.What is Root cause?

A root cause is an initiating cause of either a condition or a causal chain that leads to an outcome or effect of interest.

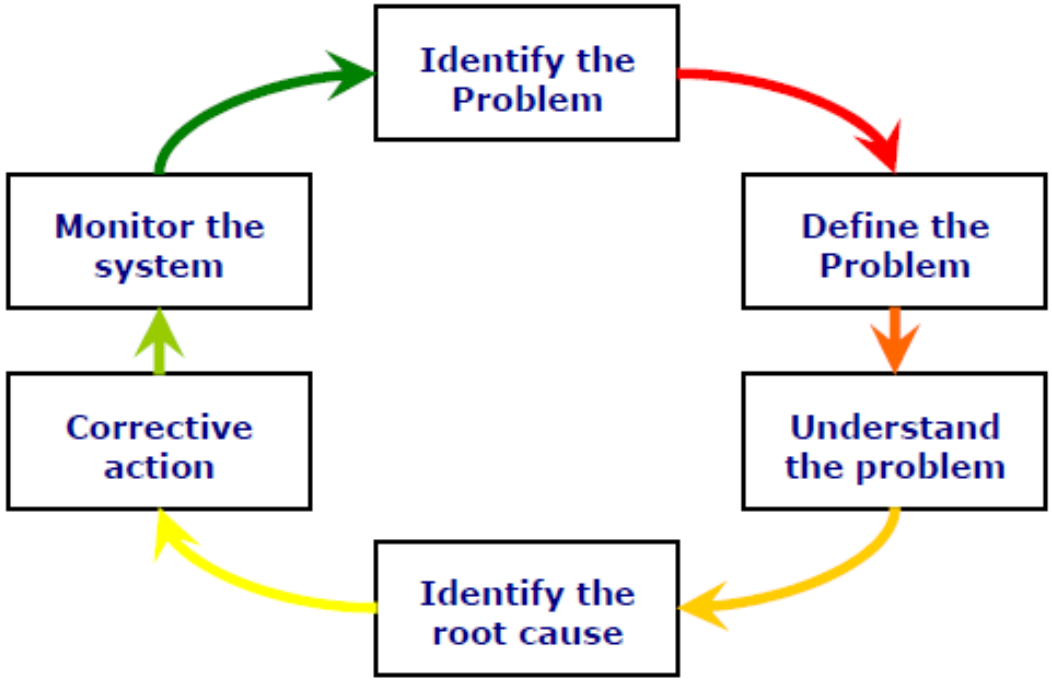
In simple words, root cause is the underlying cause that leads to the problem.



3. Introduction to RCA

Root cause analysis(RCA) is a structured method to address a problem or non conformance, in order to get to the ‘’root cause ‘’ of the problem.

RCA is simply the application of series techniques which can produce a systematic, quantified and documented approach to the identification, understanding and resolution of underlying causes.



4. Define the problem

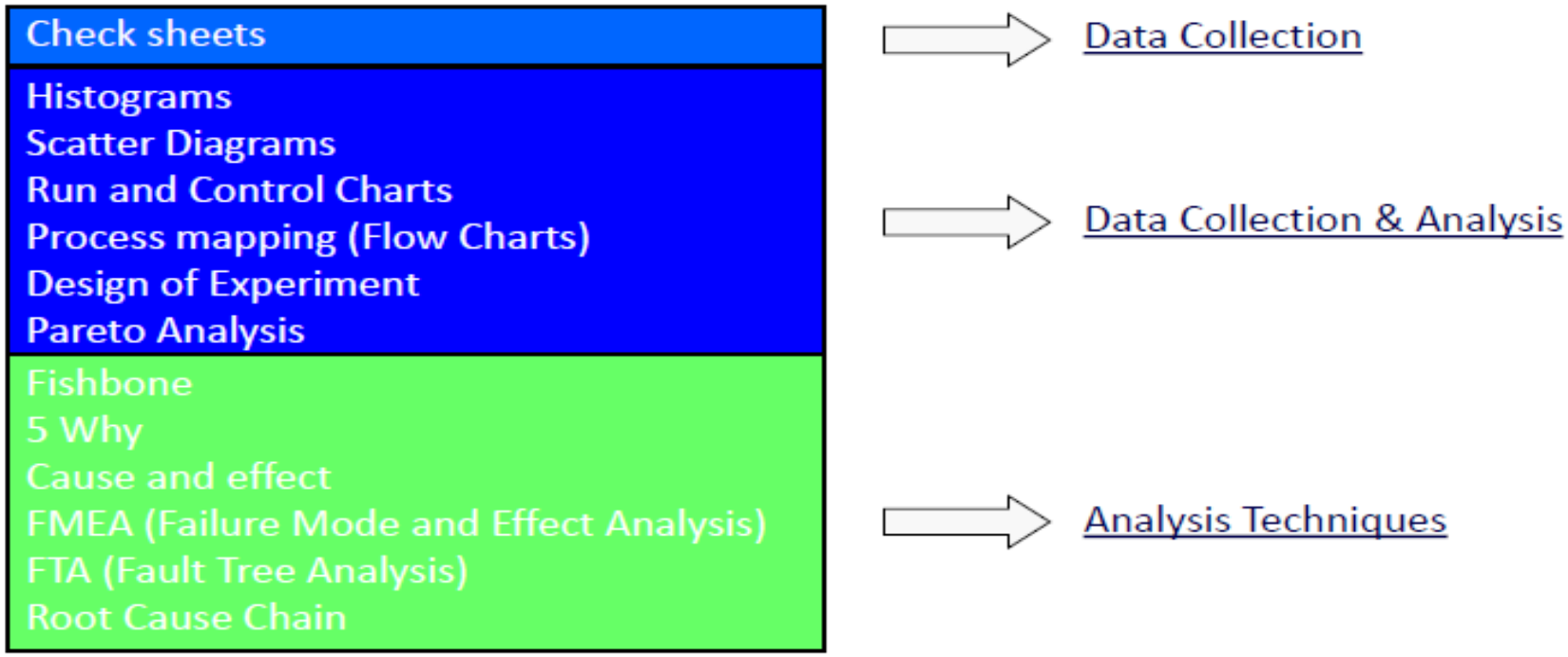
PROBLEM STATEMENT: A concise statement that identifies the object experiencing and nature of the defect. The problem statement describes clearly what is wrong is what.

PROBLEM DESCRIPTION: is process of digging down into the problem and getting a more detailed and refined understanding of the problem.

- **What** is the problem?
- **Where** was it detected?
- **Who** is affected?
- **When** did it surface?
- **How** serious is the problem?
- **How many** occurrences?

5. Identify Root Cause

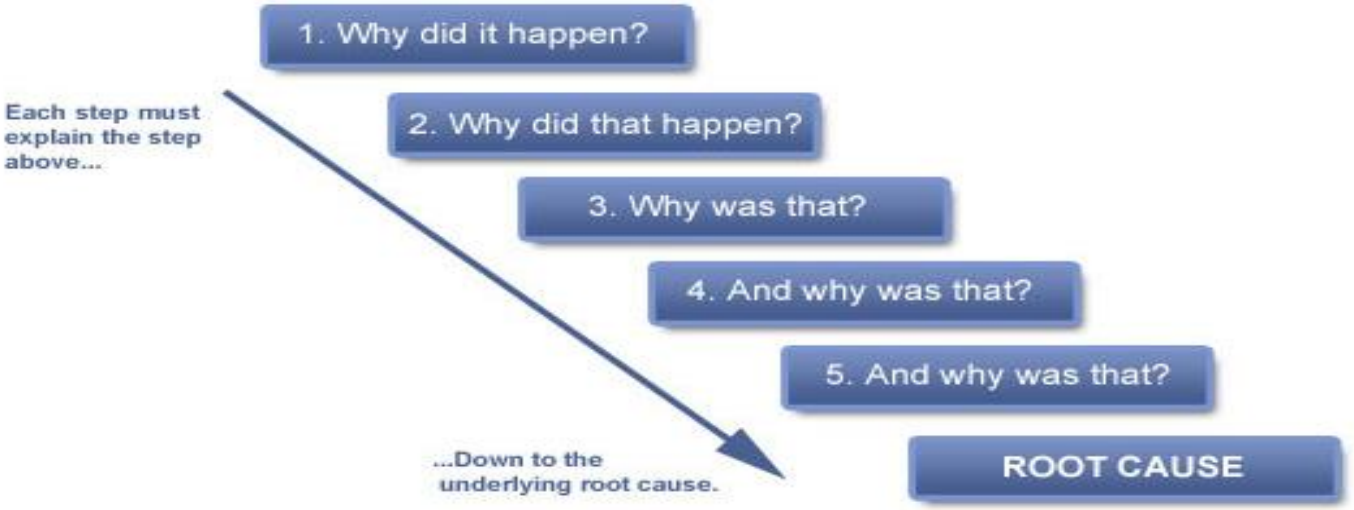
Objective: To identify, through structured root cause analysis , all causes that have or may have generated or contributed to the undesirable condition, non conformity or failure.



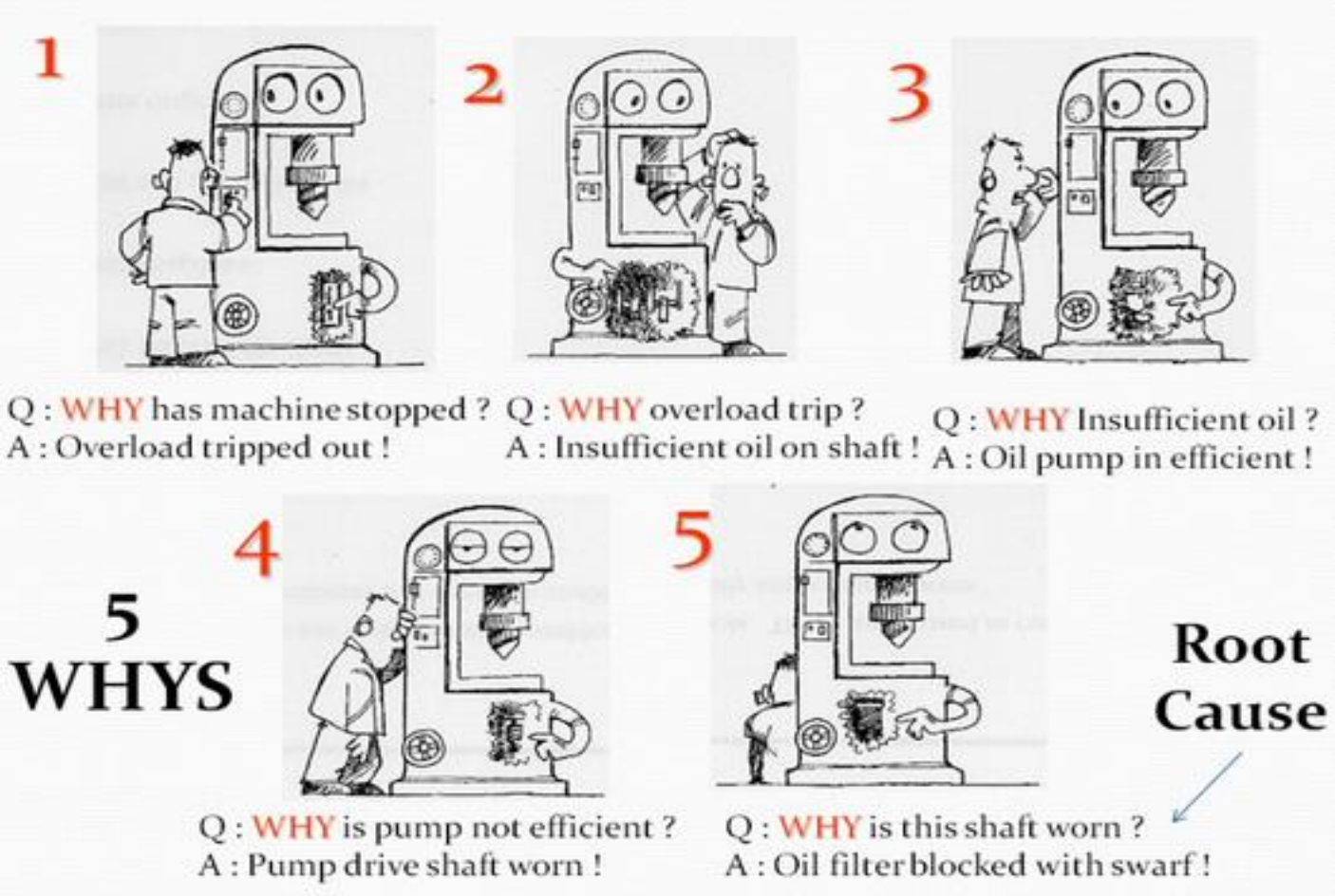
6. Why- Why Analysis

5 Whys is an iterative interrogative technique used to explore the cause-and-effect relationships underlying a particular problem.

The primary goal of the technique is to determine the root cause of a defect or problem by repeating the question "Why?“.



6.1. Why Why Example



6.2 Limitation of why-why analysis

- Why Why analysis was initially used by Toyota. Toyota has a "go and see" philosophy. This means that its decision making is based on an in-depth understanding of what's actually happening on the shop floor rather than on what someone in a boardroom thinks might be happening.

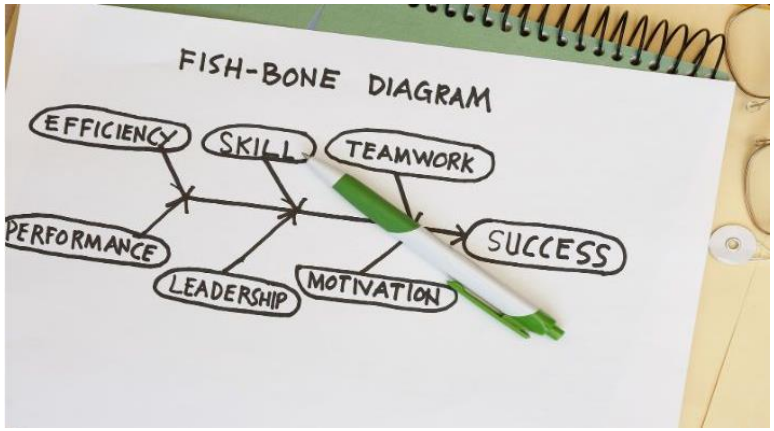
- The 5 Whys technique is true to this tradition, and it is most effective when the answers come from people who have hands-on experience of the process being examined.

- 5 why should be based on observation , not deduction.

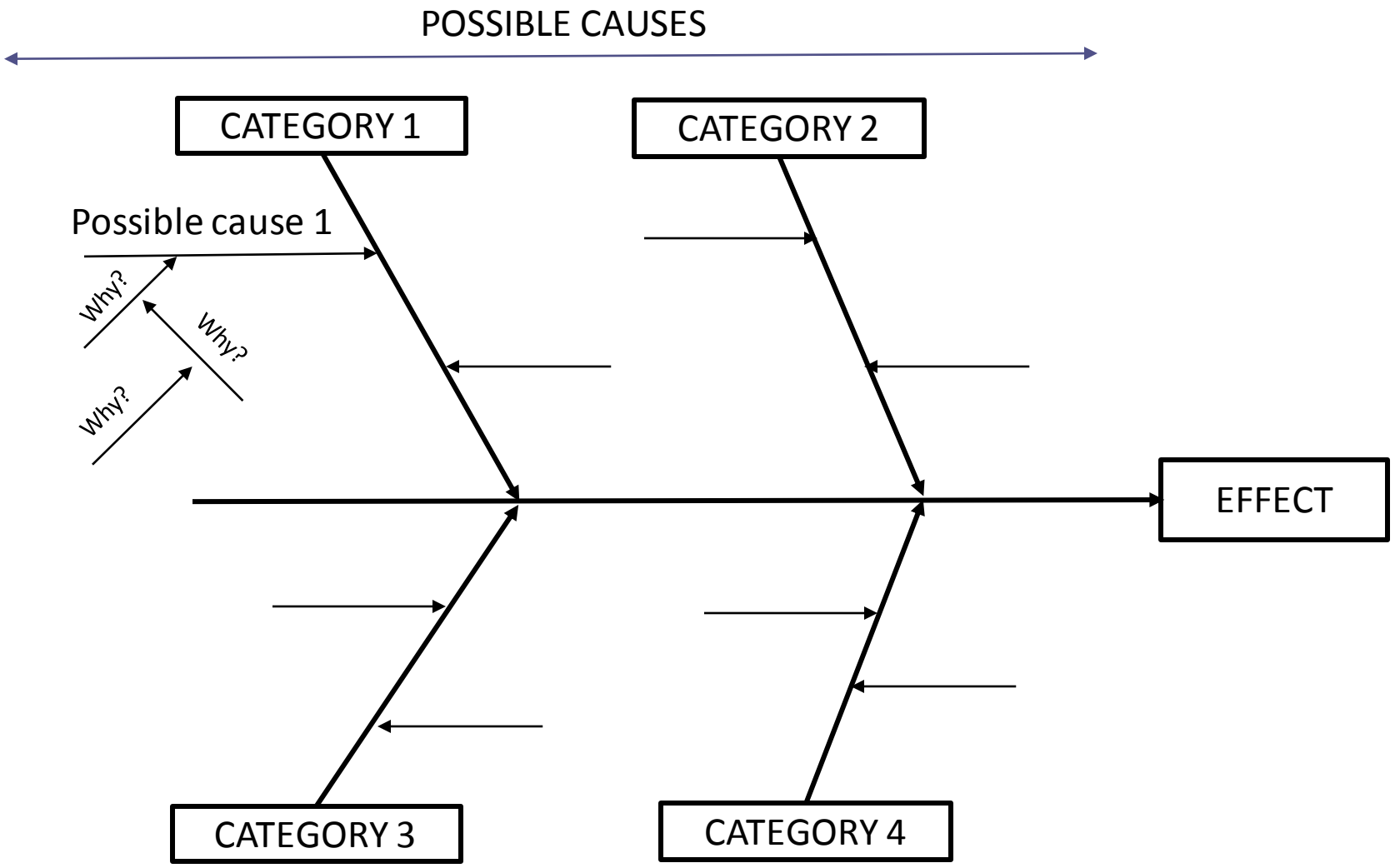
7. Fish Bone Diagram

The **Fishbone Diagram** (also known as Ishikawa diagram or cause and effect diagram) is an analysis tool invented by Dr. Kaoru Ishikawa, a Japanese quality control statistician.

The fishbone diagram provides a systematic way of identifying the **possible causes** that can contribute to the problem/effect.



7.1 Creating a Fish bone diagram



7.2 IS/IS NOT Worksheet

PROBLEM STATEMENT	IS	IS NOT	DIFFERENCES	CHANGES	DATE	POSSIBLE CAUSE 1	POSSIBLE CAUSE 2	POSSIBLE CAUSE 3
WHO?	Who is affected by the problem? Who first observed the problem? To whom was the problem reported?	Who is not affected by the problem? Who did not find the problem?				+	+	-
WHAT?	What has the problem (part id, lot #s, etc)? What is happening with the process & with containment? Do we have physical evidence of the problem?	What does not have the problem? What could be happening but is not? What could be the problem but is not?				-	-	+
WHY?	Why is this a problem (degraded performance)? Is the process stable?	Why is it not a problem?				+	+	-
WHERE?	Where was the problem observed? Where does the problem occur?	Where could the problem be located but is not? Where else could the problem be located but is not?				+	-	+
WHEN?	When was the problem first noticed? When has it been noticed since?	When could the problem have been noticed but was not?				+	-	-
HOW MANY?	Quantity of problem (ppm)? How much is the problem costing in dollars, people, & time?	How many could have the problem but don't? How big could the problem be but is not?				-	+	-
HOW OFTEN?	What is the trend (continuous, random, cyclical)? Has the problem occurred previously?	What could the trend be but is not?				+	-	-

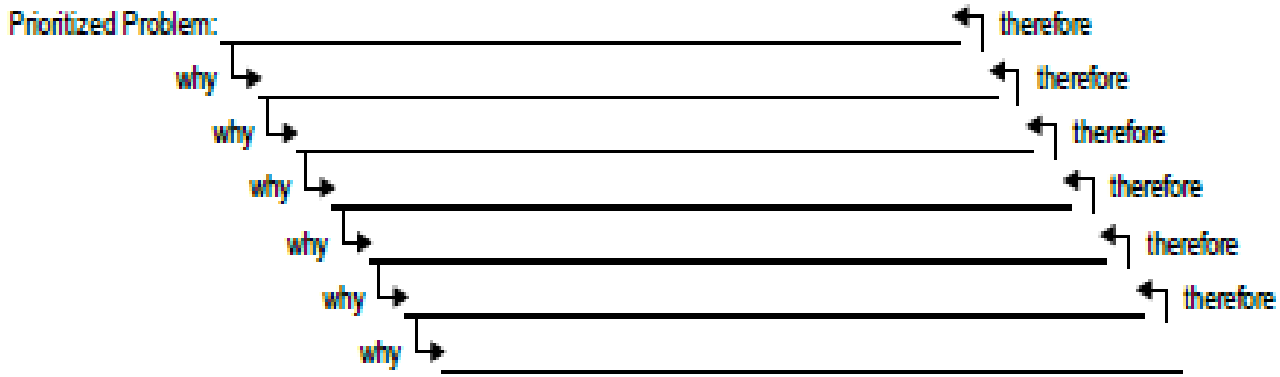
+ve sign indicates that ''is'' and ''is not'' criteria is related to the cause.

-ve sign indicates that ''is'' and ''is not'' criteria is not related to the cause.

8. Validating Why why

Can you recreate the problem, or turn it ‘’OFF’’ and ‘’ON’’?

Use the ‘’Therefore’’ test . Start with the root cause and work backwards to the problem statement.



"Color Codes" "G"-Task Completed, Issue Closed "Y"-Task May Be Late, Requires Leverage "R" - Task is Late, Reaction Required "W" Track, In Progress

8.1 ‘’Therefore’’ Example

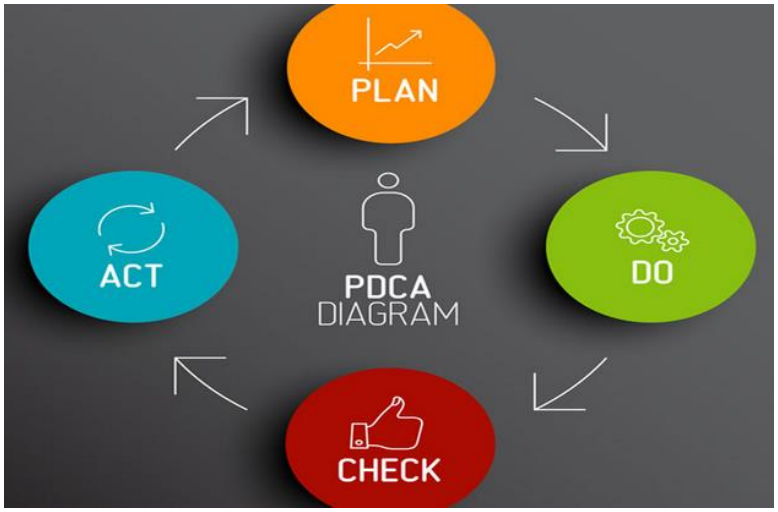
1. There’s a hole in the water pipe
    2. **Because** a nail has been hammered through the pipe
    3. **Because** the carpenter was not aware of the pipes position
    4. **Because** the carpenter had not examined a drawing showing the pipes position
    5. **Because** this **is not part of the carpenters standard work to examine a drawing**

5. It is not part of the carpenters standard work to examine the drawing
    4. **Therefore** the carpenter had not examined the drawing showing the pipes position
    3. **Therefore** the carpenter was not aware of the pipes position
    2. **Therefore** a nail has been hammered through the pipe
    1. **Therefore** there is a hole in the water pipe

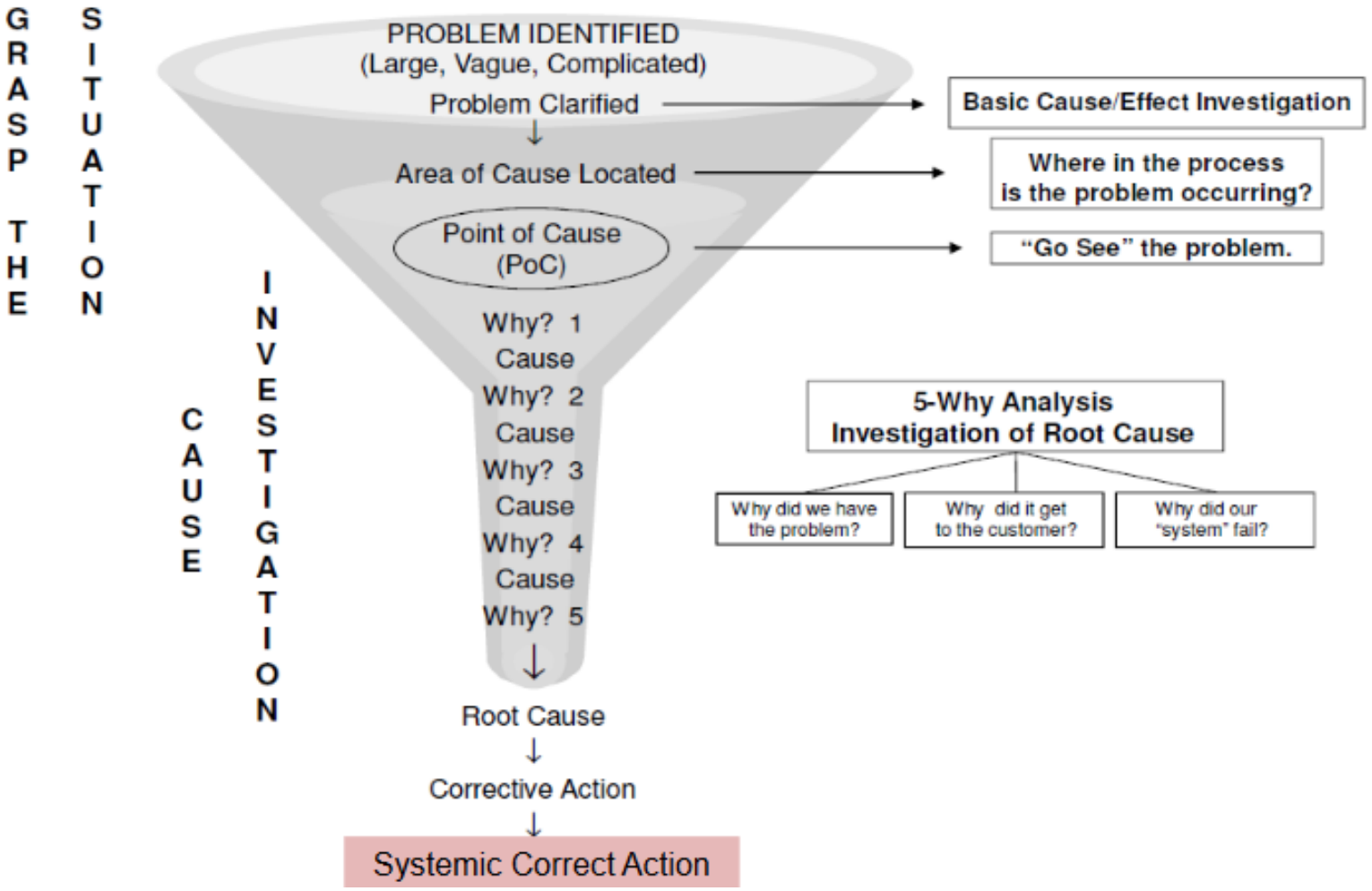
9. CAPA

Corrective actions: Actions taken to eliminate the cause of a non-conformities in order to prevent recurrence.

Preventive action: Actions taken to the eliminate the causes of potential non conformities in order to prevent occurrence.



10. RCA Summary



PRESENTATION - 9

SPECIAL CHARACTERISTICS IN ACCORDANCE WITH IATF 16949:2016 & IT'S FLOW DOWN TO SUPPLIERS

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1. Definition

Classification of a product characteristic or manufacturing process parameter that can affect safety or compliance with regulations, fit, function, performance, requirements, or subsequent processing of product.

3. Purpose of special characteristics

- Helps to focus on the "***vital few***" characteristics/parameters of product and manufacturing process to meet customer requirements.
- Formal communication of "***vital few***" characteristics and the control required throughout the supply chain.

4. Special characteristics in accordance with IATF 16949:2016

- ***4.4.1.2 Product Safety***
  - ❖ Identification of product safety related product or manufacturing process characteristics.
  - ❖ Customer notification of product safety related requirements.
  - ❖ Special approvals of DFMEA, PFMEA and control plan.
  - ❖ Training for personnel involved in product safety related products and manufacturing process.
  - ❖ Transfer of requirements throughout the supply chain.

4. Special characteristics in accordance with IATF 16949:2016

- ***8.2.2 Determining the requirements of products and services***

  Organization shall determine the requirements for products and services including,

  - ❖Statutory and regulatory requirements
  - ❖Those considered necessary by the organization

- ***8.2.2.1 Determining the requirements of products and services – supplemental***

These ***requirements*** shall include ***recycling***, ***environmental impact*** and characteristics identified as a result of organization's knowledge of product and manufacturing processes

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4. Special characteristics in accordance with IATF 16949:2016

- ***8.2.3.1.2 Customer designated special characteristics***

  Organization shall conform to designation, approval documentation and control of special characteristics.

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4. Special characteristics in accordance with IATF 16949:2016

- Multidisciplinary approach is used for the identification of special characteristics during the development of FMEAs (8.3.2.1).
- Product related special characteristics are determined during the development of DFMEA (8.3.3.1 & 8.3.51) .
- Product and process related special characteristics are determined during the development of PFMEA (8.3.3.2 & 8.3.5.2).

4. Special characteristics in accordance with IATF 16949:2016

8.3.3.3 Special Characteristics

The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

a) documentation of all special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents;

4. Special characteristics in accordance with IATF 16949:2016

8.3.3.3 Special Characteristics

b) development of control and monitoring strategies for special characteristics of products and production processes;

c) customer-specified approvals, when required;

d) compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

4. Special characteristics in accordance with IATF 16949:2016

Examples of Special characteristics.

Classification	Indicates	Criteria
CC	Critical Characteristics	Severity = 9 or 10
SC	Significant Characteristics	Severity 5 to 8 and Occurrence = 4 to 10
OS	Operator Safety	Severity = 9 or 10

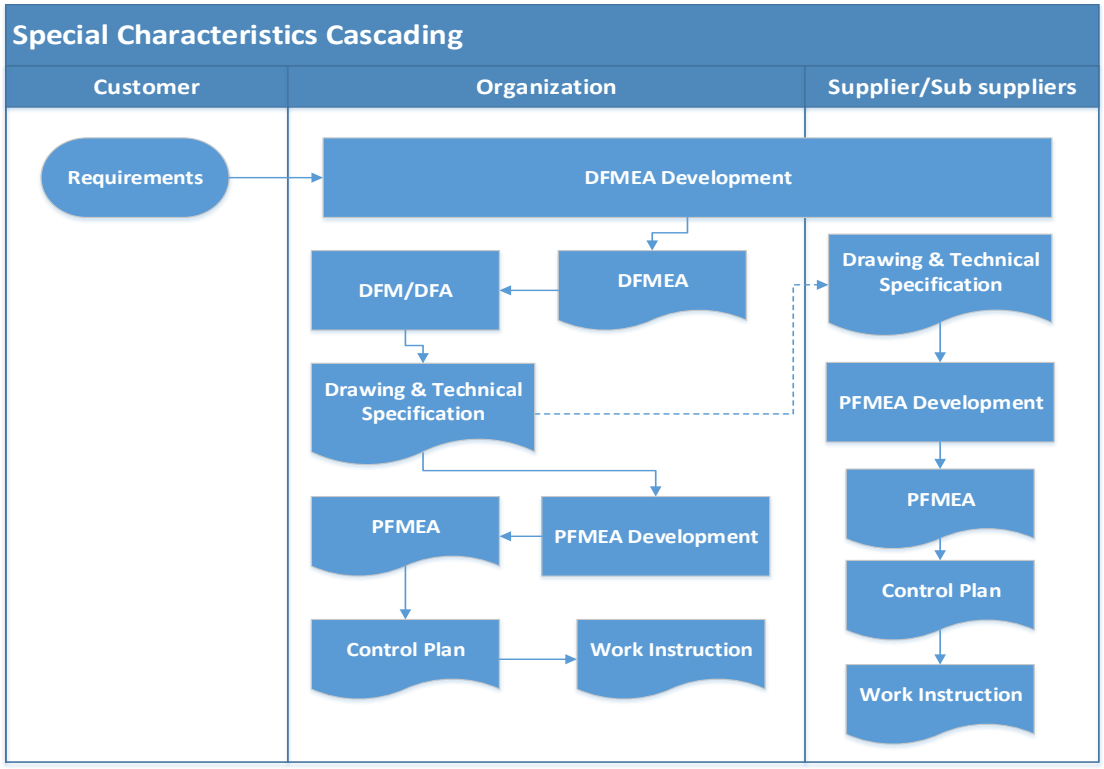
5. Transfer throughout supply chain

Special characteristics can be transferred/cascaded throughout supply chain:

- During DFMEA development or through DFMEA
- Through engineering drawings
- Through technical specification
- During PFMEA development or through PFMEA
- Through Control Plan
- Through documented information with list of special characteristics(e.g. for Ford – Special characteristics Communication & Agreement Form(SCAF)).
- Through Standard Operating Procedures
- Through Work Instructions

5. Cascading– Schematic representation

When organization is responsible for product design



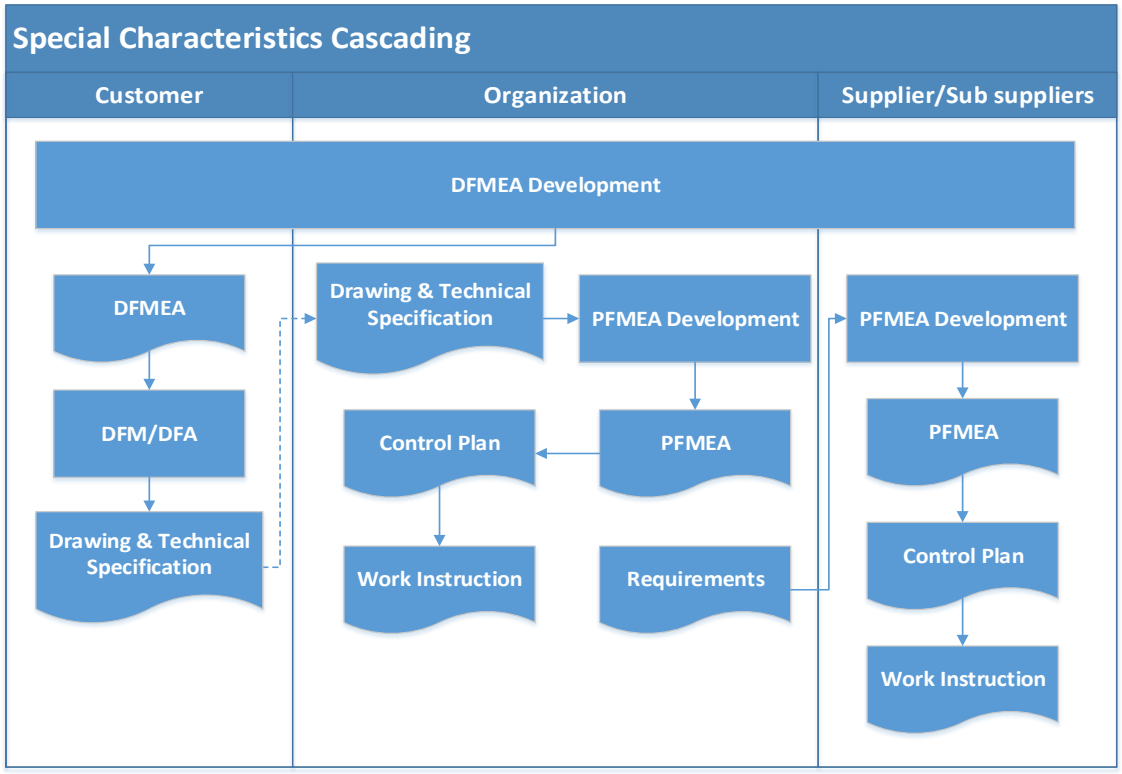
Legends

Process

Documented Information

5. Cascading– Schematic representation

When customer is responsible for product design



Legends

Process

Documented Information

6. Examples

Customer Critical Characteristics

Customer Critical Characteristics are those product requirements(dimensions, performance tests) or process parameters that can affect compliance with government regulations or safe vehicle product function.

Customer	Symbol	Characteristics
Ford	∇	Critical Characteristics
GM	S/C, ∇	Safety Compliance
FCA	S	Shield

6. Examples

Customer Special Characteristics

Customer Special Characteristics are those product features that affect subsequent operations, product function, or customer satisfaction.

Customer	Symbol	Characteristics
Ford	SC	Significant Characteristics
GM	F/F, ◇	Fit/Function
FCA	D, ◇	Key Characteristics

6. Examples

Power & Sons Special Characteristics

Power & Sons Special characteristics consist of 2 additional special characteristics, which are not Customer Characteristics. These are:

M – Major – Affects customer special characteristics as defined in the AIAG PPAP Manual, but are not identified by customer.

K – Key – Affects Power & Sons ability to Manufacture.

PRESENTATION - 10

Understanding undiscussed important words and their meaning

ISO 9001: 2015 QMS

Presented by: G.Manikandan
Date: 18 Aug 2017

Familiar Words

- **Shall - Mandatory**
- **Should- Recommendation**

Standard

- “a level of quality or attainment”
- “something used as a measure, norm, or model in comparative evaluations”

Undiscussed Terms & Interpretations

- Determine
- Monitor
- Consider
- Evaluate
- Apply
- Use

Determine

- **Meaning for determine**
  - ***The word "determine" implies a discovery process that results in knowledge***

Determine

- **Clauses where the word "determine" appears**
  - 4.1 – The organization shall determine external and internal issues that are relevant…
  - 4.2 - determine:
    - a) the interested parties that are relevant to the quality management system;
    - b) the requirements of these interested parties that are relevant to the quality management system.

The word "determine" implies a discovery process that results in knowledge

Determine

- 4.3 - The organization shall determine the boundaries and applicability of the quality management system to establish its scope
- 4.4.1 – Many
  - a) determine the inputs required and the outputs expected from these processes;
  - b) determine the sequence and interaction of these processes;
  - c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
  - d) determine the resources needed for these processes and ensure their availability;

The word "determine" implies a discovery process that results in knowledge

Determine

The word "determine" implies a discovery process that results in knowledge

- **6.2.2 When planning how to achieve its quality objectives, the organization shall determine:**
  - a) what will be done;
  - b) what resources will be required;
  - c) who will be responsible;
  - d) when it will be completed;
  - e) how the results will be evaluated.
- **6.3 – Planning of changes**
  - When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner
- **7.1.1 – General**
  - The organization shall determine and provide the resources

Determine

The word "determine" implies a discovery process that results in knowledge

- **7.1.2 – People**
  - The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.
- **7.1.3 – Infrastructure**
  - The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services
- **7.1.4 – Environment for the operation of processes**
  - The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services

Determine

The word "determine" implies a discovery process that results in knowledge

- **7.1.5.1 – Monitoring and measuring resources – General**
  - The organization shall determine and provide the resources needed to ensure valid and reliable results
- **7.1.5.2 Measurement traceability**
  - The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit
- **7.1.6 – Organizational Knowledge**
  - The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services

Determine

The word "determine" implies a discovery process that results in knowledge

- **7.2 – Competence**
  - The organization shall:
    - a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- **7.4 – Communication**
  - The organization shall determine the internal and external communications
- **8.1 – Operational Planning and Control**
  - a) determining the requirements for the products and services;
  - c) determining the resources needed to achieve conformity
  - e) determining, maintaining and retaining documented information to the extent necessary
- **8.2.2 – Determining the requirements for products and services**
  - When determining the requirements for the products and services to be offered to customers, the organization shall

Determine

The word "determine" implies a discovery process that results in knowledge

- **8.3.1 – Design and development planning**
  - In determining the stages and controls for design and development, the organization shall consider
- **8.3.3 – Design and development inputs**
  - The organization shall determine the requirements essential for the specific types of products
- **8.4.1 – Control of externally provided products, processes and services – General**
  - The organization shall determine the controls to be applied to externally provided processes, products and services when:
  - The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers,

Determine

The word "determine" implies a discovery process that results in knowledge

- **8.4.2 – Type and extent of control**
  - determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements
- **8.5.5 – Post – delivery activities**
  - In determining the extent of post-delivery activities that are required, the organization shall consider:
- **9.1.1 – Monitoring, measurement, analysis and evaluation – General**
  - The organization shall determine:
    - a) what needs to be monitored and measured;
    - b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
    - c) when the monitoring and measuring shall be performed;
    - d) when the results from monitoring and measurement shall be analysed and evaluated.

Determine

The word "determine" implies a discovery process that results in knowledge

- **9.1.2 – Customer Satisfaction**
  - The organization shall determine the methods for obtaining, monitoring and reviewing this information.
- **10.1 – Improvement – General**
  - The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.
- **10.3 – Continual Improvement**
  - The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Monitor

- **What is Monitor?**
  - *Determining the status of a system, a process (3.3.5) or an activity*

Monitor

Determining the status of a system, a process (3.3.5) or an activity

- **Clauses where the word "monitor" appears**
- **4.1 - The organization shall monitor and review information about**
- **4.2- The organization shall monitor and review information about these interested parties and their relevant requirements.**
- **9.1.2 – Customer Satisfaction**
  - The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

Consider

- **Meaning of the word "Consider"**
  - *The word "consider" means it is necessary to think about the topic but it can be excluded*

Consider

The word "consider" means it is necessary to think about the topic but it can be excluded

- **Clauses where the word "Consider" appears**
- **4.3When determining this scope, the organization shall consider:**
  - a) the external and internal issues referred to in 4.1;
  - b) the requirements of relevant interested parties referred to in 4.2;
  - c) the products and services of the organization.
- **6.1.1 – When planning for the quality management system, the organization shall *consider* the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to///**

Consider

The word "consider" means it is necessary to think about the topic but it can be excluded

- **6.3 – Planning of Changes**
  - The organization shall consider:
    - a) the purpose of the changes and their potential consequences;
    - b) the integrity of the quality management system;
    - c) the availability of resources;
    - d) the allocation or reallocation of responsibilities and authorities.
- **7.1.1 General**
  - The organization shall determine---
  - The organization shall consider:
    - a) the capabilities of, and constraints on, existing internal resources;
    - b) what needs to be obtained from external providers

Consider

The word "consider" means it is necessary to think about the topic but it can be excluded

- **8.3.1 – Design and development planning**
  - In determining the stages and controls for design and development, the organization shall consider
- **8.3.3 – Design and development inputs**
  - The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:
- **8.5.5 – Post – delivery activities**
  - In determining the extent of post-delivery activities that are required, the organization shall consider:
- **10.3 – Continual Improvement**
  - The organization shall consider the results of analysis and evaluation, and the outputs from management review

Other important words to understand….

- Take into account
- Evaluate
- Apply
- Use
- Establish
- Demonstrate

Summary

Word	Total number of times used in ISO 9001: 2015 Clauses						
	4	5	6	7	8	9	10
Determine	12	2	3	13	6	2	3
Monitor	3	0	1	0	4	8	0
Consider	1	0	2	3	4	0	1
Evaluate	1	0	2	1	1	4	1
Apply	1	0	0	0	5	0	0
Use	0	1	0	2	4	1	0

PRESENTATION - 11

Technical Presentation

on

Implementation on context, Interested party requirements and Risk & Opportunity

@

Omnex India Pvt Ltd

Chennai

18th & 19th Aug 2017

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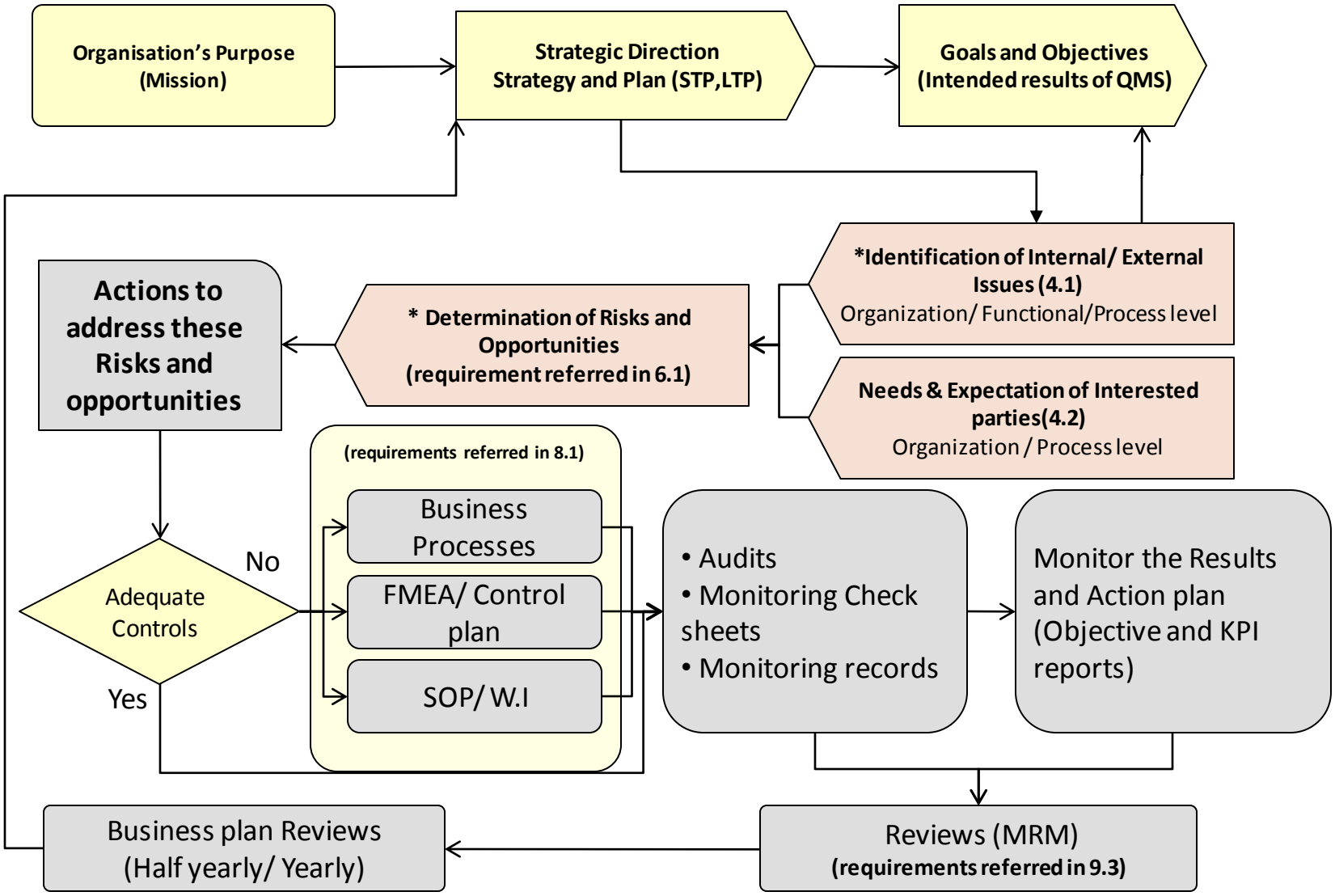
DRIVING WORLDWIDE
BUSINESS EXCELLENCE

1. RISK BASED THINKING APPROACH ON QUALITY MANAGEMENT SYSTEM



2. STRATEGIC DIRECTION

3. CONTEXT – INTERNAL AND EXTERNAL ISSUES

INTERNAL FACTORS	EXTERNAL FACTORS	TOOLS USED
Governance Organization Structure Policy Objectives and Strategies Capabilities Resources Knowledge Values and Culture Internal stakeholders	Legal Technology Culture Natural Economic environment (International, National, Regional and Local)	PESTLE Analysis SWOT Analysis Brainstorming Porter's 5 forces analysis

4. INTERESTED PARTY NEEDS AND EXPECTATIONS

INTERESTED PARTY	NEEDS AND EXPECTATIONS DERIVED FROM
Customer Supplier Employees Board of Directors Group Companies Legal bodies (To be varied from different organizations)	Experts Opinions, Feedback, Survey results, Agreements, Contractual agreements, Statutory and regulatory norms pertaining to the organization

5. RISK AND OPPORTUNITY

Context

Internal and External Issues

Interested Party Requirements

Identify the interested party and their requirements

Risk

Uncertainty of events affects objectives

Opportunity

Uncertainty of events that enhances objectives

Risk Treatment

Tolerate Risk
Treat Risk
Transfer Risk
Terminate Risk
Enhance Opportunity

Action to address Risk and Opportunities

Identify Process Establish QMS
Revise Process
Revise Existing QMS
Establish new Quality objectives and KPIs
Revise Quality objectives and KPIs

Category of Risk and Opportunity

Strategy risk
Operational risk
Human resource risk
Financial risk
Hazard risk
Regulatory risk
Technology risk
Reputational risk

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Thank You