Process Audit Matrix

Standard Section:	Process											
	Leadership	Planning	Training	Maintenance	Calibration	Sales	Purchasing / Receiving	Product Design	Production	Repair	Performance Evaluation	Improvement
4 Context of the Organization												
4.1 Understanding the organization and its context	X											
4.2 Understanding the needs and expectations of interested parties	X											
4.3 Determining the scope of the quality management system	X											
4.4 General Requirements	X											
5 Leadership												
5.1 Leadership and commitment	X											
5.2 Policy	X											
5.3 Organizational roles, responsibilities, and authorities	X											
6 Planning												
6.1 Actions to address risks and opportunities		X										
6.2 Quality objectives and planning to achieve them		X										
6.3 Planning of changes		X										
7 Support												
7.1 Resources	X	X	X	X	X	X	X	X	X	X	X	X
7.2 Competence			X									
7.3 Awareness	X	X	X	X	X	X	X	X	X	X	X	X
7.4 Communication			X									
7.5 Documented information	X	X	X	X	X	X	X	X	X	X	X	X
8 Operation												
8.1 Operation Planning and Control									X	X		
8.2 Requirements for products and services						X						
8.3 Design and Development								X				
8.4 Purchased Products and Services							X					
8.5 Production and Service Provision									X	X		
8.6 Release of products and services									X	X		
8.7 Control of Non-conforming product							X		X	X		
9 Performance Evaluation												
9.1 Monitoring, measurement, analysis, and evaluation											X	
9.2 Internal Audit											X	
9.3 Management Review											X	
10 Improvement												
10.1 General												X
10.2 Corrective Action												X
10.3 Continual Improvement												X

Process Name	Documents Defining the Process	Process Inputs	Process Outputs
Leadership and Planning	Process data worksheet; Business Operations Manual	ISO 9001 Standard	Documents and communication to the organization

Supporting Documents
QP-001 Document Control; QP-002 Control of Records; Records: QMS Scope, Organization Chart, Quality Policy, Quality Objectives, Plan to meet objectives, Planned changes to QMS

Clause	Directly Applicable Requirements	Information:	Objective Evidence	Process Measure:
4.1	Internal and External Issues	Issues		Top Line Sales
4.2	Needs of Relevant Interested Parties	Needs		Goal: Budget met
4.3	Scope	Scope		Jan: Y
4.4	QMS Processes	Process Documents		Feb: Y
5.1	Leadership Commitment			Mar: N
5.2	Policy	Quality Policy		Apr: N
5.3	Roles and Responsibilities	Responsibilities and Authorities assigned		
6.1	Risks and Opportunities	Risk / Opportunities Spreadsheet, actions to address		
6.2	Quality Objectives (documented)	Quality Objectives		
6.2.2, 6.3	Action plan to achieve Q objectives' Planning changes to the QMS	Action items, QMS changes		
4.4	Processes	Process documents		
7.3	Awareness			
7.5	Documented information	Documents, records		
8.1	Control of planned changes – including consequences and adverse effects			

Audit Notes:
Interviewed

Quality Indicators: Goal Jan17 Feb17 Mar17 Apr17

-

Intro to the Core Tools

APQP • FMEA • MSA • SPC • PPAP

WISCONSIN MANUFACTURING

EXTENSION PARTNERSHIP

Contents

Intro to the Core Tools

Chapter Objectives:

-Brief overview of Advanced Product Quality Planning

Application of APQP?

Stages of APQP?

How does APQP links to the Standard?

Benefits of APQP?

APQP

APQP stands for Advanced Product Quality Planning..

- it is how a new or revision to an existing product is designed, developed, manufactured and controlled

APQP is..

- A process, not an event
- Structured methodology
- Assures customer satisfaction

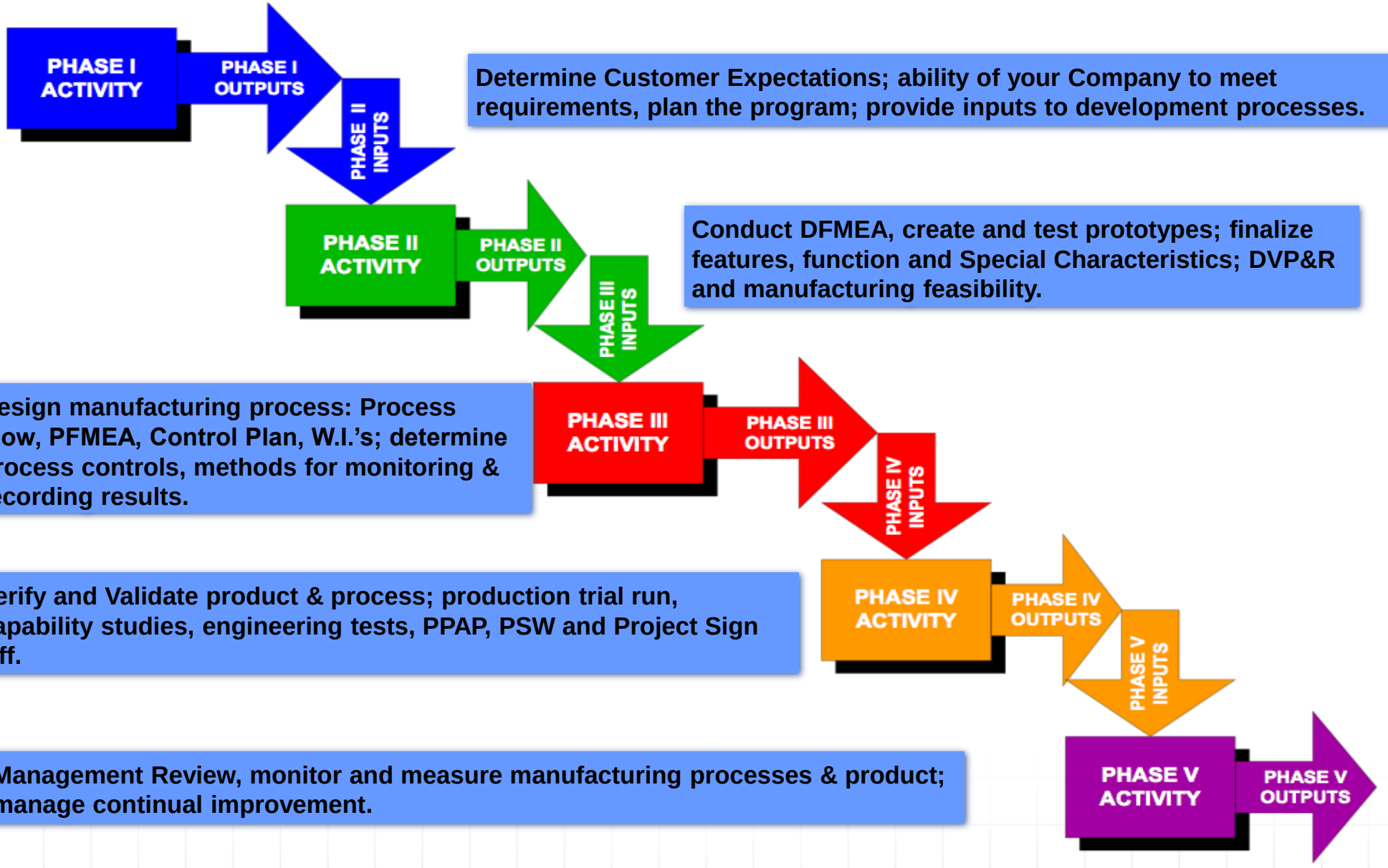
The output of APQP is..

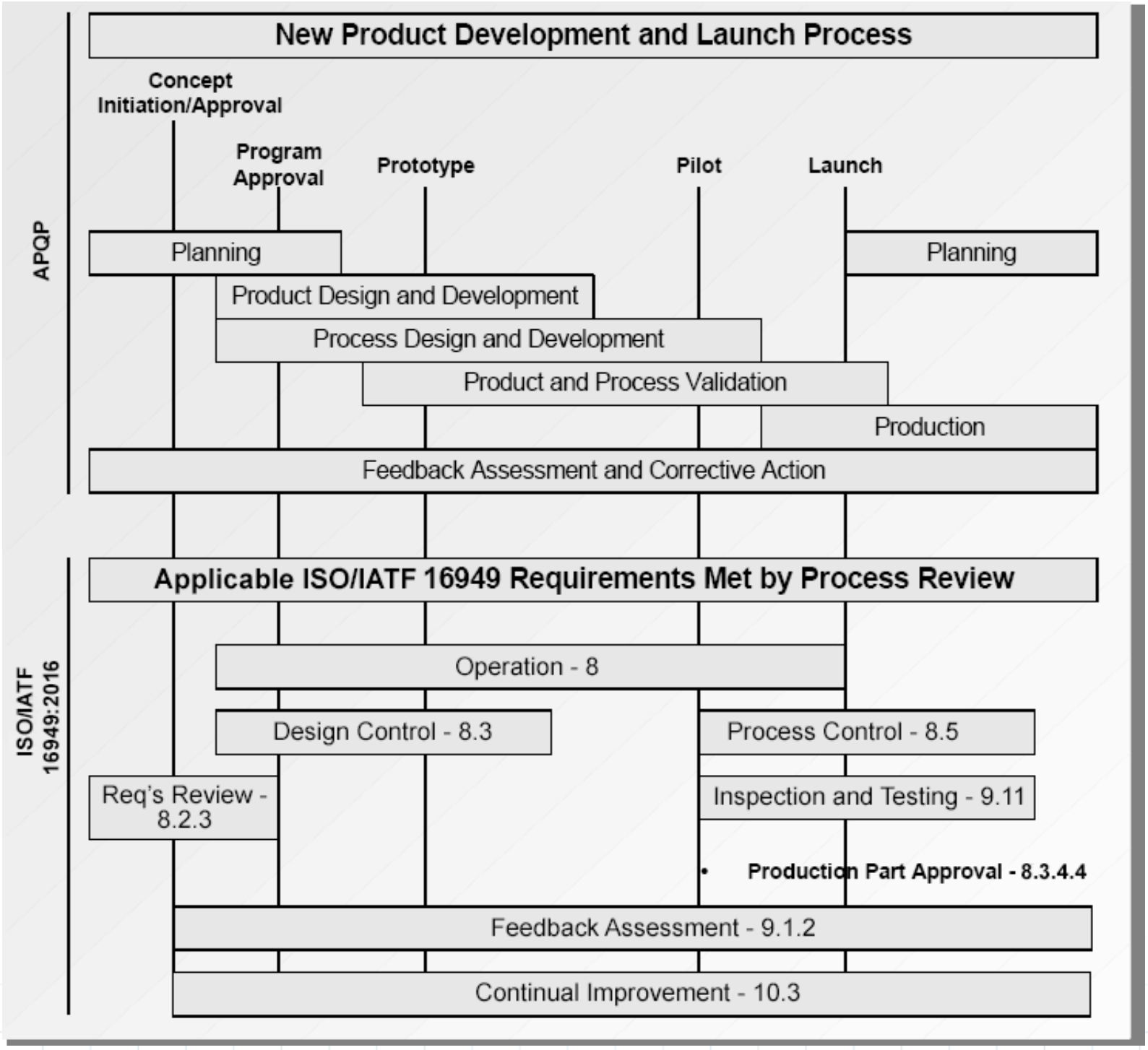
- Is the Continual Improvement of Operation (formerly "Product Realization")

Application

- **Existing Products**
  - After product launch, process monitoring and review is used …
    - as a catalyst for continual improvement
    - to prevent defects
    - as a means for enforcing plant-floor discipline for controlling characteristic variation
- **New Products**
  - For new products, the existing process monitoring and review knowledge base…
    - acts as an input to the Product Development process
    - brings the operator into the initial phases of product and process design
- **Transfer Products**
  - Moving product manufacturing from one site to another

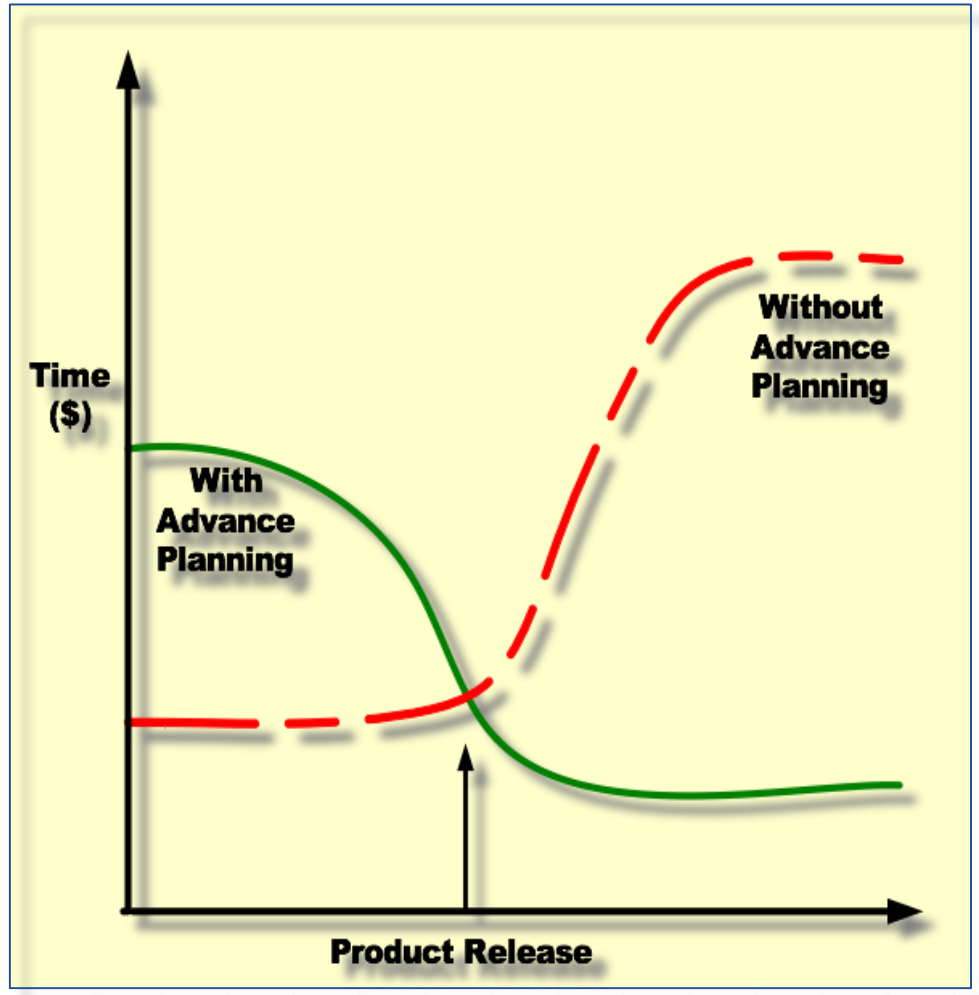
Outputs of Each Phase are Inputs to Subsequent Phases

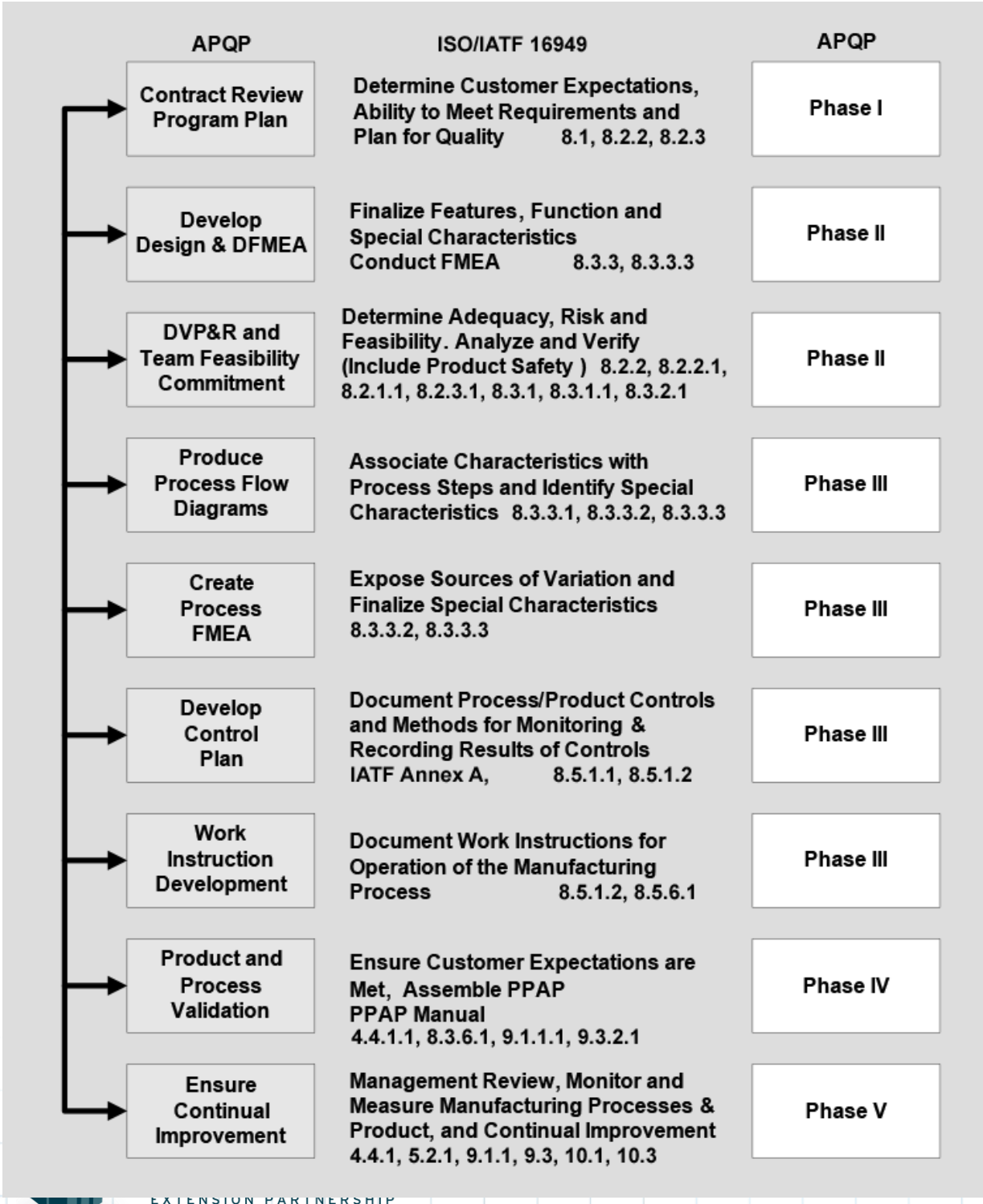



New Product Development and Launch Process
APQP
Concept Initiation/Approval
Program Approval
Prototype
Pilot
Launch
Planning
Planning
Product Design and Development
Process Design and Development
Product and Process Validation
Production
Feedback Assessment and Corrective Action
ISO/IATF 16949:2016
Applicable ISO/IATF 16949 Requirements Met by Process Review
Operation - 8
Design Control - 8.3
Process Control - 8.5
Req's Review - 8.2.3
Inspection and Testing - 9.11
• Production Part Approval - 8.3.4.4
Feedback Assessment - 9.1.2
Continual Improvement - 10.3

APQP

- **Benefits**
  - Resources are directed toward customer satisfaction
  - Early identification of required changes
  - Changes close to or after product launch are avoided
  - Process can successfully accommodate unavoidable changes
  - A quality product is provided on time at the lowest cost
  - Basis for continual improvement





Refer to APQP Manual for Phase Descriptions

APQP includes..
-Manufacturing Process Design & Review
-cannot be excluded from the Quality Management System

Management Review

Inputs (partial list)

- Results of audits
- Customer feedback
- Process performance and product conformity
- ***APQP status***
  - ***Measurements at specific stages***
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the Quality Management System
- Recommendations for improvement
- Analysis of actual and potential field-failures and their impact on quality, safety or the environment

Contents

Introduction to the Core Tools

- *Chapter 1 – APQP*
- ***Chapter 2 – FMEA*** ⟵
- *Chapter 3 – MSA*
- *Chapter 4 – SPC*
- *Chapter 5 –PPAP*

Chapter Objectives:

-Brief overview of Failure Mode & Effects Analysis

Design FMEA?
Process FMEA?
Keys to Success?
How does FMEA link to the Standard?

FMEA Definitions - DFMEA/PFMEA

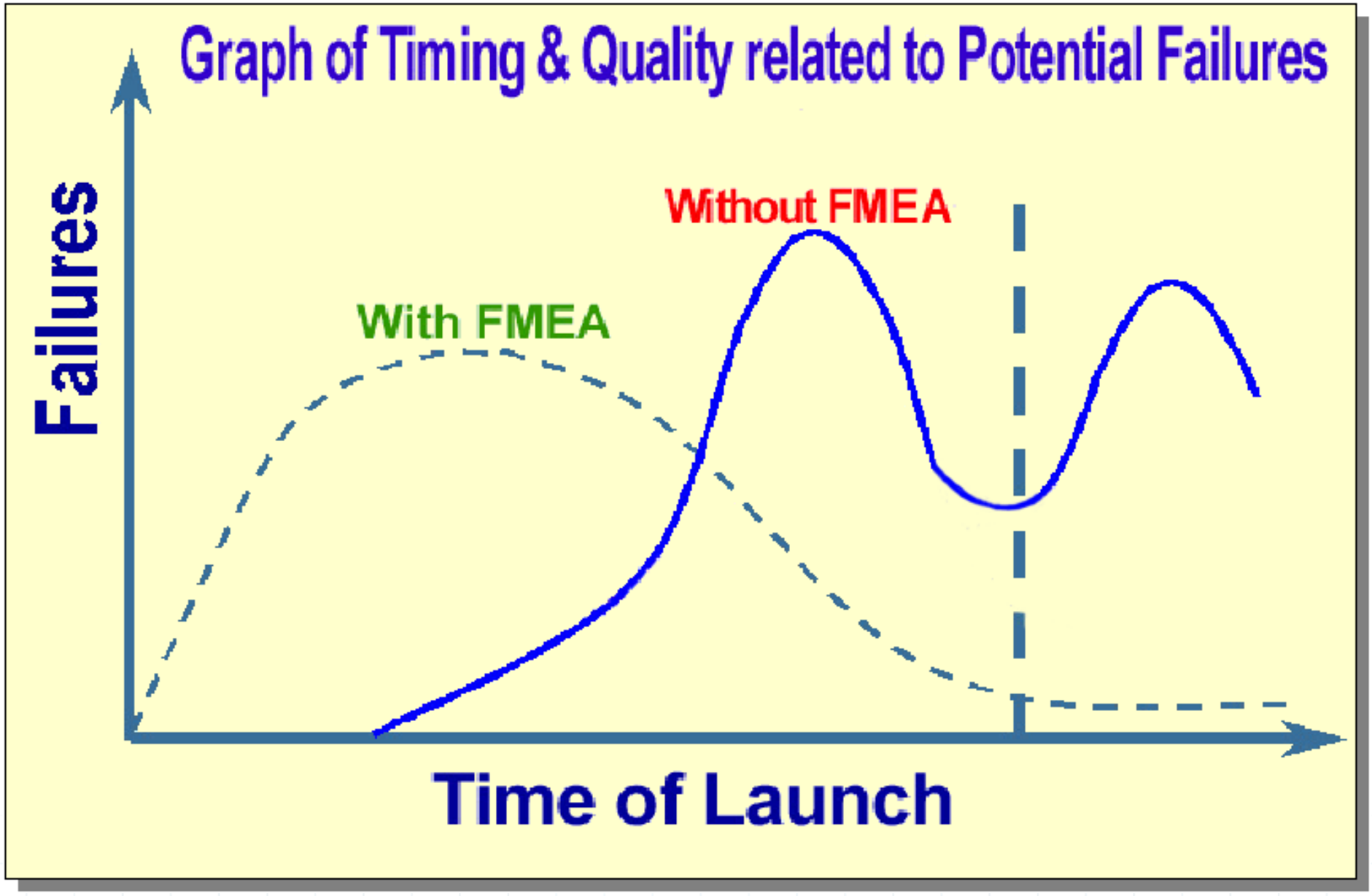
Design Failure Mode and Effects Analysis

- Analytical technique used by design responsible engineer/team
- Ensures that potential failure modes and associated cause/mechanisms are considered and addressed
- A Standardized method of identifying, evaluating, and prioritizing risks from design causes
- To prevent the “customer” from experiencing failure modes
- Design for manufacture and assembly
- Meet product expectations

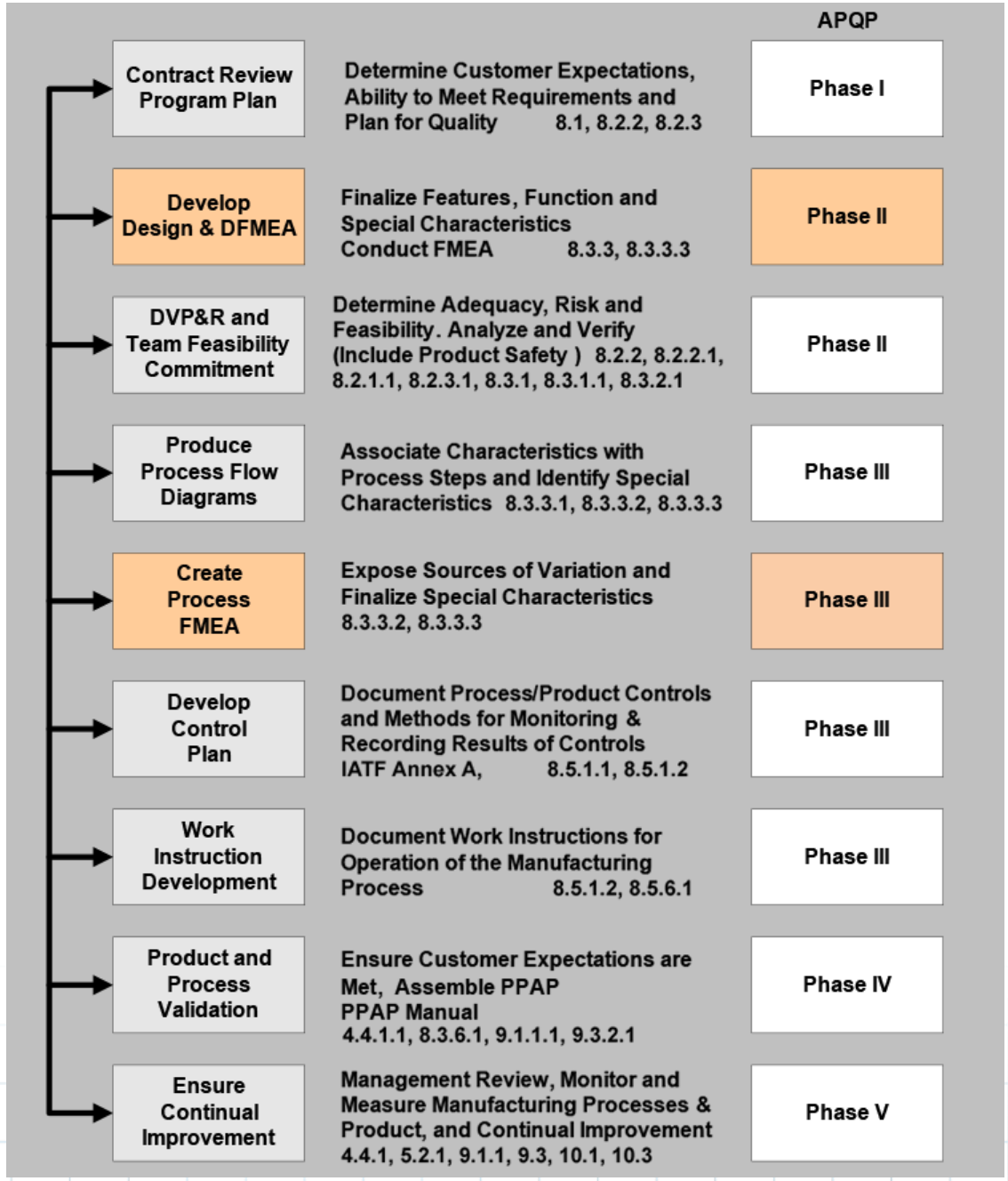
Process Failure Mode and Effects Analysis

- Analytical technique typically led by process responsible engineer
- Intent: to ensure that potential failure modes and their causes are considered and addressed
- Manufacturing, assembly, engineering team summarizes items that could go wrong as a process is developed. It formalizes the mental discipline that should be used in planning any manufacturing process.

Program Effectiveness



Process FMEA development step in Advanced Product Quality Planning



FMEA- Design/Process

Linkages to IATF 16949:2016

- 8.3.3.3– Multidisciplinary Approach
- 8.3.5.1 – Design and Development Outputs
- 8.3.3.3 – Special Characteristics
- 8.3.5.2(i)– Control Plan-Mfg. Process Design
- CSR – PPAP, APQP and FMEAs

Keys to FMEA team success

- Support from management
- Scope not too large
- Objectives well defined
- Objectives considered relevant and significant
- A measurable objective for effectiveness- identified
- Team right-sized for the task
- Time allotment for analysis and improvement
- Effective training
- Activity integrated with organization's development process
- Input information and data are available

Contents

Intro to the Core Tools

- *Chapter 1 – APQP*
- *Chapter 2 – FMEA*
- ***Chapter 3 – MSA*** ←
- *Chapter 4 – SPC*
- *Chapter 5 –PPAP*

Chapter Objectives:

-Brief overview of Measurement Systems Analysis

What is a Measurement System?
Application of MSA?
What is measurement uncertainty?
How to implement a good Measurement System?

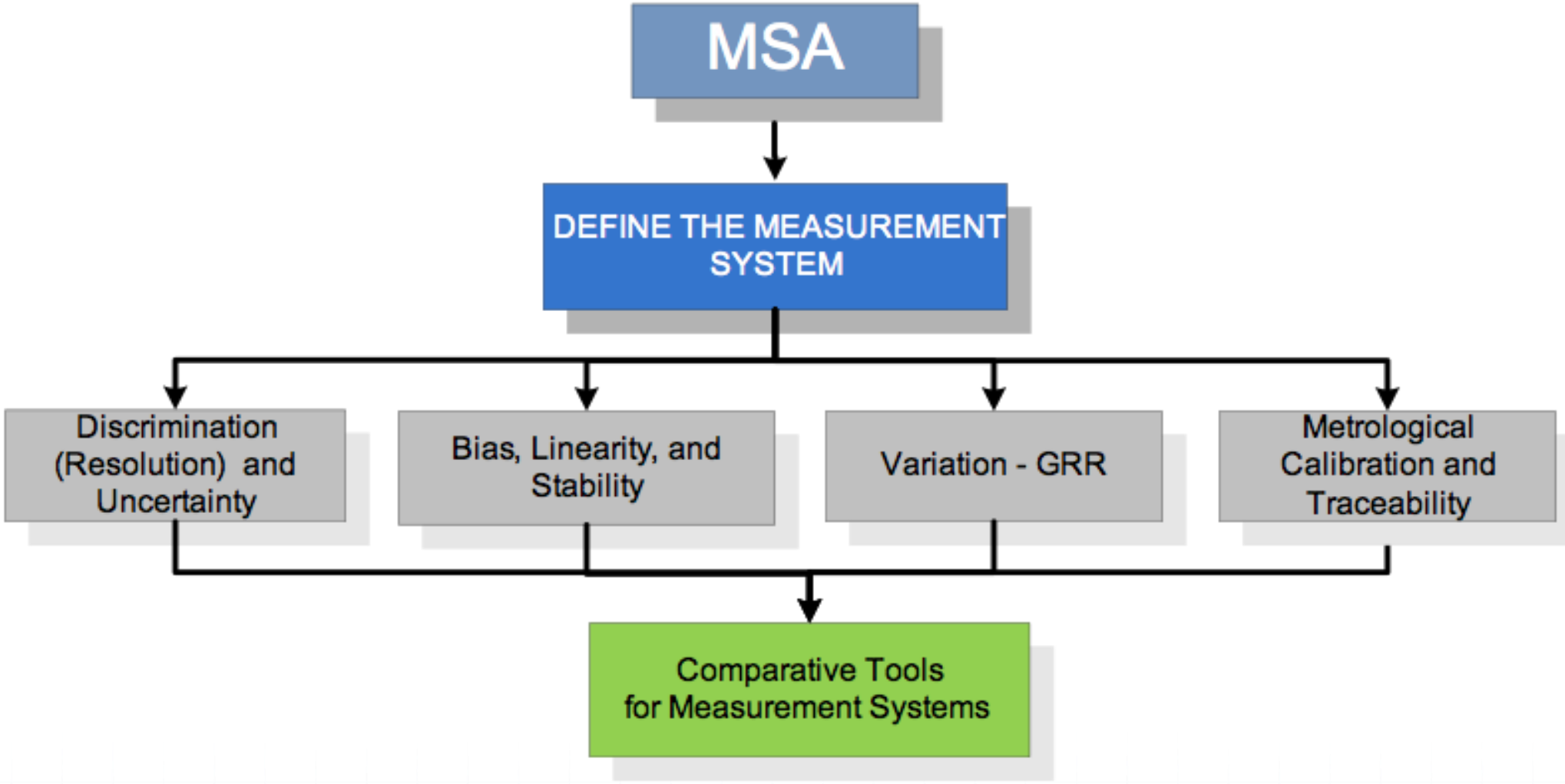
What is a Measurement System?

A 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 a feature characteristic being measured. It is the complete process used to obtain measurement.

What is MSA?

- **Measurement System Analysis (MSA)**
  - MSA establishes a uniform method to understand what measurement system analysis is
  - The objective of MSA is to qualify the measurement system for use in manufacturing
- **The measurement system is verified to determine its statistical properties, and the use of them in conformance with accepted standards, our needs and customers' requirements.**

Application of MSA



Measurement System Analysis

To evaluate a measurement system, determine if:

- It has adequate resolution
- It is statically stable over time
- Statistical properties are consistent over the expected range and are acceptable for process analysis of control
- The sum of all the variables is an acceptable level of measurement uncertainty.

Measurement System Analysis (cont'd)

Uncertainty of Measurement

- The range within which the true value of a characteristic is estimated to reside
- Can be expressed as statistical distribution of a series of measurements, standard deviations, probability, percentages, error as the difference between actual value minus the true value as a point on a control chart or diagram, etc.

Measurement knowledge to be obtained

- How large is the measurement error?
- What are the sources of measurement error?
- Is the measurement system stable over time?
- Is the measurement system capable for the study?
- How can the measurement system be improved?

Implementing Good Measurement Systems

- Identify all inspection, measuring and test equipment (IMT) and show calibration status
- Ascertain accuracy and precision of IMT
- Conduct variation studies of IMT (MSA)
- Determine validity of previous results when IMT is found out of calibration

Implementing Good Measurement Systems
(cont'd)

- Establish comprehensive procedures for handling, preservation, cleaning, maintenance and storage of all IMT
- Records of calibration shall include employee gages
- Use all criteria (requirements) of MSA

PPAP 4th edition
MSA Requirements

- **2.2.8 MEASUREMENT SYSTEM ANALYSIS** shall include bias, linearity, stability and Gage R&R studies for all new or modified gages, test and measuring equipment.

Practical Sense
MSA Requirements

- What is in the Control Plan?
- Does it cover Process and Product Parameters?
- Does it cover IMT from incoming to outgoing shipments?
- Does it cover end of line and requirements for downstream activities?
- Does it cover lab equipment used for testing and analysis?
- Does it cover IMT for characterization and validation testing?

Contents

Intro to the Core Tools

- *Chapter 1 – APQP*
- *Chapter 2 – FMEA*
- *Chapter 3 – MSA*
- ***Chapter 4 – SPC*** ←
- *Chapter 5 –PPAP*

Chapter Objectives:

-Brief overview of Statistical Process Control
What is variation?
What is stability?
What are causes of variation?
Capability vs. Stability?
What are some tools?
How does SPC link to the Standard?

SPC

Acronym for Statistical Process Control

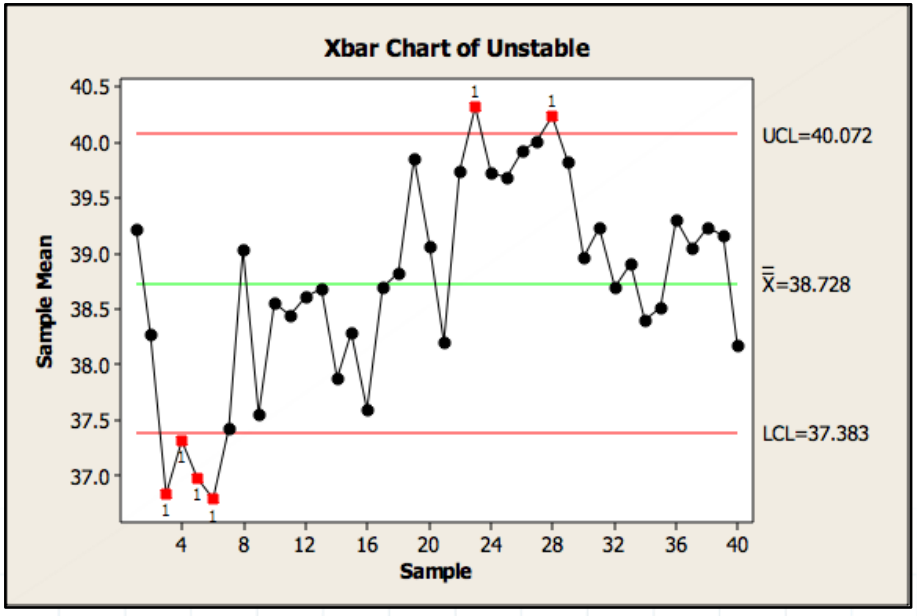
- Primarily deals with analyzing variation to improve process performance in any area or process
- Focuses on prevention not detection

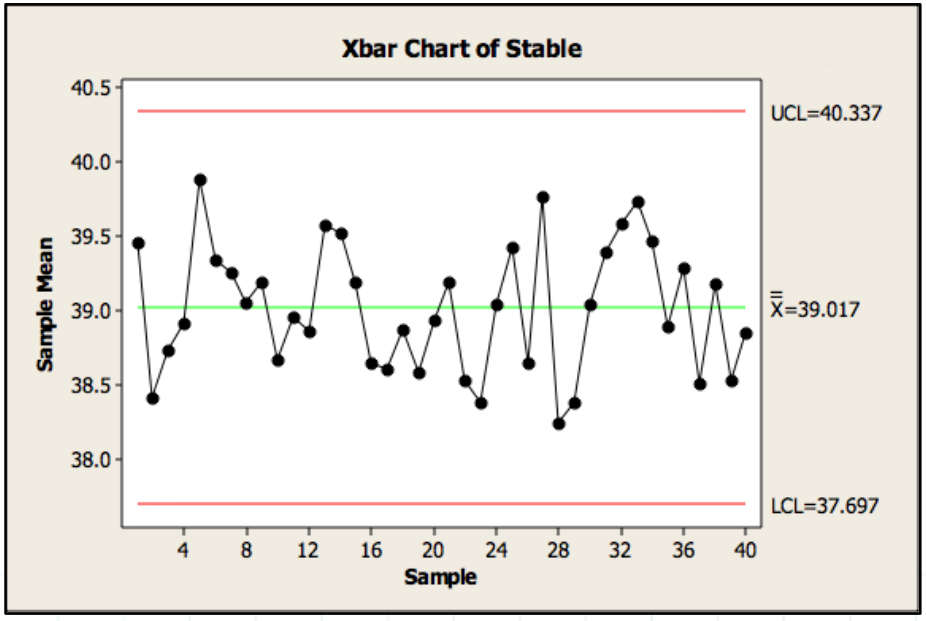
Fundamental issues

- Understanding of common vs. special cases of variation
- Understand the concept of process capability vs. process control
- Measurement system must be under control (MSA)

Stability

- When the variation is due to common causes only, the process is said to be stable
- A stable process has predictable variation
- A stable process is also called a process in “Control”
- Control Charts are used to illustrate stability





SPC – Variation

- **A process is in control (stable) if:**
  - There is no variation in the location of the center of the distribution of output over time
  - There is no variation in measures of the dispersion (spread) of the distribution of output over time
- **A process is out-of-control (unstable) if:**
  - There is variation in the location of the center of the distribution of output over time
  - There is variation in measure of the dispersion (spread) of the distribution of output over time

Causes of Variation- Examples

Common Causes of Variation

- Typical traffic on the road
- Typical play in the slides of a machine
- Human attentiveness
- Variation in dimensions in a manufactured batch

Special Causes of Variation

- Accident on the road
- Excess play in a slide, due to wear, over time
- Illness
- Variation due to change in a batch or supplier

SPC – Causes of Variation

- **Common-cause variation** is always present in a process; a process is considered stable and predictable when limited to this variation

- **Special-cause variation** is caused by unusual or external events not related to the common causes of variation, making the process unpredictable and unstable

Capability vs. Stability

- When a process is out of control, the QMS must first stabilize the process
- Capability: how effectively a process performs
- Capability is a term used in reference to a stable process

Improve Capability

- The first job of a quality specialist is to identify and eliminate special causes of variation
- Once the process becomes stable, the next step is to identify the causes of inherent variation and eliminate them.
- Improvement in capability can be fulfilled only when the process is stable

Some statistical tools used?

- X-bar, R-charts
- Capability (Cpk, Ppk)
- Run charts
- Cause & Effect Analysis
- Affinity
- Histogram
- Pareto
- Scatter Diagram

Linkages to ISO/IATF 16949:2016

- 9.1.1.2 Identification of Statistical Tools
- 9.1.1.3 Knowledge of Basic Statistical Concepts
- 8.5.1.1 Control Plan
- 7.1.5.1.1 Measurement System Analysis
- Customer Specific Requirements
- Core Tools:
  - APQP, PPAP, SPC, MSA

Contents

Intro to the Core Tools

Chapter Objectives:

-Brief overview of Production Part Approval Process

What is PPAP?

What is the purpose of PPAP?

When is PPAP required?

Notification?

Submission?

Production Part Approval Process (PPAP)

Definition: a standardized method developed for use by suppliers to automotive customers to submit approvals for new or changed parts to their customers prior to fulfilling production orders.

PPAP Manual 4th edition defines these requirements.

Purpose:

-To determine whether all automotive customer engineering design specification and record requirements are properly understood by the supplier

-To ensure the supplier has the capability to produce product consistently meeting these requirements during an actual production run

Scope of PPAP

ISO/IATF16949:2016 8.3.4.4 Product approval process states that a supplier to an automotive customer must conform with a product and manufacturing process approval procedure defined by the customer.

- The same approval procedure must also be applied to its own suppliers.

PPAP includes:

- **Internal & external suppliers of Bulk *(when requested by the customer)* and Production Materials**
  - includes service parts

- **Standard cataloged production or service parts, unless formally waived by the customer.**

PPAP is required when:

-You are producing a new part or product where the specific parts, materials or color have not previously been supplied to that specific automotive customer

-Correction of a Discrepancy on a part previously submitted

-An engineering change to design records, specifications or materials for production product/part numbers

-Product modified by engineering change

-New process technology for Bulk Materials

Customer Submission & Notification

- **Customers may require different levels of documents submitted to them for PPAP approval. This is referred to as a Submission Level.**

- **At various times during the product life cycle, the supplier to the automotive customer may be required to notify the supplier (submit documents/data) based on various criteria.**
  - Re-submission may also be required. The Customer may elect to require a PPAP re-submission or may formally waive the requirement.

Customer Notification & Re-submission Requirements

Occurs when there is any design, process, or site changes for:

Other construction or material than previously

- New or modified tooling, dies, molds, patterns
- Following an upgrade or rearrangement of existing tooling or equipment
- Production from a tooling and equipment transfer to a different plant or an additional location
- Changes of supplier for parts or services

Customer Notification & Re-submission Requirements

Occurs when there is any design, process, or site changes for:

- Product produced after tooling has been inactive for 12 months or more
- Product and process changes of components of the production product-internally or supplied
- Changes in test inspection methods-new technique (no effect on acceptance criteria)
- For bulk materials: a) new source of raw material from new or existing supplier b) change in product appearance attributes

When Submission is not Required

- **Changes to Component level drawings, made internally or by its suppliers, that do not impact the design record for the product supplied to the customer**
- **Tool movement within the same plant (used in equivalent equipment, no change in process flow, no disassembly of the tool)**
- **Equipment movement within the same plant (no change in process flow, same equipment).**
  - *Be sure to ask your customer supplier quality representative. Note: Some OEM customers do require notification and approval prior to moving equipment.*

When Submission is not Required

- **A customer waives a formal submission (must be received in writing or by email by a responsible customer representative)**
- **Identical gage replacement**
- **Rebalance of operator job content with no change in process flow.**
  - *Always ask your customer supplier quality representative. Note: Some OEM customers do require notification and approval when rebalancing operator job content.*
- **Changes resulting in reduced RPN (risk priority number) on PFMEA (no change to process flow)**

Major change from PPAP 3rd edition and the PPAP 4th edition

Your organization is required to enroll in the International Material Data System (IMDS)

You are required to input your product content into your company's IMDS profile in the system

Remember!

- All items in the PPAP file must be created, reviewed, updated and retained, regardless of what documents the customer requires for submission.
- If the customer grants a waiver, the PPAP file must contain the name of the person responsible for granting the waiver and the date
- Customer notification is required any time customer product requirements for fit, form, function, durability and performance are affected.
  - Includes both product and process changes
- PPAP documents are legal documents that must be controlled responsibly, including compliance with specified retention times

Quiz Time.

Thank you for your participation.

Understanding the Requirements of IATF 16949:2016

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EXTENSION PARTNERSHIP

Internal Auditor Training

Introduction

IATF 16949:2016 is the latest standard for Quality Management Systems Requirements for Automotive Production and Relevant Service Parts Organizations

***

The previous version was the Technical Specification ISO/TS 16949:2009.

Both the 2016 and 2009 Standards include the requirements of ISO 9001:2015 and ISO 9001:2008 respectively.

***

In this presentation, the text of the Standard is paraphrased and expressed as directives for instructional purposes.

Refer to the standards for the actual text.

Topics Covered

1. Fundamentals	2. Basics of a QMS and IATF 16949	3. IATF 16949:2016 Requirements	4. Managing the IATF 16949 QMS
• Who is IATF? • What is a Management System? • Plan Do Check Act • Process approach • Risk Based Thinking	• What is a QMS? • What is ISO 9001? • Benefits of certification • Elements of ISO 9001:2015	• Key Elements • Documenting your QMS • Implementing the QMS in your company • Training People • Auditing the QMS • Certification	• Key elements of an IATF 16949 QMS • IATF 16949 registration

Section 1 - Fundamentals

- Who is ATF?
- What is a Management System?
- P-D-C-A Continual Improvement Cycle
- Process Approach
- Risk-Based Thinking

Who is IATF?

IATF stands for International Automotive Task Force

- **IATF develops Standards for use in the automotive industry worldwide.**
- **The Automotive Quality Management System Standard, IATF 16949:2016, cannot be considered a stand-alone QMS Standard. It has to be understood as a supplement to and used in conjunction with ISO 9001:2015, a separate ISO Standard.**
- **Global standards are needed so everyone can be equally measured.**
  - Different countries can compare “apples to apples”
- **ISO Standards always defer to state, local and federal requirements.**
  - Different statutory and regulatory requirements will apply.

PDCA and the Requirements

P = Plan, the processes

- Clause 4 – Context of the Organization
- Clause 5 – Leadership
- Clause 6 – Planning

D = Do, implement the plan

- Clause 7 – Support
- Clause 8 – Operation

C = Check, the results

- Clause 9 – Performance Evaluation

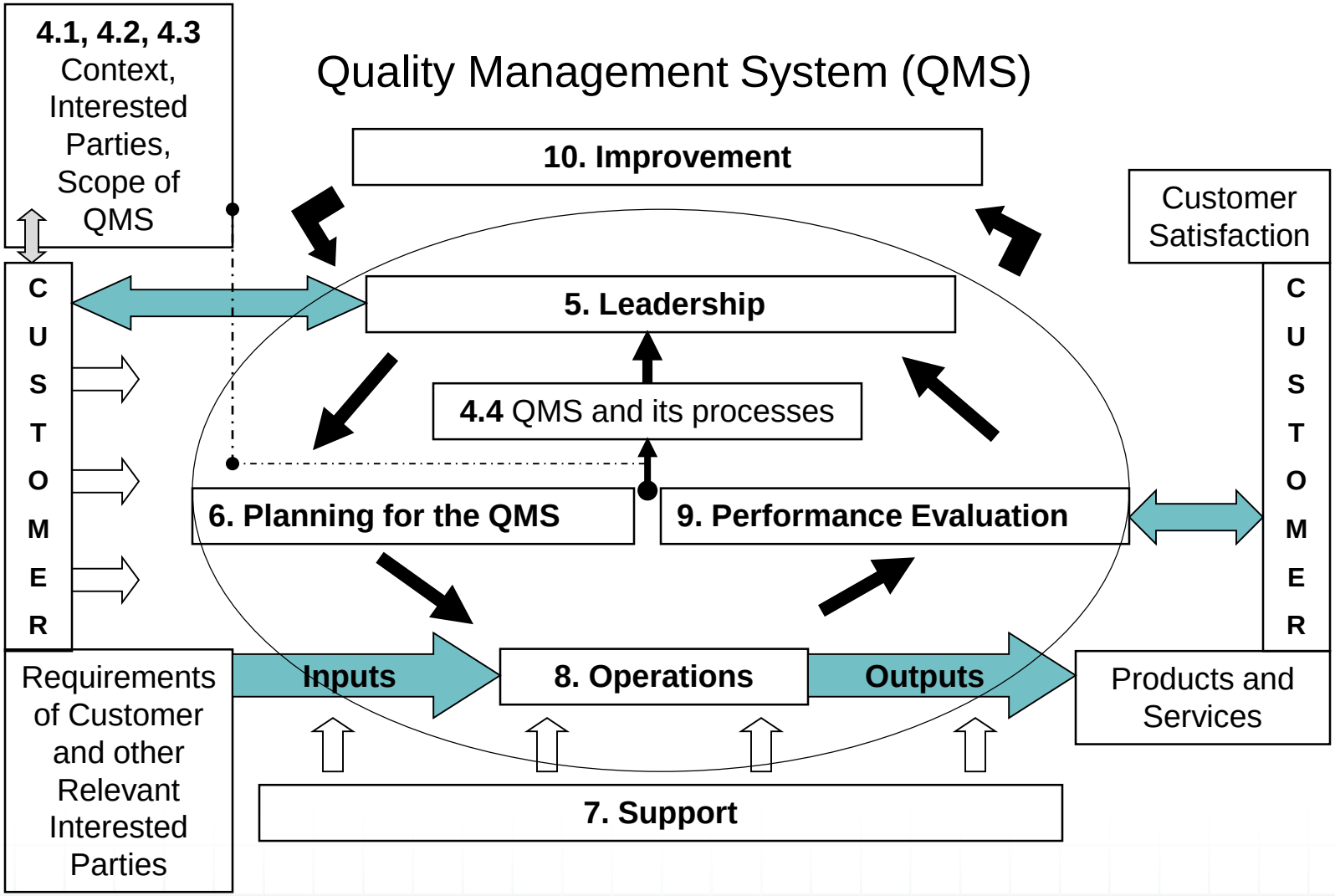
A = Act, take actions to improve

- Clause 10 – Improvement

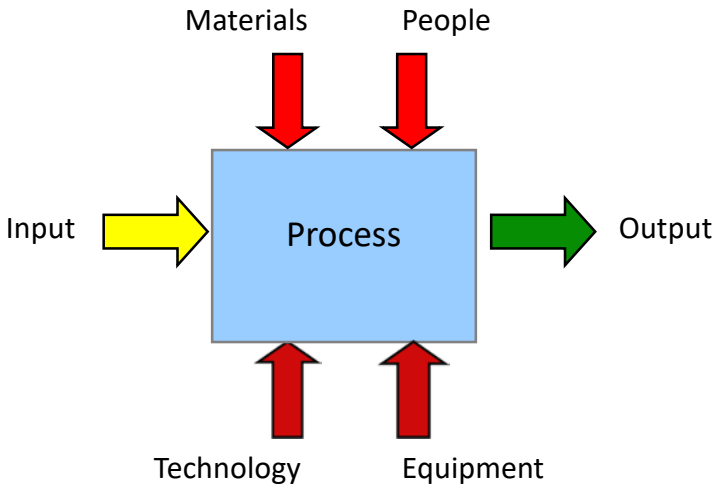
The Process-Based Model

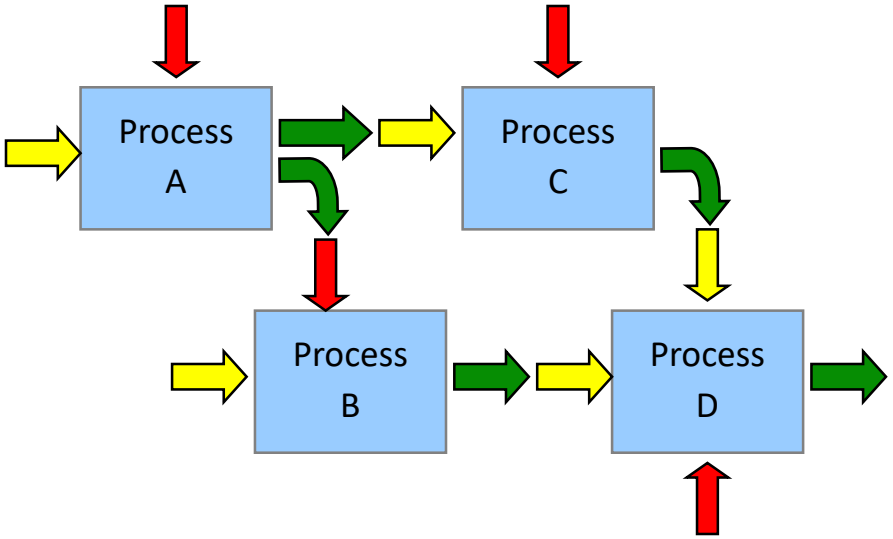
- An organization is a system of interrelated processes that function as a coherent system.
- The standard is geared at managing and improving those processes.
- Key processes, those that lead to process outputs, must be identified.
- Methods to measure and control the processes must be included.
- Risks and opportunities need to be determined and actions to address them implemented.

The Process-Based Model



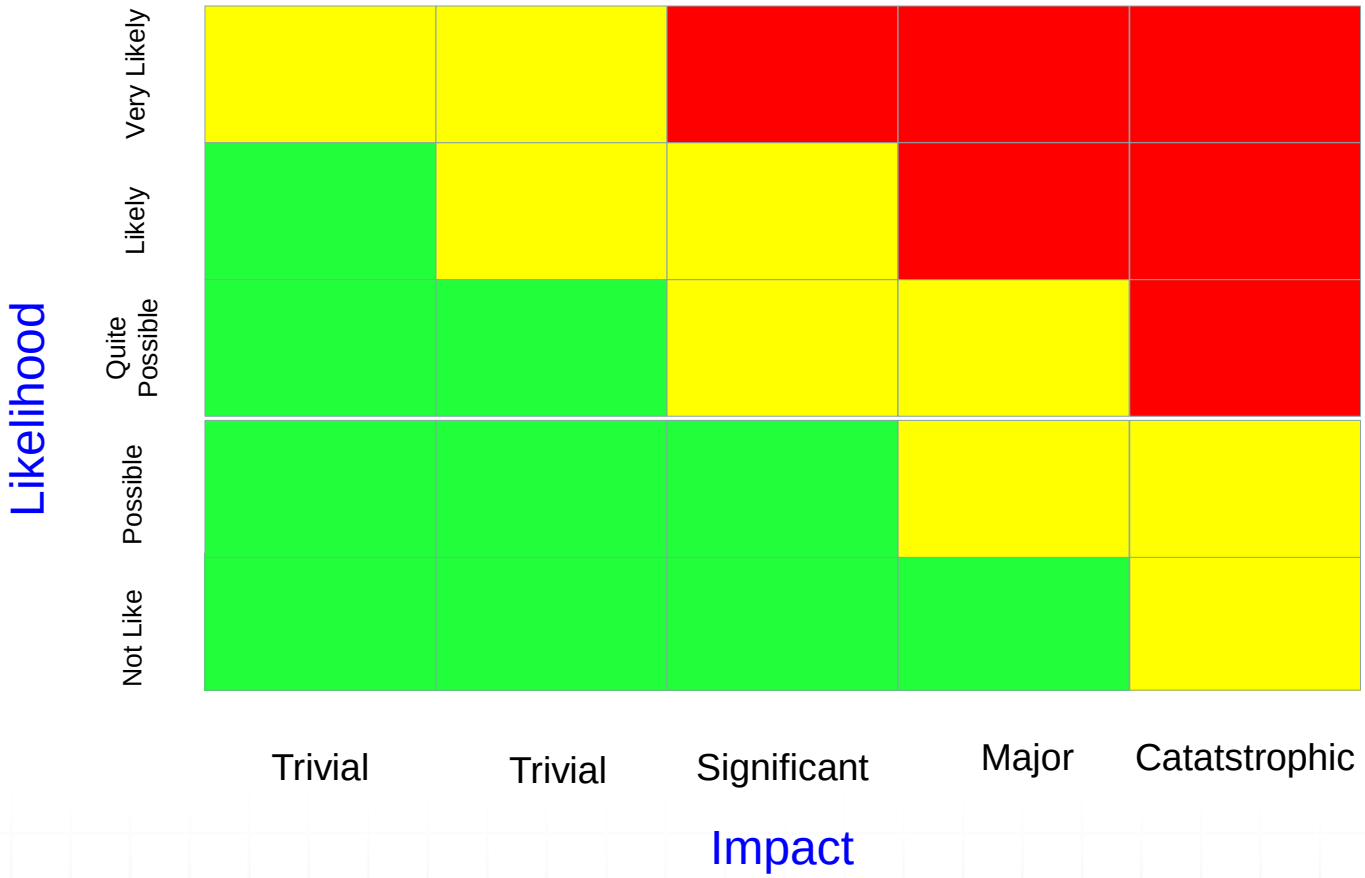
Process Approach





- **Look at your business as a *series* of interacting processes, not departments.**
- **If you break down the process, you can improve them for consistent results**
- **Require that your processes are controlled and managed for continual improvement.**

Risk-Based Thinking – An informal risk management system aimed at improvement



Risk-Based Thinking – Example: What can go wrong with a Process?

- **Purchasing Process**
  - Single Source supplier is wiped out by Tsunami
- **What is the impact?**
  - You are shut down
- **What is the likelihood it will happen?**
  - Unlikely (But it happens)
- **How do you mitigate the risk?**
  - Find another supplier
  - Revise design to allow other options

Section 2: Basics of a QMS
What is IATF 16949:2016?

- What is a QMS?
- What is IATF 16949?
- What are the requirements of IATF 16949:2016?
- PDCA and the requirements
- Benefits of IATF 16949 Registration

What is a QMS?

A Quality Management System (QMS) determines and continuously improves a company's quality performance:

- Applies to any company throughout the world
- Does not mandate criteria a company must meet, like a certain "level of quality"
- Does not "rate" your company against others – only against the goals that you set.
- It is about consistently meeting/exceeding your customers' requirements
- It requires that you seek continuous improvement

QMS Example: Manufacturing

If you baked cookies… You have a recipe for success – it doesn't matter what it is. Your QMS would ensure your processes are controlled so you can meet your customers' requirements by producing your recipe consistently:

- Document Control – ensure everyone is using the same recipe
- Customer Requirements – ensure you know what they want
- Purchasing – the right ingredients matter
- Production – same size scoop, mix same way
- Environment – train people, control workplace, etc.
- Calibration – ensure oven is correct so they don't burn
- Risk – put timer on oven to prevent burning
- Audit – review orders to see if there were errors
- Etc.

What is IATF 16949:2016?

- Outlines the basic elements of a quality management system (QMS) which are basic business practices
- Was designed by experts from many different countries.
- Has been implemented by >1M organizations
- Utilizes the PDCA Cycle, the Process Approach and Risk-Based Thinking.
- A Quality Management System based on the ISO 9001 and IATF 16949 standards should be a strategic decision for top management because --

-- A strong and healthy QMS helps to improve the overall performance and becomes an integral part of sustainable development initiatives

Benefits of IATF 16949 Registration

Internal:

+ Consistent results

+ Improved operations

+ Optimized performance

+ Improved operating margin

External:

+ Global recognition

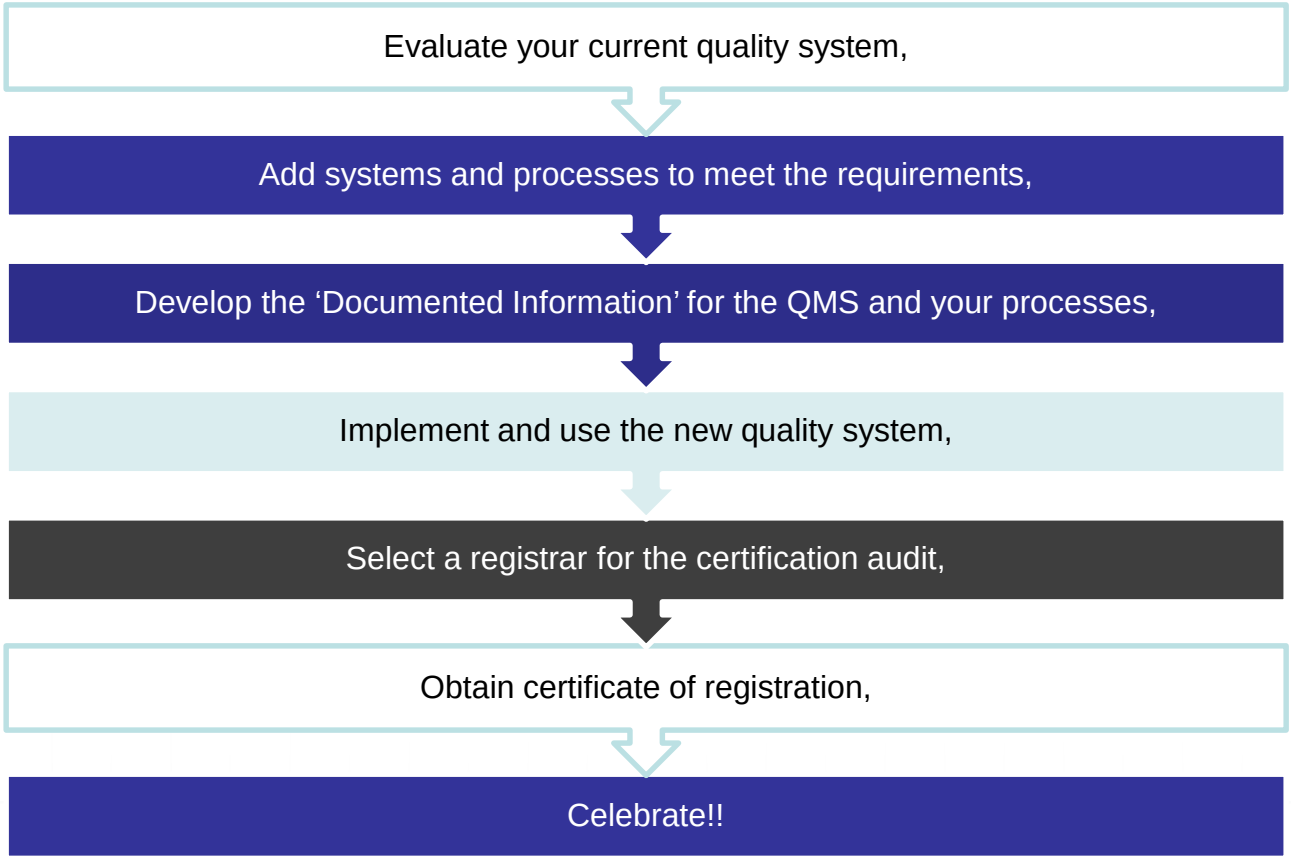
+ Market expansion

Employee Benefits of IATF 16949 Registration

- Improved communication
- Clearly defined process requirements for employees
- Training on Requirements
- Clear understanding of own roles and responsibilities
- Process to address problems
- Process to assess effectiveness of the QMS
- Ideas for continual improvement

What Is Needed for Registration?

To become registered a company must first implement the requirements of both ISO 9001:2015 and IATF 16949:2016.



Requirements

What Does IATF 16949:2016 Require?

What Are the Requirements?

The standard has 10 clauses, but only the last 7 contain requirements

- *Clause 1 - Scope*
- *Clause 2 - Normative References*
- *Clause 3 - Terms & Definitions*
- Clause 4 - Context of the Organization
- Clause 5 - Leadership
- Clause 6 - Planning
- Clause 7 - Support
- Clause 8 - Operation
- Clause 9 - Performance Evaluation
- Clause 10 - Improvement

4 Context of the Organization

This clause outlines requirements in 4 sub-clauses:

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the QMS

4.4 The QMS and its processes

4.1 Understanding the Organization and Its Context

4.1 To understand your organization and its context, you must determine the external and internal issues that are relevant and that affect the ability to achieve the intended results of the QMS,

-- and --

The information regarding these external and internal issues must be monitored and reviewed.

Remember to consider only issues relevant to your QMS

4.2 Understanding the Needs and Expectations of Interested parties

4.2 Interested parties may be customers, owners, suppliers, unions, bankers, etc. and to understand their needs and expectations, you must:

- Identify the relevant interested parties, determine, monitor and review their requirements that are Relevant to the QMS.

- Consider their expectations and needs and the impact on the ability to consistently provide products and services that meet customer and statutory and regulatory requirements.

4.3 Determining the Scope of the QMS

4.3 To determine and establish the scope of the QMS, your company must determine the boundaries and applicability of the QMS and must consider the:

- External and internal issues
- Requirements of relevant interested parties
- Requirements that can be applied
- Products and services of the company

4.3.1 Determining the scope of the QMS – IATF supplement

- Supporting functions such as on-site or off-site design centers, corporate head offices, distribution centers are included in the scope.
- Design and development of products, clause 8.3, is the only permitted exclusion.

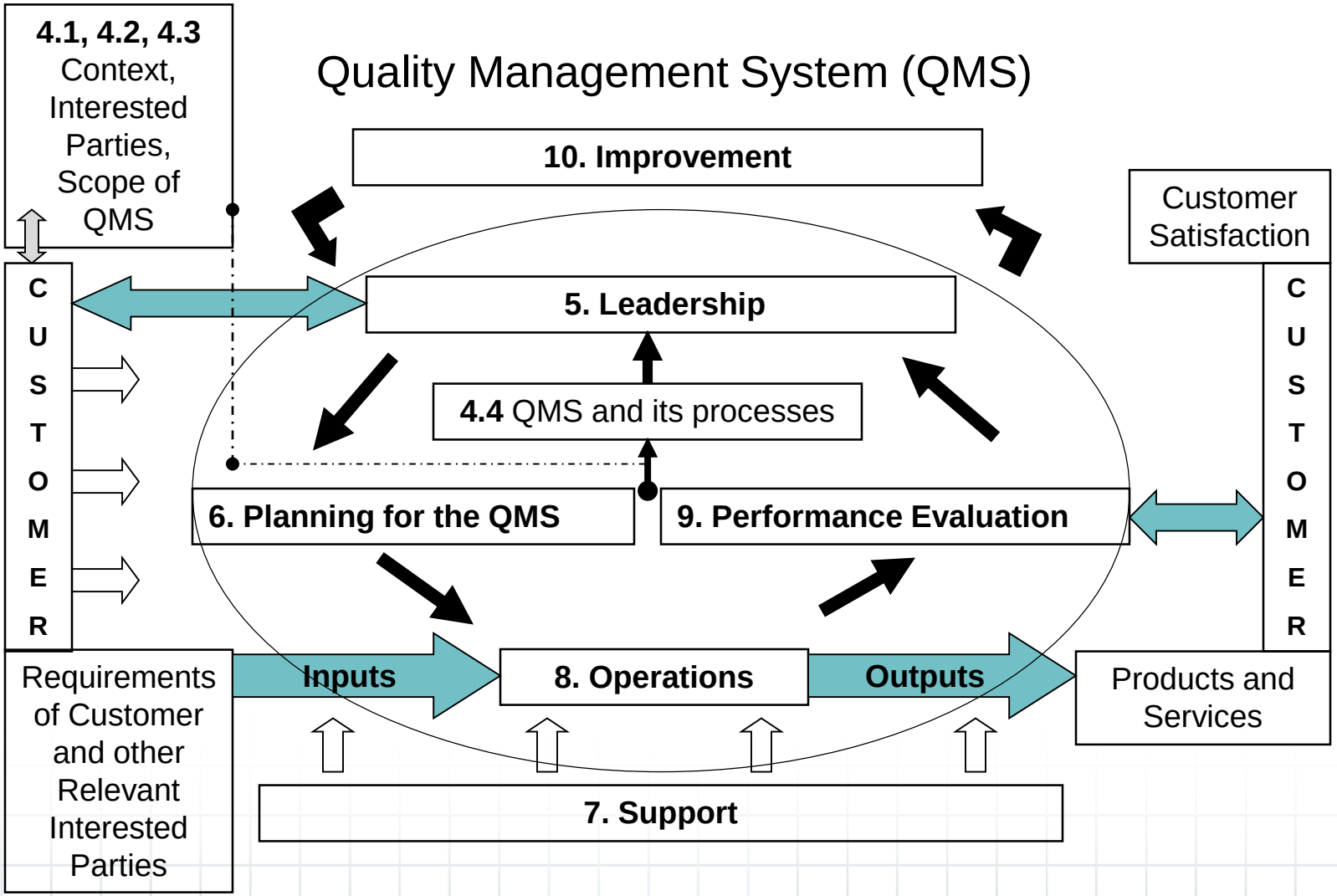
4.3.2 Customer specific requirements must be evaluated and included in the scope of the QMS.

4.4 Quality Management System and Its Processes

4.4.1 To establish, implement, maintain and improve the QMS, your company must determine the processes needed and their interaction and application throughout the company.

Keep in mind the "Process-Based" model that we saw earlier.

The Process-Based Model



4.4 Quality Management System and Its Processes

This 'process approach' will provide for the management of the QMS and its processes through the application of:

- A "Plan-Do-Check-Act" continual improvement methodology,
- A focus on "Risk-Based-Thinking" that leads to the 'prevention' of undesirable outcomes.
- An emphasis on conformance of products and services, (including those outsourced), to customer, statutory, and regulatory requirements.

4.4 Quality Management System and Its Processes

4.4.1.1 Conformance of products and processes

- Your company must ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements.

4.4.1.2 Product safety

- The company must have documented processes for the management of product safety related products and manufacturing processes, that must include items ranging from identification of statutory and regulatory product-safety requirements, to – reaction plans, to – lessons learned for new product introductions.

4.4.2 To the extent needed, the company must:

- Maintain documented information to support the operation of its processes
- Retain documented information to have confidence that the processes are being carried out as planned

5 Leadership

The requirements of clause 5 are:

5.1 Leadership

5.1.1 Leadership and commitment to the QMS

5.1.2 Customer focus

5.2 Quality policy

5.3 Organizational roles, responsibilities and authorities

5.1 Leadership

5.1.1 Leadership and commitment to the QMS

Top management must demonstrate leadership and commitment to the QMS by:

- Taking accountability for the effectiveness of the QMS,
- Ensuring that the quality policy and quality objectives are established and are compatible with the context of, and strategic direction of, the company,
- Ensuring the integration of the QMS requirements into the company's business processes,
- Promoting awareness of the process approach and risk-based thinking,
- Ensuring that the resources needed for the QMS are available,

-- cont'd --

5.1 Leadership

-- cont'd –

5.1.1 -- Demonstrate leadership and commitment by:

- Communicating the importance of an effective QMS and of conforming to the QMS requirements,
- Ensuring that the QMS achieves its intended results,
- Engaging, directing and supporting people to contribute to the effectiveness of the QMS,
- Supporting other relevant management roles to demonstrate leadership in their areas of responsibility,
- Promoting improvement.

5.1 Leadership

5.1.1.1 – Corporate responsibility

Top management must define and implement corporate responsibility policies such as for Anti-bribery policy, Ethics escalation, whistle-blowing policy, and Employee code of conduct.

5.1.1.2 – Process effectiveness and efficiency

Top management must review the product realization processes and support processes to evaluate and improve their effectiveness and efficiency – and include the results of the process review activities as input to the management review.

5.1.1.3 – Process owners

Top management needs to identify process owners responsible for managing the processes and related outputs - Process owners must understand their roles and be competent to perform those roles.

5.1 Leadership

5.1.2 Customer Focus

Top management must demonstrate leadership and commitment to customer focus by ensuring:

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met,
- The risks and opportunities that can impact conformity of products and services and the ability to enhance customer satisfaction are determined and addressed,
- The focus on enhancing customer satisfaction is maintained.

5.2 Quality Policy

5.2 Top management must establish, review and maintain a quality policy that:

- Is appropriate to the purpose and context of the organization and supports its strategic direction,
- Provides a framework for setting quality objectives,
- Includes a commitment to satisfy applicable requirements,
- Includes a commitment to continually improve the QMS.

5.2.2 Communicating the quality policy

The quality policy must be:

- Available and be maintained as documented information
- Communicated, understood and applied within the company

5.3 Organizational Roles, Responsibilities and Authorities

5.3 Top management must ensure that the authorities and Responsibilities for relevant roles are assigned, communicated and understood.

- The QMS meets the requirements of International standards,
- The intended outputs of processes are delivered,
- The reporting on the performance of the QMS, on the opportunities for improvement and on the need for change is performed,
- The promotion of customer focus is done in the company,
- The integrity of the QMS is maintained when changes are planned and implemented.

cont'd --

5.3 Organizational Roles, Responsibilities and Authorities

5.3.1 Organizational roles, responsibilities, and authorities – IATF Supplement

Top management must assign personnel with the responsibility and authority to ensure that customer requirements are met.

5.3.2 - Top management needs to ensure that:

- Responsible personnel have the authority to stop shipment and stop production to correct quality problems
- Responsible personnel are promptly informed of nonconforming products or processes to ensure that the product is not shipped to the customer and that all potential nonconforming product is identified and contained,
- All shifts are staffed with personnel in charge of or have delegated responsibility for ensuring conformity to product requirements.

6 Planning for the QMS

The requirements of clause 6 are:

6.1 Actions to Address Risks & Opportunities

6.2 Quality Objectives & Planning to Achieve them

6.3 Planning of Changes

6.1 Actions to Address Risks & Opportunities

6.1.1 The risks and opportunities must be determined to ensure that the QMS can achieve its intended results, prevent, or reduce, undesired effects, and achieve continual improvement.

6.1.2 Actions to address the risks and opportunities must be planned in order to integrate and implement them into the QMS processes and to evaluate the effectiveness of the actions.

6.1 Actions to Address Risks & Opportunities

6.1.2.1 – Risk Analysis

- Your company needs to include in its risk analysis, lessons learned from product recalls product audits, field returns and repairs, complaints, scrap, and rework
- Retain documented information as evidence of the results of risk analysis.

6.1.2.2 – Preventive action

- You must determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence
- Preventive actions are to be appropriate to the seventy of the potential issues.
- You need to establish a process to lessen the impact of negative effects of risk.

6.1 Actions to Address Risks & Opportunities

6.1.2.3 – Contingency plans - Your company needs to:

- Identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment
- Define contingency plans according to risk and impact to the customer
- Prepare contingency plans for continuity of supply in the event of key equipment failures, interruption from externally provided products, processes, and services.
- Include a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations

Cont'd --

6.1 Actions to Address Risks & Opportunities

6.1.2.3 – Contingency plans - Your company needs to:

- Periodically test the contingency plans for effectiveness
- Conduct annual reviews of contingency plan reviews using a multi-disciplinary team including top management
- Document the contingency plans and retain related documented information
- Include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

6.2 Quality Objectives & Planning to Achieve Them

6.2.1 Quality objectives at relevant functions, levels and processes must be established.

- The quality objectives must be consistent with the quality policy.
- They need to be measurable, take into account applicable requirements, and enhance customer satisfaction.
- The objectives must be monitored, communicated, and updated as required.

6.2.2 When planning how to achieve its quality objectives, your company must determine

- what will be done
- what resources will be required
- who will be responsible
- when it will be completed
- how the results will be evaluated.

6.2 Quality Objectives & Planning to Achieve Them

6.2.2.1 Quality objectives and planning to achieve them – IATF supplement

Quality objectives at relevant functions, levels and processes must be established:

- Top management must ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels through the company.

- The results of the review regarding interested parties and their relevant requirements needs to be considered when your company establishes at a minimum annual quality objectives and related internal and external performance targets.

6.3 Planning of Changes

6.3 When changes to the QMS are needed, they must be carried out in a planned and systematic manner with consideration is given to the:

- Purpose of the change and any of its consequences,
- Integrity of the QMS,
- Availability of resources,
- Assignment of responsibilities.

7 Support

The requirements of clause 7 are:

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information

7.1 Resources

7.1.1 General

Your company must determine and provide the resources needed to establish, implement, maintain and continually improve the QMS.

Considered are the capabilities of and constraints on existing internal resources, and the resources to be obtained externally.

7.1.2 People

Your company must ensure that customer and applicable statutory and regulatory requirements are consistently let by providing the personnel and the processes needed for the effective operation of the QMS.

7.1 Resources

7.1.3 Infrastructure

Your company must ensure that conformity of products and services is achieved by determining, providing and maintaining the infrastructure.

- Infrastructure needs are identified and can include buildings and associated utilities, equipment including hardware and software, transportation, information and communication technology.
- Infrastructure must be maintained.

7.1.3.1 Plant, facility, and equipment planning

You must use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans

Cont'd --

7.1 Resources

7.1.3.1 Plant, facility, and equipment planning - cont'd -

In designing plant layouts, you must optimize material flow, material handling, value-added use of floor space, control nonconforming product and facilitate synchronous material flow, as applicable.

- Methods must be developed and implemented to evaluate manufacturing feasibility for new product or new operations and feasibility assessments need to include capacity planning
- These methods need to be applied for evaluating proposed changes to existing operations.
- Your company must maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan, maintenance and verification of job set-ups.
- Assessments of manufacturing feasibility and evaluation of capacity planning become inputs to management reviews.

7.1 Resources

7.1.4 Environment for the operation of processes

Your company must ensure that conformity of products and services is achieved by determining, providing and maintaining an environment needed for the operation of its processes.

- Environment for the operation of processes can include physical, social, psychological, environmental and other factors, such as temperature, humidity, ergonomics and cleanliness.

7.1.4.1 Environment for the operation of processes – IATF supplement

Your company must maintain the premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

7.1 Resources

7.1.5.1 Monitoring and measuring resources

- Your company must determine and provide the resources needed to ensure valid and reliable monitoring and measuring results that will provide the evidence that product & service meet the requirements.
- The measurements and monitoring must be performed with the right fit-for-purpose equipment.
- Your company must ensure that measuring instruments are calibrated when measurement is considered to be an essential part of providing confidence in valid measurement results, or is a statutory or regulatory requirement, or is customer or interested party expectations

-- cont'd --

7.1 Resources

7.1.5.1.1 –Measurement systems analysis

- Statistical studies must be conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan
- The analytical methods and acceptance criteria used need to conform to those in reference manuals on measurement systems analysis.
- Other analytical methods and acceptance criteria may be used if approved by the customer.
- Records of customer acceptance of alternative methods are retained along with results from alternative measurement systems analysis.

7.1 Resources

7.1.5.2 – Measurement traceability

- Calibrations or verifications of instruments must be performed at specified intervals and prior to use against certified equipment having a valid relationship to national or international standards.
- Measuring instruments are maintained and identified in order to determine their calibration status.
- Equipment must be safeguarded from unauthorized adjustments, deterioration or damage that would invalidate the calibration status and subsequent measurement results.
- If a calibration report indicates that equipment is out of calibration, the impact on product produced since the last valid calibration date must be assessed and further action taken documented.

7.1 Resources

7.1.5.2.1 – Calibration / Verification records

The company must have a documented process for managing calibration/verification records.

- Records of the calibration/verification activity for all gauges and measuring and test equipment, including employee-owned, customer owned, or on-site supplier owned equipment, needed to provide evidence of conformity to requirements must be retained.

Your company must ensure that calibration/verification activities and records include:

- Revisions following engineering changes that impact measurement systems
- Any out-of-specification readings as received for calibration / verification
- An assessment of the risk of the intended use of the product caused by the out-of-specification condition
- Production-related software verification used for product and process control, including software installed on employee-owned, customer-owned or on-site supplier-owned equipment.

7.1.5.2.1 – Calibration / Verification records – cont'd --

Your company must ensure that calibration/verification activities and records include:

- In the event that inspection measurement and test equipment is found to be out of calibration or defective, documented information on the validity of previous measurement results obtained with this equipment must be retained, including the associated standard last calibration date and the next due date on the calibration report
- Notification to the customer if suspect product has been shipped
- Statements of conformity to specification after calibration/verification
- Verification that the software version used for product and process control is as specified
- Records of the calibration and maintenance activities for all gauging, including employee-owned, customer-owned, or on-site supplier owned equipment.

7.1 Resources

7.1.5.3 Laboratory requirements

7.1.5.3.1 – Internal Laboratory

- Your internal laboratory must have a defined scope that includes the capability to perform the required inspection, test, or calibration services
- This laboratory scope is included in the QMS documentation

7.1.5.3.2 – External Laboratory

- External laboratory facilities used for inspection, test, or calibration services by the company must have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and is accredited to ISO/IEC 17025 or national equivalent.

7.1 Resources

7.1.6 Organizational knowledge

Your company must determine the organizational knowledge needed for the operation of the processes and to achieve conformity of products and services.

Organizational knowledge includes information such as intellectual property and lessons learned.

To obtain knowledge, consider:

- Internal sources such as learning from failures and successful projects, capturing knowledge and experience of internal experts, and identifying opportunities and risks.
- External sources such as standards, conferences, academia, gathering knowledge with customers or providers

7.2 Competence

7.2 Your company must determine the competence of the personnel required for the work that affects quality performance.

7.2.1 Competence – IATF supplement

Competence issues deal with:

- Ensuring that employees are competent on the basis of appropriate education, training, or experience,
- Taking actions to acquire the necessary competence and evaluating the effectiveness of the actions taken.
- Personnel performing specific assigned tasks must be qualified, as required, with particular attention to the satisfaction of customer requirements.

7.2 Competence

7.2.2 – On-the-job training

- The company must provide on-the-job training for personnel, (including contract or agency persons), in any new or modified responsibilities affecting conformity to all requirements.

7.2.3 – Internal audit competency

- You must have a documented process to verify that internal auditors are competent and a list of qualified internal auditors is required.
- QMS auditors, manufacturing process auditors, and product auditors must be able to demonstrate relevant competencies.

7.2.4 – Second party auditor competency

- Your company must demonstrate the competence of the auditors who conduct the second-party audits.
- Second-party auditors need to meet customer specific requirements for auditor qualification and demonstrate core competencies.

7.3 Awareness

7.3 Your company must ensure that employees are aware of the:

- **Quality policy,**
- **Relevant quality objectives,**
- **Their contribution to an effective QMS,**
- **Benefits of improved quality performance,**
- **Implications of not conforming to the QMS requirements**
- **Importance of meeting customer requirements and the need for ensuring customer satisfaction,**
- **Importance of meeting regulatory, statutory requirements.**

7.3 Awareness

7.3.1 Awareness – IATF supplement

- Your company must maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product.

7.3.2 – Employee motivation and empowerment

- You must maintain a documented process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation.
- The process needs to include the promotion of quality and technological awareness throughout the company.

Competence -- Awareness -- Training

Your company must:

- Identify what training is required for each job or task,
- Provide the required training and keep records,
- The effectiveness of the training provided must also be determined.

7.4 Communication

7.4 Your company must determine the methods for internal and external communication of quality matters.

This includes:

- What it will communicate
- When to communicate
- With whom to communicate
- How to communicate

7.5 Documented Information

The requirements for clause 7.5 are:

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented information

7.5 Documented Information

7.5.1 General

Your company must include in the QMS the documented information required by the IATF and ISO standards, and the documented information determined to be needed for an effective QMS.

The extent of documented information for your QMS will depend on the:

- Size of your company and the type of activities, processes, products and services,
- Complexity of processes and their interactions,
- Competence of personnel.

7.5.1.1 QMS documentation

- Your QMS must be documented and include a Quality Manual, which can be a series of documents in electronic or hard copy format.

7.5 Documented Information

7.5.2 Creating and updating

Your company must create and update information to provide the identification and description, the format, and the media for the documented information.

Documented information must be reviewed and approved for suitability and adequacy.

7.5 Documented Information

7.5.3 Control of documented information

Your company must control documented information to ensure that itis available and suitable for use where and when it is needed and it is adequately protected from loss of confidentiality, improper use, or loss of integrity.

In controlling documented information, you must consider distribution, access, retrieval and use, storage, preservation, control of changes, retention and disposition.

Your company must identify and control the documented information from external sources that is determined to be necessary for the planning and operation of the QMS.

7.5 Documented Information

7.5.3.2.1 – Record retention

- The company must define, document, and implement a record retention policy and the control of records must satisfy statutory, regulatory, organizational, & customer requirements.
- Production part approvals, tooling records, including maintenance and ownership, product and process design records, purchase orders or contracts and amendments are retained for the length of time that the product is active, plus one calendar year unless otherwise specified by the customer or regulatory agency.

7.5 Documented Information

7.5.3.2.2 – Engineering specifications

- Your company must have a documented process describing the review, distribution, and implementation of all customer engineering standards, specifications and related revisions based on customer schedules.
- Reviews need to be completed within 10 working days of receipt of notification of engineering specifications changes.
- When an engineering specification change results in a product design change, more info in ISO 9001, clause 8.3.6.
- When an engineering specification change results in a product realization process change, more info in IATF, clause 8.5.6.1.
- The company must retain a record of the date on which each change is implemented in production and implementation includes the update of documents.

8 Operation

The requirements for clause 8 are:

8.1 Operational planning and control
8.2 Determination of requirements for products and services
8.3 Design and development of products and services
8.4 Control of externally provided products and services
8.5 Production and service provision
8.6 Release of products and services
8.7 Control of non-conforming process outputs, products and services

8.1 Operational Planning and Control

8.1 Your company must plan, implement and control the processes

Needed to meet requirements and implement actions needed to address risks and opportunities.

Operational planning and control includes:

- Determining requirements for the product and services,
- Establishing criteria for the processes and for the acceptance of products and services,
- Determining the resources needed to meet the requirements for products and services,
- Implementing control of the processes in accordance with established criteria,

-- cont'd --

8.1 Operational Planning and Control

8.1 Operational planning and control – cont'd –

- Retaining documented information to give confidence that the processes have been carried out as planned and to demonstrate that products and services meet requirements.

The output of this planning must be in a format suitable for your company's operations.

Your company must control planned changes and review the consequences of unintended changes, and take action to mitigate any adverse effects,

Your company must ensure that outsourced processes are controlled – more information in clause 8.4.

8.1 Operational Planning and Control

8.1.1 Operational planning and control – IATF supplement

When planning for product realization, you must include:

- Customer product requirements and technical specifications
- Logistics requirements
- Manufacturing feasibility
- Project planning, more info in ISO 9001, clause 8.3.2.
- Acceptance criteria.

8.1.2 – Confidentiality

You must ensure the confidentiality of customer-contracted products and projects under development, including related product information.

8.2 Requirements for Products and Services

8.2.1 Customer communication

Your company must establish the means for communicating with customers regarding:

- Information relating to products and services,
- Enquiries, contracts, order handling, including changes,
- Customer views, perceptions, including complaints,
- Handling or treatment of customer property,
- Specific requirements for contingency actions.

8.2.1.1 Written or verbal communication needs to be in the language agreed with the customer.

- You must have the ability to communicate information, including data in a customer-specified computer language and format such as computer-aided design data, electronic data interchange.

8.2 Requirements for Products and Services

8.2.2 Determination of requirements related to products and services

Your company must establish, implement and maintain a process to determine the requirements for the products and services to be offered to potential customers to ensure that:

- Requirements and applicable statutory and regulatory requirements are defined,
- It has the ability to meet the defined requirements and substantiate the claims for the products and services it offers.

8.2.2.1 Determination of requirements related to products and services – IATF supplement

- Requirements must include recycling, environmental impact, and characteristics identified as a result of your company's knowledge of the product and manufacturing processes

8.2 Requirements for Products and Services

8.2.3.1 Review of requirements related to products and services.

Your company must review:

- Requirements specified by the customer, including delivery and post-delivery activities, more info in clause 8.5.5,
- Requirements not stated by the customer, but needed for the customers' specified or intended use,
- Additional statutory and regulatory requirements that may apply to the products and services,
- Contract or order requirements that may be different from those previously expressed.

- cont'd --

8.2 Requirements for Products and Services

8.2.3.1 – cont'd -Review of requirements related to products and services.

Your company must conduct the review prior to making a commitment to supply products and services and must ensure that order requirements differing from those previously defined are resolved.

- Where the customer does not provide documented information of their requirements, they must be confirmed before acceptance.

8.2.3.1.1 Review of requirements related to products and services – IATF supplement

- You must retain documented evidence of a formal review of a customer authorized waiver.

8.2.3.1.2 You must conform to customer requirements for designation, approval documentation, and control of special characteristics.

8.2 Requirements for Products and Services

8.2.3.1.3 Organization manufacturing feasibility

- The company must use a multidisciplinary approach to conduct an analysis to determine if it is feasible that the manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer.
- The company must conduct the feasibility analysis for any new manufacturing or product technology and for any changed manufacturing process or product design.
- Also, you must validate through production runs, benchmarking studies, or other appropriate methods, your ability to make product to specifications at the required rate.

8.2.3.2 Your company must retain documented information for:

- The results of the review
- Any new requirements for the products and services.

8.2 Requirements for Products and Services

8.2.4 Changes to requirements for products and services

- Documented information describing the results of the review, including any new or changed requirements must be retained.
- Where requirements for products and services are changed, your company must ensure that relevant documented information is amended and that affected personnel are made aware of the changes.

8.3 Design and Development of Products and Services

8.3.1 General

The need for a new product, service or process is based on customer or other interested party requests, or other situations where the detailed requirements are not defined and detail requirements for products and services need to be adequate for subsequent production or service provision.

8.3.1.1 Design and development of products and services – IATF supplement

- The requirements of above section 8.3.1, applies to product and manufacturing process design and development and needs to focus on error prevention rather than detection.
- The design and development process must be documented.

8.3 Design and Development of Products and Services

8.3.2 Design and development planning. A design plan must consider:

- Nature, duration, complexity / simplicity,
- Responsibilities & authorities of the design team,
- Control of interfaces between individuals and parties,
- Requirements that specify process stages,
- Required verification and validation,
- Need for involvement of customer and user groups,
- Necessary documented information and approvals.

8.3.2.1 Design and development planning – IATF supplement

- You must ensure that design and development planning uses a multidisciplinary approach and includes all affected stakeholders within the company and, as needed in the supply chain.

8.3 Design and Development of Products and Services

8.3.2.2 Product design skills

- The company must ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques.
- Applicable tools and techniques need to be identified by your company.

8.3.2.3 - Development of products with embedded software

- You must use a process for quality assurance for your products with internally developed embedded software.
- A software development assessment methodology needs to be used to assess the software development process.
- Using prioritization based on risk and potential impact to the customer, you must retain documented information for a software development capability self assessment.
- You must include software development within the scope of the internal audit program.

8.3 Design and Development of Products and Services

8.3.3 Design and development inputs

The design team must collect and document design inputs. Inputs include:

- Essential functional and performance requirements,
- Applicable statutory and regulatory requirements,
- Standards or codes of practice,
- Internal and external resource needed,
- Potential consequences of failure due to the nature of the products and services,
- Level of control expected by customers & other relevant interested parties.

8.3 Design and Development of Products and Services

8.3.3.1 – Product design input

The company must identify, document, and review product design input requirements as a result of contract review.

- You need to have a process to deploy information gained from previous design projects, competitive product analysis, benchmarking, supplier feedback, internal input, field data, and other sources for current and future projects of a similar nature.

8.3.3.2 Manufacturing process design input.

Your company must identify, document, and review manufacturing process design input requirements.

- The manufacturing process design must include the use of error proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

8.3 Design and Development of Products and Services

8.3.3.3 Special characteristics

The company must use a multidisciplinary approach to establish, document, and implement a process to identify special characteristics, including those determined by the customer and by your risk analysis, and include:

- Documentation of all special characteristics in the drawings, risk analysis such as FMEA, control plans, and work/operator instructions,
- Special characteristics are identified with specific markings and are cascaded through each of these documents,
- Development of control and monitoring strategies for special characteristics of products and production processes,
- Customer-specified approvals, when required,
- Compliance with customer-specified definitions and symbols or your equivalent symbols or notations, as defined in a symbol conversion table, (as submitted to the customer, if required).

8.3 Design and Development of Products and Services

8.3.4 Design and development controls

The design and development process must be controlled to ensure the:

- Results to be achieved are clearly defined,
- Reviews are carried out as planned,
- Verification is conducted to ensure that the outputs meet the design and development input requirements,
- Validation is conducted to ensure that the products and services are capable of meeting the requirements for the intended use.

8.3.4.1 Monitoring

- Measurements at specified stages during the design & development of products and processes must be defined, analyzed, and reported with summary results as an input to management review.
- When required by the customer, measurements of the product and process development activity need to be reported to the customer at stages specified, or agreed to, by the customer.

8.3 Design and Development of Products and Services

8.3.4.2 Design and development validation

- Design and development validation must be performed per the customer requirements, including any applicable industry and governmental agency-issued regulatory standards
- The timing of design and development validation needs to be planned in line with customer-specified timing, as applicable.
- Where contractually agreed with the customer, this must include evaluation of the interaction of your product, including embedded software, within the system of the final customer's product.

8.3 Design and Development of Products and Services

8.3.4.3 Prototype program

- When required by the customer, your must have a prototype program and control plan.
- You must use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.
- When services are outsourced, the company must include the type and extent of control in the scope of the QMS to ensure that outsourced services conform to requirements, more info in ISO 9001, clause 8.4.

8.3 Design and Development of Products and Services

8.3.4.4 Product approval process

- The company must establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer.
- You must approve externally provided products and services, prior to submission of their part approval to the customer
- Your company need to obtain documented product approval prior to shipment, if required by the customer.
- Records of such approval are required to be retained

8.3 Design and Development of Products and Services

8.3.5 Design and development outputs

The design team must ensure that the outputs:

- Meet the input requirements,
- Are adequate for the subsequent processes,
- Reference monitoring and measuring requirements, and acceptance criteria,
- Ensure products to be produced, or services to be provided, are fit for intended purpose and are safe and proper for use.

8.3 Design and Development of Products and Services

8.3.5.1 Design and development outputs – IATF supplement

- The product design output must be expressed in terms that can be verified and validated against product design input requirements.
- The product design output must include items ranging from design risk analysis, such as FMEA, -- to product design reviews, -- to packing and labelling requirements for shipping.

8.3.5.2 – Manufacturing process design output

- Your company must document the manufacturing process design output in such a way that it can be verified against the manufacturing process design inputs.
- You need to verify the outputs against manufacturing process design input requirements.
- The manufacturing process design output must include items ranging from specifications and drawings, -- to manufacturing process PFMEA, -- to methods of rapid detection, feedback, and correction of product and manufacturing process nonconformities.

8.3 Design and Development of Products and Services

8.3.6 Design and development changes

- When changes to design inputs and outputs are needed, the team must identify, review, and control the changes.
- Documented information resulting from the design & development process, and including design changes is controlled and retained as documented information.

8.3.6.1 Design and development changes – IATF supplement

The company must evaluate all design changes after initial product approval, including the ones you proposed or by the suppliers, for potential impact on fit, form, function, performance.

- These changes must be validated against customer requirements and approved internally, prior to production implementation.
- If required by the customer, you must obtain documented approval, or a documented waiver, prior to production implementation.
- For products with embedded software, you need to document the revision level of software and hardware as part of the change record.

8.4 Control of Externally Provided Products and Services

8.4.1 General

Your company must ensure that externally provided processes, products and services conform to requirements.

Your company must identify the situations where the requirements for the control of external providers applies.

Control of external providers apply when:

- Products and services are provided for incorporation into the products and services,
- Products and services are provided directly to the customer on behalf of the company,
- A process or part of a process is provided as a result of a decision to outsource a process or function.

-- cont'd --

8.4 Control of Externally Provided Products and Services

8.4.1 When purchases have an impact on quality, the providers must be evaluated and selected based on their ability to supply products and services that meet requirements.

- Criteria for the evaluation, selection, monitoring of performance and re-evaluation of suppliers must be applied based on their ability to meet requirements.
- Documented information of the results of the valuations, monitoring and periodic re-evaluations must be retained.

8.4.1.1 General – IATF supplement

The company must include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of the definition of externally provided products, processes, and services.

-- cont'd --

8.4 Control of Externally Provided Products and Services

8.4.1.2 Supplier selection process

Your company must have a documented supplier selection process that includes:

- An assessment of the supplier's risk to product conformity and uninterrupted supply of your product to your customers
- Relevant quality and delivery performance
- An evaluation of the supplier's QMS
- Multidisciplinary decision making
- An assessment of software development capabilities, if applicable.

8.4.1.3 – Customer directed sources (aka directed-buy)

When specified by the customer, you must purchase products, materials, or services from customer-directed sources.

-- cont'd --

8.4 Control of Externally Provided Products and Services

8.4.2 Type and extent of control of eternal provision

The type and extent of controls applied to external providers must consider the:

- Potential impact the products or services have on the ability to consistently meet specified requirements,
- The effectiveness of the controls applied by the provider.

Purchased product must be verified before use to ensure that they do not adversely affect the ability to deliver conforming products and services to customers.

Outsourced processes or functions remain the responsibility of your company. You must consider the impact they have on the ability to consistently meet requirements.

You must also look at the effectiveness of the controls applied by the provider, and the controls you apply to the provider and those applied to the resulting process output.

8.4 Control of Externally Provided Products and Services

8.4.2.1 Type and extent of control – IATF supplement

- Your company must have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal and external customer requirements.
- The process must include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks

8.4 Control of Externally Provided Products and Services

8.4.2.2 Statutory and regulatory requirements

- The company must document the process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, the customer identified country of destination
- If the customer defines special controls for certain products with statutory and regulatory requirements, you must ensure they are implemented and maintained as defined, including at suppliers

8.4.2.3 Supplier quality management system development

- The company must require the suppliers to develop, implement, and improve a QMS certified to ISO 9001:2015, with the objective of becoming certified to the IATF Automotive QMS Standard.

8.4 Control of Externally Provided Products and Services

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

- The company must require the suppliers of products with embedded software to implement and maintain a process for quality assurance.
- A software development assessment methodology needs to be used to assess the suppliers software development process.
- With priorities based on risk and potential customer impact, the suppliers are required to retain documented information on software development capability self-assessment.

8.4.2.4 Supplier monitoring

- You must have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes and services to requirements.
- Supplier performance indicators, ranging from delivered product conformity, to – incidents of premium freight, to – dealer returns, and recalls are monitored.

8.4 Control of Externally Provided Products and Services

8.4.2.4.1 Second-party audits

- Your company must include a second-party audit process in the supplier management approach
- Second-party audits may be used for items such as supplier risk assessment, supplier monitoring, supplier QMS development, product audits, process audits
- Based on a risk analysis, including product safety requirements, supplier performance, and QMS certification level, you must document the criteria for determining the need, type, frequency, and scope of second-party audits.
- You need to retain records of the 2nd-party audit reports
- If the scope of the 2nd-party audit is to assess the supplier QMS, the approach must be consistent with the automotive process approach.

8.4 Control of Externally Provided Products and Services

8.4.2.5 Supplier development

- The company must determine the priority, type, extent, and timing of required supplier development actions for the active suppliers.
- Determination inputs must include items such as performance issues identified through supplier monitoring, 2nd-party audit findings, 3rd-party QMS certification status, and risk analysis.
- You must implement actions necessary to resolve unsatisfactory performance issues and pursue opportunities for continual improvement.

8.4 Control of Externally Provided Products and Services

8.4.3 Information for external providers.

Your company must ensure the adequacy of specified requirements prior to communicating them to the supplier and include information, requirements for:

- The provided products & services or the processes to be performed,
- Approval or release of products, methods, processes or equipment,
- Competence of personnel, including needed qualification,
- The control and monitoring to be applied,
- Verification activities that your company or your customer, intends to perform at the provider premises.

8.4.3.1 Information for external providers – IATF supplement.

The company must pass down all applicable statutory and regulatory requirements and special product & process characteristics to the suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

8.5 Production and Service Provision

8.5.1 Control of production and service provision

Your company must implement controlled conditions for the provision of production and service.

Controlled conditions include the:

- Availability of documented information that defines the product or service characteristics,
- Availability of documented information that defines the activities to be performed and the results to be achieved,
- Monitoring and measurement activities to verify that criteria for process outputs and for products and services, have been met
- Use and control of suitable infrastructure and process environment

-- cont'd --

8.5 Production and Service Provision

- cont'd-- 8.5.1 Controlled conditions include the:

- Availability and use of suitable monitoring and measuring resources
- Competence and, where applicable, required qualification of persons
- Validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement;
- Implementation of products and services release, delivery and post-delivery activities.

-- cont'd --

8.5 Production and Service Provision

8.5.1.1 Control plan

- Your company must develop control plans at the system, subsystem, component, and/or material level for the relevant manufacturing site and all product supplied, including those for processes producing parts as well as bulk materials.
- Family control plans are acceptable for bulk material and similar parts using a common manufacturing process.
- You need to have a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis, process flow diagram, and manufacturing process risk analysis outputs such as FMEA.

8.5 Production and Service Provision

- **cont'd -- 8.5.1.1 Control plan**

Your company must, if needed by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans.

- You must include in the control plan items ranging from controls used for the manufacturing process control, including verification of job set-ups, to – specified reaction plans, to – control plan review and update at a set frequency based on a risk analysis.
- If required by the customer, you must obtain customer approval after review or revision of the control plan

8.5 Production and Service Provision

8.5.1.2 Standardized work— Operator instructions and visual standards

Your company must ensure that standardized work documents are:

- Communicated to and understood by the employees who are responsible for performing the work
- Legible
- Presented in the language(s) understood by the personnel responsible to follow them
- Accessible for use at the designated work areas

The standardized work documents must also include rules for operator safety.

8.5 Production and Service Provision

8.5.1.3 Verification of job set-ups. Your company must:

- Verify job set-ups when done as an initial run of a job, material changeover, or job change that requires a new set-up
- Maintain documented information for set-up personnel
- Use statistical methods of verification, where applicable
- Perform first-off/last-off part validation, and when relevant
  - first-off parts are retained for comparison with the last-off parts
  - last-off-parts are retained for comparison with first-off parts in next runs
- Retain records of process and product approval following set-up and first-off / last-off part validations.

8.5.1.4 Verification after shutdown

- You must define and implement the needed actions to ensure the product meet the requirements after a planned or unplanned production shutdown period.

8.5 Production and Service Provision

8.5.1.5 Total productive maintenance

Your company must develop, implement, and maintain a documented total productive maintenance system.

At a minimum, the system needs to include items ranging from the identification of process equipment needed to produce conforming product at the required volume, to – periodic overhauls.

8.5.1.6 Management of tooling – equipment – see next slide.

8.5.1.7 Production scheduling

Your company must ensure that production is scheduled in order to meet customer orders/demands such as Just-In-Time (JIT) and is supported by an information system that permits access to production information at key stages of the process and is order driven.

You must include relevant planning information during production scheduling, such as customer orders, supplier on-time delivery performance, capacity, shared loading, lead time, inventory level, preventive maintenance, and calibration.

8.5 Production and Service Provision

8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

The company must provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials.

You must establish and implement a system for production tooling management, whether owned by your company or the customer and include items ranging from maintenance and repair facilities and personnel, to – tool change programs for perishable tools, to – tool identification.

The company must verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

You must implement a system to monitor these activities if any work is outsourced.

8.5 Production and Service Provision

8.5.2 Identification and traceability

To ensure conformity of products and services, your company must identify process outputs.

You must identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision.

When traceability is a requirement, you must control the unique identification of the process outputs, and retain any documented information necessary to maintain traceability.

8.5 Production and Service Provision

8.5.2.1 Identification and traceability –IATF supplement

To support identification of clear start and stop points for product that may contain quality and/or safety-related nonconformities your company must implement identification and traceability processes.

Traceability plans need to define the appropriate traceability systems: processes, and methods by product, process, and manufacturing location that:

- Enable the identification of nonconforming and/or suspect product
- Enable the segregation of nonconforming and/or suspect product
- Ensure the ability to meet the customer and regulatory response times
- Ensure documented information is retained in a format that enables you to meet the response time requirements
- Ensure serialized identification of individual products
- Ensure the identification and traceability requirements are extended to externally provided products with safety and regulatory characteristics.

8.5 Production and Service Provision

8.5.3 Property belonging to customers or external providers

When property is provided for use in the products and service, due care must be exercised to protect and safeguard it while it is under your control.

- Property provided by customers or external providers is identified with your identification & traceability system.
- Property is preserved and protected from damage with your system for preservation and handling.
- Any lost, damaged or unusable property must be documented and reported to the customer or provider.

8.5 Production and Service Provision

8.5.4 Preservation

Your company must ensure proper handling, packaging, storage and protection of process outputs in order to preserve the product through delivery to its intended destination.

- Preservation must include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection

8.5 Production and Service Provision

8.5.4.1 Preservation – IATF supplement

Your company must comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

- Preservation must apply to materials and components from external and internal providers from receipt through processing, including shipment and until delivery to and acceptance by the customer.
- In order to detect deterioration, your company must assess at appropriate planned intervals the condition of product in stock, the place and type of storage container, and the storage environment.
- You must use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO).
- The company must ensure that obsolete product is controlled in a manner similar to that of nonconforming product.

8.5 Production and Service Provision

8.5.5 Post-delivery activities

Your company must determine the post-delivery activities that are required with consideration given to the:

- Risks associated with the products and services,
- Nature, use & intended lifetime of the products / services,
- Customer feedback,
- Statutory and regulatory requirements.

Post-delivery activities can include maintenance services, and other services such as recycling or final disposal.

8.5 Production and Service Provision

8.5.5.1 Feedback of information from service

- The company must ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, you must:

- Verify that the relevant service centers comply with applicable requirements
- Verify the effectiveness of any special purpose tools or measurement equipment
- Ensure that all service persons are trained in relevant requirements.

8.5 Production and Service Provision

8.5.6 Control of changes

Unplanned changes necessary for production or service provision must be reviewed and controlled to ensure continuing conformity with specified requirements.

Documented information describing the results of reviews of changes, the personnel authorizing the changes, and any needed actions must be controlled and retained.

8.5 Production and Service Provision

8.5.6.1 Control of changes – IATF supplement

The company must have a documented process to control and react to changes that impact product realization.

The effects of any change, including those changes caused by the company, the customer, or any supplier, need to be assessed.

Your company must:

- Define verification and validation activities to ensure compliance with requirements
- Validate changes before implementation
- Document the evidence of related risk analysis
- Retain records of verification and validation.

8.5 Production and Service Provision

8.5.6.1 Control of changes – cont'd --

Changes, including those made at suppliers, must require a production trial run for verification of changes, such as changes to part design, manufacturing location, or manufacturing process, to validate the impact of any changes on the manufacturing process.

When required by the customer, you must:

- Notify the customer of any planned product realization changes after the most recent product approval
- Obtain documented approval, prior to implementation of the change
- Complete additional verification or identification requirements, such as production trial run and new product validation.

8.5 Production and Service Provision

8.5.6.1.1 Temporary change of process controls

Your company must identify, document, and maintain a list of the process controls, including inspection, measuring, lest, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods

- The company needs to document the process that manages the use of alternate control methods.
- You must include in this process, based on risk analysis, such as FMEAs, severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.
- Before shipping product that was inspected or tested using the alternate method, you must obtain approval from the customers.
- The company must maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan

8.5 Production and Service Provision

8.5.6.1.1 Temporary change of process controls – cont'd --

- Standard work instructions need to be available for each alternate process control method.
- You must review the operation of alternate process controls on a daily basis, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible.

Example methods include daily quality focused audits and daily leadership meetings

Restart verification must be documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

- Your company must implement traceability of all product produced while any alternate process control devices or processes are being used, such as verification and retention of first piece and last piece from every shift.

8.6 Release of Products and Services

8.6 Release of products and services

The release of products and services must not proceed until verifications have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Documented information must provide traceability to the person authorizing release for delivery to the customer.

Records must be maintained to provide evidence that the products or services have passed final inspection / test.

8.6 Release of Products and Services

8.6.1 Release of products and services – IATF supplement

The company must ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan.

- You must ensure that the planned arrangements for initial release of products and services encompass product or service approval.
- The company needs to ensure that product or service approval is accomplished after changes following initial release, per clause 8.5 6.

8.6.2 Layout inspection and functional testing

- A layout inspection and a functional verification to relevant customer engineering material and performance standards must be performed for each product as specified in the control plans and results need to be available for customer review.

8.6 Release of Products and Services

8.6.3 Appearance items

For parts designated by the customer as Appearance Items, your company must provide the necessary resources.

- Resources include lighting for evaluation, masters for color, grain, gloss, metallic brilliance, texture, etc., maintenance and control of appearance masters and evaluation equipment, and verification that personnel making appearance evaluations are competent and qualified to do so.

8.6.4 Verification and acceptance of conformity of externally provided products and services.

- The company must have a process to ensure the quality of externally provided processes, products, and services using methods ranging from receipt and evaluation of statistical data provided by the supplier, to – part evaluation by a designated laboratory, to – other method agreed with the customer.

8.6 Release of Products and Services

8.6.5 Statutory and regulatory conformity

- Prior to release of externally provided products into the production flow, your company must confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination.

8.6.6 Acceptance criteria

- Acceptance criteria must be defined and. When relevant or required, approved by the customer.
- For attribute data sampling, the acceptance level must hall be zero defects, more info in clause 9.1.1.1.

8.7 Control of non-conforming Outputs

8.7.1 Your company must ensure that non-conforming process outputs are identified and controlled to prevent their unintended use or delivery.

Corrective action based on the nature of the nonconformity and its impact on the products and services, must be determined.

If non-conforming product is detected after delivery or use, you must take action, such as:

- Segregation for disposition, correction. informing the customer, obtaining authority to accept under concession.
- Corrected product must be subjected to all inspections required by the process to verify and demonstrate conformity to requirements.
- Documented information of actions taken dealing with decisions regarding non-conforming process outputs, products and services is controlled and retained.

8.7 Control of non-conforming Outputs

8.7.1.1 Customer authorization for concession

The company must obtain a deviation permit for further processing when the product or manufacturing process is different from that which is approved

- You must obtain customer authorization prior to further processing for use as is and rework dispositions of nonconforming product.
- If sub-components are reused, the reuse needs to be clearly communicated to the customer in the concession or permit.
- You need to maintain a record of expiry date & authorized quantities
- Your company must ensure compliance with the original or superseding specs and requirements when the authorization ends.
- Material shipped under concession must be property identified on each shipping container, and also applies to purchased products.
- You must approve any requests from suppliers before submission to the customer.

8.7 Control of non-conforming Outputs

8.7.1.2 Control of nonconforming product— customer-specified process

- The company must comply with applicable customer-specified controls for nonconforming product.

8.7.1.3 Control of suspect product

- Your company must ensure that product with unidentified or suspect status is classified and controlled as nonconforming product.
- You must ensure that all relevant manufacturing personnel receive training for containment of suspect and nonconforming product.

8.7 Control of non-conforming Outputs

8.7.1.4 Control of reworked product

Your company must use risk analysis, such as FMEA, methodology to assess risks in the rework process prior to a decision to rework the products.

- If required by the customer, you must obtain approval prior to the start of rework of the product.
- The company must have a documented process for rework confirmation per the control plan or other relevant documented information to verify compliance to original specifications.
- Instructions for disassembly or rework, including re-inspection and traceability requirements, need to be accessible to and used by the personnel.
- You must retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

8.7 Control of non-conforming Outputs

8.7.1.5 Control of repaired product

Your company must use risk analysis, such as FMEA, methodology to assess risks in the repair process prior to a decision to repair products.

- You must obtain approval from the customer before starting repairs.
- The company must have a documented process for repair confirmation per the control plan or other relevant documented information.
- Instructions for disassembly or repair, including re-inspection and traceability requirements, need to be accessible to and used by the personnel
- You must obtain a documented customer authorization for concession for the product to be repaired.
- You must retain documented Information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

8.7 Control of non-conforming Outputs

8.7.1.6 Customer notification

The company must immediately notify the customer in the event that nonconforming product has been shipped and initial communication must be followed with detailed documentation of the event.

8.7.1.7 Nonconforming product disposition

Your company must have a documented process for disposition of nonconforming product not subject to rework or repair.

- For product not meeting requirements, you need to verify that the product to be scrapped is rendered unusable prior to disposal
- The company must not divert nonconforming product to service or other use without prior customer approval.

8.7 Control of non-conforming Outputs

8.7.2 The company must retain documented information that:

- Describes the nonconformity
- Describes the actions taken
- Describes any concessions obtained
- Identifies the authority deciding the action in respect of the nonconformity

9 Performance Evaluation

The requirements for clause 9 are:

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Your company must determine:

- What needs to be monitored and measured,
- Methods for monitoring, measurement, analysis and evaluation,
- When the monitoring and measuring is to be performed,
- When the results from monitoring and measurement are to be analyzed and evaluated.

You must ensure that monitoring and measuring activities are implemented and associated records retained.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1.1 Monitoring and measurement of manufacturing processes

The company must perform process studies on all new manufacturing processes to verify process capability and to provide additional input for process control, including those for special characteristics.

Your company needs to maintain manufacturing process capability or performance results as specified by the customer part approval process requirements.

You must verify that the process flow diagram, PFMEA, and control plan are implemented, and adhere to:

- Measurement techniques
- Sampling plans
- Acceptance criteria
- Records of measurement values & test results for variable data
- Reaction plans and escalation process when acceptance criteria are not met.

9.1 Monitoring, Measurement, Analysis and Evaluation

- cont'd - 9.1.1.1 Monitoring and measurement of manufacturing processes

Significant process events, such as tool change or machine repair, need to be recorded and retained as documented information.

- The company must initiate the reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or unstable.
- The reaction plans must include containment of product and 100 % inspection.
- A corrective action must be developed and implemented showing specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable.
- The plans need to be reviewed with and approved by the customer.

You must maintain records of effective dates of process changes

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1.2 Identification of statistical tools

Your company must determine the appropriate use of statistical tools.

- You need to verify that appropriate statistical tools are included as part of the advanced product quality planning process and included in the design risk analysis, such as DFMEA, the process risk analysis, such as PFMEA, and the control plan.

9.1.1.3 Application of statistical concepts

- Statistical concepts, such as variation, control, stability, process capability, and the consequences of over-adjustment, must be understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.2 Customer satisfaction

Your company must monitor the customer perceptions of how well their requirements are met.

You must obtain information relative to customer views and opinions of the company and its products and services.

The methods for obtaining and using this information must be identified – and can include surveys of customer satisfaction, data on the quality of deliveries, compliments, warranty claims, etc.

Your company must monitor the customer perceptions of how well their requirements are met.

You must obtain information relative to customer views and opinions of the company and its products and services.

The methods for obtaining and using this information must be identified – and can include surveys of customer satisfaction, data on the quality of deliveries, compliments, warranty claims, etc.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.2.1 Customer satisfaction –IATF supplement

Customer satisfaction with your company must be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specs and customer requirements.

- Performance indicators must be based on objective evidence and include items ranging from delivered part quality performance, to customer notifications related to quality or delivery issues.
- The company must monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency.
- The monitoring needs to include the review of customer performance data including online customer portals and customer scorecards, where provided.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.3 Analysis and evaluation

Your company must analyse and evaluate the data and information resulting from monitoring, measurement and other sources.

The output of analysis and evaluation must be used to:

- Demonstrate conformity to requirements,
- Assess and enhance customer satisfaction,
- Ensure conformity and effectiveness of the QMS,
- Show that planning has been successfully implemented,
- Assess the performance of processes,
- Assess the performance of external providers,
- Determine the need for improvements within the QMS.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.3 Analysis and evaluation – cont'd

The results of analysis and evaluation must also be used to provide inputs to management review.

9.1.3.1 Prioritization

Trends in quality and operational performance must be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

9.2 Internal Audit

9.2.1 Your company must conduct internal audits to ensure that the QMS conforms to requirements, is effectively implemented and maintained, and continues to be suitable, adequate and effective.

You must plan, establish, implement and maintain an audit program that includes the frequency, responsibilities, methods, planning requirements, reporting and consider:

- The quality objectives, the importance of the processes audited, customer feedback, changes impacting on the company, and the results of previous audits,
- Define the audit criteria and scope for the audit,
- Select auditors and conduct audits for objective and impartial audits,
- Ensure that the results of the audits are reported to management,
- Take prompt correction and corrective actions,
- Retain documented information as evidence of the audits.

9.2 Internal Audit

9.2.2.1 Internal audit program

Your company must have a documented internal audit process that includes the development and implementation of an internal audit program covering the entire QMS and including QMS audits, manufacturing process audits, and product audits.

- The audit program must be prioritized based upon risk, internal and external performance trends, and criticality of the processes.
- When you are responsible for software development, you must include software development capability assessments in the internal audit program.
- The frequency of audits needs to be reviewed and, if needed, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints.

The effectiveness of the audit program must be reviewed as a part of management review.

9.2 Internal Audit

9.2.2.2 Quality management system audit

The company must audit all QMS processes over each 3-year calendar period, per an annual audit program, using the process approach to verify compliance with the IATF 16949:2016 Automotive QMS Standard

- Integrated with the audits, you must sample customer-specific QMS requirements for effective implementation.

9.2.2.3 Manufacturing process audit – see next slide.

9.2.2.4 Product audit

The company must audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements.

- When not defined by the customer, your company must define the approach to be used.

9.2 Internal Audit

9.2.2.3 Manufacturing process audit

Your company must audit all manufacturing processes over each 3-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits.

- When not defined by the customer, you must determine the approach to be used.
- Within each individual audit plan, each manufacturing process need to be audited on all shifts,, including the appropriate sampling of the shift handover.
- The manufacturing process audit must include an audit of the effective implementation of the process risk analysis, such as PFMEA, control plan, and associated documents.

9.3 Management Review

9.3.1 Your company must review the QMS to ensure that it continues to be suitable, adequate and effective and aligned with the strategic direction of the company.

9.3.1.1 Management review – IATF supplement

Management review must be conducted at least annually.

- The frequency of management reviews must be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the QMS and performance related issues.

9.3 Management Review

9.3.2 Management reviews must be planned and conducted and Consider specific inputs:

- **The status of actions from previous management reviews,**
- **Changes in relevant external and internal issues & strategic direction,**
- **The effectiveness of actions taken to address risks and opportunities,**
- **New potential opportunities for continual improvement.**
- **Information on quality performance, including trends & indicators for:**
  - Nonconformities and corrective actions,
  - Monitoring and measurement results,
  - Audit results,
  - Customer satisfaction,
  - External providers & other interested parties issues,
  - Adequate resources required for an effective QMS,
  - Process performance,
  - Conformity of products and services.

9.3 Management Review

9.3.2.1 Management review inputs — IATF supplement

Input to management review must include

- Cost of poor quality from internal and external non-conformances
- Measures of process effectiveness
- Measures of process efficiency
- Product conformance
- Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product
- Customer satisfaction
- Review of performance against maintenance objectives
- Warranty performance
- Review of customer scorecards
- Identification of potential field failures identified through risk analysis, such as FMEA.
- Actual field failures and their impact on safety or the environment.

9.3 Management Review

9.3.3 Management review outputs

The outputs of the management reviews must include decisions and actions related to:

- Opportunities for continual improvement,
- Any need for changes to the QMS,
- Needs for resources.

You must retain documented information as evidence of the results of management reviews.

9.3.3.1 Management review outputs — IATF supplement

Top management must document and implement an action plan when customer performance targets are not met.

10 Improvement

The requirements for clause 10 are:

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

10 Improvement

10.1 General

Your company must determine and select opportunities for improvement and take actions to meet customer requirements and enhance customer satisfaction.

These take into consideration the improvement of:

- Processes to prevent nonconformities,
- Products and services to meet known and predicted requirements,
- Quality management system results.

10.2 Nonconformity and corrective action

Your company must ensure that non-conformances are dealt with as they occur and that corrective action is taken to eliminate the cause or to reduce the likelihood of recurrence.

10.2 Nonconformity and Corrective Action

10.2.1 Your company must ensure that non-conformances are dealt with as they occur and that corrective action is taken to eliminate the cause or to reduce the likelihood of recurrence.

Corrective actions must be appropriate to the effects of the non-conformances. When a nonconformity occurs you must:

- React to it and take action to control and correct it,
- Evaluate the need for action to eliminate the cause of the nonconformity so that it does not recur or occur elsewhere,

Include in the evaluation a review of the nonconformity, a definition of the causes, and a determination if similar nonconformities exist, or could potentially occur.

- Implement any action needed,
- Review the effectiveness of any corrective action taken,
- Make changes to the QMS, if necessary.

10.2.2 Retain documented information as evidence of nonconformities, actions taken and results of actions taken

10.2 Nonconformity and Corrective Action

Definitions

Corrective Action is action taken to eliminate the cause of a non-conformance that has occurred, and prevent its reoccurrence.

Preventive Action is action taken to eliminate the cause of a potential non-conformance and prevent it from occurring.

In the standards, and while preventive action is a requirement at clause 6.1.2.2 of IATF 16949:2016, the concept of preventive action is expressed through a risk-based approach where risks are determined and actions to address opportunities and risks are taken.

Documented information must be retained as evidence of the nature of the nonconformities, of any subsequent actions taken, and of the results of any corrective action.

10.2 Nonconformity and Corrective Action

10.2.3 Problem solving

You must have a documented process for problem solving with:

- Defined approaches for various types and scale of problems, such as new product development, and current manufacturing issues.
- Containment, interim actions, and related activities needed for control of nonconforming outputs.
- Root cause analysis, methodology used, analysis, and results
- Implementation of systemic corrective actions, including consideration of the impact on similar processes and products.
- Verification of the effectiveness of implemented corrective actions
- Reviewing and, where necessary, updating the appropriate documented information, such as PFMEA, and control plan.

When the customer specifies processes, tools, or systems for problem solving, your company must use them.

10.2 Nonconformity and Corrective Action

10.2.4 Error-proofing

Your company must have a documented process to determine the use of appropriate error-proofing methodologies.

- Details of the method used need to be documented in the process risk analysis, such as PFMEA and test frequencies must be documented in the control plan.
- The process must include the testing of error-proofing devices for failure or simulated failure.
- Records need to be maintained.
- Challenge parts, when used, must be identified, controlled, verified, and calibrated where feasible.
- Error-proofing device failures must have a reaction plan.

10.2 Nonconformity and Corrective Action

10.2.5 Warranty management systems

When your company provides warranty for your products, you must implement a warranty management process.

- The company must include in the process a method for warranty part analysis, including NTF (no trouble found).
- When specified by the customer, you need to implement the required **warranty management process.**

10.2 Nonconformity and Corrective Action

10.2.6 Customer complaints and field failure test analysis

The company must perform analysis on customer complaints and field failures, including any returned parts, and must initiate problem solving and corrective action to prevent recurrence.

- When requested by the customer, this must include analysis of the interaction of embedded software of your product with the final customer's product
- You must communicate the results of testing/analysis to the customer and also within your company.

10.3 Continual Improvement

10.3 Your company must continually improve the suitability, adequacy, and effectiveness of the QMS.

- You must consider the outputs of analysis and evaluation, and the outputs from management review to identify areas of under-performance or opportunities that must be addressed as part of continual improvement.
- Where applicable, you must select and use tools and methodologies for investigation of the causes of underperformance and for supporting continual improvement.
- Statistical techniques may be used to identify trends and problems to offer potential solutions that improve the QMS.

10.3 Continual Improvement

Such statistical techniques include:

- Frequency Distribution Report,
- Run Charts,
- Pie charts,
- Histograms,
- Pareto Analysis,
- Defect % Analysis,
- Cause & Effect Analysis, and
- Variables Control (X bar & R) Charts.

10.3 Continual Improvement

10.3.1 Continual improvement — IATF supplement

Your company must have a documented process for continual improvement.

The process needs to include:

- Identification of the methodology used, objectives, measurement, effectiveness and documented information,
- A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste,
- Risk analysis, such as FMEA.

The IATF 16949:2016 Requirements

The 7 clauses of the international standard are:

Clause 4 - Context of the Organization

Clause 5 - Leadership

Clause 6 - Planning

Clause 7 - Support

Clause 8 - Operation

Clause 9 - Performance Evaluation

Clause 10 - Improvement