IATF 16949:2016 Understanding Training

Automotive Quality Management Systems

OMNEX

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Omnex provides training, consulting and software solutions to the international market with offices in the USA, Canada, Mexico, China (PRC), Germany, India, the Middle East, and SE Asia. Omnex offers over 400 standard and customized training courses in business, quality, environmental, food safety, laboratory and health & safety management systems worldwide.

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Course Objectives

- Provide sufficient knowledge and understanding of the various clauses and requirements of the ISO 9001:2015 and IATF 16949:2016 standards.
- Provide guidance for the planning, preparation and delivery of automotive quality management system audits in accordance with the requirements and guidelines of ISO 19011:2018.
- Provide participants with adequate skills in the Exemplar Global specified competencies to become a certified Exemplar Global QM Auditor.
- Provide the necessary competencies required for internal auditors according to clause 7.2.3 of IATF 16949
  - Understanding of the automotive process approach for auditing, including risk-basked thinking;
  - Understanding of applicable customer-specific requirements;
  - Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
  - Understanding of the applicable core tool requirements related to the scope of the audit;
  - Understanding how to plan, conduct, report and close-out audit findings.

Contents

Exemplar Global Competency Units

This course has been designed to follow the Exemplar Global Training Provider and Examiner Certification Scheme (TPECS). Depending on which examinations you have chosen to take, this course may be comprised of up to three separate Exemplar Global Competency Units with the following objectives:

Quality Management Systems (Exemplar Global-QM)

- Understand the application of Quality Management Principles in the context of ISO 9001.
- Relate the QMS to the organizational products, including services, and operational processes.

Course Methodology

Breakout Exercises

- The class will be divided into teams of three to six people. The objective is to provide diversified auditing experience to each team.
- The purpose of these breakout exercises are to develop and evaluate those skills important for the audit process by having individuals or teams working on practical situations, such as evaluating a particular QMS for conformance to ISO 9001 and/or IATF 16949, or conducting quality manual reviews.

Course Methodology

Individual Presentations

- Each participant will have opportunities to make brief, prepared oral presentations.
- A certified auditor must be able to communicate effectively both orally (auditor, auditee, team leader, opening and closing meeting participant) and in writing (checklists, pre-audit planning, recording observations and nonconformities, audit reports).

Written Exercises

- Written exercises will be given to evaluate each student's understanding of subject matter discussed that day. Questions will be multiple choice or short essay style.

Evaluation of Individual Participation

- Students must receive a **Competent** rating for every written exercise and breakout exercise in order to be evaluated as **Competent** for the applicable competency unit.
- Competency will also be evaluated through class participation, which encompasses the following aspects:
  - Asking meaningful questions in class
  - Sharing professional auditing experiences
  - Taking an active role in team exercises
  - Engaging in effective role-playing
  - Demonstrating achievement of the learning objectives
- Effective class participation provides the participant with opportunities to demonstrate practical understanding of the many audit principles.

Re-Examination

- Any student that receives a **Not Yet Competent** rating for any of the written exercises will be given further opportunities to demonstrate their competence in a method deemed appropriate by the instructor. These methods may include class discussions while reviewing the exercises, interviews scheduled before and/or after classroom sessions or a re-take of the written exercises where a **NYC** rating was received.

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- If a student receives a **Not Yet Competent** rating for any breakout exercise, the instructor should schedule an interview with the student either before or after class to further assess their competency.

Complaints and Appeals

- Student complaint and appeal procedures and forms are located in the training manual.

- Any student complaints or appeals should be submitted using the printed procedures and forms.

A BRIEF INTRODUCTION TO OMNEX

Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g., ISO 9001, IATF 16949, AS9100, QOS
    - Environmental Management Systems, e.g., ISO 14001
    - Health and Safety Management Systems, e.g., ISO 45001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.

About Omnex

- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 700 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

Omnex Worldwide Offices

Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

www.omnex.com
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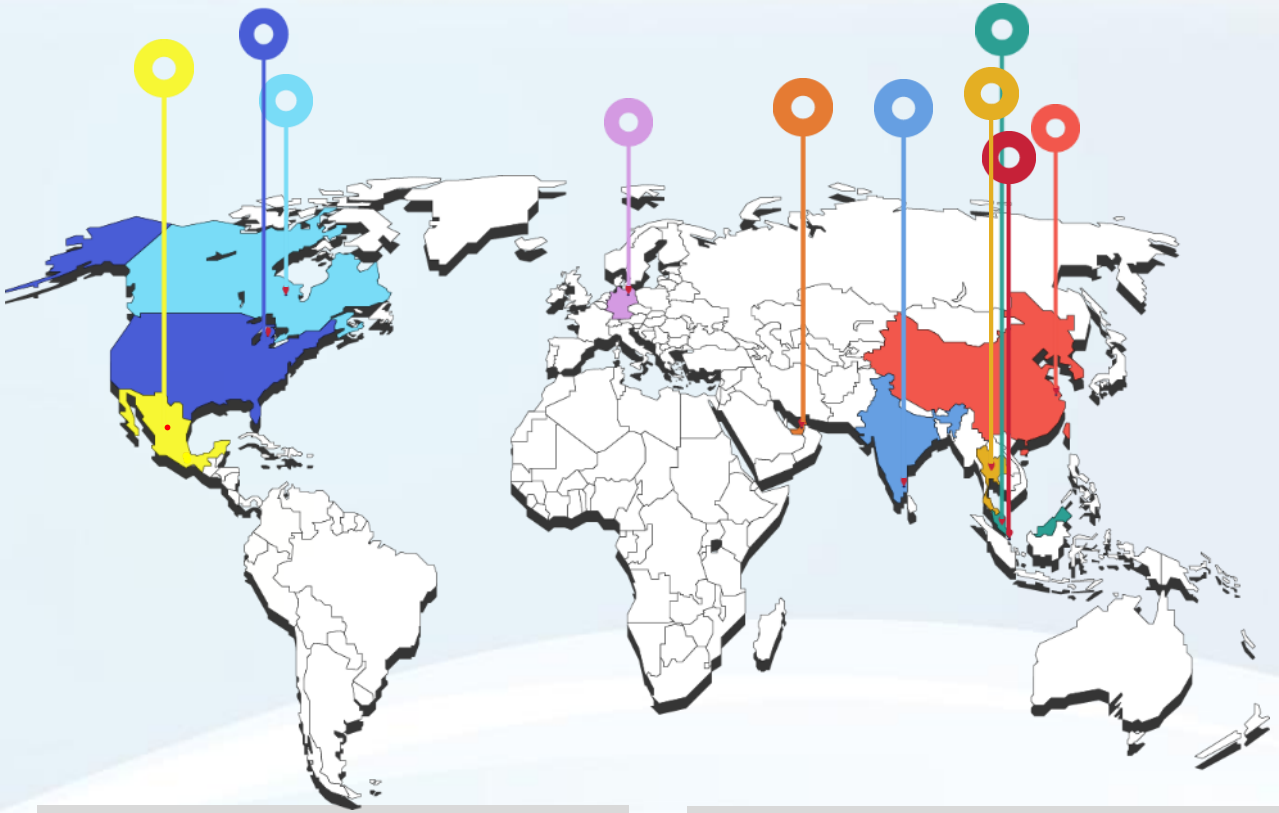

- Omnex Global Head Quarters (Michigan, USA)
  West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico (Monterrey)
- Singapore
- Malaysia (Kuala Lumpur)

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Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don’t interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others’ ideas
- ✓ No “buts” – keep an open mind
- ✓ Phones in Do Not Disturb (silent) mode
- ✓ No e-mails, texting or tweeting during class

If you must take a phone call or answer a text please leave the room for as short a period as possible

Icebreaker

- Instructor Information:
  - Name
  - Background
- Student Introductions:
  - Name
  - Position / Responsibilities
  - What is your involvement in the Quality Management System and the auditing process?
  - What do you expect to take away from this class?
  - Please share something unique and/or interesting about yourself.

Chapter 1

The ISO 9001:2015 and IATF 16949 Standards Explained

NOTE: Some pages will be skipped during the lecture portion of this chapter, but the page numbers are aligned so you can follow along with the presentation.

Chapter 1: The ISO 9001 and IATF 16949 Standards Explained — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- List and explain the documents pertaining to an Automotive QMS
- Describe the importance of Customer Oriented Processes (COPs)
- Define key IATF terms

Chapter Agenda

- ISO 9000 Series of Quality Management System Documents
- IATF 16949 Series of Automotive Quality Management System Documents
- Customer Oriented Processes
- IATF 16949 Key Definitions

Quality Management Principles

ISO 9001 & IATF 16949 are based on the following principles:

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

All of the requirements in IATF 16949 and ISO 9001:2015 are based on and support implementing these principles

High Level Structure (HLS) Core Terminology — Changes and Additions

- Changed definitions include:
  - Organization
  - Interested Party
  - Management System
  - Objective
  - Competence
  - Corrective Action
  - Continual Improvement

- New definitions added include:
  - Risk
  - Documented Information
  - Performance
  - Context of the Organization
  - Monitoring
  - Improvement
  - Knowledge

- New term with no definition:
  - Strategic Direction, cl. 4.1, 5.1.1, 9.3.1

Key Definitions in ISO 9000:2015

- **Quality:** degree to which a set of inherent characteristics of an object fulfills requirements.
- **Characteristic:** distinguishing feature.
  - There are various classes of characteristics, for example:
    - physical (e.g., mechanical, electrical, chemical or biological characteristics)
    - sensory (e.g., related to smell, touch, taste, sight, hearing)
    - behavioral (e.g., courtesy, honesty, veracity)
    - temporal (e.g., punctuality, reliability, availability)
    - ergonomic (e.g., physiological characteristic, or related to human safety)
    - functional (e.g., maximum speed of an aircraft)

ISO 9000
Fundamentals and Vocabulary

Key Definitions in ISO 9000:2015

- **Product:** output of an organization that can be produced without any transaction taking place between the organization and the customer.
  - Hardware is tangible and its amount is a countable characteristic.
  - Processed materials are tangible and their amount is a continuous characteristic.
    - Hardware and processed materials often are referred to as goods.
  - Software consists of information regardless of delivery medium.
- **Output:** result of a process.
- **Service:** output of an organization with at least one activity necessarily performed between the organization and the customer.

Key Definitions in ISO 9000:2015

- **Provider or Supplier:** organization that provides a product or a service.
  - Can be internal or external to the organization.
- **Organization:** person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.
- **Interested Party:** Person or organization that can affect, be affected by, or perceive itself to be affected by a decision of activity.
  - Examples: customers, owners, people in the organization, providers, bankers, regulators, unions, partners or societies which can include competitors or opposing pressure groups.

Key Definitions in ISO 9000:2015

- **Top Management:** person or group of people who directs and controls an organization at the highest level.
  - ***Note:*** If the scope of the management system covers only part of an organization, then Top Management refers to those who direct and control that part of the organization.
- **Management System:** set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.
  - ***Note:*** A management system can address a single discipline or several disciplines e.g., quality management, financial management or environmental management.
  - ***Note:*** The scope of a management system can include the whole of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

Key Definitions in ISO 9000:2015

- **Context of the Organization:** combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives.
- **Customer:** person or organization that could or does receive a product or a service that is intended for or required by this person or organization.
  - A customer can be internal or external to the organization.
- **Objective:** result to be achieved.

Key Definitions in ISO 9000:2015

- **Requirement:** need or expectation that is stated, generally implied or obligatory.
  - Requirements can be generated by different interested parties or by the organization itself.
- **Conformity:** Fulfillment of a requirement.
  - Contrasted with "compliance", which is no longer defined in ISO 9000 but is generally understood to be the fulfillment of a statutory or regulatory requirement.*

* if the *audit criteria* are selected from *legal (e.g., statutory or regulatory) requirements* the audit finding can use terms such as "compliance" or "non-compliance".

The IATF 16949 Family of Documents

Automotive Quality Management System Standard

Rules for Achieving and Maintaining IATF Recognition (Audit Process requirements)

Normative References With Requirements That Can Be Audited:

- ISO 9001:2015 — Quality Management Systems Requirements
- IATF 16949:2016 Sanctioned Interpretations
- Customer-specific Requirements
- Core Tools

IATF 16949 — Customer-Specific US OEMs Core Tools

- **APQP: Advance Product Quality Planning**
  - Guidelines for a product quality plan for the development of a product or service that satisfies the customer.
- **FMEA: Failure Modes and Effect Analysis**
  - Methodology used to ensure potential problems have been considered and addressed throughout the product and process development process (i.e., APQP).
- **SPC: Statistical Process Control**
  - Basic statistical methods associated with statistical process control and process capability analysis used for continual improvement efforts.
- **MSA: Measurement Systems Analysis**
  - Guidelines for assessing the quality of a measurement system where readings can be replicated on each part.
- **PPAP: Production Part Approval Process**
  - Ensures product consistently meets customer engineering specification requirements during production run at the quoted production rate.

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CUSTOMER ORIENTED PROCESSES

The Automotive COPs
(Customer Oriented Processes)

1 IN FROM THE CUSTOMER

Customer requires a specific activity done in compliance to their process

I

2

Your Organization

An Automotive COP has three criteria

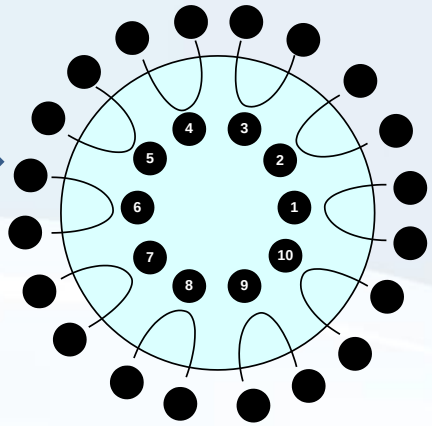
Customer's requirement is met and the output is provided to them in the format or method required

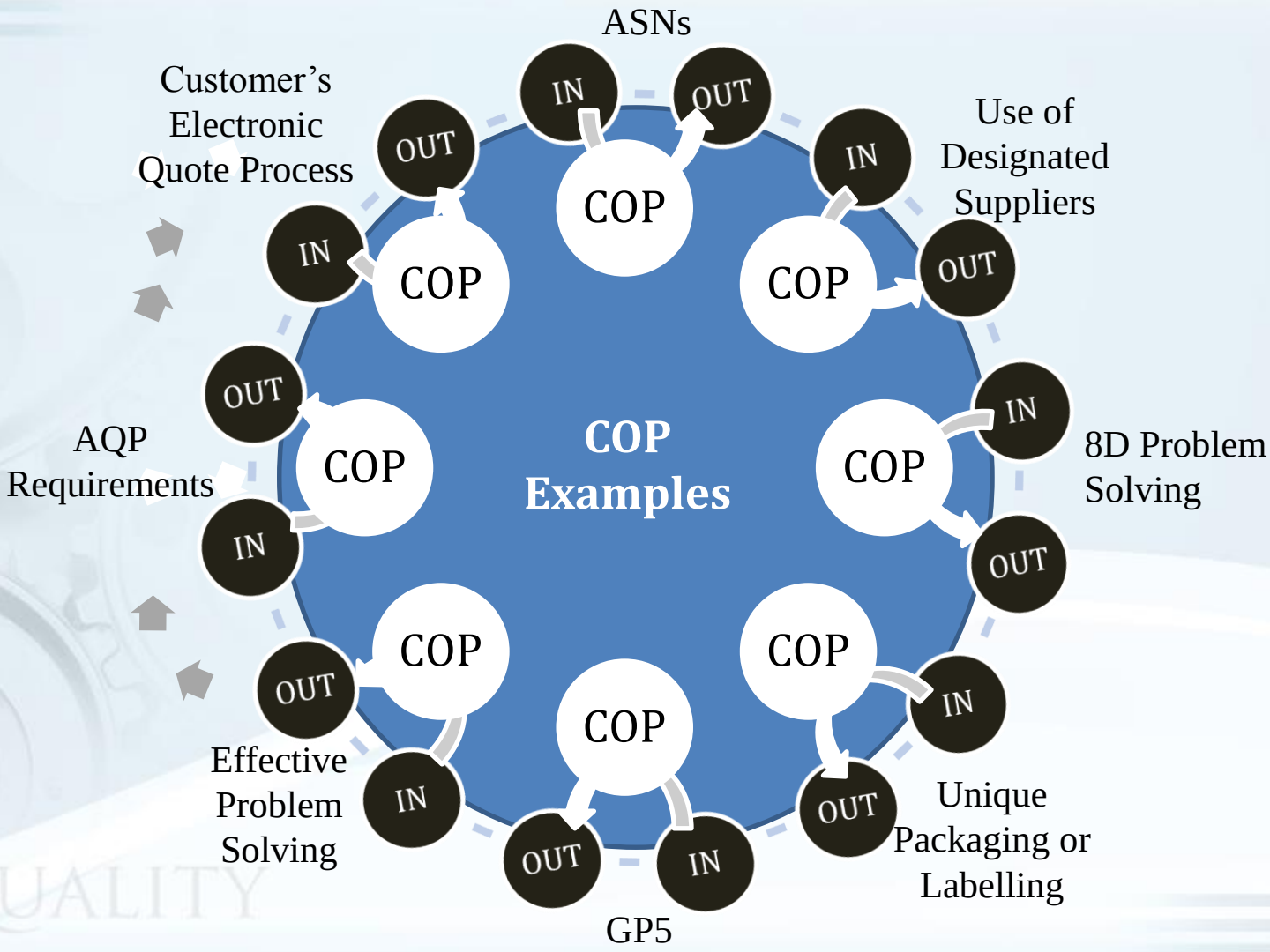
O

3 OUT TO THE CUSTOMER

Requires a sub-process within the organization's process to comply with the specific requirements of the specific customer

The Octopus Model





The Automotive COPs

The direction from the International Automotive Task Force (IATF) is that auditors focus their efforts on COPs.

IATF 16949:2016 Foreword – Automotive QMS Standard

- IATF 16949, along with applicable automotive customer-specific requirements, ISO 9001:2015 requirements and ISO 9000:2015 defines the fundamental quality management system requirements for automotive production and relevant service parts organizations.
- IATF 16949:2016 represents an innovative document, given the strong orientation to the customer, with inclusion of a number of consolidated previous customer-specific requirements.
- **Scope: the manufacture of customer-specified automotive production and service parts and accessories.**

Types of Processes

There are 3 types of processes which together encompass all activities within an organization:

- Customer Oriented Processes (COPs)
- Management Oriented Processes (MOPs)
- Support Processes (SOPs)

O-M-N-E-X

If you have an activity in your organization that doesn't fit into one of these categories, why are you doing it?

Key Definitions in IATF 16949:2016

- **Accessory Part:** customer-specified additional component(s) that are either mechanically or electronically connected to the vehicle or powertrain before (or after) delivery to the final customer (e.g., custom floor mats, truck bed liners, wheel covers, sound system enhancements, sunroofs, spoilers, super-chargers, etc.).
- **Authorization:** documented permission for a person(s) specifying rights and responsibilities related to giving or denying permissions or sanctions within an organization.
- **Challenge (master) Part:** parts(s) of known specification, calibrated and traceable to standards, with expected results (pass or fail) that are used to validate the functionality of an error-proofing device or check fixtures (e.g., go / no-go gauging).

Key Definitions in IATF 16949:2016

- **Customer Requirements:** all requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)
  Where the audited organization is a vehicle manufacturer, vehicle manufacturer subsidiary or joint venture with a vehicle manufacturer, the relevant customer is specified by the vehicle manufacturer, their subsidies, or joint ventures.*
- **Customer-specific Requirements:** interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard.

***Added by IATF 16949:2016 Sanctioned Interpretations (SI 1) to clarify that since vehicle manufacturers develop customer requirements for application in their supply chain by nature of the product realization process, where the vehicle manufacturers are being certified, the vehicle manufacturers define how customer approvals and/or input are managed.**

Key Definitions in IATF 16949:2016

- **Production Shutdown:** condition where manufacturing processes are idle; time span may be a few hours to a few months.
- **Remote Location:** location that supports manufacturing sites and at which non-production processes occur.
- **Site:** location at which value-added manufacturing processes occur.
- **Special Characteristic:** classification of a product characteristic or manufacturing process parameter that can affect safety or compliance with regulations, fit, function, performance, requirements, or subsequent processing of product.
- **Support Function:** non-production activity (conducted on site or at a remote location) that supports one (or more) manufacturing sites of the same organization.

Key Definitions in IATF 16949:2016

- **Embedded Software*:** Specialized program stored in an automotive component (typically computer chip or other non-volatile memory storage) specified by the customer, or as part of the system design, to control its function(s).
  - To be relevant in the scope of IATF 16949 certification, the part that is controlled by embedded software must be developed for an automotive application (i.e., passenger cars, light commercial vehicles, heavy trucks, buses and motorcycles. See Rules for Achieving and Maintaining IATF Recognition, 5th Edition, Section 1.0 Eligibility for Certification to IATF 16949, for what is eligible for "Automotive".
  - **NOTE:** Software to control any aspect of the manufacturing process (e.g., machine to manufacture a component or material) is not included in the definition of embedded software.

***Embedded Software Added by IATF 16949:2016 Sanctioned Interpretations (SI 15) to minimize confusion regarding embedded software and what is applicable to IATF 16949.**

Chapter 1: The IATF 16949 Standard Explained — What We Covered

Learning Objectives

You should now be able to:

- List and explain the documents pertaining to an Automotive QMS
- Describe the importance of Customer Oriented Processes (COPs)
- Define key IATF terms

Chapter Agenda

- IATF 16949 Series of Automotive Quality Management System Documents
- Customer Oriented Processes
- IATF 16949 Key Definitions

Chapter 2

ISO 9001:2015 and IATF 16949:2016 Requirements

NOTE: The lecture portion of this chapter will not cover all the clauses in detail. The requirements and further details for all clauses are in the printed text. Some pages will be skipped, but the page numbers are aligned so you can follow along with the presentation.

You will also need to refer to ISO 9001 and IATF 16949 standards during the presentation to review the actual requirements of the clauses.

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Chapter 2: ISO 9001 and IATF 16949 Requirements — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Explain the key points for each of the clauses
- Describe major sub-clauses for each of the clauses
- Explain the overall flow of the clauses
- Explain process approach

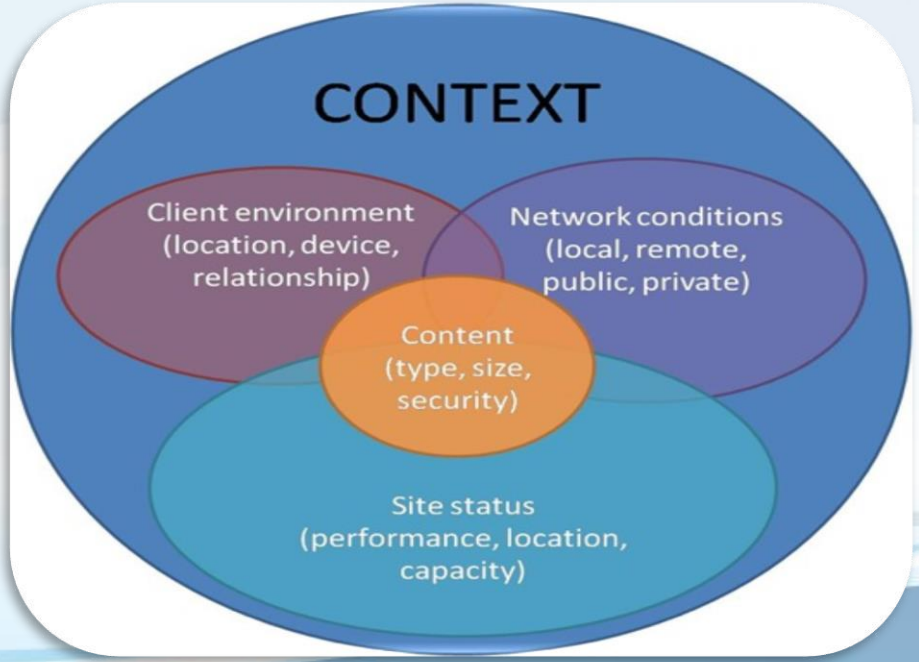
Chapter Agenda

- Clause 4 Context of the Organization
  - **Group Exercise 1 – Context**
  - **Group Exercise 2 – Interested Parties**
- Clause 5 Leadership
- Clause 6 Planning
  - **Group Exercise 3 – Audit Scenarios**
- Clause 7 Support
- Clause 8 Operation
  - **Group Exercise 4 – Audit Scenarios**
- Clause 9 Performance Evaluation
- Clause 10 Improvement
  - **Group Exercise 5 – Audit Scenarios**
  - **QMS Exams**

Requirements that have changed significantly from ISO/TS 16949 or are new to IATF 16949 are indicated by **Bold Red Underlined** text

Note!

CLAUSE 4 — CONTEXT OF THE ORGANIZATION



Clause 4 — Context of the Organization

4.1 Understanding the Organization and its Context (NEW)

4.2 Understanding the Needs and Expectations of Interested Parties (NEW)

4.3 Determining the Scope of the Quality Management System (CHANGED)

- **4.3.1 Determining the Scope of the QMS — Supplemental (CHANGED)**
- **4.3.2 Customer-Specific Requirements (NEW)**

4.4 Quality Management System and its Processes (CHANGED)

- **4.4.1 [No Title]**
  - **4.4.1.1 Conformance of Products and Processes (NEW)**
  - **4.4.1.2 Product Safety (NEW)**
- **4.4.2 [No Title]**

Clause 4 — Context of the Organization

Intent

- Understand the factors that influence the organization's purpose, objectives and sustainability
  - Understanding the context of an organization is a process!
  - An organization's purpose can be expressed in various ways, e. g., vision, mission, policies, objectives
- Understand the needs and expectations of interested parties
- Define the basic requirements of a QMS

4.1 Understanding the Organization and its Context

- The organization has to identify the issues that:
  - Are relevant to its purpose and strategic direction
  - Affect its ability to achieve the intended results of its QMS
  - ***The standard does not require strategic planning or a process for such!***
- The organization must monitor and review information about these issues, both internal and external:
  - Issues can include positive and negative factors
  - External context can be understood by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether global, regional or local
  - Internal context can be understood by considering issues related to values, culture, knowledge and performance of the organization

4.2 Understanding the Needs and Expectations of Interested Parties

- The organization must determine:
  - Interested parties ***relevant*** to the QMS
  - The requirements of these interested parties that are ***relevant*** to the QMS
- Relevant interested parties can or may affect the organization's ability to consistently meet customer and applicable statutory and regulatory requirements
  - Relevant interested parties are those who represent significant risk to organizational sustainability if their needs and expectations are not met
- Organizations identify interested parties' ***relevant*** requirements
  - Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk
  - The organization gathers and reviews information about relevant interested parties and their relevant requirements
- Interested parties are more than customers

4.2 Who is the Customer? — Guidance

- Customer
  - **Definition**: person or organization that could or does receive a product or a service that is intended for or required by this person or organization.
  - Examples
    - Consumer, client, end-user, retailer, input to internal process, beneficiary and purchaser
- Interested Parties
  - **Definition**: person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity.
  - Examples
    - Customers, owners, people in an organization, suppliers, bankers, unions, partners or society that may include competitors or opposing pressure groups

QMS Group Exercise 1

Context of the Organization
Mercury Manufacturing Case Study
(Assignment for Evening Study)

4.3 Determining the Scope of the Quality Management System

- The organization identifies the limits and applicability of its QMS to establish its scope.
- When determining the scope, the organization considers:
  - The issues referred to in the **Context of the Organization** clause **(4.1)**
  - The requirements of relevant interested parties **(4.2)**
  - Their products and/or services
- Note that the scope of a management system may include:
  - The whole organization,
  - Specific identified functions within the organization,
  - Specific and identified sections of the organization, or
  - One or more functions across a group of organizations

ISO Directives indicate that the terms "consider" and "take into account" are synonymous

4.3 Determining the Scope of the Quality Management System

- The organization applies all applicable requirements of the standard within the scope:
  - The organization justifies any requirement of the standard that they determine is **NOT** applicable.
  - This justification is only valid if those requirements do not affect the organization's ability to ensure conformity of products and services and the enhancement of customer satisfaction.
- The scope is documented and readily available
  - Includes the products and services covered, and
  - Justification for any instance where a requirement cannot be applied

Oxford dictionary: "ensure" means to make certain that (something) shall occur or be the case

4.3 Determining the Scope of the Quality Management System

4.3.1 Determining the Scope of the QMS – Supplemental

- **Supporting functions must be included in the QMS scope**.
- Examples of supporting functions include the following:
  - Design centers
  - Corporate headquarters
  - Distribution centers
- The only permitted exclusions are those related to product design and development requirements (see ISO 9001, clause 8.3).
  - **The exclusion must be justified and maintained as documented information** (see ISO 9001, clause 7.5)
- Permitted exclusions do not include manufacturing process design.

IATF Task Force Rationale: Modified to ensure supporting functions are included in the QMS scope as well as the audit. As such, this requirement applies not just to audits, but to process interfaces and the process map as well.

4.3 Determining the Scope of the Quality Management System

4.3.2 Customer-specific Requirements

- **Customer-specific requirements must be evaluated included in the QMS scope.**

IATF Task Force Rationale: Although customer-specific requirements were mentioned throughout ISO/TS 16949, this new requirement ensures customer-specific requirements are addressed and included in the QMS. Some sort of process is necessary in order to evaluate each customer-specific requirement and determine how and where it applies to the organization's QMS.

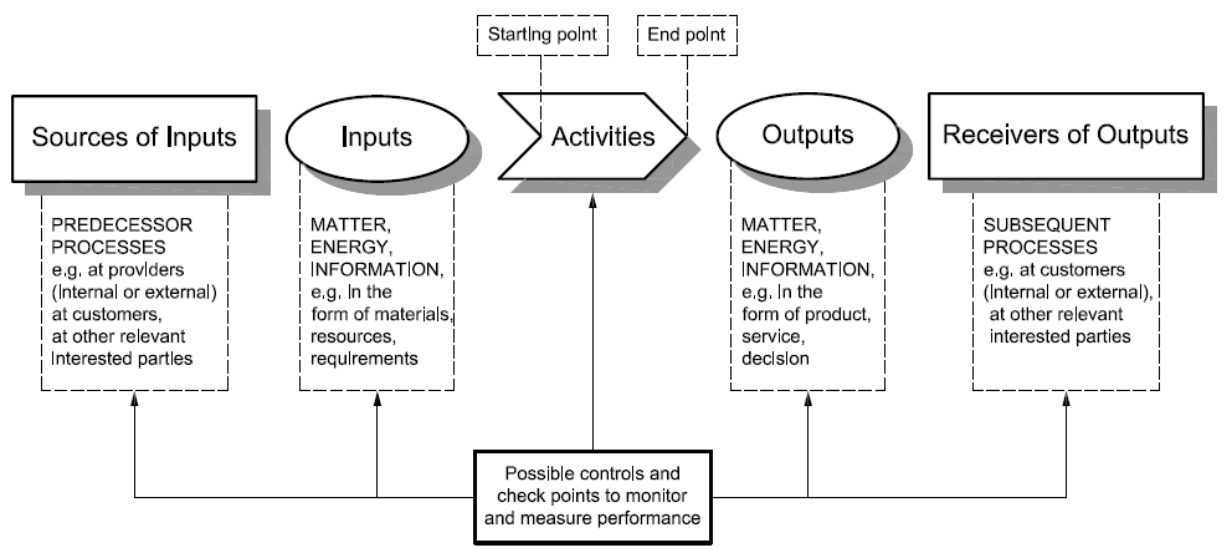
4.3 Determining the Scope — Guidance

- Audit evidence needed to demonstrate conformity can include:
  - Quality Manual
  - QMS Scope Statement **including all customer-specific requirements and all remote locations**
  - List of Products and Services of the Organization

4.4 Quality Management System and its Processes

- The organization implements, maintains and continually improves the quality management system, including the processes needed and their interactions.

- Also required:
  - Inputs
  - Outputs
  - Sequence
  - Interactions
  - Metrics
  - Process Controls
  - Resources
  - Responsibilities and Authorities
  - Addressing Risks and Opportunities
  - Process Evaluation and update as needed
  - Process and QMS Improvements



source: ISO 9001:2015

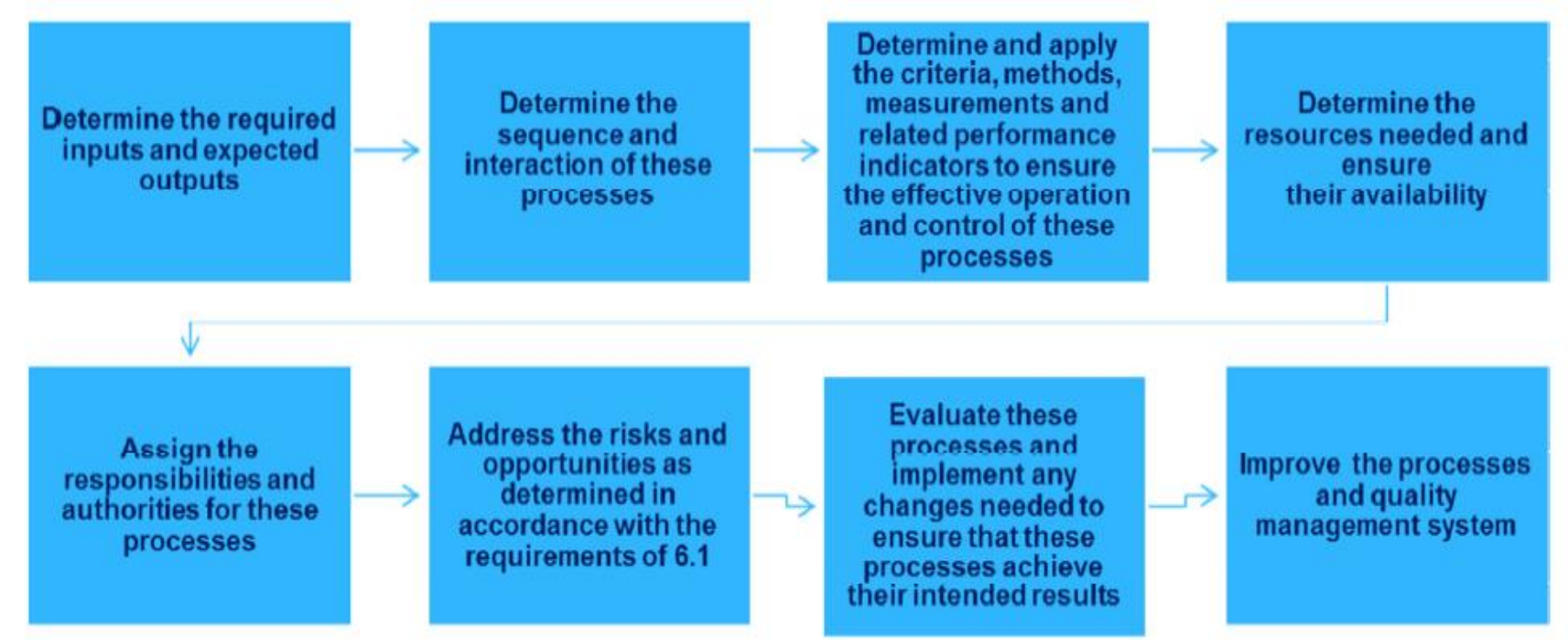
Guidance on Processes

- The use of the “process approach” is a mandatory requirement for ISO 9001:2015
- It is viewed as one of the most important for a quality management system
- Auditors have to understand that auditing a QMS is auditing an organization’s processes and their interactions
- The “process approach” is one of the core quality management principles, which is given as: “Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system”

ISO-IAF ISO 9001 Auditing Practice Group Guidance on Processes, January 1, 2016
http://isotc.iso.org/livelink/livelink/fetch/3541460/17525573/APG-Processes2015.pdf?nodeid=17531167&vernum=-2

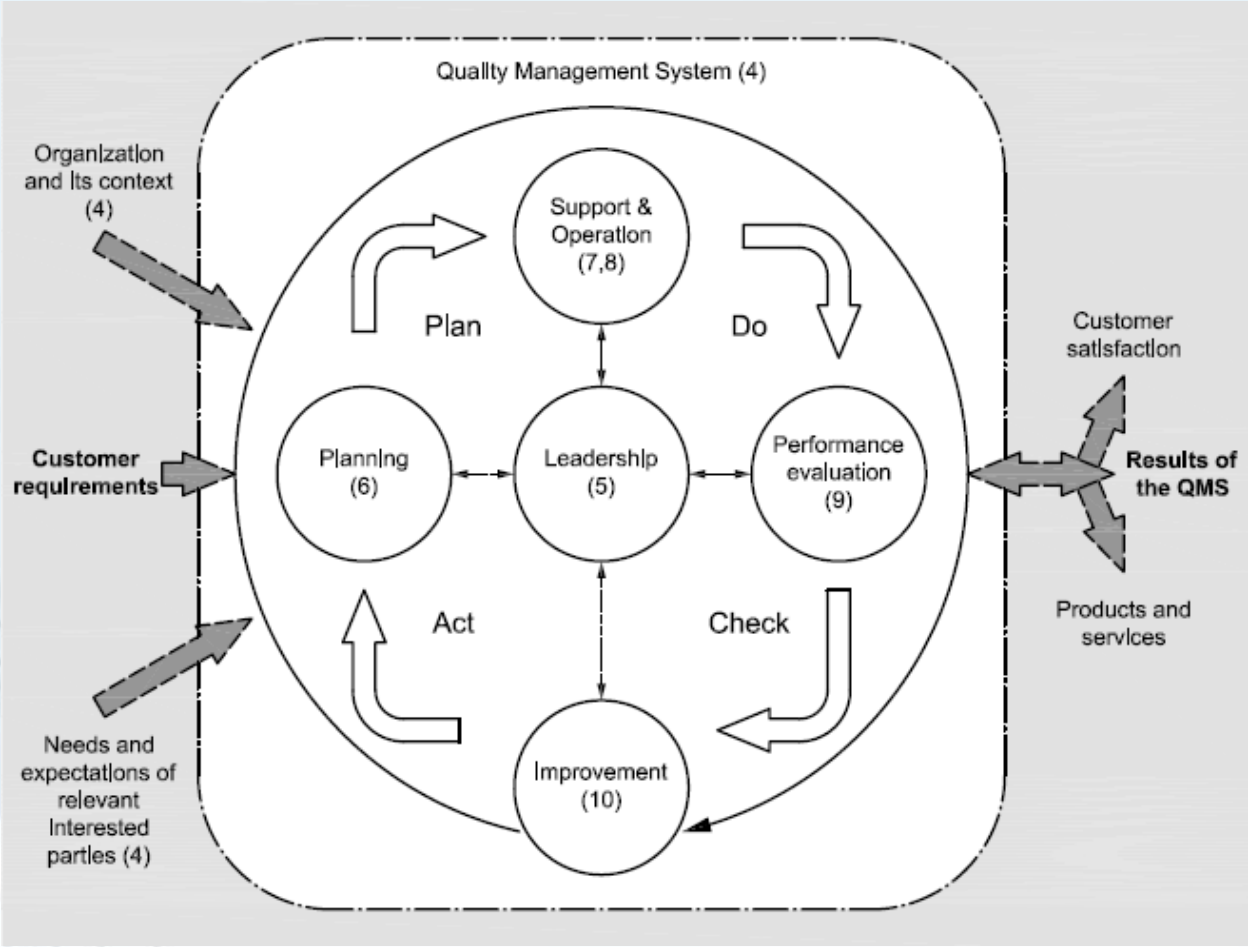
Guidance on Processes

- This diagram can assist auditors in establishing the sequence to audit the processes of the organization:



ISO-IAF ISO 9001 Auditing Practice Group Guidance on Processes, January 1, 2016
http://isotc.iso.org/livelink/livelink/fetch/3541460/17525573/APG-Processes2015.pdf?nodeid=17531167&vernum=-2

Quality Management System (QMS) Process Model

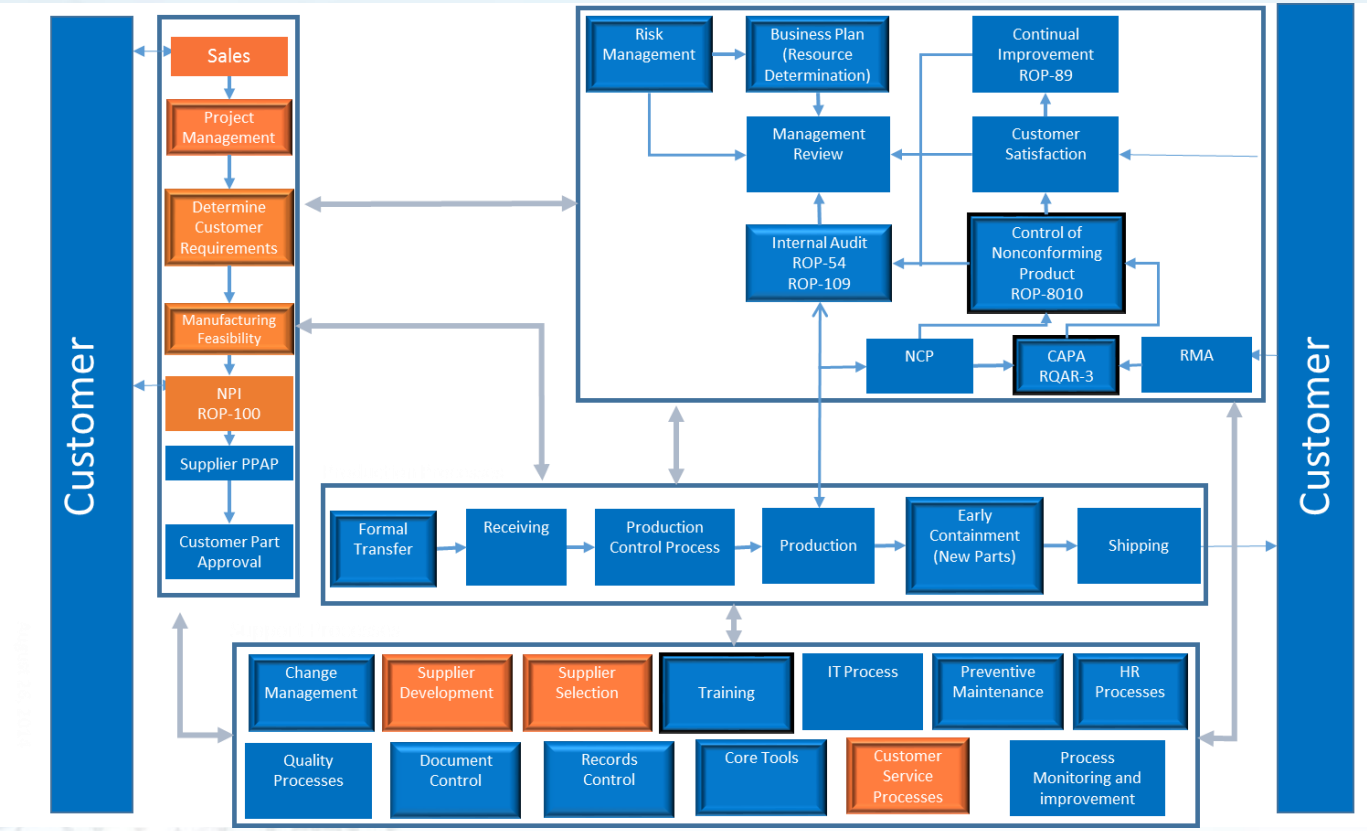


source: ISO 9001:2015

The PDCA cycle can be applied to all processes and to a QMS in whole

Typical Evidence for Process Approach

Process Map



Orange fill means that this process is out of scope of this plant

NOTE: The IATF Automotive Certification Scheme requires a "description of the remote location and the support they provide".

- Rules for Achieving and Maintaining IATF Recognition, 5th Edition

6.5.1 Stage 1 Planning, pg. 42

4.4 Quality Management System and its Processes

- Documented information is maintained to the extent necessary to:
  - Support process operation
  - Have confidence that the processes are being executed as planned

O$M$$NEX

The extent can differ between organizations due to:
- **The size of the organization and type of activities**
- **The complexity of processes and their interactions**
- **The competence of personnel**

See clause 7.5

NOTE: The IATF Automotive Certification Scheme requires "evidence that all the requirements of IATF 16949 are addressed by the client's processes".
- Rules for Achieving and Maintaining IATF Recognition, 5th Edition
6.5.1 Stage 1 Planning, pg. 42

4.4 Quality Management System and its Processes

4.4.1.1 Conformance of Products and Processes

- **All products and processes must meet all applicable customer, statutory and regulatory requirements (see 8.4.2.2).**
  - **This includes service parts and all outsourced products and processes.**

IATF Task Force Rationale: The intent of this new requirement is for a proactive approach to be adopted when assessing and addressing risks in order to move away from only using inspection. This new requirement also ensures the organization is responsible for the conformity of outsourced processes and that all products and processes meet the requirements and expectations of all interested parties.

4.4 Quality Management System and its Processes

4.4.1.2 Product Safety

- **The organization must maintain documented processes for the management of all product-safety related products and manufacturing processes, including but not limited to the following:**
  - a) Identification of statutory and regulatory product safety requirements
  - b) Customer notification of requirements of item a)
  - ***c) Special approval for Design FMEA***
  - d) Identification of product safety-related characteristics
  - e) Identification and controls of safety-related characteristics of product and at the point of manufacture
  - ***f) Special approval of Control Plans and Process FMEAs***
  - ***g) Reaction plans (see 9.1.1.1)***
  - ***h) Defined responsibilities, definition of escalation process and flow of information, including Top Management, and customer notification***

Orange (plain) Text – Requirements/Characteristics

Green (italics) Text – FMEA/Control Plan related

4.4 Quality Management System and its Processes

4.4.1.2 Product Safety *(cont'd)*

- **The organization must maintain documented processes for the management of all product-safety related products and manufacturing processes, including but not limited to the following:**
  - **i) Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes**
  - **j) Changes of product or process must be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, clause 8.3.6)**
  - k) Transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see 8.4.3.1)
  - **l) Product traceability by manufactured lot (at a minimum) throughout the supply chain (see 8.5.2.1)**
  - **m) Lessons learned for new product introduction**

4.4 Quality Management System and its Processes

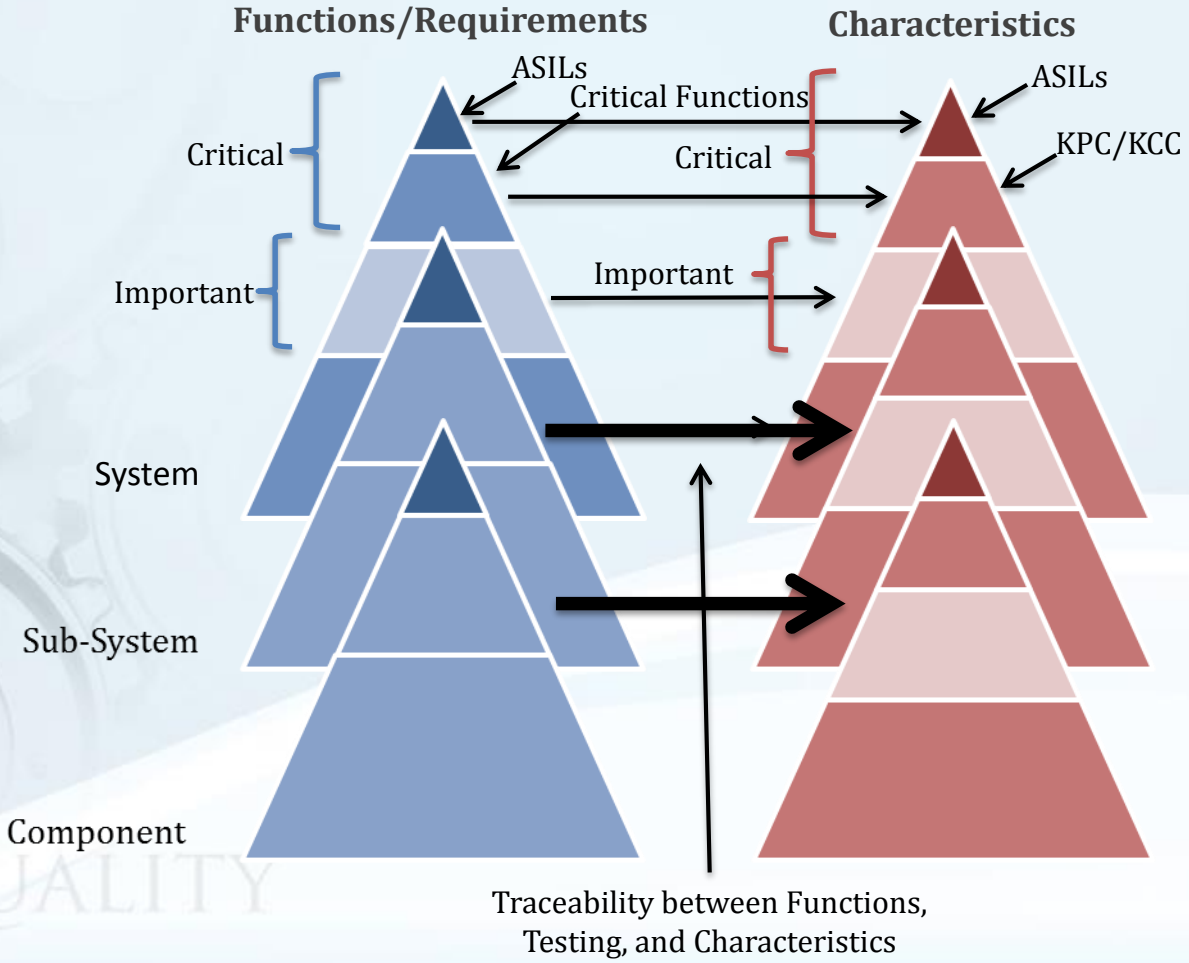
4.4.1.2 Product Safety *(cont'd)*

- NOTE: Special approval *of safety related requirements or documents may be required by the customer or the organization's internal processes.* ~~is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.~~*

IATF Task Force Rationale: Modified product and process safety requirements due to current and emerging issues in the automotive industry. Documented processes are needed to manage product safety, for both the product itself and the processes.

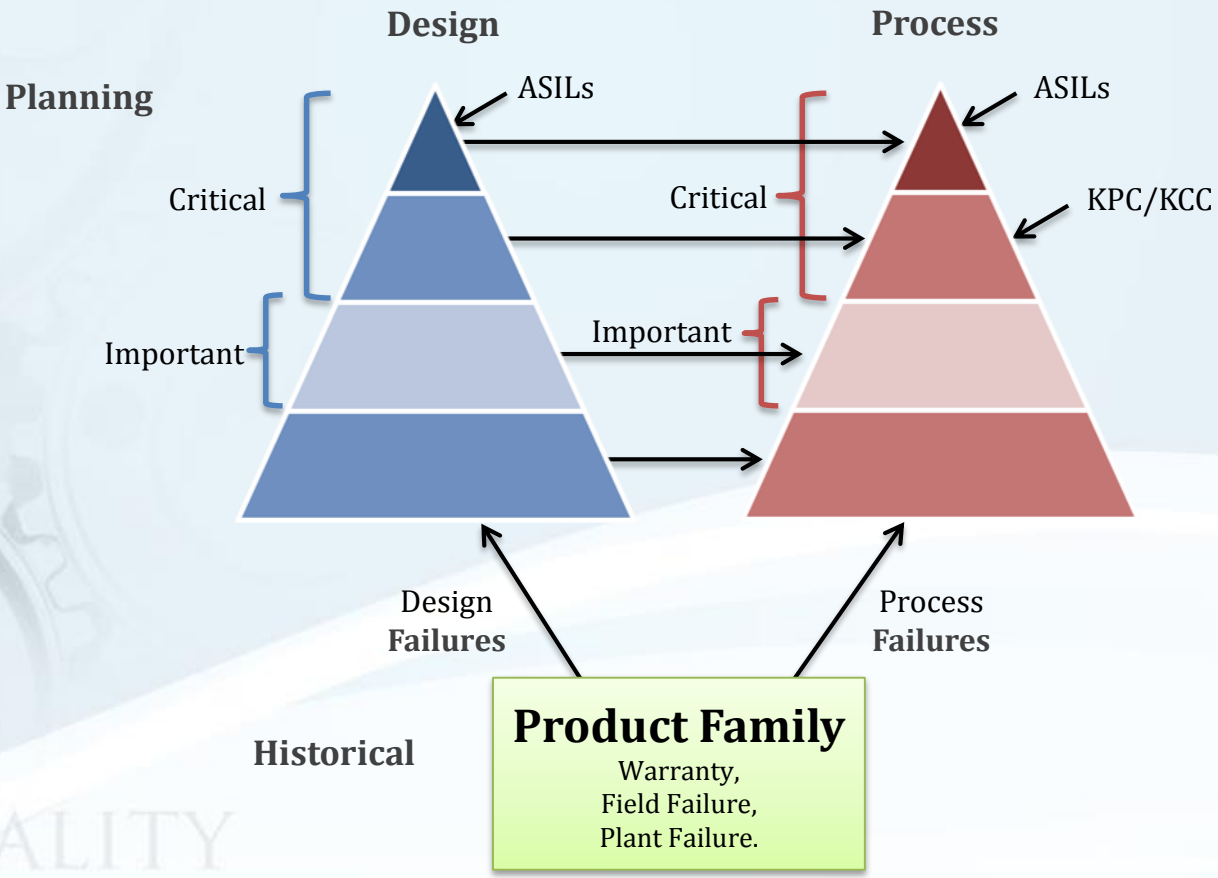
***Changed by IATF 16949:2016 Sanctioned Interpretations (SI 2) to clarify any confusion related to special approval for safety related requirements or documents.**

Requirements Management — Internal and Flow Down to Suppliers



Linkages required in Control Plan, see clause 8.5.1.1

Applying Lessons Learned



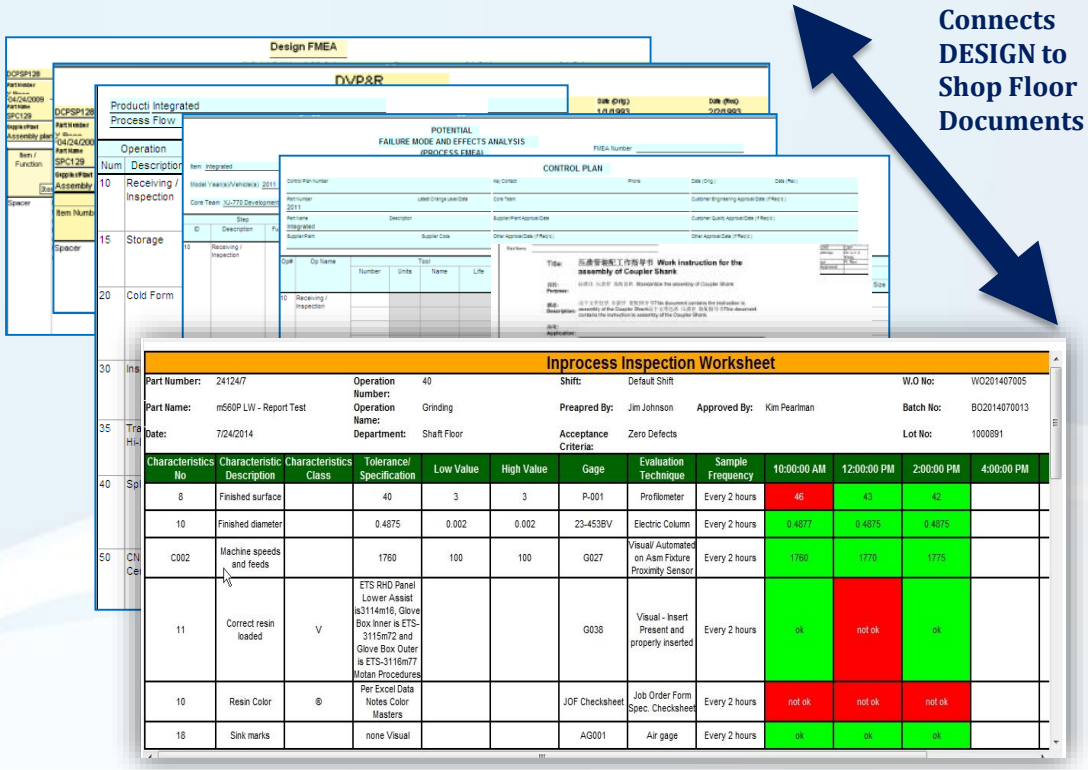
Update DFMEA and PFMEA based on customer failures, see clause 10.2.3

Linked DFMEAs, PFMEAs, Control Plans and Standardized Work using Enterprise Software

Linkages of Engineering requirements to Shop Floor

Links between Process Engineering and Shop Floor

Dynamic Linkage of Documents



Connects DESIGN to Shop Floor Documents

Linkages and updating FMEAs from Problem Solving is now a requirement

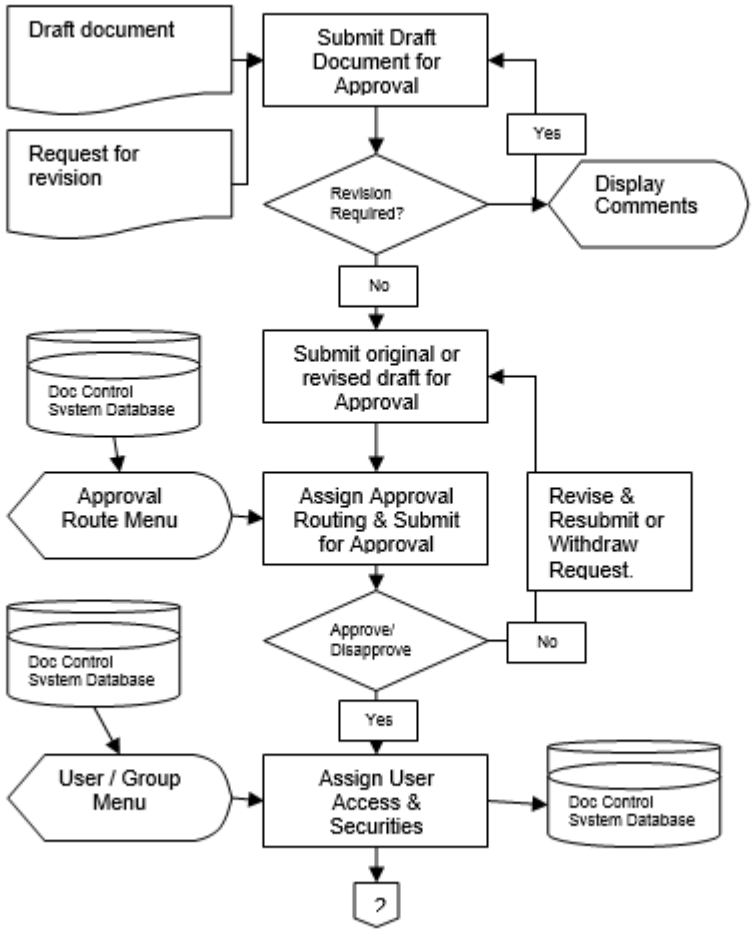
See clause 8.5.1.1 for Control Plan requirements

Instructor-led Discussion: Documentation of Processes

- Review the requirements of clause **4.4** and evaluate the process provided on the next page.
  - How could this organization update their documentation to satisfy IATF 16949:2016?

- NOTE: Assume that the provided process is complete and is only a single page.

Control of Documented Information Process

Responsibility	Flow	Remarks
Requestor Department Head Requestor System Administrator Department Head VP Operations Approver(s)		Submit via document control system. Display/download based on User Access Rights Submit via Doc Control System Preset Approval Routing Or Create New in Routing Menu List of Approved Documents in Doc Control Database Auto email notifications to approved Users/Groups

Documentation of Processes — Notes

CLAUSE 5 — LEADERSHIP

Clause 5 — Leadership

5.1 Leadership and Commitment

- 5.1.1 General (NEW)
  - 5.1.1.1 Corporate Responsibility (NEW)
  - 5.1.1.2 Process Effectiveness and Efficiency (CHANGED)
  - 5.1.1.3 Process Owners (NEW)
- 5.1.2 Customer Focus (CHANGED)

5.2 Quality Policy (CHANGED)

- 5.2.1 Establishing the Quality Policy
- 5.2.2 Communicating the Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

- 5.3.1 Organizational Roles, Responsibilities and Authorities — Supplemental (CHANGED)
- 5.3.2 Responsibility and Authority for Product Requirements and Corrective Actions (CHANGED)

Clause 5 — Leadership

Intent

- Establish requirements for leaders at all levels of the organization that address
  - Unity of purpose
  - Common direction
  - Conditions where people are engaged in achieving organizational objectives

5.1 Leadership and Commitment

5.1.1 General

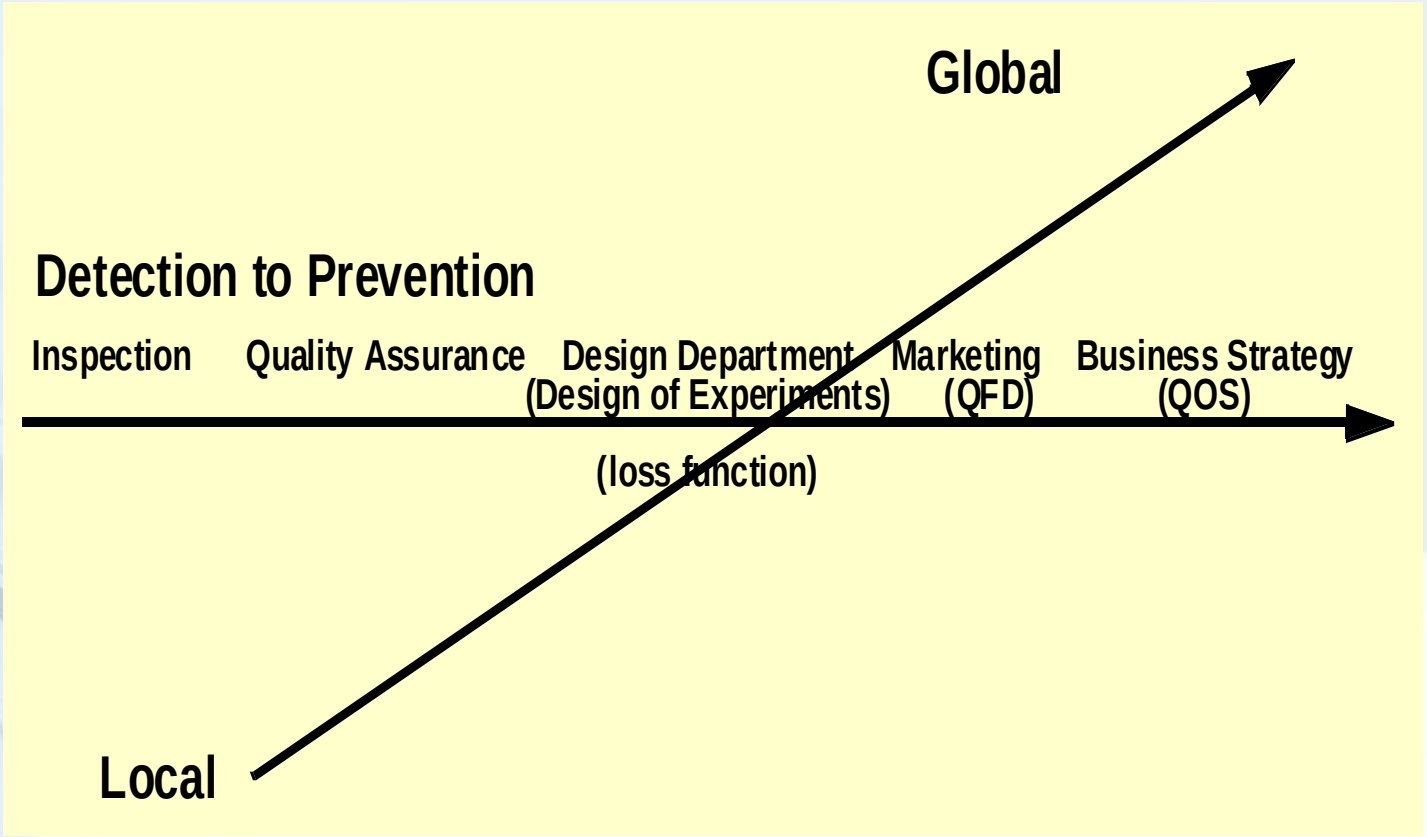
- Top Management is accountable for QMS effectiveness.
- Top Management establishes the Quality Policy and QMS objectives that are compatible with the strategic direction and the context of the organization.
- Integrate QMS requirements into the organization's business processes.
  - "Business" means those activities that are core to the purposes of the organization's existence.
- Promote use of the process approach and risk-based thinking.

5.1 Leadership and Commitment

5.1.1 General

- Top Management…
  - Provides the needed QMS resources
  - Communicates the importance of effective quality management and of conforming to QMS requirements
  - Confirms that the QMS achieves its intended results
  - Helps people contribute to QMS effectiveness
  - Promotes improvement
  - Supports other relevant management roles as it applies to their areas of responsibility

Concept of Quality is Constantly Evolving



For Product = conformance to requirements
For Organization = meeting customer and relevant interested party expectations; customer satisfaction

So What Does "Accountability" Mean?

- Does Top Management know whether the QMS is performing?
- Is Top Management involved in Planning?
  - How about Risk-Based Thinking?
  - How about the "intended results"?
  - How about Quality Objectives and the plan to achieve them?
- Are they involved in the Management Review?

Effectiveness – extent to which planned activities are realized and planned results are achieved (ISO 9000, 3.7.11)

Setting objectives to achieve QMS intended results and analyzing risks and opportunities for Planning, Product Conformance and Customer Satisfaction should involve Top Management – especially since they are accountable for QMS effectiveness

5.1 Leadership and Commitment

5.1.1.1 Corporate Responsibility

- **Corporate responsibility policies must include at a minimum:**
  - **An anti-bribery policy**
  - **An employee code of conduct**
  - **An ethics escalation policy (e.g., a "whistle-blowing" policy)**

Omnex recommends a site-by-site risk analysis and then integrate these policies and requirements into the business process for implementation. Also, consider integrate other social responsibility and sustainability initiatives.

IATF Task Force Rationale: New requirement that expands management responsibility into a set of leadership behaviors that ensure an effective QMS. These corporate responsibility policies address expectations for increased integrity in the automotive industry on social and environmental issues. This requires all levels and functions of the organization to follow an ethical approach that includes the ability to report any unethical behavior without fear of reprisal.

5.1 Leadership and Commitment

5.1.1.2 Process Effectiveness and Efficiency

- Effectiveness and efficiency of the QMS ~~Product realization processes and support processes~~* must be reviewed by Top Management in order to evaluate and improve it ~~their effectiveness and efficiency~~ *.
  - ***The results must be used as an input to Management Review (see 9.3.2.1).***

IATF Task Force Rationale: Modified to ensure the results of process review are included in the management review. Since process review activities include evaluation methods and the implementation of improvements, this means top management is essentially performing a review of the process-specific review performed by the process owners.

***Changed by Sanctioned Interpretations (SI 12) in order to clarify that not every process requires an efficiency measure.**

5.1 Leadership and Commitment

5.1.1.3 Process Owners

- **Process owners for managing processes and related outputs must be identified by Top Management.**
  - **Process owners must understand and be competent in their roles.**

IATF Task Force Rationale: New requirement that explicitly states management must ensure process owners understand and are competent in their roles. This requirement also grants process owners the authority and responsibility for the activities and results of the processes they manage.

5.1 Leadership and Commitment

5.1.2 Customer Focus

- Top Management ensures:
  - Customer and applicable regulatory requirements are determined, understood and consistently met.
  - Risks and opportunities that can affect product or service conformity and customer satisfaction are determined and addressed.
  - Focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Developing the Quality Policy

- The Quality Policy
  - Is appropriate to the purpose and context of the organization and supports its strategic direction
  - Provides a framework for quality objectives
  - Includes a commitment to satisfy applicable requirements
  - Includes a commitment to continual improvement of the QMS

5.2.2 Communicating the Quality Policy

- The Quality Policy is:
  - Available and maintained as documented information
  - Communicated, understood and applied within the organization
  - Available to relevant interested parties, as appropriate

Risk is implicit whenever "suitable" or "appropriate" is mentioned

5.3 Organizational Roles, Responsibilities and Authorities

- Top Management ensures responsibilities and authorities are assigned, communicated and **understood** within the organization.

- This includes assigning responsibility and authority for:
  - Ensuring that the QMS is effective and conforms to ISO 9001 requirements
  - Ensuring that the processes are delivering their intended outputs
  - Reporting…
    - on the QMS performance
    - on opportunities for improvement
  - Promoting customer focus throughout the organization
  - Maintenance of the integrity of the QMS when changes to the system are planned and implemented

5.3 Organizational Roles, Responsibilities and Authorities

5.3.1 Roles, Responsibilities and Authorities – Supplemental

- Top Management must assign responsibilities and authorities **that ensure customer requirements are fully met.**
- **These responsibilities and authorities must be documented and include, but are not limited to, personnel involved in:**
  - **Selection of special characteristics**
  - **Setting quality objectives and related training**
  - **Corrective and preventive actions**
  - **Product design and development**
  - **Capacity analysis**
  - **Logistics information**
  - **Customer scorecards and customer portals**

IATF Task Force Rationale: Modified to address the need to document these assignments and to clarify that the goal is to fully meet customer requirements.

5.3 Organizational Roles, Responsibilities and Authorities

5.3.2 Responsibility and Authority for Product Requirements and Corrective Actions

- **Top Management must ensure that:**
  - Personnel responsible for conformity to product requirements have the authority to stop **shipment and** production to correct quality problems. **NOTE: Due to process design, it might not always be possible to stop production immediately; in this case, the affected batch must be contained and shipment to the customer prevented.**
  - Personnel with authority and responsibility for corrective action are immediately notified when products or processes fail to meet requirements **in order to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained.**
  - Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

IATF Task Force Rationale: Modified to make Top Management responsible for ensuring conformity to product requirements and that corrective action is taken. This also clarifies that there must be a process to inform those with authority or responsibility for corrective action so they can ensure nonconforming material is identified, contained and not shipped to the customer.

CLAUSE 6 — PLANNING

Clause 6 — Planning

6.1 Actions to Address Risks and Opportunities (NEW)

- 6.1.1 and 6.1.2 [No Title]
  - 6.1.2.1 Risk Analysis (CHANGED)
  - 6.1.2.2 Preventive Action (CHANGED)
  - 6.1.2.3 Contingency Plans (CHANGED)

6.2 Quality Objectives and Planning to Achieve Them (CHANGED)

- 6.2.1 and 6.2.2 [No Title]
  - 6.2.2.1 Quality Objectives and Planning to Achieve Them — Supplemental (CHANGED)

6.3 Planning of Changes (NEW)

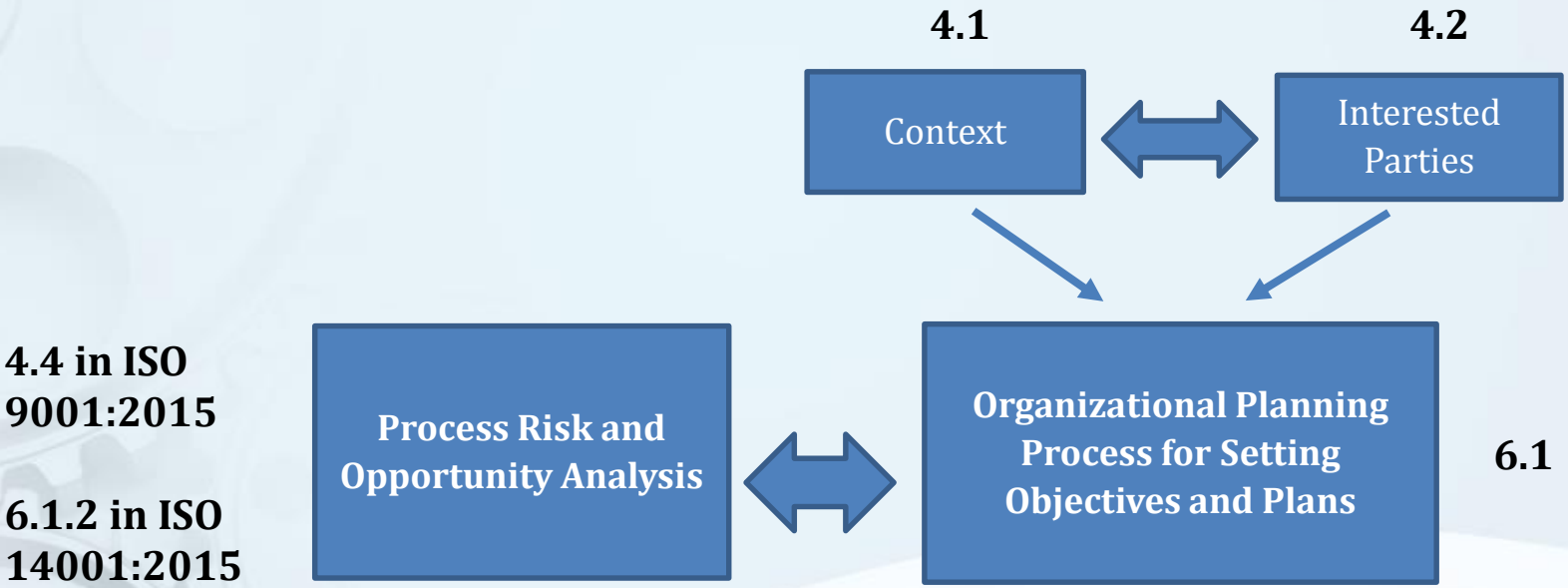
Clause 6 — Planning

Intent

- Create objectives
- Develop plans to meet those objectives
- Specify necessary operational processes
- Provide resources to achieve the objectives
- Determine appropriate metrics to monitor implementation of the planned actions

"…plans are useless, but planning is indispensable"
Dwight D. Eisenhower

Context, Interested Party Expectations, and Planning



Linkages between the requirements of the standard.
4.4 in ISO 9001:2015 and 6.1.2 in ISO 14001:2015 require the risk in the organization including processes to be analyzed

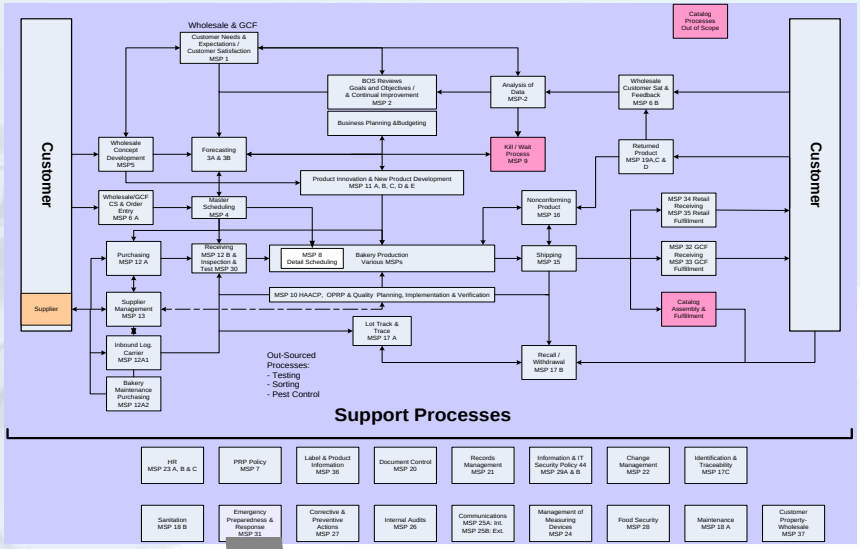
Risk and ISO 9001:2015

4.4 Process Approach

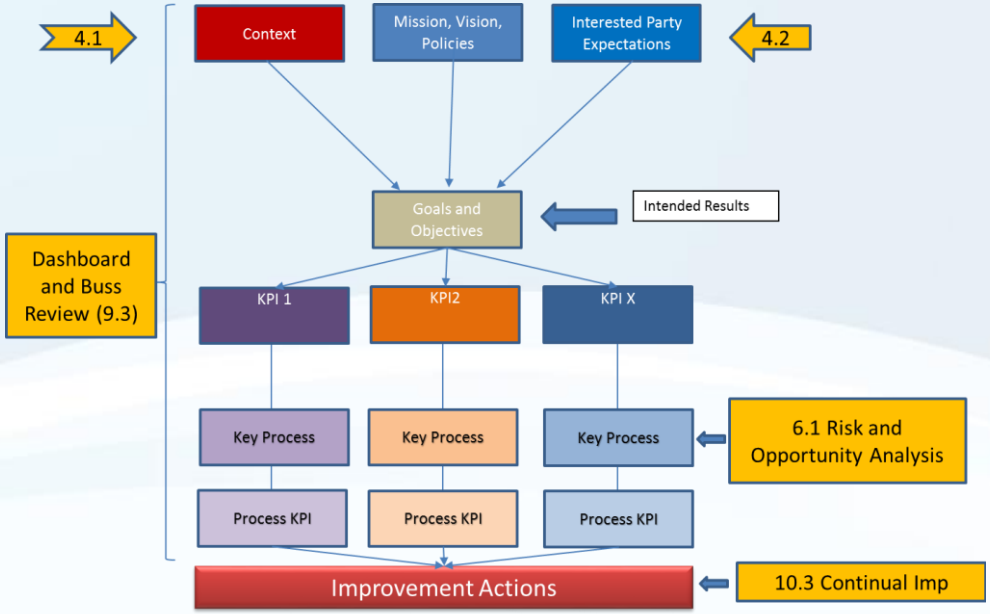
Address risk and opportunities determined, re: 6.1

6.1 Actions to Address Risks and Opportunities

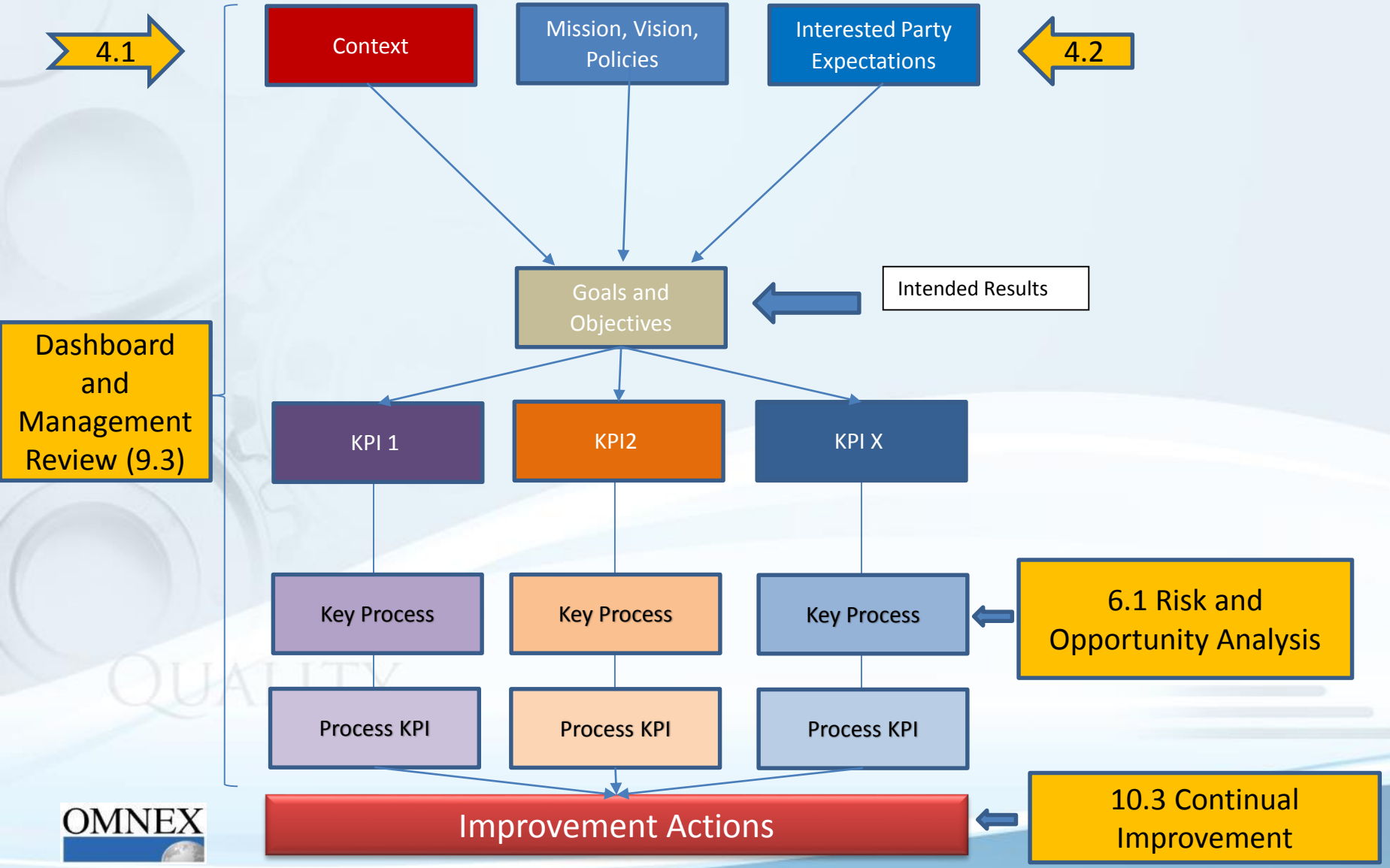
Plan and determine the actions needed



Process Map



OMNEX's BOSS Process (Alignment)



6.1 Actions to Address Risks and Opportunities

6.1.2

- The organization plans and implements actions that are integrated into its processes to address risks and opportunities then evaluates the effectiveness of the actions taken.
- Actions taken are proportionate to the potential impact on product or service conformity.
- Options to address risks and opportunities can include:
  - Avoiding risk
  - Taking risk in order to pursue an opportunity
  - Eliminating the source of the risk
  - Changing the likely occurrence or severity of the risk
  - Sharing the risk
  - Retaining risk by informed decision

Risk is defined in ISO 9000 as the effect of uncertainty

Risk-Based Thinking

Two primary clauses address risk-based thinking:

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance the quality management system can achieve its intended result(s);

(there is similar language in ISO 14001, not included) (We call this "Planning Risk")

5.1.2 Customer Focus

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

– Risk Analysis (6.1.2.1) at minimum includes product recalls, product audits, field returns and repairs, complaints, scrap, and rework

(We call this "Product Conformance and Customer Satisfaction risk")

Planning Risk

- Planning Risk asks the question:
  - *"What is the risk/opportunities of not meeting or meeting "intended outcomes" or the risk/opportunities of not meeting or meeting "QMS objectives"*

- Product Conformance and Customer Satisfaction Risk
  - Take a proactive and reactive approach to these risks
  - **Risk Analysis (6.1.2.1)** requires analysis of product data and identification of actions to improve product conformance related risk
  - **Reactive Approach:** Review data for both product conformance and customer satisfaction. Identify areas of poor product conformance risk and customer satisfaction. Conduct risk and opportunity analysis to reduce rejects and improve customer satisfaction.

6.1 Actions to Address Risks and Opportunities

6.1.2.1 Risk Analysis

- **At a minimum, risk analysis must include lessons learned from the following sources:**
  - **Product recalls**
  - **Product audits**
  - **Field returns and repairs**
  - **Complaints**
  - **Scrap**
  - **Rework**

IATF Task Force Rationale: While the need to identify, analyze and consider actual and potential risks was covered in various parts of ISO/TS 16949, this modified requirement adopts additional requirements for risk analysis and the need to analyze and respond to risks, considering specific risks associated with the automotive industry. The effectiveness of these actions should also be evaluated and integrated into the QMS.

6.1 Actions to Address Risks and Opportunities

6.1.2.2 Preventive Action

- Actions must be implemented to eliminate the causes of potential nonconformities in order to prevent their occurrence.
- Preventive actions must be appropriate to the severity of the potential issues.
- **A process to lessen the negative effects of risk must include the following:**
  - **Determining potential nonconformities and their causes**
  - **Evaluating the need for action to prevent occurrence of nonconformities**
  - **Determining and implementing action needed**
  - **Documented information of action taken**
  - **Reviewing the effectiveness of the preventive action taken**
  - **Utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, clause 7.1.6)**

IATF Task Force Rationale: Modified to include an automotive industry best practice by implementing a process to lessen the impact of the negative effects of risk.

6.1 Actions to Address Risks and Opportunities

6.1.2.3 Contingency Plans

- **The organization must perform the following:**
  - **a) Identify and evaluate internal and external risks to all manufacturing processes and equipment used to maintain production output and for ensuring customer requirements are met**
  - **b) Define contingency plans according to risk and impact to the customer**
  - c) Prepare contingency plans for continuity of supply in the event of any of the following:
    - Key equipment failures (see 8.5.6.1.1)
    - **Interruption from externally provided products, processes and services**
    - **Recurring natural disasters**
    - **Fire**
    - Utility interruptions
    - ***Cyber-attacks on IT systems****
    - Labor shortages
    - **Infrastructure disruptions**

***Added by IATF 16949:2016 Sanctioned Interpretations (SI 3) to address the possibility of a cyber-attack or ransom-ware disabling the manufacturing and logistics operations.**

6.1 Actions to Address Risks and Opportunities

6.1.2.3 Contingency Plans

- **The organization must perform the following:** ***(cont'd)***
  - d) **Include a notification process to the customer and other interested parties for any situation impacting customer operations**
  - e) **Periodically test the contingency plans for effectiveness**
    Cybersecurity testing may include simulated attacks, monitoring for known threats, dependency identification and vulnerability prioritization, and is appropriate to associated customer disruption risks; cybersecurity testing may be managed internally or subcontracted, as appropriate*
  - f) **Review contingency plan (annually, at a minimum) using a multidisciplinary team including Top Management, and update as required**
  - g) **Document the contingency plans and retain documented information describing any revisions, including the person(s) who authorized the changes**

***Added by IATF 16949:2016 Sanctioned Interpretations (SI 17) to provide details of what is to be tested as part of a cyber-attack contingency plan validation. Cybersecurity is a growing risk to manufacturing sustainability in all manufacturing facilities.**

6.1 Actions to Address Risks and Opportunities

6.1.2.3 Contingency Plans

- **The contingency plans must include provisions to validate product continues to meet customer specifications after the re-start of production following an emergency when production was stopped and the regular shutdown processes were not followed.**

IATF Task Force Rationale: Modified to ensure a systematic approach to identifying and evaluating risk for all manufacturing processes that focuses on external risks. Notification to the customer and other interested parties is also required unless there is no risk of delivering late or nonconforming product.

QMS Group Exercise 2

Assessing and Evaluating Risk (Assignment for Evening Study)

6.2 Quality Objectives and Planning to Achieve Them

6.2.1

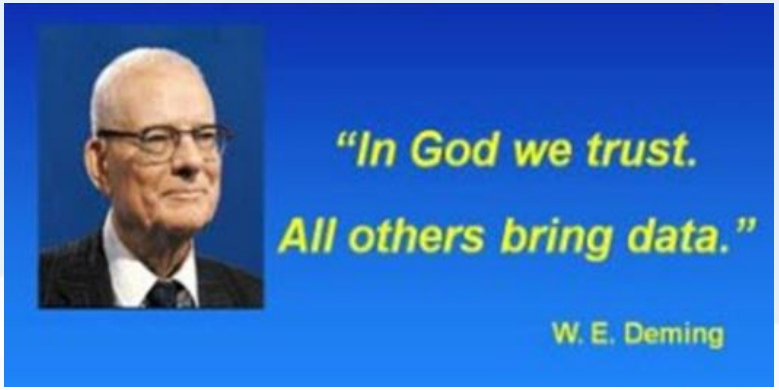
- The organization establishes quality objectives at relevant functions, levels and processes needed for the quality management system.
- Quality objectives:
  - Are consistent with the quality policy
  - Take into account applicable requirements
  - Are relevant to conformity of products, services and customer satisfaction
  - Are measurable, monitored, communicated and updated as appropriate
  - Are documented

ISO Directives indicate that the terms "consider" and "take into account" are synonymous

6.2 Quality Objectives and Planning to Achieve Them

6.2.2

- When planning how to achieve its quality objectives, the organization determines:
  - What will be done
  - What resources will be required
  - Who will be responsible
  - When it will be completed
  - How to evaluate the results



Planning the achievement of the objectives is now more prescriptive and includes the evaluation of results

6.2 Quality Objectives and Planning to Achieve Them

6.2.2.1 Quality Objectives – Supplemental

- Top Management must ensure quality objectives meeting **customer** requirements are defined, established and maintained for relevant functions, **processes and** levels throughout the organization.
- **The results of the review must be considered when the quality objectives and related performance targets, both internal and external, are established.**
  - **This must occur annually, at a minimum.**

IATF Task Force Rationale: Modified so customer requirements are addressed at all levels of the organization, including the need to consider customer targets.

6.3 Planning of Changes

- Changes needed by the organization are carried out in a planned and systematic manner (**4.4**) considering the…
  - Purpose of the changes and their potential consequences
  - Integrity of the QMS
  - Availability of resources
  - Allocation/reallocation of responsibilities and authorities

6.3 Planning of Changes — Guidance

- Audit evidence needed to demonstrate conformity can include:
  - Process for change management including process owner
  - Documented information on the process, e. g., procedure, change notices, cross-functional and customer (if applicable) approvals prior to implementation, breakpoint management
  - Audit interview results
  - Others?

QMS Group Exercise 3

Audit Scenarios: Clauses 4-6

QUALITY

OMNEX

CLAUSE 7 — SUPPORT

Clause 7 — Support

7.1 Resources

- 7.1.1 General
- 7.1.2 People
- 7.1.3 Infrastructure
  - 7.1.3.1 Plant, Facility, and Equipment Planning (CHANGED)
- 7.1.4 Environment for the Operation of Processes
  - 7.1.4.1 Environment for the Operation of Processes — Supplemental
- 7.1.5 Monitoring and Measuring Resources
  - 7.1.5.1 General
    7.1.5.1.1 Measurement Systems Analysis (CHANGED)
  - 7.1.5.2 Measurement Traceability
    7.1.5.2.1 Calibration/Verification Records (CHANGED)
  - 7.1.5.3 Laboratory Requirements
    7.1.5.3.1 Internal Laboratory
    7.1.5.3.2 External Laboratory (CHANGED)
- 7.1.6 Organizational Knowledge (NEW)

7.2 Competence

- 7.2.1 Competence — Supplemental (CHANGED)
- 7.2.2 Competence — On-the-job Training (CHANGED)
- 7.2.3 Internal Auditor Competency (CHANGED)
- 7.2.4 Second-Party Auditor Competency (NEW)

7.3 Awareness

- 7.3.1 Awareness — Supplemental (CHANGED)
- 7.3.2 Employee Motivation and Empowerment

7.4 Communication (CHANGED)

7.5 Documented Information (NEW)

- 7.5.1 General
  - 7.5.1.1 QMS Documentation (CHANGED)
- 7.5.2 Creating and Updating
- 7.5.3 Control of Documented Information
  7.5.3.1 and 7.5.3.2 [No Title]
  - 7.5.3.2.1 Record Retention (CHANGED)
  - 7.5.3.2.2 Engineering Specification (CHANGED)

Clause 7 — Support

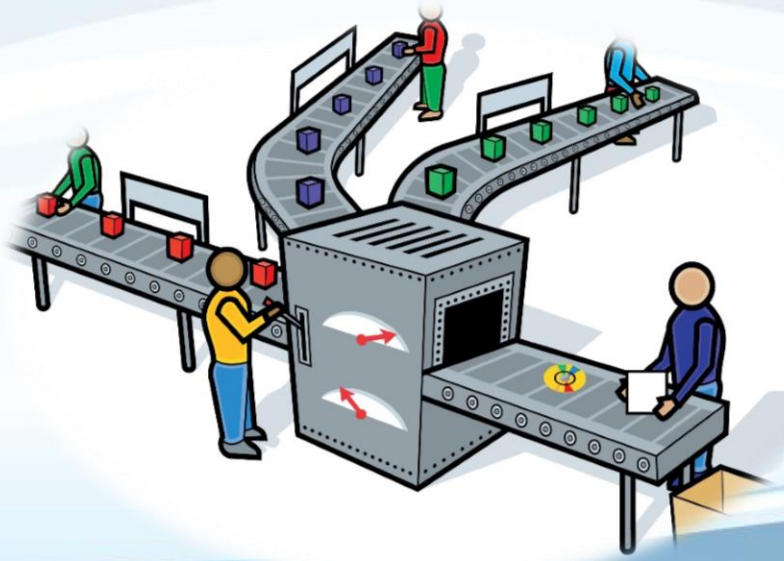
Intent

- Support for the implementation of the QMS
  - Human Resources
  - Infrastructure
  - Work Environment
  - Monitoring and Measuring Resources
  - Knowledge
  - Competence
  - Documented Information

Group Exercise and Presentations: Understanding Clause 7.0 Resources

- The instructor will assign clauses to teams – study your assigned requirements, focusing on changes to the standard
- Be prepared to provide the following feedback:
  - Summary of the clause
  - What has changed in IATF 16949
  - Impact on the documented or implemented system

CLAUSE 8 — OPERATION



Clause 8 — Operation

8.1 Operational Planning and Control

8.2 Requirements for Products and Services

8.3 Design and Development of Products and Services

8.4 Control of Externally Provided Processes, Products and Services

8.5 Production and Service Provision

8.6 Release of Products and Services

8.7 Control of Nonconforming Outputs

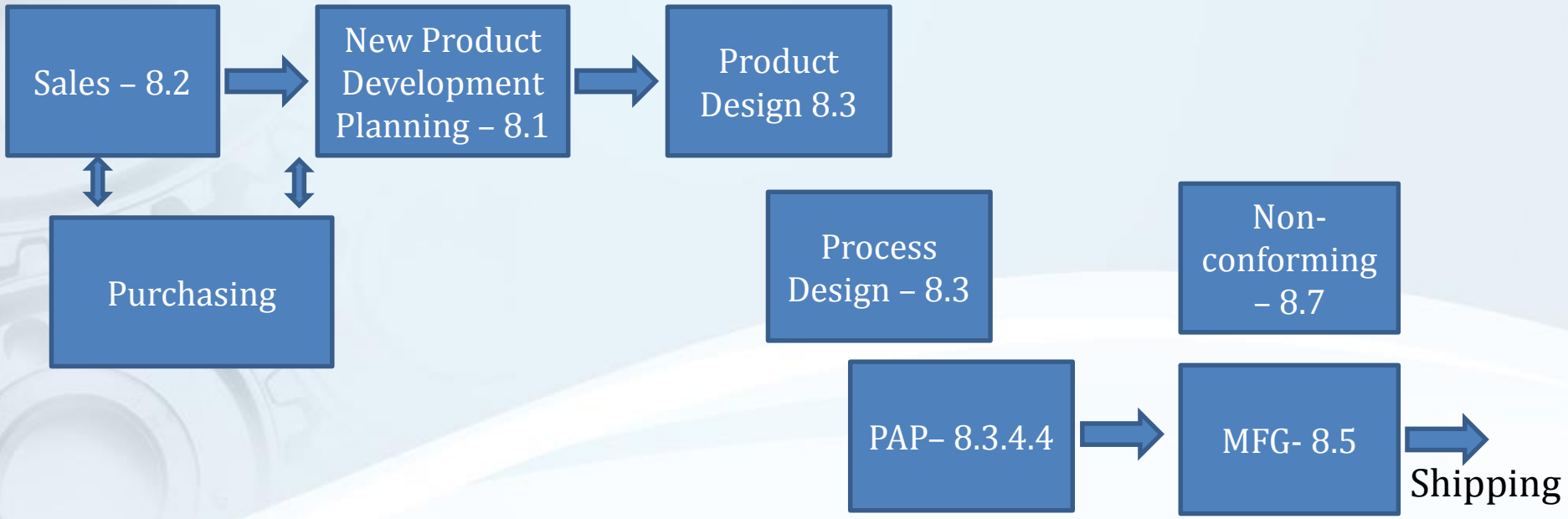
*** see details before each sub-clause for new/changed requirements**

Clause 8 — Operation

Intent

- Define the basic quality system requirements for value-added processes needed for product or service realization and other processes that are directly related.

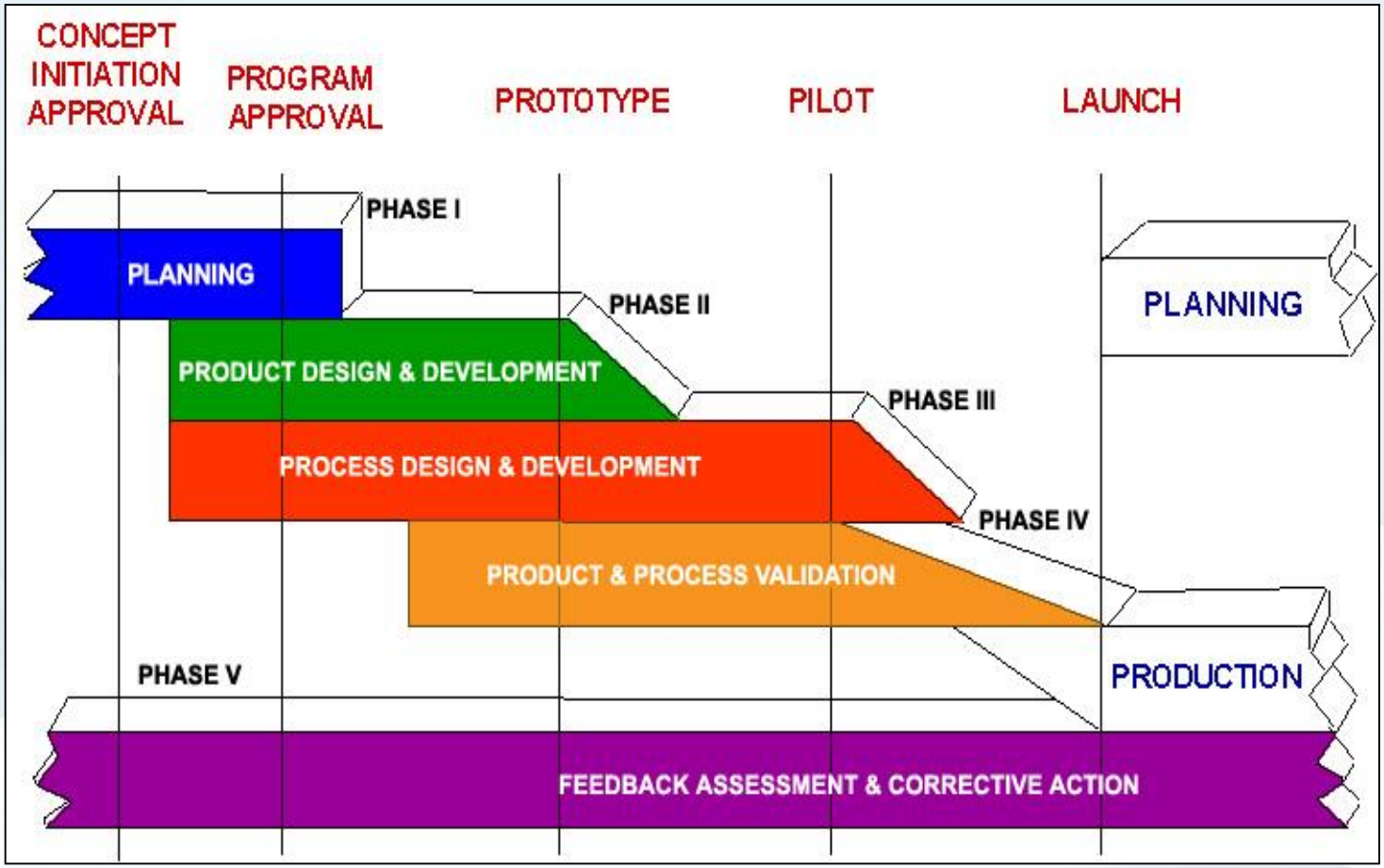
Instructor-Led Flipchart Example



Alignment of APQP Processes with IATF 16949

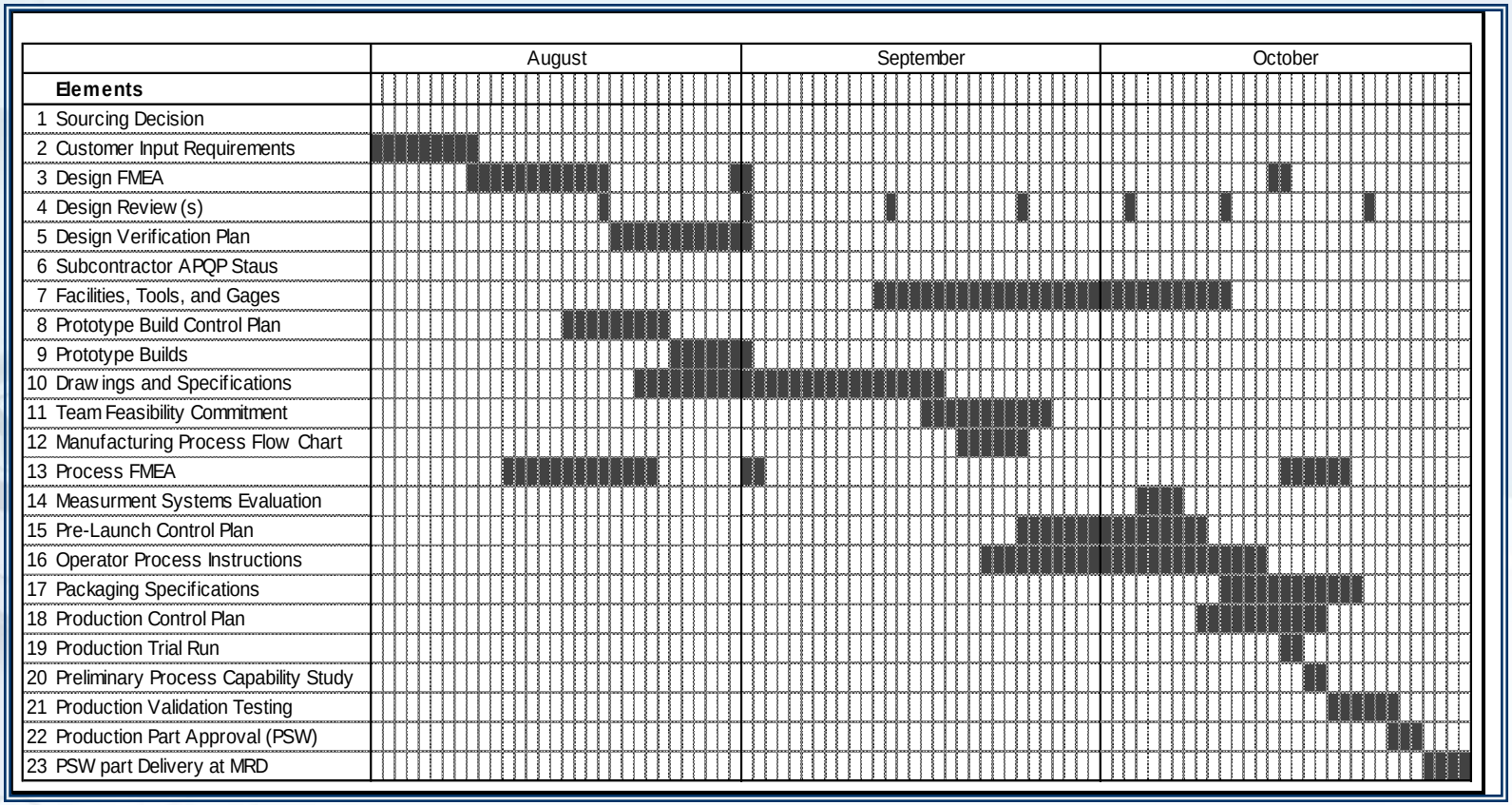
How do the IATF Clauses integrate with APQP?

Also, is there something we need to add from these clauses to fully integrate APQP and IATF 16949?



Review Clause 8 Requirements…are they satisfied by APQP?

APQP Timing Plan Chart [Gantt]



Example for purposes of illustration only

APQP and Timing Chart

Class Discussion

- For all the clauses that are shown to integrate with APQP, study the APQP Reference Manual and compare it to the IATF 16949 requirements. What additional requirements are in the new standard?

Clause 8 — Operation

8.1 Operational Planning and Control (CHANGED)

- 8.1.1 Operational Planning and Control — Supplemental (CHANGED)
- 8.1.2 Confidentiality

Clause 8 — Operation

8.2 Requirements for Products and Services

- **8.2.1 Customer Communication**
  - **8.2.1.1 Customer Communication — Supplemental (CHANGED)**
- **8.2.2 Determining the Requirements for Products and Services**
  - **8.2.2.1 Determining the Requirements for Products and Services — Supplemental (CHANGED)**
- **8.2.3 Review of Requirements for Products and Services**
  - **8.2.3.1 [No Title]**
  - **8.2.3.1.1 Review of Requirements for Products and Services — Supplemental (CHANGED)**
  - **8.2.3.1.2 Customer-designated Special Characteristics**
  - **8.2.3.1.3 Organization Manufacturing Feasibility (CHANGED)**
  - **8.2.3.2 [No Title]**
- **8.2.4 Changes to Requirements for Products and Services**

8.2 Requirements for Products and Services

8.2.1 Customer Communication

- Customer communications includes:
  - Information on products and services
  - Handling inquiries, contracts or orders, including any changes
  - Obtaining customer feedback, including any complaints
  - Handling or treatment of any customer-owned property
  - Specific requirements for contingency actions, when relevant

8.2.1.1 Customer Communication – Supplemental

- **All written and verbal communication must be in a mutually agreed language.**
- Must be able to communicate necessary information, including data, in a customer-specified computer language and format.

IATF Task Force Rationale: Modified to address language requirements for communication, which should be considered when determining competence for roles that require customer communication.

8.2 Requirements for Products and Services

8.2.2 Determining the Requirements for Products and Services

- When determining requirements for product or service to be offered to customers, the organization ensures that:
  - Regulatory and internally-specified requirements for products and services are defined
  - It can substantiate its product and service claims

8.2.2.1 Determining the Requirements – Supplemental

- These requirements must include recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes.
- **Compliance to ISO 9001, clause 8.2.2a), includes but is not limited to the following: all applicable government, safety and environmental regulations related to acquisition, storage, handling, recycling, elimination or disposal of material.**

IATF Task Force Rationale: Modified by elevating former notes to clause requirements. It is recommended to standardize organizational knowledge on recycling, environmental impact and product and manufacturing process characteristics, and review it when determining requirements for products and services.

8.2 Requirements for Products and Services

8.2.3 Review of the Requirements for Products and Services

8.2.3.1

- Where there are no documented customer requirements, the customer requirements are confirmed by the organization prior to acceptance.

8.2.3.1.1 Review of Requirements – Supplemental

- **Documented evidence of a** customer-authorized waiver for the requirements of ISO 9001, clause 8.2.3.1 **must be retained** for a formal review.

8.2.3.1.2 Customer-designated Special Characteristics

- The organization must conform to customer requirements for designation, **approval** documentation and control of special characteristics.

8.2 Requirements for Products and Services

8.2.3 Review of the Requirements for Products and Services

8.2.3.1.3 Organization Manufacturing Feasibility

- **A multidisciplinary approach must be used in a feasibility analysis to** determine if the manufacturing processes are capable of consistently producing product **that meets all customer-specified engineering and capacity requirements.**
  - **This feasibility analysis must also be performed for any new manufacturing or product technology and any changed manufacturing process or product design.**
- **The ability to produce product to specifications at the required rate should be validated through production runs, benchmarking studies, or other appropriate methods.**

IATF Task Force Rationale: Modified to strengthen requirements for feasibility through the use of a multidisciplinary approach. When validating the ability to make product at the specified rate, customer-specific requirements should be considered.

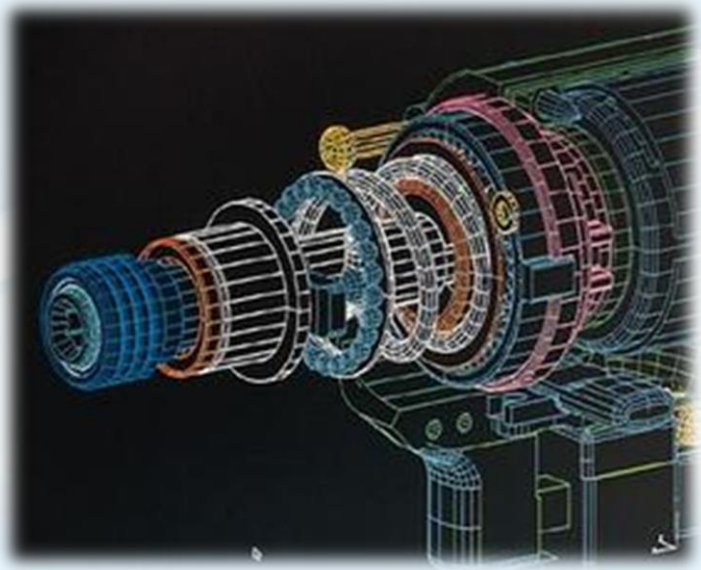
8.2.3.2

- The organization ***retains documented information*** as applicable on the results of the review, including any new or changed product or service requirements.

8.2 Requirements for Products and Services

8.2.4 Changes to Requirements for Products and Services

- Where product or service requirements are changed, the organization ensures that relevant information is amended and that relevant personnel are made aware of the changes.

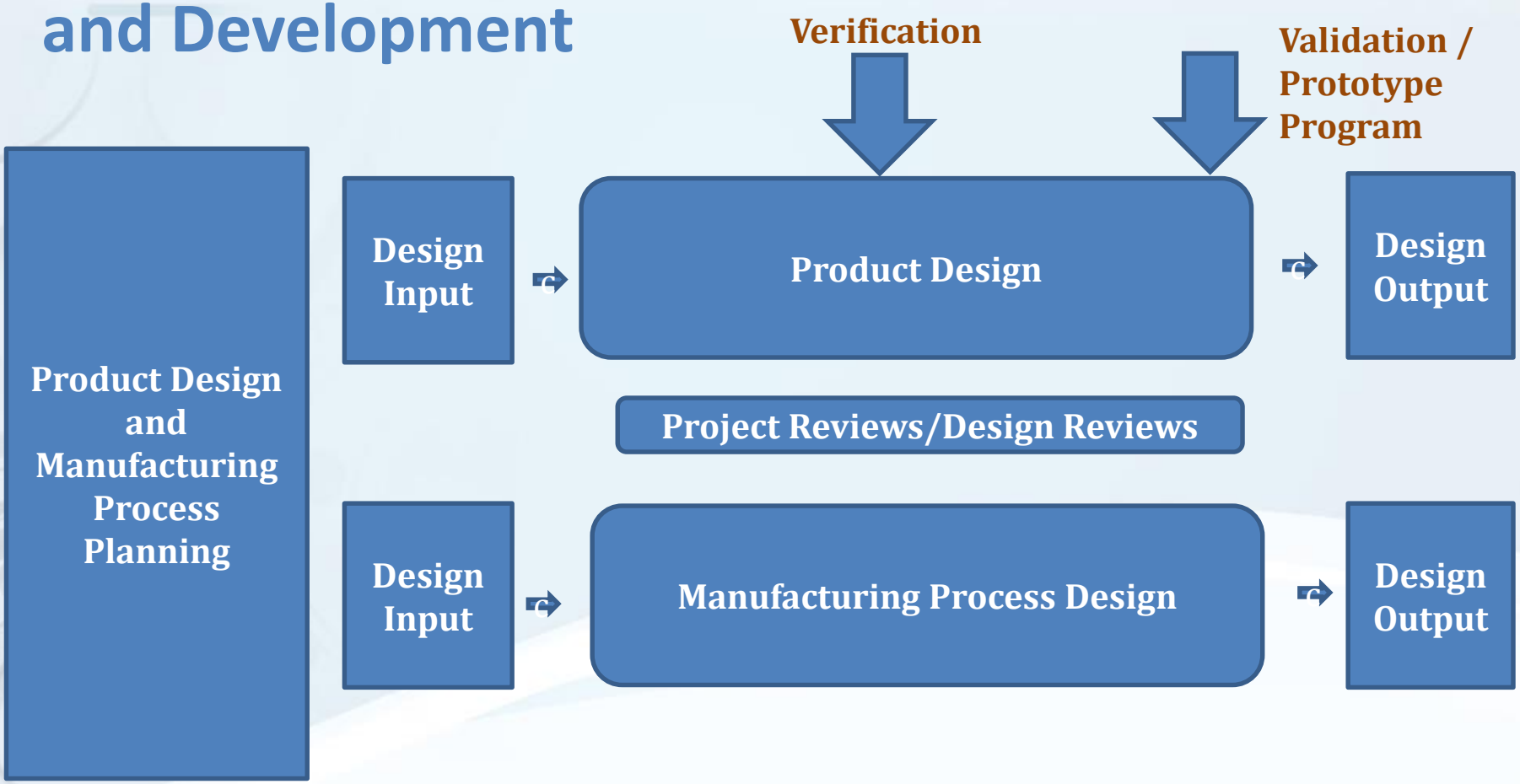


Clause 8 — Operation

8.3 Design and Development of Products and Services (CHANGED)

- **8.3.1 General**
  - **8.3.1.1 Design and Development of Products and Services — Supplemental (CHANGED)**
- **8.3.2 Design and Development Planning**
  - **8.3.2.1 Design and Development Planning — Supplemental (CHANGED)**
  - **8.3.2.2 Product Design Skills**
  - **8.3.2.3 Development of Products with Embedded Software (NEW)**
- **8.3.3 Design and Development Inputs**
  - **8.3.3.1 Product Design Input (CHANGED)**
  - **8.3.3.2 Manufacturing Process Design Input (CHANGED)**
  - **8.3.3.3 Special Characteristics (CHANGED)**
- **8.3.4 Design and Development Controls**
  - **8.3.4.1 Monitoring (CHANGED)**
  - **8.3.4.2 Design and Development Validation (CHANGED)**
  - **8.3.4.3 Prototype Program (CHANGED)**
  - **8.3.4.4 Product Approval Process (CHANGED)**
- **8.3.5 Design and Development Outputs**
  - **8.3.5.1 Design and Development Outputs — Supplemental (CHANGED)**
  - **8.3.5.2 Manufacturing Process Design Output (CHANGED)**
- **8.3.6 Design and Development Changes**
  - **8.3.6.1 Design and Development Changes — Supplemental (CHANGED)**

8.3 Product and Manufacturing Process Design and Development



Once we understand the overall process, it then becomes easier to understand the individual clauses. Let us review the ISO 9001 and IATF 16949 requirements as we walk through the standard.

8.3 Design and Development of Products and Services

8.3.2.1 Design and Development Planning – Supplemental

- **Design and development planning must include all affected stakeholders within the organization and, when applicable, its supply chain.**
- **Examples of areas where a multidisciplinary approach can be used include:**
  - **Project management (e.g., APQP or VDA-RGA)**
  - **Product and manufacturing process design activities (e.g., DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes**
  - **Development and review of product design risk analysis (FMEAs), including actions to reduce potential risks**
  - **Development and review of manufacturing process risk analysis (for example, FMEAs, Process Flows, Control Plans and standard work instructions)**

NOTE: A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance and other appropriate functions.

IATF Task Force Rationale: Modified to clarify when the multidisciplinary approach is used and who should be involved, which should include all affected stakeholders within in the organization and, as appropriate, the supply chain.

8.3 Design and Development of Products and Services

8.3.2.2 Product Design Skills

- Personnel with product design responsibility must be competent in achieving design requirements and are skilled in product design tools and techniques, as defined by the organization.

8.3.2.3 Development of Products with Embedded Software

- **A process for quality assurance for products with internally developed embedded software must be used, e.g., Automotive SPICE and ISO 26262 Part 6.**
- **A software development assessment methodology must be used to assess the process.**
  - **Documented information on the software development capability self-assessment must be retained using prioritization based on risk and potential impact on the customer.**
- **Software development must be included within the internal audit program scope (see 9.2.2.1).**

IATF Task Force Rationale: New requirement for embedded software development and software development capability self-assessments.

8.3 Design and Development of Products and Services

8.3.3.1 Product Design Input

- The organization must identify, document and review product design requirements **as a result of contract review.**
- Product design input requirements include, but are not limited to the following:
  - **a)** **Product specifications including but not limited to** special characteristics (see 8.3.3.3)
  - **b)** **Boundary and interface requirements**
  - **c)** **Identification, traceability and packaging**
  - **d)** **Consideration of design alternatives**
  - **e)** **Assessment of risks with input requirements and the ability to mitigate and/or manage the risks, including from the feasibility analysis**
  - f) Targets for conformity to product requirements including **preservation,** reliability, durability, **serviceability, health, safety, environmental, development** timing and cost
  - **g)** **Applicable statutory and regulatory requirements of the customer-identified country of destination, if provided**
  - **h)** **Embedded software requirements**

8.3 Design and Development of Products and Services

8.3.3.1 Product Design Input *(cont'd)*

- There must be a process to deploy information gained from design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE: One approach for considering design alternatives is the use of trade-off curves.

IATF Task Force Rationale: Modified the minimum set of product design input requirements, with an emphasis on regulatory and software requirements.

8.3 Design and Development of Products and Services

8.3.3.2 Manufacturing Process Design Input

- The organization must identify, document and review manufacturing process design input requirements including, but not limited to, the following:
  - Product design output data**, including special characteristics**
  - Targets for productivity, process capability, **timing,** and cost
  - **Manufacturing technology alternatives**
  - Customer requirements, if any
  - Experience from previous developments
  - New materials
  - **Product handling and ergonomic requirements**
  - **Design for manufacturing and design for assembly**
- Manufacturing process design must include the use of error-proofing methods to a degree appropriate to the magnitude of the problems and the risks encountered.

IATF Task Force Rationale: Modified to expand the list of manufacturing process design inputs, which could also include alternatives from innovation and benchmarking results and new materials in the supply chain.

8.3 Design and Development of Products and Services

8.3.3.3 Special Characteristics

- A multidisciplinary approach must be used to establish, document and implement processes to identify special characteristics, including those determined by the customer and from risk analysis, and must include the following:
  - Documentation of ~~all~~ special characteristics in the *product and/or manufacturing documents* ~~drawings~~ (as required), *relevant* risk analysis (e.g., PFMEA), Control Plans, and standard work/operator instructions*
    - Special characteristics are identified with specific markings and are *documented in the manufacturing documents which show the creation of, or the controls required, for these special characteristics* ~~throughout 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 the equivalent as defined in a symbol conversion table
    - The symbol conversion table must be submitted to the customer

IATF Task Force Rationale: Modified to identify source of special characteristics. Focus is to reduce variation in special characteristics.
***Changes by Sanctioned Interpretations (SI 6) to clarify the documentation of special characteristics in the product and/or manufacturing drawings**

8.3 Design and Development of Products and Services

8.3.4.1 Monitoring

- Measurements at defined stages during the design and development **of products and processes** must be analyzed and reported with the summary results as an input to Management Review (see 9.3.2.1).
  - **As required, these measurements must be reported to the customer at the specified agreed upon stages.**

NOTE: When appropriate, these measurements may include quality risks, lead times, critical paths, and other measurements.

IATF Task Force Rationale: Modified to align with OEM advanced quality activities in order to reduce the number of customer-specific requirements and to clarify that measurements apply at specified stages during the design and development of both products and services.

8.3 Design and Development of Products and Services

8.3.4.2 Design and Development Validation

- Design and development validation must be performed **in accordance with customer requirements, including any applicable industry and regulatory standards.**
- The timing of the validation must be planned in alignment with customer-specified timing, as applicable.
- **When included in the customer contract, validation must include evaluation of the interaction of the product, including embedded software, with the system of the final customer's product.**

IATF Task Force Rationale: Modified requirements for design and development validation, including embedded software. Customer-specific requirements and industry/regulatory standards must also be considered

8.3 Design and Development of Products and Services

8.3.4.3 Prototype Program

- As required by the customer, a prototype program and Control Plan must be in place, using, as possible, the same suppliers, tooling and manufacturing processes that will be used in production.
- All performance-testing activities must be monitored for timely completion and conformity to requirements.
- **For outsourced services, the type and extent of control must be included in the scope of the QMS to ensure the outsourced services conform to requirements (see ISO 9001, clause 8.4)**

IATF Task Force Rationale: Modified to allow the QMS to manage outsourced products and services. Regardless of whether the work is performed by the organization or an outsourced process, the prototype program and control plan are part of the QMS scope. This type of control should be considered a support process and be integrated into the design and development process.

8.3 Design and Development of Products and Services

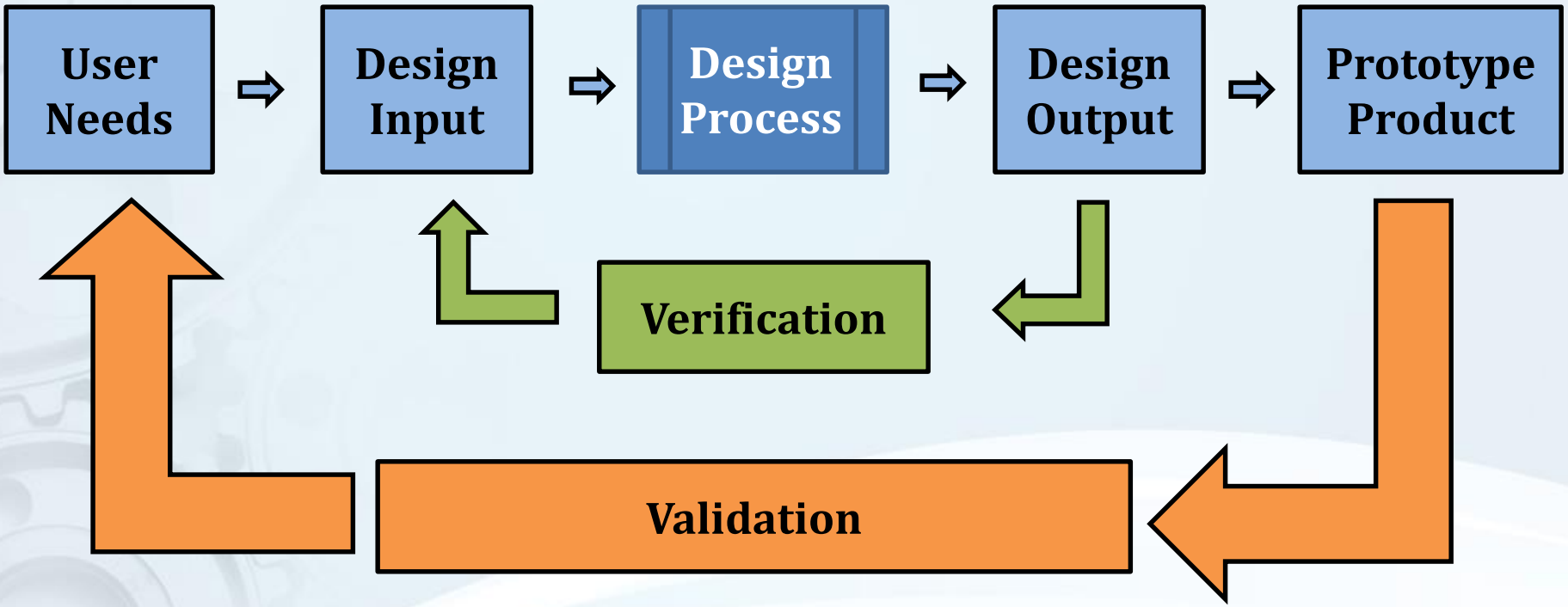
8.3.4.4 Product Approval Process

- A product and manufacturing approval process that conforms to the customer requirements **must be established, implemented and maintained.**
- **Externally provided products and services must be approved as defined in ISO 9001, clause 8.4.3, prior to submission of part approval to the customer.**
- **If required by the customer, documented product approval must be obtained prior to shipment.**
  - **Records of such approval must be retained.**

NOTE: Product approval should come after verification of the manufacturing process.

IATF Task Force Rationale: Modified to clarify approval requirements and to emphasize outsourced products and/or services and record retention. This should be managed (including an effectiveness review and improvement actions) and not simply performed.

8.3.4 Validation vs. Verification — Guidance



- Verification is confirmation through the provision of objective evidence that specified requirements have been fulfilled.
- Validation is confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

8.3 Design and Development of Products and Services

8.3.5.1 Design and Development Outputs – Supplemental

- Product design output must be expressed in terms that can be verified and validated against product design input requirements.
- Product design output includes, but is not limited to, the following:
  - Design **risk analysis** (FMEA)
  - Reliability study results
  - Product special characteristics
  - Results of product design error-proofing, **such as DFSS, DFMA and FTA**
  - Product definition **including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T)**
  - Product design review results
  - Service diagnostic guidelines **and repair and serviceability instructions**
  - **Service part requirements**
  - **Packaging and labeling requirements for shipping**

NOTE: Interim design outputs should include any engineering problems being resolved through a trade-off process.

8.3 Design and Development of Products and Services

8.3.5.2 Manufacturing Process Design Output

- Manufacturing process design output must **be documented so that it can** be verified against manufacturing process design inputs.
- Process design output should include, but not limited to, the following:
  - a) Specifications and drawings
  - **b) Special characteristics for product and manufacturing process**
  - **c) Identification of process input variables that impact characteristics**
  - **d) Tooling and equipment for production and control, including capability studies of equipment and processes**
  - e) Manufacturing process flow charts/layout, including linkage of product, process and tooling
  - **f) Capacity analysis**
  - g) Manufacturing process FMEA
  - **h) Maintenance plans and instructions**
  - i) Control Plan (see IATF 16949 Annex A)

8.3 Design and Development of Products and Services

8.3.5.2 Manufacturing Process Design Output *(cont'd)*

- Process design output should include, but not limited to, the following:
  - j) **Standard work and** work instructions
  - k) Process approval acceptance criteria
  - l) Data for quality, reliability, maintainability and measurability
  - m) Results of error-proofing **identification and verification,** as appropriate
  - n) Methods of rapid detection, feedback, **and correction** of product/manufacturing process nonconformities

IATF Task Force Rationale: Modified to clarify that the manufacturing design process requires a process approach methodology of verifying outputs against inputs.

8.3 Design and Development of Products and Services

8.3.6.1 Design and Development Changes – Supplemental

- All design changes after initial product approval, including those for potential impact on fit, form, function, performance, and/or durability must be evaluated and validated against customer requirements and approved internally prior to production implementation.
- **Documented approval, or a documented waiver must be obtained prior to production implementation, as required by the customer.**
- **For products with embedded software, the revision level of software and hardware must be documented as part of the change record.**

IATF Task Force Rationale: Modified to ensure change validation and approval prior to implementation. Design changes after initial product approval implies that products, components, and materials need to be evaluated and validated prior to production implementation.

Clause 8 — Operation

8.4 Control of Externally Provided Processes, Products and Services (CHANGED)

- **8.4.1 General**
  - **8.4.1.1 General — Supplemental (CHANGED)**
  - **8.4.1.2 Supplier Selection Process (CHANGED)**
  - **8.4.1.3 Customer-directed Sources (CHANGED)**
- **8.4.2 Type and Extent of Control**
  - **8.4.2.1 Type and Extent of Control— Supplemental (CHANGED)**
  - **8.4.2.2 Statutory and Regulatory Requirements (CHANGED)**
  - **8.4.2.3 Supplier Quality Management System Development (CHANGED)**
    8.4.2.3.1 Automotive Product-related Software or Automotive Products with Embedded Software (NEW)
  - **8.4.2.4 Supplier Monitoring (CHANGED)**
    8.4.2.4.1 Second-party Audits (NEW)
  - **8.4.2.5 Supplier Development (CHANGED)**
- **8.4.3 Information for External Providers**
  - **8.4.3.1 Information for External Providers — Supplemental (CHANGED)**

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

- The organization determines and applies appropriate criteria for the:
  - Evaluation
  - Selection
  - Monitoring of performance
  - Re-evaluation of external providers

- This criteria is based on the provider's ability to supply processes or products and services conforming to requirements.
- Evidence of results of the evaluations, monitoring of the performance and re-evaluations of the providers is retained.

Risk is implicit whenever "suitable" or "appropriate" is mentioned

Managing Suppliers

8.4.2 Type and Extent of Control

- Choose controls based on the effect of the process, product and/or services on the organization

8.4.2.1 Supplemental

- **Documented process for control of outsourced processes and to escalate or reduce controls and development based on supplier performance and product, material or service risk**
- ***Where characteristics or components "pass through" the QMS without validation or controls, the organization must ensure appropriate controls are in place at the point of manufacture.****

IATF Task Force Rationale: Modified to further strengthen the requirement for control of outsourced processes, including the assessment of risk. This implies the need to constantly monitor performance and assessment of risk-based on the established criteria, triggering the actions to increase or reduce the types and extent of control.
***Added by Sanctioned Interpretations (SI 7) to clarify the organization's responsibilities for pass through characteristics.**

Managing Suppliers

8.4.2.2 Statutory and Regulatory Requirements

- **There must be a documented process ensuring** statutory and regulatory requirements are followed **in country of receipt, shipment and destination**
- **Follow special controls that are defined, including at suppliers**

IATF Task Force Rationale: Modified to clarify that statutory and regulatory requirements must be considered in the country of receipt, shipment and delivery. When special controls are required, the organization must implement these requirements and flow the requirements down to their suppliers.

Managing Suppliers

8.4.2.3 Supplier Quality Management System Development

- Suppliers of automotive product and services must develop, implement and improve a QMS ~~certified to ISO 9001, unless otherwise authorized by the customer [see item a) below],~~ with the ultimate objective of eligible organizations* becoming certified to IATF 16949.
- ***Using a risk-based model, define a minimum acceptable level and target level of QMS development for each supplier****
  - ***Unless otherwise authorized by the customer, a QMS certified to ISO 9001 is the initial minimum acceptable level****

***Changes by IATF 16949:2016 Sanctioned Interpretations (SI 8) to clarify the expected supplier QMS development progression that supports risk-based thinking as emphasized throughout 8.4**

Managing Suppliers

8.4.2.3 Supplier Quality Management System Development

- ***Based on current performance and the potential risk to the customer, the objective is to move suppliers through the following sequence***:
  - ~~a) Compliance to ISO 9001 through 2nd party audits~~
  - b) Certification to ISO 9001 through 3rd party audits
  - c) Certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as MAQMSR) through 2nd party audits
  - d) Certification to ISO 9001 with compliance to IATF 16949 through 2nd party audits
  - e) Certification to IATF 16949 through 3rd party audits

  NOTE: The minimum acceptable level of QMS development may be compliance to ISO 9001 through 2nd party audits, if authorized by the customer

IATF Task Force Rationale: Modified to provide a progressive approach from ISO 9001 compliance to IATF 16949 certification as opposed to simply having organizations "develop" the supplier QMS.

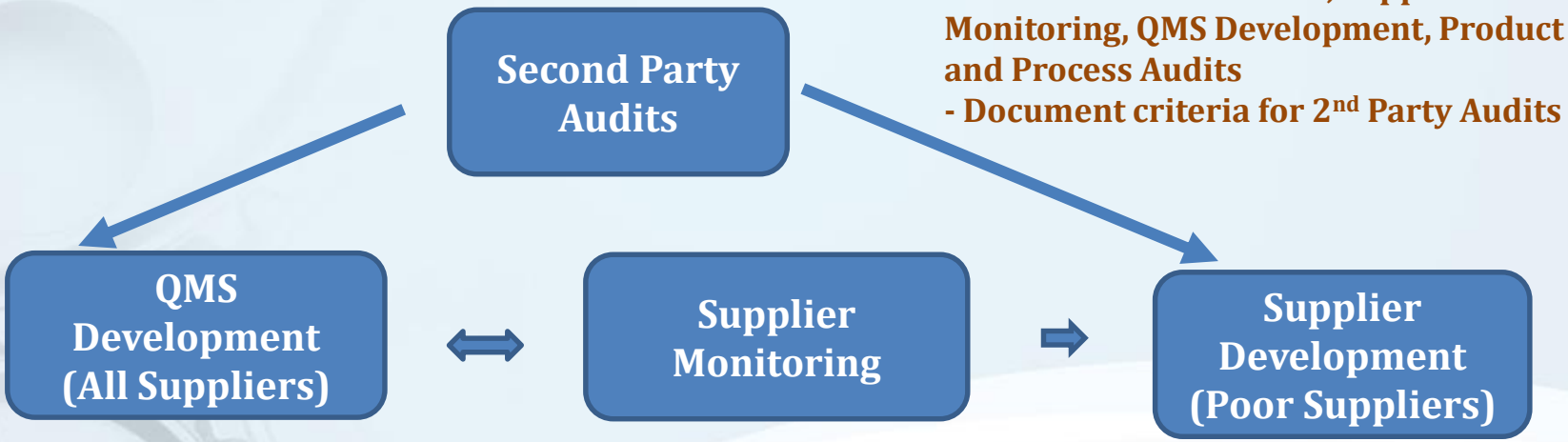
Managing Suppliers

8.4.2.3.1 Automotive Product-Related Software or Automotive Products with Embedded Software

- **Suppliers of automotive product-related software or automotive products with embedded software must implement and maintain a process for software quality assurance.**
- **A software development assessment methodology must be used to assess the supplier's software development process.**
- **The supplier must retain documented information of the software development capability self-assessment.**

IATF Task Force Rationale: New requirements for software development assessment methodology that align with 8.3 but are now cascaded down to suppliers.

Managing Suppliers



- ISO 9001:2015 2nd party
- ISO 9001:2015 3rd Party
- ISO 9001:2015 w/MAQMSR 2nd Party
- IATF 16949 2nd Party
- IATF 16949 3rd Party

- Delivered Product Conformity
- Customer Disruptions
- Delivery Schedule
- # of Occurrences of Premium Freight
- If Provided, Special Status Notification, Dealer Returns, warranty, Field Actions etc.

- Performance issues from supplier monitoring
- 2nd Party Audit Findings
- 3rd Party Audit Status
- Risk Analysis

8.4 Control of Externally Provided Processes, Products and Services

8.4.3.1 Information for External Providers – Supplemental

- **All applicable statutory and regulatory requirements and special product and process characteristics must be passed down to suppliers and through the supply chain to the point of manufacture.**

IATF Task Force Rationale: Modified to require that key information is provided to the supply chain.

8.5 Production and Service Provision

- 8.5.1 Control of Production and Service Provision (CHANGED)
  - 8.5.1.1 Control Plan (CHANGED)
  - 8.5.1.2 Standardized Work — Operator Instructions and Visual Standards (CHANGED)
  - 8.5.1.3 Verification of Job Set-ups (CHANGED)
  - 8.5.1.4 Verification After Shutdown (NEW)
  - 8.5.1.5 Total Productive Maintenance (CHANGED)
  - 8.5.1.6 Management of Production Tooling and Manufacturing, Test, Inspection Tooling and Equipment (CHANGED)
  - 8.5.1.7 Production Scheduling (CHANGED)
- 8.5.2 Identification and Traceability
  - 8.5.2.1 Identification and Traceability — Supplemental (CHANGED)
- 8.5.3 Property Belonging to Customers or External Providers
- 8.5.4 Preservation
  - 8.5.4.1 Preservation — Supplemental (CHANGED)
- 8.5.5 Post-delivery Activities
  - 8.5.5.1 Feedback of Information From Service (CHANGED)
  - 8.5.5.2 Service Agreement with Customer (CHANGED)
- 8.5.6 Control of Changes (NEW)
  - 8.5.6.1 Control of Changes — Supplemental (CHANGED)
  - 8.5.6.1.1 Temporary Change of Process Controls (NEW)

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

- The organization implements process controls for operations.
- Controlled conditions include, as applicable:
  - Availability of documented information that defines the product or service characteristics, the activities to be performed and the results to be achieved
  - The availability and use of suitable monitoring and measuring resources
  - Measurement activities at appropriate stages to verify specified requirements criteria including acceptance criteria have been met
  - Use of suitable infrastructure and work environment
  - Competent people
  - The validation and periodic revalidation of "special" processes
  - The implementation of actions to prevent human error
  - The implementation of product and service release, delivery and post-delivery activities

Risk is implicit whenever "suitable" or "appropriate" is mentioned

NOTE: Suitable infrastructure includes appropriate manufacturing equipment related to ensure product compliance. Monitoring and measuring resources include equipment required to ensure effective control of manufacturing processes.

8.5 Production and Service Provision

8.5.1.1 Control Plan (details provided on slides 256-258)

- Linkages from design risk, process flow and manufacturing risk analysis
- Control Plan content – clarified and broadened

8.5.1.2 Standardized Work

- Includes operator safety (rules) and addresses language needs of operators

8.5.1.3 Verification of Job Set-ups

- Last-off comparisons now required, as appropriate
- Requirement strengthened

8.5.1.4 Verification After Shutdown (New Requirement)

- Verification of product conformance after planned or unplanned shutdown

8.5 Production and Service Provision

8.5.1.5 Total Productive Maintenance

- Changed from Preventive and Predictive Maintenance to Total Productive Maintenance
- Strengthened requirements included OEE (Overall Equipment Effectiveness), MTBF (Mean Time between Failures) and MTTR (Mean Time to Repair) and others…

8.5.1.6 Management of Production Tooling and Manufacturing, Test Inspection Tooling and Equipment

- Applies to customer and organization tooling, including production and service materials and bulk materials
- Strengthened marking and tracking requirements, including customer-owned tooling to be marked so ownership and application is in a visible area
- Includes tool design modification information and engineering changes
- Includes system to track activities in any outsourced work

8.5 Production and Service Provision

8.5.1.7 Production Scheduling

- **Includes additional planning information such as customer orders, supplier on-time delivery performance, capacity, etc.**

IATF Task Force Rationale: Modified to stress the importance of planning information and integrated lessons learned in order to ensure customer orders/demands will be achieved. This suggests a linkage of production scheduling with feasibility review and capacity planning.

8.5 Production and Service Provision

8.5.4.1 Preservation – Supplemental

- Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection
- Enhanced to include preservation controls and locations where it can be applied
- Includes the scope of preservation and includes contamination and protection (integrity of the product)
- Additional controls for storage including checking condition of stock, place/type of storage containers and storage environment
- Treat obsolete product like nonconforming product

IATF Task Force Rationale: Modified to expand preservation activities to include both preservation controls and locations where preservation controls apply.

8.5 Production and Service Provision

8.5.5.1 Feedback from Service

- Scope extended to include **material handling and logistics**; also, **service concerns now include field failure test analysis**

8.5.5.2 Service Agreement with Customer

- When there is a service agreement with the customer:
  - Verify relevant service centers **comply with applicable requirements**
  - Verify effectiveness of any special purpose tools or measurement equipment
  - Ensure all service personnel are trained in applicable requirements

NOTE: The intent of "service concerns" is to ensure awareness of nonconforming **products and materials** that may be identified at the **customer location or in the field. "Service concerns" should include the results of field failure test analysis (see 10.2.6) where applicable.**

8.5 Production and Service Provision

8.5.6.1 Control of Changes – Supplemental

- **There must be a documented process that controls, reacts and assesses any changes that affect product conformity that:**
  - a) **Defines verification and validation activities to ensure customer requirements are met**
  - b) **Validate changes before implementation**
  - c) **Documents the evidence of related risk analysis**
  - d) **Retains records of verification and validation**

IATF Task Force Rationale: Modified to strengthen control of changes by including any change made by the organization, customer and the supplier. FMEAs should be reviewed for changes prior to implementation and production trial run activities should be planned based on the risk and complexity of changes

8.5 Production and Service Provision

8.5.6.1 Control of Changes – Supplemental *(cont'd)*

- **Requires validation before implementation, record of verification and validation, evidence of risk analysis**
- **As required by the customer, the organization must:**
  - e) **Notify customer of any planned product realization changes after the most recent product approval**
  - f) **Obtain documented approval before implementing changes**
  - g) **Complete additional verification and validation requirements**

This sub-clause does not refer to managing other document changes or the link with PPAP

8.5 Production and Service Provision

8.5.6.1.1 Temporary Change of Process Controls

- Identify, document and maintain a list of primary and approved back-up or alternate methods, *if back-up or alternate methods exist**
- Document a process that manages the use of alternate control methods that includes risk analysis (FMEA)
- Before shipping product that was inspected or tested using the alternate method, get customer approvals if needed
- Review list of alternate methods periodically
- Make standard work instructions available for each alternate method and review alternate methods daily when in use; for example, using layered process audits and daily leadership meetings
- When the regular process controls are reinstated, conduct documented verification activities and implement traceability of products produced and records of first piece and last piece

IATF Task Force Rationale: New requirement to address experienced by OEM customers. The use of alternative control methods is a process, requiring the organization to manage these activities.
*** Added by Sanctioned Interpretations (SI 11) to clarify that not every primary control requires an alternative process control**

Clause 8 — Operation

8.6 Release of Products and Services

- **8.6.1 Release of Products and Services — Supplemental (CHANGED)**
- **8.6.2 Layout Inspection and Functional Testing (CHANGED)**
- **8.6.3 Appearance Items (CHANGED)**
- **8.6.4 Verification and Acceptance of Conformity of Externally Provided Products and Services (CHANGED)**
- **8.6.5 Statutory and Regulatory Conformity (CHANGED)**
- **8.6.6 Appearance Criteria**

8.6 Release of Products and Services

8.6.1 Release of Products and Services – Supplemental

- Ensure products being shipped have met the Control Plan
- The IATF Task Force suggests performing Control Plan audits periodically to ensure conformance

8.6.2 Layout Inspection and Functional Testing

- Frequency of layout inspection being determined by customer added as a Note.

8.6.3 Appearance Items

- Masters for haptics* technology added

*Haptics is the science of applying touch (tactile) sensation and control to interaction with computer applications

8.6 Release of Products and Services

8.6.4 Verification and Acceptance of Conformity of Externally Provided Products and Services

- The quality of **externally provided processes,** products **and services** must be ensured by using one or more of the following methods:
  - Receipt and evaluation of statistical data **provided by the supplier**
  - Receiving inspection and/or testing, such as sampling based on performance
  - 2nd or 3rd party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements
  - Part evaluation by a designated laboratory
  - Another method agreed upon with the customer

IATF Task Force Rationale: Modified to align with ISO 9001:2015 terminology and to clarify the source of statistical data.

8.6 Release of Products and Services

8.6.5 Statutory and Regulatory Conformity

- **Prior to release in production flow**, externally provided **processes,** products **and services** must conform to the applicable statutory, regulatory and other requirements **in the countries in which they are manufactured and in the countries of destination.**
  - **Evidence of conformity must be provided.**

8.6.6 Acceptance Criteria

- Acceptance criteria must be defined by the organization and, as required, approved by the customer.
- The acceptance level for attribute data sampling must be zero defects (see 9.1.1.1).

IATF Task Force Rationale: Modified to strengthen statutory and regulatory conformance. "Prior to release" suggests there should be a process and/or agreement requiring suppliers to provide prevention and detection controls ensuring products meet all statutory, regulatory and other requirements.

Clause 8 — Operation

8.7 Control of Nonconforming Outputs (CHANGED)

- 8.7.1 [No Title]
  - 8.7.1.1 Customer Authorization for Concession (CHANGED)
  - 8.7.1.2 Control of Nonconforming Product — Customer-specified Process (CHANGED)
  - 8.7.1.3 Control of Suspect Product (CHANGED)
  - 8.7.1.4 Control of Reworked Product (CHANGED)
  - 8.7.1.5 Control of Repaired Product (CHANGED)
  - 8.7.1.6 Customer Notification (NEW)
  - 8.7.1.7 Nonconforming Product Disposition (CHANGED)
- 8.7.2 [No Title]

8.7 Control of Nonconforming Output

- Methods can include correction, segregation, containment, return or suspension, informing customer, concession and verification

8.7.1.1 Customer Authorization for Concession

- Required when different from what is currently approved

8.7.1.2 Control of Nonconforming Product

- **Follow customer-specified controls**

8.7.1.3 Control of Suspect Product

- Suspect product treated same as nonconforming
- **Provide training for containment of suspect and nonconforming product**

8.7.1.4 Control of Reworked Product

- **Use FMEA to assess risk with rework, get customer approval if needed**
- **Documented rework process including compliance to original specifications**
- Instructions for disassembly, rework, re-inspection, and traceability shall be accessible and utilized
- **Records of reworked product including quantity, disposition, disposition date and traceability**

8.7 Control of Nonconforming Output

8.7.1.5 Control of Repaired Product

- Use FMEA to assess risk in the repair process before decision to repair
- Get customer approval prior to performing repair
- Documented repair process including compliance to original specifications
- Instructions for disassembly, repair , re-inspection, and traceability shall be accessible and utilized
- Records of repaired product including quantity, disposition, disposition date and traceability

8.7.1.6 Customer Notification

- Notify customer immediately of nonconforming product shipped

8.7.1.7 Nonconforming Product Disposition

- Documented process required, ensure product disposed is “rendered unusable”
- Do not divert to other use without prior approval

8.7.2 Documented Information

- Describes nonconformity, actions taken, concessions obtained, authority deciding action

QMS Group Exercise 4

Audit Scenarios:
Clauses 7-8

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CLAUSE 9 — PERFORMANCE EVALUATION

Clause 9 — Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

- **9.1.1 General (NEW)**
  - **9.1.1.1 Monitoring and Measurement of Manufacturing Processes (CHANGED)**
  - **9.1.1.2 Identification of Statistical Tools (CHANGED)**
  - **9.1.1.3 Application of Statistical Concepts (CHANGED)**
- **9.1.2 Customer Satisfaction**
  - **9.1.2.1 Customer Satisfaction — Supplemental (CHANGED)**
- **9.1.3 Analysis and Evaluation (CHANGED)**
  - **9.1.3.1 Prioritization (CHANGED)**

9.2 Internal Audit

9.2.1 and 9.2.2 [No Title]

- **9.2.2.1 Internal Audit Program (CHANGED)**
- **9.2.2.2 Quality Management System Audit (CHANGED)**
- **9.2.2.3 Manufacturing Process Audit (CHANGED)**
- **9.2.2.4 Product Audit (CHANGED)**

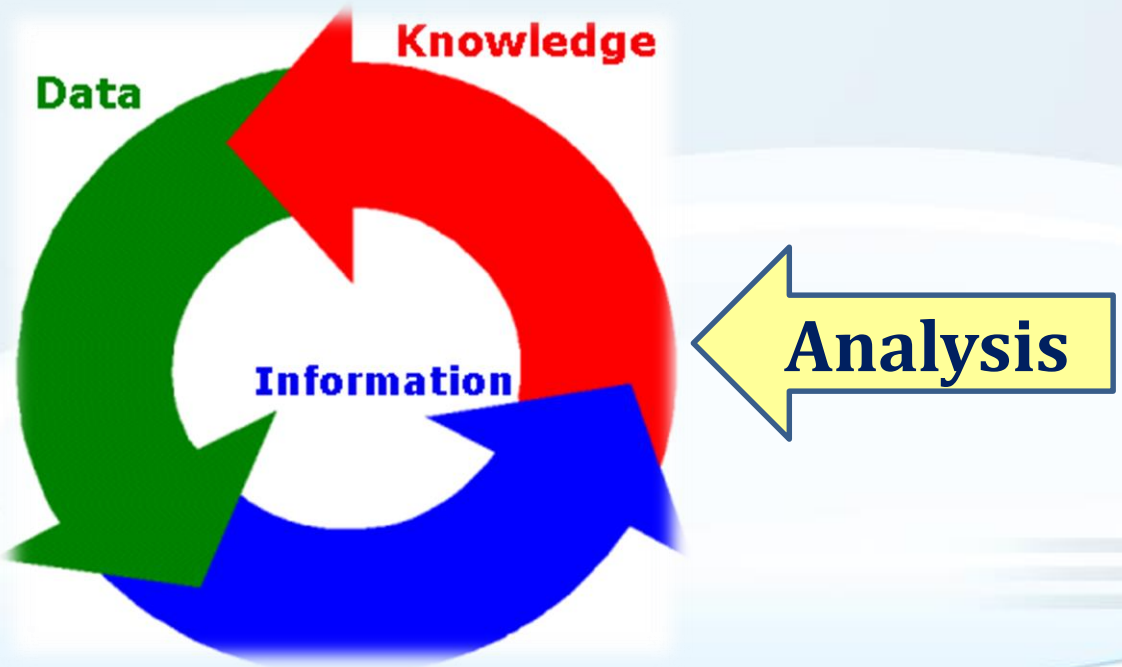
9.3 Management Review (CHANGED)

- **9.3.1 General**
  - **9.3.1.1 Management Review — Supplemental (CHANGED)**
- **9.3.2 Management Review Inputs**
  - **9.3.2.1 Management Review Inputs — Supplemental (CHANGED)**
- **9.3.3 Management Review Outputs**
  - **9.3.3.1 Management Review Outputs — Supplemental (CHANGED)**

Clause 9 — Performance Evaluation

Intent

- Identify what should be monitored and reviewed in order to determine how the QMS is performing and if improvements are needed.



9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

- The organization determines:
  - What needs to be monitored and measured
  - The methods for measurement, analysis and evaluation to ensure valid results
  - When these activities are to be performed
  - When the results from measurement will be analyzed and evaluated
- The organization evaluates the performance and effectiveness of the QMS.
- The organization retains evidence of the results.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1.1 Monitoring and Measurement of Manufacturing Processes

- Perform process studies to verify process capability for new processes **including special characteristics**
  - **NOTE: when process capability is not possible, use alternate methods such as batch conformance to specification**
- Maintain process capability or performance results over time as per PPAP
- Verify Process Flow, **PFMEA** and Control Plan are implemented (manufacturing process audits)
- **Retain as documented information** significant process events and initiate reaction plan on the Control Plan, **including evaluation of impact on compliance** for characteristics not capable or unstable; include containment and 100% inspection
- Implement corrective action plan to ensure the process become stable and **statistically** capable, approved by the customer if required
- Record effective dates for process changes

IATF Task Force Rationale: Modified to clarify process effectiveness and efficiency must be monitored and to ensure the manufacturing process is supported through defined roles, responsibilities and effective escalation processes.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1.2 Identification of Statistical Tools

- Use appropriate statistical tools with APQP, **DFMEA, PFMEA,** and Control Plan

9.1.1.3 Application of Statistical Tools

- Statistical concepts must be understood and used by those who **collect, analyze and manage statistical data**
  - **The IATF Task Force suggests this be included in those employees competencies.**

9.1.2 Customer Satisfaction

- Monitor customer perception, determine methods for obtaining, monitoring and reviewing this information

9.1.2.1 Customer Satisfaction – Supplemental

- Continual evaluation of **internal and external** performance such as delivered part quality, customer disruption, field returns, **recalls and warranty (where applicable),** delivery schedule performance including incident of premium freight, customer notification **and special status**
- Monitor manufacturing process for quality and process efficiency
- **Review customer performance data including customer portals and scorecards**

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.3 Analysis and Evaluation

- Analysis and evaluation of:
  - Conformity of products and services
  - Customer satisfaction
  - Performance and effectiveness of QMS
  - Effective implementation of planning
  - Effectiveness of actions taken for risks and opportunities
  - Performance of external providers, i.e., suppliers
  - Improvement of the QMS

9.1.3.1 Prioritization

- Compare quality and operational performance to objectives to support prioritization of action to **improve customer satisfaction**

IATF Task Force Rationale: Modified to change emphasis from analysis of data to improvement actions based on performance and risk management. Precedence needs to be given to the improvement of customer satisfaction.

So What Does "Effectiveness" Look Like?

In the QMS:

- Top Management is looking at Management Review inputs with a focus on internal audits and customer satisfaction
- Internal audits are acted on with corrective actions
- Customer satisfaction is measured and action taken for improvement
- Risk-based thinking is used and acted upon

So What Does "Effectiveness" Look Like?

In the Process Approach:

- There is an accurate process map with interactions
- The PDCA cycle is used
- Risk-based opportunities are acted upon
- All processes are being measured and monitored

So What Does "Effectiveness" Look Like?

In Customer Focus and Continual Improvement:

- Customer requirements and expectations are known and risk-based thinking is conducted
- Customer satisfaction is measured and tracked, e.g. surveys, scorecards, returns, complaints, warranty, etc.
- Continual improvement actions are improving customer metrics
- Continual improvement projects are reducing risk

9.2 Internal Audit

- Conduct internal audit on a regular basis
- Audit program with schedule planning taking into consideration importance of processes, changes affecting the organization and results of previous audits
- Provide trained auditors, report results to management and take actions promptly

9.2.2.1 Internal Audit Program

- **Documented internal audit process that includes Quality Management System, manufacturing process and product audits which are prioritized on risk, internal and external performance and criticality of the process**
- **Conduct software capability assessments for software development, where applicable**
- **Audit frequency needs to be adjusted based on process changes, internal and external nonconformities, and customer complaints**
- **Review effectiveness in management review**

IATF Task Force Rationale: Modified to bring a risk-based approach to the development and deployment of the audit program.

9.2 Internal Audit

9.2.2.2 Quality Management System Audit

- Audit all QMS processes over a three year audit cycle, using an annual program, with a process approach including sampling customer-specific requirements
- *The complete audit cycle remains three years in length; audit frequency for individual processes within the three-year audit cycle must be based upon internal and external performance and risk**
  - *Justification for the audit frequency must be maintained**
  - *All processes must be sampled throughout the three-year audit cycle and audited to all applicable IATF 16949 requirements, including the base ISO 9001 requirements and any customer-specific requirements**

***Added by IATF 16949:2016 Sanctioned Interpretations (SI 14) to clarify the three-year audit cycle duration and that all processes are to be audited during that cycle.**

IATF Task Force Rationale: Modified audit programs to ensure the automotive process approach, including risk-based thinking, is used to drive process improvements organization-wide.

9.2 Internal Audit

9.2.2.3 Manufacturing Process Audit

- Audit all manufacturing processes **over a three year schedule using customer specific approaches**
  - **NOTE: Several customer-specific approaches are described in Annex B**
- **Include in audit plan evidence of all shifts and include shift handover**
  - **The IATF Task Force suggests that shift handover be considered a significant process event requiring auditors to look for evidence of an effective communication process**
- **Look for evidence of PFMEA, Control Plan and associated document implementation**

9.2.2.4 Product Audit

- Use **customer-specified approaches when required or define your own process**

IATF Task Force Rationale: Modified audit programs to ensure the automotive process approach, including risk-based thinking, is used to drive process improvements organization-wide.

9.3 Management Review

9.3.1 General

- Top Management shall review at planned intervals… continuing **suitability, adequacy, effectiveness and alignment to strategic direction**

9.3.1.1 Management Review – Supplemental

- **Once a year minimum and increased based on risk to meeting customer requirements and internal and external changes impacting QMS and performance**

9.3.2 Management Review Inputs and **9.3.2.1 Management Review Inputs – Supplemental**

- More than 20 items – as seen on upcoming slides
- Omnex suggests review at a frequency as per existing meetings and importance to your organization

IATF Task Force Rationale: Modified to include risk assessment. As this is driven by continuous assessment of risk, the one-year frequency is a minimum and the frequency should increase as changes and issues increase.

9.3 Management Review

9.3.2 Management Review Inputs

- Management Review is planned and carried out considering:
  - The status of actions from previous management reviews
  - Changes in external and internal issues that are relevant to the QMS
  - Information on the quality performance and QMS effectiveness including trends for:
    - Customer satisfaction and feedback from relevant interested parties
    - The extent to which quality objectives have been met
    - Process performance and product or service conformity
    - Nonconformities and corrective actions
    - Measurement results
    - Audit results
    - Performance of external providers
  - Adequacy of resources
  - The effectiveness of actions taken to address risks and opportunities (see clause 6.1)
  - Opportunities for improvement

9.3 Management Review

9.3.2.1 Management Review Inputs – Supplemental

- Input to Management Review must include:
  - Cost of poor quality (internal and external nonconformance)
  - Measures of process effectiveness
  - Measures of process efficiency *for product realization processes, as applicable*
  - Product conformance
  - Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or product (see 7.1.3.1)
  - Customer satisfaction (see ISO 9001, 9.1.2)
  - Review of performance against maintenance objectives
  - Warranty performance
  - Review of customer scorecards
  - Identification of potential field failures identified through risks analysis, (e.g., FMEA)
  - Actual field failures and their impact on safety or the environment
  - *Summary results of measurements at specified stages during the design and development of products and processes, as applicable**

IATF Task Force Rationale: Modified to set minimum information for a management review. A monitoring system should be in place that triggers special unplanned management review activities.

***Added by IATF 16949:2016 Sanctioned Interpretations (SI 16) to link to the requirement for monitoring in 8.3.4.1**

9.3 Management Review

9.3.3 Management Review Outputs

- Opportunities for improvement, changes to the QMS and resource needs

9.3.3.1 Management Review Outputs – Supplemental

- **Document and implement an action plan when customer performance targets are not met**

IATF Task Force Rationale: Modified to clarify that while process owners should address performance issues, the ultimate responsibility for addressing customer performance issues and ensuring the effectiveness of corrective actions lies with Top Management

CLAUSE 10 — IMPROVEMENT

Clause 10 — Improvement

10.1 General (CHANGED)

10.2 Nonconformity and Corrective Action (CHANGED)

- **10.2.1 and 10.2.2 [No Title]**
- **10.2.3 Problem Solving (CHANGED)**
- **10.2.4 Error-Proofing (CHANGED)**
- **10.2.5 Warranty Management Systems (NEW)**
- **10.2.6 Customer Complaints and Field Failure Test Analysis (CHANGED)**

10.3 Continual Improvement

- **10.3.1 Continual Improvement — Supplemental (CHANGED)**

Clause 10 — Improvement

Intent

- Specify requirements for improvements to the QMS to drive improvement of the organization.

10.1 (Improvement) General

- The organization determines and selects opportunities for improvement and implements actions needed to meet customer requirements and improve customer satisfaction.
- This includes:
  - Product and service improvements to meet current and future needs and expectations
  - Correcting, preventing or reducing undesired effects
  - Improving QMS performance and effectiveness
- Improvement can be accomplished by correction, corrective action, continual improvement, breakthrough, innovation and re-organization.

10.2 Nonconformity and Corrective Action

- Organizations need to respond to nonconformities (complaint/problem)
- Evaluate the need for action to eliminate the cause so it does not recur (in 8D – D4 to D6) or occur in other places (i.e., systemic in 8D – D7)
  - Understand the problem, analyze it, identify the cause (in 8D – Occur, Escape and System) and determine if other similar issues exist or can happen
  - Implement actions needed (8D – D6)
  - Review effectiveness of actions taken
  - **Update risks and opportunities, if necessary, and make QMS changes**
  - Retain records

10.2.3 Problem Solving

- Documented problem solving approach needs to include **containment,** root cause analysis**, systemic corrective actions, verification of effectiveness and updating appropriate documentation such as FMEA/Control Plan; use customer prescribed processes, tools or system as applicable**

IATF Task Force Rationale: Modified to ensure a documented process and defined approach for different types of problems including scale (e.g., new product development, current manufacturing issues, field failures, audit findings)

10.2 Nonconformity and Corrective Action

10.2.4 Error-proofing

- Documented process that includes process risk analysis (FMEA) and document test frequencies in the Control Plan
- The Control Plan needs to include what the error proofing device tested, e.g., good and bad product, and frequency of testing, including records
- Include testing of error-proofing devices for failure or simulated failure, maintain the records, and have a reaction plan

IATF Task Force Rationale: Modified to consolidate customer-specific requirements and strengthen the error-proofing approach. The process should identify the need for an error-proofing device/method and its design and implementation. The FMEA should document whether it impacts occurrence (i.e., prevention control) or detection (i.e., detection control).

10.2 Nonconformity and Corrective Action

10.2.5 Warranty Management Systems

- When required to provide warranty, implement a warranty management process that includes warranty part analysis and No Trouble Found (NTF)

IATF Task Force Rationale: New requirement to address the importance of warranty management that also consolidates OEM customer specific requirements. The process should address all customer-specific requirements and NTF decisions should be agreed upon by the customer.

10.2.6 Customer Complaints and Field Failure Test Analysis

- Conduct analysis of customer complaints and field failures, include parts and start problem solving and corrective action to prevent recurrence
- When requested by the customer include analysis of embedded software
- Communicate results both to customer and internally

IATF Task Force Rationale: Modified to include embedded software. The analysis should extend to the complaints and field failures themselves

10.3 Continual Improvement

- Improve suitability, adequacy and effectiveness of the QMS
- Consider results of analysis and evaluation and outputs from management review for opportunities and improvement

10.3.1 Continual Improvement – Supplemental

- **Documented** process for continual improvement **that includes methodology, objectives, measurement, effectiveness and records, and a manufacturing process improvement plan that focuses on reduction of variation, waste and risk analysis (FMEA)**

IATF Task Force Rationale: Modified to clarify the minimum process requirements for continual improvement. Use of Lean, Six Sigma and other excellence programs and methodologies is suggested

QMS Group Exercise 5 followed by Individual QMS Exam

Audit Scenarios:
Clauses 9-10

QUALITY

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Chapter 2: ISO 9001 and IATF 16949 Requirements — What We Covered

Learning Objectives

You should now be able to:

- Explain the key points for each of the clauses
- Describe major sub-clauses for each of the clauses
- Explain the overall flow of the clauses
- Explain process approach

Chapter Agenda

- Clause 4 Context of the Organization
  - **Group Exercise 1 – Context**
  - **Group Exercise 2 – Interested Parties**
- Clause 5 Leadership
- Clause 6 Planning
  - **Group Exercise 3 – Audit Scenarios**
- Clause 7 Support
- Clause 8 Operation
  - **Group Exercise 4 – Audit Scenarios**
- Clause 9 Performance Evaluation
- Clause 10 Improvement
  - **Group Exercise 5 – Audit Scenarios**
  - **QMS Exams**

Thank You!

Questions?

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