IATF 16949:2016
Internal Auditor Training

Automotive Quality Management Systems

OMNEX

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Ninth Edition

November 2019

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.

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END OF EXEMPLAR GLOBAL-AU COMPETENCY

Note!

Throughout this course, IATF 16949:2016 requirements are indicated by boxed text

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.

Exemplar Global Competency Units

Management Systems Auditing (Exemplar Global-AU)

- Understand the application of the principles, procedures and techniques of auditing.
- Understand the conduct of an effective audit in the context of the auditee's organizational situation.
- Understand the application of the regulations, and other considerations that are relevant to the management system, and the conduct of the audit.
- Practice personal attributes necessary for the effective and efficient conduct of a management system audit.

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.
- 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

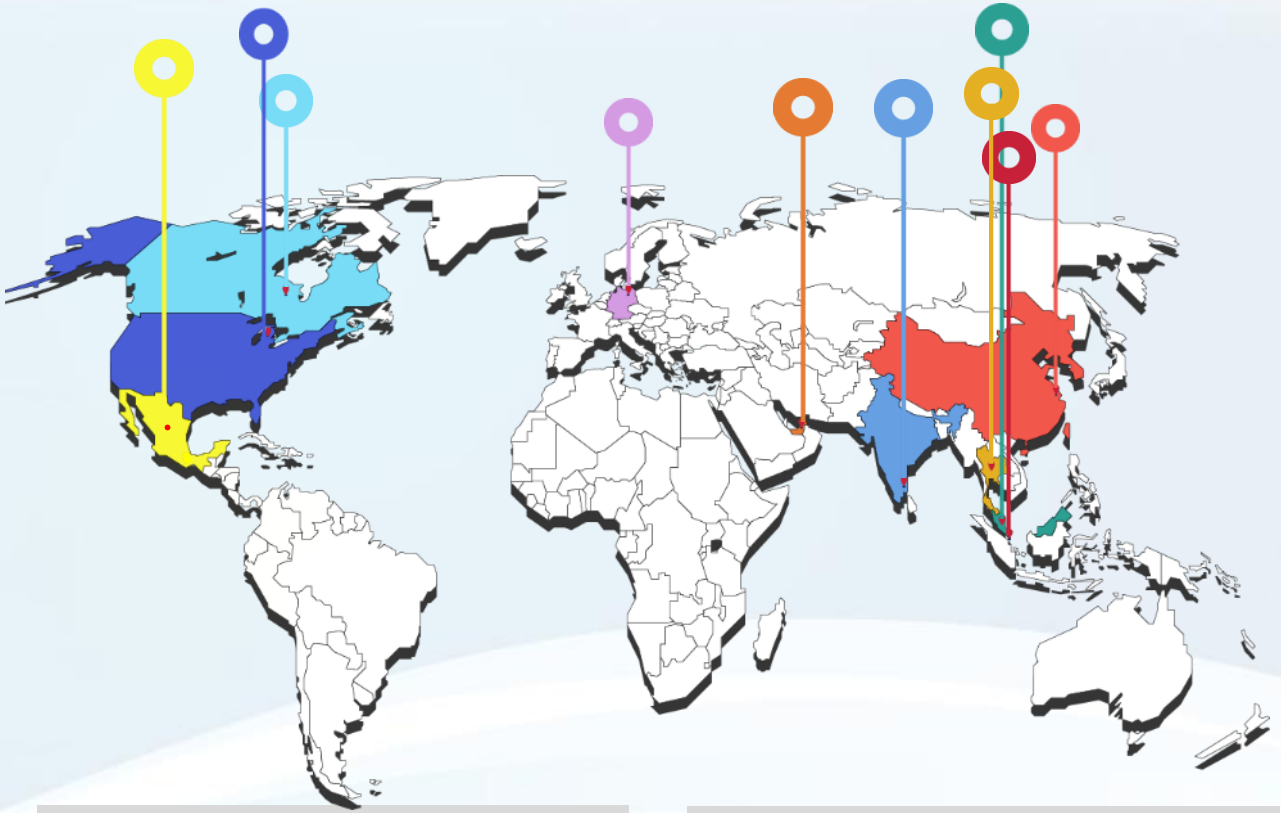
- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 700 professionals, speaking over a dozen languages.
- 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
info@omnex.com



- 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 o.m.n.ex
- ✓ 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

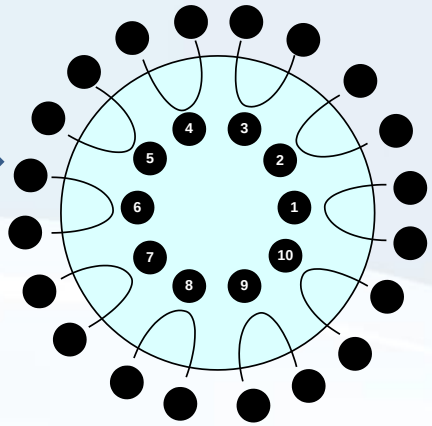
O

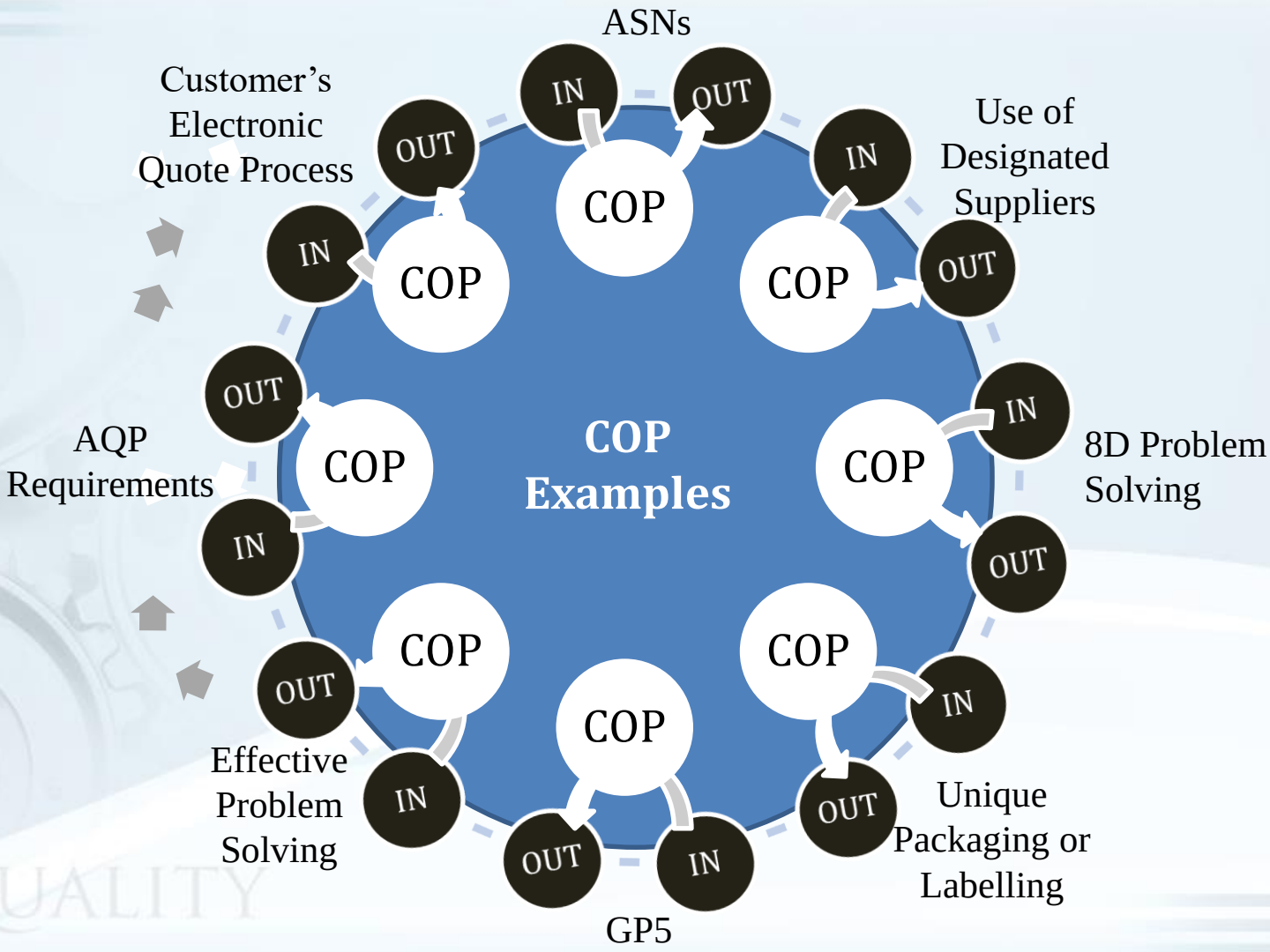
3 OUT TO THE CUSTOMER

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

O-M-N-E-X

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)

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

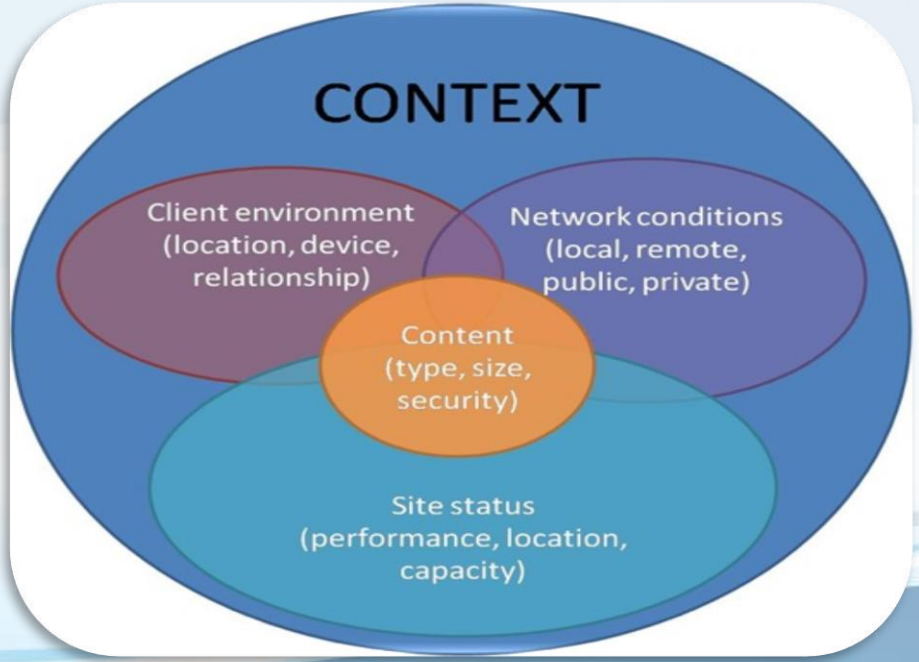
Chapter Agenda

- 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.

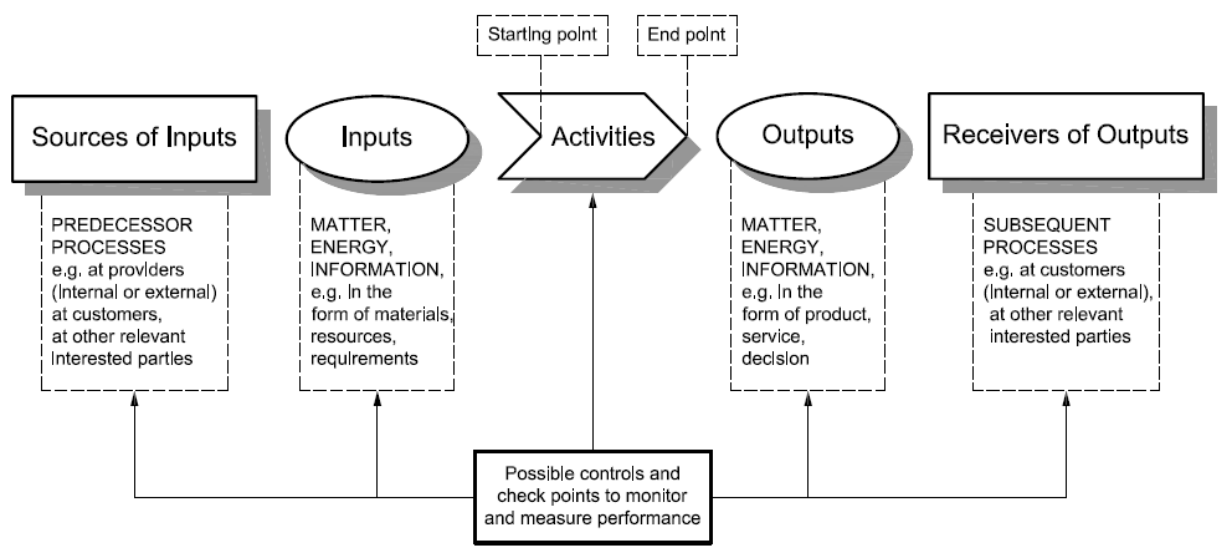
4.3 Determining the Scope — Guidance

- 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

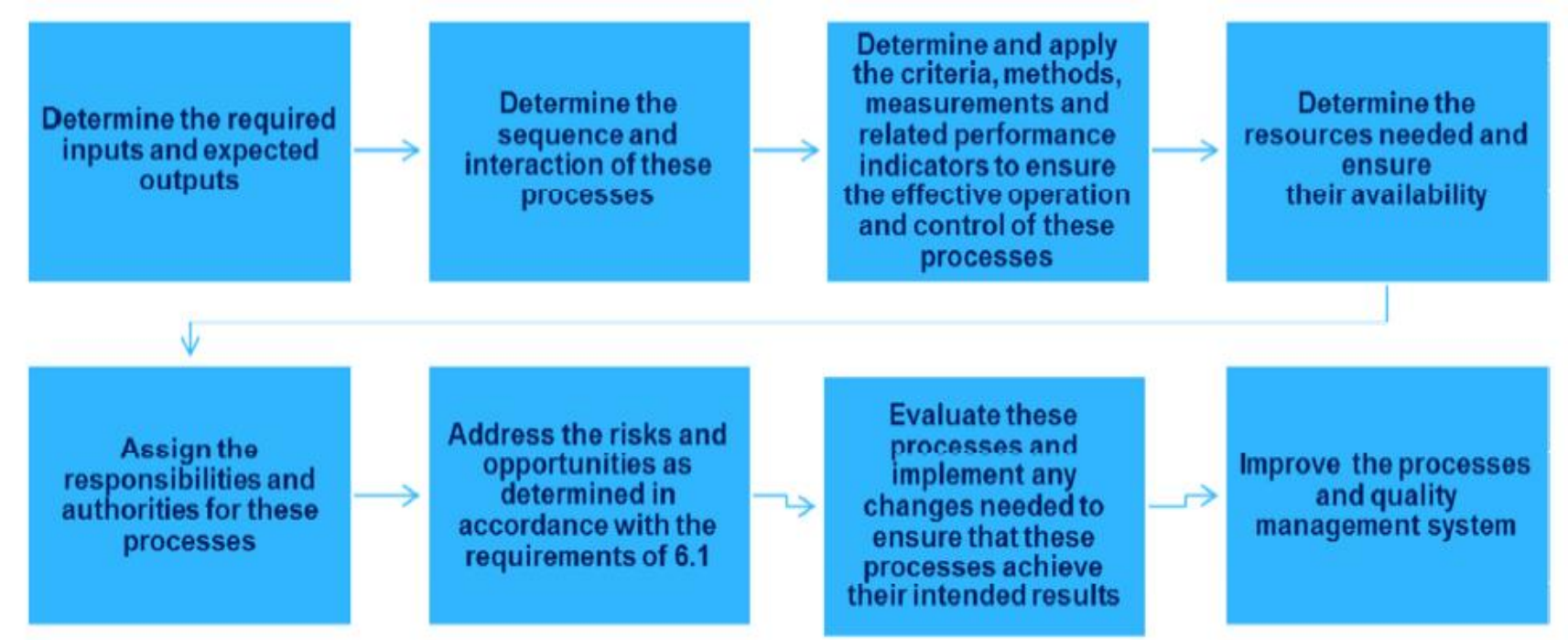
Guidance on Processes

- 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:



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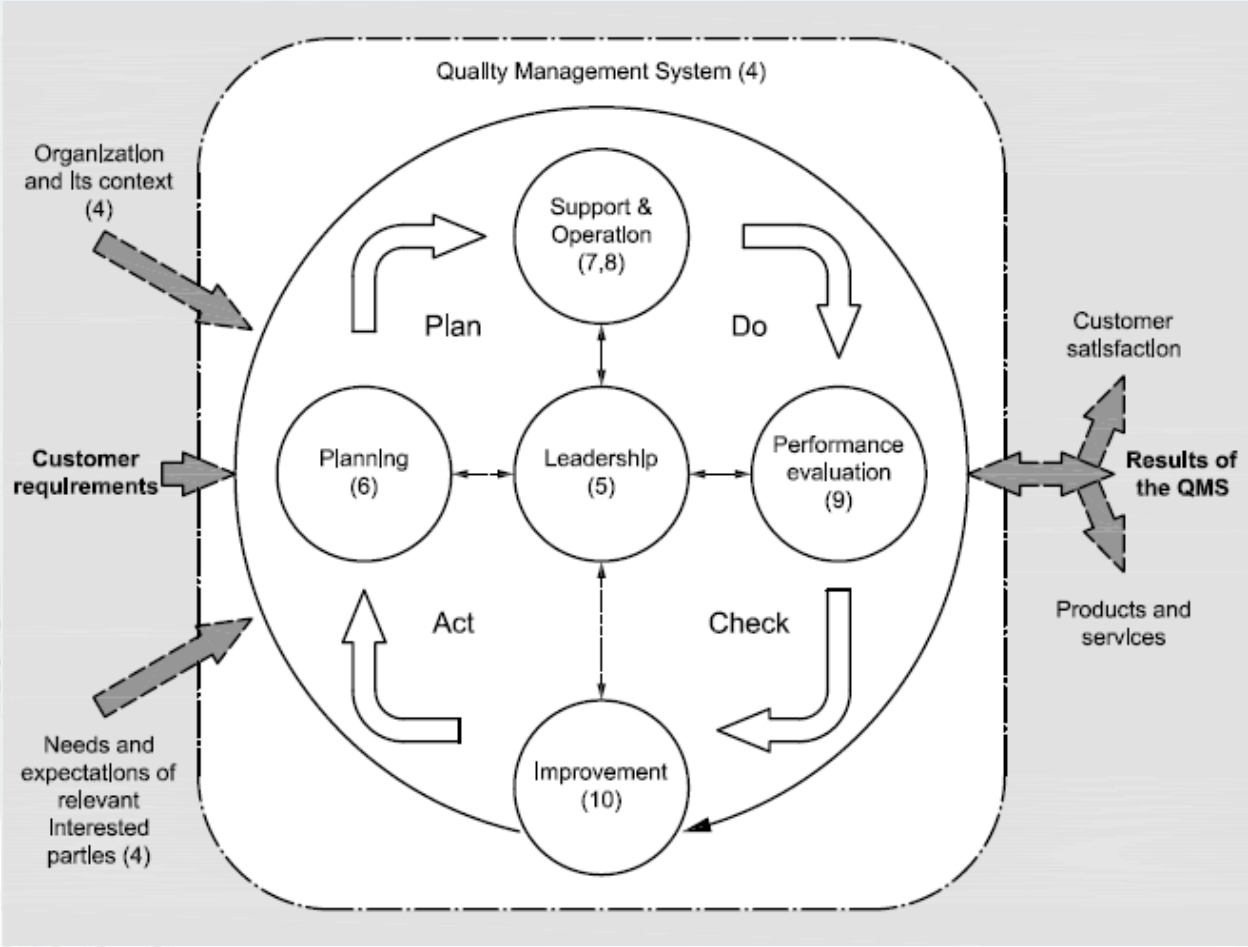
http://isotc.iso.org/livelink/livelink/fetch/3541460/17525573/APG-Processes2015.pdf?nodeid=17531167&vernum=-2

Quality Management System (QMS) Process Model

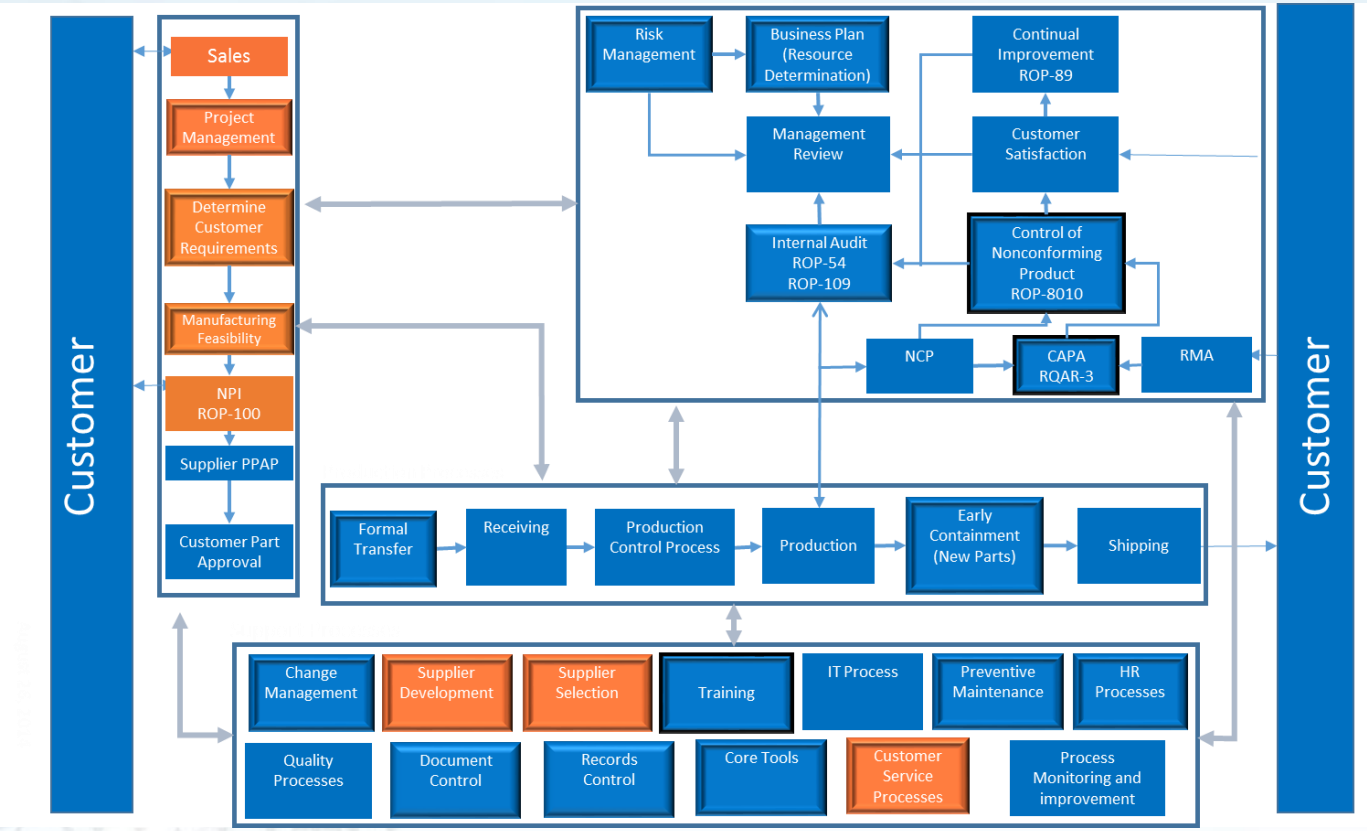


source: ISO 9001:2015

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

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

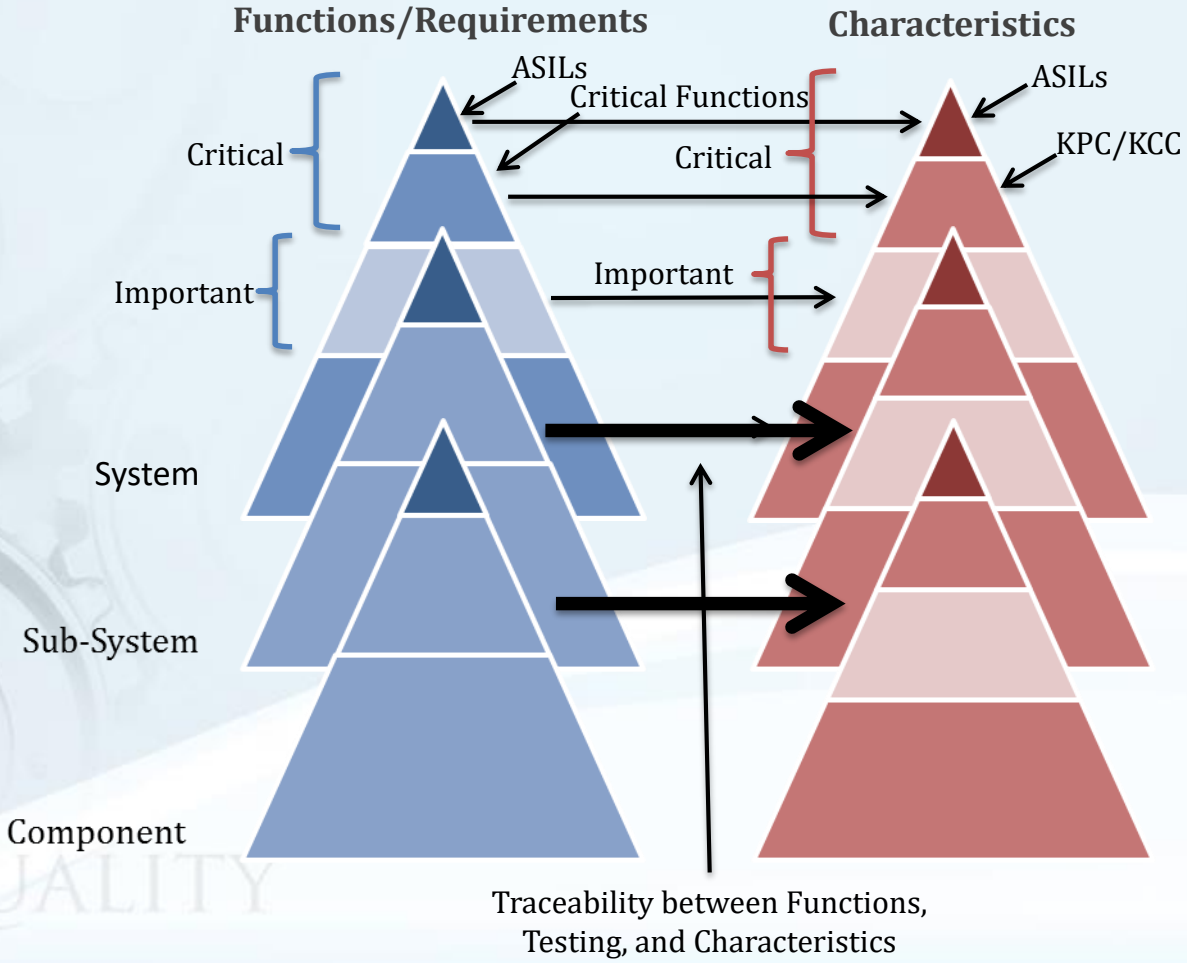
4.4.1.2 Product Safety *(cont'd)*

- 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.

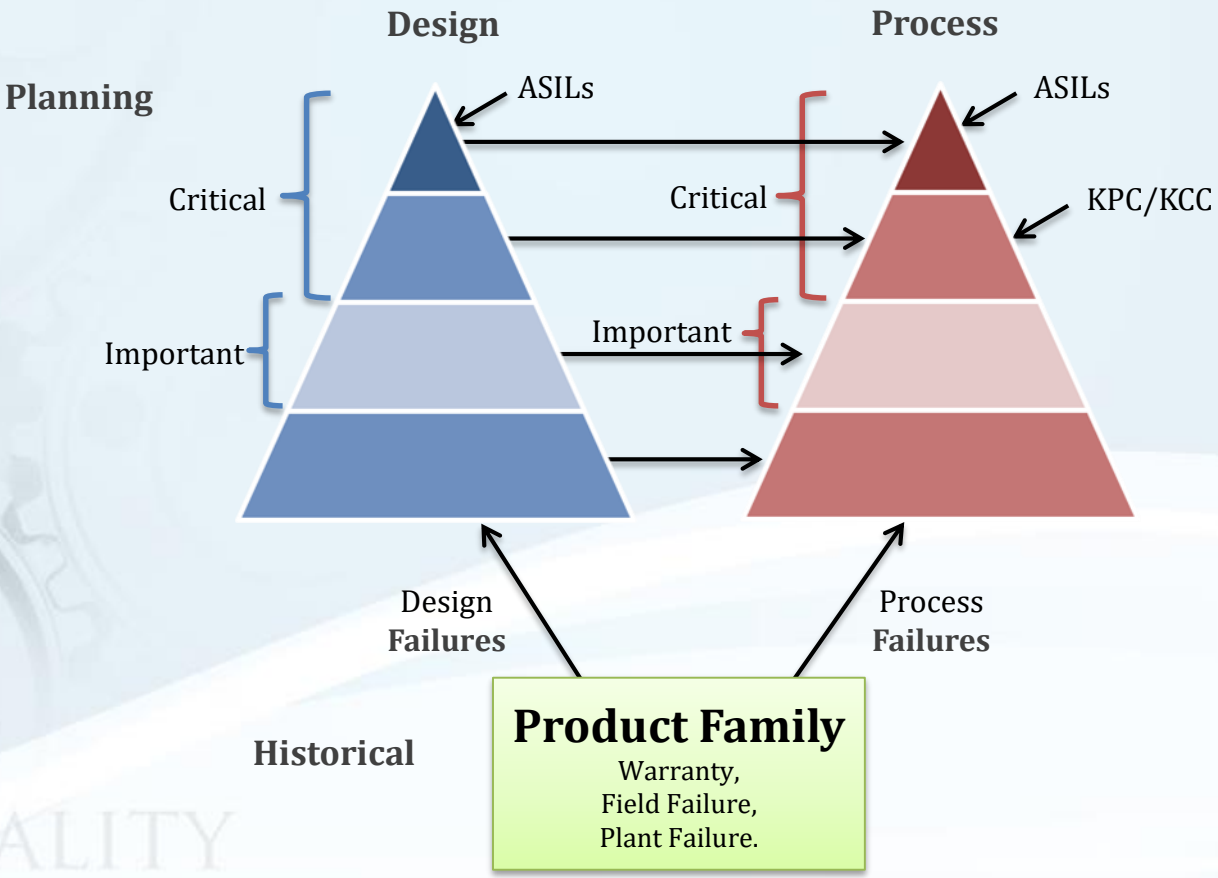
***Changed by IATF 16949:2016 Sanctioned Interpretations (SI 2) to clarify any confusion related to special approval for safety related requirements or documents.**

Requirements Management — Internal and Flow Down to Suppliers



Linkages required in Control Plan, see clause 8.5.1.1

Applying Lessons Learned



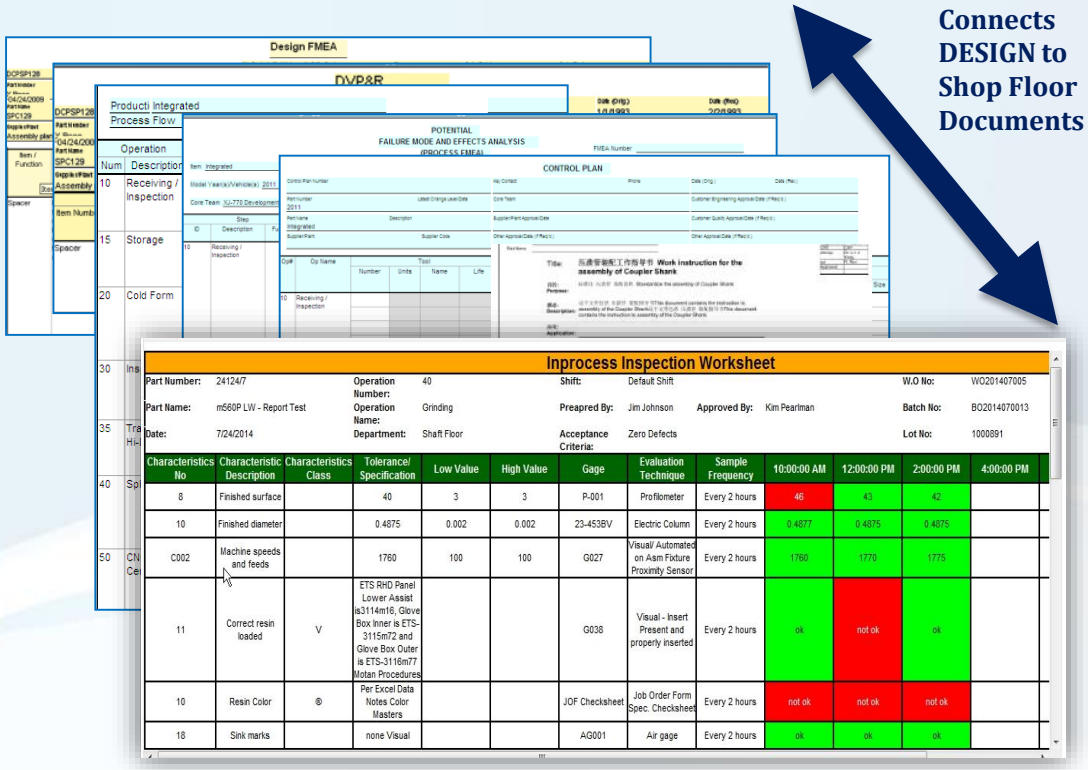
Update DFMEA and PFMEA based on customer failures, see clause 10.2.3

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

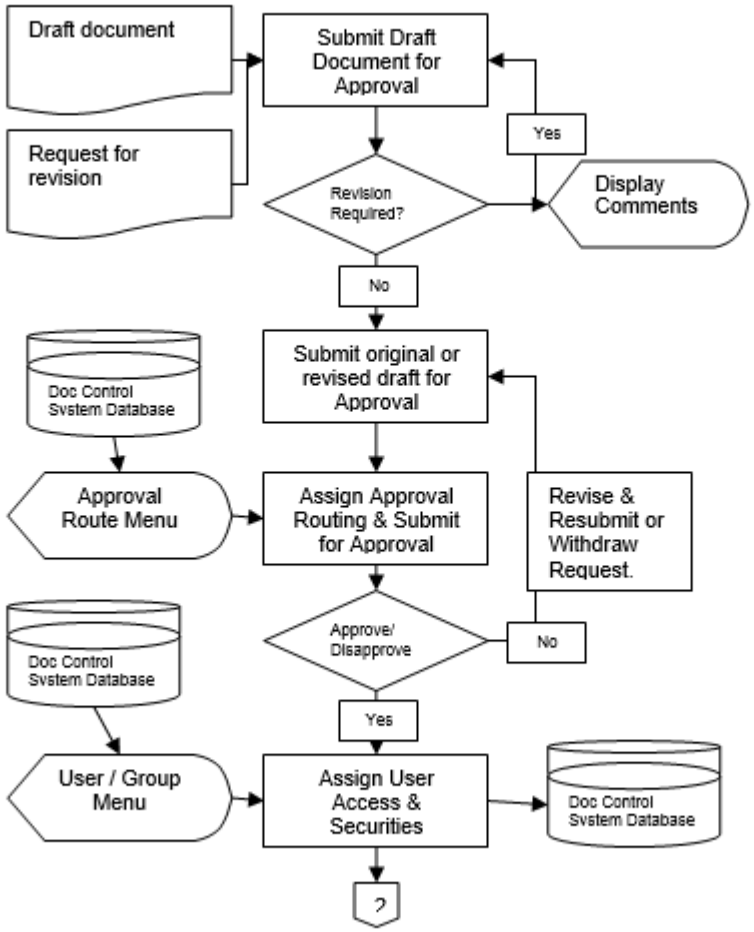
See clause 8.5.1.1 for Control Plan requirements

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

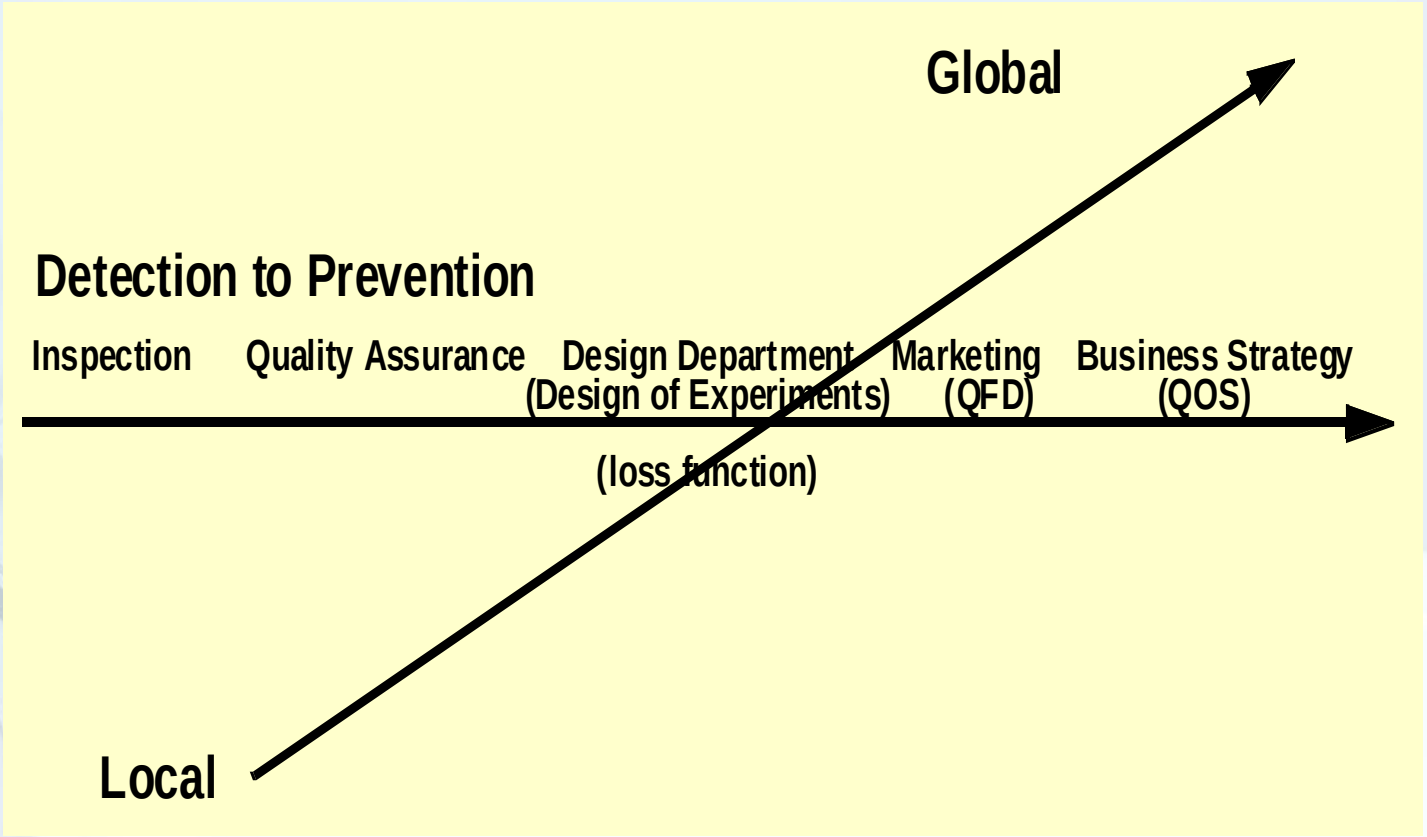
- Top Management is accountable for QMS effectiveness.
- Top Management establishes the Quality Policy and QMS objectives that are compatible with the strategic direction and the context of the organization.
- Integrate QMS requirements into the organization's business processes.
  - "Business" means 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)

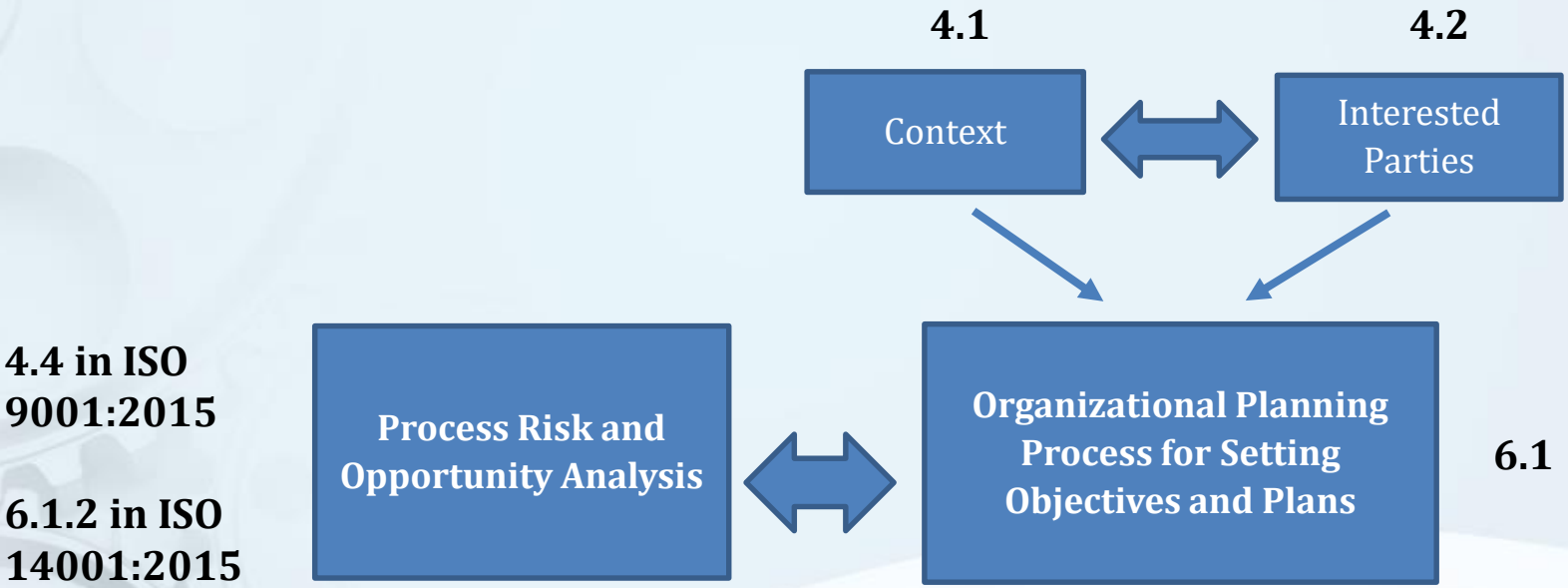
Clause 6 — Planning

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

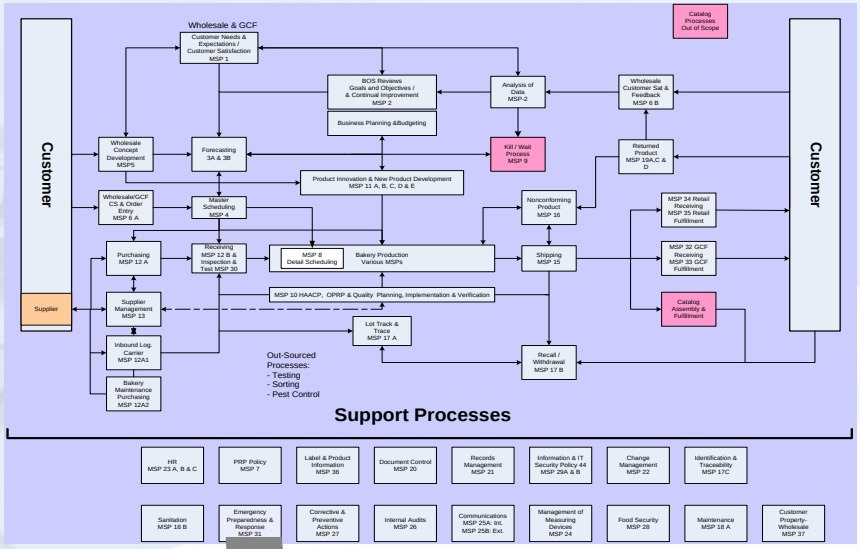
Risk and ISO 9001:2015

4.4 Process Approach

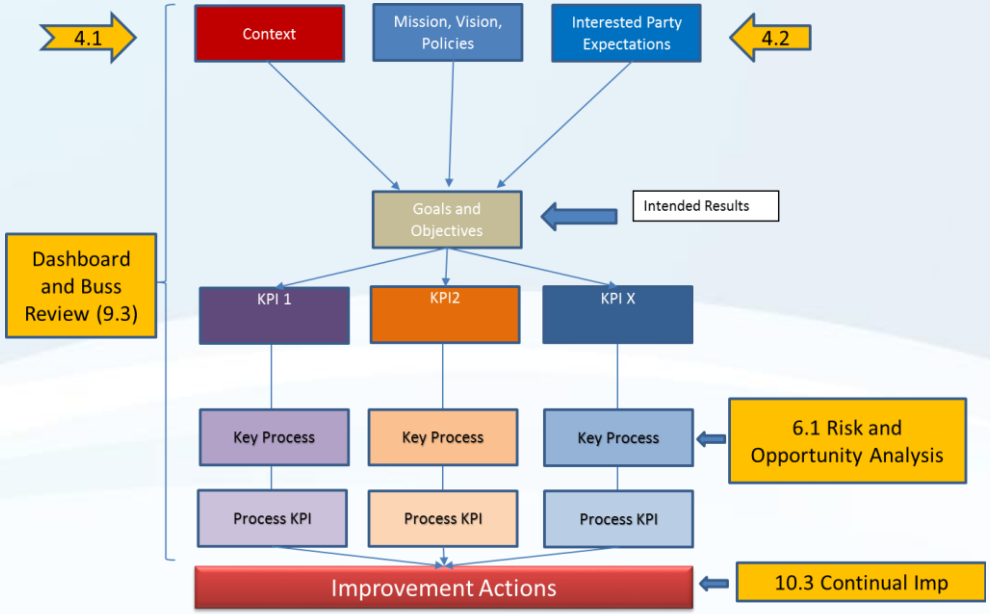
Address risk and opportunities determined, re: 6.1

6.1 Actions to Address Risks and Opportunities

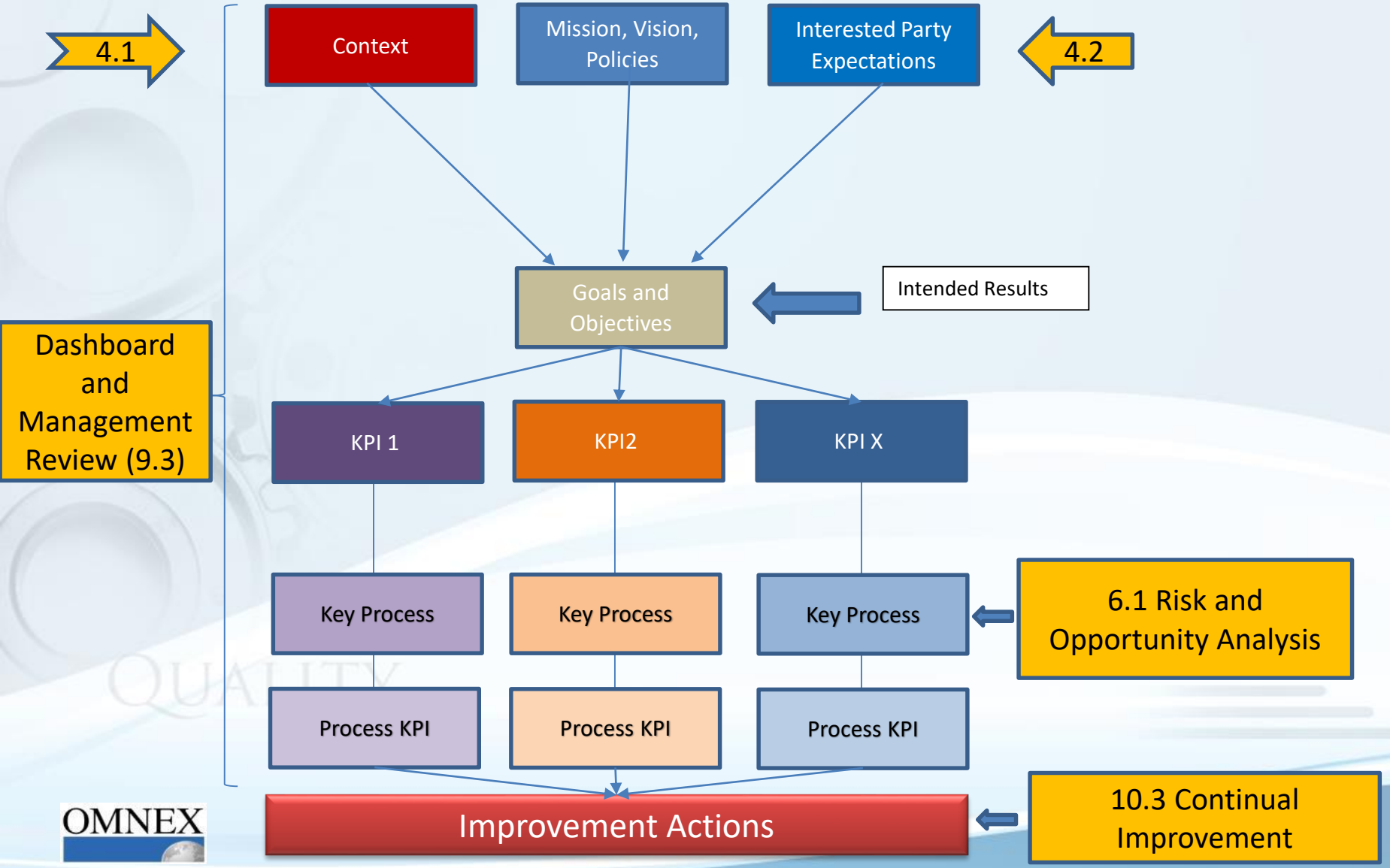
Plan and determine the actions needed



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** O*M*N*E*X*
  - 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

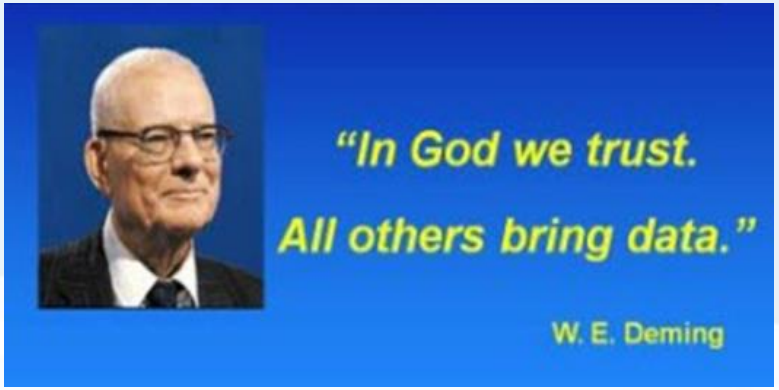
- The organization establishes quality objectives at relevant functions, levels and processes needed for the quality management system.
- Quality objectives:
  - Are consistent with the quality policy
  - Take into account applicable requirements
  - Are relevant to conformity of products, services and 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

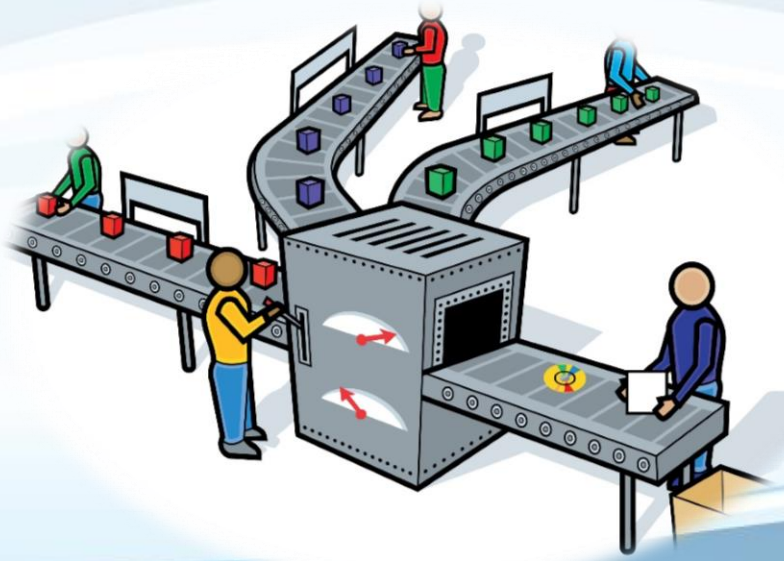
Intent

- 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

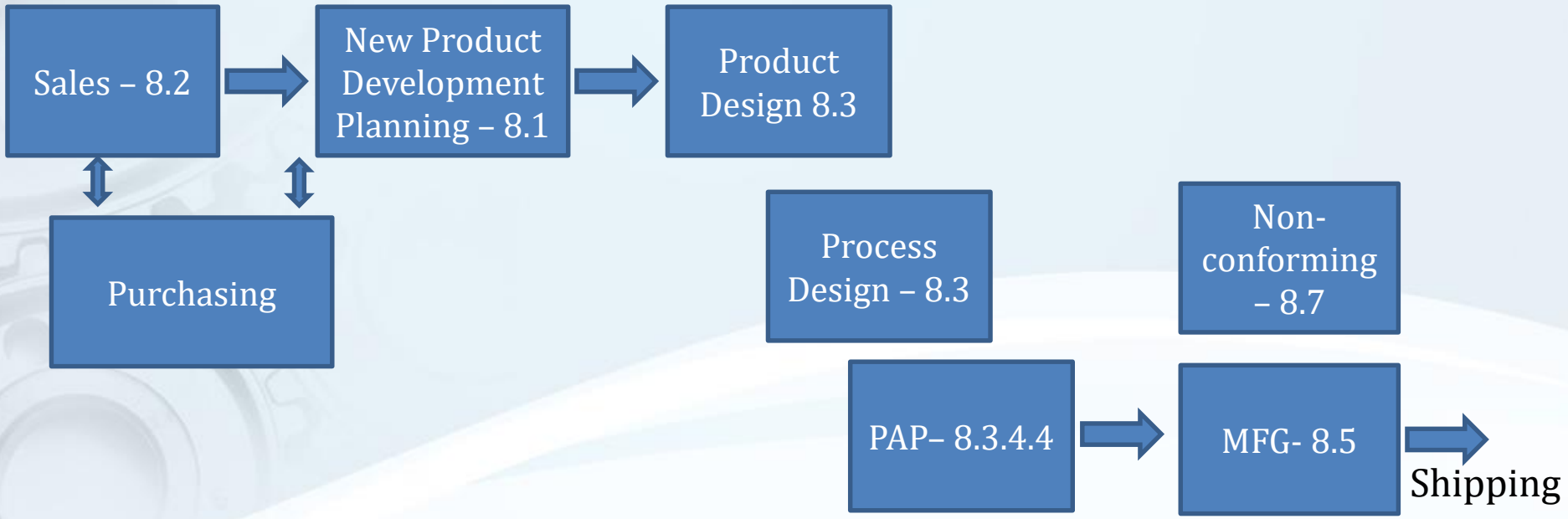
*** see details before each sub-clause for new/changed requirements**

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.

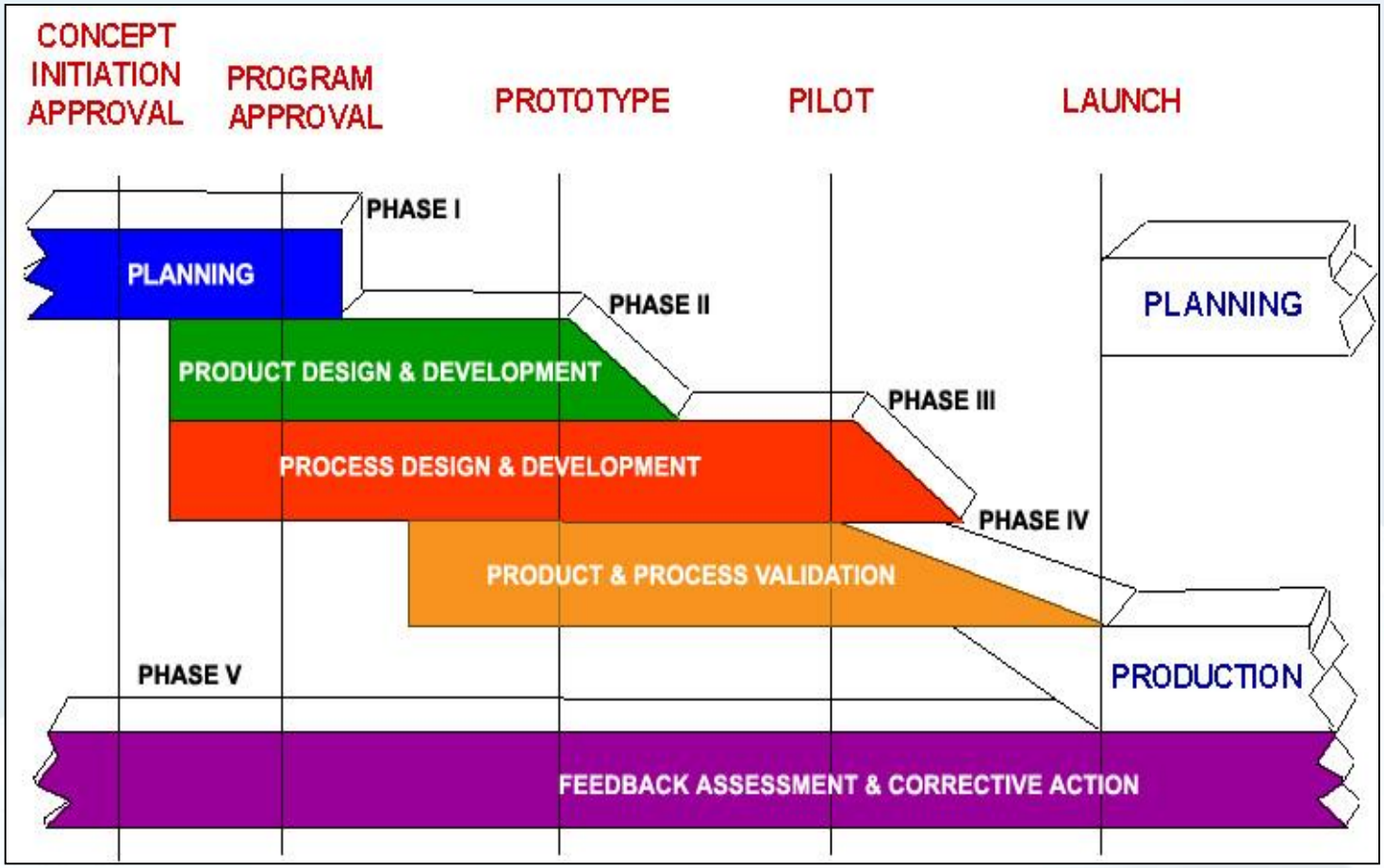
Instructor-Led Flipchart Example



Alignment of APQP Processes with IATF 16949

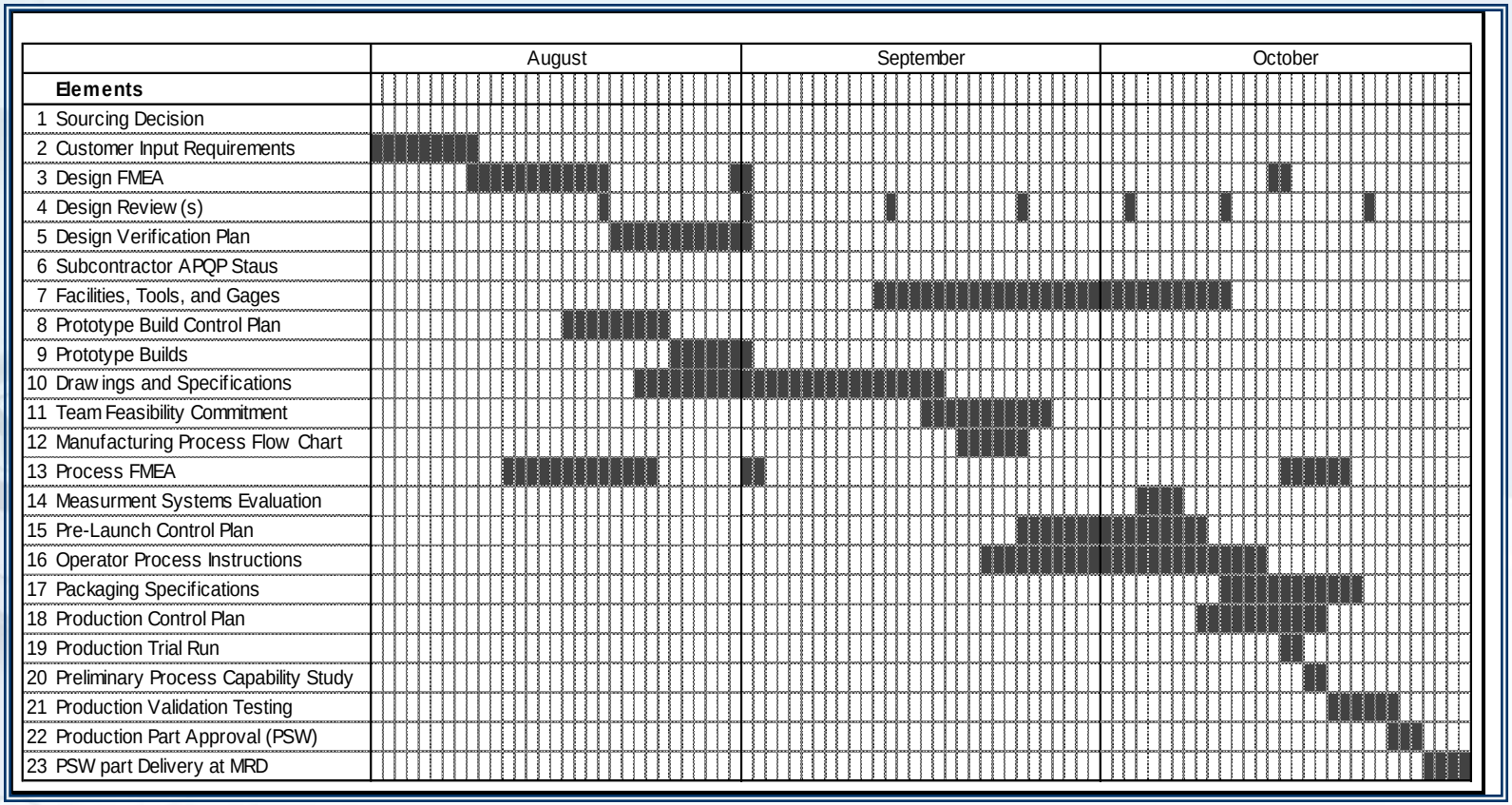
How do the IATF Clauses integrate with APQP?

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.

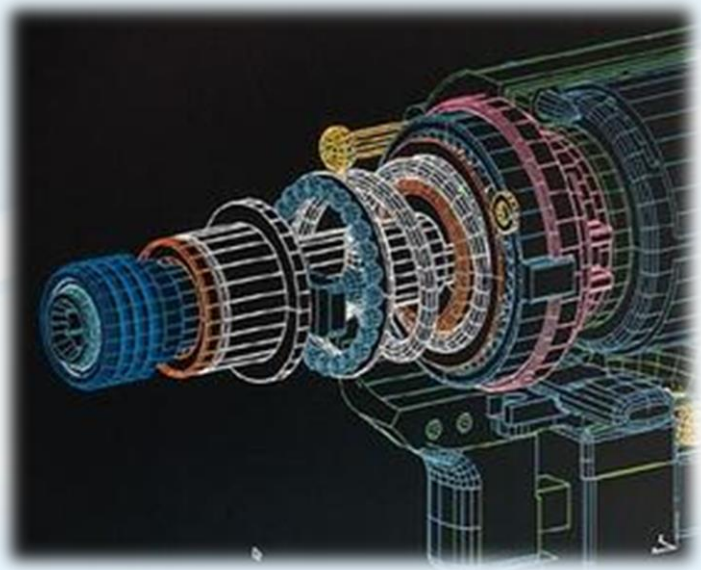
8.2.3.2

- 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.

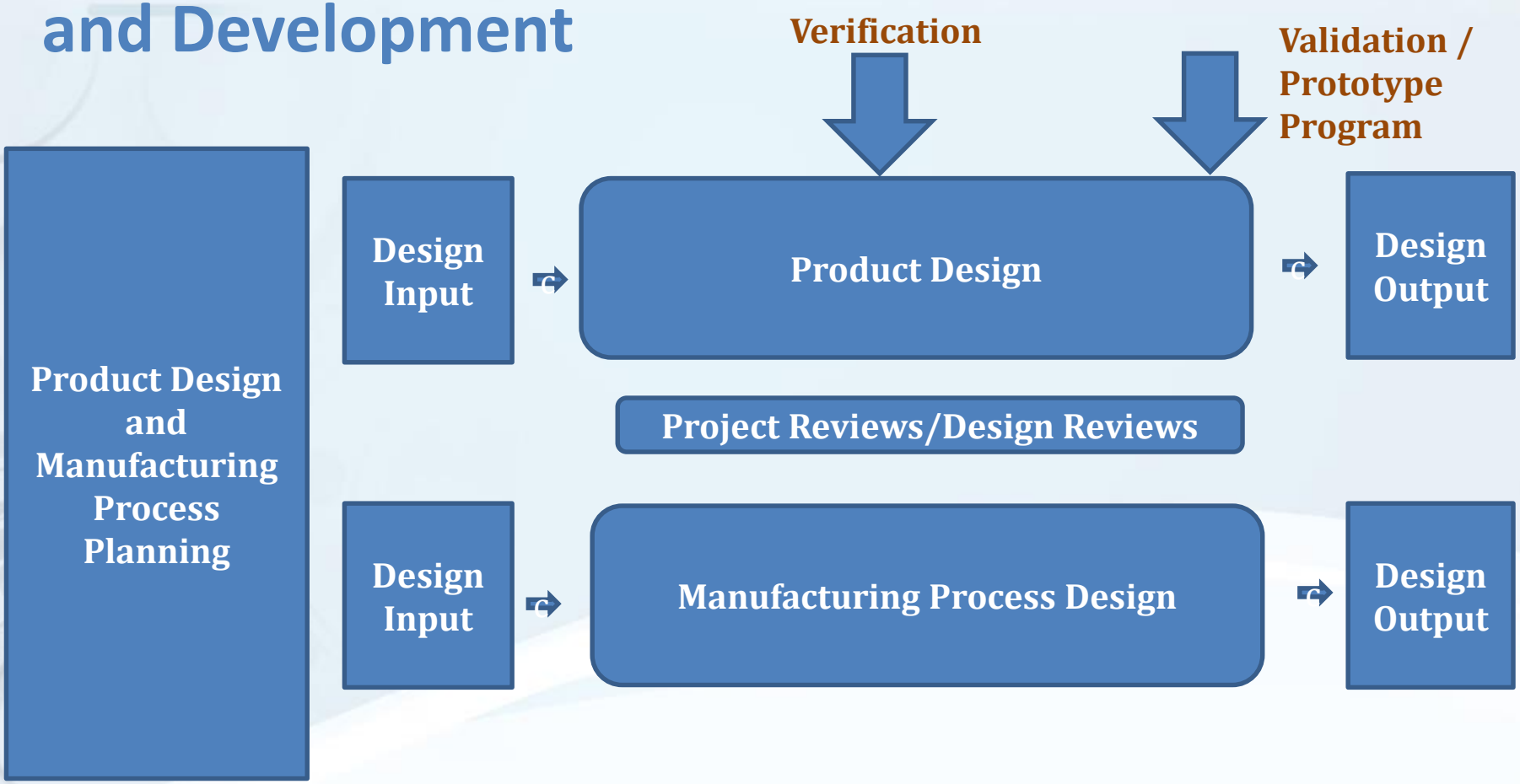


Clause 8 — Operation

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

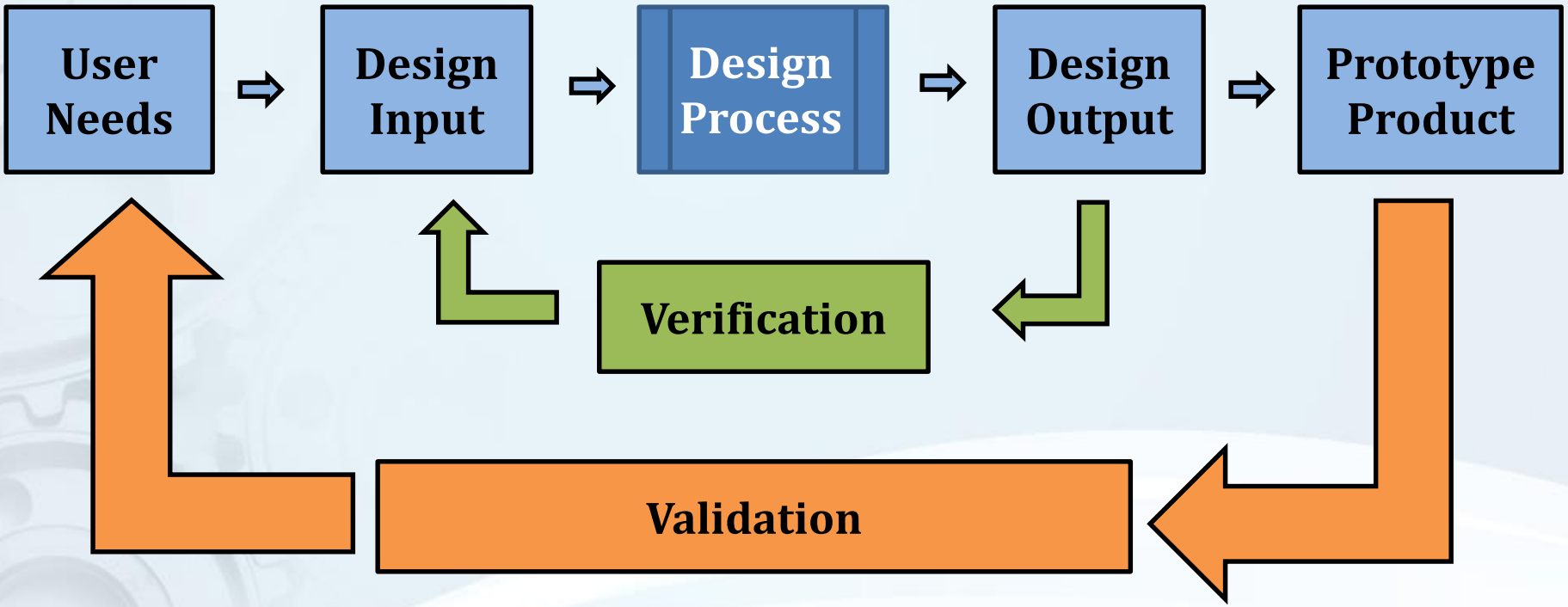
8.3.4.4 Product Approval Process

- 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.

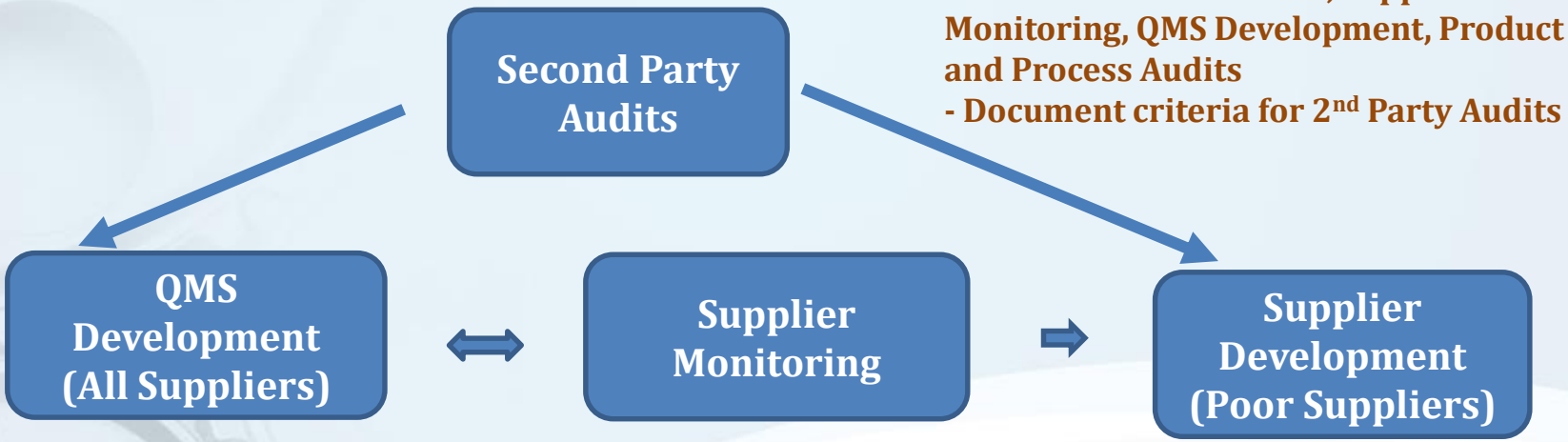
Managing Suppliers

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

QUALITY

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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)**

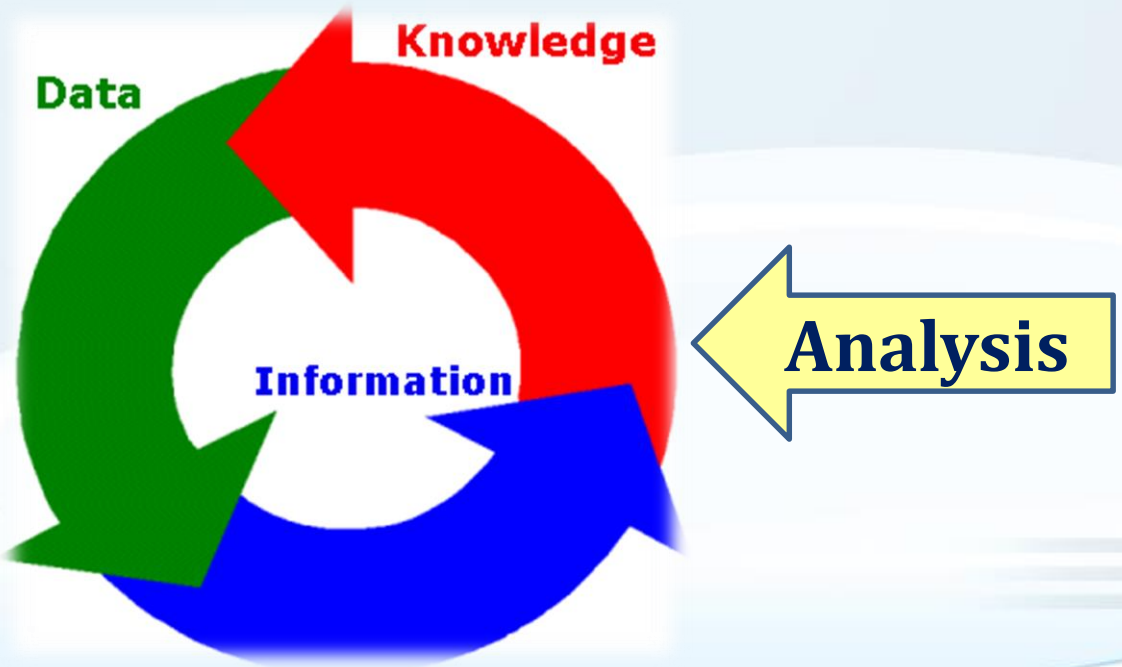
9.3 Management Review (CHANGED)

- **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**

Chapter 3

Process Approach to Auditing, Turtle Diagrams, and Audit Trails

Chapter 3: Process Approach to Auditing, Turtle Diagrams and Audit Trails — What We Will Cover

Learning Objectives

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

- Describe Conformance and Performance Audits
- Explain a Process Approach Audit
  - What is a risk-based audit?
- Describe the six elements of a Turtle Diagram
- Explain how to use the turtle concept to conduct an audit using the process approach
- Describe the concept of audit trails

Chapter Agenda

- Conformance and Performance Audits
- Process Approach to Auditing
- Turtle Diagrams
- Audit Trails

Conducting Performance and Conformance Auditing

Performance Auditing

Used with the process approach to auditing.

Used to ensure that processes are performing.

Focus is on process measurables (and performance) that support KPIs and support interested party expectations as it relates to the context (see section on 4.1 and 4.2).
Related to risk in 6.1 and QMS processes in 4.4.

Poor performance and processes are identified in the Stage I of the audit (prioritizing the audit).

Requires process measurables and goals, and actions if a process is not reaching its target.
Finally, the process may have to be rethought if it consistently fails.

Uses a turtle diagram for process analysis.

Conformance Auditing

Typically used when implementing new or revised standards.

Used for Gap Analysis and then to establish the system.

Ensures that the process covers all the “shalls” and includes who, what, and when in document reviews.

Involves sampling of the process to ensure it is being followed.

It ensures intent and effective implementation.
While the performance audit ensures that “effectiveness in practice” and risk is handled.

Uses a checklist highlighting “shalls” or a customized checklist showing process requirements of the organization.

Conformance audits need to be the focus of implementation initially. As the processes mature, the focus should become performance. However, both types of audits need to be performed in a system audit.

Conducting Performance and Conformance Auditing

Performance Results

- Auditors should focus on the intended result of the management system throughout the audit process.
- Processes and what they achieve are important but the result of the management system and its performance are most important.
- It is also important to consider the level of the integration of different management systems and their intended results.
- The absence of a process or documentation can be important in a large, high risk or complex organization but not as significant in other organizations, e.g., small organizations.

Conducting Performance and Conformance Auditing

Auditor Responsibilities

- Auditors have to assess if the organization has conducted the following for each clause or process of the audit:
  - **Intent:** has the organization understood the clause of IATF 16949 correctly?
  - **Effectively Implemented:** is the process implemented, i.e., are they doing what they are saying?
  - **Effectiveness in Practice:** if the process is being followed, is the process providing results?

Conducting Performance and Conformance Auditing

Examples for Discussion

- Receiving Inspection process — What is the intent? How do we assess **Effectiveness in Practice**?

- Internal Audit process — What is the intent? How do we assess **Effectiveness in Practice**?

- What about Continual Improvement? Management Review? Others?

PROCESS APPROACH TO AUDITING

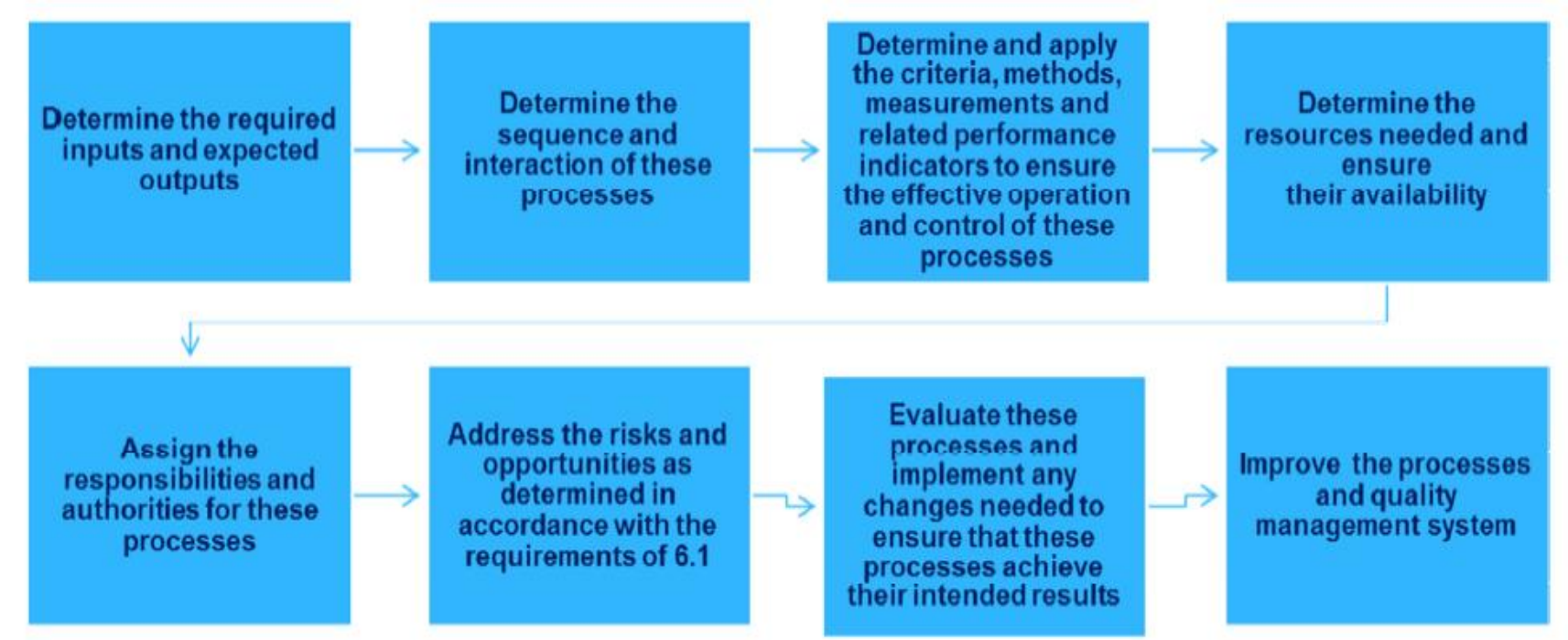
Performance Audits

Process Approach to Auditing

- The use of a “process approach” is a requirement for all ISO management system standards to comply with ISO/IEC Directives, Part 1, Annex SL.
- Auditors should understand that auditing a management system is auditing an organization’s processes and their interactions in relation to one or more management system standard(s).
- 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.

Guidance on Process Approach

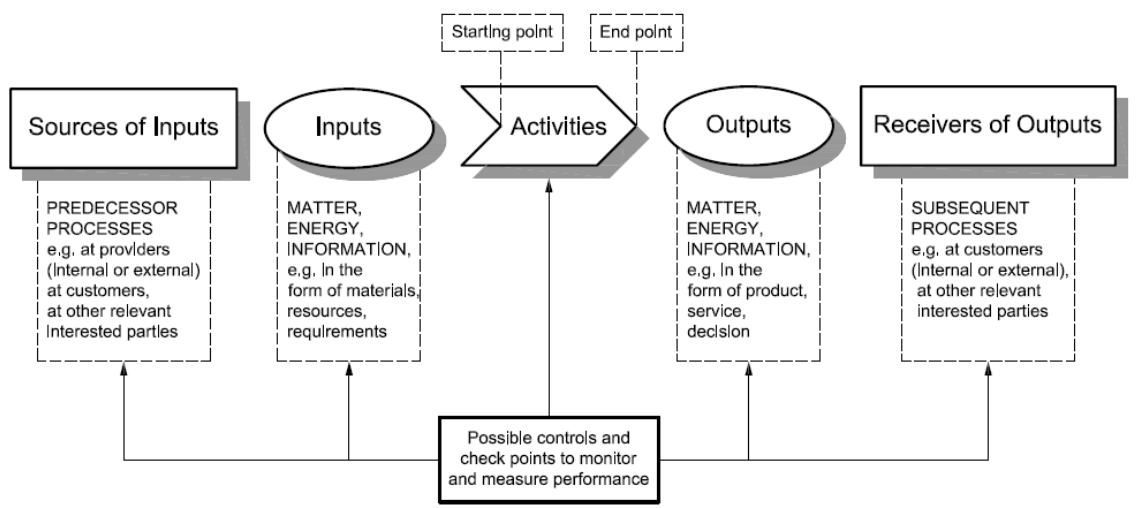
This diagram can assist auditors in establishing the sequence to audit the processes of the organization:



Source: 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 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



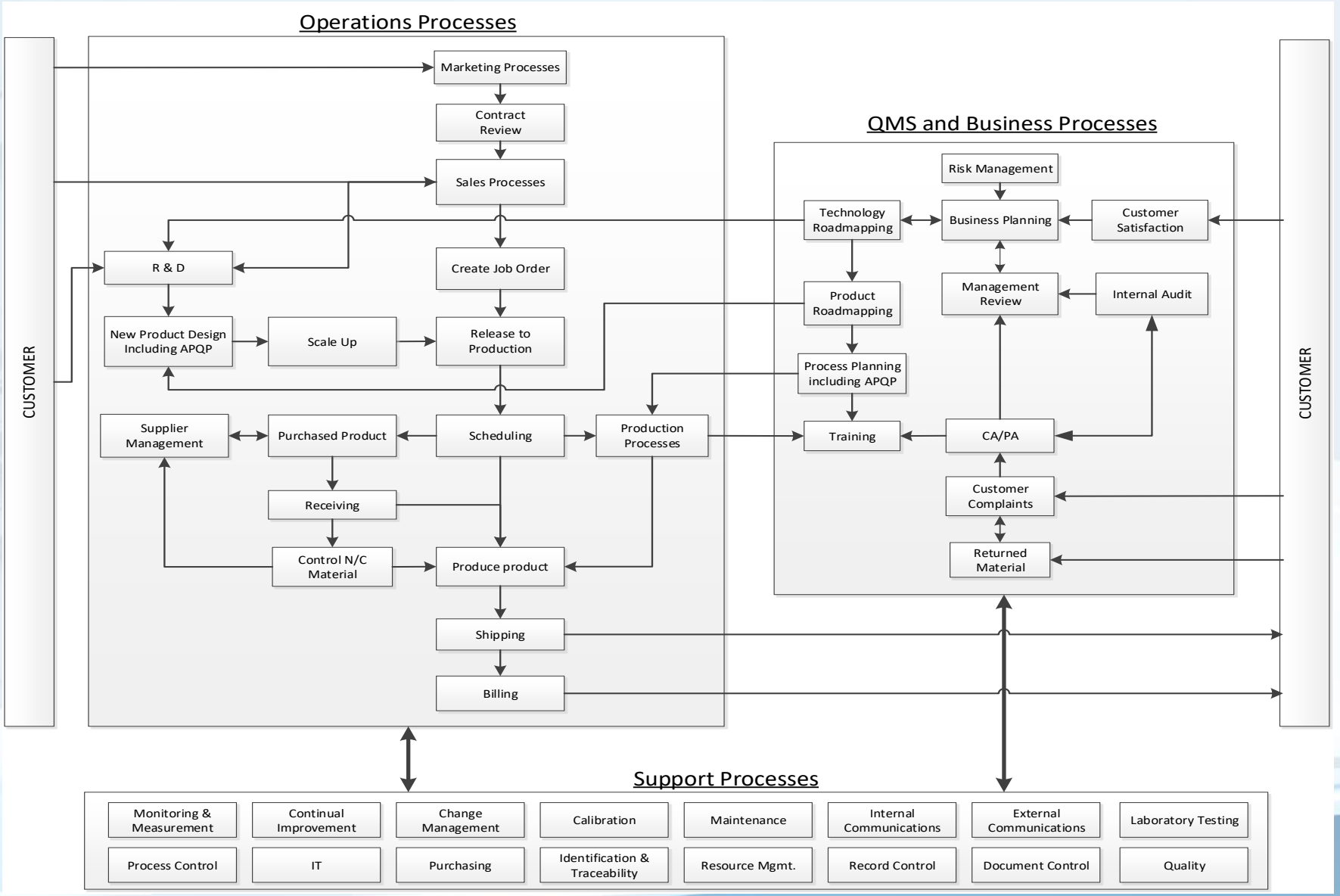
source: ISO 9001:2015, Figure 1 — Schematic Representation of the Elements of a Single Process

Process Characteristics

- A process can be identified by a series of unique, but consistent, characteristics.

- There are six characteristics of a process that are mandatory for an effective management system:
  1. A Process Owner Exists
  2. The Process is Defined
  3. The Process is Documented
  4. Process Linkages are Established
  5. The Process is Monitored and Improved
  6. Records are Maintained

Process Map — Example



Evaluating the Process Map

- Does it provide a description of the sequence and interaction and including identification of the site, remote location, and outsourced processes and their interfaces?*
  - Process Maps help define the "Process Approach" of an organization
    - Process Maps cannot be "Clause Oriented"
    - Process Maps cannot be "Functionally Oriented"
- Description of the remote location and the support they provide
  - Process Maps should define the Enterprise
    - Processes that connect the organization cannot stop within the four walls of an organization
- Evidence that all requirements of IATF 16949 are addressed by the processes *
- Evidence of COPS or Customer Oriented Processes and requisite customer representative or CSR
- Quality Manual including interactions with support functions whether on site or remote *

*Source: Rules for Achieving and Maintaining IATF Recognition, 5th Edition

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

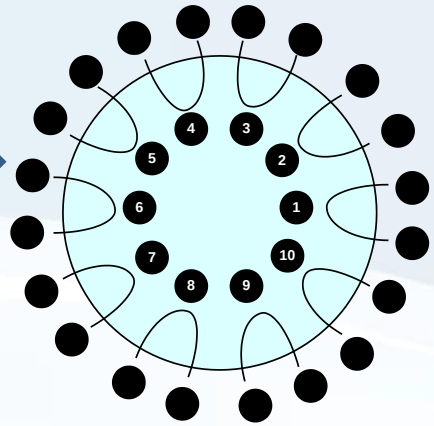
Customer's requirement is met and the output is provided to them in the format or method required

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



Categorization of Processes

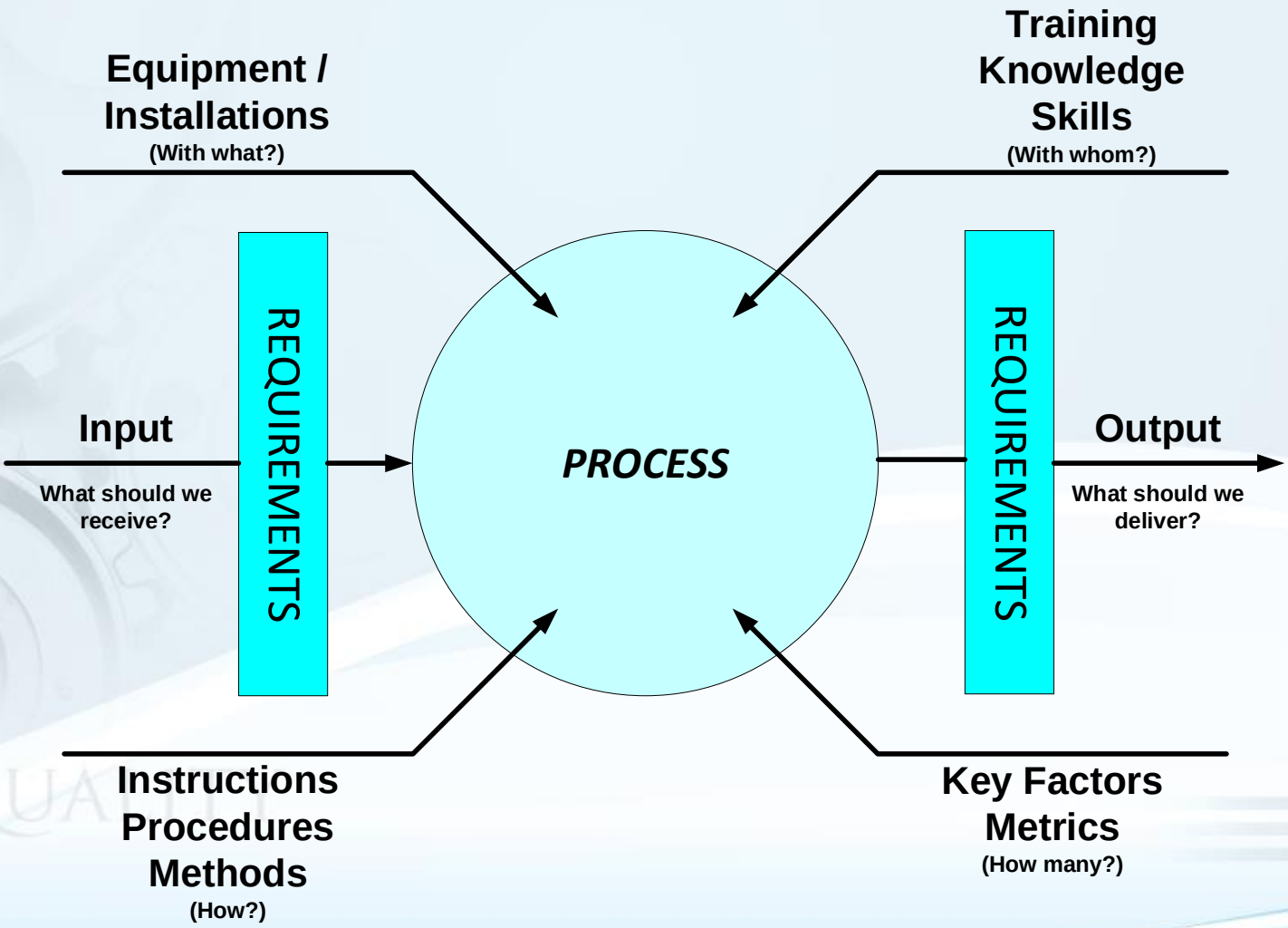
COPs, MOPs, SOPs

TURTLE DIAGRAMS

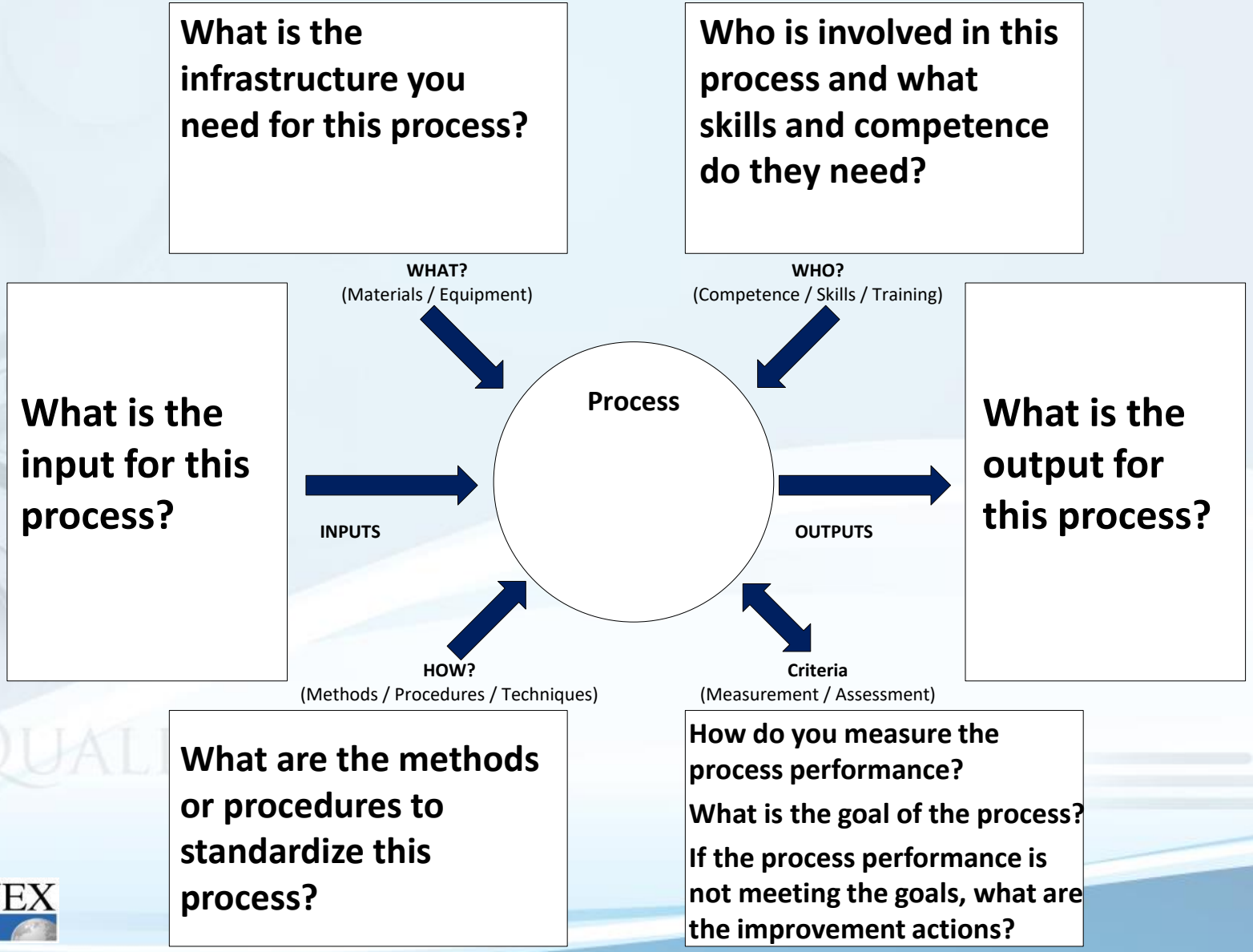
The Turtle Diagram

- A structured document which fully describes a process
- Made up of 6 sections:
  - **Inputs:** Interested Party Expectations, Resources, Product, Legal and Other Requirements, etc.
  - **Outputs:** Product, Service, Objectives/Targets, Program, Continual Improvement
  - **Process Measurements:** Performance Indicators and Metrics
  - **People:** Competencies, Responsibility, Authority
  - **Equipment/Devices:** Machines, Tests/Inspections, Software, Hardware, Material Handling, etc.
  - **Documents:** Procedures, Work Instructions, Standards/Requirements
- Each section describes a specific element of a process
- Covering each section ensures a process approach to the audit

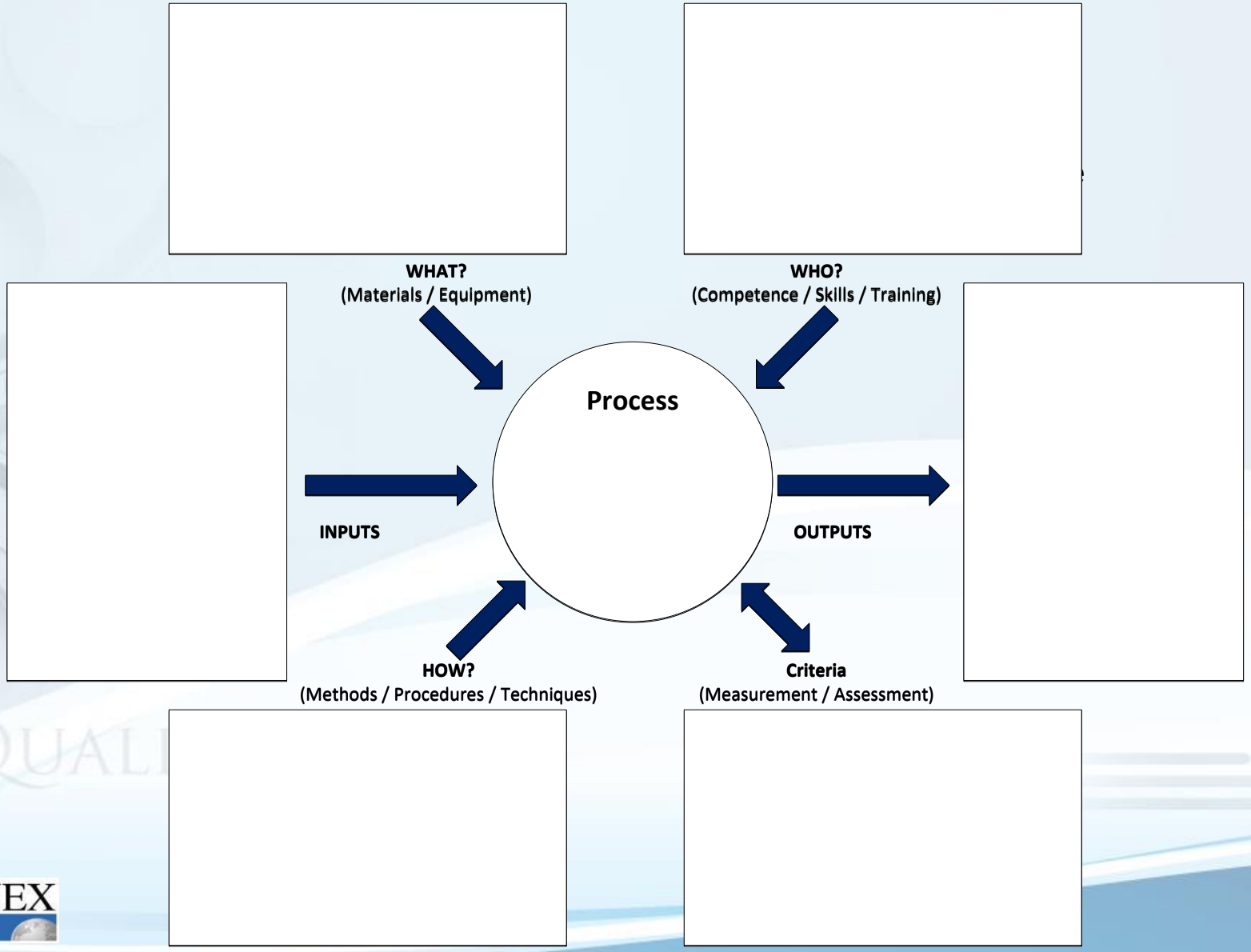
Turtle Diagram



Turtle Diagram



Process Analysis — Instructor-led Example



AUDIT TRAILS

Audit Trails

- Processes are made up of linked activities which make up an "audit trail."
- To audit a management system process, we take samples along the audit trail.
- We ask a series of questions to test conformity with the requirements of the standard at each step of the trail.
- Audit trails are created using an organization's Process Map.

Audit Trails

IATF 16949:2016 Auditing and Audit Trails

a) Planning, Performance Evaluation and Improvement Audit Trail

b) New Product Development Audit Trail

c) Production and Service Provision Audit Trail

d) Change Management, FMEA/Control Plan, and Requirements Management Audit Trail (only for IATF 16949)

Audit trails will vary from one organization to another.
The audit trail flow chart is an aid to the auditor.

- One auditor will conduct an audit of all processes/clauses in an audit trail.
  - Audit trails have linkages from one area to the next and a common linkage is the samples taken.

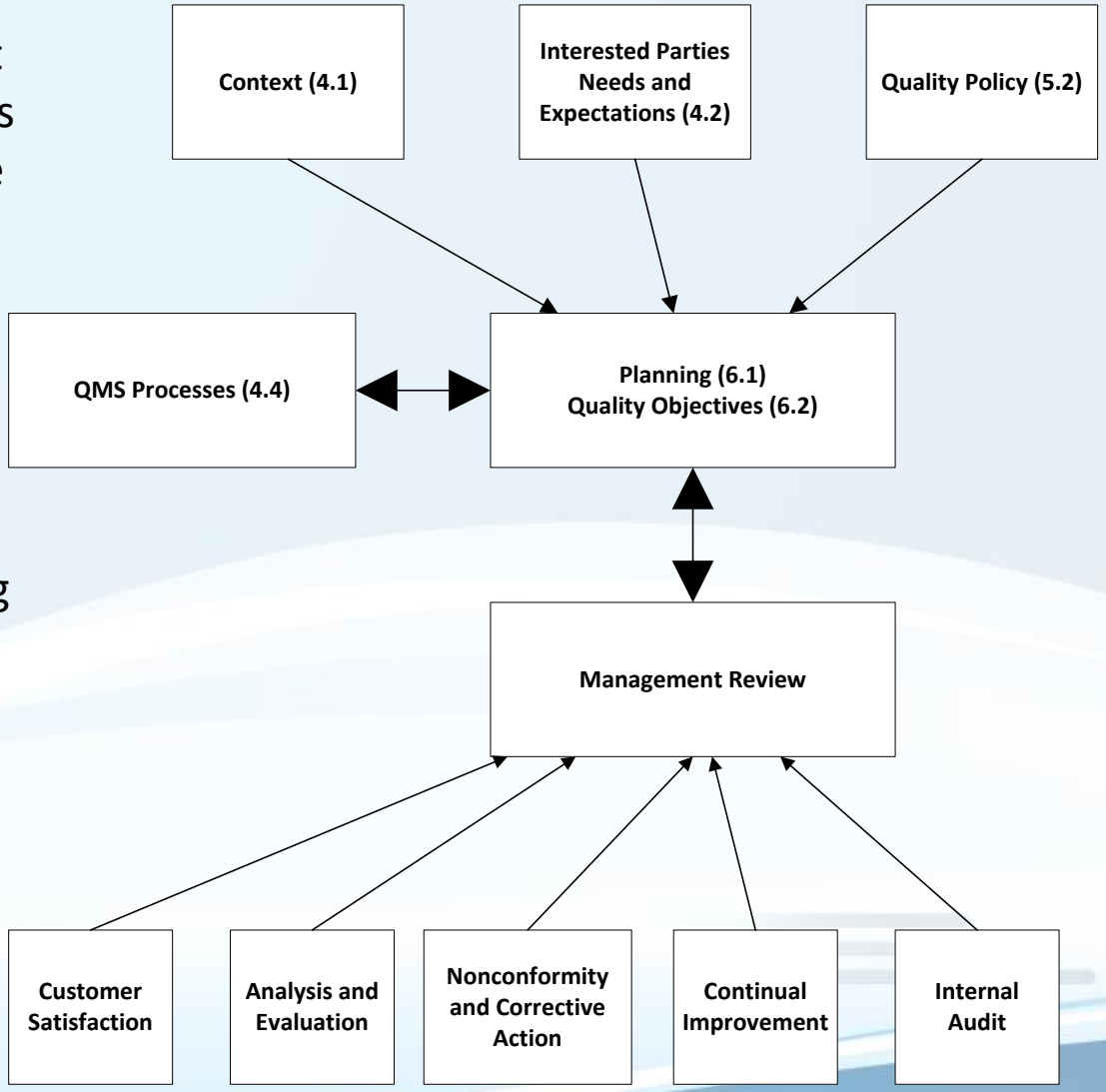
How to Use Audit Trails When Auditing Processes

- Use the company's business processes/procedures during the audit.

- Use the linkages and sampling described by audit trails to make your audits more effective.

Planning, Performance Evaluation and Improvement Audit Trail

- Evaluates the alignment of context (**4.1**), interested party expectations (**4.2**) and quality policy (**5.2**) to the objectives set (**6.2**) and whether it is deployed to organization.
- Studies Management Review, looking at results of the organization's activities to determine whether they are improving or if the QMS is meeting its intended results.

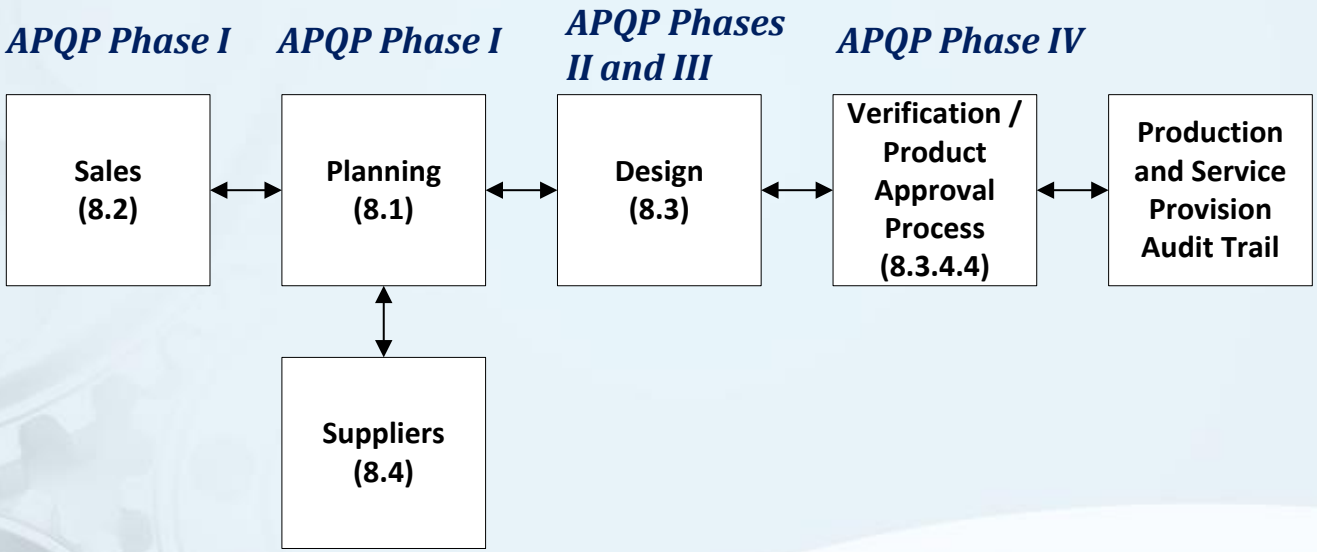


Since this audit trail is so large and has so many important topics, it is broken into two pieces so a second auditor is able to audit the bottom half

Planning, Performance Evaluation and Improvement Audit Trail

- Check the alignment between the issues in the context (**4.1**) and interested party expectations (**4.2**) in setting objectives, sampling key issues and expectations:
  - Are objectives set for key expectations?
  - Does the plan cover how the objectives are going to be achieved?
- Study the Management Review:
  - Is Top Management engaged in Management Review?
  - Does it take place on a regular basis to move the company forward?
  - Does the review include all the required management inputs in **9.3.2**?
  - Does the review include all the objectives set?
  - Are they meeting their original goals? If not, does the action plan or Management Review outputs have actions for improvement?

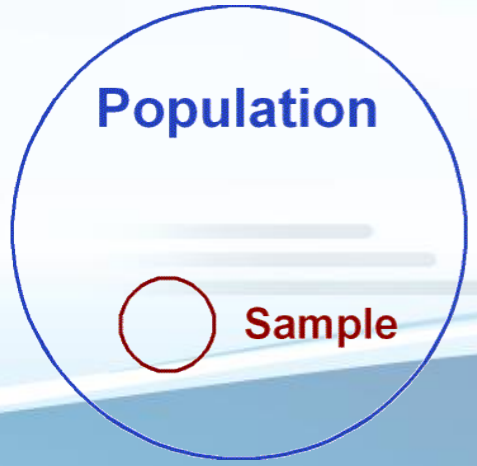
New Product / Service Development Audit Trail and Alignment with APQP



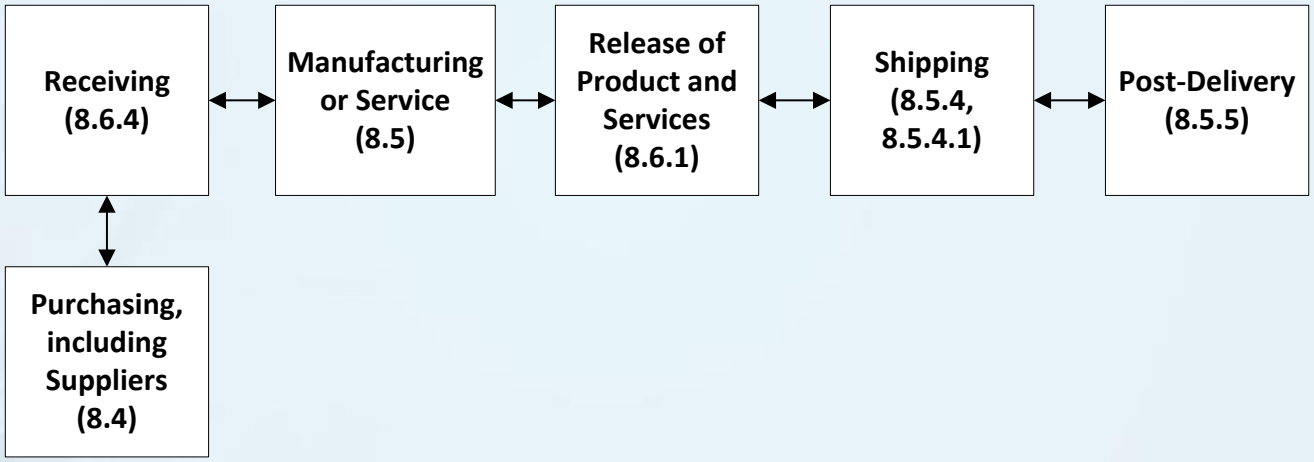
- The New Product / Service Development process starts with the sales process or the contract review process as it was referred to in earlier versions of ISO 9001.
- Next is the planning and execution of the product or service design.
- Then the planning and execution of the processes to create the product or service.

New Product / Service Development Audit Trail

- When sampling, consider:
  - A product or service that has been delivered to the customer for at least 12 months.
    - Be sure to continue this audit into the delivery time of the product or service.
  - A product or service that has recently been released to the customer, and
  - A product or service that is going through the development process.

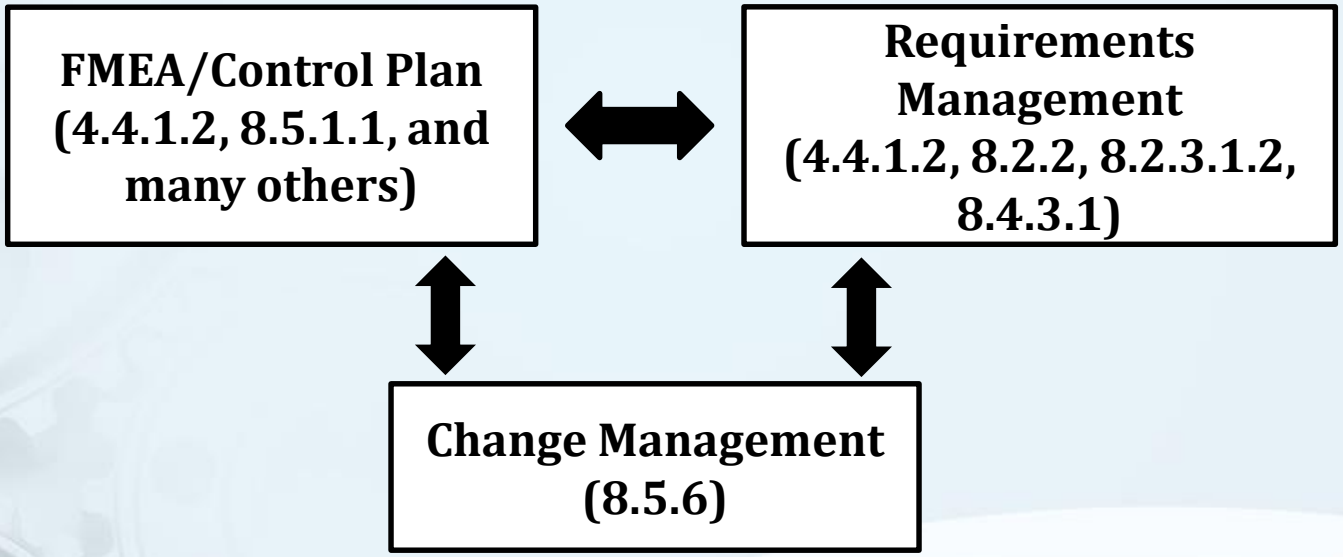


Production and Service Provision Audit Trail



- Be sure the largest product families of key customers are considered as well as smaller and less significant products.
- The samples will have to consider what products are running in the plant at the time of the audit.
- Make sure all main processes including special processes are sampled.

Change Management, FMEA/Control Plan, and Requirements Management Audit Trail



- The linkages between DFMEA, Test Plans (DVP&R), Process Flow, PFMEA, Control Plans, and Work Instructions need to be studied at the highest level i.e., system or subsystem.
- How does it relate to the related subsystem or components? How is information provided to the suppliers?
- Due to the Function/Requirement/Characteristic relationship, these linkages relate to overall requirements management.

Change Management, FMEA/Control Plan, and Requirements Management Audit Trail

- There are many linkages to test via samples:
  - When studying FMEA/Control Plan and Requirements Management, keep in mind a subset is Product Safety requirements and characteristics. How is Product Safety (**4.4.1.2**) satisfied?
  - How are special characteristics handled? (**8.2.3.1.2**)
  - Sample a few Product and Process Change Notifications. Was the customer notified? Did the organization do a subset of APQP including PPAP for major changes. Did FMEAs/Control Plans change as necessary?
  - Sample a trail from corrective action to see if systemic corrective action (**10.2.3f**) resulted in FMEAs/Control Plans changing.

Support Processes

Resources

People

Infrastructure

Environment for the Operation of Processes

- These are support processes that can be audited as they apply throughout the organization as well as how they are managed by the process owner.
- During the audit, get names of the individuals who are a cross-section of the organization and check these names when auditing training and competency requirements.

Chapter 3: Process Approach to Auditing, Turtle Diagrams and Audit Trails — What We Covered

Learning Objectives

You should now be able to:

- Describe Conformance and Performance Audits
- Explain a Process Approach Audit
  - What is a risk-based audit?
- Describe the six elements of a Turtle Diagram
- Explain how to use the turtle concept to conduct an audit using the process approach
- Describe the concept of audit trails

Chapter Agenda

- Conformance and Performance Audits
- Process Approach to Auditing
- Turtle Diagrams
- Audit Trails

Chapter 4

Audit Guidance, Definitions and Principles

Chapter 4: Audit Guidance, Definitions and Principles — What We Will Cover

Learning Objectives

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

- State key definitions related to audit activities
- Describe the three types of audits
- Explain the importance of audit principles
- Define an auditor's personal behaviors
- Define the responsibilities, roles and authorities for an audit
- Describe an overall audit program

Chapter Agenda

- Audit Definitions and Guidance
- Types of Audits
- Audit Principles and Auditor Behaviors
- Responsibilities, Roles and Authorities

ISO 19011:2018 Applicability

- ISO 19011:2018 provides **guidance** on the management of audit programs, planning and conduct of management system audits, and the competence and evaluation of auditors and audit teams **FOR ALL TYPES OF AUDITS.**
- ISO 19011:2018 concentrates on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party).
- It can be used for external audits conducted for purposes other than third party management system certification.
  - ISO/IEC 17021-1 provides requirements for auditing management systems for third party certification.
- It can also be used for the purpose of self-declaration and can be useful to organizations involved in auditor training or personnel certification.
- ISO 19011:2018 is applicable to all organizations that need to plan and conduct internal or external audits or manage an audit program.

AUDIT DEFINITIONS AND GUIDANCE

ISO 19011:2018

Audit Definitions — ISO 19011

Audit: systematic, independent and documented **process** for obtaining **objective evidence** and evaluating it fully to determine the extent to which **audit criteria** are fulfilled.

Process: set of interrelated or interacting activities that use inputs to deliver an intended result.

Combined (or Integrated) Audit: audit carried out together at a single auditee on two or more management systems.

Joint Audit: audit carried out as a single auditee by two or more auditing organizations.

Audit Definitions — ISO 19011

Audit Criteria: set of **requirements** used as a reference against which **objective evidence** is compared.

Objective Evidence: data supporting the existence or verity of something.

Audit Evidence: records, statements of fact or other information, which are relevant to the **objective evidence** and verifiable.

Audit evidence characteristics:
- **Uninfluenced by emotion or prejudice**
- **Can be stated**
- **Can be documented**
- **Can be verified (i.e., documented/based on observable phenomena)**

Audit Definitions — ISO 19011

Audit Program: arrangements for a set of one or more audits, planned for a specific time frame and directed towards a specific purpose.

Audit Scope: extent and boundaries of an audit.

Audit Plan: description of the activities and arrangements for an audit.

Audit Findings: results of the evaluation of the collected audit evidence against audit criteria.

Audit Conclusion: outcome of an audit after consideration of the audit objectives and all audit findings.

Audit Definitions — ISO 19011

Audit Client: Organization or person requesting an audit.

Auditee: Organization as a whole or parts thereof being audited.

Audit Team: One or more persons conducting an audit, supported if needed by technical experts.

Auditor: Person who conducts an audit.

Technical Expert: Person who provides specific knowledge or expertise to the audit team.

Observer: Individual who accompanies the audit team but does not act as an auditor.

Audit Definitions — ISO 19011

Risk: effect of uncertainty.

Management System: set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.

- Note 1 to entry: A management system can address a single discipline or several disciplines, e.g., quality management, financial management or environmental management
- Note 2 to entry: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

Audit Definitions — ISO 19011

Requirement: need or expectation that is stated, generally implied or obligatory.

Effectiveness: extent to which planned activities are realized and planned results achieved.

Performance: measurable result.

TYPES OF AUDITS

Types of Audits

- All audits can be classified into one of three types:
  - ***A First Party Audit (Internal Audit):*** Carried out by an organization on itself, using one of its own staff or a sub-contractor as the auditor.
  - ***A Second Party Audit (External Audit):*** Carried out by, or on behalf of, the customer on a supplier or potential supplier of goods or services.
  - ***A Third Party Audit:*** A company hires an organization to carry out an audit with the objective of obtaining independent certification of conformance with a particular standard.

1st Party Audit	2nd Party Audit	3rd Party Audit
Internal Audit	External Provider Audit	Certification and/or Accreditation Audit
	Other External Interested Party Audit	Statutory, Regulatory and Similar Audit

1st Party Audit — Internal Audit Purpose

- An internal unbiased look at a company's processes…
  - To determine the gap between the system that is written and that which is actually practiced
- Should be a "management instrument" in the development of procedures and systems and efforts toward Continual Improvement

2nd Party Audit — External Audit Purpose

- Evaluate a potential supplier to determine if they have the capabilities to meet the organization's requirements
- React to a supplier issue with an audit of the effectiveness of corrective actions
- Ongoing evaluation of a supplier

3rd Party Audit — Certification Audit Purpose

- Independent review of the management system for conformance and effectiveness
- Meet customer requirements for a certified management system
- Marketing tool to pursue new business or new markets

Third Party Audit Structure

- Information and Discussion
- Certification Application
- Pre-Assessment (optional)
- Stage 1 – Planning an Audit
- Stage 2 – On-site Audit
- Corrective Action and Follow-up
- Certificate Decision
- Certificate Issuance
- Surveillance
- Recertification

Auditing Principles

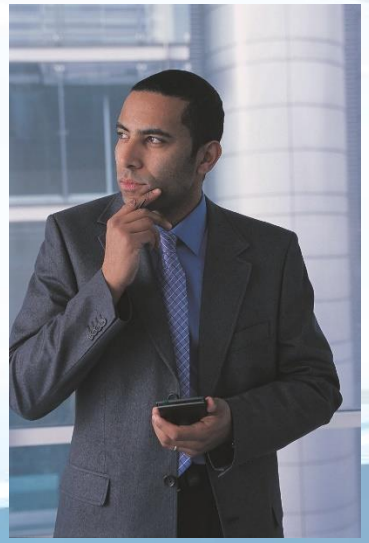
- Auditing principles help to make the audit an effective and reliable tool in support of management policies and controls by providing information upon which an organization can act in order to improve its performance.
- Adherence to these principles is needed in order to provide:
  - Audit conclusions that are relevant and sufficient.
  - For enabling auditors, working independently from one another, to reach similar conclusions in similar circumstances.

Auditing Principles

- **Integrity:** Foundation of professionalism
- **Fair Presentation:** Obligation to report truthfully and accurately
- **Due Professional Care:** Application of diligence and judgment in auditing
- **Confidentiality:** Security of information
  - Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the auditee
- **Independence:** Impartiality of the audit and objectivity in audit conclusions
- **Evidence-based Approach:** Rational method for reaching reliable and reproducible audit conclusions in a systematic audit process
- **Risk-based Approach:** An audit approach that considers risks and opportunities
  - Ensures audits are target areas of significance for the audit client and for achieving the audit program objectives

Auditor Personal Behaviors

- Ethical
- Open-minded
- Diplomatic
- Observant
- Perceptive
- Versatile
- Tenacious
- Decisive
- Self-reliant
- Able to act responsibly and ethically
- Open to improvement
- Culturally sensitive
- Collaborative



RESPONSIBILITIES, ROLES AND AUTHORITIES

Roles, Responsibilities and Authorities

- Based on the context of the organization, several roles may be defined. The related responsibilities with authority should be defined within the Management System.

- **The Auditee's Management Should…**
  - Inform employees about the objectives and scope of the audit
  - Provide resources needed for the audit team
  - Provide access to the facilities and evidential material
  - Cooperate with the auditors during the audit
  - Determine and initiate corrective actions when required

Roles, Responsibilities and Authorities

Individual(s) Managing the Audit Program

a) Establish the extent of the audit program according to the relevant objectives and any constraints

b) Determine the external and internal issues, and risks and opportunities, then implement and integrate actions to address them in auditing activities

c) Ensuring the selection and competence of audit teams by assigning roles, responsibilities and authorities, and supporting leadership

d) Establish all relevant processes including processes for:

- Coordination and scheduling of all audits within the audit program
- Establishment of audit objectives, scope(s) and criteria, determining audit methods and selecting the audit team
- Evaluating auditors
- Establishment of communication processes
- Resolution of disputes and handling complaints
- Audit follow-up
- Reporting to the audit client and interested parties

Roles, Responsibilities and Authorities

Individual(s) Managing the Audit Program

e) Determine and ensure provision of necessary resources

f) Ensure documented information is prepared and maintained, including audit program records

g) Monitor, review and improve the audit program

h) Communicate the audit program to the audit client and relevant interested parties

The audit program should be reviewed and approved by the audit client

Roles, Responsibilities and Authorities

Lead Auditor

- Ultimate responsibility for all phases of the audit
- Submits the audit report
- Determines what follow-up action, if any, is to be taken and informs the auditee of the actions to be taken
- Assist with the selection of team members
- Preparation of the audit plan
- Define the requirements of each audit assignment
- Evaluate and address risks of the audit
- Define the requirements of each audit assignment, including the required auditor qualifications
- Represent the audit team

Roles, Responsibilities and Authorities

All Auditors

- Comply with applicable auditing requirements
- Prepare working documents
- Review current documentation
- Retain and safeguard documents – ensure confidentiality
- Retain privileged information with discretion
- Report nonconformities to the auditee immediately
- Report on the audit results clearly and conclusively
- Verify the effectiveness of corrective actions taken

Roles, Responsibilities and Authorities

Expert

- The expert provides technical assistance to audit team members in special or specific areas where the audit team members do not possess the necessary experience within that functional area or audit scope

Guides

- Witness the audit on behalf of the auditee and the auditor
- Provide clarification or assist in collecting information
- Assist the auditors in identifying individuals to participate in interviews, confirming timings, and arranging access to specific locations of the auditee
- Ensure that rules concerning location safety and security procedures are known and respected by the audit team members and observers

Roles, Responsibilities and Authorities

Observers

- Represent an interested party
- Opportunity to learn auditing skills
- Do not participate in the audit

Interpreter

- Required when the audit team needs to have, or have access to, the skills necessary to deal with issues raised by language and/or culture
- The need is met by having an interpreter as a member of the team
- Interpreter should not be provided by the audit client

Chapter 4: Audit Guidance, Definitions and Principles — What We Covered

Learning Objectives

You should now be able to:

- State key definitions related to audit activities
- Describe the three types of audits
- Explain the importance of audit principles
- Define an auditor's personal behaviors
- Define the responsibilities, roles and authorities for an audit
- Describe an overall audit program

Chapter Agenda

- Audit Definitions and Guidance
- Types of Audits
- Audit Principles and Auditor Behaviors
- Responsibilities, Roles and Authorities

Chapter 5

The Audit Program

Chapter 5: The Audit Program — What We Will Cover

Learning Objectives

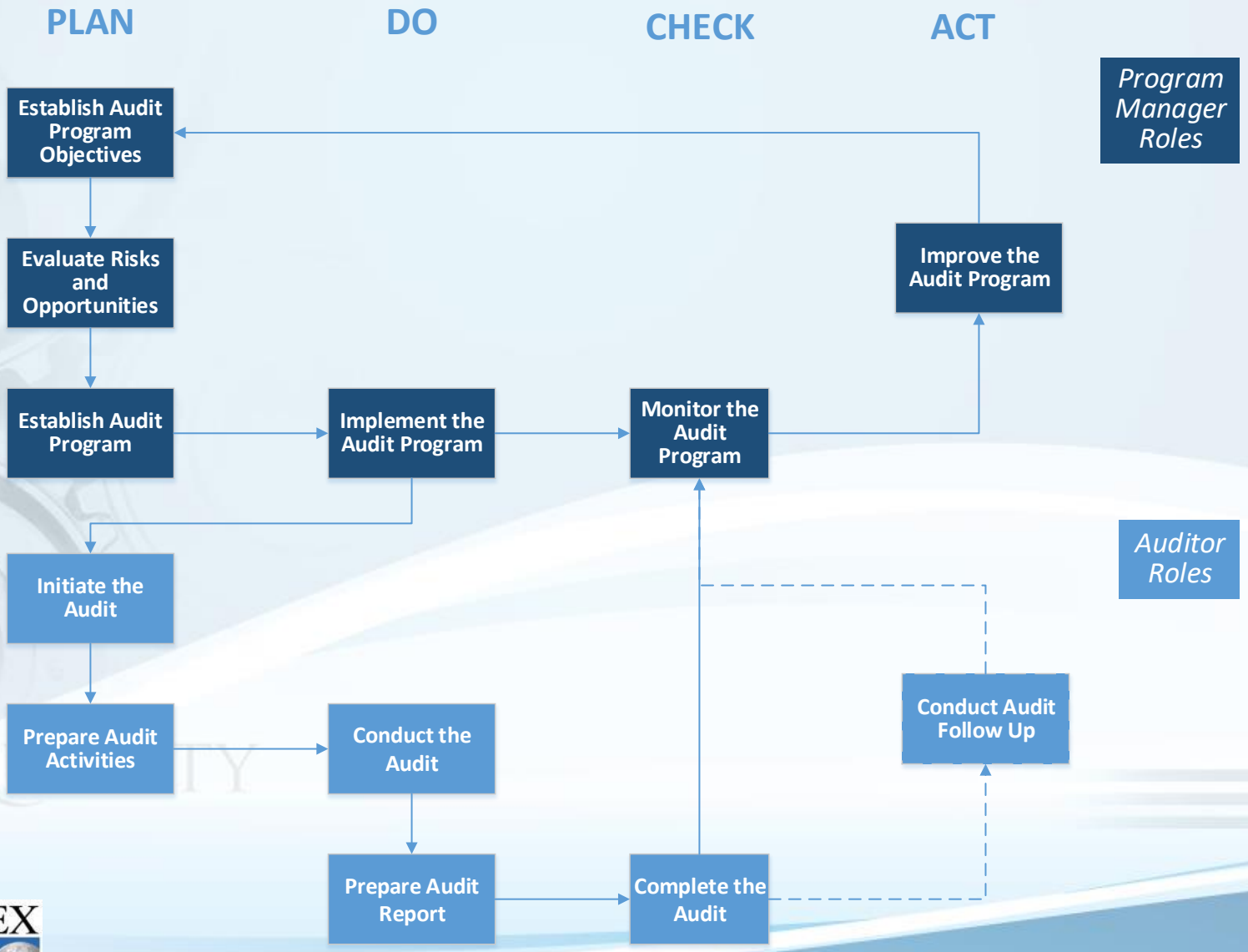
At the end of this chapter, you will be able to:

- Define the purpose and objectives of an audit program
- Describe the competency necessary for an auditor within the audit program
- List the risks associated with an audit program

Chapter Agenda

- Audit Program
- Audit Program Objectives
- Audit Program Competencies
- Audit Program Risks

Audit Program



Audit Program

- An audit program can include audits addressing one or more management system standards **(MSS)** or other requirements, and can be conducted separately or in a combined audit.
- The extent of an audit program should be based on the:
  - Size and nature of the auditee
  - MSS functionality and complexity
  - Type of risks and opportunities
  - Level of maturity of the management system
- The MSS functionality can be more complex when functions are outsourced and managed by other organizations.
- Particular attention needs to be focused on the top management of the management system.

Audit Program

- For multiple locations/sites or where important functions are outsourced, particular attention should be paid to the design, planning and ***validation*** of the audit program.
- For smaller or less complex organizations, the audit program can be scaled down.
- To understand the context of the auditee, the audit program should take into account:
  - Organizational objectives
  - Relevant external and internal issues
  - Needs and expectations of relevant interested parties
  - Information security and confidentiality requirements
- The planning of internal audit programs can be arranged to contribute to other objectives of the organization.

Guidance: What is Validation?

- As defined by ISO 9000, validation is confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.
  - The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.
- An audit program can be validated by reviewing documented information including records.

Audit Program Objectives

- The audit client should ensure audit program objectives are established and implemented effectively.
- Objectives should be consistent with the strategic direction and support management system policy and objectives based on consideration of:
  - Needs and expectations of relevant interested parties
  - Characteristics of and requirements for processes, products, services and projects including any changes to them
  - Management system requirements
  - Need for evaluation of external providers
  - Audited MSS level of performance and level of maturity as evidenced by KPIs, any nonconformities or complaints from interested parties
  - Identified risks and opportunities to the auditee
  - Results of previous audits

Audit Program Objectives

- Examples of audit program objectives include:
  - Identify opportunities for MSS improvement
  - Evaluate the capability of the auditee to determine its context
  - Evaluate the capability of the auditee to determine risks and opportunities and implement effective actions to address them
  - Conform to all specified requirements, e.g., regulatory requirements, requirements for certification to a management system standard
  - Determine the capability of an external provider
  - Determine the continuing suitability, adequacy and effectiveness of the auditee's management system
  - Evaluate the compatibility and alignment of the management system objectives with the strategic direction of the organization

Managing an Audit Program

- Those managing the audit program should ensure the integrity of the audit is maintained and that there is no undue influence exerted over the audit.
- Audit priority should be given to allocating resources and methods to processes or activities with higher risk and lower level of performance.
- Competent individuals should manage the audit program.
- Implementation should be monitored and measured on an ongoing basis.
- Audit program should be reviewed to identify the need for changes and opportunities for improvement.

Managing an Audit Program

- The audit program should identify resources necessary to allow the audit to be conducted effectively and efficiently in the defined time frame and should include:
  - Audit program objectives
  - Audit program risks and opportunities and actions to address them
  - Scope of each audit in the audit program
  - Audit schedule (number/duration/frequency)
  - Audits types, i.e., internal or external
  - Audit criteria
  - Audit methods
  - Audit team selection criteria
  - Relevant documented information

Managing Audit Program Competence

"If you get a golf lesson in the morning, don't expect to shoot par in the afternoon"

- Competence for the Audit Program is critical to meeting the overall objectives of a successful audit process.
- Audit program competencies should include:
  - Determination of competencies needed
  - Determination of the methods to obtain the necessary competencies
  - Determination of the effectiveness of the methods used to obtain competencies

Managing Audit Program Competence

Determining Auditor Competence

- Determination of the necessary competence for an audit should consider the following:
  - Size, nature, complexity, products, services and processes of auditees
  - Audit methods
  - Management system to be audited
  - Complexity and processes of the management system to be audited
  - Risks and opportunities addressed by the management system
  - Objectives and extent of the audit program
  - Uncertainty in achieving audit objectives
  - Other requirements, such as those imposed by the audit client or other relevant interested parties

Managing Audit Program Competence

Knowledge and Skills of Auditors

- Understand risks and opportunities associated with auditing and the principles of the risk-based approach to auditing
- Effectively plan and organize work
- Perform the audit within the agreed schedule
- Prioritize and focus on matters of significance
- Communicate effectively, both orally and in writing
- Collect information through effective interviewing, listening, observing and reviewing documented information including records and data
- Understand appropriate use and consequences of sampling techniques
- Understand and consider technical experts' opinions
- Audit a process from start to finish, including interrelations with other processes and different functions as appropriate
- Verify relevance and accuracy of collected information
- Confirm audit evidence supports audit findings and conclusions, and assess those factors that may affect the reliability of these findings

Managing Audit Program Competence

Maintaining and Improving Auditor Competence

- Auditors and audit team leader should continually improve their competence through regular participation in management system audits and continual professional development, such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities taking into account:
  - Changes in the needs of the individual and the organization responsible for conducting the audit
  - Developments in auditing practices, including the use of technology
  - Relevant standards and guidance/supporting documents and other requirements
  - Changes in sector of disciplines
- Those managing the audit program should establish suitable methods for continual evaluation on the performance of auditors and audit team leaders.

Audit Program Risks

- The risks associated with establishing, implementing, monitoring, reviewing and improving an audit program that may impact the achievement of audit program objectives must be considered when developing an audit program.
- Those managing the audit program should identify the risks and opportunities when developing the audit program, including resource requirements, for the audit client so they can be addressed.
- Examples of risks include:
  - Planning, e. g., failure to set relevant audit objectives and determine the extent of the audit program
  - Resources, e. g. allowing insufficient time for audit program development
  - Audit team selection, e. g., the audit team lacks the necessary competence to achieve the audit objectives
  - Implementation, e. g. ineffective communication of the audit program
  - Ineffective evaluation of audit teams and their continual professional development
  - Records and their control, e. g., failure to adequately protect audit records
  - Monitoring, reviewing and improving the audit program, e. g., ineffective monitoring of outcomes

Audit Program Risks

- The lead auditor must evaluate and address audit risks
- There can be risks associated with the following:
  - Products
  - Supply Chain
  - Resources
  - Audit Program Management
  - Change Management
  - Communications
  - Control of Documented Information
  - Cooperation of Auditee and Availability of Evidence to be Sampled
  - Infrastructure, Work Environment, Health and Safety
  - Others!
  - Processes
  - Planning
  - Objectives
  - Competence
  - Selection of the Audit Teams
  - Implementation of Processes

Evaluating Risks and Opportunities

- Opportunities for improving the audit program include:
  - Establishing metrics that provide visibility to the overall effectiveness of the management systems to be audited
  - Conducting multiple audits in a single visit
  - Auditing integrated management systems
  - Minimizing time and/or travelling distance
  - Matching the level of competence of the audit team to the level of competence needed to achieve the audit objectives
  - Aligning audit dates with the availability of auditee's key staff

Chapter 5: The Audit Program — What We Covered

Learning Objectives

You should now be able to:

- Define the purpose and objectives of an audit program
- Describe the competency necessary for an auditor within the audit program
- List the risks associated with an audit program

Chapter Agenda

- Audit Program
- Audit Program Objectives
- Audit Program Competencies
- Audit Program Risks

Chapter 6

Audit Planning and Preparation

Chapter 6: Audit Planning and Preparation — What We Will Cover

Learning Objectives

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

- Describe the risk-based approach to auditing
- Identify the steps in preparing an audit
- Write objective and scope statements
- Describe the elements that should be considered when determining the audit resource requirements
- Explain the purpose of a Stage 1 audit
- Create an audit plan
- Describe the benefits and risks of checklists

Chapter Agenda

- Risk-based Approach to Auditing
- Audit Objectives, Scope and Criteria
- **Auditing Breakout Exercise 1**
- Determine Resources
- Contact Auditee
- Document and Data Analysis – Stage 1 Audit
- **Auditing Breakout Exercise 2**
- Prepare Work Documents
- **Auditing Breakout Exercise 3**

Objectives of Planning and Preparation

- **For the auditor**

  To make the auditor aware of the purpose of the audit that is to be performed, the scope of the investigation required and to allow the auditor enough time to conduct a preliminary investigation of the audit.

- **For the auditee**

  To make the auditee aware of the purpose and scope of the audit and the audit schedule to enable preparations to be made to ensure that the audit can proceed smoothly and achieve valid results.

RISK-BASED APPROACH TO AUDIT PLANNING

Auditing Risks and Opportunities

- Core objectives when auditing risks and opportunities are to:
  - Give assurance on the credibility of the risk and opportunity process(es)
  - Verify that risks and opportunities are correctly determined and addressed
- Risks and opportunities should be audited throughout the management system including with top management, not as an independent process.
- An auditor should collect objective evidence:
  - Inputs used which may include:
    - Analysis of context, e .g. external and internal issues
    - Strategic direction of the organization
    - Interested parties and their requirements
    - Potential sources of risk, e.g., environmental aspects, safety hazards
  - Method by which risks and opportunities are evaluated, which can differ between disciplines and sectors
- Auditors need to apply good professional judgment when assessing the organization's methods for addressing risks and opportunities.

Auditing Risk-Based Thinking
IAF Guidance

- An audit of risk-based thinking in an organization cannot be performed as a stand-alone activity; it should be implicit during the entire audit of a QMS, including when interviewing top management.
- Objective evidence of adequate risk determination could include:
  - Meeting minutes
  - SWOT analysis
  - Reports on customer feedback
  - Brain-storming activities
  - Competitor analysis
  - Planning, analysis and evaluation activities for various processes
  - Management review
  - Risk determination or evaluation records
- Actions needed for risk treatment can include the revising or establishing objectives, action plans, training, work instructions.

IAF Guidance — Audit Risk Classification Examples

- **High Risk:** Where product failure could cause economic catastrophe or puts life at risk
  - Examples: food, pharma, aerospace, chemical, healthcare
- **Medium Risk:** Where failure of product could cause injury or illness
  - Examples: construction, metal fabricating, optical equipment
- **Low Risk:** Where product failure is unlikely to cause injury or illness
  - Examples: textiles, clothing, paper products, hotels, education

source: IAF MD5 Risk Classification

Health and Safety Audit Risks

- The audit program manager should communicate any health and safety requirements for the audit to the team leader who should communicate these to the audit team, any observers and technical experts needed.
  - Examples: personal protective equipment (PPE) such as safety glasses, side shields, gloves, steel-toed safety shoes; hard hats, vests, quarantined or restricted areas, gowns, hair or beard covers and any required gowning procedure.
- The team leader should confirm any health and safety requirements in the initial contact with the auditee.
- Risks to the auditee can result from the presence of the audit team members adversely influencing the auditee's arrangements for health and safety, environment and quality, and its products, services, personnel or infrastructure (e.g. contamination in clean room facilities).
- Relevant access, health and safety, security, emergency and other arrangements for the audit team should be reviewed in the opening meeting.

Preparing for an Audit

Preparing for an Audit – Five Steps

1. Define the Audit Objectives, Scope, Criteria and Methods
2. Determine the Resources Required
   - Determine audit methods
   - Audit Team
   - Audit Team Leader
   - Other (hardware, software, etc.)
3. Contact the Auditee
   - Determine audit feasibility
   - Obtain documentation
4. Data Analysis and Document Review – Stage 1 Audit
   - Evaluate customer focus and performance
   - Conduct document review
5. Prepare Work Documents
   - Prepare audit plans
   - Prepare work documents

Six Steps of Conducting an Audit

1. **Initiate the Audit**
2. **Prepare Audit Activities**
3. **Conduct Audit Activities**
4. **Prepare Audit Report**
5. **Complete Audit**
6. **Conduct Audit Follow-up**

AUDIT OBJECTIVES, SCOPE AND CRITERIA

Audit Objectives, Scope and Criteria

- The **audit objectives** describe what will be audited, the type of audit to be conducted and what the audit findings will be compared against.
- The audit **scope** describes the extent and boundaries of the audit.
- The audit **criteria** is a reference against to which conformity is determined.

Audit Objectives

- Determination of the extent of conformity of the management system to be audited, or parts of it, with audit criteria
- Conformance to a standard or requirement
- Determination of the extent of conformity of activities, processes and products with the requirements and procedures of the management system
- Conformance to an organization's documented system
- Evaluation of the capability of the management system to ensure compliance with legal and contractual requirements and other requirements to which the organization is committed
- Conformance to a contract
- Evaluation of the effectiveness of the management system in meeting its specified objectives
- Conformance of a project toward meeting stated objectives
- Identification of areas for potential improvement of the management system
- Provide management with feedback related to either preventive action or continual improvement

Audit Scope

- Scope of the Audit – consistent with audit program and objectives (as needed for clarity)
  - Which product
  - Portion of company
  - Geographic sites or operating unit
  - Processes to be audited
  - Number of audit days

Although not required, it can be helpful to list the audit criteria, such as the standard against which the system will be audited and any exclusions, to the Audit Scope statement

Example:

- Design and manufacture of stampings for the automotive industry manufactured in Saline, Michigan with corporate HQ in Troy, MI. No exclusions.
- Transportation services located in Southfield, MI. Product design excluded.

Audit Criteria

- Audit Criteria – specified requirements against which conformity is determined
  - Policies
  - Processes
  - Procedures
  - Performance criteria, including objectives, statutory and regulatory requirements
  - Management System Requirements
  - Information on the organizational context and risks and opportunities as determined by the auditee, including external/internal parties' requirements
  - Codes of Practice

Auditing Breakout Exercise 1

Writing an Objective and Scope Statement

DETERMINE RESOURCES

Determine Resources Required

- How many days will the audit take?
- How many days should be spent in each area?
  - On-site versus remote auditing
  - Sampling methods
  - Minimize disruption
  - Enough time to be thorough
- How many auditors?
- Are technical experts required?
- Appoint the audit team leader

Audit Methods

Audit methods are defined by the Team Leader and the Audit Program Manager

- **Remote Auditing**
  - Any audit activities that take place at a location other than the site of the auditee.
  - Any technology that allows the auditor and the auditee to communicate while the auditor is located at a remote location. Methods such as conference calls, video conferencing, web/internet meetings could be used.
- **On-site Auditing**
  - Audit activities conducted at the site of the auditee.
- **Human Interaction**
  - Interacting with the auditee either during on-site or remote audit activities.
- **No Human Interaction**
  - No interaction with the auditee either during on-site or remote audit activities.

Audit Methods

Extent of Involvement Between the Auditor and Auditee	Location of the Auditor	
	On-site	**Remote**
Human Interaction	Conducting interviews Completing checklists and questionnaires with auditee participation Sampling	Via interactive communication means: – conducting interviews – completing checklists and questionnaires – conducting document review with auditee participation
No Human Interaction	Conducting document review (e.g., records, data analysis) Observing work performed Conducting on-site visit Completing checklists Sampling (e.g., products)	Conducting document review (e.g., records, data analysis Observing work performed via surveillance means, considering social and statutory and regulatory requirements Analyzing data

On-site audit activities are performed at the location of the auditee. Remote audit activities are performed at any place other than the location of the auditee, regardless of distance.
Interactive audit activities involve interaction between the auditee's personnel and the audit team. Non-interactive audit activities involve no human interaction with individuals representing the auditee but do involve interaction with equipment, facilities and documentation.

The feasibility of remote activities depends on several factors, such as the level of risk to achieving the audit objectives, the level of confidence between auditor and auditee personnel, and regulatory requirements

source: ISO 19011:2018 Annex A.1

Auditing Virtual Activities and Locations

- Auditing of a virtual location, aka “virtual audits” are conducted when an organization performs work or provides a service using an on-line environment.
- Remote audits refer to using technology to gather information and to interview an auditee when “face-to-face” methods are not possible or desired.
- A virtual audit follows the standard audit process while using technology to verify objective evidence.
- Appropriate technology requirements for virtual audits can include:
  - Ensuring the audit team is using agreed remote access protocols
  - Verifying the system(s) to be used prior to the audit to prevent any technical issues
  - Ensuring contingency plans are known regarding potential interruption of access including provision for any extra audit time needed

Auditing Virtual Activities and Locations

- When planning a virtual audit, the auditor should consider:
  - Risks associated with virtual or remote audits
  - Using floor plans/diagrams of remote locations for reference or mapping of electronic information
  - Prevention of background noise disruptions and interruptions
  - Asking for permission in advance to take photos, videos or screen shots of documents, considering confidentiality and security matters
  - Ensuring confidentiality and privacy during audit breaks e.g. by muting microphones, pausing cameras
  - Limitations of non-verbal communication in virtual settings focusing instead on the type of questions to use in finding objective evidence

Auditing Virtual Activities and Locations

- For any virtual audit activities:
  - Ensure the audit team is using agreed remote access protocols
  - If taking photos or copies of any document, ask for permission in advance and consider confidentiality and security matters including any video recording
  - If an incident occurs during the remote access, the audit team leader should review the situation with the auditee and the audit client to reach agreement on whether the audit should be continued
  - Use floor plans/diagrams of the remote location for reference
  - Maintain respect for privacy during audit breaks

Audit Sampling

- In the context of auditing, our goal is to select an appropriate sample for auditors to be confident that the audit objectives will be achieved.
- Risks may be associated with the sampling methods used and variability within the population of information.
  - Samples may not be representative of the population from which they are selected, thus the auditor's conclusion may be biased and be different from that which would be reached if the whole population was examined.
  - There may be other risks depending on the variability within the population to be sampled and the method chosen.
- Sampling should be carefully planned, considering the objectives of sampling, extent and composition of the population to be sampled, sampling methods, and sample sizes.
- ISO 19011 discusses two fundamental means of sampling — judgment-based and statistical-based.

Judgment-Based Sampling

- Judgment-based sampling relies on the knowledge, skills and experiences of the audit team; the risk is that there can be no statistical estimate of sampling uncertainty.
- Judgment-based sampling should consider:
  - Previous audit experience within the audit scope
  - Complexity of requirements (including statutory and legal requirements)
  - Complexity and interaction of the organization's processes and management system elements
  - Changes in technology, human factor or management system
  - Key risk areas
  - Areas of improvement
  - Output from monitoring of management systems

A drawback to judgment-based sampling is that there can be no statistical estimate of the effect of uncertainty in the audit findings and conclusions

Statistical-Based Sampling

- Statistical sampling should be based on the audit objectives and known characteristics of the population to be sampled.
- Auditors should use sound statistical techniques for sampling, and consider the use of attribute or variable-based sampling as appropriate.
  - Attribute-based sampling is used when there are only two possible sample outcomes (e.g., correct/incorrect, pass/fail)
  - Variable-based sampling is used when the sample outcomes occur in a continuous range (e.g., occurrence of food safety incidents, number of security breaches)
- The level of sampling risk to be accepted should be considered (e.g., acceptable confidence levels).
- The sampling plan, criteria and methods used should be documented as part of the audit record.

Statistical-Based Sampling

- Elements that can affect the audit sampling plan include:
  - Context, size, nature and complexity of the organization
  - Number of competent auditors
  - Frequency of audits
  - Time of individual audit
  - Any externally required confidence levels
  - Occurrence of undesirable and/or unexpected events

Audit Sampling

- Factors to consider when choosing samples:
  - **Relevance:** do samples in fact provide appropriate evidence?
  - **Representative:** are the samples representative of current process methods?
  - **Range:** do the samples represent the full range of conditions that exist?

Audit Tip – Remember not to make audit samples too big.

Don't Nit Pick!

Audit Sampling

- **Benefits of Sampling:**
  - Allows auditor to focus on processes and their effectiveness
  - Allows for better time management

- **Risks of Sampling:**
  - Sampling uncertainty
  - Sample may not be representative if not selected carefully

Contact the Auditee

- Confirm communication channels with the auditee's representatives
- Confirm authority to audit
- Provide relevant information on audit objectives, scope, criteria, methods, and audit team composition, including any technical experts
- Request access to relevant information for planning, including information on risks and opportunities the organization has identified and how they are addressed
- Determine applicable statutory/regulatory requirements and other requirements relevant to the activities, processes, products and services of the auditee
- Confirm agreement with auditee regarding disclosure and treatment of confidential information
- Make arrangements for the audit including the schedule
- Determine any location-specific arrangements for access, health and safety, security, confidentiality, etc.
- Agree on observers and need for guides or interpreters
- Determine any areas of interest, concern or risks to the auditee
- Resolve issues regarding audit team composition with the auditee or audit client

Determining the Feasibility of the Audit

- Feasibility is determined in order to provide reasonable confidence that the audit objectives can be achieved.
- Feasibility should be determined by considering:
  - Availability of sufficient and appropriate information
  - Cooperation of the auditee
  - Adequate time and resources for conducting the audit
- Where the audit is not feasible, an alternative should be proposed.

DOCUMENT AND DATA ANALYSIS

Stage 1 Audit

Document and Data Analysis

- Stage 1 Audit includes the following:
  - Evaluate Customer Focus and Performance
  - Conduct Document Review
  - Identify Audit Risks and Feasibility
  - Finalize Audit Plans
  - Prepare Work Documents
    - Turtle Diagrams
    - Auditor Checklists

Stage I Documents (for 3rd Party)

Following the IATF Rules requirements will ensure that all internal audit expectations are complete. The following documents need to be prepared before the Stage 1:

a) Description of the remote location and support they provide

b) Description of processes showing the sequence and interactions, including the identification of remote supporting functions and outsourced processes

c) Key indicators of performance trends for previous twelve months, minimum

d) Evidence that all requirements of IATF 16949 are addressed by the processes

e) Quality manual, including the interactions with support functions on-site or remote

f) Evidence of one full cycle of internal audits to IATF 16949 followed by a management review

g) List of qualified internal auditors and the criteria for qualification

h) List of automotive customers and their customer-specific requirements, if any

i) Customer complaint summary and responses, scorecards and special status, if applicable

Review Performance

- Obtain evidence of system and/or process performance by:
  - Studying customer scorecards and customer quality history
  - Examining historic performance and previous problems
  - Identifying current quality, product and service requirements
  - Examining past audits

This review will identify poorly performing indicators directly affecting the customer or the organization. Note: IATF Rules document suggests that "critical areas to be prioritized based upon risk to the customer, performance trends, and criticality of process."

Identifying Suspect Processes — Risk-Based Auditing

- Identify poorly performing customer and or internal metrics

- Identify poorly performing related processes

Prioritize the audit by ensuring that processes at risk are identified and targeted in the audit plan.
Other targets are Customer Oriented Processes since they affect the customer.

Planning for Auditing CSRs

- Study the matrix provided in the quality manual to determine where the CSRs are covered in the QMS documentation
  - Identify the related process
- Sample enough CSRs to ensure that all key customers and less important CSRs are covered
- Include the processes in the audit plan without indicating you are sampling CSRs
- Per IATF Rules, each onsite audit must assess and evaluate plans that are used to ensure key customer performance objectives/targets are met and the corrective action plans where the objectives are not met
  - A major nonconformity must be issued if no corrective action plan is in place, if the plan is not implemented in a timely manner, and/or if the completed actions are not effectively implemented

Review of Documented Information

- The relevant management system documented information should be reviewed in order to:
  - Understand the auditee's operations and to prepare audit activities and applicable audit work documents
  - establish an overview of the extent of the documented information to determine possible conformity to the audit criteria and detect possible areas of concern, such as deficiencies, omissions or conflicts
- Should include, but not be limited to management system documents and records, previous audit reports
- Should take into account the context of the auditee's organization, such as its size, nature and complexity, related risks and opportunities, and the audit scope, criteria and objectives

Review of Documented Information

- Conducting a Document Review:
  - Determine the degree of conformity of the system as documented
  - Identify processes of possible concern
- The following documentation may be needed:
  - Quality Manual with process list, key process map, organization chart
  - Internal Audit Reports
  - Management Review Agendas and Meeting Minutes
  - Internal and Customer Scorecards
  - Lists of Context Issues (4.1), Interested Party Needs (4.2), Risks and Opportunities (6.1), Regulatory Requirements (5.1.2, 8.2.2)
- Auditors should study the process documentation to determine the feasibility of conducting the onsite audit based on any omissions or gaps to the audit criteria.

Sectors can specify additional documentation to be reviewed in Stage 1

Auditing Breakout Exercise 2

Documentation Review

PREPARE WORK DOCUMENTS

The Audit Plan

- The audit team leader prepares an audit plan with input from the audit team.
- An audit plan…
  - Is a description of the activities for an audit
  - Facilitates scheduling and coordination of activities
  - Is sufficiently flexible to permit changes when they become necessary
  - Extent of the audit plan is based on the complexity of the audit

Preparing the Audit Plan

- The audit plan should cover the following:
  - Audit objectives
  - Audit criteria and reference documents
  - Audit scope
  - Dates and places where audit activities are to be conducted
  - Expected time and duration of audit activities
    - including meetings with auditee's management, and
    - audit team meetings
  - Audit methods to be used
  - Roles and responsibilities of the audit team members
  - Allocation of resources to critical areas of the audit

Preparing the Audit Plan

- The audit plan could also cover, as appropriate:
  - Identification of the auditee's representative for each process audited
  - Working and reporting language of the audit
  - Logistic arrangements (travel, on-site facilities, etc.) and schedule
  - Actions to address risks to achieving audit objectives and opportunities
  - Matters related to confidentiality and information security
  - Any follow-up actions
- Per IATF Rules, the audit plan must include a minimum of one hour on-site, prior to the opening meeting, for verification of data and changes to the current customer and internal performance data, including the review of current online customer reports and/or customer scorecards.
  - The audit plan must be adjusted based on any new verified information collected.
- The plan should be reviewed and accepted by the auditee and the audit program manager before the audit activities begin.

Preparing the Audit Plan

- Look for and prioritize poorly performing and suspect processes
- Opening meeting, a plant tour and closing meeting are recommended
- In System Audits, management commitment, business planning and management review should come first
  - Expect to have top management in the audit. Is top management accountable for the QMS?
- Individual audit schedule **(Audit Plan Schedule)** is organized following the organization's processes **NOT** by ISO/IATF clauses
- Sample customer CSRs and regulatory requirements to see if the processes for determining and addressing them are effective
- Evidence of conformance to customer and regulatory requirements should be verified and may require assessment of a subject matter expert
- An appropriate amount of time should be used for auditor meetings or report writing
- Make sure the audit plan covers all shifts

Audit Plan

Date and Time – Day 1		
8:00am	Opening Meeting	Top Managers and Management
8:30am	Plant Tour	
9:00am	Customer Focus (5.1.2)	Marketing Manager
11:00am	Documented Information (7.5)	Quality Department
12:00pm	Lunch	

Process-Driven Audit Plan

Date and Time – Day 1		
8:00am	Opening Meeting	Top Managers and Management
8:30am	Plant Tour	
9:00am	Customer Satisfaction and Performance Data Review*	Top Management
11:00am	Operational Review*	Top Management
12:00pm	Lunch	

*** The processes on the audit plan have to match the processes in the Process Map**

Example
Audit Schedule

OMNEX
315 E. Eisenhower, Suite 214
Ann Arbor, MI 48108
Phone: (734)761-4940 Fax: (734)761-4966

Organization: ACME Company Date: 1/14 – 1/15

Auditor(s) Name: W.E. Coyote

Audit Plan

Date	Time	Activity	Person(s) Interviewed
1/14	8:00	Opening Meeting	
	8:30	Plant Tour	
	9:30	Bid Tender Process	
	12:00	Lunch	
	12:45	Design and Development Process	
	2:15	Order/Request Process	
	3:30	Delivery Process	
	5:00	Adjourn	
1/15	8:00	Review Meeting with ACME	
	8:30	Production Processes	
	12:00	Lunch	
	12:45	Warranty Service Process	
	3:15	Payment Process	
	3:45	Write-up Nonconformities	
	4:30	Close Meeting with ACME	
	5:00	Adjourn	

Clause	Processes Audited			
	Leadership & Management	New Product Development	Operations	Support
4.1 Understanding the organization and its context	X			
4.2 Needs and expectations of interested parties	X			
4.3 Determining the scope of the QMS	X			
4.4 Quality management system and its processes				X
5.1.1 Leadership - General	X			
5.1.2 Customer focus				X
5.2 Policy	X			
5.3 Organizational roles, responsibilities and authorities				X
6.1 Actions to address risks and opportunities		X		X
6.2 Quality objectives and planning	X			
6.3 Planning of changes		X	X	
7.1.1 Resources - General	X			
7.1.2 People				X
7.1.3 Infrastructure			X	
7.1.4 Environment for the operation of processes			X	
7.1.5 Monitoring and measuring resources				X
7.1.6 Organizational knowledge				X
7.2 Competence				X
7.3 Awareness				X
7.4 Communication	X			
7.5 Documented information				X
8.1 Operational planning and control			X	
8.2 Requirements for products and services		X		
8.2.1 Customer communication				X
8.2.2 Determining product/service requirements		X		X
8.2.3 Review of requirements related to products and services				X
8.2.4 Changes to requirements for products and services		X	X	
8.3 Design and Development		X		
8.4 Control of externally provided processes, products/services				X
8.5.1 Control of production and service provision			X	
8.5.2 Identification and traceability			X	
8.5.3 Property belonging to customers or external providers				X
8.5.4 Preservation			X	
8.5.5 Post-delivery activities				X
8.5.6 Control of changes including design 8.3.6		X	X	
8.6 Release of products and services		X		
8.7 Control of nonconforming outputs			X	
9.1.1 Monitoring and measurement - General			X	X
9.1.2 Customer satisfaction	X			X
9.1.3 Analysis and evaluation	X			
9.2 Internal audit				X
9.3 Management review	X			
10.1 Improvement - General			X	X
10.2 Nonconformity and corrective action			X	X
10.3 Continual improvement			X	X

Audit Plan Matrix

- The audit plan matrix is used in the beginning for planning purposes and ensures that the system includes all clauses of the standard and that it covers all organizational areas.
- After the audit, this document can also be used as objective evidence to show that the audit met all objectives.

Support includes functions such as IT, Purchasing, Sales, Marketing, Customer Support

Audit Checklists and Conformance Audits

- Audit checklists should be a fresh list of facts to be verified, not standard questions
- Checklists should identify specific areas of concern
- Checklists can identify specific evidence that needs to be gathered
- Checklists act as reminders to ensure that all audit objectives have been met
- The use of checklists and forms should not restrict audit activities
- Audit Checklists are used primarily with conformance audits

Audit Checklists

- **Benefits of Checklists:**
  - Keep audit objective clear
  - Evidence of planning
  - Maintain audit pace and continuity
  - Reduce auditor bias
  - Reduce work load during audit

- **Risks of Checklists:**
  - May restrict auditor versatility and scope (too narrow)
  - Auditor might focus too much on “clauses” vs. “process approach”

Auditing Breakout Exercise 3

Creating an Audit Plan

Chapter 6: Audit Planning and Preparation — What We Covered

Learning Objectives

You should now be able to:

- Describe the risk-based approach to auditing
- Identify the steps in preparing an audit
- Write objective and scope statements
- Describe the elements that should be considered when determining the audit resource requirements
- Explain the purpose of a Stage 1 audit
- Create an audit plan
- Describe the benefits and risks of checklists

Chapter Agenda

- Risk-based Approach to Auditing
- Audit Objectives, Scope and Criteria
- **Auditing Breakout Exercise 1**
- Determine Resources
- Contact Auditee
- Document and Data Analysis – Stage 1 Audit
- **Auditing Breakout Exercise 2**
- Prepare Work Documents
- **Auditing Breakout Exercise 3**

Chapter 7

Performing the Audit

Chapter 7: Performing the Audit — What We Will Cover

Learning Objectives

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

- List items that should be included in an opening meeting
- Describe the purpose of meeting with Top Management
- Explain methods to gather evidence
- Describe the things to do and not do for interviews
- Describe how to prevent negative reactions to audits

Chapter Agenda

- Opening Meeting
- Facility Tour
- Meet with Top Management
- Gather Evidence
- Conducting Interviews
- Negative Reactions to Audits
- **Auditing Breakout Exercise 4**

Performing the Audit

- There are six in conducting audit activities
  1. Opening Meeting
  2. Conduct Facility Tour (optional)
  3. Meet with Top Management
  4. Gather Objective Evidence
  5. Prepare Nonconformity Statements
  6. Closing Meeting

Six Steps of Conducting an Audit

1. **Initiate the Audit**
2. **Prepare Audit Activities**
3. **Conduct Audit Activities**
4. **Prepare Audit Report**
5. **Complete Audit**
6. **Conduct Audit Follow-up**

- The first four are covered in this chapter

Communication During the Audit

- The audit team should meet periodically to exchange information.
- The audit team leader should periodically communicate with the auditee's management.
- Evidence that suggests a significant risk should be reported to the auditee immediately.
- Changes to the audit scope should be reviewed with and approved by the audit client and the auditee.

OPENING MEETING

Opening Meeting

Conducting the Opening Meeting

- An opening meeting should be held with the auditee's management and the process owners of the functions to be audited.
- The purpose of an opening meeting is to:
  - Introduce the audit team and their roles and other participants such as observers, guides and interpreters
  - Confirm the audit plan and ensure all planned activities can be performed
  - Provide a short summary of how the audit activities will be undertaken
  - Establish communication channels during the audit
  - Provide an opportunity for the auditee to ask questions

Opening Meeting

Opening Meeting Checklist

- Introduce audit team and auditee/audit client attendees and their roles
- Confirm attendance
- Describe the audit process **(Process Approach Audit)**
- Review objectives, scope and criteria
- Summary of methods and procedures used for audit
  - Notes
  - Sampling
  - Small groups
  - Notification of findings
  - Questions for the lead auditor

Opening Meeting

Opening Meeting Checklist *(cont'd)*

- Confirm resources and facilities needed (guides, etc.)
- Confirm quality manual status (if applicable)
- Confidentiality
- Confirm time and date of closing meeting
- Confirm relevant safety, emergency and security procedures
- Appeals process (only for 3rd party audits)

FACILITY TOUR

Facility Tour

- Normally only conducted for 2nd or 3rd party audits:
  - A quick tour to familiarize the auditor with the layout and manufacturing processes of the organization
  - Do not let the tour drag on; take notes for reference
  - Stay with your guide and follow safety requirements
  - The tour is not an interviewing activity
  - Observe activities and the flow of materials
  - Start at receiving and walk the process through shipping

Visiting the Auditee's Location

- To minimize auditors interfering with the auditee's processes and to ensure the health and safety of the audit team during a visit, the following should be considered when planning a visit:
  - Ensure permission and access to those parts of the auditee's location, to be visited in accordance with the audit scope
  - Provide adequate information to auditors on security, health (e.g., quarantine, vaccinations), occupational health and safety, cultural norms and working hours
  - Confirm if any required personal protective equipment (PPE) will be available
  - Except for unscheduled ad-hoc audits, ensure personnel being visited will be informed about the audit objectives and scope
  - Confirm the use of any mobile devices and cameras including policy on the recording of information, e.g., photographs, screen shot copies or photocopies, taking into consideration security and confidentiality matters

Taking notes is a standard and expected practice in auditing, it is not necessary to obtain permission to take notes

Visiting the Auditee's Location

- To minimize auditors interfering with the auditee's processes and to ensure the health and safety of the audit team during a visit, the following should also be considered:
  - Avoid any unnecessary disturbance of the operational processes
  - Use of any PPE properly
  - Ensure emergency procedures are communicated
  - Schedule communication to minimize disruption
  - Use an appropriate size of the audit in order to avoid interference with the operational processes as far as practicable
  - Do not touch or manipulate any equipment, unless explicitly permitted
  - If an incident occurs during the on-site visit, the audit team leader should review the situation with the auditee and, if necessary, with the audit client and decide how to proceed, e.g., terminate, reschedule or continue
  - If taking copies of documents in any media, ask for permission in advance and consider confidentiality and security matters
  - Avoid collecting personal information unless required by the audit objectives or audit criteria

MEET WITH TOP MANAGEMENT

Top Management

- All audits should begin with a Top Management interview
  - Review the following:
    - Involvement in decision-making regarding the management system
    - Management Commitment and Accountability
    - Performance Measurements – Customer Focus
    - Policy, Goals and Objectives
    - Management Reviews
    - Identified Issues
    - Corrective Actions Taken – Status of Actions

Auditing Leadership and Commitment

- Many ISO standards have increased requirements for top management which include demonstrating commitment by taking accountability for the effectiveness of the management system and fulfilling a number of responsibilities, some of which cannot be delegated.
- Auditors should obtain objective evidence of the degree to which top management is involved in decision-making related to the management system and how they meet the specified requirements.
  - Examples include reviewing process results, policies, objectives, available resources, communications and by interviewing staff.
- Auditors should also interview top management to confirm they have an adequate understanding of the relevant issues and to ensure the management system achieves its intended results.
- Auditors should audit leadership and commitment at various levels of management, as appropriate.

Auditing Top Management
IAF Guidance

- It is important to change the focus of attention from just the quality manager to the top management of the organization.
- Top management activities are processes so audit them accordingly.
- When planning, identify top management processes, and
  - understand the organization and its management structure by reviewing information, e. g. org charts, annual reports, business plans, company profiles;
  - make time on the audit plan to interview top management;
  - understand the organization culture and adjust the audit plan accordingly;
  - maintain a professional appearance considering any dress code;
  - plan the timing of interviews to ensure convenience and punctuality.

- Assign an auditor with appropriate auditing and decision-making experience to interview top management.

Auditing Top Management
IAF Guidance

- When conducting the interview, ask relevant questions that:
  - obtains evidence of top management commitment to quality and its relevance to the organization's overall objectives and management system;
  - establish evidence of conformity to the specified requirements;
  - give special consideration to the allocation of the responsibilities and authorities for what was the “management representative” position.
- The audit team should confirm the answers received from top management including:
  - the availability and relevance of policies and objectives;
  - the establishment of linkage between the policies and objectives;
  - evidence these policies and objectives are effective and understood;
  - determining if the policies and objectives are appropriate for continual improvement of the management system and customer satisfaction;
  - confirming top management are involved in management reviews.
- Additional interviewing and gathering of evidence may be needed to provide the necessary corroboration.

GATHER OBJECTIVE EVIDENCE

Objective Evidence

- Three fundamental questions to be answered by the auditor in an audit:
  - Does the system meet the intent of the requirements?
  - Is the system effectively implemented?
  - Is the system effective in practice?

Auditing Organizational Processes

An auditor is expected to perform the following while conducting an audit of organizational processes:

- Demonstrate the use of the process approach audit
- Use the audit plan and the organization's defined processes, including sequence and interaction
- Focus on the performance of suspect processes including customer oriented processes
- Audit processes to determine if each is capable of meeting the key process indicators and customer-specific requirements
- Ensure that the customer-specific requirements are identified, addressed and maintained in the QMS
- Conduct interviews with those that are involved with the process at their location
- Document both conformities and nonconformities – the information should be clear enough for an independent review by a third party if necessary

Conducting a Process Approach Audit

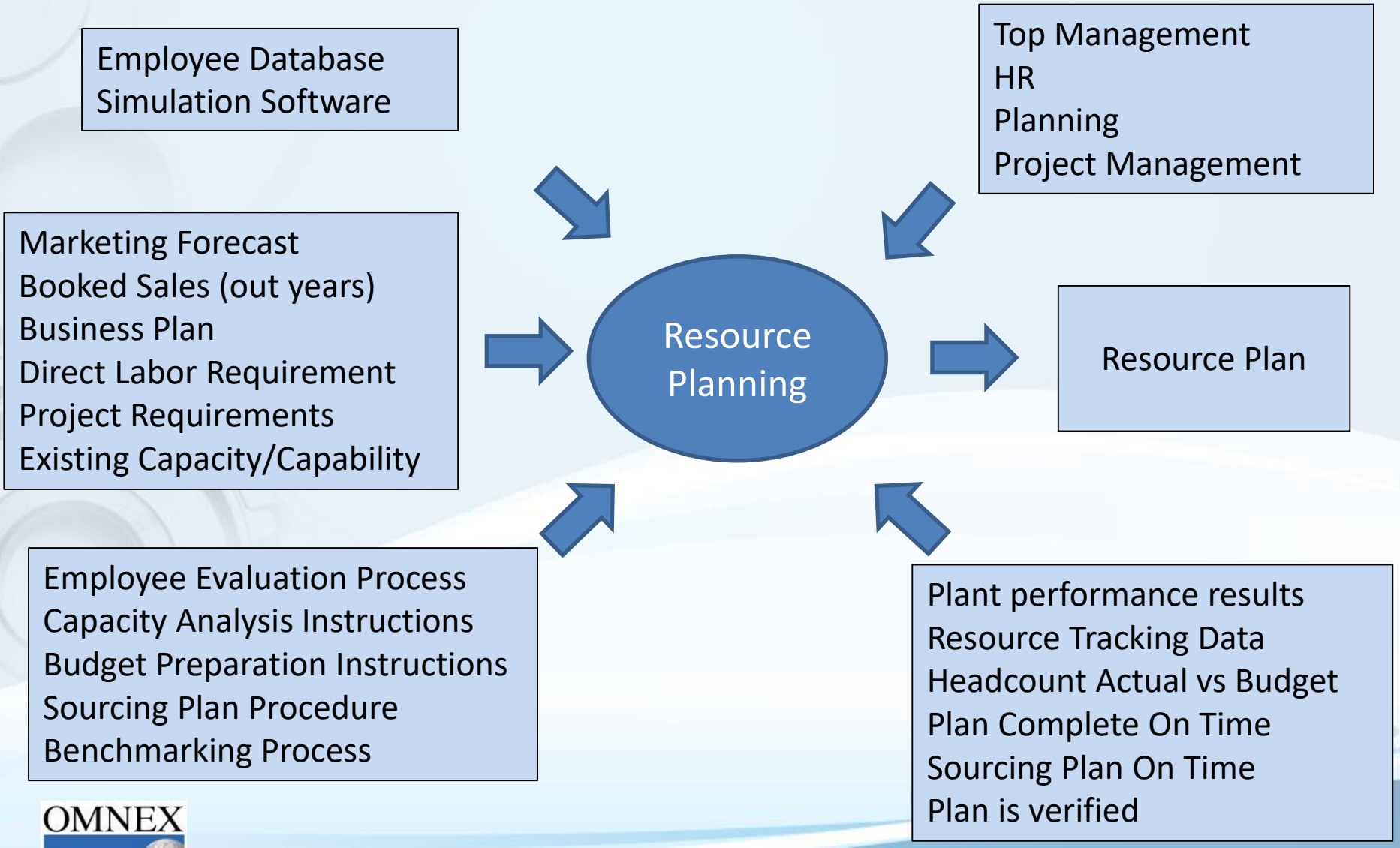
- The process approach audit is meant to **add value:**
  - It should start with a performance analysis of customer data that identifies areas of weakness or areas for improvement noted during the Stage 1 audit.
  - It should end with the identification of variations (**nonconformities**) in the process that, if eliminated, would lead to process improvement.

Conducting a Process Approach Audit

The following steps are used while conducting a process approach audit:

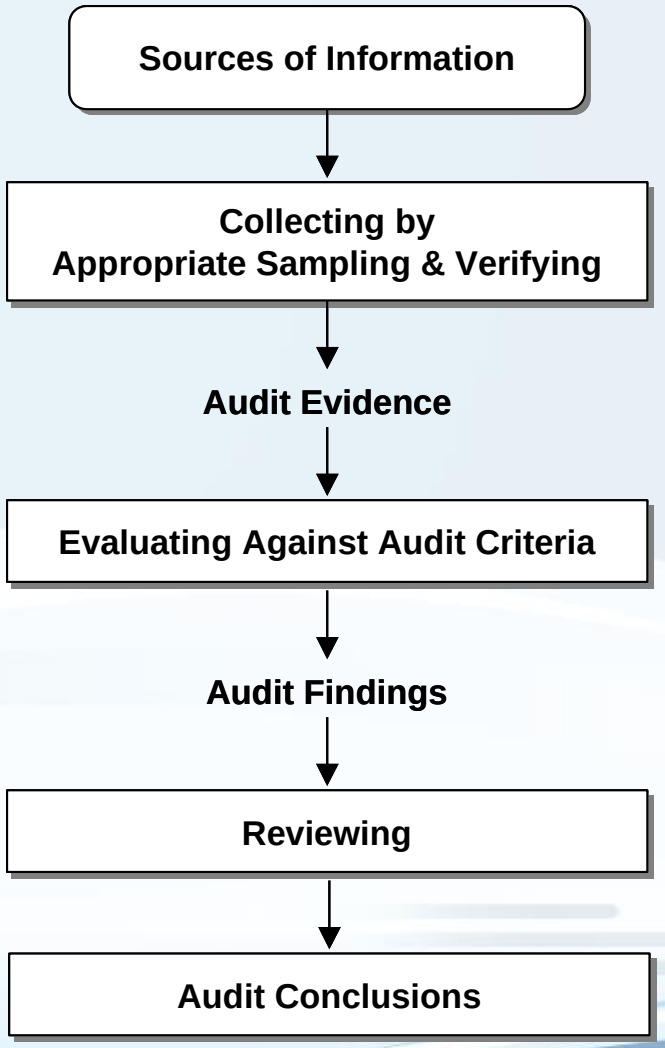
- Identify and probe process weakness:
  - Identify what is expected and the indicators and objectives of the actual performance.
  - How is the performance being improved?
  - How was the process planned?
- Follow the process using their documented flow or procedure:
  - Is the process being carried out as designed? Are the methods being applied?
  - Sample the process as applicable where the work is performed (e.g., engineering, shop floor, or workstation).
- Refer to process analysis (Turtle Diagram) as needed to identify sources of variation in support processes.

Turtle Example: Resource Planning



Collecting and Verifying Information

- During the audit, information relevant to the audit objectives, scope and criteria, and interfaces between functions, activities and processes should be collected by appropriate sampling and should be ***verified***.
  - Only information that is verifiable may be audit evidence.
  - Audit evidence should be recorded.
- The audit evidence is based on samples of the available information.



Guidance: What is Verification?

- As defined in ISO 9000, verification is confirmation through the provision of objective evidence that specified requirements have been fulfilled.
  - The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Objective Evidence

- Checked against:
  - What the management system standard requires
  - What the quality manual, procedures or working instructions state
  - What a department manager or authorized person states to be approved practice
  - Requirement of a contract, recognized standard, specification, statutory regulation, or code of practice
  - Any specified requirement

Objective Evidence

- Objective evidence can be:
  - Something you see/observe
  - Something you are told by a member of management is company policy or practice
  - Something you are told by an operator, describing their own understanding of operating procedures or work practices
- Objective evidence includes:
  - Identification of documents or products
  - Where the evidence was observed
  - Who was present during the observation

Objective Evidence

- Objective evidence examples:
  - Name and position of person interviewed
  - Statement made by person interviewed
  - Identity and revision status of documents
  - Identity and serial number of equipment or components
  - Range of samples examined
  - Location
  - Time and place of an event
  - Description of environmental conditions

Recording Evidence

- Record evidence of conformity or nonconformity
- Evaluate the document's record-pertinent data and return the document
- There is no need to copy every document
- Evidence can be hand-written and scanned electronically for records
- Objective evidence must demonstrate requirements are being met, such as, is it:
  - Complete, e.g., all expected content is provided
  - Correct, e.g., content aligns with reliable sources such as standards
  - Consistent within itself and with related documents
  - Current or up-to-date

Generating Audit Findings

- Audit evidence should be evaluated against audit criteria to generate the audit findings.
- The audit team should meet as necessary to review the audit findings.
- Conformity with audit criteria should be summarized to indicate locations, functions or processes that were audited.
- Individual audit findings of conformity and their supporting evidence should also be recorded.
- Nonconformities and their supporting evidence should be recorded.

CONDUCTING INTERVIEWS

Interviews

- Maintaining Control of an Audit:
  - Be aware (**BEWARE**) of time
  - Stick to the audit plan (don't allow diversions!)
  - Take a sample and find objective evidence for observations and then move on
  - Document objective evidence **BOTH** positive and negative

Interviews

- Interview individuals from appropriate levels and functions performing activities or tasks within the audit scope
- Interview during normal working hours and at the auditee's workplace
- Try to put the auditee at ease prior to and during the interview
- Explain the reason for the interview and any note taking
- Interviews may be initiated by asking individuals to describe their work
- Use a process approach, e.g., start with open questions probing each element of their process, use closed questions to finish, avoid leading questions as they bias the answer
- Focus in virtual auditing should be on the type of questions to use due to the limited non-verbal communication available
- Summarize the results from the interview and thank the auditee

Interviews

- **Do:**
  - Introduce yourself and others
  - Interview the person doing the job
  - Use your knowledge and experience
  - Make frequent reference to your checklist and audit plan
  - Make notes as you go; the more the better
  - Be calm, courteous and in firm control at all times
  - Seek facts, not inference
  - Select your samples carefully
  - Inform the auditee of a nonconformity finding promptly
  - Be fair and honest and if you are wrong, admit it

Interviews

- **Don't:**
  - Be late
  - Lecture or talk down to the auditee
  - Give recommendations
  - Criticize management
  - Make comparisons with other people or departments
  - Be longwinded—keep questions short and direct
  - Be afraid to say you don't understand—seek clarification
  - Nit pick

Questioning

- **Invitation to Talk**
  Open-ended question most often used to initiate the interview by asking the auditee to describe their work.
  - "Would you please explain to me what happens here?"
  - "What do you do if someone is absent?"

- **Direct Questions**
  Ask a direct question to have the auditee explain the process.
  - "What do you do next?"
  - "How are these reports distributed?"
  - "Who approves the issue of these licenses?"
  - "When (or how frequently) is this plan reviewed?"
  - "Where are these items stored when not in use?"
  - "Why is it done that way?"

Questioning

- **Closed Question**

  Solicits either a “yes” or “no” answer. Used only to confirm information.

  – *“You said that there were only two of you that do this job, is that correct?”*

- **Silent Question**

  The auditor simply asks a question and then waits; this can encourage an additional response.

- **Naïve Question**

  Often asked when the auditor already knows the answer in order to ensure the auditee understand the process. It is important to determine the knowledge of the person doing the job.

Questioning

- **Hypothetical Question**

  A “what-if” question used to identify what happens when the process doesn’t work.

- **Listening**
  - Ask the question
  - Stop talking
  - Listen to all of the answer
  - Seek clarification
  - Make notes
  - Ask another question

Questioning

- **Observing**

  Together with questioning and listening, observing provides the auditor with virtually all the tools necessary to carry out an effective audit.

- **Verifying**

  Before information becomes fact it must be verified as true:

  – Checking the records
  – Observing the activity being carried out

NEGATIVE REACTIONS TO AUDITS

Negative Reactions to Audit

- **Authority**

  The auditee becomes protective of their department.

- **Antagonism**

  Occasionally the auditee can become hostile and aggressive to auditors.

- **Diversionary Tactics**

  Anything which uses up time that was otherwise planned for auditing.

- **Internal Conflicts**

  Sometimes findings turned up in an audit instigate an argument between auditee members of staff.

- **Continual Challenge**

  The auditee has the right to challenge the auditor; however, if the auditor puts up a firm and factual case for the reached conclusion, then the auditee must accept them.

- **Enlisting Help**

  The auditee may purposely lead the auditors to deficient areas if they are having difficulty in getting management to react.

Preventing Negative Reactions

Avoiding difficult audits

- Don’t take it personally
- At the opening of the audit, try to establish a friendly cooperative environment – Don’t be overbearing
- Keep the auditee informed of how the audit is going – inform the auditee of nonconformities as they are identified
- Maintain control without taking control
- Make sure that the nonconformities you write are value added
- Don’t nit pick
- Use proper format for writing nonconformities

Auditing Breakout Exercise 4

Conducting the Audit

Chapter 7: Performing the Audit — What We Covered

Learning Objectives

You should now be able to:

- List items that should be included in an opening meeting
- Describe the purpose of meeting with Top Management
- Explain methods to gather evidence
- Describe the things to do and not do for interviews
- Describe how to prevent negative reactions to audits

Chapter Agenda

- Opening Meeting
- Facility Tour
- Meet with Top Management
- Gather Evidence
- Conducting Interviews
- Negative Reactions to Audits
- **Auditing Breakout Exercise 4**

Chapter 8

Writing Nonconformity Statements

Chapter 8: Writing Nonconformity Statements — What We Will Cover

Learning Objectives

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

- State the flow of activities to reach audit conclusions
- Identify the three parts of a nonconformity statement
- State the difference between major and minor nonconformities

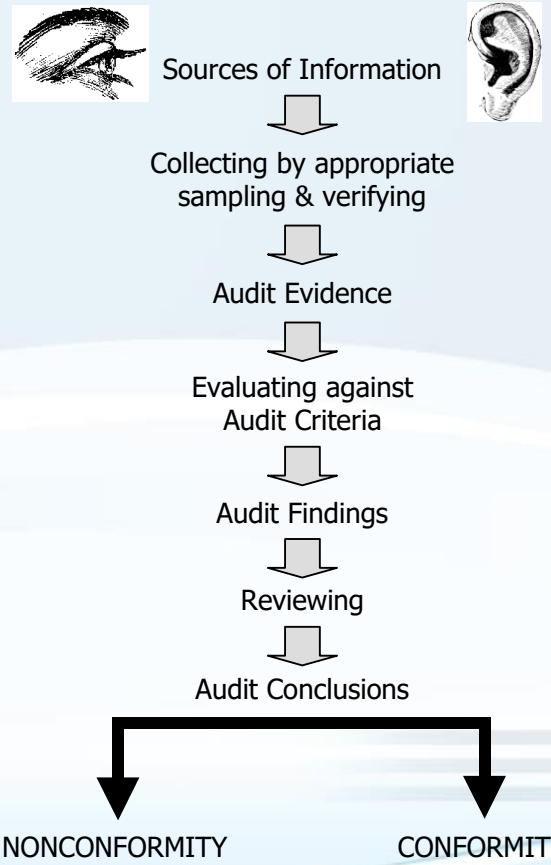
Chapter Agenda

- Audit Findings
- Nonconformity Statements
- Types of Nonconformities
- Review Findings and Conclusions
- **Auditing Breakout Exercise 5**

Audit Findings

ISO 19011 defines nonconformity as "non-fulfillment of a requirement"

- Audit findings are the results of an evaluation of the collected **audit evidence** against **audit criteria.**
- Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.



Generating Audit Findings — Nonconformities

- Nonconformities and their supporting audit evidence, including references to audit criteria, related findings, and a formal declaration of nonconformity should be recorded.
  - Nonconformities may be graded.
  - They should be reviewed with the auditee to obtain acknowledgement that the audit evidence is accurate, and that the nonconformities are understood.
  - Every attempt should be made to resolve any diverging opinions concerning the audit evidence and/or findings, and unresolved points should be recorded.
  - Audit findings can indicate either conformity or nonconformity with audit criteria.
  - When specified by the audit objectives, audit findings can identify an opportunity for improvement.

NONCONFORMITY STATEMENTS

What are Nonconformity Statements?

A nonconformity statement is…

- A record of the evidence on which an auditor bases the conclusions of the audit, so that there is nothing in the conclusions that cannot be substantiated by reading the nonconformity statements.
- Information to both the auditor's own management and the auditee's management concerning the ways in which the company's management system fails to meet requirements.
- A starting point for corrective action by the auditee to resolve the nonconformity.

Reasons for a Nonconformity

- When evaluating any clauses of the standard, you must evaluate all three situations:
  - Intent
  - Effective implementation
  - Effectiveness in practice
- If a breakdown exists in any one of these situations:
  - A nonconformity exists
  - A nonconformity statement must be written

Reasons for a Nonconformity

- **Intent**

  The organization is conforming to a standard practice

- **Effective Implementation**

  The functions are being performed to:

  - Standard practice
  - All employees involved understand the standard practice
  - All employees involved are adhering to the standard practice
  - No deviations from standard practice

- **Effectiveness in Practice**

  Results are consistent with what is expected from the intent and implementation stages:

  - Are results showing improvement?
  - Are changes made if system is not producing desired results?

Nonconformity Statements

It is much better to:

- Verbally communicate the nature of the nonconformity and the evidence for it to the process owner as soon as it is established, and get verbal agreement that the facts are correct and that the observation is accepted.
- Ensure that your notes are adequate before proceeding with the investigation.
- At the end of that part of the audit plan, review the notes and write up all nonconformity statements.
- Review all nonconformities with your audit team and lead auditor prior to writing or reviewing them with the auditee.
- Review observations with the process owner.
- Do not leave the writing of nonconformity statements until the end of the audit since you will then have to write the statements resulting from the final audit session.

Writing Nonconformity Statements

- The nonconformity statement is a criticism of the auditee's management system.
  - No one likes being criticized, so an auditor must expect to be challenged if there are any errors in the nonconformity statement – Facts can be very hard to establish.
- In order to follow a best practices approach, nonconformity statements should be based upon issues related to the system, not the symptom.
  - Major and minor nonconformities must be categorized.

Writing Nonconformity Statements

- First, review all the notes that have been taken then try to express the nonconformity in the following terms:
  - A statement of nonconformity (system level)
  - Reference to the requirement not being met
  - Objective evidence (documents, product, contracts, etc.)
- The purpose of the nonconformity statement is to describe the breakdown of the system and should not be confused with the incident-specific objective evidence.
- It is important to write nonconformities that define the system problem; otherwise, the organization may only address the specific incident instead of the system that is causing the nonconformity.
  - If the statement of nonconformity is expressed in terms of a person or incident, it is objective evidence.

Checking Nonconformity Statements

- **Correct and Complete**

  The nonconformity statement will not be correct and understandable if it omits important evidence or information regarding the nature of the requirement and the way it is being contravened.

- **Clear**

  It is no good stating all the evidence and information if it is not written in a way that can be understood. Always check very carefully what you have actually written, not what you think you have written.

- **Concise**

  Using unnecessary words in your nonconformity statement makes it unclear.

Writing Nonconformity Statements
Example

- **Nonconformity:** The process for quality objectives is not effectively implemented.
- **Requirement:** IATF 16949, clause 6.2.2.1 requires that "*Top management shall ensure quality objectives to meet customer requirements are … established at all relevant functions, processes and levels...*"
- **Objective Evidence:** Quality objectives comparable to the "Delivery" and "Lead-time" objectives in the organization's Business Plan, Rev. B have not been established for the Scheduling and Shipping processes.

Corrective Action Request

Revision B

Part A	Audit Information		
Department/Auditee	Quality Control	Audit Number	101
Activity Audited	Planning	Car Number	DAD-05
Auditor	Bob Roberts	Date Issued	3/15/xx
Auditee		Reference	16949, 6.2.2.1

Part B — Nonconformity

Nonconformity:
The process for quality objectives is not effectively implemented.

Requirement:
IATF 16949, clause 6.2.2.1 requires that "*Top management shall ensure quality objectives to meet customer requirements are … established at all relevant functions, processes and levels....*"

Objective Evidence:
Quality objectives comparable to the "Delivery" and "Lead-time" objectives in the organization's Business Plan, Rev. B have not been established for the Scheduling and Shipping processes.

Auditor	Date	Department Representative	Date

Part C — Corrective/Preventive Action

Immediate Action

Preventive Action

Root Cause

Corrective Action

Auditor	Date	Department Representative	Date

Part D — Verification of Corrective Action

Follow-up Details

TYPES OF NONCONFORMITIES

Types of Nonconformities

Major Nonconformity

(per IATF Rules)

- The absence or total breakdown of a system to meet a requirement.
  - A number of minor nonconformities against one process or related processes that may cause a complete system breakdown.
- Absence of an entire clause, sub-clause or process.
- Any nonconformity that would result in the probable shipment of a nonconforming product or a condition that may result in the failure or materially reduce the usability of the products or services for their intended purpose.
- A nonconformity that judgment and experience indicate is likely either to result in the failure of the management system or to materially reduce its ability to assure controlled processes and products.

The IATF Rules go beyond ISO 17021:2015 which defines a major nonconformity as "nonconformity that affects the capability of the management system to achieve the intended results"

Types of Nonconformities

Minor Nonconformity

(per IATF Rules)

- Failure to comply with a requirement, which – based on judgment and experience – is not likely to result in the failure of the management system or reduce its ability to assure controlled processes or products:
  - A failure in some part of the organization's documented management system relative to the standard.
  - A single observed lapse in following one item of an organization's management system.

This differs from ISO 17021:2015 which defines a minor nonconformity as "nonconformity that does not affect the capability of the management system to achieve the intended results"

REVIEW FINDINGS AND CONCLUSIONS

Reviewing Findings

- Time should be allowed within the audit program to review findings.

- It is good practice to do this at the end of each day while the information is fresh in the mind of the auditors; it also enables the auditor to:
  - Confirm that all audit objectives have been met
  - Detect any errors, omissions, or misunderstandings and, if time permits, resolve them
  - Avoid having to sift through large amounts of recorded information at a time

Nonconformity Matrix (optional)

- One way to study nonconformities is through the nonconformity matrix by looking for patterns.
  - If you see a number of minor nonconformities for one clause in several departments, then it may be identified as a major nonconformity.

Clause	Leadership	Engineering	Stamping	Assembly	Shipping Receiving	Purchasing	Others
4.1 Understanding the organization and conte							
4.2 Needs and expectations of interested part							
4.3 Determining the scope of the QMS							
4.4 Quality management system and its processes							
5.1.1 Leadership - General							
5.1.2 Customer focus							1
5.2 Policy	1						
5.3 Organizational roles, responsibilities, authorities							
6.1 Actions to address risks and opportunities							
6.2 Quality objectives and planning							
6.3 Planning of changes		2					
7.1.1 Resources - General							
7.1.2 People		1	1	1		1	3
7.1.3 Infrastructure							
7.1.4 Environment for the operation of processes							
7.1.5 Monitoring and measuring resources							
7.1.6 Organizational knowledge							1
7.2 Competence							
7.3 Awareness	1						
7.4 Communication	1						
7.5 Documented information			1	1		1	
8.1 Operational planning and control							
8.2 Requirements for products and services							
8.2.1 Customer communication							
8.2.2 Determining product/service requirements		2					
8.2.3 Review of requirements							
8.2.4 Changes to requirements		3					
8.3 Design and Development		1					
8.4 Control of externally provided products						2	
8.5.1 Control of production and service provision							
8.5.2 Identification and traceability							
8.5.3 Property belonging to external providers				1			
8.5.4 Preservation				1			
8.5.5 Post-delivery activities							2
8.5.6 Control of changes including design 8.3.6		2	2				
8.6 Release of products and services		1					
8.7 Control of nonconforming outputs							1
9.1.1 Monitoring and measurement - General				1			
9.1.2 Customer satisfaction	1						
9.1.3 Analysis and evaluation							1
9.2 Internal audit			1				1
9.3 Management review	2						
10.1 Improvement - General							
10.2 Nonconformity and corrective action				1			
10.3 Continual improvement							

- Example -

Preparing Audit Conclusions

- The audit team should confer prior to the closing meeting to:
  - Review the audit findings – and any other appropriate information collected during the audit – against the audit objectives
  - Agree on the audit conclusions, taking into account the uncertainty inherent in the audit process
  - Prepare opportunities for improvement, if specified by the audit objectives
  - Discuss audit follow-up, if included in the audit plan

Auditing Breakout Exercise 5

Writing Nonconformity Statements

Chapter 8: Writing Nonconformity Statements — What We Covered

Learning Objectives

You should now be able to:

- State the flow of activities to reach audit conclusions
- Identify the three parts of a nonconformity statement
- State the difference between major and minor nonconformities

Chapter Agenda

- Audit Findings
- Nonconformity Statements
- Types of Nonconformities
- Review Findings and Conclusions
- **Auditing Breakout Exercise 5**

Chapter 9

Closing Meeting

Chapter 9: Closing Meeting — What We Will Cover

Learning Objectives

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

- Describe the purpose of a closing meeting
- List the elements covered in a closing meeting
- Explain how to prevent a problematic closing meeting
- Write a summary statement
- Explain concerns about giving recommendations

Chapter Agenda

- Closing Meeting
- Summary Statement
- Recommendations

Closing Meeting Purpose

- A closing meeting, chaired by the audit team leader, should be held to present the audit findings and to agree on the timeframe to present a corrective and preventive action plan.
- Any diverging opinions regarding the audit findings and/or conclusions between the audit team and the auditee should be discussed and, if possible, resolved.
- If specified by the audit objectives, opportunities for improvements may be presented, but it must be emphasized that these recommendations are non-binding.

Closing Meeting Checklist

- Attendance list and statement of thanks
- Summary Scope, objectives and criteria
- Significance of audit sample and possibility that it may not be fully representative of overall process effectiveness
- Audit summary (see next slide for more detail)
  - Nonconformity statements and opportunities for improvement, if applicable
  - Clarification of nonconformity statements and summary
- How audit findings should be addressed and possible consequences for not addressing them
- Confidentiality
- Follow-up activities
- Appeals process (only for 3rd party audits)
- Close

Summary Statement

- Lead auditor provides a verbal summary at the closing meeting:
  - Positive statements about the organization audited
  - Systems working particularly well
  - Summary of nonconformities
  - Systems not working well
  - Positive statement to offer encouragement

Giving Recommendations

- Do you know all the facts?
- You may be undermining managers' responsibilities and authority
- Who will carry the costs?
- What if the advice is wrong?

3rd party auditors cannot provide recommendations

Problematic Closing Meeting

- **Senior management is not present at the Closing Meeting**
  - Senior Management should be at the closing meeting.
  - If they are not there, the team leader can ask whether someone senior is available, but cannot demand it.
  - For internal audits, the manager or supervisor of the area audited (the process owner) should be at the closing meeting.

Problematic Closing Meeting

- **Corrective action taken or additional evidence presented at the closing meeting**
  - Additional evidence cannot be presented at the closing meeting.
    - If evidence was not provided during the audit then there is another problem with the control of documented information (e.g., **7.5.3.1—***documented information …is available and suitable for use, where, and when it is needed*).
  - Corrective action cannot be submitted during the closing meeting.
    - Corrective action must be planned, implemented, verified and validated prior to acceptance. While it is feasible that corrective action could be planned and implemented during the audit, it is highly unlikely that corrective action could be verified as effective and validated during the audit.
  - At this point, a nonconformity stays a nonconformity.

Chapter 9: Closing Meeting — What We Covered

Learning Objectives

You should now be able to:

- Describe the purpose of a closing meeting
- List the elements covered in a closing meeting
- Explain how to prevent a problematic closing meeting
- Write a summary statement
- Explain concerns about giving recommendations

Chapter Agenda

- Closing Meeting
- Summary Statement
- Recommendations

Chapter 10

Completing the Audit Report

Chapter 10: Completing the Audit Report — What We Will Cover

Learning Objectives

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

- List the items contained in the audit report
- Describe confidentiality of the audit report
- List the items in an overall set of audit records

Chapter Agenda

- Preparing the Audit Report
- Completing the Audit Report
- Audit Records

The Audit Report

- The audit team leader prepares the audit report
- The audit report provides a complete, accurate, and concise record of the audit, and should include:
  - The audit objectives
  - The audit scope
  - Identification of the audit client
  - Identification of audit team and auditee's participants
  - The dates and places where the audit activities were conducted
  - The audit criteria
  - The audit findings and related evidence
  - The audit conclusions
  - Statement regarding the degree to which audit criteria have been fulfilled
  - Any unresolved diverging opinions between the audit team and auditee
  - Statement indicating that the audit is a sampling exercise and there is risk that the observed audit evidence is not representative

The Audit Report

- The audit report may also include the following:
  - The audit plan
  - A summary of the audit process, including obstacles that may decrease reliability of the audit conclusions
  - Confirmation that the audit objectives have been accomplished within the audit scope
  - Any areas not covered, although within the audit scope
  - Summary of the audit conclusions and the findings that support them
  - Good practices identified
  - Agreed follow-up action plans
  - A statement of the confidential nature of the contents
  - Any implications for the audit program or subsequent audits

Completing the Audit

Distributing the Audit Report

- The audit report should be…
  - Dated, reviewed and accepted
  - Issued within the agreed time period
  - Distributed to designated recipients
- The audit report is the property of the audit client and confidentiality must be respected.

Completing the Audit

- The audit is completed when…
  - All activities described in the audit plan have been carried out, and
  - The approved audit report has been distributed
- Documents pertaining to the audit should be retained or destroyed by agreement between the participating parties.

Audit Program Records

- Records should be maintained to demonstrate the implementation of the audit program and should include the following:
  - Audit plans
  - Audit reports
  - Nonconformity reports
  - Corrective and preventive action reports
  - Audit follow-up reports
  - Results of audit program review
  - Records related to audit personnel
  - Audit team selection
  - Maintenance and improvement of competence
- Records should be retained and suitably safeguarded

Chapter 10: Completing the Audit Report — What We Covered

Learning Objectives

You should now be able to:

- List the items contained in the audit report
- Describe confidentiality of the audit report
- List the items in an overall set of audit records

Chapter Agenda

- Preparing the Audit Report
- Completing the Audit Report
- Audit Records

Chapter 11

Corrective Action and Close-Out

Chapter 11: Corrective Action and Close-Out — What We Will Cover

Learning Objectives

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

- Describe the purpose of corrective actions for audit findings
- List auditor's responsibilities for closeout

Chapter Agenda

- Corrective Actions
- Auditor Responsibilities
- Close-out – IATF Method
- **Management Systems Auditing Exam**

Corrective Action

Following most audits, the auditee will be requested to take action to resolve nonconformities.

- In third party situations…
  - verification is necessary before a registration certificate is issued.
- In second party audits…
  - the auditing organization should follow-up.
- For supplier selection audits (also 2nd Party)…
  - the auditing organization would be most unlikely to follow-up on an audit where the results were unsatisfactory.

Corrective Action Components

- The process owner is responsible for:
  - Determining the extent of the problem
  - A corrective action plan
  - Forming a team
  - Implementing and verifying interim actions
  - Finding and verifying root causes
  - Selecting permanent corrective action
  - Implementing permanent corrective action
  - Verification and validation of corrective action
  - Preventing system problems (other similar processes)

Corrective Action — Root Causes

- Corrective Action should address three root causes:
  - **Occurrence Root Cause**
    - What occurred in the process that resulted in a nonconformity?
  - **Escape Root Cause**
    - Why did the controls fail to find the nonconformity?
  - **Systemic Root Cause**
    - Why did the system or planning process fail to identify a concern?

Auditor Responsibility for Close-Out

- The auditor is responsible for:
  - Verifying that corrective action has been taken
  - Verifying that corrective action is effective
  - Closing out the nonconformity
- Follow-up for **IATF 16949**
  - For **IATF 16949** certification purposes, nonconformities must be 100% resolved within 90 days of the final report

For a minor nonconformity, this is typically handled by reviewing a corrective action report and verifying those actions during the next audit.

For a major nonconformity, this is typically handled by conducting a special audit that is scheduled to confirm effective closure of the major nonconformance.

Conducting Close-Out — Major Nonconformities

Major Nonconformities require the following…
(IATF Rules, 5.11.1)

- Within 20 days of the closing meeting of the site audit, evidence of the following must be submitted:
  - Implemented correction
  - Root cause including methodology used, analysis and results
- Within 60 days of the closing meeting of the site audit, evidence of the following must be submitted:
  - Implemented systemic corrective actions to eliminate each nonconformity, including consideration of the impact to other similar processes and products
  - Verification of effectiveness of implemented corrective actions

Conducting Close-Out — Minor Nonconformities

Minor Nonconformities require the following…
(IATF Rules, 5.11.2)

- Within 60 days of the closing meeting of the site audit, evidence the following must be submitted:
  - Implemented correction
  - Root cause including methodology used, analysis and results
  - Implemented systemic corrective actions to eliminate each nonconformity, including consideration of the impact to other similar processes and products
  - Verification of effectiveness of implemented corrective actions

Conducting Close-Out

Requirements for a Corrective Action

- Implemented Correction (Containment)
- Root Cause – methodology used, analysis, and results
- Implemented Systemic action including similar products and processes for each non-conformity
- Verification of effectiveness

Nonconformity — If Not Closed Out in 90 Days (IATF)

Nonconformities that cannot be closed out in 90 days will be considered 100% resolved under the following conditions:

- Containment, including a review of impact of systemic impact on the customer
- Documented action plan, instructions, and records to show elimination of nonconformity condition and including a review of systemic impact on the customer
- Scheduled onsite special audit based on the action plan conducted prior to the next scheduled audit

Verify the corrective action in the next audit

Chapter 11: Corrective Action and Close-Out — What We Covered

Learning Objectives

You should now be able to:

- Describe the purpose of corrective actions for audit findings
- List auditor's responsibilities for closeout

Chapter Agenda

- Corrective Actions
- Auditor Responsibilities
- Close-out – IATF Method
- **Management Systems Auditing Exam**

Management Systems Auditing Exam

Work Independently

OMNEX

Chapter 12

Linking Core Tools to IATF 16949

Chapter 12: Linking Core Tools to IATF 16949 — What We Will Cover

Learning Objectives

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

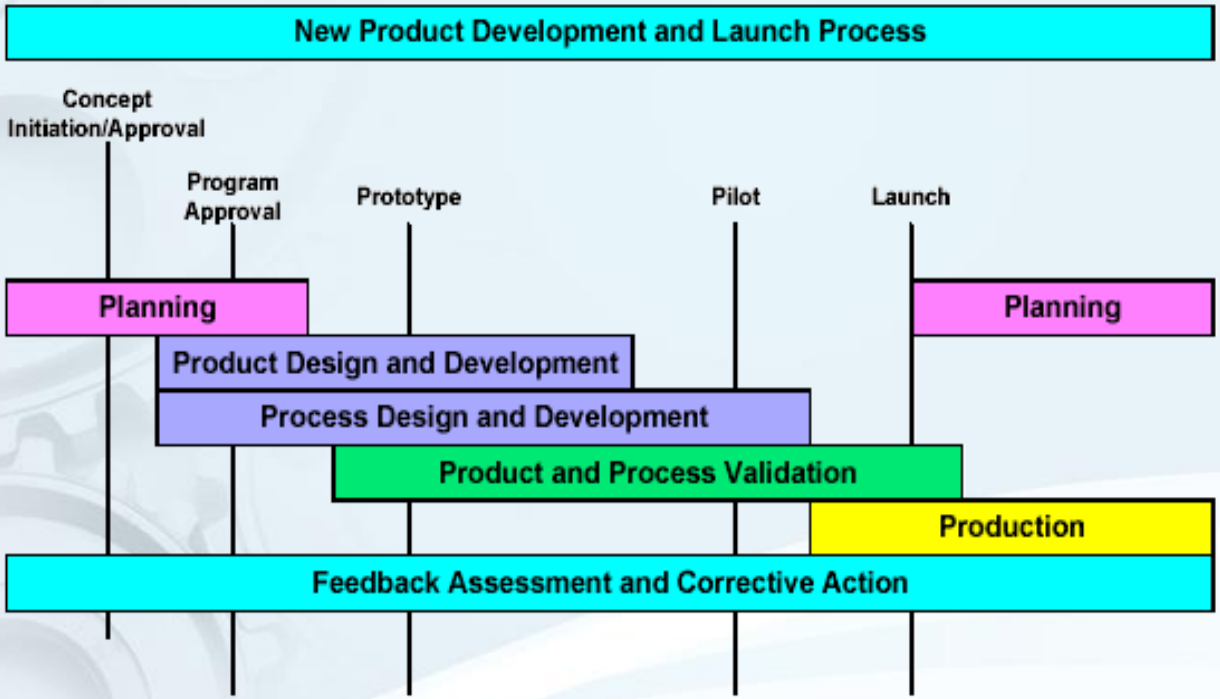
- State the purpose of each core tool
- Explain when and how each tool is used
- Link the core tools to IATF 16949

Chapter Agenda

- APQP
- FMEA
- Control Plan (Included in the APQP manual)
- MSA
- SPC
- PPAP
- **[OPTIONAL – Class Activity: Develop an Audit Checklist for a Core Tool]**

ADVANCED PRODUCT QUALITY PLANNING

APQP



Five Phases

I. Plan and Define the Program

II. Product Design and Development

III. Process Design and Development

IV. Product and Process Validation

V. Feedback Assessment and Corrective Action

The five phases of APQP relate to clauses 8.1 and 8.3 of IATF 16949

APQP Phases Defined

- **Phase I: Plan and Define Program**
  - Defining customer needs and expectations in order to plan and define an APQP project and quality program.
- **Phase II: Product Design & Development**
  - Development of product design features and characteristics into a near final form.
  - A feasible design must permit meeting production volumes and schedules, and be consistent with the ability to meet engineering requirements, and objectives for quality, reliability, investment cost, weight, unit cost and timing.

APQP Phases Defined

- **Phase III: Process Design & Development**
  - Development of the manufacturing system, processes and control plan to ensure that customer requirements, needs and expectations are met.
- **Phase IV: Product & Process Validation**
  - Validation of the product design and manufacturing process. Significant production runs should validate that control plans and process flow charts are followed and the products meet customer requirements.
- **Phase V: Feedback, Assessment and Corrective Action**
  - Measurement of the effectiveness of the product quality planning effort to meet customer requirements – identification and management of opportunities for improvement.

Plan and Define Program (Phase I)

- This phase is designed to ensure that processes are in place that…
  - Clearly define customer needs and expectations
  - Ensure that requirements are clearly understood
- Outputs of Phase I include:
  - Design goals
  - Reliability goals
  - Preliminary Bill of Material
  - Preliminary Process Flow Chart
  - Preliminary Listing of Special Product and Process Characteristics
  - Product Assurance Plan
  - Project Plan
  - Management support

This phase relates to clause 8.1 of IATF 16949

Product Design and Development (Phase II)

- A thorough review of product design requirements and concludes with a sign-off on the design reliability
- Outputs by design responsible activity
  - Design Failure Mode and Effects Analysis (DFMEA)
  - Design for Manufacturing and Assembly
  - Design verification
  - Design reviews
  - Prototype Build – Control Plan
  - Engineering drawings (including math data)
  - Engineering specifications
  - Materials specifications
  - Drawing and specification changes
  - Management support

Product Design and Development (Phase II)

- Other Outputs from Phase II
  - New equipment, tooling and facilities requirements
  - Consensus on key/critical product and process characteristics
  - Gages/testing equipment requirements
  - Team feasibility commitment and management support

This phase relates to clauses 8.3 Product Design of IATF 16949

Process Design and Development (Phase III)

- Ensures customer expectations and design requirements are incorporated into the manufacturing process
- Outputs
  - Packaging standards
  - Product/process quality system review
  - Floor plan layout
  - Process Flow Chart
  - Characteristics Matrix
  - PFMEA
  - Pre-launch Control Plan
  - Process instructions
  - Measurement System Analysis plan
  - Preliminary process capability study plan
  - Packaging specifications
  - Management support

This phase relates to clauses 8.3 Manufacturing Process Design of IATF 16949

Product and Process Validation (Phase IV)

- Concerned with validating the manufacturing process and product by a trial run and a part approval process
- Outputs
  - Production trial run
  - Measurement system evaluation
  - Preliminary process capability study
  - Product approval process
  - Product validation testing
  - Packaging evaluation
  - Production Control Plan
  - Production Pre-launch Control Plan (supplier at plant)
  - Quality planning sign-off and management support

This phase relates to clauses 8.3.2.1, 8.3.2.2, 8.3.3.3, 8.3.4.4, 8.3.5.2, 8.3.6.1 of IATF 16949

Feedback, Assessment and Corrective Action (Phase V)

- The process for production and service provision should be **continuously improved**
- Outputs
  - Reduced variation
  - Customer satisfaction
  - Delivery and service

This phase relates to clauses 10.3 of IATF 16949

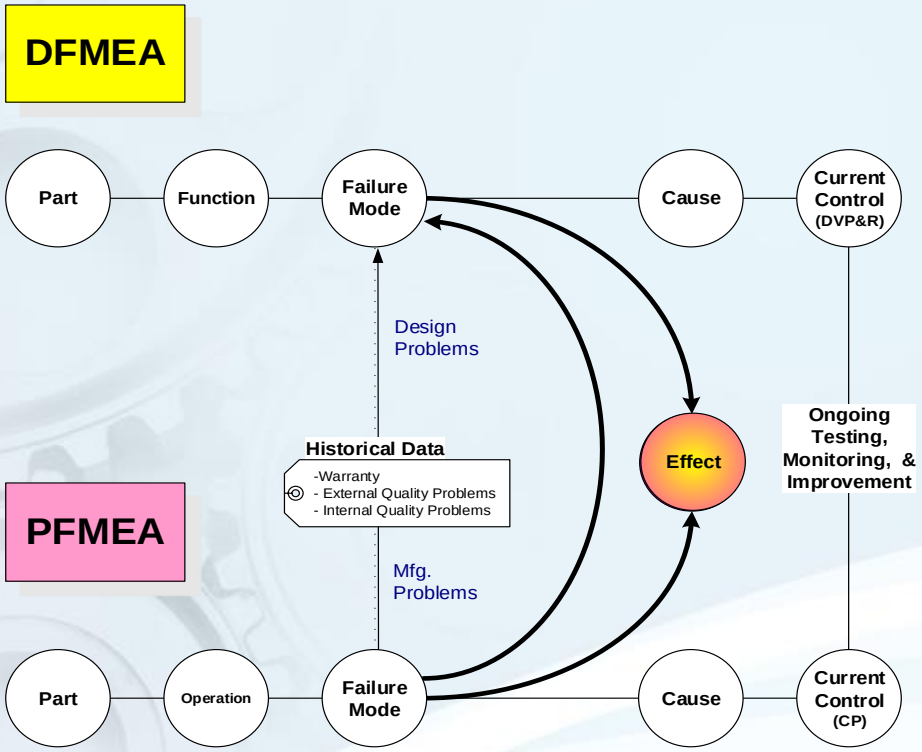
How to Audit APQP

The Product Development Process

- Look for a task list that includes or references:
  - Responsibilities, team involvement
  - Sequence / Interaction
  - Timing
  - Milestones, Gates
  - Criteria for decisions and quality of event
  - Outputs as defined previously
  - Provisions for change and improvement
  - Procedures, Work Instructions, Forms to define and control the process

FAILURE MODES AND EFFECTS ANALYSIS

FMEA



Types of FMEA

- Concept FMEA
- System FMEA
- **Design FMEA**
- Process Concept FMEA
- **Process FMEA**
- Machine FMEA

FMEA relates to many clauses of IATF 16949 8.3.5 Process and Design Output

Design FMEA

- Examines each item/function
  - Identifying potential design related failure modes
  - Assessing potential effects of failures
  - Identifying potential causes, mechanisms for design failure
  - Identifying design controls
  - Suggesting recommended actions for improving the design or design controls to reduce or eliminate risks

Standard DFMEA Form

Item	Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detection	RPN

Recommended Action	Responsibility	Target Completion Date	Action Results					
			Actions Taken	Effective Date	Severity	Occurance	Detection	RPN

Process FMEA

- Examines each operation
  - Identifying potential product related process failure modes
  - Assessing potential effects of failures
  - Identifying potential environmental manufacturing or assembly process causes
  - Identifying process control variables for prevention and/or detection of failure conditions
  - Suggesting recommended actions for improving controls or eliminating causes

Standard PFMEA Form

Process Step	Function	Requirements			Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Process Controls Prevention	Occurrence	Current Process Controls Detection	Detection	RPN
		ID	Product	Process										

Recommended Action	Responsibility	Target Completion Date	Action Results					
			Actions Taken	Effective Date	Severity	Occurance	Detection	RPN

FMEA

- Various problem solving and investigative tools should be used
  - Brainstorming
  - Cause and effect diagrams
  - Experience from previous designs
  - Pareto diagrams
  - Customer requirements
  - Field problems, warranty history
  - Competitive vehicle quality trends
  - Test and modeling data

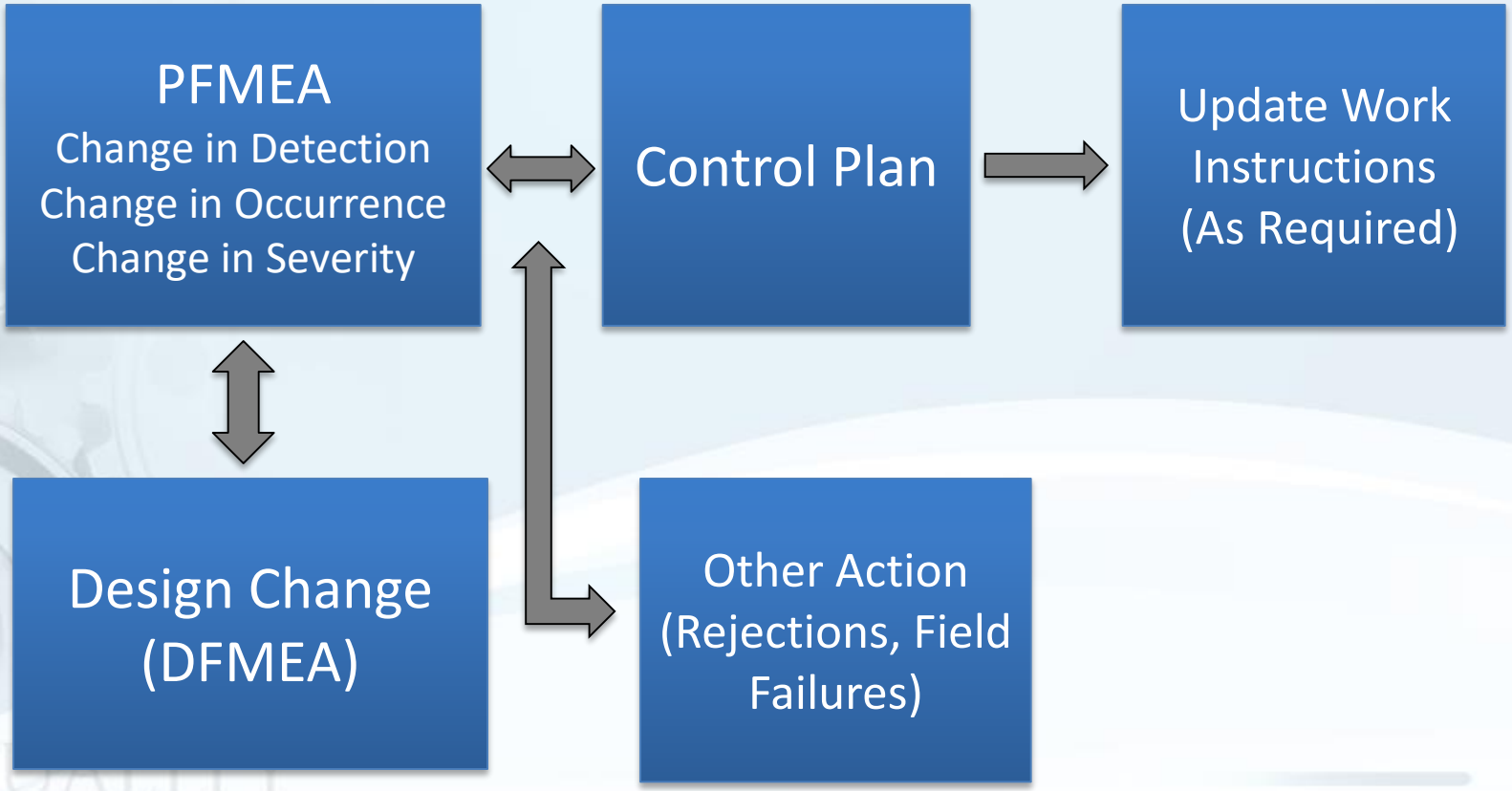
FMEA

- Uses a multidisciplinary team
- Requires creativity and investigation for:
  - Identifying potential failure modes
  - Identifying effects and causes of failure modes
  - Developing recommended actions to reduce risk of failure modes
  - Qualifying severity, occurrence and detection in order to prioritize actions

FMEA

- Uses objective historical data to identify potential failure modes
  - Warranty
  - Internal and external nonconformities
  - SPC
  - Customer concerns log

Links Between PFMEA and Other Key APQP Documents



How to Audit FMEA

- Look for:
  - Use of multidisciplinary teams
  - Methodology to prepare FMEAs and respond to high rankings and RPN numbers
  - Are failure modes the opposite of requirements
  - Are all customers considered in relation to effects
  - Are effects stated in terms of something the customer would experience
  - Are all special characteristics noted in the classification column
  - Do causes follow these three rules:
    - Only one cause per cell
    - Enough detail so that it is clear what needs to be corrected or controlled
    - If the cause were to happen the result would be the failure mode
  - Do preventive controls specifically prevent causes
  - Is it noted through proper detection ranking, the difference between detection controls that detect the cause and detection controls that detect the failure mode
  - Follow up actions completed and documented to reduce RPNs
  - Completed per APQP schedule and well in advance of PPAP
  - Living to capture new problems/solutions and link to other documents

CONTROL PLANS

Control Plan

	Prototype		Pre-launch		Production	Key Contact/Phone		Date (Original)	Date (Revised)
Control Plan Number									
Part Number/Latest change Level						Core Team		Customer Engineering Approval/Date (If Required)	
Part Name/Description						Supplier/Plant Approval/Date		Customer Quality Approval/Date (If Required)	
Supplier/Plant		Supplier Code				Other Approval/Date (If Required)		Other Approval/Date (If Required)	

Part/Process Number	Process Name/ Operation Description	Tool and/ or Technique	Characteristics			Special Characteristic Class	Methods					Reaction Plan
			No.	Product	Process		Product/Process Specification Tolerance	Evaluation Measurement Technique	Sample		Control Method	
									Size	Frequency		

Control Plan Methodology

- Types of Control Plans
  - Prototype
  - Pre-launch
  - Production
- Identify all the process controls and special characteristics
- Standardization of Control Plans

Control Plan relates to clauses 8.5.1.1 and Annex A of IATF 16949. Control Plan is cited in many parts of the IATF 16949.

Control Plan Methodology

- A written summary of the system for controlling the variation of product and process characteristics
- A contract between the supplier and customer
- A summary of the entire control strategy for a system, subsystem or component
- Identifies all customer and supplier specific special characteristics determining sources of variation

Process can be classified on the basis of the dominant influence on product characteristic variation

Control Plan Methodology

- Typical classifications may include:
  - Machine dominant
  - Operator dominant
  - Component dominant
  - Tools dominant
  - Preventive maintenance dominant
  - Fixture/pallet/position dominant
  - Setup dominant
  - Environment dominant
- A process may be dominant in more than one way

Links Between Control Plan and Other Key APQP Documents

Control Methods

- Quality check sheets or inspection sheets
- Setup, operation and reaction instructions
- PM check sheets
- Process parameter logs
- Training
- Tool change logs
- Variable control charts
- Attribute control charts
- First piece approval sheets and yearly layouts

The more capable the process, the less intense the control method

How to Audit Control Plans

- Look for the procedures/work instructions:
  - Are customers approvals required?
  - Are product characteristics controlled?
  - Are process parameters controlled?
  - Does the acceptance criteria match customer requirements?
  - Does it cover incoming to shipping?
  - Does it meet the requirements of IATF 16949 annex A?
  - Was it done to support the significant production run?
  - Does it correlate with the Process Flow and PFMEA?
  - Are reaction plans defined and evidence of use?
  - Are they living?
  - Was MSA done on the measurement equipment?

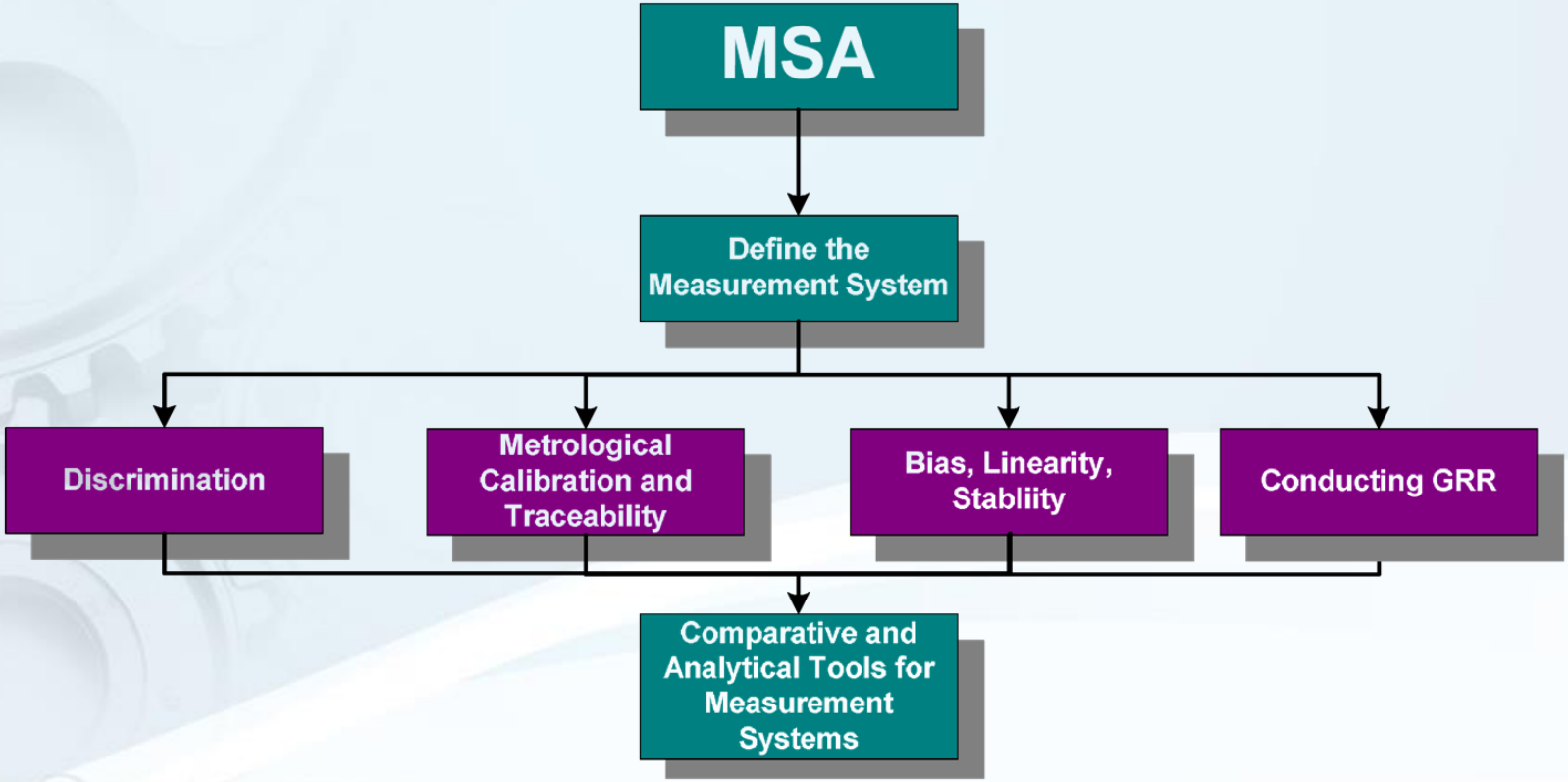
MEASUREMENT SYSTEMS ANALYSIS

Measurement System Analysis (MSA)

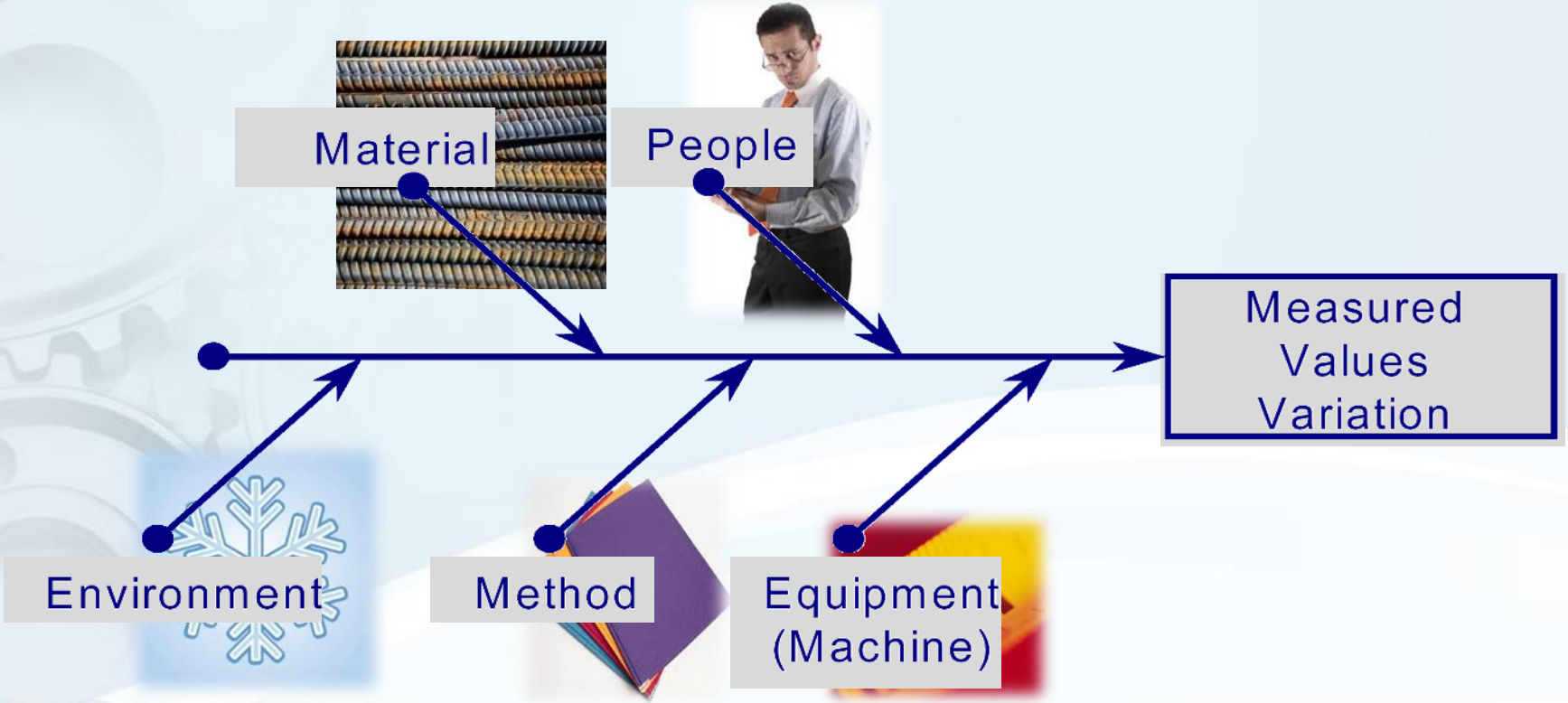
- Deals with analyzing the capability of the measurement system to effectively determine the measured value
- System is tested to determine the numerical value of its statistical properties and compare them to the accepted standards
- To evaluate a measurement system, determine:
  - If it has adequate discrimination
  - If it is statistically stable over time
  - If statistical properties are consistent over the expected range and acceptable for process analysis of control
  - If the sum of all the variables is an acceptable level of measurement uncertainty

MSA relates to clause 7.1.5.1.1 of IATF 16949

MSA



MSA



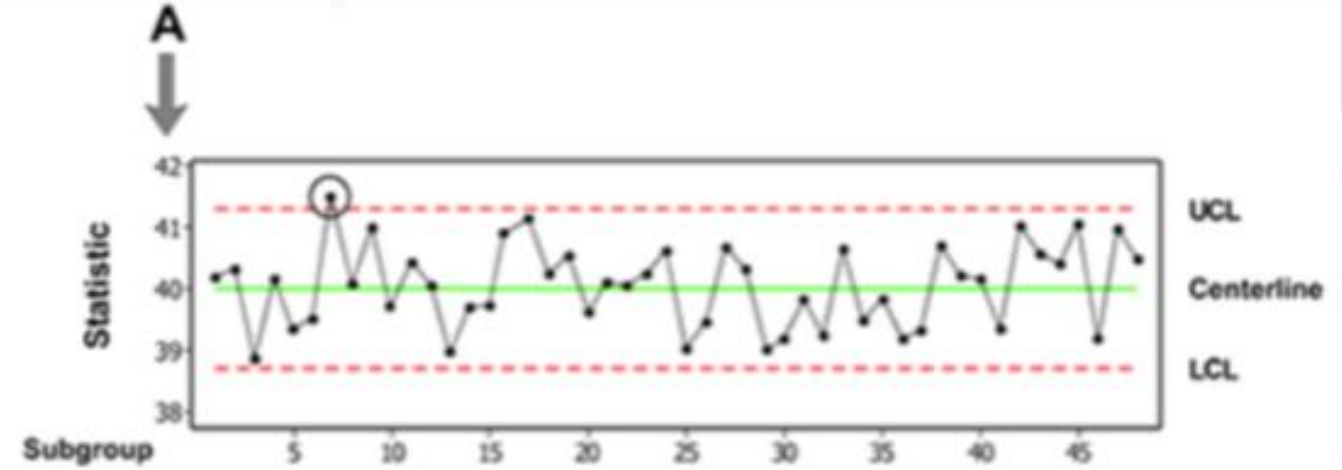
MSA

- **Common problems of MSA include:**
  - MSA not conducted by actual operators
  - All gages are tested against the same parts
  - Most stringent tolerance NOT used in calculations
  - *Not all different gage types, including all gauging suppliers, studied?*
  - GRR not conducted in actual environment

How to Audit MSA

- Were studies done on equipment referenced in Control Plan? (examine some specifics)
- What statistical methods were included?
- What criteria is used to accept results?
- How is result being used?
- Are studies done repeatedly?
- Are improvements targeted?
- When are they done?
- Explain approach to GRR study.

STATISTICAL PROCESS CONTROL



Statistical Process Control (SPC)

- Deals with studying variation
- Focuses on **prevention**, not **detection**
- Fundamental issues
  - **Common** vs. **special** cases of variation
  - **Local** action vs. actions on the **system**
  - **Process capability** vs. **meeting specifications**
  - Applicability of the different types of statistical methods to specific situations
  - Measurement system must be under control (MSA)

SPC relates to clauses 9.1.1.1, 9.1.1.2 and 9.1.1.3 of IATF 16949

Statistical Process Control (SPC)

- Tools for Controlling and Improving Processes
  - Process Flow Diagrams
  - Failure Mode and Effects Analysis (FMEA)
  - Control Plan
  - Control Charts
  - Check Sheets
  - Problem Solving Techniques
  - Designed Experiments
  - Simulations
  - Supplier Certification
  - Preventative Maintenance

SPC — Variation

- **Common-cause variation** is always present in a process
- A process is considered stable and predictable when only this variation is present
  - Reducing common-cause variation by fine-tuning a process is usually very difficult and counterproductive
  - Can be reduced only by making significant changes to the process itself
  - Primary responsibility for reducing lies with management

SPC — Variation

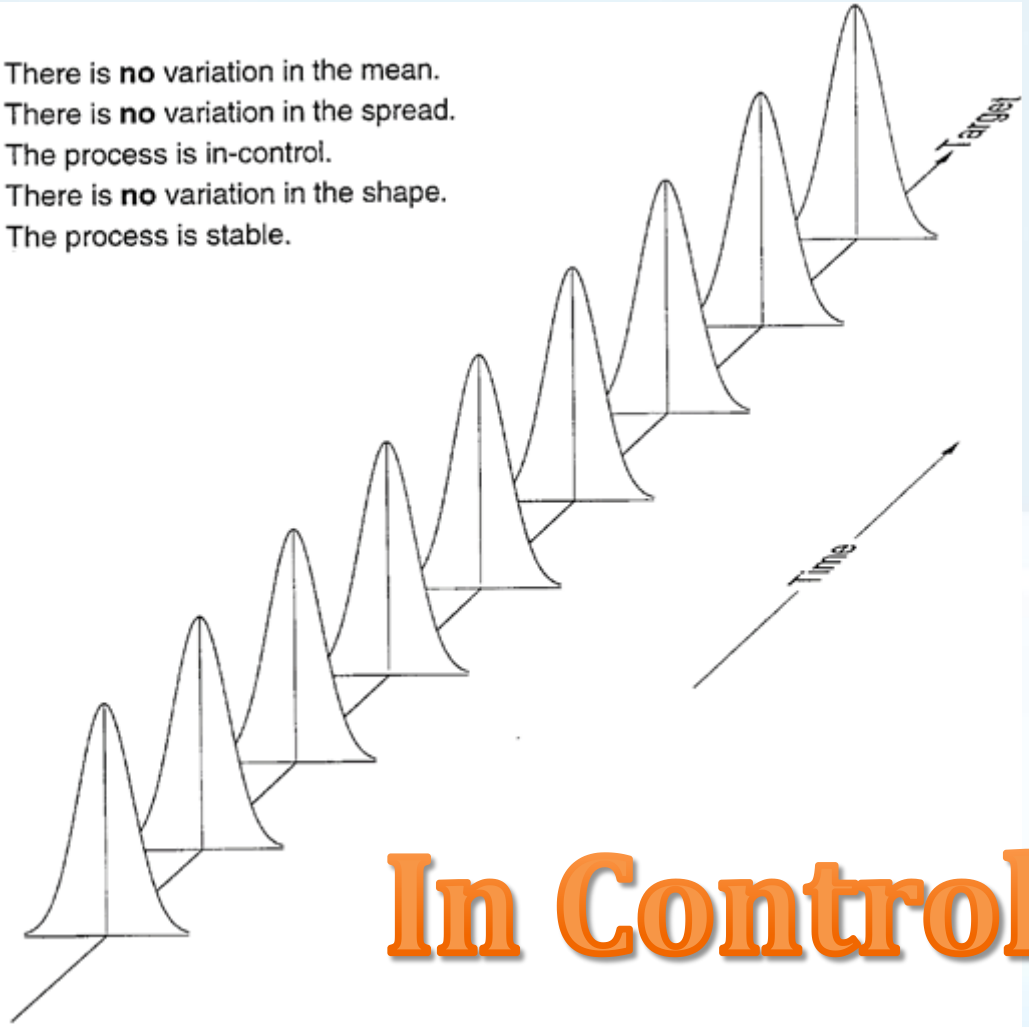
- **Special-cause variation** is caused by unusual or external events
  - Makes the process unpredictable
  - Remove special-cause variation by adjusting the process
  - Removing special-cause variation does not require significant structural changes in the process
  - Operators and supervisors usually have the primary responsibility for removing special-cause variation

SPC — Variation

- A process is **in-control** (stable) if:
  - There is no variation in location over time
  - There is no variation in spread over time
- A process is **out-of-control** (unstable) if:
  - There is variation in the location over time
  - There is variation in spread over time

SPC — Variation

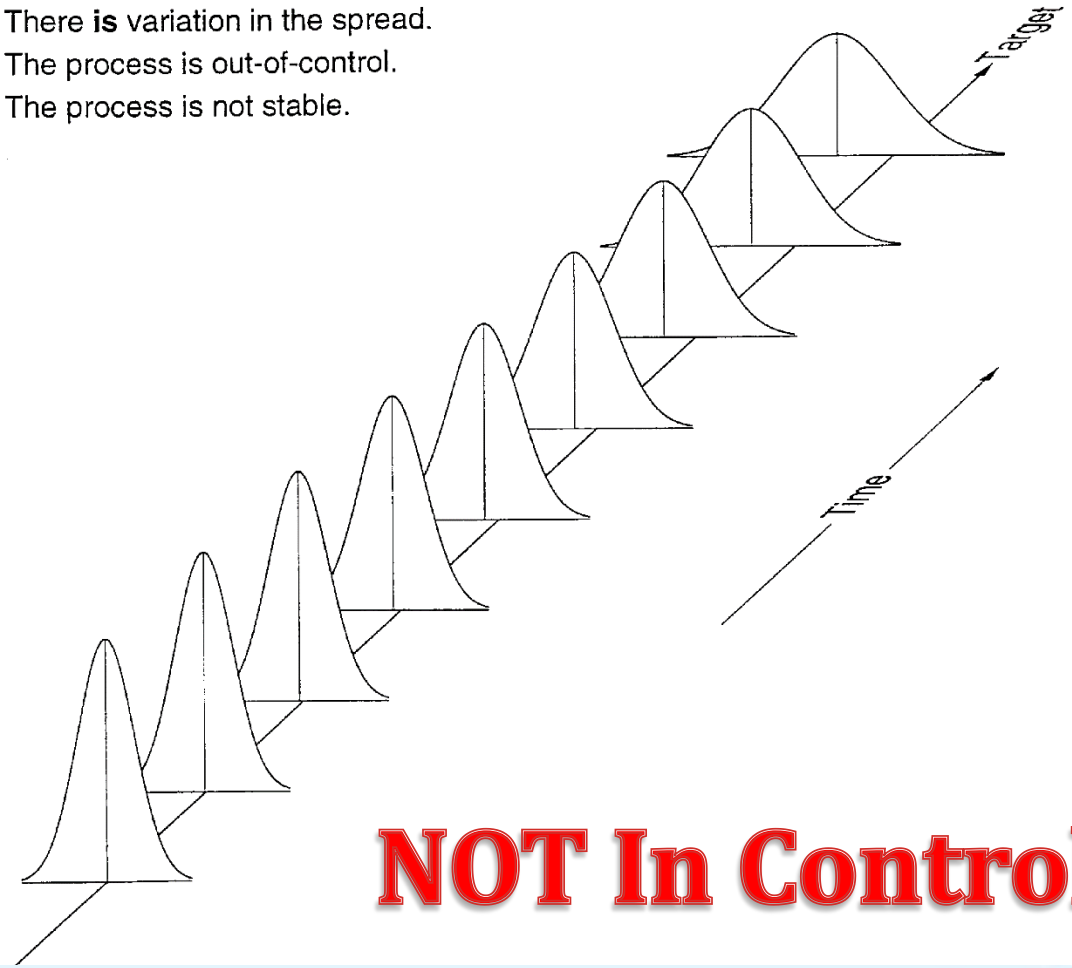
- There is **no** variation in the mean.
- There is **no** variation in the spread.
- The process is in-control.
- There is **no** variation in the shape.
- The process is stable.



In Control

SPC — Variation

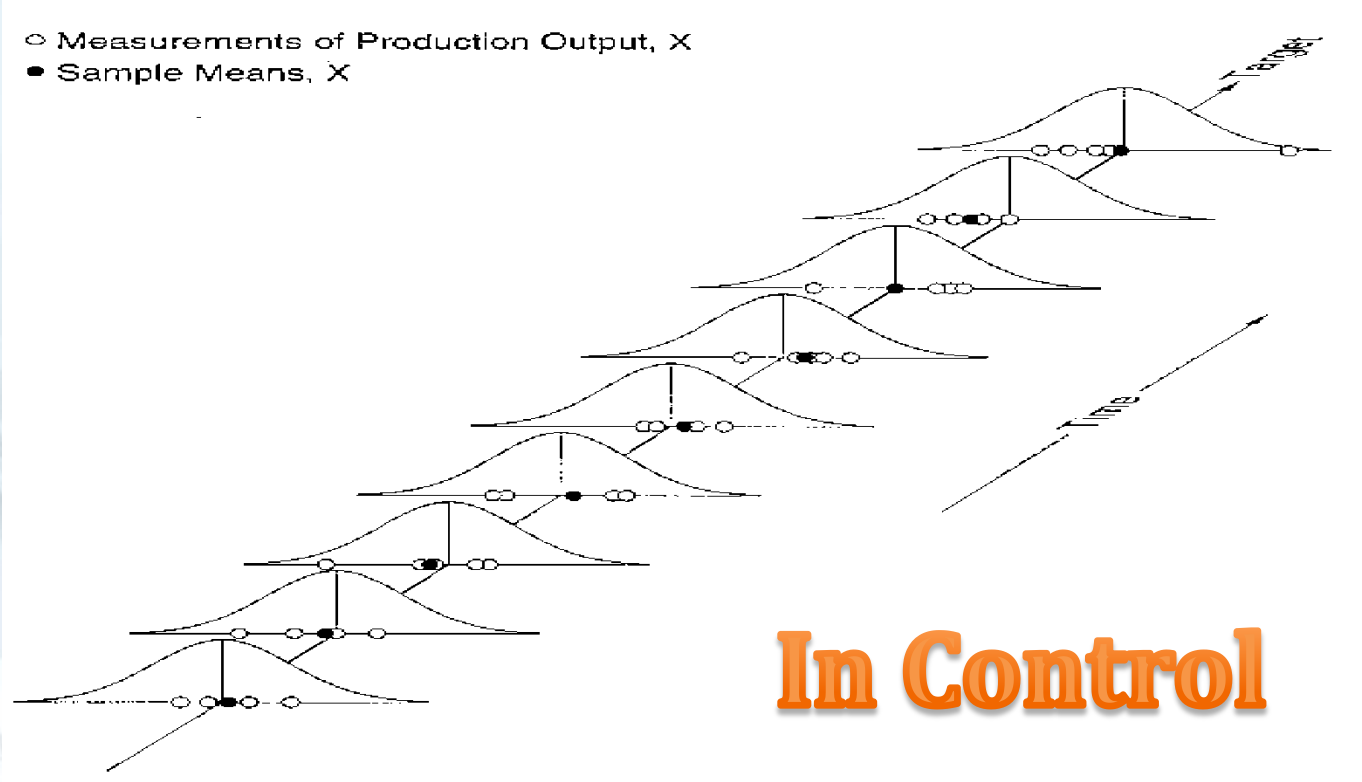
- There **is** variation in the mean.
- There **is** variation in the spread.
- The process is out-of-control.
- The process is not stable.



NOT In Control

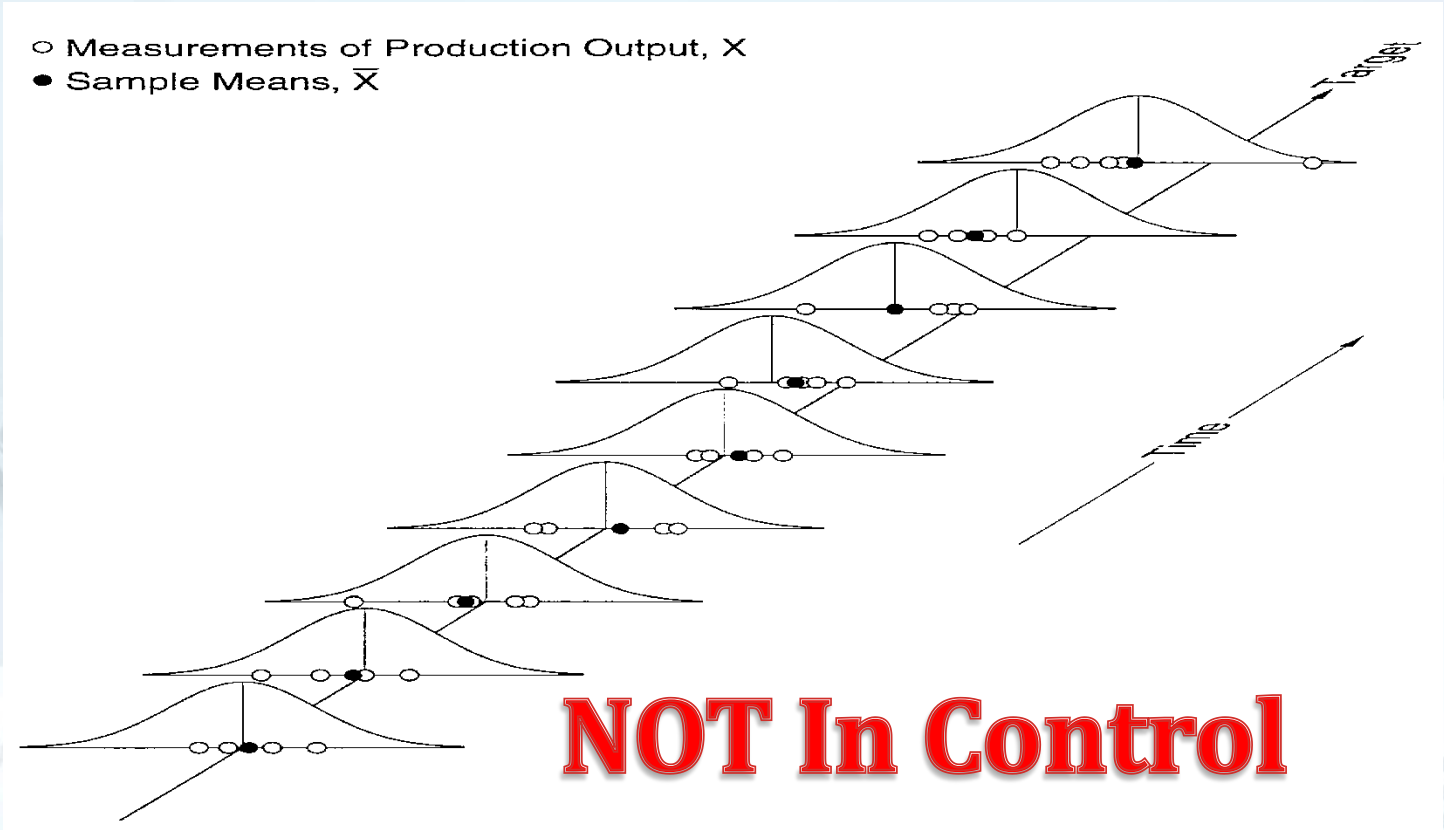
SPC — Variation

A Stable Process

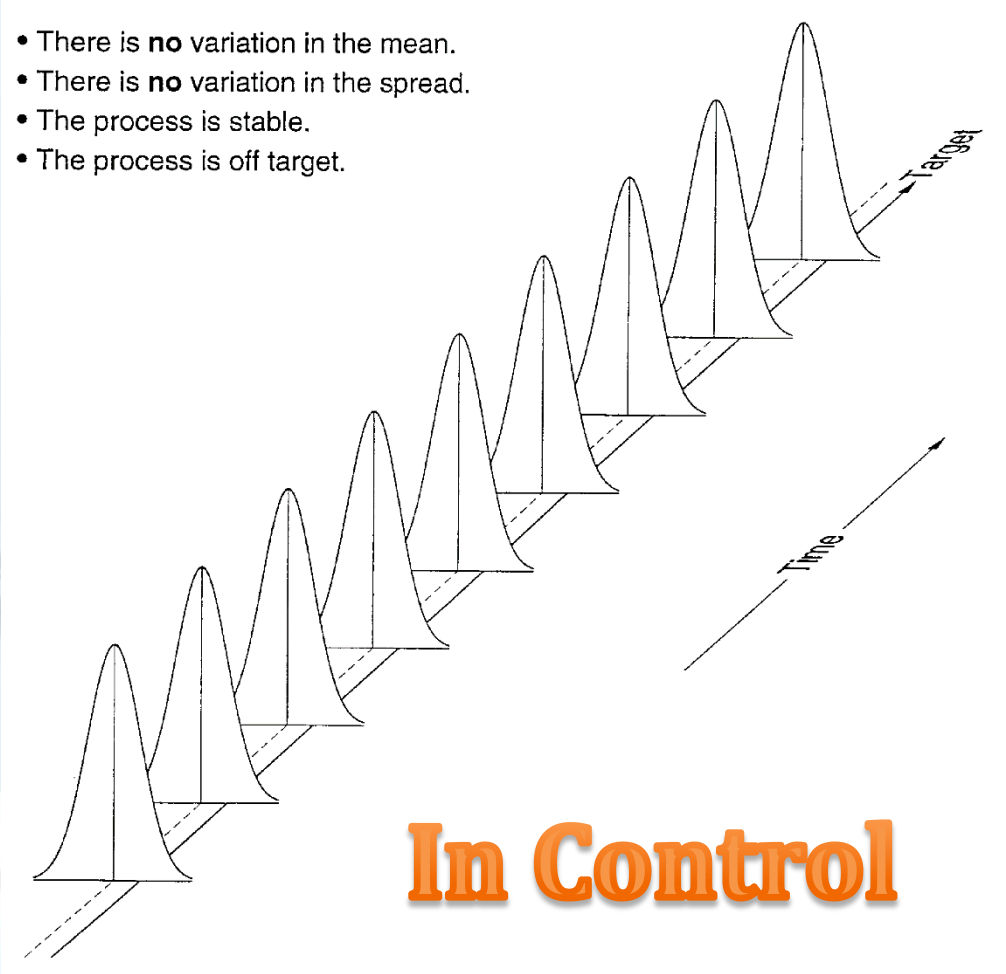


SPC — Variation

A Shift in the Mean



SPC — Variation

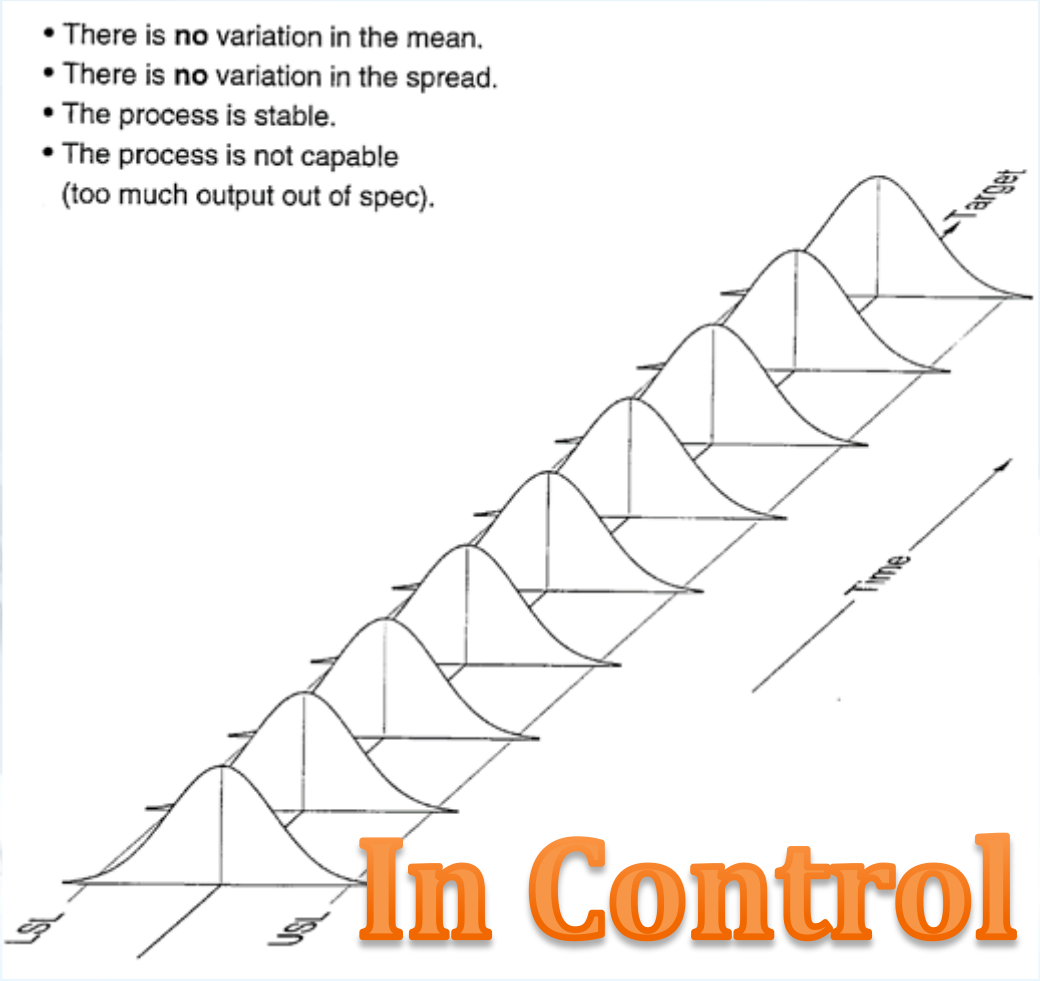


This system is considered stable since there is no variation in the centers of distribution of process output nor in the dispersions of the output.

This process is consistently off-target and may become a serious problem.

SPC — Variation

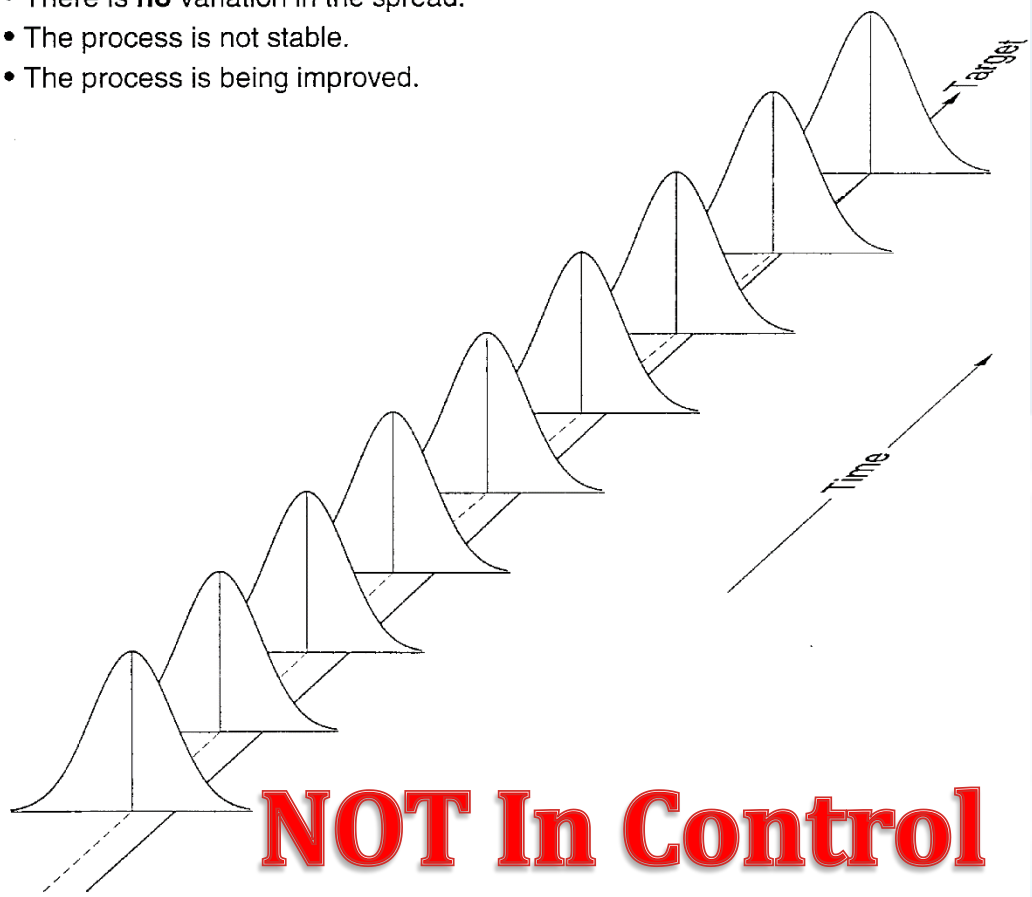
- There is **no** variation in the mean.
- There is **no** variation in the spread.
- The process is stable.
- The process is not capable (too much output out of spec).



Process is in-control and on-target, however a great deal of the process output is outside the specification limits; therefore the process is not capable.

SPC — Variation

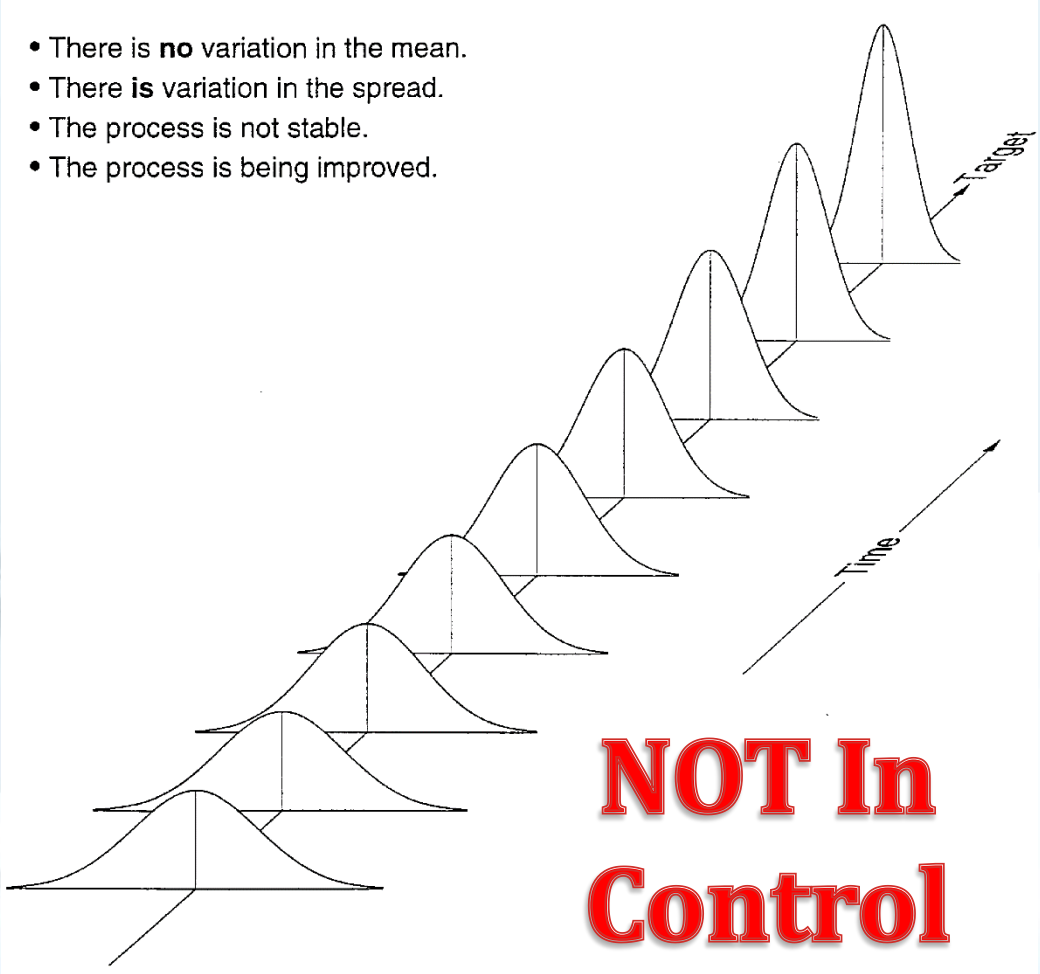
- There **is** variation in the mean.
- There is **no** variation in the spread.
- The process is not stable.
- The process is being improved.



Off-target process is improved by moving the center of process output toward the target value.

Not all off-target processes can be improved this easily.

SPC — Variation



Once a process is stable and on-target, target variance reduction is often the next step in process improvement.

Many processes cannot achieve stability in the traditional sense.

SPC — Variation

Problems Related to Common Causes		Problems Related to Special Causes
System deficiency	**Nature**	Process detail failure
All production output is affected similarly	**Scope of Influence**	Not all production output is affected similarly
Many small sources	**Sources**	A few major sources
Stable and predictable	**Process Behavior**	Sporadic and unpredictable
85%-95%	**Approximate Percent of Total Variation**	5%-15%
Requires fundamental change	**Improvement Action**	Requires point of production changes
Management	**Responsibility**	Operator/supervisor

How to Audit SPC

Management of Statistical Techniques

- SPC data from the floor is collected and analyzed by quality department.
- Conduct a visual analysis of the variable charts:
  - How is stability assessed?
  - How often are samples measured?
  - What rules do they have to react to X bar location and trend?
  - Are the means scattered about the target?
  - Are special causes from this data identified?
  - Are solutions being provided?
  - What are the trends?
  - How are control limits recalculated?
- Look at some capability studies:
  - What are the current and historical capability indexes: Cp and Cpk?
  - How often is it reported to whom?
  - Do they have reaction plans for the “low” indexes?
  - Are Cpks generally showing improvement over time?
- What records do we keep?
- Are they reviewed by management and responded to?

PRODUCTION PART APPROVAL PROCESS

Production Part Approval Process (PPAP)

- Unique methods required for each OEM
  - Generally based on the AIAG PPAP Manual
- The purpose of PPAP is to:
  - Determine if customer engineering design record and specification requirements are properly understood by the supplier
  - Determine if the process has the potential to produce product consistently meeting these requirements during an actual production run
- PPAP is required before quantity shipment and is dependent on the requirements of the customer

PPAP relates to clause 8.3.4.4 of IATF 16949

PPAP

- Suppliers shall obtain PPAP approval for:
  - A new product
  - Correction of a previously submitted product
  - Engineering change (fit, form, function)
  - New material
  - New or modified tools, dies, molds
  - Refurbishment or rearrangement of tools/equipment
  - New plant or location
  - New subcontractors
  - Tooling inactive for 12 months
  - Changes made by supplier
  - Change in test/inspection method
  - Following a suspension due to a quality concern

PPAP Customer Notification & Submission Requirements

- There are five submission levels:
  - Level 1: Warrant only
  - Level 2: Warrant, product samples, limited data
  - Level 3: Warrant, product samples, complete data submitted
  - Level 4: Warrant, other requirements as defined by the customer
  - Level 5: Warrant, product samples, complete data reviewed at supplier plant

PPAP Requirements

- Design records of salable product
  - For proprietary components/details
  - For all other components/details
- Engineering change documents
- Customer engineering approval
- Design FMEA
- Process Flow Diagrams
- Process FMEA
- Dimensional results
- Material, performance test results
- Initial process study

PPAP Requirements

- Measurement System Analysis studies
- Qualified laboratory documentation
- Control Plan
- Part Submission Warranty (PSW)
- Appearance Approval Report (AAR)
- Bulk material requirements checklist
- Sample product
- Master sample
- Checking aids
- Records of compliance with customer-specific requirements

How to Audit PPAP

- Look at Retention/Submission table and select a couple of recent PPAP packages:
  - Are all reference documents complete?
  - Was the submittal according to our APQP and customer's timetable?
  - Were approvals obtained prior to shipment?
  - How do they communicate with the customers?
- Look for an example of re-submittal due to changes.
  - Were there any waivers?

OPTIONAL — Class Activity

Develop an Audit Checklist for a Core Tool

- As a team, generate an audit checklist for one of the core tools covered using the following headings:
  - Requirements
  - What to audit
  - Notes and objective evidence
- List the questions that you would ask to determine conformance, implementation and effectiveness as well as who is the auditee.
- As a group, prepare to discuss the following:
  - What evidence you would expect to see?
  - Which process(es) would you audit for this core tool?

Chapter 12: Linking Core Tools to IATF 16949 — What We Covered

Learning Objectives

You should now be able to:

- State the purpose of each core tool
- Explain when and how each tool is used
- Link the core tools to IATF 16949

Chapter Agenda

- APQP
- FMEA
- Control Plan (Included in the APQP manual)
- MSA
- SPC
- PPAP
- **[OPTIONAL – Class Activity: Develop an Audit Checklist for a Core Tool]**

Chapter 13

Customer-Specific Requirements

Chapter 13: Customer-Specific Requirements — What We Will Cover

Learning Objectives

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

- Describe the importance of Customer-Specific Requirements and how they affect the auditing of IATF 16949
- Incorporate CSRs into an organization's processes

Chapter Agenda

- Overview of CSRs
- Importance of CSRs
- Examples of incorporating CSRs into business processes
- Planning and Preparation to Audit CSRs

Customer-Specific Requirements

- OEMs and large Tier 1 organizations have published customer-specific requirements relating to business, product, delivery and the Quality Management System.
- All organizations need to determine the processes and responsibilities within their respective organizations for determining and acquiring the applicable customer-specific information.
- The most common source of poor quality is poorly or insufficiently defined customer requirements.
- IATF 16949 requires suppliers to include customer-specific requirements in their quality management systems.

Customer-Specific Requirements

- Customer-specific requirements are those that are agreed upon between the supplier and the customer; and they typically fall into the following categories:
  - Customer-specific QMS requirements
  - Part-specific requirements (dimensions, materials, performance characteristics, etc.)
  - Delivery requirements
  - Process requirements (example: heat treat)
  - Business system requirements

Customer-Specific Requirements

- Customer-specific requirements must be fully integrated into the QMS
- Short-term requirements, e.g., deviations, must be fully controlled for the duration of the requirement
- Internal and third party audits must focus attention on customer-specific requirements
- Customer-specific requirements that provide an output to the customer are COPs

Scope of the QMS (ISO 9001)

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
- The scope of a management system must include:
  - The manufacturing site and all support processes
  - Any remote locations that support the site
  - Any outsourced products, processes or services
  - All Customer-Specific Requirements

Scope of the QMS (IATF 16949)

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.

4.3.2 Customer-specific Requirements

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

Importance of Customer-Specific Requirements

- IATF 16949:2016 addresses Customer-Specific Requirements (CSRs) specifically in clause 4.3.2 and requires that all CSRs are incorporated in the organization's business processes within its QMS.

- Each of the U.S. "Big Three" OEMs has published their CSRs in response to the changes in the IATF 16949 standard compared to the previous ISO/TS standard.

- The new CSRs documents from the "Big Three" OEMs provide guidance on the appropriate place for their inclusion into the QMS within their publication by identifying associated IATF 16949 clauses. This should make it somewhat easier for organizations to incorporate the CSRs in the associated processes.

Importance of Customer-Specific Requirements

- A practical way to view the requirements is to picture them as providing the framework for building your quality management system.
  - This framework provides the guidelines and structure for creating, implementing, managing and improving the quality management system, but it is not the whole system.
- All subscribers to IATF 16949:2016 have agreed to common requirements of a quality management system; **it is in those customer-specific requirements that they attempt to ensure the competitive edge.**

Importance of Customer-Specific Requirements

- Only when Customer-Specific Requirements are coupled with IATF 16949:2016 do quality management systems become complete and meaningful in meeting the requirements of a particular subscriber in the automotive industry.

- The OEMs do not run their businesses identically; they have developed their own competitive advantages.
  - The most common source of poor quality is poorly or insufficiently defined customer requirements; customer-specific requirements reduce that lack of definition.

Importance of Customer-Specific Requirements

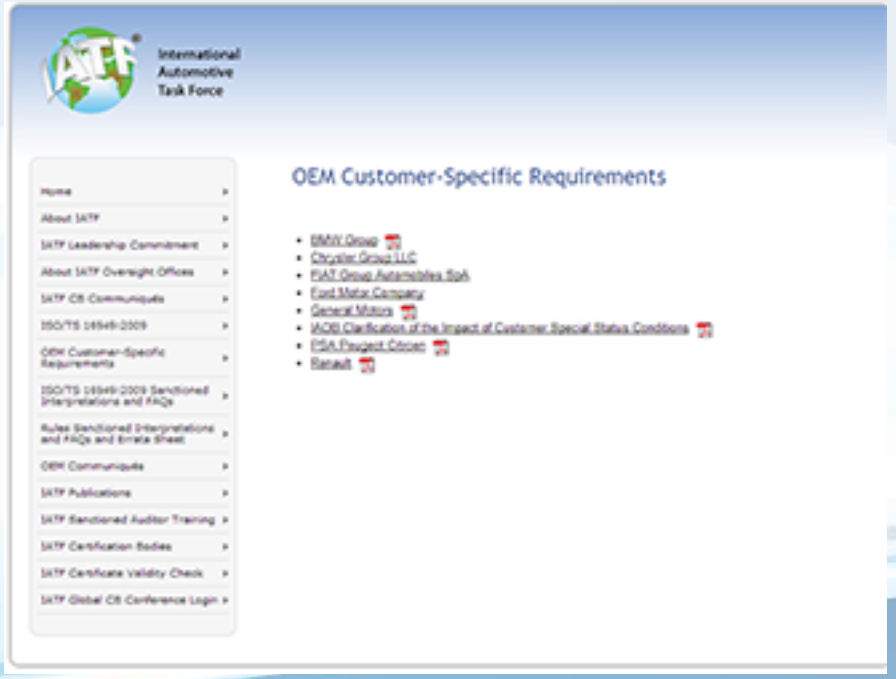
- There are eight different OEMs who subscribe to IATF 16949:
  - General Motors Company
  - FCA / Fiat Chrysler Automobiles
  - PSA Peugeot Citroen
  - Ford Motor Company
  - BMW Group
  - Daimler AG
  - Renault SA
  - Volkswagen AG
- IATF 16949:2016 requires that customer-specific requirements be integrated into the business processes of your quality management system.
- Customer-specific requirements are under constant revision, suppliers need to ensure they have the current versions.

Importance of Customer-Specific Requirements

- These requirements are implemented and maintained by using the process management approach.
- The internal audit process considers customer-specific requirements in planning for internal audits.
- Auditors must confirm that evidence is available to show effective implementation and effectiveness in practice.
- Management review includes the results of these audits, as well as other data to determine if customer-specific requirements are adequately addressed and effectively implemented.

Where to Locate Customer-Specific Requirements

- IATF web site (*http://www.iatfglobaloversight.org/*)
- Customer specific web sites
- Customer supplier quality manuals
- Customer purchase orders



Documents Available on IATF Web Site

- BMW Group
- Fiat Chrysler Automobiles US LLC
- FCA Italy SpA
- Ford Motor Company
- General Motors
- IAOB Clarification of the Impact of Customer Special Status Conditions
- PSA Peugeot Citroen
- Renault

Documenting and Organizing Customer-Specifics

- Identify your customer-specific documents
- Organize and categorize them by like topics
- Identify the process that implements the CSR topic
- Plan to verify conformance to CSR through two approaches:
  - **Document Review:** Review the content of Level 1 & 2 documents against the SHALLs in CSRs
  - **Process Audit:** Use the process auditing instructions to prepare for an on-site audit that collects evidence of CSRs in practice

Implementing CSR

- Implement the most rigorous requirement or deal with each customer in a different way.
- Omnex recommends documenting the customer-specific requirements into your process documentation.
- Where appropriate, highlight customer-specific requirements in the work instructions for the awareness of the person or persons working on that specific requirement.

Incorporating CSRs into the QMS

- Organizations must incorporate all the customer-specific requirements into their business processes in their QMS
- This requirement has a varying impact on organizations depending on their customer base and the number of customer-specific requirements
- Many organizations maintain one or more documents (such as a spreadsheet) where all the customer-specific requirements are defined
- In some instances, these requirements are already integrated into their business processes

Incorporating CSRs into the QMS

The following three-step strategy can be used to map CSRs into the organization's processes:

1. Identify and assemble all CSRs from the customer base
2. Create a matrix identifying all requirements (ISO 9001 / IATF 16949 and all CSRs)
   - For those organizations that supply multiple customers, the most comprehensive set of requirements should be used when building the matrix (e.g., Ford typically has the most comprehensive set of CSRs among the Big Three)
3. Once all requirements have been identified, select the processes or work instructions into which these requirements should be mapped
   - This matrix and subsequent processes will need to be updated when a contract review is conducted

Incorporating CSRs into the QMS

Sample CSR Matrix

ISO 9001 / IATF 16949	Ford	GM	FCA	Your Process
7.5.1	None	None	None	
7.5.1.1	None	None	None	
7.5.2	7.5.2 Documents of external origin	None	None	Control of Documented Information
7.5.3.1	None	None	None	
7.5.3.2	None	None	None	
7.5.3.2.1	7.5.3.2.1 Record Retention	7.5.3.2.1 Record Retention	7.5.3.2.1 Record Retention	Records Control
7.5.3.2.2	None	None	None	

Incorporating CSRs into the QMS

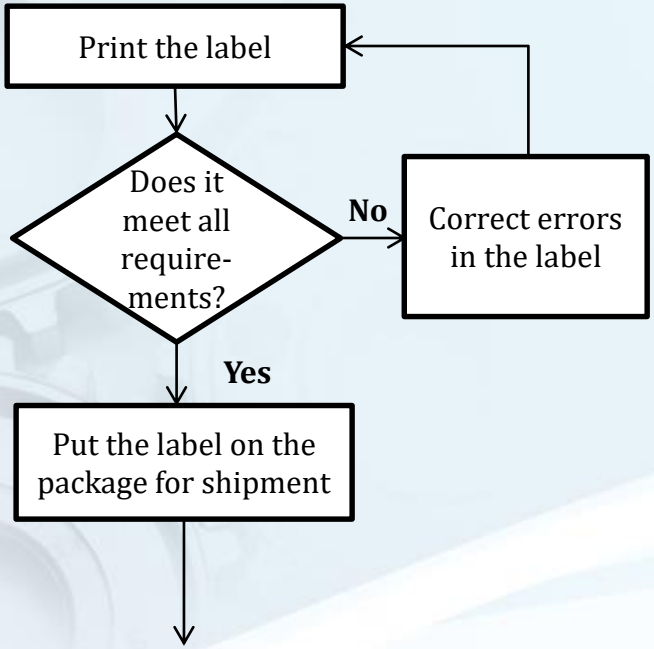
- We will review a few ways in which customer-specific requirements can be incorporated into an organization's business processes
  - Example 1: Customer-specific requirements included in the sequence of the process itself
  - Example 2: Linkages within the customer-specific documentation to specific processes where they are addressed
  - Example 3: Checklists used in the normal business process where customer-specific requirements are addressed

Incorporating CSRs into the QMS

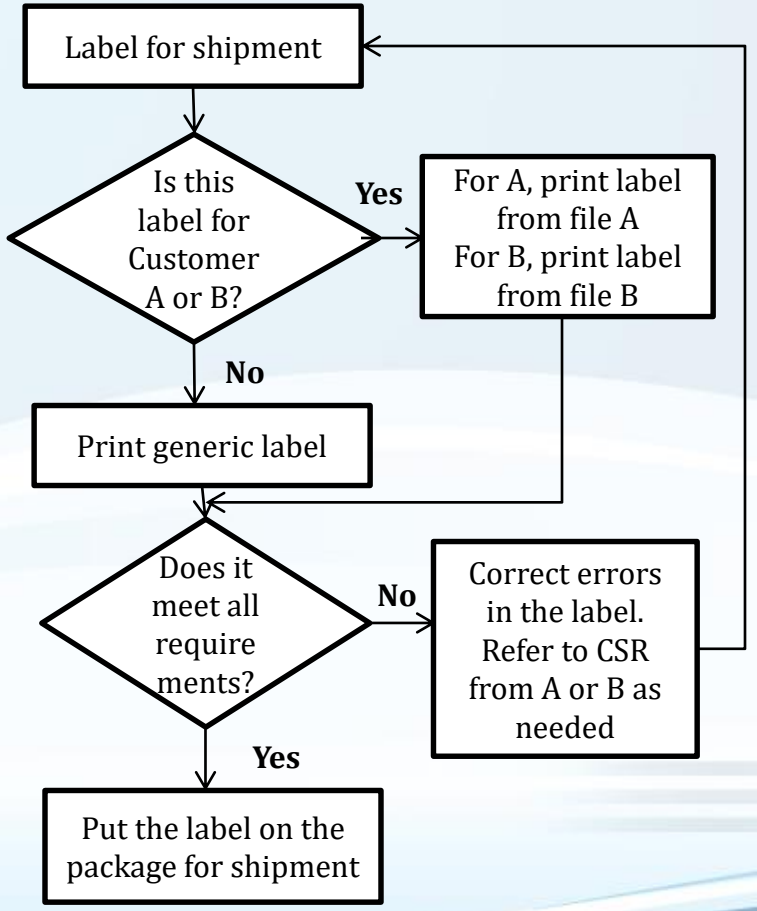
- **Example 1: Customer-specific requirements included in the sequence of the process itself**
  - We will consider the example where customers A and B have specific labeling requirements for their products
  - In this case, you can incorporate those requirements by including them directly into the process flow sequence
  - This assures that the customer-specific requirements are met as part of the normal business process and not as an additional requirement defined somewhere else
  - Use of automation ensures flawless execution of customer-specific requirements
  - This is probably the most robust and hence most effective solution

Process Flow: Before and After CSR Inclusion

Before



After



Incorporating CSRs into the QMS

- **Example 2: Linkages within the customer-specific requirements documentation to specific processes where the CSRs are addressed**
  - Identify various processes where the CSRs will be addressed
  - In the process description or flow, refer to the CSR with specific reference to understand what is requested
  - Include a verification step in the process flow so that customer-specific requirements are fulfilled
  - Show linkage in the CSR documentation as to where the CSR is addressed in the organization's business process

Linkages in the CSR Documentation

XYZ Requirement	XYZ CSR Description	Procedure Reference	Process Name
CSR_X.2	Packaging and Labeling - Starting with Delivery note, be able to trace all documents and records for product.	PD_5.5.2 PACKAGING / LABELING	Packaging / Labeling Process
CSR_X.2	Packaging and Labeling - Meet requirements in North American Labeling Requirements document	PD_5.5.2 PACKAGING / LABELING	Packaging / Labeling Process
CSR_X.2	Packaging and Labeling - Conduct periodic dock audits on packaged materials and retain evidence of such	PD_5.5.2 PACKAGING / LABELING	Packaging / Labeling Process
CSR_X.2	Packaging and Labeling - Includes cross ref to other XYZ requirements documents based on product line and region.	PD_5.5.2 PACKAGING / LABELING	Packaging / Labeling Process
CSR_X.3	PPAP-Submit per AIAG PPAP requirements. All submissions must have a copy of the drawing.	PD_3.6.3 PRODUCTION PART APPROVAL PROCESS	Production Part Approval Process
CSR_X.3	PPAP - Defines order of required PPAP documents in a table. Requires use of AIAG forms, unless approved by SDE. Requires copy of ELV/IMDS Reporting form C. Requires ES test plan and results (ES test by approved/accredited lab)	PD_3.6.3 PRODUCTION PART APPROVAL PROCESS	Production Part Approval Process
CSR_X.4	Lot Traceability requires lot definition and traceability procedure. Requires link to shipper number. Defines a lot. Requires suppliers to have traceability through the supply chain.	PD_5.3 PRODUCT IDENTIFICATION & TRACEABILITY	Product Identification and Traceability Process
CSR_X.5	SC's - Implement process controls for SC's defined by XYZ. Identify additional SC's as required. Determine Ppk during launch (1.67 requires). For variables, 100 piece sample, attributes 300 piece. Requires Cpk 1.33. Requires containment and action plans if either measure does not meet requirements. References table by system and region for SC definition and characteristics list.	PD_2.1 CONTRACT REVIEW	Contract Review Process
CSR_X.6	Prototype Fab, Quality Evaluation, Pre-Production Process Changes - Imitate the production process as closely as possible. Once parts are provided, notify XYZ of any process changes.	PD_3.6.3 PRODUCTION PART APPROVAL PROCESS	Production Part Approval Process
CSR_Y.2	Supplier Request for Change - Product or process changes require a written request and approval prior to implementation. R[illegible] requirements documents by product type and region in a [illegible]	PD_3.6.3 PRODUCTION PART APPROVAL PROCESS	Production Part Approval Process

CSR Linkages to Procedures and Processes in the QMS

Incorporating CSRs into the QMS

- **Example 3: Checklists used in the normal business process where customer-specific requirements are addressed**
  - On the next slide is an example of feasibility checklist which is done prior to the decision on whether to proceed with the project or not
  - The feasibility checklist (before) can be augmented by including customer-specific requirements (after)
  - Inclusion of customer-specific requirements in the checklist itself allows for their consideration in the feasibility/planning phase itself thereby assuring that they are taken into account
  - A similar planning/production checklist will be similarly inclusive of the customer-specific requirements at appropriate steps in the process

Checklist Example with CSR Inclusion

Before	After
Is product adequately defined to enable feasibility evaluation?	Is product adequately defined to enable feasibility evaluation?
Can Engineering Performance Specifications be met as written?	Can Engineering Performance Specifications be met as written?
Can product be manufactured to tolerances specified on drawing?	Can product be manufactured to tolerances specified on drawing?
Can product be manufactured with process capability that meets requirements?	Can product be manufactured with process capability that meets requirements? Any Customer-Specific Requirements ?
Is there adequate capacity to produce the product?	Is there adequate capacity to produce the product?
Does the design allow the use of efficient material handling techniques?	Does the design allow the use of efficient material handling techniques?
Can the product be manufactured within normal cost parameters? Abnormal cost considerations may include:	Can the product be manufactured within normal cost parameters? Are there customer designated sources affecting costs?
- Costs for capital equipment?	Costs for capital equipment?
- Costs for tooling?	Costs for tooling?
- Alternative manufacturing methods?	Alternative manufacturing methods?
- Is statistical process control required for this product?	Is statistical process control required for this product?
- Is statistical process control currently used on similar products?	Is statistical process control currently used on similar products?
Where statistical process control is used on similar products:	Where statistical process control is used on similar products:
- Are the processes in control and stable?	- Are the processes in control and stable?
- Does process capability meet customer requirements?	- Does process capability meet customer requirements?

CSR included in the Process Checklist

Planning and Preparing to Audit CSRs

- Determine the Requirements
- Analyze the Impact on Your Processes
- Determine How to Audit CSRs
  - Frequency?
  - Personnel involved?
  - Evidence?
  - Which audit trail(s)?
- Prepare an Audit Checklist
- Conduct the Audit
- Report the Results

Planning and Preparing to Audit CSRs

- CSRs are audited when processes are audited
- The best way to identify a gap in the CSRs is through a document review
- Add the CSR requirements to your audit checklist or Turtle analysis for an internal audit
- The audit plan needs to identify processes and not clauses
- When choosing processes to audit, prioritize them based on organizational performance, CSRs and COPs
- Identify the customer-specific requirements related to the process being audited
- Ensure all customer-specific requirements are audited

Process Audit with Emphasis on CSRs

- Sample the process with focus on CSRs… are they following the process? Are CSRs effectively implemented?
- Are the results of the process consistent with their organizational goals? Are customer requirements being met?
- Are they getting results? Are there any customer complaints?
- Before you go from the area being audited, review the Audit Checklist and make sure that you audited all areas and CSRs required.
- If you did not already do so, ask about them before you move on.

Chapter 13: Customer-Specific Requirements — What We Covered

Learning Objectives

You should now be able to:

- Describe the importance of Customer-Specific Requirements and how they affect the auditing of IATF 16949
- Incorporate CSRs into an organization's processes

Chapter Agenda

- Overview of CSRs
- Importance of CSRs
- Examples of incorporating CSRs into business processes
- Planning and Preparation to Audit CSRs

Thank You!

Questions?

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