AS9100D Auditor Training

Quality Management Systems for Aviation, Space and Defense Organizations

QUALITY

OMNEX

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

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Course Objectives

- Provide sufficient knowledge and understanding of the various clauses and requirements of the ISO 9001:2015 and AS9100D standards.
- Provide guidance for the planning, preparation and delivery of quality management system audits in accordance with the requirements and guidelines of ISO 19011 and AS9101F.
- Provide training for auditors in accordance with the criteria set in ISO 19011.
- Provide participants with adequate skills in the Exemplar Global specified competencies to provide for participants to become a certified Exemplar Global QM Auditor.

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END OF EXEMPLAR GLOBAL-AU COMPETENCY

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Throughout this course, AS9100D-specific requirements are highlighted by **Bold Red Underlined** text

Acronyms Referenced in This Training

8D	Eight Disciplines of Problem Solving Methodology
9S	9 Step Problem Solving Methodology
APQP	Advanced Product Quality Planning
ARP	Aerospace Recommended Practice
ASD	Aviation, Space and Defense
CAR	Corrective Action Request
CFR	Code of Federal Regulations
DCMA	Defense Contract Management Agency
DQR	Delegated Quality Representative
FAI / FAIR	First Article Inspection / First Article Inspection Report
S/D/P FMEA	System/Design/Process Failure Mode and Effects Analysis
FOD	Foreign Object Damage (or Debris)
IAQG	International Aerospace Quality Group

Acronyms Referenced in This Training

MRB	Material Review Board
MSA	Measurement System Analysis
NCR	Nonconformity Report
PDCA	Plan-Do-Check-Act Methodology
PEAR	Process Effectiveness Assessment Report
PPAP	Production Part Approval Process
QMS / AQMS	Quality Management System / Aerospace Quality Management System
RCCA	Root Cause and Corrective Action
SAE	Society for Automotive Engineers
SPC	Statistical Process Control
SQR	Supplier Quality Representative/Resident

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 no longer maintains aerospace auditor authentication. Those activities have been transferred to Probitas Authentication. This course does fulfill the knowledge requirements for an Exemplar Global QMS auditor as well as ISO 9001 Lead Auditor training as required by AS9103/4 (Lead Auditor course only).

Exemplar Global Competency Units

Management Systems Auditing (Exemplar Global-AU)

- Understand the applicationof the principles, procedures and techniques of auditing. OMNEX
- 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.

Exemplar Global Competency Units

Leading Management Systems Audit Teams (Exemplar Global-TL)

- Establish, plan and task the activities of an audit team.
- Communicate effectively with the auditee and audit client.
- Organize and direct audit team members.
- Prevent and resolve conflict with the auditee and/or within the audit team.
- Prepare and complete the audit report.

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 AS9100.

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 on 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. o.m.n.ex
- Workforce of over 700 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

Omnex Worldwide Offices

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

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

www.omnex.com
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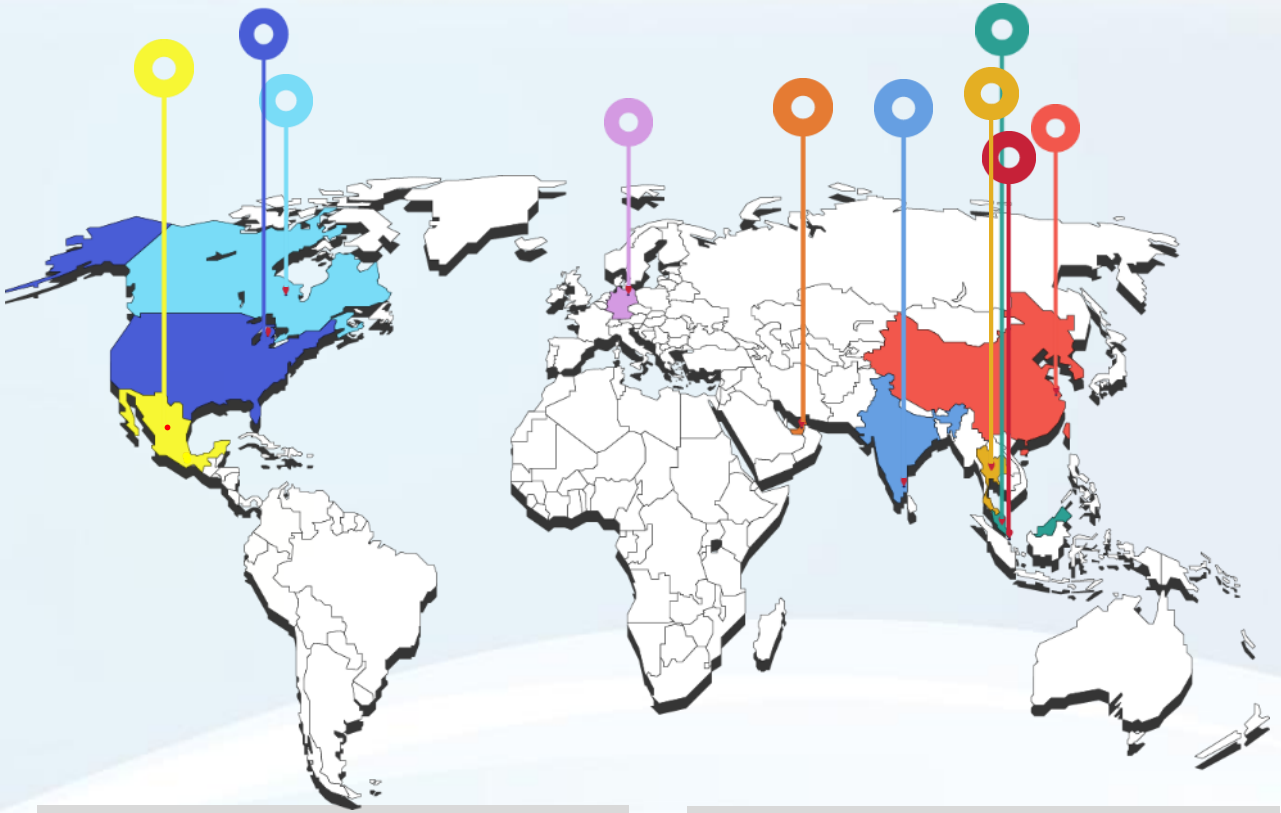


- Omnex Global Head Quarters (Michigan, USA)
  West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico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

OMNEX

Rules of the Classroom

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

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

Icebreaker

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

Chapter 1

The ISO 9000 & AS9100 Family of Standards Explained

Chapter 1: The QMS Standards Explained — What We Will Cover

Learning Objectives

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

- Describe the three documents pertaining to a QMS as well as the Aerospace series of standards
- Understand the relationship to ISO 9000:2015 and standard definitions
- Be aware of additional definitions in the AS9100 series of standards

Chapter Agenda

- ISO 9000 Series of Quality Management Documents
- Aerospace Series of Standards
- QMS clauses with Aerospace Additions
- Key Definitions in ISO 9000:2015 and AS9100D
- Other Related Documents

ISO 9000 SERIES OF QUALITY MANAGEMENT DOCUMENTS

The ISO 9000 Family of Documents

ISO 9001
System
Requirements

ISO 9001 – Specific Requirements for a Quality Management System

ISO 9000
Fundamentals and
Vocabulary

ISO 9000 – Fundamental Concepts and Principles of Quality Management

ISO 9004
Guidance to Achieve
Sustained Success

ISO 9004 — Guidance for Performance Improvement

Every five years, ISO reviews a standard to ensure its continuing suitability; it may or may not be revised at that time

ISO 9001 International Standard

ISO 9001
System Requirements

- Specifies requirements aimed primarily at bestowing confidence in the products and services provided by an organization and thereby improving customer satisfaction
- Its proper implementation can also be expected to bring other organizational benefits such as improved internal communication, better understanding and control of the organization's processes, and reduction in defects and waste
- Applies to all organizations, regardless of type, size and product provided

ISO 9001:2015/AS9100D Clauses

1. **Scope**
2. **Normative References**
3. **Terms and Definitions**
4. **Context of the Organization**
   - 4.1 Understanding the Organization and its Context
   - 4.2 Understanding the Needs and Expectations of Interested Parties
   - 4.3 Determining the Scope of the QMS
   - 4.4 QMS and its Processes
5. **Leadership**
   - 5.1 Leadership and Commitment
     - 5.1.2 Customer Focus
   - 5.2 Policy
     - 5.2.1 Establishing the Quality Policy
     - 5.2.2 Communicating the Quality Policy
   - 5.3 Organizational Roles, Responsibilities and Authorities
6. **Planning**
   - 6.1 Actions to Address Risks and Opportunities
   - 6.2 Quality Objectives and Planning to Achieve Them
   - 6.3 Planning of Changes
7. **Support**
   - 7.1 Resources
     - 7.1.2 People
     - 7.1.3 Infrastructure
     - 7.1.4 Environment for the Operation of Processes
     - 7.1.5 Monitoring and Measuring Resources
       - 7.1.5.2 Measurement Traceability
     - 7.1.6 Organizational Knowledge
   - 7.2 Competence
   - 7.3 Awareness
   - 7.4 Communication
   - 7.5 Documented Information
     - 7.5.2 Creating and Updating
     - 7.5.3 Control of Documented Information

ISO 9001:2015/AS9100D Clauses

8. Operation

8.1 Operational Planning and Control

8.1.1 Operational Risk Management

8.1.2 Configuration Management

8.1.3 Product Safety

8.1.4 Prevention of Counterfeit Parts

8.2 Requirements for Products and Services

8.2.1 Customer Communication

8.2.2 Determining the Requirements for Products and Services

8.2.3 Review of Requirements for Products and Services

8.2.4 Changes to Requirements for Products and Services

8.3 Design and Development of Products and Services

8.3.2 Design and Development Planning

8.3.3 Design and Development Inputs

8.3.4 Design and Development Controls

8.3.5 Design and Development Outputs

8.3.6 Design and Development Changes

8. Operation *(cont'd)*

8.4 Control of Externally Provided Processes, Products and Services

8.4.2 Type and Extent of Control

8.4.3 Information for External Providers

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

8.5.1.1 Control of Equipment, Tools and Software Programs

8.5.1.2 Validation and Control of Special Processes

8.5.1.3 Production Process Verification

8.5.2 Identification and Traceability

8.5.3 Property Belonging to Customers or External Providers

8.5.4 Preservation

8.5.5 Post-delivery Activities

8.5.6 Control of Changes

8.6 Release of Products and Services

8.7 Control of Nonconforming Outputs

ISO 9001:2015/AS9100D Clauses

9. Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.2 Customer Satisfaction

9.1.3 Analysis and Evaluation

9.2 Internal Audit

9.3 Management Review

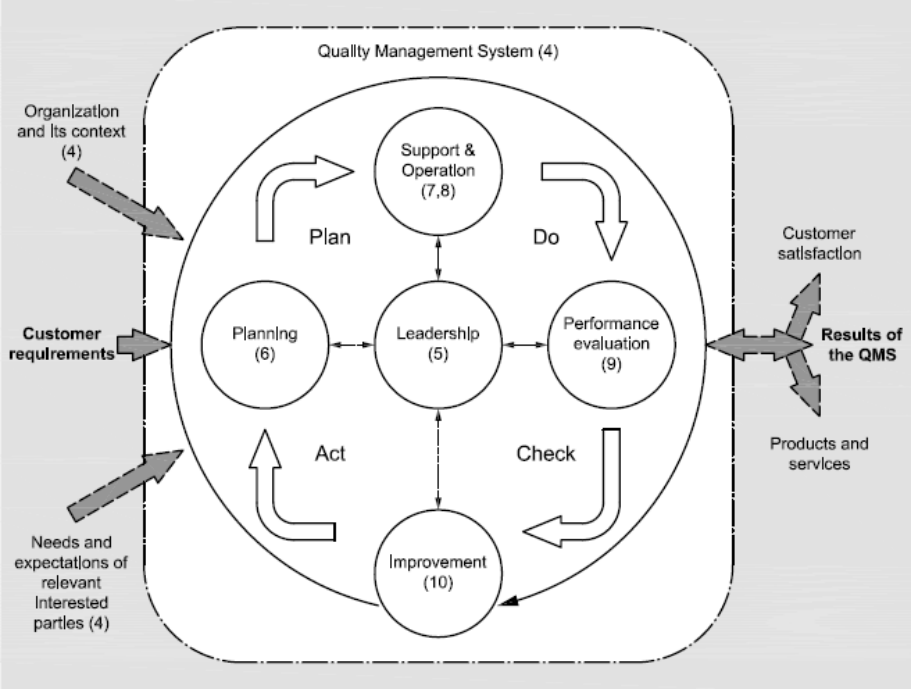
9.3.2 Management Review Inputs

9.3.3 Management Review Outputs

10. Improvement

10.2 Nonconformity and Corrective Action

10.3 Continual Improvement



source: ISO 9001:2015

ISO 9000 Fundamentals and Vocabulary

ISO 9000
Fundamentals and Vocabulary

- ***Fundamentals and Vocabulary*** provides an essential background for the proper understanding and implementation of ISO 9001 and AS9100.
- These principles are not requirements in themselves, but they form the foundation of the requirements specified by ISO 9001 and AS9100.
- ISO 9000 is a normative **(mandatory)** reference in both ISO 9001 and AS9100, which means the terms and definitions must be used with both standards.

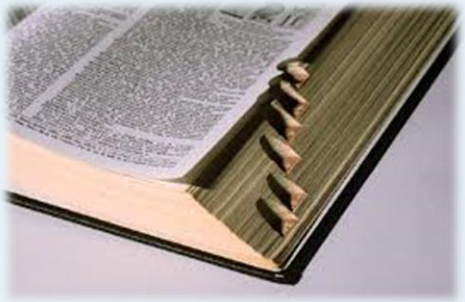
High Level Structure (HLS) Core Terminology — Changes and Additions

- 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

Terminology



- There is no requirement for the terms used by an organization to be replaced by the terms used in ISO 9001 and AS9100.
- Organizations can use other terms which suit their operations, e.g., using "*records*", "*documentation*" or "*protocols*" rather than "**documented information**" or "*supplier*", "*partner*" or "*vendor*" rather than "**external provider**".

* Documented information is information required to be controlled and maintained by an organization and the medium on which it is contained.

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".

Additional Definitions in AS9100D

- **Counterfeit Part:**
  - An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.
    - NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.
- **Critical Items:**
  - Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

Additional Definitions in AS9100D

- **Key Characteristic**
  - An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

- **Product Safety** O-M-N-E-X
  - The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

Additional Definitions in AS9100D

- **Special Requirements**
  - **Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special characteristics include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.**

    NOTE: Special requirements and critical items, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

ISO 9004:2018 Guidance

Focus is on Sustained Success

ISO 9004
Performance Improvement

- *A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of ISO 9001 to address a broader range of topics that can lead to continual improvement of the organization's overall performance.

- ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

AS9100 SERIES OF QUALITY MANAGEMENT DOCUMENTS

International Aerospace Quality Group (IAQG)

and

Affiliated Regional Organizations

American (AAQG), European (EAQG) and Asia-Pacific (APAQG)

International Aerospace Quality Group

- The IAQG is a cooperative global organization of companies providing:
  - Aviation and Space products and services
  - Land and Sea based systems for defense
- **Americas Aerospace Quality Group (AAQG)**: 21 members
- **Asia Pacific Aerospace Quality Group (APAQG)**: 25 members
- **European Aerospace Quality Group (EAQG):** 26 members

IAQG Standards

IAQG Published / Registered Standards

	#	Title	Americas (English)	Asia-Pacific (Japanese)	European (English)
b	9100	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations	AS9100D	JISQ9100	prEN 9100 P4
c	9101	Quality Management Systems Audit Requirements for Aviation, Space, and Defense Organizations	AS9101F	SJAC9101	prEN 9101 P8
b	9102	Aerospace First Article Inspection Requirement	AS9102B	SJAC9102	prEN 9102 P3
d	9103A	Quality Management Systems - Variation Management of Key Characteristics	AS9103A	SJAC9103	EN 9103
c	9104/1	Requirements for Aviation, Space, and Defense Quality Management System Certification Programs	AS9104/1	SJAC9104/1	EN-9104/1
c	9104/2	Requirements for Oversight of Aerospace Quality Management System Registration/certification Programs	AS9104/2A	SJAC9104/2	EN 9104-002
c	9104/3	Requirements for Aerospace Auditor Competency and Training Courses	AS9104/3	SJAC9104/3	EN-9104/3
d	9107	Direct Delivery Authorization Guidance for Aerospace Companies	ARP9107A		prEN 9107 P2
b	9110	Quality Management Systems - Requirements for Aviation Maintenance Organizations	AS9110C	SJAC9110	prEN 9110 P5
d	9114	Direct Ship Guidance for Aerospace Companies	ARP9114A		EN 9114:2016
b	9115	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - Deliverable Software	AS 9115A	SJAC9115	prEN9115P2

Color Code Key

a	Under Development
b	Certification required based on organization business
c	Auditing regulation
d	Guidance standards
e	Optional Standards required when invoked by the customer

IAQG Standards

IAQG Published / Registered Standards

	#	Title	Americas (English)	Asia-Pacific (Japanese)	European (English)
e	9116	Notification of Change (NOC) Requirements	AS9116	SJAC9116	EN 9116:2016
e	9117	Delegated Product Release Verification	AS9117		prEN 9117 P1
b	9120	Quality Management Systems - Requirements for Aviation, Space and Defense Distributors	AS9120B	SJAC9120	prEN 9120 P5
e	9131	Aerospace Series - Quality Management Systems - Nonconformance Data Definition and Documentation	AS9131C	SJAC9131	EN 9131
e	9132	Data Matrix Quality Requirements for Parts Marking	AS9132B	SJAC9132	prEN 9132 P3
e	9133	Qualification Procedure for Aerospace Standard Parts	AS9133A		prEN 9133 P2
d	9134	Supply Chain Risk Management Guideline	ARP9134A		prEN9134 P1
e	9136	Root Cause Analysis and Problem Solving (9S Methodology)	ARP9136	SJAC9136	prEN 9136 P1
d	9137	Guidance for the Application of AQAP 2110 within a 9100 Quality Management System	ARP9137	SJAC9137	EN-9137
e	9138	Quality Management Systems Statistical Product Acceptance Requirements	AS9138		prEN9138 P1
e	9145	Requirements for Advanced Product Quality Planning and Production Part Approval Process	AS9145		prEN 9145 P1
e	9146	Foreign Object Damage (FOD) Prevention Program - Requirements for Aviation, Space, and Defense Organizations	AS9146	SJAC9146	prEN9146 P1
e	9162	Aerospace Operator Self-Verification Programs	AS9162	SJAC9162	prEN 9162 P2

Color Code Key

a	Under Development
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What is AS9100?

- Sector-specific ISO 9001 application document developed by IAQG and distributed by the Society for Automotive Engineers (SAE)

- Intended for use by organizations that:
  - design, develop and/or produce aviation, space and defense products; and
  - by organizations providing post-delivery support, including the provision of maintenance, delivered software, spare parts or materials for their own products.

- Third party certification is required of suppliers

Why AS9100?

- To standardize aerospace quality expectations on a global level
- To achieve improvements in quality and delivery performance, and to reduce costs throughout the value stream
- Incorporate regulatory requirements and the importance of safety, reliability or maintainability, elements not adequately addressed in ISO 9001
- Captures aerospace supplements agreed upon at an international level

AS9100 Revision

Release: September 2016

- Objectives of revision
  - Incorporate the new clause structure and content of ISO 9001:2015
  - Respond to, and address, changes in stakeholder needs
  - Ensure alignment with IAQG strategy for On-Time and On-Quality Delivery (OTOQD) performance
  - Adopt new requirements based on stakeholder needs, including clarification of existing requirements

AS9100-series QMS Scope

- AS9100 Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
- AS9110 Quality Management Systems – Requirements for Aviation Maintenance Organizations
- AS9115 Quality Management Systems – Requirements for Deliverable Software
- AS9120 Quality Management Systems – Requirements for Aviation, Space and Defense Distributors

AS9100-series QMS Intended Application

- **ISO 9001:** All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.
- **AS9100:** This standard is intended for use by organizations that design, develop and/or produce aviation, space and defense products; and by organizations providing post-delivery support, including the provision of maintenance, spare parts or materials for their own products.
- **AS9110:** Organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair and overhaul operations that are operated autonomously, or that are substantiality different form their production operations; should use the IAQG-developed AS9110 standard.
  - **Note:** Certification to AS9110 is not a replacement for repair station certification issued by the FAA according to 14 CFR (Code of Federal Regulation) Part 145 Repair Station.

AS9100-series QMS Application

- **AS9115:** Organizations whose products are deliverable software, or contain deliverable software, should use the IAQG-developed AS9115 standard when planning and evaluating the software design, development, or management activities of the organization. The AS9115 standard provides guidance to the requirements of the AS9100 standard when it is desired to add “software” to the AS9100 quality management system scope.

- **AS9120:** Organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space and defense industry should use the IAQG-developed AS9120 standard. This includes organizations that procure products and split them into smaller quantities, as well as those that coordinate a customer or regulatory controlled process on the product.

Guidance and Optional IAQG Standards

AS9102B Aerospace First Article Inspection Requirement

- Standardizes FAI process requirements that can be used to validate product realization processes are capable of producing parts and assemblies meet engineering and design requirements, as well as:
  - Demonstrate that manufacturers and processes are capable of producing conforming product
  - Reduce potential risks associated with production startup and/or process changes
  - Assure product conformance at the start of production and after changes

AS9103A Variation Management of Key Characteristics

- Drives improvement of manufacturing and maintenance processes through effective management of key characteristic variation.
- Improves confidence for part features whose variation has a influence on to end-product form, fit, performance, service life and producibility.

Guidance and Optional IAQG Standards

AS9107 Direct Delivery Authorization Guidance for Aerospace Companies

- Guidance to fulfill a Production Organization (PO) request to have Direct Delivery Authorization (DDA) and an Appropriate Arrangement (AA) between the PO and Design Organization (DO).
  - DO is responsible for ensuring continuous updates of the design and airworthiness to the PO.
  - PO is responsible for assuring the article conforms to Approved Design and Airworthiness Data, as well as providing airworthiness release documentation.

ARP9114A Direct Ship Guidelines for Aerospace Companies

- Guidance for approved manufacturers, their suppliers, and customers when a supplier is requested to ship an article against the approved manufacturer's purchase document directly to a customer.
- Standardization of requirements eliminates or reduces organization-unique requirements, resulting in improved quality and safety, and decreased costs.

Guidance and Optional IAQG Standards

AS9116 Aerospace Series – Notice of Change (NOC) Requirements

- Provides a structure for submitting and managing change notification data and/or approvals that allows for concise an accurate communication using a variety of methods.
- Defines a data set that can be integrated into any form of communication (e.g., electronic data interchange, submission of paper forms).

AS9117 Delegated Product Release Verification

- Establishes common DPRV product/service requirements for use at all levels of the supply chain.

Guidance and Optional IAQG Standards

AS9131C Nonconformance Data Definition and Documentation

- Sets common requirements for nonconformance data definition and documentation exchanged between suppliers and the customer when a nonconformity that requires a formal decision is reported.
- Ensures accurate communication in submitting and managing nonconformance data, resulting in improved quality and safety, and decreased costs.

AS9132B Data Matrix Quality Requirements for Parts Making

- Establishes uniform quality and technical requirements for the marking of metallic parts using data matrix symbology.

AS9133A Qualification Procedure for Aerospace Standard Products

- Defines principles to follow when carrying out product qualification in order to enable the Certification Authority to confirm compliance in accordance with the product definition and associated controlling technical specifications by the Original Component Manufacturer.

Guidance and Optional IAQG Standards

ARP9134A Supply Chain Risk Management Guideline

- Focuses on Quality as a key risk assessment factor taking into account elements with a direct link to global quality management.
- Serves as a business protection tool used to identify and reduce risks when generating new business with new and existing suppliers.

ARP9136 Aerospace Series – Root Cause Analysis and Problem Solving (9S Methodology)

- Develops a methodology to put in place processes that detect and eliminate significant and recurrent issues (e.g., undesirable conditions, defects, failures).
  - Accomplished through well identified problems, common understanding of their impact and associated root causes, and defined and implemented actions
- Improves the way escapes and issues are managed, including communication between all parties, in order to reduce their impact, contain them as far upstream as possible, and prevent recurrence.

Guidance and Optional IAQG Standards

ARP9137 Guidance for the Application of AQAP 2110 within a 9100 QMS

- Provides information and guidance for applying AQAP 2110 (NATO Quality Assurance Requirements) when the supplier follows AS9100.

AS9138 QMS Statistical Product Acceptance Requirements

- Establishes statistical product acceptance methods to meet defined risk requirements and the minimum content that must be covered in documented procedures that govern statistical product acceptance methods.

AS9145 Requirements for APQP and PPAP

- Establishes a uniform approach to product realization to ensure quality products are delivered on time while also satisfying cost performance targets.

Guidance and Optional IAQG Standards

AS9146 Foreign Object Damage Prevention Program

- Defines the requirements for a FOD Prevention Program for organizations that design, develop and provide products and services, as well as those that provide post-delivery support, including the provision of maintenance, spare parts, or materials for their own products and services.

AS9162 Aerospace Operator Self-Verification Programs

- Provides a standard structure for operator self-verification programs for producers of commercial and military aircraft and weapons platforms, space vehicles, and all related hardware, software, electronics, engines and composite components.
- Self-verification programs are applied to Improve the overall efficiency and product quality of processes considered stable and capable of fulfilling all requirements.

Other Related Documents

- **NEW! ISO/TS 9002 – Quality management systems – Guidelines for the application of ISO 9001:2015** for:
  - Suppliers involved in the application of ISO 9001:2015;
  - Customers and third parties
- Other guidelines that have been developed to support the implementation of a quality management system include those in the ISO 10000 number range, for example:
  - Customer satisfaction
  - Quality plans
  - Quality management in projects
  - Configuration management
  - Measurement processes and measuring equipment
  - Documentation
  - Financial and economic benefits of quality management
  - Training
  - Statistical techniques
  - The involvement and competence of people
  - Selection of quality management system consultants
  - Auditing of management systems

Chapter 1: The QMS Standards Explained — What We Covered

Learning Objectives

You should now be able to:

- Describe the three documents pertaining to a QMS as well as the Aerospace series of standards
- Understand the relationship to ISO 9000:2015 and standard definitions
- Be aware of additional definitions in the AS9100 series of standards

Chapter Agenda

- ISO 9000 Series of Quality Management Documents
- Aerospace Series of Standards
- QMS clauses with Aerospace Additions
- Key Definitions in ISO 9000:2015 and AS9100D
- Other Related Documents

Chapter 2

Introduction to ISO 9001 and AS9100D

QUALITY

OMNEX

Chapter 2: Intro to ISO 9001 and AS9100 — What We Will Cover

Learning Objectives

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

- List the Quality Management Principles
- Explain how the process approach is used with a QMS
- Explain how risk is addressed in the standard

Chapter Agenda

- Quality Management Principles
- The Process Approach
- Risk-based Thinking

QUALITY MANAGEMENT PRINCIPLES

Quality Management Principles

ISO 9001 is based on these quality management principles

2008 version (8 Principles):

- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

2015 version (7 Principles):

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

THE PROCESS APPROACH

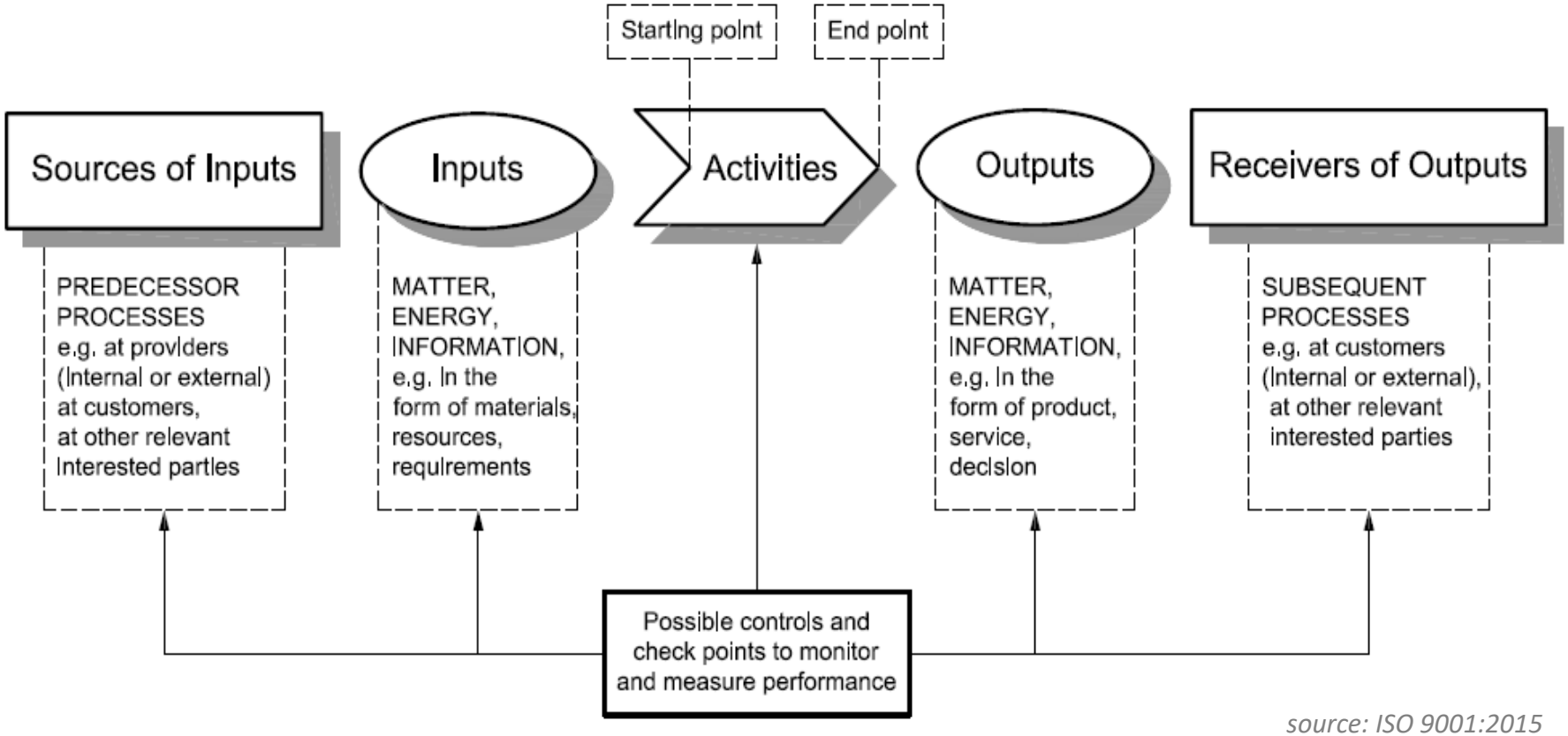
The Process Approach

- ISO 9001 promotes the adoption of a process approach when developing, implementing and improving QMS effectiveness.
- Specific requirements considered essential to the adoption of a process approach are found in clause **4.4**.
- Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results.
- This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The Process Approach

- Applies systematic definition, management of processes and their interactions to achieve the intended results aligned with the Quality Policy and strategic direction of the organization. O$M$$NEX
- Management of the processes and the system as a whole can be achieved using a "**Plan-Do-Check-Act**" (**PDCA**) methodology with an overall focus on ***risk-based thinking*** aimed at leveraging opportunities and preventing undesirable outcomes.
- Use of the process approach enables:
  - Understanding and meeting requirements
  - The consideration of processes in terms of what is "*value-added*"
  - The achievement of effective process performance
  - Improvement of processes based on evaluation of data and information

A Process and the Interaction of its Elements



source: ISO 9001:2015

Process Characteristics — Guidance

- Processes are identified by a series of unique, but consistent, characteristics.
- There are six characteristics of a process that are recommended for effective quality management:
  - A process owner exists;
  - The process is defined;
  - The process is documented;
  - The linkages of the process are established;
  - The process is monitored and improved;
  - Records are necessary.
- The standard does require documented information determined by the organization as being necessary for the effectiveness of the QMS.

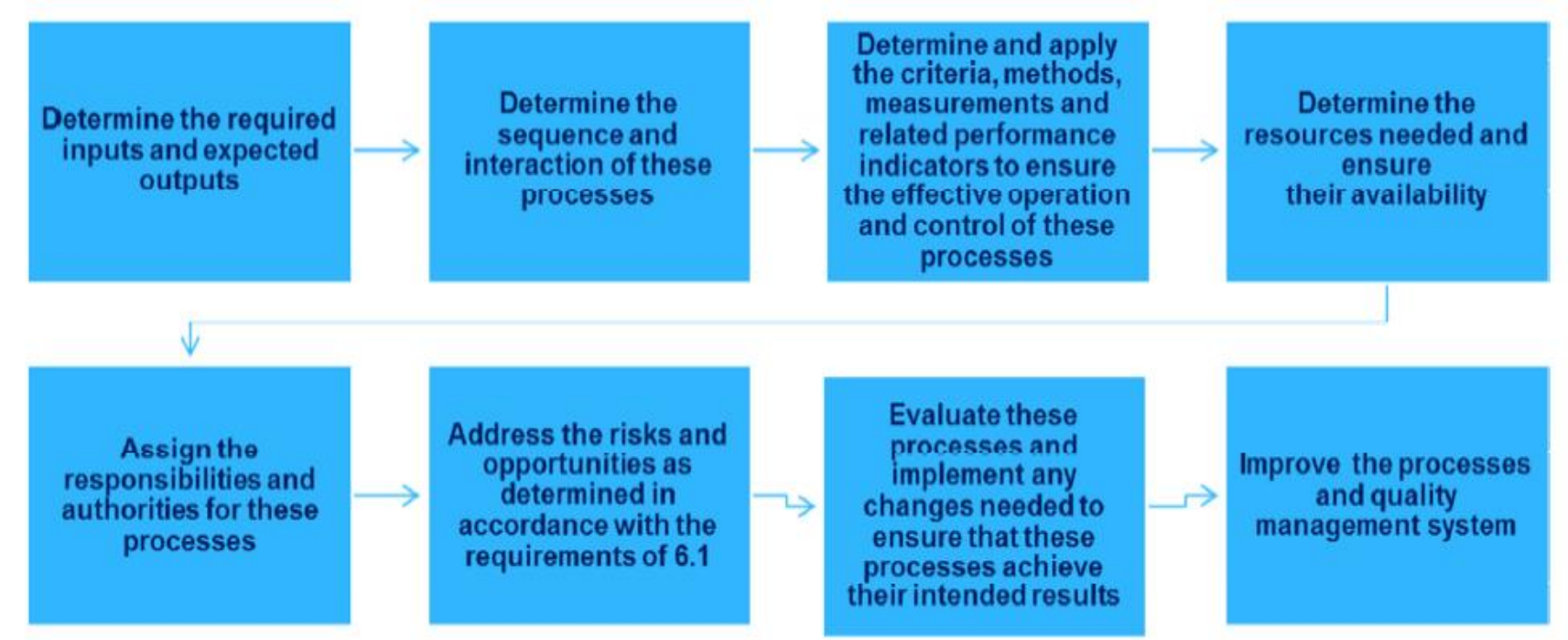
Guidance on Processes

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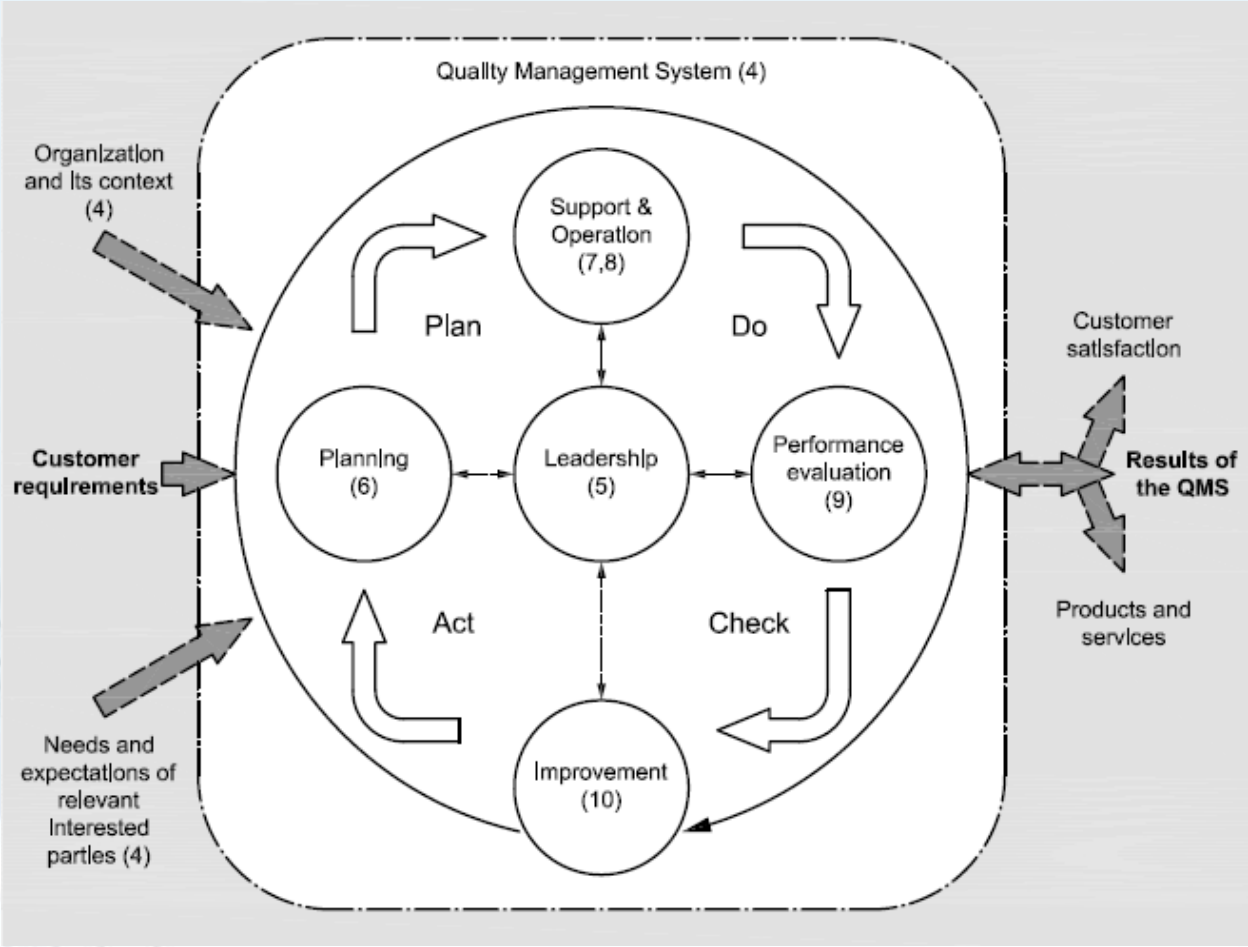
http://isotc.iso.org/livelink/livelink/fetch/3541460/17525573/APG-Processes2015.pdf?nodeid=17531167&vernum=-2

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

RISK-BASED THINKING

Risk Is "Immature" Concept in ISO Documents

- 157 ISO standards use the word "**risk**" and together have 45 unique definitions (21 specialized to hazards)
- Of these, most only consider events with negative outcomes:
  - "*A function of the probability of occurrence of a given threat and the potential adverse consequences of that threat's occurrence*"
- There is a subset that takes a broader view of risk…
  - "T*he effect of uncertainty.*"
  - "T*he combination of the consequences of an event and the associated likelihood of its occurrence.*"
  - These are consistent with PMBOK definition "*uncertain event or condition that, if it occurs, has a positive or negative effect on a project's objectives.*"*

* Source: A Guide to the Project Management Body of Knowledge (PMBOK® Guide) — Fourth Edition

Risk-Based Thinking

ISO 9001:2015 makes risk-based thinking a requirement

- Risks and opportunities are determined and addressed:
  - Implement actions to address risk
  - No requirement for formal methods for risk management or a documented risk management process
- QMS is a preventive tool…
  - No need to have a separate clause or sub-clause titled **Preventive Action.**
  - The concept of preventive action is expressed through a risk-based approach to formulating QMS requirements.
- **In AS9100D, Operational Risk is addressed directly in 8.1.1**

Risk-Based Thinking

- Risk is defined in ISO 9000 as the effect of uncertainty.
  - Uncertainty is the state—even partial—of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- All processes do not have the same level of risk in terms of the organization's ability to meet its objectives.
- The consequences of process, product, service or system nonconformities are not the same for all organizations.
- Opportunities can arise as a result of a situation favorable to achieving an intended result.
- Opportunity is not the positive side of risk.
- An opportunity is a set of circumstances which makes it possible to do something.
  - Taking or not taking an opportunity then presents different levels of risk.

Risk in ISO 9001

Legend

Refers to Risk-Based Thinking

Refers to Risk Implementation

Refers to Check and Act Cycles

Number of Times Risk or Risk-Based Thinking Appears in the Normative Portion of the Standard

Clause Number	Title	Explanation
4.4.1	No title – 4.4 – QMS and its Processes	QMS process risk and opportunities
5.1.1	*Leadership and Commitment – General*	*Promoting the use of the process approach and risk-based thinking*
5.1.2	Customer Focus	Risk and opportunities that can affect conformity of products and services – this then is broad
6.1	Actions to Address Risk and Opportunities	Appears in title
6.1.1	No title	Consider risk and opportunities as it relates to context of the organization and interested party expectations so that the QMS achieves its "intended results" or i.e., its objectives including improvement. This is the definition that now appears in ISO 31000.
6.1.2	No title – risk appears twice	Plan actions to address risk and opportunities and including their effectiveness
9.1.3	Analysis and Evaluation	Effectiveness of actions taken to address risk and opportunities
9.3.2	Management Review Inputs	Effectiveness of actions taken to address risk and opportunities as it relates to Planning (6.1)
10.2.1	Nonconformity and Corrective Action	update risks and opportunities determined during planning, if necessary

ISO 31000:2018 provides guidelines on managing risk

AS9100D, also addresses risk in 8.1, 8.1.1, 8.1.3, 8.2.2, 8.4.1, 8.4.2, 8.5.1.2, and 9.3.3

Project Risk — Guidance

- Resources
  - Project team with defined roles and responsibilities in place
  - Adequate budget secured
  - Suppliers are involved
  - Work load is taken into account in resource planning
- Timing
  - Project plan in place with internal and external milestones, critical path identified and is used to plan for resources
  - Addresses customer requirements
  - Escalation process in place to resolve “roadblocks” in a timely manner and includes “triggers” and timing
- Change
  - Change management process includes customer, including approval as applicable, and supply chain
  - Process specifies responsibilities and authorities including escalation

Chapter 2: Intro to ISO 9001 and AS9100 — What We Covered

Learning Objectives

You should now be able to:

- List the Quality Management Principles
- Explain how the process approach is used with a QMS
- Explain how risk is addressed in the standard

Chapter Agenda

- Quality Management Principles
- The Process Approach
- Risk-based Thinking

Chapter 3

Aviation, Space & Defense QMS: ISO 9001:2015 and AS9100D Supplemental Requirements

Chapter 3: ISO 9001:2015 and AS9100D Requirements — What We Will Cover

Learning Objectives

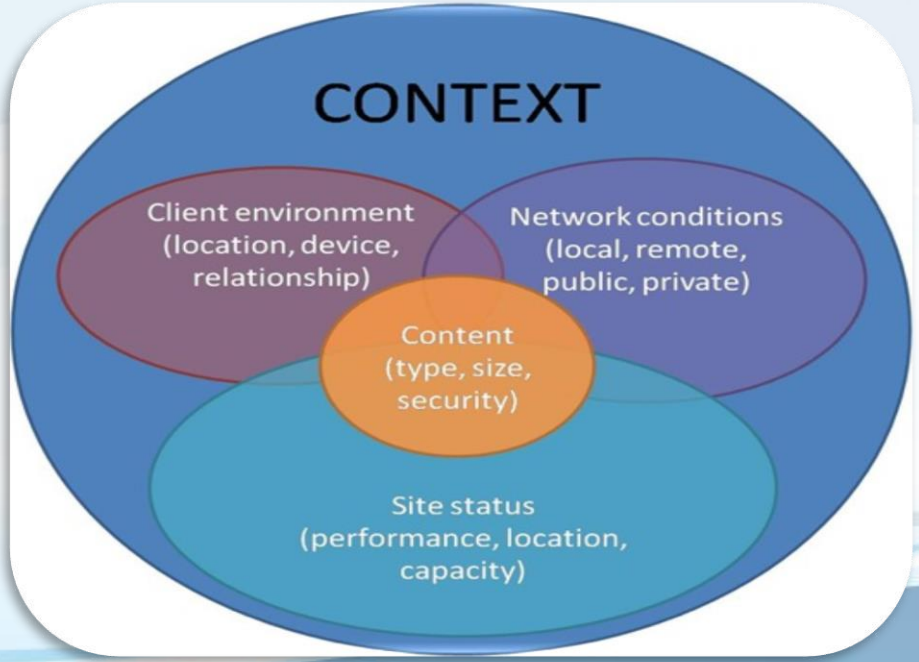
At the end of this chapter, you will be able to:

- 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 – Assessing Risk**
- 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**

CLAUSE 4 — CONTEXT OF THE ORGANIZATION



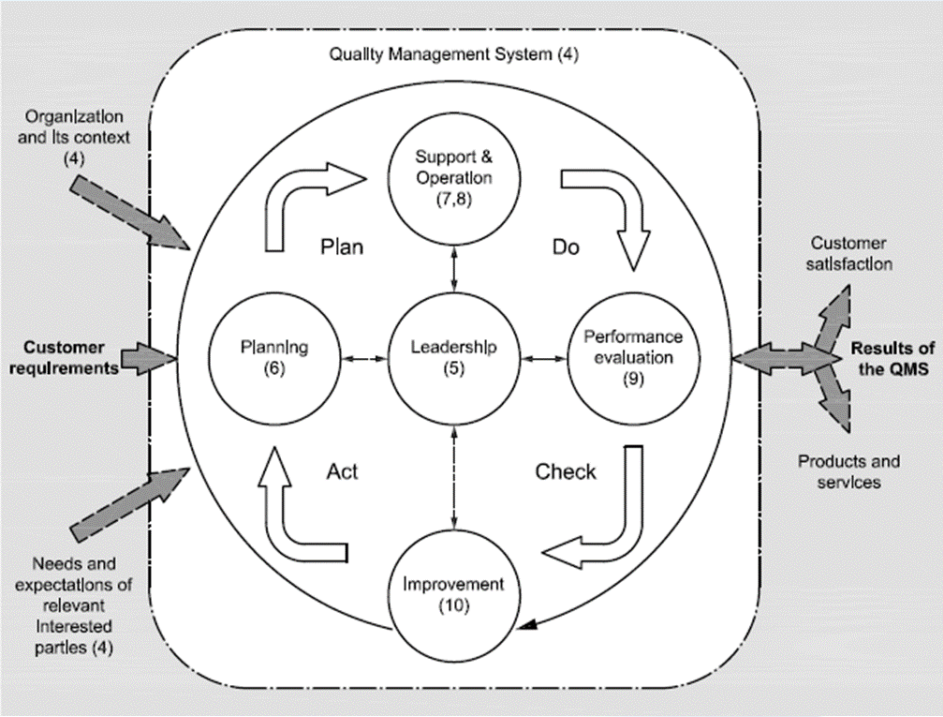
Clause 4 — Context of the Organization

4.1 Understanding the Organization and its Context

4.2 Understanding the Needs and Expectations of Interested Parties

4.3 Determining the Scope of the Quality Management System

4.4 Quality Management System and its Processes



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

4.1 Context of the Organization — Guidance

- Sources of information about the organization's external context may include:
  - Information from stakeholders, e.g., lobby groups, trading partners
  - Laws, regulations, standards, codes of practice, rules of industry regulators, corporate governance rules, and directives
  - The litigation profile of the organization and regulatory action affecting the organization
  - Economic, financial or environmental
  - Analyses from government or industry analysts
  - Media reports

4.1 Context of the Organization — Guidance

- Sources of information about the organization's internal context may include:
  - Key corporate documents such as: policies, strategies, business plans, annual reports, audit reports
  - Organizational structure, definition of legal, compliance, information technology
  - Business partners, e.g., research collaborators, trading partners, suppliers of products and services
  - Customers
  - Community groups with an interest in the organization
  - Government, including multiple governments for organizations operating across different jurisdictions

4.1 Context of the Organization — Guidance

- Audit evidence needed to demonstrate conformity can include:
  - List of issues, both external and internal
  - Benchmarking data
  - Results of legal reviews
  - Audit interview results
  - **IAQG guidance includes additional tools such as:**
    - **PEST – Political, Economic, Social, Technological**
    - **PESTLE – Political, Economic, Social, Technological, Legal, Environmental**
    - **SWOT – Strengths, Weaknesses, Opportunities, Threats**
  - Others?

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.

Specified Requirements — Guidance

- There are three groups that can specify QMS requirements:
  - Authorized Internal Representatives, e. g. Engineering
  - Customer
  - Applicable statutory and regulatory bodies
    - A statutory requirement is an obligatory requirement specified by a legislative body.
    - A regulatory requirement is an obligatory requirement specified by an authority mandated by a legislative body.

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 Aerospace 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

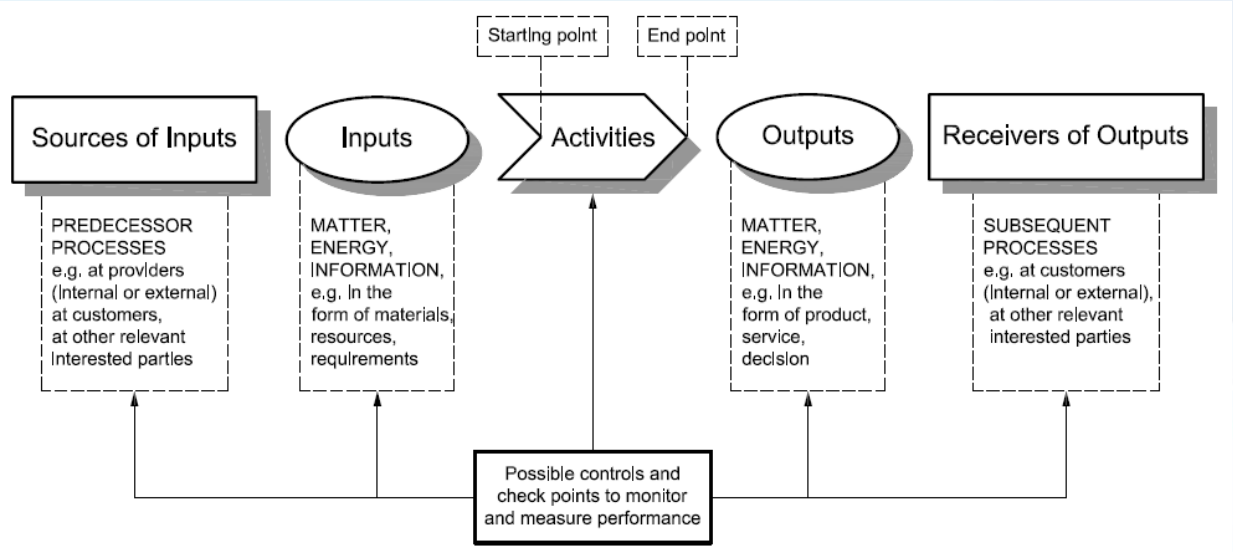
- The organization applies all applicable requirements of the standard within the scope:
  - The organization justifies any requirement of the standard that they determine is **NOT** applicable.
  - This justification is only valid if those requirements do not affect the organization's ability to ensure 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

4.4 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 Op
  - Process Evaluation and update as needed
  - Process and QMS Improvements
  - **Address customer and applicable statutory & regulatory requirements**

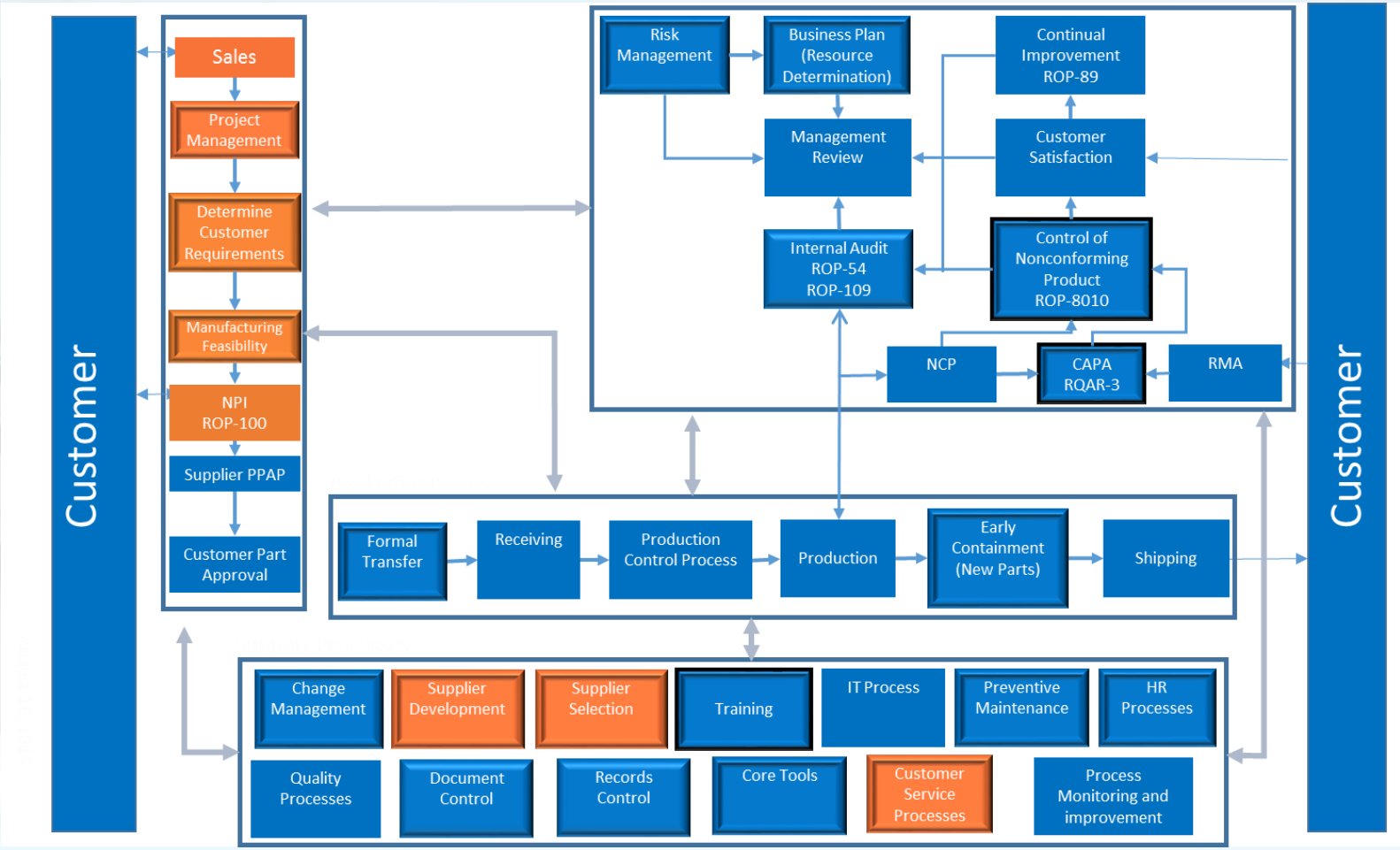


source: ISO 9001:2015

*monitoring, measurement & related performance indicators

Typical Evidence for Process Approach

Process Map



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

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**

For AS9100, refer to the next slide

See clause 7.5

AS9100D System Documentation Requirements

- **The organization must establish and maintain documented information that includes:**
  - **A general description of relevant interested parties (see 4.2a)**
  - **The scope of the quality management system, including boundaries and applicability (see 4.3)**
  - **A description of the processes needed for the quality management system and their application throughout the organization**
  - **The sequence and interaction of these processes**
  - **Assignment of the responsibilities and authorities for these processes**

The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual

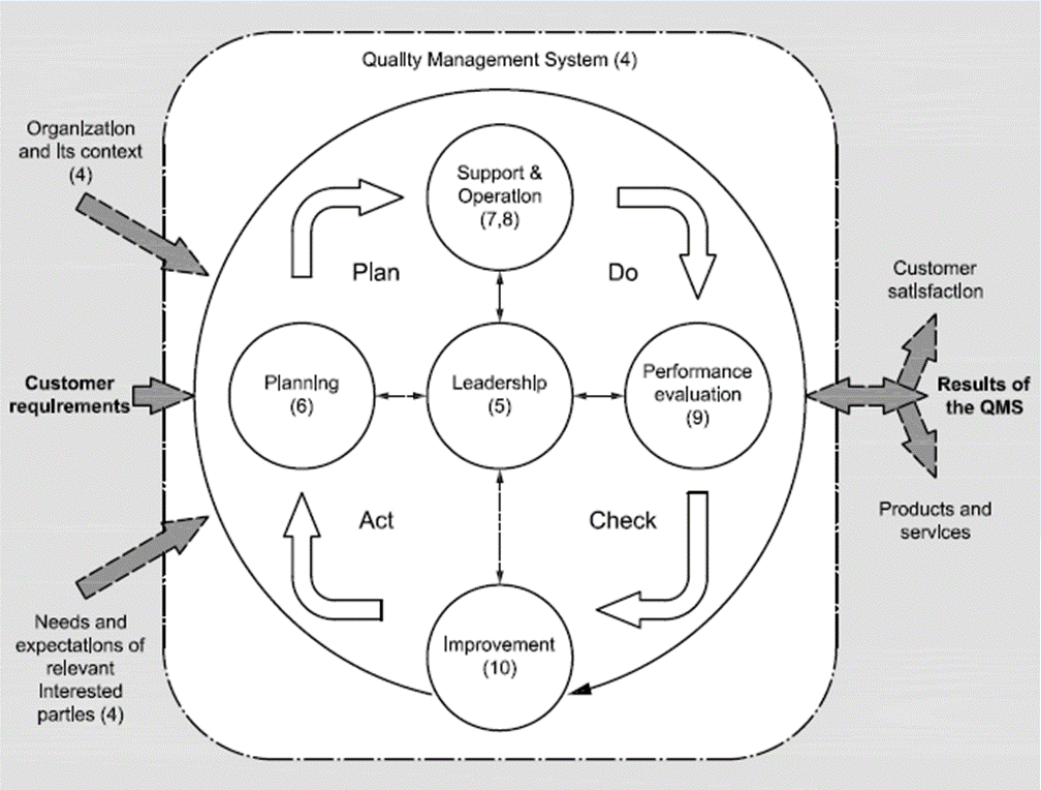
CLAUSE 5 — LEADERSHIP

Clause 5 — Leadership

5.1 Leadership and Commitment

5.2 Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities



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

Dr. Edwards Deming and Leadership

- Dr. William Edwards Deming was an American engineer, statistician, professor, author, lecturer, and management consultant.
- He said that it is insufficient for leadership to be "thoroughly committed to quality."
- He believed that "***they must know what they must do*** *to cause quality to happen.*"
- He taught that the performance of any person is governed largely by the system in which they work and that system is the responsibility of management.

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.

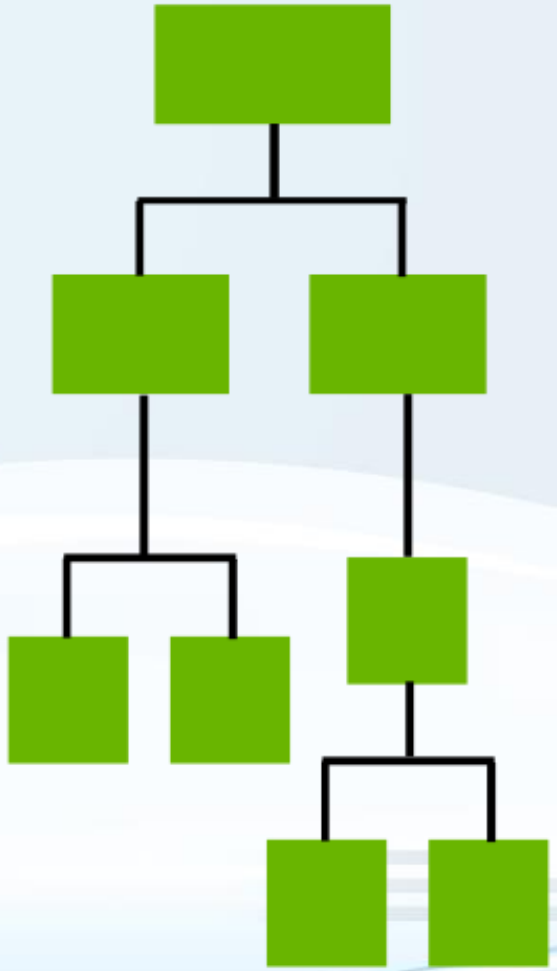
5.1 Leadership and Commitment

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

5.1.1 General — Guidance

- Top Management is the person or group of people who directs and controls an organization at the highest level.
- If the QMS scope covers only part of an organization, then Top Management refers to those who direct and control that part of the organization.

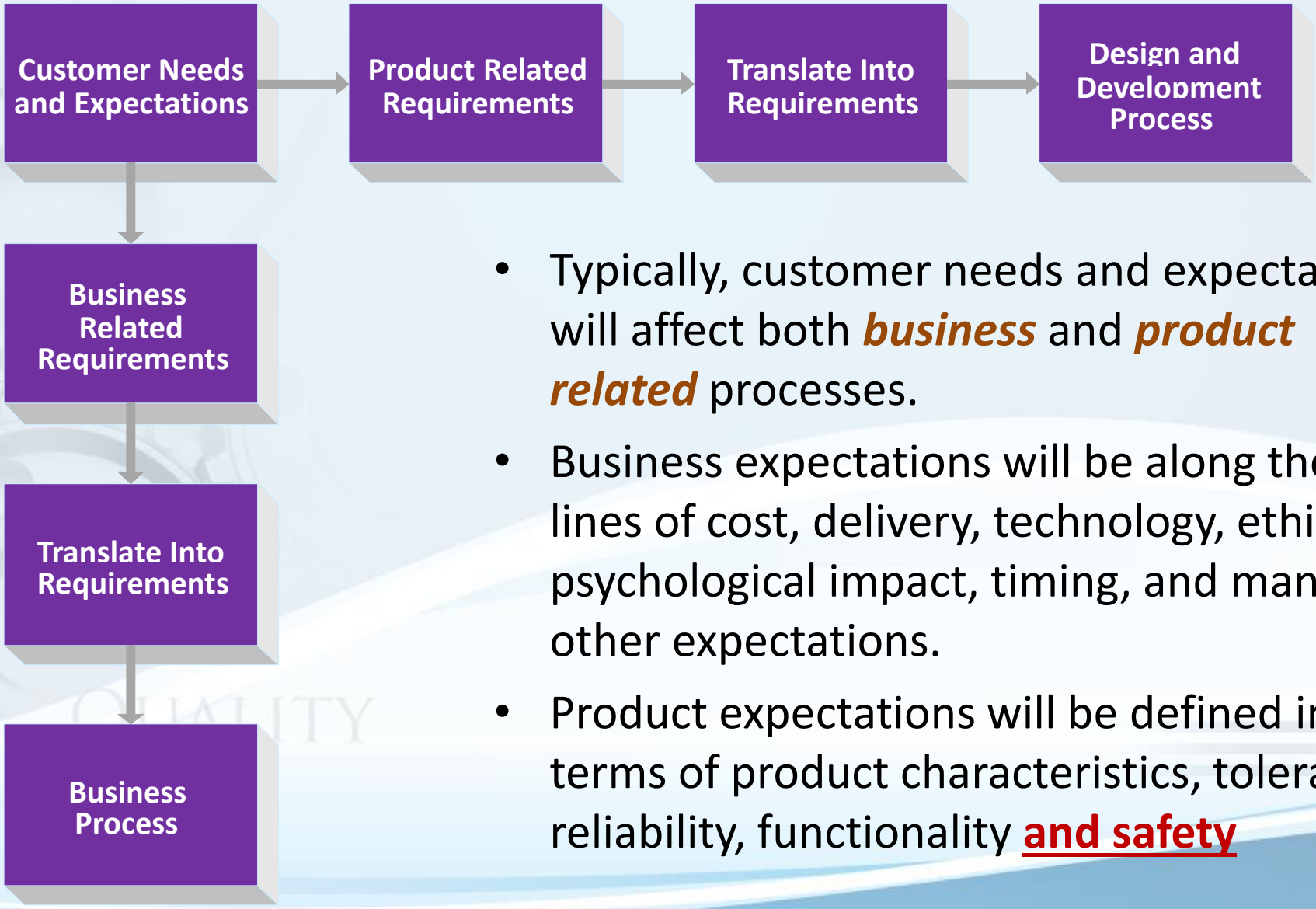


5.1 Leadership and Commitment

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.
  - **Product and service conformity and *on-time delivery performance are measured and appropriate action is taken* if planned results are not, or will not be, achieved.**

5.1.2 Customer Focus — Guidance



- Typically, customer needs and expectations will affect both ***business*** and ***product related*** processes.
- Business expectations will be along the lines of cost, delivery, technology, ethics, psychological impact, timing, and many other expectations.
- Product expectations will be defined in terms of product characteristics, tolerances, reliability, functionality **and safety**

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

AS9100D "Management Representative"

- **Top Management appoints a specific member of the organization's management, identified as *the Management Representative*, who has the responsibility and authority for oversight of the requirements listed in clause 5.3.**
- **The Management Representative must have the organizational freedom combined with unrestricted access to Top Management in order to resolve quality management issues.**
- **The responsibility of a Management Representative can include liaison with external parties on matters relating to the quality management system (e.g., certification bodies, customers, suppliers and regulatory entities).**

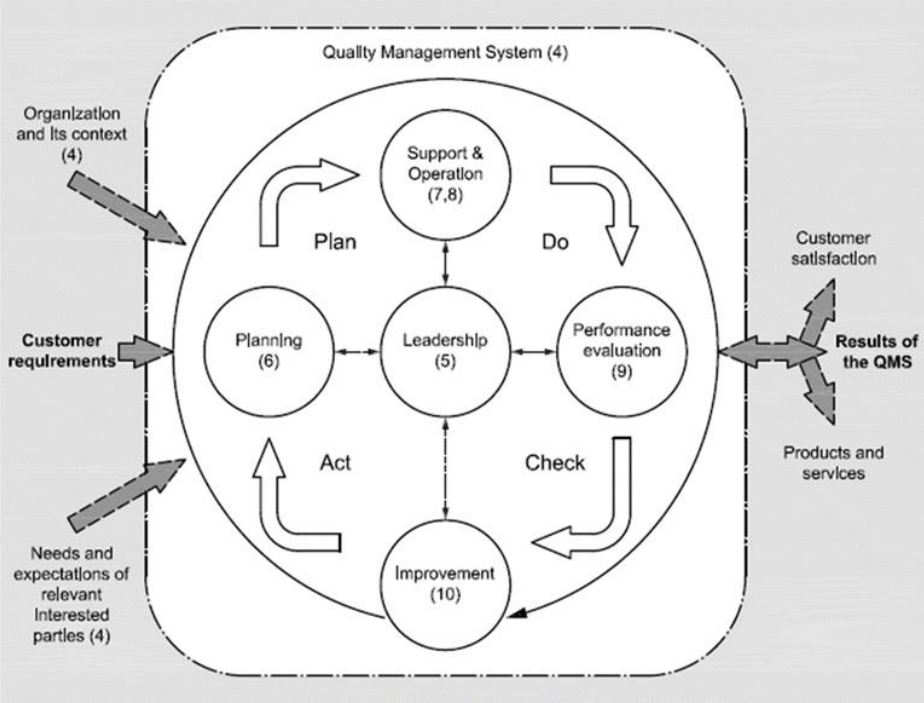
CLAUSE 6 — PLANNING

Clause 6 — Planning

6.1 Actions to Address Risks and Opportunities

6.2 Quality Objectives and Planning to Achieve Them

6.3 Planning of Changes



Clause 6 — Planning

Intent

- Create objectives
- Develop plans to meet those objectives including actions to mitigate risks associated with meeting the organization's 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

6.1 Actions to Address Risks and Opportunities

6.1.1

- When planning the QMS, the organization:
  - Considers the context of the organization (clause 4.1) and the needs and expectations of the interested parties (clause 4.2)
  - Determines the risks and opportunities that need to be addressed to:
    - Ensure that the QMS can achieve its intended result(s)
    - Enhance desirable effects
    - Prevent, or reduce, undesired effects
    - Achieve improvement

Clause 10.2.1 requires these to be updated as necessary after corrective actions are implemented

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

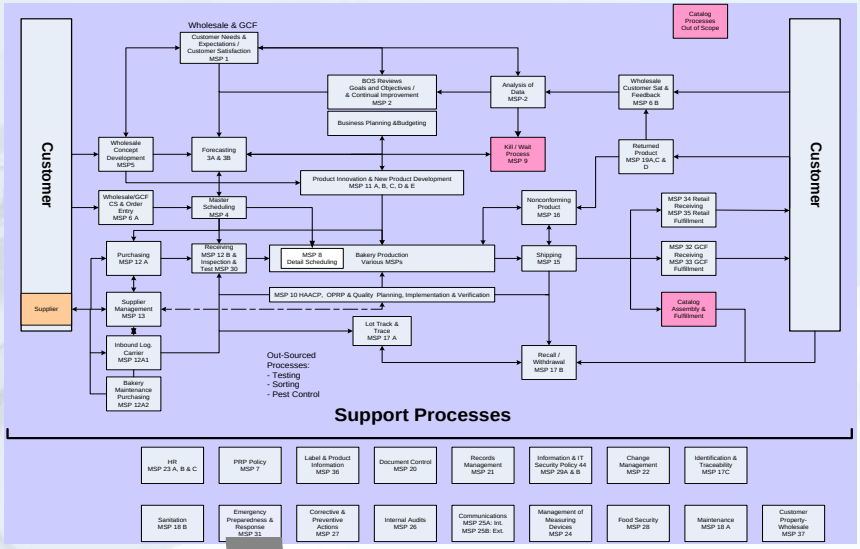
Risk and ISO 9001:2015

4.4 Process Approach

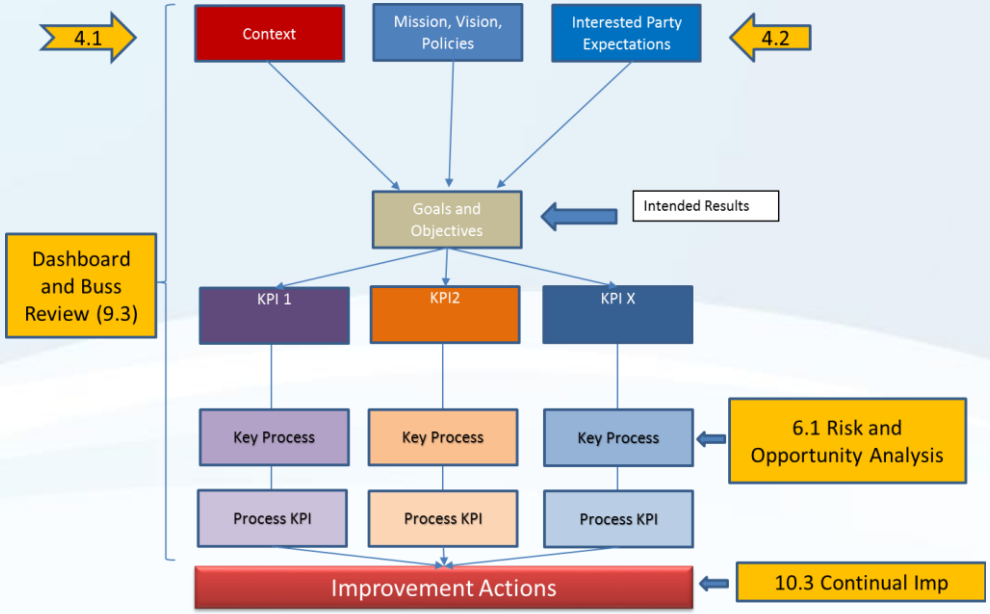
Address risk and opportunities determined, re: 6.1

6.1 Actions to Address Risks and Opportunities

Plan and determine the actions needed



Process Map



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

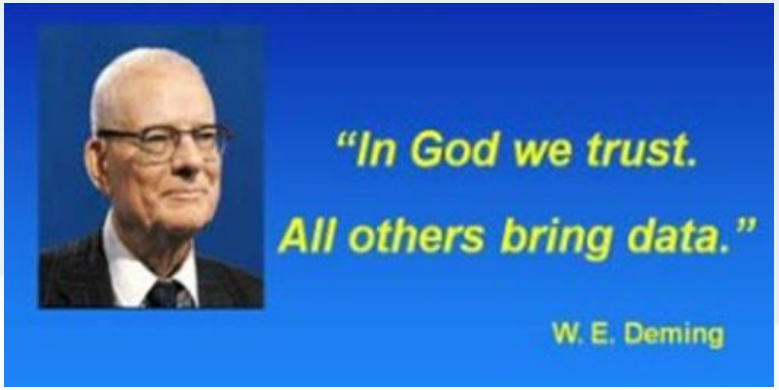
ISO Directives indicate that the terms "consider" and "take into account" are synonymous

Align Expectations, Objectives and Processes — Guidance

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

6.3 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

QMS Group Exercise 3

Audit Scenarios: Clauses 4-6

QUALITY

OMNEX

CLAUSE 7 — SUPPORT

Clause 7 — Support

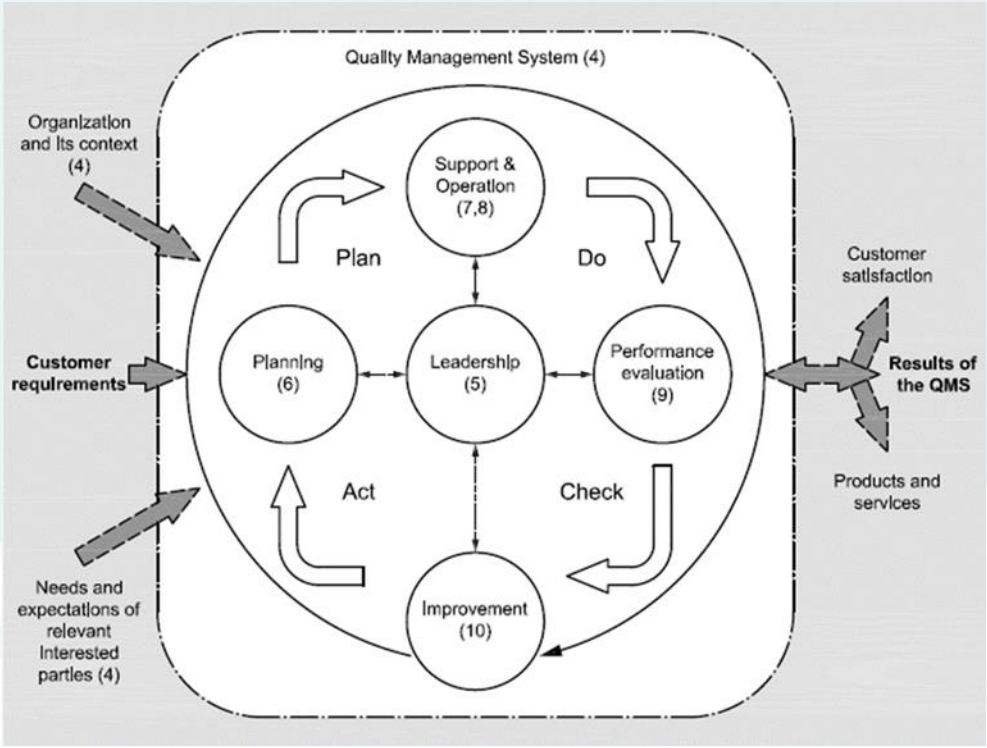
7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information



Clause 7 — Support

Intent

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

7.1 Resources

7.1.1 General

- The organization determines and provides the resources needed for the QMS including its
  - Establishment,
  - Implementation,
  - Maintenance, and
  - Continual Improvement

- The organization considers:
  - Capabilities of existing internal resources
  - Constraints on existing resources
  - What needs to be obtained from external providers

7.1 Resources

7.1.2 People

- The organization provides the people necessary for the effective implementation of the QMS and for the operation and control of its processes and to achieve product or service conformity.

7.1.3 Infrastructure

- The organization determines, provides and maintains the infrastructure for the operation of its processes to achieve conformity of products and services.
  - Infrastructure can include:
    - Buildings
    - Utilities
    - Equipment including hardware and software
    - Transportation
    - IT and Communication technology

7.1 Resources

7.1.4 Environment for the Operation of Processes

- The organization determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.
  - Environment can include:
    - Physical
    - Social
    - Psychological
    - Environmental and other factors such as:
      - Temperature
      - Humidity
      - Ergonomics
      - Cleanliness

7.1 Resources

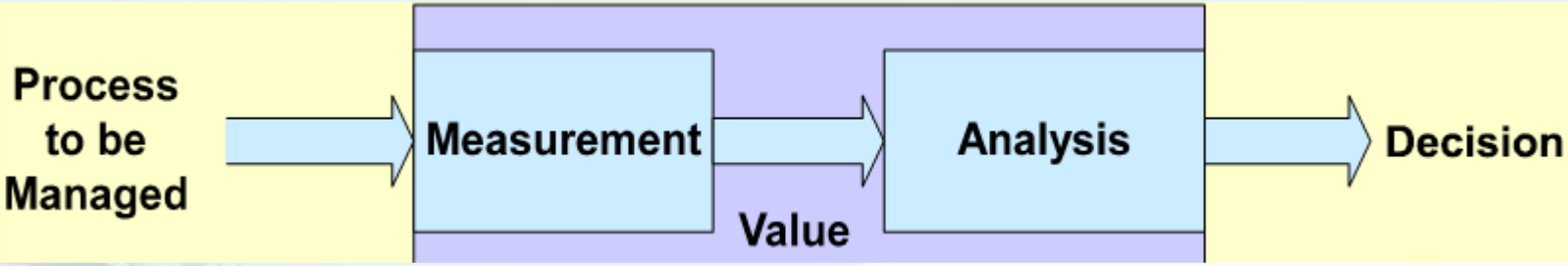
7.1.5.1 (Monitoring and Measuring Resources) General

- For measurements used to provide evidence of conformity to specified requirements, the organization must determine the resources needed to ensure valid and reliable results.
- The organization ensures that the resources provided:
  - Are suitable for the measurements
  - Are maintained
- Documented information is retained as evidence of fitness of monitoring and measurement resources.

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

7.1.5 Measurement System — Guidance

- A measurement system is the collection of instruments or gages, standards, operations, methods, fixtures, software, personnel, environment and assumptions used to quantify a unit of measure or fix assessment to the feature characteristic being measured.



- Measurement is a process and has variation.
- It is important to know the measurement uncertainty of the process in order to properly interpret the measured values.
- Note that gage R&R only represents a portion of the process variation.
- Consider discrimination and location, e. g., stability, linearity, bias, as well.

7.1 Resources

7.1.5.2 Measurement Traceability

- Where measurement traceability is needed or required, measuring instruments must be:
  - Verified or calibrated against measurement standards at specified intervals or prior to use
  - Traceable to national or international measurement standards
    - Where no such standards exist, the basis used for calibration or verification must be recorded
  - Identified in order to determine their status
  - Safeguarded from anything that would invalidate their calibration status and on-going measurement results

- When measuring equipment is found defective, the organization has to determine if previous measurement results taken with the equipment are still valid and take appropriate corrective action as necessary.

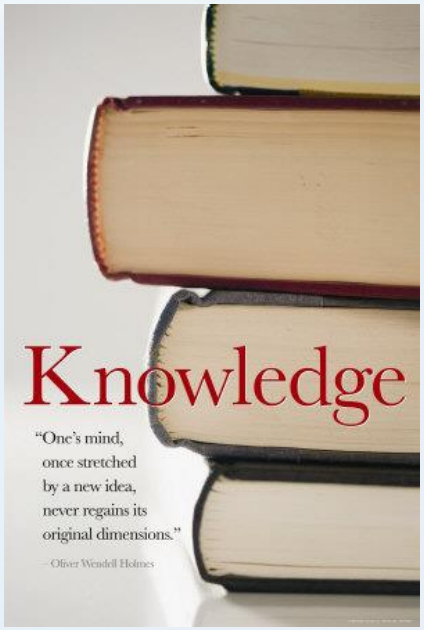
Risk is implicit whenever "suitable" or "appropriate" is mentioned

7.1.5.2 Measurement Traceability

- The organization establishes, implements, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.
- The organization maintains a register of the monitoring and measuring equipment, which includes:
  - Equipment type
  - Unique identification
  - Location
  - Calibration or verification method, frequency, and acceptance criteria
- Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).

Monitoring and measuring equipment can include, but is not limited to: test hardware and software, automated test equipment (ATE), and plotters used to produce verification data. Also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

7.1 Resources



7.1.6 Organizational Knowledge

- The organization determines what knowledge is needed to operate its processes and achieve conforming products and services.
- This knowledge is maintained and made available as necessary.
- As needs and trends change, the organization considers its current knowledge and determines how to obtain additional knowledge and required updates.

7.1.6 Organizational Knowledge — Guidance

- The process for considering and controlling past, existing and additional knowledge needs to take account of:
  - The organization's context, including its size and complexity,
  - The risks and opportunities to be addressed, and
  - The need for accessibility of knowledge.
- The balance between knowledge held by competent people and knowledge made available by other means (e.g., experts) is at the discretion of the organization, but product and service conformity must be achieved and maintained.
- Organizational knowledge is knowledge specific to an organization; it is gained by experience and is used and shared to achieve the organization's objectives.
- FMEAs are an effective tool.

7.2 Competence

- The organization shall:
  - Determine the competency requirements of people performing work under its control that affects the performance and effectiveness of the QMS.
  - Ensure these people are competent based on appropriate education, training and/or experience.
  - Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
  - Retain appropriate documented information as evidence of competence.
- **Consideration should be given for the periodic review of the necessary competence.**
- Applicable actions could include provision of training, mentoring or reassignment of employees, hiring or contracting competent people.

7.3 Awareness

- People working under the organization's control have to be aware of:
  - The Quality Policy
  - Relevant quality objectives
  - Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance
  - The implications of not conforming with the QMS requirements
  - **Relevant quality management system documented information and changes**
  - **Their contribution to product or service conformity**
  - **Their contribution to product safety**
  - **The importance of ethical behavior**

7.4 Communication

- The organization determines the internal and external communications relevant to the QMS including:
  - What it will communicate
  - When to communicate
  - With whom to communicate
  - How to communicate
  - Who communicates
- **Communication includes internal and external feedback relevant to the quality management system.**

Customer communication is part of clause 8.2.1.

Information for external providers is in clause 8.4.3.

7.5 Documented Information

7.5.1 General

- The organization's QMS includes
  - Documented information required by the standard
  - Documented information determined by the organization as being necessary for the effectiveness of the QMS

- The standard expresses the **minimum** requirements for any and all organizations. **Actual** documented information necessary for an organization varies due to the:
  - Size of organization and its type of activities, processes products and services
  - Complexity of processes and their interactions
  - Competence of persons

See 4.4 QMS and its Processes

See 4.4.2 for AS9100-specific requirements

Changes in Documentation Terminology

ISO 9001:2008		ISO 9001:2015
Documented procedure	→	Maintain documented information
Record	→	Retain documented information

Where "information" is used in ISO 9001:2015, there is no requirement that it be documented

Minimum Required Documentation — ISO 9001

2008 "Procedures" required (6)

- 4.2.3 Control of Documents
- 4.2.4 Control of Quality Records
- 8.2.2 Internal Audit
- 8.3 Control of Nonconforming Product
- 8.5.2 Corrective Action
- 8.5.3 Preventive Action

2015 "maintain documented information" replaces "procedures" (4)

- 4.3 Scope
- 4.4.2 QMS and Processes
- 5.2.2 Quality Policy
- 6.2.1 Quality Objectives
- 8.2.4 References to when changes to documented information is needed

2015 Additional Documented Information to be available:

- 7.5.1 Any required by the standard
- 7.5.1 Any determined by the organization as needed
- 7.5.3.2 Documents of external origin needed for the QMS
- 8.3.2 Information to confirm design requirements are met
- 8.5.1 Product Characteristics
- 8.5.1 Activities to be performed for process control and results
- 8.6 Traceability to person releasing products for shipment

Minimum Required Documentation — ISO 9001

2008 "records" – 19 required records, now there are 21

2015 "retain documented information"

4.4.2 QMS and Processes

7.1.5.1 Measurement Resources

7.1.5.2 Calibration Standards

7.2 Competence

8.1 Operational Planning and Control

8.2.3 Review of Product and Service Requirements

8.3.3 Design and Development Inputs

8.3.4 Design and Development Controls

8.3.5 Design Outputs

8.3.6 Design Changes

8.4.1 External Providers

2015 "retain documented information"

8.5.2 Traceability, if required

8.5.3 Lost/Damaged External Property

8.5.6 Review of Changes in Operations

8.6 Product Release

8.7.2 Control of Nonconforming Product

9.1.1 Results of Measurement

9.2.2 Audit Program and Audit Results

9.3.3 Management Review Output

10.2.2 Nature of Nonconformities, Actions Taken and Results

2015 "keeping documented information"

8.1 Process Control

("keep" means maintain and retain!)

Minimum Required Documentation for AS9100

Additionally, AS9100D identifies a number of processes requiring documented information:

- 8.1 Plan and Control Transfer of Work
- 8.1.2 Configuration Management
- 8.1.1 Operational Risk Management
- 8.1.3 Product Safety
- 8.1.3 Prevention of Counterfeit Parts
- 8.3.4.1 Test Plans, Specifications, Procedures, Methods and Records of Results
- 8.4.1.1 Register of External Suppliers with Approval Status
- 8.5.1c: Monitoring & Measurement Activity for Product Acceptance
- 8.7.1 Control of Nonconforming Outputs Process
- 10.2.1 Nonconformity and Corrective Action Process

7.5 Documented Information

7.5.2 Creating and Updating

- When creating and updating documented information, the organization ensures appropriate:
  - Identification
  - Description, e.g., a title, date, author, or reference number
  - Format, e.g., language, software version, graphics
  - Media, e.g., paper, electronic
  - Review for suitability and adequacy
  - Approval

Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization

7.5 Documented Information

7.5.3 Control of Documented Information

7.5.3.1

- Documented information required by the QMS and by the standard is controlled to ensure its:
  - Availability
  - Suitability for use, where and when it is needed
  - Protection from loss of confidentiality, improper use or loss of integrity

Control of documented information ensures that everyone in the organization:
- **Knows what they need to know**
- **Does not know of things they should not know**

7.5 Documented Information

7.5.3 Control of Documented Information

7.5.3.2

- For control of documented information, the organization addresses, as applicable:
  - Distribution, access, retrieval and use
  - Storage and preservation, including legibility
  - Change control, e. g., version control
  - Retention and disposal
  - **Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose**
- Documented information of external origin determined by the organization to be needed is identified and controlled.
- Retained documented information as evidence of conformity must be protected from unintended alterations.

7.5 Documented Information

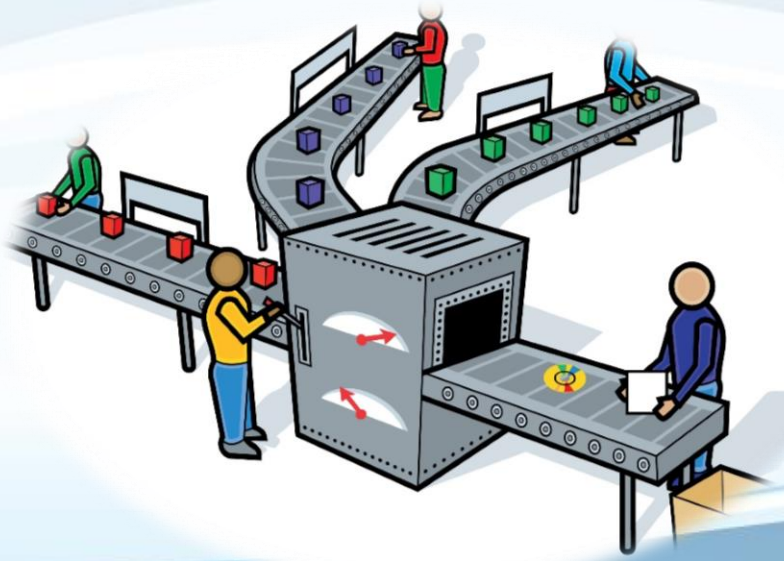
7.5.3 Control of Documented Information

7.5.3.2

- **When documented information is managed electronically, data protection processes must be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).**

- Access can imply “read-only” or “read/write” permission.

CLAUSE 8 — OPERATION



Clause 8 — Operation

8.1 Operational Planning and Control

8.2 Requirements for Products and Services

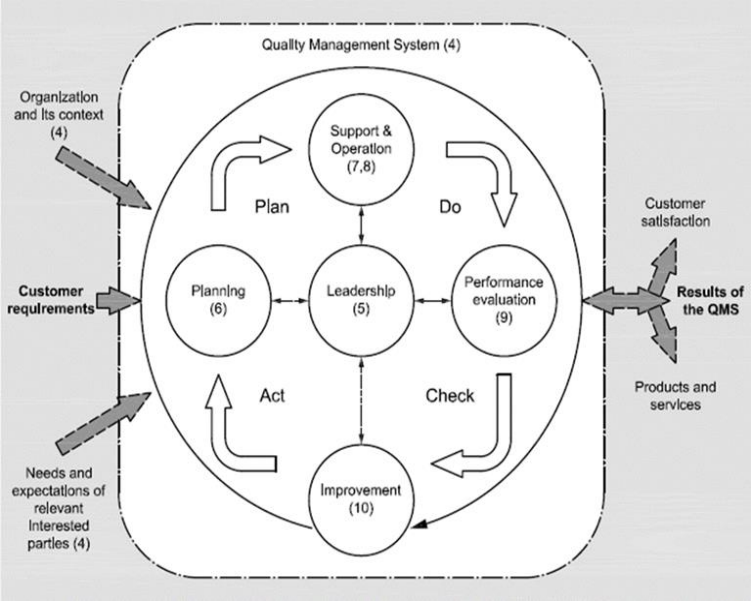
8.3 Design and Development of Products and Services

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



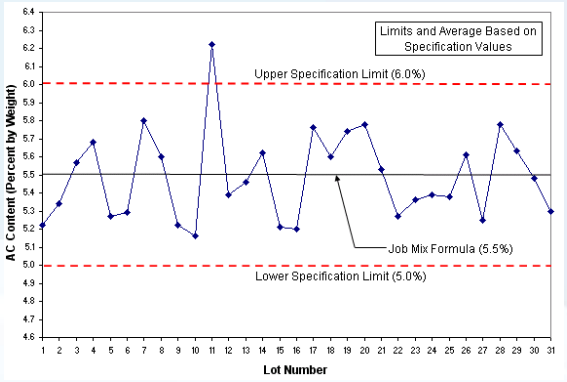
Clause 8 — Operation

Intent

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

8.1 Operational Planning and Control

- The organization plans, implements and controls the processes (cl. **4.4**) needed to meet product and service requirements and to address risks and opportunities (cl. **6**) by:
  - Determining product and service requirements†
  - Establishing criteria for the processes† †
  - Establishing acceptance criteria for products and services
  - Determining the resources needed to achieve product and service conformity to specified requirements **and to meet on-time delivery of products & services**
  - Implementing process controls
  - Keeping documented information to the extent necessary to
    - Have confidence that the processes have been carried out as planned
    - Demonstrate conformity of products and services to requirements



"Keeping" implies both maintaining and retaining

8.1 Operational Planning and Control

- The organization plans, implements and controls the processes… ***(cont'd)***:
  - **Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified**
  - **Engaging representatives of affected organization functions for operational planning and control**
  - **Determining the processes and resources to support the use and maintenance of the products and services**
  - **Determining the products and services to be obtained from external providers**
  - **Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer**

See AS9103A for the management of key characteristics

One method to achieve operational planning and control can be through the use of integrated phased processes

8.1 Operational Planning and Control

† NOTE: Determination of requirements for the products and services should include consideration of:

- Personal and product safety
- Producibility and inspectability
- Reliability, availability, and maintainability
- Suitability of parts and materials used in the product
- Selection and development of embedded software
- Product obsolescence
- Prevention, detection, and removal of foreign objects
- Handling, packaging, and preservation
- Recycling or final disposal of the product at the end of its life

8.1 Operational Planning and Control

† † NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- Design verification (e.g., reliability, maintainability, product safety)
- Process control
  - selection and verification of key characteristics
  - process capability measurements
  - statistical process control
  - design of experiments
- Verification
- Failure mode, effects, and criticality analysis (FMECA)

AS9100D retains reference to the use of statistical techniques

8.1 Operational Planning and Control

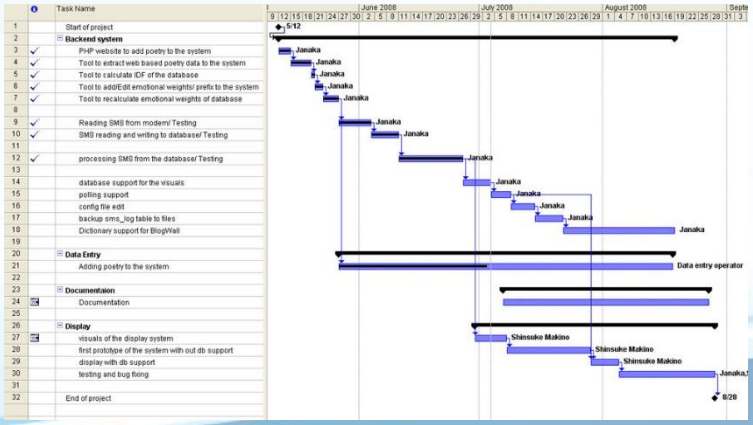
- The output of this planning is suitable for the organization's operations.
- The organization controls planned changes.
- Review the consequences of unintended changes.
  - Take action to mitigate any adverse effects as necessary.
- The organization ensures that outsourced processes are controlled (see **8.4 Control of Externally Provided Products and Services**).
  - "*Outsource*" means to make an arrangement where an external organization performs part of an organization's function or process.
  - An external organization is outside the QMS but the outsourced function or process is within the scope.

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

8.1 Operational Planning and Control

- **As appropriate to the organization, customer requirements, and products and services, the organization must plan and manage product and service provision in a structured and controlled manner.**

Documented information specifying the processes and resources to be applied to a specific product, service, project or contract can be referred to as a quality plan



8.1 Operational Planning and Control

- **The organization establishes, implements, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process must ensure that work transfer impacts and risks are managed.**
  - **NOTE: Refer to 8.4 and 8.5**

8.1.1 Operational Risk Management

- The organization must establish, implement and maintain a process for managing risk that includes:
  - Assignment of responsibilities for risk management
  - Definition of risk criteria including likelihood, consequences, risk acceptance
  - Identification, assessment and communication of risks throughout product realization
  - Identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
  - Acceptance of risks remaining after implementation of mitigating actions

Scope of 8.1.1 is limited to risks associated to operational processes for provision of product and services

Risk Management — Aerospace Industry Common Practices

Sales/Contract Review Process:

- Risk Assessment
- Feasibility Review
- Supplier Analysis

Design: System and Design

- FMEA for Design Risk – Rate Functions, Requirements and Characteristics

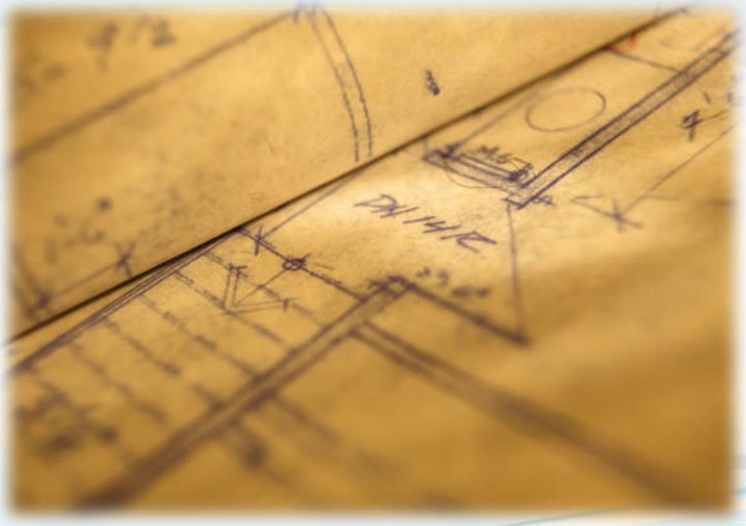
Process and Manufacturing:

- Process Flow
- PFMEA
- Control Plan
- Risk-based Work Instructions
- MSA
- SPC
- Process Capability Studies including FAI/PPAP

Risk in this context is generally expressed in terms of likelihood of occurrence and severity of the consequences

8.1.2 Configuration Management

- The organization establishes, implements and maintains a *configuration management process* to ensure identification and control of physical and functional attributes throughout the product lifecycle:
  - Product identity, traceability to requirements, and implementation of identified changes must be controlled
  - Ensure documented information corresponds with product and service attributes



8.1.3 Product Safety

- The organization plans, implements, and controls the processes needed to *assure product safety during the entire product life cycle*, as appropriate to the organization and the product.

  NOTE: Examples of these processes include:
  - Assessment of hazards and management of associated risks (see 8.1.1)
  - Management of safety critical items
  - Analysis and reporting of occurred events affecting safety
  - Communication of these events and training of persons

8.1.4 Prevention of Counterfeit Parts

- The organization plans, implements, and controls processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

- Counterfeit part prevention processes should consider:
  - Training of appropriate persons in the awareness and prevention of counterfeit parts
  - Application of a parts obsolescence monitoring program
  - Controls for acquiring product from original or authorized manufacturers, authorized distributors, or other approved sources
  - Requirements for assuring traceability of parts and components to their original or authorized manufacturers
  - Verification and test methodologies to detect counterfeit parts
  - Monitoring of counterfeit parts reporting from external sources
  - Quarantine and reporting of suspect or detected counterfeit parts

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

Explicit considerations are linked to customer communications, customer property and contingency actions.

See 7.4 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
  - **Special requirements of the products and services are determined**
  - **Operational risks (e.g., new technology, ability and capacity to provide short delivery time frame) have been identified**

8.2 Requirements for Products and Services

8.2.3 Review of the Requirements for Products and Services

8.2.3.1

- The organization ensures that it has the ability to meet the product and service requirements.
- The organization conducts a review before committing to supply products and services to a customer including:
  - Customer requirements, including delivery and post-delivery
  - Requirements not stated by the customer, but necessary for the customer-specified or intended uses, when known
  - Product and service statutory and regulatory requirements
  - Contract or order requirements differing from those previously expressed
- The organization ensures that any requirements different from those previously defined are resolved.

8.2 Requirements for Products and Services

8.2.3 Review of the Requirements for Products and Services

8.2.3.1

- **This review is coordinated with applicable functions of the organization.**
- **If, upon review, the organization determines that some customer requirements cannot be met or can only partially be met, the organization negotiates a mutually acceptable requirement with the customer.**
- Where there are no documented customer requirements, the customer requirements are confirmed by the organization prior to acceptance.

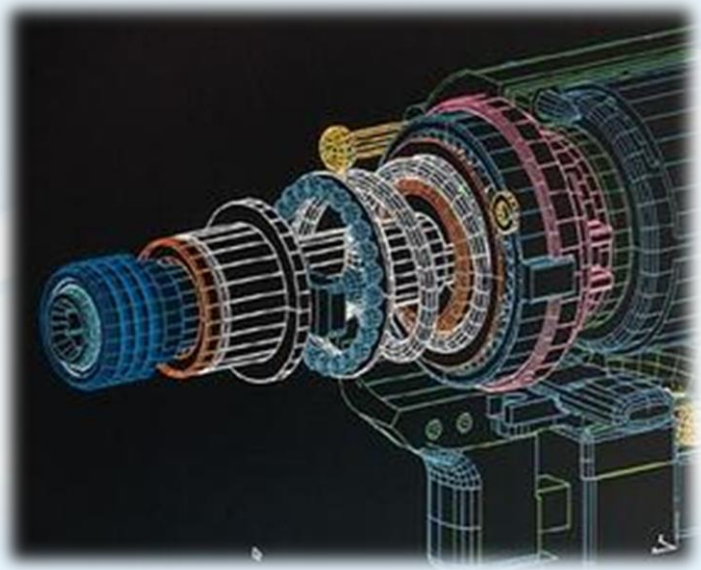
8.2.3.2

- 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

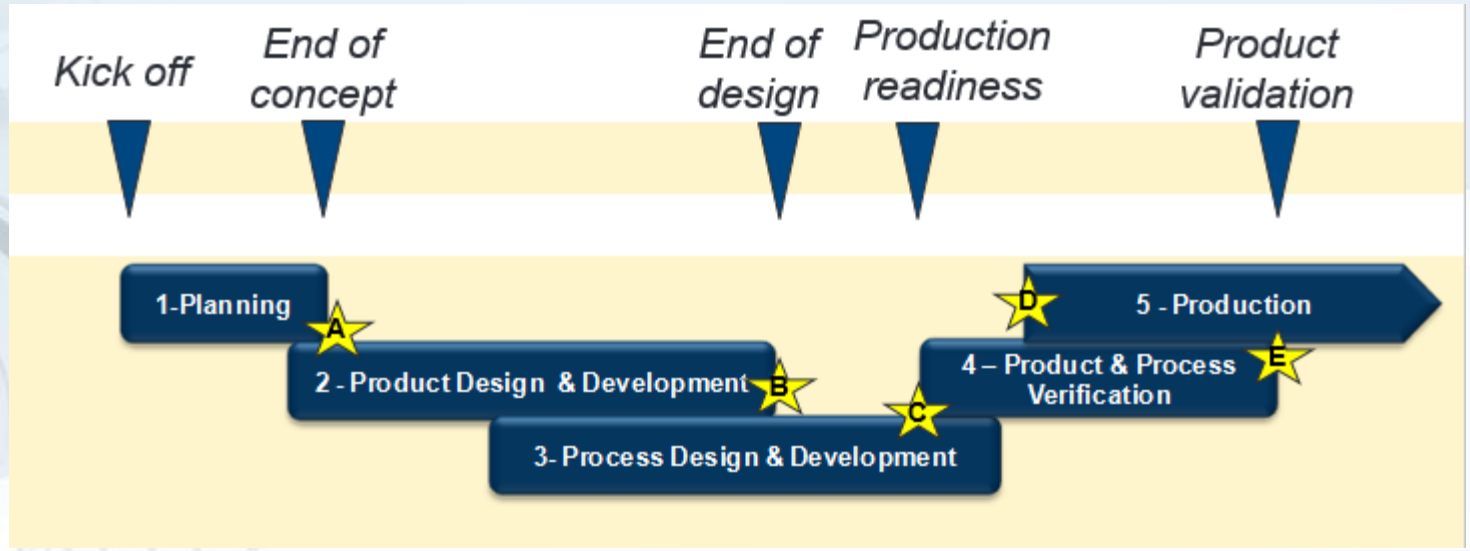
- Where product or service requirements are changed, the organization ensures that relevant information is amended and that relevant personnel are made aware of the changes.



8.3 Design and Development of Products and Services

8.3.1 General

- The organization establishes, implements and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.



The product realization phases are related to AS9145 (Requirements for APQP and PPAP)

8.3 Design and Development of Products and Services

8.3.2 Design and Development Planning

- In determining the stages and controls for design and development, the organization considers:
  - The nature, duration and complexity of the design and development activities
  - Process stages and their requirements, including design reviews
  - Design verification and validation
  - Responsibilities and authorities for the design and development process
  - The need to control interfaces between individuals involved in the process
  - The need for involvement of customers and user groups
  - The level of control expected by interested parties in this process
  - Documented information to demonstrate that design and development requirements have been met

8.3 Design and Development of Products and Services

8.3.2 Design and Development Planning

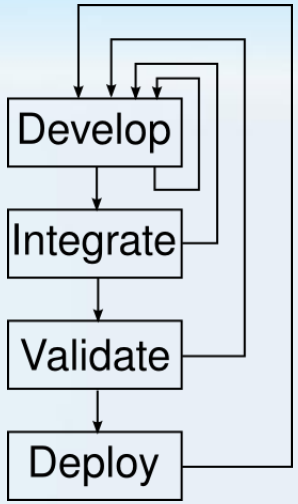
- When appropriate, the organization divides the design and development effort into distinct activities and, for each activity, defines the tasks, necessary resources, responsibilities, design content, and inputs and outputs.
- Design and development planning considers the ability to provide, verify, test and maintain products and services (reference output of 8.1a).

8.3 Design and Development of Products and Services

8.3.3 Design and Development Inputs

- The organization determines the requirements essential for products and services considering:
  - Functional and performance requirements
  - Information derived from similar design and development activities
  - Statutory and regulatory requirements
  - Standards or codes of practice that the organization has committed to implement
  - Potential consequences of product or service failure
  - **When applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products)**
- Inputs are adequate, complete, and unambiguous
- Conflicts among inputs are resolved
- The organization retains documented information on these inputs
  - **Other information such as benchmarking, external provider feedback, internally generated data, and in-service data can also be considered as design and development inputs**

8.3 Design and Development of Products and Services

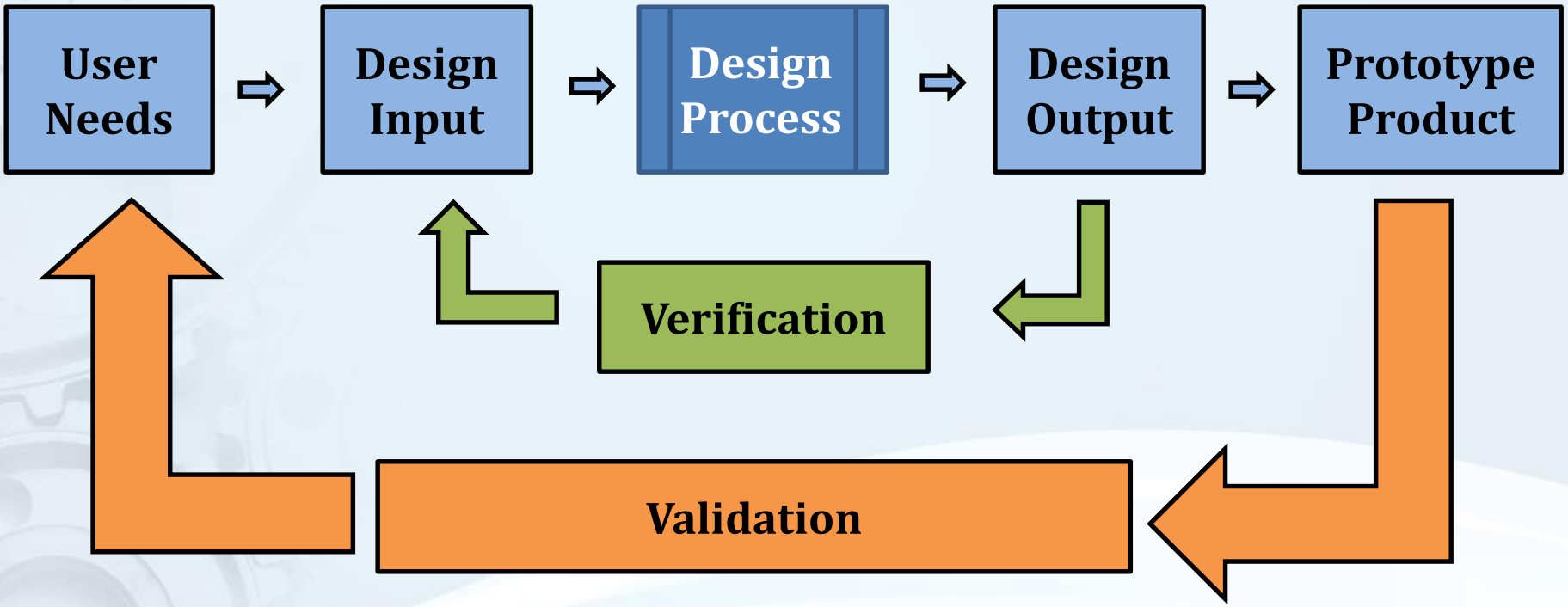


8.3.4 Design and Development Controls

- The organization applies controls to the process ensuring:
  - The results to be achieved are defined
  - Reviews are conducted to evaluate the ability of the design results to meet requirements
  - Verification is conducted to demonstrate the design outputs meet the design input requirements
  - Validation is conducted to demonstrate the resulting products and services are capable of meeting the requirements for the specified application or intended use
  - Necessary actions are taken on problems found during the process
  - Documented information on these activities is retained
  - **Progression to the next stage is authorized**

Include functions concerned with the design and development stage(s) being reviewed

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.

8.3.4 Validation and Verification

8.3.4.1

- **When tests are necessary for verification and validation, the organization plans, controls, reviews, and documents to ensure and prove the following:**
  - **Test plans or specifications identify the test item and the resources being used, as well as define test objectives and conditions, parameters to be recorded and relevant acceptance criteria**
  - **Test procedures describe the test methods to be used, how to perform the test, and how to record the results**
  - **The correct configuration of the test item is submitted for the test**
  - **The requirements of the test plan and the test procedures are observed**
  - **The acceptance criteria are met**
- **Monitoring and measuring devices used for testing must be controlled as defined in clause 7.1.5.**
- **At the completion of design and development, the organization ensures that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.**

8.3 Design and Development of Products and Services

8.3.5 Design and Development Outputs

- The organization ensures design outputs:
  - Meet the input requirements
  - Are adequate for the subsequent processes for product and service provision
  - Include, or reference, applicable monitoring and measuring requirements and acceptance criteria
  - Specify the characteristics of their products and services that are essential for intended purpose and their safe and proper provision
  - **Specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items**
  - **Are approved by authorized person(s) prior to release**

Requirements for the management of key characteristics can be found in AS9103A

8.3 Design and Development of Products and Services

8.3.5 Design and Development Outputs

- **The organization defines the data required to allow the product to be identified, manufactured, verified, used, and maintained.**

- **Data can include:**
  - **The drawings, part lists, and specifications necessary to define the configuration and the design features of the product**
  - **The material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service**
  - **The technical data and repair schemes for operating and maintaining the product**

- The organization retains the documented information resulting from the design process.

8.3 Design and Development of Products and Services

8.3.6 Design and Development Changes

- The organization manages design changes made during, or subsequent to, the product and service design phase to the extent necessary to ensure there is no adverse impact on conformity to requirements.
- **The organization implements a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.**
- The organization retains documented information on:
  - Design and development changes
  - The results of reviews
  - Change authorization
  - Actions taken to prevent adverse impacts

Design and development changes are controlled in accordance with the configuration management process

AS9116 provides change notification structure

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

- The organization ensures that externally provided processes, products and services conform to requirements.
- **The organization is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.**
- **The organization ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.**

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

- **The organization *identifies and manages the risks* associated with the external provision of processes, products, and services, as well as the selection and use of external providers.**

- **The organization requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.**

- The organization determines controls to be applied when:
  - Products and services are provided by external providers for use in the organization's own products and services
  - Products and services are shipped direct to the customer(s) by external providers on behalf of the organization
  - A process or part of a process is provided by an external provider as a result of a decision taken by the organization

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

8.4 Control of Externally Provided Processes, Products and Services

External Provider Evaluation and Selection (see 8.4.1)

- **The organization can use quality data from objective and reliable external sources, e.g., information from accredited QMS or process certification bodies, externally provided approvals from government bodies or customers.**
- **Use of such data is only one element of an organization's external provider control process and must still verify that externally provided processes, products and services meets specified requirements.**

ARP9134A provides guidance for supply chain management in order to identify and reduce risks

8.4 Control of Externally Provided Processes, Products and Services

8.4.1.1

- **The organization:**
  - ***Defines the process*, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers**
  - **Maintains a register of its external providers that includes approval status and scope of approval**
  - **Periodically reviews external provider performance including conformity and *on-time delivery* performance**
  - **Defines the necessary actions to take when dealing with external providers that do not meet requirements**
  - **Defines the requirements for controlling documented information created by and/or retained by external providers**

8.4 Control of Externally Provided Processes, Products and Services

8.4.2 Type and Extent of Control

- The organization ensures that externally provided processes, products and services do not adversely affect its ability to consistently deliver conforming products and services:
  - Ensuring externally provided processes remain within control of QMS
  - Defining controls it intends to apply to an external provider and those it intends to apply to the resulting output
  - Taking into consideration:
    - Potential impact of the externally provided processes, products and services on its ability to consistently meet customer and applicable statutory and regulatory requirements
    - Effectiveness of the controls applied by the external provider
    - **The results of the periodic review of external provider performance**
  - Determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements

8.4 Control of Externally Provided Processes, Products and Services

8.4.2 Type and Extent of Control

- Verification activities must be performed according to the risks identified by the organization, which includes inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.
- Verification activities can include:
  - Review of objective evidence (e.g., accompanying documentation, certificate of conformity, test and statistical documentation, process control documentation, results of process verification and assessment of changes to the production processes)
  - Inspection and audit at the external provider's premises
  - Review of the required documentation
  - Review of production part approval process data
  - Inspection of products or verification of services upon receipt
  - Review of delegations of product verification to the external provider

Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products and services to comply with all requirements

8.4 Control of Externally Provided Processes, Products and Services

8.4.2 Type and Extent of Control

- When externally provided product is released for production use pending completion of all required verification activities, it must be identified and recorded to allow recall and replacement if found that the product does not meet requirements.
- When verification activities have been delegated to the external provider, the organization must define the scope and requirements and maintain a list of the delegation. The organization must also periodically monitor these verification activities.
- When external provider test reports are utilized to verify externally provided products, the organization must implement a process to evaluate the data to confirm that the product meets requirements.
- When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization must implement a process to validate the accuracy of test reports.

First Article Inspection (FAI) can be used to validate product realization processes, see AS9102B
AS9133A provides principles for product qualification

8.4 Control of Externally Provided Processes, Products and Services

8.4.3 Information for External Providers

- The organization ensures the adequacy of requirements prior to their communication to the provider.
- The organization communicates requirements to providers for:
  - The processes, products and services to be provided **including identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions)**
  - Approval and release of products and services, methods, processes or equipment
  - Competence of personnel, including any required qualifications
  - Their interactions with the organization
  - The control and monitoring of the provider's performance to be applied by the organization
  - Verification or validation activities that the organization or its customer wants to check at the source

8.4 Control of Externally Provided Processes, Products and Services

8.4.3 Information for External Providers

- The organization communicates requirements to providers for: *(cont'd)*
  - **Design and development control**
  - **Special requirements, critical items, or key characteristics**
  - **Test, inspection, and verification (including production process verification)**
  - **The use of statistical techniques for product acceptance and related instructions for acceptance by the organization**
  - **The need to:**
    - **Implement a quality management system**
    - **Use customer-designated or approved external providers, including process sources (e.g., special processes)**
    - **Notify the organization of nonconforming processes, products, or services and obtain approval for their disposition**
    - **Prevent the use of counterfeit parts (see 8.1.4)**
    - **Notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval**

8.4 Control of Externally Provided Processes, Products and Services

8.4.3 Information for External Providers

- The organization communicates requirements to providers for: *(cont'd)*
  - **The need to:**
    - **Flow down to external providers applicable requirements including customer requirements**
    - **Provide test specimens for design approval, inspection/verification, investigation, or auditing**
    - **Retain documented information, including retention periods and disposition requirements**
  - **The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain**
  - **Ensuring that persons are aware of:**
    - **Their contribution to product or service conformity and product safety**
    - **The importance of ethical behavior**

Documentation and flow-down of requirements for key characteristics is addressed in AS9103A and change notification is addressed in AS9116

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
  - **Ensuring that documented information for monitoring and measurement activity for product acceptance includes:**
    - **Criteria for acceptance and rejection**
    - **Where in the sequence verification operations are to be performed**
    - **Measurement results to be retained (at a minimum an indication of acceptance or rejection)**
    - **Any specific monitoring and measurement equipment required and instructions associated with their use**

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

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

- Controlled conditions include, as applicable: *(cont'd)*
  - Measurement activities at appropriate stages to verify that specified requirements criteria including acceptance criteria have been met, **ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability)**
  - Use of suitable infrastructure and work environment
    NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.
  - Competent people
  - The validation and periodic revalidation of "special" processes **(See 8.5.1.2)**
  - 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

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

- Controlled conditions include, as applicable: *(cont'd)*
  - **The establishment of criteria for workmanship**
  - **The accountability for all products during production (e.g., parts quantities, split orders, nonconforming product)**
  - **The control and monitoring of identified critical items, including key characteristics, in accordance with established processes**
  - **The determination of methods to measure variable data**
  - **The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages**
  - **The availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized**
  - **The provision for the prevention, detection, and removal of foreign objects**
  - **The control and monitoring of utilities and supplies to the extent they affect conformity to product requirements (see 7.1.3)**
  - **The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities**

Control of key characteristics is addressed in AS9103A

8.5 Production and Service Provision

8.5.1.1 Control of Equipment, Tools, and Software Programs

- **Prior to release for production, organizations must validate and maintain equipment, tools, and software programs used to automate, control, monitor, or measure production processes.**
- **The organization must define storage requirements for production equipment or tooling, including any necessary periodic preservation or condition checks.**

8.5 Production and Service Provision

8.5.1.2 Validation and Control of Special Processes

- For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization must establish arrangements for these processes including, as applicable:
  - Definition of criteria for the review and approval of the processes
  - Determination of conditions to maintain the approval
  - Approval of facilities and equipment
  - Qualification of persons
  - Use of specific methods and procedures for implementation and monitoring the processes
  - Requirements for documented information to be retained

8.5 Production and Service Provision

8.5.1.3 Production Process Verification

- The organization implements production process verification to ensure the process is able to produce products that meet requirements.
  - NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.
- The organization uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements.
- This activity is repeated when changes occur that invalidate the original results.
  - NOTE: Can be referred to as First Article Inspection (FAI).
- The organization retains documented information on the results of production process verification.

FAI requirements can be found in AS9102B

8.5 Production and Service Provision

8.5.2 Identification and Traceability

- Organizations identify process outputs with suitable means where necessary to ensure product or service conformity.
- **The organization maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.**
- The organization identifies the inspection status of process outputs throughout operations.
- **When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization establishes controls for the media.**

8.5 Production and Service Provision

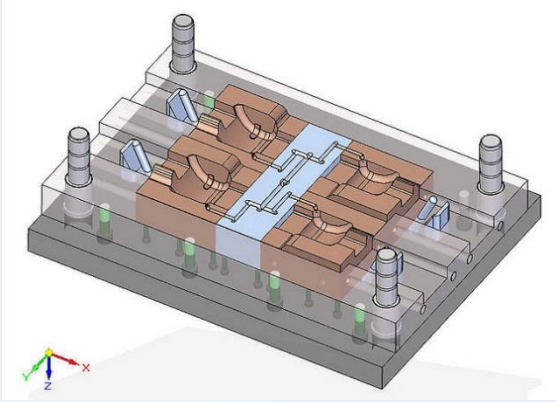
8.5.2 Identification and Traceability

- If traceability is required, the organization provides unique identification of process outputs and retains documented information necessary to enable traceability.
- **Traceability requirements can include:**
  - **The identification maintained throughout the product life**
  - **The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap)**
  - **For an assembly, the ability to trace its components to the assembly and then to the next higher assembly**
  - **For a product, a sequential record of its production**

AS9132B provides requirements for the marking of parts

8.5 Production and Service Provision

8.5.3 Property Belonging to Customers or External Providers



- The organization properly cares for any customer or supplier-owned property while it is under the organization's control.
- This includes identification, verification, protection and safeguarding the property.
- If customer or supplier-owned property is incorrectly used, lost, damaged or otherwise found to be unsuitable for use, the organization notifies the owner and retains documented information on what has occurred.
- Property includes material, components, tools, equipment, premises, intellectual property and personal data.

8.5 Production and Service Provision

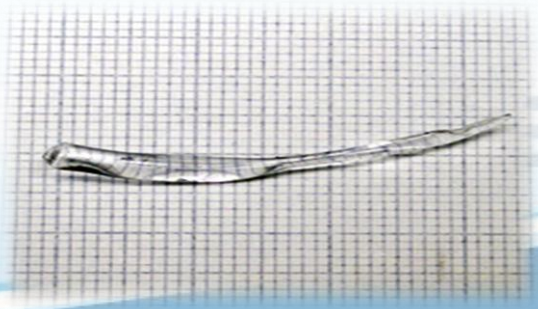
8.5.4 Preservation

- The organization protects product or service outputs during operations to maintain conformity to requirements.
- Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5 Production and Service Provision

8.5.4 Preservation

- **Preservation of outputs also includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:**
  - **Cleaning**
  - **Prevention, detection, and removal of foreign objects (FOD)**
  - **Special handling and storage for sensitive products**
  - **Marking and labeling, including safety warnings and cautions**
  - **Shelf life control and stock rotation**
  - **Special handling and storage for hazardous materials.**



8.5 Production and Service Provision

8.5.5 Post-delivery Activities

- The organization complies with any applicable post-delivery product or service requirements.
- To determine requirements, the organization considers:
  - Statutory, regulatory and customer requirements
  - Potential undesired consequences associated with its products and services
  - The nature, use and intended life of the products and services
  - Customer requirements
  - Customer feedback

8.5 Production and Service Provision

8.5.5 Post-delivery Activities

- To determine requirements, the organization considers *(cont'd)*
  - **Collection and analysis of in-service data (e.g., performance, reliability, lessons learned)**
  - **Control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul**
  - **Controls required for work undertaken external to the organization (e.g., offsite work)**
  - **Product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence)**
- **When problems are detected after delivery, the organization takes appropriate action including investigation and reporting.**
- Post-delivery activities could include warranty, maintenance services, recycling or final disposal.

8.5 Production and Service Provision

8.5.6 Control of Changes

- The organization reviews and controls changes in operations to ensure ongoing conformity with requirements.
- **Identify persons authorized to approve changes in production or service provision.**
  - **NOTE: These can include changes affecting processes, production equipment, tools, or software programs.**
- The organization retains documented information describing the results of change review, the personnel authorizing the change and any necessary actions to be taken as a result of the review.

A structure for change notification is provided in AS9116

8.6 Release of Products and Services

- The organization implements planned arrangements, at appropriate stages, to verify that product and service requirements are met.
- Products and services are not released to the customer until planned arrangements have been met unless otherwise approved by a relevant authority and, as applicable, by the customer.
- The organization retains evidence of product and service conformity with acceptance criteria and traceability to the person(s) authorizing the release.

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

8.6 Release of Products and Services

- When required to demonstrate product qualification, the organization must ensure that retained documented information provides evidence that the products and services meet the defined requirements.
- Documented information required to accompany products and services must be present at delivery.

Guidance for Direct Delivery is provided in ARP9107 while guidance for Direct Ship is provided in ARP9114

Product qualification principles can be found in AS9133A

8.7 Control of Nonconforming Outputs

8.7.1

- The organization ensures outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.
  - **NOTE: The term "nonconforming outputs" includes product or service generated internally, received from an external provider, or identified by a customer.**
- The organization takes appropriate action based on the nature of the nonconformity and its impact on the conformity of products and services.
- This also applies to nonconforming products and services detected after delivery and during or after service provision.

This clause addresses product or service nonconformance while 10.2 deals with QMS nonconformance

8.7 Control of Nonconforming Outputs

8.7.1

- **The organization *maintains documented information* on the nonconformity control process including provisions for:**
  - **Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions**
  - **Taking actions necessary to contain the effect of the nonconformity on other processes, products, or services**
  - **Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties**
  - **Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)**

Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities

8.7 Control of Nonconforming Outputs

8.7.1

- The organization deals with nonconforming outputs through one or more of the following:
  - Correction
  - Segregation
  - Containment
  - Return
  - Suspension of product provision
  - Informing the customer
  - Obtaining authorization for acceptance under concession **by a relevant authority and, when applicable, the customer**

Many customers will expect most of these to be done!

8.7 Control of Nonconforming Outputs

8.7.1

- **Disposition of "use-as-is", or repair for the acceptance of nonconforming products, is only implemented:**
  - **After approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization**
  - **After authorization by the customer, if the nonconformity results in a departure from the contract requirements**
- **Scrap product is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.**
- **Counterfeit or suspect counterfeit parts are controlled to prevent reentry into the supply chain.**
- Conformity to requirements must be verified after corrections.

8.7 Control of Nonconforming Outputs

8.7.2

- The organization retains documented information that:
  - Describes the nonconformity
  - Describes the actions taken
  - Describes any concessions obtained
  - Identifies the authority deciding the actions taken (above)

AS9131C sets common requirements for defining nonconformities and the exchange of information

This also relates to 10.2.2

QMS Group Exercise 4

Audit Scenarios:
Clauses 7-8

QUALITY

OMNEX

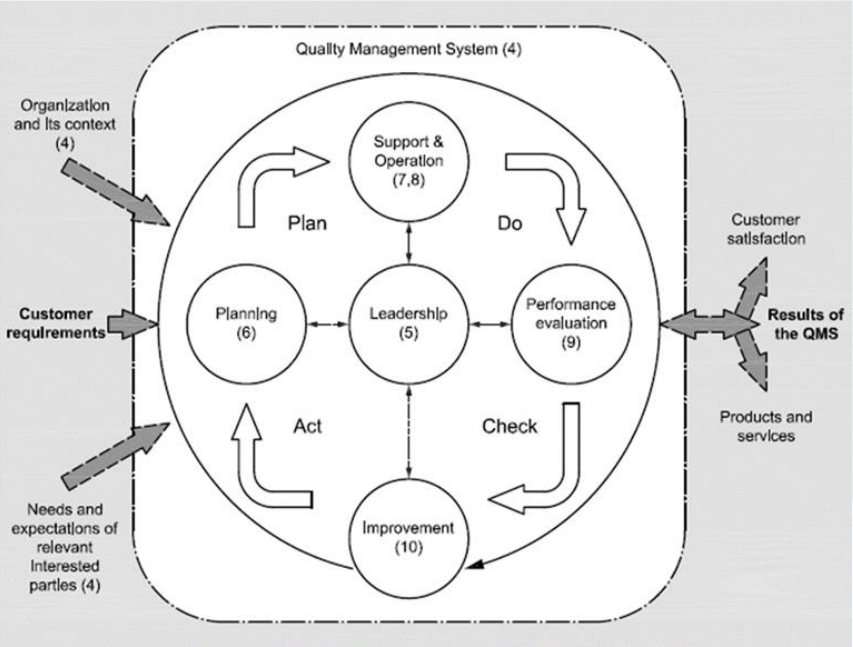
CLAUSE 9 — PERFORMANCE EVALUATION

Clause 9 — Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.2 Internal Audit

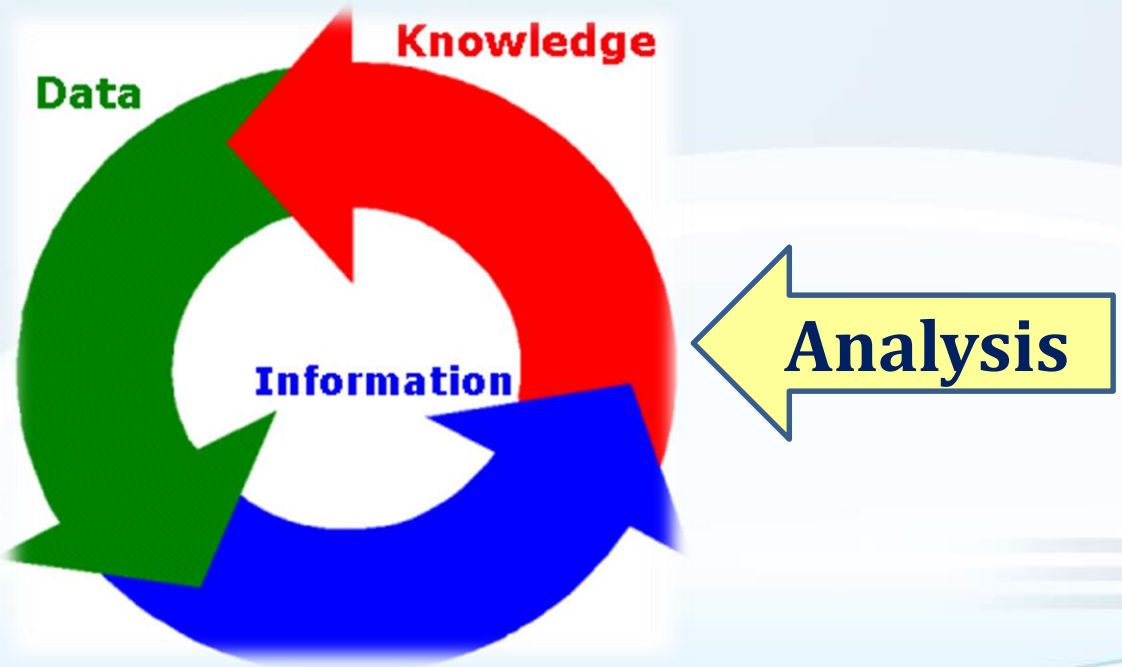
9.3 Management Review



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

9.1.2 Customer Satisfaction

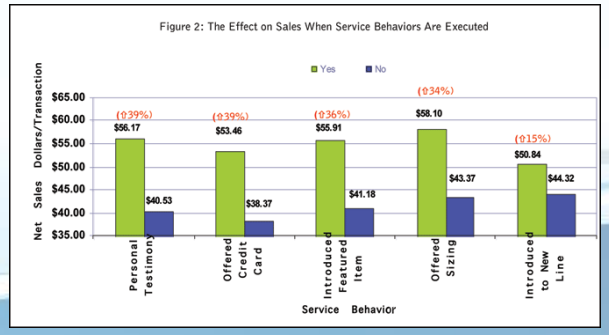
- The organization monitors customer perceptions of the degree to which their needs and expectations have been met.
- The organization determines the methods for obtaining, monitoring and reviewing this information.
- Information on customer perceptions can include customer satisfaction surveys, customer feedback, market-share analysis, compliments, warranty claims.

Many organizations only monitor customer dis-satisfaction metrics, e.g., complaints, rejects, returns.

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.2 Customer Satisfaction

- **Information to be monitored and used for the evaluation of customer satisfaction *shall include,* but is not limited to:**
  - **Product and service conformity**
  - **On-time delivery performance**
  - **Customer complaints**
  - **Corrective action requests**
- **The organization is to develop and implement plans for customer satisfaction improvements that address deficiencies identified by these evaluations, and assess the effectiveness of the results.**



9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.3 Analysis and Evaluation

- The organization analyzes and evaluates appropriate information from monitoring and measurement.
  - **NOTE: Appropriate data can include information on product and service problems reported by external sources**

- The results of this evaluation are used to evaluate:
  - Product and service conformity
  - Customer satisfaction
  - Performance and effectiveness of the QMS
  - If planning has been implemented effectively
  - The effectiveness of actions taken to address risks and opportunities
  - The performance of external providers
  - The need for improvements to the QMS

- Methods to analyze data can include statistical techniques.

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

9.2.1

- The organization conducts internal audits at planned intervals to provide information on whether the QMS conforms to specified QMS requirements, and is effectively implemented and maintained.
  - **NOTE: The organization's own requirements should include customer and applicable statutory and regulatory QMS requirements.**

Performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained

9.2 Internal Audit

9.2.2

- The organization:
  - Plans and implements an audit program(s) specifying the frequency, methods, responsibilities, planning requirements and reporting, taking into consideration:
    - The importance of the processes involved
    - Changes impacting the organization
    - Previous audit results
  - Defines audit criteria and scope for each audit
  - Selects auditors and conducts audits ensuring objectivity and impartiality
  - Ensures that audit results are reported to relevant management
  - Takes necessary and prompt correction and corrective actions
  - Retains evidence of the implementation of the audit program and audit results

See ISO 19011 and AS9101F for guidance

9.3 Management Review

9.3.1 General

- Top Management reviews the organization's QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

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
    - **On-time delivery performance**
  - Adequacy of resources
  - The effectiveness of actions taken to address risks and opportunities (see clause 6.1)
  - Opportunities for improvement

9.3 Management Review

9.3.3 Management Review Outputs

- Management Review outputs include decisions and actions related to:
  - Opportunities for improvement
  - Need for changes to the QMS
  - Resource needs
  - **Risks identified**
- Documented information is retained

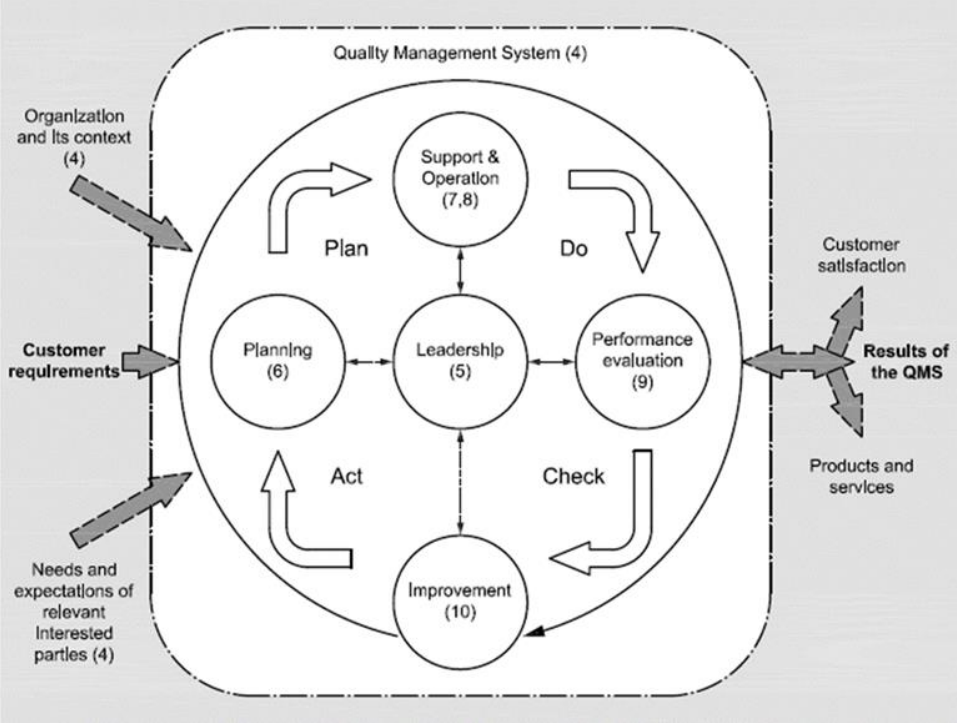
CLAUSE 10 — IMPROVEMENT

Clause 10 — Improvement

10.1 General

10.2 Nonconformity and Corrective Action

10.3 Continual Improvement



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

10.2.1

- When a nonconformity occurs, the organization:
  - Reacts, and as applicable, takes action to control and correct it, and deals with the consequences
  - Evaluates the need for action to eliminate the cause and to ensure that it does not recur or occur elsewhere, by:
    - Reviewing and analyzing the nonconformity
    - Determining the causes, **including, as applicable, those related to human factors**
    - Determining if similar nonconformities exist, or could potentially occur
    - Implementing any action needed
    - Reviewing the effectiveness of any corrective action taken
    - Updating risks and opportunities from planning, if necessary
    - Making changes to the QMS, if necessary

10.2 Nonconformity and Corrective Action

10.2.1

- When a nonconformity occurs, the organization: *(cont'd)*
  - **Flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity**
  - **Takes specific actions when timely and effective corrective actions are not achieved**
- Corrective actions are appropriate to the effects of the nonconformities encountered.
- **The organization *maintains documented information* that defines the nonconformity and corrective action management processes.**

10.2 Nonconformity and Corrective Action

10.2.2

- Documented information is retained as evidence of the nature of the nonconformities and any actions taken.
- Corrective action results are retained.

This also relates to 8.7.2

10.3 Continual Improvement

- The organization is to continually improve the suitability, adequacy and effectiveness of the QMS.
- The organization considers the results of analysis, evaluation and management review to determine if there are needs or opportunities that must be addressed for continual improvement.
- **The organization monitors the implementation of improvement activities and evaluates the effectiveness of the results.**

Examples of continual improvement opportunities can include lessons learned, problem resolutions and the benchmarking of best practices.

QMS Group Exercise 5

Audit Scenarios:
Clauses 9-10

QUALITY

OMNEX

Chapter 3: ISO 9001 and AS9100D 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 process approach

Chapter Agenda

- Clause 4 Context of the Organization
  - **Group Exercise 1 – Context**
  - **Group Exercise 2 – Assessing Risk**
- 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**

QMS Exams

Work Individually

Chapter 4

Process Approach to Auditing, Turtle Diagrams, and Audit Trails

Chapter 4: 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 AS9100 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

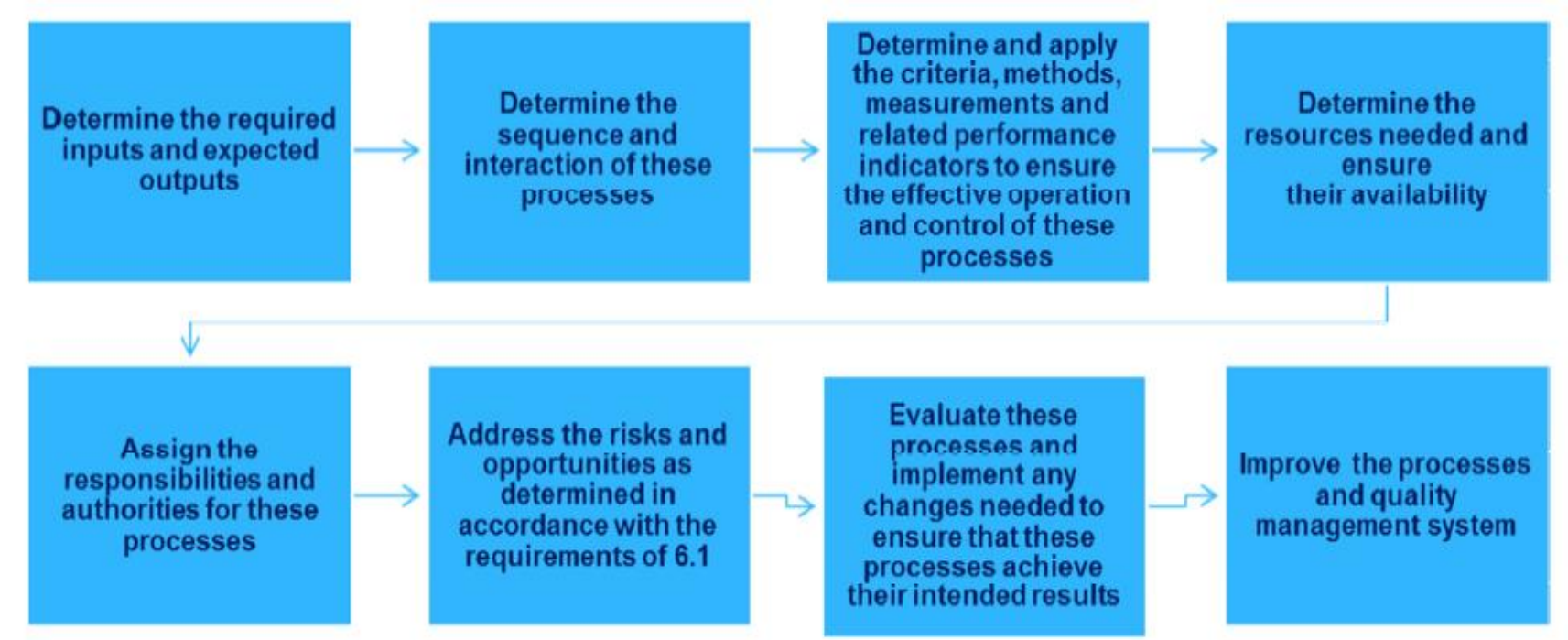
Performance Audits

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

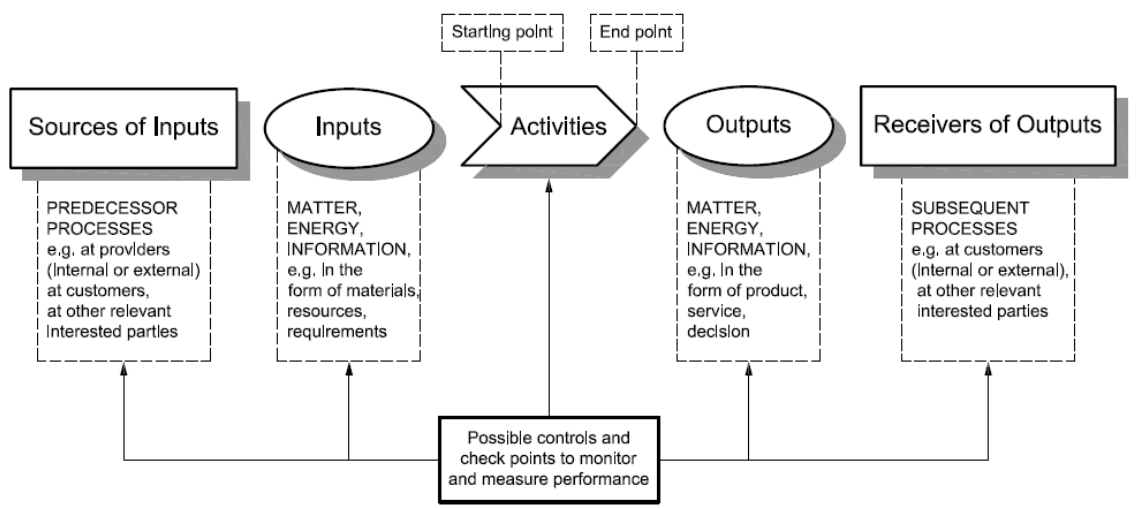
This diagram can assist auditors in establishing the sequence to audit the processes of the organization:



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



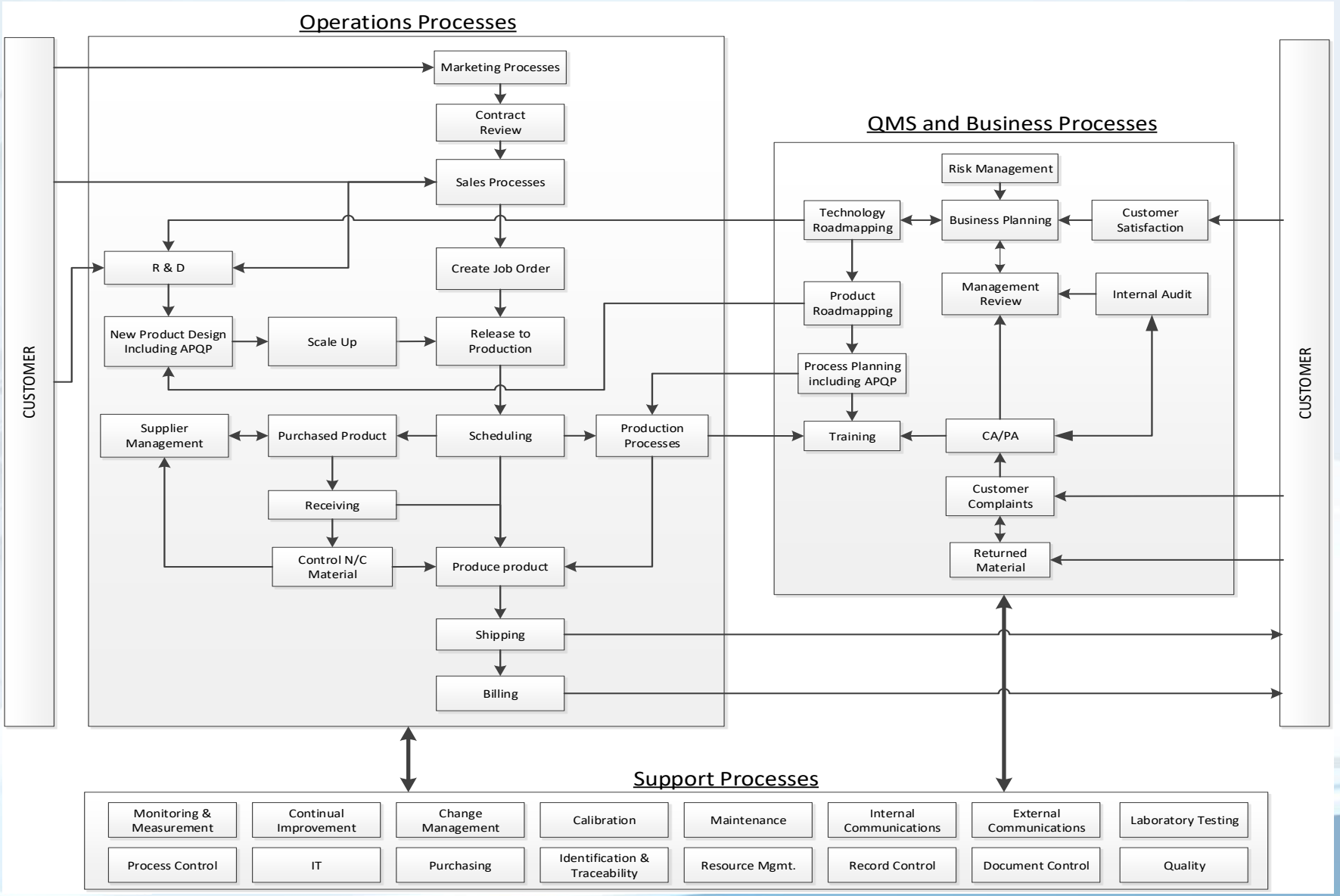
source: ISO 9001:2015, Figure 1 — Schematic Representation of the Elements of a Single Process

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 AS9100 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

Customer Oriented Processes

1 IN FROM THE CUSTOMER

Customer requires a specific activity done in compliance to their process

I

2

Your Organization

A COP has three criteria

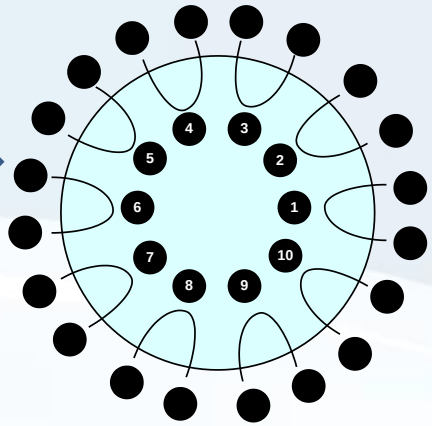
Customer's requirement is met and the output is provided to them in the format or method required

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

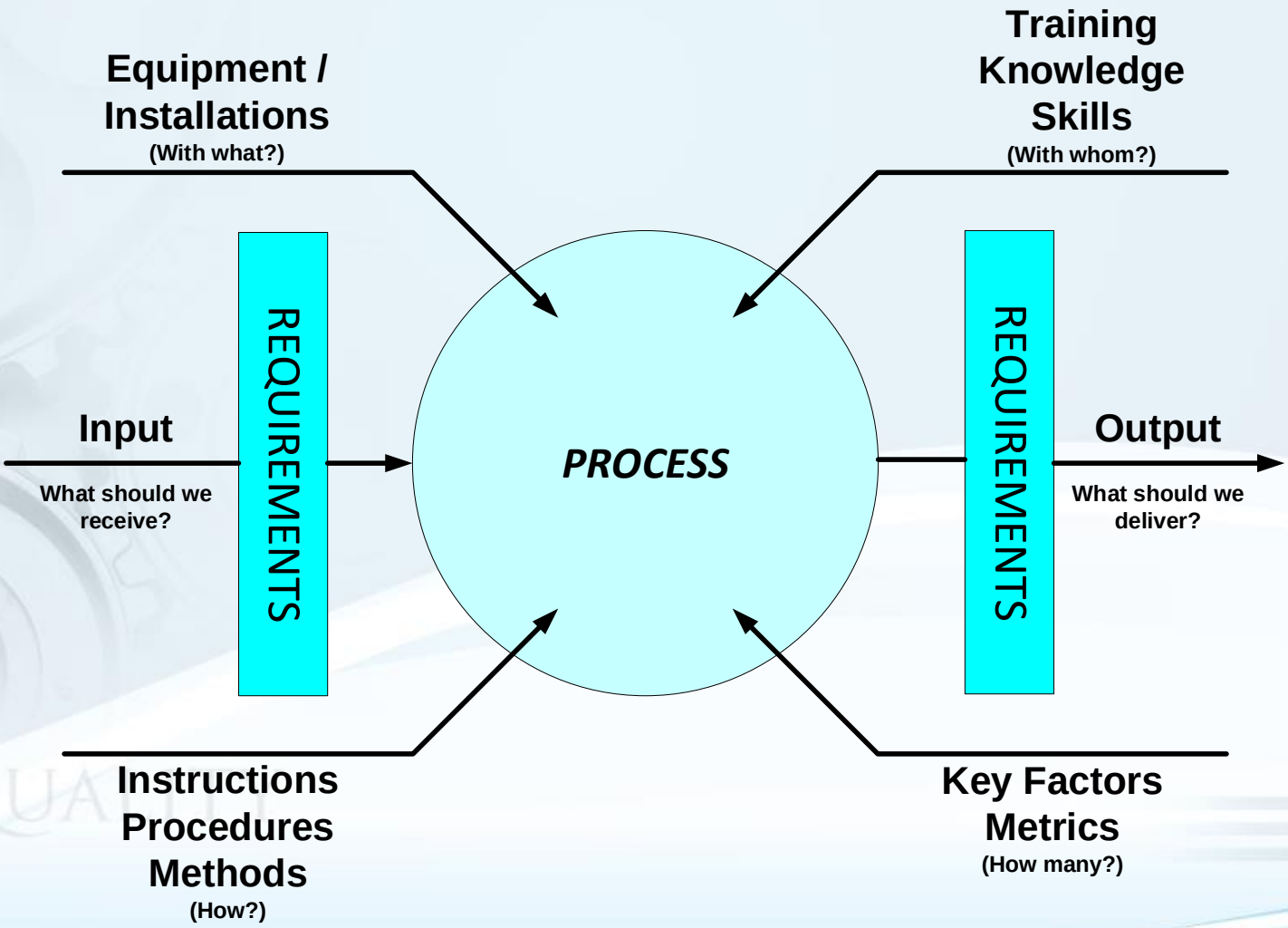
COPs, MOPs, SOPs

TURTLE DIAGRAMS

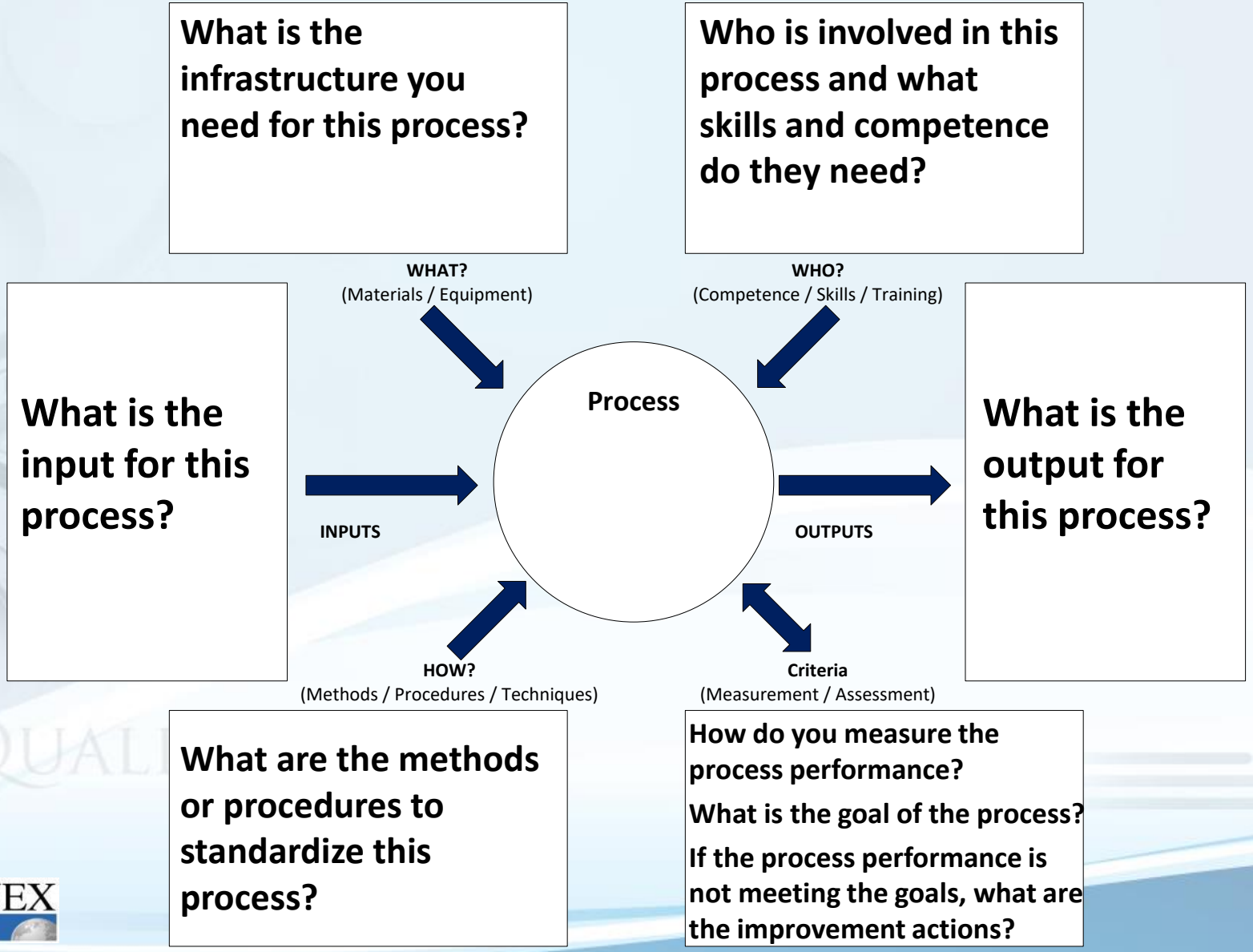
The Turtle Diagram

- 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

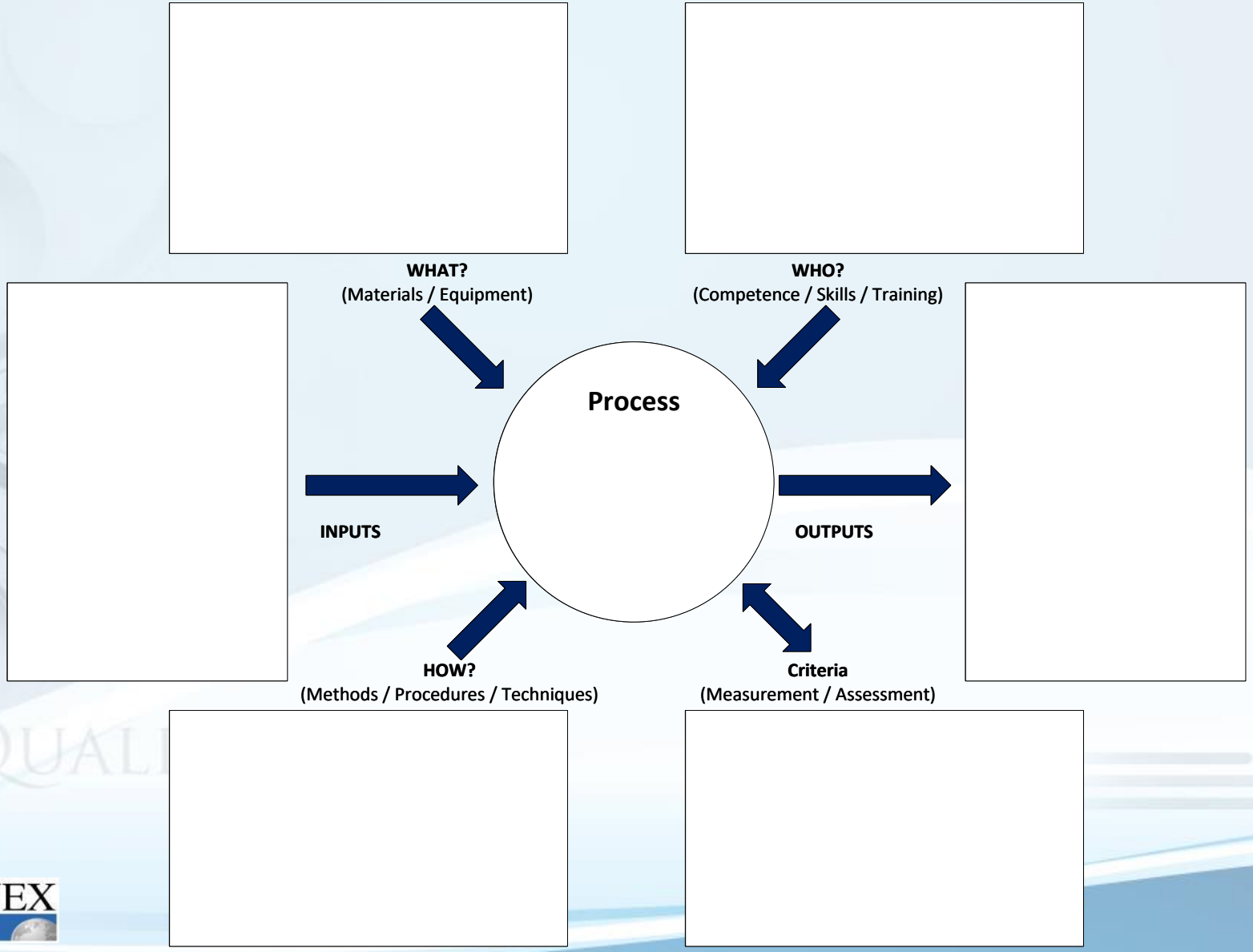
Turtle Diagram



Turtle Diagram



Process Analysis — Instructor-led Example



Process Effectiveness Assessment Report (PEAR)

[1] *CB Name*	**PROCESS EFFECTIVENESS ASSESSMENT REPORT**	[2]

[3] **Organization:**	[4] **Site(s):**	[5] **OIN(s):**
[6] **PEAR Number:**	[7] **Audit Report Number:**	[8] **Issue Date:**

SECTION 1 – PROCESS DETAILS

[9] **Process Name:**	[10] **Responsibility/Authority**		
[11] **AQMS Standard / Revision:**	☐ **9100 Rev:**	☐ **9110 Rev:**	☐ **9120 Rev:**

[12] **Applicable 9100/9110/9120 clause(s):**

[13] **Inputs:**

[14] **Activities:**

[15] **Outputs:**

[16] **Interactions/Interfaces:**

Information used to complete the Turtle Diagram can be transferred to the PEAR

Process Effectiveness Assessment Report (PEAR)

SECTION 2 – PROCESS RESULTS			
[17] Organization's method for determining process results:			
[18] Performance Measures			
KPI 1:			
KPI 2:			
KPI 3:			
[19] Auditor observations and comments supporting process result determination:			
Reference	**Target for Audited Period**	**Value Measured for Audited Period**	**Comments**
KPI 1:			
KPI 2:			
KPI 3:			
SECTION 3 – PROCESS REALIZATION			
[20] Summary of audit trails and sources of evidence:			

Process Effectiveness Assessment Report (PEAR)

Process Realisation (a)	Process Results (b): Planned results not achieved and appropriate action is not taken	Process Results (b): Planned results not achieved, but appropriate action is being taken	Process Results (b): Planned results are achieved
Planned activities fully realised	a) The process is determined, and planned activities fully realized; however, b) The process is not delivering the planned results and appropriate action is not being taken. **Minor NC** 2	a) The process is determined, and planned activities fully realized; however, b) The process is not delivering the planned results, but appropriate action is being taken. **Conforming** 4	a) The process is determined, and planned activities fully realized; and b) The process is delivering the planned results. **Conforming** 5
Planned activities not fully realised	a) The process is determined, but planned activities not fully realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **Minor NC** 2	a) The process is determined, but planned activities not fully realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **Minor NC** 3	a) The process is determined, but planned activities not fully realized; however, b) The process is delivering the planned results. **Minor NC** 4
Planned activities not realised	a) The process is not determined, and planned activities not realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **Major NC** 1	a) The process is not determined, and planned activities not realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **Minor NC** 2	a) The process is not determined, and planned activities not realized; however, b) The process is delivering the planned results. **Minor NC** 2

Completing the PEAR

- Prepare the process-related questions to be asked
  - Identify the process concerns related to:
    - Customer performance issues
    - Organizational performance issues
  - Identify the general process-related question
    - Use the turtle diagram
  - Identify potential questions relating to conformity with AS9100 requirements

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

ISO 9001:2015 / AS9100D 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

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.

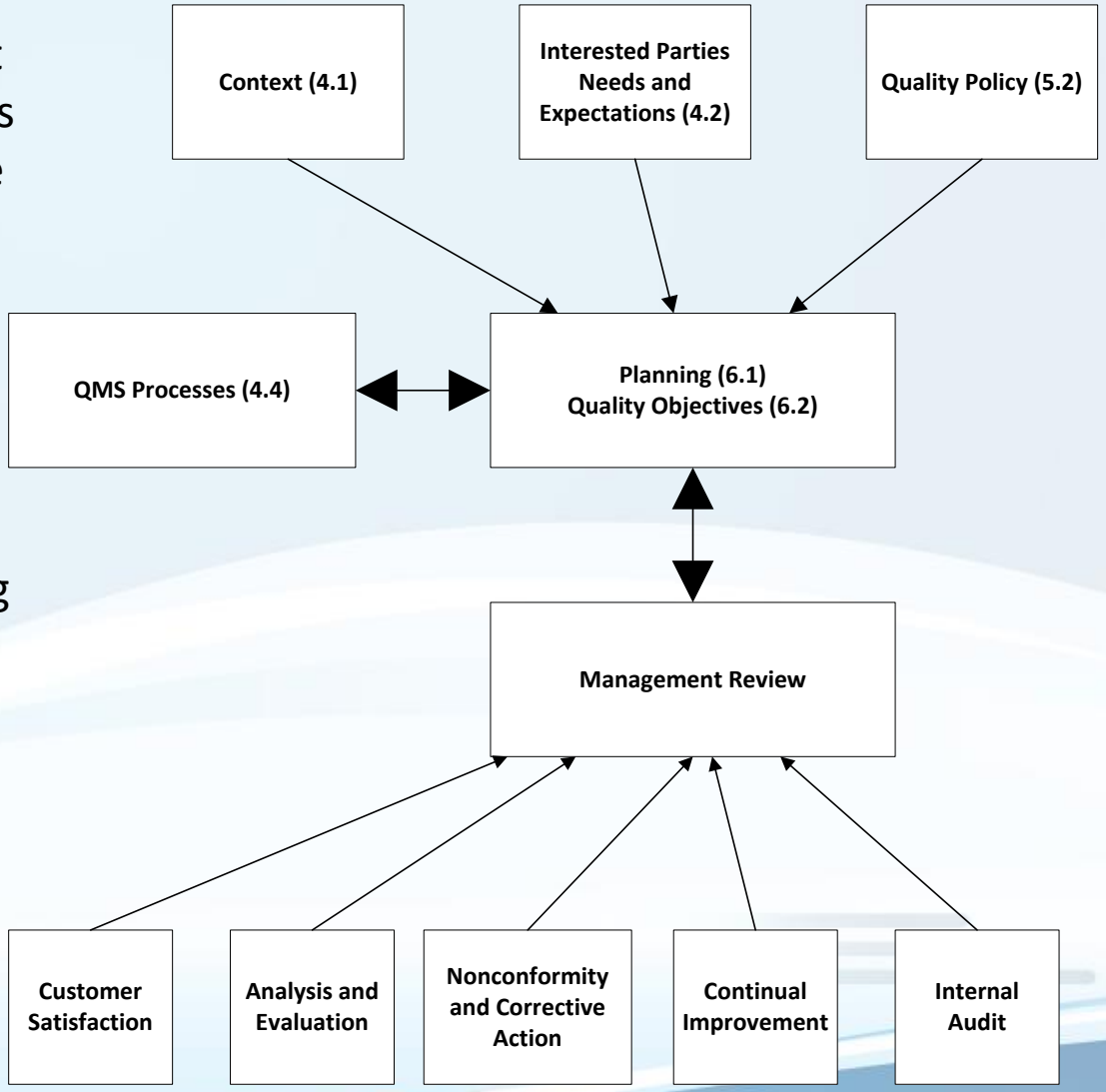
How to Use Audit Trails When Auditing Processes

- 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.

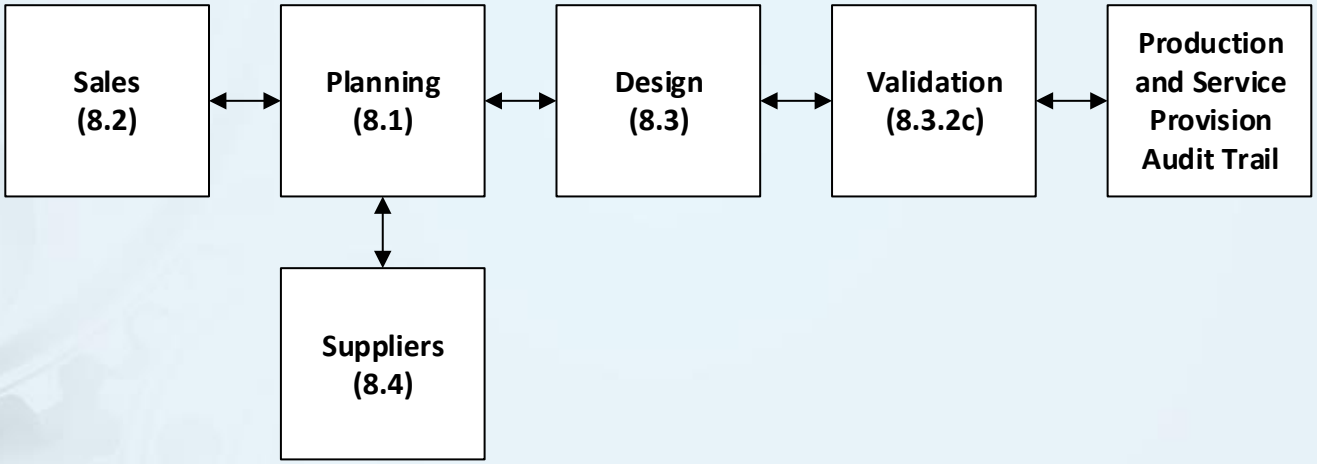


Since this audit trail is so large and has so many important topics, it is broken into two pieces so a second auditor is able to audit the bottom half

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?

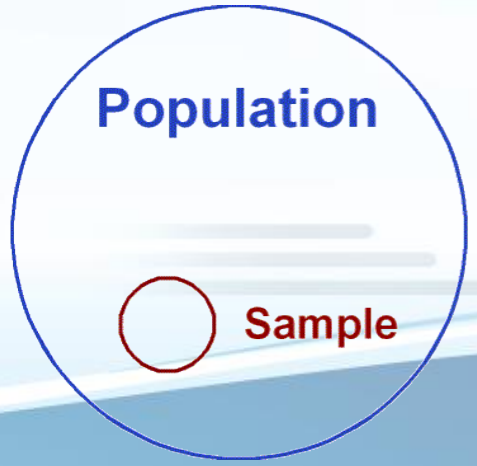
New Product / Service Development Audit Trail



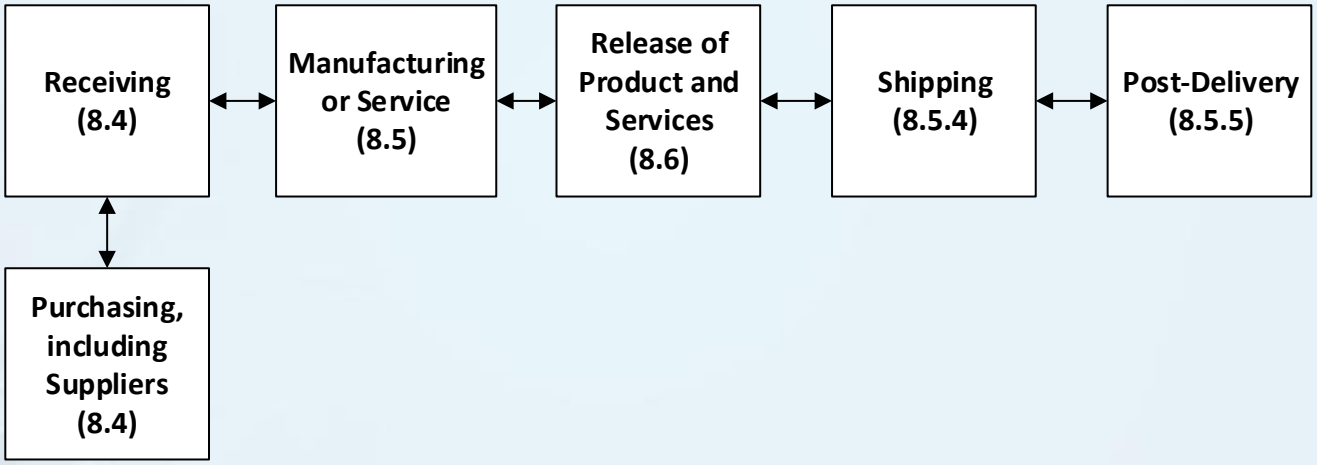
- The New Product / Service Development process starts with the sales process or the contract review process as it was referred to in earlier versions of ISO 9001.
- Next is the planning and execution of the product or service design.
- Then the planning and execution of the processes to create the product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

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 4: 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 5

Audit Guidance, Definitions and Principles

Chapter 5: 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

- ASD Audit Approach
- 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.

ASD Audit Approach

- An ASD audit is an evaluation of the organization's QMS approach, as required by the AS9100-series standards. In evaluating the QMS, there are basic questions that should be asked of every process, for example:
  - Is the process appropriately determined?
  - Are responsibilities assigned?
  - Are the processes adequately implemented and maintained?
  - Is the process effective in achieving the desired results?

  The answers to these and other associated questions will evaluate the process and determine its results.
- Product and Service quality (as delivered), customer satisfaction and QMS effectiveness should be considered as interrelated. This relationship should be reflected in the audit process and associated results.

Product and Service quality (as delivered), customer satisfaction and QMS effectiveness should be considered as interrelated. This relationship should be reflected in the audit process and associated results.

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

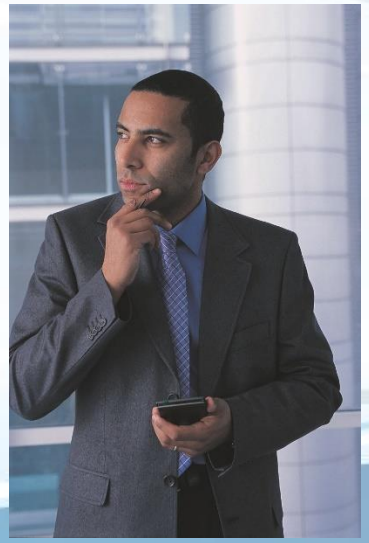
- Auditing principles help to make the audit an effective and reliable tool in support of management policies and controls by providing information upon which an organization can act in order to improve its performance.
- Adherence to these principles is needed in order to provide:
  - Audit conclusions 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

IAQG requires lead auditors to meet the requirements for an Aerospace Experience Auditor, as defined in AS9104/3

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 5: 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

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

Chapter 6

The Audit Program

Chapter 6: The Audit Program — What We Will Cover

Learning Objectives

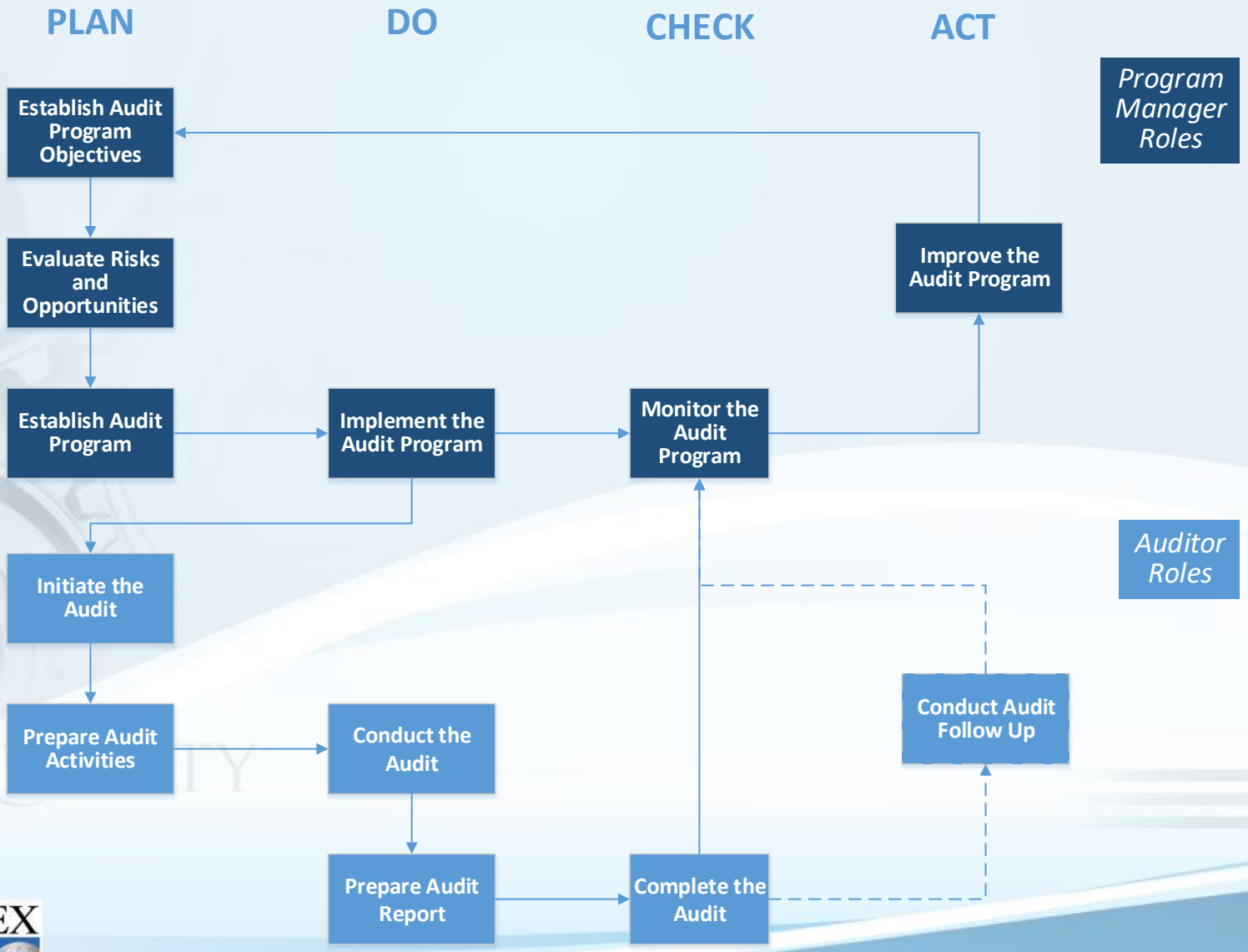
At the end of this chapter, you will be able to:

- 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 6: 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 7

Audit Planning and Preparation

Chapter 7: 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 aerospace 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?

In ASD audits, IAQG requires that you consider the proportion of the business (based on products, customer, etc.) when taking a sample. This is a good practice for internal audits as well!

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:
  - Must be performed by the audit team leader with audit team assistance if needed
  - An on-site visit is required for AS9100, AS9110 and AS9115 Stage 1 audits; for AS9120 the Stage 1 can be conducted off-site
  - Evaluate Customer Focus and Performance
  - Conduct Document Review
  - Identify Audit Risks and Feasibility
  - Finalize Audit Plans
  - Prepare Work Documents
    - Turtle Diagrams/PEAR (The PEAR will be completed on OASIS during Stage 2)
    - Auditor Checklists

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

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.

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.
- The extent of the plan is based on the complexity of the audit.
- The plan is prioritized based on business risks that could impact the customer and processes that are not achieving planned results.
- 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
  - Is based on processes documented in the QMS Process Matrix Report (Form 2 of AS9101F)

Preparing the Audit Plan

- The audit plan must take into account:
  - The sequence and interaction of processes
  - The critical level of product, services and processes
  - The risks of products, services, and processes and also the risk associated with the QMS
  - Product related safety issues
  - Results of internal and other previous audits
  - Performance measures and trends for quality and ontime delivery
  - Management review results
  - Customer, statutory and regulatory requirements
  - Customer satisfaction and performance data
  - Certification structure
  - Integrated or combined audits

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
- 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 AS clauses
- Sample customer 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 7: 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 8

Conducting the Audit

Chapter 8: Conducting 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**

Conducting the Audit

- There are six steps 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 conducted
  - 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
- Confirm the scope of certification (for 3rd party audit)
- Describe the audit process **(Process Approach Audit)**
- Confirm audit plan, including objectives, scope and criteria
- Summary of methods and procedures used for audit
  - Notes
  - Sampling
  - Small groups
  - Notification of findings
  - Questions for the lead auditor
- Determine communication channels between audit team and auditee
- Describe methods of reporting including the grading of findings

Opening Meeting

Opening Meeting Checklist *(cont'd)*

- Confirm authority to audit
- Discuss status of the previous audit findings
- Establish language of the audit
- Define conditions that may lead to premature termination of the audit
- 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)
- Provide opportunity to ask questions

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

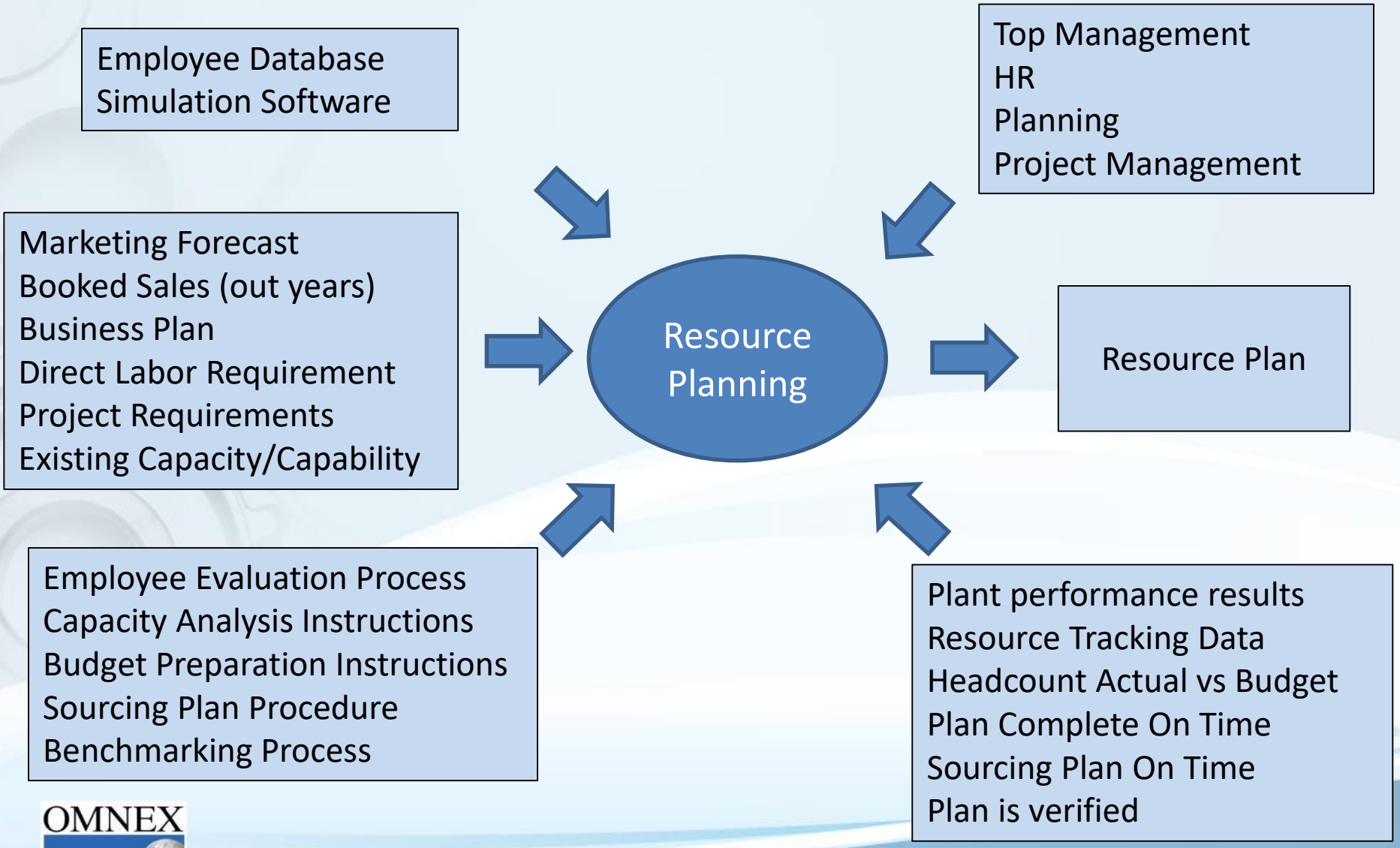
- The process approach audit is meant to **add value:**
  - It should start with a performance analysis of customer data that identifies areas of weakness or areas for improvement noted during the Stage 1 audit.
  - It should end with the identification of variations (**nonconformities**) in the process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



Process Effectiveness Assessment Report (PEAR)

[1] *CB Name*	**PROCESS EFFECTIVENESS ASSESSMENT REPORT**	[2]

[3] **Organization:**	[4] **Site(s):**	[5] **OIN(s):**
[6] **PEAR Number:**	[7] **Audit Report Number:**	[8] **Issue Date:**

SECTION 1 – PROCESS DETAILS

[9] **Process Name:**	[10] **Responsibility/Authority**		
[11] **AQMS Standard / Revision:**	☐ **9100 Rev:**	☐ **9110 Rev:**	☐ **9120 Rev:**
[12] **Applicable 9100/9110/9120 clause(s):**			
[13] **Inputs:**			
[14] **Activities:**			
[15] **Outputs:**			
[16] **Interactions/Interfaces:**			

Completing the PEAR

Header Information

1 through 8: Enter required identification items

Section 1 – Process Details

9: Identify the process being audited

10: Identify process owner

11: Identify to which standard(s) the aerospace audit is being conducted

12: Determine which AS9100-series standard/clauses that the process satisfies

13 through 16: Identify process inputs, activities, output, and interactions

- Process map and Turtle Diagrams are used for inputs, outputs and interactions
- Procedures and/or work instructions are used for the activities

Process Effectiveness Assessment Report (PEAR)

SECTION 2 – PROCESS RESULTS			
[17] Organization's method for determining process results:			
[18] Performance Measures			
KPI 1:			
KPI 2:			
KPI 3:			
[19] Auditor observations and comments supporting process result determination:			
Reference	**Target for Audited Period**	**Value Measured for Audited Period**	**Comments**
KPI 1:			
KPI 2:			
KPI 3:			
SECTION 3 – PROCESS REALIZATION			
[20] Summary of audit trails and sources of evidence:			

Completing the PEAR

Complete Section 2 – Process Results

17: Organization's Method for Determining Results

- What does the organization track?
- How do they collect information and data?
- How do they track the information and data?
- How do they report the information and data?
- How do they use the information and data to improve?

18: Performance Measures – Identify the top KPIs associated with the process

- What are the names of the performance measures?
- Are they the correct measures?
- Are they used effectively?

19: Observations – Annotate relevant performance targets, measured values and comments to support the process results determination

- Record the current target the organization is using
- Record the actual value for the measure for the audited period

Process Effectiveness Assessment Report (PEAR)

SECTION 4 – PROCESS EFFECTIVENESS

Process Realisation (a)	Process Results (b): Planned results not achieved and appropriate action is not taken	Process Results (b): Planned results not achieved, but appropriate action is being taken	Process Results (b): Planned results are achieved
Planned activities fully realised	a) The process is determined, and planned activities fully realized; however, b) The process is not delivering the planned results and appropriate action is not being taken. **Minor NC** 2	a) The process is determined, and planned activities fully realized; however, b) The process is not delivering the planned results, but appropriate action is being taken. **Conforming** 4	a) The process is determined, and planned activities fully realized; and b) The process is delivering the planned results. **Conforming** 5
Planned activities not fully realised	a) The process is determined, but planned activities not fully realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **Minor NC** 2	a) The process is determined, but planned activities not fully realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **Minor NC** 3	a) The process is determined, but planned activities not fully realized; however, b) The process is delivering the planned results. **Minor NC** 4
Planned activities not realised	a) The process is not determined, and planned activities not realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **Major NC** 1	a) The process is not determined, and planned activities not realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **Minor NC** 2	a) The process is not determined, and planned activities not realized; however, b) The process is delivering the planned results. **Minor NC** 2

Determining Process Effectiveness

- The effectiveness of each product realization process is evaluated, considering:
  - **Process Realization:** the extent to which planned activities are realized
  - **Process Results:** the extent to which planned results are achieved
- This is accomplished by evaluating the audit evidence from the PEAR.
- Once the evidence is evaluated, select the corresponding value based on descriptions in the Process Evaluation Matrix.
- A “5” is only given when the process is delivering planned results, planned activities are fully realized, and no nonconformities are identified.

Completing the PEAR

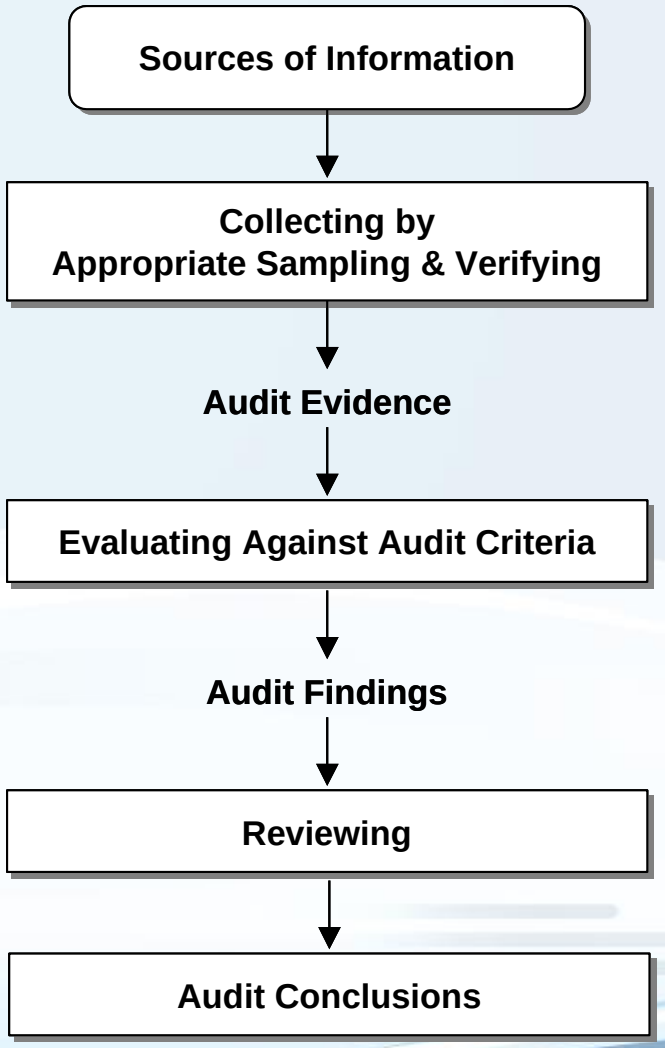
- Process characteristics and classifications are determined by the interview in the Stage 2 audit.
- The organization's method for process effectiveness is completed during the interview in Stage 2. In other words, how is effectiveness measured and maintained? Typically, the process is measured by Process Indicators or other measurements.
- Auditor observations and comments supporting process effectiveness determination refers to objective evidence supporting the auditor's conclusion for the statement of effectiveness.

Completing the PEAR

- Statement of effectiveness ranges from not implemented and planned results not achieved to implemented and planned results achieved.
- Process weaknesses noted for Stage 1, although partially completed during Stage 2, still needs additional information from the auditor.
- Process design and robustness – if the process repeatedly fails, the auditor needs to ask if the process has been satisfactorily designed and whether it will need a redesign in order to meet the process objectives.
- The Turtle can be used during the interview to audit the process.

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 8: Conducting 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 9

Writing Nonconformity Statements

Chapter 9: 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

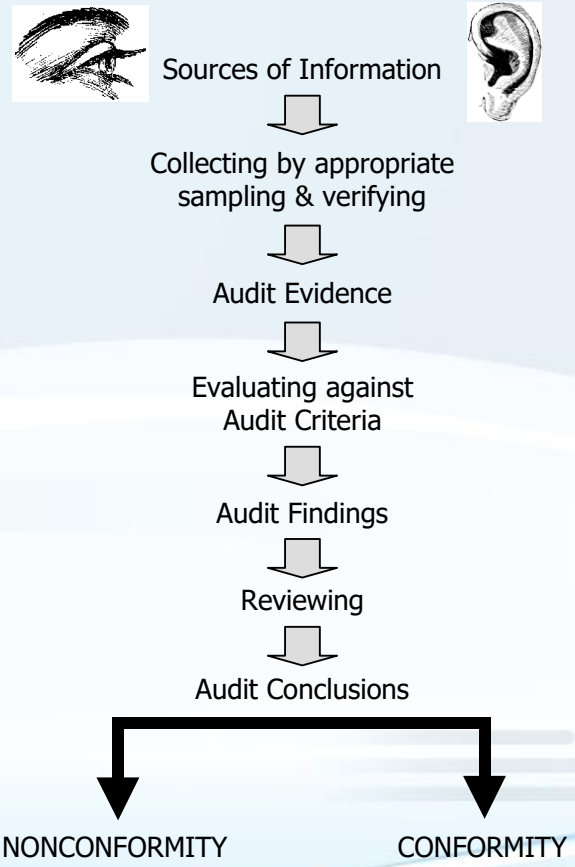
Chapter Agenda

- 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:** Evidence of conformity with dimensional acceptance criteria is not fully effective.
- **Requirement:** AS9100D 9.1.1 requires that "*The organization shall retain appropriate documented information as evidence of the results.*"
- **Objective Evidence:** Audit of Manifold operation 10, 20, and 30 machining reveal only the words "okay" or "not okay" were being recorded on check sheets. The work instruction for the check sheet (WI-14XCB) clearly requires that actual readings are to be recorded on the check sheet.

[1] ***CB Name*** ABC Certification Body	**NONCONFORMITY REPORT (NCR)**		[2] 
[3] **Organization:**	Top House Company	[5] **Audit Report Number:**	XXXX
		[6] **NCR Number:**	XX
[4] **Site/OIN:**	XXXX	[7] **Issue Date:**	xx/xx/xxxx

SECTION 1 – NONCONFORMITY DETAILS

[8] **AQMS Standard/Revision**	**X 9100 Rev: D**	☐ **9110 Rev:**	☐ **9120 Rev:**

[9] **Applicable 9100/9110/9120 requirement/clause: 9.1.1** ***The organization shall retain appropriate documented information as evidence of the results***

[10] **Process/Area/Department**	Manifold Operations	[11] **Classification (Ma/Mi): Mi**

[12] **Statement of Nonconformity: Evidence of conformity with dimensional acceptance criteria is not fully effective**

[13] **Objective Evidence:** Audit of Manifold operation 10, 20, and 30 machining reveal only the words “okay” or “not okay” were being recorded on check sheets. The work instruction for the check sheet (WI-14XCB) clearly requires that actual readings are to be recorded on the check sheet.

[14] **Containment Required?** ☐ **Yes** X **No**	[15] **Due Date:**

[16] **Auditor:**	[17] **Organization Representative:**

TYPES OF NONCONFORMITIES

Types of Nonconformities

Major Nonconformity

- Nonconformity that affects the capability of the management system to achieve the intended results.
- NOTE: Nonconformities could be classified as a major in the following circumstances:
  - If there is a significant doubt that the effective process control is in place, or that products or services will meet specified requirements;
  - A number of minor nonconformities associated with the same requirements or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor Nonconformity

- Nonconformity that does not affect the capability of the management system to achieve the intended results.

These definitions are taken from ISO 17021:2015

Types of Nonconformities

Major Nonconformity (per AS9101F)

- In addition, a major nonconformity can be one or more of the following situations:
  - A nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
  - The absence of or total breakdown of a system to meet a 9100-series standard requirement, a customer QMS requirement, or documented information defined by the organization;
  - Any nonconformity that can result in the probable delivery of nonconforming product or service; and
  - A condition that could result in the failure or reduce the usability of the product or service and its itended purpose.

Per IAQG: The nonconformity statement should state "The process/system is not effective"

Types of Nonconformities

Minor Nonconformity (per AS9101F)

- In addition, a minor nonconformity can be a single system failure or lapse in conformity to meet:
  - A 9100-series standard requirement;
  - A customer QMS requirement; or
  - A documented information defined by the organization.

Per IAQG: The nonconformity statement should state "The process/system is not fully effective or partially effective"

REVIEW FINDINGS AND CONCLUSIONS

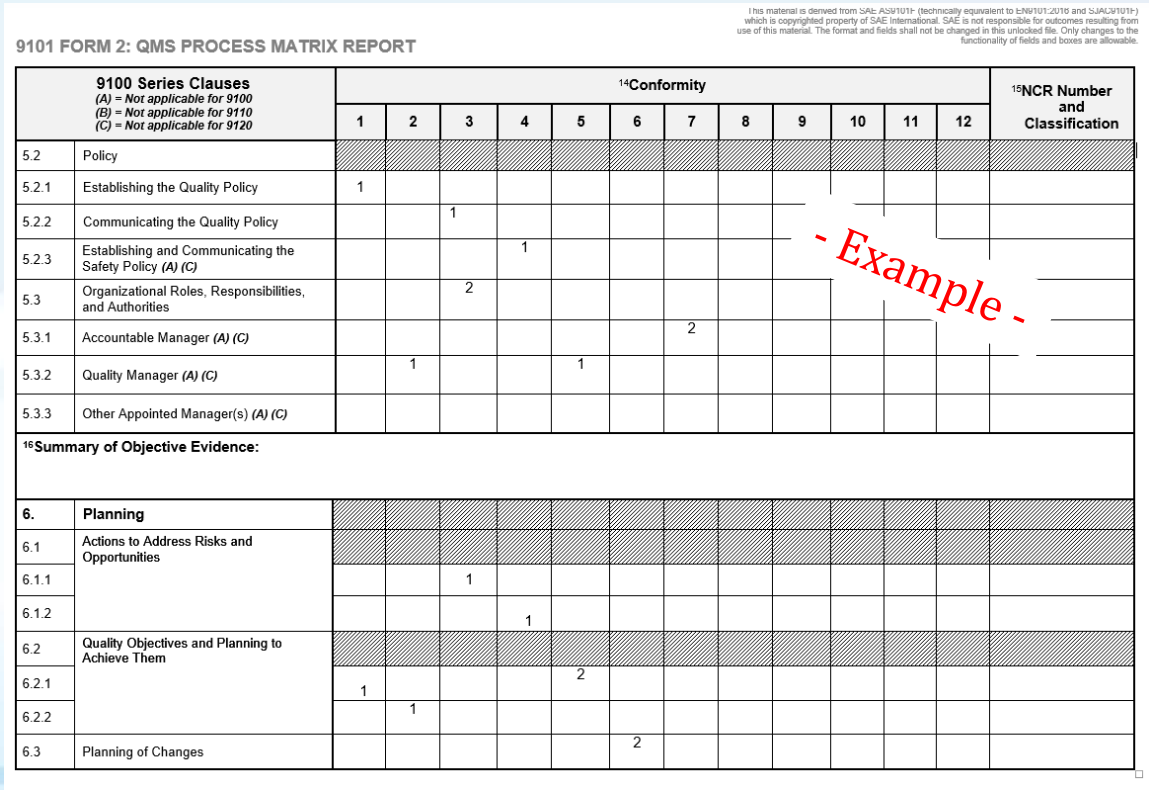
Reviewing Findings

- 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.



9101 FORM 2: QMS PROCESS MATRIX REPORT

9100 Series Clauses (A) = Not applicable for 9100 (B) = Not applicable for 9110 (C) = Not applicable for 9120		[14]Conformity												[15]NCR Number and Classification
		1	2	3	4	5	6	7	8	9	10	11	12	
5.2	Policy													
5.2.1	Establishing the Quality Policy	1												
5.2.2	Communicating the Quality Policy			1										
5.2.3	Establishing and Communicating the Safety Policy *(A) (C)*				1									
5.3	Organizational Roles, Responsibilities, and Authorities			2										
5.3.1	Accountable Manager *(A) (C)*							2						
5.3.2	Quality Manager *(A) (C)*		1			1								
5.3.3	Other Appointed Manager(s) *(A) (C)*													
[16]Summary of Objective Evidence:														
6.	Planning													
6.1	Actions to Address Risks and Opportunities													
6.1.1				1										
6.1.2					1									
6.2	Quality Objectives and Planning to Achieve Them													
6.2.1		1				2								
6.2.2			1											
6.3	Planning of Changes						2							

- 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 9: 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 10

Closing Meeting

Chapter 10: 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 slide 458 for more detail)
  - Nonconformity statements and opportunities for improvement, if applicable
  - Clarification of nonconformity statements and summary
- Method and timeframe of audit reporting and use of OASIS
- Nonconformity statements, including the PEAR ratings and any NCs based on that rating

Closing Meeting Checklist

(cont'd)

- Certification body's process for handling any nonconformities and their effect on the client certification status (3rd party audits only)
- How audit findings should be addressed and possible consequences for not addressing them
- Timeframe for auditee to present correction and corrective action for any nonconformities identified during the audit
- Confidentiality
- Follow-up, including certification body post-audit 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 10: 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 11

Completing the Audit Report

Chapter 11: 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
- Reviewing IAQG Audit Report Template

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

AS9101F Audit Forms

The following audit forms from AS9101F are provided for your reference in Appendix C of the course textbook and can also be downloaded from the IAQG website (http://www.sae.org/iaqg/forms/):

- 9101F Form 1 – Stage 1 Audit Report
- 9101F Form 2 – QMS Process Matrix Report
- 9101F Form 3 – Process Effectiveness Assessment Report
- 9101F Form 4 – Nonconformity Report
- 9101F Form 5 – Audit Report
- 9101F Form 6 – Supplemental Audit Report

Chapter 11: 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
- Reviewing IAQG Audit Report Template

Chapter 12

Corrective Action and Close-Out

Chapter 12: 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 – Recommended 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.

  For ASD certification audits, the timeframe for response to a nonconformity is:
  - **7 days for containment**
  - **30 days for corrective action**
  - **60 days for bringing system into a state of conformity**

- 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

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

This seven step process is recommended to conduct an effective close-out:

1. Has the organization expressed the problem as a system issue?

2. Has the organization taken containment actions on the specific incidents cited by the audit team in their objective evidence?
   - If external customers could be impacted, then containment actions need to be taken.

3. Has the organization found the root cause(s) of the problem in their system that allowed the incidents cited by the audit team to occur?
   - Does the organization answer the question: **What in our system failed that allowed this to happen?**

This method is also recommended for AS9100

Conducting Close-Out

4. Does the corrective action determined by the organization:
   - Address changes to the system, not specific employees or machines?
   - Address the root cause(s) they have identified?

5. Has the organization reviewed its associated FMEAs (design and/or process) based upon the nonconformities?
   - Do the occurrence or detection ratings need to change?
   - Is the FMEA treated as a living document?

6. Has the organization reviewed its associated control plans, work instructions and inspection instructions, etc.?
   - Are the plant floor instructions and the control plan treated as a living document?

7. Has the audit team verified that corrective action is implemented?

Chapter 12: 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 – Recommended Method
- **Management Systems Auditing Exam**

Management Systems Auditing Exam

Work Independently

OMNEX

Chapter 13

Leading Audit Teams

Chapter 13: Leading Audit Teams — What We Will Cover

Learning Objectives

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

- Identify and evaluate the necessary competencies for the audit team
- Identify the items that should be considered when selecting an audit team
- Assign work to the audit team
- Describe steps to take to avoid and solve conflict

Chapter Agenda

- Audit Team Competence
- Auditing Multiple Standards
- Selecting an Audit Team
- Conflict Resolution

AUDIT TEAM COMPETENCE

Audit Team Competence

Generic Competence of Audit Team Leader

a) Plan the audit and assign audit tasks according to the specific competence of audit team members

b) Discuss strategic issues with top management of the auditee to determine whether they have considered these issues when evaluating their risks and opportunities

c) Develop and maintain a collaborative working relationship among the audit team members

Audit Team Competence

Generic Competence of Audit Team Leader

d) Manage the audit process:

- Effective use of resources during the audit
- Manage uncertainty of achieving audit objectives
- Protect the health and safety of audit team members during the audit, and ensure compliance of audit team to health, safety and security arrangements
- Direct the audit team members
- Provide direction and guidance to auditors-in-training
- Prevent and resolve conflicts and problems that can occur during the audit, including those within the audit team

Audit Team Competence

Generic Competence of Audit Team Leader

e) Represent the audit team in communications with those managing the audit program, the audit client and the auditee

f) Lead the audit team in reaching audit conclusions

g) Prepare and complete the audit report

Audit Team Competence

Discipline and Sector-specific Competence of Auditors

- Collectively, the audit team should have discipline and sector-specific competence for auditing types of management systems and sectors:
  - Management system requirements and principles and their application
  - Fundamentals of the disciplines and sectors related to the management system standards as applied by the auditee
  - Application of discipline and sector-specific methods, techniques, processes and practices to enable the audit team to assess conformity within the audit scope and generate audit findings and conclusions
  - Principles, methods and techniques relevant to the discipline and sector that allows the auditor to determine and evaluate the risks and opportunities associated with the audit objectives

Audit Team Competence

Knowledge and Skills for Auditing Multiple Disciplines

- When auditing multiple standards in a combined or integrated audit, the following should be considered:
  - Understanding of the interactions and synergy between the different management systems (i.e., some requirements between the standards are the same or similar and may be addressed in the same documented information, e.g., ISO 9001:2015, ISO 14001:2015, ISO 45001:2018)
  - Understanding the requirements of each of the management system standards being audited and recognize the limits of the auditor(s) competence in each of the disciplines
  - Audits of multiple disciplines done simultaneously can be done as a combined audit or as an integrated audit covering multiple disciplines

Evaluation of Audit Team Competence

Achieving Audit Team Leader Competence

- An audit team leader should have additional audit experience gained by working under the direction and guidance of a different audit team leader.

Establishing Auditor Evaluation Criteria

- Criteria should be qualitative (demonstrated in practice) and quantitative (years of experience, number of audits, hours of training).

Evaluation of Audit Team Competence

Selecting Appropriate Auditor Evaluation Method

- Evaluation should use two or more methods from the table below:

Evaluation Method	Objectives	Examples
Review of Records	Verify background of the auditor	Analysis of records of education, training, employment, professional credentials and auditing experience
Feedback	Provide information on how performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review
Interview	Evaluate desired professional behavior and communication skills; verify information and test knowledge; acquire additional information	Personal interviews
Observation	Evaluate desired professional behavior and ability to apply knowledge/skills	Role playing, witnessed audits, on-the-job performance
Testing	Evaluate desired professional behavior and knowledge/skills and their application	Oral and written exams, psychometric testing
Post-audit Review	Provide information on auditor performance during audit activities; identify strengths and opportunities for improvement	Review of audit report, interviews with the audit team leader, the audit team, and feedback from the auditee

SELECTING THE AUDIT TEAM

Selecting the Audit Team

- Person managing the audit program appoints the team leader
- Person managing the program and/or team leader appoints team members
- The audit team needs to have the competencies to achieve the objectives and scope of the audit
- Team members are selected so that the team has all the necessary knowledge and skills to complete the audit
- When the team does not have all the necessary knowledge and skills, technical experts should be added to the team
  - Technical experts should operate under the direction of an auditor
  - Technical experts are not auditors
- Adjustments to the team may be necessary during the audit
  - Address conflicts of interest, competency issues, timing, issues between the auditor and the auditee or audit client

Selecting the Audit Team

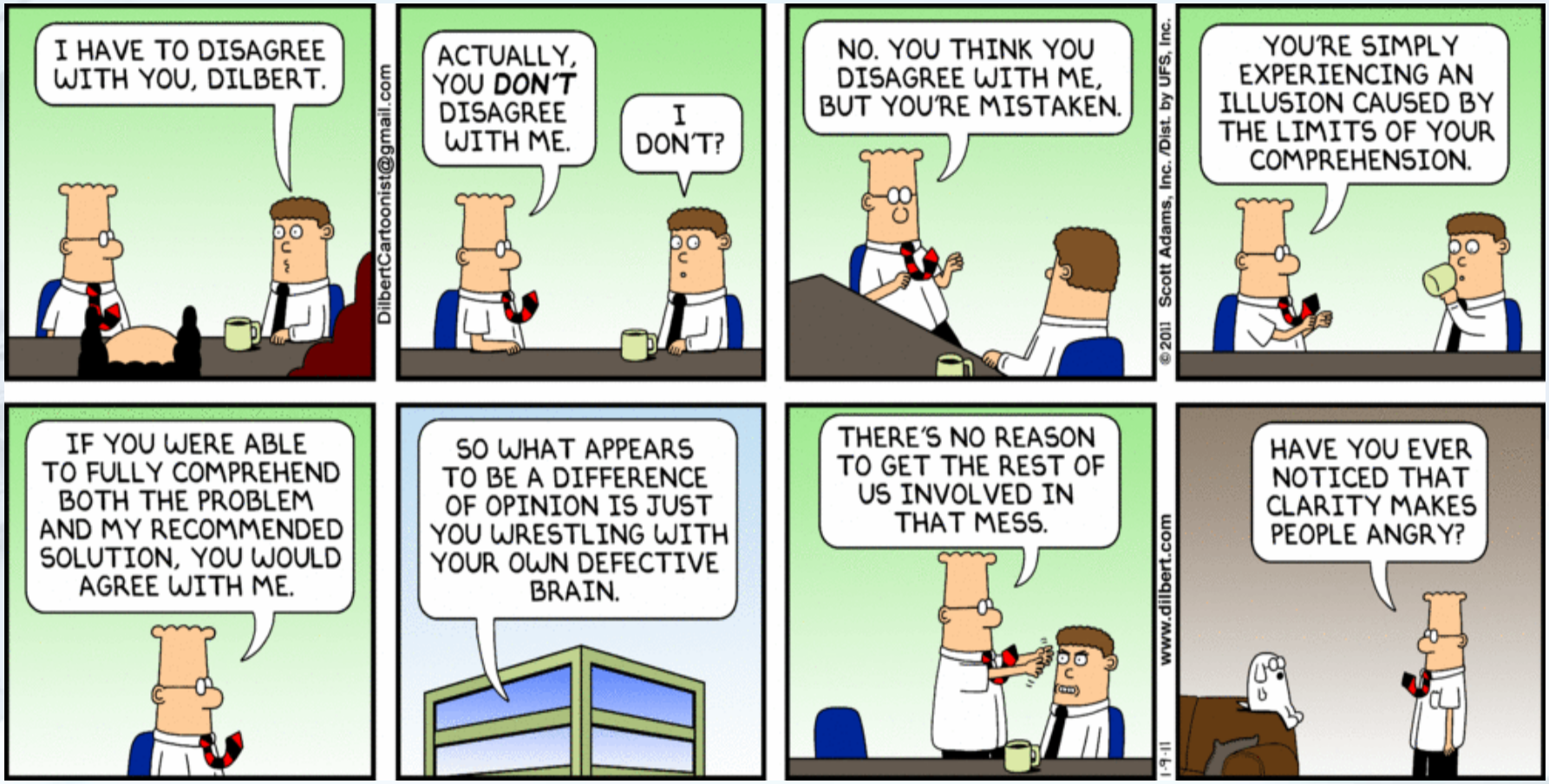
- In deciding the size and composition of the audit team, consideration should be given to:
  - The independence of all auditors on the audit team, ensuring they have not been involved with the audit client or auditee
  - Audit objectives, scope, criteria and estimated duration of the audit
  - Complexity of the audit and whether the audit is a combined or joint audit
  - The selected audit method(s)
  - The overall competence of the audit team needed to achieve the objectives of the audit
  - Statutory, regulatory, contractual and accreditation/certification requirements, as applicable
  - The need to ensure the independence of the audit team from the activities to be audited and to avoid conflict of interest
  - The ability of the audit team members to work together and interact effectively with the auditee and each other
  - The language of the audit, and an understanding of the auditee's particular social and cultural characteristics; these issues may be addressed either by the auditor's own skills or through the support of an interpreter
  - Technical expertise in complex processes
  - Understanding of the type of products produced by the auditee

Assigning Work to the Audit Team

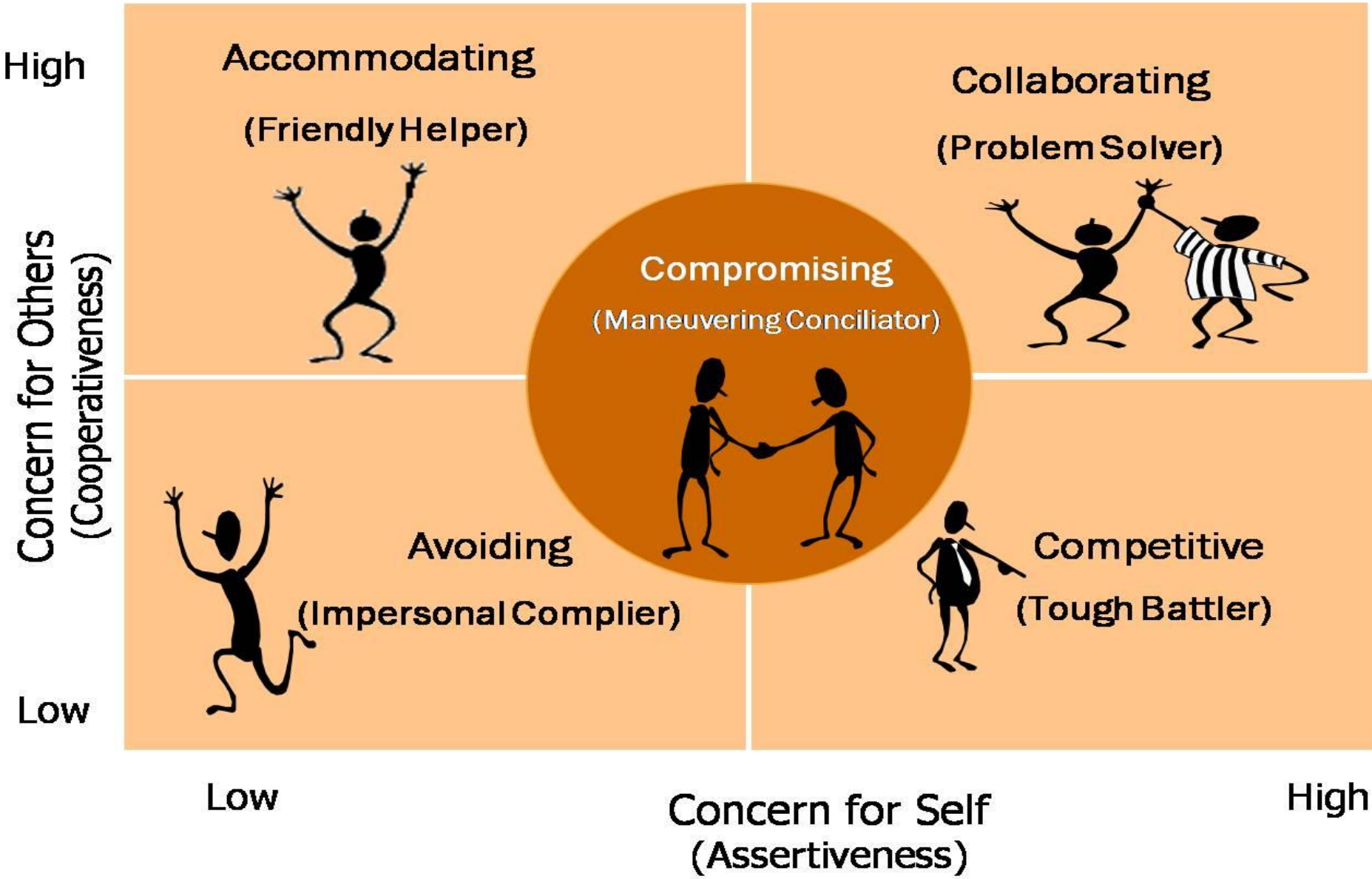
- Audit team leader, in consultation with the audit team, should assign responsibility for auditing specific processes, activities, functions or locations, and authority for decision making
- Work assignments should take into account impartiality, objectivity and competence of auditors and effective use of resources, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts
- Audit team leader should hold meetings in order to allocate work assignments and make changes as necessary
- Changes to work assignments can be made as the audit progresses in order to ensure achievement of audit objectives

CONFLICT MANAGEMENT

Conflict Resolution



CONFLICT HANDLING INTENTIONS



Conflict Resolution

- **A conflict is more than just a disagreement…**
  - It is a situation in which one or both parties perceive a threat (whether or not the threat is real).
- **Conflicts continue to fester when ignored…**
  - Because conflicts involve perceived threats to our well-being and survival, they stay with us until we face and resolve them.
- **We respond to conflicts based on…**
  - Our perceptions of the situation, not necessarily to an objective review of the facts. Our perceptions are influenced by our life experiences, culture, values, and beliefs.
- **Conflicts trigger strong emotions…**
  - If you aren't comfortable with your emotions or able to manage them in times of stress, you won't be able to resolve conflict successfully.
- **Conflicts are an opportunity for growth…**
  - When you're able to resolve conflict in a relationship, it builds trust. You can feel secure knowing your relationship can survive challenges and disagreements.

How to Avoid Conflict

- **Be positive**
  - If you want to work in a more positive environment, you have to be positive.
  - Remaining positive will make it more difficult for others to behave badly towards you, thereby reducing the likelihood of you becoming involved in serious disputes.
- **Be aware of personality clashes**
  - Personality clashes are difficult to resolve, although there is value in identifying underlying tensions before things become serious.
- **Communicate respectfully**
  - The old mantra of 'treating people as you would like to be treated' is a good tactic in avoiding workplace conflict.
- **Don't get involved in emotional manipulation**
  - A calm approach will help you to avoid unnecessary conflict and contribute to a better working environment.
- **Know what's important**
  - Disputes can grow from the smallest of issues.
  - Minor disagreements should be figured out and forgotten.

Conflict Resolution

Healthy and unhealthy ways of managing and resolving conflict	
Unhealthy responses to conflict:	**Healthy responses to conflict:**
• An inability to recognize and respond to the things that matter to the other person.	• The capacity to recognize and respond to the things that matter to the other person.
• Explosive, angry, hurtful, and resentful reactions.	• Calm, non-defensive, and respectful reactions.
• The withdrawal of attention, resulting in rejection, isolation, shaming, and fear of abandonment.	• A readiness to forgive and forget, and to move past the conflict without holding resentments or anger.
• An inability to compromise or see the other person's side.	• The ability to seek compromise and avoid punishing.
• The fear and avoidance of conflict; the expectation of bad outcomes.	• A belief that facing conflict head on is the best thing for both sides.

Managing Conflict Resolution

The audit team leader should first strive to prevent conflict from occurring within the team or between the team and the auditee. If conflict does occur, the team leader should use a conflict resolution process such as:

1. Set up an environment where all parties know the goal is to resolve the conflict.
2. Make sure all parties want to resolve it.
3. All parties must accept the conflict as a mutual problem – not a win/lose situation.
4. Explore the reasons for the conflict.
5. Generate solution options.
6. Involved parties must agree on which solution is most appropriate.
7. Implement the selected solution.
8. Evaluate the success/failure of the solution.

Consensus Decision Making

- All are involved in the decision making process
- Nobody's input is weighed more or less than others
- Better decisions because perspectives of the group are taken into account
- Better group relationships through collaboration rather than competition
- Consensus is not full group agreement nor the most desirable decision for everyone

Lack of Consensus on Findings

- The audit team leader must make every attempt to come to a consensus on findings, both within the team and between the team and the auditee.
  - When members of an audit team cannot come to agreement…
    - Note this on internal audit documents, such as notes, but this should not be communicated to the auditee or audit client.
  - When the team cannot reach consensus with the auditee…
    - Remind the auditee that the appeals processes is available.
    - Note the disagreement in the audit report.

Chapter 13: Leading Audit Teams — What We Covered

Learning Objectives

You should now be able to:

- Identify and evaluate the necessary competencies for the audit team
- Identify the items that should be considered when selecting an audit team
- Assign work to the audit team
- Describe steps to take to avoid and solve conflict

Chapter Agenda

- Audit Team Competence
- Auditing Multiple Standards
- Selecting an Audit Team
- Conflict Resolution

Chapter 14

Customer-Specific Requirements

Chapter 14: Customer-Specific Requirements — What We Will Cover

Learning Objectives

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

- Explain the importance of customer-specific requirements
- State the types of customer-specific requirements
- State where they can be found

Chapter Agenda

- Customer-Specific Requirements
- Where to Locate Customer-Specific Requirements

Customer-Specific Requirements

- Defines the fundamental QMS requirements
- The customer requirements for a QMS are generic requirements that – when properly implemented – can enable an organization to better achieve Customer Satisfaction
- The most common source of poor quality is poorly or insufficiently defined customer requirements

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 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

Where to Locate Customer-Specific Requirements

- Customer specific web sites
- Customer supplier quality manuals
- Customer purchase orders
- Customer prints

Chapter 14: Customer-Specific Requirements — What We Covered

Learning Objectives

You should now be able to:

- Explain the importance of customer-specific requirements
- State the types of customer-specific requirements
- State where they can be found

Chapter Agenda

- Customer-Specific Requirements
- Where to Locate Customer-Specific Requirements

Chapter 15

Management System Certification Scheme and Auditor Qualifications

Chapter 15: Management System Certification Scheme — What We Will Cover

Learning Objectives

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

- State auditor qualification for recognition
- Describe the audit cycle
- State key elements of the audit

Chapter Agenda

- Auditor Qualifications
- Audit Certification Cycle and Audit Days
- The Audit
- Certification Decision and the Certificate
- **Leading Management Systems Audit Teams Mock Audit**
- **Leading Management Systems Audit Teams Exam**

AUDITOR QUALIFICATIONS

Third Party Auditor

- **QMS Auditor Qualifications**:
  - Qualified according to ***ISO 10011-Part 2*** and/or ***ISO 19011*** and the certification body's defined processes, and the relevant accreditation body rule
  - Competency in:
    - ISO quality standards (e.g., ISO 9001)
    - Audit management
    - Teamwork techniques and presentation
    - Interview techniques

- **Note – ISO 17021 stresses the need for the certification body to have processes covering many areas. These processes are defined by the certification body, not ISO 17021.**

Third Party Auditor

- QMS auditors should have knowledge and skills in the following areas:
  - Quality-related methods and techniques
    - quality terminology,
    - quality management principles and their application, and
    - quality management tools and their application
  - Processes and products, including services
    - sector-specific terminology,
    - technical characteristics of processes and products, including services, and
    - sector-specific processes and practices

Grades of QMS Auditor Certification

Grade	Designed For	Training	Personal Attributes
Auditor	Auditors who audit solo or as a member of an audit team.	Exemplar Global Management Systems Auditor course (TPECS or RTP). Training must be completed in the discipline of the program in which you wish to be certified (e.g., Quality Auditor training for QMS certification).	Auditor Work Style Assessment
Lead Auditor	Auditors who lead audits and audit teams.	Exemplar Global Quality Management Systems Lead Auditor course (TPECS or RTP). Training must be completed in the discipline of the program in which you wish to be.	Lead Auditor Work Style Assessment
Master Auditor	Experienced auditors with at least twelve years of lead auditor experience.	Exemplar Global Quality Management Systems Lead Auditor course (TPECS or RTP). Training must be completed in the discipline of the program in which you wish to be certified Plus 12 years of continuous certification as a lead auditor.	Lead Auditor Work Style Assessment

An ISO 9001:2015 Quality Management System Auditor requires an ISO 9001:2015 training certificate OR 10 days audit experience using ISO 9001:2015 as the reference standard.

See Appendix A for more information on Exemplar Global requirements

ASD Auditor Certification

Certification Grade	9100 Aerospace Auditor (AA)	9100 Aerospace Experienced Auditor (AEA) *Qualification Through Training*	9100 Aerospace Experience Auditor (AEA) *Qualification Through Industry Work Experience*
Auditor Recognition	Quality Management System (QMS) auditor by nationally-recognized AAB or meet the education, training, work experience, and audit experience of ISO 19011		
AQMS Training	AS9100 Aerospace Auditor Transition Training (AATT) ***and*** AATT course prior to November 1, 2014 release, AS9101E/9101:2014 Revision Training Course ***and*** QMS (ISO 9001:2008) Auditor Training Course ***or*** AQMS AS9100 Standard Auditor Course		
Industry Specific Training	None required	Successful completion of an approved Aerospace Industry Specific course: AS9100/AS9110	None required
Audit Experience	4 full QMS or AQMS (AS9100) audits conducted for a total of 20 audit days within the past 3 years. Only 2nd or 3rd party audits will be considered.		
Witness Audit Evaluation	None required	Successful completion of 2 full AS9100 audits witnessed by a certified AEA	None required
AQMS Work Experience	None required	2 years full-time AQMS industry work experience within the past 15 years	4 years full-time AQMS work experience within the past 10 years

Third Party Auditor Requirements — AS9104/3

- Aerospace Industry Experience
  - Four years of aerospace experience within the prior ten years
  - If less than four years, completion of an in-depth aerospace industry competency course
- Auditing Experience
  - Four audits with a minimum of 20 audit days in the last three years
  - At least 2 full AS9100 audits in the last two years
  - Been witnessed by a currently qualified Aerospace Experience Auditor
- Aerospace QMS Standard Requirements Knowledge
  - Completion of a lead auditor training course that fully covers all of the requirements of AS9100
- Continuing Requirements
  - 15 hours of continuing education and 4 audits in three years

AUDIT CERTIFICATION CYCLE AND AUDIT DAYS

Audit Certification Cycle

- Three year certification and audit cycle
- First audit cycle includes Stage 1 (Document Review) and Stage 2 (On-site Audit)
- Three year cycle starts at the conclusion of the initial Stage 2 audit
- Cycle includes surveillance and recertification audit in the third year

Audit Certification Cycle

- Surveillance is done at least annually
- If surveillance timing is exceeded, suspension or withdrawal of certification may occur
- Recertification must be completed including resolution of any nonconformities prior to the expiration of existing certificate

Audit Days

- An audit day is a normal full working day of 8 hours, half an audit day is 4 hours
- Total audit days cannot be reduced by scheduling longer than 8 hour days
- An audit includes auditing on all shifts

Audit Days for ASD Certification

Number of Employees	9100 / 9110			9100 / 9110 Less Design (8.3)			9120		
	Initial	Annual Surveillance	Recertification	Initial	Annual Surveillance	Recertification	Initial	Annual Surveillance	Recertification
1-5	2.0	1.0	2.0	2.0	1.0	1.5	2.0	1.0	1.5
6-10	2.5	1.0	2.0	2.5	1.0	2.0	2.0	1.0	1.5
11-15	3.0	1.5	2.5	2.5	1.0	2.0	2.5	1.0	2.0
16-25	3.5	1.5	3.0	3.0	1.5	2.5	3.0	1.5	2.0
26-45	5.0	2.0	4.0	4.5	2.0	3.5	4.0	2.0	3.0
46-65	6.0	2.5	4.5	5.0	2.0	4.0	4.5	2.0	3.5
66-85	7.0	3.0	5.5	6.0	2.5	4.5	5.5	2.5	4.0
86-100	8.0	3.0	6.0	7.0	3.0	5.0	6.0	2.5	4.5
101-125	8.5	3.5	6.5	7.5	3.0	5.5	6.5	3.0	5.0
126-175	9.5	4.0	7.0	8.0	3.5	6.0	7.5	3.0	5.5
176-275	10.5	4.0	8.0	9.0	3.5	6.5	8.0	3.5	6.0
276-425	12.0	5.0	9.0	10.0	4.5	7.5	9.0	4.0	7.0
426-625	13.0	5.5	9.5	11.0	4.5	8.0	10.0	4.5	7.5
626-875	14.0	5.5	10.5	12.0	5.0	8.5	10.5	4.5	8.0
876-1000	15.0	6.0	11.0	12.5	5.0	9.0	11.5	5.0	8.5
1001-1175	16.0	6.5	12.0	13.5	5.5	10.0	12.5	5.5	9.5
1176-1550	17.0	7.0	12.5	14.5	6.0	11.0	13.0	5.5	10.0
1551-2025	18.0	7.0	13.5	15.0	6.0	11.5	13.5	5.5	10.5
2026-2675	19.0	7.5	14.0	16.0	6.5	12.0	14.5	6.0	11.0

THE AUDIT

The Audit

- Each initial on-site audit shall include:
  - Conformance to all requirements
  - Monitoring, measuring and reporting of key performance objectives
  - Organization's internal audit and management review results and actions
  - Progress made towards continual improvement targets
  - Legal compliance
  - Linkage between the quality policy, quality objectives and targets, responsibilities, competence of personnel, procedures, performance, internal audits, and changes to the organization

The Audit

- Each surveillance audit shall include:
  - Effectiveness of the management system including monitoring, measuring, and reporting of key performance objectives
  - Organization's internal audit and management review results and actions
  - Actions taken for complaints
  - Progress made towards continual improvement targets
  - Operational control

Third Party Audit Phases

- Information and Discussion
- Registration Application
- Submission of Documents
- Pre-assessment
- Document (Readiness) Review (Stage 1)
- On-site Assessment (Stage 2)
- Corrective Action and Follow-up
- Registration Decision
- Certification Issuance (valid for 3 years)
- Surveillance (at least annually)

CERTIFICATION DECISION AND THE CERTIFICATE

Certification Decision

- A certification decision is required for:
  - Initial audits
  - Continued certification after surveillance audits
  - Recertification audits
- Information in the final report is sufficient based on the scope
- Nonconformities identified during the audit have been acted upon by the audit client
- Certification decision after conclusion of the Stage 2 audit

Certificate

AS9100 Requirements:

- Include name of contracted office of the certification body
- Unique identification code
- Name, address and certification mark of the certification body
- Scope of registration with regard to product and processes at each site
- Include the name and geographic location of each site

Certificate

AS9100 Requirements:

- Single Site
  - Single address listing and defined certification scope
- Multiple Site
  - Site with central function identified and a scope applicability statement for each site
- Campus
  - One controlling address and scope for campus listed
  - Address for each site within campus with sub-scope of activity
  - Site with central function identified
- Several Sites
  - Central function and all sites listed on certificate
  - Overall scope statement and scope statement for each site
- Complex Organization
  - Central function and all sites and/or campuses with scope applicability using criteria for each type of sub-organization

Chapter 14: Management System Certification Scheme — What We Covered

Learning Objectives

You should now be able to:

- State auditor qualification for recognition
- Describe the audit cycle
- State key elements of the audit

Chapter Agenda

- Auditor Qualifications
- Audit Certification Cycle and Audit Days
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Leading Management Systems Audit Teams Mock Audit

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Leading Management Systems Audit Teams Exam

Work Independently

Thank You!

Questions?

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