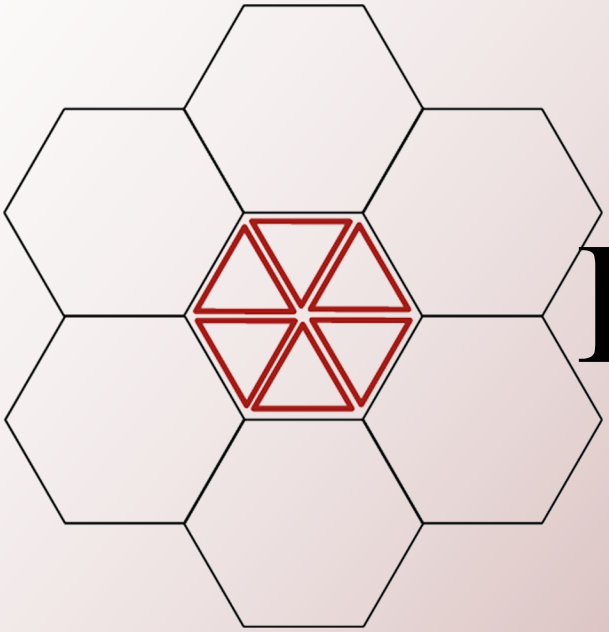

ETI Group

Six Sigma/Lean Six Sigma
Lean Enterprise
Business Management Systems
Strategic Planning
Integrated Performance Measurement
Supplier Management

ISO 9001:2015 / AS9100D Internal Auditor Training Workshop

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Camas, Washington 98006
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AS9100 Rev. D – ISO 9001:2015 Internal Auditor Workshop

Developed By

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TAB 1
Course Material

AS9100 - ISO 9001 Internal Auditor

Agenda & Introduction

Workshop Overview

Purpose:

To provide you with theory and practical experience to become an effective Quality Management System Auditor

Process:

- ✓ Workshop presentation
- ✓ Exercises and case studies
- ✓ Discussion and reasoning
- ✓ Class presentations

Payoff:

You will have a basic understanding of the tools and techniques used in performing internal audits. Practice will give you the experience!

Agenda

- Quality Management Systems and the Process Approach
- Introduction to Quality Management System Auditing
- The Four Phases of an Audit
  - Plan: Determine the Requirements & Prepare for the Audit
  - Do: Gather the Evidence
  - Check: Make a Comparison
  - Act: Take Action
- Maintaining a Successful Audit Program
- Summary

Please complete the Initial Assessment of Knowledge & Experience

The Standard

1. It's totally new to me.
2. I've heard of it.
3. I'm familiar with the general principles of the Standard.
4. I have in-depth knowledge of the parts of the Standard that apply to my functional area.
5. I live and breathe the Standard, and often read it for fun.

Internal Auditing

1. I've never been involved in an audit.
2. I've been audited but have never performed an internal audit.
3. I've been an observer on one or more internal or external audits.
4. I've performed internal audits in an organization.
5. I even perform internal audits at home!

Learning Objectives

By the end of this course, participants will be able to:

- Describe the goals of an internal audit.
- State the benefits of internal auditing.
- Determine the requirements for an Internal Audit.
- Plan an Internal Audit, and develop a guidelist.
- Perform an Internal Audit.
- Identify nonconformity to requirements during an audit.
- Report on an audit and follow up on corrective actions taken in response to audit findings.
- Describe the actions necessary for maintaining a successful audit program.

Meet & Greet

- Pair up. Interview your neighbor (2 ½ minutes each). Find out:
  - Name
  - Organization, job function, and length of employment
  - Knowledge of the Standard and internal auditing
  - Learning expectations
- Introduce neighbor to class (1 minute each).

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Quality Management Systems and the Process Approach

In a Quality Management System, you…

Say what you'll do.

Do what you say.

Prove It.

Improve It!

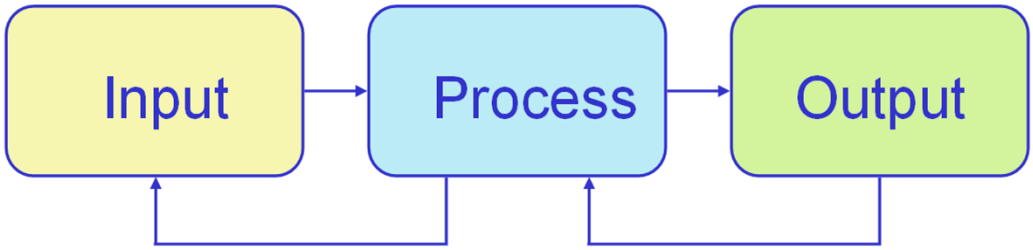
Everyone

Everywhere

Every time

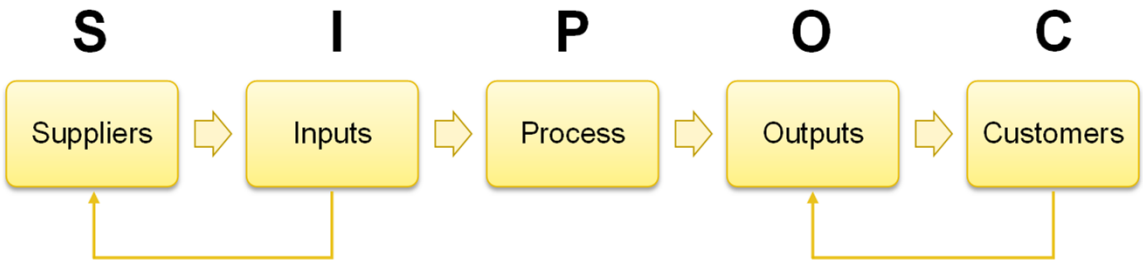
- Say what you'll do through the Quality Management System (QMS) documentation &/or training.
- Do what you say through disciplined use of the QMS.
- Prove it using Internal Audits (and External ones).
- Improve it using Corrective Action and Continual Improvement.

Simple Process Model



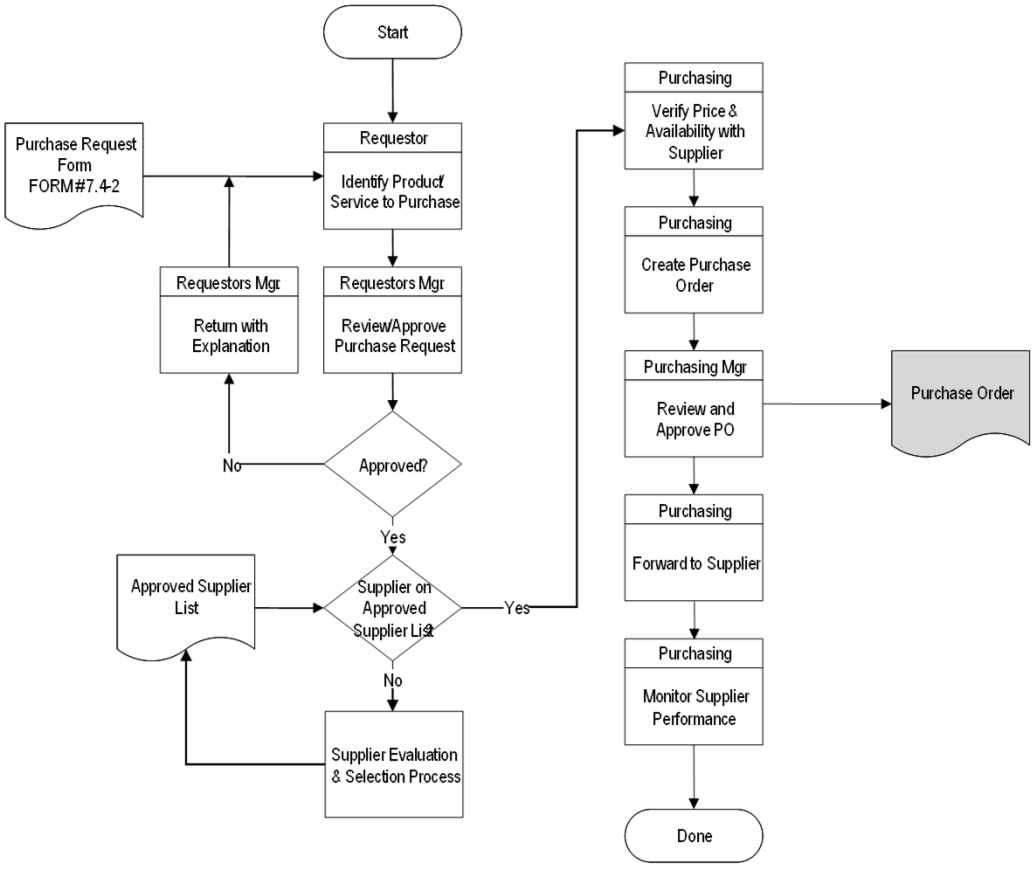
- Simply defined, a process is a set of related activities that convert inputs to outputs using resources.
- Monitors &/or measures for the process interfaces are represented by “feedback loops.”

Expanding on the Process Model



- The SIPOC chart is a helpful way to outline a process.
- "Supplier" is the entity providing input
- "Customer" is the receiver of output
- The SIPOC is scalable to macro or micro levels.

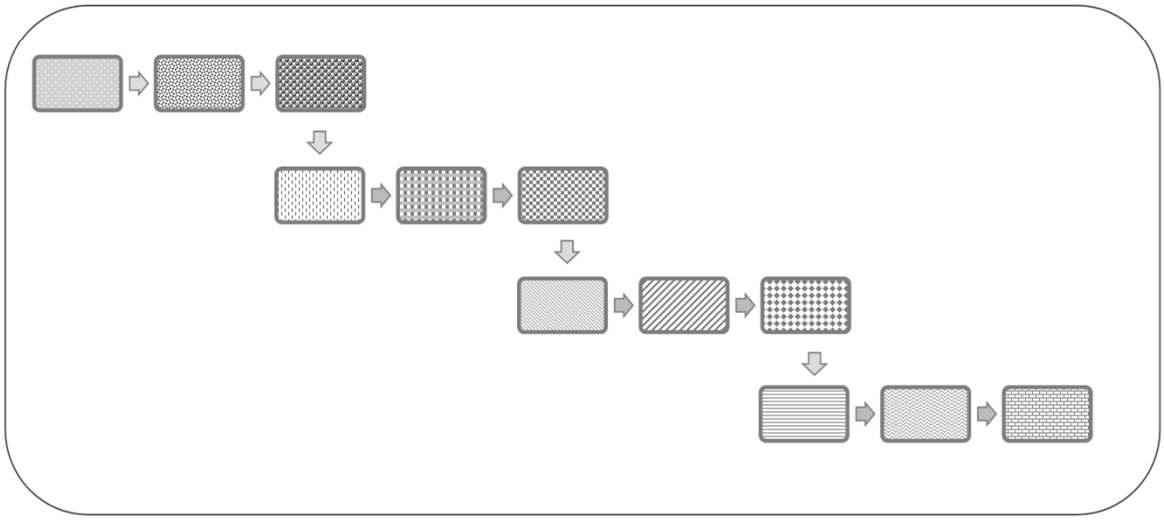
Process Flow Example



For an auditor, the SIPOC chart is a good first step toward understanding a process before delving into the detailed activities shown by a flow chart (aka process map).

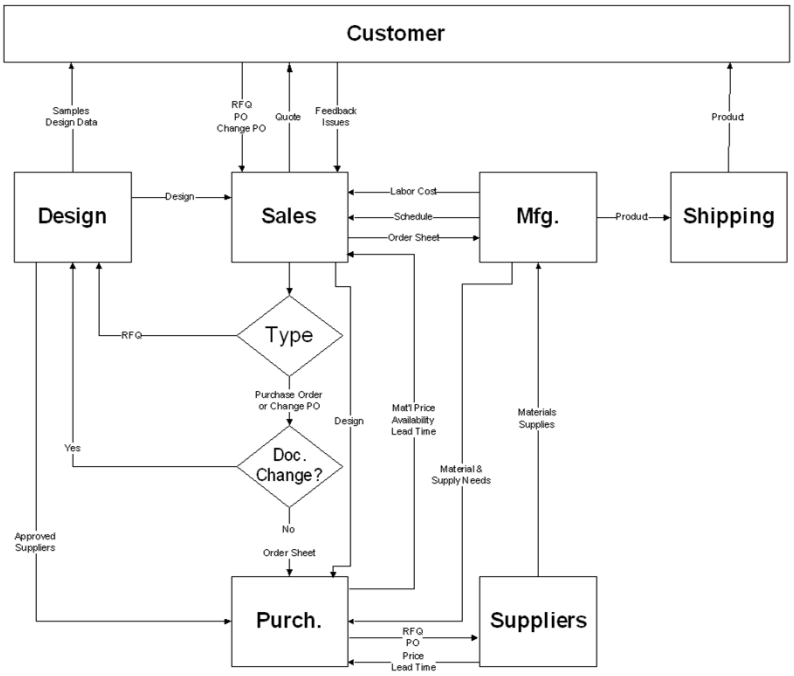
Process Interaction

- Often, the outputs of one process become the inputs to another process.
- A QMS is made up of many linked process chains.



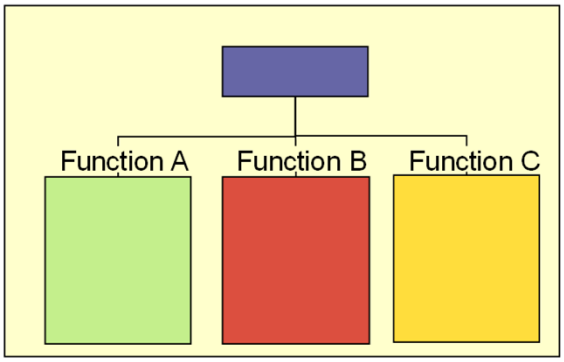
System Example

- A system is an integrated set of processes that interact with each other to meet a set of objectives.

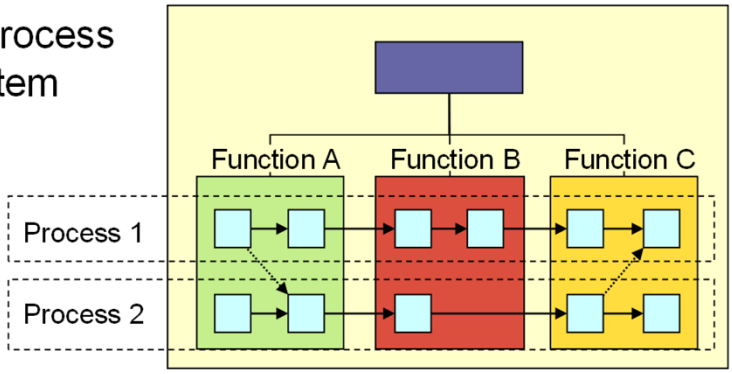


The Process Approach

Traditional/Functional View of System



Performance/Process View of System



Jobs exist in “Functions” (think of Departments on an Organization Chart), but are performed within Processes.

Process Owner

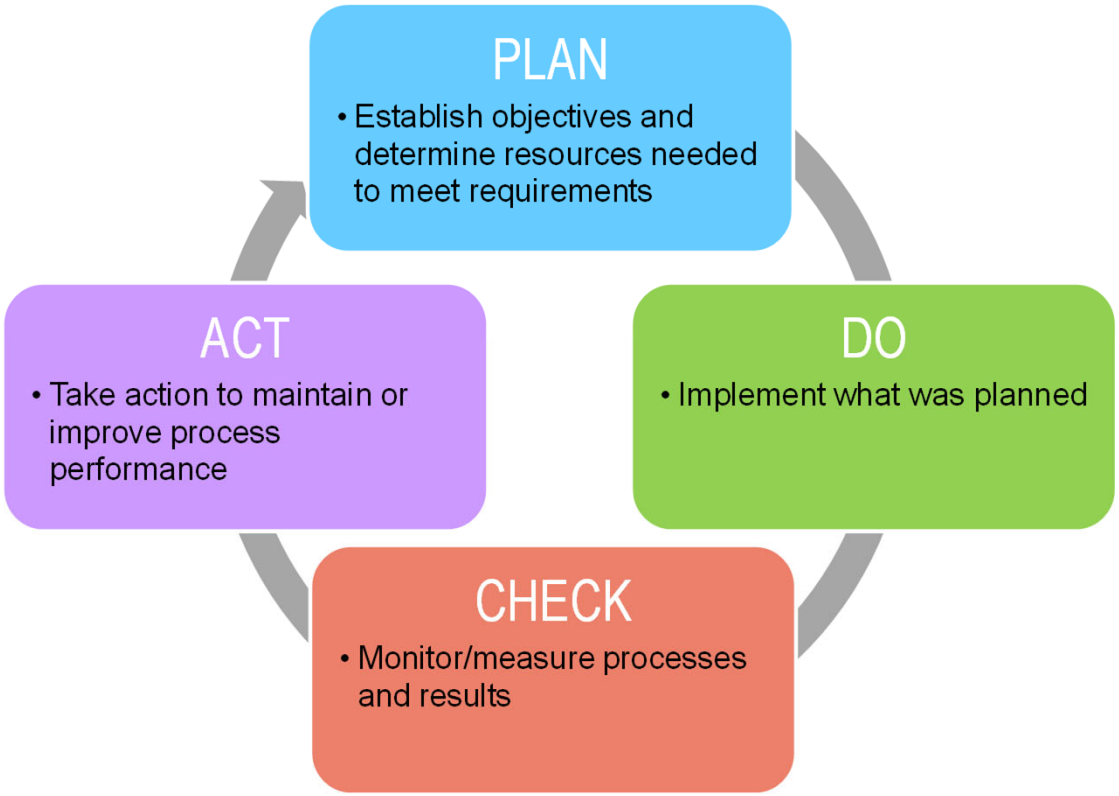
- A process approach may include the role of “Process Owner”
  - Person appointed by top management
  - Ensure total process is both effective and efficient
  - Does not replace functional organization, should support it
  - Roles and responsibilities
    - Monitor process performance and report to top management
    - Lead cross–functional process management team
    - Serve as “white space” ombud
    - Serve as champion and lead trainer for process

Characteristics of a Process Approach

- Processes are defined, managed and understood in the context of their interfaces with other processes.
- Interrelated processes are managed as a closed-loop system, with a focus on the value provided to the customer.
- The goal for processes is to achieve predictable, consistent and suitable outcomes — i.e., products &/or services.
- Monitors &/or measures and Management oversight ensure that quality requirements and performance goals are achieved.

What are some potential benefits of the process approach?

Plan-Do-Check-Act in a QMS

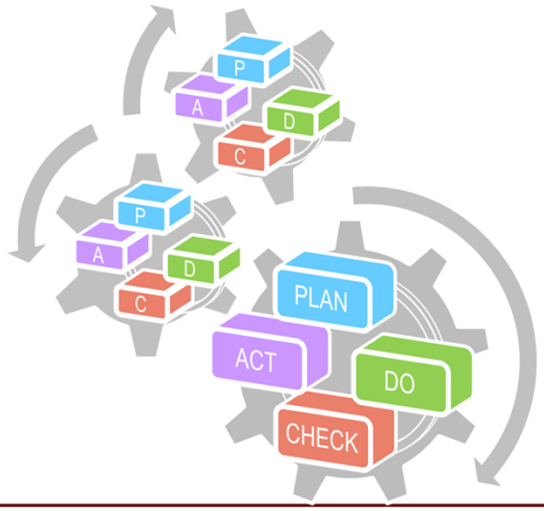


The Plan-Do-Check-Act cycle has been in use since the 1930's as a framework for problem solving and process improvement. In its original use, "Plan" involves defining the problem, "Do" is developing a solution, "Check" is analyzing results to verify that the problem is solved, and depending on whether the solution is successful, "Act" is either implementation or going back to "Plan."

This "closed-loop system" and the process approach have been found to be effective organizing principles for Quality Management Systems and form the underlying structure of the ISO 9001 Standard and all its offshoots.

Managing the QMS

- PDCA provides a way to connect all the processes into a coherent related system.
- Repetition of this closed-loop process drives improvement.
- Management ownership and direction, along with employee buy-in, are critical to achieving an effective Quality System.



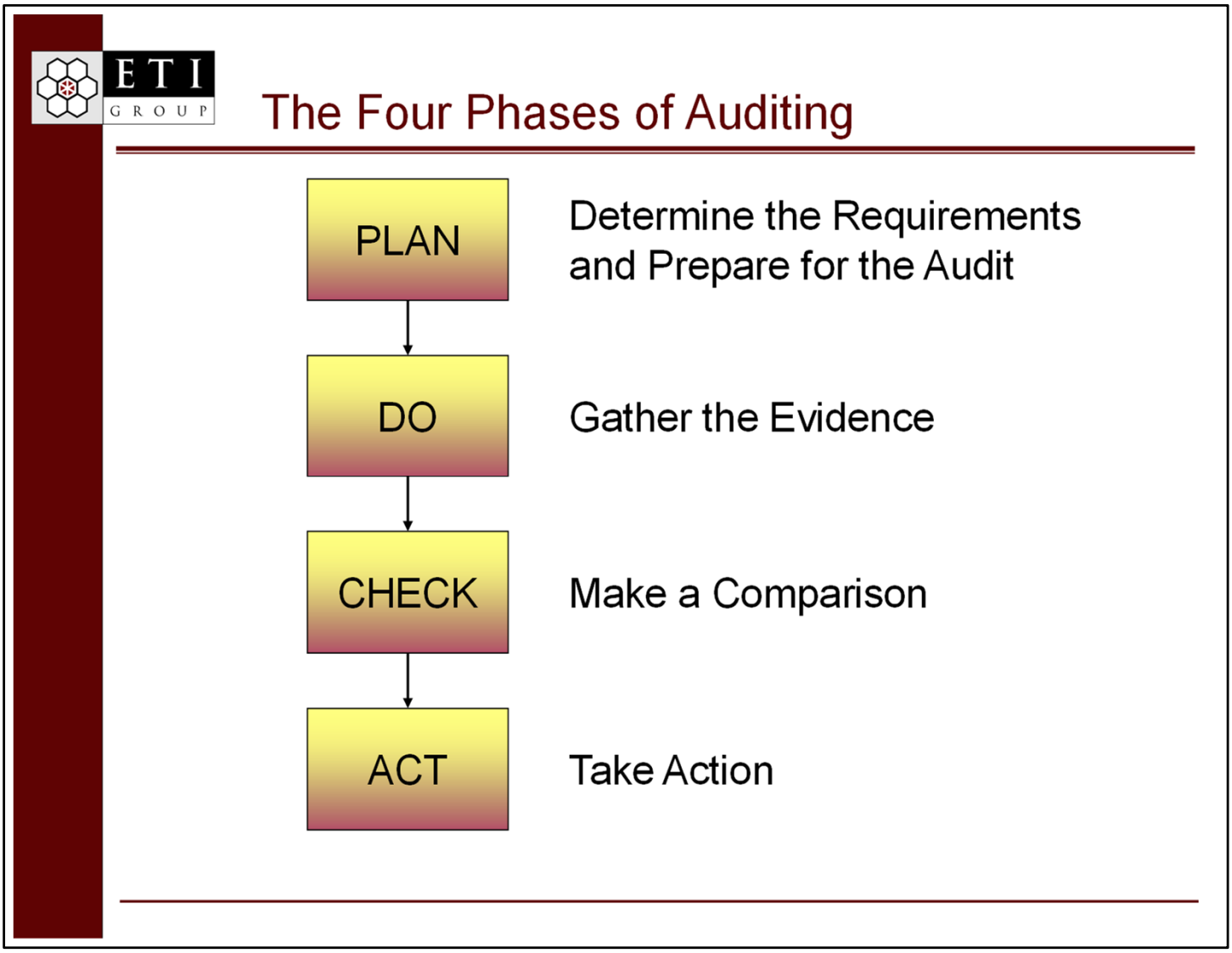
Introduction to Quality Management System Auditing

What Is a Quality System Audit?

An audit is a:

"Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled."

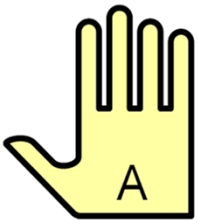
—ISO 9000:2015, 3.13.1



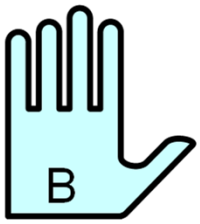
An important outcome of the Plan phase is a thorough understanding of the requirements by the auditor. This knowledge will then aid the auditor as the evidence is gathered in the Do phase, and conclusions are drawn about conformity in the Check phase.

An Auditing Formula

A = What Should Be



B = What Is



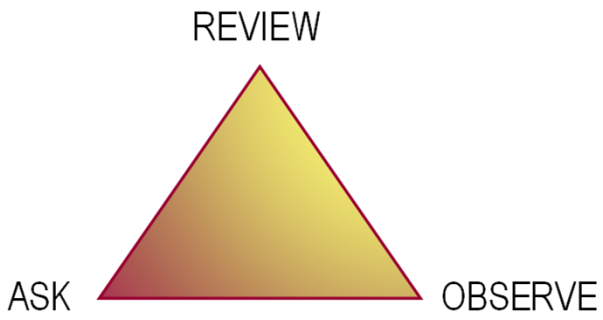
If A = B ⇨ Conformity

If A ≠ B ⇨ Nonconformity

"A" is the requirement being audited. "B" is the actual practice observed. If these two things match, the practice is considered conforming. If there is not a match, then the auditor notes a finding of nonconformity.

Methods for Gathering Evidence

- **Review** the audit criteria (requirements) and QMS documentation and records.
- **Ask** good questions and listen carefully to the answers.
- **Observe** actual practices.



Auditing Scenario

- Complete the Audit Exercise on the next page.
- Work for 5 minutes.

Audit Scenario

While performing an audit on nonconforming material, the auditor observed an employee wrapping a defective part in orange tape. The procedure, which the auditor had reviewed during audit preparation, stated that nonconforming material could be identified in one of three ways: red tape, a red "nonconforming" sign or label, or placed in an area marked off by red lines.

The auditor asked the operator if she was aware of the nonconforming identification criteria spelled out in the procedure. The operator recited the correct answer and explained that all she had was orange tape due to shortages on red tape. She also informed the auditor that her supervisor had held a meeting with the employees explaining the situation. She stated that the supervisor told them to use the orange tape for now.

Questions

1. Identify the three methods the auditor used to gather information.
2. What was the "acceptable" criteria, according to the procedure?
3. Is the operator in conformance with the documented Quality System? Why or why not?
4. Why did the auditor ask the operator of her awareness of the procedure?
5. How do you think the operator performed in the audit? Why?

Audit Purposes

Provide independent assurance that:

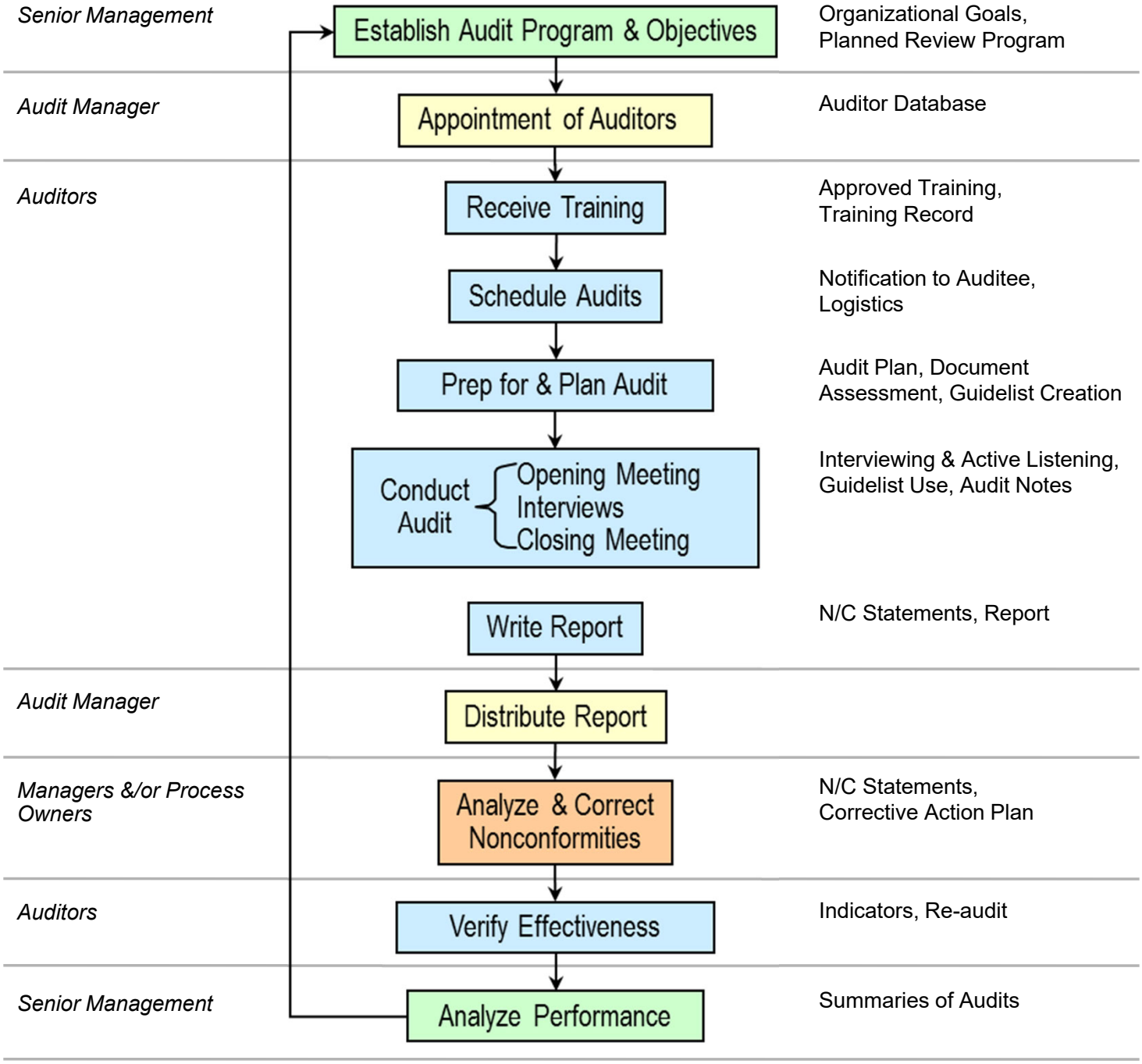
- Plans (procedures) exist and comply with requirements.
- Specifications are being met.
- Procedures are adequate and are followed.
- Data system provides appropriate, accurate information on quality.
- Deficiencies are identified and corrected.
- Improvement opportunities are identified and brought to manager's attention.

Key Principles of Auditing

- Auditing is one part of a comprehensive management program.
- Audits are sampling methods — you are only looking at a piece of a system at a point in time.
- Focus is on the requirements of the system, process and products/services to be provided.
- Remember — the organization's management owns the responsibility for conformance.

The Internal Audit Program

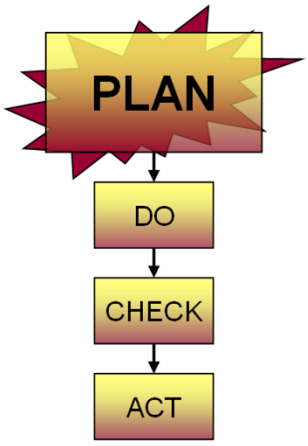
WHO does **WHAT** and **HOW**



This is the process described in ISO 19011.

PLAN: Determine the Requirements and Prepare for the Audit

"What Should Be"



Determine the Requirements

What Is AS9100?

- A common-sense way of organizing the business processes that affect the quality of your products and services.

A common-sense approach:

- Develop a good understanding of your business processes
- Document business processes based on current best practices
- Deploy documented best practices throughout the organization
- Establish and deploy measurable objectives
- Ensure best practices are followed (Internal Audits)
- Identify opportunities to correct and prevent systemic problems from occurring or re-occurring
- Ensure Changes are Controlled
- Establish a strong foundation for future performance improvements

What Is AS9100?

Background

- Basic model of a Quality Management System
- Contains all ISO 9001 requirements plus additional requirements specific to the Aerospace Industry
- Originally issued in 1999, Revision D released September 2016
- Based on 7 Quality Management Principles
- Applies to any organization (manufacturing and service) focused on Aviation, Space &/or Defense
- Internationally recognized and accepted
- Can be “registered”

The Standard, AS9100 Rev. D — Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations, originated and is updated by the IAQG (the International Aerospace Quality Group), with representatives from aviation, space and defense organizations in the Americas, Asia/Pacific and Europe. As of November 2016, there are 67 organizations listed as Active Signatories. See the website www.IAQG.org, hosted within the SAE (Society of Automotive Engineers) site, for more information.

The 7 Quality Management Principles

1. Customer focus
2. Leadership
3. Engagement of People
4. Process Approach
5. Improvement
6. Evidence-based Decision Making
7. Relationship Management

Source: *ISO 9004:2009 Managing for the sustained success of an organization — A quality management approach*

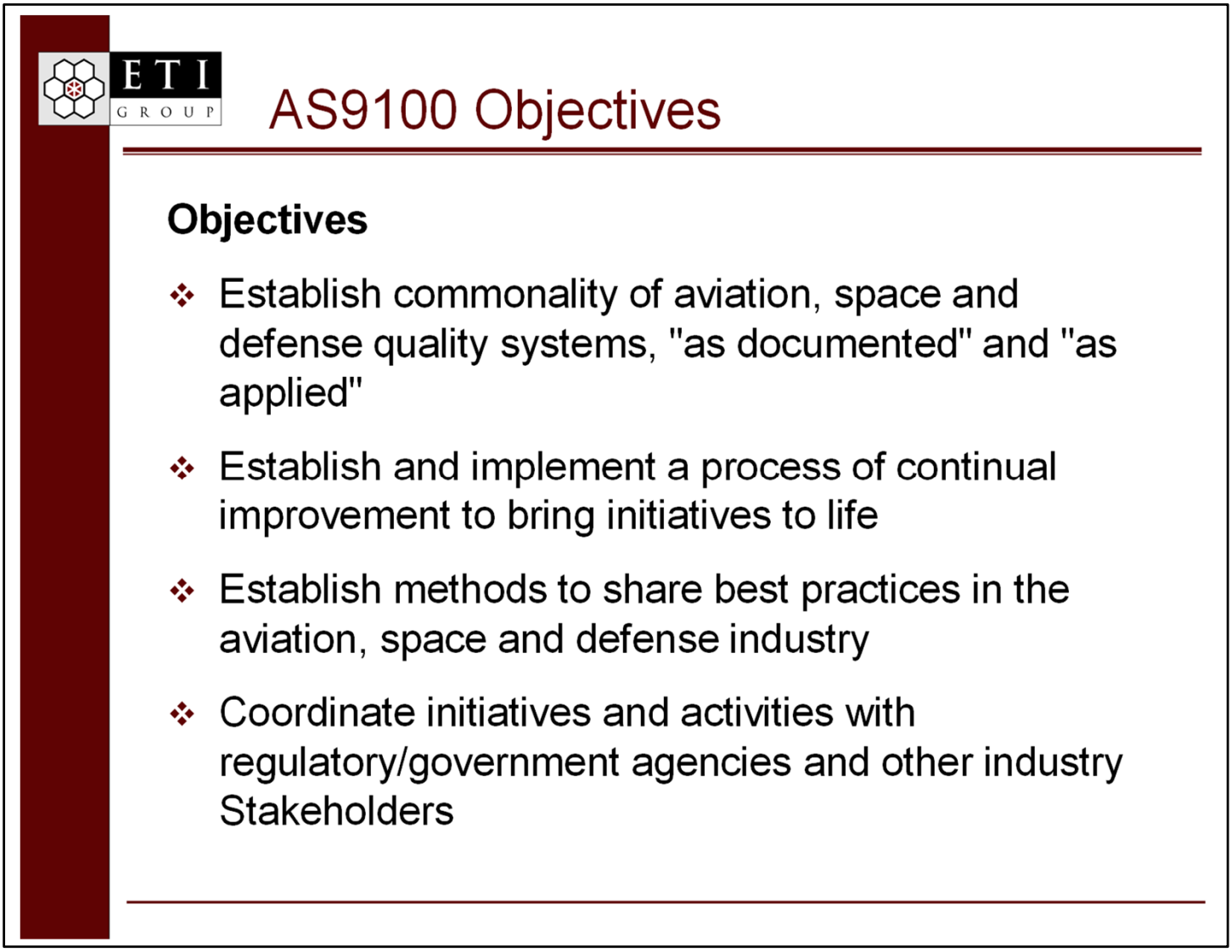
This document is helpful in deepening an understanding of AS9100 requirements.

These principles form the foundation of the ISO 9001 and AS9100 Standards.

AS9100 Purpose

Purpose

- Establish and maintain a dynamic cooperation based on trust between aerospace & defense companies on initiatives to make significant improvements in quality performance and reductions in cost throughout the value stream.
- Initial focus is to continuously improve the processes used by the supply chain to consistently deliver high quality products, thereby reducing non-value added activities and costs.



A partial listing of IAQG Standards:

- 9100 - Quality System for Aerospace Manufacturers
- 9101 – Quality Management Systems Assessment
- 9102 – Aerospace First Article Inspection Requirement
- 9103 – Variation Management of Key Characteristics
- 9104 – Requirements for Aerospace QMS Certification/Registration Programs
- 9110 - Quality System for Aerospace Maintenance Organizations
- 9120 - Quality System for Stockist [Pass-Through] Distributors
- 9134 – Supply Chain Risk Management Guideline
- 9162 – Aerospace Operator Self-Verification Programs

For a complete listing of publications, see www.IAQG.org.

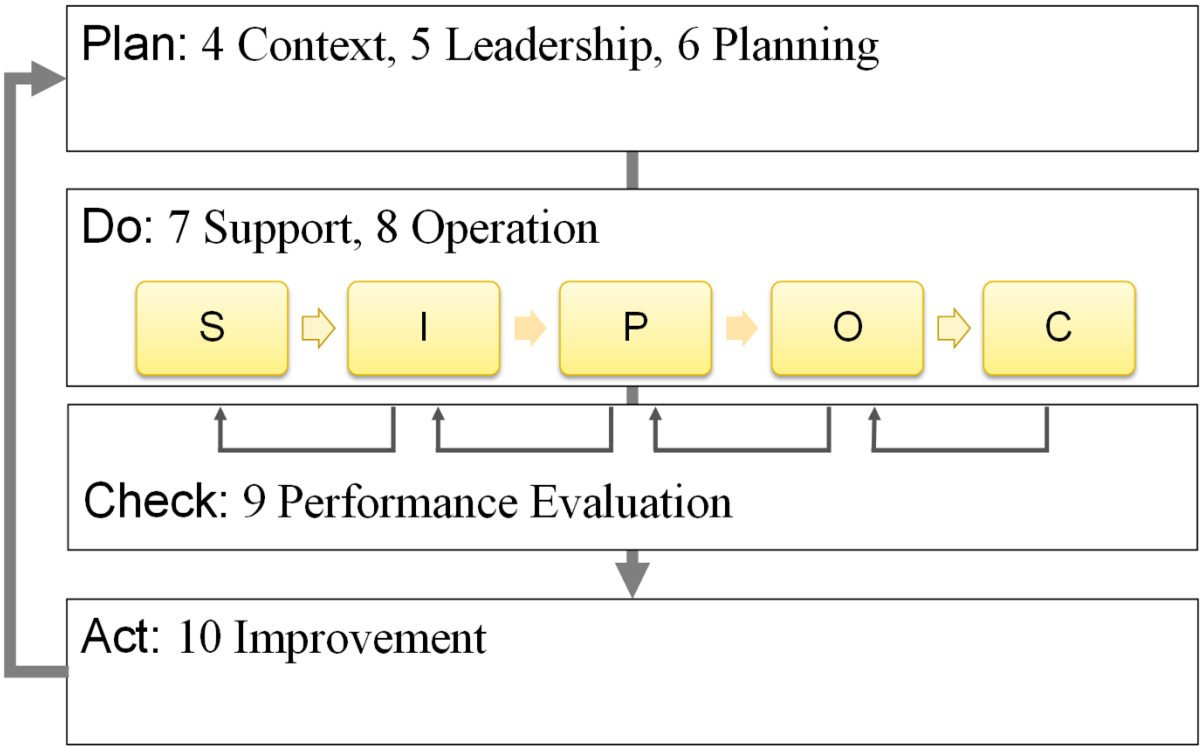
AS9100 Differences from ISO 9001

- AS9100 focuses on controls that minimize error.
- Aerospace-specific requirements are added to most of the sections of the Standard, with a detailed emphasis on:
  - Conformance to customer, regulatory and statutory requirements (safety and airworthiness)
  - Detailed operational planning and coordination of reviews and communication both within the organization and with customers and external providers, including customers' on-time delivery needs
  - Flow-down of customer requirements throughout the supply chain via management of risk, control of parts/product and supplier performance evaluation

AS9100 Differences from ISO 9001

- More aerospace-specific emphasis areas:
  - Product life cycle factors such as:
    - Configuration management
    - Product safety
    - Prevention and control of counterfeit parts
    - Consideration of special, critical and key characteristics
    - Production process verification (aka first article inspection),
    - Consequences of obsolescence
  - Change control (document information, designs, processes, equipment, tooling, etc.)
  - The importance of an awareness of the factors listed above and of ethical behavior, by both internal personnel and external providers

PDCA with AS9100 Clauses



PLAN

- Establish objectives and determine resources needed to meet requirements

DO

- Implement what was planned
- The SIPOC chart in the "Do" phase above represents the overall process of the organization, i.e., what it is "**Do**-ing" in the world.

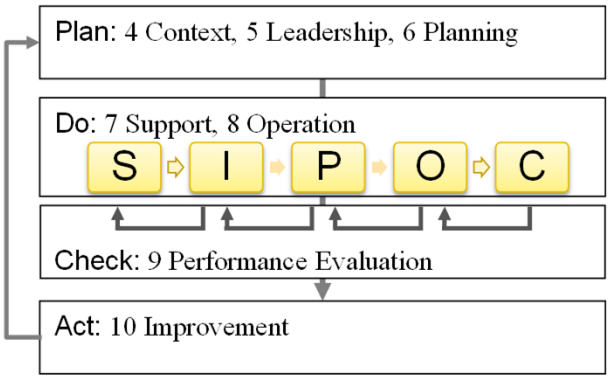
CHECK

- Monitor/measure processes and results
- Feedback loops are shown in the Check phase to represent the monitoring/measurement and Management oversight that occurs throughout the QMS.

ACT

- Take action to maintain or improve process performance

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

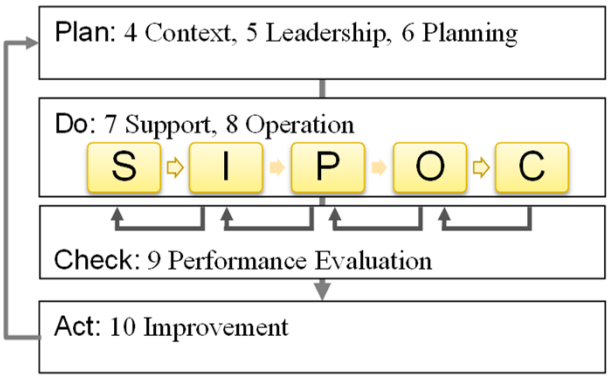
Beginning with this slide, and continuing through this section, refer to the "Detailed Outline of Headings" for the Standard, provided in the 3rd tab titled "Reference Materials."

The Context clause is a new addition to the Standard, and requires an organization to frame the QMS in terms of the organization's place in its business and regulatory (and social) setting, and to maintain an awareness of relevant external and internal issues, including requirements of "interested parties" that can impact the ability to deliver outcomes. Use of the organization context and principles of the process approach play a big part in scoping the QMS and outlining its processes. The ISO 9001:2015 Standard removed the requirement for a Quality Manual, but AS9100 Rev. D retains a requirement for a high-level document that outlines the QMS.

Intent of AS9100

- For your assigned AS9100 sub-clause, answer the following questions:
  - What is the intent of the section?
    That is, what are the requirements trying to accomplish?
    - ✓ A goal or objective
    - ✓ Not *how* they are accomplished
    - ✓ Don't confuse the *means* with the goal
  - What are some subjective words in the section?
- Express the intent in one short sentence.
  - For example, "To ensure ___*(what?)*___."

5 Leadership



5.1 Leadership and commitment

- 5.1.1 General
- 5.1.2 Customer Focus

5.2 Policy

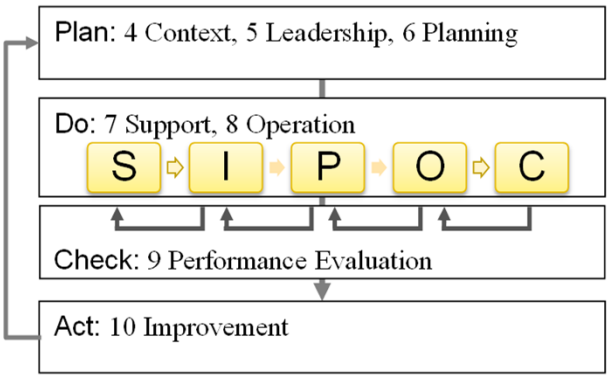
- 5.2.1 Establishing the Quality Policy
- 5.2.2 Communicating the Quality Policy

5.3 Organizational roles, responsibilities and authorities

Modifications in sub-clauses 5.1 and 5.2 incorporate the changes in Section 4 for organization context and interested parties and reinforce the use of the process approach and risk-based thinking.

Sub-clause 5.3 is largely unchanged: ISO 9001:2015 removed the role of Management Representative, but AS9100 Rev. D retains it.

6 Planning for the QMS



6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

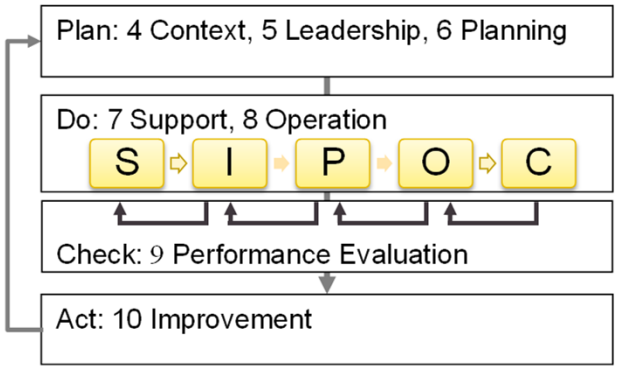
6.3 Planning of changes

Sub-clause 6.1 is new and emphasizes the use of risk-based thinking (and for this reason, the former sub-clause for Preventive Action was removed).

Sub-clause 6.2 retains the previous intent for Quality objectives and adds new specifics for planning for their achievement.

Sub-clause 6.3 modifies the previous planning requirements to reinforce risk-based thinking.

7 Support

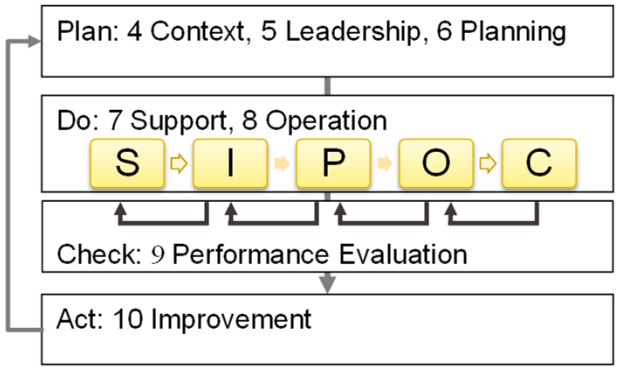


7.1 Resources

- 7.1.1 General
- 7.1.2 People
- 7.1.3 Infrastructure
- 7.1.4 Environment for the Operation of Processes

The sub-clause 7.1 broadens previous resource requirements and adds some new ones to continue the emphasis on the process approach and risk-based thinking.

7 Support

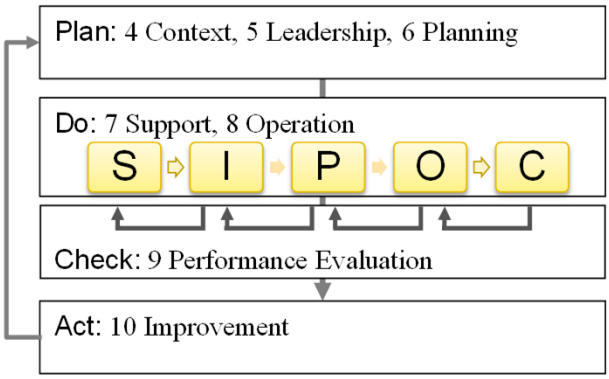


7.1 Resources, *continued*

- 7.1.5 Monitoring and Measuring Resources
  - 7.1.5.1 General
  - 7.1.5.2 Measurement Traceability
- 7.1.6 Organizational Knowledge

The emphasis on risk-based thinking is especially apparent in relation to knowledge management in 7.1.6.

7 Support



7.2 Competence

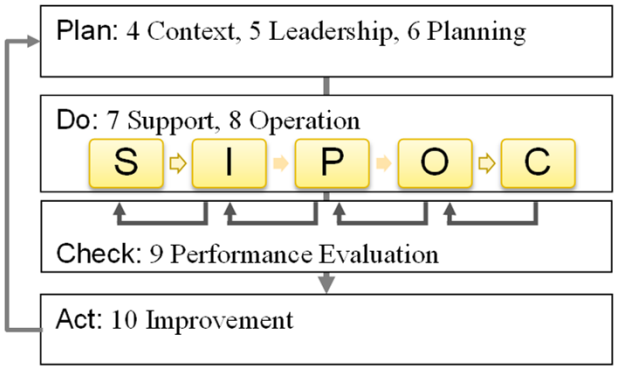
7.3 Awareness

7.4 Communication

The sub-clauses 7.2 through 7.3 continue the emphasis on the process approach and risk-based thinking, especially in relation to competence and employees' risk awareness.

Sub-clause 7.4 is modified to give more specific requirements regarding the *process* of communication and is less prescriptive on content, although AS9100 Rev. D adds a guidance note.

7 Support

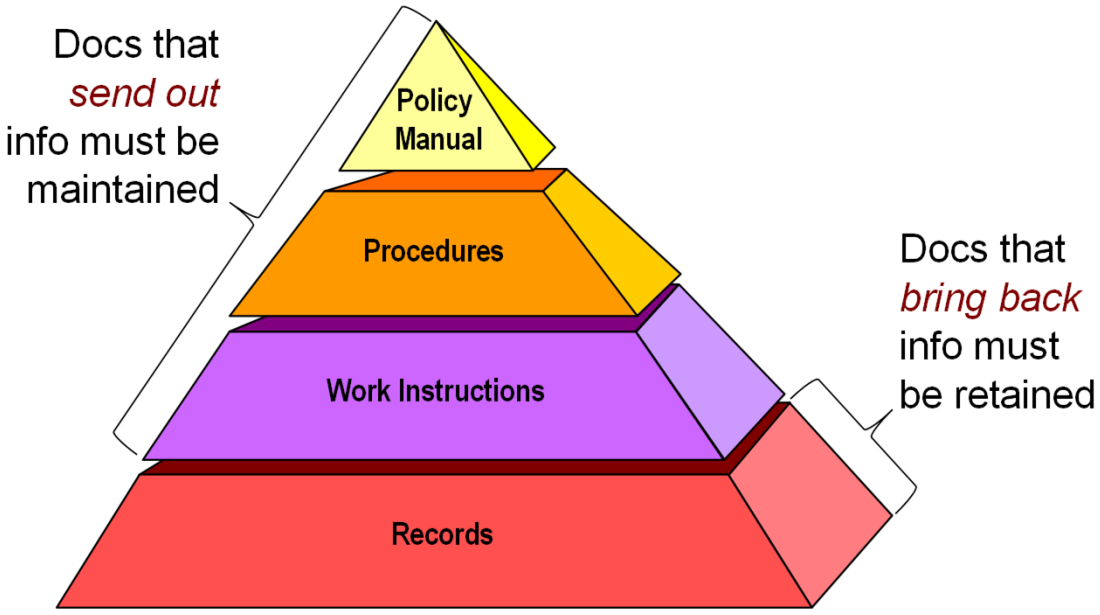


7.5 Documented information

- 7.5.1 General
- 7.5.2 Creating and Updating
- 7.5.3 Control of Documented Information

Sub-clause 7.5 changes terminology from “documents” and “records” to “documented information.” New requirements bring this section up-to-date with the use of digital information.

Documented Information Structure



Policy Manual

Document(s) stating organization's *policy* interpretation of external requirements/guidelines (e.g., International Standards, Regulations, Customer's Systems Requirements, Industry Standards, etc.) as applied to the organization. Says: *"What and why."* It provides organization's philosophy and direction.

Procedures

Documents describing the organization's high-level processes (which may be listed in a Manual). They describe methods and responsibilities in more detail. Can make use of flow diagrams to simplify this task. Says: *"Who does what and when."*

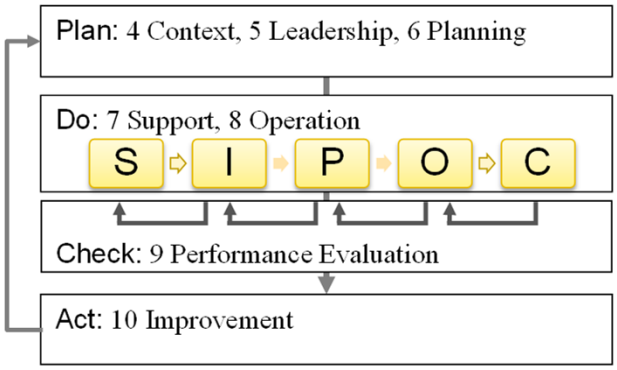
Work Instructions

Documents that provide detail to support the organization's procedures. They provide specific information on activities, tasks, and steps such as: how to build specific assemblies, how to load a program into a robot, keystrokes for order entry, etc. May also be forms, checklists, work standards/examples.
Says: *"How this part of the process is performed."*

Records

Records are the information and/or data that show a process has been performed. When a form (Work Instruction) has been filled out, it then becomes a record. Records can be such things as collected measurement/monitoring data, supplier information, computer data, test results, quality reports, etc. Records provide *"objective evidence"* that a process has been carried out.

8 Operation



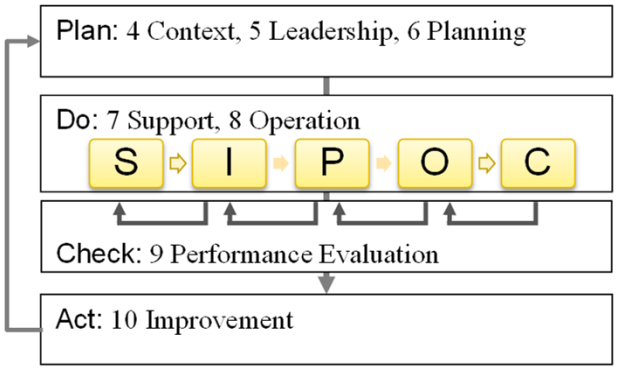
8.1 Operational planning and control

- 8.1.1 Operational Risk Management
- 8.1.2 Configuration Management
- 8.1.3 Product Safety
- 8.1.4 Prevention of Counterfeit Parts

Sub-clause 8.1 rewords and reorganizes the previous product planning and control requirements, with new additions that incorporate the increased emphasis on risk-based thinking, including product safety and prevention of counterfeit parts.

The wording of the requirements for configuration management is greatly simplified.

8 Operation

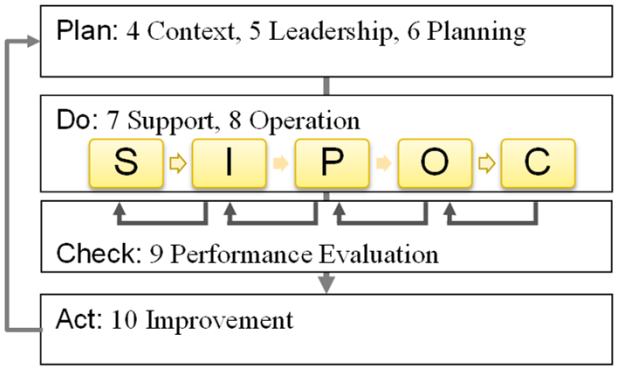


8.2 Requirements for products and services

- 8.2.1 Customer Communication
- 8.2.2 Determining the Requirements for Products and Services
- 8.2.3 Review of the Requirements for Products and Services
- 8.2.4 Changes to Requirements for Products and Services

Sub-clauses 8.2 through 8.4 have modifications that reinforce risk-based thinking and the process approach for meeting customer requirements. There are terminology changes and some new requirements in line with those in clauses 4, 6 and 8.1.

8 Operation

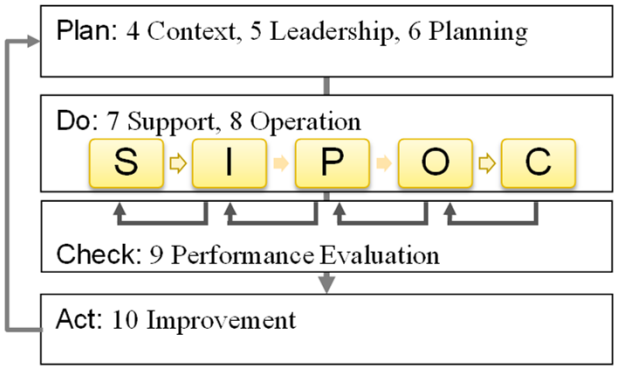


8.3 Design and development (D & D) of products and services

- 8.3.1 General
- 8.3.2 D & D Planning
- 8.3.3 D & D Inputs
- 8.3.4 D & D Controls
- 8.3.5 D & D Outputs
- 8.3.6 D & D Changes

Sub-clauses 8.2 through 8.4 have modifications that reinforce risk-based thinking and the process approach for meeting customer requirements. There are terminology changes and some new requirements in line with those in clauses 4, 6 and 8.1.

8 Operation

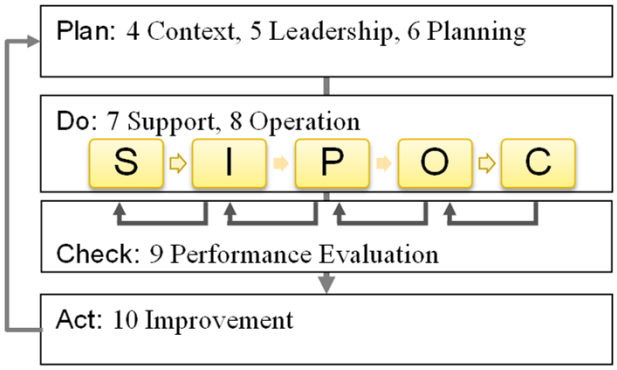


8.4 Control of externally provided processes, products and services

- 8.4.1 General
- 8.4.2 Type and Extent of Control
- 8.4.3 Information for External Providers

Sub-clauses 8.2 through 8.4 have modifications that reinforce risk-based thinking and the process approach for meeting customer requirements. There are terminology changes and some new requirements in line with those in clauses 4, 6 and 8.1.

8 Operation

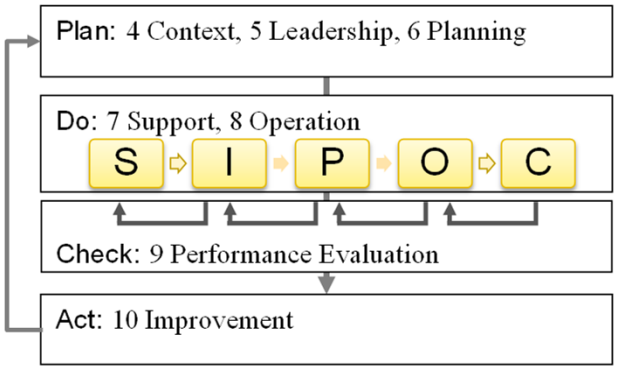


8.5 Production and service provision

- 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

Sub-clause 8.5 is largely the same, with terminology modifications in line with previous changes. It is also reworded for better application to service-based organizations. There are also new and modified requirements in line with added risk and human factors criteria earlier in the Standard.

8 Operation



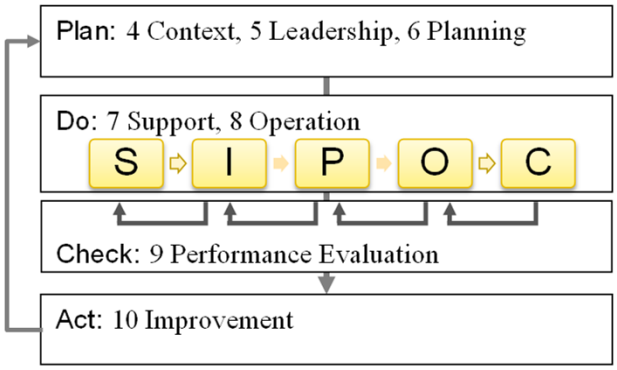
8.5 Production and service provision, *continued*

- 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

The improved application to service-based organizations is apparent in the expanded section for post-delivery activities.

The sub-clause on control of changes is new to ISO 9001:2015 but encompasses previous text from AS9100 Rev. C.

8 Operation



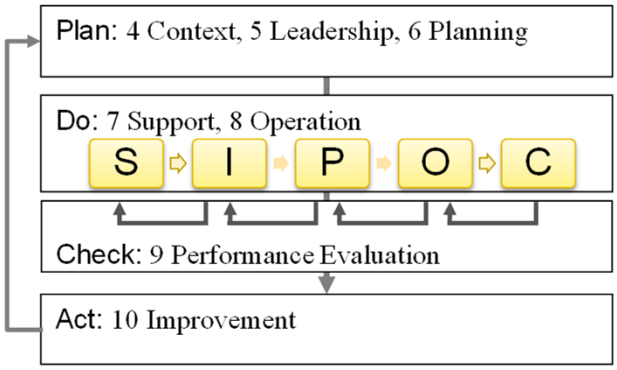
8.6 Release of products and services

8.7 Control of nonconforming outputs

Sub-clause 8.6 is mostly unchanged except for terminology modifications.

Sub-clause 8.7 also has terminology changes and incorporates consideration of counterfeit parts.

9 Performance evaluation



9.1 Monitoring, measurement, analysis and evaluation

- 9.1.1 General
- 9.1.2 Customer Satisfaction
- 9.1.3 Analysis and Evaluation

9.2 Internal audit

Sub-clause 9.1 remains the same in terms of intent and as in other clauses, incorporates terminology changes and the emphasis on risk-based thinking.

Sub-clause 9.2 is the same except for a new note regarding the use of performance indicators during internal audits.

9.2 Internal Audit: “Must Do” Requirements

9.2.1

- Conduct audits at planned intervals
- Provide info on whether the QMS conforms to :
  - Organization’s own requirements for QMS
  - Requirements of the Standard
- And is effectively implemented & maintained

9.2 Internal Audit: "Must Do" Requirements

9.2.2

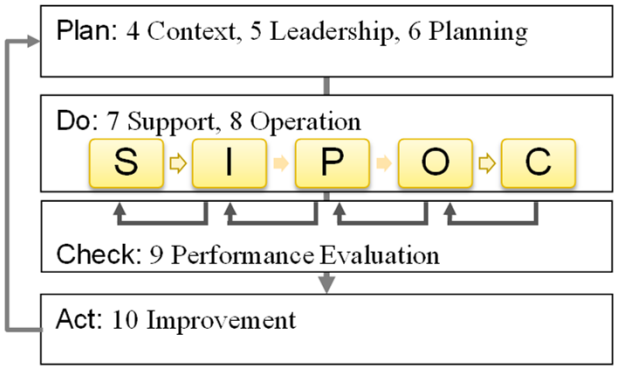
- Develop and maintain an audit program including frequency, methods, responsibilities, planning requirements and reporting
- Take into consideration:
  - importance of processes under audit
  - changes affecting the organization
  - results of previous audits
- Define each audit's criteria and scope
- Ensure objectivity and impartiality in auditor selection and audit conduct

9.2 Internal Audit: "Must Do" Requirements

9.2.2, *continued*

- Ensure audit results are reported to relevant management
- Take appropriate correction and corrective actions "without undue delay"
- Retain documented info for evidence of audit program implementation and audit results

9 Performance evaluation



9.3 Management review

9.3.1 General

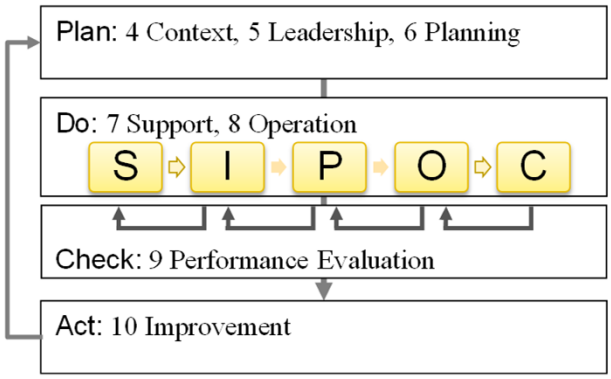
9.3.2 Management Review Inputs

9.3.3 Management Review Outputs

Sub-clause 9.3 remains the same in terms of intent and as in other clauses, incorporates terminology changes and the emphasis on risk-based thinking.

Sub-clause 9.3 also has new requirements that reinforce the use of performance indicators.

10 Improvement



10.1 General

10.2 Nonconformity and corrective action

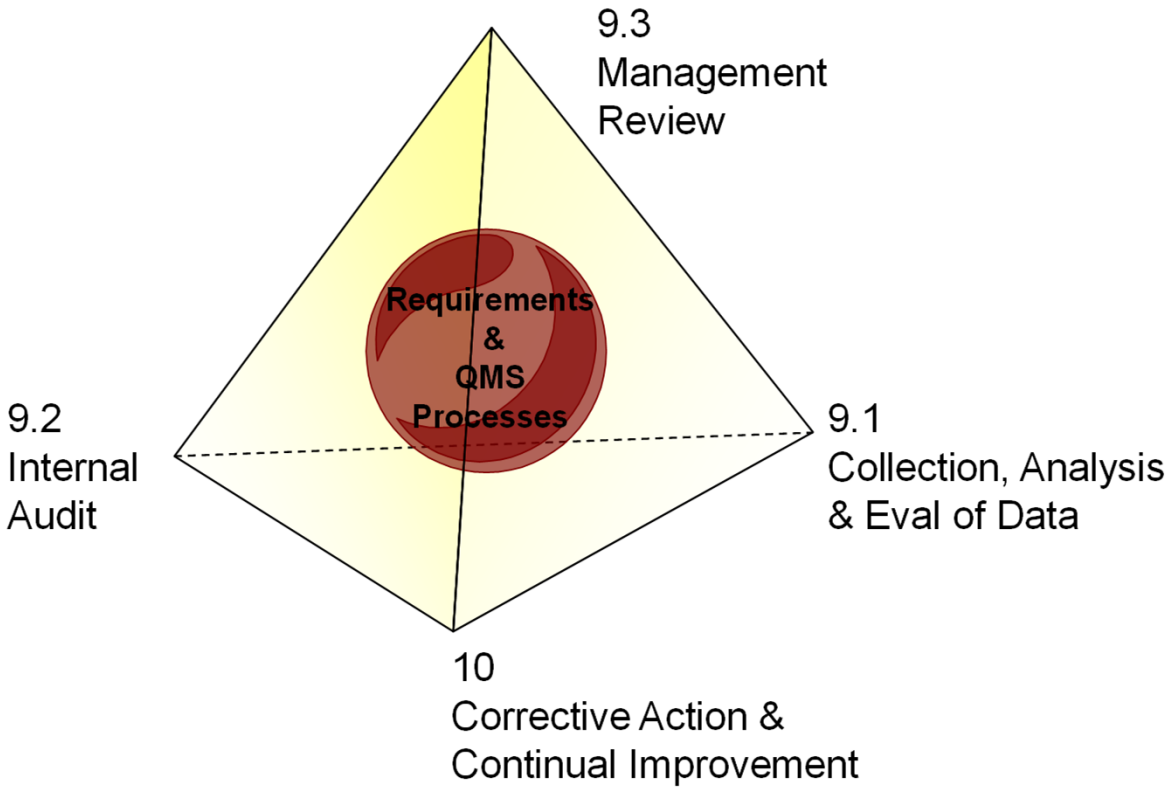
10.3 Continual improvement

Clause 10 as a whole incorporates the emphasis on management of risks and opportunities along with earlier terminology changes.

The previous AS9100 Rev. C additions for process nonconformance are incorporated in sub-clause 10.2. Consideration of human factors in nonconformance evaluation is new.

As stated before, the sub-clause for preventive action is removed.

Effective Use of the QMS



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Prepare for the Audit

Audit Preparation

Proper

Prior

Planning

Prevents

Poor

Performance

6 P's

Planning Steps

1. Select skilled, capable person/team
   - Appoint an Audit Team Leader (if more than one person)
   - Make audit assignments (Team Leader)
2. Confirm purpose & scope
3. Confirm and review audit criteria
4. Identify information sources

With Process Owner/Manager, and QMS Manager

5. Develop audit plan
6. Confirm plan with Manager/Process Owner
   - Send notification
7. Assess documentation (optional)
8. Develop guidelist

Auditor Qualifications

- Know the applicable external Standard(s) and Guidelines
- Understand your quality system
- Understand regulatory issues
- Understand audit techniques
  - audit planning
  - audit performance practices
- Possess excellent communication skills

Basic Principle:
Auditors are Effectiveness Improvement Specialists

Realities of Auditing

- The auditor must:
  - Often work alone, without supervision.
  - Gather information — sometimes from people who don't want to cooperate.
  - Often work in areas where one has little or no technical proficiency.
  - Be efficient — there is never enough time to complete the job.
  - Exercise sound business judgment.

Audit Purpose & Scope

Answer the following questions:

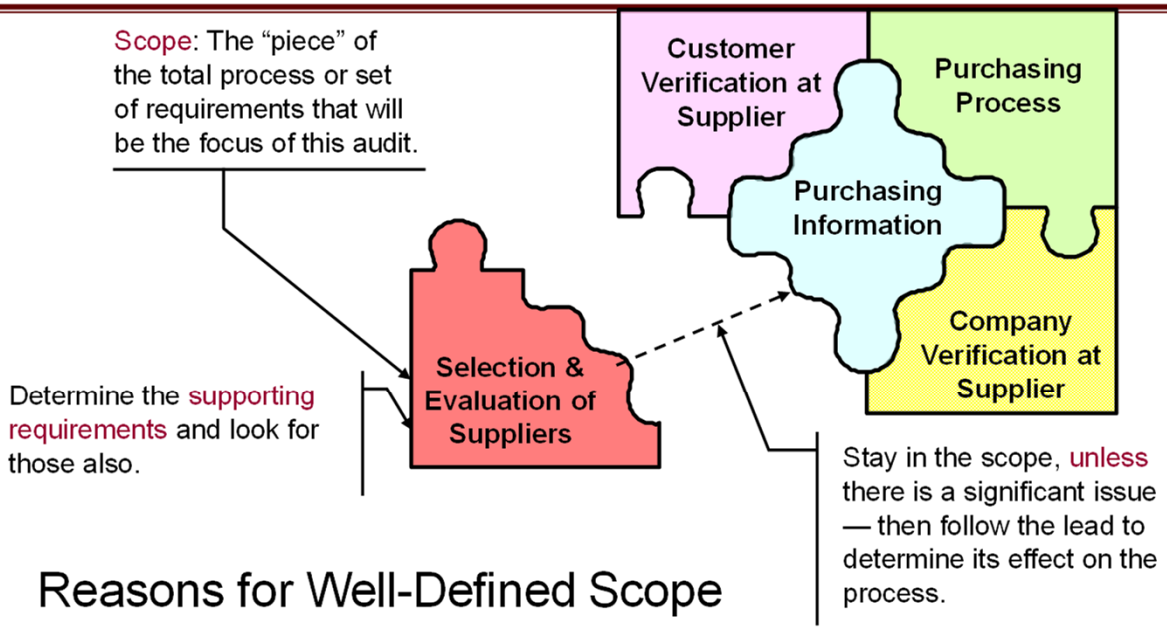
1. What system/process am I auditing?
2. Why am I auditing this process?

Determining the Purpose

1. At what point of the process do I start?
2. At what point of the process do I stop?

Determining the Scope

Audit Scope



Reasons for Well-Defined Scope

- Audit efficiency
- Reduced audit time
- Better coverage of requirements
- Less overlap between audits

Purpose and scope can be thought of on several levels. There may be an overall purpose and scope for an audit, such as to assess a supplier's quality system as part of a Supplier Certification program. To accomplish this type of large-scale audit, multiple auditors may be used. Each auditor would be assigned to one or more processes/areas within the quality system, each with a particular purpose and scope. An internal audit program as a whole can be thought of in this way as well.

Audit Criteria & Information Sources

- Review and understand the audit criteria (requirements)
  - Customer contract(s) &/or Quality System Requirements
  - Quality Manual, procedures, work instructions
  - Quality plans
  - Regulatory and/or industry requirements & standards
  - International Quality Standard requirements or recommendations
- History
  - Product and/or process issues and performance data
  - Previous audit results (internal, customer, regulatory, registrar)
  - Corrective Action commitments
- Technical Expert(s)

Audit Criteria: Set of policies, procedures, or requirements used as a reference against which objective evidence is compared.
(ISO 9000:2015, 3.13.7)

Requirement: Need or expectation that is stated, generally implied or obligatory.
(ISO 9000:2015, 3.6.4)

Technical Expert: Person who provides specific knowledge or expertise to the audit team. *(ISO 9000:2015, 3.13.16)*

Audit Plan

- Purpose, objectives and scope: consider how the process is defined and managed in terms of:
  - Process objectives
  - Inputs/outputs
  - Required resources
  - How its performance is measured
- Key requirements
- Outstanding issues
  (from history, process owner or manager)
- Activities to be evaluated
- Documents needed
- Special considerations (such as PPE to be used, language translation, non-disclosure agreements, etc.)
- Schedule: dates, times, people

Different aspects of the process should be looked at from one audit to the next (this topic will be discussed further during the section on conducting the audit).

PPE = Personal Protective Equipment

Audit Plan Example

Internal Audit Plan – Purchasing Process

Objectives:

1. Process is adequately documented
2. Process is understood and is being used by staff and Project Managers
3. Process is delivering satisfactory results that contribute to established goals

Scope:

This audit will examine the sub-process for selecting and evaluating material and service suppliers. Main focus will be on services.

Key Requirements:

- ISO 9001, subclause 8.4.1, 8.4.2
- Botta-Boom procedure OP 8.4

Activities to be Evaluated:

- Steps to request new supplier or excepted supplier
- Steps to evaluate new or excepted suppliers
- Steps to continue evaluation of suppliers
- Steps to change supplier status
- Decision process and criteria for above steps

Documents Needed:

- OP 8.4 (obtained from system)
- Approved Supplier List (obtained from system)
- Records of supplier selection and evaluation (provided by Purchasing)

Special Considerations: None

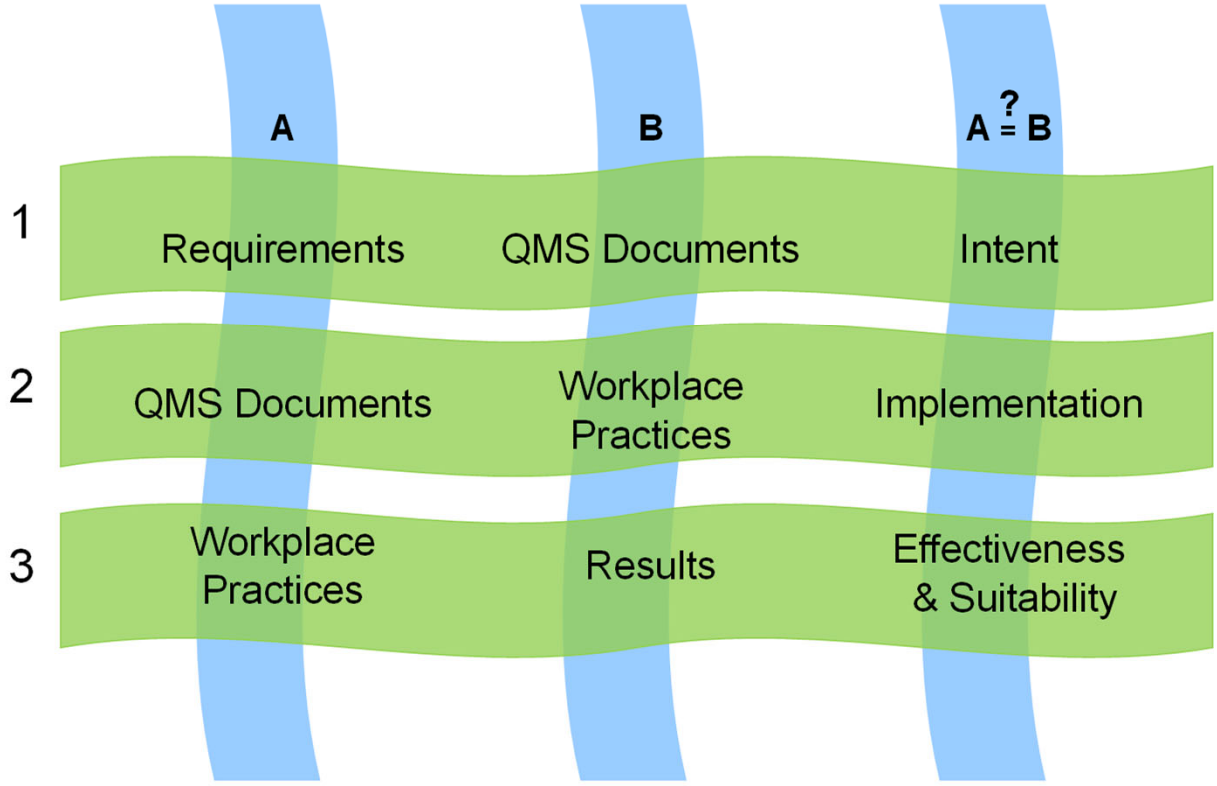
Schedule:

• Opening Meeting:	8:00 – 8:10, 8/19/XX	Maria Castillo's Office
• Internal Audit:	8:10 – 9:10, 8/19/XX	(detailed schedule provided)
• Closing Meeting:	9:10 – 9:25, 8/19/XX	Purchasing Conf. Room

Audit Notification

- Company sets own policy
  - Can be formal — in writing or by email
  - Can be informal
- Should cover following items:
  - Date of audit (as much lead time as possible)
  - Purpose and scope of audit
  - Names of audit team leader and members
  - Type of audit
    - System
    - Process
    - Service
    - Product
  - Schedule for audit
  - Specific people needed to be seen (if you know)
  - Documents or records required

The 3-Step Comparison Process

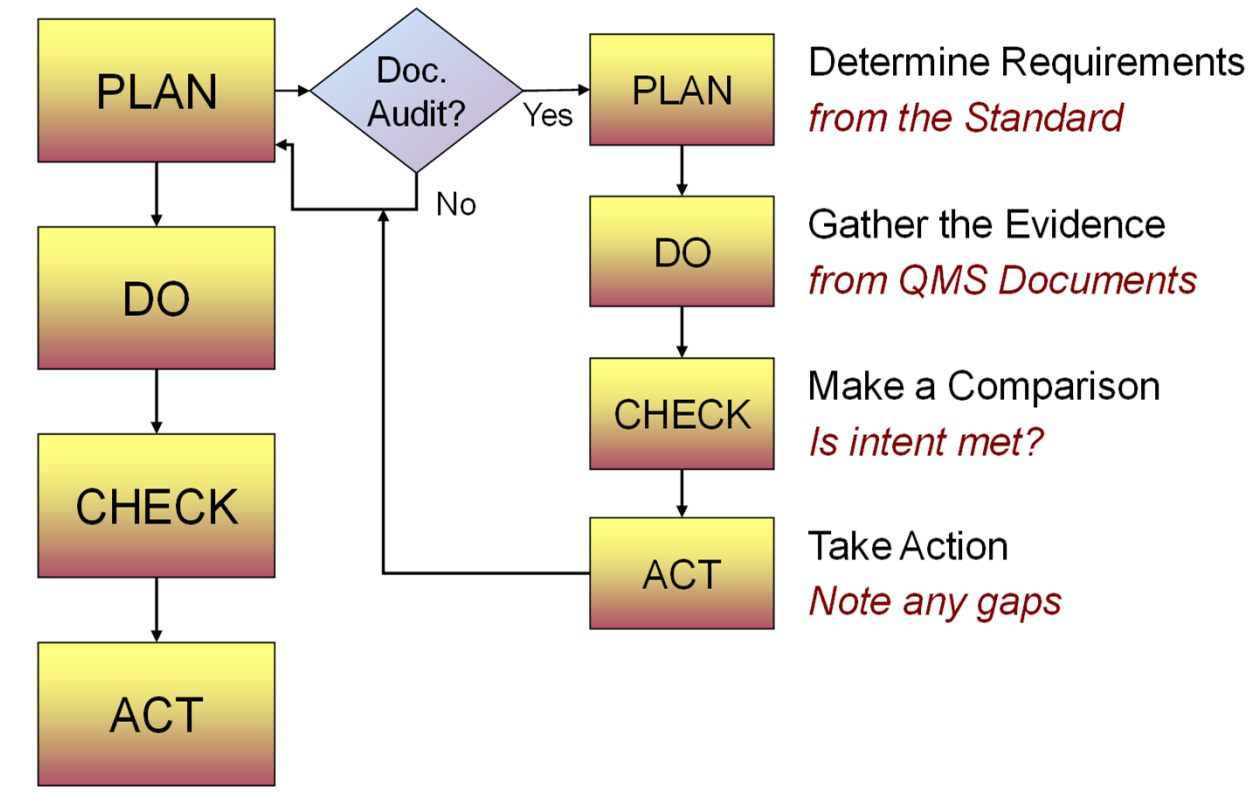


While the fundamental "A=B" comparison process is the same, the two things being compared will vary.

Each comparison looks at a different aspect of the Quality Management System:

1. Is the QMS documented and are all requirements covered?
2. Are the QMS plans (i.e. documents) being followed?
3. Does the QMS fit the organization and help it meet customer and regulatory requirements?

Documentation Assessment



Step 1: Documentation Assessment — may not happen for each Internal Audit. Good times to perform one are when documents are first being written or have significantly changed and when a Standard is revised. (It is also the first step of an external Registration Assessment.)

Requirements for the Documentation Assessment (AKA Desktop Audit) typically come from an external Quality Standard, but could also be Regulations, Industry Standards or Customer Contract Requirements, depending on the audit purpose.

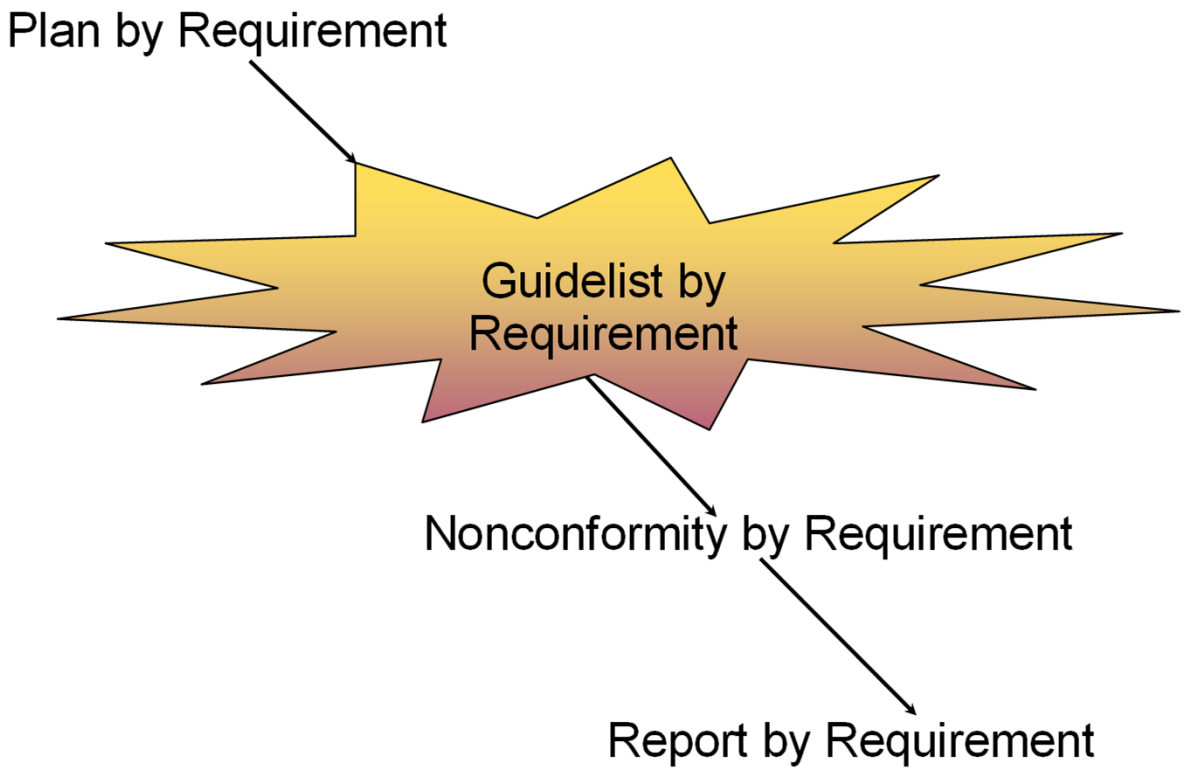
In this workshop we will use a checklist created from an external Quality Standard.

Documentation Assessment

1. Read the Botta–Boom Case Study Introduction. (See second tab titled “Case Study Materials.”)
2. Audit your assigned procedure against the Assessment tool provided.
3. Determine conformance of the procedure to each requirement.

Write notes about conformance and/or nonconformance on the documents themselves and be prepared to share results with the large group. Also note other questions/suggestions that arise during the review.

Guidelist Set-Up



Preparing an Audit Guidelist

Guidelist contents will come from the audit criteria, documentation assessment findings, and any outstanding issues.

Components of the guidelist:

1. Requirement
2. Look at:
    - What activities?
    - Who to interview (function and level)?
3. Look for:
    - What will be the objective evidence of the requirement being met?
4. Sampling Plan:
    - How many things should I look at?
    - How many people should I talk with?
    - How do I make the sample representative?

In addition, prepare templates for taking notes, particularly for your review of samples (e.g., purchase orders).

The Audit Guidelist begins at Step 2 from "The 3 Step Comparison Process." It serves as an outline for the "A to B" comparison of what is documented versus the actual workplace practices.

Note taking will be discussed in more detail in the "Do" section.

Exercise 5

Guidelist with Sampling Plan

As a large group, we will fill in the blank spaces below; first for Look At & For, then Sampling Plan.

	Requirement	Look AT (Talk To)	Sampling Plan	Look FOR
1	**Control of records** Process for storage & preservation, including preservation of legibility.	*Index of Quality Records, Form# 1234*		
2	**Control of records** Process for retention & disposition.			*Stated retention time & disposition as appropriate for type of record*
3	**Awareness of QMS** Employees are aware of their contribution to the effectiveness of the QMS.	*Personnel*		*Methods of communication, understanding of contribution re job function*
4	**Review of the requirements for products & services** Review of requirements specified by the customer.	*RFQ and Order review checklist.*		*Review checklist is filled out and signed off by all required parties.*
5	**Review of the requirements for products & services** Review of requirements not stated by the customer, but necessary for specified/intended use, where known.			

Guidelist Development

Develop a guidelist

1. Develop an audit guidelist to audit the Botta–Boom procedure assigned to you.
2. Use the blank audit guidelist worksheet in the second tab titled “Case Study Materials.”
3. For this exercise, complete only the sections for
   - Requirement
   - Look At
   - Look For
4. Share your guidelist with the members of your audit team.

Audits as Samples

- Audits represent a snapshot of the process at a point in time (past or present) and are not a guarantee that the process is perfect.
- The intent of an audit is not to examine 100 percent of a document, going line by line.
- It is more important to focus on the key points of the process, document, product or service.
- Representative sampling should be used.

Different aspects of a system/process should be looked at from audit to audit to ensure that over time, the entire system is examined. It's important to review past audit records in order to achieve this sort of rotation.

Representative Sampling

- The sampling method is best determined during the Plan phase, not the Do phase.
- The goal is for the sample to accurately reflect day-to-day operation of the process:

Quantity — how many?	Quality — which ones?
Statistically calculated sample sizes are generally *not* required.	The sample should take a "cross-section" of the process.
Sample should be large enough to give confidence that what is seen is representative.	Helpful categories to consider include: • Type • Level • Timeline

- During the audit, draw random samples within the previously determined categories.

Type: A category of people or things having a common characteristic(s) that causes them to be regarded as a group.

Level: The relative position/rank on a scale of amount, extent, quality, risk, etc.

Timeline: A chronology, for example, newest to oldest, day to night, phases of a product/service cycle, etc.

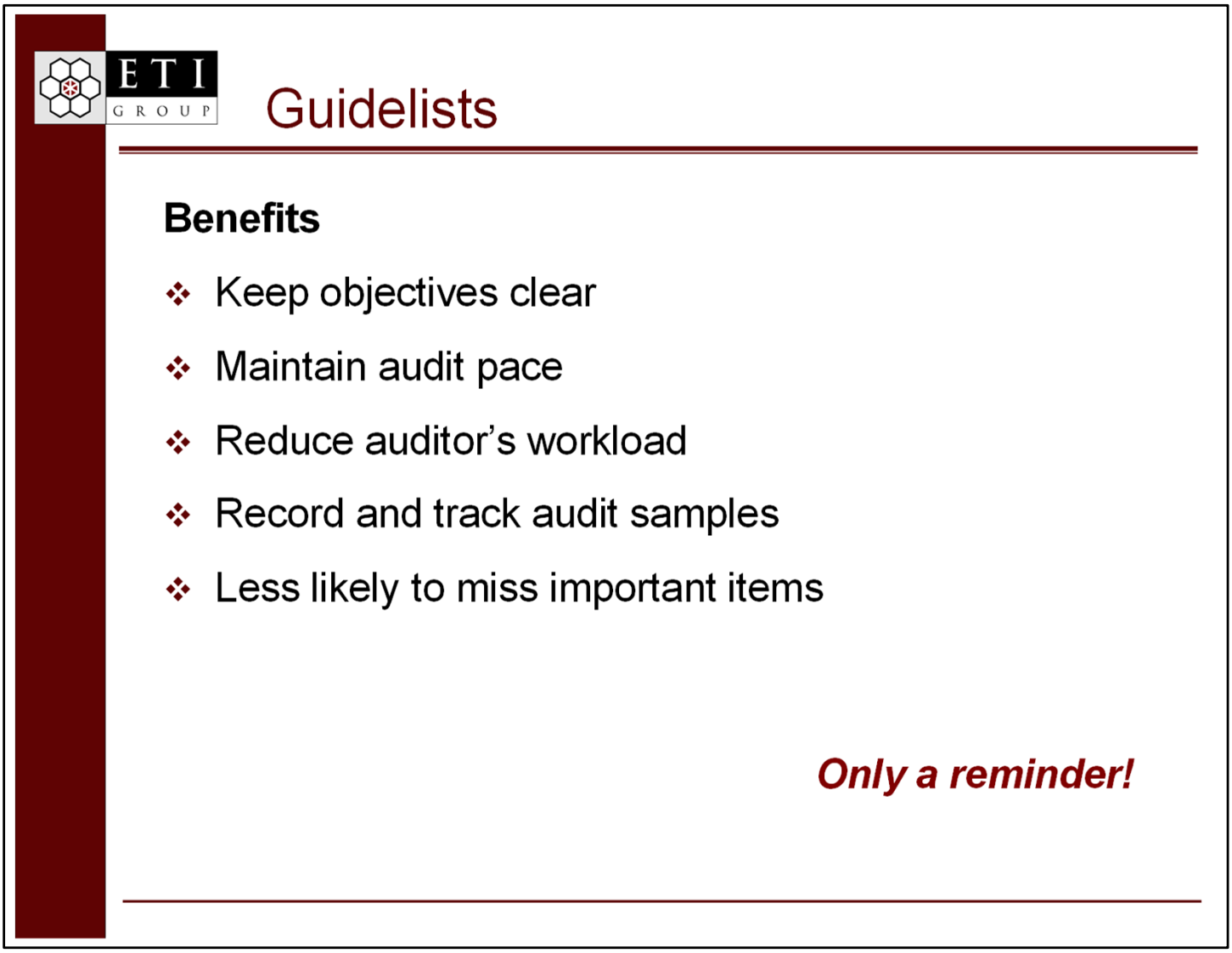
Guidelist Development

Develop a guidelist sampling plan

1. Use your audit guidelist items from the previous exercise.
2. Develop a sampling plan: consider how to collect a representative sample.
3. Share your sampling plan with the members of your audit team.

Questions for Process Points

Process Point	What to Check For
Decisions	• Who has responsibility & authority for the decision? • What are the decision criteria? • Are decisions being made: - by the correct person? - that meet criteria?
Hand-offs	• Is the item correct? • Does it arrive on time?
Records Created	• Is the correct form used (including revision level)? • Are the records filled out properly? • Are the records legible and retrievable?
Data Collected	• If it is required, is it being collected? • Is the data accurate? • How is the data used?
Exceptions	• What happens if …? • Are there processes for handling exceptions? • Are these processes followed? • Can the process survive the exceptions? (Is it robust?)
Corrective Actions	• Are there past corrective actions against part of the process? • Were the corrective actions implemented? • Were they effective?



See the Appendix for an additional guidelist example.

Checking the Audit Plan

1. Is the audit well planned?
   - Have I thought through the process?
   - Have I identified a beginning and ending point?
   - Can I take a logical sample that represents the process?
   - Can I follow the process?
   - Do I have sufficient qualified auditors?
2. Have I set achievable goals?
   - Can I see something actually happening?
   - Can I find evidence of an effective system?
   - Can I verify the links between work groups &/or processes?
3. How long will it take?
   - Does the length match the objectives?
   - Do I have the amount of time needed?
   - Have I taken into account shift changes and breaks?
   - Are there multiple work shifts that should be audited?

The audit guidelist may need to be modified based on the answers to these questions. Depending on the audit purpose, it may be better to dig deeper into a few requirements as opposed to a surface look at a lot of requirements.

After completing the guidelist, the auditor may find that the audit agenda needs to be modified in terms of flow of activities to look at, people to talk to and timing.

Case Study Audits

Botta–Boom Interviews

(See second tab titled “Case Study Materials.”)

1. Read and evaluate the Background Info and audit interview Cases 1, 2 and 3.
   - Are there nonconformities?
   - What are they?
2. Discuss your findings with your audit team.

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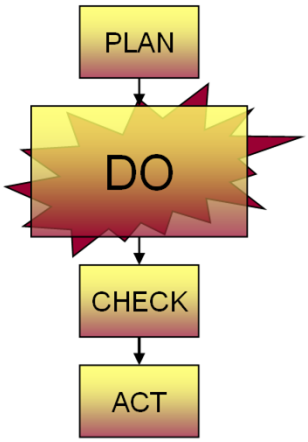
DO: Gather the Evidence

"What Is"



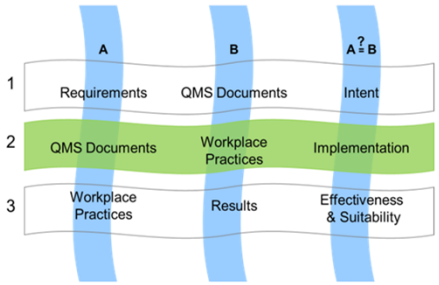
Audit Role Play

Listen and observe

1. What Quality System sub–clauses are being addressed by the auditor (either directly or indirectly)?
2. What issues, observations, or replies might concern the auditor?

Stages in Performing the Audit

- Stage 1: Hold an opening meeting
- Stage 2: Gather evidence using appropriate methods
  - Conduct effective interviews
  - Ask the right questions
  - Use good communication techniques
  - Establish facts
  - Collect objective evidence (take notes)
- Stage 3: Hold a closing meeting



Beginning the Audit: "Opening Meeting"

- Meet manager/process owner (minimum)
- Introduce team (if more than one auditor)
- Explain purpose and scope of audit activities
- Agree that audit plan is acceptable
- Confirm employees' availability
- Confirm status of documents (anything in revision?)
- Explain method of identifying & recording nonconformities
- Discuss closing meeting
  - Time
  - Location
  - Attendees

"opening meeting" and the first interview often overlap

Asking the Right Person

- Be strategic
  - Management level first
  - Operating level next
- Direct questions to the person who performs the task regularly (not the person supervising).
- Target your audience: Communicate at the same responsibility and knowledge level of the auditee. In general:
  - Don't ask the CEO how to build a widget
  - Don't ask a line-worker to discuss determination of strategic objectives

Interview Flow

1. Introduce yourself.
2. Develop a rapport. (Put auditee at ease.)
3. Explain what you want to see.
4. Focus on the process & products.
5. Investigate as much as necessary.
6. Get auditees involved.
7. Satisfy your sample.
8. No problems? Move on!
9. Problem: Assure yourself it's real, share your finding, then move on!
10. Thank auditees for their time and assistance!

If a nonconformity is found, don't try to find the cause or solve the problem during the audit. (This suggestion will be difficult to follow!)

Attitude Is Everything

- You can dig a mile deep but a foot wide
  - Dig deep enough and you can find something wrong.
  - This is auditing to find fault.
- You can dig a foot deep but a mile wide
  - Cover more ground looking for system and process strengths and weaknesses.
  - This is auditing to find conformance.

The Four-to-One Ratio

- Auditors must have very good interviewing and communication skills.
- The objective of an audit is to get the auditee talking — not the auditor!
- Part of listening is to ask the right questions.

I keep six honest serving–men
(They taught me all I knew);
Their names are What and Why and When
And How and Where and Who.

— Rudyard Kipling
The Elephant Child

Eyes, ears, mouth and…

Assuming healthy functioning, the body has a four to one ratio of "observational" organs to "speaking" organ. They should be used in that proportion during the audit interview. Your nose may come in handy too!

Asking the Right Questions

- Open Questions
  - Elicit more information
  - Preferred type in most cases
  - Don't use two questions if one will do!
  - Use What, Why, When, How, Where, and Who as much as possible
- Imperative Question
  - Add a seventh "honest servant"— the crunch question:

Please **show me**!

Asking the Right Questions

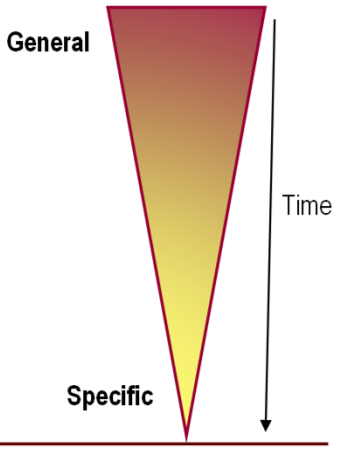
- Closed Questions
  - Elicit Yes or No answers
  - Can be useful if that is what you want
- Other useful types
  - Silent question
  - Obvious question
  - Unasked question
  - Inverse questions

Typical Questions

- Please explain your role in this organization.
- How do you know when to start your tasks?
- When are you done?
- What do you provide when your tasks are complete?
- Please explain your process to me.
- What tells you how to do your job?
- What would you do if...?
- What training did you receive about your job?
- Please demonstrate for me…
- I would like to review samples of your records…

A Questioning Sequence

1. Ask organizational questions.
   - ✓ Roles, responsibilities, training
2. Ask about their process.
   - ✓ Inputs
   - ✓ Steps they perform (start to finish)
   - ✓ Outputs
3. Ask comparison questions.
   - ✓ Listen to what's said and what's not said.
4. Ask hypothetical questions.
   - ✓ "What if …"
   - ✓ "Let's suppose …"
   - ✓ Probe for unusual conditions and responses.
5. Ask about monitoring performance.
   - ✓ How do they "control" their process?
   - ✓ Do they collect and analyze performance data?



Interview Question Critique

Below are four questions that a reviewer has asked at the start of an interview. Decide whether you think the questions are effective. If so, circle "Yes" and write why you made this decision. If not, circle "No" and rewrite the question to how you think it should be asked.

1. How do you determine which individuals are qualified to fill in on this task when the regular person is absent?

   YES NO

2. Do you record any information during the design review process?

   YES NO

3. How do you handle nonconforming items?

   YES NO

4. Does your supervisor review these records on a daily basis?

   YES NO

Listening Skills

- **CORRECT** bad listening habits by using active listening:
  - **C**oncentrating on what is being said. (Remove distractions.)
  - **O**bserving facial expressions and body language; being conscious of feelings.
  - **R**esponding by using your eyes, voice, gestures and posture to communicate empathy and understanding.
  - **R**eflecting the information you hear by paraphrasing it.
  - **E**liciting more information by asking questions.
  - **C**ontrolling the desire to interrupt, pass judgment or change the subject.
  - **T**aking notes.

The "Listening Techniques" sheet provided in the Appendix gives more information.

Human Relations in Auditing

Theory

- Auditing is an instrument used to gather independent information about processes and systems

Reality

- Auditing is based on relationships between people
- People get nervous when they're being audited

You are responsible for establishing an atmosphere of trust and open communication.

The auditor's attitude and credibility are directly linked.

Interviews — Not Inquisitions!

Don't:

- Be sarcastic, argue or criticize.
- Be negative.
- Question beyond level of knowledge.
- Discuss personalities, organizational politics or policies.
- Make the audit a secret.
- Be a Dilbert auditor!

Interviews— Not Inquisitions!

Do:

- Be professional and friendly.
- Maintain control of the agenda.
- Be persistent and pleasant.
- Stress that you are reviewing the process, not people.
- Learn — continually about your organization, auditing and performance measurement.
- Cultivate proper attitudes toward reviews.
- Recognize that you are an imposition!

Interview Techniques

- Maintain normal eye contact.
- Speak clearly and carefully.
- Follow their customs and practices.
- Be flexible: Be able to ask for the same information in different ways.
- Always give praise where it is due — but don't be phony!
- Make sure your body language doesn't intimidate the person. Examples:
  - Standing over the person
  - Tapping a foot or looking at a watch
  - Crossing arms, raising eyebrows, making faces, etc.

The Role of Credibility

Credibility – The attribute of being convincing, trusting and believable.

Remember, auditors must:

- ☑ ask questions in a professional way
- ☑ draw conclusions based on requirements and objective evidence
- ☑ be truthful
- ☑ have a positive and helpful attitude

Auditing in this manner demonstrates integrity and earns credibility.

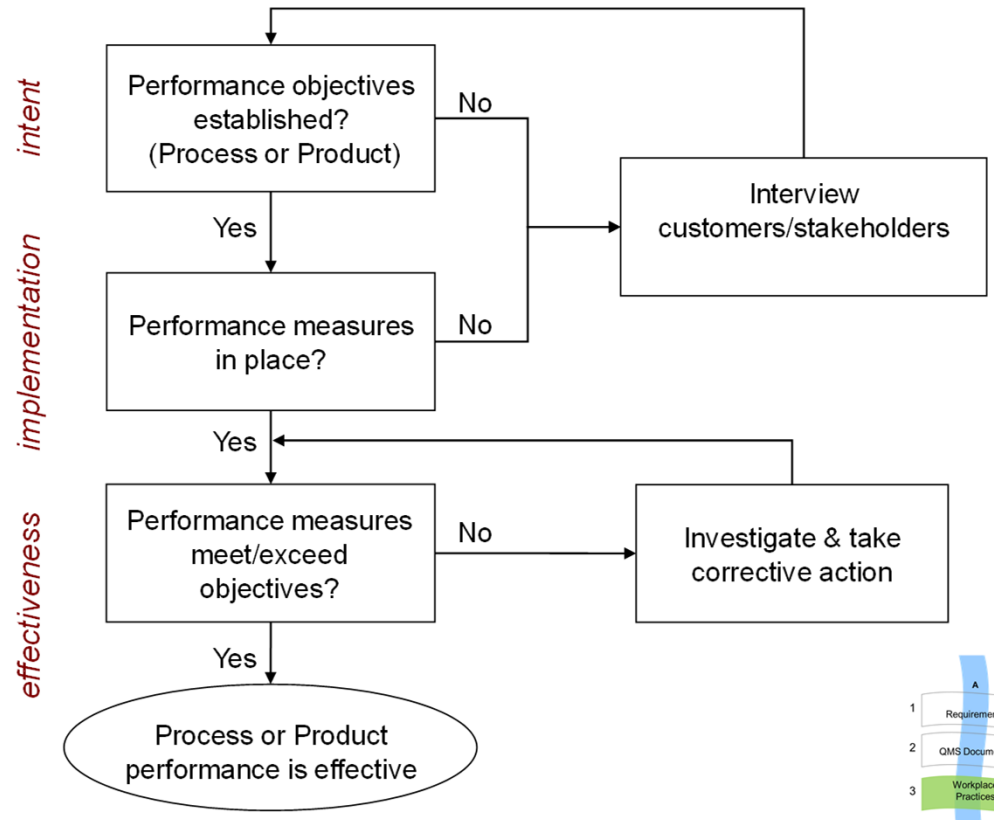
If you earn credibility, then your findings and conclusions are trusted!

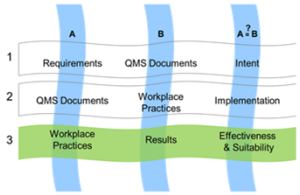
Interview Questions

1. Develop four questions about your assigned Botta–Boom procedure and associated guidelist.
   Write two open questions and two imperative (show me) questions.
   (15 minutes)

2. Share and critique questions.

Assessing Performance Measurement





Discussion Questions to take back to your organization:

Are product and process performance measures established in our organization? (Where are we covered, where are there gaps?)

How do we currently audit effectiveness of performance for products and processes?

What are some improvement ideas for auditing performance measurement in our organization?

The PEAR

- The Process Effectiveness Assessment Report is a required reporting mechanism for auditors from Certifying Bodies.
- A form is used to describe each Operational process (those in Clause 8), and serves the following purposes:
  - Outlines and and describes its interfaces with other QMS processes (think “SIPOC”)
  - Identifies the Organization’s method for determining key performance measures (KPIs)
  - Summarizes the level of implementation of the planned activities of the process and the degree of effectiveness achieved

AS9101 — *Quality Management Systems - Audit Requirements for Aviation, Space, and Defense Organizations*, Rev. F is the Standard used by Certifying Bodies (aka Registrars) for their audits of the AS9100 Rev. D Standard.

AS9101 dictates the use of a PEAR during AS9100 audits. *[Reference paragraph 4.2.2.5 .1]*

[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:

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:**

SECTION 4 – PROCESS EFFECTIVENESS

[21] **Process Effectiveness Level**

Process Realization (a)	Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved
Planned activities fully realized	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. **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. **4** ☐	a) The process is determined, and planned activities fully realized; and b) The process is delivering the planned results. **5** ☐
Planned activities not fully realized	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. **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. **3** ☐	a) The process is determined, but planned activities not fully realized; however, b) The process is delivering the planned results. **4** ☐
Planned activities not realized	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. **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. **2** ☐	a) The process is not determined, and planned activities not realized; however, b) The process is delivering the planned results. **2** ☐
	Process Results (b)		

[22] **Supporting Comments:**

[23] **Auditor(s):**	[24] **Organization Representative:**

DISCLAIMER STATEMENT

This audit was conducted based on a sampling process of the available information.

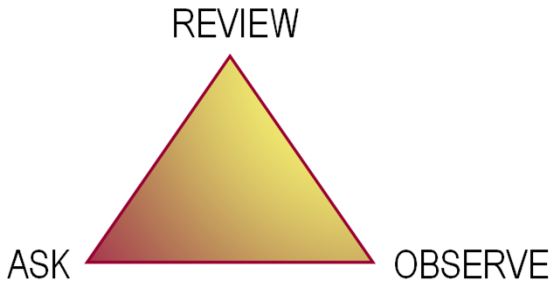
Prepare for the PEAR

- While it is the external auditor's responsibility to complete the PEAR, the audited organization must be prepared to provide the needed information.
- Some organizations find it helpful to create their own PEARs and include Support processes as well.
- For registrars' auditors, AS9101 Rev. F states that "Upon mutual agreement between the organization and the CB, other processes can be recorded on a PEAR." *[4.2.2.5.1 Note 1]*
- The PEAR clearly demonstrates a process-based approach to auditing and directs auditors toward the stakeholder goal of effective, results-oriented Quality Management Systems.

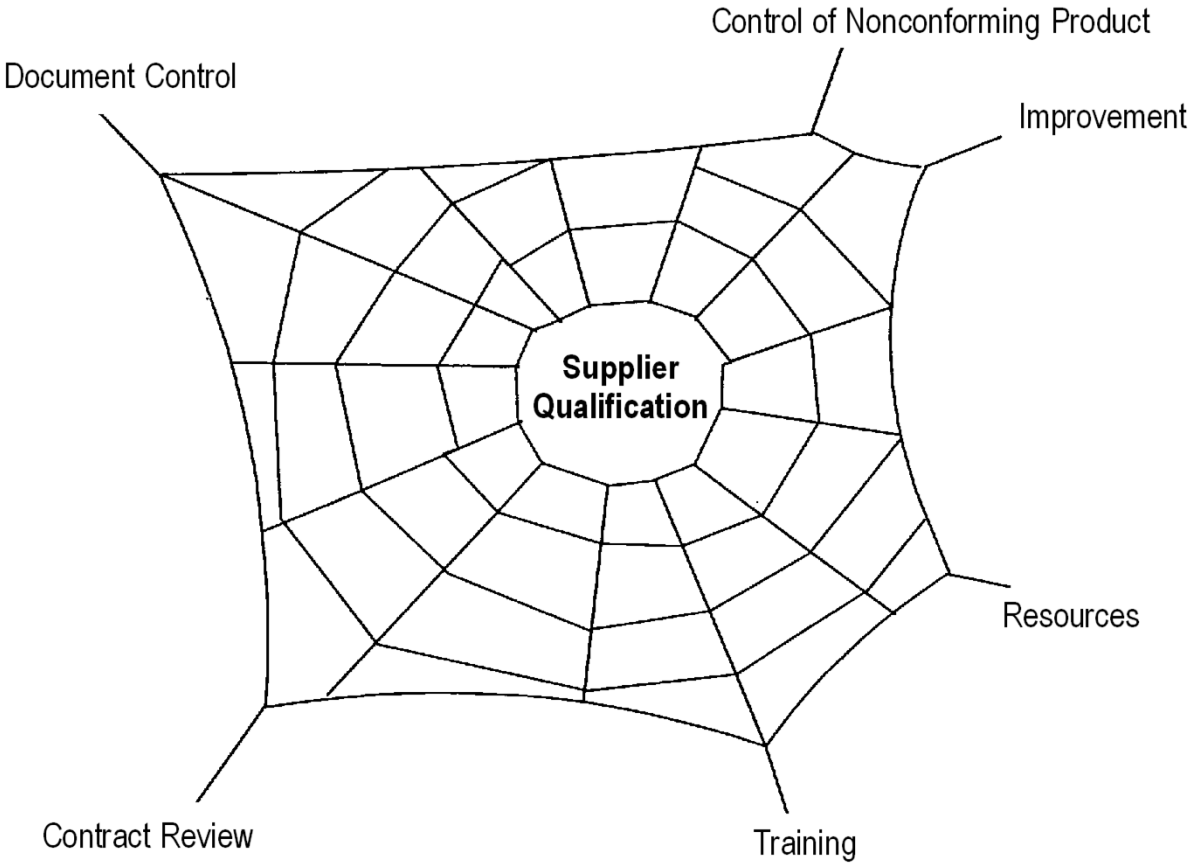
Establishing the Facts

Always verify whether they:

- Have procedures … (Ask & Review)
- Follow procedures … (Ask & Observe)
- Keep good records … (Ask & Review)
- Analyze data … (Ask & Review)
- Take corrective action when needed … (Ask & Review)



Perform "Systems" Audits



While the focus of the audit may be on a specific process, (such as Supplier Qualification), you should always be auditing the *system*—checking the links and hand-offs from and to other processes/systems.

Observation Cues

Things to watch for:

- Employee workloads
- People's reactions and attitudes — the working atmosphere
- Adequate resources — tools, supplies, information, training
- Knowledge of jobs and information
- Organization and housekeeping
- Who answers questions — managers or staff?
- People avoiding reviewers
- Employee response to problems
- Equipment conditions
- The real practices and informal organization

Bring up any observed safety issues immediately.

Being observant of resource issues—human, infrastructure and work environment—can provide good information about effectiveness of the QMS implementation.

Effective Audit = Objective Evidence

- **Audit Evidence**

  "Records, statements of fact or other information, which are relevant to the audit criteria and verifiable"

  — ISO 9000:2015, 3.13.8

  - Audit evidence can be qualitative or quantitative

- **Look For Objective Evidence** that the system is followed and effective.

Effective Audit = Objective Evidence

Objective Evidence comes in many forms:

- Meeting notes
- Training records
- Procedures and work instructions, written and followed
- Records of inspections, tests, calibration, etc
- Purchase orders
- Engineering changes and deviations
- Corrective action request/reports
- Statements by people in positions of authority
- Observations made by you personally

A caveat for verbal statements: it is best to back them up with documented evidence of the statement.

Fact or Inference?

Read the following paragraph and evaluate the statements below. Are they **factual** statements or are they **inferences***?* Circle **F** for *fact*, or circle **I** for *inference*.

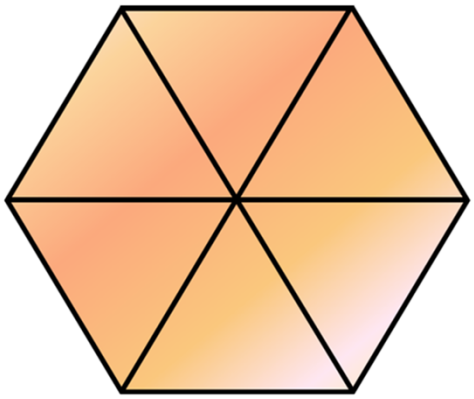
You are driving to work in nasty weather, and get caught in a traffic jam. Cars are backed up for miles, and the radio says there's an accident ahead, a three–car collision. You had noticed the roads were very slick. You're stuck, with no possible exit. At least you have some coffee to drink while you wait. You crawl along for an hour in first gear and wind up being late for your morning meeting. As you rush into the meeting, you suddenly remember you forgot to bring doughnuts!

Fact	Inferred	
F	I	1. The accident was caused by the slick roads.
F	I	2. You were assigned at the last meeting to bring doughnuts for today.
F	I	3. You had some coffee with you.
F	I	4. You heard about the accident on the radio.
F	I	5. Being stuck in the traffic jam was frustrating.
F	I	6. You were late for the morning staff meeting.
F	I	7. The collision involved three cars.
F	I	8. You didn't bring doughnuts.
F	I	9. You were in first gear for an hour.
F	I	10. The weather was nasty.
F	I	11. You were driving your car.
F	I	12. You were on the interstate in a place where you couldn't exit.

Perception of “Facts”

Same facts — different conclusions

- Two people will see the same physical evidence and draw two entirely different conclusions.
- Which is correct? Both may be.
- Look at this figure. What do you see?



Audit Bias

- **Semantic Equivalence**
  A common understanding (or lack of understanding) of the meaning of the words comprising a question or an answer.
- **Question Wording**
  The ordering or slanting of wording in a question can significantly bias the response to the question, as can non-verbal cues given by the auditor (un/consciously).
- **Halo/Horn Effect**
  The tendency to enhance the evaluation of all responses due to proper or especially good responses to earlier questions — or not.
- **Identification**
  A tendency to associate or perceive as a common attribute certain characteristics of another person or thing. This bias can markedly alter evaluation of responses to questions or even the questions asked.

Remember, your attitude is contagious and can infect both your behavior and the auditee's, for good or ill.

What are some other biases to watch out for?

What Do the Exercises Show?

- It is critically important to discuss audit findings with the person during the audit.
- Avoid misunderstandings and misinterpretation of facts.
- Make sure you are 'seeing' facts and not making inferences.
- Perform audits like you're a pilot instructor.
  - Make them talk you through what they're doing.
  - You talk them through what you're thinking!

When there is disagreement or you are uncertain about drawing a conclusion, do not be afraid to get a second opinion. Consult the audit lead, get the perspective of another auditor and/or consult resources back at your organization. It's better to leave an issue open than to make a hasty judgement that has to be withdrawn later.

Audit Notes

Keep record of:

- What was discussed/reviewed
- Who it was discussed/reviewed with
- When it was discussed/reviewed
- What the outcome was

Note Taking

- Skill you need to develop
- Develop a technique that works best for you
  - Consistent with your organization's audit process
- Suggestions:
  - Guidelist
  - Flowchart
  - Copy of procedure or contract
- Used to provide objective evidence
- Notes should be:
  - Legible
  - Concise
  - Retrievable for later reference

Generally, it is not recommended that you copy records, although there are times when the auditor may feel it's necessary. In all cases, be sure to note the information that will provide traceability: document number/revision, order number, serial number, etc.

Audit Notes Form

Form 8.2.2

Audit Review Trail

Page 1 of 1

Process/Area Audited: Design Process

Audit Reference #: 00-006

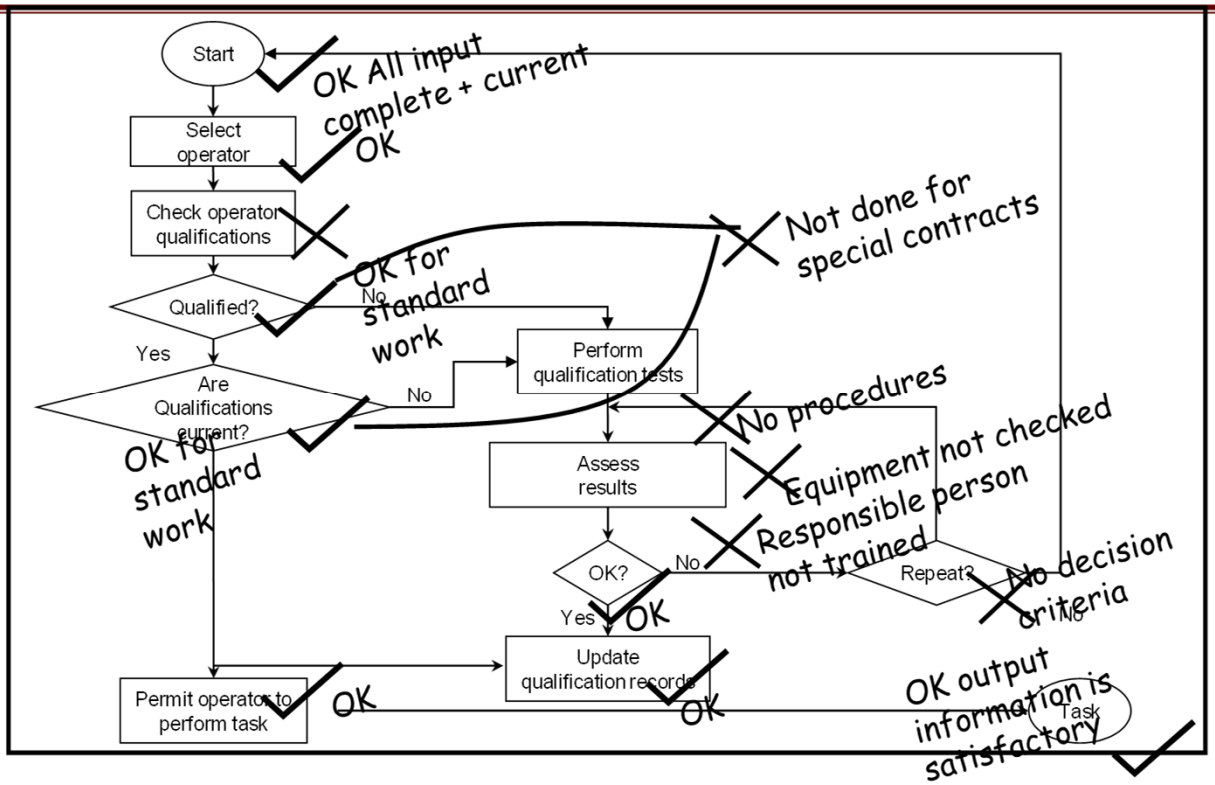
Auditor: I. M. Sharp

Date: 3/2/00

Item #	Review Trail and Details	
1	Interviewed Bob Jones, area supervisor. Jones explained process of reviewing contract drawing prep & proper approvals.	
2	Interviewed Michelle Martin, Engineering Aide. Martin explained drawing she was working on. Martin knows system and process. Referred to correct W.I.	
	Noted Production/Quality signatures same - Martin explained she just "knew" which programs required which signatures - not in the W.I. Asked 3 other aides & received same response.	N/C
3	Re-interviewed Bob Jones/ Asked about duties & responsibilities. → Follow-up	
	Examined company directives manual and draft ~~Oprng. Proc.~~ Manual.	
	Asked about program specific requirements. Jones said Prog. Mgr. attaches note to contract specifying any special requirements.	Obs?

Is this really good practice?

Notes on Flowchart



- Placing notes directly on a copy of a document is a good way to take notes.
- Put an "X" by anything that is an issue or requires more investigation.

Case Study Audits

Botta–Boom Interviews

(See second tab titled “Case Study Materials.”)

1. Read and evaluate audit interview cases 4–7.
   - Are there nonconformities?
   - What is the requirement not being fulfilled? (Refer to the Assessment tool provided in the third tab.)
   - What is your evidence?
2. Discuss your findings with your audit team.

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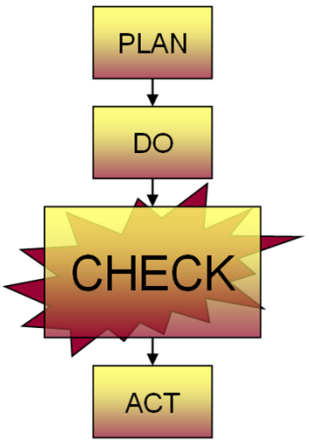
CHECK: Make a Comparison

"What Should Be" ? = "What Is"



Nonconformity: Definition

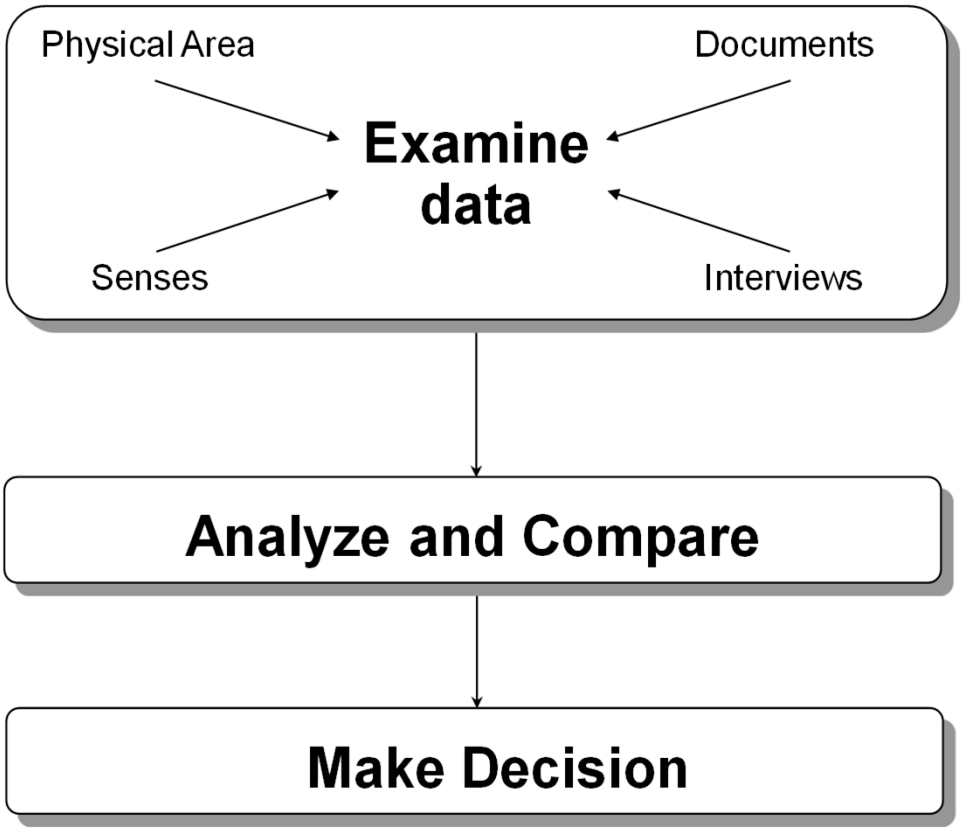
"Non–fulfillment of a requirement"

— ISO 9000:2015, 3.6.9

Specified requirements could come from:

1. Legal requirements (statutory, regulatory)
2. Customer contractual requirements
3. Management System Standards
4. Industry standards
5. Internal Management System policies and procedures

The NC Decision Process



Findings of Nonconformity must be based on Objective Evidence.

Remember the 3 Step Comparison Process. In Step 2, the auditor compares the QMS documentation to the actual practices to see if implementation has happened in all necessary areas and if processes are conforming with the requirements.

As the QMS matures, internal auditing should go beyond simply assessing conformance. In Step 3, performance audits are conducted which compare workplace practices to results. We want to see whether the QMS is effectively meeting goals for both customer satisfaction and internal efficiency and suitability. At this third level, those inside the organization may be better able to make this determination than an external auditor.

Making the Decision

- Conclusions are based on objective evidence you've gathered throughout your audit.
- You compare that objective evidence to the requirements to determine conformity (A = B?).
  - Your objective evidence must be factual and real.
  - If you don't have a requirement *and* objective evidence of it *not* being met, you don't have a nonconformance.
  - If you don't have a requirement *and* objective evidence of it being *met*, you don't have conformance.

Confirm nonconformance findings with the process owner during the audit!

Types of Issues

- Finding:
  - Result of evaluation of audit evidence against the criteria
- Finding of Nonconformity:
  - A requirement is not being met
  - There is verifiable objective evidence
- Observation: Not a nonconformity
  - Issue which is not technically a "nonconformity" but one that the auditor wants to point out to management
  - Observations are the only place for your opinion!

Give every finding or observation the "So what?" test.

Observations might be practices that are potentially risky (ineffective and/or inefficient), but where the auditor has no objective evidence of nonconformance. They can also be opportunities to improve upon the existing process and may be raised by the auditor or come from the auditee. Other terms for an Observation are Opportunity for Improvement (OFI) or Special Emphasis Item (SEI).

Adequacy is another consideration, i.e., is the requirement sufficiently implemented? For example, there may be a case where a requirement is met in one area, but not another. Or, the organization meets the bare minimum for a requirement, but it may not be enough to enable consistent conformance. This sort of situation could generate debate on whether it is a nonconformance or an observation.

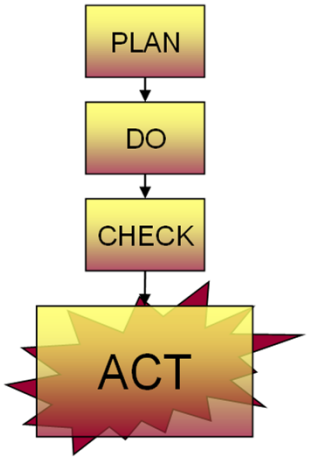
Ending the Audit — Closing Meeting

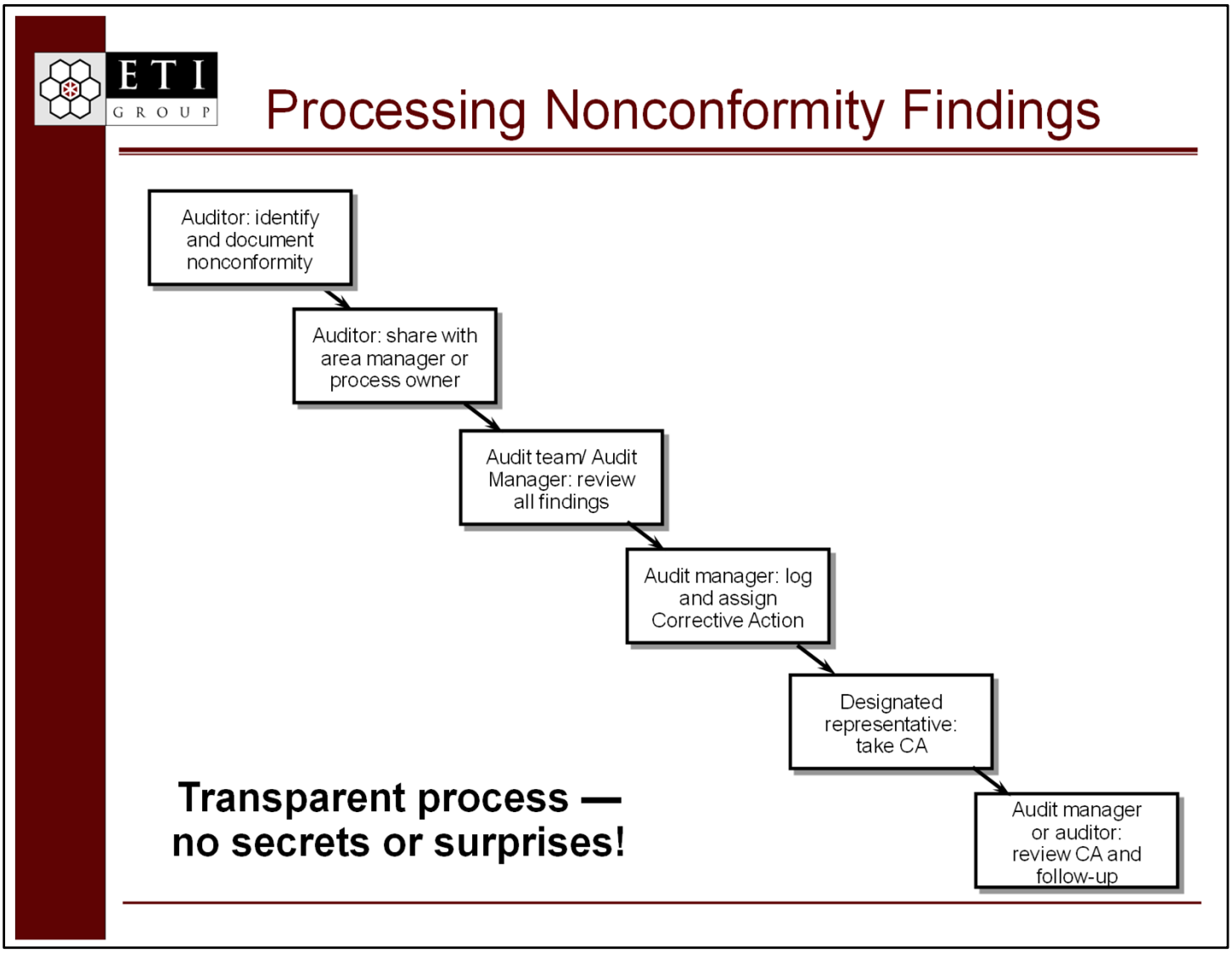
- Thank people for their hospitality and help.
- Confirm purpose and scope of audit.
- Identify key requirements documents used, including revision.
- Give positive observations.
- Discuss all findings or potential findings. (No surprises!)
- Discuss process for 'administering' findings.
- Ask whether any points need to be clarified.

- ✓ Present facts only
- ✓ Be objective
- ✓ Brief, clear and concise
- ✓ Avoid jargon

ACT: Take Action

"Close the Gaps"





Audit Conclusion: Outcome of an audit, after consideration of the audit objectives and all audit findings. *(ISO 9000:2015, 3.13.10)*

Audit Reporting Options

- Write up as Nonconformity ("Corrective Action Request")
  - Demands corrective action
- Some organizations use "major" and "minor" to designate the seriousness of the issue
  - Major: Lack of a system or system is totally ineffective
  - Minor: Weakness in some part of the system
  - Usually a subjective judgment that requires lot of experience!
- Write up as an Observation
  - Strongly recommends consideration, but does not demand action
  - Observations are an opportunity for Preventive/Improvement Actions
- Note in Audit Report to audit program manager
  - Suggests follow–up in a subsequent audit
- Forget it!
  - Not worth any further consideration or pursuit

Some organizations allow "on the spot" fixes for minor issues. Be careful with these cases! It is still important to track these fixes since multiple minor findings may aggregate to a major nonconformity.

Major issues are likely to result in the failure or limit the ability of the QMS to assure controlled processes and/or conforming products/services.

Minor issues are single failures or lapses in conformance which do not place the control of processes and/or conformance of products/services at risk.

AS9101 on Nonconformance

Rules for external AS9100 auditors:

- Each NCR shall contain only one nonconformity.
- The audit team shall:
  - Categorize NC's as "major" or "minor."
  - Identify the need for immediate containment.
  - Issue an NCR when a PEAR shows the process is not delivering the planned results and appropriate action is not being taken
- Recurrence of the same or similar NC during consecutive audits shall be considered a major NC against the corrective action process.
- Soft grading of NC's &/or identifying them as an observation or OFI benefits no one and risks no action being taken.

[Reference AS9101 — Quality Management Systems - Audit Requirements for Aviation, Space, and Defense Organizations , Rev. F: see sub-clause 4.2.2.5 in its entirety for full text of the requirements summarized on the slide.]

NCR = Nonconformance Report

NC = Nonconformity

OFI = Opportunity for Improvement

AS9101 also offers the following guidance regarding PEAR NCR's:

NOTE 2: The NCR may be issued against 9100-series standards clause 4.4.1.c and/or 4.4.1.g, if the nonconformity is related to the effective operation and control of the process.

NOTE 3: Nonconformities identified against 9100-series standards clauses 4.4.1.c and/or 4.4.1.g, resulting from multiple PEARs, may be combined into a single NCR.

[Reference paragraph 4.2.2.5 .1]

Model for Nonconformity Statement

- State the requirement
  - Cite reference (standard, customer requirement, QMS document, etc.)
  - Quote relevant portion of specific requirement
- State the nonconformity
  - Clearly and succinctly describe how the requirement was not met (intent, implementation, effectiveness)
  - Provide enough information so the process owner or manager has a good concept of the issue
- Provide the objective evidence
  - Facts only — concise but complete
  - Verifiable data — another person should be able to see the same thing

Typically just one requirement is cited per nonconformity. Conversely, it is possible to have multiple findings related to one requirement.

Nonconformity Statement Example

- The calibration procedure OP-MET-001 Rev. B, paragraph 7.5, states that devices used to measure product to make quality decisions must be calibrated.
- Several uncalibrated calipers were being used during inspection operations; serial numbers were 0547, 0589, 0595.
- This is a nonconformity; practice does not comply with the procedure.

Writing Tips

- Use local terminology (use their words, not the Standard's)
- Make information readily retrievable for future reference
- Make it helpful for the person who will have to correct the problem
- Finding statements should "stand alone"
- Finding statements should be:
  - Factual
  - Objective
  - Correct and complete
  - Traceable
  - Concise

Typically, functional titles rather than individuals' names, would be used on a finding statement.

Defining the Problem

- A Finding of Nonconformity Statement initiates problem definition — the first and most critical step to taking effective corrective action on the problem.

PROBLEM STATEMENT

WHAT… is the requirement? is missing? did you find?

WHO… is generating the problem?
is affected by the problem?
No Names

WHERE… is it happening?

WHEN… did it occur?

HOW… serious is it? (Solve safety issues immediately)

The person assigned to take corrective action should be responsible for fully answering the problem statement questions above.

Reviewing Nonconformity Statements

- Who performed the audit = reviewer
- When audit was performed = date
- Where the Audit occurred = location, dept., etc.
- What was examined = process, project numbers, records, etc.
- What was discovered = nonconformity
- Why a finding is a nonconformity = what requirement is not being fulfilled
- What documentation was affected = standard, QA Manual, procedures, WI

Nonconformity Statement

As a class:

- Review Nonconformities from the Case Study (cases 1–7) and select one to write–up.
- Write up the Nonconformity using the Finding of Nonconformity form (blank forms provided at end of second tab titled “Case Study Materials”). Make sure to include:
  - Requirement
  - Nonconformity
  - Objective evidence

Nonconformity Statements

Botta–Boom Interviews

- Make assignments for writing up nonconformities within your Team (from cases 1 through 7). Each person should use *different* nonconformities from the case study.
- Each team member write two (2) statements using the Finding of Nonconformity form (blank form provided end of second tab).
- Share and critique the Finding of Nonconformity forms with the Audit Team.

Finishing the Audit

- Perform the following actions:
- Final Review
  - Work sheets
  - Notes
    - Complete
    - Clear
    - Traceable
  - Follow up on any outstanding issues
- Organize
  - Work papers
  - Copies
  - Thoughts
- Complete
  - Audit Finding Statements
  - Summary Report
- Attach
  - Supporting work papers
  - Objective evidence

Evidence should be listed on Finding Statements or in Audit Notes; copy only if absolutely necessary

Audit Summary Report

Audit Date:

Purpose & Scope:

Process(es) Audited:

Names (Auditor(s), Responsible Mgr., Interviewees):

General Observations:

- Overall conformance
- Employee knowledge of system
- Positive observations and impressions
- Comments on audit frequency

Nonconformity Issues:

- Overall summary (e.g., areas where most issues are, etc.)
- Attach or reference Finding of N/C Statements

The Audit Report can also be a place to highlight solutions implemented as a result of previous audits, as well as to bring attention to Corrective Actions that are still open from previous audits.

Consider how Internal Audit results will be communicated throughout the organization.

Report Writing Tips

- Write in plain English.
- Avoid acronyms and jargon.
- Write with user in mind.
- Be positive, concise and value-adding.
- Make the connection between nonconformity, risks and monetary costs.
- Review and edit carefully.

Audit Summary Report Example

ABC Company
Audit
Summary Report

Audit Date: January 5, 20XX Audit Number: 01–001

Purpose & Scope: This review examined the Engineering Department to establish its compliance with the Design Control requirements of ISO 9001:2015 and ABC Design Procedure, SOP-003 Rev. C .

Area(s) Audited: Engineering and Marketing
Responsible Mgr: Juan Lopez, VP Marketing & Engineering
Interviewees: Juan Lopez; Carl Tobin, Design Engr; Zhào Lì, Marketing Mgr.
Auditor: Jane Smythe

General Observations:

1. Overall Compliance: In general, the Engineering and Marketing groups are complying with the ABC Company practices as they are written. There were some issues involved in whether the Company practices have fully met the intent of the ISO 9001 requirements. These issues are addressed in the Nonconformity Findings.

2. Employee Knowledge of Quality System: All employees interviewed were well versed in the requirements of our quality system. They knew what was required and where to locate the information. New engineers go through a clearly defined indoctrination program that has helped to ensure good knowledge of the quality system.

3. Positive Observations & Impressions: See notes above.

4. Comments on Review Frequency: The Design Control process currently is audited every quarter. Based on the results observed during this audit and the prior two audits, I recommend the audit cycle be changed to every six months.

Nonconformity Issues:

1. Overall Comments: The major issue encountered regarded the ABC Company practice of not retaining records of the review, risk assessment and authorization of design changes prior to production release (i.e. “Rev A” drawings). This practice conflicts with the ISO 9001 requirement that documented information regarding these actions is retained.

2. There were 3 Nonconformity Findings issued during the audit, which are attached to this report.

Human Relations in Audit Reporting

- Problems
  - ✓ Deficiencies seen as criticism.
  - ✓ Recommendations seen as invasion of responsibilities.
  - ✓ Grudging cooperation (both ways).
- How to reduce problems
  - ✓ Clearly explain reasons for audits to all involved
  - ✓ Avoid an atmosphere of blame and policing
  - ✓ Be improvement oriented in all audit activities.
  - ✓ Achieve balance in reporting — state both strengths and weaknesses
  - ✓ Depersonalize findings — no names unless required
  - ✓ Review conclusions/issues with people being audited
  - ✓ Offer help with corrective actions, but don't take over.

Noting best practices is a great way to reinforce desired behaviors and maintain a good working relationship with the audited area. Praise given where due will feel authentic but beware of just trying to come up with something "nice" to say, as it may sound insincere.

Fundamental Belief

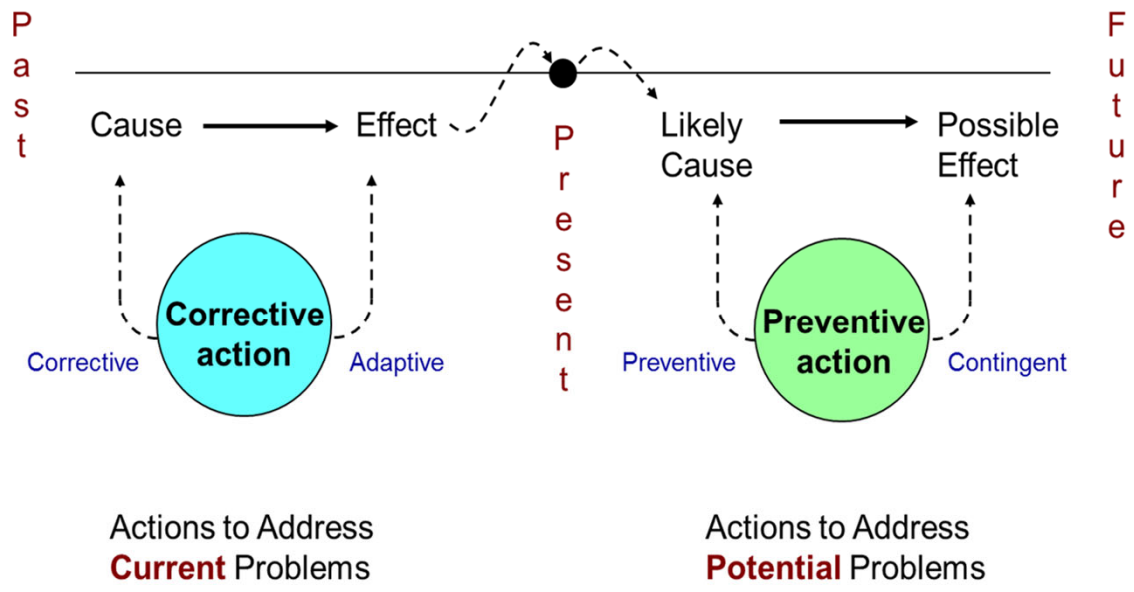
- Auditors can be teachers of improvement.
- Auditors can provide recommendations to assist with Corrective Actions.
- When auditors are credible, they are more likely to be perceived as adding value.
- When the connection to value is made, nonconformities are more likely to be addressed effectively and promptly.

Case Study Audits

Botta–Boom Interviews (See second tab titled “Case Study Materials.”)

1. Read and evaluate audit interview Cases 8, 9 and 10. Identify any nonconformities.
2. Comment on the interviews. Where should the auditor have “pulled the thread”?
3. Discuss the cases in your audit team and the “threads.”

Understanding Corrective Action



It is critical for organizations to understand the difference between preventing recurrence vs. occurrence!

Source of Model: Kepner-Tregoe, Inc.

Some Quality Management Systems models use the terms "Corrective Action" and "Preventive Action" separately. Others use "Corrective Action" to cover both aspects of preventing recurrence or occurrence. Rather than get caught up in semantics, remember that the point is to solve problems according to risk. The two types are those actions taken to eliminate the risk of a problem happening *again* and actions taken to eliminate the risk of a *potential* problem ever occurring in the first place.

Two-Stage Corrective Action

Stage 1

- Take positive action now to prevent problem from getting "worse."
- Address:
  1. Immediate: Action taken to stop further problems
  2. Remedial: Looking back to assess damage done, whether parts need to be reworked, recalls, etc.
  3. Interim: Short term, temporary fixes until permanent fix can be implemented

Stage 2

- Evaluate the "root cause(s)" of the nonconformity to determine proper longer term measures.
- Address:
  1. Root Cause: What was the systemic, true cause of this problem
  2. Permanent: System changes made to prevent future recurrence

In the ISO 9001-based Standards, Stage 1 is synonymous with "Correction" and Stage 2 with "Corrective Action."

Issuing Corrective Actions

- If an audit finds minor or major nonconformances, corrective actions should be issued.
- A few tips:
  - Make sure the nonconformance and its wording is exactly what you told them it would be in the closing meeting
  - Provide a due date for a corrective action response
  - Ask for objective evidence of solution(s)

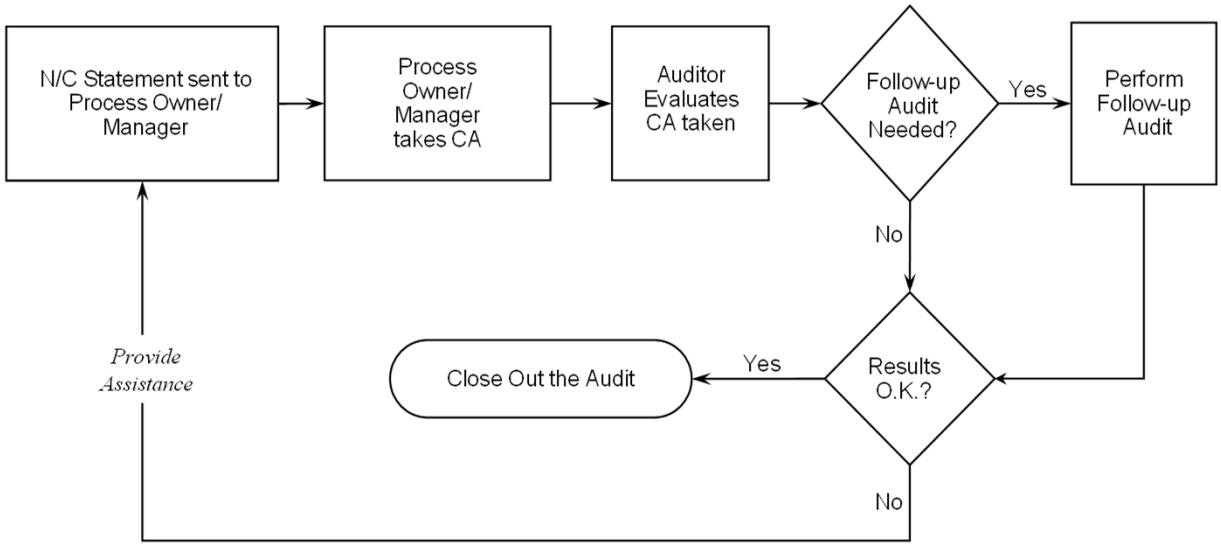
Correction Options

Intent *Compare Procedure to Standard*	If Procedure ≠ Standard: 1. Change the Procedure 2. Determine if Nonapplicable
Implementation *Compare Procedures to Practices*	If Procedure ≠ Practice: 1. Change the Practice or 2. Change the Procedure
Effectiveness *Compare Practices to Results*	If Practice ≠ Desired Results: 1. Investigate why 2. Check the Goal

Action Plans

- The development of action plans may be a collaborative exercise between auditor and auditee
- Remember when creating an action plan:
  - It is critical that the solution have a well defined root cause (The 5 Why's is a helpful technique)
  - The action plan should address and document the solution for each of the CA steps
  - Responsible persons should be identified
  - Due dates should be identified
  - Verification steps as well as evidence required for verification of effectiveness should be defined and documented (encourage the use of monitoring &/or measurement).
  - Evidence of verification activities should be available for review upon your follow-up

Post-Audit Follow-up Activities



Should track and monitor status of follow–up activities

- Ensure Corrective Action (CA) is being taken
- Manager/Process Owner completes CA section of Finding Statement
- Evaluate effectiveness of CA in correcting problem observed in original audit
- Perform follow–up audits (only as needed)

Maintain records of follow–up activities performed

Report on status of audit activities to Management

Following Up

- Follow up based on the plan for action as defined by the corrective action.
- Require objective evidence of effectiveness of the solution before signing off on the issue, and do not accept the solution unless you are comfortable with the steps taken.
- Review the issue thoroughly with the auditee.
- During future audits &/or process performance reviews, carefully review that the solution is still implemented and working well.
- Advise as needed to encourage thorough solutions.

Evaluating Corrective Action

- Use the Corrective Action Checklist on next page. Look for:
- "Symptom" restated as a problem
  - Do they really understand what you saw?
  - Is the full scope of the problem recognized?
- Action(s) to correct symptoms positive
  - Did they fix the immediate problem?
- Root cause established
  - Have they spent the time to understand & identify what it takes to prevent recurrence?
- Plan to correct root cause established
  - Is there a written plan with specific tasks?
  - Are individuals assigned each task?
  - Are realistic dates identified?
  - Can the plan be audited?
  - Has training been considered (as needed)?

Corrective Action Evaluation Checklist

Finding Being Evaluated	**Question 1:** Immediate problem corrected?	**Question 2:** Other occurrences searched for?	**Question 3:** Interim measures needed and described?	**Question 4:** Reasonable root cause established?	**Question 5:** Permanent correction measures described?

Corrective Action Review

Corrective Action responses from some of the Findings of Nonconformity in the Botta–Boom case study are provided.

Assuming that you were the lead auditor:

1. Evaluate the reply received.
2. Would you accept the reply as adequate?
3. Why or why not? Give details.
4. What action by the auditee is necessary to close out the finding?

12 Golden Rules of Reviews

1. Never challenge a person.
2. Always present a true and fair view.
3. Go fact finding, not fault finding.
4. Use systematic methods.
5. Never lose sight of the product or service.
6. Find out the interviewee's interpretation — not yours.
7. Always be properly prepared.
8. Always perform audits with a view toward helping the person.
9. Always define the audit objectives.
10. Communicate effectively with the interviewee.
11. Ensure process owner/manager finds and addresses the real cause of problems found.
12. Always follow up corrective action requests.

Source: *Management Audits*, 3rd Edition by Allan J. Sayle

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Maintaining a Successful Audit Program

ISO 19011:2011 Management of Audit Programs

- Organization
- Standards to be Used
- Staff Qualification
- Auditor Selection
- Performance Evaluation
- Audit Program Improvement
- Code of Ethics
- Operational Factors
  - Resources
  - Planning
  - Reporting
  - Corrective Action Follow–up
  - Confidentiality

This document provides general guidance for effectively implementing and conducting quality management system audit programs.

Implementing an Internal Audit Program

- Understand requirements (Standard, customer, regulatory)
- Write internal audit procedure
- Select and train auditors
- Prepare and publish schedule
- Conduct audits
- Report results
- Track Corrective Actions
- Study results at Management Review
- Improve the effectiveness of the Internal Audit Process

Roles & Responsibilities

- Audit Manager/Administrator:
  - Create and publish audit schedule
  - Assign auditors (ensure trained)
  - Review Findings of Nonconformity and reports for overall consistency
  - Track corrective actions
  - Report to management review
- Audit Team Leader:
  - Coordinate and participate in audits
  - Prepare plan for an audit
  - Conduct opening and closing meetings
  - Review all Findings of Nonconformity
  - Final arbitrator on decisions
  - Report audit findings to area management
  - Follow up on corrective actions
- Auditor:
  - Prepare for assigned audits
  - Assist with or perform audits
  - Conduct follow–up audits

Internal Audits
Team Leader = Auditor

Auditor: Person who conducts an audit. *(ISO 9000:2015, 3.13.15)*

Audit Team: One or more persons conducting an audit, supported if needed by technical experts. *(ISO 9000:2015, 3.13.14)*

Audit Schedule Example – 1

Element	Title/Content		1st Quarter		2nd Quarter		3rd Quarter		4th Quarter	
			Plan	Done	Plan	Done	Plan	Done	Plan	Done
7.5	Document Control	1	P	1/11			SA	7/22		
7.5	Records Control	1			P	4/12			SA	11/8
5	Leadership	1	P	3/8						
7.1.5	Monitoring & Measuring Resources	2			P	3/15			P	12/6
8.2	Requirements for Products	1							P	10/13
8.4	Purchasing	1			SA	5/18			P	10/12
8.5a	Production Planning	1	P	1/14			SA	7/17		
8.5b	Mold Preparation	2			P	4/14			P	10/13
8.5c	Heat Preparation & Pour	2	P	2/15			P	7/19		
8.5d	Shake Out	1							P	10/14
8.5e	Shake Out, Cleaning	1			P	6/14			SA	10/24
8.5f	Outsourced Heat Treating	1	SA	1/18			P	7/20		
8.5g	Outsourced Machining	1					P	8/16		
8.5h	Outsourced NDT	1			P	4/18				
8.5i	Shipping	1					P	9/19		
8.7	Control of Nonconforming Product	2	P				P			
9.1.2	Customer Satisfaction	2	P	2/8			P	7/12		
9.2	Internal Auditing	2			P	5/16			P(SD)	
9.3	Management Review	2	P	1/20	SA	4/13	P(SD)		SA	10/11
10.2	Nonconformity & Corrective Action	2	SA	1/13	P	6/7			P	10/18

P = Planned Audits, based upon importance(# of Audits/Year)

SA = Status Add to Plan, based upon performance SD = Status Delete from Plan, based upon performance

Audit Program: Set of one or more audits planned for a specific time frame and directed towards a specific purpose. *(ISO 9000:2015, 3.13.4)*

Audit Schedule Example – 2

Doc#123 Rev 10/05/15	XYZ Co. PROCESSES & THEIR RELATIONSHIP TO ISO 9001:2015											
X = Directly Related L = Linked Process	Sales Order Processing	Purchasing Processes	Production, Material Handling & Inspection/Test Processes	Design & Development	Control of Documents and Control of Records Processes	Internal Audit Process	Management Review Process, Provision of Resources and Work Environment	Human Resources Processes	Improvement Processes (CAPAs & IPs)	Control of Non-Conforming Product (NCP Process)	Calibration/Verification Process	Infrastructure- IT & Preventive Maintenance Processes
ISO 9001:2015 Clause												
5	**Leadership:**											
5.1	Leadership & Commitment	L	L	L	L	L	L	X	L	L	L	L	L
5.2	Policy	L	L	L		L	L	X	L	L	L	L	L
5.3	Org roles, responsibilities and authorities	L	L	L		L	L	X	X	L	L	L	L
	...												
7	**Support:**												
7.1	Resources	L	L	L	L	L		X				L	X
7.2	Competence	L	L	L	L	L	L		X	L	L	L	L
7.3	Awareness	L	L	L	L	L	L		X	L	L	L	L
7.4	Communication							X	L				L
7.5	Documented Information				L	X							L
8	**Operation:**												
8.1	Operational planning and control	X		X									
8.2	Requirements for products and services	X	L	L	L			L			L	L	L
8.3	Design and Development	L	L	L	X	L					L		
8.4	Control of extn'ly provided proc., prod., serv.	L	X	L	L			L				L	L
8.5	Production and service Provision	L	L	X	L			L			L	L	L
8.6	Release of products and services			X							L	L	
8.7	Control of nonconforming outputs	L	L	L	L						X	L	
9	**Performance evaluation:**												
9.1	Mon., meas., analysis & eval						L	X		L	L		
9.2	Internal Audit						X	L		L			
9.3	Management review							X		L			
10	**Improvement:**												
10.1	General							X		L			
10.2	Nonconformity and corrective action	L								X	X		
10.3	Continual improvement							X		X			

Audit Schedule Example – 2

(XYZ Co. Logo) Doc# 345 Rev 04/05/09	20XX INTERNAL AUDITS SCHEDULE											
PROCESS/AREA	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**
Sales Order Processing	X							X				
Purchasing	X						X					
Production, Material Handling & Inspection/Test		X			X	X		X			X	
Control of Documents & Control of Records			X			X			X			X
Internal Audit Process			X									
Management Review, Provision of Resources & Work Environment	X						X					
Human Resources Processes		X						X				
Improvement Processes (CAPA)				X						X		
Control of Non-Conforming Product (NCP Process)			X						X			
Calibration/Verification Process				X					X			
Infrastructure - IT & Preventive Maintenance					X					X		

Approved by: _____ **Date:** _____

Audit Schedule Example – 2

	Internal Audit Assignments for Q1 20XX				
Month	**QMS Process(es)**	**Area**	**Lead Auditor**	**Auditor**	**Area Rep.(s)**
Jan.	Sales Order Processing	Inside Sales	Robert Thallium	Betty Carbon	Carlos Nitrogen
Jan.	Purchasing Processes	Purchasing	Vila Aluminum	Shelly Silicon	David Phosphorus
Feb.	Production, Material Handling & Inspection/Test Processes	Painting Prep	Milo Tellurium	Lars Chlorine	Tony Argon
Feb.	Production, Material Handling & Inspection/Test Processes	Spray Booth	Jane Gallium	Ravi Germanium	Patsy Arsenic
Mar.	Control of Documents & Control of Records Processes	Final Assembly	Robert Thallium	Marlene Bromine	Pavel Krypton
Mar.	Control of Documents & Control of Records Processes	Process Engineering	Rebecca Indium	Walter Tin	Guenther Antimony
Jan.	Management Review Process	Management Team	Milo Tellurium	Sue Iodine	Xia Xenon
Feb.	Human Resources Processes	Training	Rebecca Indium	Herminio Lead	Kathryn Bismuth

Scheduling Discussion

Discussion Questions

- What is your organization's current method for linking QMS processes to the clauses of the Standard?
- How is your audit schedule organized to cover all the clauses of the Standard and your QMS processes?
- What are some ways your audit schedule could be improved? (make a sketch of what an improved schedule would look like)

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Who Audits Whom

First Party

An audit carried out by a organization on its own system for the purpose of providing assurance to Management that the system is effectively achieving planned objectives.

Second Party

An audit carried out by one organization on another with whom they have a contract or an interest. The purpose is to provide assurance to the purchasing organization that the supplier's system is capable of sustained delivery of products and services that will meet requirements.

Examples: Organization auditing Suppliers

Customers auditing Organization

Third Party

Audits carried out by independent agencies to provide assurance on the effectiveness of the organization's system.

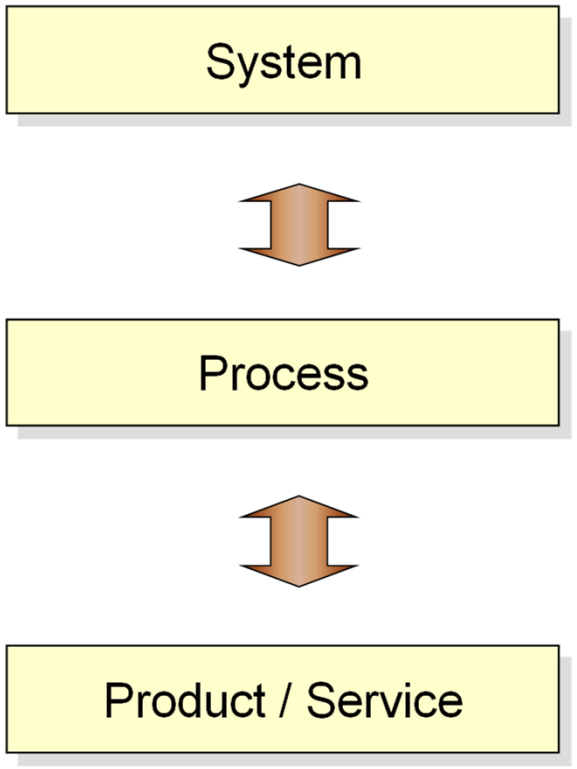
Examples: Registrars

Regulatory agencies

Audit Client: Organization or person requesting an audit *(ISO 9000:2015, 3.13.11)*

Auditee: Organization being audited *(ISO 9000:2015, 3.13.12)*

Audit Level



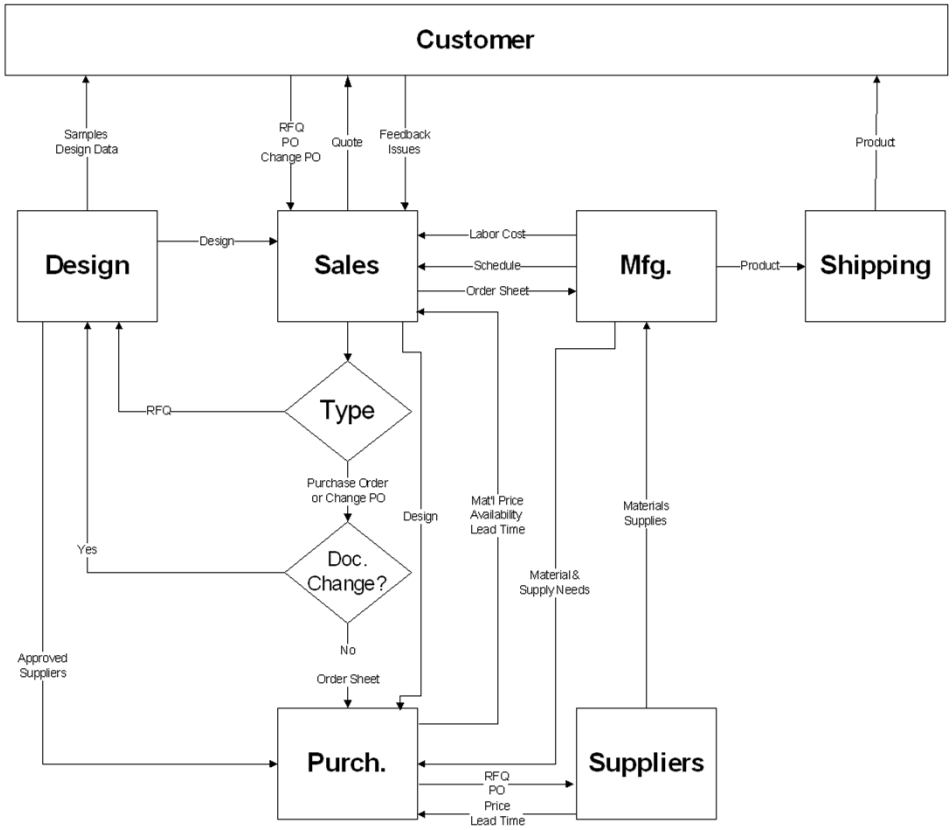
- Is the system effective?
- Do core processes work together?
- Do we manage the system and its relationships?

- Is this process effective?
- Are inputs, outputs and tasks clear?
- Is the process correct?
- Do people follow the process?

- Does the product/service meet its technical requirements?
- Do we have the proper records of having followed the processes?

Should complement each other

Systems Audits



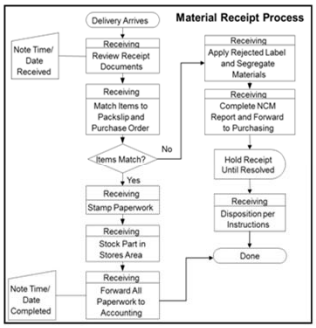
Management Reviews of the Quality System can function as systems audits.

Process Audits

Purpose

- Establish conformance to procedures and special requirements.
- Determine effectiveness of process and resulting output.

The Process



- Select process to review.
- Collect all documentation involved.
  - Procedures, work instructions
  - Performance measurement instructions
  - Special requirements (ESD, safety, etc.)
- Determine that inputs and outputs are correct and timely.
- Observe whether resources are adequate.
- Carefully review process records and performance data.
- Ask questions and follow trails.
- Document findings.

Product Audits

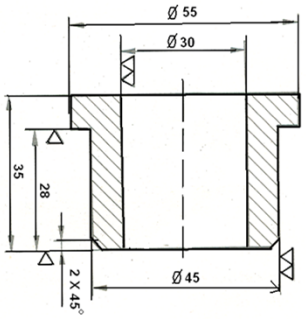
Purpose

- Ensure quality system helps to assure product integrity.
- Identify hardware status.
- Establish conformance with contract requirements.
- Identify any negative factors.

The Process

Start at the product and work back through the quality system.

- Select hardware to review.
- Collect all paperwork involved.
  - Drawings
  - Specifications
  - Regulations
  - Work Instructions
  - Plans
  - Test Records



- Inspect hardware attributes.
- Carefully review total manufacture paperwork and performance data.
- Ask questions and follow trails.
- Document findings.

This approach applies just as easily to an occurrence of service delivery. Think of following a single maintenance, repair, installation order , etc. through the entire process.

Audit Directions

	Advantages	Disadvantages
Trace Forward (most common method)	• Shows logic of system • Easy for training • Aids preplanning of arrival times at tasks • Front–end deficiencies found sooner	• Logical flow breaks if people are missing • Not as flexible • Requires more coordination for partial reviews • System problem effects not as apparent • Root cause discovery not as easy
Trace Back	• More suitable for partial reviews since can start anywhere • Easy for training • Aids preplanning of arrival times at tasks • Output from prior process seen before review of that prior process • Root cause discovery easier — generally located in direction of travel	• Logical flow is broken • Not as flexible • Entire process must be working before start • Front–end requirements not seen until end of review • Can end up not having time to spend on front end activities
Random Sequence	• Very flexible; minimizes disruptions • Review plan not upset if people missing • Provides broad picture quickly • Good for surveys • Good for partial reviews	• Requires more experienced reviewers • Can mean avid note taking • Can miss system problems (connections) • Root cause discovery is difficult • Requires more coordination between different reviews

Tracking Audit Results

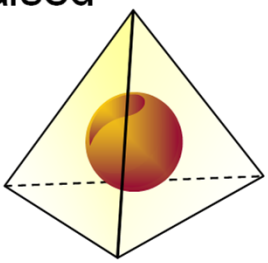
- Define what “undue delay” means in your system.
- Develop a method for tracking and following up on internal audit results.
- Analyze responsiveness to audits and report to management.
- Establish an escalation policy!

Example Database

Audit Number	N/C Clause Number	Audit Date	Responsible Manager	N/C Response Due	Date of Response	Follow-up Date	Date Verified & Closed
01-001	8.3	1/3/20XX	D. Schulte	1/17/20XX	1/22/20XX	1/31/20XX	2/1/20XX
01-002	7.3	1/5/20XX	R. Nader	1/20/20XX	1/16/20XX	1/25/20XX	1/26/20XX
01-003	7.6	1/11/20XX	G. Kuntz	1/26/20XX	1/24/20XX	3/1/20XX	
01-004	7.6	1/12/20XX	G. Marshall	1/27/20XX	1/29/20XX	2/13/20XX	

Management Review

- Audit Manager must report on audit activities:
  - Successes
  - Major problems
  - Corrective Actions
  - Follow–up required
  - Tightened controls
  - Unusual considerations
- Management must take action on issues raised



Inputs

- Status of actions from prior reviews
- Changes in external and internal issues relevant to the QMS
- Information on performance and effectiveness of QMS, including trends in:
  - Customer satisfaction and feedback from interested parties
  - Extent to which Q Objectives have been met
  - Process performance & product/service conformity
  - Nonconformities and corrective actions
  - Monitoring and measurement results
  - Audit results
  - Performance of external providers
  - On-time delivery performance [AS9100]
- Adequacy of resources
- Effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement

Outputs

- Decisions & actions related to:
  - Opportunities for improvement
  - Any need for changes to the QMS
  - Resource needs
  - Risks identified [AS9100]

Audit Performance Measures

Measurement	Goal
Auditee evaluation of effectiveness of internal audit process	≥90% of questions are rated 4 or above from surveys returned
Auditor evaluation of effectiveness of internal audit process	≥90% of questions are rated 4 or above from surveys returned
Nonconformity Findings from external assessors (quantity & minor vs. major will be recorded)	No new nonconformities found during external assessment
Corrective Actions that are not resolved before next external audit	All CA's opened from prior assessment are closed before next external audit
# of Repeat Nonconformities from last audit (external or internal)	No repeat discrepancies identified

The Guideline document *ISO 9004:2009 Managing for the sustained success of an organization — A quality management approach* contains an excellent Self-Assessment tool that uses a maturity model to identify strengths and weaknesses of a QMS and identify opportunities for improvement and innovation.

Audit Process Performance Measures

Auditee Evaluation of Internal Quality Audit

As someone who recently participated in an audit, we'd appreciate your feedback on how we might improve our audit program. Please answer the following questions:

Date:	Area Audited:	Respondent(s):

		Strongly Disagree		Neutral		Strongly Agree
	Scheduling:					
1.	Audit schedule was arranged with enough notice.	1	2	3	4	5
2.	Time was used efficiently during the audit.	1	2	3	4	5
	Audit Purpose & Scope:					
3.	The objectives and extent of the audit were made clear before the interviews began.	1	2	3	4	5
	Auditor(s):					
4.	The auditor(s) seemed prepared for the audit topic(s).	1	2	3	4	5
5.	The auditor(s) were professional and courteous.	1	2	3	4	5
6.	I felt comfortable in talking with the auditor(s).	1	2	3	4	5
	Audit Findings:					
7.	The auditor(s) made it clear when a nonconformity was found during the audit.	1	2	3	4	5
8.	The auditor(s) answered my questions about the audit results and next steps before leaving the area.	1	2	3	4	5
9.	The corrective action request provided enough information to enable me to investigate and correct the nonconformity findings.	1	2	3	4	5

Please share any questions, concerns and ideas you have for improving our Internal Auditing process. Your feedback will be helpful!

Audit Process Performance Measures

Auditor Evaluation of Internal Quality Audit

As someone who recently conducted an audit, we'd appreciate your feedback on how we might improve our audit program. Please answer the following questions:

Date:	Area Audited:	Respondent(s):

	Scheduling:	Strongly Disagree		Neutral		Strongly Agree
1.	The audit schedule was easily arranged.	1	2	3	4	5
2.	I had sufficient time to prepare for the audit.	1	2	3	4	5
3.	I had sufficient time to conduct and the audit and review findings with the area management..	1	2	3	4	5
4.	I had sufficient time complete my reporting on the audit.	1	2	3	4	5
	Audit Purpose & Scope:					
5.	The objectives and extent of the audit were made clear to me upon the audit assignment.	1	2	3	4	5
	Guidelist:					
6.	I found the guidelist helpful and easy to follow.	1	2	3	4	5
7.	The number of requirements was appropriate for the time allotted.	1	2	3	4	5
8.	The guidelist was helpful in choosing appropriate samples to assess each requirement.	1	2	3	4	5
	Audit Area Participation:					
9.	There was a contact person designated to help with the audit.	1	2	3	4	5
10.	Area personnel were aware of the audit schedule.	1	2	3	4	5
11.	Selected area personnel participated fully in the audit interviews.	1	2	3	4	5

Please share any questions, concerns and ideas you have for improving our Internal Auditing process. Your feedback will be helpful!

Successful Audit Programs

Essential ingredients:

- An uncompromising emphasis on conclusions based on facts
- Auditors who provide a service that gives system assurance and adds value
- Audits that are used as a chance to identify improvement opportunities
- A sensitivity to human aspects of reviewing performance
- Auditors who are competent, respected, valued
- Management buy-in with active use of information

Communication

To Be Successful

Everyone in organization should understand:

- What the audit process involves
- Expected benefits of audits
- How audits can evaluate and improve internal links

Audit Program Assessment

Discussion Questions

- What is looked at during the Management Review of your organization's Internal Audit Program?
- What are some actions that have resulted from this review?
- How is the effectiveness of your organization's Internal Audit Program measured?
- What are some ideas for improving your organization's Internal Audit Program?

Summary

Things to Remember

- Internal auditing is an “open book” test. No surprises.
- Audit the process, not the people.
- Auditors need to know the requirements.
- You can’t have a nonconformity (or conformity) unless you first have:
  - A requirement
  - Objective evidence which is factual and verifiable.
- Audit broadly, looking for conformance rather than narrowly looking for nonconformance.
- Make sure you have factual evidence and that you accurately interpret those facts. Test market your thoughts and conclusions.
- State problems concisely if you want them to be solved promptly and effectively.

Key Lessons

You now have a basic understanding of audit practices. Convert this to true knowledge through practice, practice and more practice!

Please take a few minutes to think about and note some key things you learned in this workshop.

What seemed most important to you?

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Appendices

Audit Guidelist Excerpt

Listening Techniques

Audit Guidelist Excerpt

INTERNAL AUDIT WORKSHEET & REPORT

This form is to be completed per Procedure# XYZ, Internal Audits

Audit#:		**Date(s):**	
Areas/Processes Audited (Scope):	Control of Non-conforming Product (NCP) Process		
Purpose:	This audit was conducted to verify compliance of the areas/processes audited with applicable sections of the ISO 9001:2015 standard, with customer and regulatory requirements, and with XYZ Company's Quality Manual and related internal procedures.		
Auditor(s):			
Personnel Interviewed:			

Documents Reviewed

Document#	Document Title	Revision Level

Area of Focus

See the XYZ Co. Processes & their Relationship to ISO 9001:2015 document (Doc#123)

Related Section of ISO 9001:2015	Requirements	Document References	Comments (including records reviewed and any resulting CAPAs and Observations/Improvement Opportunities):
8.7	If non-conforming product is reworked or repaired, is there evidence that it was inspected or tested to ensure the rework or repair was successful?		
8.7	If customer &/or regulatory approval of the disposition was required, is there a record of the approval?		
8.7	Review three or four instances of non-conforming product and complete the table below. Look for evidence that the production processes are controlled as described above.		

Customer Name and Product	NCP# (If applicable)	Date Found Non-conforming	Disposition Determined, Approved By & Date	Disposition Completed by	If Rework/ Repair, Re-inspected?	If required, Cust./Reg. Approval Obtained?	Date Closed/ Completed	Comments

Audit Guidelist Excerpt continued

Linked Processes See the XYZ Co. Processes & their Relationship to ISO 9001:2015 document (Doc#123)	
Requirement to Verify	**Comments (including records reviewed and any resulting CAPAs and Observations/Improvement Opportunities):**
Are the processes audited adequately described in the Quality Manual (Doc# XXX)?	
Were documents reviewed during the audit under document control? (Ensure documents are available for use where needed, that they are of the correct revision, etc.)	
Are records maintained as required? (Ensure records are available for review, that they are legible, identifiable, etc.)?	
Are employees competent to perform the tasks in their area of responsibility? Are they aware of their responsibilities and authority? (Competence may be based on education, training, skills and/or experience)	

Listening Techniques

This sheet provides some tips and techniques you can use to make yourself a more effective listener — a key skill to develop in becoming a good auditor. In fact, as mentioned in the course material, auditors must have very good listening skills. The objective of an audit is to **get the interviewee talking, not the interviewer!** Practice these techniques for effective listening and you will find you get better and more complete information during your interviews.

TYPE	BASIC IDEA	PURPOSE	EXAMPLES
NEUTRAL	Use noncommittal words. Don't agree or disagree with person.	1. Convey ideas of interest. 2. Keep person talking.	1. I see. 2. Uh-huh. 3. That's very interesting. 4. I understand.
EXPLORATORY	Respond with Who? What? Where? When? Why? type questions	1. Gather additional facts. 2. Help them explore all sides of a problem.	1. Who was near the machine at the time of the accident? 2. What do you feel the real problem is?
RESTATEMENT	Restate all or part of person's last sentence, or basic idea.	1. Show them you are listening and understand what they are saying. 2. Encourage them to talk.	1. If I understand, your idea is… 2. This is your decision and the reasons are…
REFLECTIVE	Similar to restatement, but you reflect the feeling they have expressed.	1. Show you understand how they feel about what they are saying. 2. Encourage them to talk and explore their problem.	1. You feel that… 2. It was a shocking thing as you saw it. 3. You felt you didn't get a fair shake.
SUMMARIZING	Add up the ideas and/or feelings; and restate and/or reflect.	1. Serves as a check point for further discussion. 2. Brings problem into perspective.	1. These are the key ideas you have expressed. 2. If I understand how you feel about the situation…

TAB 2
Case Study Material

Botta-Boom, Inc.

A Subsidiary of

Bigtime Incorporated

Internal Audit Case Study

THE BOTTA BOOM INC. CASE STUDY

This introduction sets the stage for a multiple part case study involving the design and production of parts by a fictitious company, Botta Boom Incorporated.

This case is based on actual incidents that occurred at many different companies during the design, production, assembly, test, and use of parts for different contracts. The case has been reconstructed and subdivided into a series of thought-provoking situations. Our purpose in presenting these situations is to provide you with the opportunity to:

- Use actual information and skills you have acquired to assess an audit situation and determine the nonconformity issues involved.

- Discuss possible solutions or actions for handling each situation and determine the most appropriate approach to take.

This case study serves as a basis for group discussions and asks for your response to different situations. Each situation relates to elements that have been covered in the training materials. The case study is designed to allow each individual to use analytical skills and to interact with others to share and learn as part of a team. By so doing, each individual will be better prepared when difficult problems arise during actual audits.

The case study consists of two connected parts. In the first part, you will be asked to review a Botta Boom procedure to determine whether it meets the requirements and intent of AS9100. Recall this is Step 1 in analyzing an audit situation — to determine whether the company has met the intent of the model being used. You will be asked to develop a Guidelist that you could use to audit that part of the quality system based on the procedure you will review. In part two of the case study, you will be asked to review audit interview narratives that describe situations that occurred during an audit of the Botta Boom Company. In this part, you must decide whether a nonconformity has occurred. If so, you must decide its severity and what requirement has not been fulfilled. Also in part two, you will be asked to write Nonconformity Finding notes. After the case study is completed, our answers will be provided for your guidance and study.

You should assess each of the situations independently and then discuss your assessments as a group. Each case study segment helps you focus on different aspects of the quality system issues and concerns that confront an auditor at that point in the process. For most of the case study segments, you will be asked to read the scenario or situation and answer a question or make a decision regarding the issues presented. Then you will discuss your response(s) within your small group to reach a consensus on the best approach for handling the situation presented. When you have completed the assessment, a representative from your group will present your conclusions to the class. After all the groups have presented their conclusions, the class as a whole will discuss the various approaches and determine the best course of action.

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Botta-Boom Procedure #1

OP 8.7: Control of Nonconforming Product Revision: C

1 Purpose: This procedure defines the process used to identify and properly disposition nonconforming product at Botta-Boom, Inc.

2 Responsibility:

- All Botta-Boom employees are responsible for identifying nonconforming product they may find and proceeding according to this procedure.
- The QC Inspector is responsible for logging items in the NCP log.
- The Quality Manager is responsible for the review of nonconforming product and for assigning the appropriate disposition.

3 Procedure

3.1 Nonconforming material or product is identified by a red NCP tag, available at all workstations and the inspection area. The employee who discovered the nonconforming product completes the following information on the tag:

- Material/product description
- Description of nonconformity
- Job #
- Date
- Employee name

3.2 The nonconforming material or product is placed on a shelf in the area designated for such items.

3.3 The QC Inspector assigns an NCP number to nonconforming product(s) and enters it on the NCP Log.

3.4 The Quality Manager reviews the items in the nonconforming product area and determines the disposition. The disposition is recorded on the NCP log. Possible dispositions include.

- Rework.
- Repair.
- Scrap.
- Return to Supplier
- Use-as-is; and
- Regrade for alternative applications.

3.5 The Quality Manager assigns responsibility for implementing the disposition decision to an appropriate person and records his/her name in the NCP log.
The person responsible for the disposition of the material or product notifies the functions concerned.

Documentation Review Procedure # 1
OP 8.7: Control of Nonconforming Product Revision: C

	8.7 Control of nonconforming outputs	Gap?	Notes
1.	**8.7.1** The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.		
2.	***NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.***		
3.	The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.		
4.	This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.		
5.	***The organization's nonconformity control process shall be maintained as documented information including the provisions for:***		
6.	– ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***		
7.	– ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***		
8.	– ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***		
9.	– ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***		
10.	***NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.***		
11.	The organization shall deal with nonconforming outputs in one or more of the following ways:		
12.	a) correction;		
13.	b) segregation, containment, return or suspension of provision of products and services;		
14.	c) informing the customer;		
15.	d) obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer.***		

	8.7 Control of nonconforming outputs	Gap?	Notes
16.	***Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:***		
17.	– ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***		
18.	– ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements.***		
19.	***Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.***		
20.	***Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.***		
21.	Conformity to the requirements shall be verified when nonconforming outputs are corrected.		
22.	**8.7.2** The organization shall retain documented information that:		
23.	a) describes the nonconformity;		
24.	b) describes the actions taken;		
25.	c) describes any concessions obtained;		
26.	d) identifies the authority deciding the action in respect of the nonconformity.		

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Botta-Boom Procedure #2

OP 7.5-1: Control of Documents Revision: B

1. Purpose: This procedure defines the process used to control documents at Botta-Boom, Inc. Records are controlled per OP 7.5-2.

2. Responsibility:

   - The Quality Manager is responsible for controlling quality system documents.
   - The Engineering Manager is responsible for controlling engineering drawings and specifications.

3. Procedure

   3.1. All documents and data are reviewed and approved by designated personnel before they are issued. These same personnel will review any changes to their documents. The approval authority is identified on the master list for each type of document.

   3.2. When a document is created or revised, the master list is updated. (There is a master list for quality system documents and another list for engineering drawings and specs.) The master list includes the document number, name, approval authority, and the current Revision .

   3.3. When a document is changed, the responsible party (see section 2, above) distributes the revised document and retrieves all copies of the old Revision. One old Revision document is saved for history (see OP 7.5-2 Control of Records), and all others are discarded. The archived copy is stamped “Obsolete” in red.

   3.4. Minor changes may be handwritten on the documents themselves if the approval authority signs and dates the change. If handwritten changes are to be used, ALL controlled copies must be noted with the change, signed.

   3.5.

   3.6. and dated.

   - Handwritten changes are allowed as a matter of convenience. Control of these changes is more difficult, and an effort will be made to avoid making changes in this manner.

Documentation Review Procedure # 2
OP 7.5: Control of Documents Revision: B

	7.5 Documented information	Gap?	Notes
1.	**7.5.2 Creating and updating**		
2.	When creating and updating documented information, the organization shall ensure appropriate:		
3.	a) identification and description (e.g., a title, date, author, or reference number);		
4.	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);		
5.	c) review and approval for suitability and adequacy.		
6.	***NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.***		
7.	**7.5.3 Control of documented information**		
8.	**7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure:		
9.	a) it is available and suitable for use, where and when it is needed;		
10.	b) it is adequately protected (e.g., from loss of confidentiality, improper use, or loss of integrity).		
11.	**7.5.3.2** For the control of documented information, the organization shall address the following activities, as applicable:		
12.	a) distribution, access, retrieval, and use;		
13.	b) storage and preservation, including preservation of legibility;		
14.	c) control of changes (e.g., version control);		
15.	d) retention and disposition.		
16.	e) ***prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.***		
17.	Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.		
18.	Documented information retained as evidence of conformity shall be protected from unintended alterations.		
19.	***When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).***		
20.	NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.		

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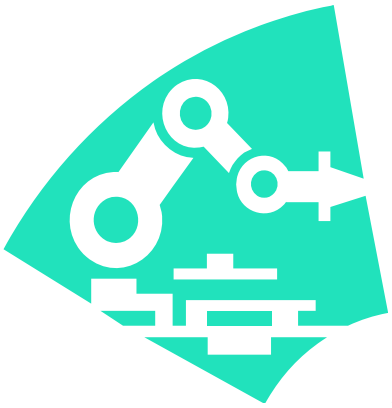

Botta-Boom, Inc.

Audit Interviews

BACKGROUND INFORMATION:

Botta-Boom, a manufacturer of assemblies and components for a variety of industrial applications, has been in business since 1988. The company has been under pressure from several large-volume customers to become AS9100 registered. A year ago, they began the process and assigned Jim Newton, the Quality Manager, as the Management Representative.

Jim produced a very professional looking Quality Manual (QM-1, Rev. A) and system level procedures covering the requirements of the AS9100 Standard. The three internal auditors completed two rounds of audits, and Jim believed the company was nearly ready for a registration audit. He hired XYZ Consulting to perform a pre-assessment audit.

Mark Chen, the auditor from XYZ, arrived first thing in the morning, October 1, 2017, and began the day with a formal opening meeting. Jim Newton, Ginny Hopkins, Ron Balewa, and Brian Murphy attended the meeting. Mark then asked if he could spend some time with the management team discussing organizational context and risk assessment while they were gathered, but Jim suggested they go on a plant tour first.

CASE 1:

Ginny Hopkins took the auditor on a tour of the plant. They began at the receiving dock, where the QC inspector was busy checking in a truckload of materials. Everything seemed to be operating smoothly, and the area was clean and well organized.

They proceeded to the assembly area, which had 10 production lines. As they walked through the area, the auditor noticed that many of the work instructions in use had handwritten notes and changes. He also noted that some of the production lines had a maintenance checklist posted while other lines did not. He looked closely at one of the checklists and saw that the most recent entry was 3/5/17.

As they walked toward the inspection area, they passed an area marked “Nonconforming Product.” There were several racks containing assemblies and various components labeled with bright yellow “HOLD” tags. Ginny smiled and proudly explained how well the nonconforming product procedure was working. Everyone in the plant had been trained and knew that whenever they found nonconforming product or material, they had to bring it to this area so the QC Inspector could decide what to do about it.

When they reached the Inspection area, the auditor took a quick look around and was impressed with how neat and well organized the room was. Ginny commented that the QC Inspector was one of their best employees and had really turned that area around in the two years since she arrived at Botta-Boom. They turned to leave, and the auditor glanced at a pair of calipers lying on a table. A sticker indicated that calibration was 6 months overdue.

CASE 2:

After the tour, Mark asked again about discussing some higher-level strategic concepts, but Jim said it would be better to wait until they met with Michael Butler. Jim said he had Michael on the agenda later in the day to discuss their processes for Strategic Planning, Risk Assessment and Management Review. Instead, the auditor went to Jim Newton's office to discuss the Corrective Action and Continuous Improvement system (OP 10, Rev. C). Jim showed him the database used to track Continuous Improvement Requests (CIRs), and Mark noted that the type of request (improvement opportunity or corrective action) was designated. Jim said internal audit findings were tracked separately by Joe Parisi. Most of the CIRs were initiated because of customer complaints. A few were generated by employees who saw a problem or had a suggestion for improvement.

Approximately half of the customer complaints stemmed from changes the customer made after the original order was taken. The complaints indicated that information about customer changes had not made it to the assembly area and so the assemblies were made without the update. The auditor studied one CIR form regarding this problem (See Exhibit D). He asked to see the specific customer complaint forms mentioned on the form. Jim said he did not keep them, but called Brian Murphy, the Sales Manager, who could get them. Brian said he would find those complaint forms and have them ready when the auditor came to interview him later that morning.

The auditor asked about the relatively low number of CIRs generated by Botta-Boom employees. Jim said that all employees had received training on the CIR system and how to fill out a CIR. The quality system was obviously well implemented and there weren't many problems for the employees to find.

CASE 3:

The auditor's next interview was with Joe Parisi, the internal audit manager. He showed Mark the database of internal audit findings (see Exhibit E). The auditor asked about the lack of closure in the engineering department. Joe said he had tried to meet with Al Stevens, the engineering manager, to work on the corrective action, but Al wouldn't return his calls or messages. Mark asked, "what's the next step?" Joe replied that there was nothing more he could do until Al decided to get back to him.

The auditor asked Joe to show him the internal audit schedule. Joe pulled out a copy from his desk and handed it to Mark. Mark checked the report files and found there were no reports for two of the three audits scheduled for June. When Mark mentioned this to Joe, he responded, "I keep telling Jim that we need some more auditors. We haven't done all of the audits that are scheduled, and we haven't followed up on any of the audits we <u>have</u> done!"

CASE 4:

The auditor continued by interviewing Maria Castillo, the Purchasing Manager. He first asked about the process of evaluating suppliers. Maria explained that they audit potential suppliers to determine their ability to meet Botta-Boom's needs for goods and/or services. If they do well in the audit, they are added to the approved supplier list. In some cases, their customer stipulates which supplier they must use, so these suppliers are just put on the approved list without an audit. She pulled a stack of files containing supplier evaluations. Mark glanced at the top three files, reports on Perfect Plastics, Inc., Benchmark Products, and Stellar Manufacturing. All three files contained audit reports indicating that the suppliers had well implemented quality systems. The most recent report was that of Stellar Manufacturing, from an audit 3 years earlier. Maria showed the auditor Botta-Boom's Approved Supplier List, which included these three vendors and their scope of approval. The auditor asked Maria how they evaluate the suppliers who are already on the list. She responded, "If they are already on the list, they're approved. We don't have to do any more evaluations!" Mark then asked how she would decide whether to tighten controls on a supplier or disapprove one, since he had not seen that requirement covered in Botta-Boom's Purchasing Procedure (OP 8.4, Rev. D). Maria replied, "I've never seen a need for that type of action."

The auditor asked to see where they kept the completed purchase orders (POs). Maria took him to a file cabinet, opened one of the drawers and told him to help himself. He pulled a sample of 10 POs and checked for approval. OP 8.4 (Rev. D) required that the Purchasing Manager sign all POs to indicate approval. Seven POs had Maria's signature and the other 3 were signed only by the buyers who had placed the orders.

CASE 5:

The auditor went to the sales department next. Brian Murphy greeted him and said they had not yet found the customer complaints he requested, but his Admin was busy searching for them. Mark thanked Brian and asked him how Botta-Boom ensured that Botta-Boom could meet the claims for the products and services they offer. Brian responded that their Design Control process was very rigorous, and they did a lot of verification and validation testing. He suggested that Mark discuss this further with Al Stevens.

The auditor then spoke with Brian and Kevin Watson, one of the salespeople, about the contract review process. The documented procedure (OP 8.2, Rev. A) was very vague, so Mark asked about the training for that department. Brian explained that there is a formal 3-day class that each new salesperson attends, and then they typically work with an experienced employee for a week until they are ready to handle incoming calls on their own. Kevin had been with the company only 3 months and confirmed that he had received the formal training and worked with another employee to prepare for his job.

Kevin described the contract review process and the records kept. Kevin said that the sales file was the key to the whole project, as it contained all of the customer and regulatory requirements, contract changes and

how Botta-Boom was to notify the customer of any changes or issues. The information relevant to production was forwarded to David Cooper, the assembly supervisor, who updated the work orders when changes were made to the order. “What about risk assessment for new or changed orders?” the auditor asked. Kevin replied that they recently documented a procedure for Risk Management (OP 6.1, Rev. A) and had added a class to the formal Sales training.

Mark asked to see an example of risk assessment for an order change, so Kevin showed him the file for Job #23761, which had been updated two days earlier. It was a big order of their newest product, the Bifurcon 2000. Their customer, ACE Supply, had called and requested that their company logo be added to each unit. Botta-Boom already had the logo since they had complied with this request on some previous orders. Mark asked if there was any record of the review of the change; Kevin replied that he didn’t need a record, since the procedure just required him to consider and address any possible risks. Kevin continued by saying “I sent an email message to David notifying him of the change and included a copy in the sales file.”

The auditor asked to meet David Cooper to follow up on this particular job. As Kevin led him out of the office, they heard Brian ask his Admin about the customer complaint records. “I’m trying, I’m trying,” he sighed. “They just don’t seem to be here!”

When they got to the assembly area, Kevin introduced the auditor to David Cooper who confirmed the change that had been made to the job they had discussed in the Sales office. He pulled up Job #23761 on the computer and proudly displayed the addition in the production instructions. He then showed Mark the box of work orders pending for the plant, where a printed copy of an updated work order for Job #23761 was located, waiting to be pulled for assembly.

Mark then asked David about how process changes were handled, for example if an assembly process needed to be modified. David replied that he would discuss something like that with Quality and Engineering. Mark asked if any records were kept and David said he didn’t know, but that the auditor could ask Al or Jim.

CASE 6:

The auditor then moved out on the assembly floor. He wandered around for a few minutes, asking several employees about Botta-Boom’s quality policy and how they contributed to the achievement of the company’s quality objectives. Of the 6 people he questioned, only 2 could tell him anything about the quality policy and objectives. The two people that were aware of the policy and objectives did not know how they contributed to achieving the objectives, although they did mention that in the training they received covered ethical behavior, product safety and the importance of quality.

He introduced himself to Carter Taylor, one of the assemblers, and asked about the job he was doing. Carter showed Mark the Bifurcon 2000 job that he was assembling and the drawing (Rev. B) he was using, and showed where he initialed each step on the work order (Job # 23778) as he completed it. Marked noted that for this order of the Bifurcon, the customer was Magnus Manufacturing. The auditor spotted a stack of CIR forms at the workstation and asked about them. “We’re supposed to fill those out if we find a problem,” Carter replied, “but it’s a whole lot quicker just to fix the problem and not hassle with the paperwork. I don’t think they really read them anyway. See Kenny over there in the red shirt? He’s filled out about 5 or 6 of those forms, and never heard back on any of them.”

The auditor asked about equipment maintenance: “did Carter have any written instructions and were there any records kept on the equipment?” Carter said he’d been working with that machine so long, he knew exactly what to do when it went down, and as far as records go, it was all in his head. Another assembler who was observing the interview said he had a procedure and went to get it for the auditor. He returned with a copy of the work instruction for Equipment Maintenance (WI 7.1.3, Rev. A), which had some handwritten changes signed and dated by David Cooper. The auditor asked Carter if he had seen it before. Carter shrugged and shook his head no.

CASE 7:

When Carter completed the current job, he called Karin Khanna, the QC Inspector. She checked the assemblies he had finished, and initialed the appropriate spaces on the work order, explaining each step to the auditor as she went along. When she finished, the auditor asked about receiving inspection. “Let’s go to my office and I’ll show you the logbook.” As they walked across the production floor, they passed a rack of new Bifurcon 2000 modules. She told Mark they were assembled the previous afternoon and had been inspected first thing this morning. Mark looked at the completed work order, which was in a folder on the rack with the modules. It was the order for ACE, Job #23761, but the modules did not have the ACE logo as the customer had requested. He examined the work order closely. It had been printed three days earlier and did not reflect the change to add the customer logo.

As they continued toward Karin’s office, they passed the nonconforming product area Mark had seen during the tour that morning. He asked Karin how that system worked at Botta-Boom. She replied, “Employees who find defective material or product bring it to this area and tag it with Yellow Hold tags like you see here. Each day I review what is in the area and decide what to do with it. Sometimes it can be fixed, sometimes it has to be scrapped and other times we may be able to get the customer to accept it as is. If a part is scrapped, I keep it here until someone has time to physically destroy it.” The auditor asked who made the decisions regarding what to do with the nonconforming product. She said that she decided in most cases, but she would ask Jim Newton for help if she wasn’t sure how to handle something.

CASE 8:

They arrived at Karin's office and Mark took a look at the receiving logbook. He noticed that a shipment of components from Stellar Manufacturing was rejected the previous day. When asked about the problem, Karin responded, "They didn't meet our dimensional spec's. We've been having this same problem for months!" Mark asked to see the receiving inspection records on all shipments from Stellar in the last six months. Five of the last ten shipments were rejected for the same reason. Karin showed Mark the report she compiled monthly for her boss on receiving inspections.

Mark asked Karin if she had any controls for the prevention of counterfeit parts. She replied that their parts were at a low risk for that type of thing, but that she made sure every lot received was accompanied by a Certificate of Conformance.

Next, they discussed the calibration system. Karin showed the auditor a copy of the calibration schedule and the procedure (OP 7.1.5, Rev. C) and work instructions (WI 7.1.5, Rev. C) she used. Mark asked what she did if any equipment was found to be out of calibration. "We pull it immediately!" Karin responded. "I label the equipment with an orange "DO NOT USE" sticker and record the information in the calibration record. Then I have it recalibrated and put back into use or scrapped and replaced if it cannot be brought back into tolerance. You can see our whole method described here in OP 7.1.5 (Rev. C)." Mark looked over her shoulder and noted that the OP also covered action to take to assess validity of previous measurement results and determination of affected products. The auditor then looked to the side and saw the pair of calipers he had noticed during the tour that morning. "The sticker indicates those are past due for calibration," he said. "Oh, that pair is not used for inspection, just for reference," Karin responded. "They aren't accurate enough, so we bought a better pair to use when checking components." The auditor walked over and picked up the calipers. He turned them over and saw a yellow sticker that said, "FOR REFERENCE ONLY."

CASE 9:

The auditor walked to Engineering and asked to speak with Al Stevens, the manager of that department. Al was on the phone, so Mark asked for their controlled document binder and looked around the area for a few minutes while he waited. On the wall was a chart showing the status of current engineering projects, all in various stages of completion. Project #BB-72 was due for final review the next week. Project #BB-69, a Revision to the Bifurcon 2000, had been completed the previous week, and led to the Revision C drawing for that product. As the auditor looked at a copy of the work instructions for Customer Notification of Design Changes (WI 8.3.4-1, Rev. B) in the controlled binder, Al Stevens hung up the phone and asked Mark to come into his office. Al described the design control process at Botta-Boom, noting that some products were designed by customers and others by Botta-Boom to a customer specification.

The auditor asked to see the file on Project #BB-72 (a Botta-Boom design), which was almost complete. Al called to Phillip Kato, the engineer in charge of that project, and asked him to bring the file. Mark flipped through the pages contained in the file as Phillip described the design stages represented there. “You’ve done a great job documenting all of your verification and validation results in the Design File, and it’s clear that product safety and the consequences of obsolescence are considered” the auditor said. “What about records of the review and approval of design changes and the related assessments of risk that took place while the product was in development?” “Well, the designs are always changing,” Phillip replied. “We’re allowed to work to red-lined drawings before production release, but we don’t keep all of those versions. Al jumped into the conversation and said “we have project meetings regularly and I make sure everyone involved knows exactly what’s happening. Besides, what’s important is having a record of the final design. Nobody cares about how we got there.”

Mark then asked Al and Phillip how production process changes were reviewed. Al said that generally those kinds of changes would be discussed by Engineering, Quality and Assembly. The auditor then asked what sorts of records were kept of the reviews and authorization of changes. Al responded that they didn’t keep records of every conversation in the company, but if a procedure got changed it would get signed by the approval authority.

CASE 10:

Next, the auditor sat down with Jim Newton and Michael Butler to discuss strategic planning and the management review process. Mark mentioned that he’d read the Quality Manual’s description of Botta-Boom’s organization context and the needs and expectations of relevant interested parties. He then asked, “how do you monitor and review information about these issues in an ongoing way and address any risks and opportunities?” Michael responded that they already figured all that out when Jim was writing the Quality Manual and he didn’t anticipate changes or see any need to keep reviewing that information.

Mark moved on and asked about the management review meetings. Michael explained that the meetings took place once a quarter, and they discussed things like internal audit results, the improvement and corrective action system and training needs. The auditor asked to see the records, so Jim went to his office and returned with the minutes from the previous two meetings. Mark took a few moments to skim the pages, and asked Michael, “I don’t see any discussion about the purchasing program, or the contract review process. How do you know your system is adequate?” “Well, we only discuss the areas that had audit findings or any internal corrective action requests,” Michael responded. “If an area hasn’t generated any need for corrective action, we can assume it’s OK. Besides, we don’t have time to discuss the entire system. We’ve got a business to run!”

The auditor then asked to speak with someone about training and was introduced to Fritz Adler in Human Resources. Fritz explained that he coordinates all of the training that takes place at Botta-Boom and pulled out a copy of the operating procedure for training (OP 7.2, Rev. A). Mark asked to see the training records as referenced in the Training Matrix of OP 7.2 for Linh Nguyen, Maria Castillo, Kevin Watson, Phillip Kato, Carter Taylor, and Karin Khanna. Fritz pulled three files, but there were no files for Phillip Kato, Carter Taylor or Linh Nguyen.

Mark asked how the organizational knowledge described in the Quality Manual would get updated and how needs for new information would be identified. Fritz paused for a moment and replied, “I don’t know, that hasn’t happened yet, but I guess Jim would let me know.” The auditor next asked if training competency needs were periodically reviewed. Fritz replied that since the documented system was fairly recent, they hadn’t seen a need yet to update any of the job descriptions or skills requirements lists.

As the auditor was leaving Fritz’s office, Brian Murphy rushed down the hall carrying several files. “Here are the customer complaint records you were looking for earlier. Sorry it took so long.” “Thank you,” replied the auditor. “I’ll review these in a few minutes and come to your office if I have any questions.” With that, Mark headed for the conference room to review his notes from the day and finalize his plan for the next day’s audit.

Exhibit A: Organization Chart

Botta-Boom, Inc.

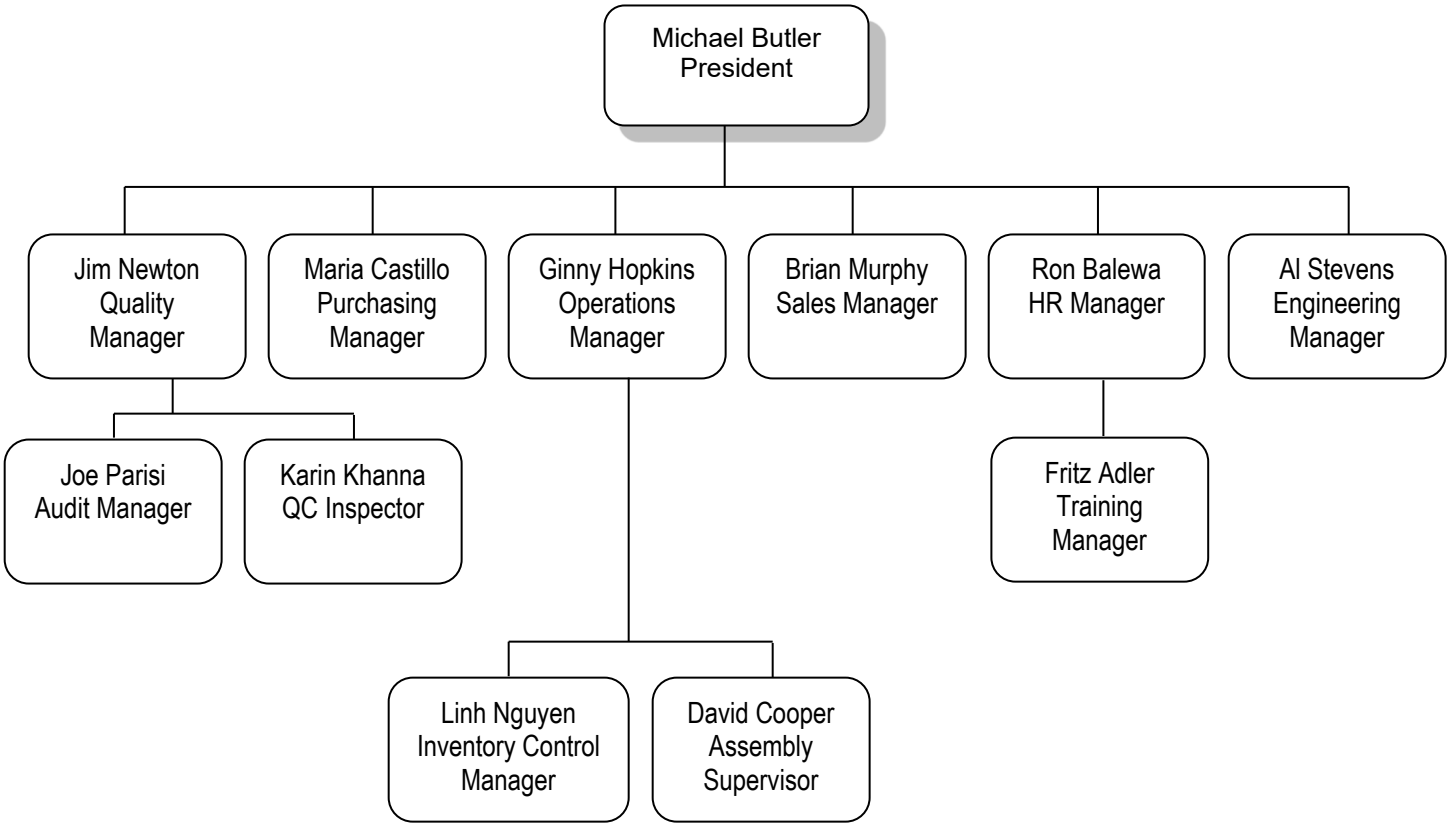

Exhibit B: Excerpt from Document Master List

Document Number	Document Name	Approved By:	Current Revision:
QM-1	Quality Manual	M. Butler	A
OP-6.1	Risk Management	B. Murphy	A
OP 7.1.5	Control of Monitoring and Measuring Devices	J. Newton	D
OP 7.2	Training	R. Balewa	A
OP 7.5-1	Control of Documents	J. Newton	B
OP 7.5-2	Control of Records	J. Newton	E
OP 8.2	Contract Review	B. Murphy	B
OP 8.3	Design and Development	A. Stevens	C
OP 8.4	Purchasing	M. Castillo	D
OP 8.5.4	Preservation of Product	G. Hopkins	B
OP 8.5.6	Control of Process Changes	G. Hopkins	A
OP 8.7	Control of Nonconforming Product	J. Newton	C
OP 9.1	Monitoring, Measurement, Analysis and Evaluation	J. Newton	C
OP 9.2	Internal Quality Audits	J. Newton	D
OP 9.3	Management Review	M. Butler	A
OP 10	Corrective Action & Continuous Improvement	J. Newton	C
WI 7.1.3	Equipment Maintenance	D. Cooper	B
WI 7.1.5	Calibration and Verification	K. Khanna	D
WI 8.3.4-1	Customer Notification of Design Changes	A. Stevens	C
WI 8.4.2	Receiving Inspection	K. Khanna	C
WI 8.5-1	Inventory Control	L. Nguyen	B
WI 8.6	Final Inspection	J. Newton	G

Exhibit C: Excerpt from Quality Records List

Record Name:	Responsible Party:	Retention time: (minimum)
Audit reports on potential suppliers	Purchasing Manager	5 years
Calibration data	QC Inspector	5 years
Continuous Improvement Request (CIR)	Quality Manager	3 years
Customer complaint forms	Sales Manager	2 years
Design file	Engineering Manager	5 years
Final Inspection reports	QC Inspector	3 years
Internal Audit reports	Audit Manager	3 years
Job files	Assembly Supervisor	2 years
Management Review minutes	Quality Manager	2 years
NCP log	QC Inspector	2 years
Preventive Maintenance records	Operations Manager	2 years
Purchase Orders	Purchasing Manager	2 years
Receiving Inspection reports	QC Inspector	1 year
Traceability certificates for calibration standards	Quality Manager	5 years
Training records	Training Manager	Term of employment + 2 years
Sales file (contract review records – including changes to orders)	Sales Manager	3 years

Exhibit D: Continuous Improvement Request

Continuous Improvement Request

CIR Number: CIR - 12 Date: 7/15/17 ☑ Corrective Action ☐ Improvement.

Initiated by: Kevin Watson Department: Sales

Description of problem:

Changes requested by customers after they have already made an order are not always incorporated into the product. Sales transfers the information to Assembly, but sometimes they don't find out about the change at all, and other times they find out too late.

Customer complaint forms numbered 12, 17, 26, 35, and 42 are all related to this type of problem.

Assigned to: Brian Murphy, Sales Manager

Improvement/Corrective Action:

Most of these errors happened because we didn't have time to get the information to Assembly. I worked with David Cooper to determine a method to correct this problem. When a customer requests a change, we immediately send David a message over company email. Before he prints any new work orders, he will check his email for updates.

We keep a copy of the email message in the sales file for that order.

Date Completed: 7/18/17 Signature of manager: Eubb#P xusk

Corrective/Preventive Action Verification: ☑ **Accepted** ☐**Not Accepted**

Audited change process and found new process being followed.

Date Closed: 7/20/17 Signature of Quality Manager: Mb#Qhzwq

Exhibit E: Excerpt from Internal Audit Database

Audit Schedule: Jan - Jun 2017

Department	January	February	March	April	May	June
Purchasing	x				x	
Assembly	x				x	
Sales			x			x
Engineering		x			x	
Inspection				x		
Human Resources		x				x
Shipping		x				
Management			x			x
Inventory Control				x		

Audit Findings for completed audits: Jan - Jun 2017

audit finding	**element**	**department**	**auditor**	**audit date**	**date closed**
7	8.5	Assembly	D. Cooper	1/7/17	3/17/17
8	8.5	Assembly	L. Nguyen	1/7/17	3/16/17
9	8.4	Purchasing	L. Nguyen	1/17/17	5/10/17
10	8.3	Engineering	J. Parisi	2/17/17	
11	8.3	Engineering	J. Parisi	2/17/17	
12	8.5	Shipping	J. Parisi	2/27/17	6/12/17
13	8.2	Sales	D. Cooper	3/15/17	7/10/17
14	9.3	Management Review	J. Parisi	3/30/17	8/16/17
15	8.4.2	Receiving Insp.	L. Nguyen	4/6/17	6/21/17
16	8.6	Inspection	D. Cooper	4/6/17	8/8/17
17	8.6	Inspection	J. Parisi	4/6/17	8/8/17
18	8.5	Assembly	L. Nguyen	5/12/17	9/20/17
19	8.5	Assembly	D. Cooper	5/12/17	9/2/17
20	7.2	Human Resources	D. Cooper	6/18/17	9/24/17

AS9100 Audit Guidelist

Requirement	Look **AT** (Talk To)	Sampling Plan	Look **FOR**

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FINDING of NONCONFORMITY

Documents Audited:	Nonconformity Severity	
	Major ☐	Minor ☐
Area Audited: Area Representative:	Date:	NC Number:
Positive Comments:		
Requirement:		
Nonconformity & Objective Evidence:		
Auditor:		Date:
Finding Assigned to:	Date:	Response Due:
Corrective Action Taken:		
Action Taken to Prevent Recurrence:		
Responsible Manager:		Date:
Verification of Corrective Action (describe evidence):		
Corrective Action Accepted:		Date:

Form 9.2.2 Attachments: ☐

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FINDING of NONCONFORMITY

Documents Audited:	Nonconformity Severity	
	Major ☐	Minor ☐
Area Audited: Area Representative:	Date:	NC Number:
Positive Comments:		
Requirement:		
Nonconformity & Objective Evidence:		
Auditor:		Date:
Finding Assigned to:	Date:	Response Due:
Corrective Action Taken:		
Action Taken to Prevent Recurrence:		
Responsible Manager:		Date:
Verification of Corrective Action (describe evidence):		
Corrective Action Accepted:		Date:

Form 9.2.2 Attachments: ☐

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FINDING of NONCONFORMITY

Documents Audited:	Nonconformity Severity	
	Major ☐	Minor ☐
Area Audited: Area Representative:	Date:	NC Number:
Positive Comments:		
Requirement:		
Nonconformity & Objective Evidence:		
Auditor:		Date:
Finding Assigned to:	Date:	Response Due:
Corrective Action Taken:		
Action Taken to Prevent Recurrence:		
Responsible Manager:		Date:
Verification of Corrective Action (describe evidence):		
Corrective Action Accepted:		Date:

Form 9.2.2 Attachments: ☐

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TAB 3
Reference Material

Detailed Outline of Headings – AS9100 Rev. D

RATIONALE

FOREWORD

INTENDED APPLICATION

INTRODUCTION

1.1 General
1.2 Quality Management Principles
1.3 Process Approach
1.3.1 General
1.3.2 Plan-Do-Check-Act Cycle
1.3.3 Risk-Based Thinking
1.4 Relationship with Other Management System Standards

QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS

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 Quality Management System
4.4 Quality Management System and Its Processes

5. LEADERSHIP
5.1 Leadership and Commitment
5.1.1 General
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

Detailed Outline of Headings – AS9100 Rev. D

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
7.1.1 General
7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the Operation of Processes
7.1.5 Monitoring and Measuring Resources
7.1.5.1 General
7.1.5.2 Measurement Traceability
7.1.6 Organizational Knowledge
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented Information
7.5.1 General
7.5.2 Creating and Updating
7.5.3 Control of Documented Information

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 the Requirements for Products and Services
8.2.4 Changes to Requirements for Products and Services
8.3 Design and Development of Products and Services
8.3.1 General
8.3.2 Design and Development Planning
8.3.3 Design and Development Inputs
8.3.4 Design and Development Controls

Detailed Outline of Headings – AS9100 Rev. D

8.3.5 Design and Development Outputs
8.3.6 Design and Development Changes
8.4 Control of Externally Provided Processes, Products, and Services
8.4.1 General
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

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis, and Evaluation
9.1.1 General
9.1.2 Customer Satisfaction
9.1.3 Analysis and Evaluation
9.2 Internal Audit
9.3 Management Review
9.3.1 General
9.3.2 Management Review Inputs
9.3.3 Management Review Outputs

10. IMPROVEMENT

10.1 General
10.2 Nonconformity and Corrective Action
10.3 Continual Improvement

Detailed Outline of Headings – AS9100 Rev. D

ANNEXES

FIGURES

ISO 9004:2009 Excerpt

8.3.3. Internal audit

Internal audits are an effective tool for determining the levels of compliance of the organization's management system against given criteria, and provide valuable information for understanding, analysing and continually improving the organization's performance. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal audits should assess the implementation and effectiveness of the management system. They can include auditing against more than one management system standard, such as ISO 9001 (quality management) and ISO 14001 (environmental management), as well as addressing specific requirements relating to customers, products, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent personnel, in accordance with an audit plan.

Internal auditing is an effective tool for identifying problems, risks and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfil its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.

The outputs of internal audits provide a useful source of information for

— addressing problems and nonconformities,

— benchmarking,

— promoting good practices within the organization, and

— increasing understanding of the interactions between processes.

The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Audit reports are also an essential input for management reviews. Top management should establish a process for the review of all internal audit reports, to identify trends that can require organization-wide corrective or preventive actions.

The organization should also take the results of other audits, such as second and third party audits, as feedback for corrective and preventive actions.

NOTE See ISO 19011 for further guidance on auditing.

ISO 9004:2009 Excerpt

8.3.4. Self-assessment

Self-assessment is a comprehensive and systematic review of the organization's activities and its performance in relation to its degree of maturity (see Annex A).

Self-assessment should be used to determine the strengths and weaknesses of the organization in terms of its performance as well as its best practices, both at an overall level and at the level of its individual processes. Self-assessment can assist the organization to prioritize, plan and implement improvements and/or innovations, where necessary.

The results of self-assessments support

- continual improvement of the organization's overall performance,
- progress towards achieving and maintaining sustained success for the organization,
- innovation in the organization's processes, products and structure, when appropriate,
- recognition of best practices, and
- the identification of further opportunities for improvement.

The results of self-assessments should be communicated to relevant people in the organization. They should be used to share understanding about the organization and its future direction. The results should be an input to management review.

NOTE 1 ISO 10014 provides a self-assessment tool directed specifically towards the financial and economic benefits of a quality management system for an organization.

NOTE 2 See Annex A for more information about self-assessment.

AS9100 Definitions

A *Counterfeit Part* is 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.

Product Safety refers to 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.

Special requirements are those which have high risks to being achieved, such as performance requirements at the limit of industry capability or the organization's technical or process capability. They can be identified by the customer or the organization.

Critical items may result from the special requirements identified during the risk assessment mentioned previously. They are items (e.g., functions, parts, software, characteristics, processes) that have a significant effect on the product realization and use of the product, including safety, performance, form, fit, function, producibility, service life, etc. They require specific actions to ensure they are adequately managed.

A *key characteristic* is 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. A critical item may be further classified as a key characteristic if its variation needs to be controlled.

Refer to AS9100 Rev. D Section 3 *Terms and Definitions* for full text.

AS9100:2016 to AS9100:2009
Correlation Matrix

AS9100:2016	AS9100:2009
4 Context of the organization	**1.0 Scope**
4.1 Understanding the organization and its context	1.1 General
4.2 Understanding the needs and expectations of interested parties	1.1 General
4.3 Determining the scope of the quality management system	1.2 Application 4.2.2 Quality manual
4.4 Quality management system and its processes	4 Quality management system 4.1 General requirements
5 Leadership	**5 Management responsibility**
5.1 Leadership and commitment	5.1 Management commitment
5.1.1 General	5.1 Management commitment
5.1.2 Customer focus	5.2 Customer focus
5.2 Policy	5.3 Quality policy
5.2.1 Establishing the Quality Policy	5.3 Quality policy
5.2.2 Communicating the Quality Policy	5.3 Quality policy
5.3 Organizational roles, responsibilities and authorities	5.5.1 Responsibility and authority 5.5.2 Management representative 5.4.2 Quality management system planning
6 Planning	5.4.2 Quality management system planning
6.1 Actions to address risks and opportunities	5.4.2 Quality management system planning 8.5.3 Preventive action
6.2 Quality objectives and planning to achieve them	5.4.1 Quality objectives
6.3 Planning of changes	5.4.2 Quality management system planning
7 Support	**6 Resource management**
7.1 Resources	6 Resource management
7.1.1 General	6.1 Provision of resources
7.1.2 People	6.1 Provision of resources
7.1.3 Infrastructure	6.3 Infrastructure
7.1.4 Environment for the operation of processes	6.4 Work environment
7.1.5 Monitoring and measuring resources	7.6 Control of monitoring and measuring equipment
7.1.5.1 General	7.6 Control of monitoring and measuring equipment
7.1.5.2 Measurement traceability	7.6 Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	*[No equivalent clause]*
7.2 Competence	6.2.1 General 6.2.2 Competence, training and awareness
7.3 Awareness	6.2.2 Competence, training and awareness *[4.2.1 Awareness of documented info & changes]*
7.4 Communication	5.5.3 Internal communication
7.5 Documented information	4.2 Documentation requirements

AS9100:2016	AS9100:2009
7.5.1 General	4.2.1 General
7.5.2 Creating and updating	4.2.3 Control of documents 4.2.4 Control of records
7.5.3 Control of documented Information	4.2.3 Control of documents 4.2.4 Control of records
8 Operation	**7 Product realization**
8.1 Operational planning and control	7.1 Planning of product realization
8.1.1 Operation risk management	7.1.2 Risk Management
8.1.2 Configuration management	7.1.3 Configuration Management
8.1.3 Product safety	7.3.1 Design and development planning
8.1.4 Prevention of counterfeit parts	*[No equivalent clause]*
8.2 Requirements for products and services	7.2 Customer-related processes
8.2.1 Customer communication	7.2.3 Customer communication
8.2.2 Determining the requirements for products and services	7.2.1 Determination of requirements related to the product
8.2.3 Review of the requirements for products and services	7.2.2 Review of requirements related to the product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to the product
8.3 Design and development of products and services	7.3.1 Design and development planning
8.3.1 General	7.3.1 Design and development planning
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8.5.2 Identification and traceability	7.5.3 Identification and traceability
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www.sae.org/iaqg/

NOTE: ETI Group has edited the original content in the tables above to add explanatory notes and additional sub-clauses. These additions are shown inside brackets with italic formatting as follows: *[ETI edit]*

*In the case of 8.5.6, the IAQG correlation matrix lists 7.3.7 as the corresponding Rev. C sub-clause. Since this clause refers to Product/Service Design and Development, ETI feels the correct correlation is 7.5.1.2, as shown in brackets.

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1.	**4 Context of the organization**		
2.	**4.1 Understanding the organization and its context**		
3.	The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.		
4.	The organization shall monitor and review information about these external and internal issues.		
5.	NOTE 1 Issues can include positive and negative factors or conditions for consideration.		
6.	NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.		
7.	NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.		
8.	**4.2 Understanding the needs and expectations of interested parties**		
9.	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:		
10.	a) the interested parties that are relevant to the quality management system;		
11.	b) the requirements of these interested parties that are relevant to the quality management system.		
12.	The organization shall monitor and review information about these interested parties and their relevant requirements.		
13.	**4.3 Determining the scope of the quality management system**		
14.	The organization shall determine the boundaries and applicability of the quality management system to establish its scope.		

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15.	When determining this scope, the organization shall consider:		
16.	a) the external and internal issues referred to in 4.1;		
17.	b) the requirements of relevant interested parties referred to in 4.2;		
18.	c) the products and services of the organization.		
19.	The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.		
20.	The scope of the organization's quality management system shall be available and be maintained as documented information.		
21.	The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.		
22.	Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.		
23.	**4.4 Quality management system and its processes**		
24.	**4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Std.		
25.	***The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.***		
26.	The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:		
27.	a) determine the inputs required and the outputs expected from these processes;		
28.	b) determine the sequence and interaction of these processes;		
29.	c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;		

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30.	d) determine the resources needed for these processes and ensure their availability;		
31.	e) assign the responsibilities and authorities for these processes;		
32.	f) address the risks and opportunities as determined in accordance with the requirements of 6.1;		
33.	g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;		
34.	h) improve the processes and the quality management system.		
35.	**4.4.2** To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes;		
36.	b) retain documented information to have confidence that the processes are being carried out as planned.		
37.	***The organization shall establish and maintain documented information that includes:*** ***– a general description of relevant interested parties (see 4.2 a);***		
38.	***– the scope of the quality management system, including boundaries and applicability (see 4.3);***		
39.	***– a description of the processes needed for the quality management system and their application throughout the organization;***		
40.	***– the sequence and interaction of these processes;***		
41.	***– assignment of the responsibilities and authorities for these processes.***		
42.	***NOTE: 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.***		
43.	**5 Leadership**		
44.	**5.1 Leadership and commitment**		

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45.	**5.1.1 General**		
46.	Top management shall demonstrate leadership and commitment with respect to the quality management system by:		
47.	a) taking accountability for the effectiveness of the quality management system;		
48.	b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;		
49.	c) ensuring the integration of the quality management system requirements into the organization's business processes;		
50.	d) promoting the use of the process approach and risk-based thinking;		
51.	e) ensuring that the resources needed for the quality management system are available;		
52.	f) communicating the importance of effective quality management and of conforming to the quality management system requirements;		
53.	g) ensuring that the quality management system achieves its intended results;		
54.	h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;		
55.	i) promoting improvement;		
56.	j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.		
57.	NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.		
58.	**5.1.2 Customer focus**		
59.	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:		

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60.	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;		
61.	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;		
62.	c) the focus on enhancing customer satisfaction is maintained.		
63.	d) ***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.***		
64.	**5.2 Policy**		
65.	**5.2.1 Establishing the quality policy**		
66.	Top management shall establish, implement and maintain a quality policy that:		
67.	a) is appropriate to the purpose and context of the organization and supports its strategic direction;		
68.	b) provides a framework for setting quality objectives;		
69.	c) includes a commitment to satisfy applicable requirements;		
70.	d) includes a commitment to continual improvement of the quality management system.		
71.	**5.2.2 Communicating the quality policy**		
72.	The quality policy shall:		
73.	a) be available and be maintained as documented information;		
74.	b) be communicated, understood and applied within the organization;		
75.	c) be available to relevant interested parties, as appropriate.		
76.	**5.3 Organizational roles, responsibilities and authorities**		
77.	Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.		

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78.	Top management shall assign the responsibility and authority for:		
79.	a) ensuring that the quality management system conforms to the requirements of this International Standard;		
80.	b) ensuring that the processes are delivering their intended outputs;		
81.	c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;		
82.	d) ensuring the promotion of customer focus throughout the organization;		
83.	e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.		
84.	***Top management shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.***		
85.	***The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.***		
86.	***NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.***		
87.	**6 Planning**		
88.	**6.1 Actions to address risks and opportunities**		
89.	**6.1.1** When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:		
90.	a) give assurance that the quality management system can achieve its intended result(s);		
91.	b) enhance desirable effects;		
92.	c) prevent, or reduce, undesired effects;		

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93.	d) achieve improvement.		
94.	**6.1.2** The organization shall plan:		
95.	a) actions to address these risks and opportunities;		
96.	b) how to:		
97.	1) integrate and implement the actions into its quality management system processes (see 4.4);		
98.	2) evaluate the effectiveness of these actions.		
99.	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.		
100.	NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.		
101.	NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.		
102.	**6.2 Quality objectives and planning to achieve them**		
103.	**6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.		
104.	The quality objectives shall:		
105.	a) be consistent with the quality policy;		
106.	b) be measurable;		
107.	c) take into account applicable requirements;		
108.	d) be relevant to conformity of products and services and to enhancement of customer satisfaction;		
109.	e) be monitored;		

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110.	f) be communicated;		
111.	g) be updated as appropriate.		
112.	The organization shall maintain documented information on the quality objectives.		
113.	**6.2.2** When planning how to achieve its quality objectives, the organization shall determine: a) what will be done;		
114.	b) what resources will be required;		
115.	c) who will be responsible;		
116.	d) when it will be completed;		
117.	e) how the results will be evaluated.		
118.	**6.3 Planning of changes**		
119.	When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).		
120.	The organization shall consider:		
121.	a) the purpose of the changes and their potential consequences;		
122.	b) the integrity of the quality management system;		
123.	c) the availability of resources;		
124.	d) the allocation or reallocation of responsibilities and authorities.		
125.	**7 Support**		
126.	**7.1 Resources**		
127.	**7.1.1 General**		
128.	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.		

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129.	The organization shall consider:		
130.	a) the capabilities of, and constraints on, existing internal resources;		
131.	b) what needs to be obtained from external providers.		
132.	**7.1.2 People**		
133.	The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.		
134.	**7.1.3 Infrastructure**		
135.	The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.		
136.	NOTE Infrastructure can include:		
137.	a) buildings and associated utilities;		
138.	b) equipment, including hardware and software;		
139.	c) transportation resources;		
140.	d) information and communication technology.		
141.	**7.1.4 Environment for the operation of processes**		
142.	The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.		
143.	NOTE A suitable environment can be a combination of human and physical factors, such as:		
144.	a) social (e.g. non-discriminatory, calm, non-confrontational);		
145.	b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);		
146.	c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).		
147.	These factors can differ substantially depending on the products and services provided.		

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148.	**7.1.5 Monitoring and measuring resources**		
149.	**7.1.5.1 General**		
150.	The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.		
151.	The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken;		
152.	b) are maintained to ensure their continuing fitness for their purpose.		
153.	The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.		
154.	**7.1.5.2 Measurement traceability**		
155.	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:		
156.	a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;		
157.	b) identified in order to determine their status;		
158.	c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.		
159.	***The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.***		
160.	***The organization shall maintain a register of the monitoring and measuring equipment.***		

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161.	***The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.***		
162.	***NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.***		
163.	***Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).***		
164.	The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose,		
165.	and shall take appropriate action as necessary.		
166.	**7.1.6 Organizational knowledge**		
167.	The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.		
168.	This knowledge shall be maintained and be made available to the extent necessary.		
169.	When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.		
170.	NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.		
171.	NOTE 2 Organizational knowledge can be based on:		
172.	a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);		

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173.	b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).		
174.	**7.2 Competence**		
175.	The organization shall:		
176.	a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;		
177.	b) ensure that these persons are competent on the basis of appropriate education, training, or experience;		
178.	c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;		
179.	d) retain appropriate documented information as evidence of competence.		
180.	NOTE: Consideration should be given for the periodic review of the necessary competence.		
181.	NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.		
182.	**7.3 Awareness**		
183.	The organization shall ensure that persons doing work under the organization's control are aware of:		
184.	a) the quality policy;		
185.	b) relevant quality objectives;		
186.	c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;		
187.	d) the implications of not conforming with the quality management system requirements.		

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188.	e) ***relevant quality management system documented information and changes thereto;***		
189.	f) ***their contribution to product or service conformity;***		
190.	g) ***their contribution to product safety;***		
191.	h) ***the importance of ethical behavior.***		
192.	**7.4 Communication**		
193.	The organization shall determine the internal and external communications relevant to the quality management system, including:		
194.	a) on what it will communicate;		
195.	b) when to communicate;		
196.	c) with whom to communicate;		
197.	d) how to communicate;		
198.	e) who communicates.		
199.	***NOTE: Communication should include internal and external feedback relevant to the quality management system.***		
200.	**7.5 Documented information**		
201.	**7.5.1 General**		
202.	The organization's quality management system shall include: a) documented information required by this International Standard;		
203.	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.		
204.	NOTE The extent of documented information for a quality management system can differ from one organization to another due to:		
205.	— the size of organization and its type of activities, processes, products and services;		

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206.	— the complexity of processes and their interactions;		
207.	— the competence of persons.		
208.	**7.5.2 Creating and updating**		
209.	When creating and updating documented information, the organization shall ensure appropriate:		
210.	a) identification and description (e.g. a title, date, author, or reference number);		
211.	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);		
212.	c) review and approval for suitability and adequacy.		
213.	***NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.***		
214.	**7.5.3 Control of documented information**		
215.	**7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure:		
216.	a) it is available and suitable for use, where and when it is needed;		
217.	b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).		
218.	**7.5.3.2** For the control of documented information, the organization shall address the following activities, as applicable:		
219.	a) distribution, access, retrieval and use;		
220.	b) storage and preservation, including preservation of legibility;		
221.	c) control of changes (e.g. version control);		
222.	d) retention and disposition.		

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223.	*e)* ***prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.***		
224.	Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.		
225.	Documented information retained as evidence of conformity shall be protected from unintended alterations.		
226.	***When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).***		
227.	NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.		
228.	**8 Operation**		
229.	**8.1 Operational planning and control**		
230.	The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:		
231.	a) determining the requirements for the products and services;		
232.	***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;***		

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	– ***prevention, detection, and removal of foreign objects;*** – ***handling, packaging, and preservation;*** – ***recycling or final disposal of the product at the end of its life.***		
233.	b) establishing criteria for: 1) the processes;		
234.	2) the acceptance of products and services;		
235.	***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.***		
236.	c) determining the resources needed to achieve conformity to the product and service requirements ***and to meet on-time delivery of products and services***;		
237.	d) implementing control of the processes in accordance with the criteria;		
238.	e) determining, maintaining and retaining documented information to the extent necessary:		
239.	1) to have confidence that the processes have been carried out as planned;		
240.	2) to demonstrate the conformity of products and services to their requirements.		
241.	*f)* ***determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;***		

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242.	*g)* ***engaging representatives of affected organization functions for operational planning and control;***		
243.	*h)* ***determining the process and resources to support the use and maintenance of the products and services;***		
244.	*i)* ***determining the products and services to be obtained from external providers;***		
245.	*j)* ***establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.***		
246.	***NOTE: One method to achieve operational planning and control can be through using integrated phased processes.***		
247.	***As appropriate to the organization, customer requirements, and products and services, the organization shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.***		
248.	***NOTE: This activity is generally referred to as project planning, project management, or program management.***		
249.	The output of this planning shall be suitable for the organization's operations.		
250.	***NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.***		
251.	The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.		
252.	The organization shall ensure that outsourced processes are controlled (see 8.4).		
253.	***The organization shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements.***		

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254.	***The process shall ensure that work transfer impacts and risks are managed.***		
255.	***NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.***		
256.	***8.1.1 Operational Risk Management***		
257.	***The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:***		
258.	*a)* ***assignment of responsibilities for operational risk management;***		
259.	*b)* ***definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);***		
260.	*c)* ***identification, assessment, and communication of risks throughout operations;***		
261.	*d)* ***identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;***		
262.	*e)* ***acceptance of risks remaining after implementation of mitigating actions.***		
263.	***NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).***		
264.	***NOTE 2: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.***		

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265.	***8.1.2 Configuration Management***		
266.	***The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:***		
267.	*a)* ***control product identity and traceability to requirements, including the implementation of identified changes;***		
268.	*b)* ***ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.***		
269.	***8.1.3 Product Safety***		
270.	***The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.***		
271.	***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.***		
272.	***8.1.4 Prevention of Counterfeit Parts***		
273.	***The organization shall plan, implement, and control 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.***		
274.	***NOTE: 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 externally provided product from original or authorized***		

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	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.***		
275.	**8.2 Requirements for products and services**		
276.	**8.2.1 Customer communication**		
277.	Communication with customers shall include: a) providing information relating to products and services;		
278.	b) handling enquiries, contracts or orders, including changes;		
279.	c) obtaining customer feedback relating to products and services, including customer complaints;		
280.	d) handling or controlling customer property;		
281.	e) establishing specific requirements for contingency actions, when relevant.		
282.	**8.2.2 Determining the requirements for products and services**		
283.	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including:		
284.	1) any applicable statutory and regulatory requirements;		
285.	2) those considered necessary by the organization;		
286.	b) the organization can meet the claims for the products and services it offers.		
287.	*c)* ***special requirements of the products and services are determined;***		
288.	*d)* ***operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.***		

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289.	**8.2.3 Review of the requirements for products and services**		
290.	**8.2.3.1** The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers.		
291.	The organization shall conduct a review before committing to supply products and services to a customer, to include:		
292.	a) requirements specified by the customer, including the requirements for delivery and post- delivery activities;		
293.	b) requirements not stated by the customer, but necessary for the specified or intended use, when known;		
294.	c) requirements specified by the organization;		
295.	d) statutory and regulatory requirements applicable to the products and services;		
296.	e) contract or order requirements differing from those previously expressed.		
297.	***This review shall be coordinated with applicable functions of the organization.***		
298.	***If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.***		
299.	The organization shall ensure that contract or order requirements differing from those previously defined are resolved.		
300.	The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.		
301.	NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.		

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302.	**8.2.3.2** The organization shall retain documented information, as applicable:		
303.	a) on the results of the review;		
304.	b) on any new requirements for the products and services.		
305.	**8.2.4 Changes to requirements for products and services**		
306.	The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.		
307.	**8.3 Design and development of products and services**		
308.	**8.3.1 General**		
309.	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.		
310.	**8.3.2 Design and development planning**		
311.	In determining the stages and controls for design and development, the organization shall consider:		
312.	a) the nature, duration and complexity of the design and development activities;		
313.	b) the required process stages, including applicable design and development reviews;		
314.	c) the required design and development verification and validation activities;		
315.	d) the responsibilities and authorities involved in the design and development process;		
316.	e) the internal and external resource needs for the design and development of products and services;		
317.	f) the need to control interfaces between persons involved in the design and development process;		

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318.	g) the need for involvement of customers and users in the design and development process;		
319.	h) the requirements for subsequent provision of products and services;		
320.	i) the level of control expected for the design and development process by customers and other relevant interested parties;		
321.	j) the documented information needed to demonstrate that design and development requirements have been met.		
322.	***When appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.***		
323.	***Design and development planning shall consider the ability to provide, verify, test and maintain products and services (reference output of 8.1a).***		
324.	**8.3.3 Design and development inputs**		
325.	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed.		
326.	The organization shall consider: a) functional and performance requirements;		
327.	b) information derived from previous similar design and development activities;		
328.	c) statutory and regulatory requirements;		
329.	d) standards or codes of practice that the organization has committed to implement;		
330.	e) potential consequences of failure due to the nature of the products and services.		
331.	*f)* ***when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products).***		
332.	Inputs shall be adequate for design and development purposes, complete and unambiguous.		
333.	Conflicting design and development inputs shall be resolved.		

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334.	The organization shall retain documented information on design and development inputs.		
335.	***NOTE: The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data.***		
336.	**8.3.4 Design and development controls**		
337.	The organization shall apply controls to the design and development process to ensure that:		
338.	a) the results to be achieved are defined;		
339.	b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;		
340.	c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;		
341.	d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;		
342.	e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;		
343.	f) documented information of these activities is retained.		
344.	*g)* ***progression to the next stage is authorized.***		
345.	***Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.***		
346.	NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.		

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347.	***8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:***		
348.	*a)* ***test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;***		
349.	*b)* ***test procedures describe the test methods to be used, how to perform the test, and how to record the results;***		
350.	*c)* ***the correct configuration of the test item is submitted for the test;***		
351.	*d)* ***the requirements of the test plan and the test procedures are observed;***		
352.	*e)* ***the acceptance criteria are met.***		
353.	***Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.***		
354.	***At the completion of design and development, the organization shall ensure 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.***		
355.	**8.3.5 Design and development outputs**		
356.	The organization shall ensure that design and development outputs:		
357.	a) meet the input requirements;		
358.	b) are adequate for the subsequent processes for the provision of products and services;		
359.	c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;		
360.	d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.		

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361.	*e)* ***specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;***		
362.	*f)* ***are approved by authorized person(s) prior to release.***		
363.	***The organization shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained.***		
364.	***NOTE: 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.***		
365.	The organization shall retain documented information on design and development outputs.		
366.	**8.3.6 Design and development changes**		
367.	The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.		
368.	***The organization shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.***		
369.	The organization shall retain documented information on:		
370.	a) design and development changes;		
371.	b) the results of reviews;		
372.	c) the authorization of the changes;		
373.	d) the actions taken to prevent adverse impacts.		

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374.	***Design and development changes shall be controlled in accordance with the configuration management process requirements.***		
375.	**8.4 Control of externally provided processes, products and services**		
376.	**8.4.1 General**		
377.	The organization shall ensure that externally provided processes, products and services conform to requirements.		
378.	***The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.***		
379.	***The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.***		
380.	***The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.***		
381.	***The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.***		
382.	The organization shall determine the controls to be applied to externally provided processes, products and services when:		
383.	a) products and services from external providers are intended for incorporation into the organization's own products and services;		
384.	b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;		
385.	c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.		

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386.	The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.		
387.	The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.		
388.	***NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.***		
389.	***8.4.1.1 The organization shall:*** ***a) define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;***		
390.	***b) maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);***		
391.	***c) periodically review external provider performance including process, product and service conformity, and on-time delivery performance;***		
392.	***d) define the necessary actions to take when dealing with external providers that do not meet requirements;***		
393.	***e) define the requirements for controlling documented information created by and/or retained by external providers.***		

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394.	**8.4.2 Type and extent of control**		
395.	The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.		
396.	The organization shall:		
397.	a) ensure that externally provided processes remain within the control of its quality management system;		
398.	b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;		
399.	c) take into consideration:		
400.	1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;		
401.	2) the effectiveness of the controls applied by the external provider;		
402.	*3)* ***the results of the periodic review of external provider performance (see 8.4.1.1 c);***		
403.	d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.		
404.	***Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization.***		
405.	***These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.***		
406.	***NOTE 1: 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 and to comply with all requirements.***		
407.	***NOTE 2: Verification activities can include:***		

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	– ***review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);*** – ***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.***		
408.	***When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.***		
409.	***When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined***		
410.	***and a register of delegations shall be maintained.***		
411.	***The organization shall periodically monitor the external provider's delegated verification activities.***		
412.	***When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements.***		
413.	***When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.***		
414.	**8.4.3 Information for external providers**		
415.	The organization shall ensure the adequacy of requirements prior to their communication to the external provider.		

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416.	The organization shall communicate to external providers its requirements for:		
417.	a) the processes, products and services to be provided ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);***		
418.	b) the approval of:		
419.	1) products and services;		
420.	2) methods, processes and equipment;		
421.	3) the release of products and services;		
422.	c) competence, including any required qualification of persons;		
423.	d) the external providers' interactions with the organization;		
424.	e) control and monitoring of the external providers' performance to be applied by the organization;		
425.	f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.		
426.	*g)* ***design and development control;***		
427.	*h)* ***special requirements, critical items, or key characteristics;***		
428.	*i)* ***test, inspection, and verification (including production process verification);***		
429.	*j)* ***the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;***		
430.	*k)* ***the need to:***		
431.	– ***implement a quality management system;***		
432.	– ***use customer-designated or approved external providers, including process sources (e.g., special processes);***		

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433.	– ***notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;***		
434.	– ***prevent the use of counterfeit parts (see 8.1.4);***		
435.	– ***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;***		
436.	– ***flow down to external providers applicable requirements including customer requirements;***		
437.	– ***provide test specimens for design approval, inspection/verification, investigation, or auditing;***		
438.	– ***retain documented information, including retention periods and disposition requirements;***		
439.	*l)* ***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;***		
440.	*m)* ***ensuring that persons are aware of:***		
441.	– ***their contribution to product or service conformity;***		
442.	– ***their contribution to product safety;***		
443.	– ***the importance of ethical behavior.***		
444.	**8.5 Production and service provision**		
445.	**8.5.1 Control of production and service provision**		
446.	The organization shall implement production and service provision under controlled conditions.		

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447.	Controlled conditions shall include, as applicable: a) the availability of documented information that defines:		
448.	1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;		
449.	2) the results to be achieved;		
450.	***NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts list, materials, and process specifications.***		
451.	***NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.***		
452.	b) the availability and use of suitable monitoring and measuring resources;		
453.	c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;		
454.	***1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:***		
455.	– ***criteria for acceptance and rejection;***		
456.	– ***where in the sequence verification operations are to be performed;***		
457.	– ***measurement results to be retained (at a minimum an indication of acceptance or rejection);***		
458.	– ***any specific monitoring and measurement equipment required and instructions associated with their use;***		

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459.	***2. 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).***		
460.	d) the use of suitable infrastructure and environment for the operation of processes;		
461.	***NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.***		
462.	e) the appointment of competent persons, including any required qualification;		
463.	f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;		
464.	***NOTE: These processes can be referred to as special processes (see 8.5.1.2).***		
465.	g) the implementation of actions to prevent human error;		
466.	h) the implementation of release, delivery and post-delivery activities.		
467.	*i)* ***the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);***		
468.	*j)* ***the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);***		
469.	*k)* ***the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;***		
470.	*l)* ***the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);***		
471.	*m)* ***the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;***		

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472.	*n)* ***the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;***		
473.	*o)* ***the provision for the prevention, detection, and removal of foreign objects;***		
474.	*p)* ***the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);***		
475.	*q)* ***the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.***		
476.	***8.5.1.1 Control of Equipment, Tools, and Software Programs***		
477.	***Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production***		
478.	***and shall be maintained.***		
479.	***Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.***		
480.	***8.5.1.2 Validation and Control of Special Processes***		
481.	***For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall establish arrangements for these processes including, as applicable:***		
482.	***a) definition of criteria for the review and approval of the processes;***		
483.	***b) determination of conditions to maintain the approval;***		
484.	***c) approval of facilities and equipment;***		
485.	***d) qualification of persons;***		

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486.	***e) use of specific methods and procedures for implementation and monitoring of the processes;***		
487.	***f) requirements for documented information to be retained.***		
488.	***8.5.1.3 Production Process Verification***		
489.	***The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.***		
490.	***NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.***		
491.	***The organization shall use 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.***		
492.	***This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).***		
493.	***NOTE: This activity can be referred to as First Article Inspection (FAI).***		
494.	***The organization shall retain documented information on the results of production process verification.***		
495.	**8.5.2 Identification and traceability**		
496.	The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.		
497.	***The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.***		
498.	The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.		

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499.	***When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.***		
500.	The organization shall control the unique identification of the outputs when traceability is a requirement,		
501.	and shall retain the documented information necessary to enable traceability.		
502.	***NOTE: Traceability requirements can include:*** – ***the identification to be 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 (manufacture, assembly, inspection/verification) to be retrievable.***		
503.	**8.5.3 Property belonging to customers or external providers**		
504.	The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.		
505.	The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.		
506.	When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider		
507.	and retain documented information on what has occurred.		
508.	NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.		
509.	**8.5.4 Preservation**		

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510.	The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.		
511.	NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.		
512.	***Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:***		
513.	***a) cleaning;***		
514.	***b) prevention, detection, and removal of foreign objects;***		
515.	***c) special handling and storage for sensitive products;***		
516.	***d) marking and labeling, including safety warnings and cautions;***		
517.	***e) shelf life control and stock rotation;***		
518.	***f) special handling and storage for hazardous materials.***		
519.	**8.5.5 Post-delivery activities**		
520.	The organization shall meet requirements for post-delivery activities associated with the products and services.		
521.	In determining the extent of post-delivery activities that are required, the organization shall consider:		
522.	a) statutory and regulatory requirements;		
523.	b) the potential undesired consequences associated with its products and services;		
524.	c) the nature, use and intended lifetime of its products and services;		
525.	d) customer requirements;		
526.	e) customer feedback.		
527.	*f)* ***collection and analysis of in-service data (e.g., performance, reliability, lessons learned);***		

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528.	*g)* ***control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;***		
529.	*h)* ***controls required for work undertaken external to the organization (e.g., off- site work);***		
530.	*i)* ***product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).***		
531.	***When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.***		
532.	NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.		
533.	**8.5.6 Control of changes**		
534.	The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.		
535.	***Persons authorized to approve production or service provision changes shall be identified.***		
536.	***NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.***		
537.	The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.		
538.	**8.6 Release of products and services**		
539.	The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.		
540.	The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.		

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541.	The organization shall retain documented information on the release of products and services.		
542.	The documented information shall include: a) evidence of conformity with the acceptance criteria;		
543.	b) traceability to the person(s) authorizing the release.		
544.	***When required to demonstrate product qualification, the organization shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.***		
545.	***The organization shall ensure that all documented information required to accompany the products and services are present at delivery.***		
546.	**8.7 Control of nonconforming outputs**		
547.	**8.7.1** The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.		
548.	***NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.***		
549.	The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.		
550.	This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.		
551.	***The organization's nonconformity control process shall be maintained as documented information including the provisions for:***		
552.	– ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***		
553.	– ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***		

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554.	– ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***		
555.	– ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***		
556.	***NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.***		
557.	The organization shall deal with nonconforming outputs in one or more of the following ways:		
558.	a) correction;		
559.	b) segregation, containment, return or suspension of provision of products and services;		
560.	c) informing the customer;		
561.	d) obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer.***		
562.	***Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:***		
563.	– ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***		
564.	– ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements.***		
565.	***Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.***		
566.	***Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.***		

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567.	Conformity to the requirements shall be verified when nonconforming outputs are corrected.		
568.	**8.7.2** The organization shall retain documented information that:		
569.	a) describes the nonconformity;		
570.	b) describes the actions taken;		
571.	c) describes any concessions obtained;		
572.	d) identifies the authority deciding the action in respect of the nonconformity.		
573.	**9 Performance evaluation**		
574.	**9.1 Monitoring, measurement, analysis and evaluation**		
575.	**9.1.1 General**		
576.	The organization shall determine:		
577.	a) what needs to be monitored and measured;		
578.	b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;		
579.	c) when the monitoring and measuring shall be performed;		
580.	d) when the results from monitoring and measurement shall be analysed and evaluated.		
581.	The organization shall evaluate the performance and the effectiveness of the quality management system.		
582.	The organization shall retain appropriate documented information as evidence of the results.		
583.	**9.1.2 Customer satisfaction**		
584.	The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.		

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585.	The organization shall determine the methods for obtaining, monitoring and reviewing this information.		
586.	NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.		
587.	***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, and corrective action requests.***		
588.	***The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.***		
589.	**9.1.3 Analysis and evaluation**		
590.	The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.		
591.	***NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).***		
592.	The results of analysis shall be used to evaluate:		
593.	a) conformity of products and services;		
594.	b) the degree of customer satisfaction;		
595.	c) the performance and effectiveness of the quality management system;		
596.	d) if planning has been implemented effectively;		
597.	e) the effectiveness of actions taken to address risks and opportunities		
598.	f) the performance of external providers;		
599.	g) the need for improvements to the quality management system.		

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600.	NOTE Methods to analyse data can include statistical techniques.		
601.	**9.2 Internal audit**		
602.	**9.2.1** The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:		
603.	a) conforms to:		
604.	1) the organization's own requirements for its quality management system;		
605.	***NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements***		
606.	2) the requirements of this International Standard;		
607.	b) is effectively implemented and maintained.		
608.	***NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.***		
609.	**9.2.2** The organization shall:		
610.	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;		
611.	b) define the audit criteria and scope for each audit;		
612.	c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;		
613.	d) ensure that the results of the audits are reported to relevant management;		
614.	e) take appropriate correction and corrective actions without undue delay;		
615.	f) retain documented information as evidence of the implementation of the audit program and the audit results.		

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616.	NOTE See ISO 19011 for guidance.		
617.	**9.3 Management Review**		
618.	**9.3.1 General**		
619.	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.		
620.	**9.3.2 Management review inputs**		
621.	The management review shall be planned and carried out taking into consideration:		
622.	a) the status of actions from previous management reviews;		
623.	b) changes in external and internal issues that are relevant to the quality management system;		
624.	c) information on the performance and effectiveness of the quality management system, including trends in:		
625.	1) customer satisfaction and feedback from relevant interested parties;		
626.	2) the extent to which quality objectives have been met;		
627.	3) process performance and conformity of products and services;		
628.	4) nonconformities and corrective actions;		
629.	5) monitoring and measurement results;		
630.	6) audit results;		
631.	7) the performance of external providers;		
632.	*8)* ***on-time delivery performance;***		
633.	d) the adequacy of resources;		
634.	e) the effectiveness of actions taken to address risks and opportunities (see 6.1);		
635.	f) opportunities for improvement.		

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636.	**9.3.3 Management review outputs**		
637.	The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement;		
638.	b) any need for changes to the quality management system;		
639.	c) resource needs.		
640.	*d)* ***risks identified.***		
641.	The organization shall retain documented information as evidence of the results of management reviews.		
642.	**10 Improvement**		
643.	**10.1 General**		
644.	The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.		
645.	These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations;		
646.	b) correcting, preventing or reducing undesired effects;		
647.	c) improving the performance and effectiveness of the quality management system.		
648.	NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.		
649.	**10.2 Nonconformity and corrective action**		
650.	**10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall:		
651.	a) react to the nonconformity and, as applicable:		
652.	1) take action to control and correct it;		

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653.	2) deal with the consequences;		
654.	b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:		
655.	1) reviewing and analysing the nonconformity;		
656.	2) determining the causes of the nonconformity including***, as applicable, those related to human factors***;		
657.	3) determining if similar nonconformities exist, or could potentially occur;		
658.	c) implement any action needed;		
659.	d) review the effectiveness of any corrective action taken;		
660.	e) update risks and opportunities determined during planning, if necessary;		
661.	f) make changes to the quality management system, if necessary.		
662.	*g)* ***flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;***		
663.	*h)* ***take specific actions when timely and effective corrective actions are not achieved.***		
664.	Corrective actions shall be appropriate to the effects of the nonconformities encountered.		
665.	***The organization shall maintain documented information that defines the nonconformity and corrective action management processes.***		
666.	**10.2.2** The organization shall retain documented information as evidence of:		
667.	a) the nature of the nonconformities and any subsequent actions taken;		
668.	b) the results of any corrective action.		

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669.	**10.3 Continual improvement**		
670.	The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.		
671.	The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.		
672.	***The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.***		
673.	***NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.***		

TAB 4
Handouts