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

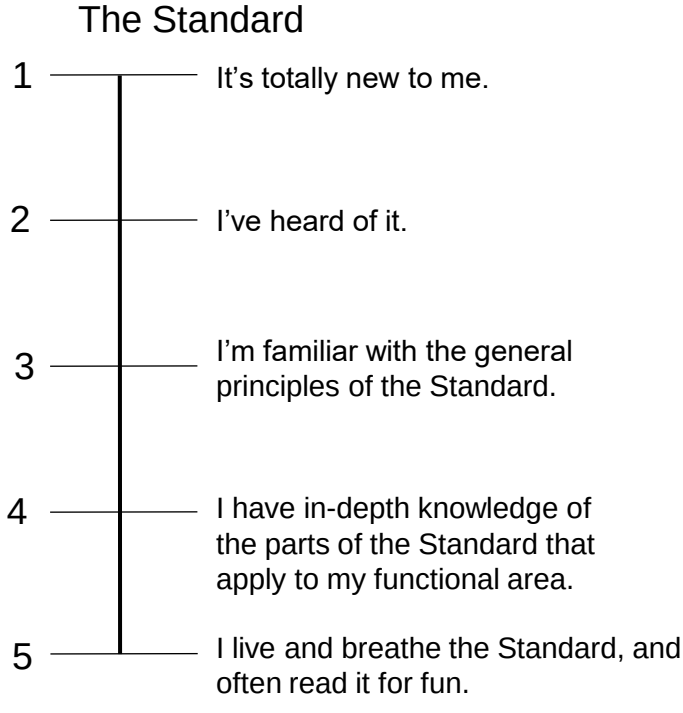
Payoff:

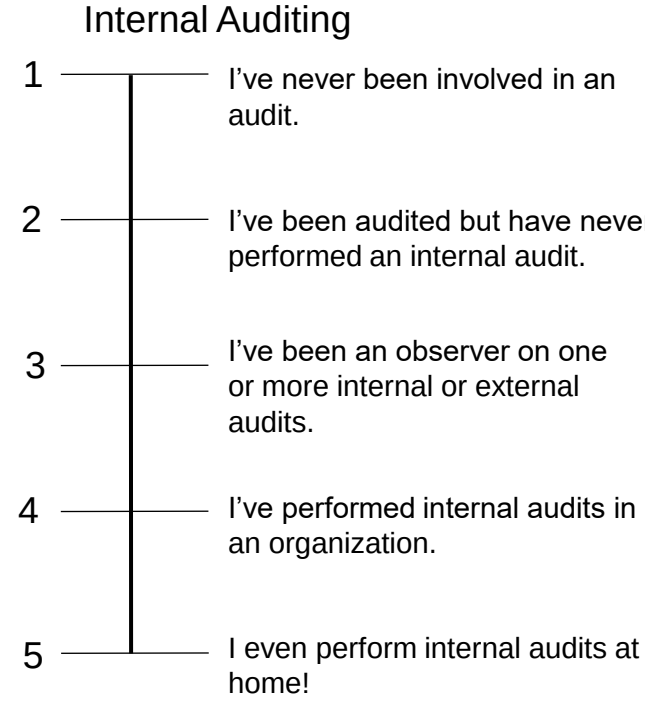
You will have a basic understanding of the tools and techniques used in performing internal audits. Practice will give you the experience!

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





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!

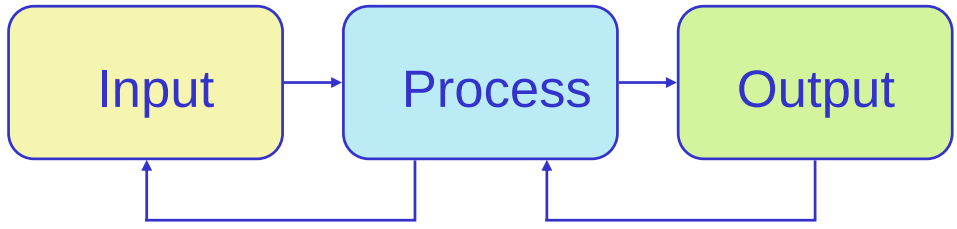
Everyone

Everywhere

Every time

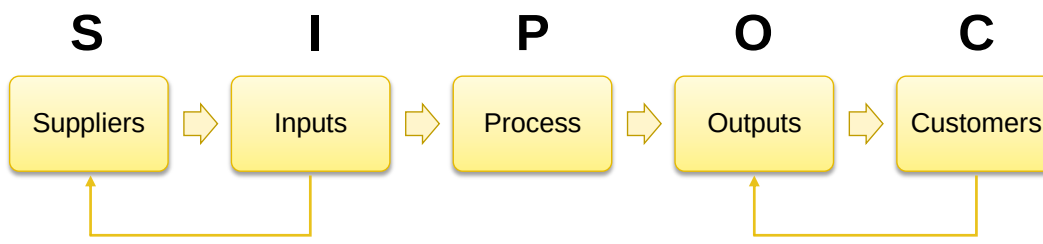
- Say what you'll do through the Quality Management System (QMS) documentation &/or training.
- Do what you say through disciplined use of the QMS.
- Prove it using Internal Audits (and External ones).
- Improve it using Corrective Action and Continual Improvement.

Simple Process Model



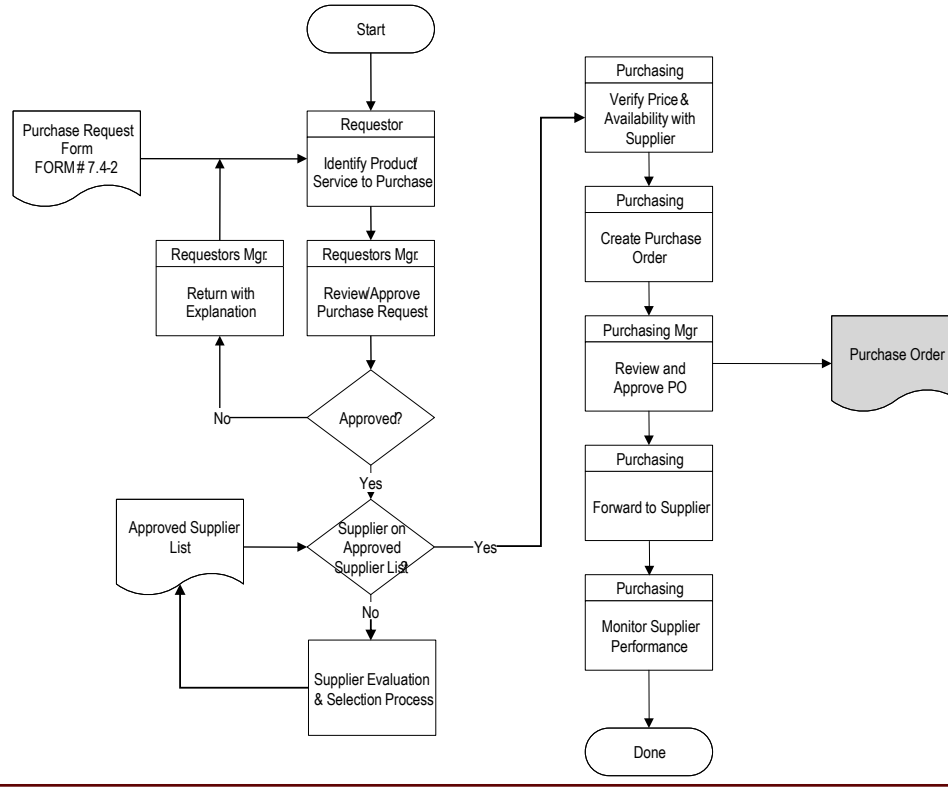
- Simply defined, a process is a set of related activities that convert inputs to outputs using resources.
- Monitors &/or measures for the process interfaces are represented by “feedback loops.”

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.

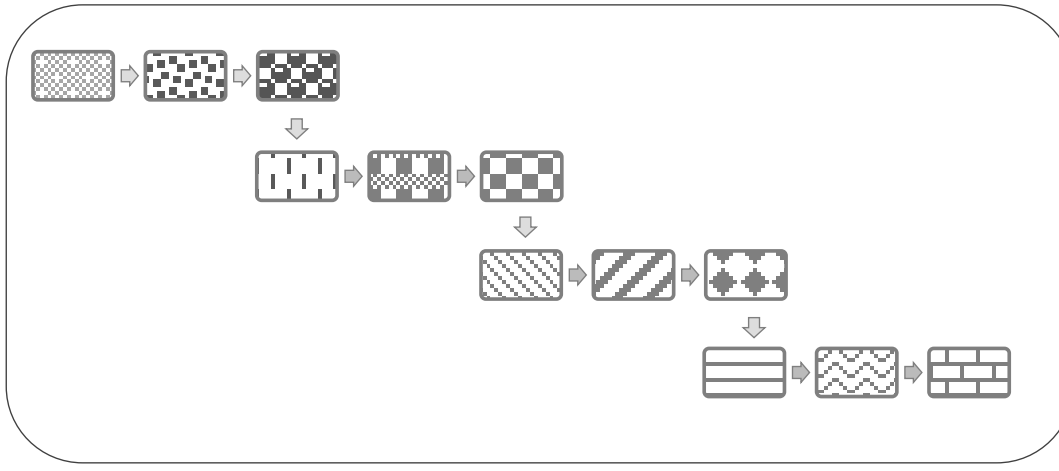
Process Flow Example



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).

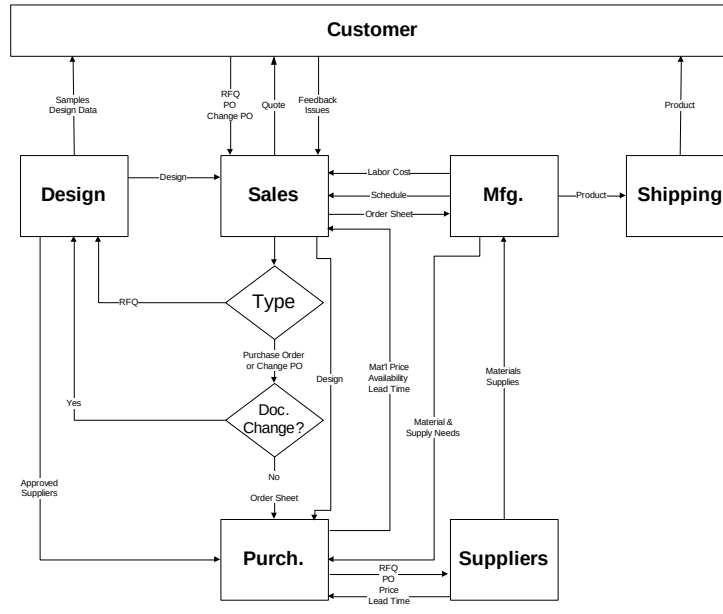
Process Interaction

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



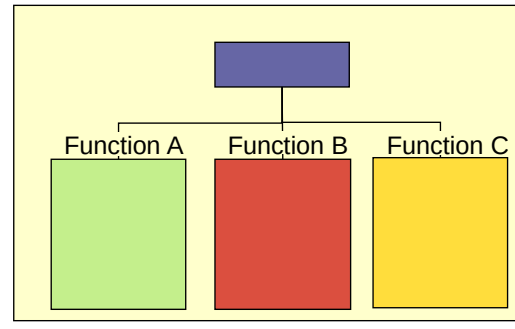
System Example

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

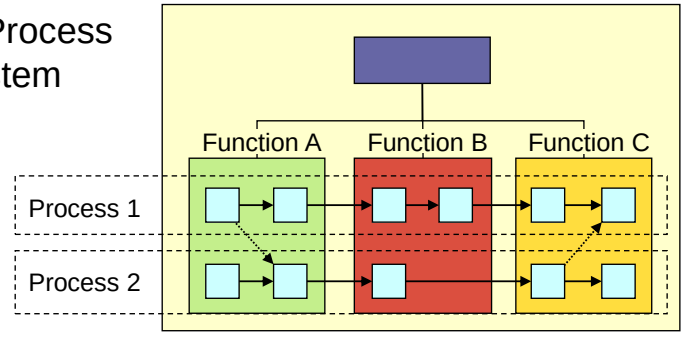


The Process Approach

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

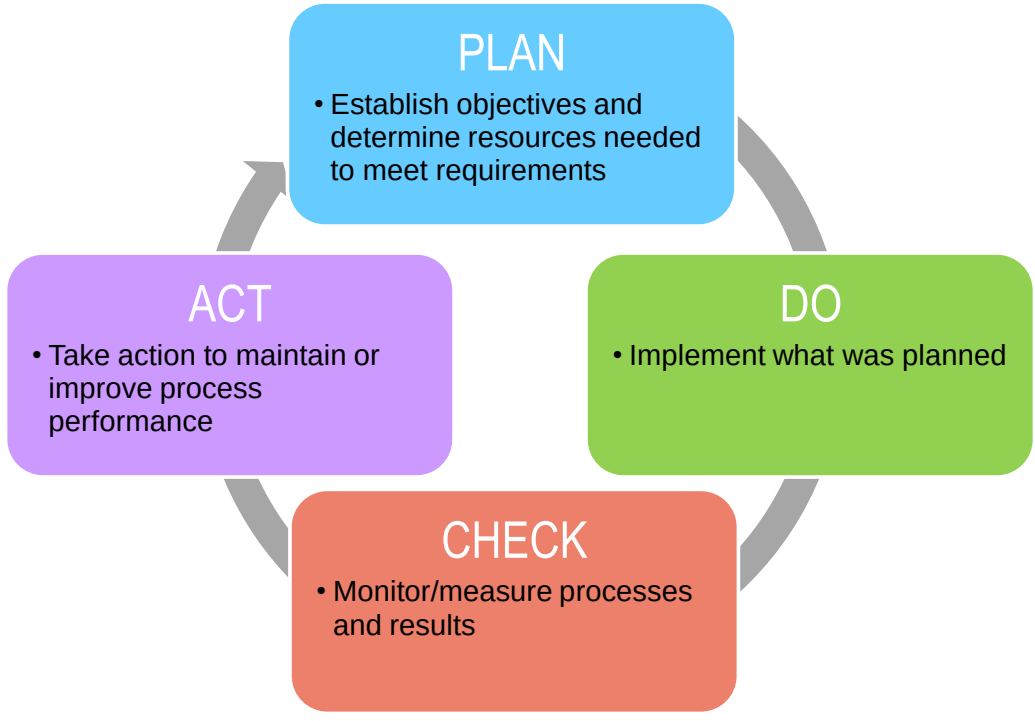
- A process approach may include the role of “Process Owner”
  - Person appointed by top management
  - Ensure total process is both effective and efficient
  - Does not replace functional organization, should support it
  - Roles and responsibilities
    - Monitor process performance and report to top 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

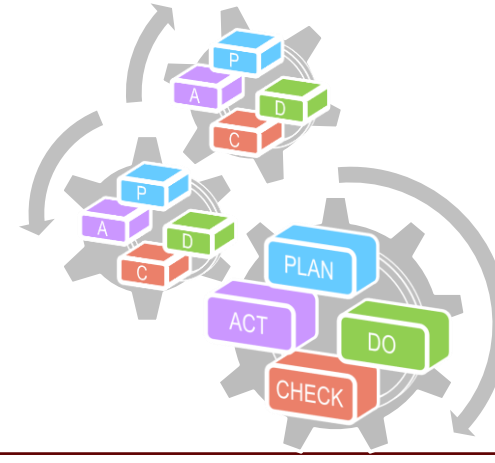


The Plan-Do-Check-Act cycle has been in use since the 1930's as a framework for problem solving and process improvement. In its original use, "Plan" involves defining the problem, "Do" is developing a solution, "Check" is analyzing results to verify that the problem is solved, and depending on whether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



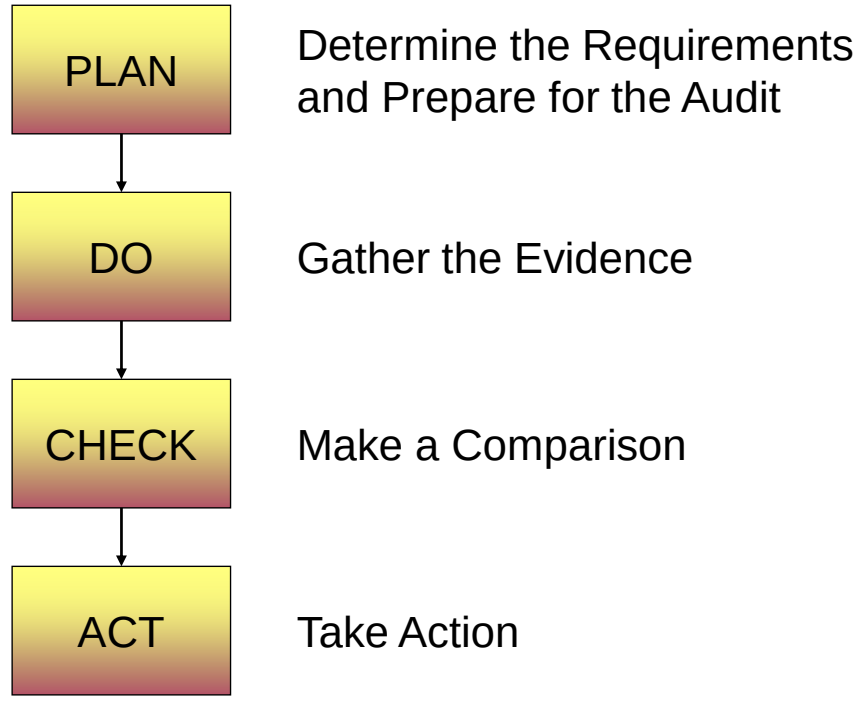
Introduction to
Quality Management System Auditing

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*

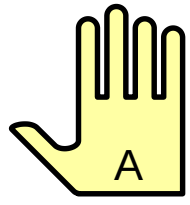
The Four Phases of Auditing



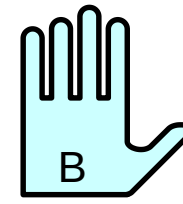
An important outcome of the Plan phase is a thorough understanding of the requirements by the auditor. This knowledge will then aid the auditor as the evidence is gathered in the Do phase, and conclusions are drawn about conformity in the Check phase.

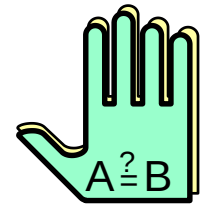
An Auditing Formula

A = What Should Be



B = What Is





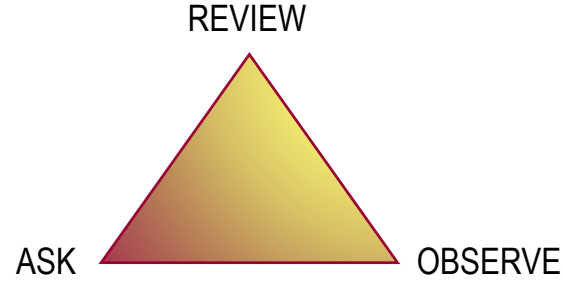
If A = B ⇨ Conformity

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:

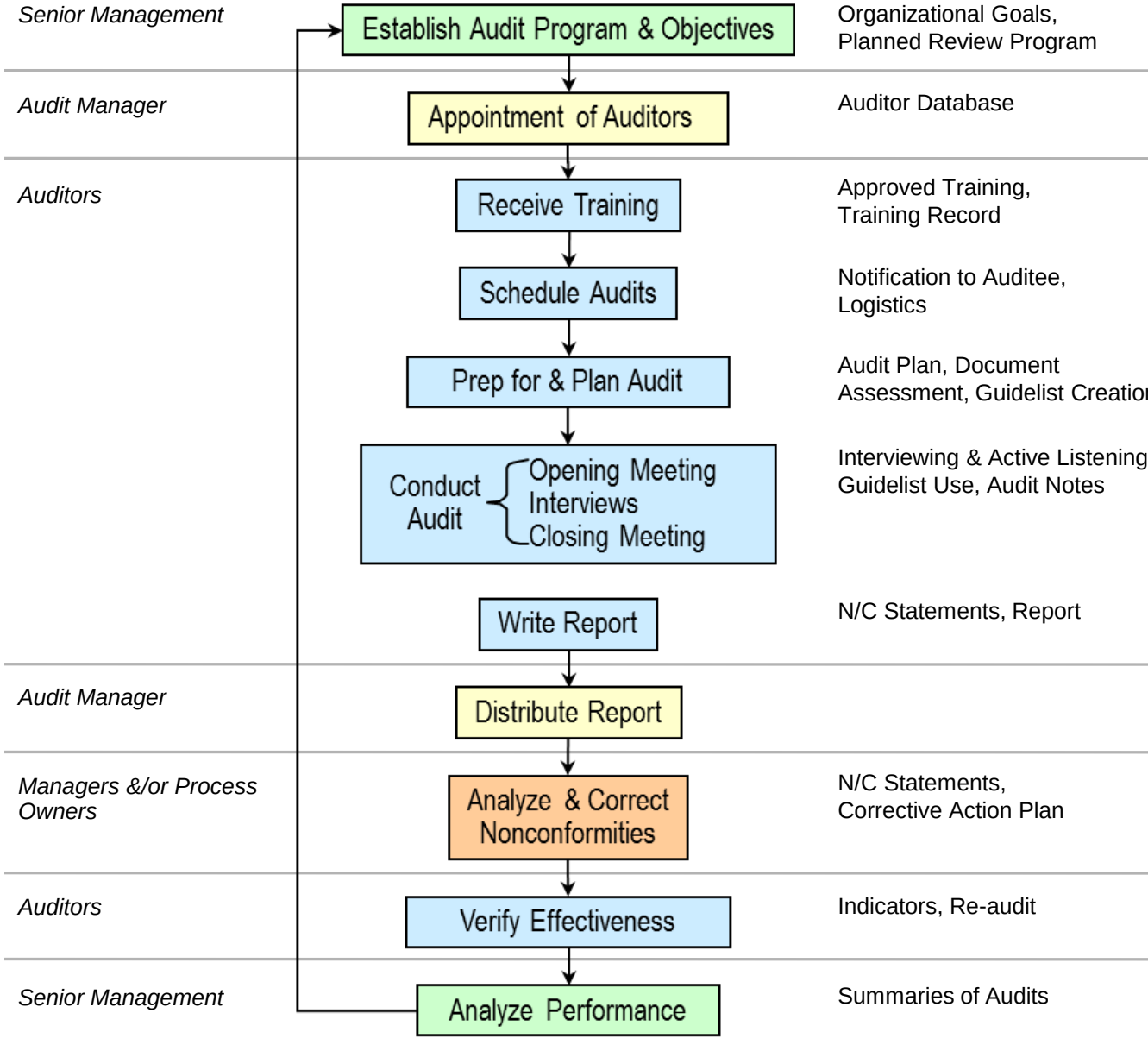
- Plans (procedures) exist and comply with requirements.
- Specifications are being met.
- Procedures are adequate and are followed.
- Data system provides appropriate, accurate information on quality.
- Deficiencies are identified and corrected.
- Improvement opportunities are identified and brought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

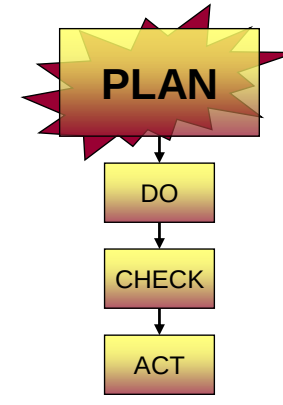
WHO does **WHAT** and **HOW**



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.

AS9100 Objectives

Objectives

- Establish commonality of aviation, space and defense quality systems, "as documented" and "as applied"
- Establish and implement a process of continual improvement to bring initiatives to life
- Establish methods to share best practices in the aviation, space and defense industry
- Coordinate initiatives and activities with regulatory/government agencies and other industry Stakeholders

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.

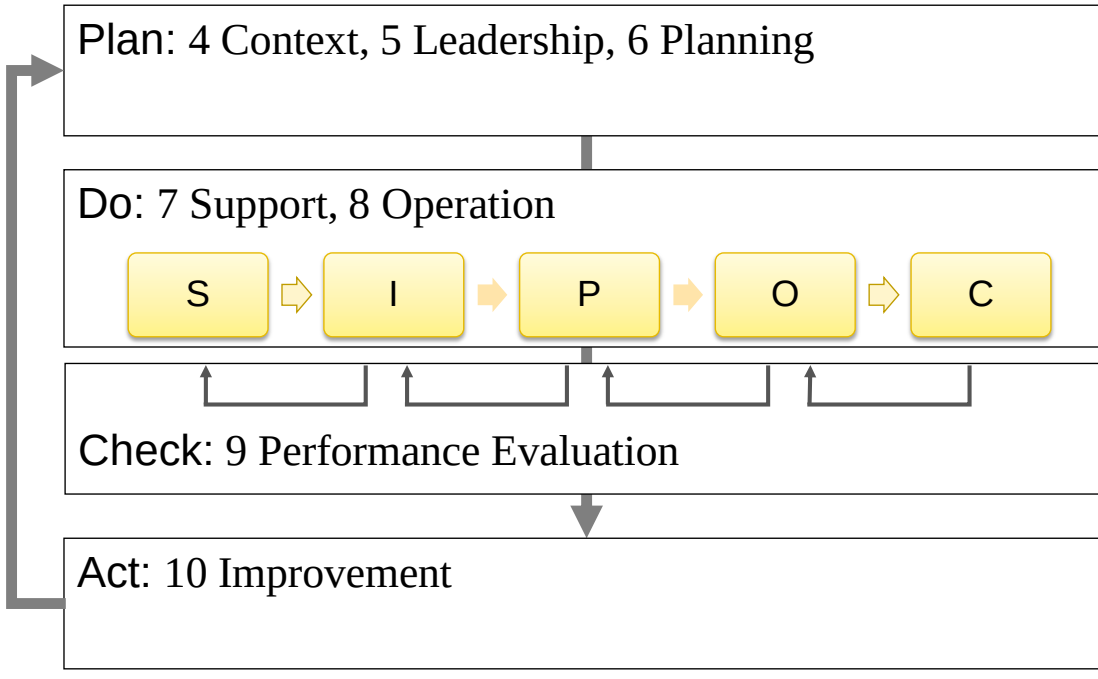
AS9100 Differences from ISO 9001

- 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.

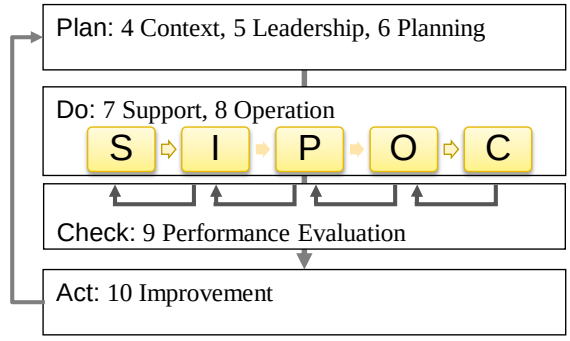
CHECK

- 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

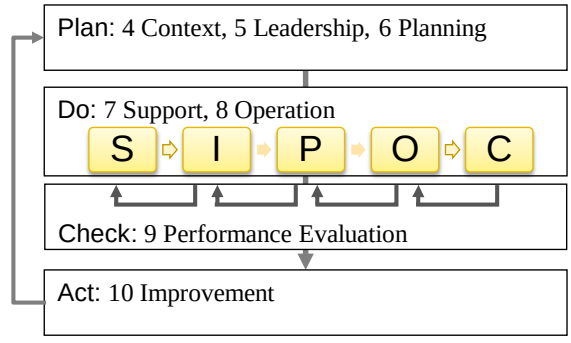
Beginning with this slide, and continuing through this section, refer to the "Detailed Outline of Headings" for the Standard, provided in the 3rd tab titled "Reference Materials."

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

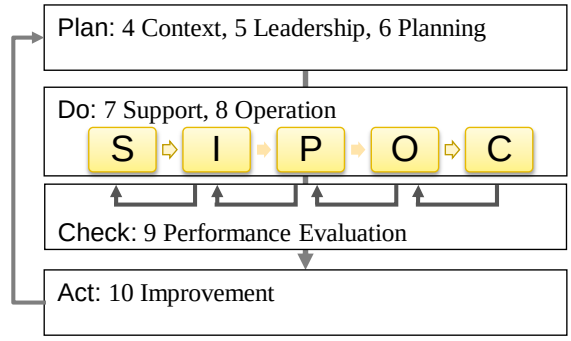
- 5.2.1 Establishing the Quality Policy
- 5.2.2 Communicating the Quality Policy

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

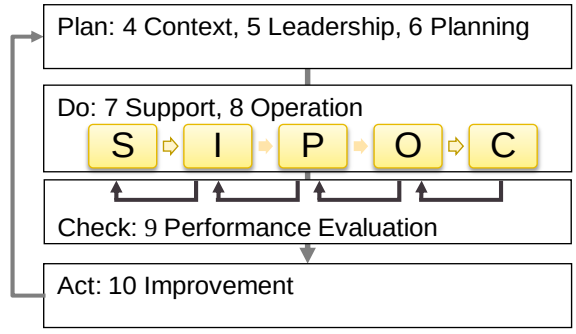
6.3 Planning of changes

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

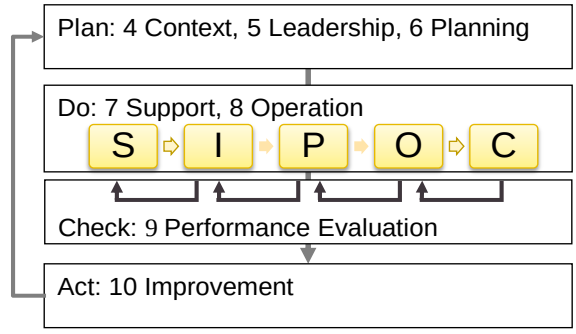


7.1 Resources

- 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

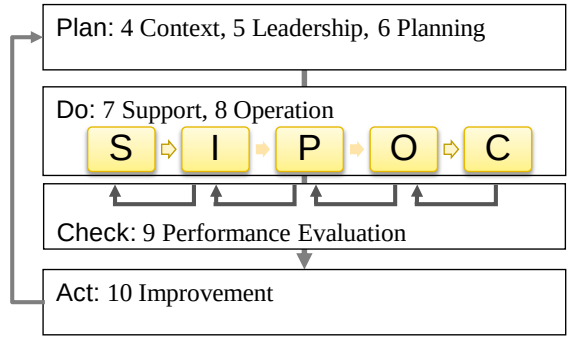


7.1 Resources, *continued*

- 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

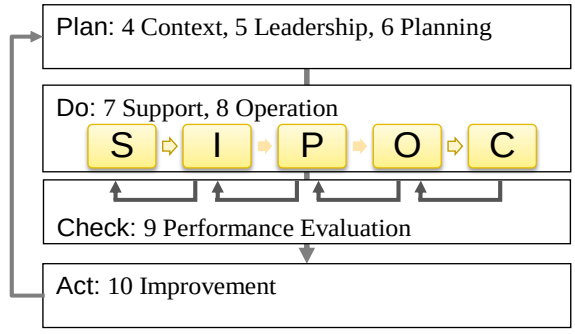
7.3 Awareness

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

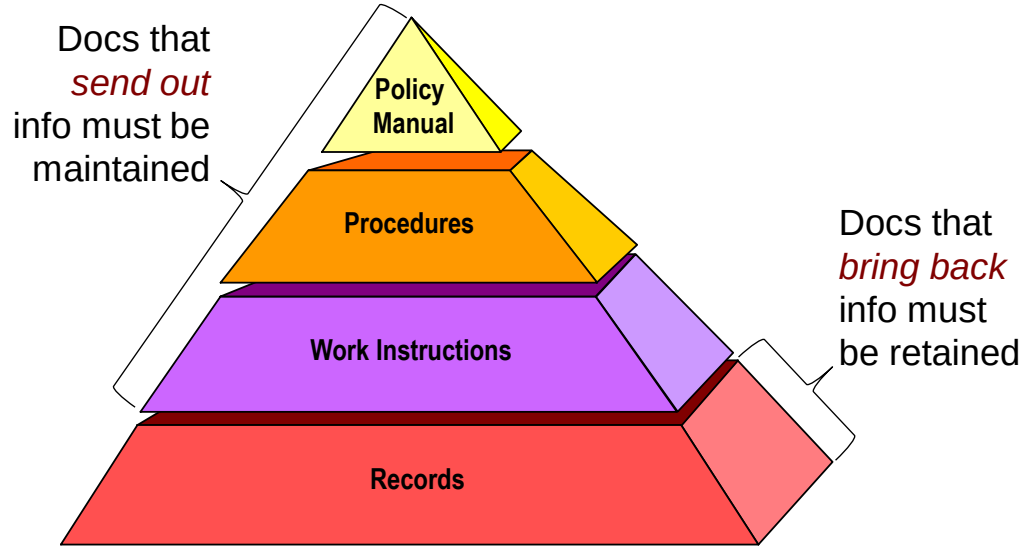


7.5 Documented information

- 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."*

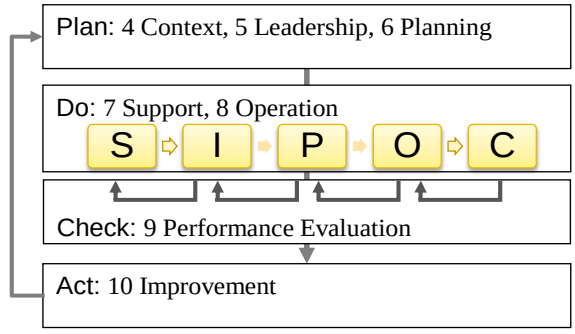
Work Instructions

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



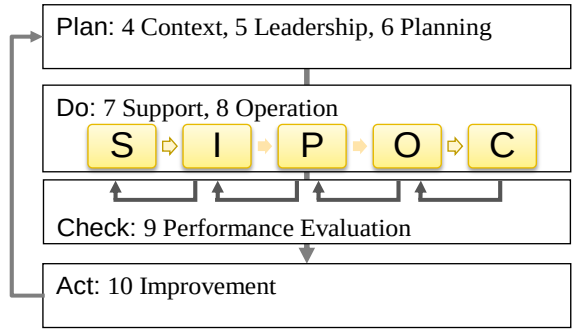
8.1 Operational planning and control

- 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

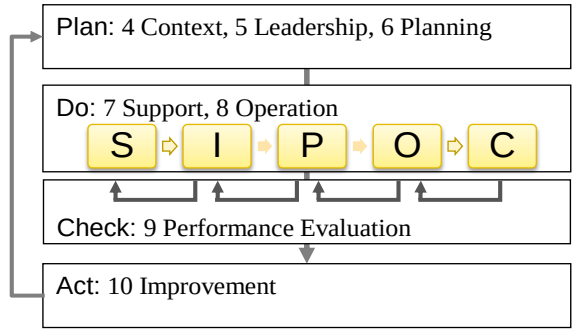


8.2 Requirements for products and services

- 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

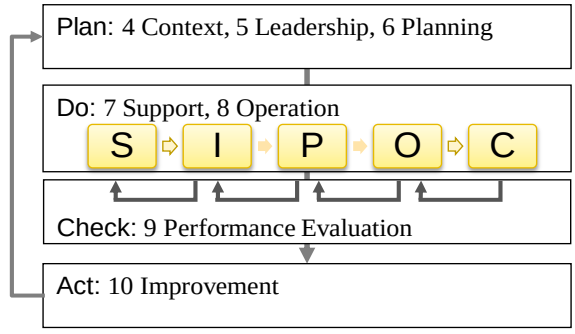


8.3 Design and development (D & D) of products and services

- 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

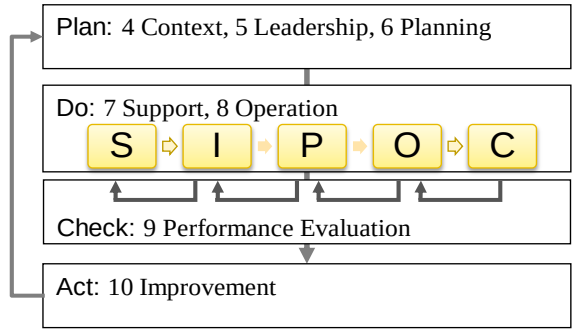


8.4 Control of externally provided processes, products and services

- 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

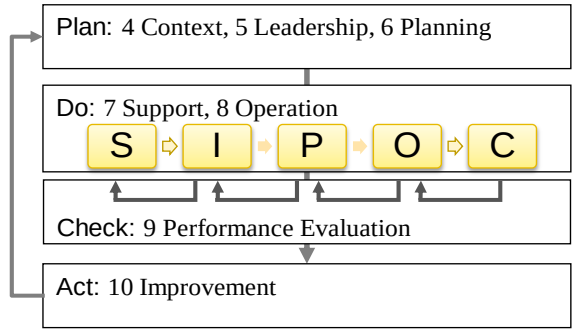


8.5 Production and service provision

- 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



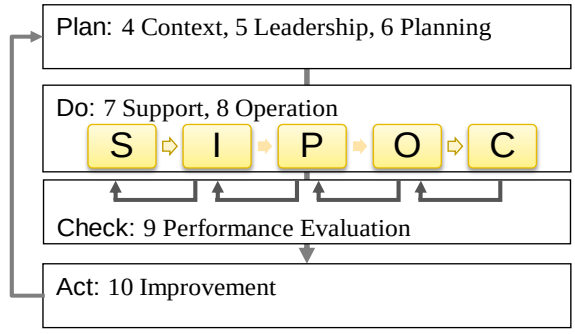
8.5 Production and service provision, *continued*

- 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



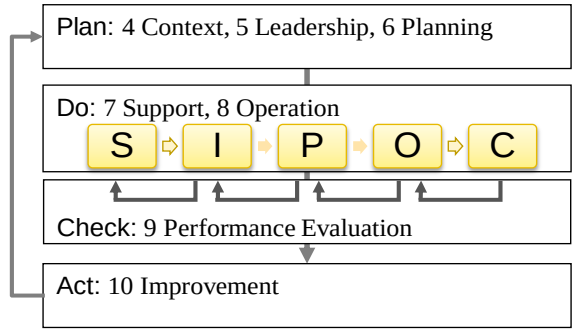
8.6 Release of products and services

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

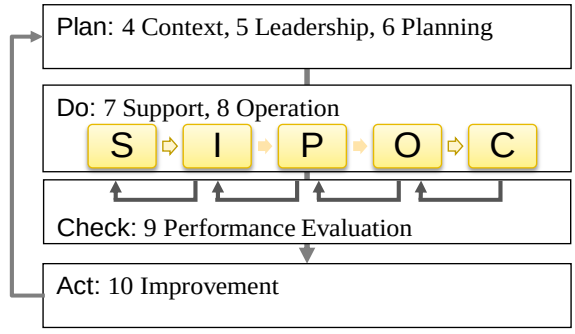
- Develop and maintain an audit program including frequency, methods, responsibilities, planning requirements and reporting
- Take into consideration:
  - importance of processes under audit
  - changes affecting the organization
  - results of previous audits
- Define each audit’s criteria and scope
- 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

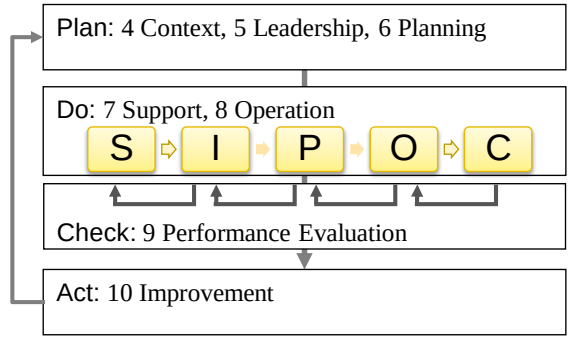
9.3.2 Management Review Inputs

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

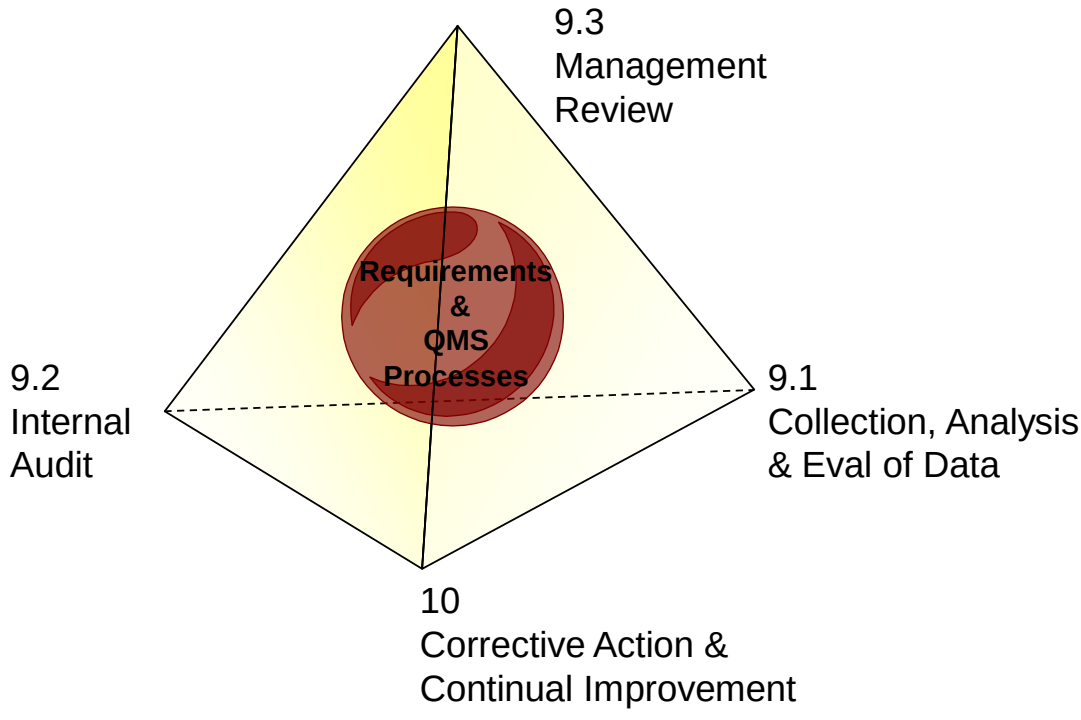
10.3 Continual improvement

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?

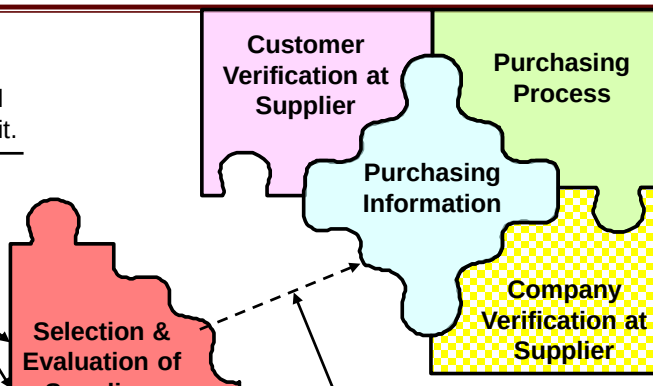
Determining the Purpose

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

Scope: The "piece" of the total process or set of requirements that will be the focus of this audit.



Determine the supporting requirements and look for those also.

Stay in the scope, unless there is a significant issue — then follow the lead to determine its effect on the process.

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

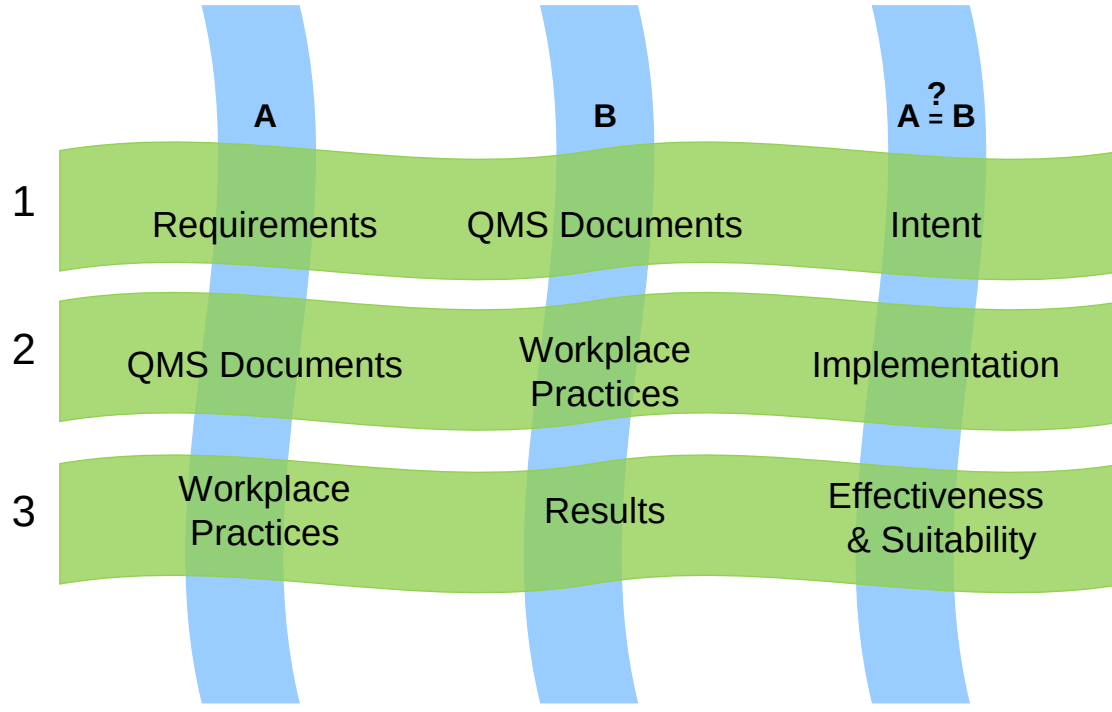
Schedule:

• 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

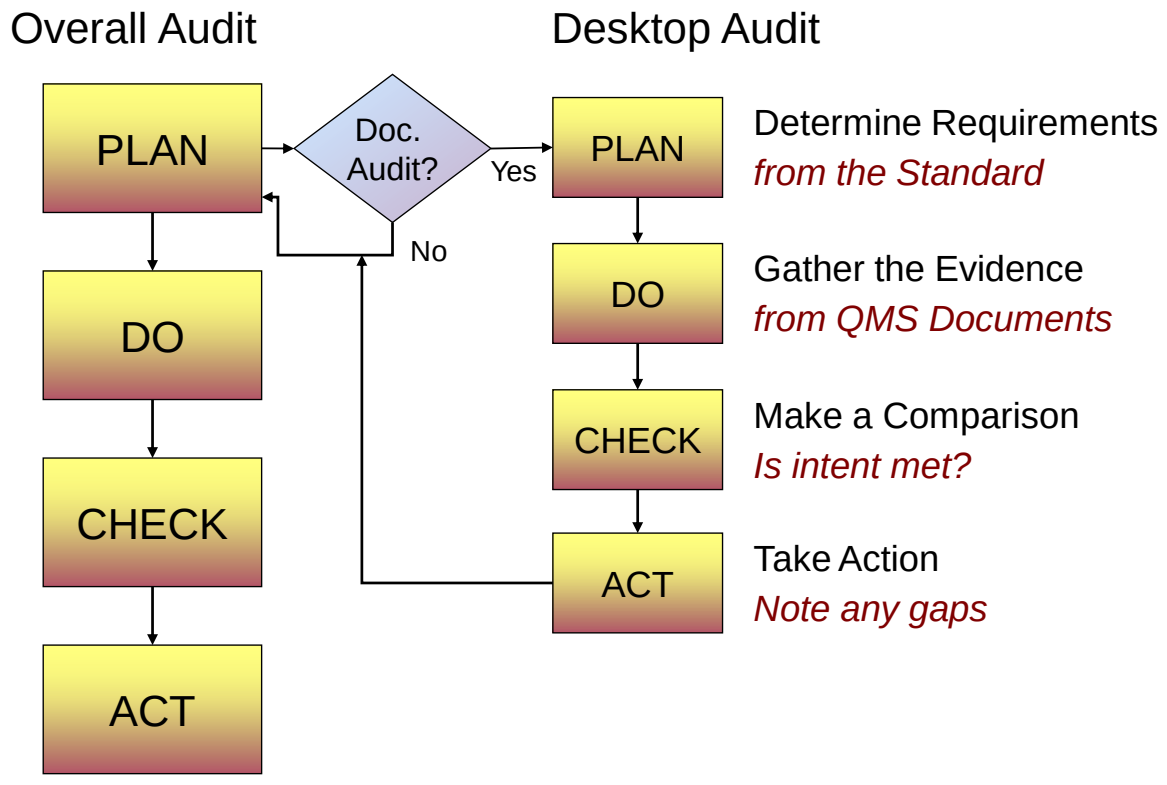


While the fundamental "A=B" comparison process is the same, the two things being compared will vary.

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.

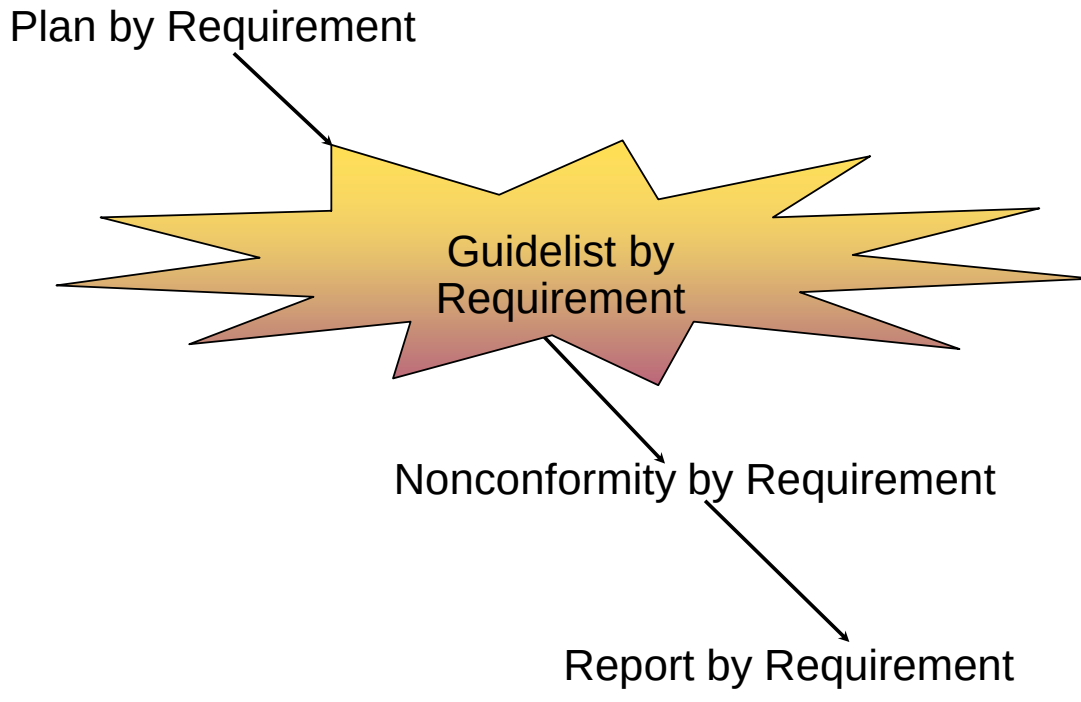
In this workshop we will use a checklist created from an external Quality Standard.

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

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?

Guidelists

Benefits

- Keep objectives clear
- Maintain audit pace
- Reduce auditor's workload
- Record and track audit samples
- Less likely to miss important items

Only a reminder!

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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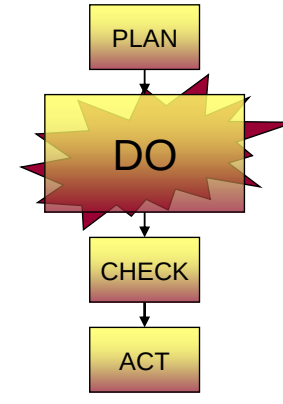
DO: Gather the Evidence

"What Is"



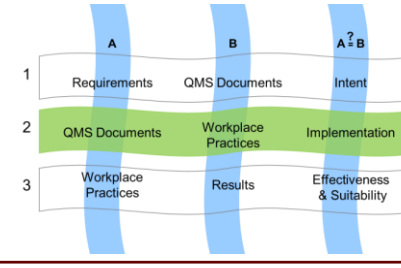
Audit Role Play

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

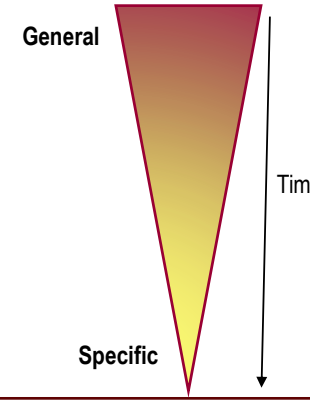
- Closed Questions
  - Elicit Yes or No answers
  - Can be useful if that is what you want
- Other useful types
  - Silent question
  - Obvious question
  - Unasked question
  - Inverse questions

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.

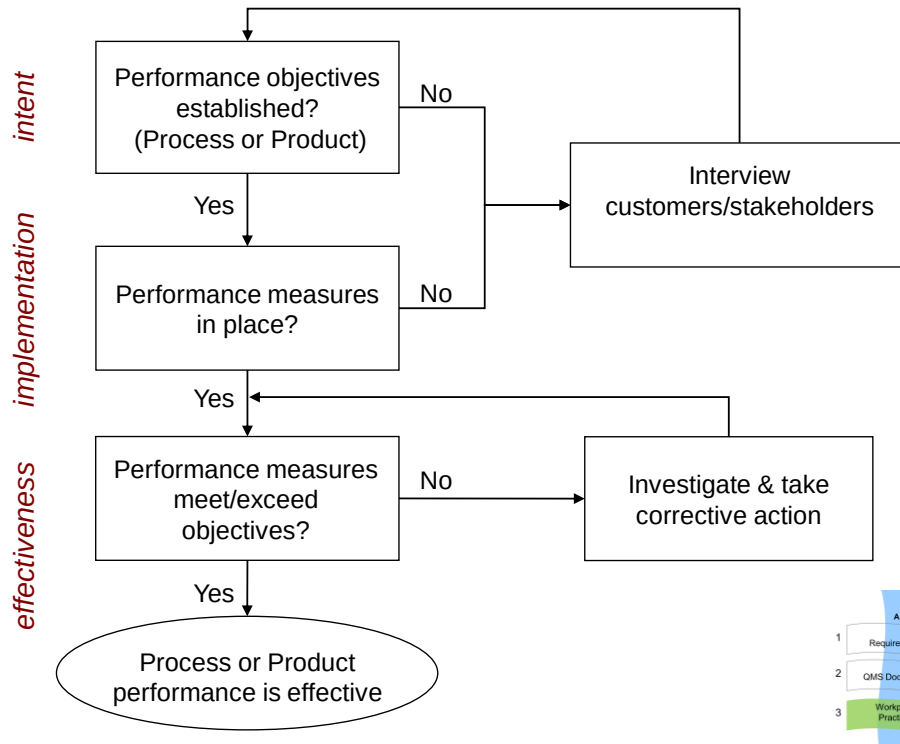
If you earn credibility, then your findings and conclusions are trusted!

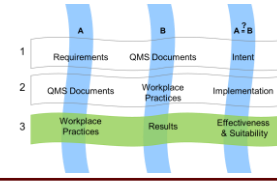
Interview Questions

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)	Process Results (b)		
	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** ☐

[22] **Supporting Comments:**

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

DISCLAIMER STATEMENT

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

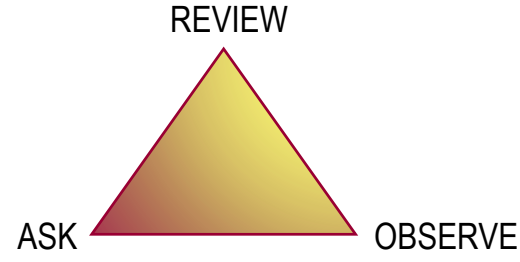
Prepare for the PEAR

- 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.

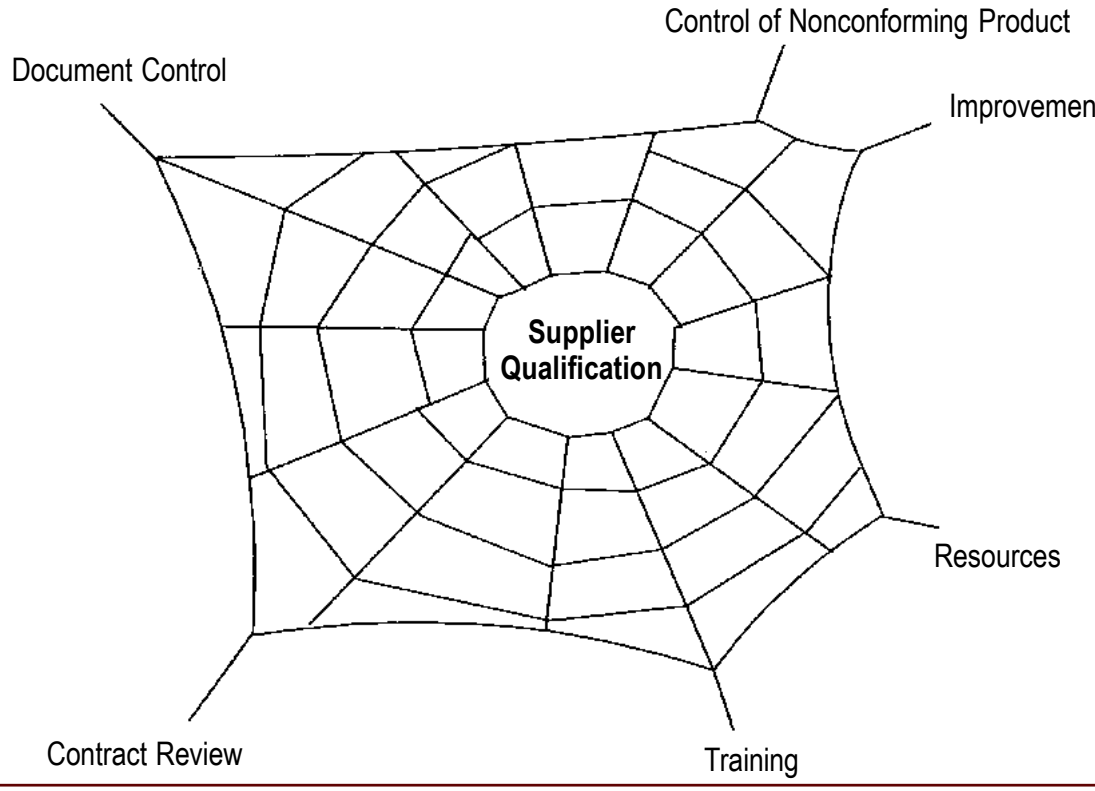
Establishing the Facts

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*.

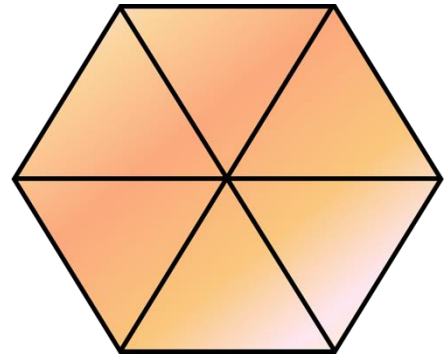
You are driving to work in nasty weather, and get caught in a traffic jam. Cars are backed up for miles, and the radio says there's an accident ahead, a three–car collision. You had noticed the roads were very slick. You're stuck, with no possible exit. At least you have some coffee to drink while you 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”

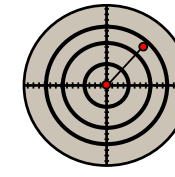
Same facts — different conclusions

- 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

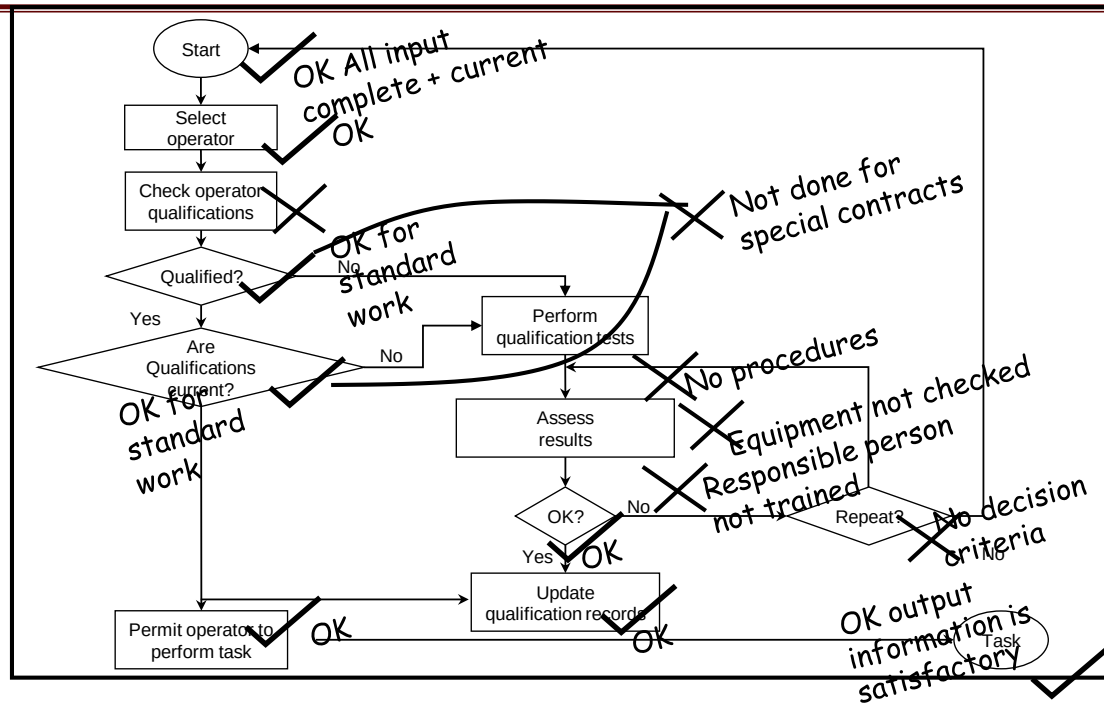
Auditor: I. M. Sharp

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 ~~Dprng. 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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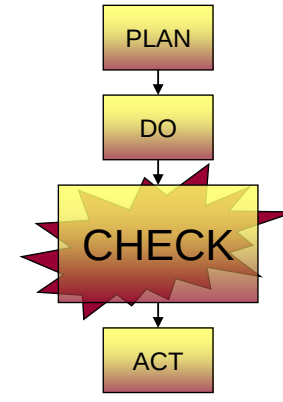
CHECK: Make a Comparison

"What Should Be" $\stackrel{?}{=}$ "What Is"



Nonconformity: Definition

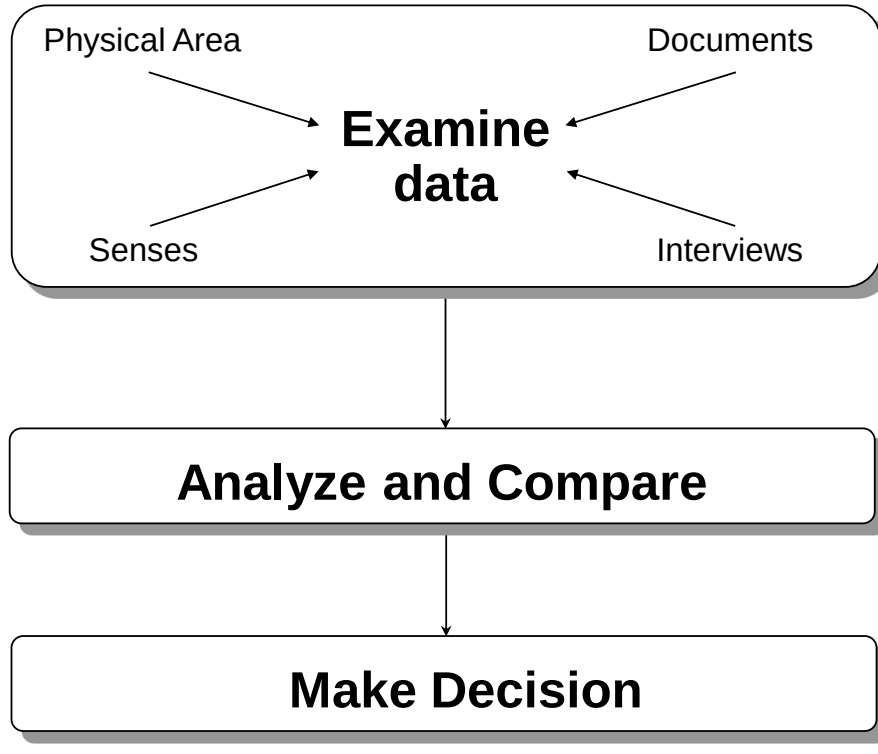
"Non–fulfillment of a requirement"

— 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.

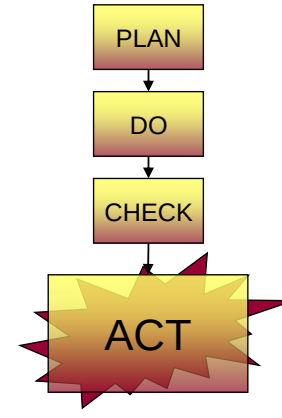
Ending the Audit — Closing Meeting

- 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.

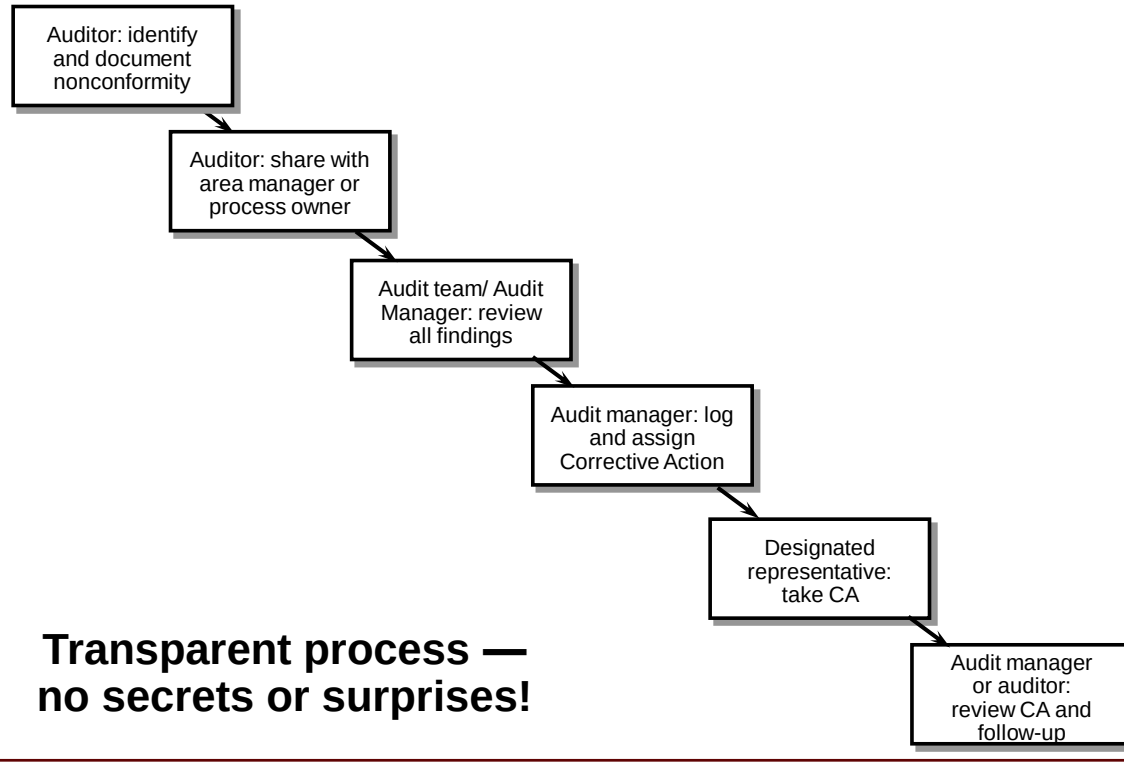
- ✓ Present facts only
- ✓ Be objective
- ✓ Brief, clear and concise
- ✓ Avoid jargon

ACT: Take Action

"Close the Gaps"



Processing Nonconformity Findings



Transparent process — no secrets or surprises!

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, W/I

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:

Auditor Name(s):

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

Auditor: Jane Smith

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 a total of 3 Nonconformity Finding Notes issued during the audit, which are attached to this report.

Distribution:
Manager, New Product Engineering
Vice President, Engineering
Manager, Market Requirements Development
Vice President, Sales and Marketing

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

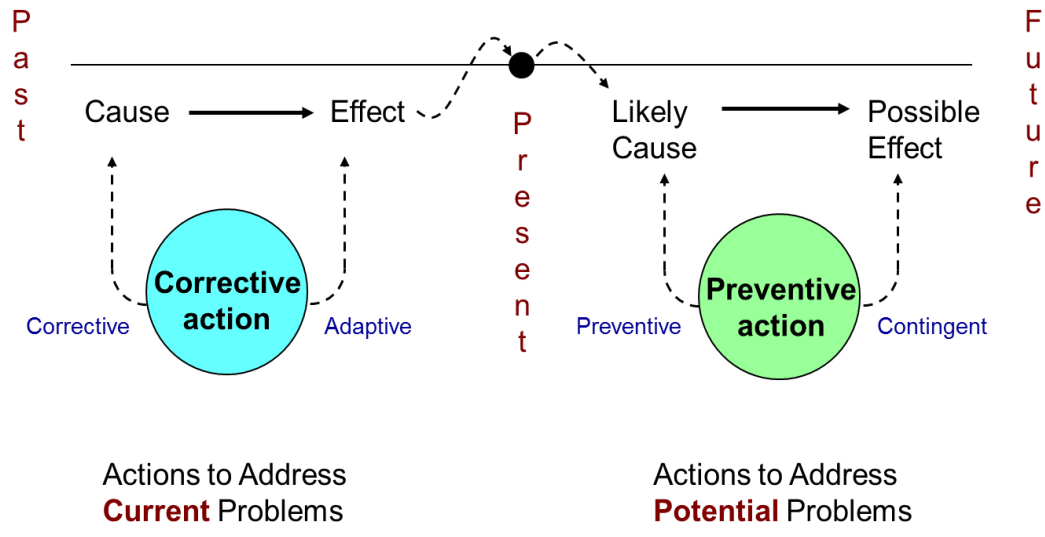
- Auditors can be teachers of improvement.
- Auditors can provide recommendations to assist with Corrective Actions.
- When auditors are credible, they are more likely to be perceived as adding value.
- When the connection to value is made, nonconformities are more likely to be addressed effectively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

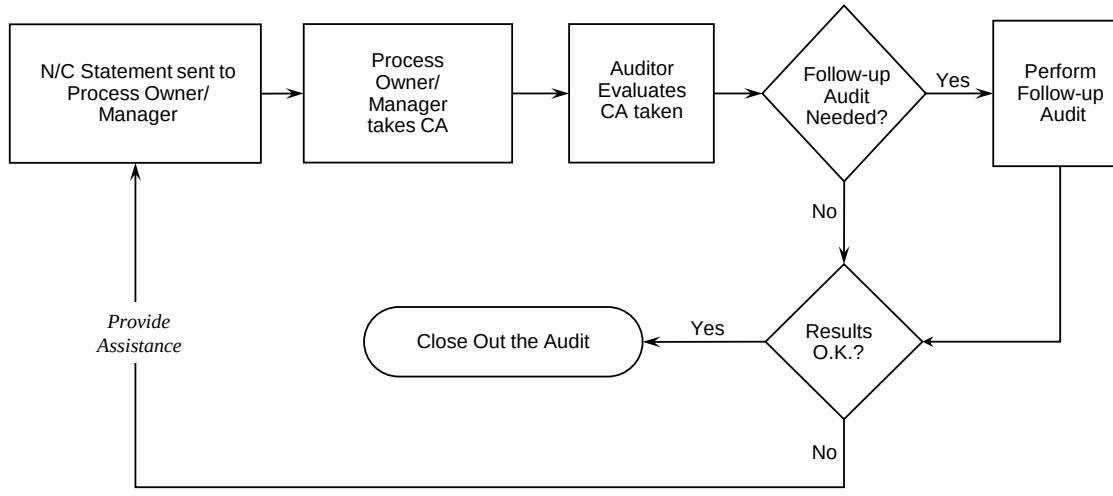
Correction Options

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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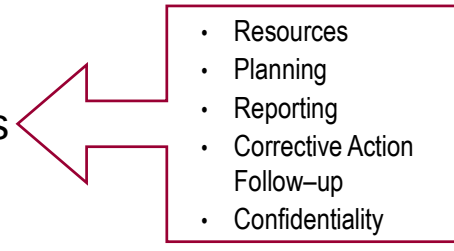
Maintaining a Successful Audit Program

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



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.

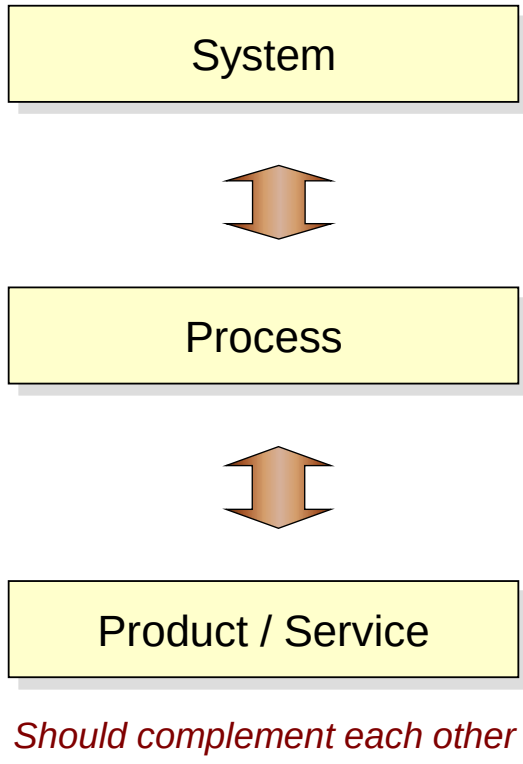
Examples: Registrars

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



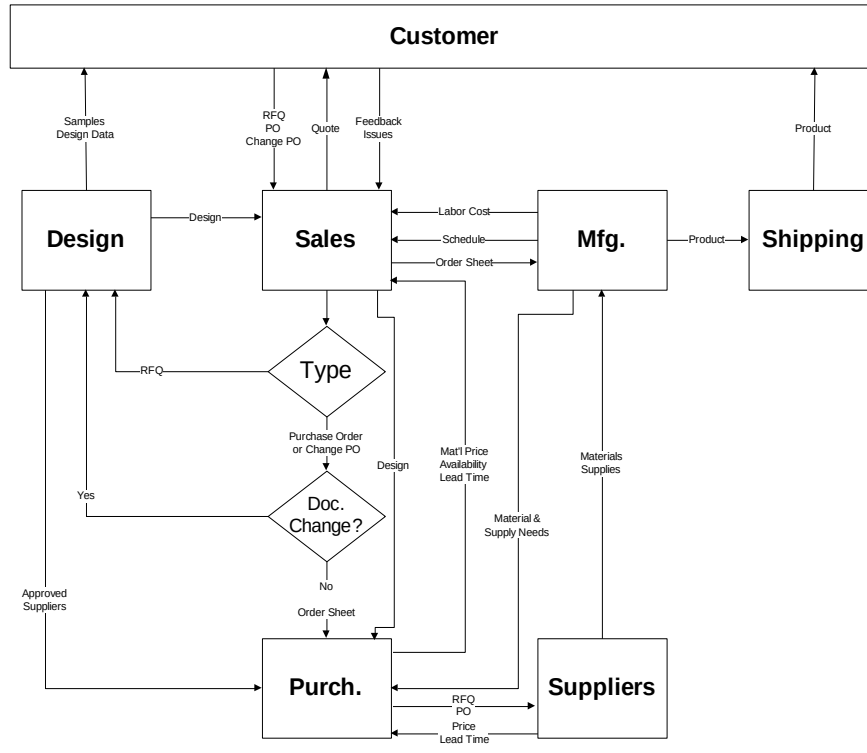
- Is the system effective?
- Do core processes work together?
- Do we manage the system and its relationships?

- 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



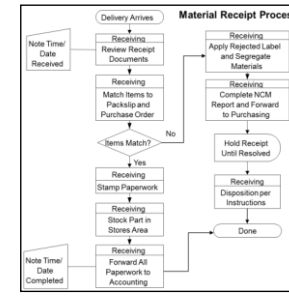
Management Reviews of the Quality System can function as systems audits.

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

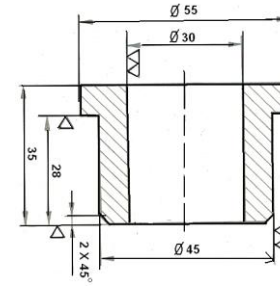
Purpose

- 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

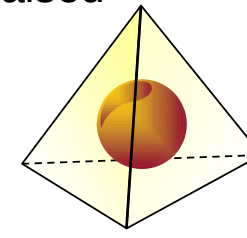
- Define what “undue delay” means in your system.
- Develop a method for tracking and following up on internal audit results.
- Analyze responsiveness to audits and report to management.
- Establish an escalation policy!

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):

		Strongly Disagree		Neutral		Strongly Agree
	Scheduling:					
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…