Compliance Auditing for AVS Personnel

Some Housekeeping

GRCC Community College:

- Emergency Exits/In case of fire alarm
- Restrooms

Class Basics:

- We start each day at 0800
- Lunch breaks
- End of Day
- Thursday
- If you cannot make class
- Interruptions – cell phones

Class Basics:

- Your Instructor
  - Clayton M. Kuehl ~ ckuehl@etigroupusa.com

The Class & Materials

The Class:

- Designed to provide you with the basics
- We'll move at the pace of you, the student
- Your participation is a must

Class Materials:

- Everything is electronic
- Your introductory emails provided links to the documentation
- Make sure you have copies of the materials on your laptop
- The materials are .pdf documents. You can easily use the comment function with your .pdf reader to take notes OR you can take handwritten notes
- You are welcome to keep the materials for future use

Workshop Overview

Purpose:

To provide you with theory and practical experience to become an effective Compliance 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 audits. Practice will give you the experience!

In this course, the term “audit” can be used interchangeably with “inspection.”

Agenda

- Introduction to Auditing
- Management Systems and the Process Approach
- Auditor Characteristics, Roles & Responsibilities
- The Audit Process
  - Plan: Plan and Prepare
  - Do: Gather the Evidence
  - Check: Make a Comparison
  - Act: Take Action
- Summary

Please complete the Initial Assessment of Knowledge & Experience

5

1 — I've never been involved in an audit/inspection.

2 — I've been audited but have never performed an audit/inspection.

3 — I've been an observer on one or more audits/inspections.

4 — I've performed audits/inspections.

5 — I even perform audits/inspections at home!

Learning Objectives

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

- Explain the purpose of an audit.
- List the Quality Management Systems commonly found in aerospace organizations.
- Describe auditor roles and responsibilities.
- Define the elements of an efficient and effective audit.
- Plan an audit and develop a guidelist.
- Perform an audit using useful methods, tools and techniques.
- Identify noncompliance to requirements during an audit.
- Document noncompliance and report on an audit.
- Evaluate effectiveness of corrective actions taken in response to audit findings.

Meet & Greet

- Pair up. Interview your neighbor (2 ½ minutes each). Find out:
  - Name
  - Job function, and length of employment with the FAA
  - Knowledge and experience with auditing/inspections
  - Something interesting about you that others may not know
  - Learning expectations

- Introduce neighbor to class (1 minute each).

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Introduction to Auditing

Learning Points:

- What is an Audit?
- Audit Purposes
- Audit Methods
- Management of Audit Programs
- The Basic Audit Process
- Audit Scheduling and Results Tracking
- Successful Audit Programs

What Is an 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."

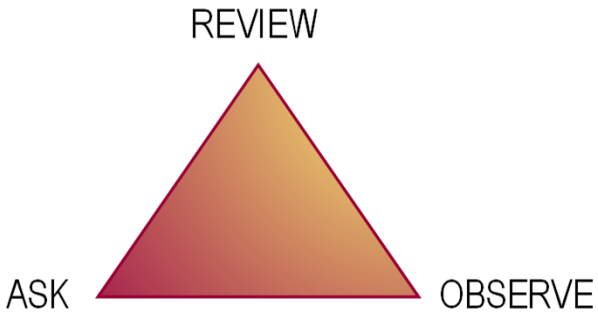
  —*ISO 9000:2015*

- Auditing is one part of a comprehensive management & safety 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 compliance.

Audit Process

Audits are performed by:

- Determining requirements
  - Audit criteria
- Gathering evidence
  - Practices
  - Records
- Comparing information
  - Activities to criteria
- Drawing conclusions
  - Compliance or noncompliance



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.

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: Windstream Airplane auditing an avionics supplier

An airline auditing Windstream Airplane

Third Party

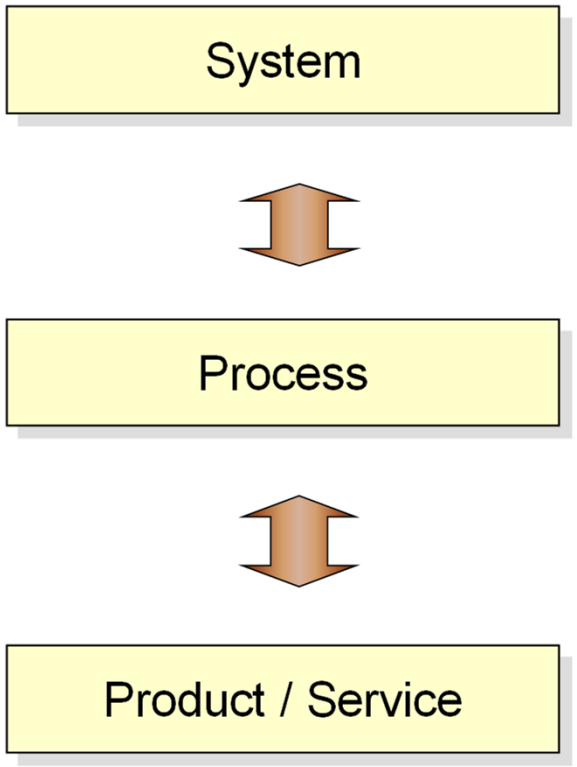
Audits carried out by independent agencies to provide assurance on the effectiveness of the organization's system.

Examples: Regulatory agencies – FAA audit programs (DOIP, QSA, Designee Supervision)

Management System Certification Bodies

"Supervision" is another FAA audit level which is not as formal as a compliance audit.

Audit Level



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

- 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?
- Are there proper records of having followed the processes?

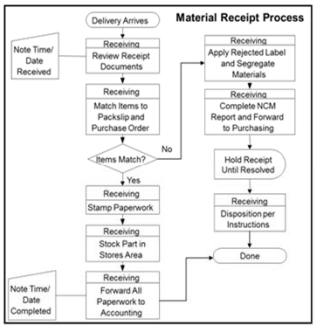
Should complement each other

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

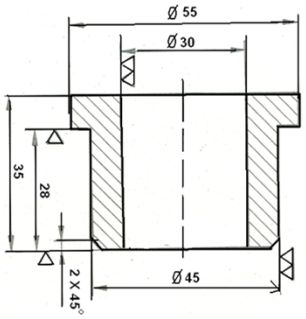
Purpose

- 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

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 compliance 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?

1. _____

2. _____

3. _____

4. _____

5. _____

_____

_____

_____

Management of Audit Programs

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

FAA Order 8120-23 provides detailed guidance on conducting Quality System Audits (QSA) as part of Certificate Management (CM) of Production Approval Holders (PAH).

ISO 19011 provides general guidance for effectively implementing and conducting management system audit programs and governs Certifying Bodies (CBs).

Auditing “Must Do” Activities

Determine if practices:

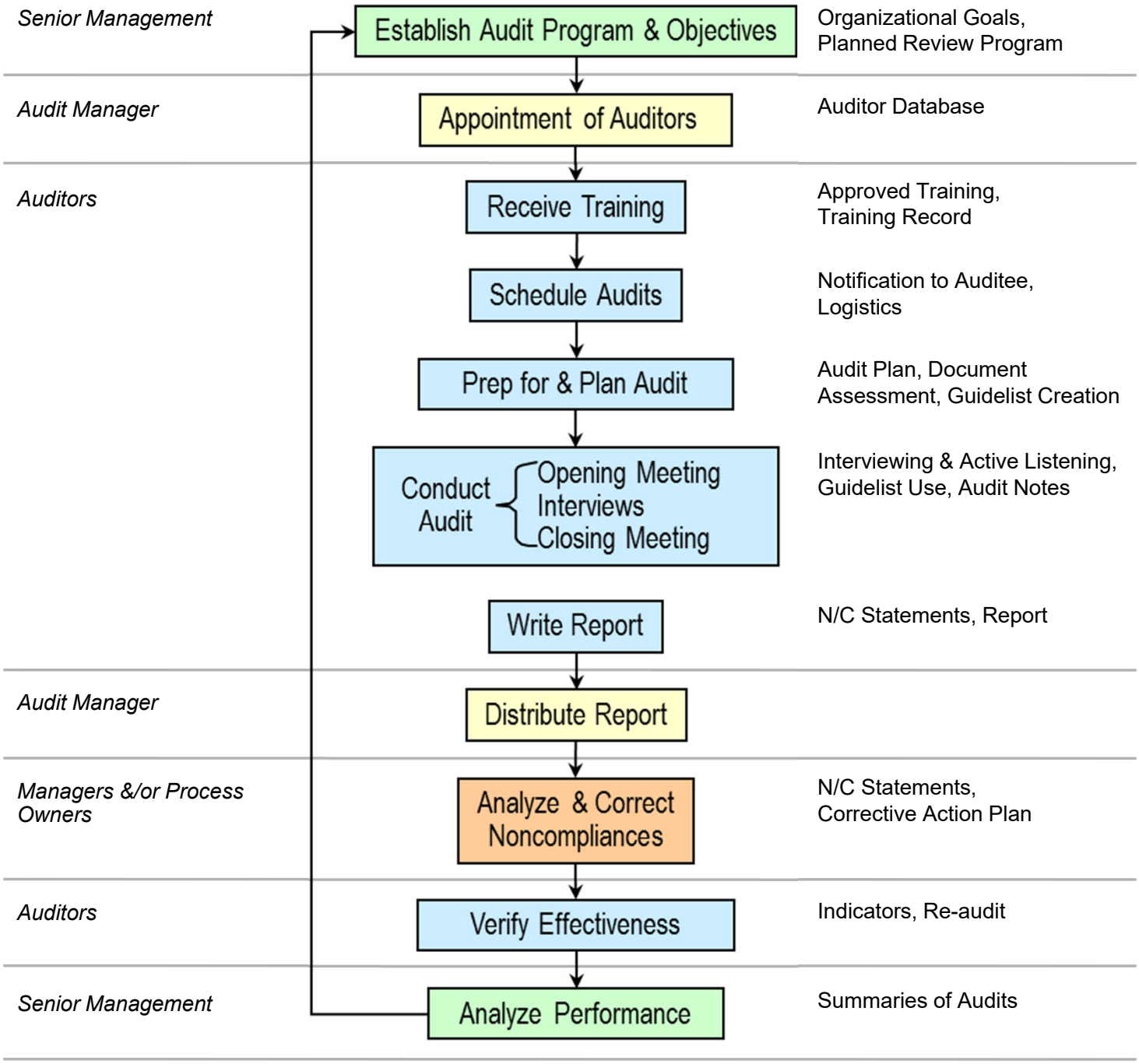
- Comply with:
  - Planned arrangements
  - Requirements (Standards, Regulations, etc.)
  - Requirements set by the organization
- Define audit criteria, scope, frequency and methods
- Ensure objectivity and impartiality in auditor selection and audit conduct

Auditing "Must Do" Activities, *continued*

- Define responsibilities
  - Planning and conducting audits
  - Reporting results
  - Keeping records
- Follow up to verify corrective actions are effective

The Basic Audit Process

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



Sample Audit Plan

Audit ID	Company Name	# Audits	Q 1		Q2		Q3		Q4	
			Plan	Done	Plan	Done	Plan	Done	Plan	Done
04-001	Jazz Aerospace	1	P	11-Jan						
04-002	Botta-Boom, Inc.	1			P	28-Mar				
04-003	Space Tours, Ltd.	1	P	15-Feb						
04-004	Rockets Are Us	2	P	10-Mar			P	22-Aug		
04-005	Advanced Aviation, Inc.	2			P	1-Apr			P	31-Oct
04-006	Tru-Circle Machining	2			P	15-Apr			SA	10-Nov
04-007	Mom & Pop Sheet Metal	1	P	2-Feb						
04-008	Big Old Eng. Industry Group	2					P	27-Jul	SA	25-Dec
04-009	Heather's Heat Treat	1			P	3-May			SD	
04-010	Sam's Shot Peen Service	2			P	5-Jun			P	5-Dec
04-011	Tri-Cities Aviation Group	1					P	4-Jul		

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

Tracking Audit Results

- Develop a method for tracking and following up on audit results
- Analyze responsiveness to audits and report to management
- Establish and use 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	

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 are used as a chance to identify improvement opportunities
- 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 involved should understand:

- What the audit process involves
- Expected benefits of audits
  - ✓ For the FAA
  - ✓ For the Audited Organizations

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Management Systems & the Process Approach

Learning Points:

- Management System Objectives
- Process Model
- The Process Approach
- PDCA in a Management System
- Effective Management Systems
- Common Quality Management Systems
- Documentation Structure

In a Management System, you…

Say what you'll do.

Do what you say.

Prove It.

Improve It!

Everyone

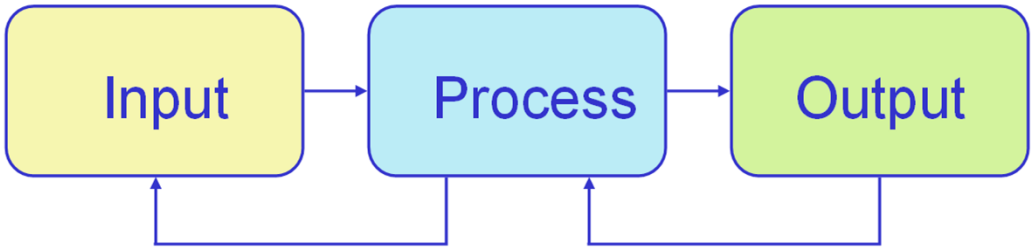
Everywhere

Every time

The focus of a Management System may be on Safety, Quality, Risk, Environmental, Financial, etc. The system is controlled using the methods below:

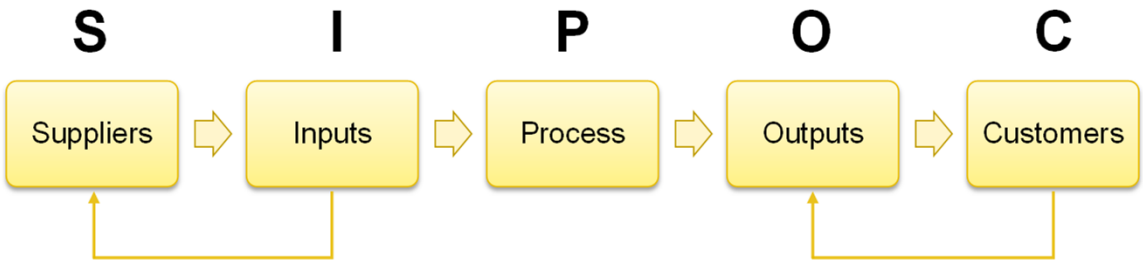
- Say what you'll do through the Management System documentation &/or training.
- Do what you say through disciplined use of the System.
- Prove it using audits (internal and external).
- Improve it using Corrective Action and Continual Improvement.

Simple Process Model



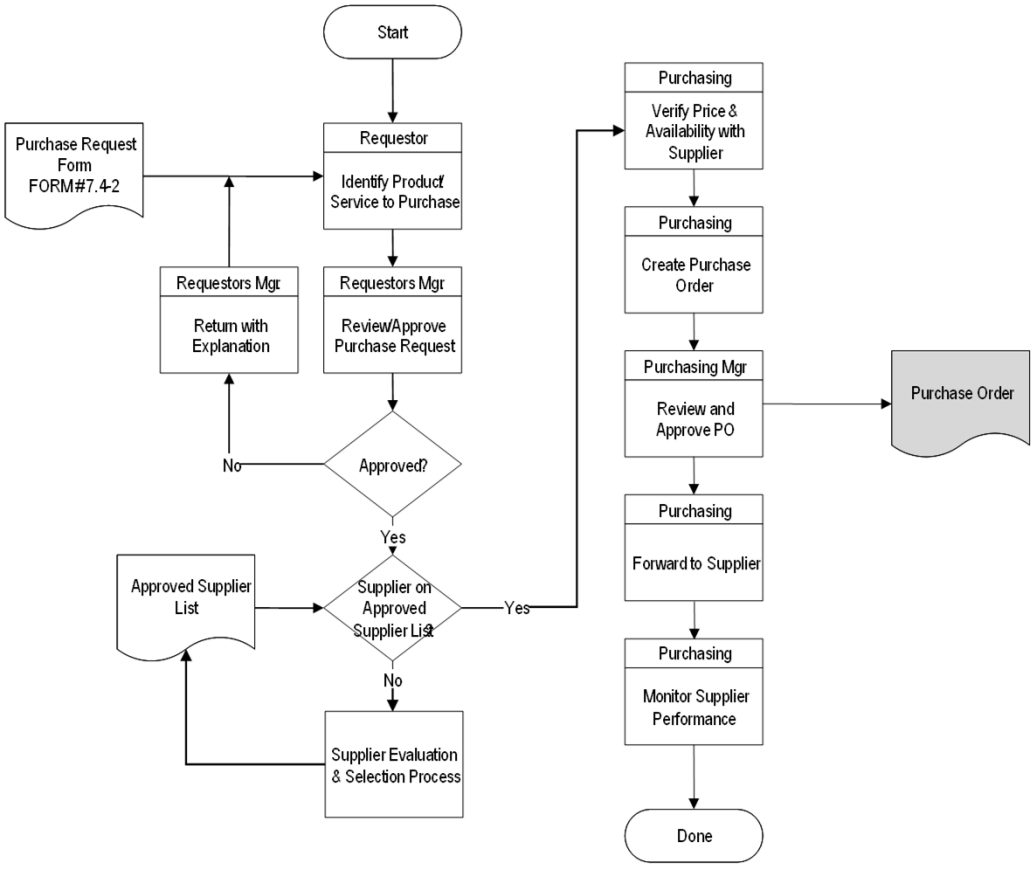
- Simply defined, a process is a set of related activities that convert inputs to outputs using resources.
- Monitors &/or measures for the process interfaces are represented by “feedback loops.”

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.

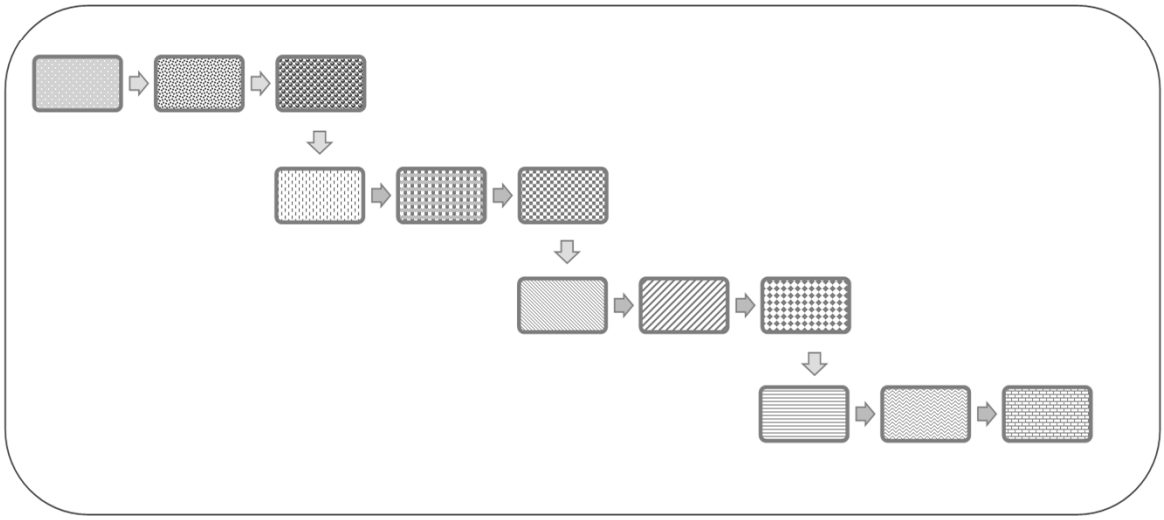
Process Flow Example



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 (a.k.a process map).

Process Interaction

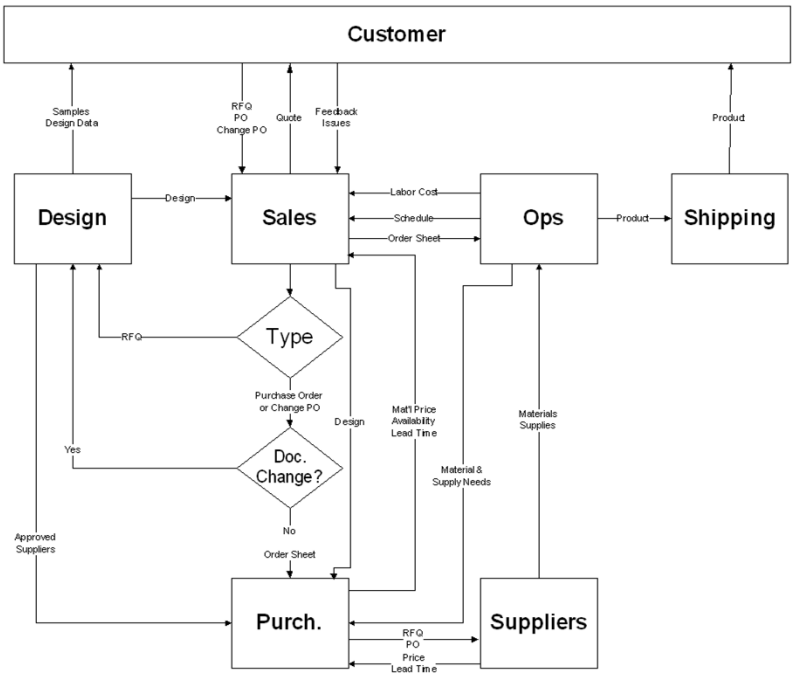
- Often, the outputs of one process become the inputs to another process.
- Management Systems are made up of many linked process chains.



These “links” are the hand-offs &/or interfaces between processes.

System Example

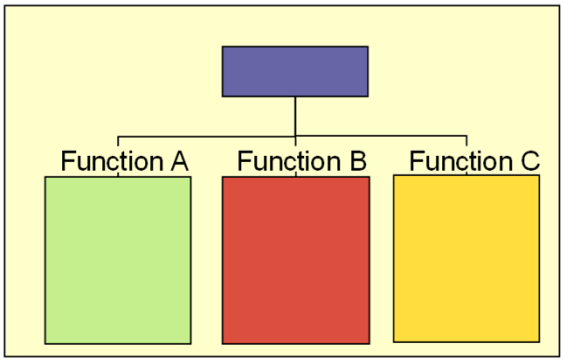
- A system is an integrated set of processes that interact with each other to meet a set of objectives.



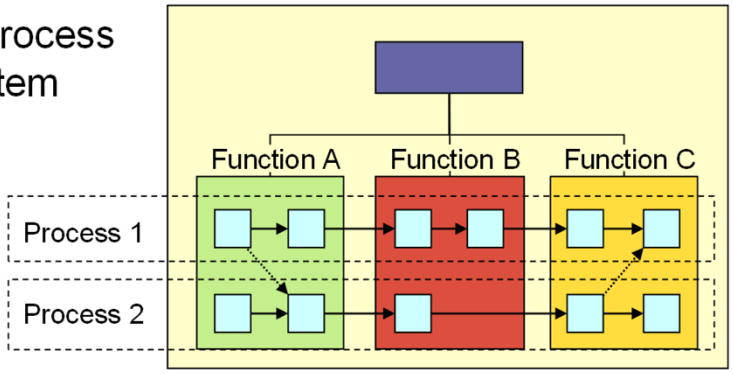
Ops stands for Operations, where the context could be production, repair, flight, maintenance, etc.

The Process Approach

Traditional/Functional View of System



Performance/Process View of System



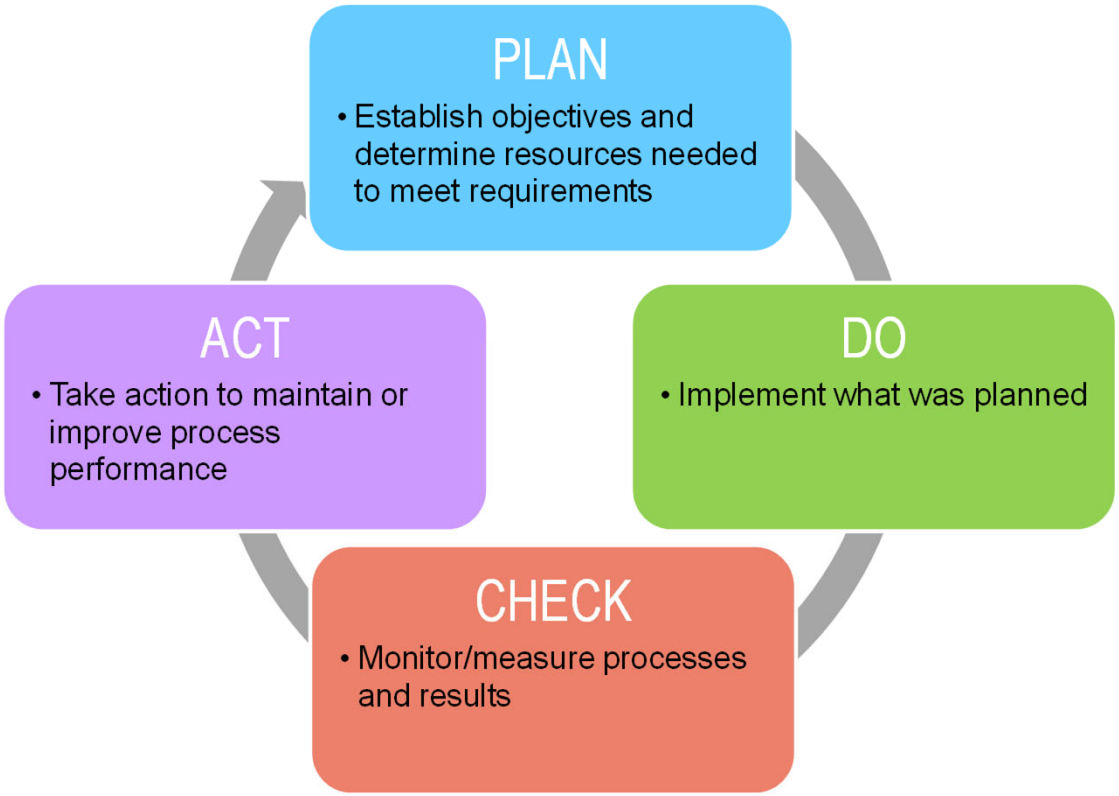
Jobs exist in “Functions” (think of Departments on an Organization Chart), but are performed within Processes.

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?

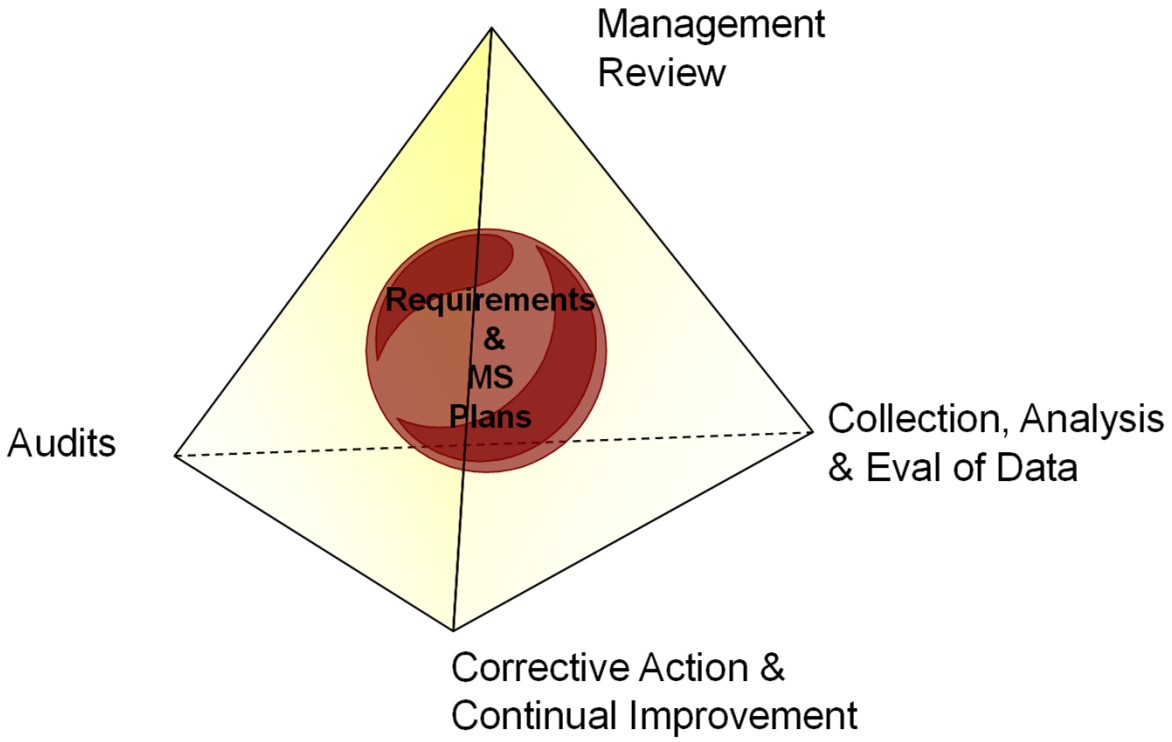
A Management System Model - PDCA



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."

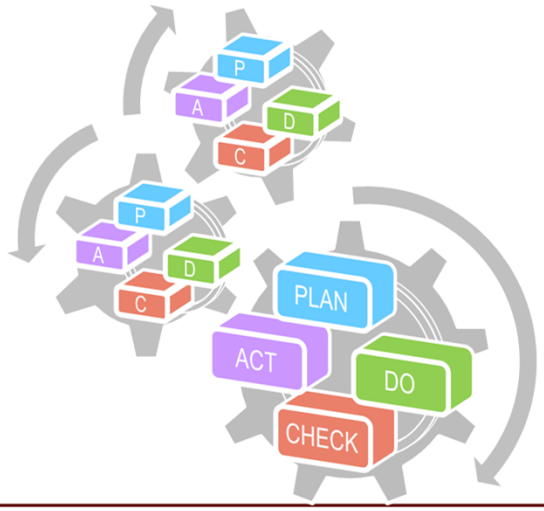
This "closed-loop system" and the process approach have been found to be effective organizing principles for Management Systems, (an example is the ISO 9001 Standard and all its offshoots).

Key MS Elements for Effectiveness



Managing the System

- 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 Management System.



Common Quality Management System Standards

Standard	Description
ISO 9001	Applies to any sort of organization, including both manufacturing and service. Has evolved from a focus on element-based procedures to a process and risk-based approach toward meeting customer requirements and continually improving the QMS.
AS9100	Embeds ISO 9001 and adds aerospace-specific requirements intended to be used in the supply chain for Aviation, Space &/or Defense. Goal is to improve both quality and on-time delivery and reduce waste throughout the supply chain.
IATF 16949	A supplement to ISO 9001, used in the Automotive industry. Contains specific requirements and tools for risk/variation/waste prevention such as FMEA, SPC, MSA, APQP and PPAP.

ISO Standards are maintained by the International Organization of Standardization; AS Standards by the International Aerospace Quality Group (IAQG). IATF stands for the International Automotive Task Force. Other acronyms stand for:

FMEA: Failure Modes and Effects Analysis

SPC: Statistical Process Control

MSA: Measurement Systems Analysis

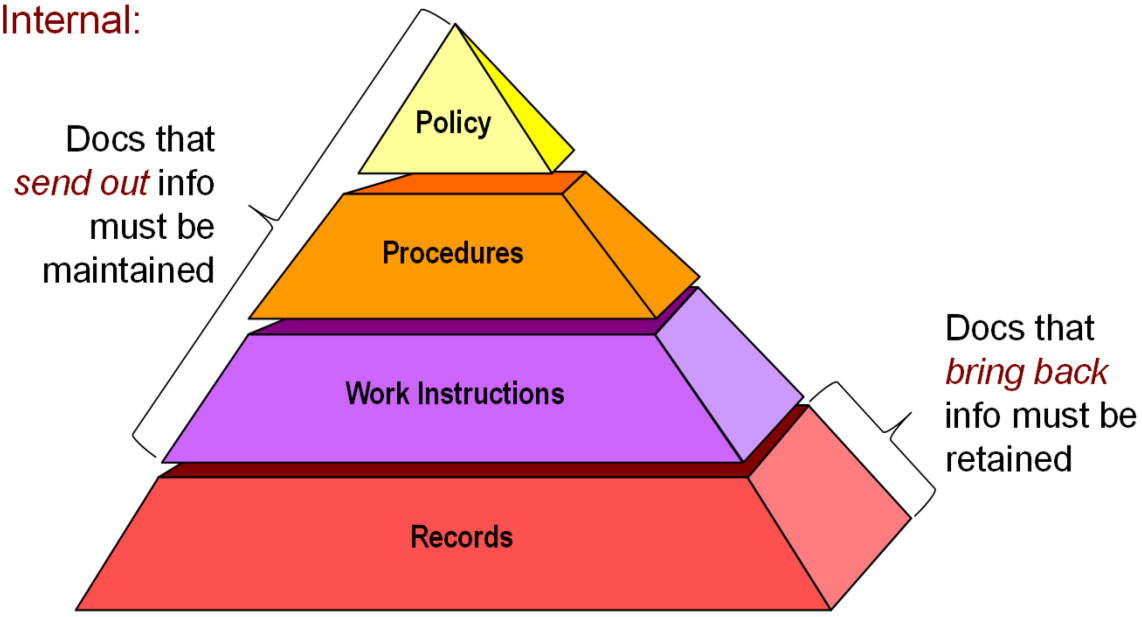
APQP: Advanced Product Quality Planning

PPAP: Production Part Approval Process

Documented Information Structure

External: FAA - Rules, Regulations, Orders; Customer Requirements; Industry Standards

Internal:



Policy

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

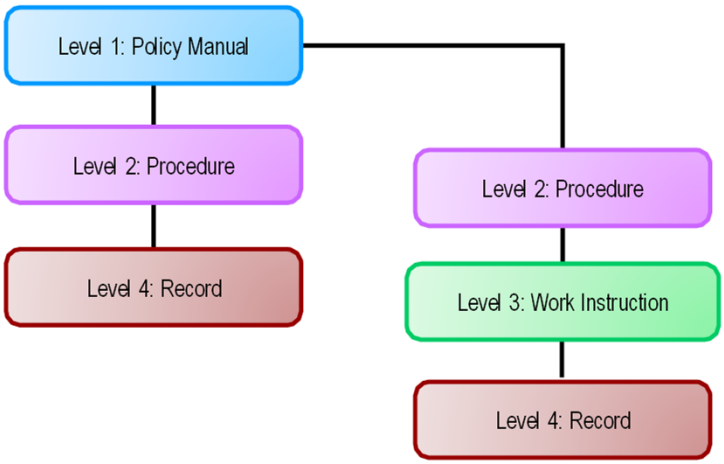
Documents that provide detail to support the organization's procedures. They provide specific information on activities, tasks, and steps such as: how to build specific assemblies, how to load a program into a robot, keystrokes for order entry, etc. May also be forms, checklists, work standards/examples.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

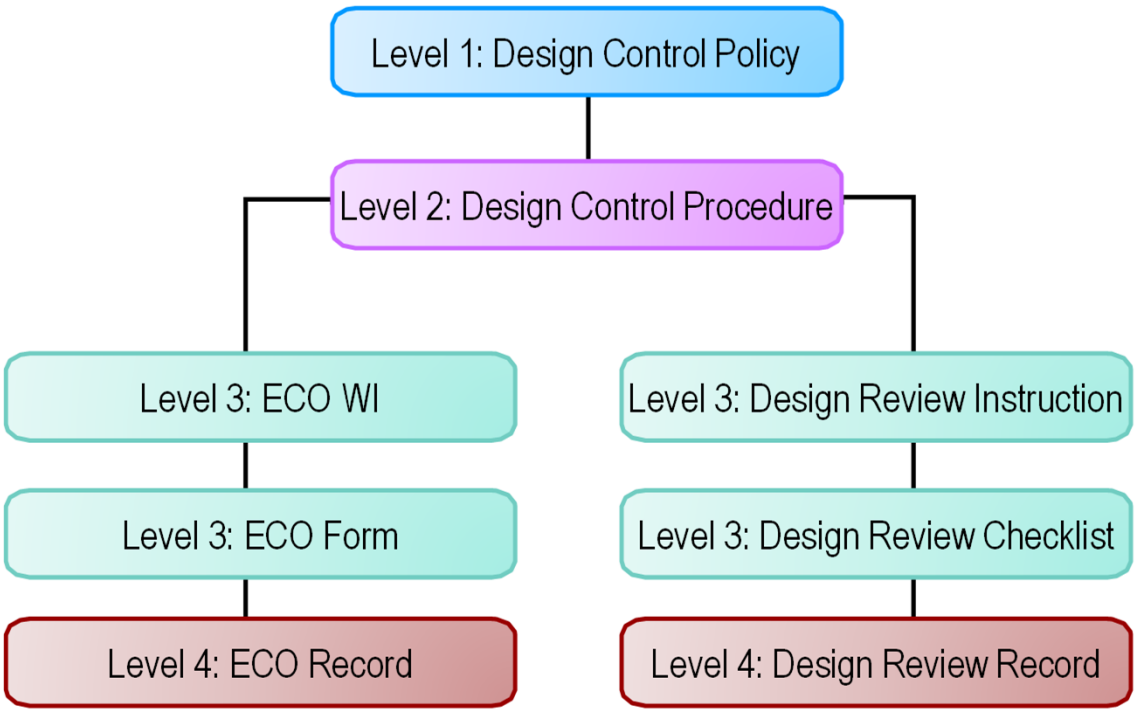
Following a Document Path

- Documentation should be connected
  - Level 1 documents lead to level 2 documents
  - Level 2 documents lead to level 3 documents
- Records created are typically initiated in levels 2 and 3



Some organizations (especially smaller ones), may combine policy, procedures and work instructions into one document, which is often referred to as a "Manual." Examples are a Repair Station Manual, Maintenance Manual, Operations Manual, etc. In ISO 9001-based Quality Management Systems, there is often a separate policy-only document, which may be referred to as a "Quality Assurance Manual" or similar term.

Document Structure Example

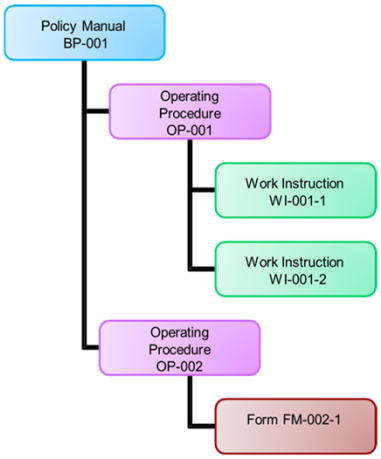


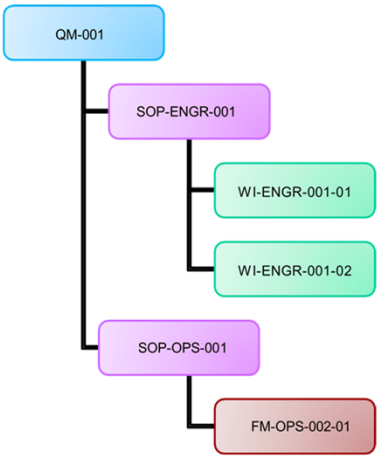
WI = Work Instruction

ECO = Engineering Change Order

Document Naming Schemes

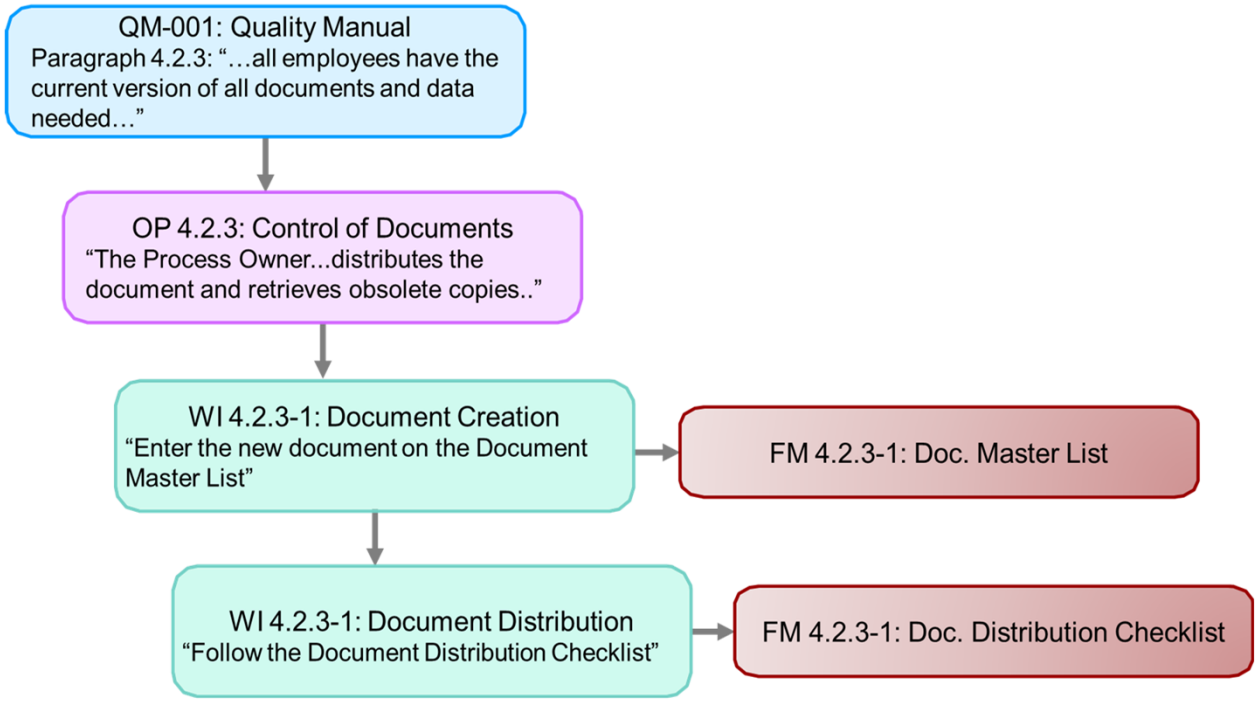
- A wide variety of naming schemes may be seen from one organization to another.
- An audit will flow much more efficiently if the auditor is familiar with the organization's document structure.
- It can be helpful to ask for a copy of the Document Control Procedure ahead of time.





SOP = Standard Operating Procedure

Auditing a Document Path



Remember the triangle of audit methods? (Review, Ask, Observe.) In the path above, the auditor would review the documentation (items along the left-hand side above) to determine the requirements, and during the audit, would review the resulting records (items on the right-hand side above).

Auditor Characteristics, Roles & Responsibilities

Learning Points:

- Auditor Qualifications
- Characteristics of a Good Auditor
- Roles and Responsibilities
- Attitude is Everything

Auditor Qualifications

- Understand the regulatory requirements
- Be familiar with good business practices
- 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.

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 requirements, audited organizations, auditing and performance measurement.
- Cultivate proper attitudes toward reviews.
- Recognize that you are an imposition!

Roles & Responsibilities

- Audit Manager/Administrator:
  - Create and publish audit schedule
  - Assign auditors (ensure trained)
  - Review Findings of Noncompliance and reports for overall consistency
  - Track Findings
  - Report to management
- Audit Team Leader (PI):
  - Coordinate and participate in audits
  - Prepare plan for an audit
  - Conduct opening and closing meetings
  - Review all Findings of Noncompliance
  - Final arbitrator on decisions
  - Report audit findings to area management

Audit Team Leader can also be referred to as the PI — Principal Inspector.

Auditor Responsibilities - External

- Prepare for assigned audits
- Assist with &/or perform audits
- Examine system
- Determine if system:
  - Meets requirements
  - Is implemented
  - Is effective (difficult to do)
- Make informed decisions about compliance — not just report facts
- Report your decision

Auditor Responsibilities - Internal

- Prepare for assigned audits
- Assist with &/or perform audits
- Examine system
- Determine if system:
  - Meets requirements
  - Is implemented
  - Is effective (easier to do)
- Make informed decisions about compliance AND effectiveness
- Report your decision

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 compliance.

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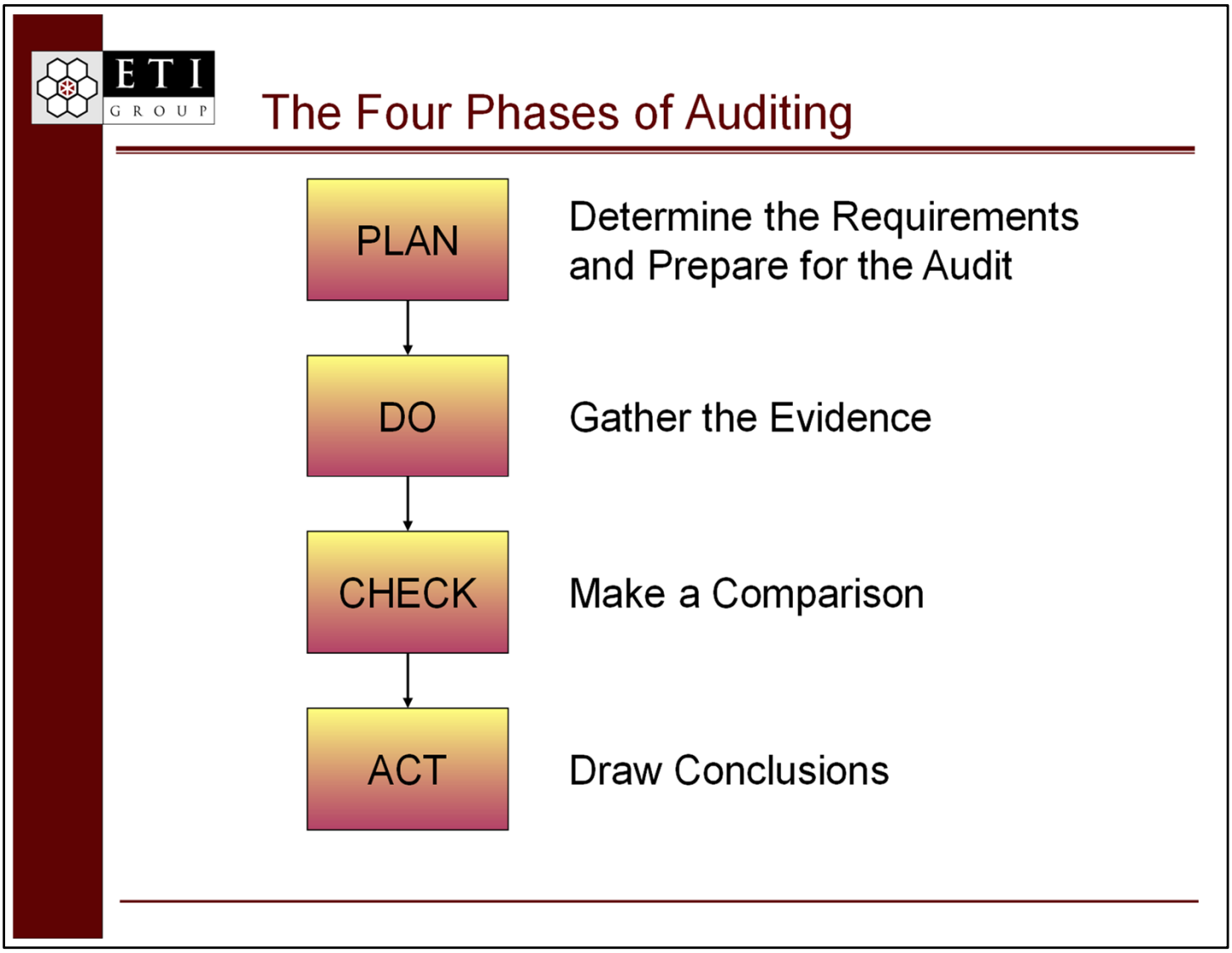
The Audit Process

Learning Points:

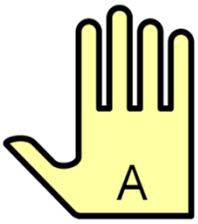
- The Four Phases of Auditing
- An Auditing Formula
- Methods for Gathering Evidence



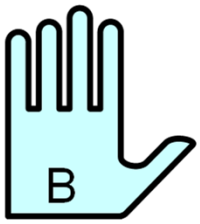
An important outcome of the Plan phase is a thorough understanding of the requirements by the auditor. This knowledge will then aid the auditor as the evidence is gathered in the Do phase, and conclusions are drawn about compliance in the Check phase.

An Auditing Formula

A = What Should Be



B = What Is



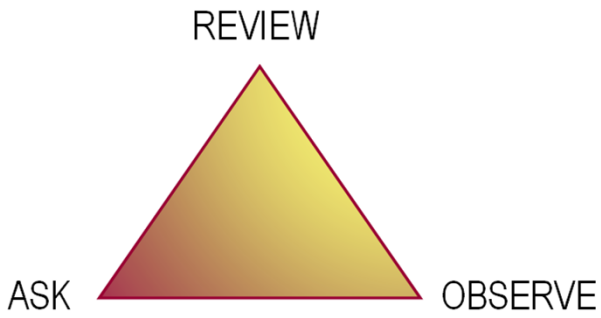
If A = B ⇨ Compliance

If A ≠ B ⇨ Noncompliance

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

Methods for Gathering Evidence

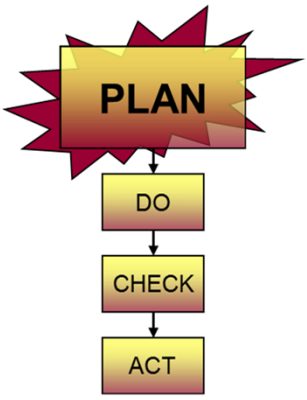
- **Review** the audit criteria (requirements) and Management System documentation and records.
- **Ask** good questions and listen carefully to the answers.
- **Observe** actual practices.



Phase 1 – Plan and Prepare

Learning Points:

- Planning Steps
- Purpose and Scope
- Audit Criteria & Information Sources
- Audit Plan
- The 3-Step Comparison Process
- Documentation Assessment
- Guidelist Preparation
- Sample Planning
- Checking the Audit Plan



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
   - Usually an approved manual
4. Identify information sources
5. Develop audit plan
6. Confirm plan
   - Send notification
7. Assess documentation (optional)
8. Develop guidelist

Audit Purpose & Scope

Answer the following questions:

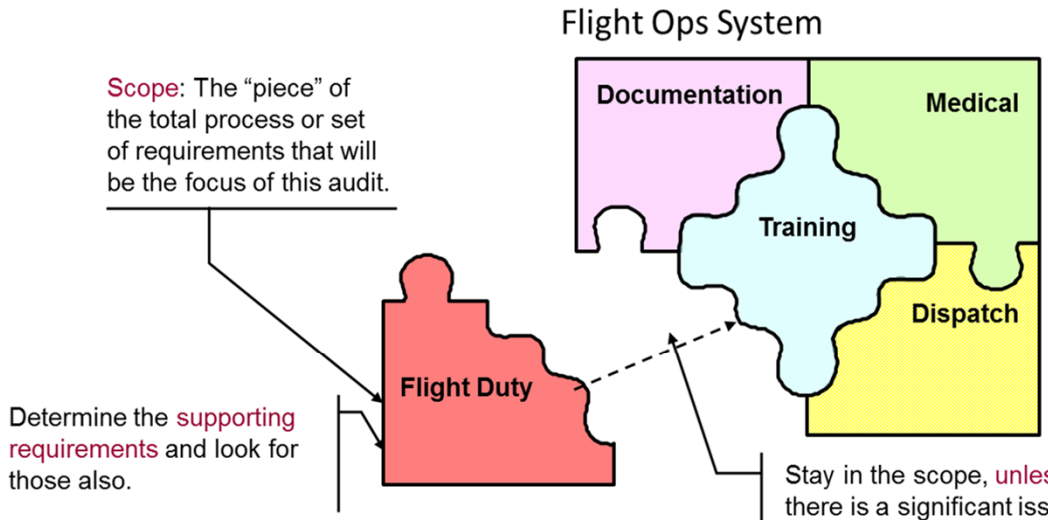
1. What system/process am I auditing?
2. Why am I auditing this process?

Determining the Purpose

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

Determining the Scope

Audit Scope



Reasons for Well-Defined Scope

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

Purpose and scope can be thought of on several levels. There may be an overall purpose and scope for an audit, such as to assess the adequacy and effectiveness of training, documentation of procedures, or record-keeping across an organization. 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 organization, each with a particular purpose and scope.

Audit Criteria & Information Sources

- Review and understand the audit criteria (requirements), which may be:
  - FAA rules, orders, regulations, etc.
  - Statutory regulations and/or industry requirements & standards
  - Customer contract(s) &/or management system-level requirements
  - The audited organization's policy, procedures, work instructions
  - Quality plans
  - International Management System 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 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, 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

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:

- Quality Assurance Manual, section 7.4 Purchasing
- Botta-Boom procedure OP 7.4

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

Special Considerations: None

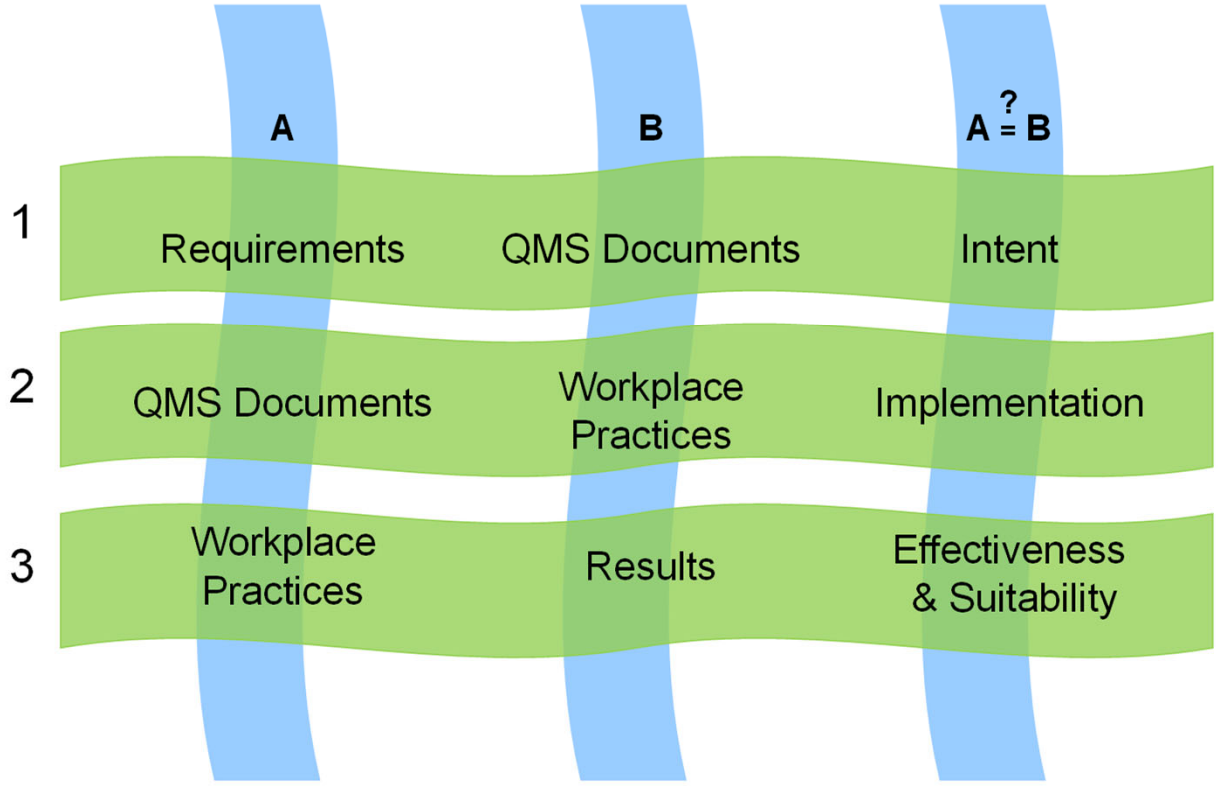
Schedule:

• Opening Meeting:	8:00 – 8:10, 8/19/XX	Maria Castillo's Office
• 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

- Follow established 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 functions/persons needed for interviews (if you know)
  - Documents or records required

The 3-Step Comparison Process

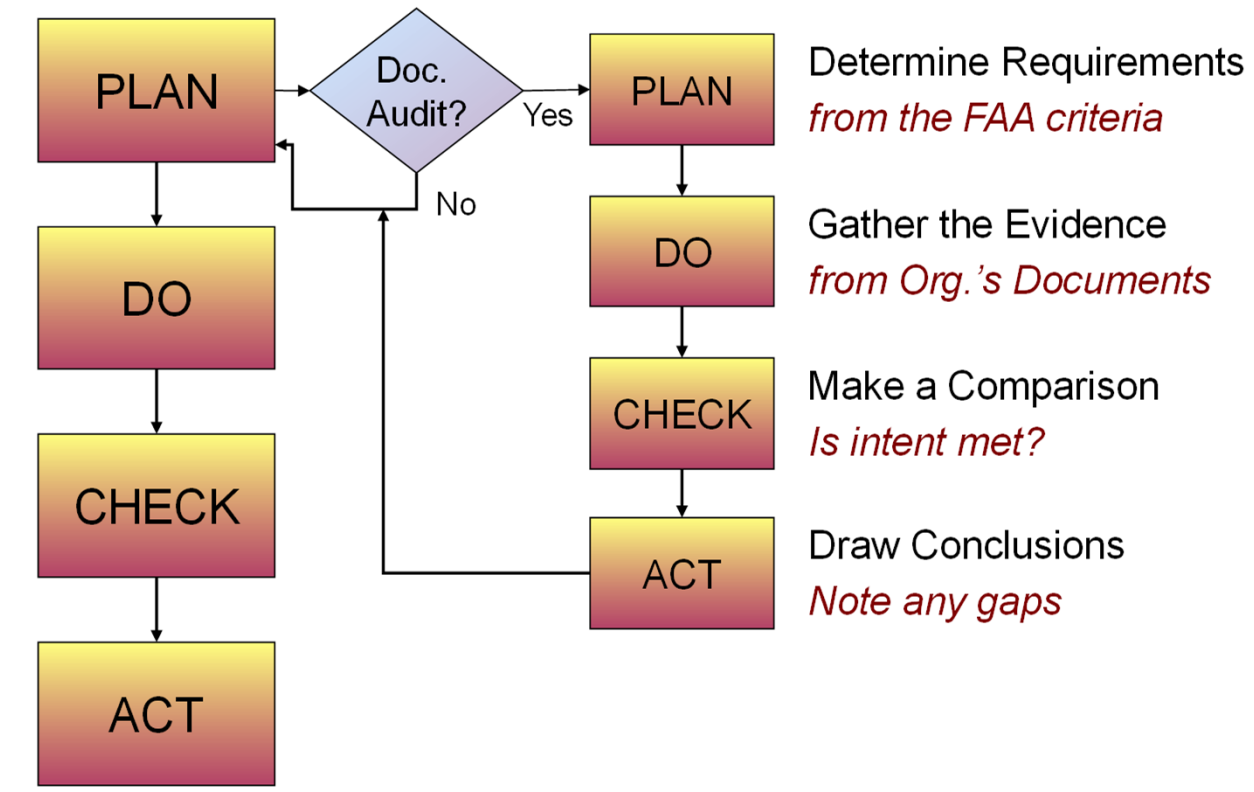


While the fundamental "A=B" comparison process is the same, the two things being compared will vary.

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

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

Documentation Assessment



Step 1: Documentation Assessment may not happen for each Audit. Good times to perform one are when the auditor is new to the audited organization, documents are first being written or have significantly changed and when external audit criteria are revised (e.g., a regulation change).

Requirements for the Documentation Assessment (a.k.a. Desktop Audit) could also come from an external Quality or Industry Standard, or Customer Contract Requirements, depending on the audit purpose.

Documentation Assessment

1. Read the Botta–Boom Case Study Introduction.

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

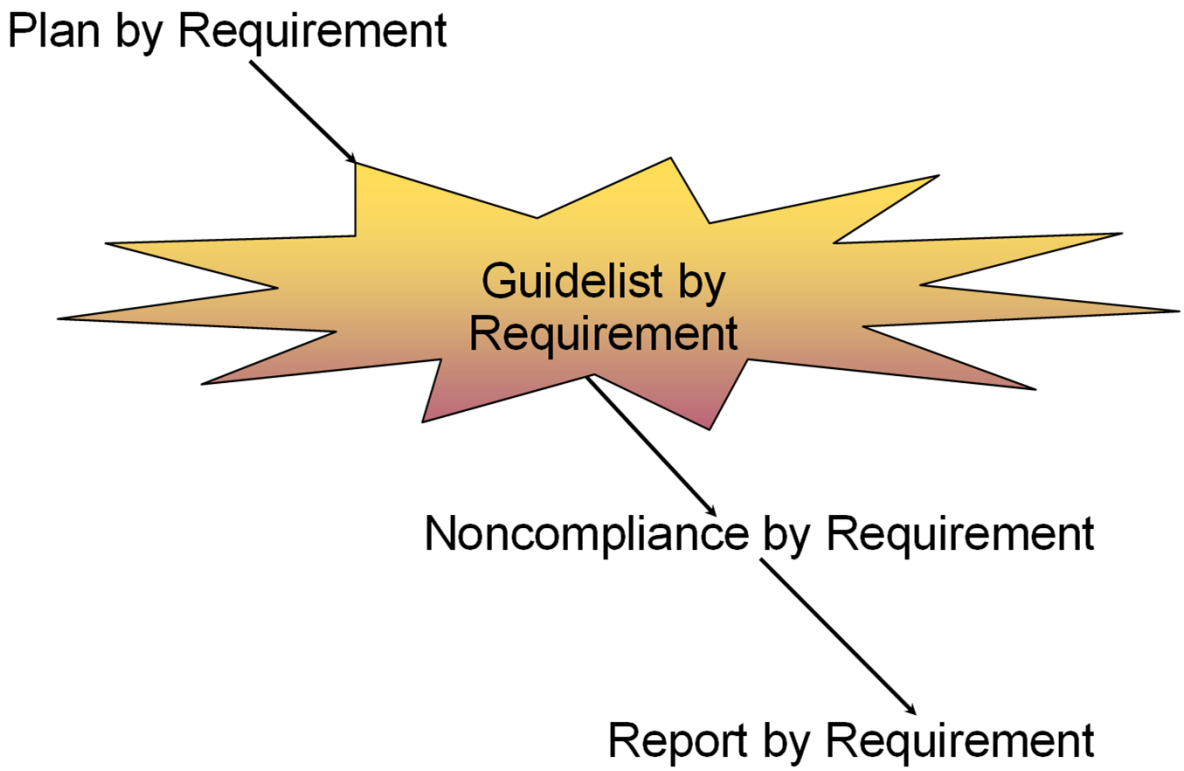
2. Audit your assigned procedure against the previously approved Quality Assurance Manual.

   (See third tab, “Reference Materials.”)

3. Determine compliance of the procedure to each Quality Assurance Manual requirement.

Write notes about compliance and/or noncompliance 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.

	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** Employees are aware of their contribution to the effectiveness of the system.	*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 provided by the Instructor.
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, etc.

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

Guidelist Development

Develop a guidelist sampling plan

1. Use your audit guidelist items from the previous exercise.
2. Using your “Look At” column: 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!

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 noncompliances?
   - What are they?
2. Discuss your findings with your audit team.

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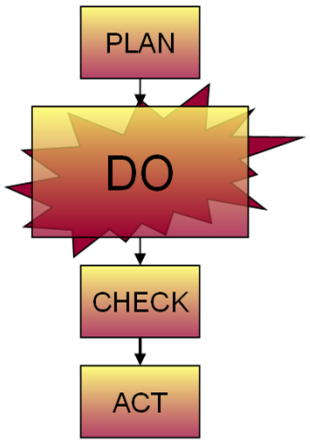
Phase 2 – Gather the Evidence

Learning Points:

- Stages in Performing the Audit
- Beginning the Audit
- Interview Techniques
- Establishing the Facts
- Objective Evidence
- Note Taking



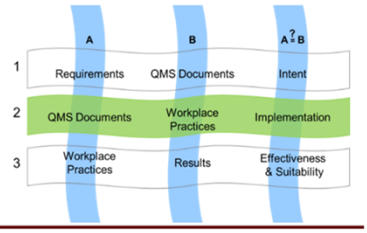
Audit Role Play

Listen and observe

1. What processes 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 “In-Brief” 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 “Out-Brief” meeting



Beginning the Audit: "In-Brief"

- Meet Sr. Executive or Quality Manager (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?)
- Discuss any special considerations (such as PPE to be used, language translation, etc.)
- Explain method of identifying & recording noncompliances
- Discuss daily debriefs and closing meeting
  - Time
  - Location
  - Attendees

"opening meeting" and the first interview often overlap

PPE = Personal Protective Equipment

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

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
- Closed Questions
  - Elicit Yes or No answers
  - Can be useful if that is what you want

Asking the Right Questions

- Imperative Question
  - Add a seventh “honest servant”— the crunch question

    Please **show me**!

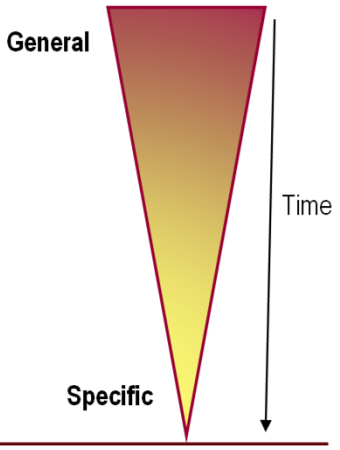
- Other useful types
  - Silent question
  - Obvious question
  - Unasked question
  - Inverse questions

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.

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…

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.

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

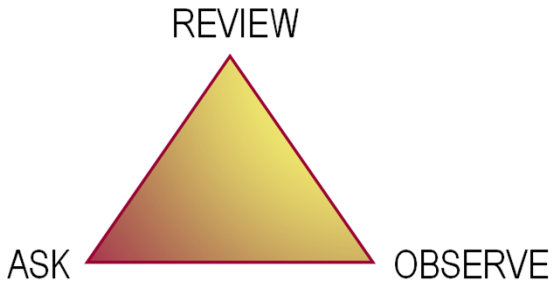
1. Develop four questions about your assigned Botta–Boom procedure and associated guidelist.
   Write two open questions and two imperative (show me) questions.
   (15 minutes)

2. Share and critique questions.

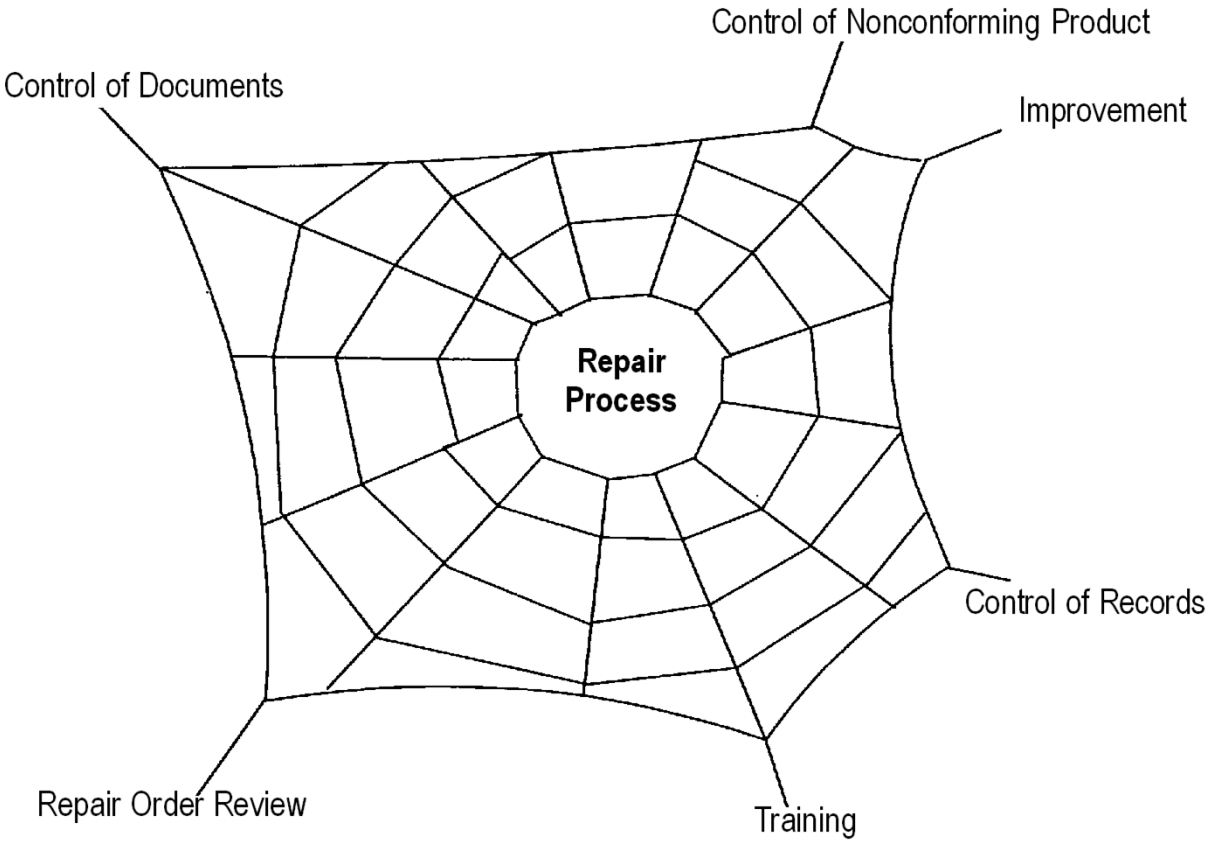
Establishing the Facts

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, (shown here as a repair process), you should always be auditing the *system*—checking the links and interfaces/hand-offs with other processes/systems.

"Human Factors" are another good consideration for systems audits. Look for countermeasures to common human errors in the organization's systems and processes.

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 auditors
- 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 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.

Another term for objective evidence is "Item of Proof" (IOP).

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*.

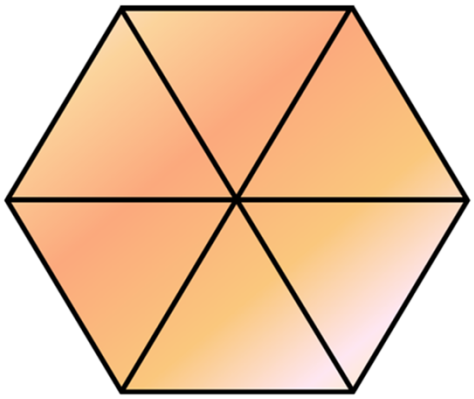
You are driving to work in nasty weather, and get caught in a traffic jam. Cars are backed up for miles, and the radio says there's an accident ahead, a three–car collision. You had noticed the roads were very slick. You're stuck, with no possible exit. At least you have some coffee to drink while you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

CFI = Certificated Flight Instructor

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

Taking a copy of a record of noncompliance may be necessary, but copies of everything looked at could become overwhelming to manage.

In all cases, be sure to note the information that will provide traceability: document number/revision, part number, serial number, purchase order (PO) number, test/inspection report number, training record name/number, etc.

Also helpful is a copy of the auditee's Organization Chart (with names & functions), both for prep before the audit and tracking of who was interviewed during the audit.

Audit Notes Form

Form 8.2.2

Audit Review Trail

Page 1 of 1

Process/Area Audited: Design Process

Audit Reference #: 00-006

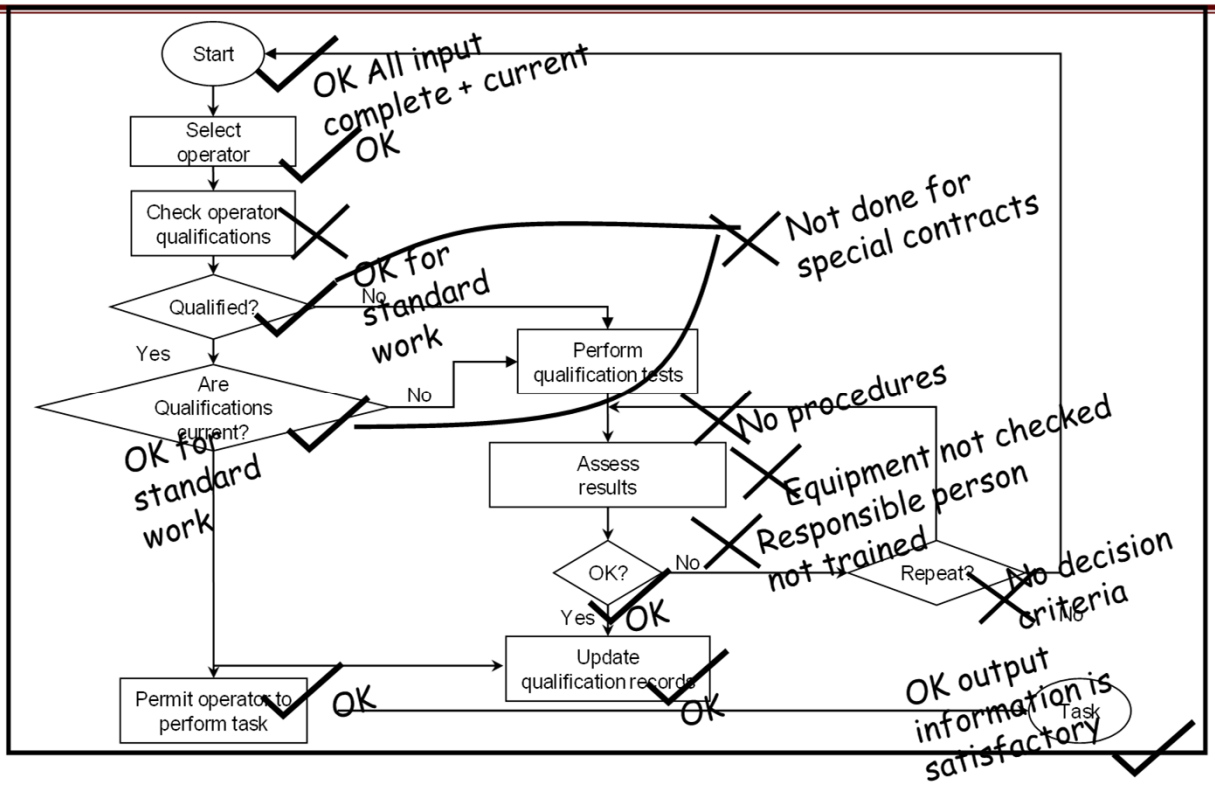
Auditor: I. M. Sharp

Date: 3/2/00

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

Is this really good practice?

Notes on Flowchart



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

Case Study Audits

Botta–Boom Interviews

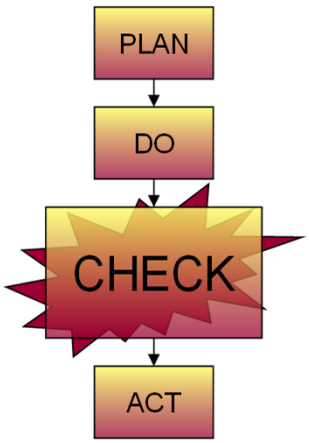
(See second tab titled “Case Study Materials.”)

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

Phase 3 – Make a Comparison

Learning Points:

- Noncompliance Definition
- Noncompliance Decision
- Ending the Audit

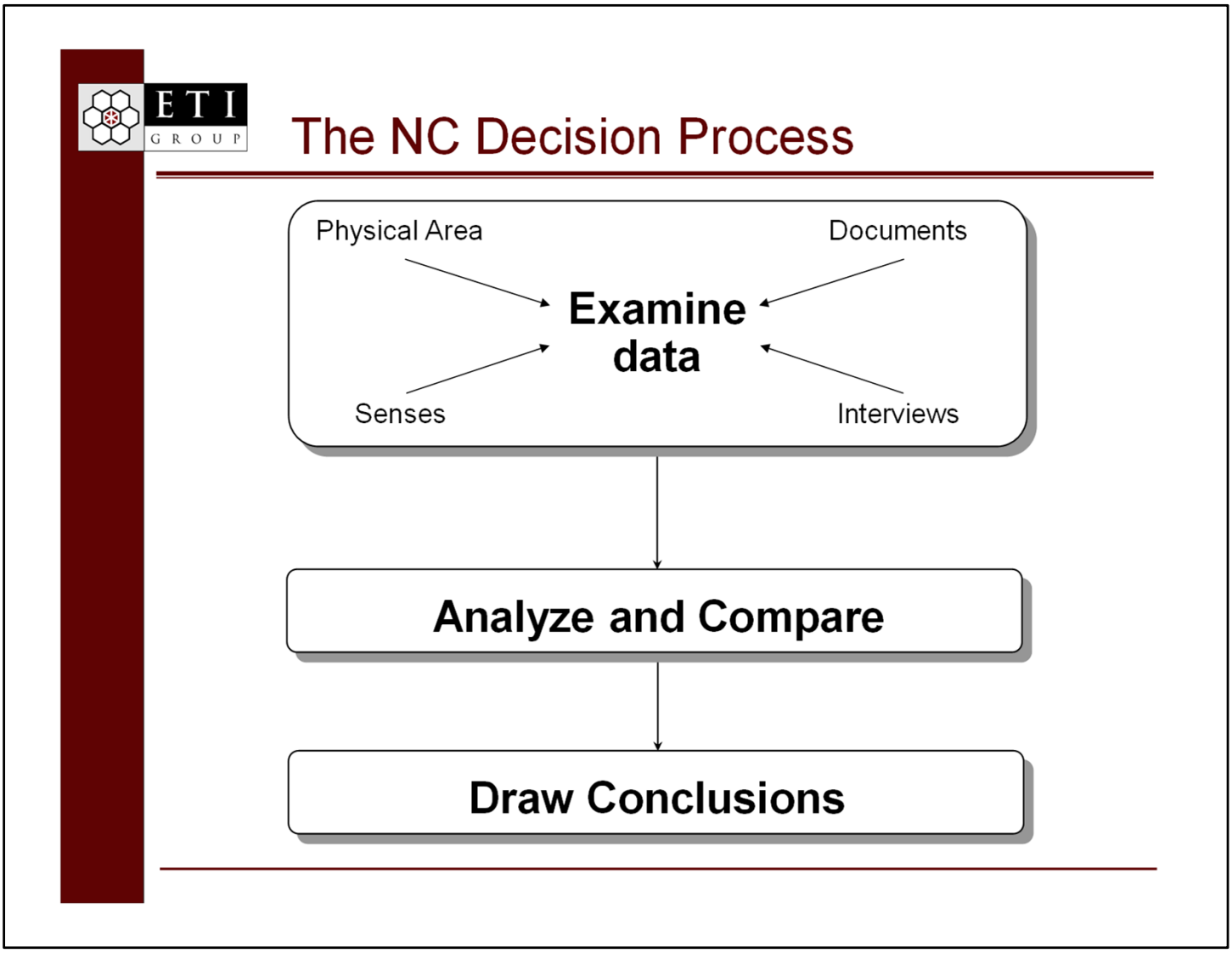


Noncompliance: Definition

"Non–fulfillment of a requirement"

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



Findings of Noncompliance must be based on Objective Evidence.

Remember the 3 Step Comparison Process. In Step 2, the auditor compares the Management System (MS) documentation to the actual practices to see if implementation has happened in all necessary areas and if processes are compliant with the requirements.

As the MS matures, auditing could go beyond simply assessing compliance. In Step 3, audits are conducted which compare workplace practices to results. We want to see whether the MS is suitable for the organization and enables it to meet regulatory (and customer) requirements effectively and efficiently. 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 compliance (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 noncompliance
  - If you don't have a requirement *and* objective evidence of it being *met*, you don't have compliance
- Confirm the evidence during the audit!
  - Conclusions drawn after the audit rely on accurate evidence at the time of the audit.

Ending the Audit — "Out-Brief"

- 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

This meeting may also be referred to as a "De-brief."

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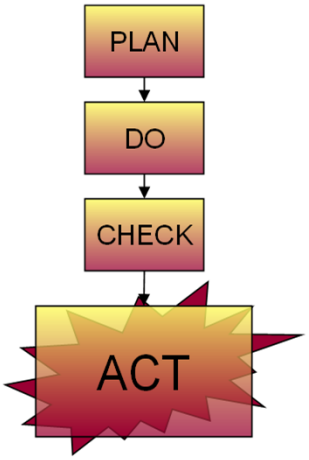
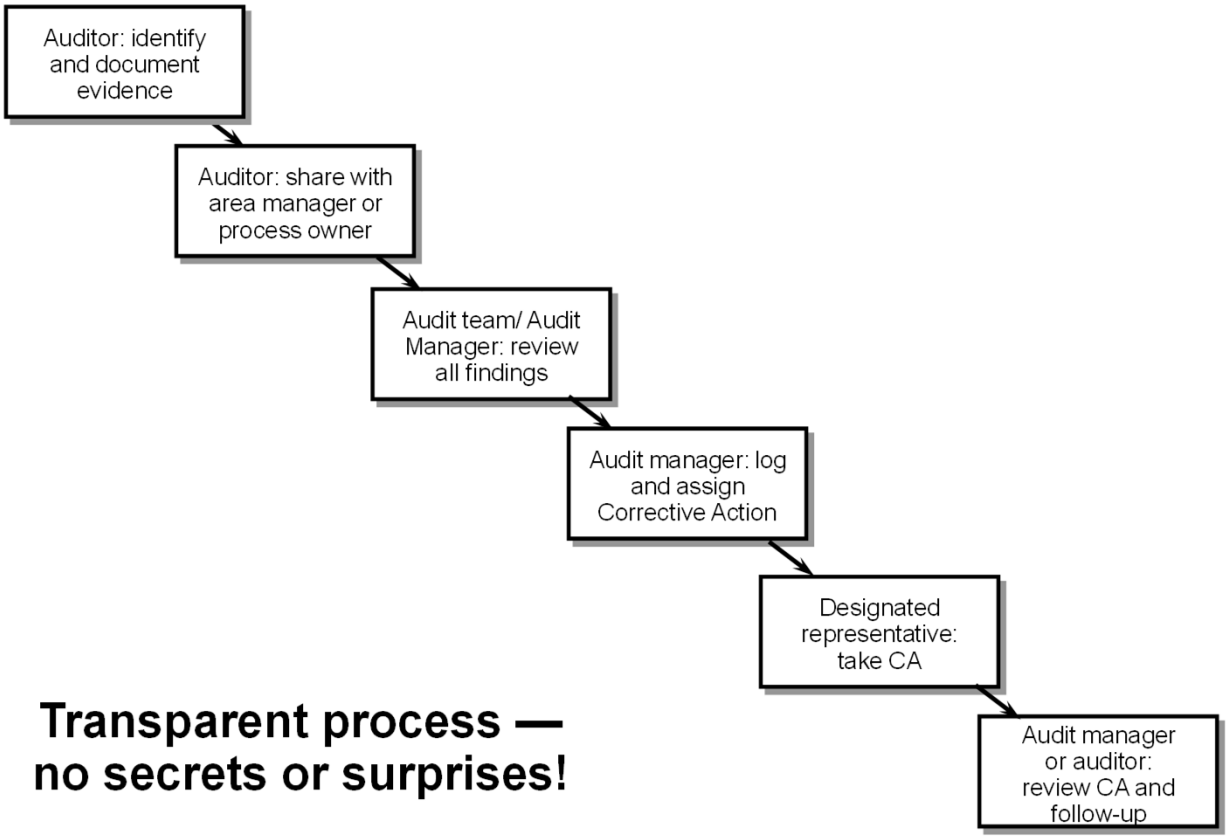
Phase 4 – Draw Conclusions

Learning Points:

- Processing Audit Findings
- Types of Issues
- Audit Reporting Options
- Noncompliance Severity
- Noncompliance Statements
- Reporting on the Audit
- Corrective Action Evaluation



Processing Noncompliance Findings



Transparent process — no secrets or surprises!

Types of Issues

- Finding:
  - Result of evaluation of audit evidence against the criteria
- Finding of Noncompliance:
  - A requirement is not being met
  - There is verifiable objective evidence
- Observation of OFI, SEI, etc.: Not a noncompliance
  - Observed issue which is not technically a "noncompliance" but one that the auditor wants to point out to management
  - These observations are the only place for your opinion!

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

There may be practices observed that are potentially risky (ineffective and/or inefficient), but where the auditor has no objective evidence of noncompliance. There may also be opportunities to improve upon the existing process; these opportunities may be raised by the auditor or the auditee. Some common terms used are Opportunity for Improvement (OFI) and Special Emphasis Item; you may encounter additional terms.

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 compliance. This sort of situation could generate debate on whether a Finding is a noncompliance or an observation.

Audit Reporting Options

- Write up as a Noncompliance
  - When a determination of noncompliance is made, Corrective Action is mandated
- Write up as an observation: OFI, SEI, etc.
  - Strongly recommends consideration, but does not mandate action
- Note in Audit Report to audit program manager/PI
  - On-the-spot fixes for minor issues
  - Suggest follow-up in a subsequent audit
- Forget it!
  - Not worth any further consideration or pursuit
  - Doesn't pass the "So what?" test

Some auditing 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 noncompliance.

PI = Principal Inspector

Noncompliance Severity

- Some organizations use “major” and “minor” to designate the seriousness of a noncompliance issue
  - Major: Lack of a system or system is totally ineffective, e.g., impacts safety of flight, limits ability to assure controlled processes and compliant, safe product/service
  - Minor: Weakness in some part of the system, e.g., single failure or lapse, no risk to control of processes and/or compliance of product/service
  - Usually a subjective judgment that requires experience!
  - Your organization and its associated regulations and procedures will provide specific guidance on determining the level of severity

Severity determination will usually involve some sort of risk assessment, perhaps ratings of impact on safety, product, process, customer, etc. along with their likelihood of occurrence.

Model for Noncompliance Statement

- State the requirement
  - Cite reference (regulation, standard, customer requirement, organization's policy/procedure, etc.)
  - Quote relevant portion of specific requirement
- State the noncompliance
  - 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 find the same thing

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

Citing References

- Describe the chain of requirements
  - Top requirement
  - Organization's manual
  - Organization's procedures
  - And so on
- Quote only the relevant portions of each requirement

Noncompliance Statement Example

- The *Quality Management Policy, QM-001 Rev. C,* paragraph 7.6 and procedure *OP 7.6 Rev. A Control of Monitoring and Measuring Devices*, paragraph 7.1.1, require that equipment used to accept product must be calibrated.
- Several uncalibrated calipers were being used during inspection operations; serial numbers were 0547, 0589, 0595.
- This is a noncompliance; practice does not comply with the procedure.

Writing Tips

- Use local terminology (use their terms where possible)
- 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 Noncompliance Statement initiates problem definition — the first and most critical step to taking effective corrective action on the problem.

PROBLEM STATEMENT

WHAT…	is the requirement/required condition?
	is missing? did you find?
WHO…	is the entity responsible for the issue?
	are the entities affected by the problem?
WHERE…	is it happening?
WHEN…	did it occur?
HOW…	serious is it? (Solve safety issues NOW)

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

Reviewing Noncompliance 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 = noncompliance
- Why a finding is a noncompliance = what requirement is not being fulfilled
- What documentation was affected = standard, QA Manual, procedures, W/I

Noncompliance Statement

As a class:

- Review non-compliances from the Case Study (cases 1–7) and select one to write–up.
- Write up the Noncompliance using the format provided by the instructor. Make sure to include:
  - Requirement
  - Noncompliance
  - Objective evidence

Noncompliance Statements

Botta–Boom Interviews

- Make assignments for writing up non-compliances within your Team (from cases 1 through 7). Each person should use *different* non-compliances from the case study.
- Each team member writes two (2) statements using the form provided by the instructor.
- Share and critique the Finding of Noncompliance 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

Objective Evidence should be listed in Noncompliance Statements and in audit notes.

Audit Summary Report

Audit Date:

Purpose & Scope:

Process(es) Audited:

Auditor Name(s):

General Observations:

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

Noncompliance Issues:

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

Report Writing Tips

- Write in plain English
- Avoid acronyms and jargon (as possible)
- Write with user in mind
- Be positive, concise and value-adding
- Make the connection between noncompliance and risks
- 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 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 ABC Design Procedure SOP-003 Rev. C. 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 ABC Design Procedure SOP-003 Rev. C 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
  - ✓ Noncompliance issues seen as criticism or threat
  - ✓ Recommendations seen as invasion of responsibilities
  - ✓ Grudging cooperation (can go 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

Sometimes a designated person's qualifications must be assessed and their name cited (e.g., a Designated Engineering Representative, DER, a Repair Station manager, etc.).

Noting best practices is a great way to reinforce desired behaviors and maintain a good working relationship with the audited organization. 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.
- When auditors are credible, they are more likely to be perceived as adding value.
- When the connection to value is made, non-compliances are more likely to be addressed effectively and promptly.

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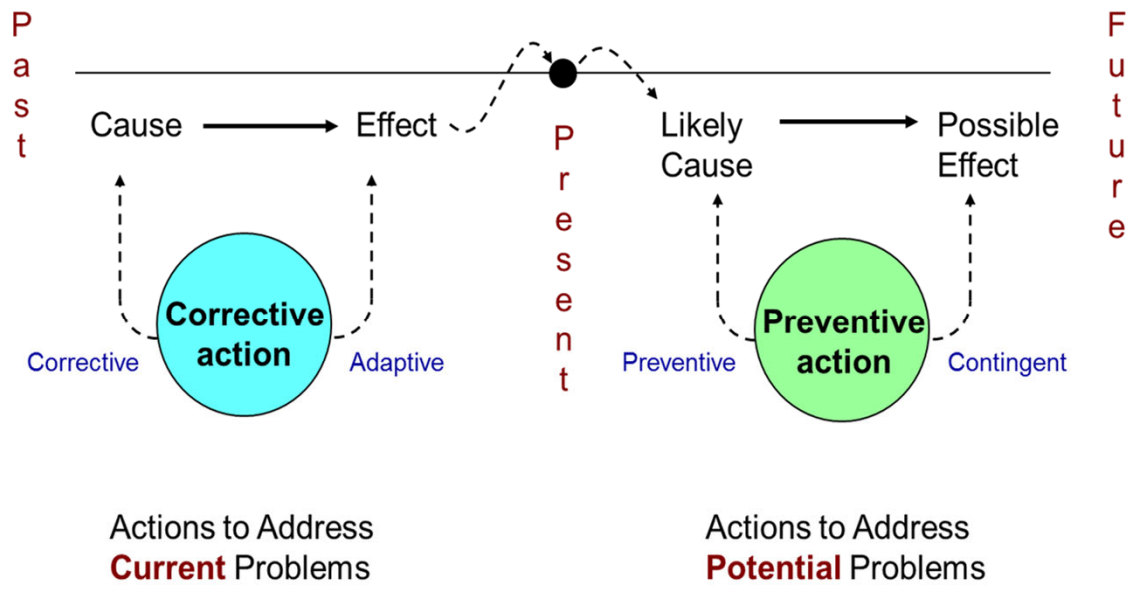
Case Study Audits

Botta–Boom Interviews

1. Read and evaluate audit interview Cases 8, 9 and 10. Identify any non-compliances. (Refer to the Quality Assurance Manual and Procedures.)
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 happening 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 noncompliance 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 non-compliances, corrective actions should be issued.
- A few tips:
  - Make sure the noncompliance 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

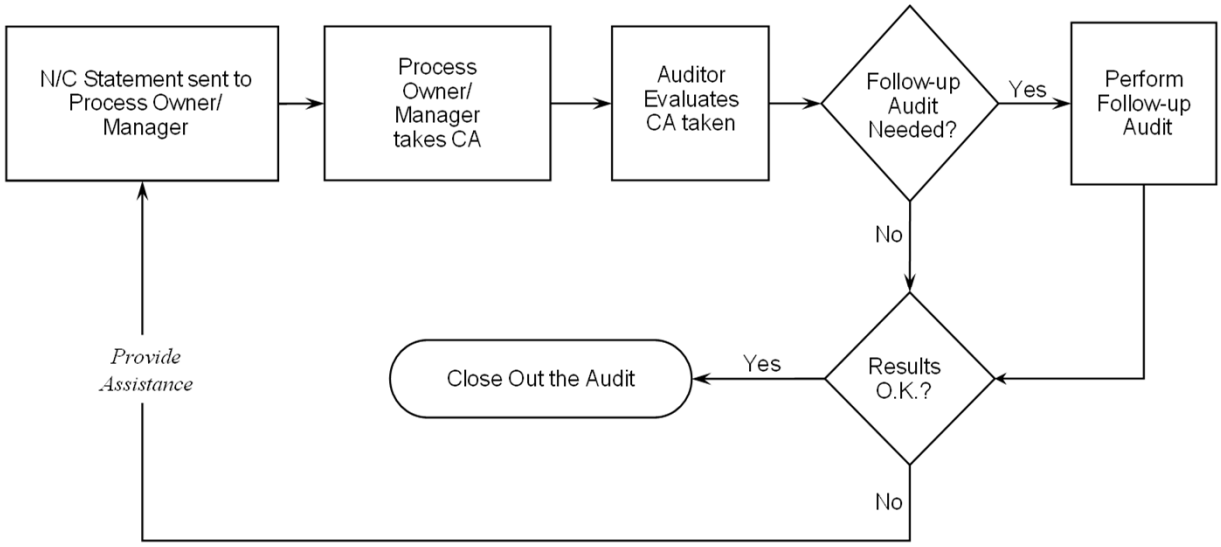
Intent *Compare Procedure to Standard*	If Procedure ≠ Standard: 1. Change the Procedure 2. Consider a Scope Exclusion
Implementation *Compare Procedures to Practices*	If Procedure ≠ Practice: 1. Change the Practice or 2. Change the Procedure
Effectiveness *Compare Practices to Results*	If Practice ≠ Desired Results: 1. Investigate why 2. Check the Goal

"Standard" meaning the audit criteria, i.e., requirements.

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 Noncompliance 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?

Summary

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

Things to Remember

- 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 noncompliance (or compliance) unless you first have:
  - A requirement
  - Objective evidence which is factual and verifiable.
- Audit broadly, looking for compliance rather than narrowly looking for noncompliance.
  - A mile wide and a foot deep
- 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.

Wrap-up

- Topics Covered:
  - Compliance Audits & the Audit Program
  - Management Systems and the Process Approach
  - Auditor Characteristics, Roles and Responsibilities
  - The Audit Process - 4 Phases of Plan-Do-Check-Act
- Key Points:
  - Auditing is a critical tool for determining compliance to standards and for guiding improvements
  - If done well, auditing can add value for both the FAA and the audited organization
  - Audits are strongly affected by the human element
  - Audits are most effective when properly planned
- What were some key points for you?

You now have a basic understanding of audit practices. *Convert it* 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?