Registrars

- Independent third parties who assess an organization's Quality Management System
- Not controlled by ISO
- US registrars have no government sanction
- Private companies performing their service for a cost

Audit

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

* definition from ISO 9000:2000

Lead Assessor

- A quality auditor that is qualified to MANAGE a quality audit
  - Overall management of the team
  - Decision making
  - Team selection/input into team selection
  - Preparation of audit plan
  - Liaison with auditee
  - Submitting final report/letters

Quality Auditor

– **A person qualified to perform quality audits:**

- Remain within scope of the audit
- Exercise objectivity
- Collect and analyze data that is relevant and sufficient to permit the drawing of a decision about the quality activity being evaluated
- Able to review documents for adequacy
- Professional and ethical at all times

Audits - Forms

- Internal Audit
- Second Party Audit
- Third Party Audit

Audit - Internal

Audits performed by an organization upon itself.

Organization's personnel assess its own performance and/or compliance.

Internal audits are considered and commonly referred to as first party audits.

Audit - Second Party

An audit of the organization performed by the customer or customers representative.

Performed to assure the organization is in compliance to contractual requirements.

Audit - Third Party

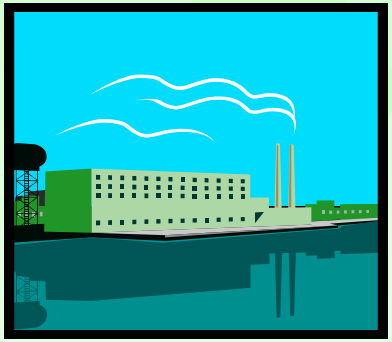
An audit of the organization performed by an independent company or regulatory authority.

Performed to assure the organization is in compliance to contractual requirements.

End result may include the issuance of a document from a “ Third Party”acknowledging the acceptability of the organizations quality system.

Quality System Certification Validation Terms

- Self Certification (Validation)
- Second Party Certification (Validation)
- Third Party Certification



Self Certification (Validation)

- The organization sets up and validates their own Quality System
- No independent valuation of the system

Second Party Certification (Validation)

- A Second party audit of the organization's Quality System
- Normally conducted by the customer or a customer representative

Note: DoD validation is considered second party validation

Third Party Certification

- The procedure by which a third party (Registrar) gives written assurance that a Quality System conforms to specified requirements
- Note: The ISO organization ***does not certify or require certification*** of Quality Management Systems

Registration

- The assessment and periodic audit of the adequacy of an organization's Quality System by a third party (Registrar)

Certificate of Registration

- Issued by the Registrar when a organization's Quality System conforms to the Registrar’s “interpretation” of standard

What is Quality Audit?

ISO 9000 : 2000 defines a Quality Audit as a systematic and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria is fulfilled.

Quality Management System Audit

A quality management system audit is conducted as a two step process

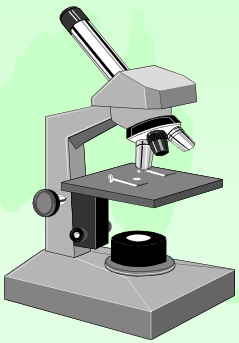
Adequacy Audit ☑

and a

Compliance Audit ☑

Adequacy Audit

- An audit which seeks to establish the extent to which an organization's documented Quality System complies with the applicable standard
- Purpose is to ensure that all clauses of the applicable standard have been adequately addressed



Compliance Audit

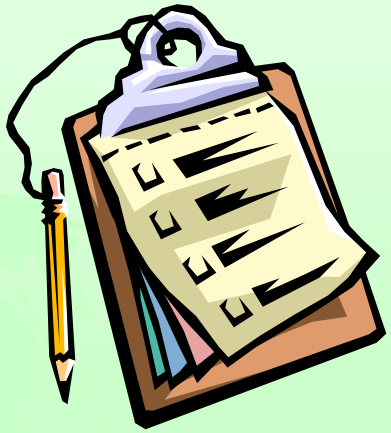
- Accomplished after the Adequacy Audit
- Normally utilizes a Memory Aid / Checklist
- Purpose: An audit which seeks to establish the extent to which the documented system is implemented and being followed

Auditing Process

The audit process is comprised of three steps:

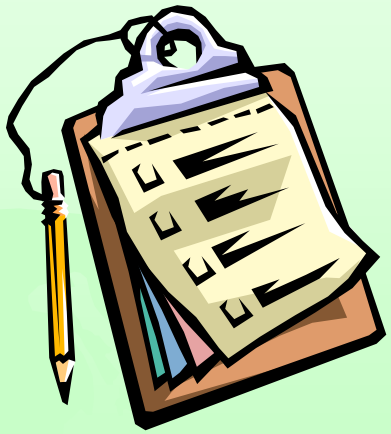
1) Audit Preparation
2) Audit Execution
3) Audit Follow-up

Audit Preparation



- Decide what you are trying to accomplish (SCOPE)
- Determine what contractual standards and requirement/revision you are required to review
- Understand audit procedures
- Familiarize yourself with criteria, areas, activities and shifts to be audited

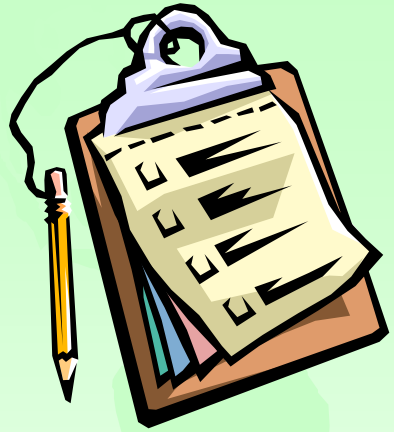
Audit Preparation



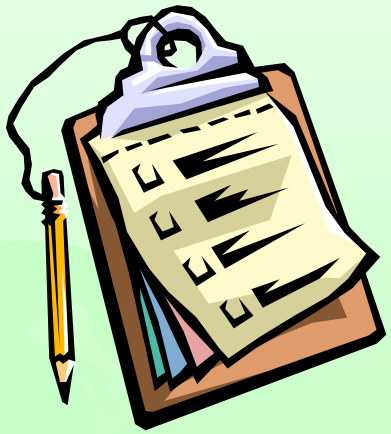
- Contract requirements
- Government and regulatory requirements
- Contractor quality documentation
- Organizational chart/floor plan
- Quality functional responsibilities
- Government data/customer complaints

Audit Preparation

- Team member selection and training
- Audit strategy/assignments
- Overall plan/schedule/areas to be audited
- Documentation review
- Preparation of checklists
- Opening meeting agenda
- CA & Follow up responsibility

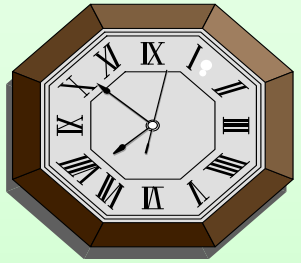


Audit Preparation
(Lead Assessor)



- Meet key contractor personnel
- Tour contractor's facility
- Discuss and agree on scope of the audit
- Determine if special skills are required
- Determine audit team size/composition
- Identify logistical requirements
- Highlight and real or potential problems

Audit Preparation Notification Letter
(Lead Assessor)



- Date and time for opening meeting
- Purpose of audit and performance standard
- Areas to be audited and work shifts
- Lead assessor and team members
- Tentative audit agenda
- Request contractor provide written acknowledgement of notification

Audit Execution

Opening Meeting

- Formal agenda of the audit
- Coordinates with the audit plan
- Contractor senior management should attend
- Should provide tentative date and time for closing meeting

Audit Process

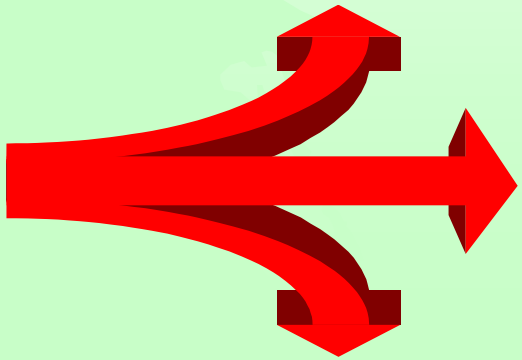
- Collect evidence
- Analyze data
- Make a decision
- Issue Nonconformance Report
- Share findings with contractor on a daily basis

Collecting Information

- Take notes as you conduct the audit
- Can be used by colleagues for later audits
- Used as objective evidence
  - Statements
  - Document numbers
  - Identifiers
- Used as an audit record

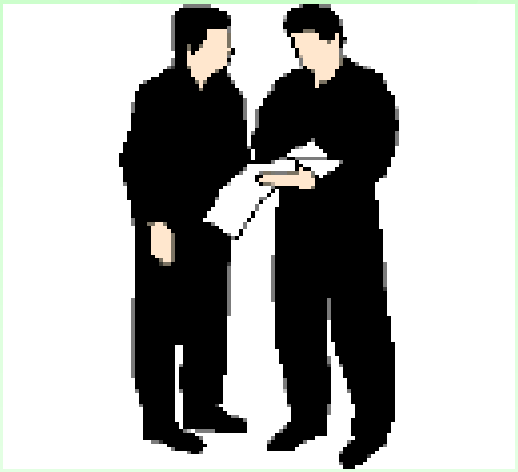
Gathering Evidence

- Observe conditions
- Interview people
- Analyze information
- Investigate systems and operations
- Evaluate situations



Interviews

Interviews are one of the primary methods used to gain insight and gather objective evidence on the implementation of the quality management system.



Importance of the Interview

Interviews are conducted to verify that:

The organization's QMS is fully implemented and effective.

Interview Philosophy

" Say what you do":

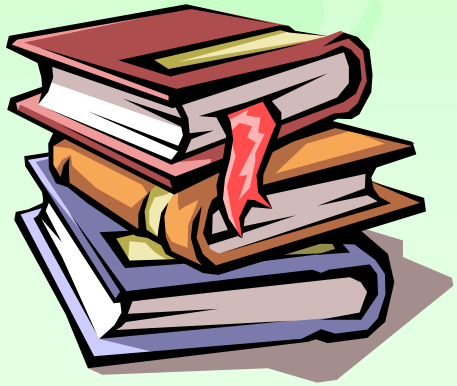
The organization has established a series of interrelated documents which "spell out" their QMS:

- **Quality Manual**
- **Procedures**
- **Work Instruction**
- **Recording Documents**

Interview Philosophy

“Do what you say”

Implementation – The organization is actually using and following the documented system as written.



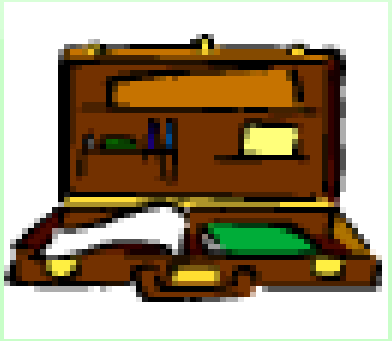
Interview Philosophy

“Have proof that it was done”

Objective Evidence -

- **Interviewing personnel**
- **Physically observing the process in action**
- **Reviewing historical records**

General Rules for Interviews

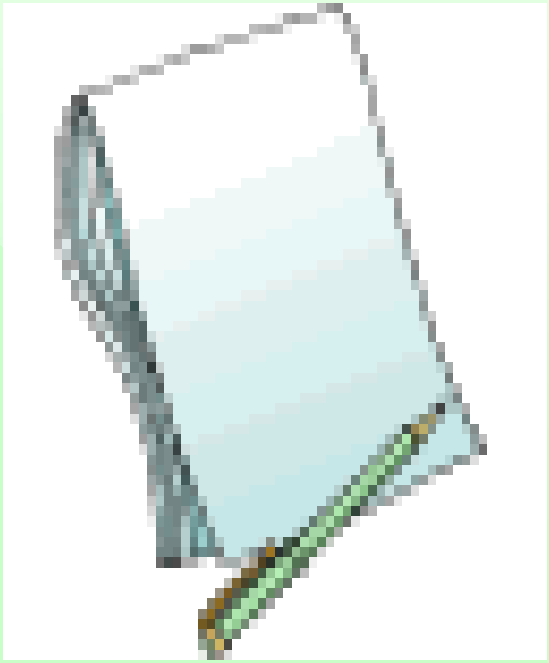


- Be brief
- Cover a single point
- Make it directly related to the topic
- Use words that the interviewee will understand
- Use words that you feel comfortable with
- Choose the right type of question

Finally thoughts...

- Ask the person who does the job...not the supervisor
- Explain your purpose for being there
- Speak clearly and carefully
- Take notes and copies of documents reviewed (if possible)
- Ask follow up questions to gain clarification
- Interview members on various shifts and locations (it possible)
- Discuss the results and thank the interviewee
- **Remember NO SURPRISES !!**

Checklists

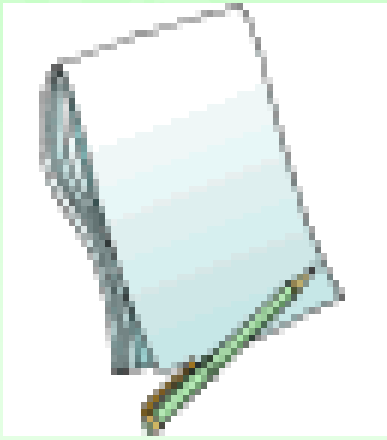


Purpose:

- Consistency
- Standardization
- Comparison of audit findings over time

Checklists

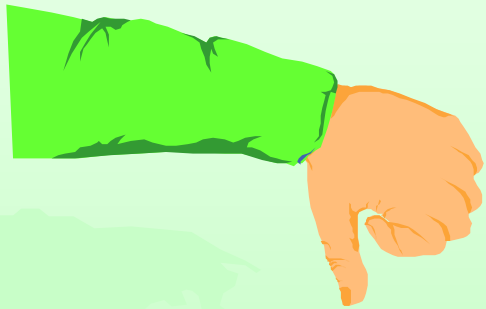
- DCMA uses the DCMA ISO 9000 Checklist
- Various Checklists developed by DoD and Industry
- Checklist can be tailored but all auditors should stay within the intent of the checklist



Audit Analysis

- The quality system does / does not reflect the required ISO 9001 requirements (and other specified contractual requirements) (Adequacy Audit)
- The actions or decisions by personnel do/do not reflect conformance to the written quality system documentation (Compliance Audit)

Types of Deficiencies



- Nonconformance –

  Favored term for describing deviations from a specification or standard

- Deviations –

  Refer to differences between what is and what should be

Categories of Nonconformance's

- Major - The absence of a required procedure or process or the total breakdown of a procedure or process
  - Greatly effect product/service quality
  - Put the contractor at risk of losing customers
  - Jeopardize industry/government certification
  - Cause great harm to other contractor operations

Categories of Nonconformance's

- Minor - A single observed lapse in a procedure or process
  - Nonconformities which do not directly affect product/service quality or may be deemed easily rectified

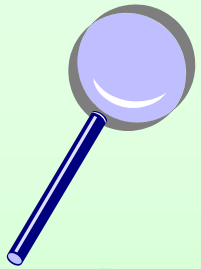
The Vital Few

- Nonconformities that can greatly effect quality, though few in number.
- Usually represent detriments to safety or economics. May also be chronic problems detected in earlier audits or specifically mentioned by auditees as ongoing problems.

The Trivial Many

- Minor nonconformities in great numbers.
- These can reflect systematic errors and affect quality due to high volume. When applied against a single requirement, can constitute a major nonconformity.

Observations

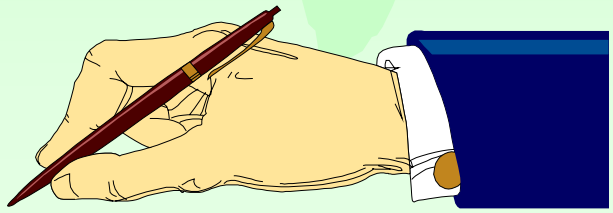


Situations which warrant clarification or investigation so as to improve the overall status and effectiveness of the quality system being audited.

Note: Recording and issuing “Observations” findings to an organization is not normally part of a DoD QMS audit.

Reporting Nonconformities

- All nonconformities will be supported by objective evidence
- All nonconformities will be directly traceable to a requirement
- All nonconformities will be documented on a Nonconformance Report Form



The Nonconformance Report

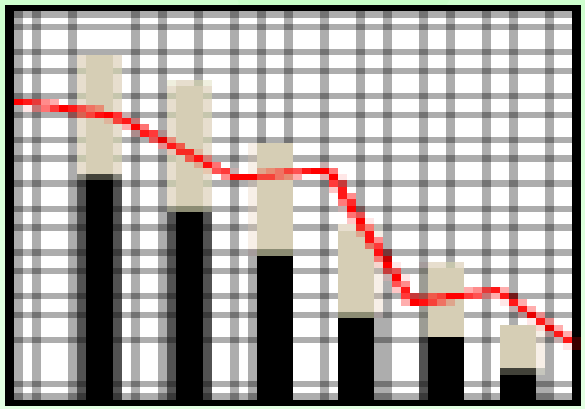
- Use sequential numbering system, e.g., DCMAE-1, DCMAE-2, etc.
- Be clear, concise and accurate
- No interviewee NAMES
- Hand to the contractor and obtain acknowledgment of receipt

The Nonconformance Report #2

Upon completion of the identification of the nonconformity, the signature of both parties -the auditor and the contractor- is required. This is accomplished either during the audit or at the closing meeting. It assures that the contractor is aware of the nonconformity and agrees that the corrective action should be implemented.

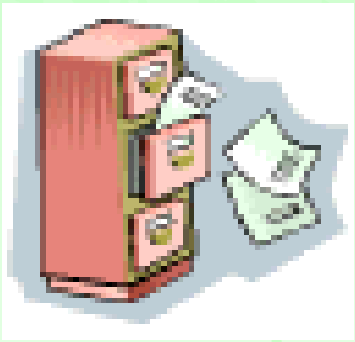
Prioritizing Findings

- Rank nonconformities by importance...most serious ones first
- Use Pareto Analysis to assist you when compiling the data



Compliance Audit Completion

- All working documents (paper, computer files, etc) will be given to the lead assessor
- All contractor documentation will be disposed of in accordance with contractor procedures



Audit Closeout

Reporting

Communicating the information, findings, and conclusions derived from the quality audit.

Closing Meeting

- Lead Auditor presents audit findings
- Purpose:

1. To present logical and factual explanations of the strengths and nonconformance's of the auditee’s system
2. To solicit commitments from the auditee for corrective action

Audit Report Content

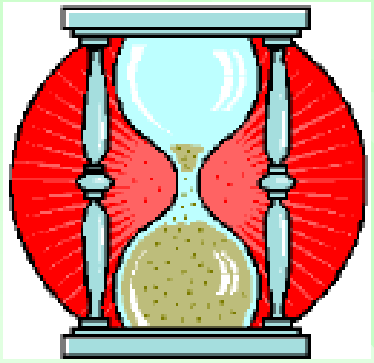
- Audit scope and objectives
- Details of audit plan
- Identification of reference documents
- Observations or nonconformities
- Audit report distribution list
- Required follow up reporting/action

Tips on Writing the Audit Report

- The lead assessor's responsibility
- Make the audit report understandable
- Provide information that people can act upon
- Set the proper tone...be professional
- Use graphics to show results
  (a picture is worth a thousand words)

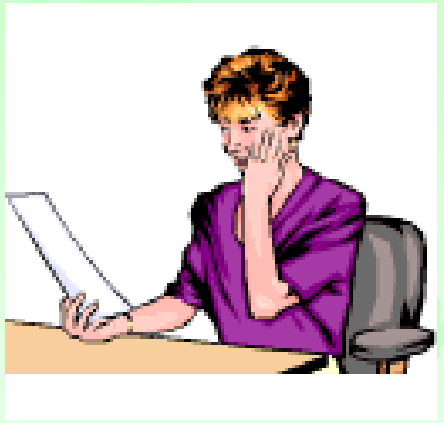
Tips on Writing the Audit Report #2

- Present independent and objective information
- Reflect positive and negative information

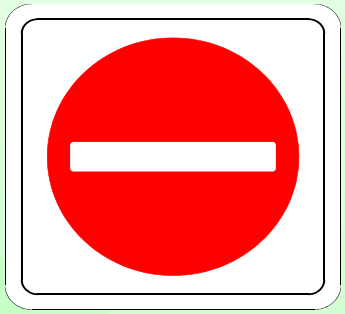


Audit Report Design

- Distribution list
- Executive summary
- Details of audit findings
- Corrective action required



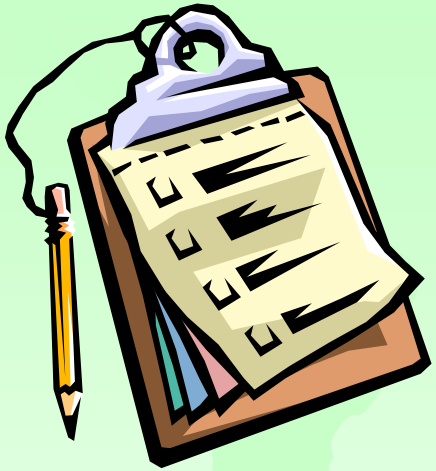
Corrective Action (CA)



Corrective Action is an action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Categories of CA

- Correction - Rework or adjustment
- Corrective Action - Changes in (quick fix, short term) procedures or systems; long term



Corrective Action -

- Auditor identified nonconformity to specific requirement
- Auditor documents nonconformity backed up by supporting objective evidence

  (copy of actual nonconforming document if possible)

Auditor Responsibilities

- Auditor obtains acknowledgment of nonconformities from the organization during the audit or at the Closing Meeting
- Auditor verifies implementation and effectiveness of Corrective Action (as appropriate and specified)

Corrective Action - Contractor Responsibilities

- Agrees to need for Corrective Action
- Proposes Corrective Action
- Introduces and implements Corrective Action
- Verifies the effectiveness of Corrective Action
- Notifies auditor when finding corrected
- Prepares for auditor’s follow-up visit (if required)

Follow-up Activities

Purpose:

- Obtain confidence that the nonconformity has been phased out
- Verify that both short and long term corrective action (as stated in a CA plan) has been implemented
- Verify that internal controls are in place to monitor the effectiveness of the CA
- Verify continuous improvement