



QUALITY MANAGEMENT

08/04/2023

QUALITY

It Does Not Happen by Magic

ISO 9001

An ISO 9001 audit is a systematic, independent, objective and documented process for gathering facts. These will help you identify areas for improvement and ensure you have best practice processes in place. Driving continual improvement is a key part of ISO 9001.

AUDIT TRADEMARKS

Quality Auditing Is an Art and a Science

Quality Audits Are Snapshots in Time

Quality Audits Should Not Be Confrontations

Quality Audits Investigate, Verify and Con-firm

The Quality Audit Should Be Used As a Tool for
Continuous Quality Improvement

ASSESSOR KNOWLEDGE

Quality System Requirements

Product Specifications

Investigation Techniques

Sampling Techniques

Communication Techniques

ASSESSOR TRAITS

Observant

Honest

Investigative

Questioning

Thorough

Communicates Well

Adaptable

Cooperative

REVIEW AND VERIFY DOCUMENTATION, IMPLEMENTATION AND EFFECTIVENESS OF:

Policy Manual (Quality Manual)

Procedure Manuals or Directives

Work Instructions, Drawings, Etc.

General Quality System Requirements

Individual Product Specifications

AUDITS CAN

Enhance Internal Quality Systems

Be Part of Continuous Quality Improvement Efforts

Help Establish Trusting Relationships

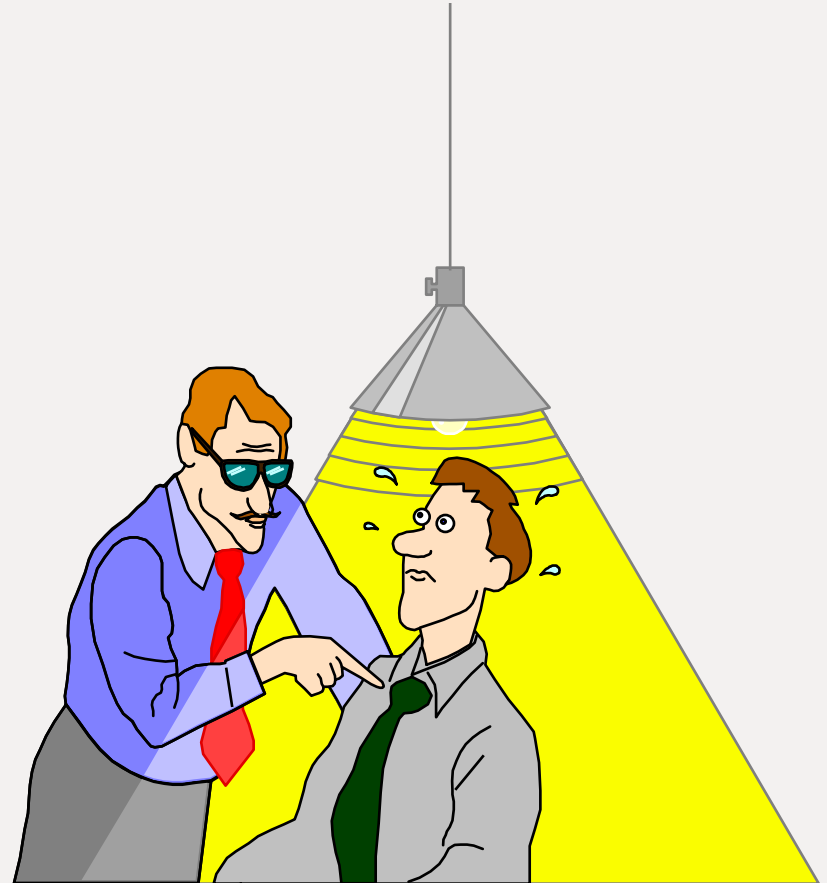
AUDITS ARE NOT

Acceptance of Product

Punch Lists

Public Hangings

Inquisitions



WHAT IS AN AUDIT?

“A Systematic and Independent Examination to Determine Whether Quality Activities and Related Results Comply With Planned Arrangements and Whether These Arrangements Are Implemented Effectively and Are Suitable to Achieve Objectives”

Quality Applications

System Audit

Process Audit

Product Audit

ADDITIONAL AUDIT TERMS

Compliance Audit-Compliance to Standards, Review Processes, Review Data

Operational Audit- Time Studies, Work Studies

Readiness Review by Internal Management
ISO900x

Management Review

Review of Processes, Procedures and Controls

Survey

Comprehensive Evaluation

SYSTEM AUDIT DEFINITION

A Documented Activity Performed to Verify, by Examination and Evaluation of Objective Evidence, That Applicable Elements of the Quality System Are Appropriate and Have Been Developed, Documented and Effectively Implemented in Accordance and in Conjunction With Specified Requirements.

TYPES OF AUDITS

Internal Audits

Management System Audits

Self-Assessments

Mini Self-Assessments

External Audits

Supplier Audits

Third-Party Audits

System Audits

Verification That a Quality System Exists (Continued)

TYPES OF AUDITS

(continued)

Process Audits

Verification That Process Procedures Exist, Are Correct and Are Being Followed

Verification That Process Procedures Are Followed Under Standard, Rushed and Adverse Conditions

Product Audits

Reinspection of Product

Verifies Inspector Capabilities and Correct Use of Specifications

HIERARCHY OF AUDITS



Survey

System Audit

Process Audit

Product Audit

CHARACTERISTICS OF AUDITS

Are Independent of Doer

Performed by a Person Not Responsible for Production or Services in Area Being Audited

Have Measurement Criteria

Specifications (Quality System Requirements and Product Requirements)

Attribute Data (Go/No Go)

Variables Data (Actual Measurements) (Continued)

CHARACTERISTICS OF AUDITS *(continued)*

Are Performed by Competent Personnel

Trained Audit Team Members

Are Cost Effective

Prevention of Problems

Are Samples of the System

Isolate One Small Moment in Time

Like Shining a Spotlight on a Forest of Trees, and Drawing a Conclusion Based on the Appearance of the Highlighted Trees

Must Be Sure the Sampling Procedure Is Correct

USE OF AUDITS

Continuous Improvement Efforts

Internal

External

Benchmarking

Value-Added Suppliers

Certification

Internal (Quality System)

External (Suppliers)

Adherence to *Auditor Code of Ethics*

WHY AUDIT?

Competition

External-We Want Low-Cost, High-Value Suppliers

Internal-We Want to Verify That Our Systems Are Adequate and Effective

Regulation

Imposed by Customers

Self-Imposed

General Quality Standards or Internal Quality Standards

Federal or State Regulations

ISO Standards

Self-Preservation to Audit Ourselves Before Someone Audits Us

AUDITS IMPROVE PERFORMANCE IF THEY:

Meet Management Needs

Provide Feedback

Provide a Forward Look in Time

Could Predict Where Process Controls or Product Measurements Are Needed

Measure Effectiveness and Compliance to Internal and External Policy and
Contract Requirements

WHO IS THE CLIENT?

There Are at Least Three Customers We Must Satisfy on Each Audit

Auditee

Boss

Buyer of the Service (Client)

WHAT MANAGERS MUST DO

Plan

Do

Check

Assessors Address the “Check” Function of the Cycle
by Checking and Monitoring a System

Act

AUDIT ADMINISTRATION

Formal Audit Procedures

Initiation and Preparation Is at Least 25% of Assessors' Time

Areas to Be Audited

Team Composition and Training

Notification of Auditee

Checklist Development

Transportation

On-Site Audit Performance Approximately 50% of Assessors' Time

Reporting and Closure Approximately 25% of Assessors' Time

Audit Report

Audit Records

Tracking and Closure

AUDIT INITIATION PHASE

Audit Initiated by the Client

Develop Audit Plan

Lead Assessor (Audit Manager) and Client

THE PREPARATION PHASE

Items to Be Covered in the Audit Plan

Audit Objective

Audit Scope

Resources

Initial Contacts

Use of Checklists

Investigation of Past History

Understanding of the Process

DEFINE THE OBJECTIVES

Why Are We Doing This?

What Type of Audit Are We to Perform (System, Process, or Product)?

What Do Our “Customers” Want?

ESTABLISH THE SCOPE

What Are the Boundaries Within Which We Will Look?

Audit Plan, Time Frame

Facilities, Organization, Departments

Product Line

A Supplier May Have Numerous Product Lines

Process Area

Geographic Location

Product Area

Quality Assurance System

Product Standards

Effect of Subsuppliers

IDENTIFY STANDARDS

Government Regulations

Industry Standards

Company Manuals

Department Procedures

Process Instructions

DEFINE RESOURCES

Team Composition

Trained and Qualified

Knowledgeable of Process to Be Audited (Technical Experience)

Humanistic

Adjust the Number of Audit Team Members to the Scope of the Audit

Team Size

One-Person Audits Are an Invitation to Trouble, Although It Can Be Done

(Continued)

DEFINE THE RESOURCES

(continued)

Balance Is Important, but More Than Six Assessors Is a Mob

Length of the Audit

*A Typical Quality System Audit Requires Between 1-5 Days to
Complete*

LEAD ASSESSOR RESPONSIBILITIES

Prepare the Audit Plan

Select the Audit Team (Most Cases)

Brief the Audit Team

Submit a Report

DESIRABLE ASSESSOR CHARACTERISTICS

Knowledge of Quality, Product Engineering and Procurement
Principles and Practices

Knowledge of Requirements

Knowledge of Techniques

Sound Judgment/Open-Mindedness

Patience

Interest

Tenacity (Strength)

Professional Attitude/Integrity

Good Listening Skills

(Continued)

DESIRABLE ASSESSOR CHARACTERISTICS

(continued)

Inquisitiveness

Good Verbal and Written Skills

Honesty

Ethics

Diplomacy

Good Planning Skills

Experience

Objectivity

Empathy

ASSESSOR MUSTS

Knowledge of Verification Techniques

Knowledge of Standards

Knowledge of Sampling Techniques

Knowledge of Human Nature

Knowledge of Time Management

UNDESIRABLE ASSESSOR CHARACTERISTICS

Argumentative

Opinionated

Lazy

Easily Influenced

Inflexible

Impulsive-Jump to Conclusions

Gullible

Uncommunicative

Devious

Poor at Planning

Unprofessional

Prescriptive

CONTACT THE AUDITEE

Informal Contact by Team Leader

Date (Firm but Flexible)

Purpose

Scope

Formal Contact by Letter or Memo

Time and Date of Audit

Purpose

Scope

(Continued)

CONTACT THE AUDITEE

(continued)

Activities to Be Audited

Interfacing Organizations

Applicable Quality Requirements

Identification of Team Members

Preliminary Schedule

Note: Review Pertinent Items With Audit Team

PERFORM DESK AUDIT

Review Quality Assurance Documentation of Auditee

Determine What Control Systems Are in Place

Review Prior Audits

Investigate Exemptions or Waivers

Review Performance History

UNDERSTAND THE PROCESS

What Are the Controls of the System?

Do a Desk Audit of the QA System

Look at the QA Policy Manual

Look at the Process and Procedure Manuals

What Facts Are Available?

Key Variables Identified

Statistics Used to Monitor Processes

Where (Who) Are the Facts?

What Is the Product?

An Audit Team Member Should Be Familiar With the Product Being Audited

REVIEW HISTORY

Prior Audits

Verify That Previous Corrective Actions Have Remained in Effect

Verify That Strengths Are Still in Place

Procurement

Files Should Be Examined for Any Changes or Exceptions the Supplier Has Requested in the Past

Customer Feedback

Frequent and Type of Past Problems Should Be Evaluated

Number of Change Orders or Waiver Requests Should Be Checked

DEVELOP CHECKLISTS TO PROVIDE

Structure

Must Define Checklist Before the Audit Is Done

Brainstorm to Develop Checklist

Required Coverage

Not Designed to Stifle Creativity

Use Common Sense Regarding Applicability

A Communication Document

A Place to Record Data

Objective Evidence Is Required for Anything Less Than Satisfactory

Help in Time Management (Pace of Audit)

CHECKLISTS-POINTS TO CONSIDER

Assessors Can Use

Canned Checklists

Yes/No Checklists (Attributes)

Rating Checklists (Variables)

Things to Consider When Developing Questions for a
Checklist Are

What Is the Process During Standard Operation?

What Is the Process Under Rushed Conditions?

What Is the Process When There Is a Problem?

SUMMARY OF PREPARATION PHASE

Define the Audit Objective

Establish the Audit Scope

Allocate Resources

Contact the Auditee

Develop Checklists

Review History

Understand the Process and Control Systems

RESULTS OF THE PREPARATION PHASE

Audit Plan

Auditee, Purpose, Scope, Activities to Be Audited, Team, Standards

Checklist Questions

Items and Reference Location of Each Requirement

Initial Evaluation

Based Upon Documentation Received

Desk Audit

QA Manual

Product Performance (Past Audits)

Plan for Action

Areas Needing Attention

Items to Be Confirmed

THE PERFORMANCE PHASE

Hold Opening Meeting

Conduct On-Site Audit

Review Controls of Quality System

Verify the System Is Working

Is It Documented, Implemented and Effective?

Share Information

THE OPENING MEETING

Must Have:

Entire Audit Team Present

Auditee's Plant Manager and Staff

Requires Two-Way Communication

Trade Introductions

Restate Objectives

Form Initial Impressions

State Areas of Concern of Assessor and Auditee

Settle Logistics: Conference Room, Telephone, Hours of Operation, Lunch, Etc.

Should Not Take More Than 30 Minutes (Continued)

THE OPENING MEETING

(continued)

If Needed: Allow Auditee 15 Minute Maximum to Present
Quality System En-hancements

Distribute the Checklists

Define the Audit Schedule

Be on Time!

CAUSES OF QUALITY ISSUES

Lack of Top Management Support

Lack of Organization

Lack of Training

Lack of Discipline

Lack of Resources

Lack of Time

Lack of Teamwork

Lack of Knowledge

Lack of Consistency

Look for Symptoms of These Issues

EVALUATING THE INFORMATION

Formal (Documented) Control Systems vs. Informal (Understood/Verbal) Control Systems

Does Management Believe in Quality and Are These Beliefs Communicated Throughout the Organization?

Is the Control System Used by Management?

Is the Control System Adequate?

Are Key Quality Variables Identified?

Is the Control System Working?

How Is It Monitored?

VERIFICATION METHODS

Three Primary Methods Used

Tracing

Corroboration

Sampling (Discussed Later)

TRACING TECHNIQUES

Go With the Flow

Techniques of Tracing

Tracing of Contract–Series of Audits Performed on a Contract As It Progresses

Random Auditing–Review Without a Pattern What Is Taking Place in a Process at the Time of the Audit

Horizontal Auditing

Backward–From the End of Process (From Order Completion Toward Beginning)

Forward–From the Beginning of Process (From Order Receipt)

Middle–Backward or Forward From Some Critical Point in the Process

(Continued)

TRACING TECHNIQUES

(continued)

Vertical Auditing–Review Management Layers for Elements
Such As Quality Goals and Quality Communications

Departmental Traces–Reviews Numerous Quality Elements
Within a Department

Element Traces–Reviews a Quality Element in Various
Departments

CORROBORATION

Because Perceptions Vary, a Statement Made During an Interview Is Not a Fact Until It Is Corroborated by Someone Else or Is Verified by a Document

The Facts Must Agree

Two Different Assessors

Two Different Records

Two Different Interviews

Combinations of the Above

Tie Conclusions to What Is Tangible

Qualitative

Quantitative

Forms, Records and Procedures

AUDIT SAMPLING

Trying to Find the Truth in a Limited Amount of Time

Estimation Sampling

Discovery Sampling

Acceptance Sampling

What to Sample?

Critical Items or Areas

Important to the Auditee, Key Quality Variables/Key Operators

Overloaded/Stressed Areas

How to Sample?

Random Sample

Unbiased Sample

How Much to Sample?

Sampling Is Discussed Later

SOURCES OF DATA COLLECTION

Physical Evidence

Reinspect, Retest, Recheck

Documentation and Records

Sensory Observations

Rusty Parts

Nonconforming Parts Stored With Good Parts

Observations of Tasks Being Performed

Comparisons and Relationships

Patterns and Trends

Interviews

Difficult to Do Effectively

A Valuable Source of Information

No Place for Sexism or Biases

METHOD FOR EFFECTIVE INTERVIEWS

Put Person at Ease

Your Presence Is Threatening

Explain Your Purpose

Demonstrate Competence

Be Aware, Not an Expert

Utilize Proper Questioning Techniques

Ask Open Ended Questions

Avoid Leading Questions

Use the “Pregnant Pause”

Ask Why Five Times (Why, Why, Why, Why, Why)

Ask the 5 W’S (Why, Who, What, When, Where) and a How

(Continued)

METHOD FOR EFFECTIVE INTERVIEWS

(continued)

Listen Twice As Much As You Talk

Analyze and Verify What Is Said

Believe a Confession

Verify a Claim

Write Your Notes Out Loud

Do Not Keep Secrets

Be Flexible—Allow for Additional Information and Discussion

Explain Your Next Step

Conclude Cordially

Follow Up

BRIEFING THE AUDITEE DURING THE AUDIT

Short and to the Point

Discuss Verifications and Concerns

About 10–15 Minutes

In Each Area As You Progress Through the Facility



ASSESSOR TEAM MEETINGS

Informal–At the End of Each Day With Audit Team Members

Assessor Sharing

Facts, Tentative Conclusions, Problems

Replanning

Any Changes to the Audit Schedule

Reporting

Preliminary Audit Results

Status of the Audit or Areas Covered

Areas Completed, Areas to Be Examined, Concerns and Issues

REPORTING PHASE

Informal Report

Exit Meeting—Approximately 60 Minutes at Completion of On–Site Investigation

Formal Report

Aim to Have Written and Distributed Within Two Weeks After the Audit

Both Types Must Be Clear and Precise

Statements of Noncompliances Contain:

Requirement

Location

Evidence

Element of Noncompliance

THE EXIT MEETING

Must Have the Exit Meeting After Completion of On-Site Investigation. Approximately 60 Minutes Should Be Allocated for This Meeting.

Limit Attendance to Managers of Areas Audited. QA Manager Alone Is Unsatisfactory (May Filter or Distort).

Present Summary (Lead Assessor). It Is Okay to Agree or Disagree.

(Continued)

THE EXIT MEETING

(continued)

State That Audit Observations Are Produced From a Limited Amount of Audit Samples of the Entire Process. Management Should Not Only Review the Incident Cited by the Audit Team, but Also Investigate the System.

Lead Assessor Should Read Through All Deficiencies First, Then Discuss Audit Details. Individual Assessors Clarify and Respond to Specific Questions.

Keep Minutes of the Meeting.

Explain Follow-up and Corrective Action Response Process.