AUDITING

Principles

AQS 115
QUALITY SYSTEMS & AUDITING PRINCIPLES

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AUDIT – General – Quick Review

Quick Review

- ## Quality Management Audit – WHY?
  - ### Provide feedback for improvement
    - #### Differs from
      inspection which focusses on accept/reject or surveillance which is continuous monitoring

Depth of analysis

System Audit

Process Audit

Product Audit

Audit Scope

Certified Quality Technician Handbook, 2nd Edition, ASQ press
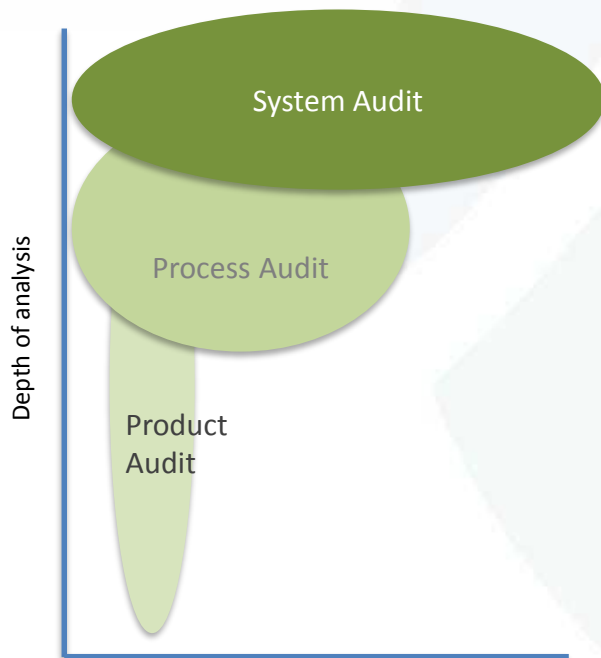
	Compliance	Performance
System	Consistent implementation of a defined system. Promotes stability	Ability to achieve organizational goals. Promote change.
Process	Performance of the ability in accordance with defined processes	Ability of the processes to achieve desired characteristics
Product	Production of goods or services to defined requirements	Suitability of the goods or services for intended use.

Arter, Quality Audits, 3rd Ed

PARTICIPANTS

- Auditee
  - Person/organization being audited
    - » Company; Division; Department
- Client
  - Person/organization requesting the audit (may be Auditee)

- Interested Party
  - Stakeholder to the audit process or results

  - ➤ *FDA – determines new product/facility compliance with regulations*
  - ➤ *Registrar – determines compliance with standard*
  - ➤ *Customer – reviews supplier systems as relates to their needs/requirements*
    - ✓ *May send own personnel or external firm*
  - ➤ *Quality Assurance – internal monitoring of quality system*

ROLES & RESPONSIBILITIES

- Auditor: Conducts the audit
  - Lead Auditor
    - » Communicates audit requirements
    - » Manages audit activities and team
    - » Reports the results
  - Team Member
    - » Conducts activities as directed by Lead
    - » Provides documented evidence for report
    - » Similar qualifications to Lead, but not as experienced
  - Technical Expert
    - » Accompanies team but not part of audit
    - » Knowledge of specific topics
  - Observer
    - » Accompanies team but not part of audit
    - » Cannot interfere or influence conduct of audit
    - » Internal audit – trainee

ROLES & RESPONSIBILITIES

- Auditee: Accommodates the audit and provides
  - Access to facilities, processes, products, documentation
  - Resources necessary
  - Guides (staff members) to accompany Auditor(s)
    - » Establish contacts/timing
    - » Ensures safety/security rules followed
    - » Witness on behalf of Auditee
    - » Clarify / assist in collecting information
  - Follow-up actions as required by Audit Report

AUDITING

- Preparing, Conducting, Reporting

AUDIT PRINCIPLES

- **Relating to Audit**
  - Independence
    - » Forms basis for impartiality of audit and objectivity of conclusions
    - » Auditors MUST
      - Be independent of activity being audited
      - Free from bias and conflict of interest
      - Maintain objective mindset throughout process
      - Ensure findings/conclusions based only on the evidence
  - Evidence-based approach
    - » Rational method for reaching reliable (reproducible) conclusions in a systematic process
      - Audit evidence is verifiable
      - Based on sample of information available *(time constraints)*
      - Proper use of sampling contributes to confidence that can be placed on conclusions

AUDIT PRINCIPLES

- **Relating to Auditor**
  - **Ethical Conduct**
    - » Trust
    - » Integrity
    - » Confidentiality
    - » Discretion
  - **Fair Presentation** (report truthfully & accurately)
    - » Audit activities - findings, conclusions, reports
    - » Significant obstacles encountered
    - » Unresolved, diverging opinions (auditee / audit team)
  - **Due professional care** (apply diligence & judgement)
    - » Exercise care related to importance of task placed by auditee
    - » Have necessary competence

AUDIT ACTIVITIES

- Extent depends on scope and complexity of specific audit and intended use of the conclusions

internal versus external

regulatory compliance versus ISO compliance

System   -   Process   -   Product

AUDIT ACTIVITIES

- Four Phases
  - Regardless of type (system, process, product)
  - Regardless of purpose (Internal, Customer, Compliance)

  1. Preparation
  2. Performance
  3. Reporting
  4. Closure (corrective action)

Audit Activities - PREPARATION

- Arter describes
  - Purpose
  - Scope
  - Audit Team (resources)
  - Authority for the audit
  - Requirements for activity
  - Develop technical understanding for process(es)
  - Prepare plan and contact
  - Perform initial evaluation
  - Prepare working papers/data collection

Audit Activities - PREPARATION

- ISO 19011-2011 describes
  - Clause 6.2 Initiating the audit
    - 6.2.1 Establish contact
    - 6.2.2 Determine feasibility
  - Clause 6.3 Preparing audit activities
    - 6.3.1 Perform document review
    - 6.3.2 Prepare audit plan
    - 6.3.3 Assign work to team
    - 6.3.4 Preparing working documents

AUDIT ACTIVITIES

- Process Flow of activities for specific audit (ISO 19011-2011)
    1. Initiate
    2. Conduct document review
    3. Prepare for on-site activities
    4. Conduct on-site activities
    5. Prepare, approve and distribute audit report
    6. Complete (closure)
    7. Conduct follow-up (if applicable)

ACTIVITIES – Initiating the Audit

- Appoint Team Leader
- Define objectives, scope and criteria
- Objective *(purpose (goal) of audit)*
  - Extent of management system conformity with audit criteria
  - Capability of management system to ensure compliance/conformity
    » Statutory, Regulatory, or Contractual requirements
  - Evaluate management system effectiveness in meeting its own specified objectives
  - Identify areas of potential improvement of management system

ACTIVITIES – Initiating the Audit

- Scope
  - Extent and boundaries
    - » Physical locations; organizational units/activities/processes
    - » Products/services
    - » Subcontracted services
    - » Time period covered by the audit
    - » Applicable QMS clauses

- Criteria
  - Set of policies/procedures or requirements used as reference for comparison to audit evidence
    - » QMS requirements - 21CFR, ISO 9001:2015, ISO 13845:2016, etc.
    - » Customer requirements/contract
    - » Industry requirements
    - » Organization's own documents

ACTIVITIES – Initiating the Audit

- ## Determine feasibility (availability)
  - Sufficient and appropriate information to plan audit
  - Adequate cooperation from Auditee
  - Adequate time and resources for audit
- ## Select team
  - Members, Observers, SME's etc.
- ## Establish contact with Auditee
  - Dates (start/finish)

AUDIT ACTIVITIES

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ACTIVITIES – Document Review

- Prior to on-site audit, review auditee's documented QMS for conformity with audit criteria
- Consider
    - Size, nature, complexity of organization
    - Objects and scope of audit
    - Scope of QMS

Internal versus External

- ✓ Internal - procedures/work instructions, etc. available
- ✓ External – confidential business information
    may defer review until on-site

Examples:

- » Previous audit reports
- » Quality Manual, Procedures
- » Contracts, Drawings/Specifications

ACTIVITIES – Document Review

- Prior to on-site audit, review auditee's documented QMS for conformity with audit criteria
- Consider
  - Size, nature, complexity of organization
  - Objects and scope of audit
  - Scope of QMS

- ISO Auditor –
  - Conduct preliminary site visit to obtain overview of available information
  - IF found to be inadequate, Team leader inform Client/Auditee
  - Make decision to suspend or continue until resolved
- Regulatory considerations
  - NDA (New Drug Application)
  - 510K (Premarket Notifications)

ACTIVITIES – Document Review

- Conducting the review
  - Are requirements of reference document addressed
  - Does documentation match audit scope
  - Have responsibilities been adequately defined
  - Has documentation structure been defined
  - Are methods consistent with requirements
  - Is lower level documentation (i.e. work instructions, forms, etc.) referenced

AUDIT ACTIVITIES

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ACTIVITIES – Preparation

- Prepare audit plan
- Prepare working documents
- Assign work to the team

ACTIVITIES – Preparation

- Prepare audit plan
  - Basis for agreement between auditee / audit team on conduct
  - Amount of detail reflects scope and complexity
  - Flexible to permit changes
  - Ensure cultural/religious concerns are considered

Internal versus External
- ✓ Internal: 1-2 hours in the department, mutually agreed on time
- ✓ External
  - ✓ Customer/Supplier typically 1 day (maybe 2)
  - ✓ Certification Body – generally 1-3 (maybe 5) depending on company size and whether certification or surveillance
  - ✓ Regulatory - 5 to 30+ days depending on purpose

ACTIVITIES – Preparation

- Prepare working documents
  - Checklists / check sheets (prepared by team members)
    - » Flexible to allow for changes during audit
  - Initial flow chart(s) based on documents reviewed
  - Sampling plans, forms
  - Use a reference for recording during audit
  - Safeguard any confidential information (CBI)
  - Retain until end of audit (closure)

ACTIVITIES – Preparation - Checklists

- Advantages
  - Keeps scope/objectives clear
  - Evidence of planning
  - Maintains audit pace/continuity
  - Reduces bias
  - Reduces workload during audit (provides direction)
  - Provides space for notes
  - Identifies anticipated (expected) evidence
- Disadvantages
  - Tend to lose value if "tick lists" or "questionnaires"
  - Rigid adherence to "pre-planned" questions

Prepare as memory aids

ACTIVITIES – Preparation - Checklists

- Prepare as memory aids
- Identify applicable factors
    - Inputs
    - Outputs
    - Measures
- Requirements
    - What to look at (process observation, procedures, etc.)
    - What to look for (records, data, evidence, etc.)

        » *Company SOP for supplier and/or internal*
        » *Develop questions based on document review*
        » *Objective Evidence*
            - *Documentation*
            - *Records*

Checklist - Example

Activity	Clause	Questions	Possible Documents or Records	Results
Purchasing materials/components for production	8.4 Control of Externally – provided Processes Products Services	What is the process for ensuring production has materials when they're needed?	• Inventory Control Procedure • Production Planning/Scheduling procedure • Purchasing Procedure	
		How is a new (potential) vendor qualified?	• Supplier Approval procedure • Completed Supplier questionnaires • Approved Supplier files	

		Please show me four completed (received) purchase orders from May – August for the following materials
		  PE Resin #4293
		  Red Dye #TT567
			• Approved Supplier List
			• Purchase order/Receiving documents	

ACTIVITIES – Preparation - Flowcharts

- Dependent on audit scope
- Utilize to estimate flow and organize plan

Turtle diagram
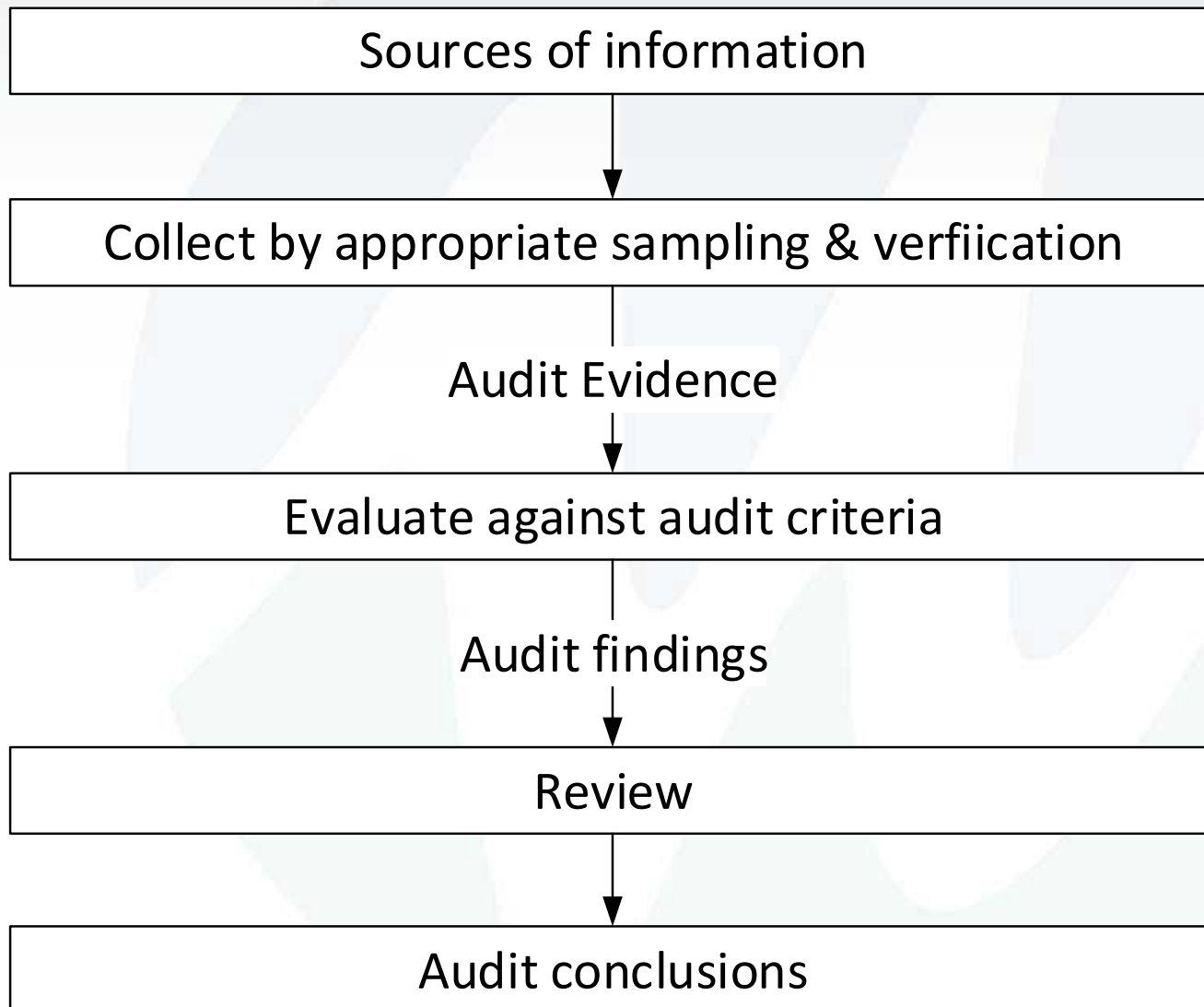
ACTIVITIES – Preparation

- Prepare audit plan
- Prepare working documents

- Assign work to the team
  - Typically coordinated amongst individuals

AUDIT ACTIVITIES

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AUDIT ACTIVITIES – Conducting On-Site

Sources of information

↓

Collect by appropriate sampling & verfiication

Audit Evidence

↓

Evaluate against audit criteria

Audit findings

↓

Review

↓

Audit conclusions

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
- Communication during the audit
- Roles/responsibilities of guides/observers
- Collecting and verifying information
- Generating audit findings
- Preparing audit conclusions
- Closing meeting

  – *Internal versus External*
    » *Not out to "get someone" or "find problems"*
    » *Respect time*
    » *Confidentiality*

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
  - Team leader prepares for / conducts the meeting
  - General topics *(internal vs external; compliance/conformance)*
    - Introductions / roles / attendance
    - Objective / scope /criteria
    - Documentation status
    - Audit plan/timetable confirmation

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    - » Documentation status
    - » Audit plan/timetable confirmation
    - » Audit methods / sampling
    - » Communication channels / language of the audit
    - » Logistics: resources (guides), safety/security rules,
    - » Audit progress / reporting methods (nonconformities)
    - » Interim meetings / Closing meeting
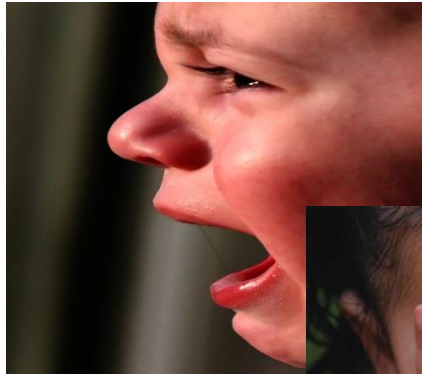
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- Generating audit findings
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- Closing meeting

"I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel."

Maya Angelou

AUDIT ACTIVITIES – Conducting On-Site

- Communication / Interpersonal Skills
    - Ask the right person
        - » Interview person from appropriate level(s) for process / task
    - Put auditee at ease
        - » Smile and show eye contact
        - » Say please and thank you
    - Ask <u>short</u> questions and <u>listen</u> to the response
        - » Follow up on audit trails
        - » Show interest
        - » Give praise when appropriate

AUDIT ACTIVITIES – Conducting On-Site

- Communication / Interpersonal Skills (cont.)
    - Be tactful, open-minded and polite
        - » Show patience and understanding
        - » Avoid "off-the-cuff" / condescending remarks
    - Reflect right attitude, tone of voice /body language /facial expression
        - » Speak appropriately to persons for different levels (hourly worker to president)
    - Be aware of cultural/social/religious customs
    - Don't say you understand when you don't

COMMUNICATION

COMMUNICATION

- The exchange of information between people by
  - Speaking
  - Writing
  - Using common systems of signs or behavior

- 5 types
  - Intrapersonal
  - Interpersonal
  - Small Group
  - Public
  - Mass Communications

COMMUNICATION

- Delivering your message
  - Direct Language
  - Factual and relevant details
  - Repetition / reiteration
  - Be aware of non-verbal message
  - Check often for understanding

- Email, Phone, Face-to-Face

COMMUNICATION

- Barriers
  - Attitude
  - Experience
  - Mood
  - Noise Level
  - Non-Verbal Messages
  - Subject Knowledge
  - Wording

COMMUNICATION

- Barriers
  - Attitude
    - negative prevent adapting to change
    - overly optimistic miss what actually occurring
  - Experience
    - Oversharing
    - Newbie wanting to prove
  - Mood
    - when grumpy may not listen
    - when joyful interrupt others
  - Noise level
  - Non-Verbal messages
  - Subject knowledge
  - Wording

COMMUNICATION

- Barriers
  - Attitude
  - Experience
  - Mood
  - Noise Level
    - Hearing all the messages
  - Non-Verbal Messages
    - Demonstrate engagement (i.e. eye contact, relaxed)
    - Back to the person indicates not interested
  - Subject Knowledge
    - The know-it-all
    - pretending loses credibility & erodes trust
  - Wording
    - be non-ambiguous,
    - get to the point,
    - maybe a quick greeting will break the ice (i.e. email salutation)

COMMUNICATION

LISTENING SKILLS

- Listening is hard work
  - Listen intentionally for people's names
  - Listen with interest
  - Try to get rid of your assumptions
  - Listen for what isn't said

- Active Listening
  - Try to understand from speaker's point of view
Versus
- Hearing
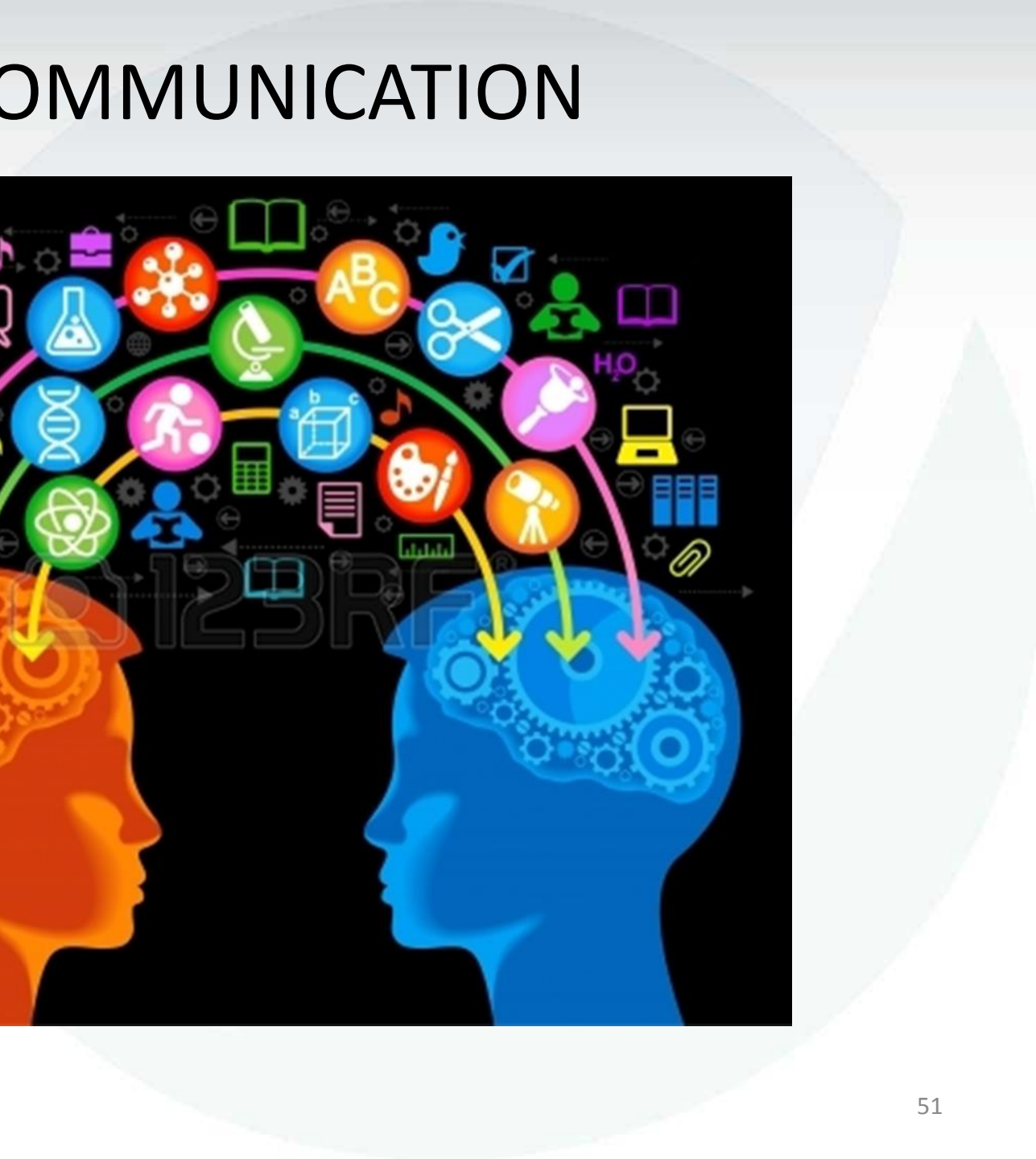 - Physical process of eardrum and brain

LISTENING SKILLS

- Listening is hard work

- Active Listening Skills
  - Make the decision to listen.
  - Don't interrupt.
  - Keep your eyes focused on the speaker and your ears tuned to their voice.
  - Ask a few questions throughout the conversation.
  - Summarizing statements

COMMUNICATION

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
- Communication during the audit
- Roles/responsibilities of guides/observers
- **Collecting and verifying information**
- Generating audit findings
- Preparing audit conclusions
- Closing meeting

AUDIT ACTIVITIES – Conducting On-Site

- Collecting and verifying information
    - Collect information relevant to
        » Audit objectives, scope and criteria
        » Interfaces between functions, activities and processes
    - Collect evidence by appropriate sampling and verification
        » Record it
        » Be aware of sampling limitations
        » Use only verifiable evidence

Sampling dependent on size of organization/ audit scope/ complexity of process(es)

newer, higher risk, high volume work flow/records

"How many" determined by auditor based on risk

Ensure adequate to control the process, move on if no nonconformities

(no findings does not equal no nonconformities in system)

AUDIT ACTIVITIES – Conducting On-Site

- Collecting and verifying information (cont.)
  - Techniques for obtaining evidence
    - » Interviewing
    - » Observation
    - » Review documents (procedures, work instructions, specifications, etc.)
    - » Review records (lot/batch records, calibration, validation reports, etc.)
  - Follow the Process *(utilize flowchart)*
    - » Forward trace
    - » Backward trace
  - Generally auditor is "probing" for information
    1. Ask open question (goes beyond yes/no)
    2. Pause (they will fill silence)
    3. Reflective or Mirroring
    4. Paraphrasing
    5. Summary question

AUDIT ACTIVITIES – Conducting On-Site

- Collecting and verifying information
  - Techniques for obtaining evidence
    » **Interviewing**
    » **Observation**
    » Review documents (procedures, work instructions, specifications, etc.)
    » Review records (lot/batch records, calibration, validation reports, etc.)

AUDIT ACTIVITIES – Conducting On-Site

- Interviewing
  - Interpersonal communication skills
  - Ask the person to describe their work
  - Conduct interviews during normal work hours
  - Explain reason for interview and that you will be taking notes
  - Avoid "leading" questions
  - Summarize results of interview with the person before leaving
  - Thank them

AUDIT ACTIVITIES – Conducting On-Site

- Interviewing Methods (types of questions)
  - » Open question
  - » Closed question
  - » Expansive question
  - » Non-verbal
  - » Repetitive question
  - » Hypothetical question
  - » Silence
  - » Avoid Leading questions

AUDIT ACTIVITIES – Conducting On-Site

- Interviewing Methods (types of questions)
  - Open question
    Using how, why, what, where, when, who

  - Closed question
    Gets a yes/no answer
    Avoid using too often
    Can be used for confirmation

  - Expansive question
    Further elaborate a current point

  - Non-verbal
    Use body language – example "raised eyebrow" (asks for more information)

AUDIT ACTIVITIES – Conducting On-Site

- Interviewing Methods (cont.)
  - Repetitive question
    Repeats back response in form of a question
    Mirror back what was heard
  - Hypothetical question
    Uses "what if….", "suppose that…"
  - Silence
    They will fill the void, draws more information
  - Avoid Leading questions

AUDIT ACTIVITIES – Conducting On-Site

- Techniques for obtaining evidence
  - » Interviewing
  - » Observation
  - » Review documents (procedures, work instructions, specifications, etc.)
  - » Review records (lot/batch records, calibration, validation reports, etc.)

Generally conducted in conference room, gather data during walk-through
        Machine numbers for preventive maintenance
        Measurement tool ID numbers for calibration
        Personnel names for training records

AUDIT ACTIVITIES – Conducting On-Site

- Collecting and verifying information
  - Documenting Observations, Findings, etc.
    - » Compliment the good
    - » Explore Improvement opportunities
      - If there aren't any move on
    - » Utilize checklists / audit preparatory materials
    - » Note taking
      - Meeting attendees
      - Name, title of person interviewed (as necessary)
      - Part Number, Lot Number,
      - Equipment ID number
      - Procedure title, document number, revision

*Notes could be used as reference for investigation
(now or later), in subsequent audits, by colleagues, etc.
Legible
Retrievable*

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
- Communication during the audit
- Roles/responsibilities of guides/observers
- Collecting and verifying information
- **Generating audit findings**
- Preparing audit conclusions
- Closing meeting

AUDIT ACTIVITIES – Conducting On-Site

- Establish the Facts
  - Get help from auditee
  - Discuss concerns (at the time they occur)
  - Verify the findings
    - » Check more than one record, interview multiple operators
  - Record all the evidence
    - » Exact observation
    - » Where, what, when, who, etc.
  - Use auditee's terminology
  - Establish why a nonconformity exists
  - Obtain agreement with the facts

Review audit progress / findings regularly
Generate rapport

Focus on conformity and effectiveness
Auditee given benefit of the doubt when insufficient evidence

AUDIT ACTIVITIES – Conducting On-Site

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  - Get help from auditee
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  - Record all the evidence
  - Use auditee's terminology
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  - Obtain agreement with the facts

Nonconformity (Findings)

AUDIT ACTIVITIES – Conducting On-Site

- Establish the Facts - Nonconformity (findings)
  - Checklists are guides, IF audit trail appears decide
    - » Disregard
    - » Note for later
    - » Follow-up immediately

  - Consider the seriousness
    - » What could go wrong if the nonconformity remains uncorrected
    - » What is the probability of it going wrong
    - » Is it likely the system would detect it before the customer is affected
    - » If not certain it's a nonconformity, it isn't. Instead may have
      - Requirement that has been broken (proof)

Regulatory compliance versus conformity with Standard (procedures)

AUDIT ACTIVITIES – Conducting On-Site

- Nonconformity report
  - » Non-fulfillment of specified requirement
    - Not doing it
    - Partially doing it
    - Doing it the wrong way
  - » Describe
    - Area under review (i.e. corrective action, clause 10.2)
    - Requirement(s) (i.e. procedure # and actions)
    - Nonconformity / finding (be very specific)

Nonconformity report form (examples)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO:	
FIRM NAME	STREET ADDRESS
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU, MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INOFMRATION TO FDA AT THE ADDRES ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION(S)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED

FORM FDA 483 (9/08)   Previous edition obsolete   INSPECTIONAL OBSERVATIONS   Page   of

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm

EXAMPLE

The management review process was being reviewed as part of internal audit. The auditor noticed in the "Management Processes" procedure (document # MR-101 V2) that reviews are scheduled two times per year, in June and in December. Upon examination of the review records, the auditor found that the last review as conducted 25 months prior. This was confirmed by the quality director.

1. What area is under review (including ISO 9001 reference)
2. Is this a nonconformity?   Yes or No
3. IF yes
   What is the requirement?
   What is the finding?

EXAMPLE

The management review process was being reviewed as part of internal audit. The auditor noticed in the "Management Processes" procedure (document # MR-101 V2) that reviews are scheduled two times per year, in June and in December. Upon examination of the review records, the auditor found that the last review as conducted 25 months prior. This was confirmed by the quality director.

Area under review: Management Review, Clause 9.3.1

Yes – this is nonconforming

Requirement: MR 101 V2 requires management reviews to be conducted 2 times per year (June / December)

Finding: Management reviews are not conducted 2 times per year. The last review was dated 25 months ago.

EXAMPLE

The audit has moved to the management system implementation group and the auditors began to ask about the internal and external issues that could impact the QMS. The implementation leader said that management had come in and sat down with them to talk about the issues so that they could be considered and addressed as needed. The auditor asked if they had documented these issues and the implementation leader stated they had not.

1. What area is under review (including ISO 9001 reference)
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EXAMPLE

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Area under review: Context of the organization Clause 4.1
No – this conforms.
Requirement: Clause 4.1 states that the internal/external issues must be determined but it does not state they must be documented.

Audit trail
– *the issues are supposed to be considered when determining risks/opportunities; see if they've been used*
– *Interview top management. They should be aware of what the issues are and should agree with the verbal evidence presented by the implementation group.*

AUDIT ACTIVITIES – Conducting On-Site

- Establish the Facts
  - Get help from auditee
  - Discuss concerns (at the time they occur)
  - Verify the findings
  - Record all the evidence
  - Use auditee's terminology
  - Establish why a nonconformity exists
  - Obtain agreement with the facts
    Try and resolve differences of opinion
    Keep record of unresolved issues

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
- Communication during the audit
- Roles/responsibilities of guides/observers
- Collecting and verifying information
- Generating audit findings
- Preparing audit conclusions
- Closing meeting

AUDIT ACTIVITIES – Conducting On-Site

- Preparing audit conclusions
  - Take same time away from Auditee to gather thoughts, notes, etc.
  - Audit Summary
    - » Strengths of processes, departments and clauses
    - » Total number of nonconformities
    - » Assessment of QMS
      - Documentation, implementation, effectiveness
    - » Opportunities for improvement
    - » Agreed follow-up actions (if any) and time-frame
      - Internal audit -- CAPA will be issued
      - External audit -- report issue and response timing
  - Audit report will serve as official record

AUDIT ACTIVITIES – Conducting On-Site

- Opening meeting
- Communication during the audit
- Roles/responsibilities of guides/observers
- Collecting and verifying information
- Generating audit findings
- Preparing audit conclusions
- Closing meeting

AUDIT ACTIVITIES – Conducting On-Site

- Closing meeting
  - Held to present audit findings and conclusions
    » No surprises !
  - Cover situations encountered during the audit
    » Review the good and the opportunities
  - Discuss and resolve diverging audit findings and conclusions
    » Keep record if not resolved
  - Sign-in for Attendees
  - Timing for report
    » Internal (7-10 days)
    » External (30 days)

AUDIT ACTIVITIES – Final Report

- Process Flow of activities for specific audit (ISO 19011-2011)
    1. Initiate
    2. Conduct document review
    3. Prepare for on-site activities
    4. Conduct on-site activities
    5. Prepare, approve and distribute audit report
    6. Complete (closure)
    7. Conduct follow-up (if applicable)

AUDIT ACTIVITIES – Audit Report

- Audit report will serve as official record
  - Contains conforming and nonconforming audit findings as well as opportunities for improvement
  - Report should be
    - » Written clearly and concisely
    - » Positive tone
    - » Fact based
    - » Reviewed and approved per audit procedure
    - » Maintained securely

AUDIT ACTIVITIES – Audit Report

- Content
  - Audit type
  - Objectives
  - Team member(s)
  - Standards & reference documents used
  - Attendees (Opening/Closing meetings, Guides)
  - Results
    - » Positives
    - » Nonconformities / Observations
  - Distribution and Approvals

AUDIT ACTIVITIES

- Process Flow of activities for specific audit (ISO 19011-2011)
  1. Initiate
  2. Conduct document review
  3. Prepare for on-site activities
  4. Conduct on-site activities
  5. Prepare, approve and distribute audit report
  6. Complete (closure)
  7. Conduct follow-up (if applicable)

AUDIT ACTIVITIES – Corrective Actions

- Audit Nonconformity / Observation Follow-up

- AUDITEE responsibility
  - Prepare corrective action plan
    » CAPA system (internal / external)
    » Response letter (external)
  - Submit plan to Auditor
    » Consensus (internal / Registrar vs Regulatory)
    » Includes timeline for implementation

- Auditor will verify completion during next audit
  - Internal
  - External (Registrar vs Customer/Supplier)
  - External - Regulatory

AUDIT ACTIVITIES

- Process Flow of activities for specific audit (ISO 19011-2011)
    1. Initiate
    2. Conduct document review
    3. Prepare for on-site activities
    4. Conduct on-site activities
    5. Prepare, approve and distribute audit report
    6. Complete (closure)
    7. Conduct follow-up (if applicable)

AUDIT ACTIVITIES - Closure

- Closure
  - Corrective Actions assigned & agreed to
    - Approvals
  - Internal / External
    - Internal per SOP
    - External per Customer SOP / requirements
    - Registrar - after verification at next visit
    - Regulatory – per notification; dependent on complexity & severity

Audit (Part 2)
Conducting & Reporting