

Follow the Path: Laboratory Auditing for Quality Improvement

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www.asq.org

- Auditing Body of Knowledge
- The Quality Audit Handbook
- Certified Quality Auditor Examination

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Tracing Philosophy

- All work is a series of processes
- Processes should be documented
- People are trained to follow the process (and procedures)
- Records are created
- Work can be traced through any process

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Purpose of Tracing

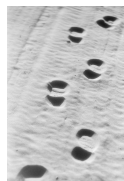
The purpose of tracing is to establish that:

- everything that was intended to happen
- in a given process
- did actually happen,
- with acceptable results.

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Why Tracing?

- Provides knowledge of processes, or lack thereof
- Proven professional method for improving quality
- Provides an excellent means for inspection preparedness



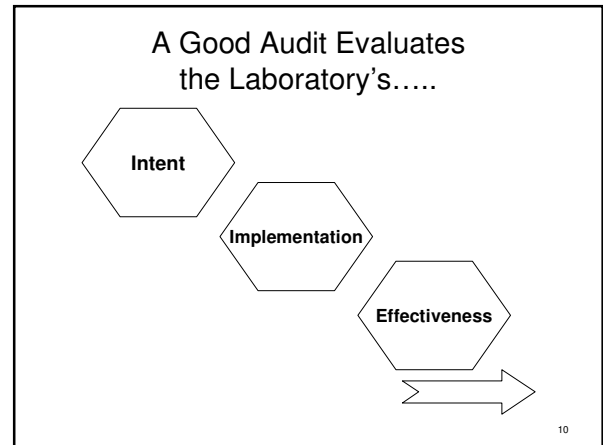
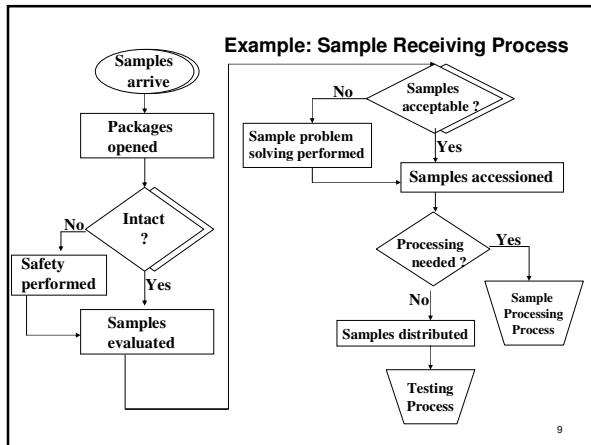
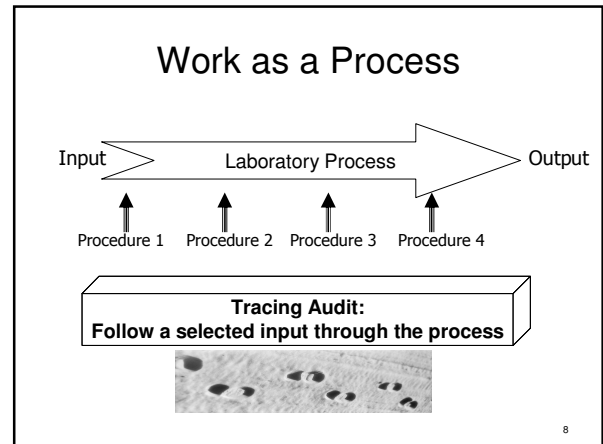
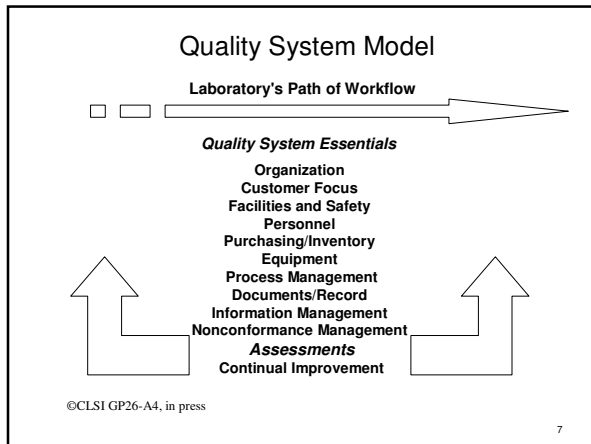
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Two Choices

**Let the external auditor
trace your processes
and find your problems**

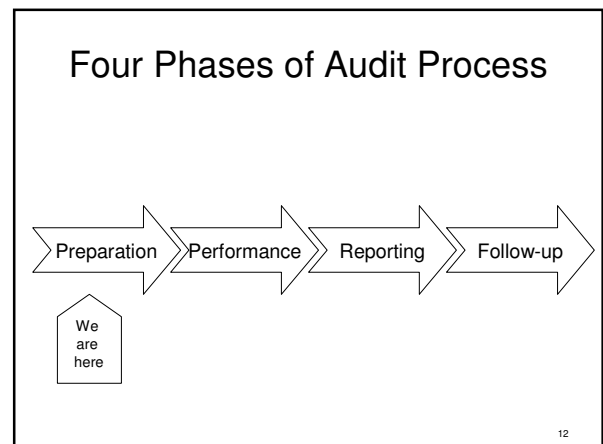
**Periodically trace
your laboratory's processes,
find and fix problems
before the external auditors do**

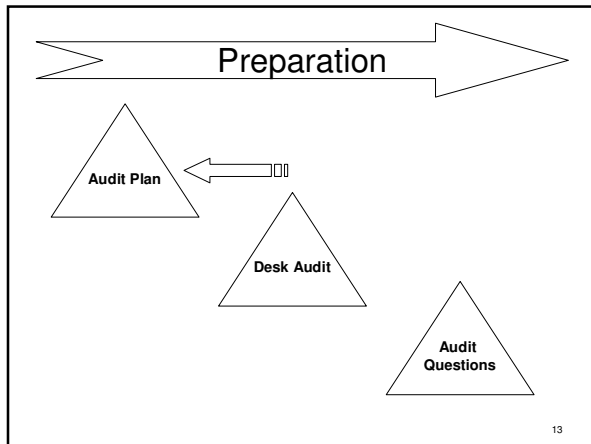
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Auditors Look At

Attribute	Document type
Intent	- Policies - Rules
Implementation	- Process flowcharts, descriptions - Procedure instructions
Effectiveness	- Records - Observations - Data





Audit Plan Sections

- Purpose statement
- Scope
- Auditor selection
- Schedule
- Reference requirements
 - Documents are requirements
 - Records are objective evidence

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Purpose Statement

- Example – Laboratory workflow
- “This audit traces the handling of samples received into the laboratory at the central receiving area.”

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Forward Tracing Examples

- QSE-based
 - A given piece of equipment from order to decommission
 - A personnel file from hire through termination
- Path of Workflow
 - A tissue from time of receipt through surgical pathology to results report
 - A send-out sample from time of pickup through receipt of report

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Backward Tracing Examples

- QSE
 - A document from archive back to creation
 - A reagent from day of use back to order
- Path of Workflow
 - A documented transfusion back to the order on the patient’s medical record
 - A microbiology workup from report back to sample receipt

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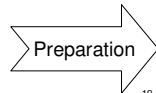
Qualified Auditors Selected

<ul style="list-style-type: none"> ■ Basic skills <ul style="list-style-type: none"> – Knowledge of the auditing process – Technical knowledge of the process to be audited – Ability to communicate effectively ■ Training <ul style="list-style-type: none"> – Resources are available (LMB; www.ASQ.org) 	<ul style="list-style-type: none"> ■ Auditors who have no vested interest in the area to be audited <ul style="list-style-type: none"> – Do not own or have not created the processes and procedures being audited
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Schedule

- Arrange dates and times
 - With the auditor(s)
 - With the functions being audited
- No unannounced internal audits!

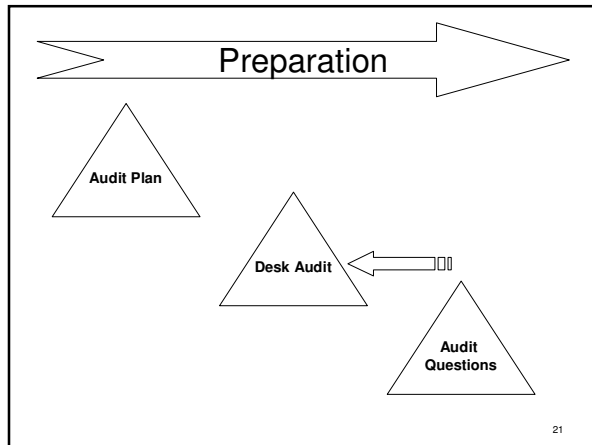


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Reference Requirements

- Any national regulation or requirement (e.g., CLIA, ISO 15189)
- Any accreditation requirement (JC, CAP, COLA, OLA, AABB)
- Your organization's policies, processes, and procedures
- Your laboratory's quality manual
- Your laboratory's policies, processes, and procedures
NOTE: This is the minimum requirement.

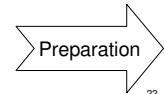
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Desk Audit 1.

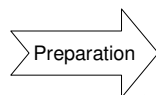
- Auditor(s) collect laboratory's policy, process, procedure documents for the scope of the audit.
- Auditors compare laboratory documents to reference requirements.
 - Cross-reference requirements to documents
- Obtain understanding of how processes work



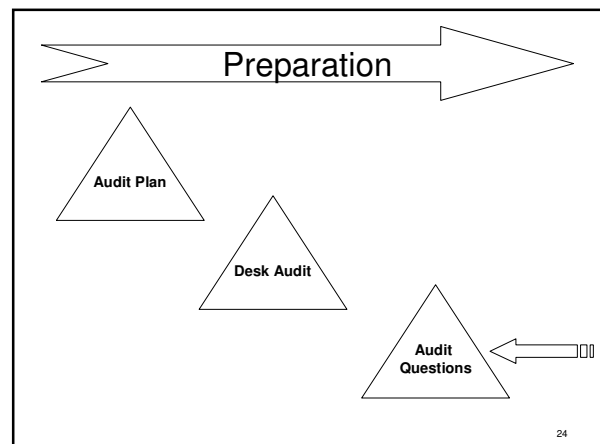
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Desk Audit 2.

- Do not shortcut this activity!
- Enables efficient and effective on-site audit
- "Prior planning prevents poor performance!"



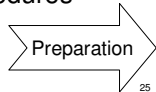
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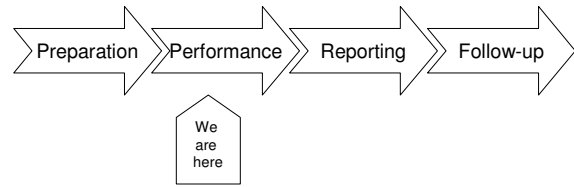
Audit Checklist Question Examples

- Is there a documented process for receiving and handling samples in the laboratory's sample receiving section?
- Have staff been trained in the process?
- When and how is staff competence assessed?
- Do staff follow approved procedures without personal deviations?



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Four Phases of Audit Process



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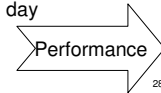
Performance

- Opening meeting
 - Introductions
 - Review purpose and scope
 - Review audit schedule
 - Present the audit question checklist
- Data collection
 - Sampling
 - Tracing
 - Corroboration

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Sampling Plan

- “Estimates the quality of a population by examining only a part of the total population”
- Sampling methods
 - Strict statistical sampling
 - Specified selection
 - Ex: 3 records per laboratory section
 - Ex: 2 tissues from each selected day
 - etc.



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Tracing

- Identify number to trace (from sampling plan)
- Select tracing method (QSE or path, forward or backward)
- Follow the process flowchart, table, or description
- Ask audit questions



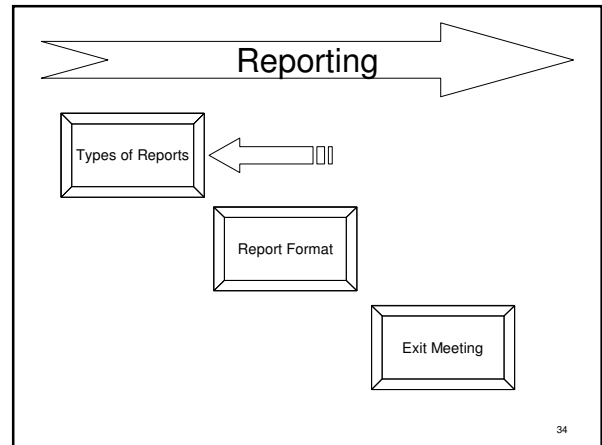
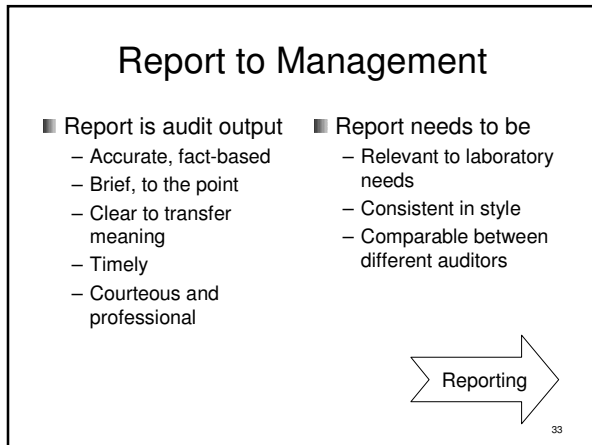
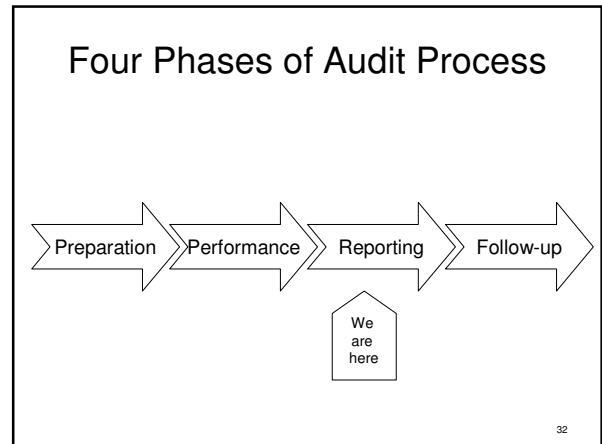
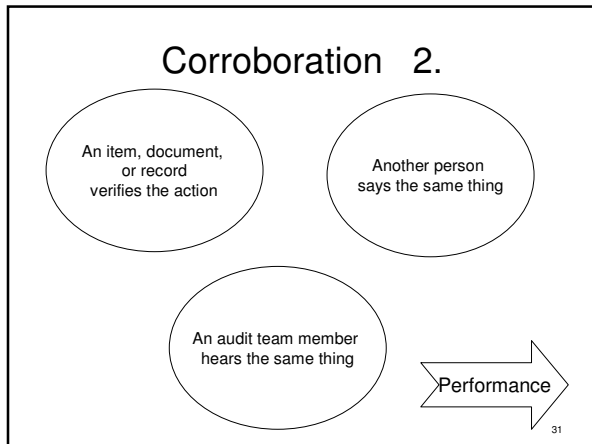
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Corroboration 1.

- Ensures statements and data collected are accurate
- Conformation of information obtained by interview
- Ask open-ended process questions
 - How do you...
 - Please explain why...
 - Show me where...



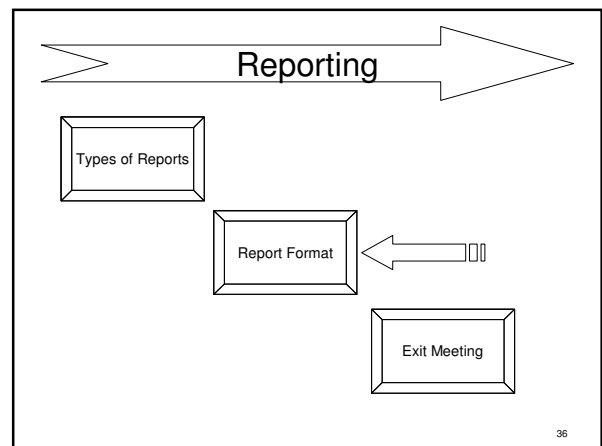
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Types of Reports

Type of Report	Description
Verbal	Presented at the exit meeting
Informal written	May be distributed at the exit meeting as <i>"Draft"</i>
Formal written	Prepared and sent after the exit meeting

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Report Format: Data into Information

Section Heading	Description
Finding or nonconformance	An audit conclusion that identifies a condition having an adverse effect on the quality of the activity under review
Applicable requirement	Citation of the requirement (e.g., clause of standard, name and page of procedure, etc.)
Objective evidence (facts)	Listing of quantifiable facts derived from data collection

Reporting

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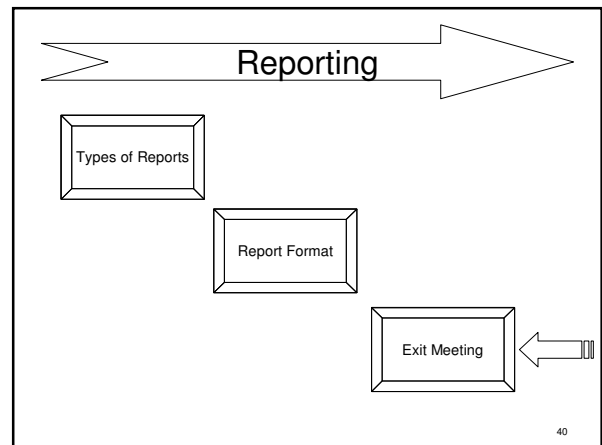
- ### Audit Findings
- Single facts combined into findings that point to system problems
 - Symptoms combined to diagnose disease
 - Analysis of problem for cause and effect
- Reporting
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Laboratory Example

Heading	Description
Finding	"The training program for new laboratory clerks is not documented properly.
Applicable requirement	- CLIA, JC, CAP, AABB (specific clauses listed) - Laboratory clerk training checklist - Sample Receiving Process and Procedure
Objective evidence (facts)	Clerk AB's training record has not been signed off, yet he was entering a CSF sample into the LIS. There are no records of ongoing competence assessment for any sample receiving staff. 3 of 5 training records examined were not complete, yet staff had been working for over a year.

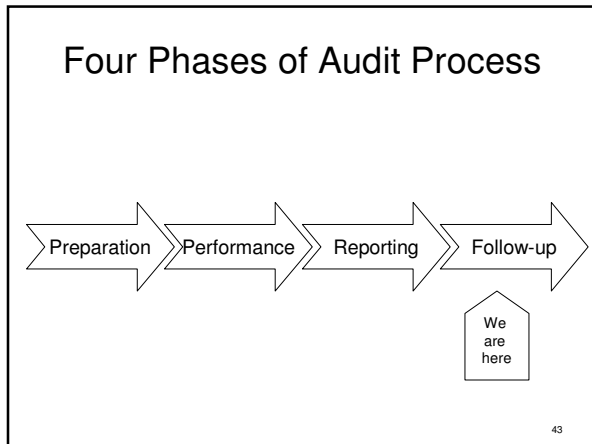
Reporting

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- ### Exit Meeting
- Verbal report made to those responsible for function or process being audited
 - Recap of audit purpose and scope
 - Review of findings
 - Presentation and explanation of all major findings (positive and negative)
 - Fact-based objective evidence is difficult to refute.
- Reporting
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- ### Quality Report
- Summary of audits performed and major findings in laboratory's periodic quality report
 - Quality report for management review
- Reporting
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- ### Follow-Up – 5 Phases
- A. “Stop the bleeding” – remedial action
 - B. Identify root cause(s)
 - C. Design, implement, verify corrective action
 - D. Determined effectiveness of action taken
 - E. Management actively involved
-
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A. Take remedial action

Action Type	What is Done
Remedial action	Immediate action to correct existing nonconformance
Short term corrective action	Stop-gap measure (workaround) until process can be improved
Corrective action	Removal of root cause through process improvement

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- ### B. Identify root causes
- Root cause(s) usually due to lack of:
 - Top management support, organization
 - Resources, time
 - Teamwork
 - Training, discipline
 - Knowledge of work process
 - Consistency
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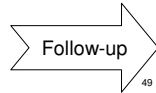
- ### C. Design, implement, verify corrective action
- Management guidance
 - Staff involvement
 - Process measures identified
-
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- ### D. Determine effectiveness of corrective action taken
- Process indicator (quality indicator)
 - Repeat audit
 - Performance on external assessment
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E. Management Involvement 1.

“Quality starts at the top...
or it doesn’t start.”

Albrecht and Zemke



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E. Management Involvement 2.

- Implement an audit program as part of QSE: Assessments
- Provide resources for auditor training
- Provide time for audit performance
- Provide time for review of findings
- Take action on findings
- Provide resources for improvements



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Successful Auditing Through...

- ...thorough preparation
- ...rigorous performance
- ...meaningful reporting, and
- ...effective follow-up

Dennis Arter
Quality Audits for Improved Performance, 3rd ed.
ASQ Press, 2003
<http://qualitypress.asq.org>



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