



From Audit Requirements to Checklist Items to Evidence Gathering Plans

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International Conference on
Software Quality – ICSQ 2011

Audit Defined

ASQ Audit Division definition: [Russell-05]

- An ***audit*** is “a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled”

ISO/IEC definition: [ISO/IEC 24765]

- An ***audit*** is an “independent evaluation of products and processes, conducted by an authorized person to assess compliance with requirements”

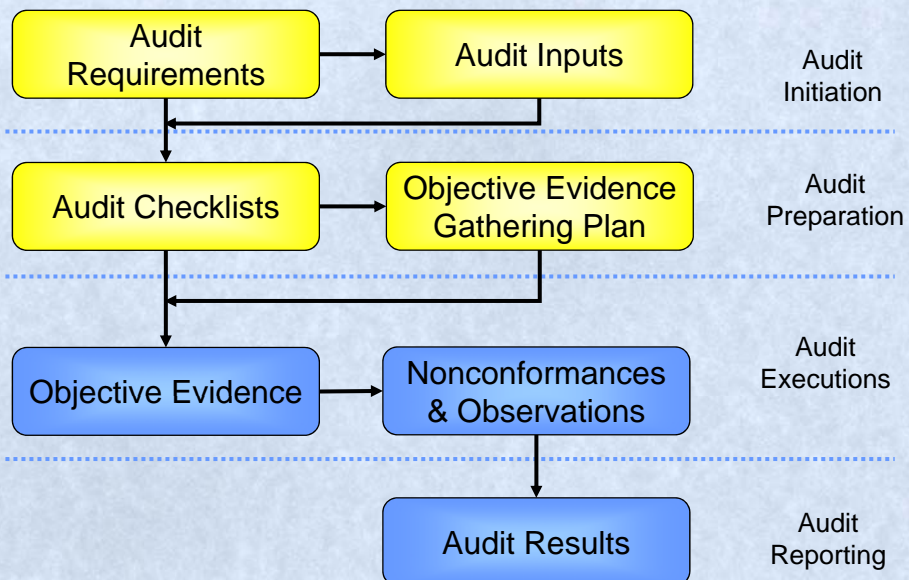
Audit Objectives

Audits are a value-added activity conducted to provide information based on an evaluation of whether the:

- ◆ Adequacy of the organization's standards, processes, systems and/or plans
- ◆ Compliance with those documented standards, processes, systems and/or plans
- ◆ Effectiveness of the standards, processes, systems and/or plans & their implementation
- ◆ Efficiency & effectiveness of resource utilization
- ◆ Identification of areas for continuous improvement
- ◆ Conformance of products to requirements & fitness for use

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Turning Requirements into Audit Results



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Audit Inputs

Inputs into the audit process include:

- ◆ Purpose & scope of the audit
- ◆ Audit requirements - evaluation criteria
- ◆ Audit related documentation
- ◆ Information about auditee organization
- ◆ If prior audits were conducted
 - Audit reports
 - Corrective action plans
 - Follow-up information

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Audit Requirements - Evaluation Criteria

Audit requirements provide the objective evaluation criteria against which conformance/compliance is evaluated.

Examples of audit requirements include:

- ◆ Written organizational quality policies
- ◆ Documented objectives (e.g., budgets, programs, contracts)
- ◆ Customer or organizational quality specifications, standards, or procedures
- ◆ Product requirements and/or specifications
- ◆ Governmental or regulatory requirements
- ◆ Industry standards

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Checklists

Checklists are:

- Lists of yes/no questions
- Tools to help add organization & structure
- Tools to ensure complete coverage of audit criteria
- Precise, measurable, factual



Checklists correspond to the audit requirements & help ensure complete coverage within the scope of the audit.

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Standard Checklist Item - Examples

Standard items to consider for checklists:

- Are the processes and/or work instructions for the task defined at the appropriate level of detail?
- Does the person performing the task have access to applicable processes or work instructions?
- Are the processes or work instructions up-to-date (latest revision)?
- Were the entry criteria to the task verified before the task began?
- Does the person performing the task have the appropriate education, training, skills & experience?

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Standard Checklist Item - Examples (cont.)

- Are the required activities being performed in accordance with the defined documentation?
- Are the environment, infrastructure & tools utilized during the task adequate to achieve conformity?
- Are the outputs from the task appropriately verified and/or approved and/or controlled?
- Are nonconformities/defects appropriately reported & tracked to closure?
- Are the appropriate records being kept?
- Were the exit criteria to the task verified before the task was considered complete?

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Gathering Objective Evidence

An auditor measures compliance/conformance by gathering & analyzing objective evidence.

Objective evidence is:

- Information which can be proved true
- Observed or documented evidence uninfluenced by prejudice, emotion or bias

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Evidence Gathering Plan

Techniques for gathering objective evidence:

- Examining records
- Examining documents
- Witnessing an event, activity or process
- Testing
- Finding patterns
- Interviewing personnel

For each checklist item -- plan the techniques that will be used to gather objective evidence for that item.

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Examining Records

Quality records are examined to ensure that evidence exists to:

- Demonstrate product conformance to requirements
- Appropriate implementation of the processes
- “If it’s not written down, it never happened”

Examples of quality records:

- Meeting minutes
- Reports
- Completed forms or checklists
- Metrics or data
- Documented approvals, waivers or deviations

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Examining Documents

If documents were supplied as audit inputs, this examination was accomplished during document review. Based upon information obtained during execution:

- Additional examination of documents supplied as input
- Examination of additional requested documents

Observing an Event or Process

An auditor can observe work in progress to see if it meets requirements.

- Witness how work is actually being performed
- Watch or be present without participating actively

The auditor observes if:

- The product was made or the activity was performed according to documented processes or work instructions
- It was done by the designated responsible person(s)
- The proper equipment and/or tools were used
- Practitioners were familiar with policies & procedures, they know their roles & responsibilities

Interviewing

When interviewing, an auditor should:

- Introduce themselves
- Explain the purpose of the interview
- Put the interviewee at ease
- Explain that notes will be taken
- Ask general introductory questions
- Ask planned open-ended questions & follow-up questions as appropriate
- Thank the interviewee for their time

Interviewing (cont.)

- Seek corroboration
 - More than one interviewee says the same thing
 - Another audit team member hears the same thing
 - A record, document or other objective evidence verifies response

Interview Questions

Interview questions should:

- Be open-ended
- Be context-free
- Have know, expected answers
- Focus on the product/process/problem -- not the individual
- Be organized in a logic order

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Open-Ended Questions

Examples of open-ended vs. close-ended questions:

Open-Ended Question	Close-Ended Question
What procedures do you follow when performing your work?	Do you follow the XYZ procedure when you do your work?
What reviews & approvals are involved in releasing your work products?	Do you perform a peer review on your work products? Does the software lead approve your work products?
How do you communicate the problems you encounter?	Do you record the problems you find in the defect tracking tool?

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Context Free Questions

Examples of context free questions:

Ask This	Not This
What documentation do you use when performing this task?	How do you use the SOW Template when performing this task?
How do you verify the quality, completeness & consistency of your work products?	What steps do you use when conducting unit testing of your work product?
How do you track your project's progress?	How do you use Microsoft Project to track your project's progress?

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Interview Questions - Example

- What are the major objectives of this project/process?
- What documentation do you use (produce)?
- What procedures do you follow when performing your work?
- How do you verify the quality, completeness & consistency of your work products?
- What reviews & approvals are involved in releasing your work products?
- How are schedules, budgets, personnel & other resource needs estimated?

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Interview Questions – Example (cont.)

- How do you track your progress?
- How do you communicate the problems you encounter?
- How are changes controlled?
- What factors are preventing you from producing work of the highest possible quality?

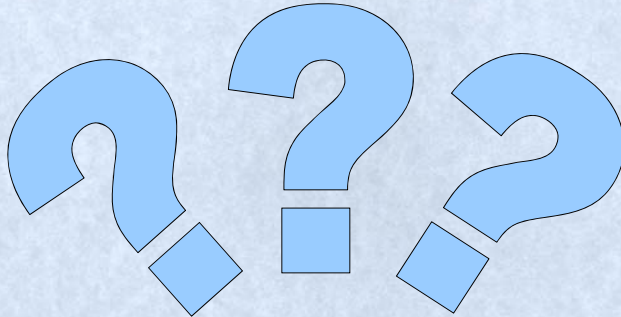
Sampling

Rarely is there enough time or resources to:

- Interview every auditee about every checklist item
- Examine every work product
- Examine every quality record

Auditing is based on the concept of sampling.

Questions?



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