Audit Division
ASQ

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19th ASQ Audit Conference
Orlando FL Oct. 7&8 2010

Audits:
Expect the
Unexpected
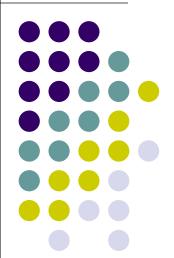
Developing a Checklist

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Orlando, Florida

Introduce our selves

- I am Bob Orkin

  PE   Master of Engineering   Lead Auditor   XX Years experience

  Nuclear Design, Operation, Procurement and Testing,

  Gas Turbine Manufacture and Procurement

  Major infrastructure design and construction QA/QC

- I have been a Lead Auditor for many years including:

  - Navy Nuclear Supplier
  - Gas Turbine Manufacturing and supplier
  - Commercial Nuclear Power Plant internal and contractor
  - Independent consultant
  - Design And construction management
  - Malcolm Baldrige Examiner

Introduce your selves

- Tell me about yourselves and your expectations?
  - Auditing experience
  - Industry
  - Expectations

What to ask and
How to ask it

You know you have to perform an Audit

You know when, where and who

So what are you going to ask?

- What do you want to ask in the Audit?
- What will you FOCUS on?
- How will you organize and manage the audit?

Purpose

- Gather Information,

- Develop and justify findings and conclusions and

- Ensure the full scope of the audit is covered

Completed checklist provides

- Evidence that audit was performed

- Order and organization

- Record that aspects of the quality program were examined

- Historical information

- The essence of the exit meeting and report

- Information for future planning

- Tool for time management

(Reference "The ASQ Auditing Handbook, 3rd edition")

Process Based Audits

- View the QMS as a set of integrated processes
- Adopt the process approach for the audit
- Add value by looking at more than just conformity
- Verify process control and identify process risk
- Alternatively could be a Product, Procedure or Specification based audit.

Focus

- Start by Focusing on your Goal or Purpose of the Audit
- Ask
  - What is the Benefit to Organization? Why Audit?
  - Process verification, is the process what needs to be verified?
  - System Review, is there a system that identifies processes, implements processes, and self corrects ongoing processes?
  - What evidence and documentation is needed as output of this audit?

Questions

- Process or System Audits require more creative questions.
  - Goal or objective to verify process or system is being Implemented and functions
  - Develop a finite set of questions that meet your goal not just collect data.

Checklist

- The Checklist is a tool, a path setter, for questioning.
- Checklist questions are not the actual question of interest.
- Ask are the Checklist questions helpful tools to obtain information you want and to achieve your goals?
- Be sure the checklist isn't just an accounting spreadsheet to ask and answer and fill in the boxes
- Does it lead to the answer of the big question?

#	Example Checklist- Procedure or Spec based			
	Does the QC Program include -Quality organization? Are all QC personnel listed along with their responsibilities for this project?			
	-QC Plan?			
	-Coordination and Mutual Understanding Meeting?			
	-Phases of control (Preparatory, Initial, Follow-up)?			
	-Submittal review?			
	-Coordination?			
	-Certifications?			
	-Documentation?			
	Does the QC Program follow the DM pre-proposal outline? Does the QCP cover the following content?			

Specification Example

Deliver the following listed items to the COTR at the times specified:

- Quality Control Daily Report: Original and 6 copies, by 12:00 noon the next working day after each day that work is performed.

- Superintendent's Daily Report: Original and 6, by 12:00 noon the next working day after each day that work is performed, attached to the Quality Control Daily Report.

- Material Receiving Inspection Report: Original and 6 copies, by 12:00 noon the next working day after each day that work is performed, attached to the Quality Control Daily Report.

- Preparatory Phase Report: Original attached to the original Quality Control Daily Report and 1 copy attached to each copy of the Quality Control Daily Report.

Process Checklist

Let's say we want to verify the auditee <u>process</u> for checking documents. The process is defined in a procedure. The procedure includes specific work items, documentation, approvals, records, personnel qualifications. We need to verify the auditees' actions for how they do the following specific work items:

- Checks reports prior to delivery
- Use of qualified checkers (personnel)
- Document check prints
- Completes the check process including comment resolution
- File the checkprint document
- Filing is accessible
- Filing is retrievable
- Filing is secure
- Staff are aware of the requirements and process
- Maintains document change control
- Other applicable requirements from the specific procedure

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Example Checklist- Process based

Explain to me, with examples your document checking process in accordance with procedure xxx. (Auditors note: verify the specifics during the auditees' presentations: LIST ABOVE)

- Tell me about your process
- Tell me who is responsible for the various functions
- Tell me the objective of the process
- While you are at it tell me about the outputs such as records, documentation, you produce
- Do you use forms or aids to consistently perform this process?

Process Based Audits - Conclusion

- You are the Lead Auditor
  - Develop Your Questions that best Fit your style and goals
  - Ask as many questions as you need
  - Look at as many samples as you need
  - Let the Auditee Tell you what they do
- Checklists are living documents to help the audit
- Work to improve the audit process just like any QMS process.