Auditing Process-based Quality Management Systems

Part 2

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Agenda

• Course objectives
• Introductions
• What is an audit
• How to prepare for and plan an audit
• How to conduct an audit
• How to report on an audit
• Course closing
Conducting An Audit

Conduct opening meeting

Interview people

Observe activities

Analyze data

Form conclusions

Conduct closing meeting

Examine records
Conducting An Audit

Two basic aspects:

– process-related aspect
– personal characteristics
Process-related Aspects

- Hold an opening meeting
- Observe processes
- Observe process outputs, including final product, if applicable
- Ask questions
- Gather objective evidence

- Keep great notes.
- Analyze objective evidence
- Synthesize all that is seen and heard; draw conclusions
- Hold a closing meeting
Opening Meeting

• Introduce all parties
• Review the audit objectives and scope
• Determine the general flow and assignments for data gathering (who will be with whom and when)
• Make arrangements for a closing meeting
• Review safety concerns
• Review housekeeping and communications (escorts, briefings, etc.)
Observe the Process

- Quality Policy
- Quality Objective
- Quality Objective
- Quality Objective

Controls

Activity → Activity → Activity

Input → Process → Output

Resources

Objectives Aligned?
Observe Process Outputs

- Do they meet customer requirements?
- Do they meet the organization’s objectives for the process?
Observe the Process – Interactions

Are appropriate controls in place to ensure requirements and objectives are met?

- **Examples**—Do people in the process have the time, knowledge, and tools needed?
Do we have a controlled process?

• Are the requirements for successful completion of work clear?

• How do individuals know that they have performed work to requirements? Are process or product metrics in place and being used?

• What is done with data that are collected related to the product or process? Who analyzes it? For what purpose? Is there evidence of use of the analyzed data?

• How is continual improvement addressed for the activity being observed?
Observe the Process

When things go wrong:
– What are the processes for:
  • Correction
  • Control of nonconforming product
  • Disposition of nonconforming product
  • Analysis for possible corrective action

When things go right:
– Are any best practices captured and shared?
Ask Questions

Questioning by:

– Closed questions
  • How long have you worked here?
  • What time is it?

– Open questions
  • How do you …?
  • Why do you …?
  • When do you …?
Auditors Ask Questions

And auditees answer them!
Information auditors actually need

Facts — supported by credible data

Credible data = “objective evidence”
Getting Facts and Supporting Data

By

• Observation of process activities
• Asking the same questions of several individuals
• Asking for “objective evidence” for everything
• Looking for normal variability in process performance
• Looking for consistency in records
Verify the Facts

- Look for alignment of process understanding by workers
- Consistency between answers to questions, data and records
- Extend sample when you spot potential problems
Keep Great Notes

• One can never have too many notes
• Note the names of people with whom you interacted with during the audit
• Note report names and numbers (as applicable)
• Note objective evidence reviewed
• Be especially careful to have good notes if any deviations from requirements are observed
Analyze

Think while you are auditing; ask yourself:

• What am I seeing?
• Is this process operating under controlled conditions?
• How do I know?
• What are the data telling me?
• Are the charts on the wall consistent with what I am observing?
• Etc., etc., etc.
Synthesize

Put all the inputs together to reach a conclusion:

– Is there evidence of failure to meet requirements?
  • A single isolated event or is it systemic?
  • Any connections to other processes and applications?
– Are there any areas that should be noted for consideration of action to improve performance?
– Are there any best practices that can be suggested for consideration by other areas of the enterprise?
– Are there any individuals or group that merit special recognition?
The Closing Meeting

A closing meeting should include:

- Restatement of the audit’s scope and objectives
- Conclusions — overall opinion on the application of the quality management system within the processes and areas audited
- Any positive practices observed
- Failures to comply with requirements, and whether such occurrences were isolated or systemic
The Closing Meeting (continued)

• Describe objective evidence to substantiate nonconformities
• Opportunities to improve performance against objectives
• Any unusual events or practices or anything unexpected that was observed
• Gain auditee’s agreement on the facts and resolve any disagreement over objective evidence or auditor conclusions
• Explain the process for corrective action
Personal Aspects

• Interviewing skills
  – Listening skills
  – What to do when no documented procedures are available
  – Asking questions
  – Summarizing
  – Observing
  – Being respectful of auditees

• Time management
• Handling uncertainty, ambiguity and conflict
• Personal hygiene
**Active Listening**

- Auditors ask questions
  - And need to *really* listen to the answers

- **Active** listening is the key
  - Listen to what is not said
  - Listen for trigger words
    - We always …
    - Sometimes we …
      - (how about the other times?)
    - We never …

- Listeners for imprecise or incomplete answers
No Documented Procedures

- Ask the leaders
- Ask the supervisors
- Ask the workers
- Observe the process

Look for Alignment

- Customer requirements being met
- Internal objectives being met

Look for Results
Asking Questions

- Auditors ask questions
- How you ask questions is important
- Remember what we covered earlier regarding open and closed questions?
- Do not be hesitant to ask questions or to make requests (e.g. for objective evidence)
Summarizing

Use summarization to

- Terminate discussions
- Demonstrate understanding
- Get discussion back on-track
Observing

- Look and **SEE** as you audit
- Subtle clues abound about true process performance
- Sometimes what you see directly contradicts what you are being told
- Observe body language
- Observe the auditee
  (do you see commitment/acceptance)
- Be careful with your own body language
- Also observe others who are present
Respect for Auditees

• Treat others as you would like to be treated!
• Special care may be required when auditing “front line personnel”
• Emphasize performance of processes, avoid trying to find fault with people
Time Management

• Time management:
  – Make your own time schedule
  – Communicate schedule to the auditee(s). A starting point could be:
    • 10% of the time for opening meeting
    • 65% of the time to investigate the process and to collect process information
    • 10% of the time to organize objective evidence, to make judgments, and to reach conclusions
    • 15% of the time for closing meeting
  – Use a watch to keep your schedule
Uncertainty, Ambiguity and Conflict

- Auditing includes elements of uncertainty and ambiguity
  - Get the facts
  - Analyze the facts to form your conclusions

- Regarding conflict
  - Don’t argue or deal in opinions
  - Be careful to remain impartial
  - If ambiguity or uncertainty cannot be resolved, and if the matter is of significance, then clearly state the facts in a balanced way in the audit report
Safety and Personal Hygiene

- **Always** follow the rules
- These are somewhat sensitive subjects
- Auditors need to be attentive to hygiene and appearance
Beware: Auditor Actions

• Too soft
• Too hard
• Not listening
• Arguing and criticizing
• Providing recommendations for corrective actions
• Exceeding scope of audit plan
• Time management
• Too many fact sheets
Beware: Auditee Actions

• Auditees providing answers to questions not asked, with much too much detail, from others than the person being addressed
• Attempts to “misdirect auditor”
  – Free nonconformity
• “Your colleague approved last time…”
• No answer to the question
• Unbundling “frustrations” with management
Documenting findings

A finding sheet should contain the following information:

– Area or department
– Process
– Audit number or identifier
– Requirement reference
– Auditee
– Finding
– Customer related?
– Organization related?
– Signature of auditor
– Reviewed with
– Date
Agenda

• Course Objectives
• Introductions
• What is an Internal Audit
• How to Prepare for and Plan an Audit
• How to Conduct an Audit
• How to Report on an Audit
• Course Closing
An audit without a good report is *not* an audit
Audit report content

• The audit report is the record of the meeting
• It is the formal presentation of the information addressed in the closing meeting
• It should include at least:
  – Purpose, scope and criteria of the audit
  – Identification of the auditors and auditee (remember to avoid names, except for the audit team)
  – Dates and places where evidence was gathered
  – Overall conclusions
  – Findings, positive practices and opportunities for improvement

Remember: the report must “stand on its own”
Typical Audit Findings

- Major non-conformity
- Minor non-conformity
- Remark/recommendation/observation

Note: this is one way of documenting audit outcomes; there are other ways
Definitions

• Major non-conformity:
  – A relevant requirement of the standard has not been met and
  – It represents a systemic failure of the quality system

• Also may include…
  – Any situation that would result in the probable shipment of non-conforming product
  – A condition that may result in the failure of products or services, or materially reduce their usability
Definitions

• Minor non-conformity:
  – Requirement of the standard has not been fully met
  – Finding is non-systemic
  – Finding is an isolated occurrence
  – Finding not likely to result in the failure of the quality system
Definitions

• Remark/recommendation/observation:
  – An opportunity for improvement in an area where requirements of the standard have been met
  – Areas of excellence
Report Template

An Internal audit report should include at least the following information:

- Department and process(es) audited
- Auditors and auditee and date of audit
- Scope and purpose of the audit
- Statement of overall effectiveness of the quality management system
- Audit findings, on fact or findings sheets, supported by objective evidence
- Note of any positive or best practices
- Opportunities for improvement
- Reference to the audit plan, documents reviewed and audit criteria
- Signature of auditor and approval (if required)
Reporting Findings

• Finding sheets – one finding per sheet
  – Place finding in context
  – be sure you can trace finding to origin
  – use clear, unambiguous, understandable language

• Findings understood/accepted by:
  – auditee
  – management of area
Reporting Conclusions

• Include a statement of effectiveness of the quality management system implementation
• Be objective and have evidence
• Base all contents of report on facts and observations
• Provide well-founded evidence on:
  – quality management system (description, implementation, and evidence)
  – system capability to meet requirements
  – improvement capability to meet future requirements
• Do not provide surprises or any items which were not mentioned before
Final Thoughts on Audit Reports

• Remember, many may read the report
• Before submitting the report, review it.
• Does it address:
  – Inputs to the process
  – The activities of the process
  – Outputs from the process
  – Improvement
  – Alignment quality policy with activities
  – Competence of personnel
  – Adequacy of documentation and records
  – Justification of all nonconformities noted
  – Etc., etc., etc…?
A Quick Review – Internal Audit

- Gather relevant background information
- Prepare a good plan
- Conduct an opening meeting - introductions & purpose of audit
- Explain the audit process to auditee
- Audit the process
- Record names and position of auditees

- Obtain and review objective evidence
- Summarize to verify understanding
- Check off elements of your work plan
- Conduct a closing meeting - Discuss results, mention good items and any issues
- Prepare a good report
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• How to prepare for and plan an audit
• How to conduct an audit
• How to report on an audit
• *Course closing*
Course Summary

We have discussed how to:

– Prepare audit plan
– Conduct an internal audit
– Document findings
– Write an audit report
– Follow-up on corrective actions
– Foster continual improvement of products and processes
Course Summary

• We all are a little unsure during the first “solo” audit, but “practice is the path to improvement”
• The best (only) way to start is to “just do it!”
• Are you prepared to conduct internal audits?
• Do you think you can add value to the company as an internal auditor?
"I have six honest serving men. They help in all I do. Their names are: Where, What and When, How, Why, and Who."

- Rudyard Kipling
Old Italian Proverb

“In God we trust. All others shall provide objective evidence.”
Further Reading
To learn more…

About the book:
• Buy it @
  http://www.asq.org/quality-press/

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About the topic:
• Search ASQ’s Knowledge Center @
  http://www.asq.org/knowledge-center/search/
• Check out ASQ’s Standards Central @
  http://www.asq.org/standards/

Don’t miss part one of this two-part series, which provides an introduction to auditing, as well as how to prepare for and plan one!

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January, 2013