Auditing Process-based Quality Management Systems

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How to Audit the Process-Based QMS

SECOND EDITION

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Agenda

- Course objectives
- 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
Course Objectives

• Learn the basics of performing internal audits of a QMS based on the process approach
  – Process mentality
  – Consider policy, objectives, processes, products and organizational alignment
  – Prepare an audit plan
  – Conduct an audit
  – Document findings
  – Write an audit report
  – Ensure follow-up on corrective actions
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- Course objectives
- Introductions
- *What is an audit?*
- How to prepare for and plan an audit
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What is an audit?

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

* Definition is from both
  – ISO 9000:2005 Quality management systems—Fundamentals and vocabulary
  – ISO 19011:2011 Guidelines for quality and/or environmental management systems auditing.
What is an internal audit?

An internal quality audit is an audit that is performed by or at the direction of members of the organization.
Why audit?

Possible reasons to audit:

– ensure compliance with ISO 9001:2008
– ensure compliance with organization requirements
– ensure compliance with regulatory requirements
– ensure the QMS is effectively implemented and maintained
Auditing for improved performance

– look for opportunities for improvement
– look for best practices that could be applied in other areas
– look for preventive action
– look for outstanding emphasis on customer satisfaction
Principles of auditing

- Ethical conduct
- Fair presentation
- Professional care
- Independence
- Objectivity
- Impartiality
- Evaluations based on evidence
- Competence
- Cooperation
- Trust
Audit vs. Management Review vs. Self-assessment

Three complementary concepts:

• What do we mean by self-assessment?
  - ISO 9004:2009 Annex A
  - Baldrige

• What do we mean by management review?
  – They are all approaches to ensuring effectiveness, efficiency, improvement and customer satisfaction
Three Types of Audits

- External independent audits – third party
- Customer audits of suppliers – second party
- Internal audits – first party
Three Types of Audits

External independent audits – third party

• Conformity to a specific standard
Three Types of Audits

Customer audits of suppliers – second party
• Conformance to customer requirements
• Customer’s special interest items

STANDARD (e.g. ISO 9001)
OTHER REQUIREMENTS

ORGANIZATION
AUDIT
CUSTOMER
Three Types of Audits

Internal audits – first party

• Performance to the organization’s objectives
• Identification of problem areas!
• Finding opportunities for improvement!
The Process Approach

Evolving nature of quality management

– Internal focus vs. customer focus
– Control vs. improvement
– QA by QA vs. QA by organization
– Leadership: from QA or from management
– Documented procedures vs. manage processes
– Independence of QA vs. integration
– Alignment of business, policy and objectives
Remember the quality management principles?

• Principle #4 – Process Approach
  A desired result is achieved more efficiently when activities and related resources are managed as a process.

• Principle #5 – System approach to management
  Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives
Process

A group of interrelated activities and related resources that transforms inputs into outputs
System: A Family of Well Managed Processes

Driven by Top Management

Continually Improving Effectiveness

Network of Interrelated Processes

Focused on CUSTOMER
The “SIPOC” model (suppliers, inputs, processes, outputs, customers) shows linkage of:

- processes from suppliers to final customers
- feedback from customers to the organization
- feedback from the organization to suppliers (see pg 16 in audit book)
ISO 9001 and Auditing

• Audits are covered in clause 8.2.2 of ISO 9001:2008 which is part of section 8 – “Measurement, analysis and improvement”

• Emphasizes determining effective implementation and maintenance of the quality management system

Note: the overall effectiveness of the Quality management system is the responsibility of top management
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Planning the Audit Program
The Audit Process – An Overview

### Internal audit

**Management**
- Provide resources
- Review results
- Use results

**Input**
- Policy
- History
- Documents
- Customer feedback
- Planning

**Resources**
- Information
- Time
- Trained personnel

**Output**
- Audit Report
- Findings/CARs
- Follow-up
- Improvement
- Conclusions
Audit Conclusions

Audit output conclusions may include:

• Conclusion regarding the conformance of the audited process to ISO requirements
• Statements regarding the suitability of a process to achieve objectives
• Comments regarding the effective implementation of a process
• Suggestions for consideration regarding possibilities for improvement
Administrative Issues to Address

• Typically an audit boss is assigned by management to oversee the internal audit process
• Clear charter for the internal audit process
• Tie with other auditing (e.g., finance, EMS)
• Overall audit plan/schedule?
• How is input provided to management review?
• Analysis of audit process and results?
Auditor Criteria

Need knowledge and skills in

- Audit principles, procedures and techniques
- Management system including quality management
- Organizational understanding
- Specific process and product knowledge
- Social interaction

Consider guidance in ISO 19011

- Education and experience

Competence
Lead Auditor Criteria

Audit team leaders need to be able to:

– Plan audits
– Effectively communicate with auditees
– Organize and direct audit team members
– Lead team in reaching conclusions
– Prevent and resolve conflicts
– Coach “auditors-in-training”
– Consolidate team inputs and prepare great reports
Making an Audit Schedule

- List main activities (processes)
- List departments involved with the QMS
- Decide what activities to audit in what departments
- Be sure to include quality-relevant supporting activities
- Be sure to include ISO system-level activities
- Check to ensure coverage of all pertinent activities
- Assign individuals or teams to perform audits
Audit Process Overview

- Prepare for the audit
- Perform the audit
- Report the results
- Perform corrective action
The Audit Process - Overview

- Prepare detailed plans for each audit
- Execute each audit
- Report audit results including conclusions and recommendations
- Corrective actions if needed
- Follow-up to ensure corrective actions are effective
Audit Approaches

• “Horizontal” audit — audit of one system across several functional groups (one thing-many places)
  – audit across several groups to evaluate if a consistent approach is being followed e.g. for competence (Clause 6.2)

• “Vertical” audit — audit each function (department) of the organization and audit all processes in each function (many things-one place)
  – audit within a manufacturing cell for process performance, product compliance, data analysis, corrective action, improvement etc., etc., Clauses 7.1, 7.5, 8.4, 8.5.2 etc.

• Some combination of all of the above
  – e.g. QA performs QMS audits (horizontal) and trained “not full time” auditors perform function audits (vertical)
Planning Individual Audits
Prepare for an Audit

- Define audit objectives
- Define audit scope
- Define audit resources
- Define audit criteria
- Prepare and distribute an audit notification to auditee
- Gather and understand relevant documents
- Prepare work plan i.e. audit plan

Typically done by audit boss
Audit Objectives

• Compliance and improved effectiveness?  
  *(Required by ISO 9001!)*

• Improved efficiency?  
  *(Perhaps needed for survival!)*

• Both?
Audit Scope

- What are the boundaries of an audit?
- What processes will we audit?
- What organizational functions are included?
- What is the audit emphasis?
- What is the timeframe?
Audit Resources

• Who will audit? A team? An individual?
• If a team, who will be the lead auditor?
• Do we have appropriate personnel (i.e. do we need any special technical expertise?)
Audit Criteria

• What policies, procedures, instructions or other requirements will we use as a reference?
• External requirements?
• Internal requirements?
“Audit” implies comparison to criteria
Must audit criteria be in writing?

Your Opinion?
Examples of Audit Criteria - Internal

- Standard operating procedures
- Quality system procedures
- Training procedures
- Calibration procedures
- Startup/shutdown procedures
- Maintenance procedures
- Emergency procedures
- Design procedures
- Records procedures
- Customer complaint procedures
- Specifications
- Drawings
- Advertising literature
Examples of Audit Criteria - External

• ISO 9001:2008
• Sector specific documents, e.g. ISO/TS 29001
• Government regulations and industry codes
• Corporate policy
• Customer requirements, reflected in the contract and purchasing specifications
• Market and customer requirements for better products, improved services, or lower prices, that have been accepted by senior management as internal goals or requirements
Audit Notification

• A unique document for each audit
• It should contain:
  – Purpose or objectives of the audit
  – Scope and boundaries of the audit
  – Identification of audit team members
  – Criteria for the audit
  – Anticipated start and stop dates and times
  – Audit interfaces, if any
• Provide notification to the auditee well in advance
• Notification to auditee can be done by auditor or audit boss
Relevant Documents

• Auditors need to review as much documentation as can be obtained
• Do the documents appear to be adequate?
• Have we obtained performance data (from internal operations and customers)?
• How about past audit reports and corrective action requests?
• Do we understand the requirements in procedures, work instructions, etc.?
Checklist Example: Relevant Documents

- ISO 9001:2008
- Quality system documentation
- Pertinent corporate policies, procedures etc.
- Customer specific requirements related to the area
- Documented objectives or goals for the area
- Procedures and work instructions for the area
- Past audit reports
- Past and open corrective action requests
- Process performance data (e.g. process yields)
- Product conformance data
- Customer feedback and complaints data
- An organization chart
Preparing the Audit Plan

• Determine what work papers we will need to conduct our audit

• Prepare work papers
  – Develop the questions to consider asking
  – Annotate procedures or work instructions
  – Do we want/need a checklist?
  – Is a flowchart of the process to be audited available? If not, should we make one?

The work papers will be our guide when we conduct the audit
Preparing the Audit Plan

Typical questions to consider related to the process input

- Do inputs meet specified requirements? How do we know?
- Are requirements defined and understood by internal suppliers?
- How is internal supplier performance measured?
- Is there a feedback mechanism to suppliers?
Preparing the Audit Plan

Typical questions to consider relating to the process:

- What are the objectives of the work center, area, process, activity or product?
- How do these relate to the overall objectives of the organization?
- Does everyone involved know the customer requirements, as appropriate (both internal and external)?
- Is there an understanding of what is necessary to meet (or exceed) customer requirements?
- Are the individuals performing work correctly? Do they know what to do and have the means to do it, including documentation, time and tools? Are applicable procedures available?
- How do individuals know that they have performed work to requirements?
- How is continual improvement addressed?
Preparing the Audit Plan

Typical questions to consider asking relating to **process outputs**

- Is the process effective in achieving the required results?
- How is conformance to customer requirements determined?
- Is the process continually improved?
- How is customer feedback (external or internal) solicited and used?
Preparing the Audit Plan

Examples of questions to consider related to *performance improvement*

- Can this process or some of its activities be combined with other processes for increased effectiveness or efficiency?
- Evidence of transferable best practices?
- Are there redundant or unnecessary activities?
- Are there significant risks of future process problems?
Considerations Before the Audit

- Clearly defined objectives and scope for the audit?
- Team identification and assignments?
- Specific audit plan for the audit including timing?
- Flowcharts or maps of the processes, areas and activities about to be examined?
- Review and preliminary analysis of the formal (documented) requirements?
- Communication and agreement with the parties about to be audited?
- Work papers prepared to guide the auditors in conducting the audit?
Have you addressed...

• Adequacy of documentation vis-a-vis ISO 9001
• Competence of personnel
• Housekeeping
• Objectives of the area you are auditing
• Measurements to determine if the process is meeting requirements
• Analysis of data
• Records
• Correction & corrective action
• Improvement
• Evidence of meeting requirements
• Feedback to suppliers & from customers
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/
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Don’t miss part two of this webcast series, which will cover how to conduct and report on an audit!

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