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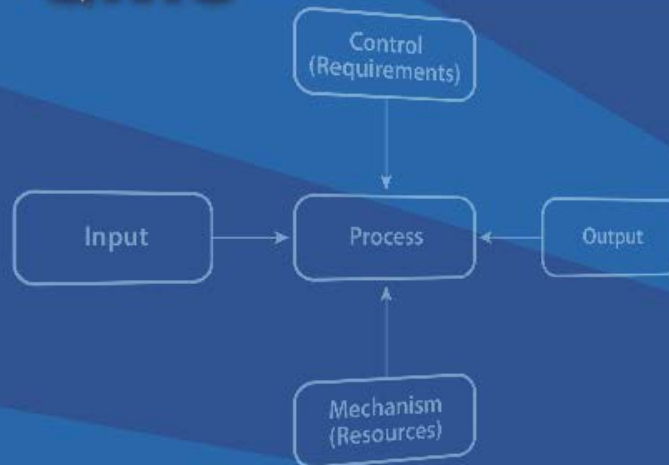
# Auditing Process-based Quality Management Systems

**Charlie Cianfrani and Jack West**



# How to Audit the Process-Based QMS

SECOND EDITION



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# Agenda

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- *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

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- 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



# Agenda

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- Course objectives
- Introductions
- *What is 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?

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## 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





# Why audit? (continued)

## 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

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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

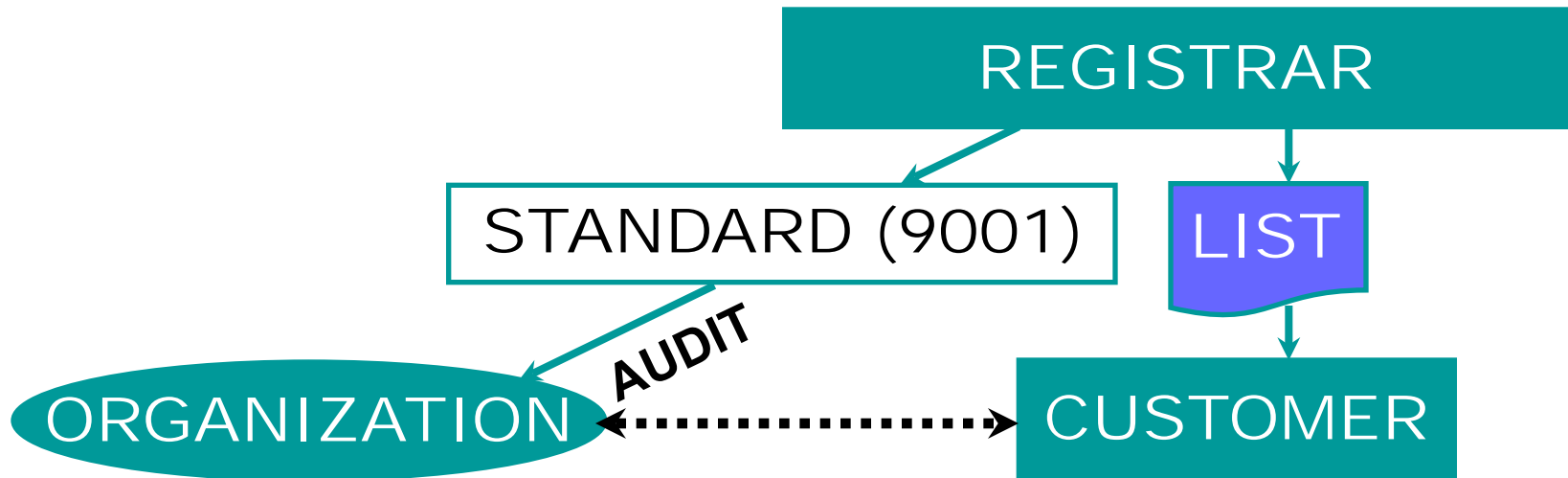
- External independent audits – third party
- Customer audits of suppliers – second party
- Internal audits – first party



# 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



# 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?

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- Principle #4 – Process Approach

*A desired result is achieved more efficiently when activities and related resources are managed as a process.*

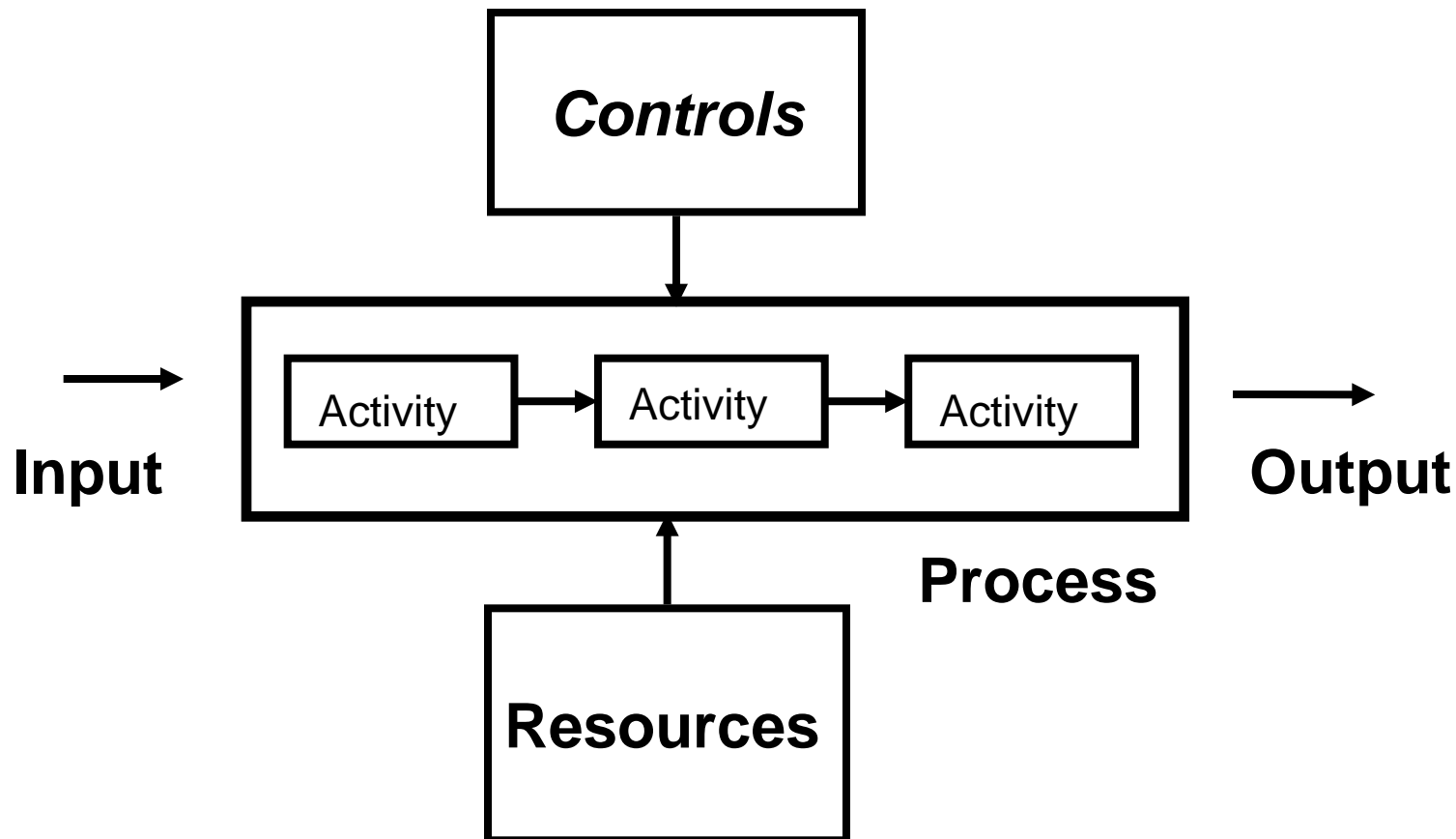
- Principle #5 – System approach to management

*Identifying, understanding, and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives*



# Process

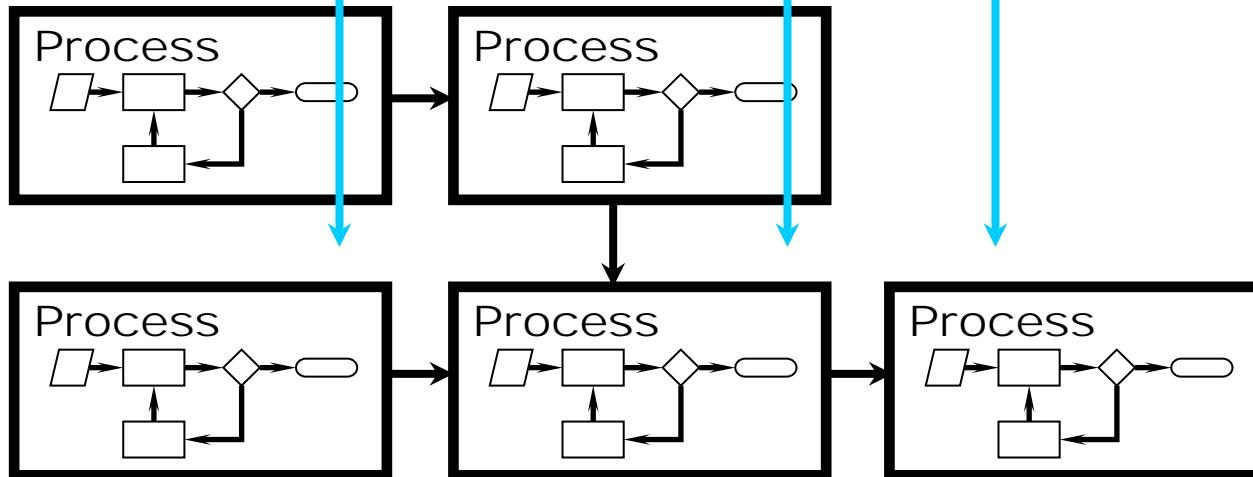
*A group of interrelated activities and related resources that transforms inputs into outputs*



# System: A Family of Well Managed Processes

Driven by Top Management

Continually Improving Effectiveness



**Network of Interrelated Processes**

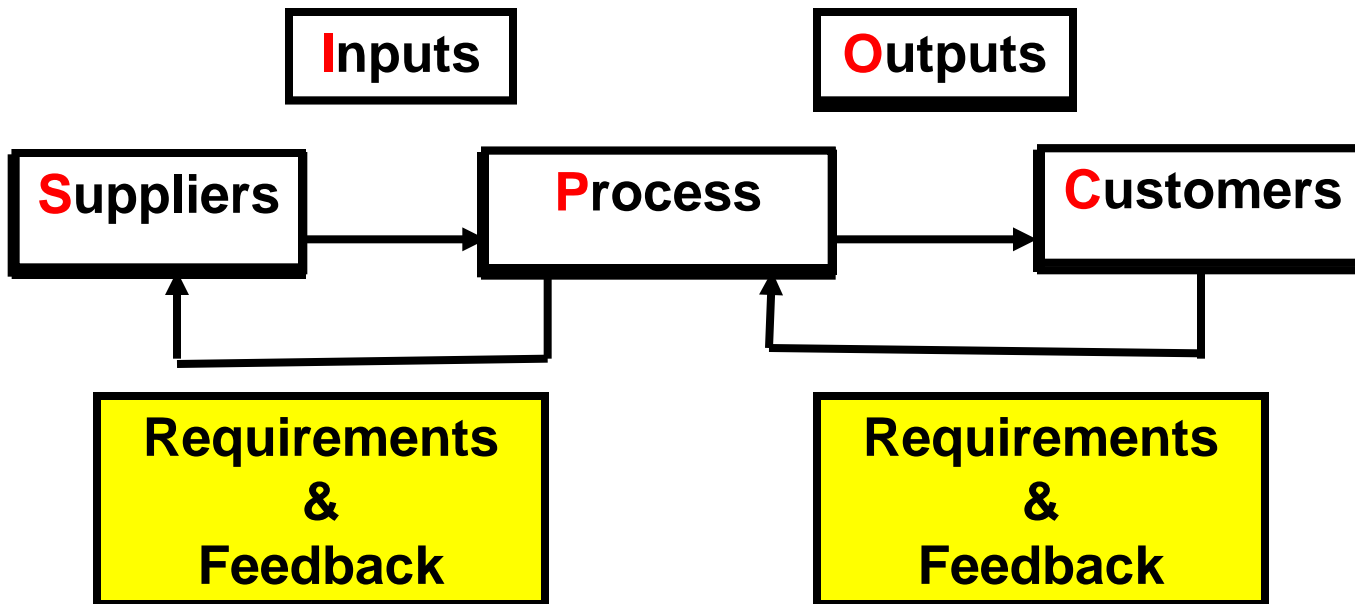
Focused on



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# The SIPOC Model of a Process



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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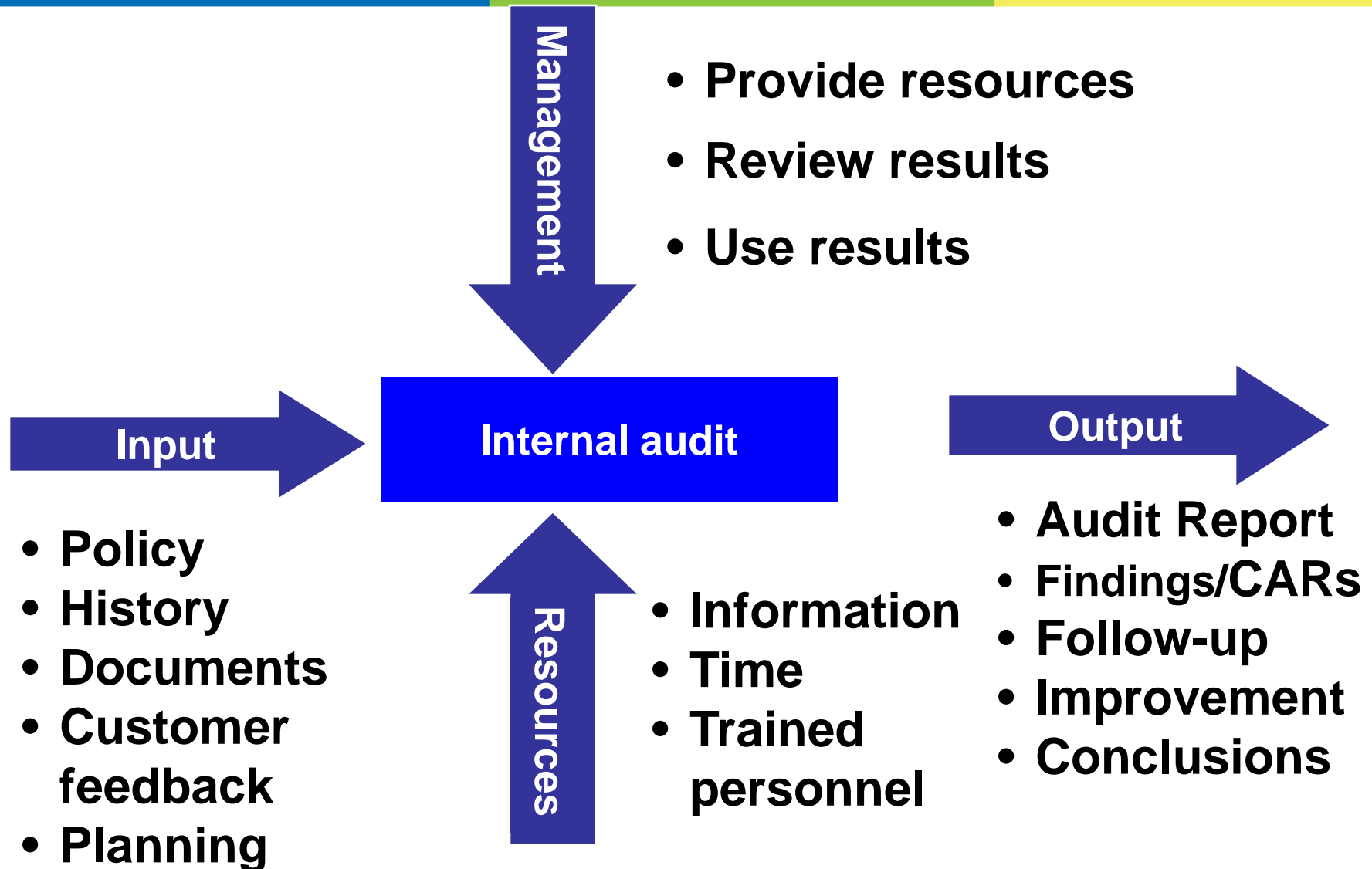


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# Planning the Audit Program



# The Audit Process – An Overview





# Audit Conclusions

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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

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- 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

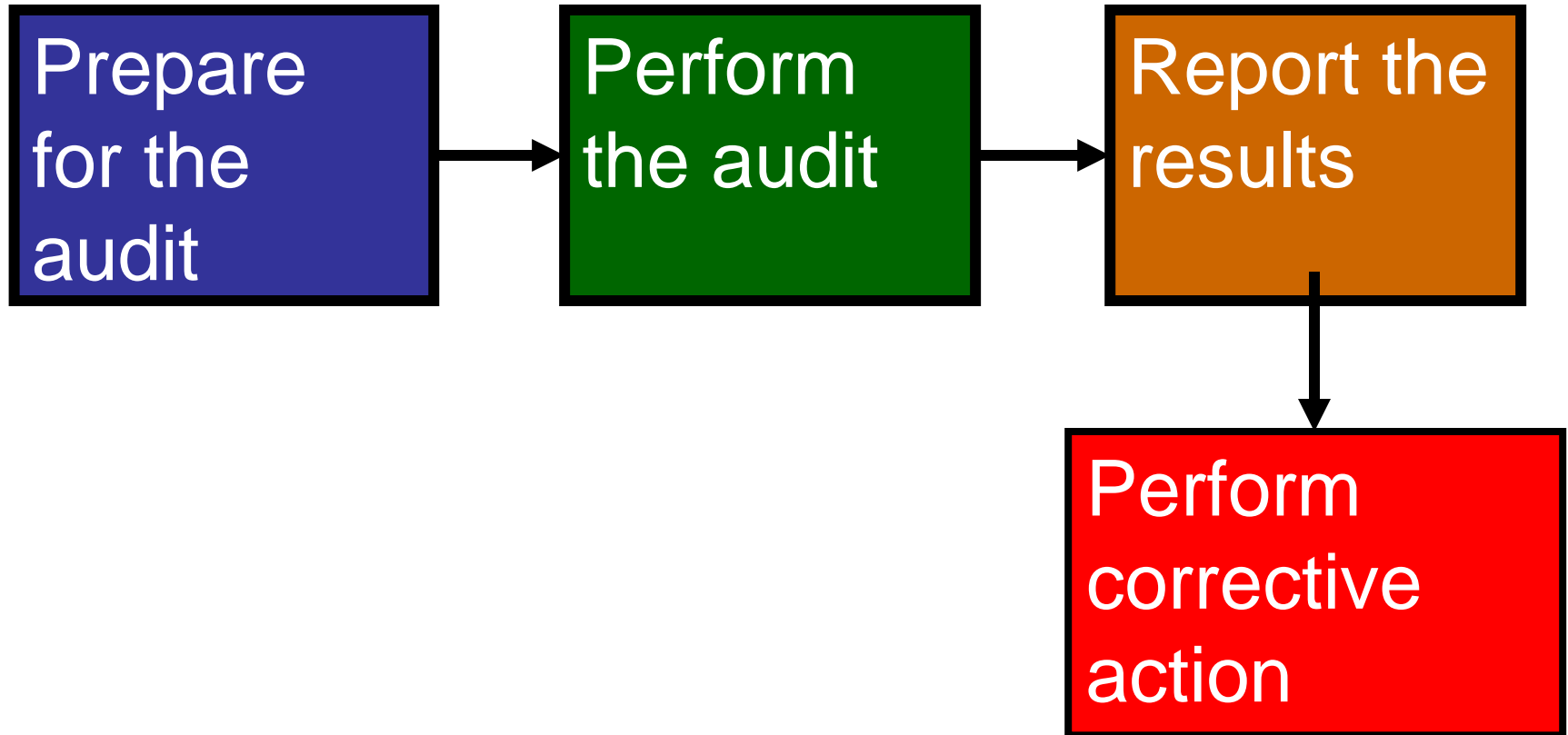


# Making an Audit Schedule

- 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



# 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)





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# 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?)

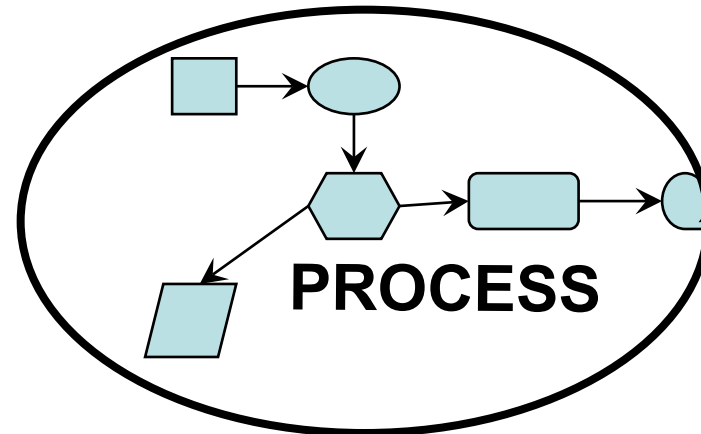
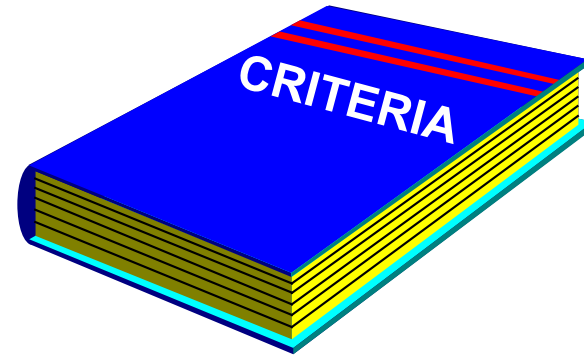


# Audit Criteria

- What policies, procedures, instructions or other requirements will we use as a reference?
- External requirements?
- Internal requirements?



# “Audit” implies comparison to criteria



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*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

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- 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/>

## About the authors:

- Charlie Cianfrani ([cianfranic@aol.com](mailto:cianfranic@aol.com))
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- Dennis R. Arter ([dennisarter@gmail.com](mailto:dennisarter@gmail.com))

## 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 two of this webcast series, which will cover how to conduct and report on an audit!**

