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# The Simple and the Not So Simple

## Managing the transition to ISO 9001:2008

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# ISO 9001:2008

Key Differences from ISO 9001:2000

## Focus of 2008 Changes

- Clarification of Wording
  - Conformity to product requirements
  - Monitoring and measuring equipment
  - Calibration, calibration verification or both
- Outsourced Process Control
- Verify effectiveness of CAPA action
- No lengthy transition period



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# What is going on? ISO 9001:2008

## Recent Developments

- Starting with the Not so Simple:
  - How can a system that has been in place have so many problems or even fail an audit to 9001:2008?





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# What is going on? ISO 9001:2008

Recent Developments

- Most can fit under one of three headings:
  - Limited understanding of the standard, its purpose or its potential.
  - Not understanding who has ownership of the QMS
  - Soft scoring by both internal auditors and third party auditors.



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# Limited understanding of the standard

- Limited understanding of the standard, its purpose or its potential :
  - No support from Top management
  - Limited or no participation during Management Review
  - Not agreeable to changes or improvements
  - Limited utilization of CA/PA
  - Unusually clean internal audits
  - No focus on tracking or evaluating processes
  - Lots of paperwork, lots of hooks that lead to unnecessarily harsh requirements





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# Who's is this anyway?

- Not understanding who has ownership of the QMS
  - Relying on third party audits to determine the evolution of the QMS...If it ain't broke, don't fix it
  - Mad dash to get ready for an audit
  - No contribution from the management team on procedures or work instructions





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# Good today...Not so good tomorrow?

- Soft scoring by both internal auditors and third party auditors
  - Breezing through audits with little or no findings or opportunities for improvement
  - Little request for objective evidence of processes being followed
  - Most of the time spent on interviewing people





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# Ok... So now what?

- Knowing is half the battle
  - Review the last few third party audits for:
    1. Misclassified findings (should have been a finding but was listed as an OFI)
    2. Little objective evidence referenced in the audit
  - Review internal audits also. Remember who owns the QMS. Re-training of internal auditors may be in order if they have been following the soft scoring practice.







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## ...and then?

- Remedy what you can before your recert audit
  - Do not be tempted to do the quick fixes
    - ✓ Give evidence to the third party auditor that you have recognized the issues before they arrived and have already been proactive about arriving at a solution.
  - Do not try to hide the issues





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# Keeping it Simple ISO 9001:2008

Recent Developments

- So, how do you make the transition easily?
  - How does an organization with a system that has been certified to ISO 9001:2000 transition to 9001:2008 quickly and easily?





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# Maintaining Commitment

## Through Cross-Organizational Engagement

### Engage Employees at All Levels

- Verify QMS Conformity at Hand-off
  - Does product/process output meet requirements?
  - Were required records/sign-offs maintained?
  - Were issues documented?
- Remove Blame from Quality Issues
  - Report issues ,not individuals
  - Review process activities to identify root cause of issues



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# Communicating about ISO 9001:2008

Communication & Training

- **Announcing the Transition**
  - Transition announcement integrated into regular monthly employee meeting
  - Reviewed the changes to activities
  - Explained impact to each operational area
- **Ensuring Understanding**
  - Ensured changed documents were available
  - Monitored completion of revised process activities
  - Reviewed compliance status 30 days before registration audit



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# Passing the Audit

A Successful Transition to ISO 9001:2008

## Demonstrating Top-Down Engagement

- **Top Management Commitment**
  - Input to monthly quality/safety meetings
  - Adaptation of quality objectives as needed
  - Regular, documented review of QMS
- **Knowledgeable Employees**
  - Employees understand their role and keep consistent records
  - Employees report quality issues immediately



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# How did they do it?

Communication & Training

- Active management involvement
- Effective internal audit program
- Consistent and regular reviews of QMS health
- Focus on enhancing and improving QMS effectiveness – Document updates, record revisions, metrics calibration, consistent training.



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Thank You  
Good luck on your transition!