

# *Notes From The Trenches*

How to Improve Your QMS Implementation, Registration  
Audit Readiness, IA Effectiveness,  
Problem Prevention, New Ideas, and things people do not  
want you to know.

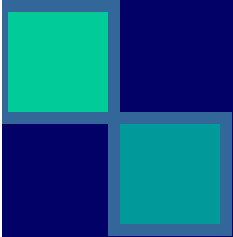


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## Key Problems, Examples and Situations

- 
- Hiring the wrong consultant to help to get you ready
    - Hiring a consultant that is just a consultant and not an auditor will limit the real world information that you will receive. It may also result in the unnecessary collection of too much data.
    - A consultant will often have you put too much into your system.





## Key Problems, Examples and Situations



- Writing a system to impress

- Writing a system that looks good and sounds good. This may require a lot of data and documentation, but ends up being too large to manage.
- Do not just rewrite the ISO standard.
- Write the standard for your company, not the audit.





## Key Problems, Examples and Situations



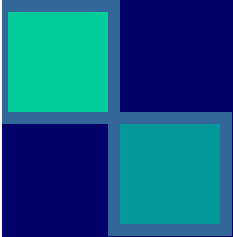
- Over kill

- Avoid over kill. After all, you have to manage the system.





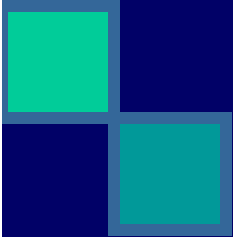
## Key Problems, Examples and Situations

- 
- Setting up a system that cannot be managed
    - Too much work for one person





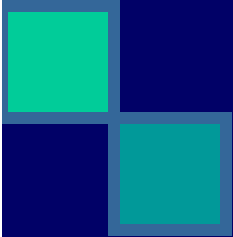
## Key Problems, Examples and Situations

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- Getting an auditor that is asking for more than is required
    - Some auditors are stuck in the mind set of an old specification.
    - Challenge the auditor when you feel you are correct.





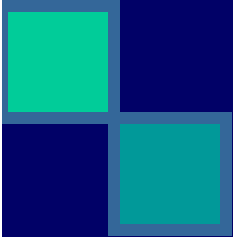
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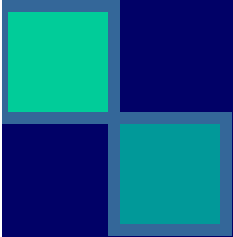
- 
- Not knowing which standard and process to use.
    - ISO 9001 for MFG.
    - AS 9100 for aerospace.
    - ISO/IEC 17025 for calibration and testing labs.







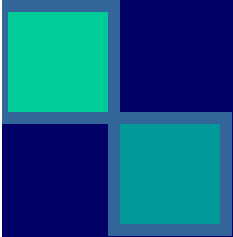
## Tools and Strategies Used To Prevent and/or Overcome Challenges

- 
- Hire a consultant that has implemented a system while they were a Quality Manager
  - Someone that has been an auditor
  - Keep it simple (KISS)
  - Pick the right champion
  - Get upper management buy in
  - Training
  - Don't worry





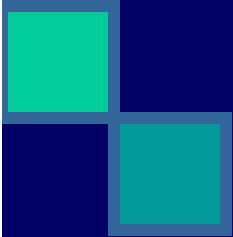
# Key Suggestions For Continual Improvement

- 
- Training
  - Use your system to improve your business
  - Use the corrective action system and perform a good root cause
  - Train your people to perform a good Kaizen event
  - Study lean practices
  - Get the right people involved
  - Find someone that will follow up on any issues
  - Collect data before you just pick something to fix





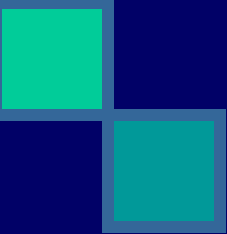
## Things to remember

- 
- When you choose your registrar you need to know who to pick.
    - Who is your customer?
    - Does your customer like one over the other?
    - What parts of the world is your market?
    - Are they recognized by an MRA.





## Who are some of the key players

- 
- A2LA [www.a2la.org](http://www.a2la.org)
  - NVLAP  
<http://ts.nist.gov/Standards/scopes/programs.htm>
  - ACLASS <http://www.aclasscorp.com/>
  - LAB <http://www.l-a-b.com/>





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# Understanding ISO/IEC 17025:2005

## A2LA Specific Applications of the Standard

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This section presents A2LA's official applications of the ISO/IEC 17025 requirements. It is expected that laboratories will implement the requirements of the standard in accordance with the applications listed here. Otherwise, areas of non-conformance will be identified by the assessor during the on-site assessment.

### Most Common Deficiencies

printable listing of A2LA ISO/IEC 17025:2005 Specific Applications of additions to the standard

Clause: [dropdown] (optional)  
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**What is meant by "key personnel"? Is this different from A2LA's term "essential personnel"? Who should I consider "key" vs. "essential"?** 06/14/2007 4.1.4, 4.1.5 2005

*The term "essential personnel" is one developed by A2LA to allow us to identify specific individuals who have a unique, technical capability within the laboratory. A2LA defines "essential personnel" as:*

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[Guidance for Handling Requests for Interpretation](#) (PDF format).

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If you have a request for interpretation on the ISO 9000 series, please contact your Member Body. A list of Member Bodies involved in the work of ISO/TC 176 can be found on this site at the page "[About ISO/TC 176](#)." Other ISO Member Bodies can be identified via ISO Central Secretariat (at [www.iso.org](http://www.iso.org)).

### ISO 9001:2000 - Interpretations

1. Scope

[Clause 1.2 - RFI-049](#) Posted 2005-10-20

2. Normative Reference

[Clause 2 - RFI-011](#) Posted 2004-02-09



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