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Putting Critical Thought Into Your QMS

Five truths to reduce complexity and the implementation cost of your Quality Management System (QMS) design

and have your management love it

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Why have this discussion?

- The ISO9001:2008 Quality Management System (QMS) Standard is a document that can be and often is difficult to interpret. In the last several years modern quality practitioners are pushing the envelope to reduce QMS complexity through simplification which leads to a reduction in “planned in” defects.

- This presentation describes five truths, which are commonly overlooked, and later the case study used to implement ISO 9001:2008 using lean principles.

We need a “no nonsense” approach focused on value and critical thinking, not just documentation

Did You Know?

- The ISO 9001:2008 standard does not require a quality manual structure that mimics the standard but rather any approach that works for the organization.

- QMS designers must understand the needs and practices of the organization first then design around it…..not the other way around.

Reference: ANSI/ISO/ASQ Q9001-2008 Section 0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by:

- *Its organizational environment, changes in that environment, and the risks associated with that environment,*
- *Its varying needs*
- *Its particular objectives,*
- *The products it provides*
- *The processes it employs*
- *Its size and organizational structure*

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

Don't make your documentation look like the standard.

Did You Know?

- A quality manual can be written with less than 15 pages and meet the requirements of a QMS regardless of organizational size?

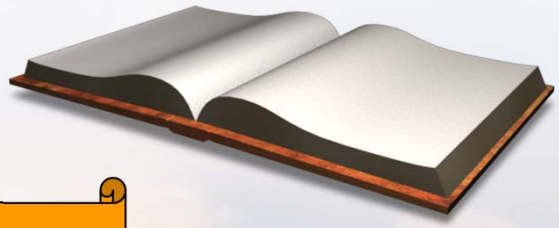
- The "typical" quality manual contains 30-50 pages and frankly, who remembers all that stuff or who is this for? This practice is a carry over from the past and is "no longer" considered a best practice.

- *There are only 3 requirements needed to draft a quality manual and they are: (1) scope of the QMS (including exclusions), (2) documented procedures or references to them, (3) a description of the interaction of processes of the QMS*

Reference: ANSI/ISO/ASQQ9001-2008 Section *0.2 Process Approach*

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements,
b) the need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) continual improvement of processes based on objective measurement.



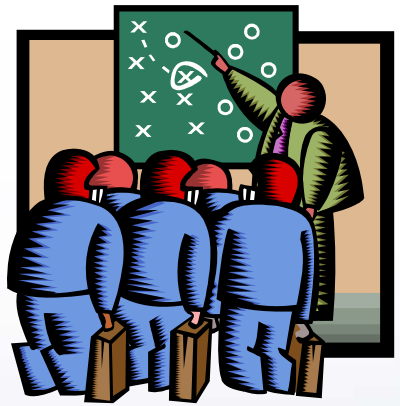
Keep it simple and people will read it!!

Did You Know?

- Demonstrating management commitment is simple and easy.
- Regardless of your organizations business model the management team must address the performance of the QMS and not just product realization.

There are only 5 requirements needed for top management to "demonstrate" commitment

- *Communicate to the organization, by any means, the importance of meeting customer and regulatory requirements.*
- *Document a quality policy statement and corresponding business objectives that the QMS processes can validate*
- *Conduct and document, by any means, a management review that reviews the performance and improvement of the QMS*
- *Ensure adequate staff is hired to design and maintain the QMS*
- *Appoint a Management Representative of the QMS*



These requirements can be integrated into your existing processes without adding additional processes or procedures

Focus on the whole pie and not just the slice!

Did You Know?

- The ISO9001:2008 standard gives an organization "freedom" to determine how much and what type of documentation is needed to define its operational activities.

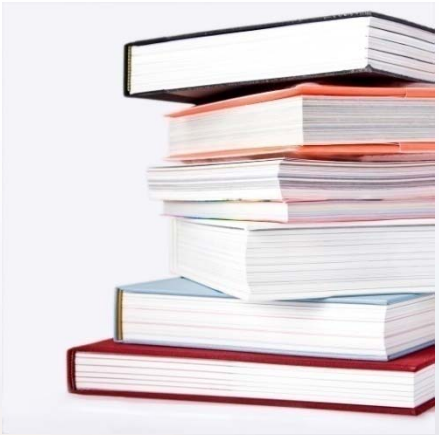
- A thorough, innovative, and lean quality planning process will ensure the appropriate level of documentation given the size of the project or organization. The four tier document structure, typically seen in quality management systems, "is not" a requirement in the standard

Reference: ANSI/ISO/ASQ Q9001-2008 Section 4.2: Documentation Requirements

The extent of the quality management system documentation can differ from one organization to another due to:

- *the size of organization and type of activities,*
- *the complexity of processes and their interactions, and, the competence of personnel.*

The documentation can be in any form or type of medium.



Manage the Standard, don't let manage you.

Did You Know?

- There exists an industry quality management system "guideline" created for scientists and technical managers in research and development organizations.
- There may be programs, projects, or organizations where this approach is more appropriate for quality planning in an R&D environment. You have to decide which is appropriate for your business.

Reference: ANSI/ASQ Z1.13-1999: Quality Guidelines for Research

The purpose of this document is to provide guidance for the development and implementation of a quality management system to scientists and managers involved in basic and applied research. Historically, quality management system guidance for researchers has been limited or nonexistent. This document will provide the scientists and technical managers with information that has been difficult to locate. Documents that have been written in the past on quality systems for research have been written more with an intent of adapting hardware and compliance-oriented quality assurance regulations to basic and applied research. The guidance in those documents has been too cumbersome or not applicable to the work of the researcher. The guidance in this document is concise and uses familiar scientific and technical terminology in order to translate quality management concepts into a document that is usable by the scientist and technical manager.

Not all process have to be equal to have an effective QMS.

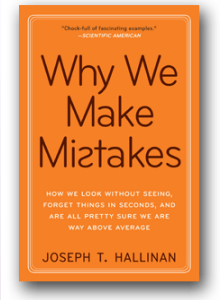
Path to Excellence

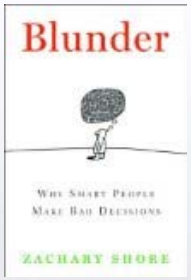
Accomplishments

We will describe the case study that yielded the following results:

- Project completion, initiation to registration, within 7 months
- Project cost at $150k
- Quality Manual 12 pages in length and completed in 1 day
- Leveraged existing product realization process
- Eliminated legacy documentation waste
- QMS tied to Center strategic planning model
- Approach designed as a cost effective model for use by other organizations within Sandia National Labs
- Project recognized by National Nuclear Security Administration (NNSA)

ISO9001:2008 LSS Project Team





Resources to stimulate your thinking

An intuitive approach to defect prevention is key

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