



R&R Newsletter

Reducing Risk/Removing Waste

ISO Support Group

SEPTEMBER 2008

**An ISO 9001:2000
Registered Company**

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LEAN JOURNEY...

Strategy 1:

- Isolate the Value Stream

Strategy 2:

- Specifying Value

Strategy 3:

- Mapping the Value Stream

Strategy 4:

- Making the Stream Flow

Strategy 5:

- Letting Customers Pull Value

Strategy 6:

- Seeking Perfection

CAN LEAN HELP?

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accepted!

As promised we are beginning a Clause by Clause review of the NEW ISO 9001:2008 Standard. This Newsletter Issue covers the topic of:

ISO 9001:2008 Clause 4.1 - General Requirements

What's new in Clause 4.1?... They've now added two new Notes (#2 and #3). Note 2 clarifies that an outsourced process is one that is needed as part of your QMS but that you've chosen an external party to carry-out. Note 3 says that even if we outsource a process we are still responsible for it, and that it's our decision on what type or level of control we impose. This can be based on the impact on the final service or product, the way responsibilities are shared with external parties and the ability to use purchasing activities (Clause 7.4) to manage an outsourced process.

The ISO 9001 Model for a Quality Management System takes into account the importance of processes by building into Clause 4.1 the basic building blocks for becoming a "process" based company. Clause 4.1 a) & b) starts by asking you to identify what your processes are, which at a very high level could be Product Development, Order Fulfillment, Distribution, etc... You then would drill deeper to map out more details below each main process. Well designed and executed processes are what prevents Customer orders from randomly wandering through department silos. Ideally you would Value Stream Map your business, on your path to becoming "Lean". You can use your maps to decide what "process measures" are needed and to help uncover bottlenecks and ways to improve. When mapping is completed post them in visible areas, like meeting rooms or hallways, and use your maps as a communication tool for pinpointing where problems occurred or for training purposes.

Clause 4.1 c) through f) asks that you effectively manage those processes that you identified previously by i) determining the techniques you will use to operate and control them so you can predict their output, ii) by giving them the necessary resources (time, people, money, equipment and information), iii) by measuring how they are performing and analyzing the results, and iv) by taking whatever actions are needed to keep them on track for what you planned, and then improve them. Once again, here is another connection to "Lean"... specifically "Lean Strategy #4: Making the value-creating steps flow continuously".

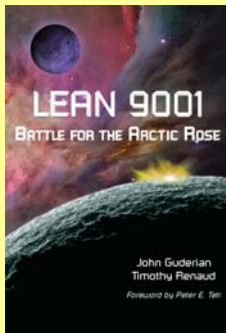
The last paragraph of 4.1 deals with the topic of "outsourcing"... this was included to make sure companies understood that even though you may "farm out" certain processes, you can't wash your hands of responsibility. Remember that when you accept an Order from your Customer, you are making a promise to meet their requirements, whether you perform the work or an outside group does it for you. Examples of outsourced processes can include: Equipment Servicing / Maintenance, Carrier/Courier services, Storage/Warehousing, Security, IT, HR services, Product/Service Design, Sales/Marketing, Measurement/Calibration, Technical Support, Warranty service, etc. By the way, money does not have to change hands for a process to be considered "outsourced"... any group outside your location (and your ISO 9001 Scope) should be looked at... including your Head Office, or other company satellite operations.

To view more of our Newsletters... you can visit our Newsletter page: www.isosupport.com/newsletters/newsletters.htm

PS: Don't forget to look at the [Q&A](#) section below for some final thoughts...

OUR NEW BOOK!

Click [HERE](#) to see inside this book.



TRAINING:

- ISO 9001:2008 Essentials
- ISO 9001:2008 Executive Overview
- ISO 9001:2008 Orientation
- Internal Process Auditing for ISO 9001:2008
- Internal Auditor Refresher + Prep Session

- Process/Value Stream Mapping
- 5S for Service/Mfg
- Lean Essentials/Kaizen
- Business Modeling and Performance Measure'ts
- Root Cause Analysis and Corrective Action
- Mistake Proofing
- Continual Process Improvement
- Strategic/Business Planning

****View [agendas](#) at our website****

Email Tim.. [HERE](#)

For more information on training provided by ISG on ISO 9001 or Process Improvement/Lean (Manufacturing/Office), please visit our website at www.isosupport.com. Once there, you will also find information about the following:

“Process Improvement/Lean Assessment: Can Lean help you?”

If you want to find out if Lean applies to your business, visit our website and read about our Lean Assessment Service by going to:

http://www.isosupport.com/services/lean/srvcs_pi_lean.htm

“The 3 Biggest Mistakes People Make with ISO 9001”; ISO 9001:2000 Tips, Tools and Techniques

Click here: <http://www.isosupport.com/books/books.htm>

If you enjoyed reading our previous ISO Newsletters you'll find that this book contains many of the practical approaches and advice that I've discussed in these Newsletters over the past 5 years.

Q: How do you audit Clause 4.1?

A: Let me begin by saying that Clause 4.1 addresses the entire QMS, which means you have to make an assessment of all of the processes contained within it. An audit checklist should cover these areas:

- Does the QMS address all of the requirements within ISO 9001:2000?
- Is there evidence that the QMS has been improved over the past year?
- Have the processes of the business been identified? How have they been documented? Who developed/defined them? Are they reviewed?
- How do these processes connect or link to each other? Are outputs identified? Is it clear who the customer is of each process? The owner?
- How are the business processes monitored, measured and controlled?
- How are improvements identified for these processes?
- Are any of these processes (or sub-processes within them) outsourced to other organizations who carry them out? If so, how are they identified and how are they controlled? Have any outsourced processes been the root cause of problems either internal or external?

Until next time...

Tim Renaud

Helping Business Professionals Reduce Risk and Remove Waste!

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Tim Renaud, P.Eng., B.A.Sc., is a senior trainer and consultant with the ISO Support Group. His business experience covers over twenty-two years with both small and large organizations within various industries. He began consulting in 1992 and achieved ISO 9001 Registration for ISO Support Group in Oct/1998. Specific areas of expertise include training and consulting on installing ISO Management Systems, as well as implementing Process Improvement Strategies, always with a focus on reducing risk and removing waste (becoming Lean). Association memberships include the American Society for Quality (ASQ) and the Professional Engineers Ontario (PEO).