



R&R Newsletter

Reducing Risk/Removing Waste

ISO Support Group

OCTOBER 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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This Newsletter Issue covers the topic of:

ISO 9001:2008 Clause 4.2 - Documentation Requirements

What's new in Clause 4.2?... Within sub-clause 4.2.1 (General) they've combined some items, with no real consequence and they've added the word 'records' to item d) which is a requirement for organizations to determine what documentation (beyond the minimum specified by ISO 9001) is needed to operate effectively. Prior to this change you only had to decide what extra Procedures or Work Instructions you needed. Note 1 has also been expanded and now states that you do not have to have six (6) separate documents for the six (6) Procedures required by ISO 9001... it can be all be covered in one document if you wish. Sub-Clause 4.2.3 (Control of Documents), Item f) has been clarified with new wording that allows you to decide which documents of external origin are 'necessary' to control. Sub-Clause 4.2.4 (Control of Records) had words added and deleted but the requirements within it essentially remained the same.

The previous Clause (4.1) asked you to identify what your business processes are and this Clause (4.2) continues by asking that you to write them down, and then keep records on how your business is running. The act of "writing it down" forces clarity on what you need to do to satisfy the needs of your Customers (i.e. fill their orders, deliver what they've asked for), and helps to encourage consistency in how you do all these activities.

Sub-Clause 4.2.1 General, outlines the extent of the documentation required. How much paperwork is needed?... First of all, keep in mind that nowhere in this Standard does it require that a paper copy be kept for anything. Secondly, ISO 9001 only requires 6 Procedures, and only 19 Records need to be kept. Thirdly, beyond these minimum requirements, you should only document what will add value to your Customers and your business, so **YOU** decide how much more paperwork you'll need.

Sub-Clause 4.2.2 Quality Manual, asks that you establish a blueprint of your Quality Management System (QMS). If you want to use it as a marketing tool for your Customers, then state all of the QMS requirements (ISO, Customers, Your own) you are committing to, and simply reference your supporting Procedures.

Sub-Clause 4.2.3 Control of Documents asks that you keep your QMS documentation current and up-to-date. In other words if you find a better way to operate your business (i.e. by applying Lean techniques), then lock it in by updating your instructions (i.e your QMS documentation), and then use that to communicate to (or train) your personnel on the new way of doing business. Why is this important?... If I'm your Customer I want the latest and greatest you can offer me, on every Order/Sale.

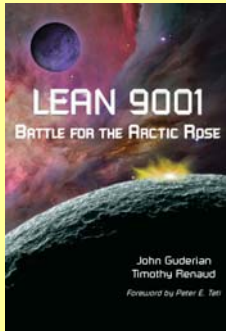
Sub-Clause 4.2.4 Control of Records asks you to keep records on how your business is operating... because what gets measured... gets managed. Record keeping is a critical activity for any business (and for your Customers) and if done effectively, allows for decisions to be made based on facts and data rather than gut feel or opinion.

To view more of our Newsletters... you can visit our Newsletter page:
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PS: Don't forget to look at the [Q&A](#) section below for some final thoughts...

OUR NEW BOOK!

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TRAINING:

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- 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

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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:

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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 4.2?

A: An audit checklist should cover these areas:

- Does the documented Quality Management System (QMS) include a Quality Policy, Quality Objectives, Quality Manual, Procedures, Work Instructions and Records?
- How does the Quality Manual address the ISO req'ts? Does it show the “not applicables”? Does it reference Procedures?
- Do the 6 Procedures and 19 Records, required by ISO, exist?
- How are QMS controlled documents identified? Master List?
- Are personnel using up-to-date “instructional” QMS documents?
- How are these QMS documents kept current? What triggers a review?
- How was the last new QMS document issued? How was the last change or revision handled? Who approved these?
- How are new/changed QMS documents communicated? Any trng done?
- Is there a list of QMS records that are controlled? Verify through sampling that they exist, are legible, are retained, and kept in a secure/safe location. Look at both electronic and paper records.

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).