



R&R Newsletter

Reducing Risk/Removing Waste

ISO Support Group

AUGUST/2009

An ISO 9001:2008
Registered Company

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LEAN JOURNEY...

Strategy 1:

- Isolate the Value Stream

Strategy 2:

- Specifying Value

Strategy 3:

- Mapping the VS

Strategy 4:

- Making it Flow

Strategy 5:

- Letting Customers Pull Value

Strategy 6:

- Seeking Perfection

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This Newsletter Issue covers the topic of:

ISO 9001:2008 Clause 7.3 Design and Development

What's new in Clause 7.3?... First, they've added a new note in 7.3.1... *"Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization."* Second, another new note was added to 7.3.3... *"Information for production and service provision can include details for the preservation of product."* Finally there were some very minor word revisions, however none of these changes will likely affect the design practices within any organization.

Clause 7.3 Design and Development... If you want to make sure you carry out your design activities in a "controlled" fashion then you will start by planning the "design" so the outcome is predictable... and not a random event. You'll make sure you understand your Customer's specific needs (as well as any statutes or regulations) that must be met, and end up with something that actually solves the Customer's problem.

This Clause represents a complete process for moving from concept to final design... translating Customer (or marketplace) general needs, into specific product or service requirements. An organization's design activities are critical to the success of the product or service once it reaches the Customer. Getting it right in the design stage can save you lots of money. Research has shown that \$100 spent on after-the-fact "fixes" in the field can be avoided by spending an extra \$1 upfront in the design phase. Mistake Proofing is an excellent tool to apply during the design phase since the techniques are inexpensive and very effective. Clause 7.3 has seven Sub-Clauses within it...

Sub-Clause 7.3.1 Design and Development Planning

Sub-Clause 7.3.2 Design and Development Inputs

Sub-Clause 7.3.3 Design and Development Outputs

Sub-Clause 7.3.4 Design and Development Review

Sub-Clause 7.3.5 Design and Development Verification

Sub-Clause 7.3.6 Design and Development Validation

Sub-Clause 7.3.7 Control of Design and Development Changes

The first decision is whether "Design" is applicable or not. There are only two justifiable reasons for taking a "Not Applicable" on Clause 7.3: a) either you simply don't perform design, or... b) you do design but it has NO impact on your Customer. The latter would be hard to justify since the Design function likely exists for some business or market reason...

The next decision has to do with what is included within the "scope" of Design. This becomes critical particularly for manufacturing organizations regarding how "Services" will be handled. Remember that "Product" means "Service" in this Standard. The idea here is that your Customer expects a well-designed "Service" also!

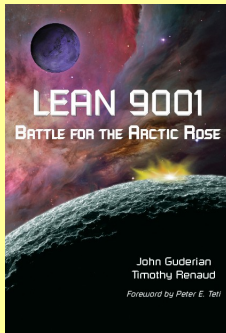
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PS: Don't forget to look at the [Q&A](#) section below for some final thoughts...

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- ISO 9001:2008 Orientation
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- 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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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 7.3?

A: An audit checklist should cover these areas:

For sub-Clause 7.3.1: How are the stages of design planned? Updated?

For sub-Clause 7.3.2: How are input requirements identified/documented?

For sub-Clause 7.3.3: Where do design outputs go? Are they approved?

For sub-Clause 7.3.4: How often are reviews done? How are all input requirements checked?

For sub-Clause 7.3.5: How is the design verified? When? Documented?

For sub-Clause 7.3.6: How is the design validated? When? Documented?

For sub-Clause 7.3.7: How are design changes reviewed? How is impact evaluated? Record kept?

(Make sure to obtain examples for each item listed above)

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).