



R&R Newsletter

Reducing Risk/Removing Waste

ISO Support Group

NOVEMBER 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 Value Stream

Strategy 4:

- Making the Stream 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 7.6 Control of Monitoring and Measuring Equipment

What's new in Clause 7.6?... First, they've changed the wording in the title (and in paragraph 1) from "devices" to "equipment", which helps to clarify the scope of this clause. Second, they added a new controlled record dealing with bullet a). Third, they've replaced the previous NOTE with a new one addressing computer software, which now provides some guidance on what should be part of the software verifying activities.

Clause 7.6 Control of Monitoring and Measuring Equipment provides the basic ingredients needed for ensuring that any equipment used for monitoring and measurement, is functioning properly... and that the data produced is believable. Management should be interested in this Clause because the data generated from the measurement equipment found within the business processes is used to make decisions that directly impact operating costs. If you're not confident in the measurement tool then how can you believe (...and act on) the information it's generating? The point of Clause 7.6 is this... why bother measuring if you can't trust the results!

Clause 7.6 is asking you to determine exactly what equipment will be needed to perform the necessary checks required when producing the product, or supplying the service, to ensure conformance to requirements, as specified by your Customer. The second paragraph of this Clause wants you to install processes that will allow monitoring and measurement to take place, and asks for it to be carried out consistently with regard to product and/or service requirements. With respect to calibration of computer software (last paragraph of Clause 7.6), it applies only to software used to perform monitoring and measuring of "specified" requirements, and the intent is that you check it prior to use and then afterwards to make sure it continues to operate correctly and bug free.

To build a list of measuring equipment devices requiring calibration (or some form of verification), start by finding out what the requirements are for the product or service you supply. For each requirement there should be a check or measurement made to ensure it's right, prior to delivery to your Customer. Next to each requirement, identify how you monitor & measure it, and then determine what equipment is used to do this. You'll then need a way to convince yourself that this measuring equipment is working properly. The above approach will give you a minimum listing of the equipment falling under the scope of this Clause.

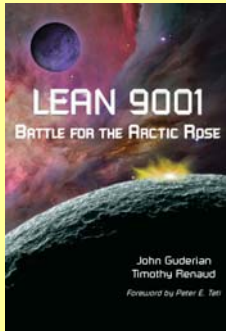
Companies are using this Clause in combination with other Clauses (7.5.1 and 8.2.4), in order to determine what, at a minimum, needs to be calibrated or verified. They are doing this to make sure they are not "over calibrating" ...by reviewing what is currently being calibrated and at what frequency. If measuring equipment is stable over time they are extending the cycle (decreasing the frequency), and they are using past calibration data as justification for doing so.

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!

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- 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

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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 7.6?

A: An audit checklist should cover these areas:

- Start by determining how product/service is measured... in-bound, in-process and out-bound. Is there a list of equipment requiring calibration? Compare this list to the measurement points in the process. Any gaps? Does the equipment listed cover at least the Customer specs? Check a sampling of equipment on the list and verify that is being calibrated.
 - Who decides the frequency of calibration? Does it ever change?
 - How is measuring equipment calibrated? For Internal: Work instructions used? For External: Was a PO issued to the calibration service provider?
 - Any employee owned tools/equipment? Are they being calibrated?
 - If equipment wasn't measuring correctly, how long before it was discovered? How much product/service would have been produced?
 - Any computer software used to measure the product/service? If yes, how do you know it's working properly?
- (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).