

<p>ISO 9001:2015 Tools & Suggestions (Part 1)</p> <p>Michael Haycock offers tools and tips for transitioning your QMS to the new standard.</p>	<p>The Value of Teamwork</p> <p>A humorous reminder of the benefits of including your team in problem solving and improvement efforts.</p>	<p>Upcoming BRC Courses</p> <p>Featured courses coming up across Canada.</p>	<p>6 Keys to Improvement (Part 1)</p> <p>Guidance and advice to help shape your improvement strategy.</p>	<p>Ask the Expert</p> <p>Ted Uffen answers a question about how to address a process that is not meeting performance targets.</p>
---	---	---	--	--

ISO 9001:2015 - Tools and Suggestions to Begin the Move (Part 1)

By Michael Haycock, Sr. BRC Quality Consultant

There appears to be real hesitation about changing to the new standard – ISO 9001:2015. We understand the responsibility for maintaining your QMS takes a lot of time and effort. Then - those people who are distant from the actual work and practices decide that it is time for a change. The “gnomes” in Switzerland have been busy again. Actually, these are real people just like you and I (I think) who are identifying what are considered to be global “best practices” – and to have their approval - we have to carry out their expectations.

Our words of encouragement are:

- 1) While the words and structure are quite different, most of the requirements and expectations are close to what you’ve done in the past.
- 2) Make it practical. Give yourself as many (or few) options as are necessary. Document what you do or expect to do. What and how does it make sense?
- 3) Work with a “registrar” who will listen to you about what you do - instead of them telling you what else you need to do. Having worked as an auditor with a registrar for years, the first thing I knew was you were a “customer”. Secondly, while I knew the standard, I also knew it would be particularly presumptuous of me to assume to know your organization or what practices would be best for you – after 2-3 days in your organization. If your registrar is not providing value, and treating you like a customer – you need to consider alternatives.
- 4) Don’t curse the darkness – light a candle. (We’ll help with the candle.)

Here’s a start...

Use what you already have - wherever you can.

The standard is the premise for your QMS (Quality Management System) so use it. I have most frequently taken the “Standard” and blended it into a “Policy” Manual. First it clearly identifies what needs to be done – and ensures all requirements are covered. Second it provides a clear map to the actual detailed activities covered by your procedures, work instructions and any related documentation.

Now I hear voices (harmless) that a Quality Manual is no longer required. True – but what is required and what is useful may be different. While a “Policy” Manual is often a close reflection of the standard, the intent AGAIN is to provide direction. Especially with all the structural changes – how will that work for you? My suggestion is to keep much of the documentation you have in the form of procedures and work instructions “the same” or almost, and use the Quality Manual to point to how the requirements will be covered.

Example:

	Requirements	Clause(s)	Reference to SOP
ISO 9001:2008	Management Responsibility	5.1 – 5.6	SOP - 5
ISO 9001:2015	Leadership	5.1 – 5.3	SOP - 5
	Planning	6.1 – 6.3	
	Management Review	9.3	

“SOP” stands for Standard Operating Procedure if you had one. My example is not an exact “one for one”, but the intent is to show we can keep much of what we’ve already done, and change and enhance whatever else is necessary. A procedure that would cover one requirement in the past could now be used to cover multiple sections - because of the structural change.

While words “procedures” and “records” are no longer specifically used, this is how most of us “humans” have identified documentation since 1987 – and will continue to do so.

There is a high level “Process Representation” of the structure of ISO 9001:2015 in the standard on Page viii. This could be a starting point for identifying processes. You may also keep much of what you already have done in process identification and add to what may not be clearly covered or needs to be enhanced.

This means the methods to identify processes – through process mapping, flow charts or your “historical” procedures - are your choice. While process mapping has been “pushed” (and I believe it is a good tool), there is no one right way. What is right is what works for you and what resources you have available to carry out these activities.

While the concept of “risk” is not new, the prominence of the word in the standard is.

Since you must identify your processes anyway, have a “process owner” identified (make this part of your Section 5 “Leadership” requirement). Once you have your processes laid out to the extent and detail necessary for your organization, use this as the starting point to identify and address risk. There are some complex tools and simple tools available to “articulate” what the risk may be and what controls may be necessary depending on the threshold the organization has established for itself. (I’m more of a “simple tool” person myself.)

While the significance of the risk is important, I believe what is most important is the actual identification of the risk in the first place. (A “risk” not identified will almost certainly be a risk not managed.) There are many ways these activities may be addressed – I always look for what is useful, practical and beneficial to the organization.



There is a need to understand how the new requirements relate to the old or current practices you have in place for ISO 9001:2008.

There is a bit of effort involved with this, but with a linkage between the old and the new this then allows you to know what you can keep, what can be modified, and finally what is new to be added. This is also the time to change what and where the organization feels there is value to be gained.

The quite radical change in structure and wording (not using procedures or records) has probably caused more concern than should be necessary. There are a number of activities that are clearly identified that would have

been covered in the past, but most frequently unspoken or not specifically documented. We don't want to overload, so we will try and provide an article with each review that will identify and hopefully "demystify" (I don't get to say that much).

There is certainly much to do – we'll work to help make it understandable.

... and our antelope and lion? We need to be running now more than ever – probably sooner and faster.

Lions and Antelopes

Mike's articles often mention the antelope and the lion as a metaphor for the competitive business world. For those of you who are not familiar with the reference, here it is...

On the vast plains of Africa, the sleek, agile antelope beds down for the night, knowing that in the morning, to survive, it must run faster than the fastest lion or it will be eaten.

On the vast plains of Africa, the powerful and majestic lion beds down for the night, knowing that in the morning, to survive, it must run faster than the slowest antelope or it will starve.

To survive, you know one thing for certain. Whether you are the lion or the antelope, in the morning **"you'd better be running!"**



The Value of Teamwork

The CEO of a toothpaste factory was made aware of a growing problem: they were increasingly shipping empty boxes, without the tube inside. Concerned about customer satisfaction, the CEO assembled his top management team, which decided to hire an external engineering company to solve the problem.

The project followed the usual process: budget and project sponsor allocated, RFP, third-parties selected, and six months and \$8 million later they had a fantastic solution - on time, on budget, high quality and everyone in the project had a great time. The solution included the use of high-tech precision scales that would sound a bell and flash lights whenever a toothpaste box weighed less than it should. The line would stop and someone had to walk over...remove the defective box...and then press a button to re-start the line.



A while later, the CEO requested an ROI report on the project. Amazing results! No empty boxes had shipped out of the factory, there were very few customer complaints, and they were gaining market share.

"That's some money well spent!" said the CEO...and then his eyes drifted to the other statistics in the report. As it turns out, the number of defects picked up by the scales after 6 weeks was exactly "0". It should have been picking up at least 300 each day, so maybe there was something wrong with the report?

The CEO re-submitted the report for further review, and after some investigation, the engineers come back saying the report was correct. The scales weren't picking up any defects because there weren't any. All the boxes that got to that point in the conveyor belt were good!

Puzzled, the CEO made his way down to the factory and over to the part of the line where the precision scales were installed. A few feet before the scale there was a \$20 desk fan, blowing the empty boxes off the belt and into a bin.

"Oh that," said one of the workers when asked, "One of the guys put it there 'cause he was tired of hearing the bell and pressing the button!"

Moral of the Story? Work hard to involve your team when looking for improvements. They have a wealth of knowledge, experience and ideas to contribute.

6 Keys to Improvement - Part I

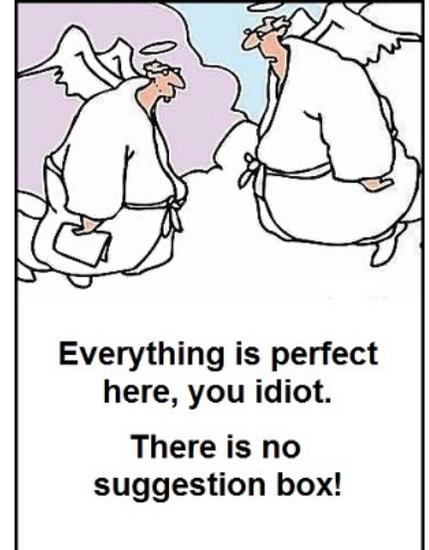
By Ted Annis, BRC President

“Improvement” is one of the 7 (now modified) quality principles outlined within ISO 9001:2015, and is a fundamental component of any management system. We often see organizations making a commendable effort to improve processes, procedures, products, etc. Unfortunately, we also see some companies that are paralyzed by the process. The intent and effort is there, but while searching for a perfect solution they miss many opportunities for incremental improvements.

Do you recall the “Leaping Frog” problem from grade school math? A frog starts in the centre of a pond and tries to hop out, but each leap covers just half the remaining distance to the edge of the pond. Will the frog ever reach land? The answer, of course, is “no”. Although in time he will come frustratingly close, he will always leap just half the distance and will never reach his goal (unless we use university math, which I long ago swore not to revisit).

In the quality business, we work on a similar principle, but with a strikingly more optimistic outlook. Though our poor amphibian friend has an absolute objective (the shore or bust!), in quality we set improvement as our goal and understand the value of taking incremental steps forward.

An effective improvement process does require some structure, but when it comes to the goal of having a positive impact on your business, our Nike-like message is to “just do it”.



We've identified 6 key elements that you can use to help shape your improvement strategy. In this issue, we'll look at the first 3...

1. Understand “Continuous” vs. “Continual”

In previous editions of the ISO 9001 standard, the operative term was “continual improvement”, and for many years we have encouraged organizations to note the difference between the concepts of “continual” and “continuous”. These terms are often used interchangeably without harm, but there is a subtle difference in meaning that can help to illustrate the point. *Continuous* is defined as “uninterrupted in time”, while *continual* means “of regular or frequent recurrence” – one long, ongoing effort vs. many independent actions.

The effort to improve should be *continuous*, but when it comes to actions supporting our QMS, we should be *continually* doing things (big and small) to make improvements.

Make sure that your approach/process/procedure is focused on doing things. It's great to have systems, plans and elaborate procedures that are “continuously” in use, but real improvement comes through “continual” action and the repeated implementation of good ideas.

2. Set Goals (Objectives) and Take Steps

Of course, in Quality Management we are also quite big on setting goals and objectives. A Health & Safety target of zero lost time incidents in a calendar year may or may not be practical or reachable (depending on the organization), but certainly there is value in setting it and striving to reach it. It is important to remember that there is no silver bullet solution that will attain the objective. Searching for a grand solution may very well distract you from implementing smaller improvements, each imperfect on its own but still of value and an important part of the long-term effort.

3. Avoid Perfectionism as a Hindering Behaviour

While setting an objective of *perfection* is good practice, we must be on guard against *perfectionism* in the implementation of solutions. Perfectionism in its positive form motivates us to continually raise our standards and strive to improve both ourselves and our organization. Perfectionism in a negative form includes the belief

that any work or output that is less than perfect is unacceptable, and often leads to the dismissal of very good ideas and solutions...on the grounds that they are not perfect.

Here are some signs to help you identify unhealthy perfectionism within your organization or QMS:

- Goals are set at unrealistic levels. If a proposed plan can not reach these unattainable goals it is dismissed, often leading to unrealistic plans that are doomed to fail.
- Mistakes are viewed as failures, and are often concealed for fear of punishment or embarrassment.
- There is no recognition or celebration of achievement unless it reaches the organization's definition of perfection.
- Risks are not taken when there is no guarantee that the task can be executed perfectly. Instead, there is a preference for safer courses of action because of a greater likelihood of achieving the stated goals.
- There is little focus on the process of learning and working; only the result matters.
- Discussions often exhibit all-or-nothing thinking: either something is perfect, or it's a failure.
- There is a real reluctance to delegate tasks down the management chain for fear that they will not be handled to certain standards.

In Part 2 (coming soon!) we'll share more suggestions and strategies to help with improvement. Visit our blog at www.thebrc.ca/category/blog or watch our next newsletter for more.



ASK THE EXPERT

Process Not Meeting Performance Target

Q:

Hoping you can settle a difference in opinion. When completing an audit, we identified that we were not meeting our performance target in a particular process.

My co-worker's stance is that it warrants an NCR, as it is a self-imposed requirement. My stance is that it is a target, not a requirement, and that not meeting it does not warrant an NCR.

Can you provide some guidance?

- Anonymous

A:

One is never wrong to initiate an NCR when a process has not achieved its intended outcome. At the same time, it also depends on the process which is being measured. If the target concerns a personnel performance target, then an NCR is not appropriate. If we are dealing with a target for process effectiveness or efficiency, I would seriously consider raising the NCR, if only to reinforce the need for process improvement to senior management.

If this is addressed as part of management review, as a specific agenda topic, then no NCR is required.

Hope this helps!

- Ted Uffen, BRC Quality Consultant

BRC Training

On-Site Training

Our 90+ courses cover a diverse range of subjects and are presented by experienced professionals. We can customize content to meet your needs and add practical, hands-on workshops that incorporate your own processes, procedures, problems or data.



Take a Look

[CLICK HERE](#) to browse through our different training categories online.



Contact Us

[CLICK HERE](#) to get more details or request a quote for on-site training.

Public Training Courses

The BRC offers 25 of our courses via public training venues in 20 different cities across Canada. The following is a partial list of highlighted courses scheduled for the near future...

City	Course	Dates	
Belleville, ON	ISO 9001:2015 Internal Auditor	May 15-16	
Calgary, AB	ISO 9001:2015 Internal Auditor	March 30-31	CONFIRMED
Edmonton, AB	ISO 9001:2015 Internal Auditor	March 30-31	CONFIRMED
Guelph, ON	Understanding & Implementing ISO 9001:2015 ISO 9001:2015 & Risk-Based Thinking ISO 17025:2005 Internal Auditor	April 3-4 April 7 April 27-28	CONFIRMED
Halifax, NS	ISO 9001:2015 Internal Auditor Understanding & Implementing ISO 9001:2015	May 4-5 June 1-2	CONFIRMED CONFIRMED
Mississauga, ON	ISO 17025:2005 Internal Auditor ISO 9001:2015 Internal Auditor Root Cause Analysis	April 27-28 April 27-28 May 15-16	CONFIRMED
Montreal, QC	Understanding & Implementing ISO 9001:2015	May 8-9	
Ottawa, ON	Transitioning to ISO 13485:2016 ISO 9001:2015 Internal Auditor ISO 13485:2016 Internal Auditor	April 3 May 15-16 May 25-26	CONFIRMED CONFIRMED
Pickering, ON	Root Cause Analysis IATF 16949:2016 Internal Auditor	April 24-25 May 4-5	
Saint John, NB	Understanding & Implementing ISO 9001:2015	April 3-4	CONFIRMED
Vancouver, BC	Understanding & Implementing ISO 9001:2015 ISO 9001:2015 Internal Auditor ISO 9001:2015 & Risk-Based Thinking	April 20-21 May 8-9 May 17	
Winnipeg, MB	Understanding & Implementing ISO 9001:2015 AS9100 Rev. D Internal Auditor	April 26-27 May 11-12	CONFIRMED

BRC Auditing & Consulting

As a full-service consulting firm, The BRC works with organizations to help implement, maintain, support and update management systems covering quality, the environment, and occupational health & safety.



Auditing

For over 15 years, The BRC has helped companies across North America in a wide variety of industries and standards keep their management systems running smoothly and efficiently.

Regardless of the industry and situation, our goal is consistent – to be professional, effective, and efficient...always with a focus on delivering value to your organization.

Internal Audits –to confirm systems are operating as intended/required, identify areas for improvement and assess the effectiveness of the management and control of processes.

Gap Analysis Audits – to gain a clear sense of work required to meet a set of requirements.

Desk Audits / Documentation Reviews –to confirm that documentation meets stated requirements.

Pre-Assessment Audits –to confirm that your management system is confirming to the requirements of a standard in advance of a registrar audit.

Supplier Audits – conducted on suppliers, contractors, distributors, and other business partners.

Operational Audits –to assess that the processes and procedures documented are being properly followed.



Consulting

The BRC offers a full range of consulting services designed to help organizations improve processes, people, and performance. Our goal is to help create and maintain management systems that add value to your organization by simplifying processes and systems, increasing effectiveness, improving efficiency, and lowering costs.

Examples of consulting projects include:

- Creating, updating, and streamlining documentation.
- Mapping processes to help document and formalize procedures and systems.
- Identifying the “root causes” of persistent problems.
- Addressing issues or corrective actions that arise from audits, customer complaints, etc.
- Integration of systems, processes, and documentation as a result of mergers, acquisitions or reorganizations.
- And more...



Contact Us

CLICK HERE to tell us more about your needs and request a quote.