



Top 10 tips to simplify your ISO System

*Jim Moran, MA Ed., President
Simplify ISO Inc.*

Shrink your Bureaucracy!

How many signatures do you require to authorize your controlled documents? A number of organizations we work with have created extra work with little or no added value when they require more than 1 approval to authorize changes to a controlled document. Some regulatory bodies have requirements for certain levels of management to authorize certain levels of documents and naturally those will be met.



ISO 9001, 14001 and 45001, however, do not have any specific requirements for maintaining documented information other than knowing who authorized the information and what the revision level is. The 2015 and newer versions of the QMS, EMS and OHS standards also removed the old requirement to identify the changes in a revised document. Great news! Same point here, though, there are some Regulatory bodies that require us to be able to demonstrate what version of a document was in circulation on any particular day. This can be helpful in a court case. ISO 13485:2016 still requires that revisions be identified (clause 4.2.4 c). It also has more prescriptive requirements for record retention.

By reducing the number of approvals required, we can shorten the time it takes from a requested change until the document is accessible for use. This typically results in more changes being requested and creates a more vibrant, relevant management system. When improvements happen, profitability increases if the improvement is controlled and tested for effectiveness.

This relates to clause 7.5 Documented Information, 7.3 Awareness, and 10.3 Improvement.

Auditing by Objectives - Make your audits pay!

Are your Quality Objectives considered when you plan Internal Audits?

One of the driving forces in a management system is the need to improve – do it faster, have fewer errors, ship on time. That’s why ISO has us set objectives – to have something to aim for and to test the effectiveness of our system. Will our processes give us the results we want?



And if we make these Quality objectives SMART (Specific, Measurable, Attainable or Action oriented, Relevant and Time limited) we will be able to see progress more clearly. Muddy objectives lead to muddy conclusions about progress!

So during internal audits we can assess whether our system will help us reach our objectives. During the audit, ask users if they are getting the results they want and are these results getting us closer to our objectives? Under the ‘Awareness’ clause (7.3) we have to make sure people

working under our control are aware of any relevant objectives. The Internal Audit is the perfect opportunity to check this out.

So make your audits pay – check for progress toward objectives and check to see that everyone is aware of his or her objectives. Listen for ideas, and make sure one of the audit goals is to come away with some Opportunities for Improvement, not just a list of non-conformances! Go beyond, “Are you following your procedure?” to “Does your procedure give you the results you’re looking for?”

This activity relates to clause 6.2 Quality Objectives, 7.3 Awareness, 9.2 Internal Audits and 10.3 Improvement.

Simplify Your System Tip #3

Just Change ONE Question!

Have you ever heard someone say, after a non-conformance has been raised, "Who screwed up?". The result? Everyone heads for the hills and tries to find someone to blame. People get defensive and the cause of the problem gets buried in accusations. Improvement? Not likely. Prevent it from happening again? A long-shot at best.



If you just change this question to, "What is the weakness in our system that allowed this to happen?" things go completely differently. Instead of diving under their desks, people are more likely to get involved and work together to find a solution. It's amazing how powerful 'collaboration' is when it comes to fixing a problem.

This way, the system gets better, people get engaged and often the 'team' solution really solves the problem. Winners all around! By using our internal experts who often know more about the situation than anyone, a much better solution is often implemented with benefits galore.

Change one question and see a world of difference!

This relates to 7.4 Communication and 10.3 Improvement

People are NOT our most valuable asset...

"People are are most valuable asset" You've heard this a thousand times, maybe more. It's simply not true. People's *involvement* is our most valuable asset. If we don't tap this vast resource in our organizations, we are missing out on infinite opportunities to improve the effectiveness of our management system (read: *make more money or for the Public Service: stay on budget*).



Just having people in our organization doesn't guarantee their involvement. In order to get people contributing, we need to find ways to acknowledge their contributions and give them credit for having a brain. There are no finer experts in any organization than the people who are on the ground meeting requirements for customers - internal and external. Not only that, Top Management must demonstrate that they are involving people in 3 of the 10 'shall' requirements in in clause 5.1.1:

- Communicate the importance of effective quality management (5.1.1f)
- Ensure people are contributing to the effectiveness of the management system (5.1.1 h)
- Enable other management roles to demonstrate 'Leadership' (5.1.1j)

These results are not easy to achieve. Nothing worthwhile ever is!

This relates to 5.1.1 g), 7.4 Communication and 10.3 Improvement

If it weren't for all these customers, we could get a lot of work done around here!

Years ago I used to deliver training in the stores of a national chain here in Canada. Most of the material was focused on the customer: How to handle difficult customers, How to tell if a customer complaint is legitimate, How to create add-on sales and so on. As you can see, there was a tone of, "...the customer may be trying to fleece us, so be on guard...". Quite normal in retail chains today, especially with thin margins and on-line sales.



Fortunately, the training always included a trip onto the floor to demonstrate or observe the concepts in action. *Unfortunately*, most of the department managers were more focused on 'getting the shelves filled' than making sure customers were looked after. This often resulted in hearing the phrase in the title, "If it weren't for all these customers we could sure get a lot of work done around here!" So the words said one thing "Customers first", but the actions didn't always support it. Typically, when humans are faced with actions that conflict with the words they hear, they tend to believe what they *see*, not what they *hear*!

By really wanting to satisfy customer needs and expectations, we can often streamline our management systems. By working closely with and listening to customers (internal and external) we might discover our audience doesn't really care about something that we thought was important. We might even be able to save time and money by eliminating a step or two or altering something we do. But we have to ask the customer.

If the customer is viewed as an annoyance, we will **not** have the chance to benefit from interacting with them!

This relates to clause 8.2.1, customer communication

Simplify Your System Tip #6

You'll be right 6% of the time...

...if you choose 'Operator error' as the cause of your latest non-conformance.

When Ishikawa introduced the world to his 'Fishbone' for doing root cause analysis, his research

showed that employees in organizations make errors, of course, but only about 6% of the time.



**The other 94% of the time,
the error is caused by a
weakness in some other part of our system.**

Remember, no one in our organization woke up this morning and asked themselves, "I wonder how badly I can do my job today?". Humans are hard wired to succeed and we will, given the right tools, the right information (including process information) and the right environment do work in.

Ishikawa suggests that we **start with a brainstorming session**. He suggests looking in four areas:

1. People (ISO 9001 7.1.2, 7.2)
2. Infrastructure (7.1.4)
3. Work environment (7.1.4), and
4. System, or methods (4.4, 8.5, etc.)

By looking beyond 'the usual suspects' we will often find a weakness that we hadn't noticed and that was a contributor to the unwanted result.

Next, he has us **put the ideas into the categories** listed above. This works really well, by the way, with flip chart paper and sticky notes.

You may add IT as a category, measurements or any other major contributor to your non-conformance. As an alternative, you can do the brainstorming but choose your categories based on the brainstorm results. This is called an 'Affinity diagram'.

Finally, choose the most likely candidates (and ones you can control) from 1 or 2 or 3 areas and **ask the question 'Why' 5 times**.

For example, if one of the reasons for a late delivery was 'The machinery broke down', the '5 why' exercise might look like this:

The machinery broke down...

#1: Why? Because the preventive maintenance schedule was abandoned

#2: Why was the preventive maintenance schedule abandoned? - Because we were too rushed

#3: Why were we too rushed? Because we were working overtime to clear up backlogged orders

#4: Why were we working overtime to clear up backlogged orders? Because the orders were not scheduled well

#5: Why were the orders not scheduled well? Because the sales and production departments are not communicating with each other

CONCLUSION -- *the late order wasn't anyone's 'fault', it was the result of poor communication between departments.*

Remember to look beyond the obvious and get to the real root of the problem. You'll be much more likely to prevent the problem from recurring.

And be sure to ask the question, "If our risk and opportunity activity were more robust, could we have prevented this from happening?"

Happy hunting, and good luck getting to the root cause of your next event!

Give your employees credit for having a brain!

One way to simplify your management system is to reduce the number of super-detailed text-based procedures. Once they are in place, you might be tempted to audit simply to see if everyone's following them.



This causes two problems.

The first problem is that the 'follow the procedures or else' message creates a culture of fear. During an internal audit employees may be tempted to hide problems and try to show how they are 'following the procedure'. Hiding problems is a recipe for disaster.

The second more damaging problem is that people will be discouraged from finding ways to improve the effectiveness of your management system. If auditors are focused on 'are you following the rules?' then they aren't assessing whether your processes are giving your organization, the results that you want.

No one in your organization woke up this morning and asked themselves, "I wonder how badly I can do my job today?" As humans, we are hard wired for success and growth. If we restrict employees in their ability to produce results, we are short-changing ourselves on the profitability side of our organization. If your people know how to do their work, give them the tools to do it and get out of their way! We would never see a set of work instructions in a surgery suite. Checklists? Yes! Surgeons putting their initials on the patient as an assurance of operating on the right part? Sure...small things can make a difference, and save huge mistakes.

If you live in a highly regulated industry that has lots of requirements for documented procedures, use flowcharts (they can become your audit path), a series of pictures or videos to document how you want to achieve the results you and your customers are looking for. There's plenty of evidence that text-based procedures simply don't work. They require a lot more maintenance and they don't encourage innovation for better results.

Tap into the potential in your employees' talents by giving them credit for having a brain and get them engaged in improving your system. Everybody wins!

This relates to clause 7.2 Competence

Supercharge your Internal Audits

When we think of getting value out of Internal Audits, sometimes we draw a blank. Or we think that asking if everyone's following their procedures will do the trick.



Here are 3 ways to get more value out of our Internal Audits:

1. Use your flowcharts as the audit path

This helps us make sure everything's in the right order and it lets us take a look at the handoff from one set of activities to the other. You'd be amazed (or not) at how many non-conformances take place in that gap – it's easy to see how that could happen.

2. Assess whether risk is being managed well at each step

This information can be used to meet the 'Performance Evaluation' requirement, clause 9.1.3 e) assess the effectiveness of '...actions taken to address risks and opportunities...'. These results can also contribute to 'Management Review' as well in clause 9.3.2 e)

3. Do these activities support our Objectives?

By asking this question during the audit, we will make our people more aware of how they contribute to our objectives (clause 7.3, b) & c). This also helps employee involvement and supports the Management requirement for engagement of people (5.1.1 h).

By using our maps, assessing risk and opportunity activities and looking at objectives we can 'Supercharge' our internal audits, enhance employee engagement and get more value out of this (sometimes) tedious activity!

This relates to clause 6.2, Objectives, 9.2.2 Internal audits and 10.3 Improvement

Employee engagement - WIIFM?

"What's in it for me?" is a question everybody asks at one time or another. You'd think 'What goes around comes around' would be enough to engage and contribute, but not everyone believes in Karma.



So if you feel that employee engagement would help your organization (I can guarantee it will!) and you want to be able to meet one of the Leadership requirements (5.1.1

h) try these ideas to get employees involved. Your employees are the experts in their field and will have the best ideas for how to improve processes. Better processes (more effective, more efficient) will lead to more profit for the Private sector and help keep you within your budget in the Public sector.

Bob Nelson wrote a whole series years ago starting with the title, "1001 Ways to Reward Employees" and he's been updating and adding to the titles. They are really worth reading. The University of Washington put together a one-pager on Nelson's first work, and proposed these ideas for us:

- 1. Match the reward to the person** - individualized recognition is certainly better than a standard pat on the back.
- 2. Match the reward to the achievement** - a gold star for taking out the garbage is not quite what we're talking about!
- 3. Be timely and specific** - "strike while the iron is hot" will get the best results, every time.

The paper goes on to talk about daily recognition, group recognition, awards and more. This is not easy and takes time to do. The return on investment will astound you!

Simplify your system by finding out what your employees will *really* respond to and trim the rest!

Simplify Your System Tip #10

Process vs Procedure - the battle continues!

This topic has been batted around for over 30 years, since the first version of ISO 9001 was released. For organizations that like LOTS of documentation these words open up a whole world of possibilities for mountains of documents.

The fact of the matter is, ISO allows for any type and amount of documented information. It needs to be adequate to control activities well enough to get you the results your organization wants - 'objectives' you might say.



One way to simplify process management is through flowcharts. The 'procedure' and the 'process' can be combined into one document to make it easier to use as an orientation tool. It also becomes the map for your internal audits. If needed, you could add a checklist to one or more of the boxes in the flowchart. If you give your employees credit for knowing how to do their work, this can eliminate redundant documentation and foster a 'continual improvement' culture.

Another advantage of the flowchart approach is that the flow also shows who your internal customers are and the communication path - remember, 'Communication is a synonym for 'Life'!