7 Ways to Simplify your Quality Management System
By: Aj Glowacki

When my father-in-law asked me to create his ISO 9001 quality management system due to pressure from one of the “Big 3” automotive companies, I had no idea what I was getting into. He bought me a couple ISO 9001 books and said,

“I do not want a complicated system. I don’t need some people who sit in a room and know nothing about my trim die business tell me how to run it. I was successful before ISO and I will be successful after it.”

Now, he talked a lot tougher than he actually was during the QMS creation process. He’s smart enough to know that you have to relent on some things, like device calibration, if you want to get ISO certified. However, he would not relent on allowing me to complicate his business with an abundance of new documentation.

See in the late 90s, early 2000s he witnessed other companies in the area get ISO certified, then complain about how much upkeep with paperwork they had. He even showed me one mold shop’s quality manual binder and it was over four inches thick. This mold shop, like many early ISO registered companies fell into the trap of creating these complex manuals and processes where every minute process is written down and dozens of forms are created. What my father-in-law knew, but so many people failed to understand, is ISO 9001 is a standard, not a step by step guide telling you exactly what your business should be doing.

I’d bet your company, like my father-in-laws, was successful before you sought ISO 9001 certification. You didn’t need a standard to tell you it was a good idea to have occasional meetings with the important people of your company to discuss problems, concerns, and customer feedback (Clause 5.6 Management Review). You didn’t need a standard to tell you to review what the customer wants before taking on a project to make sure you can handle it (Clause 7.2.2 Review of Product Requirements). And I bet you didn’t need a standard to tell you if you found a problem with a process or product to find out what went wrong and fix it (Clause 8.5 Corrective Action). Since you were already taking care of such things before ISO came along, there is no reason to change how you do everything in your business to satisfy the standard. The standard provides for flexibility and the writers never intended for it to become the big monster it has become for so many organizations. Here are five ways I’ve used to keep all my quality management systems simple:
1. **Document only the procedures required by the standard.**
   - ISO 9001 only requires six documented procedures. More procedures mean more control, more records, and more for an auditor to evaluate.

2. **Stick to the Rule of Three.**
   - Whenever you create a document or activity make sure it satisfies at least three clauses. Why create one form to record design planning, one to record design inputs, and one to record design review, when one form for all three will suffice.
   - Use management review meetings to evaluate suppliers, examine process measureables, review corrective actions, and internal audit results.

3. **Create S.M.A.R.T objectives and use data you’re already measuring.**
   - Your objectives should be “Specific,” “Measureable,” “Achievable,” “Realistic,” and “Time-Based.” If you track on-time delivery and sales per customer use these as objectives.
   - Example: Increase sales for our top ten revenue generating customers (specific) by 15% (measurable, achievable) by January 2016 (realistic, time-based).

4. **Keep your Quality Manual short.**
   - Every “shall” statement in the standard does not have to be addressed. Plus, your registering auditor already knows the standard so you don’t have to rewrite it word for word.

5. **Simplify your tool calibration procedure.**
   - Pick only the measuring tools personnel use for accurate and precise measurements. No need to calibrate calipers when micrometers are the more precise tool.

The sections that follow will explain each method in more detail.
Tip #1  Limit Your Number of Documented Procedures

As I started to write my first quality manual clause by clause, I would occasionally ask my father-in-law, president of 20 person tool shop at that time, how he did “this” or “that” in his business. I would read about a clause, say 7.1 production planning, bring my ISO book, point at the clause, and ask my father-in-law, “How do you do this?” For example, he would explain to me how his engineer and foreman would plan the build of the project. When I asked him if we needed to write out the procedure, he’d ask, “Is it required?”

This led me to search for what exactly was required within the eight ISO clauses. What did we absolutely have to have written documentation on? Google may have been around but it wasn’t the giant search engine it is now, so I couldn’t find the answer quickly. After scouring my ISO book, I found there were only 6 required procedures. I couldn’t’ believe that in this whole standard only 6 procedures were required. I stopped worrying about documenting each step within their overall business process and focused on the six procedures that were required. Here they are:

- Control of documents (4.2.3)
  - Do ensure old, unused documents are obsolete? Is all documentation current and helpful to the organization?
  - Do you have a quality policy, objectives, and quality manual?
- Control of records (4.2.4)
  - Do identify, store, and organize records which aid in product realization and other aspects of your business?
- Internal audit (8.2.2)
  - Do you regularly check to make sure what you’ve written in your quality manual and procedures is actually being done?
- Control of nonconforming product (8.3)
  - If something is broken, returned, or doesn’t work like it’s supposed to, do you control it to make sure it doesn’t re-enter the system?
- Corrective action (8.5.2)
If a there is a system or process failure or malfunction, did you identify it, then analyze why it occurred, and finally describe how you fixed it?

- Preventive action (8.5.3)

If there is potential for a problem or malfunction, did you identify it, then analyze why it occurred, and finally describe how you fixed it?

There are many requirements within the ISO 9001 clauses, but that doesn’t mean every requirement needs its own documentation. You can provide evidence your organization is satisfying a clause without having written documentation.

For example, clause 7.2.2 states that an

“organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders)…”

Now, do you review customer requirements before accepting a job? You may have a short meeting or email exchange with your head engineer to decide if accepting/quoting this job makes sense. There are a variety of ways you can review customer requirements, but there is no requirement in ISO 9001 for you to write a process for how you review customer requirements. No first we print..., second we, third we, fourth, etc. Yes, you follow a similar procedure for most customer reviews, but there is no reason to create a documented procedure. The registering auditor will ask how you review requirements and if you have records of it. Your records will be your quotes, emails, or notes from staff meeting that stay with job.

Many organizations fall into the trap of documenting every procedure within their business system. For example, they try to document their purchasing procedure, shipping procedure, receiving procedure, saving documents procedure, etc. Yes, it is good to document your procedures because it standardizes how things are done. One employee can leave and when you train another one you can be sure the new employee picks up where the old one left off. However, regardless of how well your procedure is written a new employee needs time to learn their new task and there will be some drop off in efficiency, quality, etc.

Typically when an organization complicates their procedures, they end up hurting themselves during their ISO registration audits. With too specific of procedures an organization ends up having to prove they do things within their quality management system during a registration audit the way they are not really done.
Keep how you write your processes simple too...

Keeping the number of procedures within your quality management system to six or eight is not enough. You also need to make sure you keep your procedures simple and flexible. Here are the elements you should include in each and every written procedure:

- **Responsibility**: Who is responsible for overseeing the procedure? Making changes to it?
- **Process Measureable**: How do you measure the success of the process? What data do you collect and analyze?
- **Criteria**: What resources and information is needed to perform the procedure?
- **Methods**: What are the steps from beginning to end of the procedure?
- **Revisions**: What changes have you made to the procedure?

There is no need for a long list of definitions, reference to forms, or a lengthy description of the process’ purpose. Your only goals with the written procedures are to satisfy the ISO 9001 standard and ensure consistency with your product or service.

In order to keep your procedures flexible, you want to use such language as “if applicable,” “when necessary,” “if appropriate,” “if deemed acceptable,” etc. When assigning responsibilities for procedures, record-keeping, or other activities within your quality management system, give it to at least two personnel. Here are some examples:

- With your control of documents procedure, is only one member of management allowed to approve new documentation? If not, then in your procedure write, “The President or Vice President of Manufacturing approves documentation.”
- During your design procedure, does every design absolutely receive two separate design reviews? If not, then you may want to write a statement like, “If deemed appropriate by Project Manager, a second design review will not be completed.”
- Does every problem you identify during an internal audit, receive a corrective action? If not, then in your internal audit process write, “If deemed necessary by management, a corrective action will be written for problems identified during the audit.”
Some organizations, depending on the size and products offered, may require more documented procedures. If your organization demands more written procedures, it is still possible to use my tips above and keep those procedures simple and flexible.

**Tip #2 Stick to the “Rule of Three”**

The “Rule of Three” requires that before you decide to create a document or activity within your organization to make sure it will satisfy at least three ISO 9001 requirements.

With the daunting task of satisfying hundreds, yes hundreds of requirements within the ISO 9001 standard, it is very easy to create a form for this, a meeting for that clause, and another document for that. By the time you finish your quality manual, you look up and see you have a 60 page quality manual with 12 documented procedures and fifty forms. I’ve seen some quality manuals have with 25, 40, 50 and even 75 pages for small and medium sized businesses. If it’s that long, you’re not making ISO 9001 work for you, you’re working for ISO 9001.

Quality Manuals get long when you try to have evidence for each and every clause. For example, clause 7.2.1.c states,

“In planning product realization, (Your organization’s name here) determines the following, when appropriate:

   c) required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.”

Rather than separately list what your organization does for verification, monitoring, measurement, and test activities here, they may all fall under the umbrella of one activity. For example, you might connect planning product realization to your management review meetings, pre-design meetings, or sales meetings. During a pre-design meeting, do you not go over how you plan to design the product and what the requirements are? Do you review work orders, quotes, and other information from the customer to plan for your project? If so, then your pre-design meeting also acts as your “planning of product realization.”

Here is how Clause 7.2.1 would look using my “Rule of Three” in your quality manual:

“In planning product realization, ABC Company determines the required verification, validation, monitoring, measurement, inspection, and test activities during our Pre-
In my example, a Pre-Design Meeting occurs to determine the verification, validation, inspection, etc. activities for the particular project. Three requirements of the standard (verification, validation, and final inspection) are satisfied in this one activity.

Management review meetings, if done often enough, are another great way to satisfy many ISO 9001 standards. For example, at management review meetings you can analyze the performance of your processes, the results of audits, continual improvement, customer satisfaction, etc.

“Rule of Three” and Documentation

The Rule of 3 is also a guideline to follow when creating new documents. Clause 7.3 is an easy place to get carried away with documentation. In short form, here are all the 7.3 Design requirements per the ISO 9001 standard:

- Plan design: the stages of it, any review activities, and personnel responsible (Clause 7.3.1)
- Design Inputs: Decide on what customer information you need for design and keep records of it (Clause 7.3.2)
- Design Outputs: Create design with enough information so purchasing and production can perform their jobs. (Clause 7.3.3)
- Design Review/Design Verification: Review and verify design to make sure it matches inputs. (Clause 7.3.4)( Clause 7.3.5)
- Design Validation: Make sure your design does what it is intended to do. (Clause 7.3.6)
- Design Changes: Record and control any design changes. (Clause 7.3.7)

It is very easy to create one document for design planning, one to list design inputs, one to record design reviews, and one to record any design changes. These four documents can be satisfied all in one document, however. What if the same document you used for production planning is used to kick off your design planning?

Many businesses start a project with a work order, electronic or hard copy job folder with customer requirements, or a project planning meeting. The form you use for reviewing
customer requirements of the project (clause 7.2.1) can be used to start off your design planning. What if we didn’t even have to create a brand new design planning form? If you use a Work order, job requirements file (electronic or hard copy), or a project kickoff meeting of some kind, why not use this document or record for design planning as well? A review of customer requirements during project planning certainly involves the information you are going to need to plan design.

Your design plan should list design inputs, the criteria your engineers use to create the design, so you won’t need a separate form for it. Your engineer then creates your design and the resulting output includes information personnel can purchase materials from and build the product off of. Why not have a spot on your design planning document for recording design reviews? The personnel reviewing the design can have a specific space to sign and date for accountability reasons. Also on this design planning form you can add room to note any design changes.

Let’s review the amount of documentation with the two examples I gave...

<table>
<thead>
<tr>
<th>The too much documentation method...</th>
<th>The Rule of 3 method...</th>
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<tbody>
<tr>
<td>1. Customer requirement form</td>
<td>1. Work Order Form</td>
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<td></td>
<td>- lists customer requirements</td>
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<td></td>
<td>- lists specific design instructions.</td>
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<td>- explains any specific design instructions different from customer requirements.</td>
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<td></td>
<td>- any design changes listed during both formal and informal design reviews.</td>
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<tr>
<td>2. Design planning form</td>
<td>2. Design Print (Design output)</td>
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<td></td>
<td>- design review recorded.</td>
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<td></td>
<td>- design verification recorded.</td>
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<tr>
<td>3. Design Input list</td>
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</tbody>
</table>
As you can see, the “Rule of Three” method saves you from controlling four more documents. Remember, more documentation means more control with revisions and updates.

As you go through the other ISO 9001 clauses, be aware of opportunities where the three ISO requirements can be satisfied using only one document or activity. When in doubt, do not create another meeting, procedure or document. Rather, default to what you already do and what is working. Let ISO 9001 work for you, you do not work for ISO.

Note: Depending on the nature of your business and your industry there are instances where you will have to create a new activity for a single ISO requirement. However, do the best you can to limit how many one and done documents or activities you have to create.
Tip #3 Create S.M.A.R.T Objectives and Use Data you’re Already Measuring.

Clause 4.2.1 was an early road block for me when creating my first quality management system because I knew talking about “objectives” was going to be difficult for my father-in-law. I knew his objective. He wanted to make more money on jobs then he spent so he had enough to pay his employees and himself. I also knew this was not the objective ISO was looking. After a little persistence and nudging we came up with two pretty generic objectives. While we didn’t know exactly how to write objective measures yet, we were sure we didn’t want to add more work by creating objectives where collecting data was a pain. Here is what we came up with:

- Our organization will work to continually improve our quality management system.
- Our organization is dedicated to improving customer satisfaction.

At first glance, these seem like reasonable objectives. Don’t all businesses strive to improve their business system and customer satisfaction? However, when our auditor saw these objectives for the first time during our initial registration audit, he said, “The standard requires objectives to be specific and measureable.”

We worked on becoming more specific with our objectives after our initial registration but still struggled. We created such objectives as:

- Increase overall sales by 2%.

- Increase the number of noncompliances found in our QMS by 10%. (Why increase? Well, management was having trouble documenting the problems we were fixing.)

- Each member of management must identify five problems per quarter and discuss at management review meeting (Again, we were still trying to get management to record the problems they were fixing so we could prove to the auditor our system works).

As you can tell, while our objectives did get specific and measureable, they didn’t really explain the direction our organization was headed. In reality, the business was growing at a rapid rate, adding at least ten employees a year, and we were adding more and more products to our line.
We needed to determine what our actual goals were for our business and how we planned to get there.

That’s when I did some research and found the S.M.A.R.T objective strategy. Here are all the components included in it:

S: Specific

- What is to be done? How will you know it is done? Is it observable
- Relates to a specific procedure, department, etc.

M: Measureable

- How will you know you’ve reached your goal? What data are you going to collect?
- Must be quantifiable.
- Ex. Increase on-time delivery %, quote won%, decrease lead time by 10%, etc.

A: Achievable

- Can the objective be reached? Can it be done given the resources, time, and opportunity?
- Ensure you give your business a chance to reach the objective

R: Relevant

- Does the objective make sense to your business and the product/service you provide? Should it even be done?
- The objective should help you improve in areas you want to improve in.
- If it’s not relevant, you have no reason to achieve it.

T: Time-oriented

- When will it be done? What is the time frame for evaluating whether you reached it or not?
- Ensure your time frame is relevant and allows you enough time to achieve your goal.
- Giving too long a time frame decreases your motivation to achieve the objectives.

Using the five elements of this strategy, we were able to develop some pretty fantastic objectives which showed where we wanted to get to in our business. Here are some of the objectives we created (In the first two objectives I identify where the 5 parts of SMART objectives fall and explain my reasoning):
• Increase sales by 5% (measureable/acheivable) for our top 10% revenue-generating customers (specific/relevant) by the end of 2014 (time) by sending sales personnel twice a month to these customers for visits (specific).
  
  o This objective has a measureable of 5% increase in sales and this is specific to the “top 10% revenue-generating customers. Increasing sales with our best customers is relevant to the success of our business because we like working with them and they like us. A time of “by the end of 2014” is given. I further specify how we will achieve this objective because I identify how we plan to increase sales: send our sale personnel more frequently to customers. We feel our salespeople need to be the ones most connected to customers. We want our customers to always know we are there to answer any questions and deal with any of their concerns.

• Decrease the number of nonconforming product delivered to customers (specific/relevant) by 10% (measureable) by the 2nd quarter (time/acheivable) by implementing our new design standards (specific).

  o A 10% decrease is the measureable and is specific to our customers. Delivering high quality product is the goal of any business and we want to strive to continue to improve with this. We wrote this as a decrease in N/C products overall but if we did have a serious problem with one customer, we could focus our efforts on them. This objective is relevant because improving customer satisfaction typically means more business. The goal of a 10% decrease is only achievable based on the number of previous N/C Products. 10% of 100 parts run in one month is 10 parts, which is reasonable. 10% of 1000 parts run in run month is 100 and this may not be as achievable. A time of 2nd quarter is given. The objective further specifies how we plan to decrease N/C products by instituting new design standards. Note: The design standards would be further described in another section of the QMS.

• Decrease hours to build product “x” by 5% using machine “y” instead of “z” by 2nd quarter 2015.

• Hire and train three new employees to be able to run 80% of our total inventory in CNC machines by the end of 2015.

Use Data you already track...

In order for you to know whether you’ve met your objectives or not, you need to track data. My suggestion is for you create SMART objectives around data you already collect. There is no reason to make more work for yourself or your personnel by creating elaborate objectives based on hard to track data. For example, your accounting software tracks total sales per
customer and profit per job/project. What do these numbers tell you and how can you use them within a SMART objective? What you want to avoid is more work for yourself by tracking brand new data without the aid of a computer accounting or job boss program.

Ask your management team, president, or owner, what data they already track to determine success. For example, is there a specific % increase in sales management expects each year? Do their goals include profit margins or decreasing the wage to revenue ratio? There is no one right quality objective. As long as you make it SMART, it help you achieve your business goals.