

Lean Quality Documentation Systems

Reduce ISO 9001 documentation by half without eliminating content.

by Mike Micklewright

How did your quality system get so complex and redundant?

Many companies established their quality systems after having purchased a software program with a "canned" quality manual and procedures. Software companies try to subliminally sell you the concept "more is better." Purchasing companies often don't realize they also purchase a lot of junk that adds unnecessary complexity and length to their documentation system.

Other companies employ a management representative who over-interprets the standard so much that he or she develops a quality system that is too complex. Perhaps this is the result of management representatives being so fearful of missing something that they document everything, including how to fill the kitchen sink.

Many more efforts aren't well-coordinated, with documents written in each department separately, while ignoring the big picture of the system approach. The result is several documents addressing the same issues (i.e. nonconforming product, identification of product, etc.) and tons of redundancy.

Other people who put your quality system together (including consultants):

- Simply don't write well and/or
- Don't see the big picture
- Don't think systematically
- Would rather write about philosophy than practical actions
- Think they know it all
- Use ISO as a scapegoat for getting others to do what they want to have done rather than what adds value and is required by the standard.

What's wrong with an overly complex and redundant system?

The disadvantages of an overly complex and redundant quality system are:

- Those who approve a document for implementation don't read the document in its entirety because it's too long and confusing.
- If the document isn't properly reviewed and approved, it will contain inaccuracies.
- Few people will follow lengthy, complex and redundant procedures because doing so is too tedious and confusing.
- Few people will refer back to a procedure to find out how to complete a task because it's also too tedious or confusing.

How to eliminate the "junk" from a quality system?

In assisting companies with converting their ISO 9000:1994-registered quality system to one based on ISO 9001:2000 requirements and now, once again, assisting automotive suppliers in their efforts to convert to ISO/TS 16949, I challenged them to decrease their words and documents by at least 50 percent. So far, all companies have been extremely receptive to doing so. They realize their system is too complex and cumbersome for effective implementation. The quality system should speed up the effectiveness of their operations, not slow it down.

As an example, in two cases thus far, we were able to reduce the length of a document control procedure from eight pages to two pages without eliminating content. We were able to do this by simply eliminating the junk from the procedures.

How can your company do this? In the spirit of lean operations, simply tear apart the procedure format and eliminate what isn't adding value to the document. You can determine whether or not the words in a document or the document itself add value by asking:

- Does anyone really read this section of the document (especially if you purchased a "canned" program)?
- Does this really affect the quality of the product, service or process?
- Is this redundant? Can I just refer to another document or another part of this document that already states the same requirements?
- Am I really reviewing this document or am I just signing it hoping that the other people review the document to ensure its accuracy?
- Is this just mumbo-jumbo that really doesn't tell anyone to do anything?
- Is each statement or requirement stated once or is it stated multiple times in the same document or in another document?

In my experience, the biggest failure in lean documentation is the existence of redundant statements (multiple statements that basically state the same requirement). Are documents, primarily procedures, really necessary? In trying to comply with ISO 9000:1994, many companies felt they needed procedures for each of the 20 clauses. This was an incorrect assumption. Each company was supposed to ensure that each of the requirements was addressed in a procedure, not necessarily have a separate procedure for each clause. Some questions you can ask yourself regarding your documentation system might include:

- Do we really need procedures for inspection and test status as well as identification and traceability, or can we just incorporate these requirements into an inspection procedure and/or the process control procedure?
- Do we really need a control of customer supplied material procedure or can we just incorporate the requirements into a receiving inspection procedure, control of nonconforming product procedure and/or process control procedure?
- Do we really need a customer complaint procedure and separate procedures for corrective and preventive action procedures, or can we just combine them?
- Does your internal audit procedure refer to the corrective and preventive action procedure or does it repeat some of the same requirements?
- Do you have a quality system procedure and/or a management review procedure that does not add value because it just repeats the same requirements that are stated in the quality manual?
- Do you need separate procedures (or any procedures) for handling, storage, preservation, packaging, and delivery, or can they be combined together or placed into the process control procedure?

To illustrate the points above, the following sections of a typical procedure may not add value and can probably be eliminated:

- *Policy*: This is a procedure. Policy isn't needed here. It was already recorded in the quality manual. Eliminate this section. See example in the text box.
- *Exhibits*: You probably already referred to the exhibits, or forms, within the body of the procedure. Keep it there and eliminate this redundant section. See example in the text box.
- *Vocabulary/Definitions/Abbreviations*: Address these in the body of the procedure, when the user is reading the word or phrase. For example: "Complete section II of the corrective action report (CAR)." From this period forward, refer to this form as a "CAR." Eliminate this

section.

- *Responsibilities*: Put responsibilities in the body of the procedure where it's extremely clear and force your procedure to always state the responsibility of each action. Eliminate this section. See example in the text box.

Also, dividing up a procedure by listing responsibilities by function or title doesn't allow for describing your process as a flow from one action to the next, as required by ISO 9001:2000. The "responsibilities" section should be eliminated and included in the body of the procedure so the procedure can flow from one step and person/department to the next.

- *Work instructions*: You should refer to any work instructions by title and document number within the body of a procedure to create the desired linkage. Referencing work instructions at the beginning or end of a procedure disrupts the linkage. Eliminate this section. Create a hyper-link so that one can just click on the work instruction (or procedure) when it's being referred to in the body of the procedure. See example in the text box.
- *Process review*: I've seen the requirement to review the process periodically, over and over again, in every procedure of a company's quality system. It should be stated once in one procedure (i.e. internal auditing procedure), not in many.
- *Signatures on every page*: Who really wants to sign every page of a document when one signature will suffice, as long as there are document control features (i.e. pagination and revision control) on each page? Eliminate the signature on each page.
- *Control copy number on each page*: Your master list should define where the controlled documents exist. Eliminate this feature.

The following recommendations are what I would suggest for inclusion in your lean procedure format. An example is shown in the text box.

Recommended procedures sections

For a procedure, it's recommended to only include the purpose, scope, procedure (which consists of responsibility and action), and revision record.

1. Purpose: This section should explain why the procedure exists. Often, the purpose of the procedure is written right in the standard. As an example, the purpose of the internal audit procedure is written in the first paragraph of Section 8.2.2 of ISO 9001:2000. It shouldn't be written as, "The purpose of this procedure is to define the responsibilities and requirements for planning and conducting audits, in addition to reporting audit results and maintenance of the records." This explains "what" is in the procedure, not "why" the procedure exists.

2. Scope: This section is often misunderstood, as is evidenced by the same statement written over and over again in each procedure. An example is, "This procedure applies to all operations in the ABC Company." Remember, if a statement is repeated more than once, it isn't adding value. The "Scope" statement should be broken into two sections, the "Breadth" and the "Depth."

2.1 Breadth: The key words include "from" and "to" as in the example below. If possible, this statement should reference procedures as in "From the completion of the _____ procedure to the beginning of the _____ procedure." This will also help your company comply with the ISO 9001:2000 requirement in section 4.1b, which states that your organization shall "determine the sequence and interaction of these processes." Each procedure's "Breadth" statement will then be aligned with the overall process flow perhaps depicted as an overall process flow diagram in section 4.1 of the quality manual.

2.2 Depth: The key words in this section are "Applies to," as in the text box example. In this section,

you should list every product, service, department or document this procedure applies to.

3. Procedure: I recommend dividing this section into two sections (columns) as shown in the text box example. The first section (column) is the "Responsibility" section, which forces the writer to identify "who" is responsible for each paragraph.

The second section (column) is the action that occurs. This section should always start with a verb or a participle phrase (i.e., an "if" or "when" phrase followed by a verb). See text box example.

4. Revision Record: This section should include "what" or "where" the change occurred, the new revision and the approvals, much like a print has a revision history.

Characteristics of a well-written procedure

A procedure should explain "who" does "what" and, if applicable, "when" and "where."

The following recommendations will allow for an efficient, effective, nonredundant and useful procedure.

Although there may be a few exceptions, most procedures shouldn't exceed three pages. The actual procedure should start on the first page, not on the second or third. There should never be any redundancy of statements made within a procedure or between procedures and/or work instructions.

Procedures should refer to other documents or forms within the body of the procedure.

Don't describe how to fill out a form (i.e., "Where it states "date," record today's date"). Just write "fill out the form completely" or "complete section I of the form." Make your forms self-explanatory and if necessary, insert examples. An example of this for a corrective action form might be: "Verification (i.e. review documents, training records and visually verify the action is working.)"

Procedures shouldn't have forms attached to them. Forms are stand-alone documents.

Procedures should contain electronic linkages to other documents, so that, if necessary, the user is only a click away from reading them.

Recommended work instructions sections

For a work instruction, it's recommended to include just the action and revision record. A work instruction should only describe how a procedural step is performed by one job title (i.e. inspector, engineer, customer service representative).

Action: Start with a verb. There's no need to state responsibility since it's already been stated in the procedure that's referring to the work instruction. If you're trying to write a work instruction and there are different people responsible for different tasks, then this document, or a portion of it, should be in a procedure.

Revision record: Same as a procedure.

Recommended approvals: There should be a purpose for each approval type (i.e. management representative, manager) and it should be stated in the document control procedure. The following excerpt is an example of this requirement:

3. Procedure

3.1 Responsibility	3.2 Action
Any Employee	1. Initiates the change or addition of a document (quality manual section, procedure, work instruction or form) by submitting a draft or marked-up copy to the management representative using the existing format of comparable documents.
Management Representative	<p>2. Reviews the document for initial approval and advises the employee of changes to be made. Reviews the document to ensure:</p> <ul style="list-style-type: none"> • Compatibility with ISO 9001:2000 • Compatibility with customer and internal requirements • No redundancy with current documentation • That the change/addition/deletion adds value to the system • Analysis of possible elimination of other documentation (i.e. words, sentences, paragraphs, or entire documents) <p>If acceptable, initiates the process of changing and/or adding to the document.</p>

By describing the management representative's responsibility as such, you are fighting entropy, or the law of disorder, which states that everything proceeds toward disorder. Quality systems have a tendency to grow out of control. This will help to maintain system control.

Case study

The following table illustrates the results of adhering to the guidelines defined above. This case study involved the conversion of a warehousing and distribution company's quality system from ISO 9002:1994 to ISO 9001:2001. The same results occur when converting a QS-9000 system to ISO/TS 16949.

The reduction of the number of documents and pages in the remaining documents didn't involve a reduction in content. In fact, the content was actually increased. Also, font size and type didn't change.

Topic	Measure	Before	After	Reduction
Quality manual	Number of pages	43	31	28%
Procedures	Number of procedures	20	10	50%
			+ 1 customer satisfaction	(32 pages eliminated)
Procedures	Total number of pages	80	25, including customer satisfaction	69%

Conclusion

This is the perfect time to downsize your documentation system (especially automotive suppliers) and make it more user-friendly. Your company has been registered for some time now and many of the employees know the deficiencies and complexities of your system. In the spirit of continual improvement, it's wise for companies to take advantage of making their quality system more user-

friendly by improving and downsizing it now, and putting controls in place so that it does not get out of hand again.

Use this sample meeting format to improve your QMS:

Management Review Meeting

(NOTE TO READERS: If this type of information is already contained in 5.6 of your quality manual, then keep it there and don't have a procedure like this that basically states the same requirements.)

Purpose: To define our system of reviewing the continued suitability, adequacy and effectiveness of our QMS, to ensure that the resources needed to achieve the quality objectives are identified and planned, and to assess opportunities for improvement and needed changes to our QMS, quality policy and related objectives.

Scope:

Breadth: From the scheduling of the management review meetings to the publication and distribution of minutes, and the implementation of actions in accordance with our corrective and preventive action procedure (8.5.2-01) and the quality planning procedure (7.1-01).

Depth: This procedure applies to the review of the entire management system including the policy, objectives, procedures, instructions and how well the system is functioning to achieve our stated objectives.

Procedure

Management Rep. (MR):	Schedules the management review meetings to be conducted in January, April, July, and October of every year.
MR:	Sends out an agenda of the meeting at least two weeks in advance of the scheduled meeting to the management team (as defined in section 5.5 of the quality manual).
Invitees:	Must either be present for the scheduled meeting or send a representative to the meeting and/or provide the MR with the status of any outstanding actions, data, metrics or information for which he or she is responsible.
MR or president:	<p>Conducts the meeting and, at a minimum, ensures the following topics are reviewed by the appropriate personnel:</p> <ul style="list-style-type: none"> • Review of previous meeting's notes and actions • Review of quality objectives and goals and performance • Review of plans to achieve those goals • Review of effectiveness (supported by trend data) of the quality system (to be presented by those listed) • Customer complaints (QA) • Productivity (team leaders) • Lead time (CS) • Profitability (accounting) • Internal rejects (team leaders) • On-time delivery (shipping)

		<ul style="list-style-type: none"> • Supplier performance (purchasing) • Customer feedback/survey results (GM) • Training hours and employee retention (HR) • Critical product conformance analyses (QA) • Training needs • Facility, infrastructure and work environment needs • Status of outstanding corrective and preventive actions (including those resulting from audits) • Status of quality planning activities resulting from new products/services • Status of continuous improvement projects • Status of new processes/machinery • Changes in management, company structure, markets, customer needs, etc. that could affect the system • Review need to change/improve quality system, objectives, policy
Management Team:		Initiates the corrective and preventive action procedure (8.5.2-01) based on the review and initiates the quality planning procedure (7.1-01) for new products, projects, processes or systems currently beyond the organization's capability.
MR:		Ensures the preparation and distribution of decisions made and actions to be taken on the meeting minutes form (5.6-01A). Retains these minutes in accordance with the control of quality records procedure (4.2.4-01).
President:		Uses information and data from meeting as input into the quarterly companywide meeting in accordance with the internal communication of system effectiveness work instruction (5.6-01-01).
Invitees:		Carries out or delegates actions as defined in the meeting and prepares data/information as required for the next meeting.

Figure 1: Revision Record

Revision	Description of Change	Approved	Approval
Level		By	Date
Original	None	MM	6/30/98
A	Update entire procedure to conform to ISO 9001:2000	MM	3/30/xx

About the author

Mike Micklewright is president of [QualityQuest Inc.](#), a consulting, facilitating and training company based in Arlington Heights, Illinois, that specializes in the integration of Six Sigma and lean manufacturing into ISO 9001-based quality management systems. Micklewright has developed and sells video training programs entitled "The ISO Auditors Are Coming!" and "Auditing Nuts and Bolts." Micklewright holds a degree in engineering from the University of Illinois and is an ASQ-certified Six Sigma Black Belt, CQMgr, CQA and CQE.

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