Example Quality Management System

Prior to the reissue of the ISO 9000 series in 2001, the majority of organisations wrote their Quality Manuals (QMs) to show how they met the 20 individual requirements of the 1994 standard. Although this made it easier for the manual’s authors to show the auditors that all of the requirements of the standard had been covered, quite often (especially in a very small business), the manual was of little use to the organisation itself in actually running their own business.

The new process-orientated standard now requires the QM to ‘include the scope of the system; include any justifications for exclusions; refer to established procedures and describe the interaction between processes’. A QM that simply echoes the requirements of ISO 9001:2008 will, therefore, not be compliant, as certain sections of the standard’s content may not be applicable to that particular organisation.

The QM should serve a useful purpose and so simply paraphrasing ISO 9001:2008’s requirements will not represent the best approach. Thus, an organisation should no longer use an ‘off the shelf’ generic QM to show compliance unless, it has been suitably customised to suit that particular organisation.

The whole reason for my book is to try to help small businesses (who probably have insufficient time to thoroughly read, understand, extract and implement all of the requirements of ISO 9001:2008 – and who quite likely cannot afford to employ a consultant to do the job for them) by providing them with a fully worked example. Although this generic Quality Management System (QMS) is based on one particular type of company [i.e. Aufait Associates Ltd (AAL), who are a ‘paper producing’ consultancy], it can be used as a basic template to describe the way that your particular organisation does business by leaving out those bits that are not particularly relevant to your company and/or amplifying/writing new policies, processes and procedures to cover your organisation-specific areas that I have not covered in my book.

Although a lot of consultants say that there is now no need to address each requirement, clause by clause, I tend to disagree because if you are having to identify the requirements that are not applicable to your organisation (i.e. the ‘exclusions’) and then say why they are permitted exclusions, surely there is less chance of missing a possible subrequirement by actually listing all of them.
and showing whether they are applicable or not?! If you are having to describe
the interaction between processes (which probably result from different
requirements or subrequirements scattered within ISO 9001:2008), then why
not list them all, so as to ensure that you do not miss any? I have sought ISO’s
advice on this matter and they said that ‘Although ISO 9001:2008 does not state
that there needs to be any reference to the requirements of the standard, if an
organisation chooses to list all of the requirements, then that is its choice – and
it will certainly assist external and third party auditors’.

As I understand it, the QM should be an overview of the organisation’s QMS
and show how the organisation runs its business. The Manual is primarily
intended for the Managing Director (to document his policy for running that
organisation), the Quality Manager (to give him a set of rules with which to
ensure that the organisation meets the policy requirements of the Managing
Director) and the auditors (to quickly identify which of the standard’s
requirements are applicable to that organisation and how they have been met).
Depending on the individual organisation, therefore, the QM could be just a few
A4 sheets of paper simply listing the exclusions, procedures and interaction of
processes. Or, similar to my generic example, it could be more of a reference
document aimed at assisting internal and external auditors in understanding the
organisation’s policies and how it completes its business – as well as providing
a checklist for the Quality Manager.

The same thing can be said about the Quality Procedures (QPs) contained in
Part 2. These again are meant as examples of the sort of QPs that will be needed
by an organisation to show how they implement their policies and processes.

For your convenience, in addition to a few general purpose QPs that most
organisations will need, I have also included generic examples of the two most
important mandatory ISO 9001:2008 QPs that you must produce in order to
claim compliance with ISO 9001:2008. They are:

- Control of documents (ISO 9001:2008 Section 4.2.3); and
- Internal audit (ISO 9001:2008 Section 8.2.2).

The other mandatory ISO 9001:2008 QPs that you will have to produce in order to
claim compliance with ISO 9001:2008 are:

- Control of records (ISO 9001:2008 Section 4.2.4);
- Control of non-conforming product (ISO 9001:2008 Section 8.3);
- Corrective action (ISO 9001:2008 Section 8.5.2); and
- Preventative action (ISO 9001:2008 Section 8.5.3).

There are so many different types of organisations that make use of ISO
9001:2008 (e.g. designers, manufacturers, producers, installers and maintainers
of products and services; small shops and other service industries) that it was an impossible task to include examples for all of these organisations in this chapter. I have, therefore, chosen to base these procedures around AAL and the intention is that purchasers/users of my book can take these QPs and then modify, adjust and customise them to replicate what they actually do.

For example, the Document Control procedure, whilst covering the requirements for quite a large organisation (e.g. 45 people) would probably be way over the top for a very small organisation. You do, however, need to have some form of Document Control and at the very least be able to identify where your documents are located or where they are saved on the server, etc. You may also want to show who is responsible for these documents, their revision status and their date of issue. In some circumstances (especially when dealing with foreign countries), you might even need to know who was responsible for translating a specific document.

One of the main advantages of ISO 9001:2008 is that it encourages organisations to develop systems that are specifically tailored to their own needs – even if you are a ‘one man band’. The QMS is an integral part of the business processes but you should not lose sight of the fact that it still has to meet the requirements of ISO 9001:2008.

ISO 9001:2008 for Small Businesses (Fourth Edition) is meant to save you time from having to constantly refer to the standard to see that you have covered everything. My generic example covers all of the standard’s requirements and similar to the actual standard itself, the intention is that organisations pick and choose what bits they need for themselves.

But, it is not meant to be used as an ‘off the shelf’ product!!

Note: To save you from having to copy or retype the QM, Quality Procedures (QPs) and/or Work Instructions (WIs), ‘unlocked’, fully accessible, non-PDF, soft copies of all of these files presented in the book are available – at no additional charge – direct from the publisher.

To obtain copies of these files please visit www.elsevierdirect.com/companions/9781856178617

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OBTAINING ADDITIONAL MATERIAL, INFORMATION AND SUPPORT

A CD containing a soft copy of the generic QMS featured in *ISO 9001:2008 for Small Businesses* plus a soft copy of all the check sheets and example audit forms contained in *ISO 9001:2000 Audit Procedures*, 2nd Edition (Elsevier Butterworth-Heinemann, ISBN 0 7506 661 3) is available from the author for a small additional charge. All of these files can be quickly customised to suit your organisation’s business and an ISO 9001:2008 Help Line is also available to purchasers of this CD.

For more information about this and other ISO 9000 consulting services, please visit www.herne.org.uk or www.thebestqms.com or e-mail ray@herne.org.uk.

Author’s Hint

This following example is of a QM that has been based on the assumption that AAL is a small to medium-sized enterprise (SME), employing between 45 and 50 people, which has a full-time Quality Manager plus a small part-time Quality Team.

If your organisation does not have a Quality Team, then you should leave out the irrelevant passages.

If you have a Micro-Business (i.e. less than ten employees), then you probably will not have a full-time Quality Manager and in that case it would normally be the Owner or Managing Director who performs the audits and checks.

When using this example, please do not be tempted to just ‘find and replace’ AAL with your own business name in the hope that it will satisfy an auditor – because it will not! You must go through this example QM (and its supporting processes, procedures and WIs) sentence by sentence to ensure that it replicates what your own organisation does and the type of business that you provide.