



A Handy Guide To:

# ISO 9001, 2015

## Quality Management Systems

### **This standard helps your business by:**

- Improving the consistency of your products and services
- Increasing access to tender lists and larger customers
- Encouraging measured company growth
- Acting as a market differentiator and giving added credibility

### **ISO 9001 certified businesses report:**

- Improved levels of customer satisfaction and loyalty
- Improved operational performance
- Gaining new customers and keep existing clients
- General cost savings



## Introduction

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A guiding principle when trying to interpret ISO 9001, 2015 is that it greatly reduces the amount of documentation you need to maintain. The mandatory provision of documented procedures is removed completely. As long as you can provide appropriate records to show a process or activity is operating correctly you don't need to have written down how it works. But this does mean that inexperienced staff have no guidance or instructions to follow.

## Context of the Organisation

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This section of the standard and some of its sub-clauses are among the more recent requirements among ISO standards and were implemented with the introduction of a document called "annex SL" which introduced a "standard template for standards". The clause suggests that after you have decided to form a business you should decide on the direction the business should take, its aims, products and services, customers and affected parties. You can then set the boundaries/scope of the management system you intend to develop, what it has to cover etc, and build the management system to deliver these core business aims.

Having defined aims for your business is a simple idea which is too often ignored. Similarly, standing back and taking a wider view of the influences over the business and how they could be mitigated is a simple step but regularly missed.

In considering internal and external needs and affected parties its perhaps worth noting the standard isn't asking for every need and party to be named and some grouping is acceptable to most certifiers.

## Leadership

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The leadership section of the standard really hasn't changed very much from previous versions. Although early publicity said the standard was aimed at increasing the involvement of senior management its difficult to see how this clause is going to drive such a claim. It places the responsibility for identifying roles and responsibilities with senior management, along with ensuring processes are functioning correctly and reporting on the performance of the quality system.

The clause also calls for the production of a quality policy statement and specifies requirements for its content. But there is little here which hasn't been in previous versions of the standard.

## Planning

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The planning clause starts where clause 4 and the context finishes, with the idea that once you've identified the influences on attaining your strategic aims, and the risks and opportunities they present, you should assess those risks and opportunities and develop appropriate controls. Risk assessment is a well established practice, and a fairly simplistic form of that used in Health and Safety systems can be made to work fairly simply.

This section moves on to talks about setting quality objectives, not new to ISO 9001, but then goes on to call for more detailed plans of how you are going to achieve them, who is responsible and what timescales are involved. This will stop the cynics from just making up simple objectives they don't really care about, and should cause businesses to think of genuine objectives which would be useful to achieve.

Finally the clause gets into an area where ISO 9001 has previously been quite weak, by introducing definite requirements for change management affecting the management system.

## Support

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This section starts with the provision of resources and says little that its predecessors didn't require. Measuring and Monitoring resources is also covered by this section. The once mighty calibration clause, previously the largest section of the standard, is now much reduced but says pretty much what was said in the early 90's about making sure your test gear is reliable and accurate.

The organisational knowledge sub clause is new, and raises the important issue of having an organisation which relies too heavily on the knowledge of individual people.

"Competence" and "Awareness" reflect the training section of previous versions and don't add say anything new. The "Communication" sub-clause is new, though strongly linked to that in a previous version of ISO 14001. An important consideration here is that the standard says what you have to do, but it doesn't say you have to write down how you do it.

This final part of this section finishes with the controls required over "documented information". I think this is where the standards writers have made their biggest mistake. Although you now have to control documented information, its approval, change and distribution, you no longer need to document HOW you do this, making consistency of this control over a whole organisation unlikely at best!

## Operation

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The operational requirements defined in the standard really aren't much different from previous versions. The previous requirements for contract review, controls over order processing and customer communication all now being specified in this section. There is perhaps a stronger reference to ensuring the business is aware of and meets applicable regulations and legislation, but this brings ISO 9001 into line with the Environmental and Health and Safety Standards, ISO 14001 and ISO 45001. The design requirements are as in previous versions of ISO 9001.

The next sub-clause, "Control of externally provided processes, products and services" is the old purchasing clauses with a little added to make it clearer that you are responsible for managing your sub-contractors. This brings it in line with UK legislation like CDM, and makes it clear you can't rid yourself of responsibilities simply by using sub-contractors. The clause still calls for suppliers/sub-contractors to be evaluated and periodically re-evaluated, and says that you should retain "documented information", i.e. written records of the evaluation, an area I still find companies struggle to meet.

The remains of the Operation clause requirements are as previous versions and expect you to have controlled the operational aspects of the business, including the final release of the product/service to the customer. The closing section of the clause concerns the control of non-conformance and again doesn't have any new requirements when compared with previous versions.

## Performance Evaluation

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This section encourages businesses to use statistical analysis and other valid means of assessing their performance to measure how well they are doing against their business aims, are customers satisfied with your products/services, is your output meeting that planned, are your suppliers supporting you correctly etc. The Internal Audit and Management Review clauses finish off this section, making it clear that both activities SHOULD be helping you to check the company's performance against its aims and plan any improvements which are required.

## Improvement

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The improvement clause really draws attention to the idea that you should be documenting non-conformance, failing goods, unhappy customers, excessive costs and generally things that go wrong so that you can then plan their correction and future prevention, an area where many companies are weak. This is often because of the politics involved in identifying the causes of things going wrong, and the danger of using the process as a witch hunt to find someone to blame.



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