

## ISO 9001 – What is it and what do I need to do to get it?

ISO9001:2015 is the Internationally recognised standard for Quality Management Systems (QMS), but it's not just about 'quality', it's more of a blueprint of how to run a well organised business.

There are many articles on the internet explaining at some length the benefits that achieving ISO9001 certification can bring but it's quite a lot harder to find what you actually need to do in simple terms. The purpose this short article is to give you an insight into the main elements you need to have in place to satisfy an independent UKAS accredited auditor that your company meets the requirements of the standard – i.e. that you pass the test. If you're not aware of any such companies, the UKAS website has details of every company that offers certification services. \*

All ISO management systems recently issued or revised from now on will follow the same high-level structure (Annex SL) so for example, Clause 5 in 9001, 14001, 45001 and 27001 all describe the requirements related to Leadership. This alignment has been done to make it easier in future to have one integrated system, rather than needing a system for quality, another for occupational health & safety, a different one for environmental management etc.

Under Annex SL there are 10 sections in each standard, sections 1-3 are administrative, 1 outline's what a QMS is for, 2 gives references and 3 lists terminology, the important ones from the point of view of day to day running of your system start at section 4.

- Section 4 – is called the 'Context of the Organisation' – it means you've got to demonstrate a deep understanding of the general business environment you operate in and the factors that can impact on you as a company, therefore affecting your ability to supply goods and/or services that meet all necessary requirements, including satisfied customers. Additionally, you need to show that you understand the 'needs and expectations of interested parties', so some evidence around business strategy and plans is useful here. A simple SWOT&PEST analysis is also a really useful tool.
- Section 5 – is about 'Leadership' – the exact phrase is 'top management shall demonstrate leadership and commitment' so an auditor will be looking for evidence of this, both in word and deed. One essential element is your quality policy, it needs to be relevant to your business, understood by everyone in the organisation and written down. You also need to show that everyone in the organisation understands their role in making the management system work and achieving its' objectives.
- Section 6 – Planning – in relation to the information you've developed for section 4 you need to show how you're managing and mitigating any risks and that any changes you make are thought through. You'll also need to set some measurable objectives and plans as to how they will be achieved and who will be responsible.
- Section 7 – Support – i.e. the resources you put in place to run the management system (and the company). This includes physical infrastructure, people, equipment, competence, knowledge and 'documented information'. The 2015 revision is much more flexible about what documentation is needed than previous versions but it's not possible to run a company without some documents and records. The key thing is to make them useful, documents generated for their own sake aren't usually much good – that's why it's important to develop your own system rather than an off-the-peg 'solution'.

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- Section 8 – Operations – you'll need to describe how all the day to day activities are controlled, ranging from service delivery, manufacturing, design, suppliers and sub-contractors – this is usually the easiest part of system development because most companies already do most of what's needed, but the exercise of developing the system forces you to think 'why do we do that and could we do it better?'. In terms of written procedures etc – use them if they work for you, not because you think an auditor wants them.
- Section 9 – Performance Evaluation – you have to be able to look at your performance and assess whether things are working as they should to achieve company objectives and goals. Key facets are customer satisfaction levels, internal auditing (i.e. are we doing what we said we should be doing) and a management review process.
- Section 10 – Improvement – how are you using all of the above to get better. The whole concept of ISO9001 is built on the Plan-Do-Check-Act cycle and active risk management.

All of the above will generate some documents and records but the requirements of the standard aren't onerous and certainly shouldn't impose an administrative burden, if it does, you're probably not doing it right! Put simply ISO9001 is mostly good business sense so if your current operation does have gaps against ISO requirements you need to seriously ask yourself whether you should plug them anyway, regardless of any audit requirement.

### References and useful sources

BS EN ISO9001 (2015) published in the UK by the British Standards Institute  
Better Business for All – <https://bbfa.biz>

\*United Kingdom Accreditation Service (UKAS) [www.UKAS.com](http://www.UKAS.com)