

How to Achieve ISO 9001:2015

Some real expert help from Mark Braham

As I was involved in the drafting of ISO 9001:2015, many people have asked me how best to approach certification of their Quality Management System to this Standard.

I have set out my considered answer in this paper, where I have explored:

- The intention behind the latest update of the ISO 9001 standard
- The requirements of a Quality Management System certified to ISO 9001:2015
- The thinking behind each of the seven quality management principles
- What an auditor is looking for to award ISO 9001:2015 certification



I hope that you find it both interesting and useful.

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The intention behind the latest update of the ISO 9001 standard

The core intention behind the latest update of the ISO 9001 standard is to put **quality at the heart of every organisation**.

ISO have recognised that too often quality is not viewed as strategic, important or even very useful. Too often, the quality department is viewed by the rest of the organisation (and most damningly by the leadership team) as, 'the department that gets our ISO certification' and nothing more.

Part of the reason for this negative thinking is the development history of the ISO family. It was developed to certify the quality management of manufacturing companies and supply chain management. Many people have therefore continued to think about ISO 9001 certification as being:

- Product orientated
- Factory biased
- Non-strategic
- A tick box exercise
- About achieving the certificate on the wall and nothing more

In drafting ISO 9001:2015, the aim was to **change this thinking** and to try to change how the quality profession is thought of.

So, the intention behind the latest update of the ISO 9001 standard was to:

- Make it absolutely relevant to service industries such as health, government, finance...
- Take into account current technology and ways of working - for example completely getting rid of the concept of the Quality Manual
- Make it as relevant to multi-national organisations and supply chains as to small, even micro companies



The requirements of a Quality Management System certified to ISO 9001:2015

During the drafting process of ISO 9001:2015 even the name Quality Management System (QMS) was debated long and hard. The name Business Management System (BMS) was proposed - and although rejected, the fact that it was considered is telling.

It seems that even amongst us quality professionals it is recognised that the word 'quality' is seen as synonymous with something non-strategic - not core to the real business of the organisation and dare I say it, a bit geeky.

Although a name change to Business Management System was rejected, the core requirements for a QMS to comply with ISO 9001:2015 are however that the QMS is **strategic**, **central to the core business of the organisation and relevant to all employees**.

This is because the core requirements of ISO 9001:2015 are that any QMS must:

- Meet or enhance customer satisfaction
- Meet all statutory and regulatory requirements

These of course, both align with the strategy of the organisation and are relevant to everyone in the organisation. When supported by the requirement that the context of the QMS must be:

- A process approach which enables an organisation to plan its processes and their interactions
- Within a Plan-Do-Check-Act (PDCA) cycle

 which enables an organisation to ensure
 that its processes are adequately resourced
 and managed, and that opportunities for
 improvement are acted on

 Risk based thinking - enabling organisations to determine the factors that could cause processes and its quality management system to deviate from the planned results and to put in place preventive controls

ISO 9001:2015 puts the Quality Management System firmly at the heart of any organisation.



Doing the day job

As well as sitting on and leading several quality committees, I am Head of Business Assurance at The AA.

Obviously, it's important to me that the AA's Quality Management System is compliant with the latest 9001 standard both in specifics and culture. The Quality Management System for the AA is an Integrated Management System - which supports the whole business with Quality Management, Risk and Opportunity Management, Continuity Management, Health and Safety and more ...

Our IMS sits firmly at the heart of the AA and most importantly puts our customers at the heart of everything we do.

Seven Quality Management Principles (QMP)



Certification to ISO 9001:2015 requires passing an audit to check that your Quality Management System (QMS) delivers on the requirements of the Standard as underpinned by the Seven Quality Management Principles.

These **Quality Management Principles (QMPs)** are:

QMP 1 – Customer focus: Meeting - and exceeding - your customers' current and future needs is the primary focus of quality management.

QMP 2 – Leadership: Having a unified direction and mission that comes from strong leadership is essential in promoting the right culture.

QMP 3 – Engagement of people: Competent, empowered and engaged people at all levels of your organisation.

QMP 4 – Process approach: Understanding activities as processes that link together and function as a system to yield more effective and efficient results.

QMP 5 – Improvement: Successful organisations have an ongoing improvement focus.

QMP 6 – Evidence-based decision making: Ensuring your decisions are based on the analysis and evaluation of data is more likely to produce the desired result.

QMP 7 – Relationship management: Identifying the important relationships you have with interested parties such as your suppliers - and setting out a plan to manage them - will drive sustained success.

Next I will take a look at the seven QMPs in turn and explore:

- The thinking behind each of the seven quality management principles
- What an auditor is looking for to award ISO 9001:2015 certification

QMP 1 - Customer focus: Meeting - and exceeding - your customers' current and future needs is the primary focus of quality management

As we explored previously, one of the two core requirements of ISO 9001:2015 is that any QMS must:

· Meet or enhance customer satisfaction

Customers are of course king in any organisation; bringing in revenue and paying everyone's salaries. In addition, they are the best route to new business, since a word of mouth recommendation is the most powerful route to market. These days about 58% of business purchases start with a referral.



It is therefore **absolutely key** that your QMS at least supports meeting your customers' requirements (including perceptions) and preferably **enhances** your customers' satisfaction.

To meet the requirements of QMP1, you need to show that both your customers and your Quality Management System sit at the heart of your organisation.

This is as much to do with the culture of the organisation, as created by the leadership, as with things that can be ticked off. The auditor will be checking that the Senior Management Team (SMT) are driving customer focus at all key decision points and need to see how your QMS supports this.

Practical ways to demonstrate this to an auditor are to show them your:

- Customer User Groups and surveys which capture current and future requirements
- Complaint handling process demonstrating that you record and analyse to determine where to improve your processes
- Referrals to and recommendations about your organisation
- · Targets are aligned to customer changes

The way to get the most benefit from your ISO 9001:2015 certification is to really live the customer focus principle. Ensure that the question being asked is, 'what else will enhance the experience of our customers?'

QMP 2 - Leadership: Having a unified direction or mission that comes from strong leadership, is essential in promoting the right culture

The most significant change made in the 2015 update of ISO 9001 is to the Quality Management Principle: Leadership.



In the drafting of ISO 9001:2015, it was recognised that for a QMS to sit at the heart of an organisation and for 'quality' to sit there too, the **management system must** be aligned to the organisation's core strategy; and for this to be the case the strategy must be both clear and supported by the whole leadership team.

An auditor will look to see that the whole SMT are working together to create an environment in which:

- The right work environment is cultivated
- The right training has been given, with the right qualifications to ensure that objectives are achieved
- Physical resources are provided to achieve objectives
- Clear goals, objectives and policies have been
- Quality is treated as a strategic issue
- The financial effects of failing to meet these goals is identified

Enabling:

The right people to thrive

Some of this will be behavioural. Some will be systems driven. Some will be about the communication.

All this of course adds up to the culture of the organisation. What an auditor is looking for is an open culture, where everyone is working together, from the top down, to enhance the customer experience. This is of course difficult to quantify, so what an auditor will be looking at is:

- The flow of communication from the leadership downwards
- Leadership accountability
- The analysis of management information
- **Appraisals**
- Training requirements
- Skills development
- Qualification plans

They will be reviewing the organisation's quality policy and its values. This is both the written mission and value statements, and the practical ways in which they are implemented, such as:

- Employee reward schemes
- Director awards for staff
- Annual awards that put quality and the customer at the heart of the organisation

Focusing on the QMS specifically, they will be looking for one central QMS which has all the policies, processes and resources in one place to deliver:

- On the needs of the customer
- Against statutory and regulatory requirements

QMP 3 - Engagement of people: Competent, empowered and engaged people at all levels of your organisation



The ISO 9001:2015 thinking here is to change the mindset of, 'quality is the problem of the quality team'. Just as Health and Safety is now understood to be everyone's responsibility, quality also needs to be everyone's responsibility.

It should also be recognised that **the people working** for an organisation are its biggest asset.

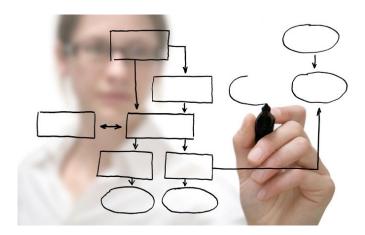
So, it is key that every organisation employs the right people in roles that match their competencies and abilities. Supported by:

- An integrated human resources plan with the strategic plan
- An approach that encourages employees to contribute to continuous improvement so that everyone who can enhance the customer experience does just that

To enable this, everyone needs to be clear about how they contribute to the business objectives and how they can contribute to enhancing customer satisfaction. Of course this can be done in many different ways, but some of the types of things that an auditor will look for are:

- That employees are given the scope to do the work they need to
- Results from employee satisfaction surveys and employee user groups
- A consistently high level of communication between leadership and employees
- Collaboration especially with union representatives and departments such as finance and marketing, who are often left out of management systems
- Knowledge sharing so there is never just one person who knows how to do something
- That employees are encouraged to contribute to your improvement strategy

QMP 4 - Process approach: Understanding activities as processes that link together and function as a system to yield more effective and efficient results



The process approach principle for quality management systems has been around for many years, but hasn't necessarily been understood or implemented as intended. This is frustrating as the approach can deliver far more value than it often has in the past.

Process mapping can and should be about predicting the results of change - not just an exercise to achieve ISO certification.

So how can the full benefits of process mapping be achieved?

The answer is in making your Quality Management System, not just a flat manual, but a 3D model of your organisation.

In order for this to be the case, your quality management systems needs to:

- Cover the whole organisation
- Contain end-to-end processes
- Realise that the inputs for one process are actually the outputs of another
- Show customer touch points
- Manage resources as processes and then optimise

If it does do this, it will clearly show your value stream - the processes which brings in your income - and be a **model of how your organisation currently** works: the AS-IS.

A Quality Management System which delivers this, can then deliver so much more.

The update of ISO 9001:2015 was to make this clear, as it has so often been misunderstood in the past. Reams and reams of process maps do not add value. A QMS which shows you the potential effects of change before you make them - that adds real value.

So what will an ISO 9001:2015 auditor be looking for?

Well that depends on the type of organisation that you are.

For tiny organisations, a paper based QMS may be sufficient. This of course won't deliver a 3D model of your organisation, but if there are only two people employed, that won't be required.

For most organisations however, a cloud-based system 'accessible from their intranet' will be most appropriate.

Document control will be required for international organisations.

Whatever system your organisation uses, just make sure that it has the capability to model the TO-BE and make changes from both a position of understanding the AS-IS and compare various potential TO-BEs, so that you can implement the best one.



QMP 5 - Improvement: Successful organisations have an ongoing improvement focus

Improvement is a major motivator for me. My favourite question that my Director asks each year at my annual review is, "How much money did you save us this year?" and I always have a great answer.

Maintaining and growing brand, profit and market share are the lifeblood of any organisation and standing still with any of these results in the organisation means getting left behind. ISO recognise this with QMP 5 -Improvement.

Improvement starts with objective setting. It is important that the appropriate objectives are set at all levels of an organisation, with tangible links to the strategic direction of the organisation.

Improvement is best achieved as an approach, a culture for all employees not just auditors or business change teams - so that it continually drives everything that the organisation (and everyone in it) does. It should be the driver behind training, skill setting and the base line expectation for how everyone works.

Practical ways to demonstrate improvement to your ISO 9001:9015 auditor - are to show your continual improvement and change programmes. Improvement can also be quantified by showing root cause analysis, especially that resulting from customer complaints. Use the plan, do, check and act process before change, during the change and after the change to ensure continual improvement and that the process is delivering the correct outputs.

Any programme that identifies the cause of errors, mistakes and defects and make changes to ensure that they are not repeated, demonstrates improvement; as do developments or innovation to enhance and improve the customer experience. Strive to achieve stretch improvement goals and seek to prevent defects or waste.



QMP 6 - Evidence-based decision making: Ensuring your decisions are based on the analysis and evaluation of data is more likely to produce the desired result

QMP 6 (evidence based decision making) links closely with QMP 5 (improvement). It is very common for management, especially new management to want to change things. The changes are of course intended to deliver improvement, but of course not all change does.

Some change can be for the worse.

The best way to try **and ensure that change does** indeed result in improvement, is to base your decisions on objective evidence. Look at the data. analyse it to identify where the improvements lie;

where tangible additional benefits can be achieved and then create a pipeline of improvement projects.

Trust the management information but always be open to challenge any statistical data. Don't forget to measure and monitor any changes to verify that those changes have produced customer business or customer benefits.

Identify say six major projects that can be addressed this year (or whatever is the appropriate number for your organisation) and then give focus to doing so.

An ISO 9001:2015 auditor will be looking for the evidence trail back from the decision to make the change. This doesn't have to be very complex, just a record of the actual data which indicated that a change should be made. Did the business case deliver the correct outcomes? Was the financial benefit realised?



QMP 7 - Relationship management: Identifying the important relationships you have with interested parties such as your suppliers - and setting out a plan to manage them - will drive sustained success

Historically QMP 7 was supplier focused and about getting the best possible price from your suppliers. However, with the latest version, the focus is much more about working in partnership with your supply chain to ensure the best possible outcome for the end customer. This approach delivers far more benefit for everyone.

Successful relationships along the supply chain are absolutely key for the organisation that I work for with critical suppliers supporting our strategic objectives. For example, we work closely with a whole host of garages, whose employees are trained by The AA, and who are also audited and certified by The AA to ensure that our customers receive the service that they expect and require.

The ISO 9001:2015 auditor will be looking for information on the relationships that are key for your organisation and how you plan to manage that relationship to the benefit of all. This control is adaptable depending on the scale, risk and cost to your organisation.

- Define and document requirements to be met by external providers
- Evaluate the external provider's ability to meet your requirements
- Work together with external providers to enhance customer satisfaction
- Consider joint working and the use of quality plans that integrate into your QMS

Some final thoughts

I hope that this review of the thinking behind each of the Seven Quality Management Principles in respect of ISO 9001:2015 has been interesting and the examples of what an ISO 2001:2015 auditor is looking to award certification against have been useful.

Just before I close off I would like to reflect on the following:

- The benefits of the changes to ISO 9001
- Choosing your ISO 9001 certification body

The benefits of the changes to ISO 9001

I was very pleased to be involved in the redrafting of the ISO 9001 standard and feel that a number of positive outcomes have been achieved in the latest version.

- The standard is now far more scalable. It applies equally to a micro-business as a global organisation. I think this is the biggest win.
- The focus on leadership is also a great improvement. If your senior management team doesn't support your quality management system, it is almost impossible to implement an effective system.
- There is far less opportunity to become ISO certified just for the badge on the wall. Your Quality Management System must be being properly utilised as a Business Management System in order to pass the audit. This is not good news for those organisations who have previously just ticked boxes to pass the audit, but for those organisations managing their businesses effectively and continually improving, ISO 9001:2015 certification is real recognition of the value being delivered.

Choosing your ISO 9001 auditor

It is important to remember that certifying bodies are a supplier. So apply the principles of ISO 9001 to choosing yours. If they don't deliver what you need - move on.

Your Quality Management System needs to work for your organisation. This means that it should be structured in a way that works for your organisation and use the language that works for your organisation too. Your auditor does not have the right to ask you to change this. Nor do they have the right to ask you for a single document to show clause-by-clause compliance with "clause XYZ".

It's all about the seven OMPs.

There is plenty of advice available about achieving ISO 9001:9015 - from the International Accreditation Forum, UKAS and the many consultants out there. Your certification body cannot deliver consultancy and in many cases you just won't need it - if you have an effective quality management system in place - you won't be far off achieving ISO 9001:2015 certification.

About the Author:

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