ISO 9001 : 2015

Your ultimate ISO 9001 certification checklist

Quality Management System Checklist

Kickstart your ISO 9001 certification journey with our handy checklist! This breaks down each key section giving you a clear roadmap of what to expect and what actions to take. Whether you're just starting or need to fine-tune your existing processes, our checklist will guide you step by step. Don't worry if you haven't got anything in place yet - we're here to provide you with templates, support and guidance throughout the certification process.

Context of the organisation

This means: understanding external and internal issues, as well as the needs and expectations of interested parties, and where you sit in all of this.

- ◯ We've thought about and set out the external and internal issues that are relevant to our organisation's vision, purpose and strategic direction.

- ◯ We've set out a way of reviewing and checking these issues as well as timescales for doing so.

- ◯ We understand which parties have an impact on the ISO 9001: 2015 Quality Management System, and the needs and expectations that they have.

- ◯ Our Quality Management System addresses the external and internal issues, the needs and expectations of all parties, as well as our strategic vision, objectives, products and services.

- ◯ We've carefully set out the processes, actions and requirements at each stage within our Quality Management System.

- ◯ We've also set out how each of these stages will be managed, who is responsible, how they need to action things and how success will be measured.

- ◯ We understand how to adjust our Quality Management System as the context of our organisation changes.

Leadership

This means: the role your top management will play in leading, not just managing, your Quality Management System and actions required during the certification process.

- ◯ Our top management understand the certification process and have taken responsibility for the effectiveness of our Quality Management System.

- ◯ Our Quality Management System is structured to reflect the strategic vision and priorities of our organisation. This has been communicated throughout the organisation so that everyone understands how it's relevant to overall success.

- ◯ We've got a framework for communicating our objectives clearly at all levels of the organisation – strategic, functional, departmental and individual.

- ◯ We're able to integrate the policies and procedures set out in the Quality Management System into our day-to-day way of working.

- ◯ Our managers understand the importance of communicating the processes set out in the Quality Management System and the role that risk-based thinking will play in our success.

- ◯ Throughout our organisation; customer, statutory and regulatory requirements are considered, set out, met and communicated.

Leadership

○ We've considered all of the possibilities that can affect whether our products and services deliver positive customer satisfaction.

○ We've considered both the risks and opportunities that exist within our own processes, taking the appropriate steps to act on these findings.

○ We've clearly set out who is responsible for making each part of the Quality Management System a success, as well as who is responsible for making decisions.

Planning

This means: evaluating success, measuring risks and opportunities and planning the steps needed to increase desirable effects, prevent unwanted effects and achieve improvements.

○ We've got a framework for identifying the risks and opportunities that affect our processes and the Quality Management System.

○ We've planned what we need to do to meet our quality objectives.

○ We've integrated the steps that need to be taken into our day-to-day practices and systems and not just treated them as 'one-off' tasks.

○ We've thought about the ways in which we might need to change the Quality Management System, over time, to make sure it stays effective.

Support

This means: making sure you have the resources and tools you need to run and continually improve your Quality Management System.

○ We understand what resources (people, infrastructure, working environment etc.) we need in order to establish, implement and maintain our Quality Management System.

○ We've also set out a plan for reviewing resources on a regular basis, to make sure we continue to provide sufficiently trained staff and the right equipment and materials to meet our customer's expectations.

○ We recognise that accurately measuring and monitoring the ways in which our products and services meet quality criteria and conformity requirements is important. So we've identified the resources required to provide valid, reliable results.

○ We've made sure that we have a good infrastructure in place so that conformance to the Management System Standard and legal compliance is met, both now and in the future.

○ We recognise the levels of understanding we need to make sure that our processes can work effectively, and our products/services conform to the expected criteria set out in our Quality Management System.

○ We've taken steps to make sure that the people impacting on our Quality Management System are appropriately trained or that training needs have been identified to help them achieve the required qualifications.

○ We've made sure that each person in our organisation understands how they can contribute to making this Quality Management System a success.

○ We've planned internal and external communications to make sure everyone knows about the Quality Management System.

○ We understand what documented information needs to be provided – both to satisfy the requirements of the Standard and to ensure the requirements continue to be implemented effectively.

Operation

This means: the steps you need to take to get going on your Quality Management System.

○ We've set out clear processes to make sure we produce products and deliver services that meet the requirements specified by the Standard.

○ Any changes that need to take place will be considered carefully, within the structure of our Quality Management System, and carried out in a way that will ensure continuing relevance and success.

○ We have a clearly defined process for communicating with customers (and gaining their feedback) in relation to all products, services, enquiries, contracts and order handling.

Operation

○ We start this communication process, with customers, before they actually 'contract' with us, so as to better understand their expectations.

○ We make sure all the processes, products and services we provide meet the requirements of the Standard.

○ We're committed to selecting, monitoring and evaluating external providers, using a clearly defined process.

○ We make sure that, when providing products and services, documentation is made available which sets out the characteristics and what we plan to achieve, and is made available to others.

○ Activities are monitored and measured, at appropriate stages, to ensure that agreed standards for processes, outputs and acceptance have been met and all people involved in the process have been proven to be competent.

○ We ensure the identification and traceability of whatever we produce/provide.

○ We make sure that any property belonging to customers or external providers, used during the provision of products or services, is controlled effectively.

○ We understand the importance of post-delivery activities and have set out clear steps for ensuring that these (e.g. warranty, maintenance, recycling, disposal etc) are understood and managed.

○ Should anything produced not conform to the standard expected, then we'll manage this to make sure that it's not used or delivered.

Performance Evaluation

This means: using your experience and knowledge to monitor, measure and analyse processes and changes, to consistently seek out ways to improve quality.

○ We understand what we need to monitor and measure and have set out the ways in which we'll do this, to get useful, valid results.

○ We've agreed when we need to analyse and evaluate these results.

○ We've set out the ways in which we will monitor customer perceptions and the ways in which their needs and expectations have been met.

○ We've agreed a formal structure for evaluating our Quality Management System, through an internal audit programme.

○ We'll agree any areas for potential improvement and development, within the Quality Management System, and how we will include these in management reviews.

○ We've set out a structure for management reviews and are committed to implementing it, to regularly monitor and evaluate the implementation of our Quality Management System.

Improvement

This means: using the results from your evaluation and analysis to identify ways to enhance the Quality Management System that serve to increase customer satisfaction.

○ We've identified areas for improvement that focus on meeting customer requirements and enhancing their satisfaction. We've also taken the steps necessary to put these changes into action.

○ We've got a process for managing the ways in which we do not conform to the Standard, and the steps we need to take to correct this.

○ We've agreed how we will prioritise the continual improvement of the suitability, adequacy and effectiveness of our Quality Management System.

Achieve certification in as little as 45 days

Want a simple route to ISO certification? You're in the right place. We've successfully implemented over 30,000 management systems across the UK and we're committed to helping organisations of any size, in any industry to become certified in the most straightforward and cost-effective way possible. That's why our clients benefit from a simple 3-stage certification process with free templates, support and access to our digital management system platform, Atlas.

If you would like to find out more about this Standard or how Citation ISO Certification can help your organisation to become certified, then get in touch today on 0333 344 3646.

Our top 10 tips for getting it right

It's no surprise that at some point in running your business, you'll hit a bump in one of your critical processes. That's why having the right procedures in place is key to minimising those risks and keeping things on track. Here's what you need to make sure your business is ready to handle anything...

1 **A documented system** – if you're not documenting all recordable processes and procedures within your organisation, you'll limit your ability to step back and take a good look at your day to day operations. This stops you from ironing out unwanted issues and improving efficiency throughout the product/service lifecycle.

2 **An error log** – errors could be repeatedly happening, but no one is bringing this to the attention of management because they don't see it as their job to do so. Logging non-conformances helps you to review and control them, stopping those little issues escalating into unhappy customers and lost business.

3 **A process for seeking customer feedback** – having customers is essential for the success of every business. Their needs should be important to you. It's easy to presume what your customers want, but with trends changing every day, knowing if these needs are being met will help you to improve your products/services, increasing repeat business, reducing errors and giving you a competitive advantage.

4 **A staff training register** – staff training is important for any business, it increases staff morale, provides you with a skilled workforce that are more competent at their jobs and a register can provide evidence of education and qualifications when required.

5 **A final inspection procedure** – knowing what you deliver and how you deliver it is valuable for any business. Carrying out inspections of the processes and procedures relating to the delivery of your services/products, at the end of the journey, can help you to spot things that you might want to do differently in future, helping you to streamline processes and reduce future costs.

6 **Regular process checks** – as well as final inspections, it's good practice for management to carry out regular checks during the service/product delivery process, making sure that everything is running efficiently and noting anything for review, that could be preventing you from achieving the desired outcome/goal.

7 **A documented procedure for design and development** – companies that are not responsible for design can claim exemption in this area. However, for those that are affected; it is important that you map out how design is undertaken, showing the stages of client involvement, because this helps to ensure a consistent delivery of service.

8 **Traceability in design and development records** – while mapping out how design is undertaken is valuable, it's important to ensure the steps that are being taken are logged along the way. Providing you with traceable records, should anything be questioned at a later stage.

9 **A procedure for calibration** – it's important that, where fine measurements and calibration are required, a procedure is in place to ensure this is carried out correctly. You should consider whether this is carried out in accordance with manufacturer's guidelines and any legal requirements which may apply, helping you to protect your reputation and avoid unnecessary fines.

10 **Staff induction records** – poorly trained staff can quickly lead to poorly delivered serviced/products. So it's vital that staff undergo a suitable induction process that will ensure your processes are adequately followed and the expected level of services maintained. It can also prove very useful should you be challenged on a staff dismissal, following staff incompetency.

Don't struggle alone, ISO 9001 can provide you with a framework to manage all of these areas and free up valuable management time.

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