The ISO 9001:2015 Transition
How am I tracking with the change?

Overview

This document acts as a checklist to help your business self-evaluate the compliance of its Quality Management System (QMS) with the requirements of the revised ISO 9001:2015. It is not an exhaustive checklist, rather it calls out some key factors that are addressed in the revised Standard and allows you to look at the various areas that your business may need to consider in order to prepare for your transition audit.

Context of the organisation

Has the scope of your organisation's QMS been determined with consideration to the organisation's products / services and justify where ISO 9001 cannot be applied?

Does this also consider 'interested parties'? (i.e. a person or organisation that can affect, be affected by, or perceive themselves to be affected by a decision or activity your organisation undertakes, such as customers, owners, staff, suppliers, partners, bankers, etc).

Have external and internal issues that will affect your organisation's purpose and strategic direction been determined? Examples of these issues include external legal, competitive or economic issues; internal culture, knowledge or process issues.

Do these issues consider any impacts to customer service, interested parties or products / services?

Have these been monitored and reviewed on an ongoing basis?

Leadership

Has top management established, reviewed and maintained a quality policy that is appropriate to the context of your organisation?

Has the quality policy been made available as documented information, applied within your organisation, and been made available to relevant interested parties as appropriate?

Has top management taken accountability for the effectiveness of the QMS and considered that it achieves its intended results?

Have they ensured that the QMS requirements are integrated into the organisation's business processes?

Have they also created awareness of the process approach; engaged, directed and supported person's that contribute to the system; and promoted continual improvement?

Have applicable statutory and regulatory requirements been determined, met and consistently maintained?

Have risks and opportunities that can affect your organisation's products / services been determined?

Do these risks and opportunities consider the ability to enhance customer satisfaction?

Have the organisational roles, responsibilities and authorities been established and do they ensure that your processes are being delivered as intended?

Planning for the QMS

Have the objectives of the QMS been established and do they consider the conformity of your organisations products /services and customer satisfaction?

Have these also been communicated, updated and monitored on an ongoing basis?

Do the objectives also determine what will be done, what resources are required, who will be responsible, when it will be completed and how the results will be evaluated?

Has the organisation planned actions to address the identified risks and opportunities and looked at how they can be integrated with the QMS?

Support

Have the capabilities of, and constraints on, existing internal and external resources been determined?

Have the appropriate people and processes been provided to effectively operate the QMS?

Have appropriate resources been allocated to ensure valid and reliable monitoring and measuring of results?

Has your organisation identified what, when, how and to whom internal and external communications relevant to the QMS need to occur?

Has your organisation determined the knowledge necessary for the operation of its processes and considered how this will be managed when addressing changing needs and trends?

Operation

Has your organisation established, implemented and maintained a process to determine the requirements for the products / services to be offered to customers (including statutory and regulatory requirements)?

Does this determine the process stages and controls needed for design and development activities?

Have these stages and controls considered the standards or codes of practice, the internal or external resources, the potential consequences of failures, or the level of control expected by customers and other interested parties?

Has your organisation determined the processes for communicating to customers in relation to:

Information relating to products / services

Enquiries, contracts, order handling

Obtaining customer feedback and complaints

Requirements for contingency actions when relevant

Has your organisation established the controls required for the provision of products / services from external providers (suppliers, outsourced parties, etc) in order to mitigate potential risks, consistently meet customer expectations and conform to statutory or regulatory requirements?

Do these controls consider the corrective action required in the event of a nonconformity and the level of impact this has on its products / services?

Performance Evaluation

Has your organisation determined what needs to be monitored and measured, and how and when these will be conducted?

Does this also consider the level of analysis and evaluation required to ensure the effectiveness of the QMS, including opportunities for improvement?

Has an audit programme that considers objectives, processes, customer feedback, potential changes and previous audit results been planned, established, implemented and maintained?

In the management review, has it been identified whether any trends or indicators have occurred in the following areas:

Nonconformities

Monitoring and measuring results

Issues raised with external providers and other interested parties

Adequacy of resources required for QMS maintenance

Does the review also include information on the performance of the QMS and any potential opportunities for continual improvement?

Improvement

Have opportunities for improvement (including the necessary actions required to meet and enhance customer satisfaction) been determined?

Has your organisation considered the performance evaluation results and identified and utilised applicable methodologies or tools in order to improve upon any underperformances?

Has your organisation identified how opportunities for improvement will be addressed in order to continually improve upon the QMS?

Other Resources

We have a number of useful resources to help you learn more about and keep up with the changes as you transition over to ISO 9001:2015:

- **Purchase the Standard here**
- **Attend Quality Management Systems Training**
- **Read ISO 9001:2015 - What are the changes?**
- **Read ISO 9001:2015 - What does it mean for me?**

About Telarc

Over the last 40 years Telarc has provided expert assessment and certification for New Zealand businesses.

With offices in Auckland, Tauranga and Christchurch and key personnel based in Wellington and Dunedin, our insight and oversight remain in high demand across the country.

With a team of over thirty talented professionals we provide auditing services that focus as much on business improvement as they do standard compliance. We work in many different sectors and offer a multi-disciplinary approach to our clients, ensuring the standard they receive is appropriate, effective and reflects performance.

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