ISO9001:2015 Overview and Guidance

Introduction

ISO9001:2015 is the most recognised international quality standard in the world and is adopted by thousands of organisations. Many companies use ISO9001:2015 as a framework for ensuring quality within their organisation and they also may achieve certification to show customers and other interested parties that they are meeting the requirements of this standard.

The standard promotes the framework known as **Plan-Do-Check-Act** which should guide the general approach companies take to ensure compliance. Although this concept isn't a specific clause within the standard, it guides the general way of thinking when operating ISO-compliant management systems.

The standard includes a number of clauses based around the general principles outlined in the standard chich include:

- **Customer Focus** – ensuring customers are appreciated and treated well is of great importance
- **Leadership –** company management are fully committed to the principles detailed in our quality policy and QMS
- **Engagement of People** – we actively welcome and have processes in place to engage with all relevant interested parties
- **Process Approach** – we take a process approach when planning and managing our operations to ensure consistency
- **Improvement –** we are committed to continual improvement of our quality management system and to achieve our quality objectives
- **Evidence-based decision making** – we make critical decisions for our business based on objective evidence
- **Relationship Management –** we are committed to ensuring our relationships with all interested parties are maintained and positive

There is no requirement to prepare documentation relating to every clause in the standard or procedures based these principles, in fact there is nothing in the standard that states you need to

have a documented quality manual. There are some documentation requirements however, you'll need to have a quality policy and various records and the standard should be reviewed or a documentation checklist completed to ensure all documentation requirements have been met.

Although there is no requirement to have a documented management systems it's a good idea to prepare documentation that provides an overview of key processes relating to quality. This documentation is useful in helping everyone within the organisation to understand and follow the key processes and will also help with the audit as it can be presented to the auditor.

ISO 9001:2015 Certification Audit

During an audit – the auditor(s) will be looking for objective evidence that each clause in the standard has been met and complied with.

The Clauses from 4 to 10 in the standard will all be reviewed for compliance bit it is also possible to state that some clauses such as the clauses relating to measuring equipment or design are 'Not Applicable' and will not require any review. These exclusions should be documented with a justification for their exclusion.

As well as reviewing all the relevant clauses there are various other things you can prepare and have in place prior to the audit:

- Completed and up-to-date management review
- Internal audit records
- Evidence of customer feedback
- Some examples of continual improvement
- Any calibration records available
- Evidence of compliance with applicable regulations
- System for logging and tracking any issues that arise within the business

Presenting evidence during the audit

For guidance on the audit process and how to prepare for the audit and an overview of the audit plan and the certification audit process please review the **Certification Audit Guidance** which is available **online here**.

In an audit involving a site visit, the auditor will likely just view evidence in person, whilst asking questions, a site tour may also be conducted. For remote audits it is often requested that photographs / videos are submitted as evidence.

Further support

- Management system documentation & resources: **isomanaged.com/alphazdocuments**

- Remote support: **isomanaged.com/iso-consultancy-support**
- ISO Consultancy: **isoassured.co.uk/iso-consultancy**