

Our guide to 'Documented Information' for ISO 9001:2015

Documented information doesn't mean paper-based systems. It includes databases such as accounting, CRM and cloud-based business records. It includes photos, forms and other records, together with traditional paper records.

To achieve ISO 9001:2015 accreditation, as well as the processes described in the standard, you'll need to have 'documented information' available for all of the following items.

Here's a checklist you may find useful.

However **before you skip straight to this**, please buy and read the standard! **You'll find it's probably easier than you expected.**

- **scope of management system** (referring back to the external and internal issues affecting the business comma and the requirements of relevant interested parties comma and the products and services of the organisation) (4.3)
- **documented information to support the operation of your processes** and to give **confidence that processes are being carried out as planned** (4.4.2)
- a **quality policy** which is appropriate to the purpose and context of the organisation and supports in strategic direction, provides a framework for setting quality objectives, includes a commitments to satisfy applicable requirements, and a commitment to continual improvement of the quality management system (5.2.2)
- **quality objectives** (6.2.1)
- where calibration or verification is required and there is no international or national measurement standards record the **basis used for calibration or verification** (7.1.5.2)
- **evidence of competence** (appropriate education, training or experience) (7.2)
- documented information required by the standard and determined by the organisation as necessary For the effectiveness of the quality management system (7.5.1)
- documented information necessary to have confidence that the operational planning and control **process has been carried out as planned** and to demonstrate the **conformity of products and services to the requirements** (8.1)
- the **results of the review of requirements for products and services**, and **any new requirements** for the product and services (8.2.3.2)
- design and development requirements have been met (8.3.2) including
 - **inputs** (8.3.3),
 - **controls** (8.3.4)

- **outputs** (8.3.5)
- **changes / results of reviews / authorisation of changes / actions taken to prevent adverse impacts** (8.3.6)
- **evaluation, selection, monitoring of performance and re-evaluation of external providers** (8.4.1)
- the **characteristics** of products to be produced, the services to be provided or the activities to be performed and the **results to be achieved** (8.5.1)
- documented information necessary **to enable traceability where required** (8.5.2)
- information about **any loss damage or other unsuitability of customer or external provider property** (8.5.3)
- **results of review of changes, the person authorising and any necessary actions arising from the review** (8.5.6)
- **release of products and services**, including evidence of conformity and traceability to the persons authorising release (8.6)
- documented information describing any **nonconformity**, actions taken, concessions obtained, and identifying the authority deciding the action in respect of the non-conformity (8.7)
- evidence of **evaluation** of the performance and effectiveness **of the quality management system** (9.1)
- evidence of **implementation of the internal audit programme** and the **audit results** (9.2.2)
- **results of management review**, which should have taken into consideration:
 - status of actions from previous reviews,
 - changes in external / internal issues relevant to the business,
 - information on performance / effectiveness of the management system, including trends in customer satisfaction, feedback from relevant parties, extent to which quality objectives met, process performance and conformity of products / services, nonconformities and corrective actions, monitoring and measurement results, audit results, the performance of external providers;
 - adequacy of resources,
 - effectiveness of actions taken to address risks and opportunities,
 - opportunities for improvement (9.3.3)
- **nonconformities** and any subsequent actions taken, results of any corrective action (10.2.2)

Notice that we referred to the relevant clause in the ISO 9001:2015 standard?

By keeping track of how your processes help you to meet the standard, you'll know which clause of the standard to check when you change your processes (which of course, you will as you improve them), and which processes to check if the standard is revised.