

What is meant by Support?

The clause relating to support gives guidance as to how the management system should be supported to enable it to run efficiently.

Support predominately focuses on your resources such as the people, infrastructure, and work environment.

Your QMS must include mandatory documentation required as well as what is necessary for you as a business.

Documented information required by the Standard (dependent on business offering all may not apply)	
Documented information	Clause
Context and scope (within manual)	4
Objectives and plans how to achieve them	6.2
Record of maintenance and calibration of monitoring and measuring equipment	7.1, 5.1

Competence records	7.2
Product/service requirements review record (contract review)	8.2.3.2
Design and development inputs record	8.3.3
Record of design and development controls	8.3.4
Design and Development outputs record	8.3.5
Record of Design and Development changes	8.3.6
Record of evaluation of external provider (supplier/sub-contractors)	8.4.1
Record of product/service characteristics (contracts, website, tenders, quotations)	8.5.1
Identification and traceability (CRM system, contracts, procurement, batch sampling)	8.5.2
Record of adverse issues to external providers'/customer's property	8.5.3
Record of changes in production/service provision (re-quotations)	8.5.6
Evidence of release of product/service (sign off)	8.6
Evidence of nonconforming outputs (product or service) and non- conformity/corrective action (complaints, procedural, suppliers letting you down) etc)	8.7.2/10.2.2/10.1
Performance evaluation information (KPI's, SLA's, customer feedback, staff performance, status of objectives)	9.1./1
Internal audit programme and results	9.2.2
Management review results (minutes)	9.3

How to Comply with Support

People, Competence, Awareness and Organisational Knowledge

Do you have the right people with the necessary skills in the appropriate roles? If not, how will you address this? Will you recruit or outsource the work? If you outsource, how will you communicate your requirements to your supplier/partner?

How confident are you that your staff have the right knowledge and skills to enable them to fulfil their job requirement?

View competence as a process from recruitment, induction, appraisal, and training needs analysis. Records of competence should be maintained and can include a skills matrix and individual training records.

Ensuring staff are also aware as to what they can and can't do is also part of this requirement. Policies, procedures, staff or employee handbook and a health and safety handbook would facilitate this.

The sharing of organisational knowledge should be considered to ensure that not all knowledge is vested in one individual. This could put the organisation at risk should that person no longer be involved within the business. Also, knowledge or expanding knowledge is key to personal development as well.

Infrastructure

Infrastructure is made up of; the building(s), office space, computers, desks, and software.

Each of these resources must be fit for purpose and it is up to top management to ensure they are sufficient for employees to complete their required tasks and duties. In addition, software licenses must be kept up-to-date, and it is critical that all data is backed up to ensure it can be retrieved.

Infrastructure also includes IT, HR and Health and Safety which may be conducted inhouse or outsourced.

Environment

Are you providing an environment that is suitable for what you are trying to achieve? Do you have the right atmosphere to enable your team to operate effectively? This means looking at temperature, lighting, airflow, hygiene, noise levels etc.

This can also include employee wellbeing, stress-reduction, appraisals, and a rewards scheme.

By law, you are expected to comply with several laws and regulations in regard to your premises and employees. Regarding health and safety laws, to demonstrate compliance to the standard, it is not enough to just 'do them' but you need to record how you are compliant. If any failures or patterns emerge, these need to be monitored by the relevant person(s) to ensure any problems are solved.

Monitoring and Measuring

The accuracy (calibration) of monitoring and measuring equipment if used and which is critical to your service delivery with records kept.

Documented Information

The term 'documented information' refers to any written document, either hard or soft copy, which is required by the <u>ISO 9001</u> standard or by the business' operations and activities. However, it also includes software and external documentation.

It is imperative that only approved documents are used throughout the organisation to ensure consistency. Should a document require an amendment or improvement, or if a new document needs to be created, the procedure below **should** be followed:



Important Note: All documented information must also be protected against a) unauthorised access or amendment b) virus or corruption. In addition, it must be backed up and stored in a way which is easily retrievable. Finally, the retention period of documented information shall be identified in line with statutory, regulatory or company practice and recorded.

It is critical all documentation, data and records are backed up. This will allow them to be retrieved in an emergency or if they are accidently lost or deleted.

It is also important to put in place certain access restrictions to ensure confidential or sensitive information is only accessible to authorised personnel.

Remember These Key Elements:



Next Steps:

- 1. Set up a quality team
- 2. Check all the above are being undertaken
- 3. Review all policies, procedures, and standard form templates to make sure they are fit for purpose and required, obsoleting/archiving those no longer required
- 4. Ensure all the above are referenced, in a format so that they cannot be amended other than approved personnel
- 5. Make sure they are in a central repository and staff know how to access them
- 6. Ensure they are reviewed annually