Episode Consultants Ltd
95 Gateland Lane
Shadwell, Leeds LS17 8LW

0113 801 9001
info@episodeltd.com
www.episodeltd.com

episode
RAISING THE STANDARD

Guide to ISO system documentation

When establishing a useful management system inevitably there is a need to document things. It is all too easy to over-engineer a system to play it safe, which whilst it might satisfy an auditor, makes its daily use less practical.

In this guide we begin to try to explain how best to use documents in a system.

The Relationship Between Processes, Procedures and Work Instructions

When a company documents its ISO based management system, it is an effective practice to clearly and concisely identify their ***processes***, ***procedures*** and ***work instructions*** in order to explain and control how it meets the requirements of ISO standard. This begins with a basic understanding of the hierarchy of these terms and how to efficiently categorize the workings of a management system within them. Simply put:

- A **process** states *what* needs to be done and why
- A **procedure** states *how* the *process* needs to be done
- A **work instruction** explains *how* to carry out the *procedure*.

Consider a process as a high level, strategic method of control, in effect a summary of objectives, specifications and broad resources needed. The procedure adds more specifics such as responsibilities, specific tools, methods and measurement. A work instruction is a step-by-step guideline to implement the process and procedure, often segmented in some way to focus those who are doing the actual work.

Many companies go overboard with documentation in the belief that they need to document every single process that is in place in their organization, without realizing that this is not necessary to meet the requirements of ISO standards. For example, with ISO 9001:2015, quality manual systems, only six documented procedures are mandatory, with any remaining procedure documentation at the discretion of the company (under certain guidelines). So, you may ask, “What should I document?” This is how we go about approaching the question.

What documentation does ISO 9001:2015 Require?

Require and need can be two different things. See the mandatory documents & records list below. Our starting point is always what do you need operationally?:

The “A” pile, “B” pile principle

Simply put, we ask our clients to forget about ISO compliance and focus on what they need ***operationally*** – the A Pile. We then work through the B pile (what is out of date – you’ll have some like this; what you think you need to comply – you’ll have some of these as well) and ruthlessly throw away what is not needed or of any use (typically most, if not all of the B Pile).

Some recommendations

Quality Manual: The ISO 9001 Quality Management System does **NOT** require a Quality Manual to be written. Nowhere in the standard (or any published since 2012) does it say a manual is mandatory. However, we can’t see a better way of capturing the essential information staff need to understand How the business works.

We think of this as the **Quality handbook** for the business. This document is the backbone of the Management System, and is where you announce your intentions. What does your company do, and are there any parts of the ISO 9001 standard that you are not doing (such as Design)? What documented procedures have you created to govern the Quality Management System? How do your company processes, both documented and not documented, interact to form your Quality system? This is often the document where the company records the Quality Policy and Objectives, and sometimes adds the company’s Mission and/or Vision Statement. Learn more in this article Writing a short Quality Manual.

As with this manual, there are ***NO mandatory requirements*** for documented procedures. However, in our experience the following are needed for an effective system:

Control of Documents: How do you approve, update and re-approve your documents? When a document is changed, how do you identify changes and make sure that people who need the current document have it and stop using older documents? How do you make sure the documents can be read and how do you control documents that come from outside of your organization for use?

Control of Records: How do you maintain your records that show your product is acceptable to use, including how you identify, store and protect the records so that they can be retrieved as necessary, for the correct amount of time, and destroyed when no longer needed – but not before?

Internal Audit: How do you audit your Quality Management System to make sure that it is performing as planned and is effective? Who is responsible for planning and carrying out the audits? How do you report results and what records are kept? How do you follow up on Corrective Actions noted in Audits?

Control of Non-Conforming Products (where a physical product is made): What controls are in place, and who is responsible, to make sure that a non-conforming product is not used? Are there terms that can be put in place to allow the use of non-conforming product such as Rework, Repair or Acceptance by Customer? How do you ensure that a corrected product is re-verified, and what records are kept of the process?

Corrective and preventative Actions: How do you review non-conformities, determine causes, and evaluate the need for actions to correct them? How do you implement the necessary actions, review that the actions were effective, and keep records of the actions taken?

At a minimum, these are the documented procedures that we feel are necessary to meet the requirements and are all that is needed to document a simple Quality Management System. However, there is often a need to provide more written documents (see clause 4.4.2

"To the extent necessary, the organization shall:

a) *maintain documented information to support the operation of its processes;*
b) *retain documented information to have confidence that the processes are being carried out as planned.".*

The trick is in knowing what else your company needs to document (see also Deciding which procedures to document in QMS).

What are other common Documented Procedures?

At this point you do not need to capture any other processes in documented procedures if you can prove that no mistakes will be made by not doing so. There are several procedures that are often documented in order to ensure that there is easy access to some important information to govern that process. Some examples are:

Purchasing: What information is needed for a supplier, and who is responsible for generating it? Who needs to approve various levels of expense (you may not want a buyer to be responsible for committing the company to pay for large purchases without other approvals)? How do you decide on the standard requirements to place on your suppliers, and how do you approve and control these suppliers?

Design: This is often turned into a documented procedure in order to capture what gates and reviews are required to ensure a good design every time. Where do all of your requirements come from? Who can approve a design to proceed? How do you control your design changes, and who can approve a change to the design?

Production/Service: For complicated products or services, it is easy to see why the process would be documented. How do you control the flow of parts and documentation to your production area for use? How do you track your service from customer order to completion to ensure customer requirements are met? How do you ensure that product status can be identified, such as what has or has not been tested? How do you track customer acceptance of your service?

Monitoring and Measurement: How do you control the equipment you use to test that your product meets the requirements and is fit for use? How do you manage measurement equipment brought in by employees (such as machinist's tools that are owned by the machinist)?

The importance of documentation in the QMS

Documentation in the Quality Management System is important to ensure that critical processes, where you need to make sure that all employees consistently do the same thing, are understood and repeatable. In order to make this work, it is wise to have these processes as uncomplicated as possible and presented in the simplest manner to make them easy to understand. Often, using a graphical flow chart can suffice to relay all the relevant information quickly and easily. The less complicated the process documentation, the easier it will be to ensure that all employees can deliver repeatable, quality outcomes for the processes. In the long run, the old adage is often right: "The simpler, the better."

Mandatory and Non-Mandatory Documentation:

As per our detailed research and work experience, here are the mandatory records (note that records marked with * are only mandatory in cases when the relevant clause is not excluded):

Mandatory documents and records:

- Scope of the system (clause 4.3)
- Operational process information (NB "to the extent necessary – i.e. you decide what is needed – see clause 8.5.1) (clause 4.4.2)
- Quality Policy (clause 5.2.2 (a))
- Quality objectives (clause 6.2.1)
- Monitoring and measuring equipment resources - records (clause 7.1.5.1)
- Measurement traceability (*) (clause 7.1.5.2)
- Records of training, skills, experience and qualifications (clause 7.2)
- Product/service requirements review records (clause 8.2.3.2)
- Record about design and development outputs review* (clause 8.3.2)
- Records about design and development inputs* (clause 8.3.3)
- Records of design and development controls* (clause 8.3.4)
- Records of design and development outputs *(clause 8.3.5)
- Design and development changes records* (clause 8.3.6)
- Characteristics of product to be produced and service to be provided (clause 8.5.1)
- Records about customer property (clause 8.5.3)
- Production/service provision change control records (clause 8.5.6)
- Record of conformity of product/service with acceptance criteria for release to customers (clause 8.6)
- Record of nonconforming outputs (clause 8.7.2)
- Monitoring and measurement results (clause 9.1.1)
- Internal audit program (clause 9.2)
- Results of internal audits (clause 9.2)
- Results of the management review (clause 9.3)
- Results of corrective actions (clause 10.1)

(*) Where you have NOT said Design is not applicable.

Non-mandatory documents

There are numerous non-mandatory documents that can be used for ISO 9001 implementation. However, we find these non-mandatory documents to be most commonly used:

- Procedure for determining context of the organization and interested parties & documents noting the findings (clauses 4.1 and 4.2)
- Procedure for addressing risks and opportunities & documents noting the findings (clause 6.1)
- Procedure for equipment maintenance and measuring equipment & (clause 7.1.5)
- Procedure for document and record control (clause 7.5)
- Sales procedure (clause 8.2)
- Procedure for design and development (clause 8.3)
- Procedure for production and service provision (clause 8.5)
- Warehousing procedure (clause 8.5.4)
- Procedure for management of nonconformities and corrective actions (clauses 8.7 and 10.2)

- Procedure for monitoring customer satisfaction (clause 9.1.2)
- Procedure for internal audit (clause 9.2)
- Procedure for management review (clause 9.3)