

## The problem

Which processes according to ISO 9001 must be documented, and what does documented mean? If one of these procedures is not written/documented would this be a major or minor nonconformance?

## Over to the expert

ISO 9001 states that something 'shall be defined in a documented procedure' or 'a documented procedure shall be established' six times throughout the standard, in areas referring to:

- control of documents
- control of records
- internal audits
- control of nonconforming products
- corrective action
- preventive action

To summarise, ISO 9000 and dictionary definitions, 'documentation' simply means 'written information'. Within the standard there is a note for section 4.2.1 that states: 'The documentation can be in any form or type of medium.'

So, there needs to be written information defining an organisation's processes in the six areas listed above but the format is only limited by imagination and usefulness. It should be noted that while these are the only sections where the standard uses the term 'documented procedure,' it is unlikely that an effectively implemented system will consist only of documents covering these six areas.

Procedures written as narrative on paper have long been used to inform employees of an organisation's policy and procedures and are still a popular method today.

Likewise, hard copies of a process in the form of flow charts or process maps provided to employees or displayed on notice boards, can supply clear evidence that an organisation has documented its procedures. Alternatives such as intranets or e-learning packages are also popular and can be very effectively used to demonstrate that processes are defined within documented procedures. They can be a useful depository for narrative, as well as providing

endless opportunities to display written information by way of diagrams, interactive presentations and exhibits.

ISO 9000 does not state that these six procedures have to be stand-alone documents. An organisation may decide that it fits with their operating practice to call a document 'control of records procedure'. However 'control of nonconforming product procedure' might confuse staff at a call centre, for example, as the terminology means nothing to them. Instead they may choose to document their procedure within text describing the call-handling or call-monitoring processes. Likewise, a consultancy firm may be able to document its preventive action process within a planning or project control procedure much more effectively than in a document entitled 'preventive action procedure'.

It is very clearly stated within the standard that documented procedures must cover the six defined areas. Again, a note within section 4.2.1 of the requirements enhances our understanding by stating: 'Where the term 'documented procedure' appears this means that the procedure is established, documented, implemented and maintained'.

So if an auditor is unable to verify that there is written information detailing the organisation's processes in these areas then a major non-conformance would need to be raised, as the requirements of the standard are not being adhered to.

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