Mandatory Documents and Records
ISO 9001:2015

It is easy to assume that every single process that is in place to support your quality management system needs to be documented, but that is not the case if the objective is only to meet the requirements of ISO 9001.

The standard refers to multiple mandatory processes, but these are not necessarily required to be documented procedures. Also identified are many records that need to be maintained, which should be generated by the processes that make up your quality management system.

Mandatory Documents:

- Scope of the QMS; 4.3
- Quality policy; 5.2
- Quality objectives; 6.2
- Criteria for evaluation and selection of suppliers; 8.4.1

Mandatory Records:

And, here are the mandatory records (note that records marked with * are only mandatory in cases when the relevant clause is not excluded):

- Monitoring and measuring equipment calibration records*; 7.1.5.1
- Records of training, skills, experience and qualifications; 7.2
- Product/service requirements review records; 8.2.3.2
- Record about design and development outputs review*; 8.3.2
- Records about design and development inputs*; 8.3.3
- Records of design and development controls*; 8.3.4
- Records of design and development outputs*; 8.3.5
- Design and development changes records*; 8.3.6
- Characteristics of product to be produced and service to be provided; 8.5.1
- Records about customer property; 8.5.3
- Production/service provision change control records; 8.5.6
- Record of conformity of product/service with acceptance criteria; 8.6
- Record of nonconforming outputs; 8.7.2
- Monitoring and measurement results; 9.1.1
- Internal audit programme; 9.2

- Results of internal audits; 9.2
- Results of the management review; 9.3
- Results of corrective actions; 10.1

These are the documents and records that are required to be maintained for the ISO 9001 quality management system. However, you should also maintain any other records that you have identified as necessary to ensure your management system can function, be maintained, and improve over time.

Additional Documentation:

However, all 'real world' systems require more than these minimum mandatory requirements to ensure a robust and reliable system. There are several additional documented procedures which are commonly employed to ensure a robust and reliable system, including:

- Determining the quality context of the organisation; 4.1, 4.2
- Procedure for competence, training and awareness; 7.2, 7.3
- Procedure for control of documents and records; 7.5
- Procedure for monitoring and measurement; 4.5.1
- Procedure for internal audit; 9.2
- Procedure for non-conformity and corrective action; 10.2

To determine what additional documentation you require, it is often just enough to ask yourself the question; do we need a documented procedure to ensure consistency between employees?

A good maxim to follow is that simple documentation is more effective than complicated documentation, in ensuring that all employees can deliver repeatable outcomes. And don't forget, procedures can be written, in the form of a flowchart, use pictures etc. – choose the most effective!