

The 10 most impactful changes in the transition from ISO 9001:2008 to ISO 9001:2015

1. **10 Elements** - The standard has been completely renumbered from an 8 element based system to a 10 element based system. You DO NOT have to renumber your Quality Management System, but if it doesn't put too much of a hardship on your company's resources, it is recommended to renumber your system in order to help your personnel be able to better relate to the new standard.
2. **Context of the Organization** – The new standard wants you to be able to demonstrate that management has a deep understanding of their company's internal and external issues, for example: strengths, weaknesses, opportunities and threats. Companies are expected to monitor these on an ongoing basis.
3. **Quality Management System and Its Processes** – This section requires an organization to demonstrate they fully understand their processes (Inputs, Outputs, Performance Indicators/Metrics). Process diagrams are one way of achieving this.
4. **Interests of External Parties** – Companies need to document a general description of who their external interested parties are. Examples would be Customers, Regulatory Authorities, Mother Corporations, Stock Holders, other.
5. **Objective Programs** – Now, instead of only having to have an action planned defined when you are not meeting an objective in order to correct it, you must have a plan for each objective which describes: what will be done; what resources will be required; who will be responsible; when it will be completed; how the results will be evaluated. We commonly refer to this as having a documented objective program.
6. **Risk Based Thinking** – Companies must show that they are assessing risk and opportunities and taking actions to mitigate risks and can include taking risk to pursue an opportunity. The results of these activities must be discussed in Management Review.
7. **Management Review** – Management Review has several new input requirements including: the performance of external providers; the adequacy of resources; the effectiveness of actions taken to address risks and opportunities. Also, action items from management review must be considered for inclusion in the continual improvement process.
8. **Organizational Knowledge** – The new wording lends itself towards having a Matrix or Database that shows a company has determined what knowledge/training is necessary for its personnel and also pushes companies further towards having Job Descriptions.
9. **Communication** – Companies must determine requirements for internal and external communication including a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.
10. **Change Management** – There is more of an emphasis throughout the standard on controlling changes to the QMS, its processes, planning, production, contracts, etc.