

Benefits Using ISO 9001 Process Approach

The authors of ISO 9001 and 9004 must have had similar cases and realized that the eight principles are necessary to deliver the product on time and meet the customer's expectations.

ISO 9001:2008 and latest ISO 9001:2015 will definitely help if you give the Quality Management System a chance to follow the requirements and use the continuous improvement guidelines.

What documented procedures and documents are ISO 9001:2008 compulsory?

ISO 9001:2008 requires documented procedures for:

- control of documents (ISO 9001:2008, para. 4.2.3)
- control of quality records (ISO 9001:2008, para. 4.2.4)
- internal audits (ISO 9001:2008, para. 8.2.2)
- control of nonconformity (ISO 9001:2008, para. 8.3)
- corrective action (ISO 9001:2008, para. 8.5.2)
- preventive action (ISO 9001:2008, para. 8.5.3)

What are the 8 principles in the new ISO 9000:2008?

- Principle 1 - customer-focused organization
- Principle 2 - leadership
- Principle 3 - involvement of people
- Principle 4 - process approach
- Principle 5 - system approach to management
- Principle 6 - continual improvement
- Principle 7 - factual approach (analysis/data)
- Principle 8 - mutually supplier relationships

What are the 7 principles in the new ISO 9000:2015?

- Principle 1 - customer-focused
- Principle 2 - leadership
- Principle 3 - engagement of people
- Principle 4 - process approach
- Principle 5 - improvement
- Principle 6 – Evidence-based decision making
- Principle 7 – relationship management

The key to getting a design through concept, functional partitioning, and development is to have a proven process documented and continuously checked for process improvement. That's where the time-to-market has real value.

Case in point:

I was having a hard time understanding why a particular business was late in their life cycle for releasing custom module specifications. I had many people who wanted to control the process, which made the first of many revisions look very busy. It took 12 revisions over a period of six months before the process was cut down to a workable and time-proven success.

Once the process was in place, constructive comments from the designers resulted in making the release process even better.