

## Challenges of Implementing Revised ISO: 9001: 2000

*by Sunil Thawani*

Third revision of the quality management system (QMS) standard released in December 2000 by ISO: International Organisation for Standardisation (ISO), Geneva. Based on the market survey and feedback, Technical Committee TC-176, responsible for reviewing it have made major changes in terms of philosophy, principles, content, structure, adopting Dr. Deming's' PDCA cycle (Plan, Do, Check, Act), reduced emphasis for documentation and so on. It will have far-reaching impact on all parties involved - organizations implementing QMS, certifying bodies & QMS consultants. ISO has provided a 3-year time frame for organisations to change over from ISO: 9001: 1994 to 9001: 2000.

Purpose of this article is to share some of the key changes and the challenges experienced by users.

**# 1) Top management commitment:** ISO: 9001 is a system standard. Though there are many definitions of system, let us try to interpret it from Dr. Deming's point of view. He defines it as " A network of independent components (read processes & resources) that work together to try to accomplish the aim of the system. System must create something of value (read results – products/ services wanted by customer)".

System has to be managed. It will not manage itself. That's where the role of top management comes in. In contrast to earlier experiences of delegating the " ownership " of the QMS to Quality Managers or ISO Coordinators, the standard requires top management to take ownership of the QMS and be responsible for it.

The challenge is to get the " uninterested and reluctant " top management believe in QMS and be responsible for it.

**# 2) Aims of QMS:** A system must have an aim (read Objectives). Without an aim there is no system. Market motivation and obtaining the certificate has so far been the most common aim of many organisations. Nothing wrong with it if in addition the intent is also to establish a system to manage and improve the business. Improved market share would be the likely by-product.

Aim of the system can be established if the top management is clear in its vision and purpose – now and in near future. The challenge here is to have clarity of purpose in a continually changing environment and establish appropriate quality policy and quality objectives. Since the aim of the system must be clear to everyone in the organisation, policy and objectives need to be cascaded at all the relevant levels. Objectives need to be **Specific, Measurable, Achievable, Relevant & Time based.**

It would be preferred if the quality policy and objectives are aligned with process measures. All the three need to be one coherent whole. Perhaps the following example may add to the clarity:

- ⇒ Quality policy states – Delight customers;
- ⇒ In line with quality policy, objective can be “ *Reduce customer order delivery time by 25 % from the current level in 1 year time*”;
- ⇒ In line with the quality objective, process measure can be to measure “ *lead time from receipt of customers order to delivery of products at customer premises in days*” and reported every month by the Sales Manager i.e. the Objectives’ Owner.

Organisations will need to establish a system of measuring, reporting, reviewing & updating the policy and objectives in line with the continually changing business needs.

**# 3) Process orientation:** Everything in life is a process. Process is an action (verb) ending with “ing” e.g. melting, assembling, bending, packing, painting or driving. Standard requires business be managed as a set of processes. Sounds easy. Isn’t it? Lets’ give a second look within our organisation. Many of us believe and claim we understand process management and are managing our processes well. But when we get down to the nuts and bolts of mapping – we will find processes are “ orphans “ i.e. there are no process owners who have authority to get the work done across departments and make a firm commitment to customers, vendor or others.

High-level business processes need to demonstrate the interaction among various processes depicting how the work is obtained, processed and delivered. It will provide a “ helicopter view of the business. At a second level processes need to get into details clearly identifying process inputs, outputs, measures and control points. Refer figure – 1.

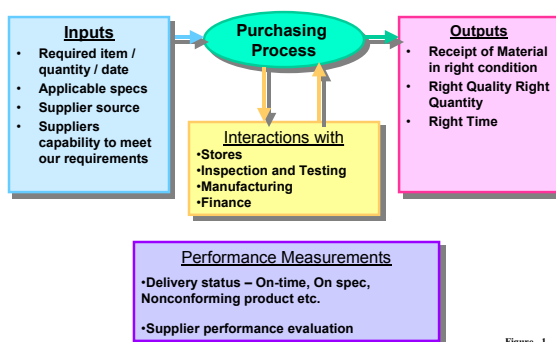


Figure - 1

Organisations which documented their QMS clause wise i.e. 4.1 to 4.20 of 9001: 1994, have a major challenge of mapping processes by not only bringing relevant functions together, but resolving inter departmental issues.

During the process mapping sessions, it is not uncommon to hear our colleagues telling us that “ I also do this and why haven’t you included in the process map”. It is a symptom of functional/ tasks mind set.

Challenge here is to break the years of functional silo working methods and gradually develop a mind set of process orientation and start managing the business as a set of interacting processes, rather than managing departments. It can even affect the organisation structure.

**# 4) Resource Management** – It is the “shortest” and overwhelming clause with an organisation wide implication. It requires organisation to determine & provide resources for maintaining & continually improving the effectiveness of QMS & customer satisfaction.

In this revision, requirement for resource management is limited to:

- Competence of personnel,
- Infrastructure and
- Work environment.

**Competence of personnel:** Competency, as defined by the standard is “ the demonstrated ability to apply knowledge and skills “. It is not uncommon to come across situations like - Trained but not competent and Competent but not trained.

Apart from individual competency skills for a position, competency can also be for problem solving skills in a team environment, conducting and managing meetings etc. required to improve the process/ product etc.

To evaluate effectiveness of training, currently most organisations collect feedback on course content, duration of course, faculty knowledge, etc. at the end of the program. Such evaluations provide feedback to trainers rather than what participants learnt. In other words, training evaluations won’t truly capture whether the training was effective and it should not be used as the only means to determine effectiveness.

Organisations will have to adopt other means to determine the competency needs of various positions/ families of positions like developing Job Descriptions, Skill matrices, use of checklists for specific jobs and so on.

Shift from meeting training requirements to developing competence in the organisations is quite a significant challenge and new addition in the standard.

**Infrastructure and Work Environment:** Because of the vague and broad nature of the requirements of infrastructure (technologies, communication/ Information management, transportation services, equipments etc.) and work environment (safety, heat, humidity, light, housekeeping, noise, pollution, employee involvement, creativity, recognition programs etc.), organisation will have to be clear about the resources needed to achieve product conformity.

In addition, organisations and Auditors could have different opinions on how this element should be addressed and assessed. Auditors will need to be flexible when reviewing this requirement.

Analysis of defects, rework, customer complaints, inspection results, vendor performance, warranty claims, audit findings, customer surveys, delivery performance etc. will provide valuable input to resource requirement. Being a “ new “ requirement in this revision, till now most organisations may neither have the experience nor would have established a system of addressing resource needs addressing above issues.

It is to be seen how organisation address the requirements of resources and its impact on the effectiveness of QMS.

**# 5) Continual Improvement** - Measurement, analysis and improvement clause requires organisations to demonstrate evidence of continual improvement. This would require data to be collected and analyzed using appropriate statistical techniques like Check sheets, Pareto, Cause & Effect, and Design of Experiments etc. It is sad to say that such useful techniques were conveniently identified as “ not applicable “ by most organisations and “ ignored “ by consultants and certifying agencies in the past.

Managements, used to managing work by opinions, will need to shift from opinion-based management to data (fact) based management. Data analysis is to be used to take operating and strategic decisions like evaluating resource requirements, increasing customer satisfaction, productivity, reducing defects, product/ services failures, monitoring product and process characteristics etc. Organisations will need to invest in training employees in data based analytical and management techniques.

**# 6) Process based audits:** Management Representatives will now have to schedule internal quality audits of procedures/ work instructions belonging to a process rather than distributing procedures of the same process to different Auditors. With process based audits, Auditors should now be able to use “ horizontal strategy “ to follow a trail and carry out effective process audits. E.g. select a sample from purchase requisitions and trace it through enquiry, purchase order, receipts, inspection, handling, storing, issue, assessing stock condition and so on. Auditors will also need to have a clear understanding of the way process works, its inputs, process control points and outputs.

The real challenge for Auditors would be to carry out process audits in absence of detailed documented procedures/ work instructions (using process maps) since now there is very less emphasis on documentation (mandatory requirement is for only 6 procedures).

Process audits have proven to be very powerful and effective. Hopefully Auditors will make significant contribution to the continual improvement of the QMS and their effort appreciated and recognised.

**Conclusion:** In addition to above, there are many more challenges offered by ISO: 9001:2000. These would also be dependent on how the organisations have addressed the ISO : 9001:1994 requirements, size and complexity of business, statutory and industry specific regulatory requirements and so on.

Ever since the 1<sup>st</sup> committee draft of 9001: 2000 standard was released about 2 years back, hundreds of experts have interpreted and commented on 9001: 2000. Even now consultants, academicians assessors, implementers continue to “ discover “ it. All of us are in the process of learning. But I have no doubt that as in the past, with the passage of time, we will successfully develop the competence to overcome the challenges and use 9001:2000 to continually improve processes & products leading to increased prosperity through Quality.

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