

05-Dec-2000

ISO: 9001: 2000 - The " Bounce " is Back

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Background:

ISO : 9000 Quality management systems standards undergo revision every 5 years. The 3rd edition of ISO: 9001: 2000, after being debated and discussed for over 2 years, is expected to be published in Dec.'00. The Final draft FDS ISO: 9001: 2000 was published few weeks back. There may be some minor changes in the content, but conceptually, the standard is unlikely to change.

The current standard i.e. 1994 edition, has been criticized for variety of reasons like excessive emphasis on documentation and records without achieving significant improvement in quality of products, services or customer satisfaction.

The 1st revision, published in 1994, did not make any significant changes over 1987. It mainly dealt with either omissions and/ or clarifications of various terms and conditions. Users interest started diminishing and not many were motivated to adopt it.

The Strong Case Of Change :

In view of the above, the experts this time adopted the " market in " approach and conducted a major users survey. The forthcoming standard incorporates the findings like suitability for all sizes and sectors of organisation, reducing bias for manufacturing, use of simple and easy to understand language, emphasis on continual improvement, process based model, compatibility with ISO: 14000 etc. It is built on the following eight principles of Quality Management (QM) :

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual approach to Decision Making
8. Mutually beneficial Supplier Relationship

World class business excellence models like Dubai Quality Award, Malcolm Baldrige National Quality award of USA etc. are also developed on the above principles of QM.

Had the experts not taken the " bold " step this time, ISO : 9000 standards would have lost the " fizz " whatever of it was left.

Macro Level Changes:

Let us look at some of the macro level changes :

1. To reduce variety and confusion, against 20 odd current 9000 standards, there will only be 4.
2. 9001: 2000 edition will cancel and replace 1994 version of 9001,9002 and 9003. There will no longer be 9002 and 9003. Organisations that do not carry out design activities (currently ISO : 9002, 9003) need to state it in the quality manual.
3. The standard encourages users to adopt process approach. Hopefully it will stop users to " fragment " their business processes, as some organisations did to meet the 20 clauses requirement 1994 edition.
4. Less emphasis on procedures (documentation)
5. Greater emphasis on the involvement on top management and understanding customer needs, expectations and satisfaction.

9004 has been developed along with 9001 as a " Consistent Pair ". It will facilitate smooth and easy transition should a organisation with 9001 QMS wish to develop a comprehensive QMS and move toward excellence.

Standard is based on Dr. W. Edwards Demings cycle - Plan, Do, Check, Act, popularly known as PDCA cycle.

Plan : Understand customer needs, plan and provide the required resources. These requirements are covered under " Management Responsibility and Resources " section of 9001.

Do: Produce & deliver product/ services in line with customer, technical, statutory, regulatory & legal requirements. These are covered under " Product Realization " section.

Check for deviations (nonconformity) during and prior to product realization process including customer satisfaction/ dissatisfaction and analyse to improve. These are covered under " Measure, Analyse & improve " section.

Act to continually improve quality system. These requirements are covered under " Continually Improvement " section.

PDCA is a natural cycle for any type and size of organisation.

New Requirements and Specific Changes

Though there are many new additions and changes, given below are some of the new additions and major specific changes which can be useful to practicing

quality professionals. For implementation purposes users need to refer to ISO : 9001:2000 standard.

Commonly used terminology of Customer, Organisation and Supplier has been adopted and earlier terminology of Customer, Supplier and Sub Contractor dropped.

To eliminate confusion as to who is management, top management is now clearly defined as the management at the highest level.

Earlier signing Quality policy by top management was " sufficient ". But now top management need to provide evidence of its commitment to the improvement of QMS, understanding customer requirements at strategic level, its involvement in Management reviews etc. Chief Executives, Directors etc. can be audited by internal and external Auditors.

Most organisations did not define Quality Objectives in measurable terms. But now, top management will be responsible for putting measurable objectives for relevant functions and levels including for continual improvement and customer satisfaction. These need to be in line with Quality policy.

As is commonly said, Plans are nothing & planning is everything. In order to meet the quality objectives, now plans need to be put in place and planning output be documented.

There is a clear logical sequencing & alignment between Quality policy, objectives and clearly detailed outputs to ensure objectives are actually achieved.

Management Representative has now additional responsibility for promoting awareness of customer requirements within the organisation. Management can appoint more than one Management Representative. Some of the large and geographically spread organisations, having branch operations, used to have multiple Management Representatives for effective operation of QMS.

A good start has been made by addressing the issue of providing relevant information and internal communication among different users. Hope this will reduce some of the rework and frustration among employees waiting for information or dealing with inaccurate information.

To ensure critical elements of QMS like improvement, results of audits, customer feedback, status of corrective and preventive actions are reviewed by the management, these have been now defined as agenda for Management Review meeting. It also requires to document the minimum actionable points arising out of meeting.

Unlike in 1994 edition, Resources have now been considered as very important part of QMS and a complete section created. Except for training, much of it is new. Assignment of competent personnel has been added. To ensure competencies are available, as a minimum, some form of job descriptions will be required from which competencies needed can be determined. Hopefully this will bring in consistency among certifying bodies as some insisted organisations to document job descriptions while others did not.

Providing training is no longer adequate, its effectiveness needs to be evaluated. It can be immediately after the training and/ or at a later date at defined intervals. On the job training evaluation, especially for skilled category, can be quite useful to achieve desired competencies.

As part of Resource requirements Organisation need to identify, provide and maintain facilities like equipment, hardware, software, support services and ensure that it has the right kind of technologies and methodologies to meet all requirements and be upto date.

As we know, processes transform inputs into outputs and are central to product realization and achieving consistent product/ service quality. If processes are out of control (not "capable") quality characteristics cannot be achieved. To address this issue, product realisation processes like product development, manufacturing, assembly, testing, etc. need to be verified, validated and evidence made available to provide necessary " confidence " that processes are capable of producing the required products/ services. This requirement may provide some difficulty for organisations from service sector like travel, education, hospitality, health care etc.

Inclusion of regulatory and legal requirements, as part of identification of customer requirements is an added requirement. Organisations exporting the products/ services need to consider the requirements of the country to which products are exported e.g. noise levels of emission levels of automobile can vary from country to country or even state to state as in USA.

A significant addition is inclusion of continual improvement of QM in a newly created section titled Measurement, Analysis and Improvement. It requires proper planning of measuring and monitoring activities to achieve conformity to specifications and improvement. This is the only clause, which refers to use of statistical techniques although these have still not been made mandatory.

Handling customer complaints is no longer enough. Measuring and monitoring of customer satisfaction and/ or dissatisfaction is a major step forward. It also includes how the information collected and analysed is used.

Most organisations used records to demonstrate evidence of performance rather use them as data and information to analyse and improve. Now pertinent

records like audit findings, management reviews, analysis of data, corrective and preventive actions etc need to be converted into useful information to determine where the improvements can be made. Organisations can begin on the path of continual improvement, if this requirement is implemented in true spirit of the standard.

Some of the earlier requirements like Process Control, Identification & Traceability, Customer Supplied Product, Handling, Storage, Delivery, Calibration, Inspection, Control of Nonconformity, Corrective and Preventive Action etc. have been considerably simplified, tidied and written in easy to understand language with some minor modifications.

ISO : 9001 : 2000 is definitely an improved document and is likely to have much greater acceptance among all sizes and types of organisations - new as well as existing users. Experts have done their best. Now it is our turn to adopt it in its true spirit.

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