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Regulatory Aspect of International Organization for Standardization (ISO)

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Abstract: ISO specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. All requirements of ISO 9001:2008 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of ISO 9001:2008 cannot be applied due to the nature of an organization and its product, this can be considered for exclusion and are made, claims of conformity to ISO 9001:2008 are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

Keywords: ISO; Certification; Standards; Quality.

INTRODUCTION

The International Organization for Standardization (ISO) was established in 1947 and is (currently) an association of 160 members, which each represent their own country. ISO employs a system of Technical Committees, Sub-committees and Working Groups to develop International Standards. Besides the National Standards Bodies, ISO permits other international organizations that develop standards to participate in its work, by accepting them as Liaison members. ISO works in accordance with an agreed set of rules of procedure, the **ISO/IEC Directives**, which also include requirements on the presentation of standards.[1]

Objectives of ISO:

1. To provide products that is customer focused or oriented
2. To produce products that meets customers' requirements
3. To enhance customer satisfaction for the products and their trust in it
4. To enhance quality management

5. To enhance effective and efficient products design and development.

QUALITY MANAGEMENT SYSTEM:

The ISO 9000 standards give organizations an opportunity to increase value to their activities and to improve their performance continually, by focusing on their major processes. The standards place great emphasis on making quality management systems closer to the processes of organizations and on continual improvement. As a result, they direct users to the achievement of business results, including the satisfaction of customers and other interested parties.

The management of an organization should be able to view the adoption of the quality management system standards as a profitable business investment, not just as a required certification issue. [1]

Among the perceived benefits of using the standards are:

- The connection of quality management systems to organizational processes

- The encouragement of a natural progression towards improved organizational performance, via:
  - the use of the Quality Management Principles
  - the adoption of a "process approach"
  - emphasis of the role of top management
  - requirements for the establishment of measurable objectives at relevant functions and levels
  - being orientated toward "continual improvement" and "customer satisfaction", including the monitoring of information on "customer satisfaction" as a measure of system performance.
  - measurement of the quality management system, processes, and product
  - consideration of statutory and regulatory requirements.
  - attention to resource availability [2]

ISO 9001:2008 aims at guaranteeing the effectiveness (but not necessarily the efficiency) of the organization. For improved organizational efficiency, however, the best results can be obtained by using ISO 9004 in addition to ISO 9001:2008. The guiding quality management principles are intended to assist an organization in continual improvement, which should lead to efficiencies throughout the organization.

QUALITY MANAGEMENT PRACTITIONERS:

As a minimum, quality management practitioners should familiarize themselves with the requirements of ISO 9001:2008, and also with the content and philosophies of ISO 9000:2005, ISO 9004 and the Quality Management Principles.

Practitioners who are already familiar with ISO 9001:2000 should become aware of the clarifications introduced in ISO 9001:2008, and their implications, prior to conducting audits to that standard, or giving training and consultancy.

They should understand their client’s activities and processes, before providing appropriate interpretations of the requirements of the standards, to add value to the client's operations.

ISO/TC 176 has developed the standard ISO 10019 Guidelines for the selection of quality management system consultants and use of their services, which may be useful to refer to for further guidance.[2]

Advantages:

It is widely acknowledged that proper quality management improves business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation. The quality principles in ISO 9000:2000 are also sound, according to Wade and also to Barnes, who says that "ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive implementing ISO often gives the following advantages:

- Create a more efficient, effective operation
- Increase customer satisfaction and retention
- Reduce audits
- Enhance marketing
- Improve employee motivation, awareness, and morale
- Promote international trade
- Increases profit

Reduce waste and increases productivity

ISO 9000 STANDARDS:

The ISO 9000 standards are a collection of formal International Standards, Technical Specifications, Technical Reports, Handbooks and web based documents on Quality Management. There are approximately 25 documents in the collection altogether, with new or revised documents being developed on an ongoing basis.

(It should be noted that many of the International Standards in the ISO 9000 family are numbered in the ISO 10000 range.)[2]

COMMITTEE RESPONSIBLE:

ISO Technical Committee (TC) number 176 (ISO/TC 176), and its Sub-committees, are responsible for the development of the standards. The work is conducted on the basis of "consensus" among quality and industry experts nominated by the National Standards Bodies, representing a wide range of interested parties.

COPIES OF STANDARDS:

Copies of the standards may be purchased from your National Standards Body or from ISO Central Secretariat through the ISO Store of by contacting the Marketing and Communication department. Many National Standards Bodies have them available in local-language versions.

INFORMATION ON ISO SATNDARDS:

There are a number of sources of information on the ISO 9000 quality management system standards, including ISO's web site (www.iso.org), which carry information on the standards. Your National Standards Body should be able to provide copies of the standards, and registrars/certification bodies will be able to provide guidance on registration arrangements.

STANDARDS REVISED:

ISO's formal review process:

- Requires continual review to keep standards up to date. Must be initiated within 3 years of publication of a standard.

User inputs from:

- A global user questionnaire/survey
- A market Justification Study
- Suggestions arising from the interpretation process
- Opportunities for increased compatibility with ISO 14001
- The need for greater clarity, ease of use, and improved translation
- Keeping up with recent developments in management system practices.

The revision process is the responsibility of ISO Technical Committee no.176, Sub-committee no.2 (ISO/TC 176/SC 2) and is conducted on the basis of consensus among quality and industry experts nominated by ISO Member bodies, and representing all interested parties.

The revised quality management system standards (ISO 9000, 9001 and 9004) are scheduled as follows:

- ISO 9000:2005 already published – no major changes expected for 2009
- Current plan is for small changes to ISO 9001 (an "amendment") to be published in November 2008.
- More significant changes are planned for ISO 9004 (a "revision") to be published in mid 2009. [3]

COST OF IMPLEMENTING NEW STANDARDS:

One of the goals of ISO/TC 176/SC 2 is to produce standards that will minimize any potential costs during a smooth implementation. Any additional costs may be considered as a value-adding investment. A key factor in the development of ISO 9001:2008 was to limit the impact of changes on users.

The starting point for any individual request for an interpretation should be with the enquirer's National Standards Body. ISO Central Secretariat and ISO/TC 176/SC 2 cannot accept direct requests from individuals for interpretations of the ISO 9000 standards. ISO/TC 176 has a Working Group that only accepts formal requests for interpretations from the National Standards Bodies. The agreed interpretations can be found at http://www.tc176.org/.[3]

REASSESMENT OF STANDARDS:

This is primarily an issue between your organization and your registration/certification body. ISO/TC 176 is working with the IAF (International Accreditation Forum) and ISO/CASCO (the ISO Policy Committee for Conformity Assessment) in order

to provide relevant information in a timely manner. ISO/CASCO is responsible for the standards to which the Certification Bodies work (ISO/IEC 17021), and the Accreditation Bodies are responsible for monitoring and approving the performance of Certification Bodies within their geographical area.

It is expected that conformity to the new ISO 9001:2008 standard will be evaluated by certification bodies during regular surveillance visits and that full reassessment will only take place once current certificates expire. However, it should be noted that ISO and the IAF have agreed that all certificates to ISO 9001 should be upgraded to ISO 9001:2008 within 2 years of publication of the amended standard.

The active participation of experts from around the world in the preparation of the new standards, and the broad distribution of the draft standards, will facilitate the timely translation of the International Standards.

Given the global importance of the quality management system standards, many National Standards Bodies are already working on the translation issue. ISO itself will publish the new standards in English and French, but if national language translations of the standards are currently available from your National Standards Body, we expect that they will have the translation of the revised standards ready at the time of publication by ISO or very soon thereafter.

ISO 9001:2008 doesn't introduce major changes to the requirements, when compared to ISO 9001:2000. However, to benefit from the changes, we suggest you get acquainted with the new version of the standard and the clarifications introduced. If, during your analysis of the clarifications you find there are differences from your current interpretation of ISO 9001:2000, then you should analyse the impact on your current documentation and make the necessary arrangements to update it. It is intended that the amendment of ISO 9001 will have minimal or no impacts on documentation.[4]

Financial issues are not addressed in ISO 9001:2008, which is a requirements standard.

The ISO 10014:2006 and ISO 9004:2000, **Guidelines for performance improvements** standards will emphasize the financial resources needed for the implementation and improvement of a quality management system.

BENEFITS OF REVISED STANDARDS:

For ISO 9001:2008 the major benefits are:

- Simple to use
- Clear in language
- Readily translatable and easily understandable
- Compatibility with other management systems such as ISO 14001.[5]

For ISO 9004:

- Facilitates improvement in users' quality management systems.
- Provides guidance to an organization for the creation of a quality management system that:
  - creates value for its customers, via the products it provides
  - creates value for all other interested parties
  - balances all interested-party viewpoints.

- Provides guidance for managers on leading their organization towards sustained success.
- Forward compatibility to allow organizations to build on existing quality management systems.[5]

Detailed stages of the development of International Standards

An International Standard is the result of an agreement between the member bodies of ISO. It may be used as such, or may be implemented through incorporation in national standards of different countries.

International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a six-step process

- Stage 1: Proposal stage
- Stage 2: Preparatory stage
- Stage 3: Committee stage
- Stage 4: Enquiry stage
- Stage 5: Approval stage
- Stage 6: Publication stage

If a document with a certain degree of maturity is available at the start of a standardization project, for example a standard developed by another organization, it is possible to omit certain stages. In the so-called "fast-track procedure", a document is submitted directly for approval as a draft International Standard (DIS) to the ISO member bodies (stage 4) or, if the document has been developed by an international standardizing body recognized by the ISO Council, as a final draft International Standard (FDIS, stage 5), without passing through the previous stages.

The following is a summary of each of the six stages:

Stages

Stage 1: Proposal stage

The first step in the development of an International Standard is to confirm that a particular International Standard is needed. A new work item proposal (NP) is submitted for vote by the members of the relevant TC or SC to determine the inclusion of the work item in the programme of work.

The proposal is accepted if a majority of the P-members of the TC/SC votes in favour and if at least five P-members declare their commitment to participate actively in the project. At this stage a project leader responsible for the work item is normally appointed.

Stage 2: Preparatory stage

Usually, a working group of experts, the chairman (convener) of which is the project leader, is set up by the TC/SC for the preparation of a working draft. Successive working drafts may be considered until the working group is satisfied that it has developed the best technical solution to the problem being addressed. At this stage, the draft is forwarded to the working group's parent committee for the consensus-building phase.

Stage 3: Committee stage

As soon as a first committee draft is available, it is registered by the ISO Central Secretariat. It is distributed for comment and, if required, voting, by the P-members of the TC/SC. Successive committee drafts may be considered until consensus is reached on the technical content. Once consensus has been attained, the text is finalized for submission as a draft International Standard (DIS).

Stage 4: Enquiry stage

The draft International Standard (DIS) is circulated to all ISO member bodies by the ISO Central Secretariat for voting and comment within a period of five months. It is approved for submission as a final draft International Standard (FDIS) if a two-thirds majority of the P-members of the TC/SC are in favour and not more than one-quarter of the total number of votes cast are negative. If the approval criteria are not met, the text is returned to the originating TC/SC for further study and a revised document will again be circulated for voting and comment as a draft International Standard.

Stage 5: Approval stage

The final draft International Standard (FDIS) is circulated to all ISO member bodies by the ISO Central Secretariat for a final Yes/No vote within a period of two months. If technical comments are received during this period, they are no longer considered at this stage, but registered for consideration during a future revision of the International Standard. The text is approved as an International Standard if a two-thirds majority of the P-members of the TC/SC is in favour and not more than one-quarter of the total number of votes cast are negative. If these approval criteria are not met, the standard is referred back to the originating TC/SC for reconsideration in light of the technical reasons submitted in support of the negative votes received.

Stage 6: Publication stage

Once a final draft International Standard has been approved, only minor editorial changes, if and where necessary, are introduced into the final text. The final text is sent to the ISO Central Secretariat which publishes the International Standard.

CHANGES IN ISO 9000:2008

ISO 9001:2008 has been developed in order to introduce clarifications to the existing requirements of ISO 9001:2000 and changes that are intended to improve compatibility with ISO 14001:2004. ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard.

Certification to ISO 9001:2008 is not an “upgrade”, and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008

All changes between ISO 9001:2000 and ISO 9001:2008 are detailed in Annex B to ISO 9001:2008. [6]

BENEFITS FOR IMPLEMENTING ISO 9004

If a quality management system is appropriately implemented, utilizing the eight Quality Management Principles, and in accordance with ISO 9004, all of an organization's interested parties should benefit. For example:

Customers and users will benefit by receiving the products that are:

- Conforming to the requirements
- Dependable and reliable
- Available when needed
- Maintainable

People in the organization will benefit by:

- Better working conditions
- Increased job satisfaction
- Improved health and safety
- Improved morale
- Improved stability of employment

Owners and investors will benefit by:

- Increased return on investment
- Improved operational results
- Increased market share
- Increased profits

Suppliers and partners will benefit by:

- Stability
- Growth
- Partnership and mutual understanding

Society will benefit by:

- Fulfilment of legal and regulatory requirements
- Improved health and safety
- Reduced environmental impact
- Increased security [7]

16 Steps For ISO 9001:2008 Certification

1. Top Management must take a firm decision to implement Quality Management System based on ISO 9001:2000 standard.

2. Top Management must allocate proper resources to implement the above decision.

a. Human Resources (Management Representative {ISO coordinator} & Core Team to "prepare, implement, maintain & improve" the Quality System)

b. Time (minimum two to three hours per day (of core team) for initial three months till achieving ISO Certification & afterwards at-least one to two hours per week (like every Saturday - of core team).

c. Financial Resources. (Fees / charges for Trainings, documentation / consultancy (if outsourced) & ISO Certification / audit charges.

3. Form a core team comprising minimum two employees (one senior & one junior) from each department and appoint one member of core team as a Management Representative (MR - ISO

coordinator) to co-ordinate all ISO 9000 related activities. (Which is mandatory as per ISO standard)

4. Establish a Training Plan.

a. Awareness Training for all employees (as it is a team work and all employees are part of Quality Management System).

b. Documentation training for core team &

c. Internal Auditors training, to at-least three to four members of core team. [For training Contact: "Quality Management Institute" E-mail: iso9001training@gmail.com

5. Implement training plan / Conduct in-house (within your company) training seminars OR send your employees to attend open house training seminars (outside your company which are open to all) for above mentioned training seminars.

a. Awareness Training for all employees &

b. Documentation training for core team.

6. Review the Existing Business Systems in your organisation in comparison with ISO 9001 requirements. (Gap analysis exercise)

7. Formulate Quality Policy [Guiding document] and Quality Objectives [functional / departmental targets / goals]

8. Formulate Six Mandatory Quality Procedures required by ISO 9001:2008 standard.

9. Formulate other Quality Procedures (QP), process flow charts (QFC), departmental work instructions (WI) & other documents [i. e. forms / formats & etc. (QR, FM, FILE, REG., etc.)] required to conduct the company operations and complete the "Quality Manual".

10. Implement the Newly established "Quality Management System" from a planned / fixed date.

11. Arrange for "Internal Quality Auditors Training" to at-least three to four members of Core Team. (Develop Self Assessment Capability)

12. Conduct first Internal Quality Audit. (After a gap of at-least 30 days from the date of implementation of system).

13. Make Application for certification to Certification Body (Submit Manuals for Approval (Documentation review / audit. Pay Initial Certification charges to Certification Body at-least one month in advance.) [For certification contact : E-mail: iso9001certification@gmail.com]

14. Conduct first Management Review Meeting and then call Certification Body for conducting on-site audit of your Quality System.

15. Initial Audit / Assessment by Certification Body and receiving "Recommendation Letter", (like a provisional certificate) at the time of closing meeting. (if CB feels that your organizations QMS is conforming to ISO 9001 requirements)

16. Receive original Certificate from Certification Body. (normal time frame - within 21 to 30 days from date of recommendation letter)

STANDARDS COMPATIBILITY:

The standards are based on 8 Quality Management Principles, which are aligned with the philosophy and objectives of most quality award programs.

These principles are:

- Customer focus,
- Leadership,
- Involvement of people,
- Process approach,
- System approach to management,
- Continual improvement,
- Factual approach to decision making, and
- Mutually beneficial supplier relationships.

ISO 9004 recommends that organizations perform self-assessments as part of their management of systems and processes, and includes an annex giving guidance on this approach. This is similar to many quality awards programmes.

CUSTOMER SATISFACTION:

"Customer satisfaction" is recognized as one of the driving criteria for any organization. In order to evaluate if a product meets customer needs and expectations, it is necessary to monitor the extent of customer satisfaction. Improvements can be made by taking action to address any identified issues and concerns.

The quality management system details that are described in the standards are based on Quality Management Principles that include the "process approach" and "customer focus". The adoption of these principles should provide customers with a higher level of confidence that products will meet their needs and increase their satisfaction. [7]

CONTINUAL IMPROVEMENT:

Continual improvement is the process focused on continually increasing the effectiveness and/or efficiency of the organization to fulfil its policies and objectives. Continual improvement (where "continual" highlights that an improvement process requires progressive consolidation steps) responds to the growing needs and expectations of the customers and ensures a dynamic evolution of the quality management system.

PROCESS:

Any activity or operation, which receives inputs and converts them to outputs, can be considered as a process. Almost all activities and operations involved in generating a product or providing a service are processes.

For organizations to function, they have to define and manage numerous inter-linked processes. Often the output from one process will directly form the input into the next process. The systematic identification and management of the various

processes employed within an organization, and particularly the interactions between such processes, may be referred to as the 'process approach' to management. [8]

PROCESS APPROACH:

The "process approach" is a key element of the ISO 9000 standards. For further guidance, please refer to the ISO 9000 Introduction and Support Package module: Guidance on the Concept and Use of the Process Approach for management systems.[8]

The PDCA cycle is an established, logical, method that can be used to improve a process.

This requires:

- (P) planning (what to do and how to do it),
- (D) executing the plan (do what was planned),
- (C) checking the results (did things happened according to plan) and
- (A) act to improve the process (how to improve next time).

The PDCA cycle can be applied within an individual process, or across a group of processes.

Many organizations already apply a "process approach" without recognizing it. They could achieve additional benefits by understanding and controlling it.

By applying the "process approach" an organization should be able to obtain the following types of benefits:

- The integration and alignment of its processes to enable the achievement of its planned results.
- An ability to focus effort on process effectiveness and efficiency.
- An increase in the confidence of customers and other interested parties as to the consistent performance of the organization.
- Transparency of operations within the organization.
- Lower costs and shorter cycle times through effective and efficient use of resources.
- Improved, consistent and predictable results.
- The identification of opportunities for focused and prioritized improvement initiatives.
- The encouragement and involvement of people, and the clarification of their responsibilities.
- The elimination of barriers between different functional units and the unification of their focus to the objectives of the organization.
- Improved management of process interfaces.[8]

SEQUENCE OF PROCESSES:

The "sequence" of processes shows how the processes follow, or link, to each other to result in a final output. For example, the output from one process may become the input of the next process or processes.

The "interactions" show how each process affects or influences one or more of the other processes. For example, the monitoring or controlling of a process may be established in a separate process.

Identify the organization's intended outputs, and the processes needed for achieving them. These will need to include processes for Management, Resources, Realization and Measurement and Improvement.

- Identify all process inputs and outputs, along with the suppliers and customers, who may be internal or external.
- Identify the sequence and interactions of the processes.

The main purpose of documentation is to enable the consistent and stable operation of an organization's processes. [8]

Although statutory, standards' or customer requirements may require certain documentation, there is no defined “catalogue”, or list of processes that has to be documented in ISO 9001, apart from the 6 indicated ones.

The organization should determine which processes are to be documented on the basis of:

- The size of the organization and type of its activities,
- The complexity of its processes and their interactions,
- The criticality of the processes and
- Availability of competent personnel.

A number of different methods can be used to document processes, such as graphical representations, written instructions, checklists, flow charts, visual media, or electronic methods.[8]

The extent of detail is likely to depend upon factors such as:

- the size of an organisation and its types of activities,
- the complexity of its processes and their interactions, and
- the competence (level of education, training, skills and experience) of its personnel.

There is no standard way to describe a process. It depends on the culture, management style, staff literacy, personal attributes and their interactions.

A process may be described using a flow chart, block diagram, responsibility matrix, written procedures or pictures.

Process flowcharts or block diagrams can show how policies, objectives, influential factors, job functions, activities, material, equipment, resources, information, people and decision making interact and/or interrelate in a logical order.[9]

To adopt the "process approach" an organization should apply the following steps:

- Identify the processes of the organization,
- Plan the processes,
- Implement and measure the processes,
- Analyse the processes,
- Improve the processes.

A person who is given the responsibility and authority for managing a particular process is sometimes referred to as the "process owner".

It may be useful for an organization's Management to appoint individual "process owners" and to define their roles and responsibilities; these should include the responsibility for ensuring the implementation, maintenance and improvement of their specific process and its interactions.

It should be noted, however, that ISO 9001:2008 does not specifically require the appointment of "process owners".[9]

PROCESS MEASUREMENT:

There are various methods of measuring process controls and process performance, ranging from simple monitoring systems up to sophisticated statistically based systems (e.g. statistical process control, or SPC, systems). The selection and use of any particular method will be dependent on the nature and complexity of an organization's processes and products. The effectiveness of an individual process may be measured by the conformity of its output or product to customer requirements. Its efficiency may be measured from its use of resources. In all cases the measurement of the process determines if its (measurable) objectives have been achieved. Sometimes it only requires monitoring to confirm process operations.

Typical factors that are useful to consider when identifying measures of process control and process performance include:

- Conformity with requirements,
- Customer satisfaction,
- Supplier performance,
- On time delivery,
- Lead times,
- Failure rates,
- Waste,
- Process costs.
- Incident frequency

A "process" may be explained as a set of interacting or interrelated activities, which are employed to add value. A "procedure" is a method of describing the way or How in which all or part of that process activities shall/should be performed. [10]

ISO 9000:2005 defines a procedure as a "specified way to carry out an activity or a process", which does not necessarily have to be documented.

If the procedures describe inputs and outputs, appropriate responsibilities, controls and resources needed to satisfy customer requirements.

ISO 9001:2008 refers specifically to only 6 documented procedures; however, other documentation (including more documented procedures not specifically mentioned in ISO 9001:2008) may be required by an organization, in order to

manage the processes that are necessary for the effective operation of the quality management system. This will vary depending on the size of the organization, the kind of activities in which it is involved and their complexity. [10]

ORGANIZATIONS REGISTERED:

Organizations have their quality management system registered/certified to ISO 9001:2008. The scope of registration/ certification will need to reflect precisely and clearly the activities covered by the organization's quality management system; any exclusion to non-applicable requirements of the standard (permitted through ISO 9001 clause 1.2 "Application") will need to be documented and justified in the quality manual. [11]

When initially starting to use ISO 9001, an organization should familiarize its personnel with the Quality Management Principles, analyze the standards (especially ISO 9000 and ISO 9004), and consider how their guidance and requirements may affect your activities and related processes. If it then wishes to proceed to registration/certification, it should perform a gap analysis against the requirements of ISO 9001 to determine where its current quality management system does not address the applicable ISO 9001:2008 requirements, before developing and implementing additional processes to ensure that compliance will be achieved. [11]

2000 VERSION:

ISO 9001:2008 will supersede ISO 9001:2000 However, noting the IAF/ISO-CASCO/ISO TC176 agreement that accredited certification to the 2000 edition should remain possible for up to 2 years after the publication of ISO 9001:2008, copies of the 2000 edition will still be available on request from ISO and the national standards bodies during that period, and possibly for even longer.

Certification to ISO 9001:2008 is not an “upgrade”, and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008. However, certificates to ISO 9001:2000 will only remain valid until 2 years after the publication of ISO 9001:2008. Contact your certification/registration body to get details on the certificates transition process.[12]

The four primary standards of the current ISO 9000 family are the following:

- ISO 9000:2005 already published – no major changes expected for 2009
- ISO 9001:2000 to be superseded by ISO 9001:2008
- More significant changes are planned for ISO 9004 with a planned publication date of late 2009.
- ISO 19011:2002 is currently beginning the revision process, with a new version expected in 2011.

The other standards and documents will be reviewed and updated as necessary. ISO 9001: 2008 certificates can only be granted after its publication as an International Standard. Since ISO 9004:2009 will be a guidance document, it is not intended to be used for third party certification purposes.

It should not delay the introduction of the quality management system in your organization. Like those who are currently in the process of being registered/certified, anything you do now to lay the foundation of a quality management system within your organization will be beneficial. [12]

Organizations in the process of certification to ISO 9001:2000 are recommended to apply for certification to ISO 9001:2008, as soon it is published. Up to its publication you can still apply for certification to ISO 9001:2000.

ISO 9004 is a guidance standard, which is not intended to be used for third party registration/certification purposes. A key element of ISO 9004 is the ability to perform self-assessments. Third party quality management system certifications/ registrations are performed to ISO 9001:2008. [13]

APPLICABILITY TO PRODUCTS:

When an organization seeks to have its quality management system registered/certified to ISO 9001:2008, it is required to agree a "scope of certification" with its registrar/certification body. This will define the products to which the organization's quality management system is applicable, and against which it will be assessed. An organization is not obliged to include within its "scope of certification" all the products that it provides (note that the ISO 9000:2005 definition of "Product" includes "services"), but may be selective about those that are included. All applicable requirements of ISO 9001:2008 will need to be addressed by the organization's quality management system that covers those products that are included in the "scope of certification".[14]

Customers should ensure that a potential supplier's "scope of certification"covers the products that they wish to order.

ISO 9001 allows for the exclusion of some of its requirements (via clause 1.2 “Application”), but only if it can be shown that these requirements are not applicable to the organization.

Exclusions are limited to the requirements given in Section 7 ("Product Realization"), where individual requirements may only be excluded if it can be shown that they do not affect the organization's ability to provide product that meets customer and applicable statutory or regulatory requirements. Justification for such exclusions is also required to be detailed within the organization's quality manual.[14]

For example, if design activities are not required by an organization to demonstrate its capability to meet customer and applicable statutory /regulatory requirements, or if its product is provided on the basis of established design, then it may be able to exclude some of the "design" requirements but still be able to be registered/certified to ISO 9001:2008. [15]

The requirements of ISO 9001 are applicable to small, medium, and large organizations alike. ISO 9001:2008 provides some flexibility, through clause 1.2 “Application”, on the exclusion of certain requirements for specific processes that may not be performed by the organization.

If, for example, the nature of your products does not require you to perform design activities, or if your product is provided on the basis of established design, you could discuss and justify the exclusion of these requirements with your certification/registration body (see also the ISO 9000 Introduction and Support Package module Guidance on ISO 9001:2008 clause 1.2 'Application'). However, individual organizations will still need to be able demonstrate their capability to meet customer and applicable statutory or regulatory requirements for their products, and will need to consider this when determining the complexity of their quality management systems. [16]

It remains fully applicable. A project has been started to update the handbook to reflect the changes in ISO 9001:2008.

RELATIONSHIP BETWEEN ISO 9001 AND 14001

Compatibility with ISO 14001:2004 has been maintained and enhanced. “Compatibility” means that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements.

The two standards are compatible. It is not expected that an ISO guideline will be prepared on this subject at the present time. If the need for such a document arises, ISO will consider the request as a new project. However, both ISO 9001 and ISO 14001 include an annex to show the correspondence between the two standards.

ISO 19011:2002 provides guidelines for quality and/or environmental management systems auditing. Note that a project to revise ISO 19011 was started in 2008, and is expected to be completed in 2011.[17]

The standards are applicable to all types of organizations, operating in all types of sectors, including service providers.

ISO 9001 is equally appropriate to all sectors, including service providers. The standard is applicable to all types of organizations.

REGULATORY BODIES & STANDARDS:

Regulatory bodies should review their regulations currently in effect (or under development) and identify points where reference to the quality management system standards would be appropriate, before making recommendations to the legislative body.

Auditors, whether external or internal, should be able to demonstrate their competence on the structure, content and terminology of the standards, and also on the underlying Quality Management Principles.[18]

The standards require that auditors are able to understand the organization's activities and processes and appropriately audit against the requirements of the ISO 9001 in relation to the organization's objectives. According to joint advice from the International Accreditation Forum (IAF), ISO's Policy Committee for Conformity Assessment (ISO-CASCO) and ISO TC 176, auditors should be able to demonstrate competency in:

- The requirements of the ISO 9001:2008.
- The concepts and terminology of the ISO 9000:2005.
- The eight Quality Management Principles
- A general understanding of ISO 9004
- Familiarity with the auditing guidance standard ISO 19011. [18]

ISO/TC 176, ISO/CASCO and the IAF have established an ISO 9001 Auditing Practices Group, which has issued a number of web based guidance notes to assist auditors (see www.iso.org/tc176/ISO9001AuditingPracticesGroup)

ISO 9001:2008 remains compatible with the existing management systems standards for specific business sectors like ISO/TS 16949, AS 9000/EN 9100 and TL 9000.

Users of a specific sector scheme are recommended to refer to the organization that is responsible for that sector scheme, e.g. for:

- ISO/TS 16 949 refer to the IATF,
- TL 9000 refer to the QuEST Forum
- For AS 9000/EN 9100 refer to the IAQG

An organization who's QMS fulfils the requirements of ISO 9001:2000 should check that they are following the clarifications introduced in the amended standard ISO 9001:2008.

ISO 9001:2008 has been developed in order to introduce clarifications to the existing requirements of ISO 9001:2000. It does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard. [18]

IMPACT OF ISO 9001:2008 ON CERTIFICATIONS:

Certification to ISO 9001:2008 is not an "upgrade", and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008.

ISO and the International Accreditation Forum (IAF) have agreed the following "Implementation Plan" with respect to accredited certification to ISO 9001:2008:

"Accredited certification to the ISO 9001:2008 shall not be granted until the publication of ISO 9001:2008 as an International Standard. [19]

Certification of conformity to ISO 9001:2008 and/or national equivalents shall only be issued after official publication of ISO 9001:2008 (which should take place before the end of 2008) and after a routine surveillance or re-certification audit against ISO 9001:2008.

Validity of certifications to ISO 9001:2000

One year after publication of ISO 9001:2008 all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008

Twenty four months after publication by ISO of ISO 9001:2008, any existing certification issued to ISO 9001:2000 shall not be valid."

Reasons companies get ISO 9001:2008 Certification

The process of getting and maintaining ISO/QS 9000 certification is an expensive process so I did some research to see how most companies can financially justify the additional cost of maintain an ISO certification. This analysis does not include companies that

maintain ISO compliance. Companies that are maintaining compliance but are not certified are usually maintaining an ISO quality system to help improving quality.

There are basically market leader and market follower. The market leader usually have great quality program that support their growth as a market leader. The other 90% of companies are followers and do not know how a great quality reputation will help their business. Since there are 9 followers for every market leader, the statistics are skewed by unsuccessful companies (companies that will always be followers).[20]

1. Competition
2. Required by European customers
3. The ISO logo can be a marketing tool
4. ISO certification helps project a quality image
5. Maintaining an ISO quality system improves quality

Implementation Cost of ISO 9001 Certification

Many companies under-estimate the cost of getting ISO 9001 certification. This is because companies only look at the direct costs. But the direct cost is probably the smallest portion of the total cost. The total cost of ISO 9001 certification come from 3 basic elements:

1. Indirect cost of maintaining a quality focused organization. This can be done with or without ISO
2. Indirect cost of doing additional operations only for purpose of maintaining an ISO certification
3. Direct cost of registration [20]

Indirect costs with a quality focus

Many elements of the ISO 9001 standard are a no-brainer for a quality-focused company. Processes like engineering change order system, revision control of documents, receiving inspection, and some form of management review should be in place at any company with a history of more than 3 years. Therefore, these are not additional cost of ISO, they are the minimum requirements for growing a long-term successful business and should not be including in the analysis of whether to implement ISO or not. [21]

Indirect costs with an ISO 9001 focus

There is a significant ISO 9001 requirements that is simply record keeping for the main purpose of maintaining the certification. This cost is dependent on the size of the business but for the sake of discussion, it is at least one half-man year per year. The ISO 9001 requirement is typically for some high level tasks that require an understanding of quality systems and the ISO 9001 standard and some low-level tasks that are basic filing, data entry, and maintenance function. Based on this my ballpark for justification purposes is $40K per year (minimum). This could be split between a clerk and a consultant or you could get luck and hire a clerk that want to learn ISO 9001 without being paid extra for responsibility. You can easily double that number if the company has poorly designed system that put a drag on all the employees.[21]

Direct Costs of Registration.

An ISO 9001 certification audit can run from $10-25K for small and mid-size companies. This is based an a 3 to 5 man-day audit with an average cost of $3000 per man-day plus travel expenses. ISO 9001 maintenance audit is usually much shorter, averaging about $5-$10K for a 2 man-day audit.[21]

EXAMPLES

Company A

Company A is interested in growing their company and they understand that quality is key to the long-term success of their business. Company A already has focused resources assigned to finding and correcting quality problems. The resources are not used for production and are motivated to build the company's quality reputation. They already have a quality goals and a continuous improvement program. The company has a basic structure for non-conforming material, ECR/ECO and maintaining calibration equipment. They are considering ISO 9001 to take the company to an even higher level of quality.

In this case the company will take the ISO 9001 program serious and will use consultants to help develop a truly efficient system that improves quality and decreases cost of manufacturing. They will add personnel to help maintain the ISO 9001 program. The ISO program will help focus the company, will increase customer satisfaction, and generate more repeat business. The moral of the company will be boasted that company will build a desirable reputation as both an employer and a supplier.

The cost of ISO 9001 is $150,000 for the first year and $100,000 per ongoing year for personnel and direct audit costs. Because of the combination of ISO 9001 and an effective, focused quality organization, the company sees an bottom line growth of around 5 to 7%. They payback on their ISO 9001 program is about 2 year and the company grows to be a leader in their field.

Company B

Company B says they are interest in quality but does NOT have any resources totally focused on improving quality. All resources are share with production and they have the goal of shipping product first and quality second. They decide to implement and ISO program because marketing says they need the certification to help sell their poor-quality products into new markets like Europe. [21]

In an attempt to Implement the absolute minimum requirements of ISO 9001, they pull engineering resources off any product or quality work and assign them work on the ISO program. The staff is stretched to limit so they develop ineffective system that are a burden on the company. The product quality continues to drop due to neglect and the company has a hard time getting any repeat business because the product failure rate is so high. Moral continues to drop as many of the more conscientious employees leave because of frustration about the lack of resources and lack of focus on product quality. The engineering team is talented (as most are) and they manage to scrap together the minimum systems to meet the external ISO9001 audit.
The direct cost is only the cost of the registration audit, about $12,000. Year after year, the company manages to squeak past the auditors and maintain the certification. The company struggle with sales since no customer will buy a second time after finding out how poor the quality of the product is. The poor resource management at the company results is no growth year after year and little or no bottom line profits. There is no payback on the ISO program because is so critically understaffed.[21]

ISO 9000 Resources was designed as a free resource for the ISO 9000 implementation process from conception to optimization (continuous improvement never ends). Although there is enough information on this site to create an ISO 9001 compliant quality system, we encourage all companies to get professional help with their ISO 9000 quality system development. A professionally designed ISO 9000 quality system will pay for itself.

The First Step Towards ISO 9000

For those companies that have not started an ISO 9000 program, we have articles discussing the cost of ISO 9000, a comparison of ISO 9000 certification vs. ISO 9000 compliance. We also have information for companies trying to implement ISO 9000 using existing resources that are already loaded to 100% before the ISO 9000 project starts. These articles discuss the effect of ISO 9000 on quality. Management commitment to ISO 9000 standard, trends in ISO 9000, and the reasons that most companies get ISO 9000 certification.

Starting An ISO 9000 Program

Once the decision has been made to start an ISO 9000 project, we have a set of articles on the 10 steps to getting a successful ISO 9000 implementation. We also have information on selecting an ISO 9000 registrar and getting ISO 9000 / ISO 9001 training (including ISO 9001 Awareness Training, How to be audited training, process training, and quality system training).

Building a great ISO 9000 quality system

Once you have your feet wet, you will want to dig into the ISO 9000 standard. There is a set of articles with sample procedures listed on this site. There is also a free sample ISO 9000 compliant quality manual. You may also want to learn some basics from the articles on Understanding the 10 basic ISO 9001 areas. (The articles include sample procedures). Once you have systems in place, you can use the ISO 9000 internal audit check sheet to check the status of the quality system. After you have a successful ISO 9000 internal audit, you are ready to schedule an external audit with the ISO 9000 registrar of your choice.[22]

Preparing for an ISO 9000 quality system audit

Check the articles page to find information about what to expect from an ISO 9000 certification audit, types of ISO 9000 auditors, and the presentation on how to be audited. The first audit can be very nerve racking so these article will help prepare your group for a smooth and painless ISO 9000 certification audit.

Optimizing ISO 9000 quality system

ISO 9000 Resources also has article to help optimize your ISO 9000 (or non-ISO 9000) quality system. If you are trying to exceed the minimum requirements of the ISO 9000 standard, then you may be interested in the articles on the 8 principals of the ISO 9000 standard, Low cost record keeping, and the ISO 9000 documentation pyramid.[22]

Beyond ISO 9000

Once you have mastered the minimum requirements of ISO 9000, you may want or need to go further. We have articles on ISO/TS 16949, ISO 13485:2003 and ATEX, which are based on ISO 9000 but have additional requirements beyond ISO 9000.

If you trying to build the ULTIMATE ISO 9000 quality system, you should review the articles on Japanese-style quality systems. Japanese-style quality systems were based on continuous improvement way before it was integrated into ISO 9000.[22]

PREFERNCE OF ISO 9000 OVER ISO 9001

This site was named ISO 9000 because prior to the 2000 revision of the 9000 standard, there were 3 standards: ISO 9001, ISO 9002, and ISO 9003. Back when I really got started with ISO quality systems, we always used ISO 9000 to describe the set of standards. The name stuck with me so I named the site ISO 9000 resources.

At the root of ISO certification, there are really 3 things you must do to maintain an ISO certified or compliant quality system:

- Document how you operate your business.
- Create documentation to comply with the standard
- Maintain records to allow auditing to the ISO standard.

The ISO 9001 standard is designed to promote quality but the certification process does not set product quality standards. It establishes requirements for a quality system that should eventually produce quality products.[22]

At the basic level:

Maintaining ISO certification = Maintaining records to prove that your quality system meets the standard

The focus of many ISO programs is the generation and maintenance of records for the purpose of maintaining certification. The secondary effect is that this system will produce quality products (if adequate resources are applied to quality).

The samples on this website are designed as the foundation for a compliant quality system. The ISO standard says you shall do specific things. Each procedure or document that you generate says "we do these things" and here is how we do it. You must add the detail of how you want to perform each specific tasks. Then you must generate records that show that you are using your system properly.

The Minimum Six Required Procedures

Throughout the years, there has always been talk about what are the absolute minimum requirements for an organization with ISO 9001 certification. This is really common for organizations that think that ISO 9001 is burden on the organization. It is true that many organization that try to implement ISO without the help of a consultant or set of products like ours, tend to over document their system and place an excessive labor requirement on the organization. For those who want the absolute minimum in a quality system, you may try meeting the absolute minimum procedural requirements.[23]

Because of the way the ISO 9001: 2008 standard is written, some people say there are six "required" procedures.

- Document Control (clause 4.2.3)
- Control of Quality Records (clause 4.2.4)
- Internal Audit (clause 8.2.2)
- Control of Nonconformity (clause 8.3)
- Corrective Action (clause 8.5.2)

- Preventive Action (clause 8.5.3)

ISO 9001 as a process

The ISO 9001 standard outlines a process approach to implementing and supporting a quality management system. As a result, there is increased involvement of top management with regards to the Quality Management System.

Top Management is engaged for the setting of the Quality Policy and Quality Goals and Objectives. It continues with Management Review looking at data from the QMS, and taking actions to make sure that Quality Goals are met, new Goals are set, and continual improvement is achieved.[23]

The Role of the QMS System in Achieving ISO 9001 and ISO 9000 Certification

With the QMS in place and working for you, the organization is focused towards the Quality Goals. Management is provided with data on a continual basis and able to see progress or lack of progress towards goals and take appropriate action. The organized, scheduled process of conducting Management Review ensures that this evaluation takes place. It provides the mechanism of reviewing goals and performance against goals on a scheduled basis, and for taking action based on the evaluation.[23]

The Results of Certification to ISO 9001

- Well defined and documented procedures improve the consistency of output.
- Quality is constantly measured
- Procedures ensure corrective action is taken whenever defects occur.
- Defect rates decrease
- Defects are caught earlier and are corrected at a lower cost.
- Defining procedures identifies current practices that are obsolete or inefficient.
- Documented procedures are easier for new employees to follow.
- Organizations retain or increase market share, increasing sales or revenues.[24]

CONCLUSION

Most companies consider ISO 9000 more of a market-driven requirement and not a quality-driven requirement. Companies are saying “ISO will increase my sales" more than they are saying " ISO will improve my quality". When the drive behind the ISO program is purely marketing, quality takes a back seat.

This philosophy gets the task of implementing ISO off to rough start. If the basis of the project is to use engineering and quality resources to help increase sales, then quality can suffer due to lack of quality emphasis. I have seen this situation at several companies and the results are always the same. The ISO program does not increase sales (long-term) because customers expect high-quality from an ISO 9001 certified company. When they don't get it, they find a company that can deliver quality. If the product or service quality is not the company's first priotity,it shows in the products and services.

The solution is to turn the requirement upside down and focus on improving quality. Make improving quality the main goal of the project and ISO certification the secondary goal. Regardless of the market, it is the quality leaders that establish the rules and control the market. Smaller companies can find the less profitable niches and survive but it is a long and hard life when your corporate plan is just surviving day-to-day.

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