

☒ 응용논문

ISO Quality System Certification and Management Quality

- ISO 품질시스템 인증과 경영품질 -

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Abstract

Ever since the ISO (International Organization for Standardization) established the ISO 9000 Family standard in 1987, many countries have selected this as their national standard and have provided support for its implementation and conducted assessment activities on the results of its implementation.

Likewise, certification assessment was first begun in Korea in 1994, with the result that over 7,600 certificates have been issued to domestic enterprises during the past 5 years or so. This is significant not only in the remarkable growth rate in terms of quantity but also in the fact that it has made possible the establishment of a quality system that meets international standards among Korean enterprises.

In this article, it will briefly introduce the establishment and certification of the ISO quality system for those organizations that are complying with the quality system as a part of the process of strengthening their quality competitiveness. For those organizations that have already established the quality system and implemented it for years, we will show the direction for continuous quality improvement in order for these organizations not only to fulfill the requirements but to maintain the superiority of the quality system and their management quality. In addition, it will show what preparations are necessary for organizations and certification bodies in order to expand a manufacturing process-oriented quality system to one that is geared to the total management quality.

Establishment of the ISO Quality System

As a way of fulfilling its guidelines and requirement, the ISO 9000 Family standard focuses on whether and how the products and/or services that are produced under the quality system of an organization can satisfy customer needs. The organization therefore must provide confidence to its internal management and to the customer that it is continuing to accomplish, maintain, and improve the quality of its products and/or services in terms of quality requirements.

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Rather than specifically showing how a particular organization should implement these elements, however, the ISO 9000 family standards describe which elements must be included in a quality system. Because the establishment and methods of implementing a quality system are affected by specific objectives, business field, scale, and level of the organization, they must be determined autonomously and independently by the organization that seeks to establish a quality system.

In this respect, an organization will be able to accomplish the basic goal of satisfying its customers only when it applies the general guidelines for quality management and outside quality requirements, as stipulated in the ISO 1900 family standard, to the establishment of its quality system correctly and precisely.

First, it is necessary to establish various functions in order to establish a quality system. The structure of a quality system is set up by defining the functions that exist inside or outside. In order to establish an effective quality system, it thus becomes necessary above all to define the adjustment and compatibility of the components and their interfaces.

In the ISO 9001 standards, there are basic functions that must be executed. These functions will include understanding customer needs, strategic guidelines, quality objectives and planning, resource management, management of products and/or services realization, document control, measurement and analysis and so on. For an organization whose goal is to assure the quality of its products and services, it is important to document the procedure involved in determined and simplified major business process according to pre-defined functions, thereby meeting the requirements of the ISO quality assurance model.

Second, relevant supervisors must clearly define responsibilities and authority in terms of all business process, thus leading to continuous quality improvement. The elements of quality management and quality system per industry as well as the guidelines for quality improvement are outlined in t

he ISO 9004 series standards. They ensure that, in order to accomplish the objectives of an organization, all technical, administrative, and human resources that affect the quality of its final products are managed, regardless of whether the final products are hardware, software, processed materials, or services. In order to assist an organization in selecting and using the elements related to its specific requirements, the ISO 9004 series standards describe quality system elements that are related to all of the stages and activities involved in the life cycle of a final product.

In addition, an organization that seeks to improve its validity regardless of whether or not it has established a formal quality system is advised to execute continuous quality improvement activities based on ISO 9004 4 within the ISO 9004 series standards. This is because ISO 9004 4 describes the basic concepts and principles, management guidelines and execution methods for customer satisfaction and continuous quality improvement.

Third, documentation is an indispensable element as it plays the important role of assuring the accomplishment of the quality required and as it is the result of an evaluation of the

quality system implemented and quality improvement activities.

ISO Quality System Certification

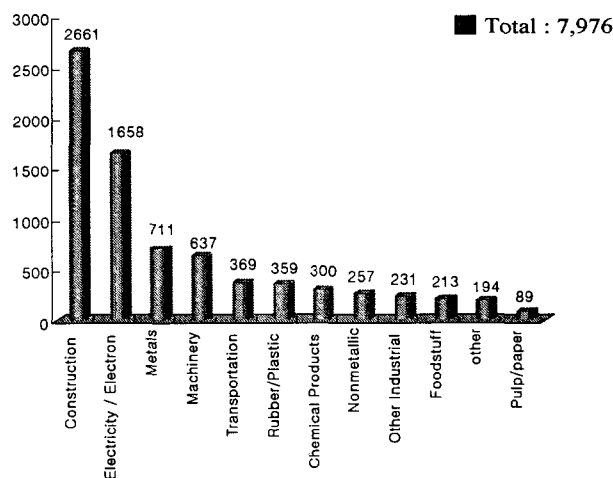
The customer who is provided with products and/or services from an organization has the right, stipulated in the contract, to demand whether or not the organization has the ability to continue manufacturing products and/or services that meet his or her needs. At this point, the organization must be able to present the specific quality assurance model that is demanded by the customer as a part of its quality system. In addition, the customer may directly evaluate the organization's quality system and officially approve its conformity to the organization. General practice, however, is to evaluate the quality system established by the organization and, unless otherwise stipulated in a contract with a specific customer, to assure that the organization maintains its quality system for all customers through the mediation of a third-party certification body.

The ISO 9000 family standards are widely used as a guideline for the following: a method of providing incentives to the stakeholder through the immediate demands of the customer or the parties involved; a method of providing incentives to the management who establish a quality system as a standard of quality management that can predict new market demands and trends in order to strengthen the organization's competitiveness, and who fulfill product quality requirements in terms of cost effectiveness.

The certification system that is currently under way maintains the objectivity of the ISO quality system certification by having a third-party certification body evaluate the establishment and implementation of quality systems regardless of whether they primarily provide incentives to the stakeholder or to the management.

[Figure 1]

Distribution of ISO Quality System Certification among Korean Enterprises
(As of 31 December, 1998)



Because the assessment of the ISO quality system is executed by a qualified certification body, the organization can assure customers actual as well as potential of the credibility of its quality system. In other words, whether or not the organization provides conforming products or services and its capacity in terms of the overall business procedure involved in manufacturing those products and services are evaluated with the requirements stipulated in the ISO quality assurance model selected by the organization as the criteria of assessment.

When a third-party certification body assesses the quality system that is established and implemented by an organization, it determines the assessment results by asking the following questions which are related to issues such as the methods, implementation, and effects of management to every process being evaluated.

- 1) Are the process adequately defined as to meet the requirements of the ISO 9000 and their procedures documented as the standard?
- 2) Are the processes fully implemented in accordance with the documented standard?
- 3) Are the processes effective in providing expected results?

This is because the requirements stipulated primarily aim at achieving customer satisfaction by preventing non-conformity throughout all stages from planning to additional services.

The Maintenance of the ISO Quality System

Currently, many organizations stop at establishing as standard only those procedures that meet the twenty elements stipulated in the ISO quality assurance model and at showing that they execute their processes in accordance with this standard, solely in preparation for certification assessment. The establishment of a conforming system, however, does not automatically ensure that the organization will always provide customers with satisfactory products and/or services. This is because products and/or services realization that satisfy customers can be provided only by a continual valid system.

In October 1994, a tragic accident occurred where the Songsu Bridge in Seoul broke and resulted in many casualties and deaths. During the analysis of the causes immediately after the accident, a majority of those involved mainly criticized the company that had originally constructed the bridge. Although many evidences of this company's disregard of the planned requirements and engineering standards during initial construction were of course discovered, I would like to know what procedures the bridge was maintained by the organization that had the final responsibility of managing it.

It must be possible to confirm the conformity and effective maintenance of the ISO quality system through an surveillance audit. Although the problem of how to maintain such a system ultimately depends on the independent and voluntary efforts of the organization, I believe that it will be possible to reduce trials and errors and promptly establish the correct system in the first place through the assistance of a qualified certification body.

The establishment of a valid system presupposes organic cooperation between the organization to be certified and the certification body. The certification body must show the precise direction for maintaining and supplementing a system's conformity and validity through the performance

of initial assessment as well as initial audit on the system involved.

In order for this to be realized, the certification body must ensure the credibility of its certification by unceasingly training assessors, maintaining the transparency of assessment, and evaluating the management process of the organization in an exact and objective manner.

Management Quality and Organizational Competitiveness

Once a continuous review and improvement of the quality system are executed through ISO quality system management activities, the goal of proving the organization's credibility to the internal management and its customer by establishing and correcting a standard for quality system in accordance with the organization's specific duties and by providing customers with satisfactory products and/or services must be accomplished. Even among organizations that have already obtained a certificate for their quality systems and have maintained the systems for years, however, similar non-conformity repeatedly occurs and doubts over the effectiveness of the ISO quality system certification system occasionally arise.

Reasons for such cases may be found in three aspects.

The first reason lies in the fact that, in terms of duty structure, the procedures for improving quality systems are not actively implemented but only on a minimal level for the maintenance of the certificate. In addition, the analysis of the reasons for existing non-conformity may be unsystematic, thus leading to an inability to establish permanent countermeasures to avoid such non-conformity, or discovering potential non-conformity may be passive.

Countermeasures for such a situation stress that preventive actions must be understood, implemented, and described in the quality system as concepts independent of corrective actions. In many cases, not a few organizations stop at passive quality improvement activities due to a confusion of the establishment of counteraction for preventing the recurrence of existing non-conformity as preventive actions. One of the reasons for this misunderstanding lies in the fact that there are not clear in the procedure of preventive actions in the ISO 8402 Quality Vocabulary and Clause 4.14.3 of the ISO 9001 Standard, and that the ISO 9004-1 Standard lists no separate category on preventive actions but describes it under Clause 15, which is about corrective actions.

An analysis of the reasons of the non-conformity and the establishment of action to prevent recurrence must then follow. The need for analyzing the causes of non-conformity may be found in: ① audit data from within or without the organization; ② reports of non-conformity discovered while executing in-house process; ③ management review; and ④ customer complaints or feedback information from the market. Rather than a simple analysis or review, however, a permanent countermeasure must be established in order to eradicate the cause of non-conformity by registering the non-conformity with the quality assurance team on an organizational level and by applying statistical techniques in analyzing the causes of the non-conformity.

Second, there are cases which organization did not follow in accordance with written procedures. Corrective actions must above all be implemented as promptly as possible in order to avoid the unintended but continuous use and provision of non-conformity. These corrective actions must include: a retry according to a predetermined procedure in case the non-conformity is due to a disregard of the procedure; and, in

case the non-conformity occurred in spite of adherence to a predetermined procedure, a review of the aspects of other products and/or services that have been planned or processed under the same procedure.

It is my expectation that citizens who use the now corrected (reconstructed) Songsu Bridge are complying with the speed limit and the loading capacity limit and that the organization responsible for follow-up management of the bridge is dealing with non-conformity (or violations) in accordance with the now systematically established analysis of causes and action for avoiding the reoccurrence of non-conformity.

Preventive actions, which are different from corrective actions that eliminate the causes of non-conformity within an organization, must include: the handling of potential non-conformity discovered while executing quality improvement activities within the organization; active quality improvement activities where the likelihood of such non-conformity from occurring within one's own organization is prevented through surveys on customer satisfaction or through case studies or benchmarking of the occurrence of non-conformity in similar situations outside the organization. In addition, such preventive actions must be mentioned in management review.

A good example of effective preventive actions is the analysis of all possible causes and simultaneous safety checkup of domestic railways that were implemented by various Asian nations when the German ICE (InterCity Express) derailed in June, 1997.

Third, in terms of behavior pattern, the employees' awareness of customer satisfaction must be strengthened through training or by awarding them with special status. The paradigm of thinking must be transformed so as to make the members of the organization feel that they are not simply "employees" but are partners of the organization and that they, as the small CEOs of respective organizational functions, have a sense of ownership (a win-win system). Quality management activities must be executed on the basis of a shift in the function of the organization from process management based on the manufacturing process to a business process realization. In addition, it must be stressed that the credibility shown to the internal customer while executing the management process within the organization is a significant functioning in securing the superiority of the organization's quality system and in strengthening its competitiveness.

TMQ and the Role of the Certification body

In Korea, too, the first organizations to acquire the ISO quality system Certificate through certification assessment have started to undergo renewal assessment due to the expiration of the certificate, which is valid for 3 years. The maintenance of the ISO quality system certification has made possible the following in this country: a stage-by-stage review of all processes; the establishment of document control systems and quality record control systems within organizations; and the opportunity for an objective evaluation of organizations' quality systems through a third-party certification body.

I firmly believe that the establishment of a documented procedure and execution of process according to this standard, in the process of establishing and implementing the ISO quality system, have provided organizations that formerly had a low level of quality management with a good opportunity to decrease defect rates in their products and to increase credibility of their products or services. Those organizations that have a long history of

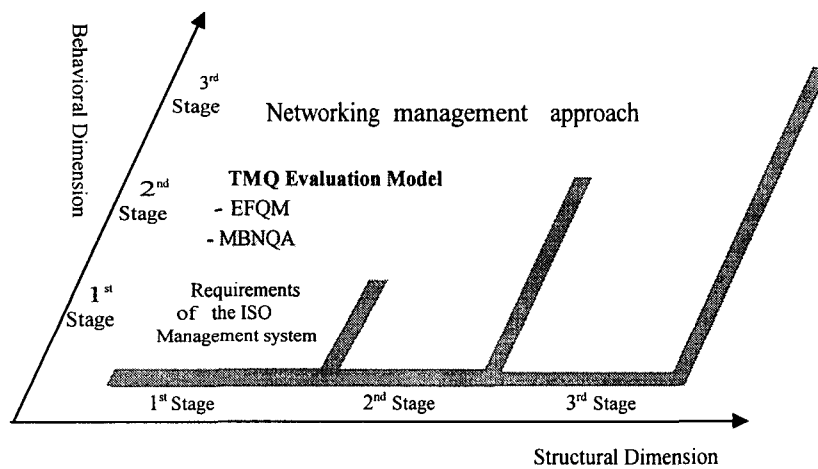
quality management and high levels of management, on the other hand, could not have been satisfied merely with the maintenance of the ISO quality system.

When compared to educational level, acquiring the ISO quality system certificate may be likened to passing the official examination whereby one is qualified to take the college entrance examinations. Follow-up management after the acquisition of the certificate, on the other hand, may be likened to the process of going on to a college of one's wishes thanks to effective assessment from a good certification body and of preparing oneself to become a member of the society and present competitive products through independent efforts.

Organizations that are satisfied with merely being qualified to take the college entrance examinations and passively accept surveillance audit and certification bodies that insist on the same contents for assessment regardless of specific organization's levels of quality management will be unable to survived in the current situation, where customers' potential demands must be grasped and new markets must be opened up.

[Figure 2]

IQNet Business Excellence Model



At this moment (the first quarter of 1999), the Korean Standards Association Quality Assurance has issued over 1,500 certificates and is actively participating as the representative for Korea in the IQNet (International Certification Network), which is an international cooperative organ consisting of representative certification bodies in 28 countries from around the world including the Canada, France, Germany, and Japan, etc.

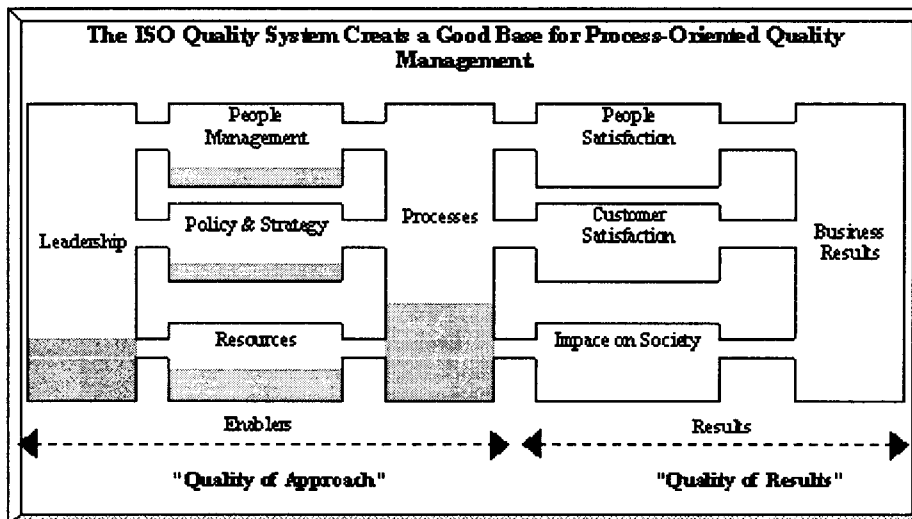
Instead of simply being satisfied with the ISO quality system certification, the IQNet likewise has established the IBEC (IQNet Business Excellence Concept), which is a new organizational evaluation model that aims to optimize organization management through the renovation of organizations' value and promotion of continuous improvement for the stakeholder by maintaining a balance in the interests of the IQNet organization's business

line and the stakeholder and by bringing about a restructuring of organizations' guidelines and strategies, and through benchmarking among the certificate-issuing organizations (estimated to be 100,000) under member organs of the IQNet.

Whereas the ISO quality system certification is limited to organizations' quality assurance systems, the evaluation model cited above includes overall contents of quality management. This evaluation model has supplemented the limitations of the ISO quality system by basing itself on the evaluation categories and methods of the Malcolm Baldrige National Quality Award (MBNQA), a quality management evaluation model of the U. S., and of the European Foundation for Quality Management (EFQM), a quality management evaluation model of Europe; and by adapting the checklist from the ISO 9000 quality assurance model to its list of questions to be asked. As a member body of the IQNet, the Korean Standards Association - Quality Assurance is expected to show organizations the direction for approaching Total Management Quality(TMQ) and thereby to have a significant impact on strengthening the competitiveness of Korean industry by evaluating the quality of management methods including organizations' leadership, employee management, guidelines and strategies, resources, and process as well as the quality of results such as employee satisfaction, customer satisfaction, social influences, and business result through this evaluation model.

[Figure 3]

ISO Quality System in TMQ



Conclusion

In implementing the ISO Quality system, an organization must: by accelerating its continuous quality improvement, focus on quality throughout its business processes instead

of proceeding with a quality management that centers on the manufacturing process; establish TMQ that can contribute to stakeholders as well as to society as a whole, with the participation of all employees and a long-term success goal for customer satisfaction including enhancing and genuine factors as the basis. In the process of implementing such action, the organization will, in terms of quality management, witness a strengthening of its human resources and the birth of a new quality culture, thereby gaining credibility of its products and/or services among customers throughout the world as well as strengthening its competitiveness. Likewise, certification bodies should provide all organizations with solid certification services by going beyond ISO quality system certification and distributing among Korean enterprises an organization evaluation model that can meet international standards and, in order to realize this goal, by concentrating all our efforts on the establishment of infrastructures resulting from in-depth research, training of assessors, and evaluation.

Reference

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