

PROPOSALS FOR THE IMPLEMENTATION AND IMPROVEMENT OF ISO 9001

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ABSTRACT

The ISO 9001 quality management system (QMS) includes a method of continuous improvement put in place in 1994. Through this system, audits and reviews are performed to identify, correct and prevent problems. Although the method of continuous improvement, combined with adherence to annual quality objectives, is an important part of the QMS, only a few business managers and quality professionals seem to acknowledge its significance. Whether the organization uses QMS or other improvement programs such as Six Sigma, Lean and TPM, it faces the same key question: how to ensure that methods that were beneficial during the execution of a project have continuity in the organization after the project has ended? One method of ensuring continuity is to apply QMS at the end of a project. Many organizations acquire and use ISO 9001 QMS in a limited way, for marketing purposes among other things, without taking a full advantage of its beneficial features. This paper analyzes various ways by which an organization can use the most beneficial characteristics of ISO 9001 QMS to improve its operations. The paper contributes to an ongoing discussion on the content and implementation of a quality system version related to ISO 9001 QMS, known as ISO 9001:2008. The paper proposes revisions that will make substantial improvements to ISO 9001:2008.

JEL: L20; L21; L23; M10; M11

KEYWORDS: ISO 9000, quality management system, performance improvement, process approach

INTRODUCTION

ISO 9001 QMS has been in use for more than 20 years and has become the most popular industrial standard with more than 1 million organizations using the technique. The suitability of ISO 9001 is therefore important for those organizations. If it is not suitable, they may invest time and energy into it without real positive impacts on their businesses. ISO 9001 is not immune to criticism. This paper discusses common arguments against ISO 9001 QMS and reviews their counter arguments. The literature review specific areas of quality and business management research issues. Two most important areas are tacit knowledge and process management. Several good features of ISO 9000 are identified and their ability to improve quality is discussed. By analyzing the present content and interpretations of ISO 9000, the author finds areas for improvement like the process approach. The paper closes with concluding comments about the present state of ISO 9001 standard.

LITERATURE REVIEW

The benefits and functionality of ISO 9001 quality management system has generated criticism from time to time. Curkovic and Pagell (1999) list some typical arguments against ISO 9000 like: the system is not directly connected to product quality, an organization does not need to demonstrate that its customers are satisfied, it is paper-driven and overly bureaucratic. Seddon (1998) identifies many examples of the harmful effects of ISO 9000: ISO 9000 makes things worse for their customers, ISO 9000 is inspection oriented and not development oriented, contract reviews have harmful effects, external auditors define quality and organizations do not achieve the promised results.

Symonds (1998), who serves as EHS (Environment, Health and Safety) Audit Manager in Mobil Corporation has responded to claims presented by Seddon. He presents two general observations. First, the people who criticize ISO 9000 are usually not directly involved in its implementation. Second, one should not blame the tool, if it is not used properly. These observations make sense in regard to all business systems, methods and tools. Thus, some companies achieve good results by implementing any well-known method while others, using the same tools, manage to only increase costs and frustration levels.

What explains the failure of some companies to use quality management tools for the benefit of the organization? Usually the root cause of failure can be found in the top and middle management who lack the skills needed for interpreting and implementing results obtained through QMS. Curiously, many researchers have overlooked this role of the management and focus on blaming or praising the methods.

When analyzing whether or not the organization has been successful in using information on best practices, the operational level of an organization also has a role. Harrington (1997) studied 60 organizations and analyzed the extent to which the best practices identified and implemented produced good results. His study showed that there were only five best practices (cycle-time analysis, process value analysis, process simplification, strategic planning and formal supplier certification programs), which always gave positive results regardless of performance level of a company: low, medium or high. In the end, Harrington concluded, it depends if management really understands the order their organization can proceed in developing its capabilities. There is no short cut into success. ISO 9001 base QMS can be easily adapted to the level of an organization, because the organization shall define quality criteria and procedural requirements based on its capabilities but still there remains room for lousy implementations.

Anderson, Daly and Johnson (1999) refer to several articles that indicate the 20 components of ISO 9000 are consistent with models of effective quality management system. The essential features of ISO 9000 are quality planning, goal setting, task authority assignments, adequate skills of staff, documenting process performance and responding to process failures. There is no scientific evidence that ISO 9000 contains elements which are harmful or dangerous in producing good quality. On the other hand it does not contain all the good characters of QMS. One good feature of ISO 9000 is that an organization can add any quality practice into their QMS (not conflicting with ISO 9000 principles) and it will be automatically part of certification. In practice almost all companies do this.

No system or method can replace human knowledge and know-how. QMS is a system for utilizing human knowledge in a systematic way. Some quality experts have learned from experience that systematic processes improvements (like Six Sigma and Lean) are possible only, if the QMS is good enough to eliminate the majority of human errors.

Tacit Knowledge

Since Polanyi (1996) introduced the concept of tacit knowledge, many studies have examined the meaning and nature of knowledge and the processes of creating and spreading it. Many researchers like Chen, Xu and Wang (2004) believe that tacit knowledge is more important than explicit knowledge in creating core competences. On the other hand there are many business philosophies that believe the opposite: tacit knowledge should be always transformed into explicit knowledge. The reason is that only explicit knowledge can be transferred between people (Kogut and Zander, 1992; Ollila, 2011).

Surely all quality philosophies including ISO 9000 argue for explicit knowledge in improving business performance. Commonly applied quality improvement methods like Six Sigma and Lean utilize documented means in analyzing and improving processes. In both methods improvements must be standardized and there must be documented evidence about results achieved. This is perfectly in line with

ISO 9000 which requires that essential procedures must be documented. When there is more than one person working in a process, it is impossible to train, to implement and to achieve evidence about the new way of working, if there is no documented material.

The basic idea of ISO 9000 is to document the best practice identified for a process or activity. Normally the improvements are achievements of systematic improvement. ISO 9001 (ISO 9001, 2008) has defined that continual improvement may happen “through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews”.

If a company has its own products, the R&D process and know-how is one of the most important assets of the company. Currently, R&D processes have been described quite well. The same is not true concerning the real know-how to develop new products. The author has experience with a company developing industrial products for more than 100 years. During the 1990’s recession the senior product development engineers were fired. The new generation of design engineers started to develop new products – and engineering errors appeared in some design details, which had not happened earlier. The reason was the tacit knowledge, which disappeared from the company.

Some might consider this is evidence of the importance of tacit knowledge. How important it is to document tacit knowledge and especially the product development know-how? This know-how is normally something, which cannot be found in text books or in scientific articles. It is the combination of engineering skills, calculation methods, material know-how and lessons learned. Normally it flows from senior persons to junior persons. In the worst case this know-how disappears from the company to competitors with people transfers. If this know-how is documented, the damage is not so large. In many instances this most valuable know-how of a company is not documented properly.

Process Management

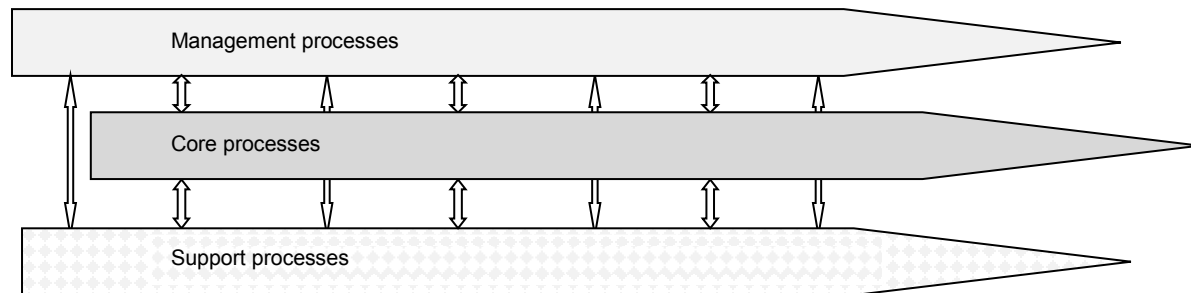
The literature reveals the ways organizations and researchers define processes. As Corallo & al. (2010) describe, the business process approach has been an actively discussed topic in the management literature since 1993. The review of some process oriented research indicates that researchers use different process definitions depending on the research angle as follows: Davenport (1993): operational and management processes, Johansson et al. (1993): core processes, Tinnilä (1995): core or key processes, supporting or non-strategic processes, Garvin (1998): work, behavioral and change processes, Rockart (1988): core processes, Lillrank (2003): standard, routine and non-routine processes, Galandere-Zile (2009): management, core and support processes, Corallo & al. (2010): management, core and support processes.

This literature review does not give a clear idea of the most common terminology. Because the process approach has been a business practice for about 20 years now, the terminology has become more consistent among companies. Also the presentation above indicates that during the most recent years, classification into three main categories is the most common solution as illustrated in Figure 1. In business improvements the core processes have a key role. For example Hammer, a specialist in process management, talks only about core processes (Hammer and Stanton, 1999), because there is major improvement potential. Kiraka and Manning (2005) have concern that organizations are facing difficulties in identifying their processes. The author has not experienced difficulties in process identification.

Lillrank (2003) explored quality as an outcome of standard, routine and non-routine processes. The definitions of his research can be summarized as follows: (1) Standard processes involve identical repetition of standardized tasks. Typical examples are mass manufacturers and high-volume service producers. (2) Routine processes are complicated, detailed and analytical processes within certain boundaries relying on existing knowledge, linear execution and predictable outcomes. A typical example

is an airline pilot making decisions about possible actions in various circumstances. (3) Non-routine processes are so complicated that the input variety is larger than the bounded rationality or experience set employed by the process. Typical examples are consultants and specialized doctors in health care. Lillrank and Liukko (2004) keep routine processes normally non-applicable for QMS.

Figure 1: The Most Common Classification of Business Processes



This figure illustrates the main process categories interacting with each other. The core processes begins from the external customer needs and ends to the satisfied customers. Support processes have internal customers mainly in core processes. Management processes tie together all other processes setting strategies and targets and carrying out follow-up.

As an example, consider a typical engineering project. It falls mainly into the category of routine processes. Project organizations realize it is important to have written procedures. A green field project starts from a feasibility study and proceeds through basic design into detailed design. Only for detailed design can exact engineering standards can be defined like ASME. Activities inside the phases and steps are based on the achieved experiences. The predefined execution of these processes is important in controlling quality. The majority of design solutions must be specified during the project execution. In this sense projects are typically routine. In some engineering solutions so much special engineering expertise is required that the most senior person must be involved utilizing their extensive experience. This implies a non-routine process. These situations are documented in written procedures, providing a proper guidance in achieving the best possible result.

Certification

The need for QMS certification for an organization is based on real need. Before certification important material suppliers and sub-contracting companies learned that their customers wanted to audit their QMS performance. The number of audits increased and some companies experienced customer audits every week. The same issues were audited again and again. Certification means that a neutral certification body carries out external audits and customers no longer need to audit. The number of certified companies has increased rapidly because it is in many cases a customer requirement. The message is that we shall not audit because the certification body will do it. Some companies have acquired the ISO 9001 certificate even though they operate in consumer business. This is an exception and usually related to improving the image of the company.

Because a reason for certification is a customer requirement, companies seek the certification in order to indicate fulfillment of regulatory requirements but not to improve quality. Anderson, Daly and Johnson (1999) carried out research with a sample of 514 certified public companies in USA. The results showed that the majority of companies (about 80 %) did not seek the certification primarily in response to regulatory requirements but to develop effective quality management practices. This result is in line with the research of Ollila (1995) who used customer satisfaction surveys and noted 8 of 10 certified ISO 9000 companies in Finland had improved quality as perceived by customers after ISO 9000 implementation.

REVIEW OF ISO 9000

In this section we pinpoint some features, which are useful in ISO 9000 and they are not usually part of any other quality philosophy or recognize areas of improvement. *Product quality:* It is true that ISO 9000 does not define product quality. Every organization must define quality in its quality documentation. The defined quality should be produced even though a customer does not specify any quality level.

Customer Satisfaction: Customer satisfaction is the first principle of ISO 9000. In his dissertation work Ollila (1995) carried out a survey of applied quality tools among 143 Finnish quality companies (94 % ISO 9000 certified). It turned out that customer satisfaction measurement was the most popular quality tool with a 90% implementation rate. In practice, ISO 9001 requires that customer satisfaction shall be measured. This is an addition for many organizations, because they normally had no customer surveys in place.

Documentation Requirements and Tacit Knowledge: ISO 9001 QMS means more paper work in an organization. The reputation for unnecessary paper work to a great extent comes from the early 90's. Quality managers asked each other "how many meters of quality documents do you have?" Companies documented their work procedures which were well-known to any professional person. This was a general miss-interpretation of ISO 9001 requirements. The latest ISO 9001:2008 version requires only six documented procedures (ISO 9001, 2008b). This change may have been a result of the unnecessary paperwork criticism. In reality much more is needed and applied in a typical certified company. As noted earlier, documentation is the only way to make tacit knowledge tangible, and is a positive feature of ISO 9000.

There are two ways to carry out improvements concerning planning and documentation activities. Some people believe in "trial and error". First we try and, if it works, we will document it, train and implement on a larger scale. This may be justified, if a change is small. Another argument is that "well-planned is half done". Well-planned means that it is documented because then it can be discussed and further developed. A team discussion without using documentation is ineffective as it is hot air created by speaking. By the terms of QMS it is better to document change first and then train and implement. A rule of thumb in ISO 9001 is that even a big change in a process or activity should be fully implemented after 6 to 12 months from its documentation.

External Auditors and Definition of Quality: Some ISO 9000 outsiders think it is external quality auditors that define the quality of a certified ISO 9000 company. The auditors simply try to find out, if an organization has defined the quality of its products or services in measureable terms and if the organization has evidence how well it can reach the quality criteria.

Contract Reviews: Even though the term "contract review" is not the official terminology of ISO 9001, it is a good expression about one of the most useful features in ensuring quality deliveries of a company. When people talk about quality, they normally have visualization that quality problems have been created in a production phase. If a product is more complicated than a standard product, the big quality problems are usually created in the order specification phase. The author's experience is that 80 % of major quality problems occur in the contract phase. If the customer is not able to specify the product in detail and the supplier does not know what is really needed, problems will ensue.

ISO 9001 requires that the organization shall review requirements related to the product (ISO 9001, 2008). The reason is well established: the organization must be sure the of product quality before committing to the customer. In practice this means the review shall be carried out for each bid, order and contract change. The type of review should be specified according to the nature of delivery. A standard product needs only an approved price list, a complicated product with options needs to be checked by a

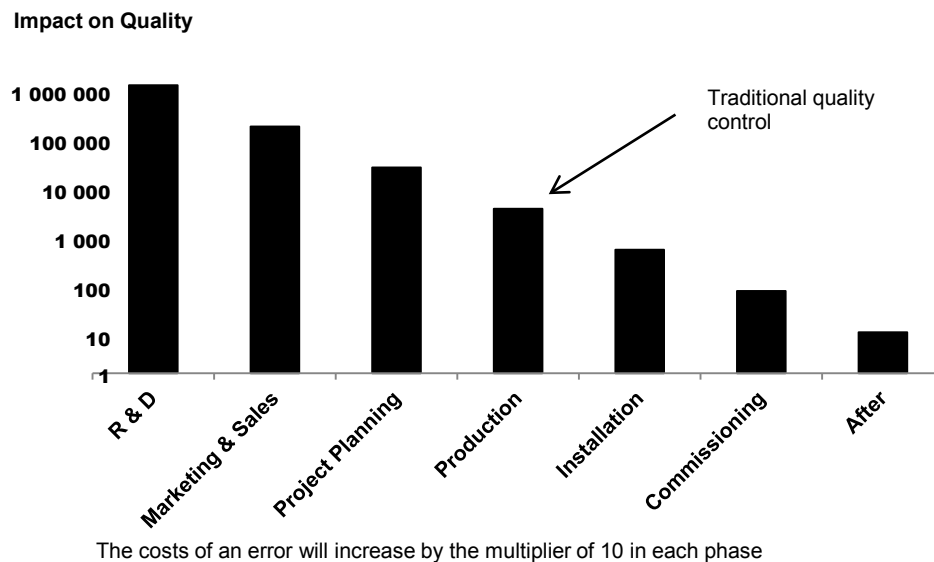
senior person. A review meeting is needed in some cases, when one person does not have all the knowledge needed to ensure quality. Project type activities always need a review meeting.

Figure 2 shows an illustration of a quality error. There is a common experience about the project work. An error created in a certain project phase is 10 times more expensive to correct in the next phase. The same applies into quality errors in any customer delivery processes. Phases described in Figure 2 are not always existing with making things easier. Project type activities are very demanding because they are a complicated series of activities and because a project is always a unique performance. In one instance the wrong electronic component choice in the R&D phase flowed through into customer deliveries and a one dollar error grew into multimillion dollar losses.

Organizations have a tendency to avoid contract review meetings sometimes with painful results. But on the other hand when in a review meeting an experienced person can bring forth a concern, which would have been otherwise neglected.

Audits: Internal audits are important in ensuring that QMS is working as planned. The major lessons learned are: A qualified auditor can find deviations from documented procedures in any organization. Second, the famous Pareto rule applies to deviations: 80% of cases should be corrected by following the documented procedure and 20% of cases the documented procedure should be modified according to the identified practice. This 20% of cases means that a piece of the organization or even an individual person has created a practice (outside of the system), which is better than the official way of working. Therefore it is essential to always receive evaluation from the process/activity owner regarding the corrective actions for each deviation. Sometimes it is a change in a procedure. A sign of a badly functioning process is many audit deviations from year to year. Third, the simplest indication of the quality culture of an organization is the promptness of corrective actions. In a good quality culture the deviations shall be swiftly corrected. In a lousy quality culture there are unnecessary delays in corrections. In the worst case the responsible person of a corrective action may even report the deviation has been corrected when it has not and it appears in a following audit. As always this means that the top and middle management has no real commitment for quality.

Figure 2: The Cost of an Quality Error from Phase to Phase



This figure illustrates that an error's impact will increase with logarithmic steps from phase to phase, if it cannot be removed. This figure illustrates the importance of the initial phases of any business activities.

The Quality of Measuring Equipment: For many companies implementing ISO 9000 for the first time, maintaining the accuracy and quality of measuring equipment in a systematic way, is something totally new. In some cases an organization has found the accuracies of measurement equipment is not sufficient to achieve the quality of the end product.

Maintenance of the Infrastructure: ISO 9001 defines how the necessary infrastructure shall be determined, provided and maintained. Modern production is not possible without production machinery and the quality of machinery has direct impact on the product quality. Ollila and Malmipuro (1999) show that poor maintenance is among the three main reasons of production quality problems.

Process Approach of ISO 9000: The process approach of ISO 9001 was introduced in version 2000. It was to be a major change. The introduction of version 2008 (ISO 9001, 2008) gives a positive idea about the general definitions being in line with general process terminology and requirements. For example a process means starting from customer requirements and ending to customer satisfaction. Also chapter 4.1 defines strict requirements for processes like: determination of processes and their interactions, criteria and methods for effective control of processes, monitoring, measuring and analyzing processes. There is confusion and problems concerning these strict requirements. If these requirements would be followed, the required evidence would not be available for the majority of certified companies for many years. Certification bodies require evidence of quality award assessments. Control of processes does not mean that there is a pair of key figures calculated for the outcome of a process. As quality professionals know, quality is not under control if you inspect the quality at the end of the production line as was practiced 70 years ago. Control of processes means other criteria than quality measurement: throughput time control, inventory control, smooth work flow, etc. Lean philosophy opens the doors for the effective process control.

When ISO 9000 introduced the process approach in 2000, it presented a big challenge for certified companies. Janas and Luczak (2002) surveyed 160 certified (ISO 9001) German companies and asked if they shall face problems because of the new requirements. The companies indicated no problems, because they already fulfilled the new requirements.

ISO 9001 does not classify processes in any terminology presented in the literature section. In paragraph 4.1 (ISO 9001, 2008) there is an expression that “The organization shall determine the processes needed for the *quality management system*”. Later requirements for processes have been addressed for QMS processes. This is confusing, because QMS is not even a core process. Janas and Luczak (2002) describe the new ISO 9001:2000 requirements as a description of work processes. There is common understanding among certification bodies and ISO appliers that the ISO 9001 terminology is misleading.

RECOMMENDATIONS FOR IMPROVEMENT

The following items are the author’s recommendations for concrete improvements of ISO 9000. *Process Approach:* As a solution for process approach ISO should follow the most common practice of process terminology and use process classification into three main categories: management, core and support processes.

A smaller problem is that process mapping (flowcharting) is not an ISO 9001 requirement. In this respect ISO 9001 lags behind common business practice. The ISO 9001:2008 introduction indicates a core process starts from the customer and ends with the customer. It is crucial in process approaches that we consider business processes as a long chain of phases (stages) and steps. In contradiction with this approach is the introduction statement of ISO 9001:2008 that “Often the output from one process directly forms the input to the next”. In properly done process identification this will not happen or it is very rare. Well-defined processes are from customer to customer – external or internal. There are interactions

between processes, which is another phenomenon. This same confusion can be found in one popular flowchart application: a process step symbol has also been called a process. This is as confusing as calling a machine part a machine. There are some examples of companies that have renamed old functional departments to be called processes. This is convenient, because you need not to change anything else, but you do not get any improvements either!

The author's opinion is that standard and routine processes can be documented and therefore also routine processes should be part of ISO 9000 QMS. The criteria of non-routine processes cannot be described in QMS but it is useful to document the process steps and actions. Tacit knowledge included in non-routine processes gradually becomes common knowledge and one day can be classified as routine and explicit knowledge fully included into QMS.

Review Terminology: Indefinite terminology of ISO 9001 causes problems for implementation of the standard. This may create disputes inside an organization. Moreover, auditors of a certification body may have different opinions of the real requirements of ISO 9001. In a few cases a procedure itself is not well-defined and has created criticism among the quality experts. The unclear terminology and content of requirements make both internal and external auditing difficult.

The word "review" has been used in different meanings (ISO 9001). Table 1, lists identified problems and proposed solutions for avoiding ambiguous meanings of the review word. The expression "review meeting" can be simply replaced by the term "review" if the review always means that a meeting must be organized. This needs to be clarified in the ISO 9001 description.

Corrective Actions: Some quality experts criticize the content of the chapter that a real cause for each nonconformity must be found. In mass production this is not possible. The text should describe each *special cause* must be identified but *system causes* can be analyzed utilizing methods specified by an organization. In many organizations these two categories of causes have not been identified even though it is crucial in analyzing quality nonconformities according to Deming (1986).

Table 1: Identified Problems and Proposed Solutions

ISO 9001	Original expression and a potential problem	Proposal
4.2.3	Control of documents: Review of documents in the meaning that the documentation is comprehensive enough and up-to-date.	This review activity of documents can be replaced by the expression "to <u>supervise</u> documents".
5.6	Management review: A management meeting has to be organized for reviewing the QMS at least once a year.	This review means a <u>review meeting</u> and it is the real and important requirement for the QMS maintenance and improvement.
7.2.2	Review of requirements related to the products (contract review): The requirements are unclear, because the same procedure is not suitable for a contract of a standard product costing 10 \$ or a complicated project costing 100 M\$.	This requirement can be replaced by the expression of " <u>Checking and reviewing</u> ". The checking procedure is a good enough practice for standard products. A real review meeting is needed for complicated products and projects. An organization has to define the criteria for different types of contract procedures.
7.3.4	Design and development review: This review should be a review meeting but sometimes an organization wants to carry out this review as a document checking activity carried out by individual persons.	These reviews should be organized as <u>review meetings</u> , because that is the only way in identifying potential problems and in finding out solutions for the problems normally laying on the borderlines of different design disciplines.
7.5.2	Validation of processes for production and service provision: The first step is "Defined criteria for review and approval of the processes".	The word "review" is not needed at all, because the word " <u>approval</u> " is a good expression for this activity.
8.5.2	Corrective action: Reviewing nonconformities in the meaning that nonconformities are collated and analyzed and reviewing the effectiveness of the corrective action taken.	Reviewing nonconformities can be replaced by the terms of " <u>Collating and analyzing nonconformities</u> ". The latter reviewing activity can be replaced by the expression " <u>ensuring the effectiveness</u> ", because that is the real content of the activity.

Preventive Actions: The preventive action chapter should be removed from ISO 9001. There is little evidence that this is needed or that it is really applicable. In a majority of certified companies there is not

a single case. The very nature of ISO 9000 QMS has been designed to prevent nonconformities: planning, document checking, contract reviews, design reviews, product quality control, maintenance of processes, etc.

Internal Audits: Many companies utilize unqualified internal auditors. There might be a large pool of trained auditors but they may carry out only 0-2 audits annually. This kind of auditor is almost incompetent. This practice has been justified on the basis that the auditors will benchmark and will learn something good from other departments. The audited activity is not normally any benchmarking case. Benchmarking is a very different process. The results of audits could be sorted out and the real best internal practices should be identified and spread to other departments and processes. Stricter requirements for internal auditors are needed in order to improve the quality of internal audits.

Quality of Certification: The real problem in certification is that the quality of certification varies. There is no scientific evidence to support this contention but experience with three certification bodies suggests this is the case. Variation is mainly due to skills and attitudes of individual auditors. An auditor may put unnecessary high demands on small details but big deficiencies do not receive sufficient attention. Sometimes auditors want to please the customer by not being too demanding. Of course there are cases where a customer wants to change an auditor for these reasons. The real problem is that customers of certified companies shall find the certification process produces too much variation. ISO organization should put more attention for controlling the quality of external auditors.

CONCLUDING COMMENTS

The goal of this paper was to analyze the state of ISO 9000 standards against the common business management principles and to identify positive features as well the improvement items. The methodology has been to study research articles related to issues which have major roles in the performance of any QMS. The paper references the findings of some research articles in order to identify the grounds for keeping the positive features of ISO 9000 or to improve some features. Some research findings based on his own experiences during 20 years of quality management are presented. The paper analyzes the general criticism for ISO 9000 QMS and found no good evidence for these allocations. ISO 9000 is still a very good basis for QMS containing all the major properties. A common mistake is to blame the tool, when management is not capable in applying the system. The good features of ISO 9001 QMS in improving the performance of an organization have been summarized: common elements for good QMS, contract reviews, turning tacit knowledge into explicit knowledge, internal and external audits and the control of quality of production machinery and equipment.

Even though 90% of the ISO 9001 content is up-to-date, there are some improvement items: process definitions and requirements, review terminology, auditor requirements, content of corrective actions and deletion of the preventive actions. Also the certification process produces fluctuations partly because of poor control of external auditors and partly because of ISO 9001 definitions and requirements.

The limitations of this paper come from the nature of this study. It contains many proposals. The positive and negative features are based both on theoretical grounds and on experiences of the author. Some improvement proposals are based on common practices in business. In those cases ISO 9000 should simply be updated to follow the best practices. The ISO organization has a way to update its standards and hopefully it can do it in a timely way.

Future research could identify differences in the business results of organizations which follow the improved practices as described here. The organizations could be compared to organizations following the present standard requirements. Because the proposed improvements are in many cases already

followed by some forerunning companies, this would not be too difficult. The need changes in ISO 9000 terminology could be identified by a survey of quality managers.

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