SAFETY OF THE ENTITY’S FUNCTIONING IN THE CONTEXT OF THE IMPLEMENTED QUALITY MANAGEMENT SYSTEM IN ACCORDANCE WITH ISO 9001:2015 – A CASE STUDY ANALYSIS

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Abstract: The aim of the article is to present what benefits for the entity result from the implemented quality management system in accordance with the ISO 9001:2015 standard and whether having such a system is about organizational security and is effective protection against threats related to its functioning.

KEYWORDS: SAFETY OF THE ORGANIZATION, THREATS, ISO 9001:2015 STANDARD, QUALITY MANAGEMENT SYSTEM

1. Introduction

The history of the development of humanity describes many spectacular examples of projects among which those that were carried out with great impetus and had political, scientific, economic and military significance deserve attention. And so, in this good company, next to the invention of a computer, sending the first man into space, constructing a nuclear submarine, or digging a tunnel under the English Channel, the introduction of standards from the ISO 9000 family is mentioned [1].

Initially, these were standards aimed at improving the quality of products (products, services) based on the developed own standards of the organization and the procedures needed to achieve these standards. The reason for this type of activity was the high pressure of the organization’s environment, which demanded the repeatability of processes as a result of which products or services of the highest quality level were to be created. It was the result of using the PDCA (Plan-Do-Check-Act) cycle, which as it turned out quickly could apply to all processes and to the quality management system as a whole. The application of a process approach associated with the PDCA cycle and a risk-based approach is a perfect integration with the requirements of other management system standards. As it is easy to understand the essence of this type of activities was to ensure the safety of any organization that has implemented this type of standard and to improve the competitiveness of its operation on the market. Originally, the introduction of quality standards was to serve the military sector as one of the main pillars of ensuring the safety of the aviation industry. It was about the safety of users of military equipment, that is, soldiers, as well as the increase of the failure-free level in terms of manufactured equipment. It quickly turned out that such standards could be implemented in the automotive sector, also in order to increase the safety of users of motor vehicles. The next important step in the use of quality standards was the implementation of their requirements in order to improve the quality of medical services, and thus to improve the quality of patients’ health care. This was to be done by developing appropriate procedures to facilitate medical staff to apply a high-quality level of treatment. As in every innovative implementation, there were no problems related to overcoming obstacles of human nature, that is, convincing people that the implementation and learning of certain organizational solutions will improve the effectiveness and efficiency of actions, and the measurable effects of such applications will quickly become known in the form of improving the competitiveness of the methods of operation of the medical facility, which took the risk of implementing such solutions in relation to the one that did not date to take such a step. Examples of the possibilities of effective application of the requirements of quality standards in various economic fields allowed to understand the usefulness of such solutions in virtually every area of human life and, consequently, to understand the ease with which they can be assimilated in almost every organization. Thus, the universality of simple system solutions can become the guardian of the safety of any organization. A lot of companies do not even realize that the activities and solutions developed by it and the solutions for the organization of various processes are nothing more than a form of applying systemic solutions with the characteristics of the requirements of quality standards. They just need to be recorded in a skilful manner and distributed among the employees as part of the trainings and monitor the effects of the application in order to make continuous improvements. Despite the voluntary application of quality standards, it should be remembered that the constantly changing environment of the organization and the development of the level of organizational culture evoke the ever-growing need to improve the quality of services and products that are the basis of the international business.

2. Analysis of selected areas of the ISO 9001:2015 standard in the context of ensuring the organization’s safety

The evolution that has taken place in the last two decades, accompanied by the constant development of the organization, has made significant changes in the thinking process in understanding the needs and expectations of stakeholders (section 4.2 EN ISO 9001:2015)[2]. It can be proven by the fact that it is becoming easier to convince the top management about the need to implement ISO 9001 at a time when large purchasing companies around the world are beginning to demand the implementation of the standard by their suppliers. An example of this kind of procedure indicates that having the implemented standard constitutes a greater security of the organization in the face of increasing globalization. Today, there is no need to convince the presidents of large corporations or directors of small and medium-sized business entities of the need to make quality efforts due to the existence of such reasons as rising legal requirements, growing market demands and constant development of marketing advantage. An important driving force for the implementation of quality standards is the fact that the customer simply demands it. This kind of approach results directly from point 5.1.2 of this standard [3], which speaks of customer orientation perceived as meeting legal requirements and existing regulations, which should be strictly defined and understood. It is easy to guess that in the case of a disputed case resolved in court, a big advantage of any organization will be that it acts in accordance...
with the law and it will undoubtedly increase the possibilities of defense regardless of whether the issue concerns the responsibility for the product or service. In this aspect of the organization’s operation, it is another element that increases its security in the functioning on the market. Another important element on the way to increase the safety of each organization’s functioning is to conduct a thorough risk analysis. A new look at the action regarding risks and opportunities (point 6.1 of this standard)[4] highlights the fact that any observed risks associated with the operation of an economic entity may, in addition to triggering actions to prevent them from occurring, also lead to the observation of a worrying phenomenon. On this basis, an economic entity may, at a later stage of the procedure, implement elements of action to eliminate the source of risk, and if it finds that it cannot be stopped, it may implement such elements of its operation as: searching for new partners, changing the profile of products or services, acquiring new customers or changing the technologies used. Sometimes it may be to make an informed decision recognizing the existence of such a risk and not taking any action in the hope that this risk is a constant element of the functioning of our organization. An important element constituting the framework of action of each organization is the establishment of a quality policy (section 5.2 of this standard)[5], which includes obligations to meet the applicable requirements, and its availability to employees and interested parties demonstrates the transparency of all activities and provides further confirmation as a permanent commitment to continuous improvement of the quality management system. The essence of such an approach, however, is not the fact of creating a heal of bureaucratic documents for the purpose of obtaining a satisfied face of an external auditor, but introducing a well-functioning system that consistently allows solving significant organizational problems. This kind of innovative solution came with the last amendment of the ISO 9001:2015 standard, which entered into force of September 15, 2018. A bow towards treating people as important entities on whom everything in the organization depends is the fact that the dry record of point 7.1.2 of this standard [6] is entitled “People”. In contrast to the standards associated with product certification, where people employed in the organization are referred to as “staff”. As is clear from this type of description, the authors of the standards for the certification of products treat the organization’s employees in an objective manner. Returning to the ISO 9001:2015 standard, it should be noted that behind every type of activity or process being carried out, there is a man with his knowledge, competences, skills, training and a number of other assets that determine his value to the organization. This is an important element proving that the new edition of the ISO 9001:2015 standard has been provided with a new humanistic form. Establishing this kind of approach to an employee may be the fact that point 7.2 of this standard [7] talks about competences, and this is also an example of increasing the sense of security of the organization’s customers because it defines the way in which the organization cares for the development of personnel development through continuous training or concluding contracts with employees being experts in a given field of knowledge, if needed. Point 7.3 [8] is an inseparable element strictly related to maintaining competence referring to “consciousness”. This is, of course, about maintaining a certain kind of specific relationship with employees of the organization resulting from identification with the organization by understanding common goals, knowledge of all procedures, instructions and methods of implementation of processes and benefits resulting from efficient operation and consequences of non-compliant activities that may lead to the occurrence of negative phenomena. A further stage of building customer confidence in the organization comes in point 7.4 [9] regarding the “communication” understood as a competent and professional approach to internal and external contacts. The importance of the area in the field of the organization’s operation is an example of how to approach the customer, there are known cases where the person is responsible for external contacts, instead of acting as a positive business card of his company, through his turbulence contributes largely to the organization’s presentation outside in a very bad light. It is worth thinking about how to bring employees closer to the importance of this area and create positive behaviour patterns regarding a professional way of communicating over the phone and using elegant forms of answers to e-mails. No less important is the method of mutual contacts between employees within the organization itself, here also one should take care of the form of the relationship, which if required by the situation, should be impeccable and polished as part of integration meetings. Very often employees do not realize that the first conversation with a company representative, with the desire to establish a business contact or the first visit to such an organization may determine whether we will become a client of such an organization or we will abandon it for fear of being exposed to bad treatment. We will go somewhere where we will be served at a level that will satisfy us and which we expect. Although within the requirements of the standard we will not find any statement related to the ability to create teams for the proper functioning of the organization, but under the terms of competence, awareness, communication lies precisely this area. An ideal solution would be a situation in which employees of the organization would be focused around leaders and formed teams based on existing informal ties developed during joint problem solving or remedial and improvement activities. It is in crisis situations that some employees have the skills that distinguish them from the environment that allow them to manage teams. If we add to this the re-naming of informal leadership over a group in making such a person a formal leader, i.e. entrusting him with managerial functions, then we can be sure of the success of such a team. The security of the organization’s functioning is also a way of storing and developing the scope of information that should be defined as necessary for the functioning of the quality management system. A lot depends on the type of organization, its size, type of processes, the need for contacts with suppliers, the number of customers and stakeholders, the products and services produced and the competences of the people employed. At this point, the ISO 9001:2015 standard also comes to the aid by defining a framework for the supervision of documented information (section 7.5.3 of this standard)[10]. The requirements of the standard for this very difficult area determine the need for appropriate actions regarding the distribution of documented information, access to it, searching and use, making it available outside, if necessary, storing and decommissioning, maintaining records in the sense of protection against unintentional changes, hence introducing control of each subsequent version of documents. There is also the resolution of the issue related to the determination of confidentiality. The use of a verbal form of what the organization “should” do indicates that it is an obligatory requirement. It applies to all points of the International Standard cited so far. A lot of points are devoted to operational activities, the implementation of which determines the safety of the activities of organizations that have a direct impact on the level of processes being implemented, and thus on the level of manufactured products and services. It is impossible to refer to all significant areas related to planning, supervision, design, production and delivery of services, release of products and services, and
supervision over non-compliant solutions. One thing is certain, namely that each of these points refers directly to protecting the organization from improper conduct, and thus protects both the security of the client and the organization itself. At the end of this short journey in selected areas, it is worth mentioning the requirements of point 8.5.2. [11], which concerns identification and traceability. This type of requirement refers directly to the maintenance of an appropriate level of standards of manufactured products and services. It does not allow for the situation in which anonymity would allow the concealment of an incompatible product. Such solutions safeguard the security and protection of the client’s interests, and on the other hand, give the organization itself the possibility to exclude negative phenomena that may occur during the implementation of processes. In addition, they initiate changes of an innovative, breakthrough and reorganization nature, which are part of continuous improvement.

3. Strengths and threats resulting from the economic entity having the implemented quality management system

The implemented quality management system increases the values of functioning of each company in relations to its competitors. This results from many aspects to which one should include greater credibility of such an organization on the market and a higher level of customer trust to use the services of such an organization. Ensuring the safety of the organization’s activities is additionally raised by the whole range of tools that are included in point 9 of this standard [12]. These activities consist of all kinds of actions related to monitoring, measurement, analysis and evaluation processes. The organization should constantly assess customer satisfaction in the form of feedback on products and services provided in the form of questionnaires, documents confirming meetings with customers, praise or complaints, all kinds of reports on commercial matters closely related to conducting market activities and all market analyses. The organization should also conduct internal audits, scheduled at a specified frequency, and in the case of sensitive areas with the probability of an increased number of irregularities, conduct appropriate corrections and corrective actions, while this type of activities should be confirmed by the reports applied, stored as evidence of implementing the results of audits and the audit program. An important form of implementing activities related to maintaining a proper level of the organization’s functioning is the management review of the top management. The transparency of this type of undertaking is closely related to the assessment of the effectiveness of the organization’s activities. The highlights and shadows shown in the course of a reliable management review confirmed by the relevant report serve to ensure constant compliance of objectives and set directions for action related with meeting requirements and increasing customer satisfaction. The level of higher trust in an organization with a quality management system is additionally confirmed by the obligation to undergo an external audit carried out by independent external auditors who are selected by the audit organization by random selection. But as in any case, there are also significant threats here, resulting not so much from the existing system solutions, but regarding the area related to the integrity of people involved in such activities. It may happen that the internal audit will be carried out in an unreliable manner, firstly because of significant competence deficiencies of the employee selected for this type of undertaking and maybe it is not the greatest threat, the case where there is a pressure on the positive result of the audit by the supervisor of the employee conducting the audit much worse, an even worse dimension of this phenomenon appears when the result of the audit may be influenced by the top management in order to cover the existing gross irregularities. It is difficult to clearly state the occurrence of this type of cases, the more so that the documented information prepared on the basis does not confirm any violations, and the more difficult it is to capture because the essence of the audit is to collect and evaluate the samples. This means that on the basis of a correct sample obtained during the audit, we acknowledge that the organization has correctly implemented and maintained a quality management system. Sampling, as it can be seen, is one of the areas that poses a threat of wrong assessment of the process under analysis. In the case of external audits, there is also a threat resulting from the actions of an external auditor and this is not a lack of competence, because these are confirmed by the certification body and always the audited entity may request their presentation. A much greater threat may be obtaining positive audit results based on an agreement with an external auditor in exchange for obtaining material benefits or other types of intangible benefits (job offer in the organization for a family member of an auditor). Such situations are very difficult to capture, and the effect of such “positively” passed audit by the organization may be the confirmation of the irregular functioning of the economic entity and irregularities that increase in it, which instead of being removed or corrected cause the piling up and consequently may lead to unpredictable occurrences of negative phenomena. Another threat may be the phenomenon of familiarity, which means that the organization attaches itself to the auditor, and this person, in turn, recognizes that he knows all the nooks and crannies of his routine and as a result of this type of activity he may not notice any malfunctioning of the system.

4. Summary

The presented problems are only a short journey describing what tool is the application of the requirements of the ISO 9001:2015 standard in order to counteract threats occurring within the organization itself as well as in its immediate environment. The very implementation of the standard in the organization significantly improves the safety of its operation, but it should always be borne in mind that the adoption of this type of solution will not guarantee full security to any organization. A lot depends on the system’s maturity and the approach to system solutions demonstrated by employees. Even the best system solutions invented by humans can make a significant contribution to increasing the level of security, but we know perfectly well that unfortunately this is not a sufficient condition. So far, no one has yet invented such a system that allows to guarantee protection against human errors. It is easier to introduce technical security measures informing about failures, irregularities in the functioning of the equipment than to determine when the employee failed. And it is not about making mistakes, it is a human thing to be wrong, but about much more difficult areas related to the employee’s ethics and integrity. Of course, one can develop the most perfect Employee Ethics Codes, but they will remain only dry records if lucrative proposals are made by competitors, which in this way may seek to destroy or hostile takeover of our organization’s potential, often built for decades by the honesty of employees. Therefore, the future must be built on the creation of criteria that everyone should observe, something like the idea of “fair play” in sport. It is about creating a system of motivation that would reward organizations and, of course, employees employed in it, e.g. “honest
businessman” or “irreplaceable employee”. These types of activities are not a kind of utopia or phantasmagoria, but a guarantee of business activities that lead to success. An important role should be played by the “National Certification Units”, which of course are not new, but it is a matter for the creation of such a mechanism that would guarantee their total independence and objectivity. Such an entity would have to help organizations, and not only to deal with judging their way of conducting business in a way far from friendly and partner-like treatment of business entities. Since it has been possible at the European Union level to prohibit the production of plastic disposable accessories and work to improve people’s awareness, it is even more possible to make appropriate changes at the EU level to increase the flexibility and improve the work of Certifying Units operating in the Member States. Someone must be the first and it remains to be hoed that appropriate solutions in this matter will defend themselves and quickly find imitators among other units on other continents. The current and unanticipated danger is the fact that a group of people may emerge who, having received appropriate tools at the EU level guided by their own interests, will encompass their knowledge needed to implement management standards and will lead to the ISO 9001:2015 standard instead of creating economic development will cause its stop [13].

Another equally important issue is the fact that up to now organizations that have implemented quality management systems, in addition to bragging about this on their websites, unfortunately do not share their knowledge and experience by treating each other as potential opponents. Maybe it’s time to change this fossilized mindset in organizations. There are, after all, various industrial sectors that are united by the same goal – customer satisfaction and development. It is not the custom of modern organizations to build an organizational culture based on providing help in the area of advice or guidance. It would be easier to join forces in related organizations and on this basis to make a diagnosis in the area of developing common procedures and solutions. But as can be seen from the presented problems, we still have a long way to go in creating a system that would allow both the national and international level to preserve the identity and traceability of certificates in order to allow an equivalent assessment of certification procedures. The International ISO 9001:2015 standard is a framework diagram of an “ideal organization”, although everyone realizes that the ideal in the modern world is the pursuit of its achievement by developing tools and instruments that are based on many years of experience. The creators of quality standards were guided by the idea of helping to discover the path to the ideal product and service, and recent years show that this is also the way to create the perfect employee, the ideal leader (in this role there is the highest management in the meaning of point 5.1 [14] talking about leadership and commitment) understood as a conscious and committed participant in social life and a satisfied customer aware of own needs. At the end, a question arises regarding ensuring the safety of the organization by implementing a quality management system in the field of supplying full-value products top own clients. Certainly, the standard itself will not do it, but it will show the right way in the pursuit of high quality solutions. On the way to achieving full success, actions are still needed from all interested parties, supported by the development of strong ethical principles. This approach will surely strengthen the clients’ trust in the organization and consolidate its market position.

5. Bibliography

[4], [5], [6], [7], [8], [9], [10], [11], [12] Polish Committee for Standardization: PN-EN ISO 9001:2015