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Threats for ISO 9001

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Abstract:

Purpose: The subject matter of the article is defining ISO 9001 standard's popularity trend and presenting chosen factors discouraging organizations to implement system based on this standard, as well as factors decreasing effectiveness of operations related to the implementation of this standard and maintaining it.

Design/Methodology/Approach: Literature study.

Findings: Despite large popularity of quality management system according to ISO 9001, global decrease of the number of implemented, related systems is noticeable. Reasons of this state of matters are strongly differentiated, however their detailed analysis and appropriate actions taken in response are able to decrease unwillingness to implement systems and increase efficiency of implementation activities.

Practical implications: Indication of threats for effectiveness of quality management system, as well as exemplary activities taken in response to them will allow organizations to minimize their negative influence.

Originality/value: The vast majority of publications describe advantages related to standardization. This article is one of a few publications discussing the threats noticeable in the area of qualitative standardization. This area is influenced by issues, awareness of which may help organizations in their minimization by means of taking appropriate correction and preventive actions.

Key words: ISO 9001, quality, quality management system, pro-quality culture, ISO 10014, effectiveness.

JEL code: L15.

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1. Introduction

The issue of quality becomes more and more popular in both organizations which seek implemented changes in its results and clients who expect more durable products which would be supplied in a faster way and be more adjusted to their taste.

Discussion concerning quality and instruments which ensure quality becomes even more significant today - in the time when the world's economy struggles with the economic result of pandemics, and the geopolitical situation connected with the war in Ukraine even more exacerbates the problems. It coincides with the times when not only the quality of products becomes more significant, but also, among others, the quality of health care system or diplomacy.

Problems related to quality are often connected with its definition (Spychalski, 2011), thus hoping its perception will be consistent on the part of organizations, that adhere to different values and function in distinct legal systems and among various cultural features. For such kinds of business relations, the possibility to make use of an international standard becomes of a great importance, since they can use unified requirements well-known to both parties.

The fulfilment of these requirements is verified by an independent entity in the certification process. As it was proved in the remaining part of this article, implementation of quality management system is related with problems, when underestimated may lead to lower efficiency of actions undertaken by an organization. At the same time, it is worth paying attention to the fact that a part of problems result from the character of the standard. Organizations implementing systems do not have any influence on this fact and can only propose mitigation efforts.

Negation of standardization in the area of quality is not the author's aim, since, as the author states, it is connected with profits significantly prevailing its shortages. The aim of the author is indicating problems noticed by him and showing exemplary issues which, when implemented, may help the organizations to minimize negative effects. Due to editorial limitations of this article, the author only focused on two chosen issues, whereas it is important to emphasize that they are not the only ones to be paid attention to.

2. Materials and Methods

For the needs of this research paper, the author analysed Polish and foreign literature in the field of standardization, including mainly quality management systems based on ISO 9001 standard, as well as source data such as statistical data and standards. It allowed for in-depth analysis of the described situation from the perspective advantages and disadvantages of standardization and quality management system, as well as related threats and possibilities.

3. Results

ISO 9000 series standard constitutes quality indicator for different kinds of organizations. Its popularity fluctuated throughout the years. However, it can be stated without any doubts that, nowadays, it is the most recognizable standard in the area of quality all over the world. The quality management system based on ISO 9001 standard is the most popular management system today.

The number of valid certificates was 916 842 and concerned 1 298 666 localisations as of 31st December 2020. Meanwhile, other listed systems, such as based on ISO 14001 system of environmental management and based on ISO 45001 system of occupational health and safety management could be characterized with 34 473 and 190 481 valid certificates and 568 798 and 251 191 localisations (International Organization of Standarization,2020).

Quality management systems based on ISO 9001 are implemented in organizations from 190 countries. Poland is on the 12th place on this list. Taking into consideration, above mentioned total number of countries, this result indicates high popularity of ISO 9001 among Polish organizations. Even though quoted numbers directly indicate the popularity scale of ISO 9001, much better view on this subject matter may be brought by its analysis throughout the years.

However, it is significantly impeded due to lack of accessible transparent and undoubtful data indicating the number of valid certificates in particular years. Figure 1 and 2 present the number of valid ISO 9001 certificates generally in the whole world and in Poland, on the basis of data presented by International Organization of Standardization (ISO).

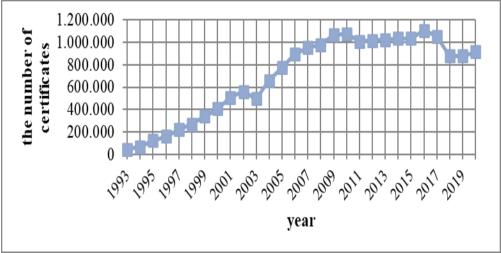
The data is published every year within the frames of a publication 'ISO Survey", created on the basis of data transferred by certification entities form particular countries, accredited by members of IAF (International Accreditation Forum). Due to the fact that this data is transferred on voluntary basis, as well as due to changing number of entities transferring it every year, ISO emphasizes that presented information is not treated as database.

Large decrease of the number of reported certificates in 2017 in comparison to 2016, is explained with, among others, changes in the way data is reported. The explanation is included in attached compilations. It is referred to both situation in Poland and to situation all over the world. The subsequent decrease of the number of certificates in the next year was explained with wrong reporting of their number by certification bodies and with the lack of share in research of entities in some of the countries.

Bearing in mind described circumstances, it is important to state that compilations published by ISO are the most detailed information concerning the implemented

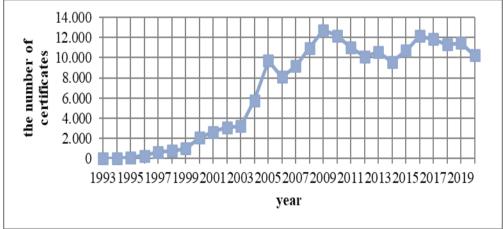
management systems all over the world. They also constitute the best instrument to observe the changes of trends in their certification.

Figure 1. The number of certificated granted to quality management systems according to ISO 9001 standard all over the world in years 1993-2020.



Source: Own study on the basis of International Organization of Standardization, The ISO Survey of Management System Standard Certifications – 1993-2020, https://www.iso.org/the-iso-survey.html [access: 04.04.2022].

Figure 2. The number of certificates granted to quality management systems according to ISO 9001 standard in Poland in years 1993-2020.



Source: Own study on the basis of International Organization of Standardization, The ISO Survey of Management System Standard Certifications – 1993-2020, https://www.iso.org/the-iso-survey.html [access: 04.04.2022].

Notwithstanding the emphasized problems connected with collecting data about certified systems by ISO, it can be stated without the shade of doubt that management systems based on ISO 9001 are at the forefront among all management systems both in Poland and all over the world.

However, some kind of slowdown, which should not be omitted in the process of situation analysis, attracts attention. Even though reason of such state of matter can be sought in other factors not related with the ISO standard and quality management system (among others with economic situation connected with pandemics and related savings or even liquidated business activities), it seems to be the signal of problems related with further increase of the number of organizations possessing ISO 9001 certificate. It should stimulate reflection on this issue. First of all factors which may influence the decreased interest of organizations in implementing the requirements of the ISO standard ought to be analyzed.

4. Discussion

As P. Rogala (2020) states, profits related to standardization, also the one referring to quality management systems, are mainly presented in publications of standardizing organizations and as a result of realized or commissioned research. Critical publications, on the other hand, are mainly published by individual experts basing on their experience or thoughts.

Paying attention to threats observable in the area of quality standardization is all the more important. As it was accented at the beginning, this area is influenced by issues, awareness of which may help organizations to minimize them by the means of appropriate correction and prevention activities. This research paper focuses on two of them:

- 1) Complications connected with the form of ISO 9000 series standard and
- 2) Financial aspect.

4.1 Complications Connected with the Form of ISO 9000 Series Standard

While reading ISO 9000 series standard, their characteristic style can be noticed. It differs a lot from available literature concerning improvement of quality in organizations. In this area, the mentioned standards related with quality management system do not differ significantly from all standards.

However, it should be noticed that users of standards related with management systems are not only people with technical education. These are also people connected with widely understood management, for whom the language characteristic for all standards may be difficult to understand.

It also ought to noticed that language used in ISO 9001 and the standard's form based on PDCA cycle –are consistent with published nowadays ISO standards related with other management systems. It is undoubtedly significant simplification for possible integration of systems.

From the point of view of discussed issue, it should be, however, noticed that mentioned integration of systems is a more advanced and complicated phenomenon than implementing single, independently functioning system.

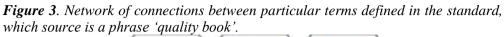
Thus resources – including human resources – which are planned by an organization to realize this aim are then significantly higher. Every additional complication of language and standard's character, even caused by the willingness of unification with other standards, may lead to wrong understanding of particular requirements and even to discouragement to implement the system.

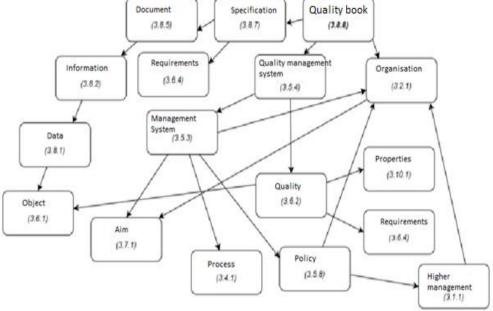
The number of implemented management systems based on ISO 9001 in Poland and all over the world mentioned at the beginning of this research paper show the scale of interest to increase quality inside an organization. Taking into consideration economic reality, it should be thought that even higher number of entities considered the system implementation, but was discouraged with, among others, difficult to understand language and complicated character of the standard.

Requirements to be met by an organization in order to be granted the certificate are included in ISO 9001 standard. Full understanding of its content is, however, not possible without using ISO 9000 terminological standard which presents the basics of quality management systems and nomenclature used within these systems. In order to present the particular terms in the most precise way, the standard, in its particular definitions, emphasizes terms which are defined in its other points.

Due to this fact, full and exact understanding of particular term is possible only after reading definitions to which the user is directed. Figure 3 presents a network of connections between particular terms defined in the standard, which source is a phrase 'quality book'. It is defined as 'specification in which organization quality management system was defined' (Polski Komitet Normalizacyjny, 2016). This definition, however, was recorded in a specific way in the ISO standard, as: 'specification (3.8.7) in which quality management system (3.5.4) of an organization (3.5.2)' was defined.

Italics used with particular terms and numbers in brackets indicate that there is a definition related to these terms. In-depth analysis of the indicated term actually requires familiarizing with 16 definitions. At the same time, it should be noticed that network, prepared for the needs of this publication, does not include comments and examples which in turn, include further references.





Source: Own study on the basis of Polski Komitet Normalizacyjny, Systemy zarządzania jakością – wymagania (PN-EN ISO 9001:2015-10), Polski Komitet Normalizacyjny, Warszawa 2016.

At this point, it is worth to ask a question, if it is not the excess of precision. Such a remark has been included in the publication of T. Kotarbiński (1965): 'All in all, in that respect in which precision is necessary, it is not necessary all the time; far from it maximal, complete precision is not always expected'. It should be borne in mind that, in case of discussed standards, we are dealing with the trial to standardize approach to an issue difficult to describe, since it is not material and often ambiguous. Precision in such case is understandable, even required. Its excess, however, according to quoted opinion of T. Kotarbiński also in this case may cause negative results, mainly discouraging organizations to use the ISO standard.

This excess of precision seems to be in contradiction with the general character of ISO 9001 standard which, does not describe the way majority of its requirements are to be fulfilled, giving organizations the possibility to make their own decisions in this scope.

Transfer of exactness in ISO standard's content formulation by its authors in this direction leads to ambiguousness and lack of clear guidelines concerning the ways of requirements fulfillment, constituting the next source of complications during implementation works.

Formulation of ISO 9000 series standards is an issue on which organizations do not have real influence. However, it is not an issue which can be ignored. This problem presents the importance of competent personnel - in this case mainly workers who are responsible for system's implementation.

Comprehensive knowledge concerning contents of ISO 9000 series standards and quality management instruments, as well as possessing analytical skills allowing for wide and precise approach to the standards requirements, is absolutely required. Psychosocial competencies, such as the ability to work in a team, delegation of tasks and verifying if they are performed, creativity, personal culture or problem solving skill are no less important.

4.2 Financial Factor

ISO 9001 standard, in its concept is not directly focused on increasing financial performance of an organization. Such results can be expected, however, it should be treated as an added value of widely understood care for quality, so mainly higher awareness concerning personnel quality, lower number of defects, higher clients' satisfaction, proper reactions to risk, as well as interference of the ISO standard in an organization's structure – mainly process approach implementation. Nonetheless, financial issues have a very important place in the discussion concerning quality management.

According to A. Simon and P. Kafel (2018), out of three most common reasons for quitting ISO 9001 certificate by organizations, two concerned economic issues, such as organizations' financial problems and too high cost of certification. This fact is also confirmed by other research. J.Rosiak – Szyrocka (2018) also pays attention to a similar reason of a decrease of interest connected with quality management system maintenance due to high costs of system maintenance and certificate.

Lack of resources to implement quality management system according to new requirements of the standard, after it was updated in 2015 is also indicated by A. Walaszczyk (2018) as the most frequent barrier in the process of implementing quality management system in small and medium businesses sector. This problem is also noticed by D. Zimon and L. Bednárová (2016), who attract attention to the issue of lack of resources to maintain highly effective quality management system in small and medium businesses.

Inappropriate perception of the ISO standard - expecting fast and effective results, lack of which may lead to management and workers' increasing frustration, looking for guilty people, as well as resigning from activities directed to organization's quality culture popularization is also not without significance.

Moreover, there is research indicating lack of essential differences between financial results recorded by organizations with implemented and certified quality

management system, and the ones which resigned from prolonging the validity of the certificate (Cândido *et al.*, 2016). It may suggest lack of the standard's application influence on organization's financial profits.

In such case, however, it is advisable to bear in mind that resigning from prolongation of certificate validity proving quality management system's implementation is not unequivocal with the loss of all profits relates with its implementation, nor can it be thoughtlessly compared with a situation of an organization which had not had the system implemented before. The lack of certificate is directly related with the lack of objective and independent confirmation of the standard's requirements fulfillment, which may, among other, limit trust towards organization and close its possibilities to launch cooperation with other companies.

However, it is not unequivocal with a disturbance of previously implemented process approach and with organization's resign from using the remaining rules presented in the standard, which correspond with other profits resulting from its use.

The influence of a resignation from ISO 9001 certificate's validity prolongation on results performed by an organization depends on a lot of variables and is not possible to define in an universal way for all organizations. On the one hand, resignation from the certificate may relate with loss of profits mentioned above. On the other hand, attention should be paid to related reduction of expenditure connected with the system's maintenance, such as certification process (Ferreira and Cândido, 2021).

Some kind of an answer to perceiving ISO 9001 as insufficient to transfer quality requirements fulfillment to the increase of profits, is ISO 10014 standard "Quality management – Guidelines to gain financial and economic profits"². The standard in its introduction puts emphasis on the possibility to achieve a lot of financial and economic profits, which may appear in case of obeying quality management rules ³ presented in ISO 9000.

There are exemplary methods and tools (together with their short presentation) in their structure. The use of them may help organization's management to gain profit. The ISO standard includes the following profits: *the increase of profitability, incomes, budget implementation, decrease of costs, increase of financial flow,*

²In 2021 a new publication of international ISO 10014:2021 was issued. During the time this article was being written, this standard did not receive a status of a Polish standard. Due to this fact, the author bases on PN-ISO 10014:2008 standard.

³In ISO 9000, in force at the time of ISO 10014 was issued, eight rules of quality management were indicated. In the edition from 2015, the number of rules was decreased to seven. A rule 'systemic approach to management' has been removed. Except for this change, there were also changes connected with other rules. However, from the point of view of this article, they are treated as of minor importance.

increase of return on investment, competitiveness increase, keeping customers and increasing their loyalty, the increase of taking decisions efficiency, optimal use of accessible resources, increasing worker's responsibilities, improvement of intellectual capital, optimal and effective processes, supply chain functioning improvement, reducing the time of supplies to market, increasing organizational efficiency, reliability and durability (Polski Komitet Normalizacyjny, 2008).

Methods and tools which can be used for better implementation of particular quality management rules have been proposed according to process approach assumptions. The following stages have been distinguished: entering into process (being in the majority of cases the results of self-assessment), exit from the process and the process itself, which particular stages are presented according to PDCA cycle.

This cycle can be referred to as a foundation for any of the pro-quality activities in an organization. Except for ISO 10014 standard, also other mentioned standards, including ISO 9001 and other currently created standards related to management system are based on this cycle. PDCA cycle should constitute a base for actions leading to fulfillment of one of management rules which is 'improvement'.

Moreover, ISO 10014 standard includes self-assessment questionnaire: the initial and comprehensive one. An organization can perform evaluation of quality management rules fulfillment on its own with the support of these questionnaires, making use of a point scale indicating the level of maturity in particular areas.

As E. Skrzypek (2012) states, this kind of self-assessment constitutes a voluntary valuation of quality management system state and shows worker's engagement and searching for possibilities of continuous improvement. K. Cholewicka – Goździk (2008) assigns additional importance to self-assessment, emphasizing its usefulness for diagnosis of management condition, which is the first step to strategy, policy and current operational tasks revitalization.

5. Conclusions

Contrary to its basic message directed towards quality, not directly to financial profits, ISO 9001 standard's in-depth analysis allows to notice that it does not omit completely the significance of expenditures for quality. Just the other way, it promotes rational activities and taking into consideration the expenditures. However, attention should be attracted to the fact that both ISO 9000 and ISO 9001 include references not only to efficiency⁴ of performed activities, however, both of these forms promote their realization in an effective way⁵. Due to the fact that financial

⁴According to ISO 9000, efficiency is referred to as 'relation of achieved results and used resources' (Polski Komited Normalizacyjny, 2016).

⁵According to ISO 9000, productivity is referred to as 'relation of achieved results and used resources' (Polski Komited Normalizacyjny, 2016).

issues are still in the background of quality requirements, it is advisable to make use of guidelines of ISO 10014, which constitutes some kind of bridge between these financial issues and a possibility to achieve considerable financial profits.

Increasing both mentioned indicators, both efficiency and productivity, facilitates making use of PDCA cycle. However, it should be remembered that the use of this cycle does not only have to limit to operations directly connected with quality management, but due to its universal character, can and should be used in current activity of an organization, both in strategic, as well as operative perspective.

The whole ISO 9001 standard ought to be considered in an analogically comprehensible way – not like control list indicating subsequent requirements to be fulfilled and ticked, but as a document being a guideline leading to creation of structured and effective organization.

Using different kinds of pro-quality solutions seems to be advisable to eliminate barriers discouraging to implement the system, as well as problems which may appear in course of its implementation and maintenance. It refers to popular quality tools, as well as solutions exceeding standard solutions associated with quality management system, such as Kaizen philosophy, 5S method.

However, there is also a great significance of method creators activity, who are responsible for the content and form of the ISO standard, and for the statistics presenting its use in organizations all over the world which currently may arise doubts as to the reliability of the way they had been created, which can manifest itself in discouragement to implement the system in new entities.

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