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# The use of quality management systems for limiting the risk of business processes

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**Abstract**
Quality management systems established in conformity with ISO 9000 standards have an over twenty-year tradition. In the article attention has been focused on relations between goals defined within the framework of QMS (Quality Management Systems) and business results. The amendment of the bill, planned for the year 2015, changes the previous concept of QMS by introducing a number of new requirements which adjust organisation management systems to the current level of knowledge and environment of the organisation. One of the requirements that will be emphasised in a new issue of ISO 9001 standard is risk management, the innovation implementation process and information management. The article reviews the requirements contained in the current issue of the standard, focussing on requirements which limit the risk of organisation functioning and the risk related to innovation design and implementation.

## Introduction

Quality management systems (QMSs) have become a tool used by many enterprises in their business practices. This tool is applied in both, big multi-division companies employing thousands of people (e.g. coal companies) and in small family firms included in the group of "micro-companies". The motives behind the implementation of Quality Management Systems vary. Numerous studies have been conducted in this scope. P. Grudowski lists external and internal motives of QMS implementation in the sector of small and medium-size enterprises. The internal motives include:

- striving to ensure a better coordination of processes;
- greater commitment of employees;
- better supervision over documentation;
- better properties of manufactured products;
- increase of profit resulting from the reduction of manufacturing costs.

According to him, external factors include the fulfilment of requirements, limitation of advertising and a more favourable market position of an enterprise [1]. J. Klimek [2] considers quality management systems implemented in small enterprises in terms of "bureaucratization" of activity and benefits provided by the implemented QMS. Among these opposing approaches he distinguishes high costs of QMS implementation and maintenance offset by an efficient system of company management, efficient management of an organisation, legal defence of products, increased share in the market, favourable image and implementation of strategic tools leading to the company's sustainable growth. E. Skrzypek draws attention to changes in mentality that accompany the implementation of QMS in organisations [3]. The quoted views on the benefits are a small fraction of research conducted in this area. In studies on QMS the problems of limiting the risk are emphasised only within a small scope. An overview of the literature regarding business risk is in most cases referred to risk insurance, liquidation of damage and prevention. R. Rudnicki [4] believes that the listed areas are only a part of the risk management concept.

Risk management with regard to quality is an important element of a management system, especially in cases where risk evaluation is imposed by legal requirements.

## Quality management systems versus business risk

Risk is uncertainty about future events or the results of a decision which lead to an unexpected loss or gain. Risk most frequently results from probable events, which are independent on us, or is a consequence of a decision. The source of risk is usually lack of information or incomplete information.

Risk management links the probability of its occurrence to intensity. The modern approach to risk is intrinsically related to uncertainty. B. Kuc claims that risk is a function of uncertainty – the greater the uncertainty, the higher the risk. Actions taken under conditions of risk may be quantified by means of the calculus of probability. Activities under conditions of uncertainty do not provide such a possibility [5].

In a few of his works the author has drawn attention to relations between quality and risk limitation [6, 7, 8]. He believes that the occurrence of nonconformity (both, in the production and service-related or management area) is not caused by a human error, but an error of the system that did not take into account the risk connected with technological progress, the proof of which are disasters in the nuclear power industry, disasters related to the extraction of raw materials, in the automotive or aircraft industry [6].

Quality management systems can also be viewed from the point of view of limiting the risk related to one's business. Quality management systems are commonly associated with 9000 series standards. These standards have been applied since 1987 and are not addressed to a particular branch, so the requirements are formulated in a general way. In the first and subsequent issues of the standard, the requirements directly related to risk management were not detailed. The interest accompanying the introduction of quality systems implemented in accordance with ISO 9000 standards resulted in the development of ISO standards for particular branches. At this point we might list the automotive industry (ISO/TS 16949:2009 Quality management systems – *Detailed requirements regarding the application of ISO9001:2008 in serial production and the production of spare parts in the automotive industry*), the medical branch (PN-EN ISO 13485:2012 *Medical products – quality management systems – Requirements for the purposes of legal regulations*), the food industry (ISO 22000:2005 *Food safety management systems. Requirements to be fulfilled by every organisation included in a food chain*). The extended system of quality management is introduced in organisations which apply welding technologies. An example are requirements for quality management systems in the welding industry contained in ISO 3834 standards – sheets 1 to 5 *Quality requirements for fusion welding of metallic materials*. The establishing of these standards was a natural consequence of the popularity of implementing the requirements contained in ISO 9000 standards and a rapid technological development which has accompanied humanity since the 1950s. The structure of the above mentioned standards is similar to that of ISO 9001 standard, or is an extension of requirements contained in ISO 9001, to which specific branch requirements have been added. The listed standards are a collection of the most frequent requirements focussed on quality and the limitation of risk connected with failure to fulfil the requirements.

Table 1. Basic national and international standards regarding risk management [9]

| Body | Name |
|---|---|
| ISO/ IEC | ISO 31000:2009 Risk management – Principles and guidelines |
| | ISO/IEC Guide 73:2002 Risk Management – Vocabulary – Guidelines for use in standards |
| | ISO/IEC Guide 51:1999 Safety aspects – Guidelines for their inclusion in standards |
| | ISO 14971:2000 Medical devices – Application of risk management to medical devices |
| | ISO 17776:2000 Petroleum and natural gas industries – Offshore production installation – Guidelines on tools and techniques for hazard identification and risk assessment |
| CSA | CSA Q 850:1997 Risk Management Guidelines for Decision Makers |
| JSA | JIS Q 2001:2001 Guidelines for development and implementation of risk management system |
| AS/ NZS | AS/NZS 4360:2004 Risk management |
| BSI | PAS 56:2003 Guide to Business Continuity |
| | BS 31100:2008 Code of practice for risk management |
| | BS 6079-3 Project Management – Part3: Guide to the management of business related project risk |
| | PD6668 Managing Risk for Corporate Governance |
| ON | ONR 49000 Risk management for organizations and systems – Terms and principles |
| | ONR 49001 Risk management for organizations and systems – Elements of the risk management systems |
| | ONR 49002-1 Risk management for organizations and systems – Part 1: Guidelines for risk management |
| | ONR 49002-2 Risk management for organizations and systems – Part 2: Guidelines for the integration of risk management into the general management system |
| | ONR 49003 Risk management for organizations and systems |
| | ONORM S 2300 Risk, security and crisis management – Concepts |
| | ONORM S 2310 Risk, security and crisis management – Selection and verification criteria for persons appointed for crisis management |

Irrespective of quality management standards which contain requirements limiting the risk there is a number of standards that directly address risk management. These standards have been given in table 1.

The application of quality management systems for achieving the strategic goals of an organisation along with business and financial goals was emphasised already during the preparation of the last amendment to ISO 9001 standard as of 2008. The concept of a gap between the goals of an organisation and the achieved results proposed in 2003 may be treated as a method striving to limit an organisation's business risk by evaluating the gap between the defined goals and the achieved results [10]. This has been illustrated in figure 1.

ISO 9001:2008 standard does not contain direct requirements regarding business risk. However, having read carefully the provisions contained in this standard, one can find a number of requirements the fulfilment of which leads to a limited risk. This approach is geared towards three management areas (Fig. 2), namely:

– fulfilment of requirements specified by the customer;
– fulfilment of legal and other requirements;
– ensuring the productiveness by making sure that the processes are effective and efficient so that the goals set on the basis of analysis of changes in the internal and external environment of an organisation can be achieved.

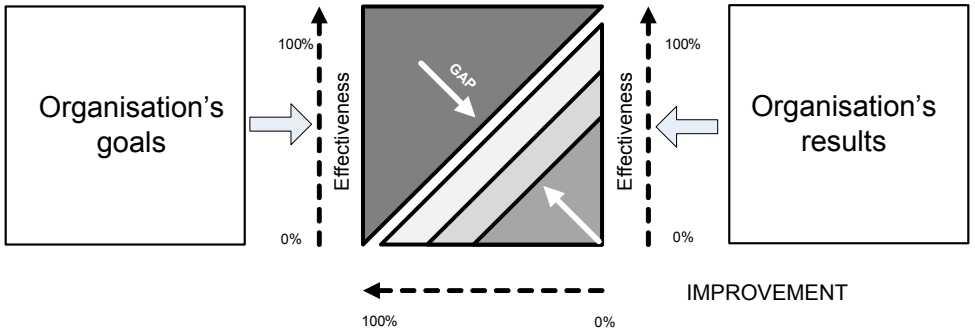


Fig. 1. Effectiveness of the QMS as a measure of gap between organizations objectives and results [11]

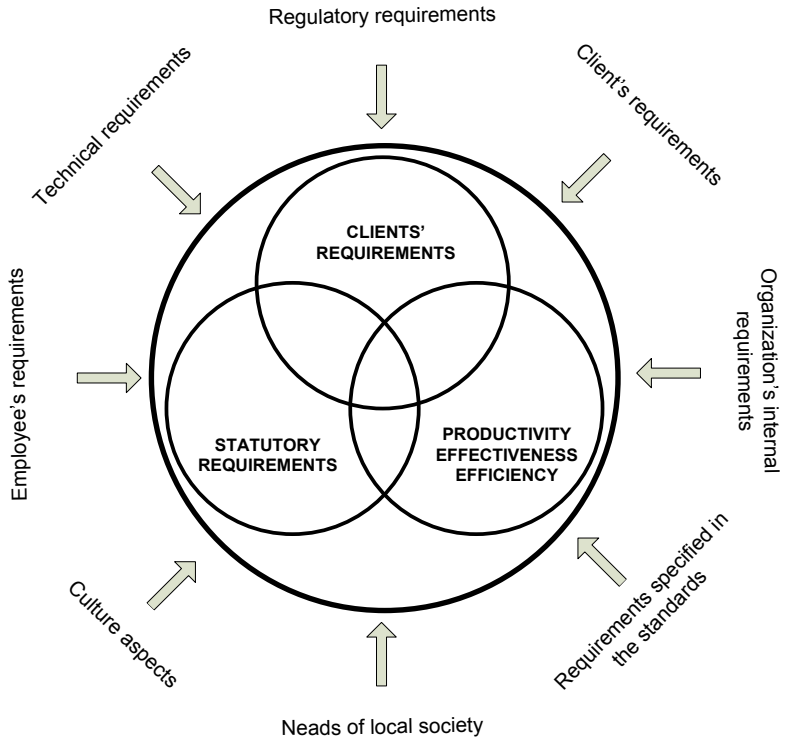


Fig. 2. Factors to be taken into consideration when developing the standards [own study]

Every organisation operates in a changing environment. Management, as well as operational processes are influenced by both, random and specific factors. Random factors have an impact on processes. The random changeability of a process can be evaluated by means of statistical tools. Specific factors can be detected and removed. Apart from the random and specific factors, J. Mothes additionally distinguishes uncertain factors that influence processes. In this group, he includes all parameters which the decision maker has no information about [12]. QMSs based on the requirements of ISO standards, both 9000 series and branch standards, are aimed at limiting the risk in the context of management processes, the fulfilment of legal requirements and operational processes. The effectiveness of operational processes is significant from the point of view of financial risk evaluation by guaranteeing the productiveness, effectiveness and stability of processes. These factors, together with improvement, may be measures of risk included in quality management systems.

Problems related to the introduction of requirements regarding the analysis of risk for standardized quality systems appeared already during the works on the amendment to ISO 9001:2000 standard. Although the „amendment" from the year 2000 and 2008 did not take these issues into consideration, risk management is present in the requirements contained in the paragraphs of ISO 9001 standard version 2008, listed in table 2.

In the big amendment to ISO 9001 standard, planned for the year 2015, risk management is to be formulated as a separate requirement. Apart from the above mentioned risk management there will be a number of requirements which in the system approach are related to risk limitation. They include management of organisation finances, aspects related to time and effectiveness, management of product life cycle, knowledge management. The details can be found in items [13, 14, 15]. Among the concepts listed in the above mentioned publications there is a proposal to include in the standard the requirements regarding innovation management. P. Merrill [16] draws attention to the risk connected with the introduction of innovation. He claims that organisations should have a portfolio consisting of potentially new products, which will be manufactured within 5–10 years. The longer the time of innovation introduction, the greater the risk. A portfolio should contain designs which are the result of improving the existing products, as well as more radical solutions that pose a greater risk for an organisation.

Table 2. Requirements contained in ISO 9001 standard referring to risk management (own study on the basis of ISO 9001:2008 standard)

| Paragraphs of ISO 9001 | Requirement |
|---|---|
| 1.1a | To show an ability to continually deliver a product that fulfils the customer's requirements as well as relevant legal and other regulations; |
| 4.1d and Note 1 | To ensure the availability of resources and information necessary to monitor and support the course of processes. The processes are related to the management of activities, resources supply, product processing, taking of measurements, analysis and improvement; |
| 5.1e | To ensure the availability of resources; |
| 5.6.3c | Management overview – to define necessary resources; |
| 6.1 | To ensure resources necessary to implement and maintain QMS and to increase customer satisfaction; |
| 6.2 | To ensure the staff competences based on education, training, skills and experience; |
| 6.3 | To ensure and maintain an infrastructure necessary to achieve conformity with requirements; |
| 7.1b | To define needs related to the establishing of processes and documents and to ensure specific resources; |
| 7.2.2 | Before undertaking to deliver a product to the customer, check if the requirements have been defined, if the discrepancies between the order and previous arrangements have been solved and if the organisation is capable of fulfilling the requirements; |
| 7.3.1 to 7.3.7 | To supervise and plan the designing and development of a product; |
| 7.4 | To define criteria for the evaluation of suppliers; |
| 7.5 | To ensure supervision over production conditions, which reduces the risk of providing the customer with nonconforming products; |
| 8.2.1 | To monitor information on the customer's perception regarding the fulfilment of the requirements. This is an important element of the identification of risk resulting from the lack of customer satisfaction, the loss of reputation and in consequence the loss of market position; |
| 8.2.2 | An internal audit supports operations risk identification; |
| 8.2.3 | An organisation should take action eliminating the risk of potential nonconformities and should prevent their occurrence. |

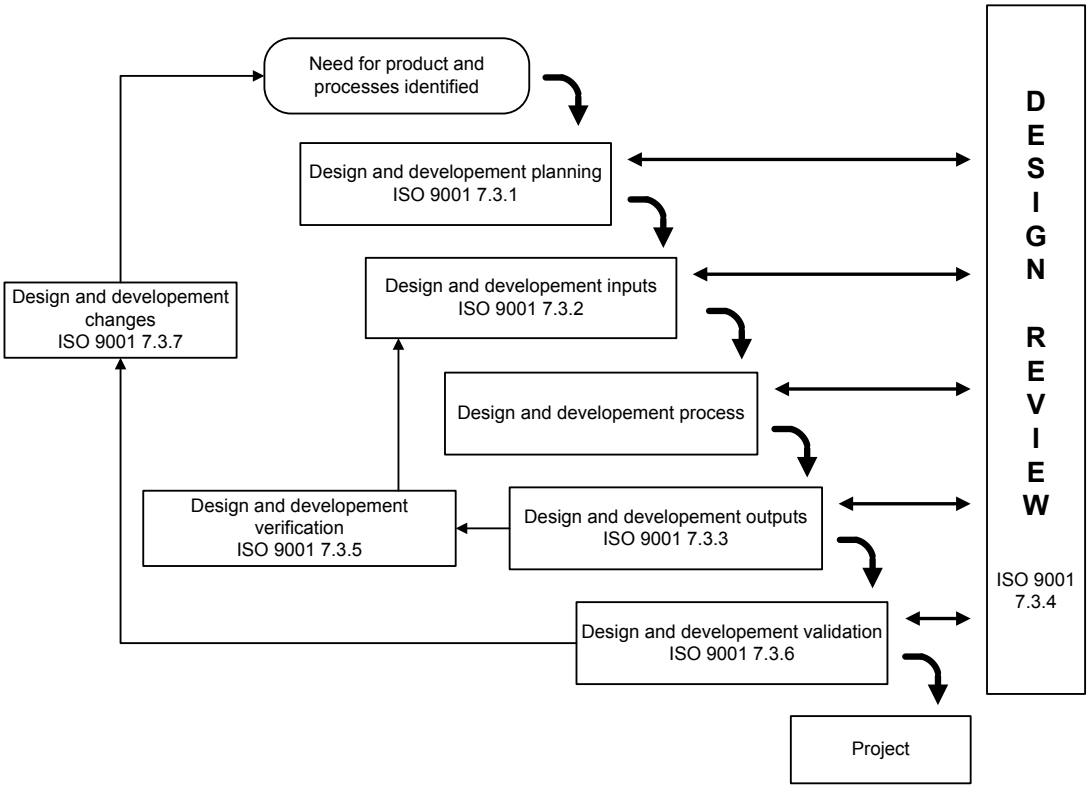


Fig. 4. Outline of the design and development process (Auditing the design and development process ISO/TC176/IAF, June 2009)

If we assume that risk management is related to the identification, evaluation and control of the undertaken activities, this issue is the most extensively discussed in paragraph 7.3 of ISO 9001 standard, which refers to designing and development. The requirements that concern risk-limiting activities – reviews, verification, validation of a design – which are related to the introduction of a new product on the market have been illustrated in figure 3 [6]. The designing cycle presented in figure 3, which results from the requirements of ISO 9001 standard, is based on Deming's cycle.

The introduction of a new product entails the appearance of new suppliers, which is related to a new area of risk. In this case, a quality system can help limit the risk by conducting the second party's audits at the suppliers' place.

The process of designing, which is extended in ISO 9001 standard, is treated as an element of product processing system. The limitation of risk related to business activity involving manufacture / provision of a service is achieved by planning:

- goals connected with the requirements to be fulfilled by a product / service;
- processes having a capacity of achieving the set goals;
- resources which include both, the infrastructure and human resources, as well as the environment in which processes are carried out;
- validation of processes, which in this case concerns the very process, equipment, competence and qualifications of the staff, methods and procedures understood as a sequence of activities;
- methods and procedures which refer to monitoring, testing and control;
- records which provide objective evidence of the achievement of planned goals required by the customer and the fulfilment of legal requirements.

In the first issues of ISO 9000 standards the approach to validation of processes was limited only to special processes, understood as processes the results of which cannot be verified by direct measurements. A consequence of this might be manufacturing a product that does not meet the requirements. Examples of such processes include the process of thermal treatment, welding, casting. Currently each implemented process should be subject to validation. Validation includes a review and approval of processes with regard to their capability of achieving the goals, approval of the equipment and staff qualifications, correctness and effectiveness of methods and procedures. Validation of a manufacturing process, no matter if we are dealing with a special process or a process which allows monitoring or measurements, must be documented in a form of records confirming the effectiveness of adopted solutions. These

endeavours are aimed at limiting the risk of providing the customer with a product/service that does not meet his expectations and does not fulfil legal or other requirements important from the point of view of the intended use of a product, which are not necessarily known to the ordering party.

Considering the relation between a quality management system and business risk limitation, attention should be paid to the aspect of corrective measures, strongly emphasised in ISO 9001 standard and in branch standards. The notion of correction was introduced together with the last amendment of the standard. Correction is removal of nonconformities, without analysis of the reason. Many tools used in QMS, apart from process monitoring, are used to identify the causes of nonconformities, i.e. failure to achieve the goals. The importance of corrective measures can be proved by the fact that the requirements highlight the obligation to develop a procedure aimed at identifying the causes of nonconformity and to establish action ensuring that the nonconformity will not occur again. It is important that these actions should be implemented without unnecessary delay. This is accompanied by records, which are an objective proof of the effectiveness of taken actions. Establishing the reason for the occurrence of nonconformities, as well as the implementation of corrective measures reduces the risk connected with failure to achieve business goals.

## Conclusions

Quality management systems based on ISO 9000 standard in their numerous requirements limit business risk. Among many approaches related to risk, in quality management systems we usually deal with risk related to the performance of design works. Limitation of risk involved in a manufacturing / service-provision business results from the process approach. The process approach guarantees the effective achievement of planned results – they engage much less material and financial resources. This way they improve the effectiveness of the set goals achievement. The process approach reduces variances in manufacturing / service-provision and managerial processes, which in consequence makes the system in an organisation more controllable and more stable. The system approach, which is one of the eight pillars of QMS, guarantees the effectiveness and efficiency of management. Risk management in quality management systems is aimed at limiting the specific changeability that processes are subject to, which allows reducing the uncertainty related to the achievement of the set goals by the process.

In the considerations on a relation between QMS and business activity risk, the aspect of human resources has been passed over. Human resources are an important resource without which neither the system nor the processes enable the achievement of business goals. P. Drucker in 2011 noticed that the future society will be a society of knowledge, which will become a key resource. He considers skilled workers a dominant group on the future labour market [17]. In the requirements contained in ISO 9001 standard special emphasis has been placed on the competences of employees and making sure that they are aware of the importance of activities. Risk related to failure to fulfil expectations of the customer understood as an individual buyer or a social group increases with technological progress.

The rapid technological development that has been observed since the middle of the 20$^{th}$ century forces organisations to take risk into account when introducing innovations, new technologies and more complex infrastructure. Risk is not only related to manufacturing processes and the use of products. Legal requirements, which have been highlighted in the last issue of ISO 9000 standards, in business processes make it necessary to take into consideration the influence of process accomplishment on the climate, noise emission, pollution or creation of the risk of illness incidence among the local community. The manufacturer becomes responsible for the influence of a product on the environment throughout the cycle of product life. QMSs deal with this problem through legal requirements to be fulfilled by an organisation, whereas system limitation of risk related to the effect on the environment is the subject of requirements contained in ISO 14000 standards.

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