

Possibilities and Methods of Risk Assessment under ISO 9001: 2015

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Abstract: *The aim of the paper is to identify selected targets and essence of planned changes in ISO 9001: 2015 with particular emphasis on the need for risk assessment in organization management. The paper presents the existing requirements of ISO 9001: 2008 and planned changes to 2015 edition. The research method adopted was a comparative analysis of ISO 9001 norm of 2008 edition and a draft of the planned edition of 2015. The second part of the study describes characteristic features of risk and its assessment methods that will allow acting entities to meet the requirements of ISO 9001: 2015 concerning introduction of risk management system.*

Keywords: *quality management system, ISO 9001: 2015, risk management*

1. INTRODUCTION

The beginning of modern quality management systems aiming at systematic improvement of quality and preventive actions striving at avoidance of mistakes may be considered to be individual methods, and later systems, initiated by motor industry producers targeted at reducing the defectiveness of produced goods.

The aim of this paper is to indicate a trend of continuous adjustment of the ISO 9001 quality management system to market requirements and users' needs, with special inclusion of the need for risk assessment in organization management. The paper presents current requirements of the ISO 9001:2008 standard as well as the changes planned in 2015 edition. The adopted research method is a comparative analysis of the ISO 9001 2008 edition and the draft of planned 2015 edition.

The second part of the paper characterises the risk features as well as methods of its assessment, which will enable business entities to meet the requirements of the ISO 9001:2015 standard concerning the introduction of a risk management system.

2. ISO 9001 STANDARD NOVELISATION

The need for ordering of various national quality standards on an international scale appeared in the 1970s. The work of the organization established for this purpose (*International Organization for Standardization*) led to development of the first version of ISO 9000 series standards in 1987, which were updated in 1994 and 2000. The ISO 9004:2000 and 2008 standard refers to requirements concerning a quality management system of an organization which are to be met in order to prove the ability to satisfy customers' demands. The ISO 9004:2000 standard is the proposal of a solution exceeding the required basic criteria of the ISO 9001 standard and it also indicates the directions for development of a comprehensive quality management system.

Novelisation of the standard in 2000 was supposed to adjust the requirements of the ISO 9001 standard to real functioning of companies as well as reduce the bureaucracy of documentation forms. The process approach is based on management staff responsibility, managing of means and resources, process management, analysis, measurement and improvement, focus on customer's needs and satisfaction, self-improvement of the organization through corrective and preventive actions. The process approach includes the use of the Deming circle in the quality management process.

Requirements concerning the 9001:2008 QMS refer to eight groups of issues: 1. focus on customers, 2. leadership, 3. employee involvement, 4. process approach, 5. system approach to management, 6. continuous improvement, 7. fact-based approach to decision making, 8. mutually beneficial relationship with suppliers.

The ISO 9001 standard does not provide any precisely defined requirements concerning the graphic layout or structure of the organization quality management system documentation. This enables organizations to develop quality manuals reflecting the methods of conducting their activity. Except for the required documents, it is an accepted practice that 2 quality manuals are prepared – an internal one, which is regularly updated as well as an external one, which customers have access to.

Table1. ISO 9001 standard novelisation

Year of issue	Important changes
ISO 9001:1987	First standard in this series
ISO 9001:1994	Minor adjustments in standard requirements
ISO 9001:2000	More significant changes and adjustments related to introduction of the process approach
ISO 9001:2008	Minor changes specifying some concepts
ISO 9001:2015	Novelisation providing for significant changes resulting from rebuilding of the standard structure (from 8 to 10 chapters), compulsory inclusion of risk management and knowledge management.

Source: The author's own work based on current standards

Aiming at improvement of the ISO 9001 standard requirements, there was a reduction in the number of documents which had to be created as documentation (QMS), whereas the main focus was on the so called process approach based on the Deming PDCA (plan – do –check – act) circle (fig. 1).

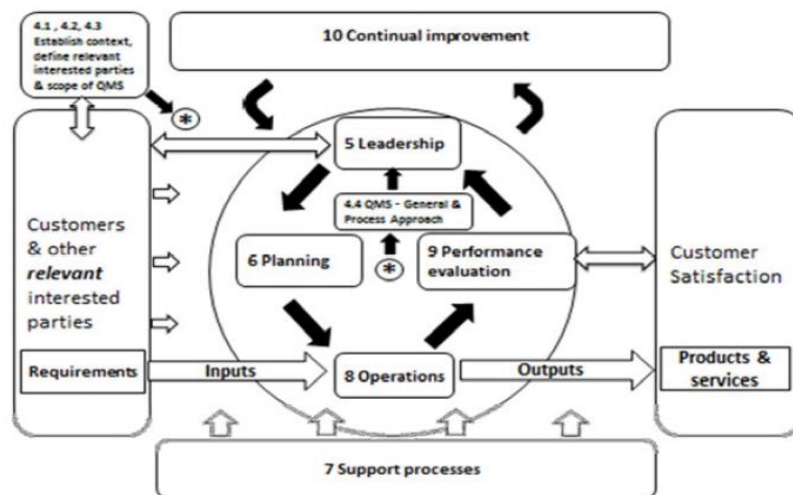


Fig1. Model of a process-based quality management system, showing the links to the clauses of this International Standard

Source: Quality management systems – Requirements (ISO/DIS 9001:2014); German and English version prEN ISO 9001:2014, Normenausschuss Qualitätsmanagement, Statistik und Zertifizierungsgrundlagen (NQSZ) im DIN, DIN Deutsches Institut für Normung e. V., Berlin, 2014, p. 64.

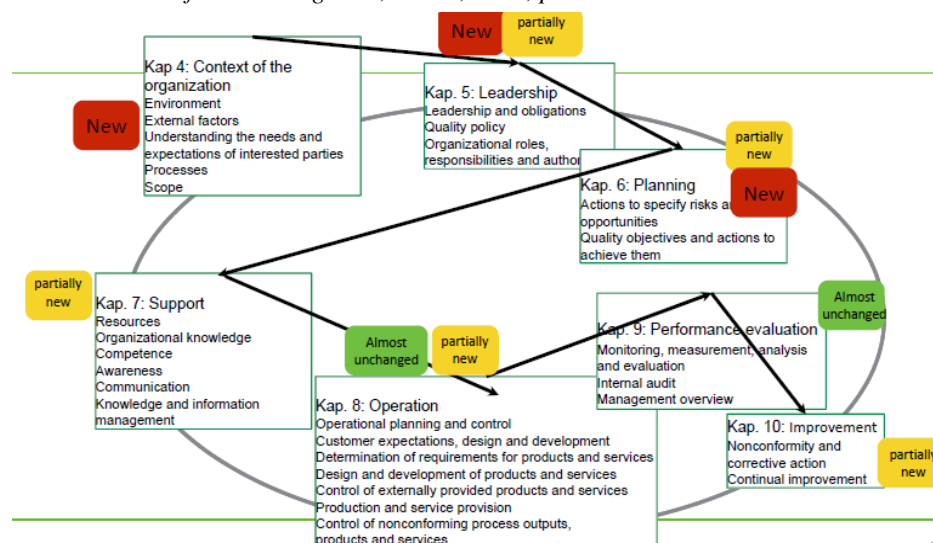


Fig2. Diagram of the requirements of ISO 9001: 2015

Source: Teaching materials Dekra Certification GmbH, Stuttgart 2015, p. 3.

Due to continued attractiveness of quality certificates, the International Organization for Standardization (ISO) began, in 2013, to work on updating of the current standard version and its further adjustment to requirements of modern organizations. These changes include, more than so far, the issues concerning the possibility of providing high quality goods and services - emphasising again the opening of the standard requirements to organizations offering services. The list of proposed requirements within ISO 9001:2015 is presented in fig. 2. The draft standard in its present form is also supposed to ensure and facilitate the compatibility with other systems, first of all with the environmental management system (ISO 14000) and the occupational health and safety management system (ISO 18001), which already have a 10-chapter structure.

The quality management requirement proposed in the ISO 9001 standard is suitable for many types of organisations because it allows the use of their own, internal solutions, provided that they meet basic formal requirements of the standard¹. The ISO 9001 standard requires that organizations fulfil its requirements beginning from identification of customer's demands, through implementation of quality management processes and ending with customer's satisfaction.

The legitimacy and need of introducing and maintaining QMS in accordance with ISO standards are undoubtedly supported with an increase in the number of certificates awarded - based on the statistics kept by the International Organization for Standardization (ISO), by 2013, over one million ISO 9001 certificates had been issued all over the world in 184 countries, whereas the biggest number of certified organizations are located in Europe and Eastern Asia (about half a million each; the remaining certificates were issued in African countries and in the USA - about 50 thousand each). In Europe the number of certificates issued increased from 44,388 in 2001 to about half a million in 2013².

Also the number of other QMS certificates issued is growing, e.g. within the scope of environmental management in accordance with ISO 14001, technical specifications (ISO/TS 16949) in motor industry companies as well as the food safety management system in accordance with ISO 2200 in the food sector; the ISO 27001 standard concerning information security is also becoming more popular.

3. RISK AND PROCESS APPROACH TO RISK MANAGEMENT IN AN ENTERPRISE

Depending on the area of human activity and the adopted criterion, it is possible to indicate various divisions of risk. Kaczmarek mentions 17 types of risk, including insurance, economic, exchange rate, organizational, political, force majeure, medical and other types of risk³. Keitsch divides risk into 3 basic areas: force majeure risk, political and economic risk as well as venture risk, including business activity risk, financial risk and enterprise functioning risk⁴. Grzywacz names 10 types of risk, including e.g. economic, operational, market, investment and exchange rate risk⁵. Jajuga, on the other hand, distinguishes 7 basic forms of risk only within the area of financial risk, including e.g. market risk with 4 sub-categories, operational, business, legal and event risk⁶.

Typical risk that may occur during business activity is a situation on the labour market, a fraud, debtors' insolvency, a demonstration, a strike, a burglary, a loss of machines necessary in the production process, e.g. due to fire, management mistakes, a loss of an employee/employees of key importance for company operation, industrial espionage, sabotage, production defects (e.g. series withdrawal), a change of the ownership structure, external influence of interested third parties, risk connected with interests, credit rating, assets liquidity and other⁷.

¹ Ejdyś J., *Model doskonalenia znormalizowanych systemów zarządzania oparty na wiedzy*, Oficyna Wydawnicza Politechniki Białostockiej, Białystok 2011.

² The ISO Survey of Management System Standard Certifications (1993-2013), ISO Central Secretariat, Geneva 2013.

³ Cf. *ibid.*, pp. 56-90.

⁴ Cf. Keitsch D., *Risikomanagement*, Schäffer-Poeschel, Stuttgart 2004, p. 5.

⁵ Cf. Grzywacz W., *Podstawy mikroekonomii*, PTE, Szczecin 2003, pp. 142-143.

⁶ Cf. Jajuga K., *Zarządzanie ryzykiem*, PWN, Warsaw 2008, p. 18 et seq.

⁷ Borner D., *Der praktische Risk Management-Prozess für KMU*, Rüegger Verlag, Zürich 2007, pp. 57-58.

Various types of risk may occur while conducting business activity. Occurrence of unexpected risk may make it impossible to continue the activity in its current form or put it to an end. Especially in small companies, daily issues may have such impact that there is no time to determine and specify the objectives concerning the future. Nevertheless, this effort should be taken in order to ensure continuation of business activity. After identification of potential risk, the possibility of its occurrence must be assessed as well as its possible influence on the conducted activity.

Organization management is a managerial activity that involves the establishment of objectives and causing of their implementation in organizations subject to the managing person. Management involves planning, organizing, motivating and controlling actions focused on meeting the organization's objectives⁸.

Process approach to risk management has been included in chapter 0.3.3 of the Draft from 2015: "Risk-based thinking is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of (...) International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity."⁹

The risk management process, as a component of organization management, is supposed to help, thanks to better risk assessment, with safe company operation and to be aimed at obtaining of higher profits. It enables better use of resources, more conscious decision making and risk taking, more focus of the management on important issues, shorter reaction time in crisis situations, etc.

Risk management is a process of identifying hazards which business entities are exposed to as well as selecting of proper methods and techniques used for protecting against them. The process of enterprise risk management includes 4 stages: risk identification, measurement, risk steering as well as monitoring and risk control¹⁰.

4 approaches to risk may be distinguished in the risk management process: risk avoidance (a company does not invest), risk mitigation (risk reduction through limiting the degree of exposure to risk), risk division (a company divides risk with a partner it cooperates with), risk absorption (a company strengthens its position in this way to be able to withstand the shock connected with occurrence of certain phenomena)¹¹. Determination of the acceptable risk level involves e.g. considering various ways of dealing with potential risk: acceptance, elimination, shifting (division) or risk, limitation through a system of internal control.

Table2. *Examples of strategic objectives and possible risk*

Strategic objective	Indicator	Corresponding risk
Customer loyalty	- number/share of regular customers	Loss of customers
Quick handling of orders	- number of orders - complaints concerning the period of waiting for order performance	Loss of orders
Winning new customers	- increase in turnover / profit - increase in the number/share of new customers	Dependence on few ordering parties
Increasing the market share	- increase in turnover / profit - expansion in a new region	Loss of a market share
Improving the level of employee satisfaction	- employee fluctuation - unfriendly atmosphere in the company	Employee dissatisfaction
Improving the company image	- more orders - positive press items	Deterioration of the company image

Source: *The author's own work based on Georg S., Weis C., Die Balanced Scorecard als Instrument des Risikomanagements in kleinen (und mittleren) Unternehmen, Shaker Media, Aachen 2008, p. 81.*

⁸ Ibid., p. 48.

⁹ FINAL DRAFT ISO/FDIS 9001 Quality management systems – Requirements, ISO/TC 176/SC 2, ISO, Geneva 2015.

¹⁰ Jajuga K., *Zarządzanie ryzykiem*, PWN, Warsaw 2008, p. 379

¹¹ Chong Y.Y., Brown E.M., *Zarządzanie ryzykiem projektu*, Dom Wydawniczy ABC, Krakow 2001, p. 53.

A strategy concerning risk management should be a part of strategic company decisions resulting from its mission, being a declaration of long- or short-term company activity objectives and vision concerning current and future company operations connected with the conducted activity¹². The risk management strategy may also be a component of the current quality management system (*TQM – Total Quality Management*), which, then, is the result of and is closely connected with the quality policy of a given company. As a strategic objective, a company may also set e.g. improvement and further maintenance of the quality management system. The corresponding risk involves, in this case, a loss of a quality certificate, which may be a factor having negative influence of competitiveness. Examples of strategic objectives and risk are presented in table 2.

An important issue in the the risk management process is focusing on the choice of personnel. It is also crucial to pay attention to the need of trainings and establishing the hierarchy of information flow as well as informing of all employees about company objectives and the established methods of achieving them.

Except for the presented possibilities of risk assessment, there are also risk management systems that are subject to certification - the ISO 31000 Risk Management Standard (RMS) introduced in 2009 may be used in any organization regardless of its size and area of activity. The standard includes general guidelines concerning design, implementation and maintenance of a risk management process. Introduction of the ISO 31000 RMS may help to increase the probability of achieving the organization's objectives, improve risk identification as well as ensure the system approach to risk management. Other RMS include e.g. Corporative risk management COSO II, Project risk management - PMBOK, Risk management process - PRINCE2, etc.

Another standard with a slightly different focus is ISO 27001:2007 determining the requirements concerning information security management systems. "This standard has been developed to provide a choice of adequate and proportional measures in the area of personal, physical and information security with simultaneous compliance with the law".¹³ Depending on the target of company's activity, RMS may also include HACCAP and ISO 22000 standards, etc. The possibilities of risk assessment and management may be supported with the above mentioned formalised requirements or one of selected techniques may be used. The new ISO 9001:2015 standard does not impose the requirement of a certified RMS. Nevertheless, it requires that risk be included, possible changes be planned and their potential consequences be taken into consideration.

4. RISK MANAGEMENT TECHNIQUES

One of the main tasks of an entrepreneur is understanding of the business surrounding where he/she is located and identification of risk which may influence the conducted activity. Moreover, it is important for the risk analysis to be of repetitive nature (risk management is a process, not a single event¹⁴) as well as to appoint a person responsible for the risk management process (a risk manager). Depending on the size of an enterprise, one person or a whole department may be responsible for risk management. The scope of activity of a responsible risk manager includes: risk identification and assessment, taking of the identified risk, planning of possible events, introducing procedures of acting in crisis situations, regular contact with company management/owner.

In business activity practice of an enterprise, it is impossible to eliminate all types of risk. Nevertheless, in accordance with PESTEL analysis, after recognising and analysing them, it is possible to reduce the probability of their occurrence through purposeful acting. PESTEL analysis includes political risk, e.g. change of government, important political decisions (e.g. introduction of euro), mechanisms of changes in the government; economic risk, e.g. the ability to attract and keep personnel on the labour market; social and cultural risk, e.g. demographic changes determining the

¹² Cf. Perenc J. (eds.) *Marketing. Sposób myślenia i działania*, Wyd. Naukowe US, Szczecin 2006, p. 315.

¹³ Cf. Certified Information Security Management System, PN-ISO/IEC 27001:2007, information leaflet of the Polish Committee for Standardization, http://www.pkn.pl/sites/default/files/broszura_pkn_szbi.pdf, (access date: 21.5.2015).

¹⁴ Bielawska A., *Ryzyko w mikro i małych przedsiębiorstwach – między szansą a zagrożeniem* [in:] Bielawska A. (eds.), *Uwarunkowania rynkowe rozwoju mikro, małych średnich Przedsiębiorstw, MIKROFIRMA 2015*, US Zeszyty Naukowe no. 848, Ekonomiczne Problemy Usług no. 116, Szczecin 2015, p. 249.

demand for services, change in customers' expectations; technological risk, e.g. technology ageing, introduction of innovative products; legislative risk, e.g. introduction of new EU directives; ecological risk, e.g. waste disposal, recycling, reducing the emission of greenhouse gases, etc.

The canon of risk management techniques is extensive. Selected techniques, which are presented below¹⁵, may be used by a manager / owner or a person responsible for risk management in micro and small enterprises without any additional costs being born.

- Brainstorming enables gathering of opinions on all sources of risk (internal and external). Employees of various ranks should participate in brainstorming as this ensures the most complete and realistic risk assessment. Risk identification is divided into strategic risk, including political, economic, social, technological, legislative and environmental risk as well as operational risk, including financial, legal, professional, physical, contractual, technological and environmental risk.
- Future scenarios / scenario analysis involves creation of various scenarios (positive scenarios/*best cases* and negative scenarios/*worst cases*), which form the basis for development of a way of acting. The basis for forecasting may be the obtained data, e.g. from audit reports or from the complaint department (number of complaints, effectiveness of complaint handling, time needed for complaint handling, time needed to contact a customer to deal with the undesired situation). The method may also be used in cases when there is no past data which forecasts could be based on as well as in cases where results depend on factors that are difficult to forecast, e.g. weather.
- SWOT analysis (*S-strengths; W-weaknesses; O-opportunities; T-threats*) belongs to the canon of strategic management methods and enables formulation of problem solutions based on gathered information. Conducting of the analyses of gathered data enables recognising of the situation in direct market surrounding, reduces the probability of taking a wrong decision, constitutes a basis for determination of the strategic situation of an enterprise on the market and enables drawing conclusions concerning the direction of development (see tab. 3).

Table3. Example SWOT questions

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> • What do you do well? • What are your unique skills? • What expert or specialized knowledge do you have? • What experience do you have? • What do you do better than your competitors? • Where are you most profitable in your business? 	<ul style="list-style-type: none"> • In what areas do you need to improve? • What resources do you lack? • What parts of your business are not very profitable? • Where do you need further education and/or experience? • What costs you time and/or money?
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> • What are the business goals you are currently working towards? • How can you do more for your existing customers or clients? • How can you use technology to enhance your business? • Are there new target audiences you have the potential to reach? • Are there related products and services that provide an opportunity for your business? 	<ul style="list-style-type: none"> • What obstacles do you face? • What are the strengths of your biggest competitors? • What are your competitors doing that you're not? • What's going on in the economy? • What's going on in the industry?

Source: <http://zestebiz.com/swot-analysis-making-business-strategy-easy/>

¹⁵ Prepared based on: Chong Y.Y., Brown E.M., *Zarządzanie ryzykiem projektu*, Dom Wydawniczy ABC, Krakow 2001, pp. 62-63; Georg S., Weis C., *Die Balanced Scorecard als Instrument des Risikomanagements in kleinen (und mittleren) Unternehmen*, Shaker Media, Aachen 2008, pp. 31-35; Janssen J., *Balanced Scorecard. Strategien erfolgreich umsetzen in KMU's*, Dt. Gesellschaft für Qualität, Frankfurt 2004, pp. 16, 58-82; Kamiske G.F., Brauer J.-P., *Qualitätsmanagement von A bis Z*, Hanser-Verlag, Munich 2008, pp. 73-79; Wawak S., *Zarządzanie jakością. Teoria i praktyka*, Helion, Gliwice 2006, pp. 187-190; *Zarządzanie ryzykiem w sektorze publicznym. Podręcznik wdrożenia systemu zarządzania ryzykiem w administracji publicznej w Polsce*, Ministry of Finance of the Republic of Poland, pp. 22-24.

- FMEA analysis (*Failure-Mode-and-Effects Analysis*) – the analysis of reasons and effects of failures, is a further development of the flow *chart* analysis and its adjustment to technological processes. It was developed by scientists at the Stanford University already in the 1960s. It may be used for assessment of systems, products and processes. It enables indication of potential failures and their analysis as well as drawing conclusions in the direction of taking the respective steps, e.g. through using proper tools, conducting trainings or introducing security measures.
- *Balanced Scorecard* (BSC) is a management technique developed in the 1990s by scientists from Harvard - Robert Kaplan and David Norton. BSC analyses the cause-and-result relationships of a company in 4 perspectives: financial, customer, business processes as well as from the perspective of organization's ability to learn and develop. Thus, it provides the overall view of the company including the past, present and future situation. The company image seen from various perspectives enables assessment of the status through answering questions: from the financial perspective - how do the shareholders perceive the company?, from customer's perspective - how does the customer perceive the company?, from process perspective - what should be improved to meet customers' and shareholders' expectations? as well as the development perspective - how to maintain the ability to introduce changes and improvements over a long-time period? An example of BSC including the above mentioned perspectives and the existing relationships is presented in figure 3.

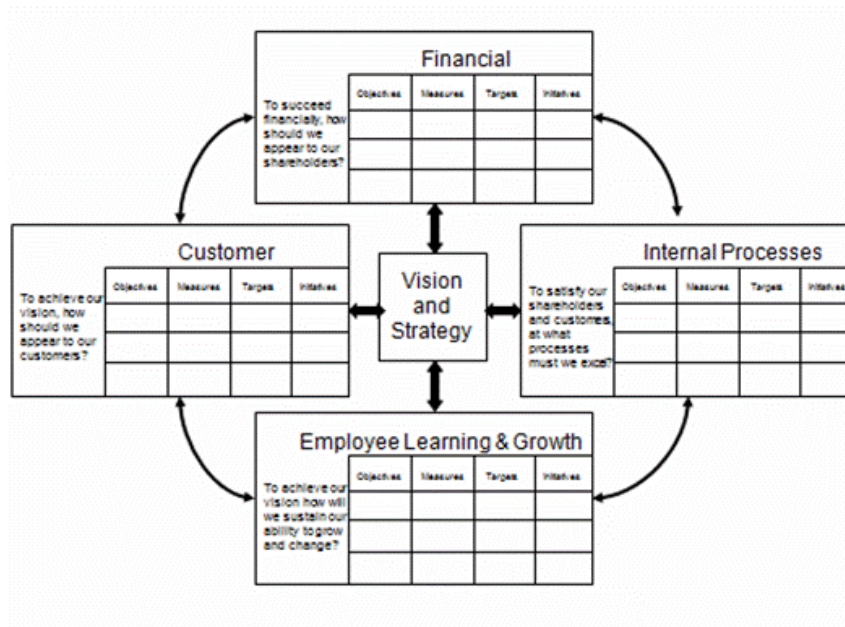


Fig3. *Balanced Scorecard*

Source: Based on Kaplan, R. S., Norton, D. P., *Balanced Scorecard. Strategien erfolgreich umsetzen*. Schäffer-Poeschel Verlag, Stuttgart 1997.

It is also possible to use the following as a risk management technique: the portfolio analysis, the strengths and weaknesses analysis, the fault tree analysis to show the relationships between a given issue with its components and the process risk which may lead to a failure, the flow chart. It is also possible that external parties conduct risk analysis as a part of the so called Delphi group. The probability of risk occurrence is assessed by a group of external experts (Delphi group), who are requested for a subjective risk assessment in categories listed in a specific order. Any possible prejudice of some experts should be eliminated by the opinions of others. The responses may be collected in the form of e.g. a table. Assessment made by the Delphi group should provide the answer to the question whether the probability distribution indicates higher risk of project failure or not¹⁶.

In the risk management process, company management may refer to their own experience, which enables realistic situation assessment, to documentation that contains description of an analogical situation in the past, e.g. internal audit reports, as well as various techniques and methods (e.g. *RAMP*

¹⁶ Borner D., *Der praktische Risk Management-Prozess für KMU*, Rüegger Verlag, Zürich 2007, pp. 63.

– *Risk Analysis and Management of Projects*, Spoce, Spocette), or even computer programmes such as e.g. Microsoft Project Manager, Hoskyns PMW, Mind Mapping, Gliffym, which provide graphic support, e.g. through creation and edition of process schemas, for risk documentation and analysis.

5. USING THE OBTAINED DATA AND HAZARDS THAT MAY OCCUR IN THE RISK MANAGEMENT PROCESS

In connection with enterprise functioning, risk may be systematic, connected with a given economic or political system, e.g. the level of inflation, unemployment, etc. or non-systematic, referring to e.g. a specific branch of industry or business activity, e.g. a strike, bankruptcy risk, etc. Its measurement enables gathering of data that makes it possible to express the risk level in the numerical form or in certain categories, e.g. low, medium, high risk. Risk assessment and hierarchy may be presented in the form of a matrix (fig. 4), which is completed with numerical data. The risk occurrence probability assessment criteria should correlate with the results of conducted PESTEL analysis. The probability of occurrence of a given risk may be calculated or conventionally classified in a descriptive manner analogically to fig. 4.

Probability	Very often 1 x daily / weekly					
	Often Once every quarter					
	Occasionally Once a year					
	Rarely Once every 10 or more years					
	Improbable Once every 500 years					
		slight	low	average	serious	catastrophic
Influence						

Fig4. Example risk assessment dot matrix

Source: Borner D., *Der praktische Risk Management-Prozess für KMU*, Rüegger Verlag, Zürich 2007, pp. 114-58.

Dot matrices are also used in the occupational health and safety system while assessing the occupational risk for individual jobs. The example assessment contains e.g. tables for assessment of risk in a three-step scale (low probability, possible risk and high risk)¹⁷.

The formula for risk assessment according to Kinney and Wiruth was developed in the 1970s and is still used: $R = S \times E \times P$, where R is risk, S – potential severity, E – exposure to hazard, P – probability of hazard occurrence¹⁸.

Depending on the branch, risk may be connected with the working place itself, e.g. the work station, dust load in the environment, noise and sometimes exposure.

The risk management process is the same for all organizations and begins with risk identification. The use of a selected method of risk analysis is supposed to enable probability assessment of its occurrence and, if possible, reduction of this probability or effects of risk occurrence. Nevertheless, problems may appear while the risk management process is being accomplished. So far, few enterprises have integrated risk management with the process of enterprise management and use it daily. In many cases, resignation from the introduction of a risk management system is a mistake, which is manifested in the number of bankruptcies resulting also from unawareness of the market and competition as well as improper assessment of the possibility of accomplishing an undertaking in given circumstances.

Mistakes in the risk management process may have influence on further company development and negative impact on strategic (developmental) decisions of the company. Such risk includes, e.g.:

¹⁷ PN - N - 18002:2000

¹⁸ G.F. Kinney, A.D. Wiruth, *Practical Risk Analysis for Safety Management*, Naval Weapons Centre, China Lake, 1976.

- The owners' risk resulting from lack of interest in differentiating the company development directions, which would lead to minimization of business activity risk. Other factors include, e.g. the owners' / manager's pre-retirement age, which may condition the lack of interest in continuation of an undertaking and introduction of changes; lack of competences of the management or negative reactions to criticism.
- company risk connected with wrong assessment by an investing company of future market conditions (e.g. assuming an unreal level of income and influx of receivables as a result of wrong calculations),
- strategic risk - enterprise objectives, strategy and mission are not (clearly) defined and are not communicated to employees,
- personnel risk connected with lack of trainings; leaving new employees on their own; unappreciated personnel, which is reflected in the quality of work; too little praising; significant personnel rotation or the fact that employees do not know which tasks are performed in other positions,
- organisational risk resulting from lack or improper functioning of communication, wrong hierarchy of decision processes (trivial issues are settled on the highest level); employees' ideas are not taken into consideration; tasks and responsibility are not clearly defined,
- Project risk connected with technical conditions of project implementation, e.g. solutions taken from another company are not good, etc.

The above mentioned risk and possibilities of preventing it were taken into consideration while preparing novelization of the ISO 9001:2015 standard explicit in points: 0.5 and 3.9 risk definition, 6.1 Precautions within the scope of dealing with risk and possibilities, 3.10, 7.1.6 as well as through the requirement of knowledge management in an organization.

6. CONCLUSION

The problem matter of risk management in an enterprise is still a soft area of management, compared to risk management in a bank or an insurance company, for which activities within the scope of risk management are a consequence of regulations being a part of Basel II and Solvency II and involve e.g. risk aggregation aiming at avoidance of unsystematic risk through diversification, as risk management in enterprises is not based on strict calculations according to some established formulas.

Undertaking the effort of risk management leads, however, to reduction of risk to the acceptable level, while inclusion of information on the types of risk of an enterprise and methods of managing it in the financial statement is a source of information for potential investors. As a part of risk management, it is also possible to draw conclusions from its analysis and identify potential hazards for further activity. Problems are visible in e.g. a decrease in liquid assets, an increase in receivables, an increase in short-term liabilities, an increase in production costs or operational costs.

In business activity practice of an enterprise, it is impossible to eliminate all types of risk. Nevertheless, in accordance with PESTEL analysis, after recognising and analysing them, it is possible to reduce the probability of their occurrence through purposeful acting.

At present, before introduction of the 2015 standard edition, it is not possible to assess how it will influence the functioning of enterprises and if it really causes the reduction of risk in business activity. In the first line, it will, nevertheless, ensure, at least in the initial phase - a change in approach to risk assessment and, most of all, its identification. Once the standard is issued, which is planned for the beginning of 2015, for three years, beginning from 2016, there will be a possibility of choice - certification of QMS in accordance with the old or new standard. From 2018, it will only be possible to obtain the ISO 9001:2015 certificate.

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