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Risk Management at the Notified Body in the Aspect of Its Impartiality

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Abstract:

State-of-the art management systems are oriented onto supporting a competiveness of organizations and a continuous quality improvement of products, services and processes.

One of essential elements of management is the risk management process which enables to manage uncertainty and risk in relation to the conducted activity by an organization.

Managing risk assists organizations in setting strategy, achieving objectives and making informed decisions. Managing risk is part of governance and leadership, and is fundamental to how the organization is managed at all levels. It contributes to the improvement of management systems. A competent use of risk management mechanisms enables each organization to use its potential to a full extent and undertake proper decisions.

The issues concerning a standardization of requirements in the case of standards from the management scope; in particular from the point of view of issues connected with risk management, are presented in the first part of the article.

A model of the process, oriented onto a risk in the quality management system which enables to conduct managing activities in the situation of uncertainty and to take decisions oriented onto preventing mistakes in managing the organization and onto ensuring the appropriate quality, is described.

The subject – matter concerning risk analysis, in particular from the point of view of meeting the EA Guidelines, concerning horizontal requirements related to the bodies assessing the conformity for notification purposes, is brought nearer.

The most essential requirements, which must be met by such a body to guarantee a competent and impartial process of the product assessment, are described.

In the following chapters the basic elements of the risk analysis process are discussed and an exemplary description of the risk assessment methodology is presented.

Keywords: quality management system, notified body, process approach, risk analysis

1. Introduction

The changes taking place in the environment of each organization cause a necessity of a continuous adaptation to changing conditions of their functioning. Due to the fact that quality management is the key issue in the scope of a continuous improvement, so organizations more and more commonly implement state-of-the-art management conceptions based on standardized quality management systems.

At present the quality management system has become a common practice and it is mainly implemented for an improvement of internal processes taking place in an organization.

One of the most popular and most universal standards from the management scope, the standards which can be used by each type of organizations – from producers, servicers, state authorities to non-profit organizations is the Standard *ISO 9001 Quality management systems - Requirements* [1].

This standard is aimed at ensuring and maintaining the organizational system through fixed procedures and attributed authorizations.

The first version of the ISO 9001 Standard was published nearly 35 years ago and it was subject to multiple amendments [2] but a popularity of this standard does not decrease and organizations all over the world still certify their managements systems.

Each year *The ISO Survey of Management System Standard Certifications* conducts an analysis oriented onto indicating a degree of popularity of management systems, defined by the number of edited certificates according to the management standards [3].

According to the official data, *The ISO Survey of Management System Standard Certifications*, in 2019, there were 883 521 certificates from the ISO 9001 scope in power all over the world.

A more detailed analysis indicated that in 2019 12951 organizations, having valid ISO 9001 certificates, were active in Poland.

For example in the same 2019 year there were:

- 60480 certificates in Germany,
- 21782 certificates in France,
- 26226 certificates in the United Kingdom of Great Britain and Northern Ireland [4,5].

It is worth highlighting that the statistics only included the organizations which have quality management systems confirmed by certificates, whereas also the organizations which implemented the mentioned system in the framework of other standards e.g. connected with the bodies, assessing conformity or conducting inspections or performing tests, such as the standards: EN ISO / IEC 17020, EN ISO / IEC 17025, EN ISO / IEC 17065, should be added to them.

In the case of the last three standards, it should be emphasized that before the year 2012, each of them had a different structure and contained different requirements. Some attempts of standardizing these documents were undertaken many times, but only the ISO / TMB / JTCG Joint Technical Coordination Group on MSS achieved an agreement in this scope [4].

The basis for this agreement was the document called the Annex SL, which standardized the principles of constructing the structure of standards from the scope of the System Management (MSS). The approved structure of standards is presented in [6].

In the result of accepting new principles gradual changes and amendments of a series of standards from the scope of management systems, including the scope of certification, were introduced [7].

In the result, still in the same year it was possible to implement the EN ISO/IEC 17065 Standard, concerning competences, coherent activity and impartiality of the bodies certifying products, processes and services [8].

The EN ISO/IEC 17020 Standard, concerning the requirements related to an operation of various types of bodies performing inspection, was issued in a further order, and in 2015 the agreed structure was also used in the EN ISO/IEC 17021-1 Standard concerning the certification of management systems [9, 10].

In 2015, the Working Group ISO / CASCO WG 44, established for up-dating the EN ISO / IEC 17025 Standard, decided that the planned changes in the standard should be directed towards its structure and content adaptation to the CASCO requirements, concerning the possibilities of using the quality management system, based on the requirements of ISO 9001 Standard in the management system of laboratories.

In 2018, the activities were finished and the new edition of EN ISO/IEC 17025 Standard was published. Therefore, the majority of standards, connected with an assessment of products was standardized as regards the structure [11].

The work on the following amendment to the ISO 9001 Standard itself was conducted in parallel.

In the same year, the work on the up-dated ISO 9001 Standard from the scope of quality management system, was finished.

In this standard, not only the structure of the document, but also the main requirements were changed. The scope of the most essential changes in the new standard edition is described in [12].

In this document the requirements, concerning a process approach based on a risk, appeared among others and they are used for:

- taking decisions,
- determining the scope of a planned process and of an indispensable supervision,
- improving the efficiency of the quality management system.

Risk assessment is a part of the risk management process, which provides systemic identification of hazards and assessment of their impact on the organization's projected goals.

An approach, based on a risk, was to ensure an identification, an analysis and supervision of the risk both during the designing as well as functioning of the quality management system [13]. Similar aspects appeared in the standards cited earlier.

2. Materials and Methods

2.1 Impartiality and independence of the notified body - legal and standardization grounds

In parallel with the activities, oriented onto standardizing the basic requirements in the scope of management systems, some work was undertaken to standardize the conformity assessment system concerning a market introduction of machines and equipment on the European Union level.

According to the assumptions of this system, before an introduction to the European Union market, each product must be subject to a procedure of conformity assessment, given in the directive, which a given product is subject to.

In some cases, determined in regulations, producers (importers and distributors) can choose from a few available modules (variants of procedure).

Some of these modules are based on testing each single product, others- on approval of the type, and sometimes an assessment of the whole production quality assurance system is required. The conformity assessment procedures, occurring in directives, are so differentiated that in relation to the category of products which they concern, the production method or potential hazards, a participation of independent notified body are settled [14, 15].

The role of a notified body is to conduct a conformity assessment under the relevant EU Directives. The notified body conducts the conformity assessment against the relevant sections of the applicable Directive.

Notified bodies are third parties, independent from their clients. The legal status of these bodies is essential as far as their independence and impartiality are guaranteed and they constitute independent legal subjects.

To guarantee a realization of activities on the same level and according to the conditions of fair competition by all notified bodies in the European Union, two regulations aimed at a framework formulation as well as at a determination of their accreditation criteria, were edited. They were:

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [16],
- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [17].

The legal frames, included in the documents mentioned earlier, accepted in 2008 were oriented onto an increase of trust for the European Union conformity assessment system due to a transparent system of principles and requirements for conformity assessing notified bodies.

These principles also foresee an increase of using accreditation as a tool supporting activities of the notifying body.

For a clarification, which accreditation standards harmonized with Regulation (EC) No 765/2008, correspond with the requirements contained in the Decision No 768/2008 / EC, the European Co-operation for Accreditation elaborated an obligatory document EA-2/17, to be applied by accrediting bodies [18].

The Guidelines EA2/17 in Item 3.1 highlight clearly that, "…*competence, impartiality, independence and consistent operation of the CAB to perform the tasks it is notified for the fulfillment by the CAB of the requirements established by each UHL within the scope of accreditation".*

In the same document, in Table 6: *Map of HS Requirements* in Sub-section *Management of impartiality;* the most important elements, decisive as regards the notified body impartiality, are mentioned.

And therefore among others:

- The notified body should have documented procedures for the identification, review and resolution of all cases where conflict of interest is suspected or proven. Records of such reviews and decisions should be kept.
- The notified body should require all staff acting on its behalf to declare any potential conflict of interest.
- If the notified body, or any part of a larger organization to which it is linked, provides consultancy services, then the documented quality system of the notified body should include a policy statement and documented procedures ensuring that assessment and consultancy services are separated. The notified body should ensure, by means of a documented agreement, that its subcontractors are aware of this guidance.

Summing up, all the aforementioned documents constitute not only the basis of activity and assessment, but they also draw an intense attention to maintaining a widely understood impartiality and confidentiality.

Therefore, an activity of notified bodies is assessed not only in the aspect of their competences and technical capabilities, but also in the scope of identification, analysis and minimization of hazards; both in the area of impartiality as well as of the whole operational activity of the body.

That is the reason why, a risk analysis, according to the decisions of the ISO Committee on Conformity Assessment (CASCO) and with the rules given in the ISO / IEC Directives, Part 2, was so to say included in the requirements of the inspection body, certification body of products and services as well as in the requirements of the body certifying system management.

2.2. Risk analysis in the aspect of notified body impartiality

The basic element of the management strategy in the notified body includes ensuring stability and safety of the conduct activity. One of the tools, supporting a correct realization of the management process, is an aspect of risk management mentioned in Chapter 2.

One of the main changes, introduced during a revision of the EN ISO/IEC 17065 Standard, at present constituting the basis of the notified body activity, was precisely an establishment of a uniform approach to risk assessment. This approach consisted in an earlier identification of problems (hazards) and in taking actions, i.e. in preventing or reducing unwelcome effects.

In relation to the issue concerning impartiality of the notified body, the most essential requirement is included in Item 4.2.3 of the EN ISO / IEC 17065 Standard, where it is stated that: „ *The certification body shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel. …*

A relationship presenting a risk to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc……" [8]

In the scope of conducting the risk analysis itself, the authors of the quality standards did not impose any suggested means or method. However, the following standards were mentioned: ISO

31000, *Risk management - Principles and guidelines and ISO 31031 Risk management - Risk assessment techniques*, which can be helpful for a realization of these activities [19, 20, 21].

These standards present techniques which can be applied and they present forms of risk procedures realized by [12]:

- avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk,
- risk elimination,
- changing the likelihood of the risk occurrence,
- changing the consequences of the risk,
- retaining the risk by informed decision without taking any activities.

The mentioned ISO 31000 Standard also establishes principles of risk analysis determined as a comprehensive process comprising the determined elements (Fig. 1).

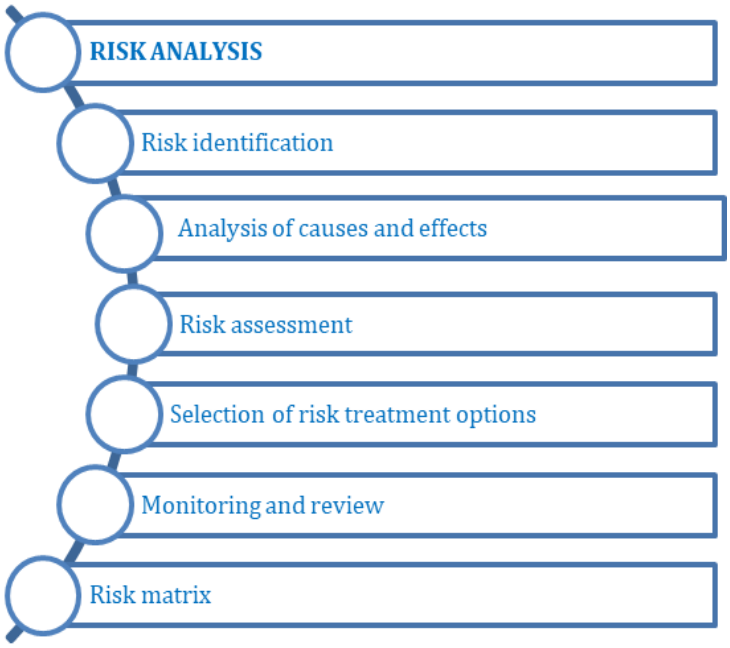

Fig. 1. Elements of risk assessment [19]

Therefore in the process approach, each risk assessment should take into consideration at least the following stages:

- risk identification - the stage to determine which risk factors affect the organization,
- qualitative analysis - the stage at which risk factors are classified according to their importance,
- quantitative risk analysis - stage of the analysis of the selected factors,
- planning the reaction to risk - the stage of taken activity connected with the risk,
- risk monitoring and control - the stage of implementing supervision and control.

It can be stated without hesitation that each risk in a notified body can be analyzed in two contexts: in internal context**,** which can include [20]:

- organizational structure,
- policies, objectives, and the strategies,
- the capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies,
- information systems, information flows and decision-making processes (both formal and informal),
- the organization's culture,
- standards, guidelines and models adopted by the organization,

and in external context**,** which can include:

- environment, international, national, regional or local;
- competitive organizations,
- factors having an impact on the organization activity objectives.

Analyzing both contexts; external and internal context, the notified body must prove meeting a series of requirements having an impact on its credibility, i.e. among others competences or impartiality of its activity (Fig. 2).

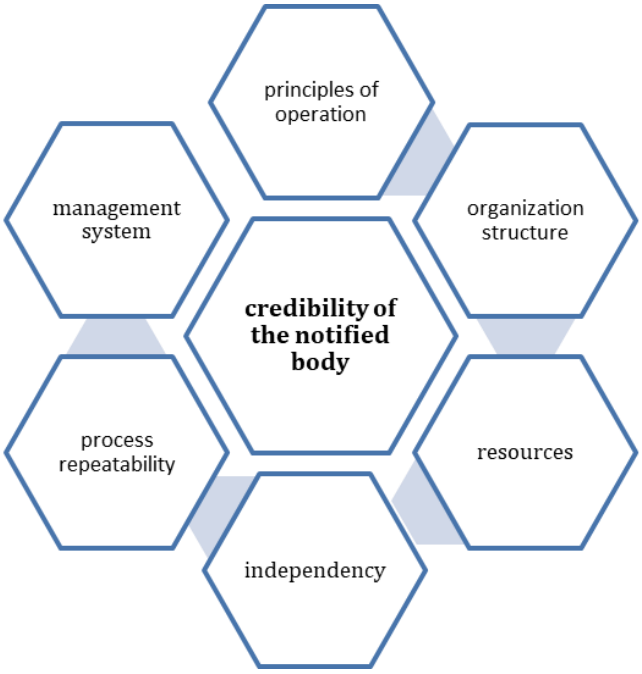

Fig. 2. Factors having an impact on credibility of the notified body [22]

Exemplary hazards to impartiality are mentioned below. They are as follows:

- the notified body is dependent on another organization (it is a part of a bigger structure or a dependent company),
- the notified body is excessively dependent on an agreement for services or on charges, or it is concerned about a loss of a client,
- the notified body is engaged in designing, producing or introducing to the market of the products under assessment,
- the notified body assesses the effect of other services, delivered by itself such as consultations,
- the notified body or its personnel declare for or against a given company, which simultaneously is its client,
- the notified body personnel has relationships with clients, there is a too close familiarity between the notified body and a client,
- a demand for the personnel of very specialistic expert knowledge limits the availability of highly qualified personnel.

3. Results – Risk Management in the Aspect of Impartiality in the Notified Body No 1456

Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State [23].

Lists of Notified Bodies are on the NANDO web site. The lists include the identification number of each notified body as well as the tasks for which it has been notified [24].

In Poland about 80 notified bodies are active in relation to different directives and EU regulations. All of them are obliged to identify and document hazards to impartiality of their processes and demonstrate the methods of eliminating or minimizing their effects.

One of such bodies is the Notified Bodies No 1456 situated in the structure of the KOMAG Institute. It acts within three directives [25]:

- 2006/42/EC Machinery,
- 2009/48/EC Safety of toys,
- 2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres.

The impartiality aspect of the Notified Bodies No 1456 has been declared since very beginning of its activity; nevertheless at the moment of introducing regulations, on the European Union level, some activities, oriented onto conducting a detailed risk analysis in the area of impartiality on all the levels: starting from the strategy and policy ending on directly conducted processes, were undertaken.

Additionally, the Notified Body extended the risk analysis in other areas, which included:

- management, including internal processes,
- operational activity,
- resources incorporating the researchers` potential and possibilities of the Notified Body staff.

For a risk identification the following tools were used:

- brainstorming,
- nominal group technique,
- analysis of the results of controls and audits,
- analysis of received complaints and other negative events taking place at the Institute.

Risk comprises two components: likelihood and impact. The likelihood-impact matrix offers a good way to categorize risk events qualitatively in terms of their probability of occurrence and their consequences.

A comprehensive risk identification enabled to elaborate a list of risk factors connected with the conducted activity, a description of likely consequences of effects in the result of their occurrence, as well as an indication of the owners of individual risks.

Determining sources, causes and drivers of risk

The conducted analysis enabled to determine:

- the likelihood of an event or consequence,
- the probable effects of mistakes in relation to the client,
- the effects of generated losses,
- the level of risk, which can be accepted by the Notified Body.
- the internal communication and reporting mechanisms.

Qualitative Risk Analysis

Based on the list of identified hazards, connected with the conducted activity, a probability assessment of its occurrence and of the impact on the Institute was performed.

In the analysis the method of determining probability in a simplified form, assuming the following criteria was accepted:

- likelihood: *0 – lack of occurrence possibility*; *1 – absolute certainty of the risk occurence*,
- frequency – the following frequencies of occurrence of events were accepted: *sporadically, rarely, often, continuously*,
- effects of losses - *to be omitted, low, big, very big.*

Estimation of Risk

For the activities of the Notified Body, the following hierarchy of risk was established:

- acceptable, not being an essential hazard to the activity,
- tolerable, which can be a reason of a hazard (quick preventive activities can be taken),

– intolerable which can cause significant losses.

The analysis enabled to develop the risk matrix presenting individual risks in a graphical form, which enabled to undertake activities oriented onto a risk reduction in critical areas.

Risk treatment

Dealing with risk is a process consisting optionally in:

– removing the risk source,
– changing the likelihood,
– changing the consequences,
– sharing the risk with another party or parties (including the agreements and financing the risk),
– retaining the risk by informed decision (acceptance of potential benefit or load of loss).

Monitoring and review

The final element of the process is a constant monitoring and control of risk, which consists in a continuous observation and supervision of identified risks, an identification of newly generated hazards and a systematic assessment of the efficiency of undertaken preventive activities.

Techniques for recording and reporting- risk matrix

Information about the magnitude of a risk can be reported in a number of different ways.

The risk analysis, conducted in the Notified Body requires an elaboration of a risk matrix. This matrix ensures a standard methodology of recording all essential information concerning the risk.

There is no determined forced, format; the records can be conducted in a paper form, in a form of calculation sheet, database or in a specialistic software.

A risk register brings together information about risks to inform those exposed to risks and those who have responsibility for their management. It can be in paper or data base format and generally includes:

– a short description of the risk,
– probability of occurrence,
– sources or causes of the risk,
– actions to control risk.

The most common method uses the consequence/likelihood matrix and this model was accepted at the KOMAG Institute.

In the elaborated record of risk factors the most essential identified risk factors, important from the point of view of conducted activity (Fig 3), are included.

		Elements of risk analysis									*Estimation*	*Risk procedure*	
				Consequence									
Risk ID	*Risk areas /area of occurrence*	*Risk factors*	*Risk*	*Financial effects*	*Effect for reputation*	*Management effects*	*Owner of risk*	*Probability*	*Frequency*	*Effects of losses strat*	*Estimation of risk*	*Reduction of risk /form of reaction*	*Risk after reduction*

Fig. 3. Structure of Risk Matrix elaborated for the Notified Body at the KOMAG Institute

In relation to each of the factors, the risk was estimated with use of the matrix. A classification of frequency (a number of events occurring in a determined time interval) and of potential effects, according to the matrix presented in Fig 4, was accepted.

Fig. 4 shows a possibility of completing a risk matrix. As an example, the matrix 4x4 is selected. Organizations choose different matrix formats (3x3, 4x5, 6x4, 5x5, ...) depending on the context of the company and the details of the risk assessment. Weighing coefficients for the consequences and frequency of events should describe real situations. Fig. 4 is just an example of applying eq.1.

4x4 Risk Matrix	Potential consequence			
Probability/Frequency	Insignificant	Minor	Severe	Major
Rare				
Unlikely				
Possible				
Likely				

Fig. 4. Example of Risk Matrix (4x4)

The Notified Body calculates risk level, choosing the limitation, and in addition, risk level is marked with colour:

- acceptable (green),
- tolerable (yellow),
- unacceptable (red).

Combinations of risk assessment and management quality supply the management of the Notified Body with the information which risk factors may be omitted and which require paying a special attention due to their negative impact on the processes. The effect of work, connected with an analysis and assessment of risk, is their arrangement according to the determined criterion. In the case of each of them, an analysis is performed and an appropriate mechanism of supervision, which enables to check if a control of hazards is ensured in a sufficient way, is applied. For most essential types of risks or risk or those which can generate a special hazard for a realization of qualitative objectives, appropriate activities are undertaken.

4. Conclusions

One of the basic elements of effective management in each organization is an efficient management of risk, which is an integral part of the organization culture [14]

An inseparable element of the management strategy, also in the case of a notified body, includes ensuring the safety of the conducted activity. One of the tools, supporting the management process, is risk management, oriented onto a probability of disadvantageous events or circumstances which have a negative impact on objectives of the notified body

In the case of notified bodies, an impartiality plays an important role because it means an independent conducting of processes from the perspective of the so-called " *third party*" .

This is a reason why an introduction of risk management to the management system of the notified body is an essential element which guarantees meeting the requirements, imposed on the notified body.

The Notified Body, acting in the structure of the KOMAG Institute, undertakes numerous activities to guarantee impartiality of activity, by implementing risk management system. These activities are oriented onto: an identification of hazards, an elimination of risk source, a change of probability of their occurrence or a change of consequences. The Institute established mechanisms which enable monitoring of implemented solutions and making an assessment of their efficiency.

The Notified Body, implementing the elements of risk management into its management system, applied a commonly used principle of the Deming`s cycle (PDCA) "Plan-Do-Check-Act" [12, 19, 26].

The experience of the Notified Body, reached so far, has enabled to state that the applied means such as:

- a creation of independent teams groups supplying opinions and advices,

- administrative decisions, a big set of internal regulations, procedures and system instructions,
- a clear and documented division of authorizations and responsibilities determined in: regulations, codes of ethics, scopes of duties of individual employees and in letters of procuratory,
- a self-control determined in regulations, and control of: work quality, quality of services,
- annual reviews of the management system in organizational areas and processes,
- internal and external audits,

guarantee a maintenance of risk on acceptable levels.

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