

Risk Assessment Concept in the New Approach Directives and its Integration in the Enterprise Risk Management (ERM)*

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Summary: In the nineties years of the previous century, the European Union achieved, through introducing the New and Global Approach to technical harmonization and standardization, a significant improvement in the approach to conformity assessment of products, by integrating the requirements for technical products safety into the process of its designing. This was achieved by preventive analyzing and quantifying of risk levels in the design process with the objective of determining the scope of the needed safety systems. On the other hand, we have witnessed a rapid development and implementation of holistic approaches to risks management in enterprises, unified in the modern business practice by the name of Enterprise Risk Management (ERM). Going along that line, the paper presents, through the basis of the EU New and Global Approach, the concept of risk assessment in the New Approach directives (Machinery, Lifts, ATEX, etc) and provides the concept of its integration into the holistic approach of risks management in enterprises, such as ERM.

Key words: Enterprise Risk Management, EU New and Global Approach, ISO 31000

Rezime: Evropska Unija je početkom devedesetih godina prošlog veka, kroz uvođenje Novog i Globalnog pristupa tehničkoj harmonizaciji i standardizaciji, ostvarila značajno unapređenje u postupku ocenjivanja usaglašenosti proizvoda na taj način što je zahteve za bezbednost tehničkih proizvoda integrisala u proces projektovanja. To je postignuto tako što se u procesu projektovanja preventivno analiziraju i kvantifikuju nivoi rizika u cilju određivanja obima potrebnih sistema bezbednosti. S druge strane, svedoci smo rapidnog razvoja i implementacije holističkih pristupa upravljanju rizicima u preduzeću koji je u savremenoj poslovnoj praksi objedinjen nazivom Menadžment rizika preduzeća (ERM – Enterprise Risk Menagment). Sledeći to u radu se preko osnova Novog i Globalnog pristupa Evropske Unije predstavlja koncept ocene rizika u direktivama Novog pristupa (mašinska, ATEX, liftovi) i daje kocept njegove integracije u holistički pristup upravljanju rizicima u preduzeću kakav je ERM.

Ključne reči: Menadžment rizika preduzeća, Novi i Globalni pristup EU, ISO 31000

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1. INTRODUCTION

A large number of accidents occurring in using various kinds of technical products show how difficult it is to accomplish the concept of safe operation of products and systems. When used adequately and with adequate protection, technical products and systems must not endanger lives and health of users and third parties. Usage of these products leads to various types of hazards and risks for operators, i.e. for the persons working directly with them in performing the activities for which these products have been designed and manufactured, or hazards for the persons participating in installing, adjusting, maintaining, cleaning, repairing and transporting these.

Also, protection of lives and health of the persons working in spaces jeopardized by explosion risk represents one of the most important aspects of safety at work. Because of the importance of this field, the regulations in the field of protecting against explosion are given highest possible significance, both at national and international levels.

Technical products have to be safe for use and the best way to realize that is by creating and realizing the “inherently safe design structures” /5/ which is achieved by the process of designing, by adequate manufacturing processes involving all testing and controls, and by adequate work processes in which they are used.

In the beginning of the nineties of the previous century, the European Union accomplished, through introducing the New Approach to technical harmonization and standardization, a breakthrough in this field by integrating the product safety requirements into the process of technical products designing /6; 9; 16/. In the directives for technical products, essential health and safety requirements have been set, which each technical product has to satisfy prior to place in the market. These requirements are defined in general form and the way of their implementation is given in the harmonized standards. In this way, designers and suppliers of technical products have got clear instructions regarding the way to accomplish conformity of these products to the directives' requirements and the way of integrating safety requirements into the phase of developing these products. In this way, fundamental change has been achieved in preventing possible occurrence of accidents in the working space in which these technical products are used. The decision regarding level of safety measures is based on previously conducted risk analysis and assessment.

Risk assessment is the methodology through which risk levels are quantified with the objective of determining the scope of required safety systems, all aimed at protecting operators, and all others coming in contact with the technical products, from possible injuries and damages /7/.

On the other hand, contemporary business practice proves how important risk analysis and assessment is for running a business successfully and for

operations of any organization, enterprise or individual. The importance of individual risks for an organization is determined by numerous factors, both internal ones depending on the organization itself and by external factors set forth by the environment in which the organization operates. Experience in the contemporary business practice in the last fifteen years has shown that the risk management concept has been in the phase of significant changes. This is substantiated by the fact that business associations, international, regional and national standardization body have created several models, standards and operation frameworks with the basic objective of defining what it is and how it is to be implemented. That is how the slogan Enterprise Risk Management – ERM originated to denote a comprehensive (holistic) approach to treating all risks in an organization /1; 8, 13; 14; 17; 18, 20/.

Analyses of major ERM models (standards or frameworks) that have so far been developed and successfully implemented in the world go beyond the scope and objectives of this paper. Therefore, the paper only partially presents the ERM model defined in the international standard ISO 31000:2009. This has been done in order to show that it is possible to integrate the risk assessment required in the EU New Approach Directives into a holistic risk management model of an enterprise, which is the basic objective of the paper. In order to fulfill this objective, the text to follow presents: (1) EU New Approach basics, (2) the concept of conformity assessment in New Approach directives (the Global Approach), (3) the concept of international standardization in the risk management field, highlighting the standards for risk assessment in the directives for machines, lifts and ATEX. At the end, the model is given of integration of the risk assessment given in the New Approach directives into the Enterprise Risk Management (ERM).

2. EUROPEAN UNION NEW AND GLOBAL APPROACH

2.1 Basic Principles of New Approach to EU Technical Harmonization

Free circulation of goods, services, people and money is the cornerstone of the single market. The objective is as follows: Removal of all technical barriers from the EU internal market, which have resulted from national technical regulations, applying of national standards and the established procedures for products testing, controlling and certification.

The mechanisms that enable accomplishing of this goal are based on:

- preventing new barriers to trade,
- mutual recognition and
- technical harmonization

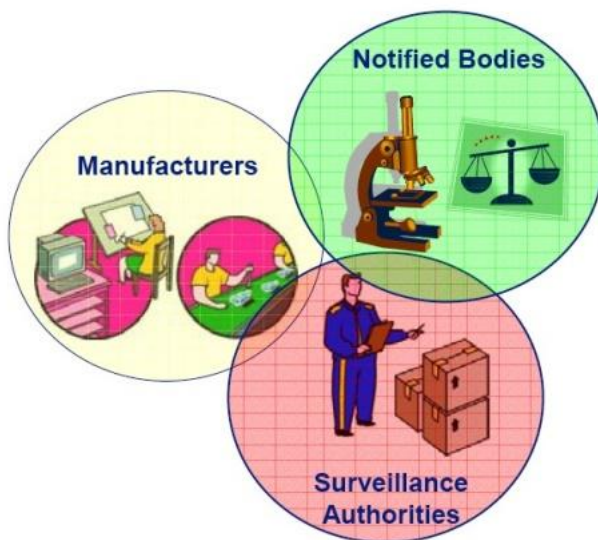


Figure 1. - Main participants in implementing technical legislation /6/

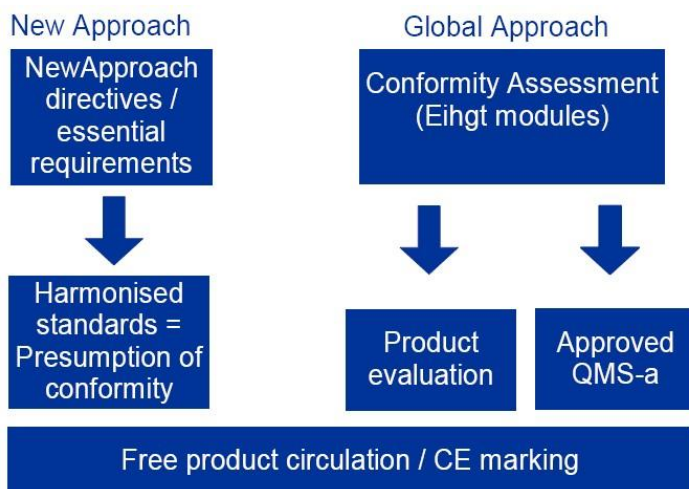


Figure 2. - New and Global Approach /6/

When talking about the New and Global Approach, we have to identify key protagonists in enforcing technical legislation at the European Union level (Figure 1). These are:

- Manufacturer

The one who manufactures the product, or its authorized representative. They are generally responsible for adjusting their product with the essential

requirements defined in the New Approach directives. The simplest way to do that is through using the European harmonized standards.

- **Notified Body**

Notified (designated) or officially appointed body is the body for conformity assessment performing testing, controlling and certifying products and QMS when the New Approach directives require engaging of a third party. Notified bodies have to be impartial with respect to all interested parties and primarily the manufacturer and authorized market surveillance authority.

- **Authorized Market Surveillance Authority**

Adequate compulsory measures, including market surveillance, are necessary to ensure correct application of the New Approach directives.

The main elements of the New Approach (Figure 2) are defined in the Council Decision on New Approach in the field of technical harmonization and standardization: These are:

- In order to secure a high level of protecting the general interests such as health, safety and consumer and environment protection, the EU compulsory essential requirements are defined for manufacturers and their authorized representatives. They are defined in such a manner that they can be applied in uniform way in all the EU Member States. Such an approach enables the Conformity assessment bodies (CAB) to assess product conformity to essential requirements, and the European standards development bodies (CEN, CENELEC and ETS) to develop standards which ensure partial or complete fulfillment of essential requirements.
- Manufacturers are free to choose any technical solution which fulfills essential requirements. Products conforming to harmonized standards are presumably conforming to essential requirements.
- Manufacturers are obliged to choose adequate conformity assessment procedure which is to conform to the risk type related to the product. Where appropriate, these procedures require engaging of conformity assessment bodies which now emerge as the third parties. These bodies are known as notified or designated bodies notified by the Member States to the European Commission for the tasks of testing, inspection and QMS and product certification coming under New Approach technical legislation. Manufacturers are free to choose the most favorable conformity assessment procedure in accordance with the requirements of the applicable directive (of adequate annex to the directive).

- Manufacturers and their authorized representatives are obliged (in most of the New Approach directives) to affix, prior to launching a product to the market, a CE marking to the product. This marking carries information that the product conforms to all harmonized provisions related to it, i.e. that it has “passed” all the requested conformity assessment procedures. As the confirmation of all this, the CE marking is affixed to the product.
- It is the obligation of the Member States to take adequate compulsory measures including market surveillance in order for products that do not satisfy the directives’ essential requirements, i.e. those that have not passed all the conformity assessment procedures, to be withdrawn from the market.
- In short, the essentials of the New Approach are based on:
 - Products assessment prior to their placing on the market
 - Products that are put on the market have to fulfill the essential requirements. Manufacturers provide for this, by affixing CE markings on products
 - Control of in-market products
 - Member States have to inspect whether the products on their market conform to the essential requirements. This is achieved by the national surveillance authority.

2.2 European approach to technical products conformity assessment – the Global Approach

There are different ways to placing products on the European Union market. In these procedures, the manufacturers, i.e. suppliers, use various techniques which very often also involve engaging independent third parties in product conformity assessment. Figure 3. offers the global depiction of the algorithm applied with “mandatory” and “voluntary” product certification /6/.

The first response requested from the manufacturer or his authorized representative is to the question whether the products have been covered by the New Approach technical legislation or not. If it falls within technical legislation, i.e. is covered by the New Approach directives, the conformity assessment procedures are defined in the European Union Council’s Decision on introducing the Conformity Assessment Modules (Figure 4).

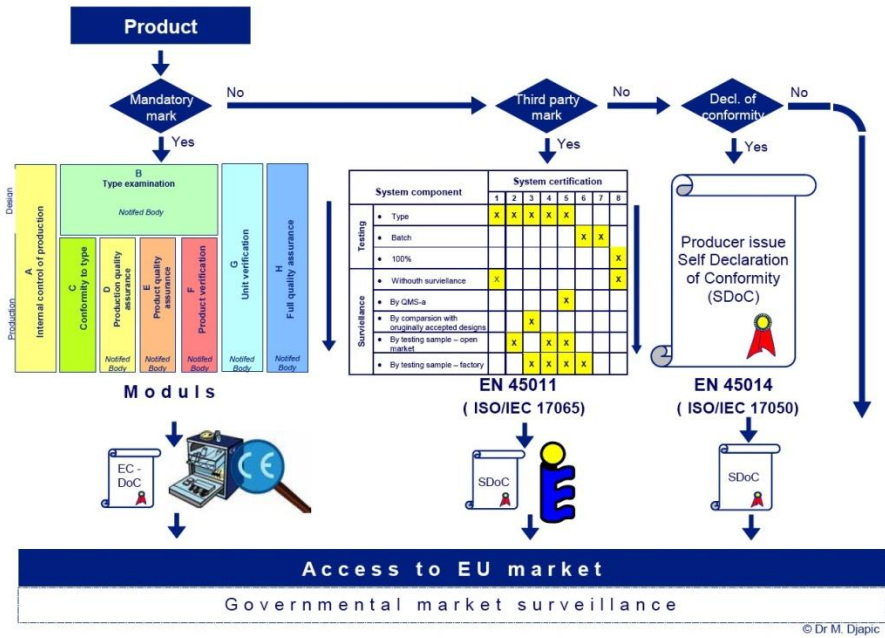


Figure 3. - European approach to product conformity assessment /6; 7/

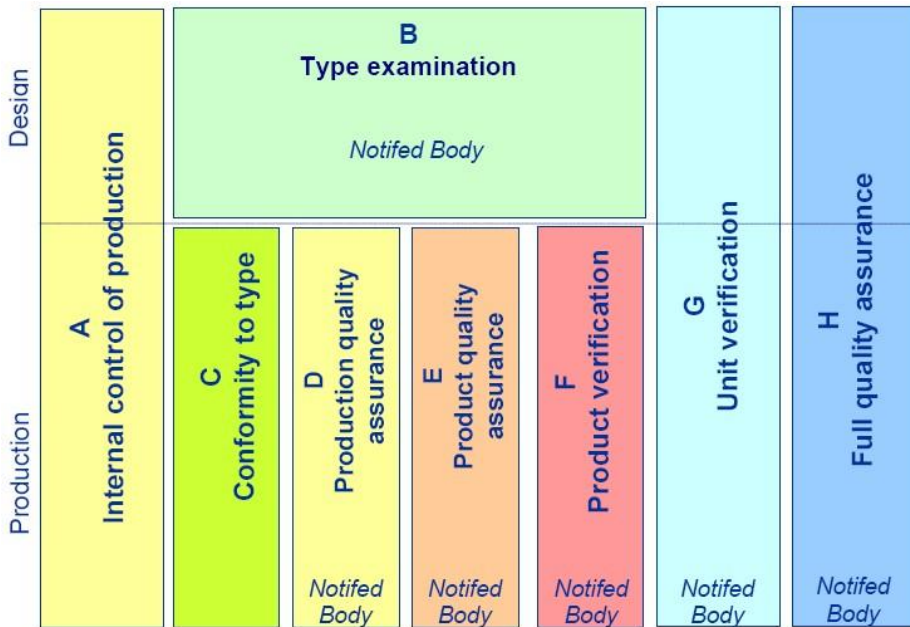


Figure 4. - Modules of product mandatory certification /6; 7/

System component		System certification							
		1	2	3	4	5	6	7	8
Testing	• Type	X	X	X	X	X			
	• Batch						X	X	
	• 100%								X
Surveillance	• Without surveillance	X							X
	• By QMS-a					X			
	• By comparison with originally accepted designs			X					
	• By testing sample – open market		X		X	X			
	• By testing sample – factory			X	X	X	X		

Figure 5. - Systems of voluntary product certification /6; 7/

Many of the modules out of the total eight of them, require the manufacturers to involve, in their conformity assessment procedure, an independent third party, i.e. designated or notified bodies. Engagement of these bodies is mainly requested in the conformity assessment procedures related to highly risky products, from the point of view of hazards for human health and environment safety. It is therefore very important that these bodies perform their function with previously proven high levels of competence, integrity and professional attitude. It is the Member States' obligation to nominate these bodies if their market requires so, i.e. if the bodies satisfy all stipulated conditions and if they explicitly state that they wish to do that. In other words, the Member States are not obligated to designate bodies for all the directives, but only for those for which there exists the interest, i.e. the market.

Designating of the conformity assessment body is an obligation imposed by the New Approach directives, while the criteria are found in the EU Council Decision no. 768/2008/EC pertaining to introducing Conformity Assessment Modules and annexes to the directives.

The other response imposed to manufacturers is to the question whether, if a product does not fall under the New Approach technical legislation, the product certification is required, out of marketing or other reasons, or not.

The ISO book "Certification and Related Activities" /10/ renders eight systems for product certification through a third party (Figure 4). In essence, the product certification systems should cover at least two activities:

- the acceptance of the product based on testing of the (design of the) product and or the production process,
- the surveillance of the continuing ability of the manufacturer to produce a conforming product.

Certification system 1, type testing only, is not seen as a “mature” certification system, because it provides no form of surveillance by which continuing assurance of conformity is usually assessed. The same is valid for system 7, whereas for system 8, surveillance is not relevant because 100% testing is a system where each and every item “marked” is tested against the applicable requirements.

Certification system 6 relates to the determination of compliance of the supplier's quality management system (ISO 9000) for designated products. No mark on a product is allowed for this system.

Comprehensive system of certification is number 5. It frames type testing in the development phase and QMS supervision in the production phase as well as sample testing where the samples are taken from market and production line.

3. CONCEPT OF RISK ASSESSMENT INTEGRATION IN THE ERM

3.1 Enterprise Risk Management (ERM)

All organizations, regardless of their field of activity and size, are faced, in realizing their objectives, with some form of risk. The objectives may vary and may be related to a strategic initiative, operative realization of a project, product, service and similar. They are reflected through environment protection, social safety and security outcomes, commercial, financial and economic measures, such as in social, cultural, political and regulatory influences.

The Enterprise Risk Management – ERM is one of the most popular and on the same time very often insufficiently understood concepts in the contemporary business practice. It is a discipline which has had rapid development and which has been viewed in multiple ways, starting from the point of view regarding what it encompasses to how it is implemented.

The concept is not overly complex nor is it cost demanding, but it can bring benefits and new values to organizations. If we define a problem correctly and share our findings with others, we can reduce the surprises which, unfortunately, often cannot be eliminated. However, they can be kept under control.

In the beginning, the risk management focused only on the negative side of risk, i.e. on protecting from hazards, while the modern practice has brought about a holistic view, treating with equal importance both positive and negative risk facets (upsides and downsides). The above risk is related to an ingoing event,

the consequences of which increase the organization's objectives realization likelihood, or have a positive effect on the interested parties. The below stated risks, on the other hand, are related to those events and their consequences that are threatening or have a negative effect on realizing the objectives and on the interested parties.

Today, risk management incites reviewing of all the factors, whether positive or negative ones, potentially affecting realization of the organization's objectives. Management of opportunities and threats represents a key portion of the organization's strategic planning process.

The basic assumption of a successful risk management in an enterprise starts from the assumption that it has to bring about additional values to the organization, i.e. in other words, the costs of developing and implementing this process, i.e. system, have to be lower than benefits it is passing on. These benefits are reflected on the one hand in reducing the potential threats' effects and consequences on realizing the organization's objectives, creating on the other hand the conditions for these possible benefits to exert more pronounced influence over these objectives themselves.

In literature, this discipline is named by the following titles /1/:

- Total Risk Management (TRM)
- Integrated Risk Management (IMR)
- Holistic Risk Management
- Enterprise Risk Management (ERM)

Regardless of which of these "buzz words" names is used, it is the risk management relating to the issue of how to organize and how to carry out identification, analysis and controlling from the managerial level of "opportunities" and "threats", that organizations face in realizing their objectives. How to relate to opportunities and threats that endanger the organizational objectives depends on how well the organization's management and employees understand the risks and the way of managing them.

3.2 Standardization in the risk management field

Enterprise Risk Management (ERM) is a discipline present in all organizations, either private owned, public, non-profit and profit ones, at all levels of hierarchy, i.e. in all circumstances. That is one of the basic reasons that more than fifteen years ago, the need was articulated for a form of standard so as to ensure agreement of all interested parties regarding /1/:

- Terminology related to this concept,
- Infrastructure, organizational structure and the processes it is implemented through,
- Risk management objectives.

At start of defining the previously stated items, it is important to designate the facts in the text below.

There are organizations in the world today, such as bodies, associations, alliances, etc. which have developed and published various forms of standards and/or “frameworks” in the field of risk management. On the other side, there is no uniform comprehends of the word “standard” with all these protagonists. Apart from the international, regional and national organizations for standards developing (such as ISO, IEC, CEN, CENELC or, for example, the Institute for standardization of the Republic of Serbia), other protagonists use the term standard and/or framework. The closest synonym for a framework could be a general instruction. However, the understanding of the concept of standard and framework differ from region to region. In the United States of America, for example, the Committee of Sponsoring Organizations of the Treadway Commission, COSO has developed ERM Integrated framework /15/, while in Europe, for instance, the Federation of European Risk Management Associations (FERMA) uses the Risk Management Standards developed by three bodies from Great Britain (Risk Management Institute, Managers’ Association of Risks and Insurance and the National Forum for Risk Management in Public Sector) /1/.

Thus, as stated by Erben in /8/, the terms standard and framework represent the same thing for some, as they are used to describe a set of rules for solving an actual problem or to fulfill some concrete requirements.

The readers should not be confused by this, as generally speaking, it is more or less the same things, i.e. defining (industrial standardization) the management process named “Enterprise Risk Management–ERM”. The purpose of these frameworks and/or standards is to serve as a general instruction primarily for the organization’s management on their onset of developing and implementing this management process.

Presenting the standards, i.e. frameworks presented in the world today surpasses the objectives of this paper. Therefore, we are going to focus further only on standardization in the field of risk conducted by the International Organization for Standardization and some of the most significant national standardization bodies (Table 1).

Significant efforts in the risk defining were exerted by the international organizations for standards ISO/IEC /22; 31/ as well as by some national ones, first and foremost the Australia & New Zealand standardization organizations (AS/NZS 4360:2004) /32/.

Thus, the “AS/NZS 4360 Risk Management Standard” defines the risk as the probability of something that may happen affecting the previously defined objectives. Risk is measured as the ratio of consequences and probabilities of some events’ occurrence. This definition was, for many years, the leading one when explaining what is risk management and what it serves for. It is still topical as it can be found in many standards applied at tactical and operation levels, such as the standards serving as guidelines for conducting the risk analysis and

assessment in the EU New Approach directives, such as, for instance, ISO 14121:2007 standard.

Table 1. - The most influential international and national standards developed by the standards developing bodies

ISO	ISO 31000:2009, Risk management -- Principles and guidelines	CSA (Canada)	CSA Q 850: 1997, Risk Management Guidelines for Decision Makers
ISO/IEC	ISO/IEC 73:2009, Risk management -- Vocabulary	JSA (Japan) (withdraw)	JIS Q 2001:2001, Guidelines for development and implementation of risk management system
	ISO/IEC 51:1999, Safety aspects -- Guidelines for their inclusion in standards	AS/NZS (Australia / New Zealand)	AS/NZS 4360:2004, Risk Management
ISO	ISO 14121-1:2007, Safety of machinery — Risk assessment — Part 1:Principles	BSI & (Great Britain)	BS 25999-2:2007, Business continuity management. Specification
	ISO/TR 14121-2:2007, Safety of machinery -- Risk assessment -- Part 2: Practical guidance and examples of methods		BS 31100:2011, Risk management. Code of practice and guidance for the implementation of BS ISO 31000
	ISO 14971:2007, Medical devices -- Application of risk management to medical devices		BS 6079-3:2000, Project management. Guide to the management of business related project risk
ISO/IEC	ISO/IEC 27005:2011, Information technology -- Security techniques -- Information security risk management		ONR 49000:2010, Risk Management for Organizations and Systems - Terms and basics - Implementation of ISO 31000
ISO	ISO 14798:2009, Lifts (elevators), escalators and moving walks -- Risk assessment and reduction methodology	ON (Austria)	ONR 49001:2010, Risk Management for Organizations and Systems - Risk Management - Implementation of ISO 31000
	ISO 17776:2000, Petroleum and natural gas industries -- Offshore production installations -- Guidelines on tools and techniques for hazard identification and risk assessment		ONR 49002-1:2010, Risk Management for Organizations and Systems - Part 1: Guidelines for embedding the risk management in the management system - Implementation of ISO 31000
EN	EN 1127-1:2011, Explosive atmospheres. Explosion prevention and protection. Basic concepts and methodology		ONR 49002-2:2010, Risk Management for Organizations and Systems - Part 2: Guideline for methodologies in risk assessment - Implementation of ISO 31000
	EN 13463-1:2009, Non-electrical equipment for use in potentially explosive atmospheres. Basic method and requirements		ONR 49002-3:2010, Risk Management for Organizations and Systems - Part 3: Guidelines for emergency, crisis and business continuity management - Implementation of ISO 31000
			ONR 49003:2010, Risk Management for Organizations and Systems - Requirements for the qualification of the Risk Manager - Implementation of ISO 31000

Standard ISO 31000:2009 /22/ on risk management and ISO/IEC 73:2009 /32/ guidelines for defining terms in the risk field, define risk as the effect of uncertainty on acquiring organization's objectives. It is the effect of a deviation from the expected outcome of an event, situation, etc., that can be in either positive or negative direction. Risk is often expressed as a combination of consequences of an event and the probability of its occurrence. Probability is defined as a chance for something to happen, no matter whether it has been defined, measured or determined, either objectively or subjectively, or whether it has been described in quantified or qualified manner by using general

mathematical terms, such as event probability (expressed in the 0-1 interval) or an event occurrence frequency in the given period of time. The uncertainty is observed as a state of lack of information and in some cases as a state of partial lack of information related to the knowledge and understanding of certain events, their consequences on the organization's objectives or corresponding likelihood /2, 3/.

Out of these definitions, the conclusions that follow can be drawn /2, 3/:

- Risk is related to achieving objectives.
- ISO/IEC organizations use the uncertainty as the basic pillar in defining risk, and not the probability as it was formerly defined by the standard AS/NZS 4360:1995.

Today, papers can be traced in literature highlighting some shortcomings of the risk being defined in this way by the ISO/IEC organizations. Readers are directed, for example, to /2/ etc. This is understandable, as the concept of risk is related to all fields of human activities and it is very difficult to find and define something that would be satisfactory to all. However, the authors of this paper consider this definition to be the best, most general definition that is acceptable for practitioners in most of the fields of human activities. This is additionally corroborated by the contemporary mathematical tools which enable mathematical modeling of uncertainty, such as the tools developed on the basis of fuzzy sets, Bayes' nets or valuation nets, developed on the basis of the Dempster–Shafer theory of belief function. This assertion can be additionally corroborated by the fact that the IEC - International Electrotechnical Commission has developed standard related to the techniques that can be used in risk management. This is the standard IEC 31010:2009 Risk Management – Risk Assessment Techniques, where there are some of the methods of modeling the uncertainty.

The above definition of risk (ISO/IEC 73:2009) relates this concept to effects of uncertainty on an organization's objectives and on their realization. The objectives may relate to various aspects within the organization, such as: finances, health protection and safety, environment protection, etc., or they can be related to different levels in an organization, such as strategic, overall organizational objectives, a program, project, product or process objectives.

If we go back to the issue of EU technical legislation, i.e. to the requirements from the New Approach directives, we can state the facts that follow. The objectives that are the subject of the analyses are related to products safety and to project of product design and development by the manufacturer. The objectives in general form are defined in the New Approach directives, i.e. in adequate standards for products, if such standards exist /5/. The requirements defined in the standards for products have been set on the basis of previously conducted risk analysis. In case of products for which there are no adequate standards, the manufacturer is obliged to conduct complete analysis, to evaluate the risk and to implement adequate measures. As the assistance in executing

the risk analysis and assessment, there is a set of standards available to manufacturers as guideline (Figure 5) in conducting this analysis.

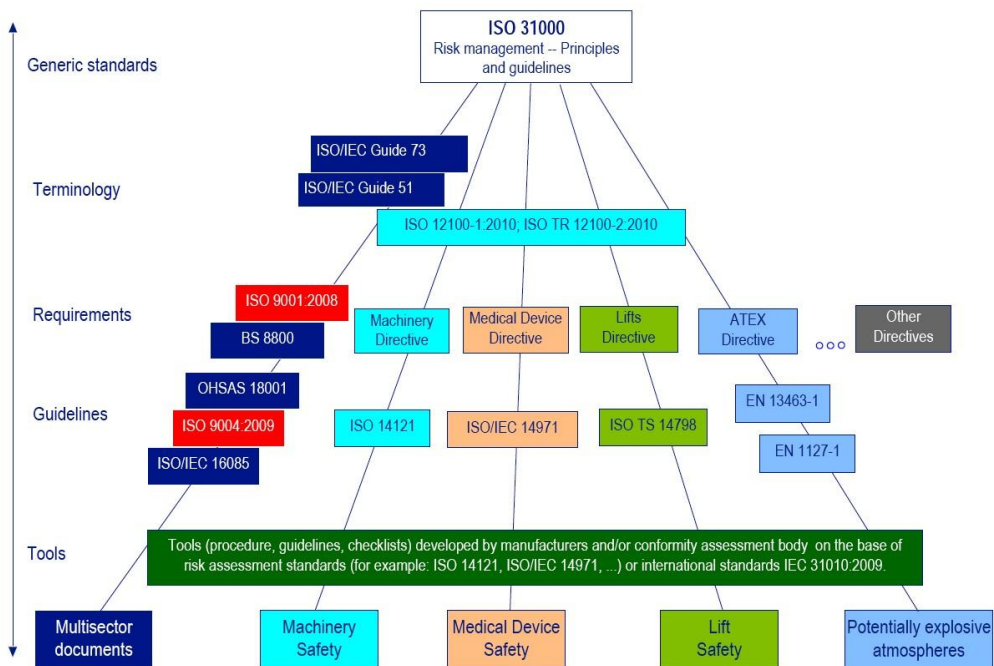


Figure 6. - Hierarchy structure of standards in the risk management field, of importance in implementing the EU technical legislation (Adjusted on the basis of /4/)

The concept of standardization in the field of risk, implemented by the International Organization for Standardization ISO and European standards bodies (CEN and CENELEC) has got the hierarchical structure of standards, as depicted in Figure 5. The concept starts from the fact that successful implementation of risk management in any organization requires a standards structure which sets up from general standards and through the standards defining terminology to standards in which risk analysis and assessment requirements are set for individual business processes and/or functions, and further on to standards in which there are guidelines directing about how to execute these analyses and assessments, and finally, there are structures defining the tools to be used in the risk analyses and assessments. Figure 5 depicts complete hierarchy structure of international and regional standards in the field of risk management, which are of importance for implementing the EU technical legislation, i.e. the New Approach directives.

At the highest generic level, there is the standard ISO 31000:2009: Risk management — Principles and guidelines, which provides for general

instructions and principles for developing and implementing risk management in any organization.

In the following level, there are the standards and guidelines incorporating the vocabularies of terms. These are ISO/IEC Guide 73:2009 - Risk management – Vocabulary and ISO/IEC Guide 51:1999 - Safety aspects -- Guidelines for their inclusion in standards /30/. ISO/IEC 73:2009 provides a basic vocabulary of the definitions of generic terms related to risk management. It aims to encourage a mutual and consistent understanding, a coherent approach to the description of activities related to risk management, and use of risk management terminology in the processes and frameworks dealing with the management of risk.

This group of standards defining the terms might also be extended by standard ISO 12100-1:2010 Safety of machinery — Basic concepts, general principles for design, Part 1: Basic terminology, methodology, expressing the basic overall methodology to be followed when designing machinery and when producing safety standards for machinery, together with the basic terminology related to the philosophy underlying this work. Although the purpose of this standard is to advance the machinery designing process, it can be successfully used in designing other technical products, such as lifts, medical devices, etc. It incorporates the methodology of risk decreasing from the New Approach directives, presented in Figure 8.

The requirements for technical products safety incorporated by the EU legislation are given in the New Approach directives. They are defined in general form so that they cannot not become obsolete so quickly. From the risk point of view, the requirements defined in such a manner represent the risk management objectives in the process of product design related to safety of the products.

In the course of product design, designers has a dilemma of how to determine if a product is safe or not, i.e. how to execute the risk analysis and assessment and how to improve the design solution on the basis of this. It is difficult to determine in practice the safety of a non-standardized product if there is no adequate reference with respect to which it can be done. In some sectors, it is not justifiable nor is it practical or economically viable to standardize all product types, as new types are constantly being developed, and most often the unique ones (as in the machinery sector). In addition, development of new products in some fields is so accelerated that some of the products go ahead of standardization. In some sectors, it is not even possible to implement standardization due to various circumstances.

In response to this problem, the European Commission has initiated with CEN the development of generic harmonized standards enabling the systematic approach and providing the guidelines for:

- identification of hazards;
- risk assessment due to these dangers, and
- assessment of acceptability of the selected safety measures.

- Thus, a set of generic standards ensued for assessing risks in the New Approach directives, such as:
- ISO 14121-1:2007 – Safety of Machinery – Risk assessment – Part 1 Principles (Replaced standard EN 1050:1996, for the field of machines safety)
- EN ISO 14971:2000/AC: 2002, Medical devices – Application of risk management to medical devices.
- ISO TR 14798:2006 Lifts (elevators) – Risk assessment and risk reduction methodology
- EN 1127-1:2007, EN 13463-1:2009, for the area of explosion prevention, etc.

From the standpoint of product safety, these standards serve as guidelines on how to conduct the risk analysis and assessment. Thus, as it is depicted in Figure 13, they have got a dual role. On the one hand, they serve as the tool (guidelines) used by designers and engineers in analyzing and assessing the level of safety of design solution in the course of product development process, while on the other hand they are also the tool for the organization's staff and/or conformity assessment body in assessment whether a product satisfies the requirements of directives and/or harmonized standards, i.e. whether they possess satisfactory levels of safety.

At the lowest level of the standards structure hierarchy, there are the tools developed as independent standards, such as, for example, ISO/IEC 31010:2009 - Risk management -- Risk assessment techniques which provides large number of techniques that can be applied in risk assessment. In addition to the standards serving as tools, organizations very often also develop specific tools in which the risk assessment methodology given in some of the standards, such as for instance ISO 14121:2007, is adjusted to products and business practice present in that particular organization. These tools are presented in the form of various procedures, instructions or, most often, in the form of checklists.

The “maturity models” developed in recent years may also be included in the risk management tools. These models serve as tolls for the executives in risk management and for others in charge of risk management responsibilities to develop sustainable Enterprise Risk Management programs. When applied, these models enable the risk management practitioners to position their program with respect to the best business practice defining in that way the directions for necessary improvements.

3.2.1 Standard ISO 31000:2009

Standard ISO 31000:2009 Risk management -- Principles and guidelines was published on November 15th, 2009, together with standard ISO/IEC Guide 73: Risk management – Vocabulary. It can be applied in a portion of, or in the whole organization, regardless of whether it is a private, public or state-owned organization, association or a group of individuals.

This international standard can be applied throughout the life of an organization, and to a wide range of activities, including strategies and decisions, operations, processes, functions, projects, products, services and assets. The generic approach described in this international standard provides the principles and guidelines for managing any type of risk, whatever its nature, whether having positive or negative consequences in a systematic, transparent and credible manner and within any scope and context /11/.

It suggests risk management principles, frameworks, processes and activities that should be followed to help organizations better meet their goals and objectives.

The basic chapters of this standard define the following (Figure 6):

- risk management principles (Chapter 3),
- risk management infrastructure, by defining the framework (Chapter 4) and
- general process for managing risks (Chapter 5)

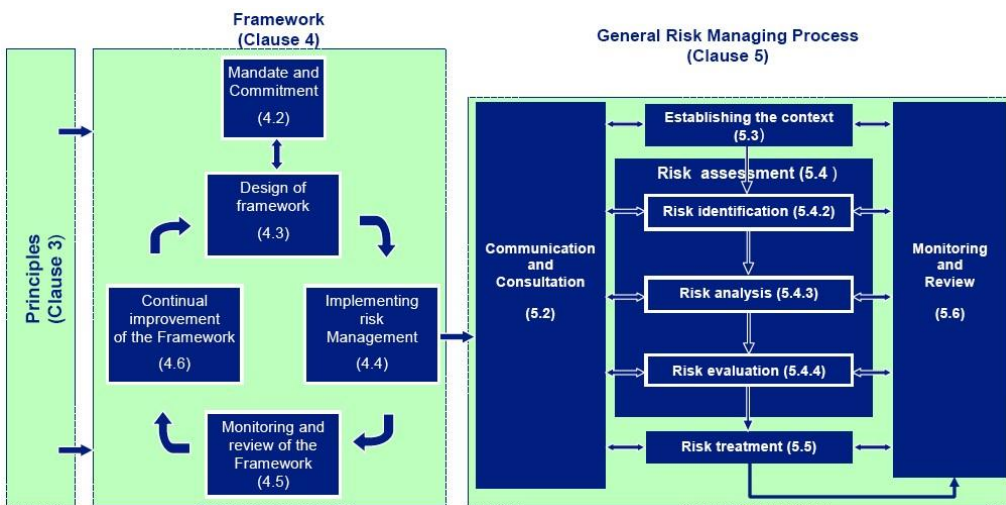


Figure 7. - Relationships between the risk management principles, framework and process (ISO 31000:2009)

In order for risk management to be effective, the organization has to integrate the risk management principles into their business practice. ISO 31000 (Clause 3) contains 11 key principles, implementation of which enables risk management positioning as one of fundamental processes on which the organization's success depends. The risk management principles are as follows:

1. Risk management creates and protects values;

2. Risk management is an integral part of all organizational processes;
3. Risk management is part of decision making;
4. Risk management explicitly addresses uncertainty;
5. Risk management is systematic, structured and timely;
6. Risk management is based on the best available information;
7. Risk management is tailored;
8. Risk management takes human and cultural factors into account;
9. Risk management is transparent and inclusive;
10. Risk management is dynamic, iterative and responsive to change;
11. Risk management facilitates continual improvement of the organization.

The above principles offer the basis for defining and implementing the ERM program according to the specific needs of any organization.

In the Clause 4 of the standard ISO 31000, the risk management framework is presented. This clause describes the necessary components of the framework for managing risk and the way in which they interrelate in an iterative manner, as shown in Figure 6 (Framework). This framework is not intended to prescribe a management system, but rather to assist the organization to integrate risk management into its overall management system. Therefore, organizations should adapt the components of the framework to their specific needs.

The success of risk management will depend on the effectiveness of the management framework providing the foundations and arrangements that will embed it throughout the organization at all levels. The "Plan, Do, Check, Act" cycle of continuous improvement is used as the basis for a risk management framework and associated risk management processes. Organizations adopting this approach will design, implement, monitor and review their risk management framework and take remedial action where necessary. A company's ERM should be continuously improved, typically on an annual basis.

The framework assists in managing risks effectively through the application of the risk management process (see Clause 5 ISO 31000:2009) at varying levels and within specific contexts of the organization. There may be thousands of such processes found in an organization. As an example of the risk management processes, the risk assessment processes are stated in the New Approach directives, in items 3.3.1 to 3.3.3 of this paper.

The framework ensures that information about risk derived from these processes is adequately reported and used as a basis for decision making and accountability at all relevant organizational levels (ISO 31000).

The risk management process should be (ISO 31000):

- an integral part of management,
- embedded in the culture and practices, and
- tailored to the business processes of the organization.

A model of the risk management process is shown in Figure 6 (General Risk Management Process). It comprises the activities described in the points 5.2 to 5.6.

Although this International Standard provides generic guidelines, it is not intended to promote uniformity of risk management across organizations. The design and implementation of risk management plans and frameworks will need to take into account the varying needs of a specific organization, its particular objectives, context, structure, operations, processes, functions, projects, products, services, or assets and specific practices employed /12; 15/.

While other ISO standards can be used for certification, ISO 31000 is non-certifiable but it does provide guidance on best practices.

ISO 31000:2009 is intended to be used by a wide range of stakeholders including:

- those responsible for implementing risk management within their organization;
- those who need to ensure that an organization manages risk;
- those who need to manage risk for the organization as a whole or within a specific area or activity;
- those needing to evaluate an organization's practices in managing risk; and
- developers of standards, guides, procedures, and codes of practice that in whole or in part set out how risk is to be managed within the specific context of these documents.

3.3 Product development process and risk assessment

Technical products have to be safe to use, while the best way to achieve this is through a well designed solution and through adequate work practice in which the products are used. The New Approach directives require the technical products risks to be assessed in the phase of designing, while adequate legislation regulations define safety of the working space in which they are used. Risk assessment has to be implemented in the phase of product designing, so that all necessary improvements ensuing from this assessment are realized in the most efficient manner /6/.

On the occasion of considering risk, the starting point is the terminology defined in standards ISO 14121:2007 Safety of machinery – Risk assessment – Part 1: Principles and ISO 12100-1:2010 Safety of machinery – Basic concepts, general principles for design – Part 1: Basic terminology, methodology.

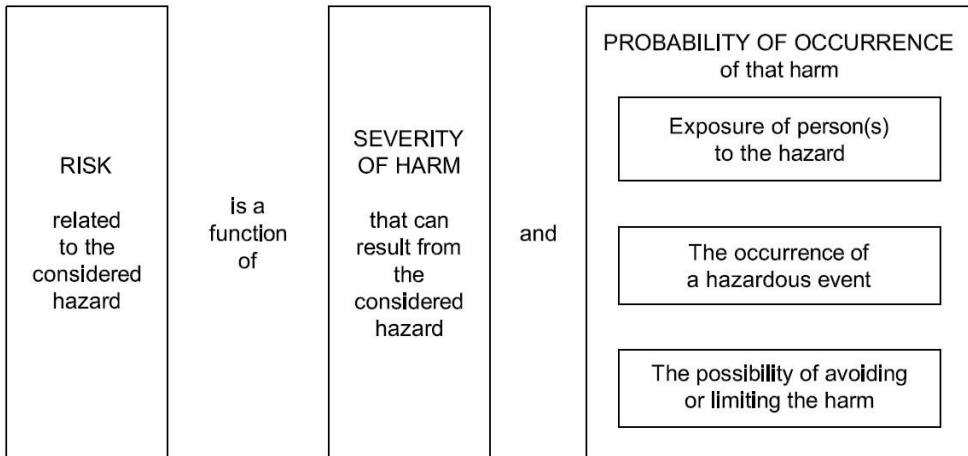


Figure 8. - The risk elements, as defined in standard ISO 14121:2007

In addition to these definitions intended for understanding risk, it is important to define also the following terms depicted in Figure 7.

- Risk Analysis:

Combination of the set machine limitations, identified hazards and risk assessments;

- Risk Estimation:

Defining of adequate injury seriousness and of probability of its occurrence;

- Risk Evaluation:

Evaluation, on the basis of risk analysis, whether the objectives of risk reduction have been achieved;

- Risk Assessment:

The overall process which includes the Risk Analysis and Risk Evaluation;

The risk assessment in the New Approach directives is based on the following principles:

- It is the obligation of the manufacturer or its authorized representative to identify all the risks from technical products;

- The risks covered by harmonized European standards – there are no further activities for these risks. This, in the example of machines, means that there are standards of type C for a machines, such for instance the standard EN 692:1996 for mechanical presses, and if the manufacturer does all in accordance with the requirements of this standard, no additional risk assessment is requested;
- As for other risks, risk analysis is to be done and risks reduced in the phase of designing. Products have to be designed and constructed taking into consideration the risk assessment. The iterative risk assessment process is to be used and risk reduced;
- Implemented protective measures are to be described so as to eliminate the identified hazards and to reduce risks;
- Residual risks, related to products, are to be pointed to in the instructions for use of the machine.

The risk reducing methodology is given in a general form in the New Approach directives. The risk reducing strategy is given in standard ISO 12100-1:2010 Safety of machinery – Basic concepts, general principles for design – Part 1: Basic terminology, methodology, while the general technical principles for risk reducing and the methodology for their implementation are given in standard ISO 12100-2:2010 Safety of machinery – Basic concepts, general principles for design – Part 2: Technical principles.

The risk assessment principles and procedures are given as guidelines in the international ISO or European EN standards, such as ISO 14121-1:2007, used in risk assessing in machines, or standard ISO 14971:2007 for medical devices, i.e. standard EN 13463-1:2009 for non-electrical equipment in use in potentially explosive atmospheres, etc. The list of most influential international and national standards, developed by standards bodies, is given in Table 1.

In order to have technical products covered by the New Approach legislation and to perform their intended functions safely, it is necessary to keep the risks from all hazards at satisfactorily low levels. The risk reducing methodology is based on several key steps:

- The manufacturer or its authorized representative determines, by using harmonized standards such as, for instance, machinery standards ISO 14121-1:2007 and ISO 12100-1:2003 Parts 1 & 2, through the risk assessment procedure, the level of risk for the identified hazards, taking into consideration the limitations within which these technical products perform their functions. In case that it is determined, after risk evaluation activities, that the identified risk level exceeds the acceptable levels, new measures are requested aimed at its reduction;
- Pursuant to the risk reduction methodology, Figure 8, the manufacturer or its authorized representative is first going to

undertake risk reduction by modifying the existing design solution, i.e. it will try to accomplish risk reduction through the so called "inherently safe design solution";

- If the risk reassessment shows that the risk level is still high, the manufacturer or its authorized representative will take certain measures, such as for example installation of adequate protection in the endeavor to additionally reduce the risk;
- It can be assumed that in spite all previously taken measures there still remain certain (residual) risks, so it is the task of manufacturer or its authorized representative to inform future users about all these tasks, on the product itself and by way of instructions for use.

In accordance with the risk reducing methodology, Figure 8, additional risk reduction is expected from users of the technical product. They are obliged to reduce risks additionally on the basis of information received from the manufacturer or its authorized representative.

This primarily refers to:

- Establishing of adequate organization of work
- Adequate work procedures
- Supervising of the technical products operation
- Clear and unambiguously defined authorizations and responsibilities.
- Use of additional protection measures
- Use of personal protection means
- Adequate trainings for operators, etc.

Out of the above described methodology, depicted in Figure 9, contributions are easily observed of the manufacturer and its authorized representative on the one hand and on the other hand those of the technical product users in the process of risk reducing, i.e. in the procedure by which it is ensured that the product has a satisfactory level of safety.

Risks are related to products, which means that if several directives relate to a product, as in most cases such as in the machinery manufacturing, the Machinery Directive usually relates to that product, as well as the Low Voltage Directive – LVD, and Electromagnetic Compatibility Directive – EMC and all essential health and safety requirements from all the directives have to be met.

If all risks are covered by the harmonized standards, there is no need for additional risk assessment and risk reduction. Otherwise, risk reductions should be attempted through a design solution and by applying some of other (harmonized) standards, and then by incorporating adequate protection and safety systems and, finally, user is to be informed of all the residual risks by way of instructions for use.

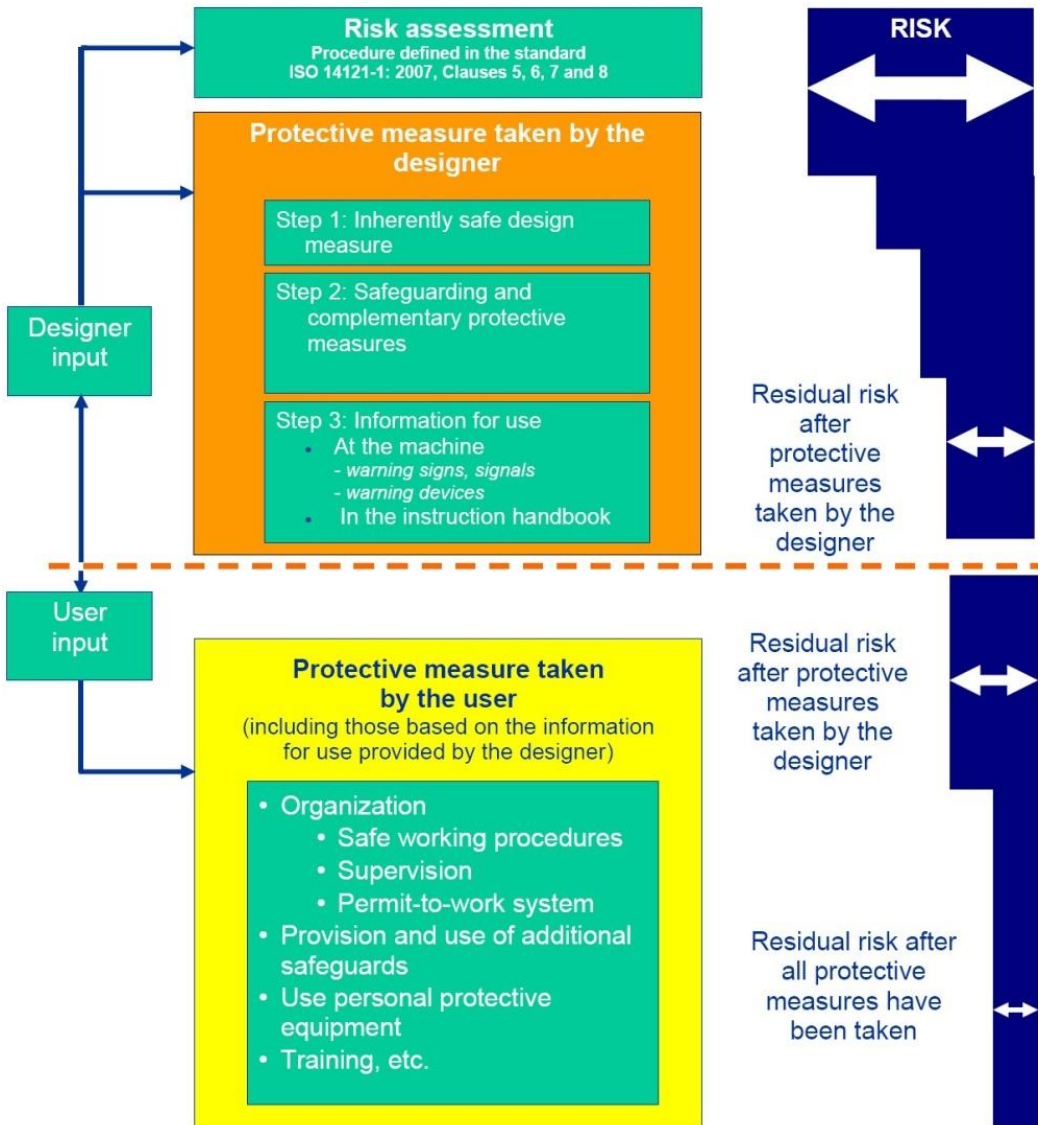


Figure 9. - The methodology for reducing risk in the New Approach directives (Adapted from the standard ISO 12100-1:2010)

3.3.1 Risk assessment in machines (standard ISO 14121-1:2007)

Standard ISO 14121-1:2007 was replaced standard EN 1050:1996. This standard (type A) defines general principles for a consistent and systematic risk assessment procedure, as given in standard ISO 12100-1:2003, item 5. The standard itself does not provide for the assumption of conformity to essential

safety and health requirements (ESHR), as it only provides guidelines regarding decision making in designing and construction of machines. It is also helpful in preparation standards of B and C types, so that machines can be manufactured with satisfactory levels of safety with respect to their intended use, all in accordance with the methodology given in standard ISO 12100-1:2003.

Practical instructions for usage of a number of methods that can be used in individual phases of risk assessment are described in ISO Technical Report, ISO TR 14121-2:2007, which, in addition provides instructions for selecting protection measures in accordance with standard ISO 12100.

Application of ISO 14121-1:2007 enables:

- Systematic approach in identifying hazards, hazardous events and risk assessment, so that no harmful events occur that could endanger human health and safety, safety of property and that of environment and work surroundings;
- Objective assessment/estimation of risk, on the basis of which it is possible to decide whether the adopted safety measures are adequate or not;
- Harmonized instructions for documenting risk assessment procedure (as a significant part of the technical file, i.e. technical documentation);
- Compatibility with harmonized standards (and vice versa) in the field of machinery.

The risk assessment in machines covers the following phases, Figure 9:

- Risk analysis
 - Determining machine limitations
 - Identification of hazards
 - Risk estimation
- Risk evaluation.

Risk analysis – Determining machine limitations: Risk analysis starts with analysis of the machine intended usage, i.e. of the needs for which the machine has been designed and manufactured. The mishandlings in using the machine that are reasonably possible, also have to be analyzed.

Risk analysis – Identified hazards : All hazards that can occur with respect to the intended machine usage within individual sub-systems and at the interface between the system and operator, have to be identified and documented.

Standard ISO 14121-1:2007 offers a list of possible hazards and hazardous events that can be used as an aid in identifying and analyzing hazards.

Risk analysis – Risk estimation: The utmost possible injury and possibility of its occurrence are the essential information characteristic for each risky situation. In

practice, various flow charts are used to depict the risk from hazardous situations.

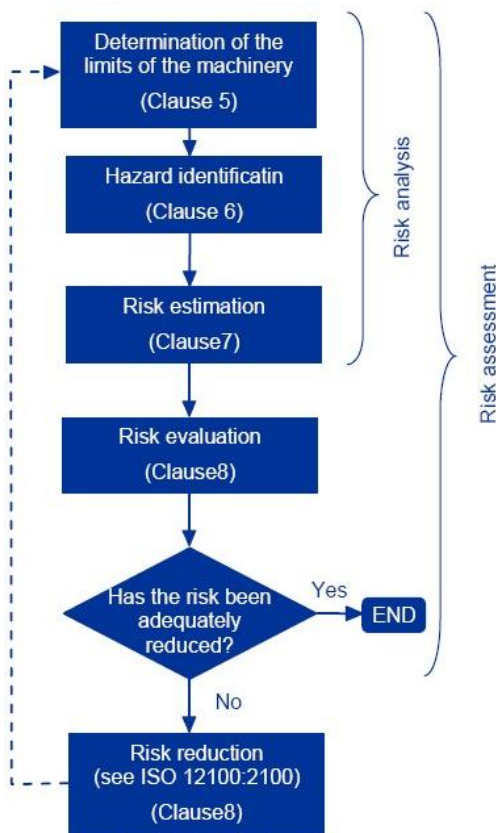


Figure 10. - The iterative process for reducing risk (ISO 14121:2007)

Risk from a hazardous event in machines is very often determined by the use of the so called "matrix diagram", similar to the one depicted in Figure 12, used in risk assessment in lifts.

Risk evaluation: The European Union technical legislation, i.e. the Machinery Directive /5/, basically requests that all health and safety related requirements, stated in Annex I, are fully met. These requirements are partially formulated as the safety objectives and partially as specific requirements.

Risk evaluation refers to whether the safety requirements have been met or not, i.e. whether the probability of a hazardous event occurrence and severity of such an event's effect are at the satisfactory level. If a risk from a hazardous event is not at a satisfactory level, measures have to be taken aimed at its reducing,

pursuant to the methodology defined in standard ISO 12100-1:2003, as depicted in Figure 8.

3.3.2 Risk assessment in lifts (standard ISO 14798:2006)

From the point of view of risk assessment in lifts, the most important are the following standards:

- ISO TS 14798:2006 Lifts, Elevators – Risk assessment and risk reduction methodology
- EN 81-XX Series of standards
- ISO 14121:2007 Machinery Safety – Risk assessment
- EN ISO 12100-1:2010 Machinery Safety – Basic concepts, general principles for designing

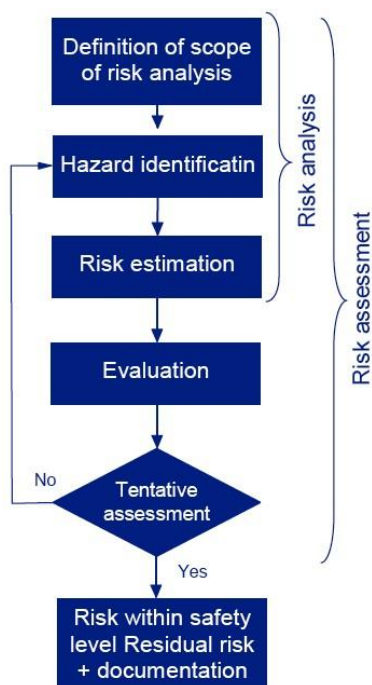


Figure 11. - Iterative process for reducing risk (Adapted from ISO TS 14798:2006)

In assessing lift risks, the most frequently used is the technical specification ISO TS 14798:2006 – Lifts, escalators and passenger conveyors – Risk analysis – Methodology part 1:General.

The procedure of risk assessment in lifts, either new or current ones, is depicted in Figure 10. The procedure has got several steps that are "more-or-less" identical to the risk assessment procedure for all technical products. The

requirements for risk analysis are found in the essential requirements related to health and safety requirements (ESR) given in:

- Directive on lifts 95/16/EC
- Directive on machines 2006/42/EC
- EMC directive 2004/108/EC and
- in additional requirements defined by users, by those in charge of maintenance and/or installation i.e. of the safety component manufacturers.

After defining the risk assessment scope, identification of hazardous situations is made with defining of the hazards, their causes and effects. The systematic approach to identifying hazardous situations is given in the ISO technical specification (standard), ISO TS 14798-1, Annex B. Generic standards can also be used for this purpose: ISO 14121:2007, ISO 12100-1:2010, ISO 12000-2:2010.

Frequency	Severity			
	I	II	III	IV
	Catastrophic	critical	Marginal	Negeligible
A Frequent	IA	IIA	IIIA	IIVA
B Probable	IB	IIB	IIIB	IIVB
C Occasional	IC	IIC	IIIC	IIVC
D Remote	ID	IID	IIID	IIVD
E Improbable	IE	IIE	IIIE	IIVE
F Impossible	IF	IIF	IIIF	IIVF

unacceptable - IA,IB,IC,IIA,IIB,IIIA	Corrective action required to eliminate the risk
undesireable - ID,IIC,IIIB	Corrective action required to mitigate the risk
acceptable with review IE,IID,IIE,IIIC,IID,IVA,IVB	Review required to determine whether any action necessary
acceptable without review IF,IIF,IIIE,IIIF,IVC,IVD,IVE,IVF	No action required

Figure 12. - The connection between risk severity/frequency and adequate risk levels (ISO TS 14798:2006)

Analysis of hazardous situations' causes and consequences, i.e. of risk, is conducted through interconnecting the frequency (likelihood) of its occurrence and severity of its consequences. ISO technical specification ISO TS 14978:2006 offers assistance regarding this task, depicted in its original form in Figure 12.

On the basis of the assessed risk, the decision is taken in the evaluation activity whether the risk, i.e. the lift safety/ components safety are at acceptable level or not. If the conclusion is that it is not, the whole process is reversed to the beginning (Figure 11), thus starting a new cycle of risk analysis and assessment. If the conclusion is that it is, complete risk analysis and assessment is entered

into the lift documentation/technical file, with stating of all residual risks and of the measures necessary to avoid them.

3.3.3 Risk assessment in ATEX Directive

ATEX Directives requires that the manufacturer must select one or more appropriate methods of risk assessment in the design phase of Ex equipment. The same methods may also be applied by the user, where he is responsible for designing and building a process plant, using components bought from many sources.

There is no golden rule as to which method and or technique ought to be adopted. There are many possible methods and/or techniques for risk assessment, especially for hazard identification. A good hazard identification technique has to be systematic, i.e. to guides the users so that all parts of the system, all phases of use and all possible hazards are considered. Risk management offers a general approach for solving this problem.

Ant explosive protection as a very specific area requires careful choosing of risk management methodology. One such methodology 'Risk Assessment Methodology for the Unit Operations and Equipment' has been offered by the RASE Project /19/ to help manufacturers and users of equipment and protective systems intended for use in potentially explosive atmospheres meet requirements of machinery and ATEX directive.

RASE methodology for risk assessment comprises five steps (Figure 12). These steps are as follows:

1. Determining the intended application of a device/equipment (functional analysis / status analysis)
2. Identification of hazards, hazardous situations and events
3. Risk estimation for the determined consequences (the probability of occurring)
4. Risk evaluation
5. Analysis of the possibilities for risk reduction.

The first three steps of the procedure are usually named the risk analysis. Risk assessment is an iterative method, since, after risk evaluation, the risks that have to be reduced require renewed evaluation.

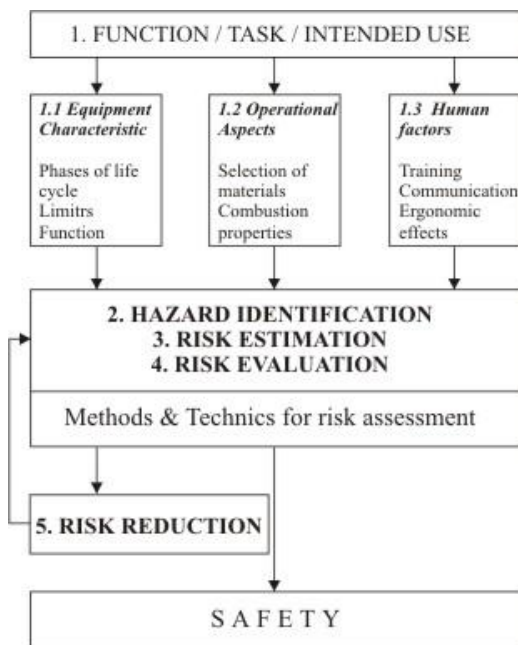


Figure 13. - Simplified Ex risk assessment process

Determining of intended usage (functional analysis / status analysis). The phase of intended usage of a device/equipment has the purpose of clarifying the functioning of the equipment and work operation which lead to hazard occurrence. This phase of the risk analysis covers: description of the system (equipment characteristics, product characteristics, i.e. characteristics of the materials used with respect to flammability and explosiveness, functional analysis/status analysis) for each phase of the operating equipment.

Results of this phase are most often given in the form of a table which provides, for each work operation, a physical status of the materials that are being processed (solid, liquid, dust...) and the operating/energy status of the processes (heating, cooling...).

Identification of hazards, hazardous situations and hazardous events – In this phase, the system should be analyzed so as to determine the possible causes of inflammation. The list of possible instigators of inflammation is given in standard EN 1127-1. The results of this phase are depicted by a table which for each possible inflammation instigator (hot surface, flame and hot gases, mechanically generated sparks, electrical apparatuses...) provides assessment of the source's relevance and its significance, out of which it can be concluded that such particular source in the actual situation presents a hazard or not.

Risk evaluation for the determined consequences – Risk assessment should be implemented for each determined hazard or hazardous event, so as to

determine the risk elements. In the field of explosive safety, two risk elements are defined: risk severity and probability of risk occurrence. The connection between risk severity and frequency of its occurrence enables us to devise a risk level matrix (levels A, B, C, D)

Risk evaluation – The phase of risk evaluation is conducted so as to establish whether it is necessary to take the measures for risk decreasing. With respect to level, risks can be grouped into two basic categories:

- Unacceptable – adequate measures have to be taken for risk level reduction.
- Acceptable – no further risk assessment is required

Risk assessment can also be performed by comparing the risk with the experiences at similar equipment.

3.4 Risk assessment in the New Approach directives integration into the ERM model according to standard ISO 31000:2009.

Standard ISO 31000:2009 defines one of possible risk management models in the enterprise (ERM). The model has got several significant advantages with respect to other models, according to Kevin Knight /12/, who was one of the driving forces behind these standards:

“ISO 31000:2009 is clearly different from existing guidelines on the management of risk in that the emphasis is shifted from something happening – the event – to the effect of uncertainty on objectives. Every organization has objectives – strategic, tactical and operational – to achieve and, in order to achieve these objectives, it must manage any uncertainty that will have an effect on their achievement.”

ISO 31000:2009 sets out principles, a framework and a process for the management of risk that are applicable to any type of organization in public or private sector. It does not mandate a "one size fits all" approach, but rather emphasizes the fact that the management of risk must be tailored to the specific needs and structure of the particular organization”.

Standards structure of the ERM mode as defined in standard ISO 31000:2009, is based on the following facts (Figures 6 and 13):

- The organization’s management is responsible for risk management framework development, implementation and continual improvement. This implies development and maintenance of an adequate organizational structure with clearly defined authorizations and responsibilities of key protagonists. The implemented risk management framework, as well as other management systems, has to be the subject of continual evaluations (most often once a year) on the basis of which necessary improvements are defined. The framework structure is given in Clause 4 of the standard;

- Risk management framework has to be integrated into the existing organization's management system structure (QMS – ISO 9001, EMS – ISO 14001, ISMS – ISO 27001 etc.), i.e. into the structure of the integrated management system (BS PAS 99:2006);
- The risk management principles given in standard ISO 31000:2009 have to be embedded into the organization's integrated management system, i.e. into the structure of the risk management framework;
- Structure of the general processes model for risk management is given in the standard (Clause 5). These processes, of which there may be thousands at all the organizational levels and functions, are integrated into the ERM framework structure through its implementation (Clause 4.4).
- All managers and employees who take decisions have to be made familiar with the general and/or specific processes for risks management and with the way in which to include the analysis results and risk assessment into the procedure of taking decisions, regardless of whether the decisions are taken at the strategic, tactical or operative levels.

If we return to the risk assessment required by implementation of the New Approach directives on actual technical products, the following conclusions can be made. Risk assessment in such cases is, on the one hand the constituent part of the development process and on the other hand the constituent part of product conformity assessment conducted by the organization itself and/or the body for conformity assessment. The model of a possible integration of this risk assessment into the ERM structure is given in Figure 13. Several important facts can be observed from this figure:

- The organizations wishing to improve the procedure of bringing decisions at all the hierarchy levels and all functions, have to implement some of the ERM models. One of these models is given in the international standard ISO 31000:2009.
- Risk assessment of technical products is the constituent part of their design and development process. It is conducted according to the requirements of directives, i.e. of harmonized standards developed and published for that purpose. Thus, the risk assessment of machinery products is done according to standard ISO 14121:2007, and that of medical devices according to standard ISO 14798:2007, etc. This risk assessment is integrated into the ERM framework through its implementation, as depicted in Figure 13. If there is no adequate harmonized standard according to which to perform the risk assessment for certain technical products, there remains available to the designers the general structure of the process for managing risks given in standard ISO 31000:2009 (Clause 5).

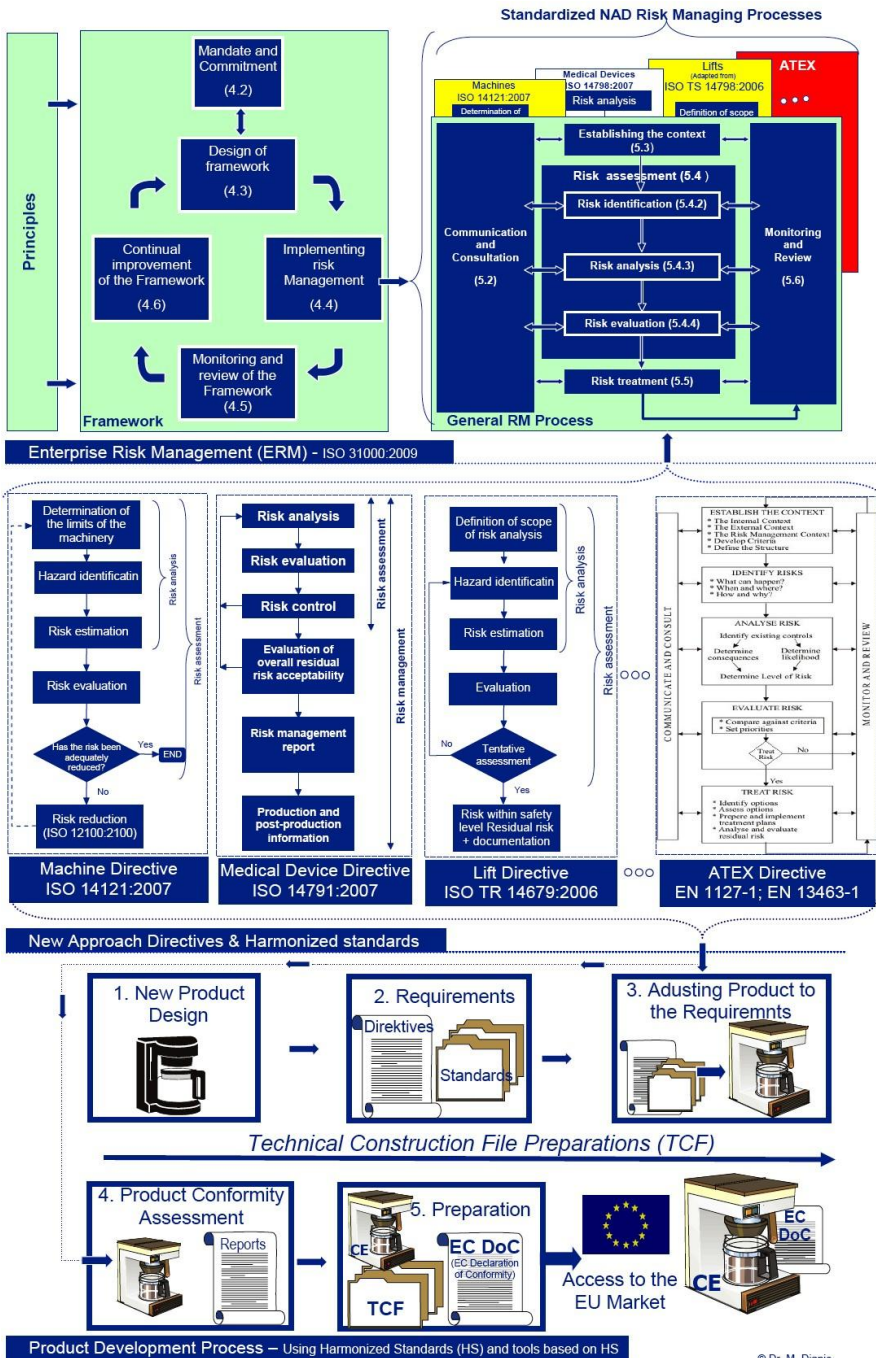


Figure 14. - Integrating risk assessment in New Approach directives into ERM model, according to standard ISO 31000:2009

- At the operational level, in the course of product conformity assessment, as shown in Figure 13, various tools are used in the form of checklists in which the risk assessment methodology, given in harmonized standards, is adjusted to the actual products in question. Each conformity assessment body develops these tools according to its own needs.
- It is important to point out that one of intended purposes of standard ISO 31000:2009 is to harmonize risk management processes in the current and future standards. It is to offer the joint approach to the standards treating specific risks and/or sectors and not to replace those standards. This means that this standard, although developed in 2009, does not replace the standards for specific risks and/or sectors that were developed earlier, such as for example ISO 14121:2007, but it only has to serve as the leading idea in harmonizing these standards on occasions of future revisions. This only points out to the fact that development of the risk management standards has not developed in logical sequence, i.e. the general generic ERM standard and terminology standard were not developed first, and then followed by standards for specific risks, but the business practice has imposed that just the standards treating risks in specific fields were developed first. It is certain that future development of the standardization system in this field will establish a harmonized standards structure, as shown in Figure 5.

4. CONCLUSION

European Union has accomplished, through introducing New Approach to technical harmonization and standardization, a breakthrough in the field of technical products safety and in assessing their conformity, in such a manner that it integrated products safety requirements into the process of products design and development. This is achieved by quantifying risk levels, in the course of the designing process, with the aim of determining the scope of the required safety systems, where the safety requirements are preventively considered during the designing process. In that respect, the European Commission has given a task to CEN to develop generic standards to serve as guidelines and to alleviate technical products' risk assessment in the phase of assessing their conformity.

On the other hand, contemporary business practice has imposed the request for quality improvement in the process of taking decisions, which inevitably brought about the request to analyze and assess the risks for each business objective of the organization. This resulted in the occurrence of several standards/frameworks in which the models of a holistic (integrated) risk management in enterprises have been presented. A new "buzz words" -

Enterprise Risk management (ERM) has emerged, which encompassed all of that.

Standard ISO 31000:2009 Risk management - Principles and guidelines, defines one of the ERM models. Pursuant to this standard, the ERM model is based on (1) eleven risk management principles, (2) framework within which the P-D-C-A cycle is integrated, and (3) the general process for risk management. The risk management framework is the management system that defines and describes how risk management will be embedded and executed at all levels of the organization. An effective framework is critical to the success of ERM in whatever business. Framework does not exist separate from other organization's management systems, but its integration into the existing management systems structure is requested. In connection with the implementation of the framework (item D from the PDCA cycle), the standard proposed a general process structure for risk management in enterprises. There may be thousands of such processes, depending on the organization's size and line of activity.

The processes of risk assessment required by the New Approach directives refer to a group of these processes. Since risk assessment in these processes is defined in the harmonized standards which appeared prior to the ERM model (ISO 31000:2009), the paper gives a model on how they are integrated into the holistic approach of the enterprise risk management (ERM). In many of the New Approach directives there are no harmonized standards for risk assessment, so that manufacturers in such cases can use the general model of risk management processes given in Clause 5 of the ISO 31000:2009 standard.

LITERATURE

1. AIRMIC, Alarm, IRIM, A structured approach to Enterprise Risk Management (ERM) and the requirements of ISO 31000, The Public Risk Management Association, London, UK, 2010.
2. Aven, T., Perspectives on risk in a decision-making context – Review and discussion, *Safety Science*, Vol. 47, 2009, pp. 798–806.
3. Aven, T., A holistic framework for conceptualizing and describing risk. In Kolowrocki, K., Soszynska, J. & Zio, E. (eds.) *Proceedings SSARS 2010*, Journal of Polish Safety and Reliability Association. Vol. 1, 2010, pp. 7-14.
4. CEN/BT WG 160, Implementation of Risk Assessment in European Standardization, Annex 3, 2005
5. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC Official Journal of the European Union L 154/24/2006
6. Djapic, M., Lukic, Lj., Ivanovic, S., Machine Safety Requirement Integration in the Process Designing – Risk Assessment in the Machinery Directive,

- Journal of IMK-14 Research and Development, Institute IMK 14. October, Krusevac, Vol. XV, No. (30-31) ,1-2/2009, pp. 43- 58, ISSN 0354-6829
7. Djapic, M., Zeljkovic, V., Vojinovic, M., Machine Tools Harmonization with EU Technical Legalizations Requirements, International Journal for Quality research, Vol. 2, No. 3, pp 171-177, 2008
 8. Erben, E. B., Risk Management Standards– role, benefits & applicability –, 2nd European Risk Conference, Università Bocconi, September 11th & 12th, 2008.
 9. Guide to the Implementation of Directives Based on the New Approach and Global Approach, by the European Commission (Blue Guide), (November 2011) <http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/>
 10. International Organization for Standardization, Certification and related Activities, 1992.
 11. Knight, K., Future ISO 31000 standard on risk management, ISO Management Systems, July-August, 2007, pp. 8-11.
 12. Knight, K., ISO 31000 and the Icelandic volcano crisis, International Organization for Standardization, http://www.iso.org/iso/iso-focus-plus_index/isofocusplus_online-bonus-articles/isofocusplus_bonus_iso31000-icelandic-volcano-crisis.htm (September 2011)
 13. Lazic, J., Cvijanovic, J., Zeremski, A, Some of Organization Structure Contingent Determiners, Industrija, pp 43-55, 1/2009
 14. Leitch, M., ISO 31000:2009—The New International Standard on Risk Management, Risk Analysis, Vol. 30, No. 6, 2010, pp. 887-892.
 15. Moeller, R. R., COSO Enterprise Risk Management, Understanding the New Integrated ERM Framework, John Wiley & Sons Inc., Hobaken, New Jersey, 2007, ISBN 978-0-0471-74115-2
 16. Popovic, P., Mitrovic, R., Jelic, M., Development of the National Infrastructure for Quality, Industrija, pp 223 – 245, 3/2011)
 17. Purdy, G., How to bring your ERM Framework in line with ISO 31000, LexisNexis 5th Annual Risk Management Conference, Sydney, Australia, 2008.
 18. Purdy, G., ISO 31000:2009—Setting a New Standard for Risk Management, Risk Analysis, Vol. 30, No. 6, 2010, pp. 881-886.
 19. Rogers L. R.: The RASE Project: Methodology for the Risk Assessment of Unit Operations and Equipment for use in Potentially Explosive Atmospheres, EU project No SMT4-CT97-2169, March, 2000.
 20. Shortrees, J., Enterprise risk management and ISO 31000, The Journal of Policy Engagement, Vol. 2, No. 3, pp. 8-10, June 2010
 21. BS EN 13463-1:2009, Non-electrical, equipment for use in potentially explosive atmospheres, Part 1: Basic method and requirements, British Standard, www.bsi.org

22. IEC 31010:2009, Risk management — Risk assessment techniques, International Electrotechnical Commission, www.iec.org
23. ISO 12100-1:2010 Safety of machinery — Basic concepts, general principles for design, Part 1: Basic terminology, methodology, International Organization for Standardization, www.iso.org
24. ISO 12100-2:2010 Safety of machinery – Basic concepts, general principles for design – Part 2: Technical principles, International Organization for Standardization, www.iso.org
25. ISO 14121-1:2007 – Safety of machinery — Risk assessment — Part 1: Principles, International Organization for Standardization, www.iso.org
26. ISO 14971:2007 - Medical devices -- Application of risk management to medical devices, International Organization for Standardization, www.iso.org
27. ISO 31000:2009 Risk management -- Principles and guidelines, International Organization for Standardization, www.iso.org
28. ISO EN 1127-1 2007 Explosive atmospheres - explosive prevention and protection basic concepts and methodology, International Organization for Standardization, www.iso.org
29. ISO TR 14798:2006 Lifts (elevators), escalators and moving walks -- Risk assessment and reduction methodology, International Organization for Standardization, www.iso.org
30. ISO/IEC Guide 51:1999 Safety aspects - Guidelines for their inclusion in standards. International Organization for Standardization, www.iso.org
31. ISO/IEC Guide 73 Risk Management - Vocabulary - Guidelines for use in standards, International Organization for Standardization, www.iso.org
32. Standards Australia & Standards New Zealand Committee OB/7 on Risk Management, Risk management, AS/NZS 4360:2004, www.saiglobal.com

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